ORIGINAL ARTICLE

The influence of surgeons and technicians on the learning curve of femtosecond-laser cataract surgery

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Received 5 February 2019; accepted 7 January 2020
Available online 31 January 2020

KEYWORDS
Learning curve; Femtosecond laser; Cataract

Abstract
Purpose: To demonstrate the influence of the surgeon’s and the operating room (OR) technicians’ experience upon the outcome of femtosecond laser-assisted cataract surgery (FLACS).

Materials and methods: Our study included 250 eyes from 156 patients who had undergone either cataract surgery or clear-crystalline-lens extraction and where capsulorhexis and lens fragmentation had been performed using the CATALYS® Precision System femtosecond platform (Abbott Medical Optics Inc., Santa Ana, CA, USA). The patients were operated either by an experienced surgeon in the use of femtosecond laser or by an inexperienced surgeon in that field and two technicians. The quantitative outcome measures were: Suction loss rate, vacuum time, number of consumables used by the patient and intraoperative complication rate.

Results: Both for the experienced and the inexperienced surgeons, suction loss rates as well as vacuum time decreased progressively as time went by and more surgical procedures had been completed by that surgeon. For a given surgeon suction time decreased significantly, going from 137 to 99s, as the assisting technician gradually gained experience. The number of consumables used in each procedure by the experienced surgeon ranged from 1.10 (for the first 50 cases) to 1.02 from those initial cases onwards. Regarding intraoperative complications, they also decreased progressively as the number of procedures completed by the surgeon increased.

Conclusions: The experience of each team member involved in such procedures—be it surgeons or technicians—have an impact, to a greater or lesser extent, upon the surgery’s outcome, as quantified by the outcome variables of choice.

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https://doi.org/10.1016/j.optom.2020.01.001
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Influencia de los cirujanos y técnicos en la curva de enseñanza de la cirugía de cataratas con láser de femtosegundo

Resumen
Objetivo: Demostrar la influencia de la experiencia del cirujano y los técnicos de quirófano en los resultados de la cirugía de cataratas asistida por láser de femtosegundo (FLACS).
Materiales y métodos: Nuestro estudio incluyó 250 ojos de 156 pacientes sometidos a cirugía de cataratas extracción de cristalino transparente, en las que la capsulorhexis y la fragmentación de lente se habían realizado utilizando la plataforma de femtosegundo CATALYS® Precision System (Abbott Medical Optics Inc., Santa Ana, CA, EEUU). Los pacientes fueron operados, bien por un cirujano con experiencia en el uso del láser de femtosegundo, o bien por un cirujano sin experiencia en dicho campo, y dos técnicos. Las medidas del resultado cuantitativo fueron: tasa de pérdida de succión, tiempo de vacío, número de consumibles utilizados por el paciente, y tasa de complicación intraoperatoria.
Resultados: Tanto para cirujanos expertos como inexpertos, las tasas de pérdida de succión, así como el tiempo de vacio disminuyeron progresivamente a medida que transcurria el tiempo, y que se incrementaba el número de intervenciones quirúrgicas completadas por el cirujano. Para un cirujano dado, el tiempo de succión disminuyó significativamente, pasando de 137 a 99 segundos, a medida que el técnico asistente ganaba experiencia gradualmente. El número de consumibles utilizados en cada procedimiento por un cirujano experto oscilaba entre 1,10 para los primeros 50 casos y 1,02 desde los casos iniciales en adelante. En cuanto a complicaciones intraoperatorias, también disminuyeron progresivamente a medida que aumentaba el número de intervenciones completadas por el cirujano.
Conclusiones: La experiencia de cada miembro del equipo involucrado en dichos procedimientos —bien fueran cirujanos o técnicos— tiene un impacto, en mayor o menor medida, sobre el resultado de la cirugía, según lo cuantificado por las variables de elección del resultado.
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Introduction
Cataract surgery is the most commonly performed medical procedure in the world. Greater life expectancy, an increasingly older population together with a world-wide growing incidence of diabetes will lead in the coming decades to a significant rise in the number of cataract surgical procedures. Cataract surgery has considerably evolved since the initial times of intracapsular cataract extraction. We have witnessed numerous advances in terms of surgical techniques, surgical instrumentarium or intraocular lens (IOL) designs and models. This progress has led to greater safety, efficacy and reliability of this surgery.
Phacoemulsification is nowadays considered the ‘gold standard’, or reference technique for cataract surgery. However, in the last few years, femtosecond-laser-based devices have been introduced in this surgical field, thus opening a wide range of ground-breaking possibilities for our surgical activity.
But as is the case for most technological advances, at the beginning controversy arises regarding its outcomes. Therefore, Femto-phaco for cataract surgery, as with any other medical technology, needs to undergo a thorough clinical assessment to see whether the results it yields support the adoption and integration of this technology into routine clinical practice.
However, the evaluation of the technique should only be undertaken once it has been checked that the learning-related factors are no longer interfering with the results that the technique produces. Consequently, in this context, the aim of the present study is to assess this technique’s learning curve for both the surgeons as well as the technical staff who are involved in the surgical procedure.

Materials and methods
This was a single-center, prospective, consecutive study that included 250 eyes from 156 patients. For those patients who had bilateral surgery, each eye was operated on in a separate procedure. The surgical procedures took place between January and December 2016.
According to the surgical protocol, that is followed for all cataract surgeries performed in our eye center, the staff members taking part in the first stage of the process—capsulorhexis and lens fragmentation with the femtosecond laser—are the surgeon, the technician controlling the laser settings (who, in our case, is an optometrist), and the operating-room assistant who is in charge of placing the patient onto the stretcher.
About the surgeon and the technician, there were 2 ophthalmologists—an experienced one and another with no experience at this type of procedures—plus 2 technical staff members: Technician 1 and Technician 2. Prior to study initiation, they were all trained by the manufacturer on the use of the femtosecond device.
During the phacoemulsification, the staff members involved in this second stage are the surgeon (the same one that carried out the Femtosecond-laser procedure) and the scrub nurse. In the context of the present study, the technician who had been involved in the femtosecond-laser procedure stage did stay in the operating room, although he did not actively take part in subsequent stages; he simply followed the phacoemulsification process so as to know if there were any complications stemming from the preceding capsulorhexis or crystalline-lens fragmentation.

When the study was designed, different phases were defined so as to be able to evaluate whether the learning curve influenced the process and whether there were any study-related complications.

As for the study endpoints, these were: suction losses, vacuum time, intraoperative complications and the number of Liquid Optics Interfaces (LOI™) that were used for each procedure.

All patients completed and signed the informed consent. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee.

**Surgical procedure**

Right before the surgical procedure, the technician lays down the patient on the surgery table and fixes their head in an appropriate position, so as to avoid any risk of bumping into or interfering with the patient’s nose during the procedure and to facilitate LOI™ placing (hyperextension of the head should be avoided too).

Next, it is the technician who always checks the parameters for the incision (irrespective of whether or not it will be performed), capsulorhexis — centred relative to either the lens’s equator or the pupil —, and crystalline lens fragmentation pattern.

The surgeon then places the LOI™ inside the patient’s eye. When it comes to choosing its size, the decision is made by both the surgeon and the technician, after assessing the patient’s ocular parameter and taking into account whether or not incisions will be performed. CATALYS® Precision System uses a LOI™, in which the patient interface is filled with BSS and a lens is immersed into the liquid, and centered over the limbus. The system has a double vacuum system with an integrated vacuum pump, and the patient is moved towards the system moving the integrated patient bed. Part of the docking includes following the predefined software path and reviewing the integral guidance oct. Vacuum is generally low which requires the user to perform a more gentle docking and monitoring of the integrated force sensor to minimize the XYZ forces. Once the doctor has completed the suction step, the technician instills normal saline solution in the LOI™ until it is completely filled. Next, it is capture and lock’s turn; and the staff checks then that there are no air bubbles inside the cone. If there are any the technician has to warn the surgeon, who will then repeat the docking step and, if they persist, it is the technician who will remove the air bubbles from the LOI™ aided by a compressor.

The next step is taking an OCT image of the eye, including both the anterior and posterior corneal surfaces as well as the lens’ anterior surface.

The technician is responsible for confirming that the different structures do indeed match the OCT’s demarcation lines.

Once it has been verified that the pupil, the corneoscleral junction and the crystalline lens’ posterior surface match up with the guiding lines shown by the Femtosecond platform, the capsulorhexis size is then programmed. If there is no matching between the ocular surfaces and the lines that provide guidance to the Femtosecond platform, it is the technician who is in charge of modifying them. When programming the capsulorhexis size, the technician verifies that it is not too tight relative to the pupil size. If the programmed capsulorhexis happens to interfere with an ocular tissue (one that is not the anterior capsule; for instance, the iris) the technician must give the following warning: ‘pupil maximized’ option should be applied: In that case, the device will then center the capsulorhexis relative to the pupil instead of the lens’ equator, thus resulting in a smaller-size capsulorhexis.

If the surgeon considers the new size to be suitable, that value is then confirmed, and the surgery continues.

Otherwise, manual capsulorhexis centering can be used instead. In that case, it would be the surgeon who would decide which diameter to use. Another alternative would be to program a special option that the platform has available, which creates a capsulorhexis having a ‘maximized pupil’. This results in a capsulorhexis that is centered relative to the pupil, while achieving the largest diameter possible (although smaller than the one previously programmed), which is usually 5.5 mm.

The following step is checking that the fragmentation pattern matches the crystalline lens’ surface.

Following all these verifications, it is the surgeon who delivers the treatment by operating the pedal. Once the treatment is completed, the surgeon stops the vacuum and releases the LOI™.

During the process that involved using the Femtosecond platform, the only staff members that took part were one surgeon and one technician. Once this phase was over and the patient was then operated under the surgical microscope and with the phacoemulsifier device, the surgeon was assisted at all times by a scrub nurse. There is no additional staff member involved in the surgical procedure itself or in the decision-making process occurring during the surgical procedure.

**Stages**

As the learning curve was one of the key points to be evaluated (and bearing in mind that there were no previous studies in the literature that would allow us to calculate the optimum sample size, and knowing that the surgeons had already gained experience with femtosecond-laser use for refractive surgery), it was decided to make groups comprising 50 surgeries each so as to be able to analyze the results. It was considered important to evaluate consecutive surgeries, regardless of whether or not they involved the patient’s second eye. The fact that we operated on the second eye of the same patient, in our opinion did not influence the parameters being evaluated.
Surgeon 1 is familiar and has experience with other femtosecond platforms but not with that particular one assessed in this study. As a result, in Stage 1a neither of the two staff members had any prior experience with that platform; in this sense, both Technician 1 and Surgeon 1 gained their experience simultaneously and in parallel. When Surgeon 2—who had no prior experience with any femtosecond platform—joined the OR team, he partnered with Technician 1, who was already experienced since he had been involved in the first 100 cases. In subsequent Stages 1c and 2b, both Surgeon 1 as well as Surgeon 2 perform additional surgeries but with the assistance of a new Technician (Technician 2), who had no prior experience with femtosecond platforms. The first 50 surgical procedures (Stage 1a) were carried out by an experienced surgeon in femtosecond-laser surgery (surgeon 1, whose initials are FG) but not with that particular one assessed in this study, and Technician 1 who had no prior experience with any platform. As a result, in Stage 1a neither of the two staff members had any prior experience with that platform. In this sense, both Surgeon 1 and Technician 1 gained their experience simultaneously and in parallel. Stage 1b started when they had performed 50 surgeries together.

When Surgeon 2—who had no prior experience with any femtosecond platform—joined the OR team, he partnered with Technician 1, who was already experienced since he had been involved in the first 100 cases. In subsequent Stages 1c and 2b, both Surgeon 1 as well as Surgeon 2 perform additional surgeries but with the assistance of a new technician (Technician 2, ILB), who had no prior experience with femtosecond platforms and that replaced the previous technician. Each of the different stages includes 50 surgeries (Table 1).

Femtosecond-laser platform

The femtosecond platform used throughout this study was the CATALYS® Precision Laser System (Abbott Medical Optics Inc., Santa Ana, CA, USA), which combines a laser having a pulse temporal width below 600 fs with a 3D spectral-domain optical coherence tomography (OCT) imaging device. The Liquid Optics Interface (LOI™) delivers a gentle docking with minimal intraocular pressure rise and no contact with the corneal tissue, yielding an unaltered optical path. The OCT-based integral guidance system identifies the patient’s anatomical landmarks and maps safety zones so as to ensure a safe accurate laser-pulse projection. It also allows the user to modify and customize treatment on a case-by-case basis.

Surgical protocol

The femtosecond laser was used to perform the anterior capsulotomy as well as lens fragmentation. For this purpose, the two-piece LOI™—comprising a suction ring and a disposable non-orientable immersion lens—was placed on the corneoscleral junction (limbus) and suction was then applied. Once suction was confirmed and the eyeball was securely fixed, the suction ring’s fluid tank was filled with a sterile buffered saline solution and the patient’s eye was placed under the laser’s lens. The anterior chamber and the lens dimensions were then measured using the abovementioned 3D spectral-domain OCT system that is included in this laser platform. These measurements are performed automatically, as part of every procedure. The selected treatment began once the surgeon confirmed that the measurements were correct, and that the location of the treatment zones was adequate.

The capsulotomy relied on a pre-programmed 5.0 mm-diameter circular pattern having a spot spacing of 5 μm horizontally and 10 μm vertically. The pulse energy amounted to 4.0 μJ per pulse.

As for the phacoemulsification procedure, the segmentation and softening pattern was quadrant-based. This pattern went beyond the capsulotomy area, covering the whole pupil diameter and including even an additional 500-micron safety margin ring. The spot spacing was 10 μm in the horizontal direction and 40 μm vertically. The pulse energy was set to 9 μJ, and safety zones to be left unfragmented were defined to be 500 microns for the anterior capsule and 600 microns for the posterior capsule. These values were maintained through the whole lens thickness and were automatically computed by the laser system itself.

The incisions were performed using a 2.2 mm lancet on clear corneal tissue. As for phacoemulsification, we employed the Centurion Vision System platform (Alcon Laboratories, Inc., Fort Worth, TX, USA). All implanted lenses were foldable ones.

Results

Evolution of vacuum time

Surgeon 1

Mean vacuum time for the surgeon-1-led procedures (including all 150 cases) was 107.17 ± 5.17 s (range: 60–254 seconds). Focusing only on the first 50 cases—which were all performed by this surgeon with the technician 1 assistance—mean vacuum time was 137.75 ± 15.7 s (range: 83–330 s), whereas for cases 51–100 mean vacuum time dropped to 99.48 ± 4.92 s (range: 65–150 s). For his last 50 cases, where he was now being assisted by the technician 2, mean suction-time outcomes were 101.93 ± 4.79 s (range: 79–153 s). If we compare these mean suction-time values, all corresponding to procedures that were carried out by the experienced surgeon, statistically significant differences emerge between Stage 1a and 1b (p = 0.0000) and between Stage 1a and Stage 1c (p = 0.0025), whereas between 1b and 1c the resulting differences were not statistically significant (p = 0.0630) (see Table 2).

Surgeon 2

For the second surgeon, who had a complete lack of experience regarding femtosecond platform usage, the overall mean suction time was 107.78 ± 5.55 s (range: 60–254 s). When we compared the overall mean suction time for the experienced surgeon vs. the inexperienced one no statistically significant differences were found (p > 0.05).

If we break down this second surgeon’s cases based on the assistant that assisted him during the procedure, for the
first 50 cases (performed with the help of the technician 1, who had already taken part in 100 previous procedures while assisting the other surgeon; Stage 2a), mean suction time was 115.66 ± 9.64 s (range: 78–254). When the technician 1 was replaced by the inexperienced technician 2 (Stage 2b), the resulting mean suction times were 99.73 ± 4.72 s (range: 60–142). The comparison of Stage 2a and 2b results revealed statistically significant differences (p = 0.00) (Table 2).

### Suction loss

**Surgeon 1**
Across the 150 procedures led by the experienced surgeon, there were a total of 17 suction losses. Eleven of them occurred during Stage 1a and 6 during Stage 1b, whereas during phase 1c no suction-loss events occurred.

**Surgeon 2**
Across the 100 procedures led by the inexperienced surgeon, there was only 1 suction loss, which occurred during Stage 2a, whereas no suction-loss incidences happened during Stage 2b.

### Intraoperative complications

**Surgeon 1**
Three intraoperative complications related to the use of the femtosecond laser device occurred during the procedures led by the experienced surgeon. All three of them were tears during capsulorhexis and happened during Stage 1a. No other intraoperative complications occurred from case number 22 onwards (Table 2).

**Surgeon 2**
As for the inexperienced surgeon, the number of intraoperative complications related to the use of the femtosecond-laser device was just 1, which happened during the first 50-case batch; namely it was case number 8 (Table 2).

### Number of LOI™s used

**Surgeon 1**
The overall mean number of LOI™s used by the experienced surgeon in each procedure was 1.04 ± 0.04 (range: 1–4). If we break down these results by Stage, the mean number of LOI™s amounted to 1.10 ± 0.13 (range: 1–4) in Stage 1a, 1.02 ± 0.04 (range: 1–2) in Stage 1b, and 1 ± 0 in Stage 1c (in this particular case no surgeries required more than one LOI™). The case requiring 4 LOI™s (Stage 1a) was due to the eye being particularly small and sunken.

**Surgeon 2**
The inexperienced surgeon used only one LOI™ in each of the surgeries included in the present paper.

### Discussion

Femtosecond laser (FL) technology was introduced in cataract surgery back in 2009 with the aim of automating and enhancing the efficacy and safety of specific surgical steps.¹
Any new medical technology needs to be assessed in a real-life clinical environment so as to see whether the outcomes it yields support the adoption of that technology and its integration into routine clinical practice. Nonetheless, such study needs to be undertaken once the users have learned to handle and operate the devices related to that technology; otherwise the results could be biased or misleading.

There are numerous papers in the literature comparing conventional cataract surgery with femtosecond-assisted cataract surgery, but the results are, at times, seemingly contradictory. Most of those comparisons don’t include information on how experienced the surgeons and technicians were in that technology. We had hypothesized that the effect of the different learning curve profiles and different position of the health-care professional along that learning curve—at its beginning, for the femtosecond technique vs. completed learning curve, for the conventional technique—may be the cause of some of those discrepancies found in the literature. For instance, a recent meta-analysis didn’t show any significant safety and efficacy benefits of femtosecond-assisted cataract surgery vs. conventional cataract surgery, whereas another study showed a categorial advantage for the femtosecond laser technique. A study by Pitter reported that the outcomes delivered by resident surgeons when using femtosecond-laser surgery may be worse than those yielded with conventional surgery, where they have already gained and built up experience.

As our study results have also shown, it is not only the surgeon’s experience that influences the outcome of the capsulorhexis and lens-fragmentation process, but also the experience of the technical staff assisting the surgeon during that part of the procedure. As far as we are aware, this is the first research study that analyses the impact of the learning curve from this perspective. Regarding surgical complications related to the use of a femtosecond system, Roberts assessed a more experienced surgeon and found a 4% rate of anterior capsular breakage and 3.5% of posterior capsule breakage in a study that included 1500 eyes treated with the LenSx Laser System (Alcon Laboratories, Inc., Fort Worth, TX, USA). Nagy, in an initial series of nine patients and using also the same LenSx Laser System platform as above, reported a similar rate of anterior capsular breakage (4%), whereas in our study there were 3 occurrences in the first 22 procedures, but from that moment onwards no other capsule breakage occurred. As for the study by Day, describing the initial outcomes following the installation of the same platform we employed, it reported no anterior capsular breaks but 3 posterior ones. It has to be noted that Day’s study included up to 32 surgeons. In Hou’s study, based on the LenSx Laser System platform and where the surgeons were still undergoing their specialty training, the complication rate was as high as 7%. In summary, if we compare the number of complications occurred with each platform, it can be observed that the CATALYS® Precision Laser System has the lowest complication rate.

Some studies have suggested that, when using a femtosecond system, the utmost care must be taken—particularly at the beginning of the learning process—so as to avoid capsular breakage since, in many cases, it forces the surgeon to follow a different surgical protocol from the standard one. We do believe that the learning curve of the technique plays a very significant role in this adverse event. Similarly to Nagy’s study, during their learning curve—and despite those anterior capsule breakages mentioned above—none of the patients required vitrectomy. On the contrary, in Day’s case, up to 4 patients needed to undergo vitrectomy. As for our study, the worst outcomes correspond to those stages where neither the surgeon nor the technical assistant had any prior experience in the use of the platform, even if one of them (Surgeon 1 in this case) was familiar with other femtosecond-laser platforms and had even used them in the past. None of the 250 patients required vitrectomy and all the IOLs could be successfully implanted inside the capsular bag.

Regarding suction losses, in Nagy’s study, for the first 100 patients, there was a 2% rate among their first 100 cases, which is lower than in our study, where it reached 17% for the first 100 cases handled by the experienced surgeon together with the new technician (technician 2), but from then on no further suction-loss events were reported. A similar pattern was observed with the inexperienced surgeon assisted by the experienced technician. It is worth highlighting the fact that none of these suction losses led to the cancellation of the femtosecond-laser procedure. Being experienced in these procedures will help to tackle and solve those potential problems that may arise during femtosecond-laser-based surgery.

Suction time seems to be the parameter that is most influenced by the presence of a technician assisting the surgeon. Wang et al., in a study about the CATALYS® Precision Laser System, reported a mean suction time of 101.27 s, which is slightly higher than the mean value reported by us. However, bearing in mind that Wang’s study included 300 eyes, we assume that in their initial procedures the suction times may have been above average. This claim is supported by our own findings: for a given surgeon (Surgeon 1) suction time decreased significantly, dropping from 137 to 99 s, as the assisting technician gradually gained experience. When another technician who had no experience in the use of that platform joined the team, mean suction times increased again to almost 102 s. In the case of the inexperienced surgeon, his lack of experience seemed to have greater impact than the assisting technician’s familiarity and experience with the platform. Consequently, we concluded that both the surgeon and the technical staff member considerably influence the surgical process, although the surgeon’s experience carries greater weight in this matter. In any case, these time values are markedly lower than the ones reported by Chang for a study comprising 170 eyes, where the average time was 6.72 min (counting from the suction’s beginning until the end), although it’s true that they used a different laser system platform (LensAR, LensAR Inc., FL, USA).

When surgeons are asked about their preferences, the obstacle they see to the adoption of femtosecond-laser technology is mainly of financial nature: A survey that included 1047 cataract surgeons revealed that over 70% of them believed that the overall cost of this technology was a limiting factor for its adoption, hence the importance of knowing the amount of consumables (i.e., LOIs) used per surgery. In our case, the number of LOIs used in each procedure by the experienced surgeon ranged from 1.10 (for the first 50 cases) to 1.02 from those initial cases onwards. As for the inex-
experienced surgeon, he consistently used only one LOI™per patient, following in some occasions the indications given by the more experienced assisting technicians.

Regarding suction loss, the saline solution is then aspirated and retained in the LOI™'s tank, thus preventing it from being aspirated inside the device’s suction pump, which could damage the equipment. In the next suction attempt using the same consumable (i.e., LOI™), if the tank gets completely full, it is advisable to replace the LOI™ so as to prevent it from overflowing if another suction loss occurs. This scenario can result in more than one LOI™ being required for a given surgical procedure.

According to the results of the present study, the experience of each team member involved in cataract procedures—be it surgeons or technicians—have an impact, to a greater or lesser extent, upon the femtosecond surgery’s outcome, as quantified by the outcome variables of choice (vacuum time, suction losses, number of LOI™, number of laser-related complications). Therefore, comparative studies evaluating this femtosecond-laser technique—based on either its efficacy, the complications ratio or cost-effectiveness—must be initiated once the learning curve has been completed, to avoid the lack of experience’s potential influence upon the study’s outcome.

Once the learning curve has been completed, the use of a femtosecond platform for cataract surgery is a safe option, with a low complication rate which, furthermore, continues to decrease considerably as the surgeon gains additional experience.

Financial interest

The authors declare neither financial nor commercial interest in any of the products mentioned in the present study.

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