Hand-held femtosecond laser instrument to assist anterior capsulotomy in cataract surgery.

D. Touboul, PhD	CHU Bordeaux	P. Deslandes	ILASIS Laser
F. Lignereux, MD	Institut Ophtalmologique Sourdille Atlantique Nantes	B. Jouannaud	ILASIS Laser
F. Deloison, PhD	ILASIS Laser	F. Salin, PhD	ILASIS Laser

Abstract

Introduction: Cataract is a partial or total opacification of the eye lens that induces a decrease of the visual acuity and ends to blindness if not treated. Standard of care to treat cataract is phacoemulsification. Even if manual surgery remains the most practiced surgery, femtosecond lasers have been introduced since 2009 to perform the first three key steps of the cataract procedure: incisions in the cornea, capsule rhexis and lens fragmentation. Rx, the product developed by Ilasis Laser has the same femtosecond technology than these lasers but is optimized to exclusively perform rhexis. Therefore, Rx device is foreseen to deliver same performances as other femtosecond systems but with usability improvements for surgeons and workflows.

This article presents the results of the first clinical trial performed with this device.

Objective: To validate performance of Rx i.e. to demonstrate that rhexis are completely cut and that there are no tears that can generate the rupture of the capsule at the end of rhexis removal.

Material and methods: From February 2022 to March 2023, 78 patients had a cataract surgery with Rx and were followed-up at 1 week and 30 days after operation. The five first patients were only included in the safety set (part of the learning curve). Therefore, 78 patients were included in the safety set, and 73, from them were included in the performance set. The study was interventional, prospective, single-arm, single center, and open trial. It was performed with the first prototype of Rx (named Catsys during the clinical trial).

Results and discussion: Performance of Rx was confirmed in 70 out of the 73 patients of the performance set (95,9%). No peripheric tear or capsular rupture was induced by Rx (safety and performance sets). As regards to the three patients not meeting the primary endpoint, it was due to device deficiencies (DD). These DD did not induce any clinical outcome for the patients. For two of them, there was no laser cut because of a machine failure. The third one was a human error imputed to a usability failure since the handpiece was held crooked. These three patients who did not meet primary endpoint were the first three patients of the performance set. No DD was reported for the subsequent patients included in the trial.

Conclusion: In the performance set, three (4.1%) patients did not meet the primary endpoint. Excluding machine failures that did not induce any complication for the patients, a success rate of 98,6% was reached for the primary endpoint. Despite a very new holding method, it's ergonomic made it easy to learn and use.

Rx is a new concept of Femto Laser instrument that was designed for the capsulotomy only. The capsulotomy was identified as the most critical step in the cataract procedures. Thanks to its optimized ergonomics, cost efficiency, flexibility, speed of use and patient flow integration, Rx is expected to improve access to this technology while maintaining the performances of available FLACS.

The Rx medical device consists of:

- A mobile battery powered station, including the laser, the control electronics and the charger,
- A wired handpiece (HP),
- A wire firing footswitch,

The Rx device is used with:

- A patient Interface, a sterile single-use accessory,
- A laser shoot authorisation system with a licence card,
- Test accessories (power meter and stability control),
- Laser Safety goggles.

This paper presents the results of the first Rx clinical study on human patients. The purpose of this study was to validate the performances of Rx and to confirm its safety.

These results led to the CE-marking of Rx Instrument in December 2023.

Material and methods

An interventional prospective, monocentric, single-arm study was held at Sourdille Atlantic clinic, France, and supported by Ilasis company for CE marking purpose. Patients were consecutively recruited from February 2022 to March 2023 to have conventional cataract surgery with the help of the Rx femtosecond laser instrument for the capsulotomy. Surgeries were performed by the same surgeon (FL) and informed consent were signed by patients according to Helsinki's declaration.

Only adult patients diagnosed with cataract requiring surgery were included in this study.

Surgical protocol was similar to the one in place for manual cataract surgery. The use of Rx laser only replaced the manual CCC (continuous curvilinear capsulorhexis) at the beginning of the surgical procedure prior to corneal incisions. The trial was conducted with the prototype equipment CATSYS, (Rx code name during clinical trial).

Success was defined as complete cut rhexis, and non-occurrence of tears and capsular rupture due to the laser. For security reasons, recruitment was staggered, and a Data Safety Monitoring Board was responsible for authorizing the continuation of the trial after follow-up on the fifth and the 29th patient of the performance set. Patients had 1 week and 30 days follow-up.

Safety was evaluated as a secondary endpoint.

Patients' opinion was evaluated through patients' assessment, on a 4-grade scale for intraoperative pain and discomfort.

Patient overall satisfaction with the use of the device was also assessed.

Usability was evaluated through assessment of the investigator. On a 4-level scale, the investigator was asked to assess the seven surgical steps of Rx procedure: preparation of the device before surgery; handling of the device in the operating field; visualization of the eye through the device; centering of the device on the capsule; holding the device in the correct position; activation of the laser beam and removal of the device from the eye after capsulorhexis.

Visual acuity was measured at 30 ± 10 days post-surgery with measure of the Best Corrected Visual Acuity.

1. Results

Patients' demography

78 patients were operated with Rx between February 3rd, 2022, and February 6th, 2023, among which the five first patients were only included in the safety set (part of the learning curve). Then, performance set comprised then 73 patients, followed-up for 30 days. Majority of patients were female (> 62.8%) with a median age of 73.0 (68.0; 76.0) years old. The median anterior chamber depth was 3.115 (2.940; 3.280) in the safety set. All the eyes were prepared according to standard of care (mydriasis and anesthetic drugs). The most frequent implant used was the Alcon Clareon (50% of patients in the safety set) followed by the Hoya Vivinex (38.5%). Compliance to treatments prescribed between D0 and Day 4 was excellent (100%).

Success

Rx performance was confirmed in 70 out of the 73 patients of the performance set (95.9% [IC95%: 88.5;99.1]). Total anterior capsule cut (floating rhexis or easy to remove) couldn't be achieved for five patients (6.4% of the safety set) of which two belonged to the learning curve. Therefore, the cutting defect only concerned three patients from the performance (4.1%) (for two of them, it was due to machine failure and for the remaining one it was due to misuse).

Safety

No Adverse Events related to Rx were observed. As an example, no peripheric tears that could generate the rupture of the capsule was observed in any of the operated patients (all sets).

Patients' opinion

93.6% of patients of the safety set declared no per operative pain. Similarly, patients' perception of per operative comfort was overall very good with 92,3% of the safety set **stating they did not feel any per operative discomfort due to Rx laser use.**

Patient overall satisfaction

Majority of patients were very satisfied (89.7% of safety set). Remaining patients were rather satisfied (10,3% of safety set).

Usability

For more than 82% patients from the safety set, Rx' preparation was assessed as "very easy". Likewise, the handling of the medical device in the operating room was considered "very easy" for 97.4% of the patients operated on. Regarding the visualization of the eye through Rx, it was considered "quite easy" and "very easy" by the investigator for 65,4% and 34.6% of the patients. Centering of the device on the capsule was considered "quite easy" and "very easy" in 47.4% and 17.9% of the cases respectively.

Keeping Rx in the correct position during shot was recorded as "very easy" or "quite easy" for 76 patients (97.4%). Laser activation as withdrawal of the device from eye were evaluated as "very easy" for all the cases (100%).

Visual acuity

The mean residual refractive error at 1 month was ≤ 0.5 diopters in 96% of cases.

Tables

Table 1: Primary, Performance and Safety endpoints in patients operated on with Rx (Safety and Performance sets).

	Performance Set (n=73) **(N=73)**
Primary endpoint, N (%)	73
Success	70 (95.9)
95% CI (Exact)	[88.5;99.1]
Failure	3 (4.1)
95% CI (Exact)	[0.9;11.5]
Cut anterior capsule, N (%)	73
Yes	70 (95.9)
95% CI (Exact)	[88.5;99.1]
No	3 (4.1)
95% CI (Exact)	[0.9;11.5]
Peripheral tears, N (%)	73
No	73 (100.0)
95% CI (Exact)	[95.1;100.0]
Yes	0 (0.0)
95% CI (Exact)	NA

2. Discussion

One of the most important results of our study is that we demonstrated the stability control of patient's eye, handpiece and surgeon during capsulotomy with Rx. Despite the operation is performed without suction, keeping Rx in the correct position during shot was recorded as "very easy" or "quite easy" for 76 patients (97.4% of the Safety Set). Suction can therefore be considered unnecessary for a 4-seconds shot.

With 96% of BCVAs (best-corrected visual acuity) having a spherical equivalent of less than 0.5 D, the quality of vision of patients operated on with Rx is particularly remarkable. Although this result needs to be confirmed, it is clearly more favorable than the one obtained in the Femcat study, with 86% better than over 0.75D.

This pre CE-marking clinical trial was done with the first prototype of this new laser instrument. The results were used to meet the requirements of the new European Medical Device Regulation (MDR 2017/745). In the performance set, 3 patients (4.1%) failed to meet the primary endpoint. When excluding machine failure, a success rate of 98,6% was reached for the primary endpoint. Despite a very new holding method, its ergonomic made it easy to learn and to use. The failure due to crooked handpiece happened on the 8th patient and could have been considered as part of the learning curve since the learning curve is not well established yet and should be analyzed in the future.

In terms of safety, no Adverse Events related to Rx were observed.

Furthermore, patients perception of per-operative pain and discomfort as well as patients satisfaction were excellent. As a result, we can consider that patient comfort is improved compared to devices requiring suction (which induce pain, bleeding and increased opacity).

Last but not least, an additional Rx advantage is its possibility to be used in the non-sterile induction room, allowing smooth patient flow.

3. Conclusions

This study describes the use of Rx, a handheld femtosecond laser performing anterior capsulotomy during cataract surgery. 78 patients were operated on with Rx, among which the five first patients were only included in the safety set (part of the learning curve).

Excluding the two machines failures that occur at the very beginning of the study, capsulotomy was complete in 70 out of 71 patients of the performance set (98,6%). The mean residual refractive error at 1 month was ≤ 0.5 diopters in 96% of cases. No peripheric tears that could generate the rupture of the capsule was observed in any of the operated patients.

The Rx device has proven to be equivalent to the state of the art but with a total cost of ownership (Rx device, consumables, maintenance) up to 70% cheaper than current FLACS equipement. Rx is easy to use and can be perfectly integrated in the patient workflow. Its battery powered system weighs only 50 kg, making it trivial to move from one patient to another.

References

1. Walkow, Anders et al. 2000, Taban, Behrens et al. 2005, Gulkilik, Kocabora et al. 2006, Russell, Gaskin et al. 2006, Clark, Morlet et al. 2011

2. Nagy Z, Takacs A, Filkorn T, Sarayba M (2019) : Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. J Refract Surg 2009; 25: 1053–1060

3. Sugar 2002, Chung and Mazur 2009

4. A'Hern RP (2001) : Sample size tables for exact single-stage phase II designs Stat Med 20(6): 859-866

5. Siegfried Mariacher, Peter Laubichler, Jascha Wendelstein, Martina Mariacher and Matthias Bolz (2019) : Preoperative intraocular pressure as a strong predictive factor for intraocular pressure rise during vacuum application in femtosecond laser assisted cataract surgery

6. Cedric Schweitzer, Antoine Brezin, Beatrice Cochener, Dominique Monnet, Christine Germain, Stephanie Roseng, Remi Sitta, Aline Maillard, Nathalie Hayes, Philippe Denis, Pierre-Jean Pisella, Antoine Benard (2020) : Femtosecond laser-assisted versus phacoemulsification cataract surgery (FEMCAT): a multicenter participant-masked randomized superiority and cost-effectiveness trial 2020 Jan 18;395(10219):212-224.