

The Femto capsulotomy performed with Rx by Helix Surgical

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Context

FLACS or «Femtosecond laser to assist cataract surgery» appeared in the early 2010s in continuity with the emergence of femtosecond lasers dedicated to corneal refractive surgery, which appeared in the late 90s. Initially, they were designed to soften the lens and compensate for presbyopia, this arduous task was unfortunately fruitless, and the various companies launched into this project have «fallen back» on assistance with cataract surgery. The commercialization of these lasers finally came up against the mediocre medico-economic profitability of the concept. Thus, since the added value of the Laser could not be formally demonstrated, the penetration rate of FLACS on the cataract market remained anecdotal. Various alternatives have since emerged, but none has ended up reaching a large audience.

Background

The frugal project that led to RX by Helix Surgical was born ten years ago, in the context known as market maturity for FLACS. Resulting from the collaboration of the CHU of Bordeaux and the industrial environment, it finally led in 2019 to the creation of the Bordeaux based startup ILASIS Laser. The concepts of frugality of design and use are the DNA of the Rx instrument which is solely dedicated to the realization of a perfect anterior capsulotomy assisted by femtosecond laser. Indeed, it seems logical to use the laser, a sophisticated and expensive tool, only for situations where the human hand cannot operate. In this case, the surgeon's hand cannot make a perfectly circular and centered pre-cut infallibly and without having to open the patient's cornea beforehand. It has been shown in studies of cataract learning curves that the 2 most difficult times in cataract surgery are, on the one hand, the achievement of a perfect capsulorhexis and, on the other hand, the division of lens fragments. The particularly light, economical, and autonomous (battery powered) logistics of the Rx instrument makes it possible to cut the lens before the patient enters the operating room. This point is extremely important so that it can be integrated without effective loss of time within the workflow of any structure performing cataract surgery.

The challenge behind the use of assistance for anterior capsulorhexis is based on the one hand, on helping to learn about surgery and, on the other hand, on the guarantee of a calibrated gesture, enhancing the implantation of so-called premium intraocular lenses, ie with increased optical susceptibility (toric, multifocal, EDOF). Other frugal design systems have been introduced in recent years, but none allow as much flexibility as the Rx instrument. Let us quote for example the Capsulaser® system which requires the opening of the anterior chamber for staining of the capsule with blue then alignment of a thermal laser connected to the operating microscope in order to carry out, thermally, in about 1.5 seconds, a circular anterior capsulotomy. The advantage is certainly the solidity of the rhexis but on the other hand there are many technical constraints and usage complexity. The Zepto® system also makes it possible to open the capsule in a calibrated

way. It nevertheless requires the introduction of a lens suction system which must be centered in contact with it through a widely dilated pupil in order to trigger a wave of radiofrequency which perfectly cuts the anterior capsule. It is then necessary to remove the device, whose size is relatively substantial, by an incision which contradicts the logic of implantations by corneal minimally invasive incision.

Frugality of design and use



Figure 1: Rx station with its fiber handpiece (right), docking interface with coupling liquid (middle), bimanual positioning of the handpiece in contact with the cornea with sighting reticle seen from the side (to the left).

Frugality does not mean degradation of the technical quality or the level of innovation. On the contrary, it is a question of being more efficient with fewer technological resources, by concentrating on the essential goal to be achieved. This is in fact the opposite path to the one taken historically by the FLACS. For the design, the Rx station is of a space-saving mobile design and autonomous in its power supply. It uses a fiber femtosecond laser guaranteeing better laser stability and lightest optical maintenance. It was deliberately avoided to perform suctioning of the eyeball or to add any imaging system. Only the preoperative measurement of the anterior chamber depth is needed to choose the appropriate spacer. The visualization is done directly through a reticle by the eyes of the surgeon, as if he were aiming with a rifle, the system thus frees itself from the use of any operating microscope. In use, the laser is a handpiece that the surgeon must keep in contact with the eyeball. There is therefore a learning curve to position the tool and decide on the laser shot once the target is centered on the pupil. The latter must of course be dilated beforehand. See figure 1. The regularity and transparency of the cornea as well as the adjustment of the implantation interface to the depth of the anterior chamber measured preoperatively are necessary prerequisites. The patient interface in contact with the cornea is sterile, the gesture can thus be carried out either in the operating room or in the front room, with a simple blepharostat and a drop of local anesthesia on the cornea. Positioning the system on the patient's eye is very similar to the docking gesture performed for corneal refractive surgery. A first sterile curved implantation interface is positioned on the cornea with one of the surgeon's two hands. A BSS-type liquid is placed into the patient interface to guarantee the «optical link» with the handpiece, itself held with the surgeon's other hand. The practitioner must then insert it into the interface and center the laser thanks to the residual clearance between the interface and the handpiece.

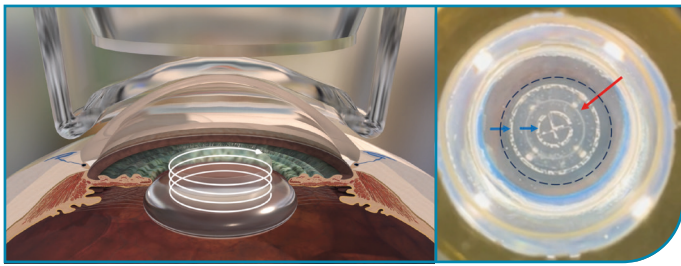


Figure 2: Rx's helix shaped cutting concept (left); visualization and centering system (right): dotted lines = edges of the pupil, blue arrows = engraving for centering, red arrow = cutting of the capsule between the two engravings

To do this, the surgeon only must look through the reticle of the handpiece and align an engraved target making it possible to materialize the cutting zone with respect to the position of the pupillary edge. Once correctly centered, the surgeon must press the pedal which triggers the shot. A laser spiral approximately 2.5 millimeters in height and 5 millimeters in diameter is produced to obtain, ultimately, a rhexis of approximately 5.5 to 6 millimeters in diameter depending on the capsular elasticity. The laser starts in the lens and ends in the anterior chamber, straddling the anterior capsule. Adjusting the laser avoids any risk of displacement towards the posterior capsule or towards the corneal endothelium. The helix shaped laser shot is triggered by a pedal and lasts 3 to 4 seconds, but the cutting of the anterior capsular plane only lasts 20 milliseconds. Thus, even if the patient or the interface were to move suddenly, the probability of incomplete cutting would remain very low. The firing will be centered according to the skills acquired by the surgeon, which are raising during the learning curve. This learning curve is estimated to a few procedures and allows the surgeon to develop the needed surgical skills. Cf. figure 2. Removing the Rhexis along the laser's cut involves the usage of a curved needle or distal forceps type of instrument. See figure 3. Similarly, to FLACS, some limited part may remain attached but do not alter the easiness of capsule removal by applying the dimple down method described by Pr Dick. The ablation step of the lens masses is a little different compared to the manual gesture because the adherence of the masses is more important, a careful hydro-dissection is thus recommended. As with all femtoseconds assisted cataract Surgery devices, it is not recommended to exert excessive traction on the aperture. Also, it is recommended to avoid dislocating the nucleus in the anterior chamber during phacoemulsification surgery.

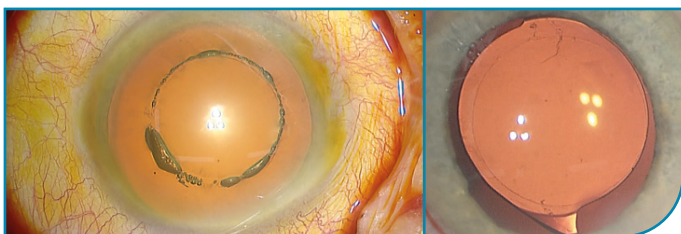


Figure 3: surgical view before opening the cornea of the Rx cutout (left), view of the cutout once the implant is in place.

Preliminary results

The first clinical results should be put in the context of the CE marking of the Rx instrument for cataract surgery. They were carried out between 2022 and 2023 at the Sourdilles Atlantique clinic in Nantes by Doctor François Lignereux. We excluded any ocular pathology, extreme anterior chambers, and poor pupil dilation. The primary endpoint was the achievement of continuous and complete anterior capsulotomy. Naturally, the centering, the side effects as well as the opinion of the surgeon and the patients were evaluated. It was thus possible to operate on 78 eyes of 78 patients consecutively with an efficiency of complete continuous cuts of 95.9%, perfect circularity at 98% and an average decentration at less than 360 microns from the pupillary center (in dilation). The average residual refractive error at 1 month was for 96% of cases less than 0.5 diopters. We were able to deplore 2 laser system failures which did not allow the cutting to be carried out, an anterior capsular rupture linked to the dislocation of the lens in the anterior chamber, a posterior capsular rupture not linked to the use of the Laser, with successful implantation in sulcus in both cases. No other adverse effects could be observed for this cohort. The surgeon was able to describe a very great ease of manipulation and maintenance of the Laser during firing. Centering has been named as the trickiest point on the learning curve. The level of patient satisfaction and comfort was excellent.

Next steps

The first commercially available version of the Rx Femto Laser instrument is expected before the end of 2023 and will gradually see technical improvements. A study on the learning curve according to the level of expertise of surgeons is in perspective. Future developments are expected to facilitate the first steps and diversify the indications for other procedures whose simplification would be relevant, particularly for corneal surgery.

Conclusion

The preliminary results of the Rx Femto laser instrument by Helix Surgical are very encouraging. The preferred target is aimed at surgeons in the learning phase and at surgeons motivated for optimized surgery with premium implants. In the era of energy sobriety and the crisis of health institutions, the ILASIS team thinks that frugality is a serious track. Rx provides a solution to the contradictory injunction between the desire for perfection and medico-economic constraints.

Useful references

- www.helixsurgical.com
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Financial Disclosure

Pr Touboul is a partner, consultant and investigator for ILASIS Laser, the company designing and commercializing Rx instrument under Helix Surgical brand.