

LUXSMART EDFOF IOL: A NOVEL LENS DESIGN FOR PRESBYOPIA CORRECTION

The LuxSmart platform of preloaded IOLs includes the presbyopia-correcting LuxSmart and its monofocal version LuxGood. Both will be available in toric models.

BY GERD U. AUFFARTH, MD, FEBO; PAVEL STODULKA, MD; FRANCISCO JAVIER CASTRO ALONSO, MD; AND MAYANK A. NANAVATY, MBBS, DO, FRCOPHTH, PHD

An Introduction to the LuxSmart EDFOF IOL

BY GERD U. AUFFARTH, MD, PHD, FEBO



We are experiencing an explosion of new IOL technologies. Prior to 15 years ago, patients had only two choices: monofocal and multifocal. In addition to these, today's patients can select monofocal plus, extended depth of

focus (EDOF), extended range of vision, bifocal (diffractive and refractive), trifocal, and accommodating IOLs, to name a few. Each lens has a slightly different concept with its own set of advantages and disadvantages. In my opinion, one of the most exciting new lens technologies that I have experience with is the LuxSmart EDFOF IOL (Bausch + Lomb).

OVERALL DESIGN

The LuxSmart EDFOF platform is offered in both UV and clear or violet light-filtering models, and it is available in 1.00 D steps from 0.00 to +10.00 D and in 0.50 D steps from +10.00 to +34.00 D. This one-piece hydrophobic acrylic lens has four-point fixation and a 360° square edge design. The biconvex, aspheric optic incorporates Pure Refractive Optics (PRO) Technology with an EDFOF center, a patented transition zone, and a monofocal periphery (Figure 1). The lens creates a continuous area of vision and has no diffractive rings.

The center. The 2-mm central part of the LuxSmart EDFOF IOL contains a pure refractive optic that combines sixth-order and fourth-order spherical aberration (SA6 and SA4) of opposite signs to optimize and increase the subjective depth of focus.

According to Benard et al,¹ the combination of SA6 and SA4 in various levels can increase depth of focus more than three times for pupil sizes larger than 4.5 mm.

The transition zone.

The patented transition zone of the LuxSmart EDFOF IOL is designed to

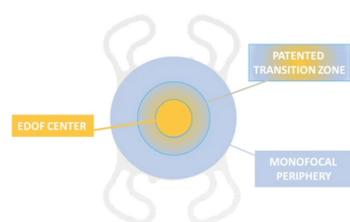


Figure 1. The LuxSmart EDFOF IOL integrates pure refractive optic technology with an EDFOF center, a patented transition zone, and a monofocal periphery.

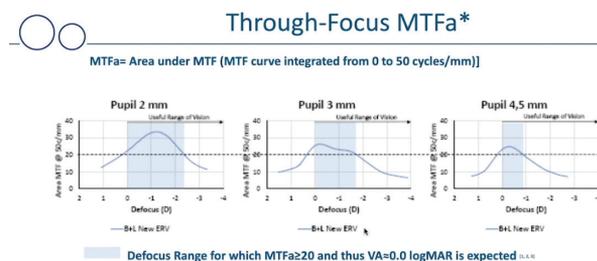


Figure 2. Defocus curve on an optical bench with the LuxSmart EDFOF IOL.

smoothly decrease the optic vergence from the center to the periphery and to control the trajectory of light rays in order to avoid light loss. It also helps to manage the amounts of SA6 and SA4 that are introduced in the EDFOF center of the lens.

The periphery. This sector of the LuxSmart EDFOF is a monofocal aspheric surface to create a standard optical field in the periphery of the lens.

LENS PERFORMANCE

Defocus curve. On the optical bench, modular transfer function curves show that, for a threshold of 20 corresponding to a predicted visual acuity of 0.0 logMAR, the LuxSmart EDFOF IOL provides a depth of field of approximately 1.70 D for a 3-mm pupil with a wide and smooth transition between distance and intermediate (Figure 2).

Resistance to decentration and tilt. In an optical model, the LuxSmart demonstrated high resistance to decentration and tilt even at large pupil sizes (Figure 3).

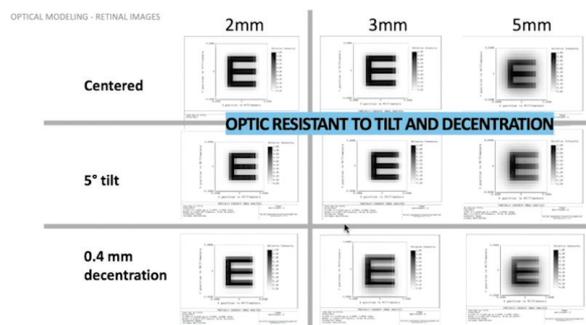


Figure 3. Optic resistance to decentration and tilt with the LuxSmart EDFOF IOL.

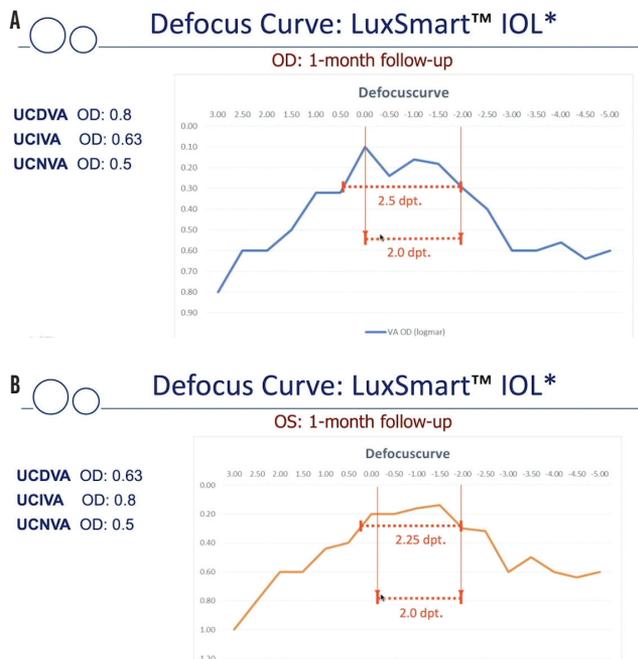


Figure 4. One-month postoperative defocus curves in the right (A) and left (B) eyes of Professor Auffarth's first patient who received the LuxSmart EDOF IOL.

Biomaterial. The intensity of the glistenings vary by lens material. In an in vitro evaluation of glistenings formation, the biomaterial of the LuxSmart EDOF IOL was classified as grade zero on the Miyata scale.

First Clinical Outcomes With the LuxSmart

BY PAVEL STODULKA, MD, PHD, FEBOS-CR



I was the first surgeon worldwide to use the LuxSmart EDOF IOL. Since that time, I have implanted this lens in more than 50 patients (scan the QR code now to watch a video of Dr. Stodulka implanting the LuxSmart EDOF

IOL). This article outlines the 3-month results in my first clinical series of 30 patients. We plan to continue the study through 6 months of follow-up to evaluate the quality of vision at different distances and time intervals.

STUDY OVERVIEW

All patients enrolled in this prospective study underwent bilateral cataract surgery and received the LuxSmart IOL in both eyes. Patients were at least 50 years of age and had bilateral cataract with no comorbidity. Patients with irregular astigmatism, previous intraocular or corneal surgery, traumatic cataract, advanced glaucoma, or significant dry eye were excluded from the study.

PERSONAL EXPERIENCE

I was the first in Germany to use the LuxSmart EDOF IOL. My first implantation was in a 76-year-old man with a normal cataract with distance UCVA of 0.5 OD and 0.4 OS. By 1 month postoperative, distance UCVA improved to 0.8 OD and 1.0 OS.

Overall, the patient was pleased with his good binocular visual acuity (20/20) and range of vision. The lens provided more than 2.00 D depth of focus in both eyes. The defocus curve in the right and left eyes at 1 month postoperative are seen in Figure 4.

CONCLUSION

The LuxSmart EDOF preloaded IOL is based on PRO Technology. The 2-mm central zone of the lens is designed to increase subjective depth of field. There is no more light loss with this lens compared to monofocals, and in our early experience we have seen good results.

1. Bernard Y, Lopez-Gil N, Legras R. Optimizing the subjective depth-of-focus with combinations of fourth- and sixth-order spherical aberration. *Vision Res.* 2011;51(23-24):2471-2477.

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Three-month results are available for 38 eyes of 19 patients with a mean age of 63.5 years (range, 50–80 years). The mean IOL power in this population was 21.50 D (range, 18.50–23.00 D). All surgeries were performed by me, and the Victus femtosecond laser (Bausch + Lomb) was used for capsulotomy and lens fragmentation in all cases.



RESULTS

In the first 24 eyes, we noticed a tendency toward a myopic result (Figure 1). This group of eyes before surgery was about a mean of 1.00 D hyperopic, and at 1-month postoperative the mean was -0.38 D. Based on this result, we recommend a shift in the A constant from 119.2 to 118.6. We have since been using this new A constant, and with it, we seem to hit exactly emmetropia in most eyes.

Regarding corrected visual acuity, the LuxSmart EDOF IOL performed extremely well at distance (BCDVA, -0.03 logMAR) and intermediate (DCIVA at 80 and 66 cm, mean 0.07 and 0.14 logMAR, respectively). DCNVA at 40 cm reached

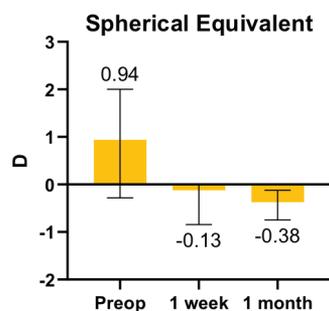


Figure 1. Manifest refraction spherical equivalent at 1 month postoperative in the first 24 eyes.

0.38 logMAR. The LuxSmart EDOF IOL was designed to provide great distance and intermediate vision; however, our patients achieved surprisingly good near visual acuity as well, providing a potential for uncorrected reading. Defocus curve shows ≤ 0.2 logMAR range between -1.75 and +0.75 D, which is beyond the result that we expect from EDOF lenses.

Longer follow-up with more eyes is needed to confirm these results, but for

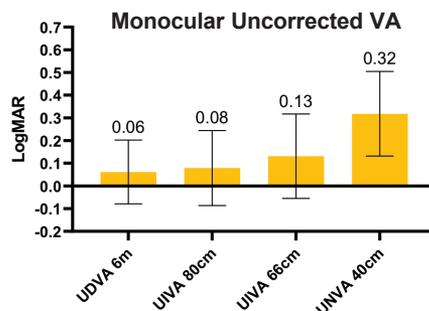


Figure 2. Monocular distance at 3 months postoperative in the first 40 eyes.

our first cases the results are extremely impressive.

LENS IMPLANTATION

The LuxSmart EDOF IOL comes preloaded. To activate the inside coating of the injector, one must add balanced saline solution for smooth lens delivery through a 2.2-mm incision. As the lens unfolds, it is directed into the capsular bag.

In my experience, the LuxSmart centers well, and it is easy to rotate and aspirate the remnants of OVD from under the lens optic. Incisions are closed by hydration to conclude the surgery.

CONCLUSION

In my experience, the LuxSmart EDOF IOL provides patients with a great opportunity to achieve high-quality uncorrected distance (Figure 2) and intermediate vision with significantly lower risk of dysphotopias as compared to trifocal lenses. This EDOF IOL is a significant new option in our armamentarium, and I suspect we will hear more about it in the near future.

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Positive Early Experience With a New EDOF IOL

BY MAYANK NANAATY, MBBS, DO, FRCOPHTH, PHD



I work in both a National Health Service and private setting and have more than 19 years of experience specializing in routine and complex cataract surgery, refractive lens exchange, laser vision correction, and corneal

surgery. Over the years, I have participated in many clinical evaluations and trials for a variety of IOLs and devices. Most recently, I had the opportunity to evaluate the LuxSmart EDOF IOL, and it is safe to say that my early experience with this lens was nothing short of positive.

Most EDOF IOLs have a diffractive design, which can cause unwanted visual effects such as halos and glare postoperatively. To some patients, the benefit of the extended range of vision is not worth the tradeoff of visual side effects. The LuxSmart, however, is an EDOF IOL that does not depend on the diffractive principle and therefore should not cause more halos and glare than a monofocal IOL.

PERSONAL EXPERIENCE

At the time of this writing, I have implanted the LuxSmart in 37 eyes. All lenses were implanted during routine cataract

surgery, and the mean age of patients was 76 years. Both the postoperative visual outcomes in these eyes and patient feedback have been excellent. The visual clarity and the level of intermediate vision without glare and halos is the most impressive outcome for my patients. Another additional advantage is the lens' hydrophobic acrylic platform, which has a lower predicted rate of posterior capsular opacification.

The results so far have showed that 93.5% of patients achieved 6/9 or better monocular UDVA and 70% achieved N8 monocular UIVA. All patients were at 6/6 for CDVA. In the 14 patients who had 0.75 to 2.50 D of astigmatism, I combined lens implantation with placement of limbal relaxing incisions. In the future, availability of a toric version of the LuxSmart will streamline the astigmatism correction process.

The patient feedback with the LuxSmart EDOF IOL has been phenomenal. Patients use words like *bright*, *colorful*, and *clear* and phrases like *excellent improvement*, *fantastic vision*, *over the moon*, and *easy to read the newspaper* to describe their vision.

PEARLS FOR USE

Patient selection. I typically recommend an EDOF IOL for patients whose life depends on clear distance and

intermediate vision and who do not do much reading or close work. Typically, this includes individuals who do a lot of work on computers, laptops, and mobile phones.

In the OR. There are two special tips I like to use with the LuxSmart EDOF IOL. First, I like to prime the IOL with balanced saline solution before I start my surgery. This allows sufficient time for the material to be adequately primed and avoids any issues with rigidity of IOL material during implantation. Second, the blue plunger of the preloaded injector can be vulnerable to mushrooming at the nozzle tip.

To avoid this, care should be taken to ensure that, at no time, the blue plunger comes out of the nozzle tip. This can be achieved by gentle and repeated taps on the injector with the thumb rather than a single push. As soon as the IOL optic is inside the anterior chamber, the nozzle should be gently withdrawn. The proximal haptics should slide out of

the nozzle into the main wound without need for the blue plunger pushing the IOL.

CONCLUSION

My early experience with the LuxSmart IOL is encouraging and I am eager to use this lens for patients whose lives are dependent on screen work and distance work. The LuxSmart EDOF IOL will have its place in the market for the right patients.

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Proficiency With the LuxSmart

BY FRANCISCO J. CASTRO-ALONSO, MD, PHD



In the history of IOL designs, there has not yet been one perfect lens. Some IOLs come close, but all have at least one drawback. It is therefore crucial for surgeons to weigh the benefits and drawbacks of any new lens design, especially those designs that compete with tried-and-true IOL technologies.

BILATERAL AND UNILATERAL IMPLANTATION

I performed the first LuxSmart EDOF IOL implants in Spain, done bilaterally in six patients and unilaterally in 10. My overall experience was positive, with very good outcomes after these first surgeries. Patient satisfaction was high, and there were no complaints of dysphotopsia phenomena and other disturbances.

In my first cases, I selected patients with no significant preoperative ocular astigmatism who expect spectacle independence for most of their daily activities, especially in the social distance. It is also advisable to select patients who comfortably accept spectacle use for specific near vision tasks.

In my early experience with the LuxSmart IOL, some patients were left slightly myopic postoperatively in the first eye, as the IOL constant was not yet optimized. After adjusting the A constant, their second eye, which was emmetropic, achieved binocular UCVA between 0.9 and 1 decimal at distance and 0.8 and 1 decimal at intermediate. They even achieved good near visual acuity from 0.5 to 0.6 decimal.

SHORT LEARNING CURVE

Like with any new IOL, a brief learning curve is to be expected

with the LuxSmart EDOF IOL. After the first few cases, surgeons should feel comfortable performing the implantation technique with the lens' preloaded injector.

During the injection into the capsular bag, the lens must be properly unfolded. The key step, in my opinion, is perfect unfolding and extending of the haptics to achieve the correct lens position in the bag (Figure). The stability and centration of the LuxSmart lens are maintained in the short and medium term, according to our first results. More long-term experience is required to confirm our findings and to assess the rate of posterior capsular opacification.

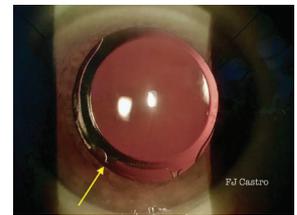


Figure. The LuxSmart IOL in situ. Note the clear visibility of an orientation mark.

CONCLUSION

Postoperative outcomes and patient satisfaction are excellent with the LuxSmart EDOF lens to date. I predict that this IOL has a promising future with good market share thanks to the lens' unique design, based on Pure Refractive Optics Technology, optical quality, refractive results, and the absence of dysphotopsic phenomena postoperatively. ■

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