Pre-clinical study report

ZEISS AT LARA 829MP: Next generation EDoF (Extended Depth of Focus) IOL

In general, today's multifocal intraocular lenses (IOLs) provide patients with adequate visual acuity at all distances, but can, at least for some patients, come with a compromise in the quality of vision – e.g. visual side effects at night such as halos and glare. For patients who are particularly sensitive to these symptoms, a monofocal IOL is commonly utilized but which often requires postoperative spectacles or contact lenses to provide a full range of vision.

Recently, the advent of extended depth of focus (EDoF) IOLs has brought about the "best-of-both-worlds" balance for these patients, combining the benefits of multifocal IOLs, i.e. more spectacle independence, with an optical performance closer to that of monofocal IOLs (meaning reduced halos and glare). This combination of benefits is particularly attractive to patients with an active lifestyle.

Carl Zeiss Meditec AG believes this EDoF technology can be significantly enhanced. AT LARA 829MP (Figure 1), a next generation EDoF IOL is designed to provide an even wider range of focus while providing superior optical performance and quality of vision.

Figure 1. ZEISS AT LARA 829MP EDoF IOL.

Unique Design

The new ZEISS AT LARA 829MP EDoF IOL features a unique diffractive optical design to optimize continuous distance to intermediate vision. This patented "light bridge" optical design enables the IOL to extend depth of focus and create a continuous range of sharp vision from far to intermediate distances (Figure 2).

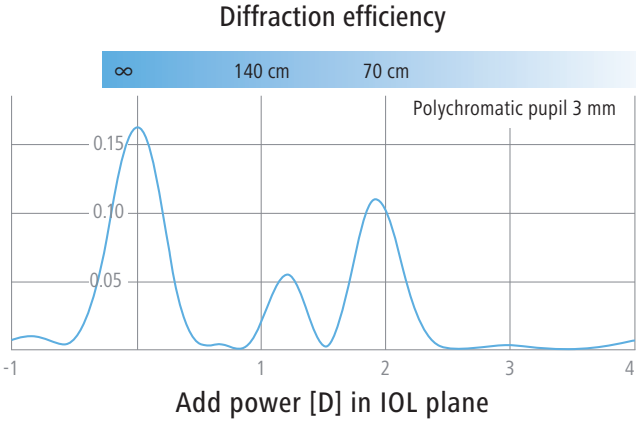

Figure 2. AT LARA "light bridge" diffractive optical design.

The new IOL also features patented "Smooth Micro Phase" technology (Figure 3), which optimizes the design and manufacturing of a diffractive IOL to minimize light scattering – the cause of troublesome visual side effects.

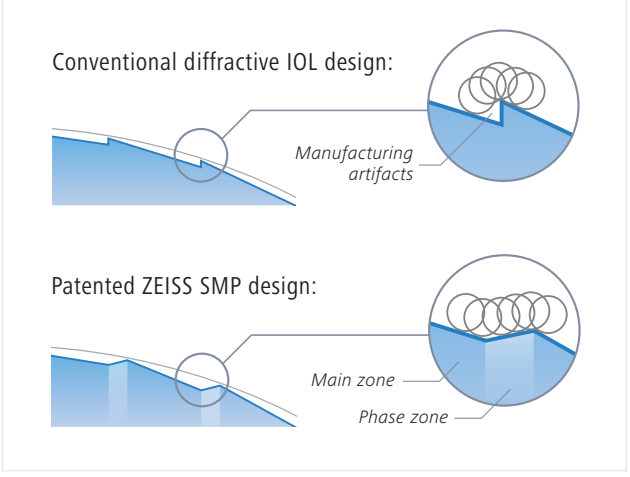

Figure 3. Smooth Micro Phase technology minimizes light scattering.

Whereas conventional diffractive EDoF IOL designs feature surface steps that, with available manufacturing technologies, do not allow for optimized manufacturing, Smooth Micro Phase technology enables the creation of a smooth and continuous diffractive surface profile within the AT LARA design. Each diffractive zone is composed of a main sub-zone and a phase sub-zone, creating a surface profile that can be manufactured more precisely, thereby reducing light scattering.

Finally, the AT LARA 829MP also features an aberration neutral aspheric design and advanced chromatic balancing for optimized contrast sensitivity.

Pre-Clinical Evaluation

The performance of AT LARA was assessed in two comparative pre-clinical trials investigating the range of focus and the overall (subjective) quality of vision.

These two prospective, "cross-over", subject-masked trials were performed using a proprietary real-world, visual environment simulation device called the VirtIOL (Figure 4).[1] In essence, the VirtIOL allowed the investigators to "virtually implant" an IOL by placing it in the optical path while a normal phakic study subject looked through the device. The test person saw the environment in an optically equivalent manner as if the IOL was implanted in his/her eye, allowing investigators to assess the optical performance of the IOLs without inserting them into subjects' eyes. This setup can be used to do standard vision tests with non-implanted subjects.

Figure 4. VirtIOL assessment tool.

Evaluation of Optical Performance

In the first trial, 25 of the subjects were asked to view an image at 6 mm distance through each of two IOLs – the AT LARA 829MP and the TECNIS Symfony – and visual acuity, among other parameters was assessed using the Freiburg Visual Acuity & Contrast Test (FrACT version 3.9.3).

A pair-wise comparison of depth of focus between -4.00D to +1.00D for the two IOLs is presented in Figure 5. As these findings demonstrate, the range of focus is wider with the ZEISS AT LARA 829MP compared to the TECNIS Symfony, and the AT LARA also has better visual acuity at 0 defocus.[2]

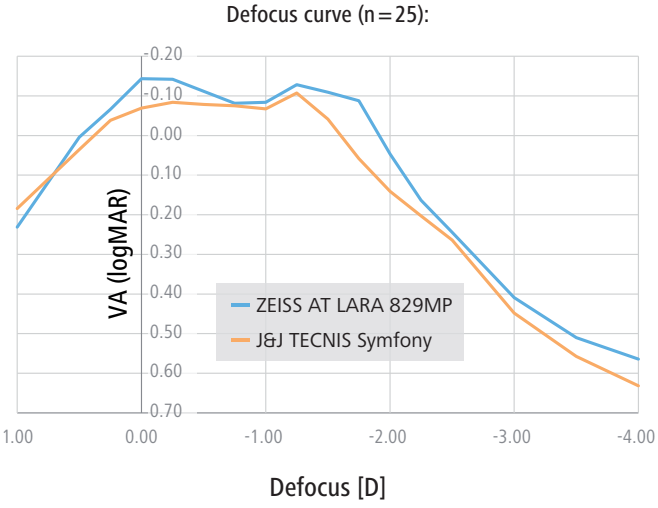

Figure 5. Defocus curve of ZEISS AT LARA 829MP versus J&J TECNIS Symfony.

Subjective Visual Comfort / Experience

In the second study of IOL performance in night vision conditions,[3] the VirtIOL was found to be a "suitable tool to study the relation between night vision phenomena [e.g., halos and glare] and optical design." The study included 48 volunteers and compared four different IOLs – one monofocal IOL (ZEISS CT ASPHINA), two EDoF IOLs (ZEISS AT LARA and J&J TECNIS Symfony), and one trifocal IOL (ZEISS AT LISA tri). Using the same test setup (virtual implantation with the VirtIOL), the 48 study subjects were seated in a darkened room and exposed to a typical night traffic situation displayed on a monitor (Figure 6).

Figure 6. Simulated night driving situation.

A LED point light source was placed in front of the scene. All test subjects were presented with the same scene four times with different IOLs placed in the optical path of the test device in random order and without the test person knowing the IOL type. The test subjects were then asked to select the IOL they preferred or would choose with regards to the level of disturbance (halo and glare) originating from the LED light source for all situations (visual symptoms represent an important component leading to visual discomfort).

Not surprisingly, the monofocal IOL was rated best (least disturbing side effects), and both EDoF IOLs were rated better than the trifocal IOL in this comparison. Notably, the ZEISS AT LARA 829MP was ranked second, better than TECNIS Symfony and the trifocal IOL, with a statistically significant difference for both (Figure 7).

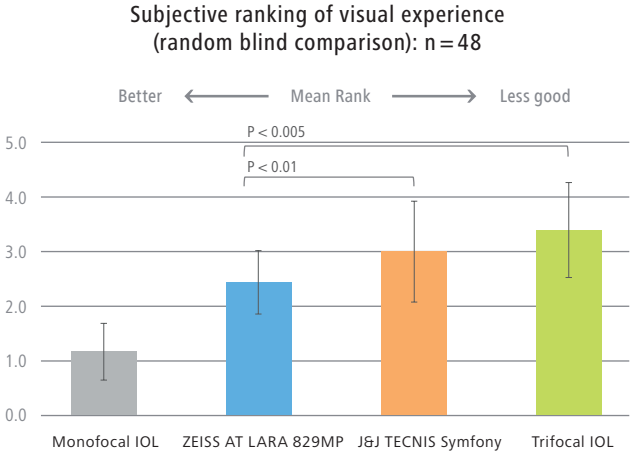

Figure 7. Subjective ranking of visual side effects (random blind comparison). (1 = best out of 4; 2 = 2nd best out of 4; etc)

Summary

The new ZEISS AT LARA 829MP EDoF IOL is a next generation design offering:

- A wider range of focus than competitor EDoF IOLs
- Fewer visual side effects than multifocal IOLs

Overall, AT LARA 829MP provides surgeons with the capability to extend their premium IOL portfolio and offer to a broader group of patients more spectacle independence for an active lifestyle.

1. *VirtIOL. virtiol.wixsite.com/virtiol/technology. Accessed August 31, 2017.*
2. *Marx S, Gerlach M, Kolbe O, Sickenberger W. Bewertung der optischen Wahrnehmung durch refraktiv-diffraktive optische Linsen durch virtuelle Implantation: final report to Ethics Committee (PJV-1603 version 2.3), August 24, 2016.*
3. *Guthoff R et al. Characterization of starburst and halo size for different virtually implanted intraocular lenses in comparison to subject's quality of vision. Presented at ARVO; April 29–May 3, 2017. Honolulu, Hawaii.*