



Supplement
September 2022

ELON



Extended Depth of Focus with the Bi-Flex ELON IOL

Empowered by Wavefront Linking technology
for an elongated depth of field

| Technical overview | Clinical experience | Future perspectives

MEDICENTUR

Material. Design. Optics.

INTRODUCTION

Non-diffractive Extended Depth of Focus (EDoF) IOLs represent the latest generation of presbyopia-correcting IOLs. Using various physical or optical principles, these lenses aim to satisfy patients' visual needs with an active lifestyle while minimizing the risk of dysphotopsia compared to diffractive technologies. This article introduces Medicontur's latest innovation, the ELON IOL, as a new option within the non-diffractive EDoF IOL category. The article describes ELON's proprietary Wavefront Linking technology that is designed to create a true ELONGated Focus and presents the first clinical experiences of ELON users.

WAVEFRONT LINKING FOR AN ELONGATED FOCUS

To achieve the goal of creating a true EDoF IOL with minimal optical disturbances, Medicontur developed Wavefront Linking. This proprietary non-diffractive technology is based on a series of central concentric refractive zones varying in curvature linked by specially designed linking zones (Figure 1).

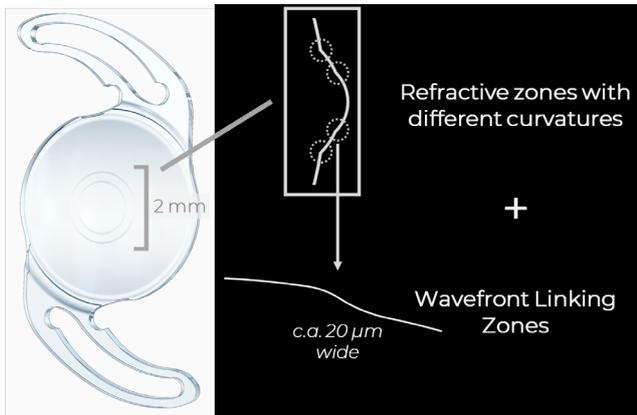


Figure 1: Optic design of the ELON IOL using Wavefront Linking technology.

Wavefront Linking causes light energy to be distributed continuously along the optical axis (Figure 2). The focal points are connected, resulting in a singular elongated focus that is useful across the entire range of vision.

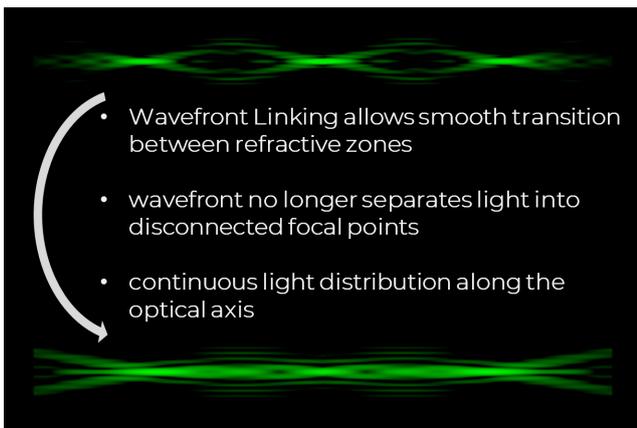


Figure 2: Wavefront Linking uses special linking zones to create a continuous distribution of light along the optical axis.

Compared to EDoF designs that are based on aspheric surfaces, Wavefront Linking technology enables a more flexible modification of light energy distribution that results in higher intermediate light intensity and a wider range of functional vision. Because it contains no diffractive rings, Wavefront Linking technology lowers the risk of visual disturbances

compared to diffractive EDoF solutions. Figure 3 highlights focal point differences between different IOL optical solutions.

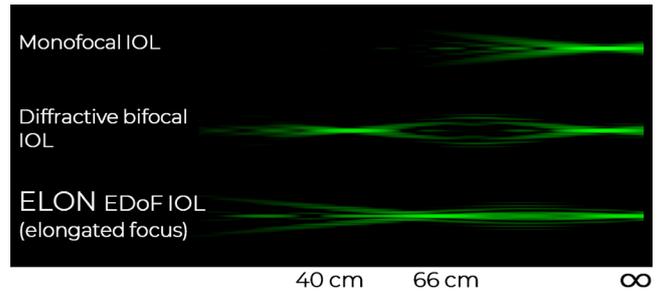


Figure 3: Simulated through-focus point spread functions for a monofocal, diffractive bifocal, and the ELON EDoF IOL, which creates a single elongated focus.

“The ELON IOL model utilizes Wavefront Linking to create real EDoF performance, providing functional vision from far to intermediate distances.”

The area under the modulation transfer function (MTFa) curve was chosen to compare the optical performance of ELON with a widely-used competitor IOL.¹ Figure 4 shows the results of laboratory measurements of the two IOL models.

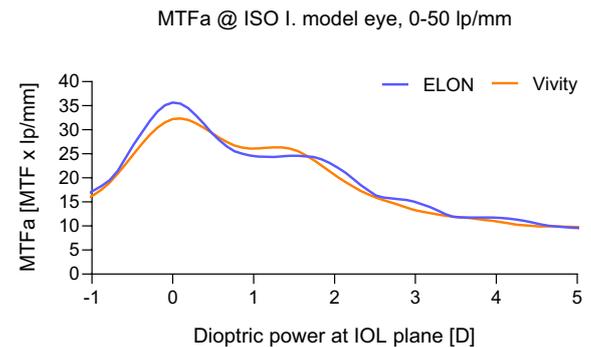


Figure 4. MTFa curves for the ELON IOL and a competitor EDoF IOL (Vivity). (Data on file).

EXTENDED RANGE OF VISION

In late May 2022, Medicontur brought together an international group of leading cataract surgeons to share their initial experiences with the ELON lens (Bi-Flex 877PEY).² The experts represented different practice settings, different markets, and countries with different healthcare reimbursement systems. Most of the surgeons have long-term experience with other presbyopia-correcting IOLs, including other EDoF lenses. All members of the group agreed that the new ELON lens provides outstanding unaided distance and intermediate vision both monocularly and binocularly – along with a high degree of functional unaided near vision.²

“It provides excellent vision at distance and intermediate ranges and great near vision that exceeds expectations.”

said Dr Johann Kruger from Cape Town, South Africa. “The near vision performance of the ELON lens is truly better than what I expected,” agreed Dr Gábor Németh from Hungary. Dr József Gyóry, the principal investigator of a multicentre comparative clinical investigation focusing on the safety and performance

of the ELON lens shared that all of the study participants achieved uncorrected distance vision of at least 20/25 (0.1 logMAR), and the average binocular intermediate visual acuity was as good as 0.08 ± 0.18 logMAR. Binocular distance-corrected defocus curves confirmed a functional vision of at least 0.3 logMAR throughout a continuous defocus range of 3.25 dioptres (Figure 5).³

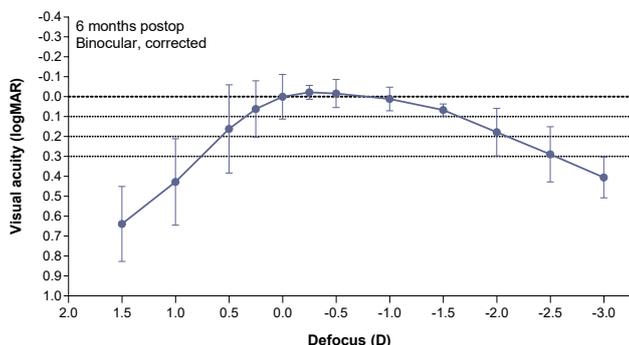


Figure 5. ELON binocular distance-corrected defocus curves demonstrate a continuous range of vision and a broad depth of focus.³

To achieve the best visual performance and optimize the range of vision for patients, the surgeons all recommended binocular implantation of the ELON lens. “Using it in a micro-monovision approach that targets the dominant eye for emmetropia and the non-dominant eye for slight myopia will maximize the advantage of the elongated focus and Wavefront Linking technology,” added Dr Kruger. “We believe that this micro-monovision strategy might be the best option for achieving complete spectacle independence,” confirmed Dr Joaquín Fernández from Almería, Spain. According to Dr Németh, this micro-monovision approach improves near vision without compromising far and intermediate performance. “The micro-monovision technique being discussed is also a good option for patients with anisometropia or a history of laser refractive surgery,” said Dr Iveta Nemcová, Prague, The Czech Republic.

PERFORMANCE OF DAILY ACTIVITIES

Dr Kruger shared that most of his patients seek an IOL solution allowing them to see well at distance, drive without glasses, and comfortably read their notebooks or smart-phones. Most of them would not mind needing slight vision correction for occasional near activities like reading fine print texts. Dr Nemcová said that her patients are highly satisfied with their vision following ELON implantation. “They can perform daily activities like driving, cooking, and working at their computer without difficulty. Some of them can also read normal-size fonts. They all report using glasses only rarely,” she claimed. “The ELON provides an excellent visual experience for everyday activities,” said Dr Németh (Figure 6).

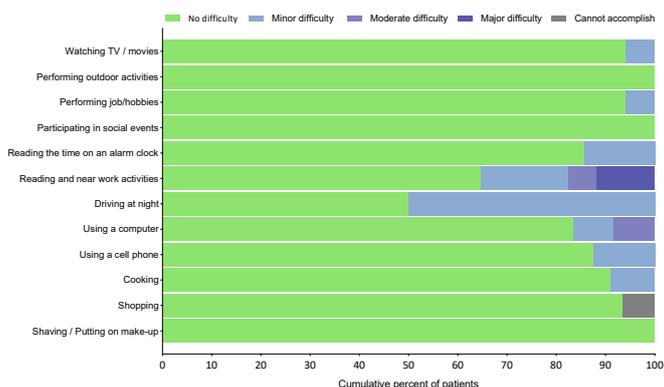


Figure 6. Daily visual tasks are performed with no or only minor difficulties.³

MINIMIZING DYSPHOTOPSIA—THE KEY TO SATISFIED PATIENTS

Apart from an excellent continuous range of vision, all surgeons emphasized that another important attribute of a new EDoF lens is to minimize the level of dysphotopsia and other photic disturbances. “In the past, monofocal lenses were our only option for having a low level of photic phenomena,” stated Dr Fernández.

The subjective perception of light distortion is an indicator of visual quality. The lower the light distortion index (LDI), the better the visual quality. Published LDI data for marketed IOLs show their performance varies (Table 1).

Table 1. LDI data for selected IOL models

| Author ⁴⁻⁷ | Follow-up (months) | IOL model | LDI% monocular |
|--------------------------|--------------------|--------------------------|----------------|
| Brito P, 2005 | 3-14 | Tecnis ZCB00 (monofocal) | 23.9 |
| | | AT LISA tri 839M | 46.9 |
| Alió J, 2018 | 6 | AcrySof IQ PanOptix | 36.8 |
| Vargas V, 2020 | 12 | LENTIS MPlus | 20.6/26.5 |
| Fernández J, 2022 | 12 | ELON 877PEY | 18.9* |

**The figure reflects preliminary data; further investigation is required to confirm the current results.*

“The trifocal Liberty lens by Medicontur causes little dysphotopsia, but ELON gives surgeons the opportunity to minimize even mild photic phenomena while providing better intermediate and near vision compared to monofocal IOLs,” continued Dr Fernández. “The ELON IOL provides an excellent range of visual functions providing spectacle independence for most daily activities with no dysphotopsias,” said Prof Sathish Srinivasan from Ayr, Scotland. “In this regard, ELON is just like a monofocal lens, but with enhanced unaided distance and intermediate vision,” he added.

“ELON gives surgeons the opportunity to minimize even mild photic phenomena.”
J. Fernández, Spain

PROPRIETARY HYDROPHOBIC MATERIAL FOR HIGH-QUALITY VISION

IOLs made of hydrophobic acrylic material are the most widely used, but not all hydrophobic acrylic materials are alike. ELON is made from SEMTE, a unique hydrophobic acrylic developed by Medicontur that contains significantly fewer microvacuoles (no glistening) than a hydrophobic acrylic used by a major IOL manufacturer.⁸ Less glistening results in fewer visual disturbances and higher visual quality.⁸ The low refractive index (RI=1.47), the high Abbe number (58) of the SEMTE material and the aspheric neutral design all contribute to an outstanding visual experience. Additionally, thanks to its low glass transition temperature (4°C), SEMTE allows easy injection and offers excellent IOL behavior. The ELON lens is marketed in a preloaded system called POB-MA. “This is a good and unique injector system,” said Prof Srinivasan. The other surgeons agreed that the IOL-injector combination is easy-to-use. “It always worked properly and never caused scratches on the IOL,” added Dr Győry.

BI-FLEX DESIGN FOR LONG-TERM STABILITY

Laboratory measurements have shown that different IOL designs result in varying contact angle values between the lens haptics and the wall of the capsular bag. A higher contact

angle ensures higher IOL stability.⁹ The ELON lens with Bi-Flex haptics has an overall contact angle of 117.9° (measured in a capsular bag model of 10 mm in diameter), while a widely used competitor lens has a contact angle of 80.9° (Figure 7).¹⁰

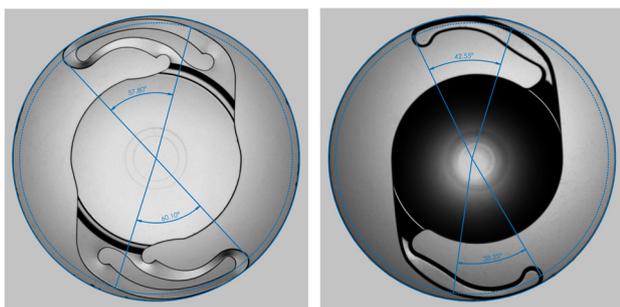


Figure 7. Higher contact angle with the Bi-Flex design (left) ensures long-term stability.

Various published studies have investigated the long-term refractive and rotational stability of other Medcontur IOLs with the Bi-Flex design.¹¹⁻¹² These investigations showed that visual performance was maintained over time, and the authors concluded that the Bi-Flex design serves as a reliable platform for astigmatism-correcting toric optics where stability is of utmost importance.¹¹⁻¹²

“The haptic design of the ELON lens is different than other IOLs,” said Dr Kruger. “With its two double-loop haptics, the Bi-Flex design is great for stability,” he continued. “After implantation, the lens is well-centered and maintains a stable position,” said Dr Nemcová. “According to my experiences, it is resistant to physiological fibrotic deformations,” added Dr Györy.

“I like the hydrophobic material, and the unique design of the lens is great for stability. ELON is a very versatile lens for a refractive type of practice.”

J. Kruger, South Africa

A VERSATILE LENS FOR VARIOUS PATIENTS

The ELON EDoF lens is an optimal choice for patients regardless of age who live an active lifestyle and would like to improve their visual quality but would not mind occasionally wearing spectacles for close-up activities. Dr Antonis Aristeideu from Athens, Greece recommends this lens to his patients when a trifocal IOL would be contraindicated. “I also implant ELON when the patient already has a monofocal IOL in the fellow eye. “Moreover, it is a great solution for subjects with well-controlled glaucoma,” he added. Prof Srinivasan prefers ELON for his patients who previously had LASIK, PRK, or other laser vision correction surgery, while Dr Németh and Dr Nemcová report good experience implanting it in patients with mild age-related macular degeneration or diabetic retinopathy. All surgeons agreed that the ELON might be the primary choice for patients with borderline anatomic findings, who are historically considered debatable candidates for presbyopia-correcting lenses, or for cases when the visual outcome with a trifocal IOL is either questionable or somewhat unpredictable.

“It’s exactly what our patients needed from an EDoF – 9-10/10 far vision, excellent intermediate, and very good near vision.”

A. Aristeideu, Greece

Given that the ELON IOL is new to the market, clinical experience is still limited. Early feedback, however, is positive. “Our initial findings are promising, and all our patients are highly satisfied,” said Dr Györy. “We plan for long-term follow-up of our patients and are increasing the number of subjects enrolled in our formal evaluation. Fortunately, patient interest in the lens is huge,” he added. “ELON extends the depth of focus in a broader range than the Tecnis Eyhance and guarantees intermediate spectacle independence that could not be achieved with the Johnson & Johnson competitor,” added Dr Fernández. “It is very exciting that newer technologies differ from others that are described as EDoF IOLs, but in fact, are not,” mentioned Dr Kruger. “I believe that ELON is a real EDoF lens, not a ‘monofocal plus’ IOL,” he concluded.

“The company always strives to convert surgeons’ ideas to innovation,” confirmed Dr Fernández, who along with his respected colleagues is looking forward to sharing their latest ELON experiences with a larger audience of professionals during the next congress of the European Society of Cataract & Refractive Surgeons (ESCRS) this September in Milan, Italy.

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