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# SIMULATION OF THE EFFECT OF DIFFERENT PRESBYOPIA-CORRECTING INTRAOCULAR LENSES IN WITH EYES WITH PREVIOUS LASER REFRACTIVE SURGERY

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**Running head:** Presbyopia-correcting IOLs in eyes with previous myopic or hyperopic LASIK

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The authors have no proprietary or commercial interest in the medical devices that are involved in this manuscript.

## Abstract

*Purpose:* To simulate the optical performance of three presbyopia-correcting IOLs implanted in eyes with previous laser refractive surgery with a new method.

*Methods*: Theoretical through-focus MTF of the Mini WELL (MW), the TECNIS Symfony (SYM) and the Lentis Mplus (MP) was simulated. Topographic data of the eyes and wavefront profile of each IOL were used.

*Results:* In the eye with myopic LASIK, all IOLs lost optical quality at near and intermediate distances for 4 and 4.7 mm pupil size. For 3-mm, the MW showed the best intermediate and near MTF and maintained the far focus independently of the pupil. With MW and SYM, spherical aberration (SA) ranged from 0 to +0.4 µm as pupil increased and in MP from +0.110 to +0.325 µm.

In the eye with hyperopic LASIK, MW showed an intermediate, distance and -4 D foci for all pupils. SYM showed a depth of focus at far and intermediate distance for 3-mm and a focus at -2.5 D in the rest. MP showed a focus of -4.5 and -3 D for 3 and 4 mm pupil respectively. All IOLs increased the level of negative SA, obtaining ocular values higher than -0.5 µm for 4.7-mm pupil size.

*Conclusions:* MW and SYM work better than the MP in eye with myopic LASIK. With hyperopic LASIK, MW showed acceptable near, intermediate and far foci for all pupil sizes. Both SYM and MP lost the far focus, only showing a near or intermediate focus, as the pupil increased.

## Keywords

Myopic refractive surgery, Hyperopic refractive surgery, Multifocal Intraocular lenses; Throughfocus MTF, Simulations, Spherical Aberration.

## Introduction

Currently, in-vitro measurements of the optical quality of an IOL are based on the International Organization for Standardization (ISO) standards 11979-2[1] and 11979-9[2]. One of the metrics proposed as a standard for characterizing the optic behavior of an IOL is the modulation transfer function (MTF). Optical bench evaluation of the MTF provides valuable information about the optical quality of IOLs. Devices as the PMTF (Lambda-X) have been used to measure the optical quality in accordance with ISO guidelines[3-5]. However, these studies do not commonly assess the wavefront aberrations of IOLs. Several authors have proposed different methods for measuring the aberration map of IOLs, all of them based on the use of Hartman-Shack sensors[6-8].

It has been demonstrated that higher order aberrations (HOAs) increase after laser refractive surgery[9-12]. The most commonly affected aberration is the spherical aberration which increases positively after myopic laser surgery and negatively after laser correction for hyperopia. [9-12] It is crucial to know the type of aberrations induced by currently available presbyopia-correcting IOLs for evaluating if their implantation is recommendable in eyes with previous laser refractive surgery that are already aberrated. From a clinical perspective, the outcomes of the implantation of presbyopia-correcting IOLs, including different types of multifocal IOLs, in eyes with previous refractive surgery have been evaluated[13-15]. However, as far as we know, the study of the effect of these IOLs on the aberrations of an eye with previous refractive surgery has not been performed, either clinically or in vitro. The possibility of knowing the aberrometric induction of any presbyopia-correcting IOL before its implantation is a valuable tool to predict the consequences on the patients' visual quality of such implantation and to define an optimize selection of the IOL to implant.

The aim of the current investigation was to propose a technique to simulate the optical performance of three presbyopia-correcting IOLs implanted in eyes with previous myopic or hyperopic laser refractive surgery. This methodology combines in-vitro IOL wavefront aberration measurement, the use of real corneal topographic data and ray-tracing simulation. Previously, we have implemented an optical system that allows the measurement in vitro of the wavefront aberration of some types of presbyopia-correcting IOLs[16].

## Methods

### *Description of IOLs measured*

The Mini-WELL (SIFI Meditech SRL, Lavinaio, Italy) is a progressive extended depth-of-focus (EDOF) IOL, with an equivalent addition of +3.0 D. It has a patented optical design based on the application of positive and negative spherical aberration in the central part of the IOL in order to increase the depth of focus. The optic is divided into three different annular zones: the inner and middle zones have different spherical aberrations with opposite signs, whereas the outer one is a monofocal aspherical zone. The IOL overall diameter is 10.75 mm, its optical surface diameter is 6 mm, and it includes an ultraviolet filter. Furthermore, the dioptric spectrum that is commercially available ranges from 0 to +30 D. In our in-vitro study, we used an IOL with 20 D of optical power.

The TECNIS Symfony ZXR00 IOL (Johnson and Johnson Vision) is a biconvex and pupil-independent diffractive IOL, which combines an achromatic diffractive surface with an echelette design. Its overall diameter is 13.0 mm and its optical zone diameter is

6.0 mm. The power spectrum available ranges from +5.0 to +34.0 D, and incorporates an ultraviolet (UV) light-absorbing filter. We used for the current study an IOL of 20 D.

The Lentis Mplus X LS-313 MF30 IOL (Oculentis GmbH, Berlin, Germany) is a refractive bifocal IOL composed by an aspheric distance vision zone combined with a posterior sector-shaped near-vision zone allowing seamless varifocal transition between the zones. The IOL overall diameter is 11.0 mm and its optical zone diameter is 6.0 mm. The power spectrum available ranges from -10 to +36.0 D. In our study, we used an IOL with a power of 20 D and an addition of 3 D.

*Measurement simulation set-up*

As mentioned above, the in-vitro optical quality of an IOL can be evaluated by measuring the through-focus MTF for a spatial frequency of 50 cycles/mm (MTF values for different levels of vergence) using an aberration-free eye model, where the studied IOL is inserted.

In the current study, the theoretical through-focus MTF of each specific IOL was evaluated in eyes with previous laser refractive surgery. Specifically, simulations were conducted in two eyes, one with previous myopic laser in situ keratomileusis (LASIK) and another with previous hyperopic LASIK. The simulations were made according to the following steps:

1) The wavefront profile of each IOL was characterized using a Hartmann-Shack wavefront sensor while the IOL was placed in a liquid medium contained between two flat windows. Once characterized the wavefront aberration profile of the IOL, the phase transformation introduced by each IOL was calculated.
2) An eye model was built using the OpTaliX software (Optenso, Optical Engineering Software). The topographic data of the two eyes used for the

simulations was uploaded once exported in .csv format from the Sirius system (CSO, Firenze, Italy).

3) The IOL was introduced as a phase element in the eye model and the trough-focus MTF for each IOL was simulated by ray tracing.

It has been suggested that Hartmann-Shack-type wavefront sensors may bias some aberrometric measurements obtained with some diffractive IOLs due to split of lenslet spots produced by more than one diffractive zone within the same lenslet[17, 18]. In our study, the only diffractive IOL evaluated was the TECNIS Symfony ZXR00 IOL that have diffractive zones that are large enough (only 10 diffractive zones) to be resolved by our Hartmann-Shack configuration based on the use of a lenslet pitch of 150 µm and a low wavelength 532 nm[17, 18]. In our measurements with the diffractive IOL mentioned, only some isolated spots were not well defined due to the registration of the wavefront using information coming from a diffractive transition zone.

Ray tracing has already been employed to determine the optimal intraocular lens power after laser surgery[19, 20]. The main drawback of these studies is that real IOL data (radius of curvature of its surfaces, thickness, and refractive index) are required. In most of cases, this type of data is not accessible or even patent protected. As we mentioned above, we have circumvented this situation by measuring the phase transformation that the IOL induces and implementing it on our simulated eye model that uses real topographic data. All measurements were performed for three exit pupil sizes, 3, 4 and 4.7 mm of diameter.

*Clinical data*

The topographic data of two eyes were used for the ray tracing simulations conducted in the current study (figure 1). These are the main clinical data of these two cases:

1.- Myopic LASIK: 37 years, male, manifest refraction: -8.00 sphere -0.25 x 115º cylinder, corrected distance visual acuity (CDVA) of 0.00 logMAR and scotopic pupil diameter of 5 mm.

2.- Hyperopic LASIK: 38 years, male, manifest refraction: +3.75 sphere -0.50 x 95º cylinder, corrected distance visual acuity (CDVA) of 0.00 logMAR and scotopic pupil diameter of 5 mm.

Both eyes were operated on with LASIK using the Pulzar Z1 solid-state laser platform (CustomVis Laser Pty Ltd, Osborne Park, Australia, currently CV Laser Pty Ltd) and an automated mechanical microkeratome (M2, Moria, Antony, France), creating a 110-µm thickness flap with superior hinge and 9.0-9.5 mm of diameter at the Department of Ophthalmology (Oftalmar) of Vithas Medimar International Hospital (Alicante, Spain).

## Results

The through-focus MTF for all IOLs and the three pupil sizes are shown in figures 2 and 3. All these figures are presented with the same scale for direct comparison. Furthermore, in this section, we use tables showing the level of spherical aberration for each pupil size before and after IOL implantation.

### *Simulations in the eye with previous myopic LASIK*

As can be seen in Figure 2A, the Mini-Well IOL showed a well-defined peak for far vision and a smooth transition between the intermediate and near focus higher than for the rest of IOLs for a pupil size of 3 mm. The Symfony IOL showed a wider far zone but the MTF values for near and intermediate zones were narrower. The Mplus IOL showed the worst through-focus curve showing only peaks for far and near vision. For the pupil size of 4 mm (Figure 2B), the Mini-Well IOL improved the MTF for far vision and maintained two focus for near and intermediate vision, the Symfony IOL showed a similar behavior than for 3 mm and the Mplus worsened the through-focus curve far all defocus levels. For the pupil size of 4.7 mm (Figure 2C), the Mini-Well IOL showed the best through-focus curve for distance, intermediate and near as the Symfony IOL only showed a lower peak for far vision and the Mplus did not provide any peak.

The spherical aberration of the eye with previous myopic LASIK, changed from +0.087 µm for 3-mm pupil to +0.57 µm for 4.7-mm pupil without IOL (see Table 1). The behavior of the Mini-Well and Symfony IOLs were very similar, compensating both the positive spherical aberration of the eye. With these two IOLs, the spherical aberration ranged from 0 µm for 3-mm pupil to +0.4 µm for 4.7-mm pupil. With the Mplus IOL, the spherical aberration ranged from +0.110 µm to +0.325 µm, respectively.

*Simulations in the eye with previous hyperopic refractive surgery*

In general, the best through-focus MTF values were obtained for the 3-mm pupil size (Figure 3A). The Mini-Well IOL showed two peaks for far and intermediate (-1.5 D defocus). For near distance, a depth of focus between 3.5 and 5.5 D was observed. For a pupil size of 3 mm, the Symfony IOL showed a wider area for far (0 D) and intermediate vision (-1 D) with a smooth transition. However, for near vision any focus was obtained. The Mplus IOL showed a peak for near vision (-5 D) and another two lower peaks for -

2.5 D and -0.75 D defocus levels. For 4 mm pupil size (Figure 3B), the Mini-Well IOL displayed a similar behavior than for 3 mm but with decreased far vision MTF. With the Symfony IOL, the far focus diminished drastically and showed a wider area of focus for intermediate and near vision, between -1.5 and -3 D defocus levels. The best focus with the Mplus IOL was obtained for near (-3 D), with some focal increase of the MTF for intermediate and far vision. For 4.7-mm pupil size (Figure 3C), the Mini-Well IOL maintained the peak for far focus and displayed an extended depth of focus for near, inducing some level of depth of focus for intermediate vision. The Symfony IOL only showed a wider focus for intermediate vision centered at -2.5 D defocus level. The Mplus IOL did not show any focus for these pupil sizes (Figures 3A, B and C).

As can be seen in Table 2, the Mini-Well and Symfony IOLs increased the level of negative spherical aberration of the eye for all pupil sizes, but the Mini-Well IOL maintained it within an acceptable clinical range (highest value: -0.588 µm for 4.7 mm pupil size). In contrast, the Symfony IOL provided a spherical aberration value of -0.734 µm for 4.7-mm pupil size, and the Mplus IOL induced acceptable spherical aberration values for 3 and 4 mm pupil sizes, but not for 4.7 mm (-0.933 µm).

## Discussion

Our simulations have shown that the optical quality of the system eye + IOL is worsened in eyes with previous laser refractive surgery when the pupil size increases. This is consistent with the scientific evidence reported to this date supporting the fact that laser refractive surgery leads to some level of aberrometric induction, even when aspheric profiles are used.[9-12] Considering the spherical aberration, the three IOLs compensated the positive spherical aberration of the eye that had undergone previous myopic LASIK and increased the negative spherical aberration of the eye that had undergone previous hyperopic LASIK. This suggests that a careful study of corneal aberrations should be performed before implanting multifocal IOLs in eyes with previous laser refractive surgery in order to control the potential aberrometric change induced by the IOL.

The analysis of the results in the eye with previous myopic LASIK shows a better ocular optical quality with the Mini-Well and Symfony IOLs rather than with the Mplus IOL, as the through-focus MTF achieves higher values. The Mini-Well and Symfony IOLs maintained the far focus independently of the pupil size, with the Mini-Well IOL showing the highest MTF values as the pupil size increased. In general, the three IOLs evaluated lost some level of optical quality at near and intermediate distances for 4 and 4.7 mm. For 3-mm pupil size, the Mini-Well IOL showed the best intermediate and near ocular optical quality outcome. This is consistent with results of previous simulations performed in optical bench evaluating the same IOLs in the ISO model eye with no previous refractive surgery.[21-23] Domínguez-Vicent and colleagues showed that the Mini-Well IOL provided 2 main focus areas in the ISO eye model, 1 corresponding to distance vision focus and the other including both intermediate and near vision foci. In our simulations, a similar behavior is observed although the change induced in spherical aberration introduced some minimal modifications. The positive spherical aberration of the eye with previous myopic refractive LASIK was always compensated with the IOLs evaluated and was maintained within acceptable clinical values for all pupil sizes. This compensation was higher for the Symfony and Mplus IOLs as the pupil size increased, because the spherical aberration remained constant with the Mini-Well IOL regardless the pupil size increased.

In the eye with previous hyperopic refractive LASIK, the Mini-Well IOL showed two peaks for intermediate and far distance and wider area for near vision around – 4 D of defocus for all pupil sizes. Despite the Symfony IOL showed a wider focus area for far and intermediate distance for 3-mm pupil size, this area disappeared as the pupil size increased, with the presence only of a near focus (-2.5 D defocus level). The Mplus IOL only showed a near focus for 3 and 4 mm pupil size for defocus levels of -4.5 and -3 D, respectively. All IOLs increased the level of negative spherical aberration of the eye, leading to ocular values higher than -0.5 μm for 4.7-mm pupil size. This may be the reason of the worsening of the ocular optical quality with the three IOLs for the highest pupil size evaluated. This suggests that this combination of previous hyperopic LASIK and presbyopic-correcting IOL should be only used in eyes with small pupil sizes in order to avoid a potentially significant deterioration of the visual quality.

In summary, our simulations suggest that the Mini-Well and Symfony IOLs work better than the Mplus IOL in eyes with previous myopic LASIK. In general, there is a loss of near and intermediate optical quality for the three IOLs analyzed as the pupil size increased, being the Mini-Well IOL showing the best intermediate and near optical quality performance for 3-mm pupil size. For far distance, both Mini-Well and Symfony IOLs provided a good focus, showing the Mini-Well IOL the highest MTF values. In eyes with previous hyperopic LASIK, our simulations indicated that the Mini-Well IOL showed acceptable near, intermediate and far foci for all pupil sizes. Both Symfony and Mplus IOLs gradually lost the far focus, only showing a near or intermediate focus, as the pupil size increased.

In conclusion, a new method that combines in-vitro IOL wavefront aberration measurement, real topographies and ray-tracing simulation is able to simulate the ocular optical performance after presbyopia-correcting IOL implantation in eyes with previous laser refractive surgery. The results shown in this paper are not generalizable since more patients should be analyzed. In future works, larger sample sizes will be studied in order to confirm our results and if they are consistent with those obtained in clinical practice. Furthermore, this methodology may be applied to other IOLs whose aberrometric pattern may be reproducible with Hartmann-Shack sensors.

WHAT WAS KNOWN

• Some studies have evaluated in clinical practice the ocular internal aberrometric pattern of eyes implanted with the Lentis Mplus X LS-313 MF30 showing the presence of significant amounts of primary coma.

• Tecnis Symfony IOL shows some spherical aberration depending the pupil size.

• Previous studies demonstrated that the Mini WELL might enlarge the depth of focus and provides better optical quality than trifocal IOLs at distant vision focus for large apertures.

WHAT THIS PAPER ADDS

• A simple method of Multifocal IOLs aberrations measurement based on a Hartmann-Shack sensor has been proposed.

• The Mini WELL IOL maintains a similar aberrometric profile with increasing pupil size, meanwhile the Lentis Mplus X LS-313 MF30 and TECNIS Symfony ZXR00 IOLs increase the aberrations as the pupil size increased.

• This behavior of the Mini Well may be in relation with a negligible induction of night vision disturbances.

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Table 1: Spherical Aberration (SA) for the eye with previous myopic refractive surgery with each IOL (MW: Mini WELL, SYM: Symfony, MP: Mplus).

| **SA (μm)** | **ϕ=3 mm** | | | **ϕ=4 mm** | | | **ϕ=4.7 mm** | | |
|---|---|---|---|---|---|---|---|---|---|
| **EYE** | +0.087 | | | +0.289 | | | +0.57 | | |
| | MW | SYM | MP | MW | SYM | MP | MW | SYM | MP |
| **IOL** | -0.128 | -0.007 | 0.017 | -0.121 | -0.117 | 0.023 | -0.111 | -0.207 | -0.298 |
| **EYE+IOL** | -0.038 | 0.085 | 0.110 | 0.181 | 0.188 | 0.329 | 0.484 | 0.395 | 0.325 |

Table 2: Spherical Aberration (SA) for the eye with previous hyperopic refractive surgery with each IOL (MW: Mini WELL, SYM: Symfony, MP: Mplus).

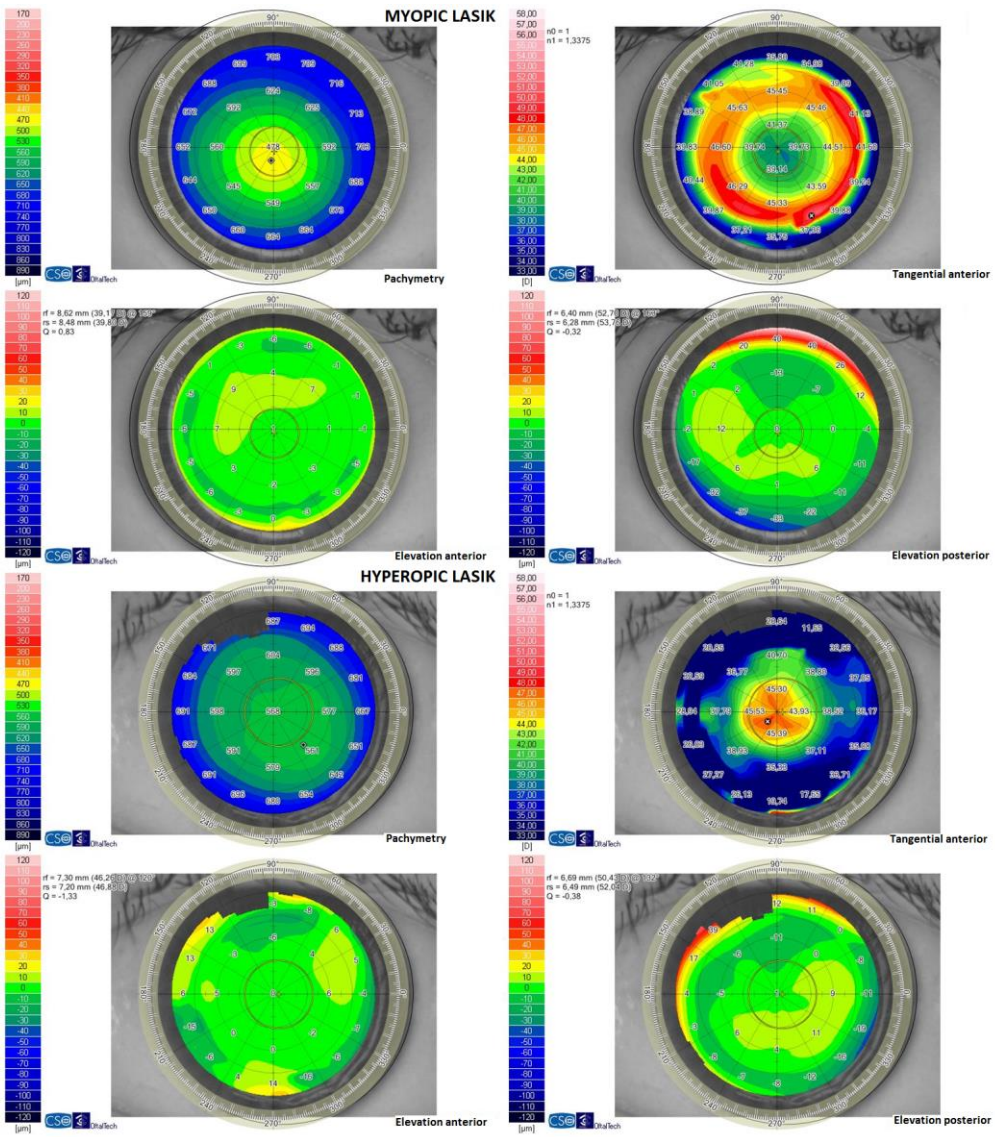
| **SA (μm)** | **ϕ=3 mm** | | | **ϕ=4 mm** | | | **ϕ=4.7 mm** | | |
|---|---|---|---|---|---|---|---|---|---|
| **EYE** | -0.096 | | | -0.289 | | | -0.560 | | |
| | MW | SYM | MP | MW | SYM | MP | MW | SYM | MP |
| **IOL** | -0.128 | -0.007 | 0.017 | -0.121 | -0.117 | 0.023 | -0.111 | -0.207 | -0.298 |
| **EYE+IOL** | -0.199 | -0.092 | -0.065 | -0.373 | -0.393 | -0.242 | -0.588 | -0.734 | -0.933 |

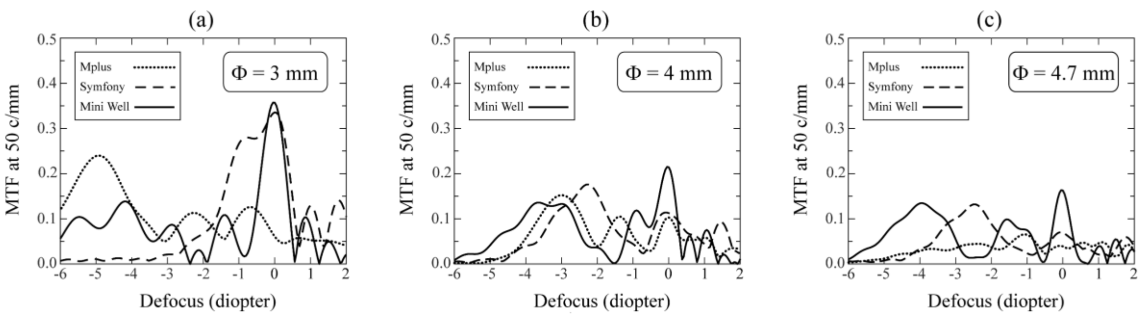
## Figure legends

Figure 1.- Corneal topographic data of the two eyes used for our simulations: post-myopic LASIK (up) and post-hyperopic LASIK (down).

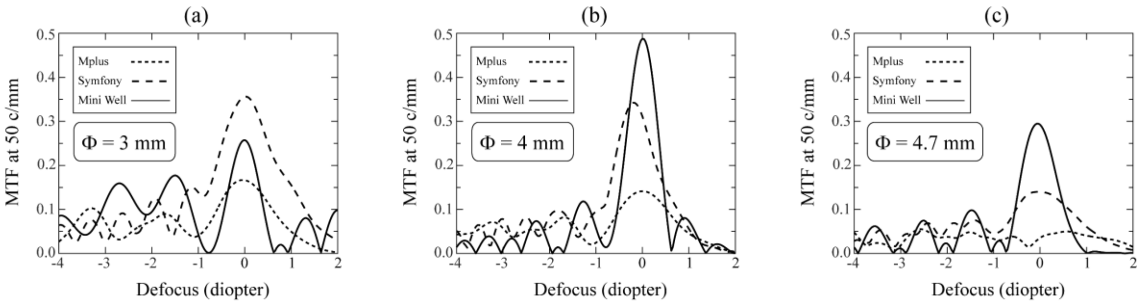
Figure 2.- Simulated through-focus MTF obtained in our simulations for pupil sizes of 3 (a), 4 (b) and 4.7 mm (c) with the Mplus, Symfony and Mini-Well IOLs in the eye with previous myopic LASIK.

Figure 3.- Simulated through-focus MTF obtained in our simulations for pupil sizes of 3 (a), 4 (b) and 4.7 mm (c) with the Mplus, Symfony and Mini-Well IOLs in the eye with previous hyperopic LASIK.




HYPEROPIC LASIK




MYOPIC LASIK