On the evaluation of multifocal IOLs by means of a vision simulator

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Multifocal solutions to presbyopia, as contact lenses or intraocular lenses (MIOL), are growing in the last years. One of the strongest points of MIOLs is enabling far and near clear vision. However, due to the particular design of these lenses there are some disadvantages associated as perception of halos, reduced contrast sensitivity or adaptation problems. In the particular case of the intraocular lenses, there was no way to measure in real eyes the impact of those issues during the design process or prior to the implantation of the lens in a patient. In this work we have measured the visual performance of intraocular lenses in real eyes during the design process and prior to the implantation by means of a vision simulator. The measurements have helped improving a prototype under development and have shown the performance of a commercial intraocular lens before surgery.

Keywords: multifocal; intraocular lens; presbyopia; simulator.

1. Introduction

The human eye is able to see clearly at difference distances due to the dioptric adjustment of the crystalline lens, this process is known as accommodation [1]. With the ageing, there is a progressive loss of amplitude of accommodation and presbyopia appears, complicating near object focusing [2]. Another consequence of eye ageing is cataract, an opacification of the crystalline lens. The only solution to the cataract is the surgery for crystalline extraction and substitution by an intraocular lens (IOL). When monofocal IOLs are implanted, the patient loses the ability of focusing near objects. In order to solve this problem several solutions have been proposed: monovision [3], the accommodation restoration by means of gel refilling [4] or accommodative IOLs [5] and the implantation of multifocal IOLs. The latter option is probably the more widely adopted and has shown a big increase in the last years.

Multifocal IOLs have two or more foci, by means of refractive, diffractive or hybrid designs. Having more than one focus enables good vision for different distances, thus the patient can see at near objects. On the other hand, due to the several foci and the IOL design, they show certain disadvantages as the adaptation, contrast sensitivity reduction and halos [6]. Predicting the amount of those disadvantages during the design process of the multifocal IOL is difficult, due to the complexity of the design and being a subjective perception. From the point of view of the patient, choosing a multifocal IOL is a no turning back decision, with the risk of adaptation problems. Recent studies have used adaptive optics to predict the performance of aspheric IOLs before implantation [7]. But this technology has not been used yet in multifocal IOLs, probably due to the complex wavefronts of those lenses, which are difficult to replicate. In this sense, a new instrument designed for vision simulation through IOL lenses (VirtIOL, 101Lens S.L.U.) has been recently developed.

The main goal of the present study has been to simulate the performance by means of the VirtIOL vision simulator in a new multifocal intraocular lens design and in a commercial multifocal IOL. Using VirtIOL during the prototype phase of a MIOL can be a powerful tool in order to improve the final design.

2. Material & Methods

The VirtIOL vision simulator is an instrument based on projecting an IOL onto the patients' pupil plane (Figure 1). Each IOL was inserted in the model eye (2) becoming the conjugate of the patient's pupil plane thanks to the optical system formed by the different lenses and mirrors (4, 5, 6, 8, 9, 10) and the variable pupil of the system (7).Thus, the test (1) is observed for the patient (11) through the IOL (3) inserted in the model eye (2) of the system simulating the vision once the IOL is implanted. There is no magnification effect and the refraction is compensated for far vision. The VirtIOL shows an open-field visual field, allowing different optometric test presentation such as visual acuity (VA) or others. Moreover, accommodative stimulation can be modified moving the test closer to the patient or by means of negative lens addition.

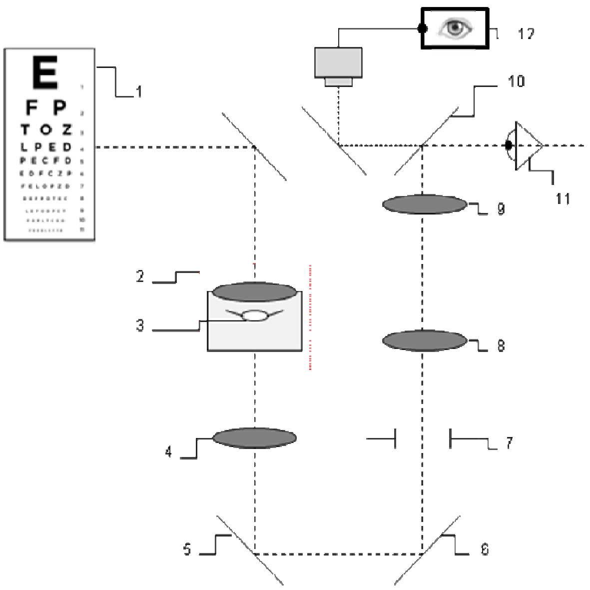

Figure 1: Set-up scheme where: 1. Vision Test; 2. Model Eye; 3. IOL submerged in water; 4. and 8., 9. Lens; 5. and 6. , 10. Mirror; 7. Variable Pupil 11. Patient's eye; 12. Display.

Four IOLs were measured in the present study. Three MIOLs were tested. A new MIOL design (NDIOL, OPHTEC prototype, Add=2,75D) with the central zone corresponding to far refraction (NDIOL-FC) and with the central zone corresponding to the near refraction (NDIOL-NC and a commercial MIOL (MPlus, Oculentis® Add=+3D). Finally, a monofocal IOL was also tested and used as reference.

The measurement protocol included: a throughfocus scanning with different contrast levels, evaluation of decentration and rotation effect and performance under small pupils for high (L=250cd/m^2), intermediate (L=150cd/m^2) and low (L=15cd/m^2) background luminance. The throughfocus scanning consisted on a scanning from far (0D) to near vision (-3D) in 0.5D steps, evaluating at each step the VA and subjective perception. The VA for far and near vision was evaluated with contrast of 100%, 25% and 10%. The subjective perception was assessed whereby a questionnaire in which the patient has to gradate the intensity of the double vision and the halos from 0 (there was no perception of double vision or halos) to 3 (double vision or halos were clearly presents) for each lens. The effect of decentration was evaluated measuring the VA and subjective perception when a positioning error of ±0.5mm is induced in x and y axis. The decentration is controlled through the reticle of the display of the VirtIOL (Figure 1(12)). The effect of orientation was evaluated measuring the VA and subjective perception at three IOL rotations (0º, 120º and 240º). And finally performance under small pupils was evaluated by means of a throughfocus scanning with different contrast levels at fixed 3mm pupil. All the measurements were performed by the same operator and the same well trained observer in order to maintain the same criterion. The observer is a male of 54 years old. Measurements were repeated 3 times showing similar results.

3. Results

The throughfocus scanning results referring the VA for all the evaluated lenses for a high background luminance are shown in figure 2. In far vision conditions the best VA was obtained, as expected with the monofocal IOL (-0.20±0.00 logMAR). MIOL lenses showed similar values, with little or no differences, specifically VA for the MPlus was -0.10±0.00 logMAR, for the NDIOL-CF -0.10±0.00 logMAR and for the NDIOL-CN -0.07±0.05 logMAR. In near vision, the best VA was obtained with the NDIOL-CN (-0.07±0.05 logMAR) followed by MPlus (-0.05±0.07 logMAR), the NDIOL-CF (-0.03±0.05 logMAR) and, as expected, by the monofocal IOL (0.50±0.00 logMAR). When measuring under intermediate background luminance, the throughfocus curves changed slightly, the MPlus showed a more marked bifocal behaviour than the NDIOL. This behaviour consists on an accommodative curve with well identified peaks for far and near vision and decreased intermediate vision. For low luminance conditions NDIOL lens can have a nearly flat curve all over the stimulus range, while the MPlus IOL showed two peaks for far and near vision.

In terms of subjective perception, the MPlus and NDIOL lenses showed similar results, with low scattering in all the steps of the scanning and increasing double vision in the steps where the VA decreases.

The VA with lower contrasts measurements showed the monofocal IOL losing 0.03±0.00 logMAR units at 25% contrast, while the MPlus and NDIOL decreased 0.13±0.05 logMAR units at the same contrast. When reducing the contrast up to 10%, all the three lenses showed a similar decrease in the VA of around 2 lines.

When inducing positioning errors by means of decentrations in x and y axis, we found no effect on the VA. The only case when there was a change in VA due to decentration was with MPlus IOL in upper decentration, where there was an improvement of a line in the VA.

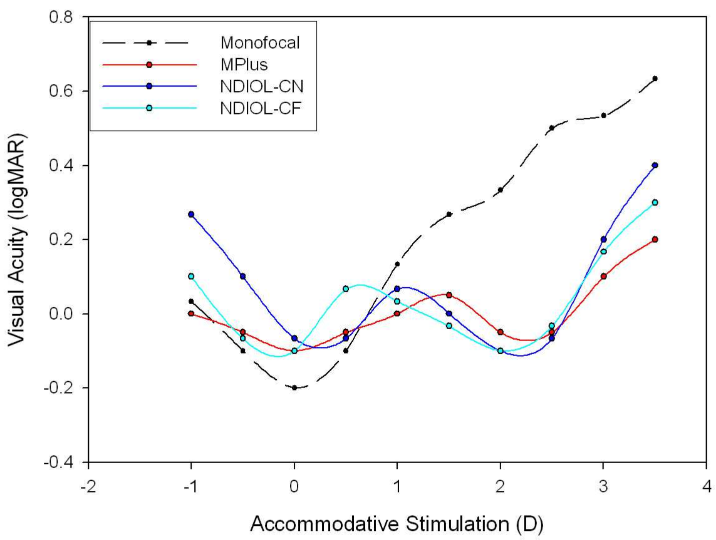

Figure 2. Visual acuity results for the throughfocus scanning for all lenses with natural pupils in high luminance conditions.

Regarding the rotation of the lens, the monofocal and NDIOL showed no changes in the throughfocus scanning curves of the VA at the three different rotating positions, while MPlus showed big changes.

Finally, when measuring with small pupils, the overall performance in terms of throughfocus scanning with different contrast levels was similar to the obtained under natural conditions. In the MPlus IOL there was a decrease of 0.05±0.05 logMAR units at the peak VA with 3mm pupils, while in the NDIOL there was an increase to 0.08±0.05 logMAR units.

4. Conclusions

VirtIOL vision simulator allows assessing VP of IOL before surgery. In the present study this instrument has been used to evaluate the performance of the MPlus IOL and to assess the development of a new multifocal IOL prototype, NDIOL. The VirtIOL can simulate any IOL design, even the more complex as the multifocal IOLs. The results obtained with the MPlus are in good agreement with the results previously published by other authors [8] when measuring throughfocus scanning in patients implanted with MPlus IOL. The throughfocus scanning measurements of the VA showed that the MPlus has more marked bifocal lens behaviour than NDIOL lenses. Both lenses showed good subjective perception in terms of double vision and halos, and in the preliminary steps of the NDIOL development those measurements helped in a design improvement of the lens.

In terms of VA with lower contrast levels, there were small differences between lenses. As expected, the monofocal IOL showed the best performance under low contrast conditions, with the multifocal designs having slightly higher VA decrease in those conditions.

There was no or little impact of the positioning errors on the visual performance of the IOLs. The only case where there was a change of VA was in the MPlus upper decentration for far vision, where there was an increase of one line of VA as the lens was acting as a monofocal lens due to the decentration.

Due to rotational symmetry of the NDIOL and monofocal IOL, there was no effect on the visual performance when measuring at the different rotation positions of the lenses. On the other hand, the MPlus, which has a non-rotational symmetrical design, showed angle dependent visual performance.

When measuring with small pupils, the MPlus IOL increased the VA in half line, which is a small difference and could be attributed to be acting as a monofocal lens when operating with such small pupils. On the other hand, the NDIOL lens, suffered a decrease of 0.085 logMAR units when using small pupils of 3mm.

References

[1] Keeney, A.H., Hagman, R.E., & Fratello, C.J. *Dictionary of ophthalmic optics. Boston: Butterworth-Heinemann* 1995.

[2] Atchison, D.A.. Accommodation and presbyopia. *J.Ophthalmic and Physiological Optics*. 1995: 15: 255-272.

[3] Jain S, Ou R, Azar D.T, Monovision outcomes in presbyopic individuals after refractive surgery, *Ophthalmology*. 2001: 108: 1430-1433.

[4] Koopmans S.A, Terwee T, Barkhof J, Haitjema H.J, Kooijman A.C. Polymer refilling of presbyopic human lenses in vitro restores the ability to undergo accommodative changes. *Invest. Ophthalmol.*

Vis. Sci. 2003: 44: 250-257.

[5] Menapace R, Findl O, Kriechbaum K, Leydolt-Koeppl Ch. Accommodating intraocular lenses: a critical review of present and future concepts. *Graefes Arch. Clin. Exp. Ophthalmol*. 2007: 245: 473-489.

[6] Vries N.E, Nuijts R.M.M.A. Multifocal intraocular lenses in cataract surgery: Literature review of benefits and side effects. *J Cataract Refract Surg.* 2013: 39: 268-278.

[7] Madrid-Costa D, Ruiz-Alcocer J, Pérez-Vives C, Ferrer-Blasco T, López-Gil N, Montés-Micó R. Visual simulation through different intraocular lenses using adaptive optics: effect of tilt and decentration. *J Cataract Refract Surg*. 2012; 38(6): 947-58.

[8] Alfonso JF, Fernández-Vega L, Blázquez JI, Montés-Micó R. Visual function comparison of 2 aspheric multifocal intraocular lenses. *J Cataract Refract Surg.* 2012: 38(2): 242-8.