Title: Tolerance to residual astigmatism and defocus in eyes with a non-diffractive extended depth of focus (EDoF) intraocular lens

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INTRODUCTION

Multifocal intraocular lenses have been shown to be a good option for cataract surgeons aiming to offer improved vision at different distances. Trifocal IOLs provide enhanced vision at far, intermediate and near distances and have overcome the characteristic V-pattern with 2 peaks corresponding to near and far vision provided by bifocal IOLs.[1] Although multifocal IOLs could increase spectacle independence in patients undergoing cataract surgery, these lenses could also increase some visual disturbances such as glare or haloes.[2]

"Extended depth of focus" (EDoF) IOLs are currently available for cataract surgeons. They employ different optical technologies to achieve extended vision[3], increasing the range of vision while minimizing visual disturbances induced by classical diffractive multifocal designs.[3] In fact, current clinical results show that EDoF lenses could increase the range of vision from far to intermediate distances and reduce the perception of visual disturbances of the patients.[4]

In addition, while it has been reported that issues such as biomechanical properties of the cornea, inaccurate calculations, or misalignments of the IOLs may lead into residual refractive errors that will likely decrease the visual quality of patients with bifocal or trifocal IOLs[5], less is known about their impact on EDoF designs.

Therefore, regardless of the optical improvements achieved by EDoF lenses, better knowledge of the spherical and/or astigmatic tolerance of EDoF IOLs is crucial

for an appropriate surgical planning and for avoiding postoperative refractive corrections. Thus, the aim of this study is to analyze the impact of mild amounts of residual spherical defocus and astigmatism in patients implanted with a novel non-diffractive EDoF IOL.

PATIENTS AND METHODS

Prospective study, which will include patients undergoing bilateral cataract surgery with bilateral implantation of a Vivity non-toric lens

Performed at Clínica Rementería, Madrid, Spain

Inclusion criteria:

-Patients >40 years old undergoing bilateral cataract surgery with Vivity IOL implantation

Exclusion criteria:

- corneal astigmatism ≥1.0 diopters (D)
- amblyopia
- previous ocular surgery
- presence of ocular pathologies
- abnormal iris
- intra- or postoperative complications
- postoperative distance corrected visual acuity (DCVA) < 20/20
- postoperative refractive astigmatism > 0.50D.

Postoperative clinical assessment

Patients will be evaluated one day, one week, one month, and three months postoperatively. Patients fulfilling inclusion criteria will be approached to be included in the study at the three-month visit.

Explorations to be performed at the three-month visit

- Uncorrected distance, intermediate (60cm) and near (40cm) visual acuity (VA) with an ETDRS chart, followed by subjective refraction.
- Once the best distance correction is obtained, further VA evaluation procedures will be performed with the FrACT3.9.9a version of the Freiburg Acuity Test software package.[11] Once patients achieve the best distance correction (reference situation), a monocular analysis of VA at distance vision will conducted under different induced conditions.
    - both a myopic and hyperopic defocus of 0.50 D will be simulated
    - after these measurements, a mixed astigmatism with different orientation will also induced by adding a combination of -0.25 diopter (D) spherical and 0.50 D cylindrical lenses placed in vertical (against the rule - ATR), oblique and horizontal (with the rule – WTR) positions.

Statistical Analysis

The calculation of the required sample size was based on monocular CDVA. A difference of 0.2 logMAR units was assumed to be clinically significant and a standard deviation of 0.05 was considered.[12] Based on this assumption and α of 0.05 and power of 0.8, it was calculated that 25 eyes were required.

Data analysis will be performed using SPSS for Windows V.20.0 (SPSS Inc, Chicago, IL). The normal distribution of variables will be assessed using the Kolmogorov-Smirnov test. A repeated- measures analysis of variance (ANOVA) will be

used to gauge any statistically significant difference within the different situations. Post hoc multiple comparison testing will be performed using the Holm-Sidak method. Differences will be considered to be statistically significant when the P value is <0.05 (i.e., at the 5% level).

Protocol approved by Hospital Clínico San Carlos, code C.I. 21/365-O_P

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