## TITLE PAGE

TITLE: Laser corneal enhancement after trifocal intraocular lens implantation in eyes that had previously undergone photoablative corneal refractive surgery.

SHORT TITLE: Laser refractive surgery, trifocal IOL and laser enhancement.

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## ABSTRACT

PURPOSE: To evaluate visual and refractive outcomes of laser corneal enhancement (LCE) after trifocal intraocular lens (IOL) implantation in eyes previously treated with myopic/ hyperopic laser corneal refractive surgery (LCRS).

SETTING: Clinica Baviera-AIER-Eye group, Spain.

DESIGN: Retrospective comparative case series

METHODS: Patients were classified by primary LCRS (myopic/hyperopic). We evaluated uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA), uncorrected near visual acuity (UNVA), predictability, safety, efficacy, and satisfaction after implantation of two trifocal IOL models (Physiol-FineVision and Zeiss-ATLisa 839) and subsequent laser enhancement.

RESULTS: We assessed 186 eyes from 146 patients (89 myopic, 97 hyperopic). At the last visit, refractive outcomes were better in myopic than in hyperopic eyes, with statistically significant differences for sphere (p<0.001), cylinder (p<0.001), MRSE (p=0.003), CDVA (p=0.005), UDVA (p=0.047) and UNVA (p=0.003) but not for UIVA (p=0.580), binocular UIVA (p=0.660), or binocular UNVA (p=0.836). Predictability differences were nonsignificant between groups for a final MRSE of  $\pm 0.5$  D and  $\pm 1.0$  D (p=0.167 and 0.502). Efficacy and safety were similar in both groups (p=0.235 and p=0.080). A greater myopic MRSE was present after trifocal implantation in myopic than hyperopic eyes (MRSE=-0.93D vs-0.69D, p=0.013) and the differences were maintained after enhancement between both groups (MRSE -0.00 D vs 0.00 D, p=0.003) respectively. Overall satisfaction was similar in both groups (p>0.05 all items).

CONCLUSION: Corneal laser enhancement after implantation of a trifocal IOL in eyes previously treated for myopia/hyperopia with LCRS is safe, effective, predictable, and highly satisfactory.

### INTRODUCTION

Laser corneal refractive surgery (LCRS) has been the most widely used surgical procedure for correction of refractive errors in nonpresbyopic patients for the last 30 years.<sup>1</sup> As patients who underwent LCRS to correct myopia or hyperopia grow older, the number of those with presbyopia or cataract requesting a new refractive procedure is increasing. Nowadays, the most effective technique to achieve spectacle independence in presbyopic or cataractous patients is lens surgery phacoemulsification with multifocal intraocular lens (IOL) implantation<sup>2,3</sup> and thus, this procedure is becoming more common in patients with prior corneal refractive surgery who wish to be independent of glasses or contact lenses.<sup>4</sup>

The higher complexity of the IOL power calculation after corneal ablation is now a matter for concern because residual ametropia is a major source of patient dissatisfaction after multifocal IOLs implantation<sup>5</sup> which need emmetropia to achieve maximum effectiveness; therefore, residual refractive errors may require an additional laser corneal enhancement (LCE) on a previously ablated cornea. Consequently, the number of eyes requiring a third refractive procedure will increase because LCRS is the best and most effective, non-invasive and predictable approach to treat residual ametropia after IOL implantation.<sup>6</sup>

Another important concern in affected patients is the positive and negative shift in corneal spherical aberration (SA) after myopic and hyperopic ablation,<sup>7</sup> respectively; modifications of the corneal spherical and other high order aberrations after two ablative procedures, and the dysphotopic phenomena and contrast sensitivity loss induced by trifocal lenses may rise uncertainty regarding final visual outcomes after a triple refractive procedure.

Finally, although during the last years diffractive trifocal IOL have become the more commonly used type of multifocal lenses due to the excellent visual, refractive and patient satisfaction results obtained,<sup>8,9</sup> these multifocal IOLs are not free from visual problems such as halo, glare, straylight, and contrast sensitivity impairment, being another source of patient dissatisfaction.<sup>5</sup>

Besides, few studies have assessed visual outcomes, quality of vision, and patient satisfaction after implantation of trifocal IOLs in patients with a previous LCRS procedure. The present study analyzes visual and refractive outcomes and

patient satisfaction in eyes that have undergone a myopic or hyperopic LCRS procedure, trifocal IOL implantation, and subsequent LCE.

## PATIENTS, MATERIAL AND METHODS

### <u>Design</u>

This multicenter, multisurgeon, single-protocol, retrospective, case series study consecutively enrolled eyes that had undergone lensectomy with implantation of a trifocal IOL after previous LCRS to treat myopia or hyperopia at our institution (all preoperative data known). As we consider it necessary to separate and compare the results between groups to provide surgeons with significant information about outcomes, the sample was divided into myopic and hyperopic patients according to the primary LCRS procedure. All patients underwent laser refractive corneal enhancement after the lensectomy.

## **Subjects**

Data were recorded from the central computerized clinical records system at Clinica Baviera, Spain, from 2001-09-14 to 2021-03-22 and the enhancement treatments were between 2013-04-27 and 2020-01-24. The study was approved by our institutional legal and ethics committee. All patients received detailed information before surgery and gave their written informed consent for multifocal lensectomy after corneal surgery and laser enhancement after lensectomy, as well as for the use of their anonymous and aggregated medical data for clinical research.

The study inclusion criteria were as follows: (i) aspheric trifocal IOL lens exchange surgery (clear lens or cataracts) with a previous refractive corneal laser procedure (laser in situ keratomileusis -LASIK- or surface ablation [laser epithelial keratomileusis - LASEK - / photorefractive keratectomy -PRK-]) for correction of myopia or hyperopia; (ii) corneal laser enhancement after lensectomy to treat residual ametropia; (iii) good potential visual acuity (baseline pre-LASIK logMAR

corrected distance visual acuity [CDVA] <0.5); and (iv) at least three months of follow-up after corneal laser enhancement.

The exclusion criteria were as follows: (i) eyes with subnormal optics, such as corneal topographic abnormalities (small optical zones, decentered ablations, suspected ectasia); and (ii) any baseline anatomical disorder (vitreoretinal or surface/anterior segment disorder) or any perioperative anatomical complications (corneal and/or lens surgeries) in order to rule out organic disease that could mask the functional outcomes of both refractive procedures.

## Intraocular lenses

The diffractive trifocal IOLs implanted during the study period were the FineVision (Micro-F and Pod-F, both from PhysIOL, Liêge, Belgium) and the ATLisa-Tri 839MP (Carl Zeiss AG, Jena, Germany).

Both lenses are made of foldable hydrophilic acrylic material. The FineVision Micro-F (single-piece, four loop haptics) and FineVision Pod-F (single-piece, double-C loop haptics) combine two diffractive structures adjusted to offer a +3.5 D addition for near vision and a +1.75 D addition for intermediate vision; both have a negative aspheric profile of  $-0.11 \mu m$ . The ATLisa-Tri IOL comprises a single piece with a plate haptic design and +3.33 D near and +1.66 D intermediate additions in the IOL plane, as well as a negative aspheric profile of  $-0.18 \mu m$ .

## Surgical procedures

Corneal and lens surgical procedures were performed by experienced surgeons based on homogeneous perioperative protocols. Primary corneal refractive surgery was mainly by LASIK, which was performed with two microkeratomes with nasal hinges (Moria LSK-ONE and Moria ONE-USE-PLUS-SBK, Microtech Inc., Moria Ophthalmic Instruments, Anthony, France) and three excimer laser models: Technolas 217C, 217-Z-100 (Bausch & Lomb, Claremont, California, USA), Mel-80 (Carl Zeiss Meditec, Jena, Germany), and WaveLight-Allegretto Wave-Eye-Q (Alcon Laboratories, Fort Worth, Texas, USA).

Patients who had previously undergone LASIK or surface ablation returned to the clinic for lens surgery because of reduced distance and/or near visual acuity by

presbyopia and/or cataracts. Standard uneventful phacoemulsification was performed with implantation of a trifocal IOL in the capsular bag.

All LCRS data were available. The IOL calculation was performed using the online American Society of Cataract and Refractive Surgery (ASCRS) calculator (https://iolcalc.ascrs.org) and/or the Barret True-K Formula (https://www.apacrs.org/apacrsbiometry/True-K.aspx) by entering the refractive, keratometric, topographic, and biometric data, based on a multiformula approach. The post-operative target for the IOL power calculation was emmetropia in all cases.

An additional corneal laser enhancement after trifocal IOL implantation was performed in all cases because of a post-operative refractive error that resulted in unsatisfactory visual outcome (uncorrected distance visual acuity [UDVA] or uncorrected near visual acuity [UNVA]) at least three months after lens surgery. Enhancement laser procedures were performed mainly using an alcohol-assisted PRK technique and the same excimer laser models and microkeratomes used for the first primary LCRS procedure.

#### Clinical evaluation

All surgical procedures were performed at our institution with homogeneous preoperative assessment protocols. Patients underwent a complete ophthalmologic examination that included measurement of visual acuity data, namely, distance vision (Snellen auto chart projectors, Topcon Corp, Tokyo, Japan), near vision (Runge Near Vision Card, Good-Lite, Elgin, Illinois, USA) and refraction (uncorrected and corrected, manifest and cycloplegic), topography, slit-lamp biomicroscopy, ocular surface/tear film evaluation, and fundoscopy. However, due to diversity in practice locations and development of devices over time, the preoperative evaluation was not standardized. Three corneal

topographers were used during the study period (Orbscan II [Bausch&Lomb, Claremont, California, USA], Pentacam [Oculus Optikgerate GmbH, Wetzlar, Germany], and the Wavelight-Oculyzer [Alcon Laboratories, Foxworth, Texas, USA]).

The preoperative examination for lens surgery also included endothelial cell count (SP 3000P; Topcon, Capelle, The Netherlands) and macular optical

coherence tomography (SOCT Copernicus-REVO, Optopol-Tech, Zawircie, Poland). Depending on the study time point, biometric parameters were assessed using an ultrasonic immersion biometer (Ocuscan-RPX; Alcon, Foxworth, Texas, USA) or an optical biometer (IOLMaster 500; Carl-Zeiss-Meditec, AG, Jena, Germany).

### Refractive and visual measures

The main measurements were visual and refractive outcomes and patient satisfaction, which were obtained from the last available visit, with at least three months of follow-up after laser corneal enhancement. Visual results included average logMAR UDVA, CDVA, uncorrected intermediate visual acuity (UIVA), and UNVA. Refractive data included post-operative sphere, cylinder, manifest refraction spherical equivalent (MRSE), and accuracy (percentage of eyes within  $\pm$  0.50 D and  $\pm$  1.0 D). We also defined safety outcomes as the percentage of eyes with a loss of  $\geq$ 1 and  $\geq$ 2 lines of CDVA between the time after lens surgery and corneal laser enhancement; efficacy outcomes were measured as the percentage of eyes with a difference between post-lensectomy CDVA and post-enhancement UDVA  $\geq$ 0 lines.

The percentage of pre-enhancement Neodymium:YAG (Nd:YAG) laser capsulotomy procedures was recorded as a secondary measurement.

#### Statistical Analysis

Independent groups were compared by assessing the distributions with regard to outliers and normality and homogeneity of the variances. Outliers were assessed using the box plot method. Normality was examined using the Shapiro-Wilk test and Q-Q plots. Homogeneity of variances was verified using the Levene test. Since these assumptions were met in most cases, the independent *t* test was performed. In the case of extreme outliers, a robust Yuen test for trimmed means was performed. The most unusual distributions were compared using the Mann-Whitney test. The *t* test was used for means and standard deviations. With the Yuen Test, 20% trimmed means and Winsorized standard deviations are reported. Finally, the result of the Mann-Whitney test is reported using median and interquartile range <sup>A, B</sup>.

#### RESULTS

The study sample comprised 186 eyes (92 right, 49.5%) from 146 patients (85 females, 58.2%) who had undergone a triple refractive procedure at our institution (Table 1). The series was divided into two groups according to the primary LCRS: the myopic group (n=89 eyes, 47.8%) and the hyperopic group (n=97 eyes, 52.1%). Table 1 also displays the distribution of trifocal IOLs in both groups, percentage of YAG capsulotomy before the enhancement, the main primary corneal laser technique in both groups and if the enhancement was lifting the flap or with PRK over the flap. The mean time from first laser to lensectomy surgery was 9.62 ± 3.93 years with range between 0.5 to 18.4 years. The mean time from lensectomy to enhancement was 7.02 ± 8.22 months with range between 1 to 70.4 months.

Table 2 displays the main refractive and visual data from baseline to the postlensectomy period and the results of the comparison of post-lensectomy visual and refractive outcomes for the myopic and the hyperopic groups at the thirdmonth visit. The myopic group had significantly worse refractive outcomes than the hyperopic group, with myopic shift (MRSE of -0.93 D  $\pm$  0.29 D vs -0.69 D $\pm$ 0.49 D, respectively, p=0.013). In contrast, the myopic group achieved better CDVA, UIVA and UNVA than the hyperopic group.

Table 3 shows enhancement laser data and post-enhancement outcomes in both groups. The enhancement laser treatment refraction is also represented in figure 1, which shows that a myopic defect was treated in both groups. A statistically significant higher sphere (-0.73  $\pm$  0.45 D vs -0.13  $\pm$  0.59 D, p<0.001) and MRSE (-0.95  $\pm$  0.29 vs -0.64  $\pm$  0.52, p=0.003), was performed in the myopic group whereas the treated cylinder defect was higher in the hyperopic group (-0.89  $\pm$  0.39 vs -0.44  $\pm$  0.40, p <0.001).

The final postoperative refractive and visual outcomes after corneal laser enhancement results are displayed in table 3. Most parameters were significantly better in the myopic group than in the hyperopic group, with statistically significant differences between groups for sphere (p<0.001), cylinder (p<0.001), MRSE (p=0.003), UDVA (p=0.047), CDVA (p= 0.005), and UNVA (p= 0.003). Regarding visual indicators, figure 2 shows post-enhancement safety and efficacy indices in both groups. The safety index was  $0.95 \pm 0.09$  in the hyperopic group and  $0.99 \pm 0.08$  in the myopic group; the post enhancement efficacy index was  $0.91 \pm 0.11$  in the hyperopic group and  $0.94 \pm 0.10$  in the myopic groups. No statistically significant differences were found between groups for either index (Table 3).

In addition, supplemental figure 1 displays safety standard graphics and risk of vision loss in both groups, with no statistical differences (p=0.426) in the percentage of eyes that lost more than one line of CDVA (20% vs 15% in hyperopic and myopic groups, respectively). Supplemental figure 2 shows efficacy in terms of the difference in Snellen lines between post-enhancement UDVA and pre-enhancement CDVA: 68.1% and 76.4% of the eyes had no change or improvement in the hyperopic or myopic group, respectively, with no statistically significant differences between groups (p=0.249).

Regarding predictability, values were within  $\pm 0.5$  D in 78.0% and 86.6% of eyes and within  $\pm 1.0$  D in 93.4% and 96.3% in the hyperopic and myopic group, respectively (supplemental figure 3) with no statistically significant differences (Table 3).

Finally, Table 4 shows the results of the postoperative spectacle independence questionnaires regarding visual acuity (Table 4A), dependence on spectacles or contact lenses (Table 4B), and global satisfaction (Table 4C). Similar subjective perceived outcomes can be observed in all items, with no statistically significant differences between the groups.

## DISCUSSION

Previous studies have evaluated outcomes after myopic<sup>10-14</sup> and hyperopic<sup>15-17</sup> LCRS and subsequent implantation of a bifocal IOL, whereas others have assessed outcomes after LCRS and subsequent implantation of a trifocal IOL.<sup>18-21</sup> This study goes one step further examining eyes with LCE using diffractive trifocal IOLs after LCRS for myopia or hyperopia, obtaining good visual and refractive outcomes and high level of patient subjective satisfaction after the nonconsecutive triple refractive procedure.

Only one paper has reported results after laser enhancement in patients with LCRS and subsequent implantation of a multifocal IOL.<sup>22</sup> Bifocal IOLs (AcrySof ReSTOR SA60D3 or SN60D3) implanted after previous myopic LASIK were studied. Forty-nine eyes were included. Of these, 21 (42.9%) needed laser enhancement and 25 eyes (51%) underwent Nd:YAG capsulotomy (before enhancement). The mean follow-up was 14.2 months (range 9 to 29 months). UDVA at 1 month and 6 months was significantly worse in the enhancement group than in the non-enhancement group, although there were no significant differences between the groups at the end of follow-up. The same was found for UNVA. Predictability was 84% of eyes within ±0.5 D and 94% within ±1 D; no data were reported for the safety index or efficacy index. The authors concluded that implantation of a ReSTOR IOL after laser treatment of myopia could provide good visual and refractive results, with no significant differences between groups after laser enhancement. The frequency of enhancement and YAG capsulotomy was high.

This previous study showed positive refractive and visual outcomes but in patients implanted with bifocal IOL, after myopic LCRS and in a smaller case series compared to our study. Furthermore, they find a similar predictability than we find in our study for the myopic group. Their results demonstrate that laser enhancement can improve visual, refractive, and satisfaction results in myopic eyes previously treated with LCRS and subsequent implantation of a multifocal IOL.

Our positive results emphasize that a second corneal photoablation can be performed safely after a previous initial one (myopic or hyperopic) and a trifocal lens implantation between both surgeries. Poorer visual outcomes could be expected, considering that the cornea receives laser treatment twice and a trifocal diffractive IOL with negative SA has been implanted. In this sense, if these lenses are implanted after a myopic LCRS procedure, we might expect a better visual outcome than after a hyperopic one. However, predictability, efficacy, safety and satisfaction were similar after LCE for both myopic and hyperopic groups. Due to the fact that we were unable to identify a published work that analyzes visual and refractive outcomes and patient satisfaction in eyes that have undergone a myopic or hyperopic LCRS procedure, trifocal IOL implantation and subsequent excimer laser enhancement we were not able to compare with similar studies.

However, comparing our results to those that we obtained in eyes with a trifocal IOL implantation with no previous or subsequent LCRS,<sup>8</sup> we find slightly worse results in the present study. This was expected because the induced HOAs by two corneal ablations were increased by to those induced after the IOL implantation.<sup>7,23</sup>

Some of the final parameters were slightly better in the previously myopic group. Although we cannot determine the exact cause for this difference, one factor could be the higher incidence of laser enhancement rate in the initial corneal photoablative procedure among hyperopic eyes and the greater HOAs induced in hyperopic ablation compared to the myopic one.<sup>23,24</sup> Furthermore, the IOLs used in the study have a negative SA that increases those induced by the ablation in hyperopic eyes.<sup>7,24</sup>

Regarding subjective patient perception, the postoperative spectacle independence questionnaires in our study showed better results than reported in other similar studies. In this sense, Chang et al<sup>13</sup> and Li et al<sup>19</sup> reported that 78% and 81% of the patients had complete spectacle independence after implantation of bifocal and trifocal IOLs, respectively. In our study, the results for spectacle independence were stratified by distance, with values of 98.9.0%, 96.8%, and 93.8% for far, intermediate, and near distances, respectively. However, despite these results, the percentages of patients that would repeat the procedure in our study were 85.7% for myopia and 87.5% for hyperopia. These data contrast with those we previously reported after implanting trifocal IOLs in eyes with no previous LCRS, for which spectacle independence rates of around 99% were obtained for intermediate and distance and around 93% for near, but with around 97% of the patients saying that they would undergo the same procedure again.<sup>8</sup>

Our study is limited by its retrospective design, and some data, such as objective quality parameters (aberrometry, contrast sensitivity, and topographic corneal aberrations), have not been evaluated. However, we recorded real-life subjective patient satisfaction and assessed spectacle independence using the same questionnaire as applied elsewhere.<sup>8,25</sup> In addition, the large number of surgeons

and the different excimer lasers, treatment and measurement devices used during the study period constitute an unavoidable drawback in a retrospective multicenter study that includes three different surgical procedures over several years of follow-up.

Although we are a large group of surgeons, we work with homogeneous protocols, we share the same clinical computerized recording data platform and have similar diagnostic and surgical devices; however certain variability has been inescapable and we are aware that this is a main shortcoming of the study. Despite this fact, we believe that the study-findings contribute to related literature with real-life data about the performance of trifocal IOLs in post refractive eyes and has relevance at the present time with the current state of the art on this topic.

Regarding the patient satisfaction questionnaire, we are aware that other type of questionnaires could lead to different outcomes, but this is the questionnaire that was available from the records of our patients. This was also used in two recent papers by our group.<sup>8,25</sup> Furthermore, ours is the first series to assess laser enhancement after an LCRS procedure and subsequent implantation of a trifocal IOL.

In conclusion, our study demonstrates that laser enhancement after implantation of a trifocal IOL in eyes that had previously undergone corneal photoablation to treat hyperopia or myopia is safe, effective, and predictable and provides a high degree of satisfaction and spectacle independence.

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## VALUE STATEMENT:

What was known:

Multifocal IOL implantation in eyes previously treated with a photoablative corneal procedure is safe, effective, and predictable and provides a high degree of patient satisfaction.

Most of the studies assessing outcomes after LCRS and implantation of a multifocal IOL involved bifocal IOLs implanted after myopic corneal ablation.

## What this paper adds:

Laser corneal enhancement after implantation of a trifocal IOL in eyes that underwent myopic or hyperopic laser corneal refractive surgery is safe, effective, and predictable and provides a high level of patient satisfaction and spectacle independence.

Laser corneal enhancement in eyes implanted with a trifocal IOL that have undergone laser corneal refractive surgery for myopia or hyperopia leads to a better result in eyes that have undergone a primary myopic ablation in terms of refractive data; however, predictability, efficacy, safety and satisfaction are similar after corneal ablation for both myopia and hyperopia.

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# FIGURE LEGENDS

## Figure 1

Title: Laser enhancement treatment in myopic and hyperopic groups: Box-plot diagrams regarding sphere (fig 1A), cylinder (fig 1B) and MRSE (fig 1C).

## Figure 2

Title: Post-enhancement visual indicators: Box-plot Efficacy index (fig 2A) and Safety index (fig 2B) in hyperopic and myopic groups

# SUPPLEMENTAL FIGURE LEGENDS

## Supplemental figure 1

Title: Post-enhancement safety outcomes in myopic group and hyperopic group: Change in CDVA lines after enhancement

Myopic group: Loss ≥1 lines = 15% eyes

Hyperopic group: Loss ≥1 lines = 20% eyes

# Supplemental figure 2

Title: Post-enhancement efficacy outcomes in myopic group and hyperopic group: Change in post-operative UDVA and preoperative CDVA

Myopic group: No change or gain VA lines: = 76.4% eyes

Hyperopic group: No change or gain VA lines = 68.1% eyes

## Supplemental figure 3

Title: Bar-graph showing accuracy in myopic group and hyperopic group after enhancement.

Percentage of eyes between  $\pm$  0.5D: Hyperopic group = 78%; Myopic group = 87%

Percentage of eyes between  $\pm$  1.0: Hyperopic group = 93% Myopic group = 96%