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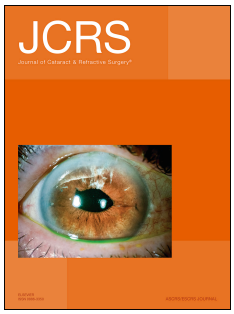

Presbyopic Refractive Lens Exchange with Trifocal Intraocular Lens Implantation After Corneal Laser Vision Correction: Refractive Results and Biometry Analysis of 241 Eyes

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"Presbyopic Refractive Lens Exchange with Trifocal Intraocular Lens Implantation After Corneal Laser Vision Correction: Refractive Results and Biometry Analysis of 241 Eyes"

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Abstract

Purpose: To evaluate both refractive and biometry results of presbyopic refractive lens exchange (RLE) with trifocal intraocular lens (IOL) implantation in eyes previously submitted to corneal laser vision correction (LVC).

Settings: Memira AS, Scandinavia.

Design: Multi-centric, multi-surgeon, single-protocol, single-IOL platform, retrospective, interventional case series.

Methods: The refractive results were measured in terms of manifest refraction spherical equivalent, UNVA, UDVA, CDVA, safety, efficacy and precision. The biometry analysis was evaluated in terms of refractive prediction error (RPE), median absolute error (MedAE) and the percentage of eyes within certain range of refractive prediction error for the formulas from the ASCRS online calculator.

Results: The study comprised 241 eyes with previous myopic or hyperopic LVC that underwent presbyopic RLE with trifocal IOL implantation. Six months postoperatively, 60% of eyes were within 0.25 D, 80.9% within 0.50 D and 97.9% within 1.00 D from emmetropia. There were no statistical differences between myopic and hyperopic groups regarding monocular UDVA (0.87 ± 0.20), safety index (0.81 ± 0.18) or efficacy index (0.98 ± 0.09). Binocularly, 85% of the patients presented simultaneous UDVA and UNVA ≥ 0.9 and J3.

The formulas from the ASCRS on-line calculator presented different performances for myopic or hyperopic previous ablation profiles. The use of optimized constants associated with a nomogram for correcting the mean RPE improved the MedAE.

Conclusion: Presbyopic RLE is a safe and effective procedure in selected cases with history of previous LVC. The utilization of optimized IOL constants and nomograms can improve the refractive precision of lens-based refractive surgery.

Introduction

Presbyopia is the gradual loss of the crystalline lens ability to focus on nearby objects due to a physiological degenerative process.[1] It affects approximately all individuals after the age of 45 years and the global prevalence of presbyopia is predicted to increase to 1.4 billion by 2020 and to 1.8 billion by 2050.[2]

Although the physiopathology of presbyopia is acknowledged, its surgical treatment still involving some challenges. Some surgeons consider refractive lens exchange (RLE) as the surgical procedure of choice for presbyopic patients, mainly due to the ability to provide stable and functional uncorrected vision over a range of distances.[3,4] The aim of the presbyopic RLE is to replace the natural dysfunctional crystalline lens preferentially with an artificial diffractive trifocal intraocular lens (IOL) to produce the three main focus distances (far, intermediate, and near).[5,6]

At the same time, corneal laser vision correction (LVC) is one of the most common surgical procedures in the world. It is believed that more than 40 million procedures have been performed since 1991. In Europe, over 1 million procedures have been performed per year between 2002 and 2007, which implies in a current growing demand for cataract surgery and presbyopic RLE with previous LVC. Although the sources of biometry errors for patients who have had LVC are well known, IOL power calculations in these eyes remain a clinical challenge.[7-11]

Thus, the primary objective of the current study is to evaluate the refractive results of presbyopic RLE with trifocal IOL implantation in eyes with previous LVC. Our secondary objective is to analyze the IOL power prediction based on the available online calculator and to develop a protocol in order to minimize refractive deviations.

Methods

Patient selection criteria

The study is a multi-centric, multi-surgeon, single-protocol, single-IOL platform, retrospective analysis of 241 consecutive eyes with ophthalmologic history of previous LVC submitted to presbyopic RLE with implantation of a trifocal IOL (FineVision Trifocal, PhysIOL SA, Liege, Belgium). The procedures were performed at Memira Clinics in Norway, Sweden and Denmark from 2015 to 2017.

Eyes with abnormal optics, such as decentralized ablations, small optical zones, high ammetropic ablations and preoperative corrected distance visual acuity (CDVA) inferior to 0.8 (Snellen), or those with vitreomacular abnormalities by optical coherence tomography, such as epiretinal membrane, vitreomacular traction or age-related macular disease, were considered unsuitable for RLE and trifocal IOL implants.

In addition, the presbyopic RLE candidates had a comprehensive preoperative counseling, in which their needs, wishes, preferences and expectations were

evaluated. If these did not match with the likely results from our clinical evidence, the patient was advised against surgery.

The study was registered with the number 2018/1569 at the Regional Committee for Medical and Health Research Ethics (REK), Norway. The REK considered this retrospective analysis as quality control and did not require study consent. Patient-protected information was properly safeguarded. All patients provided specific surgical informed consent about presbyopic RLE with trifocal IOL implantation after LVC.

Clinical evaluation

All patients submitted to presbyopic RLE had a comprehensive preoperative ophthalmologic examination that included uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), corrected distance visual acuity (CDVA), manifest refraction (sphere and cylinder), slit-lamp biomicroscopy and fundoscopy. The tear film, ocular surface and eyelids were carefully examined before surgery indication. Abnormalities, such as dry eye syndrome, Meibomian gland dysfunction and blepharitis were previously evaluated and treated, in order to obtain more reliable measurements for IOL power calculation, optimized refractive results and increased patient satisfaction. Biometry data was obtained by partial coherence interferometry (IOLMaster V5, Carl Zeiss Meditec, Jena, Germany), which measured the axial length (AL), keratometry (K1, K2 and Km), and anterior chamber depth (ACD). Corneal tomography was performed with slit scanning imaging (Orbscan, Bausch & Lomb, Rochester, NY), rotating

Scheimpflug imaging (Pentacam, Oculus, Wetzlar, Germany) or rotating Scheimpflug imaging with Placido disc (Sirius, CSO, Florence, Italy). Macula, fovea and vitreomacular interface were preoperatively evaluated with fundoscopy and / or optical coherence tomography (OCT).

Intraocular Lens

The FineVision Micro F is a single-piece trifocal diffractive IOL with 4-loop haptics, 25% hydrophilic acrylic, biconvex aspheric with a spherical aberration (SA) of -0.11 µm. The total diameter is 10.75 mm and the optic body diameter is 6.15 mm, with 5 degrees of haptic angulation. The FineVision Pod F is a single-piece trifocal diffractive toric IOL with 2-Y haptics, 26% hydrophilic acrylic, biconvex aspheric IOL with a SA of -0.11 µm. The total diameter is 11.40 mm and the optic body diameter is 6.0 mm, with 5 degrees of haptic angulation. Both models combine two diffractive gratings, with +1.75 and +3.50 diopters (D) additions. At a 3 mm pupil aperture, 43% of the light energy is allocated to far vision, whereas 28% to near vision and 15% to intermediate vision. The distribution of light energy is pupil dependent, benefiting far vision with larger pupil diameters.

IOL Power Calculation

The lens power calculation was performed using the ASCRS calculator from 2015 to 2016 with target zero. From 2016 to 2017 the lens power was calculated after IOL constant optimization and the application of a nomogram for previous myopic

ablations (target +0.25 D) to adjust for the standard myopic refractive error identified by our quality department. For the purpose of the study, the refractive results were analysed in its totality, whereas the IOL power predictions were all recalculated with optimized constants for the entire group.

IOL Constant Optimization

The optimization process is performed to refine the refractive results for a variety of practice-specific variables, such as keratometers, biometers, surgical technique and IOL power calculation formulas. Our IOL constant optimization was calculated based on a previous analysis of 1,434 normal eyes submitted to uncomplicated presbyopic RLE implanted with FineVision Trifocal IOLs in our settings. From this analysis we obtained the following optimized constants for this specific IOL platform:

- Spherical IOL: SRK-T (A-constant): 119.16; Holladay (SF): 1.84; Haigis (a0, a1 and a2): 1.415, 0.400 and 0.100.
- Toric IOL: SRK-T (A-constant): 119.2; Holladay (SF): 1.87; Haigis (a0, a1 and a2): 1.441, 0.400 and 0.100.

Surgical Procedure

The presbyopic RLE procedures were performed by different experienced surgeons using the following technique: clear corneal incision of 2.2-mm,

intracameral anesthesia with Xylocain 10 mg/ml (AstraZeneca A/S, Copenhagen, Denmark), viscoelastic device (Provisc, Alcon Laboratories, Inc., Fort Worth, USA), anterior continuous capsulorrexis of approximated 5.0-mm, phacoaspiration, cortical cleanup, posterior capsule polishing, single-piece IOL injection into the capsule bag (Finevision Trifocal, Physiol SA, Liege, Belgium), viscoelastic removal from behind the IOL and from the anterior chamber, incision hydration with balanced salt solution, and injection of intracameral Cefuroxime 10 mg/ml (Aprokam, Laboratoires Théa, Clermont-Ferrend, France). All surgeries were uncomplicated and no patient required suture closure.

Refractive Results

The postoperative presbyopic RLE data was obtained at a median of 6 months from surgery. The objective of the study is to evaluate the refractive results in terms of manifest refraction (sphere and cylinder), manifest refraction spherical equivalent (MRSE = sphere + cylinder / 2), defocus equivalent (MRSE + cylinder / 2, in absolute values), UDVA, UNVA, CDVA, safety index (postoperative CDVA / preoperative CDVA), efficacy index (postoperative UDVA / preoperative CDVA) and accuracy (percentage of eyes within ± 0.25, ± 0.50, ± 0.75, and ± 1.00 D. Standardized graphics for refractive surgery and lens-based refractive surgery were provided.[12,13]

Biometry Analysis

The current study intended to evaluate different IOL power calculation formulas and to develop a biometry protocol based on the clinical results of a high volume lens-based refractive surgery center. For this purpose, we employ the convenient ASCRS online IOL power calculator version 4.8 (http://iolcalc.ascrs.org/).

For IOL power calculation analysis, we eliminate the systematic error for the entire group of 241 eyes by adjusting the arithmetic mean error to zero. By assuming that 1.0 D of IOL power error produces 0.7 D of refractive error at the spectacle plane,[14-16] we calculated the ideal IOL power from the postoperative MRSE and the known IOL power implanted:

- Postoperative MRSE + 0.7 (implanted IOL power - ideal IOL power) = 0

From the ideal IOL power, we calculated the implanted IOL error (ideal IOL – implanted IOL) and the following metrics for each formula from the ASCRS calculator and nomograms: IOL prediction error (ideal IOL – predicted IOL), the mean refractive prediction error (RPE) with its standard deviation (SD), the median absolute error (MedAE) and the percentage of eyes within 0.25, 0.50, 0.75 and 1.00 D of absolute prediction error. The biometry analysis variables were provided as suggested by the guest editorials by Hill, Abulafia, Wang and Koch.[15,17]

Nomogram Development

For the nomogram development, we selected the formulas with lowest RPE SD and applied different targets in order to obtain the lowest MedAE and the higher

number of eyes within 0.25, 0.50, 0.75 and 1.00 D from emmetropia. The idea was to develop a protocol to be used internally and maybe to expand it to surgeons using the same surgical platform (IOL Master optical biometer + Finevision Physiol IOL with the proposed optimized constants).

Statistical Analysis

The SPSS for Mac statistical software package (version 20.0, IBM-SPSS, Inc.) was used for the statistical analysis. Normality of all data samples was checked initially by the Shapiro-Wilk test. Since parametric analysis was not possible for most variables, the Mann-Whitney U test was used to compare variables between myopic and hyperopic groups. The Wilcoxon signed ranks test was applied to assess the differences between two paired variables or the absolute prediction error between two formulas. One sample t-test was applied to assess whether RPE was significantly different from zero. The McNemar test was used to evaluate whether the percentages of eyes within certain refractive prediction errors are significantly different between two formulas, whereas the Cochran Q test was used among three or more formulas. P values < 0.05 were considered significant.

Results

The study comprised 241 eyes from 143 patients that underwent presbyopic RLE with trifocal IOL implantation, of which 155 eyes (64.3%) had previous myopic ablation and 86 (35.7%) hyperopic. In 121 eyes (62 patients) we had access to the objective LVC data (83 eyes or 53.5% in the myopic group and 38 eyes or 44.2%

in the hyperopic group). From the eyes with previous history, the mean preoperative MRSE was -3.05 ± 1.57 D (from -0.75 to -7.00 D) in the myopic group and +1.99 ± 0.84 D (from 0.00 to +4.00 D) in the hyperopic group.

Table 1 shows the preoperative RLE clinical data for both myopic and hyperopic groups. There were statistical differences in all preoperative presbyopic RLE variables between myopic and hyperopic ablation groups. Eighty-one percent of the eyes (N = 195 eyes) were implanted with spherical IOLs, whereas 19% (N = 46 eyes) were implanted with toric IOLs. All surgeries were uncomplicated and all patients completed a minimum 3-months postoperative follow-up, with a median of 6 months (mean 6.38 ± 5.88, from 3 to 12 months).

Table 2 shows the postoperative presbyopic RLE clinical data for both myopic and hyperopic groups. The hyperopic group demonstrated better IOL precision, with significant lower postoperative MRSE and IOL error. The UDVA did not present significant differences between the groups, as well as safety and efficacy indices. The safety index for the entire group was 0.98 ± 0.09 (from 0.80 to 1.29), whereas the efficacy index was 0.81 ± 0.18 (from 0.30 to 1.22). The efficacy index was negatively influenced by the myopic trend observed in the first 130 eyes, in which the mean refractive error was -0.29 ± 0.44, with 76% of the eyes between ± 0.50 D. After IOL constant optimization and the nomogram (target +0.25 D) application, the following 111 eyes presented mean refractive error of -0.14 ± 0.39, with 84% of the eyes between ± 0.50 D.

Figure 1 shows a bar graph composite of postoperative MRSE accuracy. Six months postoperatively, 60% of eyes were within 0.25 D, 80.9% within 0.50 D and 97.9% within 1.00 D from emmetropia. Figure 2A shows the scattergram of the attempted vs. achieved MRSE, with the trend line demonstrating a tendency towards undercorrection. Figure 2B shows the postoperative astigmatism, with 80% of the eyes within 0.50 D. Sixty-seven percent of the eyes presented defocus equivalent within 0.50 D, 91.5% within 1.00 D and 98.8% within 1.50 D, as shown in Figure 2C.

Figure 3 shows efficacy bar graphs with the cumulative Snellen visual acuity for the preoperative CDVA vs. postoperative UDVA for the entire group, with 81.3% of the eyes with 0.8 and 92.1% with 0.7 of postoperative UDVA. Regarding the change in Snellen lines of CDVA, 79.7% of the eyes maintained the preoperative CDVA, whereas 14.5% lost 1 line, 0.4% lost 2 lines and 4.6% gained 1 line of CDVA.

Figure 4 shows the scattergram of the postoperative UDVA vs. MRSE, with a tendency towards better distance visual performance when the MRSE is closer to zero or slightly hyperopic for both groups. This result indicates that the optimal target for trifocal IOLs should be approximately +0.12 D of the expected postoperative refractive error. When analyzed separately, the myopic group demonstrated a significant better CDVA than the hyperopic group, both preoperatively (1.09 ± 0.10 D vs. 1.05 ± 0.11 D, $P < 0.01$) and postoperatively (1.06 ± 0.09 vs. 1.03 ± 0.10, $P < 0.03$).

Figure 5 shows the bar graph of the presbyopic RLE performance in terms of monocular UDVA and UNVA, with 46.5% of the eyes ≥ 1.0 and J3, and 81.4 % ≥ 0.8 and J4. The binocular performance evaluation demonstrated that 68% of the patients presented UDVA and UNVA better than 1.0 and J3, whereas 85% better than 0.9 and J3. Twelve percent of the patients presented binocular UDVA < 0.8 mainly due to bilateral postoperative myopic errors, which provided UNVA of J3 in all those cases. Only 2% of the patients showed binocular UNVA of J4. These patients had a history of hyperopic ablations higher than +2.00 D with hyperopic regression prior to the presbyopic RLE.

Regarding the biometry analysis, Tables 3 and 4 show the RPE and MedAE for the different formulas (with and without previous history data) for both myopic and hyperopic groups, respectively. For the purpose of the current study, we have evaluated different target nomograms with the objective to reduce both RPE and MedAE. The nomograms with the best performances were also displayed within Tables 3 and 4.

Figure 6 shows the RPE box-plot graphs for the myopic group, divided into previous history (A) and no-history data (B) formulas subgroups. For the myopic cases with previous history data, we observed that the Masket formula, ASCRS Minimum, the nomograms Barrett True-K with target +0.15 D and Haigis-L with target +0.45D presented the lowest RPE, and were not statistically different from zero (one sample T-test, with P > 0.2). The lowest MedAE (Table 3) were obtained with the formulas Masket (0.34 D), Barrett True-K (0.35 D), ASCRS Minimum (0.33 D) and the nomograms Barrett True-K with target +0.15 D (0.33 D) and

Haigis-L with target +0.45 D (0.32 D). The Wilcoxon Signed Ranks Test did not show statistical differences between pairs of those formulas ($P > 0.5$). For the myopic cases without previous history data, we observed that the nomogram Haigis-L with target +0.45 D presented the lowest RPE (0.03 ± 0.39 D) and MedAE (0.32 D). Only the nomogram Haigis-L with target +0.45 D did not show statistical differences from zero (one sample T-test, with $P = 0.255$), and presented statistical differences between pairs of formulas (Wilcoxon, with $P < 0.001$).

Figure 7 shows the stacked histogram comparing the percentage of eyes within certain range of absolute prediction error for the myopic group, divided into previous history (A) and no-history data (B) subgroups. Regarding the myopic group with previous history data, the percentage of eyes with an absolute prediction error within 0.50, 0.75 and 1.00 D presented statistical differences among the following IOL power calculations: Masket formula (73%, 96% and 100%, respectively), ASCRS Minimum (71%, 96% and 100%), nomograms Barrett True-K with target +0.15 D (72%, 97% and 100%) and Haigis-L with target +0.45 D (81%, 94% and 100%), $P < 0.05$ with the Cochran Q test for the different formulas above. On the other hand, when analyzing the myopic group with no-history data, the Haigis-L formula with target of +0.45 D presented statistically significant higher number of eyes within 0.50 D (83%), with $P < 0.001$ with the McNemar test for pairs of formulas.

The overall precision for the hyperopic group was better than for the myopic group, with reduced variability among the different formulas. Figure 8 shows the RPE box-plot graphs for the hyperopic group, divided into previous history (A) and no-

history data (B) subgroups. For the previous history data subgroup, the Modified Masket, Haigis-L, ASCRS Minimum and nomogram ASCRS Average with target +0.20 D presented the lowest RPE, and were not statistically different from zero (one sample T-test, with $P > 0.08$). The lowest MedAE (Table 4) were obtained with the ASCRS Minimum (0.35 D) and the nomogram ASCRS Average with target +0.20 D (0.34 D), with no statistical differences between these formulas (Wilcoxon Signed Ranks Test, with $P > 0.5$). For the no-history data subgroup, the Haigis-L formula, ASCRS minimum and the nomogram ASCRS Average with target +0.20 D presented the lowest RPE, and were not statistically different from zero (one sample T-test, with $P > 0.2$). The lowest MedAE were obtained with Barrett no-History (0.29 D), Haigis-L (0.30 D), ASCRS Minimum (0.29 D) and the nomogram ASCRS Average with target +0.20 D (0.29 D). The Wilcoxon Signed Ranks Test did not show statistical differences between pairs of formulas ($P > 0.5$).

Figure 9 shows the stacked histogram comparing the percentage of eyes within certain range of absolute prediction error for the hyperopic group, divided into previous history (A) and no-history data (B) formulas subgroups. Regarding the subgroup of hyperopic ablation with previous history data, the percentage of eyes with a absolute prediction error within 0.50, 0.75 and 1.00 D presented statistical differences among the following formulas: Modified Masket (69%, 90% and 100%, respectively), Haigis-L (76%, 87% and 97%), ASCRS Minimum (79%, 95% and 100%) and ASCRS Average with target +0.20 D (81%, 97% and 100%), $P < 0.01$ with the Cochran Q test for the different formulas above. The hyperopic group without history data presented more than 80% of the eyes within 0.50 D. The

percentage of eyes with a absolute prediction error within 0.50, 0.75 and 1.00 D did not present statistically differences among the following formulas: Barrett no-history (85%, 94% and 99%, respectively), Haigis-L (85%, 93% and 99%), ASCRS Minimum (87%, 96% and 100%) and ASCRS Average with target +0.20 D (84%, 97% and 100%), P > 0.09 with the Cochran Q test for the different formulas above.

We identified 13 outliers (5.4% of the eyes) with a MRSE outside ±2 SD. Each patient was analyzed individually through the available information, including data reviewing, clinical consultation and IOL power recalculations. All cases presented a myopic refractive outcome. In 3 eyes the myopia was unexplained. Ten eyes had a combination of at least 2 possible factors: 5 of those eyes were operated before the IOL constant optimization and nomogram adjustment after 2016. In 5 eyes, a myopic target was primarily chosen. One eye had a bitoric ablation profile due to mixed astigmatism (with zero of spherical equivalent) and was calculated as hyperopic previous ablation.

Discussion

The modern cataract surgery has evolved to a genuinely refractive procedure. Advances in the surgical technique, biometry calculations and IOL optical designs have improved the safety and the outcomes of phacoemulsification, expanding the use of lens-based refractive surgery to patients with clear crystalline lenses. Currently RLE has its main indication for the treatment of presbyopia[18] and presents several advantages over corneal laser surgery, such as increased

monocular depth of focus, greater spectacle independence and longer-term stability.[19] In addition, patients previously submitted to corneal laser surgery have higher expectation for spectacle independence; by reaching presbyopia they search for a novel refractive solution. The current study addresses exactly this increasing demand.

A recent metaanalysis evaluated the efficacy and safety of multifocal IOLs after cataract surgery and presbyopic RLE.[3] Based on current evidence, they stated that the solution for presbyopic pseudophakia is multifocal IOLs. Even younger presbyopic patients can benefit from this treatment modality, with good UDVA and UNVA performances. Although patient satisfaction was considered high, with approximately 80% recommending the procedure, the metaanalysis comprised mostly bifocal IOLs studies with both refractive and first-generation diffractive optical concepts. Recent trifocal IOLs studies have shown even better results, with improved biometric precision and visual performances at the different distances.[20-22] The defocus curves of these IOLs demonstrate a flattening between -1.0 and -2.0 D of defocus, without worsening of contrast sensitivity tests and a high quality-of-life score on visual function questionnaires.[23,24] In our study, the mean monocular UDVA achieved was 0.87 ± 0.19, with 99% of the eyes achieving monocular UDVA of 0.5, 81% achieving monocular UDVA of 0.8 and 47% achieving monocular UDVA of 1.0. These results were comparable to those observed in previous studies with trifocal IOLs in non-operated corneas.[5,25-27]

A review on RLE trends concluded that RLE is currently a safer procedure mainly due to advances in the surgical technique.[18] Our safety index of 0.98

demonstrated that presbyopic RLE in eyes previously submitted to corneal laser correction is also a safe procedure. Although 14.52% of the patients lost 1 line of CDVA, the individual analysis of those cases showed a mean binocular CDVA of 1.01 ± 0,08 (from 0.90 to 1.20) and binocular UDVA of 0.97 ± 0.13 (from 0.65 to 1.20). Although the study did not evaluate the optical quality in terms of ocular aberrations, the use of an IOL with a negative SA of -0.11 µm in eyes previously submitted to hyperopic ablations apparently did not influence the outcomes in this specific group from our series. Our mean hyperopic ablation of +1.99 ± 0.84 D induced a corneal asphericity of approximately -0.50, which is close to the oval Cartesian and produces a corneal SA of zero.

Eighty-five percent of the patients presented binocular UDVA and UNVA of 0.9 and J3, which is comparable to previous studies with trifocal IOLs.[5,25] Although information about spectacle independence were not available, we considered that this threshold above provided a valid impression about the overall performance for daily tasks. Almost 92% of the eyes presented UNVA of J3 (point-type 5), which is the smaller letter in the reading chart we used. Our reading chart is used for clinical purposes only, and we must address this as a limitation of our study. However, modern typography recommends that the body of printed texts should be written with point-type 12, whereas digital content for desktop, tablet or smartphone should have 16 pixels, which in a screen with 96 dots per inch resolution provides also a point-type 12 font size. So, from a practical perspective, 98% of the patients with binocular J3 (point-type 5) represented a very satisfactory performance for daily near tasks, such as reading or mobile phone using.

The efficacy index of 0.81 demonstrated that the IOL power calculation is still a challenge in lens-based refractive surgery, especially with this specific group of patients. We are absolutely aware about the importance of the near-emmetropic status after presbyopic RLE[28,29] and 15% of the eyes were submitted to refractive enhancement after the presbyopic RLE to ensure optimal IOL functioning (12% surface ablation and 3% supplementary IOL). A recent study by Gundersen et al. showed a retreatment rate of 10.8% after multifocal IOL implantation in eyes with no previous laser surgery, most of them due to residual refractive astigmatism.[30]
In our study, the myopic refractive outcome was the main indication for surgical enhancement. This trend was observed by our quality sector during the patients' follow-up and an empirical nomogram targeting approximately +0.25 D was applied to the Haigis-L formula, with improved accuracy for the following eyes.

Our accuracy of 80.9%, 90.9% and 97.9% of the eyes between ± 0.50, 0.75 and 1.00 D, respectively, was higher than previous studies of biometry after corneal laser surgery and comparable to those with untreated corneas.[5,21,25,31] Our defocus equivalent of 91% of the eyes within 1.00 D is slightly lower than the 95% of a previous study with the same IOL platform implanted in patients with untreated corneas.[26] We attributed our good results to the following reasons; the exclusion criteria of corneas with abnormal optics, such as decentralized ablations, small optical zones, and high ammetropic ablations, which could not be excluded in post-laser cataract patients studies. The mean previous corneal ablation of our study was smaller than previous studies, and possibly more recent ablation profiles with better transitions zones, which permitted more reliable keratometric readings for IOL power calculations. The use of the same IOL platform with our

own optimized constants based on 1,434 normal eyes previously submitted to uncomplicated presbyopic RLE provided a more reliable information about the effective lens position. Finally, the use of the nomogram for fine-tuning the mean refractive error observed in the first 130 eyes has improved the total accuracy.

Regarding the IOL power calculation after corneal laser surgery, three main sources of error have been previously identified: erroneous central keratometric measurements, incorrect keratometric index for corneal power calculation and fail effective lens position derived from a previously altered corneal power.[32-34] The basic approach to manage these problems depends on the pattern of the previous laser ablation (myopic or hyperopic) and the availability of objective information about the corneal refractive treatment (previous history or no-history). Besides, newer methods have been proposed, such as OCT-based IOL power formula,[10] intraoperative aberrometry[9] and ray tracing analysis.[11] For the development of an IOL power calculation protocol, we employed straightforward measurements derived from a clinically accessible optical biometer (IOL Master) and the formulas available in the ASCRS online calculator. We divided the eyes in 4 groups according with the laser ablation profile and the availability of previous corneal laser surgical data. It is important to reinforce that only objective previous data should be introduced into the ASCRS calculator.

For the myopic group, we observed a trend towards myopia for most of the ASCRS online calculator formulas, as previously demonstrated by IOL power calculation studies.[7,8] In the group with previous history, the best results were obtained with the Masket formula, ASCRS Minimum, and the nomograms Barrett

True-K with target +0.15 D and the Haigis-L with target +0.45 D. For the no-history subgroup, the nomogram Haigis-L with target +0.45 D demonstrated the lowest RPE and Med AE. The nomogram Haigis-L with target +0.45 D was set as our new protocol for patients with previous myopic ablation (with and without previous history data).

The RPE in the hyperopic group were lower than in the myopic group for most formulas, which demonstrates a higher accuracy and precision for those cases. For the hyperopia with previous history subgroup, the best results were obtained with Modified Masket and Haigis-L formulas, ASCRS Minimum and the nomogram ASCRS Average with target +0.20 D. The Haigis-L formula for hyperopia presented better precision than the Haigis-L for myopia, with lower RPE and MedAE, and no nomogram could be applied for further improvement. In this subgroup, the best results were obtained with the Haigis-L formula, ASCRS Minimum and the nomogram ASCRS Average with Target +0.20 D. The nomogram ASCRS Average with target +0.20 D was set as our current protocol for patients with previous hyperopic ablation (with and without previous history data).

Although Masket, Barrett true-K with target +0.15 D and Haigis-L with target +0.45 D presented similar results for the previous history subgroup, the nomogram Haigis-L with target +0.45 D presented the best results for the no-history subgroup. In order to make the clinical process easier to implement in our settings, we have chosen to set Haigis-L as our protocol for patients with previous myopic ablation. The same principle was used for the ASCRS average target +0.20D, although other formulas (modified Masket, Haigis-L and ASCRS minimum) had

compatible results, our choice was basically the nomograms with the best RPE and MedAE, that could be used for both history and no-history subgroups in order to make their adoption to our routine more straightforward.

The higher precision for the hyperopic ablation group can be explained by a more reliable measurement from the central keratometry due to lower power treatments, hyperopic regression with keratometric reshaping, and consequently less intense geometrical changes when compared with myopic cases. Previous studies focused exclusively on myopic[8,10,11] or hyperopic[35,36] treatments and did not provide a comparison between the different ablation profiles. A recent study by Fram et al. included both myopic and hyperopic previous ablations for evaluating intraoperative aberrometry and OCT-Based IOL formulas.[9] However, the study did not evaluate the groups separately, although we observed that the unlike myopic and hyperopic ablation geometries lead to remarkable differences concerning IOL power calculations.

It has been shown that IOL constant optimization improves the refractive outcomes after cataract surgery.[37] Although the triple optimization of the Haigis formula can provide more accurate results with less refractive variability, for the purpose of the study we adopted the conversion from our optimized A-constant into the different constants: surgeon factor (SF), pseudophakic anterior chamber depth (pACD) and the single a0 optimization constant for the Haigis-L formula. The rationale for this approach was to compare the results from each formula with the same optimized constant based on a larger number of cases from our service

(1,434 eyes with SRK/T vs. 300 eyes with triple Haigis constant optimization), thus not introducing a variable of confusion for biometry analysis.

In conclusion, our results show that presbyopic RLE is a safe and effective procedure in selected cases with previous corneal laser vision correction. The screening for those patients should include analysis of the corneal optical quality and a comprehensive counseling on expected individual benefits and possible limitations. Presbyopic RLE patients should also be informed about the possibility of refractive enhancement with corneal laser surgery or supplementary IOL for optimal postoperative performance. The ASCRS on line calculator has shown to be a valuable tool for IOL power calculation. The formulas from the calculator presented different performances when applied to myopic or hyperopic previous ablations. The proposed nomograms are not interchangeable and should be applied only by surgeons using the same platform as evaluated in the study.

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What was known

Presbyopic RLE with trifocal IOL implantation is a safe and effective procedure for the treatment of presbyopia, however there is a lack of studies evaluating this procedure after LVC.

Some surgeons consider trifocal IOLs as a relative contraindication for implanting in cataract patients previously operated with LVC.

IOL power calculations after LVC are more challenging and the results are not so accurate as in non-operated corneas.

What this paper adds

Presbyopic RLE with trifocal IOL is a safe and effective procedure in selected cases with previous LVC. The candidate selection should include analysis of the corneal optical quality.

The ASCRS on line calculator is a valuable tool for IOL power calculations in eyes that have undergone LVC. The use of optimized constants and nomograms can improve the accuracy of presbyopic RLE in this specific group of patients.

Figure Legends

Figure1: Bar graph composite of postoperative refractive spherical equivalent accuracy. Figure 1A) Entire group (N = 241 eyes). Figure 1B) Myopic ablation group (N = 155 eyes). Figure 1C) Hyperopic ablation group (N = 86 eyes).

Figure 2: Precision composite graphs for the entire group (N = 241 eyes). Figure 2A: Scattergram of the attempted vs. achieved manifest refraction spherical equivalent. Figure 2B) Postoperative astigmatism. Figure 2C) Postoperative defocus equivalent.

Figure 3: Efficacy bar graphs with the cumulative Snellen visual acuity for the preoperative CDVA vs. postoperative UDVA for the entire group (N = 241 eyes).

Figure 4: Scattergram of the postoperative UDVA vs. postoperative manifest refraction spherical equivalent. Figure 4A: Entire group (N = 241 eyes). Figure 4B) Myopic ablation group (N = 155 eyes). Figure 4C) Hyperopic ablation group (N = 86 eyes).

Figure 5: Bar graph of the presbyopic RLE performance of monocular UDVA and UNVA for the entire group (N = 241 eyes).

Figure 6: Refractive prediction error (RPE) box-plot graphs for the myopic ablation group (N = 155 eyes). Figure 6A) Previous history data subgroup (N = 83 eyes). Figure 6B) No-history data subgroup (N = 155 eyes).

Figure 7: Stacked histogram comparing the percentage of eyes within certain range of absolute prediction error for the myopic ablation group (N = 155 eyes). Figure 7A) Previous history data subgroup (N = 83 eyes). Figure 7B) No-history

data subgroup (N = 155 eyes).

Figure 8: Refractive prediction error (RPE) box-plot graphs for the hyperopic ablation group (N = 86 eyes). Figure 8A) Previous history data subgroup (N = 38 eyes). Figure 8B) No-history data subgroup (N = 86 eyes).

Figure 9: Stacked histogram comparing the percentage of eyes within certain range of absolute prediction error for the hyperopic ablation group (N = 86 eyes). Figure 9A) Previous history data subgroup (N = 38 eyes). Figure 9B) No-history data subgroup (N = 86 eyes).

Table 1. Preoperative RLE clinical data for myopic and hyperopic groups:

Parameter	**Myopic Ablation Group Mean ± SD (Range) (N = 155 eyes)**	**Hyperopic Ablation Group Mean ± SD (Range) (N = 86 eyes)**
Age (years)*	55.34 ± 4.84 (47 to 69)	57.50 ± 7.22 (46 to 72)
MRSE (D)*	-0.06 ± 0.78 (-2.75 to +2.00)	1.05 ± 0.90 (-1.38 to +3.50)
CDVA (Snellen)*	1.09 ± 0.10 (0.80 to 1.30)	1.05 ± 0.12 (0.80 to 1.30)
UNVA (Point-Type)*	12.42 ± 6.23 (5 to 30)	18.47 ± 8.98 (6 to 48)
Mean Keratometry (D)*	41.09 ± 1.82 (36.87 to 45.49)	44.08 ± 1.81 (40.13 to 49.02)
Corneal Astigmatism (D)*	0.81 ± 0.38 (0.15 to 1.95)	1.00 ± 0.51 (0.00 to 2.76)
AL (mm)*	24.88 ± 0.92 (22.57 to 27.65)	22.93 ± 0.96 (20.29 to 24.99)
ACD (mm)*	3.40 ± 0.30 (2.49 to 4.10)	2.99 ± 0.34 (2.41 to 3.74)
IOL Power*	21.29 ± 1.62 (18.00 to 26.00)	22.38 ± 2.36 (15.50 to 27.50)

Abbreviations: MRSE, manifest refraction spherical equivalent; D, diopters; AL, axial length; ACD, anterior chamber depth; IOL, intraocular lens.

* Statistical differences between Myopic and Hyperopic Ablation Groups (Mann-Whitney U Test, $P < 0.02$).

Table 2. Postoperative RLE clinical data for myopic and hyperopic groups:

Parameter	Myopic Ablation Group Mean ± SD (Range) (N = 155 eyes)	Hyperopic Ablation Group Mean ± SD (Range) (N = 86 eyes)
UDVA (Snellen)	0.88 ± 0.20 (0.30 to 1.20)	0.85 ± 0.19 (0.30 to 1.20)
UNVA (Point-Type)*	5.11 ± 0.46 (5.00 to 8.00)	5.25 ± 0.75 (5.00 to 10.00)
CDVA (Snellen)*	1.06 ± 0.10 (0.75 to 1.20)	1.03 ± 0.10 (0.80 to 1.20)
Sphere (D)*	-0.08 ± 0.38 (-1.25 to +1.00)	0.22 ± 0.42 (-1.00 to 1.25)
Cylinder (D)*	-0.33 ± 0.29 (0.00 to -1.25)	-0.49 ± 0.40 (0.00 to -2.25)
MRSE (D)*	-0.25 ± 0.38 (-1.25 to 0.75)	-0.02 ± 0.42 (-1.38 to 0.88)
IOL Error (D)*	0.35 ± 0.55 (-1.07 to 1.79)	0.03 ± 0.60 (-1.26 to 1.97)
Safety Index	0.97 ± 0.08 (0.82 to 1.26)	0.98 ± 0.09 (0.80 to 1.29)
Efficacy Index	0.80 ± 0.18 (0.30 to 1.10)	0.82 ± 0.17 (0.35 to 1.22)

Abbreviations: UDVA, uncorrected distance visual acuity; UNVA, uncorrected near visual acuity; CDVA, corrected distance visual acuity; MRSE, manifest refraction spherical equivalent; SD, standard deviation; D, Diopters.

* Statistical Differences Between Myopic and Hyperopic Ablation Groups (Mann-Whitney U Test, $P < 0.02$).

Table 3. Biometry analysis for the myopic ablation group. RPE and MedAE for the different formulas from the ASCRS on-line calculator.

	Myopic Ablation Group	
Previous History Data (N = 83)	**Refractive Prediction Error (D) Mean ± SD (Range)**	**Median Absolute Error (D) Median ± SD (Range)**
Masket*	-0.05 ± 0.41 (-0.90 to 0.77)	0.34 ± 0.23 (0.01 to 0.90)
Modified Masket	-0.22 ± 0.47 (-1.11 to 0.89)	0.44 ± 0.27 (0.01 to 1.11)
Barrett True-K	-0.14 ± 0.39 (-0.90 to 0.67)	0.35 ± 0.23 (0.01 to 0.90)
Barrett no-History	-0.42 ± 0.43 (-1.53 to 0.52)	0.48 ± 0.35 (0.02 to 1.53)
Shammas	-0.67 ± 0.49 (-1.97 to 0.35)	0.69 ± 0.46 (0.00 to 1.97)
Haigis-L	-0.45 ± 0.40 (-1.44 to 0.54)	0.50 ± 0.33 (0.00 to 1.44)
ASCRS Average	-0.32 ± 0.37 (-1.06 to 0.51)	0.40 ± 0.29 (0.02 to 1.06)
ASCRS Minimum*	-0.01 ± 0.41 (-0.88 to 0.89)	0.33 ± 0.23 (0.00 to 0.89)
ASCRS Maximum	-0.75 ± 0.43 (-1.97 to 0.20)	0.76 ± 0.41 (0.02 to 1.97)
Barrett True-K (+0.15)*	0.01 ± 0.39 (-0.74 to 0.82)	0.33 ± 0.21 (0.00 to 0.82)
Haigis-L (+0.45)*	-0.01 ± 0.40 (-0.99 to 0.99)	0.32 ± 0.23 (0.01 to 0.99)
No-History Data (N = 155)		
Barrett no-History	-0.36 ± 0.40 (-1.53 to 0.52)	0.43 ± 0.33 (0.01 to 1.53)
Shammas	-0.63 ± 0.47 (-1.97 to 0.35)	0.65 ± 0.44 (0.00 to 1.97)
Haigis-L	-0.41 ± 0.39 (-1.44 to 0.54)	0.46 ± 0.32 (0.00 to 1.44)
ASCRS Average	-0.46 ± 0.40 (-1.64 to 0.41)	0.50 ± 0.35 (0.00 to 1.64)
ASCRS Minimum	-0.31 ± 0.39 (-1.44 to 0.54)	0.39 ± 0.31 (0.00 to 1.44)
ASCRS Maximum	-0.68 ± 0.44 (-1.97 to 0.35)	0.69 ± 0.42 (0.00 to 1.97)
Haigis-L (+0.45)*	0.03 ± 0.39 (-0.99 to 0.99)	0.32 ± 0.22 (0.01 to 0.99)

Abbreviations: SD, standard deviation; D, Diopters.

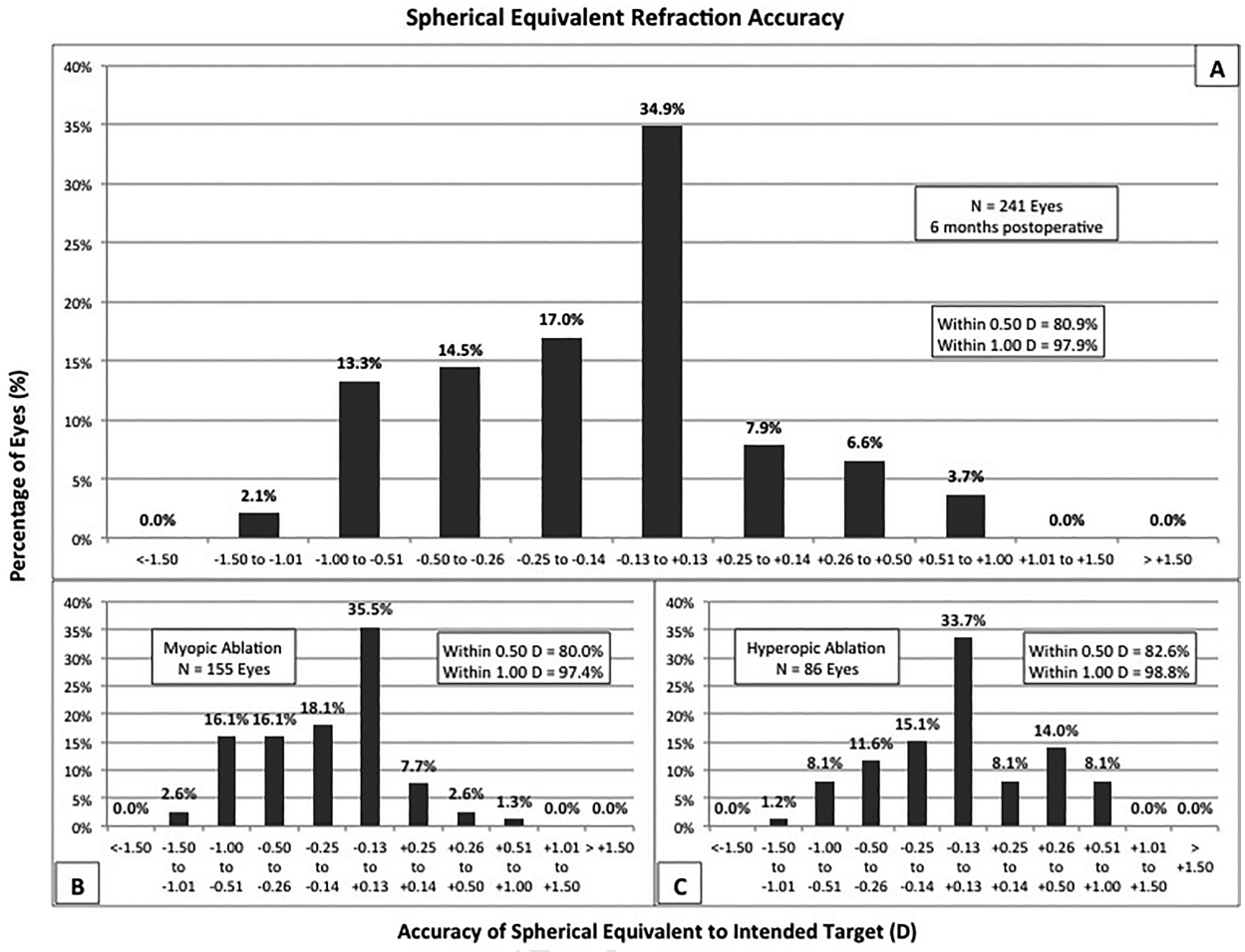
* Mean refractive prediction error (RPE) not statistically different from zero (One sample t-test, with P > 0.2).

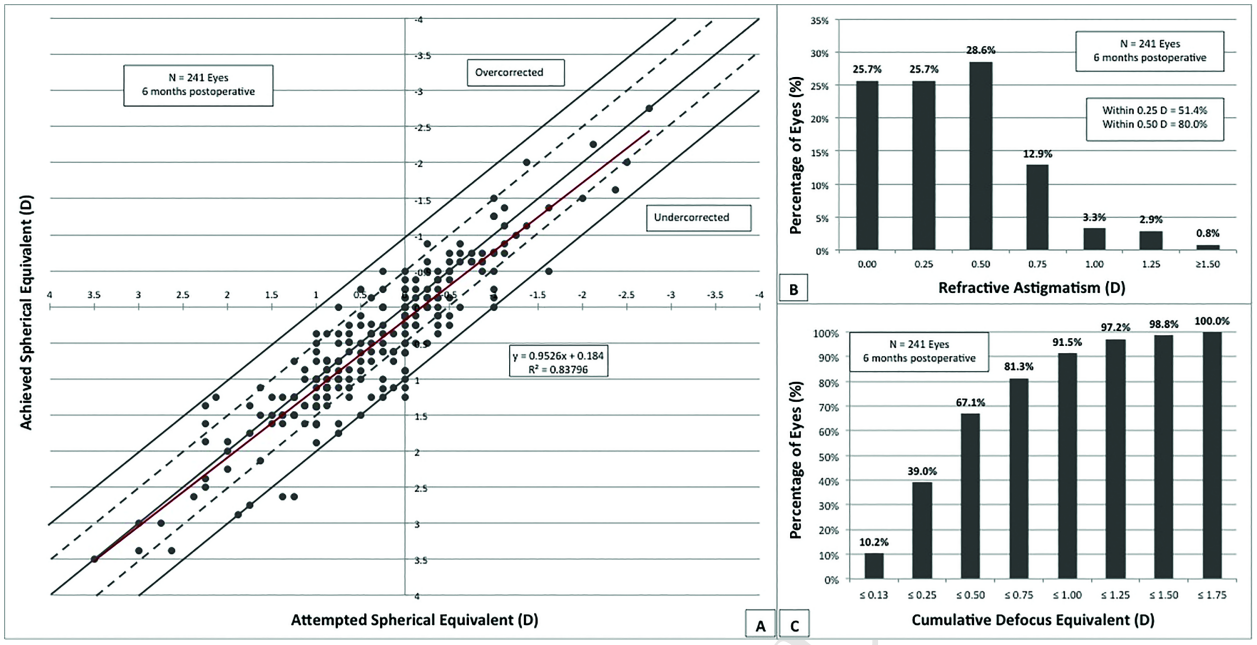
Table 4. Biometry analysis for the hyperopic ablation group. RPE and MedAE for the different formulas from the ASCRS on-line calculator.

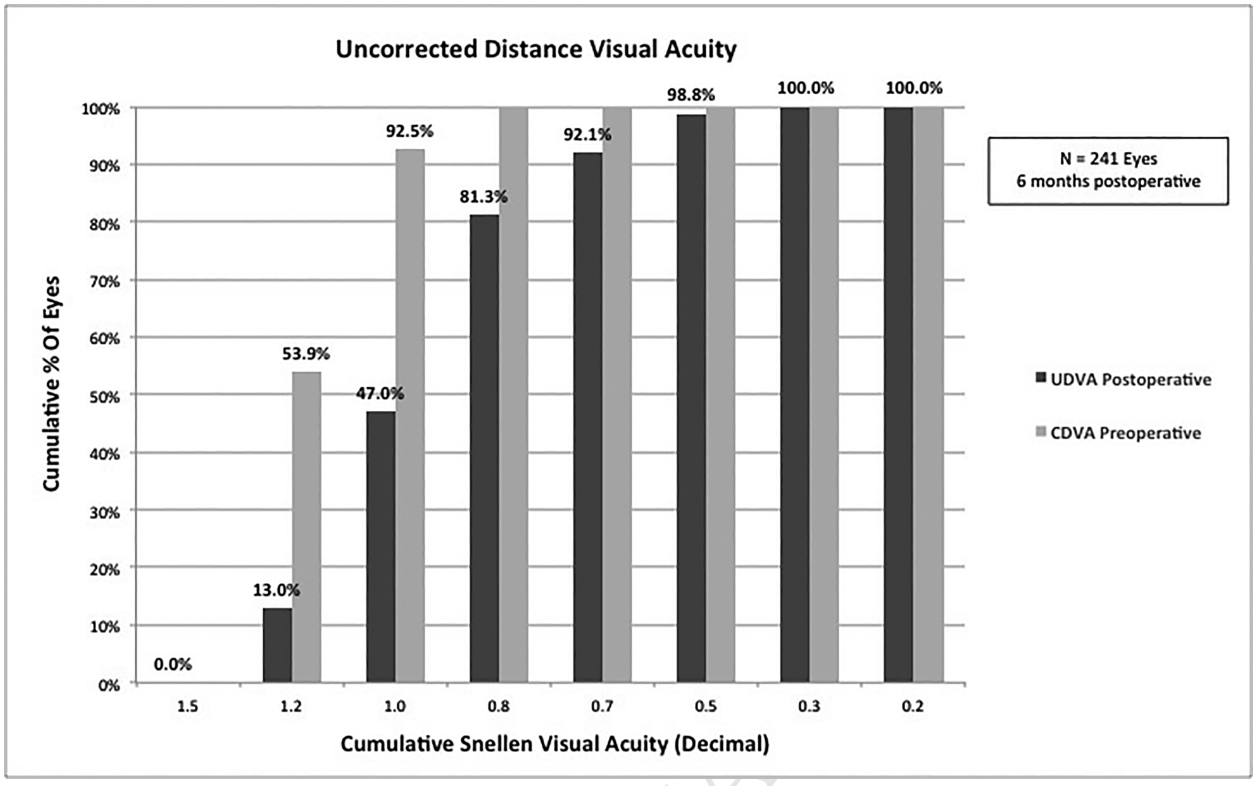
	Hyperopic Ablation Group	
Previous History Data (N = 38)	**Refractive Prediction Error (D) Mean ± SD (Range)**	**Median Absolute Error (D) Median ± SD (Range)**
Masket	-0.16 ± 0.44 (-0.97 to 0.71)	0.39 ± 0.26 (0.01 to 0.97)
Modified Masket*	0.00 ± 0.48 (-0.84 to 0.97)	0.39 ± 0.28 (0.00 to 0.97)
Barrett True-K	-0.20 ± 0.44 (-0.95 to 0.67)	0.41 ± 0.26 (0.01 to 0.95)
Barrett no-History	-0.16 ± 0.42 (-1.03 to 0.68)	0.37 ± 0.24 (0.01 to 1.03)
Shammas	-0.48 ± 0.43 (-1.27 to 0.41)	0.53 ± 0.37 (0.06 to 1.27)
Haigis-L*	-0.13 ± 0.46 (-1.33 to 0.49)	0.37 ± 0.29 (0.01 to 1.33)
ASCRS Average	-0.19 ± 0.41 (-0.95 to 0.64)	0.38 ± 0.24 (0.02 to 0.95)
ASCRS Minimum*	0.11 ± 0.43 (-0.75 to 0.97)	0.35 ± 0.25 (0.01 to 0.97)
ASCRS Maximum	-0.51 ± 0.44 (-1.33 to 0.41)	0.55 ± 0.38 (0.02 to 1.33)
ASCRS Average (+0.20)*	0.00 ± 0.41 (-0.75 to 0.84)	0.34 ± 0.22 (0.01 to 0.84)
No-History Data (N = 86)		
Barrett no-History	-0.07 ± 0.36 (-1.03 to 0.81)	0.29 ± 0.23 (0.00 to 1.03)
Shammas	-0.39 ± 0.40 (-1.54 to 0.41)	0.44 ± 0.35 (0.01 to 1.54)
Haigis-L*	-0.05 ± 0.39 (-1.33 to 0.67)	0.30 ± 0.25 (0.01 to 1.33)
ASCRS Average	-0.17 ± 0.36 (-1.07 to 0.52)	0.31 ± 0.25 (0.00 to 1.07)
ASCRS Minimum*	0.02 ± 0.36 (-0.86 to 0.81)	0.29 ± 0.21 (0.01 to 0.86)
ASCRS Maximum	-0.41 ± 0.40 (-1.54 to 0.41)	0.45 ± 0.36 (0.01 to 1.54)
ASCRS Average (+0.20)*	0.02 ± 0.36 (-0.87 to 0.72)	0.29 ± 0.21 (0.00 to 0.87)

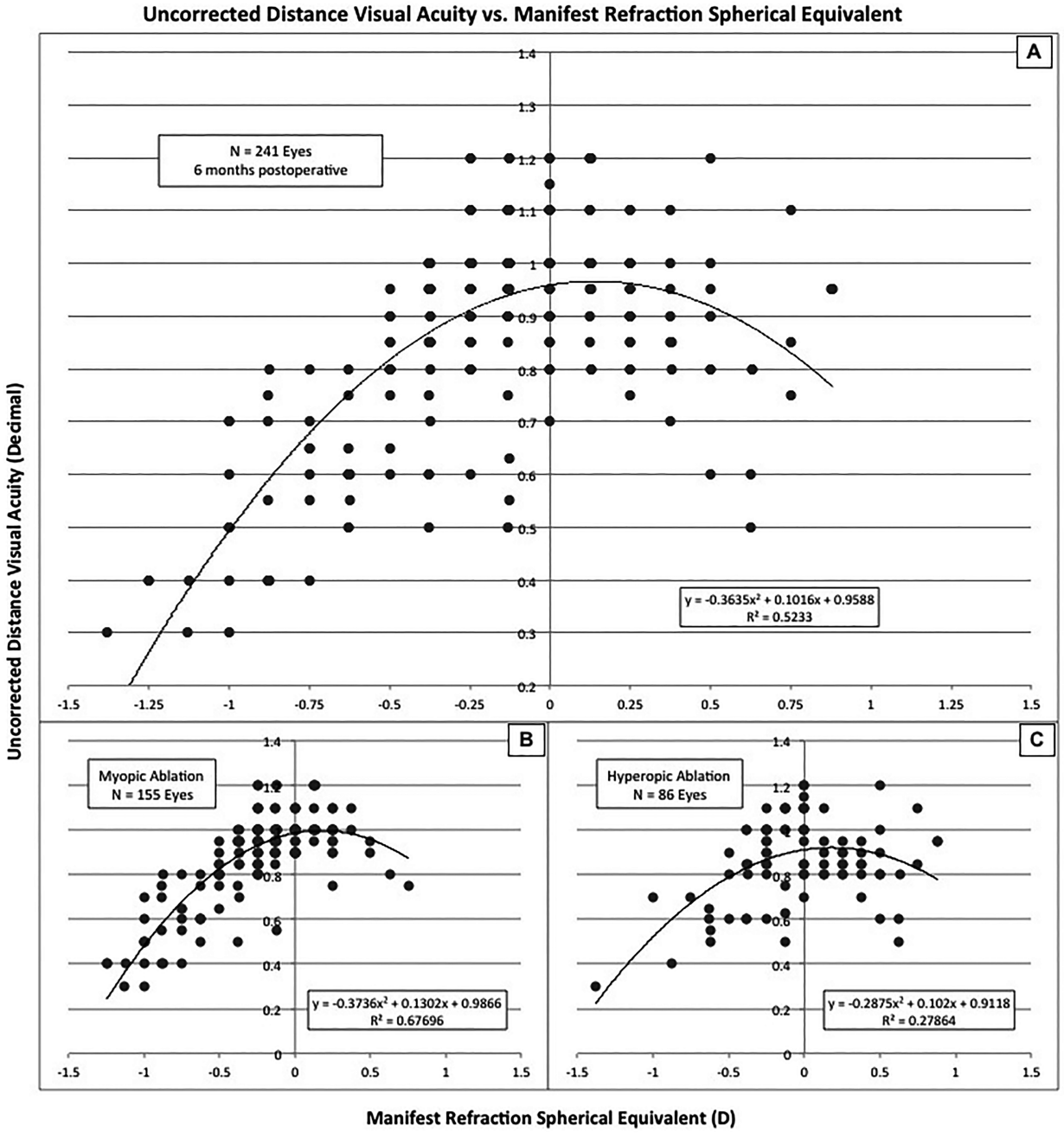
Abbreviations: SD, standard deviation; D, Diopters.

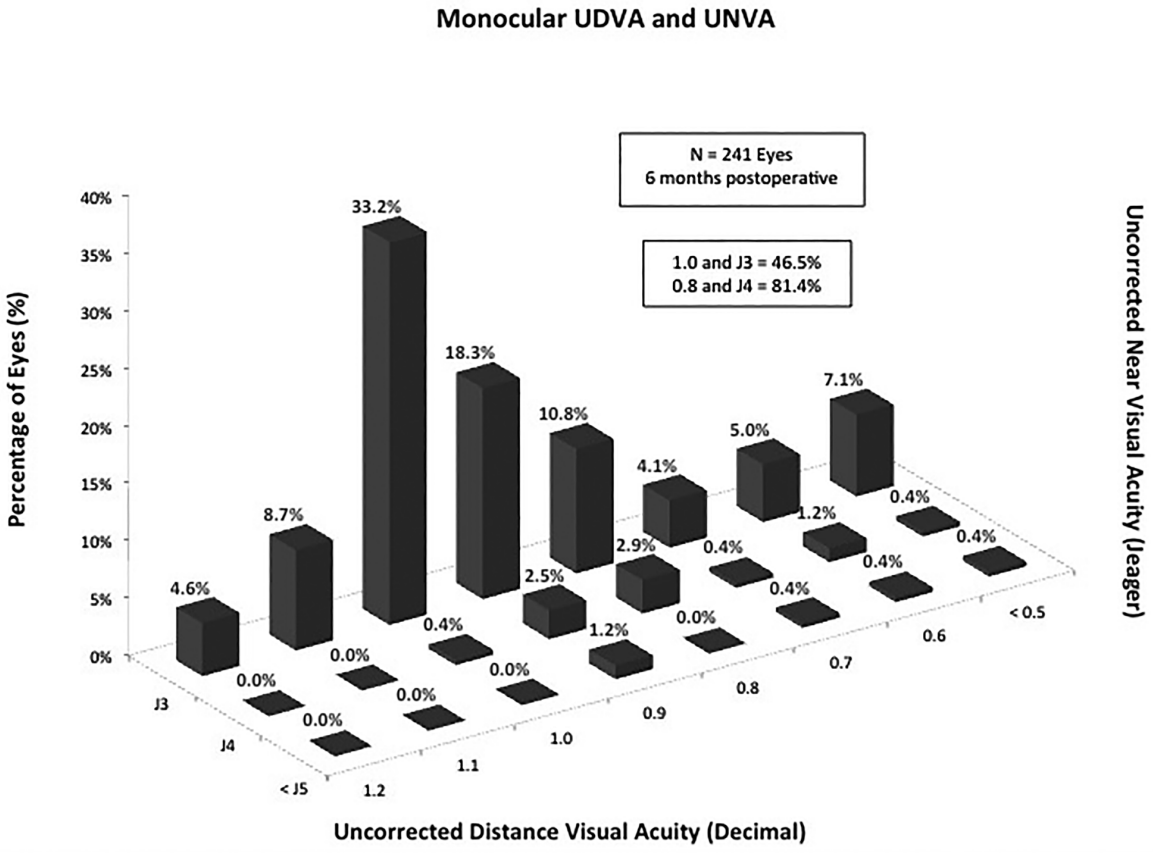
* Mean refractive prediction error (RPE) not statistically different from zero (One sample t-test, with P > 0.05).

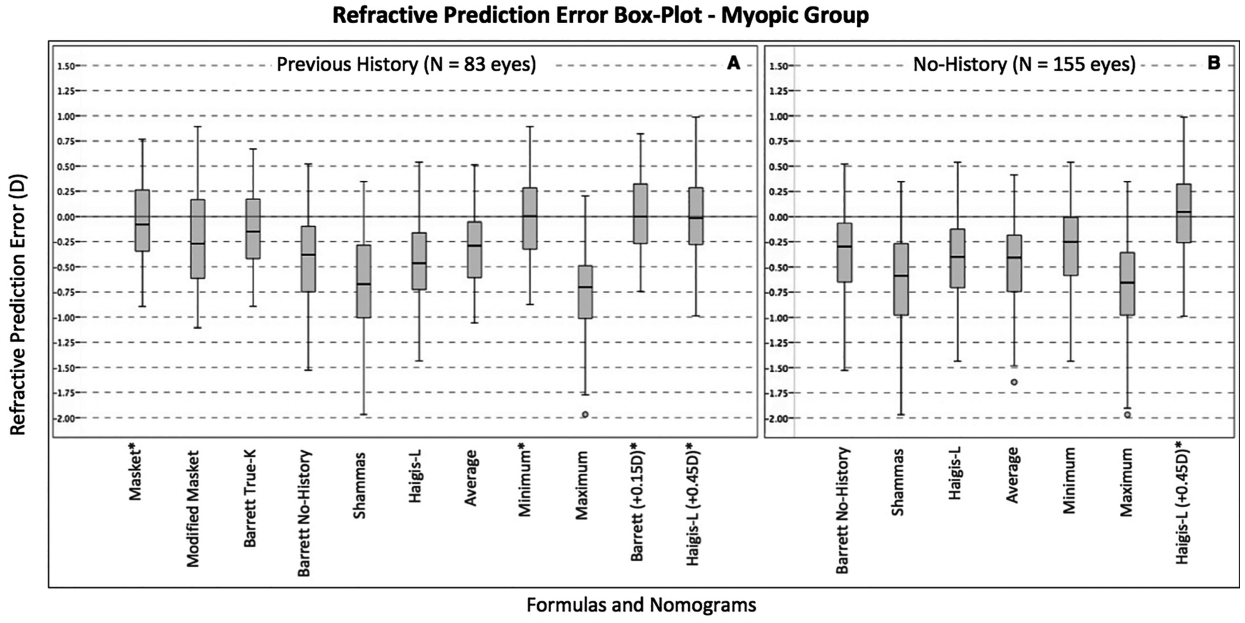


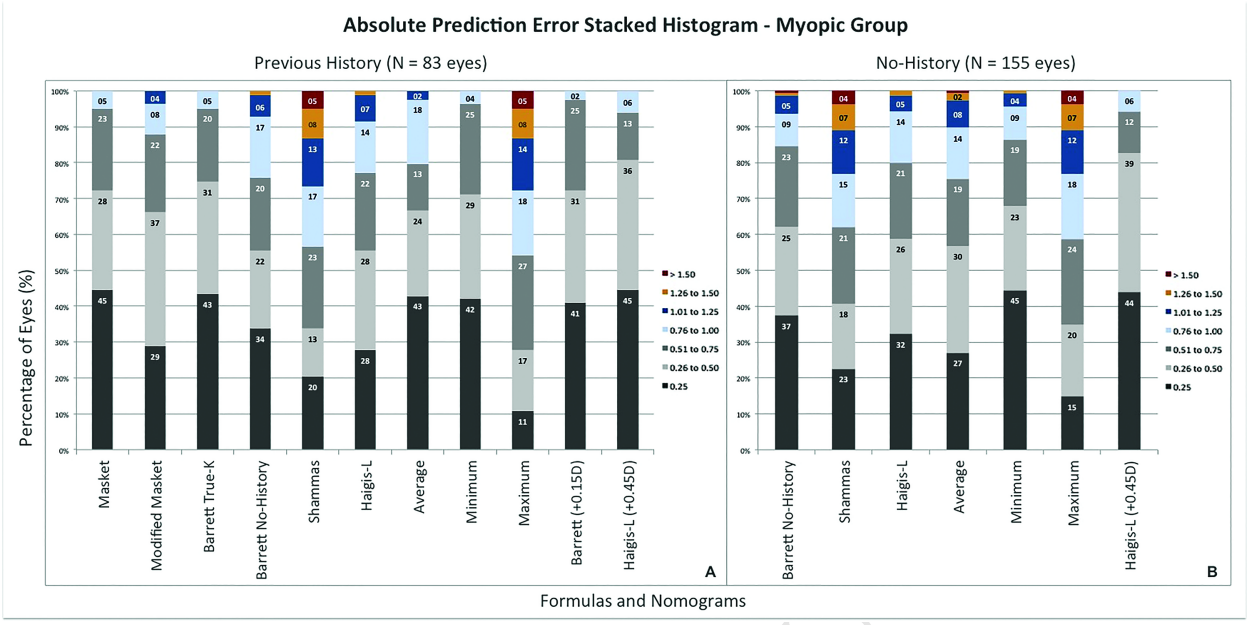


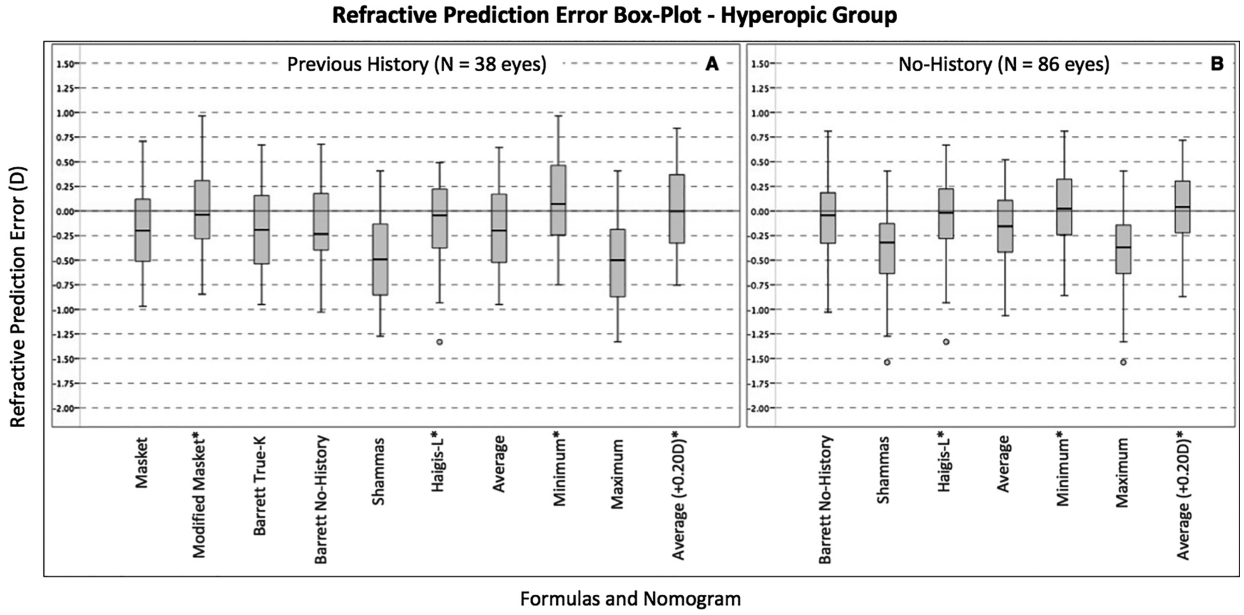


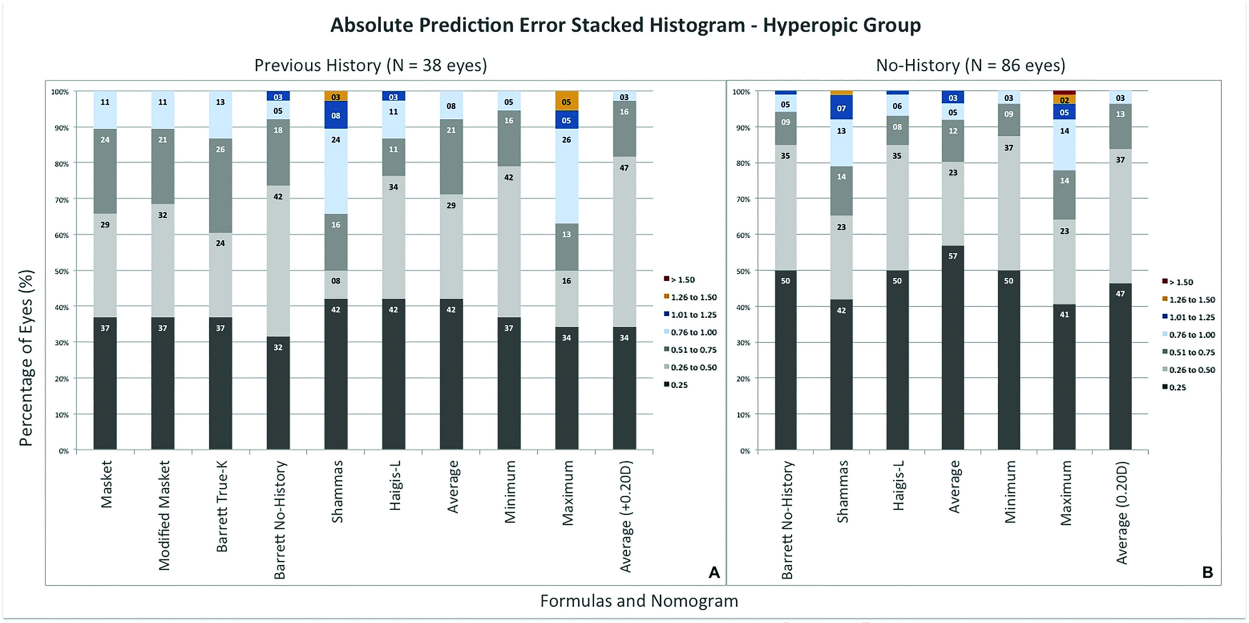












Synopsis

Presbyopic RLE provided useful distance and near vision in patients submitted to prior LVC. The improvements in biometry formulas yielded more precise IOL power calculations for this specific patient group.