Presbyopia Management with Diffractive Phakic Posterior Chamber IOL.

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Research article

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Abstract

Background : To evaluate safety and refractive efficiency after posterior chamber diffractive implantable phakic contact lens (IPCL) surgery was performed.

Methods: A prospective n on-randomized observational case-series study was performed in 54 myopic eyes from 27 patients who underwent diffractive IPCL surgery. The corneal endothelial cell density (ECD), central corneal thickness (CCT), intra-ocular pressure (IOP), vault, uncorrected distance (UDVA), spherical equivalent (SE) and defocus curve, were evaluated 12 months after implantation of the diffractive IPCL. By slit-lap, the presence of cataract was evaluated during post-operative follow-up.

Results: Mean age was 47 ±2.62 years-old. The mean SE decreased from -5.95 ±2.56 D pre-operatively to -0.25 ± 0.25 D at 12 months after surgery . The UDVA achieved was 20/20 in 24.1%, 20/25 in 74.1%, remaining eyes obtained 20/32, and no eye lost lines of vision. The binocular defocus curve was 0.06 ±0.05 logMAR for -3.0 D of defocus, 0.11 ±0.04 logMAR for -1.5 D of defocus and 0.08 ±0.03 logMAR for 0 D of defocus. The mean ECD decrease 1.43% and the mean CCT increase 0.06% at 12 months post-operative, without a statistically significant difference (p : 0.28 and p : 0.93 respectively). No difference (p : 0.86) in vault was observed at 6 months vs. 12 months, as well as between IOP measurements (p : 0.22). Non intra or post-operative complications occurred, and specifically cataract did not develop.

Conclusions: Diffractive IPCL was implanted safely. Corneal endothelial CD, CCT, vault and IOP remained stable 12 months after surgery. Visual acuity for distance, intermediate and near sight could be improved without spectacles in myopic population with presbyopia.

Background

Presbyopia is becoming a rising problem among adults in their forties. Therefore, presbyopia correction has become an evolving and rapidly-progressing field in refractive surgery. Corneal procedures have limitations, related to the corneal structure and to the total amount of the ametropia [1-3]. Pseudophakic procedures with multifocal intra-ocular lens (IOL) could be selected [4]. Nevertheless, the clear lens extraction is controversial in myopic eyes, because of its association with an increased risk of retinal complications [5-7].

Phakic intra-ocular lens (pIOL) can correct high myopia and hyperopia, with the advantages of reversibility, stability of correction, and preservation of accommodation [8-14]. Also, there is the expectation of a superior quality of vision obtained with pIOL implantation with respect to keratorefractive surgery for the correction of high ametropias [15-18]. But pIOL implantation in the anterior chamber was associated with complications, which are widely described [19-21]. The posterior chamber implantable phakic contact lens called IPCL (Care Group, India) has proved its safety and efficacy for correction of myopia and myopic astigmatism [22-24] and the new model, “Diffractive IPCL V 2.0”, arises as an option for presbyopia management. Based on these observations, the purpose of this

work is to evaluate the safety and refractive efficiency of Diffractive IPCL V 2.0 in patients with myopia and/or myopic astigmatism and presbyopia.

Methods

Study Design

A prospective non-randomized case-series was designed to evaluate the safety and efficiency of diffractive IPCL surgeries, performed between February 2018 and August 2018, with a 12 months follow-up. This study followed the tenets of the “Declaration of Helsinki”, and was developed with the approval of the “Clínica de Ojos Dr. Nano´s” Institutional Review Board/Ethics Committee. A written consent was obtained after patients were informed about the characteristics and risks of the surgical procedure.

Inclusion/Exclusion Criteria.

Inclusion Criteria. Patients between 40 to 55 years of age, with myopia, with or without astigmatism, and with stable refraction for a minimum period of one year, were included.

Exclusion Criteria. Patients with cataracts and/or less than a corneal endothelial cell density (ECD) of 2000 cell/mm2, anterior chamber depth (ACD) less than 2.8 mm, and a history of glaucoma and/or glaucoma or retinal surgery. Also, cases with corneal disease (dystrophies, degeneration or injuries that could affect corneal transparency) were excluded. In the present series, hyperopia patients were also excluded.

Pre-operative Studies and Parameters to be Evaluated.

At baseline, all patients underwent a complete ophthalmic examination and the population information regarding age and gender was registered. The Pentacam imaging system (Oculus, Wetzlar, Germany) was used for pre-operative evaluation of the cornea (to detect regular vs. irregular astigmatism), and to measure the ACD. The IPCL lens size was determined based on the horizontal white-to-white distance (using the IOL-Master equipment).

The target in all cases was emmetropia. Manifested spherical equivalent (SE), and cylinder refraction were evaluated before and 12 months after surgery. The post-operative uncorrected distance visual acuity (UDVA) was compared with pre-operative corrected distance visual acuity (CDVA) in Snellen, and also, the logarithm of the minimal angle of resolution (logMAR) was also calculated to perform a defocus curve (additions from -4.0 to +2.0 D), 12 months after surgery.

Selection of the Addition.

The amount of near addition was calculated based on the age of the patients and their grade of myopia, with a personal nomogram (Table 1). A subjective evaluation was performed pre-operatively, with both eyes with the best correct visual acuity refraction, and two options could be possible.

Option A: In the dominant eye, put the highest addition that could be tolerated, and in the non-dominant eye always put more addition, between 0.50 to 1.0 D, as is shown in Table 1. This “addition blend” is designed with the purpose of avoiding spectacles for near vision, for the following years during the presbyopia period.

Option B: If the difference between the dominant and non-dominant eye was not pre-operatively tolerated, the addition chosen for both eyes is the same. Always choosing the highest amount of addition which could be subjectively tolerated, according age and amount of myopia.

The corneal ECD and CCT were registered pre-operative and 12 months post-operation using an electronic specular microscope (TOMEY EM4000). Intra-ocular pressure (IOP) was evaluated at baseline, day1, day 7, month 1 and month 12 after surgery, using a Goldmann tonometer. Previous iridotomy was not performed. The IPCL vault was evaluated at 6 and 12 months post-surgery with the ultra-bio microscopy AvisoTM; Quantel Medical.

If the astigmatism was ≥ 1.0 D, a toric diffractive IPCL V2.0 model was selected. The presence of intraoperative and/or post-operative complications was also evaluated, specifically to detect signs of cataract development (by slit lamp graded always by the same observer) according to the LOCS III classification.

Diffractive IPCL V2.0 Characteristics (obtained from the official brochure at http://caregroupiol.com/products/phakic-lenses/ipcl/)

The IPCL is a foldable, hydrophilic acrylic, single-piece, injectable, posterior chamber pIOL. It is designed to be placed in the posterior chamber of the eye behind the iris, with the haptic zone resting on the ciliary sulcus, and can be directly delivered through a 2.8 mm corneal incision. Its design includes 6 haptics to increase stability, 2 holes in the peripheral portion from the upper zone to decrease glare and halos, and 4 holes outside the optical zone. The V 2.0 has a central conic hole (380 μm) to facilitate its alignment and aqueous humor circulation. The thickness of the IPCL is 80 μm. It is designed to correct myopia in a dioptric power range of −1.00 to −33.00 diopters (D) and hyperopia from +1.0 to +15.0 D. It has an aspheric optic zone, with zero aberration. The diameter of the optic is from 5.75 to 6.20 mm, and the

overall diameter ranges from 11.0 mm to 14.00 mm (with 0.25 mm steps). Moreover, the optical diameter could be customized to 6.50, 6.80, 7.20 or 7.50 mm, according to the patient´s pupil size. This lens has a diffractive-refractive technology (trifocal optical design) with concentric rings to support near addition (ADD) from +1.5 to +4.0 (with 0.5 D steps), and intermediate Add of +2.10. The diffractive zone has an angle step to decrease light-scattering to 8% or less. The angle steps progression goes from 6° at the center to 65° at the lens´ periphery. And the angles from this step decrease from the center to the periphery, beginning from 1.8 µm at the center, to 90Nm at the periphery.

Surgical Technique Description: Steps and Tips.

All surgeries were performed by the same surgeon, and the use of viscoelastic substances were completely avoided, as was previously published [24]. Briefly, under corneal topical anesthesia, a corneal incision (located at 45 degrees) was made with the 20g V-lance, and the anterior chamber was maintained with an infusion/irrigation cannula (a 23g bi-manual I/A cannula). A second corneal 2.8-mm incision was performed (located at 130 degrees) following the first one. Finally, the phakic lens was inserted while the anterior chamber was irrigated with the balanced salt solution (BSS) fluid circulation. The lens was then unfolded carefully with the aid of an I/A cannula, and the haptics were correctly placed behind the iris, into the sulcus, from 3 o'clock to 9 o'clock. The post-operative topical treatment was the same for all cases, starting three days before the surgery with gatifloxacin 0.5% and bromfenac 0.09%, four times daily. Patients continued the treatment after surgery, adding one more drop of difluprednate 0.05%, four times daily. All drops were maintained for two weeks.

Statistical Evaluation

Descriptive statistical results were presented as mean, standard deviation (SD) and range. Normality of data was checked using the Kolmogorov-Smirnov test. To compare the differences between the mean endothelial CD, CCT (baseline vs. 12 months post-operative) and vault (6 vs. 12 months after surgery), a Wilcoxon signed-rank test was performed. To compare the mean IOP, ANOVA (single factor) was used. A statistically significant result was considered with a *p*-value less than 0.05. The coefficient of determination (R2) was calculated as part of the linear regression analysis to evaluate the correlation between the attempted and achieved spherical equivalent (SE) change. Statistical analysis was performed with the XLMiner Analysis ToolPak software (Frontline Systems Inc.). Data is available at "Clínica de Ojos Dr. Nano".

Results

Study Population.

A total of 27 patients (54 eyes) were operated (only 13 eyes with toric diffractive IPCL V2.0 model). The mean age was 47 ±2.62 years old (43-53). The relation between female/male was: 15/12. All the surgeries were performed without intraoperative complications, and 12 months after surgery none of the eyes had developed cataracts.

Corneal Safety, IOP and Vault.

The mean ECD decreased 1.43% (38.74 cell/mm^2), and the mean CCT increased 0.06% (0.35 µm) 12 months post-operative, without any statistically significant differences (complete data is shown in Table 2). The IOP values remained similar at different time-points, with no statistical significant difference (Table 2). A slight increase was observed 1 day post-operation, with values always in the normal IOP range. The mean vault decreased 0.55% (2.89 µm) 6 to 12 months after surgery, without statistically significant differences (*p*: 0.86), as could be seen in Table 2.

Objective Refraction, Visual Acuity and Defocus Curve.

No eye lost lines of vision (59.6% without change) and improvements were observed in 40.6% (gain 1 Snellen line of vision) as shown in Figure 1 and 2. The mean pre-operative SE was -5.96 ±2.10 D (-3.12 to -12.50), which was decreased 12 months after surgery to -0.25 ±0.25 D (+0.25 to -0.75). Figure 3 shows the coefficient of correlation (R^2: 0.93), which denotes the strength of the correlation between the attempted and achieved SE change. The spherical efficacy of refractive accuracy is illustrated in Figure 4. Pre-operative manifest cylinder was -0.77 ±0.59 (0 to -2.5). The refractive astigmatism obtained and its pre-operative comparison is shown in Figure 5. Good outcomes were obtained for different defocus additions, as seen in Figure 6. The blend addition (Option A) was chosen for 21 patients and for the remaining patients, addition was the same for both eyes (Option B).

Discussion

The author of this study has experience implanting IPCL lenses to correct high myopia patients since 2015. The present study reports the first results with the diffractive IPCL V 2.0. Its safety and efficiency was evaluated by different items, 12 months after surgery and is discussed below.

Presbyopia is an unsolved problem with different surgical and non-surgical therapeutic management options. Refractive procedures with phakic and/or pseudophakic IOLs are aiming to improve the quality of vision and life for people in their forties. Laser refractive procedures for presbyopia patients with thin corneas and high myopia are not indicated. Posterior chamber phakic IOLs surgeries are growing and some works postulate advantages over corneal refractive procedures, to avoid complications such as post-operative ectasia [2, 25, 26], refractive regressions, high index aberration [3, 17, 18, 27], corneal

wound-healing problems [28, 29] and ocular surface disease (dry eye, neuropathic pain) [30, 31]. Presbyopia management for myopic population is not easy. Naturally, most people with myopia have good near-sight without the aid of glasses, and after their forties, they need to change their usual visual behavior (taking-off glasses, leaving the use of contact lenses, or starting the use of multifocal glasses). And when people with myopia have been operated to avoid glasses or contact lenses, after showing good results for distance and near sigh for some time, they usually need glasses again for presbyopia.

The pIOL is a reversible refractive procedure that preserves the accommodative function with minimal induction of higher-order aberrations compared to corneal photoablative procedures [18]. Posterior chamber pIOLs have improved considerably, however, to date, there are no extensive studies of the IPCL model. In two studies [22, 23], authors have evaluated the previous IPCL model V1.0 (which needed a previous iridotomy). And with few differences, both works have reported best refractive outcomes without complications for correction of myopia and myopic astigmatism. Also, a study with IPCL V2.0 (the new model with a central hole) was published, obtaining safe and good results [24]. The present study is the first one reporting results with diffractive IPCL V2.0, emphasizing the safety concerns and visual performance.

Safety Concerns: Intra-ocular Pressure, Cornea (endothelial cell density and central corneal thickness), and Vault.

As could be seen in the results of the present series, the post-operative IOP remained stable over time, similar as a previously-published study with the same IPCL platform (with a central hole) and with the same surgical technique, completely performed avoiding the use of viscoelastic substances [24]. Perhaps, this surgical method has an “extra value” to avoid the potential IOP peak after surgery associated to a deficient viscoelastic extraction [21, 32]. Moreover, the safety of the procedure to implant IPCL without viscoelastic substances, was evaluated through the corneal ECD and CCT measurements. Both remain stable, without statistical significant differences 12 months after surgery. And a similar result was obtained in a previous study, but only with a 6 month follow-up for the IPCL V 2.0 model [24]. However, with the previous IPCL platform (V 1.0) evaluated by other authors, using a surgical technique with the aid of viscoelastic substances, similar safe values were obtained [22, 23]. For this reason, and to confirm this aspect, a prospective cohort multicentric study comparing the present technique with surgeries performed with viscoelastic substances will be necessary.

The central vault is the distance between the posterior surface of the IPCL and the anterior surfaces of the crystalline lens. It’s an important safety parameter which is also related to the refractive outcome. If the IPCL size (diameter) is not correctly selected, several problems could arise, because with lower vault

there is a greater risk of developing cataracts. A secure vault value had to be between 250 to 750 µm, otherwise, the risk for secondary cataract formation was increased, and when it was close to 1000 µm, the lens had to be explanted [21, 33, 34]. The vault observed in the present study was stable over time, without a statistical significant difference after a 6 to 12 months follow-up, emphasizing the post-operative stability and security of IPCL (as none of the cases developed cataracts).

Visual Performance.

The refractive efficacy was demonstrated by the SE decrease after surgery and the coefficient of determination, which was close to 1 (R^2: 0.93). No eye lost lines of vision, the UDVA was similar to the pre-operative CDVA, and most of the cases achieved 20/25 or better. Only 1.9% of eyes got 20/32 UDVA. Good refractive outcome was similar to what was previously reported for IPCL [22-24], which gives information about the efficiency of this lens to correct ametropias. Moreover, the obtained defocus curve gives information about how patients were capable of seeing at different distances without the aid of spectacles. The data shows very good results for distance and near sight with a slight decrease for intermediate vision 12 months after surgery. The nomogram utilized in this study was designed to give long-term spectacles independence (all the presbyopic period), giving patients the highest amount of addition that could be tolerated. The blend option was selected for most of the cases. Results were not compared between both strategies (blend vs. both with equal addition), but it is another aspect which will be interesting to compare in the future.

The diffractive IPCL model seems to be a very interesting choice for patients in their 40s to 50s, but its efficacy must be studied with a greater number of patients and with a longer follow-up. The main aspect to resolve is regarding the near-sight of operated myopic patients. It is well known that the nearsighted patients seek help for presbyopic symptoms much later than the rest. Even so, these individuals remove their glasses to perform near work. The mean age from the present series was 47 ±2.62 years old (43-53 years-old). The maximum subjective measured accommodation amplitude declined about 0.6D per year of age [36], and some works postulate that there was no relationship between refractive error and accommodative amplitude [36, 37]. Moreover, Abraham LM et al. conclude that there exist a higher amplitude of accommodation among nearsighted patients in the 35 to 44 age group, compared to emmetropes and hyperopes; and, after the age of 44, the amplitude of accommodation converges to similar values [37]. Therefore, the total amount of residual accommodation from the present series, and the total effect produced by the diffractive IPCL is not clear. Possibly, diffractive IPCL interacts with the crystalline lens to enhance patient's residual accommodation [38]. And they will not make any use of the diffractive component of the lens while they retain accommodation, but once they start becoming presbyopic, the brain will automatically select it for reading, and no spectacles will be needed.

Undoubtedly, a longer follow-up will be necessary to evaluate for how long these patients can maintain their spectacles´ independence.

In the past, authors have evaluated posterior chamber phakics lenses to manage presbyopia problems, but with a monofocal lens and monovision. Takahashi M. et al. [39] work with a population of 21 patients, aged 45.0 ±3.8 (ranging from 40 to 53 years of age), implanting the *Visian Implantable Collamer Lens* (ICL). Performing an intentional under-correction in the non-dominant eye, they have obtained acceptable results 6 months after surgery. Another similar work, with mono-vision and ICL implantation was published by Kamiya K. et al. [40] with 17 patients, aged 46.1 ±4.2 (ranging from 40 to 53 years of age). And after 6 months of follow-up, they have obtained spectacles´ independence without complications. Mono-vision procedures for presbyopia management is a good option, having studied extensively its limitations and problems [41].

Presbyopia-correcting IOLs options are growing, but their scientific and objective evaluation is not easy, as Alio JL discussed in an interesting editorial article [42]. The novelty and strength of this report is that it is the first study with the use of the diffractive ICPL, as a new option to solve a frequent problem. Another original aspect arises from the information provided in Table 1, which is a nomogram to select the appropriate “blend” addition, taking into account the pre-operative subjective refraction and the potential future addition. Nevertheless, this aspect will need a longer follow-up to evaluate for how long these patients can do without spectacles for presbyopia. And regarding the surgical technique, even though it was not this work´s objective, because the results could be influenced by that, it was described, but was not compared.

Conclusions

The present study reports that the corneal ECD and CCT were not affected 12 months after diffractive IPCL implantation, using a surgical technique that completely avoided viscoelastic substances. Vault remained stable, within safe parameters, 6 and 12 months after surgery, and cataracts were developed. The post-operative refraction achieved was good enough to obtain spectacles´ independence, and was aligned with the pre-operative expectations for both spherical and toric models in a myopic population with presbyopia. Future studies with diffractive IPCL performed by different surgeons with a longer follow-up will be necessary to confirm present good outcomes.

Abbreviations

ACD: anterior chamber depth.

ADD: addition.

ANOVA: analysis of variance.

BSS: balanced salt solution.

CCT: central corneal thickness.

CDVA: corrected Distance visual acuity.

D: diopters.

ECD: endothelial cell density.

IOL: intra-ocular lens.

IOP: intra-ocular pressure.

IPCL: implantable phakic contact lens.

logMAR: logarithm of the minimal angle of resolution.

PIOL: phakic intra-ocular lens.

SE: spherical equivalent.

UDVA: uncorrected Distance visual acuity.

Declarations

Ethics approval and consent to participate. This study followed the tenets of the “Declaration of Helsinki”, and was developed with the approval of the “Clínica de Ojos Dr. Nano´s” Institutional Review Board/Ethics Committee. A written consent was obtained after patients were informed about the characteristics and risks of the surgical procedure.

Consent for publication: Not applicable

Availability of data and materials. The datasets generated and/or analysed during the current study are available at “Clínica de Ojos Dr. Nano”.

Competing interests. The authors declare that they have no competing interests, no conflict of interest or financial ties to disclose.

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Authors' contributions. All authors read and approved the final manuscript."

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Tables

Table 1. Nomogram to select the best presbyopic addition (ADD) for each eye, according to the age, myopic amount, dominant or non-dominant eye condition, and patient´s tolerance (Option A and Option B).

Myopia	Age (years old)	Option A		Option B
		Dominant Eye ADD (D)	NON-Dominant Eye ADD (D)	Both with the same ADD (D)
-3 to -6	40-44	1.5	2.0	1.5 to 2
	45-50	2.0	3.0	2.0 to 2.5
	> 50	2.5	3.5	2.5 to 3.5
-7 to -10	40-44	2.0	2.5	1.5 to 2.0
	45-50	2.5	3.0	2.0 to 2.5
	> 50	3.0	3.5	3.0 to 3.5
> -11.0	40-44	2.5	3.0	2.5 to 3.0
	45-50	3.0	3.5	3.0
	> 50	3.5	3.5	3.5

Table 2. The mean values, standard deviation [range] from endothelial cell density (ECD), central corneal thickness (CCT), vault and intra-ocular pressure (IOP), were compared at different time-points. The statistical significant difference was compared ($p < 0.05$).

	Baseline			12 months later		*p*
Endothelial Cell Density (cell/mm^2)	2695.11 ±184.85 [2299-3096]			2656.37 ±183.11 [2264-3002]		0.28
Corneal Central Thickness (µm)	510.77 ±23.43 [445-564]			511.12 ±23.40 [442-562]		0.93
	Month 6			**Month 12**		*p*
Vault (mm)	523.05 ±90.46 [300-702]			520.16 ±90.53 [299-698]		0.86
	Baseline	**Day 1**	**Day 7**	**Month 1**	**Month 12**	*p*
IOP (mm Hg)	13.8 ±1.5 [11-17]	14.25 ±1.2 [11-16]	13.83 ±1.3 [12-16]	13.74 ±1.2 [11-16]	13.76 ±1.2 [12-16]	0.22

Figures

Figure 1

Uncorrected Distance Visual Acuity (UDVA). Cumulative percentages of eyes attaining specified levels of post-operative uncorrected distance visual acuity (UDVA) compared to the cumulative percentages of

eyes attaining specified levels of pre-operative corrected distance visual acuity (CDVA), after Diffractive ICPL implantation.

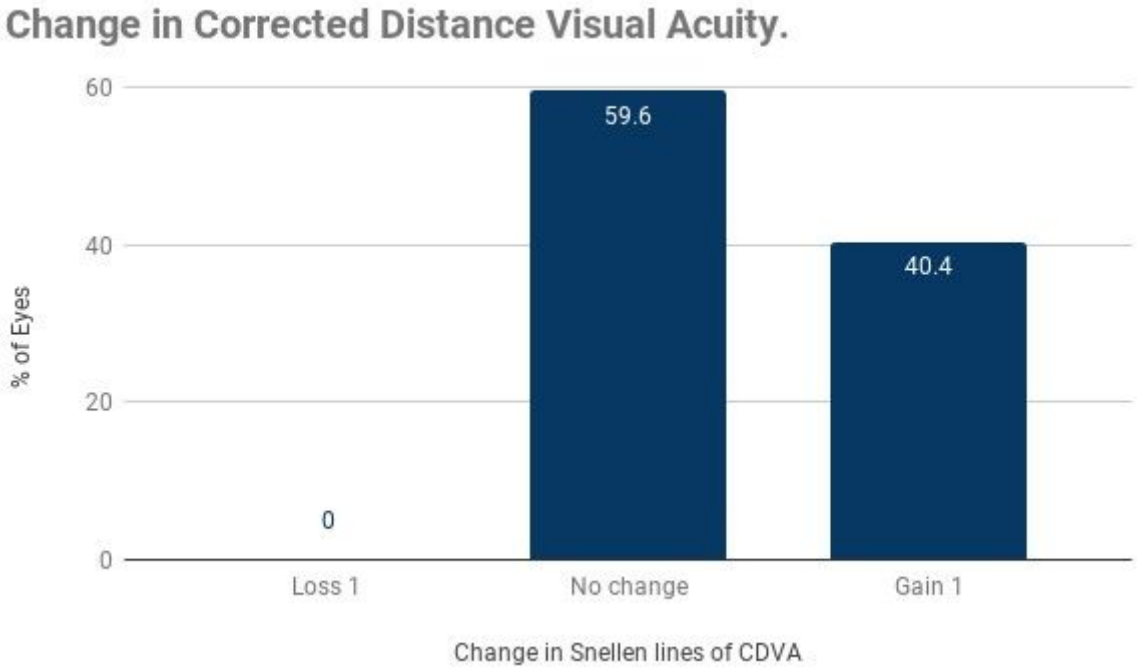

Figure 2

Changes in corrected distance visual acuity (CDVA), 12 months after surgery. Spherical Equivalent Refractive Accuracy. The 6 months post-operative spherical equivalent achieved is related to the % of eyes.

Figure 3

Spherical Equivalent Attempted vs. Achieved. The correlation between the attempted and achieved spherical equivalent change is shown with the coefficient of determination (R2).

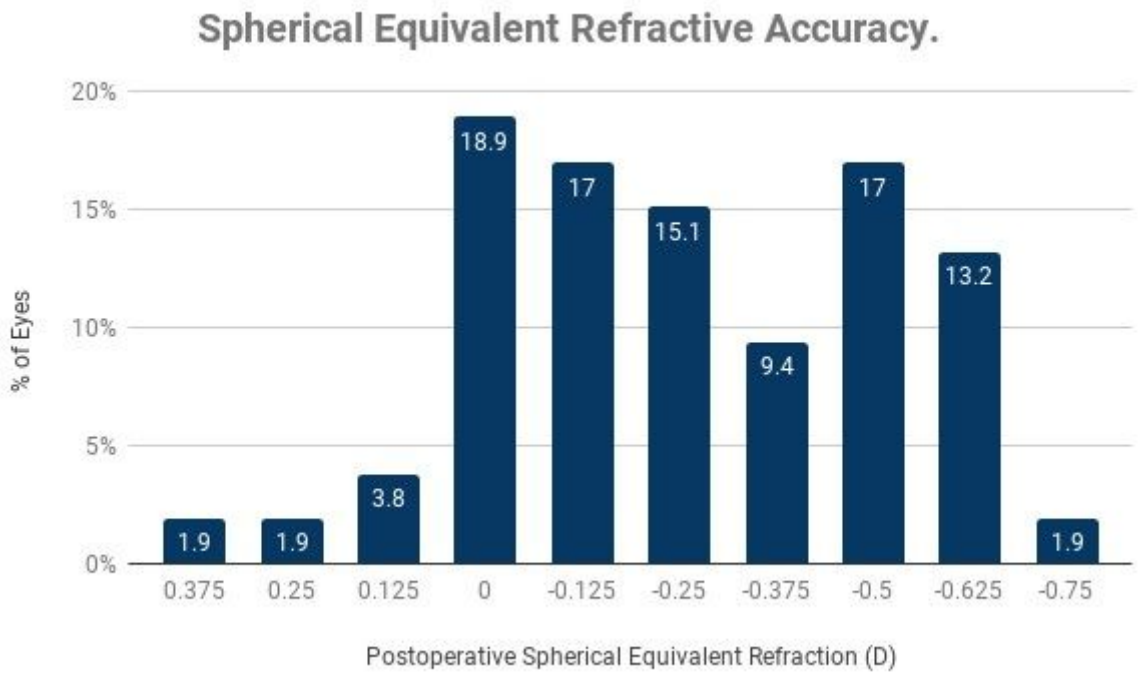

Figure 4

Spherical Equivalent Refractive Accuracy, 12 months after surgery.

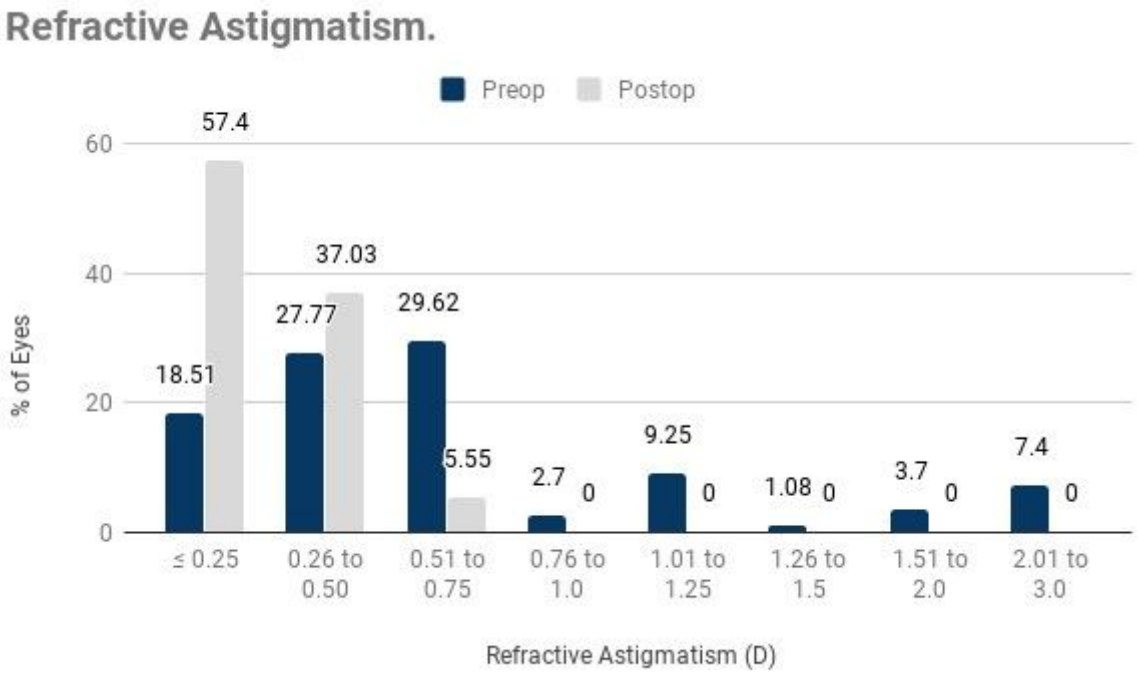

Figure 5

Refractive Astigmatism obtained 12 months after surgery and the pre-operative comparison.

Figure 6

Defocus curve (binocular) at 6 months after surgery (n=27 patients; logMAR lines).