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Astigmatism correction with toric implantable collamer lens in low and high astigmatism groups

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Abstract

Purpose: To analyze the target induced astigmatism (TIA), surgically induced astigmatism (SIA), difference vector (DV), and correction index (CI) in the correction of astigmatism with phakic lenses, and its influence on visual acuity, and to analyze the safety and efficacy indexes of the correction of high and low power astigmatism with toric phakic lenses.
Design: Retrospective comparative study.
Methods: The medical records of patients that were operated on at the research center during the period were analyzed. Results were divided into Low Astigmatism Group – LAG (33 eyes) and High Astigmatism Group – HAG (93 eyes) according to the implanted toric ICL lens power. Preoperative refraction and resultant postoperative refraction were analyzed by vector analysis. Visual acuity pre and postop, with and without optical correction, were compared.
Results: A total of 126 eyes were studied. The average preop refraction was −5.02 D sphere with −2.61 D cylinder. The average ICL lens power implanted was −8.31 D sphere +2.77 D cylinder. Refractive remaining was -0.01 ± 0.11 D sphere -0.15 ± 0.28 D cylinder. The arithmetic average angle of error in the astigmatism correction was 1.08°. The resultant cylinder was -0.03 ± 0.12 D and -0.19 ± 0.30 D in the low and high astigmatism groups, respectively, with a mean UDVA -0.01 ± 0.10 and 0.01 ± 0.16 and CDVA -0.03 ± 0.08 and -0.01 ± 0.17 for each group. The safety and efficacy indexes for the low astigmatism group were 1.09 ± 0.16 and 1.05 ± 0.17, respectively, with 1.11 ± 0.17 and 1.06 ± 0.16 for the high astigmatism group.
Conclusions: The correction of astigmatism by the implantation of toric phakic lenses of the posterior chamber is safe and effective, independently of the amount of cylinder corrected.

Keywords
Corneal procedures for astigmatism, refractive surgery, refractive phakic IOLs, corneal procedures for hyperopia, corneal procedures for myopia, corneal optics

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Introduction

Astigmatism is a common refractive defect in the population that requires optical correction in nearsighted and farsighted people to maintain good visual acuity. Specifically, it has been described that astigmatism is present in 87% of patients, 36% of which have greater than 1.25 diopters.[1] In astigmatism treatment, alignment of the axis is extremely important to avoid unsatisfactory results. It is well known that in the supine position our eyes undergo cyclotorsion, which can make it difficult to properly position the patient's eye when performing corneal techniques or intraocular lens implant techniques. This can cause misalignment of a toric lens, resulting in a 3.3% loss of effectiveness for each degree of error.[2,3]

Numerous articles have been published comparing corneal techniques versus phakic lenses for the correction of

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astigmatism, with variable results among them: Ganesh et al.[4] compared patients who underwent the Femto-LASIK technique, the SMILE technique, and patients with implanted toric ICL (Visian Implantable Collamer Lens, model V4c, STAAR Surgical, United States). Despite the fact that the groups were not demographically comparable, patients with toric ICL showed similar uncorrected distance visual acuity (UDVA), equivalent outcomes in spherical equivalent, and postoperative cylinder in comparison to the Femto-LASIK and the SMILE groups. The following year, Chen et al.[5], studied refractive outcomes of patients who underwent Femto-LASIK and implanted toric ICL for the correction of moderate and high astigmatism. They concluded that both techniques are effective in correcting moderate and high astigmatism, although if lens misalignment occurs, it generates a greater angle error than in the excimer laser procedure. In 2019 Moshirfar et al. compared the visual results between 249 patients who underwent Femto-LASIK, 357 who underwent SMILE, and 201 with toric ICL. As in the study by Ganesh et al., the toric ICL group had patients with a higher spherical equivalent and preoperative astigmatism. All three groups had similar UDVA at 12 months, but the SMILE group had a lower UDVA at 6 months, exhibiting slower recovery of visual acuity in this group of patients.

Currently, the available model of ICL is V5 EVO + with an enlarged optical zone compared to the V4c model, maintaining the 360-μ central hole. Hyun et al.[6] demonstrated that the stability of the V4 and V4c lens is similar with an average rotation of 4.17° ± 3.31° and 3.39° ± 2.36°, respectively, with no statistically significant difference between the vector analysis of each group.

The final effectiveness of astigmatism treatment will depend on the final centering of the lens or its ability to remain stable in its centering. In case there is a misalignment, effectiveness will be related to the cylindrical power of the lens and the extent of the misalignment, such that the greater the misalignment in the correction meridian in high cylinders, the greater the resultant error. Therefore, when faced with similar misalignments the correction of low power astigmatism could have greater effectiveness or correction index (CI) than high astigmatism. To our knowledge, there is no study of effectiveness and safety in the correction of astigmatism using a phakic lens implant, which segments the analysis into groups according to low or high astigmatism. The objective of this analysis is to establish and compare the safety and efficacy indexes in the correction of astigmatism independently in high and low refractive cylinders.

Methods

This is a retrospective study, analyzing medical records of subjects who underwent refractive surgery at Hospital La Arruzafa – Córdoba, Spain, between January 2018 and December 2019, using the implant of a toric ICL lens (Visian Implantable Collamer Lens, STAAR Surgical AG, Nidau, Switzerland). The study adhered to the tenets of the Declaration of Helsinki and all the clinical data were anonymized. The inclusion criteria included patients undergoing refractive surgery to correct myopic/hyperopic/mixed astigmatism between −18.00 D and +10.00 D sphere and with astigmatism greater than or equal to 0.75 D of the cylinder according to subjective refraction. Additionally, myopic subjects were required to have an anterior chamber depth greater than 2.80 mm, or 3.00 mm in the case of hyperopia, measured from corneal endothelium to anterior capsule of the crystalline lens, with an endothelial cell count greater than 2000 cells/mm^2. Finally, patients with associated ocular pathology were excluded along with all subjects who did not meet these conditions.

ICL power was calculated with the patient's subjective refraction and the vergence formula used by the manufacturer calculator webpage – OCOS (Online Calculation and Ordering System, STAAR Surgical AG, Nidau, Switzerland). ICL Size was also calculated according to OCOS with the measurement of white-to-white distance (horizontal corneal diameter), as measured with a Pentacam ALX (Oculus Optikgeräte GmbH, Wetzlar, Germany) once it had been checked that the measurement was reliable and the image acquisition met the manufacturer's quality criteria.

Surgery was performed by two surgeons from the Cornea and Refractive Surgery Unit of Hospital La Arruzafa (AVC-ACO) under topical anesthesia in all patients, making an incision in the temporal meridian of 3.2 mm and a paracentesis of 1 mm. Prior to the introduction of the toric ICL lens, the anterior chamber was provided with cohesive viscoelastic material (1% sodium hyaluronate), which was completely removed at the end of the intervention. As a marking technique, marks were made on the axis of 0°–180° in a slit lamp and these marks were subsequently photographed in order to export the image to the alignment system, Goniotrans. Once the 0°–180° axis was established, the lens was aligned to the planned axis with the aid of a Mendez ring.

Postoperative treatment consisted of instilling moxifloxacin 5 mg/ml every 6 h for 1 week, dexamethasone 1 mg/ml every 6 h for 1 week, and bromfenac 0.9 mg/ml every 12 h for 1 month. Patients were examined 1 day, 1 week, and 1, 3, and 6 months after the intervention. All surgeries were uneventful.

Examinations performed in the post-surgical revision included subjective non-mydriatic refraction with schiascopy, autorefraction (ARK-1, Nidek, Maehama Hiroishi, Japan), uncorrected and corrected distance visual acuity (UDVA and CDVA), intraocular pressure, slit-lamp examination, corneal tomography (Pentacam AXL, Oculus Optikgeräte GmbH, Wetzlar, Germany), measurement of

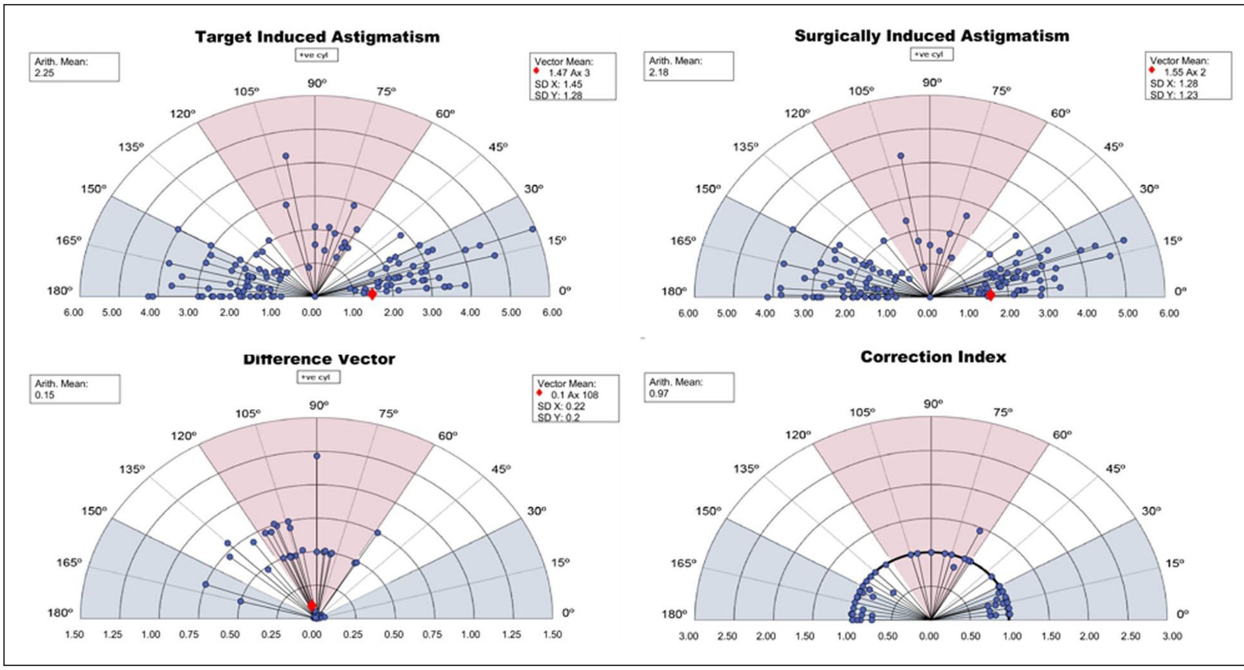

Figure 1. Vector analysis and representation of target induced astigmatism (TIA), surgically induced astigmatism (SIA), difference vector (DV), and correction index (CI).

the distance between the central posterior surface of the ICL and the anterior capsule of the lens (Vault), iridocorneal angle aperture measurement by OCT (Visante OCT, Zeiss Meditec AG, Jena, Germany), endothelial count (CEM-530, Nidek, Maehama Hiroishi, Japan), as well as visualization of the fundus.

Descriptive statistical analysis was performed using SPSS (V.22 IBM Corp) and Matlab2019 (Mathworks) using the Refractive Analysis Toolbox designed by Rodriguez-Vallejo.[7] Results were analyzed on the whole dataset, in two groups according to the level of astigmatism: astigmatisms less than 2 diopters were part of group 1 (Low Astigmatism Group – LAG) and astigmatisms greater than 2 diopters were part of group 2 (High Astigmatism Group – HAG). Astigmatism analysis was performed according to the Alpins method,[8,9] and the outcomes were reported according to the standard outcomes report methodology.[10]

Results

A total of 126 eyes from 126 subjects were analyzed, including 67 right eyes and 59 left eyes from 53 males and 73 females, with a mean age of 30.82 ± 6.04 (range 22–51) years. The mean refraction was −5.02 ± 4.31 (−16.50 to +7.50) diopters sphere and 2.61 ± 1.07 (−6.00 to −1.00) for diopters cylinder. The mean implanted toric ICL power was −8.31 ± 4.92 (−18.00 to +8.00) diopters sphere and 2.77 ± 1.27 (1.00 to +6.00) diopters cylinder.

Vector representation is described in Figure 1. Arithmetical mean target induced astigmatism (TIA) was 2.25 D (vector mean = 1.47@3°; X = 1.45; Y = 1.28) and arithmetical mean surgical induced astigmatism (SIA) was 2.18 D (vector mean = 1.38@2°; X = 1.42; Y = 1.27), leading to an arithmetic mean difference vector (DV) of 0.15 D (vector mean = 0.1@108°; X = 0.22; Y = 0.20) and a correction index (CI) of 0.97.

Mean preop CDVA was 0.03 ± 0.08 LogMAR, and mean UDVA and CDVA 6 months after surgery was 0.01 ± 0.08 and −0.01 ± 0.07 LogMAR, respectively. Therefore, the efficacy and security indexes were 1.06 ± 0.16 and 1.11 ± 0.16, respectively. More than 70% of eyes had the same CDVA as in preop, and 23.8% had an improvement of 1 or more lines of UDVA compared to preop CDVA (Figure 2(b)). The predictability of spherical equivalent (SEQ) is described in Figure 2(d). Finally, 98% and 100% of eyes were in spherical equivalent ranges of ±0.50 D and ±1.00 D, respectively. The precision of SEQ is described in Figure 2(c). Linear correlation of attempted SEQ versus achieved SEQ had an R^2 of 0.99, with a minor under-correction according to a linear equation factor of 0.9998. Regarding the precision of cylinder correction, the linear correlation had an $R^2 = 0.9618$, with a small under-correction according to a linear equation factor of 0.9437 (Figure 2(e)). About 75% of eyes had a remaining cylinder <0.25 D, and 14% had ±0.50 D. Therefore, 89% of eyes had within ±0.50 D and 99% within ±1.00 D (Figure 2(f)). The mean arithmetic angle of error (AE) was −1.08° ± 3.29° with 90.5% resultant cylinder rotation of ±5° (Figure 2(g)) and the mean absolute angle of error was 1.37° ± 3.17°.

The demography of the analysis in low and high astigmatism groups is presented in Table 1.

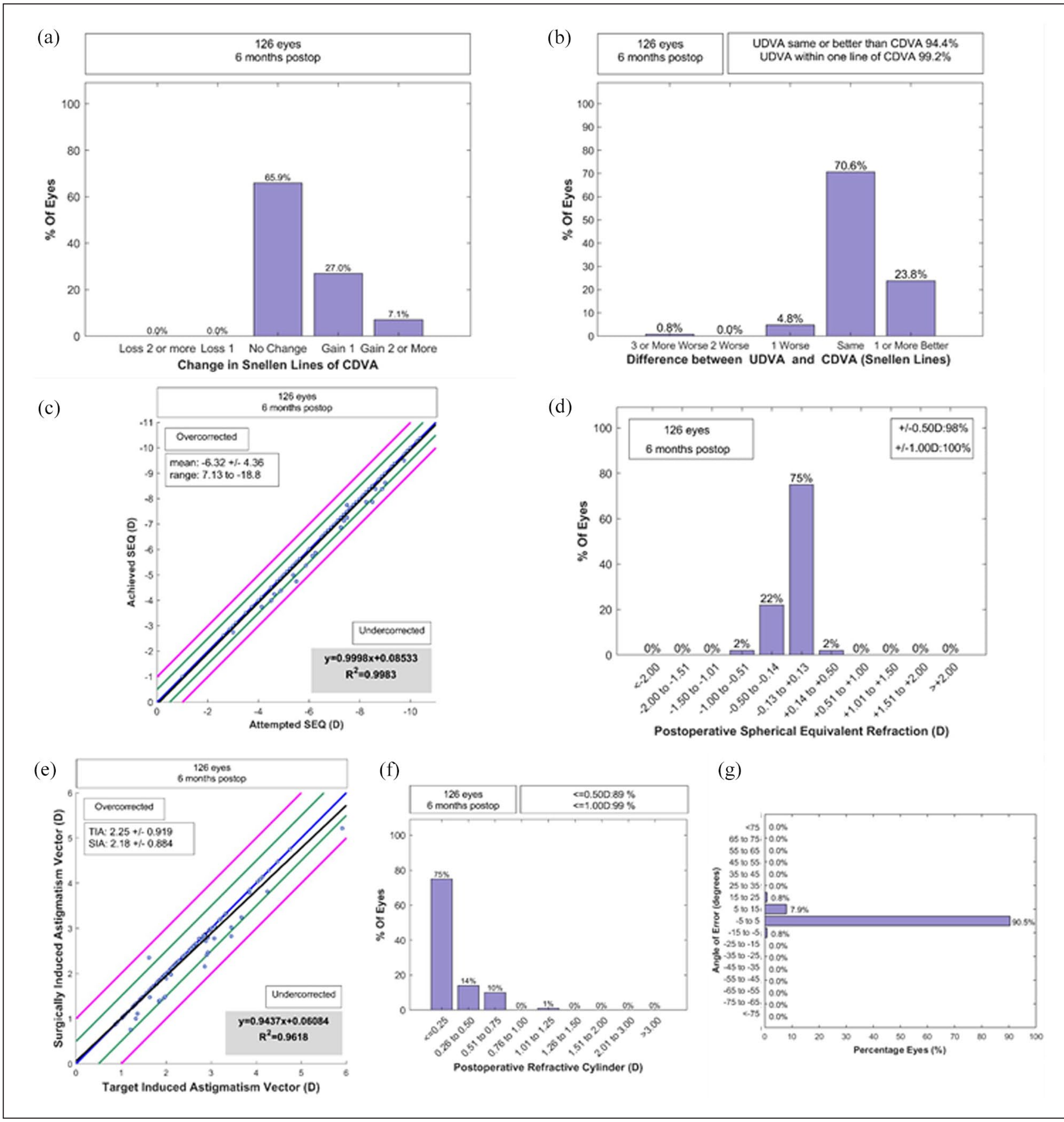

Figure 2. High and low astigmatism: (a) change in snellen lines of corrected distance visual acuity, (b) difference between uncorrected distance visual acuity and corrected distance visual acuity, (c) relationship between attempted spherical equivalent and achieved spherical equivalent, (d) postoperative spherical equivalent refraction in diopters, (e) relationship between target induced astigmatism vector and surgically induced astigmatism vector, (f) postoperative refractive cylinder refraction in diopters, and (g) angle of error in degrees.

Table 1. Low and high astigmatism groups demography.

	Low astigmatism group	High astigmatism group
Number of eyes (%)	33 (26.2%)	93 (73.8%)
Previous sphere (D)	−5.17 ± 4.27 (−15.50 to +7.00)	−5.00 ± 4.22 (−16.50 to +7.50)
Previous cylinder (D)	−1.50 ± 0.25 (−1.75 to −1.00)	−3.00 ± 0.97 (−6.00 to −2.00)

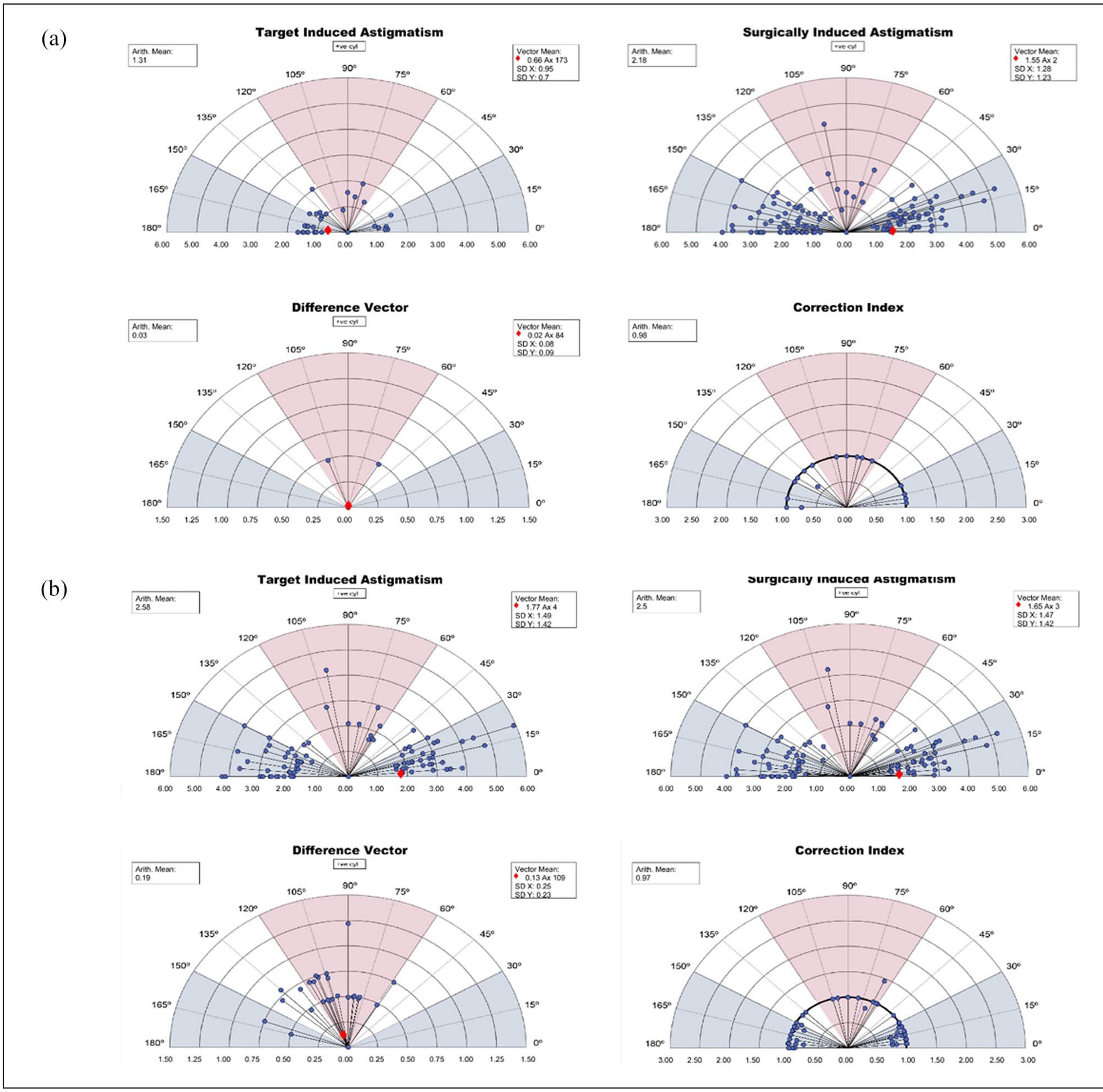

Figure 3. Vector analysis for low and high astigmatism groups. TIA, SIA, DV, and CI for Low (a) and High (b) astigmatism.

Vector representation of both groups is described in Figure 3 (Low and High Astigmatism group vector analysis, respectively). The arithmetic mean TIA for Low astigmatism group (LAG) was 1.31 D (vector mean = 0.66@173°; X = 0.95; Y = 0.70) and for the High astigmatism group (HAG) it was 2.58 D (vector mean = 1.77@4°; X = 1.49; Y = 1.42). The arithmetic mean SIA for LAG was 1.29 D (vector mean = 0.64@173°; X = 0.95; Y = 0.68) and for HAG was 2.50 D (vector mean = 1.65@3°; X = 1.47; Y = 1.42), leading to an arithmetic mean DV of 0.03 D (vector mean = 0.02@84°; X = 0.08; Y = 0.09) for LAG and 0.19 D (vector mean = 0.13@109°; X = 0.25; Y = 0.23) for HAG, and a correction index (CI) of 0.98 and 0.97 for LAG and HAG, respectively.

The predictability of SEQ in both groups is described in Figures 4 and 5. Finally, 100% of eyes were in spherical equivalent ranges of ±0.50 D in LAG (Figure 4(d)) and, on the other hand, 98% and 100% achieved spherical equivalent in the range of ±0.50 D and ±1.00 D in the HAG group (Figure 5(d)), respectively. The precision of SEQ in both groups is described according to the linear correlation of attempted SEQ versus Achieved SEQ, which had an R^2 of 0.9998 for LAG (Figure 4(c)) and 0.998 for HAG (Figure 5(c)), with a small under-correction according to the lineal

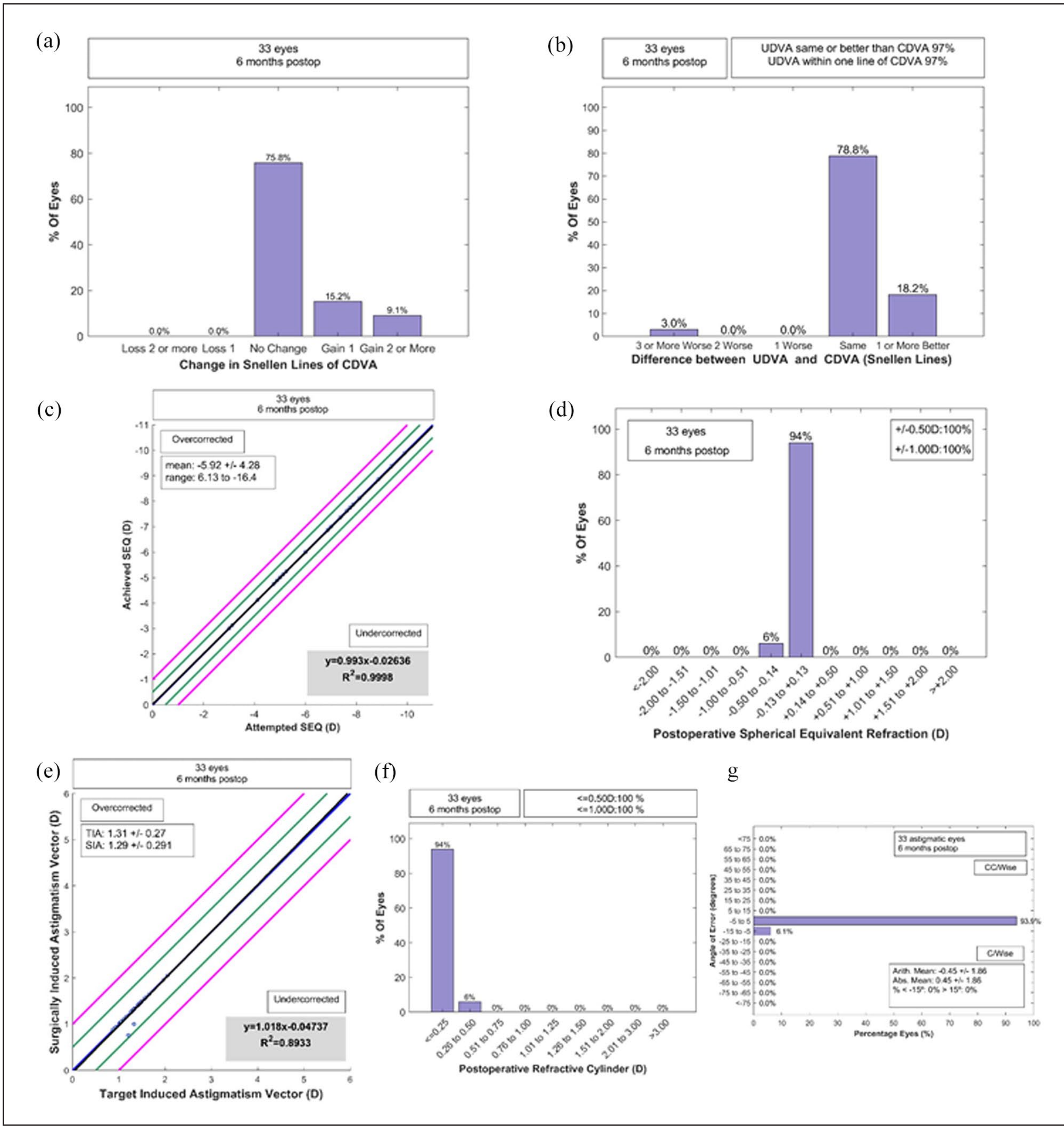

Figure 4. Low astigmatism: (a) change in snellen lines of corrected distance visual acuity, (b) difference between uncorrected distance visual acuity and corrected distance visual acuity, (c) relationship between attempted spherical equivalent and achieved spherical equivalent, (d) postoperative spherical equivalent refraction in diopters, (e) relationship between target induced astigmatism vector and surgically induced astigmatism vector, (f) postoperative refractive cylinder refraction in diopters, and (g) angle of error in degrees.

equation factor of 0.993 for LAG and a small overcorrection of 1.003 for HAG. Regarding the precision of cylinder correction, the lineal correlation had an $R^2=0.8933$, with the lineal equation factor of 1.018 for the LAG (Figure 4(e)), and a linear correlation of $R^2=0.9424$ with a lineal equation factor of 0.9341 for the HAG (Figure 5(e)). In LAG, 100% of eyes were within a ±0.50 D range of resultant cylinder (Figure 4(f)), meanwhile, in HAG 86% of eyes were in the ±0.50 D range, and 99% in the ±1.00 D range of resultant cylinder (Figure 5(f)). The arithmetic mean angle of error (AE) was −0.45° ± 1.85° with 93.9% of resultant cylinder rotation in ±5° for the LAG (Figure 4(g)), and −1.31° ± 3.65° with 89.2% of resultant cylinder rotation in ±5° for the HAG (Figure 5(g)).

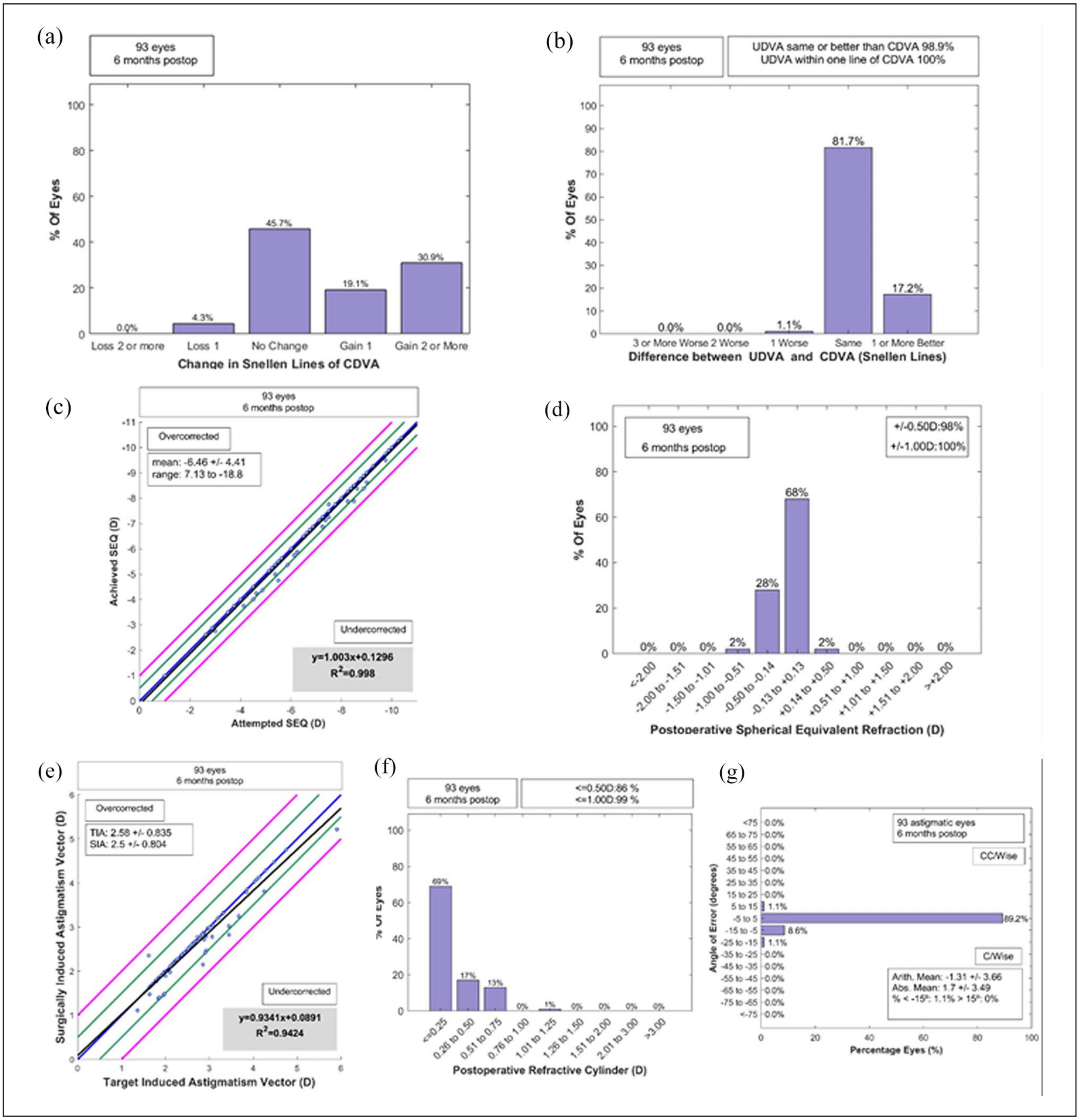

Figure 5. High astigmatism: (a) change in snellen lines of corrected distance visual acuity, (b) difference between uncorrected distance visual acuity and corrected distance visual acuity, (c) relationship between attempted spherical equivalent and achieved spherical equivalent, (d) postoperative spherical equivalent refraction in diopters, (e) relationship between target induced astigmatism vector and surgically induced astigmatism vector, (f) postoperative refractive cylinder refraction in diopters, and (g) angle of error in degrees.

Concerning visual acuity, for LAG, mean preop CDVA was 0.01 ± 0.06 LogMAR, mean UDVA after surgery was -0.01 ± 0.10 LogMAR, and mean CDVA after surgery was -0.03 ± 0.08 LogMAR (Figure 4(a) and (b)). Regarding HAG, preop CDVA was 0.03 ± 0.07, postop UDVA was 0.01 ± 0.16, and postop CDVA was 0.01 ± 0.17 LogMAR (Figure 5(a) and (b)). Therefore, the efficacy and security indexes were 1.05 ± 0.17 and 1.09 ± 0.16, respectively, for LAG, and 1.06 ± 0.16 and 1.11 ± 0.17 for HAG, respectively. In LAG, more than 78% of eyes had the same CDVA as in preop, and 18.2% had an improvement of 1 or more lines of UDVA compared to preop CDVA (Figure 4(b)).

On the other hand, in HAG 81.7% of eyes had the same VA as compared to preop, and 17.2% had an improvement of at least 1 line of VA (Figure 5(b)).

Discussion

Astigmatism correction can be performed on the cornea or by implanting intraocular lenses. In corneal procedures, excimer laser treatment or femtosecond laser treatment has shown great visual and refractive results, comparable to the results of the toric ICL phakic lens, even though the groups that have been compared were not homogeneous in sphere and cylinder.[4,5,11] The main advantage of phakic lens implantation is reversibility, since it does not alter the corneal architecture or remove corneal tissue, unlike surface procedures.[12] A previous study aimed at identifying a procedure for relaxing corneal incisions required a considerable series of cases with comparable conditions and variables to obtain a reliable nomogram and allow for enough predictability in the treatment calculation.[13,14] Although technically the use of relaxing incisions for the management of astigmatism is a safe procedure, it has a correction rate of only around 77%, compared with other techniques such as laser procedures or phakic lens implantation.[14] These facts, besides the complications associated with the use of relaxing incisions, such as induction of high-order coma aberration, keratitis, neurotrophic ulcers, or endophthalmitis,[15–20] along with promising published results including follow-ups of up to 10 years, and with the certainty of reversibility, indicate that the use of toric lenses for astigmatism management is an option to consider.

The novelty of our work is the analysis in groups according to high and low astigmatism. This allowed us to compare the efficacy and safety of the procedures regardless of the amount of the cylinder to be compensated. Some previously published studies have analyzed the efficacy of phakic toric lens implant treatment in comparison to other techniques; however, they used heterogeneous groups. Moshirfar et al.[21] compared ICL toric lens implant to SMILE and LASIK, however the groups were heterogeneous, with higher dioptric powers in the ICL group, which, in case of eventual lens rotation, will induce higher resultant refractive outcomes than with the other techniques. Similarly, in Ganesh et al.[4], the cylinder of the toric ICL group was statistically significantly higher than the other groups.In our study, we compared refractive outcomes, visual acuities, and efficacy and security indexes as a unique sample of patients and also between high and low astigmatism groups. In all cases, the refractive results are excellent as are the efficacy and security indexes as well.

According to the amount of the cylinder, the Chen et al.[5] study is quite similar to the one we describe here. In that study, the authors compared the outcomes of the FS-LASIK technique and the toric ICL lens implant. The average cylinders in each group were equivalent, although slightly larger than our average cylinder in the low astigmatism group (−2.28 D vs −1.50 D). In their work, 95.45% of the eyes were in an SEQ ±0.50 D, in good agreement with our results, in which 100% of eyes were in the range of ±0.50 D. Similarly, the remaining cylinder was 81.8% in ±0.50 D in their study, and 100% in ours. Nakamura et al.[22] also considered low astigmatisms with the toric ICL lens implant.They included myopic eyes of all ranges with a mean cylinder of −1.72 D. The UDVA results and the efficacy and safety indexes were similar to those presented here, with values of 0.98 ± 0.22 and 1.08 ± 0.18, respectively, 6 months after surgery, similar to ours of 1.05 ± 0.17 and 1.09 ± 0.16.

Analyzing high astigmatism data we can compare our results with those described by Kamiya et al.[23] In their study, they included patients with a mean refractive astigmatism of −3.21 D, comparable to our High Astigmatism Group (−2.58 D), and showed predictability in spherical equivalent of 94.6% with a slight hypercorrection and an index of 1.075 in the correlation line. In our case, the predictability in spherical equivalent is even higher (99.8%) and the hypercorrection somewhat lower (index correlation line 1.003). The efficacy and safety indices in our High Astigmatism Group (1.06 ± 0.16 and 1.11 ± 0.17, respectively) are comparable to those described by Kamiya et al.[24] in previous work. In that work, the authors described efficacy and safety indexes of 1.01 ± 0.25 and 1.12 ± 0.18, respectively, 6 months after the intervention. It is also interesting to note that in their work, 85% of the eyes were in the ±0.50 D range at 6 months, whereas our results are significantly better, with 98% of eyes in the same range.

Regarding the hyperopic subjects, although our study only included eleven eyes with hyperopic astigmatism, our results are similar to those described by Coskuseven et al.[25] In their study, they do not carry out an exhaustive analysis of the refractive results in the correction of the cylinder; however, they do indicate an improvement in the UDVA and the resulting cylinder, similar to our results. Our study has some limitations that should be highlighted: the sample size of both groups is not equivalent, although both samples are large enough to extrapolate consistent statistical results. The follow-up of the results has been reduced exclusively to the first 6 months, although this study was not intended to be a medium or long-term follow-up study.

The system of image-guided mobile software used in this study for the orientation of the toric lens was also very efficient according to the results, allowing a mean angle error lower than 2° in all cases, in both the low and high astigmatism groups. These results are in contrast to those described by Chen et al.[5] in 2018, who described an angle of 8°, but are in the same line as those described by

Emerah[26], in which he obtained an error angle of 1.9° in the implant of toric ICL lenses with the aid of a digital image centering system. In summary, meticulous marking and centering of the final orientation of the lens, as a refined surgical technique, are essential elements for good refractive outcomes.

Conclusion

Based on our results, we affirm that astigmatism correction with the Visian toric ICL lens is precise, predictable, safe, and effective, both in myopic and hyperopic astigmatisms.

Declaration of conflicting interests

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