

**“CAROL DAVILA” UNIVERSITY OF MEDICINE AND
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**PARTICULAR ASPECTS OF OCULAR SURGERY IN
PATIENTS WITH HIGH ASTIGMATISM**

SUMMARY OF THE DOCTORAL THESIS

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1. THE CENTRAL RESEARCH PROBLEM: Surgical Particularities of High-Astigmatism Patients

The present doctoral thesis investigates the particular surgical aspects of eyes with high astigmatism, of at least 2.00 diopters (D). Although astigmatism is one of the most common refractive errors in the general population, high-magnitude astigmatism is rare[1] and raises particular therapeutic challenges.

Unlike spherical refractive errors, which can be defined by their dioptric power alone, astigmatism has an intrinsic complexity arising from its two-dimensional nature, comprising simultaneously a cylindrical dioptric-power component and a directional, axial component. For refractive surgery, correcting astigmatism differs fundamentally from correcting spherical ametropias precisely because of the need to act concurrently on both the magnitude and the direction of the intended correction. Moreover, sensitivity to alignment errors increases proportionally with the magnitude of astigmatism[2,3]. For example, in toric intraocular lens implantation, it is estimated that for every degree of misalignment from the intended axis, the lens loses approximately 3.3% of its effective cylindrical power, the correction becoming null at 30° of axial deviation and reversing its effect beyond this threshold[4,5]. Consequently, in high astigmatism, the accuracy of the preoperative assessment and of the surgical technique acquires a proportionally greater importance than in low-magnitude astigmatism [3,4].

Ocular astigmatism should not be regarded as a single refractive entity, but the summed contribution of several toric ocular structures, primarily the cornea (anterior and posterior surfaces) and the crystalline lens (subchapter 1.4). Accordingly, the precise characterization of preoperative astigmatism requires the corroboration of complementary measurements of the anterior corneal surface, the posterior surface (more difficult to measure directly), the lenticular component, and the wavefront aberrations[6–8]. The multitude of available measurement modalities (keratometry, topography, corneal tomography, optical biometry, autorefractometry, subjective refraction) constitutes both a valuable diagnostic resource and a cause of variability, since the results cannot always be used interchangeably between devices[6,7,9] (subchapter 1.4.1). The association of high astigmatism with significant spherical ametropias further complicates intraocular lens calculation formulas, treatment nomograms, and ablation-profile selection [10–12]. Consequently, the modern preoperative assessment of high astigmatism relies on the complementary use of several imaging

instruments and the agreement between measurements has become an essential quality criterion for adequate surgical planning[6,9].

The clinical characterization of astigmatism involves several types of classification, all relevant to surgical planning (chapters 1.2 and 1.4). According to the method of determination, a distinction is drawn between refractive astigmatism (quantified by manifest subjective refraction, which expresses the eye's global refractive error), fundamental to the visual outcome perceived by the patient but without identifying the anatomical source, and corneal astigmatism, determined objectively by measuring the curvature of the corneal surfaces[6]. Manifest refraction remains the gold standard for quantifying the functional refractive error from a clinical point of view, but the modern preoperative assessment generally combines refractive measurements with objective measurements of the ocular structures[13]. According to the orientation of the steepest meridian, regular astigmatism is classified into: with-the-rule astigmatism, frequently encountered in young subjects, against-the-rule astigmatism, more frequent in elderly subjects, and oblique astigmatism, which is the rarest form[1]. The distribution of these three types changes with age and influences the surgical strategy[6]. According to the regularity of the corneal surface (chapter 1.2), a distinction is drawn between regular astigmatism (two perpendicular principal meridians) and irregular astigmatism (asymmetric, uneven curvatures). All cohorts in the present thesis are exclusively comprised of patients with regular astigmatism, with or without associated spherical errors (myopic, hyperopic, or mixed astigmatism). Irregular astigmatism and its specific surgical management are beyond the scope of the present research.

Astigmatism correction can be achieved by optical or surgical means. The practical effectiveness of conventional optical correction methods (spectacles and contact lenses) decreases as cylindrical magnitude increases: patients with high astigmatism often tolerate spectacle correction poorly and frequently remain undercorrected, while long-term contact lens wear may be difficult to maintain and carries specific risks (chapter 1.5). These limitations can reduce quality of life and have a significant socio-economic impact[1] In high-magnitude astigmatism, these constraints become more pronounced, and surgical strategies assume an important therapeutic role.

Surgical correction derives, somewhat paradoxically, an advantage that arises from the anatomical complexity of astigmatism: the refractive error can be addressed at different anatomical planes (not necessarily at the dominant source plane). From an anatomical perspective, the surgical approaches discussed in chapter 1.5 of the thesis can be grouped into two broad categories:

- **Corneal surgery** (chapter 1.5.2) includes techniques that modify the geometry of the anterior corneal surface in order to change its refractive power. These procedures include laser ablation methods—PRK and its modern variant Trans-PRK, LASIK and its modern variant FS-LASIK, and SMILE—as well as, in selected cases, limbal relaxing incisions. In high astigmatism, laser correction has several specific constraints[14]. Stromal ablation depth increases in direct proportion to the magnitude of the cylinder being treated, making pachymetric reserve a limiting factor. At the same time, precise axial alignment becomes increasingly important as astigmatism magnitude rises. To improve predictability, current platforms incorporate optimized aspheric ablation profiles, intraoperative eye-tracking, and cyclotorsion compensation[12,14].
- **Intraocular surgery** (chapters 1.5.1 and 1.5.3) corrects astigmatism at the lenticular plane and includes two main approaches: toric intraocular lens implantation which replaces the natural crystalline lens with a toric intraocular lens (toric IOL), either during cataract surgery[7,15] or as refractive lens exchange (RLE)[3,16] (in presbyopic patients who are candidates for lens-based refractive surgery, including, where appropriate, multifocal or extended-depth-of-focus implants) and toric phakic intraocular lens implantation that preserves the natural crystalline lens[17] and is particularly suited for younger patients with extreme spherocylindrical ametropias, in whom corneal laser surgery is limited by corneal biomechanics and refractive lens exchange would compromise their natural accommodation.

Each approach is constrained by specific biological and biomechanical factors, which become especially relevant in patients with high astigmatism. In corneal laser surgery, the main limiting factors are the ablation profile selection, corneal biomechanics, and healing processes[12,18–20]. In lens-based surgery, the main determinants are biometric accuracy, calculation algorithms, and IOL rotational stability within the capsular bag[7,21,22]. In toric phakic lens implantation, outcomes depend on appropriate lens sizing and on the anatomical relationships of the lens within the anterior segment, which significantly influence its postoperative vault[23–25].

In cases of extreme ametropia, where a single procedure cannot fully neutralize the refractive error, a *bioptics* approach may be considered[26]. This combined surgical strategy distributes the correction between the intraocular plane (phakic or pseudophakic lens) and the corneal plane (laser procedures), with the goal of achieving a postoperative refraction as close to emmetropia as possible (chapter 1.5.4).

2. RESEARCH HYPOTHESIS AND OBJECTIVES

Main research hypothesis: modern surgical techniques for correcting astigmatism ≥ 2.00 D provide effective, predictable, safe, and accurate visual and refractive outcomes in real-world routine clinical practice, the performance of each modality being modulated, however, by the anatomical particularities of the treated eye, by the specific postoperative biological response, and by the technical characteristics of the surgical procedure.

The **general objectives** of the research were:

- To evaluate the visual, refractive, and vectorial outcomes of the four modern surgical techniques investigated in consecutive cohorts with preoperative astigmatism ≥ 2.00 D (Trans-PRK and FS-LASIK for the corneal approach, toric IOL for lens surgery, toric ICL for phakic implantation);
- To characterize the accuracy of astigmatic correction through the Alpins vector analysis applied consistently across all studies, allowing for simultaneous magnitude evaluation and axial alignment;
- To evaluate refractive predictability relative to the individually planned target, and refractive stability over the postoperative follow-up period;
- To identify the anatomical, biometric, and refractive factors associated with outcome performance (in particular, the independent predictive factors of residual astigmatic error and the relationship between biometric parameters and the postoperative vault of the phakic implant);
- To characterize the safety profile of each surgical modality in the high-astigmatism population;
- To evaluate postoperative independence from optical correction, as a clinically relevant functional outcome for the patient.

The specific objectives of each study are detailed in the dedicated subchapters, "Introduction (working hypothesis and specific objectives)": 5.1, 6.1, and 7.1 of the thesis, respectively.

3. RESEARCH METHODOLOGY

3.1. Study design and study populations

The research was structured as three independent observational clinical studies, with data collected prospectively during routine clinical activity and analyzed retrospectively. The results of each study were published in peer-reviewed journals[27–29]. The studies were conducted at the ALCOR Clinic, Bucharest, between 2021 and 2025, all interventions being performed by the same surgeon experienced in anterior segment surgery (Prof. Dr. C.P. Tătaru). **The three studies evaluated three distinct surgical approaches for the correction of high-magnitude astigmatism:**

- corneal laser refractive surgery (Trans-PRK and FS-LASIK);
- toric intraocular lens implantation (either cataract surgery or refractive lens exchange in presbyopic patients);
- implantation of toric Visian ICL (in young patients with preserved accommodation who were not eligible for corneal surgery).

Patients were not randomized to a specific surgical procedure; procedure selection was individualized according to clinical evaluation, ocular anatomical characteristics, and the therapeutic indication in each case, reflecting routine clinical practice. The common inclusion criterion across all three studies was the presence of **preoperative astigmatism of at least 2.00 cylindrical diopters (D)**. The inclusion and exclusion criteria for each study are described in the respective subchapters. Patients were included consecutively. The heterogeneity of the analyzed cohorts, deriving from the inclusion of patients with distinct anatomical profiles, surgical indications, and refractive strategies, represented a deliberate methodological decision, constituting simultaneously a limitation and a source of clinical relevance, by offering a picture close to the reality of practical surgical decision-making. The foundation of the research was not the formal comparison of the three techniques, but the in-depth understanding of the particularities of each modality in the high-astigmatism population, through the implementation of a common methodological framework applied transversally across the three studies.

3.2. Visual and refractive assessment and study variables

Visual function assessment included uncorrected distance visual acuity (**UDVA**) and corrected distance visual acuity (**CDVA**), recorded in decimal notation, subsequently

converted to the logMAR scale for statistical analysis (owing to its superior statistical properties and approximately linear distribution between levels) and to Snellen equivalents, for calculations and graphical representations. Very low values (“CF”, “HM”, “LP”) were conventionally converted to logMAR values according to the methodology detailed in the subchapters specific to each study.

Refraction assessment included autorefractometry and manifest subjective refraction, supplemented with cycloplegic refraction depending on the clinical indication. Refractive results were expressed through the spherical, cylindrical, and axial components, as well as through the spherical equivalent (SE). The postoperative **refractive target** constituted the reference for evaluating predictability; in most cases the objective was emmetropia, but in IOL or ICL implantation the target was influenced by the specifics of the calculation formulas and by the available dioptric powers of the implants, while in patients with high axial myopia undergoing lens exchange a moderate residual myopia (~ -2.50 D) was intentionally aimed for, to preserve functional near vision. In this context, refractive predictability was evaluated through the **agreement between the achieved postoperative refraction and the individually planned target**.

The postoperative variables analyzed included UDVA, CDVA, residual refraction, the stability of results, and the identification of any complications specific to each technique.

3.3. Optical conventions and refraction analysis

The conversion of manifest refraction from the spectacle plane (vertex distance 12 mm) to the corneal plane (vertex distance 0 mm), required for vector analysis, was performed using the standard vertex-distance formula applied at the level of the principal meridians. The transposition of the cylinder between the negative and positive sign conventions was carried out according to the standard formulas. The classification of (regular) corneal astigmatism by the orientation of the steepest meridian (positive-cylinder clinical notation) used: with-the-rule astigmatism (between 60° – 120°), against-the-rule astigmatism (between 0° – 30° or 150° – 180°), and oblique astigmatism (between 30° – 60° or 120° – 150°).

3.4. Vector analysis of astigmatism

Unlike spherical errors, astigmatism is an intrinsically two-dimensional entity, defined simultaneously by magnitude (cylinder power) and orientation (cylinder axis between 0° and 180°). Conventional arithmetic operations therefore cannot adequately capture this dual

nature of astigmatism. By doubling the angle of orientation to the trigonometric space 0° – 360° , astigmatism acquires vector-like behaviour (with magnitude and direction), to which standard vector operations can be applied at the end of the calculations, the resulting angle is halved to recover the clinical representation in the 0° – 180° interval (detailed in Appendix 1 of the thesis). The analysis employed the Alpins methodology [30], performed at the corneal plane, one of the most validated and widely used contemporary methods for evaluating astigmatic correction[6,31–33]. This defines three fundamental vectors[30,33]:

- **TIA (target-induced astigmatism)** — the astigmatic change intended (targeted) to be surgically induced;
- **SIA (surgically-induced astigmatism)** — the astigmatic change actually achieved by surgery, the vector difference between preoperative and postoperative astigmatism;
- **DV (difference vector)** — the residual astigmatism that would still be required to achieve the target result (it quantifies the overall error of the treatment, both in magnitude and direction with an ideal value of zero).

Based on the relationships among these vectors, a series of derived indices are calculated that answer specific clinical questions[30,33,34]:

- **CI (correction index, SIA/TIA)** — "was the magnitude of treatment adequate?"; ideal value = 1.0; values below unity indicate undercorrection, above unity overcorrection;
- **IOS (index of success, DV/TIA)** — "how close to the target did the refraction get?"; ideal value = 0;
- **ME (magnitude of error)** — the difference between the SIA and TIA magnitudes;
- **AoE (angle of error)** — the angular difference between the SIA and the TIA axes.

The source of preoperative astigmatism was specific to each study: manifest refraction (converted to the corneal plane) in laser surgery (Study 1) and keratometric astigmatism (K2–K1) in intraocular surgery (Studies 2 and 3). The target astigmatism was represented by the planning data specific to each technique, while the postoperative manifest refraction (converted to corneal plane) represented the achieved astigmatism.

3.5. Statistical analysis and standard graphical reporting of outcomes

Continuous variables were presented as mean $\pm$ standard deviation or as median and interquartile range, depending on the distribution of the data (assessed through normality

tests and/or graphical inspection). Categorical variables were reported as absolute frequencies and percentages. Statistical comparisons used appropriate parametric or non-parametric methods, and regression analyses were used to identify the factors associated with residual refractive or astigmatic error. The threshold of statistical significance was $p < 0.05$. The analytical methods specific to each study are detailed in the dedicated chapters.

Refractive outcomes were reported according to current standards for refractive and lens-based surgery, using the key parameters of efficacy, safety, predictability, and stability[33,34]. The summary metrics were:

- the **efficacy index (EI)** —postoperative UDVA / postoperative CDVA;
- the **safety index (SI)** —postoperative CDVA / preoperative CDVA;
- **predictability** —% eyes with postoperative refraction within ± 0.50 D and ± 1.00 D of the planned target;
- **stability** of the refraction over the follow-up period.

The results were presented both numerically and through standardized sets of graphs. **The standard graphs** include cumulative histograms of UDVA and CDVA, spherical-equivalent predictability plots, representations of astigmatic correction accuracy, and **polar vector diagrams**. Data processing and analyses used Microsoft Excel (Microsoft Corp., Redmond, WA, USA), Minitab (Minitab LLC, State College, PA, USA), and dedicated applications for vector analysis and graphical representation of refractive outcomes (mentioned in the methodology of each study, chapters 5.2, 6.2, 7.2).

3.6. General methodological considerations and limitations

The observational and real-world nature of the studies is both a strength in terms of clinical relevance of the findings, and a source of methodological limitations. Population and procedural heterogeneity, the non-randomized allocation, the relatively small sizes of some analyzed subgroups (reflecting restrictive eligibility criteria or the rarity of certain cases), the loss to follow-up, and the bilateral inclusion of eyes in certain analyses (introducing partial statistical dependence between observations, addressed through one-eye-per-patient sensitivity analyses when relevant) constituted the main limitations common to all three studies. The limitations specific to each study are detailed in the dedicated chapters. Overall, the methodology sought to maintain a balance between analytical rigor and the practical clinical relevance in the evaluation of different modern surgical strategies for the correction in different high-astigmatism cases.

4. SYNTHESIS OF STUDY 1 (CHAPTER 5)

4.1. INTRODUCTION. HYPOTHESIS. OBJECTIVES

Nowadays, laser refractive surgery is one of the most widely used methods for the permanent correction of refractive errors. However, the performance of these techniques in cases with high-magnitude astigmatism entails a number of specific challenges: the depth of stromal ablation increases proportionally with the treated spherocylindrical magnitude, raising concerns in cases with limited pachymetric reserve; the predictability of correction decreases with higher cylindrical dioptric values[35,36]; and the precision of the axial alignment of the treatment on the corresponding corneal meridian gains a proportionally greater importance [12,20,37]. In this context, the choice of surgical technique between a surface procedure such as Trans-PRK and a flap-based procedure (FS-LASIK) is guided by the preoperative refractive profile and by the corneal biomechanical considerations specific to each case. **Hypothesis and objectives:** the evaluation of the one-month postoperative outcomes obtained with two techniques available on the same platform (Alcon WaveLight Refractive Suite, Alcon Laboratories Inc., Fort Worth, TX, USA): **StreamLight Trans-PRK** (single-step transepithelial photorefractive keratectomy, a technique introduced rather recently into clinical practice) and **FS-LASIK** (femtosecond laser-assisted in situ keratomileusis with a corneal flap created using the femtosecond laser, an established and widely used technique). The specific **objectives** included the evaluation of **visual and refractive outcomes**, the **Alpins vector analysis of astigmatic correction** accuracy (conducted at the early one-month postoperative time point), the descriptive evaluation of **refractive stability** in the subgroup with extended follow-up, the characterization of the **safety profile**, and the measurement of **independence from optical correction**. Given that the procedural allocation followed clinical criteria and not a randomized protocol, the study is not constructed as a direct comparison between the two techniques, but as an evaluation of each surgical technique, presented within the same methodological design. The results of the StreamLight Trans-PRK cohort are reported in the article “*Early Visual, Refractive and Astigmatism Vector Outcomes of StreamLight Trans-PRK for High Astigmatism (≥ 2.00 D)*” in the Romanian Journal of Ophthalmology[29]; the FS-LASIK cohort is presented in the thesis as complementary data.

4.2. PATIENTS AND METHOD

4.2.1 Study population:

The cohort included 218 eyes from 135 consecutive patients with preoperative manifest refractive cylinder ≥ 2.00 D, operated at the ALCOR Clinic, Bucharest, between January 2021 and December 2025, on the Alcon WaveLight platform, by the same surgeon. The surgical technique was determined on clinical criteria and indication, independently of the conduct of this study: **171 eyes** (78.4%) were operated by **StreamLight Trans-PRK** (mean preoperative refractive cylinder 3.29 ± 0.81 D) and **47 eyes** (21.6%) by **FS-LASIK** (mean preoperative cylinder 3.85 ± 0.94 D). The additional inclusion criteria were: age ≥ 18 years, emmetropic target, absence of corneal cross-linking, and availability of postoperative data at the 1-month follow-up visit. The exclusion criteria were: history of ocular surgery, keratoconus, cases lost to follow-up before the primary analysis time point, or incomplete electronic patient record.

4.2.2 Preoperative assessment

All patients underwent a complete refractive surgery ophthalmological evaluation: patient history, slit-lamp examination, ocular surface assessment, measurement of UDVA and CDVA, manifest and cycloplegic refraction, tonometry, ophthalmoscopy under pharmacological mydriasis, and anterior segment imaging investigations. Corneal topography, tomography, pachymetry and anterior segment biometry were performed with the imaging system incorporated in the Alcon WaveLight refractive suite: the WaveLight Oculyzer II and the WaveLight Topolyzer Vario (WaveLight AG, Erlangen, Germany). Soft contact lens wearers discontinued wear 10–14 days before the preoperative assessment. The treatment plan and the ablation profile were established by the surgical team, integrating keratometric, topographic, and biometric measurements from the different imaging modalities. All cases included in this analysis presented regular astigmatism, and the surgical parameters were calculated using the computer system integrated with the excimer and femtosecond laser of the refractive platform. The ablation used wavefront optimised profiles. All cases targeted emmetropia.

4.2.3 Surgical procedure

All interventions were performed under topical anesthesia, on the Alcon WaveLight Refractive Suite, comprising the EX500 excimer laser and, for FS-LASIK cases, the FS200 femtosecond laser. The integrated eye-tracking and cyclotorsion-compensation systems were active throughout the operations. In Trans-PRK, the epithelial and stromal ablations were performed in the same continuous step, using the EX500 laser. At the end of the ablation, mitomycin C 0.02% was applied. At the conclusion of the operation, a therapeutic contact lens was applied. In FS-LASIK cases, after docking to the suction cone, the corneal flap was created with the FS200 laser; after lifting the flap, the stromal ablation was performed with the EX500 laser, followed by repositioning of the flap. No case included in this study presented intraoperative complications. The standard postoperative treatment regimen included topical antibiotic and topical corticosteroid anti-inflammatory on a tapering schedule.

4.2.4 Follow-up

The primary analysis was conducted on the **1-month follow-up** visit, which assessed UDVA, CDVA, manifest refraction, and slit-lamp examination. A subgroup of 75 eyes with extended postoperative follow-up allowed the descriptive analysis of refractive stability. Independence from optical correction was analyzed at patient level, to functionally evaluate the outcome of the refractive surgery, and was defined in this study as the absence of an optical correction prescription issuance in the electronic patient record.

4.2.5 Statistical analysis

The descriptive comparison between the preoperative characteristics of the two cohorts used the Welch t-test for continuous variables, and the Pearson χ^2 test or Fisher's exact test for categorical variables. A single-eye-per-patient sensitivity analysis was applied to the primary visual and refractive parameters (UDVA, CDVA, SE, residual cylinder).

4.2.6 Vector analysis of astigmatism

The vector analysis was performed according to the method detailed in subchapter 4.4 of the general research methodology, at the corneal plane; the preoperative astigmatism used to calculate the target-induced astigmatism vector (TIA) was the manifest refractive cylinder converted to the corneal plane. The targeted refraction was emmetropia in all cases. Thus, the vectors and indices calculated were: TIA, SIA, the difference vector (DV), the correction index ($CI = SIA/TIA$), the index of success ($IOS = DV/TIA$), the magnitude of error (ME),

and the angle of error (AoE). The graphs were generated according to the standard format[33] using the mEYEstro software[38]. The vector diagrams were produced with AstigMATIC[39], and the synthetic tables of vector parameters were generated with the AstigMETRICS software [40].

4.2.7 Methodological limitations

The most important limitation was the short follow-up interval at which the primary analysis was reported, particularly for the Trans-PRK cohort (in which the healing of the corneal epithelium continues over a longer period[41]). The sub-analysis of eyes with additional visits (subchapter 5.3.6) represents an attempt to partially mitigate this limitation but is strictly descriptive owing to the suboptimal follow-up presentation rate and the non-uniform distribution of analysis time points. Second, the non-randomized allocation of the surgical technique produces two cohorts with different preoperative refractive profiles, which precludes the use of this research for a statistical comparison between Trans-PRK and FS-LASIK. Consequently, the results are reported per technique, and the differences between cohorts are strictly descriptive. Third, the presence of bilateral cases (61.5% of patients) introduces a partial dependence between observations, addressed through a sensitivity analysis. Finally, the significantly different sizes of the two cohorts (171 vs 47 eyes) may affect the precision of the findings for the FS-LASIK cohort.

4.3. RESULTS

4.3.1 Demographic data and preoperative clinical profile[29]

The demographic characteristics did not show significant differences between the cases undergoing Trans-PRK or FS-LASIK (age $p = 0.053$; sex distribution $p = 0.913$). Preoperative visual acuities were not significantly different between the two cohorts, for both corrected and uncorrected VA. The **Trans-PRK cohort was composed predominantly of eyes with myopic astigmatism** (69.6%; preoperative SE -2.73 ± 2.56 D), whereas the **FS-LASIK cohort** includes a majority of eyes with **hyperopic or mixed astigmatism** (89.4%; preoperative SE $+1.06 \pm 2.92$ D), with a value of $p < 0.001$ for the type of astigmatism. The difference between the mean SE of the two cohorts is approximately 3.8 D ($p < 0.001$). Both refractive, as well as keratometric astigmatism showed differences between groups, $p < 0.001$. The distribution of astigmatism orientation was similar between cohorts, with a marked predominance of with-the-rule orientation in both groups (94.7%

Trans-PRK, 95.7% FS-LASIK; $p = 0.393$). Mean central pachymetry, 542 ± 35 vs 554 ± 30 μm , differed between the two groups ($p = 0.022$). These differences reflect in fact the clinical criteria underlying the procedural allocation: patients with predominantly myopic astigmatism and lower central pachymetry were directed toward Trans-PRK, owing to the technique's superior safety profile in this context, while patients with hyperopic or mixed astigmatism and adequate pachymetry were directed toward FS-LASIK. Thus, **two distinct clinical cohorts can be observed**, and the study's primary results are presented per technique, separately for each cohort, not comparatively.

4.3.2 Visual and refractive outcomes at 1 month postoperatively for Trans-PRK

Postoperative UDVA was 0.05 ± 0.09 logMAR[29]. The cumulative proportion of the Snellen VA: 60% of eyes achieved UDVA $\geq 20/20$ and 98% $\geq 20/40$ (Fig. 4.1)[29]. CDVA was 0.03 ± 0.07 logMAR, superior to the preoperative CDVA (0.06 ± 0.10 logMAR), confirming the absence of best-corrected acuity loss[29]. From a clinical standpoint, 83 patients (78.30%) achieved spectacle independence at one month. The efficacy index was 1.04 ± 0.22 , with 96% of eyes within a single-line difference between CDVA and UDVA[29] (Fig. 4.1, panel B). The safety index was 1.10 ± 0.22 ; 99% of eyes maintained or gained lines of CDVA and no eye showed a loss of ≥ 2 lines of CDVA (Fig. 4.1, panel C). SE showed a mean of -0.22 ± 0.47 D (Figure 4.1, D), a slight residual myopic shift[29]. The distribution of SE accuracy relative to the planned emmetropic objective showed 71.3% within ± 0.50 D and 97.1% within ± 1.00 D (Fig. 4.1, D)[24]. Linear regression of the achieved SE against intended SE generated a slope of 1.04 ($R^2 = 0.97$), demonstrating high refractive predictability across the entire range of treated diopters (mean SE -2.73 ± 2.56 D, range -8.12 to $+3.75$ D)[29]. (Fig. 4.1, panel E). The mean postoperative residual refractive cylinder (in absolute value) was 0.65 ± 0.44 D[29] (Fig. 4.1, G). The cumulative distribution of residual astigmatism showed that 53.2% of eyes fell below 0.50 D of cylinder and 90.1% below 1.00 D[29].

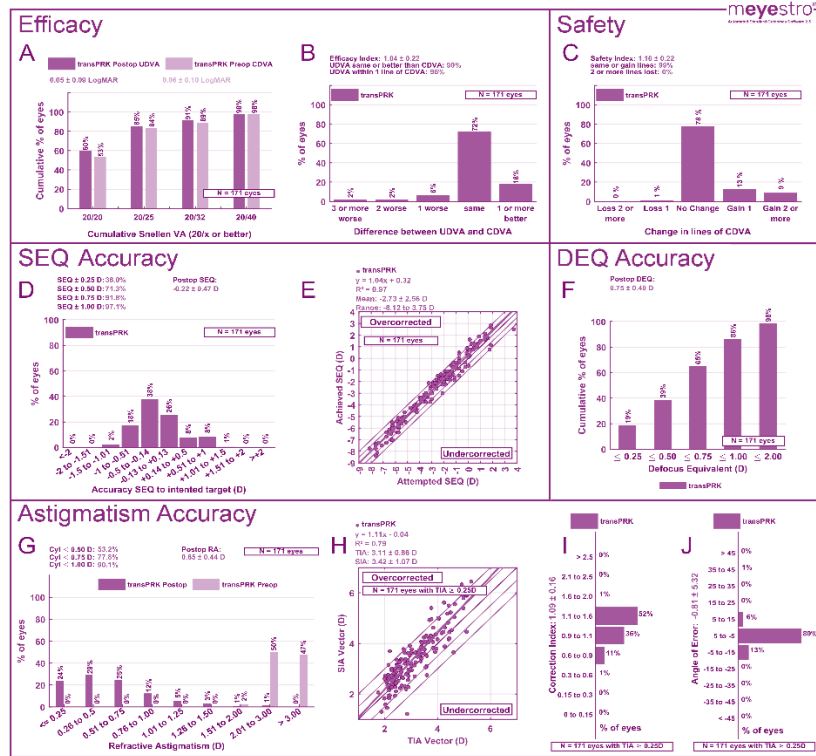


Fig. 4.1. Standard Graphs for Trans-PRK ($n=171$), adapted from Prodescu et al., 2026[29]

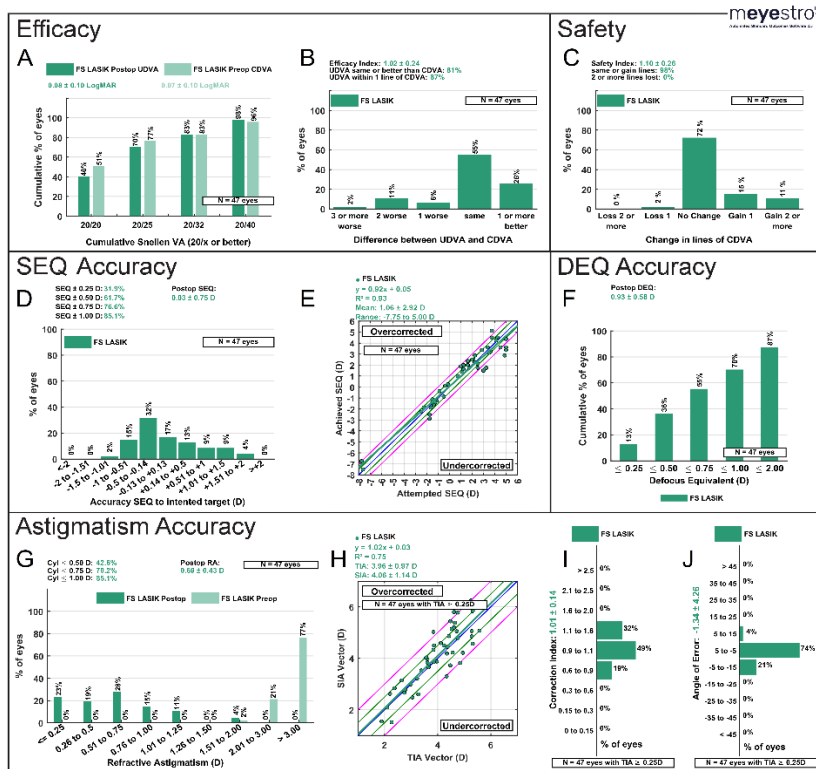


Fig. 4.2. Standard Graphs for FS-LASIK ($n=47$)

4.3.3 Visual and refractive outcomes at 1 month postoperatively for FS-LASIK

Postoperative UDVA was 0.08 ± 0.10 logMAR at one month (Fig. 4.2, A): 40% of eyes achieved UDVA $\geq 20/20$ and 98% $\geq 20/40$. Postoperative CDVA was 0.04 ± 0.07 logMAR, indicating an improvement over preoperative CDVA (0.07 ± 0.10 logMAR), and no eye lost ≥ 2 lines of CDVA (Fig. 4.2, C). Reported at patient level, independence from optical correction at one month was achieved in 79.3% of patients. The **efficacy index was above unity (1.02 ± 0.24)**, with 81% of eyes showing postoperative UDVA $\geq$ preoperative CDVA and 87% within a single Snellen line of difference (Fig. 4.2, B). The **safety index, also above unity, was 1.10 ± 0.26** , and 98% of eyes maintained or gained lines of CDVA, with 15% gaining one line and 11% gaining two or more lines. SE was $+0.03 \pm 0.75$ D (Fig. 4.2, D), close to the targeted emmetropic objective. The distribution of SE accuracy relative to the target showed 61.7% within ± 0.50 D and 85.1% within ± 1.00 D. Linear regression of the achieved postoperative SE against the intended SE generated a slope of 0.92 ($R^2 = 0.93$), demonstrating **good refractive predictability across the entire range of treated diopters** (mean SE $+1.06 \pm 2.92$ D, range -7.75 to $+5.00$ D) (Fig. 4.2, E). The mean postoperative residual refractive cylinder was 0.69 ± 0.43 D at the spectacle plane (Fig. 4.2, G). The cumulative distribution of residual astigmatism showed that 42.6% of eyes fell below 0.50 D and 85.1% below 1.00 D.

4.3.4 Vector analysis for Trans-PRK[29]

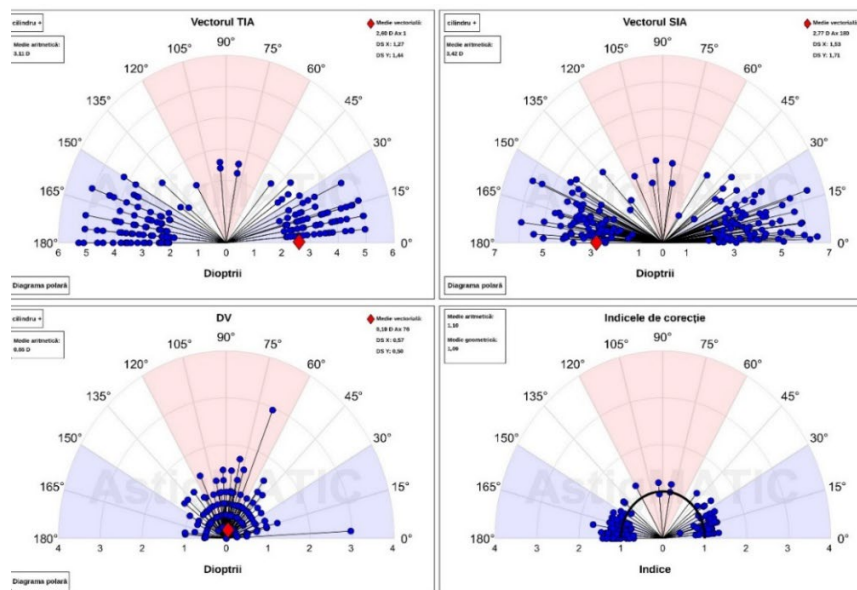


Fig. 4.3. Vector plots for StreamLight Trans-PRK ($n = 171$, corneal plane TIA, SIA, DV, CI). **Source:** adapted from Prodescu et al., 2026[29]

The target astigmatism (TIA, the planned astigmatic correction) had an arithmetic mean magnitude of 3.11 ± 0.86 D, with a vector mean of 2.60 D at an axis of 1° (Fig. 4.3)[29]. The SIA (the astigmatic change actually produced by the surgical procedure) had an arithmetic mean magnitude of 3.42 ± 1.07 D, with a vector mean of 2.77 D at an axis of 180° (Fig.4.3), closely aligned with the TIA axis[29]. The DV, the magnitude of the residual astigmatic error, had an arithmetic mean of 0.65 ± 0.44 D, with a vector mean of 0.19 D at an axis of 76° [29]. The angular difference between the SIA and TIA axes had a mean of $-0.81^\circ \pm 5.32^\circ$, indicating excellent accuracy of alignment with no systematic tendency toward a specific orientation[29]. The distribution of AoE showed that 80% of eyes were within $\pm 5^\circ$ of the intended axis, and 99% within $\pm 15^\circ$ [29]. The correction index (SIA/TIA) had an arithmetic mean of 1.09 ± 0.16 (geometric median 1.08), slightly above the ideal value of 1.0, suggesting a slight tendency toward overcorrection at the cohort level at the one-month time point[29]; 36% of eyes were within the target range (CI 0.9–1.1), 11% were undercorrected (CI 0.6–0.9), and 53% showed overcorrection (CI >1.1)[29]. The index of success showed a mean value of 0.21 ± 0.14 [29]. The magnitude of error (the difference between the SIA and TIA magnitudes) had a mean of 0.31 ± 0.50 D, with 64.9% of eyes within ± 0.50 D and 93.0% within ± 1.00 D[29]. Linear regression of SIA versus TIA generated a slope of 1.11 ($R^2 = 0.79$), confirming the tendency toward overcorrection consistent with the value of the correction index[29] (Fig. 4.1 and 4.3).

4.3.1 Vector analysis for FS-LASIK

The target-induced astigmatism had a mean magnitude of 3.96 ± 0.97 D, with a vector mean of 3.45 D at an axis of 180° (Fig. 4.4). The surgically-induced astigmatism had an arithmetic mean of 4.06 ± 1.14 D, with a vector mean of 3.44 D at 178° , closely aligned with the TIA axis. The difference vector showed an arithmetic mean of 0.69 ± 0.44 D, and a vector mean of 0.14 D at an axis of 42° (Fig. 4.4). The AoE had a mean of $-1.34^\circ \pm 4.26^\circ$, indicating excellent accuracy of the surgical treatment regarding the alignment of the correction on the planned axis and with low variability; 74% of eyes fell within $\pm 5^\circ$ of the intended axis, and **100% within $\pm 15^\circ$** . The CI had an arithmetic mean of **1.01 ± 0.14** (geometric median 1.01), a value almost identical to the ideal of 1.0, indicating an **astigmatic correction centered on the intended refractive target**, with no systematic tendency toward over- or undercorrection at the cohort level; 49% of eyes fell within the target range (CI 0.9–1.1), 19% showed undercorrection, and 32% slight overcorrection (CI 1.1–1.6). The index of success had a mean value of 0.18 ± 0.12 . The magnitude of error showed a mean of $0.10 \pm$

0.57 D, with 61.7% of eyes within ± 0.50 D and 89.4% within ± 1.00 D. The SIA vs TIA plot (Fig. 4.2) generated a slope of 1.02 ($R^2 = 0.75$), **confirming an almost direct relationship between the intended and the achieved astigmatic correction, across the entire range of treated diopters.**

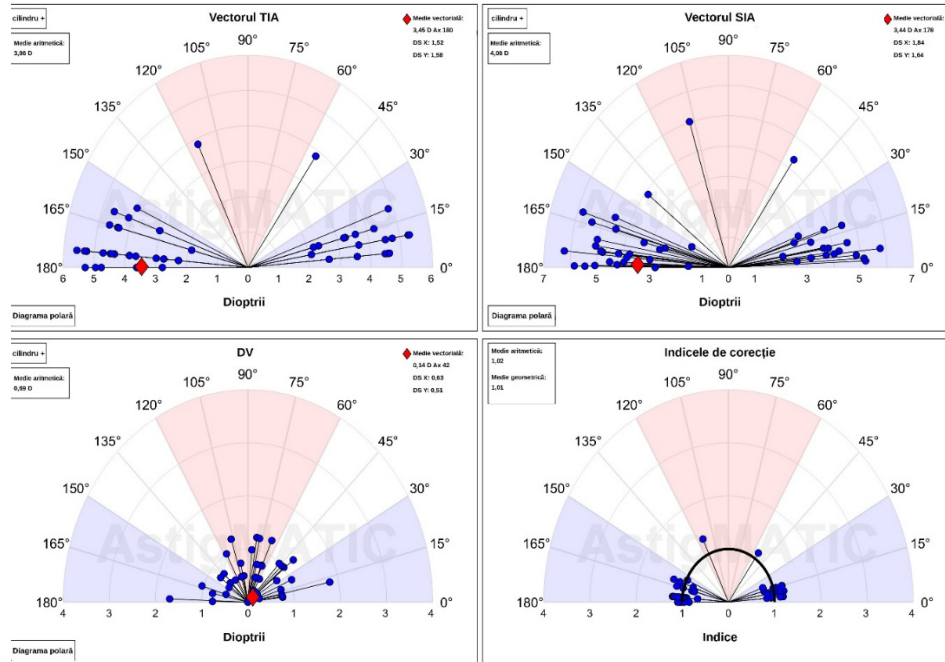


Fig. 4.4. Vector plots for FS-LASIK ($n = 47$, corneal plane TIA, SIA, DV, CI)

4.3.2 Refractive stability sub-analysis in eyes with extended follow-up

The overall presentation rates at later follow-up visits were low: 57 of 171 eyes (33.3%) in the Trans-PRK cohort and 18 of 47 eyes (38.3%) in the FS-LASIK cohort. In the Trans-PRK cohort (mean follow-up of 10.3 ± 7.4 months postoperatively, median 7.2 months)[29], SE showed minimal change, from -0.14 ± 0.45 D to -0.07 ± 0.51 D, as a slight shift toward emmetropia[29]. The standard deviation of the mean SE remained similar, indicating that the statistical spread of the results did not widen over time[29]. The mean residual refractive cylinder, however, remained practically unchanged, from 0.61 ± 0.37 D at one month to 0.61 ± 0.43 D at the subsequent available visit, indicating the absence of progressive astigmatic degradation over this interval[29]. UDVA and CDVA were maintained at similar levels to those at one month. Notably, however, that the proportion of eyes in which a change > 0.50 D in SE occurred between the two time points was 22.81%, suggesting that individual changes, of potential clinical relevance, may occur in some eyes[29]. No new cases of late-onset corneal haze were identified. In the FS-LASIK cohort (18 eyes, mean follow-up of 8.08 months postoperatively, median 6.9 months), SE showed

a slight hyperopic shift, from -0.22 ± 0.64 D to $+0.06 \pm 0.57$ D. The mean residual refractive cylinder remained relatively stable, with a slight increase from 0.54 ± 0.47 D at one month to 0.60 ± 0.40 D at the subsequent visit, a difference without clinical significance. UDVA and CDVA were maintained at levels comparable to those at one month. The proportion of eyes with a change > 0.50 D in SE between the two time points was 11.11%. No new cases of late complications or signs of corneal ectasia were identified during the follow-up period.

4.3.3 Postoperative complications for trans-PRK

Corneal **haze** was observed in **17 eyes** (9.9%)[29]. The cases were managed with topical corticosteroid anti-inflammatory and followed clinically. Dry eye symptoms were reported in 13 eyes (7.6%) and were managed by prolonged administration of preservative-free tear substitutes[29]. Dysphotopsia were reported by 2 patients (1.2%)[29].

4.3.4 Postoperative complications for FS-LASIK

Symptomatic **dry eye** syndrome was the most frequent complication, reported in 4 eyes (8.51%), and was managed through prolonged administration of preservative-free artificial tears. A central corneal erosion was identified in 1 eye (2.13%) and resolved without sequelae under topical treatment. One case (2.13%) presented chromatic-aberration phenomena.

4.4. CONCLUSIONS

Both StreamLight Trans-PRK and FS-LASIK represent high-performing therapeutic options in the correction of astigmatism ≥ 2.00 D, with **good visual, refractive, and functional outcomes, a favorable safety profile, and high vectorial accuracy**. The selection between the two techniques remains an individualized decision depending on the preoperative refractive and pachymetric characteristics. The signal of intra-individual refractive instability observed in a larger proportion of Trans-PRK eyes **justifies extended postoperative follow-up over a longer period** for this technique, in order to fully portray medium- and long-term stability.

5. SYNTHESIS OF STUDY 2 (CHAPTER 6)

5.1. INTRODUCTION. HYPOTHESIS. OBJECTIVES

This chapter presents the results of the study on astigmatism correction through toric intraocular lens (IOL) implantation, published in the article “*Early Real-World Clinical Outcomes and Astigmatism Vector Analysis of Toric Intraocular Lenses for High Astigmatism (≥ 2.0 D)*” in the Journal of Clinical Medicine[28]. Toric IOL implantation represents the method of choice in routine clinical practice for the correction of astigmatism in the context of lens-based surgery, whether cataract surgery or refractive lens exchange (RLE) [5,7] that is electively performed in presbyopic patients with associated astigmatic refractive errors, using presbyopia correcting toric IOLs[5,16]. However, in the particular context of high-magnitude astigmatism, the relative contribution of specific preoperative parameters such as the magnitude and orientation of astigmatism, axial length, the contribution of the posterior corneal surface as well as of the surgical parameters (the cylindrical power of the IOL, the type of IOL used, the calculation formula, its rotational stability) is not fully explained[21,42,43]. Moreover, sensitivity to alignment errors in the case of postoperative rotation are amplified at higher cylindrical magnitudes[4,21]. The **study hypothesis** is that **toric IOL implantation provides effective and predictable astigmatic correction in a heterogeneous cohort with high-magnitude preoperative astigmatism**, with favourable visual, refractive, and vectorial outcomes, and that the **identification of independent predictive factors of residual astigmatic error** is possible. The **objectives of the study** consist of: **visual, refractive, and vectorial evaluation** of astigmatism correction through toric IOL implantation at 1 month postoperatively, the identification of **independent predictive factors of astigmatism** (multivariate regression), the evaluation of **refractive stability** in the subgroup with extended follow-up, the comparison of results between the different refractive strategies implemented (**emmetropic target vs intentional myopic target**) and between surgical indications (**cataract vs RLE**), the evaluation of **spectacle independence** postoperatively, and the **safety profile** of the procedure.

5.2. PATIENTS AND METHOD

The study represents a retrospective analysis of toric IOL implantation results, in a real-world setting, conducted at the ALCOR Clinic between June 2023 and December 2025.

All surgical procedures were performed by the same surgeon, using the same surgical platform.

5.2.1 Study population

Inclusion and exclusion criteria. The cohort was composed of **consecutive** patients who underwent lens-based surgery with toric intraocular lens (IOL) implantation, either for cataract surgery or for refractive lens exchange (RLE). The main inclusion criterion was the presence of **preoperative corneal astigmatism ≥ 2.00 D**. **Additional inclusion criteria:** age ≥ 18 years, availability of complete postoperative data at the 1-month follow-up visit. **Exclusion criteria:** refusal to take part in the study, loss to follow-up before the primary end point, lack of / incomplete data in the electronic medical record, history of corneal refractive surgery. After applying the inclusion and exclusion criteria, the final cohort comprised **161 eyes** from **118 consecutive patients**. ***Methodological considerations.*** The deliberate heterogenous nature of the cohort (cataract surgery/RLE surgery, different toric IOL models, different refractive targets, the selective use of a capsular tension ring) introduces a clinical variability that limits the statistical evaluations specific of each individual clinical scenario, but offers a closer picture to real-world casuistry, and as such, becomes more informative for evaluating the performance of the method under routine clinical practice conditions. Ocular comorbidities with the potential to limit visual acuity (amblyopia, glaucoma, retinal pathology, etc.) did not constitute exclusion criteria in this study because they did not alter the surgical planning or the validity of the vector analysis (which evaluates the outcome independently of the final visual potential), and their inclusion reflects the real population encountered in clinical practice (a sensitivity analysis excluding these cases was, however, performed separately and is presented in the thesis' Appendix). ***Treatment planning and refractive strategies.*** No clinical, therapeutic, or surgical decision was determined by randomization. Monovision strategy was not applied in any case in this cohort.

5.2.2 Preoperative assessment and surgical planning

Preoperative ophthalmological examination[28]: complete ophthalmological examination, visual acuities (UDVA, CDVA, measured in decimal notation, subsequently converted to Snellen and to logMAR), manifest refraction, IOP, slit-lamp examination, and fundus examination (in cases with advanced cataract that prevented fundoscopic visualization, B-mode ultrasonography was performed), macular or optic-nerve OCT, or other paraclinical examinations performed according to the clinical indication. Preoperative

refraction was measurable in 130 of 161 eyes; the vector analysis of astigmatic correction was based on preoperative corneal astigmatism obtained from biometry, which was available in all 161 eyes. ***Biometry and corneal astigmatism measurement***[28]: Ocular biometry was performed with ANTERION® (Heidelberg Engineering, Heidelberg, Germany), and in cases where optical biometry was not feasible owing to advanced lens opacification or extreme axial length, A-scan ultrasonography (by immersion) or another biometer was used. ***IOL selection and power calculation***: The spherical and cylindrical dioptric power and the alignment axis were calculated using toric calculators (Alcon Toric Calculator, ESCRS Toric IOL Calculator, and Zeiss Toric Calculator), and for the spherical power of the IOL the Kane formula (44.1%), the Barrett Universal II formula (31.1%), or the proprietary Zeiss formula (24.7%) was used[28]. The implanted toric IOL models: toric monofocals (Alcon AcrySof IQ Toric, Alcon Clareon Toric, Zeiss AT TORBI), toric trifocals (Zeiss AT LISA Tri Toric, Alcon AcrySof IQ PanOptix Toric), and toric extended-depth-of-focus (EDOF) (Alcon AcrySof IQ Vivify Toric, SIFI Miniwell Toric) [28].

5.2.3 Surgical Technique and postoperative protocol

Surgical technique. All surgical procedures were performed by the same surgeon on the Centurion® Vision System (Alcon Healthcare, Fort Worth, TX, USA) under topical or retrobulbar anesthesia. Preoperative marking of the toric axis was performed at the slit lamp. The standard surgical technique involved a 2.2 mm triplanar main incision, placed at 170–180° (or 0–10° in left eyes) in most cases, or on-axis in selected cases, secondary paracenteses, followed by the placement of an AC maintainer. The standard surgical steps were: capsulorhexis, hydrodissection and hydrodelineation, phacoemulsification, irrigation and aspiration of cortical material, polishing of the posterior capsule, and implantation of the toric IOL using an injector. IOL was aligned on the axis marked preoperatively. Both dispersive and cohesive viscoelastic materials were used, the entire viscoelastic material being removed at the end of the procedure. The wounds were hydrosutured at the end of the operation. In eyes presenting zonular laxity or high axial myopia, a **capsular tension ring** was implanted to optimize the postoperative stability of the IOL within the capsular bag ($n = 28$ eyes, 17.4% of the cohort[28]). In some cases, additional procedures were performed: pupilloplasty in one case of post-traumatic cataract, intravitreal anti-VEGF injection in two cases with pre-existing macular pathology, and synechiolysis in one eye [28]. ***Intraoperative events***[28]: one posterior capsule rupture was managed by anterior vitrectomy but allowed the successful implantation and alignment of the planned IOL in the capsular bag, and in

another case a corneal suture was prophylactically placed at the main incision and removed at 3 weeks postoperatively. **Postoperative protocol.** Topical treatment with antibiotic, corticosteroid, and artificial-tear ophthalmic solutions with gradual tapering.

5.2.4 Postoperative follow-up and primary outcomes

The 1-month visit constituted the primary endpoint for collecting postoperative data: UDVA, CDVA, manifest refraction, evaluation of spectacle (in)dependence, ophthalmological examination, and assessment of complications. Patients with postoperative corneal edema or increased IOP were re-evaluated more frequently. A subgroup of patients had extended follow-up data available beyond the 1-month time point ($n = 75$ eyes); these data were used for the refractive stability analysis. Spectacle independence was evaluated at the patient level ($n = 118$), based on the issuance of an optical correction prescription documented at the 1-month visit. The achievement of the planned functional refractive outcome according to the preoperatively established strategy was defined as an indicator of specific success: for monofocal eyes with myopic target – distance correction only; for monofocal eyes with emmetropic target – reading correction only; for eyes implanted with multifocal/EDOF IOLs – complete independence from optical correction[28].

5.2.5 Statistical analysis

For the **stratified sub-analyses** (subchapter 6.3.6), the following subgroups were defined: emmetropic target (targeted SE ≥ -0.50 D) vs myopic target (targeted SE between -1.00 and -2.50 D); cataract vs RLE; and the extended-follow-up sub-group[28]. Between-group analyses used the Mann-Whitney U test for continuous variables (the Student t-test for normally distributed variables), the Chi-square test or Fisher's exact test for categorical variables. The multivariate linear regression analysis for identifying predictive factors of residual astigmatic error used univariate screening as a preliminary step (variables with $p < 0.20$ were included in the multivariate model). The Spearman correlation coefficient was calculated as a non-parametric sensitivity analysis for the identified predictive factors.

5.2.6 Vector analysis

Keratometric astigmatism was used as preoperative astigmatism vector data. The target refraction was that of the predicted refraction provided by the IOL formulae. The calculated vectors are presented in detail in Chapter 4, General Methodology (TIA, SIA, DV, AoE), as well as the derived indices (CI, IOS). The vector calculations used Microsoft Excel and

AstigMETRICS[40]; the graphical representation of the astigmatic vectors used the ASCRS Astigmatism Double Angle Plot Tool for Excel[44], and the standardized graphs of refractive outcomes were generated with mEYEstro[38]. The box plot representation of the refractive astigmatism prediction error was produced using Eyetemis Analysis Tool[45]. To assess the robustness of the vector analysis, a sensitivity analysis was performed excluding the two eyes with intraoperative events ($n = 159$).

5.2.7 Methodological limitations of the study[28]

The study design induces several limitations deriving from the characteristics of the cohort and of the setting: the data analysis is retrospective; the design is single-center and single-surgeon (which, although it ensures procedural uniformity, it limits the generalizability of the results); 36.4% of patients contributed two eyes to the analysis (bilateral cases); the extended-follow-up subgroup ($n = 75$ eyes) included a limited number of patients; no systematic documentation of postoperative IOL rotation data in the patient records. In addition, the heterogeneity induced by different surgical indications or toric IOL models, and the inclusion of eyes with pre-existing pathologies limits the interpretation of this study's results regarding the evaluation of a particular IOL, a specific biometer, or a specific toric calculation formula.

5.3. RESULTS

5.3.1 General characteristics of the study cohort

The mean age at surgery was 64.1 ± 15.1 years, with a left-skewed distribution, reflecting the inclusion of a subgroup of younger patients[28]. Bilateral cases represented 36.4% of patients. The majority of eyes were operated for cataract (82.6%), the remainder for refractive clear lens exchange (17.4%); the refractive target was emmetropia in 70.2% of eyes and residual myopia in 29.8%, this latter category predominantly including patients with high axial myopia[28]. Preoperative corneal astigmatism was 2.66 ± 1.23 D, with a slightly right-skewed distribution[28]; 26.1% (42 eyes) exceeded the 3.0 D threshold and 11.2% (18 eyes) the 4.0 D threshold, indicating the presence of a substantial subgroup of very-high-magnitude astigmatism eyes[28]. The distribution according to axis orientation: with-the-rule astigmatism (52.2%), followed by against-the-rule (40.4%); oblique astigmatism, 7.5%[28]. The biometric parameters reflected the heterogeneity of the cohort:

the mean axial length was 24.73 ± 2.40 mm, and 23.6% of eyes had an axial length >26 mm[28].

5.3.2 Surgical characteristics

Distribution of toric IOLs: monofocal (78.9%) presbyopia-correcting IOLs (trifocal or EDOF, 21.1%)[28]. The breakdown by individual model is presented in the thesis Appendix 3. The cylindrical power of the IOLs was above 3 D in 33.5% eyes[28]. Capsular tension ring was used in 17.4% eyes, predominantly in those with high AL. The main incision was placed temporally at $170\text{--}180^\circ$ in 82.0% of cases, and on-axis in 18.0% of eyes[28].

5.3.3 Visual and refractive outcomes[28]

The standard graphical representation of the outcomes is synthetically presented in the figure below.

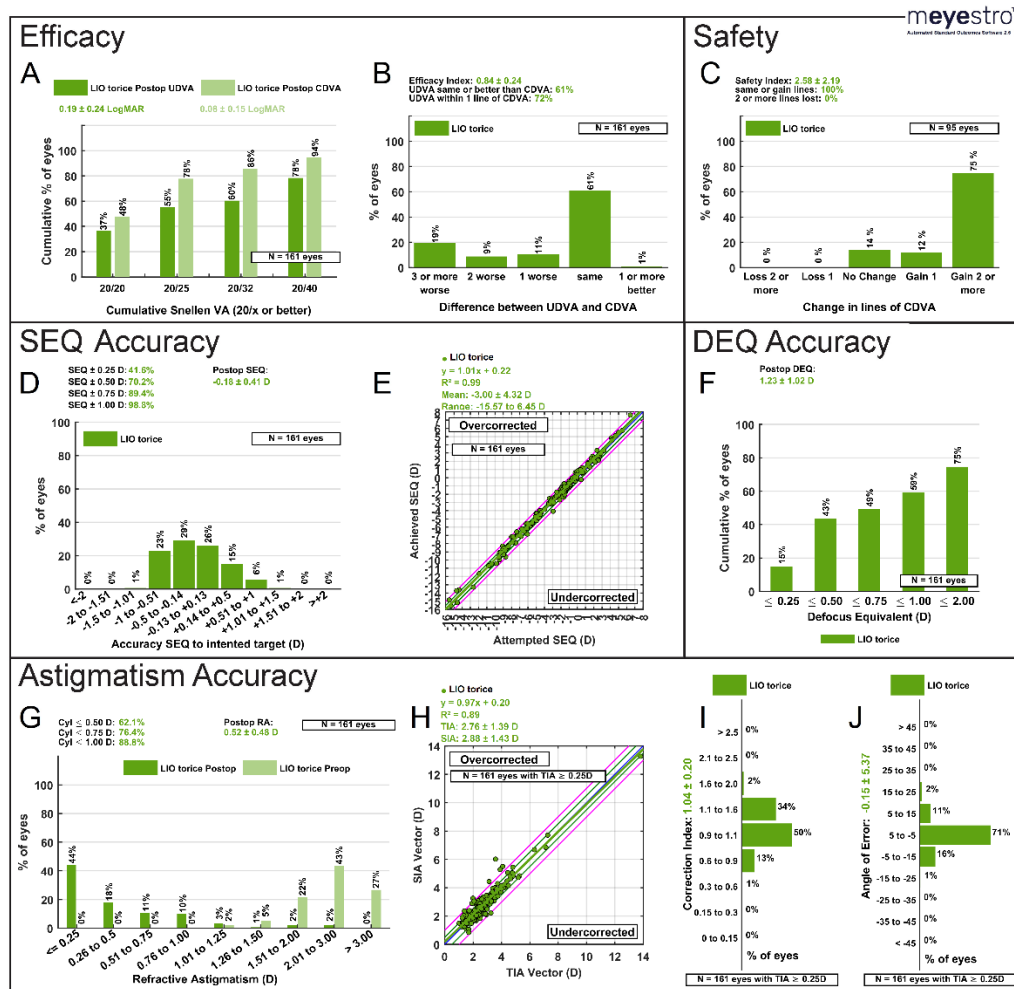


Fig. 5.1 Standard Graphs of Study 2 Visual and Refractive Outcomes. (A) Cumulative VA, (B) Difference between UDVA and CDVA, (C) Safety – CDVA change, (D) SE accuracy (E) Achieved vs Attempted SE, (F) Defocus Equivalent Accuracy, (G) Refractive Astigmatism Histogram, (H) TIA vs SIA, (I) CI Histogram, (J) AoE histogram. Graphs generated with mEYestro[38]. Source: adapted from Prodescu et al., 2026[28].

UDVA improved significantly, from 1.29 ± 0.67 preoperatively to 0.19 ± 0.24 logMAR postoperatively at 1 month, and **CDVA** also increased from 0.55 ± 0.51 to 0.09 ± 0.15 logMAR[28]; 37% of eyes achieved uncorrected vision of 20/20 and 48% best-corrected vision of 20/20[28]. The difference observed between the distributions of postoperative visual acuities with and without correction partly reflects the 29.8% of eyes with an intentionally myopic refractive target (~ -2.50 D). The sensitivity analysis restricted to the 126 eyes without preoperatively documented ocular comorbidities showed a mean postoperative UDVA of 0.11 ± 0.15 logMAR (median 0.05) and a mean postoperative CDVA of 0.03 ± 0.05 logMAR (median 0.00), confirming the performance of the procedure in the absence of the confounding factors associated with ocular comorbidities[28]. **SE accuracy relative to the planned target was high**, with 69.6% of eyes (112) within ± 0.50 D of target and 98.1% (158 eyes) within ± 1.00 D[28]. The mean prediction error for the spherical equivalent was -0.19 ± 0.42 D (median -0.18 D), indicating a slight myopic shift, possibly associated with the presence of a significant proportion of eyes with high AL in the cohort (23.6% of cases >26 mm) [28]. The regression line between the targeted and achieved SE had a slope of 1.01 with $R^2 = 0.99$ (range of preoperative SE values: from -15.57 D to $+6.45$ D), confirming **excellent SE predictability across the entire range of the cohort's ametropias**[28]. The residual refractive astigmatism showed a mean of 0.52 ± 0.48 D, decreasing from 2.80 ± 1.29 D preoperatively[28]. The clinical threshold of 0.50 D was achieved by 62.1% of eyes (100 eyes), and the 1.00 D threshold by 88.8% (143 eyes); only 11.2% (18 eyes) showed residual astigmatism above 1.00 D[28]. The **safety index** (calculated on $n = 95$ eyes with preoperative VA measurable in Snellen lines) was 2.58 ± 2.19 , a value that reflects the substantial visual rehabilitation achieved in eyes with advanced cataract; no eye showed a clinically significant loss of CDVA (≥ 2 lines), and 75% of eyes gained ≥ 2 lines[28]. The **efficacy index** was 0.84 ± 0.24 for the entire cohort and 0.87 ± 0.21 for the subgroup with an emmetropic target ($n = 113$)[28]. The postoperative defocus equivalent, integrating both the spherical and cylindrical components of the refraction into a single metric, had a mean value of 1.23 ± 1.02 D.

5.3.4 Vector analysis[28]

TIA had a mean magnitude of 2.76 ± 1.39 D and SIA of 2.88 ± 1.43 D, indicating correction was generally in concordance with the planned target[28]. DV had a mean magnitude of 0.53 ± 0.44 D (median 0.42 D), a value close to that of the mean residual refractive astigmatism of 0.52 D[28]. The slope of the TIA vs SIA regression (Fig. 5.1, H):

0.97 with $R^2 = 0.89$. The R^2 coefficient value reflects the inherently greater variability of astigmatic correction compared with SE correction ($R^2 = 0.99$ for the SE)[28]. The CI of 1.04 ± 0.20 suggests a slight tendency toward overcorrection. The distribution of the achieved correction (Fig. 5.1, I): 50.3% of eyes fell within the ideal correction range (CI 0.9–1.1), 36.0% (58 eyes) overcorrected (CI >1.1), and 13.7% (22 eyes) undercorrected (CI <0.9)[28]. The index of success had a mean value of 0.22 ± 0.18 , reflecting low magnitude of residual astigmatism relative to the corrected magnitude[28]. The mean AoE of $-0.15^\circ \pm 5.37^\circ$ (median 0°), centered around zero (Fig. 5.1, J), indicates the absence of a systematic rotational bias[28]. Its distribution was symmetric, and 97.5% were within $\pm 15^\circ$ [28]. The distribution of residual astigmatism presented in the double-angle plot at the corneal plane (Fig. 5.2) showed a centroid located at 0.03 D @ 43° , with an SD of 0.69 D[28], indicating absence of a directional prediction error bias of the toric calculator formula[28]. The absolute prediction error of refractive astigmatism was 0.53 ± 0.44 D (at the corneal plane). The sensitivity analysis excluding the two eyes with intraoperative events that might influence astigmatism measurement (posterior capsule breach and corneal suture) demonstrated similar results[28].

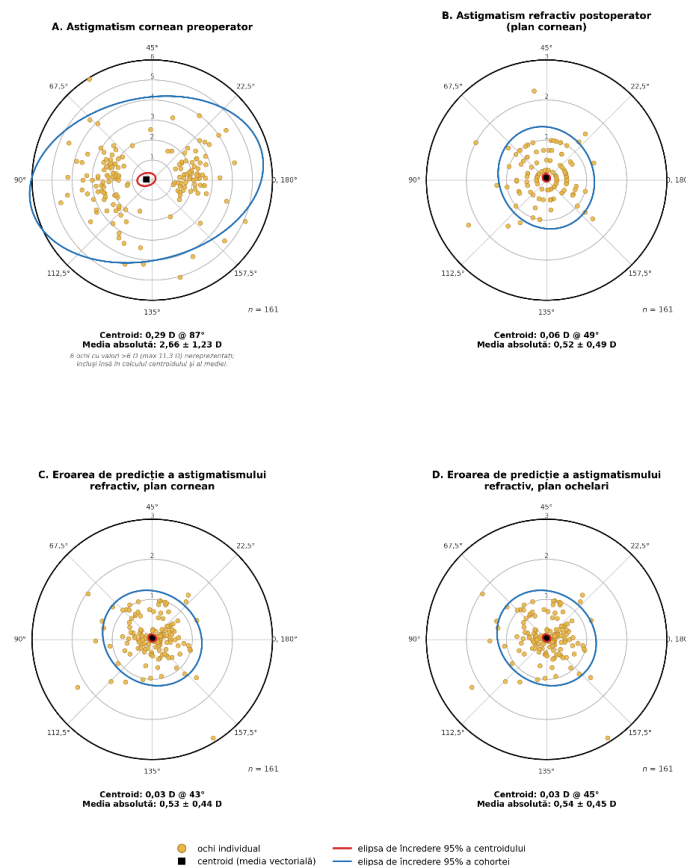


Fig. 5.2. Double-angle plots of refractive astigmatism (A – preoperative, B – postoperative, corneal plane) and refractive astigmatism prediction error (C – corneal plane, D – spectacle plane). Source: adapted from Prodescu et al. [28]

5.3.5 Multivariate analysis: predictive factors of residual astigmatic error

To identify the independent predictive factors of residual astigmatic error, the magnitude of the difference vector (DV) was used as the dependent variable (outcome variable), and candidate factors for predictive value were: demographic parameters, biometric parameters, preoperative astigmatism (magnitude and orientation), IOL parameters, and surgical parameters (use of a capsular tension ring, type of surgery, intended refractive target)[28]. The variables that reached the $p < 0.20$ in the univariate regression were included in the multivariate statistical model[28]: the cylindrical power of the IOL ($p = 0.003$), the use of a capsular tension ring ($p = 0.162$), and astigmatism orientation (categorical variable, $p = 0.041$)[28]. The multivariate model thus created explained 8.9% of the variability of DV ($R^2 = 0.089$), a modest but statistically significant value at the model level ($p = 0.005$), reflecting the complexity of the factors that influence the astigmatic refractive outcome at the individual level[28]. **Two independent predictive factors were identified for residual astigmatic error: the cylindrical power of the IOL ($\beta = 0.051$, $p = 0.031$) and the oblique orientation of preoperative astigmatism ($\beta = 0.299$, $p = 0.032$)[28].**

5.3.6 Stratified sub-analyses[28]

The heterogeneity of the study cohort allowed and at the same time imposed the implementation of sub-analyses to examine the distinct results obtained in subgroups of clinical relevance. **Refractive stability** was evaluated in 75 eyes (46.6% of the initial cohort) with extended follow-up data, mean follow-up period of 8 months. SE in this subgroup was -0.71 ± 1.24 D at 1 month and -0.68 ± 1.22 D at the last available visit, corresponding to a **mean change of $+0.02 \pm 0.31$ D**, a minimal hyperopic shift between the two time points, without clinical relevance[28]. The change in SE occurring between the two postoperative time points fell within the ± 0.50 D interval in 90.7% of eyes[28]. **Comparison of refractive strategies** (the targeted refraction planned at the time of the preoperative evaluation and used in the IOL calculator): monofocal eyes with **emmetropic target** ($n = 78$) *versus* those with **residual myopic target** ($n = 48$) demonstrated **similar accuracy** between the two groups regarding the main vectorial and refractive parameters (DV, $p = 0.310$; AoE, $p = 0.858$; residual cylinder, $p = 0.370$; % of eyes with residual cylinder ≤ 0.50 D, $p = 0.771$, and ≤ 1.00 D, $p = 1.000$) [28]. The only **statistically significant difference was the CI**: median 1.019 vs 0.975, $p = 0.049$, the eyes with an emmetropic target showing a correction slightly closer

to the intended target[28], though both values were within the ideal range (close to unity). The comparison between the indications for toric IOL implantation, **cataract versus RLE**: postoperative **UDVA and CDVA were different** between the two groups ($p = 0.043$ and $p = 0.031$, respectively), a difference that could technically be attributed to different preoperative characteristics (the RLE indication takes into account the visual potential)[28]. In terms of accuracy, the groups showed no significant differences (DV, CI, AoE, residual cylinder, SE prediction error).

5.3.7 Spectacle independence

Postoperative independence from optical correction was evaluated at the patient level ($n = 118$), and the functional success achieved, taking into account the planned refractive strategies, was: 85.3% of monofocal patients with myopic target (~ -2.50 D) required distance only correction, 72.6% of monofocal patients with an emmetropic target required reading only correction, and 63.6% of patients with multifocal or EDOF IOLs achieved complete independence from optical correction. The differences between the rates of success across the three functional strategies did not reach statistical significance (χ^2 test, $p = 0.167$), suggesting a comparable probability of achieving the planned functional outcome despite the heterogeneity of the cohort[28].

5.3.8 Complications and safety profile

Intraoperative events: a single intraoperative complication occurred — a posterior capsule rupture managed by anterior vitrectomy (1 eye, 0.6%) — without impact on IOL implantation or its positioning[28]. Corneal suture was a prophylactic measure applied in one case (0.6%) to secure the wound and was not considered an actual complication.

Postoperative complications: In the immediate postoperative period (up to 1 month), the most frequent was corneal edema (10 eyes, 6.2%), treated topically and fully resolved by the time of the 1-month assessment in all cases[28]. Raised IOP was recorded in 4 eyes (2.5%), all in patients without pre-existing glaucoma, and was managed with topical medication and adjustment of the tapering of the topical corticosteroid administration[28]. Three eyes (1.9%) presented dry-eye symptomatology. In 2 eyes (1.2%), rotation of the toric IOL by $\geq 15^\circ$ was identified (residual astigmatism of 0.75 D in both cases and satisfactory functional visual outcomes; surgical repositioning was not considered necessary) [28]. Posterior capsule opacification was detected in 7 eyes (4.3%) during the primary follow-up period, of which 4 were treated by Nd:YAG capsulotomy[28].

5.4. CONCLUSIONS

Toric IOL implantation yielded a **significant improvement in visual acuity**, high **accuracy of spherocylindrical refractive correction and vectorial outcomes** (mean DV of 0.53 ± 0.44 D, mean CI of 1.04 ± 0.20) with **good predictability and alignment** (91.9% of eyes within $\pm 10^\circ$ of the intended axis) and without systematic prediction errors bias (residual astigmatism centroid of 0.03 D @ 43°)[28].

The multivariate regression analysis identified two **independent predictive factors of residual astigmatic error**: the **cylindrical power of the implanted IOL** ($\beta = 0.051$, $p = 0.031$) and the **oblique astigmatism** ($\beta = 0.299$, $p = 0.032$), while the magnitude of preoperative astigmatism, axial length, age, type of intervention, and refractive target showed no significant associations with the residual error in this study[28].

Refractive stability in the extended-follow-up subgroup ($n = 75$) was indicated by a **clinically insignificant change in the SE** ($+0.02 \pm 0.31$ D) between the 1-month assessment and the last available follow-up, with 90.7% of eyes within ± 0.50 D of difference[28].

The comparison of results between the monofocal refractive strategies (**emmetropic target vs residual myopia**) and between surgical indications (**cataract vs RLE**) revealed **equivalent astigmatic correction accuracy** in terms of the main vectorial parameters[28].

The intended **functional outcome according to the refractive strategy** was achieved in 85.3% of patients with a myopic target, 72.6% of patients with a monofocal emmetropic-target IOL, and 63.6% of patients with toric multifocal/EDOF IOLs with regard to **spectacle independence**[28].

The **safety profile of the procedure was favorable**, with a single intraoperative complication (0.6%) and a postoperative complication rate reported at 1 month of 10.6%, with no cases of permanent vision loss[28].

Taken together, these results support the efficacy and predictability of toric IOL implantation in the correction of high astigmatism in a heterogeneous real-world cohort, with consistent performance across the spectrum of surgical indications and refractive strategies. The simultaneous identification of independent predictive factors (the cylindrical power of the IOL and oblique astigmatism) suggests the existence of specific subgroups in which the residual error is systematically higher, pointing towards further research directions toward refining toric calculation and surgical strategy in high-magnitude astigmatism.

6. SYNTHESIS OF STUDY 3 (CHAPTER 7)

6.1. INTRODUCTION. HYPOTHESIS. OBJECTIVES

The toric Visian ICL (phakic intraocular lens implanted in the ciliary sulcus, anterior to the natural crystalline lens) represents a valuable therapeutic option in young patients with high spherical or spherocylindrical ametropias that exceed the safety limits of corneal laser surgery, but who are not optimal candidates for refractive lens exchange, as that would compromise their natural accommodation. The technique offers the possibility of correcting high refractive errors and improving optical quality while demonstrating favourable safety profile that has been continuously enhanced by the introduction of modern lens designs (for example, the introduction of the KS Aquaport® central hole in the EVO/EVO+ models)[46,47], yielding stable results[48,49] while having the advantage of reversibility (the lens can be explanted in case of age-related cataract development or in the rare event of complications[50]). At the same time, the performance of the implant depends significantly on its relationships with intraocular anatomy[25,51,52]. The reduction of the risk of complications such as corneal endothelial cells loss, increase in intraocular pressure, or cataract formation[50,53,54] is strongly influenced by the optimal lens size selection, suitable to the individual anatomy[25,51,52]. The performance of toric ICL implantation in patients with high-magnitude preoperative astigmatism is less frequently characterized in the existing literature[23,55], and the scientific community's debate on the optimal preoperative parameters for determining lens size is continually being updated[51,56,57].

Hypothesis and objectives.

The research investigated **the hypothesis that Visian toric ICL implantation provides effective, safe, and predictable astigmatic correction in the population with preoperative cylinder ≥ 2.00 D, and that the postoperative vault value is modulated by the lens size and the internal anatomy of the anterior segment.**

The specific objectives were: to evaluate the visual and refractive outcomes at 1 year postoperatively, vector analysis of astigmatic correction, the investigation of the relationship between the postoperative vault and the size of the implanted ICL and between the vault and the white-to-white (WTW) diameter, the evaluation of the agreement between the automated (ANTERION) and manual (Castroviejo caliper) methods of measuring the WTW diameter, and the characterization of the safety profile

of the procedure. The results were published in the article “*Clinical Outcomes and Astigmatism Vector Analysis of High Toricity Visian ICL*”, Romanian Journal of Ophthalmology (2026) [27].

6.2. PACIENTS AND METHODS

6.2.1 Study population

The study was conducted between April 2021 and April 2025 at the ALCOR Clinic, Bucharest, and included **consecutive patients** according to the following criteria: inclusion criteria: age ≥ 18 years, **astigmatism ≥ 2 D** (manifest refraction), **eligibility for toric Visian ICL implantation** (established following the ophthalmological evaluation, clinical decision, and doctor–patient discussion); exclusion criteria: refusal to participate in the study, incomplete medical records, loss to follow-up before 1 year, anterior chamber angle or endothelial cell density below the safety threshold levels of the proposed intervention, glaucoma, cataract, keratoconus, *bioptics* strategy. In the final analysis, **25 eyes/16 patients** were included.

6.2.2 Preoperative assessment

- Ophthalmological evaluation: **UDVA, CDVA**, manifest and cycloplegic **refraction**, IOP, slit-lamp examination and ophthalmoscopy, peripheral retina examination;
- **Tomography, topography, and biometry** with the ANTERION (Heidelberg Engineering, Heidelberg, Germany) and the Allegro Oculyzer WaveLight (Alcon Laboratories, Inc., Fort Worth, TX, USA) devices;
- **WTW diameter**: measured **automatically** with the ANTERION device and **manually** (with the Castroviejo caliper) under the operating microscope;
- Corneal endothelial cell density, determination of the anterior chamber angle (classified as $<30^\circ$, between 30° and 45° , or $\geq 45^\circ$), anterior chamber depth (measured from both the corneal endothelium and from the epithelium);
- Additional investigations according to the clinical indication (posterior pole OCT, binocular vision examination, etc.).

6.2.3 ICL selection[27]

The ICL parameters (spherical and cylindrical power, model, size, implantation axis) were established using the specialized calculation algorithm provided by the manufacturer.

The implanted toric ICL (STAAR Surgical AG, Nidau, Switzerland) models: VTICM0, V4c; VTICM5, V5; VTICH, with sizes of 12.1 mm, 12.6 mm, and 13.2 mm (the ICL parameters are detailed in the thesis, in Appendix 4).

In all cases included in the study, the planned refractive aim was (as close as possible to) emmetropia (0.0 D), but this ideal is limited in practice by the maximum available ICL power (the maximum toricity available: 6 D of cylinder; the maximum preoperative astigmatism value in this study: 8 D of cylinder) and by the fixed dioptric increments (which entail discrete values, in steps of 0.50 D for the cylindrical power). As such, some residual refractive error was to be expected. Thus, the **target refraction used in the vector analysis was the refraction predicted by the calculation formula.**

6.2.4 Surgical technique for toric Visian ICL implantation

All surgical interventions were performed in the same operating room, by the same surgeon. Preoperatively, axis marking at the limbus was performed along with topical anesthesia. The surgical technique: corneal incisions, injection of viscoelastic substance into the anterior chamber, implantation of the ICL into the anterior chamber via a dedicated injector, positioning the haptics in the ciliary sulcus, alignment of the toric markings to the preoperatively marked axis, complete removal of the viscoelastic, and hydrosuture of the incisions. The postoperative treatment consisted of the topical administration of antibiotic, corticosteroid, and artificial tears according to a tapering schedule.

6.2.5 Postoperative follow-up[27]

Patients were examined at 3–5 days, 1 month, and 1 year. The primary analysis time point was at **1 year postoperatively**. The variables collected: UDVA, CDVA, refraction. The measurement of the ICL vault was recorded at the 1-month visit and was done with the *Metrics* app of the ANTERION (see Fig. 6.1).

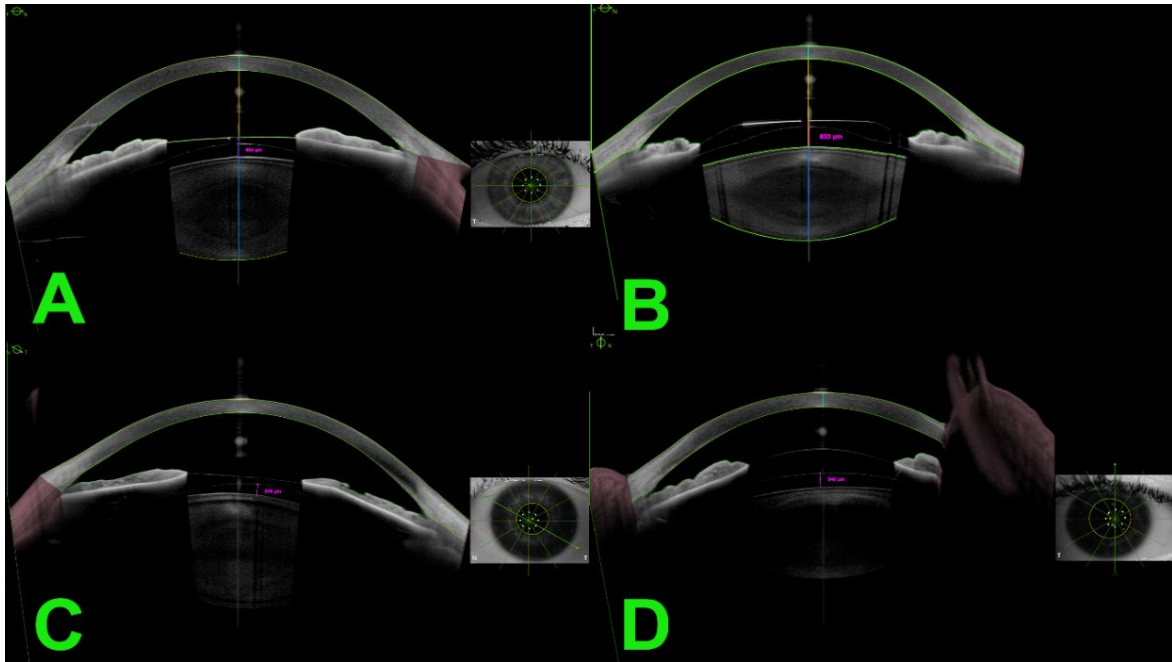


Fig. 6.1 ICL vault assessment with AS-OCT on ANTERION (Metrics app): horizontal scans for measuring the distance (in μm , visible as magenta perpendicular line) between the posterior aspect of the ICL and the anterior lens surface plane (A) optimal vault (464 μm). (B) High vault (833 μm). (C) lower vault but within the optimal range (378 μm .) (D) Optimal vault (540 μm) of an ICL VTICH without central port. Vault was classified as: low ($< 250 \mu\text{m}$), optimal (250–750 μm), high ($> 750 \mu\text{m}$).

6.2.6 Variables collected for data analysis[27]

Pre- and postoperative (at one year) UDVA and CDVA (collected in decimal and converted to the logMAR scale and to the Snellen scale). The analysis of functional independence from optical correction was performed with the patient as the unit of analysis and used the prescription issuance information from the electronic medical records.

6.2.7 Statistical analysis

The determination of the limits of agreement between the WTW values obtained by automated measurement and those by manual measurement implemented the Bland-Altman analysis. The paired comparisons implemented the paired t-test. The association between the vault and ICL size was evaluated through the Kruskal-Wallis test, and the statistical correlation between the WTW diameter and the vault through the Spearman coefficient (ρ) with 95% confidence intervals.

6.2.8 Vector analysis of astigmatism

The astigmatism correction was analyzed vectorially (the vectors and vector indices TIA, SIA, DV, CI, IOS, ME, and AoE) according to the method described by Alpíns[30], in accordance with the general methodology of the doctoral research (chapter 4.4 of the thesis), at the corneal plane and using the AstigMETRICS[40] and mEYEstro[38] software. The

standard graphs were generated using mEYEstro[38], and the double-angle plots and the calculation of the vector centroid used the Excel tool ASCRS Astigmatism Double Angle Plot Tool[44]. The keratometric astigmatism measured with the ANTERION was used as preoperative data for analysis.

6.3. RESULTS

6.3.1 Demographic data

The mean age at the time of surgery was 26.8 ± 5.4 years, within the 20–39 range[27]. The sex distribution was balanced, with 8 female patients (50%) and 8 male (50%)[27]. Bilateral implantation was performed in 9 patients (56.3%)[27].

6.3.2 Preoperative characteristics

Preoperatively, all cases had “CF” UDVA, and the mean CDVA was 0.26 ± 0.21 logMAR[27]. Mean spherical equivalent (SE) was -11.26 ± 6.62 D, mean refractive cylinder (absolute value) was 3.72 ± 1.27 D, both with wide intervals, **from -17.38 to $+8.50$ D** for SE and **from 2.25 to 8.00 D** for astigmatism[27]. Astigmatism was predominantly with-the-rule (88%) and myopic (88%)[27]. Mean keratometric astigmatism was 3.13 ± 1.22 D[27].

6.3.3 White-to-White (WTW) diameter

Device-measured WTW (Anterior) = 11.96 ± 0.35 mm; WTW measured manually = 11.67 ± 0.36 mm, mean paired difference of 0.26 mm (95% CI 0.17 to 0.35 mm, $p < 0.001$). Bland-Altman analysis: 95% **limits of agreement between -0.18 and 0.69 mm** (Fig. 6.2):

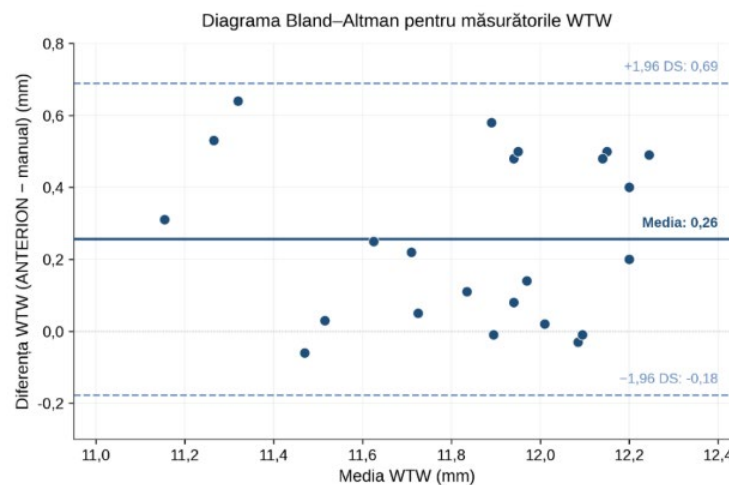


Fig. 6.2 **Bland-Altman plot for the Limits of Agreement between manual and device measured WTW** ($n = 25$). The central continuous line represents the mean paired difference (0.26 mm; CI 95% 0.17 to 0.35; $p < 0,001$, paired t test). Dashed lines represent the limits of agreement 95%. **Source:** adapted from published data by Prodescu et al., 2026[27]

6.3.4 Surgical parameters[27]

The mean spherical power of the implanted ICLs was -13.70 ± 7.07 D, and the cylindrical power 3.72 ± 1.27 D[27]. ICL sizes: 12.1 mm (24%), 12.6 mm (32%), 13.2 mm (44%). The mean target refraction: sphere of -0.39 ± 0.65 D and cylinder of 0.46 ± 0.82 D.

6.3.5 Visual and refractive outcomes of toric ICL implantation[27]

UDVA = 0.16 ± 0.16 logMAR (from logMAR 2.00 preoperatively) and **CDVA** = 0.09 ± 0.11 logMAR (from 0.26 ± 0.21 logMAR preoperatively). The **efficacy index** = 1.38 ± 0.61 ; 80% of eyes achieved a postoperative UDVA equal to or better than the preoperative CDVA, with 96% of eyes within a 1-Snellen-line difference between postoperative UDVA and preoperative CDVA[27] (Fig. 6.3). The **safety index** was 1.57 ± 0.60 . No eye lost ≥ 2 Snellen lines of CDVA, and 72% gained at least one line at the optotype[27]. (Fig. 6.3, C). Full **spectacle independence** was achieved in 88% of patients. Mean **postoperative SE** was -0.56 ± 0.77 D, demonstrating predictability relative to the target with[27]: 44% of eyes within ± 0.50 D and 88% of eyes within ± 1.00 D of intended target. The target vs achieved SE illustrates a strong correlation, with a **slight tendency toward undercorrection** [27]. (Fig. 6.3, E). **Refractive stability**: a mean difference of -0.12 D between the 1-month and 1-year postoperative visits, clinically negligible[27]. A proportion of 20% of eyes showed a change greater than 0.50 D in SE over this follow-up period[27].

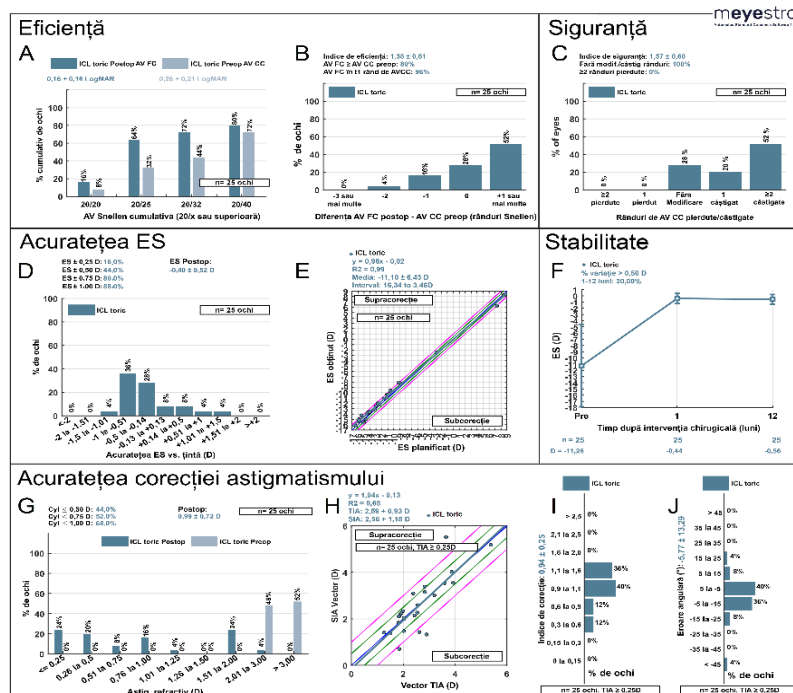


Fig. 6.3. Standard Graphs for visual and refractive outcomes of Toric ICL (n = 25). Source: adapted from Prodescu et al., 2026[27].

6.3.6 Astigmatism correction (scalar) [27]

The mean postoperative refractive cylinder was 0.99 ± 0.72 D, and the proportion of eyes with residual astigmatism: in 44% residual cylinder ≤ 0.50 D, and 68% of eyes fell within the ≤ 1.00 D threshold (Fig. 6.3, panel G). One case presented significant residual astigmatism (2.75 D), due to exceeding the maximum toricity available.

6.3.7 Vector analysis of astigmatism[27]

The vector analysis showed[27]: TIA: 2.59 ± 0.93 D, SIA: 2.56 ± 1.18 D, **DV: 0.84 ± 0.63 D, correction index: 0.94 ± 0.25 , index of success: 0.35 ± 0.27** . The mean magnitude of error: -0.03 ± 0.67 D (with 72% of eyes within the ± 0.50 D interval and 84% within the ± 1.00 D interval), without the identification of any systematic tendency toward over- or undercorrection[22]. Regarding the intraocular orientation of the ICL, the mean AoE was $-5.77 \pm 13.29^\circ$ (Figure 6.3, J), with **84% of eyes within the $\pm 15^\circ$** [27]. The TIA vs SIA regression (Figure 6.3, H): an adequate proportional correction between what was intended and what was achieved in terms of the magnitude of astigmatic correction[27].

A significant reduction in astigmatism, the **centroid** decreasing from 2.67 D @ 88° to 0.48 D @ 100° [22] is illustrated in Figure 6.4:

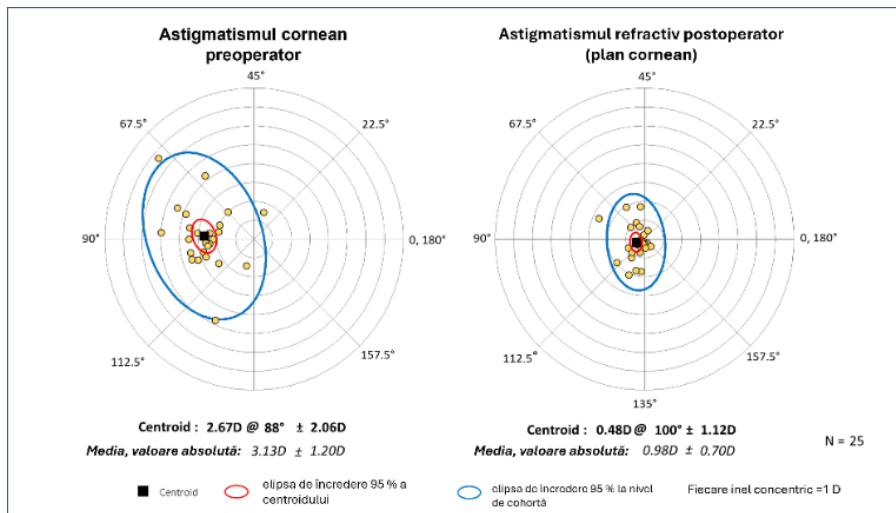


Fig. 6.4. Double-angle plots of pre- and postoperative astigmatism (corneal plane). Source: adapted from Prodescu et al., 2026[27]

In Fig. 6.5, a relatively symmetric distribution of residual astigmatism around the point of intersection, with a minor systematic error (prediction-error centroid 0.29 D @ 114° at the corneal plane[27]) is shown:

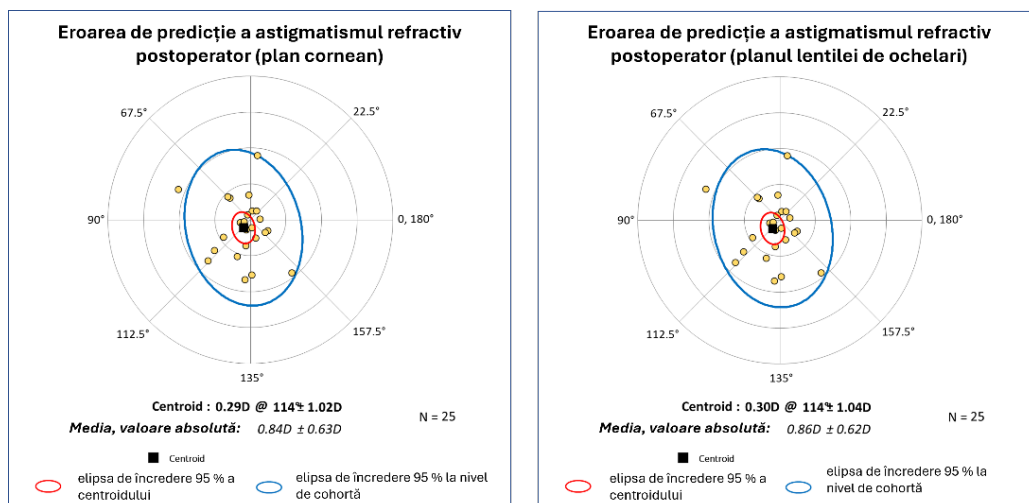


Fig. 6.5. *Refractive Astigmatism Prediction Error. Left – corneal plane. Right – spectacle plane. Each ring = 1 D. Source: adapted from Prodescu et al., 2026[27]*

6.3.8 ICL vault analysis[27]

The mean vault (at 1 month) = $615.5 \pm 192.3 \mu\text{m}$, with a range between 286 and 924 μm (Fig. 6.6); the distribution: optimal values (250–750 μm) in 68% of eyes, increased (>750 μm) in 32% of eyes (in all high-vault cases, the size of the implanted ICL was 13.2 mm), and low in 0%. A significant association was demonstrated between vault and ICL size (Fig. 6.6, Kruskal-Wallis test, $p = 0.002$), but no significant correlation with the WTW diameter (device-measured) was found, Figure 6.6, Spearman $\rho = 0.15$) [27]:

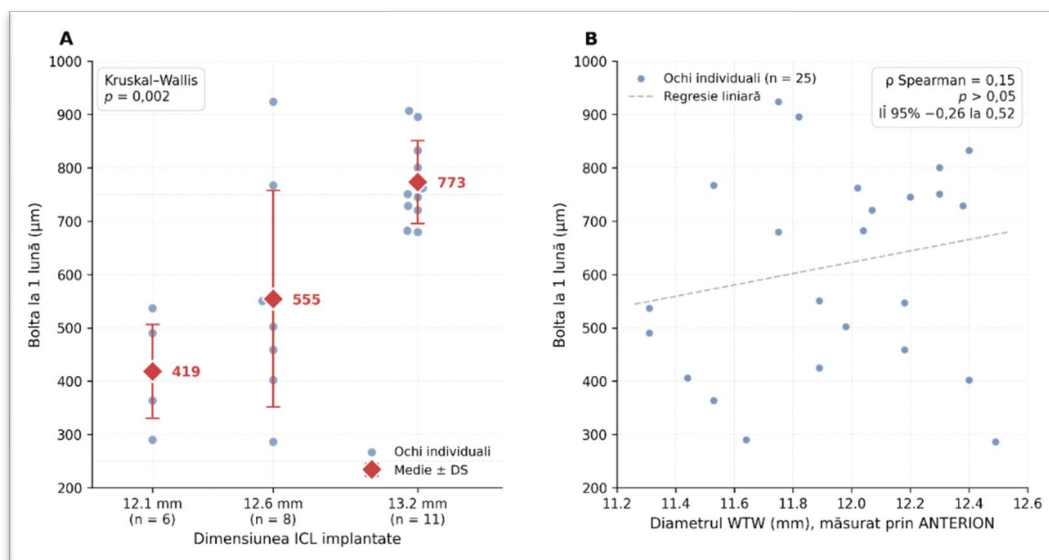


Fig. 6.6 *ICL vault (n = 25, 1 month postop). (A) Vault vs ICL size (12,1 mm, n = 6; 12,6 mm, n = 8; 13,2 mm, n = 11) (B) Vault vs WTW (measured with Anterior). Source: adapted from published data by Prodescu et al., 2026 [27]*

6.3.9 Safety profile and postoperative complications[27]

No sight-threatening complications or loss of CDVA were recorded during the postoperative follow-up. At one year postoperatively, no cases of cataract or endothelial cell loss were detected in this cohort[27]. Cases of increased intraocular pressure were recorded in the immediate postoperative period (16% at 5 days and 24% at 1 month), but these were transient, with complete resolution (0% of cases at one year)[27]. On the other hand, an increase in cases of dry-eye symptomatology was observed, from 12% at one month to 28% at one year[27].

6.4. CONCLUSIONS

Visian Toric ICL implantation resulted in a significant postoperative improvement in UDVA and CDVA, with efficacy and safety indices above unity[27].

Refractive predictability was good, the majority of eyes falling within the ± 1.00 D range relative to the refractive target for the spherical equivalent and residual astigmatism, although the values were slightly inferior to those reported in other studies, probably in the context of the inclusion of cases with higher-grade astigmatism in this study[27].

The vector analysis revealed an effective and proportional astigmatic correction, with a correction index close to the ideal value and good directional accuracy[27].

The postoperative vault was predominantly within the optimal range and was significantly associated with the size of the implanted lens, but did not demonstrate a correlation with the WTW diameter measured with the ANTERION, supporting the role of the internal anatomy of the anterior segment — and not of an external surrogate parameter such as WTW — as the major influencing factor of the intraocular behavior of the implant[27].

The WTW diameter measurement with the ANTERION device and manually, with the Castroviejo calliper, should not be considered interchangeable methods in the preoperative ICL sizing[27].

Toric ICL implantation represents a safe and effective option for the correction of high-grade astigmatism in patients with preserved accommodation in whom corneal surgery is not indicated[27].

7. CONCLUSIONS AND PERSONAL CONTRIBUTIONS

The research evaluated the surgical correction of high astigmatism (≥ 2.00 D) through four modern techniques (Trans-PRK, FS-LASIK, toric IOL, and toric ICL), grouped into three independent studies conducted under a unified methodological framework based on standardized vector analysis. Each study was disseminated through the publication of a scientific article[27–29].

The heterogeneity of the cohorts was a deliberate methodological choice. Although all patients shared the same defining criterion—high astigmatism—they differed in anatomical profile, surgical indication, and refractive strategy. The purpose of this design was not to engage in a formal comparison between techniques, but to characterize how high astigmatism is managed across different surgical contexts. This approach made it possible to evaluate treatment strategies in a wide range of functional and clinical scenarios, from young patients with preserved accommodation who were eligible for laser refractive surgery to cataract patients in whom correction of the refractive component has become an integral part of modern surgical care.

The findings demonstrated that all the studied techniques can provide **favorable and safe visual and refractive outcomes** in appropriately selected populations, contributing to the **reduction of optical correction dependence** and to the functional improvement of visual quality. No eye showed a clinically significant loss of corrected visual acuity, and the **safety indices** were above unity in all three studies. The **efficacy indices** were likewise above unity (except for the toric IOL cataract cohort, where the distinct refractive targets influence the typical interpretation of this index), with **80–90% of eyes having postoperative acuity better than the preoperative corrected vision**.

Functional **spectacle independence was achieved in the majority of patients** in the emmetropic-target cohorts, and in lens-based surgery the functional success rate remained comparable across the refractive strategies (emmetropia, residual myopia, presbyopia-correcting IOLs).

Scalar analysis of the results demonstrated:

Spherical equivalent accuracy: within ± 1.00 D in 88–98% of eyes and within ± 0.50 D in 44–71%, satisfactory given the high spherocylindrical magnitude.

Spherical equivalent predictability: regression slopes of 0.92–1.04 ($R^2 \geq 0.93$) across all four techniques, with a proportion of 88–98% of eyes within ± 1.00 D of the refractive target.

Vector analysis demonstrated:

Accuracy of astigmatic correction: correction indices close to ideal, with slight deviations at cohort level — mild overcorrection in Trans-PRK and toric IOL, a near-ideal result in FS-LASIK, mild undercorrection in toric ICL.

Predictability of astigmatic correction: a SIA vs TIA slope close to unity (1.11 Trans-PRK; 1.02 FS-LASIK; 0.97 IOL; 1.04 ICL).

Alignment accuracy: an angle of error within $\pm 15^\circ$ in 84–100% of eyes, confirming excellent axial alignment across the entire range of treated cylindrical magnitudes.

Refractive stability: globally satisfactory, but was evaluated in cohorts with suboptimal follow-up attendance; in Trans-PRK, a greater intra-individual variability was observed, suggesting prolonged epithelial and stromal remodelling.

In the toric IOL cohort, the multivariate regression identified the **oblique orientation of astigmatism and the cylindrical power of the implant as independent predictive factors of residual astigmatic error**, while the preoperative magnitude, axial length, type of intervention, and refractive strategy were not independently associated with the outcome.

In the study dedicated to toric ICL implantation, the strong relationship between the **postoperative vault and ICL size** was demonstrated, along with the **absence of such association with the WTW diameter**, as well as the **lack of agreement between automated and manual WTW measurements**, observations with direct clinical implications for lens-selection strategy.

Validation of the general hypothesis. Taken together, the results support the hypothesis from chapter 3: modern techniques for correcting astigmatism ≥ 2.00 D provide predictable and safe visual, refractive, and vectorial outcomes, the performance of each modality being modulated, however, by the anatomical particularities of the eye, by the technical and biomechanical limits intrinsic to each method, and by the postoperative biological response.

ORIGINAL CONTRIBUTIONS

Vector analysis of the Single-Step StreamLight Trans-PRK platform in the population with cylinder ≥ 2.00 D (171 eyes), a rather underrepresented refractive segment in the literature.

Identification of oblique astigmatism as an independent predictive factor of residual astigmatic error after toric IOL implantation.

Identification of the cylindrical power of the IOL as an independent predictive factor of residual error ($\beta = 0.051$ D, $p = 0.031$).

Documentation of toric ICL vault behavior: a significant association with ICL size (Kruskal-Wallis $p = 0.002$) and the absence of a correlation with the WTW diameter measured with the ANTERION (Spearman $\rho = 0.15$), with direct implications for ICL sizing.

Demonstration of the non-interchangeability of automated vs manual WTW measurements (mean difference 0.26 mm, 95% CI 0.17–0.35; $p < 0.001$) through Bland-Altman analysis.

Real-world evaluation of three modern modalities, with clinical implications for technique selection and preoperative counselling.

Methodological contributions: the consistent application of the Alpins methodology at the corneal plane, transversally across the three studies, in accordance with recent consensus statements; the stratified sub-analysis of a heterogeneous toric IOL cohort; the conceptual adaptation of the reporting of functional independence from optical correction, differentiated by refractive strategy.

Limitations and future research directions

The interpretation of the findings is subject to the limitations discussed in the individual chapters: the retrospective, single-center and single-surgeon design, unequal cohort sizes, and suboptimal extended follow-up attendance. Bilateral cases were addressed through one-eye-per-patient sensitivity analyses.

Future research should prioritize extending postoperative follow-up (particularly in Trans-PRK patients, given the prolonged remodeling response), independent validation of the predictive factors identified for toric IOL outcomes in multicenteric cohorts, exploration of possible adjustments to toric calculation in cases of oblique astigmatism, incorporation of additional parameters of subjective visual quality, and prospective studies stratified by cylindrical magnitude or by the anatomical source of astigmatism.

Overall, the conclusions of the thesis confirm that modern surgical methods can correct high astigmatism effectively and safely. However, successful outcomes depend on the rigor of every component of the therapeutic process—from appropriate indication and correct patient selection to the accuracy of preoperative measurements, the precision of the surgical technique, and the careful interpretation of postoperative results. Maintaining these standards consistently, while continuing to refine them through dedicated scientific research, is essential for further optimizing outcomes in this complex refractive segment, to the benefit of patients with high astigmatism.

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PUBLISHED ARTICLES

1. **Prodescu SV**, Curcă PF, Tătaru CI, Tătaru CP. *Clinical Outcomes and Astigmatism Vector Analysis of High Toricity Visian ICL*. *Romanian Journal of Ophthalmology*. 20 April 2026;70(1). doi:10.22336/rjo.2026.15.
 - From **chapter 7** “STUDY 3 - Surgery of high astigmatism with toric Visian ICL implantation” (**pages 110 – 129 & Appendix 4**)
 - Indexed in PubMed/MEDLINE
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2. **Prodescu SV**, Curcă PF, Tătaru CI, Tătaru CP. *Early Real-World Clinical Outcomes and Astigmatism Vector Analysis of Toric Intraocular Lenses for High Astigmatism (≥ 2.0 D)*. *Journal of Clinical Medicine*. 28 April 2026;15(9):3343. doi:10.3390/jcm15093343
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