Title

Influence of Tomographic and Biomechanical Corneal Indexes on Refractive Surgery Indications: A Cross-sectional and Multicenter Study

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Abstract

Purpose: To evaluate the influence of corneal tomographic and biomechanical indexes on the refractive technique indication.

Methods: 251 eyes from 251 patients interested in refractive surgery were enrolled in this cross-sectional and multicenter study. Previous to surgeon decision, a preoperative protocol was performed by refractive optometrists, containing four sections: refraction, biometry, corneal tomography and biomechanics. The refractive surgeons made a first decision based only on refraction, biometric and tomographic information. Biomechanical indexes were revealed, and refractive surgeons made a second indication. Additionally, for LASIK cases the percent tissue altered (PTA) were calculated. Possible indications were no refractive surgery, photorefractive keratectomy (PRK), Laser Assisted in-situ Keratomileusis (LASIK) or intraocular collamer lens (ICL).

Results: After the first surgery indication, the distribution were PRK (47.4%), LASIK (48.2%) while ICL achieved 2.8%. This proportion changed significantly after second indication regarding corneal biomechanics and PRK and LASIK decreased in a 24% while ICL increased 19%. 69 eyes changed the indication (27.5%) and 182 eyes (72.5%) remained unchanged. All indications changes were from PRK or LASIK to ICL or no surgery. Indication changes to ICL were observed in 49 eyes (71%). Tomographic, biomechanical indexes, ablation depth and PTA achieved statistically significant differences between eyes without and with indication changes (all, $P < .01$).

Conclusion: New corneal biomechanical indexes could change the indication decision regarding biometric and tomographic data alone. ICL was the preferred indication for eyes at risk of ectasia or with subclinical keratoconus due to corneal biomechanical parameters.

Keywords: corneal biomechanics; corneal tomography; refractive surgery decision; BAD; CBI; TBI

Introduction

Corneal biomechanics has become a significant issue for research in refractive surgery procedures.(1) It has been linked to the ectasia development susceptibility as a crucial factor for evaluating iatrogenic ectasia risk after laser vision correction (LVC).(2) First risk of ectasia assessment methodology was described and validated by Randleman et al.(3,4) as Ectasia Risk Score System for Laser Assisted in-situ Keratomileusis (LASIK). This system was founded on age, residual stromal bed (RSB), topography, corneal central thickness (CCT) and manifest refraction spherical equivalent (MRSE). Santhiago et al.(5) introduced percent tissue altered (PTA) formula, as a risk factor for post LASIK ectasia. They demonstrated that there is a correlation between preoperative CCT, ablation depth, and flap thickness in determining the relative amount of biomechanical change that has occurred after a LASIK procedure.(6–8) Current corneal tomography(9) allows to measure anterior and posterior faces of the cornea. All this anterior segment tomographic information could be merged into an LVC screening program, such Belin-Ambrosio Enhanced Ectasia Display (BAD) available on the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany). Recently, a new index based on Relational Thickness to horizontal profile (ARTh) and multiple deformation parameters was evaluated to screen normal from subclinical and keratoconus corneas.(10) The Corvis Biomechanical Index (CBI) available on the Corvis ST (Oculus Optikgeräte GmbH, Wetzlar, Germany) was launched as the first non-contact tonometer that measured biomechanical corneal reaction with an air stress pulse employing an ultra-high speed Scheimpflug camera. Both software could be combined into a Tomographic and Biomechanical Index (TBI) firstly described by Ambrosio et al.(11) The integration of both technologies was compared by Chan et al.(12) and they achieved that the combined use of BAD and CBI parameters demonstrated higher keratoconus screening rates than tomographic assessment alone.

A wide range of LVC procedures have been developed to eliminate refractive error by removing corneal tissue.(13) Photorefractive keratectomy (PRK) and mechanical or femtosecond LASIK are widely used LVC techniques. Phakic intraocular lens (pIOL) implantation has emerged as a refractive surgery procedure option without removing corneal tissue. Alfonso et al.(14) found excellent long-term efficacy and safety results in moderate to high myopia with the Visian Implantable Collamer Lens (ICL)

(STAAR Surgical AG, Nidau, Switzerland). The latest model incorporates a central hole of 0.36 mm to facilitate posterior to anterior chamber aqueous humor crossing, avoiding iridotomies. Sixty-seven peer reviewed papers were included in the Packer et al.(15) review. He found that pIOL provide high ametropia correction that lie down further than the suggested range of LVC such PRK or LASIK. Therefore, multiple refractive surgery patients were candidates for both an LVC and pIOL procedures. In addition, refractive surgeons must analyze ectasia risk factor of all the techniques and plan accordingly. In this sense, artificial intelligence and machine-learning algorithms included in new diagnostic software devices could play a decisive role for ectasia risk assessment.(16)

The aim was to evaluate the influence of tomographic and biomechanical indexes on the surgeon indication and their influence on surgical indications.

Patients and Methods

Design

This was a cross-sectional and multicenter study including 251 eyes (251 patients) which had the following indications: no refractive surgery, LVC (PRK or LASIK) or pIOL (V4c ICL) to correct myopia and astigmatism. Centers included were five private practice refractive surgery centers: Institut Català de Retina, ICR (Barcelona, Spain), Visióon López-Marín Clinic (Granada, Spain), Tecnolaser Clinic Vision (Seville, Spain), Vista Sánchez Trancón (Badajoz, Spain) and Qvision, Vithas Virgen del Mar Hospital (Almería, Spain). Data collection was performed between November 2019 and January 2020.

Ethical Considerations

All patients included were amply informed verbally and in writing of the benefits, characteristics and risks of all surgery's procedures. All patients signed an informed consent and received a patient information sheet prior to all surgery and after the interview with the ophthalmologist. Since it was a cross-sectional study, all refractive surgical procedures were included in the usual clinical protocol.

This study was performed in agreement with the Helsinki Declaration tenets and receives approval by the Ethical Committee for Research with Medicines (IDC Health) from Catalonia, Spain.

Subjects

Inclusion criteria were: (1) voluntary refractive surgery candidates from any of the five centers, (2) age between 21 and 60 years old, (3) stable refraction for at least twelve months, this is, a change ≤ of 0.50 diopters (D) in the spherical and cylindrical refraction, (4) existence of myopia in spherical equivalent (SE) between – 1.00 D and – 6.00 D, (5) maximum corneal astigmatism of – 2.00 D, measured with the Pentacam (Oculus Optikgeräte GmbH, Wetzlar, Germany), (6) corrected distance visual acuity (CDVA) of 20/30 or better in each eye, (7) CCT between 500 µm and 575 µm (The upper limit of 575 µm has been established to do not create comparative grievance between techniques. In a 600-micron cornea, most surgeons would opt for a laser technique, and this would imply a bias in decision making), (8) the maximum and minimum values of the corneal curvature could not differ by more than 10 D and (9) a disparity of ≤ 0.50 D in the keratometry between two measurements with a minimum interval of one week in contact lens wearers. Soft contact lens wearers were advised not to use them at least 7 days before preoperative assessment and hard contact lens wearers a longer period of 15 days prior to examinations, (10) anterior chamber depth (ACD) from endothelium ≥ 2.8 mm (11) endothelium cell density (ECD) ≥ 2000 cells/mm^2. Exclusion criteria were: (12) hyperopia, (13) eye diseases, such as glaucoma and cataracts, (14) progressive corneal diseases, such as keratoconus or the presumed keratoconus and pellucid marginal degeneration (Topographical Keratoconus Classification ≥ 1), (15) ocular surface diseases, (16) signs of retinal vascular pathology, (17) immunodeficient patients or those diagnosed with connective tissue diseases, (18) pregnant or breastfeeding patients, (19) patients with known sensitivity to the drugs used in LVC or pIOL surgery, (20) patients with eye muscle disorders such as strabismus or nystagmus, or any other disorder that affects ocular fixation and (21) patients without visibility or with amblyopia in the other eye.

Preoperative examinations

Before LVC or pIOL procedures, all patients undertook a full preoperative examination performed by refractive optometrists, containing four sections. Refraction section contained: uncorrected distance visual acuity (UDVA) and CDVA in Snellen scale, manifest refraction without and with cycloplegia by the maximum positive method. Binocular vision and accommodation were assessed in all patients. Biometry section contained: maximum and minimum keratometry, ACD (measured from endothelium to the lens capsule), axial length (AXL) and white to white (WTW) measured with low-coherence or swept-source optical biometer. Corneal tomography section contained: minimum and maximum keratometry, apex corneal thickness, ACD, WTW, pupil diameter, anterior chamber angle width (ACAW) and BAD measured with Pentacam, Pentacam HR or Pentacam AXL single rotation Scheimpflug (all from Oculus Optikgeräte GmbH, Wetzlar, Germany). Corneal biomechanics section contained: CBI and TBI measured with the Corvis ST (Oculus Optikgeräte GmbH, Wetzlar, Germany). Mean CBI and TBI were obtained after three measures. Finally, safety items such intraocular pressure (IOP) and ECD were measured with the Corvis ST and a non-contact specular microscopy (Nidek Co Ltd, Japan or Tomey, GmbH, Germany), respectively. All measurements were achieved prior any drugs instillation.

First and second indication procedure

The refractive surgeons made a first indication decision based only on refraction, biometric and tomographic information. Refractive surgeon made the indication of both eyes, but only one eye was included on the study. Eye selection was made with randomization software, right and left eye were selected as options and 251 values were taken. The choice of the eye to participate in the study was established prior to the surgeon's decision. At this point, ophthalmologist was masked from corneal biomechanics. CBI and TBI indexes were revealed and refractive surgeons made a second indication. Among the described indications were found; surgery is not recommended, PRK, LASIK, ICL or IOL. Same surgery was indicated in both eyes for all patients. Surgeons were free to change the second indication or not. Anonymous data was evaluated by a second masked refractive surgeon. With this, the clinical preference for a technique was avoided. In cases of disagreement, a third surgeon broke the tie. Additionally, for LASIK cases the PTA was calculated according the following formula:(17)

$PTA\ (\%) = \frac{Flap\ Thickness\ (FT) + Ablation\ Depth(AD)}{Central\ corneal\ thickness\ (CCT)}$, where FT (µm) was standard set on 100 µm, CCT (µm) was collected from Pentacam device and AD (µm) was calculated according Munnerlyn formula:(18) $AD\ (\mu m) = \frac{Optical\ Zone^2\ (OZ)\ x\ Intended\ Correction\ (D)}{3}$, where OZ (mm) was standard set on 6.00 mm for scotopic pupil under 6.00 mm and on 6.50 mm for scotopic pupil above 6.00 mm. Finally, D (Diopters) was collected with the spherical equivalent. To establish the risk of ectasia or subclinical keratoconus diagnosis, cut-off points were set for tomographic and biomechanical index. Based on Belin and Ambrosio(19) (for BAD), Vinciguerra et al.(10) (for CBI) and Ambrosio et al.(11) (for TBI), indexes were set on 1.2, 0.2 and 0.16, respectively.

Statistical analysis

Sample size was assessed with the GRANMO® calculator (Institut Municipal d'Investigació Mèdica, Barcelona, Spain. Version 7.12). Two-sided test was used. Alpha and beta risk were set in 5% and 20%, respectively. Estimated standard deviation (SD) of differences was set in 0.47, Minimum TBI expected difference was set in 0.09 and finally loss to follow-up rate was set in 0.10. This achieved a recommended sample size of 238 eyes. Statistical analysis was performed with SPSS statistical software (version 26.0, IBM Corp, Armonk, New York, USA). Descriptive analysis was accomplished with mean ± SD (range value). Data normality distribution was assessed with Kolmogorov-Smirnov test. Differences in indication changes were assessed with Chi-squared test. Differences between first and second indication variables with t-student test or U of Mann Whitney. Correlation study was assessed with Spearmen Rho test. For all test, level of significance was established in 95% (*P* value < .05).

Results

This study enrolled 251 eyes from 251 patients (140 were right eyes and 111 were left eyes). Patient mean age was 32.07 ± 8.85 (21 to 60) years old. Ninety-nine patients were male (39.4%) and One-hundred fifty-two patients were female (60.6%). The frequency of older patients (> 55 years) was 1.2% (5 patients). All patient preoperative demographic data were summarized in Table 1. After the first

surgery indication 95.6% were LVC while ICL was indicated in 2.8% and no surgery indicated only 1.6%. This proportion change significantly after second indication and LVC decreased in a 24% while ICL and no surgery increased 19% and 4.8%, respectively. Detailed proportion changes between first and second refractive surgery indication were presented in Figure 1. Sixty-nine eyes changed the indication (27.5%) and 182 eyes (72.5%) remained unchanged. Regarding indication changes, all modifications were from PRK or LASIK to ICL or no surgery. 13 eyes (18.8%) changed to no surgery. Indication changes to ICL were observed in 49 eyes (71%). Finally, only 5 (7.2%) and 2 (2.9%) changed to PRK and LASIK, respectively. 3 eyes changed from LASIK to PRK (4.3%) and 2 eyes changed from PRK to LASIK (2.9%). All indication changes were statistically significant ($\chi^2 = 159.1$, $P < .01$). The sample was split into surgeries without and with indication changes and all studied parameters where faced against. Values of each group and significant *P* values were reported in Table 2. Statistically significant differences were found in sphere, SE, keratometry, WTW, Apex thickness, BAD, CBI, TBI and ablation depth. (All, $P < .01$).

Distribution between ectasia risk / subclinical keratoconus and no ectasia risk / subclinical keratoconus for the three indexes were presented in Figure 2. The number of changes in indications was 69 and based on CBI and TBI ectasia risk or subclinical keratoconus eyes were 79 and 70, respectively. Only based on BAD Index ectasia risk eyes or subclinical keratoconus were 55. Regarding PTA calculation, all LASIK eyes (121) achieved values under 40%. Therefore, according Santhiago et al.(5) criteria no eye would be at ectasia risk. Mean PTA was 27.63 ± 3.18% (20.17 to 33.14). However, LASIK eyes without indication changed (91 eyes with 27.03 ± 3.08 %) reported statistically significant lower PTA than LASIK eyes with indication changed (30 eyes with 29.48 ± 2.77), $t = 3.87$, $P < .01$. Correlation study was assessed between BAD, CBI and TBI with PTA index and our findings revealed no correlation between PTA with BAD or CBI ($r = 0.14$, $P = .13$ and $r = -0.05$, $P = .53$, respectively) while low relationship where achieved between PTA and TBI ($r = 0.20$, $P < .05$).

Discussion

Corneal biomechanics has created huge discussion amongst clinicians and researches in LVC. In the present study, corneal biomechanical influence on refractive surgery indication decision against biometric and tomographic data was evaluated. In sixty-nine eyes (27.5%) the second indication changed regarding the first indication, based exclusively on refraction, biometer and corneal tomography data. The second indication of preference, when considering corneal biomechanics, was ICL (72%). BAD, CBI, TBI, PTA and ablation depth achieved statistically significant differences between eyes without and with indication changes (all, $P < .01$). Refraction range was conventional LVC refractive zone (with spherical equivalent between -1.00 D and -6.00 D), and corneal biomechanics study involved a 27.5% indication change with a 72% implant of phakic ICL lenses, with the subsequent reduction of LVC.

Ambrosio et al.(11) identified the TBI as a new Scheimpflug-based Index described by tomography and corneal biomechanics along with artificial intelligence on ectasia detection. Ferreira-Mendes et al.(20) provided validation accuracy of TBI on subclinical forms of ectasia in subjects with ostensibly normal topography and they found that TBI achieved better accurate results than BAD and CBI. In our study, regarding corneal biomechanics analysis, 69 cases (27.5%) changed refractive surgery indication. The TBI cut-off point separated the sample into 70 patients with ectasia risk or subclinical keratoconus and 181 without ectasia risk or subclinical keratoconus. In our study, cut-off points for BAD, CBI and TBI were set on 1.2, 0.2 and 0.16, respectively. Mean ectasia risk or subclinical keratoconus BAD (0.99 ± 0.54) was under BAD cut-off point while mean CBI and mean TBI (0.25 ± 0.28 and 0.21 ± 0.18, respectively) were above CBI and TBI cut-off points. Consequently, corneal biomechanics justifies the change and without that data, and only with tomographic information, 14 eyes would be at risk of ectasia or with subclinical keratoconus. Therefore, the second indication due to corneal biomechanics clearly matched with indication changes obtained and all eyes at risk of ectasia or with subclinical keratoconus diagnose change the indication due CBI and TBI. Recently, Salomão et al.(21) found that the TBI area under the curve (AUC) was 0.992, which achieved statistically significant differences with BAD, CBI, Pentacam Random Forest Index (PRFI), Pentacam Topographic Keratoconus Classification (TKC) Index and other tomographic-based index alone. In the same study, they reported that TBI obtained

100% sensitivity to detect frank ectasia. These results supported the change decision found in our refractive surgeons based on corneal biomechanics. In addition, Lopes et al.(22) has demonstrated that provided excellent results in terms of repeatability and reproducibility for corneal biomechanical measurements with the Corvis ST. In addition, age sample was heterogenous and future research should narrow down this inclusion criteria. Our findings strengthens the idea that the integration of tomographic parameters together with the biomechanical corneal characterization provide an increase in the decision-making safety in refractive surgery indications.

Phakic IOL, such ICL, has demonstrated that provide excellent refractive results in a wide myopia refraction range.(23) According to our results 71% (48 eyes) of the indications changes were to ICL when the corneal biomechanical data was revealed. Hence, this is a hint that gives more weight to the decision and pIOL in biomechanically compromised eyes. Previous authors(14,24,25) showed excellent efficacy, predictable and stable results in moderate to high myopia correction with ICL. However, there was a lack of evidence in pIOL correction for low to moderate myopia. Kamiya et al.(26) showed that visual, refractive and safety outcomes of low to moderate myopia were comparable to those for high myopia. In addition, Kobashi et al.(27) reported that pIOL presented fewer activities limitations and better quality of life over LASIK for myopia correction in a long term follow-up. As an added bonus, ICL implantation involve a slight learning curve since foldable posterior chamber pseudophakic IOL implantation was relatively comparable.(28) Nonetheless, this procedure is not exempt from complications; cataract, IOP decompensation and even blindness due to ocular infections.(29) Thus, accurate candidate choice, complete anterior and posterior segment assessment, manifest and cycloplegic refraction, and detailed preoperative measurements and calculations are mandatory for precise sizing in order to decrease complications linked with pIOL implantation. In the absence of contraindications, pIOL represent an excellent cornea saving, reversible option for myopia and astigmatism correction. In addition pIOL avoid dry eye disease and reported excellent visual quality.(23)

Santhiago et al.(5) demonstrated that PTA achieved higher prevalence, odds ratio, and predictive capabilities than Ectasia Risk Score System. Previous studies(30,31) have shown success in refractive surgery on thin corneas. These findings are in contradiction with the theory proposed by Santhiago and associates. Nevertheless, PTA index was based on few individual items and it should be considered as complementary ectasia risk criteria to the tomographic and biomechanical indexes that integrate artificial intelligence in their software. Our results showed that no eye, according to the PTA calculation, was at risk of ectasia, while the TBI included 27.9% within the ectasia risk or subclinical keratoconus group. Consequently, PTA correlation was non-existent versus BAD and CBI ($r = 0.14$, $P = .13$ and $r = -0.05$, $P = .53$, respectively) and very low versus TBI ($r = 0.20$, $P < .05$). TBI has greater relevance over PTA to indicate LVC. Our results indicate that despite having a low PTA value, there were eyes at risk of ectasia or with subclinical keratoconus through TBI. However Sorkin et al.(32) achieved, in a retrospective case series that high-myopic PRK with mitomycin-C in the eyes at risk of developing ectasia because of high preoperative PTA was safe and effective alternative to the LASIK procedure. According to Ambrosio(16) a possible future research line would be that the tomography and biomechanical devices could auto-update the cut-off points in real time based on all the measurements made by Pentacam and Corvis in a common worldwide data cloud. Consequently, thanks to these machine-learning algorithms, the refractive surgeon would have more tools in making the best indication decision.

Within the limitations, since it was a multicenter study, heterogeneity in clinical practice among centers may be a major confounding factor. Observational design was another potential limitation, since no intervention occur, and no follow-up was collected. However, the preoperative protocol has been implemented in the five participating clinics to improve safety in their surgical indications. Another limitation was the lack of interobserver agreement reliability study. Among the strengths, however, due to being a multicenter study, the indication decision was not biased by the unique experience of one refractive surgeon. To the best of our knowledge, this is the first refractive surgery study to assess a theorical second indication according to corneal biomechanical data.

In conclusion, corneal biomechanical indexes play a crucial role in the refractive surgery indication decision compared to biometric and corneal tomographic data alone. ICL was the preferred indication for eyes at risk of ectasia or with subclinical keratoconus due to corneal biomechanical parameters. The PTA index showed no correlation with tomographic / biomechanical indexes.

Conflict of interest statement: The authors declare that there is no conflict of interest

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Figure captions

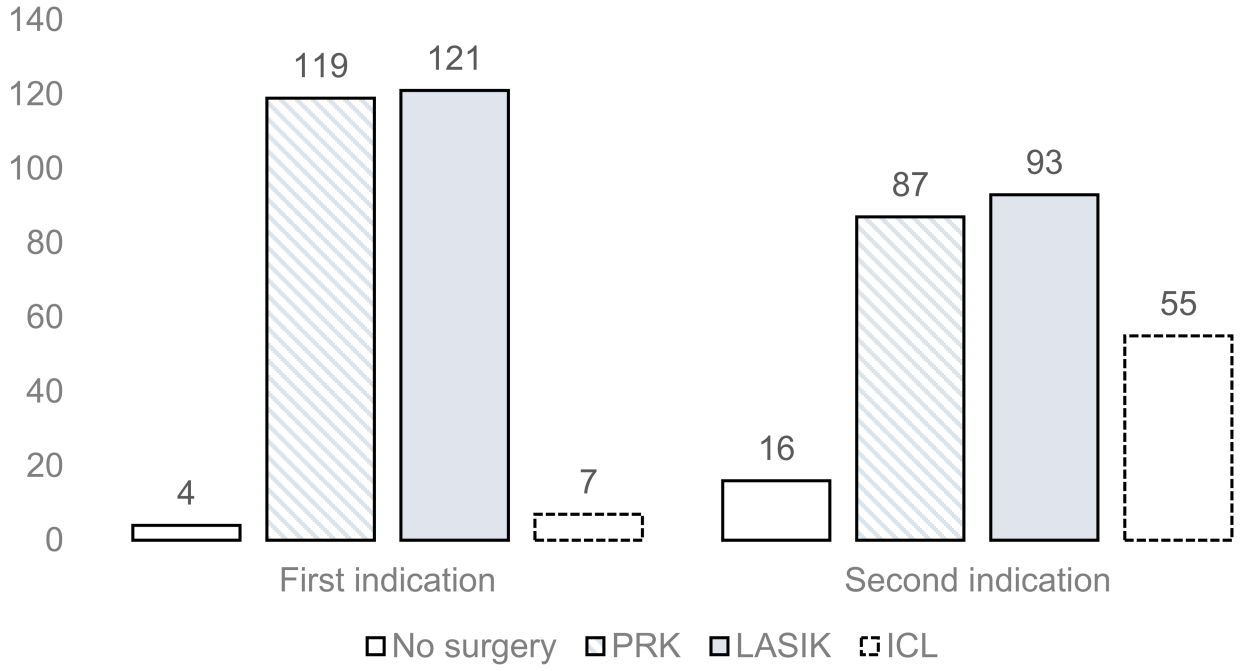
Figure 1 – First and second refractive surgery indications distribution. Data expressed in number of eyes.

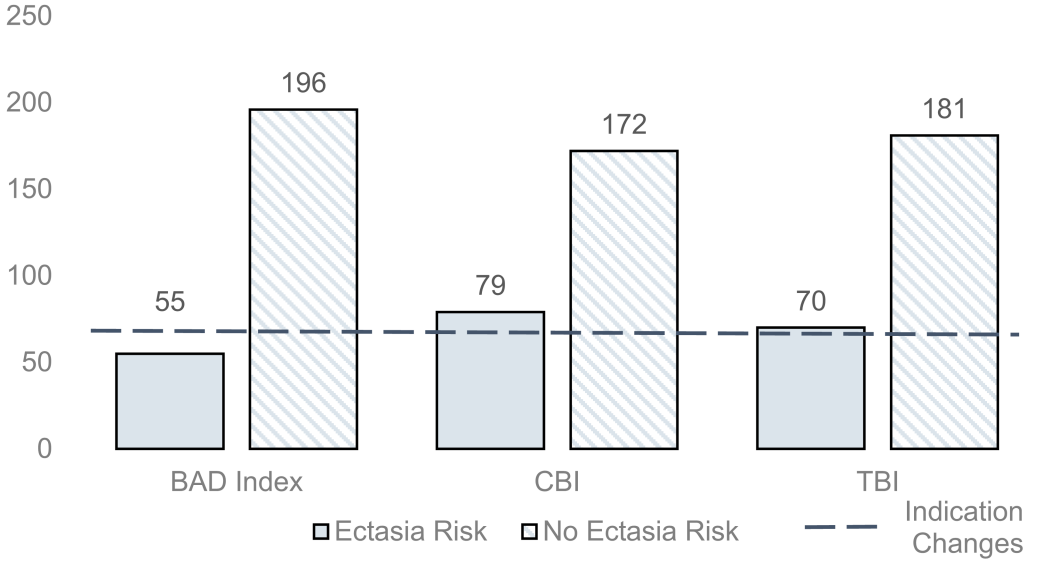
Figure 2 - Distribution between ectasia risk or subclinical keratoconus and no ectasia risk or subclinical keratoconus for Belin / Ambrosio Display (BAD) Index, Corvis Biomechanical Index (CBI) and Tomographic Biomechanical Index (TBI). Data expressed in number of eyes. The dashed line represents the 69 eyes that have changed their indication.

Table 1. Preoperative demographic data of all patients

Parameter (n = 251)	Mean ± SD (range)
Refraction Data	
Sphere Refraction (D)	-3.34 ± 1.37 (-6.00 to -0.50)
Cylinder Refraction (D)	-0.63 ± 0.52 (-2.00 to 0.00)
Axis (Degrees, °)	80.03 ± 65.46 (0.00 to 180.00)
SE Refraction (D)	-3.67 ± 1.37 (-6.00 to -1.00)
Thibos Vectorial Notation	M -3.655 ± 1.37 J_0 -0.296 ± 0.35 J_{45} 0.107 ± 0.20
Biometric Data	
K min (D)	43.34 ± 1.52 (39.20 to 48.20)
K max (D)	44.23 ± 1.58 (39.89 to 49.30)
$ACD_{epithelium}$ (mm)	3.67 ± 0.32 (2.43 to 4.49)
AXL (mm)	24.71 ± 1.03 (21.78 to 27.40)
WTW (mm)	12.20 ± 0.52 (11.00 to 13.57)
Tomographic Data	
K min (D)	43.22 ± 1.48 (39.20 to 48.20)
K max (D)	44.08 ± 1.53 (40.20 to 49.30)
Apex Thickness (µm)	543.96 ± 20.22 (506 to 609)
$ACD_{endothelium}$ (mm)	3.29 ± 0.24 (2.80 to 3.99)
Pupil diameter (mm)	3.06 ± 0.56 (1.76 to 5.58)
WTW (mm)	12.02 ± 0.54 (10.80 to 13.57)
ACAW (degrees, °)	41.55 ± 7.26 (15.3 to 85.6)
BAD Index	0.75 ± 0.56 (-0.55 to 2.30)
Biomechanical Data	
CBI	0.17 ± 0.22 (0.00 to 0.94)
TBI	0.11 ± 0.16 (0.00 to 1.00)

SD: standard deviation; D: diopters; SE: spherical equivalent; K min: minimum keratometry; K max: maximum keratometry; ACD: anterior chamber depth; AXL: axial length; WTW: white to white; ACAW: anterior chamber angle width; BAD: Belin / Ambrosio display; CBI: Corvis biomechanical index; TBI: tomographic biomechanical index


140
120
100
80
60
40
20
0
4
119
121
7
16
87
93
55
First indication
Second indication
No surgery
PRK
LASIK
ICL


250
200
150
100
50
0
196
172
181
55
79
70
BAD Index
CBI
TBI
Ectasia Risk
No Ectasia Risk
Indication Changes