**RESUMO**

**TITLE: Keratometric index variation in keratoconic eyes before and after Intacs-SK implantation**

**TÍTULO: Variação do Índice Queratométrico em olhos com Queratocone implantados com Intacs SK.**

**Objetivos:** Avaliar a variação do índice queratométrico (IQ) em olhos com queratocone (QC), relativamente a olhos normais e após o implante de Intacs-Sk (Addition Technology Inc); **Material e métodos:** Estudaram-se retrospetivamente 19 olhos com QC, antes e após o implante de Intacs-SK (mínimo 6 meses), e um grupo controlo de 26 olhos. Avaliaram-se, nos 3 mm centrais, os raios de curvatura anterior (RCA) e posterior (RCP), o rácio entre estes (rácio RCA/RCP) e o poder pupilar médio (PPM), avaliado por ray-tracing, usando um tomógrafo com câmara rotacional de Scheimpflug e disco de Plácido. O IQ calculou-se, pela fórmula paraxial para lentes finas, assumindo o PPM como poder dióptrico corneano central; **Resultados:** Os valores médios de RCA, RCP, rácio RCA/RCP e IQ foram, respetivamente, para o grupo controlo e para os olhos com QC antes da cirurgia: 7,71±0,30 e 6,78±0,52mm (p<0,05); 6,35±0,67 e 5,59±0,86mm (p<0,05), 1,236±0,220 e 1,234±0,159 (p>0,05); e 1,3317±0,0031 e 1,3321±0,0521 (p>0,05). Nos olhos com QC, após um período médio de 9,47 meses após a cirurgia, o RCA médio aumentou para 7,26±0,56mm (p=0,000), e o RCP aumentou para 5,63±0,95mm (p>0,05), embora sem significância estatística. O rácio RCA/RCP médio aumentou para 1,314±0,190 (p<0,05) e o IQ médio diminuiu para 1,3285±0,0817 (p<0,05); **Conclusões:** Após o implante de Intacs-SK, apenas a superfície corneana anterior foi significativamente aplanada, com consequente diminuição no IQ. Assim, valores de IQ estandardizados podem não ser adequados no cálculo do poder dióptrico de lentes intra-oculares nestes doentes. Não foram encontradas diferenças no rácio RCA/RCP e no IQ entre olhos com e sem QC.

**Palavras-chave:** intacs SK, queratocone, índice queratométrico, anéis intracorneanos estromais, cálculo de lente intraocular

**ABSTRACT**

**Purpose:** To evaluate the variation in keratometric index (KI) in eyes with keratoconus (KC), before and after the implantation of Intacs SK (Addition Technology Inc); **Patients and Methods:** 19 eyes with keratoconus, before and after Intacs-SK implantation (minimum follow-up of 6 months), and a control group of 26 healthy eyes were retrospectively studied. The anterior (ARC) and posterior radius of curvature (PRC), the ratio between them (ratio ARC/PRC) and the mean pupil power (MPP) were evaluated for the central 3 mm, using a tomographic system combining Scheimpflug photography and placido-disc analysis. The KI was calculated using the paraxial formula for thin lens, assuming the MPP (accessed by ray-tracing) as the true corneal power; **Results:** The mean values for ARC, PRC, ratio ARC/PRC and KI were, respectively, for the control group and for the keratoconic eyes before surgery: 7,71±0,30 e 6,78±0,52mm (p<0,05); 6,35±0,67 e 5,59±0,86mm (p<0,05), 1,236±0,220 e 1,234±0,159 (p>0,05); e 1,3317±0,0031 e 1,3321±0,0521 (p>0,05). In keratoconic eyes, after a mean follow-up of 9,47 months after Intacs-SK implantation, the ARC increased to 7,26±0,56mm (p<0,001), and the PRC increased to 5,63±0,95mm(p>0,05), which was not statistically significant. The mean ratio ARC/PRC increased to 1,314±0,190 (p<0,05) and the mean KI decreased to 1,3285±0,0817 (p<0,05); **Conclusions:** After Intacs-SK implantation, only the anterior cornea surface seems to be significantly flattened, with a consequent decrease in the KI. Thus, the standardized KI values may not be suitable for intra-ocular lens calculation in these patients. No statistical differences were found in the ratio ARC/PRC and in the KI between normal and keratoconic eyes.

**Key-words:** intacs SK, keratoconus, keratometric index, intracorneal ring segments, intraocular lens calculation

**INTRODUCTION**

The exact determination of central corneal power (CCP) is more complex after keratorefractive surgery (KS), being the main cause of error in the calculation of the dioptric power of an intraocular lens (IOL) in these cases2,11,17,26. The CCP is not only one of the three variables of the classical vergence formula, with the axial length and the effective lens position. It is also important, along with the axial length in the determination of the effective lens position in some of the new theoretical formulas of third and fourth generations (Hoffer Q, Holladay 1 e 2, SRK/T, but not in Haigis)1,11. In general, these two uses of the CCP, if incorrect, lead to an underestimation of the dioptric power of the IOL to implant in eyes with previous correction of myopia and the opposite in eyes with previous correction of hypermetropia2,13,24,28.

The reasons for the errors in the calculation of CCP after KS are essentially of two types: errors of the measuring instrument and refractive index errors11,17. The first error is due to the fact that most keratometers consider the cornea as a spherical surface and measure outside the central 3mm, the most important and altered zone after KS11,17. This occurs typically in ablative laser surgery such as LASIK and PRK11. The second error occurs because the oldest keratometers and topographers do not measure the posterior corneal surface and, consequently, calculate the CCP considering the cornea as a single refractive surface based only on the anterior cornea curvature17. This relies on the assumption of a constant ratio between the anterior and posterior curvatures and therefore an universal keratometric index (KI) (often 1.3375 or 1.3315)18.

The debatable assumption of a constant ratio between the anterior and posterior corneal radius of curvature (ARC/PRC ratio), which in healthy corneas allows to calculate with relative precision the CCP, is no longer applicable after the most part of KS procedures. Myopia ablative laser surgery only flattens the anterior surface, with a consequent increase in the ARC/PRC ratio and a subsequent reduction of the KI11. In radial keratotomy only recently Camellin et al.4 showed that only the posterior surface is significantly flattened with a consequent lower ARC/PRC ratio and increase in KI. Intracorneal rings segments (ICRS) implantation was considered a purely additive procedure, i.e. with equal flattening of both corneal surfaces5. However, in 2014, Rojas et al.21, using the same methodology, with the Ferrara ICRS, showed that only the front surface was significantly flattened, resulting in an increased ARC/PRC ratio and a lower KI 21.

Corneal power calculation in eyes with previous KS is itself complex and has been evaluated in several studies31, with differing results in the issue of variation of ARC/PRC ratio and in KI16,21,27.

We designed this study to evaluate the ARC/PRC ratio and the KI in eyes with keratoconus (KC) before and after ICRS implantation. We calculated a fictitious KI, using a similar methodology to the one used by Camellin et al.4 and Rojas et al21, based on the paraxial formula for thin lenses, but assuming the "mean pupillary power" (MPP) obtained in Sirius (calculated by ray-tracing) instead of the "pupil dioptric power" (PDP) obtained in Pentacam (calculated by the Gauss's formula) as the true CCP.

**MATHERIAL E METHODS**

A longitudinal, retrospective, descriptive and observational study was performed.

To determine the sample, we analysed the medical records of patients undergoing Intacs SK (Addition Technology Inc) implantation in our department between January 2012 and February 2014. Only eyes with a minimum follow-up of 6 months were included. 19 eyes of 19 patients were therefore studied. For the study purposes, in order to homogenize the postoperative results, the last postoperative consultation between 6 and 12 months after surgery was considered. All surgeries were performed by one of two refractive surgeons (PR or RAR). All cases had a transparent cornea, a minimum thickness of 450μm at the incision site and were intolerant to contact lens usage. In all cases two segments (symmetric or asymmetric) were inserted, assisted with vacuum and diamond knife, with incision in the steepest axis and at a depth of 70-80% of the corneal thickness. Surgeries and follow-up period went without major complications and no eyes lost lines of visual acuity, with or without correction15.

The control group was defined based on the voluntary study of the topography of the healthy right eyes with best-corrected visual acuity of 10/10 of 26 patients. All patients were informed about the nature of the study and signed an informed consent.

We collected, in addition to the demographic data (age and sex) and the post-operative period, the topographic data assessed in a Placido disc tomographic system with a rotational Scheimpflug camera - Sirius (CSO, Italy). We accessed in the central 3 mm, the ARC and PRC (mm), the ARC/PRC ratio and the MPP (D). As the repeatability of measurements of Sirius had been already demonstrated23, the first valid examination free of artefacts was accepted for analysis.

For descriptive purposes, the eyes with KC were classified according to Amsler-Krumeich classification.

KI was calculated by the paraxial formula for thin lens (see below), assuming the MPP as the true central corneal power (CCP).

*CCP (D) = (KI - 1)/ ARC (mm)*

⇿

***KI = CCP (D) x ARC (mm) +1***

This methodology was based on the studies of Camellin et al.4 and Rojas et al.21, but assuming the "mean pupillary power" (MPP) obtained in the Sirius instead of the "pupil diopter power" (PDP) obtained in the Pentacam as the true CCP. Although both use the known refractive indexes of air (1000), corneal stroma (1,336) and aqueous humour (1.376), while the PDP calculates the CCP by the paraxial Gauss formula for thick lenses based on the Pentacam measurements for the ARC, PRC and central corneal thickness, the MPP in Sirius is calculated by ray-tracing. This method, which does not rely on any paraxial or spherical approximation, determines the CCP as a function of pupil diameter, based on Snell's law through wavefront analysis. In the Sirius the calculation is also made according to the Stiles-Crawford effect, which gives more weight to the central points. Some studies have demonstrated the ability of this method to reflect the CCP after KS with excimer laser24,30 and it was even shown its superiority against the Gauss formula in these cases30.

Statistical analysis was performed using the software IBM Statistical Package for Social Sciences (SPSS) version 20.0®. The normality of the variables was checked using the Kolmogorov-Smirnov test. Simple t-tests were used to compare the control group and patients with KC before surgery and paired t-tests to compare, in patients with KC, the preoperative values and for the mean duration of follow-up. Significance was settled for p<0,05. Descriptive statistics are presented as mean± standard deviation.

**RESULTS**

A total of 19 eyes of 19 patients with KC who underwent Intacs SK implantation were included in the study. The mean age of the 19 patients was 36.42 ± 12.72 years, with a predominance of males (11 patients, 57.9%). The mean follow-up was 9.47 ± 3.04 months, ranging between 6 and 12 months. The mean Keratometry value before surgery was 48.86 ± 3,32D, being the distribution by Amsler-Krumeich stages as follows: 47.4% Grade 1 (n = 9) 31.6% grade 2 (n = 6) 15.8% grade 3 (n = 3) and 5.3% grade 4 (n = 1). The mean age of the 26 patients in the control group was 36.85 ± 9.23 years (p> 0.05), with a female predominance (18 patients, 69.2%). The mean values for ARC, PRC, ratio ARC/PRC and KI were, respectively, for the control group and for the keratoconic eyes before surgery: 7,71±0,30 and 6,78±0,52mm (p<0,05); 6,35±0,67 and 5,59±0,86mm (p<0,05), 1,236±0,220 and 1,234±0,159 (p>0,05); 43,10±1,72 and 49,24±4,10D (p<0,05); and 1,3317±0,0031 and 1,3321±0,0521 (p>0,05). In the eyes with KC, after a mean period of 9.47 months after INTACS-SK implantation, the mean ARC increased to 7.26±0,56mm (p<0,001), and the PRC increased to 5,63±0,95mm(p>0,05), which was not statistically significant. MPP decreased to 45,53±3,84D (p<0,05). The mean ARC/PRC ratio increased to 1,314±0,190 (p<0,05) and the mean KI decreased to 1,3285±0,0817 (p<0,05). (Table1).

Table 1 |Results of the studied parameters in the control group and in the eyes with KC before and after implantation of Intacs-SK.

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| --- | --- | --- | --- | --- |
| **Parameter** | **Mean ± SD****Control vs. KC (pre-op)**  | **p value****(KC –control)** | **Mean ± SD****KC (post-op)** | **p value****(post-op - pré-op)** |
| **ARC (mm)** | 7,71 ± 0,30 | 6,78 ± 0,52 | 0,000 | 7,26 ± 0,56 | 0,000 |
| **PRC (mm)** | 6,35 ± 0,67 | 5,59 ± 0,86 | 0,002 | 5,63 ± 0,95 | 0,809 |
| **ARC/PRC ratio** | 1,236 ± 0,220 | 1,234 ± 0,159 | 0,981 | 1,314 ± 0,190 | 0,046 |
| **MPP (D)** | 43,10 ± 1,72 | 49,24 ± 4,10 | 0,000 | 45,53 ± 3,84 | 0,000 |
| **Calculated KI** | 1,3317 ± 0,0031 | 1,3321 ± 0,0521 | 0,723 | 1,3285 ±0,0817 | 0,018 |
| **Age (years)** | 36,85 ± 9,23 | 36,42 ± 12,72 | 0,897 | --- | --- |

**DISCUSSION**

The KI is a fictitious number that allows to considerate the cornea as a single refractive surface and thus calculate the CCP based only on the ARC. Its determination was a need imposed by the inability of keratometers and conventional topography to measure the PRC and allows calculating with relative precision the CCP in the majority of cases. The most commonly used values are 1.3375 (by convention for a 7.5mm ARC match a CCP of 45D) and 1.331518. A universal value depends necessarily also on a constant ARC/PRC ratio (e.g. 7.7 / 6.8 in the Gullstrand schematic eye), debatable even in normal eyes6,7,8, and that can change dramatically in eyes with corneal pathology or after KS.

In the control group, the mean ARC/PRC ratio was 1,236 and the mean KI was 1.3317. The first value reinforces the theory that the classical ratios, for example as the Gullstrand Schematic Eye (7.7 / 6.8 = 1.132), are probably underestimated. The values found in the literature, in recent studies, range between 1,215 and 1.286,9,10,14,22, being 1.22 in the study of Rojas et al.21 with the Pentacam, and 1.19 in the study of Montalban et al.16 with the Sirius. The KI is, as said, a fictitious value and, to date, impossible to determine directly. It was not our goal the validation of a new KI value due to the small number of studied eyes, but rather to compare the change in the calculated value in our sample of keratoconic eyes compared with normal eyes and after the implantation of Intacs-SK. Even so, we obtained a KI of 1.3317 in normal eyes, value that supports the idea that the conventional value of 1.3375 is probably overestimated 6,8,10,12. In the study of Rojas et al.21, the KI value obtained in the group of normal eyes was 1.328221.

In KC both corneal surfaces are changed with possibly earlier and more marked alterations in the posterior cornea surface25,28. In this study, in the eyes with KC prior to surgery, both ARC and PRC were significantly steeper compared to the control group. However, there were no differences in the ARC/PRC ratio and in the KI (Table 1). This is contrary to the results of Rojas et al.21. In our opinion, this can be explained by the fact that the eyes included in this study had relatively low keratometry values and were mostly stages 1 and 2 of Krumeich. Piñero et al.19 and Montalban et al.16 only found a significant increase in the ARC/PRC ratio in eyes with more advanced stages of KC16,19. In this study, the small number of studied eyes prevented an analysis per Krumeich stage.

ICRS, of which Intacs SK are an example (with a 6 mm optic zone), consist of a PMMA ring which, once inserted in the deep corneal stroma, distend and mechanically flatten the central corneal lamellae and reduce their arc length3(Fig.1). Its effect depends on its optic area, thickness, arc length, symmetry /asymmetry of the placed rings and if are inserted just one or two ICRS20,32. In terms of impact on the ARC/PRC ratio and in KI, ICRS were considered until very recently purely additive, i.e., without any effect. The mean reduction in keratometry, accessed by the MPP, was 3,71D. This value falls within the values described in the literature, with reductions of more than 3D in keratometry allowed by the smaller diameter (6mm) of Intacs SK20.

After Intacs SK implantation, in this study, only the mean ARC increased significantly and the average PRC remained almost unchanged. This translated into a significant increase in the ARC/PRC ratio and also a significant decrease in the calculated KI (Table 1). These results corroborate the findings of Rojas et al.21, with the Ferrara ICRS, in a similar study based on Pentacam with CCP calculation by the Gauss formula 21. Both studies prove that ICRS, although being an additive procedure, only flattens substantially the anterior corneal surface and induces a significant change in the ARC/PRC ratio and in the KI. However, also in a recent study, Sogutlu et al.27, with KeraRing ICRS, showed different results: flattening of both corneal surfaces, but with greater magnitude of ARC27. Although held in Pentacam, this study evaluated the front and back elevations in terms of "best-fit sphere" and maximum elevation and not the ARC or PRC themselves. This study does not contradict, therefore, in our view, our results.

As a conclusion, we can say that eyes previously implanted with ICRS suffer from the same limitations in determining CCP as eyes with other types of KS, including: measuring instrument errors as well as refractive index errors. Olsen estimated that a change in the KI of 0.001 induces a change in keratometry of approximately 0,13D18 with a similar error in the calculation of the dioptric power of an IOL (not corrected for vertex distance). In the future, rather than creating new formulas or optimizing constants, determining the true CCP, by the Gauss formula, ray-tracing or other methods, will therefore be the real challenge and the essential step in the calculation of an IOL to implant in these patients.



Figure 1 |Tangential anterior curvature map (Sirius, CSO) showing the effect of Intacs-SK in the ARC (mm), in a patient 6 months after surgery.

**BIBLIOGRAPHY**

1. Aramberri J. Intraocular lens power calculation after corneal refractive surgery: double K-method. J Cataract Refract Surg 2003; 29:2063-2068.
2. Bernardo MD, Capasso L, Caliendo L, Paolercio F, Rosa N. IOL Power Calculation after Corneal Refractive Surgery. Biomed Res Int 2014; ID 809037.
3. Burris TE, Ayer CT, Everson DA, Davenport JM. Et al. Changes in keratoconic corneas after intrastromal cornealring size and thickness on corneal flattening in human eyes. Refract Corneal Surg 1991; 111:747-751.
4. Camellin M, Savini G, Hoffer KJ, Carboneli M, Barboni P. Scheimpflug camera measurement of anterior and posterior corneal curvature in eyes with previous radial keratotomy. J Refract Surg 2012; 28-275-279.
5. Cezón J. Cirurgía de cataratas en pacientes con segmentos intraestromales. In: Lorente R, Mendicute J. Cirurgía del Cristalino. LXXXIV Ponencia Oficial de la Sociedad Española de Oftalmologia 2008; 961-971.
6. Dubbelman M, Sicam VADP, van der Heijde GL. The shape of the anterior and posterior surface of the aging human cornea. Vision Res 2006; 46:993–1001.
7. Dubbelman M, Weeber HA, van der Heijde RGL, Volker-Dieben HJ. Radius and asphericity of the posterior corneal surface determined by corrected Scheimpflug photography. Acta Ophthalmol Scand 2002; 80:379-383.
8. Dunne MCM, Royston JM, Barnes DA. Normal variations of the posterior corneal surface. Acta Ophthalmol (copenh) 1992; 70:255-261.
9. Edmund C. Posterior corneal curvature and its influence on corneal dioptric power. Acta Ophthalmol (Copenh) 1994; 72: 715–720.
10. Fam HB, Lim KL. Validity of the keratometric index: large population based study. J Cataract Surg 2007; 33:686-691.
11. Hoffer KJ, Calogero D, Faaland RW, Ilev IK. Testing the dioptric power accuracy of exact-power-labeled intraocular lenses. J Cataract Refract Surg 2009; 35 (11): 1995-1999.
12. Ho JD, Tsai CY, Jui-Fang R, Kuo LL, Tsai IL, Liou SW. Validity of keratometric index: evaluation by the pentacam rotating Scheimpflug camera. J Cataract Refract Surg 2008; 34: 137-145.
13. Holladay JT. Cataract surgery in patients with previous keratorefractive surgery (RK, PRK and LASIK). Ophthalmic Pract 1997; 15:238-244.
14. Lim K-L, Fam H-B. Relationship between the corneal surface and the anterior segment of the cornea: an Asian perspective. J Cataract Refract Surg 2006; 32:1814–1819.
15. Menezes C et al, Intacs SK e Queratocone. Eficácia, Segurança e Efeito sobre o Índice Queratométrico Corneano. Comunicação apresentada em: 57º Congresso da Sociedade Portuguesa de Oftalmologia, Dezembro de 2014, Vilamoura).
16. Montalbán R, Alio J, Javaloy J, Piñero D. Comparative analysis of the relationship between anterior and posterior corneal shape analyzed by Scheimpflug photography in normal and keratoconus eyes. Graefes Arch Clin Exp Ophthalmol 2013; 251: 1547-1555.
17. Olsen T. Calculation of intraocular lens power: a review. Acta Ophthalmol Scand 2007; 85: 472-485.
18. Olsen T. On the calculation of power from curvature of the córnea. Br J Ophthtalmol 1986; 70:152-154.
19. Piñero DP. Alió JL, Alesón A, Escaf Vergara M, Miranda M. Corneal volume, pachymetry and correlation of anterior and posterior corneal shape in subclinical and different stages of clinical keratoconus. J Cataract Refract Surg 2010; 36:814-825.
20. Rabinowitz Y. INTACS for keratoconus. Int Ophthalmol Clin 2010; 50(3):63-76.
21. Rojas V, Gestoso A, Gómez A, Fuente M, López M, Rodrígues R et al. Keratometric índex in keratoconic eyes before and after intracorneal ring segment implantation. J Emmetropia 2014; 5: 9-13.
22. Royston JM, Dunne MCM, Barnes DA. Measurement of posterior corneal surface toricity. Optom Vis Sci 1990; 67:757–763.
23. Savini G, Barboni P, Carbonelli M, Hoffer KJ. Repeteability of automatic measurements by a new Scheimpflug camera combined with Placido topography. J Cataratact Refract Surg 2011; 37:1809-1816.
24. Savini G, Calossi A, Camellin M, Carones F, Fantozzi M, Hoffer K. Corneal ray tracing versus simulated keratometry for estimating corneal power changes after excimer laser surgery. J Cataract Refract Surg 2014; 40:1109-1115.
25. Schlegel Z, Hoang-Xuan T, Gatinel D. Comparison of and correlation between anterior and posterior corneal elevations maps in normal and keratoconus-suspected eyes. J Cataract Refract Surg 2008; 34:789-797.
26. Seitz B, Langenbucher A. Intraocular lens power calculation in eyes after corneal refractive surgery. J Refract Surg 2000; 16:349-361.
27. Sögütlü E, Piñero DP, Kubaloglu A, Alió JL, Cinar Y. Elevation Changes of Central Posterior Corneal Surface After Intracorneal Ring Segment Implantation in Keratoconus. Cornea 2012; 31:387–395.
28. Tomikodoro A, Oshika T, Amano S, Higaki S, Maela N, Miyata K. Changes in anterior and posterior corneal curvatures in keratoconus. Ophthalmology 2000; 107:1328-1332.
29. Wang L, Jackson DW, Koch DD. Methods of estimating corneal refractive power after hyperopic laser in situ keratomieleusis. J Cataract Refract Surg 2002; 28(6): 954-961.
30. Wang L, Mahmoud AM, Anderson BL, Koch DD, Roberts CJ. Total corneal power estimation: ray tracing versus Gaussian optics formula. Invest Ophthalmol Vis 2011; 52: 1716-1722.
31. Watson MP, Amand S, Bhogal M, Gore D, Moriyama A, Pullum K et al. Cataract surgery outcome in eyes with keratoconus. Br J Ophthalmol 2014; 98(3): 361-364.
32. Wilson SE. Lin DT, Klyce SD. Corneal topography of keratoconus. Cornea 1991; 10:2-8.