Artigo Original

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

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RESUMO

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 cases[2,11,17,26]. 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 hypermetropia[2,13,24,28].

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 errors[11,17]. 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 KS[11,17]. This occurs typically in ablative laser surgery such as LASIK and PRK[11]. 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 curvature[17]. 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 KI[11]. 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 surfaces[5]. 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 studies[31], with differing results in the issue of variation of ARC/PRC ratio and in KI[16,21,27].

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 al[21], 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 visit 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 correction[15].

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 demonstrated[23], 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).

$$CCP\ (D) = (KI - 1)/ ARC\ (mm)$$

$$\leftrightarrow$$

$$\boldsymbol{KI = CCP\ (D)\ x\ ARC\ (mm) + 1}$$

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 laser[24,30] and it was even shown its superiority against the Gauss formula in these cases[30].

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).

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 1.28[6,9,10,14,22], 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 1.3282[21].

In KC both corneal surfaces are changed with possibly earlier and more marked alterations in the posterior cor-

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

Parameter	Mean ± SD Control vs. KC (pre-op)		p value (KC –control)	Mean ± SD KC (post-op)	p value (post-op - pre-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 1.3315[18]. 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 eyes[6,7,8], 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 nea surface[25,28]. 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 KC[16,19]. 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 length[3] (Fig.1). Its effect depends on its optic area, thickness, arc length, symmetry /asymmetry of the placed rings and if are

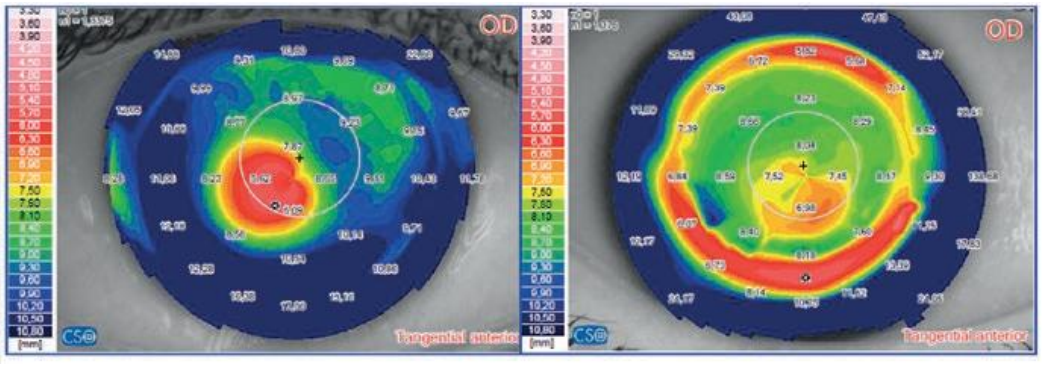

Fig. 1 | Tangential anterior curvature map (Sirius, CSO) showing the effect of Intacs-SK in the ARC (mm), in a patient 6 months after surgery.

inserted just one or two ICRS[20,32]. 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 SK[20].

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 ARC[27]. 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 0,13D[18] 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.

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