Comparison of Tomography Suspect Keratoconus Defined by Sirius and Pentacam in a Chinese Cohort

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Research Article

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Abstract

Purpose: To compare the proportion of tomography suspect keratoconus (TSK) defined by Sirius and Pentacam, and to explore the possible causes of the differences between them in a Chinese cohort.

Methods: Single center retrospect cohort study. All subjects were selected from the Peking University Third Hospital Ectasia Cornea Disease Cohort Project database, which included myopic patients seeking corneal refractive surgical corrections since the year of 2013. Demographic information, basic eye examination, and auxiliary equipment examination including refraction, IOL-master, Pentacam, Sirius, and Topolyzer were recorded. In this study, all cases which were examined by Sirius and Pentacam respectively and have been followed up at least 2 years without abnormalities after laser corneal refractive surgeries (LASEK, FS-LASIK or SMILE). The composition ratio of TSK from Sirius and Pentacam were compared using *Pearson Chi-square tests*. *Unpaired t tests* and *Chi-square tests* were used to compare the differences of corneal diameter, corneal thickness, and variables of corneal tomographers between the normal eyes and the TSK eyes defined by Sirius and Pentacam separately.

Results: To the date of December 31, 2018, total 171 cases (278 eyes) were selected in this study, the mean age is 28.4 years old. Total 167 (167/278, 60.1%) eyes were diagnosed of TSK by Sirius, and 203 (203/278, 73.0%) eyes were diagnosed of TSK by Pentacam ($P < 0.001$). The corneal horizontal diameter is 11.40 and 11.60 mm in normal eyes and Sirius-TSK eyes ($P < 0.001$). The corneal horizontal diameter is 11.74 and 11.43 mm in normal eyes and Pentacam-TSK eyes ($P < 0.001$). The central corneal thickness measured by Sirius is 530.1 μm and 518.1 μm ($P = 0.001$) in normal eyes and Sirius-TSK eyes. The central corneal thickness measured by Pentacam is 521.5 μm and 526.6 μm ($P = 0.102$) in normal eyes and Pentacam-TSK eyes. There is statistical significance between normal eyes and TSK eyes defined by Sirius in the proportion of “yellow or red” S1f and S1b. There is statistical significance between the normal eyes and the TSK eyes defined by Pentacam in the proportion of “yellow or red” Df, Db, Dp, and Da, and there is no difference in Dt between them.

Conclusions: The proportion of TSK eyes diagnosed by Sirius is less than those diagnosed by Pentacam in Chinese. Smaller corneal diameter is liable to be judged as TSK by Pentacam in Chinese compared with Sirius. Thinner corneal thickness is liable to be judged as TSK by Sirius in Chinese compared with Pentacam. The variables of S1f and S1b are the main factors leading to TSK in Sirius, the Dt is more stable in Pentacam using for screening normal Chinese cases.

Introduction

Laser corneal refractive surgery that began in the 1990s has been well developed and widely applied in ametropia correction for millions of patients. Following more and more young people has the demanding for the freedom from glasses, laser corneal refractive surgery has become extremely popular in the world. [1] It's very important to screen subclinical keratoconus preoperatively, for undetected Keratoconus (KC) is one of the most common causes of the development of ectasia after surgery, that is a bilateral, non-

inflammatory ectatic corneal disease, in which cornea is cone-shaped with anterior surface contour emphasized over the central and paracentral cornea resulting in myopia, irregular astigmatism, and eventually visual impairment.[2, 3] There are reports about the prevalence of KC. It was 1.2%, or 1 in 84 in an Australian population-based study of 20-year-old adults,[4] and in Denmark, the average incidence rate 2011-2015 was 3.60 per 100 000 person-years.[5] In South Korea, the incidence was nearly 15.1 cases per 100,000 person-years.[6] Though there are no exactly number of KC in China, a great number of patients likely be diagnosed each year for the great mass of population.

Various of corneal tomographers provide more sensitive estimates of prevalence/incidence[7, 8] with the advent of Scheimpflug technology, such as Pentacam and Sirius, which are two of most commonly used preoperational keratoconus screening instruments[9–11]. Following the enhancing tomographic assessment technique, the susceptibility of detection corneal ectasia are improved.[10] From the clinical perspective, however, increasing sensitivity will cause more tomography suspect keratoconus (TSK), among them there were lots of normal patients were misdiagnosed with 'suspect' KC, for the database that tomographic equipment based on are consisted of different races. Besides, publications[12–14] also reported that the sensitivity and specificity of any topometric and tomographic parameters were not high enough to be used alone. The previous publication[15] has demonstrated the difference criteria using for screening the suspect KC and ascertained the corneal diameter and thickness that maybe result in the "TSK" cases, especially in Chinese in screening suspect KC before laser corneal refractive surgeries.

In this study, we are going to compare the proportion of TSK between Sirius and Pentacam in a Chinese cohort, and explore the possible reasons for them.

Methods And Patients

The study conformed to the Declaration of Helsinki and was approved by the review board/ethics committee of the Peking University Third Hospital. A review of all patients was conducted and informed consents were obtained from the participants.

The methods and cohort have been published in previous study[15] and briefly described here. The cases in this study came from a cohort project - Peking University Third Hospital Ectasia Cornea Disease Cohort Project, which is a single center prospective cohort based on the outpatient of Peking University Third Hospital and was established in 2013, all cases of the cohort were from the patients who came to Peking University Third Hospital Eye Center seeking refractive surgeries and consented to join in the cohort study.

All patients had a series of ocular examinations including corrected distance visual acuity and near vision, the slit lamp biomicroscopy for anterior and posterior segment. Demographic information of these cases such as ages, history of refractive error, ocular surgery history, and family history were recorded. Besides, Sirius (Costruzione Strumenti Oftalmici, Florence, Italy), Pentacam HR (Oculus, Wetzlar, Germany), and Allegro Topolyzer (Alcon Inc., TX, USA) were used for every cases. All the examination results of the patients were analyzed by a professor who is also the chief-surgeon of refractive surgery

and decided whether the subject is suitable for refractive surgeries. All cases were followed up regularly in the first 6 months and the necessary examinations were applied at the visit. All the data files of baseline and the follow-ups were collected by an assigned employer and the data was input in Microsoft Excel data frame by two assistants.

To the date of 2018.12.31, total 171 cases (278 eyes) were conformed to the inclusion criteria of this study in the cohort project database, the inclusion criterion and exclusion criterion as follows:

Inclusion criterion: In this study, all cases were selected from the cohort project database. All cases were diagnosed as 'suspect KC' by Sirius or the final D value reported as 'yellow or red' by Pentacam Belin/Ambrósio Display (BAD-D), and those have stable refraction and vision without any signs of cornea ectasia after at least 2 years of follow-up after laser corneal refractive surgeries (LASEK, FS-LASIK or SMILE).

Exclusion criterion: Eyes with incomplete baseline information, or without records of follow-up.

Keratoconus diagnosis: referred the criterion[3], clinical diagnosis for keratoconus by one chief professor doctor based on comprehensive judgment. Those eyes diagnosed with KC were excluded from any corneal refractive surgeries.

All the auxiliary examinations for cases in the cohort project database were repeated for 3-4 times, including Sirius, Pentacam, and Topolyzer. In this study, we compared the cornea horizontal diameter measured by Topolyzer, central cornea thickness measured by Sirius or Pentacam, and ThkMin (minimum thickness) in Sirius or Pentacam, between the 'normal eyes' and 'TSK eyes' defined by Sirius and Pentacam respectively.

Variables of tomography in this study:

Usually, variables of corneal tomographers are marked in different colors according to different range of values.

In Sirius, Slf (symmetry index of front corneal curvature) < 0.85 (white), 0.85-1.25 (yellow), > 1.25 (red); Slb (symmetry index of back corneal curvature) < 0.22 (white), 0.22-0.37 (yellow), > 0.37 (red); KVf (keratoconus vertex front) < 15um (white), >= 15um (red); KVb (keratoconus vertex back) < 15um (white), >= 15um (red); BCVf (Baiocchi Calossi Versaci front) < 0.80 (white), 0.80-1.20 (yellow), > 1.20 (red); BCVb (Baiocchi Calossi Versaci back) < 0.80 (white), 0.80-1.20 (yellow), > 1.20 (red).

In Pentacam, the difference index comparing with normal cornea including Df (deviation of front elevation difference map), Db (deviation of back elevation difference map), Dp (deviation of average pachymetric progression index), Dt (deviation of minimum thickness), Da (deviation of Ambrosio's Relational Thickness maximum), D (Belin/Ambrosio enhanced ectasia total derivation value).

Df: Deviation of front elevation difference map. The value Df is normalized to its mean value and is reported as the standard deviation from the mean. The value is color coded based on its variation from the norm: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 2.6SD$ from the mean, abnormal.

Db: Deviation of back elevation difference map. The value Db is normalized to its mean value and is reported as the standard deviation from the mean. The value is color coded based on its variation from the norm: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 2.6SD$ from the mean, abnormal.

Dp: Deviation of average pachymetric progression. The value Dp is normalized to its mean value and is reported as the standard deviation from the mean. The value is color coded based on its variation from the norm: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 2.6SD$ from the mean, abnormal.

Dt: Deviation of minimum thickness. The value Dt is normalized to its mean value and is reported as the standard deviation from the mean. The value is color coded based on its variation from the norm: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 2.6SD$ from the mean, abnormal.

Da: Deviation of ARTmax. The value Da is normalized to its mean value and is reported as the standard deviation from the mean. The value is color coded based on its variation from the norm: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 2.6SD$ from the mean, abnormal.

D: Total Deviation value. The five parameters (Df, Db, Dp, Dt, Da) are taken into account and a regression analysis is performed against a standard data base of normal and keratoconic corneas. The results are displayed color coded: White: within normal limits; Yellow: $\geq 1.6SD$ from the mean, suspicious; Red: $\geq 3.0SD$ from the mean, abnormal.

Statistical analysis

Statistical description includes calculation of the mean, standard deviation, 95% confidence interval. *Unpaired student t test* was used for cornea horizontal diameter and cornea thickness and *Chi square test* was used for ratio. Statistical significance was defined as $P < 0.05$. All the eligible data was analyzed using IBM SPSS Version 26 statistic software (IBM SPSS Inc. Chicago, Illinois, USA). And the figures were made by GraphPad Prism 8.0.2 (GraphPad Software, Inc. San Diego, California, U.S.)

Results

In this study, total 171 patients (278 eyes) are included, and there are 40 male and 131 female among them. The mean age is 28.43 (SD, 7.03; range 17.0 - 48.0) years old.

In total 278 eyes, 167 (60.1%, 167/278) were diagnosed tomography suspect keratoconus (TSK) by Sirius; and 203 (73.0%, 203/278) were diagnosed TSK by Pentacam based on BAD-D. There is a

statistical significance between them (*Pearson Chi-Square* = 68.27, $P < 0.001$) (see Figure 1.)

The mean cornea horizontal diameter is 11.40 (SD 0.37) mm and 11.60 (SD 0.35) mm in normal group and TSK group ($P < 0.001$) examined by Sirius. The mean cornea horizontal diameter is 11.74 mm (SD 0.36) and 11.43 mm (SD 0.35) in normal group and TSK group ($P < 0.001$) examined by Pentacam. (see Fig. 2.)

The normal and TSK group grouped by Sirius, the central corneal thickness (CCT) measured by Sirius is 530.1 μm (SD 31.2) and 518.1 μm (SD 23.5) respectively ($P = 0.001$). The normal and TSK eyes defined by Pentacam, the CCT measured by Pentacam is 521.5 μm (SD 21.0) and 526.6 μm (SD 28.1) respectively ($P = 0.102$) (see Fig. 3.). The normal and TSK eyes defined by Sirius, the thinnest thickness of cornea examined by Sirius is 526.3 μm (SD 30.7) and 514.7 μm (SD 23.3) respective ($P = 0.001$); The normal and TSK eyes defined by Pentacam, the thinnest thickness of cornea examined by Pentacam is 516.4 μm (SD 20.4) and 519.7 μm (SD 27.7) respective ($P = 0.28$). (see Fig. 4.)

As for the variables in Sirius and Pentacam. The proportion of reporting “white, yellow, or red” of Slf, Slb, KVf, KVb, BCVf, BCVb in Sirius are listed in Table 1. The proportion of reporting “white, yellow, or red” of Da, Dt, Dp, Db, and Df are listed in Table 2.

Table 1
Comparison of the variables between normal and TSK defined by Sirius.

		Count (N%)				Chi2 (P^*)			
		Normal		TSK		White vs. (Yellow + Red)		White vs. Yellow vs. Red	
Slf	White (<0.85)	81	(73.0)	84	(50.3)	14.21	(<0.001)	15.11	(0.001)
	Yellow (0.85-1.25)	22	(19.8)	52	(31.1)				
	Red (>1.25)	8	(7.2)	31	(18.6)				
Slb	White (<0.22)	89	(80.2)	80	(47.9)	29.14	(<0.001)	29.16	(<0.001)
	Yellow (0.22-0.37)	20	(18.0)	78	(46.7)				
	Red (>0.37)	2	(1.8)	9	(5.4)				
KVf	White (<15um)	111	(100.0)	166	(99.4)	-	(1.00)	-	-
	Red (>=15um)	0	(0.0)	1	(0.6)				
KVb	White (<15um)	77	(69.4)	102	(61.1)	2.00	(0.16)	-	-
	Red (>=15um)	34	(30.6)	65	(38.9)				
BCVf	White (<0.80)	107	(96.4)	156	(93.4)	1.16	(0.28)	-	(0.12)
	Yellow (0.80-1.20)	3	(2.7)	11	(6.6)				
	Red (>1.20)	1	(0.9)	0	(0.0)				
BCVb	White (<0.80)	101	(91.0)	148	(88.6)	0.40	(0.53)	0.87	(0.65)
	Yellow (0.80-1.20)	8	(7.2)	17	(10.2)				
	Red (>1.20)	2	(1.8)	2	(1.2)				
*Pearson Chi2 test, Exact test was used when the number is 0 in any grid. TSK, tomography suspect keratoconus.									

Table 2
Comparison of the variables between normal and TSK defined by Pentacam.

		Count (N%)				Chi2 (P^*)			
		Normal		TSK		White vs. (Yellow + Red)		White vs. Yellow vs. Red	
Da	White	74	(98.7)	164	(80.8)	14.21	<0.001	-	(<0.001)
	Yellow	1	(1.3)	39	(19.2)				
	Red	0	(0.0)	0	(0.0)				
Dt	White	68	(90.7)	183	(90.1)	0.02	(0.90)	-	(1.00)
	Yellow	7	(9.3)	19	(9.4)				
	Red	0	(0.0)	1	(0.5)				
Dp	White	71	(94.7)	121	(59.6)	31.51	(<0.001)		(<0.001)
	Yellow	4	(5.3)	64	(31.5)				
	Red	0	(0.0)	18	(8.9)				
Db	White	73	(97.3)	175	(86.2)	7.04	(0.008)	-	(0.022)
	Yellow	2	(2.7)	24	(11.8)				
	Red	0	(0.0)	4	(2.0)				
Df	White	71	(94.7)	130	(64.0)	25.65	(<0.001)	-	(<0.001)
	Yellow	4	(5.3)	60	(29.6)				
	Red	0	(0.0)	13	(6.4)				
*Pearson Chi2 test, Exact test was used when the number is 0 in any grid. TSK, tomography suspect keratoconus.									

The laser corneal refractory surgeries employed for subjects in the study are listed in Table 3.

Table 3
The refractory surgery in this series cases.

Treatment	Count	Column N %
EK	186	66.9%
FS-Lasik	77	27.7%
SMILE	15	5.4%
LASEK Laser assisted Subepithelial Keratomileusis, FS-LASIK Femtosecond laser assisted Laser in-situ Keratomileusis, SMILE Small incision lenticule extraction.		

Discussion

There are higher incidence and prevalence of keratoconus whatever in Asia or other countries[16–19]. So it is very important to screen accuracy for "suspicious keratoconus" for outpatients, especially before laser corneal refractive surgeries. With the widespread use of Scheimpflug technology, such as Pentacam and Sirius, more and more suspicious patients were detected. However, it will lead to screen more and more tomography suspect keratoconus (TSK) cases, who lose the chance of refractive surgery. In the Peking University Third Hospital Ectasia Cornea Disease Cohort Project, we found that the corneal shape is still stable for more than 2 years after corneal refractive surgeries in some cases which had been suggested with abnormalities by tomography and there were no signs of ectasia in them. Previously publication[15] has suggested that the possible causes of TSK. This article is to compare the proportion of TSK eyes suggested by Sirius and Pentacam, and to explore the clinical features of those eyes and 'sensitive indicators' for TSK in Sirius and Pentacam.

The Pentacam and Sirius have become standard and wide accepted equipments in the evaluation of the preoperative refractive surgical candidate[20, 21]. Although the previous studies evaluated the agreement in the corneal thickness, anterior chamber depth in normal eyes between Sirius and Pentacam[22], there are also studies focused on the repeatability and comparability of anterior segment biometry obtained by the Sirius and the Pentacam analyzers[23]. However, few studies on the comparison of TSK eyes suggested by Sirius and Pentacam, especially in East Asian. This study is focused on the comparison of the TSK screened by two corneal tomographic equipment. In this study, the authors selected a series eyes diagnosed as TSK by Sirius or Pentacam. All cases have already been followed up at least 2 years without abnormalities after one of the laser corneal refractive surgeries (Table 3.).

There is statistically significant differences ($P < 0.001$) for both two groups judged by Sirius and Pentacam (Figure 1.), there is less proportion of TSK in Sirius than that in Pentacam. *Boyd* and his college members focused on the variations in tomographic parameters in different geographic and ethnic populations, including the influence of corneal diameter on the parameters[24], the previous study also demonstrate that the corneal horizontal diameter and central corneal thickness have great influences on the results of corneal tomography in detecting the suspect keratoconus[15]. On the difference of Sirius and Pentacam, *Nasser* and his college members[11] found that the Sirius showed good to excellent repeatability for all measured parameters, but Sirius and Pentacam should not be used interchangeably, for there were statistically significant measured parameters, which have been demonstrated by *Anayol et al.*[22] From the results of the study, we suggested that both Sirius and Pentacam should be used before corneal refractory surgery to ensure the safety of post-operation. But the diagnosis of KC should be based on the subjective judgment of experienced doctors.

From our previous study, some of the patients lost the opportunity for surgery due to the diagnosis of TSK[15]. Eyes with TSK have certain characteristics, such as the feature of small corneal diameter[15]. But the Sirius and Pentacam have the different sensitive to the cornea horizontal diameter from our clinical observation. In this study, there is statistical difference in mean cornea horizontal diameter

between the two groups defined by Sirius and Pentacam (Figure 2). From the difference of the corneal diameter, the smaller diameter may lead to higher ratio of TSK in Pentacam. The cornea horizontal diameter has little effect on the screening results in Sirius compared with Pentacam. In the normal and TSK group defined by Pentacam, the mean cornea horizontal diameter is 11.74 (SD 0.36) and 11.43 (SD 0.35) respective, and there is statistical significance between them ($P < 0.001$) (Figure 2). The eyes with a smaller cornea are easier to be judged as TSK. Previous publications[15, 24–26] have reported that Chinese have been observed having smaller corneal diameters than North American (white and African-American) patients. Similar to views of our previous publication[15], we considered that the eye globes of Chinese are with a smaller corneal diameter. Therefore, the corneal diameter has more effects on some tomographic indices obtained from the Pentacam comparing with European and American. Because, the patients used for Pentacam are European and American, the cases using for Sirius are much closer to Eastern people. The Pentacam has been golden criteria for screening KC, therefore, more Eastern should be included in the database. In this study, the corneal diameter of all cases measured by Topolyzer, for the Topolyzer examined based on the white to white, which is more accurate. And it is more rational to compare the results of Sirius and Pentacam using a third equipment. the corneal diameter has effects on the results judged by different tomography, for the database they based on are of different ethnic populations. Authors suggested that Sirius and Pentacam should include more corneal data from Asian people.

The central corneal thickness or the thinnest point corneal thickness was measured by Sirius, and Pentacam, and there were statistical differences between the normal group and the TSK group defined by Sirius and pentacam (see Figure 3. and Figure 4.). As previous study[15], not only the corneal diameter but the corneal thickness was needed to consider in screening KC. From the study, we found that the cornea thickness is more sensitive for screening KC in Sirius than that in Pentacam. Moreover, no statistical difference between the normal eyes and the Pentacam-TSK eyes in Dt can demonstrate that the cornea thickness is more stable for screening KC in Chinese (Table 2). In Sirius, the SIf/SIb (symmetry index of front/back corneal curvature) is more “sensitive” than KVf/KVb and BCVf/BCVb in Chinese, for there is statistical significance in those variables between the normal eyes and the Sirius-TSK eyes.

As mentioned in Pentacam, a normal or abnormal total Deviation value does not replace a detailed ophthalmologic examination of the patients’ eyes in order to make any medical diagnosis. While an individual parameter may fall outside the norm, the final overall comprehensive reading may still be viewed as normal. Conversely, multiple yellow or suspicious parameters may be significantly enough for the final reading D to be red or abnormal. From the study, the authors recommend that the variables in tomography should only be considered as assistants especially in Eastern. The main reasons are that the features of cornea in Eastern, including the diameter, thickness, and morphology of the front and back surfaces, are different from Western. With further investigation, more appropriate indicators are suitable for Asian should be developed.

From this study, we demonstrated that Pentacam is more liable to TSK compared with Sirius in Chinese, for the Pentacam is more sensitive to cornea horizontal diameter compared with Sirius. Therefore, Sirius

can be considered for screening KC for Eastern patients if it was defined as suspicious KC by Pentacam. In addition, it is worth thinking about 'false negative', which is what we will elaborate on in the next article. The main limitation of this study is less time of the last visit, which is 2 years or more, and longer follow-up time may be better. Furthermore, more cases included maybe improve the accuracy of evidence of this study.

In conclusion, we recommend that Sirius may be more adaptable for Chinese and Eastern in screening the KC before refractive surgery. To compare the results of Sirius and Pentacam can improve the accuracy of KC and avoid the TSK which makes lots of patients losing the chance of refractive surgeries. Further studies on integrations with corneal biomechanical parameters are needed for assessing suspect KC in the future, and the AI technique can be used to enhance screening the suspect KC as the Pentacam Random Forest Index (PRFI).[10]

Declarations

Ethics approval and consent to participate: The study conformed to the Declaration of Helsinki and was approved by the review board/ethics committee of the Peking University Third Hospital. A review of all patients was conducted and informed consents were obtained from all participants.

Consent for publication: All authors of this article have made substantive contribution to the study and agree to publish this article.

Availability of data and materials: The datasets generated and/or analyzed during the current study are not publicly available due the database is under construction but are available from the corresponding author on reasonable request.

Competing interests: The authors have no financial interests in any of the materials discussed in this article.

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Contributions of Authors: Design of this study (KANG FENG, YUE-GUO CHEN); conduct of this study (KANG FENG); collection of the data (KANG FENG, YU ZHANG, YUE-GUO CHEN); analysis and interpretation of the data (KANG FENG); review and approval of this manuscript (YUE-GUO CHEN).

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Figures

Figure 1

The proportion of true negative (normal eyes) and false positive (TSK eyes) judged by Sirius and Pentacam.

Figure 2

Compare the corneal diameter measured by Topolyzer between true negative group (normal eyes) and false positive group

(TSK eyes) judged by Sirius and Pentacam respectively in this series cases.

Figure 3

Compare the central corneal thickness measured by Sirius and Pentacam between true negative group (normal eyes) and

false positive group (TSK eyes), which judged by Sirius and Pentacam respectively.

Figure 4

Compare the thinnest point corneal thickness measured by Sirius and Pentacam between true negative group (normal eyes) and false positive group (TSK eyes), which judged by Sirius and Pentacam respectively.