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Research Article / Araştırma Makalesi

# Evaluation of the TRK-2P Instrument Reliability in Normal and Keratoconus Eyes: A Preliminary Observation

## *Normal ve Keratokonuslu Gözlerde TRK-2P Cihazının Güvenilirliğinin Değerlendirilmesi: Bir Ön Gözlem*

**[1]Feride Tuncer Orhan, [2]Eray Atalay,[2]Nilgün Yıldırım**

[1]Department of Ophthalmology, Eskisehir City Hospital, Eskişehir, Turkey

[2]Department of Ophthalmology, Eskisehir Osmangazi University Medical School, Eskişehir, Turkey

## Abstract

To compare keratometry and corneal thickness measurements by the TRK-2P instrument (Topcon Medical Systems Inc., Oakland NJ) with the anterior cornea keratometry and pachymetry values obtained by the Pentacam-HR instrument (Oculus; Optikgeräte GmbH, Wetzlar, Germany). Patients who had full records of two both instruments in our databases were included in the observational study. Keratoconus diagnosed twenty-three eyes of twelve patients and thirty-two eyes of sixteen patients with no eye problem (controls) were included. The keratometry and the central corneal thickness (CCT) outputs were collected by TRK-2P and Pentacam-HR. The consistency of the mean anterior cornea keratometry and pachymetry data were correlated using the intraclass correlation coefficient (ICC). Means were statistically correlated using a Paired t-test seeking significant correlations (α=0.05). Mean keratometry of TRK-2P and Pentacam-HR were 42.64D±2.02 and 42.79D±1.95 in controls whereas, these were 47.64D±5.24 and 47.16D±4.65 in keratoconus, respectively. The mean differences in keratometry data were 0.14D for controls and 0.48D for keratoconus(p<0.001). Mean CCT of TRK-2P and Pentacam-HR were 560.27±42.18µm and 537.63±36µm in controls whereas, these were 489.67±45.13µm and 470.22±38.14µm in keratoconus, respectively. The mean differences in CCT data were 22.63µm for controls and 19.44µm for keratoconus(p<0.001). ICC values between two instruments for controls and keratoconus, respectively were as follows: 0.987 and 0.983 for keratometry, 0.998 and 0.994 for CCT (p<0.001). TRK-2P produces consistent result outputs in normal and pathological corneas. Also, TRK-2P is a reliable instrument when correlated with a reference high-reliable instrument. However, in terms of monitoring the progression of keratoconus, these instruments cannot be interchangeable alternatives
**Keywords**: Central corneal thickness, Keratoconus, Pentacam HR, TRK-2P

## Özet

Bu çalışmanın amacı TRK-2P cihazı (Topcon Medical Systems Inc., Oakland NJ) ile elde edilen keratometri ve kornea kalınlık değerlerini, Pentacam-HR cihazı (Oculus; Optikgeräte GmbH, Wetzlar, Almanya) ile elde edilen ön kornea keratometrisi ve pakimetri değerleri ile karşılaştırmaktır. Veri tabanlarımızda her iki cihazın tam kayıtlarına sahip olan hastalar bu gözlemsel çalışmaya dahil edildi. On iki hastanın keratokonus tanılı yirmi üç gözü ve herhangi bir göz sorunu olmayan on altı hastanın otuz iki gözü çalışmaya dahil edildi (kontrol). Keratometri ve santral kornea kalınlığı (SKK) çıktıları TRK-2P ve Pentacam-HR ile elde edilmiştir. Ortalama ön kornea keratometrisi ve pakimetri verilerinin tutarlılığı, sınıf içi korelasyon katsayısı (ICC) kullanılarak ilişkilendirildi. Ortalamalar paired t-testi kullanılarak istatistiksel olarak analiz edildi (α=0.05). Ortalama keratometri TRK-2P ve Pentacam-HR kontrollerde 42.64 D±2.02 ve 42.79 D±1.95 iken keratokonusta 47.64 D±5.24 ve 47.16 D±4.65 idi. Keratometri verilerindeki ortalama farklılıklar kontroller için 0.14 D ve keratokonus için 0.48 D idi (p<0.001). TRK-2P ve Pentacam-HR ortalama SKK değerleri sırasıyla kontrollerde 560,27±42,18 µm ve 537,63±36 µm iken keratokonus hastaları için sırasıyla 489,67±45,13 µm ve 470,22±38,14 µm idi. SKK verilerindeki ortalama farklar kontroller için 22.63 µm ve keratokonus için 19.44 µm idi (p<0.001). Kontrol ve keratokonus grupları için iki cihaz arasındaki ICC değerleri sırasıyla keratometri için 0,987 ve 0,983, SKK için 0,998 ve 0.994 idi (p<0.001). Çalışmamızın sonuçları, TRK-2P, normal ve patolojik kornealarda tutarlı sonuç çıktıları üretir. Ayrıca, TRK-2P, yüksek güvenilirliğe sahip referans bir cihazla ilişkilendirildiğinde güvenilir bir araçtır. Ancak keratokonus progresyonunun izlenmesi açısından bu enstrümanlar birbirinin yerine geçebilecek alternatifler olamaz.
**Anahtar Kelimeler:** Santral kornea kalınlığı, Keratokonus, Pentacam HC, TRK-2P

**Correspondence:**
Feride TUNCER ORHAN
Department of Ophthalmology, Eskisehir City Hospital, Eskişehir, Turkey
e-mail:feridetncr@gmail.com

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## 1. Introduction

The accuracy of corneal analysis is necessary to diagnose, treatment planning, and maintenance of refractive surgery patients or pathological corneas such as keratoconus, glaucoma. Keratoconus (KC) is a corneal disease characterized by conical protrusion of the cornea. The thickness and durability of the cornea are adversely affected due to the degeneration in eye defects. Also, advanced pathology of KC can be caused to vision loss (1). Periodically analyses of the corneal thickness measurements at the central zone (CCT) and keratometry are as the standard ocular diagnostic parameters used to detect the cornea health (2).

In the past, KC could only be diagnosed in its advanced pathological stages with the slit lamp technique, but with contemporary precise and rapid instrumentation technology, early diagnosis has also become possible. The Pentacam HR instrument (PC-HR) (Oculus; Optikgeräte GmbH, Wetzlar, Germany) is a non-contact, high-resolution rotating 'Scheimpflug' camera system for anterior segment analysis (3-5). Mainly, PC-HR calculates the thickness of the cornea. Besides, the anterior and posterior corneal topography and elevation, total corneal refractive power, corneal power distribution, automatic chamber angle measurement in 360 °, chamber depth measurement, corneal and crystalline lens optical opacities are analyzed with the PC-HR instrument (Pentcam product brochure). Recently introduced all-in-one TRK-2P (TRK-2P; Topcon Medical Systems, Inc., Oakland, NJ) is a 4 in 1 instrument consisting of a refractometer, keratometer, non-contact tonometer, and pachymeter (6). All-in-one TRK-2P provides operator flexibility and time-efficient measurements or analyzes. All-in-one TRK-2P utilizes an optical pachymetry mode as dissimilar with the PC-HR principles to measure CCT, which includes using a tangential slit of light directed onto the cornea surface at aligned angles. Subsequently, CCT is calculated with a trigonometrical function accordance with intersection angles (7). However, there is limited information available on the recently introduced all-in-one TRK-2P instrument (7-10).

The above-mentioned instruments are categorized as non-contact and non-invasive instruments. Manufacturers claim accurate diagnostic outputs of keratometry and CCT for corneal topography analysis instruments. Though all-in-one TRK-2P or PC-HR instruments provide keratometry and CCT outputs, their operating fundamentals are dissimilar. Different types of instruments assessing the anterior segment yield an information about identical parameters. In this case, the agreement of these instruments has utmost importance for assessing the patient data in clinical practice. For this purpose, to understand the correlation among different instruments, specific clinical studies have been designed concerning their interchangeably used. However, interchangeably using instruments is still a controversial issue. Particularly, specialists often seek an information about cutting-edge novel instruments, in the reference of the current standards or well-known instruments. Also, this issue gains more major importance in corneal degeneration such as keratoconus eyes. With these justifications, this observational study aimed to correlate keratometry and corneal thickness outputs by the all-in-one TRK-2P instrument with the anterior cornea keratometry and pachymetry outputs obtained by the PC-HR instrument.

## 2. Patients and Methods

### *2.1. Ethical statement*

The study protocol adhered to the tenets of the declaration of Helsinki. The protocol was approved by the Human Subjects Office, Office of Non-Invasive Research Compliance – Eskisehir Osmangazi University (Study no. 26, issue date: 15.02.2022 with reference #: 2022/26).

### *2.2. Sample size estimation*

A priori t-test (means: difference between two independent mean, two groups) was selected from the t-test family in G*Power v3.1.7 software (Heinrich Heine Universität, Düsseldorf, Germany). Based on an effect size of 0.6, an alpha-type error of 0.05, and a power of 60%, the findings of a previous

study7 required minimum sample size of 21 per group to identify significant differences between the two research groups in terms of the parameter of each instrument type and keratoconus condition.

### *2.3. Inclusion criteria*

In this study, the patient records between January 2017 – January 2018 were obtained from the database of the department of ophthalmology, Eskisehir Osmangazi University, Eskisehir, Turkey. This observation analyzed the full records of two instruments using the routine clinical examination procedures for a cohort of subjects examined and does not use experimental or new protocols. All data analyzed were collected as a part of the routine diagnosis of KC. Inclusion criteria of the cohort subjects were as follows

A clinical and topographic diagnoses of KC were included in the study. The main inclusion criteria of subjects were no additional ocular problems except refractive errors. For this purpose, ptosis, pterygium, dry eye, cataracts, retinal disease, strabismus, corneal scar, edema, contact lens usage history, previous ophthalmic surgery in any eye, or uncooperative patients were not included in the study. The common inclusion criteria were (1) subjects with no systemically compromised and (2) having fully achievable records with both instruments.

### *2.4. Ocular examination*

All examinations were performed by ophthalmologists with 2-4 years of clinical experience using both instruments registered in the unit per the manufacturers' instructions. At first, automatic refraction, keratometry, and pachymetry outputs were obtained from the all-in-one TRK-2P instrument. Accordingly, keratometry was recorded utilizing the keratometry mode as K1 (flat keratometry) and K2 (steep keratometry). Then, the CCT outputs were collected utilizing the pachymetry mode. In routine diagnostic protocol, triplet optical analyses were obtained from each patient (three-time).

Second, the slit-lamp examination and high-resolution anterior corneal analyses were performed with PC-HR. To measure the corneal power and dioptric equivalents, two-perpendicular meridians (K1 and K2) were considered at the central 3mm of the corneal ring. Outputs were monitored via the software module of the instrument (Oculus; Optikgeräte GmbH, Wetzlar, Germany). Tomographic scans with an analysis quality that appeared as "OK" were recorded. The refractive indexes of both devices use 1.3375 for diopter conversion.

### *2.5. Statistical analysis*

Statistical analyses were conducted utilizing statistical package software (IBM SPSS Statistics for Windows, v20.0. IBM Corp., Armonk, NY). The normality of data was confirmed using the Kolmogorov-Smirnov test. The consistency of the mean anterior cornea keratometry and pachymetry data were correlated using the intraclass correlation coefficient (ICC). Means were statistically correlated using a s t-test seeking significant correlations. Statistical significance was assumed at $p < 0.05$.

## 3. Results

Twenty-three eyes from twelve KC patients were included in the study according to the criteria whereas, thirty-two eye from sixteen patients was included as healthy controls (Demographic data not shown).

The mean keratometry and CCT outputs are summarized in Table 1. Mean keratometry of all-in-one TRK-2P and PC-HR were 42.64 D ± 2.02 and 42.79 D ± 1.95 in controls whereas, these were 47.64 D ± 5.24 and 47.16 D ± 4.65 in keratoconus, respectively. The mean differences of keratometry data were 0.14 D for controls and 0.48 D for keratoconus ($p<0.001$). Mean CCT of TRK-2P and Pentacam-HR were 560.27 ± 42.18 µm and 537.63 ± 36 µm in controls whereas, these were 489.67 ± 45.13 µm and 470.22 ± 38.14 µm in keratoconus, respectively. The mean differences of CCT data were 22.63 µm for controls and 19.44 µm for keratoconus ($p<0.001$).

**Table 1.** The mean keratometry and corneal thickness at the central zone values measured by different instruments along with the paired differences between the instruments.

| Parameters | Eye | TRK-2P | Pentacam HR | ICC | *p* value |
|---|---|---|---|---|---|
| Keratometry (D) | Control (healthy) | 42.64D ± 2.02 | 42.79D ± 1.95 | 0.987 | <0.001 |
| | Keratoconus | 47.64D ± 5.24 | 47.16D ± 4.65 | 0.983 | <0.001 |
| CCT (µm) | Control (healthy) | 560.27 ± 42.18 | 537.63 ± 36.00 | 0.998 | <0.001 |
| | Keratoconus | 489.67 ± 45.13 | 470.22 ± 38.14 | 0.994 | <0.001 |

*CCT: Corneal thickness at the central zone; ICC: In-observation correlation coefficient. D: Dioptry.*

ICC values between two instruments for controls and keratoconus, respectively were as follows: 0.987 and 0.983 for keratometry, 0.998 and 0.994 for CCT ($p<0.001$). Accordingly, mean keratometry and CCT outputs obtained with the all-in-one TRK-2P showed a significant relationship with the measurements obtained with the PC-HR for both keratoconus and healthy eyes.

Overall, the conflicting outputs were observed between all-in-one TRK-2P and PC-HR instrument. Concerning PC-HR results, the CCT yielded thicker outputs for keratoconus and healthy eye. Also, keratometry yielded lower in healthy eye (flat keratometry) whereas, higher in keratoconus (Steep keratometry).

## 4. Discussion

Due to the requirement for precise measurements of anterior segment characteristics, novel reliable measurement instruments have been introduced parallel to the biomedical developments. However, interchangeable usage can occur in clinical practice among the instruments with overlapped modes by operators with intentionally or unintentionally. Thus, ophthalmologists should be informed such these instruments' interchangeability both in normal eyes and eyes with pathologies (7). In a previous study, it has been recommended that further study was needed to assess the agreement of CCT measurements in abnormal corneas such as keratoconus cornea (8). Accordingly, this observational study compared keratometry and corneal thickness measured in normal eyes and keratoconus by the all-in-one TRK-2P with the anterior cornea keratometry and pachymetry obtained by the PC-HR.

In the present study, CCT and keratometry data obtained by the all-in-one TRK-2P and PC-HR instruments in normal and KC eyes were evaluated for the first time. In-observation correlation coefficient values of the observation parameters obtained from TRK-2P and PC-HR instruments showed consistency. There was a strong correlation between the two instruments in both keratoconus and normal eyes. It has been reported that all-in-one TRK-2P and PC-HR were both reliable instruments in previous reports (7,8,11-13). Regarding all-in-one TRK-2P, it has been associated with optical low-coherence reflectometry (Lenstar LS 900) in a previous study and was found to show excellent agreement between the two instruments in terms of CCT outputs in healthy eyes (8). Similarly, the CCT parameter obtained from four optical instruments which included among of the PC-HR and all-in-one TRK-2P instruments were correlated by Özyol & Özyol (7). Regarding their results, it has been recommended that PC-HR and all-in-one TRK-2P instruments could not be used interchangeably with healthy eyes (7).

As mentioned earlier, keratometry readings of proficient instrument shows the radius of the corneal curvature. Notably, keratometry readings are specific parameter in the diagnosis of ectatic disorders as keratoconus. For this reason, keratometry readings have importance for staging, monitoring the progression, and creating treatment plans in KC patients (12). Hashemi et al. (13) have correlated keratometry readings of a handheld auto-refractokeratometer and PC-HR instruments. Regarding their results, two instruments has the worst agreement except for in emmetropic cases (13). Considering the progressive nature of KC, potential reading

errors may occur due to variations of amongst corneal phenotype. Additionally, it has been reported that the keratometry and pachymetry outputs can be affected by different tonometry instruments in KC cases (14-16).

Previously, all-in-one TRK-2P and PC-HR instruments have significantly correlated according to the CCT parameter in healthy eyes (7). Regarding the result of the previous study, the mean differences of CCT data had 13.6 ± 7.5 µm ($p < .001$) (7). In agreement with the previous study, we found a significant correlation that the mean differences of CCT data were 22.63 µm for controls and 19.44 µm for keratoconus ($p< 0.001$). We consider that the disparity of the means of thickness between our results and the previous report might be originated the demographic character of selected cohorts such as age, gender, or body mass index. Additionally, the disparity is considering clinically insignificant.

The ICC values of controls and keratoconus were (ICC= 0.987), and 0.983 for keratometry, while there were 0.998 and 0.994 for CCT, respectively ($p < 0.001$) in the present study. Regardless of the eye condition, excellent repeatability was seen in PC-HR (ICC= 0.987) whereas, high repeatability was seen in all-in-one TRK-2P (ICC= 0.983) for the CCT parameter. Hence, our results were in concordance with the previous correlations. Previously, having excellent-repeatability had been reported for PC-HR with ICC=0.981(7,17), and ICC=0.987 (18). In addition, having excellent-repeatability had been reported for all-in-one TRK-2P with ICC=0.974 (7).

PC-HR is a Scheimpflug imaging topography instrument that uses a single Scheimpflug camera (rotating from 0° to 180°) (19). The utilized camera can capture up to 50 slit-images from the reflected tear-film layer of the anterior segment in approximately 2 s (20, 21). Principally, the electromagnetic energy source of the PC-HR generates the blue-colored light at 470 nm wavelength. The wavelength of energy might be caused by a high amount of scattering of light via corneal reflections (19-22). Therefore, the scattered energy could adversely affect the thickness determination (23, 24). This drawback could be more distinctive in eyes with pathological corneas such as keratoconus (24). According to its manufacturer, all-in-one TRK-2P includes a registered 'Rotary Prism Technology' that provides reliable measurements. Accordingly, automatic refractometry and keratometry modes of all-in-one TRK-2P use this unique rotary prism (6). Principally, the infrared light source of the all-in-one TRK-2P generates electromagnetic energy at a longer wavelength that causes less scattering in corneal tissue (24). However, all-in-one TRK-2P evaluates only two perpendicular meridians of the anterior cornea. Thus, all-in-one TRK-2P does not provide keratometry outputs of the entire cornea whereas PC-HR do.

The sample size of the present study conducted on a group of Turkish population was in agreement with the previous studies (7,16). However, authors considered that the demographic characteristics of the patients is a limitation of this study due to racial characteristics. In addition, the cohort subjects of this study considered that do not reflect the general Turkish population. Within the limitation of this study, this is the first information in the literature associating the CCT and keratometry data obtained by the all-in-one TRK-2P and PC-HR in normal and KC eyes. Further studies are needed to provide data variability of the overlapped instruments on keratoconus or different eye defects.

Currently, PC-HR is known as a reliable and high-precise instrument among ophthalmologists, however, there is no standard technology for corneal topography characterization and it is not also possible to define which instrument provides the most precise measurements (19). To make an examination with the all-in-one instruments reduces the time loss and therefore the clinical workload. Besides its advantages during operation, being accurate and reliable is fundamental.

## 5. Conclusion

Within the limitations of this observational study, the following conclusions can be

drawn: All-in-one TRK-2P is a reliable instrument when correlated with Pentacam HR as a reference high-reliable instrument. Also, TRK-2P can produce consistent results in normal and pathological corneas.

***Approved by the following research ethics committee***

*Yes. The study protocol was performed in accordance with relevant guidelines and regulations. The protocol was approved by the Human Subjects Office, Office of Non-Invasive Research Compliance – Eskisehir Osmangazi University (Study no. 26, issue date: 15.02.2022 with reference #: 2022/26).*

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