

## Ocular response analyzer (ORA) derived parameters compared to Sirius corneal topography in analyzing corneal pathology

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### Abstract

**Purpose:** To evaluate the ability of Ocular Response Analyzer (ORA) to differentiate between normal and abnormal corneas as compared to Sirius corneal topography.

**Methods:** This retrospective study included 302 eyes of 151 patients. All patients underwent evaluation with ORA and Sirius corneal topography. Parameters included disease classification results on both instruments (device software classification), Surface asymmetry index (SAI) on Sirius, Corneal Hysteresis (CH), Corneal Resistant Factor (CRF), Keratoconus Match Index (KMI), Goldmann-correlated intraocular pressure (IOPg), Corneal compensated intraocular pressure (IOPcc) and waveform score (WS) on ORA.

**Results:** On Sirius, 198 eyes (65.6%) were classified as normal. On ORA, 121 eyes (40.1%) were documented as normal. Overall, 105 eyes (34.8%) were classified as normal and 88 eyes (29.1%) with non-normal classification on both Sirius and ORA. Of the 198 eyes classified as normal on Sirius, 53% were classified as normal, 39% as suspect and 8% as mild keratoconus on ORA (47% non-normal). Of the 121 eyes classified as normal on ORA, 87% were classified as normal, 6% as suspect, and 2% as keratoconus compatible on Sirius (13% non-normal). Four percent of the eyes classified as keratoconus compatible on Sirius were classified as normal on ORA. There was a significant difference when comparing normal and non-normal classifications between ORA and Sirius ( $p < 0.001$ ) with poor agreement (Kappa=0.32). When including only normal and Keratoconus eyes in the analysis, good agreement was found between the two machines (Kappa=0.75).

**Conclusion:** According to our results there seems to be a significant difference between ORA and Sirius in their ability to differentiate between normal and non-normal eyes. As such, we recommend that these devices not to be used interchangeably for assessing patients prior to refractive surgery.

**Keywords:** Cornea; Corneal biomechanics; Keratoconus; Ocular response analyzer; Sirius corneal topography

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**DOI:**

10.5958/2395-1451.2016.00037.8

### Introduction

With the increasing popularity of refractive surgery over the past decade, the detection of corneal irregularities particularly keratoconus (KC) has received lots of attention<sup>(1)</sup>. In the presence of classical findings on routine slit-lamp biomicroscopy and retinoscopy, moderate to severe cases of KC can be clinically diagnosed with little or no difficulty<sup>(2)</sup>. Since KC is known to increase the risk of iatrogenic ectasia after refractive surgery by weakening the corneal stroma, the challenge today remains in identifying early cases of subclinical keratoconus that lack specific corneal findings, particularly when screening patients prior to refractive procedures<sup>(3-5)</sup>.

To date, many techniques have been suggested to help differentiate between normal and Forme Fruste Keratoconus eyes (FFKC). Corneal topography has shown its value in its ability to detect cases of FFKC<sup>(6-9)</sup>. Accordingly, several topography based screening tools

have been developed for commercial use to detect eyes with KC<sup>(10-12)</sup>. Sirius corneal topography (Sirius; Costruzione Strumenti Oftalmici, Florence, Italy) has proven to be valuable in preoperative evaluation and management of corneal abnormalities prior to performing any refractive surgical procedures<sup>(2,6,13)</sup>. It combines both the Scheimpflug camera with Placido disk topography, allowing full analysis of the cornea by combining data from both mechanisms of mapping<sup>(13)</sup>. The machine software features a classifier that aims in detecting the presence of KC or suspect KC based on a combination of topographic and tomographic corneal measurements<sup>(2)</sup>.

Until 2005, there had been no in vivo methods to determine biomechanical properties of the cornea<sup>(14,15)</sup>. The Ocular Response Analyzer (ORA; Reichert Technologies, Depew, New York) was introduced as the first commercial device claiming to provide in vivo measurements of corneal biomechanics by using an applied force displacement relationship<sup>(14,16)</sup>. Corneal biomechanical testing holds a promise for early detection of corneal pathologies that cause any subtle changes in the corneal structure<sup>(15,16)</sup>. Thus, corneal biomechanical evaluation is considered clinically important since it can improve the safety of refractive surgeries by minimizing the risk of ectasia following the procedure<sup>(17)</sup>.

The ORA (Reichert Technologies, Depew, New York) utilizes a rapid air pulse to indent the cornea and an electro-optical system to record two applanation pressure measurements:  $P_1$  while the cornea is moving inward and  $P_2$  while it returns<sup>(15)</sup>. These variables are used to measure the Goldmann-correlated intra-ocular pressure (IOP) (average of  $P_1$  and  $P_2$ ), corneal hysteresis ( $CH=P_1-P_2$ ) which is the result of viscous damping within corneal tissue, and corneal resistant factor (CRF), an indicator of the overall resistance of the cornea<sup>(15,18)</sup>. The 3.01 ORA software features an optional analysis function that results in two new indices: Keratoconus Match Index (KMI) and Keratoconus Match Probability (KMP). The results of these indices from an individual eye are compared to average values from clinically classified population in a normative database: Normal, Suspect KC, Mild KC, Moderate KC, and Severe KC. The software determines into which population the patient's measurement best fits and classifies it accordingly<sup>(19)</sup>.

In our manuscript, we compared classification results of the Ocular Response Analyzer (ORA; Reichert Technologies, Depew, New York) to the Sirius corneal topography (Sirius; Costruzione Strumenti Oftalmici, Florence, Italy) in differentiating normal and abnormal corneas.

## Materials and Methods

We retrospectively evaluated 153 consecutive patients presenting to the outpatient clinic over a one year period from January 2012 to January 2013. The study included only patients with normal corneas, keratoconus and keratoconus suspects without any bias to their age, gender, or previous medical history.

After initial history was taken, each patient underwent routine slit-lamp examination by a cornea specialist (E.W), corneal topography (Sirius; Costruzione Strumenti Oftalmici, Florence, Italy) and ORA measurements (Reichert Technologies, Depew, New York- software version 3.01). One scan on each machine was taken for each patient and all measurements were taken on the same visit on both instruments within minutes of each other to minimize intrasubject measurement variability. All scans were obtained by two trained ophthalmic technicians. Patients with poor scan qualities were excluded from the study.

Data entry and statistical analysis were performed using SPSS 19.0 for Windows (SPSS Inc, Chicago, IL, USA). The variables collected included (1) demographics (Gender and age); (2) disease classification results on both instruments (device software classification) (3) Surface asymmetry index (SAI) on Sirius; (4) Corneal Hysteresis (CH); (5) Corneal resistant factor (CRF); (6) Keratoconus Match Index (KMI); (7) Goldmann-correlated intraocular pressure (IOPg); (8) Corneal compensated intraocular pressure (IOPcc) and (9) waveform score (WS) on ORA.

Cases with missing variables were excluded from the analysis.

Chi-square tests were used to compare proportions of categorical variables. Kappa was used as a measure of agreement between the two diagnostic machines. Statistical significance was defined as  $p$  values less than 0.05. Data are shown as mean  $\pm$  standard deviation (range) unless otherwise stated.

## Results

One hundred and fifty three patients were initially recruited. Two patients with missing information were excluded from the final analysis. A total of 151 patients, 78 females (51.7%) and 73 males (48.3%) ranging in age from 14 to 76 years (mean  $34.6 \pm 13.33$  years), were included in the final data analysis.

Overall, 302 eyes completed the study on each instrument (Sirius and ORA). According to the machine readings (device software classification), cases were classified as follows:

1. **On Sirius corneal topography:** Out of a total of 302 eyes, measurements were read as "Normal" in 198 eyes (65.6%), keratoconus "Compatible" in 50 eyes (16.6%), "Abnormal" in 30 eyes (9.9%) and keratoconus "Suspect" in 24 eyes (7.9%). Sirius maps were subjectively assessed and confirmed by a cornea specialist.
2. **On ORA:** Out of a total of 302 eyes, measurements were read as "Normal" in 121 eyes (40.1%), keratoconus "Suspect" in 100 eyes (33.1%), "Mild" keratoconus in 58 eyes (19.2%), "Moderate" keratoconus in 15 eyes (5%) and "Severe" keratoconus in 8 eyes (2.6%).

Table 1 shows a cross-tabulation of all patients' classification results on both Sirius corneal topography and ORA. Overall, a total of 105 (34.8%) eyes were classified as "Normal" and 88 eyes (29.1%) with non-normal classification on both Sirius and ORA concurrently. Of the 198 eyes classified as normal on Sirius, 53% were classified as normal, 39% as suspect and 8% as mild on ORA (47% non-normal). Of the 121 eyes classified as normal on ORA, 87% were classified as normal, 6% as suspect, 2% as compatible and 5% as abnormal on Sirius (13% non-normal). (Table 1) Of the 100 (33.1%) eyes classified as suspect on ORA, 77% were classified as normal on Sirius. The remaining 23 eyes were classified as suspect, compatible, and abnormal (Table 1). Approximately 27% of the eyes that were classified as mild keratoconus on ORA were classified as normal on Sirius Topography (16 out of 58 eyes) (Table 1). 4% of the eyes classified as keratoconus compatible on Sirius were classified as normal on ORA. There was a significant difference when comparing normal and other non-normal classifications between ORA and Sirius ( $p < 0.001$ ). Poor agreement was found between the two machines in this case (Kappa=0.32).

**Table 1: Cross-tabulation of patient classification based on both Sirius corneal topography<sup>a</sup> and ORA<sup>b</sup> (N=302)**

ORA <sup>b</sup>	Sirius corneal topography <sup>a</sup> [N (%)]				
	Normal	Suspect	Compatible	Abnormal	Total
Normal	105 (34.8)	8 (2.6)	2 (0.7)	6 (2.0)	121 (40.1)
Suspect	77 (25.5)	9 (3.0)	4 (1.3)	10 (3.3)	100 (33.1)
Mild	16 (5.3)	7 (2.3)	22 (7.3)	13 (4.3)	58 (19.2)
Moderate	0 (0)	0 (0)	14 (4.6)	1 (0.3)	15 (5.0)
Severe	0 (0)	0 (0)	8 (2.6)	0 (0)	8 (2.6)
Total	198 (65.6)	24 (7.9)	50 (16.6)	30 (9.9)	302 (100)

<sup>a</sup>(Sirius; Costruzione Strumenti Oftalmici, Florence, Italy).

<sup>b</sup>Ocular Response Analyzer (ORA; Reichert Technologies, Depew, New York).

When including only normal and Keratoconus eyes (compatible in Sirius and mild, moderate, severe in ORA) in the analysis, good agreement was found between ORA and Sirius (Kappa=0.75).

Based on Sirius topography measurements, the mean surface asymmetry index (SAI) was  $0.54 \pm 0.38$  diopters (0.11-3.11) for normal eyes and  $2.69 \pm 2.62$  (0.16-17.94) for non-normal eyes ( $p < 0.001$ ) (Table 2). ORA measurements were as follows: corneal hysteresis (CH) for normal eyes was  $11.49 \pm 2.04$  mmHg (2.9-17.9) while that for non-normal eyes was  $9.6 \pm 2.16$  mmHg (3.8-17.3) ( $p < 0.001$ ); corneal resistance factor (CRF) was  $11.19 \pm 2.13$  mmHg (6.2-18.3) for normal eyes and  $8.97 \pm 2.41$  mmHg (3.6-19.5) in non-normal eyes ( $p < 0.001$ ); keratoconus match index (KMI) was  $0.98 \pm 1.84$  (0.51-1.57) for normal eyes and  $0.32 \pm 0.32$  (-0.57 - +0.76) for non-normal eyes ( $p < 0.001$ ); Goldmann-correlated intraocular pressure (IOPg) for normal eyes was  $15.03 \pm 3.88$  mmHg (8.10-36) and  $12.94 \pm 3.82$  (2.8-30.8) for those with non-normal classification ( $p < 0.001$ ); Corneal compensated intraocular pressure (IOPcc) for normal eyes had a mean of  $14.41 \pm 3.92$  mmHg (7.40-41.80) and  $14.63 \pm 3.47$  (6-27.5) for non-normal eyes ( $p = 0.722$ ). Waveform scores (WS) had a mean of  $7.29 \pm 1.27$  (3.20-9.20) in patients with normal eyes while those with non-normal classification had a mean score of  $4.65 \pm 1.98$  (0-8.8) ( $p < 0.001$ ) (Table 2).

**Table 2: Summary of parameters of data of all 302 eyes on both Sirius corneal topography<sup>a</sup> and ORA<sup>b</sup>**

Parameter	Normal eyes			Non-normal eyes			p value
	Mean	SD	Range	Mean	SD	Range	
SAI <sup>a</sup>	0.543	0.3799	0.11-3.11	2.688	2.615	0.16-17.94	< 0.001
CH <sup>b</sup>	11.487	2.042	2.9-17.9	9.603	2.158	3.80-17.30	< 0.001
CRF <sup>b</sup>	11.193	2.134	6.2-18.3	8.967	2.413	3.6-19.5	< 0.001
KMI <sup>b</sup>	0.976	1.844	0.508-1.57	0.319	0.323	-0.566 - +0.756	< 0.001
IOPg <sup>b</sup>	15.029	3.882	8.10-36	12.936	3.818	2.80-30.80	< 0.001
IOPcc <sup>b</sup>	14.413	3.920	7.40-41.80	14.634	3.472	6-27.5	0.722
WS <sup>b</sup>	7.288	1.272	3.20-9.20	4.655	1.982	0-8.8	< 0.001

<sup>a</sup>(Sirius; Costruzione Strumenti Oftalmici, Florence, Italy).

<sup>b</sup>Ocular Response Analyzer (ORA; Reichert Technologies, Depew, New York).

SD= Standard deviation; SAI= Surface asymmetry index; CH=Corneal Hysteresis; CRF= Corneal resistant factor; KMI=Keratoconus Match Index; IOPg=Goldmann-correlated intraocular pressure; IOPcc= Corneal compensated intraocular pressure and WS=waveform score.

**Table 3: Table showing our values of CH and CRF in “normal” and keratoconic eyes measured on ORA\* (data expressed as mean  $\pm$  standard deviation) compared to those reported in the literature**

Studies	Normal			Keratoconus		
	Eyes (N)	CH	CRF	Eyes (N)	CH	CRF
Luce DA <sup>16</sup>	339	9.6	NA	60	8.1	NA
Shah et al. <sup>23</sup>	207	10.7 $\pm$ 2.0	NA	93	9.6 $\pm$ 2.2	NA
Ortiz et al. <sup>27</sup>	165	10.8 $\pm$ 1.5	11.0 $\pm$ 1.6	21	7.5 $\pm$ 1.2	6.2 $\pm$ 1.9
Mollan et al. <sup>24</sup>	118	10.6 $\pm$ 2.2	10.0 $\pm$ 2.5	76	8.7 $\pm$ 2.2	6.9 $\pm$ 2.4
Touboul et al. <sup>22</sup>	122	10.3	11.0	88	8.3	7.6
Saad et al. <sup>21</sup>	252	10.6 $\pm$ 1.4	10.6 $\pm$ 1.6	172	8.1 $\pm$ 1.4	7.1 $\pm$ 1.6
Current study	121	11.5 $\pm$ 2.0	11.2 $\pm$ 2.1	181	9.6 $\pm$ 2.2	8.9 $\pm$ 2.4

\*Ocular Response Analyzer (ORA; Reichert Technologies, Depew, New York).

Adapted from: Saad A et al.<sup>21</sup>

## Discussion

In today's era of advances in refractive surgery, corneal imaging is rapidly becoming a progressing field with many instruments commercially available for corneal assessment. As new instruments become available, it is of critical importance to evaluate and compare their validity to that of existing reliable technologies.

Measuring the geometric corneal parameters such as corneal thickness, curvature and topography as well as detecting and treating any corneal abnormality such as subclinical KC are essential prior to any refractive procedure<sup>(2,6,15,20)</sup>. Until recent years, and owing to the lack of adequate technology, the additional influence of biomechanical properties on the cornea had received little attention<sup>(15)</sup>. Biomechanical evaluation of the cornea could help improving the safety of refractive procedures and minimize the incidence of ectasia due to undetected or subclinical keratoconus<sup>(17)</sup>.

A cross tabulation of classification results on both instruments shows that a total of 105 eyes (34.8% of all eyes) were classified as "Normal" and only 9 (3% of all eyes) as keratoconus "Suspect" on both Sirius and ORA simultaneously (Table 1). Of the 198 eyes classified as normal on Sirius topography, only 105 eyes (53%) were classified as normal on ORA (Table 1). This suggests that ORA might misclassify normal eyes by giving a false positive results (labeling normal eyes as keratoconus). Also, of the 121 eyes classified as normal on ORA, 87% were classified as normal, 6% as suspect, 2% as compatible and 5% as abnormal on Sirius. In fact, 4% of the eyes classified as keratoconus compatible on Sirius were classified as normal on ORA. (Table 1). Therefore, ORA might be misclassifying eyes with keratoconus as normal (false negative). In other words, the sensitivity and specificity of the ORA machine in detecting normal and abnormal corneas may be low. Hence, when used for keratoconus screening prior to refractive procedures, ORA might be excluding patients with normal topography by labeling them as keratoconus suspects or permitting high-risk patients with keratoconus compatible topography by labeling them as normal.

In fact, poor agreement was found between ORA and Sirius in classifying normal and non-normal eyes (Kappa=0.32). However, good agreement was found, when including only normal and Keratoconus eyes (compatible in Sirius and mild, moderate, severe in ORA) in the analysis (Kappa=0.75). Therefore, ORA is less reliable in detecting early cases of keratoconus (Forme Fruste keratoconus) with better reliability in detecting more advanced cases.

So far, numerous studies have discussed and compared biomechanical properties of normal and keratoconic eyes and found diagnostic potential of CH and CRF values in keratoconic eyes<sup>(14,21-23)</sup>. A recent study by Luz A *et al* demonstrated that after analyzing 37 waveform signal parameters using ORA 2.04

software, the classic CH and CRF pressure parameters might fail to distinguish normal eyes from those with keratoconus<sup>(18)</sup>. In a review by Terai N *et al* on the biomechanical properties of the cornea measured on ORA, the authors state that variations in CH and CRF may be a reflection of ground substance changes in the structure of the cornea<sup>(15)</sup>. Although they convey useful information, these two parameters are influenced by central corneal thickness (CCT) and intraocular pressure, highlighting the significance of correcting for these factors when obtaining standardized indices that can be used in the clinical setting successfully<sup>(15,21,24,25)</sup>. Several authors have studied the biomechanical properties of normal corneas as compared to those with KC and have found the CH and CRF values to be lower in those with KC<sup>(14,20-23,26)</sup>. Our data was similar to the published results with a slight variation in absolute values (Table 3).

Along the same lines, a study by Labiris *et al* concluded that although KC match index (KMI) may be reliable in diagnosis and staging of KC, the keratoconus match probability (KMP) classifies as suspect a significant percentage of topographically defined KC patients and normal eyes<sup>(27)</sup>. However, the challenges remain in identifying early subtle changes of subclinical keratoconus that lack defined topographic criteria and the diagnostic capacities of these novel indices need further exploration<sup>(19,27)</sup>.

This study is not the first to assess the measurements of the Sirius imaging system or that of ORA. In 2 studies by Nasser *et al* and Savini *et al*, both compare the Sirius to the Pentacam HR and Placido corneal topographer respectively, and report statistically significant differences in measurements<sup>(13,28)</sup>. Along the same lines, numerous studies have attempted to explore the diagnostic competence of ORA parameters in KC, either alone or combined with topographic or tomographic parameters<sup>(14,22,29)</sup>. However, to our knowledge, so far there have been no studies in the literature that compare Sirius and ORA in their ability to differentiate between normal and keratoconic eyes. While the Scheimpflug technology combined with Placido disc corneal topography gains status as a reliable method for assessing the cornea as part of Sirius imaging, ORA is rapidly gaining its reputation for being the first corneal biomechanical testing device approved for clinical use<sup>(13,30)</sup>. There still remain many questions to be answered regarding the properties of corneal biomechanics. Furthermore, the lack of normative database in ORA limits its current usefulness in clinical settings<sup>(30)</sup>. In the future, the role of the biomechanical analysis of the cornea may be to reclassify a suspect cornea on the topography as "true" suspect or as a normal cornea depending on its viscoelastic properties.

According to our results, there seems to be a significant difference between ORA and Sirius in their ability to distinguish normal and keratoconus eyes. As such, we recommend that these devices not to be used

interchangeably for assessing patients in their evaluation prior to refractive surgery as the clinical application for their usefulness requires caution and further investigation.

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