A New Fitting Approach for Providing Adequate Comfort and Visual Performance in Keratoconus: Soft HydroCone (Toris K) Lenses

Koray Gumus, M.D., FEBOphth. and Nisa Kahraman, M.D.

Objective: To evaluate the comfort and visual performance of soft HydroCone (Toris K) silicone hydrogel lenses in keratoconus patients.

Methods: Fifty eyes of 50 keratoconic patients who were fitted with the Toris K lens were included in the study. All patients were evaluated at baseline and after 2 weeks of lens wear. Uncorrected and best-corrected visual acuities were measured. Corneal topography, ocular aberrations, and point spread function (PSF) were obtained using NIDEK-OPD Scan. Comfort level and visual performance in daytime and nighttime conditions were scored from 0 to 5 after 2 weeks of lens wear.

Results: Best-corrected visual acuity was significantly better with the Toris K lens ($P<0.001$). Mean increase in visual acuity with the lens was 4.5 lines. Mean K_1, K_2, and K_{max} values significantly decreased with the lens ($P<0.001$). Both total and higher-order root-mean-square errors were significantly corrected with the Toris K lens ($P<0.001$ and $P=0.038$, respectively). A significant correction of total coma and trefoil aberrations was achieved with the lens. Also, PSF values were significantly increased with the lens ($P<0.001$). Although comfort scores in 46 eyes (92.0%) were classified as good/excellent, only 4 eyes (8.0%) had moderate comfort scores. Visual acuity was classified as good/excellent in 46 eyes (92.0%) in daytime and in 38 eyes (76%) in nighttime conditions.

Conclusions: Soft HydroCone silicone hydrogel keratoconus lenses should be considered as alternative visual correction for keratoconus patients. The soft and full-custom design provides optimal comfort and visual performance for the patients' daily requirements.

Key Words: Keratoconus—Contact lens—Soft HydroCone contact lens.

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Keratoconus is one of the most leading causes for visual disability in the developed world. It is typically diagnosed in the patient's adolescent years.[1–3] With contemporary technological and medical advancements such as improved corneal topographic systems, early signs of keratoconus have been detected, resulting in an apparent increase in the incidence and prevalence of keratoconus.[4]

Keratoconus can cause different kinds of visual distortions, such as ghosting, multiple images, glare, halos, starbursts around lights, and blurred vision.[1,2] Multiple unsatisfactory attempts to obtain optimum spectacle correction should be a warning sign of keratoconus for clinicians. Visual rehabilitation is certainly the most important step in management. Although patients with early keratoconus may successfully use spectacles or spherical/toric soft contact lenses (SCLs), patients with moderate-to-advanced keratoconus often require other alternatives, including rigid contact lenses, hybrid lenses, piggyback contact lenses, scleral lenses, intrastromal corneal rings, phakic intraocular lenses, and eventually corneal transplantation.[5–8]

Even though gas-permeable contact lenses have been widely used for many years because of their success in improving visual acuity, prolonged use may lead to lens intolerance and ocular discomfort in most patients with keratoconus.[9] In such cases, today's special design SCLs for keratoconus should be considered. One type of lens is soft HydroCone (Toris K) lens (SwissLens, Prilly, Switzerland), which have a silicone hydrogel material (definite 74/Igel 77). Toris K lenses include a front toric surface and have a dynamic stabilization with nasal and temporal bumps. Toris K lenses cause spherical with aspherical flattening on the back surface. Basically, there are 2 types of lenses in a trial set: HydroCone-K12 (for grade 1–2 keratoconus) and HydroCone-K34 (for grade 3–4 keratoconus).

In this research, we aimed to evaluate the comfort and visual performance of this new alternative approach, soft HydroCone silicone hydrogel lenses, in keratoconus patients.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board of the Erciyes University School of Medicine. The research protocol adhered to the tenets of the Declaration of Helsinki for clinical research. Written informed consent was obtained from all the participants after explanation of the purpose and possible consequences of the study.

Fifty eyes of 50 keratoconic patients (18 men and 32 women; mean age, 24.5 years; range, 18–45 years) who were fitted with soft HydroCone silicone hydrogel lenses were included in the study. The parameters of the lenses and a fitting guide are shown in Tables 1 and 2. Exclusion criteria included those patients who underwent any ocular surgery, with a history of ocular trauma, or any ocular disease (e.g., active ocular infection, corneal dystrophies, severe dry eye, corneal dystrophies, clinically significant nuclear sclerosis/cataract, etc) that might affect the results.

From the Ocular Surface & Contact Lens Division (K.G., N.K.), Department of Ophthalmology, Erciyes University School of Medicine, Kayseri, Turkey.

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Address correspondence to Koray Gumus, M.D., FEBOphth., Erciyes University School of Medicine, Department of Ophthalmology, Kayseri 38039, Turkey; e-mail: drkorayg@hotmail.com

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TABLE 1. *The Fitting Set Parameters of Soft HydroCone (Toris K) Lens*

Technical Data	Values
Total diameter	13.70 mm (HydroCone K12) 14.00 mm (HydroCone K34)
Base curve	7.20 to 8.40 D
Sphere	−40.0 to +40.0 D
Cylinder	−0.01 to −8.00 D
Axis	0–180°
Optimized center thickness	Standard K12=0.42 mm, K34=0.52 mm Range of thickness: 0.35−0.59 mm
Flattening	HydroCone K12+ HydroCone K34++

All patients were evaluated at baseline and after 2 weeks of lens wear. Uncorrected and best-spectacle-corrected visual acuities were measured with the logarithm of the minimum angle of resolution (logMAR) chart (Smart System II 2020 Visual Acuity System; M&S Technologies, Inc, Skokie, IL). Subjective refraction, including spherical error, cylindrical error, and spherical equivalent (spherical error+[cylindrical error/2]) were performed. Biomicroscopy and fundoscopy were also performed.

Corneal topography, ocular aberrometry, and point spread function (PSF) (the Strehl's ratio) were obtained using NIDEK-Optical Path Difference Scanning System ARK-10000 refractive power/corneal analyzer (version 1.12iAC; NIDEK, Co, Ltd, Gamagori, Japan). Three images were recorded for each eye across a natural (undilated) pupil. The image with the best alignment and at least six digitized rings were selected for analysis. The simulated keratometry values in the two major axes were noted from each selected axial map. Ocular aberrations were measured using sixth-order Zernike's polynomials decomposition. The parameters analyzed included the root-mean-square (RMS) values of total aberrations (Total), tilt (S1), higher-order aberrations (HOA), total coma (T. Coma) aberrations, total trefoil (T. trefoil), total tetrafoil (T. 4foil), total spherical aberrations (T. Sph), and higher-order astigmatism (HiAstig).

TABLE 2. *Fitting Assessment Procedure of Soft HydroCone (Toris K) Lens*

First contact lens choice
It is suggested working with trial lenses with cylindrical power −0.01 D
Keratoconus classification
First apply topographical indications or follow the rules:
Vcc>0.6 and/or keratometry>6.8: grade 1 or 2 (choose HydroCone K12)
Vcc<0.6 and/or keratometry<6.8: grade 3 or 4 (choose HydroCone K34)
Diameter and base curve selection
Add 0.8 diopters to the average K value, then select a trial lens
HydroCone K12/ØT=14.00 mm
HydroCone K34/ØT=13.70 mm
Further steps
The first lens helps to validate base curve and total diameter
The patient should wait for 30 min
Dynamic stabilization marks should be evaluated to measure the stabilization axis
Push-up test should be done
The fitting curve should demonstrate typical fitting of characteristics of a standard soft lens fit
If the fitting curve is too flat, there will be excessive movement and/or edge lift, then switch to a steeper trial lens
Little or no movement and/or edge impingement would indicate the fitting curve is too steep, then switch to a flatter trial lens
Over refraction should be done
Prescription should include both spherical and cylindrical errors with its axis
In case of glare and/or halo, you can request to enlarge the optical zone

ØT, total diameter.

Ocular health status, including bulbar hyperemia and corneal and conjunctival staining, was also evaluated. Comfort level and visual performance in both daytime and nighttime conditions were scored from 0 to 5 (0, worst; 1, bad; 2, fair; 3, moderate; 4, good; 5, excellent) after 2 weeks of lens wear.

The data were analyzed using SPSS 20.0 for Mac (SPSS, Inc, Chicago, IL). A paired sample *t* test was performed to compare the difference in the means "before" and "after" fitting the lens. The correlations between the two study parameters were analyzed using the Spearman's correlation test. A *P* value of <0.05 was considered statistically significant.

RESULTS

Although 10 patients (20.0%) wore nothing for visual rehabilitation, 35 patients (70.0%) wore glasses and 5 patients (10.0%) wore rigid gas-permeable (RGP) contact lenses before the study. Thirty eyes (60.0%) had a history of accelerated corneal cross-linking (CCL) with riboflavin/UV-A (30 minutes+9 minutes) in our clinic. These eyes were fitted with the lens at least 6 months after the uneventful CCL.

Best-corrected visual acuity was significantly better with the lens than that with spectacles ($P<0.001$) (Fig. 1). When using the logMAR chart, the mean increase in logMAR visual acuity with the Toris K lens was 4.5 lines (range, 1–9 lines).

With the Toris K lens, mean K1, K2, and K_{max} values were significantly decreased by 6.4±3.1 (from 51.4 to 45.0), 3.9±3.3 (from 46.3 to 42.4), and 7.9±3.6 diopters (from 54.5 to 46.6), respectively ($P<0.001$). Moreover, mean baseline topographical spherical equivalent values were significantly decreased from −6.0 to −1.3 with the lens ($P<0.001$).

Both total and higher-order (HO) ocular RMS wavefront errors were significantly corrected with the Toris K lens ($P<0.001$ and $P=0.038$, respectively). A detailed analysis of HO aberrations revealed a significant correction of total coma and trefoil aberrations with the lens. However, other aberrations such as tetrafoil, spherical, and HO astigmatism RMS values were nearly identical. Moreover, PSF, the Strehl's ratio, was significantly increased with the lens ($P<0.001$). The higher the Strehl's ratio, the better the potential image quality. Details of above-mentioned analysis are given in Figure 2. An example of corneal topography before and after fitting the lens is shown in Figure 3.

A subgroup analysis was performed according to the history of CCL. All ocular aberration and PSF values were compared in two groups to evaluate the impact of CCL on visual performance of the Toris K lens. Data regarding this analysis are summarized in Table 3.

Although comfort score in 46 eyes (92.0%) was classified as good/excellent, only 4 eyes (8.0%) had moderate comfort scores. Visual acuity was classified as good/excellent in 46 eyes (92.0%) in daytime and in 38 eyes (76%) in nighttime conditions. Among the study parameters, lower total coma and the higher Strehl's ratio values appeared to be correlated to better visual performance in daytime (−0.352/$P=0.014$ and 0.334/$P=0.020$, respectively). In addition, visual performance in nighttime conditions was negatively correlated with larger photopic and mesopic pupil sizes (−0.376/$P=0.007$ and −0.401/$P=0.004$, respectively).

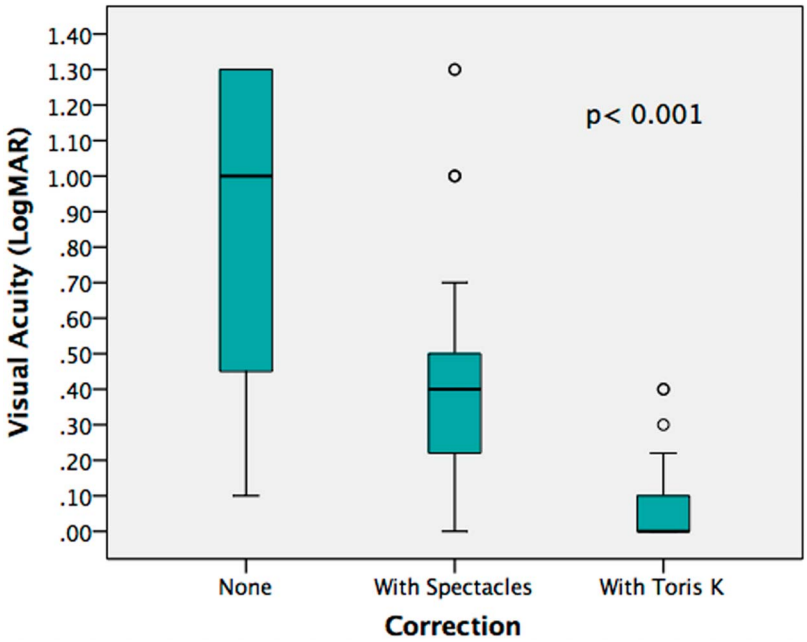

FIG. 1. Box plot reveals that the Toris K contact lens provides much better logMAR (logarithm of the minimum angle of resolution) visual acuity levels according to the uncorrected and corrected values with spectacles.

DISCUSSION

The range of contact lens options in the market for the successful optical correction of keratoconus has greatly expanded over the past few decades. In this study, we assessed the optical performance of a new soft HydroCone (Toris K) silicone hydrogel lens for keratoconus.

In early keratoconus, spherical and toric SCLs can provide successful optical correction.[5,10] While selecting SCL, thicker lenses with low water content should be preferred to neutralize the irregular astigmatism.[5] However, with increasing severity of keratoconus, these lenses are not given preference because of their inadequate optical performance. So, management should be switched to other lens modalities such as RGP lenses, hybrid lenses, piggyback lenses, and scleral lenses, depending on the severity and location of the cone.[5]

In keratoconus patients, RGP lenses have been used as the first lens of choice for visual improvement since the late 1970s because of their benefits such as better vision, oxygen permeability, and simple cleaning procedures. The overall purpose of RGP contact lenses in keratoconus is to provide vision correction by "masking" the anterior corneal surface irregularity and secondary visual distortion through the creation of a regular anterior optical surface. A tear layer at the posterior surface of the lens may contribute to refractive error correction by compensating for slight irregularities of the corneal anterior surface.[11] One important disadvantage of these lenses is the potential to damage the cornea, which has been largely overcome by specially designed multicurve RGP lenses.[12] Even, these newer designs of keratoconic RGP lenses should be fit without touching the apical cornea. Numerous studies have demonstrated that the use of RGP lenses can also improve visual performance by altering ocular aberrations and increasing contrast sensitivity[13–15]; however, ocular discomfort as a result of the rigid material of the lens still remains the most common reason for discontinuation. In addition, rigid lenses still have the potential to decenter, entrap dust or debris, and dislodge. In these patients who become intolerant to RGP contact lenses, other options should be evaluated. Switching from the rigid to

TABLE 3. *Total and Higher-Order Aberrations and Point Spread Function Data at Baseline and With the Toris K Lens According to the History of Corneal Cross-linking*

	No CXL (n=20)			CXL (n=30)		
Parameters	Baseline	Toris K	*P*	Baseline	Toris K	*P*
T. aberration	3.54±1.21	1.86±1.00	**<0.001**	3.77±1.46	1.29±0.45	**<0.001**
T. HOA	0.83±0.59	0.71±0.67	0.583	0.74±0.30	0.49±0.23	**0.001**
T. coma	0.38±0.25	0.32±0.33	0.479	0.47±0.19	0.23±0.15	**<0.001**
T. trefoil	0.55±0.39	0.40±0.30	0.192	0.54±0.29	0.33±0.13	**<0.001**
T. tetrafoil	0.20±0.43	0.18±0.45	0.918	0.09±0.04	0.11±0.11	0.449
T. spherical	0.13±0.09	0.16±0.16	0.526	0.13±0.08	0.11±0.09	0.204
T. HOAst	0.11±0.05	0.13±0.12	0.466	0.09±0.03	0.12±0.09	0.111
PSF	0.03±0.03	0.05±0.04	**0.056**	0.02±0.02	0.05±0.03	**<0.001**

Bold numbers represent statistically significant *P* values.

CXL, corneal cross-linking with riboflavin/UV-A; HOA, higher-order aberration; HOAst, higher-order astigmatism; PSF, point spread function; T, total.

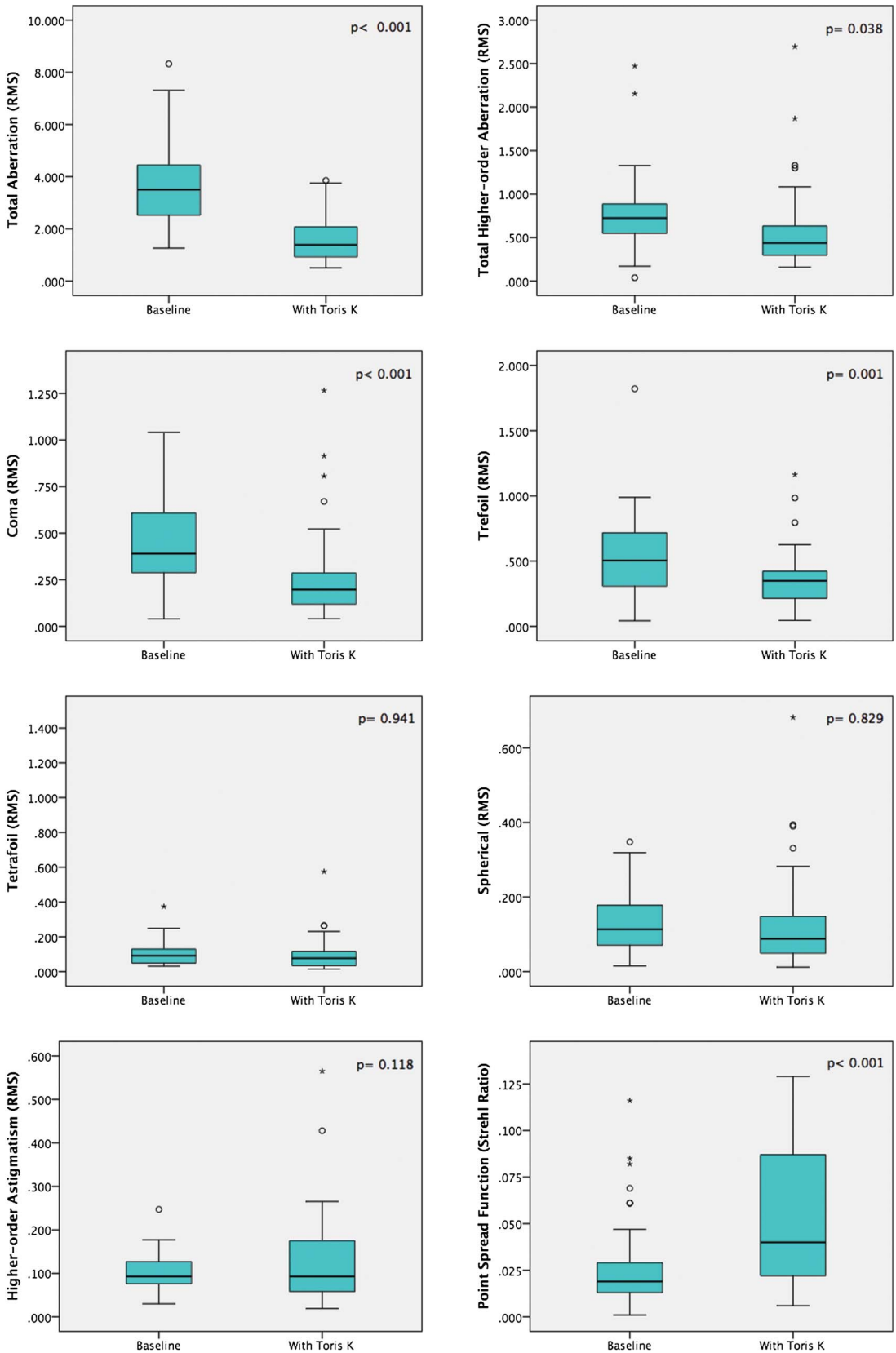

FIG. 2. Box plots reveal the change of total and higher-order aberration RMS (root-mean-square) values and PSF (point spread function) ratio with the Toris K lens.

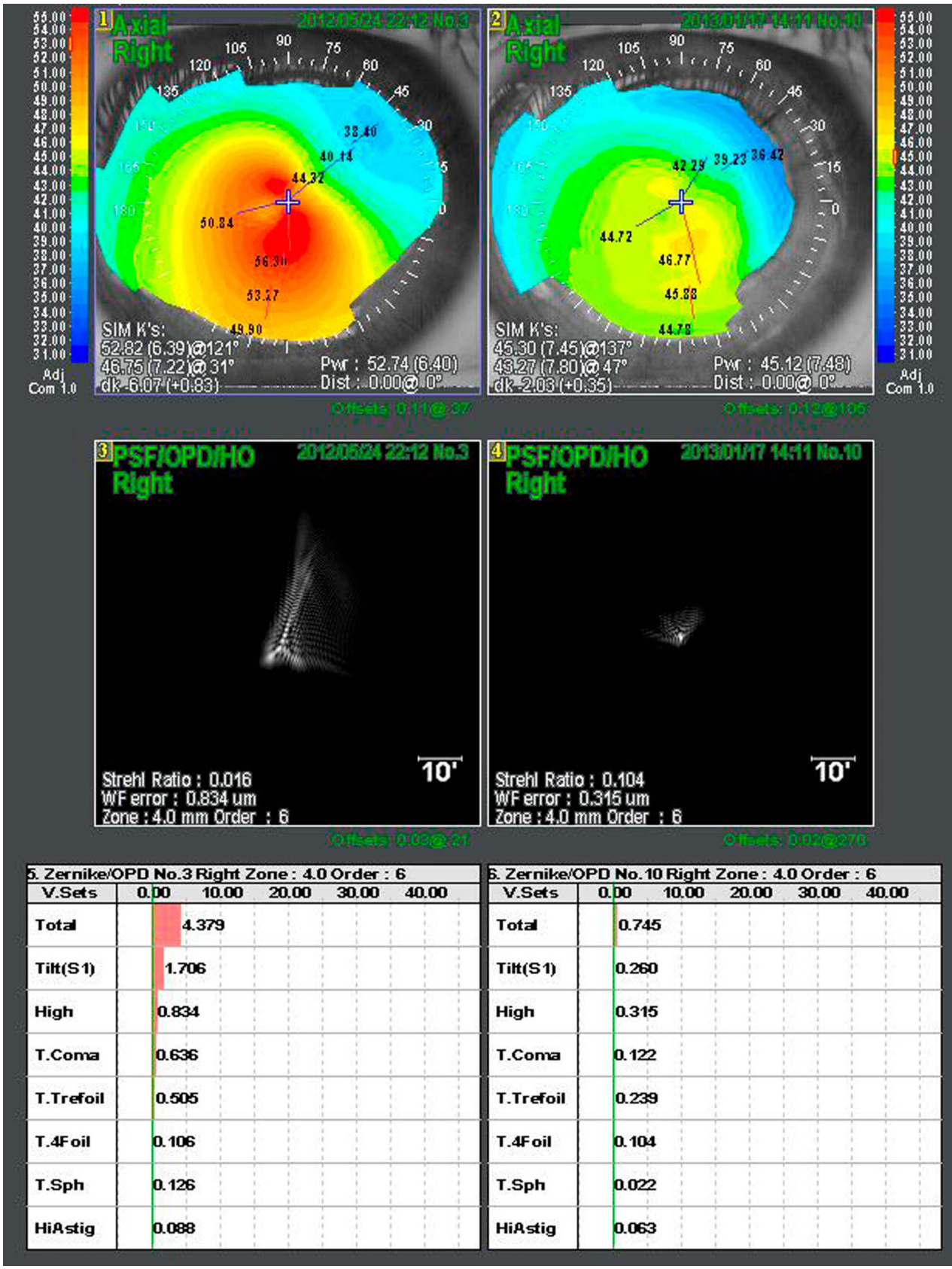

FIG. 3. An example of an Optical Path Difference scan before (left side) and after (right side) fitting the Toris K lens.

soft material seems to be logical to alleviate lens-related ocular discomfort.

Currently, there are few studies that have addressed the question of whether soft keratoconus lenses can provide adequate vision as compared with rigid lenses. One possible way to increase visual performance of SCLs is the customization of lenses. Marsack et al.[16] produced such a lens and evaluated whether custom wavefront-guided SCLs provide visual and optical performance equivalent to habitual gas-permeable corrections. Finally, this investigation concluded that custom wavefront-guided SCLs can provide equivalent photopic high-contrast logMAR visual acuity to that achieved with rigid lens correction in three keratoconus subjects.[16] Other alternatives may include KeraSoft IC (Bausch & Lomb, Inc., Rochester, NY) and NovaKone (Alden Optical, Lancaster, NY) soft lenses, which are also designed for the keratoconic eye.[17] These lenses can be a viable solution for all stages of keratoconus and seem to be good alternatives to RGP lenses before trying to fit more sophisticated lenses such as hybrid or scleral lenses.[17]

In this study, a new alternative, soft HydroCone (Toris K) silicone hydrogel keratoconus lenses, was investigated in detail. These lenses can be categorized as full-custom lenses because both spherical and cylindrical corrections are added to the toric surface of the lens to increase the visual performance. In our case series, BCVA values were significantly better with the lens than with the spectacles ($P<0.001$). When compared with spectacles, the mean increase in visual acuity with the Toris K lens was 4.5 lines (range, 1–9 lines). With the Toris K lens, mean K1, K2, and K_{max} values and baseline topographical spherical equivalent values were significantly decreased ($P<0.001$). All these results are better than RGP lenses as documented in the literature. Moreover, both total and HO ocular RMS wavefront errors significantly corrected with the Toris K lens ($P<0.001$ and $P=0.038$, respectively), which is an important indicative value of satisfactory visual performance. A detailed analysis revealed that although total coma and trefoil aberrations were significantly corrected with the Toris K lens, other aberrations such as tetrafoil, spherical, and HO astigmatism RMS values were nearly identical. Whereas, another study showed that the use of RGP contact lenses exhibited a large corrective effect on spherical aberration.[11] This diversity can be attributed to different design, material, and functional properties of these two different lenses. Furthermore, PSF, the Strehl's ratio, was significantly increased with the lens ($P<0.001$), meaning much better image quality. Both these results and survey scores implied that Toris K provides satisfactory visual performance particularly in daytime. This performance seems to decline at night because of glare and halos reported by some patients with larger photopic and scotopic pupils.

The association between history of CCL and clinical outcomes using the lens was analyzed in this study. Interestingly, a strong association was found in which CCL seems to contribute to better visual performance in patients fitted with the Toris K lens. This issue is still being investigated in our ongoing studies to clarify this association in a larger sample size.

To date, the results reported here demonstrate that soft HydroCone (Toris K) silicone hydrogel keratoconus lenses should be considered as a new alternative fitting approach for keratoconus patients. A customized lens design provides optimal comfort and visual performance for the patients' daily requirements.

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