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Clinical performance of Rose K2 soft contact lens for keratoconus

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圆锥角膜患者使用 Rose K2 软性角膜接触镜的临床表现

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摘要

目的:评价圆锥角膜患者使用 Rose K2 软性角膜接触镜的舒适度及视觉表现。

方法:横断面研究。50 例患者(50 眼)接受全面的眼科检查,包括屈光度、裸眼视力(UCVA)、最佳矫正视力(BCVA)、裂隙灯显微镜及眼底检查、泪膜破裂时间(BUT)、角膜地形图和对比敏感度。戴镜后,测量最佳戴镜矫正视力(BCLCVA)、对比敏感度及舒适度通过平均视觉模拟量(VAS)呈现。

结果:患者平均年龄为 26.2±6.0(16~39)y。使用 Rose K2 软性角膜接触镜 UCVA, BCVA, 和 BCLCVA 的平均 logMAR 值依次为 0.61±0.37 (0.15~1.3), 0.42±0.32 (0~1.3) 和 0.18±0.20 (0~1.3)。使用接触镜后视敏度显著提高(P<0.05),在明视和暗视条件下,对比敏感度数值明显增加(P<0.05)。Rose K2 软性角膜接触镜的视觉模拟量(VAS)值为 8.02±1.64(5~10)。

结论:圆锥角膜患者使用 Rose K2 软性角膜接触镜能够改善视力,对比敏感度以及舒适度。

关键词:角膜接触镜;圆锥角膜患者;软性角膜接触镜

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Abstract

• AIM: To evaluate the comfort and visual performance of Rose K2 soft contact lenses in patients with keratoconus.

• METHODS: Fifty eyes of 50 participants were included in this cross-sectional study. Each participant received a full ophthalmologic examination involving refraction, uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BCVA), slit-lamp biomicroscopy-fundoscopy, break-up time (BUT), corneal topography, and contrast sensitivity. After contact lens was fitted best contact lens corrected visual acuity (BCLCVA), contrast sensitivity, and comfort rating *via* visual analogue scales (VAS) were performed.

• RESULTS: The mean age was 26.2±6.0 (range: 16 to 39)y. The mean logMAR UCVA, BCVA, and BCLCVA with Rose K2 soft (in order) were 0.61±0.37 (range: 0.15-1.3), 0.42±0.32 (range: 0-1.3), and 0.18±0.20 (range: 0-1.3). There were significant increases in visual acuities with contact lenses (P < 0.05). The mean contrast sensitivity scores were significantly better with both contact lens in mesopic and photopic conditions (P < 0.05). The mean VAS score was 8.02±1.64 (range: 5-10) for Rose K2 soft.

• CONCLUSION: Rose K2 soft contact lens can improve visual acuity, contrast sensitivity with comfort in patients with keratoconus.

• KEYWORDS: contact lens; keratoconus; soft contact lens

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INTRODUCTION

Keratoconus is a progressive, non-inflammatory disorder characterized by steepening, thinning, distortion of the cornea, and scarring[1]. It is generally a bilateral and progresses asymmetrically in both eyes[2]. Progressive ectasia and thinning of the cornea causes an irregular astigmatism and visual symptoms[3].

Spectacles are useful inoptical management of keratoconus when the astigmatism is mild[4]. However, for moderate-to-advanced keratoconus, spectacles are not very useful for improving vision[4-5]. In this stage of the disease, when patients have serious irregular astigmatism, contact lenses become a alternative option[5].

Various options for contact lenses are available such as rigid gas permeable (RGP) lenses[6-7], hybrid lenses[8-9], piggyback lenses[10-11] and scleral lenses[12-13]. RGP lenses have been commonly used because of their success in

improving visual acuity[3,7]. However, prolonged use of RGP lenses may lead to lens intolerance and ocular discomfort[7]. In such cases, new specially designed soft contact lenses (SCL) should be considered. Rose K2 soft (Menicon Co. Ltd., Nagoya, Japan) SCL is an example of these kinds of lenses for keratoconus.

In this study, we aimed to evaluate the comfort and visual performance of this new alternative lens in keratoconus patients. To the best of our knowledge, this will be the first report of Rose K2 soft in literature.

SUBJECTS AND METHODS

Participants Exclusion criteria included: a history of ocular surgery, history of ocular trauma, any ocular disease (*e. g.* active ocular infection, clinically significant nuclear sclerosis/cataract, retinal diseases) that might affect the results, break-up time (BUT) under 10s, and a history of wearing any contact lenses in the previous week.

Eligible consecutive individuals that had applied the contact lens department of our hospital in November and December 2015 were included in this cross-section study. For participants whom were fitted contact lenses both his eyes, the right eye was designated as the eye for study for those with an even birth month number, while the left eye was designated for those with an odd birth month number.

The study was performed in Istanbul, and conducted according to the principles of the Declaration of Helsinki. Local ethic committee approval and all participants' informed consent were obtained.

Examination Each participant received a full ophthalmologic examination involving refraction, uncorrected visual acuity (UCVA), best spectacle corrected visual acuity (BCVA), and best contact lens corrected visual acuity (BCLCVA), slit-lamp biomicroscopy-fundoscopy, break-up time (BUT), and corneal topography *via* Sirius (Schwind eye-tech-solutions GmbH & Co. KG, Kleinostheim, Germany). For visual acuity measurements, Bailey-Lovie chart was used from 6 meters under photopic (85 cd/m^2) luminance conditions. After UCVA and BCVA were measured, contact lens was fitted as provided in its technical fitting guide and manufacturer's specifications were followed. A dedicated set of lenses is needed for this purpose in different base curves and peripheral radii with power of -3 diopter (D). The lens was allowed to settle for approximately 5min. and then the movement, rotation, and centration were checked with a slit-lamp. After correct fit and patient comfort were achieved, residual refractive error was measured *via* retinoscopy. Then over-refraction was performed with correcting spectacle lenses and BCLCVA was measured. After 30min, a contrast sensitivity test was performed. Contrast sensitivity was measured under mesopic and photopic conditions at spatial frequency of 1.5, 3, 6, 12, and 18 cycles per degree (CPD) using Optec 3500 Vision Tester (Stereo Optical Co, ABD). After two hours, comfort rating *via* visual analogue scales (VAS) was performed. VAS previously used to rate comfort with contact lenses[4,15]. VAS were administered by asking patients to record their subjective impressions of vision and comfort using a scale from 0 (lowest) to 10 (highest). The scale was horizontally oriented, measuring 10cm, and the value for statistical analysis was measured with a rule at the point where the mark was inserted by the patient.

Table 1 The fitting set parameters of Rose K2 soft contact lens

Technical Data	Values
Total diameter	14.30 mm to 15.30 mm Standard diameter: 14.80 mm
Base curve	7.40 to 9.00 D
Sphere	-30.0 to +30.0 D
Cylinder	-0.25 to -10.00 D
Axis	0-180°
Center thickness	0.25mm to 0.60mm Standard center thickness: 0.3 mm

Table 2 Fitting assessment procedure of Rose K2 soft contact lens

Feature	Practice
Base curve selection	Select the base curve which yields the best visual acuity, fitting as flat as possible
Peripheral fit	Adjust the periphery to optimizelens fit, location and movement
Location	The lens should center equally around the limbus
Movement	On blink, 1.0mm-1.5mm of movement should be observed

Contact Lens and Fitting Contact lens used in the study has a silicone hydrogel material. Tables 1 and Table 2 show the parameters and a fitting guide for the Rose K2 soft contact lens.

Data Analysis Data were expressed as mean ± SD. The Kolmogorov-Smirnov test was applied to assess the normal distribution of data. To compare visual acuity and contrast sensitivity between spectacle correction and contact lens paired samples t-test was used. The Statistical Package for the Social Sciences version 23 (SPSS, Chicago, IL, USA) was used for data analysis, for which values of $P<0.05$ were considered to be statistically significant.

RESULTS

Demographic Characteristics The study sample consisted of 50 eyes of 50 participants (23 females and 27 males), all of whom were Caucasian. The mean age was 26.2±6.0 (range: 16-39) y. Table 3 shows participants' demographic characteristics.

The mean base curve (BC) was 7.80±0.45 (range: 6.50-8.60). The mean spherical and cylindrical power (D) of prescribed Rose K2 soft contact lens were -3.57±2.25 (range: -9.75 to -0.50) and -2.34±1.12 (range: -5.25 to -0.50).

There was a significant difference between BCVA and BCLCVA with Rose K2 soft ($P=0.001$).

Table 3 Demographic information of the population enrolled in the study

Parameter	Values
Number of patients	n=50
F	23
M	27
Age	
mean±sd	26.2±6.0
min./max	16 / 39
Refractive error (D) (n=44)	
Spherical	
mean±sd	−3.62±3.74
min./max.	−12 / 0
Cylindrical	n=44
mean±sd	−3.12±1.75
min./max.	−5.75 / 0
Keratometry (D)	
Flat	
mean±sd	48.36±4.02
min./max.	41.50 / 56.75
Steep	
mean±sd	53.28±4.82
min./max.	46.75 / 61.75
SimK	
mean±sd	50.82±4.35
min./max.	44.25 / 59.00

SD: Standard deviation; D, diopter; BUT: Break-up time.

Table 4 Visual Acuity (logMAR)

Parameter	Values
UCVA	
mean±sd	0.61±0.37
min./max.	0.15 / 1.3
BCVA	
mean±sd	0.42±0.32
min./max.	0 / 1.3
BCLCVA (Rose K2 soft)	
mean±sd	0.18±0.20
min./max.	0 / 1.3

UCVA: Uncorrected visual acuity; BCVA: Best corrected visual acuity; BCLCVA: Best contact lens corrected visual acuity; SD: Standard deviation; D: Diopter.

Visual Acuity Table 4 shows the visual acuities.

Contrast Sensitivity Figure 1 shows the contrast sensitivity measurements with spectacle correction, and with contact lens correction. The mean photopic contrast sensitivities were improved significantly with at all spatial frequencies measured (P=0.041 for 1.5 cpd; P=0.033 for 3 cpd; P=0.037 for 6 cpd; P=0.035 for 12 cpd; P=0.038 for 18 cpd). The mean mesopic contrast sensitivities were improved significantly with at all spatial frequencies measured (P=0.040 for 1.5 cpd; P=0.034 for 3 cpd; P=0.036 for 6 cpd; P=0.033 for 12 cpd; P=0.012 for 18 cpd).

Subjective Patient Comfort The mean VAS score was 8.02±1.64 (range: 5-10).

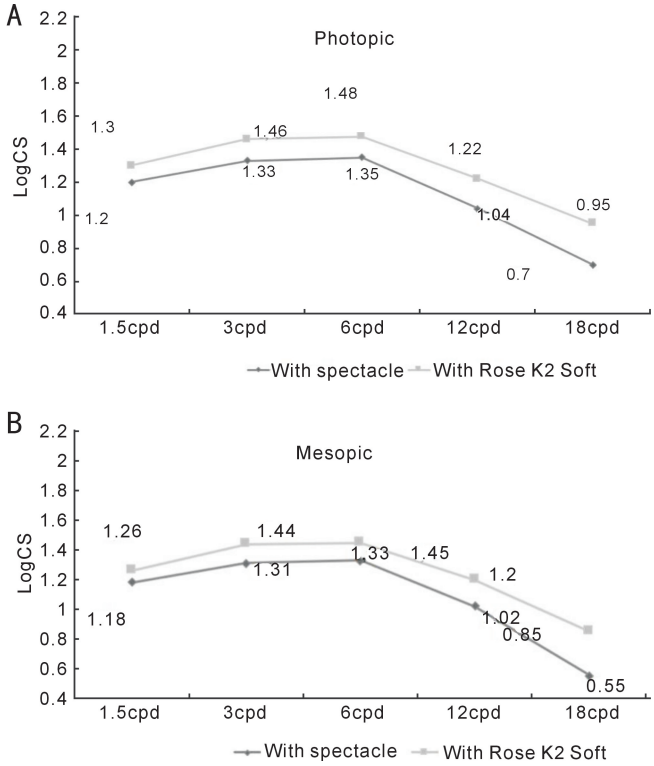

Figure 1 The mean contrast sensitivity in photopic (A) and mesopic (B) conditions (logCS).

DISCUSSION

Contact lenses are important in the management of visual symptoms of patients with keratoconus. The purpose of fitting contact lenses in such patients is to improve visual acuity with comfort[4]. It is well known that RPG contact lenses produce good visual acuity results and improve patients' quality of life[7]. One important disadvantage of RPG lenses is the potential for damage to the cornea[16-17]. Yazar *et al*[18] showed that RPG contact lenses may causes some serious complications such as corneal erosion, hidrops, allergic conjunctivitis, and dry eye. Another downside of RPG lenses is that many patients cannot tolerate them because of comfort issues[8]. Soft contact lenses are known for comfort and they may be a good alternative to RGP lenses in patients who experienced intolerance to RGP lenses[19]. Gumus *et al*[20] reported results of Toris K contact lens in keratoconus. In their study, comfort scores with SCL were classified good/excellent in 46 eyes (92% of participants), and moderate in only 4 eyes (8% of participant)[20]. Similarly, comfort scores were very good for Rose K2 soft contact lenses in our study. The high VAS score provides strong evidence that patients who cannot tolerate to RGP lenses due to discomfort may find Rose K2 soft an acceptable option.

This study showed that a new soft contact, lens Rose K2 soft, improved the patients' vision significantly. The mean visual acuity was significantly better with the contact lens than with spectacles and improved with Rose K2 soft to 0.18±0.18 logMAR from 0.63±0.35 logMAR. In Gumus *et al*. study, the mean increase in visual acuity was reported 4.5 lines (range: 1-9 lines)[20], 92% of their participants (46 eyes)

were classified their visual acuity as good in daytime, and 76% (38 eyes) were classified as good in nighttime[20].

Previous studies showed that RPG lenses can improve contrast sensitivity[21-22]. Similarly, this study showed that the soft contact lens can also improved contrast sensitivity of the keratoconic patients. The contrast sensitivities with the lens were significantly better in both mesopic and photopic lamination conditions than with the spectacles.

There are some limitations of this study. The study does not show the lens behaviors over the long term. The strongest aspect of the study is that is the first report in the literature that examines the new Rose K2 soft contact lens.

In sum, Rose K2 soft contact lenses can improve visual acuity, contrast sensitivity, and subjective comfort in patients with keratoconus. There are some other SCLs for keratoconus in the market such as NovaKone (Alden Optical, Lancaster, NY) soft lenses, KeraSoft IC (Bausch & Lomb, Inc., Rochester, NY). Further studies with longer follow-up period that compared the SCLs are needed.

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