

# Utility of orthokeratology contact lenses; efficacy of myopia correction and level of patient satisfaction in Iranian myopic/myope-astigmatic patients

Mohammad Taher Rajabi<sup>a</sup>, Seyedeh Simindokht Hosseini<sup>a,\*</sup>, Zahra Ghorbani<sup>b</sup>,  
Fereshteh Nobahari<sup>b</sup>, Fatemeh Bazvand<sup>a</sup>, Askar Doostdar<sup>b</sup>, Parviz Zarrinbakhsh<sup>c</sup>,  
Mohammad Bagher Rajabi<sup>a</sup>

<sup>a</sup> Farabi Eye Hospital, Tehran University of Medical Sciences, Tehran, Iran

<sup>b</sup> Department of Optometry, Tehran University of Medical Sciences, Tehran, Iran

<sup>c</sup> Zarrinbakhsh Clinic, Tehran, Iran

Received 19 October 2015; revised 7 January 2016; accepted 7 January 2016

Available online 5 February 2016

## Abstract

**Purpose:** To investigate the medical profiles of patients referred to Iran Lens Clinic with myopic/myope-astigmatic refractive errors.

**Methods:** Medical records of 182 patients (364 eyes) with myopic/myope-astigmatic refractive errors that underwent orthokeratology contact lens wear and fulfilled a 6-month period of follow-up were recruited. Efficacy and safety of these contact lenses in improving the visual acuity and correction of the refractive errors were investigated. Time needed to achieve final targeted visual acuity and association of various factors in this time course and level of acuity were investigated. Complications related to these lenses that were recorded in the medical profiles were studied.

**Results:** In manifest refraction, the amount of spherical equivalent and myopia decreased significantly after orthokeratology contact lens wear ( $P < 0.001$ ). A significant negative association was found between amount of mean baseline spherical equivalent and final achieved mean uncorrected visual acuity ( $P < 0.001$ ). None of the parameters of age, gender, and keratometric findings influenced the outcomes significantly ( $P > 0.1$ ).

**Conclusion:** Patients with myopic refractive error lower than  $-5.0$  Diopters achieved higher final visual acuities rather than patients with higher amounts of myopic refractive errors.

Copyright © 2016, Iranian Society of Ophthalmology. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**Keywords:** Orthokeratology; Myopia progression; Spherical equivalent

## Introduction

As the most common human eye disorder, myopia has a various prevalence rate in different parts of the world. It is reported to affect 33% of adults in the US versus 85–90% in Asian countries.<sup>1</sup> Many modes of refractive correction have

been investigated to hasten the progression of myopia. Orthokeratology (OK) is a developing field that has been established to slow down the progression of myopia.<sup>1,2</sup> Utility of contact lenses to alter the characteristics of the cornea to achieve stable improvement in visual acuity is in progress.<sup>2</sup> Uncorrected high myopia impairs functional capacity and is associated with concomitant retinal changes, cataract, and glaucoma, which might exclude the patients from being an eligible candidate for refractive surgery.<sup>1–4</sup> Meanwhile, not all patients have compliance for refractive surgery because of existing complications such as lower and higher order aberrations and decreased contrast sensitivity after correcting high

\* Corresponding author. Eye Research Center, Farabi Eye Hospital, Qazvin Square, Tehran, Zip code: 1336616351, Iran. Tel.: +98 9121884153; fax: +98 21 55416134.

E-mail address: [simindokht\\_hosseini@yahoo.com](mailto:simindokht_hosseini@yahoo.com) (S.S. Hosseini).

Peer review under responsibility of the Iranian Society of Ophthalmology.

amounts of myopia and astigmatism.<sup>5</sup> Modern orthokeratology introduces overnight use of reverse geometric designed rigid gas permeable contact lenses that are developed for reduction of myopia and astigmatism, by imposing some of the changes in corneal characteristics. These lenses can flatten the corneal apex and steepen the peripheral cornea, resulting in corneal sphericalization.<sup>2</sup> These alterations occur very rapidly and are shown to begin even in the first 10 min of lens wearing.<sup>2</sup> OK lenses also are supposed to slow down the progression of myopia.<sup>3,4,6</sup>

Besides growing techniques of modes of refractive correction, utility of OK lenses has its own certain field of indications, and due to the lack of information about clinical outcomes in Iranian patients, the current study was designed to investigate the efficacy of the orthokeratology contact lenses and to assess the satisfaction of the patients and rate of complications in the Iranian population.

## Methods

The medical profiles of 182 myopic/myope-astigmatic patients (364 eyes) who had fulfilled a minimum of 6 months of follow-up in a contact lens clinic from June 2003 to January 2008 were evaluated. Only the medical profiles containing detailed results of auto kerato refractometry and manifest refraction, ocular slit-lamp examination, Goldmann tonometry, and funduscopic examination of the patients were included. Patients with any ocular abnormality other than refractive error, such as ocular hypertension, degrees of chorioretinal atrophy, and history of previous ocular surgery, were excluded. The modern overnight OK lenses (BOSTON XO) with 4 curves that were manufactured in Iran Lens Gostar Company were fitted for patients. The empirical lens fitting process had been performed by aid of a computer software program to obtain an ideal fit. First, back optic zone radius was chosen flatter than the flattest Kr. The initial base curve of the OK lens to initiate lens fitting is 0.3–1.4 mm flatter than the flattest Kr. By considering the amount of targeted refractive change, the mean of  $-0.75$  was added to this figure. The sum of these two figures was subtracted from the dioptric power of back optic zone, and the radius was then calculated. The back vertex power is always  $+0.75$  D because of the formation of the tear lens, no matter what the amount of myopia is. The reverse lens curve is chosen steeper than the steepest Kr of the cornea. The back optic zone diameter is commonly 6–6.5 mm. The fitting curve (the first back peripheral optic radius) is chosen 0.05 mm (0.25 D) flatter than flattest Kr. Lens fitting can be performed individually by manipulation various parameters to achieve the best outcomes. Fluorescein pattern of the eyes had been studied by slit lamp. Age, gender, baseline, final manifest refraction, spherical equivalent (SE), baseline corrected Snellen visual acuity (BCVA), final uncorrected Snellen visual acuity (UCVA), and baseline keratometry readings (Kr) were gathered for analysis. Recorded complications as found by the examiner or noted by the patients were extracted from the medical profiles. Eyes were divided into 4 age groups: 3

groups based on keratometric findings, and 4 groups upon their amount of spherical equivalent. Eyes also were divided into two groups based on recorded complications, and any significant difference between these groups were investigated. Complications had been listed in preformed papers that were included in each individual's medical profile in each follow-up session. Even the subtlest complications were recorded and were considered in the analysis. Statistical analysis was performed using SPSS for Windows software (Version 16, SPSS Inc.). A *P* less than 0.05 was considered statistically significant. Data are given as mean  $\pm$  SD.

## Results

In this study, there were 50 males and 132 females aged from seven to 58 years ( $21.91 \pm 8.35$ ); mean keratometry reading was ( $7.68 \pm 0.26$  mm); mean baseline BCVA was  $0.003 \pm 0.05$  logMAR; mean final UCVA was  $0.075 \pm 0.2$  logMAR. Mean spherical equivalent at baseline was  $-3.12 \pm 0.63$  D (ranged from  $-1.00$  to  $-4.00$  D) whereas mean final spherical equivalent was  $-1.36 \pm 1.38$  D ( $P < 0.001$ , paired T-test). Mean sphere at baseline was  $-2.87 \pm 1.14$  (ranged from  $-0.25$  to  $-7.00$  D) versus  $-0.98 \pm 1.27$  D finally. Mean astigmatism at baseline was  $-0.50 \pm 0.52$  D (ranged from  $-0.25$  to  $-3.75$  D), and final refraction revealed mean astigmatism of  $-0.75 \pm 0.73$  D.

As presented in Table 1, there was a significant association between baseline spherical equivalent and final UCVA ( $P < 0.001$ ). A decreasing trend is detected in final UCVA as long as the increment of baseline spherical equivalent in the study population. There is no statistically significant association found between age and Kr, with final UCVA (Table 1).

The time to achieve the targeted visual acuity was compared between eyes with different spherical equivalents. As shown in Table 2, as the spherical equivalent of the study population increases, the time needed to achieve this parameter is more (Table 2). Also, analysis of our data considering mean amount of myopia revealed that patients with myopia lower than  $-5$  D achieved better final permanent visual acuities and less time was needed for this achievement in comparison to patients with higher amounts of myopia ( $P < 0.01$ ).

Table 1  
Comparison of the final UCVA in different patient groups.

Final UCVA	Patient groups	Mean (logMAR)	SD	<i>P</i>
SE groups	SE $\leq -1.50$	0.023	0.1	<0.001
	$-1.50 < SE \leq -3.50$	0.077	0.2	
	$-3.50 \leq SE \leq -5.50$	0.101	0.2	
	SE $> -5.50$	0.192	0.2	
Kr groups	7 < Kr $\leq$ 7.5	0.085	0.2	0.70
	7.5 < Kr $\leq$ 8	0.079	0.2	
	Kr > 8	0.095	0.25	
Age groups	Age $\leq$ 15	0.085	0.2	0.26
	15 < age $\leq$ 25	0.078	0.2	
	25 < age $\leq$ 35	0.078	0.2	
	Age > 35	0.136	0.3	

Table 2  
Time to achieve the final permanent visual acuity in patient groups.

Time to achieve the final permanent visual acuity	Eye groups	Number of eyes in each group	Mean (days)	SD	P
SE groups	SE ≤ -1.50	49	12.87	14.32	<0.01
	-1.50 < SE ≤ -3.50	188	16.71	14.42	
	-3.50 < SE ≤ -5.50	101	20.43	16.91	
	SE > -5.50	26	22.57	17.63	
Kr groups	7 < Kr ≤ 7.5	87	16.92	14.9	0.77
	7.5 < Kr ≤ 8	229	17.65	15.4	
	Kr > 8	48	18.92	17.56	
Age groups	Age ≤ 15	98	21.03	17.13	0.05
	15 < age ≤ 25	162	16.43	15.05	
	25 < age ≤ 35	84	17.15	14.49	
	Age > 35	20	12.88	13.81	

There was a statistically significant association between this time period, and age of an individual, and more time is needed in younger cases to achieve the targeted visual acuity ( $P = 0.05$ ); however, the association of the time period and Kr did not reach statistical significance ( $P = 0.77$ ). There was also no significant difference in the amount of this time period between the two genders ( $P = 0.9$ ).

Based on reports of patients and findings of the clinician in the follow-up sessions and in medical profiles, in general, none of the cases had major complication such as bacterial keratitis. 82 eyes had minor and subtle complications (22.5%), and 282 eyes had no complications (77.5%). The recorded complications were irritation (11 eyes), fine corneal infiltration (5 cases), blurred vision (2 eyes), transient diplopia in first day of use (3 patients), halo (6 eyes), photophobia (2 eyes), corneal edema (2 eyes), redness (4 eyes), lens adhesion (2 eyes), giant papillary conjunctivitis (3 eyes), lens high riding (3 eyes), lens low riding (2 eyes), and punctate epithelial erosion (3 eyes). Other complications such as burning sensation, solution allergy, transient fine central corneal opacity, dry eye, difficulty in reading, infectious conjunctivitis, corneal epithelial defect, toxic allergy to lens material, and punctate keratoconjunctivitis each presented in one of the cases. Many of these complications were addressed by means of close follow-up, mild doses of anti-inflammatory drugs in low frequency, antibiotic eye drops, and artificial tear administration. In the cases with high or low riding lens positions and lens adhesion, the lens fitting process was reconsidered. None of the cases that declared complications had complaints about that in the subsequent follow-up session.

As demonstrated in Table 3, patients in the group that had encountered at least one of these complications had higher baseline spherical equivalents compared to patients that did

not report any complication and had no finding in examination (Table 3).

## Discussion

As a large population of patients with myope-astigmatic refractive errors were recruited in this study, it can be a good representative for the estimation of efficacy and the safety of modern overnight OK contact lenses. In comparison to our study, 16 patients that participated in Mika<sup>6</sup> et al.'s study in 2007 had lower mean baseline SE ( $-2.06 \pm 0.75$  D), and the mean final SE was  $-0.16 \pm 0.38$  D after 6 months follow-up. Hiraoka et al<sup>4</sup> evaluated 52 eyes during one year in 2004. The manifest refraction reduced from  $-2.32 \pm 1.18$  D to  $-0.16 \pm 0.33$  D ( $P < 0.001$ ) in their study population. In his other study in 2009, 17 patients completed 1-year follow-up examinations after OK lens wear. Manifest refraction significantly decreased from  $-2.17 \pm 0.84$  D at baseline to  $-0.17 \pm 0.30$  D after treatment ( $P < 0.001$ ).<sup>7</sup> Kang et al<sup>8</sup> fitted sixteen myopic children with an OK lenses in one eye for overnight wear and a gas permeable contact lens in the other eye for daily wear. OK lenses significantly reduced myopia from  $-2.37 \pm 1.10$  D to  $-0.54 \pm 0.95$  D after 3 months of wear ( $P < 0.001$ ).

Overnight wear of these lenses is comfortable, and the rate of complications is not high.<sup>9</sup> Advantages of overnight contact lens wear upon daytime wear lenses are earlier adaptation, lower risk of lens loss and daytime dry eye, and faster correction of the refractive error. In addition, reversibility of the refractive error after seizing lens wear is lower in comparison.<sup>10,11</sup>

In the current study, we noticed that there is a lower rate of improvement in final UCVA as the baseline spherical equivalent increases. In addition, individuals with myopia lower than  $-5.0$  D achieved better final UCVA. As found in the current study and the literature, OK lenses have limited effect range for reshaping the corneal epithelium and stroma<sup>11</sup> and to correct the refractive error; thus, the maximal effective alteration of the cornea by OK lenses happens in myopia lower than  $-5.0$  D; therefore, orthokeratology contact lens is supposed to be recommended in myopia lower than  $-5.0$  D to get the maximal refractive correction.

The time to achieve the final targeted visual acuity (VA) is estimated  $17.6 \pm 15.5$  days in our study population; also, a shorter period of time is needed to establish a stable amount of refractive error in patients with myopia less than  $-5.0$  D. Fan et al<sup>12</sup> reached final acuity after one week. They claimed that other researchers had announced a two-week period as the minimum time needed whereas most of the refractive improvement happened much earlier.<sup>6</sup> The mechanism of action of overnight OK lenses are not completely understood. By the idea of redistribution of the corneal epithelial cells and reshaping of epithelium and stroma, very early refractive improvements can be explained. However, hastening the process of axial lengthening of the globe is also another finding that might take a longer period of time to impose its corrective effects.<sup>13</sup>

Table 3  
Association of complications and baseline spherical equivalent.

Complications	Baseline spherical equivalent (SE) mean(D)	SD	P
Present	-3.62	1.38	<0.001
Absent	-2.97	1.44	

In the present study, 23 complications were recorded that irritation had a maximum frequency found in 11 eyes of 11 patients. It is noticeable that 77.5% of the eyes in the current population manifested none of the complications. As even the subtlest complications were considered in data analysis, the rate of complication is high to some extent. However, as OK lenses induce hypoxia during nighttime and cause epithelium-thinning and redistribution, complications such as bacterial keratitis have been reported in many cases in previous series.<sup>1</sup> As patients referred to our center were observed closely, we did not find such complications in our study population. We also found a statistically significant association between baseline SE with rate of complications reported by patients. It is considered that, as extreme flattening of back optic zone radius is needed when the dioptric power of refractive error increases, this may possibly lead to more manipulation of the central cornea and cause its thinning and finally predisposing the cornea to abrasion and subsequent infection and opacity in cases with higher refractive errors.

This study was the first to investigate the utility of modern overnight OK contact lenses in an Iranian population. Some drawbacks exist that should be considered in the interpretation of the outcomes. Aside from the retrospectively designed manner, as the amount of astigmatic refractive error included in this study was high, it could have influenced our outcomes, as the sphericalization of the cornea largely differs in the different meridians. Use of topography for lens fitting and for evaluating the final corneal parameters could add a large amount of reliability to our study which should be considered in ongoing studies on this issue.

## References

1. Leo SW, Young TL. An evidence-based update on myopia and interventions to retard its progression. *J AAPOS*. 2011;15:181–189.
2. Jayakumar J, Swarbrick HA. The effect of age on short-term orthokeratology. *Optom Vis Sci*. 2004;82:505–511.
3. Lui Wai-on, Edwards MH. Orthokeratology in low myopia. Part 2: corneal topographic changes and safety over 100 day. *Cont Lens Anterior Eye*. 2000;23:90–99.
4. Hiraoka T, Furuya A, Matsumoto Y, Okamoto F, Kakita T, Oshika T. Influence of overnight orthokeratology on corneal endothelium. *Cornea*. 2004;23(suppl 8):S82–S86.
5. Cheng Z-Y, Chu R-Y, Zhou X-T. Influence of diameter of optical zone ablation on LASIK-induced higher order optical aberrations in myopia [Chinese] [Abs] *ZhonghuaYanKeZaZhi*. 2006;42:772–777.
6. Cheung SW, Cho P, Fan D. Asymmetrical increase in axial length in the two eyes of a monocular orthokeratology patient. *Optom Vis Sci*. 2004;81:653–656.
7. Mika R, Morgan B, Cron M, Lotoczky J, Pole J. Safety and efficacy of overnight orthokeratology in myopic children. *Optometry*. 2007;78:225–231.
8. Hiraoka T, Okamoto C, Ishii Y, Kakita Okamoto F, Takahashi H, Oshika T. Patient satisfaction and clinical outcomes after overnight orthokeratology. *Optom Vis Sci*. 2009;86:875–882.
9. Kang P, Swarbrick H. Peripheral refraction in myopic children wearing orthokeratology and gas-permeable lenses. *Optom Vis Sic*. 2011;88:476–482.
10. Walline JJ, Rah MJ, Jones LA. The children's overnight orthokeratology investigation (COOKI) pilot study. *Optom Vis Sci*. 2004;81:407–413.
11. Alharbi A, La HD, Swarbrick HA. Overnight orthokeratology lens wear can inhibit central stromal edema response. *Invest Ophthalmol Vis Sci*. 2005;46:2334–2340.
12. Fan L, Jun J, Jia Q, Wangqing J, Xinjie M, Yi S. Clinical study of orthokeratology in young myopic adolescents. *Int Contact Lens Clin*. 1999;26:113–116.
13. Walline JJ, Jones LA, Sinnott LT. Corneal reshaping and myopia progression. *Br J Ophthalmol*. 2009;93:1183–1185.