Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/mjafi

Original Article

A prospective interventional study of effect of accelerated orthokeratology on the corneal curvature and refraction among young adults with myopia

Gp Capt M.A. Khan^{a,*}, Maj Ashutosh Gupta^b, Maj Gen T.S. Ahluwalia^c,
Brig P.S. Moulick^d, Brig V.S. Gurunadh, VSM^e, Lt Col Sandeep Gupta^f

^a Associate Professor, Dept of Ophthalmology, Armed Forces Medical College, Pune 411040, India

^b Resident, Dept of Ophthalmology, Armed Forces Medical College, Pune 411040, India

^c Commandant, Command Hospital (Eastern Command), Kolkata, India

^d Professor and Head, Dept of Ophthalmology, Armed Forces Medical College, Pune 411040, India

^e Commandant, Military Hospital Wellington, Tamil Nadu, India

^f Assistant Professor, Dept of Ophthalmology, Armed Forces Medical College, Pune 411040, India

ARTICLE INFO

Article history:

Received 14 March 2015

Accepted 12 February 2016

Available online 16 April 2016

Keywords:

Contact lens

Orthokeratology

Myopia

ABSTRACT

Background: Orthokeratology with reverse geometry contact lens is a non-surgical alternative to conventional contact lenses for correction of myopia. However, the strength of evidence for its efficacy and safety is limited to retrospective studies and only a few prospective studies. This prospective study, the first on Indian subjects, evaluated the outcome of orthokeratology among young myopes.

Methods: Fifty eyes of 25 young myopes (age 19–29 years) with myopia of –1 to 5.0 diopter underwent accelerated orthokeratology using the reverse geometry ortho K – LK lenses for correction of myopia. They were followed up prospectively with weekly vision, refraction, corneal topography, and pachymetry to assess the correction of myopia.

Results: The mean Log MAR vision corrected from 0.748 ± 0.225 at base line to 0.025 ± 0.0630 at 12 weeks with 86% achieving 6/6 unaided day time vision. This was associated with significant central corneal flattening and thinning. The lenses were well tolerated with no significant complications.

Conclusion: Overnight accelerated orthokeratology effectively corrects moderate degree of myopia and provide excellent spectacle free day time vision without any significant adverse effects in the short term.

© 2016 Published by Elsevier B.V. on behalf of Director General, Armed Forces Medical Services.

* Corresponding author. Tel.: +91 08412977115.

E-mail address: mansurophthal@gmail.com (M.A. Khan).

<http://dx.doi.org/10.1016/j.mjafi.2016.02.016>

0377-1237/© 2016 Published by Elsevier B.V. on behalf of Director General, Armed Forces Medical Services.

Introduction

Orthokeratology (OK) is a clinical contact lens procedure used for the reduction, modification, or elimination of refractive error by the application of contact lenses.¹ Specially designed rigid gas permeable corneal contact lenses are worn overnight to reduce patient's myopia. The correction of myopia is achieved by molding of the cornea and the lenses have to be worn constantly overnight for sustained spectacle/lens free correction throughout the day. Though the origin of this technique dates back to the 1940s,² it has gained clinical acceptance only recently with the introduction of the high oxygen permeable reverse geometry contact lenses, which are now able to produce fast results (overnight correction) with greater safety and better positioning over the cornea.³ This new design termed as accelerated OK, due to the rapid correction, was approved by the United States Food and Drug Administration in 2002 for correction of myopia up to -6 diopter.⁴ This method includes overnight lens wear with removal of lens immediately after awakening, allowing clear vision through waking hours without glasses. It offers an alternative to myopes, who want spectacle free vision without having to undergo surgery or wear contact lens throughout the day. Although an approved technique, the larger body of evidence for its safety and efficacy is in the form of case series and retrospective studies and very few prospective studies.⁵ There is no study on Indian subjects. This prospective interventional study was, therefore, carried out to evaluate the safety and efficacy of this procedure on Indian subjects.

Materials and methods

The study was designed as a prospective interventional study carried out over a period of 2 years in the ophthalmology department of a tertiary care military hospital. Since there was no Indian data available, a pilot study with 20 eyes was conducted initially to calculate sample size using α error = 0.01%, power of study = 90% (these eyes were not included into actual study). In the pilot study the mean Log MAR (minimum angle of resolution) visual acuity improved from 0.65 (SD 0.27) to 0.27 (SD 0.23) after OK treatment and the calculated sample size based on this result was 10 eyes. The mean corneal curvature and corneal thickness changed 43.4 diopter (SD 1.45) to 41.9 diopter (SD 1.43) and 529.68 μ (SD 12.35) to 518.39 μ (SD 13.21), respectively. The required sample size based on the above two parameters was 28 and 39 eyes respectively. The minimum sample size required to study all three parameters was 39 eyes, and in the final study 50 eyes were included.

The study was approved by the Institutional ethics committee. Subjects were enlisted consecutively from those, who reported to the outpatient department and opted for OK procedure after being explained the pros and cons and all the alternatives available including kerato-refractive surgeries and after a written informed consent. Patients 15 years or older with a myopia of -1.00 to -5.00 D sphere and with the rule astigmatism of less than 1.5 D were included in the

study. Those with any ocular surface disorder, ocular inflammation, keratoconus suspect, past intraocular surgery, or any other condition contraindicated for contact lens wear were excluded. All patients underwent baseline comprehensive ophthalmic evaluation, which included refraction and best corrected Snellen visual acuity, slit lamp examination, Schirmers test and tear film break up time, dilated fundus examination, applanation tonometry, pachymetry for central corneal thickness with ultrasound pachymeter, Pachette 2 (model DGH-550) and corneal topography with Topcon 1000 Placido based system. At baseline visit participants were fitted with OK lens of model ortho-K LK lenses, using a trial lens. The trial lens was selected based on the flattest keratometric measurement, the targeted reduction in myopia, and the corneal eccentricity on topography. Based on these criteria, trial lenses, each with slightly different parameters were tried out on the eyes under topical anesthesia till the fit was found suitable. A lens which was well-centered with a fluorescein pattern of 2–4 mm diameter of central bearing with surrounding bright and narrow ring of fluorescein pooling and alignment to moderate bearing at alignment zone with good edge clearance, was taken as a suitable fit. Once the fit was found acceptable fresh pair of lenses with the same parameters was prescribed. Before prescription for overnight wearing the patient was called for a second visit, when the fit was reassessed on the slit lamp and patient allowed to wear the lens continuously for 8 h and examined at 1 h and 8 h for any adverse effects such as redness, pain or corneal oedema. If there were no adverse effects and the lens was well tolerated it was prescribed for overnight wear.

The patients were then followed up at first day after overnight wear and then at 1 week, 2 weeks, 4 weeks and 12 weeks later, from the initiation of lens wear. Visual acuity, refraction, slit lamp examination, pachymeter and corneal topography done at each follow-up visit at the OPD (morning and evening) and results compiled and analyzed at 12 weeks of follow-up. Snellens acuity was converted to Log MAR for analysis. Data analysis was performed by using SPSS (statistical package for social sciences) version 19.0 with paired *t* test for pre- and post-treatment outcome and multivariate analysis (ANOVA) for repeated measurements. *p*-Value <0.05 was considered as significant.

Results

The demographic characteristics, baseline vision, and refraction are as listed in Table 1. All patients completed the treatment and remained available during the study period. The mean age was 21.4 years (19–29 years) with a slight male preponderance. The follow-up period ranged from 3 months to 6 months (average 4.2 months). Table 2 shows results of ortho-K at final follow-up compared to the basal line parameters mean (SD) and Table 3 shows the continues change in the various parameters at different follow-up intervals. Baseline unaided visual acuity ranged from 3/60 to 6/24 (mean Log MAR 0.748, SD 0.225) with best corrected acuity of 6/6 in all subjects with refraction ranging from -1.0 to -5.0 diopter sphere. Post-OK by 12 weeks 43/50 (86%) had unaided

Table 1 – Demographic and baseline data (gender, age groups and pre-ortho K unaided vision).

	Male	Female	≤20	21–25	>25	6/24	6/36	6/60	5/60	4/60	3/60
Gender	15 (60%)	10 (40%)									
Age			11 (44%)	12 (48%)	02 (8%)						
Vision unaided n = 50 eyes						29 (58%)	12 (24%)	02 (4%)	01 (2%)	02 (4%)	04 (8%)

Table 2 – Pre- versus post-orthokeratology mean vision, refraction (spherical equivalent), keratometry and pachymetry.

	Pre-OK	Post-OK final (12 weeks)	Difference pre and post at 12 weeks	95% confidence limit of the difference		Significance post vs pre at 12 weeks
				Lower	Upper	
Unaided VA [#]	0.748 (±0.22) [*]	0.025 ± 0.063 [*]	0.722 ± (0.172) [*]	0.674	0.772	p = 0.000
Log MAR ^a						
Refraction SE ^b	−2.02 (±0.91) [*]	−0.22 ± 0.25 [*]	1.82 ± (0.71) [*]	−2.02	−1.62	p = 0.000
Sim K1 (D) ^c	43.97 ± (1.49) [*]	42.38 ± 1.65 [*]	1.5 ± (1.015) [*]	1.21	1.79	p = 0.000
Sim K2 (D)	43.178 ± (1.41) [*]	41.7 ± (1.43) [*]	1.68 ± (1.186) [*]	1.34	2.02	p = 0.000
CCT ^d in μ	527.84 ± (19.88) [*]	518.58 ± (20.02) [*]	9.260 ± (2.31) [*]	8.6	9.9	p = 0.000

^{*} Mean (SD).[#] VA, visual acuity.^a MAR, minimum angle of resolution.^b SE, spherical equivalent.^c D, diopters.^d CCT, central corneal thickness.**Table 3 – Data showing chronological continuous change in unaided vision, spherical equivalent, central keratometry, and pachymetry after fitting of orthokeratology lenses.**

	At 1st day overnight	At 1 week	At 2 weeks	At 4 weeks	At 12 weeks
Mean increase in unaided vision Log MAR	−0.602 p = 0.000 (−0.632 to 0.571) [*]	−0.121 p = 0.000 (−0.153 to 0.090) [*]	0.00 –	0.00 –	0.00 –
Mean reduction in myopia spherical equivalent	−1.30 p = 0.000 (−1.46 to −1.33) [*]	−0.34 p = 0.000 (−0.40 to −0.28) [*]	0.005 p = 0.709 (−0.03 to −0.02) [*]	0.045 p = 0.005 (−0.76 to −0.14) [*]	0.12 p = 0.000 (−0.17 to −0.07) [*]
Mean amount of flattening Sim K1 in diopters	−1.145 p = 0.000 (−1.479 to 0.810) [*]	−0.235 p = 0.176 (−0.578 to 0.108) [*]	−0.575 p = 0.001 (−0.895 to 0.254) [*]	0.779 p = 0.000 (0.914 to 0.614) [*]	−0.428 p = 0.000 (−0.639 to 0.216) [*]
Mean amount of flattening Sim K2 in diopters	−1.156 p = 0.000 (−1.457 to 0.855) [*]	−0.128 p = 0.404 (−0.433 to 0.177) [*]	0.137 p = 0.255 (−0.102 to 0.375) [*]	−0.218 p = 0.105 (−0.482 to 0.047) [*]	−0.109 p = 0.130 (−0.255 to 0.037) [*]
Mean reduction in central corneal thickness (μ)	6.540 p = 0.000 (6.035 to 7.045) [*]	0.300 p = 0.000 (0.168 to 0.432) [*]	0.760 p = 0.000 (0.541 to 0.971) [*]	1.520 p = 0.000 (1.232 to 1.808) [*]	0.140 p = 0.09 (0.022 to 0.302) [*]

Multivariate analysis for repeated measurements shows maximum effect within 1 week of treatment and minimal effect thereafter.

^{*} 95% confidence limit of the difference.

6/6 vision (mean Log MAR 0.025, SD 0.0630). All of them actually attained 6/6 unaided visual acuity during the waking hours by the first week of treatment and retained this vision till the end of the follow-up. The pre-treatment myopia in these eyes was between −1 and 4 diopters. The remaining seven eyes with an initial myopia of between 4 and 5 could be corrected to 6/9 unaided with a residual refraction of −0.5 diopters up to the last follow-up. Two of these seven eyes had initial myopia of −5 diopters. None of these however reported additional use of spectacles since binocularly the vision was 6/6. The refractive correction was associated with a flattening of central cornea (Fig. 1) and decrease in central pachymetry (Table 2). Corneal topography showed a change toward central flattening and mid peripheral steepening (Fig. 2). Reduction of myopia was seen with just 1 day overnight wear

with further correction after 1 week, which was statistically significant ($p < 0.0001$) and was maintained thereafter. Similarly the largest central flattening and central corneal thinning was seen within a week of wearing the lenses. Unaided vision remained stable at around 6/6 from 1 week onward despite small fluctuations in keratometry and pachymetry. The mean myopic correction in terms of spherical equivalent was around −2.0 D and the range of correction was −0.75 to −4.5 for sphere and −0.25 to −0.75 for cylinder. Morning and evening visual acuity and keratometer reading did not show significant variation from 1 week onwards suggesting stability and sustainability of the effect on the cornea and visual acuity throughout the day, after 1 week (Fig. 3). Apart from mild irritation and hyperemia during the initial few days of treatment there were no complications

Fig. 1 – Graph showing reduction in central Sim K1 and K2 post-orthokeratology. Maximum flattening achieved by 1 week.

Fig. 2 – Corneal Topography picture shows central flattening post-orthokeratology.

Fig. 3 – Graph shows the morning evening variation in unaided vision post-orthokeratology which attained stability after 1 week.

or adverse effects during the period of study. The lenses were well tolerated and there were no drop out.

Discussion

Orthokeratology with reverse geometry RGP lenses has been reported to correct myopia rapidly over days and therefore this technique has been termed as accelerated OK.⁶ The myopic reverse geometry lens has a flat fitting central optical zone surrounded by a steeper reverse curve and peripheral alignment zone. The central flat zone induces flattening of central cornea whereas the peripheral curves are primarily responsible for centering and stability.⁷ The lenses worn overnight mold the central cornea rapidly to provide clear unaided daytime vision and this effect can be reversed on discontinuation of wear, which is an advantage over kerato refractive surgery.⁸ Greater comfort and convenience, minimal discomfort due to lens lid interaction and lesser incidence of dry eyes are some of the advantages of overnight contact lens wear over conventional day time contact lens wear.⁹ Several studies reporting good correction with excellent safety using these high oxygen permeable RGP lenses of reverse geometry design have led to a renewed interest in this technique.^{5,10} However, there are very few prospective studies and also no published data on accelerated OK in the Indian population. Ours is a prospective interventional study of accelerated OK among young Indian patients in the age group of 19–29 years with myopia up to –5 diopters. The outcome measures that were analyzed included gain in daytime unaided visual acuity, change in refraction, corneal topography and corneal thickness. In this study the desired visual outcome of 6/6 unaided day time vision was achieved in 86% of subjects with just 1 week of overnight wear, which was sustained through the day. An average reduction of about 2.0 diopter myopia was achieved with a range of 1–5 diopters. The corrective effect was similar in all meridians, and there was no significant induced astigmatism. What was remarkable was the rapidity of the effect as a significant reduction could be seen with just 1 day of overnight wear. In a large prospective study Sridharan et al.¹¹ reported 80% of target refraction after single overnight wear in myopes up to –4 diopters. Similar results for overnight OK were also reported by Mika et al and Soni et al.^{12,13} Most of these studies however have excluded refractory error above –4 diopters, whereas we found in our study that the technique was effective in myopia up to –5 diopters. At higher degrees of myopia partial correction with varying degrees of residual uncorrected myopia has been reported.¹⁴ In our study, the eyes with myopia more than 4 diopters had a residual error –0.5 diopters, but all of them were binocularly 6/6. The correction was sustained through the day after just 1 week of regular wear in the current study. The day time sustainability of OK lenses was studied by Sung et al.,¹⁵ who reported sustainable effect only after 4 weeks of regular wear in subjects of age ranging from 19 to 39 years. The earlier sustainability achieved in our study could be attributable to the younger average age (average 24 years). The corrective effect has been reported to be faster in younger patients.¹⁶ OK induces a central flattening with mid peripheral steepening similar to

LASIK surgery effectively turning the aspherical surface of the normal cornea into a more spherical shape.¹⁷ The central flattening is responsible for the correction of myopia. It has been postulated that rather than a simple molding or bending effect, there is a central thinning and peripheral thickening accounting for the corresponding topographic change in curvature.^{18,19} This pattern of central flattening with mid peripheral steepening and significant central corneal thinning was seen in this study as well. The mechanism of the central thinning is still unclear. Both stromal and epithelial component have been reported.^{20,21} Peripheral migration of central epithelial cells and/or flattening of the epithelial cell and central stromal dehydration under pressure of the lens are some of the postulated mechanisms.^{22,23} Conventional corneal lenses have been associated with increased risk of infective keratitis, when worn overnight and this has raised concerns over the safety of closed eye lens wear as in OK.²⁴ Although there have been sporadic reports of infective keratitis following OK a systematic review of this procedure did not reveal any increased risk directly attributable to overnight OK.²⁵ No infectious keratitis was seen in this study as well. OK lenses are worn overnight over a short period of 8–9 h unlike the 24 h wearing pattern of extended wear lenses, where the risk is highest. However the studies conducted so far were not designed to assess the relative risk of infection in OK versus conventional contact lenses. Undoubtedly, there is a need to exercise caution in the use and the care of these lenses, though under ideal conditions of wear, it appears to be safe. Larger controlled studies designed to study the relative risk are needed to investigate this issue.

Conclusion

The study results show that accelerated OK as an alternative to conventional contact lenses is effective and safe in correcting myopia up to –5.0 diopters, providing sustained spectacle free unaided vision of 6/6 or thereabouts after just 1 week of regular wear. However the short follow-up and lack of comparative control are the limitations of this study and further investigations with an RCT design are suggested to firmly establish the safety and efficacy of this promising non-surgical method of correcting moderate degrees of myopia.

Conflicts of interest

The authors have none to declare.

Acknowledgements

- (1) This paper is based on Armed Forces Medical Research Committee Project 4322/2012 granted and funded by the office of the Director General Armed Forces Medical Services and Defence Research and Development Organization, Government of India.
- (2) Dr Seema Patrikar, Lecturer in Biostatistics, Department of Community Medicine, AFMC for statistical analysis.

REFERENCES

1. Jessen GN. Contact lenses as a therapeutic device. *Am J Optom*. 1964;41:429-435.
2. Jessen GN. Orthofocus techniques. *Contacto*. 1962;6(7): 200-204.
3. Barr J, Rah M, Jackson JM, Jones JL. Orthokeratology and corneal refractive therapy: a review and recent findings. *Eye Contact Lens*. 2003;29(1):49-53.
4. Saviola JF. The current FDA view on orthokeratology: how we got here and where are we going. *Cornea*. 2005;24(7): 770-771.
5. Swarbrick H. Orthokeratology review and update. *Clin Exp Optom*. 2006;83(3):124-143.
6. Tahhan N, Du Toit R, Papas E, Chung H, LaHood D, Holden BA. Comparison of reverse-geometry lens designs for overnight orthokeratology. *Optom Vis Sci*. 2003;80:796-804.
7. Mountford J. An analysis of the changes in corneal shape and refractive error induced by accelerated orthokeratology. *Int Contact Lens Clin*. 1997;24:128-143.
8. Soni PS, Nguyen TT, Bonnano JA. Overnight orthokeratology refractive and corneal recovery after discontinuation of reverse geometry lenses. *Eye Contact Lens*. 2004;30:254-262.
9. Nichols JJ, Marsich MM, Nguyen M, Barr JT, Bullimore MA. Overnight orthokeratology. *Optom Vis Sci*. 2000;77:252-259.
10. Johnson KL, Carney LG, Mountford JA, Collins MJ. Visual performance after overnight orthokeratology. *Eye Contact Lens*. 2007;30(1):29-36.
11. Sridharan R, Swarbrick HA. Corneal response to short-term orthokeratology lens wear. *Optom Vis Sci*. 2003;80:200-206.
12. Mika R, Morgan B, Cron M, Lotoczky J, Pole J. Safety and efficacy of overnight orthokeratology in myopic children. *Optometry*. 2007;78(May (5)):225-231.
13. Soni PS, Nguyen TT, Bonanno JA. Overnight orthokeratology: visual and corneal changes. *Eye Contact Lens*. 2003;July (29):137-145.
14. Charm J, Cho P. High myopia-partial reduction ortho-K: a two year randomised study. *Optom Vis Sci*. 2013;90:530-539.
15. Sung YK, Bong KK, Young JB. Sustainability of orthokeratology as demonstrated by corneal topography. *Korean J Ophthalmol*. 2007;21(2):74-78.
16. Jayakumar J, Swarbrick H. The effect of age on short-term orthokeratology. *Optom Vis Sci*. 2005;82(6):505-511.
17. Lu F, Simpson T, Sorbara L, Fonn D. Malleability of the ocular surface in response to mechanical stress induced by orthokeratology contact lenses. *Cornea*. 2008;27(2): 133-141.
18. Cheah P, Norhani M, Bariah M, Myint M, Lye M, Azian A. Histomorphometric profile of the corneal response to short-term reverse-geometry orthokeratology lens wear in primate corneas: a pilot study. *Cornea*. 2008;27(4):461-470.
19. Swarbrick HA, Alharbi A. Overnight orthokeratology induces central corneal epithelial thinning. *Investig Ophthalmol Vis Sci*. 2001;42:597-600.
20. Reinstein DZ, Gobbe M, Archer TJ, Couch D, Bloom B. Epithelial, stromal and corneal pachymetry changes during orthokeratology. *Optom Vis Sci*. 2009;86(8):1006-1014.
21. Lian Y, Shen M, Jiang J, et al. Vertical and horizontal thickness profile of corneal epithelium and Bowman's layer after orthokeratology. *Investig Ophthalmol Vis Sci*. 2013;54 (1):691-696.
22. Choo J, Caroline PJ, Harlin DD, Papas EB, Holden BA. Morphological changes in cat epithelium following continuous wear of orthokeratology lenses: a pilot study. *Contact Lens Anterior Eye*. 2008;31(1):29-37.
23. Wang J, Fonn D, Simpson TL, Sorbara L, Kort R, Jones L. Topographic thickness of epithelium and whole cornea after overnight wear of reverse geometry rigid contact lens for reduction of myopia. *Investig Ophthalmol Vis Sci*. 2003;44 (11):4742-4746.
24. Young AL, Leung ATS, Cheng LL, Law RWK, Wong AKK, Lam DSC. Ortho-keratology lens related ulcers in children: a case series. *Ophthalmology*. 2004;111(3):590-596.
25. Woodford SVM, David CM, Deborah SJ, Stephen CK, William JR, Ira JU. Safety of overnight orthokeratology for myopia: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2008;115:2301-2313.