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Original Article

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

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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.

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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 Placedo 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