Prevention of myopia progression using orthokeratology

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The prevalence of myopia in children and juveniles has increased significantly in Korea and worldwide; in particular, the rates of myopia and high myopia in East Asia have grown rapidly. Myopia is easily corrected with spectacles or contact lenses. However, as children grow and mature, myopia can progress irreversibly and lead to vision-threatening complications. Thus, the prevention of myopia progression is an essential treatment goal. Many treatment strategies are being employed, including atropine eyedrops, specialized glasses, and orthokeratology (Ortho-K) lenses. Ortho-K is an effective treatment in managing myopia progression by lowering the rate of increase in refractive error and axial length. In this article, we review Ortho-K as a treatment for myopia progression, its history, mechanism, treatment regimen, and safety profile.

**Keywords:** Atropine; Axial length, eye; Contact lenses; Eyeglasses; Myopia

**Introduction**

Myopia, more commonly known as nearsightedness, is a condition in which the image of a distant object is formed in front of the retina due to a mismatch between the optical refractive power of the eye and the axial length. Myopia is derived from the Greek *myōps* (myein, to close + ὤπς, the eye) meaning “short-sighted.” This concept dates back to B.C. 350 where a link between myopia, bulging eyes, frequent blinking, eyelid squeezing, close reading were theorized [1,2]. Now, after two millennia, myopia is one of the most common eye conditions worldwide. This increased prevalence has led to increased interest and awareness of myopia progression and the risk of sight-threatening complications. To mitigate the risk of these complications, many strategies to delay the progression of myopia are being used and investigated. Through this review based on traditional methods [3], we focused on the role of orthokeratology (Ortho-K) in decreasing the progression of myopia.

**Epidemiology of myopia**

Myopia is prevalent worldwide but has a strikingly higher prevalence in East Asia [4]. The prevalence in schoolchildren were reported at 80.2% in Korea [5], 80.7% in China [6], 76.67% in Taiwan [4], and 74.2% in Singapore [7]. In addition, an increased prevalence was also found in children of Asian descent living elsewhere [8]. With these numbers projected to rise in the coming decades, myopia is considered a global epidemic and an imminent public health concern. The estimated worldwide prevalence of myopia was 22.9% of the world population [9]. It is projected that by 2050, 49.8% of the population will be myopic, with 9.8% having high myopia of more than 5.00 D [9]. Traditionally, vision is
Progression of myopia

Generally, children are born with hyperopic eyes. Emmetropization of eyes occur within first 2 years after birth [11]. Significant changes in the axial length, cornea, and crystalline lens contribute to emmetropization in the early years of life and are usually completed at age 6 years [12]. Factors which interfere with this process and disrupt the balance of anatomical development have been known to cause myopia in both animal and human models [13,14]. Although the exact mechanism is unknown, the occurrence and progression of myopia is determined by a complex interplay of environmental and genetic factors. Environmental factors such as intensive education at a young age are contributory to increased myopia while others, such as increased time doing outdoor activities in bright light have been identified to have a protective effect [15-17]. In 2018, the Ministry of Education in China released a Comprehensive Plan to Prevent Nearsightedness among Children and Teenagers (CPPNCT) to curb myopia among children [18]. In 2023, these guidelines were updated and included reducing electronic device use, adequate lighting in schools, and at least 2 hours of outdoor activities daily [19]. Although the recent increase in myopia has been largely due to environmental changes, genetic factors have been postulated for many years as evidenced by family clustering and twin studies [7,14]. Studies of genetic linkage have identified almost 200 genetic loci for refractive error and myopia, with identified genes having a wide variety of functions thus indicating multigenic and heterogeneous origin [20,21]. However, the rapid increase in myopia over a single generation is inadequate to significantly change the gene pool and thus suggests a greater effect of gene-environment interactions on myopia [13,22].

Myopia is commonly detected in the early school years and usually progresses until around 20 years of age [23]. Children with an earlier onset of myopia were found to have a greater rate of progression than children whose onset were later [24]. This effect is magnified in girls, those of Asian descent, and those with a myopic spherical equivalent [24,25]. Some older children and teens may still show myopic progression but, more commonly, this slows down after 12 to 13 years of age [26]. Minimal axial elongation and myopic progression is observed in the third decade of life [27].

Myopia control

Apart from managing the increasing prevalence of myopia, it is also necessary to mitigate the progression to high myopia and its significant risks to ocular health in individuals. Current treatment strategies for myopia address the known mechanisms that work by reducing lag of accommodation, reducing defocus of central and peripheral retina, and blocking myopiagenic signaling [28,29].

1. Spectacles

Bifocal spectacle lenses and progressive addition spectacle lenses were widely used to control myopia. The addition of plus lenses was hypothesized to reduce accommodative demand which was thought to stimulate axial elongation [30,31]. Novel spectacle lenses were designed to reduce peripheral hyperopic defocus, another factor hypothesized to increase axial elongation. Several studies have found statistically significant effects with these treatment options [31,32]. However, effects were minimal and were not considered clinically significant [33-36].

2. Pharmaceutical agents

Atropine is a nonselective antimuscarinic and a long-acting mydriatic and cycloplegic agent. Earliest studies for its use in myopia treatment was first reported in the 1970s [37]. Larger randomized controlled trials including ATOM1 and ATOM2 have investigated different concentrations in different degrees of myopia and its effects on refractive error and axial length [38-40]. Although atropine use in the context of myopia is widely investigated and used, the exact mechanism is still unclear [41]. Common practice of atropine use covers a wide range of concentrations from 0.01% to 0.05%, and less commonly, even higher concentrations [42]. There is no current consensus on the optimal concentration and duration to delay myopia progression but higher concentrations were associated with greater adverse effect such as photophobia, loss of accommodation, blurred near
vision, and allergic reactions [38,43]. A rebound phenomenon was also found wherein discontinuation of atropine in those with myopia progression of greater than 0.5 D/year required greater concentrations upon resuming treatment [28].

3. Behavior
Several studies suggest that outdoor activity time slows both myopia onset and progression [16,44,45]. In a study comparing time spent outdoors and physical activity as predictors of incident myopia, time spent outdoors had a significantly larger effect [16]. Further investigations suggest that the increased level of vitamin D, dopamine, or ultraviolet light during outdoor activities may be contributory to the mechanism of the observed effect on delaying myopia progression [46-48]. A meta-analysis reported an odds ratio of 0.87 for every additional hour of time spent outdoors each day [49].

4. Contact lenses and Ortho-K
Spectacles and contact lenses are common first line options for myopia correction. They are readily available, well-tolerated, affordable, and provide immediate improvement of vision [13]. Variations in contact lenses which aim to deliver peripheral myopic defocus show evidence in delaying myopia progression [50-52]. This is based on the theory that providing additional positive power in the periphery of these lenses creates a myopic defocus in the peripheral retina, causing reduction in axial growth [14]. The effects of soft multifocal contact lenses have also been studied. In the Bifocal Lenses In Nearsighted Kids (BLINK) study randomized controlled trial, high power add (+2.50D) multifocal lenses compared to medium power add (+1.5D) and single vision lenses reduced the rate of myopia progression over 3 years [53]. Further studies for long-term effectiveness and concerns on myopic rebound are necessary [54]. While these lenses rely on manipulating the optical properties of the eye, Ortho-K uses rigid contact lenses which mechanically change the shape of the cornea to correct myopia and decrease its progression.

History of Ortho-K
According to unconfirmed stories, the Chinese put small weights on their eyelids during sleep to improve vision [55]. This concept of mechanically altering the shape of the cornea is the cornerstone of the mechanism of Ortho-K. In the 1950s, polymethyl methacrylate (PMMA) contact lenses were introduced. Because of the rigidity of these lenses, unintended changes of corneal curvature and refractive error became evident specially when these lenses were fitted flatter than the corneal curvature [55]. During its inception in the 1960s, Jessen [56] initially described the “orthofocus” technique for reducing myopia methods [56]. Myopes were fitted with PMMA lenses which fit flatter than the corneal curvature and the resulting tear lens corrected the myopia [40]. After removal of these rigid lenses, the flattening effect persisted and allowed improved unaided vision [55]. Early attempts to correct refractive error lacked data on the corneal topography and were generally based on measured refractive error, thus limiting the effect and efficacy of contact lenses [57]. The technique was renamed “orthokeratology” and was accompanied by further clinical studies in the late 1970s. Corneal flattening control was made by changing the base curve and modifying optic zone diameter, peripheral curves of lens [55]. In the 1980s and 1990s, technological breakthroughs gave Ortho-K significant improvements. Rigid gas-permeable (RGP) contact lenses became more widely available. This type of contact lens reduced the risk of corneal hypoxia and edema, addressing a primary concern for contact lenses that required prolonged overnight wear. Increased customization for patients was achieved with computerized corneal topography and computer-driven lathing systems allowing for improved accuracy. Initially, a series of progressively flatter lenses were used until the desired refractive outcome are achieved [58]. Continued developments in modern Ortho-K allowed for increased molding of the corneal surface, allowing for longer intervals between lens changes. A significant development in modern Ortho-K is the use of a reverse geometry design consisting of a central flat area corresponding to the optical zone surrounded by steeper curve. This design became highly favored because it allowed optimized centration and improved tear exchanges [59].

The U.S. Food and Drug Administration (FDA) approval granted the first approval for an Ortho-K device in 1998 for Contex OK, a rigid RGP for reduction of myopia of up to 3.00D (FDA Summary of Safety and Effectiveness Data: K973697). In 2002, corneal refractive therapy lenses gained FDA approval for myopia of 6.00D with up to 1.75D of astig-
matism [60]. In 2019, MiSight (CooperVision, Inc.) gained pre-market FDA approval for myopia correction and decreasing progression in children aged 8 to 12 at the start of treatment (FDA Summary of Safety and Effectiveness Data: PMA P180035). In 2021, the FDA approved to Acuvue Abiliti (Johnson & Johnson Vision Care Inc.) lenses which reports a decrease in myopia of 1.00 D over a 2-year treatment period. Many improvements have been made to the reverse geometry lenses and lens materials are continuously being improved to abate complications [55].

**Mechanism of Ortho-K**

Ortho-K lenses are rigid contact lenses that work under the premise that overnight wear can alter the corneal surface, making the cornea flatter and thus temporarily reducing myopia in the daytime (Fig. 1) [61]. Although this flattening effect is temporary, many also use Ortho-K lenses to control myopia progression. It is postulated that visual experience affects the growth of the eye and therefore its refractive capacity. Several theories have emerged attributing this effect to factors such as retinal peripheral defocus, corneal higher order aberrations (HOAs), and changes in accommodative response which seem to regulate axial length elongation [62-65].

**1. Peripheral myopic defocus**

Peripheral retinal defocus occurs when the central focal point is on the retina while the peripheral focal points are not. In peripheral hyperopic defocus, the peripheral focal points are behind the retina while in peripheral myopic defocus they are in front. Animal studies show evidence of peripheral hyperopic defocus stimulating an increase in axial growth [66,67]. It is worth noting that in myopes, the eye is prolate resulting to a greater degree of peripheral hyperopic defocus [68]. To address this, Ortho-K is designed to create peripheral myopic defocus, in turn decreasing or reversing the stimulus for axial elongation.

MiSight 1 day (omafilcon A; CooperVision, Inc.) is a daily disposable soft contact lens developed for both myopia correction and control of progression. It employs a dual-focus optical design composed of concentric rings with alternating refractive correction zones and peripheral myopic defocus treatment zones. These concentric rings were developed to ensure adequate distance vision as well as peripheral myopic defocus in all gazes. A clinical trial found that use of MiSight slowed axial length growth in treated myopes and, after 6 years of treatment, was found similar to age-matched controls (source 3). Lumb et al. [69] report that these lenses are highly rated in terms of comfort, ease of handling, vision, and satisfaction by children. Although investigations are still underway for this contact lens, the

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**Fig. 1.** Overview of orthokeratology (Ortho-K). (A) In myopia, the focus is formed in front of the retina. (B) Ortho-K lenses make the focus form on the retina. (C) After taking off the lenses, the cornea remains flattened and the focus is on the retina.
reported outcomes and advantages make it an attractive option for both parents and medical providers [69].

2. HOAs and accommodative response
Apart from peripheral defocus, other HOAs have also been found to affect the regulation of eye growth [70]. HOAs with higher root-mean-square error values lessen accommodative effort and thus decreases the mechanical tension at the equator, leading to slower axial elongation [71]. Some studies reported that more positive spherical aberration and vertical trefoil were associated with less axial growth [71,72]. Ortho-K treatment effectively alters the corneal shape and profile and in turn, increases total HOA that, based on this theory, is desirable in the treatment of myopia progression [73]. Some have attempted to slow axial elongation by using contact lenses that increased spherical aberrations which had modest effects in both children and adults [74]. It is important to note that these lenses induced much smaller spherical aberrations than that of Ortho-K lenses which may not be sufficient to produce the desired effect.

Similarly, another hypothesized mechanism is the improvement of accommodative response. It has been documented that myopic children have greater accommodative lags than emmetropic children, providing another stimulus for myopia progression. Ortho-K is theorized to improve the accommodative response in myopes [75]. However, studies have inconclusive results [76]. In addition to these effects, the use of Ortho-K has been reported to increase subfoveal choroidal thickness which is usually subnormal in myopic eyes [77]. Although the mechanism remains unclear, it is speculated that the use of Ortho-K induces relaxation of large choroidal vessels, increasing blood supply to support choroidal thickening [60,78].

3. Rebound effect
Although Ortho-K shows a significant slowing effect in myopic progression, the results vary with each report and across individuals. As with other modalities of myopia control, rebound effect after discontinuation is an important concern that should be discussed with the patient. It is unclear whether the effects on myopia control are sustained upon discontinuation. Some have reported the potential for this phenomenon with Ortho-K similar to that seen in atropine use [79-81]. The Discontinuation of Orthokeratology on Eyeball Elongation (DOEE) study reported that discontinuation of Ortho-K use before age 14 years led to an increased rate of axial length elongation. Upon reinstallation of treatment after 6 months, the decrease in myopia progression effect is regained although at a slower rate [79]. This may imply that the use of Ortho-K lenses may need to be continued well past age 14 years to achieve an adequate level of control [63,79]. At present, the optimal duration for an Ortho-K treatment regimen is still unknown. Some clinical trials, such as the Longitudinal Orthokeratology Research in Children (LORIC) [82] and the Retardation of Myopia in Orthokeratology (ROMIO) [52] studies conducted in Hong Kong, were conducted over 2 years and showed promising results in decreasing the rates of axial elongation and myopia progression. Previous studies have also reported greater myopia control in the first 2 years of treatment [52,63]. However, data is limited beyond this period. It is widely accepted that further investigation is necessary to optimize this aspect of treatment.

Safety

1. Keratitis
The primary concern with prolonged overnight contact lens use is corneal health. In particular, this environment reduces the ocular surface defense, changes the epithelial surface integrity, and allows bacterial colonization thus increasing susceptibility to microbial keratitis [83]. Reported rates vary but were found to be similar with daily soft contact lens wear [84]. Poor outcomes are usually based on delayed identification and treatment. Majority of cases show positive microbial cultures, with Acanthamoeba and Pseudomonas aeruginosa being the most common offending agents [85]. Both organisms present with rapidly progressing keratitis, with Acanthamoeba keratitis being particularly severe and sight-threatening, often resulting to corneal scarring [17,81]. Early recognition and prompt treatment is necessary to avert these complications. Associated risk factors for keratitis are similar to those for contact lens use including lack of training on proper hygiene, improper fit, use of tap water, poor compliance, and poor follow-up [86]. Care must be made in educating the patient and their guardians of the importance of compliance to proper lens caring regimen, particularly in the context of Ortho-K which is used overnight. This increased risk of a potentially vision-threatening complication must be

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discussed with the patient and guardians and must be weighed against the potential benefits.

2. **Corneal staining, deposits, and lens associated problems**

Corneal staining is the most common adverse effect and can present in different patterns with continued Ortho-K use. Some distinctive patterns described are sporadic or diffuse punctate staining, patchy central staining, and whorl-shaped staining [83]. Higher myopia, corneal eccentricity, and smaller corneal horizontal radius can increase the risk of repeated corneal staining episodes [83]. Lens binding is a complication seen with RGP lenses wherein the contact tear viscosity between the lens and cornea increases during sleep and results in a fluid adhesion force between the two surfaces [87]. Patients may complain that the contact lens feels stuck upon waking up. Forceful removal of the Ortho-K may result in further corneal damage. This may be avoided by using a lubricant before removal. Pigmented ring-shaped corneal deposits resembling Fleischer rings have been reported with Ortho-K use [88,89]. Some suggest that this is caused by stress forces to the epithelium or tear stagnation in the reverse curve area of the lens [88]. It has been reported widely in the Asian population [89] but has also been seen in Caucasian patients [90]. Other lens associated problems are lens tilting and decentration. The treatment zone of Ortho-K lens is important because it compresses the cornea and flattens the cornea to make it see well without glasses. Sometimes the factors including increased eyelid tension, corneal astigmatism, movement of lens might cause the lens being out of center [91]. The effort of avoiding this kind of lens associated problems is required before description.

3. **Other complications**

Other reported but less frequent complications of Ortho-K are bulbar hyperemia, papillary conjunctivitis, corneal edema, palpebral edema, nebular corneal opacity, viral keratoconjunctivitis, band keratopathy, and corneal ulcers. Overall, complications are more common in the first year of use and are less frequent and less severe in children than in adults [92].

**Considerations with Ortho-K lens prescription**

In Korea, the approximate cost of Ortho-K lenses is USD 1,000. The total cost of treatment increases with each subsequent update or replacement of the lenses after 1 to 2 years. This high cost compared to other treatment modalities like atropine eyedrops may be a financial burden and a barrier to consideration of this treatment.

With overnight use of Ortho-K, it is imperative that careful and regular follow-up be conducted to ensure corneal health and maintain clean contact lenses. For those prescribing Ortho-K, specialized training, certification, and experience are required to become skillful in optimizing lens fitting and management. For the Ortho-K wearer, aside from knowing the benefits for myopia control, they must also be fully aware of the possible adverse outcomes. Lens care and hygiene are critical for maintaining a healthy cornea and minimizing the potential of complications [83,93].

**Future of Ortho-K**

Although the promising reports regarding Ortho-K use in treatment of myopia, still there are some studies required. Including not only Asian population, but also non-Asians are needed to prove the effect and efficacy of Ortho-K. Further studies are needed about the effective age, period of lens wearing, terms of maximizing stabilization of myopia, potential rebound effect [81]. The education of hand hygiene and warning of safety like corneal infection, opacifications which can cause permanent vision loss. And to evaluate that the effect of Ortho-K is equivalent, noninferior or synergistic effect to low dose atropine on myopia is necessary.

**Conclusions**

Ortho-K is a treatment modality for the correction of myopia and the slowing of its progression. By addressing different mechanisms of myopia progression, Ortho-K has shown promising outcomes. Rapid advances in this technology have improved the efficacy and safety of prolonged use. However, treatment duration for maximum effect still remains unclear.

Knowledge of the efficacy, safety profile, and limitations of Ortho-K lenses will be invaluable in guiding treatment decisions for both patients and medical professionals.
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