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Review Article

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Orthokeratology for Myopia Control

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Abstract

Myopia is a common cause of ocular morbidity and an emerging global public health challenge of the 21st century. With high prevalence, myopia poses a long-term burden on the health care system, impact on the global economy, and quality of life. This calls for collaborative global action to identify intervention for the onset and progression of myopia. Common strategies to halt myopia progression include optical, pharmacological, and behavioral methods. The concepts of Orthokeratology (Ortho-K) evolved in the mid-1960s and showed promising results; however, it did not gain much attention essentially due to a lack of knowledge and researches. Despite undergoing a drastic transition, Ortho-K for myopia control remains poorly understood even to ophthalmic professionals. In this review, the existing knowledge of Ortho-K, its effectiveness, and safety are discussed. It also aims to identify the research gap and provide recommendations for future studies.

Keywords: Efficacy; Myopia Control; Orthokeratology; Refractive Error; Safety

Abbreviations: URE: Uncorrected Refractive Error; PALs: Progressive Addition Lenses; CRT: Corneal Refractive Therapy; VST: Vision Shaping Treatment; CKR: Controlled Kerato-Reformation; CMS: Corneal Molding System; BCVA: Best-Corrected Visual Acuity.

Introduction

Uncorrected refractive error (URE) is the leading cause of visual impairment with an estimated 2.5 billion myopes in 2020 [1]. In the US, the prevalence of myopia has increased from 25% in 1971-1972 to 41.6% in 1999-2004. In East China, the prevalence of myopia in young adults is as high as 80% which increases with older age, female gender, and urban region. Sun, et al. (2012) studied the prevalence of myopia in 5083 students of a Chinese university and found that 95.5% of them to be myopia. The Sydney Adolescent Vascular and Eye Study (2013) followed two cohorts of children for 5-6 years and found that the prevalence of myopia increased from 1.4% to 14.4% in the 12-year-old group and from 13.0% to 29.6 % in the 17-year-old group. The Gutenberg Health Study (2014) revealed that the prevalence of myopia was 35.1% in the European adult population aged 35-74 years. A prominent study in India found that the prevalence of myopia in adults above 40 years was 34.6%. Raju, et al. (2004) found that 30.97% of the adult population(>39 years) were myopic in a rural South India. Epidemiological shreds of evidence show the children of myopic parents have 2 to 8 times higher risk of developing myopia, and the number of myopic children can be significant [2-9].

Pan, et al. (2012) reviewed the worldwide prevalence and risk factors for myopia and found prevalences of myopia vary across populations of different regions and ethnicities. Asian children, especially those of Chinese origin, are found to be more susceptible to myopia compared with the Western population. Over the last few years, myopia has gained a lot of attention due to its dramatic increases in its prevalence worldwide. Nevertheless, these increasing rates of myopia is not a concern to East Asia but the whole world. Optical therapies for slowing myopia progression studied are binocular under correction, bifocal spectacles, progressive addition lenses (PALs), radial refractive gradient spectacle lenses, multifocal and radial refractive gradient contact lenses. At present, orthokeratology (Ortho-K) stands as the most effective intervention of myopia control [10,11]. Now, with more researches and clinical trials, Ortho-K is viewed as a prospectus technology for vision correction and particularly for the control of myopia progression. This review attempts to provide an overview of Ortho-K, its working principle, and its effectiveness and safety in myopia control.

Myopia Progression and the Need for its Control

Causes of Myopia Progression

The exact pathogenic mechanism of myopia is still not clearly understood. However, recent evidence suggests that both genetic factors and environmental factors greatly influence the growth of the eye and progression of myopia [12]. Several factors that include more time spent on near work, less time outdoors, higher educational level, urbanization, and history of parents having myopia is reported to increase the risk of myopia [10]. A person who spends more time outdoor is believed to have a slower progression of myopia [13]. This could be because sunlight could stimulate the production and release of retinal dopamine, which controls the growth of the eye.

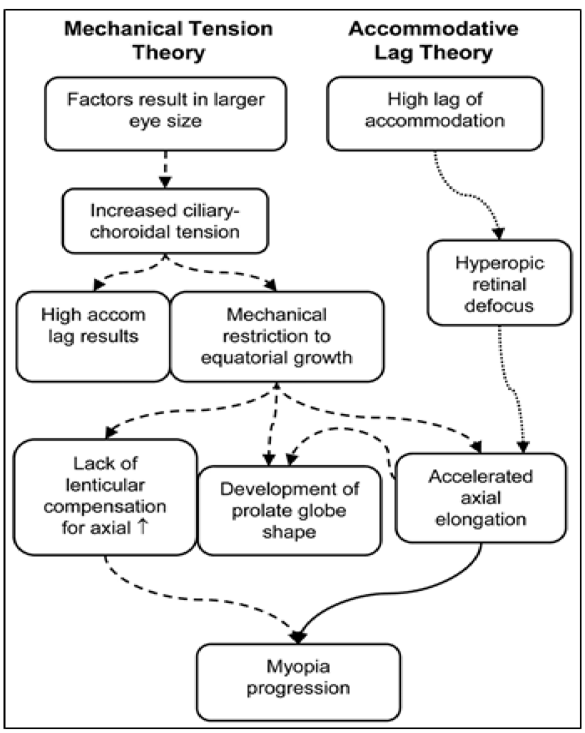

Figure 1: Theories of Accommodative of myopia progression. (Dashed lines = Mechanical Tension Theory; Dotted lines = Accommodative Lag Theory; Solid line = common to both theories) (Courtsey of David A. Berntsen).

The increase of axial length is found to a major culprit in the progression of myopia. True reversal of myopia would therefore mean permanently reducing the axial length of the eye, which is yet not feasible. The two theories put forward to try explaining the progression of myopia include (1) mechanical tension theory and (2) accommodative lag theory as shown in Figure 1.

The Need for Myopia Control

Myopia is typically progressive in early to middle childhood.16 Early-onset myopia frequently leads to the development of high myopia, which can be a risk factor for ocular complications, such as cataract, glaucoma, macular degeneration, myopic retinopathy, and retinal detachment [14-19]. These ocular conditions are progressive and can cause sight-threatening complications if not diagnosed and treated in an early stage. Correction of myopia is usually done with the use of optical aid like spectacle and contact lens, and refractive surgery, however, they do not prevent the progression of myopia. Children with significant degrees of myopia remain at increased risk of developing these sight-threatening conditions later in life. Therefore, myopia should not merely be viewed as a refractive error that causes blurring of distance vision, but as a risk factor for various sight-threatening conditions. This calls for interventions to slow or even stop the progression of myopia in children. Evidences show that the quality of life (QOL) is compromised in individuals with high refractive error compared to those with low or moderate myopia. Myopia is a significant public health problem, which places a substantial socioeconomic burden on society. The fact that the prevalence of myopia is increasing is well documented and recognized. However, the alarming increase of myopia prevalence in East Asia is a concern, and it requires urgent attention. Myopia is also a major health concern amongst school children in India [20-25]. This demands the need for screening and intervention for myopia control to be initiated at an earlier age when the progression is faster. With China and India accounting for more than 36% of the global population, the effect of increasing myopia will considerable if appropriate interventions are not explored, adopted, and implemented. Prevention and control of myopia need to be considered a major public health concern and deserve adequate attention.

Currently, there are many pieces of research been conducted to explore measures for controlling the progression of myopia by modifying the environment or reducing the exposure of the eye to the various stimulus to the eye through the use of the optical device but the most promising of current treatments are the use of low-percentage atropine, bifocal soft contact lenses, Ortho-K, and multifocal spectacles. The Cochrane Collaboration (2011), a comprehensive review of the dominant theories about myopia progression along with an in-depth analysis of various therapies suggested topical Antimuscarinic medication is the most likely effective treatment to slow myopia progression [26,27]. The Atropine Treatment of Myopia 2 (ATOM2) study indeed cited evidence that doses as low as 0.01% atropine can quite effectively slow myopia progression, especially in Asian children. But the use of atropine may be limited and not practical due to the adverse effects of the drug. Furthermore, the Cochrane group suggested Ortho-K as a good option though there weren't any randomized controlled clinical trials then.

Orthokeratology in Myopia Control

Overview of Ortho-K

The term orthokeratology has a Greek origin (Ortho: straight, kerat: cornea, logy: knowledge) [28]. In 1971, the International Orthokeratology section of the National Eye Research Foundation defined orthokeratology as "the reduction, modification or elimination of refractive anomalies by the programmed application of contact lenses."Ortho-K utilizes a non-surgical, topographical approach to reshape the cornea and correct the ametropia. Though there is a significant change in the ortho-K design, material, and wearing regimens, its earlier definition still stands unchanged. Orthokeratology is also known as OK, ortho-k, corneal reshaping, corneal refractive therapy (CRT), and vision shaping treatment (VST). Other terminologies for the modern-day orthokeratology include Overnight Orthokeratology (OOK), Accelerated Orthokeratology, Reversible Corneal Therapy, Controlled Kerato-Reformation (CKR) Overnight Corneal Reshaping and Corneal Molding System (CMS).Ortho-K was initially designed only as an optical correction mainly for correcting low-to-moderate myopia; recent researches have come up to prove that it has the potential to reduce the progression of myopia. Ortho-K can correct up to -6.00 D of myopia and +4 D of hyperopia, though many authors claim that it is very difficult to correct hyperopia of more than +2.50 D. It is found to be more effective in children. In 2002, the Food and Drug Administration (FDA) approved Paragon (Grand Rapids, Michigan, USA) and Euclid Systems (Bausch and Lomb, Rochester, New York, USA) as overnight orthokeratology lenses [29-36]. Other prominent researches and proponents in orthokeratology include Ziff, May, Grant, Fontana, Tabb, Carter, Holden, Swarbrick, Caroline, and Mountford.

Design of 'Reverse Geometry' Ortho-K lenses

Ortho-K is used for temporary correction of low to moderate myopia. It uses four- or five curve reverse-geometry lenses in high Dk materials in an overnight lens-wearing modality. Modern Ortho-K shaping lenses typically consist of four zones

1. Base curve
2. Reverse (steeper) curve
3. Fitting (alignment) curve
4. Peripheral curve as shown in Figure 2.

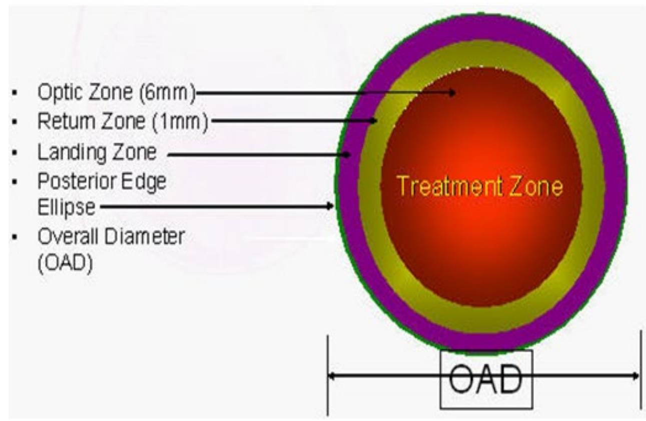

Figure 2: Design of ortho-K lenses (Photo courtesy: Paragon CRT 2003).

Mechanism of Corneal Change with Orthokeratology

The changes in corneal topographic induced by reverse-geometry lenses worn for myopic OK is well documented in several studies. Ortho-K creates a flattening of the cornea to reduce the overall refractive power of the eye. Zhong, et al. (2009) mention that change in corneal structural is the result of a mid-peripheral thickening and central thinning conflicting evidence on the time sequence of these changes. Some authors have observed that structural changes to the cornea can be observed after as little as 15 minutes of lens wear [37,38]. It has also been shown that in the first 30 minutes, the corneal changes are almost universal irrespective of the refractive correction target after which the changes become dependent on the refractive target of the custom made Ortho-K lens [39].

Structural change (both size and shape) of the epithelium is responsible for the corneal reshaping as shown in Figure 3**.** However, layers of the cell are not changed.

1. The flatter central fitting relationship results in positive pressure or applanating force on the cornea induces a possible compression and/or flattening of the corneal epithelial cells, but with no loss or migration of the cells.
2. The mid-peripheral epithelial cells are larger and more oval. The thickened mid-peripheral cornea maintains normal cell layers [11].

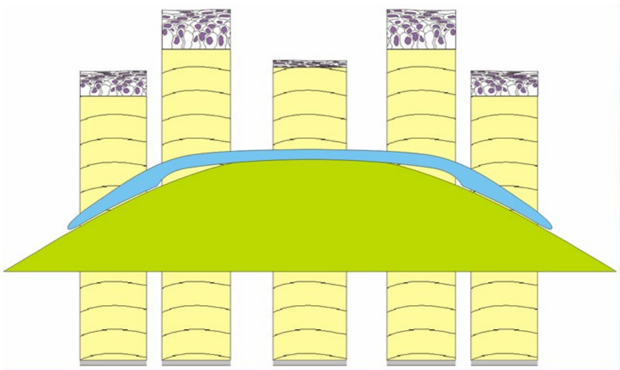

Figure 3: Overall profile of corneal changes in myopia (Photo courtesy: IACLE).

These structural changes result in a reduction of the corneal sagittal height resulting in a decrease in manifest myopia. Ortho-K changes are an anterior corneal phenomenon, and there is no significant effect on the shape of the posterior cornea or the anterior chamber depth. Ortho-K is considered to respond best in prolate corneas (steep in the center and flat in the periphery) and moderate curvature (46.00 to 49.00 diopters). It was believed that cornea with flatter curves (36.00 to 39.00 diopters) is thought to be more resistant to change, although this is an area that has recently become controversial. Munnerlyn's formula is used to calculate the amount of tissue displaced in Ortho-K. It relates the change in cornea sagittal height to the treatment zone diameter and the power change required. The simplified version of the formula is $\mathbf{S= t_d{}^2 \times D/3}$, where **s** is the absolute sagittal height change (μm), $\mathbf{t_d}$ is the treatment zone diameter (mm), and **D** is the intended refractive change (diopters). For example, for a 1 D effect over a 6 mm zone, we will 'lose' (or redistribute) 12μ m of corneal tissue. It is important to remember that corneal epithelium has a normal thickness of approximately 50 to 60 μm and according to Mount ford, [40-43] the mean maximum sagittal change for the cornea in Ortho-K is approximately 20μm. The theory behind that the degree of myopia reduction achieved is dependent on the diameter over which the cornea is spherical; with completely spherical corneas (e = 0) generally not amenable to Ortho-K.

Higher refractive changes are possible if the spherical treatment zone is made smaller but as treatment diameter decreases, less sagittal change is required for a specific target dioptric change as tabulated in Table 1. So practically it is not desirable to have a treatment zone diameter of less than 3 mm due to the vision problems associated with larger pupil sizes especially under conditions of reduced illumination.

Treatment depth (Flattening / thinning)	Treatment diameter ('Optic zone')	Expected Change
20μm	6.0 mm	–1.75 D
20μm	5.0 mm	–2.50 D
20μm	4.0 mm	–3.75 D
20μm	3.0 mm	–6.75 D

Table 1: Treatment diameter versus dioptric change for a fixed sagittal depth change (i.e. Flattening or thinning).

Indication for Orthokeratology

The indication for use oforthokeratology includes; (1) children to young adult myopes (6-20 years),(2) spherical refractive error (-1.00 D to -5.00 D), (3) cylindrical refractive error of 1.50 D or less "with-the-rule" corneal astigmatism or 0.75 D or less "against-the-rule" astigmatism, (4) contact sports and activities requiring periods without visual correction wear, (5) professionals who require good unaided visual acuity such as police, firemen, military, deep-sea divers, high altitude pilots, etc. (6) free of corneal dystrophies (e.g. keratoconus), ocular diseases, or any condition that contraindicate wearing of any type of GP lens, and (7) motivated to undergo full or partial myopia reduction and willing to follow up fortwo to three months of active treatment and every six months for passive treatment.

Efficacy and Safety of Ortho-K for Myopia Control

Efficacy of Ortho-K

One of the most important reasons for opting Ortho-K for vision correction over conventional spectacles, RGP, and a soft contact lens is that it helps in the reduction of myopia progression apart from just correcting the vision. It has been well documented that Ortho-K halts or inhibits the myopia progression by significant percentages. It is postulated that the peripheral optic error, or defocus, controls central refractive development. Ortho-K reduces myopia in the central 20 to 25-degree field, and it causes a contrasting relative myopic shift in the peripheral field. Various researches conducted assessing the effectiveness of Ortho-K for myopia control is enumerated in Table 2.

Sl No.	Study (Year)	Design	Sample size (OK/control)	Age group (years)	Followup (years)	Result/ Conclusion
1.	Charm, et al. 2013 [30]	RCT	28(12/16)	8-11	2	The study showed that partial reduction (PR) ortho-k effectively slowed progression of myopia in high myopes.PR ortho-k-treated children had 63 % slower axial length elongation than that of children wearing spectacles.
2	Cho P, et al. 2012 [29]	RCT	78(37/41)	6-10	2	Ortho-k lenses wearing subject's 43% slower axial elongation compared single-vision glasses wearing subjects. Younger children tended to have faster axial elongation and could benefit from early ortho-k treatment.
3	Cho P, et al. 2005 [31]	Non-RCT	70(35/35)	7-12	2	Ortho-k can have both a corrective and preventive/ control effect in childhood myopia. But there was substantial variations in changes in eye length among children. No ways to predict the effect for individual subjects was found.
4	Chen C, et al. 2013 [35]	Non-RCT	58(35/23)	6-12	2	In children withmoderate-to-high astigmatism, toric ortho-k lenses has proved to slow axial elongation effectively.
5	Kakita, et al. 2011 [33]	Non-RCT	92(42/50)	8-16	2	Ort haltedaxial elongation in myopic children. It suggested ortho-K lenses can slow the progression of myopia to a certain extent.
6.	Santodomingo-Rubido, et al. 2012 [34]	Non-RCT	61(31/30)	6-12	2	Orthokeratology contact lens wear reduces axial elongation in comparison to distance single-vision spectacles in children by an average of 31%.
7.	Walline, et al. 2009 [32]	Non-RCT	56(28/28)	8-11	2	Eye growth can be slowed by 56 %. This result supported previous reports of slowed eye growth following corneal reshaping contact lens wear.
8	Walline, et al. 2005 [44]	Non-RCT	23	8-11	6 months	Overnight cornea-reshaping contact lenses are efficacious for young myopic patients, and no children experienced a serious adverse event during the study.
9.	Zhu, et al. 2014 [45]	Retro-spective	128(65/63)	7-14	2	This 2-year study indicated that ortho-k contact lens wear is effective for reducing myopia progression in children with low, moderate and high myopia.
10	Santodomingo-Rubidoo, et al. 2013 [46]	Non-RCT	61(31/30)	6-12	2	Ortho-K significantly improved vision-related quality of life (QoL) and acceptability with OK contact lenses is an incentive to engage in its use for the control of myopia in children.
11.	Swarbrick, et al. 2010 [47]	Non-RCT	28(14/14)	10-17	6 months	Compared todaily wear of conventional GP lenses,overnight OK slows myopia progression atleast in the initial months of lens wear.

Table 2: Summary of efficacy of orthokeratology as a potential vision treatment andmyopia control measure.

Meta-analysis on the effects of orthokeratology in slowing myopia progression concluded that orthokeratology slows myopia progression in children [48]. They further suggested the need to substantiate their result with large-scale studies and also investigate the long-term effects of orthokeratology in myopia control.Though there is a lack of large scales studies to support the use of Ortho-K for myopia control, several studies are conducted throughout the world. It holds enough evidence to support that progression of myopia can be reduced. The reduction can be ascribed to the reduction in axial length elongation.Studies have found that there is a significant reduction in the progression of myopia with the use of ortho-K lenses. Charm, et al. (2013) has found that Ortho-K can halt the progression of myopia by as high as 63%. Charman, et al. (2006) found that orthokeratology lenses were also able to reduce the peripheral hyperopic retinal focus [49]. This, in turn, would stop the signal to the eye that caused myopic growth, which might support why orthokeratology is successful in arresting myopia.With evidences from literatures, it can be considered that Ortho-K is a good refractive correction option for mild to moderate ametropia as shown . It is also effective in reducing the progression of myopia by slowing the axial growth of the eye compared to single vision glasses and conventional RGP lenses. It is to be more beneficial in children in Figure 4.

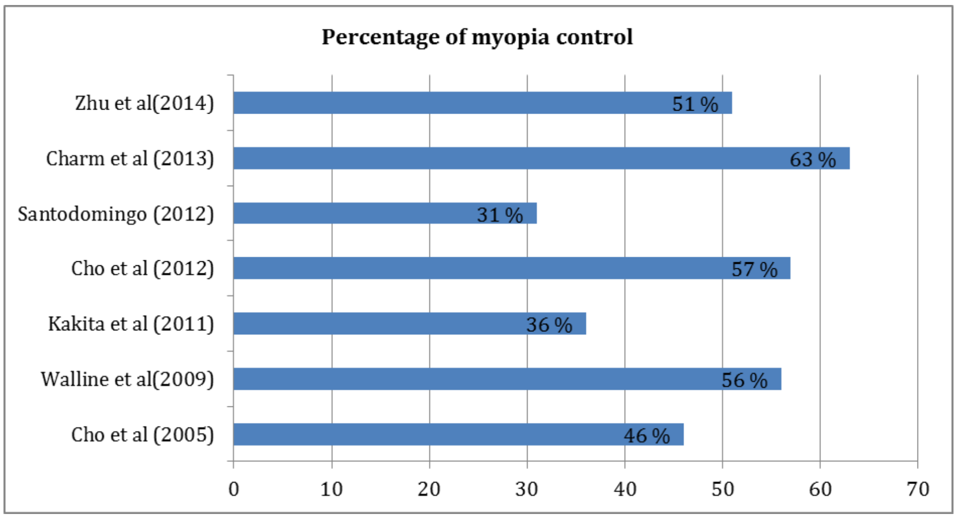

Figure 4: Summary of reduction of myopia progression in percentage by various studies.

Safety of Ortho-K Use

Chan, et al. (2008) reported that lens binding and ocular discharges are commonly reported problems during Ortho-K treatment; the symptoms may be managed satisfactorily with ocular lubricants and lid hygiene. Mika, et al. (2007) studied the safety and efficacy of overnight Ortho-K in myopic children. The study found that 40% of eyes undergoing Ortho-K treatment may show corneal epithelial staining; however, this was not associated with any adverse events [50,51]. Campbell (2013) review of several studies investigating Ortho-K for myopia control did not report any adverse events [11]. Lipson (2008) after a long term study concluded that there is no difference in safety using Ortho-K lenses in children under the age of 12 compared to the children over the age of 12 and adults [52]. However, several studies have documented cases of microbial keratitis in overnight Ortho-K. Therefore it is always recommended and suggested to the patient overnight Ortho-K lens wearers to maintain good cleaning and hygiene. Frequent follow-up to assure the safety of cornea may not be overlooked. Patients with poor hygiene and poor compliance to care, previous RGP wears failure, active corneal, and other ocular diseases may be contraindicated. Therefore, it can be concluded that Ortho-K lenses can be safe for patients of all ages provided good care and maintenance regimen is ensured.

Should the Use of Ortho-K be Encouraged?

Apart from the most significant advantage of Ortho-K as myopia control measures, there are other indications as to why Ortho-K could be encouraged. Regarding the quality of vision, Ortho-K fulfills the patient's expectations. Berntsen, et al. (2006) found that quality of life in patients aged 21-37 years old treated with Ortho-K was generally not troubled by the clarity of vision, near vision, distance vision, diurnal fluctuations, or activity limitations although glare was reported during night driving [53]. Chan, et al. (2008) studied 108 children undergoing Ortho-K treatment and reported that 90% of participants responded satisfactory to very good with the treatment [50]. Except in patients experiencing significant adverse events, reductions in best-corrected visual acuity (BCVA) following OK treatment have rarely reported.

Brand (2009) concluded that Ortho-K can improve accommodation and convergence function in children [54]. It was hypothesized that a reduction in the peripheral retinal hyperopic defocus alters the ambient visual function, resulting in the normalization of convergence and accommodation. The main reasons why Ortho-K should be encouraged are as follows: (1) it can temporarily correct mild to moderate ametropia and allow clear vision without having to wear any refractive correction during the day, (2) unlike a surgical procedure, it is a painless, non-surgical procedure and the condition can be reversed if the result is not satisfactory, (3) no significant adverse effect on ocular health is reported in patients with good compliance and approved by FDA, and (4) it can slow the progression on myopia better than any other measures currently available.

Discussion

This review aimed to provide an overview of Ortho-K for myopia control. Shreds of evidence from the review of literature suggest that Ortho-K can be considered an effective intervention for myopia control. Though the exact etiology of myopia progression is poorly understood, it is largely attributed to the elongation in axial length. Recent studies focus in measure to halt the elongation of axial length. In recent years there is an increasing prevalence of myopia, particularly in the East Asian region. Therefore, the need for strategies to control myopia should be emphasized. Though the concept of Ortho-K evolved during the mid-1960s, it did not gain much attention primarily because of its material and inadequate researches to support its advantages. In the mid-1990s, with the modern reverse geometry design and technological development like corneal topography, it has led to the recent growth in interest in Ortho-K. Since 2005, studies have provided that overnight Ortho-K can reduce the progression of myopia as high as 63%. It has compared with findings with RGP lenses, soft contact lenses, and single-vision spectacles. This largely favors the use of o Ortho-K lenses especially in children and young adults. Though, these lenses have the safety concern just as that of RGP lenses, proper care, and maintenance to the risk of microbial keratitis can be drastically decreased. Moreover, the advantages outweigh the compromise on ocular health. Ortho-K can be considered as an effective mode of optical correction with the advantage of myopia control in children and has a great scope for growth as a potential vision treatment. Training of practitioners, making Ortho-K affortable and accessible along with advocay are key to increasing use and uptake of Ortho-K lenses.

Conclusion

Myopia is documented to be significantly increasing and control of its progression is necessary. Ortho-K serves as a good alternative for the temporary correction of mild to moderate ametropia, particularly myopia. It works by changing the shape of the cornea, thereby reducing refractive error and has the advantage of providing a good vision without the hassle of using refractive correction during the day. It is of significant advantage to the professionals who require good unaided vision during work. Though the use of overnight Ortho-K as a myopia control intervention continues, and large scale collaborative studies are recommended. Further studies in Ortho-K may be required to answer the questions on what is the optimum treatment duration to slow progression.

How long use of overnight Ortho-K can completely stop myopia to reverse? At what age is the myopia progression the greatest and what is the optimum age to initiate the treatment? Can shorter wearing duration give similar results as that of overnight wear? Can it design be modified further to treat higher degrees of myopia? Can the risk of microbial keratitis (MK) be further decreased? While some questions remains unanswered, Ortho-K has not only proved to be an alternative to refractive correction but also as an efficient measure for myopia control especially in children. Epidemoilogical evidences show that Ortho-K for myopia control is effective,safe and can be used in all age groups of people who can ensure proper care and maintenance of the lenses. The use of Ortho-K should be explored further and encouraged. The ophthalmic professional has good scope to practice overnight Ortho-K and conducts researches to enchance knowledge better understanding of Ortho-K for myopia control.

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Conflict of Interest

The author declares that there is no conflict of interest.

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