ORTHOKERATOLOGY IN CLINICAL PRACTICE ACROSS THE WORLD

Many factors must be taken into account when controlling myopia progression. There is no doubt genetics plays a role in the development of myopia in children. But lifestyle is also an important factor to consider. In terms of safe and effective treatment, orthokeratology is now known to be successful in controlling myopia and has even been shown to slow down progression in individuals with high myopia. While it has developed substantially in Latin America, it is effectively mainstream in the US and a common treatment in China, where there are numerous orthokeratology clinics in city hospitals. Currently, orthokeratology is also on the rise in Europe.

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There has been a tremendous increase over the past few decades in the prevalence of myopia worldwide. Practitioners are more and more concerned with regard to the increased incidence of patients moving into the category of high myopia. The ocular health consequences of sequelae related to high myopia can be devastating in later life. Many clinicians are implementing a systematic approach to establish a control protocol for their patients with rapidly progressing myopia.

A comparative survey of methods for controlling progressive myopia

"Looking at ways to manage progressive myopia first requires identifying those who are at highest risk," explains Dr. Bruce T. Williams, OD, FIAO. Some of the risk factors include whether or not one or both parents are myopic, especially if one or both are highly myopic. Other factors to consider are myopic siblings or a **family history** of ocular disease associated with myopia. **Ethnicity** is important, as the literature shows us that Asians are at a much higher risk.

It is becoming increasingly apparent that **lifestyle** plays a significant role in how myopia develops in young individuals. Several studies have shown that time spent outdoors has a protective effect.[1,2,3,4,5,6,7,8] Whether it is higher levels of illumination, less near-distance tasks or increased levels of vitamin D, the effect has been clearly demonstrated. Limiting the amount of near work like reading and the use of electronic devices, could be beneficial, especially for kids that have higher associated risk factors.

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Most children should reach emmetropia by the age of eight-years-old. A six-to-eight-year-old child at approximately -1.00 diopter will typically add a half diopter per year and end up at -5.00 to -6.00 by the mid-teens. It is important to initiate a protocol to limit the progression of myopia. By reducing the rate of progression by 1/3, you reduce the likelihood of the individual developing high myopia by 70%. If you can reduce the rate by 50%, the likelihood is reduced by 90%.

When designing a strategy to develop a protocol for myopia prevention, encouraging the patient and parents to incorporate beneficial lifestyle changes should be the first priority. The practitioner can then look at the available options for implementing a plan for the individual. We know that correcting the refractive error with traditional single vision spectacle lenses or regular soft/rigid contact lenses will inherently cause more peripheral hyperopic defocus, encouraging axial elongation and an increase in myopia.

Progressive addition lenses have been shown to reduce progression by 14% (and up to 37.2% in esophoric children, with high lags of accommodation when compared to the regular single vision lens group).[9] This is certainly an alternative, but it is not as effective as we would like. The industry is working on developing **executive-style bifocals that contain a prismatic component**, which makes them a more effective spectacle lens alternative (they show three-year results of myopia progression reduction of 51% when compared to regular single visions lenses).[10]

Pharmacological intervention has had a profound effect. It is as much as 90% effective in reduction rates.[11] There are certainly concerns, especially in children, when starting with pharmaceutical agents. A six-year-old child on anti-muscarinic drug therapy for the next 12 years could face serious unknown consequences. Proper dosage for safe and effective treatment has not been firmly established, and there are reports of a significant rebound effect after discontinuation.

Soft multifocal lenses have recently shown promise but have some disadvantages, such as blurred distance vision and dryness, not to mention they limit some of the activities in which children can participate.

Orthokeratology has consistently been shown to reduce the progression by approximately 45%.[12] Orthokeratology has the advantage of only being worn overnight while sleeping. Parents are usually there to supervise insertion and removal, and the child wears no lenses while at school during the day. Orthokeratology sets up a unique topographical shape on the anterior cornea. The central cornea is flattened to focus on the fovea, and the mid-peripheral cornea is steepened to create a myopic defocus on the peripheral retina, reducing the stimulus of the normal hyperopic defocus for axial elongation and subsequent increases in myopia (Fig. 1 and Fig. 2).

By designing lenses with specific optic zone diameters, radii and reverse curve radii and widths, effective treatment can be accomplished for most minus refractive errors and astigmatic components. Fortunately, the positive effect of myopia control is even greater for patients that have already progressed to higher states of myopia. This procedure can literally stop further progression of those already in the category of high myopia.

The following pictures show the axial (Fig. 3) and tangential (Fig. 4) topographical plots of a high myope. Note the area under the reverse curve is much steeper and rises above the original reference sphere, producing a peripheral add power of well over the recommended minimum of +4.00 diopters. This produces a substantial myopic peripheral defocus to eliminate the stimulus for axial elongation and progressive myopia.

The advantages of orthokeratology over other forms of myopia prevention are clear and numerous. It has proven to be safe and effective when compared to all forms of contact lens wear. Even in cases where full myopic correction could not be achieved, the rate of progression

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has been slowed by greater than 50%, as in a study published by Pauline Cho at Hong Kong Polytechnic University.[13] The child has parental supervision; the lenses are only worn in a closed eye environment, reducing the chance for loss or foreign body involvement. The child is free to participate in swimming and all kinds of activities that might be limited by the use of other solutions.

Orthokeratology should be presented to all young patients with progressive myopia as the safest and most effective strategy to reduce the progression of myopia to proven "safe" levels. If that turns out not to be accepted, then other forms should be presented as well. Some form of progressive myopia reduction should become the standard of care for these patients to reduce the possibility of eventual sight-threatening complications.

Latest achievements in orthokeratology

In 2010, Bourne et.al estimated that 108 million people were affected by myopia, making it the leading cause of vision impairment worldwide.[14] He also noted that it was the second most common cause of blindness. This is estimated to cost US$202 billion per annum. That said, what are rank-and-file eye care professionals doing to address the problem? "If any one of us had a patient sitting in the chair with a known sight-threatening condition, which was in anyway treatable, would we tell them that we were going to cover the symptoms and just watch the condition progress until it reached the end point? Of course not. Yet this is what many of us are doing today," explains Dr. Williams.

The worldwide epidemic of progressive myopia is gaining strength every day. In the article "Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050,"[15] authors stated: "Myopia and high myopia estimates from 2000 to 2050 suggest significant increases in prevalence globally, with implications for planning services, including managing and preventing myopia-related ocular complications and vision loss among

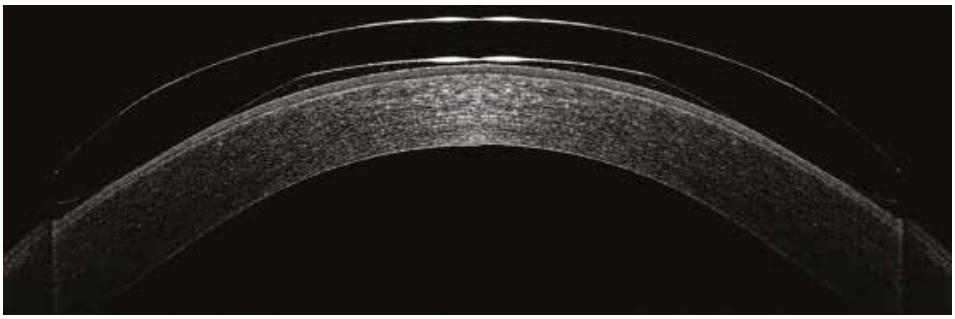

FIG. 1| OCT view of Reverse Geometry Orthokeratology lens on the Cornea

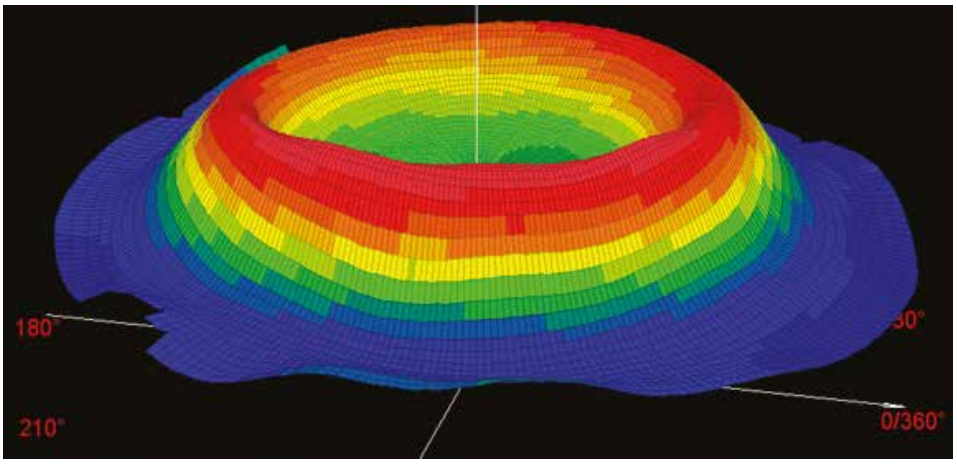

FIG. 2| Topographical perspective view of post Ortho-K cornea.

almost 1 billion people with high myopia."A study conducted in Shanghai, China, of more than 5000 subjects published in November 2012 found that 95.5% of university students were myopic.[16] Of them, 19.5% were highly myopic, greater than -6.00 diopters. Myopic prevalence in the United States rose from 25% in the early 1970s to 41.6% in the early 2000s. Study after study in virtually every sector of the planet has shown an alarming increase in the number of people with myopia.

For years clinicians and scientist have debated whether myopia is a result of genetics (nature) or environmentally induced (nurture). Studies have shown that having one or two myopic parents significantly increases a child's chance of becoming myopic. Children today have significantly increased near demand and tend to spend less time outdoors in natural light. It has been shown that spending more time outdoors results in less myopia. This is possibly due to less near demand, pupil constriction or the release of retinal transmitters such as dopamine and vitamin D that may inhibit eye growth. It stands to reason that if we subscribe to the theory of emmetropization being regulated by visual feedback, the majority of the feedback should come from some distance substantially greater than 20cm.

Walline (2012) suggests that a 50% reduction in the rate of myopia progression of -0.75D/yr. would keep a seven-year-old -1.00 diopter child at -3.62D instead of -7.00D in the span of just eight years.[17] This would significantly reduce the possibilities of developing severe ocular manifestations of myopia-related intraocular disease.

These increases are not going unnoticed by industry. Many companies are hurriedly trying to develop specialty lenses for both contacts and spectacles to in some way slow or stop the progression of myopia in those patients that are at high risk of reaching severe myopia.

Today, there are several ways to halt the formerly inevitable process that leads to severe myopic degenerative disease. There are many controlled studies that prove effective measures can be taken to slow the steady rate of increasing axial elongation and the devastating consequences thereof. These include pharmaceutical agents such Atropine and Pirenzapine, multifocal contact lenses, executive bifocals, progressive spectacle lenses, prismatic multifocal spectacle lenses and vision therapy.
One method that has been shown to be particularly effective in reducing the myopia progression rate by 50% is orthokeratology.[18] This is the programmed use of specially designed contact lenses to flatten the central cornea while steepening the mid-peripheral cornea to temporarily reduce myopia. This procedure has the beneficial side effect of altering the peripheral retinal defocus from a hyperopic posture to a myopic posture. That, in effect, removes the stimulus for axial elongation. Hence, the progression of myopia is significantly reduced and sometimes stopped altogether.

Orthokeratology has evolved significantly over the last 50+ years since George Jessen first suggested it. It started as a programmed sequential fitting of flatter and flatter contact lenses to alter the anterior corneal curvature to temporarily correct myopia. We now have designs that can

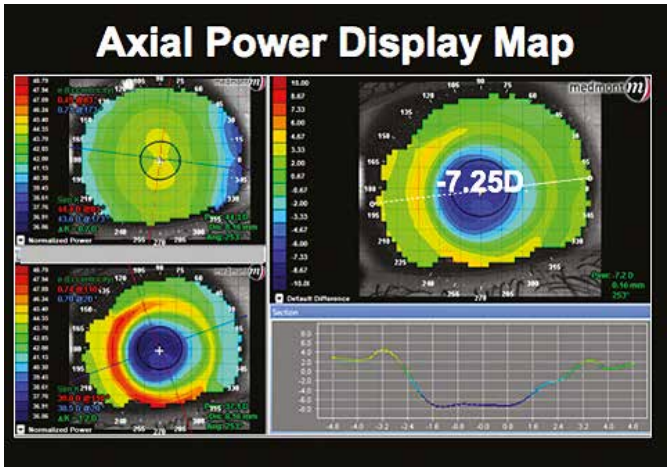

FIG. 3| Axial difference topography map of post Ortho-K cornea showing -7.25D refractive change.

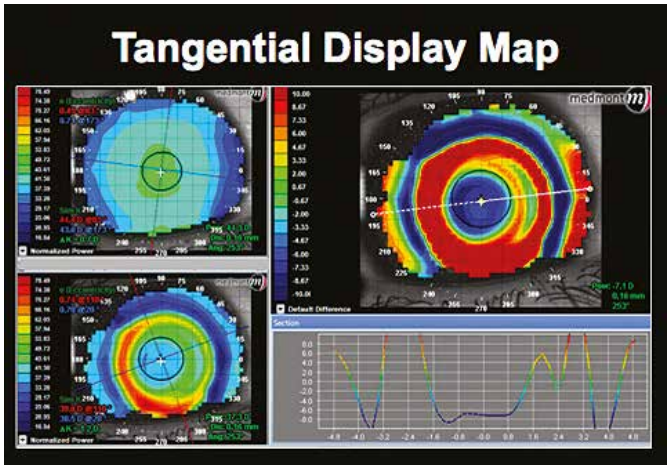

FIG. 4| Tangential difference topography map of post Ortho-K cornea showing -7.25D refractive change.

address nearly every scenario that is presented. Designs that correct low myopia and high myopia, astigmatism and mixed astigmatism, hyperopia and ectasia. We can produce lenses that have toric base curves, toric alignment curves, oval treatment zones and varied return zone depths. The reverse geometry lenses have moved from the original 3 curve designs to 4, 5 and 6 curves. There are computer-assisted programs that import topographies and design lenses to align up to 8 semi-meridians of the cornea to optimize the fluid forces behind the lens for maximum treatment. There is work going on to decenter the treatment zone to align better with the line of sight instead of the geometric center of the cornea so as to reduce induced astigmatism and higher order aberrations.

As the technology advances so will our ability to design lenses that do the best job possible to retard the progression of myopia, increasing the odds of sparing the vision of so many.

Ortho-K in Latin America

In Latin America, orthokeratology (Ortho K) formally began to be practiced after the first global Ortho-K meeting held in Toronto, Canada in 2002. A small group of innovators from different countries, including Mexico, Guatemala, Costa Rica, Colombia, Venezuela, Uruguay, Chile and Brazil, went and participated in the first meetings, although only few of them decided in the coming years to offer the treatment to patients. This was mostly due to the lack of digital or CNC (Computer Numerical Control) lathes in Latin America needed to produce the lenses, which have a reversed curve (they cannot be manufactured with common lathes).

Today, there are have fitters in Mexico, Guatemala, Costa Rica, Colombia, Peru, Brazil, Argentina, Uruguay and Chile, although recent studies from the one-year-old Academia Latino Americana de Ortho K y Control de Miopia (ALOCM), showed that the most cases fitted and currently in use are **in Costa Rica and Colombia, with around one thousand patients using the treatment with success**.

Evidence has been provided for both countries that the orthokeratology is a safe treatment, with an about 55% rate of myopia progression control (three- year study by Javier Prada et al. in Costa Rica, presented at WCO in Medellin in 2015) reported on 50 patients, with an average of 20/20 for both eye and without infections.

The academy is working on statistics and screening in the different countries to develop a Latin American sample census of the percentage of the prevalence of myopia. This will help prevention and treatment with different methods to avoid a rise in high myopia in the future.

Ortho-K in the US & China

In the United States, the FDA approved nightwear Ortho-K by Paragon CRT in June 2002. Since then, Ortho-K has become a mainstream practice in optometry. Today, there are thousands of Ortho-K fitters that use CRT lenses and also other innovative Ortho-K designs such as GOV, Ortho-tools and Wave, to name a few. Many experienced Ortho-K specialists find that by the off-label use of these other designs, they can correct the degree of myopia at a much higher range than that approved for CRT lenses. It is not unusual for a patient with myopia of 8 diopters or even higher to see 20/20 after just one week of treatment using these custom designed lenses.

The American Academy of Ortho-K and Myopia Control also fuels the enthusiasm for use of Ortho-K in the US, and there are more than 500 members. Each year, the academy hosts the Vision By Design (VBD) conference in different locations around the country. The next VBD will be held in April 2017 in Dallas, Texas; the event is expected to attract hundreds of old and new Ortho-K fitters. They will learn and share knowledge about fitting techniques and concepts regarding myopia control and prevention. Custom soft lenses and diluted Atropine treatment have been introduced in recent years at VBD, which adds more tools to address the growing trends in myopia.

On the opposite side of the globe in Asia and the Pacific Rim, due to the large percentage and high degree of myopia among Asians, Ortho-K is most often promoted as a means of myopia control. In China, a large number of hospitals in all of the major cities have specialized Ortho-K clinics. The number of patients successfully treated by Ortho-K is greater than that in the rest of the world. However, due to government restrictions, many new design innovations available in US are not available in China. Other countries in the Pacific Rim where

Ortho-K are very popular include Taiwan, Singapore, Hong Kong and Australia, where the Orthokeratology Society of Oceania will host its annual congress in September 2016. While the number of eye care providers in Asia and the Pacific Rim practicing Ortho-K is likely to outnumber the US it is certain the number of patients that need treatment for myopia may be many times higher.

Ortho-K in Europe

Unlike in the US or China, it is much easier in Europe to bring a new product to market, especially one that is innovative and groundbreaking. The CE certification required to sell a product in the European market has been in place since 1985. It guarantees the manufacture's product meets the requirements of the applicable European community directives. This environment brings the ultimate in innovative new products to Europe's doors much more quickly in certain cases, especially those that fall in between the "cracks". A classic example is the new versions of lens design software, which can be accessed for yearly fees and provide state-of-the-art lens designing possibilities. This would be illegal in China if the product hadn't first been approved by the CFDA, a process that is expansive and time consuming. Ortho-K prescriptions for myopia control have been on the rise these last few years, but they still trail behind China and the US. This can be attributed in part to the lower incidence of myopia in Europe, especially when compared with China. •

KEY TAKEAWAYS

- Lifestyle changes should be the number one priority for patients when developing a strategy to prevent myopia.
- According to a study by Pauline Cho of Hong Kong Polytecnic University, orthokeratology slows the rate of progression of myopia more than 50%.
- Children today spend less time outdoors, which has been shown to foster myopia progression.
- Orthokeratology prescriptions for myopia control are on the rise in Europe, but they are still behind those in the US, where the lenses have become mainstream, and China, where many hospitals in cities have specialized orthokeratology clinics.

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