A LOOK AT PROGRESS IN ORTHOKERATOLOGY

Corneal reshaping through orthokeratology as a means to control myopia progression has made tremendous progress over the past decade. Below, Dr. Cary M Herzberg, president of the International Academy of Orthokeratology and Myopia Control (IAOMC), discusses the developments that have been made in the field and how the IAOMC hopes to continue to push the scientific envelope in the years to come. Dr. Gonzalo Carracedo of the University Complutense in Madrid then details how orthokeratology has come to be recognized worldwide as a safe and effective procedure in the long term.

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Dr. Herzberg has been practicing Orthokeratology and myopia control for over thirty-five years. He has lectured extensively on the topic, written numerous articles and holds a patent on the first scleral Orthokeratology design. He is co-founder, President, board member and fellow of the International Academy of Orthokeratology & Myopia Control (IAOMC) and the founder, President and a board member American Academy of Orthokeratology and Myopia Control(AAOMC) formerly The Orthokeratology Academy of America(OAA). He is an advisory board member of the Gas Permeable Lens Institute (GPLI) and a former contact lens design consultant to C&H Contact Lens. He has visiting Professor status at Tianjin Medical University, Shandong Medical University and He Eye Hospital/University.

Dr. Gonzalo Carracedo
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Dr. Gonzalo Carracedo joined the University Complutense of Madrid as an assistant professor of optometry and contact lenses in 2006. He is also currently a lecturer at the European University of Madrid, where he teaches about specialty contact lenses. He obtained his PhD (European mention) with a thesis entitled "Adenine dinucleotides as molecular biomarkers of dry eye". He belongs to the Ocupharm Diagnostics research group, which focuses on the ocular surface, contact lenses and dry eye research and development. He is also a member of the GICO research group, which is specialized in myopia control, corneal aberrations and vision. His PhD thesis dealt with nucleotides as a marker of dry eye in different conditions, including when wearing contact lenses or in the context of refractive surgery and systemic disease related to dry eye. He is the author of 38 papers (some related to myopia control and orthokeratology) in peer-review journals such as IOVS, Current Eye Research and Experimental Eye Research. He has also been a reviewer for these journals, plus the Journal of Optometry and the Journal of Ocular Pharmacology and Therapeutics. He has been involved in 16 research projects (four as the main researcher) regarding the ocular surface (i.e. keratoconus, dry eye myopia and contact lenses) and glaucoma.

KEYWORDS
Orthokeratology, Ortho-K, myopia control, corneal reshaping, peripheral defocus

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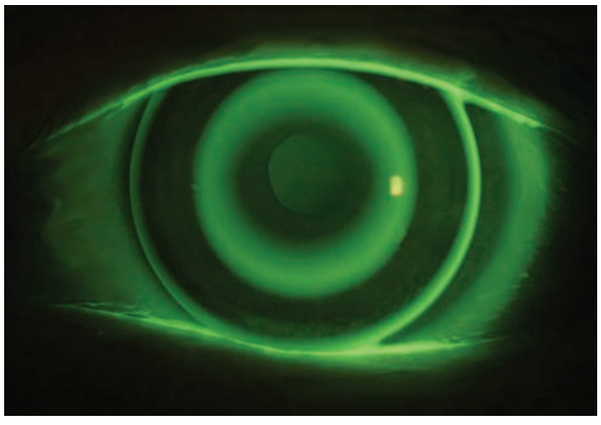
The orthokeratology (Ortho-K) effect was first observed as a side effect of contact lenses made of Poly methyl methacrylate (PMMA), which flattened in their radius of curvature over time. "What started as a method to reduce temporarily the refractive error of nearsighted individuals evolved, with the help of innovative design choices, to advanced engineering of the corneal surface of the eye," explains Dr. Cary M. Herzberg, OD FIAO, president of the International Academy of Orthokeratology and Myopia Control (IAOMC).

With the optics and resulting aberrations of an oblate corneal surface including spherical aberration, advanced design choices could provide solutions for progressive myopia and presbyopia. Ortho-K also attracted maverick practitioners, who brought a spirit of imaginative innovation to the world. "It has been my honor to have led several of these organizations and to have helped found the international academy, which now spans the globe," continued Dr. Herzberg. "Our mission is in part to help find solutions to the myopia epidemic which threatens the eye health of present and future generations".

Ten years of progress

Three overriding themes stand out in the past decade of progress in orthokeratology. They are the **technologies, safety/efficacy and myopia control.** "The progress in these three areas has been nothing short of astounding and has cleared the path forward to an exciting new era for the non-surgical treatment of refractive states of the human visual system," says Dr. Herzberg.

The last decade has seen phenomenal growth in the technologies that impact orthokeratology design. It's difficult to comprehend how much progress has been made in such a short period of time. Little more than a decade ago the FDA approved Bausch&Lomb's Vision Shaping Treatment (VST) for applications of low to moderate myopia and astigmatism. This came just a couple of years on the heels of the



certification of Paragon Vision Sciences' CRT® contact lenses. What would prove even more significant was the approval of topographical mapping, combined with CAD/CAM (computer-aided design and computer-aided manufacturing) technology for state-of-the-art Ortho-K lens designing. This meant the imagination became the limit for exciting new breakthroughs in orthokeratology.

Having FDA approval of corneal reshaping was a major advance, but what took place after was inspired by an industry poised to develop the vast potential promise that had been lying dormant for decades. Almost ten years prior to the FDA's decision new lens fabrication technologies experienced a new era of accuracy in producing products that had better process tolerance than the equipment utilized to measure the human visual system for them. Along with this was the use of computer-assisted lathing systems to make a reality of even the most complex designs, themselves the product of powerful new technologies. The FDA approval allowed research and development to focus on more accurate and faster procedures for the Ortho-K effect. At the same time, research and development of non-FDA approved areas – specifically high myopia and astigmatism – brought new investment and products. Lastly, developments in hyperopia and presbyopia seemed more likely in light of recent success in more conventional designs, which pointed to potential ways these new applications would be possible.

Hard as it is to believe, less than a decade ago Ortho-K was illegal in China. This was because of a laissez-faire attitude and risks present in the care of lenses that existed at the time. Dozens of cases of corneal scarring with sight loss led to the government ban as the new century dawned. "Today, a much different picture exists due to the regulation of the industry and the elimination of questionable and dangerous behavior in the care of Ortho-K lenses," Dr. Herzberg explains. "The numbers coming out of China speak for themselves – over 1.5 million lenses have been fit with zero incidences of sight-threatening outcomes." The Ortho-K environment in the US has always been focused on safety first, and the experiences there with corneal molding reflect that. In addition, **numerous studies have shown that risks inherent in wearing Ortho-K lenses only at night are no more significant than with any soft lens worn overnight.**

Most practitioners who perform corneal reshaping do so for myopia control. Surprisingly, the first landmark study demonstrating this procedure was the one on Longitudinal Orthokeratology Research In Children (LORIC) by Pauline Cho a little more than a decade ago. Since its publication many more have been done providing an unequivocal answer to the growing myopia epidemic that affects young people, damaging their visual system as they age. Along with low dose atropine, bifocal soft contacts and a change in lifestyle, Ortho-K is set to play a huge role going forward in slowing down myopic progression and its sight-threatening complications.

The future of the International Academy of Orthokeratology & Myopia Control

"The International Academy of Orthokeratology (IAO) was founded five years ago in Orlando, Florida, at the fifth annual meeting of the Orthokeratology Academy of America(OAA), which has since become the American Academy of Orthokeratology & Myopia Control (AAOMC)," says Herzberg. This year at the annual meeting of the IAO in Gold Coast, Australia, the name will officially be changed to include the words myopia control. The organization is open to all disciplines that promise answers to the growing myopia epidemic afflicting present and future generations. Including myopia control was brought about by an over ninety percent approval rating in each of our five sections: Europe (EurOK), Latin America (ALOCM), Oceania (OSO), Asia (IAOA) and North America (AAOMC). Emphasis on myopia control as well as Ortho-K has been a reality in the IAO for the last five years, making the name change a mere formality.

The academy over the years has remained in relative terms a group that is small in numbers but very influential and effective in achieving results. As an example, the concept of an international body to set standards of practice and oversee development worldwide for Ortho-K was first proposed in 2002 at the first Global Orthokeratology Symposium (GOS) in Toronto, Canada. Over the next almost ten years there were many efforts to launch such a group which ended in failure. The first substantial talks, which related to bringing a worldwide organization into existence within our academy, took place in 2009 at an education meeting in Phoenix, Arizona. Despite many challenges, which caused previous efforts to fail, the group was launched two years later. We expect exponential growth in the future, but we will strive to retain the feel of a small and flexible organization, which has served us so well in the past.

The academy will place more emphasis on research in the field of myopia control and Ortho-K in the next decade. Indeed, the change in our name was only one small part in this process, as structurally the organization changed as well, opening up vast new funding resources for further research. "The future looks especially bright – we will continue in our worldwide efforts to help contain the disease of myopia, which threatens the health and well-being of our chil-dren," concludes Dr. Herzberg.

The evidence-based effectiveness and safety of orthokeratology

The role of peripheral refraction in myopia progression control and how the peripheral defocus image influences eye growth has been studied for the past decade (Smith EL, 2013).[1] "The development of animal models of refractive errors has made a huge contribution to our understanding of the regulation of eye growth," explains Gonzalo Carracedo, OD, MsC, PhD, University Complutense of Madrid, Spain.

This field has also generated a huge body of literature linking retinal defocus and eye growth. The first evidence that visual experience has an influence on eye growth was discovered by

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Wiesel and Raviola in 1977.[2] They demonstrated that the sutured eyes of monkeys developed myopia associated with expansion of the posterior segment both equatorially and axially, postulating that this was due to lack of a clear retinal image. The evidence that the peripheral retinal image can influence eye growth has recently been provided by experiments in rhesus monkeys (Smith EL, 2005).[3] These experiments demonstrated that deprivation of the peripheral retina can stimulate axial eye growth despite normal central vision and indicates that influences on the peripheral retina can outweigh signals from the central retina.

More recently lens-induced peripheral hyperopia has also been shown to produce central myopia (Smith EL, 2009).[4] In humans, the role of the peripheral retina in relation to refractive error and eye growth has largely been evaluated, with numerous studies examining the relationship between foveal refraction and off-axis or peripheral refraction (Flitcroft DI., 2012).[5] Current research interest is centered heavily around the influence of peripheral refraction on myopic progression. Based on this theory different optical treatment strategies have been proposed and tested, and as with orthokeratology (Ortho-K), used to reshape the cornea of a myopic eye.

There are several studies performed since 2004 linking orthokeratology and myopia control. Walline et al. in the CRANYON study found that children who wore orthokeratology for two years showed less axial length growth and therefore less myopia progression (57%) than children who wore monofocal soft contact lenses (Walline et al., 2009).[6] However, the MICOS

study only found a 32% reduction in myopia in the ortho-K group compared to the eyeglasses group (Santodoming et al., 2012).[7]

Regarding orthokeratology safety, there have been a total of 123 instances of microbial keratitis in ortho-keratology patients reported between 1997 and 2007. Most of the reported cases were found in East Asian children ranging in age from 9 to 15 years of age, mainly due to inappropriate lens care, the patient not following practitioner's instructions and continuation of lens wear despite discomfort. Common organisms found were Pseudomonas aeruginosa and Acanthamoeba. Other studies have found an incidence of microbial keratitis of 7.7 per 10,000 patients per year of wear, making orthokeratology wearers only slightly more susceptible to infection than daily soft contact lens wearers (4.1 per 10,000) and better than 30-day extended wear silicone hydrogel lens wearers (14.4 per 10,000 patients) wear. Also, the incidence for orthokeratology is slightly less than with LASIK surgery, which has an incidence of 9 per 10,000 patients per year (Solomon et al., 2003).[8] In conclusion, **the long-term safety and efficacy of orthokeratology use has been demonstrated, with few cases of severe adverse incidents reported and a high efficacy in reducing and controlling the progression of myopia.**

Remaining scientific and clinical challenges ahead

Although peripheral refraction is the most accepted hypothesis, results from all studies show that other mechanisms are involved in myopia control with ortho-keratology. Accommodation, high-order aberration as well as light power could be participating in the complex task to control eye growth. Moreover, these are just the physical mechanisms, which trigger a biochemistry signal pathway (Young et al., 2009).[9] "In the coming years, research should be focused on understanding the whole mechanism (physical or optic and biochemical) to develop better, more efficient solutions, to completely halt the progression of myopia," suggests Dr. Carracedo. In terms of the clinical challenges, the current question to answer is not if orthokeratology controls myopia progression but when this treatment must be applied. How much growth of myopia every year is necessary to make orthokeratology treatment mandatory? In this matter, **clinicians should develop an international protocol suggesting the best way to use myopia control devices such as Ortho-K.** •

KEY TAKEAWAYS

- In the past decade orthokeratology has progressed in leaps and bounds to non-surgical advanced engineering of the corneal surface.
- The IAOMC is set to enjoy exponential growth, with a focus on orthokeratology and myopia control in the next decade.
- Several studies over the past 12 years have linked orthokeratology to myopia control.
- Orthokeratology has been shown to be effective in reducing and controlling the progression of myopia.
- The question today is not whether orthokeratology halts myopia progression but rather when should it be applied.

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