ACADEMY 2020

AT HOME

Presented by AMERICAN ACADEMY of OPTOMETRY
MYOPIA MANAGEMENT

The Evidence is In…
Now Let’s Make this Happen

Cornea, Contact Lens and Refractive Technology Symposium
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University of Chicago Hospital 1993 - 2017

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ESTEEMED PANEL

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S. Barry Eiden, OD, FAAO, FSLS
Susan Resnick, OD, FAAO, FSLS
Padmaja Sankaridurg, Bopt, MIP, PhD
Jeff Walline, OD, FAAO, PhD
INTENTION OF THIS COURSE

The Evidence is In... NOW
Let’s Make Myopia Management Happen
Three ODs dedicate their research efforts to myopia progression, its causes and treatment.

Short-sightedness is reaching epidemic proportions. Some scientists think they have found a reason why.
Dedicated to Honor his Passion and Vision
Professor Brien Holden 1942-2015

“Optometry should be on the frontline of this battle. It not only has a responsibility to provide the best care to patients but to remain informed about epidemiological trends and understand the latest range of treatment options for progressive myopia”
DWIGHT AKERMAN, OD, MBA, FAAO

AAO Diplomate, Cornea, Contact Lens and Refractive Technology Section

Chief Medical Editor, Review of Myopia Management

Vice President and Global Head of Professional Affairs
CIBA Vision/Alcon 1999-2019
Is Myopia a Disease?

Dwight Akerman, OD, MBA, FAAO
Chief Medical Editor, Review of Myopia Management

This is an important question because the answer will influence our approach to managing myopia.
Relevant Financial Disclosure

During the past three years, I have received honoraria, travel, or consulting fees from:

Alcon, Bain & Company, Bausch & Lomb, Boston Consulting Group, Euclid, Jobson Medical Information, McKinsey & Company, Novartis

Neither I, nor any member of my family, have a financial interest in any company or product mentioned in my lecture.

DWIGHT AKERMAN, OD, MBA, FAAO
MYOPIA MANAGEMENT...
When to Start and When to Stop

Dwight Akerman, OD, MBA, FAAO
What is Myopia Management?

Being proactive!

Identifying risk factors for myopia and high myopia

Providing information, advice, and recommendations to children and parents

Prescribing appropriate interventions to slow myopia progression and reduce the risk of developing high myopia
“When faced with a pediatric progressive myope, most eye care practitioners play it safe, add another -0.50 DS to the child’s prescription, and tell the parents to bring the child back in one year for another eye exam. Nothing is prescribed to slow the progression of myopia.”

Mark Bullimore, MCOptom, PhD, FAAO 2014
When to Start Myopia Management?
• Although the ratio varies with age and refractive error (Cruickshank et al, 2018), 0.1mm of axial length can be considered to be equivalent to 0.20D to 0.25D. (Chamberlain et al, 2019; Hyman et al, 2005)

• Eye growth is highest in the first years of life. At birth, the average AL is 17.3 mm, which increases to 22.3 mm at 6 years of age, 23.1 mm at 9 years of age, and 23.5 mm in the adult population. (Lim et al, 2015; Fotedar et al, 2010)

• Axial Length increase between 6 and 9 years old European children: (Tideman et al, 2018)
  – Myopia 0.34 mm/ year
  – Emmetropia 0.21 mm/ year
  – Hyperopes 0.16 mm/ year
• Parental myopia
  – If one parent is myopic, a child is at 3X greater risk to develop myopia by age 13 and 6-7X greater risk if both parents are myopic (Mutti et al, 2002; Parssinen et al, 2018, McCullough et al, 2016, O’Donoghue et al, 2015)

• Ethnicity
  – East Asian children aged 11 to 15 years are 8X more likely to be myopic than their Caucasian counterparts (Ip et al, 2008)

• Near work
  – The risk of myopia development and progression is significantly associated with reading at very close distances (<30 cm) and for continuous periods of time (>30 minutes) rather than being associated with total time spent on all near activities. (Ip et al, 2008)
• Outdoor time
  – Low outdoor time (less than 90-120 minutes per day) has been associated with 2-3X increased risk for the onset of myopia. (Rose et al, 2008)

• Urban environment
  – Children from urban environments have 2.6 times the odds of myopia compared with those from rural environments. (Rudnicka et al, 2016)

• Refractive error
  – Lower hyperopia than age-normal can indicate risk of developing myopia (Zadnik & CLEERE Study Group, 2015)
Children with less hyperopia than the age norm are at greater risk for myopia development.

<table>
<thead>
<tr>
<th>AGE</th>
<th>REFRACTIVE ERROR</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 years</td>
<td>+0.75 D or less</td>
</tr>
<tr>
<td>7-8 years</td>
<td>+0.50 D or less</td>
</tr>
<tr>
<td>9-10 years</td>
<td>+0.25 D or less</td>
</tr>
<tr>
<td>11 years</td>
<td>plano</td>
</tr>
</tbody>
</table>

“Spherical equivalent refractive error relative to age is the single best predictor of future myopia.”

Zadnik & The CLEERE Study Group, 2015

The National Eye Institute–funded Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) Study was a 5-center cohort study of almost 5000 children examined annually during school grades 1 through 8 (ages 6-13 years).
Risk factors for developing high myopia

• High myopia defined as ≥ -6.00D and axial length ≥ 26mm (Flitcroft et al, 2019, Tideman et al, 2018)
• Risk factors for developing high myopia
  – Onset less than 8 years old (Chua et al, 2016)
  – East Asian ancestry (Wong et al, 2016)
  – Reside in urban environment (Donovan et al, 2012)
  – Less than 90 minutes per day of outdoor activity (Ho et al, 2019)
  – History of fast progression greater than -0.75D per year for Caucasian and greater than -1.00D for East Asians (Donovan et al, 2012)
  – One or both parents high myopes (Zhang et al, 2015)
• Age of onset of myopia is the strongest predictor of high myopia (Chua et al, 2016)
When to Start?

- “There is no safe level of myopia...” (Flitcroft, 2012)
- Start lifestyle recommendations as early as possible
  - 20-20-2 Rule
- Ages 6 to 12 years old myopia progresses the most
- Recommend treatment for all children with -0.50D or more of myopia
  - Research indicates that any young myopic child is likely to be a progressor until proven otherwise. (Chua et al, 2016)
- 75th percentile or greater in age/axial length growth charts at risk for high myopia (Tideman et al, 2018, Sanz Diez, et al, 2019)
Parents are familiar with CDC stature-for-age and weight-for-age charts.

2 to 20 years: Girls
Stature-for-age and Weight-for-age percentiles

2 to 20 years: Boys
Stature-for-age and Weight-for-age percentiles
Axial length growth & risk of developing myopia in Chinese children

Axial length growth & risk of developing myopia & high myopia in European children

Axial length percentiles in 6, 9, and 15-year old European and Chinese children

<table>
<thead>
<tr>
<th>Percentile</th>
<th>Female</th>
<th></th>
<th>Male</th>
<th></th>
<th></th>
</tr>
</thead>
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<tr>
<td></td>
<td>European</td>
<td>Chinese</td>
<td>European</td>
<td>Chinese</td>
<td></td>
</tr>
<tr>
<td>6 years</td>
<td>25</td>
<td>21.66</td>
<td>22.03</td>
<td>22.14</td>
<td>22.55</td>
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<tr>
<td></td>
<td>50</td>
<td>22.06</td>
<td>22.54</td>
<td>22.59</td>
<td>22.99</td>
</tr>
<tr>
<td></td>
<td>75</td>
<td>22.49</td>
<td>23.04</td>
<td>23.01</td>
<td>23.50</td>
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<tr>
<td>9 years</td>
<td>25</td>
<td>22.33</td>
<td>23.16</td>
<td>22.83</td>
<td>23.70</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td>22.79</td>
<td>23.72</td>
<td>23.31</td>
<td>24.32</td>
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<tr>
<td></td>
<td>75</td>
<td>23.25</td>
<td>24.31</td>
<td>23.79</td>
<td>24.89</td>
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<tr>
<td>15 years</td>
<td>25</td>
<td>22.68</td>
<td>23.83</td>
<td>23.17</td>
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<td>75</td>
<td>23.65</td>
<td>25.20</td>
<td>24.21</td>
<td>25.80</td>
</tr>
</tbody>
</table>

Sanz Diez, et al, 2019; Tideman, et al, 2018
WHEN TO STOP?

• Is treatment effective?
  – Non-responders who continue progressing greater than - 0.75D after one year of treatment
  – Role of non-compliance

• After one year of treatment
  – Good Success:
    SER ≤ 0.50D/year progression
    Axial length ≤ 0.20mm/year progression
    (Erasmus MC Rotterdam, Tideman et al, 2016)
WHEN TO STOP?

• Goal: stop progression of both axial length and SE Rx (Tideman et al, 2016)
  – Axial length goal: less than 26 mm
  – SE Rx goal: less than -6.00D

• Taper then potentially stop treatment when: Myopia (SER) progression < -0.25D per year AND Axial length progression is ≤ 0.05 mm per year
  (Klaver et al 2020, www.myopie.nl)

• Myopia often stabilizes by age 18 ... but not always...especially in today’s myopia-genic world.
RECOMMENDATIONS FOR TAPERING ATROPINE

• Decrease dose or frequency\(^1\)
  – No data on possible rebound effects after cessation of treatment with 0.05% atropine
  – Decrease dose stepwise: 0.05% > 0.025% for six months > 0.01% for six months
  – If child already on 0.01%, decrease frequency to every other day for six months\(^2\)

• Stop completely
  – In ATOM 2 clinical trial least amount of rebound found in 0.01% atropine\(^3\)

• After cessation of treatment monitor axial length & Rx every six months

\(^1\)Wu, 2020; \(^2\)Brenner, 1985; \(^3\)Chia et al, 2016
WHEN DOES MYOPIA STABILIZE?

- COMET study (2013) enrolled 469 ethnically diverse children aged 6 to younger than 12 years with spherical equivalent refraction between −1.25 and −4.50 diopters (D).
- Data analyzed on 426 of the original cohort: At least seven refraction measurements over 11 years.

Myopia Stabilization and Associated Factors Among Participants in the Correction of Myopia Evaluation Trial (COMET)

The COMET Group

Purpose: To use the Gompertz function to estimate the age and the amount of myopia at stabilization and to evaluate associated factors in the Correction of Myopia Evaluation Trial (COMET) cohort, a large ethnically diverse group of myopic children.

Methods: The COMET enrolled 469 ethnically diverse children aged 6 to younger than 12 years with spherical equivalent refraction between −1.25 and −4.50 diopters (D). Noncyclopic refraction was measured sequentially for 4 years and annually thereafter. Right eye data were fit to individual Gompertz functions in participants with at least 6 years of follow-up and at least seven refraction measurements over 11 years. Function parameters were estimated using a nonlinear least squares procedure. Associated factors were evaluated using linear regression.

Results: In total, 426 participants (91%) had valid Gompertz curve fits. The mean (SD) age at myopia stabilization was 15.64 (4.17) years, and the mean (SD) amount of myopia at stabilization was −4.87 (2.01) D. Ethnicity (P < 0.0001) but not sex or the number of myopic parents was associated with the age at stabilization. Ethnicity (P = 0.002) and the number of myopic parents (P = 0.01) but not sex were associated with myopia magnitude at stabilization. At stabilization, African Americans were youngest (mean age, 13.58 ± 2 years) and had the least myopia (mean, −4.56 ± D). Participants with two versus no myopic parents had approximately 1.60 D more myopia at stabilization. The age and the amount of myopia at stabilization were correlated (r = 0.66, P < 0.0001).

Conclusions: The Gompertz function provides estimates of the age and the amount of myopia at stabilization in an ethnically diverse cohort. These findings should provide guidance on the time course of myopia and on decisions regarding the type and timing of interventions.

Keywords: myopia, myopia stabilization, Gompertz function, associated factors, myopia progression.
WHEN DOES MYOPIA STABILIZE?

Large variation in age of stabilization:

- 50% stabilize by 15 years, 50% progress beyond 15 years
- 75% stabilize by 18 years, 25% progress beyond 18 years
- 90% stabilize by 21 years, 10% progress beyond 21 years
- 95% stabilize by 24 years, 5% progress beyond 24 years

(COMET Group 2013, n=426)
Myopia is the primary eye health threat of the 21ST century. Let’s get PROACTIVE!

ACADEMY 2020
S. Barry Eiden, OD, FAAO, FSLA

North Suburban Vision Consultants, Ltd.
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Adjunct Faculty:
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SUNY Colleges of Optometry
During the past three years, I have received honoraria, travel, or consulting fees from:

- Alcon
- Allergan
- Avellino
- Bausch & Lomb / B&L Specialty Vision
- Cooper Vision
- Euclid
- Oculus
- Optovue
- Novartis
- Sight Sciences
- Sight Glass
- Special Eyes
- SynergEyes
- Visible Genomics*
- VTI

Neither I, nor any member of my family, have a financial interest in any company or product mentioned in my lecture.

S. Barry Eiden, OD, FAAO, FSLS
WHEN OK IS BETTER THAN OK...
Implementing Corneal Reshaping/Ortho K into Clinical Practice

S. Barry Eiden OD, FAAO
EVIDENCE BASED DATA

• “Orthokeratology and Myopia Control”
  • 417 PubMed cited articles (08/20)
• More published every year
  • Articles accepted in both optometry and ophthalmology peer reviewed journals
OUR JOURNEY:
How it all began for us (2001):
Sometimes things just work out right!

In The Press

North Suburban Vision Consultants were interviewed by ABC 7's Sylvia Perez for a HealthBeat segment on Corneal Reshaping Therapy.
In 2002, The Journey for All Begins:
FDA Approved Lens Designs

- Paragon CRT (June 2002)
- B&L Vision Shaping Treatment (VST) (1st: December 2004)
  - "Emerald"
  - “Forge Ortho k"
  - "Wave Ortho K“
  - “Superbridge"
  - "BE Retainer”
  - “Contex OK-E System“
  - "DreamLens"
  - "MiracLens"
  - "NightMove"
- Vipok, Orthofocus, CKR, +++
CANDIDATES & FDA APPROVED PARAMETERS

MYOPIA
• - 0.50 -> - 6.00* Paragon
• -5.00*B&L VST
• (optimal range up to -4.00D)

ASTIGMATISM
• -.25 to -1.50
• optimal range <1D, m90

OTHER FACTORS
• Age: not restricted
• Active Lifestyle
• Progressive RX Changes due to potential myopic stabilization effect- OFF LABEL.
  AGE: not restricted
Establishing Myopia Management With Ortho-K and CRT

“Chicago Ortho-K Group”
Meeting 2004
Origin of the “SMART” Study
Stabilizing Myopia by Accelerating Reshaping Technique (SMART)-Study Three Year Outcomes and Overview

Abstract

Objectives: The SMART study is a three-year, longitudinal, multicenter evaluation comparing corneal reshaping contact lenses (CRCL) influence on the progression of myopia in children (age 8 to 14 at enrollment) to the wearing of soft silicone hydrogel contact lenses (SCL) worn on a daily wear basis with monthly replacement. This study represents one of the largest patient enrollment with ten investigators and adds to the literature by verifying the outcomes of smaller enrolled investigations strengthen the outcomes of corneal reshaping techniques.

Methods: At enrollment 172 subjects were fit with corneal reshaping contact lenses worn overnight on a nightly basis (Emerald design by Euclid Systems) and 110 subjects were fit with silicone hydrogel contact lenses on a daily wear monthly-replacement basis (Pure Vision by Bausch & Lomb). Visits were conducted at 24 hours, one week, one month, three months, and every six months thereafter for three years. A regression protocol was conducted for the CRCL subjects at each yearly visit for three years by discontinuing lens wear and monitoring for stability of refraction and topography for consecutive visits until baseline was reached.

Results: The outcome of the three-year investigation indicated that myopia progressed at a statistically significantly higher degree in the SCL group as compared to the CRCL group. Mean spherical equivalent change in myopia for the CRCL group was 

Volume 2 Issue 2 - 2015

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Received: March 12, 2015 | Published: April 21, 2015
“The induction of relative peripheral myopic defocus by OK corneal reshaping has been demonstrated in many studies, and it is this effect that is believed to underlie the myopia control effects of OK.”
Professor Helen A. Swarbrick 2018
ORTHO-K/CR AND MYOPIA MANAGEMENT
THINGS TO CONSIDER:

• Application of Ortho-K/CR specifically for MM
  – Beyond FDA, what to consider

• Technologies utilized for Ortho-K/CR for MM
  – Topography/Biometry/Specular Microscopy/Pupillometry, etc.

• Establishment of MM utilizing Ortho-K/CR
  – Office systems, Agreements, Financial policies, Informed consent

• Risk Management considerations w/Ortho-K/CR
CONSIDERATIONS BEYOND FDA PARAMETERS RE: ORTHO-K/CR AND MYOPIA MANAGEMENT

CORNEAL SHAPE
• Greater corneal power modulation (>eccentricity), greater corneal response**

ADEQUATE INDUCED PERIPHERAL MYOPIC DEFOCUS *

PUPIL SIZE
• >4.5mm for std. OK designs to achieve access to tx zone for myopic defocus*

TREATMENT ZONE SIZE
• Design modification can reduce Tx zone size to emphasize myopic defocus. ***

EXPECTED INFLUENCE ON PROGRESSION OF REFRACTIVE ERROR & AXIAL LENGTH
• Studies average approximately 50% reduction refractive progression & 45% reduction of elongation

SAFETY CONCERNS

**J Wang, et. al. A New Method to Analyze the Relative Corneal Refractive Power and Its Association to Myopic Progression Control With Orthokeratology. Transl Vis Sci Technol. 11/2018
SAFETY CONCERNS IN ORTHO-K/CR

• SERIOUS COMPLICATIONS:
  – MK
  – Vision loss

• STUDIES:
  – **Metanalysis** – Yus and Xie 2016 (The Safety of Orthokeratology—A Systematic Review) “The risk of microbial keratitis in overnight OrthoK was similar to that of other overnight modalities. Ortho-K is a safe option for myopia correction and retardation.”
  – **FDA post-market study** - estimated incidence of microbial keratitis is **7.7 per 10,000 patient-years**. Vs. apx. 2-12/10,000 for DW soft contact lenses & 18-25/10,000 for EW SCL
  – **Bullimore Ortho-K review** – overview of literature “The incidence of microbial keratitis for overnight orthokeratology is similar to overnight wear of soft lenses [113] and while rare, higher than other myopia control options including DW multifocal soft lenses and atropine.”
SUMMARY: CORNEAL RESHAPING AND MYOPIA MANAGEMENT

• CR/Ortho-K results in apx. 50+% reduction in the progression of myopia
• Evidence based as safe and effective
• Can be used in young children***
• Drop out rate – about 20% @yr 1 (long term = to other CLs, but happen early on w/in first month per SMART study)
• Concern for corneal infection about =/< other overnight CL rates
• WOW factor / “Double Whammy” = happy kids

*** medical-legal liability issues – FDA approved guidelines
CORNEAL RESHAPING/ORTHO-K
CLINICAL FITTING METHODS

EMPIRICAL FITTING (K’s, M, CD, + other parameters)
– SMART Study: 80.5% first lens, 95.5% 1 change,
– 99.5% 2 changes

TOPOGRAPHY BASED “VIRTUAL” FITTING***
– Software based fitting/Simulated patterns

DIAGNOSTIC LENS & INVENTORY
FIT & DISPENSING
CORNEAL RESHAPING/ORTHO-K
KEY TECHNOLOGIES

TOPOGRAPHY
required for monitoring/problem solving

AXIAL LENGTH MEASUREMENT
measure what you are trying to control

NICE TO HAVE: pupillometry, specular microscopy, aberrometry, ASOCT (epi-thickness), osmolarity, + others
CORNEAL SHAPE ANALYSIS & ORTHO-K/CR

• Not required for initial lens design
  Although if used may increase first lens success!

• Critical & Required to establish baseline

• Critical & Required to understand the lens effect and assist in problem solving
CORNEAL SHAPE MEASUREMENT
CONSIDERATIONS IN ORTHO-K/CR

• Use of “difference maps”

• What “map” for what purpose

• “Problem Maps”
DIFFERENCE or SUBTRACTION or CHANGE MAPS

• These Maps tell us what lenses did Overnight!
WHAT MAPS FOR WHAT PURPOSE?

• NORMALIZED scale for comparisons for same patient
• ABSOLUTE scale to compare different patient’s maps

• AXIAL
  – map for Rx change at apex*
• TANGENTIAL
  – map for evaluating centration of Tx
• REFRACTIVE POWER
  – map to measure treatment diameter

Axial: Rx change
Tangential: Centration
Refractive Power: Tx zone diameter
PROBLEM MAPS

“Smile Face” - insufficient sagittal depth

“Frown Face” - too great to sagittal depth

Lateral decentration - Helped w/ increased diameter.

Central island - Lens too steep / Sagittal depth too great vs. sagittal depth of cornea
INSTRUMENTATION FOR CORNEAL SHAPE

- Placido Topography
- Multi-functional Placido Topography
- Scheimpflug Tomography
HOW TO MEASURE AXIAL LENGTH and INSTRUMENT ISSUES

A-scan ultrasound biometry
- *Requires anesthesia and is less repeatable in children
- (eg. A-2500 Sonomed) repeatability about 60um
- (eg. DGH Scan Mate 6000) repeatability 30 um

A-scan partial coherence interferometry (PCI)
- (eg. IOLMaster 500 & Pentacam AXL)
- repeatability about 30um

A-scan optical low-coherence interferometry
- (eg. Lenstar LS 900)
- repeatability about 35um

B-scan swept-source optical coherence tomography (SS-OCT)
- (eg. IOLMaster 700)
- repeatability about 24um
Axial Length and Myopia Management

WE NEED TO MEASURE WHAT WE WANT TO CONTROL!
ESTABLISHMENT OF A MYOPIA PROGRESSION MANAGEMENT SUB-SPECIALTY PRACTICE

• Dedication to education and evidence based approach
• Staff training & “Buy-In”
• Office protocols, fee structures/policies, program materials/informed consent docs
• Instrumentation
• Comprehensive treatment options
• Internal / External marketing
GETTING STARTED IN MYOPIA MANAGEMENT
WHAT’S NEEDED?

OFFICE SYSTEMS ***
– Clinical care systems, Staff education, patient educational info, office policies, consent forms, etc.

BASIC EXAMINATION INSTRUMENTATION
– Refraction (obj and subj), K’s, SLE (w/ wratten filter), ...

CORNEAL TOPOGRAPHY (OR TOMOGRAPHY)
– For C.R. - Today is **required** surely for after care and problem solving ***

AXIAL LENGTH MEASUREMENTS (BIOMETRY)
– For M.M. – Today is **required** if we want to measure what we care about ***

OPTIONAL ADVANCED TECHNOLOGY
– Specular microscopy, ASOCT, aberrometry, pupillometry, dry eye dx’s ...

C.R. DESIGN OPTIONS AND LAB RELATIONSHIPS ***
– “Go To” design + “Back Up” designs (1 or 2)
OFFICE SYSTEMS AND FEE MANAGEMENT

**Examination Protocols**
- Patient screening protocols
- Myopia management diagnostic evaluations – initial and subsequent
- Myopia management treatment options and protocols

**Myopia Management patient information folders**
- Treatment options / treatment details / Implications of myopia
- Fees involved / dissatisfaction & discontinuation policies
- Informed consent (risks/benefits/alternative treatments)
- Reference lists / additional supportive materials

**Myopia Management Fee Structures/Policies:**
- Initial
- Subsequent
Corneal Reshaping Therapy (CRT), also known as accelerated orthokeratology, is a non-surgical treatment method to reduce nearsightedness (myopia) and/or astigmatism. The process involves the use of specialized “reverse geometry” gas permeable contact lenses that are specifically designed to alter the topography (curvature) of the cornea. Following removal of the contact lenses visual acuity improves beyond pre-treatment levels and will most often improve vision to normal eyesight without the use of glasses. The CRT contact lenses will need to be worn as a “retainer” for limited periods of time (typically while sleeping at night) in order to maintain the therapeutic effect. The results of CRT will vary to some degree from patient to patient, but are typically related to the degree of refractive error (i.e. prescription levels). Although results are typically excellent for appropriate candidates, results cannot be guaranteed due to individual cornea and eye response variability. North Suburban Vision Consultants will make every effort to achieve maximum therapeutic effect for all of our patients.

The duration of effect and the period of time between contact lens wear that retains clear uncorrected vision will be patient dependent and should be discussed with your doctor. The CRT lenses, once stable in parameters, will have a normal life expectancy of one year. Vision while wearing CRT lenses is typically 20/20 with lenses on from day one throughout CRT treatment. CRT lenses will need to be replaced annually and will be modified in parameters based on the results of your comprehensive eye health and CRT examination at that time.

Initial Corneal Reshaping Therapy fees will include all contact lenses required to achieve the maximum therapeutic effect (including all lens changes and modifications made by your doctor for the first 6 months), all professional services involved in monitoring the contact lens response in order to achieve maximum therapeutic effect, and ensuring optimal eye health response to the CRT contact lenses for a period of ONE YEAR (12 months) following the initial comprehensive CRT examination. Following year one, an annual comprehensive eye health examination and CRT diagnostic evaluation is required to ensure ongoing optimal ocular health and the stability of the therapeutic effect of CRT.
Myopia is a refractive condition of the eye where light focuses anterior to, or in front of the retina. This results in poor vision that is worse for distant objects as compared to near objects. Myopia results when the length of the eye (axial length) as measured from the front of the cornea to the back of the retina is elongated. The higher the degree of myopia – the greater the distance vision blur and the closer the point of clear focus becomes for the individual.

The prevalence of myopia is dramatically increasing worldwide. In the United States the percentage of myopic individuals increased as measured in 1972 and in 2002 from 25% of the population to 46% and growing from there! That increase was even more dramatic in other parts of the world. By the year 2050 over 50% of the world's population is predicted to be myopic. Of great concern is the fact that higher levels of myopia are increasing in prevalence at an even faster rate. Higher myopia has greater risks for vision loss.
CONSENT TO TREAT:

Risks of CRT and Contact Lens Wear: any deviations from the prescribed lens wear regimen or incorrect use of solutions or contact lens disinfection procedures can result in lens damage, eye irritation, infection, or potentially a loss of vision. The use of contact lenses, including CRT lenses, may result in eye infections, inflammations, or potentially loss.

In the unlikely event of complications associated with contact lens wear and CRT, there is a possibility of eye pain, redness, infection, or loss of vision. Immediate professional attention to any complications will significantly reduce the likelihood of ocular damage or vision loss.

In cases of emergency, please contact our office immediately. During non-office hours our practice has a 24-hour emergency service. Call (phone number) and our service will page one of our doctors. All appointments must be kept as scheduled. If you are unable to keep an appointment, we strongly urge you to contact us at least 24 hours in advance if at all possible. In all cases, you must reschedule missed appointments. Failure to keep follow up appointments can result in prolonging the treatment time and reduce the likelihood of achieving the maximum therapeutic effect.

Other options exist to treat, reduce or eliminate myopia and astigmatism. They include: glasses, traditional contact lenses, and refractive surgical procedures. Each modality has its own unique advantages, disadvantages, risks, and benefits. Your doctor has reviewed these options with you during your examination and consultation.

Additional Comments:

__________________________________________________________________________________________________

__________________________________________________________________________________________________

I, the undersigned, fully understand the Corneal Reshaping Therapy Program that has been explained by the doctor, staff member, and/or literature provided by (Practice Name). I have been given the opportunity to ask any questions regarding CRT and I am satisfied with the answers provided.

I agree to enroll in the Corneal Reshaping Therapy program and understand and agree to all of the information indicated in this document.

_____________________________________________ Date:  
Patient Signature or Parent/Guardian Signature for minors

_____________________________________________ Date:  
Doctor or Staff Signature (Practice Name)
Myopia (nearsightedness) is a condition that is most associated with blurred vision at distance. Increasing amounts of myopia do not only cause difficulty seeing. Myopia is also associated with an increase in sight threatening eye diseases such as myopic macular degeneration, cataract, glaucoma, retinal holes and tears, and retinal detachments. Your doctor has recommended that you consider an intervention to help limit the progression of your child’s increasing myopia.

The use of specially designed multifocal contact lenses has been shown in numerous studies to significantly limit the progression of myopia when compared to traditional single vision contact lenses or glasses. The effectiveness of these multifocal therapeutic contact lenses have been reported to reduce the rate of myopic progression by 35 to 50% depending on studies cited.
Myopia (nearsightedness) is a condition that is most associated with blurred vision at distance. Increasing amounts of myopia do not only cause difficulty seeing. Myopia is also associated with an increase in sight threatening eye diseases such as myopic macular degeneration, cataract, glaucoma, retinal holes and tears, and retinal detachments. Your doctor has recommended that you consider an intervention to help limit the progression of your child’s increasing myopia.

The use of Atropine in slowing down the progression of myopia was first reported in the 19th century. The effectiveness of Atropine for myopia control is higher than any other form of treatment currently available. Then why has the use of Atropine not become widespread for myopia progression? The answer is side effects. The commercially available concentration for Atropine is 1.0%. At this concentration the medication causes blurred near vision, pupil dilation and significant light sensitivity. There are also systemic side effects at this high concentration that can in rare instances cause increased heart rate, flushing of the skin, dry mouth and confusion.
Corneal reshaping therapy (CRT, also known as orthokeratology) is a non-surgical, safe, effective, and FDA approved treatment for myopia (nearsightedness) and certain degrees and forms of astigmatism. As compared to conventional methods of vision correction, CRT’s goal is the temporary elimination of refractive error so that the CRT patient is able to see clearly for all daytime hours without the use of glasses or conventional contact lenses.

CRT involves the use of highly specialized therapeutic corneal contact lenses which are worn during sleep in order to gently reshape the central curvature of the cornea. Upon waking, the CRT lenses are removed. Due to the central flattening of the corneal curvature overnight, myopia and corneal astigmatism is reduced which results in clear vision without the use of any corrective lenses. Depending on the degree of initial refractive error and the individual response of the eye to treatment, clear vision is maintained all day long and in many cases for up to 2 to 3 days without vision correction appliances (glasses or conventional contact lenses). If the treatment lenses are not worn overnight eventually the corneal shape will return to baseline as will the original degree of myopia and astigmatism.

The advantages of CRT are numerous. The freedom from the need to use vision correction appliances is obvious, especially for active young people. Clear vision without glasses or conventional contact lenses is advantageous for those involved in sports, most notably if performed in a dusty environment or if involving water sports. The use of the CRT lenses in a generally more controlled and hygienic environment at home often avoids the common complications of infections and inflammations seen with the use of conventional contact lenses. Of greatest interest to parents of progressively nearsighted children is the potential ability of CRT to control and often halt the progression of myopia. A number of well controlled scientific studies, have suggested that this form of therapy is highly effective controlling the rate of progression of myopia. Large multi-center clinical trials have been completed and others are currently under way to scientifically establish this tremendous advantage of CRT.

Your student ______________________________ is currently undergoing CRT at North Suburban Vision Consultants, Ltd. Should you have any specific questions regarding this exciting form of vision correction, please do not hesitate to contact us at NSVC. For further detailed information about CRT and many other eye and vision topics, please visit our web site at www.nsvc.com.
Dear Dr. [Name],

The prevalence of myopia (near-sightedness) is on the rise and now we can do something about it! The rates of myopia in the United States have increased 65% from the 1970s to the late 1980's and are even higher today. Myopia is not just an inconvenience of sight. Childhood myopia typically progresses and is often due to an increasing axial length of the eye. As myopia increases so does the lifetime risks of sight-threatening conditions such as retinal detachments, glaucoma, and maculopathies.

As a pediatrician, you know the benefits of children spending time outdoors. While we know technology has likely played a role in the increasing levels of myopia, the only method supported by research to be effective in reducing myopia before its onset is increased time outdoors. Now that the weather is nice, we should be encouraging average, of at least 2 hours per day outdoors with proper UV protection.

If myopia does develop in your patients, North Suburban Vision Consultants is a leader in actively managing myopia progression. Our practice has been successfully utilizing evidence-based medicine to abate myopic progression. There are three methods that current research supports for myopia progression which are: low dose atropine, specialty multifocal contact lenses, and orthokeratology. A study by Conneal Reshaping Therapy (CRT) reveals that the rate of myopia progression among children treated with CRT was significantly lower than in the control group.

If you have any questions about pediatric myopia or our pediatric optometrists would be happy to talk to you. Please email Dr. [Name] at DJP@NSVC.COM or Dr. [Name] at [Name]@NSVC.COM to set up a time. As a pediatric optometrist, Doctor. Bruce Koffler writes in “The Case for Myopia Control Now”, “…new clinical technologies allow us to harness these insights and slow myopia progression in developing eyes.”

Sincerely,

[Signature]
MYOPIA MANAGEMENT FEE MANAGEMENT

• Myopia Management Diagnostic Evaluation
  – Initial
  – Subsequent

• Myopia Management Treatment Programs
  – Initial annual fee
  – Subsequent fees

• Material Fees (if applicable)

• Discontinuation Policies
## MYOPIA MANAGEMENT FEE MANAGEMENT

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<tr>
<td>Myopia Management Subsequent Evaluation</td>
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<tr>
<td>Myopia Management Aftercare Program (aftercare scheduled 6mo + any req. other visits)</td>
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<tr>
<td>Atropine Myopia Treatment Program</td>
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</table>
DISSATISFACTION/DISCONTINUATION POLICIES
Refund and Credit Policies

You, and your doctor may decide to discontinue CRT during the initial fitting and follow up care period. Should the decision to discontinue CRT be made, the following refund/credit policies will be applied:

- Discontinuation of CRT up to two months following dispensing of CRT lenses – a refund or office credit of 50% of the CRT program fee will be made.
- Beyond two months no credit or refunds will be made if CRT is discontinued.
- All refunds or credits associated with discontinuation of CRT require the return of all contact lens materials.
- No refunds are available for post surgical and other complex CRT cases (your doctor or ophthalmic technician will discuss this with you at the time of agreement to CRT policies). However, during the initial 12 month period following initial CRT should discontinuation of CRT occur, alternative contact lens options may be agreed to without additional fees (this will also be discussed with you at the appropriate point in time).
MARKETING AND PATIENT EDUCATION IN CORNEAL RESHAPING PRACTICE

INTERNAL MARKETING:
Patient education (staff, doctor, materials, etc.)
Direct mail campaigns / email blasts***
Social media education
Seminars, free screenings
Referral programs

EXTERNAL MARKETING: cost vs. return calculations
Advertising
Direct mail / Web and Blog S.E.O.
Media (print, radio, TV/cable)
Public relations/PR***
Myopia Management

NSVC Myopia

Corneal Reshaping Treatment (CRT) — Vision Correction Without Surgery

Eye to Eye with North Suburban Vision Consultants

A blog about specialty eye care and how to improve your quality of life.

Another Approach to Controlling Myopia Progression. By Emily Stark, MD, FRCSC on 07/29/2013 in The Medical Post

A recent study published in the journal Ophthalmology has found that the use of a new contact lens design can help slow the progression of myopia in children. The study looked at the impact of this new contact lens design on children.

http://www.medicalpost.com/ophtalmology/a-171669251344

By Emily Stark, MD, FRCSC

Today we have a number of highly effective ways to control myopia progression in young people which include: corneal oxygen saturation, use of an orthokeratology contact lens, and sometimes a combination of these therapies. Let’s talk about the prevention of myopia progression in children. This comes from a study called the EyeMyopia Research Collaborative. In this new study, the researchers discovered that 76% of myopic children who were not treated with myopia control techniques had an increase in their refractive error. In contrast, the study showed that 36% of myopic children who were treated with myopia control techniques had an increase in their refractive error. The researchers also found that children who were treated with myopia control techniques had an increase in their refractive error. The researchers also found that children who were treated with myopia control techniques had an increase in their refractive error.

For more information on myopia, contact lenses, eye diseases, and other eye topics, please visit our website at www.northsuburbavision.com.

Corneal Reshaping Treatment (CRT) is a non-surgical alternative to correction of myopia. This is a therapeutic process that involves blotting the nerves before treatment and allowing the treatment to continue without vision correction. The procedure involves a series of gentle pressure pulses that are applied to the peripheral corneal tissues. These pressure pulses cause the nerves to be pushed out of the way, allowing the peripheral corneal tissues to move into the central area of the eye. This results in a flattening of the cornea, which reduces the amount of light that is focused on the retina. This leads to a decrease in the amount of myopia, which can be measured using an eye chart. The treatment is usually performed on both eyes and can be done on an outpatient basis.

Although results are typically excellent for children with high myopia, the treatment can be effective for adults as well. However, it is important to note that the treatment is not a cure and requires ongoing monitoring and follow-up visits to ensure it continues to be effective.

How is atropine used for myopia control?

Atropine eye drops or solution are applied to the eyes, usually once a day. The treatment is continued as long as myopia progression is considered a risk.

How does atropine work for myopia control?

Atropine has been found to slow the progression of myopia, meaning that students who use eye drops or solution on one or both eyes in schools to reduce the incidence of myopia. Different studies have shown different results. The ATOM study showed that atropine reduced the incidence of myopia by 67%. In contrast, the low atropine group reduced the incidence of myopia by 34%. Therefore, it is important to note that the treatment is not a cure and requires ongoing monitoring and follow-up visits to ensure it continues to be effective.

Although results are typically excellent for children with high myopia, the treatment can be effective for adults as well. However, it is important to note that the treatment is not a cure and requires ongoing monitoring and follow-up visits to ensure it continues to be effective.

What is atropine?

Atropine is a medicine derived from different plants that will affect itself to what we call melanocortin receptors, specific structures found throughout the body as part of the hypothalamic-pituitary axis. The actions of this compound are fluid. For instance, atropine affects the body by blocking noradrenergic
DON’T LET VISION STAND IN THE WAY OF YOUR CHILD’S FUTURE

Myopia (or nearsightedness) is reaching epidemic levels and having a serious impact on today’s children around the world. With cases nearly doubling since the 1970’s, it is expected to become the leading cause of permanent blindness. The condition also significantly increases the risk of more serious ocular health issues including:

- Glaucoma
  - 14.4x for myopia >6.00D
  - 7.8x for myopia
- Cataract
  - 3.3x for myopia >6.00D
- Retinal Pathology
  - 7.8x for myopia

At NSVC, we take a proactive approach to myopia management with a safe, effective, and FDA-approved treatment called Corneal Reshaping Therapy/Orthokeratology (Ortho-K). Proven on millions of eyes around the world, numerous studies show children using this treatment are increasing in myopia at a much slower rate than those wearing glasses or daytime contact lenses.

If you think a Proactive Myopia Management program might be right for you or your child, please schedule an appointment for an evaluation by calling 847-412-0133.

NORTH SUBURBAN VISION CONSULTANTS

July 16, 2019

Dear [Patient Name],

As a valued patient of North Suburban Vision Consultants, we would like to make you aware of the importance of Proactively Managing Myopia in children. Myopia (or nearsightedness) is reaching epidemic levels and having a serious impact on today’s children around the world. With cases nearly doubling since the 1970’s, it is estimated that 5 billion people, or 50% of the world’s population will be myopic by 2050. Not only is it expected to become the leading cause of permanent blindness, myopia significantly increases the risk of more serious ocular health issues including:

- Glaucoma
  - 14.4x for myopia >6.00D
  - 7.8x for myopia
- Cataract
  - 3.3x for myopia >6.00D
- Retinal Pathology
  - 7.8x for myopia

The good news is there is a proven Proactive Myopia Management treatment available called Corneal Reshaping Treatment/Orthokeratology (Ortho-K). This is a non-surgical treatment that uses overnight contact lenses to gently reshape the thin front surface of the eye (cornea) as you sleep, and eliminates the need for glasses or daytime contact lenses to correct vision.

Corneal Reshaping/Ortho-K lenses are safe, effective, FDA-approved, and proven on millions of eyes around the world. In fact, numerous studies show youngsters using this treatment are increasing in myopia at a much slower rate than similarly aged children wearing daytime use contact lenses or glasses.

If you think a Proactive Myopia Management program might be right for you or your child, please schedule an appointment for an evaluation by calling NSVC at 847-412-0133.

EXCLUSIVE OFFER

Proactive Myopia Management Treatment with Corneal Reshaping/Ognight Orthokeratology Lenses

Use Code DB619-2

Already have overnight orthokeratology lenses? Refer a friend and receive a $150 credit toward replacement lenses. Please notify us of the referral at the time of your friend’s evaluation.

Very truly yours,

S. Barry Elden, O.D., F.A.A.O.
President and Medical Director,
NSVC

Milana Matz, O.D.
Co-director, Contact Lens Specialty Services, NSVC

Vessa Salić, O.D.
Director, Pediatric Eye Care Services, NSVC

Restrictions apply, please see your Eyescare professional for further details.
• Myopia prevalence is increasing at an alarming rate worldwide
• Implications of high myopia are medically significant in addition to the QOL implications
• We have effective and safe evidence based treatment methods to control myopia progression

*Passively correcting myopic refractive error without attention to progression control may soon conflict with standard of care*
ACADEMY 2020
AT HOME
Presented by AMERICAN ACADEMY of OPTOMETRY
Susan A. Resnick OD, FAAO, FSLS

AAO Diplomate, Cornea, Contact Lens and Refractive Technology Section

President,
Drs. Farkas, Kassalow, Resnick and Associates, P.C.

Vision Source Administrator, Metro NY and LI
## Relevant Financial Disclosure

During the past three years, I have received honoraria, travel, or consulting fees from:

- **Speaker/Consultant**
  - Alcon, Bausch + Lomb, Every Day Contacts, JNJ Vision
  - Osmotica Pharmaceuticals, Sight Sciences

Neither I, nor any member of my family, have a financial interest in any company or product mentioned in my lecture.

Susan A. Resnick OD, FAAO, FSLS
PERIPHERAL BLUR TO CLEAR THE WORLD

Susan A. Resnick, OD, FAAO, FSLS
BE IN CONTROL WITH MULTIFOCAL CONTACT LENSES

• How do they work?
• How well do they work?
• Why choose multifocals?
• Who’s ready for them?
• What are the design options and how do we choose?
• Anything different about fitting these?
• Follow up, follow through and make a difference!
MM: The MOA of MFs

• Correct or reduce accommodative lag
• Reduce myopia progression by reducing peripheral hyperopic defocus
• Increase myopic peripheral defocus
• Walline et al (2013) observed a 50% reduction in myopia and a 29% reduction in axial length in a group of 27 myopic children age 8 to 11 years who wore Proclear multifocal “D” lenses with +2.00 D add for 2 years compared with an age-matched control group.

• Walline et al (2020)
  – Effect of High Add Power, Medium Add Power, or Single-Vision Contact Lenses on Myopia Progression in Children
  – The BLINK Randomized Clinical Trial
  – Among children with myopia, treatment with high add power multifocal contact lenses compared with medium add power multifocal and single-vision contact lenses reduced the rate of myopia progression over 3 years, but further research is needed to understand the clinical importance of the observed differences as well as long-term outcomes.
MYOPIA CONTROL WITH CONTACT LENSES
SANKARIDURG

Clin Exp Optom 2017; 100: 432–437
GOT MYOPIA?

• Patient Motivation
• Parental “support”
• Age
• Refractive Error
• Genetic risk factors
WHY CHOOSE MULTIFOCALS?

• Relative ease of fitting
  – Fewer visits
• Easier transition between CLs and spectacles
• Less care involved
• Eliminates risk of overnight wear
• Less “drop out” with age?
“PARENTAL CONTROLS”

• Explanation of purpose/mechanism of action
• Discussion of modality/lens choice
  – FDA approved vs. off label
• Setting expectations
• Care and Handling
• Resources:
  – mymyopia.com
  – Mykidsvision.org
  – Globalmyopiacentre.org (for ECPs)
PROPOSED LENS SELECTION SCHEME

DWD
- MI Sight
- NaturalVue

PR Cylinder*
- Acuvue Oasys
- PC MF*
- Biofinity MF*

Economics

Hybrid Custom Soft Stable & More Cylinder Zone Control
- SynergEyes
- SpecialEyes
- Intelliwave Pro (Art Optical)
- AVT NaturaSoft
POWER PROFILES
MiSight 1 day contact lenses were clinically validated in a multi-year comprehensive study that enrolled children between 8 and 12. Over three years, MiSight reduced myopia progression by 59%, versus a single vision 1 day lens.¹

- Two treatment zones create myopic defocus with image focus in front of the retina, rather than behind it to slow axial elongation
- Two correction zones correct myopia in all gaze positions

The minimum recommended wear time for myopia management is 10 hours a day for 6 days a week.

Congratulations on your successful completion of the Brilliant Futures™ Myopia Management Program certification exam.

We welcome you to the growing community of certified eye care professionals who are taking on myopia. Your personal Myopia Management Specialist (MMS) will contact you at this email address to review next steps to activate your Brilliant Futures™ account. As soon as those steps are completed, CooperVision will provide you with the following:

- MiSight® 1 day diagnostic fitting set
- 1 Practitioner starter kit
- 2 Parent and child starter kits
- Enrollment in a training course specific to the MiSight® App
- Access to additional learning modules, tools, & marketing support
- Two complimentary Brilliant Futures™ programs to build confidence
• Moving outward from the center of the lens, RELATIVE PLUS POWER rises dramatically in a smooth and continuous manner and creates an area of relative plus power (on the retina).

• The area of relative plus power is designed to be suppressed by the brain. This allows creation of a virtual aperture by the visual cortex, resulting in an extended depth of focus in which distance, intermediate, and near are all clear.

NaturalVue Multifocal 1-Day is an extended depth of focus lens with a center-distance design with relative plus power of 8.00 D to 11.00 D at the edge of the pupil and about 20.00 D at the edge of the optical zone.
NaturalVue® Multifocal –
Refractive error change vs. prior correction
Cooper, et al. n=32

In children who have worn NaturalVue® Multifocal for 6-25 months:

Annualized Refractive Error Change¹ (D)

<table>
<thead>
<tr>
<th>Prior Correction OD</th>
<th>NaturalVue® Multifocal OD</th>
<th>Prior Correction OS</th>
<th>NaturalVue® Multifocal OS</th>
<th>NaturalVue® Multifocal Both Eyes Combined</th>
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</thead>
<tbody>
<tr>
<td>-0.85</td>
<td>-0.04*</td>
<td>-0.90</td>
<td>-0.03*</td>
<td>-0.04*</td>
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The decrease in the annualized refractive error change was 95.4% OD and 96.25% OS (96% for both eyes combined) with the most frequently observed decrease in refractive error change (mode) of 100% in each eye.

Percentage decrease with NaturalVue® Multifocal = 96% (both eyes combined)

CENTER DISTANCE PROGRESSIVE HYBRIDS

- Corneal Astigmatism correction
- Variable ADD powers
  - High as possible... => +2.50
- Control of Central Zone Size
  - 1 mm < photopic pupil
  - Typically 4 mm
- Dry Eye (THP)
- Consistency of Vision... no rotation
- Off Label
Hybrid Multifocal Contact Lens Design for Myopia Management in Astigmatic Children

Alamo Eye Care & Contact Lens Institute of San Antonio
Melanie Frogozo OD

BACKGROUND

High myopia increases the risk of irreversible vision loss and is correlated with comorbidities such as glaucoma, macular degeneration, retinal detachments, and premature cataracts. Children who are myopic are at the most risk since there is more time for progression to higher myopia. Thus, early intervention is crucial for preventing high myopia and its associated visual impairments.

Myopia management (MM) with contact lenses is accomplished by creating myopic peripheral defocus which is assumed to act as a retinal cue in order to slow myopic eye growth. Gas permeable (GP) lenses offer good optical correction for astigmatism; additionally, multifocal optics can be easily placed on the front surface for MM. The following presents a case series of 3 pediatric patients who were fitted into center distance bifocal hybrid lenses (SynergEyes, Carlsbad, CA) for MM.

PATIENT # 1

Chief Complaint & History of Present Illness
A 14-year-old Caucasian male gymnast with high myopia and astigmatism that progressed 2.00 diopters in the previous 2 years. He was wearing soft toric lenses for distance correction.

Manifest Refraction, Axial Length, and Visual Acuity
OD: -6.25-0.75x170 25.24 mm 20/20
OS: -6.25-1.25x030 25.32 mm 20/20

Corneal Topography
OD: 43.88/45.34@091
OS: 44.21/45.30@098

Lens Design for Myopia Management
OD: 7.60/-6.50 / 14.50 8.10 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20
OS: 7.60/-6.75 / 14.50 8.10 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20

PATIENT # 2

Chief Complaint & History of Present Illness
A 13-year-old Asian female ice skater with myopia and astigmatism that progressed 1.00 diopters in the past 1 year. She was wearing soft toric lenses for distance correction.

Manifest Refraction, Axial Length, and Visual Acuity
OD: -1.75-4.50x178 22.90 mm 20/20
OS: -2.50-2.50x011 22.57 mm 20/20

Corneal Topography
OD: 42.34/46.75@086
OS: 43.66/46.60@092

Lens Design for Myopia Management
OD: 7.70/-0.25 / 14.50 8.40 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20
OS: 7.60/-0.25 / 14.50 8.40 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20

PATIENT # 3

Chief Complaint & History of Present Illness
A 8-year-old Caucasian female basketball player with myopia and astigmatism. She was new to contact lens wear and had progressed 0.75 D in the past year.

Manifest Refraction, Axial Length, and Visual Acuity
OD: -1.25-0.50x008 25.24 mm 20/20
OS: -1.00-2.75x161 25.32 mm 20/20

Corneal Topography
OD: 43.50/44.87@097
OS: 43.37/47.12@077

Lens Design for Myopia Management
OD: 7.80/-1.25 / 14.50 8.40 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20
OS: 7.80/-0.75 / 14.50 8.40 Skirt
Distance Zone 4.00 mm ADD +2.50 VA 20/20

RESULTS AND DISCUSSION

At the 2 and 6 weeks progress evaluation, all patients reported good vision and has no issues with the lenses while participating in athletic activities. At 6 month follow-up, no progression in myopic refraction or axial eye length was noted in either eye for all patient.

Typical orthokeratology treatments do not aim to correct for high myopia and astigmatism. Similar to orthokeratology, bifocal contact lenses opt to slow the progression of myopia. A study revealed that during a 2-year treatment period, bifocal contact lenses were in a reduction of 50% in the progression of myopia and 29% reduction in axial elongation compared to single vision contact lenses.

For patients with high myopia and astigmatism center distance hybrid lenses (Figure 1) offer good comfort and more stable optics in comparison to soft toric lenses. Adding a front surface center distance bifocal to hybrid lenses is an option for myopia management in children with myopia and astigmatism.

CONCLUSION

Myopia is increasing worldwide; however, with early intervention, high myopia can be prevented. Myopia control through contact lenses aims to create myopic defocus in order slow eye growth. Center distance hybrid bifocal contact lenses are a good choice for contact lens myopia management in children with high astigmatism and myopia.

SELECTED REFERENCES


3rd Place at GSSLS 2019
FAMILIAR PROCESS: LOFTIER GOAL!

• Centration
• Movement
• Choosing Add Power (if indicated)
• Choosing Center Zone size (if indicated)
• Room illumination
• Over-refracting

Follow the fitting guide!
DISPENSING AND FOLLOW UP

- Insertion and Removal Training
- Wearing schedule
- Up to date spectacle correction
- One week, one month three months
- Every three to six months, thereafter
- Annual comprehensive exams including cycloplegic refraction and axial length measurement if available
FINAL CONSIDERATIONS ... Just in Case

- Incidence of corneal infiltrative events in children wearing soft contact lenses is no higher than in adults and if anything may be markedly lower. (Mark A. Bullimore; Optom Vis Sci. 2017 Jun; 94(6): 638–646.)
  - May be lower in 8-11-year olds due to daily disposables, daily wear and parental supervision

- Allergy
- Visual Quality
  - Contrast
  - Acuity
  - Aberrations

---

The Safety of Soft Contact Lenses in Children

Mark A. Bullimore*

**ABSTRACT**

**Purpose.** There is increasing interest in fitting children with soft contact lenses. This review collates data from a range of studies to estimate the incidence of complications, specifically corneal infiltrative events and microbial keratitis, in patients under the age of 18 years.

**Methods.** Peer-review papers were identified using PubMed and the Web of Science. A broad range of studies are summarized including large-scale epidemiological studies of contact lens–related complications, hospital-based case series, long- and short-term prospective studies, and multicenter retrospective studies.

**Results.** Nine prospective studies representing 1800 patient years of wear in 7- to 15-year-olds include safety outcomes. In these large prospective studies representing between 159 and 723 patient years of soft contact lens wear in patients 8 to 14 years, the incidence of corneal infiltrative events is up to 1.6 per 10,000 years. Data from a large retrospective study show similar rates of corneal infiltrative events: 0.7 per 10,000 years in 8- to 12-year-olds (based on 411 patient years of wear) and 3.3 per 10,000 years in 13- to 17-year-olds (based on 1372 patient years of wear). None of the prospective studies report any cases of microbial keratitis. Five clinical studies where safety data are not reported constitute a further 493 patient years. One retrospective study found no cases of microbial keratitis occurred in 8- to 12-year-olds (411 patient years) and an incidence of 15 per 10,000 patient years in 13- to 17-year-olds (1372 patient years)—no higher than the incidence of microbial keratitis in adults wearing soft contact lenses on an overnight basis.

**Conclusions.** The overall picture is that the incidence of corneal infiltrative events in children is no higher than in adults, and in the youngest age range of 8 to 11 years, it may be markedly lower. (Optom Vis Sci 2017;94(6): 638–646)
Padmaja Sankaridurg, Bopt, MIP, PhD

Head, Myopia Program,
Head, Intellectual Property,
Brien Holden Vision Institute

Advisory Board,
International Myopia Institute
Advisory Board Member,
Review of MM
Relevant Financial Disclosure

During the past three years, I have received honoraria, travel, or consulting fees from:

- ALCON
- Mark Ennovy
- SEED

I am the inventor on multiple patents/patents applications related to myopia. I am a salaried employed of BHVI. BHVO has commercial interests in myopia control.

Padmaja Sankaridurg, Bopt, MIP, PhD
Understanding Extended Depth of Focus... and The International Experience

Padmaja Sankaridurg, Boptom, PhD
PREVALENCE - MYOPIA

2010: 1.3 billion
2020: 1.8 billion
2030: 2.5 billion
2040: 4.1 billion
2050: 4.9 billion

Myopes: 27.4%, 33.1%, 39.4%, 45.8%, 51.7%
Non Myopes: 72.6%, 66.9%, 60.6%, 54.2%, 48.3%

911 million high myopes in 2050

Holden et al. 2016
**MYOPIA CONTROL STRATEGIES**

**SPECTACLES**
- Progressive addition lenses
- Executive bifocals
- Peripheral asphericized PAL
- Peripheral defocus
- Defocus incorporated multiple segments

**REDUCTION IN MYOPIA PROGRESSION**
between 11.1% and 52.0% for SE

**CONTACT LENSES**
- Multifocal
- Multifocal-like
- Peripheral plus test
- Extended depth of focus test

**REDUCTION IN MYOPIA PROGRESSION**
between 20.6% and 72.0% for SE

**CONTACT LENSES**
- Orthokeratology

**REDUCTION IN MYOPIA PROGRESSION**
between 30.0% and 56.0% for AL

**ATROPINE (0.01% concentration)**

**REDUCTION IN MYOPIA PROGRESSION**
between 27% and 80% for SE
EXTENDED DEPTH OF FOCUS (EDOF) FOR MYOPIA
IDEA

Incorporation of higher order aberrations to create a power profile that is non-monotonic (varying power profile) and aperiodic (i.e. no discrete zones)

Results in

- *Elongated focal point i.e. extended focus instead of a distinct focus (e.g. single vision) or foci (e.g. bifocals)*
- *More robust for pupil changes, aberrations and decentration*
GLOBAL RETINAL IMAGE QUALITY (GRIQ)
SINGLE VISION

On the retinal plane

GRIQ maps - for illustrative purposes only
Log transformed image quality
red = better retinal image quality

Better retinal image quality centrally than periphery
GLOBAL RETINAL IMAGE QUALITY (GRIQ) SINGLE VISION

On the retinal plane

GRIQ maps - for illustrative purposes only
Log transformed image quality
red = better retinal image quality

Better retinal image quality centrally than periphery

Behind the retinal plane

Better retinal image quality peripherally than centrally
GLOBAL RETINAL IMAGE QUALITY (GRIQ) SINGLE VISION

On the retinal plane

Drives eye growth

Better retinal image quality centrally than periphery

Behind the retinal plane

Better retinal image quality peripherally than centrally

GRIQ maps - for illustrative purposes only
Log transformed image quality
red = better retinal image quality
GLOBAL RETINAL IMAGE QUALITY (GRIQ) EDOF

On the retinal plane:
- Better retinal image quality centrally than periphery
- Log transformed image quality
  - red = better retinal image quality

Behind the retinal plane:
- Reduce retinal image quality to reduce/slow eye growth

Slow eye growth
EXTENDED DEPTH OF FOCUS (EDOF) FOR MYOPIA
Study 1 of 3: Subjective Visual Performance

Double-blind; cross over 35 non-presbyopes
Age 18 – 35 1 wk

* EDOF better than MiSight or Proclear

Sha et al 2018 ClinOptom
Study 2 of 3: Prospective, randomised, double masked 2 yr. trial

- 508 participants; aged 7-13 yrs; daily wear, daily disposable basis; randomised to 5 groups (4 test; 1 control)
- Study conducted at Guangzhou, China
- Control: Single vision contact lens

Sankaridurg et al 2019 Ophthalmology & Physiological Optics
STUDY RESULTS

EDOF lenses significantly slowed myopia

Sankaridurg et al. 2019

Axial Length Progression

- SV CONTROL: 0.60
- EDOF 1: -27% 0.43
- EDOF 2: -25% 0.45

Sph Eq. Progression

- SV CONTROL: -1.15
- EDOF 1: -0.85 -26%
- EDOF 2: -0.78 -32%
SUBJECTIVE VARIABLES

EDOF lenses performed similar to SV lenses
DISCONTINUATIONS - REASONS

- Low vision related drop-out rates
- No difference between lenses
### Rationale for myopia control

<table>
<thead>
<tr>
<th></th>
<th>MiSight</th>
<th>BHVI EDOF</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simultaneous defocus</strong></td>
<td>Concentric rings of plus power</td>
<td>Reduce retinal image quality for points posterior to retina to slow eye growth</td>
</tr>
<tr>
<td><strong>Non-monotonic power profile</strong></td>
<td></td>
<td>Non-monotonic power profile</td>
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</table>

### Efficacy

<table>
<thead>
<tr>
<th></th>
<th>2 yr -59% reduction in SE -53% reduction in AL <em>(CV reports)</em></th>
<th>Approx 30% for SE and AL <em>(Sankaridurg et al. 2019)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 yr - 39% reduction in SE -36% reduction in AL <em>(Ruiz-Pomeda et al 2017)</em></td>
<td></td>
</tr>
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</table>
METHODS:

CONTRALATERAL 6 MONTHS CROSS OVER; DAILY DISPOSABLE HYDROGELS

- 95 participants; aged 7-14 yrs;
- Three groups:

  1. Bilateral single vision (n=30)
  2. Contralateral single vision v MiSight (n=31)
  3. Contralateral single vision v BHVI EDOF (n=34)

- Change in SE and AL: First and second 6 months
- AIER, Changsha, China
BHVI CONTRALATERAL STUDY

Group I: Bilateral SV

Group II: MiSight v SV

Group III: EDOF v SV

Test < Control
SE: MiSight: 71%; EDOF: 80%
AL: MiSight 84%; EDOF: 97%

BHVI CONTRALATERAL STUDY

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BHVI CONTRALATERAL STUDY

Group I: Bilateral SV

Group II: MiSight v SV

Group III: EDOF v SV

No rebound in BHVI contralateral
**BOTH 6 MONTH PERIODS- CHANGE IN AXIAL LENGTH**

**Group II**

**MiSight**

\[ y = 0.4637x + 0.0119 \]

**R² = 0.3046**

**Group III**

**EDOF**

\[ y = 0.7516x - 0.0625 \]

**R² = 0.4659**

**MiSight; 84% test < Control**

**EDOF: 97% Test<Control**
WHAT IS HAPPENING IN REAL WORLD

40 practices/1278 customer evaluations, 5 different countries, Spain, Holland, Italy, Australia, and Bulgaria.

Some additional questions were performed to evaluate the efficiency of MYLO lenses in myopia management. A total of 123 evaluations were gathered from 108 users that wore the lenses.

For the question, rate the level of satisfaction of MYLO efficiency of myopia management in a scale where 1 is poor and 5 excellent, the average score was $4.38 \pm 0.67$. 
EDOFT FOR MYOPIA: SUMMARY

• Hypothesis - reduce image quality behind retina. Good image quality on and in front of retina
• Study 1: Better subjective visual performance with EDOF
• Study 2: Demonstrated myopia control over 2 years.
• Study 3: In a contralateral study, both MiSight and BHVI EDOF lenses slowed myopia. Lens performance was similar
• Early data on real life experiences
Jeffrey J. Walline, OD, PhD, FAAO

AAO Diplomate, Cornea, Contact Lens and Refractive Technology Section

Board Member, AAO Board of Directors
Past Chair, AOA Cornea and Contact Lens Section

Professor of Optometry and
Associate Dean for Research
Ohio State University, School of Optometry
Relevant Financial Disclosure

During the past three years, I have received honoraria, travel, or consulting fees from:

Received research materials from Bausch & Lomb

Neither I, nor any member of my family, have a financial interest in any company or product mentioned in my lecture.
WHICH IS BETTER FOR MYOPIA MANAGEMENT: 1 or 2?

Jeffrey J. Walline, OD, PhD, FAAO
Optical Myopia Control

Single Vision Contact Lens

Orthokeratology or Soft/Hybrid Multifocal Contact Lens
Pharmaceutical Myopia Control
Synergy or Antagonism

Optical Signal

Pharmaceutical Signal

Common Pathway

Saturated, then no additional treatment effect

Unsaturated, then additional treatment effect
Synergy or Antagonism

Optical Signal

Pharmaceutical Signal

Alternate Pathway

Additive

Overwhelm
Combination Therapies
0.125% Atropine + Acupoint Stimulation

0.125% Atropine + Acupoint Stimulation

0.125% Atropine + Acupoint Stimulation

<table>
<thead>
<tr>
<th></th>
<th>0.125A group</th>
<th>p value</th>
<th>0.125A + ACU group</th>
<th>p value</th>
<th>Comparison between two groups</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Changes per year</td>
<td></td>
<td>Changes per year</td>
<td></td>
<td></td>
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<tr>
<td>SE (diopter)</td>
<td>-0.66</td>
<td>&lt;0.0001</td>
<td>-0.41</td>
<td>&lt;0.0001</td>
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<td>&lt;0.0001</td>
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<tr>
<td>AL (mm)</td>
<td>0.32</td>
<td>&lt;0.0001</td>
<td>0.24</td>
<td>&lt;0.0001</td>
<td></td>
<td>0.02</td>
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<tr>
<td>ACD (mm)</td>
<td>0.031</td>
<td>&lt;0.0001</td>
<td>0.076</td>
<td>&lt;0.0001</td>
<td></td>
<td>0.0004</td>
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<tr>
<td>IOP (mmHg)</td>
<td>-0.03</td>
<td>0.86</td>
<td>-1.01</td>
<td>0.003</td>
<td></td>
<td>0.007</td>
</tr>
</tbody>
</table>

* After adjustment for age and sex.

<table>
<thead>
<tr>
<th>Myopia</th>
<th>[Atropine]</th>
<th>Combination</th>
<th>Orthokeratology</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6.00 D</td>
<td>0.125%</td>
<td>0.55 ± 0.12</td>
<td>0.58 ± 0.09</td>
<td>0.022</td>
</tr>
<tr>
<td>&lt; 6.00 D</td>
<td>0.025%</td>
<td>0.65 ± 0.18</td>
<td>0.83 ± 0.16</td>
<td>0.029</td>
</tr>
<tr>
<td>≥6.00 D</td>
<td>0.125%</td>
<td>0.57 ± 0.17</td>
<td>0.64 ± 0.14</td>
<td>0.015</td>
</tr>
<tr>
<td>≥ 6.00 D</td>
<td>0.025%</td>
<td>0.58 ± 0.08</td>
<td>0.4 ± 0.15</td>
<td>0.023</td>
</tr>
<tr>
<td>All subjects</td>
<td>Both</td>
<td>0.59</td>
<td>0.61</td>
<td>N/A</td>
</tr>
</tbody>
</table>

“Combined treatment with atropine and OK lenses would be a choice of treatment to control the development of myopia.”

0.01% Atropine + OK

0.01% Atropine + OK

OK Then OK Plus 0.01% Atropine

Meta-Analysis

• Results: Four studies were ultimately included, involving a total of 267 subjects. This meta-analysis revealed that the mean axial length of the subjects in the experimental group was 0.09 mm less than that of subjects in the control group [WMD=-0.09, 95%CI (-0.15, -0.03), P=0.003].
0.01% Atropine + Multifocal CLs

- 49 participants
  - Biofinity Multifocal D +2.50 D add
  - 1 gtt 0.01% atropine qhs OU

- Historical control groups from BLINK Study
  - Biofinity Multifocal D +2.50 D add
  - Biofinity single vision

Bifocal & Atropine in Myopia Study
Start With Combination?

• KISS it
  – Keep it simple, stupid
  – Additional treatment if nervous

• Why hold back?
  – Start with the big guns
  – Give maximum treatment
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PANEL DISCUSSION

Now’s your chance! ASK US !!!