

## Myopia Control: The Good, The Bad, and The Ugly

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### Financial Disclosures (Compton, Davison, Morrison)

Dr. Compton	Dr. Davison	Dr. Morrison
Johnson & Johnson	RVL Pharmaceuticals	Blanchard
CooperVision	IDOC Alliance	Boston Sight
Alcon	Review of Optometric Business	CooperVision
Contamac	Twenty Twenty Beauty	Eaglet
	Oulaire Skincare	Euclid
	Lunovus	Paragon
	Sight Sciences	Pentavision
	Oyster Point	Vistakon / Johnson & Johnson
	Tarsus Pharmaceuticals	Valley Contax
		Wave

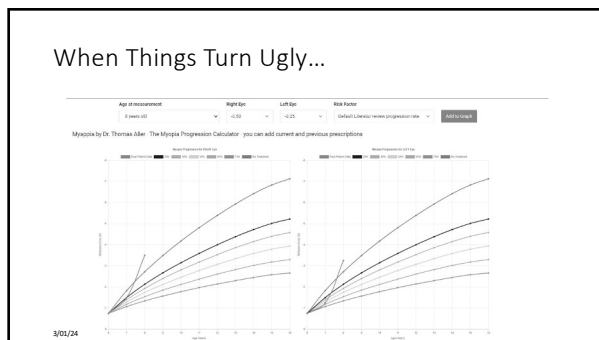
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### Financial Disclosures (Jones)

*Over the past three years, CORE has received research funding and/or honoraria from the following 17 companies & 7 funding agencies:*

• Alcon	• i-Med Pharma	• Santen
• Azura Ophthalmics	• Johnson & Johnson Vision	• SightGlass
• Bausch + Lomb Corp	• Menicon	• SightSage
• CooperVision	• Novartis	• Topcon
• Essilor	• Ophtecs	• Visioneering
• Hoya	• Oté Pharma	• Tech Inc

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### How Do We Prevent Ugly Myopia Management?

1. Embody the **WHY** in how you practice and communicate
2. **KNOW** your options... ALL of them, including when and where to refer
3. Discuss **EVIDENCE-BASED SAFETY**
4. Practice from a **BEST ETHICS** perspective
5. Understand consequences of non-compliance and implement strategies to **ENHANCE COMPLIANCE**

Figure 1. An early model for evidence based clinical decisions from Haynes et al. 2002. Image retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1255444.pdf

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### Good: Start With Your Why

- It was all good until 7<sup>th</sup> grade
- -1.25D onset of myopia
- Progressed each year
- Successful Lasek 2009

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**In the 90's- Limited options and limited knowledge**

Younger Brother -6.50D (onset age 4)  
 Me -4.75D (onset age 13)  
 Younger sister -1.25D (onset 16)

Parents Presbyopia onset 40+

**3 blind mice**

Data gathered by COMET II Study

**Saga Continues**

My youngest daughter -0.75D onset age 9

**Why: Parents Are Interested**

**70%** of parents wanted to pursue myopia control

**88%** were unaware of myopia control & complications of high myopia

Parents Perceptions of Myopia and Myopia Control  
 Meyer, M.D., et al. Ophthalmology 2019; 126(11):2118-21 Abstract  
 156 subjects, 3 University Sites

Global Myopia Awareness Coalition Survey 2021  
 McCrann S et al. Ophthalmic Physiol Opt. 2018

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**When Practitioners Will Consider Myopia Management Options?**

Minimum Age (years)      Minimum Refraction (D)

**7.7 ± 5.9**      SV Specs      **-0.7 ± 0.4**

**Myopia Management**

**9.4 ± 4.9**      MF Soft      **-1.2 ± 0.7**  
 Approved Myopia Control Soft      **-1.3 ± 0.7**  
**10.7 ± 6.1**      Ortho-K      **-1.3 ± 1.0**

Mean ± SD

Wallford JS, Galani A, Cho P, et al. Global trends in myopia management attitudes and strategies in clinical practice - 2019 Update. Contact Lens-Spectrum Epub 2020/01/15.

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**Why: Each Diopter of Myopia Matters**

**Every 1D increase in myopia increases the risk of MMD by 67% and RD by 30%.**

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Bullimore MA, Bracken MA. Myopia Control: Why Each Diopter Matters. Optom. 2014; 95(4): 12-5. <https://doi.org/10.1016/j.optbase.2014.02.005>

**Why: Myopia Carries a Risk of Ocular Pathology**

The increased likelihood (odds ratio) of a myopic person > 60 years developing eye disease versus an emmetrope by degree of myopia

	DEGREE OF MYOPIA		
	-0.50 to -3.00 D	-3.00 to -6.00 D	-6.00 D or more myopic
MMD	13.6	73	846
RETINAL DETACHMENT	3.2	8.8	12.6
VISUAL IMPAIRMENT*	0.9	1.7	5.5*

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Hawton AG et al. The Consequences of Myopia in Retina and Macula. Invest Ophthalmol & Vis Science 2020; April 01:46. <https://doi.org/10.1167/19.10.046>

## New Literature Alert: Updated US Data

HOME > SCIENTIFIC RESEARCH > ARTICLES > ARTICLE

Article | Open Access | Published 23 September 2023

### The underestimated role of myopia in uncorrectable visual impairment in the United States

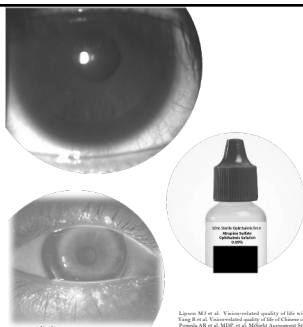
Mark A. Bullimore<sup>1,2</sup> & Neil A. Stanton

Scientific Reports 13, Article number: 19283 (2023) | Cite this article

460 Accesses | Metrics

- It is predicted that between 27 and 43% of uncorrectable visual impairment in the US population in 2050 will be directly attributable to myopia.
- Failure to account for the increasing prevalence of myopia among the aging population leads to a substantial underestimate of the prevalence of visual impairment.

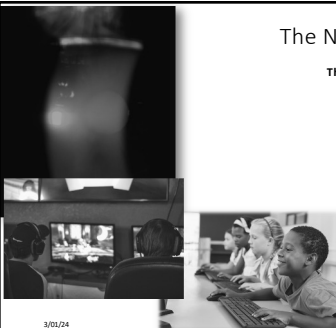
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## Good: Vision-Related Quality of Life

- Higher VR-QoL scores for children wearing **Ortho-K** than SCLs or SV spectacles
- Higher VR-QoL for **SCL wear for myopia control** than SV spectacles
- Minimal impact on VR-QoL with daily use of various concentrations of **atropine**, **recommended it to near**.

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## The New Ugly: Dry Eye

**The incidence of dry eye and myopia have increased dramatically in modern society: Coincidence? 2022 Update**

Tear film break up time was associated significantly with the choroidal thickness in children 4-16 years-old.<sup>1</sup>

Significant clinical findings dry eye symptoms and TBUT<sub>1</sub> in patients with high myopia might be associated with high myopia in teenagers.<sup>2</sup>

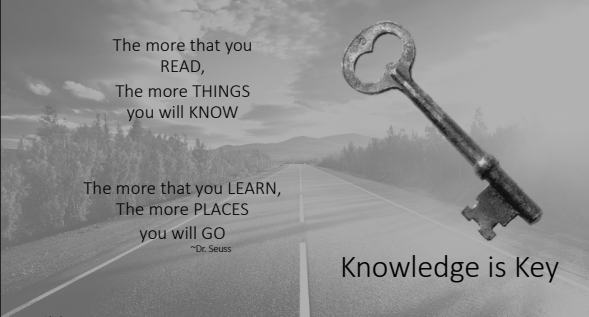
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## Panel Discussion: Let's Talk Dry Eye

Do you think there is starting to be a need for dry eye protocols for children in the myopia clinic?




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The more that you READ,  
The more THINGS you will KNOW

The more that you LEARN,  
The more PLACES you will GO

~Dr. Seuss

## Knowledge is Key

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## Guide with Knowledge

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# Take A Proactive Approach


Evaluate and Educate



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## Educate Parents and Minor Patients

- The Copenhagen Child Cohort 2000 Eye Study is a prospective, population-based, observational study.
- 1443 participants (45%) boys
- Healthy 16-17-year-olds, lower physical activity and more use of screen devices
- 25% prevalence of myopia
  - low activity in teens increase myopia.




Low physical activity and higher use of screen devices are associated with increased risk of myopia in 16-17 year olds in the C2000 Eye Study.

Hansen MM, Lagaard PP, Olsen EM, Skougard AM, Larsen M, Kessel L, Marchi IC. Low physical activity and higher use of screen devices are associated with myopia in the age of 16-17 years in the C2000 Eye Study. *Acta Ophthalmol.* 2020 May;98(3):322-321. doi: 10.1111/aos.14242. Epub 2019 Sep 9. PMID: 3152414.

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## Tips how to start the conversation

- Ask parent and child to list his or her extra curricula activities for the school year.
- Provide information on the importance of "Device Holiday"
  - Recommend everyday power down devices for 1-2 hours and replace with outdoor activity or family activity.
  - Hold handheld devices (phone, tablet) at 14 inches. View gaming console sitting 8 feet from TV.
- Be supportive and understanding of various family dynamics
  - Single family household
  - Unsafe outdoor space
  - Meet people where they are.
  - Practice assistance
- Determine the family vision goals and value proposition.



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## GOOD Current Myopia Treatments




- Contact Lenses
- Atropine
- Spectacles
- Environment
- New Treatments??

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## BAD Barriers To Adoption



- Equipment Concerns:** Often requires specialized equipment, representing a significant investment for practices.
- Time Commitment:** These treatments often demand more time for patient education and follow-up, which can strain resources.
- Out-of-Pocket Costs for Patients:** Effective myopia management strategies are not covered by insurance, possibly making them financially inaccessible for some families.

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## Turning BAD into GOOD

- Equipment Concerns: LEVEL UP!!**
  - Level 1 – Beginner**
    - Diagnose / Educate / Refer
  - Level 2 – Competent**
    - Diagnose / Educate / Limited Treatment
    - Spectacles, Atropine, Soft Lenses
  - Level 3 – Proficient**
    - Diagnose / Educate / Treatment
    - Orthokeratology, Axial Length Measurements
  - Level 4 – Expert**



**Financial Concerns**  
Leasing Equipment: Instead of purchasing, consider leasing options  
**Shared Resources:** Collaborate with other local practices to share the use and cost of specialized equipment.

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## Turning **BAD** into **GOOD**


- **Time Commitment:**
  - **Delegation and Team Training:** Train staff members to take on certain aspects of myopia management, such as initial screenings or patient education. This allows the practitioner to focus on diagnosis and treatment planning.
  - **Efficient Scheduling:** Allocate specific days or hours for myopia management appointments. This can streamline the process, making it more time-efficient and less disruptive to the practice's regular flow.




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## Turning **BAD** into **GOOD**

- **Out-of-Pocket Costs for Patients**




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We need to build our own confidence in financial discussions. Starts with being able to understand the value ourselves.

- Tools**
1. Equip yourself with data and narratives that emphasize the long-term benefits and cost savings of effective myopia management.
  2. Develop clear pricing structures for myopia management services and communicate these openly on the practice's website, brochures, and during initial consultations.
  3. Provide a detailed breakdown of what the treatment includes, such as the extent of follow-up care, the technology used, and the personalized nature of the treatment plan.

## **UGLY** Perceived Complexity


- **Complexity of Treatment:** Myopia management is seen as a complex field, with a need for specialized knowledge and skills. This complexity can be overwhelming, especially for practitioners without access to continued education or mentorship in this area.



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## Turning **UGLY** into **GOOD**

- **Complexity of Treatment:**
  - Training Aspect
  - Practice Efficiency
  - Patient Education and Engagement




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Training Aspect:

**Don't Do It Yourself:** Lean on the manufacturers. Utilize decision support tools that guide you through the diagnosis and treatment process. These tools can help in selecting the most appropriate management strategy based on individual patient profiles.

## Turning **UGLY** into **GOOD**

- **Complexity of Treatment:**
  - Training Aspect
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Practice Efficiency:

**Feedback Loops:** Establish mechanisms for regular feedback from both patients and staff on the MM process. Use this feedback to identify areas for improvement and implement changes to enhance efficiency and patient satisfaction.

## Turning **UGLY** into **GOOD**

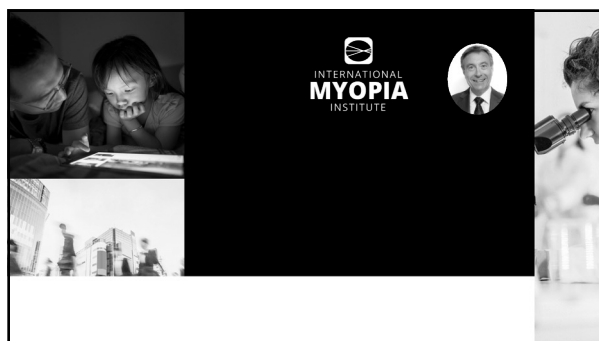
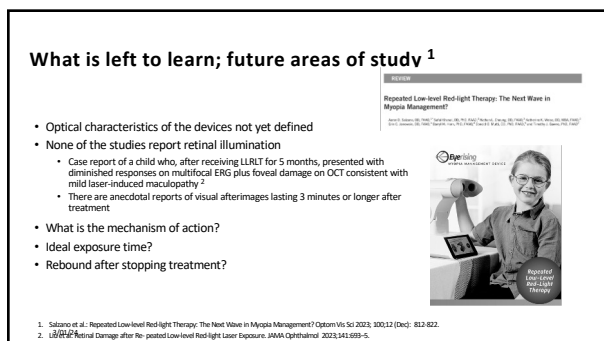
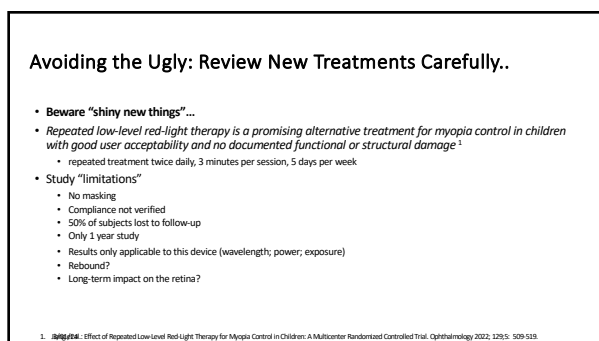
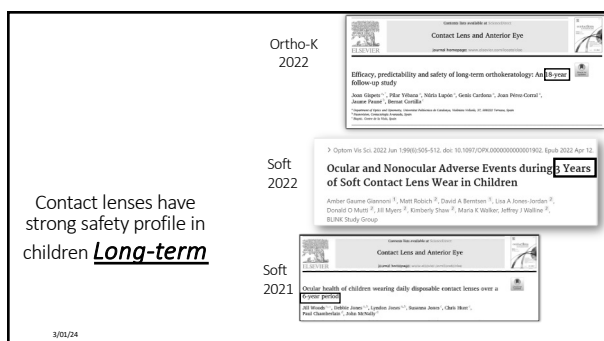
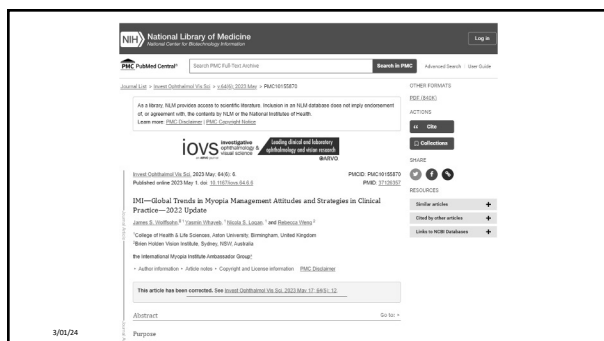
- **Complexity of Treatment:**
  - Training Aspect
  - Practice Efficiency
  - Patient Education and Engagement




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Patient Education / Engagement:

**Simplified Communication:** Develop patient education materials that explain myopia management in simple, understandable terms. Use visuals and analogies to explain complex concepts.



Jones et al.: IMI - Industry Guidelines and Ethical Considerations for Myopia Control Report. Invest Ophthalmol Vis Sci 2019; 60:3: M161-M183.



14 academics; 3 industry employees  
8 countries

Lyndon Jones, Björn Drobe, José Manuel González-Méjome, Lyle Gray, Timo Kratzert, Steve Newman, Jason J. Nichols, Arne Ohlendorf, Stephanie Ramdani, Jacinto Santodomingo-Rubido, Katrina L. Schmidt, Donald Tan, Kah-Ooi Tan, Fuesanta A. Vera-Diaz, Yee-Ling Wong, Kate L. Gifford, Serge Resnikoff

**The aim of this subcommittee was to discuss guidelines and ethical considerations associated with the development and prescribing of treatments intended for myopia control (MC).**


Update: Sankaridurg et al.: IMI 2023 Digest. Invest Ophthalmol Vis Sci 2023; 64:6: 7.

**IMI 2023 Digest**

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### Ethical considerations in implementing MC treatment


- Deciding whether to implement a MC strategy represents the classical medical 'risk versus benefit' ratio
- A principal motivation is based on the unverified premise that limiting the extent of myopia progression reduces the risk of the development of vision-threatening disease in later life
- Conclusive evidence** showing that preventing myopia onset and/or slowing myopia progression results in the prevention of myopia-related ocular pathology is unlikely to be available for decades
  - BUT - if this assumption is correct, then the benefits to individuals and society could be substantial
- Thus, the risk-benefit analysis must take account of the outcomes arising from non-intervention



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### Quality of Life (QoL) considerations

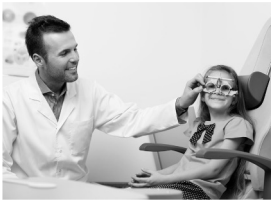
- QoL issues
  - inconvenience of spectacle or CL wear
  - increasing reliance on corrective devices
  - cultural stereotyping associated with corrective devices
- Spectacle and CL-corrected myopes report increased concerns regarding the likelihood of injuring themselves, difficulties coping with normal demands of daily life and less confidence in everyday activities
- Adults with pathologic myopia report significant social and emotional impacts and reduced life satisfaction
- These issues may lead to introversion, anxiety, low self-esteem, and less perceived attractiveness



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### Dealing with vulnerable populations


- Deciding to implement MC places a **burden of responsibility on the practitioner**:
  - be fully cognizant of the risks for the patient of developing different levels of myopia
  - be aware of the implications that progression to higher levels of myopia may have
  - understand the likely benefits of treatment
  - appreciate the potential side-effects of treatment



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### Conflicts of Interest (COI) considerations


- COI considerations
  - all ECPs function in positions of trust
  - researchers must appropriately present results of research without overstating their significance, so as not to unduly influence a clinician/patient in deciding to undertake MC treatment
- Researchers and clinicians often partner with companies to conduct MC studies
  - there is a risk for these partnerships to introduce bias and ECPs should be aware of the importance of evaluating any real or perceived COI when recommending a management plan for MC



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### Conflicts of Interest (COI) considerations


- These interactions between practitioners and companies must meet the highest possible standards of integrity and transparency
  - relationships between clinicians and patients should not be compromised by commercial or other interests that could subvert the principle that the interests of patients are the primary concern
- All entities involved in MC practice or product development must disclose any potential COI, including any research funding sources, when discussing or presenting their findings, regardless of the medium being used



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### Informed consent (IC) considerations


- IC considerations
  - not simply a signature on a piece of paper
  - an important piece of communication between the ECP and the patient
- Each patient must be fully informed
  - balance the risks of no treatment against the risks of treatment
  - encouraging them to participate in the decision-making process is vital
- Some MC treatments remain off-label in some countries
  - most organizations do not restrict the ECP from discussing off-label treatment uses or distributing written materials on them
    - as long as the patient is informed of this
- Given that patients and their families generally assume that a treatment prescribed by their clinician has been proven safe and effective and is supported by scientific evidence, we recommend all practitioners use an informed consent process
  - regardless of whether the treatment is on-label or off-label – but especially if it is off-label



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### Ethical considerations in implementing MC treatment

- As this population is categorized as a vulnerable population for clinical research and care, parents should sign an informed consent document
- Could also consider providing information in the form of a written “assent” document for the child that includes:
  - age-appropriate language aimed to help them understand:
    - the nature of the condition (i.e., myopia)
    - what to expect with each of the recommended MC treatment(s)
    - that there is no pressure to accept the MC therapy
- Current literature suggests that adolescents aged 14 and older typically have well-developed decisional skills and are capable of making informed health care decisions



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**MYOPIA**  
INSTITUTE

### Regulatory bodies

- Marketing a medicinal product requires a marketing authorization (“product license”) for specified indications under specified conditions (e.g., target population, indication, and specific use), regulated by the country’s medicines and health care products regulatory agency
- Prescribing a licensed product outside of the approved scope of use is called “off-label” prescribing, whereas prescribing a product that does not hold a marketing authorization is termed “unlicensed” prescribing
- Manufacturers are prohibited from marketing (or promoting) off-label or unlicensed use of products
- The prescribing of a product (regardless of whether on-label, off-label, or unlicensed) is a decision taken within the relationship between the patient and the ECP

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### Regulatory bodies

- The term “off-label use” is widely used
- The most common definition is “the prescription of a medication or device that is available and marketed but for a different indication than it was approved for, by the appropriate regulatory body”
- Off-label uses include:
  - giving an approved drug (or device) for a disease or indication other than the disease for which it is approved
  - prescribing a drug at a different dose, frequency, or route of administration than specified in the label
  - using the drug/device to treat a child when the product is only approved to treat adults
- If an ECP uses a product for an indication not in the approved labeling, they have the responsibility to:
  - be well informed about the product
  - base its use on firm scientific rationale and on sound medical evidence
  - maintain records on the product’s use and effects

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### Regulatory bodies

- Frequency of off-label use is high, covers a broad range of therapeutic areas, and is common practice all over the world
  - in particular in pediatrics, oncology, neurology, infection and geriatrics
- The majority of medical and surgical devices used in children do not have approval from regulatory bodies for use in pediatric populations
  - morphine has never been approved by the FDA for pain treatment in children, but is widely used
  - many inhaled bronchodilators, antimicrobials, anticonvulsants, and proton pump inhibitors are used in pediatric patients, without approval
- CL, which typically have a marketing authorization for lens wear in adults only, are frequently fitted “off-label” to minors
- Several MC methods have been “shown” to work in well-controlled studies but are not yet approved for the control of myopia progression




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### Manufacturers



- Manufacturers have a large part to play in the ethical decisions around the ECP prescribing of MC treatments
  - ensuring that the discussion of the efficacy of a treatment is appropriately reported
  - that the treatments are manufactured using rigorous methods to ensure their quality
- Efficacy claims
  - randomized, controlled clinical trials are the gold standard to minimize bias
    - but case-control trials are also a commonly accepted means of assessing efficacy
  - changes in refractive error and/or axial length are compared between test and control devices to evaluate MC efficacy
- Ultimately, MC efficacy should be demonstrated in controlled clinical studies on human participants and regulatory approval sought to authorise "on-label" prescribing of the product



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### Academics


- Academics have an important role in disseminating scientific information related to MC treatments, which is typically undertaken in the form of
  - peer-reviewed journal articles
  - abstracts and presentations at major scientific conferences
- Many academic institutions and professional organizations offer continuing education programs, courses, and workshop options
  - ECPs using these resources seek high-quality, evidence-based education to implement into their clinical practices
- Other potential sources of educating ECPs include professional (non-peer-reviewed) publications and direct peer-to-peer interaction
- The evidence provided must be credible, evidence-based and not influenced by any COI issues

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### Eyecare practitioners


- Practitioners have a responsibility to care for their patients by recommending MC treatments using evidence-based practice
  - this means using published evidence + clinical judgment to determine the best management for the young myopic patient
- To avoid the potential for a malpractice claim, the ECP has to justify the professional rationale behind the MC treatment prescribed
- When prescribing an off-label/unlicensed MC treatment, an increased level of caution and monitoring must be demonstrated to monitor for any adverse events.
- The ECP should only consider prescribing an off-label/unlicensed treatment option for MC if there is sufficient evidence supporting its safety and efficacy
  - when such proof exists, failure to prescribe an off-label/unlicensed MC treatment could, arguably, result in an ECP being liable for not following the appropriate standard of care for their patient



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### Responsibilities in marketing support and education

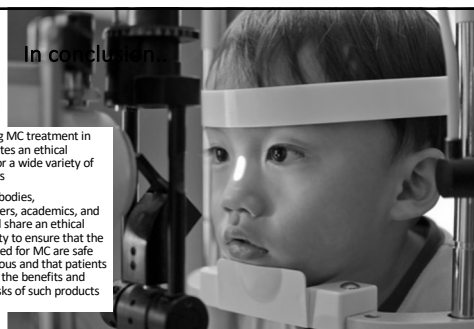
- MC cannot be implemented widely without a strategy for transferring the required knowledge and skills to
  - ECPs - who are in the front-line seeing patients
  - academics - who are key in training future clinicians
- Many scientific conferences that include information on MC are typically annual or biannual events that many practitioners will not have an opportunity to attend
- Structured and locally delivered CPD is critical to equip clinicians and academics with the knowledge and skills required
- There is a need for
  - CPD programs for a variety of ECP and support staff
  - standardized educational materials to cater for the varying levels of training required in various countries or regions
- Industry partners are likely a key source of funding
  - sponsorship for such programs needs to be managed ethically and professionally to avoid any potential COI



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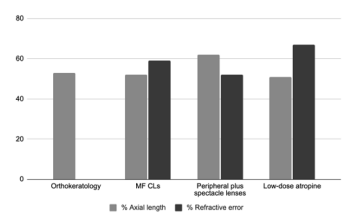
### In conclusion

- Undertaking MC treatment in minors creates an ethical challenge for a wide variety of stakeholders
- Regulatory bodies, manufacturers, academics, and clinicians all share an ethical responsibility to ensure that the products used for MC are safe and efficacious and that patients understand the benefits and potential risks of such products




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### From Ethics to Efficacy



Treatment	% Axial length	% Refractive error
Orthokeratology	~55	~55
MF CLs	~55	~60
Peripheral plus spectacle lenses	~60	~55
Low-dose atropine	~55	~65

Figure 1. The percent slowing of axial elongation and myopic refraction progression in orthokeratology contact lenses, soft multifocal contact lenses (MF CLs), orthokeratology contact lenses, and low-dose atropine. Adapted from Myopia Control in 2019, by Jeffrey Walline, March 2019.



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### What Does Compliance Involve?

- Efficacy is ALSO the product of patient action, and appropriate treatment selection by a myopia management provider to best match a patient's ocular shape, refractive error, and lifestyle.
- Patients are more likely to be compliant with therapies when they are motivated and involved in the process. When it comes to contact lens use, discussing lifestyle and hobbies may uncover benefits such as freedom from glasses for performance.
- Any medical devices will only be successful with safe and compliant use; careful consideration of the patient's whole physical structure, lifestyle, home support, and personality are essential for myopia management success.

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### Compliance Driven Success... The Ugly

**Scenario 1:** A careful discussion about all treatment options for a 7-year-old patient with -0.75 diopters of myopia yielded a final decision between starting atropine drops or full-time wear of myopia control glasses; gasses were selected. The patient returned to the clinic for follow up 6 months later and had nearly doubled in refractive error. It turned out that while parents thought the patient was wearing glasses full-time as directed at school, the patient would remove them.

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### Compliance Driven Success... The Ugly

**Scenario 2:** It was recommended that a patient use both glasses and contact lenses, with myopia control optics in them; only myopia control daily wear contact lenses were purchased with the intention to wear the devices at least 70% of waking hours to be effective, with the patient's habitual single vision glasses the remaining 30% of the time. The patient returned to the clinic for follow up 18 months later and had increased in axial length by 0.4mm (~1.3D). It turned out that the patient ran out of myopia control contact lenses after wearing them about 50% of the time for a year and single vision glasses the remaining 50% of the first year and then full time for six more months

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### Compliance Driven Success... The Ugly

**Scenario 3:** A high myope (-6D) with corneal astigmatism (-2.5D) was selected for orthokeratology treatment. Despite best lens modifications and training with lens handling, the patient struggled with lens adhesion and inadequate final treatment. This resulted in a lengthy fitting process with multiple times out of lenses, blurry distance vision, and eventual drop out of the devices. The patient progressed during this time.

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### Panel Discussion: Compliance Driven Success



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### Ugly: State of Myopia Management in Underprivileged Countries

1. There is a need for **global** awareness about options to prevent myopic progression.
2. There is an need for specialty eye care, specifically for dry eye and myopia management.
3. There is a need for continued development of sustainable clinics, which can be accomplished by training local eye care providers.
4. Economics play a significant role in access to care and materials in all countries globally; future effort for international mission trips could seek to establish access to myopia control spectacles or other therapies.
5. Specialty contact lenses are largely underutilized in developing countries due to practicality and access of care, including for infant aphakia, irregular corneas, and myopia management.
6. Local COs and OMDs in Jamaica were highly interested in learning about myopia management, and specialty contact lenses; I would guess this would also be the case in many other Caribbean countries around the world.




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## Managing Patients to Prevent Adverse Events

1. Key Areas to Consider:
  - i. Eye considerations versus lifestyle considerations
  - ii. Communication with patients and caregivers/parents in the myopia clinic
    1. Do not minimize risks
    2. Provide written information
  - iii. Appropriate follow-up schedules
    1. Book next return to clinic when patient checks out
  - iv. Adverse event management triage and clinical protocols
    1. Red eye
    2. Solution mis-use
  - v. Setting up systems for improved compliance
  - vi. In-office adverse events

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## Conclusion

- Ethics are at the root of all responsible medical practices
- Safety and compliance are necessary to continue to practice how we want, with best outcomes for patients, and build/maintain trust of our colleagues in other professions

