FROM DARKNESS TO LIGHT ®

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All India Ophthalmological Society

Consensus Guidelines for Prevention and Management of **Childhood Myopia**

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In children with **Progressive Myopia***

RX **Kidtro**™

Atropine 0.01% w/v Ophthalmic Solution

No kidding with progressive myopia

FIRST DCGI APPROVED FORMULATION

With **well tolerated preservative of PHMB** Polyhexamethylene biguanide hydrochloride 0.05mg[1^]

- Only drug approved to control the progression of myopia[2]
- Safe and efficacious in controlling myopia progression in Indian children[3]
- Myopic rebound lowest with atropine 0.01% as compared to 0.1% and 0.5%[4]

References: *Kidtro is indicated to control the progression of myopia in children of 5 years and above. ^ Data on file. DCGI: Drugs Controller General of India PHMB: Polyhexamethylene Biguanide | 1. Mashat BH. Polyhexamethylene biguanide hydrochloride: features and applications. British Journal of Environmental Sciences. 2016;4(1):49-55. | 2. Available from cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTIxNg== as accessed on 22.01.2021. | 3. Vidhya C, Murali K, Sowmya R. Safety and efficacy of reconstituted atropine 0.01% eye drops for Indian children with myopic progression. Asian Journal of Ophthalmology. 2020 Apr 30;17(2):209-15. | 4. Chia A, Chua WH, Wen L, Fong A, Goon YY, Tan D. Atropine for the treatment of childhood myopia: changes after stopping atropine 0.01%, 0.1% and 0.5%. American journal of ophthalmology. 2014 Feb 1;157(2):451-7.

Abridged Prescribing Information Generic Name: Atropine Sulfate Ophthalmic Solution USP 0.01% w/v **Kidtro Composition** Each ml of **Kidtro** Contains: Atropine Sulphate IP 0.1 mg Polyhexamethylene biguanide hydrochloride 0.05 mg (As preservative) Sterile Aqueous Vehicle q.s. **Dosage form and strength** Ophthalmic solution; 0.1 mg/ml **Therapeutic Indications Kidtro** is indicated to control the progression of myopia in children of 5 years and above. **Posology and method of administration** Instill one drop daily to each affected eye(s) at night or as directed by the Physician. **Contraindications Kidtro** is contraindicated in: patients with glaucoma or narrow angle glaucoma. patients with history of hypersensitivity to atropine or any of the inactive ingredients in this formulation. **Special warnings and precautions for use** FOR EXTERNAL USE ONLY. NOT FOR INJECTION. Overdose and allergy to any of ingredients may cause systemic toxicity in children. Blurred vision may occur after use. Due to low pH which is necessary to stabilize atropine, the drop may cause mild burning. **Drugs interactions** The use of atropine and monoamine oxidase inhibitors (MAOI) is generally not recommended because of the potential to precipitate hypertensive crisis. **Use in special populations** Atropine Sulfate Ophthalmic Solution USP 0.01% w/v is indicated for the children. It is contraindicated in patients with glaucoma or narrow angle glaucoma. **Effects on ability to drive and use machines** Blurred vision may occur after the use of Atropine Sulfate Ophthalmic Solution USP 0.01% w/v. Patient should avoid driving a vehicle. **Undesirable effects** During use, photophobia and lack of adequate vision may occur. There have been reports of eyelid allergic reaction, local irritation, hyperaemia, swelling, follicular conjunctivitis or dermatitis.**Overdose** Due to single administration and low expected systemic passage of atropine, overdose is not expected. However, a risk of overdose cannot be excluded. Symptoms of systemic atropine toxicity include flushing of the face, dry skin (red rash may occur in children), blurred vision, accelerated or irregular heartbeat, fever, abdominal distention, constipation, delirium, uncoordinated nerves and muscles, trance and long-term mydriasis in the elderly. In case of overdose, rinse with water or 0.9% normal saline water. In case of accidental ingestion (if swallowed), it may cause vomiting or gastric lavage. Systemic support measures and intravenous injection of physostigmine should be used, if necessary. Refer to full prescribing information of Kidtro before use. Full prescribing information available on request.

Myopia Consensus Group

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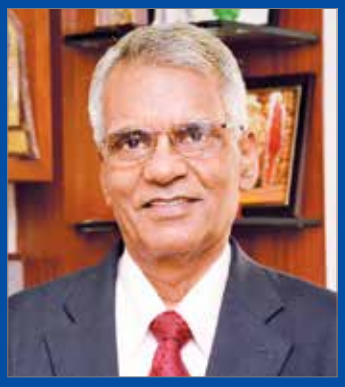

Dr. Barun Kumar Nayak
President
All India Ophthalmological Society

MESSAGE

Dear Colleagues,

Myopia is a major visual problem in children which compounds if it is not detected and left untreatment. The treatment of Myopia has two elements. The first being the correction of the refractive error resulting in normal vision without jeopardizing the activities of the children whether it is study, sports or day to day activities, which if remains unattended hampers the child's all round development significantly. While in some children it remains stable, others show gradual progression till the age of 18 to 20 years. This makes the 2nd part of preventing and arresting the progress of Myopia, equally important.

Till a decade ago it was presumed that we cannot prevent the incidence or arrest the progression of Myopia. However, a lot of studies in the recent past have proved otherwise.

I am happy to note that Dr Rohit Saxena along with prominent pediatric ophthalmologists have come together and created a consensus guidelines based on the multiple published literature for prevention and management of childhood Myopia. This deals with the various aspects of Myopia such as classification, appropriate clinical evaluation, corrective options of management, counseling and guidelines for the measures taken for arrest of progression in myopia.

I congratulate the entire group in sparing their valuable time and creating these guidelines which will be extremely useful for the practicing ophthalmologists. This will not only help build a better career of the children but also reduce a huge economic burden on the nation.

I recommend this document for all the fellow members to go through and make good use of the information.

Sincerely yours,

Dr Barun Kumar Nayak
President
All India Ophthalmological Society

Prof. (Dr.) Namrata Sharma
Hony. General Secretary
All India Ophthalmological Society

MESSAGE

Dear friends,

It is indeed a proud privilege to bring out this National, Expert Based Consensus Statement regarding Management of childhood myopia. While there have been many guidelines published by pediatric ophthalmologists from the west, there has been no such practice patterns available for Indian ophthalmologists and what would be the preferred clinical practice for our country. This document hopes to fill this void and provide guidelines best suited in the Indian scenario.

This is a document that has evolved after some of the most experienced and learned in this field have got together and evolved a consensus on this topic. It contains essential information and practice patterns that every ophthalmologist must be aware of whenever examining and managing a child with myopia.

I wish to thank Sun for funding this extremely important endeavor and providing the logistics for holding the meeting. I also wish to thank all the participants who have taken out time to provide their knowledge and experience that has enabled this document to become an essential tool for every ophthalmologist. I must also express my gratitude to Prof. Rohit Saxena who helped us to organize this meeting and put the document in place.

We hope that you all will find this a useful and practical guide and use it in your day to day clinical practice.

With best wishes,

Prof Namrata Sharma
Secretary,
All India Ophthalmological Society

Prof. Rajesh Sinha
Hony. Treasurer
All India Ophthalmological Society

MESSAGE

Dear Friends,

I am writing to you with the hope that your practice and patent load has come back to normal as it was in the pre-covid era. The covid situation in the country is quite satisfactory and better than most of the country world-wide; however, adequate precautions and use of mask have to be continued in order to maintain safety and well-being.

The focussed group meeting on the Myopia control was a wonderful initiative by Prof Rohit Saxena and we at AIOS like to support all such initiatives which helps in improving the academics amongst our fellow ophthalmologists which thereby improves patient care. Prevention of progression of myopia is a burning issue amongst all and especially the paediatric ophthalmologists. A lot of research is being performed in this field making use of various concentrations of atropine eye drops. Although there are some positive outcomes, however it needs more work in order to establish the use of atropine eye drops as a definitive measure to prevent progression of myopia. The guidelines that we are sending to you is one effort in the direction of handling progression of myopia. I hope it will act as a food for thought for everyone to work in this direction so that in due course of time we will be in a position to make a definitive statement in front of our patients.

The AIOC 2022 is being organised at the JIO convention centre at BKC, Mumbai. The convention centre is a world class venue and I am sure a physical meeting in such a venue will provide a lot of positivity in the minds of our colleagues. Meeting the members of our fraternity after such a long gap has already created a lot of excitement amongst our ophthalmology colleagues. I urge the members to attend the conference and make it successful.

I wish you all a very safe and successful year ahead.

Best regards

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Prof. Rohit Saxena
Convenor
Myopia Consensus Group

EDITORIAL

Myopia or short sightedness constitutes a significant health problem in children worldwide. The prevalence of myopia has shown a rising trend in the past few decades not only globally, but also in India. Moreover, in the ongoing COVID pandemic, virtual platforms have replaced physical teaching and outdoor activities have decreased due to various restrictions in place. This has led to increased screen time and near work, further accelerating the development of myopia in school going children.

Hence there is an urgent need to address this potential public health crisis and raise awareness among ophthalmologists about the various modifiable environmental risk factors for myopia, available anti myopia interventions and their correct usage.

The International Myopia Institute has featured a series of white papers defining and classifying myopia, potential interventions and clinical management guidelines in myopia. However, there is a need for standardized guidelines applicable to Indian scenario due to ethnic differences and disparity in the availability, regulatory approval and affordability of the existing interventions.

With this shared goal in mind, paediatric ophthalmologists across India held a hybrid meeting and formulated guidelines that can be followed pan India to curb the growth of myopia amongst school going children. These guidelines have been formed keeping in view the current scientific literature available and will keep evolving as new evidence generates. This consensus guideline attempts to provide a continuum of care for preventing myopia onset and progression based on the current evidence. However, the standard of myopia care may change in the light of new research and therefore the clinicians must keep themselves updated with any new developments in this rapidly evolving field.

I wish to thank all the participants of the meeting who have provided great insights during the creation of this document as also Dr Swati Phuljhele, Dr Rebika Dhiman, Dr Asmita Mahajan, Dr Vaishali Rakheja and Vinay Gupta who have helped me in compiling all the information discussed in the meeting and put it together in a simple and easy to understand text.

I also wish to thank AIOS and particularly Dr Barun Nayak, the President, Dr Namrata Sharma, the Secretary and Dr Rajesh Sinha Treasurer who gave us the opportunity and support without which this document would not have been possible.

I hope all the readers find this a useful document and use the information provided in their routine clinical practice.

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Consensus Guidelines for Prevention and Management of Childhood Myopia

Uncorrected myopia or short sightedness is a major cause of visual impairment in the young population. There is an urgent need to address childhood myopia as an important health issue and take steps to prevent its onset and decrease its progression.

The objective of the meeting was to generate a national level expert consensus statement on the management of childhood myopia in Indian scenario.

Paediatric ophthalmologists from across India met in a hybrid meet organized on 8th August 2021 to discuss the current practice patterns for childhood myopia encompassing the basic definitions, essential work-up, indications for intervention to slow progression in myopes and to prevent the development of myopia in pre-myopes. The experts shared their experiences and discussed challenges currently faced in managing this refractive error. The expert panel deliberated on different aspects of childhood myopia and reached a consensus regarding the practice patterns in the Indian scenario.

All expert panelists and key opinion leaders in the field of paediatric ophthalmology concurred with regards to the lack of clear recommendations as to the exact definition of myopia, refraction techniques, components and methods of work-up, initiation of anti-myopia treatment, type and timing of interventions, follow-up schedule and indications for revised or combination treatment.

The final consensus statement derived is below.

Extent of the problem

Myopia is emerging as a public health problem worldwide and in India.

Globally

- The current prevalence of myopia is 22.9% (2.7% high myopes) and by 2050, it is expected to affect 50% (4758 million) of the world's population with 10% (938 million) being high myopes[1]
- Prevalence is highest in developed parts of East Asia and South East Asia
  - 80-90% in young adults in Singapore, Hong Kong, Taiwan, South Korea and Japan [2,3]
- Prevalence in Europe and North America is 30-40% [4,5]
  - Higher than Africans, Hispanics, and South Asians
- Prevalence is expected to rise further after COVID lockdown restrictions leading to lesser outdoor activity and greater near work

In India

- Prevalence in last 4 decades- 7.5% in Indian children aged 5-15 years with an increasing trend in last 4 decades [6]
  - 8.5% in urban areas
  - 6.1% in rural areas of India- a significant increment is noted in rural children from 4.6% in 1980-2008 to 6.8% in 2009–2019
  - Near doubling of myopia prevalence in both rural and urban children aged 11-15 years
  - Data unavailable for high myopia
- Though the prevalence is comparatively less in India, considering the huge population of the country the actual numbers may be staggering
- Myopia prevalence in urban India has been projected to spike to 48% by 2050 [7]
- Possible factors responsible for rising prevalence in the country are:
  - Competitive and intensive educational environment in India with more emphasis on extra classes and private tuitions
  - Greater number of hours on computers and video games
  - Less involvement in outdoor sports

Effect of early onset and progression of myopia

- Clinical impact:
  - Visual complications can occur related to uncorrected myopia / high myopia such as
    - Retinal degenerations and detachment
    - Other retinal complications- myopic macular degeneration, choroidal neovascularization, myopic traction maculopathy
    - Myopia associated glaucoma-like optic neuropathy
    - Complicated cataract, esotropia, exotropia, strabismus fixus, etc.
- Socioeconomic impact:
  - Psychological Impact
    - Affects academic performance, personal and psychological well-being with poor quality of life and low self-esteem
  - Economic Impact – Myopia has a global economic impact due to loss of work productivity and due to expenditure on myopia management
    - Affects work productivity by
      - Absence or leave from work
      - Causing visual impairment and blindness
    - Estimated global productivity loss due to uncorrected myopia and myopic macular degeneration is around 244 billion USD per year; Asia being worst affected [8]
    - Millions are spent worldwide on myopia management
      - Economic burden increases with longer duration and early onset of myopia
      - Using estimates of prevalence of uncorrected refractive error in India and the cost of spectacle provision, it would cost approximately 6.3 billion

INR (US$131.6million) to 24.6 billion INR (US$513.7million) to treat the entire affected Indian population with ready-made spectacles and custom spectacles respectively [9]

The rising prevalence of myopia in India can adversely impact the country's economy. This highlights the need for formulating standardized guidelines for prevention and management of myopia.

Standard definitions of myopia (Adopted from IMI) (Annexure I)

International Myopia Institute (IMI) has provided the quantitative and qualitative definition of myopia and structural complications of the disease in IMI White papers. In accordance with this and to maintain consistency with the international standards, the same have been adopted by this committee (Annexure I).

Risk Factors for Myopia

Risk factor assessment helps the clinician to predict the future risk of myopia development and progression.

- **Genetics**
  - Genome-environment-wide interaction study (GEWIS) revealed gene-environment interaction as a major cause of increase in myopia- Higher education with a high genetic load have greater risk of developing myopia
  - Strong genetic basis for secondary myopia that can accompany other systemic or ocular abnormalities- Generally monogenic
- **Age**
  - Younger age of onset is associated with greater myopia progression and related vision-threatening complications- Myopia progresses rapidly in children aged 6 - 11 years
  - Age may also influence the outcome of anti-myopia therapy
- **Gender**
  - Gender differences begin to surface at the age of 9 years- earlier onset of puberty in girls is associated with increased axial length elongation
  - Female predisposition for myopia has been noted in few studies that has been attributed to:
    - Lesser outdoor activities
    - Greater involvement in indoor work
  - Higher myopia prevalence was noted in orthodox Jewish boys as they are more engaged in reading religious texts than girls
- **Parental Myopia**
  - Myopia is heritable
  - History of parental myopia is associated with greater risk of
    - Developing myopia

- Early age of onset of myopia
- Number of myopic parents is a risk factor for onset and progression of myopia.
  - One myopia parent- Risk increases two-fold
  - Two myopia parents- Risk increases three-fold or more

- **Ethnicity**
  - Myopia in East Asian children progresses more rapidly than their European counterparts
  - East Asian and South Asian children are more likely to be myopic even if residing in another country
  - Indians are a low progressing cohort (-0.3 D/year) as compared to the East Asian (-0.6 to -0.8 D/year) [10]

- **Baseline refractive error**
  - Less hyperopic or more myopic refractive error at baseline is the most important risk factor predictive of juvenile onset myopia
  - The cut-offs of age-normal hyperopia (at baseline) for identifying at-risk group for myopia are:
    - <+0.75D for grade 1 (6 years),
    - ≤+0.50 D for grades 2-3 (7 and 8 years),
    - ≤+0.25D for grade 4 (9 and 10 years), and
    - Emmetropia for 11 years
  - Amount of baseline myopia may influence the treatment response - Lower myopia is related with better response to anti-myopia intervention [11]

- **Visual environment**

  This is a major contributor to school-age myopia
  - Outdoor activity:
    - Myopic children appear to spend less time outdoors
    - 40-120 minutes of outdoor time is associated with reduced myopia incidence
  - Near work:
    - Increased risk with higher odds of becoming myopic by
      - Sustained near work (>45 minutes)
      - Reading at very close distance (<20 cm)
      - 2% for every 1 dioptric hour of extra near work per week
  - Educational curriculum
    - Heavy school curriculum leads to greater near work demand resulting in
      - Higher rate of myopia occurrence
      - Faster rate of myopia progression
    - Extensive engagement in afterschool tuition is associated with high prevalence of myopia
    - Higher academic degree- rate of myopia progression is -0.27 D for every additional year of academics
    - Higher academic and intelligence quotient (IQ) scores have been associated with increased risk of myopia in Singaporean population.

- **Accommodation anomalies**
  - Several accommodation anomalies are noted in myopes like
    - Esophoria
    - High accommodative lag
    - High AC/A ratio
  - Accommodation lag and consequent hyperopic blur has been implicated with greater axial length elongation and myopia progression

- **Miscellaneous risk factors**
  - Physical attributes: Height, weight, body mass index, etc.
  - History of low birth weight, prematurity, etc.
  - Increased digital screen time
  - Socioeconomic status
  - Improper diet
  - Reduced physical activity
  - Irregular sleep pattern, poor sleep quality

Workup and management guidelines in childhood myopia (assessing available interventions for prevention and control) (Annexure II)

Baseline work-up in a case of childhood myopia should include

History

- Age and gender
- History of ocular and general health including
  - Perinatal history, history of prematurity, birth weight, developmental milestones, etc.
  - History of Down's syndrome, cerebral palsy, etc.
  - Known allergy to any drug
  - Assessment of nutritional status & vaccination history
- Parental history of myopia- single or both parents & age of onset in parents
- Number of siblings and their refractive error, if any
- History of ocular complaints – frequent rubbing of eyes, headache, watering, holding the books too close to read
- Brief details of child's visual environment such as
  - Amount of time spent outdoors during the day
  - Amount of time spent on near work, type of near work activities, etc.
  - Digital screen-duration, type of digital screen used, etc.
  - Lighting condition at home and at school

If already using glasses for myopia:

- Age of onset of myopia- Congenital, childhood or juvenile onset
- First glass prescription; present glass power; duration of use

- Amount of myopia- Low, moderate, high, pathological
- History of pathological changes- peripheral degeneration, macular changes, glaucoma
- History of progression-Frequency of change in power of glasses
- History of previous myopia control treatments, if any

Ocular examination

Following tests should preferably be done for the work-up of childhood myopia wherever possible based on the cooperation of the child and the availability of instruments.

- Visual acuity
  - Uncorrected and best corrected distance visual acuity (UCVA & BCVA)- ETDRS, Snellen, LogMAR charts
  - Distance corrected near visual acuity (DCNVA)
- Pupillary reaction
- Intraocular Pressure
- Slit lamp Examination for anterior segment and ocular surface
- Dilated fundus Examination- OCT images and/or fundus photos may be taken for documentation
- Cycloplegic refraction- A cycloplegic refraction using 2% homatropine or 1% cyclopentolate is a must for children with myopia as lack of cycloplegia will increase the risk of misclassification. Refractive error can be assessed by:
  - Retinoscopy
  - Autorefractometry: Take at least 3 readings and record the median
  - Open-field autorefractors are recommended to minimize variability due to residual accommodation and instrument myopia and should be used for distance readings.
  - Instruments should be validated and calibrated at regular intervals
  - In case of change in power of glasses, prescribe spectacles based on the current refraction and document the myopia progression in D/year

  Ideally, same method of refraction should be used at baseline and on follow-up.

Certain treatment specific ocular tests may be indicated in some cases:

- Axial length measurement
  - Ultrasound biometry (Immersion technique) and/or
  - Optical biometry (IOL Master, Lenstar, etc.)
    - Other ocular biometric parameter(s) such as keratometry (Km), anterior chamber depth (ACD), vitreous chamber depth (VCD) and lens thickness (LT) may be documented for research purposes

  Multiple measurements should be taken and the mean of the values should be recorded.
- Binocular vision assessment using these tests where possible:
  - Stereopsis & Worth 4-dot test for distance & near with best correction.

- Accommodation lag or lead- using open field autorefractors, Monocular estimate method (MEM) retinoscopy, dynamic retinoscopy or aberrometers
- Amplitude of Accommodation using 'push-up' method or 'minus lens' technique; Royal Air Force (RAF) ruler for measuring near point of accommodation (NPA)
- AC/A Ratio- using gradient method or distance-near disparity method
- Distance and near heterophorias using alternating cover test or Risley prism and Maddox rod, etc.

- Corneal Topography may be indicated in suspicious cases of keratoconus or for contact lens fittings. It may be assessed using keratometer, videokeratography (VKG), pentacam, etc.
- Tear-film assessment using Schirmer test and non-invasive tear break-up time (TBUT) is indicated in older children on chronic topical medications or using orthokeratology lenses
- Other exploratory tests that may be done if indicated are:
  - Peripheral Refraction
  - Pupillometry- photopic and mesopic pupil size
  - Aberrometry for higher order aberrations
  - Macular Optical coherence tomography (OCT) for subfoveal choroidal thickness

MUST DO	GOOD TO DO	EXPLORATORY/ RESEARCH
Visual Acuity	Open Field autorefraction	Peripheral Refraction
Intra-ocular pressure	Axial Length	Pupillometry
Slit Lamp examination	Binocular vision assessment	Aberrometry
Fundus evaluation	Corneal Topography	Macular OCT
Cycloplegic Refraction	Tear-film assessment	

Risk factor Identification

- Assessment is based on child's history
- Risk factor identification is based on the following parameters:
  - Age of the child
  - Age of onset of myopia
  - Parental history of myopia- single/both parents & age of onset in parents
  - Refractive error (cycloplegic refraction)
  - Axial length.

  In addition, environmental risk factors may be considered.
- Factors associated with greater myopia progression are-
  - Younger age of onset of myopia,
  - Higher baseline myopia,
  - Past myopia progression rate of >0.50 D/year
  - Parental myopia

- Environmental risk factors - Decreased outdoor activities + increased near work and digital screen time
- Vitamin D levels

Based on this, risk factor stratification may be done for the child. Greater the number of risk factors, higher will be the risk of progression. While these factors can predict the risk of progression, it cannot determine the rate of progression.

Management

Premyopes

- Compare their refractive error to the age-normal values
- Pre-myopes may show specific binocular vision disorders like increased accommodative lag and higher AC/A ratio
- Management is not yet defined. We can recommend lifestyle and environmental modifications like:
  - Increase in outdoor activities- upto 120 minutes/day of outdoor activity is advocated
  - Reduced near work and decreased screen time
  - Other measures like frequent breaks (20-20-20 rule), ambient indoor lighting, maximizing natural lighting, adequate posture (preferably sitting) and appropriate reading distance while doing near work (25 inches (about at arm's length) from the computer screen)
  - Progressive Addition Lenses (PAL) can be prescribed in patients with accommodative lag

Myopes

Lay terminology communication with parents and patients

Communication with the parents and patients using simple layman terms is of utmost importance that should include following points:

- Explain that the treatment will not limit the activities of the child and he/she can participate in any activity with appropriate corrections (spectacles or contact lenses)
- Make them aware about potential risks associated with progressive myopia & the need for periodic comprehensive examinations including cycloplegic refraction & retinal evaluation
- Help parents understand their child's risk profile and ways to reduce exposure to avoidable risk factors
- Inform them about myopia control treatment options, expected efficacy, and potential benefits associated with them
- Explain to them the risks and associated side effects of myopia control treatment and how we can minimize them
- Take informed consent if myopia control option involves off-label use

Available interventions for myopia control: This list provide all the options available for myopia control in children. The parents should make informed decision after discussing the benefits and risks associated with various treatment options. There is no evidence at present for their use in myopia associated with retinopathy of prematurity, congenital cataracts, etc.

- **Optical Intervention**
  - **Spectacles**
    - Special spectacles are designed with the aim to reduce or eliminate accommodation lag during extended near work by inducing relative myopic shifts in peripheral refractive error. Various types of spectacle designs used in myopia include:
      - Defocus incorporated multiple segment spectacles (DIMS)
      - Spectacles with aspheric lenslets
      - Progressive addition spectacles
      - Bifocal spectacles

    Bifocals and progressive addition lens spectacles are preferred in patients with esophorias and accommodation lag.
  - Some companies like Zeiss (Myovision Pro), HOYA and Essilor have come up with commercially available designs
  - Advantages
    - Simple to use and easy to fit
    - Well tolerated and accepted
    - Effective with peripheral hyperopic defocus
  - Disadvantages
    - Efficacy is less than other interventions
  - Recommendations for the prescription of spectacles in children have been previously published. [12]
  - **Contact Lenses**
    - Orthokeratology (OK)
      - Based on reshaping (flattening) of the cornea resulting in relative myopic shift in peripheral retina
      - The benefit is found to be maximum in the first 2 years of therapy and wanes off later
      - Advantage- Eliminates the need to wear daytime correction
      - Disadvantages
        - Low acceptance in most countries including India
        - Risk of microbial keratitis
        - Frequent non-availability of products
        - Shortage of trained practitioners for fitting OK lenses
        - Rebound effect noted after treatment cessation
        - Off-label use

- Soft multifocal contact lens (SMFCL)
  - May involve off-label use of presbyopic correction
  - MiSight® 1 day (CooperVision) and NaturalVue® (Visioneering Technologies) are daily disposable lenses specially designed and approved for use in myopia in some countries
  - SEED 1-day Pure EDOF soft contact lens is a centre-distance contact lens with peripheral add working on extended depth of focus principle to control myopia and is available in India
  - Proclear® Toric Multifocal (CooperVision) lenses have been used in myopia with astigmatism
  - Disadvantages are the same as for OK lenses

Children may notice mild blurring of vision or changes in their focusing with either orthokeratology or multifocal soft contact lenses

◆ **Pharmacological Intervention**

❖ **Low dose atropine**

- Most tried drug in studies and most accepted clinically
- In Indian scenario, atropine therapy remains the easiest and the most accepted intervention for myopia control
- Group of Paediatric Ophthalmologist and Strabismologists, Mumbai (GPOS) have recommended the use of 0.01% atropine in progressive simple myopia [13]
- It is a nonselective irreversible antimuscarinic agent
- Reduces myopia progression by slowing axial length elongation
- Different concentrations can be used (0.01%, 0.025%, 0.05%, 0.1% etc.)
- 0.01% atropine is commercially available in India and recently approved by Central Drug Standard Control Organization (CDSCO)
- Reconstitution of atropine eye drops in the clinic has been demonstrated to be safe and may be done where it is unavailable commercially
- Use of other concentrations of atropine is off-label and informed consent is needed before starting the therapy. As side effects like blurring of near vision and glare are commonly reported with higher concentration atropine, photochromatic or bifocal glasses may be prescribed along with atropine.
- Advantages
  - Easy availability and administration
  - Affordable
  - Minimal side effects with 0.01% atropine- temporary stinging or burning, blurred vision and sensitivity to light, allergic conjunctivitis, etc.
- Disadvantages
  - Rebound phenomenon after stopping the drug may be noted with higher atropine concentrations. So, tapering the dose and/or frequency of the drug may be considered before stopping it when using higher concentrations.

- Should be prescribed with caution in myopes with accommodation lag; one can consider adding bifocals along with atropine in such cases

- Other issues related to therapy
  - Unaddressed questions like optimum duration of treatment, concentration, frequency and time of application
  - Potential tapering schedule before stopping the drug
  - Exact mechanism of action is unknown

- Contraindications for starting atropine therapy
  - Down's syndrome- due to concerns regarding excessive mydriatic and cycloplegic effects and potential systemic toxicity
  - Congenital syndrome or a heart condition
  - Cerebral palsy
  - History of asthma or other lung diseases
  - Patients taking other medications that may have anticholinergic or antimuscarinic effects, e.g. some anti-depressants and antihistamines

- Lifestyle & Environmental Influences
  They are same as discussed in the management of premyopes.

- Surgical Intervention (in high myopia)
  No available surgical option is yet accepted for slowing myopia progression

When to initiate anti-myopia therapy in myopes

- Progression of myopic refractive error ≥-0.50 D/year is the most important indication for initiating anti-myopia therapy
  - Progression can be noted by comparison of the past and the present prescription of glasses
  - Or, it can be implied based on the history of recent increase or change in the power of glasses

- Younger age of onset- As most young myopes would progress, especially during pre-teenage years (7–12 years), some advocate targeting this group for starting myopia treatment.

- Parental history of myopia and early age of onset of myopia in parents are important risk factors to consider when initiating myopia control.

- If there is no evidence of progression in a patient with minimal risk factors, then it may be preferable to observe such cases and keep them on follow-up with regular cycloplegic refraction.

- Current treatment modalities have been evaluated in children from 4-6 years upto 12-16 years of age and therefore the use of these treatment options should be restricted to this age group. However, appropriate consent should be taken from the parents before initiating any treatment.

Selection of treatment strategies

This would be based on following considerations:

- Rate of progression- Estimation of the rate at which myopia progresses for a given individual may help identify an appropriate strategy
- Ethnicity (for example, a recent meta-analysis suggested greater myopia control with atropine treatment in children of Asian compared to European ethnicity) [14]
- Baseline refractive error and age (younger age generally leads to faster myopia progression)
- Binocular vision status (greater myopia control effects with progressive spectacles were reported in children with larger lags of accommodation and near esophoria) [15]
- Safety, compliance, and cost considerations
- Environmental & lifestyle modifications must be advised with any form of optical or pharmacological intervention
- Discussion with parent/guardian and patient: Treatment strategy should be in consultation with the patient and parents/guardian with respect to risks/benefits of treatment, the patient's lifestyle, economic status, and ease of compliance.

Children who possess multiple risk factors may require more strategic management and frequent review, compared to those with little or no associated risk factors. Maintain follow-up at the scheduled time and record the parameters accordingly. Keep an eye on the ocular health of the child and examine whenever necessary. Analyze changes in refractive error and other ocular parameters and decide the clinical management accordingly.

Advice and clinical care

- Wearing schedule
  - Children should be encouraged to wear their appropriate myopic correction full time unless asked by the clinician
  - OK lens wear should be encouraged daily for a minimum of 8 hours overnight
  - MFSCLs should be worn for at least 5 to 8 hours during school time and for school work at home
- Children who are prescribed optical modalities like OK lenses, multifocal spectacles or contact lenses, should have spectacles as a back-up for when they are not using contact lenses. The parents should be aware of the efficacy of these optical options compared to pharmacological interventions.
- Ask them to monitor and report any acute adverse effect
- Inform the patients about where to report in case of emergency
- Encourage the children to develop healthy visual habits e.g.
  - Spending more time outdoors,
  - Maintain appropriate reading distance- 25 inches (about at arm's length) from the computer screen

- Regular breaks after continuous near work (20-20-20 rule)
- Fixation change while reading or watching screen

Recommendations for healthy screen use behaviour are available online. [16,17]

- Maximising both indoor and natural lighting
- General advice to contact lens users (Annexure III)
- General advice to atropine users (Annexure IV)
- Ask them to follow-up at the scheduled time

Review schedule:

The minimum recommended review schedule based on the type of treatment prescribed should be (Figure 1):

Figure 1- Recommended review schedule

Table 1 provides the clinical tests that should preferably be done on various follow-ups

Follow up	Tests on follow-up
For initial follow-ups	- Relevant history related to the treatment like side effects, compliance, etc. - Distance and near VA - Atropine specific- Pupillometry, IOP - OK specific- Corneal topography - MFSCL & OK specific- CL fit
3 months-	- All the above + - Cycloplegic refraction - Ocular health examination - Binocular vision assessment including accommodation
Then 6 monthly	- All the above ± - Ocular biometry- Axial length
Every 1 year	- All the above ± - Dilated fundus examination

One can maintain the myopia growth curve or chart that will help monitor the treatment response effectively.

This review schedule is the minimum recommended and can be individualized on a case-to-case basis on the discretion of the treating ophthalmologist.

Analysis of treatment efficacy

- In terms of myopia progression
  - Change in spherical equivalent refractive error from baseline to the last visit
- In terms of axial length elongation
  - Change in axial length from baseline to the last visit
  - Refractive error cannot be used as an effective treatment indicator for OK lenses
- Change in other ocular parameters from baseline/pre-treatment visit to last follow-up visit
  - ACD, LT, Km
  - Binocular vision etc.

Treatment duration

- For atropine
  - The World Health Organization (WHO) currently recommends limiting the duration of atropine treatment to 2 years.
  - The current data support the safe use of atropine for 2 years and a maximum of 5 years.
- Similarly, for OK and multifocal contact lenses, mostly two years efficacy is reported.
  - Long term use of these contact lenses is not contraindicated if the ocular health is maintained
- Best approach would be to individualise the treatment
  - Monitor the response on follow-up and prescribe or discontinue the treatment on a case-to-case basis.

Non-responders/Poor responders

- Nearly 10-20% of patients are non-responders or poor responders that show progression despite the best of treatment
- Increase in myopic refractive error of ≥0.5D/year despite the best possible intervention is defined as progression
- Increase in myopic refractive error of ≥1D/year despite the best possible intervention is rapid progression
- Characteristics of non-responders are:
  - Both parents are myopic
  - Young age
  - Higher baseline myopia and faster progression
- Environmental modifications should be implemented early in such cases along with other interventions
- Trial of higher concentrations of atropine / more frequent dosing regimen (side effects will increase: photo chromatic glasses and PALs may be used) along with combination therapy.

When to stop/change treatment

- Ideally, the anti-myopia therapy should continue till the myopic refractive error stabilizes. The childhood myopia is known to stabilize in most cases by mid-teens (around 14-16 years of age)
- Usually, a treatment period of 2-3 years is acceptable with most interventions. However, the decision should be taken by the treating ophthalmologist.
- After completion and stopping of any treatment, schedule close follow-ups to document any myopia progression, either due to rebound effect of treatment cessation or as a natural growth process of myopia.
- Rebound phenomenon is reported with the cessation of atropine (especially higher concentrations) and OK lenses
- Tapering of treatment may be considered especially with higher doses of atropine to prevent the rebound effect
- Recommencement of treatment or switching to other treatment modalities may be considered if the myopia progression is significant
- Switching to another form of therapy or combined therapy may be considered when
  - Myopia progression is not sufficiently controlled, in comparison to expected progression
  - Intolerable side effects with the current therapy
  - Compliance and safety issues
- Combination therapy
  - OK + atropine: Preliminary results are promising
  - Combination of lifestyle modification along with pharmacological or optical interventions must be advised
- One must keep in mind that the available anti-myopia therapy can slow the progression but cannot stop it completely.

Public health initiatives

This includes measures of creating awareness about the disease burden, promoting collaborative research and aid the development of public health initiatives to prevent myopia onset and progression.

- It is essential to educate all working in the healthcare community including ophthalmologists, optometrists, paediatricians and related policy makers about the public health costs related to childhood myopia and recognizing that myopia is a public health burden. Several ophthalmological and optometry societies and paediatricians at national and state level can play an important role in this regard.
- There is a need to create educational resources for medical professionals that will assist in decision making regarding the treatment of childhood myopia.

- Availability of Information, Education and Communication (IEC) material for the general public, patients and their parents to promote healthy lifestyle choices to prevent and reduce myopic progression
- Advocacy to include annual school screening programmes nationwide for early identification of refractive errors, to adopt healthier school curriculum with adequate outdoor activities/ play during school hours
- Collaborative research among Indian ophthalmologists, optometrists, and industry to develop novel and affordable interventions for myopia control.
- Working with educationists in ensuring that a school day includes adequate outdoor exposure in sunlight as a routine

Conclusion

The purpose of this article is to establish the clinical guidelines for the management of premyopes and progressing myopes. As the research in myopia management is continuously evolving, clinicians must remain well updated with the recent literature. The above recommendations for myopia management are based on the current understanding of the disease and are bound to change as new evidence generates. Ophthalmologists play a key role in myopia management and these practise patterns will enable them to provide efficient and standard care by early identification and treatment of myopia.

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ANNEXURE I: Definitions of Myopia (Adopted from IMI)

Qualitative definitions

Myopia	A refractive error in which rays of light entering the eye parallel to the optic axis are brought to a focus in front of the retina when ocular accommodation is relaxed. This usually results from the eyeball being too long from front to back, but can be caused by an overly curved cornea and/or a lens with increased optical power. It also is called near sightedness.
Axial myopia	A myopic refractive state primarily resulting from a greater than normal axial length.
Refractive myopia	A myopic refractive state that can be attributed to changes in the structure or location of the image forming structures of the eye, i.e. the cornea and lens.
Secondary myopia	A myopic refractive state for which a single, specific cause (e.g., drug, corneal disease or systemic clinical syndrome) /lenticular disease (index myopia) can be identified that is not a recognized population risk factor for myopia development.

Quantitative definitions

Myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ -0.50 D (SE less than -0.50D) when ocular accommodation is relaxed.
Low myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ -0.50 and > -6.00 D (SE less than -0.50D but more than -6.00D) when ocular accommodation is relaxed.
High myopia	A condition in which the spherical equivalent refractive error of an eye is ≤ -6.00 D (SE less than -6.00D) when ocular accommodation is relaxed.
Pre-myopia	A refractive state of an eye of ≤ +0.75 D and > -0.50 D (SE less than +0.75D but more than -0.50D) in children where a combination of baseline refraction, age, and other quantifiable risk factors provide a sufficient likelihood of the future development of myopia to merit preventative interventions.

Annexure II- Work up in Childhood Myopia

Baseline work-up:

1. Best corrected visual Acuity for distance and near
2. Intra-ocular pressure
3. Axial Length measurement
4. Cycloplegic refraction
5. Slit lamp examination
6. Dilated fundus evaluation

Treatment related tests:

1. Accommodation lag or lead
2. Amplitude of Accommodation
3. AC/A Ratio
4. Distance and near heterophorias
5. Tests for ocular surface assessment
6. Corneal topography

Exploratory tests:

1. Peripheral Refraction
2. Pupillometry- photopic and mesopic pupil size
3. Aberrometry for higher order aberrations
4. Macular Optical coherence tomography (OCT) for subfoveal choroidal thickness

ANNEXURE III: Guidelines for use and care while using contact lenses

Use of contact lenses in children demand lots of care and caution. Therefore, the clinician must ensure that the child and parents follow the standard contact lens care guidelines.

- Always wash, rinse, and dry hands before handling contact lenses
- Always use fresh, unexpired lens care solutions
- Use the recommended lens care system and carefully follow instructions on solution labels.
- Always remove, clean, rinse and enzyme disinfect your lenses according to the schedule prescribed by your eye care professional
- Lenses prescribed in a frequent replacement program should be thrown away after the expiration of the wearing period
- Never rinse your lenses or lens case in tap water
- To store lenses, disinfect and leave them in the closed/unopened case with storage solution until ready to wear. Lens case should be replaced every 3 to 6 months
- After removing your lenses from the lens case, empty and rinse the lens storage case with solution(s) recommended by the lens case manufacturer and then allow the lens case to air dry
- Never swim or shower with contact lenses
- Don’t wear your contact lenses if you have a cold or are unwell
- Unless directed by your doctor (for OK), don’t sleep or nap in your lenses
- If you notice any issue with your contact lenses such as eye stinging, burning, itching, eye pain, etc. immediately remove the contact lens and consult your ophthalmologist

ANNEXURE IV: Guidelines for use and care while using atropine eye drops

- Atropine eye drops are given once daily (preferably at night) to reduce any potential side effects like blurring of vision or photophobia
- Atropine eye drops 0.01 % is commercially available in bottles
- Never touch the tip of the bottle with the hand or any other surface to avoid contamination
- To apply the drop, gently pull down the lower lid and squeeze one drop in the pocket of the lower lid
- One drop is sufficient; do not put multiple drops
- Avoid excessive blinking, keep the eyes closed and do punctal occlusion by pressing your index finger near the inside corner of your eye for 2 minutes after instilling the eye drop for better penetration
- Do not use the bottle past the expiration date
- Other higher concentrations of atropine (0.025%, 0.05%) need to be reconstituted after informed consent is obtained
- If the patient is using other eye drops like artificial tears, etc. along with atropine, then a gap of 5-10 minutes is recommended between instilling different types of drops
- If the patient complains of any intolerable side effects like redness, itching, etc. then discontinuation of drops is recommended
- If there is deterioration of near vision or glare on follow-up, bifocals and/or photochromatic glasses should be prescribed


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Terms of Use

Aim of these guidelines is to assist the ophthalmologist in identifying and reducing the progression of childhood myopia.

These are based on our current understanding of trends and are bound to evolve as new evidence is established.

These guidelines are mere suggestions and cannot be used in court of law to safe-guard against or for any legal proceedings.

AIOS has no financial or any other interest in formulation of these guidelines.

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