MANAGING MYOPIA
A Clinical Response to the Growing Epidemic
WHAT IS MYOPIA?

Myopia is a chronic, progressive disease characterized by excessive eye elongation, risk of associated pathological complications, and a negative-poweered refractive error.

GROWING GLOBAL EPIDEMIC

• Reports of increased myopia prevalence in children first emerged in the 1800s.2,3
• The prevalence has nearly doubled within the past 20 years in both eastern and western societies.
• Prevalence among young adults is above 80% in many Asian regions,4,5 and 50% in the U.S. and parts of Europe.6
• Children in the first wave of high myopia prevalence (those born after 1970) are now on the cusp of experiencing sight-threatening complications as adults.

NO SAFE LEVEL OF MYOPIA

• The elongated eye is susceptible to pathological complications with significant risks to eye health and vision.
• Any degree of myopia increases the risk of sight-threatening complications, with some complications leading to blindness in adulthood.7
• Each diopter increase in myopia results in 67% increased risk of myopic macular degeneration (MMD).

CONTROLLING MYOPIA PROGRESSION

• Eye care professionals now have the opportunity to treat the underlying cause of myopia rather than just the symptoms.
• Increased time outdoors can delay myopia's onset.
• Several myopia control therapies have shown efficacy of over 0.3 mm (around 0.75 D) over two to three years of treatment.10

ASSOCIATED RISKS OF MYOPIA

Of these diseases, MMD and retinal detachment are the most devastating and have the strongest relationship to myopia and longer axial lengths (Table 1).5,9 Among people aged 75 years or older, cumulative risk of visual impairment (decimal VA 0.30 to 0.05 [approx. 20/60 to 20/400]) or blindness (decimal VA worse than 0.05 [20/200]) from all causes increases from 3.8% in eyes with an axial length less than 26 mm to 25% in eyes with an axial length of 26 mm or greater and more than 90% in eyes with an axial length of 30 mm or greater.

Table 1. The increased likelihood (odds ratio) of a myopic person > 60 years developing eye disease versus an emmetrope by degree of myopia.

<table>
<thead>
<tr>
<th>DEGREE OF MYOPIA</th>
<th>MMD</th>
<th>RETINAL DETACHMENT</th>
<th>VISUAL IMPAIRMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>-0.50 to -3.00 D</td>
<td>13.6</td>
<td>3.2</td>
<td>0.9</td>
</tr>
<tr>
<td>-3.00 to -6.00 D</td>
<td>73</td>
<td>8.8</td>
<td>17</td>
</tr>
<tr>
<td>-6.00 D or more myopic</td>
<td>846</td>
<td>12.6</td>
<td>5.5</td>
</tr>
</tbody>
</table>

• Applies only to myopia of -0.50 to -10.00 D. Odds ratios are 7.8 for myopia of -10.00 to -15.00 D and 88 for myopia more than -15.00 D.1

REFERENCES

MYOPIA IS THE BIGGEST THREAT TO EYE HEALTH OF THE 21ST CENTURY

Eye care professionals should embrace new therapies treating children as soon as signs of myopia appear in order to reduce the risk of sight-threatening complications in later life.

Myopia's prevalence has nearly doubled over the past 20 years.¹

Both Eastern and Western populations exhibit the same troubling trend of increasing myopia.²

25% of people with axial length ≥26 mm will develop visual impairment by age 75.³

Every additional diopter of myopia increases the risk of MMD by 67%.⁴

No safe level of myopia, with over 30% of MMD occurring in people less myopic than -6.00 D.²

Every additional diopter of myopia increases the risk of MMD by 67%.¹

25% of people with over 30% of MMD occurring in people less myopic than -6.00 D.²

MANAGING MYOPIA IN CHILDREN: THE NEED FOR A NEW APPROACH

Myopia is a continuum of disease stages which should be assessed as early as possible. Myopia may continue to progress beyond the teenage years and the associated disease risk increases exponentially with myopia's severity,¹⁰ making early diagnosis and treatment crucial to lifetime eye health.

Early myopia onset increases risk of high myopia

Myopia progresses more quickly in younger children.⁵ Because early onset implies more years of progression, myopes younger than 12 are at greater risk of developing high myopia. This is why it's essential to:

- Examine children at least once between the ages of 3-5 years to establish baseline measurements
- Examine all children at least annually until they're 17

Refractive error predicts myopia onset

Numerous risk factors can help predict myopia's onset, but the best predictor is cycloplegic spherical equivalent refractive error at a given age. A child with low hypermetropic refraction for a given age (Table 3) has greater than an 80% likelihood of myopia onset by age 13.¹¹ This approach provides a simple clinical method to evaluate risk of myopia onset that is just as accurate as more complex algorithms.

<table>
<thead>
<tr>
<th>AGE</th>
<th>REFRACTIVE ERROR</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>&lt; +0.75 D</td>
</tr>
<tr>
<td>7-8</td>
<td>≤ +0.5 D</td>
</tr>
<tr>
<td>9-10</td>
<td>≤ +0.25 D</td>
</tr>
<tr>
<td>11</td>
<td>≤ +0.00 D</td>
</tr>
</tbody>
</table>


Table 2: Classification of myopia by spherical equivalent refractive error⁶

<table>
<thead>
<tr>
<th>REFRACTIVE ERROR</th>
<th>Emmetropia (Pre-Myopia if ≤ age 12)</th>
<th>Myopia</th>
<th>High Myopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>+0.75 to -0.49 D</td>
<td>≤ -0.50 to -4.99 D</td>
<td>≤ -5.00 D and more myopic</td>
<td></td>
</tr>
</tbody>
</table>

Table 3: Cycloplegic spherical equivalent autorefraction threshold by age, for children at high risk of becoming myopic by 8th grade⁴

<table>
<thead>
<tr>
<th>AGE</th>
<th>REFRACTIVE ERROR</th>
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</tr>
<tr>
<td>9-10</td>
<td>≤ +0.25 D</td>
</tr>
<tr>
<td>11</td>
<td>≤ +0.00 D</td>
</tr>
</tbody>
</table>
DECIDING WHEN AND HOW TO TREAT MYOPIA

Importance of early treatment: every dioptral matters

- Progression is highly likely once a child is identified as pre-myopic or myopic.1 The goal of myopia control is to restrict axial length and refraction as much as possible but certainly to keep axial length below 26 mm10 and less than 5 D of myopia.13
- Reducing myopia by 100 D reduces the likelihood of a patient developing myopic macular degeneration by about 40%.11
- Begin clinical treatment for all myopic children 12 years of age or less and offer lifestyle guidance at a minimum for pre-myopic children

Risk factors for myopia

- Younger age6
- Refractive error (see Table 3)11
- Minimal time outdoors (< 2 hrs/day)9
- Near work for longer duration or at a shorter working distance11
- Myopic parents8

Lifestyle guidance

One evidence-based method to delay the onset of myopia in children is spending time outdoors.8 Growing evidence supports that more time outdoors may also slow the progression of myopia.11 Increased outdoor time may benefit all children.

Table 4: Likelihood of myopia progression or onset and recommended clinical action by age and refractive status

<table>
<thead>
<tr>
<th>REFRACTIVE STATUS</th>
<th>Pre-myopia (≤ 12 yrs)</th>
<th>Myopia (≥ 13 yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROBABILITY</td>
<td>Myopia onset highly likely</td>
<td>Progression highly likely</td>
</tr>
<tr>
<td>CLINICAL ACTION</td>
<td>Close monitoring</td>
<td>Myopia control highly recommended</td>
</tr>
</tbody>
</table>

11. Lifestyle guidance is a suggested component of all myopia control therapy.
12. Treatment of pre-myopia at the discretion of the parent/patient and clinician.

EVALUATING PRE-MYOPA AND MYOPIA

REFRACTIVE ERROR

- Primary method for diagnosing myopia and a routine measurement in every comprehensive eye examination
- Accuracy and repeatability improve with use of cycloplegia and objective measurements (autorefractometry)2
- Strongly correlated with axial length, but substantially less repeatable than optical biometry even with cycloplegia11
- Misleading interpretation can occur with orthokeratology and/or atropine

AXIAL LENGTH (Optical Biometry)

- Primary metric for monitoring eye elongation
- Highly repeatable measurement
- Relates directly to the pathological processes in myopia
- Doesn’t require cycloplegia
- Less susceptible to changes in the anterior optics of the eye which may occur over the course of orthokeratology or atropine therapy

KEY POINTS FOR MONITORING

- Young myopes will progress, so set this as the expectation6
- Average treatment efficacy can be referenced from randomized clinical trials
- Monitor myopia control therapy use, acceptance, and maintenance every six months
- Evaluate progression using at least one (1) year of data to avoid seasonal changes and reduce measurement noise (even with optical biometry)
- Treatment efficacy cannot be determined for an individual patient because there is no way to know how that individual would have progressed if left untreated
- Refer to population-based normative data to assess progression (see Table 5)
MONITORING AND EFFICACY

Expected progression without myopia control
Eye growth should be expected in all young patients, with even stable emmetropic eyes growing around 0.1 mm per year from age 6 to 14. Younger myopes will progress faster on average, with average rate of progression in 7-year-old children nearly double that of 11-year-old children. Individual progression near the mean values by age in Table 5 should not be considered normal or healthy, since any myopia progression will exponentially increase associated disease risk. Individual progression rates vary considerably across the population.

Caution with myopia control calculators
Myopia control calculators offer reasonable estimates of normal progression without myopia control therapy. The calculated myopia control effect, however, extrapolates a few years treatment effect for up to 11 years, omitting that treatment effect decreases over time and misleading users with overly optimistic treatment expectations.

Communicating myopia control efficacy
While “percentage treatment” effect is easy to understand, it leads to inconsistent representation across the progression range and fails to capture that myopia control efficacy slows over time. Myopia control treatment effect tends to be more of an absolute effect than a proportional effect. The best descriptor of myopia control efficacy is the cumulative absolute reduction in elongation or refractive error (e.g., total mm or D).

Average myopia control treatment effect
Numerous clinical studies provide cumulative myopia control effect for individual therapies in millimeters or diopters over a 2 to 3-year period, with multiple studies providing evidence of a 0.30 mm reduction in elongation (about 0.75 D). The maximum effect observed to date is 0.44 mm (about 1.00 D) over a 7-year period, treatment should begin as early as possible. Combination therapy may enhance myopia control efficacy compared to a single treatment.

Monitoring
Myopia control therapy use, acceptance, and maintenance should be frequently monitored following treatment initiation or modification and at least every six (6) months once treatment is established. Frequent monitoring helps reduce barriers to use, identify non-compliant or risky behaviors, and address any problems as early as possible, supporting safe and consistent use of the myopia control therapy. Axial length and cycloplegic refractive error may be measured at frequent intervals, but should be evaluated over at least one year before considering therapeutic changes or supplemental therapy because progression can vary seasonally.

Stopping treatment
Once myopia control treatment has begun, myopia stabilization cannot be differentiated from an effective myopia control therapy. Because there is evidence for progression in some adults, myopia control can be continued beyond the teenage years if the treatment is well accepted. If not well accepted, an alternative myopia control therapy can be considered. Rebound after myopia control discontinuation may occur and regular monitoring should be continued after stopping therapy.

Table 5. Mean progression for myopic Asians and non-Asians by axial length and refractive error across age

<table>
<thead>
<tr>
<th>AGE</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AXIAL LENGTH (mm)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0.52</td>
<td>0.46</td>
<td>0.41</td>
<td>0.36</td>
<td>0.32</td>
<td>0.28</td>
</tr>
<tr>
<td>Non-Asian</td>
<td>0.35</td>
<td>0.31</td>
<td>0.28</td>
<td>0.25</td>
<td>0.22</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>REFRACTIVE ERROR (D)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>-1.12</td>
<td>-0.94</td>
<td>-0.78</td>
<td>-0.66</td>
<td>-0.56</td>
<td>-0.50</td>
</tr>
<tr>
<td>Non-Asian</td>
<td>-0.98</td>
<td>-0.82</td>
<td>-0.69</td>
<td>-0.56</td>
<td>-0.45</td>
<td>-0.35</td>
</tr>
</tbody>
</table>

REFERENCES
Perform baseline measurements as appropriate (e.g., train both child and parent to apply, remove, disinfect). Monitor myopia control therapy use, acceptance, and adherence. Discuss available treatment options, expectations, potential side effects, and performance may vary significantly between products (e.g., for different brands) and it is important to note that some treatments are prescribed off-label. Choosing the right one(s) is dependent on the individual patient's lifestyle, age, maturity, and refractive error. This diagram can be helpful in guiding your conversation with patients and their parents.

### Orthokeratology
Gas permeable lenses worn overnight to temporarily reshape the cornea, allowing their use during the day. Soft multifocal contact lenses are also offered, subjectively improved appearance and myopia control compared to glasses. Used overnight at home, allowing for parental oversight.

### Clinical Considerations
- Refractive error and astigmatism
- Myopia control treatment history
- Other vision corrections prescribed (e.g., for different brands)
- Lifestyle considerations
  - Sports/physical activity
  - Patient responsibility/hygiene
- Myopia Control Spectacles
  - Optics specifically designed to slow myopia progression. Safe and easy option for a range of prescribers; subject to non-compliant wear and lens/breakage. Optical designs and myopia control efficacy vary greatly.

### Myopia Control Consultation
Consultation with patients can be helpful in guiding your conversation with patients and their parents.

### Personalizing Myopia Control Therapy
Treatments described here have been demonstrated to be effective and safe in clinical studies. However, efficacy and performance may vary significantly between products (e.g., for different brands) and it is important to note that some treatments are prescribed off-label. Choosing the right one(s) is dependent on the individual patient's lifestyle, age, maturity, and refractive error. This diagram can be helpful in guiding your conversation with patients and their parents.

### Atropine Eye Drops
Allow complete parental control of treatment. Concentrations of 0.025% to 0.05% have demonstrated efficacy in myopia control and limited side effects of photophobia and reduced accommodation. Atropine must be supplemented with glasses or contact lenses and could be combined with other myopia control therapies.

### Soft Multifocal Contact Lenses
The optics were originally designed to improve near vision in presbyopic patients, but some have been shown to slow myopia progression. Preferred for athletics and water activities, also offering subjectively improved appearance and myopia control compared to glasses. Younger children can wear these lenses and do not appear to be at increased risk of infection compared to older wearers.

### References
While the regulatory requirements regarding myopia management vary across countries, practitioners should use this guidance in accordance with their local regulations. Johnson & Johnson Vision does not engage in the practice of medicine and this document is not intended as a substitute for appropriate medical education and training or for the exercise of independent medical judgment. Practitioners should use their own medical judgment when determining how to treat their patients.

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