Financial Disclosure

I receive consulting fee from:
- Paragon Vision Sciences
- Essilor China

No financial interests in products mentioned in the lecture.

Heterogeneous Anti-Myopia Efficacy of OrthoK

<table>
<thead>
<tr>
<th>Study or Reference</th>
<th>Orthokeratology M</th>
<th>OD Total</th>
<th>Control OD Total</th>
<th>Mean Difference</th>
<th>IV Randomized [% CI]</th>
<th>IV Randomized [% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen 2015</td>
<td>0.31 0.27</td>
<td>35 0.04</td>
<td>31 0.31</td>
<td>16 0.06</td>
<td>-0.50 [-0.65, -0.35]</td>
<td>-0.50 [-0.65, -0.35]</td>
</tr>
<tr>
<td>Chao 2006</td>
<td>0.29 0.27</td>
<td>35 0.04</td>
<td>31 0.27</td>
<td>19 0.06</td>
<td>-0.20 [-0.35, -0.05]</td>
<td>-0.20 [-0.35, -0.05]</td>
</tr>
<tr>
<td>Wu et al. 2014</td>
<td>0.25 0.22</td>
<td>29 0.02</td>
<td>29 0.22</td>
<td>20 0.06</td>
<td>-0.10 [-0.25, 0.05]</td>
<td>-0.10 [-0.25, 0.05]</td>
</tr>
<tr>
<td>Kapila et al. 2014</td>
<td>0.30 0.27</td>
<td>12 0.01</td>
<td>10 0.27</td>
<td>19 0.06</td>
<td>-0.22 [-0.35, -0.09]</td>
<td>-0.22 [-0.35, -0.09]</td>
</tr>
<tr>
<td>Webster 2018</td>
<td>0.25 0.22</td>
<td>29 0.02</td>
<td>29 0.22</td>
<td>18 0.06</td>
<td>-0.32 [-0.45, -0.19]</td>
<td>-0.32 [-0.45, -0.19]</td>
</tr>
<tr>
<td>Total (N=104 eyes)</td>
<td>0.30 0.27</td>
<td>316</td>
<td>216</td>
<td>100%</td>
<td>0.24 [-0.31, -0.27]</td>
<td>0.24 [-0.31, -0.27]</td>
</tr>
</tbody>
</table>

Reasonable consistency but significant individual variability!

Source of Variance of Effect Size

- Issues in defining anti-myopia efficacy
  - Absolute vs. relative efficacy (nonlinear for baseline AL & stage of myopia)
  - Confounding effects from physiological axial growth
- Complex genetic vs. environmental contributions to myopia etiology
  - Stronger genetic predisposition, less responsive to intervention
- OrthoK-specific challenges
  - Exact mechanisms unclear
  - Treatment lacks specificity (i.e. treatment dosage difficult to measure)

Confounding from Physiological Ocular Growth

Annual Physiological AL increase
- 4-8yr: 0.30±0.17mm (n=243 eyes) 5-12yr: 0.12±0.12mm (n=404 eyes)

Hypothetical Dataset

<table>
<thead>
<tr>
<th>AL(mm)</th>
<th>Baseline</th>
<th>Post-TM</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physiological</td>
<td>23.00</td>
<td>23.12</td>
<td>0.12</td>
</tr>
<tr>
<td>Control</td>
<td>23.00</td>
<td>23.50</td>
<td>0.50</td>
</tr>
<tr>
<td>Treatment</td>
<td>23.00</td>
<td>23.25</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Myopia Control Efficacy
- Without considering physiological AL growth: -0.25mm; 36%
- After accounting for physiological AL growth: 64%

3D progression/mm axial elongation is NOT TRUE!
Accelerated Axial Growth Prior to Onset of Myopia

Annual AL growth at age 8 (persistent emmetropes): 0.12±0.24mm
Annual AL growth at age 8 (myopia onset at age 11): 0.35±0.20mm

Multifactorial Anti-Myopia Mechanisms of OrthoK
• Non-uniform (oblate) central flattening
  - ▲ defocus; ▲ SA & coma
  - Higher contribution to central image quality
• Significant paracentral steepening
  - Higher contribution to peripheral image quality
• Behavioral benefit cannot be ignored

“Proposed” Myopia Control Orthok Design?

Little Impact of Pupil Size on Peripheral Defocus
• Paraxial rays: little impact from pupil size, projecting to central retina
• Marginal (peripheral) rays: large impact from pupil, projecting to central retina
• Oblique rays: little impact from pupil size, projecting to peripheral retina

Orthok Design Difference ≠ Induced Topographical Difference

Back surface profile of the lens cannot predict post-OrthoK front corneal shape

OrthoK Lacks Treatment Specificity
• Same design induces drastically different post-TM corneal shape

Maria Liu, PhD, MPH, MBA, FAAO
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Baseline Myopia & Controlling Efficacy of OrthoK - Confounding from Age

- The earlier the onset, the more genetic predisposition, less responsive to interventions
- Central flattening vs. paracentral steepening, not necessarily 1:1 relationship

Baseline Myopia & Controlling Efficacy of OrthoK

Age of Onset

Baseline myopia Anti-myopia efficacy

G: aspiring OrthoK efficacy into a 6yr -1D vs. a 12yr -4D is meaningless!

Baseline myopia

Comparison orthoK efficacy btw a 6yr -1D vs. 12yr -4D is meaningless!

Baseline myopia

Age of Onset

Baseline myopia

Anti-myopia efficacy

Post-OrthoK Corneal Shape as Treatment Variable in Myopia

Control Studies of OrthoK

- Central flattening
  - Size of treatment zone (not OZ of the lens)
  - Grading of non-uniform treatment
  - Quantification of asphericity of treatment zone

- Paracentral steepening
  - Width (area of + defocus)
  - Magnitude (amount of + defocus)
  - Location (eccentricity of + defocus)

Summary

- Myopia-inhibiting effect subject to significant variability
  - Definition of “anti-myopia” efficacy needs further improvement
  - AL elongation not only myopia progression but age-dependent
  - Various response to treatment

- Myopia-controlling dosage induced by OrthoK
  - Comes from both central non-uniform flattening & paracentral steepening
  - Lacks design-specificity, hence post-treatment corneal shape as exposure

- Anti-myopia efficacy independent of baseline myopia
  - Earliest intervention possible to minimize risk of excessive scleral stretching

The eye sees only what the mind is prepared to comprehend.

Henri Bergson

Questions?

Breadth of Portfolio & Education

Presented by:
Andy Jackson, Director, Specialty Vision Products

Specialty Vision Products

Maria Liu, PhD, MPH, MBA, FAAO
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  - wetlabs@abboptical.com
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Thank You!