Corneal Reshaping: What the latest research means for your patients...and YOU

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Disclosure

• I have received research funding from:
  – Bausch and Lomb
  – Paragon Vision Science
• I am a consultant to Bausch and Lomb’s Specialty Vision Products Division

What Corneal Reshaping RESEARCH means for YOU

• More research = More awareness
• ECP’s and General Public
• Patients will ask you about it !!!
• How have you responded/ How will you respond?

What Corneal Reshaping research means for YOUR Patients

• More research = More credibility
• Another refractive correction option
• Intervention for Myopia Control

Prevalence of Myopia

- **Worldwide**
  - Prevalence of Myopia – 2010
  - **US** ~ 45% (~145 Million)
  - **High Myopia (~5.0D)** ~2.1% (6.9 Million)
  - Projection of Myopia - 2050
  - **US (est)** (~200 Million)
  - **High Myopia (~5.0D)** (12 Million)

Myopia: Prevalence and Projection

- **Canada** 72.4%
- **US** 44.9%
- **UK** 52%
- **Europe** 42.3%
- **China** 95.5%
- **Taiwan** 14.6%
- **Singapore** 14.7%
- **South Korea** 96.5%


Current OrthoK use – U.S.

- OrthoK received FDA approval in June 2002
- OrthoK practitioners - unknown –
  - Est. ~ 6,000 – 8,000 certified
  - Est. ~ 400-500 doing more than 2 patients/month
- OrthoK users – 100K-500K
  - ~ less than 1% of US CL market

Who is fitting OrthoK?

Ortho-k International Survey
By Joan Pérez, March 2016

<table>
<thead>
<tr>
<th>Country</th>
<th>Population</th>
<th>OrthoK Users</th>
<th>OrthoK Fitter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>24,000,000</td>
<td>100,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Brazil</td>
<td>207,000,000</td>
<td>50,000</td>
<td>500</td>
</tr>
<tr>
<td>China</td>
<td>1,400,000,000</td>
<td>200,000</td>
<td>2,000</td>
</tr>
<tr>
<td>India</td>
<td>1,300,000,000</td>
<td>150,000</td>
<td>1,500</td>
</tr>
<tr>
<td>Japan</td>
<td>128,000,000</td>
<td>100,000</td>
<td>1,000</td>
</tr>
<tr>
<td>Mexico</td>
<td>126,000,000</td>
<td>50,000</td>
<td>500</td>
</tr>
<tr>
<td>Russia</td>
<td>144,000,000</td>
<td>200,000</td>
<td>2,000</td>
</tr>
<tr>
<td>Spain</td>
<td>47,000,000</td>
<td>50,000</td>
<td>500</td>
</tr>
<tr>
<td>United States</td>
<td>323,000,000</td>
<td>100,000</td>
<td>1,000</td>
</tr>
</tbody>
</table>

Myopia

- Myopia is a "disease" and a significant contributor to Visual Impairment (VI)
  - In 2015, approximately 3.22 million people in the United States had VI (reduced BVA in better eye)
  - By 2050, the these numbers are projected to double
    - 6.95 million people with VI
- Myopia plays a significant part of these #’s

Myopia – Complications-Glaucoma

- Myopia is associated with an increased prevalence of all forms of open-angle glaucoma and OHTN* (n=34 K GLC, 400K controls)
- A recent meta-analysis of myopia as a risk factor for glaucoma pooled data from 11 different studies and concluded that:
  - for low myopia (myopia up to 3 D) the odds ratio - 1.65 (95% CI 1.26-2.17)
  - for higher myopia (in excess of 3 D) the odds ratio - 2.46 (95% CI 1.93-3.15)

Myopia – Complications-Cataract

- Myopia is associated with an increased odds ratio of development of cataracts (particularly PSC, but nuclear also)
- Odds ratio for PSC 1.59 (95%CI 0.90-2.80) for myopia between 0.50 D and 1.99 D
- 3.22 (95%CI 1.53-6.79) for myopia between 2.00 D and 3.99 D
- 5.36 (95%CI 2.17-13.26) for myopia between 4.00 D and 5.99 D
- 12.34 (95% CI 4.85-31.42) for myopia 6.00 D or greater

Myopia – Complications-Retina

- Myopia is a significant risk factor for retinal detachment
  - Retinal Detachment Risk
    - Ongawa & Tanaka

Retinal Detachment

- Odds ratio for retinal detachment:
  - < 75 to 2.75D: 3.1 (2.6-3.8)
  - 2 to 6.75D: 9.0 (7.5-10.8)
  - > 6.75D: 21.5 (17.3-26.7)
  - 9 to 14.75D: 44.2 (34.3-57.2)
  - > 14.75D: 88.2 (56.1-138.9)

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Summary of Myopia Risks

<table>
<thead>
<tr>
<th>Emmetropia (0x)</th>
<th>Cataract (PSCC)</th>
<th>Glaucoma</th>
<th>Retinal Detachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1.00 to -3.00</td>
<td>2 x</td>
<td>4 x</td>
<td>4 x</td>
</tr>
<tr>
<td>-3.00 to -6.00</td>
<td>3 x</td>
<td>4 x</td>
<td>10 x</td>
</tr>
<tr>
<td>-6.00 or greater</td>
<td>5 x</td>
<td>4 x</td>
<td>16 x</td>
</tr>
</tbody>
</table>

**Emmetropia** = 1x

- **Cataract** (PSCC)
- **Glaucoma**
- **Retinal Detachment**


OrthoK creates spherical aberration – potential for night glare

Ortho K works !!

- FDA approval CRT: Myopia – up to -6.00D
- Astigmatism – up to -1.75
- VST: Myopia – up to -5.00D
- Astigmatism – 1.50D or less
- Off-Label – hyperopia
- Higher rx’s

Ortho K works !!

- Effect is reversible
  - Refraction recovers 100% in 5-7 days +
  - Topography recovers 100% in 3-8 weeks*

- VA acuity is good
  - 90% achieve 20/25 or better **
  - Pts report equal or better VA than with SCL 
  - Equally effective in children and adults *

Ortho K works !!

• Refraction - Lasts most waking hours


OrthoK works

VA- Lasts most waking hours


OrthoK is Safe

• Potential Complications
  – SPK
  – Abrasion
  – Microbial Keratitis
  – Infection

• Contributing Factors
  – Age
  – Compliance
  – Care System/Storage Case
  – Dryness
  – Allergies
  – Hygiene
  – Swimming

“The relatively low incidence of adverse events and discontinuations with OK is conducive for the correction of myopia in children with OK contact lenses.”


OrthoK is SAFE !!

• Retrospective studies in the US
  – safety and efficacy
  – 296 pts – 52% under 12, 48% over 12 or adults
  – 4.5 yr period
  – 507 patient-years of wear

【Lipson MJ. Long-term Clinical Outcomes for Overnight Corneal Reshaping In Children and Adults. Eye & Contact Lens. 2008;34:94-99.】

Results - Safety

• No difference in efficacy – kids vs. adults
• 3 adverse events during study period
  – All were in kids
  – All were significant spk (3+ or greater)
  – All resolved – 1 resulted in a small scar
  – No loss of BCVA
  – All continue to use corneal reshaping

Safety in OrthoK

Efficacy and safety of OrthoK is directly related to:
• precise lens fitting
• patient compliance
• regular monitoring of:
  – cornea, topography and lens condition

Another US Study*

- 1316 OCR patients
- 2593 patient-years of wear
- 2 events of MK reported
- Equals 7.7 events per 10,000 pt-yrs of wear

-- for Sil-hyd- annual rate of MK 18/10,000 wearers#


Summary of OrthoK Safety

- Early reports of problems were in Asia (12 yrs ago)
- Excellent track record in US since approval in 2002
- Potential Problems minimized with:
  - Precise fitting
  - Patient Compliance with Lens Care/Cleaning
  - Regular monitoring of corneal health and lens condition

"This review incorporated a total of 170 publications, including 58 English and 112 Chinese literature. The risk of microbial keratitis in overnight OrthoK was similar to that of other overnight modalities. The most common complication was corneal staining."


Summary of Risk factors

<table>
<thead>
<tr>
<th>Risk per year</th>
<th>Lifetime risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinal detachment (RD) (any)</td>
<td>0.65% to 0.03%</td>
</tr>
<tr>
<td>Incident of RD</td>
<td>3 in 50 to 1 in 3000</td>
</tr>
<tr>
<td>RD after cataract surgery</td>
<td>0.5 to 2.0%</td>
</tr>
<tr>
<td>High risk: up to 7%</td>
<td>3 in 5 to 200</td>
</tr>
<tr>
<td>RD with 6/12 or worse final acuity after treatment</td>
<td>5% risk in 0.01 to 1.00</td>
</tr>
<tr>
<td>12% risk in 3.00 or more</td>
<td>3 in 65</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>2.5% in monovision or myopic</td>
</tr>
<tr>
<td>4.2% in 1.00 and more</td>
<td>3 in 25</td>
</tr>
<tr>
<td>Microbial keratitis (MK)}</td>
<td>1.00</td>
</tr>
<tr>
<td>Corneal injury</td>
<td>9.3%</td>
</tr>
<tr>
<td>MK with 2 line loss of BCVA</td>
<td>9.3%</td>
</tr>
<tr>
<td>Daily wear</td>
<td>3 in 50</td>
</tr>
</tbody>
</table>

for a SD or greater myopia:
The lifetime risk of RD is 2.5 times higher than their risk of MK with daily wear daily disposable lenses.
The lifetime risk of RD is 2.5 times higher than the risk of MK with loss of BCVA with extended wear soft lenses.

OrthoK Provides better Quality of Life

What is Vision-Related Quality of Life?

- Attributes include:
  - Distance Acuity/Clarity of Vision
  - Near Acuity
  - Activity Restrictions
  - Diurnal changes of vision
  - Self-Image/Self Confidence/Appearance
  - Symptoms (Dryness, itching, discomfort, etc)
  - Night vision
  - glare
  - Dependence on Correction
  - Worry (re: ability to do things or about vision worsening)
  - Overall satisfaction with vision/vision correction
  - Expectations

Quality of Life Studies

- Crossover study-OrthoK and SCL (n=65) — 2 mo each mode
- OrthoK wearers report (compared to SCL wear)
  - Less activity restrictions
  - More night glare
  - More self-confidence
  - Less Worry
  - Less dependence on correction


Quality of Life Studies

- “This study demonstrated a relatively high level of patient satisfaction following overnight orthokeratology. Post-treatment uncorrected visual acuity is associated with patient satisfaction, and patients with higher myopia (>−4.50) are predisposed to lower levels of subjective satisfaction. (n=17)”

**Quality of Life Studies**

- OrthoK compares favorably with LASIK for minimal effects on vision-related quality of life.
  - “LASIK showed the lowest average decrease in quality of vision compared with emmetropes. OK was comparable with LASIK in independence of visual correction, and SCL wear was superior to LASIK and OK lens wear in glare.”


**Quality of Life Studies**

- Important area to measure the success of our efforts
- Extensive review of the properties, features and validity of QOL questionnaires


**OrthoK slows Myopic Progression**

- Mechanism of action
  - Not due to accommodation or change in central refraction
  - Change in peripheral refraction from hyperopic to myopic


OrthoK slows Myopic Progression

- Numerous studies showing OrthoK Slows Myopia progression 40-60% (both refractive change and axial length)
- Dependent on:
  - Age at start: better when started younger
  - Degree of Myopia: best -1.50 to -6.00
  - Pupil Size (Conflicting study results)

Effect of OrthoK on Myopia Progression


Myopia Management with OrthoK

- Study of 16 different Myopia Control Strategies
- Considering Spectacles, Contact Lenses and Pharmaceuticals
  - OrthoK is #3 in efficacy (preceded by Atropine 0.5% and Atropine 1%)

Myopia Control with OrthoK

- 1st RCT on effect of OrthoK on Myopic Progression
  - Showed 43% less change in axial length than spectacles
  - n= 51 controls, n=41 orthoK
  - Mean age – 9.39 controls, 9.23 orthoK
  - Faster myopia progression in younger age
  - More impact on final myopia when OCR started younger

Myopia Control

### Studies - OrthoK vs other Myopia Control Techniques

<table>
<thead>
<tr>
<th>Author(s)</th>
<th>Myopia Control Approach</th>
<th>Reduction in Myopia Compared to Controls (%)</th>
</tr>
</thead>
</table>

### Myopia Management

- **3 recent Meta-Analysis Studies Published**
  - Summary is that OrthoK is an effective tool to control myopia progression (about **45%**)


### Projected Myopia Progression

- **Is 40-60% reduction significant??**

  "The clinical conundrum here is that there is perhaps a greater risk to loss of sight through not considering a myopia-controlling intervention."

  "... reducing the progression of myopia by 33% would result in a 73% reduction in frequency of myopia higher than 5.00D and that there would be 90% less high myopes if progression was arrested by 50%.”


### One More Recent Publication

- “Orthokeratology was perceived (by practitioners) to be the most effective method of myopia control, followed by increased time outdoors and pharmaceutical approaches…”

- "In view of the increasing prevalence of myopia and existing evidence for interventions to slow myopia progression, clear guidelines for myopia management need to be established."

- 50% of practitioners still prescribe SV spectacles to correct myopia!!!


### Ortho K is a Viable Refractive Option

- Compared to glasses, scl, LASIK
  - **Children**
    - No daytime correction
    - Myopia control
  - **Adults**
    - No daytime correction
    - Less dry eye issues than SCL
    - Adjustable for monovision
Patients Prefer OrthoK

- In a crossover study – pts wore OCR and SCL (2 mo each)
- At study conclusion
  - 69% chose OrthoK (for -3.00 or less – 90% OrthoK)
  - 31% chose SCL (for more than -3.00 – 50-50)

“I prefer OrthoK“


Summary – Studies Demonstrate

- OrthoK is an effective refractive option
- OrthoK is safe
- OrthoK slows myopic progression
- OrthoK is a viable alternative to:
  - glasses
  - daytime contacts
  - LASIK.

OrthoK Resources

- GPLI – http://www.gpli.info
- Contact Lens Update
  - http://contactlensupdate.com/?s=orthokeratology&x=0&y=0
  - American Academy of Orthok and Myopia Control
  - http://www.orthokacademy.com/heritage/

Thank you for attending!!

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