Myopia Control Via Corneal Refractive Therapy

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Myopia Control

• Bifocal Lenses
  – Relaxing accommodation
• Rigid Contact Lenses
  – ???
• CL Corneal Reshaping
  – Anterior aspheric optics
• Pharmacologic Intervention
  – Target specific anatomic structures of the eye

Bifocal Spectacle Studies

• Fulk et. al. IOVS (2000)
  0.25 D. Difference
• Edwards et. al. IOVS (2002)
  <0.25 D. Difference

COMET Trial

Gwiazda et. al. 2003  Three Year Results

SV Spec -1.40D  BF Spec -1.20D  < Myopia = 0.20D

Do Bifocal Spectacle Lenses Decrease Myopia Children?

More Consistent, Full Time, Correction
All previous studies plagued with patient non-compliance

Sir Stewart Duke-Elder, 1970

“The etiology of myopia has excited an immense amount of speculation and controversy...and the theories which have been put forward to explain its development are as ingenious, fanciful and contradictory as have accumulated around any subject in medicine.”
Myopia has Historically Been Associated With Nearwork

![Graph showing nearsightedness by occupation]

Today’s Myopia Epidemic

- Leading form of refractive error
  - 30% of Americans 85% East Asians affected
  - 96.54% Korean 19 year olds have myopia
- Instances increase with education level
  (Jung S, et al. 2012)
- Increase chance in near work (computers, cell phones)

Rigid Contact Lens and Myopia Control

- Early Studies
  - Morrison
  - Grosvenor
  - Am J Ophthalmology
  - Arch of Ophthalmology

A Randomized Trial of the Effects of Rigid Contact Lenses on Myopia Progression

J. J. Walline, OD, PhD, L.A. Jones PhD, D.O. Mutti OD, PhD, K. Zadnik OD, PhD

Walline Study
Axial Growth Results

Change in Axial Length

RGP = 0.81 mm  SCL = 0.76 mm  Difference = 0.05 mm

Change in Axial Eye Growth
Two Year Data

The Longitudinal Orthokeratology Research In Children (LORIC) study in Hong Kong

A pilot study on refractive changes and myopic control in 35 children 7-12

Pauline Cho, PhD, Associate Professor
Sin Wan Cheung, MPhil, Research Associate
Marion Edwards, PhD

Department of Optometry & Radiography
The Hong Kong Polytechnic University

Vitreous Chamber Elongation

Crayon Study
Corneal Reshaping and Yearly Observation of Nearsightedness

Jeffrey J. Walline, OD, PhD
AOCLE Conference Montreal Canada, June 2006

Inclusion Criteria
- Ages 9 to 12 years
- Sphere -0.75 D to -4.00 D
- Cylinder less than -1.00 D
- 20/20 OU
- No previous RGP wear

Contact Lenses
- Orthokeratology / Paragon CRT
- CIBA Vision Focus 2 Week (SCL)
Walline *One Year Results*

Vitreous Chamber Depth

<table>
<thead>
<tr>
<th></th>
<th>SCL Control</th>
<th>CRT</th>
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</thead>
<tbody>
<tr>
<td>0.27</td>
<td>0.14</td>
<td></td>
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Walline and Cho *One Year Results*

Vitreous Chamber Depth

<table>
<thead>
<tr>
<th></th>
<th>Walline SCL Control</th>
<th>Walline CRT</th>
<th>Cho Glasses Control</th>
<th>Cho OK</th>
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<tbody>
<tr>
<td>0.27</td>
<td>0.14</td>
<td>0.12</td>
<td>0.12</td>
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CRAYON - Conclusions

- 3 out of 4 children can wear lenses for corneal reshaping
- Confirms study by Cho, et al.
  - Corneal reshaping contact lenses slow axial growth of the eye.

Myopia Control Through Optical Intervention

Myopia Development

- In all species, (including humans) the two eyes typically grow in a highly coordinated manner towards the ideal optical state, a process called *Emmetropization*
- The process is regulated by visual feedback.

Form Deprivation Myopia

*Wiesel & Raviola 1977*

Conditions that prevent the formation of a clear retinal image cause the eye to grow abnormally long and become myopic.

*"Form-Deprivation Myopia"*

The ocular changes in FDM are similar to those associated with juvenile-onset myopia.

The potential for a clear retinal image is essential for normal refractive development.
Form Deprivation Myopia

If an eye that has form-deprivation myopia is corrected with spectacle lenses no recovery takes place.

However, if the eye is allowed unrestricted (uncorrected) vision, the eye will recover through a visual feedback mechanism.

Therefore

• In “NORMAL” humans, the mechanisms that are responsible for emmetropization, monitor the retinal image and adjust axial growth rates to eliminate refractive errors.

Does the Fovea Control the Axial Growth of the Eye?

*Earl Smith et.al. University of Houston*

Peripheral Form Deprivation

4.0 mm Apertures

Smith et. al. Univ of Houston

Is an Intact Fovea Essential for NORMAL Emmetropization?

Foveal Ablations n=5

The fovea and most of the peri-fovea were ablated in one eye using an argon laser (500 mW; 400 micron spot size; 50 msec)

Age

19.0 +/- 1/6 days

Smith et. al. Univ of Houston

Smith et. al. Univ of Houston

Smith et. al. Univ of Houston
Peripheral Ablations (n=5)
The mid and far peripheral retina of one eye was ablated with a frequency-doubled YAG laser (150 mW, 150 msec).

Half-burn Width Spacing. Number of Burns: 2,316 +/- 884

Smith et. al. Univ of Houston

Conclusions
- Peripheral form deprivation can produce axial myopia at the fovea.
- A functioning fovea is not essential for emmetropization.
- An intact periphery is essential for emmetropization.

What Does This Mean ???

These data demonstrate that the fovea DOES NOT play the dominate role in refractive development.

Instead peripheral retinal image plays the MAJOR role in determining overall eye growth.

Chicks and hyperopic defocus
- Dr. Liu and Dr. Wildsoet at UC Berkely
- Lenses were placed on the chickens to mimic central and peripheral defocus
- Lenses worn for 5-17 days
Corneal Reshaping / Orthokeratology

Ideal Optical System

Reflected light from an object is focused precisely along the image-receiving surface. Typically, for conventional optical systems, the imaging-receiving surface is a flat surface i.e. a camera with film.

Optical System With a Positive Curvature of Field

The central image remains in focus while the peripheral image falls posterior to the focal plane.

Optical System With a Negative Curvature of Field

The central image remains in focus while the peripheral image falls anterior to the focal plane.

Undercorrection

Positive Curvature of Field

Central rays of light are focused anterior to the retina however, due to the positive curvature of field the peripheral rays of light are focused behind the retina.

The “Image Shell” With Correction

Positive Curvature of Field

As a consequence of eye shape and/or aspheric optical surfaces, "corrected" myopic eyes experience significant HYPEROPIC defocus across the visual field.
Emmetropization

- Peripheral retina is able to influence ocular growth and refractive development.
- Hyperopic defocus in the periphery promotes axial myopia in monkeys and humans.
- Corrective lenses do not appear to help.

The “Image Shell” Post OK

Earl Smith 2005

Eye growth may possibly be retarded, or halted through:

“A precise and pre-determined optical system at the corneal plane that will manipulate the peripheral optics of the eye.”

The post OK cornea generates a negative curvature of field. Central rays of light are focused on the fovea. Peripheral rays of light are focused more anteriorly (in front) of the retina.

LORIC Results

- Dr. Pauline Cho 2-year study in Hong Kong
- Ortho-k vs. spectacle wearers
- The SER for the patients was between -0.25D and -4.50D and an astigmatism <2.00D.
- Ortho-k group showed a mean myopic reduction of 2.09 ± 1.34D and an AL increase of 0.29mm.
- Spectacle group showed a mean myopic increase of 1.20 ± 0.61D and an AL increase of 0.54mm.

Contact lenses
Orthokeratology
Refractive surgery
Intraocular lens
Corneal implants
**COOKI Results**

- Dr. Jeffery Walline measured SER of patients.
- Ortho-k compared to past RGP data.
- Ortho-k wearers SER changed from -2.44 ±1.38D to -0.16±0.66D at the 6 month period.
- 47.4% of eyes achieved a UCVA of 20/20 and 100% achieved 20/40.
- Ideal UCVA was reached at 1 week compared to 300 days of RGP wear.

**CRAYON Results**

- Dr. Walline study to determine efficacy of the LORIC study
- Ortho-k vs. SCL
- Mean AL elongation was 0.16mm less in Ortho-k groups compared to SCL wearers.
- Mean VCD elongation was 0.10mm less in Ortho-k patients.
- Ortho-k halves AL elongation.

**SMART Study**

Stabilization of Myopia thru Accelerated Refractive Therapy

- Large scale study across 10 practices measured UCVA and SER of patients.
- Ortho-k vs. SCL
- UCVA at 3 year mark:
  - 85% of OK patients achieved an uncorrected visual acuity of 20/20 or better.
  - 99% achieved 20/40 or better.
- SER at 3 year mark had a change of OD -0.19D and OS -0.15D in the Ortho-k group and OD -1.00D and OS -1.02D in the SCL group.
- Key point- Ortho-k eyes had lenses removed each year. SER and topography had to stabilize.

**Influence of Overnight Orthokeratology on Axial Length Elongation in Childhood Myopia**

- Dr. Tetsuhiko Kakita long-term study in Japan measured SER and AL elongation.
- Ortho-k vs. SV Spectacles.
- Ortho-k Group:
  - Mean SER (baseline)- -2.55 ±1.82D
  - Mean AL (baseline)- 24.66 ±1.11mm
  - Mean SER (2-years)- -0.68 ±1.02D
  - Mean AL increase (2-years)- 0.39 ±0.27mm
- Spectacle Group:
  - Mean SER (baseline)- -2.59 ±1.66D
  - Mean AL (baseline)- 24.79 ±0.80mm
  - Mean SER (2-years)- -3.83 ± 1.76D
  - Mean AL increase (2-years)- 0.61 ± 0.24mm

**MCOS Results**

Myopia Control with OK Lenses in Spain

- Dr. Jacinto Santodomingo-Rubido’s study in Madrid, Spain measured AL elongation.
- Ortho-k vs. SV Spectacles
- 0.47mm elongation in Ortho-k
- 0.69mm elongation in SV spectacles.
What age is Ortho-k most effective?

• Dr. Pauline Cho 2012 study IOVS
• 102 patients aged 6-10
• Ortho-k slowed AL elongation by 43% average increase of AL in Ortho-k patients as $0.36 \pm 0.24$mm and average increase in SV spectacles was $0.63 \pm 0.26$mm
• AL moves at a faster rate in children aged 7-8 making ortho-k most effective for these children.

<table>
<thead>
<tr>
<th>Age</th>
<th>Change in AL (Orthokeratology)</th>
<th>Change in AL (Control)</th>
<th>Modality of Control</th>
<th>Length of Study</th>
<th>% Increase of AL in Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>LORIC 7-12 years</td>
<td>0.29mm</td>
<td>0.54mm</td>
<td>glasses</td>
<td>2 years</td>
<td>46.30%</td>
</tr>
<tr>
<td>CRAYON 6-11 years</td>
<td>0.25mm</td>
<td>0.57mm</td>
<td>SCL</td>
<td>2 years</td>
<td>56.14%</td>
</tr>
<tr>
<td>Kakita 8-16 years</td>
<td>0.30mm</td>
<td>0.51mm</td>
<td>glasses</td>
<td>2 years</td>
<td>36%</td>
</tr>
<tr>
<td>MCOS 6-12 years</td>
<td>0.47mm</td>
<td>0.69mm</td>
<td>glasses</td>
<td>2 years</td>
<td>31.88%</td>
</tr>
<tr>
<td>Kakita 5-year 16 years</td>
<td>0.99mm</td>
<td>1.41mm</td>
<td>glasses</td>
<td>5 years</td>
<td>29.78%</td>
</tr>
</tbody>
</table>

Myopia Control

• Bifocal Lenses
  – Relaxing accommodation
• Rigid Contact Lenses
  – Improving retinal imagery
• Myopia correction
  - OrthoKeratology
• Optical Interventions
  – Curvature of field modification
• Pharmacologic Intervention
  – Topical Atropine

Atropine

• Readily available
• Anti-cholinergic receptor antagonist
• Shown to slow the progression of myopia (Chia A, et al. 2012) - now using .01% Atropine
• Difficult to control eye dilation causing blurry vision
• Did not affect hyperopic defocus.

LASIK

• Requires a trained surgeon
• Can be costly
• Permanent change to the corneal shape
• May still require contacts/glasses
• Not suitable for younger children

My Personal Statement AAO 10/11

"There is now enough evidence to state that the technique of OK Corneal Reshaping Therapy can reduce myopia progression in children thru the reduction in Axial Length. What we don’t know is whether this has a temporary or permanent effect."
Summary

• Thank you for your attention!

www.kofflervisiongroup.com