

ORTHOKERATOLOGY and MYOPIA CONTROL

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Definition of orthokeratology (OK)

- “...the reduction, modification or elimination of refractive anomalies by the programmed application of contact lenses” (*International Orthokeratology Section of NERF, 1971*)



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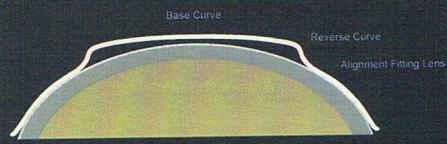
Modern OK

- specially designed rigid contact lenses
 - reverse geometry design
- worn overnight only
 - no lens wear during the day
- provide temporary correction for refractive error
 - effect is reversible if lens wear ceases
- mainly used for low-moderate myopia



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OK lens design

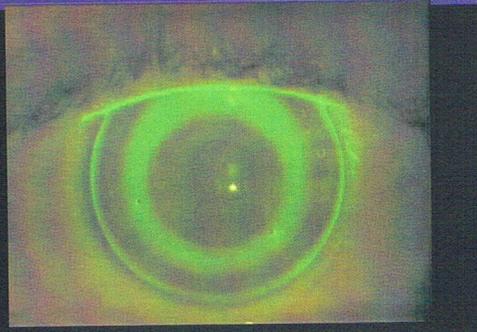


Base Curve
Reverse Curve
Alignment Fitting Lens



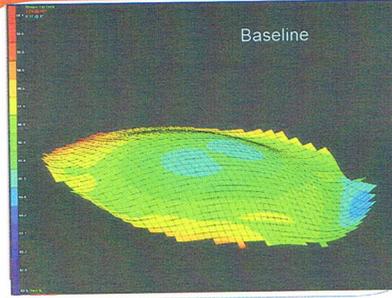
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OK lens - fluorescein pattern



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Corneal shape in OK



Baseline



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Myopia correction vs control

- myopia correction is what we do every day to provide clear vision for myopes
 - spectacles, contact lenses
 - orthokeratology
 - refractive surgery
- myopia control refers to the reduction or elimination of **progression** of myopia in developing myopes

Myopia control

- progression of childhood myopia
 - most change between 8 and 15 years of age
 - rate influenced by age of onset, gender, age at measurement time, degree of myopia
 - most myopia is axial (due to axial elongation)
 - strong correlations found between changes in axial length and increases in myopia

Myopia control

- how to monitor myopia progression?
 - rate of refractive change
 - change in dioptres per year
 - based on objective/subjective refraction
 - axial growth rate
 - change in mm per year
 - A-scan ultrasonography (contact)
 - IOL Master biometer (non-contact)

Myopia control

- Optical
 - under/over-correction of refractive error, full-time vs occasional (distance) spectacle use
 - bifocals, multifocals/PALs
 - rigid and soft contact lenses
 - orthokeratology
- Pharmaceutical
 - atropine
 - pirenzepine
- Other
 - behavioural vision training, ultrasound therapy, biofeedback, hypnosis, exercises, diet

Myopia control with contact lenses

Year	Author	CL Subjects*	Control (Change in D/yr)	Contact Lenses (Change in D/yr)
1976	Stone	80	-0.37	-0.08
1990	Grosvenor et al	100	-0.51	-0.16
2003	Katz et al	158	-0.64	-0.67
2004	Walline et al	59	-0.73	-0.52
1999	Horner et al (SCLs)	175	-0.30	-0.36

* number of subjects enrolled

Myopia control with OK lenses

- anecdotal evidence abounds that OK may slow progression of myopia
- thousands of children in East Asia are wearing ON OK specifically for myopia control
- promising results from early clinical studies of overnight OK

Role of peripheral refraction?

- evidence from animal studies suggests that peripheral rather than central retinal image plays the key role in controlling eye growth
- progressing myopes tend to show relatively hyperopic peripheral refraction

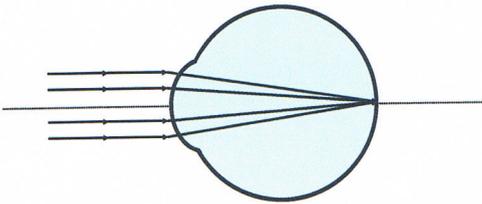
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Schematic eye



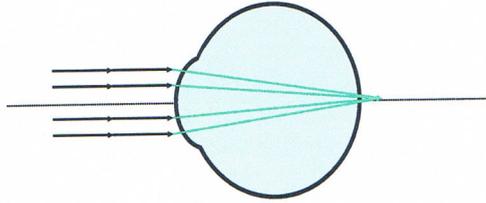
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Emmetropia



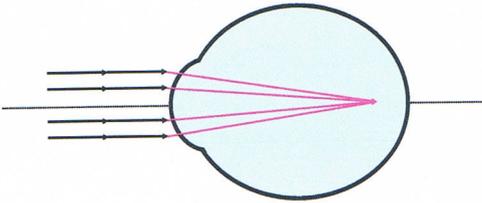
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Hyperopia



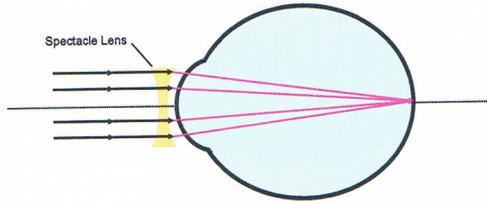
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Myopia



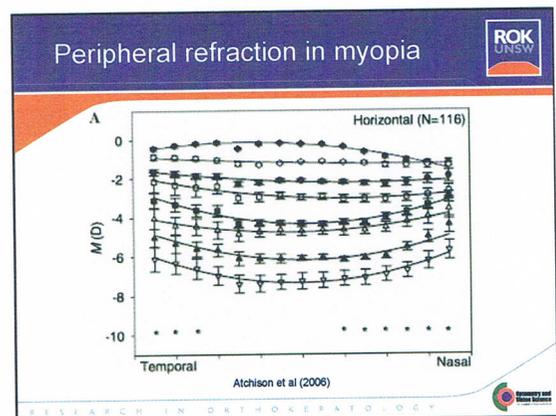
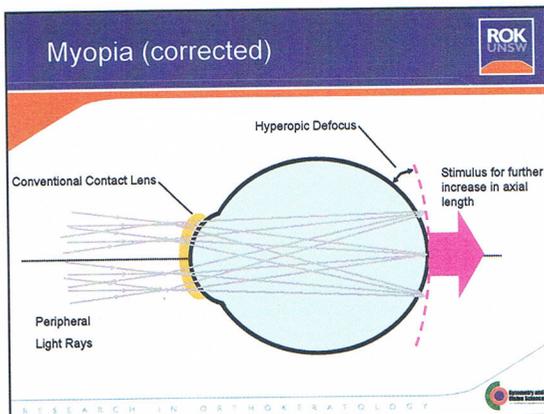
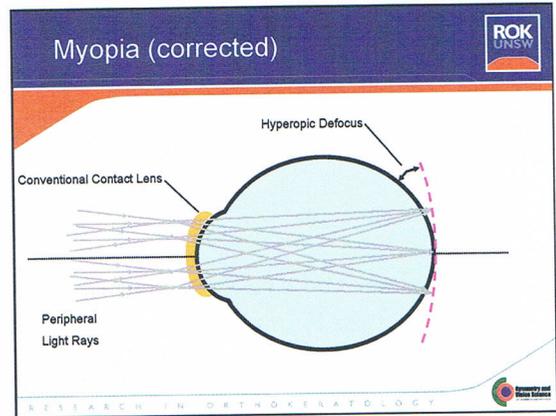
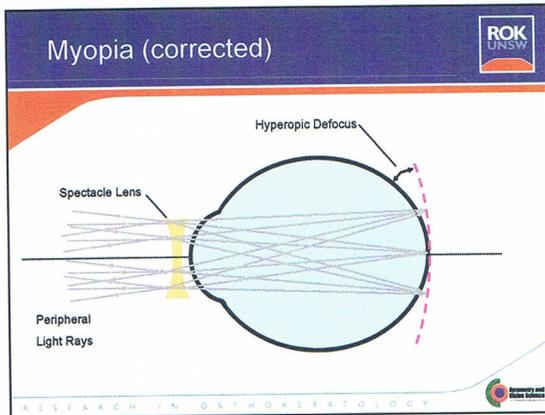
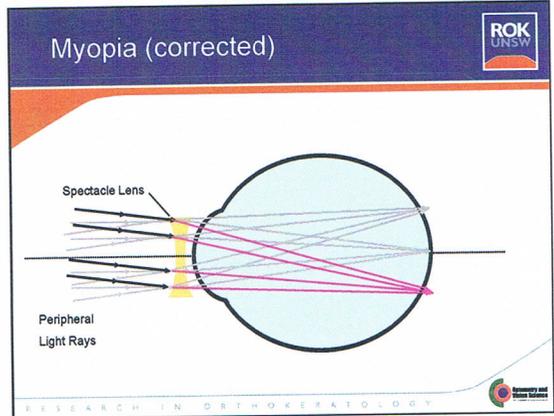
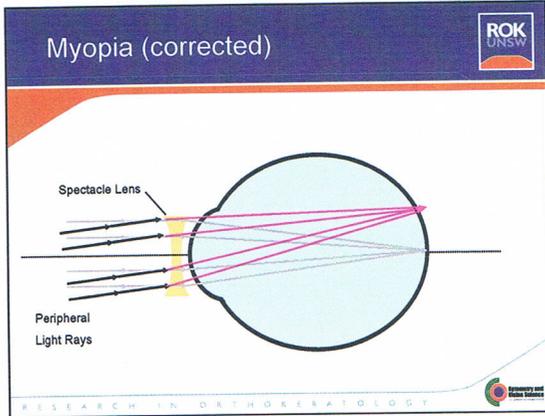
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Myopia (corrected)



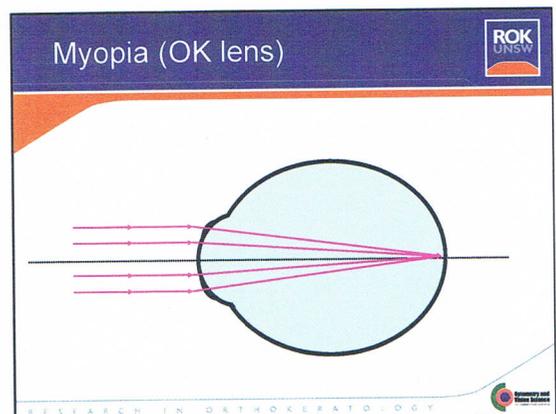
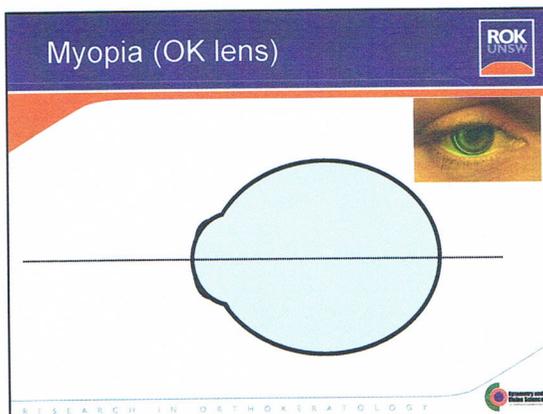
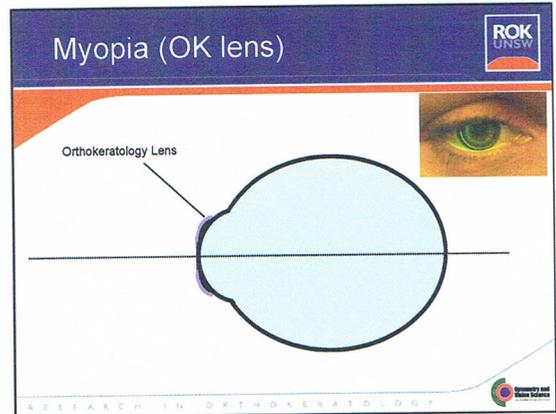
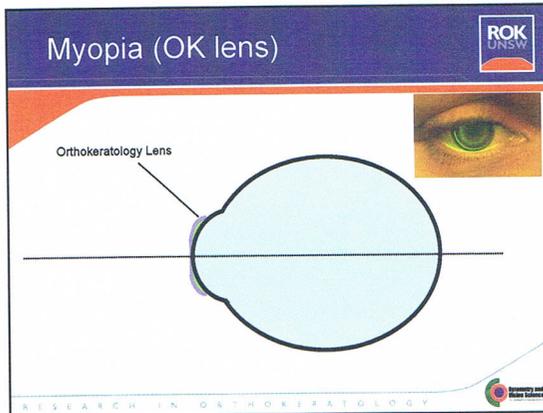
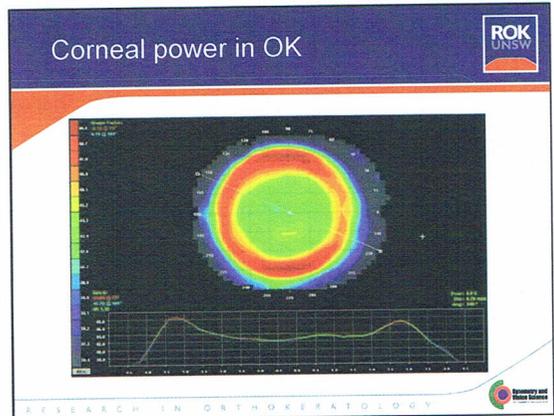
Spectacle Lens

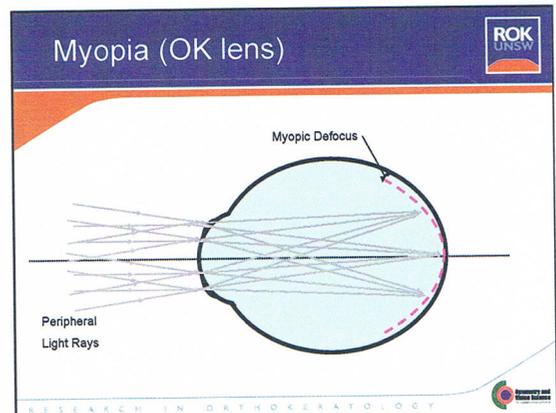
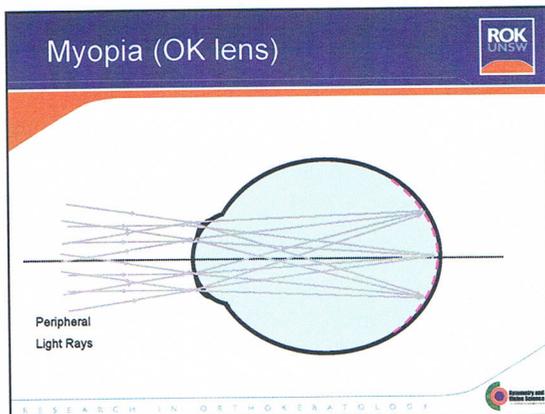
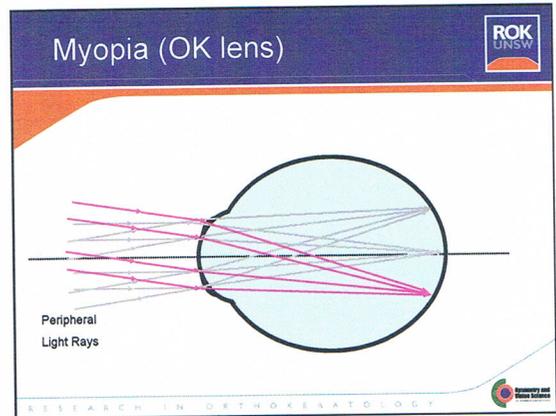
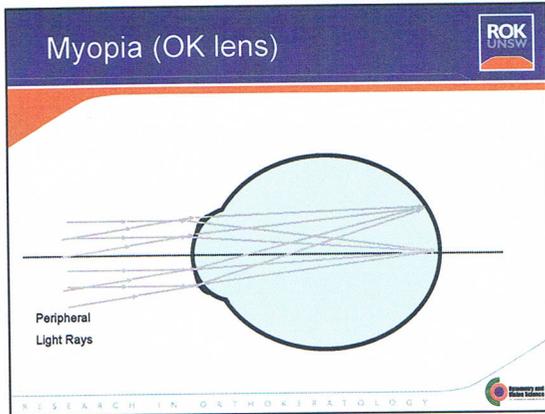
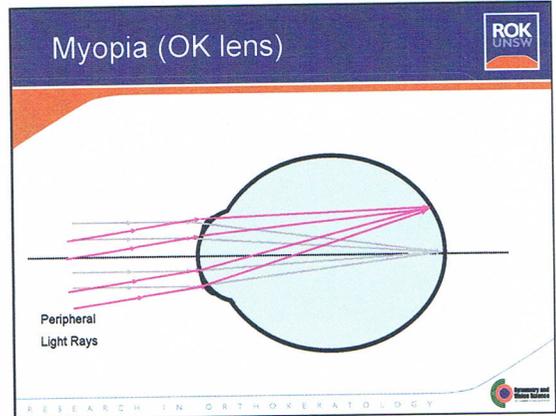
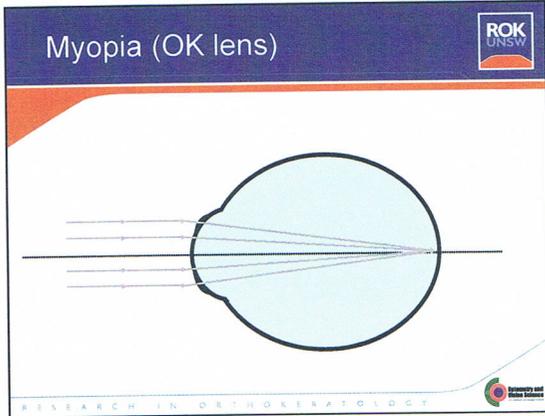
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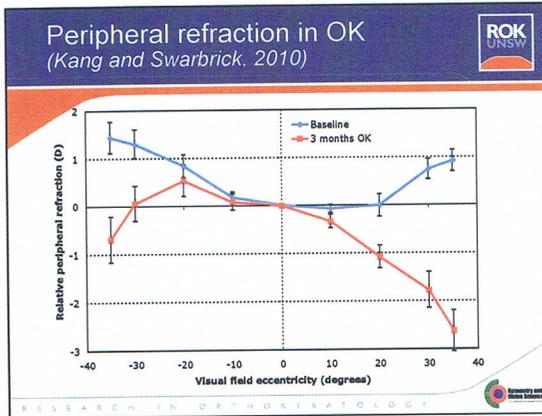


Role of peripheral refraction?

- progressing myopes tend to show relatively hyperopic peripheral refraction
- manipulation of peripheral refraction towards relative myopia may act to slow myopia progression
 - this may be achievable with OK!

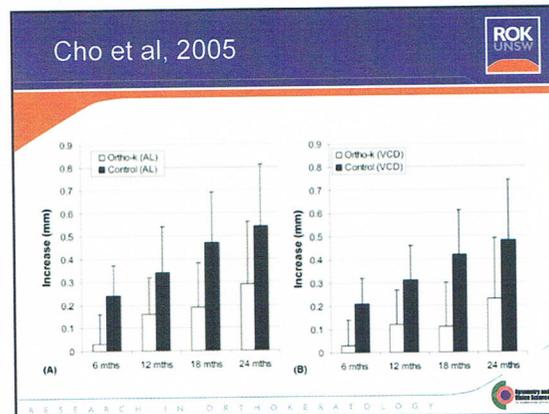




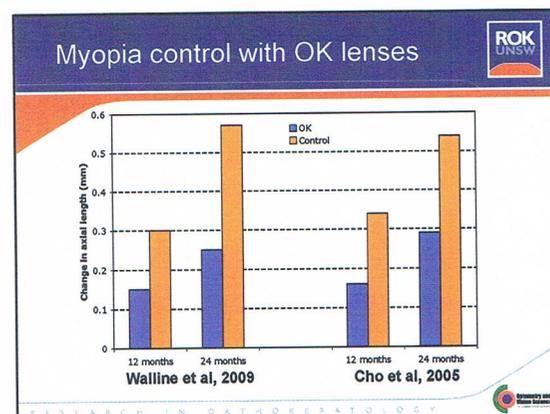


- ### Role of peripheral refraction?
- progressing myopes tend to show relatively hyperopic peripheral refraction
 - manipulation of peripheral refraction towards relative myopia may act to slow myopia progression
 - this may be achievable with OK!
 - is there any evidence for myopia control with OK?

- ### Myopia control with OK lenses
- #### Cho et al (2005) - LORIC Study
- 35 myopic children, 7-12 years
 - control group: 35 spectacle wearers
 - 2 years of overnight OK
 - axial length and vitreous chamber depth monitored
 - reduced eye growth in OK group



- ### Myopia control with OK lenses
- #### Walline et al (2009) - CRAYON Study
- 28 myopic children, 8-11 years
 - control group: 28 soft contact lens wearers
 - 2 years of overnight OK
 - axial length and vitreous chamber depth monitored
 - reduced eye growth in OK group



Myopia control with OK lenses

- both of these studies showed very promising outcomes
- both of these studies had significant shortcomings in study design
- prospective, randomized clinical trials necessary to confirm this early promise

Myopia control with OK

- controlled, prospective, randomized clinical trials are underway worldwide
 - MCOS study (Spain)
 - SMART study (USA)
 - ROMIO study (Hong Kong)
- study design based on comparison between OK and control groups

Myopia control with OK

MCOS (*Myopia Control with OK contact lenses in Spain*)

- 2 year study, sponsored by Menicon
- Menicon Z Night lens (similar to CRT); control group in spectacles
- axial length using IOL Master
- 24-month results show AL and Rx differences between groups

Myopia control with OK

SMART (*Stabilizing Myopia by Accelerated Reshaping Technique*)

- 5-year multi-centre study in USA, sponsored by Bausch & Lomb
- Emerald OK lenses; control group in PureVision daily wear
- axial length using A-Scan ultrasound
- 24-month results suggest small differences in Rx only between groups

Myopia control with OK

ROMIO (*Retardation of Myopia In Orthokeratology*) - Cho et al

- 2 year study, sponsored by Menicon
- NKL OK design in Menicon Z material; control group in spectacles
- axial length using IOL Master
- 12-month results suggest significant AL differences between groups

Myopia control with OK

- controlled, prospective, randomized clinical trials are underway worldwide
 - SMART study (USA)
 - MCOS study (Spain)
 - ROMIO study (Hong Kong)
- ROK Group study (UNSW, Sydney)
 - novel contralateral-eye study design

OK and myopia control:
ROK clinical study team






Ahmed Alharbi Kathleen Watt Helen O' Shea

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OK and myopia control:
ROK clinical study team






Ahmed Alharbi Edward Lum Helen O' Shea

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OK and myopia control



- East Asian subjects
 - age 8-16 years
 - progressive myopes
- contralateral-eye study design
 - daily wear GP lens in one eye (“Day Lens”)
 - overnight OK lens in other eye (“Night Lens”)
- 12 months study
 - lens/eye crossover after 6 months

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Methods - contact lenses



- overnight orthokeratology lenses
 - BE or ABE reverse geometry lenses (Capricornia Contact Lens)
- conventional alignment GP lenses
 - J-Contour aspheric lenses (Capricornia Contact Lens)
- Boston XO₂ material (Dk 141 ISO)

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Methods - measurements




- progression of myopia monitored by measuring changes in axial length
 - Zeiss IOL Master
- study measurements taken after 3, 6, 9, 12 months of lens wear

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Methods - measurements



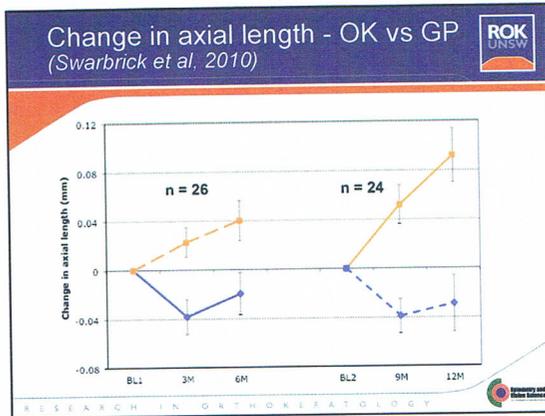
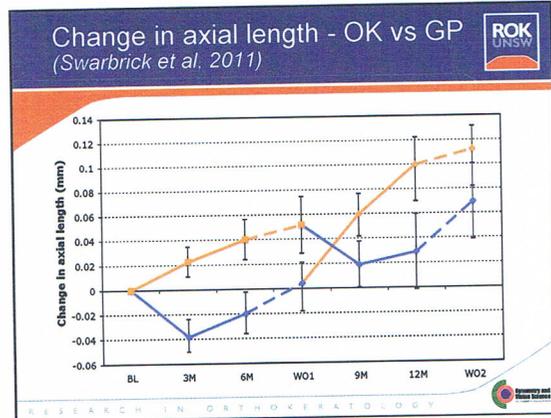
- objective refractive error measured using Shin-Nippon N-Vision K5001 autorefractor
 - at baseline and following 2-week washout (no lens wear) at 6 and 12 months
 - no cycloplegia
 - spherical equivalent recorded

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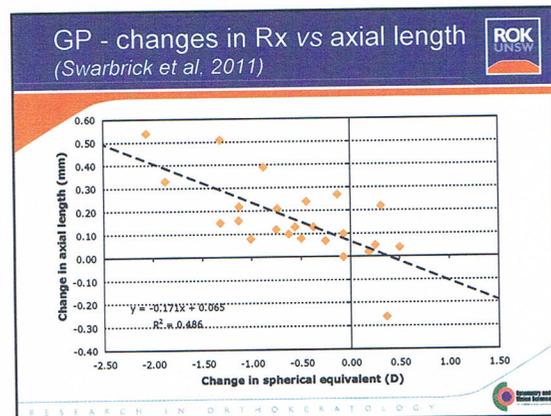
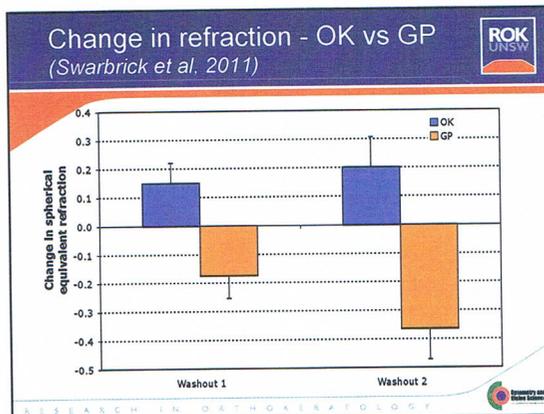
Subject discontinuations

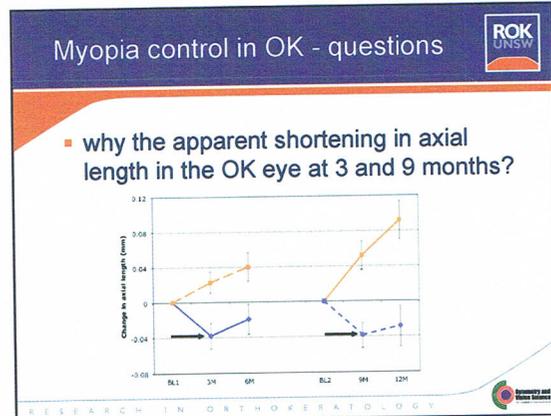
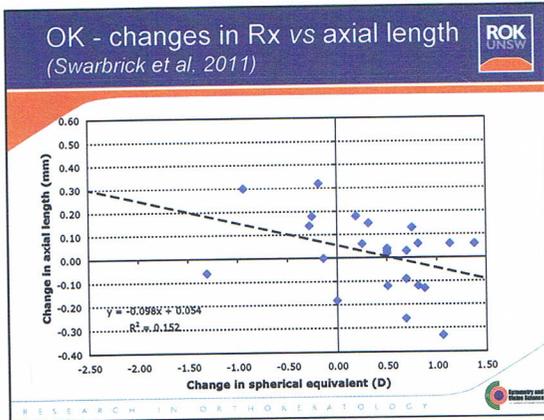
- 32 subjects commenced study
 - 2 unable to adapt to GP daily wear
 - 1 lens-related discontinuation (GP eye)
 - 2 discontinued because of travel distance
 - data for 1 subject deleted - noncompliance
- 26 subjects completed 6 months
 - 2 discontinued at 6 months because of travel
- 24 subjects completed 12 months



Change in axial length - OK vs GP

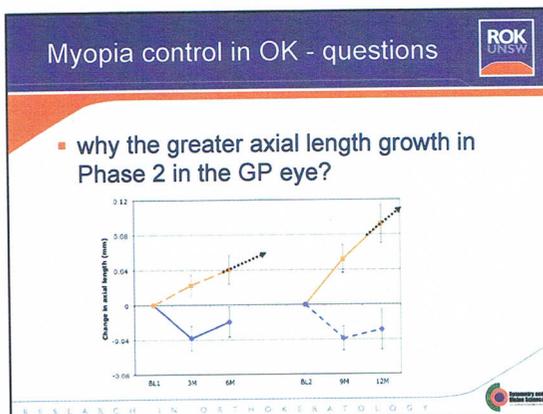
- significantly less axial length growth in OK vs GP eyes (ANOVA; $p < 0.02$)
 - progressive axial length growth in GP eyes
 - no difference from baseline in OK eyes at 6 and 12 months
- cross-over effect compelling





- ### Myopia control in OK - questions
- why the apparent shortening in axial length in the OK eye at 3 and 9 months?
 - IOL Master measures from corneal front surface to retinal pigment epithelium
 - some apparent shortening is due to central epithelial thinning (about 20 μ m)
 - some apparent shortening may be due to choroidal thickening

- ### Myopia control in OK - questions
- choroidal thickening?
 - well documented in animal models of myopia (chicken through to primate)
 - choroid thins on application of myopigenic stimulus (e.g. defocus, occlusion)
 - choroid shows rapid thickening (recovery) on removal of myopigenic stimulus
 - implication: OK neutralizes the myopigenic stimulus in progressive myopes



- ### Myopia control in OK - questions
- why the greater axial length growth in Phase 2 in the GP eye?
 - “rebound” effect?
 - what happens if OK lens wear is discontinued?
 - how long must OK lenses be worn to maintain myopia control effect?

Myopia control in OK - questions

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- what happens in the OK eye after 6 months?

Time	B:1 (mm)	B:2 (mm)
B:1	0.00	0.00
3M	-0.04	-0.04
6M	-0.04	-0.04
B:2	0.00	0.00
9M	0.04	0.04
12M	0.08	0.04

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Myopia control in OK - questions

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- what happens in the OK eye after 6 months?
 - short-term study, long-term effects unknown
 - is there accrual of effect over time?
 - follow-up on ROK Group subjects ongoing
 - long-term OK myopia control studies will help to resolve this question

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Myopia control with OK

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- in the short term, overnight OK inhibits axial length growth and myopia progression in myopic children
 - this confirms its potential for myopia control
 - long-term studies are now required to demonstrate effects over time

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Myopia control with OK

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- myopia control with OK works better for some children than others
 - can we predict the successful wearers?
 - can we individualize OK lens design to target effective myopia control for all kids?

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Myopia control with OK

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- myopia control vs. myopia prevention?
 - can we prevent development of myopia?
 - what causes myopia in the first place?

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Acknowledgements

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- The UNSW ROK Group:
 - Edward Lum, Kathleen Watt, Ahmed Alharbi, Paul Gifford, Pauline Kang, Helen O'Shea, Gavin Boneham, Vinod Maseedupally
- Research support:
 - Australian Research Council Linkage Project Scheme
 - Bausch & Lomb Boston
 - BE Enterprises Pty Ltd
 - Capricornia Contact Lens Pty Ltd
 - OK Society of Oceania, Contact Lens Society of Australia, Bausch & Lomb (Australia)

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