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Assess Efficacy of a Dual-Focus Myopia Control Contact Lens for Faster and Slower Progressing Eyes

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PURPOSE

Most randomized clinical trials compare myopia progression between control & treatment cohorts.

The 6 year MiSight 1 day clinical trial¹ control group commenced treatment in year 4, therefore the relationship between pre-treatment progression and treatment effectiveness can be made.

The clinical trial approach allows us to test the hypotheses

- Do some untreated eye consistently progress faster than others?
- Do some eyes fail to respond to treatment creating two distinct subpopulations of treated eyes?
- Is growth during treatment proportional to growth prior to treatment?
- Can myopia control with MiSight 1 day effectively treat both faster and slower progressing eyes?

METHODS

Clinical Data: 6 year clinical trial of MiSight 1 day[®] (omafilcon A, CooperVision Inc.) myopia control dual focus soft contact lens.
ClinicalTrials.gov Identifier: NCT01729208
This trial was sponsored by CooperVision, Inc.

Cohort: Treatment for 3 years (T3)

- 90 eyes
- Proclear 1 day (single vision) years 1-3
- MiSight 1 day years 4-6

Myopia Metrics:

- Optical biometry to determine axial length change from baseline
- Cycloplegic autorefraction change to baseline

Analysis:

- Frequency histograms
- Cumulative Z-score (Q-Q) plots
- Quartile analysis of single vision eye growth year 1-3 to assess uniformity of treatment effects
- Model untreated growth continuation using
 - Jones² equation for axial length
= $17.808 + 2.5680 \ln(\text{age})$
 - Shamp³ model approximation axial length & refraction
= $0.85 \times \text{previous annualized AL or SE change}$

RESULTS

Quantile-quantile (Q-Q plots) to assess distribution

Untreated

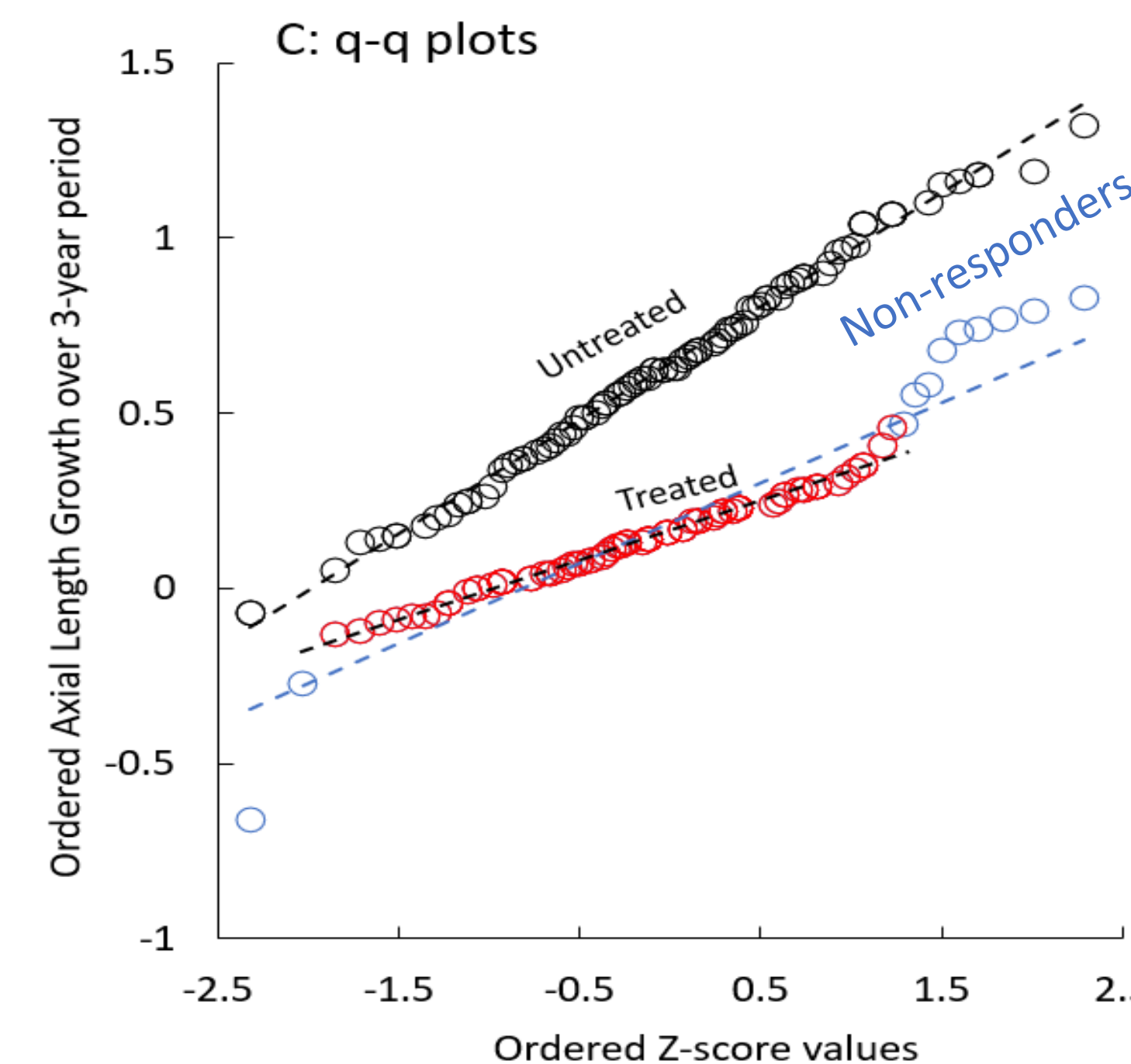
- Follows normal distribution

All treated data

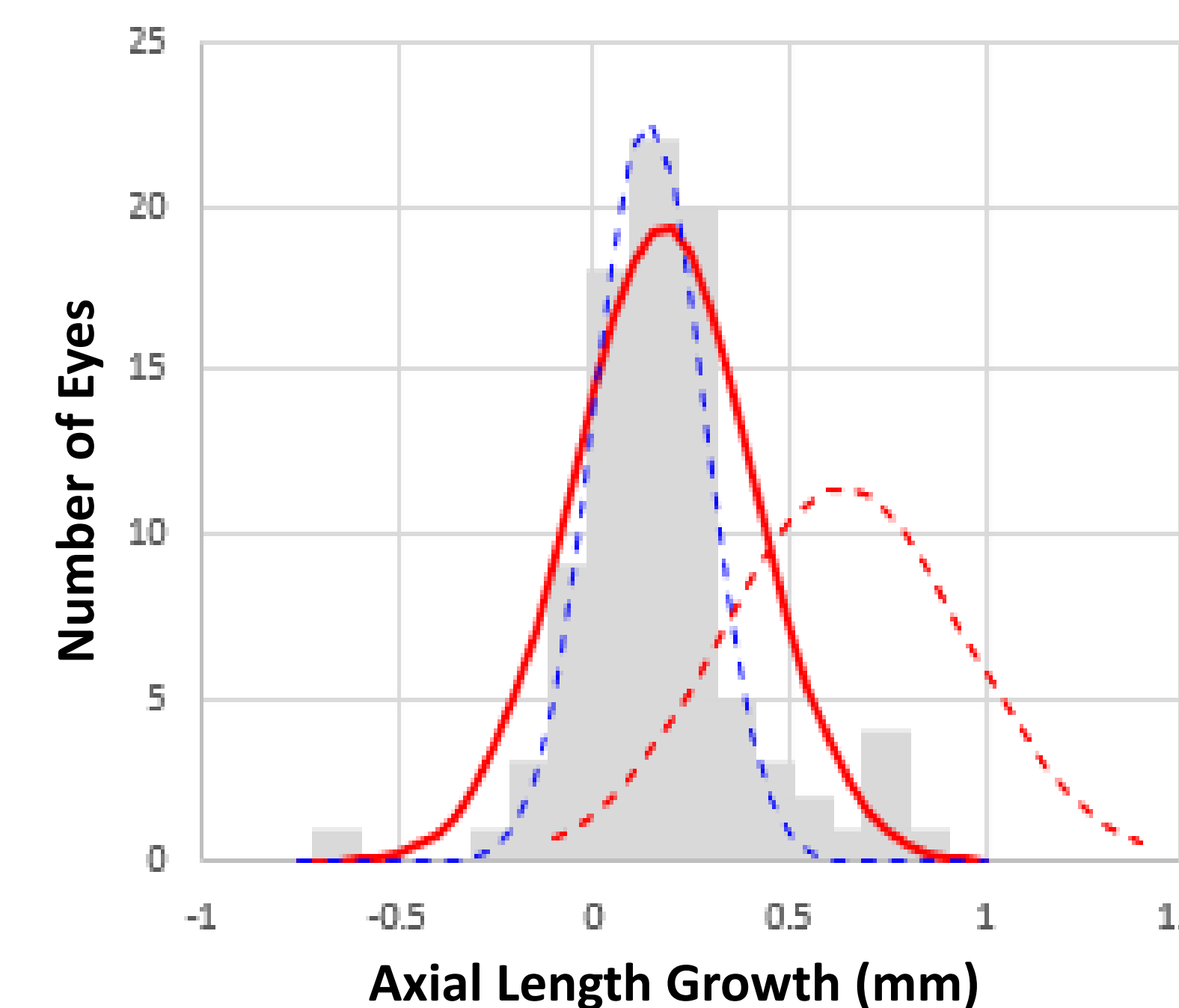
- Non-normal distribution

Outliers

- 9/90 eyes : 10% **Non-responders**
- 2/90 eyes : Negative growth each year
- 79/90 eyes: 88% **Responders**
: Normally distributed



Gaussian Fits of Accumulated Axial Growth



Untreated (Year 1-3)

- Gaussian model of growth
- Standard deviation = 0.31 mm

Treated (Year 4-6)

All eyes

- Gaussian model of growth
- Standard deviation = 0.23 mm

Responder eyes (90% of cohort)

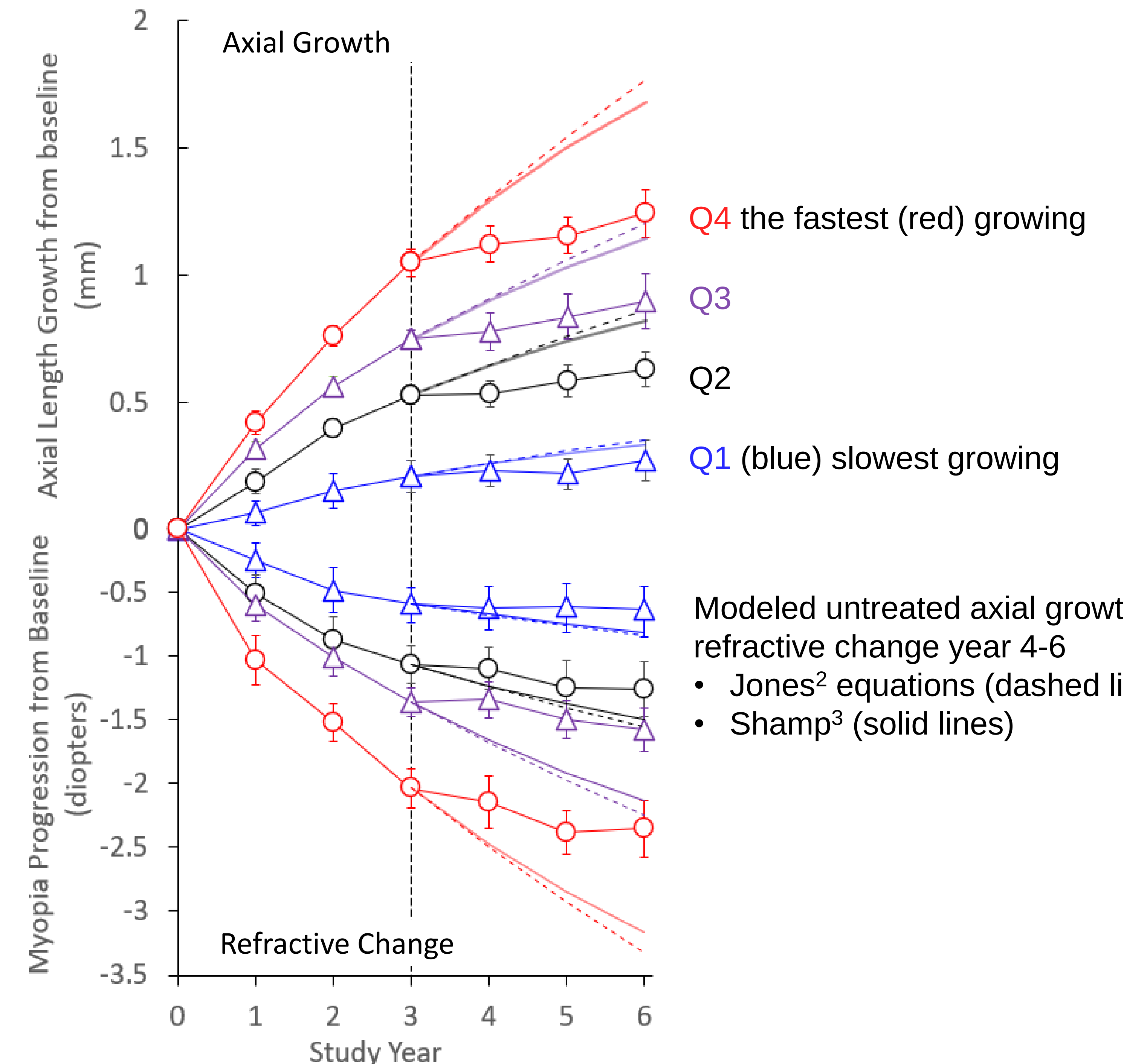
- Narrowed range of growth
- Standard deviation = 0.14 mm

Responder eyes growth distribution narrows with MiSight 1 day treatment

- SD of responder eyes = 0.45 x untreated SD
- Inconsistent with fixed treatment effect

Responder Quartile Grouping Analysis

- Quartiles derived from accumulated axial growth years 1-3
- Error bars are 2x standard error measurement



- Modeled untreated axial growth & refractive change year 4-6
- Jones² equations (dashed lines)
 - Shamp³ (solid lines)

- Faster growing eyes slowed more than slower growing eyes with MiSight 1 day treatment
- Treated growth = 0.29x untreated growth
 - Inconsistent with fixed treatment effect

CONCLUSIONS

- Faster growing eyes treated with MiSight 1 day show greater absolute slowing (in mm) than those initially slower growing eyes over each treatment year
- Non-responders exist, with 10% of eyes whose growth was unchanged by treatment
- Axial growth in the majority of treated eyes were consistent with a simple proportional treatment effect
- Uniformity in myopia control treatment effect is that of a proportional effect, with a percentage treatment effect
 - All progressing myopes will receive treatment effect
 - Faster progression myopes get the greatest treatment benefits
- Findings inconsistent with a regression to the mean as predicted by random growth models

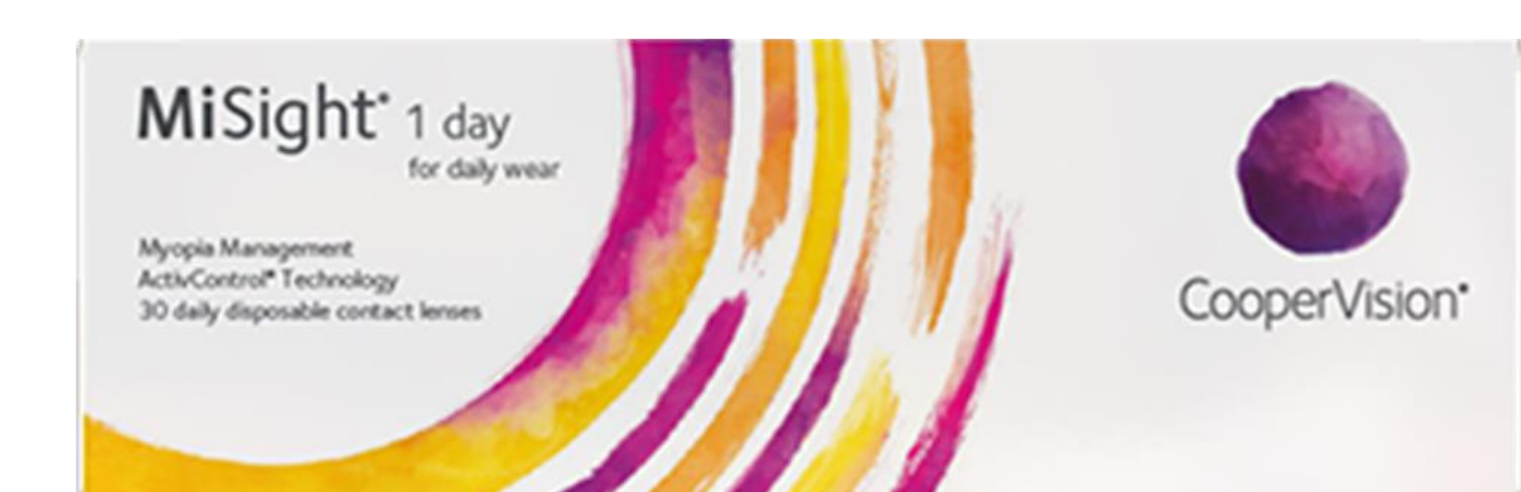
REFERENCES

1. Chamberlain, Paul, et al. Long-term effect of dual-focus contact lenses on myopia progression in children: A 6-year multicenter clinical trial. *Optometry and Vision Science* 99.3 (2022): 204-212.
2. Jones, Lisa A., et al. Comparison of ocular component growth curves among refractive error groups in children. *Investigative ophthalmology & visual science* 46.7 (2005): 2317-2327.
3. Shamp, Wright, et al. Influence of age and race on axial elongation in myopic children. *Investigative Ophthalmology & Visual Science* 63.7 (2022): 257-A0111.

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Indications for use: MiSight® 1 day (omafilcon A) soft (hydrophilic) contact lenses for daily wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have refraction of -0.75 to -4.00DS (spherical equivalent) with ≤ 0.75DC. The lens is to be discarded after each removal.