Real-world Safety and Performance of a Novel Soft Contact Lens for Myopia Management in Chinese Children

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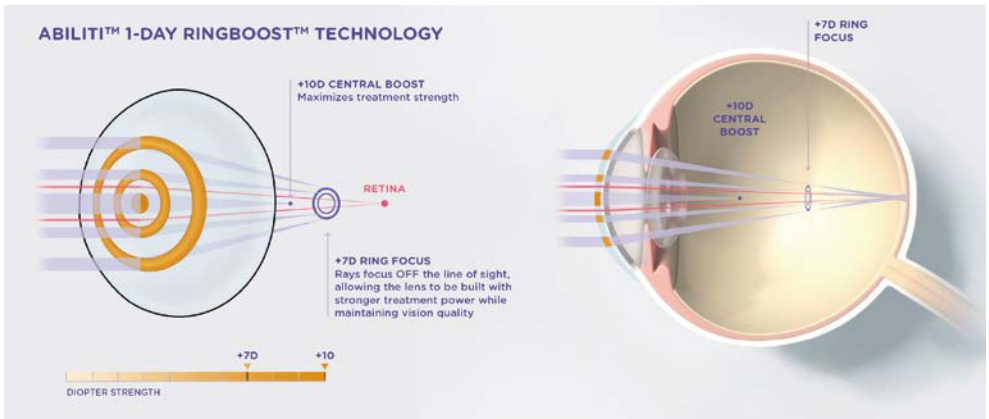
Introduction

- A soft contact lens (EE) with the RingBoost Technology™ is designed to enhance myopia control efficacy while providing good vision (Figure 1).
- Safety and Efficacy of the EE lens was demonstrated in a 6-month[1] and an on-going 3-year minimum, multinational randomized, controlled, double masked trial, which supported marketing approvals of the EE lens in several countries.
- The objective of this study was to assess safety and performance of the EE lens in Chinese children in a real-world clinical setting in China.
- 12-month interim outcomes of this real-world study are reported.

Figure 1: Comparing RingBoost Technology™ with typical dual focus designs



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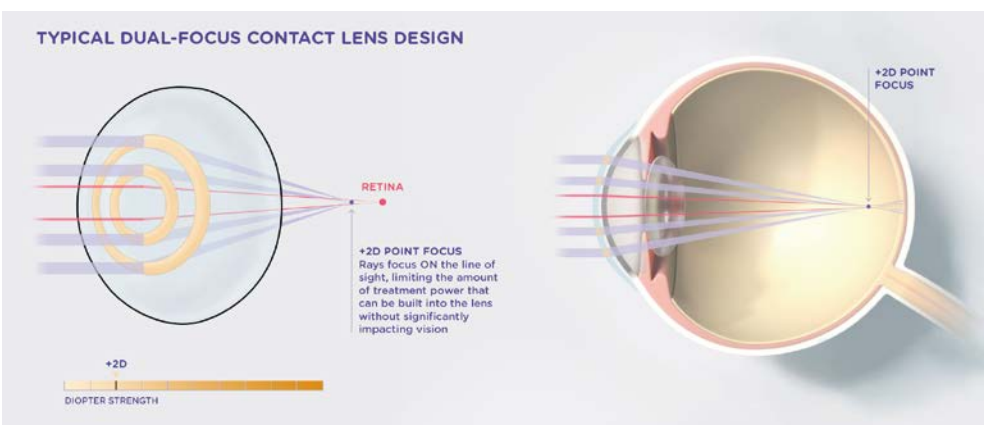


Method

- Single-site, prospective, single-arm, open-label, 2-year real-world evidence study
- Subjects: 7-12 years, -0.75 to -4.50 D myopia, ≤1 D astigmatism
- Follow-up schedule: 1-week, 1- and 3-months, and every 6 months thereafter
- Co-primary efficacy endpoints:
  - Axial length (by IOLMaster 700)
  - Spherical equivalent cycloplegic auto refraction (SECAR, by Topcon KR-1)
- Safety endpoints:
  - Contact lens related or possibly related adverse events
  - Slit lamp findings
- Other performance endpoints included:
  - Visual acuity (VA)
  - Lens fit
  - Lens wear time compliance
- Analysis:
  - Intention-to-treat subjects with observed case data
  - Descriptive summary
  - Least-square means (LSMs) estimates with 2-sided 95% confidence intervals (95%CIs) using linear mixed models for repeated measurements including follow-up time, age, gender and baseline measures as fixed effects

Results

Figure 2: Subject disposition & reasons for discontinuation

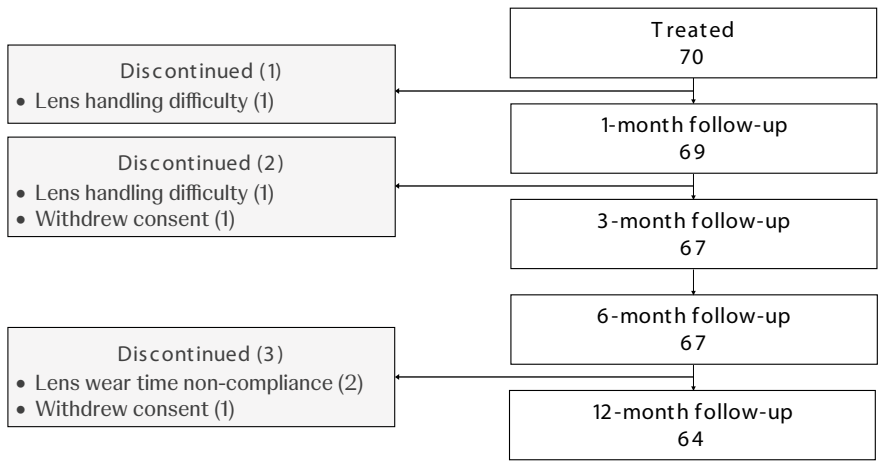
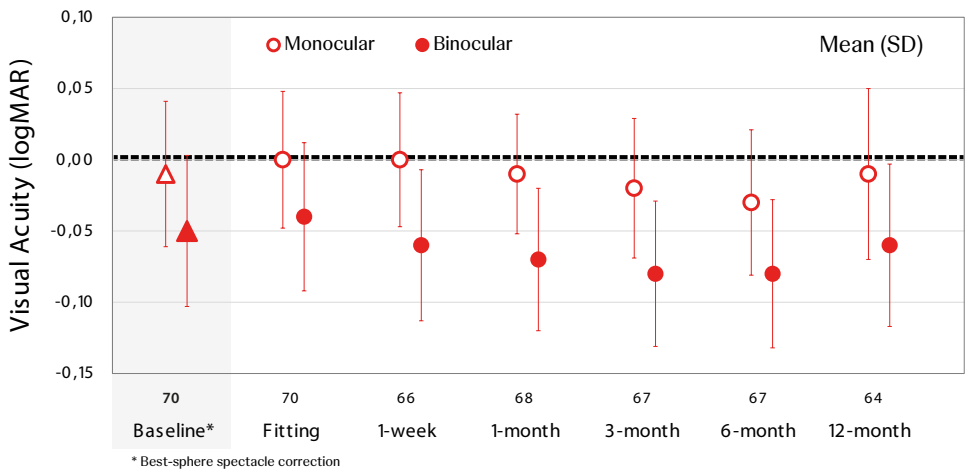


Figure 3: Monocular & binocular best-corrected visual acuity



* Best-sphere spectacle correction

Table 1: LSMs (alpha unadjusted 2-sided 95% CIs) of change in axial length and SECAR from baseline at the 12-month follow

Follow-up	Sample Size	Change in AL (mm)	Change in SECAR (D)
6-month	67	0.04 (0.01, 0.06)	-0.11 (-0.17, -0.04)
12-	63	0.10 (0.06, 0.15)	-0.25 (-0.35, -0.16)

- Safety:
  - No serious or significant ocular adverse events reported to date
  - No clinically significant slit lamp findings
- Lens fit:
  - 100% of eyes had acceptable lens fit
- Lens wear time (at 12 months):
  - On average, 13.5 (SD: 1.8) hours per day; 6.7 (SD: 0.6) days per week
  - All 64 subjects had cumulative lens wear time meeting or exceeding the requirement

Conclusion

- The 12-month outcomes of the real-world study demonstrated excellent safety, vision and fit performance of the EE lens.
- Minimal axial elongation & myopia progression were observed within the 12 months of treatment with EE, compared to an expected 0.39 mm/0.80 D progression in untreated 10.3-year-old Asian children,[2,3] and a reported 0.33 (SD: 0.02) mm/0.54 (SD: 0.06) D progression in untreated Chinese children aged 8-12 years participating in a one-year randomized clinical trial in the control group.[4]
- Future research includes comparing long-term myopia progression in EE treated children with untreated Chinese children to assess myopia control effect size.

DISCLOSURES

XC, JX, and AN are employees of Johnson & Johnson; NAB is a retiree of Johnson & Johnson;

XC and NAB are named patent inventors of the EE lens;

WL is a paid principal investigator of the study.

REFERENCES

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4. Chen et al. Impact of wearing dual-focus soft contact lenses on myopia progression: a one-year randomized clinical trial in Chinese school-age children. BMC Ophthalmol. 2024;24(1):426