

Short-term Clinical and Visual Performance of Dual-focus Soft Contact Lenses in Chinese children

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PURPOSE

The incidence of myopia among Chinese children is among the highest of any cultural or ethnic group¹. Dual-focus soft contact lenses (DF-SCL) have been demonstrated effective for myopia control^{2,3}. This study aimed to investigate the clinical and visual performance of DF-SCL (MiSight® 1 day, M1d, CooperVision, Inc.) in Chinese children throughout 1 month of daily wear.

METHODS

This self-controlled study involved 4 visits (*Fig 1*). Subject acceptability, visual performance, and slit-lamp biomicroscopy were assessed at Baseline (wearing Proclear® 1 day , P1d, and M1d), M1d-1 week, and M1d-1 month. Compliance with recommended wear schedule (no less than 10 hours per day, 6 days per week) was checked by a wearing diary. Visual performance covered distance and near-high contrast visual acuity (HCVA). Participants’ wearing experience satisfaction was evaluated by a 50-score subjective acceptability questionnaire comprising vision quality, comfort, lens handling, and preference (10 items, a numeric rating scale of 0-5). Types of adverse events were defined according to a previous DF-SCL study⁴.

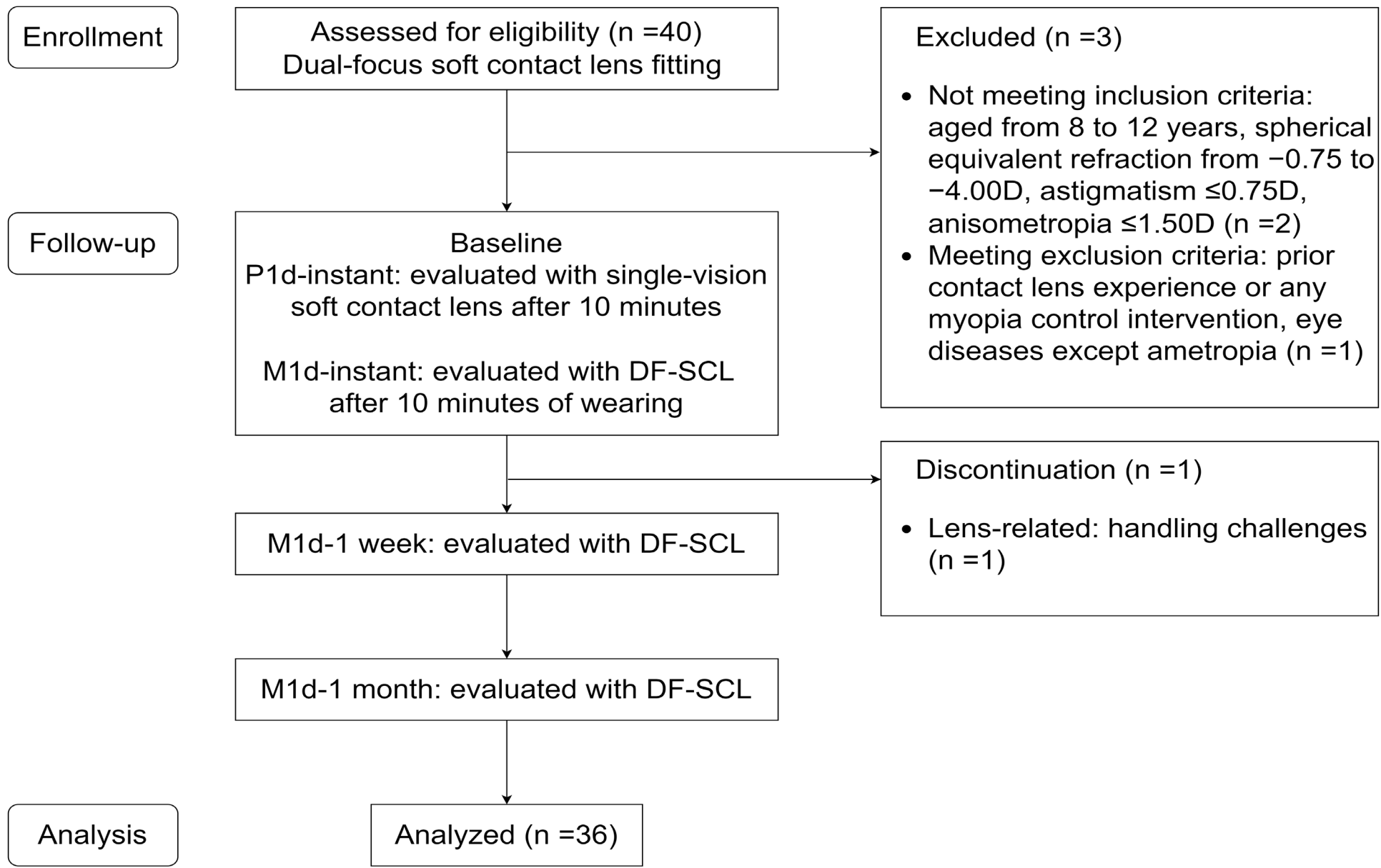


Fig. 1 Method: Subjects flow diagram from screening to study completion.

RESULTS

36 subjects (18 female, 18 male; age, 10.51±1.96 years; spherical equivalent refraction -1.81±0.71D) completed the study. The wearing time was 12.08±1.51 hours/day and 6.44±0.68 days/week.

- Visual outcome:** There was a statistically significant difference between distance HCVA with P1d and M1d at Baseline although the average difference of 1-2 letters was not clinically significant (*Fig 2a*). The near HCVA at M1d-1 month (-0.05±0.07 logMAR) was significantly improved ($p < 0.05$) compared to M1d-instant although the average difference of 1-2 letters was not clinically significant (*Fig 2b*). Children with M1d achieved comparable distance and near HCVA to P1d-instant after a week of wearing M1d.
- Questionnaire:** Overall satisfaction scores significantly improved at 1 week and 1 month compared to M1d-instant (*Fig 3a*). More than 80% described the M1d as providing good vision and comfort and were easy to handle (top 2 positive box response) at 1 week and 1 month (*Fig 3b*).
- Adverse events:** There were no significant slit lamp findings; no serious and significant ocular adverse events were seen (*Table 1*).
- Self-reported symptoms:** 21 subjects reported ocular symptoms including mild dryness, stinging and foreign body in diaries. Most symptoms happened after a routine nap in school and were relieved partially with rewetting eye drops.

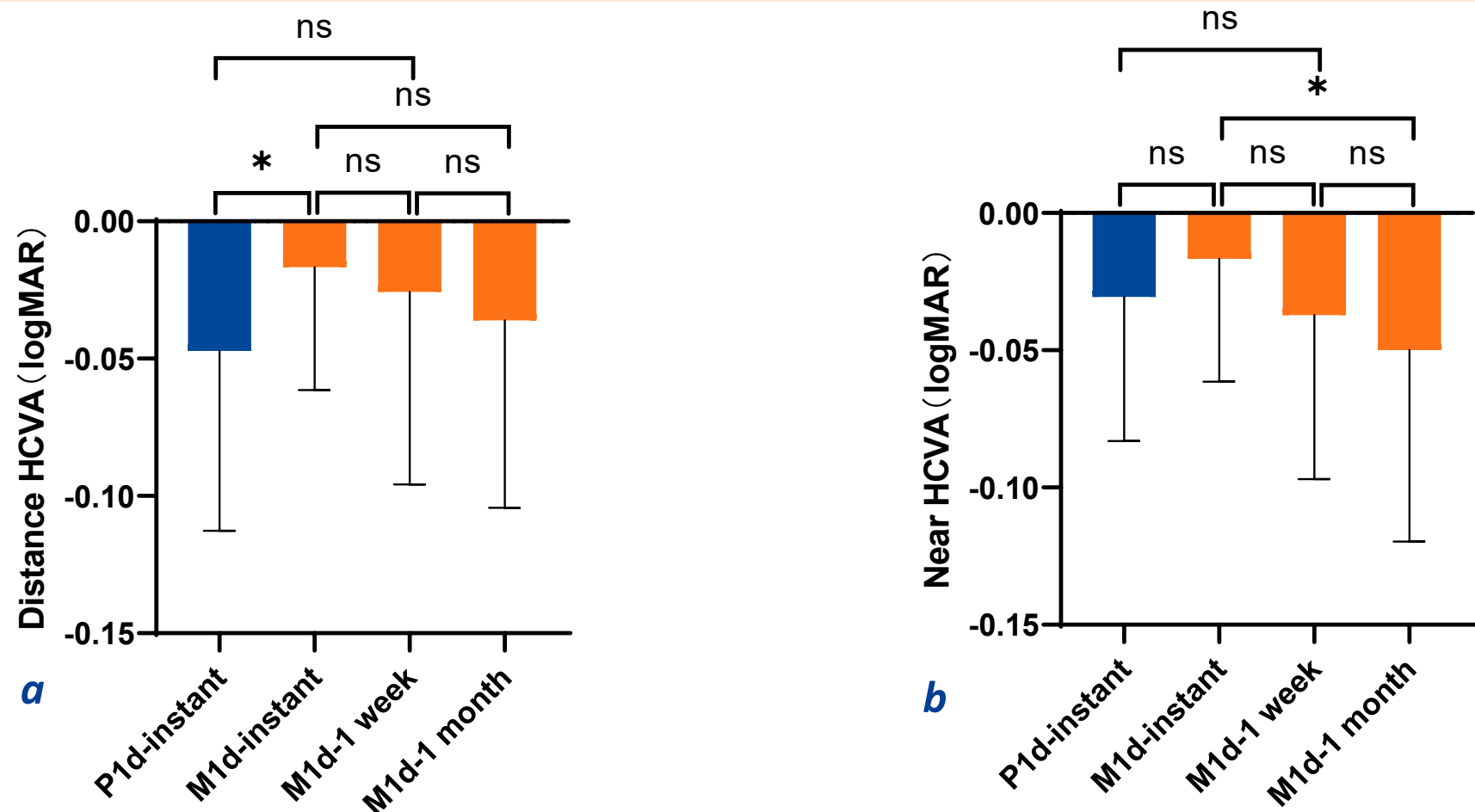


Fig. 2 Visual performance of MiSight 1 day contact lens.
Notes: ns indicates non-significant, $P \geq 0.05$; * indicates $P < 0.05$.

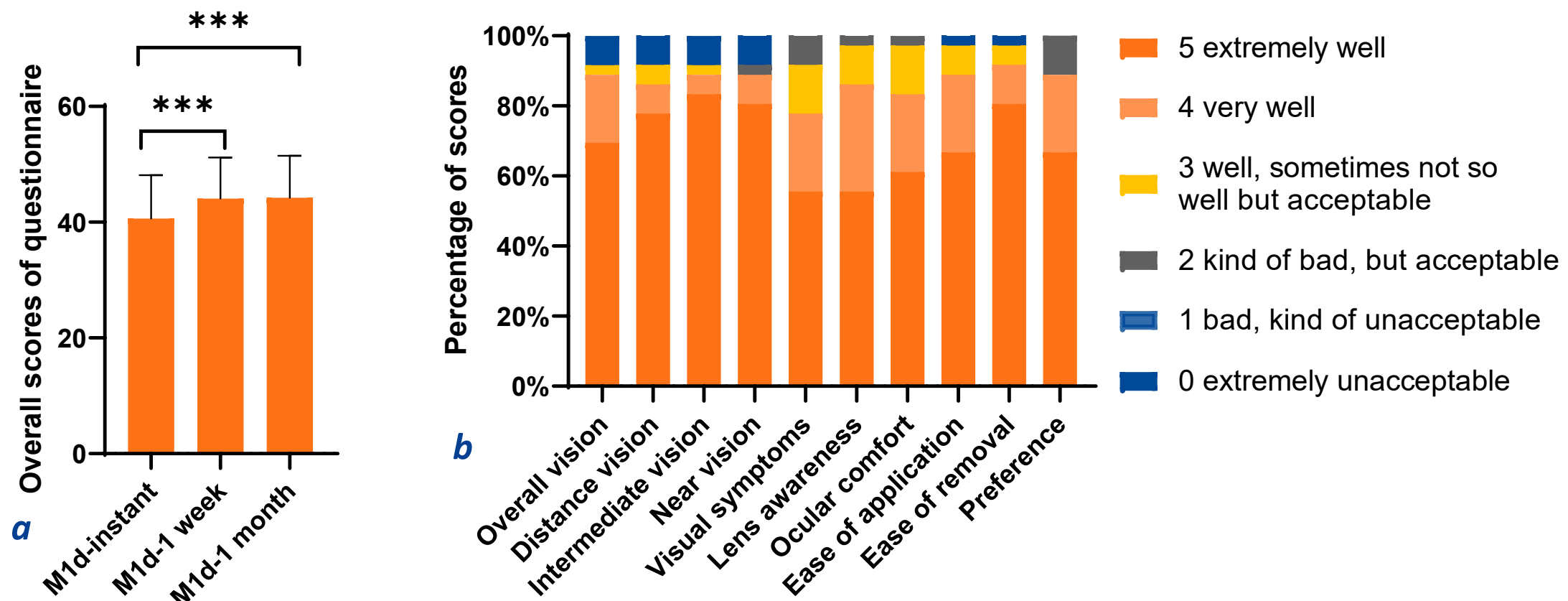


Fig. 3 Subject acceptability of MiSight 1 day contact lens after 1 month of daily wear.
Note: *** indicates $P < 0.001$.

Table 1 Ocular adverse event summary.

	Monocular(each count = 1 eye)	Binocular(each count = 2 eyes)	# potentially CL Related(events)
Serious / Significant Events (n = 0)	0	0	0
Non-Significant Events (n = 36)	0	0	0
● Non-Significant Infiltrative Events (<Grade 2);	5	6	11
● Any event which necessitates lens discontinuation of 1~3 days: foreign body; corneal staining; red eye.	3	1	2

CONCLUSION

The Chinese children demonstrated good clinical and subjective performance with MiSight 1 day contact lens. Children were compliant with the wear schedule and majority were able to independently handle their contact lenses. Visual performance was good and overall subjective satisfaction improved over 1 month lens wear. This study is continuing for 6 months and further results about clinical and visual performance will be reported in the future.

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