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Eye growth and myopia progression following cessation of myopia control therapy with a dual-focus soft contact lens

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SIGNIFICANCE: This 7-year clinical study assessed the impact of age and number of years of myopia control treatment with MiSight 1 day (omafilcon A; CooperVision, Inc., Pleasanton, CA) dual-focus contact lenses on post-treatment eye growth and myopia progression. Growth and progression after treatment were ceased and returned to age-normal levels retaining prior accrued treatment gains.

PURPOSE: This study aimed to assess eye growth and refractive changes after cessation of prolonged myopia control treatment with a dual-focus contact lens.

METHODS: Eighty-three subjects completing a 6-year clinical trial of a dual-focus myopia control contact lens (MiSight 1 day) continued into a follow-on 1-year "wash-out" phase in which all subjects were fit with a single-vision contact lens (Proclear 1 day, omafilcon A; CooperVision, Inc.). Right and left eye data were analyzed from 38 subjects with 6 years of prior treatment (T6) and 40 receiving treatment during study years 4 to 6 (T3). Axial length and cyclopleged spherical equivalent refractive errors were monitored annually for 7 years. Expected axial growth and myopia progression during years 4 to 7 if treatment had not been started were estimated by extrapolating growth of untreated myopic control eyes collected during years 1 to 3 using population-based estimates of age effects on growth rates.

RESULTS: During the untreated year 7, annualized axial growth and refractive changes were 0.09 ± 0.09 (T3) and 0.10 ± 0.10 mm/y (T6), and −0.23 ± 0.36 (T3) and −0.21 ± 0.40 D/y (T6), respectively, each slightly greater than observed during the previous year of treatment (0.07 ± 0.12 [T3] and 0.08 ± 0.07 mm [T6], and −0.04 ± 0.34 [T3] and −0.13 ± 0.42 D [T6]). Year 7 progression was less for the older (11 to 12 at baseline, −0.17 ± 0.40 D/0.05 ± 0.07 mm) than the younger (8 to 10 at baseline, −0.26 ± 0.36 D/0.13 ± 0.10 mm) subgroup. Years in treatment (3 vs. 6) did not influence post-treatment growth or progression.

CONCLUSIONS: A cessation study following 3 or 6 years of myopia control treatment with the dual-focus myopia control contact lens found axial growth and myopia progression rates similar to those expected of untreated myopic eyes at these ages. This finding reveals that accrued treatment gains were retained and neither amplified nor diminished after cessation of treatment.

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Successful interventions to slow the accelerated growth of myopic eyes and the accompanying myopia progression rely on their ability to deliver a sustained slowing over multiple years and a retention of accrued treatment effects after cessation of treatment.[1] Although multiyear studies have demonstrated sustained treatment effects over more than 1 year,[2] some treatments that appeared successful in the short term were unable to sustain their treatment,[3–5] whereas others have shown treatment over 5[6] or more years.[7,8] These differences may be due to study design, significant dropout, or the treatment itself.[9] Accelerated eye growth and progression after cessation of myopia control treatment have been observed in numerous studies,[10] some demonstrating faster eye growth than what would have been expected with no treatment, nullifying prior treatment gains,[11–14] and others with growth and progression returning to expected levels for age-matched untreated myopic eyes.[6,15–17] Post-treatment accelerations were generally smaller with myopia control soft contact lenses than with other forms of treatment.[16–18]

A 6-year clinical trial of a dual-focus myopia control contact lens employed 6 consecutive years of treatment of the initial treated cohort and 3 years treatment of the initial control group who were switched to the treatment lens for years 4 through 6.[19] Results from this trial indicate that the treatment effect continued to accumulate over the period of wear.[7] At the end of study year 6, subjects were refit with single-vision lenses, and axial growth and myopia progression were monitored during the year following cessation of treatment. Observed growth and progression rates after treatment cessation were compared with those expected of an untreated cohort of the same age. These virtual controls were used to assess whether any observed acceleration of axial growth or myopia progression reflected age-normal growth or abnormally fast growth. A virtual control group was used because it was considered unethical and impractical to continue the control group once efficacy had been demonstrated.[7] The impact of years in treatment (3 or 6) and age (younger and older subgroups) on post-treatment axial growth and myopia progression was also assessed.

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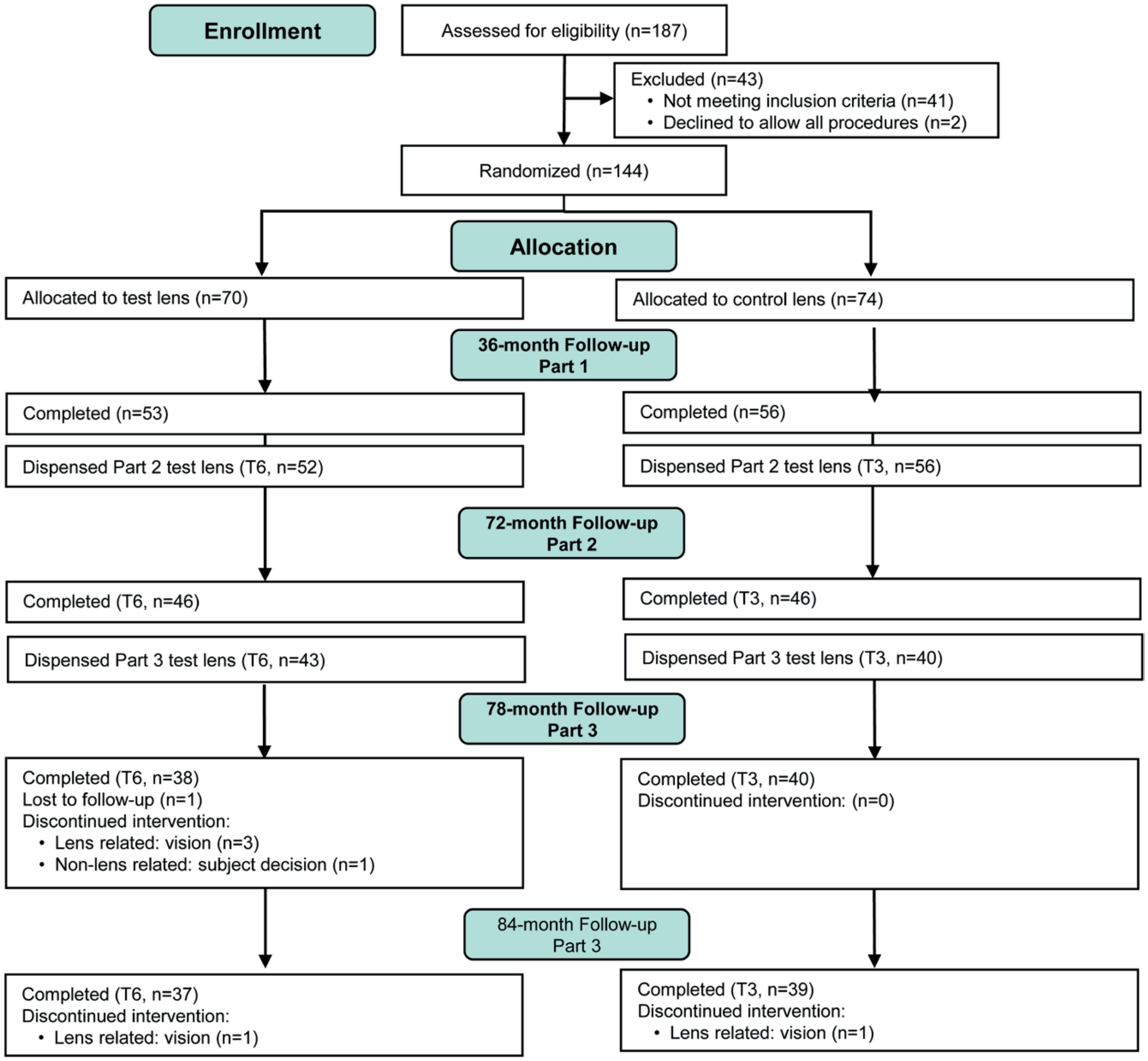

FIGURE 1. Flowchart showing treatment allocations and subject numbers for Parts 1, 2, and 3. See 6-year paper for details regarding loss to follow-up in Parts 1 and 2.[17]

METHODS

Study design

This study examined axial growth and myopia progression during the third part of a 7-year clinical trial (Fig. 1). Part 1 (years 1 to 3; ClinicalTrials.gov identifier: NCT01729208) was a multicenter (Europe, Southeast Asia, and North America), double-masked, controlled clinical trial in which myopic children 8 to 12 years of age were randomized to wear single-vision control lenses (Proclear 1 day, omafilcon A; CooperVision, Inc., Pleasanton, CA) or dual-focus myopia control treatment lenses (MiSight 1 day, omafilcon A; CooperVision, Inc.).[20] After 3 years, subjects continuing to Part 2 (years 4 to 6) were all assigned MiSight 1 day in an open-label trial using the same clinical sites.[19] Children who were treated for 6 years were referred to as T6 and started treatment between the ages of 8 and 12 years, and those who were treated only in Part 2 for 3 years and started treatment between the ages of 11 to 15 years were referred to as T3. On completion of Part 2, subjects from both T3 and T6 groups were invited to participate in Part 3 (year 7), a bilateral, open-label trial in which all eyes were refit into single-vision contact lenses (Proclear 1 day). Visits for Part 3 commenced, on average, 2 weeks after the end of Part 2. Follow-up visits were scheduled for 6 months and a final visit, 1 year after the start of the washout period.

The study adhered to the ethical principles in the Declaration of Helsinki, with the International Council for Harmonization guidelines for Good Clinical Practice and all applicable local regulations. This research was reviewed by independent ethical review boards and conformed to the principles and applicable guidelines for the protection of human subjects in biomedical research. In accordance with local regulatory requirements, informed consent/assent/parental permission documents were explained to, read, and signed by each study subject and parent, as appropriate, for participation in Part 3. Standardized measurements were used across sites, each under the same protocol.[20] The same two primary outcome measures (spherical equivalent refractive error [SERE] measured with autorefraction [WR-5100K or WAM-5500; Grand Seiko Co., Hiroshima, Japan] and ocular axial length [AL] measured with optical biometry [IOLMaster; Carl Zeiss Meditec, Dublin, CA]) used through Parts 1 and 2 were retained for Part 3 (see 3- and 6-year publications for full details of methodology[19,20]). Both primary outcome measures were conducted under cycloplegia. Cycloplegia was induced using the following procedure:

- One drop of either 0.5% proparacaine or 0.4% benoxinate in each eye (anesthetic)
- One minute later, instill 1 drop of 1% tropicamide, and wait 5 minutes before instilling a further single drop.
- Wait 25 minutes before conducting cycloplegic assessments.
- For autorefraction, subjects were instructed to view a distance target.
- Part 3 data reported here reflect the mean of five repeat AL and autorefraction measurements (during Parts 1 and 2, 10 repeat measurements were collected).

Statistical analysis

Data from all subjects who were dispensed lenses in Part 3 and completed at least one follow-up visit were analyzed (Fig. 1). Because of COVID-19 disruptions, some visits were delayed. Of the 83 subjects enrolled in Part 3, data from 78 were included in the analysis, of which there were 41 who were late and two who attended only the 78-month visit. Right and left eye data from these 78 subjects were analyzed for each study visit over 7 years. All year 6 of Part 2 and year 7 of Part 3 data were linearly interpolated/extrapolated to estimate annualized growths and progressions in millimeters per year and diopters per year. A model that assumed 15% axial slowing per year[21] provided an accurate fit to the untreated growth experienced by the myopic control group during years 2 and 3 and was used to estimate growth if eyes had been left untreated for years 4 to 6[7] and further extrapolated into year 7 for comparison with observed growth of T3 and T6 eyes after treatment cessation. An expected trend of 10% slowing of the refractive changes (Smotherman, et al. IOVS 2023;64:E-Abstract 811) was similarly used after observing that progression of SERE of the initial untreated control group was 10% slower during year 3 than during year 2. To assess the impact of age, Welch test was applied to compare untreated expected growth with observed growth and progression upon cessation of treatment of both the younger and older subgroups (ages 8 to 10 and 11 to 12 years, respectively).

RESULTS

Part 3 commenced in March 2019, and the last subject completed the last visit in March 2021. Of the original 144 subjects enrolled in Part 1, 83 subjects continued to Part 3 (year 7): 40 had worn the MiSight 1 day dual-focus myopia control lenses for the previous 3 years (T3 group) and 43 for all previous 6 years (T6 group). As observed for both Parts 1 and 2,[19] the T3 and T6 populations enrolled in the washout study remained well matched for demographic factors known to influence myopia progression (Table 1), being well balanced for race, sex, and age. As the T3 group had 3 years of untreated myopia progression in Part 1, SERE and ALs at the start of year 7 were greater for the T3 group than for the T6 group by 0.71 D (95% confidence interval [CI], 0.67 to 0.74) and by 0.26 mm (95% CI, 0.24 to 0.28).

Of the 83 subjects dispensed single-vision soft contact lenses, 76 subjects (39 and 37 subjects in the T3 and T6 groups, respectively) completed the 84-month visit. Four T6 subjects and one T3 subject were discontinued because their measured visual acuities were too low when fitted in spherical single-vision lenses due to uncorrected astigmatism that had progressed during the trial; one T6 subject was lost to follow-up. Two subjects' data were extrapolated from the 78-month visit (one T3, one T6). At the

TABLE 1. Demographics of T6 (6 years of myopia control treatment) and T3 (3 years of myopia control treatment) groups at start of study year 7

	T6 group	T3 group	p Value
Subjects (n)	43	40	
Age (y) at start of cessation			
Mean	16.3	16.1	0.55
Standard deviation	1.20	1.58	
Range	14–18	14–19	
Sex, n (%)			
Male	22 (51.2%)	20 (50.0%)	0.92
Female	21 (48.8%)	20 (50.0%)	
Self-reported ethnicities, n (%)			
Caucasian	28 (65.1%)	27 (67.5%)	0.82
East Asian	13 (30.2%)	10 (25.0%)	0.59
Indian/Pakistani/Sri Lankan	3 (7.0%)	5 (12.5%)	0.39
Middle Eastern	0 (0.0%)	1 (2.5%)	0.30
Hispanic-Latino	1 (2.3%)	0 (0.0%)	0.33
Mediterranean	0 (0.0%)	1 (2.5%)	0.30
Black British	1 (2.3%)	0 (0.0%)	0.33
SERE (D)			
Mean	−3.14	−3.85	<0.0001
Standard deviation	1.24	1.25	
AL (mm)			
Mean	25.07	25.33	<0.0001
Standard deviation	0.70	0.76	

Ethnicities do not sum to 100% as subjects could select more than one. AL = axial length; SERE = spherical equivalent refractive error.

TABLE 2. Unadjusted raw annualized SERE progression and AL growth during years 6 and 7 observed in the T3 and T6 cohorts and predicted year 7 growth and progression if the T3 eyes were left untreated

Study period	Group	n	Annual change in SERE (D) Mean ± SD	Annual change in AL (mm) Mean ± SD
Year 6: last year of treatment	T6	76	−0.13 ± 0.42	+0.08 ± 0.07
	T3	78	−0.04 ± 0.34	+0.07 ± 0.12
Year 7: post-treatment	T6	76	−0.21 ± 0.40	+0.10 ± 0.10
	T3	80	−0.23 ± 0.36	+ 0.09 ± 0.09
Year 7: model predictions for untreated growth and progression in subjects of the same age			−0.17 ± 0.22	+0.08 ± 0.05

One T3 subject missed the 5-year visit; hence, 6-year annualized T3 data were only available for 78 eyes. AL = axial length; SD = standard deviation; SERE = spherical equivalent refractive error.

final 84-month visit, 22 (56%) and 20 (54%) subjects in the T3 and T6 groups, respectively, completed the 12-month visit within the specified range (360 ± 44 days from dispensing). Although there was a large percent of subjects completing outside the visit window, there was no difference in the average number of days from baseline to final study visit between the T3 and T6 groups (408 ± 78 days for T3 and 405 ± 75 days for T6, p = 0.77).

Myopia progression and eye growth

Average uncorrected axial growth and myopia progression rates were greater in year 7 than in year 6 (Table 2). During year 7, myopia progression and axial elongation increased by −0.19 D (95% CI, −0.1798 to −0.1975) and 0.022 mm (95% CI, 0.0196 to 0.0249) for the T3 group and by −0.087 D (95% CI, −0.0760 to −0.0974) and 0.016 mm (95% CI, 0.0136 to 0.0183) for the T6 group. Within-group comparisons between years 6 and 7 were made for the same eyes in each year, and hence, potential covariates were perfectly matched. Although the T3 and T6 groups were well matched, a linear mixed model was used to isolate the impact of different treatment histories on post-treatment growth and progression. Year 7 myopia progression and axial elongation rates in the T3 and T6 groups were compared using a linear mixed model including fixed effects of age, sex, ethnicity, site, and baseline refractive error and AL and with subject and eye as random effects. Differences of 0.03 D and 0.01 mm were almost the same as the unadjusted values (Table 2) and not significantly different (p = 0.49 and 0.56 for the refractive error and AL differences, respectively), indicating that length of prior treatment was not a factor influencing post-treatment growth or progression rates.

Comparison of measured and expected eye growth and myopia progression

A model that assumed 15% axial growth slowing per year[21] used the growth of untreated control eyes (T3) during year 3 (mean, 0.16 mm ± 0.10) to estimate growth during years 4 through 7 had these eyes remained untreated (Fig. 2, dashed lines). Short dashed lines show the same predicted untreated growth during year 7, anchored at year 7 baseline data for the T3 and T6 eyes. The predicted average growth during year 7 was 0.08 mm (standard deviation, 0.05 mm). The observed average growth rates of 0.09 and 0.10 mm for the T3 and T6 groups (Table 2) were greater by approximately 0.01 mm from that expected if left untreated (p = 0.39 and p = 0.16, respectively). Using an estimated 10% slowing of myopia progression per year (Smotherman, et al. IOVS 2023;E-Abstract 811), the estimated myopia progression during year 7 if left untreated was −0.17 D, compared with the observed −0.23 (T3) and −0.21 D (T6) progression; again, these differences (−0.06 and −0.04 D) were not statistically significant (p = 0.16 and p = 0.37, respectively). Further, the differences observed between measured and expected year 7 growth and progression are within the predicted CIs and not clinically meaningful.

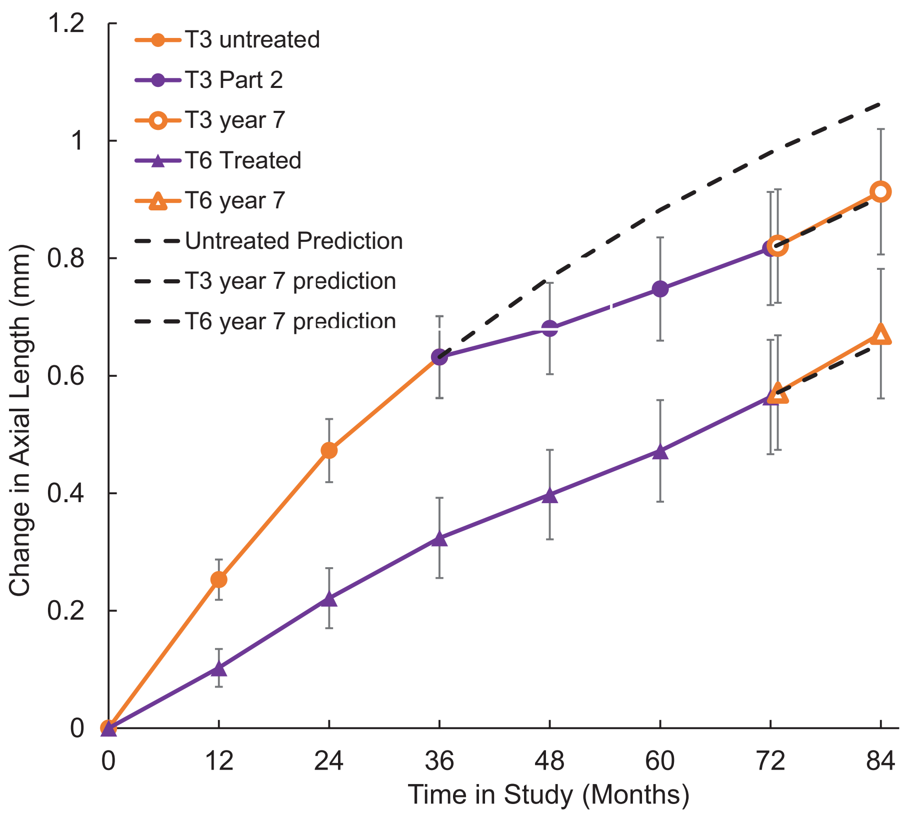

FIGURE 2. Unadjusted mean accumulated growth in AL from baseline plotted as a function of months in study for all tested eyes that completed year 7 (80 T3 eyes and 76 T6 eyes). Axial measures were obtained during years when eyes were treated with dual-focus contact lenses (purple) or single-vision (orange) contact lenses. Error bars are ±2 SEM. Black dashed lines are the expected growth if the untreated cohort had remained untreated. Two data points at 72 months reflect both the end-of-treatment (study Part 2) visit and the approximately 2-week-later start of the washout year 7 (Part 3). Subjects continued wearing the treatment lens until the start of year 7. AL = axial length; SEM = standard error of the mean.

To explore the influence of age, the axial growth (15% slowing per year) and myopia progression (10% slowing per year) models were applied separately to both the younger (8 to 10 years at baseline, n = 46) and older (11 to 12 years at baseline, n = 34) subgroups of the T3 eyes. The predicted year-7 untreated axial growths for the younger (14 to 16 years) and older (17 to 19 years) subjects were 0.10 ± 0.05 and 0.06 ± 0.05 mm, respectively, and the predicted myopia progressions in the younger and older T3 cohorts were −0.20 ± 0.24 and −0.12 ± 0.18 D, respectively.

Average measured year-7 axial growth was greater (0.13 ± 0.10 mm) for the younger subgroup and less (0.05 ± 0.07 mm) for the older subgroup. Average year-7 myopia progression was also greater for the younger subgroup (−0.26 ± 0.36 D) than for the older subgroup (−0.17 ± 0.40 D). Without correcting for multiple comparisons, the year-7 myopia progression and the axial growth of the older cohort were not statistically different from the predictions of Shamp and Smotherman models. The average 0.03 mm (standard deviation, 0.01 mm) faster than predicted measured axial growth in the younger subgroup reached significance with the Welch test ($p = 0.03$).

Safety evaluation

During year 7, there were seven ocular adverse events in five subjects; four were bacterial conjunctivitis, and three related to corneal staining. All of these were deemed by the investigators to be nonsignificant and classified as mild and resolved quickly. These types and rates of adverse events are similar to those observed in earlier phases of the study.[22] Average best-corrected visual acuity at the end of year 7 remained slightly better than 20/20 (T3, logMAR −0.03; T6, −0.02) and unchanged from cohort mean acuities observed at study baseline and at end of year 6.[19] Average contact lens wear time remained consistent between groups 6.5 ± 0.5 days per week and 13.3 ± 1.6 hours per day on weekdays for T3 and 6.4 ± 0.5 days per week and 13.0 ± 1.8 hours per day on weekdays for T6. These numbers were similar to those reported in Parts 1 and 2.[19,20]

DISCUSSION

Data from Parts 1 and 2 (years 1 to 6) of this clinical trial of the MiSight 1 day dual-focus contact lens provide evidence of a sustained slowed eye growth and slowed myopia progression in a population of myopic children who commenced treatment between the ages of 8 and 12 years (T6) or 3 years later at ages 11 to 15 years (T3).[19] Terminating the dual-focus contact lens myopia control treatment after different numbers of years of accrued benefits is a scenario likely to occur in clinical practice.

The observed AL growth and myopia progression during year 7 were on average 0.019 mm and −0.14 D greater than observed during the last year of treatment and on average similar to the age-normal expected growth and myopia progression of untreated myopic eyes for both the T6 and T3 cohorts (Table 2, Fig. 2).

Extrapolation of the untreated axial growth in years 1 to 3 to allow comparisons with age-matched untreated eyes in year 7 was applied using a model of 15% per year slowing that had successfully predicted the successive slowing of untreated axial growth in years 2 and 3 (compared with year 1).[7] The model of 10% slowing of myopia progression was applied after observing a 10% slowing of progression in untreated eyes during year 3 (compared with year 2). However, myopia progression of these untreated eyes during year 2 had slowed by more than 10% of that observed during year 1 of the study.

Observed axial growth and myopia progressions in the younger and older subjects were also similar to age-expected progression. Slight differences from expected growth and progression observed in the younger cohort (0.03 mm and −0.06 D), which reached significance for AL, may not be clinically meaningful. These small differences between model and study data could reflect noise, a slightly greater progression in the younger cohort, an effect of dropout over the course of the study, or, conversely, a model that inappropriately extrapolated these expected values over 4 years. The current investigation cannot distinguish between these three possibilities. Because of the slightly faster than predicted (0.03 mm faster, $p < 0.05$) axial growth seen in the younger cohort (ages 14 to 16 years at start of year 7), it may be prudent to continue treatment into the later teen years to reduce the possibility of post-treatment growths that could cancel some of the accrued benefits. The post hoc nature of the year 7 data with sample sizes approximately half those of the originally powered clinical trial may also contribute to failures to observe significant differences. Similar issues apply to the younger and older subgroup analyses.

Regardless of number of years of prior treatment, these results generally support the hypothesis that, once myopia control treatment with this dual-focus contact lens is terminated, eyes then grow at rates expected at these ages if they had remained untreated. When eyes return to age-normal growth after treatment, prior accrued treatment gains are retained but not further amplified. Post-treatment axial growth and myopia progression observed in the current study are consistent with previous observations after cessation of dual-focus myopia control[16] and other optical interventions[15,17] but differ from the report of faster-than-expected eye growth after some atropine, red-light, and orthokeratology myopia control treatments were stopped.[11–14] The presence of faster-than-expected axial growth and myopia progression would imply a reduction in the prior accrued treatment benefits once treatment was ceased. Differences in post-treatment progression between studies could be due to differences in the mechanism of action (e.g., pharmacological vs. optical) or the study designs (e.g., within eye-crossover, parallel groups, and unilateral vs. bilateral treatments).

This discussion, so far, has avoided use of the oft-applied term “rebound”[18] to describe accelerated post-treatment growth, preferring a direct comparison of post-treatment growth to that expected of untreated myopic eyes at the age of treatment cessation. The term “rebound” has been applied to any acceleration of growth or progression after treatment cessation,[10] which fails to capture the crucial distinction of age-normal versus greater than age-normal growth.[23] Age-normal growth after treatment cessation returns an eye to growth levels that would have been experienced without treatment, and therefore, the smaller and less myopic eye created by prior treatment will continue to be smaller and less myopic than if the patient had not been treated. However, if post-treatment growth and progression accelerate to levels greater than expected for untreated myopic eyes of a given age, the faster-than-expected accelerated growth will start to eliminate prior treatment gains.[11–14] Use of “rebound” terminology to describe any accelerated eye growth after treatment cessation fails to recognize the different clinical implications of these two types of post-treatment growth. Upon treatment cessation, do eyes return to age-normal or greater than age-normal growth and progression?

The conclusion that post-treatment eye growth and myopia progression was unaffected by the 3 or 6 years of prior treatment centers on the extrapolation of measured untreated growth from the initial control cohort using average growth and progression rates observed in untreated myopic eyes. Conclusions would be better supported if the control group had been retained for 7 years. However, because of the success revealed after the first 3 years of the MiSight 1 day clinical trial,[20] it was considered to be unethical and impractical to retain the control group for additional years of the study.[19] The return of post-treatment axial growth and myopia progression to levels expected for untreated myopic eyes at the ages of our subjects is generally consistent with published reports of post-treatment growth and progression after periods of myopia control therapy with optical interventions.[23,24]

CONCLUSIONS

Removal of MiSight 1 day dual-focus myopia control treatment returns a population to age-expected untreated myopia progression and eye growth, irrespective of treatment duration (3 or 6 years) or of age at cessation (14 to 16 or 17 to 19 years). There is no evidence that prior treatment gains are lost after treatment is terminated, but rather that accrued treatment benefits are retained if treatment is ceased during the teenage years. These conclusions may apply only to those ceasing treatment during the teenage years and rely upon an extrapolated model of expected untreated growth and progression and not a concurrent untreated control group.

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