MAKE CHILDREN'S SIGHT YOUR FIGHT™.

# MiSight® 1 day*

## is the FIRST and ONLY one for myopia control in age-appropriate children.*†

Setting a clinical standard with the **longest continuous** soft contact lens **study for myopia control**[1,2]


## A 7-year clinical trial separated into three parts:[1,3]

| | Part 1 (Years 1-3)[1] | Part 2 (Years 4-6)[3] | Part 3 (Year 7)[6] |
|---|---|---|---|
| Objective | Assess the difference in myopia progression over a 3-year period between children wearing MiSight® 1 day and children wearing a single-vision 1-day lens‡<br>• **Randomized + double-masked**<br>• Ages 8–12<br>• 144 children | Compare the rate of myopia progression between children new to MiSight® 1 day and those who had worn MiSight® 1 day for the previous 3 years<br>• **All children wearing MiSight® 1 day**<br>• Ages 11–15<br>• 108 children from Part 1 continued in the study | Assess the impact of cessation on the prior accumulated treatment effect following 3 or 6 years of treatment with MiSight® 1 day<br>• **All children wearing Proclear® 1 day**<br>• Ages 14-18<br>• 83 children from Part 2 continued in the study |
| Prospective | ✓ | ✓ | ✓ |
| Double-masked | ✓ | N/A | N/A |
| Randomized | ✓ | N/A | N/A |
| Multicenter (Singapore, Canada, England, Portugal) | ✓ | ✓ | ✓ |
| **Participants:** | | | |
| Test group (MiSight® 1 day) | 70 children aged **8–12 years** | 108 children aged **11-15 years** All wearing MiSight® 1 day | 83 children aged **14-18 years** All wearing Proclear® 1 day |
| Control group (Proclear® 1 day) | 74 children aged **8–12 years** | | |

***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 a refraction of -0.75 to -4.00 diopters(spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.

† Only FDA approved soft contact lens designed for myopia control in the U.S.

‡ Proclear 1 day.

# **MiSight® 1 day** contact lenses are FDA approved* to slow the progression of myopia in children aged 8–12 at the initiation of treatment[1≠]

## MiSight® 1 day clinical trial — Overall Findings

- Over a 3 year period, MiSight® 1 day slowed the progression of myopia in age-appropriate children by 59% on average, and 41% of eyes had no progression[1+]
- Among MiSight® 1 day wearers, 23% percent of eyes had no progression at 6 years[3†]
- On average, age-appropriate children wearing MiSight® 1 day progressed less than -1.00D over 6 years[3+]
- MiSight® 1 day treatment period of 6 years vs 3 years did not alter the rate of slowing refractive error or axial length[3]
- Age-appropriate children wearing MiSight® 1 day achieved excellent visual acuity across all visits throughout 6 years of clinical study[1,3‡+]
- Age-appropriate children can successfully wear MiSight® 1 day contact lenses with minimal impact on ocular physiology[1,3§+]
- Evidence indicates that there is no rebound effect with MiSight® 1 day contact lenses[5,6||]

## MiSight® 1 day clinical trial — Part 1

- 41% of the MiSight® group showed no meaningful progression in refractive error‡ after 3 years, compared with 4% in the control group[1†+]
- Children as young as 8 can be successfully fit with soft, daily disposable contact lenses[1#]
- Children as young as 8 are able to handle their lenses soon after initial fitting[1**]

## MiSight® 1 day clinical trial — Part 2

- New and established MiSight® 1 day wearers have comparable rates of myopic progression and axial length growth[3]
- Children adapted to spherical contact lenses achieved excellent visual acuity when they switched to MiSight® 1 day[3‡]

## MiSight® 1 day clinical trial — Part 3

- Evidence indicates that there is no rebound effect with MiSight® 1 day contact lenses – myopia control treatment gains were retained over 12 months after treatment ceased[5,6||]

***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 a refraction of -0.75 to -4.00 diopters (spherical equivalent) with ≤ 0.75 diopters of astigmatism. The lens is to be discarded after each removal.

≠ Compared to a single vision 1-day lens over a 3 year period.

\+ Fitted at 8–12 years of age at initiation of treatment.

† No clinically meaningful change in refractive error -0.25D or less from baseline.

‡ VA (LogMAR) > 6/6 (20/20) at all visits from dispensing to 6-year visit.

§ No slit-lamp observations recorded above grade 2 at any visits apart from 1 observation of grade 3 GPC attributed to a foreign body at the 1-month visit.

|| Preliminary international study data shows that, on average, for children that discontinued treatment at age 14–19 following 3 or 6 years of MiSight® 1 day wear, the eye growth reverted to age-expected average myopic progression rates. Disclaimer: The stability of the myopia reduction effect 1-year post-treatment is being further evaluated in a post-approval study in the U.S. as a condition of FDA approval for MiSight 1 day.

# 138/144 children aged 8–12 were successfully fitted with either MiSight® 1 day or Proclear® 1 day daily disposable soft contact lenses.

** At initial dispense, 66/67 children successfully fit with MiSight® 1 day aged 8–12 were able to handle their lenses.

# MiSight® 1 day clinical study outcomes

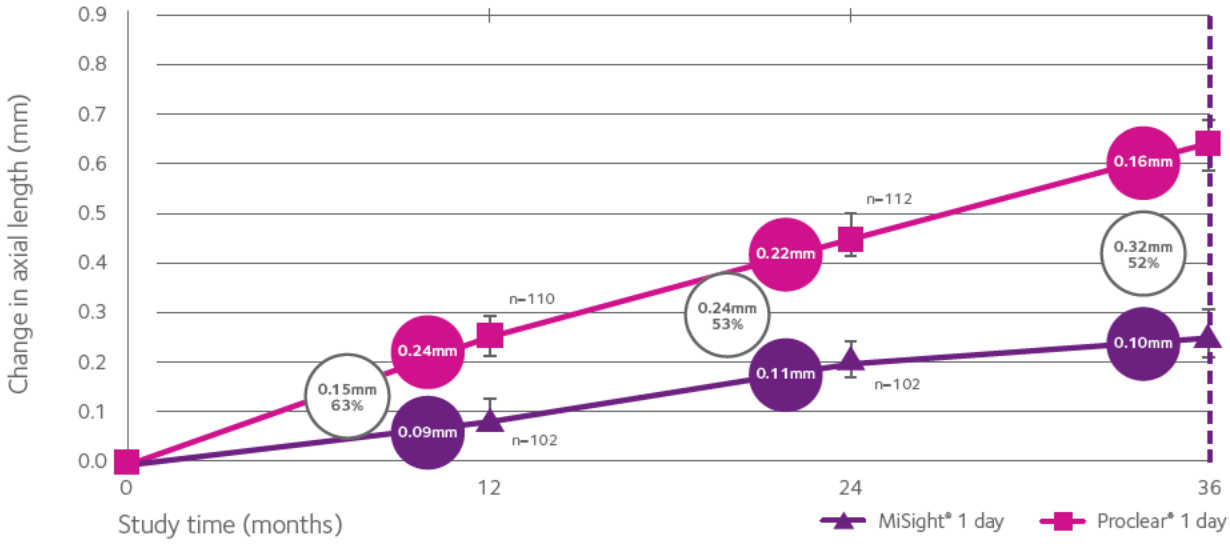
## Part 1 (Years 1-3)

**Objective:** Quantify the effectiveness of MiSight® 1 day in **slowing the rate of myopia progression** compared to a single vision 1-day lens over a 3-year period

**Result: 52% average reduction** in axial elongation with **MiSight® 1 day**[1*]

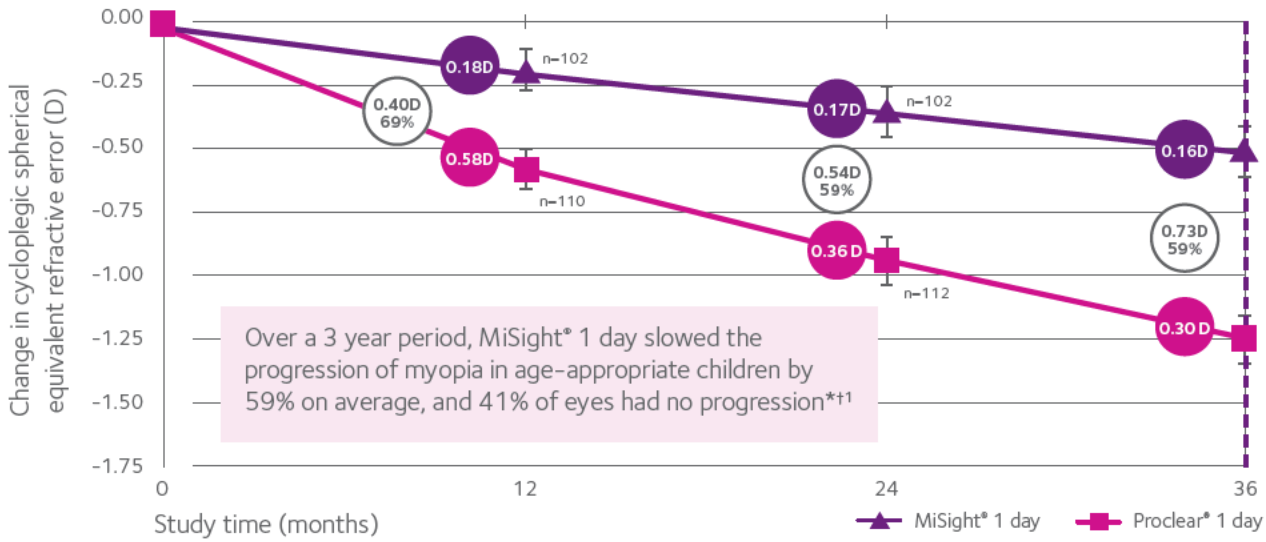
### Changes in axial length[1,3]

- Increased axial length is associated with a higher likelihood of visual impairment[4]




**Result: 59% on average reduction** in myopia progression with **MiSight® 1 day**[1*]

### Changes in refractive error[1,3]




Over a 3 year period, MiSight® 1 day slowed the progression of myopia in age-appropriate children by 59% on average, and 41% of eyes had no progression*†[1]

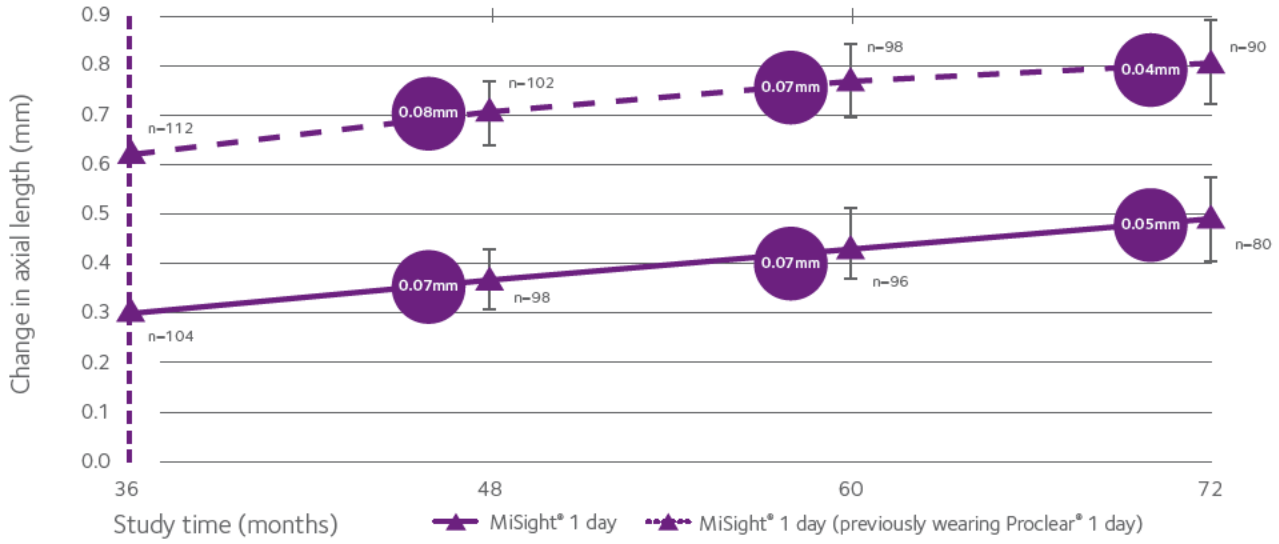

* Compared to a single vision 1-day lens over a 3 year period.

† -0.25D or less of change. Fitted at 8-12 years of age at initiation of treatment.

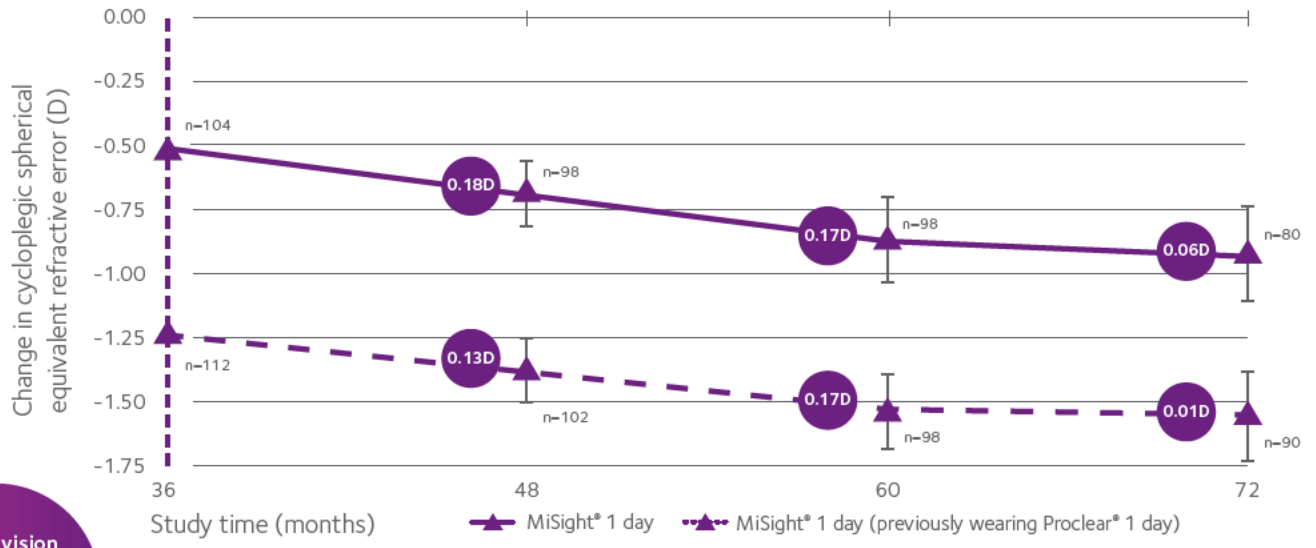
## Part 2 (Years 4-6)

**Objective:** Compare **the rate of myopia progression** between children new to MiSight® 1 day and those who had worn MiSight® 1 day for the previous 3 years

**Result:** New and established **MiSight® 1 day** wearers had comparable rates of axial length growth[3]




**Result:** New and established **MiSight® 1 day** wearers had comparable rates of myopic progression[3]

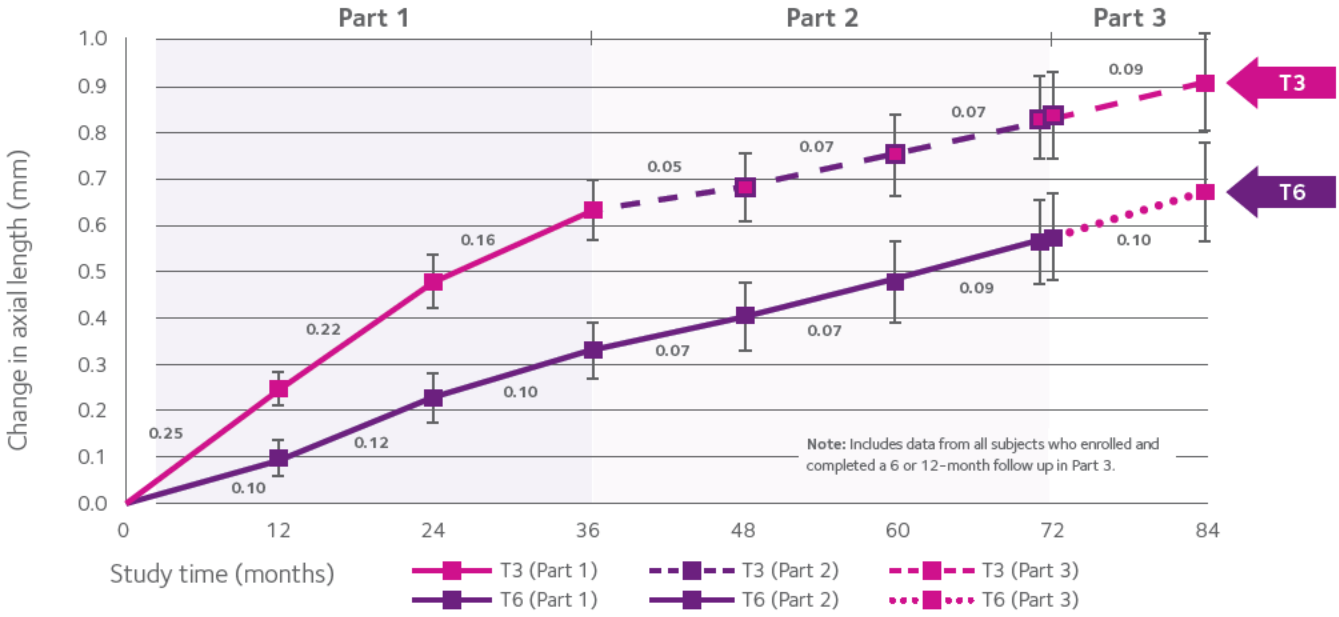



Single-vision 1-day wearers were switched to MiSight® 1 day at 3 years

## Part 3 (Year 7)

**Objective:** Assess **the impact of cessation on the prior accumulated treatment effect** following 3 or 6 years of treatment with MiSight® 1 day (T3 and T6, respectively)

**Result:** Evidence indicates that there is no rebound effect with **MiSight® 1 day** contact lenses[5,6*]




**Result:** After MiSight 1 day treatment ceased, myopia control treatment gains were retained over 12 months[5,6*]

### Axial length growth control modeling and measured values (mm)

| Year | Control group model† | T3 group (measured) | T6 group (measured) |
|---|---|---|---|
| 1 | 0.247 | 0.253 | 0.103 |
| 2 | 0.207 | 0.216 | 0.115 |
| 3 | 0.178 | 0.159 | 0.109 |
| 4 | 0.153 | 0.049 | 0.074 |
| 5 | 0.131 | 0.065 | 0.074 |
| 6 | 0.115 | 0.072 | 0.089 |
| 7 | 0.100 | 0.091 | 0.109 |

† Using the age and ethnicity of the control cohort, a virtual control group was developed to extend estimates of untreated axial elongation through to the 7th year of the study.

Proclear® 1 day  MiSight® 1 day

All children were switched to Proclear® 1 day for the final year.

38

7 YRS

40

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For further details, please contact your local CooperVision sales representative or visit coopervision.com

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**References: 1.** Chamberlain P, et al. A 3-year randomized clinical trial of MiSight® lenses for myopia control. *Optom Vis Sci.* 2019; 96(8):556–567. **2.** CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomized trials BMJ. 2010;340:c869 doi: 10.1136/bmj.c869. **3.** Chamberlain P, Arumugam B, Jones D et al. Myopia Progression in Children wearing Dual-Focus Contact Lenses: 6-year findings. *Optom Vis Sci* 2020;97(E-abstract): 200038. **4.** Tideman J, et al. Association of axial length with risk of uncorrectable visual impairment for Europeans with myopia. *JAMA Ophthalmol.* 2016;134:1355–1363. **5.** Chamberlain P, Arumugam B, et al. Myopia progression on cessation of Dual-Focus contact lens wear: MiSight 1 day 7 year findings. *Optom Vis Sci* 2021;98:E-abstract 210049. **6.** Hammond D, Arumugam B, et al. Myopia Control Treatment Gains are Retained after Termination of Dual-focus Contact Lens Wear with no Evidence of a Rebound Effect. *Optom Vis Sci* 2021;98:E-abstract 215130.



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