

ActivControl[®] Technology

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CooperVision Professional & Academic Affairs



CooperVision[®]

Myopia Management

Key Points

- MiSight® 1 day* lenses utilize ActivControl® Technology, an optical design specifically created to simultaneously correct vision and may help slow myopia progression in age-appropriate children at the initiation of treatment.^{†1}
- It is the first and only contact lens approved by the US FDA* and China NMPA[‡] to slow myopia progression in children aged 8–12 at the initiation of treatment.^{†1}
- The 7-year international MiSight® 1 day clinical trial is the longest continuous soft contact lens study for myopia control.
- Clinical efficacy and associated benefits of ActivControl® Technology:
 - MiSight® 1 day slowed myopia progression in children 8–12 at the initiation of treatment by an average of 59% over three years and slowed myopic growth rates back down to emmetropic growth rates.^{††§1,3}
 - MiSight® 1 day shows sustained slowing of eye growth over time on average, which could help reduce the risk of vision and eye health complications associated with higher levels of myopia later in life.^{‡3,4}
 - Results from the 7-year international clinical study found no evidence of rebound per mean axial length once treatment was discontinued.^{¶5,6}
 - Gives age-appropriate children with myopia freedom from glasses, while providing excellent visual acuity across all visits throughout 6 years of clinical study.^{††††1,7}
 - Children as young as 8 years old demonstrate successful handling and confidence soon after initial fitting.^{‡†1}
 - Convenient to use daily disposable contact lenses – no need to clean or store.
 - Covers nearly 100% of spherical prescriptions for children initially fit between ages 8–12 with myopia.^{*§§8}

*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.

‡China Indications for Use: MiSight® 1 day is indicated for the correction of myopia for patients with non-diseased phakic eyes, who at the initiation of treatment are 8–12 years of age and have a refraction of -0.75 D to -4.00 D with ≤ 0.75 diopters of astigmatism. It has the dual focal design with alternating multiple rings, which allows part of the light passing through the optical zone to focus in front of the retina, forming myopic defocus with the expectation to slow the change of axial length of the patients. Fitting and evaluation of the product should be in medical institutions by ophthalmologists with an intermediate title or above and with regular monitoring. It must be used in strict accordance with the IFU requirements.

§In clinical study, the average 3-year elongation in MiSight® 1 day treated myopes approached that of virtual cohorts of emmetropes with the same age distribution.

‡While eyes are still growing; children fit ages 8–12 and followed for 6-years. n=40.

¶ 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.

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

††Children aged 8–12 at the initiation of treatment.

‡‡Children new to contact lens wear aged 8–12, n= 130 at 1 month after dispense.

§§Includes prescriptions up to 0.75DC.

Introduction

Childhood eye development

As infants grow into toddlers, the anterior and posterior eye components grow significantly. In an ideal situation, this coordinated growth resulted in a match of the eye's focal length with its anatomical length, which ensured that most eyes were emmetropic. This coordinated growth process, called emmetropization, now fails in many eyes. Myopia develops when the posterior eye grows faster and longer than required for emmetropia, and the cornea and crystalline lens cannot compensate, resulting in progressive myopia.

Problem of Myopia

Myopia, or nearsightedness, has emerged as a rapidly growing global public health crisis. Projections indicate that by 2050, nearly 5 billion people worldwide will be affected by this refractive error.⁹ While the symptoms of nearsightedness can be temporarily corrected with single-vision glasses or contact lenses, all myopia levels are associated with an increased risk of sight-threatening ocular pathologies later in life, such as myopic maculopathy, cataracts, retinal detachment, and glaucoma.¹⁰⁻¹² Axial length, the distance from the front to the back of the eye, plays a crucial role in determining the severity of myopia and its associated risks.¹³ As axial length increases, the risk of developing sight-threatening complications rises significantly, making it a key predictor of future visual impairment in individuals with myopia.¹¹

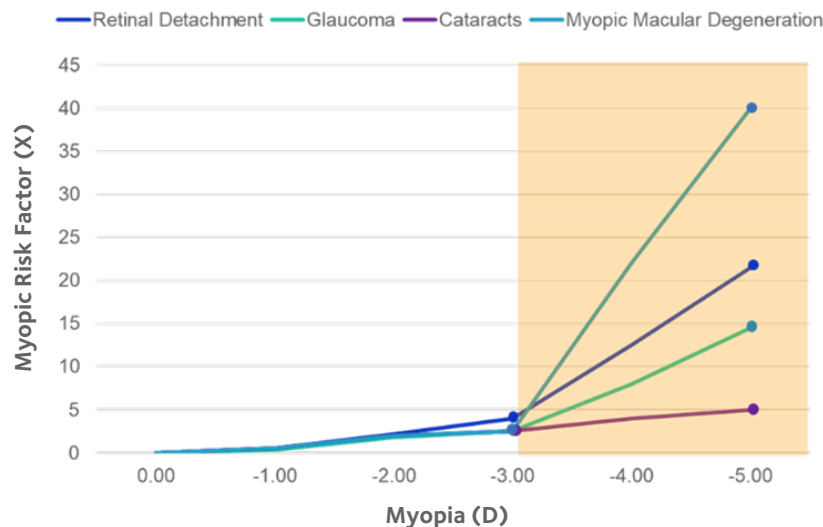


Figure 1: The increased likelihood (odds ratio) of developing eye disease in adults >60 years old with myopia versus those with emmetropia

Reference: Haarman AE et al. The Complications of Myopia: A Review and Meta-Analysis. *Investigative Ophthalmology & Visual Science*. 2020 Apr 9;61:49.

This myopia “epidemic” poses substantial personal, societal, and economic burdens, driving an urgent need for effective myopia management strategies.¹⁵⁻¹⁷ Early onset of myopia and faster progression during childhood are associated with a higher final degree of myopia and a greater risk of developing high myopia and related vision impairment.^{18,19} Thus, there is a growing interest in myopia control methods that can reduce the rate of refractive error progression and axial elongation of the eye, resulting in a reduced final degree of myopic refractive error in adulthood and a reduced risk of vision impairment. Traditional optical corrections like single-vision glasses and contact lenses compensate for the refractive error but do not treat the underlying pathology (excessive growth of the posterior eye) or slow the progression of myopia.^{20,21}

Peripheral Retinal Defocus as a possible mechanism of action for Myopia Control

One prominent theory of myopia control hypothesizes that introducing myopic defocus (light focused in front of the retina) can slow the progression of myopia.²² Studies on animal models of myopia have shown that placing the retinal image plane behind the retina (hyperopic retinal defocus) triggers compensatory axial elongation,²³⁻²⁵ leading to myopic refractive error. Conversely, the image plane in front of the peripheral retina (relative peripheral myopic defocus) slows axial elongation and myopia development, even if the foveal region experiences hyperopic defocus.²² These important research studies stimulated the design of ActivControl® Technology implemented in MiSight® 1 day contact lenses.

The Solution: Myopia Control

What is ActivControl® Technology?

ActivControl® Technology was designed to reduce the eye elongation rate during the myopic progression phase in age-appropriate myopic children.¹ Slowed progression over multiple years can lead to an accumulated decrease in the magnitude of final myopia, which is expected to reduce the lifetime risk of developing vision-threatening pathological complications.²⁶



Slowed progression over multiple years can lead to an accumulated decrease in the magnitude of final myopia.²⁶

Technology Overview

CooperVision MiSight® 1 day contact lenses feature a specific dual-focus optical design called ActivControl® Technology (Figure 2). A dual-focus optical lens design consists of alternating concentric zones of different dioptric powers that create two focal planes in the eye — one for clear distance vision, and another that focuses light in front of the retina (myopic defocus). Unlike multifocal optics for presbyopia, dual-focus lenses have discrete power zones with abrupt changes between them. The power profile centrally corrects the refractive error, and the surrounding concentric rings of power alternate between treatment zones with approximately +2.00D of myopic defocus, and an additional distance correction zone. The correction zone contains the lens's labeled power.

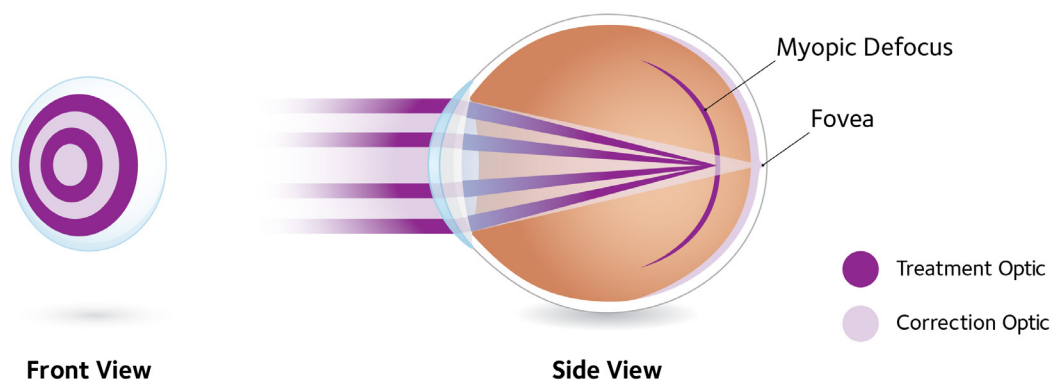


Figure 2: ActivControl® Technology Design Illustration of alternative correction and treatment zones creating myopic defocus on the retina.

Features of a Lens Designed for Children and its Long-Term Outcomes

1. Safety/Ocular Health

MiSight® 1 day has a strong safety profile as a 1-day lens.²⁷

A six-year study involving MiSight® 1 day and Proclear 1 day contact lenses showed no significant impact on ocular health, with biomicroscopy evaluations revealing no serious contact lens related adverse events.²⁷ Additionally, this study identified bulbar and tarsal hyperemia as the most common biomicroscopy findings across 653 lens-wearing years; however, despite the frequency, 99% of these findings were graded as mild (grade 1 or lower), indicating minimal effect to overall anterior segment eye health.²⁷ Throughout the six years, there were no serious adverse events related to contact lens wear²⁷, suggesting that with proper management and education, pediatric patients can safely wear contact lenses with minimal risk of significant ocular complications.^{27, 28}

While the material used in MiSight® 1 day lenses has been FDA-cleared for use in a variety of soft contact lens products since 1998, it is important to consider the long-term safety profile of hydrogel lenses in general. Over thirty years of experience with hydrogel contact lenses have demonstrated a robust safety profile characterized by low inflammatory responses and minimal risk of infection, contributing to a stable ‘quiet eye’ among wearers.²⁹ While conventional hydrogel lenses exhibit lower oxygen transmissibility than silicone hydrogel lenses, both types of lenses provide similar levels of corneal oxygenation at the central cornea when worn daily.²⁹

2. Comfort and Convenience

The material (omafilcon A) used in MiSight® 1 day is a high-quality, biocompatible hydrogel material. Omafalcon A incorporates phosphorylcholine (PC) polymers, which mimic the ocular surface due to their similarity to phospholipids found in human cell membranes.³⁰ These polymers, which have positive and negative charges, bond with water molecules, retaining moisture in the contact lenses without additional wetting agents. As a result, the lenses remain moist and comfortable even after more than 10 hours of wear.³⁰

The daily disposable nature of MiSight® 1 day minimizes the risk of infections and allergic reactions by eliminating the need for cleaning and disinfecting solutions.²⁷ This ease of use encourages consistent daily wear, which is important for delivering the myopia control signal in age-appropriate children.

The comfort and convenience of MiSight® 1 day is evident in children’s wearing habits.²⁷ While the clinical trial protocol instructed participants to wear the lenses for at least 10 hours per day, children consistently exceeded this requirement, wearing their lenses for 13–14 hours daily throughout the study.²⁷ The fact that children voluntarily chose to wear their lenses for additional hours implies that MiSight® lenses provide a comfortable and convenient full-day vision correction option that integrates seamlessly into their daily lives.²⁷ Throughout the clinical trial, over 94% of children reported that they either “don’t notice” or “sometimes notice” the lenses on their eyes, indicating a high level of comfort, and nearly 90% of age-appropriate children preferred MiSight® 1 day contact lenses over their glasses.^{*31}

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3. Visual Performance/Quality of Vision

The visual performance of MiSight® 1 day is optimized to address the unique needs of age-appropriate children with myopia. The innovative ActivControl® Technology features a central optical zone that provides clear distance vision, while the treatment zones help to slow the progression of myopia. Age-appropriate children wearing ActivControl® Technology achieved better than 20/20 vision across all visits over a 6-year period.^{†1,7} More than 96% of children report good visual performance with ActivControl® Technology when completing schoolwork, playing outside, watching TV, playing video games, or reading.³²

Under certain circumstances (such as low light levels), ActivControl® Technology can cause noticeable ghosting, and/or glare or haloes around bright lights.³³ Despite the potential for these visual disturbances, most children adapt well to the lenses.³³ In the clinical trials, around 90% of participants reported that visual disturbances, such as ghosting, or haloes, were “not noticeable” or “not annoying.”³³ Only a small percentage (about 10%) found these disturbances slightly annoying, which did not significantly affect their willingness to wear the lenses.³³ Only one of the 70 participants in the treatment group from the 3- year study discontinued lens wear due to unacceptable vision.³³ It is the unique design of MiSight® 1 day with ActivControl® Technology that provides a high-quality optical correction for myopia while simultaneously delivering effective myopia control with only minor and rarely observed visual disturbances.^{†1}

Wearing MiSight® contact lenses does not significantly impact binocular vision or accommodation in children, as studies have shown no notable changes in these parameters compared to single-vision spectacles over time.³⁴

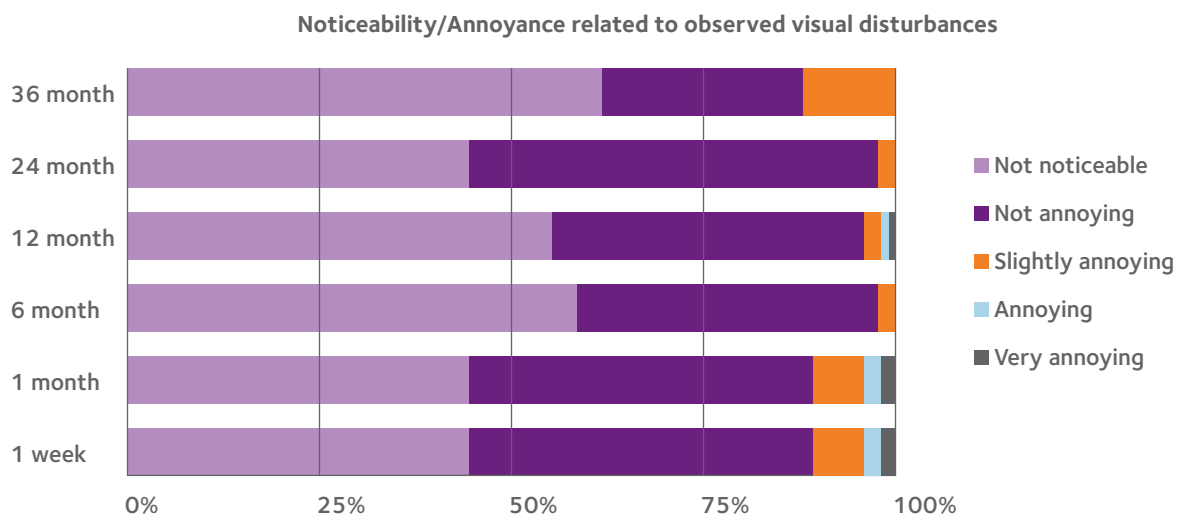


Figure 3: Noticeability/annoyance related to observed visual disturbances: ‘How much do you notice ghosting, haloes or glare when you are wearing your contact lenses?’ by lens group in the MiSight® 1 day clinical study.

Reference: Lumb E, Sulley A, Logan NS, Jones D, Chamberlain P. Six years of wearer experience in children participating in a myopia control study of MiSight® 1 day. *Cont Lens Anterior Eye.* 2023 Aug;46(4):101849. doi: 10.1016/j.clae.2023.101849. Epub 2023 May 6. PMID: 37156658.

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

◇◇Soft contact lens with BOZR and diameter intended to fit majority of general population.

4. Fit success

The base curve, sagittal depth, and the lens diameter of MiSight® 1 day are optimized to fit a wide range of eye shapes, which contributes to a high first-fit success rate at 96%.^{1,35}

MiSight® 1 day comes in a standard 14.2mm diameter, which is suitable for most young wearers.^{◇◇1,36,37} This size is appropriate because children's corneal dimensions are almost adult size by age 3.³⁵

In the MiSight® 1 day clinical study, only 6 out of 144 children (about 4%) showed unacceptable lens fit and did not proceed with the study.² This high success rate suggests that the standard size of MiSight® 1 day accommodates the corneal variations typically seen in the target age group.

5. Handling

A survey conducted with 8 to 12 year old children who were new to contact lens wear revealed that 57% found handling the lenses to be 'kind of easy' or 'really easy' after one week, which improved to 85% by 1 month.³¹ This figure rose to 97% from six months through the end of the 36-month study.³¹ Age did not influence handling ratings for the lenses, as similar proportions of younger (8–10 years at recruitment) and older (11–12 years at recruitment) children rated MiSight® 1 day as 'really easy' or 'kind of easy' to apply and remove.³¹ For lens removal, 94% of parents indicated minimal intervention was needed after the first month, reflecting a reduction in parental support as children became more adept at handling their lenses.³¹

6. Efficacy for Myopia Control

Clinical Test Results

3-YEAR STUDY: MiSight® 1 day with ActivControl® Technology slowed the progression of myopia in age-appropriate children by 59% on average, and 41% of treated eyes experienced no progression.^{†,††,¶¶1}

6-YEAR STUDY: Among MiSight® 1 day wearers, 23% percent of eyes had no progression at 6 years.^{***7} On average, age-appropriate children wearing MiSight® 1 day progressed less than -1.00D over 6 years.^{††7}

7-YEAR STUDY: 7 year results from the international MiSight® 1 day clinical study indicate that there is no clinically significant rebound effect with MiSight® 1 day contact lenses.⁵ After treatment cessation, eye growth returns to age-expected levels and the accumulated myopia control treatment gains were retained over 12 months after treatment ceased.^{¶5,6}

◇◇Soft contact lens with BOZR and diameter intended to fit majority of general population.

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

¶ 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.

††Children aged 8-12 at the initiation of treatment.

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

***-0.25D or less of change. Fitted between the ages of 8-12 at the initiation of treatment.

†††90% of myopic eyes respond to MiSight® 1 day treatment; ages 11-15 at start of wear, n=90.

Long term efficacy: When treatment was initiated between ages 8-12, it reduced the probability of fast eye growth, defined as >0.3 mm of axial elongation over 3 years, by 95%.³⁸

Number Needed to Treat: MiSight® 1 day soft contact lenses demonstrate exceptional efficacy in controlling myopia progression, as reflected by their Number Needed to Treat (NNT) of 1.1.³⁹ The NNT represents the average number of patients who need to be treated to prevent one negative outcome. An NNT of 1.1 for MiSight® indicates that for every 11 children fitted with these lenses, 10 children will benefit from reduced myopia progression. To place the remarkably low NNT for MiSight® into context, the NNT for treating ocular hypertension with IOP-lowering medication is 20 to 24,⁴⁰ and the NNT for antibiotic use for acute bacterial conjunctivitis is 9.41. This reinforces that ActivControl® Technology is almost universally effective at controlling myopia.

Response rates: The response rate (percent of treated that experience treatment effect) of a myopia control intervention is a critical factor in determining its effectiveness. Let’s compare the response rates of MiSight® 1 day to that of other medical interventions:

Treatment	Response Rate	Definition of Non responder to treatment
MiSight® 1 day for myopia control	90% ^{†††}	Treated axial length growth=Untreated axial length growth
Prostaglandin Analogues for Normal-Tension Glaucoma ^{†††}	85% ⁴²	Patients with IOP reduction rate <10% at two visits
Low Dose (0.02%) Atropine for Myopia Control ^{†††}	22% ⁴³	>0.50D myopia progression at 36 months
Metformin for Type II Diabetes ^{†††}	57% ⁴⁴	Lack of a target glycated hemoglobin (HbA1c) (<7%) within 18 months of index or the start of dual therapy.

Sustained benefit: Research shows that age-appropriate children wearing MiSight® 1 day lenses not only experience a reduction in myopia progression during the first three years of wear,^{†1} but also benefit from cumulative effects in subsequent years.^{◊3} This prolonged treatment effect suggests that the lenses may alter the eye’s growth patterns over time, leading to sustained benefits even after the initial treatment phase.^{◊3}

†††This is an off-label treatment that has not been FDA-approved for pediatric myopia control.

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

◊While eyes are still growing; children fit ages 8-12 and followed for 6-years. n=40.

Parent Perceptions

MiSight® 1 day received FDA approval* based on a multicenter randomized and controlled 3-year study that provided insights into the perceptions of parents on their children’s use of contact lenses.³¹ One of the most compelling findings from the study is the correlation between child satisfaction and parental happiness.³¹ As age-appropriate children reported increased comfort and satisfaction with wearing MiSight® 1 day,³¹ parents also expressed their children were more happy with the overall experience of wearing contact lenses after 3 years of wear.^{§§§45}

Short-Term Benefits

At baseline, 79% of parents felt either extremely or somewhat comfortable with the idea of their child wearing contact lenses.³¹ From the 1-month visit onwards, this figure soared to over 98%!³¹ This shift illustrates how positive experiences with MiSight® 1 day can enhance parental perceptions and acceptance of contact lens wear for their children.

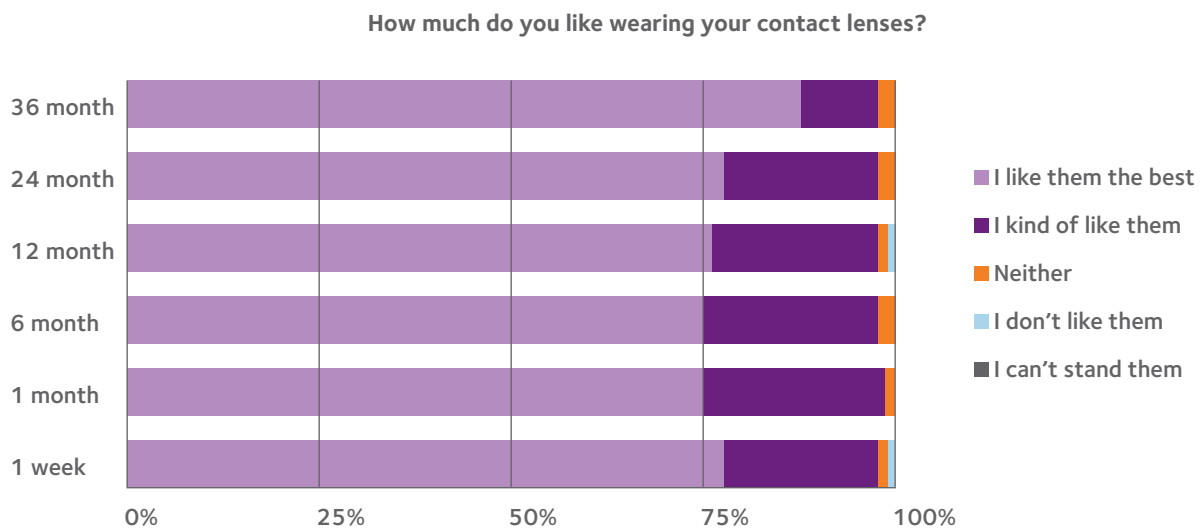


Figure 4: Percent of reports of “like them the best” or “I kind of like them” when questioned about overall satisfaction with wearing contact..

Reference: Lumb E, Sulley A, Logan NS, Jones D, Chamberlain P. Six years of wearer experience in children participating in a myopia control study of MiSight® 1 day. *Cont Lens Anterior Eye.* 2023 Aug;46(4):101849. doi: 10.1016/j.clae.2023.101849. Epub 2023 May 6. PMID: 37156658.

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§§§Overall experience as defined as children’s comfort, vision, lens handling, and freedom from spectacles. Children aged 8-15 years.

Summary

MiSight® 1 day is a significant and differentiating advancement in myopia control for age-appropriate children, combining innovative design with clinically proven results with its ActivControl® Technology.^{†1} The unique lens design delivers clarity and comfort needed for active lifestyles while slowing the progression of myopia in the eyes.²⁷



Unique Design for Myopia Control

ActivControl® Technology is specifically designed to address one of the underlying causes of myopia progression in age-appropriate children.^{†1} It features a unique lens design that combines peripheral treatment zones with central distance correction zones. This innovative design helps slow eye elongation rates while correcting vision, allowing children to engage in their daily activities with clarity and comfort.^{†1}



FDA- Approved* Efficacy and Safety

MiSight® 1 day is the first and only FDA-approved* soft contact lens proven to slow myopia progression in children aged 8-12 at the initiation of treatment.^{†1} It has been clinically shown to reduce myopia progression by half on average for age-appropriate children wearing these contact lenses as prescribed.^{*◇◇¶¶¶3,46} Additionally, it boasts a strong safety profile as a 1-day lens,²⁷ and is backed by 7 years of international clinical research confirming its effectiveness in children aged 8-12 at initiation of treatment.^{¶5,6}



Convenience and Comfort

Designed as daily disposable contact lenses, MiSight® 1 day lenses are convenient and comfortable for both age-appropriate children and parents.^{1,31,47} There is no need for cleaning or storage, making it easy to use and suitable for active lifestyles.

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◇◇◇ Using measured and modeled data, pooled across ages (8-17), MiSight® 1 day slowed myopia progression by an average of approximately 50%.

¶¶¶ Myopic children fit with MiSight® 1 day contact lenses ages 8-15 continued to experience slowed myopia progression as long as they remained wearing the lenses as prescribed.

Take the Next Step in Myopia Management

Empower your practice and deliver the care your patients need by integrating MiSight® 1 day contact lenses with ActivControl® Technology into your myopia management strategy. Schedule a consultation with our myopia sales team to learn how these innovative lenses can slow myopia progression in age-appropriate children at the initiation of treatment, and help protect their vision for better long-term eye health. *†****1,3



Contact us now to discuss how we can work together to provide the best vision care for your age-appropriate patients!

MiSight® 1 day Product Specifications

The physical/optical properties of the lens are:	
Refractive Index	1.395 ± 0.005
Light Transmittance	>90%
Water Content	60% ± 2%
Oxygen Permeability	25 x 10 ⁻¹¹ (cm ² /sec)(ml O ₂ /ml x mmHg) (Polarographic FATT Method)
Lens Parameters Available:	
Diameter	14.2 mm
Base Curve	8.7 mm
Center Thickness	0.08 mm to 0.14 mm (varies with power)
Sphere Power	-0.50 D to -6.00 D; 0.25 steps, -6.00D to -7.00D; 0.50D steps

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†Compared to a single vision 1 day lens.

****MiSight® 1 day, designed for myopia control, shows sustained slowing of eye growth over time on average. While eyes are still growing; children fit ages 8-12 and followed for 6-years. n=40.

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