MiSight 1 day, risultati studio clinico

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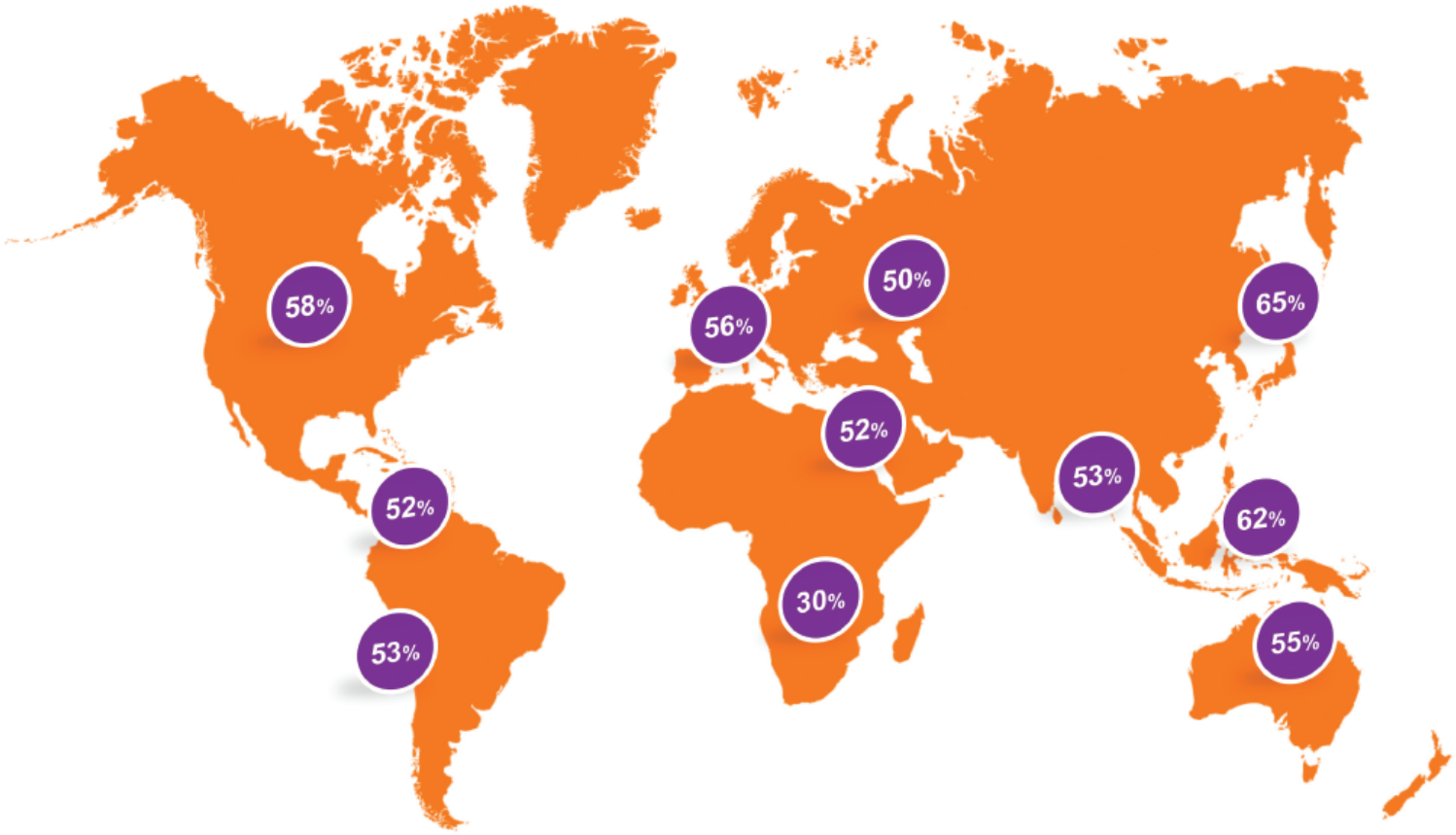
(Cooper Vision)

Affrontare la miopia è più urgente che mai

Più del 50% della popolazione globale entro il 2050[2] sarà miope



Il rallentamento della progressione miopica può ridurre significativamente il rischio delle complicanze associate alla miopia

- Livelli elevati di miopia possono portare a una sostanziale riduzione della vista dovuta all'allungamento assiale[3]
- La miopia aumenta significativamente il rischio di **distacco della retina** e di **maculopatia miopica**[3]
- Anche livelli più bassi di miopia sono associati ad una maggiore incidenza di **glaucoma** e **cataratta**[3]

Le attuali opzioni di trattamento, pur presentando alcuni limiti sono:

- Occhiali multifocali
- Ortocheratologia (ortho-K)
- Lenti a contatto multifocali morbide
- Atropina

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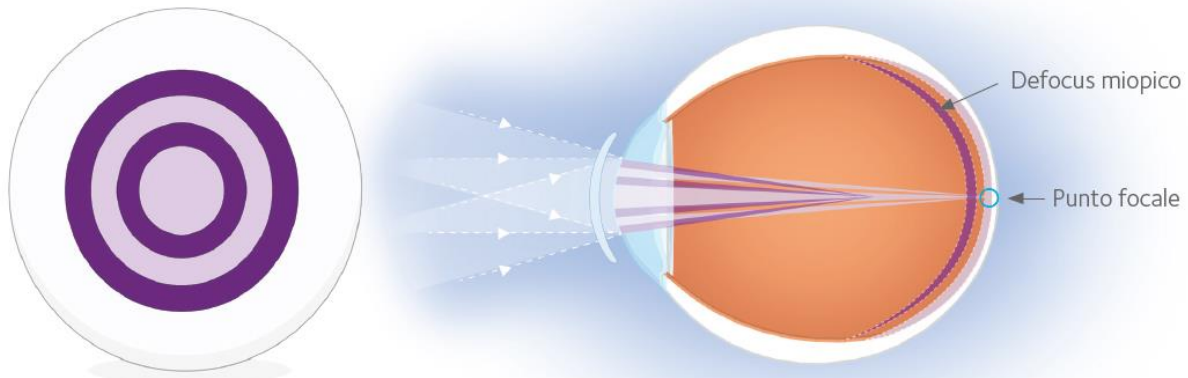
- Lente a contatto a ricambio giornaliero con tecnologia ActivControl® per il controllo della progressione miopica
- Facile da usare come una lente a contatto monofocale
- Semplice da applicare, rispetto alle opzioni di trattamento alternative

Le innovative lenti a contatto MiSight® 1 day con tecnologia ActivControl® contengono sia l'aumento della lunghezza assiale che la progressione della miopia, correggendo completamente l'errore refrattivo[1,4]



- Due zone di trattamento creano un defocus miopico (con messa a fuoco dell'immagine davanti alla retina) per rallentare l'allungamento assiale
- Due zone di correzione per compensare la miopia in tutte le posizioni di sguardo
- Le zone di trattamento sono progettate per garantire un defocus miopico adeguato rispetto a diverse prescrizioni, cambiamenti nelle dimensioni della pupilla e alle variazioni nella centratura della lente

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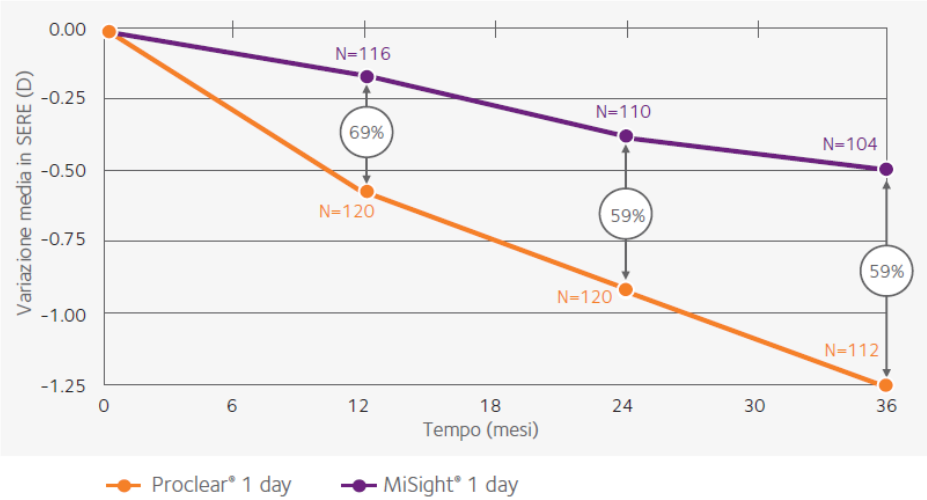
MiSight® 1 day: progetto di studio clinico[1]

Sperimentazione clinica triennale, multicentrica, doppio cieca condotta in quattro siti (Canada, Inghilterra, Portogallo e Singapore)

- I soggetti per l'applicazione di MiSight® 1 day (gruppo test) o di Proclear® 1 day (gruppo di controllo) sono stati selezionati in modo casuale.
- 144 bambini miopi idonei di età compresa tra 8 e 12 anni
  - Età: 10 ± 1 anni; (57% 8-9 anni, 43% 10-12 anni)
  - Sesso: 52% maschi, 48% femmine
  - Etnia: 55% caucasica, 32% asiatica, 9% mista, 4% altro
- Refrazione basata sull'equivalente sferico per entrambi i gruppi di studio
- Cilindro: ≤0.75D

Dopo tre anni, le lenti a contatto MiSight® 1 day hanno ridotto la progressione della miopia del 59%[1]*



- Lo studio clinico di MiSight® 1 day è stato il primo a dimostrare una riduzione sostenuta della progressione miopica attraverso l'utilizzo di una lente a contatto morbida per un periodo di tre anni[1]*

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Le lenti a contatto MiSight® 1 day riducono l'allungamento assiale del 52%[1*]

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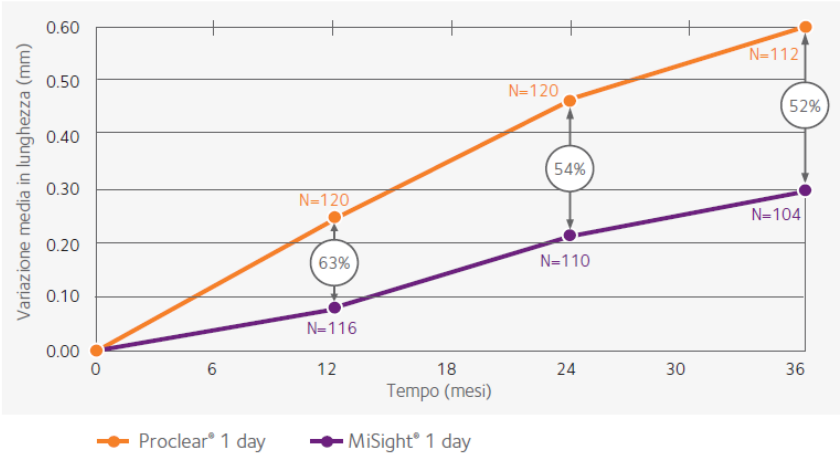
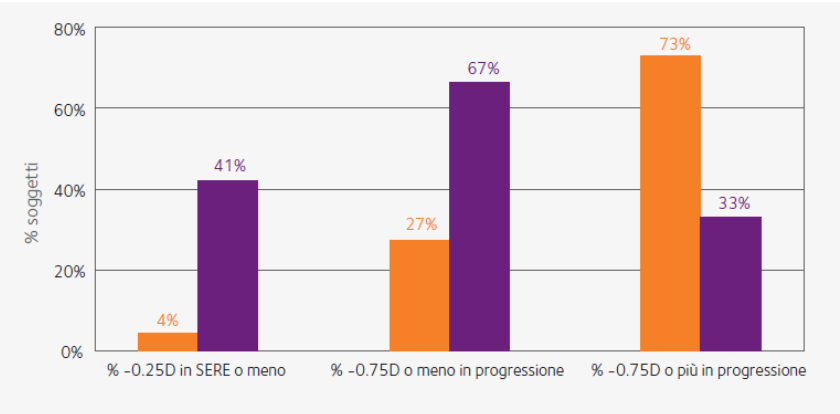
Variazione della lunghezza assiale



- La riduzione dell'allungamento assiale aiuta a ridurre il rischio delle complicanze associate alla miopia

Distribuzione della popolazione



- Solo un bambino su tre con le lenti a contatto MiSight® 1day ha avuto un aumento della miopia ≥ 0.75D, rispetto a tre bambini su quattro che hanno utilizzato una lente monofocale a ricambio giornaliero[1]

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CLINICAL TRIAL

A 3-Year Randomized Clinical Trial of MiSight Lenses for Myopia Control

Paul Chamberlain, BSc,[1]* Sofia C. Peixoto-de-Matos, MSc,[2] Nicola S. Logan, PhD,[3] Cheryl Ngo, MBBS, MMed,[4] Deborah Jones, BSc, FAAO,[5] and Graeme Young, PhD, FAAO[6]

SIGNIFICANCE: Results of this randomized, double-masked clinical trial demonstrate the effectiveness of the MiSight soft contact lens in slowing myopia progression over multiple years.

PURPOSE: The purpose of this study was to quantify the effectiveness of MiSight daily disposable soft contact lens in slowing the progression of juvenile-onset myopia.

METHODS: Myopic children (spherical equivalent refraction, –0.75 to –4.00 D; astigmatism, <1.00 D) aged 8 to 12 years with no prior contact lens experience were enrolled in a 3-year, double-masked, randomized clinical trial at four investigational sites in four countries. Subjects in each group were matched for age, sex, and ethnicity and were randomized to either a MiSight 1-day contact lens (test) or Proclear 1-day (control; omafilcon A) and worn on a daily disposable basis. Primary outcome measures were the change in cycloplegic spherical equivalent refraction and axial length.

RESULTS: Of the subjects enrolled, 75.5% (109/144) completed the clinical trial (53 test, 56 control). Unadjusted change in spherical equivalent refraction was –0.73 D (59%) less in the test group than in the control group (–0.51 ± 0.64 vs. –1.24 ± 0.61 D, $P < .001$). Mean change in axial length was 0.32 mm (52%) less in the test group than in the control group (0.30 ± 0.27 vs. 0.62 ± 0.30 mm, $P < .001$). Changes in spherical equivalent refraction and axial length were highly correlated ($r = –0.90$, $P < .001$). Over the course of the study, there were no cases of serious ocular adverse events reported. Four asymptomatic corneal infiltrative (one test, three control) events were observed at scheduled study visits.

CONCLUSIONS: Results of this clinical trial demonstrate the effectiveness of the MiSight daily disposable soft contact lens in slowing change in spherical equivalent refraction and axial length.

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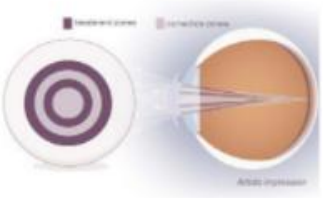

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MiSight® 1 day

CLINICAL TRIAL

Long-term Effect of Dual-focus Contact Lenses on Myopia Progression in Children: A 6-year Multicenter Clinical Trial

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SIGNIFICANCE: Treatment of myopic children with a dual-focus soft contact lens (DFCL; MiSight 1 day) produced sustained slowing of myopia progression over a 6-year period. Significant slowing was also observed in children switched from a single vision control to treatment lenses (3 years in each lens).

PURPOSE: This study aimed to evaluate the effectiveness of DFCLs in sustaining slowed progression of juvenile-onset myopia over a 6-year treatment period and assess myopia progression in children who were switched to a DFCL at the end of year 3.

METHODS: Part 1 was a 3-year clinical trial comparing DFCLs with a control contact lens (Proclear 1 day) at four investigational sites. In part 2, subjects completing part 1 were invited to continue for 3 additional years during which all children were treated with MiSight 1 day DFCLs (52 and 56 from the initially treated [T6] and control [T3] groups, respectively). Eighty-five subjects (45 [T3] and 40 [T6]) completed part 2. Cyclopleged spherical equivalent refractive errors (SEREs) and axial lengths (ALs) were monitored, and a linear mixed model was used to compare their adjusted change annually.

RESULTS: Average ages at part 2 baseline were 13.2 ± 1.3 and 13.0 ± 1.5 years for the T6 and T3 groups, respectively. Slowed myopia progression in the T6 group observed during part 1 was sustained throughout part 2 (mean ± standard error of the mean: change from baseline SERE [in diopters], −0.52 ± 0.076 vs. −0.51 ± 0.076; change in AL [in millimeters], 0.28 ± 0.033 vs. 0.23 ± 0.033; both $P > .05$). Comparing progression rates in part 2 for the T6 and T3 groups, respectively, indicates that prior treatment does not influence efficacy (SERE, −0.51 ± 0.076 vs. −0.34 ± 0.077; AL, 0.23 ± 0.03 vs. 0.18 ± 0.03; both $P > .05$). Within-eye comparisons of AL growth revealed a 71% slowing for the T3 group (3 years older than part 1) and further revealed a small subset of eyes (10%) that did not respond to treatment.

CONCLUSIONS: Dual-focus soft contact lenses continue to slow the progression of myopia in children over a 6-year period revealing an accumulation of treatment effect. Eye growth of the initial control cohort with DFCL was slowed by 71% over the subsequent 3-year treatment period.

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Ocular health of children wearing daily disposable contact lenses over a 6-year period

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ABSTRACT

Purpose: To report on the ocular health and safety of children fit with soft hydrogel daily-disposable contact lenses, and followed for 6-years in a double-masked clinical trial investigating the performance of a dual-focus contact lens designed to control myopia progression.

Methods: Children aged 8–12 years, naïve to contact lens wear, were enrolled across four international sites. During years 1–3, children were randomised to either MiSight® 1 day or Proclear® 1 day (both omafilcon A, CooperVision, Inc.). The lenses were identical in material and geometry except for the front optical zone design. At the end of year-3, all those wearing Proclear 1 day were switched to MiSight 1 day, therefore all wore MiSight 1 day in years 4–6. Subjects agreed to wear the lenses at least 10-hours/day, 6-days/week. After dispensing, study visits were at 1-week, 1-month, 6-months and every 6-months until 6-years. At each visit, ocular measurements and subjective responses were recorded. Biomicroscopy used 0–4 grading scales; grade 0 represented no findings.

Results: 144 children were enrolled: 69F:75M; mean age 10.1 years; mean cycloplegic spherical-equivalent refraction -2.11D; ethnicities included 34 East-Asian, 12 West-Asian, and 79 Caucasian. 92 completed the 6-years. Only three subjects discontinued due to an ocular adverse event (AE). No contact lens related AEs were classified as serious. The incidence rate of infiltrative AEs was 0.61% (6.1/1000 wearing-years; 95%CI: 0.24%–1.57%). The most common biomicroscopy findings were limbal, bulbar and tarsal hyperaemia and tarsal roughness. 99% of all biomicroscopy findings were grade-1 or lower. After 6-years of lens wear, ocular health by biomicroscopy was similar to pre-lens wear.

Conclusions: Across the 6-years, there were no contact lens related serious AEs and biomicroscopy showed no significant changes. Results suggest that children this age can successfully wear daily-disposable hydrogel contact lenses with minimal impact on ocular physiology.

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