EsSiLOr Stellest Lenses Multicentre European Study

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To demonstrate the efficacy, safety, acceptability, and quality of life implications of Essilor® Stellest® spectacle lenses in slowing myopia progression in children and adolescents.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON56621

Source
ToetsingOnline

Brief title
SLOMES

Condition

- Vision disorders

Synonym
Myopia, nearsightedness

Research involving
Human

Sponsors and support

Primary sponsor: Essilor International
Source(s) of monetary or material Support: Fabrikant onderzoeksproduct (Essilor International)

Intervention

Keyword: Children, Myopia, Stellest

Outcome measures

Primary outcome

Change in axial length and cycloplegic autorefraction from baseline to 24 months compared to expected change based on axial length and refraction centile positions at baseline.

Secondary outcome

• Change in axial length and cycloplegic autorefraction from baseline to 12 and 24 months compared to expected change based on axial length and refraction centile positions at baseline.

• Change in refraction progression centile from 12 months to 24 months visits.

• Change in refraction compared to that observed in control group participants during the first and second year of the Myopia Outcome Study of Atropine In Children (MOSAIC) study, a contemporaneous (ongoing) myopia control trial conducted in Ireland from 2019 to 2023.

• Change in axial length compared to that observed in control group participants during the first and second year (separate comparisons for each year) of the MOSAIC study.

• Change in choroidal thickness compared to that observed in control group participants during the first and second year (separate comparisons for each year) of the MOSAIC study.

• Change in refraction compared to children treated with 0.01% atropine during the first and second year (separate comparisons for each year) of the MOSAIC

study.

• Change in axial length compared to children treated with 0.01% atropine during the first and second year (separate comparisons for each year) of the MOSAIC study.

• Change in choroidal thickness compared to children treated with 0.01% atropine during the first and second year (separate comparisons for each year) of the MOSAIC study.

• Change in Paediatric Refractive Error Profile (PREP-2) score from baseline (pre-Stellest®) to 12 and 24 months (post-Stellest ®).

• Incidence of adverse and serious adverse events over the course of the study.

• Treatment adaptation, acceptability, and compliance to the Essilor® Stellest® spectacle lenses, assessed using questionnaires at each post-baseline study visit.

• Quality of life questionnaire (PREP-2)

Study description

Background summary

Myopia (short-sightedness) prevalence varies markedly across the globe, with 13.9% of South Asia and 22.8% of white populations affected by age 18, whilst almost 80% of East Asians are myopic by 18 years of age. In addition to ethnicity, educational pressure and limited time spent outdoors are risk factors for myopia development. A thin, stretched retina due to axial elongation, particularly in higher degrees of myopia, can lead to blinding ocular pathology including retinal detachment and myopic maculopathy, while lower levels of myopia is significantly associated with the two most common ocular diseases; glaucoma and cataract.
Considering that almost 50% of the world*s population are expected to be myopic by 2050 with approximately 10% of those being affected by high myopia (*-5.00D), it is not surprising that many clinical trials have focused on

developing viable myopia control treatments such as atropine eye drops, contact lenses, including multifocal soft contact lenses, and ortho-keratology, in addition to multifocal spectacle lenses including bifocals, progressive addition lenses (PALs), and peripheral defocus lenses.
Such above-mentioned myopia control methods have various levels of efficacy. Low-dose atropine eye drops have been reported to reduce myopia progression by 50-59%, but have still not been approved for myopia control use. Myopia control soft contact lenses and ortho-keratology are commercially available treatment options, reported to reduce myopia progression by 52-59% and 46% - 56% respectively. Nonetheless, these methods are invasive and may not be suitable for young children.
Myopic children wear single vision spectacles as part of their daily routine. Consequently, myopia control lenses are a simple treatment option, inbuilt to spectacles with the added benefit of slowing myopia progression. Until recently, bifocals were the best myopia control spectacles with a three- year treatment effect of 33-51%, dependent on lag of accommodation and whether bifocal or prismatic bifocal spectacles were used.18 However, bifocals have aesthetical limitations. More recent lens designs apply persistent peripheral myopic defocus on the retina to slow myopia progression.22- 25,28 Spectacle lenses with highly aspherical lenslets (HAL) demonstrated a reduction in myopic SER by 55% (0.8D) and axial length by 51% (0.35mm) compared to single vision lenses (SVL), over a two-year period.22 Although very promising results, this study was conducted on Chinese children only.
Extrapolation to other population* is limited due to ethnic differences in myopia prevalence, even when children are living in the same country and exposed to the same schooling environment.29 Considering this, investigation of the efficacy and safety of the HAL spectacle lenses (Essilor® Stellest®) is the primary aim of this study.

Study objective

To demonstrate the efficacy, safety, acceptability, and quality of life implications of Essilor® Stellest® spectacle lenses in slowing myopia progression in children and adolescents.

Study design

Multicentre, international, prospective, interventional study with single group assignment
All participants receive Essilor® Stellest® at inclusion visit.
Active treatment period: 24 months for all participants

Intervention

Essilor® Stellest® spectacle lenses

Study burden and risks

Cycloplegic eye drops are used by optometrists and ophthalmologists daily and are extremely unlikely to cause unusual symptoms due to an adverse reaction. These include pain and redness in or around the eyes, feeling disorientated, incoherent speech, visual disturbances and racing pulse or palpitations. The risk of these occurring is the same as the routine use of cycloplegic eye drops in optometry or ophthalmology eye clinics. Participants and their parents will be advised to contact their optometrist, ophthalmologist or seek advice immediately if the participant experiences any unusual symptoms. Additionally, slit lamp examination of the anterior chamber angle will be conducted prior to drop instillation as a precaution to ensure it is safe to perform cycloplegia. Participants and their parents will also be advised on the expected symptoms associated with cycloplegic eye drops. These include photophobia due to larger pupil size and blurred near vision due to temporarily altering the near-focus system. Symptoms should not persist longer than 24 hours, and the participant*s will be advised to contact their optometrist, ophthalmologist or seek medical advice should this be the case. Wearing sunglasses or a peaked cap for following cycloplegia, will also be advised, to minimise photophobia and protect the eyes from glare.
The spectacle lens under test (Essilor® Stellest®) is designed to cause peripheral myopic defocus and are deemed safe and without side effects on peripheral vision development in Chinese children. Other studies investigating the effect of myopia progression with multifocal contact lenses,11 progression addition21 and peripheral defocus spectacle lenses25 have not reported to affect peripheral vision development.
Considering the above, there are minimal risks associated with the study examination and the effect of the investigational device on peripheral vision development. These are outweighed by the benefits of guaranteed myopia control, and reduction in the risk of associated visual impairment for all participants enrolled.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1 - Myopia as determined by cycloplegic autorefraction as follows:
- Each meridian SER of plano to - 8;00 D in each eye
- Astigmatism < 2.50 D
- Anisometropia <= 1.50 D
2 - Monocular corrected VA of at least 0.2 LogMAR in both eyes
3 - Age: 6 - 16 years old, inclusive at the time of inclusion

Exclusion criteria

1 - Concomitant or previous therapies for myopia
2 - Eye diseases/conditions:
- Strabismus by cover test at near or distance
- Any ocular disease that would influence refractive development
- Any systemic or neurodevelopmental conditions that may influence refractive development
3 - Use of ocular or systemic medication which may affect myopia progression or visual acuity
4 - Participation in another study which may influence vision or interfere with study assessments
5 - Myopia onset before 5 years of age
6 - Contact lens wearers

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-04-2024
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Stellest Lens
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-03-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL84888.078.23
Other	Not available yet