EssilorLuxottica

Managing Myopia – A new epidemic

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Dusseldorf, June 2025

EssilorLuxottica – pivotal position for visual health

Revenue[1]	People	Customers	Production Facilities
$ 26.5bn	>200,000 employees	>300,000	>630

600 mn Patients

Ametropia
Presbyopia

Dry Eye Disease

Cataract

Retinopathies

[1] Full Year 2024

Future of myopia management

- Myopia – A global epidemic
- Medical interventions under development
- Optical technologies enable Class 2 devices
- Regulatory clearance expected
- Opportunity for a new market

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Myopia reclassification as a disease

Myopia

Simple Refractive Error

or

Medical Condition and Serious Disease*

** NASEM Report;Myopia: Causes, Prevention, and Treatment of an Increasingly Common Disease – Nov. 2024*

Myopia and high myopia

Nearsightedness or Myopia

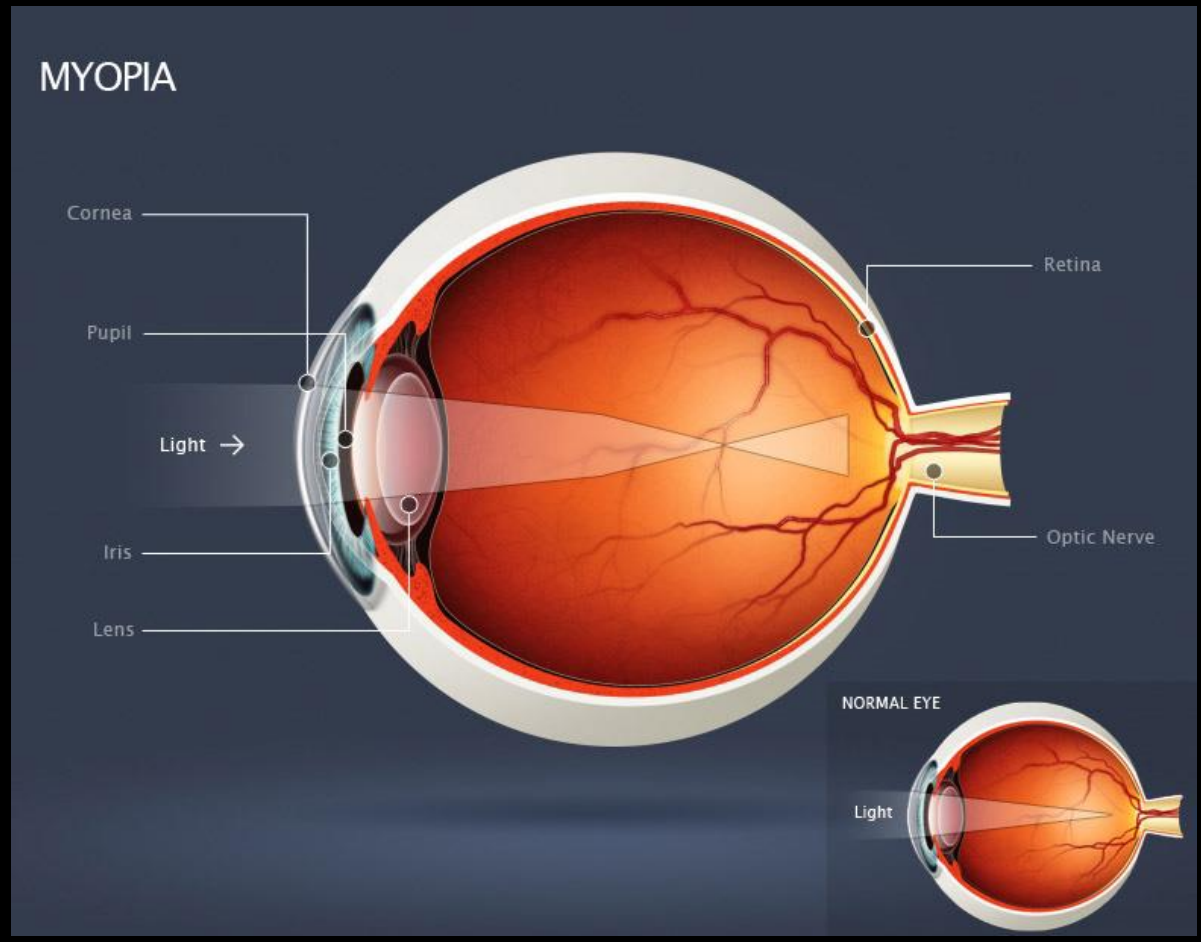
Vision condition in which people can see close objects clearly, but objects farther away appear blurred[1].

Caused by an increase in eye length (more common type[2]) or overly curved cornea and/or lens

Condition in which the spherical equivalent refractive error is ≤ –0.50 diopter (-0.50 D) in the eye when ocular accommodation is relaxed[2].

High Myopia

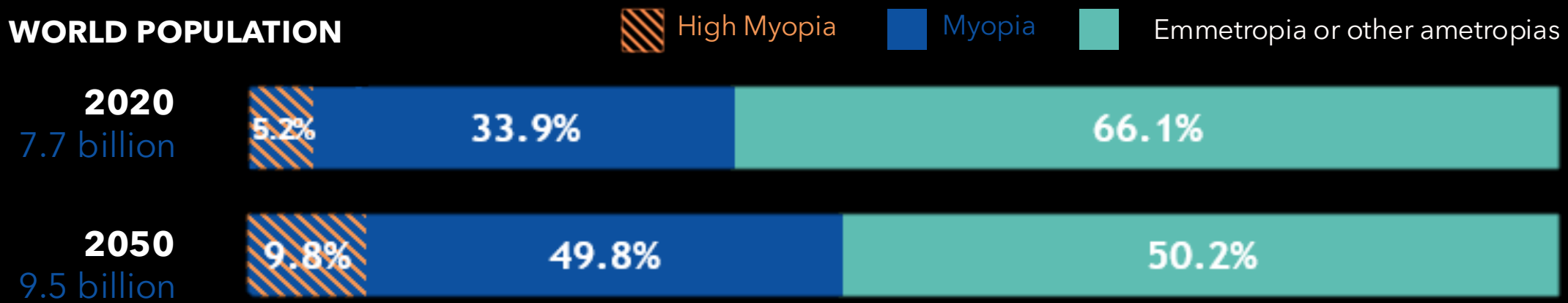
Condition in which the spherical equivalent refractive error is ≤ –6.00 D in the eye when ocular accommodation is relaxed[3].



1. American Optometric Association;
2. Flitcroft, D.I., He, M., Jonas, J.B., Jong, M., Naidoo, K., Ohno-Matsui, K., Rahi, J., Resnikoff, S., Vitale, S., Yannuzzi, L., 2019. IMI - Defining and Classifying Myopia: A Proposed Set of Standards for Clinical and Epidemiologic Studies. Invest. Ophthalmol. Vis. Sci. 60, M20-M30. https://doi.org/10.1167/iovs.18-25957
3. The impact of myopia and high myopia: report of the Joint World Health Organization-Brien Holden Vision Institute Global Scientific Meeting on Myopia, University of New South Wales, Sydney, Australia, 16-18 March 2015. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA .0 IGO.

Myopia and high myopia prevalence

MYOPIA RISING PREVALENCE



Half of the world's population is predicted to be myopic

Almost **1 billion** people are predicted to have high myopia

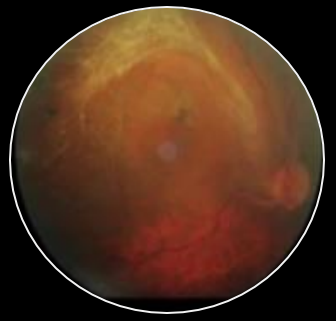
≤ -5.00 D

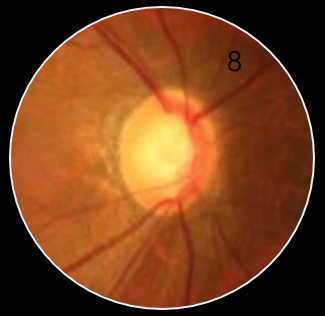
Holden BA, Fricke TR, Wilson DA, et al. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. Ophthalmology. 2016;123(5):1036-1042. doi:10.1016/j.ophtha.2016.01.006

Myopia can lead to serious long-term risks

RISKS ASSOCIATED WITH MYOPIA

Any level of myopia increases the risks of the below mentioned ocular conditions, compared to emmetropes, but **the risk increases exponentially once reaching high myopia[5].**





PRESCRIPTION	MYOPIC MACULAR DEGENERATION[1]	RETINAL DETACHMENT[2]	CATARACT PSC[3]	GLAUCOMA[4]
-6.00 to -9.00	**40.6 x risk**	21.5	5.5	2.46
-3.00 to -6.00	9.7	9.0	3.1	2.46
-1.00 to -3.00	2.2	3.1	2.1	1.65

1. Vongphanit J, Mitchell P, Wang J. Prevalence and progression of myopic retinopathy in an older population. Ophthalmology 2002; 109: 704-711.
2. Ogawa A, Tanaka M. The relationship between refractive errors and retinal detachment--analysis of 1,166 retinal detachment cases. Jpn J Ophthalmol 1988; 32(3):310-5.
3. Lim R, Mitchell P and Cumming R. Refractive association with cataract: the Blue Mountains Eye Study. IOVS 1999, 40(12): 3021-3026
4. Marcus MW, de Vries MM, Jonoy Montolio FG, Jansonius NM. Myopia as a risk factor for open-angle glaucoma: a systematic review and meta-analysis. Ophthalmology 2011, 118(10):1989-1994.
5. https://www.brienholdenvision.org/news/item/95-changing-the-way-optometrists-think-about-myopia.html

What factors may cause myopia?

MYOPIA ONSET AND PROGRESSION

Family History[1]

Parental History

Ethnicity

Optical And Environmental Influences[1]

Optical factors

Near work activities

Time spent outdoors

1. *The impact of myopia and high myopia: report of the Joint World Health Organization–Brien Holden Vision Institute Global Scientific Meeting on Myopia, University of New South Wales, Sydney, Australia, 16–18 March 2015. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO.*

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Strategies for mitigating myopia progression

Environmental Behaviour

- Time spent outdoor in daylight
- Near vision accommodation

Optical Treatments

- Myopia defocus
- Contrast reduction
- Chromatic stimuli

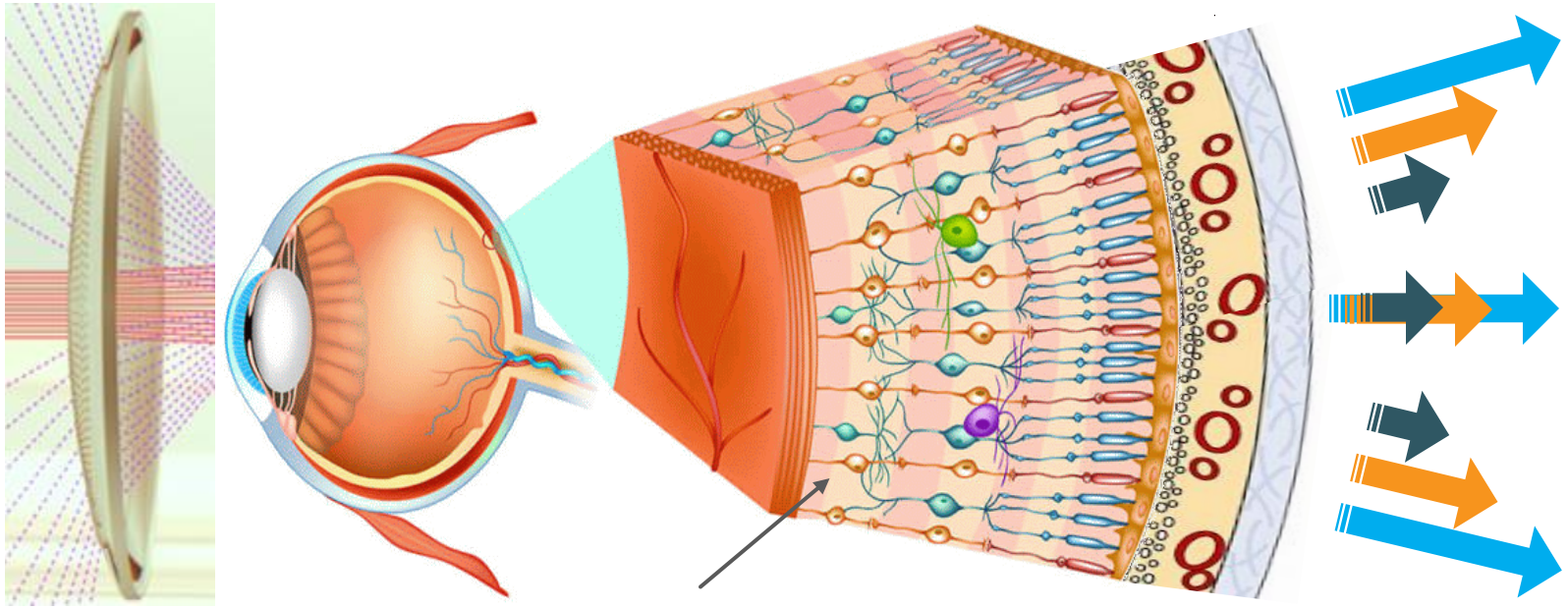
Pharmacol. Treatments

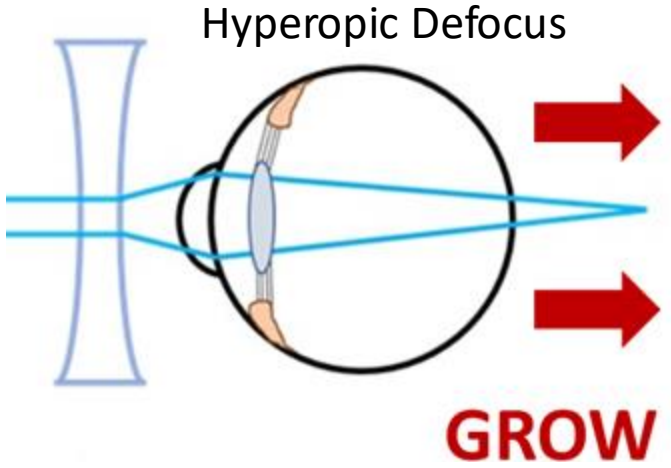
- Low-dose atropine
- 7 Methylxanthine

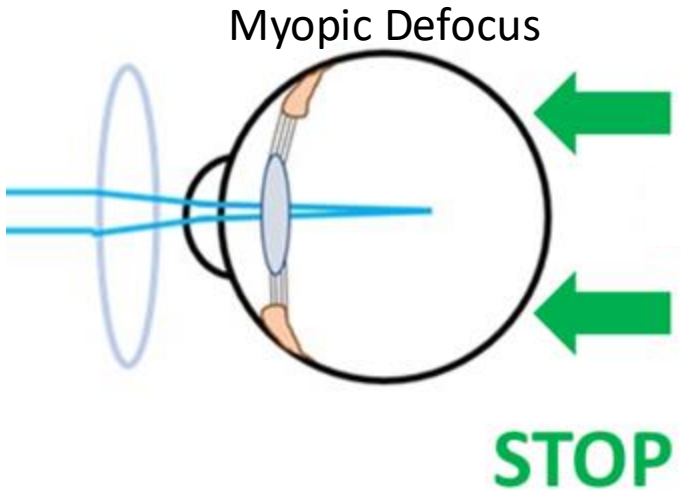
Structural Treatments

- Scleral cross linking

Advancement in medical research allows better understanding of myopia control mechanism







Eye growth regulated by Optical defocus and diffusion

MOUSE MODEL

Refractive eye development

Optical Defocus (+ /-)

↓

Retina

↓

Pigment Epithelium

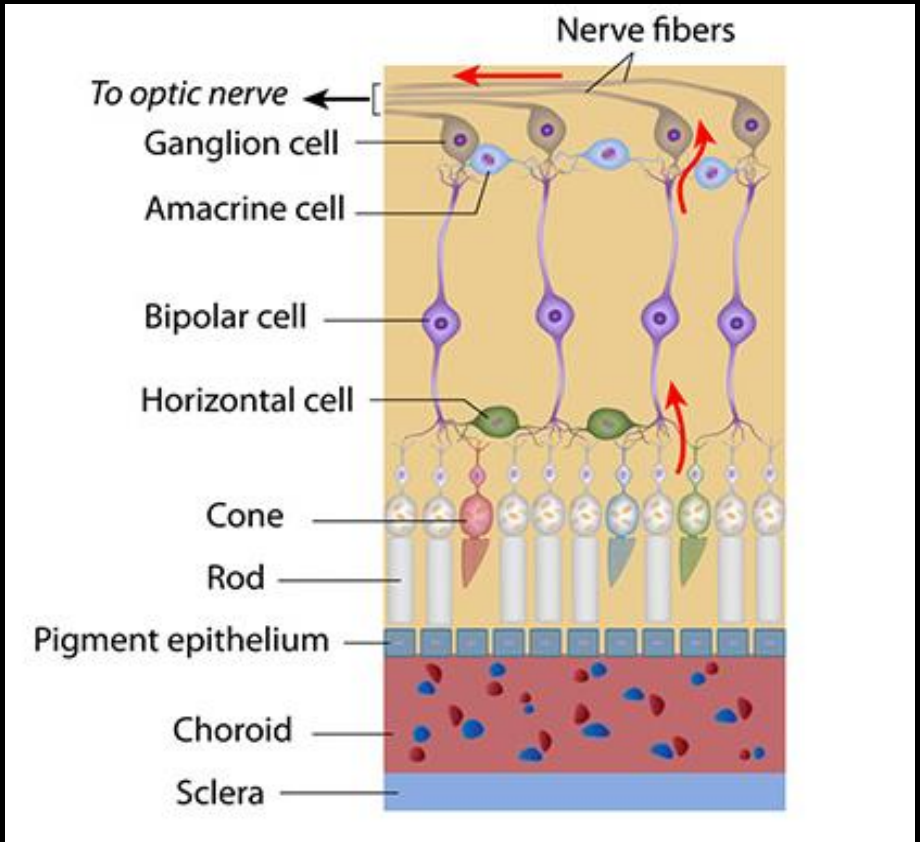
↓

Choroid

↓

Sclera

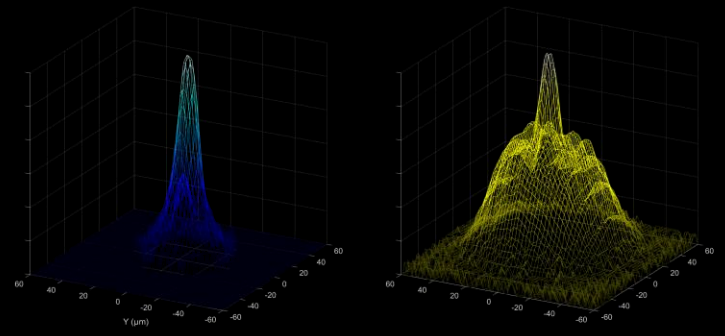
Structure of the retina



- Specific RGL decodes optical signal
- Differentiation between myopic and hyperopic defocus

Point Spread Function

Regular MyoControl



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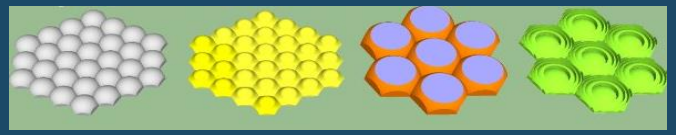
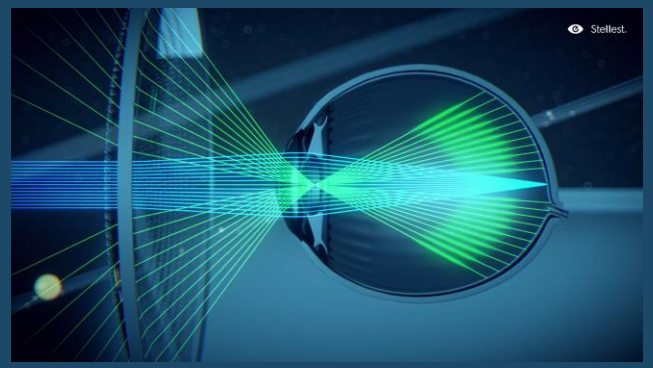
Technologies with breakthrough designation by the FDA: Stellest and DOT

Stellest designs





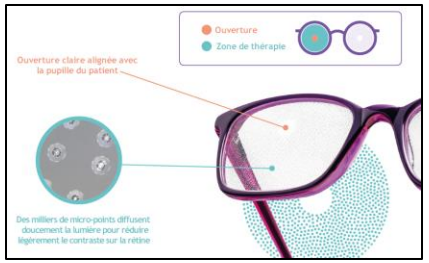
Technical description STELLEST

Microlenslets designs create optical defocus necessary for enhanced myopia control.

Technical description DOT

Diffusion Optics Technology™ (DOT) consisting of thousands of small elements across the lens that reduce the contrast of the image formed on the retina.

DOT design

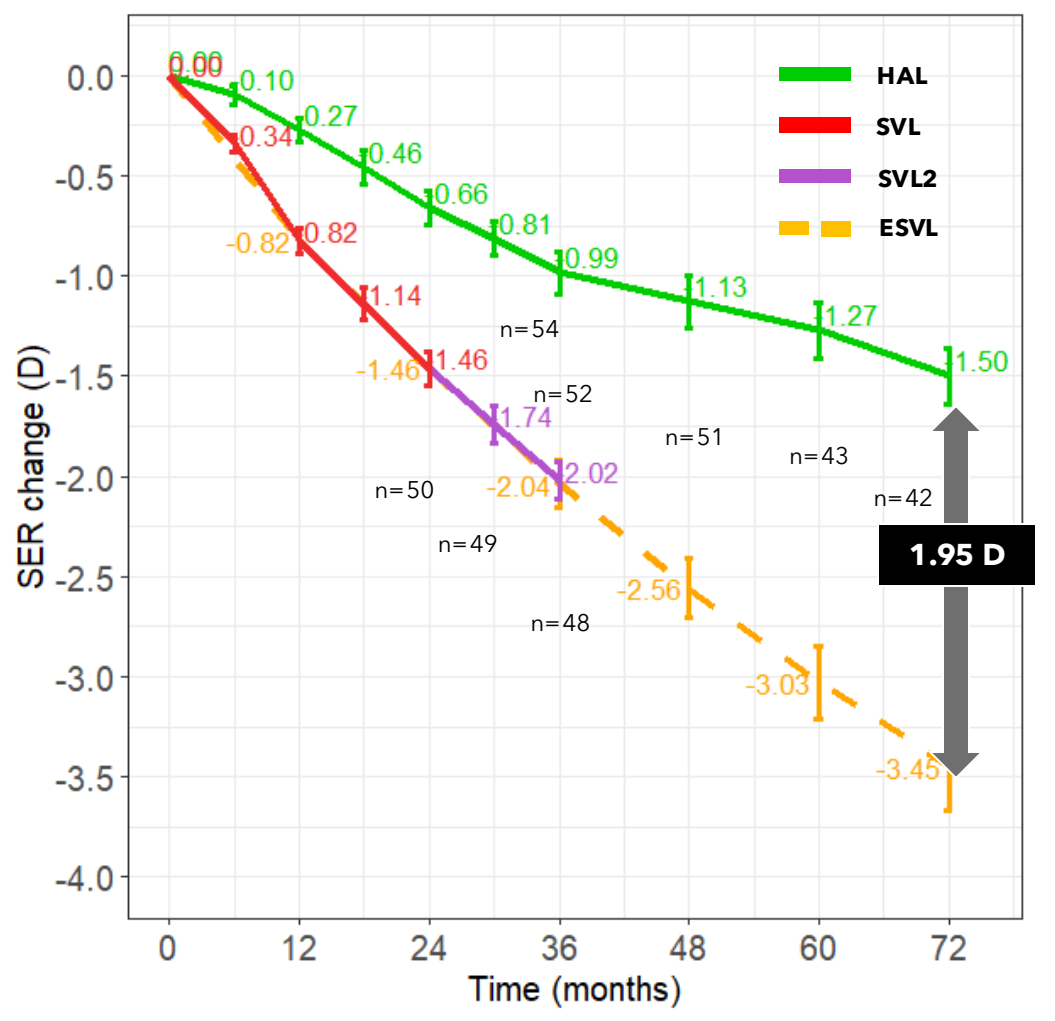


Original picture

Reduced contrast

Stellest Technology maintains efficacy after six years

Mean change in Spherical Equivalent Refraction (D) - unadjusted



- **Stellest slows myopia progression by 1.95D* over 6 years**
- **D AL 0.81 mm over the same period**
- **No rebound effect**
- **Several clinical studies confirm treatment success**

**Compared to the 72-month progression of the Extrapolated Single Vision Lens (ESVL) based on predicted average annual decrease in SER by 9.7% (Smotherman C, et al. IOVS 2023;64:ARVO E-Abstract 811).*

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As of today, only two devices approved by the FDA

Approved

- MiSight Contact Lens (2019) (3y) Progression Control
- ACUVUE Ability Overnight (2021) (2y) Management

In process

- Several Ophthalmic and Soft Lenses
- Atropine

- Preliminary endpoints set not achieved by any product approved
- Endpoints applied outdated?
- No differentiation between drug and device
- Risk-Benefit-Ratio considered insufficiently
- De Novo clearance expected in 25/26

How EssilorLuxottica has managed its transformation

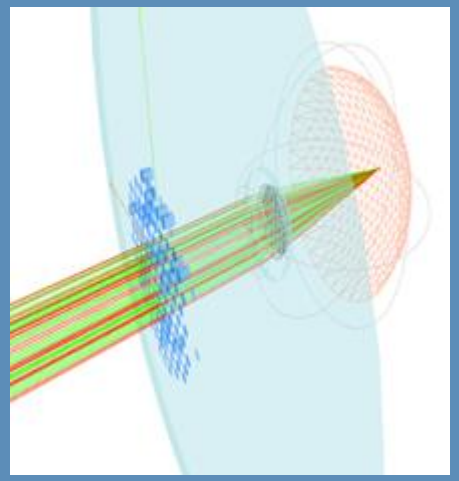
Opportunity	Challenge	Solution

• For the 1st time, an ophthalmic lens design cleared as class 2 medical device	• Eyecare industry must transform into med-tech, rapidly	• Global taskforce representing
		  • R&D, Marketing
		  • Medical Affairs
		  • QM
		  • SCM
		  • Manufacturing
		  • Legal

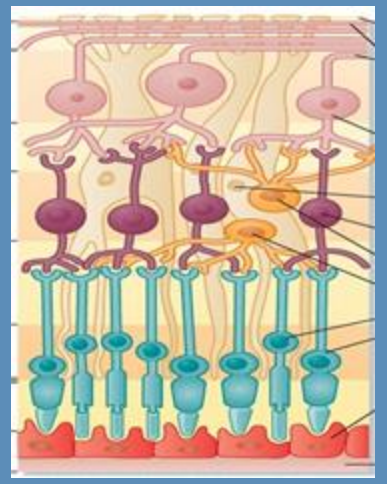
• Besides soft contact lenses, multiple product concepts under development	• Design controls, GMP, risk management, clinical evaluation, post-market surveillance	• Define FDA requirements as global standard, then adapt locally, e.g. CE, MDR
• Opportunity to eradicate high myopia	• Significant variance and dynamics in Regulatory environment	• Adapt the development process from exploratory research to post-market studies

Acceleration through AI-driven modelling – example myopia

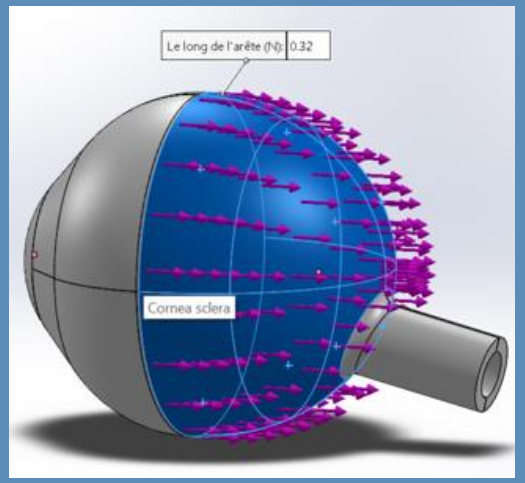
Eye & Retina Model



Optics

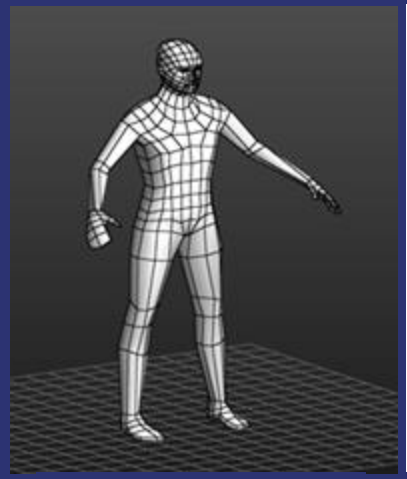


Retinal processing

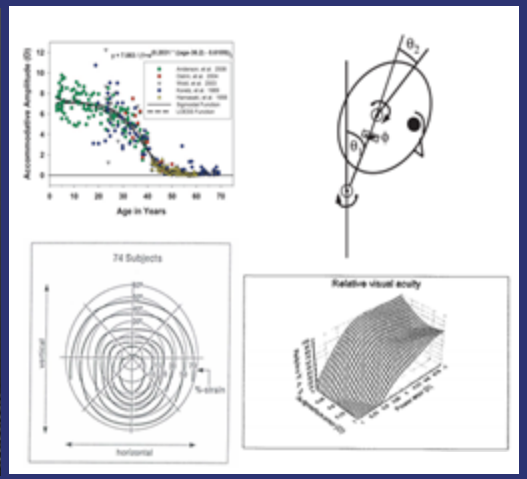


Biomechanics

Wearer Model



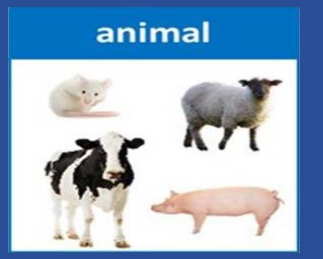
Person

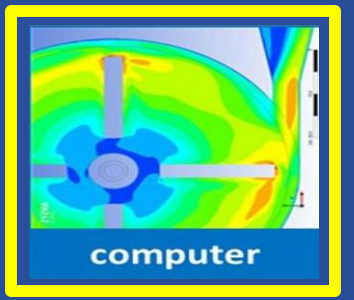


Behavior

Environment

FDA





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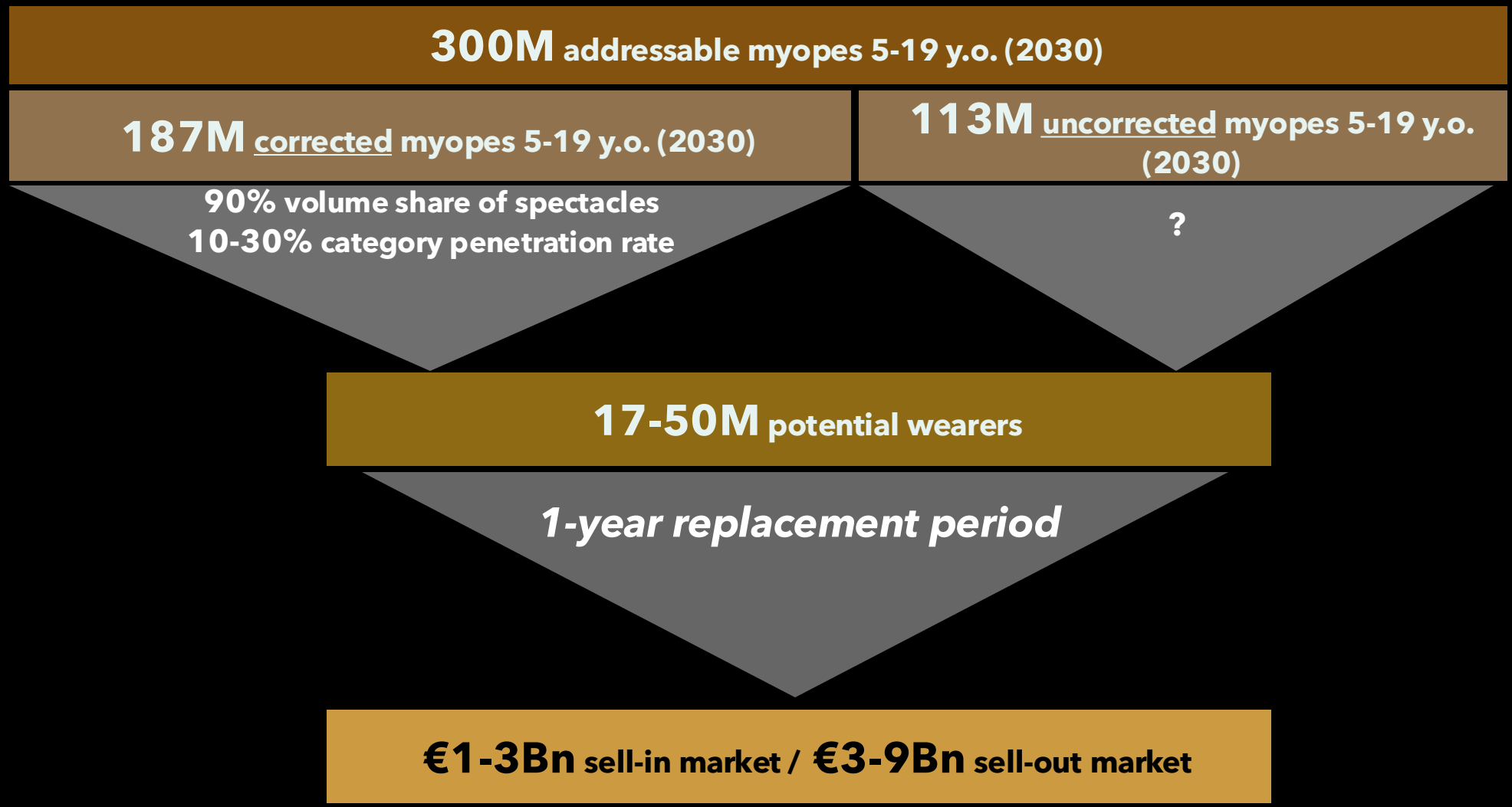
Myopia Progression Control market could reach €1-3Bn sell-in / €3-9Bn sell-out value by 2030



THANK YOU

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See more. Be more.