

# imperium.

## Myopia Management Lenses

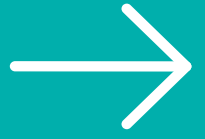
*Whitepaper*

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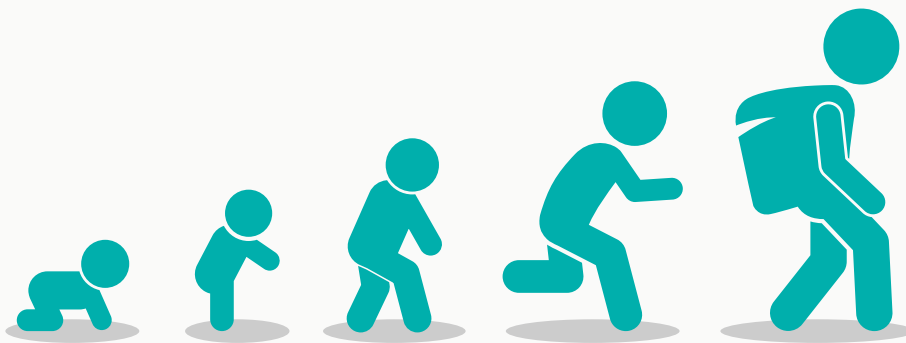
# Why myopia occurs?



## Refractive development

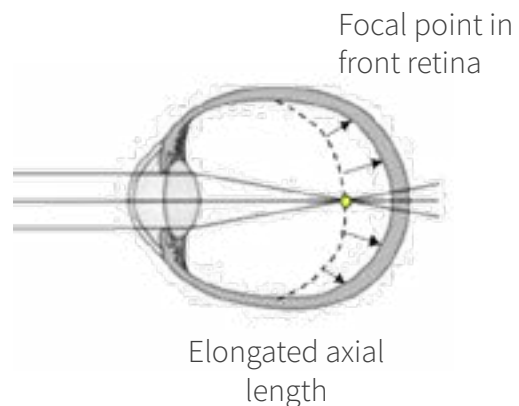
During the first months of life of a child, most eyes have a hyperopic refractive error that is gradually reduced as consequence of the continuing changes of eye dimensions during the period of growth<sup>1</sup>. Emmetropization is the process whereby the refractive error and the axial length of the eye come into a balance. The enlargement of the optical elements of the eye causes a loss of power that is balanced with increased axial length. The most part of ocular growth occurs in

the first few years of life. After this, the eye growth slows down, with an average increase of 0.16mm per year for age 6–9 years, 0.08 mm per year for age 9–12 and 0.02 mm annually for age group 11–14 years.<sup>2</sup> So, it is considered that the average axial length growth during the whole period is of **0.1mm per year**. However, when the axial length growth does not match the changes in the cornea and the lens, the emmetropization process fails, which leads to refractive error.



## Myopia definition

Myopia is a refractive error in which rays of light entering the eye are focused in front of the retina when accommodation is relaxed. This usually can be attributed to an excessive axial elongation that in the most extreme cases can produce structural changes in the retina associated to irreversible blindness. The axial length of myopic eyes grows much faster than that of emmetropic eyes, the growth rate being around **0.3mm per year in younger children and 0.2mm per year in older children**<sup>3</sup>.



# Myopia factor risks

The causes for myopia onset are complex and multifactorial with many studies suggesting that it could be linked to **genetics and environmental conditions**<sup>4</sup>:

- Hundreds of genes have been associated with myopia onset. The presence of parental myopia and certain Asian ethnicities increase the risk of myopia.
- The environmental factors associated with myopia includes limited outdoors activities, excessive near vision work and characteristics of light exposure to which the individual is exposed to.



## Why to be concerned about myopia?



When the amount of myopia is higher than 6.00D, there is a greater risk to suffer from structural changes in the eye that can cause significant visual disability and, as a consequence, affect the quality

## Pathological myopia

of life of myopic patients. People with high myopia have a higher risk of developing some ocular pathologies<sup>5</sup>:

**41X**

more risk to have  
myopic maculopathy

**22X**

more likely to develop  
retinal detachment

**6X**

higher risk to develop  
cataracts

**3X**

more likely to present  
glaucoma

Some studies have shown **that slowing myopia progression by 1 diopter during childhood reduces by 40% the risk to develop myopic maculopathy**, the most common and serious

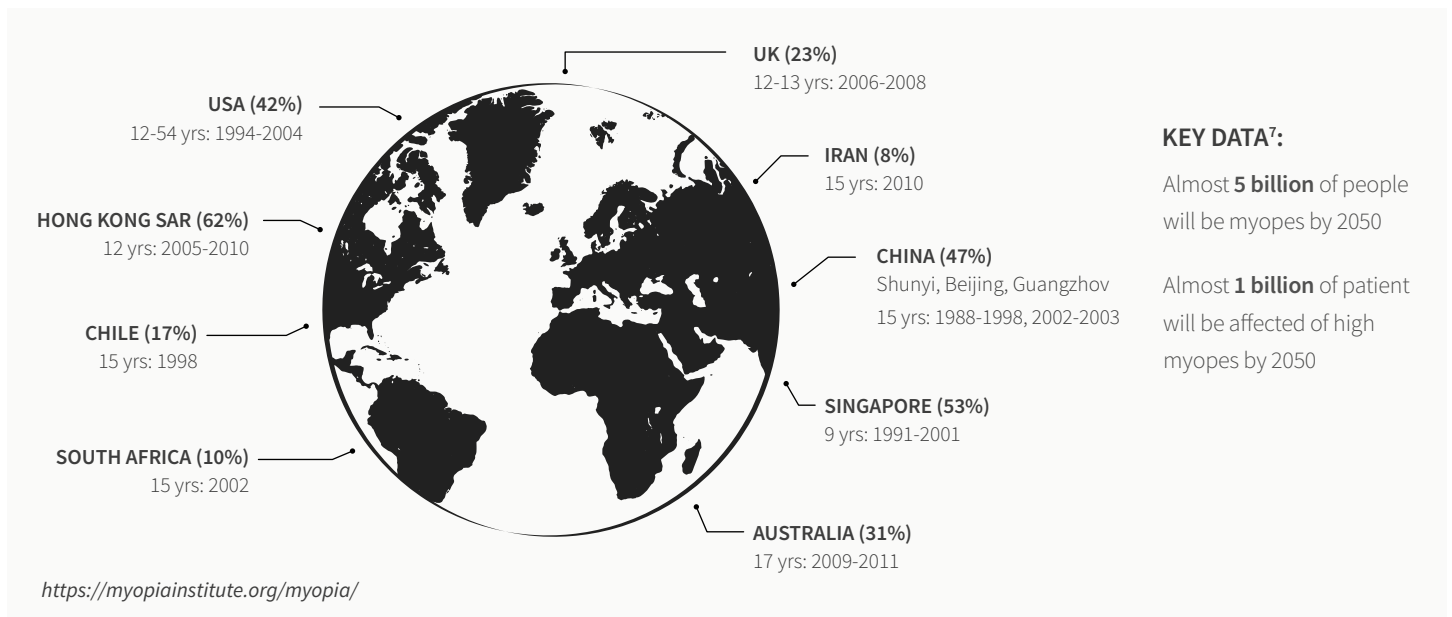
sight-threatening complication of myopia and the main cause of irreversible vision loss in the world.<sup>6</sup>

# Myopia prevalence

Myopia prevalence is growing at an alarming rate all over the world.

According to the Myopia Institute, **5 billion people will be myopic by 2050**, and 20% of them will become highly myopic. Henceforth, myopia is expected to become one of the leading causes of permanent blindness in the world.

The significant increase of global prevalence of myopia and its dramatic adverse effect has generated a great interest in practitioners to implement Imperium in their routine practice.



## KEY DATA<sup>7</sup>:

Almost **5 billion** of people will be myopes by 2050

Almost **1 billion** of patient will be affected of high myopes by 2050

## What can be done?



## Myopia treatment

Eye care professionals from across the globe are concerned about the increasing level of myopia in their practices and report that simply correcting the refractive error is not enough. In fact, many eye care professionals have implemented specific strategies for myopia management in their routine practice over the last years.

Practitioners consider that **active management of myopia is critical** to reduce the risk of irreversible visual impairment from the pathological conditions associated with high myopia. So, **reducing axial elongation is the key target for myopia management**.

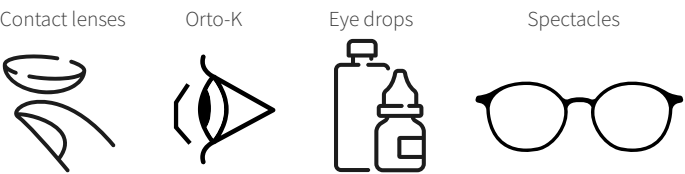


Myopia management describe the methods and strategies prescribed by eye care professionals for keeping the level of myopia as low as possible.

# Myopia management options

Currently, there are some treatments that may help to reduce myopia progression, such as spectacle lenses, contact lenses, orthokeratology, or eye drops. However, there is a special interest in **spectacle options** for myopia management because of their **ease of use, great acceptance and their lack of health-related side effects**.

Researchers and clinicians are increasingly exploring the combination of different therapies to improve the efficacy of myopia progression management strategies. Although further work is needed to understand the optimization of the treatment methods, **the combination of different therapies may be especially valuable** in children at risk of fast progression or patients who have not responded adequately to monotherapy alone.



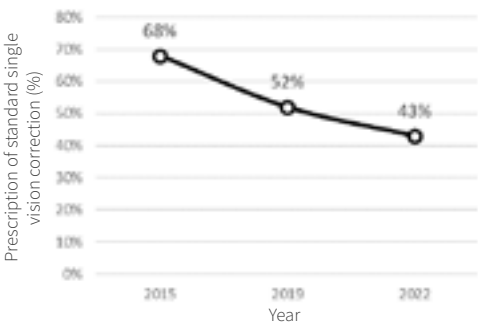
For example, as topical low-dose atropine slows myopia but does not compensate vision impairment, it could be combined with myopia management spectacles to correct and treat myopia. Another example is the combination of myopia management soft contact lenses with myopia management spectacles to avoid overuse of contact lenses and to keep the treatment effective at any time.

## Global trends in myopia management strategies

According to an interview with more than 3000 eye care professionals across the globe, the prescription of standard, single vision, spectacle or contact lenses for compensating myopia is being progressively replaced

by other treatment options specifically designed for myopia management. However, standard lenses are still the most favored prescription for young progressing myopes, with an average of 43% worldwide<sup>8</sup>.

Prescription of standard single vision correction



According to the World Council of Optometry, applying methods to reduce myopia progression should be the default vision care standard.

Prescription of special myopia management spectacles

Region	Percentage
Europe	15%
North America	13%
South America	7%
Asia	17%
Australasia	22%
Africa	11%

# Imperium



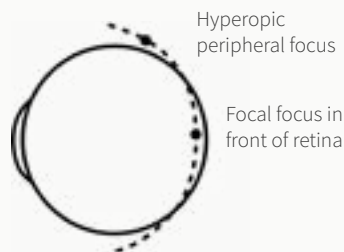
Imperium is the Imperium developed and tested by IOT that is produced with standard free-form technology. The geometry of the lens is based on theoretical backgrounds such as peripheral positive/myopic defocus and asymmetric defocus.

## Peripheral positive/myopic defocus

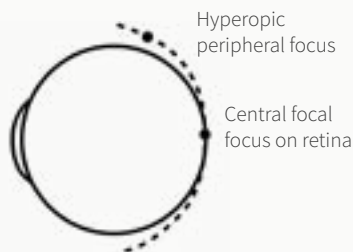
Several studies have suggested that **peripheral refractive error may play an important role in eye growth**. Specifically, it has been hypothesized that **peripheral hyperopic defocus provides a stimulus for axial elongation and the consequent progression of myopia**. Also, experiments in animals have shown that **myopic defocus induced with positive power in the peripheral retina reduce axial elongation**<sup>9</sup>.

In myopic eyes, images form in front of the retinal plane, leading to blurred vision. To correct myopia, standard negative lenses are prescribed to shift images onto the retinal plane. However, the use of standard lenses results in images falling behind the retinal plane in the peripheral retina, likely leading to eye elongation. Thus, **Imperium has been specifically designed to fully correct the refractive error at the fovea while inducing a myopic defocus on the peripheral retina**. This defocus is achieved by a carefully designed distribution of positive power at the lens periphery.

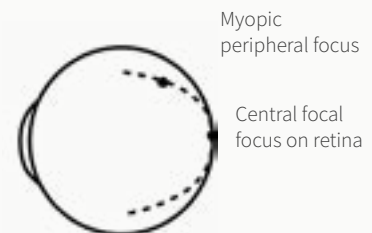
Uncorrected myope



Standard SV Lens



Imperium Lens



## Progressive asymmetric defocus

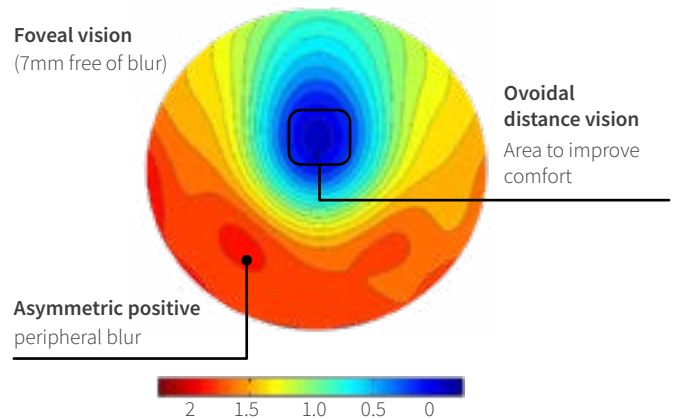
It is well known that **the retina is asymmetrical**. Specially, differences between nasal and temporal retinal hemifields have been found for anatomical neural characteristics, peripheral refraction, and axial growth<sup>10-12</sup>. In this sense, it has been suggested that **sensitivity of the retina could be different between the nasal and temporal hemifields**<sup>12</sup> being probably **the nasal half of the retina more important** regarding the mechanism driving eye growth in the presence of hyperopic defocus.<sup>12</sup>

The Imperium has been designed considering the morphological characteristics of the myopic retina. For that reason, the design presents **slightly higher positive power in the temporal area of the lens**, inducing a **higher myopic defocus in the nasal area of the retina**.



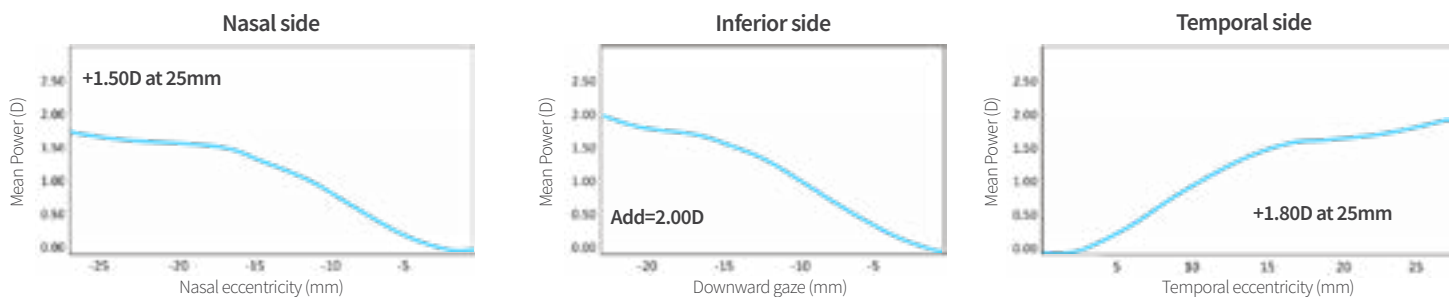
# Design characteristics

The power distribution of the lens Imperium consists of a **blur-free small area around the optical center providing clear and sharp central vision**. The area has ovoidal shape, with **horizontal size of 7mm** and with a larger vertical dimension extending to the upper part of the lens to achieve the best balance between the treatment region and the central correction area, to provide **better comfort** and maximize the user compliance with the treatment.



The central area is surrounded by a **progressive power distribution producing asymmetrical positive/myopic defocus**. Along the horizontal meridian of the lens, asymmetric additions are induced to the nasal and temporal side. The nasal area of the lens has an addition value of 1.50D at 25mm, creating a moderate defocus in the temporal retina. The temporal side of the lens reaches an addition value of

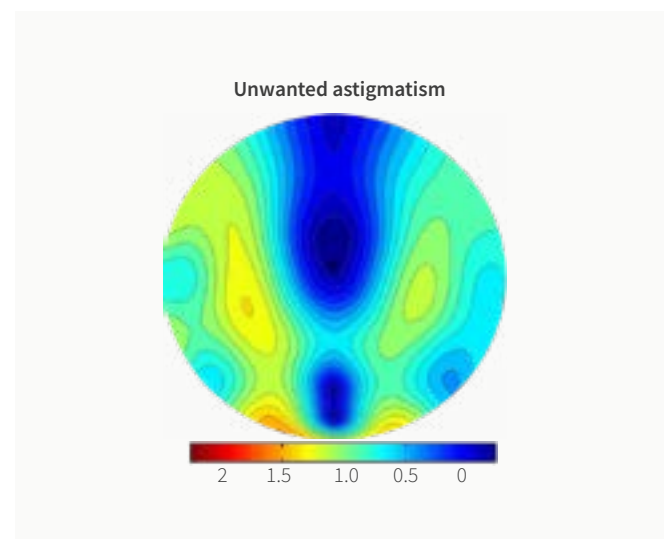
1.80D at 25mm, inducing a **slightly higher level of defocus in the nasal retina**. The lower part of the lens also presents positive power, reaching an addition value of 2.00D. This distribution increases the size of the regions producing myopic peripheral defocus for far vision, and delivers a **large usable area at the lower part of the lens for near vision tasks**.



\* The defocus of the temporal area of the lens falls on the nasal retina and the defocus of the nasal side of the lens falls on the temporal retina.

The spatial variation of spherical power just described implies that some unwanted astigmatism will be present as in any lens with progressive power variation. However, the balanced design obtained by IOT produces an **astigmatism distribution with low gradient and very small peaks**. Besides, the critical regions for far and near vision are mainly **free from astigmatism**, while the peaks are laterally located, helping to increase blur in the lateral peripheral retina.

This smooth progressive power distribution produces a lens with a **natural and aesthetic appearance**, very similar to regular single vision lenses. Also, due to the positive power increment in the peripheral area, **Imperium is thinner than the equivalent standard negative lens**, conforming a product with an unbeatable cosmetic appearance.



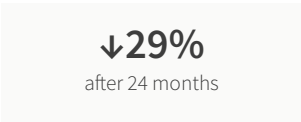
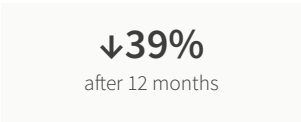
# Clinical trial

Imperium is being tested through a **prospective, controlled, randomized, double-masked clinical trial** led by the **Universidad Europea de Madrid in a European population**, (clinical trial NCT05250206) and following the recommendations of the International Myopia Institute<sup>14</sup>.

The goal of the study is to test the efficacy of the Imperium on the progression of axial length. Additionally, as compliance to the treatment is fundamental for the treatment efficacy, subjective wearability of the lenses has also been analyzed.

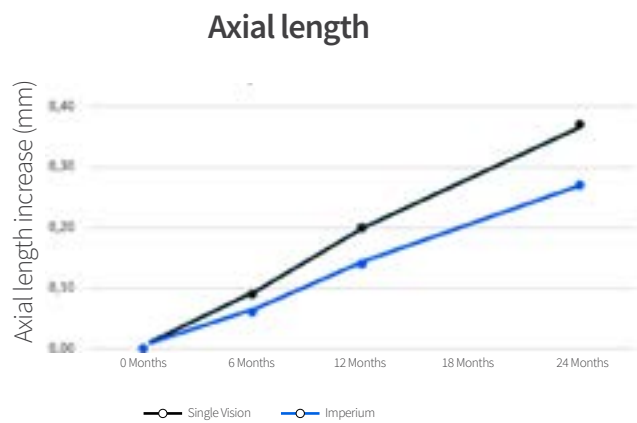
## Efficacy of Imperium

Results of the study showed that Imperium **reduces myopia progression** in comparison to the use of standard single vision lenses. To be more precise, we can conclude that with the Imperium lens, axial length growth was **39% lower after 12 months** and **29% lower after 24 months** compared to standard single-vision lenses.



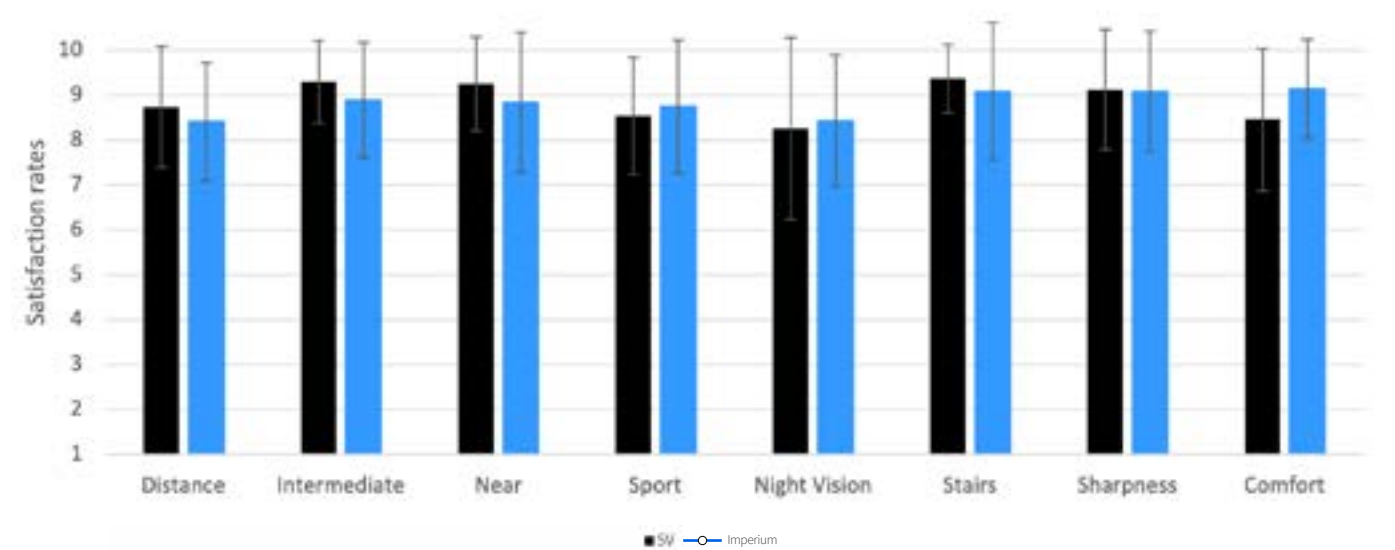
First double-masked study done with European myopic children for testing a spectacle solution for myopia management.

The study consisted of a group of myopic children who used a single-vision lens and another group of myopic children who used the **Imperium lens for a period of 24 months**.

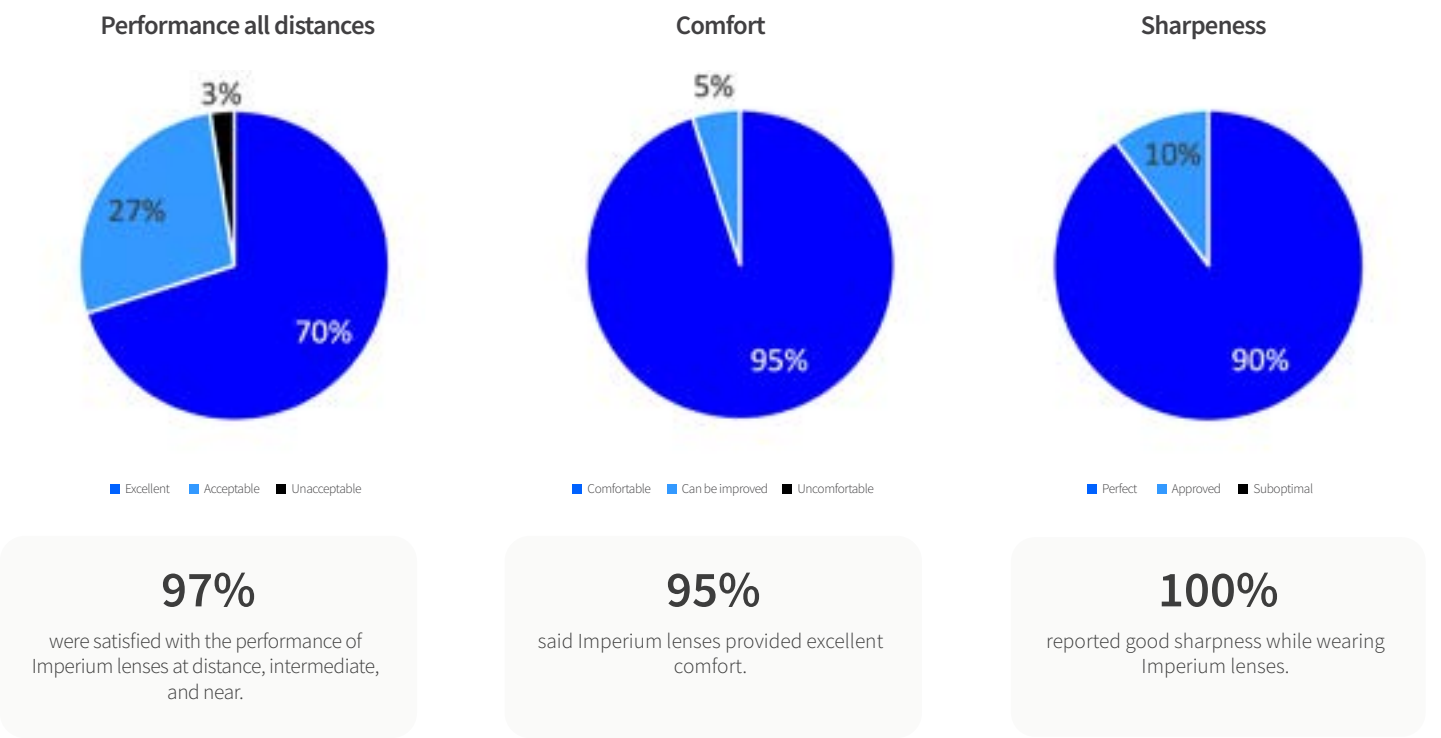


## Satisfaction with Imperium

Imperium scores similarly to a standard single vision lens. It obtains **high satisfaction rates** for all the variables analyzed, ensuring that **the lens is comfortable and its wearability good**.



The overall excellent performance of Imperium is the result of the correct balance between the sizes of the optical and treatment areas and the right choosing of asymmetrical power profiles for peripheral defocus. All this makes a **very comfortable lens that provides good performance and sharpness for distance, intermediate and near vision.**



\* Patients rates their performance in a scale from 1 to 10. Rates between 8 and 10 were considered excellent performance, acceptable were considered rates between 5 and 7 and unacceptable rates below 5.

# Technical specifications

LNAM	Imperium
Material	Available for all refractive indexes and materials. Compatible with all coatings used in the industry.
Power ranges	Same power and prism ranges than standard free-form lenses.
Manufacturing	Free-form production. Imperium lenses are laser engraved and stamped.
Label	Lenses should be labelled indicating the legal protection: "Technology licensed from Brien Holden Institute. Covered by one or more of US Patents 7025460, 7665842, 7997727, 8342684, 9423633 and corresponding foreign patents"
Mounting	Design fitting cross to be aligned with pupil position. Pupillary distances and SEGHT are necessary for proper lens mounting.

# Frequently asked questions



## How to take care of myopic children?

The standard of care for myopia management by Optometrist according to the World Council of Optometry<sup>15</sup> recommends 3 steps for a standard of care for myopia management:

Mitigation	Measurement	Management
Instructions on lifestyle, nutritional habits and modification of other factors that can prevent or delay the onset of myopia	Routine visual exams including refractive error and axial length if possible.	Correction of myopia and provide interventions that reduce myopia progression.

## How to do the refraction of myopic children?

The refraction of myopic children should be provided as the lower spherical prescription that provides the best visual acuity. Under-correction is not recommended.

## When myopia management treatment should be started?

According to an interview study done in 3195 worldwide respondents<sup>8</sup>, practitioners consider that a refractive error of -0.50D to -1.00D and a minimum age of 6 years are suitable to recommend myopia management spectacles.

## When intervention should be discontinued?

According to World Council of Optometry<sup>15</sup>, spectacle lens wear for myopia management should continue until end of childhood (18 years) and possibly into adulthood to avoid later progression.

## What is the expected effectiveness of the treatment?

The results of myopia management treatment differ from child to child and depend on factors such as age of onset of myopia or region of the world. The target of any myopia management strategy is to get an axial length growth similar to the one expected for an emmetropic eye. Axial length growth charts are interesting tools that allow to track the growth progression in children by means of percentile curves. Anyway, it is expected that the earlier the treatment is started, the higher its efficacy.



## How often and what to check during a patient follow-up appointment?

The standard of care for myopia management by Optometrist according to the World Council of Optometry<sup>15</sup> recommends a frequency of follow-up of 1 month >> 6 months >> 1 year. The follow-up actions recommended for each visit are the following:

At each follow-up	Every 6 months (if available)	Every 1 year:
<ul style="list-style-type: none"><li>• Review case history</li><li>• Issues with spectacles</li><li>• Corrected visual acuity</li><li>• Over-refraction</li></ul>	<ul style="list-style-type: none"><li>• Cycloplegic refraction</li><li>• Axial length (biometry)</li></ul>	<ul style="list-style-type: none"><li>• Eye health and fundus check</li></ul>

However, sometimes the cycloplegic refraction and biometry are not available for all clinicians. In those cases, alternative evaluations can be done for checking the progression of myopia. Mohindra retinoscopy performed in darkness or measurement of corneal curvature can provide an estimation of the growth of myopia.

## What data should be collected for ordering Imperium?

Due to the lens geometry, proper fitting is fundamental to provide good visual performance and comfort. The fitting cross must be carefully aligned with the pupil, as in any regular progressive lens. For that reason, the eye care professional should measure the monocular pupillary distances (IPD) and the pupil heights (SEGHT). Proper dispensing should include frame adjustment to the child's face before measuring pupil height.

## How to dispense Imperium?

It is recommended to explain to children and parents the characteristics of the lens, indicating that the lens provides clear vision in the central area and a somewhat blurred vision when looking through the lateral areas of the lens. Lenses should be fitted ensuring that the fitting cross is aligned with the pupil at the main viewing position. Useful advice to children and parents:

- Avoidance of active sports with the lenses specially during the adaptation period.
- The spectacles must be used permanently, only removing them during sleeping and active sports.
- Periodic check of the frame fitting, avoiding the frame sliding down the nose and checking for potential frame deformation. .
- Healthy lifestyle habits.
- Address the eye care professional for any further questions or problem.



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