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H.O.R.I. - a further step forward of myopia management lens

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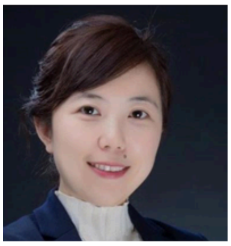

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Abstract：
Based on the insight of various micro-structured myopia management lens designs, H.O.R.I technology (Hexagon Optimized Reticular Integration), taking use of the highly packed hexagonal micro-lens to form a dense reticular pattern, is proposed in order to pursue the best potential of myopia management efficacy. With historically high filling ratio of 67%, stronger and more efficient defocus intensty is achieved with H.O.R.I. In the mean time, symmetric and consistent structure improves wearability. A 12m RCT (Random Clinical Trial) study suggests great myopia management efficacy and wearability.

Patent: WO2023/065556A1

Key words：**Myopia Management Lens, Myopia defocus, H.O.R.I, EDI, Filling Ratio**

1 Background

1.1 Introduction of Myopia

Myopia is a global public health issue. One study estimated that myopia and high myopia will grow significantly in prevalence globally, affecting around 4.76 billion people and 1 billion people, respectively, by 2050[1]. The prevalence of myopia is even higher in China. According to data released by the Health Commission of China, the overall myopia rate among Chinese adolescents is 53.6%, with rates for primary school, middle school, high school, and university students being 36.0%, 71.6%, 81.0%, and 90%, respectively[2]. If myopia progresses to high myopia, it may lead to serious eye complications such as glaucoma, cataracts, and retinal detachment[3,4,5]. Complications of high myopia have become the second leading cause of blindness in China. Therefore, it is crucial to prevent the onset of myopia and control its progression.Genetic and environmental factors are the two main causes of myopia. From a genetic perspective, if one parent is myopic, the likelihood of their child becoming myopic is 2 times higher, and if both parents are myopic, the likelihood of becoming myopic is 8 times higher[6]. Up to 2018, a total of 284 genes have been identified to be associated with myopia[7]. From an environmental perspective, increased near-work activities and reduced outdoor time are major risk factors for myopia. Children with less outdoor activity and longer periods of near-work are 2-3 times more likely to develop myopia compared to children with more outdoor activity and shorter periods of near

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1 Holden B, Fricke T, Wilson D, Jong M, Naidoo K, Sankaridurg P, Wong T, Naduvilath T, Resnikoff S: **Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050**. Ophthalmology 2016, **123**(5):1036-1042.

2 中国眼健康白皮书; 2020.

3 Xu L, Wang Y, Wang S, Wang Y, Jonas J: **High myopia and glaucoma susceptibility the Beijing Eye Study**. Ophthalmology 2007, **114**(2):216-220.

4 Praveen M, Shah G, Vasavada A, Mehta P, Gilbert C, Bhagat G: **A study to explore the risk factors for the early onset of cataract in India.** Eye (London, England) 2010, **24**(4):686-694.

5 Bier C, Kampik A, Gandorfer A, Ehrt O, Rudolph G: [**Retinal detachment in pediatrics : Etiology and risk factors**]. Ophthalmologe 2010, **107**(2):165-174.

6 Mutti DO, Mitchell GL, Moeschberger ML, Jones LA, Zadnik K: **Parental myopia, near work, school achievement, and children's refractive error**. *Invest Ophthalmol Vis Sci* 2002, **43**(12):3633-3640.

7 Tedja M, Wojciechowski R, Hysi P, Eriksson N, Furlotte N, Verhoeven V, Iglesias A, Meester-Smoor M, Tompson S, Fan Q *et al*: **Genome-wide association meta-analysis highlights light-induced signaling as a driver for refractive error**. *Nature genetics* 2018, **50**(6):834-848.

work[8]. Therefore, it is recommended that children spend at least 2 hours outdoors each day and follow the 20-20-20 rule [9] for near reading to effectively prevent myopia.
Research on the mechanisms of myopia has a history of over 100 years, yet there is still no single theory that can fully explain the onset and development of myopia. Mechanisms proposed for myopia development include transient myopia leading to permanent myopia, accommodative lag-induced myopia[10], peripheral hyperopia defocus-induced myopia[11,12,13], dopamine imbalance[14,15], and scleral hypoxia-induced myopia theory[16], among others. Currently, the non-pharmacological methods for myopia control primarily rely on theories related to controlling peripheral hyperopia defocus, such as orthokeratology lenses, defocus-incorporated spectacle lenses, and defocus soft contact lenses.
Besides, there are also some new findings to indicate that by modulating the image quality (blur level) on retina, Myopia Management efficacy can also be achieved.[17,18] These control methods have shown some clinical efficacy[19].

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[8] Rose K, Morgan I, Ip J, Kifley A, Huynh S, Smith W, Mitchell P: **Outdoor activity reduces the prevalence of myopia in children**. *Ophthalmology* 2008, **115**(8):1279-1285.

[9] 吕帆，瞿佳: 学习网课时如何科学用眼: 人民卫生出版社; 2020.

[10] Gwiazda J, Thorn F, Bauer J, Held R: **Myopic children show insufficient accommodative response to blur**. *Invest Ophth Vis Sci* 1993, **34**(3):690-694.

[11] Smith E, Kee C, Ramamirtham R, Qiao-Grider Y, Hung L: **Peripheral vision can influence eye growth and refractive development in infant monkeys**. *Invest Ophth Vis Sci* 2005, **46**(11):3965-3972.

[12] Schaeffel F, Glasser A, Howland H: **Accommodation, refractive error and eye growth in chickens**. *Vision research* 1988, **28**(5):639-657.

[13] Troilo D, Smith E, Nickla D, Ashby R, Tkatchenko A, Ostrin L, Gawne T, Pardue M, Summers J, Kee C *et al*: **IMI - Report on Experimental Models of Emmetropization and Myopia**. *Invest Ophth Vis Sci* 2019, **60**(3):M31-M88.

[14] Stone R, Lin T, Laties A, Iuvone P: **Retinal dopamine and form-deprivation myopia.** Proceedings of the National Academy of Sciences of the United States of America 1989, **86**(2):704-706.

[15] Papastergiou G, Schmid G, Laties A, Pendrak K, Lin T, Stone R: **Induction of axial eye elongation and myopic refractive shift in one-year-old chickens**. *Vision research* 1998, **38**(12):1883-1888.

[16] Wu H, Chen W, Zhao F, Zhou Q, Reinach PS, Deng L, Ma L, Luo S, Srinivasalu N, Pan M *et al*: **Scleral hypoxia is a target for myopia control**. *Proc Natl Acad Sci U S A* 2018, **115**(30):E7091-e7100.

[17] PETROS PAPADOGIANNIS, **Comparison of optical myopia control interventions: effect on peripheral image quality and vision**, Vol. 14, No. 7 / 1 Jul 2023 / Biomedical Optics Express **3125**

[18] Javier Gantes-Nuñez, Optical characterisation of two novel myopia control spectacle lenses, Ophthalmic Physiol Opt. 2023;00:1–14.

[19] Huang J, Wen D, Wang Q, McAlinden C, Flitcroft I, Chen H, Saw S, Chen H, Bao F, Zhao Y *et al*: **Efficacy Comparison of 16 Interventions for Myopia Control in Children: A Network Meta-analysis**. *Ophthalmology* 2016, **123**(4):697-708.

1.2 Myopia defocus spectacles product roadmap

In recent years, as research advance , there have been continuous innovations in the field of spectcle lenses used for myopia control. Based on the accommodative lag theory, new types of lenses such as bifocal lenses, dual-focus prismatic lenses, and progressive multifocal lenses have emerged. Based on the peripheral defocus theory, lenses like Myovision by Zeiss, which represent peripheral defocus lenses, were developed. Furthermore, lenses following the competitive defocus theory, represented by DIMS (Defocus Incorporated Multiple Segment Lens) from HOYA, opened up a wide market for myopia control lenses. Subsequently, the Essilor's Stellest (HALT,Highly Aspherical Lenslets Technology) launched, offering a different approach to defocus control with aspherical lenslet, performing well in the market as well.

The First-Generation Products Based on Peripheral Defocus Theory

Myopia control lenses based on the peripheral defocus theory have their center at normal distance power, gradually transitioning to positive power from the center to the periphery. This design aims to create a state of peripheral myopic defocus on the retina.

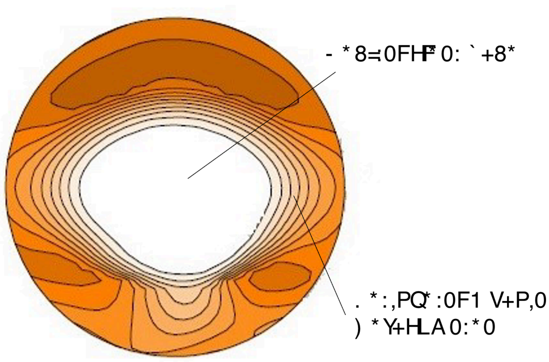

Figure 1 Schematic Diagram of Peripheral Defocus Lens design

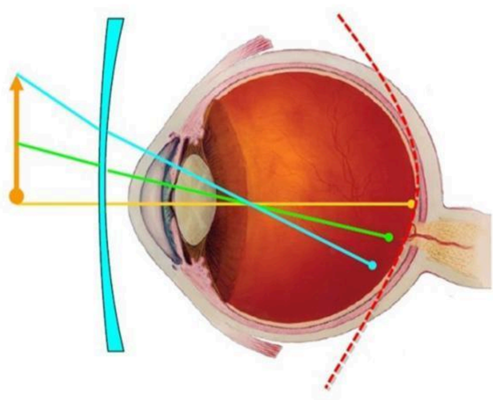

Figure 2 Imaging Schematic Diagram of Peripheral Defocus Lens

Based on a clinical study conducted on 210 Chinese children aged 6 to 16 by the Zhongshan Ophthalmic Center, lenses like Myovision, which are based on the peripheral defocus theory, showed approximately 30% efficacy for Myopia control over traditional single-vision lenses after 12 months. [20]

The Second-Generation Products Based on Competitive Defocus Theory

In 2007, Tse D.Y and others published an article titled "Simultaneous defocus integration during refractive development" in IOVS, where they tested different annular defocus lenses on chicks.

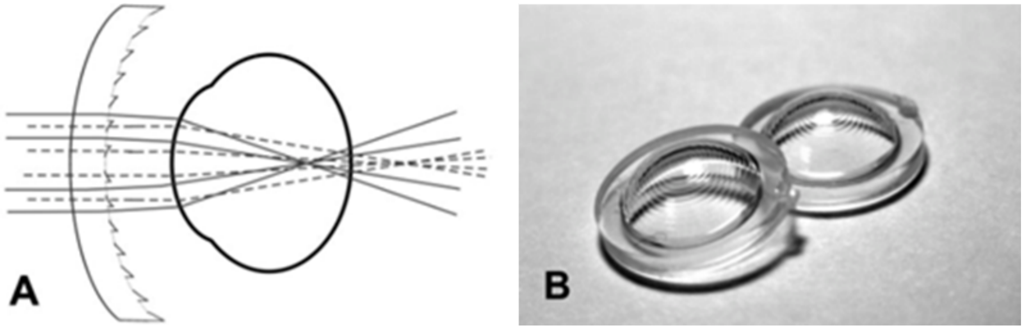

Figure 3 Schematic Diagram of Annular Defocus Lens

The experiments showed that competitive bi-directional defocus, with a stronger effect on myopic defocus, had the potential to reduce myopia development (inhibit axial elongation). [21]

Based on the competitive defocus theory, HOYA launched DIMS in 2018, and in 2020,Essilor launched Stellest.

1) DIMS(Defocus Incorporated Multiple Segment Lens)

In DIMS lenses, designers used a unique multi-zone positive optical defocus by placing 396 independent circular micro-lenses with a diameter of 1mm and power of +3.5D in a hexagonal pattern around the central 33mm area of the lens. This arrangement created competitive defocus in front of the retina, providing a constant amount of defocus (+3.5D) and defocus area (50% of the lens area) for any direction of gaze. Clinical studies over 2 years with DIMS lenses showed an equivalent sphere control effect of 59% and axial length control effect of 60% in slowing myopia progression.[22]

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20 **Spectacle Lenses Designed to Reduce Progression of Myopia: 12-Month Results**,Optom Vis Sci. 2010 September ; **87**(9): 631–641.

21 Tse, Y. Y., Lam, S. Y., Guggenheim, J. A., Lam, C., Li, K. K., Liu, Q., & To, C. H. (2007). **Simultaneous defocus integration during refractive development.** Investigative Ophthalmology and Visual Science, **48**(12), 5352-5359. https://doi.org/10.1167/iovs.07-0383

22 Lam CSY, Tang WC, Lee RPK, Chun RKM, To CH. **A randomized clinical trial for myopia control-use of myopic defocus spectacle lens.** 8th International Congress of Behavioral Optometry (ICBO), 26-29 of April 2018. Sydney, Australia.

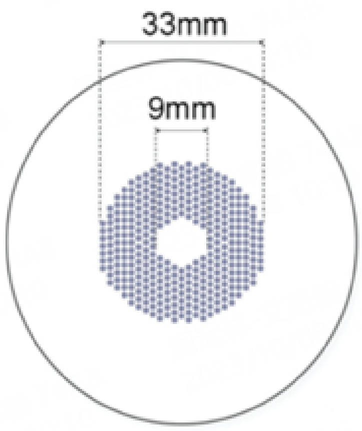

Figure 4 Schematic Diagram of DIMS

2) Stellest (HALT,Highly Aspherical Lenslets Technology)

In HALT lenses,1021 circular micro-lenses are arranged in concentric circles starting from the central 9mm and extending outward, forming 11 concentric rings with adjacent micro-lenses. The defocus power of these micro-lenses gradually increases from the center to the periphery (3.5-5D), aiming to enhance the blurring effect in the defocus signal zone and improve myopia control. Clinical studies over 2 years with HALT lenses showed an equivalent sphere control effect of 55% and axial length control effect of 51% in slowing myopia progression. [23]

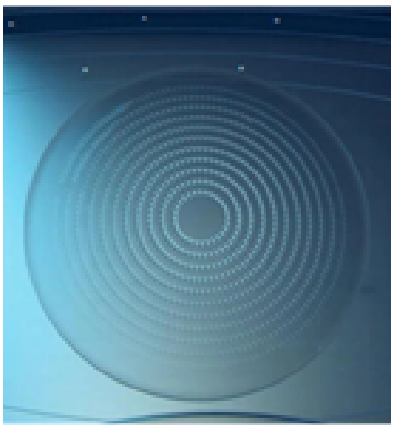

Figure 5 Schematic Diagram of HALT lenses

In the context of strong myopia prevalence, better products are always welcomed. It's widely accepcted that still there are great opportunity .

First of all, we need to find the right strategy to explore the best potential of myopia management efficacy.

[23] Huang Yingying, Li Xue, Wu Junqian, Huo Jiawen, Zhou Fengchao, Zhang Jiali, Yang Adeline, Spiegel Daniel P., Chen Hao, Bao Jinhua. (2022). **Effect of spectacle lenses with aspherical lenslets on choroidal thickness in myopic children: a 2-year randomized clinical trial.** Br J Ophthalmol. doi:10.1136/bjo-2022-321815

2 H.O.R.I Innovation, theory and realization

How to achieve better myopia control while ensuring good comfort, these are two key factors needs to be considered in the design of micro-lens defocus spectacles. There are dozens of micro-lens spectacles on the market, most of which claim to be very comfortable but vary in terms of their myopia management efficacy. Based on this insight, the new-generation Hexagon Optimized Reticular Integration (H.O.R.I) technology aims to explore the maximum potential of such technology and has made significant upgrade to existing products.

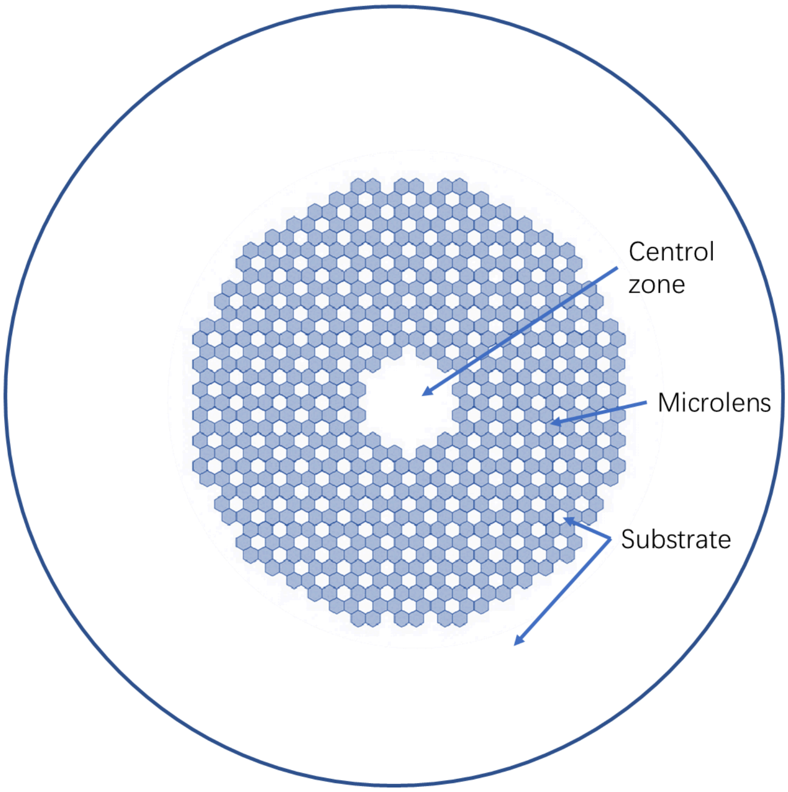

Figure 6 HORI design illustration with different area

HORI design is typically a SV lens with extra microstructure on the front side, formed by 540 hexgonal sub-element. Compared to traditional DIMS micro-lens design and CARE like ring structure design, H.O.R.I technology offers several advantages in its design by upgrading into a reticular pattern:

➢ It opens up a new dimension, transforming lenses from circular to hexagonal and connecting them into a cohesive network.
➢ Simplicity. Each micro-lens has same 3D Addition, maintaining a consistent arrangement cycle to improve dynamic field stability.
➢ The functional area filling ratio reaches historically 67%, meaning that the micro-lens area is twice that of the base area, providing stronger defocus stimulation.

➢ The central zone size has been compressed comparing to the traditional 9-10mm central zone, reaching a minimum of 7.2mm diameter, allowing more defocus stimulation to enter the sensitive area of the retina.

In summary, the design of HORI integrated reticular defocus lenses opens up new dimensions and explores new frontiers, effectively enhancing defocus stimulation , airming to achieve better myopia management efficacy.

2.1 Evaluate defocus intensity objectively

Before study, a quantitative evaluation method should be established to objectively assess the stimulation intensity of the myopia defocus lens.

The current marketing mainly emphasizes on the factors like microstructure quantity, microstructure power and defocus area, which couldn't comprehensively assess the stimulation effects, while the professional evaluation methods based on MTF (Modulation Transfer Function) and wavefront analysis require modeling or instruments and cannot intuitively assess the stimulating effects produced by different microstructure lenses. To provide a more intuitive and comprehensive assessment of the performance of defocus lenses, the **Equivalent Defocus Index (EDI)** is proposed as a simple and fast way to quantify the stimulation intensity .

There are many influence factors of defocus lenses to consider. The lens areas can be divided into the central clear zone, micro-structure zone, and edge zone (see diagram) by function. The central clear zone is used for clear imaging in the central field. The micro-structure zone creates defocus stimulation for different field for view. The edge zone is on the periphery of the lens without micro-structures and generally is not quite relevent.

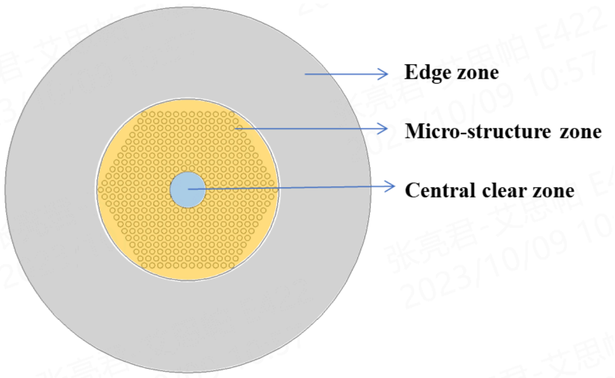

Figure 7 Typical micro-structure lens design with different regions

The micro-structure zone contains hundreds to thousands of micro-lens that provide additional power besides the base lens. The additional power and filling ratio are two essential influence factors on the lens optical performance.

Calculation of EDI

Based on the understanding about myopia defocus [24,25,26], the calculation of the evaluation parameter EDI is proposed to include the additional power, filling ratio, and weight.

$$EDI = \sum_{k=1}^{n} ADD_k \times FR_k \times Weight_k$$

(Formula 1)

Where 'n' represents the number of divided regions on the lens, corresponding to different visual angles on the retina.

The additional power and filling ratio are the primary factors affecting the optical performance of micro-structure lens. The weight parameter shows the different effects related with defocus stimulation positions. Based on some finding from OthorK [27], the closer to the center, the stronger the stimulation effects. For not a rigorous purpose , we take the density distribution of photoreceptor cells on the retina(Figure 8) as the position weighting factor.[28]

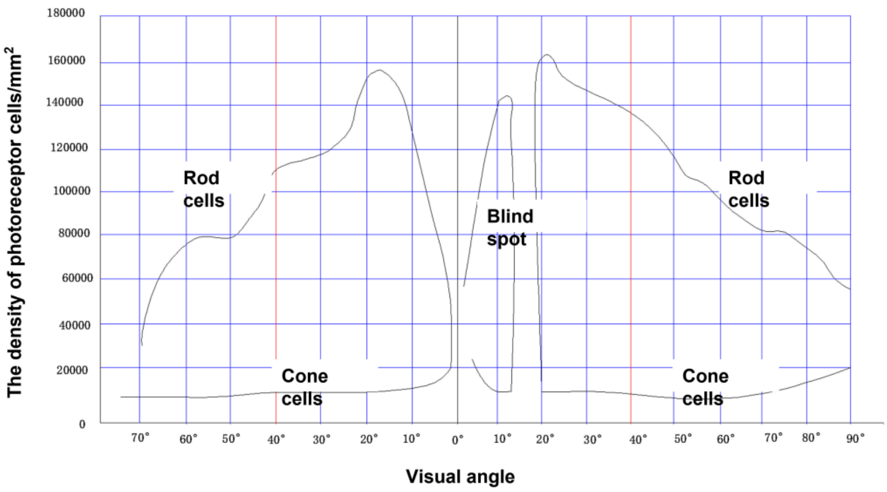

Figure 8 Distribution of photoreceptor cells on the retina

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24 Smith EL. Optical treatment strategies to slow myopia progression: effects of the visual extent of the optical treatment zone. Exp Eye Res 2013;114:77-88.

25 Hu Y, Wen C, Li Z, Zhao W, Ding X, Yang X. **Areal summed corneal power shift is an important determinant for axial length elongation in myopic children treated with overnight orthokeratology**. Br J Ophthalmol. 2019;103(11):1571-5.

26 Yuzhuo Fan, Yan Li, Kai Wang, Jia Qu, Mingwei Zhao. **Weighted Zernike defocus coefficient of treatment zone is a meaningful indicator for myopia control efficacy of Ortho-K lenses**. Eye Vis (Lond). 2022 Jul 1;9(1):24.

27 Guo B, Cheung SW, Kojima R, & Cho P. **One-year results of the Variation of Orthokeratology Lens Treatment Zone (VOLTZ)Study: a prospective randomised clinical trial**.Ophthalmic Physiol Opt. 2021. https://doi.org/10.1111/opo.12834

28 Nigel W.Daw. Visual development[M],third Edition. Beijing: Peking University Medical Press,2022:7

It’s interesting that especially within the range of 10° to 20°, cell density is the highest, well alignd with some clinical findings[29]. By establishing a correspondence between the radius of the micro-structure zone and the visual angle, the density of photoreceptor cells in different lens radii is obtained. When determining the correspondence between the radius and visual angle, the model is shown in Figure 9: the micro-structure lens locates 12mm from the corneal vertex. A simplified eye model is used with an eye axial length of 24mm and a nodal distance of 8mm from the corneal vertex.
As a result, when the micro-structure lens zone ranges from 4mm to 15mm (semidiameter), the corresponding visual angle is approximately from 11° to 37°.

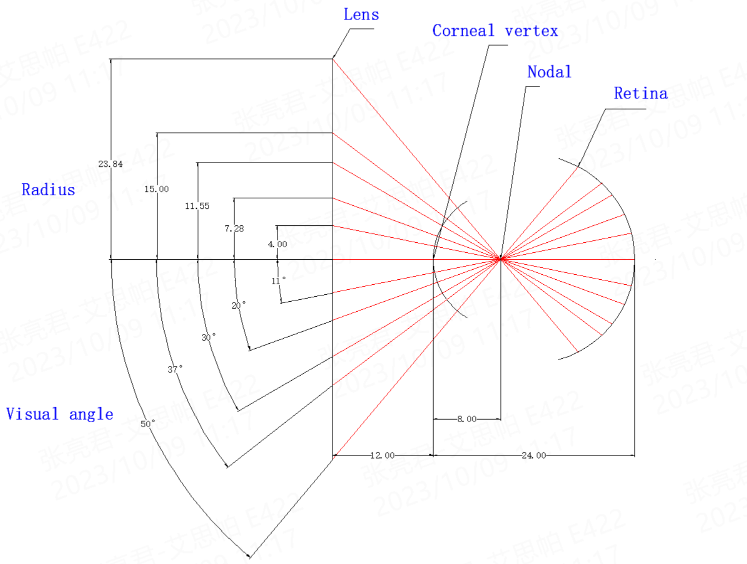


Figure 9 Geometrical diagram of lens-eye system

Within the micro-structure lens zone, different areas of concentric rings are obtained at intervals of 0.5mm. Therefore, in (formula 1), 'n' equals 30, then the density of photoreceptor cells for this radius is defined as the weight. The sum of all values within the 15mm range is the Equivalent Defocus Index (EDI) for this type of micro-structure lens, which can be considered as the stimulation intensity.

[29] Earl L. Smith I. The Charles F. Prentice Award Lecture 2010: **A Case for Peripheral Optical Treatment Strategies for Myopia**[J]. Optom Vis Sci. 2011 September ; **88**(9): 1029–1044.reference

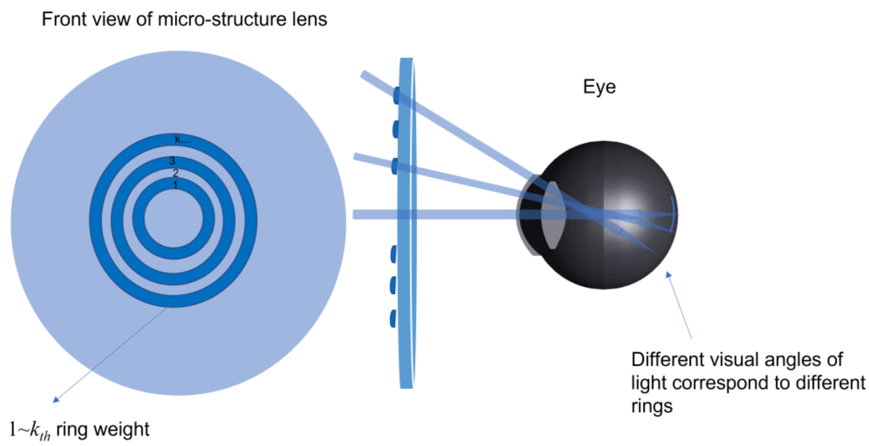


Figure 10 Methodology of how the lens are divided for EDI calculation

2.2 Fair Grid：Filling Ratio as another Efficient Means to Increase Defocus Stimulus

Highest filling ratio ever: 67%

Coming back to the lens design, let's take a look of the another factor besides Addition. Filling ratio, in simple terms, refers to the proportion of micro-lens area within a certain region to the total area. For example, a filling ratio of 50% means an equal division of micro-lens and substrate area.

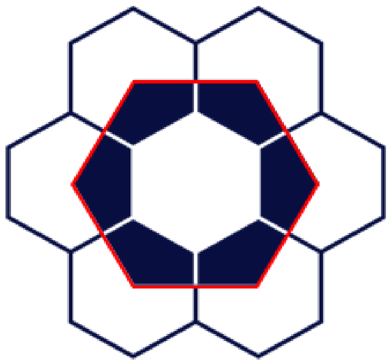
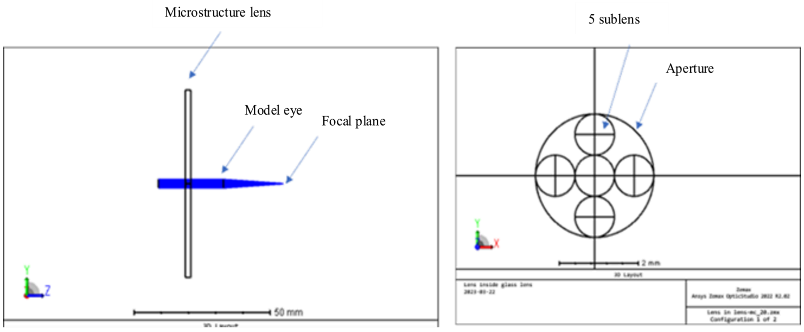


Figure 11 Basic defocus periodic unit (within red shape) of HORI design

In the densely packed grid structure like HORI, the filling ratio in functional area is historically high (67%). In Figure 11, the portion highlighted by the red dashed frame in the illustration (including the blank areas within) represents the "Basic defocus periodic unit" of this structure. This means that this structure can be closely arranged to create the entire pattern across the whole surface (excluding the central blank area). Within this unit, you can clearly see that it is composed of 1 complete blank (white hexagon) and six 1/3 hexagons (dark blue). So, the lens area in this calculation is 6 * 1/3 = 2 hexagonal lenses, plus the central blank, results in a filling ratio of 2/3, which is 67%. To the best of our knowledge, this may be one of the designs with the highest filling ratio in the market.

Why Filling ratio matters more- from simulation

We chose to use MTF (Modulation Transfer Function) as a representation of retinal imaging quality, which to some extent reflects the intensity of defocus stimulus.



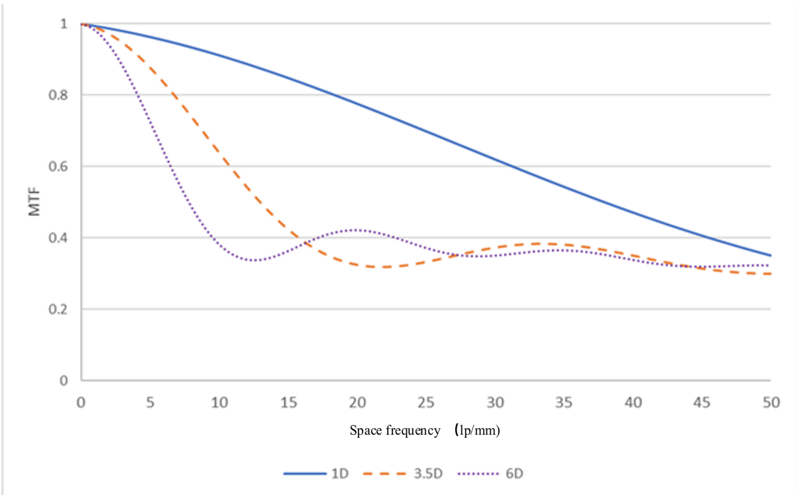
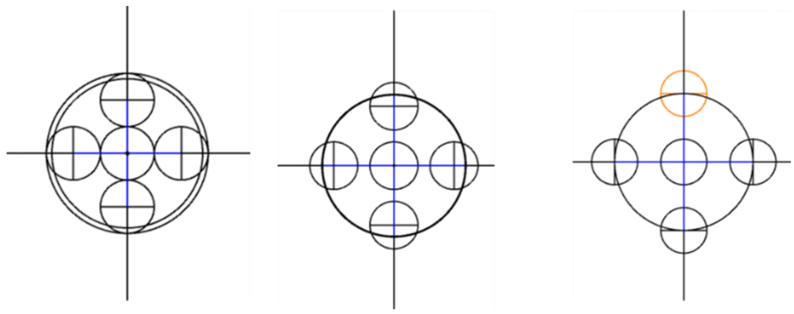


Figure 12 MTF simulation results in terms of different addition (same filling ratio)

Through simulations (with a typical pattern), we found that saturation occurs as defocus increases to a certain extent (like 3.5D), meaning that further increases have little impact on image quality. This finding aligns with some clinical observations in the literature[30].

[30] Mutti DO, Sinnott LT, Mitchell GL, et al. **Relative peripheral refractive error and the risk of onset and progression of myopia in children.** Invest Ophthalmol Vis Sci 2011;**52**: 199–205



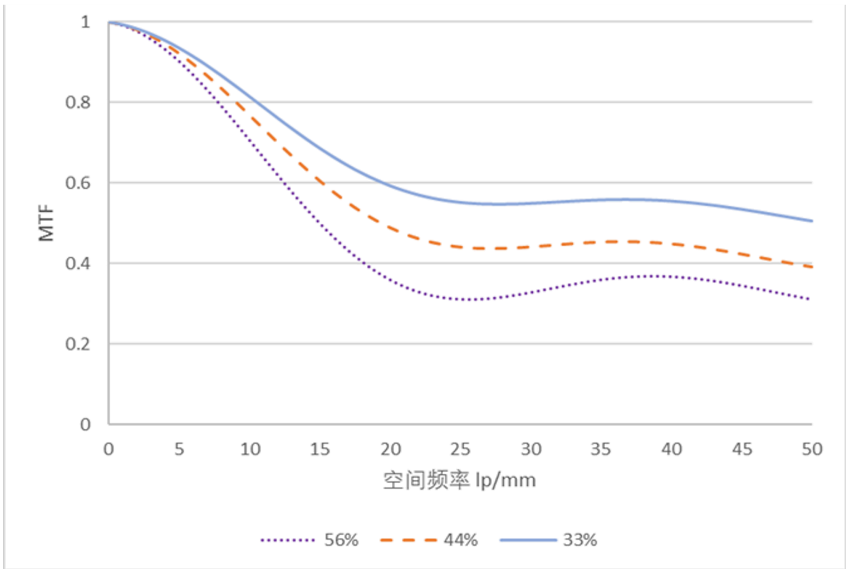


Figure 13 MTF simulation in terms of different filling ratio (same addition)

Things are a little bit different considering the impact of filling ratio on defocus stimulus. From 33% to 44% and then to 56% (making the micro-lenses denser), there are noticeable changes in both high-frequency and low-frequency MTF. In other words, within a certain range, changes in filling ratio can significantly modulate the defocus stimulus on the retina.

To explain this in the context of competitive myopia defocus theory, meaning the two images on and in front of the retina (myopia image) providing stimulus simutaneously. An increase in defocus power results in the myopic image in front of the retina moving further forward (for example, 3D corresponds to approximately 1mm offset). However, further increase on top of this might no longer have significant "pulling" effect on the eye's axial length. On the other hand, an increase in filling ratio adjusts the proportion of myopic and on-focal images at their original positions, distributing greater intensity to the myopic image in front. This is expected to produce a more pronounced defocus stimulus.

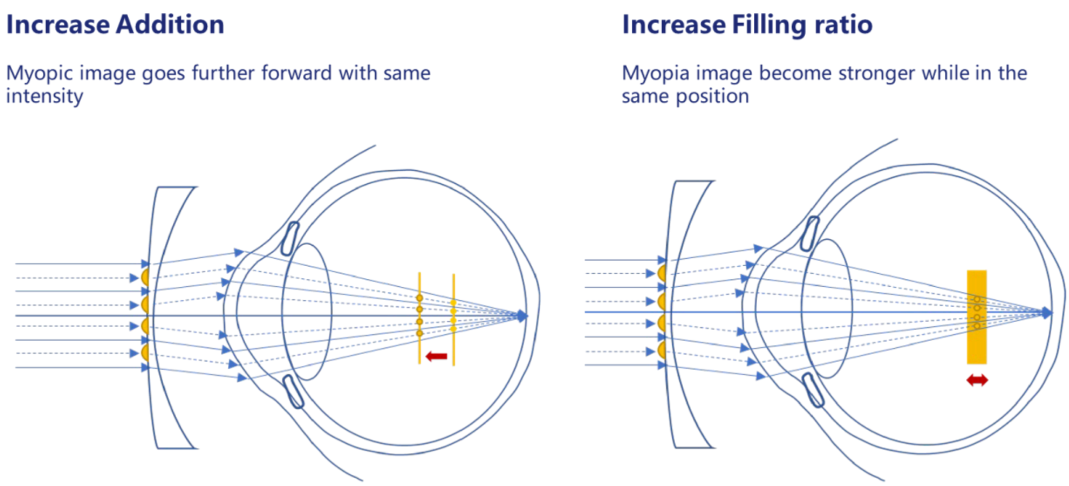


Figure 14 Illustration of how Addition and Filling ratio impact defocus stimulus in the competitive defocus way

More filling ratio with densely packed lens, this represents a significant advantage of HORI's technology. We call it “Fair Grid”.

Table 1 The EDI of three types of defocus lens

	Add	Filling Ratio	Weight	EDI
A-Ring like structure	3.5D	34%	19.8	24
B-Honeycomb like structure	3.5D	50%	19.8	35
C- HORI	3D	67%	20.5	41

A&B are three typical types of defocus lens in the market . According to the Formula 1, the EDI of each defocus lens has been calculated(Table 1). HORI lens shows the highest EDI , which means the strongest stimulation intensity.

2.3 Full Symmetry: Advantages of Periodic Structure

The HORI technology's design employs a hexagonal structure with excellent spatial symmetry. An important advantage of this structure is that, regardless of how the field of view moves, the number of sublens entering the pupil remains relatively stable, reducing the potential for a "swimming effect" that may occur during wear. This is believed to help adaptation well, especially in spectacles senario.
We call it “Full symmetry”.

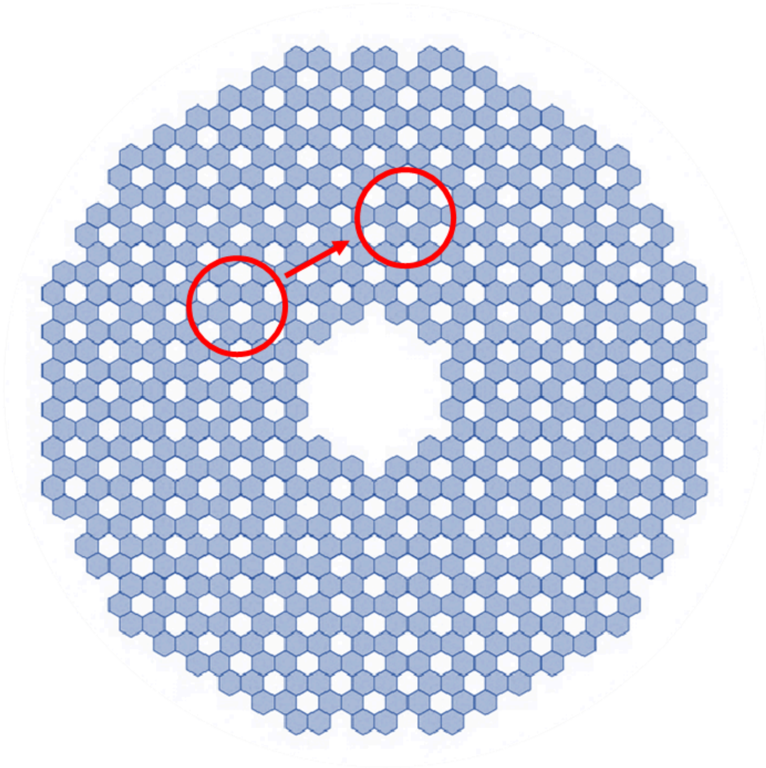


Figure 15 Micro-lens packed with perfect symmetry in HORI design, resulting in stable visual performance no matter where field of view moves

2.4 Fractal boundary: Considerations for Central Zone Design

In the design of the central zone, HORI technology has made two attempts. First, it compressed the size of the central zone from the typical 9mm to a minimum of 7.2mm diameter. From simple geometric relationships, it can be inferred that such compression can bring more defocus stimulus closer to the sensitive area near the fovea, often referred to as the 10-20 degree range. (Figure 16) [31]

[31] Earl L. Smith et al. **Eccentricity-dependent effects of simultaneous competing defocus on emmetropization in infant rhesus monkeys**, Vision Research 177 (2020) 32–40

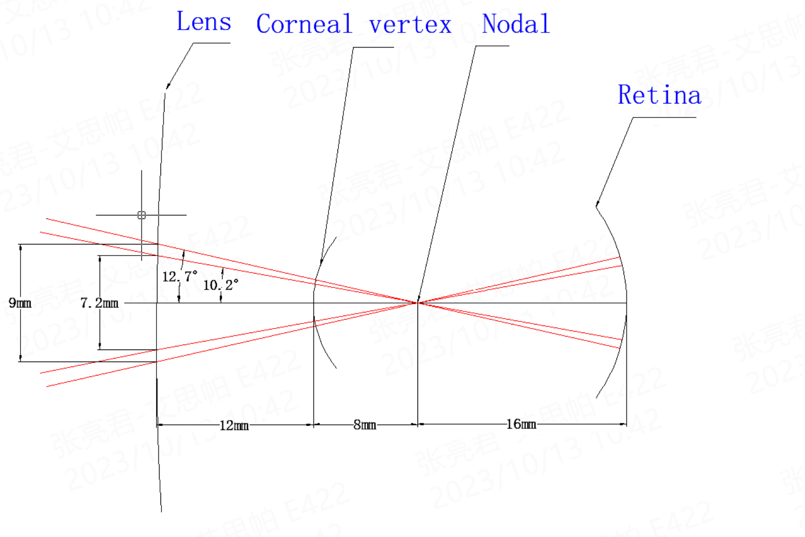


Figure 16 Geometrical diagram of central area size and angle, 7.2mm right corresponds to 10°

In addition, based on some findings of human retina cells [32], the human eye is more sensitive to boundary stimuli and the selectivity for certain orientations of boundary stimuli. HORI also attempts the so-called "Fractal Boundary" technology, which involves different orientations of boundary stimuli, aiming to achieve a better defocus stimulus effect.

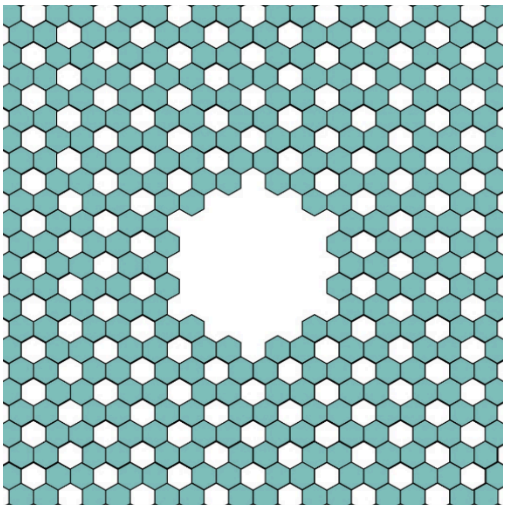


Figure 17 Central clear zone design smaller size and “rough” boundary

[32] **"Neural Mechanisms of Vision"** edited by Yang Xiongli, Shanghai Scientific and Technical Publishers, pages 228, 229, 230, 232

3 Engineernig Realization of Hexagonal Micro-lens array

3.1 Manufacturing process

The typical manufacturing process of micro-structured lens is a little bit different from traditional lens production. Taking Poly Rx as an example, by super-precision machining on nickel-coated molds, the desired structures are created. Followed by a replication process, the front surface of the lens are realized using injection molding technology. Afterward, the semi-finished lens are sent to the Rx lab for further processing. The subsequent processes are essentially the same as regular single-vision lens, Surfacing ->Hard coating->AR coating. Then the wearable product with right prescription can be realized and ready for fitting into frames.

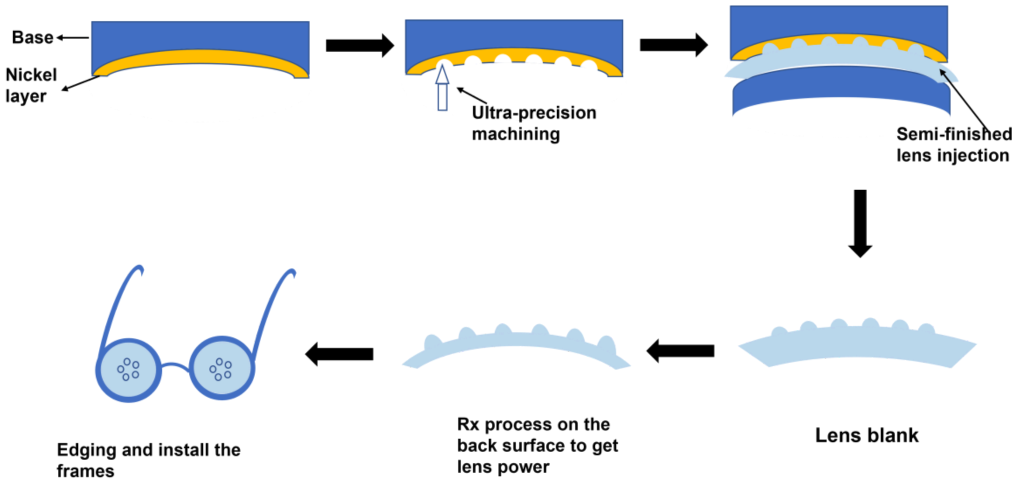


Figure 18 Typical process to realize a micro-structure Rx lens

3.2 Quality assurance

To ensure the reliability of the molding quality, we have conducted corresponding inspections of the processing and molding conditions. Considering the structure is typically 1mm for lateral size and 1um for sag, two instruments are generally used for metrology.

Zygo 3D Optical Profiler NEXVIEW NX2:

Measurement Principle: A white light interferometer is an optical instrument that uses the principle of interference to measure the difference in optical path length and determine optical properties. Any change in the optical path length between two coherent beams of light will cause sensitive shifts in interference fringes. The change in the optical path length of one coherent beam is caused by variations in the geometric path or refractive index of the medium it passes through. Therefore, the movement of interference fringes can be used to measure tiny changes in geometric length or refractive index, and subsequently, other related physical quantities. The measurement accuracy depends on the precision of measuring the optical path length difference. For every fringe shift, the optical path difference changes by one wavelength, so interferometers measure optical path differences in terms of wavelengths, providing an extremely high level of precision.

Type	NEXVIEW NX2
Measurement accuracy	Surface Topography Repeatability: 0.041nm Repeatability of the RMS: 0.0010nm Step Height Repeatability: 0.04%
Measurement range	17.49mm*17.49mm

Figure 19 Device we used for structure evaluation

Lambda-X Ophthalmics : Nimo evo Micro-Lens Measurement Instrument

Measurement Principle: NIMO evo® is based on the proprietary Phase Shifting Schlieren (PSS) technology[33], which combines the schlieren principle with the phase-shifting technique that is generally used in interferometry. With an appropriate schlieren filter and appropriately tailoredsetup, some schlieren fringes are generated. After application of the phase-shift technique, the schlieren phase is calculated and converted into beam deviation values. In some cases, it can compete with interferometric methods but with better dynamic range and adjustable sensitivity. [34]

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[33] https://ophthalmics.lambda-x.com/nimoevo/

[34] Joannes L., Dubois F., Legros J.C., **Phase-shifting schlieren : high-resolution quantitative schlieren that uses the phase-shifting technique principle.** Appl Opt 2003;**42**:5046-53.

Measurement field	0.5mmx0.5mm~18mmx18mm
Measurement range	+/-30D
Repeatability of power	Better than 0.007D

Figure 20 Mechanism of Nimo instrument

3.3 Analysis of the measurement results

Surface profile

The Zygo measurement report includes surface wavefront maps, surface profiles, and numerical data. To measure the sag of micro lens, a line is drawn across the wavefront map. The X-axis represents the coordinates of this line and the Y-axis represents the sag. By reading the Y distance of the highest point, the sag of the micro lens can be obtained. Comparing with the design value, we can get good feeling about manufacture deviation.

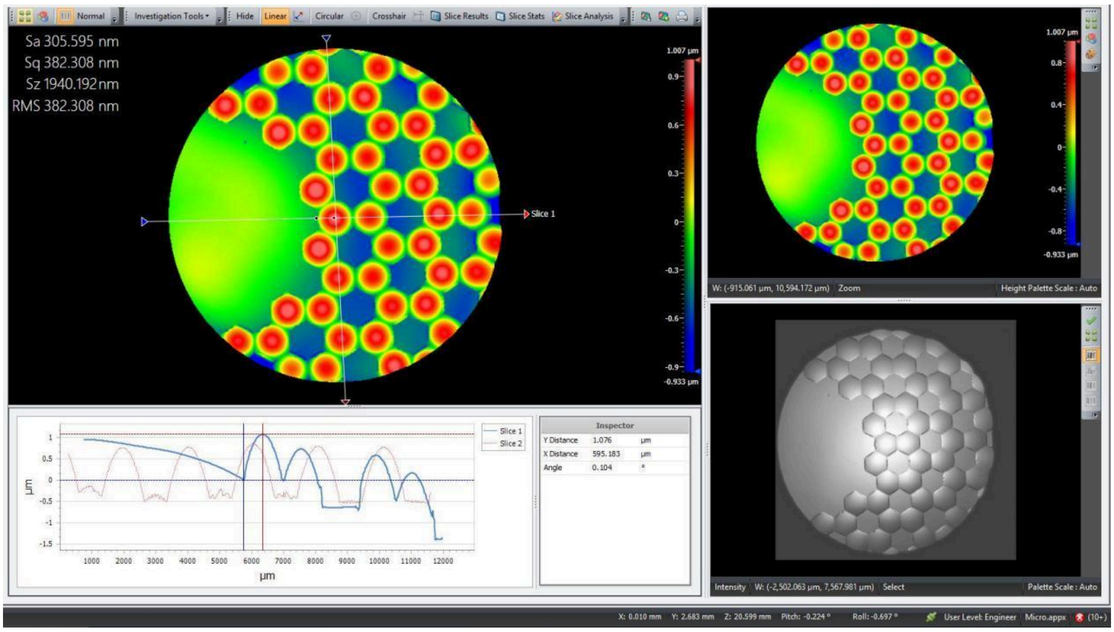

Figure 21 A typical Measurement data of HORI lens, indicating the hexgan sub-element are well realized

As shown in the Figure 21, the HORI lens demonstrates good implementation of periodicity, with lateral size approximately 1.2 mm and sag around 1 µm. Besides, beautiful hexgonal shape can be seen unther the microscopy, which reflects perfect ultra-precision maching process.

Power mapping

The Nimo micro-lens measurement instrument is a powerful instrument designed for measuring the surface profile of optical lenses. The measurement results include images, power maps, SPH (sphere), CYL (cylinder), AXIS values, power histograms and etc.

The parameters of micro lens mainly include the additional power and the filling ratio. Therefore, measurements focused on individual micro-lens and micro-lenses within 6 mm diameter range.

1) Measurements of single micro-lens:

The measurement range is set according to the size of an individual micro-lens, typically around 1 mm. A horizontal line is drawn across the entire lens, and the power distribution curve along this line is examined. A smoother curve that closely matches the design power indicates higher processing accuracy.

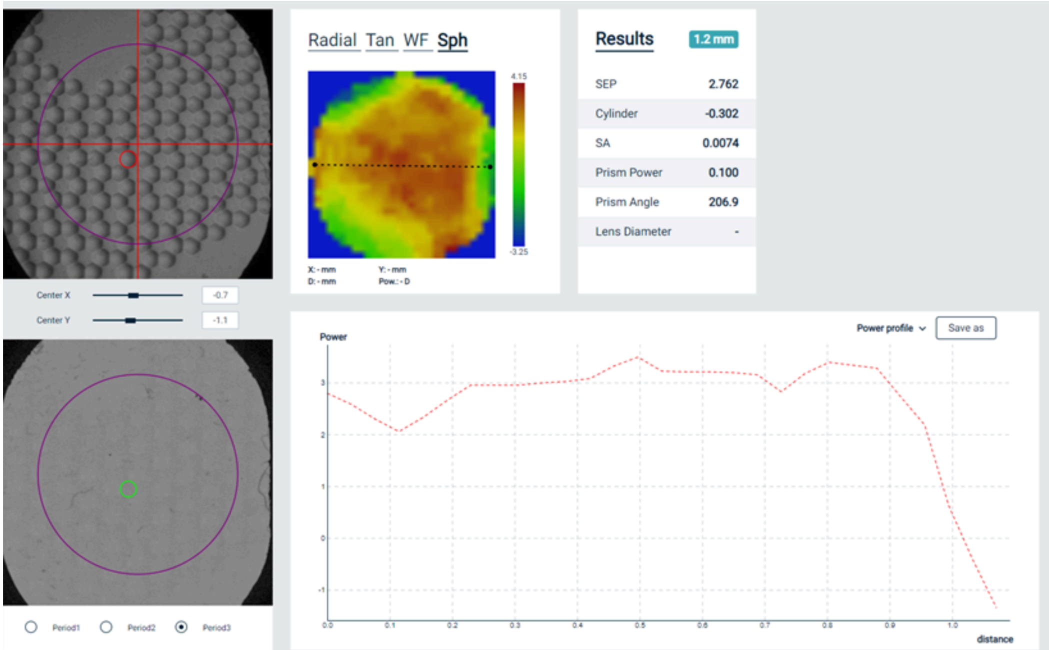

Figure 22 Measurement of single micro-lens measurement mode of Nimo

2) Measurement of group micro-lens within certain range:

A 6 mm diameter aperture is selected for measurement, then the power distribution histogram is obtained (Figure 24). The X-axis represents power values, while the Y-axis represents quantity. A higher peak indicates a larger percentage of certain power within the 6 mm diameter range. Since this range contains the lens base and micro-lenses, there are generally two peaks representing the power distribution of the base and micro-lenses with addition. The distance between two peaks indicate the addtion. A narrower peak for micro-lens power indicates better processing stability. The ratio between the power peaks of micro-lenses and the base can be used to characterize the filling ratio.

From the comparison of two peaks, it's clearly seen that the 2nd peak (from micro-lens) is higher than the 1st peak (substrate) for HORI design while the other one shows typical higher 1st peak.

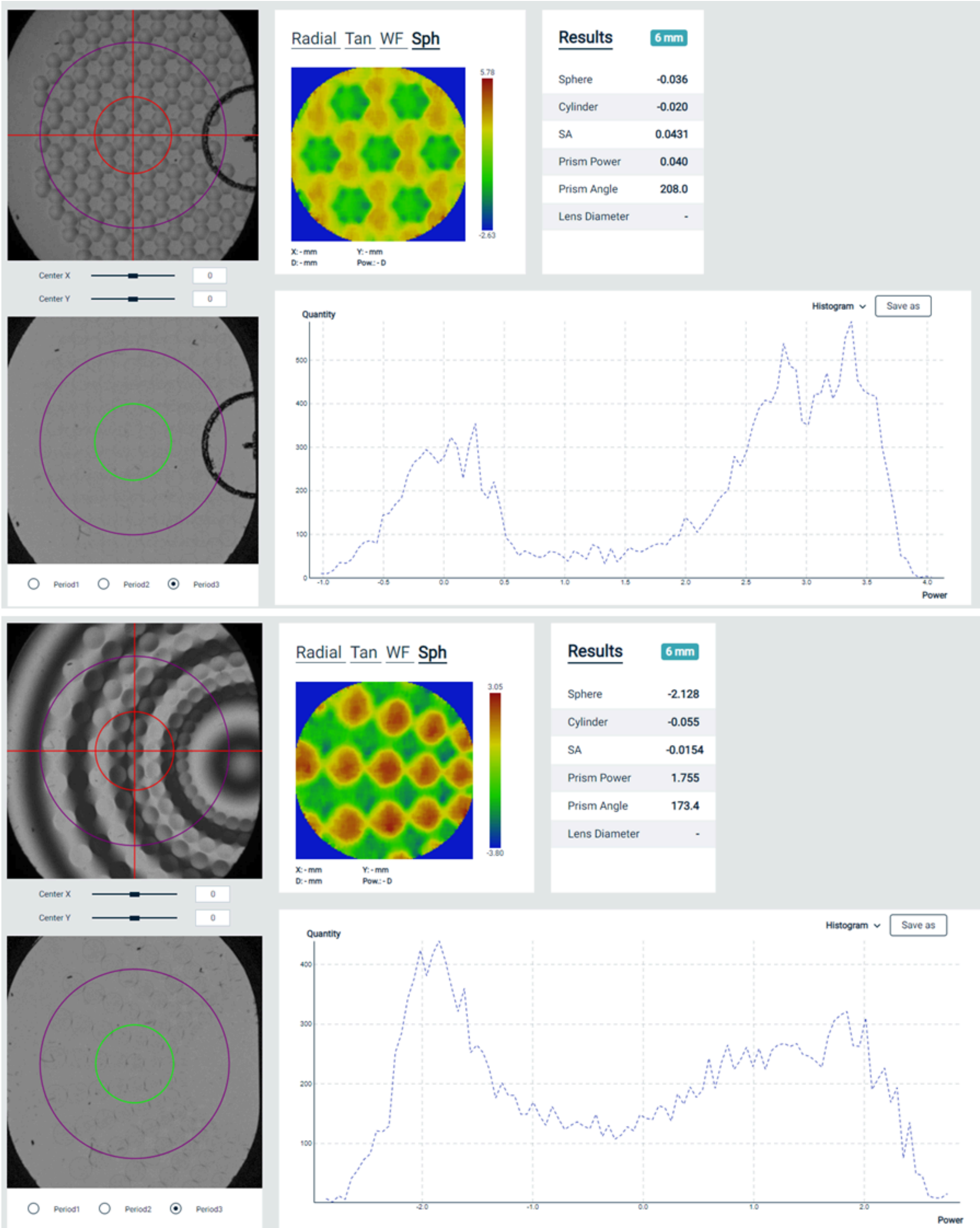

Figure 23 Group measurement for HORI (top) and aother typical product(bottom)

In general, the designed micro-structure can be well manufactured and maintained in the lens surface, showing good quality. This for sure laid good founcation for further product realization.

4 Clinical results and intepretation

To validate the wearability and effectiveness of this new design, Wenzhou Medical University conducted a one-year randomized double-blind clinical trial (RCT). The trial consists of three groups, each with 80 participants aged 6-12. One group served as a control group using single-vision (SV) lens, while the other two groups used two different designs based on HORI technology. This study was initiated from May 2022 so the 1st 6month was mainly in COVID lock down when kids have much time indoor.

4.1 Regarding Wearability

During the initial phase, both SV and HORI group, received excellent ratings from over 65% of participants. Over 98% of participants rated comfort as comfortable or above, with little difference compared to the SV lens group.
After wearing the lenses for one month, over 96% of participants rated them as excellent. This indicates that after wearing the lenses for a period of time, the experience is similar to that of single-vision lenses.

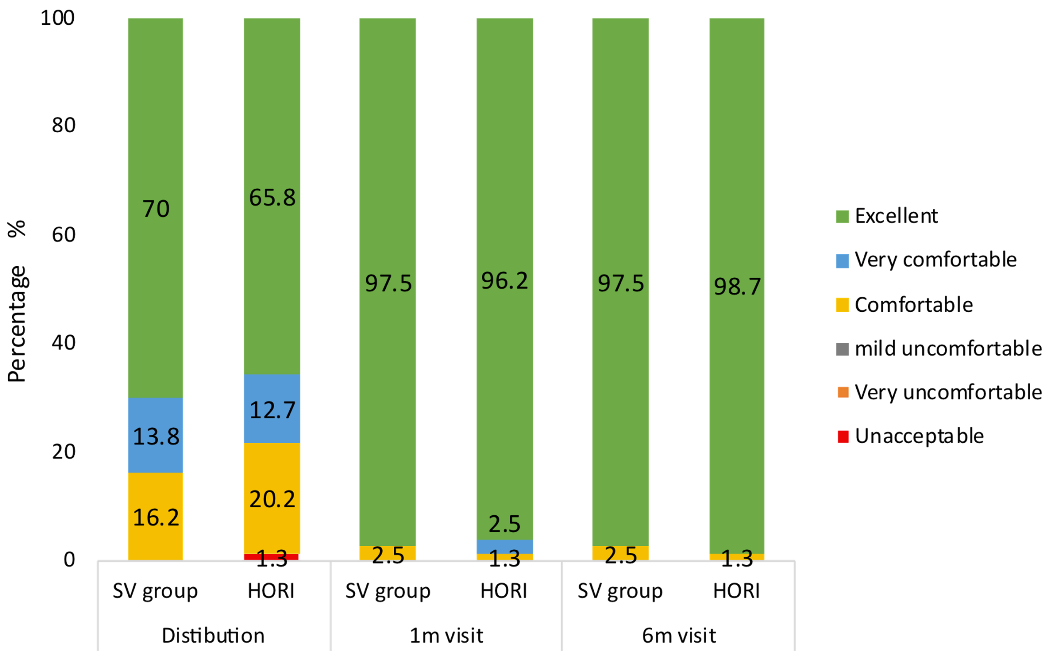

Figure 24 Wearability assessment during RCT, based on questionairs

The assessment of visual quality followed a similar trend. At the beginning, wearers could perceive differences compared to single-vision lens. However, with time, this gap significantly narrowed, and there were no significant differences among the groups at the 1month visit and beyond.

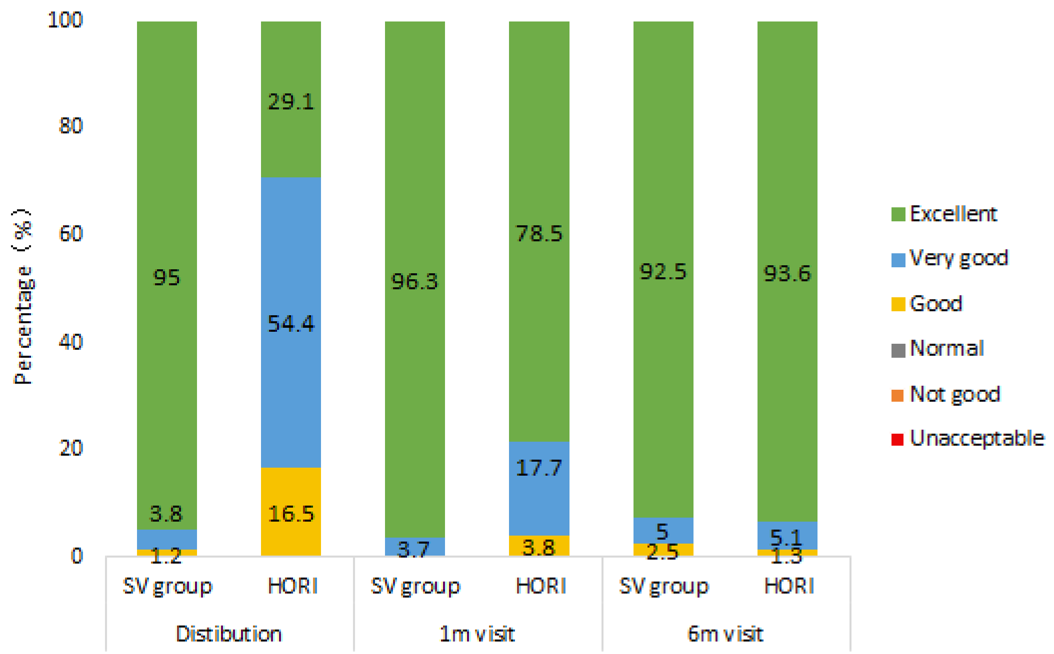

Figure 25 Visual quality assessment during RCT, based on questionairs

To conclude, even though the defocus stimulation is significantly enhanced, satisfied adaptation was still achieved among adolescents aged 6-12. Besides, the dropout rate after 12 months wearing was less than 5%, also indicating the product's excellent wearability.

4.2 Myopia Control Efficacy

Based on the 12-month follow-up of lens wear, products related to HORI designs showed significantly slower myopia growth, approximately 48% control efficacy for axial length (0.18mm vs 0.35mm) and 56% control efficacy for refractive power (-0.29D vs -0.66D) within the entire group (80 participants each).

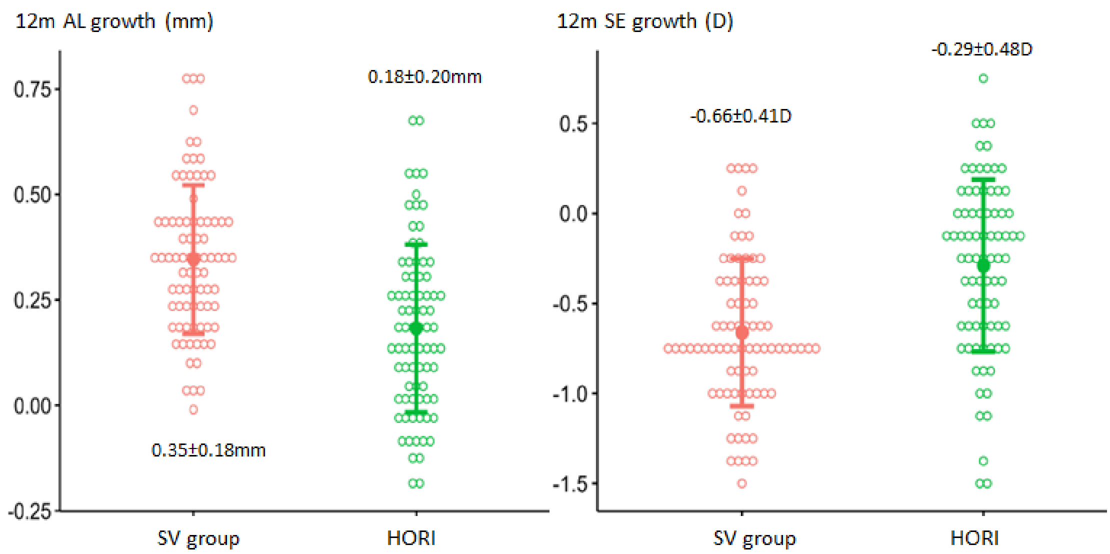

Figure 26 Myopia control efficacy with 12months AL growth (L) and Spherical Equivalent change (R) , with each open circle represents one participant

From the detailed analysis, we found in average

- Kids only grow anually -0.29D in average, much lower than -0.66D who are wearing SV lens.
- 78% grow less (include) than -0.50D, 95% for 10-12 age group.

This is quite amazing achievement in the available report, especially after COVID. Considering the recruitment age is mainly above 8 for a few famous study for Myopia management, we also analyze from this perspective. For older children (10-12 years old). The performance was even more outstanding, with control effectiveness reaching 81%. This shows signifcant progress in the market.

Table 2: Sub-group analysis of 10-12yrs age group

12m visit	*SV Group*	*HORI*
Participants	50	37
ΔAL (mm)	0.27±0.12	0.09±0.14
AL Efficacy		67%
ΔSE (D)	-0.54±0.33	-0.10±0.34
SE Efficacy		81%

(Official publication in preparation)

5 Conclusion

A new Myopia Management spectacles design, called H.O.R.I (Hexagon Optimized Reticular Integration), is proposed aiming for the best potential of efficacy. Different from traditional microstructure lens, HORI showed innovations in micro-lens shape (hexagon vs circular) forming a grid, smaller central clear zone with rough edge, filling ratio (historically high 67%), and consistent and symmetric layout all through the surface. These are summarized into Fair Grid, Fractal boundary and Full symmetry. Initial RCT run in Wenzhou eye hospital showed inspiring results for Myopia Management efficacy while maintaining excellent wearability.