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**C-77616** Approved for one CET Point

# Myopia progression and management

By Tina Arbon Black BSc (Hons), FBDO CL

**R**esearch into halting the progression of myopia has been on the optical agenda for several decades. The author recollects that during the 1980s, hospital eye departments and progressive optometrists routinely prescribed executive bifocals, typically with a +2.50 add, set with the segment bisecting the pupil, in order to halt the progression of 'juvenile stress myopia'. A lack of evidence and a GOS system ill-fitted to paying for 'experimental' treatments meant that this practice fell by the wayside. However, interest in myopia has never gone away – and has come to the fore in the last decade.

Evidence suggests that myopia is reaching epidemic proportions with predictions that 49.8 per cent of the world's population will be myopic by 2050, with 9.8 per cent having high myopia (standardised to spherical equivalent of -5.00D and greater) with consequences of serious pathology including retinal detachment, myopic maculopathy, glaucoma and cataract<sup>1</sup>.

Clearly, reducing myopic progression is important to relieve the public health burden and improve quality of life for myopes; slowing myopia by 1.00D can reduce myopic maculopathy by 40 per cent<sup>2</sup>.

This article aims to give an insight into current thinking regarding myopia, existing

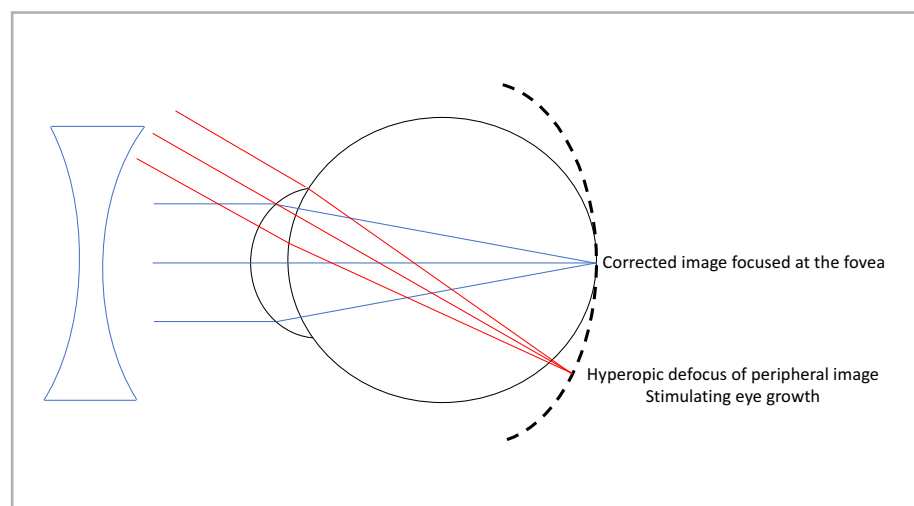


Figure 1. Corrected eye with retinal image focussed at the fovea

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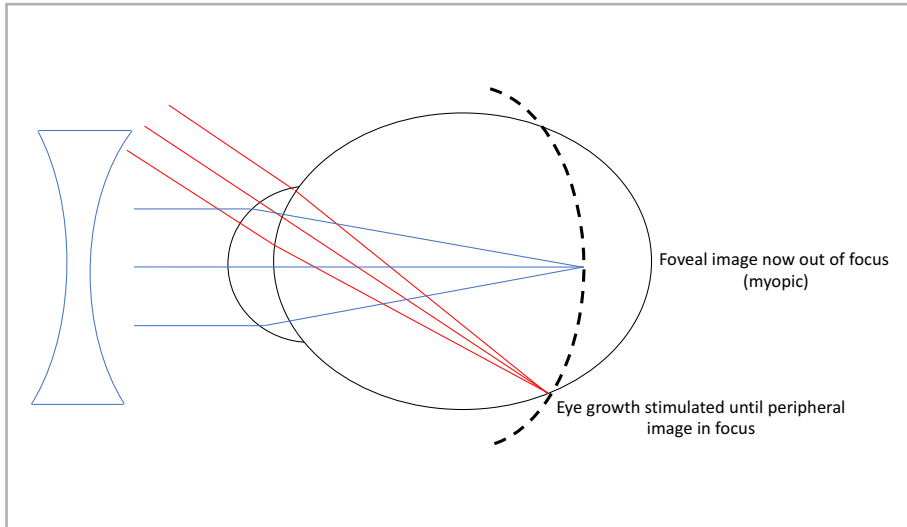


Figure 2. Peripheral image in focus with eye growth

interventions and some new spectacle and contact lens designs that have been gaining interest. Dispensing opticians, contact lens opticians and optometrists have an exciting opportunity to play a part in myopia management, and now more than at any other time evaluating and understanding evidence is essential.

General Optical Council registrants' responsibilities are very clear within the standards of practice for optometrists and dispensing opticians: 3.1, 3.1.4, 3.3 and 5.3<sup>3</sup>, so with evidence mounting of this growing problem it is not an option to just say nothing – hoping someone else will.

### CURRENT OPINION ON MYOPIA PROGRESSION

Today, causes of myopia still generate much debate and research. It is clear there is a link between genetics, environmental and now optical factors like eye shape and off axis refraction<sup>4,5</sup>.

Heritability of myopia is between 60 and 80 per cent<sup>6</sup> and children of two myopic parents having a greater risk of developing myopia than children of one myopic parent<sup>7</sup>.

Current thinking is that eye growth is visually guided with relative peripheral retinal refraction playing a more significant role than foveal refraction in driving eye growth<sup>5,8,9</sup>.

**Figure 1** shows that even though a corrected eye with retinal image focused at the fovea, the peripheral image plane is behind the retina creating hyperopic defocus and stimulating horizontal axial elongation. Eye growth continues until the peripheral image is in focus (**Figure 2**) and the foveal image becomes myopic.

By creating peripheral myopic defocus, the stimulus for eye growth is discouraged. The foveal image must remain in focus allowing full visual development, avoiding amblyopia. **Figure 3** shows a peripheral

myopic defocus image plane and in-focus foveal image.

Measuring peripheral refraction and eye lengths in myopic children that took part in the bifocal lenses in near-sighted kids (BLINK) study, found more hyperopic relative peripheral error in the horizontal meridian and more myopic relative peripheral error in the vertical<sup>10</sup>. Both vertical and horizontal axial lengths were shorter compared to the central area, and the more foveal myopia the more relative peripheral hyperopia horizontally and less relative peripheral myopia vertically. Simply: the greater the myopia, the steeper the retinal profile.

A study of 18 to 30-year-olds found steeper retinas in East Asian populations compared to Caucasians when viewed with increased myopia prevalence in East Asia retinal shape could indicate development of myopia<sup>11</sup>.

Children from the Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error (CLEERE) study were found to show relative peripheral hyperopia one year before myopia onset in Caucasian children, and three years before in Asian children. This supports the theory that relative peripheral hyperopia is a driver not an effect of myopia<sup>12</sup>.

Contradictory evidence from Atchison *et al*<sup>13</sup> (Chinese children aged seven years and aged 14 years) found that when myopia developed, relative peripheral refraction was myopic not hyperopic as expected. This makes the point that spectacle lenses inducing relative peripheral myopia would be unsuccessful.

Clearly, more research is needed to understand the dominating factors driving myopia progression.

### TERMINOLOGY AND CLASSIFICATION

After a meeting in 2015 between the World Health Organisation (WHO) and the Brien Holden Vision Institute (BHVI) on myopia and high myopia, the International Myopia Institute (IMI) was formed as the global burden of myopia and its sight-threatening complications were clearly evident.

The IMI consists of experts from around the world who created a series of white papers and clinical summaries (free to access) to aid eyecare practitioners, governments educators and the general public understanding of myopia.

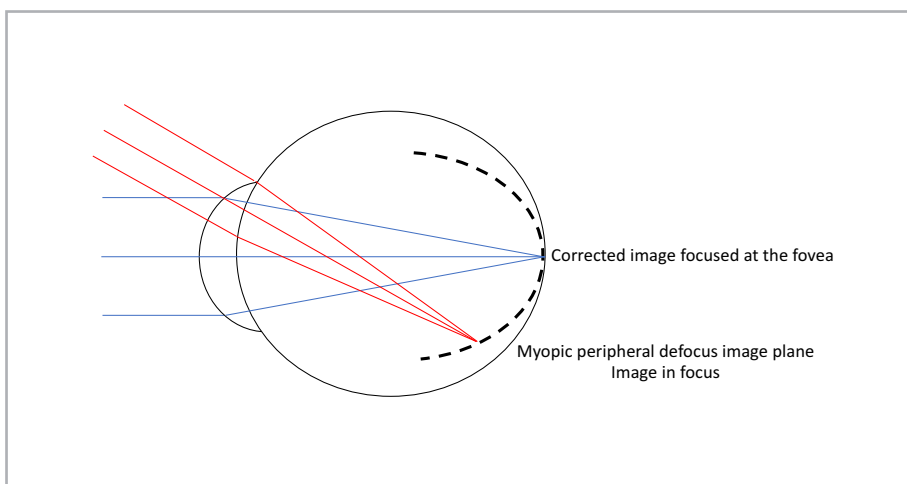


Figure 3. Eye corrected with peripheral myopic defocus

## MYOPIA MERMINOLOGY

Myopia	A condition where the spherical equivalent refractive error is $\leq -0.50\text{D}$ with relaxed accommodation
Low myopia	A condition where the spherical equivalent refractive error is $\leq -0.50\text{D}$ and $> -6.00\text{D}$ with relaxed accommodation
High myopia	A condition where the spherical equivalent refractive error is $\leq -6.00\text{D}$ with relaxed accommodation
Pathological myopia	A condition where structural changes in the posterior segment of the eye are caused by the excessive axial elongation associated with myopia such as; myopic maculopathy, posterior staphyloma (irregular configuration of the retina due to scleral thinning and bulging from excessive elongation), and high myopia associated optic neuropathy
Axial myopia	Myopia due to excessive axial elongation of the eye
Refractive myopia	Myopia due to the cornea and/or the crystalline lens
Secondary myopia	Myopia due to a specific cause for example a drug, corneal disease or systemic clinical syndrome which is not a known population risk factor for development of myopia
Premyopia	Refractive status of the eye $\leq +0.75\text{D}$ and $> -0.50\text{D}$ in children where age, refraction and considered risk factors show a likelihood of future myopia development to warrant preventative interventions

Table 1. Myopia terminology

**Table 1** explains the definitions and classifications of myopia set out by the IMI to create consistency. Note: high myopia is now defined as  $\leq -6.00\text{D}$  using mathematically valid descriptors, meaning more myopic than  $-6.00\text{D}$ <sup>14</sup>.

## EXISTING INTERVENTIONS: EVIDENCE AND EFFECTIVENESS

### Time spent outdoors

Time outdoors is an area of extensive research, which has shown to protect against myopia onset but not myopia progression in subjects who were already myopic<sup>15</sup>. Forty minutes of daily outdoor activity provided a relative 23 per cent reduction in myopia incidence among six-year-old children in China<sup>16</sup>. Unsurprisingly, lockdown restrictions during the Covid-19 pandemic have impacted on the amount of time spent outdoors. A recently published prospective cross-sectional study found the prevalence of myopia was 3x higher in children aged six years, 2x higher for children aged seven years and 1.4x higher for children aged eight years compared to previous years<sup>17</sup>.

Interestingly Huang *et al* in 2020<sup>18</sup> found that ensuring working distances of  $>30\text{cm}$  for near work, stopping every 30 minutes then having time outdoors, decreased myopia progression and prevalence.

### Pharmacological interventions

Evidence from Chua *et al*<sup>19</sup> (ATOM1 phase

one study) showed atropine one per cent concentration produced a 77 per cent reduction in myopia progression over two years. During a one-year cessation of atropine, participants were followed and a considerable myopic progression (rebound effect) was observed comparable to the control group at two years, negating the effectiveness of the treatment<sup>20</sup>.

Due to the rebound effect and other potential side-effects (mydriasis, reduced accommodation, potential glare, near vision blur, allergic conjunctivitis) lower concentrations were studied. Chia, Lu and Tan<sup>21</sup> (Atom2 phase three study) found 0.01 per cent atropine concentration proved effective – with a 50 per cent reduction in myopic progression over five years with fewer side-effects.

There are still many unanswered questions regarding the use of atropine, which is not currently licensed in the UK for myopia control. These include: the cellular and pharmacological process; whether the sclera, choroid or retina is the location which impedes myopic progression; concentration; treatment duration; drug holidays; and safety of long-term use<sup>22</sup>.

### Spectacle wear

Under correction of myopes, giving rise to foveal myopic defocus potentially diminishing myopic progression stimulus, initially showed success in animal studies<sup>23,24</sup>. However, in humans the

evidence is contradictory. In a systematic review, Logan and Wolffsohn<sup>25</sup> found that most evidence showed an increase in myopic progression compared to full correction. Current clinical guidance supports myopes being fully corrected.

A randomised clinical trial conducted by Gwiazda *et al*<sup>26</sup> involved 462 children using Varilux comfort (+2.00D add) compared to single vision lenses. The trial achieved a reduction in myopic progression of 0.20D, and an axial length reduction 0.11mm. Disappointingly, these results were clinically insignificant. The treatment effects of progressive power lenses have shown to be greatest in the initial six to 12 months, but diminish in later intervals. The reasons for this are unknown, however, accommodation adaption may be a factor<sup>27</sup>.

Bifocal lenses – more effective results have been found using two executive bifocal (+1.50 Add) designs, one with no prism and one incorporating 3Δ base in at near. Myopic progression was reduced by 39% and 51% respectively over 3 years, compared to single vision lenses. The prismatic lenses had a greater effect for children with low lag of accommodation<sup>28</sup>.

### Contact lens wear

With conventional soft multifocal contact lenses, centre distance lenses do provide some reduction in myopic progression (43 per cent) and axial elongation (36 per cent) as recorded by Walline *et al*<sup>29</sup> (Blink

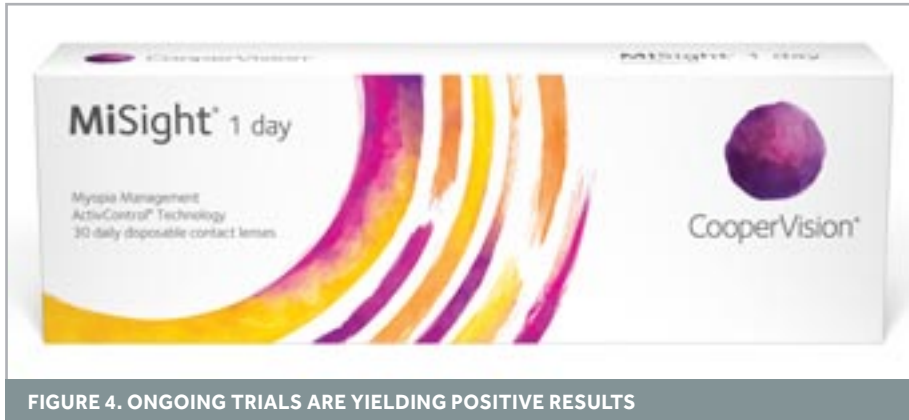


FIGURE 4. ONGOING TRIALS ARE YIELDING POSITIVE RESULTS

randomised clinical trial). The results are similar to a previous meta-analysis with a 25-50 per cent reduction in myopic progression<sup>30</sup>.

Reverse geometry high DK rigid gas permeable contact lens designs, which reshape the cornea when worn overnight to reduce myopic refraction, were originally designed to eliminate need for vision correction during the day. Orthokeratology (OK) lenses have now been shown to be successful in myopia management. Results of a two-year randomised clinical trial found axial elongation slowed by 43 per cent, compared to single vision spectacles, with greatest results in the first six months<sup>31</sup>. This concurs with meta-analysis results from Sun *et al*<sup>32</sup>.

The OK lens design creates a steepening in the mid-peripheral corneal zone, creating myopic defocus. The amount of myopic defocus created is believed to be dependent upon the degree of centrally corrected myopia<sup>33</sup>.

OK lenses require exact specialist fitting. It should also be noted that the risk of microbial keratitis is considered similar to other overnight wear modalities<sup>34</sup>. Rebound effects have been observed with this method of intervention<sup>35</sup>, although there is a lack of robust comparable data.

## COMMERCIAL SOFT CONTACT LENS DESIGNS

### MiSight 1 day

MiSight 1 day (CooperVision) (Figure 4) is a dual focus soft daily disposable contact lens with a central distance correction zone (3.36mm) surrounded by a treatment zone, creating 2.00D myopic defocus zone (+2.00D add). This alternating pattern is then repeated<sup>36,37</sup>

When viewing a distant object, the

distance correction zone is focused on the retina and the myopic defocus treatment zone in front of the retina, which is consistent for near vision with accommodation. Full lens specifications can be found on the CooperVision UK practitioner website.

### Evidence for myopia management

A multicentre trial being conducted in Portugal, England, Singapore and Canada is ongoing with results that appear very promising. This is a randomised, double-masked clinical trial being conducted over three years among 144 children aged eight to 13 years old<sup>38</sup> – with one group wearing MiSight 1 day lens and the other group Proclear 1 day. Changes in cycloplegic refraction measured by autorefractor recorded as spherical equivalent refraction over three years showed a 59 per cent reduction in myopic progression for those wearing the MiSight 1 day lens, and a 52 per cent reduction in axial length measured in mm. Weekday wearing times were around 13 hours, with weekends 12 hours worn over 6.5 days per week.

Results from a parallel group – the MiSight Assessment Study Spain (MASS)<sup>39</sup> two-year randomised clinical trial – compared MiSight 1 day to single vision spectacles and found lower results: a 39.32 per cent reduction in myopic progression and a 36.04 per cent reduced axial elongation. It was noted that 86-87 per cent were Caucasian children, whereas many other myopia intervention studies only include Asian subjects.

The multicentre study showed myopia progression consistent across population groups within the study<sup>38</sup> differing from existing evidence where progression has been linked with ethnicity<sup>40,41</sup>.

The 'rebound effect' when treatment stops is an issue of concern, which has

been found with atropine and OK<sup>42,43</sup>.

However, cessation of MiSight 1 day lens wear over a one-year period found no rebound effect<sup>44</sup>. This concurs with the opinion that intervention by altering retinal image profile is a more natural, less invasive approach unlike pharmacological interventions<sup>45</sup>. Accommodative and binocular functions showed no changes in the MASS study<sup>46</sup>.

### Key points:

- Multicentre, double-masked randomised controlled trial over three years
- Children aged eight to 13 years
- Study is ongoing so further results will provide even more information
- Evidence relating to ethnicity and myopic progression
- This study did not include any children with high myopia (no participants over -5.00D)
- Fifty-nine per cent reduction in myopic progression and 52 per cent reduction in axial elongation

### NaturalVue Multifocal 1 day

NaturalVue Multifocal 1 day (NVMF) (Visioneering Technologies) is an extended depth of focus (centre distance) simultaneous vision multifocal contact lens.

The lens design features Neurofocus Optics technology (a patented aspheric design) which rapidly increases relative plus power from the central zone inducing a virtual pinhole effect<sup>48</sup>. The non-conical, aspheric surface design creates a smooth power distribution. Full lens specifications can be found on Visioneering Technologies' UK practitioner website.

### Evidence for myopia management

Cooper *et al*<sup>48</sup> conducted a retrospective case series analysis (report on a series of patients with an intervention that was studied) of 32 patients aged six to 19 years fitted in 10 practices across America with NVMF lenses between March 2015 and August 2016 (Table 2). This research method does not have a separate control group like randomised clinical trials, making assessment of a single variable difficult.

The study created a starting point from previous spectacle refraction and time interval (months) until initial visit.



## METHOD OF CORRECTION PRIOR TO NATURALVUE LENS

Spectacles (type of lens not specified)	44%
Single vision spherical contact lenses	37.5%
Multifocal soft contact lenses	15.6%
Orthokeratology (OK)	3% date OK ceased not specified

Table 2. NaturalVue Multifocal study, prior methods of correction

The monthly progression figure was annualised, forming the basis of using each participant as their own control. Inclusion criteria was by practitioner clinical judgement where  $-0.50\text{D}$  of refractive myopic progression was evident compared to previous examination. It is not clear if cycloplegic refraction was undertaken.

Subjects were seen approximately every six months. Progression was recorded and divided by the number of months since the previous visit, then again annualised with each eye analysed separately. The time NVMF lenses were worn varied from six to 25 months with an 'average' of 10.94 months. However, eight (25 per cent) children only wore the lenses for six months, and two children (6.2 per cent) wore them for 24 months. Daily wearing times were not specified. The data shows that for 75 per cent of children, myopia progression completely stopped. For 6.25 per cent of children, refraction actually regressed; 90.6 per cent of the children showed a 70 per cent or greater reduction in myopia progression.

Care needs to be taken when interpreting these results, as the use of percentages could lead to confusion. For example, it states that 1.56 per cent of 32 children showed an increase, which relates to half of one child, or one eye. Annualised myopic progression rates were calculated from the initial visit.

Unfortunately, full baseline refractive assessment details were not given – but appear not to include use of cycloplegics, or if refraction methods differed across the 10 practices. No axial length measurements were given.

The study itself acknowledges that retrospective case series analysis lacks the scrutiny of double-masked randomised controlled clinical trials, and interpreting these results must be considered alongside that fact that no topography or axial length measurements were taken.

A recent product focus article in *Optician* magazine, 'A common sense approach to myopia management', mentions new clinical data involving a larger case sample (153) – but this data seems unpublished as yet<sup>49</sup>. Standardised refraction protocols would have improved both reliability and validity of the study.

Case studies provide real world evidence and clearly MVMF worked for these patients. Presentation of the data implies this intervention is very effective, although the results need to be considered alongside the limitations of this study method.

**Key points:**

- Real world evidence
- Children aged six to 19 years
- Small number of participants

- No control group
- Consistency across practices regarding refraction not discussed
- Cycloplegic refraction not specified
- No axial length measurements

**COMMERCIAL SPECTACLE LENS DESIGNS****Hoya Miyosmart lens**

Launched in the UK in February 2021, the Hoya Miyosmart spectacle lens has gained considerable interest.

Development started from the defocus incorporated soft contact (DISC) lens; a simultaneous vision correction with central clear distance zone and a 50:50 ratio of (2.50D) myopic defocus zones<sup>50</sup>.

Myopia progression has been shown to reduce by 58 per cent when the lenses are worn for at least seven hours; time worn or 'dose' of myopia management was linked to the effect. This concept was applied to spectacle lenses by defocus incorporated multiple segments (DIMS) technology – as not everyone is suitable for contact lens wear<sup>51</sup>.

Miyosmart is a simultaneous vision lens consisting of a hexagonal central distance zone surrounded by a ring of micro lens segments (lenslets) creating 3.50D of myopic defocus (+3.50D add) so there is optical defocus in all regions of the lens<sup>51</sup>. Lenslets are very discreet, and only visible if the lens is tilted and a light source is used to show the multiple segments by reflection (**Figure 5**). Full lens specifications can be obtained on request from Hoya.

**Evidence for myopia management**

Lam *et al*<sup>51</sup> conducted a two-year, double-masked, randomised controlled trial of Chinese children aged eight to 13 years; one group wore a single vision lens and the other group wore the DIMS lens. It was accepted that while it was difficult to differentiate single vision and DIMS lenses, some children may have identified the multiple segments but no adaption difficulties were noted. Changes in cycloplegic refraction measured by autorefractor were recorded as spherical equivalent refraction, and showed 52 per cent less myopia progression in the DIMS group over 24 months. The greatest effect was seen in the first six months.

Axial length growth was measured in millimetres (mm) and showed a 62 per cent reduction in the DIMS group



FIGURE 5. HOYA MIYOSMART LENS



Figure 6. Practitioners must educate patients and parents about myopia management options

compared to the single vision group; 21.5 per cent of children wearing the DIMS lens had no myopia progression over two years compared to 7.4 per cent in the single vision control group. Constant wear of spectacles was achieved in both subject groups (around 15 hours).

To determine if the DIMS lens had any effect on visual function, a further study was conducted. This showed no significant differences between children who wore the DIMS lens compared to those in single vision lenses, although it was accepted that further studies were required covering a longer time period<sup>52</sup>.

Changes in relative peripheral refraction (RPR) of children wearing DIMS showed a decrease in hyperopic RPR in contrast to the single vision group, where it increased. Also, it was concluded that using a lens that induced peripheral myopic defocus slowed myopia progression and altered the overall retinal shape<sup>53</sup>.

#### Key points:

- Double masked randomised controlled trial
- Children aged eight to 13 years
- Study is ongoing so further results will provide even more information
- Population studied was Chinese children, therefore the effect in differing ethnicities will need further research
- This study did not include any children with high myopia (no participants over -5.00D)
- Fifty-two per cent reduction in myopic

progression and 60 per cent reduction in axial elongation

#### Stellest spectacle lenses

In July 2020, Essilor launched its Stellest spectacle lens for myopia management in the Wenzhou Medical University Eye Hospital, China. In September 2020, the company reported that interim findings after one year of an ongoing clinical trial showed more than a 60 per cent slowdown in myopia progression on average, when compared to children wearing single vision lenses. The trial also showed that axial elongation was prevented in 28 per cent of children.

Described as using highly aspherical lenslet target (HALT) technology – the lens features a central distance zone with aspherical lenslets spread on 11 rings ensuring visual signals are always in front of the retina, following the retinal profile<sup>54</sup>.

#### SightGlass Vision DOT lenses

In February 2021, CooperCompanies and EssilorLuxottica entered into a joint venture agreement to accelerate the commercialisation of SightGlass Vision spectacle lenses, designed to reduce myopia progression in children.

SightGlass Vision Diffusion Optics Technology (DOT) lenses are said to modulate peripheral contrast with no impact to on-axis vision; contrast modulation is quantified and controlled, and the amount of contrast reduction is not vergence dependent<sup>55</sup>.

In June 2020, DOT lenses received CE mark declaration, allowing market growth across the EU, UK and other EEA countries.

#### CONCLUSION

Evidence suggests myopia progression can be slowed significantly by spectacle lenses and contact lenses, creating relative peripheral myopic defocus. Being able to offer spectacles and contact lenses for the management of myopia progression provides an exciting opportunity for eyecare practitioners – but mechanisms of myopia progression are clearly extremely complex and questions still remain:

- How much peripheral myopic defocus reduces growth stimulus?
- What is the minimum dose/ treatment time?
- Is peripheral hyperopic defocus the primary factor in myopic progression?

With many questions remaining and new products being trialled, following the evidence is essential.

Combined with this opportunity is an obligation and responsibility to educate patients and parents. Presenting evidence with accuracy and clarity is essential so that clear consent and informed choice is achieved.

At present, it needs to be remembered that no intervention/treatment is 100 per cent effective and research is still ongoing. Equally, practitioners who fail to offer myopia management options, or fail to inform young myopes and their parents of the risks of myopia progression and the different treatments available, may be failing to observe the first duty of any registered optician: to act in the patient's best interests at all times.

It should also be mentioned where products and treatment strategies are not licensed for myopia management and used 'off licence', failure to ensure full patient awareness and understanding could become subject to investigation by the General Optical Council.

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