SPECIAL REPORT

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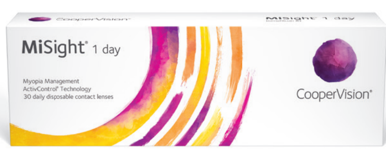

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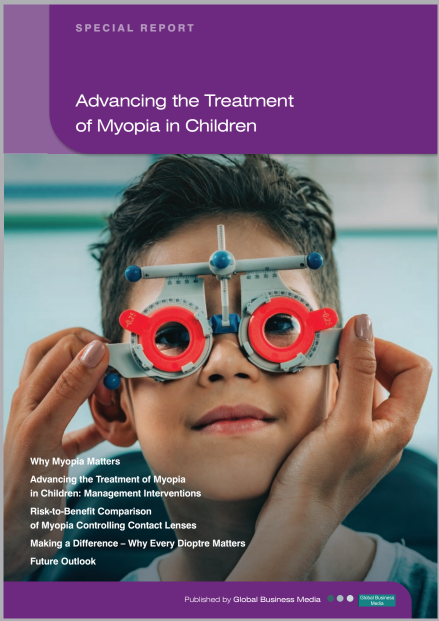
1. Chamberlain P et al A 3-year Randomized Clinical Trial of MiSight® Lenses for Myopia Control. Optom Vis Sci 2019;96:556–567. *Over a 3 year period, MiSight® 1 day reduced myopia progression on average by 59% compared to a single vision contact lens.* 2. Tideman JW, Snabel MC, Tedja MS, et al. Association of axial length with risk of uncorrectable visual impairment for Europeans with myopia. JAMA Ophthalmol. 2016;134:1355-1363.



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Foreword

Myopia (short-sightedness) is defined as 'a refractive error in which rays of light entering the eye are brought to a focus in front of the retina when ocular accommodation is relaxed'. This usually results from the eyeball being too long from front to back but can be caused by an overly curved cornea and/or a lens with increased optical power.'[1] Myopia is the most common cause of distance vision impairment in the world and has gained attention over the last few decades due to its alarming rate of increased prevalence, reaching epidemic levels in many countries, notably, but not limited to Far East Asia.[2] Indeed, The Northern Ireland Childhood Errors of Refraction (NICER) study conducted on school children identified a doubling of myopia in U.K. children over the past 50 years.[3]

Myopia in children progresses as children grow and a low myopic prescription in a young child is often just the start. As a child grows throughout the school years, myopic children may experience an associated increase in their myopia leading to greater dependence on their spectacles or contact lenses to compensate for their increasingly blurred distance vision. A myopic eye grows abnormally long, and this makes the eye vulnerable to various myopia-associated pathologies later in life including myopic maculopathy, retinal detachment, glaucoma and cataract later.[4,5,6,7] An eye with an axial length greater than 26mm and more than -6.00 dioptres refractive error is significantly associated with a lifetime risk of untreatable visual impairment.[8]

Correcting myopia with conventional spectacles or contact lenses helps children see, but doesn't slow down the increased growth of the myopic eye. Myopia management is an emerging field in optometry and ophthalmology of clinically relevant importance which can ultimately result in the child being a lower myope than they were destined to become as they enter adulthood. This may result in a lower final prescription and perhaps less dependence on their spectacles, but more importantly, a shorter axial length with potentially less vulnerability to sight-threatening myopia-associated pathologies.[8]

This report outlines the growing prevalence of myopia across the global and the genetic and environmental aetiologies that might offer an explanation. The consequences of myopia are outlined with the corresponding burden on health care systems. The strength of the evidence-base in supporting the management of myopia through a variety of interventions is described, along with a risk-benefit model of optical myopia management with contact lenses. Early intervention to slow myopia progression using a range of clinically useful options, from optical methods to pharmaceuticals, has the potential for significant socio-economic importance and the report concludes with a far-sighted view on the future landscape of myopia management.

Martin Richards
Editor-in-Chief

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Why Myopia Matters

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Introduction

Our perception of myopia is changing. Whilst it was for long considered a mere inconvenience, there is now an increasing recognition that myopia can lead to sight-threatening conditions later in life. All over Europe, and in fact all over the world, children begin to develop myopia at an earlier age, and in many children and young people it progresses faster than it used to. Earlier onset and faster progression mean that increasing numbers of adults are short-sighted, and have myopia of greater severity, leading to an increased risk of sight-threatening complications. This article reviews our current understanding of factors that have led to this rise in myopia prevalence and severity, and the burden it will place on individuals and healthcare systems across Europe.

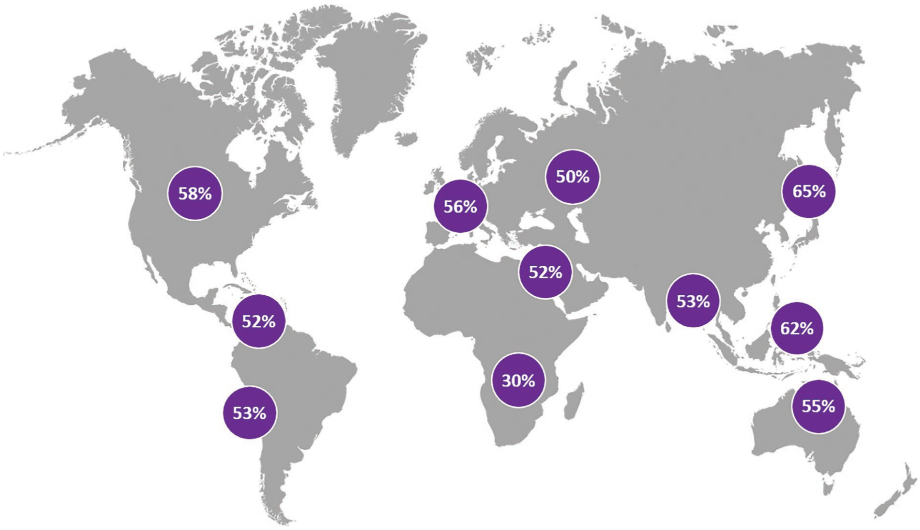

Figure 1. By 2050, 50% of the global population is predicted to by myopic

Myopia on the Rise

Eye care professionals (ECP) are seeing increasing numbers of children and young people with myopia. Whilst the predominant reason for prescribing spectacles in young children in a hospital setting is still hypermetropia (long-sightedness), there is an undeniable rise in myopic prescriptions.[1] Across Europe, myopia now seems to start at a younger age and to progress faster. In the UK, the prevalence has doubled over the last 50 years. Now, 1.9% of 6-year-olds, 10-16% of 12-13 year-olds and 28% of 15-16 year-olds have myopia.[2] Figures are similar across Europe: In the Netherlands, 2.4% of 6-year olds are short-sighted[3]. In France, a myopia prevalence of 19.6% has been reported in children up to the age of 9 years, and of 42.7% in 10-19 year olds.[4] In Denmark, the prevalence in teenagers with a mean age of 15.4 years is 17.9%.[5]

Epidemiological studies across adult populations also reflect this trend (Fig 1, after[6]). Far from being a rare condition, myopia is now very common, particularly in younger adults. Across Europe, 30.6% of people between the age of 25 and 90 years have myopia, with a far higher prevalence of 47.2% in 25-29 year-olds.[7]

Whilst these prevalence rates are not as high as those in East Asia, where over 80-90% of young adults are short-sighted, the rising trend is observed around the world. As a result, the WHO lists refractive error as a priority eye disease,[8] recognising that by 2050 half the world population may have myopia.[9] Figure 1.

Myopia and Vision Loss

With increasing prevalence of myopia, including an increasing prevalence of high myopia, the number of people suffering permanent loss of vision from complications in middle and older age is also on the rise. Myopia increases the lifetime risk of permanent sight loss from retinal detachment, myopic macular degeneration, and optic neuropathy.[10] The risk increases with the degree of myopia; in the Netherlands, people with more than -6.00 D have been reported to

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have a 39% risk of permanent sight loss by the age of 75 years.[10]

Already in 2013, the UK National Ophthalmology Database study of vitreoretinal surgery found that half of the annual 12,000 vitreoretinal interventions were for retinal tears and rhegmatogenous retinal detachments (detachments caused by retinal breaks), which are usually myopia complications.[11] More recently, in the Netherlands an annual increase in retinal detachment repairs mirroring the rising prevalence of myopia has been observed.[12]

As early as 1998, the Rotterdam Study reported macular degeneration to be the predominant cause of sight impairment in people younger than 75 years.[13] According to the UK National Institute for Clinical Excellence, 200,000 people in the UK have pathological myopia, around 0.3% of the population.[14] Whilst it is not known how many may develop choroidal neovascularisation, of those who do develop myopic maculopathy in one eye, 30% will develop it in the other eye within 8 years.[14] In Russia, the prevalence of myopic maculopathy is 1.3%, with associated moderate to severe vision impairment/blindness in 47%.[15] In France, in a clinical setting, myopic maculopathy has been observed in 4.27% of patients with myopia greater than -10D, and in 0.5% of those with myopia between -6 and -10D, leading to a prevalence of certifiable sight impairment/blindness in 10.1% of those with myopia greater than -10D.[16] At 60 years old or over, the prevalence of blindness or vision impairment was 25.71% and 9.75%, respectively, in these two groups.[16]

Unfortunately, national sight loss registers mostly do not distinguish between age-related and myopia-related macular degeneration, and do not collect information on refractive errors at the time of sight impairment certification. Figures for myopia-related sight loss are therefore often an estimate. Global modelling indicated that in 2018, 32% of moderate to severe sight impairment and 47% of blindness were associated with myopia, with a projected increase to 35% and 61%, respectively, by 2050.[17] In Western Europe, between 2000 and 2050, the age-standardised prevalence of visual impairment associated with myopic maculopathy across all ages is estimated to increase from 0.01 to 0.05%, and that of blindness from 0.002 to 0.012%.[18]

Impact of Myopia

From its onset, myopia incurs costs which are born either by children's parents/carers or their healthcare systems. As adults, people continue to require spectacles and contact lenses, with some opting for corrective refractive surgery. Major costs are linked to secondary complications and their treatments, as well as to irreversible sight loss with its impact on productivity and quality of life. The UK National Health Service currently spends 3 billion GBP a year on eye care, and the cost of sight loss is 15.8 billion GBP/year; specific figures for myopia-associated costs are not available.[19]

Globally, in 2015, the potential productivity loss from myopic macular degeneration was estimated at 6 billion USD.[20] Worldwide, in 2018 direct, productivity and social security costs associated with myopia exceeded 670 billion USD and were estimated to rise to 1.7 trillion USD, putting its costs ahead of heart failure and lung or breast cancer.[17]

Development of Myopia

The common form of myopia with onset and progression in childhood and teenage years is caused by a gradual elongation of the eye. It follows on from the normal eye growth from birth to around 7 years, when the eye length increases from around 16-18mm to 22mm, with the fastest increase during the first 2 years of life.[21,22] Whilst the rate of elongation typically slows down during childhood and the teenage years, a significant minority of children now experience further rapid axial growth with resulting myopia.[23,24]

This axial elongation is driven by both genetic and environmental factors. Children whose parents are short-sighted have a higher risk of developing myopia, as do those who spend little time outdoors, and much time on near-vision activities. Some epidemiological studies also observed that children in families in lower socioeconomic circumstances have a higher risk.[3] Children with myopia tend to spend less time outdoors than their normal-sighted peers, and lack of sunlight linked with an increasingly urban lifestyle is a key environmental risk factor for the earlier onset of myopia.[3,25,26] Sunlight has higher intensity than any indoor lighting, and light falling onto the retina releases the neuro-chemical dopamine. In animal models dopamine release triggers a signalling pathway from retina to sclera which slows down eye elongation.[27,28] In humans, genome-wide association studies have identified many genetic variants associated with myopia which are light-dependent and related to cell-cycle and growth pathways, underlining the critical importance of the light environment in the development of myopia.[29]

Causes of Myopia

People who were children in the 1970s are likely to remember spending their afternoons outside, with friends, and with no or little adult

Figure 2. Increased time spent indoors, and the use of electronic devices may contribute to the increase in myopia prevalence in children

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supervision. Since then, childhood has become far more structured, with adult-led after-school activities, many of which take place indoors. Many schools have sold their playing fields to housing developers. UK surveys indicate that children today spend 68 minutes a day outdoors or on sports, including indoor sports. [30] Children from ethnic minority and socioeconomically disadvantaged communities spend less time outdoors than their more affluent peers, with 7% spending time in green and natural spaces less than once a month.[31] Conversely, access to green spaces in urban areas is associated with a reduced prevalence of spectacle wear in children, as observed in in Barcelona, Spain.[32]

In addition to a lack of time spent outdoors, increased near-vision activities and education are considered an additional environmental risk factor for myopia development, though the causal relationship is less clear.[26,35,6] Educational pressure has increased, and many parents invest in after-school tutoring offered in supermarkets, shopping centres and on the high street. Some children may also receive additional lessons to acquire extra-curricular skills and knowledge. Electronic devices which are ever decreasing in size have entered the mass market, and the rise in myopia prevalence parallels the rise in the use of interactive electronic devices. In the UK, children and young people age 5-15 years spend on average 2 hours per day online and 2 hours watching TV.[36] Children use electronic media to be in touch with their friends, for gaming and other leisure activities.[37] Two-thirds of 12-15 year olds use their phone in bed, and a third can access a tablet computer in bed.[36] Screen use by children in the UK is the second-highest in the world, at 44 hours per week.[33] By the age of 7 years, they will have spent twice a long looking at screens (4 hours per day) than playing outside (2 hours per day).[38,39] At the same time as spending more time on screens, children and young people spend less time outdoors and on sports.[34] Figure 2. Smartphones are now available to many,[40] and increased smartphone data usage is associated with myopia.[41] The rise of electronic devices and lack of outdoor activities is not only linked with myopia, but also to sleep problems and increasing levels of anxiety and obesity, particularly in ethnic minority groups and poorer communities.[39,42,43]

Myopia – A Preventable Condition?

If at population level myopia is largely caused by environmental factors, can it be prevented in the individual child? There are two parts to this problem: identifying those at risk, and taking preventative action.

Identifiable predictive factors include parental myopia and a greater axial length and lower refractive error than age-peers.[44,45] However, these are not evaluated in current vision screening programmes. Whilst vision screening is available in many European countries and regions, variations in funding, target age group and tests used persist.[46] Many are linked to other public-health initiatives to assess child health. All aim to detect reduced visual acuity, typically in children approaching school entry – those old enough to co-operate with optotype-based assessment by lay screeners. However, as in Europe, myopia typically develops after the age of 6 years and neither parental myopia nor the child's refraction are routinely evaluated, current screening programmes will not be able to identify children at risk of developing myopia.

However, eye examinations for children by ECPs may be available free of charge, if covered by a national health programme. Local ECPs are the first point of call when parents/carers or teachers are concerned about a child's eyesight. Nevertheless, parents/carers from communities perceived as "hard to reach" – ethnic minority and socio-economically disadvantaged groups – may not know about the availability of these services, or may be reluctant to engage with them, due to language and cultural barriers. In general, parents also tend not be aware of complications of myopia in later life,[47] and may therefore not seek advice until the child manifestly struggles with distance vision. Eye health education in schools, provided as part of mainstream education or by local campaigns such as the "Eye Heroes", can help spread the word within communities.[48,49]

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The second part of the problem is how to prevent or delay the onset of myopia in those at risk. Clinical trials in East Asia have shown that myopia onset can be delayed by children spending more time outdoors, though the effect on myopia progression is small.[50,51,35] From these trials comes the recommendation of spending around 1.5 hours a day outdoors, as advocated by the Recess Outside Classroom Trial 711 (ROCT711) programme – over 7 days, this adds up to 11 hours.[50] A meta-analysis calculated that every additional hour of outdoor time per week is associated with a 2% reduction in the risk of myopia onset.[52] Whilst strong evidence for a therapeutic effect of outdoor light is yet lacking for children in Europe, it is generally recommended that children should spend more time outdoors.[53] Some ECPs recommend eye rests during prolonged near work, such as the "20-20-20 rule": rest your eyes for 20 seconds, looking at something 20 feet away, after every 20 minutes of near work, which was originally developed for Computer Vision Syndrome / Digital Eye Strain.[54]

No intervention other than "more time outdoors" has been tested in pre-myopic children. It may be some time until the ethical question of whether an intervention which can potentially cause problems (blurred near vision, light sensitivity from pharmaceutical interventions and the rare, but serious complication of keratitis from contact lens wear) is justified in children who do not yet have the target condition.

Conclusions

Myopia can no longer be considered as a mere inconvenience. Increasing prevalence and severity will place an increasing burden on individual quality of life and cause a rise in healthcare expenditure to both individuals and healthcare systems across Europe. Early detection of predictive factors may enable families to delay the onset of myopia by engaging with outdoor activities. As the evidence of the burden of the condition on individuals and society increases and low-risk interventions emerge, the identification of children at risk of developing myopia and pre-emptive management options may become ethically acceptable.

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Predictive factors for childhood myopia including refractive status are not typically evaluated in current vision screening programmes.

Advancing the Treatment of Myopia in Children: Management Interventions

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Introduction

The previous article discussed myopia prevalence predicting that myopia may affect approximately 50% of the world's population by the year 2050 based on trending myopia prevalence figures.[1] Critical to minimising the irreversible visual impairment of myopia-related ocular pathologies are interventions to actively manage myopia.[2] These interventions may prevent or delay the onset of myopia, or halt or slow its progression.[3] The physiological axial length changes associated with the progression of myopia is the precipitating factor in sight-threatening ocular conditions such as retinal detachment. Consequently, any intervention to slow myopia progression must also reduce the rate of axial elongation of the eye.

Management strategies are growing in number with a significant body of research committed to enhancing and developing new approaches. However, we are at an exciting time whereby we can translate the evidence from research evidence through to commercially available interventions that can be used in clinical practice. This article highlights the research behind such interventions under three categories, behavioural, optical, and pharmacological and discusses the evidence to integrate these into clinical practice.

Behavioural Interventions

Epidemiological and animal studies have suggested that an individual's environment and lifestyle play a key role in myopia development.[4]

Time outdoors

There is a large body of epidemiological evidence that points to the protective effect of time outdoors in delaying or preventing the onset of myopia. A systematic review and meta-analysis found that the odds of myopia can be reduced by 2% per additional hour of time spent outdoors.[5] Additionally, it has been found that different amounts of light exposure correlate with the axial growth rate of the eye.[6]

The research prompted three intervention trials to take place, all of which were based in China where the prevalence of myopia in school-aged children is as high as 60%.[7] He *et al*,[8] and Jin *et al*,[9] introduced an extra 40 minutes of outdoor activity during the school day and both found a significant reduction in myopia progression of 11% and 18%, respectively. Wu et al introduced an additional 80 minutes per day and found a 23% reduction in myopia progression and reported a reduction of 50% in the incidence of new myopic cases over a one-year period.[10] This research supports the theory that increased time outdoors is influential in myopia development. The research evidence is stronger in terms of delaying the onset of myopia compared with slowing progression and this in itself is beneficial, as we know that the younger a child is when they develop myopia the greater the final amount of myopia is likely to be.[11]

The protective effect of time outdoors on myopia onset has been widely investigated however, despite this large body of supportive evidence the exact mechanism behind this protective effect is still unclear. It has been suggested that circadian rhythms and their associated hormones triggered by sunlight may play a role in myopic growth. The retinal dopamine system has been found to be involved in the control of eye growth and the production of dopamine in the retina is stimulated by light.[12] Additionally, research has found that myopes have significantly higher levels of serum melatonin concentration than non-myopes.[13] It may also be related to the different dioptric environment, we observe much greater distances when outdoors compared to the many close objects we view indoors.[2]

Despite the lack of certainty surrounding the mechanism of the protective effect of time outdoors, it should be considered as an effective and straightforward strategy to reduce the risk of myopia development in children. Countries in East Asia such as Singapore and Malaysia have launched campaigns to educate parents and promote time outdoors. Advocating a little extra

There is a large body of epidemiological evidence that points to the protective effect of time outdoors in delaying or preventing the onset of myopia

Figure 1: Children should be encouraged to take regular breaks from nearwork and increase time spent outdoors

Despite the lack of certainty surrounding the mechanism of the protective effect of time outdoors, it should be considered as an effective and straightforward strategy to reduce the risk of myopia development in children

time outdoors is better than none and it is ideally aimed at children not yet myopic but with a high risk of developing myopia.[14]

Nearwork

The other aspect of behaviour that has long been associated with myopia is nearwork. With the increase in use of digital devices, many parents question the impact on their child's eyes. Evidence is equivocal as to whether there is any impact on myopia development and progression.[15] Given the high association with nearwork the recommendation is to take regular breaks and increase working distance whenever possible.[16] Figure 1

Interventions to Slow Myopia Progression

For decades, we have corrected the visual error resulting from myopia with standard single vision spectacle or contact lenses. Current evidence supports optometrists to actively manage myopia in children through use of a range of options. The evidence of treatment efficacy is variable both between intervention strategies and among individuals; however, research is directed at improving efficacy and refining individual response.

Optical Interventions

Various optical approaches to myopia control have been developed and evaluated over the past few decades. Optical interventions to slow myopia progression have stemmed from two key theories that in relation to a connection between amount of blur the eye receives and myopia progression. The first theory proposes that excessive accommodative demand caused by near work and a small focussing error at near could be influential in myopia development.[47] The second hypothesis is that even in the presence of a clear image centrally the amount and type of blur falling elsewhere on the retina may influence myopia development.[48]

Spectacles

As a minimum children should have full correction of their myopia as there is some evidence that under-correction accelerates rate of growth of the eye and faster myopia progression.[17] Numerous studies have investigated the impact of different designs of spectacle lenses on myopia progression. Early studies focused on the use of bifocal and progressive addition lenses. A modest reduction in myopia progression was found when compared with single vision spectacles.[18] However, although these studies have found a statistically significant result their outcomes are less impactful clinically. For instance, the largest clinical trial of 469 children aged six to 11 years found a difference of 0.20D myopic progression when comparing progressive addition lenses to controls;[19] this change was over a three-year period and is, therefore, of limited value clinically. Interestingly, a study examining the effect of an executive bifocal found that over a three-year period the degree of myopia progression was reduced by 0.75D equating to 39% compared to single vision spectacles and this was increased to 1.00D (51%) with prismatic bifocals.[20] However, the cosmetic appearance of executive bifocals may deter children and their parents from considering this option.

More recently some novel spectacle lenses have gained attention. One such design has a central zone that corrects for distance vision surrounded by micro lenses of a relatively more plus power have shown reduction in myopia progression and rate of axial length growth in two year randomised controlled trials compared with single vision spectacles. The efficacy of these lenses is around 50-60%.[20] (https://www.opticianonline.net/features/in-focus-spectacle-lenses-that-slow-myopia-progression). Another novel design of spectacle lens using light scattering technology has shown promising one year clinical study results in slowing myopia progression in children.[21] Spectacle lens options for myopia management are becoming available commercially in some parts of the world and are expected to be launched in the UK and Europe in the coming months.

Contact lenses

Different designs of contact lenses have been successful in slowing the progression of myopia. In addition to the myopia control benefits contact lens wear provides other advantages to children and adolescents who do not enjoy wearing spectacles. As well as providing the necessary vision correction, they have been shown to improve vision-specific quality of life in myopic children younger than 12 years of age.[22]

Orthokeratology

Orthokeratology (also known as orthoK) is an effective way to correct myopia through corneal reshaping with overnight wear of rigid gas permeable contact lenses. It has also been found to be a successful strategy in myopia control by causing central corneal flattening and paracentral corneal steepening, which alters the image shell and thus the type of blur falling on the retina. Two recent meta-analyses both concluded that orthokeratology can slow eye growth on average by 48%.[23,24] Further studies have found between 32–63% reduction in myopia progression compared to controls.[25,26] Most importantly, orthokeratology appears to slow axial elongation, which is the precipitating factor in many of the pathological consequences of myopia, such as retinal detachment. Cho and Cheung concluded that orthokeratology could reduce the risk of rapid axial elongation (>0.36mm/year) by 88.8%.[27] There is large amount of research supporting orthokeratology as an effective and successful strategy for myopia control. The other advantage of orthokeratology is that children are then both spectacle and contact lens free during the daytime.

Multifocal and dual focus contact lenses

Both innovative myopia control specific soft contact lens designs and multifocal soft contact lenses (with a centre-distance design originally intended for presbyopia correction) have been trialled in children. A novel dual-focus daily disposable contact lens, MiSight® 1 day by CooperVision, has been licensed for myopia control use and is available commercially, it is CE marked in Europe and it is the only FDA approved intervention for myopia control. The lens has a large central distance area and several concentric peripheral 'treatment' zones which create 2.00D of relative peripheral myopic defocus.[28] The simultaneous defocus from the distance and

Recent data published from a three-year randomised double-masked multi-centre clinical trial involving 144 children aged eight to 12 years, found that the dual-focus contact lens was able to slow myopia progression by 59% and axial elongation by 52%

Children from as young as eight are able to confidently handle contact lenses

We have access to a range of interventions with good evidence that should inform our clinical practice and ensure that myopia management becomes the standard of care for children with myopia

relative plus zones seems to slow the progression of myopia. Recent data published from a three-year randomised double-masked multi-centre clinical trial involving 144 children aged eight to 12 years, found that the dual-focus contact lens was able to slow myopia progression by 59% and axial elongation by 52%.28 A recent study using multifocal soft contact lenses in children with myopia found treatment with high add power multifocal contact lenses significantly reduced the rate of myopia progression over 3 years compared with medium add power multifocal and single-vision contact lenses.[29] Other designs of soft contact lenses have also shown promising results for myopia management.[30,31] Multifocal and dual focus contact lenses are an effective interventional strategy for practitioners working in primary care to implement and actively manage myopia progression in children.

Pharmacological Interventions

Atropine

Atropine has been widely investigated in myopia control research for decades. It is a non-selective muscarinic receptor antagonist which causes mydriasis and cycloplegia. The typical indication is for 1% atropine eye drops to be used in children to treat inflammation, as a potent cycloplegic agent or for penalisation treatment in amblyopia (www.medicines.org.uk/). The majority of research with atropine in the field of myopia stems from East Asia and in particular Singapore. The Atropine for Treatment of Myopia (ATOM) study investigated the efficacy of using 1.0% atropine for myopia control.[32] It found that children who used 1.0% atropine had a significantly reduced myopic progression over a two-year period; however, a rebound effect was found after cessation of treatment. This study was followed up by ATOM2 which compared three lower doses of atropine 0.5%, 0.1% and 0.01%.[33] Over a five-year period the 0.01% atropine dose was found to be the most effective in slowing myopia progression with an overall progression of -1.38D compared to -1.83D in the 0.1% dose group, and -1.98D in the 0.5% dose group; the 0.01% dose also showed less of a rebound effect. Furthermore, atropine at the lowest dose demonstrated the least number of side effects compared to the higher doses, in particular there was minimal impact on pupil size and accommodation[34] There are some queries however over the impact of this low concentration of atropine on axial length progression suggesting that we do not currently know the optimum concentration of atropine for use in management of myopia. In Europe there are a number of ongoing trials using low concentrations of atropine to determine the efficacy in European populations.[35] It should be noted that the mechanism behind this myopic control strategy is not well understood at this stage.

Other pharmaceutical interventions

Other pharmaceutical options that have been used in clinical trials are pirenzepine and 7–methylzanthine. Pirenzepine is also an anti-muscarinic drug that has been used in the treatment of gastric ulcers. It is more selective than atropine and as such produces fewer side effects, such as photophobia and blurred near vision.[36] Studies in the US and Singapore have found a reduction in myopia progression of approximately 50%.[18] However, it is not currently approved for commercial use in myopia control in any countries.

7-methylxanthine (7-mx) is a metabolite of caffeine and theobromine that is created when coffee or chocolate is consumed. Animal studies have found that 7-mx thickens the sclera by increasing the diameter of the scleral collagen fibrils. A study of children aged eight to 13 years in Denmark investigated the effect of a 400mg dose of 7-mx taken twice a day.[37] After a year, the myopia progression was reduced by 44% compared to a placebo. It appears to have a low toxicity and minimal side effects and, therefore, further work in this area could identify a prospective myopia control intervention.

It should be remembered that with any pharmacological intervention, the child would still require an optical correction for their myopia to allow them to see clearly in the distance. Therefore a natural question would be to consider if combination therapies could be additive in their effect. Work is underway with both optical and atropine interventions with some supportive evidence emerging.[38]

Conclusions

This review highlights that although no one treatment is 100% effective in all patients, substantial benefit is obtained in terms of slowing the rate of myopia progression in children. Myopia management is time sensitive with greater impact on younger children. By slowing myopia progression and rate of axial length growth in a child's eye we not only benefit the individual from reduced risk of future ocular pathology but make gains on a public heath scale. The subsequent article in this series on myopia will explore the risk and benefits of myopia management in more detail. Myopia management is a rapidly advancing field with new evidence and strategies emerging. In the meantime, we have access to a range of interventions with good evidence that should inform our clinical practice and ensure that myopia management becomes the standard of care for children with myopia.

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Risk-to-Benefit Comparison of Myopia Controlling Contact Lenses

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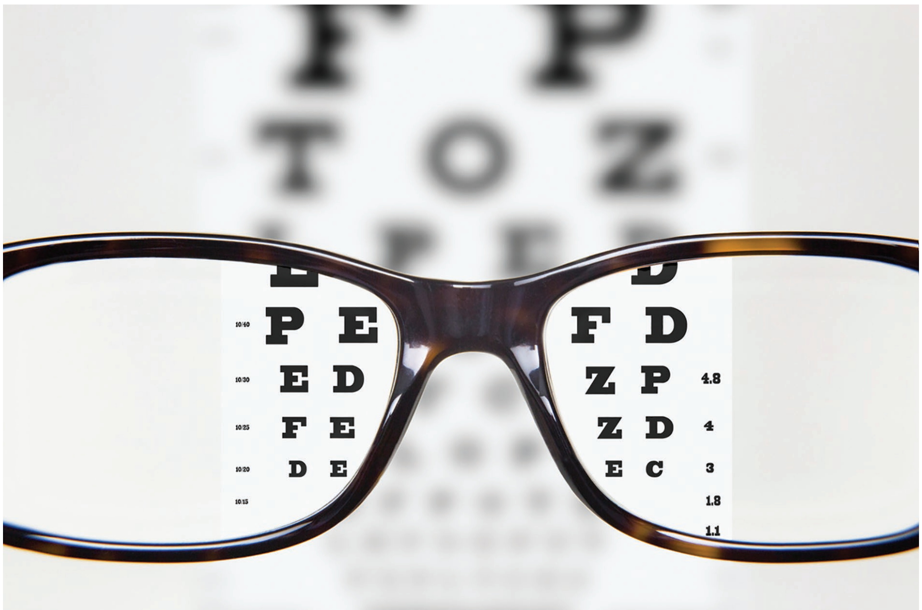
An analysis of the safety of myopia controlling contact lens wear in childhood compared to the lifetime risks of eye disease and vision impairment associated with myopia.

The lifetime risk of vision impairment (by age 75) increased from 1.6% in eyes with an axial length of less than 26mm to 13% in eyes of 26mm or greater



Myopia is now recognised as a disease and not just a simple vison condition corrected with spectacles or contact lenses.

Myopia is becoming more prevalent across ages and ethnicities of populations around the world. By 2050, it is predicted that half of the world's population - five billion people - will be myopic, with nearly one billion high myopes at significant risk of myopia related ocular pathology and vision impairment.[1] While high myopia is strongly linked to higher risk of eye diseases such as cataract, retinal detachment and myopic macular degeneration, even lower levels of myopia are associated with increased lifelong risk of pathology compared to the risk for non-myopes.[2] Hence, myopia is now recognized as a disease rather than a simple refractive condition. The International Myopia Institute White Paper reports, a worldwide academic consensus project, have reaffirmed the growing public health burden of myopia[3] and explored the research,[4] industry[5] and clinical[6,7] landscape required to meet this challenge.

Understanding the Lifetime Risks of Myopia

Myopia is defined by both refractive error and abnormally long axial length of the eye.[8] A large cross-sectional study from the Netherlands[9] described the risks of uncorrectable vision impairment in myopia (defined according to the World Health Organization criteria as a visual acuity less than 0.3 logMAR, being 6/12 or 20/40 in Snellen[10]) by both refractive error and axial length, including data from almost 16,000 people of European descent with an average age of 61 years. The lifetime risk of vision impairment (by age 75) increased from 1.6% in eyes with an axial length of less than 26mm to 13% in eyes of 26mm or greater. Similarly, more than 6D myopia was accompanied by a 39% risk of vision impairment by age 75 while lower than 6D of myopia carried a 3.8% risk.

This risk is already evident in Asian countries, where the high frequency of myopia has resulted in myopic macular degeneration becoming the leading cause of monocular blindness (worse than 6/120 or 20/400) in Japanese adults of middle age,[11] and in new cases of blindness in Chinese adults, accounting for almost 20% of all new blindness cases registered.[12]

Rationale for Myopia Control with Contact Lenses

'Myopia control' is the terminology for any intervention which reduces the axial and refractive progression of childhood myopia, by whatever mechanism and statistically significant level of efficacy compared to a control.[4] The appeal of myopia controlling contact lenses is in both correction and control of myopia, with better efficacy for control than most commercially available spectacle lens options[13] except for one specific prismatic bifocal design[14] and a novel multi-segment defocus design which currently has limited commercial release.[15] These two spectacle lens options appear to have similar, but not higher, efficacy than myopia controlling contact lens options which include dual-focus and multifocal soft contact lenses (SCLs), and overnight-wear orthokeratology (OK).[16]

Demonstrating propensity for slowing both refractive and axial length myopia progression by around 50% over two and three year studies,[17,18] myopia controlling contact lenses also appear to have similar efficacy as pharmacological intervention with atropine 0.025% and 0.05% eye drops, and better efficacy than the clinically popular 0.01% atropine eye drops in current compounded formulations.[19] Restricted access of primary eye care professionals (ECPs) to atropine across the world also limits its widespread application, compared to the ready availability of contact lenses. In addition to myopia control, there are clear functional and psychological benefits of paediatric contact lens wear, especially in younger children aged 8-11 years who feel that their confidence, physical appearance, competence in activities of school and sport and social acceptance is improved.[20]

Contact Lens Safety in Children and Teens

Healthy contact lens wear in children is a primary concern for ECPs and parents alike. Parents believe that contact lens wear in adolescents is less safe than that in the general population.[21] This is at odds with the evidence that children and teens appear to be at least as safe in soft contact lens wear as adults, and in the case of children aged 8-12 years, perhaps safer than teens and adults.[22]

Myopia controlling contact lens modalities include daily disposable and reusable SCLs, the latter of which are typically worn each day for a month, being removed and disinfected overnight, before disposal. OK 'rigid gas permeable' (RGP) contact lenses are worn only overnight and removed upon waking, such that clear corrected vision is enjoyed without contact lenses during waking hours.[23] The safest modality of the myopia controlling contact lens wear is daily disposable SCLs,[24] although the risk of adverse events is also very low for reusable SCL and OK modalities.

The overall frequency of corneal infiltrative events (CIEs) has been estimated at 97 per 10,000 patient wearing years in children (aged 8-12 years), and 335 per 10,000 in teens (aged 13-17 years). The frequency of the most serious

Restricted access of primary eye care professionals (ECPs) to atropine across the world also limits its widespread application, compared to the ready availability of contact lenses

Contact lens wear in children improves their confidence and self-perception of competence in school and sport activities.

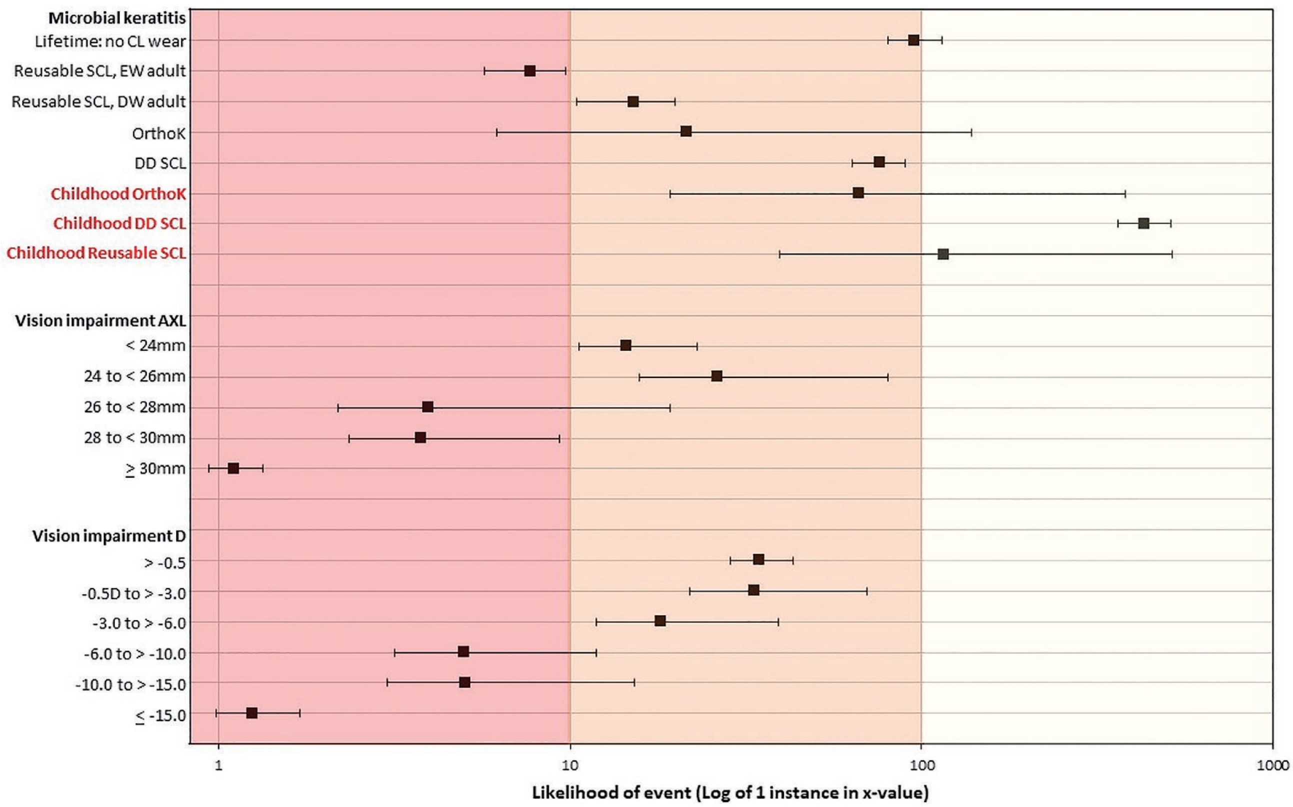


FIGURE 1: Likelihood of each ocular health event occurring once for an individual, with 95% confidence intervals presented on a Log scale. All likelihoods are presented over a lifetime, except for three childhood microbial keratitis risks as indicated. The WHO CIOMS classification system[33] for frequency of adverse events is indicated by coloured shading – red indicates very common (more than 1/10), orange indicates common / frequent (between 1/10 and 1/100) and yellow indicates uncommon / infrequent (between 1/100 and 1/1000). CL = contact lens; SCL = soft contact lens; EW = extended (overnight) wear; DW = daily wear; DD = daily disposable; AXL = axial length of the eye; D = dioptres of myopia. Reproduced with permission from Gifford KL. Childhood and lifetime risk comparison of myopia control with contact lenses. Contact Lens Anterior Eye 2020;43:26-32. doi: 10.1016/j.clae.2019.11.007.[31]

form of CIE, microbial keratitis (MK), appears be very low in childhood contact lens wear. In a retrospective study of 1054 mostly reusable SCL wearers encompassing 1372 patient-wearing years, children aged 8-12 years showed no cases of MK while teens (13-17 years) demonstrated an MK frequency of 15 per 10,000 patient-wearing years (95% confidence interval (CI): 2, 48, calculated by Bullimore[22]).[25] One prospective study of 247 children aged 8-11 years, of whom over 90% wore daily disposable lenses for a total of 723 patient-wearing years, showed no cases of MK.[26] A recently published, retrospective chart review of 963 children fitted at age 8-12 with a mean of 2.8 ± 1.5 years of wear provided data on 2713 patient wearing years and 4611 contact lens visits. Around 60% of the children were wearing daily disposable contact lenses, with data pooled from both community clinics and clinical trials. The annualised rate of non-infectious inflammatory adverse events was 0.66% per year (CI: 0.39-1.05). Only two probably MK cases were identified, giving a rate of 7.4 per 10,000 years of wear (CI: 1.8-29.6), and both were in teens.[27] Regarding OK safety, Bullimore and colleagues' retrospective case analysis of 1319 OK wearers representing 2599 patient years of wear indicated an incidence of MK of 13.9 per 10,000 in children (CI: 1.7, 50.4) and 7.7 in 10,000 for patients of all ages (CI: 0.9, 7.7).[28]

The general functional benefits of contact lens wear for children[20] as well as for paediatric myopia control[13] being increasingly recognized across eye care professions – a recent international survey published in 2020 showed growth in contact lens fits for myopia control from 0.2% of all lens fits in 2011 to almost 7% in 2018.[29] Given these multitude of benefits, though, myopia controlling contact lens uptake is still very low, likely indicating both professional and parental reticence to consider contact lenses as a first line treatment for myopia control. Confidence may be increased with better understanding of the short-term risks of contact lens wear compared to the lifetime risks of myopia associated pathologies, to best inform proactive clinical management.[30]

Comparing the Short-Term and Long-Term Risks

A recent analysis the likelihood of contact-lens related infections in children to myopia-associated ocular pathology and vision impairment provides the foundation for this comparison. Gifford[31] utilized peer reviewed data on contact lens safety in children and adults, alongside findings of the cumulative risk of vision impairment by age 75, based on axial length and level of myopia as presented by Tideman et al.[9] A model was constructed assuming contact lens wear commenced at age 8, in alignment with available safety data[22] and proactive commencement of a myopia control intervention.[6]

To calculate childhood risk, the same modality was assumed from age 8 until age 18 (10 years of wear). To calculate lifetime risk, the contact lens wearer was presumed to continue the same modality of contact lens wear from age 8 until 10 years before end of life, to bias the model towards the largest estimation of contact lens risk. A lifetime was set as 75 years, in alignment with the data of Tideman et al.[9] The risk of MK in a non-contact lens wearing population was also calculated for reference[32] to give an additional comparative lifetime risk (Figure 1). Non-contact lens wearing periods of a lifetime – modelled as the first 8 and last 10 years of life (18 years total) – were also added to the cumulative risk calculations for contact lens wearing scenarios.

Figure 1 demonstrates the lifetime likelihood of an adverse event, categorized in frequency according to the World Health Organization (WHO) and Council of International Organizations of Medical Sciences (CIOMS) classification system of 'very common', 'common / frequent' and 'uncommon / infrequent'.[32] The lifetime likelihood of MK in five 'lifetime' and three 'childhood' contact lens wearing scenarios was compared to the lifetime likelihood of vision impairment in myopia.

Contact Lens Wear is Safe in the Short-Term and Beneficial in the Long-Term

As described by Gifford,[31] "The comparative lifetime risks of contact lens wear commenced at age 8 for myopia control, and continued throughout life until age 65, are relatively less than the lifetime risks of vision impairment from myopia-associated pathology when myopia is over 3D or axial length in excess of 26mm. When only childhood CL wear is considered, the risk comparison is clearly skewed towards the positive impact of CL wear, especially in daily disposable CL wear." The results indicate that the likelihood of one case of MK in a childhood of daily disposable (1 in 431) or reusable (1 in 116) SCL wear is 'uncommon / infrequent' (less than 1/100) while the risk in OK wear is 'common' at 1 in 67. Since the confidence intervals overlap, though, reusable SCLs and OK are likely of a similar safety profile.

Currently, the median age of a child fit with a myopia controlling contact lens is 13 years, with around 30% fit to children under age 12.[29] Since the fastest time of childhood myopia progression occurs before age 12,[34] proactive contact lens fitting for myopia control should have a lower median age than 13, with a majority fit by age 12. There is a positive risk-to-benefit picture of fitting children with myopia controlling contact lenses at younger ages, where limitation of myopic refractive progression and axial elongation has more potential impact on the final level of myopia and length of the eye.[34] Moreover, the

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Contact lenses can be safely and confidently prescribed to children and teens to control myopia progression.

safety profile of contact lens wear in childhood (before age 12) is robust.[22] Even continued CL wear into adulthood shows lower risk than that of vision impairment in higher levels of myopia. If daily disposable CLs cannot be fit, maximizing the CL safety profile in younger children involves reinforcement of care and maintenance instructions. A small reduction in the percentage of children correctly answering CL care and handling questions after three months of wear has been observed compared to teens,[35] although in general children and teens demonstrate higher levels of compliance with lens disinfection and hand washing than their adult counterparts.[36, 37]

Contact lenses can be safely and confidently prescribed to children and teens to control myopia progression.

Gifford[31] stated that "the effectiveness of health relevant messages depend on framing both the gains and losses, and to what degree a particular health behaviour is perceived as risky.[38] As such, [the] data indicates that myopia controlling CL wear for children can be framed in discussion as a health-affirming choice in the short term, when balanced against uncontrolled myopia progression to more than 3 dioptres or 26mm axial length which increases the lifetime risk of vision impairment." While all myopia controlling contact lens modalities show strong safety profiles when worn in childhood, daily disposable SCL wear shows the most obvious weighting towards maximum benefit and minimal risk. The functional, psychological and preventative eye health benefits of myopia controlling contact lenses should give ECPs and parents confidence to consider them a first line management option for children under 12 with progressive myopia.

While all myopia controlling contact lens modalities show strong safety profiles when worn in childhood, daily disposable SCL wear shows the most obvious weighting towards maximum benefit and minimal risk

Artistic interpretation of myopia as experienced without spectacles or contact lenses.

As children grow, their myopia grows with them leading to greater dependence on vision correction and greater lifetime risks of vision impairment.

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Making a Difference – Why Every Dioptre Matters

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Eye care professionals (ECPs) may ask why, when we can correct myopia with spectacles, contact lenses and laser refractive surgery, should we worry about slowing its progression?

In the accompanying articles, we have learned about the increasing prevalence around the world,[1,2] the sight-threatening consequences of higher levels of myopia,[3] and the growing evidence-based literature supporting a variety of management options for its control along woth the risk-to-benefit equation of intervention. Nonetheless, eye care professionals (ECPs) may ask why, when we can correct myopia with spectacles, contact lenses and laser refractive surgery, should we worry about slowing its progression? Bullimore and Brennan propose three evidence-based answers to this question for practitioners and parents alike.[4] Central to these issues is the need to care about the long-term visual health of every patient, and not just address their current visual needs. Thus, there are three broad benefits of lowering a patient's ultimate level of myopia to the long-term care of a patient:

- The higher myope will have poorer visual acuity, even when corrected, more difficulty performing everyday tasks, and report more challenges related to their vision. Higher myopes also have a higher incidence of adverse events, probably because they take more risks with their contact lenses.[5]
- Myopic children may consider laser vision correction as adults. Lower levels of myopia are associated less post-surgical refractive error, with better postoperative uncorrected visual acuity and fewer secondary surgical enhancements. Postoperative visual quality is poorer with greater levels of preoperative myopia.[6]
- Higher levels of myopia are associated with increased risk of eye disease and visual impairment later in life.[7]

It is this third issue that is driving interest in myopia management. Reducing the incidence or prevalence of any disease by a meaningful amount is of huge public health significance. Myopia has long been associated with increased risk of cataract, glaucoma and retinal detachment, but the greatest myopia-related cause of irreversible vision loss is myopic maculopathy, also referred to as myopic retinopathy or myopic macular degeneration.[8-10] Furthermore, recent research has allowed for the quantification of the risks associated with the *level* of myopia and we now know that slowing myopia progression by 1 dioptre in children can make a huge difference.

Myopic maculopathy is characterised by stretched blood vessels, peripapillary atrophy, posterior staphyloma, lacquer cracks in Bruch's membrane, geographic atrophy of the retinal pigment epithelium and choroid, subretinal haemorrhages, and choroidal neovascularisation. These sight-threatening retinal changes occur later in life, but the underlying myopia develops during childhood and has often stabilised by the age of 21.[11] Unlike other common eye diseases, it does not have an established treatment.[12]

Bullimore and Brennan4 combined data from five large population-based studies of the prevalence myopic maculopathy from three continents.13-17 Collectively, these studies represent 21,000 patients, mostly above 50 years old. Figure 1 plots the prevalence of myopic maculopathy as a function of degree of myopia using data are taken directly from the publications. The similarity of the slopes across the five studies is remarkable thanks, in part, to the use of a logarithmic scale. The crude average of the slopes is 1.67x per dioptre. In other words, each dioptre increase in myopia is associated with a 67% increase in the prevalence of myopic maculopathy. Restated, slowing myopia such that a patient's refractive error is lower by 1 D should reduce the likelihood of them developing myopic maculopathy by 40%, regardless of race or disease definition. This is a huge public health effect. Furthermore, given the constant slope, the treatment benefit should accrue regardless of the level of myopia. Thus, while the overall risk of myopic maculopathy is higher in a –6 D myope than in a –3 D myope, slowing their myopic progression by 1 D during childhood should lower the risk by 40% in both. Finally, we should consider myopic maculopathy a disease of myopia, rather than a disease of high myopia. Myopes below 5 D contribute around half of the cases of myopic maculopathy,[13,18] because there are far more myopes at the low end of the refractive spectrum.

The same process can be applied to other eye diseases. For example, each additional dioptre of

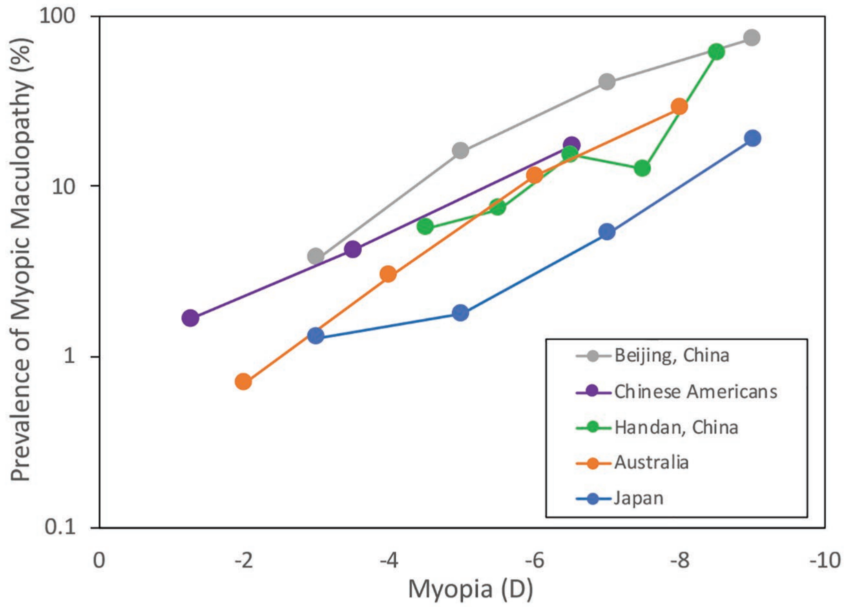

Figure 1. The prevalence of myopic maculopathy as a function of level of myopia in five studies (redrawn from Bullimore and Brennan).[4]

myopia is associated with a 20% increase in the prevalence of primary open angle glaucoma and posterior subcapsular cataract. Likewise, each dioptre increases the annual incidence of retinal detachment by 30%.

Myopia and Visual Impairment

With the exception of myopic maculopathy, the aforementioned eye diseases can be managed, but what about the relationship between level of myopia and visual impairment? The data are again compelling. Tideman et al. published the most comprehensive data on visual impairment and myopia, analysing data from 15,404 adults in the Netherlands (mean age 61±11 years) in whom refractive error and visual acuity had been measured.[7] In their paper, they plot the cumulative risk of visual impairment as a function of age for five levels of myopia. Their graph was digitized, and the cumulative risk of visual impairment is replotted as a function of myopia level for five ages in Figure 2. The midpoint of each refractive error range was used. On a logarithmic scale, the data show a clear parallel trajectory at all ages. The slopes of the lines are around 1.35x per dioptre, so we can say that, regardless of age, each dioptre of myopia is associated with a 35% increase in the

Myopic maculopathy is characterised by stretched blood vessels, peripapillary atrophy, posterior staphyloma, lacquer cracks in Bruch's membrane, geographic atrophy of the retinal pigment epithelium and choroid, subretinal haemorrhages, and choroidal neovascularisation

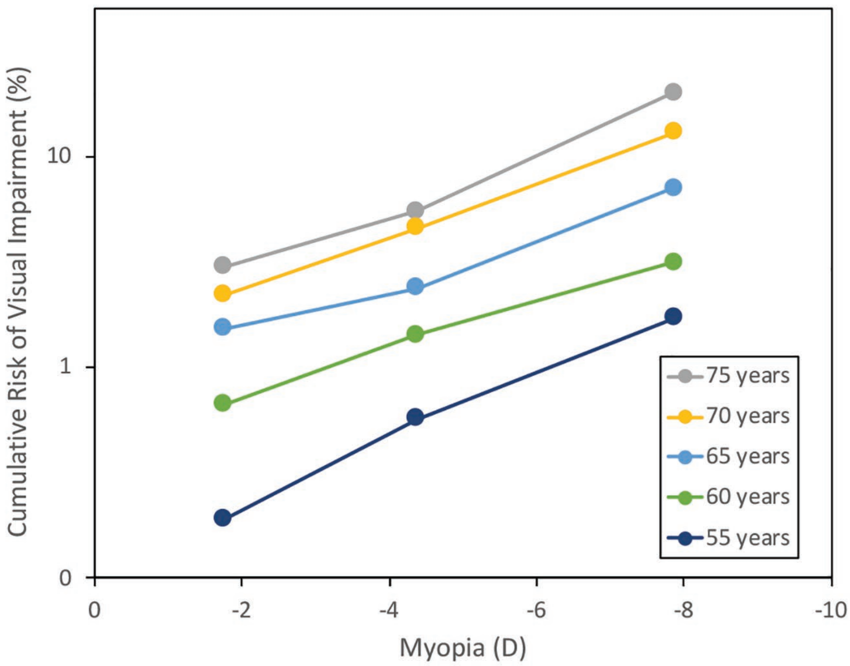

Figure 2. The cumulative risk of visual impairment as a function of level of myopia at five ages on a logarithmic scale. Data are from Figure 2 of Tideman et al.[7]

cumulative risk of visual impairment. Likewise, slowing myopia by one dioptre could reduce visual impairment by around 25%.

The relationship among age, myopia and visual impairment can be explored further. For example, in a multivariate model, one dioptre of myopia has the same effect on the risk of visual impairment as two years of aging. Likewise, each additional dioptre of myopia is associated with an extra year of visual impairment experienced by an individual patient. Thus, slowing myopia progression has the potential to improve the quality of an individual patient's life. In terms of the population, by 2050 around one third of all visual impairment will be attributable to myopia and slowing it by one dioptre could reduce the prevalence of visual impairment by 10%.

By 2050 around one third of all visual impairment will be attributable to myopia and slowing it by one dioptre could reduce the prevalence of visual impairment by 10%

A Call to Action

In summary, enthusiasm for myopia management relies on assumption that interventions in childhood will reduce risk of disease later in life and like all major public health issues, myopia requires a coordinated effort and a range of solutions. Indeed, an editorial in the journal of the American Academy of Ophthalmology states that "it is essential for ophthalmologists to work with optometrists, who are frontline providers, to determine a collaborative frame work and referral patterns to prevent myopic progression, educate patients on the risks of myopia, and proactively address associated pathology to serve the best interest of our patients."[19]

As described in an accompanying article, there are a range of modalities to slow myopia progression, with more options in the pipeline. Some, though not all, spectacle, contact lenses, and pharmaceutical treatments are effective.[20] The choice depends on the age of the child and their lifestyle. A discussion between parent and practitioner will identify what is best for an individual patient.

Myopia management won't affect the overall prevalence, just the severity of the disease and its consequences to vision. The next decade will likely see the emergence of options to help delay myopia onset. We already know that a child spending more time outdoors lowers the risk, and pharmaceutical and spectacle-based preventive treatments are under evaluation.

In closing, young, myopic children can be offered a range of clinically useful myopia control interventions that have the potential to reduce the risk of visual impairment later in life. Myopia should no longer be considered an inconvenience, but a manageable condition with a narrow window of opportunity to have the biggest impact. Stay informed and connected to remain up to date in this rapidly advancing field.

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Future Outlook

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The prevalence of myopia is high and increasing with approximately 5 billion people around the world expected to be myopic by the year 2050.[1] Methods to delay the onset and slow the progression of myopia, and therefore potentially decrease the myopia-associated sight threatening complications, have the potential to impact the individual, the economy and health care systems.

Routine Appointments for Childhood Eye Examinations Should Be Routinely Scheduled

Parent surveys provide insights into awareness about their child's ocular health; they believe that vision screening is the same as a comprehensive eye examination, and are only likely to visit their eye care professional if they or someone they know, like a schoolteacher, notices a problem.[2] This can be the case even for myopic parents who may not be aware that their myopia might be hereditary.[3] Given that the age of onset of myopia typically occurs between age six and fourteen years of age, comprehensive eye examinations must be on the agenda for all children as part of their overall healthcare assessments through the school years. Good vision is critical to help ensure that children do not miss out educationally, or suffer detrimental effects to their social development with long lasting impact into adulthood.[4] The importance of comprehensive eye examinations for young children has never been more important with enforced lock-downs and quarantines resulting in a swift educational restructuring that relies primarily on extra time spent indoors in front of screens to attend classes, likely exacerbating environmental issues that have been shown to affect myopic progression.[5] While these changes are not permanent, the push toward digital reliance and remote work has inevitably impacted the nature of work and study, placing more responsibility on parents to implement and maintain conscientious approaches to balancing outdoor time, and imposing breaks and time limits on near work and the use of digital devices.[5]

Understanding the refractive status of children and comparing this with expected age-normal values is well within the remit of eye care professionals and can help to identify those children at risk of over-shooting the emmetropinisation process and becoming a myope of the future. This knowledge can support a clinical management protocol where

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children identified as 'pre-myopes' (children at risk of becoming myopic) can be advised on increased time outdoors and reduced near work, and an appointment schedule for close follow-up agreed. Delaying the onset of myopia may help reduce the magnitude of the final prescription.[6] Children who become myopic, or those that already are myopic and wearing conventional single-vision correction, can be offered myopia management options to help slow down eye growth progression rates to help reduce the risk of myopia related vision complications later in life.[7]

Advancements in the Landscape of Childhood Myopia Management

MiSight® 1 day (CooperVision, Inc.) is a soft, daily disposable contact lens designed specifically for myopic children and was the first myopia control intervention to be granted a CE indication and has been available for a decade. Several other optical interventions for myopia control with CE approval have become available including other soft contact lenses and orthokeratology. In 2019, MiSight® 1 day became the world's first and remains the only myopia management intervention to be FDA approved in the USA.[8*] It is expected more innovation and research will be seen in the coming years, resulting in an increasing array of interventions that offer clinical benefits in reducing myopia progression in children. The American Academy of Ophthalmology has recently created a taskforce in recognition of the substantial global increases in myopia prevalence and associated complications and has set out their key objectives to help formulate an action plan to address the issue from a range of perspectives including education, collaboration and advocacy.[9] This aligns with their 2018 stance that makes it clear that 'it is essential for ophthalmologists to work with optometrists, who are frontline providers, to determine a collaborative frame work and referral patterns to prevent myopic progression, educate patients on the risks of myopia, and proactively address associated pathology to serve the best interest of our patients'.[10]

The window of opportunity to intervene with myopia management is small, and eye care professionals need to act with a sense of urgency to offer the best options for children to benefit the most leading to better visual outcomes both in the short and longer term.[11]

References:

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* FOOTNOTE (Applies to USA only): Indications for use: MiSight® 1 day (omafilcon A) soft (hydrophilic) contact lenses for daily wear are indicated for the correction of myopic ametropia and for slowing the progression of myopia in children with non-diseased eyes, who at the initiation of treatment are 8-12 years of age and have a refraction of -0.75 to -4.00 diopters (spherical equivalent) with ≤0.75 diopters of astigmatism. The lens is to be discarded after each removal.

Notes:


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