

## Contact lenses to slow progression of myopia

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The prevalence of myopia has been steadily rising, with 28 per cent of the global population said to be affected in 2010 and to rise to affect nearly 50 per cent by 2050. Increasing levels of myopia increase the risk of vision impairment and in particular, high myopia is associated with the risk of serious and permanent visual disability due to associated sight-threatening complications. To stem the burden associated with higher levels of myopia, there are efforts to slow the progression of myopia, and several optical and pharmaceutical strategies have been found useful in slowing myopia to varying degrees. More recently, numerous multifocal soft contact lenses and extended depth of focus soft contact lenses (collectively referred to as myopia control contact lenses) were found effective in slowing myopia. As opposed to overnight orthokeratology, myopia control contact lenses are worn during the day and the hypotheses proposed to explain the efficacy of these lenses are generally based on the premise that the stimulus for eye growth is a defocused retinal image with hyperopic blur either centrally or peripherally. Although the individual power profiles of the lenses vary, the contact lens generally incorporates 'positive power' to reduce the hyperopic blur and/or impose myopic defocus or in the case of the extended depth of focus lens, has a power profile designed to optimise retinal image quality for points on or in front of the retina. The use of soft contact lenses as a platform for myopia control offers an exciting and effective avenue to manage myopia but there is a need for further research on issues such as the mechanism underlying control of myopia, improving efficacy with lenses, and understanding rebound on discontinuation. More significantly, although contact lenses are generally safe and improve quality of life in older children, one of the major challenges for improved uptake and acceptance of contact lenses centres on the perceived risk of complications with lens wear. This issue needs to be addressed.

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Owing to the vast global population affected and the burden of visual disability imposed by the condition, myopia is considered to be a pressing public health issue. With an estimated 1.5 billion people affected in 2010, myopia is the most common cause of distance vision impairment and is expected to rise to nearly five billion by 2050.<sup>1</sup>

For many, the visual disability of myopia is easily remedied with corrective devices but the risk of uncorrectable visual impairment rises with increasing myopia.<sup>2</sup> For some, especially during adulthood, myopia can result in permanent visual disability due to co-morbid conditions such as myopic macular degeneration, myopic maculopathy, retinal detachment and glaucoma.<sup>3–8</sup> Data from Japan and Taiwan suggest that myopic macular degeneration is already a major cause of blindness in these

societies<sup>9,10</sup> and models projecting future prevalence rates for myopia, high myopia and myopic retinopathy suggest that visual impairment and myopic retinopathy are likely to increase substantially by 2050.<sup>1,2,11</sup>

In recent years, there has been a surge of interest in solutions to better manage myopia to reduce:

- the risk of the eye becoming high myopic and the associated risk of developing sight-threatening complications
- the burden associated with progressing myopia, for example, reduce replacing optical devices frequently
- vision impairment due to uncorrected myopia.

Currently, myopia management mostly involves correction with spectacles and contact lenses, and to a lesser extent refractive surgery and orthokeratology. These approaches correct for the refractive error and

eliminate blurred vision at distance but with the exception of orthokeratology do not arrest or slow the axial length increase that leads to progression.

While myopia is multifactorial with both genetic and environmental factors playing a role in onset and progression, research indicates that it is well within the reach of the practitioner to slow the progress of myopia. In this regard, there is compelling evidence from animal studies that environmental factors such as form deprivation and defocus can be used to predictably manipulate the development and progression of refractive errors.<sup>12,13</sup> Significantly, experiments have demonstrated that optical defocus (plus and minus lenses creating myopic and hyperopic defocus) can be used to alter eye growth in a highly regulated manner involving both direction and magnitude.<sup>14–16</sup> Specifically, lenses with

concentric, plus powered zones that impose myopic defocus were shown to significantly influence emmetropisation.<sup>17,18</sup> In addition, over the years, anecdotal reports as well as optical and pharmaceutical approaches trialled in humans have indicated the feasibility of slowing the progression of myopia. For example, spectacle interventions using bifocal or multifocal spectacle lenses, or overnight orthokeratology, provide evidence for controlling the progression of myopia.<sup>19,20</sup>

This review discusses the role of contact lenses, other than overnight orthokeratology, for myopia control.

### CONTACT LENSES FOR MYOPIA CONTROL

The idea that contact lenses might play a role in slowing myopia progression was considered as early as 1975 with a finding that rigid contact lens wear slowed myopia progression compared to spectacles but not compared to atropine.<sup>21</sup> However, the lack of use of a controlled clinical trial approach makes it difficult to put the results into perspective. It is also not clear if corneal flattening seen with rigid lens wear may have influenced the result.

A later study from the 1990s found daytime wear of rigid gas-permeable (RGP) contact lenses (as opposed to orthokeratology lenses) slowed myopia compared to matched spectacle lens wearers. Some corneal flattening was found with rigid lens wear but the refractive power change attributable to corneal flattening did not fully explain the significant difference in progression between rigid lens and spectacle lens wear.<sup>22</sup> However, this finding was not supported by later evidence that found no difference in progression between those wearing RGPs versus spectacles.<sup>23</sup>

A subsequent trial found myopia progression to be less with RGPs compared to soft contact lenses, but the difference was noted only for spherical equivalent ( $-1.56 \pm 0.95$  D with RGP versus  $-2.19 \pm 0.89$  D with soft lenses) and not for axial length.<sup>24</sup> Therefore, the change in spherical equivalent was attributed to possibly corneal flattening with the RGP wearing eyes.

In contrast, earlier studies reporting on myopia progression with soft contact lenses in adult contact lens wearers reported 'myopia creep' – a phenomenon resulting in an increase in myopia with low Dk/t soft

lens wear, especially extended wear, due to corneal hypoxia and swelling.<sup>25–28</sup> No 'myopic creep' has been reported with the use of the new generation of lens materials used on a daily wear basis.

In studies involving children, use of soft contact lenses as opposed to spectacle lens wear did not result in a change in the rate of progression in myopia.<sup>29,30</sup> Interestingly, the power profiles across the optic zones of commercially available soft contact lenses vary greatly and are thought to affect peripheral refraction and possibly the growth of the eye.<sup>31–34</sup> If that is the case, one could expect to see differences in myopia progression with different contact lenses and also with other modalities. In this respect, a single group matched study, albeit with only six months of follow-up data, reported less progression with single vision soft contact lens compared to spectacle lenses.<sup>35</sup>

More robust evidence for slowing myopia was found with use of multifocal or multifocal-like contact lenses with data from case reports, cross over studies, comparative group and randomised longitudinal studies supporting the use of multifocal or multifocal-like contact lenses to slow the progression of myopia.<sup>36–45</sup> Indeed, as seen from Figure 1, soft contact lenses are one of the more effective modalities besides orthokeratology and atropine.<sup>46–64</sup> It is likely that for myopia control, contact lenses are a platform superior to spectacles or time outdoors. In relation to duration of mechanism for correction, contact lenses are worn for longer each day than time typically spent outdoors. Additionally, in relation to position of correction, contact lenses are superior to spectacles because the contact lens is coupled to eye movement.

Various hypotheses proposed to explain the myopia control effect of these lenses include:

- reduction/correction of accommodative lag<sup>45</sup>
- alteration of the position of the peripheral retinal image to reduce hyperopic defocus<sup>39</sup>
- imposition of sustained myopic defocus across the retina<sup>38,40,65</sup>
- correction of the hyperopic blur caused by negative spherical aberration during accommodation<sup>43</sup>
- alteration/optimisation of the retinal image quality for points on and in front of the retina and degradation of retinal

image quality for points behind the retina.<sup>44</sup>

Most of these hypotheses are generally based on the premise that the stimulus for eye growth is a defocused retinal image with hyperopic blur either centrally and/or peripherally. Therefore, lenses are designed to minimise hyperopic defocus and/or impose myopic defocus and the efficacy of such designs is assessed by monitoring the change in axial length and spherical equivalent refractive error over a period.

The contact lens that features most often in these experiments is a multifocal lens with two portions in the optical zone. One portion is devoted to correction of the distance refractive error at the fovea and the remaining portion that is relatively positive compared to the distance portion. The distance portion is commonly located at the centre (centre distance) of the optical zone to provide for uniformly clear vision at the fovea and the diameter depends on the lens design. The relatively positive zone is commonly +1.50 D or +2.00 D more positive compared to the portion devoted to distance power and is delivered either as concentric zones or a gradient power.

An exception to the above-mentioned lens profile is that which alters retinal image quality for extended depth of focus, wherein the mean power profile of the lens varies above and below the normal (distance refractive power) across the optic zone. Overall, these lenses were assessed in clinical trials for durations ranging from one to two years and show efficacy with respect to slowing myopia anywhere from 20 to 72 per cent for spherical equivalent and in similar magnitude for change in axial length (Table 1).

In the studies supporting the effect of lenses in slowing myopia progression, lens wear was mostly daily wear with regular replacement or daily disposable. Additional benefits may accrue with the use of soft contact lenses in comparison to other modalities by way of reduced side effects in comparison to atropine; improved quality of life, especially in older children and teens with wear of contact lenses in comparison to spectacle lens wear; and reduced risk of microbial keratitis compared to overnight orthokeratology.<sup>66,67</sup> Children aged seven years and older were found to be capable of handling and wearing most contact lens modalities.<sup>30,39,68</sup> With some lenses commercially available (although at

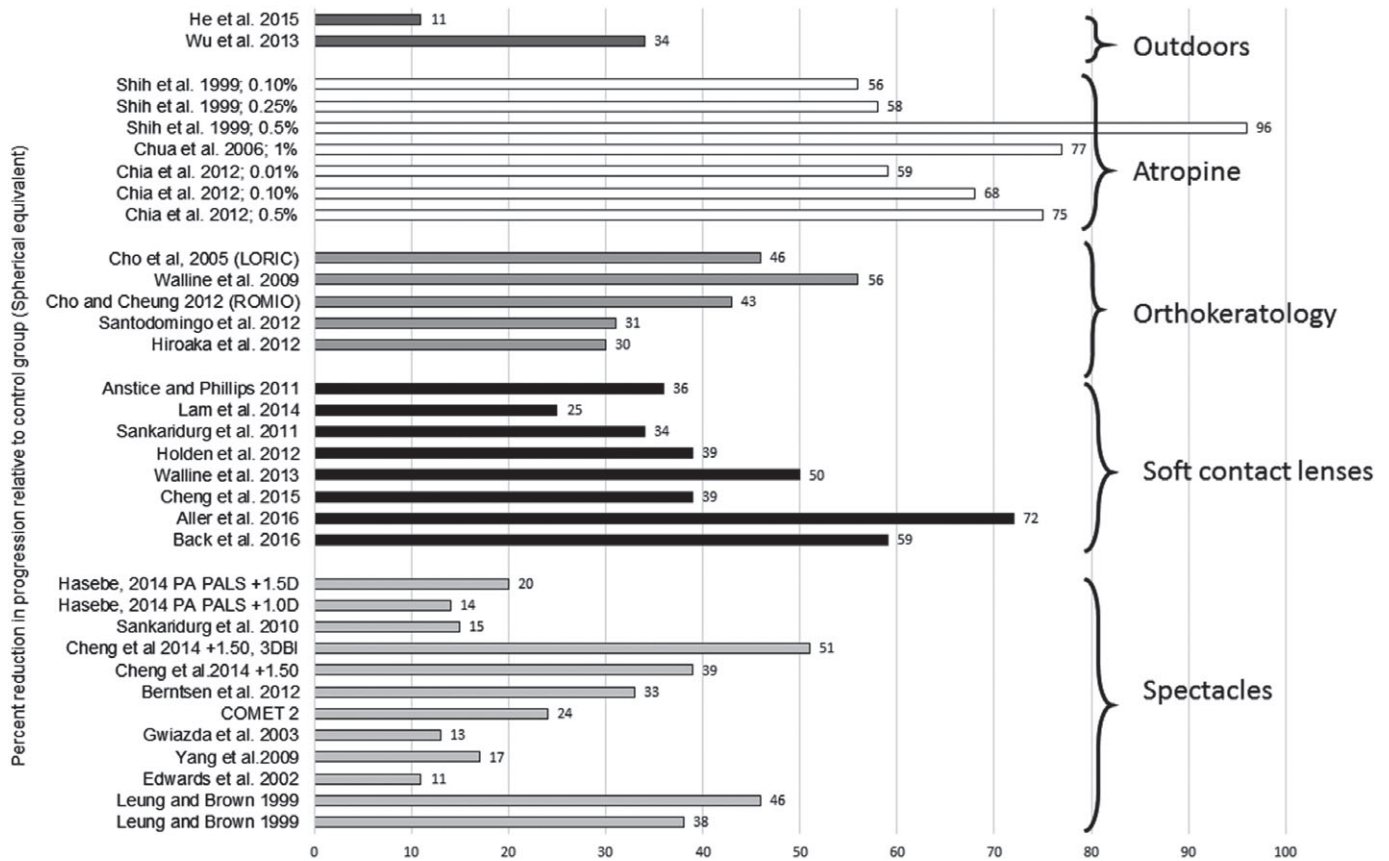


Figure 1. Myopia control with outdoor, atropine, contact lens and spectacle lens strategies

the time of this review, none of them has had specific regulatory approvals for myopia control), clinicians are able to incorporate soft contact lenses as a tool for myopia control in their practices.

As much as contact lenses are an effective and an attractive option for myopia control, contact lens wear is not without problems. The central issue weighing on the performance of contact lenses is related to safety of lens wear. In children wearing contact lenses, even though not serious, complications have been reported; however, the risks did not appear to be different or less compared to those of adult contact lens wearers.<sup>43,69-71</sup> Although contact lenses are generally safe, the increased risk of developing microbial keratitis with overnight wear and unsafe practices has resulted in an increased focus on the benefit versus risk ratio of contact lenses as a platform for myopia control compared to some of the other interventions (see <https://www.fda.gov/downloads/MedicalDevices>

/NewsEvents/WorkshopsConferences/UC M536686.pdf).

Issues around discomfort and inconveniences related to lens handling might further limit survival in lens wear and effective use of contact lenses for myopia control.<sup>72</sup> In fitting multifocal contact lenses for myopia control, consideration needs to be given to the fact that power variations across the optical zone might affect vision performance which might in turn affect compliance to lens wear. Indeed, compliance with proper procedures for lens wear was assessed and found to be important in slowing progression of myopia with defocus incorporated soft contact lenses.<sup>40</sup> In this respect, visual acuity with a dual focus lens designed for myopia control was found to be effective but the subjective visual performance as reported by patients was less compared to habitual vision.<sup>73</sup> In non-presbyopic myopic participants, lenses featuring multifocality were found to decrease visual performance, in particular when power variations across the optic

zone were large or when the lens was decentred.<sup>74</sup>

#### IMPROVING PERFORMANCE OF MYOPIA CONTROL LENSES

The performance of myopia control contact lenses so far has spurred thoughts and questions on various aspects, such as, for example, improving efficacy with myopia control contact lenses, rebound on discontinuation of lens wear, efficacy with long-term wear and use of combination treatments to improve efficacy.

With respect to improving efficacy, evaluating the response of an individual to treatment with any myopia control option, including contact lenses, continues to challenge researchers and practitioners alike. Although the efficacy as reported from the various clinical trials, that is, a range of 20 to 72 per cent, is encouraging, the result is an average and therefore some eyes are

Lens type	Authors	Control group	Per cent reduction versus control		Study duration (years)	Significant difference between groups	Dioptic difference* (D)	Evidence for myopia control
			Spherical equivalent	Axial length				
Rigid gas-permeable	Katz and colleagues 2003 <sup>23</sup>	Spectacle	-4	-6	2	×	0.05, (worse)	No evidence for myopia control Some change in spherical equivalent but not substantiated by axial growth patterns No evidence for myopia control Progression may be influenced by material, mode of lens wear and lens power profile Slow progress of myopia
	Walline and colleagues 2004 <sup>24</sup>	Soft CL	29	-7	3	✓	0.63, unadjusted	
Soft contact lens	Horner and colleagues 1999 <sup>29</sup>	Spectacle	-18	Not perf.	3	×	0.18, (worse)	
	Walline and colleagues 2008 <sup>30</sup>	Spectacle	-17	-7	3	×	0.22, adjusted, 0.19, unadjusted (worse)	
Multifocals								
Bifocals	Walline and colleagues 2013 <sup>41</sup>	Soft CL	50	29	2	✓	0.50, adjusted	
	Aller 2016 <sup>45</sup>	Soft CL	72	79	1	✓	0.57, unadjusted	
Peripheral defocus management	Holden and colleagues 2012 <sup>42</sup>	Soft CL	39	41	3.6	✓	0.64, unadjusted	
	Sankaridurg and colleagues 2011 <sup>39</sup>	Spectacle	34	33	1	✓	0.29, adjusted	
Simultaneous dual focus	Lam and colleagues 2014 <sup>40</sup>	Soft CL	25	42	2	✓	0.20, unadjusted	
	Anstice and Phillips 2011 <sup>38</sup>	Soft CL; contralateral	36	50	0.8	✓	0.25	
Positive spherical aberration	Back and colleagues 2016 <sup>65</sup>	Soft CL	59	53	2	✓	0.54	
	Cheng and colleagues 2016 <sup>43</sup>	Soft CL	20	39	1	×	0.14, adjusted	
Extended depth of focus	Bakaraju and colleagues 2015 <sup>44</sup>	Soft CL	51 53	58 53	0.5	✓	0.25, unadjusted 0.26, unadjusted	

\*Adjusted for factors influencing progression of myopia, for example, age. CL: contact lens.

**Table 1. Summary of evidence for myopia control with contact lenses**

likely to derive greater benefit from the treatment compared to others.

A significantly higher level of myopia control was achieved in a clinical trial that was limited to children with near esofixation disparity,<sup>45</sup> but other than this risk factor, there are no other reliable indicators identified of who is likely to respond to myopia control strategies. Conducting further clinical trials might shed light on factors related to improved efficacy but the lack of understanding of the underlying mechanism limits our ability to maximise the chance of obtaining positive responses. Research is required with regard to: selection of individuals based on age, ethnicity or other patient-related factors; the amount of relative positive power; type of design; effect of combination treatments et cetera.

While the ocular response to optical defocus is well characterised in animal models, little is known about how optical signals are decoded and relayed along the pathways in the retina, choroid and sclera, and how this is translated to structural changes that lead to increased axial length. In this respect, even though the choroid is found to respond to defocus,<sup>75</sup> much more research is needed to determine how the optical signals are translated, if any, to long-term changes in the sclera, or if there are other independent mechanisms in the retina and/or sclera that drive changes in eye length.

Regarding long-term efficacy, clearly there is need for research. In a five-year study in which children were randomised to either multifocal or single vision contact

lenses for the first 3.5 years, a consistent and significant myopia control was found with the use of the multifocal lens. For the remainder of the study, both groups were continued in multifocal lenses and there was a change in slope of progression similar to those seen with multifocal lenses, when eyes wearing control single vision lenses were switched to multifocal lenses.<sup>42</sup>

With respect to rebound of myopia upon discontinuation from lens wear, to date, there have been no studies that have monitored the progression in soft contact lens wear after discontinuation from myopia control contact lens wear. In considering evidence from other optical strategies, children wearing former progressive addition spectacle lenses showed no difference in progression compared to children wearing

single vision spectacles.<sup>57</sup> This suggests that while there was still eye growth, there was no faster progression or rebound.

However, data from contralateral studies involving multifocal soft contact lenses or orthokeratology suggest otherwise. In a contralateral study involving orthokeratology lens wear in one eye and RGP lens wear in the other eye, lenses were crossed over after six months. In the eye that previously wore an orthokeratology lens there was faster than normal axial length progression during the second period when subjects were switched to rigid lens wear, suggesting a rebound effect.<sup>76</sup> A similar result was seen in another study that involved contralateral wear of bifocal soft contact lenses versus single vision soft lenses for 10 months.<sup>38</sup> Clearly, further work is needed to determine whether there is rebound on discontinuation and whether there is variation in the magnitude of rebound depending on whether the discontinuation occurs during the sensitive period of ocular growth or after growth has stabilised.

## CONCLUSIONS

The use of multifocal contact lenses to slow the progress of myopia is substantiated by independent clinical trials and has proven to be one of the more effective myopia control strategies available to date. However, there remain unanswered questions around improving and retaining the efficacy observed with these lenses, many of which can be improved by further research. Because myopia control contact lenses are to be employed predominantly in children and teenagers when myopia is most progressive, practitioners need to consider not only patient and carer expectations around contact lenses, but also the risks and benefits of multifocal contact lenses compared to other strategies.

## DISCLOSURE

The author is an employee of the Brien Holden Vision Institute, which has a commercial interest in the control of myopia. The author is a co-inventor on patents and patent applications in relation to optical designs and methods for the control of myopia.

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