

Bifocal soft contact lenses as a possible myopia control treatment: a case report involving identical twins

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Background: Several studies have suggested that bifocal and progressive spectacles can reduce progression of myopia in esophoric children. This study compared myopic progression with bifocal (BSCL) and single vision soft contact lenses (SVSCL) in identical twins with near point esophoria.

Methods: Two 12-year-old myopic girls were randomly assigned to wear either BSCL or SVSCL for one year using a double-masked design. Both twins then wore BSCLs for another year. Ocular measurements included cycloplegic and manifest refractions, corneal curvature and axial length. Distance and near phorias were measured through distance corrections and near associated phorias, with both types of contact lenses.

Results: Through their SVSCLs, both children exhibited near associated esophorias, which were neutralised by the BSCLs. The child wearing SVSCLs over the first year showed significant myopic progression, increasing -1.19 D (binocular average), while the child wearing BSCLs showed no progression (+0.13 D). The latter child showed limited progression (-0.28 D) over the second year, while switching from SVSCLs to BSCLs arrested progression in the other child (+0.44 D after one year). Axial length data were consistent with the refractive findings; the child exhibiting more myopia at the end of the first 12 months of the study had longer eyes (by 0.64 mm) than her sister, although their corneas also had steepened more (by 0.44 D compared to 0.18 D). The children showed similar, small increases in eye size over the second year when both wore BSCLs (binocular averages: 0.05, 0.09 mm, respectively).

Conclusion: The apparent inhibitory effect of BSCLs on myopic progression reported in this twin study argues for further study of their efficacy as a control treatment for myopes with near esophoria.

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The increasing prevalence of myopia in some cultures and societies, in excess of 90 per cent for some university populations in Asia, supports the view that myopia and/or its progression is influenced by the environment.^{1,2} Myopia is now considered a major public health problem in some

Asian countries because of the potentially blinding complications associated with high myopia, which is also increasing in prevalence.^{3–5}

An environmental contribution to myopia suggests that appropriate intervention to prevent or slow the progression of

myopia should be possible. In terms of potential treatments for myopia, bifocal and progressive lenses prescribed as spectacles have been trialled with varying success in slowing myopic progression. In none of the reported studies has myopic progression been prevented, although

	Near phoria (Δ)	CL corrected near phoria (Δ)	Near associated phoria (D)	CL corrected associated phoria (D)	Contact lens initially worn
Twin A	4 Eso	Ortho	+2.00	0.00	-1.75/+2.00 -1.75/+2.00
Twin B	4 Eso	4 Eso	+1.25	+1.25	-1.25 -1.75

Table 1. The binocular status of the twins, measured with and without their initially assigned contact lens (CL) corrections in place. Twin A was wearing bifocal lenses, twin B, single vision lenses.

slowing of the progression of myopia has been reported in some studies and some subgroups of myopes.⁶⁻¹⁰ For example, in the COMET study, a large-scale prospective study in which progressive addition spectacle lenses (PALs) were prescribed to children, there was a clinically insignificant reduction in progression in myopic children fitted with PALs as compared with single vision lenses (SVLs) overall,¹¹ although significant slowing of myopic progression was found in those exhibiting near esophoria and/or high accommodative lags.¹² The effectiveness of the PALs for those with significant accommodative lags is also predicted from animal model studies showing increased rates of ocular elongation in response to hyperopic defocus.¹³ Specifically, by correcting accommodative lags and thus the resulting hyperopic defocus, PALs should lessen any related ocular growth response.

While there are many possible reasons for the bifocal and progressive lens treatment modalities not being very successful as therapies to control myopia, one possibility of relevance to children is that they do not use the near correction when presented in spectacle form.¹⁴ This problem is avoided with simultaneous vision bifocal contact lenses, which have become standard care, used off-label, for young progressing myopes in the practice of one of the authors (TA).

In the case study reported here, a pair of identical twin girls, presenting with similar amounts of binocular low myopia combined with near esophoria measured through their distance correction, partici-

pated in a masked study, in which one twin was assigned to wear bifocal soft contact lenses for one year, while the other twin wore single vision soft contact lenses. After one year, the child wearing the single vision lenses was switched to bifocal contact lenses. The data reported here are consistent with data compiled retrospectively from TAs practice.¹⁵ Each of these studies showed slowed progression of myopia with bifocal contact lenses although the cycloplegic refractions included in the current study make a more convincing case. Some of these data have been reported in abstract form.^{16,17}

METHODS

Study design

Two 12-year-old identical twin girls who presented with similar ocular profiles, with low myopia combined with near esophoria measured through their distance correction, were fitted respectively with bifocal (Twin A) and single vision (Twin B) soft contact lenses. The initial allocation of lenses was done under double-masked conditions, after obtaining appropriate informed consent from both the children and their parents. At the first review appointment, 13.7 months later, Twin B was switched to bifocal lenses with the approval of both the child and her parents. A further review examination was completed approximately 12 months later, bringing the total study duration to just over two years.

Contact lens treatments

The single vision lens used in this study was a 58 per cent water, two-week disposable spherical lens. The bifocal lens was made of the same material, by the same manufacturer and had a multi-zone simultaneous vision design (distance centre with alternating near and distance zones). Each of the subjects underwent a contact lens evaluation for both single vision and bifocal soft contact lenses. The subjectively determined spherical equivalent distance correction was used as the starting point in determining the single vision contact lens correction and the distance correction for the bifocal contact lens prescription. The final prescriptions achieved maximum distance vision with the least minus power. The near addition for the bifocal contact lens prescription was determined as the least plus power required to neutralise the near fixation disparity (plus lens required to neutralise associated phoria). These phoria data, including the associated phorias corresponding to the initially assigned contact lenses, as well as the powers of the prescribed lenses are summarised in Table 1.

Orders were placed for both lens types for each subject and an outside party randomly assigned the type of lens (bifocal or single vision) to be worn by each of the two children. Both children and their parents were informed that the lens manufacturer might mislabel the lenses, as a way of avoiding the unmasking of the children to their assigned treatments. Neither their practitioner (author TA) nor his staff was aware of the lens allocation or saw the lens packages. The lenses also were indistinguishable in terms of colour, lens markings, shape and size. The treatments were unmasked after the first annual review examination, when the child initially assigned to wear single vision lenses was refitted with bifocal contact lenses.

Measurements

A routine eye examination was followed by two further examinations, approximately one and two years after the commencement of contact lens wear. In addition to subjective refractions, data on objective refractive errors were collected at each

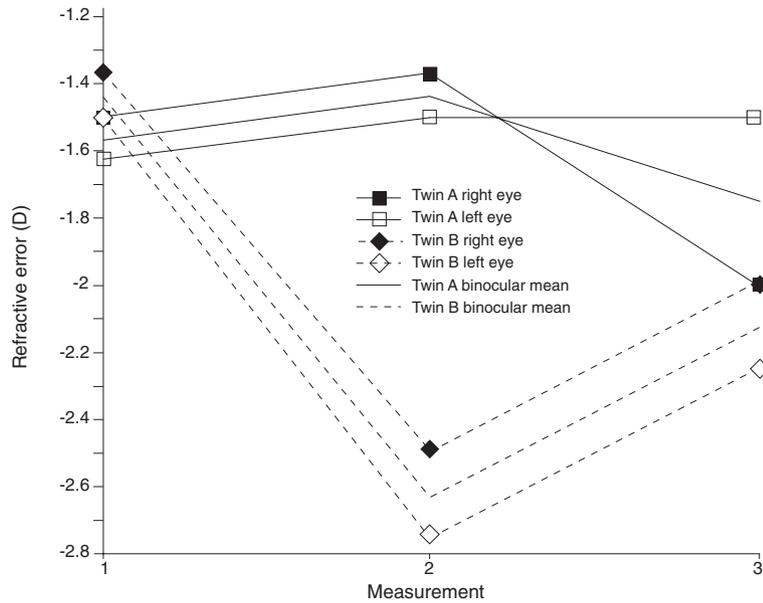


Figure 1. Refractive errors measured under cycloplegia before (measurement 1) as well as approximately one (measurement 2) and two (measurement 3) years after the fitting of soft contact lenses to two 12-year-old identical twin girls (A and B). Twin A wore bifocal soft contact lenses throughout the study; twin B was switched from single vision lenses to bifocal lenses after measurement 2. Only twin B showed significant progression of myopia, and only over the initial 12-month period of single vision lens wear.

examination with an autorefractor (Humphrey autorefractor initially, Marco refractometer at second and third examinations). Cycloplegic refractions (1% cyclogyl, 1 gt × 2, five minutes apart), were performed as part of the first and two-year examinations. Manual keratometry was performed at all times and axial length measurement at the two follow-up visits when an IOLMaster became available. Assessments of binocular vision comprised near phorias measured by cover test through distance corrections, as well as associated phorias, defined as the plus lenses required to neutralise the fixation disparity (Bernell near point examination card), measured through both single vision distance and bifocal contact lenses. Because the presence or absence of esophoria and/or fixation disparity would effectively unmask the examiner to the type of contact lens being worn, these measurements were not included in the battery of tests applied prior to unmasking at the one-year examination.

This research followed the tenets of the Declaration of Helsinki.

RESULTS

Over the initial 12 months of the study, the child wearing the bifocal lenses showed minimal progression while in contrast, her twin sister showed significant progression of myopia over the same period. When the latter child was subsequently switched to bifocal lenses, her myopia also stabilised. These trends are summarised in Figure 1 and described in more detail below.

While both twins had similar refractive profiles at the start of the study (binocular average refractive errors: -1.57 D, Twin A; -1.44 D, Twin B), they differed by more than 1.0 D at the first annual follow-up visit (binocular average refractive errors: -1.43 D, Twin A; -2.63 D, Twin B) (Table 2). This difference reflects continued myopic progression of -1.19 D, averaged across both eyes in Twin B, com-

pared to the negligible change in refractive error in Twin A (+0.13 D). Axial lengths recorded at 12 months are consistent with the different refractive error profiles of the two children; Twin B, who was more myopic, also had longer eyes than Twin A, by approximately 0.64 mm, averaged across both eyes of each child. The widely quoted conversion factor of three dioptres per millimetre for the human eye¹⁸ predicts a refractive error difference of 1.92 D, slightly larger than observed.

Extension of bifocal lens wear to a total of 28 months saw the refractive errors of Twin A remain relatively stable. There was no change in the refractive error of her left eye, while her right eye recorded an increase in myopia of -0.56 D over the second year and -0.5 D overall (over the 28 months). In contrast, the refractive errors of Twin B underwent a slight regression of myopia over the bifocal lens-wearing period; her refractive errors changed over this period by +0.44 D, averaged across both eyes. The equivalent axial length changes were -0.05 mm for Twin A and -0.09 mm for Twin B, minimal in both cases. Corneal curvature changes over the study period were minimal for Twin A (0.18 D, averaged across both eyes), while Twin B showed transient corneal steepening (0.44 D, averaged across both eyes), contributing to the progression in the myopia over the initial single vision lens-wearing period. Both corneal and refractive error changes regressed with the switch to bifocal contact lenses for Twin B.

While compliance was not strictly monitored, both twins reported average wearing times in the range of 12 to 14 hour per day and they wore them every day with occasional weekend days off. Neither twin had alternative visual correction, that is, spectacles, so they had every incentive to wear their contact lenses. There were no differences in reported wearing schedule based on lens type.

DISCUSSION

In each of the two genetically identical twin girls, the commencement of bifocal contact lens wear was followed by periods of relatively stable myopia, at an age when

Parameter			Baseline	Year 1	Year 2
Twin A					
BFL/BFL	Refractive error (D)	OD	-1.50	-1.25 / -0.25 × 160	-1.75 / -0.50 × 165
		OS	-1.50 / -0.25 × 110	-1.50	-1.50
	Corneal curvature (D)	OD	44.00, 44.50 (44.25, 0.50)*	44.12, 45.12 (44.62, 1.00)	43.62, 45.00 (44.31, 1.37)
		OS	44.00, 44.50 (44.25, 0.50)	44.50, 45.37 (44.94, 0.88)	44.00, 45.12 (44.56, 1.44)
	Axial length (mm)	OD	N/A	23.67	23.64
		OS	N/A	23.55	23.49
Twin B					
SVL/BFL	Refractive error (D)	OD	-1.25 / -0.25 × 85	-2.50	-1.75 / -0.50 × 162
		OS	-1.50	-2.75	-2.00 / -0.50 × 12
	Corneal curvature (D)	OD	43.50, 44.25 (43.87, 0.75)	44.12, 44.62 (44.37, 0.50)	42.62, 44.12 (43.37, 1.50)
		OS	43.50, 44.25 (43.87, 0.75)	43.87, 44.62 (44.25, 0.75)	42.75, 44.25 (43.50, 1.50)
	Axial length (mm)	OD	N/A	24.19	24.11
		OS	N/A	24.31	24.21

*mean corneal curvature and astigmatism in brackets

Table 2. Refractive, corneal curvature and biometric data collected under cycloplegia prior to and after one and two years of soft contact lens wear. Twin A wore bifocal lenses throughout the two-year study period, while twin B was switched to bifocal lenses after wearing single vision lenses for the first year.

myopia is expected to progress rapidly. For the child wearing single vision lenses for the first 12 months of the study, the cessation of progression of myopia after the switch to bifocal lenses provides a dramatic contrast with her earlier relatively high rate of progression. That progression of myopia was halted in her bifocal contact lens-wearing twin sister is also a unique finding among studies on the control of myopia involving humans. Whether optical or pharmacological intervention, the best results from such studies are statistically significant reductions in the progression of myopia rather than arrest of progression.^{19,20}

The axial length data collected over the second phase of the study are suggestive of an inhibitory effect on progression of myopia resulting from a slowing of ocular elongation. This is an important result, given the potentially blinding ocular complications associated with the excessive elongation of the eye in myopia.^{4,21} That bifocal contact lenses can inhibit myopia-inducing ocular elongation is also implied by the longer axial lengths, at the end of the first phase of the study, of the now more myopic twin who had been wearing single vision lenses compared to those of her sister, who had been wearing

bifocal contact lenses. However, this conclusion is speculative as baseline axial length data were not collected.

Two features of the current cases warrant discussion. First, it is noteworthy that the child wearing bifocal contact lenses over the first year, while showing stable myopia over the same period, appeared to progress slightly over the second year (Figure 1). This result provides an interesting parallel with results of the COMET study, in which the effect of treatment with PALs was largely confined to the first year,¹¹ although in the current study, progression was limited to one eye of the affected child. Nonetheless, transient inter-ocular differences in refractions are a common finding in young progressing myopes. Second, the child who switched to bifocal contact lenses during the second year of the study showed a decrease in axial lengths in both eyes over the same period. While the scale of the changes is larger than previously described diurnal fluctuations in axial length,^{22,23} an alternative explanation for this apparent ocular shrinkage is not currently available.

Noting that the current study involves only two subjects, is there any reason to believe that bifocal contact lenses would

be more effective than bifocal or PAL spectacles in controlling myopia? To address this question, we consider several arguments.

As alluded to in the introduction, bifocal and PAL spectacles share certain features that impose practical limitations for young users. Specifically, compared to presbyopic adults, children are less likely to use prescribed near additions during near work because of the unusual head and eye postures required (head up and eyes lowered) and because of the optical distortions encountered on viewing obliquely through the lower regions of such spectacle lenses. Indeed, one recent study involving video monitoring of children participating in a study on the control of myopia using PALs found that frequently, they were not obtaining the maximum therapeutic benefit of their lenses.¹⁴ Most of the bifocal and PAL spectacle studies to control myopia report training their subjects in the proper use of their spectacles and many of them also sought to measure compliance. It is not clear how effective these strategies were in ensuring their proper use in everyday tasks by children. Furthermore, with the extensive use by today's children and adolescents of computers with screens at or

above eye level, one could argue that multifocal spectacles are not a practical treatment for the control of myopia. The use of bifocal contact lenses removes the influence of gaze and training on treatment efficacy, the only requirement being that the lenses are worn on a daily basis. Also, once the contact lenses are inserted, they are more likely to be left in place throughout the day than spectacle lenses for practical reasons, thereby promoting compliance.

The case presented above rests on the assumptions that accommodation lags are the stimulus to increased eye elongation in myopia, that the bifocal lenses serve to correct them and that the superiority of bifocal contact lenses reflects the near addition being available at all angles of gaze and distances. Addressing these assumptions, two recent studies investigated the effect of positive addition spectacle lenses (+1, +2 D), on accommodation behaviour of young adults.^{24,25} Both report decreases in accommodative lags and in some cases over-accommodation with the lenses under binocular conditions. However, no consideration was given to the status of the binocular vision of the subjects and it is likely that subjects presenting with near esophoria would show less tendency to over-accommodate.

In this context, it also is important to note that in the COMET study, myopes presenting with larger accommodative lags in combination with near esophoria were one of the groups to benefit most from PAL spectacles. In the current study, both twins exhibited near associated esophorias, which were neutralised by bifocal additions, as part of the treatment protocol. The failure to take binocular visual status into account and/or the use of standardised near additions in many spectacle lens-based studies to control myopia,⁸⁻¹⁰ may contribute to the lower efficacies reported therein.

That a simple analogy between bifocal spectacles and bifocal contact lenses is not appropriate in comparing their effects on accommodation is suggested by the results of another recent study, in which accommodation was measured through both bifocal soft contact lenses and single vision

contact lenses incorporating the near addition power. Surprisingly, myopes as well as emmetropes over-accommodated with the bifocal lenses, while only emmetropes showed this behaviour for the single vision lenses and only at some distances.²⁶ These different effects of bifocal contact lenses on accommodation may reflect lens-induced changes in the ocular aberrations,²⁷ a subject of on-going study, opening the further possibility that such changes also underlie the apparent efficacy of the bifocal contact lenses in controlling the progression of myopia.

There are other characteristics of bifocal contact lenses that may play a role in their apparently greater effectiveness than spectacle lenses as a treatment to control myopia. For example, animal studies suggest that the imposition of sustained myopic defocus strongly inhibits ocular growth, and when competing myopic and hyperopic defocus signals are presented using lens formats similar to those encountered in bifocal contact lenses, growth inhibition is also observed.²⁸ Thus, the improved efficacy of bifocal contact lenses over their spectacle lens equivalent may be related to the different defocus (including sustained myopic defocus) provided. In addition, there has been renewed interest in differences in the peripheral refractive profiles between myopes and emmetropes, with recent animal studies providing some support for speculation that peripheral refractive errors are the trigger for increased ocular elongation in myopes.^{29,30} While the effects of bifocal contact lenses on peripheral refractive errors have not been specifically investigated, they necessarily will be different from those of bifocal spectacle lenses.

Finally, what weight can be put on the results of the current study, given it was limited to two subjects? That identical twins were involved reduces the possibility that the results occurred by chance alone for the following reasons:

- the refractive errors of monozygotic twins have been found to be highly correlated³¹
- it is likely that these monozygotic twins shared a very similar environment, given their young age.

Thus it is likely that the rate of myopic progression seen in the child wearing single vision contact lenses during the first phase of the study is a good indicator of the likely progression rate for her sister, had she not been wearing bifocal contact lenses. This finding also is consistent with trends in retrospective data.¹⁵ Nonetheless, this discussion is still speculative and thus the efficacy of bifocal contact lenses as a myopic control treatment remains to be confirmed in an appropriately designed, large-scale clinical trial. Such testing could also examine the usefulness of this treatment strategy beyond esophoric myopia.

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The primary author has received a patent, since assigned to a third party, on the use of bifocal contact lenses for myopic progression control (US Patent No. 6,752,499 B2; Issued June 22, 2004).

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