

CONTACT LENSES

Development in multifocal contact lens design

Neil Retallic and **Keiji Sugimoto** ask whether multifocal contact lens technology is keeping pace with the demands of the modern presbyope and introduces the novel design of the Miru monthly lens

Miru 1month multifocal contact lenses (from Menicon) feature a novel approach to lens design based around the physiological differences found in early versus more advanced presbyopia. Here we review both the theory behind the optics and the features that may positively influence both practitioner and wearer experience.

BACKGROUND

Presbyopia is a rare constant in our changing world, the totally predictable physiological change as we approach our 40s¹ is well understood and the dioptric progression marches on like clock-work year by year.

Our approach to correcting presbyopia has slowly evolved over the centuries, from the very first reading stones of the 13th century to the most sophisticated of 21st century progressive spectacles, multifocal contact lenses and IOLs.

We are living longer, healthier lives which equals more, young at heart active presbyopes.

It is estimated that today around a quarter of the global population (c1.9 billion) are presbyopic with the prediction this will increase to c2.1 billion by 2030.²

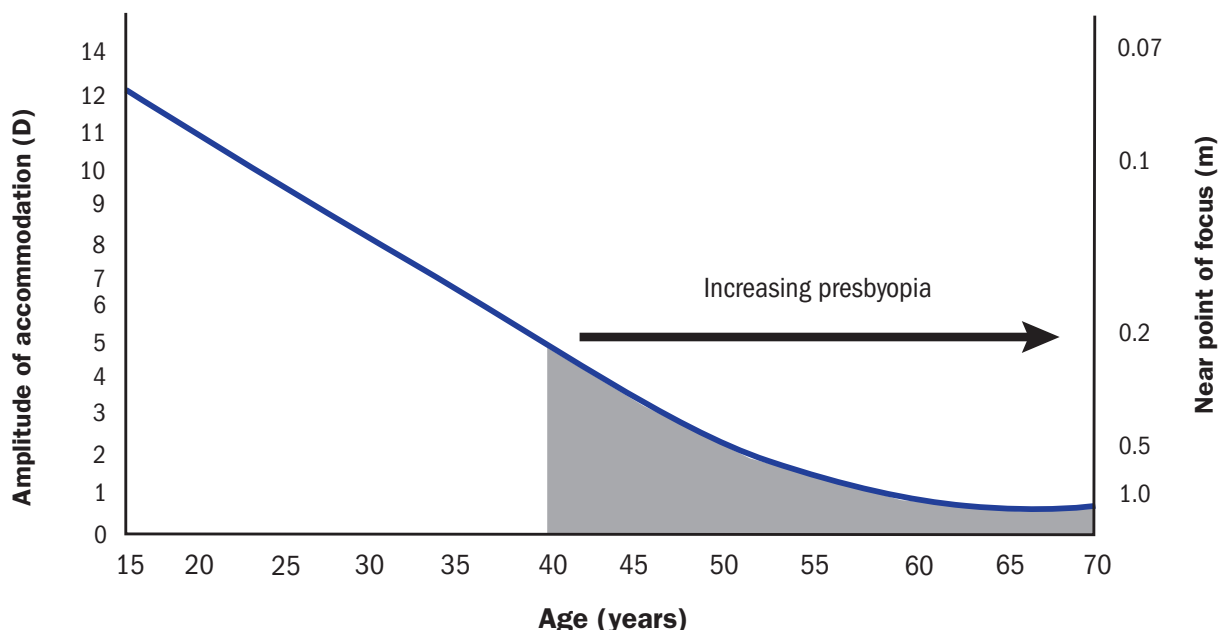
While the physiology and progression of presbyopia remains unchanged, in contrast, the lifestyles of our presbyopes have shown remarkable change becoming almost unrecognisable from just a few generations ago.

During the past decade, we find ourselves living in a world of digital dependency³ and our visual worlds have become ever closer. Unlike our ancestors who spent a greater degree of time outdoors in manual or rural labour. A typical distance world today may simply be the extent of our office with the greater part of our work and leisure time spent multitasking between several close-up devices.⁴ This change in lifestyle has placed increased demand on our visual system and helped drive innovation and change in how we manage presbyopia.

Soft multifocal contact lenses are an increasingly popular choice for presbyopes. The 2019 annual prescribing report concludes 'the proportion of presbyopes within the pool of fitted contact lens patients has increased from c20% to c35% of all fits over the last 15 years.'⁵

Indeed, over the past decade there have been significant developments in multifocal soft contact lenses, reflecting the changing needs of our presbyopes.

FIGURE 1 Relationship between age, accommodation and near point of focus



So, how is technology keeping up with the needs of today's presbyope?

Presbyopes can be loosely grouped into early or advanced. Early presbyopes will still retain some natural accommodative ability and will not be totally dependent on a near vision correction. In comparison, advanced presbyopes lose all natural accommodation and are generally fully dependent on a near vision correction (figure 1). There are also other differences between the early and mature presbyope to consider such as variations in spherical aberration, refraction, pupil size (figure 2)^{6,7} and neuro adaptive ability for suppression of blur.

A hypothesis could be made that the two groups may well suit a different presbyopic optical contact lens design based on these differences.

MIRU 1MONTH MULTIFOCAL

Miru 1month multifocal with its trademarked Dual Balanced design takes these differences into account with a centre near low add for the early presbyope and a unique high design with a decentred near add for the more advanced presbyopes.

To understand the rationale behind this approach first consider some basic principles of current multifocal design and their potential strengths and weaknesses. The most common design promoted in mainstream soft contact lenses of today is of the progressive design, either centre near (CN) or centre distance (CD). These are available in various combinations of low, medium and high add powers for low medium and advanced presbyopia respectively. Progressive designs work on the concept of 'simultaneous images' with multiple power gradients presented to the pupillary plane. The resulting superimposed blurred images on the retina require interpretation or suppression of those elements of the image not required for the task in hand.

The younger presbyope can be considered well suited to traditional low add CN designs, their typically larger pupil size allowing adequate access to the surrounding distance zone, while taking advantage of the centrally paced near add when pupils constrict for near viewing. The relatively lower add power across the central near zone and transitional zones placing minimal stress on the neuro adaptive system of the younger presbyope. The central near addition may even offer additional support in an ever-closer working and living environment.

Conversely for a mature presbyope with smaller pupils and fitted with a CN design, the available distance viewing area may be reduced. There will also be increased demand on the neuro adaptive system to suppress the greater blur of the central high add power as well as that of the transition zones, leaving increased potential for disruption to visual performance.

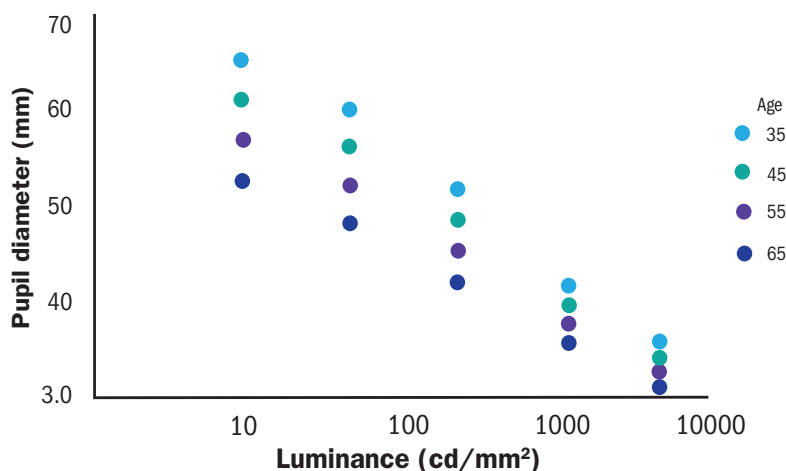
When faced with a choice between either CN or CD, an older presbyope with a smaller pupil size may choose to preserve distance vision quality potentially at the expense of their near vision and accept a CD option, whereas others where near vision is more important may favour a CN design.

There will, however, always be greater blur to negotiate through the progression of CD and CN higher add powers when compared to low add powers.

The decentred near zone of the Miru 1month multifocal high design addresses this for the older presbyope by locating the NV zone inferio-nasally, just where the eyes naturally converge during near vision tasks, leaving the distance areas essentially blur free (figure 3).

In addition the power transition zones are abbreviated in a pseudo bifocal form rather than a progressive lens type, which reduces shift related blur or 'noise' for the neuro adaptive system

FIGURE 2 Relationship between pupil size and age measured under different illuminations



to suppress. The theory being that two discrete areas of clear focus as opposed to multiple blurred images of the progressive design is neurologically less invasive for the advanced presbyope. Unlike some other multifocal lens designs where a combination of a low and a high add lens may be recommended for an individual, with Miru 1month multifocal this is not the case. To preserve the benefits of the design differences between the designs, discussed above, a mixture of high/low combinations is not recommended for initial fitting (figure 4).

CLINICAL PERFORMANCE

A clinical study was undertaken to investigate both fitter and wearer experience of the Miru 1month multifocal lens compared to two other monthly reusable silicone hydrogel multifocal lenses.

A subject-masked, randomised, crossover, bilateral study compared the general performance of Miru 1month multifocal, Air Optix plus HydraGlyde Multifocal Biofinity multifocal contact lenses.

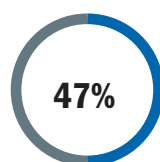
Twenty-seven experienced contact lens wearers of presbyopic age, with no previous experience of wearing the test lenses wore each lens type for two weeks in random sequence. For each lens, the manufacturers fitting guides were adhered to and follow-up visits for each lens performed after two weeks of wear.

At each two-week follow-up visit, subjects completed a comparative evaluation questionnaire for each lens along with a comprehensive clinical assessment. A discussion around the key findings follows.

Fitting

The initial fitting experience of a lens will influence practitioner and wearer attitudes towards a lens and be a determining factor in the adoption and success of a particular lens.

Despite the current wide choice of multifocal contact lenses and the increase in multifocal fitting rates; nearly half of presbyopes fitted with contact lenses in 2019 were still estimated to be fitted with non-presbyopic options.⁵

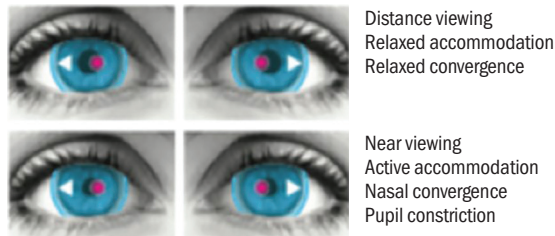


47% of presbyopes are still fitted with single vision lenses⁵



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FIGURE 3 The novel decentred design and dynamic stabilisation of Miru multifocal HIGH design, mimics the natural viewing process and places the near zone optimally for both distance and near vision viewing



The relationship between the decentred near zone and pupil in far and near viewing. The temporal locator mark makes for easy application

If this is due to a perception that multifocal contact lens fitting requires more contact lens appointments and several fitting attempts this study shows by following the manufacturers fitting guides this need not be the case.

This study demonstrated 100% fitting success with all test lenses on all wearers with a high first lens fit success rate.



100% fitting success with all test lenses on all wearers with a high first fit success rate

Centration is also an essential element to multifocal contact lens success. Again, the study showed good centration on all lenses 1month multifocal had an 83% first lens success rate and 100% with in two lenses.

Handling

Just as the fitting experience is important in establishing first impressions and ultimate success of a lens, so too is handling, the study recorded positive scores for handling of all three lenses. For Miru 1month multifocal it was also evident that the triangular marker location on the Miru 1month multifocal high add lens proved no issue for the wearers, with a 100% success rate in both ability to find and correctly place the location marker (figure 4).



100% success applying Miru 1month multifocal correctly

Vision

Overall visual performance was good with some notable differences in the vision scores taken at different stages throughout the study between the lenses. Miru 1month multifocal showed strong distance vision performance, significantly outperforming both competitor lenses at fitting and follow up visits as well as in the subjective ratings given in the two-week follow up assessment for day and night distance vision. The other significant differences noted were for Biofinity multifocal which scored better for intermediate low contrast vision at the follow up visit and for near vision in the follow up subjective score. See figures 6 and 7 below.

When comparing the visual performance and characteristic of the low (CN) and the novel high (decentred near) of Miru 1month multifocal, it is noteworthy that the low add lens tended

FIGURE 4 A closer look at Miru 1month multifocal Dual balanced design

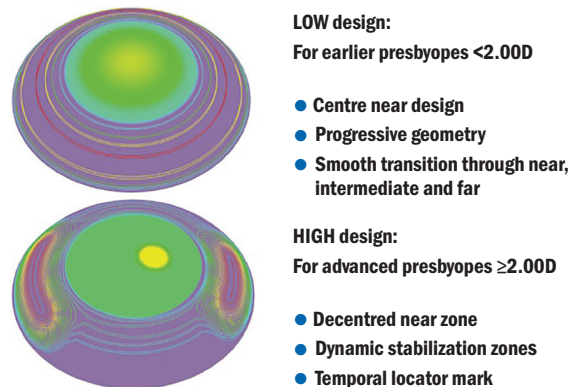
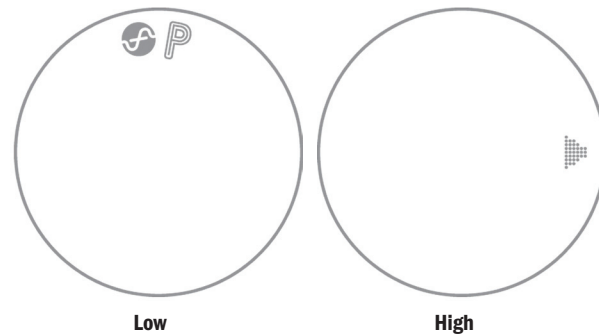


FIGURE 5 Miru locator mark



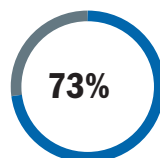
towards a preference for distance while the high add demonstrated more balance between distance and near. This brings opportunities when matching lens selection with a wearer's viewing preference.

Wearing times

All wearers chose to wear the lenses longer than the study criteria specified which shows good tolerance to all lenses (see table 1). Miru multifocal was in fact worn for the most days per week which may have been due to its better distance vision performance. This study demonstrates that monthly replacement multifocal contact lenses can be successfully worn on a full time daily wear basis.

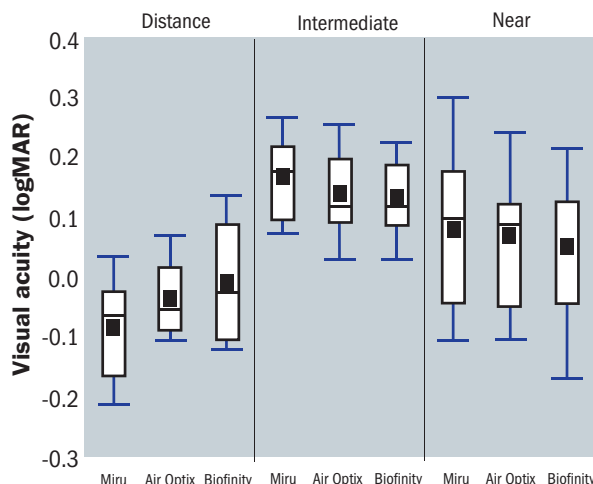
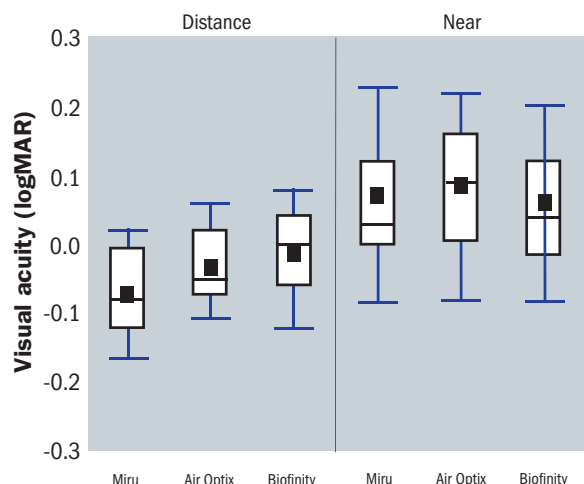
Subjective feedback

All the usual parameters around, comfort, handling, visual disturbances, tiredness, etc, were assessed, and excluding the differences in vision described above, all subjective ratings were remarkably similar between lenses with no other statistically significant differences found (figure 8). The study concluded that the three lenses used in this study were all well-received with comparative performance and subject acceptance scores alike, concluding that the Miru multifocal lens showed good adaptation, performed well, especially for distance viewing and delivered an overall the highest subjective rating score of 73 out of 100.



73% overall satisfaction score for Miru 1month multifocal

FIGURE 6 Vision scores at initial fitting and two week follow up visits



ADDITIONAL CONSIDERATIONS FOR THE PRESBYOPIC EYE

As well as the visual challenges facing presbyopes there are other age-related factors we must be mindful of when designing and fitting contact lenses for presbyopes.

For example, it is generally accepted that tear production, quality and stability all decrease with age.^{8,9} Both age and contact lens wear having been shown to be a consistent risk factors in dry eye disease,¹⁰ with around 15% of over 65-year-olds reporting symptoms of 'dry eye'.¹¹ Other metabolic changes of the cornea such as decreased endothelial pump function¹² and the potential for slower rates of recovery from corneal oedema and healing of wounds¹³⁻¹⁵ are also important considerations in the presbyopic eye.

It is therefore especially important that both the optical and material components of a contact lens support the changing visual and physiological requirements of the presbyopic eye.

MIRU 1MONTH MULTIFOCAL; SUPPORTING THE PRESBYOPE

With its novel Dual Balanced optical design, Miru 1month multifocal recognises the changes which occur through early to late presbyopia by adopting two distinct designs; a CN low add and a decentered high add respectively.

As well as meeting visual needs, the material and surface components of Miru 1month multifocal; MeniSilk and NanoGloss, take account of the other essential requirements of the ageing ocular physiology (figure 9).

- MeniSilk material technology: an ultra-high 161 Dk/t silicone hydrogel for optimum oxygen delivery
- Nano Gloss surface technology; highly smooth, hydrophilic surface, with proven resistance to bacterial adhesion.¹⁶

The ultra-high Dk/t silicone hydrogel, Asmofilcon A, delivers optimal oxygenation which combined with the highly smooth, hydrophilic, bacterial resistant surface¹⁶ set the foundations for a happy and healthy ocular surface.

CONCLUSION

Presbyopes will always face greater visual challenges so it is not surprising that presbyopes, especially those new to contact lenses commonly cite visual related reasons for dropping out of contact

FIGURE 7 Summary of clinically significant differences in vision

Initial fitting visit measurements	Miru multifocal	Air Optix multifocal	Biofinity multifocal
Distance HC	+		
Near HC	=	=	=

Follow up visit measurement	Miru multifocal	Air Optix multifocal	Biofinity multifocal
Distance HC	+		
Distance LC	+		
Intermediate HC	=	=	=
Intermediate LC			+
Near HC	=	=	=
Near LC	=	=	=

Follow up visit subjective scores	Miru multifocal	Air Optix multifocal	Biofinity multifocal
Distance during day	+		
Distance at night	+		
Intermediate vision	=	=	=
Near vision			+



Score of 84% given for Miru 1month multifocal distance vision

+ Clinically significantly better

= No clinically significant difference

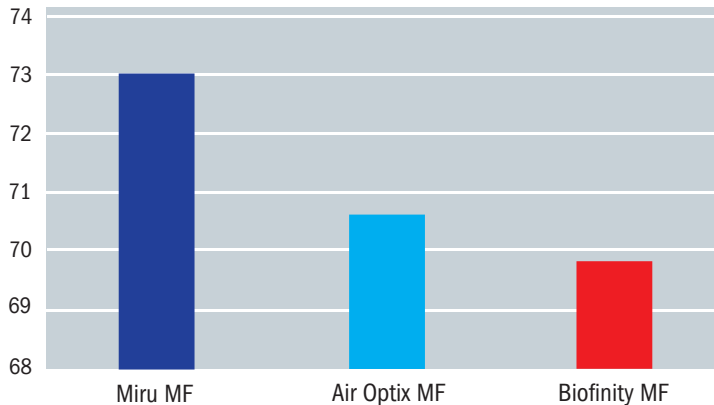
lens wear.^{17,18} With an active, increasingly digitally dependant presbyopic population, demanding quality vision, innovation in multifocal optical design is to be welcomed now more than ever. So why are we still prescribing almost half our presbyopes with single vision options?⁵

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TABLE 1 Lens wearing patterns

Lens wear parameter	Miru 1month multifocal	Air Optix multifocal	Biofinity multifocal
Days per week	6.10 ± 1.08	5.60 ± 1.04	5.89 ± 1.17
Hours per day	10.45 ± 2.35	10.37 ± 3.30	10.41 ± 2.97

FIGURE 8 Overall satisfaction scores rated out of 100. No statistical significance differences between lenses



No two presbyopes are the same and Miru 1month multifocal takes a refreshing approach, embracing both the visual and physiological differences between early and advanced presbyopes while providing all the material and surface features expected in a modern silicone hydrogel lens.

Miru 1month multifocal has been shown to have the essential ingredients to justify its position amongst its competitors in terms of ease of fit, vision and subjective responses, and will be a welcome addition for practitioners looking to expand their scope of presbyopic care.

This article demonstrates we have an excellent choice of quality reusable multifocal contact lenses for presbyopia. With the support of well thought out fitting guides and digital fitting tools such as the Menicon multifocal calculator, excellent fitting success can be achieved and practitioners should feel more confident than ever in tackling one of the most challenging yet rewarding aspects of contact lens practice.

With the right approach and an open mind there is little reason why multifocal contact lenses should not form an integral part of the recommended eye wear options for presbyopes.

Miru 1month multifocal forms part of the continuing technological journey with our presbyopes, which will continue to evolve along with their aspirations. **○**

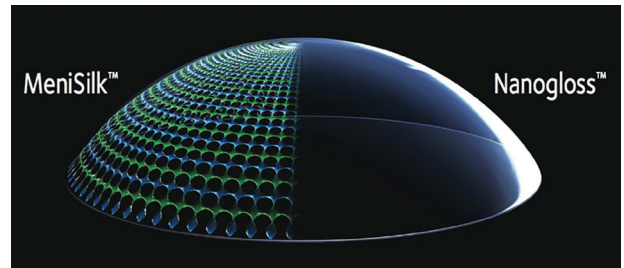
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Keiji Sugimoto-Manager is responsible for International Clinical Studies at Menicon, part of the Menicon R&D team.

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FIGURE 9 Material and surface of the Miru 1month multifocal



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