

ORIGINAL ARTICLE

Investigation of the Performance of the Menifocal Z Gas-Permeable Bifocal Contact Lens During Continuous Wear

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ABSTRACT: *Purpose.* The Menifocal Z is an alternating vision, concentric, bifocal gas-permeable (GP) contact lens; center distance is connected to near periphery by a smooth transition zone. The lens is produced using tisiilfocon A (Menicon Z material), which is approved for up to 30 days of continuous wear (CW). The aim of this study was to evaluate the clinical performance of the Menifocal Z when worn for up to 30 days of CW for 6 months. *Methods.* Thirty-five existing GP lens wearers were enrolled in the study. Subjects were fitted with Menifocal Z lenses and follow-up visits were conducted after 2 weeks of daily wear and 1 day, 1 week, 6 weeks, 3 and 6 months of CW. A range of objective and subjective clinical performance measures were assessed, including distance and near visual acuity, the physiological response to CW, and subjective evaluation of vision and comfort. *Results.* Twenty-seven subjects (77%) completed the study and eight (23%) discontinued: five (14%) as a result of lens-related problems (four vision, one comfort) and three (9%) as a result of non-lens related reasons. Average CW time achieved by the subjects was 22 ± 2 days. Mean binocular logarithm of the minimum angle of resolution (logMAR) acuities at 6 months were: high contrast distance 0.03 (20/20-), low contrast distance 0.63 (20/80-), and high contrast near 0.26 (20/25, N4). Adverse responses and lens binding were minimal, and there were no significant increases in corneal staining, corneal vascularization, or superior palpebral conjunctival papillae over time ($p > 0.05$). Problems with night vision (distance and near) with the lenses were the most common difficulties reported by the subjects. *Conclusions.* The Menifocal Z appears to be a promising option for presbyopic vision correction, providing successful correction of distance and near vision in a group of experienced GP lens wearers. The hyper Dk tisiilfocon A (Menicon Z) material allowed for safe wear of the lenses on a CW basis. (*Optom Vis Sci* 2005;82:1022-1029)

Key Words: gas-permeable contact lens, continuous wear, hyper-Dk material, bifocal contact lens, presbyopia

There is an increasing demand for presbyopic contact lens corrections with the aging population.¹⁻³ In addition to monovision, a variety of bifocal/multifocal contact lens designs are currently available for correcting presbyopia; however, the success of these lenses has been variable.⁴⁻⁸

The Menifocal Z (Menicon Co. Ltd., Nagoya, Japan) is a recently developed bifocal gas-permeable (GP) lens. It is an alternating vision, concentric bifocal design; center distance is connected to near periphery by a smooth transition zone. A unique feature of the design is that the optic zone diameters vary with add power; as

add power increases, the distance and transition optic zone diameters decrease, whereas the near optic zone diameter increases. This design feature has the potential to improve visual performance at both distance and near compared with currently available alternating/concentric lens designs, which do not adjust for increasing add power.

The development and introduction of hyper oxygen-transmitting (hyper-Dk) contact lens materials has resulted in a growing interest in continuous wear (CW).^{5,9} The Menifocal Z is produced using tisiilfocon A (marketed as Menicon Z, Menicon), which is approved for up to 30 days of CW (Dk = 163, ISO 9913:1).¹⁰ Clinical studies using single-vision tisiilfocon A lenses have demonstrated the lenses to be safe when worn on a CW basis for up to 30

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days.^{10–12} Therefore, the Menifocal Z has the potential to provide presbyopic vision correction on a CW basis.

The aim of this study was to evaluate the clinical performance of the Menifocal Z when worn for up to 30 days of CW over a 6-month period. A range of objective and subjective performance measures were assessed, including distance and near logMAR visual acuity (VA), length of wear achieved, the physiological response to CW and subjective evaluation of vision, comfort, and lens binding.

METHODS

Subjects

Thirty-five existing GP lens wearers were enrolled in the study. Inclusion criteria included spherical refractive error of +5.00 D to -10.00 D, corneal cylinder of <2.50 D, and near addition of +0.75 D to +2.50 D. Subjects with ocular signs graded >2.0 with slit lamp biomicroscopy (Efron grading scales),¹³ active systemic or ocular disease, or currently using medications affecting ocular physiology were excluded from the study. Subjects were also excluded if a satisfactory fit with the study lenses could not be achieved during the fitting process.

This study was approved by the VCO/Department of Optometry and Vision Sciences/NVRI Human Research Ethics Committee and was conducted following the tenets of the Declaration of Helsinki. Informed consent was obtained from each subject after a detailed explanation of the nature and risks associated with participation in the study was provided.

Contact Lenses and Solutions

Subjects were fitted with Menifocal Z lenses according to the manufacturer's fitting guidelines using trial lens sets provided by Menicon. Selection of initial back optic zone radius (BOZR) during trial lens fitting was based on the recommended fitting guideline of a mean keratometry (K) reading +0.06 mm. The lenses were available in BOZR steps of 0.10 mm over the range of 7.10 mm to 8.50 mm, near addition powers of +1.00 D to +2.50 D (0.50 D steps), and total diameters of either 9.6 or 9.8 mm. Near addition power was determined by overrefraction at near with subjects looking downward.

Menicare Plus (Menicon) was prescribed for cleaning, rinsing, and disinfection. Progent (Menicon) was prescribed for enzyme treatment whenever the lenses were removed during CW (i.e., at least once every 30 days). Subjects were instructed to use nonpreserved artificial tear supplements (Refresh, Allergan Australia) every morning on awakening and every evening before retiring.

Study Design

After successful screening, subjects were fitted with the study lenses and on lens delivery, wore the lenses on a daily wear basis for either 2 weeks or until parameter changes to optimize fit and vision were concluded. Evaluations were conducted after 2 weeks of daily wear (DW) and 1 day, 1 week, 6 weeks, 3 and 6 months of CW.

Subjects recorded their contact lens-wearing patterns in a study diary, including brief and overnight lens removals. Subjects were also asked to inspect their lenses immediately on awakening and

record any lens binding observed. In the event of binding, the length of time taken for the lens to unbind was also recorded in the diary.

On conclusion of the study, subjects were given the choice of being provided with new single-vision GP lenses, new monovision lenses, or the study bifocal lenses at no cost.

Visual Acuity

Monocular and binocular high and low (10% Weber)¹⁴ contrast distance logMAR VA (HCDVA and LCDVA, respectively) and high contrast near logMAR VA (HCNVA) were measured at each visit under standard room illumination conditions.

Contact Lens and Ocular Assessments

Lens centration, translation in downgaze, and fluorescein fitting patterns were evaluated at each visit and front surface wettability/deposits were graded using a zero to 4 scale.

Corneal epithelial fluorescein staining, corneal edema, corneal endothelial polymegethism, corneal vascularization, corneal infiltrates, conjunctival fluorescein staining, corneal distortion, conjunctival hyperemia, and superior palpebral conjunctival papillae were assessed at each visit. Fluorescein tear breakup time (TBUT) was measured on lens removal. Observations were graded using the Efron grading scales.¹³

Subjective Evaluation of the Study Lenses

At each visit, subjects were asked to verbally grade the performance of the lenses using a zero to 10 scale (in which zero = intolerable and 10 = perfect)¹⁵ with respect to quality of distance vision, quality of near vision, and comfort.

In addition, at the final visit, a more detailed questionnaire was administered, in which subjects were asked to grade overall comfort, distance vision quality, near vision quality, vision stability, and ease of insertion and removal using visual analog scales (zero to 100 scale, in which zero represented the poorest outcome and 100 represented the most favorable outcome). Subjects were also asked to grade how likely they were to continue sleeping in GP lenses (zero = never again and 100 = the only option) and the success of using the study lenses on a CW basis (zero = total failure and 100 = very successful).

Subjects were asked to comment on whether they found any vision tasks to be difficult with the Menifocal lenses and were asked a forced-choice question regarding their preference for the Menifocal lenses versus their previous contact lenses at the end of the study.

Data Analyses

Parametric data were analyzed using repeated-measures analysis of variance (ANOVA) and Bonferroni post hoc tests. Nonparametric data were analyzed using the Friedman test for repeated measures and Dunn's post hoc test. Data from the right eye of each subject was entered for analysis, except when binocular measures were assessed. The 2-week daily wear visit was considered to be the baseline visit for analysis purposes and only subjects who completed the 6-month trial were included in the data analysis.

Data from participants in the Gleason et al¹⁰ evaluation of Menicon Z (tisilfocon A) spherical lenses during 30-day CW were used as a historical control. The incidence of key slit lamp findings was calculated following the methods of Gleason et al¹⁰ and compared with incidence data reported in the Menicon Z (tisilfocon A) spherical lens study using the chi-squared test. The total number of positive findings was calculated for each slit lamp measure and divided by the total number of examinations performed in our study (27 subjects × 6 visits = 162 examinations). The rate of adverse events was also compared between our study and the Menicon Z study.¹⁰

Parametric data have been reported as mean ± standard error (SE). A *p* value of < 0.05 was considered to be statistically significant and differences in Efron grading of 1.0 or greater were considered clinically significant.¹³

RESULTS

Subjects

Twenty-seven (77%) subjects completed the trial. Eight (23%) of the enrolled subjects discontinued from the study: four (11%) as a result of vision problems (two night, one intermediate, one overall), one (3%) as a result of discomfort at the end of the day during DW, and three (9%) for non-lens related reasons. Subject characteristics are provided in Table 1.

Lens Fitting and Specifications

Approximately 50% of eyes (*n* = 35) were successfully fitted with the first trial lens and an average of 1.6 lenses per eye were required to achieve the final correction. Six percent of eyes (*n* = 4) required three lenses to achieve the final correction. The final contact lens near addition was within ±0.50 D of the spectacle near addition in 87% of eyes (*n* = 61), with 47% of eyes (*n* = 33) fitted with the same contact lens addition as the spectacle addition. The most commonly required change in lens parameters was steepening of the BOZR (*n* = 12 lenses). The final lens specifications for each eye are summarized in Table 2.

Visual Acuity Measures

A summary of the monocular and binocular VA measures obtained with the Menifocal lenses is presented in Table 3. Excellent binocular high contrast acuities were achieved throughout the study, with mean HCDVA of 0.03 (20/20-) and HCNVA of 0.26 (20/25, N4) obtained at 6 months. As expected, monocular VA measures were reduced when compared with binocular measures (*p* < 0.05). Binocular LCDVA was significantly reduced by approximately five lines at each visit when compared with binocular HCDVA (*p* < 0.05). This difference increased to approximately seven lines when monocular measures were compared (Table 3).

Monocular LCDVA was significantly reduced by one line at 6 months compared with baseline (*p* < 0.05). There were no significant changes in any of the other VA measures over time when compared with baseline (*p* > 0.05).

Slit Lamp Observations and Contact Lens Measures

The majority of slit lamp observations recorded and contact lens measures assessed showed no significant changes over time (Table 4). Fluorescein TBUT was significantly reduced at 3 months compared with baseline (*p* < 0.05); however, this effect was not observed at 6 months and was not considered to be clinically significant. Corneal endothelial polymegethism was significantly reduced by a grade of 0.1 at 6 months compared with baseline (*p* < 0.05); however, this reduction was also not considered to be clinically relevant.

When compared with the control group wearing Menicon Z spherical lenses,¹⁰ Menifocal Z wearers had a higher incidence of corneal staining, palpebral conjunctival papillae, and corneal vascularization (Table 5). However, the average severity of these findings was low and ranged from 0.2 to 0.4.

Wearing Time and Lens Removals

Diaries were collected from 24 of 27 (89%) subjects that completed the study and diary entries were analyzed to calculate the

TABLE 1.
Subject characteristics

Enrolled		35
Discontinued		8
Completed up to 6 months		27
Age (years)	Mean ± SE	53.2 ± 1.1
	Range	40–66
Gender (M:F)		7:20
Gas-permeable wear experience (years)	Mean ± SE	26.2 ± 2.0
	Range	3–40
Current contact lenses	Single vision	22
	Monovision	4
	Bifocal	0
	Multifocal	1
Refraction (D)	Sphere (mean ± SE)	−4.86 ± 0.57
	Cylinder (mean ± SE)	−0.71 ± 0.10
	Near add (mean ± SE)	+2.00 ± 0.08
Keratometry (mm)	Steepest meridian (mean ± SE)	7.69 ± 0.04
	Flattest meridian (mean ± SE)	7.89 ± 0.05

SE, standard error.

TABLE 2.
Lens specifications for the 27 subjects who completed the study

Parameter		Right	Left
BOZR	Mean \pm SE (mm)	7.83 \pm 0.04	7.81 \pm 0.04
	Range (mm)	7.40 – 8.30	7.40 – 8.30
Diameter	9.8 mm (%)	85	85
	9.6 mm (%)	15	15
Distance power	Mean \pm SE (D)	-4.90 \pm 0.53	-4.68 \pm 0.55
	Range (D)	+5.00 to -9.75	+4.75 to -10.00
Near addition	Mean \pm SE (D)	+2.07 \pm 0.07	+2.07 \pm 0.07
	+1.50 (%)	22	22
	+2.00 (%)	41	41
	+2.50 (%)	37	37

BOZR, back optic zone radius; SE, standard error.

TABLE 3.
Monocular and binocular visual acuity measures (mean \pm SE) at the various study visits

Visual Acuity Measures		2 W DW	1 day CW	1 W CW	6 W CW	3 M CW	6 M CW	p Value
HCDVA	Monocular	0.08 \pm 0.02	0.06 \pm 0.01	0.07 \pm 0.02	0.08 \pm 0.02	0.07 \pm 0.02	0.09 \pm 0.02	> 0.05
	Binocular	0.03 \pm 0.01	0.00 \pm 0.01	0.01 \pm 0.01	0.02 \pm 0.01	0.03 \pm 0.01	0.03 \pm 0.01	> 0.05
LCDVA	Monocular	0.77 \pm 0.04	0.75 \pm 0.03	0.73 \pm 0.04	0.77 \pm 0.03	0.81 \pm 0.03	*0.87 \pm 0.04	* < 0.05
	Binocular	0.56 \pm 0.03	0.54 \pm 0.03	0.52 \pm 0.03	0.55 \pm 0.02	0.57 \pm 0.03	0.63 \pm 0.03	> 0.05
HCNVA	Monocular	0.39 \pm 0.03	0.37 \pm 0.02	0.36 \pm 0.03	0.37 \pm 0.03	0.39 \pm 0.03	0.41 \pm 0.02	> 0.05
	Binocular	0.25 \pm 0.02	0.26 \pm 0.02	0.25 \pm 0.02	0.25 \pm 0.02	0.24 \pm 0.02	0.26 \pm 0.02	> 0.05

*p < 0.05, statistically significant difference compared with baseline. Monocular LCVA was significantly reduced at 6 months compared with baseline.

SE, standard error; HCDVA, high contrast distance visual acuity; LCDVA, low contrast distance visual acuity; HCNVA, high contrast near visual acuity; W, weeks; DW, daily wear; M, months; CW, continuous wear.

TABLE 4.
Key slit lamp and contact lens measures (mean \pm SE) at the various study visits

Measured Variable	2 W DW	1 day CW	1 W CW	6 W CW	3 M CW	6 M CW	p Value
Conjunctival papillae	0.0 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.0 \pm 0.0	0.1 \pm 0.0	0.0 \pm 0.0	> 0.05
Corneal staining	0.2 \pm 0.1	0.2 \pm 0.1	0.2 \pm 0.1	0.2 \pm 0.1	0.2 \pm 0.0	0.1 \pm 0.0	> 0.05
Conjunctival staining	0.2 \pm 0.1	0.2 \pm 0.1	0.2 \pm 0.1	0.1 \pm 0.0	0.2 \pm 0.0	0.1 \pm 0.0	> 0.05
Corneal vascularization	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	> 0.05
Corneal endothelial polymegethism	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	0.1 \pm 0.0	*0.0 \pm 0.0	* < 0.05
Fluorescein TBUT (s)	6.9 \pm 0.8	5.7 \pm 0.7	6.0 \pm 0.7	5.2 \pm 0.5	*4.0 \pm 0.2	5.0 \pm 0.4	* < 0.05
Wettability/deposits	0.8 \pm 0.1	1.0 \pm 0.1	1.1 \pm 0.1	1.0 \pm 0.1	1.1 \pm 0.1	1.1 \pm 0.1	> 0.05

*p < 0.05, statistically significant difference compared with baseline. Endothelial polymegethism was significantly reduced at 6 months compared with baseline and TBUT was significantly lower at 3 months compared with baseline; however, these reductions were not considered to be clinically significant.

SE, standard error; W, weeks; DW, daily wear; M, months; CW, continuous wear; TBUT, tear breakup time.

average number of days of CW achieved. Subjects wore the lenses on a CW basis for an average of 22 days (21 nights) \pm 2 days. The distribution of average wearing days reported by the subjects is presented in Table 6. Forty-six percent (n = 11) of subjects reported average CW times of 22 to 30 days and 8% (n = 2) of subjects wore their lenses for an average of >30 days (32 and 34 days, respectively). The maximum wearing time reported was 73 days (72 nights) and 16 subjects wore their lenses continuously for >30 days at least once throughout the course of the trial.

Subjects also recorded the number of times the lenses were removed briefly. An average of 6 \pm 2 brief removals of each lens were

made during the study, suggesting that subjects removed each lens once briefly during each month of lens wear.

Lens Binding

The incidence of binding was 1.7% overall, with an average of three binding episodes per eye over the 6-month wearing period. There were no reports of lens binding in the Menicon Z CW study.¹⁰ Binding was reported by only 25% of subjects in this study (n = 6 of the 24 subjects who returned their diaries). For those who experienced binding, the number of incidents ranged

TABLE 5. Incidence (average severity) of positive key slit lamp findings compared with control subjects wearing Menicon Z spherical lenses on a 30-day continuous-wear (CW) basis

Measured Variable	Menifocal Z	Menicon Z	p Value
Palpebral conjunctival papillae	17.9% (0.2)	8.1% (1.3)	<0.05
Corneal staining (overall)	46.9% (0.4)	34.6% (1.2)	>0.05
Stromal edema	0% (0)	0.3% (1.3)	>0.05
Corneal vascularization	51.2% (0.2)	7.4% (1.1)	<0.05
Infiltrates	0% (0)	0.2% (2.1)	>0.05

Incidence rates are based on $n = 162$ Menifocal Z examinations over 6 months of CW and $n = 3901$ Menicon Z examinations over 12 months of CW. Menifocal Z observations were graded in 0.1 steps from zero to 4 using the Efron grading scales, whereas Menicon Z observations were graded from zero to 4 in whole number steps, with zero indicating an absence of a finding and one to 4 indicating the presence and severity of a finding.

TABLE 6. Average number of days of continuous wear (CW) achieved by the subjects over the course of the study*

Average CW Time (days)	N	Percent of Subjects
≤7	1	4
8–14	5	21
15–21	5	21
22–30	11	46
31–34	2	8

*Data for 24 of 27 completed subjects.

from one to 39 per eye over the course of the study, with a mean of 11 episodes per eye over the 6-month wearing period. Lenses were bound for an average of 6 minutes, ranging from less than 1 minute up to a maximum of 15 minutes.

Adverse Events

There were no incidents of corneal infection or inflammation during the course of the study. Two subjects experienced significant, but nonserious, adverse events. One subject developed an internal hordeolum, which resolved with treatment with warm compresses. Another subject developed bilateral nasal corneal erosions, approximately 1 mm in diameter, after 1 week of CW. The etiology of the erosions was not clear. The erosions resolved with the use of nonpreserved artificial tears (Refresh, Allergan) over a 3-week period, while the subject wore her lenses on a DW basis. Minor scarring (less than grade 1) was evident on resolution and the subject resumed overnight lens wear without further complications.

Overall, 7.4% (two of 27) of subjects experienced adverse events in this study compared with 8.2% (26 of 317) in the Menicon Z CW study.¹⁰

Subjective Evaluation of the Study Lenses

There were no significant changes in the grading of binocular distance and near vision and lens comfort by the subjects over time

($p > 0.05$; Figs. 1–3). Binocular distance vision was rated highly by the subjects at all visits, with a mean score of 8.6 ± 0.3 at baseline and 8.1 ± 0.4 at the 6-month visit (Fig. 1). Binocular near vision was also graded favorably by the subjects at all visits, with a mean rating of 7.1 ± 0.3 at baseline and 7.5 ± 0.5 at 6 months (Fig. 2). Subjects reported excellent comfort levels with the lenses at all visits, with a mean score of 8.8 ± 0.2 at baseline and 6 months (Fig. 3).

The Menifocal Z lenses were rated highly in all categories assessed at the final visit: comfort 88 ± 2 , distance vision 81 ± 4 , near vision 75 ± 5 , vision stability 81 ± 4 , ease of insertion 94 ± 2 , and ease of removal 81 ± 4 . The mean score for the likelihood to continue sleeping in GP lenses was 85 ± 3 and success of CW was rated as 88 ± 3 . Twenty-six percent of subjects ($n = 7$) reported no difficulties with the study lenses. For the remaining subjects, the most common difficulties were problems with distance and near vision tasks at night/under dim illumination, followed by problems with intermediate tasks such as computer use.

On conclusion of the study, when subjects were given the choice of new single-vision lenses, new monovision lenses, or the study multifocal lenses, 26 of 27 subjects (96%) chose to keep the study multifocal lenses. One subject (4%) chose single-vision distance lenses, which was the mode of correction worn before entering the study. When forced to choose between the study bifocal lenses and their previous contact lenses, 89% ($n = 24$) preferred the study contact lenses overall.

DISCUSSION

Better fitting success was achieved with the Menifocal Z compared with other bifocal and multifocal GP lenses. An average of 1.6 lenses per eye was required to achieve the final correction, whereas studies of alternative GP lens designs have reported averages of 1.8 to 1.9 lenses per eye.^{8,16} The most common lens parameter change required was steepening of the BOZR to assist with lens centration and translation. Approximately one third of lenses that were successfully worn during the study were fitted at least 0.05 mm steeper than recommended in the guidelines. Our results

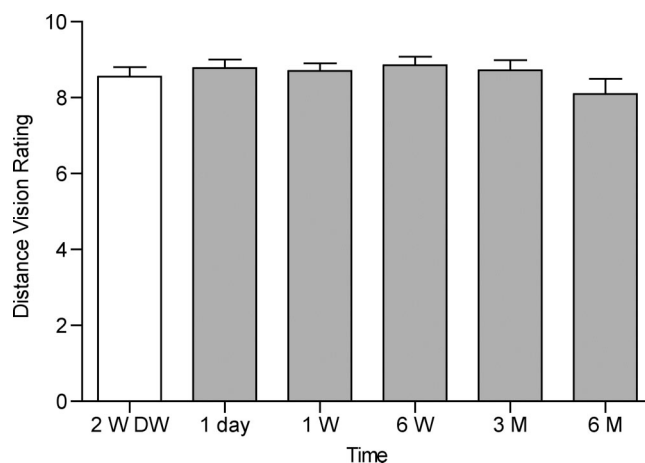


FIGURE 1. Binocular distance vision grades (mean \pm standard error), in which zero = intolerable, 10 = perfect. There were no significant changes in distance vision grades over time ($p > 0.05$).

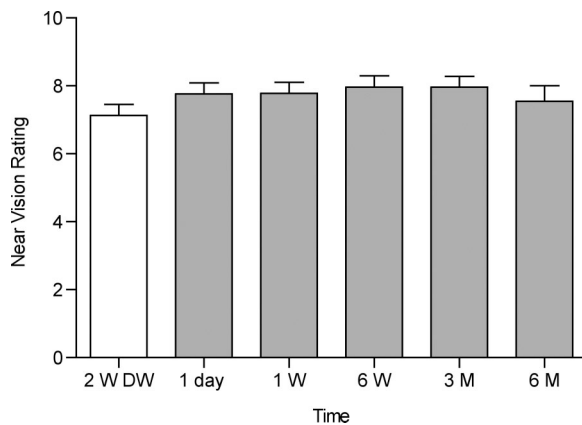


FIGURE 2.

Binocular near vision grades (mean \pm standard error), in which zero = intolerable, 10 = perfect. There were no significant changes in near vision grades over the course of the study ($p > 0.05$).

suggest that practitioners should consider fitting the Menifocal Z lenses steeper than recommended in the fitting guidelines, particularly if there is significant lid attachment present.

Excellent high contrast distance and near VA measures were achieved by the subjects (Table 3), and the lenses were rated well with respect to vision quality (Figs. 1 and 2). There were no significant changes in high contrast VA measures over time. LCDVA is normally expected to be reduced by two to three lines compared with HCDVA.^{17,18} LCDVA measures were lower than expected, with subjects showing monocular and binocular reductions of seven and five lines, respectively. These findings suggest that some Menifocal Z wearers may have difficulties with activities such as night driving. Four of the eight discontinuations in this study were the result of vision-related problems. However, only two subjects discontinued specifically because of night vision problems. Problems with night vision at both distance and near were the most common difficulties reported by the subjects when asked to comment on the lenses.

Subjective grading of vision was not affected by the poorer LCDVA measures; however, a limitation of the study design was that subjects were not asked to specifically grade their vision at night or under dim illumination conditions. No significant changes in binocular LCDVA were observed over time; however, monocular LCDVA was significantly reduced by one line at 6 months compared with baseline. It is unclear whether further reductions in LCDVA may have occurred with increasing lens age.

The Menicon Z material has been worn successfully on a CW basis in subject groups of an average age of 41 years.^{10,12} Successful CW was achieved with the Menicon Z material in this presbyopic population of an average age of 53 years. The majority of slit lamp and contact lens measures showed no clinically significant changes over time. Increased incidence of corneal vascularization and palpebral conjunctival papillae were observed in Menifocal Z wearers compared with Menicon Z wearers (Table 5), which may have been the result of the older average age of the Menifocal Z lens wearers or the differences between the grading scales used in each study. In this study, the Menifocal Z wearers were assessed using a zero to 4 grading scale in 0.1 increments, whereas the Menicon Z study used whole number increments. The incidence rate of posi-

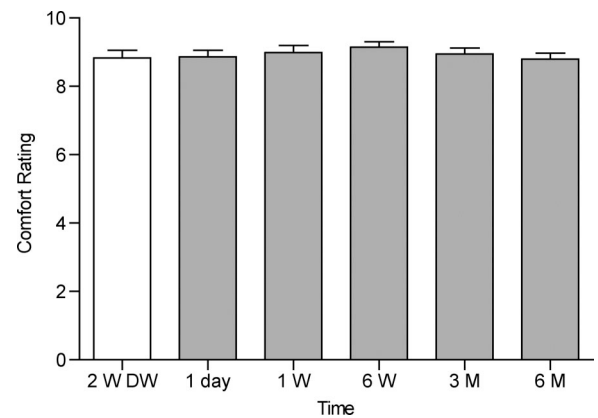


FIGURE 3.

Binocular comfort grades (mean \pm standard error), in which zero = intolerable, 10 = perfect. There were no significant changes in comfort grades over time ($p > 0.05$).

tive slit lamp findings may have been higher in the Menifocal Z group because any finding above zero was recorded as positive, including low grades such as 0.1 or 0.2, whereas examiners in the Menicon Z study rounded their grades to the nearest whole number and may have rounded down low grades to zero. It is worthwhile noting that the average severity of positive findings in Menifocal Z wearers was low. There was a significant reduction in fluorescein TBUT at 3 months, but this reduction was not evident at 6 months (Table 1). Lens wettability remained unchanged over the course of the study. The effects of CW on tear film stability are not well established, and it is not clear why the reduction in TBUT at 3 months occurred. Further investigations, ideally using noninvasive measurement techniques, may provide additional insight into changes in tear film stability during CW.

Minimal adverse responses were observed during the course of the study, which was consistent with reports from other clinical investigations of the tisiifocon (Menicon Z) material.¹⁰⁻¹² There were no incidents of corneal infection or inflammation over the 6-month study period. The incidence of corneal infection with silicone hydrogel CW lenses is yet to be established; however, reports of infections with silicone hydrogel lenses when worn on a CW basis are appearing in the literature.¹⁹⁻²¹ A variety of inflammatory conditions occur with CW of silicone hydrogel lenses, including contact lens-induced peripheral ulcers (CLPU) and contact lens acute red eye (CLARE).^{22,23} Currently, there are no bifocal lens designs made from silicone hydrogel materials available on the market; however, it is expected that such lenses will become available in the near future. Evaluation of the clinical performance of the Menifocal Z compared with new silicone hydrogel bifocal designs will be warranted in due course.

Lens binding is considered to be a significant complication of GP contact lens extended wear, with the incidence of binding reported to be between 10% and 80%.²⁴⁻²⁷ In this study, the incidence of lens binding was 1.7%, with binding reported by 25% of subjects. Lenses were bound for an average of 6 minutes, which was less than durations reported by other studies.^{24,28} The reduced frequency of lens binding may have been the result of underreporting by subjects; however, it has been shown that diary recording of lens binding is a reliable method for monitoring this phenomenon.^{24,29} The reduced frequency of lens binding may have been

the result of the higher oxygen permeability of the tasilfocon A (Menicon Z) material used to produce Menifocal Z lenses. Minimal lens binding has also been reported with Menicon Z lenses when worn on a CW basis over 1 year.¹⁰ Subjects were using lubricating drops routinely every morning and night, which may have also contributed to the decreased incidence of binding compared with other studies in which lubricants were not used.^{24,27} Duration of lens binding has been shown to be shorter in steep-fitting lenses compared with flat-fitting lenses.²⁸ As discussed earlier, there was a tendency toward steepening the fit of the Menifocal Z lenses, and this may have contributed to the shorter durations of lens binding observed in this study.

The Menifocal Z lenses were rated highly by the subjects in terms of distance and near vision quality, vision stability, and comfort. Mean comfort scores were 8.8 ± 0.2 (using a zero to 10 scale) at baseline and 6 months, and were very similar to the comfort scores of 88 ± 12 (using a zero to 100 scale) reported by Morgan et al³⁰ for experienced lens wearers who wore the Menicon Z α lens on a CW basis.

Currently, all available bifocal contact lenses result in some level of visual compromise.^{4,8,31} The most common difficulties reported with the use of the Menifocal Z lenses were problems with distance and near vision tasks under dim illumination. This finding is not surprising in view of the reduced levels of low contrast VA experienced by the subjects in this study. Pupil sizes in bright and dim illumination were not measured in this study, and subjects were not asked to specifically grade distance and near vision under dim illumination conditions. The addition of these measures in future studies is likely to assist in gaining a better understanding of the factors contributing to the reduced performance of the Menifocal Z lenses in dim illumination.

A measure of the success of the Menifocal Z lens design is the duration of CW achieved by the subjects throughout the course of the study. Average wearing times of 22 days were reported, with 54% of subjects achieving wearing times of at least 22 days throughout the trial. These findings compare favorably with the figures reported by Gleason et al¹⁰ in their evaluation of the Menicon Z lens during CW, in which 66.5% of subjects wore lenses for >22 days.

It is worthwhile noting that a significant proportion of subjects were noncompliant with respect to overnight lens removal after 30 days (29 nights) of wear. Sixty-seven percent of subjects wore their lenses continuously for >30 days at least once throughout the course of the study despite repeated instruction regarding lens removal requirements at each study visit. The data from the two subjects who had average wearing times of 32 and 34 days, respectively, were retained in the analysis because outliers were not detected. Although none of the subjects experienced adverse events as a result of lens overwear, these findings highlight the need for repeated emphasis to lens wearers regarding adherence to approved wearing schedules.

In addition to overnight removals, subjects briefly removed each lens once per month during the course of the study. There is no data available regarding the frequency of brief lens removals during CW of GP or silicone hydrogel lenses. However, it could be anticipated that GP lenses worn on a CW basis may need to be removed more often than silicone hydrogel lenses because of a higher incidence of foreign body sensation as a result of debris entrapment

beneath the lenses. Foreign body abrasions have been reported more frequently in GP CW when compared with hydrogel extended wear.¹⁰

Subjects responded favorably to their experience with CW and were highly likely to continue to sleep in the lenses on conclusion of the study. When forced to choose, 89% of subjects who completed the study preferred the Menifocal Z lenses compared with their previous contact lenses. Ninety-six percent of subjects who completed the study chose to keep the Menifocal Z lenses on conclusion of the trial. These results suggest that the Menifocal Z lens provided acceptable distance and near correction for the majority of subjects who participated in this study.

Our 23% discontinuation rate compares favorably with other CW clinical trials.^{10,32} The majority of discontinuations were the result of vision-related problems and only one subject discontinued as a result of comfort-related issues, which occurred during the DW phase of the study. It is difficult to compare success rates between different bifocal/multifocal lens studies as a result of differences in study design and definitions of success. Success has been defined as the number of subjects who have completed a trial (37% to 82%),^{8,31} chosen a bifocal/multifocal lens as a preference (70% to 86%),^{16,33} or purchased multifocals at the end of a study (53%).⁴ Taking the various definitions into account, our success rates were not dissimilar to other reports, with 77% completing the study and 89% preferring the bifocal lens design.

The Menifocal Z appears to be a promising option for CW in a presbyopic population, providing successful correction of distance and near vision in a group of experienced GP lens wearers. Minimal adverse responses were observed over the 6-month study period, suggesting that the hyper-Dk Menicon Z material allows for safe wear of the lenses on a CW basis.

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