Silicone hydrogel options for presbyopes

Bill Long and **Tim Giles** describe the Air Optix Aqua Multifocal, a new silicone hydrogel multifocal lens from CIBA Vision

Spherical and toric contact lens wearers have enjoyed the clinical and subjective benefits of many different silicone hydrogel contact lens materials and designs for several years. The high oxygen transmissibility of silicone hydrogel materials has been linked to improvement in clinical signs of inflammation,[1] hypoxia,[2,3] epithelial and endothelial cell integrity,[4,5] and corneal stability.[6,7,8] Subjective benefits of improved symptoms of dryness, photophobia, lens awareness, blurred vision, and comfort have been consistently reported.[9,10,11,12,13]

Presbyopic patients have not previously enjoyed the luxury of options available to other wearers when it comes to contact lens correction in these high oxygen transmissibility materials. With only one silicone hydrogel multifocal contact lens on the market, eye care practitioners and their patients have not had the opportunity to choose from options that are arguably better suited to the ocular health and comfort requirements of the ageing eye. CIBA Vision has designed a multifocal option for the lotrafilcon B material (Air Optix Aqua Multifocal) and has performed a clinical study to compare it to the currently marketed balafilcon A multifocal lens (PureVision Multifocal). Table 1 compares the lenses.

This study was conducted under International Ethics Committee/ Institutional Review Board approval and Informed Consent was signed by each subject before any study procedures were performed. The primary objective was to compare subject comfort and visual satisfaction, purchase intent, lens preference, and investigator ease of use with LB MF (Lotrafilcon B Multifocal) and BA MF (Balifilcon A Multifocal) silicone hydrogel contact lenses. The secondary objective was to compare other objective visual performance measures of both lens types. Additionally, investigator sentiment on LB MF product performance in comparison to other contact lens options were evaluated and biomicroscopy signs were monitored for safety evaluation. Subjects were dispensed and fit according to their spectacle prescription and add requirement in a prospective, randomised, bilateral, crossover trial. All subjects had spectacle adds of +0.50D, +0.75D, or +1.00D based on a new spectacle refraction with add determination completed at the baseline visit. All subjects were selected from the patient population at each investigational site and were screened to ensure suitability. Other inclusion and exclusion criteria are noted in Table 2.

To ensure matching of the emerging presbyopic market, each site was required to enroll at least one, but no more than three habitual monovision subjects. Additionally, each investigator was required to have experience fitting PureVision Multifocal contact lenses and the Bausch & Lomb PureVision Multifocal. Expert Tips For Exceptional Fits was required for fitting BA MF lenses. LB MF lenses were to be fit according to the Lotrafilcon B Multifocal Fitting Guidelines (Modified).

Subjects were masked to lens brands by dispensing lenses directly from their packaging with the foil removed. Two add designs of LB MF lenses were ▶

TABLE 1 Lotrafilcon B and Balafilcon A multifocal contact lenses

	% water	BC/Dia	Sphere powers*	Add powers	Add type	Dk/t
Lotrafilcon B multifocal (LB MF)	33%	8.6 / 14.2	+6.00 to -10.00	LO MED HI**	Precision transition lens design	138
Balafilcon A multifocal (BA MF)	36%	8.6 / 14.0	+6.00 to -10.00	Low High	Aspheric, centre near	110

*Powers used in this study were +1.75 to -6.00. **Not used in this study

TABLE 2 Inclusion and exclusion criteria

Inclusion criteria	● Was at least 35 years of age ● Able to read, understand, and sign informed consent ● Spectacle add of +0.50D, +0.75D, or +1.00D
Exclusion criteria	● Required concurrent ocular medication ● Eye injury or surgery within 12 weeks immediately prior to enrollment ● Pre-existing ocular irritation that precluded contact lens fitting ● Currently enrolled in an ophthalmic clinical trial ● Evidence of systemic or ocular abnormality, infection or disease likely to affect successful wear of contact lenses or use of their accessory solutions ● Aphakia, pseudoaphakia, or previous refractive surgery ● Astigmatism >1.00D ● Habitually uncorrected anisometropia ≥2.00D ● Clinically significant anisocoria ● Strabismus/amblyopia ● Currently wearing PureVision Multifocal, SofLens Multifocal, or Unilens C-Vue Multifocal

provided to investigators for this trial, LO and MED, and the distance powers available ranged from +1.75 to -6.00D. Two add designs of BA MF lenses were also provided to investigators, Low and High, and the distance powers available ranged from +1.75 to -6.00D. Subjects wore each pair of lenses on a daily wear basis for up to eight days ± two days and used AOSept Plus for their cleaning and disinfecting solution. No spare lenses were provided and refits were not allowed after the dispensing visit. When necessary, study lenses were rinsed with SoftWear saline and lens drops were allowed at the subject's discretion.

During the baseline exam, investigators performed a spectacle refraction and determined each subject's spectacle add. Based on this information, investigators fit and dispensed study lenses using a randomisation schedule supplied by the study sponsor. If a subject could not be fitted with the randomised lens brand, they were crossed over to pair 2 or exited from the trial.

Due to the lack of historical data with similar trial designs with multifocal lenses, sample size and power for the study could not be rigorously estimated. Pilot data from a two-week crossover study estimated that a sample size of 78 would provide 80 per cent power to detect a paired difference of 1.0 grade (two-sided α=0.05) and that attainable power decreased to 59 per cent with a sample size of 48.

TABLE 3 Enrolled subject profile

Mean age was 43.4 ± 3.2 (range 36 to 50) years
Female/male ratio was 77%/23%
69% wore distance-only contact lenses before entering the trial
15% were habitual bifocal or multifocal contact lens wearers
17% were habitual monovision wearers
The three most common habitual contact lens brands were: PureVision 19% Acuvue Oasys 12% Biomedics EP 10%
Distribution of spectacle adds: +0.50: 13% +0.75: 37% +1.00: 50%

Results

Forty-eight subjects were dispensed and 47 completed the study. One subject was discontinued when they were dispensed the incorrect lens assignment. When this error was discovered, the subject returned to the site and was discontinued from the trial. Profiles of the enrolled subjects are in Table 3, the dispensed lenses in Table 4, and wear time during the study in Table 5. The average sphere power ranges for dispensed lenses were similar for LB MF and BA MF, as well as the average days/week and hours/day of wear time. While not variables that were tested for statistical significance, the average wear time for BA MF tended to be an hour lower than for LB MF, which may have been from subjective performance factors that were reported during the study.

Clinical differences that were statistically significant were found for visual acuity (VA) and range of clear vision at follow-up visits. The statistically significant differences were for monocular distance VA (p=0.018), range of clear far vision (p=0.010), and the difference between near and far clear vision p=0.007) and are summarised in Table 6. Ratings for ghost images were also evaluated and no statistically significant differences were found, as noted in Table 7. More impactful differences were found for subjective vision ratings with statistically significant differences for all aspects rated after experience with the lenses (Table 8). No statistically significant differences were found for the subjective vision ratings taken at dispensing.

While performance for vision may be the initial criteria for assessing a vision correction device, research has shown that subjective satisfaction maintains their use.[14] Subjective comfort was evaluated as a rating for each lens and as preference compared to habitual lenses. Statistically significant differences ranging from 0.7 to 2.9 were found for all comfort ratings (Figure 1). When compared to habitual lenses, statistically significant differences were also found for all comfort ratings (Table 9). Calculation of net comfort preference also revealed negative values for BA MF for all comfort ratings.[15]

While statistical significance was not tested for every variable collected, LB MF and BA MF lenses were closely comparable for many lens fitting variables assessed in this study. Table 10 summarises fit assessment variables. Both lenses could be successfully dispensed with the first lens tried on the majority of subjects. LB MF lens fitting tended to be judged as optimal slightly more often and they tended to have better centration. Decentration for

Figure 1 Average comfort rating

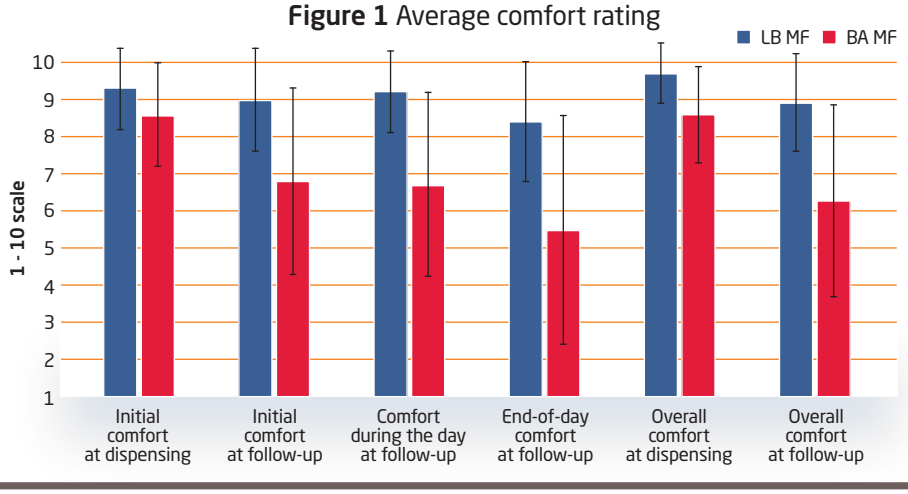

TABLE 4 Dispensed lens profile

	LB MF	BA MF
Average sphere power (D)	-2.76 ± 1.84	-2.80 ± 1.82
Sphere power range (D)	-6.00 to +1.75	-6.00 to +1.50
LO/low add use (%)	95	95
MED/high add use (%)	5	5

TABLE 5 Wear time

		LB MF	BA MF
Avg days/wk	Mean±STD	6.8 ± 0.6	6.6 ± 0.9
	Range	5 to 7	2 to 7
Avg hrs/day	Mean±STD	12.7 ± 2.6	11.7 ± 3.1
	Range	8 to 17	4 to 17

TABLE 6 Clinical VA and range of clear vision

		LB MF	PV MF	P-Value
Monocular distance logMAR VA	Dispense	0.02 ± 0.06	0.03 ± 0.06	
	Follow-up	0.02 ± 0.08	0.05 ± 0.10	p=0.018*
Binocular distance logMAR VA	Dispense	-0.01 ± 0.04	0.00 ± 0.05	p=0.197
	Follow-up	-0.01 ± 0.05	0.00 ± 0.05	
Binocular Intermediate logMAR VA	Dispense	-0.07 ± 0.09	-0.06 ± 0.13	p=0.901
	Follow-up	-0.04 ± 0.15	-0.05 ± 0.10	
Binocular near logMAR VA	Dispense	-0.01 ± 0.09	0.00 ± 0.12	p=0.715
	Follow-up	0.02 ± 0.11	0.03 ± 0.13	
Range of clear vision (cm)	Near (disp)	21.2 ± 6.7	22.3 ± 10.5	p=0.118
	Near (f/u)	21.2 ± 7.3	23.0 ± 8.6	
	Far (disp)	121.5 ± 20.4	115.3 ± 20.4	
	Far (f/u)	121.6 ± 22.7	117.5 ± 19.5	p=0.010*
	Far - Near (disp)	100.3 ± 23.5	93.0 ± 26.6	
	Far - Near (f/u)	100.4 ± 25.7	94.6 ± 24.7	p=0.007*

*Statistically significant difference. Highlighted values indicate better performance

TABLE 7
Ghost images: % of subjects reporting none

	Follow-up		
	LB MF	BA MF	P-value
Binocular distance vision	93%	81%	0.053
Binocular interme-diate vision	91%	87%	0.494
Binocular near vision	91%	85%	0.327

TABLE 8 Subjective vision ratings

		Dispensing		Follow-up	
		LB MF	BA MF	LB MF	BA MF
Distance vision	Mean ± STD	9.3 ± 0.9	8.9 ± 1.3	8.5 ± 1.5	6.9 ± 2.4
	P-Value	0.061		<.001*	
Intermediate vision	Mean ± STD	9.3 ± 1.1	9.0 ± 1.1	8.8 ± 1.5	7.7 ± 1.9
	P-Value	0.086		0.001*	
Near vision	Mean ± STD	9.2 ± 1.4	9.0 ± 1.3	8.4 ± 1.8	7.2 ± 2.3
	P-Value	0.544		0.002*	
Night vision	Mean ± STD	Not rated at dispensing visit		8.6 ± 1.3	7.1 ± 2.6
	P-Value			0.002*	
Vision when using computer	Mean ± STD			8.9 ± 1.7	8.0 ± 1.8
	P-Value			0.011*	
Minimising eye fatigue/strain	Mean ± STD			8.5 ± 1.9	6.4 ± 2.7
	P-Value			<.001*	
Ease of transition close-up/distance	Mean ± STD			9.0 ± 1.1	7.0 ± 2.6
	P-Value			<.001*	
Overall vision	Mean ± STD	9.2 ± 1.0	8.9 ± 1.2	8.8 ± 1.3	7.3 ± 2.0
	P-Value	0.095		<.001*	

*Statistically significant difference. Highlighted values indicate better rating score

both tended to change with wear so that about 75 per cent decentred inferiorly. A statistically significant difference was found for investigator assessment of ease of fit. BA MF tended to show more surface deposition and drying in this one-week study, a characteristic that has been reported with the material (Table 11).

The safety performance was also similar between LB MF and BA MF. Almost all eyes showed trace or no signs and no moderate or severe signs were seen after wearing either lens. Mild bulbar redness was reported in 3 per cent of eyes after wearing BA MF and mild conjunctival staining in 2 per cent after wearing LB MF. Biomicroscopy signs are illustrated in Figure 2.

Finally, the important question of intent to purchase was asked and it was found to strongly and statistically favour LB MF lenses (Table 12).

Summary

Myopic and hyperopic spherical and toric contact lens wearers and eye care practitioners have had many silicone hydrogel options to meet their needs since first introduced in 1998. Now, choices are becoming available for presbyopes and are expected to show benefits of continued research and development. In this trial, objective and subjective assessment measures of comfort, vision and ocular health showed a very high performance with both the LB MF and BA MF. With the sample size provided, LB MF appears to outperform the BA MF in many areas relating to comfort, vision, fitting and patient intent to purchase. The increased range of clear vision found objectively with the LB MF material appears to be consistent with the higher subjective ratings found at the computer and intermediate distance with this lens type. In addition, given that increased chair time has historically been a concern for practitioners, it is pleasing to see such high success rates with first fit lenses with both lens types, particularly with the LB MF.

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TABLE 9 Comfort preference compared to habitual lenses*

	Initial comfort		Comfort during the day		End of day comfort		Overall comfort	
	LB MF	PV MF	LB MF	PV MF	LB MF	PV MF	LB MF	PV MF
Much better	11%	0%	20%	0%	15%	0%	22%	0%
Somewhat better	26%	4%	22%	6%	24%	11%	20%	11%
About the same	52%	40%	39%	40%	33%	30%	37%	28%
Somewhat worse	9%	34%	20%	32%	26%	23%	22%	38%
Much worse	2%	21%	0%	21%	2%	36%	0%	23%
Net preference**	26%	-51%	22%	-47%	11%	-49%	20%	-51%

*Statistically significant differences were found for all paired comparisons with p-values <0.001
**(much better + somewhat better) - (somewhat worse + much worse)

TABLE 10 Investigator assessment of lens fitting

	Dispensing		Follow-up	
	LB MF	BA MF	LB MF	BA MF
Number of lenses tried				
1	86%	81%		
2	13%	19%		
Overall fit				
Optimal	96%	81%	96%	89%
Centration				
Centred	91%	81%	91%	84%
Decentration				
Temporal	50%	39%	25%	14%
Inferior	50%	44%	75%	71%
Easy to fit for each subject				
Strongly agree	76%	51%		
Agree	24%	43%		
P-value	0.001			

TABLE 11 Lens surfaces

	Dispensing		Follow-up	
	LB MF	BA MF	LB MF	BA MF
Front surface deposits				
None	99%	99%	87%	72%
Back surface debris				
None	100%	100%	100%	100%
Haziness/ filmy/oily				
None	100%	96%	89%	91%
Dry areas/ non-wetting				
None	100%	100%	99%	91%

TABLE 12

Assume your practitioner said you could use this product. How likely would you be to purchase the lenses you wore during the past week of the study?

	Lotrafilcon B MF	Balafilcon A
Definitely would	30%	6%
Probably would	28%	15%
Might/might not	30%	36%
Probably would not	9%	9%
Definitely would not	2%	34%
Net purchase intent	48%	-21%
P-value	<.001	

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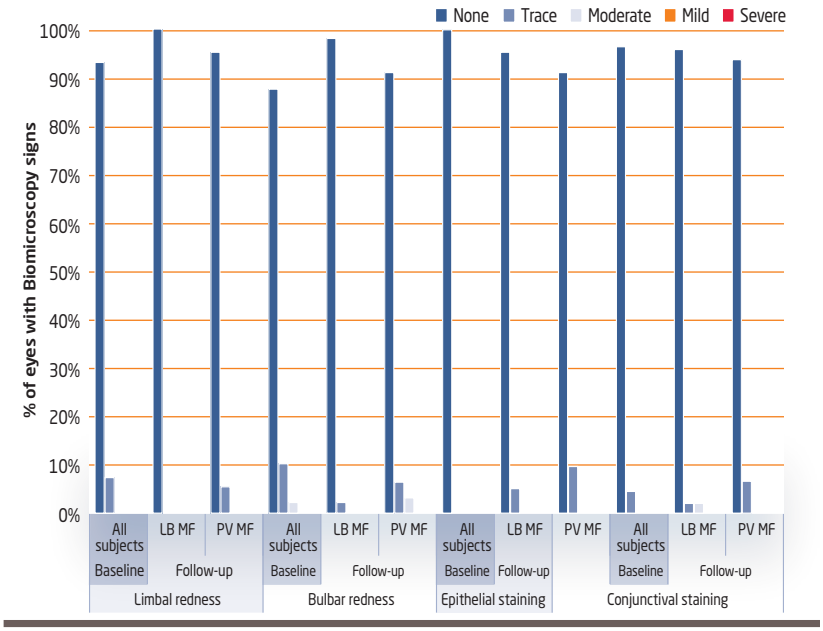
Figure 2 Biomicroscopy signs



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