CONTACT LENS

A Clinical Evaluation of the ALGES™ (hefilcon A) Bifocal Contact Lens

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Abstract

A new, soft bifocal contact lens design is described and its performance is assessed on the basis of sustained wearing time, refraction, acuity for near and far, k readings and pupil diameter. Recommendations are made to help improve success. Characteristics of successful and unsuccessful users are listed.

Résumé

Ce travail décrit un nouveau model de lentille contact souple double foyer. Sa performance est évalué en fonction de la durée du port, réfraction, acuité au loin et de près, courbes kératométriques et diametre de la pupille. Quelques recommandations pour rehausser le succès sont offerts. Les caractéristiques des porteurs qui ont réussi et ceux qui ont échoué sont énumérés.

Introduction

North American contact lens wearers' needs have changed gradually from their early requirements as adolescents to their current requirements as middle aged presbyopes. As a result of this change, it appears that a bifocal contact lens inventory has become mandatory in any up to date contact lens practice.

The theory that one contact lens design, or even one contact lens manufacturer, can meet all patient requirements is, of course, a fallacy. The contact lens practitioner, as a result, must be able to choose from an "arsenal" of bifocal type contact lenses.

The intent of this study was to evaluate the ALGES™ (hefilcon A) Bifocal Contact Lens from University Optical Products Company and determine its position and benefit in this "arsenal".

Material

The ALGES™ (hefilcon A) Bifocal Contact Lens is manufactured from PHP™ I, a random copolymer of 2-hydroxyethyl methacrylate and N-vinyl-2-pyrrolidone crosslinked with ethylene glycol dimethacrylate. When hydrated in normal isotonic saline, the lens has a water content of 45%.

Design

The ALGES™ Lens is a concentric bifocal design with a central near add zone of 2.12 and 2.35mm in diameter, surrounded by a distance annulus optic zone of typically 8.5mm diameter (figure 1).

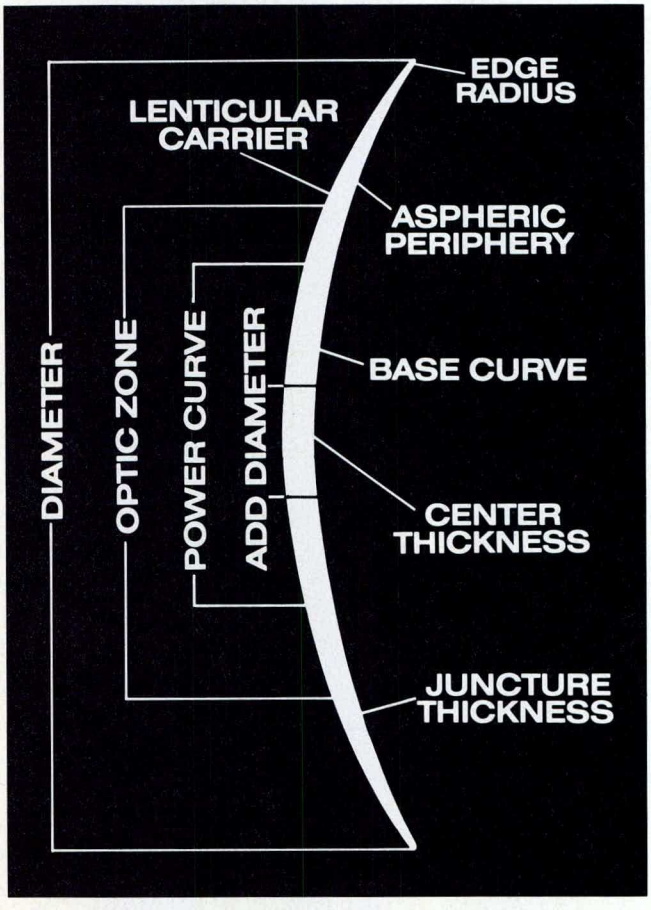

Fig. 1 ALGES™ Bifocal Contact Lens

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Standard lens diameter is 14.0mm and the lens is available in 8.6 and 8.9mm base curves. (An 8.3mm lens was initially considered as well.) Powers are available from -6.00 to +6.00 diopters with add powers of 2.00, 2.50, 3.00 and 3.50 diopters.

This concentric design is based on the theory that the near add zone focuses rays from near objects on the retina (figure 2a), while rays from distance objects are focused on the retina through the distance annulus (figure 2b). By selecting a central add diameter to cover 50% of the pupil under illumination levels appropriate for reading, near and distance vision can theoretically be balanced.

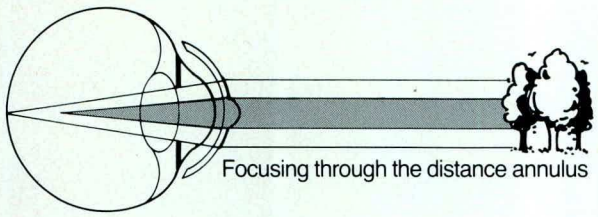

Fig. 2a
Focusing through the near add optic

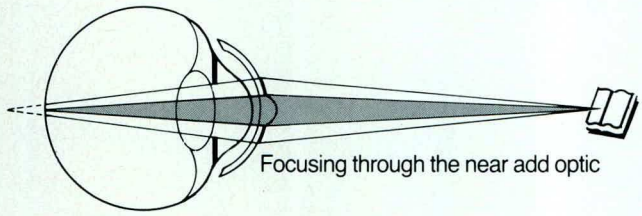

Fig. 2b
Focusing through the distance annulus

Methods

Twenty patients were selected for the study from a waiting list composed of successfully fitted non-astigmatic pre-presbyopes who have, over the last 12 to 15 months become presbyopic, and whose distance prescriptions were within the range of powers available from the manufacturer.

During the course of the study, there was no attempt to enhance the performance of these bifocal lenses by simulating monovision fitting techniques. The final contact lens prescription was the most plus or least minus that gave the best corrected monocular vision possible. The final base curve selected was the flattest one that centered well and did not restrict free movement over the bulbar conjunctiva.

Patients were deemed to be successful if:

1. They could maintain their existing wear times.
2. They achieved 20/25 binocularly or at least the same acuity for distance as they had with their existing lenses.
3. They were able to read 20/25 binocularly for near. (Jaeger 2)

Clinical Data

Pertinent clinical data on the 20 patients include:

1. Distance and near visual acuities uncorrected, with existing lenses and with the ALGES™ Bifocal Contact Lens.
2. Keratometric findings.
3. Refraction findings.
4. Horizontal visible iris diameter measurements.
5. Stimulated pupil diameter measurements: taken with a pen light held at a distance of about one inch from the eye and 20 to 30° temporally.
6. Pupil excursion ranges: the difference in pupil diameters going from those measured under the general illumination of the author's office, to those measured with penlight stimulation.
7. Patient age and sex.

Results:

Of the twenty patients selected for this study, fourteen (70%) were deemed successful according to the previously stated criteria. Of the six unsuccessful patients, two discontinued due to poor near acuities and four discontinued due to distance acuities.

It was found that the unaided binocular acuities of the successful study group were generally worse, both at distance and at near, than those of the unsuccessful group (Table 1).

Successful patients achieved almost the same quality of binocular distance acuities with their ALGES™ lenses as they did with their existing ones (20/25 versus 20/22 respectively).

As expected, however, their binocular near acuities improved from an average of 20/75 with existing lenses, to an average of 20/22.5 with the ALGES™ Lenses.

An interesting statistic was the fact that a ratio of 2.5 females to 1.0 male made up the unsuccessful group, while 6.0 females to 1.0 male made up the successful group (Table 2).

The average contact lens bifocal adds required were approximately one diopter higher than those required in spectacles (Table 2). The distribution of base curves (Figure 3 and 4) shows that the 8.9mm base curve was most often used. There was a statistically even split between the 2.12 and 2.35mm near add zone diameters (Table 2).

Discussion:

A previous study conducted with different concentric design lenses reported that the simultaneous imaging found with multifocal lenses created a "competition for the macula" which was accompanied by visual confusion."[1]. Practically speaking, this translated into patient complaints and discontinuation of lens use due to diplopia, glare, blurring and ghost images. The complaints resulted in 92.5% of the patients in the study to discontinue wear.

Table 1
Comparison Table of Acuities

	Patients	
	Unsuccessful	Successful
Range of Binocular Unaided Distance Acuities	20/80 - 20/400	20/100 - 20/800
Average Binocular Unaided Distance Acuity	20/215	20/340
Range of Binocular Unaided Near Acuities	20/20 - 20/300	20/25 - 20/400
Average Binocular Unaided Near Acuities	20/122	20/188
Range of Binocular Distance Acuities with Existing Lenses	20/20 - 20/25	20/20 - 20/30
Average Binocular Distance Acuities with Existing Lenses	20/21	20/25
Range of Binocular Distance Acuities with ALGES™ Lenses	20/25 - 20/60	20/20 - 20/30
Average Binocular Distance Acuity with ALGES™ Lenses	20/34	20/25
Range of Binocular Near Acuities with Existing Lenses	20/40 - 20/200	20/30 - 20/100
Average Binocular Near Acuity with Existing Lenses	20/50	20/75
Range of Binocular Near Acuities with ALGES™ Lenses	20/30 - 20/80	20/20 - 20/25
Average Binocular Near Acuity with ALGES™ Lenses	20/44.3	20/22.5

Table 2
Comparison of Ocular Parameters

	Patients	
	Unsuccessful	Successful
Range of Flattest Keratometric Reading	42.00 - 45.00	41.50 - 47.50
Average of Flattest Keratometric Reading	43.25	43.58
Range of Horizontal V.I.D.	11.0 - 12.0mm	11.0 - 12.5mm
Average of Horizontal V.I.D.	11.54mm	11.64mm
Range of Stimulated Pupil Diameters	2.0 - 4.0mm	2.0 - 4.0mm
Average of S.P.D.	3.11mm	3.04mm
Average Pupil Excursion Range	1.54mm	2.34mm
Range of Ages in Study Group	44 - 60 yrs.	42 - 55 yrs.
Average Age of Study Group	49.57 yrs.	48.36 yrs.
Ratio of Females to Males	2.5 : 1	6 : 1
Range of Spectacle Rx Bifocal Adds	+1.25 D to +2.50 D	+1.25 D to +2.50 D
Average of Spectacle Rx Bifocal Adds	+2.00 D	+2.00 D
Range of Contact Lens Bifocal Adds	+2.50 D to +4.00 D	+2.00 D to +4.00 D
Average of Contact Lens Bifocal Adds	+3.00 D	+3.00 D
Ratio of 2.12 to 2.35 Add Diameters Used	1 : 2	4 : 3

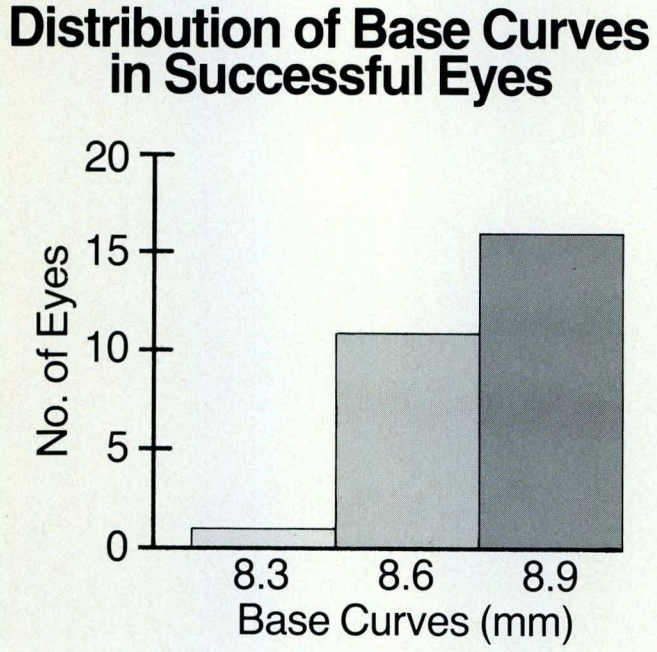

Fig. 3

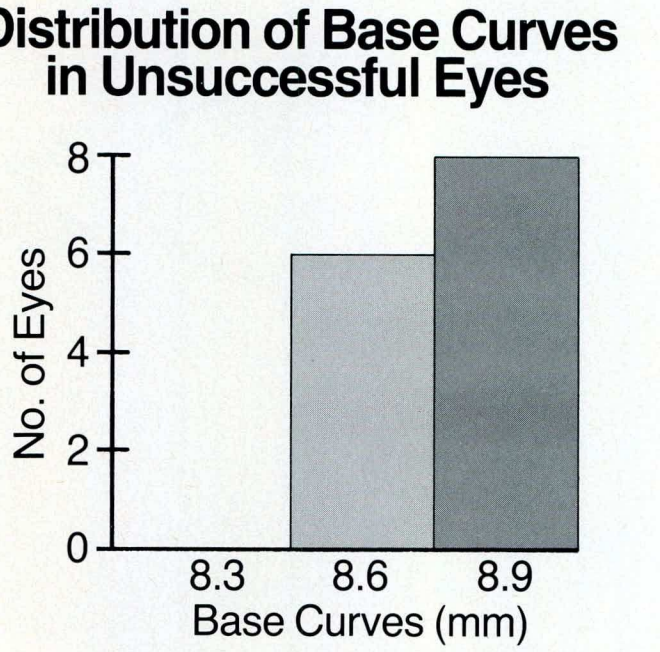

Fig. 4

The major difference in the ALGES™ (hefilcon A) Bifocal Contact Lens and the earlier designs studied is the placement of the near vision optic in the center of the lens surrounded by the distance annulus optic. This design configuration, which averages a seven micron transition between optics, plays to the synkinetic pupil response. This response, a result of pupil constriction during accommodative convergence, allows 60 to 70% of all available light to pass through the central near add zone optic, which greatly enhances near acuity when reading.

Conversely, during normal or low lighting conditions when the pupil is dilated, up to 80% of all available light passes through the distance optic

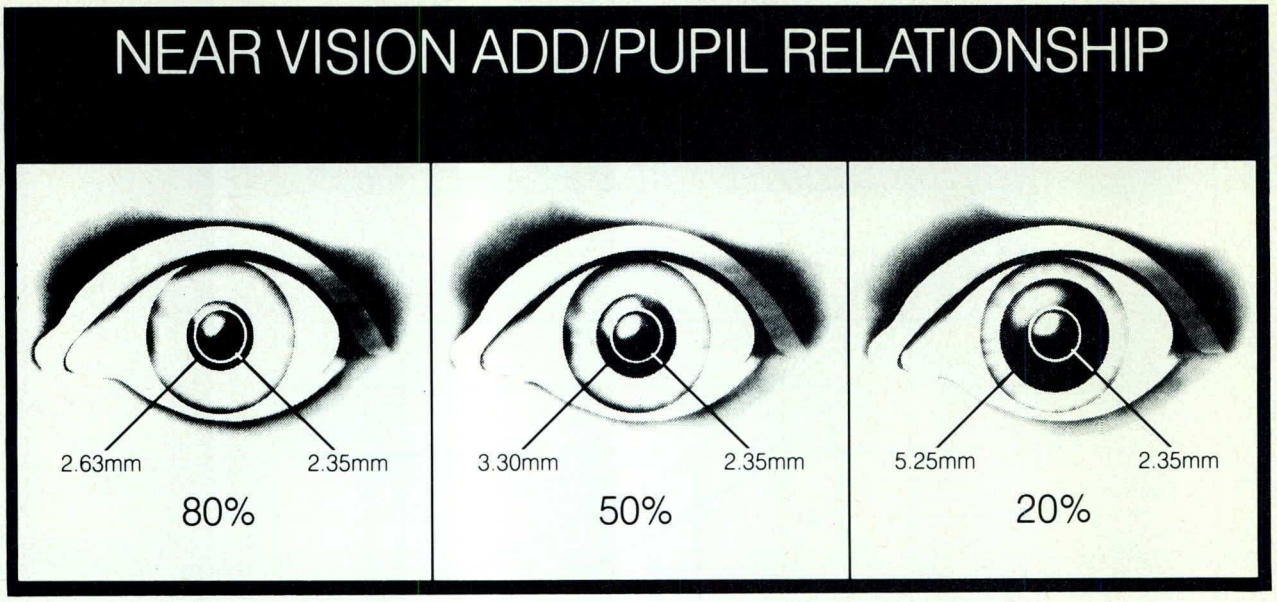

Fig. 5

zone. This is best demonstrated by use of the illustrations in Figure 5 and the graph in Figure 6 which show the relationship between pupil size and the central near add zone at varying light levels.

True to expected form, no complaints were found among the successful patient group, (those achieving 20/25 binocularly), concerning distance vision at night. However, some patients outside the successful patient group are motivated to accept 20/30 and J-3.

Almost all of the study patients found the ALGES™ lenses to be very comfortable. It was also noted that any lens which had to be replaced as a result of loss or damage, demonstrated excellent reproducibility by performing the same as the original lens.

The ALGES™ Bifocal Contact Lens comes in a large assortment of inventoried parameters which enable the practitioner to try various combinations in order to achieve the best possible fit. This is definitely not a "one size fits all" type lens. The ability to select between 2.12 and 2.35mm add diameters for instance, saved a number of potential failures.

There were a few drawbacks to the lens that are worth noting:

1. Satisfactory distance acuities sometimes could not be obtained under very bright lighting conditions (although, good quality sunglasses did help in this case).
2. Almost all of the study patients (both successful and unsuccessful) initially mentioned experiencing some shadows or even a "3D" effect while reading under lower than normal light levels. The successful patients adapted to these phenomena in little time, while the unsuccessful ones had greater difficulty. Careful patient counselling concerning this phenomenon was vital to adaptation. The patients were advised that with continued wear, the visual symptoms would automatically be ignored, much like spectacle frames or the lines of a bifocal spectacle which are no longer noticed after a few days' wear. It was found that if the patients were warned about the likelihood of shadowing or "3D" effects the ability to adapt to the situation increased significantly.

Suggestions for improving success rate include:

1. Increasing add power or size of near add zone if there are complaints of shadows or ghosting.
2. Remembering that the age group of patients that are going to be wearing this lens is 40 to 55 plus. As a result they may have drier eyes than those of younger patients. Fitting the flattest possible lens and using lots of ocular lubricants daily is then highly recommended.
3. Steepening the base curve and/or increasing the near add zone diameter if a lens decenters temporally resulting in reduced acuity at near.

Some of the problems that the test group encountered were as follows:

1. Difficulty in determining lens eversion, especially in low distance powers. The teaching of patience in these cases proved invaluable in determining a favourable outcome to the situation.
2. The study patients, in particular the older group, found the lenses to be somewhat more susceptible to tearing than previously experienced. However, this problem was significantly reduced with instructions to lubricate the eyes just prior to lens removal.

Conclusions

Based on this study, the ALGES™ Bifocal Contact Lens worked well with previous contact lens wearers who were highly motivated to continue wearing their

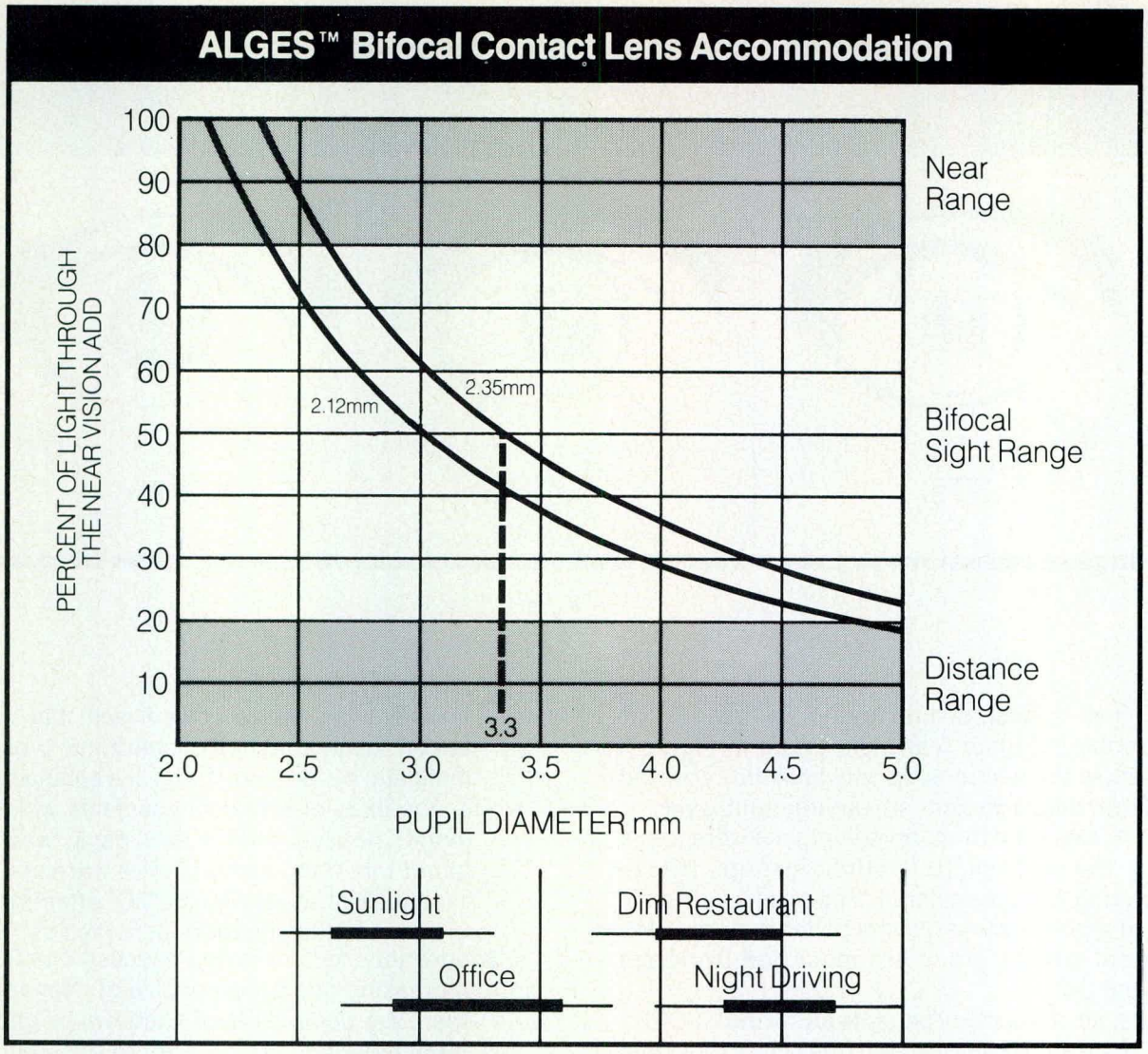

Fig. 6

contacts into their presbyopic years. The most successful patients were those who:

1. Had little or no astigmatism.
2. Had good ranges of pupillary excursions.
3. Were female.
4. Suffered relatively poor distance and near unaided acuities.

The ones who weren't successful were those who:

1. Had distance Rx's of 0.75D to 1.00D and lacked visual motivation.
2. Had professions involving excessive reading or other forms of near work.
3. Had very small or very large, sluggish pupils.
4. Had advanced well into their presbyopic years, and as a result, would not accept any acuity that was less than that achieved with their glasses.

As stated before, the ALGES™ Bifocal Contact Lens won't fit 100% of all presbyopes. However, the average contact lens practitioner can easily utilize the variety in parameter selection to figure out which patient will or won't work out. The fact that this can be done without spending an exorbitant amount of time on the case, makes this a prominent addition to one's bifocal contact lens fitting "arsenal".

Acknowledgement

This study was supported in part by University Optical Products Company. The author wishes to thank them for their technical expertise and cooperation.

Reference

1. Maltzman, B.A., Harris, M., and Espy, J. "Experience with Soft Bifocal Contact Lenses." *The CLAO journal* Vol. 11, Number 1, pp. 73-77, 1985.