

## Comparison of visual performance between a single- and a dual-focus contact lens for the control of myopic progression

V. VILLANI<sup>(1)</sup>, D. PIETRONI<sup>(1)</sup>, F. OFFI<sup>(1)</sup> and D. PETRINI<sup>(1)</sup>(<sup>2</sup>)

<sup>(1)</sup> *Dipartimento di Scienze, Università degli Studi Roma Tre - Via della Vasca Navale 84, 00146 Rome, Italy*

<sup>(2)</sup> *Vision Optika - Via del Gambero 11, 00187 Rome, Italy*

received 20 February 2023

**Summary.** — Myopia is a globally widespread ametropia. This has motivated the development of approaches to slow myopic progression, including the use of specific dual-focus contact lenses for myopia control. In this study, the visual performance of a dual focus contact lens (MiSight<sup>TM</sup>) and a single vision contact lens (Bausch & Lomb Ultra) was compared. To this aim, 25 myopic subjects were recruited (Sp from  $-0.50$  D to  $-6.00$  D, with max astigmatism of 1.00 CD). During the visit, the monocular and binocular visual acuity without correction was recorded, and the total topoaberrometry was performed. Subsequently, for each subject, monocular and binocular low-contrast visual acuity and high-contrast visual acuity was addressed with both type of lens. Visual quality was objectively evaluated by performing total ocular aberrometry. The results allow evaluating the effect of dual focus contact lens on vision.

### 1. – Introduction

It is well known that myopia represents a global issue. The results from the study by Holden *et al.* [1] in 2016 show worrisome estimates for the total number of people with myopia globally: in 2000 it was 1406 million (22.9% of the global population), increasing to 1950 million in 2010 (28.3% of the population), with the forecast of 2620 million people in 2020 (34% of the population), 3361 million in 2030 (39.9% of the population), 4089 million in 2040 (45.2%), up to 4758 million in 2050 (49.8%). It is thus important to elaborate guidelines to be followed in order to try to prevent this condition. Indeed, it has been suggested that myopia depends on environmental factors, such as time devoted to activities in proximity close range, time spent outdoors, exposure to the sun, lack of physical activity and level of education, making it possible to highlight differences in the global distribution (see [2] and references therein).

A further important problem is that high myopia can lead to serious complications, such as myopic macular degeneration and choroid neovascularization, hence the need to

evaluate the strategies for the control of its progression that have been reported in the scientific literature, including both optical and pharmaceutical approaches [3]. Among the latter, we can mention the use of atropine, a non-selective muscarinic antagonist that acts through a photochemical cascade [4]. Concerning optical methods, under-correction of myopia has been adopted in the past with the aim of creating a myopic defocus, but this is now considered unfavourably [5]. At present, bifocal and multifocal ophthalmic lenses represent a more reliable alternative for the control of myopic progression [6]. Contact lenses (CLs) can also play a role in controlling myopic progression, especially multifocal, dual-focus, and orthokeratology CLs. Studies carried out for the dual-focus CLs have demonstrated excellent results: it has been well established that dual-focus CLs are effective in controlling the progression of myopia, presenting a clinically relevant effect [7]. This stimulates questions about the visual performance that these innovative types of dual-focus CLs (DFCLs) can provide to young subjects and whether or not the DFCLs can be compared to the vision obtained through single-vision CLs (SVCLs). For this reason, we conceived the present experimental study to compare the visual performances of these two classes of lenses. In particular, the aim of the study is to compare low-contrast visual acuity (LCVA), high-contrast visual acuity (HCVA), and visual quality by means the evaluation of the aberrometric pattern between a DFCL (MiSight<sup>TM</sup>- Omafilcon A - Coopervision) and a control SVCL (Ultra 1 day - Kalifilcon A - Bausch & Lomb). The measurements have been carried out at the contact lens cabinet at Vision Optika in Rome.

## 2. – Materials and methods

25 subjects (15 females, 10 males, 50 eyes) were recruited, with a mean age of  $15 \pm 3$  years (range 10–19 years), in the period from February 2022 to April 2022. The subjects were inspected to verify they met the inclusion criteria of the study:

- Absence of ocular pathologies or ocular surface irregularities;
- Myopia from Sf  $-0.50$  D to  $-6.00$  D; maximum astigmatism of 1.00 CD;
- Maximum age of 19 years;
- Wearers of dual-focus CL for the control of myopic progression.

SVCLs have no effect on the control of myopia progression since they create a hypermetropic peripheral defocus while bringing the focal plane of the image to the fovea [8]. The geometry of the dual-focus CL implies a central optical zone for the correction of myopia and two peripheral concentric treatment zones that alternate a fixed positive power of  $+2.00$  D (myopic defocus) and a negative power for the nearsightedness correction. Specifically, these MiSight<sup>TM</sup> CLs are designed to favour an adequate myopic defocus with respect to different prescriptions, changes in pupil size and variations in the centering of the CL, through a geometry called ActivControl® allowing to contain the increase in axial length, thus, the progression of myopia, completely correcting the refractive error [9]. Some areas of blurred vision are possible with these lenses, especially in the first period of adaptation.

The tests were carried out after about 5–10 minutes from the application of the CLs. In particular, the LCVA and HCVA, in both monocular and binocular vision, were evaluated in ambient light conditions, such as to induce photopic adaptation, by an LCD Snellen chart (Nidek SC-1600 polarized) held 6 meters away from the 25 subjects,

with the test CL (MiSight<sup>TM</sup>, CL1) and the control CL (Bausch & Lomb Ultra 1 day, CL2). Visual quality was objectively assessed by performing total corneal aberrometry in ‘TopoAberrometry’ mode, with measurements carried out by a Keratron Onda model. It was then possible to assess the visual performance induced by the two types of CLs from a subjective point of view, namely by evaluating visual acuity, as well as from an objective one, by estimating the aberrometric values of the Strehl ratio (SR). Indeed, while in the second case the SR is an instrumental value, in the first the results obtained cannot be completely separated from the judgment of the operator and the subject being analysed.

### 3. – Results and discussion

In table I, the average values of visual acuity and Strehl ratio are reported from the 25 subjects sample, accompanied by the respective standard errors. Data for the right eye (RE), the left eye (LE) and binocular vision (EE) are shown separately for the case of no lens applied (no correction) and upon wearing the test lens (CL1) and the control lens (CL2). Visual acuity is expressed in logMAR. It is apparent that values of visual acuity and Strehl ratio are reduced upon wearing both types of lenses compared to the case of no correction.

In order to perform a statistical analysis of our results, we first verified whether the data pertinent to both types of CL have a normal distribution: we used a quantile-quantile method based on the linear correlation coefficient  $R^2$  between the measured and expected quantiles of our distributions. Since not all data shows normal distribution, both parametric and non-parametric tests were performed.

Initially, a Student’s t test was performed for paired data to evaluate the efficacy of the two types of CL, by first comparing the LCVA, HCVA and SR data of each subject without any type of correction with CL1 first, and then with CL2: the averages of the differences of the three quantities were inspected to verify their compatibility. The results obtained from this comparison are reported in table II. All values exceed the critical threshold  $t_c = 2.06$  for a 5% confidence level and 24 degrees of freedom, thus confirming there is a difference between the uncorrected condition and that with either CL applied. One can thus state that both types of lenses are effective in improving visual

TABLE I. – Average data of LCVA, HCVA, Strehl ratio for no correction, CL1 and CL2 lenses. RE = right eye, LE = left eye, EE = binocular vision. Visual acuity is expressed in logMAR.

	No correction	CL1	CL2
LCVA RE	0.74±0.08	0.04±0.01	0.00±0.01
LCVA LE	0.83±0.07	0.05±0.01	0.02±0.02
LCVA EE	0.58±0.07	−0.05±0.01	−0.09±0.01
HCVA RE	0.58±0.08	−0.02±0.01	−0.05±0.01
HCVA LE	0.64±0.07	−0.02±0.01	−0.04±0.01
HCVA EE	0.41±0.07	−0.12±0.01	−0.13±0.01
SR RE	0.46±0.04	0.07±0.01	0.32±0.04
SR LE	0.41±0.04	0.06±0.01	0.29±0.03

TABLE II. – Student’s  $t$  values for the comparison of CL1 and CL2 against no correction. RE = right eye, LE = left eye, EE = binocular vision.

MiSight™		Ultra 1 day	
HCVA RE	7.97	HCVA RE	8.25
HCVA LE	9.50	HCVA LE	9.68
HCVA EE	8.18	HCVA EE	8.36
LCVA RE	8.46	LCVA RE	9.16
LCVA LE	10.17	LCVA LE	11.22
LCVA EE	19.37	LCVA EE	9.76
SR RE	9.42	SR RE	3.00
SR LE	8.38	SR LE	2.77

acuity while, at the same time, affecting the aberrometric pattern. We remark that the Student’s  $t$  value obtained for the aberrometric data of SR for CL1 is much larger than the one obtained for CL2: although the difference is statistically significant for both lenses, this suggests the aberrometric influence on any subject is more pronounced with the MiSight™ test lens.

Subsequently, the same test was performed to compare the two types of CLs to each other. The values of the  $t$  variable, as reported in table III, are less than the critical value ( $t_c = 2.06$ ) for HCVA, both monocular and binocular, showing that values are compatible, while its value suggests excluding statistical compatibility for the LCVA, either monocular or binocular, and for the SR. A non-parametric Wilconox test was also performed, leading to the same results as the Student’s  $t$ -test.

Therefore, while both CLs perform their correction of the visual defects, as expected, the influence on the aberrometric picture is greater with the test CL, precisely because of the design of its optical zones. The difference between the two types of CLs is clinically significant. Note that while there is no statistically significant difference for what concerns the HCVA obtained with CL1 and CL2, a high statistical significance is recorded for the difference in LCVA, even if this result bears little clinical implications as its reduction is on average less than a logMAR line. The difference in visual acuity between low and high contrast is in agreement with other studies in the presbyopic using multifocal CLs [10]: a certain degree of visual impairment at a distance can be experienced that may not be noticeable at high contrast, but can occur at low contrast. This behaviour

TABLE III. – Student’s  $t$  values for the comparison between CL1 and CL2. RE = right eye, LE = left eye, EE = binocular vision.

HCVA RE	1.83	LCVA RE	3.99
HCVA LE	1.73	LCVA LE	2.83
HCVA EE	1.19	LCVA EE	2.90
SR RE	6.60		
SR LE	6.42		

is precisely due to the geometry of the lenses used in this study, which in the center have the prescription power for distance, and peripherally two treatment rings with fixed positive addition of sf +2.00 D, and is common to center distance multifocal contact lenses [11]. With these designs, the difference in visual acuity between single vision and multifocal CL will be slight in high contrast mode, where the high difference between background and detail facilitates the distinction of details, and more accentuated in low contrast, due to the influence of the peripheral zones of greater positive dioptric power while the subject observes an object at a large distance.

#### 4. – Conclusion

Among the strategies to control myopic progression, the use of specific dual-focus CL led to excellent results. Our experimental study was carried out with the aim of evaluating whether visual performance can be compared to what provided by SVCLs. Our evaluation was carried out from both a subjective and an objective point of view, assessing the aberrometric picture, which influences visual performance. It is possible to state that the two types of CLs do not show statistically significant differences with respect to HCVA, while there are more consistent differences with respect to LCVA. This result is in agreement with the literature assessing a more compromised LCVA in certain conditions [10, 11].

The statistical analysis of the values of the Strehl ratio as an aberrometric index shows that the influence on the total ocular aberrometric picture is greater with CL1 than with CL2, but in both cases incompatible with the pristine condition (no correction), thus demonstrating that both CLs have an effect, although the one from the DFCL is larger. Our analysis provides an answer to the initial question that guided this research: DFCL can provide means to control myopic progression without seriously compromising the visual performance. Even though the reduction in LCVA is statistically significant, this was found to be, on average, 0.04 logMAR for single vision RE and 0.03 logMAR for single vision LE and 0.04 in binocular vision (see table I), thus not particularly hindering in daily activities. On the other hand, the influence on the aberrometric picture has been found clinically relevant (0.25 for the right eye, 0.23 for the left eye), and calls for attention in future investigations.

#### REFERENCES

- [1] HOLDEN B. A., FRICKE T. R., WILSON D. A., JONG M., NAIDOO K. S., SNKARIDURG P., WONG T. Y., NDUVILATH T. J. and RESNIKOFF S., *Ophthalmology*, **123** (2016) 1036.
- [2] PAN C.-W., RAMAMURTHY D. and SEANG-MEI SAW S.-M., *Ophthalmic Physiol. Opt.*, **32** (2012) 3.
- [3] RAMAMURTHY D., CHUA S. Y. L., and SAW S., *Clin. Exp. Optom.*, **98** (2015) 497.
- [4] TRAN H. M., TRAN Y. H., TRAN T. D., JONG M., CORONEO M. and SANKARIDURG P., *J. Ocul. Pharmacol. Ther.*, **34** (2018) 374.
- [5] LI S. Y., LI S. M., ZHOU Y. H., LIU L. R., LI H., KANG M. T., ZHAN S. Y., WANG N., and MILLODOT M., *Graefes Arch. Clin. Exp. Ophthalmol.*, **253** (2015) 1363.
- [6] WILDSOET C. F., CHIA A., CHO P., GUGGENHEIM J. A., POLLING J. R., READ S., SANKARIDURG P., SAW S. M., TRIER K., WALLINE J. J., WU P. C. and WOLFFSOHN J. S., *Investig. Ophthalmol. Vis. Sci.*, **60** (2019) 106.
- [7] VERA J., REDONDO B., GALAN T., MACHADO P., MOLINA R., KOULIERIS G. A. and JIMÉNEZ R., *Contact Lens Anterior Eye*. (2021) in press.

- [8] LIN Z., MARTINEZ A., CHEN X., LI L., SANKARIDURG P., HOLDEN B. A. and GE J., *Opt. Vis. Sci.*, **87** (2010) 4.
- [9] Technical product description available at <https://coopervision.it/professionista/i-nostri-prodotti/misight1day>.
- [10] SHA J., BAKARAJU R. C., TILIA D., CHUNG J., DELANEY S., MUNRO A., EHRMANN K., THOMAS V. and HOLDEN B. A., *Arq. Bras. Oftalmol.*, **79** (2016) 73.
- [11] GREGORY H. R., AUGUSTINE N., WOLFFSOHN, J. S., BERNTSEN D. A. and RITCHEY E. R., *Opt. Vis. Sci.*, **98** (2021) 272.