OBJECTIVE AND SUBJECTIVE VISUAL PERFORMANCE OF A DAILY SOFT CONTACT LENS FOR PRESBYOPIA

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Introduction

Although there is an increasing demand for presbyopic CL corrections with the aging population[1] the number of wearers is still relatively low[2,3]. Several reasons can be considered to explain this result. One of them is related to vision issues and represent the most important reason for ceasing to wear contact lenses[4-6] in patients aged over 40. During the last years, numerous designs of soft CLs have been developed in an effort to satisfy the visual needs of presbyopes[7]. In particular, many manufacturers produce simultaneous-image (vision) lenses in which the power varies with rotational symmetry around the lens center. A well centered multifocal CL induces changes in the ocular high order aberrations (HOAs) with greater effect on spherical aberration (SA)[8-10]. This gives an advantage to increase the depth of focus of the eye due to longitudinal spread of the image in the retinal plane, but at the cost of aberration-induced loss of image clarity[5-9]. In addition these designs are sensitive to optical centration and their decentration induce coma[11] with effects on retinal image quality[12-13]. Recently a new design of soft CL for presbyopia (*Deseyne Daily Disposable for Presbyopia* - Bruno VisionCare LLC) is under FDA approval. This EDOF design increases the depth of focus of the eye without significant changes of HOAs using a central "optically inactive" region of 1,2 mm of diameter [14]

Purpose

To evaluate the effects of *Deseyne Daily Disposable for Presbyopia* (DDDP) soft hydrogel CL on objective and subjective visual performance of presbyopic subjects.

Methods

The study involved 40 presbyopic subjects not CL wearers with a refractive astigmatism <1.25D and a best-corrected VA ≤0.10logMar in each eye. Subjects with a history of refractive surgery, or other contraindications to CL wear were excluded. Before CL fitting, the best spectacle correction for far (5m) and near (40cm) distances were measured and the binocular VA measured at high (95%) and low (25%) contrast under photopic (85cd/m^2) condition. The measure of defocus curve and pseudo-accommodation were also evaluated using two DD CLs: one for single vision (*Deseyne Daily Disposable for myopia and hyperopia*) and the other one indicated for presbyopia compensation (*DDDP*). Both CLs are in hydrogel material that releases hyaluronic acid and TSP and have the same parameters (Table 1). The power of first SV CLs to try were determined starting from subjective best spherical equivalent (SE) and the power of the DDDP CLs considering the subjective best SE plus half of addition power. The power of CLs was confirmed in monocular over-refraction for SV CLs and binocularly for DDDP CLs and if changes were necessary the CLs replaced. Defocus curves were performed binocularly by assessing VA at distance using high contrast optotypes in presence of defocus lenses (+1,00 /–3.00D in 0.50D steps) using a phoropter and randomizing the test letters between lens presentations[15-16]. Monocular objective pseudo-accommodations were also measured, for 4mm of pupillary diameter, using a double pass instrument (HD Analyzer, Visiometrics, Es) considering the dioptric range between best SE correction and the point at which the simulated VA decreases to a 50% of its maximum for effect of negative defocus[17]. In addition a plot of an image quality index for each value of defocus were evaluated. These image quality values represents the widths of the profile of point spread function (PSF) at 50% of its maximum value in minutes of arch normalized considering a score 1 for the value measured at defocus 0,00D[17]. After two weeks of DDDP CLs wear subjective quality of vision (far, intermediate and near) and comfort with CLs were also assessed with a numerical rating scale (NRS) from 10 to 100 (with higher scores for better performance).

Tab. 1. *Material and contact lenses specifications*

Material	H_2O	Dk/t	Ct	P	BC	TD
Vifilcon C	60%	29	0,07mm P-3,00D	+8,00D to - 10,00D	8,60	14.10

Results

The study participants presented an age (AVE±SD) of 51± 6yrs (from 41 to 63 years of age), a spherical refraction of -0.18±2.64D (from +5.50 to -8.00D) and a spectacle addition of +1.70±0.50D (range +1.00 to +2.50D). High and low contrast binocular visual acuities with DDDP CLs compared to best spectacle correction, were significantly lower (paired t-test, p<0.05) even the reduction was lower than one line, (high contrast VA -0.03±0.09logMAR versus -0.11±0.08 logMAR and low contrast VA 0.12±0.11logMAR versus 0.04±0.10logMAR) (Fig.1); although binocular near acuities were not significantly different (p>0.05) between the two conditions (Fig.1). The subjects rated the performance of DDDP CLs for far vision 76±17, intermediate vision 90±9, near vision 87±14 and comfort 85±14 (Fig.2). The binocular defocus curve showed a peak of best VA with with 0,00D stimulus vergence of -0.01±0.06logMAR and -0.03±0.09logMAR for single vision CLs and for DDDP CLs respectively. Statistical analysis showed no significant differences between both conditions only for -0.50 and +1.00D stimulus vergences (p>0.05) (Fig.3). The objective pseudo accommodation was 0.81±0.15D and 1.79±0.34D and the image quality index measured at defocus 0,00D was 2.94±0.67 arc min and 3.15±0.68 arc min respectively with single vision lens and with DDDP CLs (Fig.3 and 4).

Fig. 1. *Binocular high (HCVA) and low contrast (LCVA) Visual Acuity*

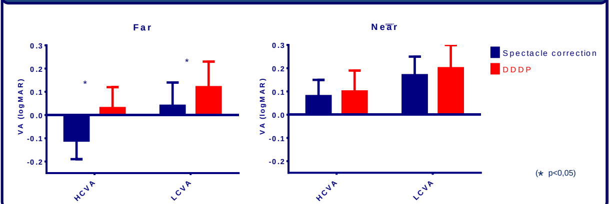


Fig. 2. *Subjective performance of DDDP measured with NRSs*

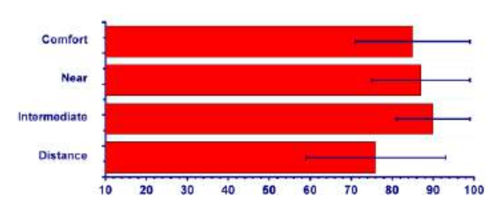


Fig. 3. *Defocus curves and pseudo accomodations*

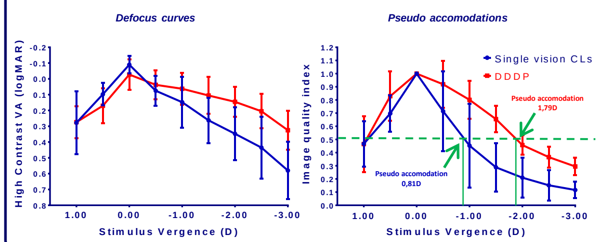
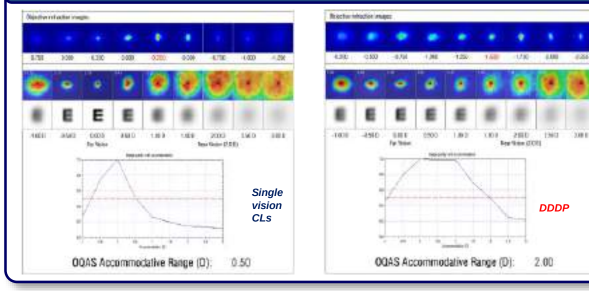


Fig. 4. *Objective depth of focus*



Conclusions

Data obtained in this study have reported the efficacy of contact lens tested to provide an increased depth of focus of the eye in presbyopic subjects. The pseudo-accommodation measured objectively with a double pass technique show a significant increased value with DDDP design contact lens in respect to single vision one. These measurements consider only the optical quality factor not the neural processing performed to the retinal image[18] and the effect of binocular summation[19]. These aspects are considered during the evaluation of defocus curve that present the subjective range of clear vision. The differences between the two measured defocus curves present a slight reduction of visual results for distance confirmed by the measurements of high and low contrast VA, image quality values and from subjective performance. The defocus curve with negative stimulus vergences support the effect of the optical lens design to increase the depth of focus of the eye and highlight a better results for intermediate distances as reported by the subjective results and a near vision results close to values obtained with spectacle correction. In conclusion this study suggested that the contact lens evaluated is a good option to compensate presbyopia, providing the patients good distance vision, optimal intermediate and near visual quality associated with high comfort.

References

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