IL NUOVO CIMENTO **46 C** (2023) 175
DOI 10.1393/ncc/i2023-23175-9

COMMUNICATIONS: SIF Congress 2022

Visual performance with an extended depth of focus contact lens for myopia control and corneal topography in assessing lens centration

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received 6 February 2023

Summary. — Increasing in myopia prevalence worldwide led to develop control strategies to slow down myopia progression. One option is represented by extended depth of focus (EDOF) contact lens (CL) to control retinal defocus. Decentration in EDOF CLs can decrease the quality of vision. This study was carried out to evaluate accuracy and repeatability of the centration assessment of EDOF CLs using corneal topography; data in term of visual performance with EDOF CLs were also collected. For each EDOF CL, a topography over the CL and a slit lamp (SL) digital picture were taken. For the SL images, a software was used to assess the position of the lens; for the topography acquisitions, the position was detected using a qualitative procedure, by two observers and repeated after 15 days. Visual acuity (VA), was evaluated at high contrast. After the analysis, the accuracy of the topographical assessment with respect to SL assessment resulted good. Intra- and inter-observer reliability of the measurement were good, but the clinical experience of the observer affected the repeatability of the method. VA with EDOF CLs was significantly lower compared to spectacles.

1. – Introduction

Holden *et al.* [1] estimated that in 2050 myopia will affect about half of the population worldwide. Myopes are more likely to develop myopic-related ocular conditions [2], so developing myopia control treatments is of paramount importance to limit the risk of sight-threatening ocular conditions. An increasing number of evidence has been published regarding myopia control strategies, such as outdoor activity, orthokeratology, antimuscarinic eye drops and multifocal contact lenses (MCL) [3]. An important role in refractive development seems to be played by peripheral defocus in the retina [4]. Optical strategies such as a MCL with positive power increasing towards the edge of the optic zone can balance the peripheral hyperopic defocus induced when monofocal lenses

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are used to correct myopia [5]. Three different optical designs of soft MCLs for myopia control can be identified [6]: bifocal concentric (*e.g.*, MiSight (CooperVision, Inc., Pleasanton, CA)), peripheral gradient (*e.g.*, Relax (SwissLens, Prilly, Switzerland)), and extended depth of focus (EDOF) (*e.g.*, Mylo (Mark'Ennovy, Majadahonda, Spain)) . Recently, a new concentric ring 1-day soft contact lens has been introduced on the market (Acuvue Abiliti 1-day (Johnson and Johnson Vision Care, Inc., Jacksonville, FL)); all of them with interesting outcomes in terms of myopia control. Contact lenses offer benefits (aesthetic, vision, convenience) and there is a positive attitude in using them particularly in sport and among teenagers [7, 8]. However, visual performance is of paramount importance, and what emerged in the literature about traditional MCLs highlights as a potential issue is a reduction in visual acuity and contrast sensitivity [9], and the presence of holes and ghost images caused by the design of the lenses. Decentration of a MCL will cause unwanted aberrations, and could also negatively affect the process of myopia control. Different methods can be used to evaluate the centration of a CL; two main methods [10, 11] that have proven to be accurate, reliable, and repeatable for the assessment of soft contact lens fit have been proposed: a subjective method, performed by the operator through the observation of the CL with a slit lamp, and an objective method, performed through the analysis of the image captured through slit-lamp with specific digital tools. This study was performed to evaluate both the accuracy and the inter- and intra-observer reliability in the centration assessment of EDOF CLs through a method recently proposed for scleral lenses [12] and MCLs [13] using a corneal topography image acquired over the CL. Visual acuity at high contrast (96.5%) was also evaluated.

2. – Materials and methods

According to inclusion criteria (table I) thirty-three myopic students (8 males) were recruited at the University of Milano-Bicocca (Milan) with a mean ± SD age of 22.7 ± 2.0 years (table II). Thirty-two right and left eyes were considered, because for two participants, only one eye was eligible for the measurements to be made. The study followed the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the University of Milano-Bicocca (Prot. 0025266, 23/4/2020). All participants provided informed consent. All the measurements were performed at the Research Centre in Optics and Optometry of the University of Milano-Bicocca (COMiB). The flow diagram of the study design has been reported in Rizzo *et al.* [14]. For the study, a monthly replacement CL with an EDOF design (Mylo; Mark'ennovy, Majadahonda, Spain), which was described by the manufacturer as having a non-monotonic, aperiodic, refractive power profile across its optic zone diameter, was used. Technical characteristics are reported in table III.

TABLE I. – *Inclusion and exclusion criteria.*

Inclusion	Exclusion
myopia from −0.25 DS to −10.00 DS; astigmatism < 1.00 DC; best corrected visual acuity at least 0.10 logMAR.	evidence or history of visual anomalies; any eye surgery; ocular or general pathologies that can affect vision.

TABLE II. – *Demographic and optometric information of the participants.*

Whole sample	$n = 33$
Gender (Men/Women)	8 (24.2 %) / 25 (75.8%)
Age (Years)	22.7 ± 2.0 (min 18.6; max 27.9)
Spherical equivalent (D) right eye	-2.9 ± 2.0 (min -9.63; max -0.50)
Spherical equivalent (D) left eye	-3.0 ± 2.0 (min -9.88; max -0.25)

Following a preliminary examination, performed by the same eye-care practitioner (ECP), the eligible candidates were enrolled in the study. After case history, slit lamp assessment and videokeratography, each volunteer received monocular subjective refraction, at this moment high (96.5%) contrast distance monocular visual acuity with the spherical equivalent refraction (SER) mounted in the trial frame was measured by using an LCD logMAR Sloan Chart (Vision Chart, CSO, Italy) with a scoring letter-by-letter procedure. Monocular subjective refraction was used to determine the CL back vertex power, back optic zone radius was chosen through the manufacturer's Online Fitting Calculator (markennovy.com/fitting-calculator/), with a fixed total diameter of 15.00 mm, starting from the corneal parameters obtained from videokeratography. According to this criteria, EDOF CLs were fitted, and after a settling time of 10 minutes, two different procedures performed in quick sequence to minimise possible decentration between the measurements were used to acquire images of the CLs on both eyes, in a randomised order. High contrast monocular VA, using the procedure mentioned above, was also measured with the EDOF CLs. A detailed centration procedure is reported in Rizzo *et al.* [14]. In brief, to identify the position of the CLs high-resolution digital slit lamp (HR Elite, CSO, Florence, Italy) images were acquired and considered as the reference values (gold standard) to evaluate the accuracy of the method in study that consisted in acquiring topographical imaging over the CL by a videokeratography (Osiris-T, CSO, Florence, Italy). In the slit lamp image acquisition it was asked to all subjects to fixate exactly in the centre of the left objective lens of the SL which was connected to the camera. On focus and without any artefacts, a picture for each eye of each participant was acquired. For the topographical image, volunteers were asked to fixate exactly in the centre of Placido's rings. The operator verified that fixation and corneal coverage were good and wide enough; if this was not the case, the acquisition was repeated. In both cases, the image was acquired within two seconds after the last blink and with the eye not under examination occluded. Subsequently to this collecting phase, two databases

TABLE III. – *Technical characteristics of the contact lens in study.*

Commercial name	Mylo
Manufacturer	Mark'ennovy (Spain)
Material	Filcon V3
%H2O	75%
Design	EDOF
Base Curve (mm)	7.10–9.80 (steps 0.30)
Diameter (mm)	13.50–15.50 (steps 0.50)
Spherical Power (D)	from -0.25 to -15.00 (steps 0.25)

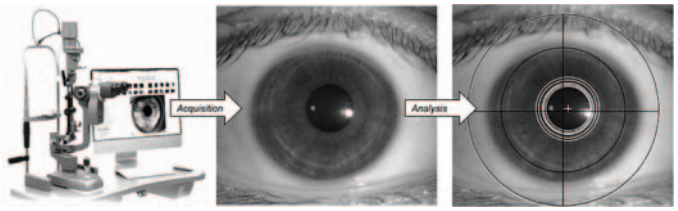

Fig. 1. – Schematic representation of the slit lamp procedure to evaluate the centration of the EDOF CL.

were created to allow for the analysis of the images. The analysis was performed by the same ECP who acquired them using software Phoenix v.3.7 (CSO, Florence, Italy). Sixty-four SL images were analysed to assess the position of the EDOF CL centre with respect to the pupillary centre in a Cartesian plane (fig. 1). After the detection of the edges of EDOF CL and the pupil, a transparent acetate sheet with concentric circular templates was aligned to the picture on the screen overlapping to the circumference of the pupil and of the CL edge to identify respective centres. The distance between the two centres was measured by the digital ruler device and through trigonometric formulae x and y coordinates of the EDOF CL centre, with respect to the pupil centre, were derived. These x, y coordinates represented the reference with which to compare the position of the EDOF CL centre determined by the in study topographical procedure.

Sixty-four topographical images acquired over the EDOF CL were analysed by two new ECPs: Observer 1 and Observer 2 were optometrists without and with more than 20 years of clinical experience respectively. The two observers determined independently the position of the EDOF CL centre with respect to the pupil centre from each topographical image settled in the format of tangential map algorithm. Once the topographical map previously stored in a personal information free database was displayed in a full-screen modality, a transparent sheet in acetate with concentric circles was overlaid on the map by the observer to detect the position of the CL centre (fig. 2), that was reported in x and y coordinates with respect to the pupil centre. This procedure was repeated twice for each image and for the first and the second session performed after a fortnight. In this second session, the observers repeated the assessment on the same 64 topographical images provided in random order and without any information about the measures determined during the first session.

Normal distribution was evaluated through Shapiro-Wilk. For accuracy, a Student's t-test for paired data and Pearson correlation coefficient were used. Intra-observer reliability was evaluated through coefficient of precision (CP) and coefficient of repeatability (CR) [15]. Test-retest intra-observer reliability was calculated by the Intraclass correlation coefficient (ICC) for each observer [16]. For visual performance, a Wilcoxon test was used. Right eye data were treated statistically separately from left eye data. Data were analysed using IBM© SPSS© Statistics v26.0 (SPSS Inc., Chicago, IL, USA).

3. – Results

3˙1. *Accuracy in assessing centration.* – With the two procedures, on average, EDOF CLs resulted decentred temporally and inferiorly both for the right and the left eye (fig. 3). Accuracy of the topographical assessment in determining coordinates of the EDOF CL centre with respect to SL assessment was good. No statistical differences were

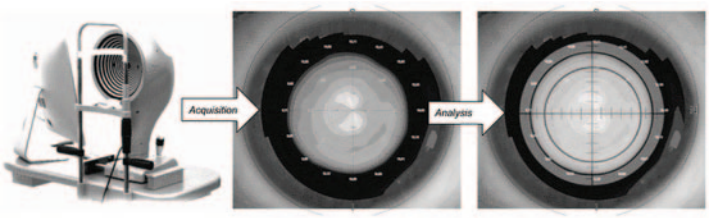

Fig. 2. – Schematic representation of the in-study procedure to evaluate the centration of the EDOF CL using a corneal topography image acquired over the CL.

found for both coordinates in the left eye, whereas in the right eyes a less temporally decentred position of the CLs was detected (paired t-test, $p < 0.05$) by topographical assessment. Nevertheless, this difference appeared clinically negligible.

Correlation coefficients between the two procedures to assess EDOF CLs centration resulted in 0.30 ($p = 0.09$) and 0.30 ($p = 0.09$) for the x and y coordinates respectively in the right eye, and 0.23 ($p = 0.21$) and 0.43 ($p = 0.01$) for the x and y coordinates respectively in the left eye.

3˙2. *Inter-observer reliability.* – For the topographical assessment, no statistical differences were found between the two observers for horizontal decentration (x), while for vertical coordinate (y), a significant difference (paired t-test, $p < 0.05$) was found for both eyes: observer 1 reported a less inferiorly decentration. In terms of ICC, substantial inter-observer reliability was found for the assessment of x and y coordinates, except for the vertical coordinate of the left eye, where it was only moderate.

3˙3. *Intra-observer reliability.* – In table IV are reported, for each eye and coordinate (x, y), CP and CR of the measures of centration obtained by the two observers with topography. ICCs calculated for the two observers (0–15 days) ranged from 0.58 for the Observer 1 with less experience to 0.96 for the expert one (Observer 2).

3˙4. *Visual perfromance.* – High contrast visual acuity (HCVA) with the SER mounted in the trial frame resulted significantly (Wilcoxon test ($p < 0.05$)) better than with the EDOF CLs. The mean difference (mean ± SD) in HCVA between the SER and the lens in study was 0.12 ± 0.10 and 0.09 ± 0.12 for the right and left eye, respectively. This difference also appeared clinically relevant.

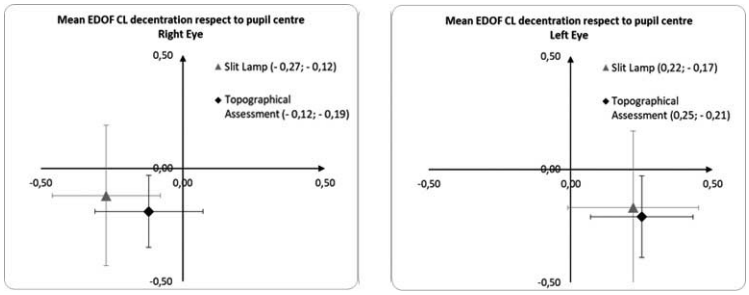

Fig. 3. – EDOF CL centre coordinates (x, y) with respect to pupil centre according to the 2 different procedures used to assess CL centration.

TABLE IV. – *Coefficient of precision (CP) and coefficient of repeatability (CR) for the measurements made by the two observers.*

	Right eye		Left eye	
	x (mm)	y (mm)	x (mm)	y (mm)
Obs1	CP=0.25 CR=0.35	CP=0.24 CR=0.35	CP=0.25 CR=0.36	CP=0.19 CR=0.27
Obs2	CP=0.08 CR=0.11	CP=0.08 CR=0.11	CP=0.06 CR=0.08	CP=0.11 CR=0.15

4. – Conclusion

In conclusion, corneal topography performed over the CLs can be considered as an accurate method to assess EDOF CL centration; however, a certain potential effect of the observer practice experience could affect the level of reliability of the technique. Further studies to evaluate accuracy and repeatability of the technique on other CLs to control myopia progression would be desirable. In term of visual performance, a significant reduction in high contrast visual acuity was found with the EDOF CL in study.

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