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Response of the ageing eye to first day of modern material contact lens wear
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Abstract:	ABSTRACT Objectives: To investigate the ocular surface of an aged population wearing a daily disposable contact lens over their first day of wear. Methods: Forty eyes from forty presbyopic subjects were fitted a daily CL (Delefilcon A). Tear osmolarity, tear meniscus area (TMA) and ocular surface aberrations (total higher order root means square (RMS)) were assessed at baseline (t0), at 20 minutes (t1) and after 8 hours (t2) of wear. Fluorescein corneal and conjunctival staining and tear break up time (TBUT) were performed at t0 and t2. Results: No statistically significant changes were found between t0, t1 and t2 for TMA, and between t0 and t2 for fluorescein corneal and conjunctival staining. TBUT worsened by the end of the day from 10.4±0.4 seconds t0 to 9.0±0.3 seconds t2 (P < 0.05). Osmolarity showed significant changes between t0 306.9±2.3 mOsm/L and t1 312.4±2.4 mOsmol/L (P = 0.02), but returned to baseline values at 8 hours (310.40±2.26 mOsm/L; P = 0.09). Total higher order root means square (RMS) showed significant changes between t0 0.38±0.02 µm and t1 0.61±0.04 µm (P ≤ 0.001) and between t0 and t2 0.64±0.41 µm (P ≤ 0.001). Conclusions: Delefilcon A may induce measures changes (osmolarity and TBUT values) in a presbyopic population, however TMA and vital staining were maintained at the baseline level over the day. Keywords: Contact lenses, multifocal, presbyopia, osmolarity

Response of the ageing eye to first day of modern material contact lens wear

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1   **ABSTRACT**

2

3   **Objectives:** To investigate the ocular surface of an aged population wearing a daily

4   disposable contact lens over their first day of wear.

5   **Methods:** Forty eyes from forty presbyopic subjects were fitted a daily CL (Delefilcon A).

6   Tear osmolarity, tear meniscus area (TMA) and ocular surface aberrations (total higher

7   order root means square (RMS) were assessed at baseline (t_0), at 20 minutes (t_1) and

8   after 8 hours (t_2) of wear. Fluorescein corneal and conjunctival staining and tear break

9   up time (TBUT) were performed at t_0 and t_2.

10   **Results:** No statistically significant changes were found between t_0, t_1 and t_2 for TMA,

11   and between t_0 and t_2 for fluorescein corneal and conjunctival staining. TBUT worsened

12   by the end of the day from 10.4±0.4 seconds t_0 to 9.0±0.3 seconds t_2 ($P < 0.05$).

13   Osmolarity showed significant changes between t_0 306.9±2.3 mOsm/L and t_1 312.4±2.4

14   mOsmol/L ($P = 0.02$), but returned to baseline values at 8 hours (310.40±2.26 mOsm/L;

15   $P = 0.09$). Total higher order root means square (RMS) showed significant changes

16   between t_0 0.38±0.02 μm and t_1 0.61±0.04 μm ($P \leq 0.001$) and between t_0 and t_2

17   0.64±0.41 μm ($P \leq 0.001$).

18   **Conclusions:** Delefilcon A may induce measures changes (osmolarity and TBUT values)

19   in a presbyopic population, however TMA and vital staining were maintained at the

20   baseline level over the day.

21   **Keywords:** Contact lenses, multifocal, presbyopia, osmolarity

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23

24   **INTRODUCTION**

25   The lacrimal functional unit is a system composed of the ocular surface, its secretory

26   glands (lacrymal glands, meibomian glands, conjunctival goblet cells), the nerves that

27   connect them[1] and the nasolacrimal passage[2]. A healthy ocular surface is maintained by

28   proper tear production and drainage; any perturbation in this balance may lead to

29   dryness of the ocular surface and eventually to Dry Eye Disease (DED)[3].

30   Increasing age leads to several changes to the tear film (TF) and the ocular

31   surface[4], which include: a reduced tear volume[4,5] (lacrimal gland dysfunction, decrease

32   in lacrimal gland mass) which is thought to increase tear osmolarity and compromise TF

33   stability[5]; reduced reflex tear secretion and breakup time (TBUT)[6]; and to decline the

34   function of goblet and meibomian glands cells[7].

35   Given the increase in life expectancy, an increase in the prevalence of dry eye in

36   the population is also expected[4]. Nonetheless, information regarding the prevalence of

37   DED in the elderly is quite equivocal[8-11]. Several consequences of the normal aging

38   process could explain why the elderly population could be more prone to dry eye; this

39   includes raised oxidative stress, hormonal changes, inflammatory systemic conditions[4],

40   lid laxity and the use of systemic and topical medication[4,12]. DED has been considered

41   as a significant concern in the aging contact lens (CL) wearing population[1,13]. Bennet et

42   al. highlighted that a comprehensive anterior segment exam is an essential prerequisite

43   to CL fitting, due to the higher prevalence of the anterior segment conjunctival

44   degenerative processes that may disrupt the TF layer[14]. When a CL is fitted on a patient's

45   eye, the TF is separated into pre- and post-lens TF. In addition to the changes in

46   composition, pre-lens TF (PLTF) stability is reduced due to the thinning of the lipid layer

47   and the tear volume on the anterior surface of the CL is also diminished, both events

48   leading to an increased evaporation rate and dewetting compared to normal TF[15].

49   CL discomfort has been identified as the primary reason for CL discontinuation[15,16,17,18].

50   CL material (silicone hydrogel[19]), parameters (lower sphere power[16]) and wearing

51   schedule (daily disposable[19]) have been reported as the main aspects associated with CL

52   dropouts[19]. According to a recent survey[19], increased age is the main factor impacting

53   retention rate, with multifocal CL fittings presenting the lowest continuation of use

54   (57%) in comparison with other CL designs for the same age range population; poor

55   achieved vision was identified as a key factor in multifocal CL wearers that stopped

56   wearing contact lenses. Besides, Patel et al. suggest that the presbyopic population

57   might be more susceptible to dryness-related comfort problems[20], mainly due to

58   decreased TF stability, eventually leading to CL discomfort and dropout.

59   The purpose of this study was to assess the performance of a new daily

60   disposable CL material on the ocular surface of a presbyopic population. To the best of

61   our knowledge, this is the first study reporting the clinical outcomes of a water gradient

62   daily CL material in a presbyopic population over their first day of CL wear. To achieve

63   that goal, TF and ocular surface parameters were investigated along a day of CL wear.

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MATERIAL AND METHODS

Forty subjects, neophyte CL wearers, were recruited. This prospective, nonrandomized study was approved by the Institutional Ethics Committee of the University of Valencia. Informed consent was obtained for all subjects enrolled in the study. The clinical study adhered to the tenets of the Declaration of Helsinki.

Each of the subjects underwent a comprehensive ophthalmic examination, which included (in the following sequence): visual acuity, monocular and binocular refraction, anterior segment slit lamp biomicroscopy, osmolarity, measurement of the inferior tear meniscus area (TMA), topographic examination and TBUT assessment using fluorescein.

The room temperature was controlled and maintained between 20 and 25 degrees Celsius; the room humidity was maintained between 35 to 40%. The same investigator carried out all measurements and subsequent data analysis. Inclusion criteria were spherical equivalent refractive error between +6.00 to -10.00D, astigmatism ≤0.75D, monocular corrected distance visual acuity of 0.0 logMAR or better and normal binocularity. Patients who experienced any anterior segment pathology, previous corneal surgery, corneal abnormalities, DED or any general health condition were excluded from the study.

Slit Lamp Examination

Anterior ocular assessment was performed by biomicroscopy and included bulbar conjunctiva and cornea evaluation at a magnification of 10x to 32x for the presence of active inflammation and structural changes/abnormalities of the corneal layers.

89   Anterior chamber and iris were evaluated for inflammation, eyelids for crusts and/or

90   collarettes. Fifteen minutes after material insertion, contact lens fit quality was

91   evaluated for centration, coverage, movement as well as push-up recovery speed.

92

93   *Tear Osmolarity*

94   Tear film osmolarity was measured using a laboratory-on-a-chip system (TearLab[TM]

95   Corp, San Diego, CA) in order to collect (using passive capillary action) and analyze the

96   electrical impedance of a minimal (50 nL) tear sample from the infero-lateral tear

97   meniscus. According to Foulks and al. osmolarity values below 308mOsm/L should be

98   considered as normal[21]. Readings between 308 and 325 mOsm/L are representative of

99   mild-to-moderate dry eye, and values above 325mOsm/L indicate the severe state of

100 the disease[21].

101

102 *Inferior Tear Meniscus Area*

103 Details of the anterior segment optical coherence tomography (AS-OCT) imaging

104 technology have been described previously[22,23]. The SL SCAN-1 (Topcon, Japan) is a

105 spectral-domain OCT integrated into a slit lamp which uses an 840 nm superluminescent

106 diode and provides 5000 A-scans/s with an axial resolution of 8-9 μm and a lateral

107 resolution <20 μm. This device allows images of the inferior tear meniscus to be

108 obtained using the B-scan mode by scanning at the 6 o'clock ocular position with a cross

109 line centered on the inferior lid edge. Measurements of the inferior tear meniscus area

6

110   (TMA), defined as the triangular area formed by the anterior corneal boundary, anterior

111   boundary of the lower eyelid and anterior borderline of the tear meniscus, were

112   performed manually using image analysis software imageJ (http://imagej.nih.gov/ij/).

113
114   *Aberrations Analysis*

115   The corneal front surface wavefront aberrations derived from the Placido-based

116   corneal topographer Atlas 9000 (software v3.0.0.39; Carl Zeiss Meditec, Jena, Germany)

117   over a 6 mm central zone was assessed with a non-dilated pupil and repeated three

118   times between 4-6 seconds after a blink[24,25]. The choice not to control pupil diameter

119   was deliberate, as this study intended to assess the effect of this multifocal CL material

120   in normal conditions of illumination, under the condition patients are usually assessed.

121   Since the device used to quantify aberrometry is a Placido disk-based topographer, it

122   uses the first Purkinje image which is formed on the PLTF, to calculate topographic and

123   aberrometric values. Image capture was timed for the same time post blink for each

124   subject, as it has been found that TF stability is achieved approximately 6 seconds after

125   a blink, and overall aberrations tend to rise for about 10 seconds after a blink[25].

126

127   *Tear Film Breakup Time and Corneal-Conjunctival Staining Score*

128   TBUT was measured subjectively with a slit lamp (equipped with a blue filter) by

129   inserting into the lower fornix a fluorescein strip moistened with one drop of a non-

130   preserved saline solution. The strip was then removed and the patient asked to blink

131   three times and look forward during the procedure. The average of three consecutive

132   TBUT measurements (time between the last blink and the appearance of the first

133   random dry spot on the corneal surface, manually timed) was then calculated. Corneal

134 staining was evaluated after TBUT under blue illumination, 3.0 minutes after fluorescein

135 instillation. Corneal and conjunctival subjective assessment followed the grading

136 scheme from Efron's scale (grades from 0-4) observed with 16x slit lamp magnification.

137 Eligible patients (based on inclusion and exclusion criteria) were fitted

138 binocularly with multifocal CLs (Delefilcon A, Dailies Total1® Multifocal). According to

139 manufacturers' information, Delefilcon A is a silicone-hydrogel material with a silicone

140 core water content of 33% and a hydrogel surface water content above 80 %. Its Dk/t is

141 159 @ -3.00D at a central thickness of 0.09 mm. Power ranges from +6.00 to -10.00 (in

142 0.25 steps) with a base curve of 8.5 mm. All baseline measures were repeated at 20

143 minutes and 8 hours after CL insertion.

144

145 *Statistical Analysis*

146 Statistical analysis was performed using the Statistical Package for Social Science

147 software (Version17.0, SPSS, Inc., Chicago, IL, USA). Only right eye data was analyzed to

148 avoid bias due to the similarities between the eyes of an individual. Friedman's

149 nonparametric statistical test was used to detect differences over time of TMA,

150 osmolarity and aberrations as they were not normally distributed. The Sign test was

151 used to compare related intergroups for ordinal parameters (conjunctival and corneal

152 staining), whereas a related samples average *t* test was used in the intergroup

153 parameters with normal distribution (TBUT). Differences were considered statistically

154 significant at $p \leq 0.05$.

155 **RESULTS**

156 The average age of the participants was 50.0±4.4 years, ranging between 41 and 60

157 years old. Mean spherical equivalent refractive error was +1.11±0.35 D and ranged from

158 -4.25 to +2.50 D. From the 40 eyes included, 18 were myopic (mean spherical equivalent

159 error -2.80±0.72D) and 22 hypermetropic (+0.90±0.24D). Mean values and standard

160 deviations of the parameters assessed at each visit over the day are presented in table

161 1. Osmolarity showed significant changes between baseline (306.93±2.32 mOsm/L) and

162 20 minutes (312.43±2.42 mOsm/L) (P=0.02) (Figure 1). No statistically significant

163 changes were found between baseline (306.93±2.32 mOsm/L) and 8 hours (310.40±2.26

164 mOsm/L) (P=0.09). TMA values diminished across the day (from 0.020±0.003 mm^2 to

165 0.017±0.03 mm^2) (P=0.061), but was not statistically significant.

166 Figure 2 displays aberrometric root mean square (RMS) data before CL adaptation at 20

167 minutes and 8 hours after CL insertion. Ocular surface higher order RMS aberrations

168 showed a statistically significant increase between baseline (0.38±0.21 μm) and 20

169 minutes (0.61±0.44 μm) (P≤0.001) and between baseline and 8 hours (0.64±0.41 μm)

170 (P≤0.001). No statistically significant changes were found between 20 minutes

171 (0.61±0.44 μm) and 8 hours (0.64±0.41 μm) (P=0.711). TBUT worsened by the end of the

172 day from 10.4±0.4 seconds at baseline to 9.0±0.3 seconds after 8 hours of CL wear

173 (P<0.05) (Figure3). No statistically significant differences were found between the

174 measurements at baseline, and after 8 hours of CL wear regarding fluorescein corneal

175 (P=0.727) and conjunctival staining (P=0.092).

176

177

DISCUSSION

178

179   A healthy tear film is a key factor in order to maintain a functional and efficient

180   ocular surface. Ocular dryness and discomfort represent the main complaints in CL

181   wearers[16-18,26]; CL discomfort (CLD) (24%) and dryness (20%) being the primary reasons

182   for discontinuation[16,17,19]. According to Dumbleton et al., "discomfort" is the most

183   frequently cited reason for CL dropout[17], but its precise meaning to the individuals is

184   more complex to assess. Indeed, the terms dry eye and CL discomfort closely interlace,

185   since a patient that presents signs and symptoms of dry eye has more propensity to

186   have CL discomfort when fitted with CLs[27].

187   Tear hyperosmolarity is a key mechanism of ocular surface inflammation leading

188   to dry eye clinical features[28,29]. Environment, CL materials and parameters, and TF

189   factors such as stability have been described as triggers for the rise of osmolarity[30-32]. TF

190   stability is altered by CL wear regardless of the lens type as CLs induce changes in TF

191   structure, creating a PLTF and a postlens TF, that is, new interfaces within the ocular

192   environment[15]. PLTF is mainly responsible for the hydration and wettability of the CL

193   front surface, facilitating the interaction with palpebral conjunctiva, by reducing friction

194   forces and hence providing a smooth optical surface[33,34]. PLTF instability can be found in

195   hydrogel high water content and thin CLs, leading to a rise of osmolarity, since it has

196   been suggested that this type of lens can dehydrate easily partly due to its elevated

197   water content[31,35].

198   Previous studies demonstrated that refractive index (RI) of a CL material and its

199   water content are closely related, showing the interest of evaluating RI to assess lens

200   water content[36].Delefilcon A provides a water gradient and a surface water content

201 corresponding to a high-water content hydrogel material, and as such, it may be

202 expected to induce a rise in osmolarity values when fitted, due to partial dehydration of

203 the outermost part of the CL material. This hypothesis seems robust since in Schafer et

204 al. study, an index change was found to occur on the CL surface after 15 minutes of lens

205 wear, shifting from a high-water content RI to a level compatible with a low water

206 content material RI[37]. However, Iskander et al.[38] found that this water gradient material

207 provided a better end of the day TF surface quality (TFSQ) than a high-water content

208 hydrogel material. This finding implies that the rate of superficial dehydration of this

209 material is lower than other CLs[38].

210   Previous studies of existing, largely young, CL wearers reported significant rises

211 in tear osmolarity in CL wearers during the time of use[39-41]. Iskeleli et al. found that

212 monthly hydrogel soft CLs induced a raise in osmolarity values between 1-2 hours after

213 insertion[40]. Sarac et al. evaluated osmolarity with daily wear silicone-hydrogel CLs over

214 the course of a day and found a rise in tear osmolarity after 4 hours of CL wear, followed

215 by an insignificant reduction in osmolarity values at the end of the day[41]. These results

216 are in agreement with the present study. Indeed, statistically significant differences have

217 been found between baseline and 20 minutes showing that an increase in osmolarity

218 values occurs even sooner than evaluated before; while over the course of the day a

219 reduction in tear osmolarity values could be observed, although not statistically

220 significant, but consistent with the findings of Sarac and al[41].

221   According to Nichols et al. the on-eye CL sits in and not on the TF[34]; CLs are many

222 times thicker than the TF so its insertion is expected to induce perturbation to the ocular

223 surface as noted earlier[42]. Furthermore, CL interaction with the eyelid and cornea can

224   modify tear composition and electrolytes levels, as shown by Tighe and al.[43]. The

225   hypothesis explored in the present study was that CL initially disturbs the newly formed

226   PLTF (by inducing reflex tearing), leading to decreased TF stability and increased

227   evaporation, resulting in elevated tear osmolarity values at 20 minutes. Besides, it is

228   speculated that increases in osmolarity at 20 minutes might also be partly due to both

229   an ocular surface response to CL insertion, and an individual tear interaction with the CL

230   material.

231   At the end of the day (i.e after 8 hours of CL wear), osmolarity values were lower

232   than those obtained at 20 minutes, but did not reach the baseline level. Furthermore,

233   both values obtained at 20 minutes and after 8 hours of CL wear were higher than the

234   cut-off value of 308mOsm/L, which, according to Foulks, can be considered as a mild

235   form of dry eye[21].

236   It is important to emphasize that no significant changes were found regarding

237   corneal or conjunctival staining by the end of the day, which means that even if

238   osmolarity was above cut-off values, it was not clinically significant since there was no

239   significant cellular damage. Osmolarity values did not change over the time of wear,

240   which may imply that CL surface properties remain rather stable during the 8 hours of

241   CL wear and provide enough oxygen transmission and lubrication to the ocular surface

242   in order not to induce any additional staining. However, if the osmolarity changes occur

243   in a similar pattern over longer-term wear, corneal integrity could well be compromised.

244   It is known that tear hyperosmolarity induces epithelial cell hyperosomolarity[44-

245   46], leading to intracelular activation involving MAP Kinase and NFκB pathways and

246   therefore liberation of pro-inflammatory cytokines, which eventually induce epithelial

247 cell apoptosis[44-46]. Further investigation is needed in order to assess the rise in

248 osmolarity values from baseline and the duration of this elevation that could trigger an

249 inflammatory response from the ocular surface, leading to cellular apoptosis and the

250 corresponding positive vital dye staining.

251   Tear meniscus can be defined as the accumulation of tears between the lid

252 margin and the bulbar conjunctiva; it is present on both superior and inferior eyelids[47,48].

253 It is believed that tear meniscus contains 75%-90% of the total volume of the TF [47], which

254 makes it a useful clinical parameter to assess TF volume and its possible changes over

255 time. AS-OCT is a useful device for *in vivo* non-invasive quantification of tear meniscus

256 parameters, with[48,49] or without CLs[50,51]. Czajkowski et al. showed that AS-OCT presents

257 sensitivity and specificity for dry eye diagnosis of 86.1% and 85.3% for TMA and a strong

258 positive correlation to tear meniscus height (r=0.763, p<0.0001), making this device a

259 valuable tool for diagnosis and follow-up of patients with dry eye disease[52].

260   In the present study, TMA values did not show significant changes across the day.

261 It suggests that short-term CL wear may have limited impact on tear meniscus

262 parameters in a non-dry eye presbyopic population, which is in agreement with Wang

263 et al. work on the influence of CL wear on upper and lower meniscus in a normal young

264 adult population[53]. Chen et al. evaluated CL wearers with self-reported dryness,

265 asymptomatic wearers and asymptomatic non lens wearers[51]. No significant statistical

266 changes were found between baseline and after 30 minutes for the asymptomatic

267 wearers, which is in agreement with the results obtained in this study. According to our

268 results, it seems very likely that CL insertion induces reflex lacrimation responsible for

269 an immediate increase of tear volume and decreased TF stability, but it tends to return

270   back to normal values by 20 minutes after CL lens insertion. PLTF quality mainly relies

271   on surface wettability and the water content of CL materials[54,55]. In this study, no

272   difference was found at the end of the day in comparison to baseline, even if TMA

273   diminished over the day, which suggests that PLTF surface quality remained stable over

274   time. Higher-order aberrations are believed to contribute up to seven percent of retinal

275   image quality[56,57]. The main difference between a perfect wavefront and the one

276   displayed by the human eye mainly is due to higher order aberrations, more precisely

277   third order coma-like and fourth-order spherical aberrations[58-60]. It is known that the

278   effect of coma and spherical aberrations is pupil dependent, the greater the pupil size,

279   the greater the aberrations and the depreciation of the final retinal image[61].

280   In this study, the CL geometric characteristics were a front and back surface

281   aspheric center-near multifocal design, which is expected to induce a certain amount of

282   spherical aberration[62]. Moreover, decentration of a CL on the eye due to eye movement

283   or to the lag in the replacement of the CL after blink are expected to induce coma-like

284   aberrations proportional to the amount of decentration from the visual axis[61,63,64]. For

285   these reasons it was decided to only assess ocular surface high order RMS of coma-like

286   and spherical aberration in this study. Data were converted into RMS values for spherical

287   aberrations and coma combined[61,65] in order to follow-up changes of the total RMS over

288   time and to assess the influence of the CL insertion over this parameter.

289   A statistical significant increase in ocular surface higher order RMS was found

290   between baseline and 20 minutes, i.e from the CL insertion. In the majority of

291   participants, the set of ocular surface higher order RMS increased 20 minutes after CL

292   insertion, but remained stable over the day; no significant difference was found

293 between 20 minutes and 8 hours of CL wear. This could be explained by the behaviour

294 of the lens on the eye, remaining stable throughout the day, and the time the lens took

295 to centre after a blink, which was approximately the same at 20 minutes and 8 hours,

296 thus obtaining similar aberrations values for all participants.

297 Tear quality, stability and dynamics play a key role in optical performance of CLs

298 [25,66,67]. Indeed, local variation of PLTF thickness influences the amount of ocular

299 aberrations being measured[68]. DED, according to its severity, is also known to induce a

300 significant rise in aberrations, so the fact that corneal high order RMS remained rather

301 stable during the day may imply that the pre-lens TFSQ and dynamics were minimally

302 impacted over the course of the day.

303 TBUT is one of the clinical methods used to assess compromised tear film stability

304 [69]. In the present study, a significant decrease in TBUT was found between baseline and

305 8 hours of wear. This decrease in TF stability was an expected outcome, since TF

306 structure is altered by CL (increased evaporation and perturbation in TF spreading[15-18]).

307 Since measurement was carried out just after CL removal, it was expected that complete

308 recovery of the TF would not yet have been achieved at that moment. So, even if a

309 statistical decrease in TBUT was evidenced, it is unlikely to have any clinical significance.

310 Fluorescein dye is not the first option to assess TF stability (since its efficiency relies on

311 a controlled amount of fluorescein instilled and on the practitioner's experience to

312 detect the first dry spot on corneal surface), as objective, non-invasive methods are now

313 available[70]. The topographer used in the current study was the Atlas 9000, even if based

314 on Placido disks, does not include in the software an automatic delimitation of the BUT.

15

315 Instead the TFOS DEWS II standardized methodology for use of fluorescein to assess

316 subjectively tear film stability was adopted[70] using a single investigator applicating the

317 strip onto the inferior conjunctiva to ensure minimal variability and give reproducible

318 results. The subjective assessment of TBUT and vital staining, as discussed before, could

319 be limitations of the study along with the time between visits that was not masked to

320 the investigator and could have influenced the results. Duration of wear might be

321 another limitation of the current study as previous works reported a longer average time

322 of wear with up to 25% of the patients wearing their lenses up to 16 hours[71,72]. The

323 duration evaluated in this study is more in agreement with a recreational wear including

324 hobbies or social activities[73,74], which gives valuable information, but does not represent

325 a typical day for usual CL wearers.

326

327 **CONCLUSIONS**

328 This study reports the clinical performance of a water gradient daily disposable soft CL

329 on the ocular surface and the TF in a neophyte presbyopic population over their first 8

330 hours of wear. CL insertion induces an initial decrease in TF stability observed by

331 osmolarity values rising after 20 minutes of wear, but it did not impact tear meniscus

332 metrics and seemed to be transitory, as a decrease, without reaching baseline values,

333 occurred by the end of the wearing period. Ocular surface aberrations remained largely

334 stable from CL insertion, demonstrating an even repartition of TF over the CL material

335 surface.

336

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508

509

510   **Table 1:** Comparison of the objective measurements of the non-previous CL wearers at

511   the initial visit (t_0), 20 minutes (t_1) and 8 hours (t_2) after CL insertion (mean ± SD). TMA:

512   tear meniscus area; TBUT: tear break-up time.

513

514   **FIGURE LEGENDS**

515   **Figure 1.** Box-plot of osmolarity at baseline, 20 minutes and 8 hours of Cl wear. Medians

516   are shown for each plot, quartiles are shown as boxes, ranges as whiskers and outliers

517   as dots.

518

519   **Figure 2.** Box-plot of RMS at baseline, 20 minutes and 8 hours of Cl wear. Medians are

520   shown for each plot, quartiles are shown as boxes, ranges as whiskers and outliers as

521   dots.

522

523   **Figure 3.** Box-plot of TBUT at baseline, 20 minutes and 8 hours of Cl wear. Medians are

524   shown for each plot, quartiles are shown as boxes, ranges as whiskers and outliers as

525   dots.

526

TABLES

Table 1: Comparison of the objective measurements of the non-previous CL wearers at the initial visit (t_0), 20 minutes (t_1) and 8 hours (t_2) after CL insertion (mean ± SD). TMA: tear meniscus area; TBUT: tear break-up time.

	Baseline (t_0)	At 20 minutes (t_1)	At 8 hours (t_2)	P value
Aberrations (μm)	0.38 ± 0.21	0.61 ± 0.04	0.64 ± 0.41	(t_0)/ (t_1) P< 0.01 (t_0)/(t_2) P< 0.01 (t_1)/(t_2) P=0.71
Osmolarity (mOsm/L)	306.93 ± 2.32	312.43 ± 2.42	310.40 ± 2.26	(t_0)/ (t_1) P=0.02 (t_0)/(t_2) P=0.09 (t_1)/(t_2) P=0.71
TMA (mm^2)	0.020 ± 0.003	0.019 ± 0.002	0.017 ± 0.003	P=0.061
TBUT (s)	10.4 ± 0.4	-	9.0 ± 0.3	P <0.01

Figure

TEAR OSMOLARITY (mOsm/L)

■ Baseline ▨ 20 minutes □ 8 hours

Total RMS (µm)

TBUT (s)

■ Baseline ☐ At 8 hours