

1 INTRODUCTION

2 Customization of the relative peripheral refractive error (RPRE) has become a research
3 topic with the aim of interfering with myopia progression. Treatments to reduce myopia
4 progression in children are available, mainly contact lenses, that induce increased
5 vergence of the light entering the eye at an oblique angle (peripheral or off-axis
6 refraction). Orthokeratology provides this effect by reshaping the anterior corneal
7 surface although this effect is intrinsically dependent on the amount of myopia being
8 corrected.^{1,2} This effect also can be achieved with center-distance multifocal contact
9 lenses³ or spectacles.⁴ The use of contact lens is preferred because they follow the
10 ocular movements and remain centered on the visual axis. Thus, there is a demand for
11 customized contact lenses that can change the pattern of the peripheral refraction,
12 irrespective of the axial refractive error. In this manuscript, the terms myopia regulation
13 or myopia control will be used to refer to the decrease in the rate of axial elongation of
14 the eye with different treatments.

15 We showed in a recent pilot study that experimental rigid and soft contact lenses
16 can induce peripheral myopic defocus irrespective of the patient's baseline axial myopia
17 presented. In that study, the rigid gas permeable (RGP) lens was more effective than the
18 soft lens for creating the peripheral myopic defocus.⁵

19 The better on-eye stability of the RGP material compared to the soft contact lens
20 materials might explain this outcome. Furthermore, that study showed that a standard
21 aspheric RGP lens might also provide some peripheral myopic defocus. Other
22 investigators recently reported a similar observation.⁶

23 Purpose of current study was to evaluate the effectiveness of an experimental
24 RGP (ExpRGP) lens to create peripheral myopic defocus in a cohort of myopic patients

25 compared with a standard RGP (StdRGP) design and determine if the axial refraction
26 affects the outcomes.

27

28 **METHODS**

29 **Subjects and Lenses**

30 Fifty two neophyte myopic subjects were enrolled in the study. Measurements
31 were obtained from the right eye only, initially without a lens (baseline), and then with a
32 StdRGP and an ExpRGP lens intended to change the pattern of the RPRE. The two
33 lenses were worn in randomized order on two different days between 9:00 and 11:00
34 a.m. and at least 2 hours after awakening.

35 After receiving an explanation of the nature of the study, each patient signed a
36 consent form before enrollment. The research followed the tenets of the Declaration of
37 Helsinki and the Ethics Committee for Clinical Research at Clínica Teknon, Barcelona,
38 Spain, reviewed and approved the protocol. The inclusion criteria required that the
39 subjects had up to -8.00 D of myopia, astigmatism less than -1.00 diopters of cylinder
40 (DC), did not have a current ocular disease or injury, were not taking any ocular or
41 systemic medications, and had no contraindications to contact lens wear.

42 The RGP lenses were made of Boston XO2 (hexafocon B) material with nominal
43 properties of oxygen permeability of 141 barrers, according to the polymer
44 manufacturer (Polymer Technology, MA, USA). The central thicknesses varied
45 depending on the back vertex power of the lenses according to the vertex corrected
46 spherical equivalent of the non-cycloplegic subjective refraction of each eye. The
47 overall diameter was 10.60 mm for the ExpRGP lens and 10.50 mm for the StdRGP
48 lens. The base curve radii varied from 7.50 to 8.20mm across the subject group, and the
49 same base curve radius was used for both the StdGP and ExpGP lens for each subject.

50 An alignment fit was attempted in all eyes by selecting the base curve radius as a
51 function of the flat keratometric reading and corneal eccentricity.-

52 ExpRGP lens was designed using Zemax-EE software v.6 (Radiant ZEMAX,
53 WA, USA). Parameters for theoretical eyes were obtained from the study of Atchison⁷
54 assuming a standard corneal eccentricity of 0.50. ExpRGP lenses has 9 mm aspheric
55 front and back optic zones. This design affords +1.50 D add increase at 2 mm from
56 center (4 mm chord diameter) corresponding to approximately 30° of retinal
57 eccentricity, and achieving around +6.5 D at the edge of the optic zone (9 mm chord
58 diameter) as described in Spanish Patent Application P-201030694.

59 StdRGP were commercial lenses PRE AS (Precilens, France) with a central
60 spherical surface followed by a peripheral aspheric surface.

61 StdRGP and ExpRGP lenses were fitted according the topographical information
62 (simK readings measured over the 3 mm of the central cornea and eccentricity over a
63 chord diameter of 9.0 mm). Trial lenses were used to achieve optimal fitting in a pre-
64 study visit. Lenses were ordered based on the vertexed spherical equivalent refraction.
65 Over-refraction was done at the trial visit over the contact lenses and a new lens was
66 ordered if discrepancies over ± 0.25 were found. StdRGP and ExpRGP had the same
67 central distance power.

68

69 **Peripheral Refraction**

70 Measurements of the central and peripheral (off-axis) refractions were obtained
71 with an open-field Auto-Refractometer/Keratometer WAM-5500 (Grand Seiko Co.,
72 Ltd., Hiroshima, Japan) up to 30 degrees in the nasal and temporal visual field along the
73 horizontal meridian in 5-degree increments. After lens insertion, peripheral refraction
74 was evaluated after cessation of excessive tearing and once the lens was centered in the

75 inter-blink interval. This took between 5 to 15 minutes after insertion for all eyes
76 evaluated. Each automated refraction measurement was obtained only 1 to 2 seconds
77 after a blink to allow the lens to center and settle. If a blink occurred in the middle of a
78 measurement, the measurement was repeated. To minimize lens decentration during
79 peripheral fixation, head rotation instead of ocular rotation has been used. We used a
80 previously reported method.^{8,9} A laser pointer positioned over the patient's head was
81 oriented toward the primary gaze position. The patient rotated his or her head, avoiding
82 lateral displacement, until the laser pointer reached the given eccentric location while
83 the eyes remained in the primary gaze position.

84 Descriptive statistics (mean \pm standard deviation [SD]) were obtained for the
85 refraction vector components $M = \text{Sph} + \text{Cyl}/2$, $J_0 = -\text{Cyl} \cdot \cos(2\alpha)/2$ and $J_45 = -$
86 $\text{Cyl} \cdot \sin(2\alpha)/2$ where Sph, Cyl, and α are the sphere, cylinder, and axis obtained with the
87 autorefractometer, respectively. RPRE was obtained by subtracting the central refractive
88 error from each eccentric measurement.

89

90 **Statistical Analysis**

91 SPSS software package version 19 (SPSS Inc., Chicago, IL) was used for statistical
92 analysis. Kolmogorov-Smirnov test was applied to assess the normality of data
93 distribution. Considering that we are evaluating different conditions on the same
94 subjects (repeated measures) we used repeated measures analysis of variance (RM-
95 ANOVA) and the Friedman non-parametric test to compare the outcomes between the
96 three conditions (baseline, StdRGP, and ExpRGP values) for normally or non-normally
97 distributed variables, respectively. The Bonferroni post-hoc correction for multiple
98 comparisons was applied.

99 Spearman's rho correlation was applied when normality could not be assumed, and
100 the Pearson correlation was used when normal distribution of data was verified to
101 evaluate the relationship between the RPRE change and baseline refractive error.

102 For statistical purposes, p value < 0.05 was considered significant.

103

104 **RESULTS**

105 Average central baseline spherical equivalent was -3.22 ± 1.66 D (range, -0.75 to $-$
106 8.00 D) of sphere with less than 1.00 DC of refractive astigmatism in the spectacle
107 plane. Mean flat keratometric reading was 7.85 ± 0.25 mm.

108 Statistical analysis showed an interaction between the type of correction and the
109 eccentricity for M and J0 ($p < 0.05$), but not for J45. For the most peripheral
110 eccentricities, the M and J0 components of refraction became significantly different
111 between the experimental conditions evaluated (no lens, ExpRGP and StdRRP). The
112 comparisons between such conditions at each eccentricity is provided below for M, J0
113 and J45 components of refraction.

114 Figure 1A shows the RPRE for the M component of refraction in the no lens
115 condition (baseline) and for the StdRGP and ExpRGP lenses. Statistical analysis
116 showed significant differences in the M component between all examination conditions
117 for the nasal retina beyond 10 degrees (i.e., $p < 0.05$ for 15 degrees and beyond
118 according to ANOVA) and for the temporal retina beyond 5 degrees (i.e., $p < 0.05$ for
119 10 degrees and beyond according to the Friedman test). Post-hoc tests showed a
120 statistically significant difference between no lens and ExpRGP for all eccentricities
121 beyond 10° in the nasal field and 5° in the temporal field. StdRGP was significantly
122 different from no lens condition for the nasal field beyond 5° of eccentricity and
123 between 15 and 25° of temporal field; however, in this case the differences were much

124 lower than with the ExpRGP. Differences between StdRGP and ExpRGP were
125 statistically significant beyond 10° of nasal field and beyond 5° of the temporal field.

126 Figures 1B and C show the RPRE for J0 and J45, respectively, with no lens and
127 with StdRGP and ExpRGP lenses. Regarding changes in the J0 component, all
128 eccentricities except 15 degrees nasal to 5 degrees temporal showed significant
129 differences when compared with the baseline condition. Post-hoc tests showed that
130 ExpRGP presented significantly different RPRE compared with no lens for the nasal
131 eccentricity beyond 10° and for the temporal eccentricity beyond 5°. The same applied
132 for the comparison between StdRGP and ExpRGP. Regarding changes in J45,
133 differences between ExpRGP and no lens or between StdRGP and ExpRGP are not
134 statistically significant and are very low.

135 Figure 2 shows the relationship between the spherical equivalent axial refraction
136 without lens and the averaged RPRE at 30 degrees of eccentricity (average of 30
137 degrees nasal and 30 degrees temporal) for the StdRGP and ExpRGP lenses.
138 Correlations were very weak ($r=0.05$; $r=0.19$; $r=0.04$ for no lens, StdRGP and ExpRGP,
139 respectively) and non-significant. The same results were confirmed when the Nasal or
140 Temporal RPRE were evaluated independently, instead of averaged.

141 Figure 3 shows the relationship between the amount of RPRE induced by the
142 ExpRGP lens (ExpRGP minus Baseline) at the 30° of the temporal and nasal visual field
143 as a function of the baseline axial spherical equivalent. There was negligible or no
144 relationship between central refractive error and RPRE with the ExpRGP lens at the 30°
145 nasal ($r=0.05$; $p<0.05$) or 30° temporal ($r=0.16$; $p<0.001$) eccentricities of the visual field.
146 Despite the statistical significance of the correlation, both showed poor correlation. This
147 means that the RPRE induced was independent of the central refractive error. Overall,
148 in 60% of the eyes, the ExpRGP lens provided a change in RPRE of at least -2.00 D of

149 myopia at 30° with an average change in this group of -2.83 ± 0.56 D (range, -2.01 to -
150 3.69 D).

151 Figure 4 shows the averaged nasal and temporal RPRE values for no lens
152 condition (baseline) as well as with StdRGP and ExprRGP lenses. Without lens, only
153 12% of the eyes presented some degree of relative peripheral refractive myopia. This
154 increased to 29% with the StdRGP lens with most of the eyes showing myopic RPRE
155 below 1.00 D (21%) and a few cases (8%) between 1.00 and 2.00 D. With the ExprRGP
156 lens, up to 89% of the eyes presented some degree of myopic RPRE. In 60% of the
157 eyes, the ExprRGP lens provided at least 1.00 diopter of relative peripheral myopia at
158 the 30° of eccentricity. The total proportion of eyes with RPRE over -1.00 was
159 significantly higher with the ExprRGP compared to StdRGP and no lens conditions
160 ($p < 0.05$ for both comparisons, Cochran Q). When the analysis was conducted for the
161 30° eccentricity in the nasal and temporal fields separately, it was evident that the
162 proportion of eyes with relative peripheral myopia over -1.00 was higher in the
163 temporal visual field (79%) compared to the nasal visual field (43%).

164 Figure 5 shows the effectiveness of the ExprRGP lens. The following information
165 is depicted in the figure:

- 166 - Change induced in RPRE by ExprRGP (ExprRGP minus Baseline)
- 167 - Change induced in RPRE by StdRGP (StdRGP minus Baseline)
- 168 - Change induced in RPRE attributable to the special design of the ExprRGP
169 (ExprRGP minus StdRGP)

170 The ExprRGP lens induced a myopic RPRE change of more than 3.00 D in 37% of
171 the eyes, between -2.01 and -3.00 D in 23%, and between -1.01 and 2.00 D in 25%.
172 This makes up to 85% of the eyes with a difference of at least -1.00D of myopic RPRE
173 compared to the no lens condition. Conversely, the StdRGP lens induced such

174 differences in only 6%, 8%, and 19%, respectively (total 33%). When the analysis was
175 conducted for the 30° eccentricity in the nasal and temporal fields separately, it was
176 evident that the ExpRGP lens provided larger changes in myopic defocus in the
177 temporal field compared to the nasal field. The total amount of eyes presenting changes
178 in RPRE over -1.00 of myopia were 45% when the nasal field was considered and 66%
179 when the temporal field was considered. Those presenting changes of -3.00 D or higher
180 were 15% when the nasal field was considered and 29% when the temporal field was
181 considered.

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183

184 **DISCUSSION**

185 RGP materials are excellent platforms for contact lens design because of their
186 optical properties and resistance to flexure forces while on the eye. They ~~also~~ are
187 considered safe because they are associated with low risks of infection and other
188 adverse events.¹⁰ Despite this, they represent a small part of the contact lens market
189 because of their initial discomfort and the need for longer periods of adaptation
190 compared to soft contact lenses.¹¹

191 The current study showed for the first time that a custom RGP lens might
192 effectively induce relative peripheral myopic defocus across a wide range of values of
193 axial myopia. Contrary to the relationship between induced peripheral myopic defocus
194 and central refractive error in orthokeratology treatments,¹ the amount of myopia
195 induced in the periphery of the visual field with the lens evaluated in the present study
196 is not limited by or related to the axial refraction.

197 Queiros et al. reported that the relationship between the amount of myopia
198 corrected in the corneal center and the amount of peripheral myopia induced after

199 treatment follows an almost 1:1 pattern, such that for 1.00 D of myopia to be
200 compensated for there is the potential to induce 1.00 D of RPRE at 30 degrees in the
201 extremes of the horizontal visual field.¹ Cho et al. showed that for myopes with less
202 than 2.00 D of myopia, the progression of the axial elongation was very similar to
203 subjects wearing spectacles.¹² Kakita et al. found a similar trend in Japanese myopic
204 children,¹³ but this result was not observed in other two recently published studies from
205 Spain^{14,15} and Hong Kong.¹⁶

206 Soft contact lenses currently in use to address myopia regulation incorporate
207 treatments zones of +2.00 diopters including multifocal center-distance, peripheral
208 gradient¹⁷ and dual-focus lens designs.¹⁸ Because the mechanism underlying myopia
209 control through manipulation of the peripheral optics is not fully understood, it is not
210 possible to establish the minimal effective level of peripheral myopia to reduce myopia
211 progression. However, assuming that a difference of at least 2.00 D of the RPRE should
212 be provided by any solution attempting to effectively interfere with myopic progression
213 based on manipulation of the peripheral optics. Our results showed that if at least 2.00 D
214 of relative peripheral myopic defocus might effectively be used to manipulate the
215 relative peripheral myopic defocus, such an effect could be achieved in 60% of eyes
216 evaluated in the current study.

217 While soft contact lenses might result in faster adaptation associated with better
218 comfort and centration with the pupil,¹⁹ RGPs seem to offer the best platform to create a
219 given optical design and maintain such properties while being worn on the eye. Such an
220 effect cannot be provided in the same way using soft contact lens material. In our
221 previous study Proclear center-distance multifocal contact lenses with +4.00 D of add
222 did not show significantly different peripheral myopic defocus compared to the +3.00 D
223 add lenses; similarly, +1.00 D of add did not show any measurable benefit compared

224 with the naked eye.³ We reported a similar effect with the same lens in myopic
225 subjects.²⁰ Recently, Ticak and Walline did not find a significant peripheral myopic
226 defocus effect with the Proclear Multifocal lenses compared with the effect produced by
227 orthokeratology. However, they used an add power of +2.00 D,²¹ which in our studies
228 showed only a slight peripheral myopic defocus effect compared with the more effective
229 +3.00 D add. This means that a given increase in the peripheral power addition on a soft
230 contact lens material does not necessarily increase the effect in the same proportion
231 when measured by peripheral refraction. This has been confirmed recently ~~this~~ in a pilot
232 study that compared the peripheral refraction between the current experimental RGP
233 design and the same design manufactured in a hydrogel material.⁵ In contrast, it seems
234 that the effect of the RGP lens might be stronger (average change in RPRE, -2.00 D)
235 than the one intended to be reproduced (-1.50 D as expected from the lens design at
236 30°). In the present work it has been found that the change induced in the RPRE can be
237 over 2.00 or even 3.00 D in a significant proportion of eyes with the ExpRGP lens. This
238 would not be expected as the lens is designed to induce up to 1.5 D of myopic defocus.
239 To find an explanation to the higher spherical equivalent obtained compared to the
240 theoretical peripheral myopic defocus induced by the lens design we have to consider
241 the astigmatism induced by the oblique incidence of light. When computed as spherical
242 equivalent, the astigmatism induced by the optical surfaces for oblique incidence of
243 light into the eye contributes to an overall increase in the myopic defocus that is beyond
244 the change expected due solely to the increase in spherical power by the design of the
245 lens. Additionally, the use of an autorefractor which averages refraction over a 2.3mm
246 diameter measurement ring is likely to give highly myopic readings as the power add
247 continues increasing up to the edge of the optic zone as explained in the methods
248 section.

249 Ticak and Walline suggested in their recent study, more accurate instruments are
250 needed to measure the power at discrete points in lenses with strong changes in power
251 across their surface while the lenses are on the eye to better understand the refractive
252 effect of orthokeratology treatment and multifocal contact lenses in the context of
253 myopia progression.²¹ However, previous studies have shown similar effects of the
254 Proclear center-distance lens using an aberrometer that measures the full pupillary
255 area.²² Furthermore, because previous studies of orthokeratology and other lenses also
256 have been conducted with the Grand Seiko or the Shin-Nippon instruments, the current
257 results were comparable to those previously reported.

258 From the results of the present study cannot be assumed that the average
259 peripheral myopic defocus achieved ensures that the entire retina might be under a
260 similar defocus effect. As an example, while over 80% of the eyes will experience a
261 change in RPRE of at least -1.00 D, this amount reduces to 45% when we consider the
262 nasal field. For 29% of the subjects, the amount of the RPRE with the ExpRGP lens
263 ranged from 0.25 to 1.00 D of myopia. The peripheral refraction and probably the
264 retinal shape are not the same between the horizontal and vertical meridians,^{21,23} not
265 even between the nasal and temporal sides.²⁴ Our results show that with the present
266 lenses, higher myopic defocus is usually achieved in the temporal visual field compared
267 to the nasal visual field. We cannot justify these outcomes by the decentration of the
268 lens with gaze changes. However, slight temporal decentration of the RGP lenses is
269 usually observed, even when the lens remains within the accepted levels of centration
270 (0.50 mm).²⁵ In the present study lens centration was improved using the large diameter
271 lens (10.60 mm for ExpRGP lens and 10.50 mm for the StdRGP lens). This is critical
272 when fitting RGP lenses to maximize the symmetry in the myopic defocus induced

273 around the foveal area. To maximize centration during the peripheral measurements,
274 head turn instead of eye turn was used to fixate peripheral targets.

275 Results presented in this study show that the asymmetry between refraction in the
276 nasal and temporal retinal eccentricity was approximately constant without and with
277 lenses. Any significant decentration of the lens during measurements would result in
278 reduction or exaggeration of the asymmetry found. This asymmetry in baseline data has
279 been previously documented.^{8,20,26,27} This might be related with the asymmetry in the
280 nasal and tempoeral eye length and corresponding posterior retinal contour in
281 myopia.^{24,28} It could be also related with the measuring technique as we centered our
282 measurements on the pupillary center. Asymmetries between nasal and temporal corneal
283 curvature could also account for some differences. Kwok et al found that asymmetries
284 between nasal and temporal peripheral refractive error would be minimized if
285 measurements were referred to the optical axis of the eye instead of the foveal axis.⁸
286 Overall, it can be concluded that lens decentration does not contribute to a change in the
287 asymmetry of the nasal and temporal refraction and the factors previously mentioned
288 should be considered.

289 Considering that treatments attempting to slow myopia progression should be
290 more effective in younger children, safety becomes a major concern. Different authors
291 have reported that RGP lenses worn overnight during orthokeratology treatment are
292 well tolerated by children^{13,14,29} which is probably related to the fast adaptation to this
293 modality.³⁰ Children also have been shown to successfully adapt to RGP lenses on a
294 daily wear basis in different clinical trials.^{19,31} This makes RGP lenses a viable option
295 for controlling myopia progression even if they have to be worn on a daily wear basis.
296 One relevant aspect is the higher drop-out rate that might be present with RGP
297 compared to soft contact lenses. In a randomized clinical trial addressing the potential

298 efficacy of conventional RGP lenses for myopia progression, Walline et al reported a
299 70% retention rate in the RGP arm compared with a 93% in the soft contact lens control
300 arm.³¹ While the tolerance must be a limitation for patients who previously wore soft
301 contact lenses, this might not be the case for most young children wearing lenses for the
302 first time to control myopia. Finally, the data summarized in the TFOS CLD workshop
303 showed a trend for RGP lenses with larger diameters being more comfortable.^{32,33} As in
304 the present study, RGP lenses intended for myopia regulation should be manufactured
305 in larger than average diameters to improve centration and provide a sufficiently large
306 treatment zone over the larger pupil areas of kids children. Furthermore, to overcome
307 the short-term discomfort issues with corneal RGP lenses, other strategies might be
308 considered in the future, such as large diameter scleral or hybrid lenses. These lenses
309 also can provide more lens stability and centration against misalignments related to
310 ocular rotation and blinking.

311 In summary, the present study showed that RGP lenses can be custom designed
312 to provide myopic RPRE in most of the myopic eyes irrespective of the degree of axial
313 myopia within the range from -1.00 to -8.00 D of spherical equivalent included in this
314 study. Comfort related aspects of this modality compared with soft contact lenses need
315 to be considered. Finally, while the efficacy of this device in providing myopic RPRE
316 has been shown, the efficacy to inhibit myopia progression still needs to be investigated
317 with the appropriate clinical trial.

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404 **LEGENDS**

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406 **FIGURE 1.**

407 (A) Spherical equivalent component (M) of the relative peripheral refractive error (RPRE)
408 without lenses (baseline), with standard RGP (StdRGP) and an experimental RGP (ExpRGP)
409 lenses. (B, C) Astigmatic component (J0 and J45) of the RPRE without lenses (baseline), with
410 the StdRGP and the ExpRGP lenses. Lines represent the second-order polynomial fitting. The
411 error bars represent the standard error of the mean (SEM).

412

413 **FIGURE 2.**

414 The correlation between the baseline axial refraction and the amount of relative peripheral
415 refractive error (average between 30 degrees in the nasal and temporal visual fields) at baseline
416 without a lens ($y = -0.0275x + 1.0227$; $r = 0.05$; $p = 0.745$ represented by the light grey circles and
417 dashed line) and the standard gas permeable lens ($y = 0.1815x + 1.2827$; $r = 0.19$; $p = 0.117$;
418 represented by the dark grey diamonds and dark grey line), and the experimental gas permeable
419 lens ($y = 0.0268x + 1.3164$; $r = 0.04$; $p = 0.756$ represented by the black squares and black line).

420

421 **FIGURE 3.**

422 Correlation between the axial refraction at baseline and the amount of change in relative
423 peripheral refractive error achieved with the experimental gas permeable lens compared to
424 baseline for 30 degrees of eccentricity in the nasal (30 degrees nasal; $y = -0.0715x - 2.585$;
425 $r = 0.05$; $p < 0.05$; black diamonds, black line) and temporal (30 degrees temporal; $y = 0.1802x -$
426 2.0931 ; $r = 0.16$; $p < 0.001$; grey circles, grey line) visual fields.

427

428 **FIGURE 4.**

429 The proportion of eyes with a given relative peripheral refractive error (RPRE) (average
430 between 30 degrees in the nasal and temporal visual fields) at baseline, with the standard gas
431 permeable and the experimental gas permeable lenses. Negative values indicate myopic RPRE
432 and positive values indicate hyperopic RPRE.

433

434 **FIGURE 5.**

435 The proportion of eyes with a given change in relative peripheral refractive error (RPRE)
436 (average between 30 degrees in the nasal and temporal visual fields) for the paired comparisons
437 between baseline, the standard gas permeable lens and the experimental gas permeable lens.
438 Negative values indicate myopic RPRE and positive values indicate hyperopic RPRE.