Comfort and Vision Scores at Insertion and Removal During 1 Month of Wear of Paragon CRT for Corneal Reshaping

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Purpose: The goal of this study was to evaluate the pattern of initial adaptation of neophytes to corneal refractive therapy (CRT) for overnight corneal reshaping in terms of comfort and subjective visual performance at lens insertion at night and lens removal in the morning.

Methods: Twenty-two young healthy subjects were enrolled in this study. All of them had been trialed to assess adaptation to conventional alignment-fit rigid gas permeable lenses and were only enrolled in this study after a 2-week wash-out period. Visual analog scales for subjective comfort and vision were recorded on a form given to the patient on days 1, 2, 3, 5, 7, 14, 21, and 28. Additionally, the patient attended the clinic on days 1, 7, 15, and 30 after fitting, for follow-up.

Results: Successful adaptation was obtained in 21 of the 22 initially enrolled individuals. The average overnight wearing time remained constant during the study at 8 hrs per day. Overall comfort rates increased significantly up to values of 8.02 and 9.12 out of 10 at insertion and removal, respectively ($P<0.001$). Subjective vision scores also increased significantly at the end of the 1-month study period ($P<0.001$).

Conclusions: Adaptation to CRT is rapid in terms of subjective comfort and vision. Comfort significantly increases by day 5, whereas subjective vision in the morning reaches its maximum by days 15 to 21 and at the end of the day by days 10 to 15. These results are of interest to clinicians to provide evidence-based information to their patients about the expected time to adapt to CRT in terms of self-reported comfort and vision.

Key Words: Comfort—Contact lenses—Adaptation—Corneal refractive therapy—Orthokeratology—Visual analog scales.

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Comfort related to contact lens (CL) wear has been one of the major concerns during the last few years, particularly with soft CLs because this seems to be one of the major causes for the discontinuation of CLs.[1] Although discomfort issues seem to be improved with silicone hydrogel CLs,[2–4] there are still reports on lens-related discomfort in patients fitted with either conventional hydrogels or silicone hydrogels, altogether representing approximately 95% of the worldwide CL market.[5,6] Partly because of their minor role in current fitting strategies, comfort-related questions in rigid gas permeable (RGP) lenses have been marginally considered in recent clinical research.[7,8] It seems clear that despite the advantages of these lenses in physiologic and optical performance, the low comfort achieved in the short-term and the adaptation time needed preclude most professionals from fitting RGP lenses.

A specific case within the RGP field is overnight corneal reshaping or corneal refractive therapy (CRT) with CLs. Clinicians are aware that the eyelids play a major role in RGP CL–related discomfort during blinking, and this is common at first and within the adaptation period to all RGP lenses.[8,9] This inconvenience is minimized in CRT because the lenses are worn overnight with no blinking effects. However, with CRT, the patient still feels some discomfort during the first few days at insertion and at the moment of lens removal. Despite the growth of overnight corneal reshaping in clinical practice in this decade,[10] no single study has directly addressed the question of comfort and adaptation to CRT lenses during the first month of lenses wear, and this represents the starting point for this study wherein we surveyed the self-reported comfort and vision during the first month of CRT. The purpose of this article is to show the time period and subjective ratings for the physical and visual adaptation to these CRT lenses. This information will be useful for clinicians so that they can tell their patients in advance of the potential effects that might be experienced during the first month of lens wear.

METHODS

Subjects and Lenses

Twenty-two patients were recruited from the student population at the Clinical and Experimental Optometry Research Laboratory (University of Minho, Braga, Portugal). More detailed demographic characteristics of the population being sampled are shown in Table 1. The study protocol was approved at the Clinical Experimental Optometry Research Lab Review Board, and the tenets of the Declaration of Helsinki were followed. After the purpose of the study was explained and all doubts clarified to the participants, a consent form was presented and signed by both the patient and the researcher. All the patients had participated in a 1-month trial with daily wear of conventional alignment-fit RGP lenses, followed by a wash-out period of 2 weeks. At the beginning of the first trial, none of the subjects had experienced any CL wear.

All the participants were fitted with Paragon CRT lenses for corneal reshaping (Paragon Vision Sciences, Mesa, AZ) according to manufacturer guidelines as described below.

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The authors do not have any financial interest on the materials and instruments used in this study.

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TABLE 1. *Demographic Characteristics of Patients in the Study*

Parameter	Values
Number of patients	22
Mean age (yr)±SD	23.47±4.49
Age range (yr)	[19 to 36]
Gender (male/female)	12/10
Mean keratometry (D)	
Flat	42.91±1.13
Steep	43.74±1.36
Mean refractive sphere (D)±SD	−1.92±1.23
Range of refractive sphere (D)	[−0.25 to 5.25]
Mean refractive cylinder (D)±SD	−0.30±0.33
Range of refractive cylinder (D)	[0 to −0.75]

SD, standard deviation.

Fitting Procedures

The fitting approach has been previously described.[11] Base optical zone radius, return zone depth (RZD), and landing zone angle (LZA) for the first diagnostic lenses were derived from nomograms produced by the manufacturer. Fitting evaluation included fluorescein assessment, lens centration, and movement followed by overrefraction. The parameters of RZD and LZA were manipulated until a satisfactory fluorescein fitting pattern was achieved with excellent centration, light apical bearing over a central 4-mm zone, a paracentral tear reservoir free of air bubbles, tangential peripheral zone and adequate axial edge clearance with an overrefraction between plano and +0.50 D.

Lenses were then prescribed, and instructions about the wearing schedule, insertion, removal, and care system were given to the patient. The care system prescribed was a multipurpose solution for RGP lenses (Boston Simplus, Bausch & Lomb, Rochester, NY). Rewetting drops (Moisture Eyes, Bausch & Lomb) were advised before and after lens wear.

Data Collection

Visual analog scales (VASs) were given to the patients so that they could record their subjective vision and comfort rates from 0 (poorer vision or comfort) to 10 (excellent vision or comfort). Figure 1 shows an example of the scales used in this study. The scale was horizontally oriented, measuring exactly 10 cm, and the value for statistical analysis was measured with a rule at the point where the mark inserted by the patient crossed the scale. The use of VAS in RGP lens adaptation assessment has been common in the literature.[8,12] The patients also recorded the overnight wearing time for the same days (1, 2, 3, 5, 7, 10, 15, 21, and 28 days after fitting).

Aftercare visits were scheduled on 1, 7, 15, and 30 days when the clinical assessment of unaided visual acuity, best-corrected visual acuity, and overrefraction, along with slitlamp examination, was carried out. During the month of the study, the patients wore the lenses overnight only, and they kept a recording sheet with the VAS to grade their subjective perception of vision and comfort for days 1, 2, 3, 5, 7, 10, 15, 21, and 28 along with the number of hours sleeping in lenses. At the end of the month reported here, all the patients, except one patient, continued wearing the lenses by choice.

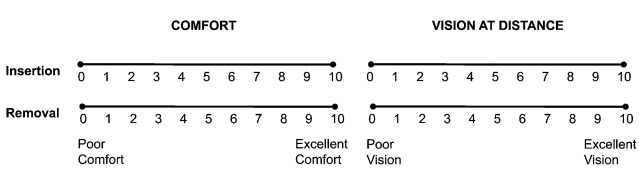

FIG. 1. Visual analog scales used to record subjective perceptions of participants regarding vision and comfort. These scales were implemented in a form wherein the patient marked up the scores on days 1, 2, 3, 5, 7, 10, 15, 21, and 28 after fitting.

Statistical Analyses

Statistical analysis was conducted using SPSS 15.0 software (SPSS Inc. Chicago, IL). Normal distribution of data was tested using Shapiro–Wilk test. When appropriate, nonparametric statistics were used for comparisons along the period of study by Kruskal–Wallis test or Wilcoxon and Mann–Whitney tests for comparisons between pairs of visits. Statistical significance of results was considered when the P value was <0.05. Differences among different follow-up times were compared with baseline values (to explore the time needed to experience significant improvement or worsening of signs and symptoms) as compared with 1-month scores to detect from which instant the signs and symptoms did not vary compared with the final value.

RESULTS

Twenty-one of the 22 initially fitted individuals successfully completed the 1-month study. Over this period, the average monocular subjective refraction of the patients changed from −2.06±1.13 D of spherical equivalent at baseline to −0.82±0.75 D after 1 night of overnight wear, −0.24±0.37 D after 7 days, −0.04±0.12 D after 15 days, and −0.02±0.09 D after 28 days ($P<0.001$).

The patient who failed to complete the study did so because of the inconvenience of the wearing regime that was incompatible with variable sleep habits. Visual analog scores for comfort are given in Figure 2. Comfort rates improved from 5.33±2.42 at insertion for the first day to 8.02±2.01 at 1 month ($P<0.001$); comfort at removal increased from 6.72±2.79 on the first day to 9.12±0.87 at 1 month ($P<0.001$). Table 2 shows the statistical comparison of the means at each study period compared with baseline values.

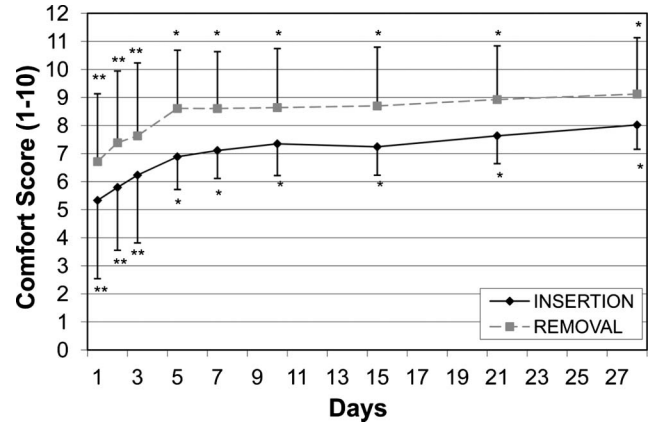

FIG. 2. Subjective comfort scores at lens insertion before sleep (*black bins*) and at lens removal (*gray bins*) from days 1 to 28. *Statistical significance for values versus baseline scores (day 1). **Statistical significance for values versus end of study scores (day 28).

TABLE 2. *Statistical Significance for Comparisons Between Different Time Points in the Study Vs. Their Respective Baseline Scores or Final Scores*

Variable	Term of comparison	Day 1	Day 2	Day 3	Day 5	Day 7	Day 10	Day 15	Day 21	Day 28
Comfort at insertion	Baseline[a]		NS	NS	0.046	0.025	0.012	0.016	0.003	0.001
	End of study[b]	0.001	0.006	0.027	NS	NS	NS	NS	NS	
Comfort at removal	Baseline[a]		NS	NS	0.012	0.013	0.01	0.008	0.003	0.001
	End of study[b]	0.001	0.004	0.019	NS	NS	NS	NS	NS	
Vision in the morning	Baseline[a]		NS	NS	0.019	0.002	>0.001	>0.001	>0.001	>0.001
	End of study[b]	>0.001	>0.001	0.001	0.007	NS	NS	NS	NS	
Vision at end-of-day	Baseline[a]		NS	NS	0.005	>0.001	>0.001	>0.001	>0.001	>0.001
	End of study[b]	>0.001	>0.001	0.001	0.018	0.032	NS	NS	NS	
Wearing time	Baseline[a]		NS	NS	NS	NS	NS	NS	NS	NS
	End of study[b]	NS	NS	NS	NS	NS	NS	NS	NS	

Wilcoxon–Mann–Whitney test was used.

[a]Statistical significance for values vs. baseline scores (day 1).

[b]Statistical significance for values vs. end of study scores (day 28).

NS, nonstatistically significant ($P>0.05$).

Visual analog scores for vision are presented in Figure 3. Subjective vision scores improved from 5.83±2.57 after lens removal in the morning of day 1 to 9.07±2.01 at 1 month ($P<0.001$), whereas at the end of the day, the subjective vision score increased from 4.30±2.46 before lens insertion at the end of the day after the first night with lenses to 8.41±1.61 at 1 month ($P<0.001$). In this case, vision at the end of the day before lens insertion was attained by day 15, whereas the vision scores immediately after lens removal (beginning of the day) approached their maximum recorded in this trial by day 10. Although standard deviations seemed to decrease from the beginning of the study toward the end of the month, this was more evident for vision after lens removal, whereas subjective vision scores at lens insertion seemed to remain variable during the 1-month study period. Statistical analysis shows that significant improvements in comfort are obtained after 5 days of wear. After day 7 for lens removal and after day 10 for lens insertion, subjective vision scores were not significantly different from those obtained at the end of the month. The average wearing time remained statistically stable during the whole month ranging from 7.42±1.44 to 8.99±1.32 hrs per night. Time course of wearing time is presented in Figure 4. None of the patients reported that their sleep was interrupted because of pain or discomfort caused by their lenses or reported having trouble getting to sleep with their lenses. Although some of them reported that the lens was uncomfortable immediately after insertion, they also reported that this sensation improved after closing their eyes, and therefore, this discomfort was not a limitation to starting and continuing the treatment.

DISCUSSION

The time to fully reasonably adapt to the physical sensation at insertion and removal of a CRT contact lens is fairly rapid. The period of time to achieve stable visual scores is in agreement with those of previous studies[13,14] that showed the time necessary to achieve full and stable correction of refractive error. Obviously, this time will be different for every patient because it depends on the amount of refractive error to be corrected.[15] In this study, the time to notice statistically significant changes in vision was 5 days, whereas the time to reach stable vision scores with no statistically significant changes compared with the 1-month results was 7 days for morning (after lens removal) results and 10 days on average for evening (before lens insertion) vision scores.

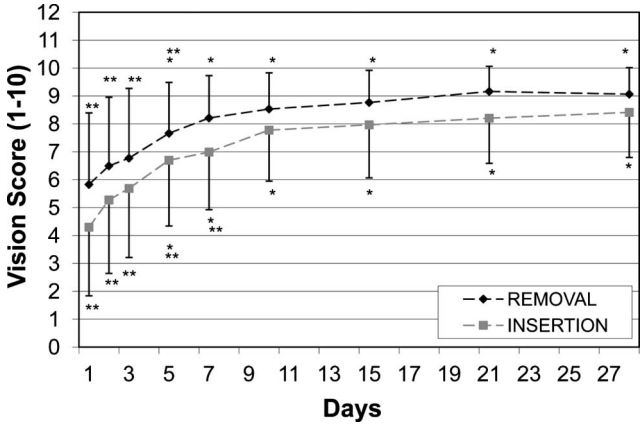

FIG. 3. Subjective vision scores at lens insertion (*gray bins*) and at lens removal (*black bins*) from days 1 to 28. *Statistical significance for values versus baseline scores (day 1). **Statistical significance for values versus end of study scores (day 28).

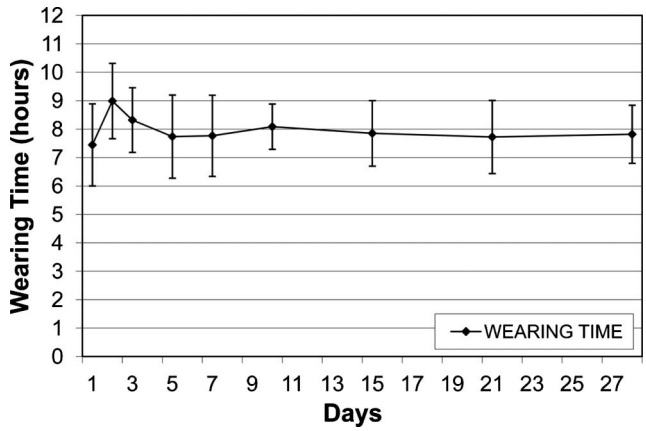

FIG. 4. Wearing time per night of wear during the 1-month study period from days 1 to 28.

Regarding diurnal variations, the differences between vision scores in the morning and those at the end of the day show a decrease over time as the treatment stabilizes. Because of the regression experienced during the day, these scores were lower compared with the vision scores in the morning after lens removal. These differences are not statistically significant, but they are clinically significant (from the patient's and practitioner's perspectives) until day 10 when they tend to remain stable at a higher rate, in agreement with the findings of previous authors.[13]

There was also a significant difference between comfort in the morning before removal and that in the evening at insertion. Insertion comfort is always lower on average. Comfort increased with the values approaching final scores by day 10 for insertion data and day 5 for removal. Two reasons that would explain the difference between insertion and removal are that on awakening the lens has less movement than immediately after insertion and corneal sensitivity has also demonstrated to be lower on awakening, recovering to those values obtained before sleep.[16] There is also another study that gauged the subjective vision ratings immediately after lens removal and after 14 hours without lenses by day 1, day 4, day 10, and over 28 days. Our results agree with those reported in that study concerning the lower variability in vision scores because the treatment stabilizes after 10 days.[13] The outcomes from this study show that comfort, despite not being optimal from the beginning, should not be a limitation to CRT adaptation. This might be different in alignment fit of RGP lenses wherein some patients might not adapt because of comfort-related issues.[8] The absence of control in the use of artificial tears (who is using them and how much) might be considered as a potential limitation because it could affect the comfort and vision ratings. However, although direct mechanisms were not adopted to gauge the use of rewetting drops, at every follow-up visit, verbal and written (on the back of the VAS) advice was given to remind the patient of the use of artificial tears and of the cleaning solution According to this, we might assume that the patients used the rewetting solution at least at the recommended times (at insertion and at removal). Moreover, unless discomfort during the sleep period had been noticed, it is hard to expect that a patient will use the solution further during the night. Considering that no patients included in the study reported such symptoms when asked directly in follow-up visits, we might assume that the use of rewetting drops might be consistently similar for all the patients.

Regarding vision, as expected from previous studies,[13] both scores before insertion and after removal seem to have reduced variability toward the end of the 1-month study period compared with initial scores. The interindividual effect of regression might play a significant role, with different factors being potentially involved as amount or refractive error[17] or corneal biomechanical properties,[18,19] among others.

The fact that all the patients had already had some experience with other CLs before this study could be considered a limitation. Thus, it could be argued that the results presented here might not be directly applicable to neophyte patients. It could be also argued that the participants will change their ratings because of previous experience with the somewhat more uncomfortable alignment-fit RGP lenses worn on a daily wear basis; this effect will raise the scores of the CRT lens because of previous experience with the alignment-fit RGP lenses. However, the initial ratings given in this study on the first day at insertion (5.3 ± 2.4) were almost exactly the same as the 5.2 ± 2.2 reported by the successfully adapted CL wearers in the previous study with alignment-fit RGP lenses (Carracedo et al. Conference of Optometry, Contact Lenses and Ophthalmic Optics, Madrid, 2010, conference abstract). However, the refractive outcomes expressed in spherical equivalents in the *Results* section support the rapid increment in subjective vision scores during the first week of treatment. Of course, this is directly linked to the reduction in refractive error and improvement in both high and low contrast visual acuities as previous authors have already demonstrated.[13,14] Finally, these results can only be applicable to Paragon CRT lens. Specific features of other designs and materials used in current overnight corneal reshaping could render slightly different results in comfort and vision as measured in this study.

In summary, when practitioners opt to fit a CRT lens for overnight corneal reshaping within the treatment range reported in this study, they should explain to the patient that comfort will potentially increase rapidly within the first 3–5 days, whereas satisfactory and stable vision might take up to 5 to 10 days to be achieved. Although improved comfort at lens insertion increases with time consistently among patients, comfort at removal (in the morning), although greater than in the evening, will remain subject to more intersubject variability.

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