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Symptoms and Signs in Rigid Gas Permeable Lens Wearers During Adaptation Period

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Objectives: To evaluate neophyte contact lens wearers' fitting to rigid gas permeable (RGP) contact lenses in terms of wearing time, tear volume, stability, corneal staining, and subjective ratings, over a 1-month period of time.

Methods: Twenty-two young healthy subjects were enrolled for wearing RGP on a daily wear basis. The participants included in this study never wore contact lenses and showed a value under 10 in McMonnies Questionnaire. Contact Lens Dry Eye Questionnaire, Visual Analog Scales, Schirmer test, tear film break-up time (BUT), and corneal staining grading were performed. Follow-up visits were scheduled at 1, 7, 15, and 28 days.

Results: Six subjects dropped out due to discomfort from the study before 1 month (27% of discontinuation rate). Successful RGP wearers (16 participants) achieved high levels of subjective vision and reported comfort scores of approximately 9 of 10 between 10 and 15 days. They reported wearing their lenses for an average of 10.12±2.43 hr after 1 month of wear. Conversely, unsuccessful wearers discontinued wearing the lenses after the first 10 to 15 days, showing comfort scores and wearing time significantly lower compared with the first day of wear. Schirmer test showed a significant increase at 10 days ($P<0.001$), and the BUT trends decreased after the first week of wear in unsuccessful group.

Conclusions: Symptomatology related with dryness and discomfort, detected during the first 10 days of the adaptation, may help the clinician to predict those participants who will potentially fail to adapt to RGP lens wear.

Key Words: Adaptation period—Rigid gas permeable—Symptoms.

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Contact lens comfort is one of the major concerns for patients and practitioners as it can compromise the fitting success rate in the short and long terms. Contact lens–related comfort issues might have a wide range of factors involved, particularly when working under certain environmental conditions.[1,2] It is commonly accepted that the initial comfort for rigid gas permeable (RGP) lenses to be low, increasing during the first few days until regular wearing during the entire day. When compared with soft contact lenses (SCL), RGP lenses generally fit better in terms of physiological interaction with the ocular surface by increased tear turnover, high oxygen transmissibility and safety, with a lower incidence of adverse events such as microbial keratitis.[3] However, there is awareness by patients that the adaptation to these lenses is much more difficult in the short term. This limits the use of these lenses worldwide[4,5] to 10.8% of all contact lenses fitted according to the International Contact Lens Survey.[6]

However, when we look to the regional trends there are significant differences in the pattern of fitting for these lenses ranging from 0.2% for Lithuania to 37% for Malaysia, Germany being the European country with the highest percentage of RGP lens fitting (over 30%).[6] It is usually observed that RGP fitting rates are higher for refits than new fits, which suggest that practitioners perceive these lenses as physiologically and optically superior to improve tolerance and optical quality when other modalities fail or do not warrant satisfactory outcomes.[5]

There is limited information available regarding the time needed to achieve full adaptation to RGP lens wear and how this is affected by the number of hours the lenses are worn and the subjective perceived vision and comfort. There is also few information in the peer-review literature, only two studies from the same group research,[7,8] regarding the reasons for nonadaptation and how this can be expected to change after the first few days of wear, or if failures can be predicted or anticipated during the very first days after fitting.

Despite the overall low fitting incidence for these lenses worldwide, modern therapies, such as corneal refractive therapy and the need to correct corneal irregularities in corneal ectasia, distorted postsurgical corneas, and the potential use as myopia retention devices in children, make RGP lenses still a field of study that deserves attention.[9–11]

Therefore, the aim of this study was to evaluate the pattern of initial adaptation of neophytes to RGP lenses. The study also evaluated the time course of adaptation regarding number of hours of wear, subjective visual perception, and different subjective symptoms pertaining to different tear parameters and corneal staining scores.

METHODS

Subjects and Lenses

Twenty-two subjects (12 men and 10 women) with ages ranging from 19 to 36 (23.5±4.5 years) were recruited from the student population at the Clinical and Experimental Optometry Research Lab (University of Minho, Braga, Portugal). The demographic characteristics of these patients are detailed in Table 1. The Ethical

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

Parameter	Values
Number of patients	22
Age, mean±SD, yr	23.47±4.49
Age, range, yr	19 to 36
Gender (male/female)	12/10
Corneal astigmatism (D), mean±SD	−0.83±0.36
Range of corneal astigmatism (D)	−0.10 to −1.14
Mean keratometry (D)	
Flat	42.91±1.13
Steep	43.74±1.36
Refractive sphere (D), mean±SD	−1.92±1.23
Range of refractive sphere (D)	0.25 to 5.25
Refractive cylinder (D), mean±SD	−0.30±0.33
Range of refractive cylinder (D)	0 to −0.75

Committee of the University of Minho reviewed the study following the tenets of the Declaration of Helsinki.[12] After the purpose of the study was explained and all doubts were clarified to the participants, a consent form was presented and signed by both the patient and the researcher. Inclusion criteria required that the patients had never worn any kind of contact lens previously and did not present any current or recent ocular disease including complaints of dry eyes or previous surgical intervention, and to obtain a value under 10 in the McMonnies Dry Eye Index.[13] Study participants were subjected to a complete preliminary optometric examination, including objective and subjective refraction, and ocular surface inspection, including slitlamp examination and keratometry.

Lenses fitted were made of high oxygen permeability material (paflufocon D, Dk=100 barrer; Paragon Vision Sciences, Mesa, AZ), whose technical parameters are shown in Table 2 and were lathed by Lenticon SA (Madrid, Spain). Fitting was performed following manufacturer's guidelines and using a trial set with curvatures from 7.10 to 8.40 mm in 0.10 mm steps. The participants were advised not to use the lenses more than 4 hr for the first day increasing the wearing time, during the first week, in 2 hr daily until they achieve the maximum number of hours they will need in their daytime activities.

The care system consisted of a multipurpose solution for RGP lenses (Boston Simplus; Bausch & Lomb, Rochester, NY).

TABLE 2. *Technical Details of the Contact Lenses Being Used and Parameters Fitted to Patients in this Study*

Parameter	Values
Manufacturer	Lenticon SA (Madrid, Spain)
Material (USAN)	HDS 100
Brand	Elipsys
Manufacturing process	Lathe-cut
Back surface geometry	Central 5 mm: spherical periphery: aspheric (eccentricity=0.35)
Front surface geometry	Spherical
Overall diameter, mm	9.80
Optic zone diameter, mm	8.20
Center thickness at −3.00 D in millimeters	18
Dk (barrer)	100
Contact angle	14.8
Hardness (Shore)	84
UV filter	No
Powers fitted, D	0.25 to −6.75
Back optic zone radius, mm	7.00–9.00

Barrer=10^{-11} (cm^2/sec) (mL O_2/[mL × mm Hg]); D, diopters; t_c, central thickness.

Aftercare visits were scheduled at 1, 2, 7, 15, and 28 days. For the month of duration of the study, the subjects wore the lenses daily. Tear and ocular surface analysis and recording of subjective symptoms using Contact Lens Dry Eye Questionnaire (CLDEQ) were performed in follow-up visits. The participants removed the contact lenses in the consulting room before performing the tests and after the clinician had evaluated the lens fitting.

Tear and Ocular Surface Analysis

At follow-up visits, visual acuity, corneal staining, tear break-up time (BUT) and tear collection were reassessed. The tear collection was always performed following Van Bijsterveld[14] criteria. The Schirmer strip (Tear Flo; HUB pharmaceuticals) was placed on the temporal tarsal conjunctiva of the lower lid for 5 min with the eyes closed. Tear volume was recorded as millimeters of moistened strip. The patients removed the lenses at the beginning of each visit to fill the CLDEQ, and the Schirmer test was performed later. Five minutes after Schirmer test, fluorescein was applied to evaluate BUT and corneal staining. To warrant repeatability in the staining procedure, a solution was prepared using a 10% concentration of sodium fluorescein diluted in saline. For each application, only 5 μL of diluted fluorescein solution was applied in the inferior conjunctival sac, and 20 sec later, BUT was analyzed using a chronograph to record the time for tears to break up after the patient was asked to blink twice and keep the eyes open. The cornea was divided in five areas to record the staining grade as proposed in the Report of the National Eye Institute and Industry–Sponsored Dry Eye Workshop[15] and the Cornea and Contact Lens Research Unit.[16] Grading scales were used to grade corneal staining to the nearest 0.1 value.[16]

Visual Analog Scales

During the study, Visual Analog Scales (VAS) were given to the subjects to record their subjective impressions of vision and comfort using a scale from 0 (lowest) to 10 (highest) at home at 1, 2, 3, 5, 7, 10, 15, 21, and 28 days after fitting. The scale was horizontally oriented and measured exactly 10 cm. The value for statistical analysis was measured with a ruler at the point where the mark inserted by the patient crossed the scale. Subjects were instructed to complete the VAS each indicated day both at the same time of the day immediately after insertion and immediately before lens removal. The participants also recorded the wearing time for the same days.

Contact Lens Dry Eye Questionnaire

The CLDEQ was designed to assess the prevalence, frequency, and intensity of symptoms such as discomfort, dryness, visual fluctuations, soreness and irritation, grittiness and scratchiness, foreign body sensation, burning, light sensitivity, and itching.[17] Subjects reporting a symptom as "frequent" or "constantly" must be considered symptomatic, and symptoms were considered intense when participants reported "4" or "5" in a scale of "1" to "5." The test was performed at the clinic at 1, 7, 15, and 28 days after fitting.

Statistical Analysis

Statistical analysis was conducted using SPSS 15.0 software (SPSS Inc., Chicago, IL). The values presented are mean±SD for each studied variable. McNemar test was used to compare the signs and symptoms between follow-up visits and the baseline visit. Data

AU1

from successful and unsuccessful wearers were compared between these visits using the Mann–Whitney test for independent samples. For statistical analysis of CLDEQ symptoms data, we used the authors' validation criteria,[17] and the Chi-square test was used to contrast frequencies and intensity of symptoms between groups. $P<0.05$ was considered statistically significant.

RESULTS

Sixteen subjects of the 22 enrolled (73%) had a successful adaptation to RGP lenses and completed the study. For analysis of results, these participants were included into the successful group. On the contrary, 6 participants (27%) dropped out from the study, all of them due to discomfort, between 10 and 15 days after fitting. These unsuccessful wearers were unable to wear the RGP lenses on a regular schedule for more than 6 hr a day. For the analysis of this study's data, these participants formed the unsuccessful group, and their last follow-up visit was performed at 15 days without contact lenses. No significant differences existed between the successful and unsuccessful patients regarding their demographic characteristics (result not shown).

Comfort, Wearing Time, and Subjective Visual Scores

Wearing time, comfort, and subjective visual scores are shown in Figure 1(A–C) for the successful group and the unsuccessful group. There were statistically significant differences in the wearing time and comfort ratings between the first and last follow-up visits ($P<0.001$ and $P=0.002$, respectively) in the successful group, whereas no differences were present in any of the parameters under investigation for the unsuccessful group. At the same time, there were statistically significant differences in all parameters studied between both groups, which are identified in the graphs.

F1

In the successful group, the data showed that there were no significant differences in wearing time from the 2-day visit compared with the final value ($P=0.056$). Regarding the comfort ratings, they improved from a range (minimum to maximum) of 2 to 8 after the first day of wear to 7.5 to 9.5 score in the last day. Moreover, there were no statistically significant differences in comfort ratings from the 10-day visit to the final ratings (28 days) ($P=0.11$).

Unsuccessful wearers to RGP lens achieved similar values of maximum and minimum subjective vision scores during the first few days compared with successful wearers. However, maximum and minimum wearing time and subjective comfort scores were significantly lower in unsuccessful than successful wearers during the first 10 days.

T3

Table 3 shows the significant values between baseline and different intermediate visits and between different intermediate visits compared with final value at 28 days (1 month) in the successful group. Data for the unsuccessful group are not presented because all differences lack statistical significance.

Tear Parameters and Corneal Staining

F2

The results of Schirmer and BUT tests are shown in Figure 2. Tear volume was not statistically different at baseline, or after the first day wearing the lenses, between successful and unsuccessful groups. However, the unsuccessful group showed a significant trend for increasing Schirmer values from 20 to 27 mm ($P<0.001$) during the second week until discontinuing from the study.

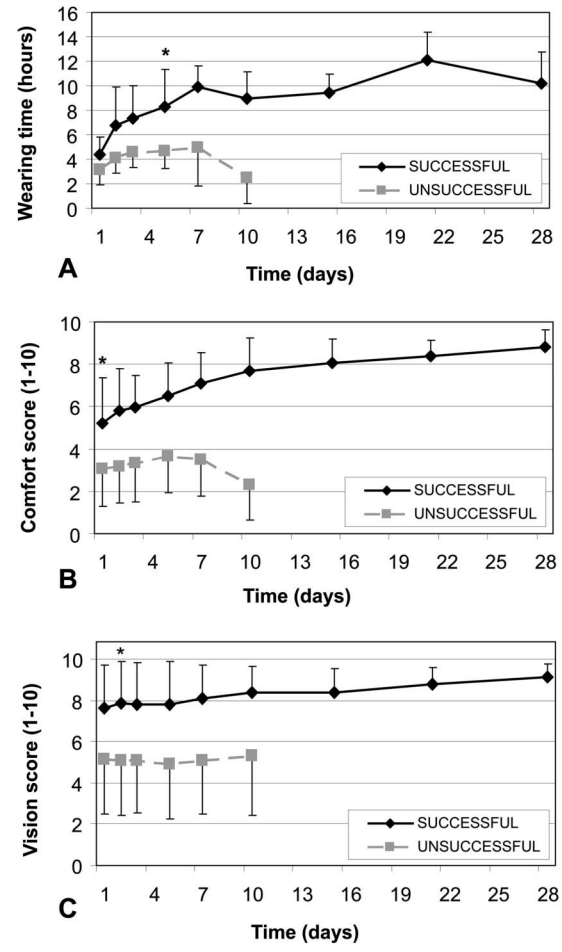

FIG. 1. Wearing time (A), subjective comfort (B), and visual ratings (C) for successful and unsuccessful wearers. *P-values less than 0.05, which represents the first visit when the differences between successful and unsuccessful groups began to be significant. Mann–Whitney test for independent samples.

Regarding tear stability measured with BUT, it is observed that the differences between unsuccessful and successful wearers were statistically significant from the beginning of the study. These values were lower in the unsuccessful group, and the differences became statistically significant after the seventh day. Moreover, BUT values remained stable in the successful group while it showed a decreasing trend in the unsuccessful group. However, no significant differences were detected from baseline to different intermediate visits and between different intermediate visits compared with final value at 28 days (1 month) in either group.

F3

Regarding corneal staining, which is shown in Figure 3, any degree of staining was present in approximately 70% of patients at baseline, and this did not change significantly during the first month of RGP lens wear. At the same time, the average degree of staining was clinically insignificant (less than 1 in a 4 step scale), and it remained unchanged during the period of fitting. These results were similar between successful and unsuccessful groups during the first 15 days until unsuccessful wearers dropped out permanently from the study.

TABLE 3. *Statistical Comparisons of Different Aspects During the Follow-up Period in Successful Group*

	Day Variable	1	2	3	5	7	10	15	21	28
VAS and wearing time	Wearing Time	—	0.051	0.01[a]	0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]	<0.001[a]
		<0.001[a]	0.056	0.064	0.3	0.96	0.475	0.659	0.092	—
	VAS Comfort	—	0.52	0.56	0.20	0.04[a]	0.01[a]	0.003[a]	<0.001[a]	0.002[a]
		0.002[b]	0.003[b]	0.001[b]	0.004[b]	0.01[b]	0.11	0.17	0.377	—
	VAS Vision	—	0.65	0.79	0.76	0.65	0.403	0.494	0.139	0.03[a]
		0.03[b]	0.05[b]	0.05[b]	0.044[b]	0.06[b]	0.09[b]	0.06[b]	0.142	—

[a]Statistical significance for values against baseline (day 1) on top of each cell.

[b]Statistical significance for values against final value (day 28) at bottom of each cell. (Mann–Whitney test).

Symptoms Reported

F4 Figure 4 shows the percentage of patients in each group showing frequency and intensity symptoms according to the Dry Eye Questionnaire. There were no statistically significant differences for any of the parameters at baseline between successful and unsuccessful patients ($P>0.05$). At day 1, the frequency and intensity of all symptoms recorded were not statistically different between both groups except for frequency and severity of burning sensation and frequency of itchiness and light sensitivity ($P<0.05$). Nevertheless, there were statistically significant differences for all parameters 7 days after fitting between both groups. The graphs show the first visit when differences with baseline values began to be statistically significant.

Overall, all symptoms showed a significant increase over the first 15 days in the unsuccessful group, both in frequency and intensity. At the same time, the successful group showed a general trend to decrease or to remain stable in both frequency and intensity of symptoms, particularly for frequency and intensity of discomfort and frequency of foreign body sensation.

DISCUSSION

Discomfort, dryness symptoms, and tear film instability have been previously described as the main reasons for discontinuation of contact lens wear.[18–20] Consistent with these studies, our results have shown an increase in frequency and/or intensity in all symptoms related to dryness in the unsuccessful group, such as dryness itself, discomfort, foreign body sensation, sand sensation, and irritation, rather than a trend to decrease after 7 days. The successful group showed a general trend to decrease or to remain stable both in frequency and intensity of symptoms, except for intensity of itchiness and foreign body sensation, which showed a trend to increase after 15 days. However, this was not significant, and this did not preclude the success of adaptation. Moreover, it is

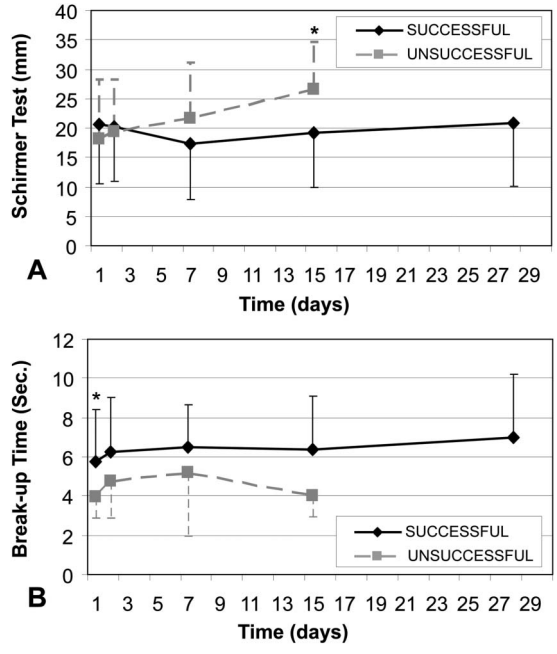

FIG. 2. Tear analysis in successful and unsuccessful rigid gas permeable lens wearers. Graphs show tear volume (A) and tear stability as measured with break-up time (B) at different follow-up visits. *P-value less than 0.05, which represented the first visit when the differences between successful and unsuccessful groups began to be significant. Mann–Whitney test for independent samples.

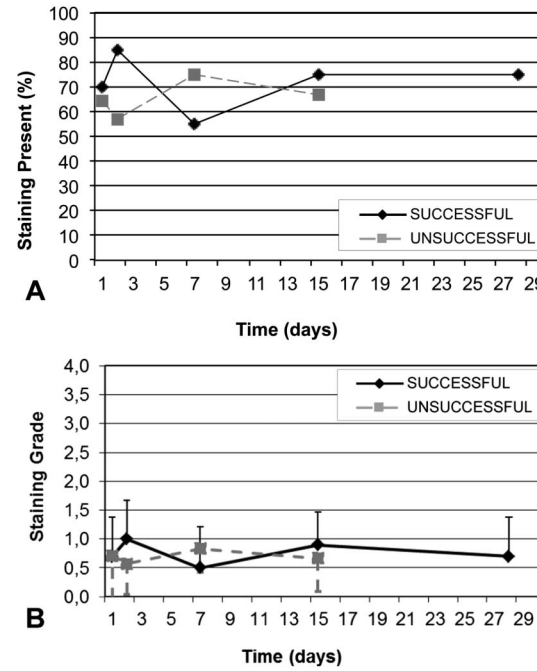

FIG. 3. Staining pattern in successful and unsuccessful patients including percentage of patients with some degree of staining (A) and the level of staining (B). No significant differences between both groups. *P-value less than 0.05; Mann–Whitney test for independent samples.

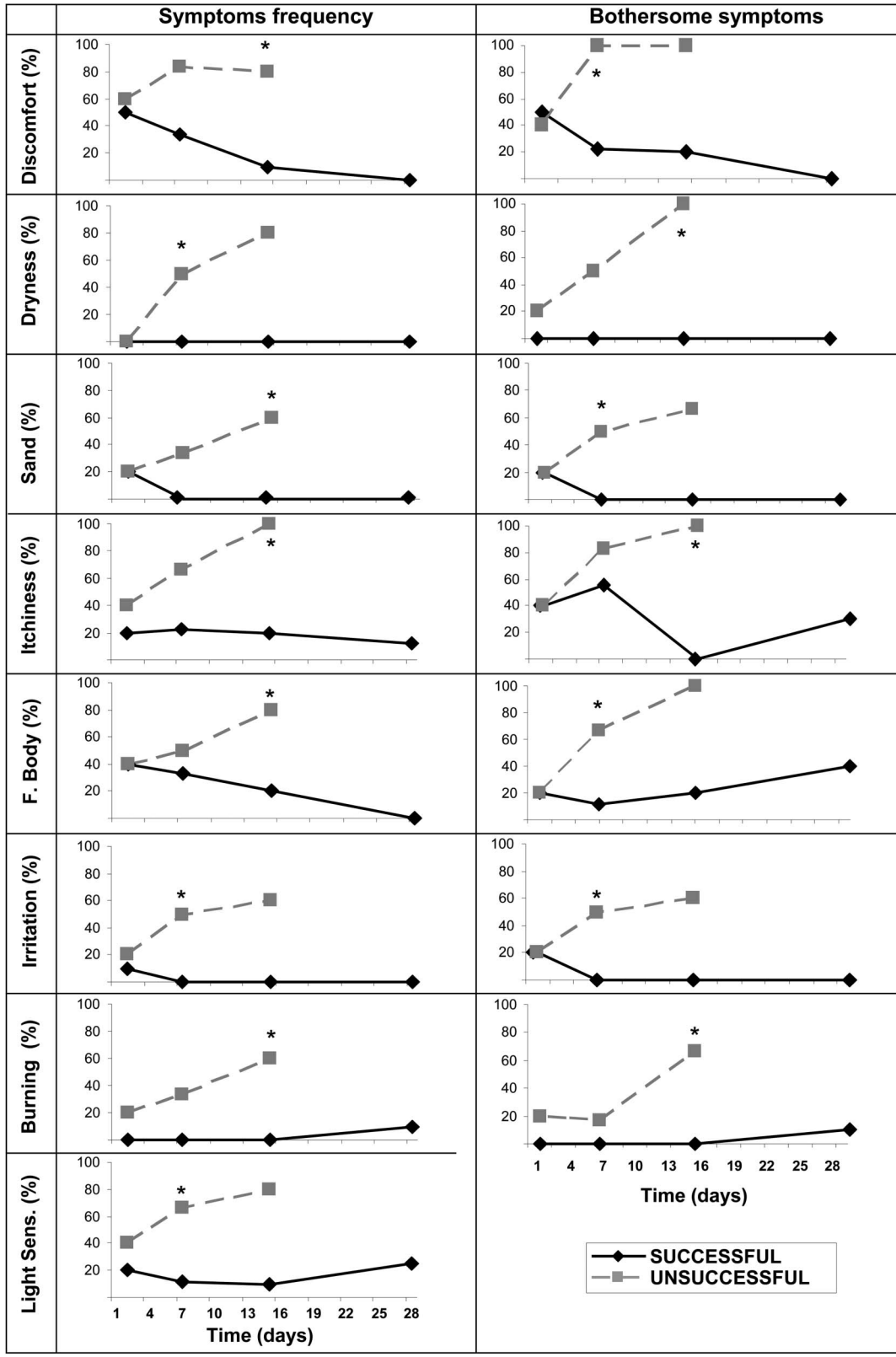

FIG. 4. Proportion of patients with a certain symptom (left column) and level of disturbance associated (right column) according to the Contact Lens Dry Eye Questionnaire for successful and unsuccessful patients. **P*-value less than 0.05 showed in graphs represented the first visit when there were significant differences with baseline values within each group (χ^2 test).

interesting to note that in the unsuccessful group at baseline, frequency and severity of burning sensation, severity of dryness, and frequency of itchiness, and light sensitivity were higher than reported by the successful group.

Despite an increased intensity of foreign body sensation, it was not enough for the patients to drop out. There could be several possible reasons for why these patients were able to continue. It could be argued that those patients who presented the symptoms and reported more intensity of discomfort were more seriously affected. But, this seems unlikely as this will probably imply an increase in dropouts during the second part of the study in the successful group which was not the case. Another more convincing reason could be due to the patient's psychological mindset. This can be concluded as successful wearers in whom the initial symptoms were not totally relieved after 1 month, despite being less prevalent and less severe overall, who expressed some form of disappointment with the slow path of the improvement but were still satisfied with the overall comfort and performance of their lenses.

In the same way, we also used VAS to assess comfort and vision during RGP lens adaptation, which has been commonly described in the literature[21,22] and has showed good reliability.[23] In our study, the successful group achieved high levels of subjective vision and comfort scores, approximately 9 of 10 after 10 days, with an average wearing time of 10 hr after 7 days of daily wear. Conversely, unsuccessful wearers stopped wearing the lens within the first 15 days, reporting comfort scores and wearing times significantly lower after 10 days than at the beginning, with subjective vision remaining at a fairly constant value of 5 on a scale of 10. Our results are in agreement with a large study conducted in Japan by Fujita et al.,[22] where 95.5% of 89 patients were adapted successfully to RGP contact lens wear after an average "adaptation time" of 23±22.1 days. Moreover, in their study, the VAS scores were significantly worse in the unsuccessful group after 7 days. However, the time to achieve adaptation by successful wearers in our study was slightly lower than reported by Fujita because our successful wearers did not experience any significant changes in symptoms and signs from days 15 to 28.

Conversely, our results have shown that although BUT and Schirmer values remained stable in the successful group, unsuccessful subjects showed a significant trend to increase tear volume and to decrease tear stability during the first 2 weeks until dropout. These results are in agreement with previous works from other authors, which reported significantly lower NI-TBUT in RGP contact lens intolerant subjects than in RGP tolerant subjects,[19,24] although they reported approximately 15 sec higher values for both groups than those described for us. Surprisingly, they reported a significant reduction of tear volume in contrast with our results.[19] We argue that a poorly stable tear film, together with the discomfort sensation, would increase tear production in a reflex manner, which is consistent with our findings. Those sensations might exacerbate, or might be exacerbated by, a higher tear production and an unstable tear film. Regarding if the defense mechanism of the eye is in one or the other direction, apparently the coexistence of dryness sensation and significant higher production of tears suggests that the dryness and other discomfort symptoms cause an increase of tear secretion, rather than the opposite, although this needs further investigation. It seems clear that there is a correlation between dryness symptoms and tear film stability in RGP fitting, as previously reported,[19,25] unlike what occurs with SCL wearers.[26]

Despite this, the ocular surface integrity does not seem to be affected in a significantly different way for successful and unsuccessful RGP lens wearers in contradiction to the results described by other authors.[25] We argue that this can be a starting point for investigating molecular markers of dry eye[27] that might be altered during the adaptation period to RGP lenses.[28]

The primary limitation of the study was the few patients in the unsuccessful group, which prevents us from extracting more information. Also, another limitation could be the lens-to-cornea fitting relationship and expected astigmatic correction, taking in account that both have demonstrated to be related with adaptation success.[29] Despite this, it is expected that patients showing poor visual results with the VAS in the unsuccessful group will have greater values of uncorrected astigmatism than successful group. In addition, greater tear volume and poor stability of prelens tear film would also contribute to some watery sensation that impacts on vision stability. All of these findings could justify the decrease in visual subjective experience reported in the VAS by these patients wearing the lenses over the first 10 days.

In summary, with this study, we have observed that patients who failed in adapting to RGP lenses showed an overall trend to have a more unstable tear film, worsening with time and a higher production of tears, probably as a consequence of increased discomfort that was observed during the first 10 days of wear. Moreover, overall comfort and wearing time decreased significantly during the initial adaptation period, and this can be noticed already during the first 7 days. Conversely, successful RGP wearers showed a steep trend to improve in their average wearing times and comfort rates during the first 7 to 15 days, respectively, reaching an average of 10 hr per day of wearing time, and approximately 9 of 10 values VAS within a month of wear.

Taken together, these findings suggest that a specific well-conducted questionnaire related to dry eye and discomfort along with tests to analyze tear parameters might help the clinician to detect those patients who will potentially fail to adapt to RGP lens wear. In such analysis, those patients who show a trend to maintain the same level of dryness, showing a significant decrease in discomfort and foreign body sensation and showing stable values of tear volume and stability at the 10th day visit, would be a potentially successful patient. Studies with a greater sample size should be conducted to confirm this assumption.

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