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# Adaptation of the Standardized Patient Evaluation of Eye Dryness Questionnaire to European Portuguese (SPEED-Vp) in a Non-Clinical Sample

# Adaptação do Questionário Standardized Patient Evaluation of Eye Dryness para Português (SPEED-Vp) numa População Não Clínica

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## ABSTRACT

**Introduction:** The aim of this study was to translate and adapt the Standardized Patient Evaluation of Eye Dryness questionnaire to European Portuguese, as well as assess the psychometric performance of the translated version, including repeatability and agreement.

**Methods:** The original Standardized Patient Evaluation of Eye Dryness - SPEED questionnaire was translated and adapted to the Portuguese cultural context by following a scientifically valid methodology commonly used in the process of adapting tools to other cultures and languages. The questionnaire resulting from the translation into the new language was subject to a pre-test where the comments of the participants were written and considered for the final version of the questionnaire. For the scale validation of the final version of the translated questionnaire, 89 subjects from a non-clinical population, aged 18 to 84 years, were asked to answer the questionnaire (61% were women). One week later, the same questionnaire was repeated by 63 subjects. The internal reliability of the questionnaire was analyzed by Cronbach's alpha, temporal stability by test-retest, and analysis of agreement between measures by the Bland-Altman method.

**Results:** The internal consistency of the translated questionnaire, SPEED-vP was high (α = 0.871) and all questionnaire items contributed to an increase in this index. This consistency was also confirmed to be high in the retest (α = 0.856) and when the sample was stratified by age and sex. The SPEED--complete questionnaire also showed high consistency (α = 0.88). The repeatability of the instrument was high (ICC 0.933; 95% CI: 0.899 and 0.960) and the Bland-Altman plot revealed good agreement between measures.

**Conclusion:** The Standardized Patient Evaluation of Eye Dryness in Portuguese (SPEED-vP) showed good psychometric properties for the Portuguese population. Therefore, the translated version of the SPEED-vP questionnaire could be used to quantitatively measure the presence of dry eye symptoms in the Portuguese population.

**Keywords:** Dry Eye Syndromes; Language; Portugal; Psychometrics; Reproducibility of Results; Surveys and Questionnaires

## RESUMO

**Introdução:** O objetivo deste estudo foi traduzir e adaptar o questionário de avaliação padronizada do paciente com secura ocular para a língua portuguesa, bem como avaliar o desempenho psicométrico da escala da versão traduzida, incluindo a sua repetibilidade e concordância entre medidas.

**Métodos:** O questionário original *Standardized Patient Evaluation of Eye Dryness – SPEED* foi traduzido e adaptado à cultura portuguesa, seguindo uma metodologia cientificamente válida e habitualmente utilizada no processo de adaptação de ferramentas a outras culturas e línguas. O questionário resultante da tradução para a nova língua foi sujeito a um pré-teste onde se registaram os comentários dos participantes e estes foram considerados para a versão final do questionário. Para a validação da escala da versão final do questionário traduzido participaram 89 indivíduos de uma população não clínica, com idades compreendidas entre os 18 e os 84 anos, dos quais 61% eram mulheres. Uma semana depois, o mesmo questionário foi preenchido pela segunda vez por 63 indivíduos. A confiabilidade interna do questionário foi analisada pelo alfa de Cronbach, a estabilidade temporal pelo teste-reteste e a análise da concordância entre medidas pelo método Bland-Altman.

**Resultados:** A consistência interna do questionário traduzido, SPEED-vP, foi alta (α = 0,871) e todos os itens do questionário contribuíram para um aumento deste índice. Esta consistência confirmou-se também alta no reteste (α = 0,856) e quando a amostra foi estratificada por idades e por sexo. O questionário SPEED-completo também apresentou alta consistência (α = 0,88). A repetibilidade do instrumento foi alta (ICC 0,933; 95% IC: 0,899 e 0,960) e o gráfico de Bland-Altman revela boa concordância entre medidas.

**Conclusão:** O questionário *Standardized Patient Evaluation of Eye Dryness*, na língua portuguesa (SPEED-vP) demonstrou boas propriedades psicométricas na população portuguesa. Consequentemente, a versão traduzida do questionário SPEED poderá ser usada para medir quantitativamente a presença de sintomas de olho seco, na população portuguesa.

**Palavras-chave:** Idioma; Inquéritos e Questionários; Portugal; Psicometria; Reprodutibilidade dos Testes; Síndromes de Olho Seco

## INTRODUCTION

Dry eye disease (DED) is defined as a multifactorial disease of the ocular surface, involving the loss of tear film homeostasis leading to symptoms of ocular discomfort, due to the impairment of tear film osmolarity, ocular surface inflammation and neuro-sensory changes.[1] Due to its multifactorial aetiology, it is associated with pathologies including diabetes, as well as behavioural habits leading to digital asthenopia and dry eye.[2,3]

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An estimated prevalence of DED ranging between 5% and 50% has been found and ageing and female gender have been described as risk factors.[4] Increased exposure to digital screens has also been identified as one of the modifiable lifestyle risk factors most associated with dry eye symptoms.[5]

To date, there is no specific clinical test considered the 'gold standard' for diagnosing DED. The poor correlation between signs and symptoms has been challenging.[6-8]

The use of symptom questionnaires has proved useful in the analysis of subjective sensations, which are not observable.[9] The diagnosis of DED has shown a greater correlation with symptoms than with clinical signs, suggesting that symptoms carry a great deal of weight in diagnosis and classification of the disease.[10]

There are different questionnaires aimed at assessing and managing DED. The Ocular Surface Disease Index (OSDI) questionnaire is the most widely used in clinical trials and measures the frequency of symptoms, environmental factors, and vision-related quality of life.[4] Other more recent questionnaires with similar validity have emerged in clinical research, particularly the 5-item Dry Eye Questionnaire (DEQ-5) and the Standardized Patient Evaluation of Eye Dryness (SPEED), as these are quickly and easily applied.[11]

Different studies have shown that the SPEED questionnaire is comparable to the OSDI in several clinical aspects and reliable in the distinction between symptomatic and asymptomatic patients. It is a standardised, quick, and repeatable dry eye symptom assessment tool adequate for both clinical and non-clinical populations and for the assessment of the frequency and severity of symptoms.[6-8] It has also been adapted to other cultures and languages.[12]

This study was aimed at the translation and adaptation of the SPEED questionnaire to the Portuguese language and culture, at the psychometric validity of the scale and assessing its repeatability in a non-clinical sample aged over 18, covering different age groups.

## METHODS

The study was approved by the Ethics Committee of the University of Beira Interior and consent was obtained from the participants. The translation and cultural adaptation into Portuguese were followed by the psychometric validity of the scale.

The translation and cultural adaptation were based on the principles of good practice.[13,14] The cultural adaptation included a pre-test, aimed at assessing the understanding of the questions by a target audience and the presented response options as intended, in addition to assessing whether the responders were able to answer each item independently and with no constraints.[15]

The psychometric validity of the translated questionnaire was carried out by analysing internal consistency, temporal stability, and reproducibility. The questionnaire was administered twice by two different researchers. One week was established as the time interval for the test-retest, as this is the time suggested in literature for the analysis of the reliability of a measuring instrument related to health status.[8]

### Participants

A group of 30 respondents aged 18 - 68 were used for the translation and adaptation process (pre-test). A sample size of 30 was recommended for the pre-test stage.[15]

A total of 89 respondents were included in the psychometric validity, a larger sample size than what was recommended by other authors.[16] According to Bonett's calculation formula, a minimum sample size of 19 would be required for a probability of type I error ($\alpha$) set at 0.05 and a test power of 90% (1-β), to obtain a Cronbach's alpha ≥ 0.7 and considering this was an eight-item questionnaire.[16]

A convenience group of 89 respondents were used, divided into two groups of different age groups (18 - 40 and > 40). The younger group was recruited from university students, and the remaining participants were recruited from the general population. This fragmentation was aimed at the validity of the interpretation of the questionnaire in individuals with different levels of academic training. European Portuguese was the mother tongue of all the participants.

One week later, the questionnaire was responded by 63 out of the 89 participants.

### SPEED questionnaire

The SPEED questionnaire was used in the study, assessing the patient's symptoms, monitoring changes in current and long-term (three months) symptoms, and assessing the frequency and severity of four typical dry eye symptoms, including dryness/foreign body sensation in the eye, pain or irritation, burning or tearing and tired eyes.[8,17] Respondents were asked to describe the frequency of each symptom on a four-point Likert scale ranging from 0 to 3, with 0 corresponding to "never", 1 to "sometimes", 2 to "often", and 3 to "constant". The severity questions were also asked using a five-point Likert scale ranging from 0 to 4, with 0 representing "no problem", 1 "tolerable", 2 "uncomfortable", 3 "bothersome" and 4 "intolerable". Responses to the eight items were added to obtain the total SPEED score [$SPEED = (\sum_{frequency} + \sum_{severity})$]. A total score > 4 corresponded to a suspicion of dry eye symptoms, which is one of the cut-off values suggested in literature.[7,17]

In addition to the frequency and severity of symptoms, the SPEED complete questionnaire also includes the time of occurrence. The use of the score of the SPEED complete questionnaire may be helpful in follow-up, with a

recommended cut-off point of 19.[8] The scores of the twenty questions (12 related to the duration of symptoms, 4 related to frequency and 4 related to severity) are added up to obtain the score with the complete version questionnaire.

The time-related questions are scored on a dichotomous scale (0 is "no" and 1 is "yes"). These twelve questions are integrated into the categories: "today", "past 72 hours" and "past 3 months".

### Procedures

A digital format version was requested to the authors of the original questionnaire, in addition to their authorisation to the adaptation to the Portuguese language. Once this authorisation was obtained, and upon approval by the Ethics Committee to carry out the study, the process was carried out.

### Translation and adaptation of the questionnaire

The process of translating and culturally adapting the questionnaire from its original language into Portuguese was carried out in three stages (initial translation; back-translation and final revision) as shown in Fig. 1.

At first, three independent translations were prepared by three bilingual translators. This was followed by the first evaluation meeting, in which the three translations were analysed by a committee including two eye-care professionals, a professional from the social sciences and independent translators, also comparing them with the original questionnaire. The result of the meeting was the development of the first Portuguese version (SPEED-vP1) of the questionnaire obtained by consensus between all the committee members.

The SPEED-vP1 questionnaire was translated into its original language (English) by a professional translator, with no knowledge of the original version, leading to a retro-translation version. The retro-translation stage was the subject of a second evaluation meeting, attended by the same committee as the first meeting and the professional translator.

At this meeting, the original questionnaire (SPEED), both the first version of the translated questionnaire (SPEED-vP1) and the retro-translation were analysed, compared, and evaluated, resulting in minor syntax changes which were integrated into a new version (SPEED-vP2).

For the final revision, a pre-test was carried out by applying the SPEED-vP2 version to 30 respondents aged 18 - 68, aimed at assessing the constraints in understanding and interpreting the content of the different items. A "I don't understand the question" response option was added to each item. Respondents were also asked to comment on any questions they had doubts about. After analysing the results of this pre-test, the final layout of the Portuguese version of the visual symptoms questionnaire (SPEED-vP) was drawn up.

### Psychometric validity of the questionnaire

For the psychometric validity of the instrument adapted to the Portuguese language, the SPEED-vP version of the questionnaire was answered by 89 respondents selected from a non-clinical population. The questionnaire was distributed on paper and each volunteer answered it individually; 63 respondents answered the same questionnaire one week later.

### Statistical analysis

All statistical procedures were carried out using IBM® SPSS Statistics software, version 26.

The reliability of the questionnaire scale (a measuring instrument based on a Likert scale) was assessed using Cronbach's a coefficient. This coefficient assesses the internal consistency of a set of items, i.e., showing the extent to which responses are sufficiently coherent (related to each other) to conclude that they all measure the same parameter and that they all add up to a single score. Values < 0.6 are considered unacceptable, 0.6 - 0.8 are considered high and > 0.8 are considered very high.[18]

Different tests were used to assess the questionnaire's temporal stability and reliability. The differences in the questionnaire score at two points in time between two measurements were analysed using the sign test. The intraclass correlation coefficient (ICC) was used to assess the degree

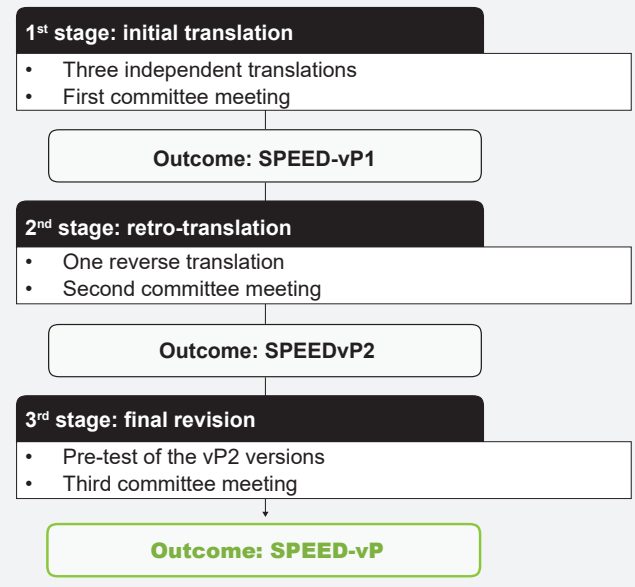


Figure 1 – Stages of the translation and adaptation process of the SPEED questionnaire to Portuguese (SPEED-vP)

of reliability between assessments at two different points in time. The interpretation of the ICC was based on the suggestions of other authors; values < 0.4 were considered unacceptable, 0.41 to 0.6 as having good reproducibility, 0.61 to 0.80 as having high reproducibility and 0.81 to 1.0 as having excellent reproducibility.[19] The agreement between the measures was also analysed graphically, using the Bland-Altman limits of agreement.[20]

## RESULTS

### Translation and adaptation of the questionnaire

Any inconsistencies between the independent translations that were found during the first and second stages of the process were discussed at the first and second meetings, respectively, and corrected by consensus between the committee members.

No constraints were found as regards the interpretation of the items during the pre-test. However, a small percentage of respondents (10%) have asked for clarification regarding the possibility of selecting more than one symptom in the first question, which was unclear. In addition, some respondents also asked about the meaning of "during the medical appointment". Considering that these questions were only asked by respondents older than 40, the committee felt that the language should be adjusted, making the content clearer. The changes that were made at this stage are shown in Table 1.

The new version was tested with a small group of respondents older than 50 (n = 8) and did not raise any questions.

The end of this process led to the final version of the questionnaire in Portuguese (SPEED-vP), the layout of which can be found in Appendix 1 (Appendix 1: https://www.actamedicaportuguesa.com/revista/index.php/amp/article/view/18597/Apendice_01.pdf).

### Psychometric validity of the questionnaire

The responses to the survey were analysed by stratifying the sample by age group and gender to validate the scale of the translated instrument. The general characteristics of these groups are shown in Table 2. The result of the statistical inference for the differences in questionnaire scores between both samples, using the Mann-Whitney test, is also shown. The scale's internal consistency was assessed for the total sample and for the different stratifications, as well as in the sample that repeated the questionnaire. The SPEED-vP score represents the sum of the four symptoms, assessed in terms of frequency and severity. The complete SPEED-vP score also includes the component related to the duration of symptoms.

The study of the differences between the SPEED-vP score and the SPEED-vP complete questionnaire score, using the Mann-Whitney test, showed no statistically significant differences between the age groups *(p* > 0.05), nor were there any statistically significant differences between genders (*p* > 0.05).

Cronbach's alpha showed that the internal consistency, both for the SPEED-vP score and the SPEED-vP complete questionnaire, has a very high reliability value ($\alpha$ > 0.8) both in the total sample and the different stratifications, as well as in the re-test (Table 2).

The item-total correlation analyses showed a moderate correlation between all the items related to frequency and intensity, suggesting that these can be added together for both the SPEED-vP and SPEED-vP complete questionnaire scores. The analysis of total internal consistency showed that all the items contribute to greater consistency, both for the SPEED-vP score and the SPEED-vP complete questionnaire. The results of this analysis are shown in Table 3.

The temporal reliability and reproducibility of the instrument were measured through a test-retest analysis, by studying the differences between the two moments (sign test), by analysing the agreement between both measures (Bland-Altman plot) and by the ICC between observers.

The mean differences in the total score of the SPEED-vP questionnaire and the complete SPEED-vP between the first and second assessments were 0.14 ± 2.2 and -0.15 ± 3.4 respectively, showing minimal bias between the two

Table 1 – Cultural and linguistic adaptation after pre-test

| Original | Consensus at the 1st meeting | Consensus after pre-test |
|---|---|---|
| Report the type of SYMPTOMS you experience and when they occur: | *Selecione o tipo de SINTOMAS que experienciou e quando ocorreram:* | *Para cada um dos SINTOMAS, indique se o experienciou e quando aconteceu.* |
| **At this visit** | **At this medical appointment** | **Today** |
| Report the FREQUENCY of your symptoms using the rating list below: | *Selecione a FREQUÊNCIA dos seus sintomas usando a escala em baixo:* | *Para cada um dos sintomas, selecione a FREQUÊNCIA com que ocorre, usando a escala em baixo:* |
| Report the SEVERITY of your symptoms using the rating list below: | *Selecione a SEVERIDADE dos seus sintomas usando a escala em baixo:* | *Para cada um dos sintomas, selecione a SEVERIDADE com que ocorre, usando a escala em baixo:* |

Table 2 – Descriptive statistics, difference test and internal consistency

| | | Total sample | Age ≤ 40 | Age > 40 | Male | Female | Re-testing |
|---|---|---|---|---|---|---|---|
| **Sample size** (n) | | 89 | 55 | 34 | 35 | 54 | 63 |
| **Age** (years) | | 36.3 ± 19.3 | 22.1 ± 2.8 | 59.4 ± 9.7 | 36.4 ± 18.3 | 36.3 ± 20.1 | 34.4 ± 19.7 |
| **SPEED-vP** | | 7.3 ± 5.0 | 7.6 ± 4.7 | 6.9 ± 5.6 | 7.5 ± 6.1 | 7.2 ± 4.2 | 7.2 ± 4.4 |
| **SPEED-vP complete questionnaire** | | 11.0 ± 7.02 | 11.2 ± 6.2 | 10.6 ± 8.3 | 11.3 ± 8.2 | 10.8 ± 6.2 | 11.2 ± 6.8 |
| **Mann-Whitney** (*p*-value) | **SPEED-vP** | --- | 0.733 | | 0.363 | | --- |
| | **SPEED-vP complete questionnaire** | | 0.820 | | 0.368 | | |
| **Cronbach's alpha** | **SPEED-vP** | 0.871 | 0.852 | 0.894 | 0.920 | 0.812 | 0.856 |
| | **SPEED-vP complete questionnaire** | 0.880 | 0.842 | 0.915 | 0.904 | 0.856 | 0.893 |

administrations (sign test; $p = 0.635$; 0.671) and good temporal reliability. The inter-observer ICC was 0.933 (95% CI: 0.899 and 0.960), corresponding to an excellent degree of agreement.

The Bland Altman plot (Fig. 2) has shown that the mean difference for both the SPEED-vP score (Fig. 2A) and the SPEED-vP complete questionnaire score (Fig. 2B) is close to zero and the variations were mostly within the 95% confidence interval. The linear regression of the difference of averages shows that there is no proportion bias (SPEED-vP complete questionnaire: $p = 0.795$; SPEED-vP: $p = 0.661$).

Table 3 – Reliability: internal consistency of the Portuguese version of the SPEED-vP questionnaire

| Item | | SPEED- vP | | SPEED-vP completa | |
|---|---|---|---|---|---|
| | | Corrected item-total correlation | Cronbach's alpha if item deleted | Corrected item-total correlation | Cronbach's alpha if item deleted |
| Today | 1 | | | 0.402 | 0.741 |
| | 2 | | | 0.313 | 0.742 |
| | 3 | | | 0.283 | 0.742 |
| | 4 | | | 0.367 | 0.739 |
| 72 hours | 1 | | | 0.543 | 0.735 |
| | 2 | | | 0.488 | 0.737 |
| | 3 | | | 0.472 | 0.736 |
| | 4 | | | 0.490 | 0.735 |
| 3 months | 1 | | | 0.518 | 0.735 |
| | 2 | | | 0.516 | 0.735 |
| | 3 | | | 0.342 | 0.739 |
| | 4 | | | 0.257 | 0.741 |
| Frequency | 1 | 0.643 | 0.854 | 0.706 | 0.723 |
| | 2 | 0.660 | 0.853 | 0.693 | 0.724 |
| | 3 | 0.610 | 0.857 | 0.612 | 0.726 |
| | 4 | 0.550 | 0.864 | 0.536 | 0.727 |
| Severity | 1 | 0.597 | 0.859 | 0.675 | 0.720 |
| | 2 | 0.699 | 0.847 | 0.712 | 0.719 |
| | 3 | 0.619 | 0.856 | 0.644 | 0.723 |
| | 4 | 0.668 | 0.851 | 0.641 | 0.719 |
| **Total of the instrument** | | | 0.871 | | 0.88 |

## DISCUSSION

This study was aimed at the translation and cultural adaptation of the SPEED questionnaire into Portuguese and at the assessment of the psychometric properties of the translated version, including repeatability in a non-clinical sample of a wide age range. The results have shown that the Portuguese version of the SPEED questionnaire is an easy-to-apply tool and showed good psychometric properties, representing a reliable measurement tool. The high internal consistency of the responses ($\alpha$ > 0.8) and the high intraclass correlation (ICC > 0.9) have shown that the SPEED-vP version has an excellent degree of reliability.

The translation and cultural adaptation of the original questionnaire into the new language met the standards of good practice as described in literature.[13,14] Qualitative and quantitative methods were used to identify and address different issues during the translation and cultural adaptation stages. The use of three independent translators, who did not know each other, proved to be very useful because it allowed three different versions to being confronted and discussed. The inclusion of members from different backgrounds in the evaluation committee allowed for the comparison between different opinions from experienced professionals. The debates resulting from the discrepancies found and the search for consensual solutions proved to be crucial to the process of semantic equivalence. A pre-test was crucial for cultural adaptation, allowing the adaptation of the language and thus ensuring that all age and social strata understood the tool.

It was found that the total group of participants recruited for this study showed a wide variation in SPEED scores, ranging from the absence of symptoms to more severe conditions, but with average values in line with those found by other authors in randomly selected non-clinical samples.[12]

Ageing and gender were considered potential risk factors for dry eye symptoms.[4] The study group was stratified by age group and gender in the psychometric validity of the scale. Results ranging from 0.812 to 0.920 were found in the internal consistency analysis for each of the groups, showing that the internal consistency of the SPEED-vP questionnaire is excellent for all the population strata.

Even though the diagnosis of DED was not the aim of this study, it was found that the SPEED score showed no significant differences either in terms of gender or between the different age groups. A meta-analysis study on the subject confirmed that the prevalence of DED increases with age. However, this is more significant for signs than for symptoms.[4] On the other hand, studies carried out on university students have shown a very high rate of dry eye symptoms[7,21] and recent studies have found that young patients presenting with DED show a reduction in the lipid layer, decreased blinking and more severe symptoms.[22] In addition, some factors such as performing leisure tasks, prolonged use of digital screens and e-learning could promote the presence of dry eye at any age, even though symptoms are mostly found in younger patients.[5,23] There isn't always a consensus on significant differences between genders, and there are also studies describing similar prevalence rates in men and women.[24] It was confirmed in a meta-analysis study that women showed a higher prevalence of DED than men, although these differences only become significant with age.[4]

Overall, the final Portuguese version of the SPEED questionnaire proved to be a reliable and repeatable instrument for the assessment of dry eye symptoms in the adult population. The internal consistency of the questionnaire showed excellent values and each of the items contributed significantly to the total score, showing the relevance of keeping the eight items that make up the original questionnaire. This finding is in line with what has been described in other studies carried out in non-clinical populations with the SPEED questionnaire in other languages.[7,12]

The interrater agreement was 0.933 (95% CI: 0.899 to 0.960), showing that the SPEED-vP questionnaire has excellent reproducibility.[19,20] The average difference, as well as the analysis of the variance between both evaluation moments, showed a minimum bias between these (one week apart). This is in line with the results of other studies in which the original questionnaire was used.[8]

### Strengths and limitations

The strengths of this study included the following: the SPEED questionnaire is universally accepted and scientifically valid, and has been adapted into European Portuguese in accordance with the international guidelines applicable to similar tools; the characteristics of the sample used for the cultural validity of this questionnaire cover different age and social strata, ensuring a better cultural adaptation of the tool; the psychometric properties showed that it can be used reliably in the Portuguese population.

The lack of clinical data was the main limitation of the study. The design of this study prevented from reaching the best cut-off point for interpreting the results, and the values indicated by the author of the questionnaire were used by default. This limitation could be overcome in a future study, with clinical validity of the questionnaire.

## CONCLUSION

Considering that the main objective of the study was the translation and cultural adaptation of the Standardized Patient Evaluation of Eye Dryness questionnaire for the Portuguese population (SPEED-vP), this is considered to have been achieved. The psychometric properties have confirmed the characteristics of the original questionnaire.

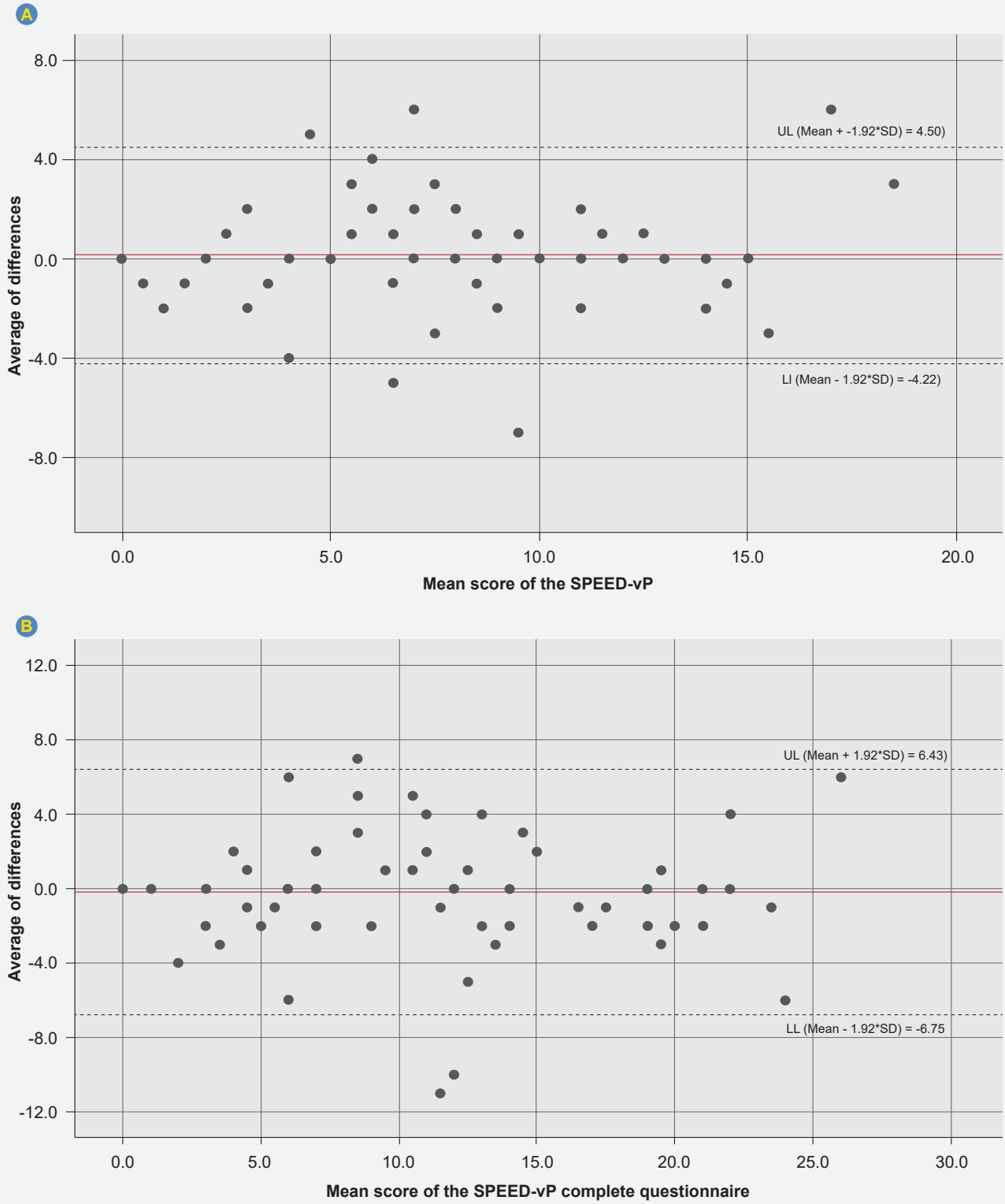


Figure 2 – Bland-Altman plot for the study of the agreement between measures. The average of differences is shown with the red line. The 95 percent limits of agreement are shown with the dotted lines. (A) regards the SPEED-vP; (B) regards the SPEED-vP complete questionnaire.

UL: upper limit; LL: lower limit.

The measurement scale showed high levels of internal reliability (Cronbach's alpha), temporal stability (test-retest) and agreement between measurements, showing that it is a reliable and reproducible tool for the assessment of dry eye symptoms in the Portuguese population. The SPEED questionnaire is described as a standardised, rapid, and repeatable tool for the assessment of dry eye symptoms. Considering the psychometric properties found in the validity of the Portuguese version, we believe that this is a simple and easy-to-use tool, representing a relevant clinical tool for the diagnosis of DED.

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## AUTHOR CONTRIBUTION

AS: Significant contribution to the study design; data collection; statistics; data interpretation; writing of the manuscript.

SL: Significant contribution to the study design; data collection; statistics; writing of the manuscript.

AN: Significant contribution to the study design; data interpretation; critical revision.

MC, PM, AN: Significant contribution to the study design; writing of the manuscript; data interpretation; critical revision.

## HUMAN AND ANIMAL PROTECTION

The authors declare that this project complied with the regulations that were established by the Ethics and Clinical Research Committee, according to the 2013 update of the Helsinki Declaration of the World Medical Association.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## FINANCIAL SUPPORT

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