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A novel mobile phone and tablet application for automatized calculation of pain extent

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ABSTRACT

Background: Pain drawings (PDs) are used for assessing pain extent as a complementary outcome to other pain measurements, consisting of shading a body chart template to report the location and extent of pain. However, the accuracy and reliability of digital PDs remain controversial due to the heterogeneity of methods used. This study aimed to develop an easy-to-use application for assessing its diagnostic accuracy in comparison with the classic paper-and-pencil method. **Methods**: A test-retest reliability study was conducted, recruiting 95 patients with musculoskeletal pain symptoms. Participants shaded 2 sets of 3 different PDs (paper-and-pencil PD, digital PD using the finger and digital PD using the digital stylus). Intraclass correlation coefficients (ICC), standard error of measurement and minimal detectable changes (MDC) were calculated for each method. Finally, repeated measure analysis of variance assessed the mean differences between trials and methods and the convergent validity between methods was calculated using Pearson's correlation coefficients. **Results:** All methods were excellently reliable (all, ICC>0.94). However, digital PDs obtained higher ICCs (ICC≥0.970) and greater accuracy to detect whether changes reflect a real change and are not due to a measurement errors (MDC = 0.72%–0.80 % for digital PDs versus MDC = 1.13 % for paper-and-Pencil PDs). No significant score differences were found among the instruments for assessing pain extent ($p > 0.05$). Finally, the PAIN EXTENT app showed adequate convergent validity ($r > 0.850$). **Conclusion:** The PAIN EXTENT app is a fast and easy-to-use instrument compatible with operative systems and devices commonly used for assessing and monitoring pain extent in the clinical and research settings.

1. Introduction

According with the International Association for the Study of Pain (IASP), pain is defined as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage that is always a personal experienced influenced by biological, psychological and social factors" [1]. Due to its complexity and the internal private nature of this experience, self-report tools are still considered the gold standard for pain measurement [2]. For instance, sensory and affective qualities of pain including pain intensity (how strong is the pain), affect (how unpleasant or disturbing the pain feels), and the perceptual qualities of pain (how the pain feels) are assessed with different patient-reported outcomes measurements with contrasted validity, reliability, specificity and sensitivity such as the Numeric Pain Rating Scale [3] and the Visual Analogue Scale [4] for assessing pain intensity and affect and McGill Pain Questionnaire [5], PainDETECT questionnaire [6], Neuropathic Pain Symptom Inventory [7], Leeds Assessment of Neuropathic Symptoms and Signs [8] or the

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Dolour Neuropathique-4 Questions [9] for identifying neuropathic pain features.

In addition, collecting information about temporal characteristics of pain is of high diagnostic importance and highly encouraged to collect. Pain duration (the time passed since the pain onset) is the main criterion for classifying pain as acute, subacute or chronic [10]. In addition, assessing pain variability (fluctuations in pain intensity or appearance), modifying factors (conditions exacerbating or ameliorating the perceived pain), pain location (identification of areas where the pain is perceived) and pain extent (bodily extent of pain) is encouraged to discriminate the etiologic nature of pain and its clinical severity [11].

Regarding the pain extent measurement, pain drawing (PD) is the most extended tools for assessing this metric. Patients are asked to shade different views of a body chart template (normally front, back and lateral views or augmented regional templates for specific conditions such as headache or orofacial pain) to report the areas where they experience pain and how extended is it [12]. PDs were firstly introduced in 1949 by Harold Palmer and latterly incorporated in several pain instruments including the McGill Pain Questionnaire, the PainDETECT questionnaire and the Leeds Assessment of Neuropathic Symptoms and Signs questionnaire [13].

Although the classic method used for assessing the pain extent is the paper-and-pencil method, current recommendations support the use of digital PDs [12]. However, the accuracy and reliability of digital PD remain controversial, probably due to the heterogeneity of accuracy levels for shading the templates (i.e., most of the methods consists of transparent grids placed over the PD, ranging from 45 regions to +60, 000 cells) [13].

Since these limitations could be potentially overcome by assessing the number and location of pixels instead of regions, new studies proposing technological innovations with acceptable levels of accuracy and reliability are needed for supporting this digital transformation. Therefore, the aim of this study was to develop an easy-to-use application compatible with commonly used operative systems and devices to 1) analyze the test-retest reliability estimates of the application using a digital stylus and the finger for coloring the area and the paper-and-pencil methods, 2) compare the pain extent scores obtained with the 3 methods and 3) corroborate the validity of the application by calculating the association between the 3 methods.

2. Methods

2.1. Study design

A cross-sectional observational study with a diagnostic accuracy design was conducted between February 2023 and March 2023 in a private physiotherapy center located in París (France). This report followed the directives for Reporting Reliability and Agreement Studies (GRRAS) [14] and the Enhancing the QUAlity and Transparency Of health Research (EQUATOR) guidelines for ensuring an adequate report quality [15]. Additionally, the Ethics Committee of Universidad Rey Juan Carlos (URJC 1512202200823) supervised and approved the protocol developed for this study prior to the data collection.

2.2. Participants

A convenient sample of patients visiting a third-part physiotherapy center were recruited after signing a collaborative contract. To be eligible for participation, volunteers had to be aged +18 years old and report musculoskeletal pain symptoms at the moment of their participation in the study. Participants were excluded if they presented difficulties in fine motor skills which may potentially affect the accuracy of paper-and-pencil PDs, eye diseases (e.g., corneal diseases, eye abnormalities, lens diseases, optic nerve diseases, refractive errors, retinal diseases, vitreous detachment, vision disorders, uveal diseases or scleral diseases) or movement disorders (e.g., dyskinesias, dystonic disorders, essential tremor, multiple system atrophy or parkinsonian disorders). Once eligibility criteria were verified, participants had to read and sign an informed written consent to be included in the data collection.

2.3. Sample size estimation

The minimum sample size needed for obtaining acceptable statistical power was calculated using the directives provided by Walter et al. based on intraclass correlation coefficients (ICC) [16]. Using as a reference the results obtained in previous studies which calculated the reliability of digital PD procedures [13], a value ICC>0.92 (since this was the minimum ICC obtained in the cited study [13]) was considered as the minimally acceptable.

Since 1) an expected ICC value = 0.97 was hypothesized (since this was the best ICC obtained in the cited study [13]); 2) a 95 % of power and a 5 % significance level were set; and 3) 10 % losses were assumed considering the longitudinal nature of this study (participants had to be explored twice for each device with an intermediate time between trials), the minimum sample size required for analyzing the reliability estimates with acceptable statistical power in this study was set at 59 participants.

3. Procedures

All participants filled out a standardized form asking for demographic information (age, height, weight and sex). Then, body mass index was calculated following the formula $\mathrm{BMI} = \frac{weight\ (kg)}{height\ (m)^2}$ as described in the literature [17].

For assessing pain extent, all participants had to complete three different procedures: digital application using the finger for coloring the pain area, digital application using a digital stylus for coloring the pain area and the classic paper-and-pencil method. All body charts were standardized and identic for all participants. One model was designed for each gender (male and female), each one with 4 views (front, back and lateral) as shown in Fig. 1. Each PD was completed twice in randomized order, spacing 10 min each trial, giving a maximum time of 2 min for each trial and retiring the previous PD for avoiding references and ensuring participants' blinding. All participants had a 5-min familiarization time with the device, paper template, stylus and markers.

A trained operator who participated in the application development gave to the patients standardized verbal instructions about how to complete the digital (i.e., how to correct the drawing with a digital eraser if needed and how to modify the size of the marker tool) and paper-and-pencil (i.e., taking care of staying within the lines) PDs. Additionally, participants were instructed to filled out the PD properly, coloring those areas where they felt their current pain (independently from the type or severity of pain) and avoiding the use of marks such as crosses or circles, highlighting the importance of illustrating all pain locations for each view. After completing each PD, participants were asked to verify if the PD was accurate in terms of pain extension and location before saving the trial. Finally, participants were not aware of the score for each trial until they finished their participation.

3.1. Instrumentation

3.1.1. Digital pain drawing

All PDs were carried out on the same 10.2″ digital tablet (iPad 9th generation, Apple Computer, Cupertino, CA, USA) using a stylus pen for digital tables (Apple Pencil 1st generation, Apple Computer, Cupertino, CA, USA). Digital PDs were completed using the developed application "PAIN EXTENT" (Juan Antonio Valera-Calero, Madrid, Spain) to be launched in the Apple Store (Apple Computer, Cupertino, CA, USA) and Google Play (Google, Mountain View, CA, USA). This application contains one standardized body chart for each gender, each with 4 views

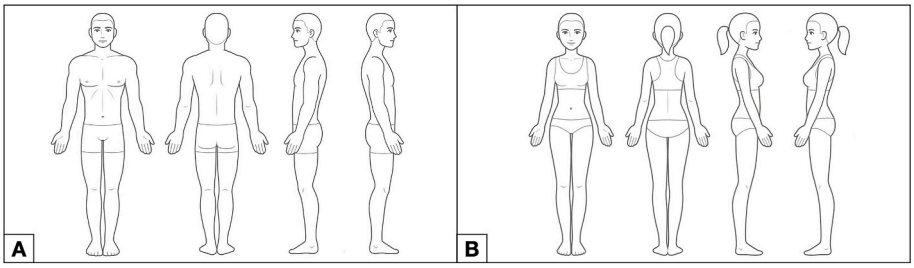

Fig. 1. Body chart templates for males (A) and females (B).

(frontal, dorsal, lateral left and lateral right) in a single canvas with a size of 3,508 pixels width and 2,480 pixels height. This canvas consists of two layers, a deep layer (totally blank) and a superficial layer (which contains the 4 body chart views, transparent inside the body charts to make the deeper layer visible and white outside the body charts to hide the pixels drawn outside the body chart area in the deep layer (Fig. 2). The menu for selecting the tools (pencil or eraser) and its size was placed to the bottom of the screen and minimized for disturbing as less as possible during the PD completion.

After completing each PD, the software automatically calculated the percentage of colored pixels within the body charts without any other additional tool or software. Both canvases had a size of 8,699,840 pixels. For the female PD, 453,523 colored pixels made up the female body chart contour completely empty inside (0 % of pain extent) and 2,590,812 colored pixels made up the body chart contour totally filled (100 % of pain extent). In spite, the male PD had 342,948 colored pixels for a 0 % pain extent and 2,453,876 colored pixels for a 100 % pain extent. Supplementary Material 1 contains screenshots illustrating how the application works.

3.1.2. *Paper-and-pencil pain drawing*

All paper-and-pencil PDs sheets were printed in DIN-A4 papers, using the same body chart templates described previously. To fill out the templates, participants used a red marker with a 2 mm-width tip. Then, all PDs were scanned and exported to the ImageJ offline DICOM software (National Institute of Health, Bethesda, MD, USA, v.1.53a). All the images were transformed to a 32-bit format (which is a 256 Gy scale image), the selected brightness range was set (0 for the lower limit and 158 for the upper limit). By selecting this range, the body chart lines and the colored area are selected while the non-colored areas and light-gray pixels produced during the image scanning are not selected. Each image was verified manually in order to erase the "scanning noise" pixels if included within the range of pixels not to overestimate the pain extent and avoid errors. All the scanned PDs had a size of 2,176,200 pixels. The number of pixels corresponding to 0 % and 100 % of pain extent for the male and female body charts were proportional with the digital PD described previously.

3.2. *Statistical analysis*

All analyses were conducted using the Statistical Package for the Social Sciences (SPSS v.27, Armonk, NY, USA) for Mac OS, setting the significance level at $p < 0.05$ for all the analyses. Firstly, data distribution was verified using histograms and Shapiro-Wilk tests for continuous variables. P values < 0.05 were considered as non-normally distributed and $p > 0.05$ as normally distributed [18].

Secondly, descriptive statistics for were used for reporting the total sample's characteristics. Categorical data were reported as frequency and percentage for each category (e.g., number and percentage of women and men). Continuous variables were reported using central tendency metrics (i.e., mean for normal variables and median for non-normal variables) and dispersion metrics (i.e., standard deviation for normal variables and interquartile range for non-normal variables). Additionally, sociodemographic characteristics were independently reported for men and women while muscle morphology and quality characteristics were reported by gender and side. Between-group differences were analyzed using the Student's T-tests for independent samples, reporting the mean difference with a 95 % confidence interval and considering a p value < 0.05 as statistically significant.

Test-retest reliability analyses consisted of reporting 1) mean average and standard deviation of each metric score, 3) absolute error between attempts for each method used (absolute error was calculated since signs could underestimate the disagreement magnitude), 4) intraclass correlation coefficients ($ICC_{3,1}$, calculated with a 2-way mixed model, consistency type), 5) standard error of measurement (SEM= Standard Deviation of the mean average * $\sqrt{1-ICC}$) and 6) minimal detectable changes (MDC = 1.96* $\sqrt{2}$*SEM) [19]. Regarding the analyses for assessing the score differences between instruments, a repeated measure analysis of variance (ANOVA) with time-point (Trial 1 and Trial 2) as the within-subject factor and instrument used (Digital PD with stylus, Digital PD with finger and Paper-and-Pencil PD) as the between-subjects factor was conducted, using the first trial values as covariates [20]. Then, a Bonferroni post hoc correction was carried out for analyzing specific differences between trials and between instruments, such that only $p < 0.017$ (=0.05/3) was assumed to be significant. The effect size was calculated as the partial eta squared, considering values of 0.01 as small, 0.06 as medium and 0.14 large respectively [21].

Finally, the association between instruments were assessed by calculating a Pearson's correlation matrix. The association strength was interpreted based on the r values (considering 0.0–0.3 as poorly associated, 0.3–0.5 fairly associated, 0.5–0.7 moderately associated and

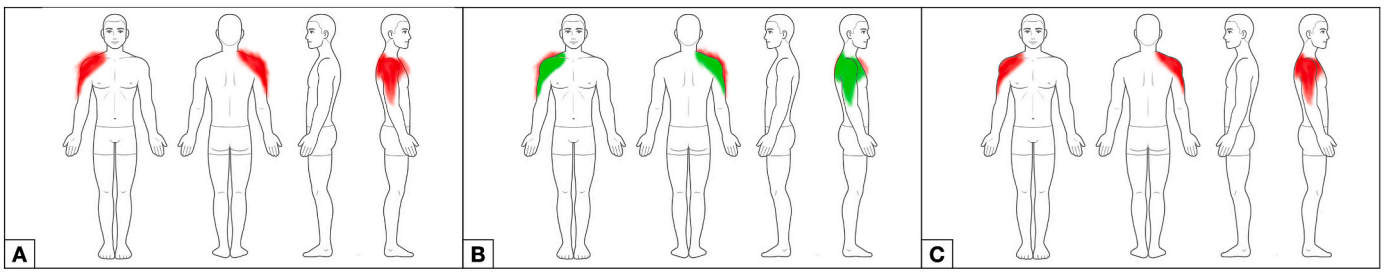

Fig. 2. Pain extent calculation process: (A) Participant's shaded body chart templates; (B) pixels cleaning and (C) pain extent calculation.

0.8–1.0 strongly associated) and the association direction was interpreted based on the r sign (negative values were interpreted as an indirectly proportional associations and positive values as directly proportional associations) [22]. A minimum r value of 0.70 was set in order to confirm the instruments' convergent validity [23].

4. Results

From a total of 103 volunteers who initially responded to the announcements, 6 did not meet the eligibility criteria and were excluded (n = 2 reported pain the previous days but not during the data collection and n = 4 presented movement disorders). Therefore, 95 volunteers (48.4 % males) were finally included and analyzed, acquiring a total of 570 PDs (n = 190 with each method). The descriptive analyses for the participants' sociodemographic characteristics described in Table 1, demonstrated that the males analyzed in this study were significantly taller ($p < 0.001$), heavier ($p = 0.001$) and overweighted ($p = 0.014$) than the female participants.

Table 2 summarizes the test-retest reliability estimates for each instrument used during the pain extent assessment. In general, all methods demonstrated excellent test-retest reliability (all, ICC>0.94). However, the highest reliability estimates were obtained using the Digital PD (with digital stylus ICC = 0.983 and using the finger ICC = 0.970). In addition, the use of digital PDs could be recommended over Paper-and-Pencil PDs since between-trials differences were smaller in digital PDs (0.39–0.46 %) in comparison with Paper-and-Pencil PDs (0.62 %) and demonstrated greater accuracy to detect whether changes reflect a real change and are not due to a measurement errors (MDC = 0.72 %–0.80 % for digital PDs versus MDC = 1.13 % for Paper-and-Pencil PDs).

The score differences found between instruments are reported in Table 3. The ANOVA analysis found no significant differences between methods ($p = 0.214$). Although paired comparisons were not either significant, mean differences, 95 % confidence intervals and p values are also stated in Table 3.

Finally, the Pearson's correlation matrix is shown in Table 4. We found strong associations among the instruments (all, $r > 0.850$), confirming an adequate convergent validity.

5. Discussion

This study presents a novel digital tool accessible for phones and tablets compatible with iOS and Android for simplifying the pain extent measurement in the clinical and research settings. This novelty provides an alternative to the paper-and-pencil tool, more accessibility compared with other software where computers are needed as shown in the workflow diagram illustrated in Fig. 3 (e.g., Ref. [13]), and gives the patient the opportunity of select a gender-specific template. This tool was tested assessing the test-retest reliability and the score differences among 3 PD modalities: a paper-and-pencil PD and the digital tool using the finger and a digital stylus for shading the templates.

All participants shaded the 6 PDs, spacing each trial with 10 min of time to guarantee as much as possible symptom stability and avoid the shading memorization. Bias induced by potential changes in pain symptomatology between the first and last attempt were controlled by randomizing the order of the methodologies used. However, since up to 6 trials were assessed, potential learning effects due to repetition could not be totally prevented.

Although this is not the first study evaluating the pain extent using two-dimensional body charts displayed on a digital tablet, the present study overcome some limitations reported in previous studies [13]. Perhaps one of the most important is the option to customize body charts according with the anthropometric characteristics of the patients as several gender differences have been reported regarding the body image [24] and body composition (i.e., fat percentage and distribution) [25,26]. In accordance with a previous study which investigated the variability of body shapes considering stature normalization for identifying the key factors to explain the body shape variability [27] fat deposit patterns, muscle mass distribution and skeletal structures are more determinant than other measures such as body mass index for explaining the body shape variance. In fact, an investigation conducted by Geer and Sheen [28] found that, for a given body mass index, males present greater lean mass while women show greater adiposity (especially subcutaneous adipose tissue). Although several studies focused on body image perception and body composition [29–31], up to date studies comparing the use of standard templates with gender specific templates are lacking. Therefore, future studies may include different templates for improving the participants' body recognition in accordance with their self-image and assess the diagnostic accuracy in comparison with standard body charts for measuring pain extent.

5.1. Clinical implications

The use of PDs has a considerable diagnostic value use as the assessment of pain location and extent in combination with other qualitative and quantitative pain descriptors (e.g., sensory, perceptual and affective pain qualities) [12]., for both the research and clinical settings. This app may help to improve the communication between patients and healthcare providers, leading to more accurate diagnoses and treatment plans. In addition, this app provides an automatic calculation of the pain extent deleting those pixels out of the body chart. Consequently, this automatization reduces the time required in comparison with other methods and facilitates its use into the clinical practice. The implementation of this tool can help patients to better understanding and tracking of their pain and monitoring changes over time, which can lead to improved self-management of pain [32].

5.2. Limitations

Certain limitations identified during the study should be acknowledged. First, the pain extent standard deviation of the sample analyzed was considerably small and therefore, the diagnostic accuracy values reported may not be applicable for smaller or larger pain extent scores. Further research including patients with widespread pain conditions and localized pain conditions will overcome this limitation in the future. Secondly, the application was recently launched, and some improvements are planned. In Future updates include data about the number of pixels shaded out of the PDs as this data may be clinically relevant or including more than two templates. Finally, this app was tested using a single device model. Further studies should analyze if screen size or devices models (e.g., phones) show similar diagnostic accuracy estimates.

6. Conclusion

In conclusion, an easy-to use application compatible with commonly

Table 1
Participants' sociodemographic characteristics.

Variables	Total sample (n = 95)	Gender		
		Male (n = 46)	Female (n = 49)	*Difference*
Age (y)	45.0 ± 19.1	42.1 ± 17.3	47.8 ± 20.4	5.6 (−2.1; 13.4) p = 0.149
Height (m)	1.72 ± 0.08	1.77 ± 0.06	1.65 ± 0.06	0.11 (0.01; 0.08) p < 0.001
Weight (kg)	69.3 ± 16.3	77.5 ± 18.7	61.6 ± 8.3	16.0 (10.1; 21.8) p=<0.001
Body Mass Index (kg/m^2)	23.3 ± 4.7	24.5 ± 6.22	22.2 ± 2.2	2.4 (0.5; 4.2) p = 0.014

Scores are expressed as Mean ± Standard Deviation and Differences expressed as Mean (95 % Confidence Interval).

Table 2
Test-retest reliability of each instrument for assessing pain extent (%).

Instrument	Trial 1	Trial 2	Mean	Absolute Difference	$ICC_{3,2}$ (95 % CI)	SEM	MDC	CV
Digital Pain Drawing (Finger)	12.08 ± 1.67	12.02 ± 1.70	12.05 ± 1.67	0.46 ± 0.33	0.970 (0.955; 0.980)	0.29	0.80	0.22
Digital Pain Drawing (Stylus)	12.25 ± 2.03	12.18 ± 1.99	12.22 ± 2.00	0.39 ± 0.33	0.983 (0.975; 0.989)	0.26	0.72	0.17
Paper Pain Drawing	12.49 ± 1.82	12.52 ± 1.70	12.51 ± 1.71	0.62 ± 0.53	0.943 (0.915; 0.962)	0.41	1.13	0.24

SEM and MDC_{95} are expressed in the units described for each parameter.

Table 3
Differences between methods for assessing pain extent (%).

Variable	ANOVA interaction effect	Bonferroni Post-Hoc analysis		
		Digital Pain Drawing (Finger) vs Digital Pain Drawing (Pencil)	Digital Pain Drawing (Finger) vs Paper Pain Drawing	Digital Pain Drawing (Pencil) vs Paper Pain Drawing
Pain Extent (%)	F = 1.552 p = 0.214 η_p^2 = 0.011	0.16 [-0.46; 0.79] p = 1.000	0.45 [-0.17; 1.08] p = 0.248	0.28 [-0.34; 0.91] p = 0.811

Table 4
Correlation among methods for assessing pain extent (%).

Instrument	1	2
1. Digital Pain Drawing (Finger)		
2. Digital Pain Drawing (Pencil)	r = 0.935; p < 0.001	
3. Paper Pain Drawing	r = 0.851; p < 0.001	r = 0.880; p < 0.001

used operative systems and device is a valid tool to assess the area of pain. Additionally, this study found that digital stylus and the finger method using an application and paper-and-pencil show an excellent test-retest reliability to assess the area of pain. Also, the minimal detectable change of digital stylus and finger is smaller than paper-and-pencil method. Finally, a good association was found between the three evaluation methods.

Declarations

Ethics approval and consent to participate

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Clinical Ethics Committee of Universidad Rey Juan Carlos (ID: URJC 1512202200823). Informed consent was obtained from all subjects involved in the study.

Consent for publication

No individual data were reported in this manuscript.

Availability of data and materials

All data derived from this study are presented in the text. Data are available from the corresponding author upon reasonable request.

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CRediT authorship contribution statement

Juan Antonio Valera-Calero: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft, Writing – review & editing, Project administration, Funding acquisition. **Darío López-Zanoni:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – review & editing. **Sandra Sánchez-Jorge:** Formal analysis, Investigation, Writing – review & editing. **César Fernández-de-las-Peñas:** Formal analysis, Investigation, Writing – review & editing. **Marcos José Navarro-Santana:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – review & editing. **Sofía Olivia Calvo-Moreno:** Formal analysis, Investigation, Writing – review & editing, Funding acquisition, All authors have read and agreed to the published version of the manuscript. **Gustavo Plaza-Manzano:** Methodology, Formal analysis, Investigation, Writing – review & editing, Supervision.

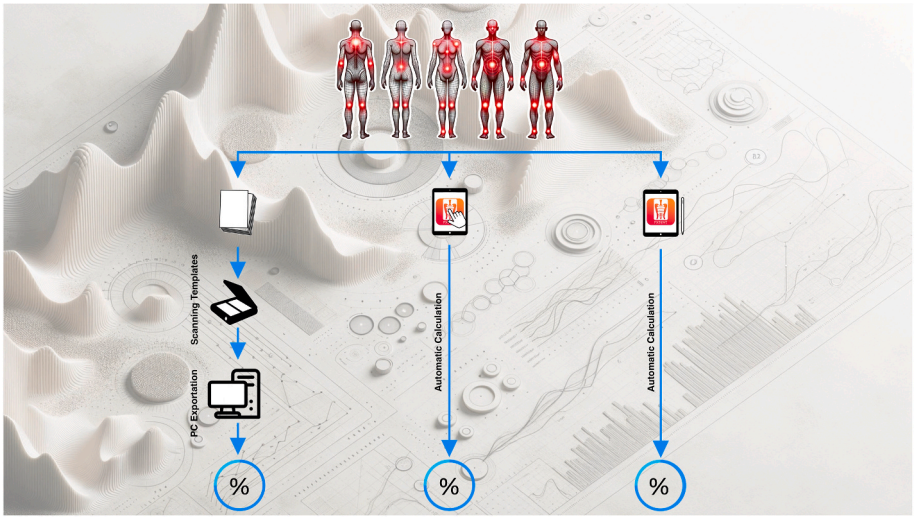

Fig. 3. Workflow diagram for each method assessed. In contrast with the paper-and-pencil method, which requires the template to be scanned and exported to obtain the score in a computer software, the PAINEXTENT app provides an automatic calculation once the patient complete the pain drawing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.compbiomed.2023.107699.

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