UNIVERSIDADE FEDERAL DO RIO GRANDE DO SUL
ESCOLA DE EDUCAÇÃO FÍSICA, FISIOTERAPIA E DANÇA
PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIA DO MOVIMENTO HUMANO

PROPOSIÇÃO DE UM PROTOCOLO DE AVALIAÇÃO PARA ESCOLIOSE IDIOPÁTICA POR FOTOGRAMETRIA ATRAVÉS DA TELE CONSULTA: DESENVOLVIMENTO, VALIDAÇÃO E REPRODUTIBILIDADE DO DIPA-S© EHEALTH

Isis Juliene Rodrigues Leite Navarro

PORTO ALEGRE

2023

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Isis Juliene Rodrigues Leite Navarro

Tese de doutorado submetida ao Programa de Pós-Graduação em Ciências do Movimento Humano da Escola de Educação Física, Fisioterapia e Dança da Universidade Federal do Rio Grande do Sul.

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RESUMO

O objetivo desta pesquisa foi desenvolver e avaliar a validade, acurácia diagnóstica e reprodutibilidade de um protocolo de avaliação para escoliose idiopática por fotogrametria, através da tele consulta. **Capítulo 1** (revisão sistemática) objetivo: (a) Identificar as variáveis posturais clínicas avaliadas no paciente com escoliose através da telemedicina; (b) Como essas variáveis foram mensuradas (captura e análise) e (c) determinar o grau de confiabilidade (validade e/ou reprodutibilidade) dos instrumentos/métodos usados para obter as variáveis mensuradas. Seis estudos foram incluídos para síntese quantitativa, todos com alta qualidade metodológica. Conclusão: (a) variáveis clínicas posturais obtidas por telemedicina: ângulo de rotação do tronco, ângulo entre os segmentos corporais (em desenvolvimento), movimento – oscilações por segundos (Hz/s), impedância (Ohms), observação postural síncrona e estética da deformidade; (b) Os métodos de captura foram síncronos e assíncronos e análises realizadas por aplicativos ou softwares específicos; e (c) Não foi possível quantificar o grau de confiabilidade através de metanálise. **Capítulo 2** (nota técnica) objetivo: apresentar o desenvolvimento do sistema de captura e análise (Digital Imaged-based Postural Assessment – Scoliosis) DIPA-S© eHealth e avaliar a acurácia de medida desse sistema, como parte de um protocolo de avaliação de pacientes com escoliose idiopática por tele consulta. As imagens foram obtidas usando o aplicativo DIPA-S© eHealth e as medidas foram realizadas utilizando o software DIPA-S© eHealth Analysis. Um total de 50 imagens capturadas pelo aplicativo compôs esta amostra. A diferença média entre as inclinações dos dois fios de prumo (RPL - VPL) foi muito pequena -0,1°± 0,04° (p = 0,017) e o erro RMS foi de 0,3°. O sistema de captura e análise DIPA-S© eHealth foi desenvolvido e está pronto para ser testado em pacientes. **Capítulo 3** (observacional) objetivo: (a) Avaliar a validade concorrente e (b) Acurácia diagnóstica do sistema de captura e análise DIPA-S© eHealth em relação ao exame clínico presencial. Inclusão: idade entre 7 e 25 anos, habilidade de se manter em ortostase sem ajuda e discrepância de membros menor que 2 cm. Exclusão: intervenção cirúrgica na coluna prévia, amputação de membros (inferiores ou superiores) ou qualquer causa diagnosticável de escoliose. Cada participante foi avaliado por dois procedimentos: avaliação clínica presencial e usando o sistema de captura e análise DIPA-S© eHealth. A amostra foi composta de 68 pacientes. A correlação variou de moderada a muito alta (0.6, 07 e 0.9), com baixos valores de erro RMS (10 mm, 20 mm e 4°). A área sob a curva (AUC) foi excelente para o ângulo de rotação do tronco (ART) com ponto de corte de 4° (Se = 96%; Es = 95%). O sistema de captura e análise DIPA-S© eHealth (a) É válido para mensuração de variáveis posturais nos planos frontal e transversal por tele consulta e (b) Possui acurácia diagnóstica para medida do ART. **Capítulo 4** (observacional) objetivo: avaliar a repetibilidade e reprodutibilidade intra e inter avaliador do sistema de captura e análise DIPA-S© eHealth. Foram obtidas imagens dos pacientes em três posições com o app DIPA-S© eHealth capture, estas imagens foram analisadas no software DIPA-S© eHealth Analysis, por três avaliadores independentes. Um total de 262 imagens foram analisadas. A repetibilidade foi excelente para os três avaliadores nos três planos (ICC de 0,94 a 1,00), com baixos valores de SEM (0,02 a 0,8) e MDC (0,03 a 1,7). A reprodutibilidade intra-avaliador foi excelente nos três planos (ICC de 0,88 a 0,99) com baixos valores de SEM (0,2 a 2,1) e MDC (0,4 a 4,1). A análise inter avaliador foi excelente para os planos frontal e transversal com ICC de 0,98 e 0,93; SEM de 0,4 e 0,9; MDC de 0,7e 1,8, respectivamente, porém foi fraca para o plano sagital ICC 0,32; SEM 17,6 e MDC 34,6. Conclusão: o sistema de captura e análise DIPA-S© eHealth apresenta confiabilidade para ser utilizado na avaliação clínica da escoliose através da tele consulta.

Palavras-chave: escoliose, postura, consulta remota, telerreabilitação, telemedicina.

ABSTRACT

The objective of this research was to develop and assess the validity, diagnostic accuracy, and reproducibility of an assessment protocol for idiopathic scoliosis through photogrammetry via teleconsultation. **Chapter 1** (Systematic Review): Objective: (a) Identify the clinical postural variables assessed in scoliosis patients through telemedicine; (b) How these variables were measured (capture and analysis); and (c) Determine the degree of reliability (validity and/or reproducibility) of the instruments/methods used to obtain the measured variables. Six studies were included for quantitative synthesis, all with high methodological quality. Conclusion: (a) Clinical postural variables obtained through telemedicine: trunk rotation angle, angle between body segments (under development), movement – oscillations per second (Hz/s), impedance (Ohms), synchronous postural observation, and aesthetics of deformity; (b) Capture methods were synchronous and asynchronous, with analyses performed by specific applications or software; and (c) It was not possible to quantify the degree of reliability through meta-analysis. **Chapter 2** (Technical Report): Objective: Present the development of the capture and analysis system (Digital Image-based Postural Assessment – Scoliosis) DIPA-S© eHealth and assess the measurement accuracy of this system as part of an evaluation protocol for idiopathic scoliosis via teleconsultation. Images were obtained using the DIPA-S© eHealth app, and measurements were performed using the DIPA-S© eHealth Analysis software. A total of 50 images captured by the app comprised this sample. The mean difference between the inclinations of the two plumb lines (RPL - VPL) was very small -0.1°± 0.04° ($p = 0.017$), and the RMS error was 0.3°. The capture and analysis system DIPA-S© eHealth has been developed and is ready to be tested on patients. **Chapter 3** (Observational Study): Objective: (a) Assess concurrent validity; and (b) Diagnostic accuracy of the DIPA-S© eHealth capture and analysis system compared to in-person clinical examination. Inclusion criteria: age between 7 and 25 years, ability to maintain a standing position without assistance, and leg length discrepancy less than 2 cm. Exclusion criteria: previous spinal surgery, limb amputation (lower or upper), or any diagnosable cause of scoliosis. Each participant was evaluated by two procedures: in-person clinical assessment and using the DIPA-S© eHealth capture and analysis system. The sample consisted of 68 patients. Correlation ranged from moderate to very high (0.6, 0.7, and 0.9), with low RMS error values (10 mm, 20 mm, and 4°). The area under the curve (AUC) was excellent for the trunk rotation angle (ART) with a cutoff point of 4° (Sensitivity = 96%; Specificity = 95%). The DIPA-S© eHealth capture and analysis system (a) is valid for measuring postural variables in the frontal and transversal planes via teleconsultation; and (b) has diagnostic accuracy for ART measurement. **Chapter 4** (Reliability Observational Study): Objective: Evaluate intra and inter-rater repeatability and reproducibility of the DIPA-S© eHealth capture and analysis system. Images of patients in three positions were obtained using the DIPA-S© eHealth Capture app, and these images were analyzed in the DIPA-S© eHealth Analysis software by three independent raters. A total of 262 images were analyzed. Repeatability was excellent for all three raters in all three planes (ICC from 0.94 to 1.00), with low SEM values (0.02 to 0.8) and MDC (0.03 to 1.7). Intra-rater reproducibility was excellent in all three planes (ICC from 0.88 to 0.99) with low SEM values (0.2 to 2.1) and MDC (0.4 to 4.1). Inter-rater analysis was excellent for the frontal and transversal planes with ICC of 0.98 and 0.93; SEM of 0.4 and 0.9; MDC of 0.7 and 1.8, respectively, but weak for the sagittal plane (ICC 0.32; SEM 17.6; MDC 34.6). Conclusion: The DIPA-S© eHealth capture and analysis system has reliability for use in the clinical evaluation of scoliosis through teleconsultation.

Keywords: scoliosis, posture, remote consultation, telerehabilitation, telemedicine.

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APRESENTAÇÃO

Esta tese de doutorado foi desenvolvida na Escola de Educação Física, Fisioterapia e Dança (ESEFID) da Universidade Federal do Rio Grande do Sul (UFRGS) e teve sua coleta de dados realizada em parceria com a Clínica Linear Saúde e Movimento com objetivo de contribuir para o avanço da avaliação clínica quantitativa do paciente com escoliose através da tele consulta. Os dados fornecidos pela avaliação remota foram explorados e analisados em comparação com a avaliação clínica presencial e o exame de Raios-X.

Com base na investigação crítica da literatura científica, na coleta, exploração e na análise dos dados obtidos, esta tese de doutorado está apresentada da seguinte forma: Introdução; 1. Capítulo 1 – Artigo de revisão Sistemática intitulado "Clinical Posture Evaluation of Patients with Scoliosis through Telemedicine: a Systematic Review" submetido à revista Gait & Posture, em agosto de 2023; 2. Capítulo 2 – Nota técnica intitulada "A Telehealth Assessment Protocol for Idiopathic Scoliosis by Means of Photogrammetry: Development and Measurement Accuracy" submetido à revista Cureus, em novembro de 2023; 3. Capítulo 3 – Artigo original intitulado "Validade concorrente e acurácia diagnóstica do sistema de captura e análise DIPA-S© eHealth para avaliação de pacientes com escoliose por tele consulta" submetido à revista Cureus em novembro de 2023. 4. Capítulo 4 – Artigo Original intitulado "Repeatability and Intra and Interrater Reproducibility of the DIPA-S© eHealth Capture and Analysis System for Clinical Assessment of Scoliosis" sumetido à revista European Spine Journal em outubro de 2023. 5. Considerações finais; 6. Limitações; 7. Perspectivas; Referências bibliográficas referentes à introdução.

INTRODUÇÃO

A pandemia causada pelo novo coronavírus vivida nos últimos três anos causou uma transformação na forma de realização das consultas periódicas convencionais na área da saúde (Organization, 2020). O lockdown foi necessário e tornou a circulação mais difícil, abrindo espaço para modalidade de atendimento através da tele consulta, contribuindo para a acelerada e dinâmica migração para o meio digital (Piche et al., 2020; Satin & Lieberman, 2021).

Em um cenário paralelo a esse contexto, as doenças de característica crônica, não deixaram de existir e permaneceram carecendo de cuidados (Kmetik et al., 2021). A escoliose idiopática (EI) é uma condição tridimensional da coluna vertebral e do tronco de característica progressiva, afetando de 2 a 3 % da população e sendo mais comum em adolescentes do sexo feminino (Negrini et al., 2012, 2018). Silenciosa e progressiva, a escoliose tende a piorar de forma acentuada durante os períodos de estirão de crescimento, tornando seu diagnóstico e acompanhamento periódico fundamentais (Sarwark et al., 2021).

Ao longo dos anos de 2020 e 2021 foi crescente o número de pacientes com deformidades da coluna que necessitaram de atendimento através da tele consulta (Pereira et al., 2022). Romano et al. (2021) tiveram mais de 2 mil atendimentos de fisioterapia por tele consulta para pacientes com escoliose, durante 2 meses de lockdown na Itália. Segundo os autores “mesmo após o retorno dos atendimentos presencias, 10% dos atendimentos (532 de 5.091) permaneceram por tele consulta”.

Embora já utilizada em outros países, no Brasil a modalidade de atendimento remoto foi regularizada para os fisioterapeutas e terapeutas ocupacionais apenas em março de 2020. A nova modalidade de atendimento ganhou espaço ao longo dos últimos três anos e essa nova era começa a se consolidar na literatura científica (Marin et al., 2021; Raiszadeh et al., 2021; Romano et al., 2021).

Embora já se tenha a possibilidade de um exame físico realizado de forma remota, os testes aplicados têm caráter subjetivo, impossibilitando sua a quantificação, tão necessária no acompanhamento da progressão da escoliose (Satin & Lieberman, 2021). É possível perceber que há uma lacuna quanto às evidências de confiabilidade e validade dos procedimentos de avaliação clínica do paciente com escoliose através da tele consulta.

Tendo em vista o envolvimento tridimensional da coluna vertebral e do tronco nas alterações encontradas nos pacientes com escoliose idiopática é fundamental que na avaliação destes pacientes se obtenha informações dos três planos (frontal, sagital e transversal). Além disso, é relevante quantificar essas informações, possibilitando não só o diagnóstico, mas também o acompanhamento desses pacientes através de variáveis clínicas quantitativas.

Neste contexto e pressupondo que seja possível desenvolver e testar uma metodologia para este fim através da fotogrametria, este estudo buscará desenvolver e avaliar a validade, acurácia diagnóstica e reprodutibilidade de um protocolo de avaliação para escoliose idiopática por fotogrametria através da tele consulta.

1 CAPÍTULO 1 – CLINICAL POSTURE EVALUATION OF PATIENTS WITH SCOLIOSIS THROUGH TELEMEDICINE: A SYSTEMATIC ARTIGO DE REVISÃO SISTEMÁTICA

Revisão Sistemática.

Submetido à Revista *Gait & Posture* em agosto 2023.

Clinical Posture Evaluation of Patients with Scoliosis through Telemedicine: A Systematic Review

Abstract

Background: The increasing use of remote patient care for individuals with scoliosis has created opportunities for the development and utilization of different tools and methods of evaluation. Research question: What are the clinical postural variables evaluated in scoliotic patients through telemedicine? Methods: Systematic searches were conducted by two independent reviewers in the PubMed, Scopus, EMBASE, and IEEE databases using the MeSH terms "scoliosis" and "telemedicine" and their synonyms. This study followed the MOOSE guideline (Meta-analysis of Observational Studies in Epidemiology). The methodological quality assessment was performed using the Critical Appraisal Skills Program (CASP). Results: 136 studies were found in the databases, and 20 were found through manual search of references. After removing duplicates (n= 41), 81 studies were excluded, leaving 14 for full-text reading. Of these, six studies were included for qualitative synthesis, with a total of 1002 subjects. The following clinical postural variables were identified: angle of trunk rotation (ATR), angle between body segments (in development), movement - oscillations per second (Hz/s), impedance (Ohms/mm), synchronous postural observation, and aesthetic deformity. Only two studies provided validity and reproducibility coefficients, however, it was not possible to quantify through meta-analysis because the coefficients were different. Significance: This review provided the clinical postural variables evaluated in patients with scoliosis through telemedicine, including trunk rotation angle, angle between body segments (under development), movement - oscillations per second (Hz/s), impedance (Ohms/mm), synchronous postural observation, and aesthetic deformity. The data capture methods employed both synchronous and asynchronous approaches, utilizing smartphones, tablets, or sensors. Different analyses were performed using specific applications or software. The meta-analysis did not allow for quantification of the reliability degree of the instruments/methods used to obtain the clinical variables. Further research is needed to focus on the development, validation, and reproducibility of assessment instruments for patients with scoliosis through telemedicine.

Keywords: eHealth, idiopathic scoliosis, posture, validity, reproducibility.

Introduction

Idiopathic scoliosis (IS) is a progressive condition affecting the three-dimensional alignment of the spine and trunk that affects 2-3% of the population, that is more common in adolescent females [1]. As a silent and progressive condition, scoliosis tends to worsen dramatically during growth spurts, and regular diagnosis and follow-ups are crucial for successful treatment [2].

The COVID-19 pandemic accelerated the migration of conventional periodic consultations with physicians, physiotherapists, or psychologists to remote monitoring [3,4] [5]. The rapid shift to new forms of remote patient care has opened space for the use and development of remote assessment tools for scoliosis patients [6,7].

Knowing the complexity of IS, three-dimensional assessment is essential for identifying changes in each plane. However, 3D measurements can be complex and difficult to acquire and/or analyze through telemedicine. In this scenario, new forms and/or assessment instruments are needed. Since the beginning of telemedicine use in the 1960s, different forms of evaluation have been proposed, and it is worth noting that innovation and technological advancement have recently seen a significant progression [4]. However, there still seems to be a gap in the literature regarding the evidence of validity and reproducibility of scoliosis patient assessment procedures by telemedicine available to date [8].

In this context, the primary objective of this review was to identify the clinical postural variables evaluated in scoliosis patients through telemedicine. The secondary objectives are (a) to determine how clinical postural variables were measured (capture and analysis) and (b) to determine the degree of reliability (validity and/or reproducibility) of the instruments/methods used to obtain the measured clinical variables.

Methods

Type of study

The present study is a systematic review, the protocol was pre-registered on PROSPERO (CRD42023394149).

Search strategies

Two reviewers conducted the screening of titles and abstracts, full-text screening, and data extraction in a blinded and independent manner. Systematic searches of the literature were conducted in June 2023 on PubMed, Scopus, EMBASE, and IEEE following the MOOSE guideline (Meta-analysis of Observational Studies in Epidemiology) [9].

The MeSH terms "scoliosis"[MeSH Terms] and "telemedicine"[MeSH Terms] with their corresponding respective free text terms were used with the Boolean operators OR and AND. The complete search strategy used in PubMed can be seen in Figure 1. The searches were conducted in June 19th 2023. There were no restrictions on language or publication date. Manual searches were performed on the references of the included articles.

("telemedicine"[MeSH Terms] OR "telemedicine"[All Fields] OR "telemedicine s"[All Fields] OR ("mobile"[All Fields] AND "health"[All Fields]) OR "mobile health"[All Fields] OR "health mobile"[All Fields] OR "mhealth s"[All Fields] OR "mhealth"[All Fields] OR "telehealth s"[All Fields] OR "telehealth"[All Fields] OR "ehealth"[All Fields])

AND

("scoliosis"[MeSH Terms] OR "scoliosis"[All Fields] OR "scolioses"[All Fields])

Figure 1 - Search strategy of pubmed

Eligibility criteria

Studies were considered eligible if they met the following criteria: (1) Patients with idiopathic scoliosis in any chronological classification juvenile, adolescent, or adult, (2) Postural Evaluation through telemedicine, which means that all the assessments had to be performed by using telehealth online or remotely, (3) There were no restrictions on the types of study design eligible for inclusion. The exclusion criteria were Infantile idiopathic scoliosis and patients with any diagnosed specific cause of scoliosis. Abstracts alone were excluded.

Study selection and data extraction

The bibliographic information of the included studies was stored in Zotero software. The two reviewers independently selected potentially relevant studies based on screening the titles and abstracts. Reviewer 1 (I.J.R.L.N) is a physiotherapist, PhD student, with 12 years of experience in the evaluation and treatment of patients with scoliosis. Reviewer 2 (F.P.P) is a final year undergraduate physiotherapy student. When the study did not provide enough information to be excluded, the full text was read.

In the next step, the reviewers performed a full-text screening of the studies, selecting them according to eligibility criteria. Studies that presented only clinical variables extracted through questionnaires or radiographic variables were excluded. Disagreements were resolved by consensus or by a third reviewer (C.T.C.).

Only the included studies were submitted to data extraction and assessment of methodological quality. Data were extracted by two reviewers independently in a standardized way through a spreadsheet containing: author, publication year, age of participants, and sample size. Outcomes were: (1) clinical postural variables evaluated, (2) capture method, (3) analysis method, (4) statistical coefficients for validity and/or reproducibility analysis. A clinical postural variable refers to a measurable characteristic or parameter related to an individual's body posture.

Quality assessment

The assessment of methodological quality and risk of bias was performed by the same two reviewers independently using the Critical Appraisal Skills Programme (CASP) for diagnostic studies [10]. The scale consists of 12 items organized into three sections (A - Are the results valid? B - What are the results? and C - Will the results help locally?). The scale comprises 9 objective questions with the options of "yes," "no," and "cannot tell," as well as 3 descriptive questions. The score was composed of the 9 objective questions and one descriptive question that, in addition to the description, was converted to "yes" or "no". The original descriptive question 8 was converted to a 'yes' or 'no' format based on the presentation of a confidence interval in statistics. The score was quantified as "yes" = 1 and "no" or "cannot tell" = 0. The sum of the final score was converted to a percentage. The included studies were considered to have high methodological quality if they achieved a score of ≥ 60%, as proposed by previous studies using other scales for assessing methodological quality and risk of bias [11,12].

Statistical analysis

The planned statistical analysis was to be carried out using the Comprehensive Meta-Analysis V3 software. A minimal necessary sample of two studies were to be grouped according to the type of coefficient (correlation r or intra-class correlation coefficient ICC) and the reference standard used (clinical or radiological). The random-effect model was selected for the meta-analysis of reproducibility and validity estimates if there were at least N studies sufficiently similar in terms of patient assessed, capture method and variable assessed to attempt the meta-analysis. Heterogeneity was to be verified by the Higgins Inconsistence test (I^2). As no study met our meta-analysis inclusion criteria, we did not need to handle missing results nor to convert data to enter in the meta-analysis.

Results

Initially, 136 studies were identified in the systematic searches, and 20 through manual searches of references, of which 41 were duplicates, and 101 were excluded, leaving 14 for full-text reading. Based on eligibility criteria, 8 articles were excluded, leaving 6 studies included for analysis and data extraction. Figure 2 shows the flowchart of included studies [13].

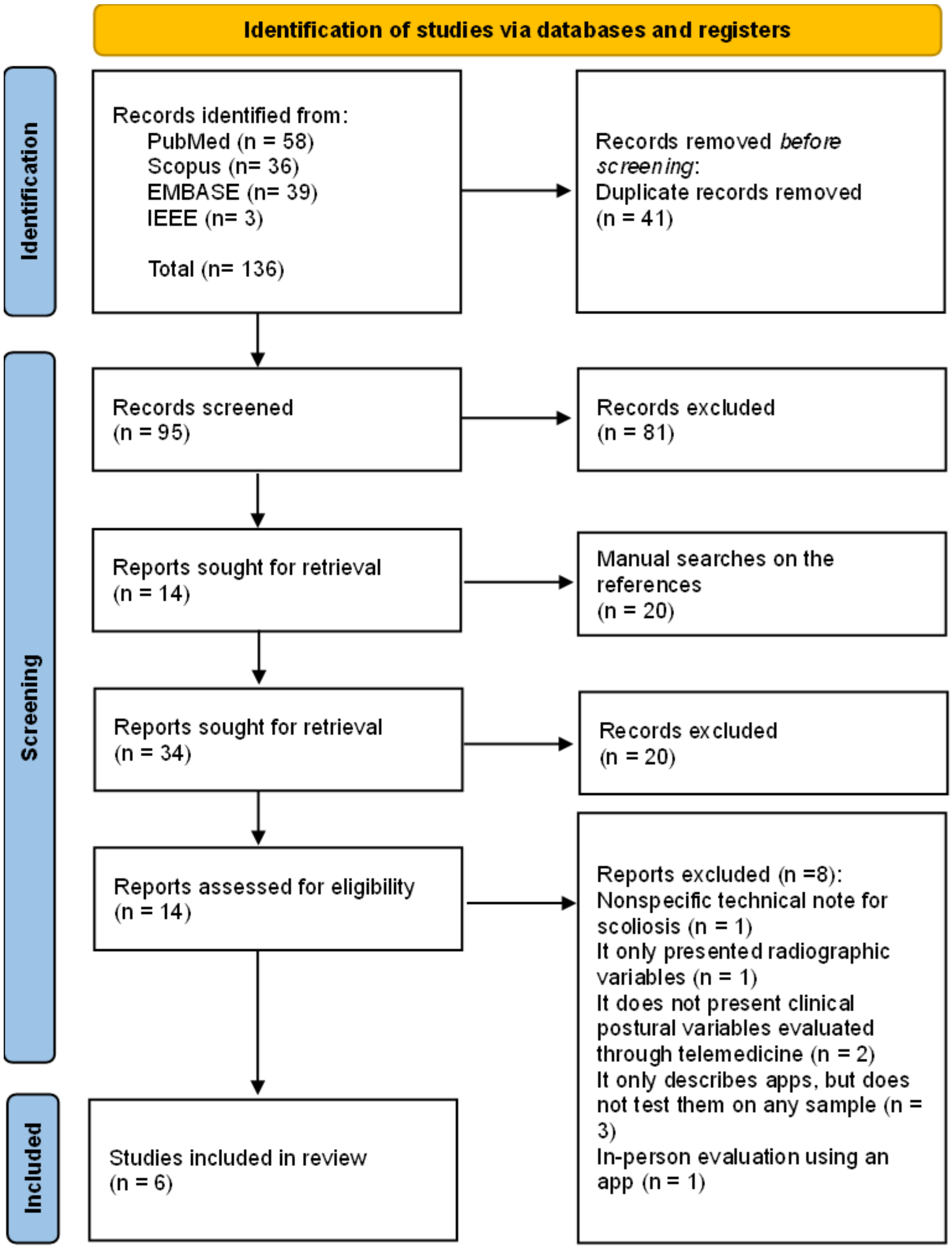

Figure 2 - Flowchart of included studies.

The publication year of the included studies ranged from 2012 to 2023, with a total sample size of 1002 subjects. The clinical postural variables evaluated were angle of trunk rotation, angle between body segments (under development), movement - oscillations per second (Hz/s), impedance (Ohms/mm), synchronous observation (in anterior, lateral and posterior view), and aesthetic deformity (observation of the scapula asymmetry, the difference in shoulder levels from the anterior view, the difference in shoulder levels from the posterior view, the height difference of the pelvis from the anterior view, the height difference of the pelvis from the posterior view, pelvic shift to one side, and positive Adams' test). Among the proposed methodologies for clinical postural assessment through telemedicine were mobile application (photo or video-based apps), accelerometer, instrumented t-shirt with sensor, and synchronous observation: via video conference (by a professional) and in person (by the parents) (Table 1).

The assessment was performed asynchronously in one study [14] synchronously in four studies [4,15–17] and presented both synchronous and asynchronous possibilities in only one study [18]. The devices used were smartphones in three studies [14–16] smartphone, tablet or computer in two studies [4,17] and instrumented t-shirt with sensor in one study [18]. Three smartphone applications [14–16] and one commercial impedance analyzer [18] were identified for analysis.

Only two studies reported measurement properties in terms of concurrent validity and reproducibility for different measurements [15,17] (Table 1). In the study by Beauséjour et al., intraclass correlation coefficient was used to verify the validity of the angle of trunk rotation measurement by non-professionals compared to an expert as reference (ICC $_{(2,1)}$ of 0.82 to 0.84). The authors also reported ICC $_{(2,1)}$ values (0.92), MDC (4°) and SEM (1.5°) for both intra- and inter-evaluator reproducibility coefficients. For the intra evaluator analysis 15 to 45 minutes separated the two measurement sessions. For Yilmaz at al., the Scoliosis Tele-Screening Test (STS-Test) was correlated to other variables (clinical and radiological). We extracted the correlation value between the STS-Test and TRACE score (Rho = 0.947) for validation purpose. The authors also reported the Cronbach's α (0.901) for internal consistency (inter-items). Meta-analysis was therefore not possible, considering the different statistics used in the two studies.

In the assessment of methodological quality and risk of bias using the CASP for diagnostic studies, all studies achieved high methodological quality (≥60%). The average quality assessment score was 78,3% (figure 3). The main weaknesses of the studies were related to the lack of comparison with the reference gold standard, lack of evaluation of patients with the gold standard and the new test, inadequate description of the disease status of the tested population, and unclear certainty about the results (lack of confidence interval), with the latter point being evaluated by the only descriptive question that integrated the score.

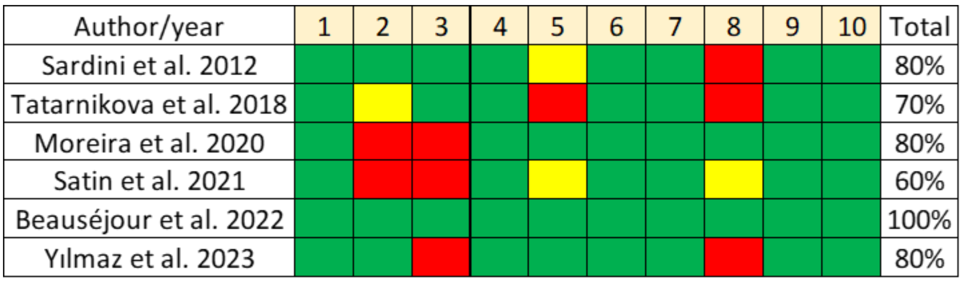

Figure 3 – Quality assessment through the Critical Appraisal Skills Program (CASP) for diagnostic studies.

*green = yes; red = no; yellow = can't tell. 1. Was there a clear question for the study to address?; 2. Was there a comparison with an appropriate reference standard?; 3. Did all patients get the diagnostic test and reference standard?; 4. . Could the results of the test have been influenced by the results of the reference standard?; 5. Is the disease status of the tested population clearly described?; 6. Were the methods for performing the test described in sufficient detail?; 7. How sure are we about the results? Consequences and cost of alternatives performed?; 8. . Can the results be applied to your patients/the population of interest?; 9. Can the test be applied to your patient or population of interest?; 10. Were all outcomes important to the individual or population considered?

Table 1. Characteristics of the Included Studies, Primary and Secondary Outcomes.

Author/ year	Sample	Age	Gender	Postural variables evaluated	Evaluation procedure	Capture method (photo, video, synchronous, asynchronous)	Analysis method (application or software)	Device (cell phone, tablet, laptop, computer)	Validity	Reproducibility
Sardini et al. 2012	no scoliosis n=1	not reported	male	Impedance (ohms)	linear distance between the two points (T1 and sacrum) and the impedance (ohms) obtained by the sensor at the sensorized t-shirt	Synchronous or asynchronous (The data are transmitted wireless to a readout unit, which can be connected to a PC (Personal Computer) or directly to the internet for telemedicine activity)	commercial impedance analyzer (HP4194A)	A t-shirt instrumented sensors and a readout unit for posture measurement	not reported	not reported
A. A. Tatarnikova, 2018	total n= 67 scoliosis n= 16	from 18 to >70 y.o.	F=27 M= 40	Movement (Hz)	The values of the frequencies of global maximums are compared with each other. Frequency values on three peaks are compared between each other, and if they are not equal between each other, a decision is made that the subject has scoliosis.	Asynchronous (remote) capture system	Custom mobile application was developed in Java Android (Google, USA). Custom software was developed in Matlab (The MathWorks, USA).	smartphone mobile phone HTC Desire 300 on the Android 4.1	not reported	not reported

Table 1. Characteristics of the Included Studies, Primary and Secondary Outcomes.

Author/ year	Sample	Age	Gender	Postural variables evaluated	Evaluation procedure	Capture method (photo, video, synchronous, asynchronous)	Analysis method (application or software)	Device (cell phone, tablet, laptop, computer)	Validity	Reproducibility
Moreira et al. 2020	not reported	not reported	not reported	Angle formed be tween body segments and range of motion	Automatic identification of anatomical landmarks for future measurement of angles between body segments and range of motion (under development)	Synchronous (photo)	Mobile application prototype and embedded both TensorFlow and PoseNet	smartphone (Android)	not reported	not reported
Satin 2021	not reported	not reported	not reported	Clinical postural observation	Clinical postural observation made with the patient standing. Anterior view: Asymmetry of the back, pelvis, and shoulders. Trunk balance in the frontal plane. Lateral view: Increased kyphosis or alterations in the sagittal plane should be noted. Posterior view: Adams test for gibbosity and lateral trunk flexion to assess the mobility of the curve (thoracic and lumbar)	Synchronous (Videoconferencing app)	Videoconferen cing app	smartphone or tablet	not reported	not reported

Table 1. Characteristics of the Included Studies, Primary and Secondary Outcomes.

Author/ year	Sample	Age	Gender	Postural variables evaluated	Evaluation procedure	Capture method (photo, video, synchronous, asynchronous)	Analysis method (application or software)	Device (cell phone, tablet, laptop, computer)	Validity	Reproducibility
Beauséjour et al. 2022	scoliosis n= 69	10 to 18 y.o (14.2±1.6 years)	F= 51 M= 17	Angle of trunk rotation (ATR)	Measurement of the angle of trunk rotation using a smartphone application	Synchronous (Measurement conducted by parents)	app scolioscreen	smartphone	ICC from 0.82 to 0.84 between experts and non-professionals (for three observers) and an agreement between non-professionals and the expert ranging from 83% to 90% of cases	ϕ ICC intra = 0.92; SEM = 1.5°; MDC = 4°; ϕ ICC inter = 0.92; SEM = 1.5°; MDC = 4°
Yılmaz et al, 2023	n = 865	12±4.5 y.o.	F=511 M= 354	Aesthetic deformity (scapula asymmetry, the difference of shoulder levels from anterior, the difference of shoulder levels from posterior, the height difference of the pelvis from anterior, the height difference of the pelvis from posterior, pelvic shifting to one side, and positive Adams' test	Classification of the Aesthetic deformity performed by the parents based on images	Synchronous (Virtual test aplied by the parents)	Scoliosis Tele-Screening Test	smartphone, tablet, laptop or computer	Rho = 0.428 (STS-Test X cobb) Rho = 0.947 (STS-Test X TRACE)	cronbach 0.901

Discussion

Recent advancements in technology have allowed for innovation in the use of technology for patient care and assessment, both in-person and remotely [19]. The primary objective of this review was to identify the clinical postural variables evaluated in patients with scoliosis through telemedicine. This systematic review comprised 6 studies. No meta-analysis was possible. Only two studies reported measurement properties on validity and reproducibility. Different methods were used for capture and analysis. From the qualitative data synthesis, the angle of trunk rotation (ATR) was identified as the variable most frequently evaluated in the included studies, appearing in three studies [4,15,17].

It is important to note that in these studies, the examination of gibbosity was performed in different ways. In the study of Satin et al. [4], the authors proposed a comprehensive spinal examination conducted synchronously via videoconference through observation of trunk appearance and clinical tests. In the session dedicated to scoliosis examination, the authors suggest that the patient face away from the camera and perform the forward bending movement of the trunk (Adams Test). The same observation evaluation was used by Yilmaz et al. [17], with the examination of the spine during the forward bending position by the parents or care givers.

Described for the first time in the 1960s, the Adams Test was one of the first clinical tests intended for the screening of scoliosis patients [20]. Although the test has good sensitivity and specificity, the test result is provided through a categorical variable (positive or negative) [21]. A positive test indicates the presence of gibbosity, where upon observing the trunk from a posterior view, the evaluator visualizes an asymmetry in the contour of the trunk during the forward bending movement, with one side being higher and the other depressed [22]. In Satin's study [4], the authors suggest the use of the Adams Test in remote care, performed synchronously identically to the examination done in-person.

One limitation of the use of the Adams Test is the absence of a quantitative measurement and the high number of false negatives [23]. Knowing that early diagnosis of scoliosis is essential for the success of conservative treatment, the choice of tests with adequate diagnostic accuracy is indispensable to avoid the "false negative," which would result if a patient who has the disease and is not diagnosed, thus progressing freely [24].

The use of the angle of trunk rotation (ATR) measurement through the scoliometer was introduced in 1984 by Bunnel [25]. The scoliometer is intended to measure gibbosity in degrees during the Adams Test. The value is obtained in discrete degrees from 0° to 30° for both sides. An important feature of the objective evaluation made by the scoliometer is the assignment of a cutoff point. Initially, the cutoff point suggested to indicate the presence of scoliosis was 5° [26]; however, in order to achieve the best values of sensitivity and specificity, the use of the 7° cutoff point has since been recommended [27].

In the second study using ATR [15], the authors used a scoliometer to remotely evaluate scoliosis patients, adopting a cut-off point of $\geq 6°$ to indicate the need for consultation with a specialist. The authors compared the use of the smartphone application scolioscreen for ATR measurement made by parents and experts. Adequate ICC values and low SEM values were reported in this study demonstrating that parents can use the app properly [15].

Romano et al. [28] argue that parental/caregiver involvement is necessary for both assessment and specific physiotherapy care for scoliosis through teleconsultation. In their study discussing lessons learned in two months of exclusive application of telephysiotherapy, the authors emphasize the importance of the caregiver's presence, not only during synchronous consultation through a free video communication App, but also prior to the consultation by supporting patients to fill out the assessment form in advance of their appointment [28].

Yilmaz et al. [17] developed the STS-Test, a virtual tool for scoliosis screening and identification of risk factors, to be administered by parents. The STS-Test facilitates the classification of individuals into low, moderate, and high-risk categories for scoliosis. According to parental feedback, 93.3% of the parents reported the STS-Test as easy to apply, while 97.7% found it to be useful. The authors conducted a correlation analysis to examine the relationship between the STS-Test and various variables, including TRACE (Trunk Aesthetic Clinical Evaluation), scoliosis diagnosis (based on the results of the STS-Test administered by a healthcare professional), Cobb angle, and the forward bending test. The correlation between the STS-Test and the Cobb angle was determined to be the weakest. Although the authors assessed internal consistency as a measure of reproducibility, it is worth noting that this approach may not adequately evaluate reproducibility, considering that the internal consistency does not reflect test-retest differences or inter-rater errors. Thus, highlighting a limitation of the study, in our view, the utilization of ICC or Kappa statistics for intra and inter-rater analysis would provide a more appropriate assessment of reproducibility [29].

In the study by Sardini [18], impedance (in ohms) measurement was used for posture monitoring, through an instrumented T-shirt for posture measurement, which allows for synchronous or asynchronous data capture. The authors showed an impedance of 50 ohms/mm, indicating good sensitivity, but the clinical significance of the variable was not established. To determine the sensitivity of the measurement based on impedance (Ohms), the impedance modulus values were calculated at different position for a fixed frequency of about 3.92 MHz and it was compared with the distance between the points placed on T1 and sacrum. The authors sought to monitor trunk positioning by placing sensors in the central (anterior and posterior) region of the shirt. The clinical postural variable evaluated is related to changes in spine length in the seated position. This length change generates a variation in the geometry of the inductor sensor coils. The authors also argue that axial spine elongation is an exercise for reinforcing correct posture performed by the patient in the seated position.

Different schools of specific physiotherapy exercises for scoliosis have been well described in the scientific literature [30], and indeed axial elongation is cited as an important element in specific scoliosis treatment by some of these schools.

However, the use of the T-shirt instrumented for posture measurement for specific monitoring of patients with scoliosis presents two major limitations: 1. It does not provide three-dimensional information about the spine and trunk, and 2. It does not provide information in units commonly used for postural measurements and with clinical applicability, which inevitably limits its use in clinical practice.

With the advancement of smartphone technology, relying on the accelerometer and gyroscope sensors, various functionalities became available. The accelerometer has been explored as a way of assessing and diagnosing musculoskeletal diseases. Tatarnikova et al. [14] developed an algorithm capable of differentiating and monitoring people with scoliosis, coxarthrosis, mixed musculoskeletal system diseases, and healthy individuals. In this study, movement was measured using the accelerometer, providing the measurement in Hz (oscillations per second), and the analysis of the information obtained after discrete fourier transform (DFT) showed that the strongest fluctuations were seen in the vertical and medio-lateral directions in patients with scoliosis.

Although more frequently used and tested, there is still very limited information provided by accelerometer applied as a form of remote evaluation of patients with scoliosis. Through the methodology proposed by Tatarnikova, it is not possible to obtain postural clinical parameters. The authors only proposed to differentiate those with scoliosis from those without it. In this sense, the inclusion of diagnostic accuracy analysis is highly recommended [31]. Despite presenting good methodological quality, the authors did not report any type of measurement property (validity and/or reproducibility) and did not present any analysis towards the diagnostic accuracy of the new test.

Moreira et al. [16] also used the smartphone to evaluate posture and range of motion. The authors developed the prototype of the application (PostureScreen Mobile) that aims to measure static posture in standing position and range of motion through machine learning. The study was the first step in the development of the app, however, clinical postural variables that can be evaluated have not yet been presented, nor their measurement properties or diagnostic accuracy.

In the evaluation of methodological quality and risk of bias, considering the established cutoff point according to different scales reported in previous studies (≥ 60%), all studies included in this review presented high methodological quality. The main points of methodological weakness can be overcome adopting the comparison of the alternative test with the reference standard, allowing an understanding of clinical significance of the results and the sources of errors. Another important aspect is the evaluation of all the sample with the reference standard and with the new test, also it is necessary to clearly describe the disease status in the tested population and specify which is the intended use population. Finally, confidence interval for the results should be always presented to allow an understanding of how sure we are about the results of the study. All questions answered with "no" or "do not know" were scored with 0, and the four questions present in the methodological weakness are linked to the study design of validity and reproducibility. This finding highlights the scarcity of studies focused on evaluating the measurement properties of different forms of remote evaluation of patients with scoliosis through telemedicine.

In this review, synchronous and asynchronous forms of postural clinical evaluation of patients with scoliosis were presented, performed through mobile devices such as smartphones and tablets and even an instrumented shirt. The intense pandemic period and severe restrictions experienced in the years 2020 and 2021 led many healthcare professionals to rapidly migrate to the digital environment, enabling the continuity of treatment and periodic evaluations of their patients [28]. However, it is essential to emphasize the great gap in terms of validity, reproducibility, and diagnostic accuracy of the available forms of evaluation for patients with scoliosis. The difficulty seems to start with the very limited availability of objective remote measurement tools for clinical parameters known to be relevant for the evaluation and follow-up of these patients.

As limitations, we can mention the restricted search terms applied in this review, which may have contributed to the scarce number of studies found on the development and testing new forms of remote evaluation of patients with scoliosis, and those showing their reliability. Although limited, the search terms adopted in this research allowed for the location of articles directly related to the studied topic. The evident gap in the literature pointed out in this review should encourage the conduct of studies focused on the validity and reproducibility of remote evaluation of patients with scoliosis through telemedicine. Moreover, the only two studies included in this review that reported measurement properties (validity and/or reproducibility) used different coefficients, which made it impossible to perform a meta-analysis of these data.

Conclusion

In conclusion, this review provided an overview of the postural clinical variables that can be evaluated in patients with scoliosis through telemedicine, including angle of trunk rotation, angle between body segments (under development), movement - oscillations per second (Hz/s), impedance measures reflecting torso elongation (Ohms), and synchronous postural observation and aesthetic deformity. Both synchronous and asynchronous capture methods were used, using smartphones, tablets, or sensors, and various analyses were performed using dedicated apps or software. However, as too few and heterogeneous studies reported measurement properties, it was not possible to meta-analyse the reliability (validity and/or reproducibility) of the measured clinical variables using the remote instruments/methods included in this review.

Conflict of interest statement: Nothing to declare.

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2 CAPÍTULO 2 – A Telehealth Assessment Protocol For Idiopathic Scoliosis By Means Of Photogrammetry: Development And Measurement Accuracy

Nota técnica.

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A Telehealth Assessment Protocol for Idiopathic Scoliosis by Means of Photogrammetry: Development and Measurement Accuracy

Abstract

The aim of this study was to present the development and assessment of the measurement accuracy of variables obtained with the Digital Imaged-based Postural Assessment (DIPA©) Capture app and Analysis software as part of a telehealth assessment protocol for idiopathic scoliosis. To enable the correct capture of photographic images for further analysis, the development of an application, called DIPA-S© eHealth Capture, was performed. A photo is automatically obtained only when the smartphone is aligned. The sample of this prospective study was composed of consecutive images of a real plumb line (RPL) taken by using the DIPA-S© eHealth Capture app. Once the photo was captured the app automatically drew a virtual plumb line (VPL). The inclination of the RPL and VPL was measured using the DIPA-S© eHealth Analysis software. A total of 50 images using the App comprised this sample. The median (min-max) inclination angle of the real and virtual plumb lines was 89.8° (88.6°-90°) with a 1.4° range and 90° (89.4°-90°) with a 0.6° range, respectively. The mean difference between the inclination of the two plumb lines (RPL - VPL) was very small -0.1°±0.04° ($p= 0.017$). The RMS error was 0.3°. The DIPA-S© eHealth Capture app and Analysis software for image acquisition and measurement was developed and is ready for testing with patients. The app accurately captures the alignment of the smartphone during the image acquisition and the software shows adequate measurement accuracy for future assessment of idiopathic scoliosis by photogrammetry.

Keywords: Telemedicine, Remote consultation, Posture, Scoliosis.

Resumo

O objetivo deste estudo foi apresentar o desenvolvimento e a avaliação da precisão das medidas de variáveis obtidas com o aplicativo Digital Imaged-based Postural Assessment (DIPA©) Capture e o software de análise, como parte de um protocolo de avaliação de telemedicina para escoliose idiopática. Para possibilitar a correta captura de imagens fotográficas para análises posteriores, foi realizado o desenvolvimento de um aplicativo chamado DIPA-S© eHealth Capture. Uma foto é automaticamente obtida apenas quando o smartphone está alinhado. A amostra deste estudo prospectivo foi composta por imagens consecutivas de uma linha de prumo real (LPR) tiradas usando o aplicativo DIPA-S© eHealth Capture. Uma vez capturada a foto, o aplicativo desenhou automaticamente uma linha de prumo virtual (LPV). A inclinação da LPR e da LPV foi medida usando o software de Análise DIPA-S© eHealth. Um total de 50 imagens usando o aplicativo compôs esta amostra. A mediana (min-máx) do ângulo de inclinação das linhas prumo real e virtual foi de 89,8° (88,6°-90°) com uma variação de 1,4° e 90° (89,4°-90°) com uma variação de 0,6°, respectivamente. A diferença média entre a inclinação das duas linhas prumo (LPR - LPV) foi muito pequena, -0,1°±0,04° (p= 0,017). O erro RMS foi de 0,3°. O aplicativo DIPA-S© eHealth Capture e o software de Análise para aquisição e medição de imagens foram desenvolvidos e estão prontos para testes com pacientes. O aplicativo captura com precisão o alinhamento do smartphone durante a aquisição de imagens, e o software apresenta uma precisão de medição adequada para avaliações futuras da escoliose idiopática por fotogrametria.

Palavras-chave: Telemedicina, Consulta remota, postura, Escoliose

Resúmen El objetivo de este estudio fue presentar el desarrollo y la evaluación de la precisión de las medidas de variables obtenidas con la aplicación Digital Imaged-based Postural Assessment (DIPA©) Capture y el software de Análisis, como parte de un protocolo de evaluación de telemedicina para la escoliosis idiopática. Para permitir la correcta captura de imágenes fotográficas para análisis posteriores, se llevó a cabo el desarrollo de una aplicación llamada DIPA-S© eHealth Capture. Una foto se obtiene automáticamente solo cuando el smartphone está alineado. La muestra de este estudio prospectivo estuvo compuesta por imágenes consecutivas de una línea de plomada real (LPR) tomadas utilizando la aplicación DIPA-S© eHealth Capture. Una vez capturada la foto, la aplicación dibujó automáticamente una línea de plomada virtual (LPV). La inclinación de la LPR y la LPV se midió utilizando el software de Análisis DIPA-S© eHealth. Un total de 50 imágenes utilizando la aplicación compusieron esta muestra. La mediana (mín.-máx.) del ángulo de inclinación de las líneas de plomada real y virtual fue de 89,8° (88,6°-90°) con un rango de 1,4° y 90° (89,4°-90°) con un rango de 0,6°, respectivamente. La diferencia media entre la inclinación de las dos líneas de plomada (LPR - LPV) fue muy pequeña, -0,1°±0,04° (p= 0,017). El error RMS fue de 0,3°. La aplicación DIPA-S© eHealth Capture y el software de Análisis para la adquisición y medición de imágenes fueron desarrollados y están listos para ser probados con pacientes. La aplicación captura con precisión el alineamiento del smartphone durante la adquisición de imágenes y el software muestra una precisión de medición adecuada para la evaluación futura de la escoliosis idiopática mediante fotogrametría.

Palabras-clave: Telemedicina, Consulta remota, postura, Escoliosis

Nível de Evidência: III

Tipo de estudo: Estudos diagnósticos – Investigação de um exame para diagnóstico

Introduction

Idiopathic scoliosis is an orthopedic condition of the spinal column and trunk that tends to progress rapidly during periods of growth spurts in children and adolescents, requiring constant monitoring[1]. The increasing technological innovation has opened up new possibilities in assessment and treatment tools for various orthopedic issues, particularly concerning spinal conditions[2].

The teleconsultation mode of care substantially increases the reach of healthcare professionals and patients' access to specialized care in different areas. The screening and evaluation of patients with scoliosis have been widely conducted through the scoliometer and direct observation of postural asymmetries, characteristic of the condition. However, these methods either require in-person presence or are limited to an observational assessment[3].

The development of applications, software, and the use of artificial intelligence itself are strengths of the current period, optimizing certain procedures in the assessment of patients with scoliosis[4]. Furthermore, new reliable, affordable, and low-cost alternatives are desirable for the advancement of screening programs and the periodic assessment of patients with scoliosis.

The DIPA-S© eHealth capture and analysis system is presented as a new way of evaluating patients with scoliosis, allowing for the extraction of quantitative information from clinical parameters, where measurements can be objectively conducted by professionals, all done entirely remotely.

The aim of this technical report was to present the development and assessment of the measurement accuracy of variables obtained with the (Digital Imaged-based Postural Assessment – Scoliosis) DIPA-S© eHealth Capture app and Analysis software as part of a telehealth assessment protocol for patients with idiopathic scoliosis.

Technical Report

Development

To enable the correct capture of photographic images for subsequent analysis, the development of an application, named DIPA-S© eHealth Capture, was proposed with the aim of minimizing artifacts stemming from the traditional method of acquiring photographic images and facilitating the collection process, as image acquisition will be performed by users in a home environment, without the presence of a healthcare professional, in other words, without a professional or trained evaluator.

The smartphone application DIPA-S© eHealth Capture was programmed in Java with the assistance of the Android Studio 4.1.3 Integrated Development Environment (IDE). To determine the orientation of the smartphone's axes (Figure 1), its internal accelerometer was used. The accelerometer is a sensor that can operate on various principles, such as piezoresistive, piezoelectric, capacitive, etc. However, they all convert the displacement of a known mass into an electrical signal that can then be amplified and used in a wide range of applications. It's worth noting that accelerometers are designed to read in a specific direction of force. Therefore, to obtain 3D acceleration, three orthogonal sensors are required.

Among the sensors available on the smartphone, only the accelerometer was used in this project, as the axis orientations in this research project can be determined statically, since the user will be holding the phone for capturing a photograph.

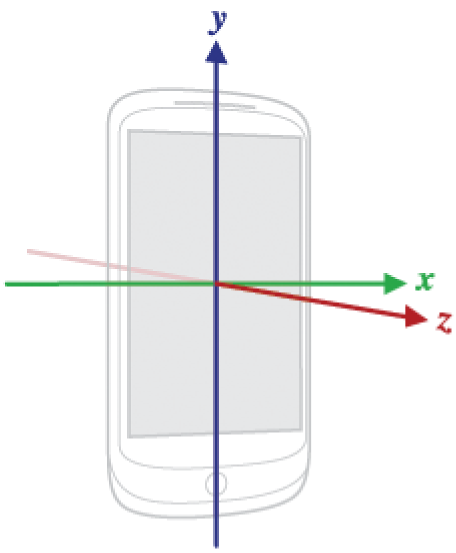


Figure 1. Orientation of local axes on a smartphone. Source: https://developer.android.com/reference/android/hardware/SensorEvent

In programming languages like Java, the use of interfaces is widely spread. An interface is a tool used by developers to require the programmer to implement methods according to their application so that the functions of that interface execute correctly and yield the expected results in each solution. For this application, the SensorEventListener[1] interface was used, making it possible to use the onSensorChanged method (SensorEvent event), which is executed whenever a change in sensor values occurs, at a maximum time interval. This method takes, as an argument, an object of type SensorEvent[2], which contains various information such as the sensor type (in case multiple types are used with the same interface), values read by the sensor, the date on which the values were read, precision, and more.

It's worth noting that the way the interface obtains these values is not within the scope of this technical report and can vary drastically depending on the sensor's operating principle and the Android version in which the application is running. From the application's perspective, this is a significant advantage of using interfaces since the hardware and software developer of the device is responsible for correctly

[1] https://developer.android.com/reference/android/hardware/SensorEventListener
[2] https://developer.android.com/reference/android/hardware/SensorEvent

obtaining and processing the values read by the sensor, while the application programmer is responsible for the correct use of the information obtained from the sensor.

Therefore, with each change in the sensor at a specified time interval, the device's rotation around the Z-axis can be determined by equations 1 and 2:

$$\vec{G} = g_x\vec{\imath} + g_y\vec{\jmath} + g_z\overrightarrow{k} \left[\frac{m}{S^2}\right] \quad \text{equation 1}$$

$$r_Z = \arctan\left(\frac{g_x}{g_y}\right) [rads] \quad \text{equation 2}$$

Where:

$\vec{G}$ => Vector acceleration obtained by the sensor

r_z => Rotation around Z

The rotation around the X-axis of the device is given by equation 3:

$$r_x = \arccos\left(\frac{g_z}{|\vec{G}|}\right) [rads] \quad \text{equation 3}$$

Where:

$\vec{G}$=> Vector acceleration obtained by the sensor

r_x => Rotation around X

Once the values of rotation around X and Z are obtained, image capture is enabled when the rotation around X is between 89° and 91°, and the rotation around Z is between -1° and 1°.

To capture images with the device's camera, the android.hardware.camera2[3] package was used. By using the createCaptureRequest method of a CaptureRequestBuilder object, the camera's preview was created, and with the events of a CameraCaptureSession object, CaptureCallback in conjunction with CaptureRequestBuilder, a photo is automatically obtained and saved on the device.

Measurement accuracy

The sample of this prospective study was composed of consecutive images of a real plumb line (RPL) taken for a physiotherapy student by using the DIPA-S© eHealth Capture app (Figure 2). To assess the measurement accuracy, determining

[3] https://developer.android.com/reference/android/hardware/camera2/package-summary?hl=en

whether the image acquisition occurs without artifacts and with the smartphone perfectly vertical, once the photo was captured the app the DIPA-S© eHealth Capture automatically drew a virtual plumb line (VPL) to ensure the absence of inclination (greater than 1°) during the image acquisition (Figure 2). by.

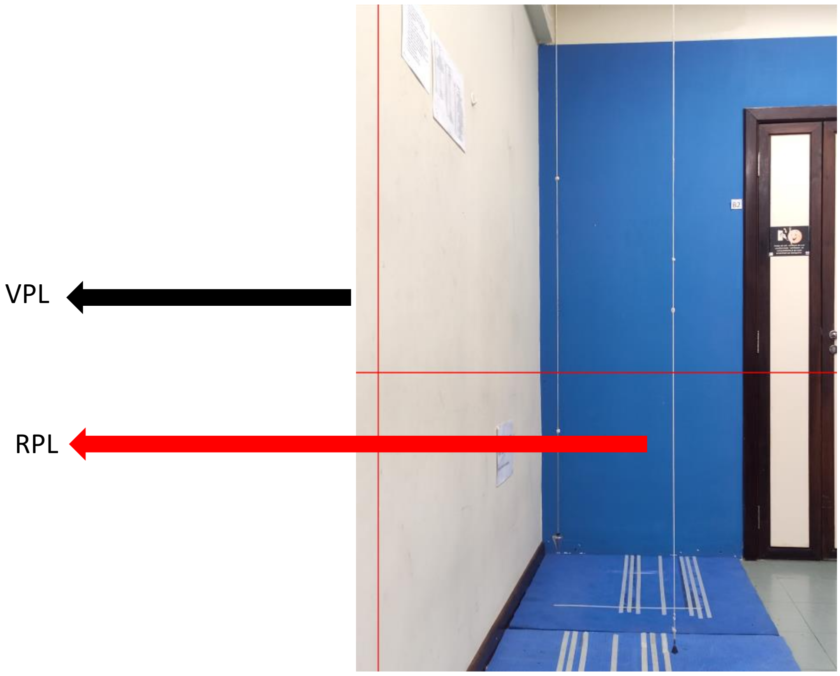


Figure 2. Photos taken using DIPA-S© eHealthcapture. Black arrow indicating the VPL: Virtual Plumb Line (red color); Red arrow indicating the RPL: Real Plumb Line (white color).

The DIPA-S© eHealth Analysis program was developed in the C# (C Sharp) programming language using the Visual Studio development platform with the use of a community license. The programming language was chosen because of its widespread use in developing applications in the Windows environment, while the development platform was selected for its free use in educational projects and academic research. In Figure 3, the application screen is presented, where it is possible to open an image to select an analysis plane (Figure 3).

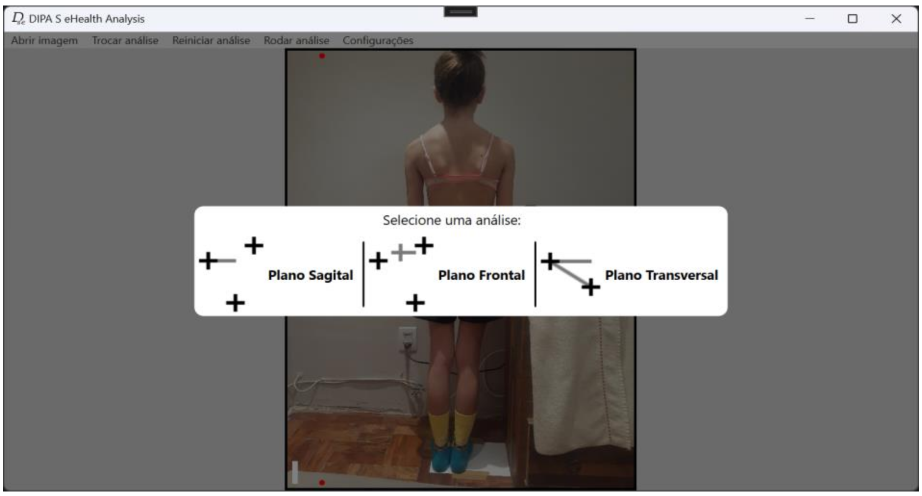
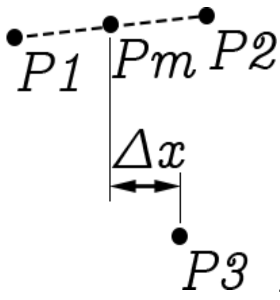


Figure 3. Example of analysis selection.

Depending on the selected analysis, the measurement of variables in each plane will be possible. The mathematical definitions and equations of each variable are described below.

In the frontal plane, the user inputs five points, with the first two exclusively for system calibration by entering a known distance in the image. Next, the midpoint (Pm) between the following two points, P1 and P2, is calculated, and the horizontal variation (Δx) from this midpoint to the third user-input point (P3) is determined, as illustrated in Figure 4 and Equation 4.



$$\Delta_x = \left| \frac{P1_x - P2_x}{2} - P3_x \right| \quad \text{Equation 4}$$

Figure 4. Ilustration of the calculation and Equation performed in the frontal plane analysis.

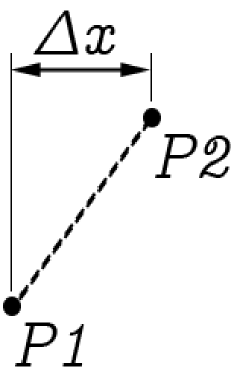
Where:

Δx => distance in millimiters between Pm and P3.

Pm => calculated point

P1, P2 and P3 => cliked points

In the sagittal plane, four points are specified by the user, with the first two dedicated to calibration. Then, two points (P1 and P2) are provided, and the application returns the horizontal distance between them (Δx) in millimeters based on the current mm/pixel conversion. Figure 5 and Equation 5 illustrates the calculation performed in this analysis.



$$\Delta_x = |P1_x - P2_x| \quad \text{Equation 5}$$

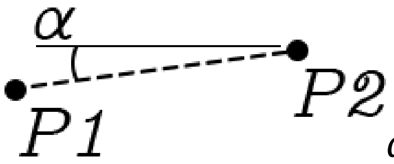
Figure 5. Illustration of the calculation and equation performed in the sagittal plane analysis.

Where:

Δx => distance in millimiters between P1 and P1.

P1 and P2 => cliked points

In the axial plane, only two points are provided by the user (P1 and P2), and then the angle between the horizontal line and the line formed by these points is calculated (α), as shown in Figure 6 and Equation 6.



$$\alpha = arctan\left(\frac{P2_y - P1_y}{P2_x - P1_x}\right)$$ Equation 6

Figure 6. Illustration of the calculation and equation performed in the axial plane analysis.

Where:

α => angle formed by the line connecting the two cliked points (P1 and P2) and the horizontal.

P1 and P2 => cliked points

To measure the inclination of the plumb line (RPL and VPL), the DIPA-S© eHealth Analysis software for the measurement in the axial plane was used (Figure 7). In the software, the image can be input directly from the server, where the images were automatically saved by the DIPA-S© eHealth Capture app, or by opening it from a local folder. This feature of the system will allow the professionals themselves to take measurements using the software from images collected in the home environment by parents or caregivers, eliminating the need for the professional's in-person presence.

In the future, this vertical line will be used to measure actual clinical postural variables as angle of trunk rotation, frontal and sagittal trunk imbalance. The rater clicked on the two extremities of the RPL (greatest distance). The software automatically calculated the angle formed between the straight line that passes through the two points clicked on the RPL and the horizontal reference line. The same procedure was done by the rater for the VPL on the same image.

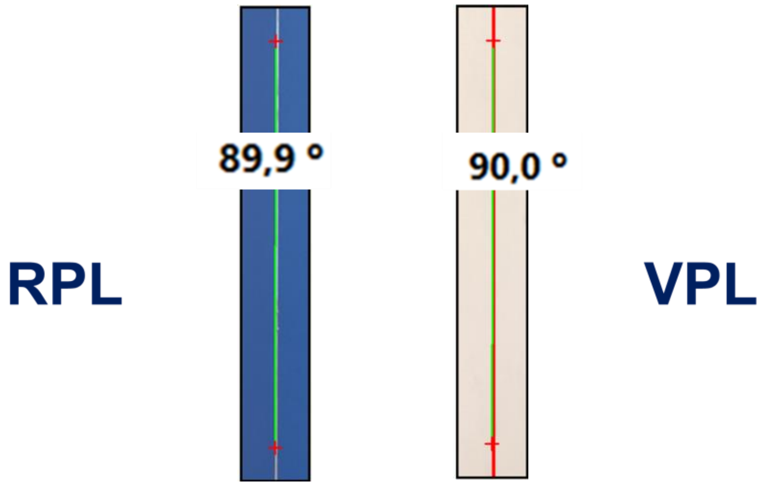


Figure 7. Measurement of the inclination angle of the real and virtual plumb line obtained using the DIPA-S© eHealth analysis software. RPL = 89.9°; VPL = 90°

The Wilcoxon test, median, minimum, maximum, range, mean difference and RMS error were calculated ($p<.05$). A total of 50 images using the App comprised this sample. There was no exclusion or sample loss. The median (min-max) inclination angle of the real and virtual plumb lines was 89.8° (88.6°-90°) with a 1.4° range and 90° (89.4°-90°) with a 0.6° range, respectively. The mean difference between the inclination of the two plumb lines (RPL - VPL) was very small -0.1°±0.04° ($p= 0.017$). The RMS error was 0.3°.

Discussion

The DIPA-S© eHealth capture and analysis system was developed to enable a reliable and accurate assessment of patients with scoliosis through teleconsultation, applied entirely remotely. In addition to its strengths such as dispensing with in-person presence, expanding the reach of specialized professionals in spinal deformities, its use will represent a significant advancement in the acquisition of quantitative postural variables through teleconsultation. A relevant feature of the system is that it will allow the image capture by the parents or care givers at home environment while the measurement of clinical variables in patients with scoliosis can be performed directly by the professionals themselves using the software, reducing sources of error, and increasing its applicability in the follow-up of these patients.

Recognizing the existing gap in the scientific literature and clinical practice regarding the quantitative clinical assessment of scoliosis patients through telemedicine[5], the DIPA-S© eHealth Capture App and Analysis Software could contribute to screening and both the diagnosis and monitoring of patients in the virtual environment. In the future, studies using the DIPA-S© eHealth system by different evaluators and at different times, and even in comparison with in-person clinical assessment and X-ray examination, should be conducted to verify its reproducibility, validity, and diagnostic accuracy.

Conclusion

The DIPA-S© eHealth Capture app and Analysis software for image acquisition and measurement was developed and is ready for testing with patients. The app accurately captures the alignment of the smartphone during the image acquisition and the software shows adequate measurement accuracy for future assessment of idiopathic scoliosis by photogrammetry.

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Declaração de contribuição dos autores

Cada autor contribuiu individual e significantemente para o desenvolvimento deste artigo. Navarro I: Contribuição substancial na concepção ou desenho do trabalho, ou aquisição, análise ou interpretação dos dados para o trabalho, redação do trabalho, aprovação final da versão do manuscrito a ser publicado. Parent E: Contribuição substancial na concepção ou desenho do trabalho, ou aquisição, análise ou interpretação dos dados para o trabalho, redação do trabalho, revisão crítica do seu conteúdo intelectual. Loss J: Contribuição substancial na concepção ou desenho do trabalho, ou aquisição, análise ou interpretação dos dados para o trabalho, redação do trabalho, revisão crítica do seu conteúdo intelectual. Candotti C: Contribuição substancial na concepção ou desenho do trabalho, ou aquisição, análise ou interpretação dos dados para o trabalho, redação do trabalho, revisão crítica do seu conteúdo intelectual.

3 CAPÍTULO 3 – Concurrent Validity And Diagnostic Accuracy Of The Dipa-S© eHealthCapture And Analysis System For The Assessment Of Patients With Scoliosis Through Teleconsultation

Artigo original.

Será submetido à revista *European Spine Journal*.

Concurrent Validity And Diagnostic Accuracy Of The Dipa-S© eHealth Capture And Analysis System For The Assessment Of Patients With Scoliosis Through Teleconsultation

Abstract

Purpose: The growing trend towards new ways of assessing patients with scoliosis in the digital environment, aiming for greater reliability in teleconsultation appointments, has been increasing. The development of assessment tools that do not require in-person presence has been gaining traction; however, there is still a gap in the literature regarding studies on the validity and diagnostic accuracy of new instruments. The aim of this study was to evaluate concurrent validity and diagnostic accuracy, determining cutoff points for variables obtained by the DIPA-S© eHealth capture and analysis system in relation to in-person clinical assessment.

Methods: A cross-sectional study on diagnostic accuracy was conducted between December 2022 and April 2023. Eligibility criteria included age between 7 and 25 years old, the ability to maintain a standing position without help, and leg length discrepancy less than 2 cm. Participants were excluded if they had undergone surgical intervention of the spine, lower limb amputation, or any diagnosable cause of scoliosis. Each participant underwent two procedures: in-person clinical assessment measuring trunk imbalance in frontal (PFTI) and sagittal planes (PSTI) (in millimeters) and the angle of trunk rotation (PATR) (in degrees) and using the DIPA-S© eHealth capture and analysis system measuring FTI, STI, and ATR. The in-person assessment was performed by an experienced physiotherapist, while the capture of images using the DIPA-S© eHealth capture app was performed by a different person (parents, physiotherapist, or surgeon). All analyses were performed using the DIPA-S© eHealth analysis software by the same physiotherapist after the data collection period. For statistical purposes, correlation tests, simple linear regression, Bland Altman plot analysis, and ROC curve were conducted, and the RMS error was calculated ($p < 0.05$).

Results: The sample consisted of 68 patients, 69% girls, with a mean Cobb angle of 29.1°±18.5° and 56% of thoracic curves. The correlation ranged from moderate to very high (0.6, 0.7, and 0.9), with low values of RMS error (10 mm, 20 mm, and 4°) for the frontal, sagittal, and axial planes, respectively. The AUC was excellent only for the ATR measured using the DIPA-S© eHealth with a cutoff point of 4° (Se = 96%; Sp = 95%).

Conclusion: The DIPA-S© eHealth capture and analysis system is valid for measuring postural variables in the frontal (FTI) and transverse (ATR) planes through teleconsultation and has diagnostic accuracy for ATR measurement (cutoff point of 4°).

Keywords: Telemedicine, Telehealth, Telerehabilitation, Posture, Spinal curvatures.

Introduction

Scoliosis is a three-dimensional condition of the vertebral column and trunk that requires periodic monitoring. Traditionally, its diagnosis is conducted through a full spine X-ray. However, clinical variables such as angle of trunk rotation, frontal and sagittal plane trunk balance, shoulder height, and waistline profile are crucial aspects in determining conservative and surgical treatment indications [1].

According to scientific literature, the age group with the highest prevalence of scoliosis is between 10 and 14 years, classified chronologically as adolescent idiopathic scoliosis. It is also in this age range that scoliosis tends to worsen significantly due to the pubertal growth spurt. Thus, monitoring these patients during this phase is essential to prevent curve progression and the consequent need for more aggressive treatments [2].

Over the last 20 years, new validated and accurate tools for diagnosing and monitoring patients with scoliosis have emerged. In this period, there has been a significant effort by the scientific community to minimize the exposure of children and adolescents to ionizing radiation present in repeated X-ray exams. Digital scoliometer, photogrammetry, ultrasound, and surface topography are some of the innovations developed to replace or at least reduce the number of necessary X-ray exams [3].

Currently, there is a growing movement towards new forms of assessment in the digital environment, enhancing the quality of teleconsultation appointments. The significant impact of the coronavirus-induced pandemic, especially in the years 2020 and 2021, intensified the need for teleconsultation appointments in various healthcare areas. This reality contributed to greater access to treatment, facilitating the connection between patients and professionals. The development of assessment methods that do not require in-person presence has been gaining traction; however, the literature remains scarce regarding studies proposing quantitative assessment methods in this format, with confirmed validity and diagnostic accuracy [4].

The new DIPA-S© eHealth capture and analysis system aims to enable a clinical assessment of patients with scoliosis, allowing for the measurement of relevant clinical variables in all three planes, entirely remotely. In this study, we hypothesize that a valid and accurate form of quantitative assessment of patients with scoliosis is possible through teleconsultation. In this context, the objective of this study was to evaluate concurrent validity and diagnostic accuracy, determining cutoff points for variables obtained by the DIPA-S© eHealth capture and analysis system in relation to in-person clinical assessment.

Materials and methods

Study design

This is an observational cross-sectional study. The study adheres to the STARD checklist for cross-sectional studies on diagnostic accuracy [5].

Participants

The sample was consecutive and comprised patients of both sexes. Eligibility criteria included age between 7 and 25 years old, ability to maintain standing position without help, and leg length discrepancy less than 2 cm. Participants were excluded if they had undergone surgical intervention of the spine, lower limbs amputation or any diagnosable scoliosis cause.

Ethical approval was granted by the Research Ethics Committee of the University under the number 52894421.7.0000.5347. Informed consent was obtained from all individual participants included in the study. The individuals participated if they had agreed to be evaluated and for minor age only once their parents had signed the informed consent form before the assessments.

The sample size was calculated using G*Power 3.1.9.4 software based on the family of exact tests (bivariate correlation for normal models), assuming a one-tailed test, with the null hypothesis $H_0 = 0.5$ and alternative hypothesis $H_1 = 0.75$, where $\alpha = 0.05$ and $\beta = 0.80$, resulting in a minimum sample size of 37 subjects. Considering the possibility of sample loss, a 20% margin was added, totaling 45 subjects.

Data collection and analysis procedures

The in-person clinical assessment and capture with the DIPA-S© eHealth system were conducted on the same day, with the capture using the app performed by family members, physiotherapists, or surgeons. The order of assessments was determined by randomization. The analysis of images was only carried out after the end of the data collection period, which spanned from December 2022 to April 2023.

Clinical assessment

For the in-person assessment, patients were wearing minimal clothing, barefoot, and with their hair tied back. Trunk imbalance in the frontal plane (PFTI) and sagittal plane (PFTS) was measured using a laser plumb line and tape measure, and the angle of trunk rotation (PATR) was measured with a scoliometer.

The frontal plane in-person trunk imbalance (PFTI) is defined as the distance in millimeters from the prominent vertebra (C7 or T1) to the laser plumb line passing through the intergluteal cleft (Figure 1). Positive values indicate a displacement of the trunk to the right, and negative values to the left. The patient was positioned with their back to the evaluator, with the intergluteal cleft visible, and feet apart in a self-referenced position. The prominent vertebra (C7 or T1) was palpated and marked, and then the laser plumb line was projected, passing through the intergluteal cleft. Using a tape measure, the distance between the marked point (C7 or T1) and the plumb line was measured [6, 7].

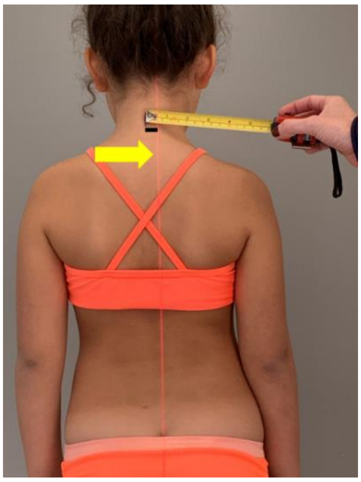


Figure 1. Manual measurement (in-person) with a tape measure and laser plumb line of frontal plane trunk imbalance (PFTI).

The sagittal plane trunk imbalance (PSTI) is defined as the difference in millimeters between the measurement of the distance from the prominent vertebra (C7 or T1) to the plumb line (Figure 2b) and the distance in centimeters from S1 to the plumb line (Figure 2a). Positive values indicate an anterior displacement of the trunk, and negative values indicate a posterior displacement of the trunk [7]. The patient was positioned with the right profile to the evaluator, and the spinous process of the prominent vertebra (C7 or T1) and the first sacral vertebra (S1) were palpated and marked. The laser plumb line was then projected behind the patient without touching any region of the patient's body. The distance between the prominent vertebra and the plumb line and S1 and the plumb line was measured with the tape measure.

Figure 2. a) Linear measurement in centimeters between the sacral vertebra (S1 or S2) and the plumb line in the sagittal plane. b) Linear measurement in millimeters between the prominent vertebra (C7 or T1) and the plumb line in the sagittal plane. PSTI = (b – a)

The in-person angle of trunk rotation (PART) was measured with the scoliometer, defined as the angle formed by the posterior prominence of the ribs or the transverse processes in the lumbar region and the horizontal, during the forward bending of the trunk (Figure 3). The measurements were expressed in degrees with one degree of sensitivity [8].

Figure 3 – Patient and scoliometer positioning for measuring the angle of trunk rotation.

Image capture (DIPA-S© eHealth)

To acquire the images, parents and professionals received a video tutorial describing the preparation of the environment and the capture process. All patients were photographed in minimal clothing, with the intergluteal cleft visible and hair tied back. The patients' positioning was standardized for image acquisition. For capturing the image in the frontal plane from the back and in the sagittal plane on the right profile, they were positioned on top of a sheet of paper (Figure 1a and 1b). For capturing the image from the back, the heels were aligned with the outer edge of this sheet. For capturing the side view image, the right lateral malleolus was aligned with the outer edge of the sheet. The sheet of paper, which had known dimensions (210 mm x 297 mm), was taped to the floor. For capturing the image of the back in the forward bending of the trunk, it was not necessary to position the patient on top of the sheet.

Figure 4. a) Patient positioning on the sheet of paper for capturing the image in the frontal plane. b) Patient positioning on the sheet of paper for capturing the image in the sagittal plane.

The patients were photographed by their own family members or by professionals (physiotherapist or surgeon), using the DIPA-S© eHealth Capture app. Three images were obtained in each position, all in the orthostatic position: back, right profile, and with forward bending of the trunk (posterior view). The app automatically captures the image when the phone is aligned on the X and Z axes (Figure 5), with an accuracy of 1° on each axis (Figure 4), and the images are saved on the server, and can also be sent via email by the user.

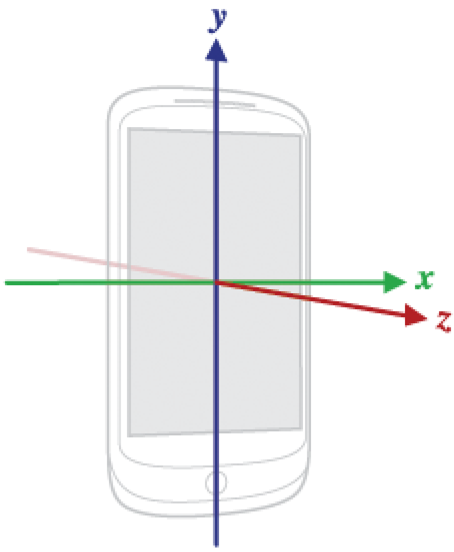


Figure 4. Orientation of the local axes of a smartphone.
Source:https://developer.android.com/reference/android/hardware/SensorEvent

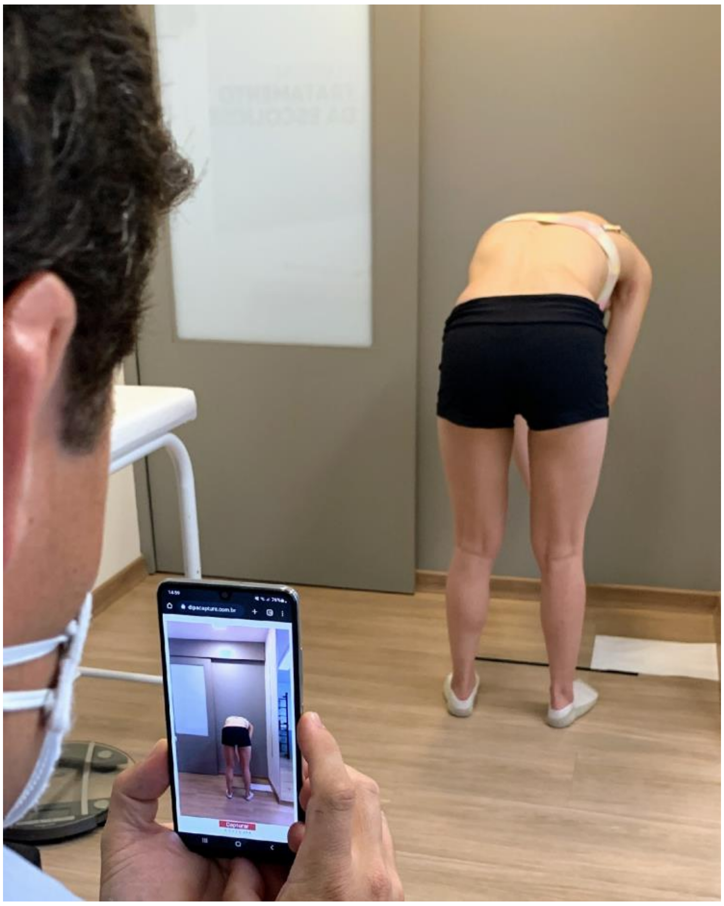


Figure 5. Example of image capture in the axial plane.

Analysis (DIPA-S© eHealth)

The analysis was performed using the DIPA-S© eHealth Analysis software, which allows importing the image from a local folder or the server. In the image obtained in the frontal plane from the back, trunk imbalance in the frontal plane (FTI) was measured in millimeters. FTI is defined as the horizontal distance between the plumb line passing through the intergluteal cleft and the midpoint of the neck (representing C7 or T1). FTI (Figure 6a) indicates deviations in the positioning of the trunk to the right (positive values) or to the left (negative values).

To measure the FTI, the evaluator made five ordered clicks on the image at the following points: two clicks on the paper fixed to the ground, one at each end, necessary for image calibration. One click on the intergluteal cleft, where the virtual plumb line generated by the software is then positioned. Two clicks on the neck, one on each side, at the C7-T1 level, delineating the lateral margin of the neck. From the clicks on the side of the neck, the midpoint between the two points of the lateral margins is calculated. This midpoint is defined as the point representing C7 or T1. From there, the horizontal distance between the plumb line (passing through the intergluteal cleft) and the calculated midpoint of the neck (representing C7 or T1) is calculated.

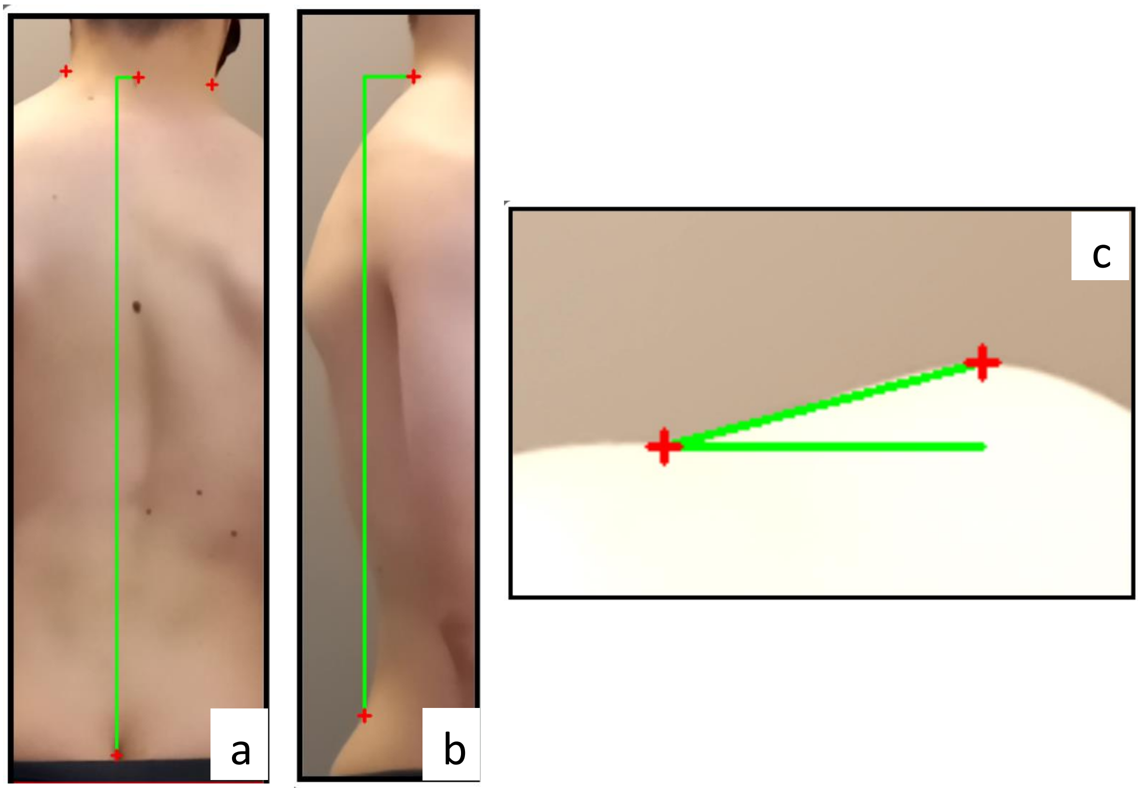


Figure 6. Images obtained in the DIPA-S© eHealth Analysis software. a) Trunk imbalance in the frontal plane (FTI). b) Trunk imbalance in the sagittal plane (STI). c) Angle of trunk rotation (ATR).

In the image obtained in the sagittal plane, in the right profile, the trunk imbalance in the sagittal plane (STI) was measured in millimeters, defined as the horizontal distance between the plumb line passing through S2 and C7 or T1. The

STI (Figure 6b) indicates the position of the trunk in the sagittal plane, pointing out anterior (positive values) or posterior (negative values) deviations. The evaluator made four ordered clicks in the image at the following points: two clicks on the fixed sheet on the ground, one at each end, one click on the point representing S2 in the image, where the virtual plumb line generated by the software passes, and one click on the point representing the spinous process of the vertebra C7 or T1.

In the image obtained in the axial plane, with the patient positioned to allow a posterior view of the forward bending of the trunk, the angle of trunk rotation (ATR) in degrees was measured. The ATR (Figure 6c) is defined by the angle formed by the line passing through the points of the gibbosity on each hemibody (right and left), i.e., the apices (highest and lowest) on each side, and the horizontal. The evaluator made two clicks, one at the apex (highest and lowest point) of each hemibody (right and left), close to the spine.

Statistical analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 20.0, and the MedCalc software. For concurrent validity analysis, the correlation test (Pearson or Spearman), simple linear regression for developing correction equation, RMS error calculation, and Bland & Altman graphical analysis were performed. The correlation values were classified as follows: "insignificant" (<0.3); "low" (0.3 to <0.5); "moderate" (0.5 to <0.7), "high" (0.7 to <0.9), and "very high" (>0.9) [9]. In this study, correlation values above 0.7 were accepted as true to indicate concurrent validity between in-person assessment and teleconsultation (DIPA-S© eHealth capture and analysis system).

To verify diagnostic accuracy, ROC curve analysis (Receiver Operating Characteristic) was conducted to determine the sensitivity and specificity of the cutoff points for variables obtained through DIPA-S© eHealth teleconsultation. The area under the curve (AUC) was classified as having no or low discriminative ability (0.5 to 0.7), moderate discriminative ability (0.7 to 0.9), and high discriminative ability (≥ 0.9) [10]. In this study, values of the area under the curve above 0.7 were accepted as true to indicate diagnostic accuracy of the DIPA-S© eHealth capture and analysis system in identifying scoliosis.

Results

Seventy patients were evaluated, of which two were excluded due to having diagnosable causes of scoliosis (Scheuermann's Disease and neurofibromatosis). During the frontal plane analysis, one patient was excluded due to image quality issues (n=67), and the same occurred during the sagittal plane analysis (n=67).

The total sample consisted of 68 patients, with 47 girls (69%). The mean age was 13.9±4 years, body mass 49.1±14 kg, and height 157.1±11 cm. The average Cobb angle was 29.1°±18.5°, with 56% of the curves in the thoracic region (n=38). Additionally, 31% of the patients (n=21) were undergoing treatment with a brace, in addition to physiotherapeutic scoliosis specific exercises.

Concurrent validity

For concurrent validation, the correlation between the variables obtained through teleconsultation with the DIPA-S© eHealth and the in-person assessment was positive and significant. The correlation was high for the variable in the frontal plane (FTI), moderate for the variable in the sagittal plane (STI), and very high for the variable in the axial plane (ATR) (Table 1). The R^2 values ranged from 0.32 to 0.83, and the correction equations obtained through simple linear regression analysis and their respective coefficients are described below:

Correction equations for the variables FTI, STI, and ATR obtained through teleconsultation using the DIPA-S© eHealth.

$$FTI = 0{,}6045 * PFTI - 0{,}7715$$

$$STI = 0{,}4809 * PSTI + 24{,}936$$

$$ATR = 0{,}8255 * PATR - 0{,}0863$$

Table 1. Correlation between in-person clinical assessment and teleconsultation using the DIPA-S© eHealth.

	n	In-person assessment	DIPA-S© eHealth	Correlation	p	R^2	RMS error
*FTI (mm)	67	-5,6±12,8	-4,3±7,4	0,7	<0,001	0,40	10
STI (mm)	67	30,1±18,4	43,9±7,5	0,6	<0,001	0,32	20
*ATR (°)	68	2,6±9,1	1,6±6,8	0,9	<0,001	0,83	4

FTI: Frontal Trunk Imbalance; STI: Sagittal Trunk Imbalance; ATR: Angle of Trunk Rotation; n: sample size; RMS: Root Mean Square; * Spearman's Correlation.

In the Bland & Altman graphical analysis, the mean difference for FTI was -2.34 mm, for STI was -13.8 mm, and for ATR was 0.99°. A total of n=6 (FTI), n=3 (STI), and n=4 (ATR) subjects were observed outside the limits of agreement in the analysis of frontal, sagittal, and axial planes, respectively, as presented in Figures 5, 6, and 7. Additionally, a trend line in the data dispersion was observed in the frontal and sagittal plane analyses (Figures 5 and 6), indicating that the higher the measured value, both for FTI and STI, the greater the associated error and the lower the agreement between in-person and remote assessment. In Figure 7, no trend line in data dispersion was observed, indicating a lower associated error in different magnitudes of ATR measurements and better agreement between the measures.

Figure 5. Bland & Altman graphical analysis (PFTI X FTI) for the variable obtained in the frontal plane through teleconsultation using DIPA-S© eHealth.

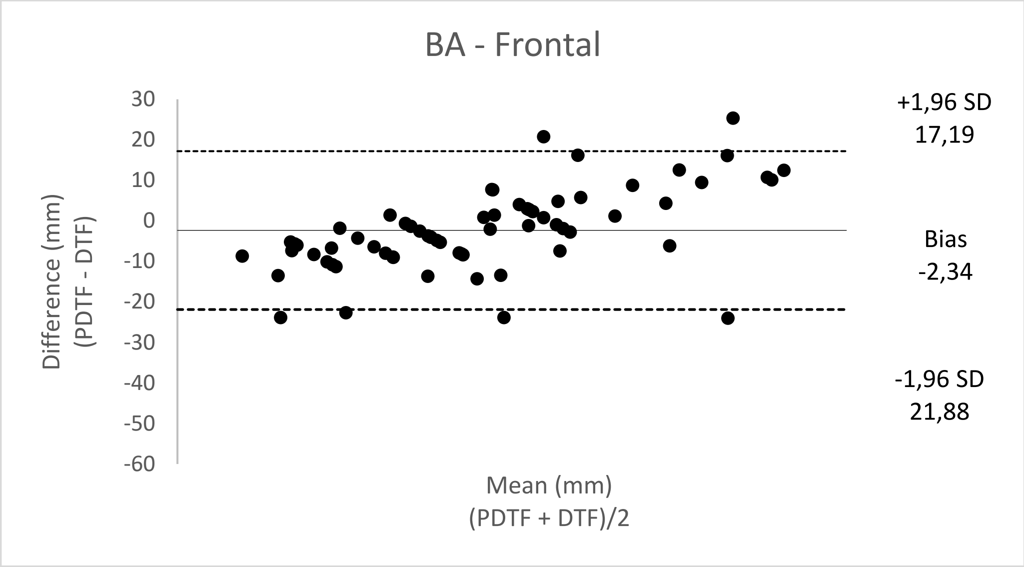


Figura 6. Bland & Altman graphical analysis (PSTI X STI) for the variable obtained in the sagittal plane through teleconsultation using DIPA-S© eHealth.

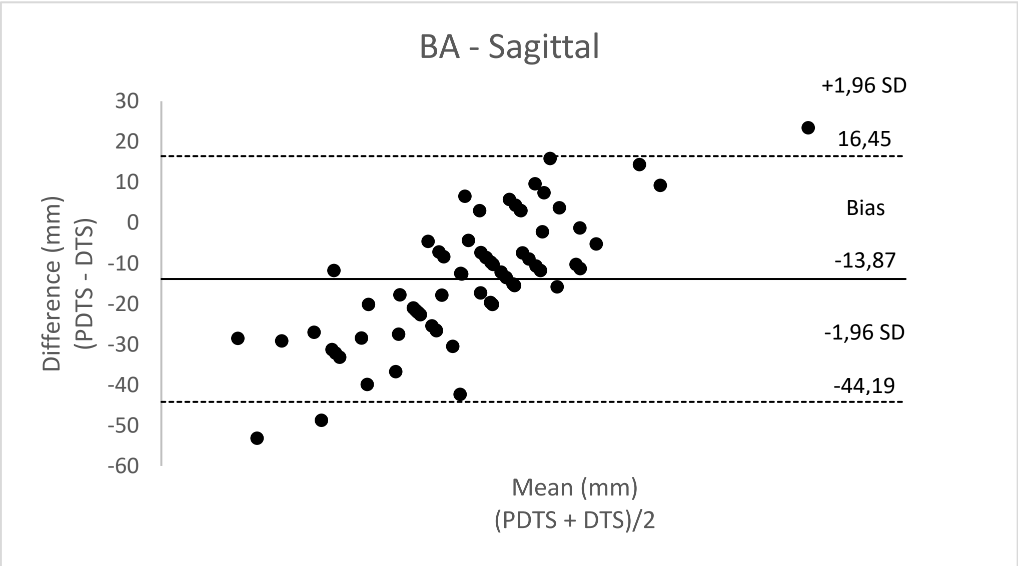
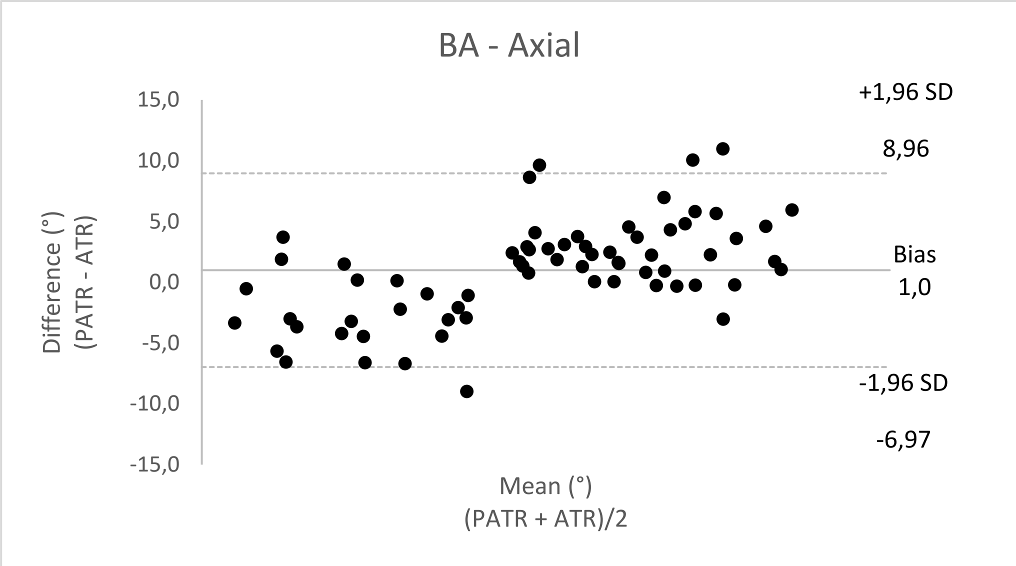


Figura 7. Bland & Altman graphical analysis (PATR X ATR) for the variable obtained in the axial plane through teleconsultation using DIPA-S© eHealth.



Diagnostic accuracy

For diagnostic accuracy, ROC curve analysis was performed, adopting the values obtained with the scoliometer in the in-person assessment as the gold standard reference. The sample is described in the flowchart (Figure 8).

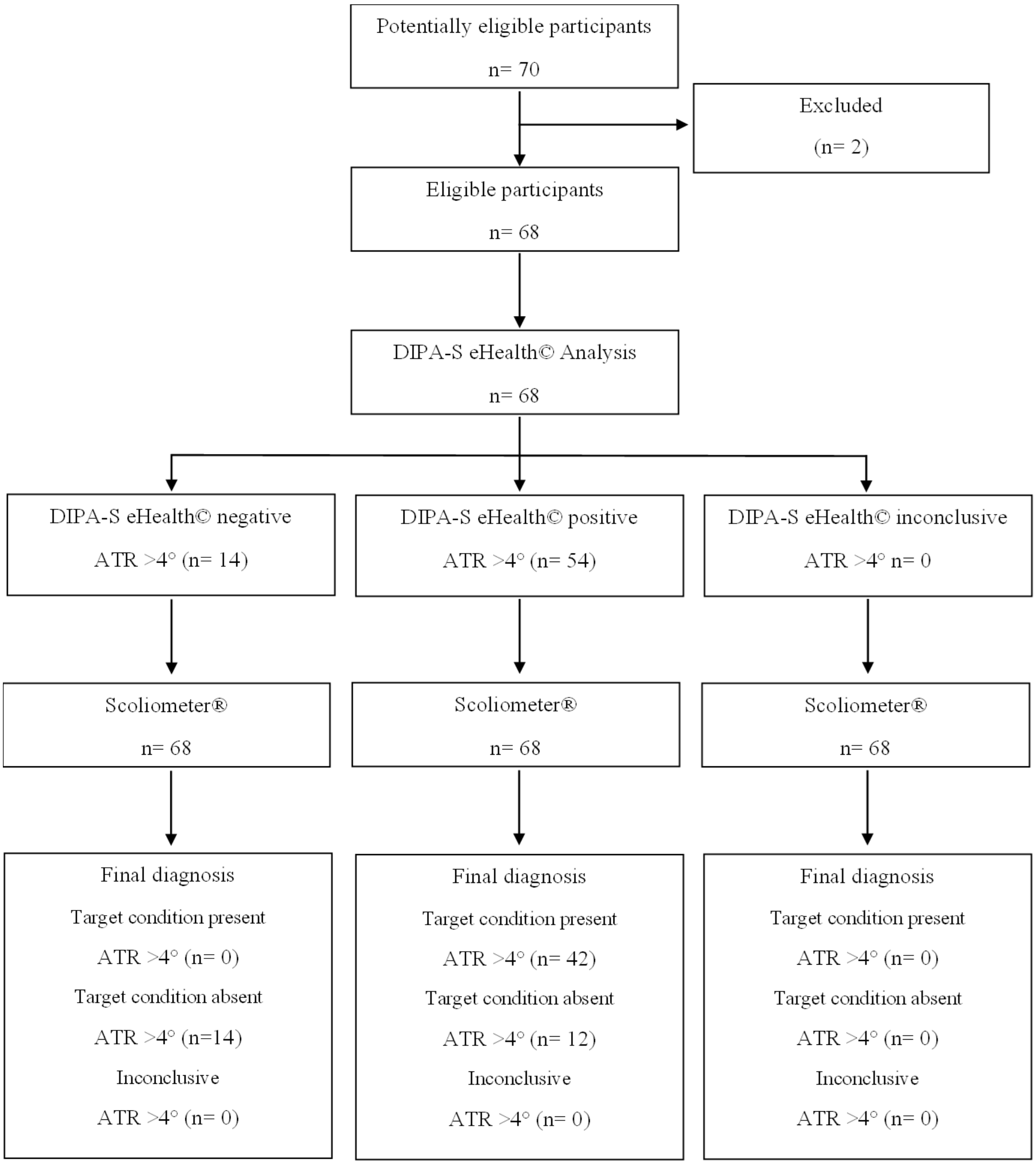


Figure 8. Flow diagram of the participants. ATR: angle of trunk rotation.

Values of low discriminative capacity were found for the variables FTI (58%) and STI (60%), but high discriminative capacity for the variable ATR (97% with $p<0.001$), as shown in Figures 9a, 9b, and 9c, respectively. The cutoff point of 4° for ATR showed the best values for sensitivity (96%) and specificity (95%). As an additional exploratory analysis, ROC curves were performed using the Cobb angle as the gold standard reference, and the analyses are available in Appendix 1.

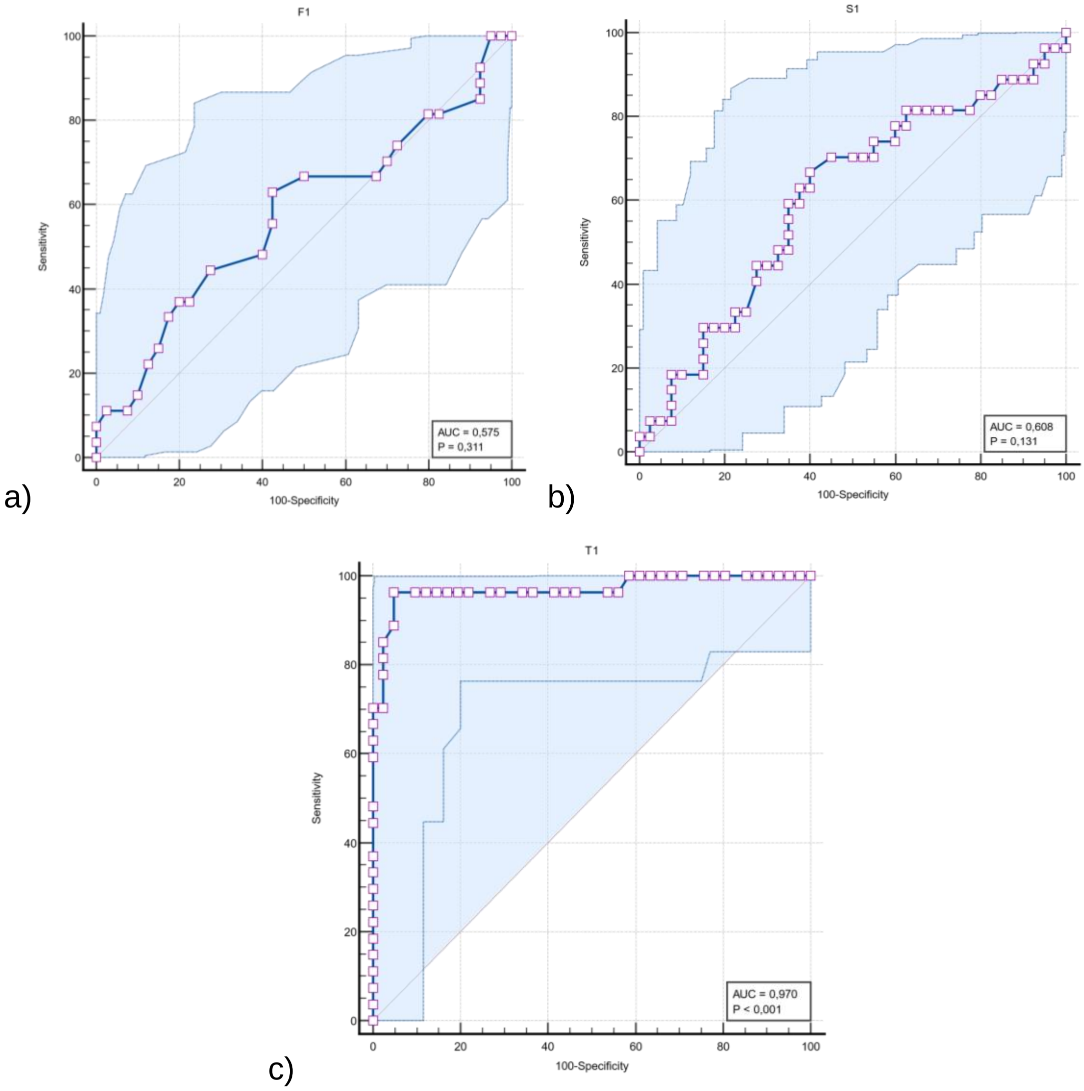


Figure 9. a) ROC Curve for FTI variable with scoliometer as reference. b) ROC Curve for STI variable with scoliometer as reference. c) ROC Curve for ATR variable with scoliometer as reference.

Discussion

The new DIPA-S© eHealth capture and analysis system was developed to fill a gap in the scientific literature and, more importantly, in clinical practice, aiming to provide a valid and accurate way to clinically evaluate patients with scoliosis entirely remotely. The correlations of the variables obtained in the in-person and teleconsultation assessments ranged from moderate to very high (0.6 to 0.9), with acceptable RMS error values and good agreement. However, only the ATR variable (axial plane) showed diagnostic accuracy when compared to the scoliometer as the clinical reference standard (AUC 97%; p<0.001).

The use of photogrammetry has been widely explored and is seen as a valuable assessment tool in clinical practice for patients with scoliosis [11, 12]. Photogrammetry provides a reliable method for evaluating various relevant variables in monitoring patients with scoliosis. It is easy to use, cost-effective, and does not involve ionizing radiation [13]. Although highly useful, its application is based on and dependent on a specific protocol. This protocol requires the preparation of the environment for camera positioning with fixed distance and height, the inclusion of a visible real plumb line during image acquisition, palpation and marking of anatomical reference points, among other aspects related to the detailed protocol associated with the technique.

The intrinsic characteristics of photogrammetry protocols currently require in-person execution, and, as far as we know, there are no protocols for using photogrammetry in a virtual environment, specifically in the context of telemedicine. The DIPA-S© eHealth capture and analysis system introduces a new way of employing photogrammetry for the evaluation of patients with scoliosis through telemedicine, eliminating the need for in-person presence.

The three-dimensionality of scoliosis necessitates assessment tools capable of measuring changes in all three planes. Similar to radiography, where variables are obtained from different views of the patient (anteroposterior and lateral X-rays), clinical evaluation using photogrammetry requires images from different planes.

In the frontal plane, the image used by DIPA-S© eHealth was captured with the patient in the orthostatic position facing backward. In this image, the Frontal Trunk Imbalance (FTI) was measured, showing a high correlation with the in-person clinical assessment and a low Root Mean Square (RMS) error (ρ= 0.7; 10 mm; mean difference = -2.34 mm). Similarly, in the study by Fortin et al., 2010, the authors evaluated 50 patients in-person using photogrammetry and compared it with radiography. The mean frontal trunk imbalance was 11.4±19.7 mm, and the study also demonstrated a correlation of 0.76 between photogrammetry and trunk imbalance measured in X-ray examinations [14].

In the study by Zheng et al., 2023, the variable called C7 deviation was defined as "the distance between C7 and virtual plumb line across the gluteal cleft," precisely what we referred to as Frontal Trunk Imbalance (FTI) in our study. The authors found a low correlation (from -0.01 to 0.5) between C7 deviation and the Cobb angle for different curve topographies (thoracic, thoracolumbar, and lumbar) [15]. It is noteworthy that both in Fortin's study and Zheng's study, photogrammetry assessments were conducted in- person.

In the ROC curve analysis, using the scoliometer as a clinical reference, the Frontal Trunk Imbalance (FTI) variable showed low discriminative capacity, with a non-significant area under the curve of 58%. Considering the low discriminative capacity found, it was not feasible to establish a cutoff point for DTF. Although frontal trunk imbalance is a common alteration among scoliosis patients [16], no studies were found using this variable for scoliosis diagnosis through ROC curve analysis.

The clinical assessment of trunk position in the frontal plane in patients with scoliosis has implications for both conservative [17] and surgical [18] treatment, making it a relevant variable in the clinical practice of various professionals involved in the spectrum of scoliosis treatment. The ability to measure Frontal Trunk Imbalance (FTI) without the need for in-person visits, as demonstrated by DIPA-S©

eHealth in this study, represents a significant advancement in the use of telemedicine for the assessment and monitoring of patients with scoliosis.

The assessment of changes in the sagittal plane is an important aspect for patients with scoliosis [19]. Radiographic parameters typically measured in the evaluation of the sagittal plane include thoracic kyphosis and lumbar lordosis, as well as spinopelvic parameters that are especially crucial in adults. The well-known angular measurements of the sagittal plane are complemented by the linear measurement of global trunk balance in the sagittal plane (in millimeters), called the Sagittal Vertical Axis (SVA). The SVA informs about the position of the trunk in the sagittal plane by establishing the relationship between the line passing through the center of the body of C7 and the posterior region of the sacrum, characterizing anterior imbalances of C7 in relation to the sacrum with positive values and posterior imbalances of C7 in relation to the sacrum with negative values [20].

Many of these radiographic variables can also be clinically measured, such as thoracic kyphosis and lumbar lordosis, using different instruments like the flexicurve, photogrammetry, and sagittal index (plumb line distances) [7, 21, 22]. Additionally, sagittal balance (SB) corresponds to SVA and determines the position of the trunk in the sagittal plane clinically. SB is defined as the difference between the distances from C7 and S2 to the plumb line. In our study, we used SB, measured as sagittal trunk imbalance (STI). We found a moderate correlation between the in-person clinical assessment and teleconsultation with a low RMS error value ($r = 0.6$; RMS error 20 mm; mean difference = -13.8 mm).

Negrini et al., 2019 presented reference values for SB in a study with 584 healthy subjects. The authors indicated 19.3±17 mm as the reference value for SB, characterizing a balanced trunk [7]. In our study, the mean STI obtained through teleconsultation was 43.9±7.5 mm, while the mean of the in-person assessment (PSTI) was 30.1±18.4 mm, indicating an anterior trunk imbalance in the studied sample.

The variable STI showed low discriminative capacity using the scoliometer as the clinical reference standard (AUC 60%; $p= 0.131$). Other studies have also used ROC curves in analyses involving surface measurements in the sagittal plane, such as photogrammetry and surface topography. Negrini et al., 2016, presented a moderate discriminative capacity (AUC 83%) in identifying junctional kyphosis through surface topography compared to X-ray examination [23]. Navarro et al., 2021, showed discriminative capacities ranging from moderate to excellent (86% and 93%) for cutoff points determining hyperkyphosis and hypokyphosis in surface topography compared to photogrammetry as the clinical reference standard [24]. However, no studies were found analyzing the diagnostic accuracy of trunk position given by SVA or its clinical equivalent, SB, for patients with scoliosis.

The DIPA-S© eHealth capture and analysis system was developed to quantify postural variables in all three planes, considering the three-dimensionality of scoliosis. Among the three variables obtained with DIPA-S© eHealth the ATR (transverse plane) showed the best performance in terms of validity ($\rho = 0.9$; RMS error 4°; mean difference = 1°), being the only variable with high discriminative capacity (cutoff point 4°; Sensitivity = 96%; Specificity = 95%; AUC 97%; $p<0.001$). The scoliometer has been widely used as a reliable tool for screening and monitoring patients with scoliosis due to its high diagnostic accuracy [25].

In addition to its direct use on the patient's trunk during the Adams test, tools similar to the scoliometer have been developed. The initiative includes simple tools such as the "torsion bottle," as well as photogrammetry and the use of artificial intelligence [11, 26, 27]. Although it is very useful in clinical practice, influencing clinical decision-making, most studies involve in-person use of the scoliometer or similar tools.

In the study conducted by Romano and Mastrantonio in 2018 [26], a high agreement was found between the measurements taken by the torsion bottle and the scoliometer (kappa = 0.9278; standard error = 0.7094), using the same reference cutoff point for the scoliometer adopted in our study (ATR ≥ 7°). Navarro et al., 2019 found an excellent correlation between photogrammetry and the scoliometer for ATR measurement, also indicating a high discriminative capacity in the use of photogrammetry for scoliosis diagnosis, using the scoliometer as the clinical reference standard (AUC ≥ 90%) [11]. Negrini et al., 2023 developed artificial intelligence prediction models based on ATR in combination with other easily collected clinical variables for non-invasive scoliosis screening. The models showed moderate accuracy (from 74% to 84%) for different cutoff points, always including ATR among the five most important for prediction [27].

In the study by Beauséjour et al., 2022, the authors used the scoliometer through a smartphone app for ATR measurement performed by parents at home, eliminating the need for a professional's presence. The authors found an agreement between non-professionals and the expert in 83% to 90% of cases on the identification of the threshold to seek medical advice (ATR ≥ 6 °) [28]. Similarly, our study showed a high discriminative capacity (AUC 97%) in ATR measurement using the DIPA-S© eHealth capture and analysis system. Importantly, we emphasize a positive aspect of the DIPA-S© eHealth use, where, in addition to the confirmed diagnostic accuracy, the ATR measurement is performed by the professional entirely remotely.

Larson et al., 2018, demonstrated in a retrospective study with 59 patients with scoliosis that the use of the scoliometer reduces exposure to ionizing radiation from 0.4 to 0.62 millisieverts of radiation in pre-menarcheal (stable and unstable) and post-menarcheal groups, also reducing costs with radiographs by up to $161.76 per patient [29]. The authors emphasize the importance and benefits of clinical monitoring through ATR measurements. However, they based their significant findings on assessments conducted by professionals only in-person.

According to Pereira et al., 2022, there was a significant decrease in the number of initial specialized consultations for spinal deformities during the COVID-19 pandemic caused by the novel coronavirus. Consultations had a significant reduction in 2020 ($p<0.001$), being less than 75% between April and June when compared to 2019. The authors also noted that in 2020, 22% of appointments were conducted online. Furthermore, idiopathic scoliosis (IS) was the primary diagnosis in 50% of patients observed for the first time during the three-year period (2019-2021). There was an 18% increase in the number of IS patients requiring bracing in 2021. The authors emphasized that the increase in the percentage of patients needing bracing might reflect a delayed first consultation [30]. These findings reinforce the importance of a reliable and accurate protocol for the evaluation (screening and diagnosis) of patients with scoliosis through teleconsultation.

As a limitation of this study, we can mention the difficulty families faced in capturing images using the DIPA-S© eHealth capture app due to its high sensitivity for automatic image acquisition, requiring skill in handling the phone during capture. Additionally, the use of the system is limited to children, adolescents, and young adults, as per the age range tested in this study (7 to 25 years). However, it is known that significant changes in trunk sagittal balance occur during aging, making it desirable to have a reliable and accurate way to measure postural variables through teleconsultation in older individuals as well.

Conclusion

The results obtained in our study indicate that the DIPA-S© eHealth capture and analysis system is a valid form of assessment for measuring postural variables in the frontal (FTI) and axial (ATR) planes through teleconsultation when compared to in-person clinical assessment. Furthermore, the system demonstrated diagnostic accuracy for ATR measurement, with a cutoff point of 4° and high discriminative capacity.

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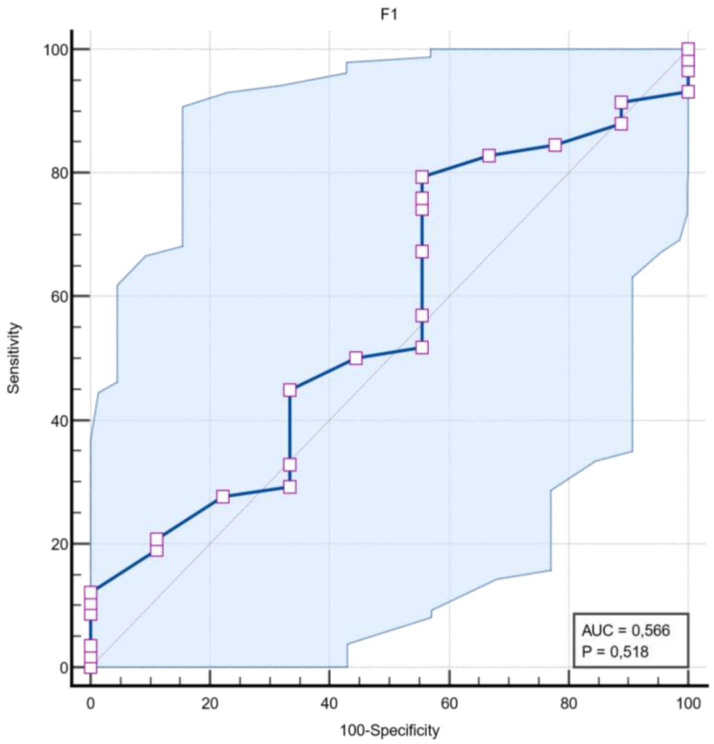
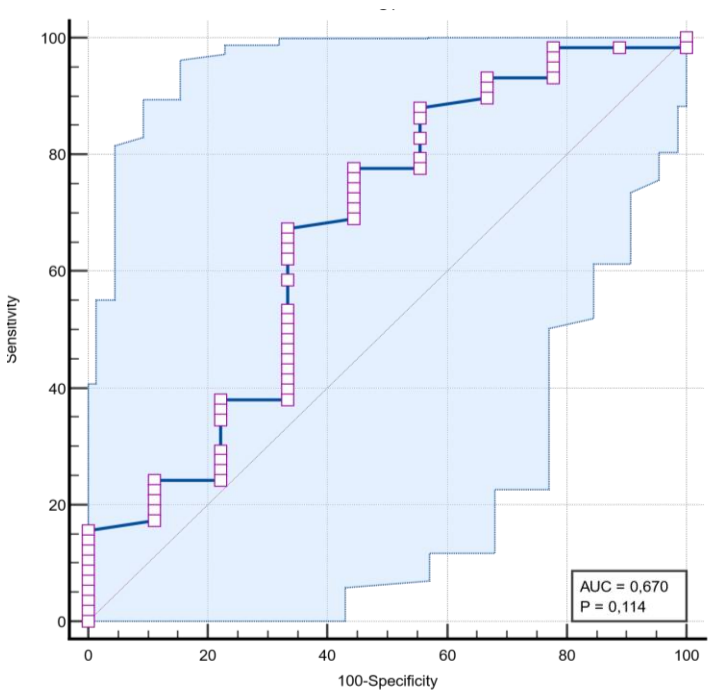
Apêndice

Nas análises de curva ROC adotando o ângulo Cobb como padrão-ouro de referência foram encontrados valores de área sob a curva de baixa capacidade discriminatória para as três variáveis, sendo DTF 57% (p>0.05), DTS 67% (p>0.05) e ART 64% (p= 0,02), não sendo confiável estabelecer pontos de corte para cada variável.

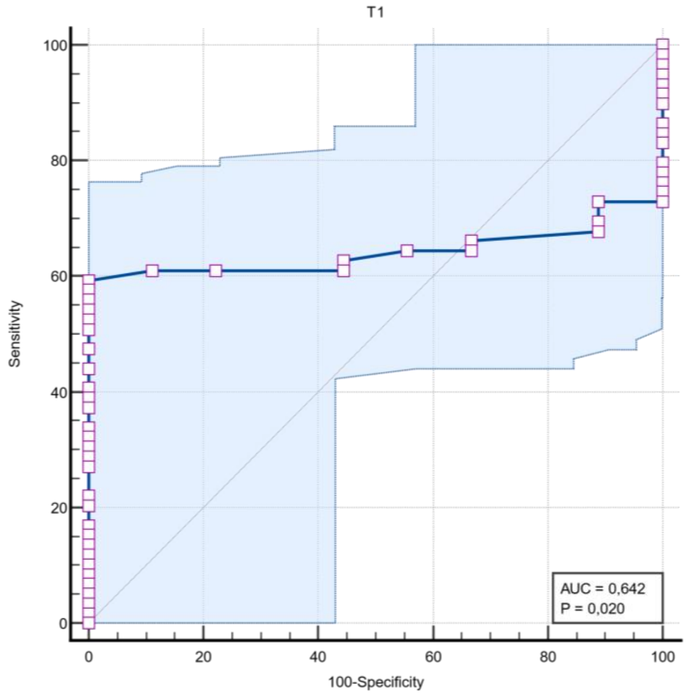
1.Curva ROC para variável DTF com Cobb como referência.



2.Curva ROC para variável DTS com Cobb como referência.



3. Curva ROC para variável ATR com Cobb como referência.



4 CAPÍTULO 4 – Repeatability And Intra And Interrater Reproducibility Of The Dipa-S eHealth© Capture And Analysis System For Clinical Assessment Of Scoliosis

Artigo original.

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Repeatability And Intra And Interrater Reproducibility Of The Dipa-S eHealth© Capture And Analysis System For Clinical Assessment Of Scoliosis

Abstract

Purpose: To assess the repeatability, intra and interrater reproducibility of the DIPA-S eHealth© system for capturing and measuring clinical variables of scoliosis, including frontal trunk imbalance (FTI), sagittal trunk imbalance (STI), and angle of trunk rotation (ATR).

Methods: Patients were photographed using the DIPA-S eHealth Capture© mobile application by family members, physiotherapists, or surgeons. Three photos were taken in each position: standing in the frontal and sagittal planes and in the axial plane in forward bending position of the trunk. The photos were analyzed by three independent evaluators using the DIPA-S eHealth Analysis© software. For repeatability, each photo was analyzed twice consecutively by the three evaluators. For intrarater reproducibility, only one evaluator reanalyzed the first photo from each plane with a 5-day interval. For interrater reproducibility, the three evaluators analyzed the first photo from each plane. The intraclass correlation coefficient (ICC), standard error of measurement (SEM), and minimal detectable change (MDC) were used ($p < 0.05$).

Results: The sample comprised 262 images (n=30). Repeatability was excellent for all three evaluators in all three planes (ICC 0.94 to 1.00). Intrarater reproducibility was excellent in all three planes (ICC 0.88 to 0.99). Interrater analysis was excellent for the frontal and axial planes (ICC 0.98 and 0.93), respectively. However, it was weak in the sagittal plane ICC 0.32. The SEM ranged from 0.02 to 17.6 and MDC from 0.03 to 34.6.

Conclusion: The DIPA-S eHealth© Capture and Analysis system demonstrates reproducibility for use in the clinical assessment of scoliosis through teleconsultations.

Keywords: Telemedicine, Posture, Scoliosis, Reproducibility of Results.

Introduction

The quantitative assessment of patients with scoliosis is a crucial aspect for diagnosis and monitoring, as well as being essential for clinical decision-making concerning various treatment indications [1]. Technological advancements and the rapid shift to the digital realm have brought innovations in assessment tools, along with the possibility of providing care through teleconsultation [2, 3].

While scoliosis is known for its three-dimensionality, the gold standard for diagnosis and monitoring of the condition remains the full X-ray spine examination in standing position [4, 5]. However, clinical assessment is highly recommended by experts in the field and should be performed in conjunction with or even as a substitute for radiography when possible. It allows for the quantification of clinical variables that enable the measurement of different aspects of the alteration caused by scoliosis in all three planes and in different structures (spine, thorax, and trunk) [6].

The new scoliosis clinical assessment protocol proposed by the DIPA-S eHealth© capture and analysis system seeks a reliable way to measure relevant clinical variables widely used in face-to-face scoliosis patient assessments through teleconsultation. The DIPA-S eHealth© capture and analysis system was developed to enable assessment where in-person patient contact is not possible or necessary, applying a fully remote protocol.

Recognizing the importance of early scoliosis diagnosis and the potential for rapid progression during growth spurts, new methods of screening, assessment, and monitoring are desirable. Clinical assessment via teleconsultation is an excellent alternative to expand the availability of a detailed examination of scoliosis patients. However, this attractive and necessary new assessment tool must always undergo scientific procedures to verify its reliability.

The reproducibility of measurements obtained by a new instrument is an essential aspect of its use in both clinical practice and the scientific community [7]. In this study, we hypothesized that a reliable assessment of patients with scoliosis is possible through teleconsultation. Our objective was to assess the repeatability, intra and interrater reproducibility of the DIPA-S eHealth© capture and analysis system for measuring clinical variables of scoliosis: Frontal Trunk Imbalance (FTI), Sagittal Trunk Imbalance (STI), and Angle of Trunk Rotation (ATR) through teleconsultation.

Materials and methods

Study design

This is an observational, cross-sectional study. The study adheres to the GRRAS checklist [7] for cross-sectional studies on reliability and agreement.

Participants

The sample was consecutive and comprised patients of both genders. Eligibility criteria included age between 7 and 25 years old, the ability to maintain a standing position without assistance, and leg length discrepancy less than 2 cm. Participants were excluded if they had undergone spinal surgery, lower limb amputation, or had a diagnosable cause of scoliosis. Ethical approval was granted by the Research Ethics Committee of the University under the number 52894421.7.0000.5347. Informed consent was obtained from all individual participants included in the study. For minors, their parents signed the informed consent form before the assessments.

The sample size was determined based on the study by Walter, Eliasziw, and Donner (1998) [8]. A significance level of 5% and a power of 80% were used, with H_0 ICC of 0.5 and H_1 of 0.80 [9]. Considering that each set of images obtained from teleconsultation would be evaluated twice, this resulted in a minimal sample of 22 individuals.

Data Collection and Analysis Procedures

Image Capture

To obtain the images, parents and professionals received a video tutorial describing the setup of the environment and the image capture procedure. All patients were photographed in minimal clothing, with the intergluteal cleft visible and their hair tied back. Patient positioning was standardized for image acquisition. For capturing the image in the frontal plane from the back and in the sagittal plane on the right profile, they were placed on top of a sheet of paper (figure 1a and 1b). To capture the back image, their heels were aligned with the outer edge of this sheet. For capturing the profile image, the right lateral malleolus was aligned with the outer edge of the sheet. The sheet of paper had known dimensions (210 mm x 297 mm) and was secured to the ground with adhesive tape. For capturing the image of the back in a forward bending of the trunk position (axial plane), there was no need for the patient to be positioned on the sheet.

Figure 1a. Patient Positioning for Image Capture in the Frontal Plane. 1b. Patient Positioning for Image Capture in the Sagittal Plane.

The patients were photographed by their own family members or by professionals (physiotherapists or surgeons) using the DIPA-S eHealth Capture© app. Three images were obtained in each position, all of them in the orthostatic position: from the back, right profile, and in forward bending of the trunk (posterior view). The app automatically captures the image when the smartphone is aligned on the X and Z axes (Figure 2), with an accuracy of 1° on each axis (Figure 3), and the images are saved on the server, which also allows users to send them via email.

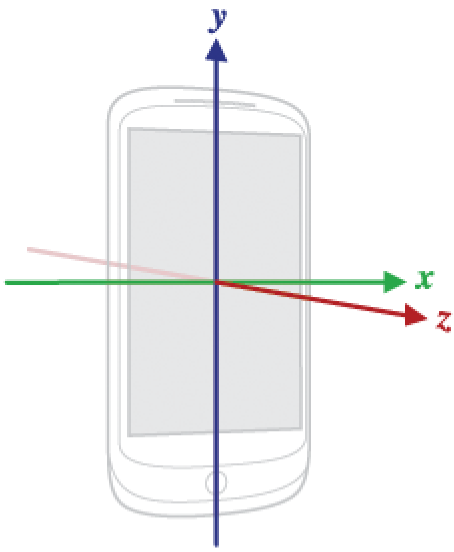

Figure 2. Orientation of local smartphone axes. Source: https://developer.android.com/reference/android/hardware/SensorEvent

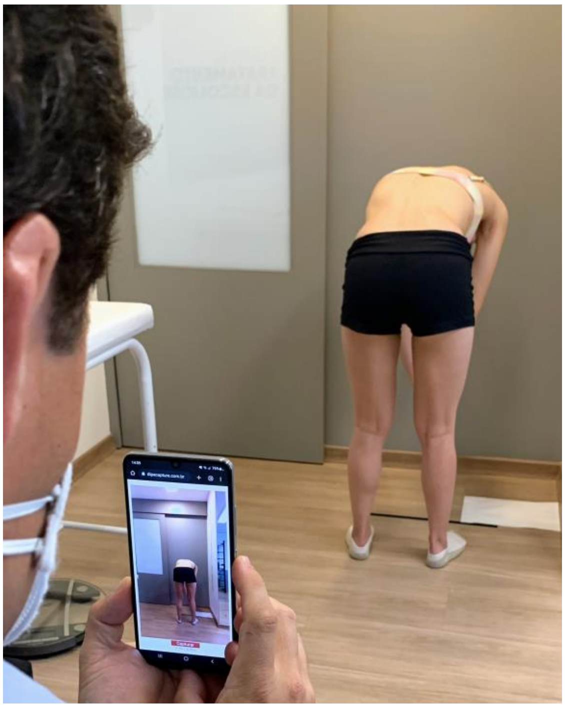

Figure 3. Example of image capture in the axial plane.

Image Analysis

The analysis was conducted using the DIPA-S eHealth Analysis© software, which allows image import from a local folder or the server. In the image obtained in the frontal plane of the back, the frontal trunk imbalance (FTI) was measured in millimeters. FTI is defined as the horizontal distance between the plumb line passing through the gluteal cleft and the midpoint of the neck (representing C7 or T1). FTI (Figure 4a) indicates deviations in trunk positioning to the right (positive values) or to the left (negative values).

For this purpose, the evaluator performed five ordered clicks on the image at the following points: two clicks on the sheet fixed to the floor, one at each end, which were necessary for image calibration. One click on the gluteal cleft, where the virtual plumb line generated by the software was then positioned. Two clicks on the neck, one on each side, at the level of C7-T1, delimiting the lateral margin of the neck. From the clicks on the neck's sides, the midpoint between the two points of the lateral margins was calculated, which is defined as the point representing C7 or T1. From there, the horizontal distance between the plumb line (passing through the gluteal cleft) and the calculated midpoint of the neck (representing C7 or T1) was measured.

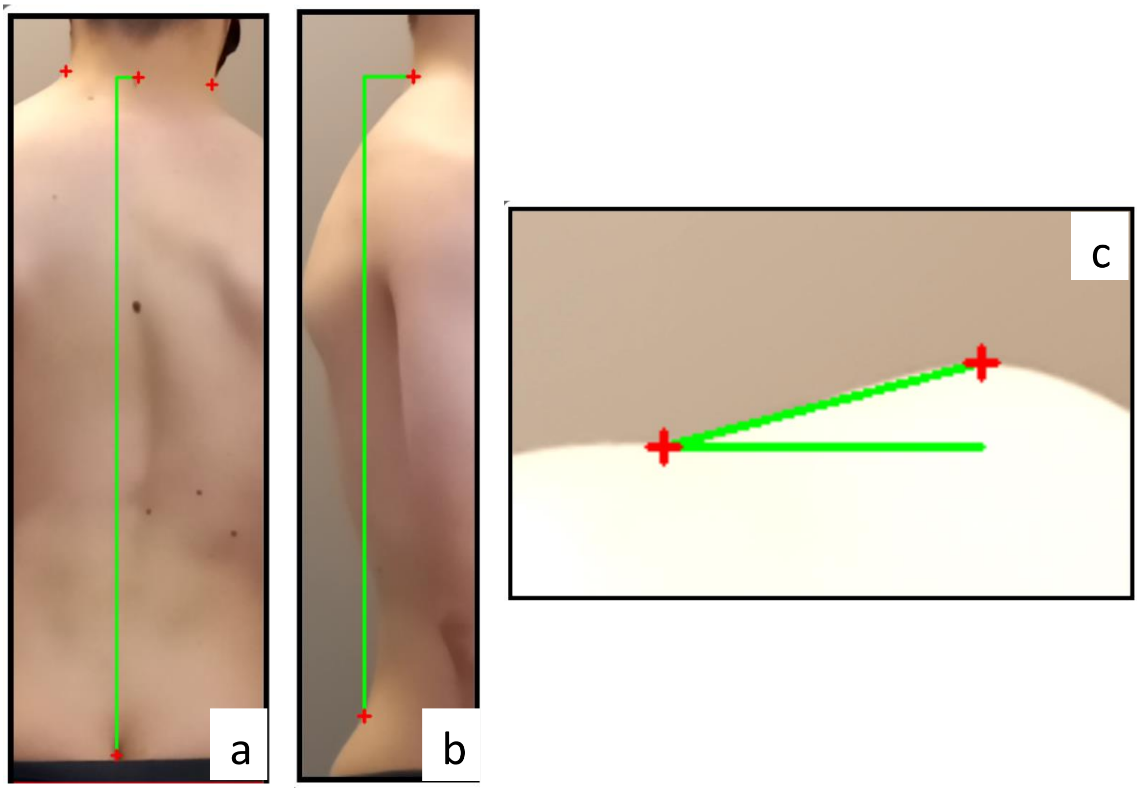

Figure 4. Images obtained in the DIPA-S eHealth Analysis© software. a) Frontal trunk imbalance (FTI). b) Sagittal trunk imbalance (STI). c) Angle of trunk rotation (ATR).

In the image obtained in the sagittal plane, on the right profile, sagittal trunk imbalance (STI) was measured in millimeters, defined as the horizontal distance between the plumb line passing through S2 and C7 or T1. STI (Figure 4b) indicates the sagittal plane position of the trunk, indicating anterior deviations (positive values) or posterior deviations (negative values). The evaluator made four ordered clicks in the image at the following points: two clicks on the sheet fixed to the ground, one at each end, one click on the point representing S2 in the image, through which the virtual plumb line generated by the software passes, and one click on the point representing the spinous process of the C7 or T1 vertebrae.

In the image obtained in the axial plane, with the patient positioned to allow a posterior view of the forward bending of the trunk, the angle of trunk rotation (ATR) was measured in degrees. ATR (Figure 4c) is defined as the angle formed by the line passing through the points of hump in each hemibody (right and left), i.e., the apices (highest and lowest) on each side, and the horizontal line. The evaluator made two clicks, one at the apex (highest and lowest point) of each hemibody (right and left), close to the spinal column.

The reliability of the DIPA-S eHealth© capture and analysis system was determined by analyzing repeatability, intra- and interrater reproducibility. For this purpose, three independent and blinded evaluators (E1, E2, E3) analyzed the images obtained during data collection. The evaluators included two physiotherapists and one physiotherapy student, with professional clinical practice experience ranging from 4 to 13 years. All evaluators received standardized prior training lasting one hour. For repeatability analysis, each image was analyzed twice consecutively by each of the three evaluators. For intrarater reproducibility, only E1 reanalyzed the first image obtained in each position, with a 5-day interval between measurements. For interrater analysis, all three evaluators analyzed the first image from each position.

Statistical Analysis

To assess reproducibility, the intraclass correlation coefficient (ICC) with the two-way mixed model and absolute agreement (3,k) was employed. The ICC was classified as "poor" (ICC < 0.4), "moderate" (0.4 ≤ ICC < 0.75), and "excellent" (ICC ≥ 0.75) [10]. In this study, ICC values above 0.8 were accepted as indicating reproducibility. The standard error of measurement (SEM) was calculated as $SEM = \sqrt{(1 - ICC)} \times SD$, and the minimal detectable change (MDC) was calculated as $MDC = z \times SD \times \sqrt{(2(1 - ICC))}$, both expressed in the unit of measurement tested, where z is the critical value corresponding to the desired level of significance (α=0.05).

Results

The sample consisted of 262 images from 30 patients of both genders, with 70% being girls. The average age was 14.7 ± 3.4 years, body mass of 49.7 ± 11 kg, and height of 160.7 ± 8.3 cm, with an average Cobb angle of 30.7° ± 15°, including 18 curves in the thoracic region. For the analyses, the sample varied from 26 to 30 patients, with the losses attributed to image quality or failure in the server submission system.

Repeatability (Table 1) and intrarater reproducibility (Table 2) were excellent with low SEM and MDC values for all three evaluators. Interrater reproducibility (Table 3) was excellent for the analysis in the frontal and axial planes, with low SEM and MDC values, but it was weak for the sagittal plane, with higher SEM and MDC values.

Table 1. ICC, SEM, and MDC Values for Repeatability Analysis by the Three Evaluators.

	Repeatability Evaluator 1						
	n	Photo	ICC	CI (95%)		SEM	MDC
Frontal (mm)	30	1	0,99	0,99	0,997	0,1	0,2
	30	2	1,00	0,99	1,00	0,1	0,1
	28	3	0,99	0,99	1,00	0,1	0,2
Sagittal (mm)	30	1	0,95	0,90	0,98	0,8	1,5
	30	2	0,95	0,90	0,98	0,8	1,7
	29	3	0,98	0,96	0,99	0,4	0,8
Axial (°)	30	1	0,99	0,98	1,00	0,1	0,2
	29	2	1,00	0,99	1,00	0,1	0,1
	26	3	0,94	0,87	0,97	0,9	1,8
	Repeatability Evaluator 2						
	n	Photo	ICC	CI (95%)		SEM	MDC
Frontal (mm)	30	1	0,99	0,98	0,995	0,1	0,3
	30	2	0,99	0,99	1,00	0,1	0,2
	28	3	1,00	1,00	1,00	0,04	0,1
Sagittal (mm)	30	1	0,96	0,92	0,98	0,6	1,1
	30	2	0,96	0,92	0,98	0,5	1,0
	29	3	0,98	0,95	0,99	0,5	0,9
Axial (°)	30	1	1,00	0,99	1,00	0,1	0,1
	29	2	1,00	0,99	1,00	0,05	0,1
	26	3	1,00	1,00	1,00	0,02	0,03
	Repeatability Evaluator 3						
	n	Photo	ICC	CI (95%)		SEM	MDC
Frontal (mm)	30	1	0,99	0,97	0,994	0,2	0,4
	30	2	0,99	0,98	0,99	0,2	0,4
	28	3	0,99	0,97	0,99	0,2	0,5
Sagittal (mm)	29	1	0,98	0,95	0,99	0,4	0,9
	30	2	0,98	0,95	0,99	0,5	1,0
	29	3	0,98	0,96	0,99	0,4	0,8
Axial (°)	30	1	0,99	0,97	0,99	0,2	0,4
	29	2	0,99	0,98	1,00	0,1	0,2
	26	3	0,99	0,99	1,00	0,1	0,2

mm: measurement provided in millimeters; (°): measurement provided in degrees; n= sample size; ICC: Intraclass correlation coefficient; CI: 95% Confidence interval; SEM: Standard error of measurement; MDC: Minimal detectable change.

Table 2. ICC, SEM, and MDC values for intrarater reproducibility analysis conducted by evaluator 1.

	Intrarater reproducibility					
	n	Mean	ICC	CI (95%)	SEM	MDC
Frontal (mm)	30	-5,7	0,99	0,98 - 0,99	0,2	0,4
Sagittal (mm)	30	42,4	0,88	0,76 - 0,94	2,1	4,1
Axial (°)	30	8,8	0,95	0,90 - 0,98	0,7	1,4

mm: measurement provided in millimeters; (°): measurement provided in degrees; n = sample size; ICC: Intraclass Correlation Coefficient; CI: 95% Confidence Interval; SEM: Standard Error of Measurement; MDC: Minimal Detectable Change.

Table 3. ICC, SEM, and MDC values for interrater analysis performed by three independent evaluators.

	Interrater reproducibility						
	n	Mean	ICC	CI (95%)		SEM	MDC
Frontal (mm)	30	-5,2	0,98*	0,96	0,99	0,4	0,7
Sagittal (mm)	29	44,8	0,32	-0,004	0,64	17,6	34,6
Axial (°)	30	7,8	0,93*	0,87	0,96	0,9	1,8

mm: measurement provided in millimeters; (°): measurement provided in degrees; n= sample size; ICC: Intraclass correlation coefficient; CI: 95% Confidence Interval; SEM: Standard error of measurement; MDC: Minimal detectable change; * $p<0.001$.

Discussion

The possibility of a new entirely remote evaluation method will enable professionals involved in the treatment of patients with scoliosis to have a broader reach, allowing for quantitative clinical assessment to be conducted anywhere in the world. In this proposed protocol, physical presence is not necessary. In this study, we aimed to assess the reproducibility of the DIPA-S eHealth© capture and analysis system for the quantitative evaluation of clinical variables in patients with scoliosis through teleconsultation. The DIPA-S eHealth© system exhibited excellent repeatability among all three assessors and excellent intrarater reproducibility for the variables in all three planes. Interrater reproducibility was excellent for variables in the frontal and axial planes (FTI and ATR) and weak for the variable in the sagittal plane (STI).

The clinical assessment of patients with scoliosis is a recommended priority among experts in the field [6]. In the frontal plane, the measurement of trunk imbalance, i.e., the lateral displacement of C7 concerning the midline (plumb line passing through the gluteal cleft), is a parameter with high priority of recommendation. This parameter is relevant in both conservative and surgical treatment scenarios [11].

Trunk imbalance in the frontal plane has a high prevalence among patients with scoliosis, ranging from 67.5% in the study by Wen et al. 2022 [12] to 85% in the study perfomed by Fortin et al 2016 [13]. Furthermore, trunk imbalance in the frontal plane showed a positive and significant correlation with the Cobb angle [13]. The reproducibility of C7 deviation in the frontal plane, measured clinically and in-person in patients with scoliosis, was reported in a study conducted by Zheng et al. 2023 [14] with 110 subjects. The authors measured trunk imbalance in the frontal plane (defined as the distance between C7 and a virtual plumb line across the gluteal cleft) clinically, using photogrammetry, and reported an excellent interrater ICC of 0.89 (0.85 to 0.92) with an MDC of 7.2 mm.

In our study, this innovative method for measuring trunk imbalance in the frontal plane through teleconsultation also demonstrated excellent ICC values for both repeatability and intra- and interrater reproducibility, with ICC ranging from 0.98 to 0.99. Furthermore, we provided SEM and MDC values for this variable, which help to understand the inherent error in the measurement and assign clinical significance to the magnitude of changes found in the measurement for daily clinical practice. Notably, in our study, the interrater MDC was 0.7 mm, which is ten times smaller than the value reported by Zheng et al. 2023 for in-person photogrammetry assessments [14].

Currently, even though teleconsultation allows for subjective, observational assessment of trunk positioning in the frontal plane [15], there is no quantitative method to measure this imbalance through entirely remote evaluation. There is a gap in the literature regarding the reproducibility of quantitative tools for remote assessment of patients with scoliosis, particularly for measurements in the frontal plane. In the study by Yilmaz et al. 2023 [16], the authors proposed a screening method to be performed by parents or caregivers in a home environment. However, the tool used is a questionnaire called the Scoliosis Tele-Screening Test (STS-Test), which comprises domains related to risk factors and aesthetic deformity. While the study demonstrated high internal consistency and diagnostic accuracy, the authors did not report an objective measurement method for patients with scoliosis (quantitative assessment), but rather an observational evaluation.

The measurement of the angle of trunk rotation using a scoliometer is widely used for screening and monitoring scoliosis patients [17]. Various methods for measuring this angle have been proposed in the scientific literature, ranging from the use of acrylic bases to support mobile phones, digital scoliometers via smartphone apps [18], and even using paper clips on smartphones. Additionally, surface topography has been explored for assessing trunk rotation [19].

In the study by Navarro et al. (2019), the authors used photogrammetry to measure the angle of trunk rotation, which showed excellent correlation with scoliometer measurements and low RMS error (3°). However, this study did not report the reproducibility of the measurements, which was one of its limitations. The authors argued that scoliometers are difficult to access in Brazil and that an alternative, reliable, and accurate method for measuring the angle of trunk rotation is desirable. This method can be achieved through the proposed protocol using photogrammetry and the DIPA (Digital Image-based Postural Assessment) software [20].

In the study by Beauséjour et al. (2022), the authors investigated the intra and interrater reproducibility of measurements of the angle of trunk rotation performed with a smartphone by parents in a home setting. This approach represents a form of remote assessment, eliminating the need for an in-person meeting between the patient and healthcare professional. The authors also compared the measurements taken by parents with those obtained by specialists, validating that parents were capable of detecting and conducting a regular trunk examination of their children [21].

Furthermore, in the study by Yilmaz et al. (2023), one of the items in the questionnaire proposed by the authors, known as the STS-Test, involved the examination of gibbosities by parents. The authors found a high correlation (0.89; $p<0.001$) between the examination conducted by parents in the home environment and that performed by a doctor during an in-person clinical assessment. Moreover, the aesthetic deformity domain exhibited excellent internal consistency (0.90), indicating good reproducibility. These findings suggest that remote assessment methods involving parental participation can yield reliable results for measurement of the angle of trunk rotation [16].

In the study conducted by Engel et al. in 2022, a novel web-based scoliosis screening tool was developed and compared with the scoliometer. This new screening tool consists of an 8-item questionnaire that the evaluator must complete while observing the subject from behind or in the Adams Forward Bend Test position. Two questions within the questionnaire are dedicated to assessing the presence of humps or gibbosities, both in the thoracic and lumbar regions. The application could be used by parents at home, potentially replacing the need for a scoliometer. However, it's worth noting that in this study, the authors did not report the reproducibility of the tool and found only fair agreement between the app and the scoliometer [22].

The reproducibility of the angle of trunk rotation (ATR) measurement using the Scoliogauge app on the iPhone was reported in the study conducted by Getnet et al. in 2020. In this study, the measurement was performed by two different evaluators using the Scoliogauge app, with their thumbs placed under the phone to position the device on the subject's back [23]. The authors reported excellent intrarater and interrater reliability, with ICC values ranging from 0.87 to 0.93 in a sample of 62 individuals. Notably, the study also differentiated the trunk into upper, lower thorax, and lumbar segments, providing a more detailed analysis of the angle of trunk rotation in these specific regions.

In our study, the analysis was considered for the entire spine, without distinguishing between the thoracic or lumbar regions, and it also showed excellent intra and interrater reliability for measuring the angle of trunk rotation (ATR). However, our findings not only indicate a system with excellent reproducibility for

ATR measurement but also eliminate the need for in-person evaluation, unlike the approach proposed by Getnet et al. in 2020, where the presented results are related to measurements performed by two consultant musculoskeletal physiotherapists in person [23].

While there have been efforts towards developing tools for measuring clinical variables in both the frontal and axial planes in patients with scoliosis, to date, it has not been possible to find in the literature protocols or systems similar to the one proposed in this study, where a quantitative assessment of these variables is conducted entirely remotely.

Understanding the three-dimensionality of scoliosis, it is known that in the sagittal plane, the main alteration found is the reduction of thoracic kyphosis, typically measured in the lateral panoramic radiograph [24]. However, in the clinical assessment of scoliosis patients in the sagittal plane, two important parameters described in the study by Negrini et al. 2019 are highlighted: the sagittal index and sagittal balance. The sagittal index is understood as the indirect clinical measurement of thoracic kyphosis, obtained through the plumb line distances on the sagittal plane measured at C7, T5-T6, and L3, with the index being the sum of C7+L3. The authors reported reference values for the sagittal index (79.8 mm ± 26.8 mm), associating a flatback to measurements smaller and an hyper kyphosis to measurements greater than the reference values provided [25].

Although the sagittal index provides relevant clinical information, its calculation relies on measuring the distance from the plumb line at the apex of thoracic kyphosis, typically obtained at the T5-T6 level. We understand that obtaining this measurement is currently only possible in-person, and calculating this parameter remotely is not feasible. In our study, we chose to develop a remote method for measuring sagittal balance in the DIPA-S eHealth capture and analysis system. Sagittal balance is defined as the measurement of the overall trunk position, indicating anterior and posterior trunk imbalances. Its calculation is based on the difference between the distances from the plumb line obtained at C7 and S2 (C7-S2) on sagittal plane.

In the study by Negrini et al. 2019, the authors reported a reference value of 19.3 ± 17 mm for sagittal balance, where higher values indicate an anterior displacement, and lower values indicate a posterior displacement of the trunk. In our study, the mean STI was 44.8 mm, and although repeatability and intrarater reproducibility were excellent (0.95 and 0.88), interrater reproducibility showed a weak ICC of 0.32. Additionally, when examining the minimal detectable change (MDC) values for the variables analyzed (FTI, STI, and ATR), the MDC for sagittal balance (STI) was the highest (34.6 mm) and proportionally the largest (77% of the mean) compared to the variables in the frontal plane (FTI) at 13% and axial plane (ATR) at 23%.

When describing the measurement of sagittal imbalance in Negrini et al. 2019 [25], the authors performed palpation and marking of the anatomical structures where the distances should be measured. In our study, we believe that a significant source of variability in the measurements could be the difficulty of visualizing C7 and

S2 in the profile view and the absence of reference markers. Considering a protocol designed to be entirely remote, without the need for in-person presence, we attempted to measure STI by estimating the locations of the anatomical structures involved in the parameter's measurement. This may have been a significant source of variability in the measurements between evaluators.

Conclusion

The DIPA-S eHealth Capture and Analysis system demonstrates reproducibility for use in the clinical evaluation of scoliosis through teleconsultation, with excellent repeatability and intrarater reproducibility for the variables FTI, STI, and ATR, and excellent interrater reproducibility for FTI and ATR, and weak for STI.

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5 CONSIDERAÇÕES FINAIS

Baseando-se nos resultados encontrados no capítulo 1, caracterizado como um estudo de revisão sistemática, que objetivou (a) Identificar as variáveis posturais clínicas avaliadas no paciente com escoliose através da telemedicina; (b) Como essas variáveis foram mensuradas (captura e análise) e (c) determinar o grau de confiabilidade (validade e/ou reprodutibilidade) dos instrumentos/métodos usados para obter as variáveis mensuradas, foi possível identificar seis variáveis posturais avaliadas nos pacientes com escoliose por telemedicina. As formas de avaliações evidenciadas neste capítulo foram síncronas e assíncronas, utilizando diferentes dispositivos como tablet, smartphone e camiseta instrumentada com sensor. Apenas dois estudos reportaram propriedades de medidas para validade concorrente e reprodutibilidade. No entanto, a heterogeneidade entre os coeficientes reportados foi muito grande, impossibilitando a realização de meta-análise para confiabilidade. Com tudo, foi possível observar um importante gap na literatura científica em relação a estudos de validade e reprodutibilidade de instrumentos/métodos de avaliação clínica dos pacientes com escoliose através da telemedicina.

No capítulo 2, caracterizado como uma nota técnica, que buscou apresentar o desenvolvimento e avaliar a acurácia de medida do sistema de captura e análise (Digital Imaged-based Postural Assessment – Scoliosis) DIPA-S eHealth© como parte de um protocolo de avaliação de pacientes com escoliose idiopática por tele consulta, foi possível mostrar que o sistema de captura e análise DIPA-S eHelath© foi desenvolvido e está pronto para ser testado em pacientes. O aplicativo captura de forma acurada o alinhamento do smartphone durante a aquisição das imagens e o software mostrou adequada acurácia de medida para avaliação de pacientes com escoliose através da fotogrametria.

Os capítulos 3 e 4 foram estudos originais dedicados a testar o sistema DIPA-S eHealth© na população específica para que foi desenvolvido. Nestes capítulos foram desenvolvidos (a) Estudo de validade concorrente e acurácia diagnóstica e (b) Estudo de repetibilidade e reprodutibilidade intra e inter avaliador. Foi possível determinar que o sistema DIPA-S eHealth© é valido para as variáveis no plano frontal (DTF) e transversal (ART), apresentando adequada acurácia diagnóstica apenas para variável ART, com ponto de corte de 4°. Ainda, o sistema de captura e análise DIPA-S eHealth demonstrou ser reprodutível para o uso na avaliação de pacientes com escoliose através da tele consulta, com excelente repetibilidade e reprodutibilidade intra-avaliador para as variáveis nos três planos (DTF, DTS e ART) e excelente reprodutibilidade inter avaliador para as variáveis nos planos frontal (DTF) e transversal (ART), porém fraca para a variável no plano sagital (DTS).

A partir da realização desta pesquisa foi possível desenvolver o sistema de captura e análise DIPA-S eHealth© fundamental para aplicação do protocolo de avaliação para o paciente com escoliose por fotogrametria através da tele consulta. A partir desse sistema, a captura das imagens pode ser feita no ambiente domiciliar pelos pais ou responsáveis, usando o aplicativo para celular, e a análise das imagens pode ser feita pelos profissionais, usando o software. A validade, acurácia diagnóstica e reprodutibilidade foram testadas e o sistema mostrou ser válido para as variáveis no plano frontal (DTF) e transversal (ART), acurado no plano transversal (ART), sendo reprodutível para as três variáveis (DTF, DTS e ART) na análise intra-avaliador e para duas variáveis (DTF e ART) na análise interavaliador. Foi possível observar que a variável no plano sagital (DTS) utilizada neste estudo foi a que apresentou maior dificuldades para mensuração através da tele consulta e novos ajustes devem ser feitos para melhorar a obtenção desta variável de forma remota.

6 LIMITAÇÕES

Embora o sistema DIPA-S eHealth© tenha sido desenvolvido e testado, e contribua valorosamente para avaliação quantitativa do paciente com escoliose através da tele consulta, até o momento o aplicativo DIPA-S eHealth© capture está disponível apenas para smartphone com sistema operacional Android. Buscando aumentar a abrangência de utilização uma nova versão para IOS já está sendo desenvolvida, porém ainda não está pronto para uso.

Segundo alguns relatos recebidos ao longo da realização do estudo o manuseio do aplicativo pelos usuários (pais ou cuidadores) no ambiente domiciliar foi difícil. Na tentativa de minimizar possíveis artefatos na aquisição das imagens no ambiente domiciliar e sem a presença de um profissional o aplicativo foi programado para fazer a aquisição automática da imagem somente quando o celular estivesse alinhado. A sensibilidade para este posicionamento foi de apenas 1º o que exigia muita precisão no momento do manejo com o smartphone pelo usuário para captura da imagem.

Neste estudo não foi possível validar, afirmar acurácia diagnóstica e a reprodutibilidade inter avaliador da variável clínica no plano sagital (DTS). Uma alternativa de avaliação quantitativa válida, acurada e reprodutível para diferentes avaliadores no plano sagital ainda carece ser desenvolvida e testada.

7 PERSPECTIVAS

Inicialmente entende-se que é importante a divulgação no meio científico dos avanços obtidos através desta pesquisa na avaliação dos pacientes com escoliose, por tele consulta, usando o sistema de captura e análise DIPA-S eHealth©. A partir da publicação de artigos científicos e/ou da participação em congressos (nacionais e internacionais) reportando os achados desta extensa pesquisa, será possível viabilizar a reprodução dos procedimentos aqui realizados em futuros estudos científicos, bem como na prática clínica, oportunizando a ampla utilização de variáveis clínicas posturais quantitativas (nos três planos) em pacientes com escoliose através da tele consulta.

De fato, é fundamental a divulgação no ambiento clínico, tendo em vista que a modalidade de atendimentos por tele consulta está em franca expansão e que a utilização de novas ferramentas de avaliação como o proposto pelo sistema DIPA-S eHealth© deve ser encorajado, testado e criticado, corroborando com o avanço das evidências científicas sobre este tópico e atualizações para o usuário.

Além disso, os resultados encontrados nessa pesquisa sustentam a possibilidade de utilização do sistema DIPA-S eHealth© em estudos experimentais, pois a condução de uma intervenção de tratamento conservador para escoliose idiopática, tanto de forma presencial quanto remota, poderá ter seus desfechos mensurados através das variáveis DTF, DTS e ART oriundas do sistema DIPA-S eHealth©. Por fim, surge ainda a possibilidade de extrapolar o alcance do sistema DIPA-S eHealth© e utilizá-lo para mensurar os efeitos do tratamento cirúrgico da escoliose idiopática.

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