A Patient-Worn Instrument to Assess Functional Impact of Chronic Pain – A Pilot Study

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Introduction

Accurate assessment of the functional impact of chronic pain is essential for effective clinical evaluation and treatment planning [1]. Current limitations include subjectivity and bias inherent in commonly used self-reported measures along with the time, cost, and validity concerns associated with physical performance tests. The aim of this pilot study was to evaluate the feasibility and validity of a lightweight, easy-to-use, wrist-worn instrument for assessing the functional impact from chronic pain via physiologic and kinematic measurements.

Materials and Methods

A prototype instrument was designed based on a custom printed circuit board and a 3D printed case. It included a six degrees-of-freedom inertial sensor (i.e., employing triaxial accelerometers and gyroscopes for translation and rotation along three orthogonal axes), a reflectance photo plethysmography sensor (to measure heart rate), a skin conductance sensor, a thermistor (for skin temperature), and a high-fidelity pressure sensor (to measure changes in height). Figure 1 is a model of the instrument that will be used in the next phase of research and development.

Twenty patients (13 female, 7 male) with chronic low back pain were recruited from a university-based pain management center. Demographic and basic pain history were obtained from all participants. Participants were asked to wear the prototype device for 7 days and to maintain a paper log of their general activities and sleep times. At the conclusion of this period, patients completed a set of self-reported measures: Roland-Morris Disability Questionnaire (RMDQ), Pain Disability Index (PDI), Pain Disability Questionnaire (PDQ), and RAND Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) [2-5]. Participants also completed a usability questionnaire comprised of open-ended questions and a modified System Usability Scale (SUS). A sample of clinical pain management providers also completed an online usability survey consisting of several short-answer questions and a modified SUS questionnaire. Multiple regression analyses were performed on data collected from the participant-worn device and each of the self-reported usability questionnaire assessments.
Informed consent was obtained from all participants and the study was approved by the university’s Institutional Review Board.

Results/Case Report

Several categories of regressors (metrics for activity/movement, heart rate, skin temperature, electrodermal activity) were investigated. The correlations between the wrist-worn device and each of the self-reported scales (SF-36 Pain, SF-36 Physical Functioning, SF-36 Role Limitations Due to Physical Health, PDI Total, PDQ Functional, PDQ Total and RMDQ Total) ranged from 0.75 to 0.84 with p < 0.05 for each self-reported scale and subscale.

The criterion for success for the usability survey was an average score of 68 or higher (representing the 50th percentile). The average score for patient participants was 87 (median 90) and 85 for clinicians (median 88).

Discussion

A prototype patient-worn kinematic and physiologic sensor instrument to assess the functional impact of chronic pain was successfully designed, implemented and tested in this pilot study. Data collected from the sensor during the 7-day participant assessment period were strong predictors of commonly used patient self-reported scale scores. The sensor instrument was well accepted by participants and usability scores were high for both chronic pain patients and clinicians. Further development and evaluation of the instrument is underway.

References


Disclosures

No

Tables / Images