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ORIGINAL PAPER

Patient and practitioner experience with clinical lumbar motion monitor wearable technology

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Abstract

Low back pain (LBP) is the leading cause of disability worldwide. Unfortunately, there is no gold standard for objectively quantifying low back function. The clinical lumbar motion monitor (CLMM), a wearable technology, has been developed to provide an objective measure of low back function. The evaluation for the patient is like playing a video game with their back. For health care practitioners the CLMM provides three metrics including overall impairment, structural/muscular and test reliability (do we have good data). This study had two goals. 1) To evaluate the ease of use for the patients. 2) To evaluate how the health care practitioners were able to use the results. Sixty-six low back pain patients were evaluated in the study and 18 health care practitioners were interviewed after receiving CLMM results on their patients. The patients were given a survey immediately after evaluation completion. The practitioners participated in a phone survey after all patient evaluations were completed. Ninety-two percent of the patients either agreed or strongly agreed that the monitor was comfortable and 98% either agreed or strongly agreed that the instructions were clear. One hundred percent of the health care practitioners agreed the test reliability metric was informative and provided a new perspective to their clinical impression. Overall LBP patients were satisfied with the evaluation and health care practitioners thought the results added to their clinical impression. The CLMM technology provides an objective quantitative measure of low back function that may change the way health care practitioners treat LBP patients.

Keywords Low back pain · Clinical lumbar motion monitor · Low back function

1 Introduction

Low back pain continues to be a common and costly health issue in the United State and around the world [1, 2]. Globally, there are approximately 540 million people with low back pain symptoms at any one time [3]. Unfortunately, there is no consistency among health care practitioners as to how to measure low back pain recovery [4]. There are questionnaires such as the Oswestry Disability Index [5] used to assess patient outcomes. However, these questionnaires are subjective, influenced by patient impression of pain and do not directly measure low back function and the extent of low back impairment.

In order to provide a meaningful measure of low back impairment, a tool called the clinical lumbar motion monitor (CLMM) was developed to quantify low back function and objectively track low back functional recovery [6–10]. As shown in Fig. 1 the CLMM is a wearable motion sensing system with a waist belt and shoulder harness. The CLMM measures position, velocity and acceleration by quantifying the difference between the waist belt sensor and the shoulder harness sensor in all three planes of the body. While wearing the monitor, the participant plays a video game with their back flexing forward and back to upright while controlling their twisting position. Figure 2 illustrates

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Fig. 1 CLMM on participant

the three outcome measures generated from the CLMM evaluation. The first outcome metric is the overall impairment score, which combines sagittal range of motion, velocity and acceleration as well as number of control tasks completed into a single score and is normalized to a healthy data base by age (every 10 years) and gender [6]. The overall impairment score as illustrated in Fig. 2 is from 0.00 to 1.00. A score from 0 to 0.42 indicates impaired low back function for that individual's age and gender. A score from 0.58 to 1.00 indicates a healthy low back performance shown in green in Fig. 2. A score from 0.42 to 0.58 is in the yellow zone indicating not clearly healthy and not clearly injured or a cautionary functional performance score. The example data in Fig. 2 shows a score of 0.09, indicating that participant has an impaired low back function for his or her age and gender.

The second outcome metric in Fig. 2 is the type of impairment, again on a scale from 0.00 to 1.00 where less than 0.5 indicates a structural type of back impairment and a score above 0.5 indicates a muscular type of impairment. The type of impairment score is based on a patient database where structural group patients were diagnosed with herniated discs, spinal stenosis or spondylolisthesis moved differently than patients diagnosed with muscular back pain and no radicular symptoms [6]. The current study patients' sagittal acceleration data was compared to the patient database of structural and muscular groups to determine the type of impairment score [6]. The patient's data in Fig. 2 has a type of impairment score of 0.67 suggesting a muscular type of impairment. The third outcome metric generated by the CLMM is the test reliability score indicating the quality of the data. The test reliability also ranges from 0.00 to 1.00. The example data in Fig. 2 illustrate a score of 0.94 indicating good quality data. Thus, the

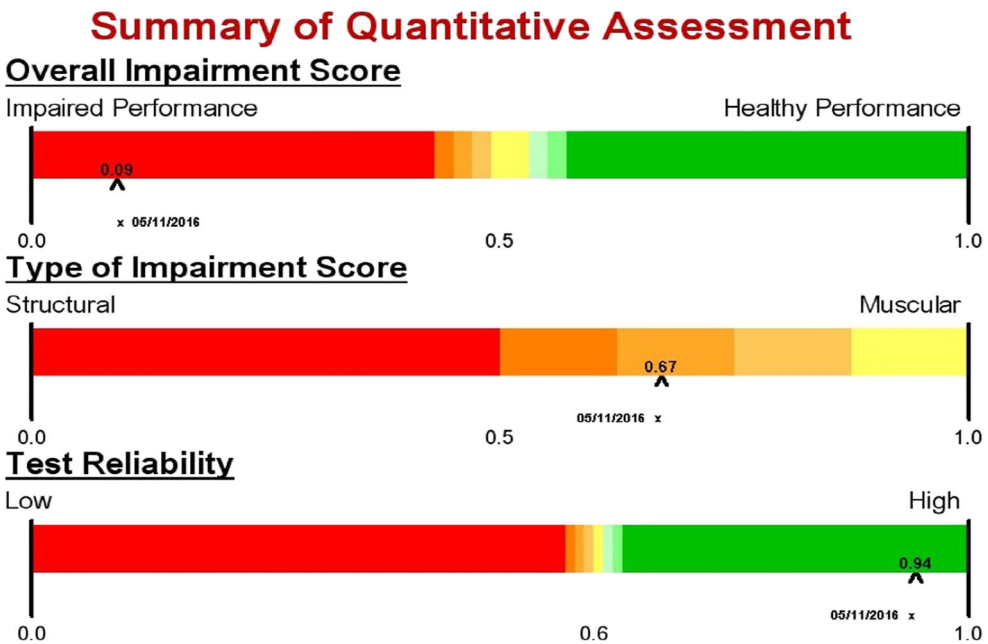

Fig. 2 Example results page

practitioner can trust that the CLMM evaluation is providing reliable results.

The objectives of the current study are two-fold. The first objective was to gain an understanding of the patient experience during the testing process including the perceived acceptability and appropriateness of the test from the patient's perspective. The second objective was to understand the health care practitioner's viewpoint of the result page and whether or not the practitioner gained insight or new perspective from the quantitative assessment outcomes.

2 Methods

2.1 Subjects

There were two categories of subjects in the study. First, were the low back pain patients and the second category were the health care practitioners. The authors declare that this research was approved by the university's institutional review board.

2.1.1 Patients

Sixty-eight low back pain patients signed an approved university informed consent and health insurance portability and accountability act (HIPAA) form prior to participating in the study. The consent allowed for up to two follow-up visits coinciding with practitioner visits.

2.1.2 Health care practitioners

Eighteen health care practitioners from the central Ohio area referred patients into the study. The health care practitioners included eleven physicians, one physician assistant, two nurse practitioners and four chiropractors. All the practitioners signed an informed consent prior to referring any patients into the study.

2.2 Setting/equipment

All patients were tested in a clinic setting in a patient exam room or recovery room area. The CLMM shown in Fig. 1 was used by a research team member to collect low back functional performance data. Custom software was used to generate an overall impairment score, type of impairment and test reliability scores as shown in Fig. 2. A results page similar to that in Fig. 2 was sent to the referring physician within 24 h of the testing. Typically, the results for each patient were discussed with their respective practitioners in a one-on-one conversation with a member of the research team.

2.3 Questionnaires

Table 1 lists the questions and possible responses given to the patients. These questions were developed to gain an understanding of the usability of the CLMM from the patient's perspective. Table 2 lists the questions and possible responses given to the health care practitioners once all the patients were collected. These questions were developed to gain insight into whether or not practitioners thought the results page added to their clinical understanding of the patient's low back impairment. Practitioners were also asked to provide additional feedback on the usability of the tool in their practice.

2.4 Procedure

Recruitment of health care practitioners was done via newsletters as well as email from Ohio Bureau of Worker's Compensation. Once a practitioner or practitioner group responded to recruitment information, a research team

Table 1 Patient questionnaire, number and percentage of responses

Question	Responses				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. Computer display was easy to understand?	$N=50$ 76%	$N=12$ 18%	$N=3$ 4%	$N=1$ 2%	$N=0$
2. Videos of the tasks were helpful?	$N=51$ 77%	$N=14$ 21%	$N=1$ 2%	$N=0$	$N=0$
3. Instructions for testing were clear?	$N=57$ 86%	$N=8$ 12%	$N=1$ 2%	$N=0$	$N=0$
4. The monitor was comfortable?	$N=41$ 62%	$N=20$ 30%	$N=5$ 8%	$N=0$	$N=0$
5. Overall satisfied with motion testing experience?	$N=47$ 71%	$N=14$ 21%	$N=4$ 6%	$N=1$ 2%	$N=0$

Table 2 Practitioner questionnaire, number and percentage of responses

Question	Responses				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. The overall impairment score was informative?	$N = 8$ 44%	$N = 9$ 50%	$N = 1$ 6%	$N = 0$	$N = 0$
2. The overall impairment score provided a new perspective to your clinical impression?	$N = 8$ 44%	$N = 7$ 39%	$N = 2$ 11%	$N = 1$ 6%	$N = 0$
3. The type of impairment score was informative?	$N = 7$ 39%	$N = 9$ 50%	$N = 1$ 6%	$N = 1$ 6%	$N = 0$
4. The type of impairment provided a new perspective compared to imaging findings?	$N = 6$ 33%	N = 7 39%	$N = 5$ 28%	$N = 0$	$N = 0$
5. The test reliability score was informative?	$N = 12$ 67%	$N = 6$ 33%	$N = 0$	$N = 0$	$N = 0$
6. The test reliability score provided a new perspective of your clinical impression?	$N = 10$ 56%	$N = 8$ 44%	$N = 0$	$N = 0$	$N = 0$

member scheduled a presentation. At the practitioner presentation, the research team would provide a detailed explanation of the study including a demonstration of the CLMM and several example results similar to Fig. 2. If the practitioner chose to participate the practitioner would sign a consent form. Once the practitioner was enrolled in the study he or she could refer patients into the study by submitting a C-9 form, which is a form that medical practitioners supply to Managed Care Organizations or self-insured employers to request authorization for additional medical testing.

The C-9 form was approved by two Managed Care Organizations as well as one self-insured company that participated in the study. Once the research team received the approved C-9 form an appointment was set up for the CLMM evaluation. The time and location of the testing was scheduled at the convenience of the patient. There were several clinic locations available in some cases the CLMM testing coincided with a practitioner visit.

Once the patient arrived at the appointment, the patient would be shown the CLMM in the case as well as the waist belt and shoulder harness. The research team member would go over the consent form with the patient and answer any questions. Once the patient signed the consent and HIPAA form then testing would begin. The monitor was placed on the patient with a waist belt and shoulder harness. The patient was asked if the monitor was comfortable and adjustments were made when necessary. The patient then played the video game with his or her back, which consisted of flexing forward and back while controlling the twisting position on a display screen. There were up to 5 control zones depending on the patients twisting capabilities. After the control tasks, patients performed 3 additional tasks bending forward and back, side to side and twisting clockwise and counter-clockwise without any visual feedback. Each motion was collected for 10 to 16 s. The instructions for the motions were to move as fast as you feel comfortable in a comfortable range of motion. Immediately after the testing the patients completed the questionnaire. The entire session was approximately 30 min.

2.5 Statistical analysis

Descriptive statistics of the number and percentage of responses by question for the patient questionnaire as well as practitioner questionnaire were completed. The patient questionnaire measures and CLMM low back functional performance scores were checked for normality with q-q plots. Pearson correlation analyses were completed between the patient questionnaire measures and the CLMM low back functional performance scores. Only 10 patients had follow-up data therefore no statistical analyses were performed with this data. Finally, provider comments will be presented in the results and discussion section.

3 Results

3.1 Patient results

Sixty-eight patients participated in the research. The average age of participants was 44 years with a standard deviation of 11 years. Fifty-four percent of the population was male. However, two patients left the clinic before completing their questionnaire. Thus, the patient questionnaire responses are for 66 patients. Table 1 lists the question and number as well as percentage responses for each question. Note that on every question the patients responded with either agree or strongly agree suggesting a positive patient experience with the CLMM testing. The biggest concern for further development may be the comfort of the monitor with 8% responding neutral.

The q-q plots appeared linear for all the data confirming the assumption of a normal distribution for each of the variables. Table 3 lists the Pearson Correlation Coefficients between the CLMM functional performance scores and the questionnaire responses from the patients. The overall impairment score was not significantly correlated to any of the questionnaire questions. The type of impairment score was also not significantly correlated to any of the questionnaire questions. The test reliability score was statistically significantly correlated to the comfort of the monitor as well as the overall satisfaction of the patient's experience. Thus, all the correlation values were poor between the subjective patient impression questionnaire measures and the objective patient CLMM low back functional performance measures.

3.2 Health care practitioner results

3.2.1 Questionnaire results

Eighteen practitioners participated in the study. Table 2 lists the questions, number of participants and percentage of participant responses for each of the questions. In addition, the practitioners were asked to provide additional comments. Table 2 shows that most of the practitioner either strongly agreed or agreed that the 3 outcome measures were informative and/or provided a new perspective to their clinical impression.

3.2.2 Practitioner comments

Several practitioners' had additional comments on either the entire study or specific patient results. Next are four specific comments from four different practitioners.

1. "The type of impairment score either structural or muscular being in the muscular region helped to reinforce thoughts of physical therapy as the treatment".
2. "The results provided another piece of the puzzle in understanding the patient's back problem".
3. "The results were informative and it was interesting to see the progress made on the results after treatment with physical therapy".
4. "Cannot stress enough the importance of the test reliability scores in worker's compensation patients vs. my other patients".

Table 3 Patient population Pearson correlation coefficients between CLMM scores and questionnaire responses

CLMM score	Questionnaire question				
	Q1	Q2	Q3	Q4	Q5
Overall impairment score	0.1199	0.2193	0.1093	0.2019	0.2207
Type of impairment score	0.0427	0.0058	−0.0736	0.0798	0.0934
Test reliability	0.2226	0.1005	0.0631	0.3688[a]	0.3566[a]

[a] Indicates statistical significance at alpha = 0.05

4 Discussion

In general both patients and practitioners had positive comments regarding the usability of the CLMM and the outcome measures. The CLMM evaluation provides an objective low back evaluation with a quantitative score as to the severity of a patient's overall low back impairment for the individual's age and gender. It also provides an objective quantitative evaluation of the type of impairment being structural or muscular. Finally, the CLMM assessment provides a test reliability score indicating quality of data from that patient's assessment. All three scores are objective, quantitative scores based solely on the motion data collected and not on subjective impression of the patient or the health care practitioner. The extremely weak correlation values between patient questionnaire responses and CLMM functional performance scores support the idea that the CLMM scores are objective measures of low back function independent of the subjective impression of the patient. This new wearable technology potentially provides health care practitioners with an objective tool for quantifying a patient's low back functional status.

4.1 Patient experience

There are many wearable technologies on the market today that may be placed into two categories 1) fitness wearables and 2) medical wearables [11]. The CLMM is a medical wearable technology however it is only worn while the patient performs the testing in the health care setting. Even with its short time use, during clinical testing, it is important to assess the usability and comfort of this new technology and testing procedure on patients. The instructions for the testing are for the patients to move as fast as he or she feels is comfortable in a comfortable range of motion. This allows the patient to be their own best judge during the testing. Overall, the patient experience was positive from the questionnaire responses and the patients perceived impression of the system did not affect how they performed during the assessment. One patient that participated at a baseline and follow up appointment commented that it gave her an understanding of how much she improved functionally from the prior visit. The patient reported that this objective evidence was valuable to her. One reason for technology to fail is a lack of user acceptance

[12], thus, the positive feedback from patients suggests that use of a CLMM for clinical evaluation appears acceptable to patients.

4.2 Health care practitioner experience

The questionnaire responses demonstrate that the practitioners had a favorable impression of the CLMM results overall. The specific comments reported in the results from four of the practitioners were very insightful. The first comment regarding the type of impairment score suggests that the health care practitioner, in this case a chiropractor, may have used the score to help guide treatment selection. This particular patient had been having low back pain symptoms for nearly 4 months at the time of testing, thus the practitioner may have been thinking of additional diagnostic testing and the type of impairment score result corroborated the physical therapy/exercise treatment plan that was in place. This comment in particular may illustrate how the timing of testing in the patient's course of treatment with the practitioner may influence the practitioner's thought process. If the patient had been tested earlier in the course of treatment the practitioner may not have been as interested in the type of impairment score. It should be noted that this practitioner only had one patient in the study and therefore did not have a large sample of patient results from which to draw.

The second comment from one of the physicians suggests that the CLMM results may be combined with physical exam as well as other diagnostic tests to gain a better understanding of the low back pain patient's impairment. The practitioner that made this comment referred approximately 20 patients into study. This practitioner was a physician with the largest number of results to consider including 5 of the follow-up patients. It is thought that this large number of referrals provided the practitioner the ability to understand the CLMM measures better than other practitioners with fewer referrals and gain an understanding of how the measures varied among the patients and how it compared to clinical examine as well as other diagnostic measures already in place. This comment illustrates the concept of the CLMM results being incorporated into clinical decision making.

Ten of the 66 patients were tested more than once with the CLMM. One of the practitioners that received the results on the follow-up evaluation could then quantify the improvement in that patient that had occurred during the 2 weeks of physical therapy. The third comment in the list above is from the physician assistant that examined one of those select patients with follow-up data. Thus one could use the CLMM to quantify low back functional improvement or lack thereof with various types of treatments. In this particular case the patient had physical therapy but one could also quantify before and after massage, chiropractic care, injections or even surgery. Thus the CLMM is a tool that could be used serially to objectively quantify change in low back functional performance over time.

The final comment regarding the importance of the test reliability score was from a spine surgeon that participated in the study. The worker's compensation population clearly presents a complex group of patients to a spine surgeon with a myriad of secondary gain issues thus the objective information from the test reliability score in particular provides an objective metric not previously available. The worker's compensation patient with a good test reliability score and a low overall impairment score indicates that the functional impairment is objectively quantified and may potentially be a good surgical candidate. Furthermore, any secondary gain issues that the patient may have are not influencing the overall impairment score. Thus, the practitioner in this a case a surgeon can treat the patient with confidence in the degree of impairment.

One issue with low back pain patients is the recurrent nature of the problem. The CLMM may provide insights to health care practitioners regarding this issue. When patients feel better or symptom free the patient may not return to the health care practitioner. However, the patient may not be functionally recovered thus putting the patient at higher risk for recurrent low back pain. Thus an objective quantitative measure of low back function may provide practitioners as well as patients with an objective assessment of the level of recovery that has occurred and ensure a safe return to work with lower risk of re-injury.

4.3 Limitations

There were only 18 practitioners that referred patients into the study that participated. This is a rather small sample of practitioners given that the practitioners were in a variety of specialties. Another limitation was the small number of patients with follow-up visits. To give practitioner a better understanding of the value of the CLMM results it would have been better to have more patients with follow-up evaluations. Finally, the objective of this study was to examine the practitioner and patient experience with the CLMM results and testing respectively, therefore patient pain scores were not collected as part of the study, which may be considered a limitation.

5 Recommendations

The positive feedback from this study justifies continued development of the CLMM for use in healthcare settings to inform clinicians in their decision making, enhance care-efficiency, reduce costs and improve patient outcomes for the treatment of chronic low back pain.

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Compliance with ethical standards

Statement of informed consent All participants both patients and health care providers signed an informed consent.

Statement of human and animal rights All data collected during this study followed and were in accordance with the ethical standards of the institutional review board on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000 and 2008.

Conflict of interest All authors declare they have no conflict of interest.

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