

A Reliability Study of the New Back Strain Monitor Based on Clinical Trials.

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Abstract—A new Back Strain Monitor (BSM) device has been developed in order to measure, record and analyze movements of the lower back. The purpose of this study was to examine the inter-tester and the intra-tester reliability of the movement measurements given by the BSM accelerometers, and compare it with the reliability of two other conventional measurement methods: the Double Inclinator method (DI) and the Modified-Modified Schober (MMS) method. The clinical studies included 23 participants (16 males, 7 females) with no recent history of lower back pain, who wore the device during a combination of different anatomical movements (flexion, extension, left lateral flexion and right lateral flexion of the lumbar spine). The tests were conducted by three therapists (testers). The reliability results for the BSM accelerometers clearly outperform the results obtained for the DI and the MMS methods. The inter-tester reliability gives the Intra-Class Correlation (ICC) value of 0.95 for the BSM flexion, 0.89 for the DI flexion and 0.74 for the MMS. The intra-tester reliability gives the ICC value of 0.99 for BSM flexion, 0.94 for DI flexion and 0.77 for the MMS. The BSM accelerometers were highly reliable in assessing back movements, measuring these movements with less error than the DI and MMS methods.

INTRODUCTION

Lower back pain continues to be a major problem with studies stating that 20-25% of all injuries affect the lower back and that these lower back injuries account for 40% of compensation costs [24]. Once injured the recurrence rate of lumbar spine injuries is 60-85% within the first three years [25]. Previous techniques have attempted to quantify the movements of the lower back in real time and with minimal impedance to the wearer. C.Snijders [2] looked at continuous

measurements of spine movements and attached various sensors to the spine to measure movements over time. W.Marras [22] built the Lumbar Motion Monitor and used this device to analyze over 400 jobs in order to assess the three dimensional trunk motion's role in the development of lower back dysfunction.

The Back Strain Monitor (BSM) is a new device for measuring lumbar spine movement, within a controlled setting. The device is unobtrusive, compact, easy to apply and is designed to measure movement in three planes (Flexion, Lateral Flexion and Rotation), muscle activity around the lumbar spine and vibration affecting the lumbosacral region. The aim of this study is to assess the reliability of the BSM for measuring flexion/extension and left/right lateral flexion of the lumbar spine.

A reliable dynamic recording of lumbar spine movement in a real-life occupational environment represents a complex and challenging task. An appropriate measuring protocol for real-time lumbar spine movement has to be capable of a quantitative registration and measurement of factors including the spine's three dimensional movement, body weight, gravity, amount of active and passive support of the spine, weight being lifted, various environmental factors, as well as the psychological and social aspects of the working environment.

A number of different existing methods for measuring lower back movement were reviewed in order to find techniques to compare the BSM with. The Byplanar Radiography due to radiation concerns and lack of portability, was not appropriate. The Flexirule uses a flexible ruler placed on the spine to follow the curvature of the lumbar spine. There seems to be trouble with obtaining accurate tangents with this method and it was shown to have no inter tester reliability [23]. The finger to floor method is quick and simple and shown to have inter-tester reliability [6,7,12], but was deemed not valid by Moll and Wright in [8], and it is not comparable from one subject to another. Two methods were finally chosen for comparison with the BSM: the Modified-Modified Schober (MMS) method and the Double Inclinator (DI) method. Both methods have been shown to have inter and intra-tester reliability [7,9,10]. The Modified-Modified Schober method uses a flexible tape measure and measures the change in skin stretch when the lumbar spine flexes from a neutral position to a fully flexed position. The landmarks are at the lumbosacral junction and a line drawn 150mm superior to this point. The Double Inclinator

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technique measures the angular difference between the upper lumbar spine and the lower lumbar spine in a given position and subtracts one from the other. These measurements are then retaken once a movement has been performed and again subtracted from one another. The difference in degrees from the initial measurement to the subsequent measurement represents the amount of lumbar spine movement.

Most of the currently available lumbar movement measuring devices have the disadvantage of being large, cumbersome, expensive and lack the capability to analyse the measurement data in real time. Such devices cannot be easily used over long periods of time in real occupational environments.

The new BSM eliminates most of these drawbacks, however, the reliability and validity of the BSM needed to be reviewed to establish whether it can be used as a diagnostic/therapeutic tool.

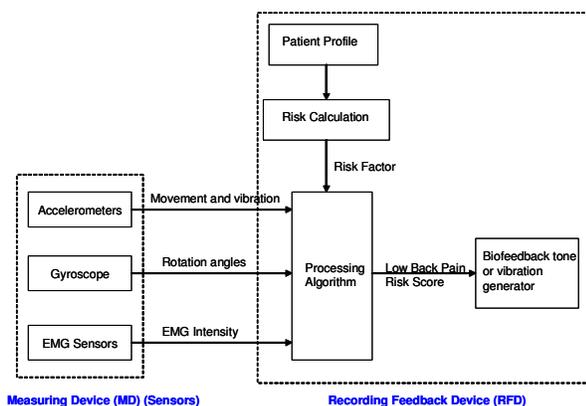
The paper analyses lumbar spine movement and compares the measurement results given by two pre-existing and well recognized methods: MMS and DI with the results given by the new BSM. The reliability tests were performed using a clinical trial protocol which has already been field tested. The trials were conducted within a controlled setting.

The comparison between the BSM measurements and the MMS and DI measurements was determined using the intra- and inter-tester reliability measure based on the intraclass correlation coefficient (ICC) [21].

I. METHODS

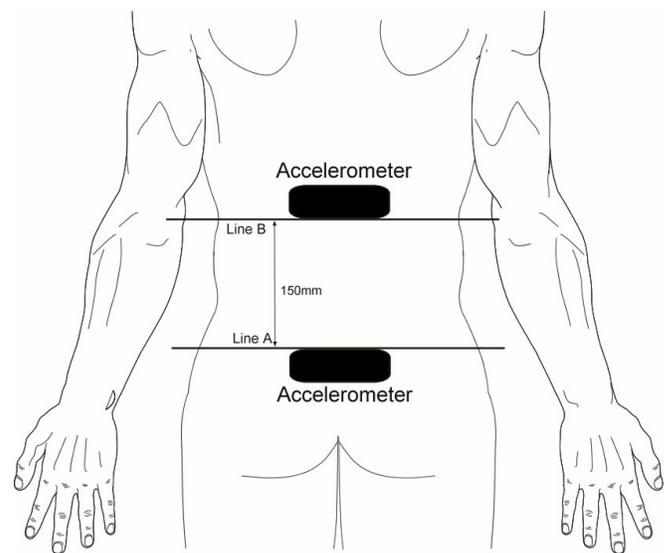
A. The Back Strain Monitor

The Back Strain Monitor is a recently developed electronic and programmable device. The BSM can be used by patients presenting with low back pain or patients at risk of developing low back pain, to monitor movement, estimate the amount of strain on the lower back, and to provide real-time feedback to the patient about potentially provocative postures for their lumbar spine. Real-time feedback allows the patient to immediately correct the body posture or to stop the physical activity that may carry a higher risk of injury.



Picture1. Functional Flowchart of the BSM.

As illustrated in Picture 1, the BSM consists of two parts: the Measuring Device (MD) and the Recording Feedback Device (RFD). The Measuring Device contains the transducer components collecting raw, real-time movement and muscle activity data from the patients via sensors placed on the patient's body. The Recording Feedback Device is an electronic, programmable component that uses a numerical algorithm to extract and process information from the sensors, and from the Patient Profile stored in the memory, to calculate a low back pain risk score. When the risk score exceeds a certain threshold value, a real-time feedback signal (sound or vibration) is activated to inform the patient of the excessive load or high risk activity their low back may be experiencing.



Picture2. The BSM fitted on the participant's back.

B. The reliability testing in a controlled setting

The aim of the experiment was to assess the inter- and intra-tester reliability of the BSM, MMS and DI methods.

Participants

The sample study included participants who never suffered from the Lower back Pain (LBP) as well as participants who suffered from LBP in the past. Those who suffered from LBP in the past were accepted only under the condition that the pain had not occurred for at least 3 months and it was not occurring during the trial. All participants were examined by a physiotherapist immediately before the trial to ensure that each subject had full pain free movement during their warm up period prior to the trial. The participants were also required to have no history of spinal surgery to the lumbar, thoracic or cervical spine. A sample of 23 participants including 16 males (average age of 40) and 7 females (average age of 42) were tested. The participant's age ranged from 21 to 62 years (average age 40.4). The participants were recruited on a voluntary basis. No payment was offered. The participants were spread across different occupational groups. Prior to the tests, the participants were briefly interviewed by a practitioner to confirm that they

fulfilled the inclusion criteria. All participants signed a consent form for the project which had received institutional ethics approval.

Testers

The study was carried out within a physiotherapy centre. During the tests, the participants were assisted by three experienced practitioners with 12 to 17 years of clinical experience. The practitioners fitted the BSM device and instructed movements via the study protocol. They also conducted the DI and MMS measurements. A scribe was provided to improve efficiency and to allow the tester's full focus on the subject and their explanation of the movements required. Each tester had their own room with no visual contact with the other testers or subjects to ensure the study was double blind. The subjects were allocated a tester in a random order and the landmarks were removed completely prior to the subject moving from one tester to another.

Fitting the BSM device

The BSM devices were installed on the participant's back such that the accelerometers were placed above line A and below line B (see Picture 2).

Experimental procedure

The experimental procedure included the following steps:

1. Subject Starting Position

Each subject before commencing movements, was asked to ensure the following: stand facing the door of the room with head and shoulders straight; feet shoulder width apart; arms relaxed by side; and legs and trunk in an erect but relaxed stance.

2. Movements

The following four movements were performed in a random sequence to avoid any potential bias.

2.1 Lumbar spine Flexion

2.2 Lumbar spine extension:

2.3 Lumbar spine Lateral Flexion:

2.4 Thoraco-lumbar rotation:

II. RESULTS AND DISCUSSION

The statistical analysis reviewed measurements in two ways. Firstly, the Inter-tester Reliability, as described by D.Streiner [1], was used to determine the variability between different testers. Secondly, the Intra tester Reliability [1], was used to determine the variability between the same tester but on different days.

In both cases, methods described by Shrout and Fleiss [21] were used to derive the intraclass correlation coefficient (ICC) for each aspect of movement: flexion, extension, left lateral flexion and right lateral flexion.

A. The inter-tester reliability results

The inter-tester reliability results for the flexion movement are summarized in Table I along with the results for extension of the lumbar spine and lateral flexion of the lumbar spine. Note that there are no results for the MMS for extension and lateral flexion's as this technique is not well recognized as a method for measuring extension and lateral flexion.

Table I. Results of the inter-tester reliability test. The ICC values for the BSM accelerometers, DI and MMS.

Type of movement	ICCs for BSM	ICCs for DI	ICCs for MMS
Flexion Plane	0.954	0.892	0.736
Extension Plane	0.947	0.909	N/A
Left Lateral Flexion	0.887	0.845	N/A
Right Lateral Flexion	0.859	0.834	N/A

The results in Table I indicate that the BSM accelerometers showed the best overall reliability for all four types of the lower back movement. The ICC values for the BSM accelerometers ranged from 0.859 to 0.954.

The DI method shows lower overall reliability compared to the BSM, and the method with the poorest results was the MMS, with the ICC value of 0.736.

B. The intra-tester reliability results

The intra-class correlation was again used to compare the results obtained by the same tester but on different days. One of the three testers repeated the BSM accelerometer method, the DI and the MMS method measurements on twenty two of the twenty three subjects, five weeks after the first testing, in order to reduce memory effect.

Table II. Results of the intra-tester reliability test. The ICC values for the BSM accelerometers, DI and MMS..

Method	ICC
BSM_extension	0.98191
BSM_flexion	0.99315
BSM_llflexion	0.89168
BSM_rlflexion	0.93040
DI_extension	0.95345
DI_flexion	0.94487
DI_llflexion	0.88403
DI_rlflexion	0.86140
MMS_flexion	0.77018

The same settings and protocol were used; however the order of subjects was randomized again to avoid any memory effect. The intra-tester reliability results are summarized in Table II.

III. CONCLUSION

A new Back Strain Monitor (BSM) device has been developed in order to measure, record and analyze movements of the lower back within a real job setting, with minimal inconvenience to the wearer.

The purpose of this study was to examine the inter-tester and the intra-tester reliability of the movement measurements given by the BSM accelerometers. The reliability tests of the BSM accelerometers were compared with the reliability of two other conventional measurement methods: the Double Inclinator method (DI) and the Modified-Modified Schober (MMS) method.

The clinical studies included 23 participants (16 males, 7 females) with no recent history of lower back pain. During the tests the participants wore the device during a combination of different anatomical movements (flexion, extension, left lateral flexion and right lateral flexion of the lumbar spine). The tests were conducted by three experienced practitioners (testers).

The reliability of the tested methods was measured using the Intra-Class Correlation Coefficient (ICC).

The inter-tester reliability for the BSM ranges from 0.859 to 0.954.

The inter-tester reliability for the DI ranges from 0.834 to 0.909.

For the MMS it was only possible to obtain one value of the inter-tester ICC (flexion plane) of 0.736.

The intra-tester reliability for the BSM ranges from 0.89 to 0.99.

The intra-tester reliability for the DI ranges from 0.86 to 0.95.

Again, for the MMS it was only possible to obtain one value of the inter-tester ICC (flexion plane) of 0.77.

In conclusion, the reliability results for the BSM accelerometers were positive, showing slightly higher reliability than the DI method and moderately higher reliability than the MMS method. The results indicate that the BSM can reliably measure movement of the lower back. Further validity testing is required before the BSM can be considered as a useful management tool for back pain sufferers.

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