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Kieran O'Sullivan^a; Luciana Galeotti^{ab}; Wim Dankaerts^{bc}; Leonard O'Sullivan^a; Peter O'Sullivan^d

^a University of Limerick, Limerick, Republic of Ireland ^b Catholic University, Leuven, Belgium ^c

University College Limburg, Hasselt, Belgium ^d Curtin University of Technology, Perth, Australia

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The between-day and inter-rater reliability of a novel wireless system to analyse lumbar spine posture

Kieran O'Sullivan^{a*}, Luciana Galeotti^{a,b}, Wim Dankaerts^{b,c}, Leonard O'Sullivan^a and Peter O'Sullivan^d

^aUniversity of Limerick, Limerick, Republic of Ireland; ^bCatholic University, Leuven, Belgium; ^cUniversity College Limburg, Hasselt, Belgium; ^dCurtin University of Technology, Perth, Australia

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Lumbar posture is commonly assessed in non-specific chronic low back pain (NSCLBP), although quantitative measures have mostly been limited to laboratory environments. The BodyGuardTM is a spinal position monitoring device that can monitor posture in real time, both inside and outside the laboratory. The reliability of this wireless device was examined in 18 healthy participants during usual sitting and forward bending, two tasks that are commonly provocative in NSCLBP. Reliability was determined using intraclass correlation coefficients (ICC), the standard error of measurement (SEM), the mean difference and the minimal detectable change (MDC90). Between-day ICC values ranged from 0.84 to 0.87, with small SEM (5%), mean difference (<9%) and MDC90 (<14%) values. Inter-rater ICC values ranged from 0.91 to 0.94, with small SEM (4%), mean difference (6%) and MDC90 (9%) values. Between-day and inter-rater reliability are essential requirements for clinical utility and were excellent in this study. Further studies into the validity of this device and its application in clinical trials in occupational settings are required.

Statement of Relevance: A novel device that can analyse spinal posture exposure in occupational settings in a minimally invasive manner has been developed. This study established that the device has excellent between-day and inter-rater reliability in healthy pain-free subjects. Further studies in people with low back pain are planned.

Keywords: back pain; posture; reliability

1. Introduction

Low back pain (LBP) is a very common and costly disorder that should be considered within a biopsychosocial framework (Maniadakis and Gray 2000, O'Sullivan 2005, Hansson *et al.* 2006, Linton *et al.* 2007). Most LBP lacks a specific radiological diagnosis and has been termed non-specific chronic low back pain (NSCLBP) (Borkan *et al.* 2002, Dankaerts *et al.* 2006a). It is increasingly recognised that within the broad NSCLBP population, specific subgroups exist, which require management addressing the specific mechanism underlying their NSCLBP (Boersma and Linton 2002, Borkan *et al.* 2002, McCarthy *et al.* 2004, Dunn and Croft 2005, O'Sullivan 2005, Kent *et al.* 2009). It has been proposed that in a subgroup of NSCLBP subjects, the adoption of altered patterns of spinal movement and posture represents a primary mechanism for their NSCLBP disorder (O'Sullivan 2005). It has been proposed that these patients present with maladaptive spinal postures and movement patterns that expose their spines to increased loads and strain (O'Sullivan 2005). In line with this, spinal

posture is considered by many in both clinical practice and research to be a factor in the development and maintenance of LBP (van Dillen *et al.* 2003b, Poitras *et al.* 2005, Dankaerts *et al.* 2006a, Womersley and May 2006, van Wyk *et al.* 2009). A number of studies now support the existence of these altered spinal postures in subjects with NSCLBP when examined in a laboratory environment (Burnett *et al.* 2004, Dankaerts *et al.* 2006a,b, 2009, Womersley and May 2006, Smith *et al.* 2008) and modification of posture has been associated with improved clinical outcomes (van Dillen *et al.* 2003a, Dankaerts *et al.* 2007).

There are numerous methods for analysing lumbar spine posture, from simple visual observation in clinical practice (Poitras *et al.* 2005), the use of photographic markers (Perry *et al.* 2008, Smith *et al.* 2008) to more complex laboratory-based motion analysis systems used in much LBP research (Percy and Hindle 1989, Schuit *et al.* 1997, Mannion and Troke 1999, Dankaerts *et al.* 2006a). Many laboratory-based methods of analysing posture have been shown to be both reliable and valid (Percy and Hindle 1989,

*Corresponding author. Email: kieran.osullivan@ul.ie

Schuit *et al.* 1997). Unfortunately, these systems are complex and time-consuming to use and cannot be easily used to analyse posture outside the laboratory setting.

The use of portable, minimally invasive methods of analysing posture in 'real-world' settings has been advocated to provide a quantitative measurement of posture in the workplace (Hermens and Vollenbroek-Hutton 2008). In recent years a number of devices have been developed to analyse spinal posture outside the laboratory (Donatell *et al.* 2005, Dean and Dean 2006, Horton and Abbott 2008). Spinal posture analysis is now possible using accelerometers (Bazzarelli *et al.* 2001, Nevins *et al.* 2002, Wong and Wong 2008), gyroscopes (Lee *et al.* 2003), strain gauges and/or optical sensors (Donatell *et al.* 2005, Dean and Dean 2006) and even sensing fabrics (de Rossi *et al.* 2003, Walsh *et al.* 2006). Recent reviews have highlighted that, despite the potential of such devices, there is a lack of empirical data supporting their use (Wong *et al.* 2007, Hermens and Vollenbroek-Hutton 2008). Unfortunately, some of the devices are relatively large and invasive, such that they cannot be concealed easily (Donatell *et al.* 2005, Magnusson *et al.* 2008) or only used under supervision (Magnusson *et al.* 2008). While some of these devices have at least some evidence of initial reliability and/or validity studies being completed (Donatell *et al.* 2005, Intolo *et al.* 2010), this is not the case with all devices (Dean and Dean 2006, Magnusson *et al.* 2008, Mork and Westgaard 2009). It is critical that the desire to promptly use these devices in clinical trials is balanced against the requirement to initially establish the scientific robustness of the device itself.

Another significant limitation of traditional laboratory-based motion analysis systems is that they cannot provide instantaneous postural feedback while the NSCLBP patient performs daily tasks. This shortcoming is significant considering the role that reduced postural awareness and position sense may play in NSCLBP (O'Sullivan *et al.* 2003). In fact recent studies demonstrate that provision of postural awareness training may help improve clinical outcomes in both acute LBP and NSCLBP (Horton and Abbott 2008, Magnusson *et al.* 2008)

The BodyGuardTM (Sels Instruments, Vorselaar, Belgium), a novel wireless method of measuring spinal sagittal plane posture, has recently been developed. This small device can monitor spinal posture in real time without the need for cumbersome cables, thus facilitating more normal movement and function in a wide variety of tasks compared to some existing options (Donatell *et al.* 2005, Magnusson *et al.* 2008). The data are accessible for immediate presentation and analysis. The BodyGuardTM device can also be used to provide immediate real-time postural

biofeedback (audio or vibratory) with a view to modifying posture or movement patterns and even enhancing the exercise performance of those using the device. While the BodyGuardTM device clearly demonstrates potential clinical utility, and could be trialled immediately in clinical trials as an intervention tool, it is believed that there is a clear need for robust scientific validation initially before progressing to clinical trials. Therefore, a multi-stage investigation into the validity of this device for monitoring posture in NSCLBP patients has been outlined. This first study examines the between-day and inter-rater reliability of the device for analysing sagittal plane spinal posture during functional tasks. In order to minimise postural variation due to pain or external environmental factors, the reliability of the device will first be established among pain-free, healthy control subjects performing closely controlled postures and movements. Since forward bending (FB) and sitting are common aggravating factors in NSCLBP, and are commonly analysed in clinical practice and research (O'Sullivan *et al.* 2002, O'Sullivan 2005, Dankaerts *et al.* 2006a, Womersley and May 2006), they were deemed suitable for this reliability study.

The aim of the study was to establish the between-day and inter-rater reliability of the BodyGuardTM for monitoring these sagittal plane tasks.

2. Methods

2.1. Participants

A total of 18 participants (four males, 14 females) were recruited from within the university campus. These participants had a mean (\pm SD) age of 21(\pm 2) years, height of 169 (\pm 7) cm, mass of 65.4 (\pm 6.9) kg and BMI of 22.8 (\pm 2.1) kg/m². Ethical approval from the local university research ethics committee was obtained prior to the study. All participants provided written informed consent prior to participation. Participants were excluded if they were pregnant, aged less than 18 years, had current LBP, previous LBP for greater than 3 months, previous back surgery, a history of previous leg pain over the previous 2 years, previous postural education or a known skin allergic reaction to tape.

2.2. Instrumentation

All posture measurements were performed with the BodyGuardTM, which was adhered to the skin using adhesive tape (Figure 1). The BodyGuardTM incorporates a strain gauge that provides information about the relative distance between anatomical landmarks, estimating flexion/extension of the lumbar spine by the degree of strain gauge elongation.

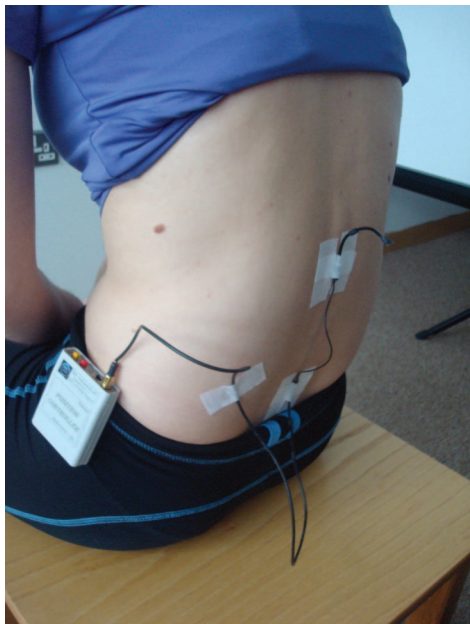


Figure 1. The posture monitoring device.

Elongation of the strain gauge alters its internal resistance and therefore the voltage of the signal. This alteration in voltage occurs in a linear manner in response to elongation. Therefore, the voltage output is directly related to the length (flexion vs. extension) of the strain gauge. Postural data are recorded in real time at 20 Hz. Based on the elongation of the strain gauge, lower lumbar spine sagittal plane posture is expressed as a percentage of range of motion (ROM). Therefore, the degree of spinal flexion/extension is expressed relative to a referenced ROM, for example, total lumbar flexion ROM, rather than being expressed in degrees (O'Sullivan *et al.* 2010). This reflects the clinical assessment of patients, where sitting posture is often considered relative to individual ROM. It is also similar to electromyography normalisation of muscle activity relative to maximal or sub-maximal voluntary contraction (Dankaerts *et al.* 2006b). The linearity of the BodyGuard™ has been established as excellent (correlation with digital callipers >0.99, mean difference <2.5% elongation). In comparison to other devices based on strain gauges (Donatell *et al.* 2005), the BodyGuard™ is very small, incorporating only a single strain gauge, with no other optical or inertial sensors being required. The device is operationally stable within a temperature range of 10–40°C. The BodyGuard™ has been validated as a measure of lumbo–pelvic posture and movement against a traditional flexible electrogoniometer (Biometrics, Cwmfelinfach, Gwent, UK), in both sitting ($r=0.98$) and standing ($r=0.99$) (O'Sullivan 2010).

2.3. Study design

A between-day and inter-rater test–retest design was used. Two raters assessed participants on 1 d and one rater repeated the procedure on a second test day. The raters were a musculoskeletal physiotherapist with 10 years clinical experience and an occupational therapist with 3 years clinical experience. Both raters agreed and practised a procedure for palpation of the spine prior to testing. The BodyGuard™ was removed by each rater after testing and reapplied by the other rater. Both raters were blind to previous results during testing. The mean (\pm SD) number of days between testing was 5 (\pm 2) d.

2.4. Experimental protocol

2.4.1. Participant preparation

Participants removed their shoes and wore shorts during testing. The skin was cleaned with alcohol wipes prior to testing. The BodyGuard™ was positioned directly over the spine at the spinal levels of L3 and S1, as determined by palpation. These spinal levels were chosen as the lower lumbar spine is the most common area for subjects to report LBP (Dankaerts *et al.* 2006a and recent research suggests that the upper and lower lumbar spine regions demonstrate functional independence (Dankaerts *et al.* 2006a, Mitchell *et al.* 2008). The BodyGuard™ was applied with participants sitting in a slouched position. Based on preliminary pilot testing, a 6 cm strain gauge was used for all participants and was secured with tape (Figure 1). Once the BodyGuard™ was positioned, participants stood up and performed repeated maximal flexion movements in standing to ensure the device was securely attached and that its available length would not be exceeded during testing. Further, the BodyGuard™ was calibrated to full lumbar flexion ROM during standing flexion. To do this, each subject was first asked to maintain a relaxed standing position (Figure 2), which was set as 0% of their lumbar flexion ROM, and then to perform full flexion of the spine ('bend as far as possible towards your toes while keeping your knees straight'). This flexed position was set as 100% of their lumbar flexion ROM (Figure 3). Once this calibration procedure was completed, participants were asked to complete three repetitions of maximum ROM into full lumbar flexion in standing to ensure comfort and consistency of movement was possible while wearing the BodyGuard™. Participants then resumed a seated position and were instructed in the tasks to be performed.

All tasks were timed using an electronic clock (www.online-stopwatch.com). The following procedure was repeated in the same manner by both raters, on both test occasions.



Figure 2. Calibration to 0% flexion in standing.



Figure 4. Forward bending task.



Figure 3. Calibration to 100% flexion in standing.

2.4.2. Forward bending

For the FB task, participants were asked to bend forward in standing to touch a 45 cm high target ('bend to touch the target while keeping your knees straight, and arms and fingers outstretched') (Figure 4). Foot position and distance from the target were standardised. To minimise the degree of natural

variation in how participants performed the task, they were asked to perform it a few times for practice, taking breaks in between, until the rater was satisfied they were performing the task consistently. Participants then bent forward under verbal instruction, maintained this position for 5 s and then returned to their relaxed standing posture. This was performed three times.

2.4.3. Usual sitting

For the usual sitting (USit) task, participants sat unsupported on a flat wooden 45 cm high stool with their knees and ankles positioned at 90°, both feet flat on the ground, forearms over their thighs, while looking at a convenient fixed point straight ahead (Figure 5). In this position, participants were asked to assume their USit position ('sit as you usually do and look at the mark on the wall'). Similar to the FB task, participants adopted what they perceived as their USit posture a few times for practice, until the tester was satisfied they were performing this consistently, to minimise the degree of natural variation. Participants were asked to remain in this position for 60 s and this USit posture was recorded once.

2.5. Data analysis

Data were automatically uploaded to a Microsoft Excel file via a proprietary wireless signal developed by the manufacturers. For FB, the entire 5 s of each sustained FB movement was analysed and the average

posture (%ROM) was used for comparison. For USit, the entire 60 s was analysed and the average USit posture was used for comparison. Data were then analysed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). The reliability analysis used in many studies (Troke *et al.* 1996, Schuit *et al.* 1997, Mannion and Troke 1999, Ng *et al.* 2001) has been criticised since the level of association between the data is assessed and no information on the level of agreement between measures is provided (Bland and Altman 1986, McGinley *et al.* 2009). To overcome this, it has been recommended that intraclass correlation coefficient (ICC) values are complemented with data that examine the level of agreement between measurements, for example, using Bland and Altman methods (Bland and Altman 1986, Rankin and Stokes 1998). Therefore, for this study the association between values was analysed using one-way random (ICC_{2,1}) and two-way mixed (ICC_{3,2}) ICC, for between-day and inter-rater data respectively. In addition, Bland and Altman methods were used to determine the level of agreement between data (Bland and Altman 1986). Finally, the standard error of measurement (SEM) and minimal detectable change at the 90% confidence level (MDC90) were calculated to provide an indication of the dispersion of the measurement error and the difference required between measurements to be considered real change. The mean difference, SEM and MDC90 values were all expressed as a percentage of flexion ROM.

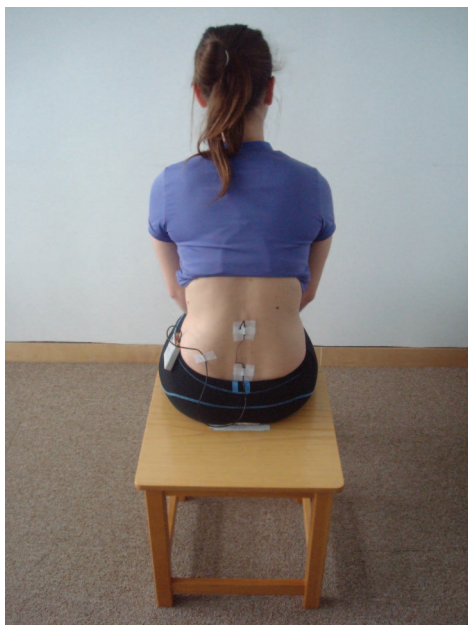


Figure 5. Usual sitting task.

3. Results

The mean (\pm SD) posture during each task for each rater is displayed in Figure 6.

3.1. Between-day reliability

Between-day values displayed excellent association for both FB (ICC_{2,1} = 0.87) and USit (ICC_{2,1} = 0.84) (Landis and Koch 1977). In addition, the between-day level of agreement was very good, with mean difference values of 8.99% and 7.85% for FB and USit respectively. The SEM was relatively small for both FB (5.91%) and USit (4.78%). Finally, the MDC90 was 13.77% for FB and 11.14% for USit (Table 1).

3.2. Inter-rater reliability

Inter-rater values also displayed excellent association for both FB (ICC_{3,2} = 0.94) and USit (ICC_{3,2} = 0.91) (Landis and Koch 1977). In addition, the inter-rater level of agreement was very good, with mean difference values of 6.31% and 6.17% for FB and USit respectively. The SEM was again relatively small for both FB (4.16%) and USit (3.87%) Finally, the MDC90 was 9.72% for FB and 9.03% for USit (Table 1).

4. Discussion

Good between-day and inter-rater reliability is a basic requirement for validity. Between-day reliability is important if the device is to be used as an outcome measure, while inter-rater reliability is important if different raters are to perform consistent measurements. The results indicate that the reliability of the device for analysing lumbar spine posture during sagittal plane tasks is excellent. All ICC values were

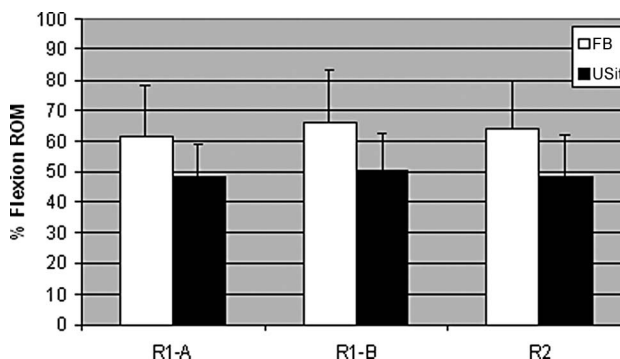


Figure 6. Mean (\pm SD) lumbar posture during forward bending (FB) and usual sitting (USit) for rater 1 on two occasions (R1-A and R1-B), as well as rater 2 (R2) on one occasion. ROM=range of motion.

Table 1. Reliability of the spinal position monitoring device.

	ICC	95% ICC	\bar{d}	95% CI for \bar{d}	SD_{diff}	95% LOA	SEM	MDC90
FB-between	0.87	0.67, 0.95	8.99	5.11, 12.89	7.84	24.35, -6.36	5.91	13.77
FB-inter	0.94	0.84, 0.98	6.32	3.69, 8.95	5.29	16.68, -4.04	4.16	9.72
USit-between	0.84	0.57, 0.94	7.85	5.59, 10.12	4.56	16.78, -1.08	4.78	11.14
USit-inter	0.91	0.77, 0.97	6.17	3.95, 8.40	4.47	14.93, -2.58	3.87	9.03

ICC=Intraclass correlation coefficient; \bar{d} =mean differences between measures, expressed as % range of motion (ROM); 95% CI for \bar{d} = 95% CI of the mean difference between measures, expressed as %ROM; SD_{diff} =standard deviation of the mean difference, expressed as %ROM; 95%LOA=95% limits of agreement (calculated by $\bar{d} \pm [SD_{diff} \text{ multiplied by } 1.96]$), expressed as %ROM; SEM=standard error of measurement, calculated as $SD \times \sqrt{(1 - ICC)}$; MDC90=minimal detectable change at the 90% CI; FB=forward bending; USit=usual sitting. Note: ICC_{2,1} is used for between-day analysis, ICC_{3,2} is used for inter-rater analysis.

over 0.81, which has been described as an 'almost perfect' association between measurements (Landis and Koch 1977). Reliability of spinal posture measurement is critical to ensure that the presence or absence of an association between spinal posture and NSCLBP can be accurately estimated (Dartt *et al.* 2009). A high degree of measurement error could result in subtle alterations in posture going unnoticed or, indeed, non-existent postural differences could be assumed on the basis of poor reliability.

The ICC values observed in this study for sagittal plane postural measurement using the BodyGuardTM are similar to those reported for measurement of standing sagittal plane lumbar posture using laboratory motion analysis systems (Levine and Whittle 1996, Norton *et al.* 2002, Schuit *et al.* 2004, Troke *et al.* 2007), as well as simpler devices, such as inclinometers (Ng *et al.* 2001). Furthermore, the ICC values are superior to those reported for digital photography for measurement of either standing or sitting lumbar sagittal plane postures (Dunk *et al.* 2004, Perry *et al.* 2008, Pownall *et al.* 2008). It is acknowledged that no study has previously examined the repeatability of the FB task performed in this study. However, the reliability of digital photography to measure lumbar flexion using a different standardised FB task was also slightly lower than that reported here (Corben *et al.* 2008). This, in addition to the fact that the device displays greater reliability during the sitting task compared to digital photography (Pownall *et al.* 2008), implies that the device itself may be more reliable than digital photography. Overall, the ICC values were slightly better for inter-rater measurements, possibly due to these tests being conducted on the same day.

As previously mentioned, many reliability studies simply describe the association between measurements, but not the true level of agreement, which has been criticised (Bland and Altman 1986, McGinley *et al.* 2009). The mean differences obtained in this study, which varied between 6% and 9% of lumbar flexion ROM, appear to represent a relatively small amount of

variation between testers. The SEM similarly varied between 4% and 6% for all measurements and the MDC90 varied from 9% to 14%. Ideally, the mean difference, SEM and MDC90 should be small and close to zero. It is difficult to estimate what is an acceptable level of difference between repeated measurements using the BodyGuardTM as this depends on the extent of the hypothesised postural differences between NSCLBP subjects and matched controls, which is the scope of current further investigation. Since this discriminative validity of the device has not yet been fully investigated, this information is unknown. However, based on NSCLBP research using angular measurements during laboratory testing (Dankaerts *et al.* 2006a, the degree of measurement error reported here for the BodyGuardTM appears to be acceptable. Therefore, based on previous research it appears that the reliability of this postural monitoring device is as good as, or better than, other lumbar posture measurement devices, either large laboratory-based systems or smaller, portable devices.

4.1. Applications and implications

The BodyGuardTM is a relatively simple, economical, and minimally invasive postural monitoring system. It is considerably smaller than some alternative devices (Donatell *et al.* 2005), so that it should not interfere with normal movements and function. Many other similar-sized devices are based on overall trunk flexion rather than local spinal flexion (Intolo *et al.* 2010), which is a considerable disadvantage when addressing subtle local changes in lumbar spine posture. It is difficult to compare the output regarding spinal posture with the results of other devices as the output of this device is not expressed in degrees and currently only measures sagittal plane motion. Despite this, research indicates that expressing lumbar posture relative to ROM (as the BodyGuardTM does) may be very useful, since postural differences between healthy controls and NSCLBP subjects have been observed in

laboratory settings (Dankaerts *et al.* 2006a). Only moderate human resources are needed for data collection and analysis and very little training is required, reducing potential barriers to its application in practice. This is the first in a series of studies planned to determine the clinical utility of the device for research in NSCLBP populations. While the device has been validated in simple sagittal plane postures and movements against an electrogoniometer, future studies will be performed to compare this device to a standard laboratory-based motion system, as well as digital video fluoroscopy, similar to the approach used with the validation of other motion analysis systems (Schuit *et al.* 1997, Mannion and Troke 1999, Bull and McGregor 2000, Ripani *et al.* 2008, Intolo *et al.* 2010). Further studies are also required to determine if the device can discriminate between subgroups of subjects with NSCLBP and matched controls, similar to existing laboratory-based systems (Dankaerts *et al.* 2006a). Similarly, whether the provision of postural feedback via the BodyGuardTM improves outcomes in NSCLBP requires investigation. The potential to provide patients with feedback regarding the control of their movement patterns may motivate patients (Horton and Abbott 2008), improve exercise performance (Magnusson *et al.* 2008), reduce the link between pain and movement (Zusman 2008) and might decrease the enormous rehabilitation costs associated with NSCLBP (Hermens and Vollenbroek-Hutton 2008).

As stated earlier, the use of spinal biofeedback to change motor patterns was supported in a recent study (Magnusson *et al.* 2008) and the BodyGuardTM is more portable and less invasive than many existing devices. The BodyGuardTM may allow investigation of whether factors such as postural variability or prolonged exposure to near end-range postures are predictors of LBP, as detailed examination of these relationships in the past has been constrained by technological limitations. Currently, digital photography and video analysis are commonly used in ergonomic research as they are the least invasive (Spielholz *et al.* 2001, Dartt *et al.* 2009, Straker *et al.* 2009). In future trials, the device may offer more specific assessment of postural exposure while still allowing maximal work productivity. Indeed, it is now possible to remotely monitor several subjects simultaneously and longitudinally using the BodyGuardTM, so that the temporal relationship between postural exposure and musculoskeletal pain and discomfort can be studied in greater detail.

The device may also help bridge the gap between advice given to NSCLBP patients in the laboratory or clinic and the challenges faced in implementing these postural changes into daily life.

4.2. Limitations

The sample size, although larger than some previous studies examining the reliability of lumbar posture and movement (Mannion and Troke 1999, Ng *et al.* 2001, Pownall *et al.* 2008), is small. Errors of palpation are always possible between raters; however, every effort was made to ensure consistency of palpation technique between raters. The values obtained reflect those of two raters, who practised palpation and device application in advance, so that it is possible that reliability would be lower for other raters. Inconsistent movement or postures by participants may explain some of the observed variation; however, this was minimised by giving clear instructions, along with time to practise each procedure. This study only evaluated the reliability of the BodyGuardTM for the lower lumbar spine during sagittal plane flexion tasks. The ability of the BodyGuardTM to monitor other spinal regions and planes of motion requires further study. The reliability of the BodyGuardTM in occupational environments, or when self-applied by the NSCLBP patient, has yet to be evaluated. Similar to all skin-mounted spinal measurement systems, the BodyGuardTM may not reflect actual spinal motion, particularly as its output is related to linear strain gauge elongation and not angular displacement. The risk that motion in planes other than the sagittal plane (e.g. rotation or side-flexion) could compromise or contaminate the output must be examined in future validity studies. The limitations associated with not providing an angular output and analysing only sagittal plane postures has already been highlighted. In future studies the calibration procedure may need to be specific to the task being analysed, e.g. seated ROM if examining USit task; however, this was not deemed necessary for this initial study.

While there is emerging evidence that, for subgroups of NSCLBP, postural factors can be significant (Dankaerts *et al.* 2006a, 2007), it is acknowledged that there is still little agreement on what constitutes ideal posture (O'Sullivan *et al.* 2006, Claus *et al.* 2009, Reeve and Dilley 2009, O'Sullivan *et al.* 2010). Further, it is acknowledged that NSCLBP is a multifactorial biopsychosocial disorder, where numerous factors other than posture and movement patterns must be considered (McCarthy *et al.* 2004, Linton *et al.* 2007).

5. Conclusion

The results indicate that the BodyGuardTM has excellent reliability for analysis of lower lumbar spine sagittal posture, both between-days and between-raters. It has several potential advantages over existing methods of analysing spinal posture, although the lack of an angular output is a limitation.

Further validation studies using this device are indicated before progressing to clinical trials.

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