Device, protocol and measurement of regional spinal stiffness

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Abstract

Spinal stiffness is commonly assessed by manual therapists but the methodology varies widely. The current study presents a novel device – Therapeutic Spinal Mobilizer – to measure spinal stiffness safely and reliably. The methodology developed allows exertion of a force perpendicular to the spinal skin surface over a selected spinous process at a preselected frequency for predetermined duration cyclically in a repeatable manner. The loading rate is governed by the gravity feed. The force applied and displacements produced were used to calculate the spinal stiffness at that level.

The results revealed a significant difference in stiffness due to magnitude of load (loading rate) \( p < 0.01 \) but no significant difference in stiffness between different cycles of loading with same load. The phase of respiration significantly affected stiffness, with total lung capacity being stiffest and residual functional capacity the least stiff \( p < 0.05 \). There was a significant difference in stiffness of the three spinal levels tested \( p < 0.05 \).

In conclusion, the standardized methodology revealed that spinal stiffness of one region may be very different from another. Different loads yield significantly different stiffness \( p < 0.01 \).

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1. Introduction

Spinal motion testing and spinal stiffness assessment using manually applied force has been practiced for a long time. However, a controversy over its reproducibility and effectiveness has persisted. In two recent reviews significant ground has been covered on these issues (Seffinger et al., 2004; Stochkendahl et al., 2006). In their systematic review Seffinger et al. (2004) reported on the intra-examiner and inter-examiner reliability in spinal palpation diagnostic procedures. This multidisciplinary team performed a comprehensive review of the primary literature obtained from 13 electronic data bases over 35 years (1966–2001) and identified 797 primary research articles but finally selected 49 of them. The regional range of motion assessment was more reliable than segmental motion. The intra-examiner reliability was better than inter-examiner reliability. Interestingly, the examiner’s discipline, experience level, consensus on procedure used, training just before the study or use of symptomatic subjects did not add to reliability. Stochkendahl et al. (2006), in their critical systematic review of literature, considered studies published between 1965 and 2005. They conducted a meta-analysis of only high quality studies to investigate consistency of data. The 48 studies included in the meta-analysis varied in quality drastically. These authors reported that the spinal procedures other than pain provocation were either not reproducible or the evidence was conflicting or preliminary.

The value of any treatment is limited if it is based on unreliable data and administered or interpreted in an inconsistent manner. Clearly there is a need to standardize manual techniques in a quantitative manner to improve their efficacy and reliability. Hence the development of a standardized device and a standard protocol to carry out spinal stiffness test is of clinical significance. To this end several devices have been published in the literature to provide posterior–anterior (PA) stiffness. While they all have the same aim, that is to apply a PA load to the selected spinous process, they tend to achieve this goal in a slightly different way. The “spinal physiotherapy simulator” (Lee and Svensson, 1990) was driven by a variable speed DC motor connected to a cam. The padded load application stylus was actuated via a four-bar linkage system under the action of a dead weight. Lee and Evans (1992) reported a motor driven spinal mobilizer with a force applicator located between two linear variable differential transducers (LVDTs) on each of the adjacent spinous processes. It is unclear however, how the segmental displacements were calculated from this setup. Latimer et al. (1996) have argued that it is unlikely that the measures obtained from the device presented by Lee and Evans (1992) could be used to show a relationship with the clinically evaluated PA stiffness. These authors go onto describe their own portable version of a stiffness assessment device. This device, also operated with a computer controlled motor, works using a pulley driven system for load applications and a compression spring mounted to the force actuator. The force is calculated based on the...
compressive deformation of the spring with a calibrated spring constant. The authors state that the deformation of the spring was calibrated using a dial indicator, but neither the methodology nor the dial indicator is described or shown in the diagram representing the device. In a more recent study, Kawchuk et al. (2006) describe using an ultrasonic system, tested on a tissue simulator, and report superior measurements of displacement.

Other methodology used to study spinal stiffness includes a computer controlled voice coil actuator (Colloca et al., 2004). Instruments using similar concept (Chiropractic Adjusting Tool – CAT; Activator Adjusting Instrument IV and Impulse Adjusting Instrument) have also been developed and used by Keller et al. (2007). The authors have published a number of papers, some on sheep spine and others with the application of mechanical thrusts on patients (Keller et al., 2002, 2003; Keller and Colloca, 2007). However, a standard device and protocol has not emerged that addresses most aspects of spinal stiffness testing.

Therefore, the objective of this study was to design a device with which a predetermined and standardized load is applied to a preselected spinal level at a preselected frequency and loading rate and resulting deformation is measured to derive spinal stiffness at that level under those conditions. Additionally, the device must be valid, reliable and allow multiple testing regimens with varying loads and loading frequency.

2. Methods

2.1. System

The Therapeutic Spinal Mobilizer System (TSM) was developed (Fig. 1a) that consisted of a 1/6 horsepower, 16 RPM AC gear motor that drove a loading piston that applied pressure to a patient’s spine. The TSM was controlled by a special software developed in LabView to operate the device, collect the generated data and write it to pre-created files. Using this software the frequency of loading, the duration of load application within the chosen frequency, and the number of loading cycles could be selected. The excursion of the loading piston could be determined by selecting a cam of appropriate diameter. For the current experiment a cam was selected to allow a total excursion of 5 cm. However, as the load was resisted by the back of the subject it rested there till the lever driven by the motor and the cam lifted it on return portion of the cycle. The entire sequence of events was repeated in the next loading cycle. The force was applied by placing desired load on the load receptacle of the piston which in turn applied pressure onto the patient’s back as it was lowered on it by the motor and cam assembly. This load was measured by an intervening load cell built into the piston. The cylindrical loading block with a diameter of 2 cm and rounded edges has high density polymer padding coating on the surface for contact with the patient’s back. This loading block is attached to the loading piston which is raised and lowered by raising and lowering the lever through the cam (Fig. 1b). The desired maximum force and loading rate was obtained by selecting an appropriate static load placed on the load receptacle of the loading piston. The displacement of the piston was monitored by a Linear Variable Differential Transducer (LVDT) to determine the displacement of a patient’s spine. Force measurements from the load cell (Newton, N) and displacement measurements (millimeters, mm) were logged into the file and plotted in real time using LabView platform that allowed verification of the force that was exerted on the subject’s spine and the resulting magnitude of displacement.

2.1.1. Design of Therapeutic Spinal Mobilizer (TSM)

The TSM (Fig. 1a and b) consisted of a capacitive load cell (iLoad Analog TM, Integrated Load Cell from Loadstar Sensors, Model #iLoad Analog 100 lb, Fremont, CA) which has a built-in signal conditioning electronics and has an accuracy of 0.15% full scale. The sensor is powered by a 5 V DC input signal and outputs an analog 0.5–4.5 V DC signal proportional to the applied load. The full scale output range is 4000 mV. The load cell is incorporated in the loading piston across the path of its loading axis. The TSM is a heavy and sturdy device on lockable castors that can be rolled from one place to another on a level floor and can be fixed at any place. The TSM is designed to be wheeled over a patient lying prone on a plinth and locked in place such that the loading piston overlays the spinous process of choice. The weight of the TSM is eight times greater than the maximum load applied to human spine for stiffness testing preventing any upward motion of the device during testing. Load is applied to the spine via a rigid indenter with high density polymer padding on the surface contacting the spine. Displacement of the indenter is measured directly using a linear variable displacement transducer (LD621-100 DC, Omega, Stamford, CT) measuring range 0–100 mm full scale with an accuracy of 0.02%. The transducer is excited by a 12 V DC input signal and outputs an analog 0–10 V DC signal proportional to the displacement. The load cell and LVDT are both attached to the loading piston that can be raised or lowered by the cam and lever assembly (Fig. 1b) in order to facilitate subject positioning during testing. A permanent split capacitor AC gear motor is used to drive the loading piston. A capacitor is connected in series and used to create a second phase from the single phase AC current and it is the interaction between these two phases that causes the motor to run. This provides high power and high starting torque. The control box consisted of a power supply and a current buffer. The Meanwell RT-6SD triple outputs power supply provides power for the load cell, LVDT, AC motor, and the current buffer.

In order to run the motor and interface the load cell and LVDT with LabView, a multifunction data acquisition card (DAQ) is used. The National Instruments Data Acquisition card (Model No. USB-6009, National Instruments, Austin, TX) provides data acquisition functionality for applications. It has eight analog inputs (14-bit, 48 kS/s), two analog outputs (12-bit, 150 S/s), 12 digital I/O, and 32-bit counter. Also, it has a built-in signal connectivity and bus-powered for high mobility.

2.1.2. Testing reliability and validity of the Therapeutic Mobilizer

The reliability and validity of the Therapeutic Spinal Mobilizer was tested against one segment electromechanical spinal model (Kumar, 1995). This device has been previously used and results published in peer reviewed literature (Simmonds et al., 1995; Bjornsodt and Kumar, 1997). This electromechanical model was set on an treatment bed (Make: Hill Adjustable) and the loading block of the Therapeutic Spinal Mobilizer (TSM) was aligned over the vertebral spinous process and positioned appropriately to begin mobilization. The mobilizer was run over the model cyclically for varying periods of time for a repeatable pattern, time after time with respect to the duration of load application, the magnitude of load application, the frequency of loading. For testing the validity of the TSM the values of load and displacement reading obtained from the load cell and the LVDT of the TSM were recorded and compared against those of previously validated values of the load cell and LVDT of the spinal model (SM). These experiments consisted of 10 trials at each of the loads: 22, 45, 90, 135 and 157 N on three separate days. These validation plots with means and standard deviations are presented in (Fig. 2a and b).

2.2. Protocol development

The measurement of spinal stiffness can be affected by factors such as padding of the plinth, the magnitudes of the loading rate, number of loading cycles applied, frequency of loading and the...
phase of the respiratory cycle in which the testing is performed. These variables are considered below. Based on the type of the measurement desired, the examiner can control or vary loading rate by either changing the load at fixed frequency or changing the frequency with fixed load. Any combination of these variables could be selected. However, in the current experiment the interaction between the load and frequency is less consequential as explained in Section 2.2.2 under load variables. Additionally, the examiner can choose different plinths with varying amount of padding.

2.2.1. Padding

The protocol for spinal stiffness testing was developed based on information published in the literature and subject’s feedback with respect to their comfort. Whereas the plinth padding has been reported to make difference in the stiffness measure (Maher et al., 1999), a rigid wooden plinth with no cover was considered uncomfortable by the subjects. The stiffness was reported systematically 2.86 N/mm higher for rigid surface compared to padded surface ($p < 0.01$) (Latimer et al., 1997). However, these differences had a constant systematic pattern;

Fig. 1. (a) The Therapeutic Spinal Mobilizer. (b) The motor and cam assembly of the Therapeutic Spinal Mobilizer.
the authors reported a relatively constant 20% reduction in stiffness when using plinth padding. Furthermore, variations in methodology for testing of posterior–anterior (PA) stiffness with respect to this variable are also considerable. Edmondston et al. (1998) tested subjects on a manual therapy plinth with padding and Lee and Evans (1992) had their subjects lay on a mattress on the floor. On the contrary Latimer et al. (1996) used their device for stiffness measurement on an unpadded testing bed. Though not specifically mentioned by Caling and Lee (2001) it would appear from their illustration that their subjects lay on a rigid surface, and Stanton and Kawchuk (2009) do not indicate if they used plinth for their subjects when testing for stiffness. Reconciling these two factors it was decided to use a standard clinical plinth used in most clinical facilities (Make: Hill Adjustable). It was also argued that almost all clinics have padded plinth for patient assessment and treatment.

2.2.2. Load variables

Stiffness being the relationship between load and deformation (N/mm) and biological tissues being viscoelastic, non-homogenous, and structurally complex are likely to be affected by the loading rate in stiffness testing. Latimer et al. (1998) tested the effect of different force ranges on the stiffness’ value obtained. They reported different values of stiffness for different force ranges which was considered to be a factor in poor reliability of manual judgments of PA stiffness.

However, Latimer et al. (1998) applied up to 275 N PA load to two asymptomatic subjects at L3 and measured the load-deformation response. They found this relationship to be linear throughout the range with a tendency for the stiffness to increase at higher values of load. Their finding indicates that loads above 30 N largely remain linear. Others show a linear response above 20 N (Latimer et al., 1998; Snodgrass et al., 2008; Owens et al., 2007). Thus it would appear that very high loads are not necessary to obtain reliable values of stiffness. A range of values between 45 and 135 N may be optimal for testing to obtain stiffness from the linear range. This range has been used to determine the most comfortable loads for such testing. By keeping the loading piston rate of advancement fixed due to gravity feed, the loading rate was increased by increasing loads.

Another matter for consideration in load application on the spine is its curvature. To compensate for it Allison et al. (1998) and Caling and Lee (2001) tested the spinal stiffness with load perpendicular to vertebra as well as in vertical direction of loading. Allison et al. (1998) found only a small difference in stiffness values at L1, L3 and L5 due to the direction of loading and it generally did not reach statistical significance except at L4. Caling and Lee (2001) on the other hand reported a mean difference of up to 11.32% in 20-degree range around vertical at L3 and 3.81% at L4. Given the fact that absolute value of spinal stiffness has not been clinically related with any firm diagnosis or specific treatment regimen a vertical direction of loading was chosen as being technically the most convenient and repeatable.

Loading rates of 0.5, 1.0 Hz and application of a quasi-static load (where the load was applied for a period of 20 s) was studied by Lee and Svensson (1993). Their study revealed that each load showed the same general pattern of force displacement relationship. This response was nonlinear below 20 N but linear beyond this value yielding a mean stiffness value of 15.3 N mm\(^{-1}\). However, clearly with quasistatic loading significantly more deformation was achieved due to creep, and the difference between 0.5 and 1 Hz was small. From the foregoing it would appear that if the objective is measurement of spinal stiffness, a range of loading frequencies may yield similar results. However, a prolonged loading which will create creep is not desirable for stiffness measurement.

There is an inherent interaction between the load and frequency of loading to yield the loading rate. This phenomenon is dependent on the assumption that only the desired fraction of the load will be applied over a predetermined time and that this rate be maintained through the process. However, in human in vivo testing when the entire organ is loaded while it is integrated with the rest of the body this precise loading rate will be hard to determine. As soon as the applied load makes contact with the body an undetermined portion of the load will be transferred to the structure and shortly after the rest will be delivered. This poses difficulty in determining the loading rate in experimental condition as is the case in the current project. Bearing this consideration in mind the loading rate was not controlled in this study. Varying loads were delivered to pre-selected spinous processes using gravity feed method. The frequency chosen for this protocol was 0.1 Hz for the reasons described above.

Yet another variable of interest is the number of loading cycles used for determination of spinal stiffness. Due to silence of
literature in this matter two volunteers were subjected to 30 cycles of loading. The stiffness was calculated at five cycle interval with no significant differences in stiffness between cycles. Subsequently, three other subjects were loaded for 15 cycles and the stiffness was calculated for 5, 10 and 15 cycles (Fig. 3). The mean stiffness at each of these cycle intervals for the spinal Level L3 for two male subjects was 7.6, 7.7 and 7.7 N mm\(^{-1}\); and Level T8 for one female subject was 4.7, 4.7 and 4.65 N mm\(^{-1}\), respectively. Based on the observations of a lack of significant difference due to number of cycles used a set of five loading cycles was selected.

2.2.3. Respiratory cycle
Spinal stiffness is reported to be significantly affected by the phase of the respiratory cycle (Allison et al., 1998). It was reported that the PA stiffness of the lumbar spine was influenced by trunk muscle activity and intra-abdominal pressure and these factors vary with breathing. The authors reported that L2 and L4 stiffness increased above the base level of functional residual capacity with both inspiratory and expiratory efforts. It was greatest during maximum expiration with their experimental protocol. The authors also concluded that the changes in trunk muscle activity and intra-abdominal pressure with respiratory efforts modulated spinal stiffness. Therefore, the phase of the respiratory cycle representing the functional residual capacity was used in stiffness testing.

2.3. Device validation with human subjects
Subsequent to testing the reliability and validity of the TSM and establishment of protocol for measurement of spinal stiffness data collection in a pilot sample of five male subjects began. The project had received IRB approval. The mean age, mean height, and mean weight of the sample were 29.8 years (SD 8.5 years), 173.6 cm (SD 6.4 cm), and 82.7 kg (SD 3.6 kg), respectively. Upon arrival, each subject was given information on the project through a letter of information and the procedure was also verbally described. The volunteers were given opportunity to ask questions for clarification. Once the consenting volunteer signed the consent form the test began. These subjects were tested at the spinal levels of 6th and 11th thoracic vertebrae and the 4th lumbar vertebra. The selected three spinous processes were marked after palpating the back. The subjects were positioned prone on a treatment table (Hill Adjustable) with their back exposed. The TSM was then wheeled over the prone subject lying on the treatment table such that the loading block of the TSM was just above the appropriate vertebral level. No pre-load was applied to the spine. The experiment was started by initiating computer controlled data acquisition. The latter initiated the cyclic loading by starting the TSM motor. The cycles were designed such that the load stayed on the spinous process for 5 s before rising above it for 5 s. As the load was applied to the spinous process the deformation began. The load cell and the LVDT continuously recorded the load on the spinous process and the ensuing deformation and were sampled at 1 kHz. Each tested vertebral level was subjected to five cycles of testing with each of the four loads (22, 45, 90 and 135 N) or to their lower tolerance level (Fig. 4a).

Graphical programming with LabView 8.6 was used to implement the system. It consisted of a digital portion and an analog portion. These multiple channels were combined in the same task to acquire data from all of them at the same time.

2.4. Data analysis
The collected and stored data were accessed from the hard drive and subjected to a linear regression. The line of best fit was used to calculate the slope as the stiffness coefficient value. The mean and standard deviation for five cycles of each testing condition were calculated and averaged to represent the stiffness of that condition for that subject. The data were subjected to t-test to discern significant differences between stiffness calculated at different load levels and significant difference between the stiffness at different spinal levels.

Fig. 3. Load deformation plot of 15 cycles at lumbar level with 45 N load.

Fig. 4. (a) Force displacement plots of a single subject at T4 spinal level. (b) The spinal stiffness at T4 with four loads.
Table 1
Stiffness calculated for 5, 10 and 15 cycles of loading in two subjects with an external load of 45 N and the load of the piston.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Spinal level</th>
<th>Cycles</th>
<th>Force (N)</th>
<th>Displacement (mm)</th>
<th>Stiffness (N mm⁻¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Male</td>
<td>L₃</td>
<td>5</td>
<td>56.74</td>
<td>0.20</td>
<td>7.51</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>56.56</td>
<td>0.70</td>
<td>7.33</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15</td>
<td>56.45</td>
<td>0.73</td>
<td>7.31</td>
</tr>
<tr>
<td>Female</td>
<td>T₆</td>
<td>5</td>
<td>54.34</td>
<td>0.21</td>
<td>11.54</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10</td>
<td>54.36</td>
<td>0.22</td>
<td>11.48</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15</td>
<td>53.67</td>
<td>0.57</td>
<td>11.55</td>
</tr>
</tbody>
</table>

Table 2
Spinal stiffness of the sample (n = 5 males) at three spinal levels with four loads.

<table>
<thead>
<tr>
<th>Average stiffness of T₁₂, T₁₁, and L₄ vertebrae in 5 males</th>
<th>22 N</th>
<th>45 N</th>
<th>90 N</th>
<th>135 N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>STD</td>
<td>Mean</td>
<td>STD</td>
</tr>
<tr>
<td>T₀</td>
<td>3.99</td>
<td>1.94</td>
<td>5.58</td>
<td>2.48</td>
</tr>
<tr>
<td>T₁</td>
<td>3.83</td>
<td>2.44</td>
<td>5.61</td>
<td>3.62</td>
</tr>
<tr>
<td>L₄</td>
<td>4.47</td>
<td>2.44</td>
<td>5.61</td>
<td>3.51</td>
</tr>
</tbody>
</table>

3. Results

The repeated cycles of loading demonstrated similar load deformation relationship (Fig. 3). The stiffness values of these loading cycles remained stable throughout the loading period (Table 1). The effect of the magnitude of the load on spinal stiffness values were progressive and significant (p < 0.01) increasing with load and thereby loading rate at which testing was done (Fig. 4a and b). The spinal stiffness at different spinal levels were also significantly different from each other (p < 0.01) (Table 2). The effect of the phase of the breathing cycle in measurement of spinal stiffness was significant (p < 0.05). The stiffness was high when the subject had taken a deep breath and held it as compared to the functional residual capacity and full exhalation. However, while performing Valsalva Maneuver the stiffness was the highest recorded (Table 3).

4. Discussion

Clinicians commonly employ palpation and motion testing techniques in assessment of low back pain patients. Such testing is done in posterior–anterior (PA) direction. Based on such assessments patients of low back pain are commonly stated to have stiff spines. However, manual clinical assessment of PA stiffness has been demonstrated to be inaccurate (Simmonds et al., 1995; Björnsdóttir and Kumar, 1997) and with poor inter-rater reliability (Shirley et al., 2003; Matyas and Bach, 1985; Maher and Adams, 1997) and subsequently to make the measuring device portable.

Development of instruments leads to reliable measurement and become more acceptable when the validity is established. Through several research papers published in the literature (Lee and Svensson, 1990; Lee and Evans, 1992; Latimer et al., 1996; Edmondston et al., 1998; Stanton and Kawchuk, 2009; Latimer et al., 1998; Latimer et al., 1996). Recent advance in PA stiffness measuring device has been reported by Keller and Colloca (2007). The general considerations in technology development have been driven initially to improve the reliability of safe measurement and subsequently to make the measuring device portable.

The results presented here show a significant difference in the stiffness due to the magnitude of the load. This is expected and thought to be due to increasing rate of loading caused by larger load undergoing the same excursion as the smaller loads in the same time. Human tissues being viscoelastic increased stiffness is expected. Small standard deviations in stiffness value at each level of loading indicate the reliability of the measure. Considering the need for valid and reliable measure within the comfort zone of human tolerance, an optimum load of 90 N is suggested. Additionally, an insignificant difference in stiffness value obtained between different cycles obviates the need for multiple cycle measurements. Two to three cycles of loading may be sufficient for a valid and reliable measure. Varying the frequency of loading did not reveal significant difference between stiffness values. Therefore, a technical advances reporting devices to measure PA stiffness (Lee and Svensson, 1990; Lee and Evans, 1992; Latimer et al., 1996; Edmondston et al., 1998; Stanton and Kawchuk, 2009; Latimer et al., 1998; Latimer et al., 1996). Recent advance in PA stiffness measuring device has been reported by Keller and Colloca (2007). The general considerations in technology development have been driven initially to improve the reliability of safe measurement and subsequently to make the measuring device portable.

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comfortable loading frequency between 0.5 and 0.1 Hz is being recommended. Also, testing stiffness on a standard clinical plinth will have a systematic reduction in stiffness value which will cancel out in comparison between patients and normal controls. Additionally, the functional residual capacity phase of respiratory cycle is suggested as the phase of choice for stiffness measurement when the lungs are neither inflated nor deflated.

The recommendations made in this paper are supported by information published in the scientific literature and data recorded in this study. The spinal stiffness varies with location of test (Kawchuk and Herzog, 1996; Latimer et al., 1999), posture of test (Edmondston et al., 1998), padding of the test surface (Matyas and Bach, 1985), load of test (Binkley et al., 1995), orientation of the load (Lee and Svensson, 1993; Edmondston et al., 1998; Latimer et al., 1996), loading frequency (Owens et al., 2007), and phase of the respiratory cycle (Shirley et al., 2003).

5. Conclusion

In conclusion, a safe, valid, and reliable device has been developed that allows easy spinal stiffness testing. The device is sturdy, portable or easily movable within a clinic for use in different locations and by different clinicians. The TSM allows for standardized testing conditions repeatedly with little variation. It uses a standard load with gravity feed for a constant loading rate within a safe range of testing. The number of cycles and loading duration are selectable but a fixed regimen is recommended.

The recommended protocol requires choosing the spinal site of interest using a load 90 N using a loading frequency between 0.5 and 0.1 Hz as desired recording 3–5 cycles in prone position on a standard plinth at residual functional capacity in breathing cycle. This will yield stiffness value that can be compared between cases.

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