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Reliability of Myotonometric Measurement of Stiffness in Patients with Spinal Cord Injury

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Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
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Funds Collection G

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Background: Contracture is related to modulation of passive stiffness in muscle and tendon after spinal cord injury (SCI). Current clinical assessments of stiffness in muscles and tendons are subjective in patients with spinal cord injury. We proposed a quantitative method to evaluate stiffness of the gastrocnemius and Achilles tendon (AT) with a portable device, the MyotonPRO. The purpose of this study was to investigate the intraoperator and interoperator reliability of the MyotonPRO when used in patients after spinal cord injury.

Material/Methods: Fourteen patients with SCI participated in this study. Gastrocnemius stiffness and AT stiffness were measured with the MyotonPRO.

Results: In participants with SCI, the intraclass correlation coefficient (ICC) values for intraoperator and interoperator reliability of stiffness measurements in the gastrocnemius and AT were excellent (all ICC >0.87), with relatively low values for standard error measurement (SEM) and minimal detectable change (MDC).

Conclusions: Our findings suggest that use of the MyotonPRO is feasible for evaluating stiffness of the gastrocnemius and AT in the lower limbs of patients with spinal cord injury.

MeSH Keywords: **Achilles Tendon • Elastic Tissue • Spinal Cord Injuries**

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Background

Spinal cord injury (SCI) is the second most serious and frequent traumatic event after craniocerebral injury, and can lead to a high rate of disability [1]. It leads to physical, psychological, social, and economic dysfunction for patients and their families [2]. Muscle dysfunction and contracture are common complications in patients with SCI and can lead to pain, deformity, and failure of a nerve recovery plan [3]. The contracture always occurs in the ankle joint, because of the variation in passive stiffness in muscles and tendons [4]. Thus, it is vital to quantify the stiffness of muscles and tendons to prevent secondary diseases after SCI and to offer targeted treatments.

There are various methods of evaluating the stiffness of muscles and tendons. Passive joint stiffness can be accurately evaluated by monitoring joint torque and using surface electromyography (EMG), but clinical application is impractical [5]. The modified Ashworth Scale, palpation, and the pendulum test are usually used to evaluate joint stiffness clinically [6,7]. Although these methods have been used globally by physiotherapists because they are low cost, they have been criticized for subjective limitations and non-repeatability [6,8,9]. Shear wave elastography (SWE) also has been used to quantitatively assess muscle and tendon stiffness [10,11], but it requires more expensive equipment and more professional operating skills.

The MyotonPRO is a noninvasive and portable device that has recently been used to quantify modulations in muscle and tendon stiffness. Our previous studies have demonstrated the feasibility of using the MyotonPRO to evaluate stiffness in the gastrocnemius [12], upper trapezius [13] and Achilles tendon (AT) [14] in healthy populations. Furthermore, our previous study also found a significant correlation between shear elastic modulus values determined by SWE and stiffness obtained by the MyotonPRO. Several studies also have confirmed that the MyotonPRO is a reliable method of assessing soft-tissue stiffness in patients with tendinopathy [15], stroke [16], Parkinson's disease [17], and dementia [18]. It is unclear, however, whether the MyotonPRO is reliable for quantifying stiffness of muscles and tendons in patients with SCI.

Therefore, the objectives of this study were to: 1) establish intraoperator and interoperator reliability of the MyotonPRO for quantifying muscle and AT stiffness in patients with SCI; and 2) calculate the minimal detectable change (MDC) and standard error measurement (SEM) of measurements to provide a reference for clinical evaluation in the future. We hypothesized that the MyotonPRO would be a reliable method of quantifying stiffness of muscles and tendons in patients with SCI.

Material and Methods

Ethics

This study received institutional approval by the Human Subjects Ethics committee of Luoyang Orthopaedic Hospital of Henan Province (No. 2019-001-01) and followed the recommendations of the Declaration of Helsinki. Before participating in the experiment, all subjects understood the experiment procedures and signed written informed consent.

Participants

Fourteen patients with SCI (traumatic or non-traumatic) were recruited from the inpatient rehabilitation department of Henan Province Orthopaedic Hospital. The sample size was determined through the method described by Walter et al. 1998. It was decided that for three repeated measurements in each subject, based on the assumptions of $\alpha=0.05$ and 80% power, $P_{0(I\text{CC})}=0.5$. When $P_{1(I\text{CC})}=0.8$, the sample size was 14.4, and $P_{1(I\text{CC})}=0.9$, the sample size was 5.9. Therefore, 14 patients were enough for both interoperator and intrapoperator reliability analyses [19]. Basic information for each subject was recorded before participating in the trial, such as age, height, weight, injury level and injury time (Table 1). All consecutively admitted patients with SCI were screened by clinical team members. The level of injury ranged from C5 to S2. Data collection was completed from 14:00 to 16:00. Inclusion criteria included: 1) SCI within the last 12 months; 2) history of stable spasticity over 2 weeks before the test; 3) age over 18 years; 4) Mini-Mental State Examination score >25 ; and 5) no change in spasticity treatment during the study. Exclusion criteria included: 1) SCI within the last month; 2) multiple central nervous system lesions; 3) medical instability; 4) significant complications, such as decubitus ulcers, heterotopic ossification, urinary tract infections, and any other infections; 5) musculoskeletal impairments that could confound results of the experiment; 6) skin lesions at the measuring region; and 7) inability to give informed consent.

Equipment

The machine used for measuring muscle and tendon stiffness was the MyotonPRO (MyotonAS, Tallinn, Estonia). The probe of the MyotonPRO sends out short impulses to soft tissue after precompression of the skin in region to be measured at 0.8-sec intervals. These impulses cause oscillations in the measured soft tissue. Then, the oscillation wave form is recorded by a triaxial accelerometer, and five mechanical parameters of soft tissue are calculated by the MyotonPRO. Stiffness is one of the parameters, and the higher the stiffness value, the greater the capability of tissue to resist deforming forces. Any data with a coefficient of variation greater than 3% in any measurement of quintuple scanning mode were remeasured.

Table 1. Demographic data on subjects.

Subject	Age (years)	Height (cm)	Weight (kg)	ASIA	Injury level	Injury duration (months)
S1	27	168	54	A	T12	6
S2	18	175	53	A	T8	5
S3	31	170	72	D	S1	5
S4	36	170	70	A	S2	3
S5	67	175	75	D	C8	8
S6	49	175	61	A	S1	4
S7	49	160	53	A	C5	4
S8	61	170	65	A	T7	7
S9	37	177	70	C	T6	2
S10	46	160	50	B	S1	9
S11	29	178	70	B	L1	4
S12	46	165	65	A	L1	7
S13	45	160	63	A	T12	7
S14	49	170	65	D	T1	5

ASIA – American Spinal Injury Association Impairment Scale (grade range A–E).

Procedures

Methods to quantify the gastrocnemius and AT stiffness by MyotonPRO were adopted from our previous studies [14,20]. Stiffness of the medial head of the gastrocnemius (MG) was measured at near 30% of the length between the popliteal fossa and the lateral malleolus, where the cross-sectional area of the muscle is the largest [20,21]. The lateral head of the gastrocnemius (LG) was measured at one-third of the length between the small head of the fibula and the heel [20,22]. AT stiffness was measured 4 cm above the calcaneal tuberosity [14].

All measurements were made in the ward with a room temperature of 25°C. All stiffness measurements in the right limb were performed with the subject in the prone position, and the subject was asked to completely relax their upper and lower limbs. The measurement regions were located by a physical therapist when the ankle was in a relaxed, resting position [23–25]. The probe of the MyotonPRO was placed on and perpendicular to the measured region when evaluating stiffness of muscle and tendon. Rater A measured stiffness of the LG, MG and AT first; then, rater B repeated the procedure using MyotonPRO. The order was as follows: LG, MG, AT. The order of the raters was always rater A performing a measurement first. Both raters were blinded to all measurement results. In addition, rater A measured again after 5 days, following the same steps.

Statistical analyses

SPSS software (SPSS version 22.0, IBM, United States) was used for data analysis. Normality distribution of the data was assessed using the Shapiro-Wilk test. Demographic data from participants including age, weight, and height were evaluated by descriptive statistics. All stiffness data were presented as mean±standard deviation. The significance level was set to 0.05 for all stiffness analyses. The interclass correlation coefficient (ICC) (2,2) and ICC (3,1) models were used to evaluate the interoperator and intraoperator reliability of the test. Strength of correlations was interpreted as low (0.00–0.25), fair (0.25–0.50), moderate to good (0.50–0.75), and good to excellent (>0.75) [26]. The Bland-Altman diagram drawn by medcalc 18 (Software bvba, Ostend, Belgium), shows the reliability of the intraoperator and interoperator. The calculation formula of standard error measurement (SEM) was $SEM = \text{standard deviation} \times \sqrt{1 - ICC}$. The formula of minimal detectable change (MDC) was $MDC = 1.96 \times SEM \times \sqrt{2}$.

Results

Demographic data

Fourteen subjects with SCI were enrolled (age: 42.14 ± 13.38 y; height: 169.50 ± 6.28 cm; weight: 63.25 ± 8.07 kg) (Table1).

Table 2. Intraoperator reliability of muscle and tendon.

	Mean±SD (N/m)	Intra-operator reliability ICC (95% CI)	SEM (N/m)	MDC (N/m)
LG(A)	308.43±45.59	0.91 (0.74–0.97)	12.18	33.76
LG(C)	312.21±42.26		11.29	31.29
MG(A)	252.64±23.14	0.87 (0.61–0.96)	6.18	17.13
MG(C)	260.21±36.79		9.83	27.25
AT(A)	581.50±115.99	0.89 (0.68–0.97)	31.00	85.93
AT(C)	605.57±140.09		37.44	103.78

MG – medial head of gastrocnemius; LG – lateral head of gastrocnemius; AT – Achilles tendon; (A) – rater A; (B) – rater B; (C) – rater A (5 days later); ICC – intraclass correlation coefficients; CI – confidence intervals; SEM – the standard error measurement; MDC – the minimal detectable change.

Table 3. Interoperator reliability of muscle and tendon.

	Mean±SD (N/m)	Intra-operator reliability ICC (95% CI)	SEM (N/m)	MDC (N/m)
LG(A)	308.43±45.59	0.98 (0.93–0.99)	12.18	33.76
LG(B)	307.79±47.65		12.74	35.31
MG(A)	252.64±23.14	0.98 (0.95–1.00)	6.18	17.13
MG(B)	252.21±25.17		6.73	18.65
AT(A)	581.50±115.99	0.98 (0.93–0.99)	31.00	85.93
AT(B)	574.79±111.29		29.74	82.44

MG – medial head of gastrocnemius; LG – lateral head of gastrocnemius; AT – Achilles tendon; (A) – rater A; (B) – rater B; (C) – rater A (5 days later); ICC – intraclass correlation coefficients; CI – confidence intervals; SEM – standard error measurement; MDC – minimal detectable change.

All participants were able to successfully complete the experiment without any discomfort.

Intraoperator and interoperator reliability

ICCs of the intraoperator and interoperator reliability for the three studied muscles and tendon are shown in Tables 2, 3. All intraoperator and interoperator reliabilities were 0.87 and above. The ICC values for LG reliabilities ranged from 0.91 to 0.98. The ICC values for intraoperator reliability [ICC=0.91; 95% confidence interval (CI)=0.74–0.97; SEM <12.18 N/m; and MDC <33.76 N/m] and interoperator reliability (ICC=0.98; 95% CI=0.93–0.99; SEM <12.74 N/m; and MDC <35.31 N/m) were excellent. The ICC values for MG reliabilities ranged from 0.87 to 0.98. The ICC values for intraoperator reliability (ICC=0.87; 95% CI=0.61–0.96; SEM <9.83 N/m; and MDC <27.25 N/m) and interoperator reliability (ICC=0.98; 95% CI=0.95–1.00; SEM <6.73 N/m; and MDC <18.65 N/m) were excellent. The ICC values for AT reliabilities ranged from 0.89 to 0.98. The ICC values for intraoperator reliability (ICC=0.89; 95% CI=0.68–0.97; SEM <37.44 N/m; and MDC <103.78 N/m) and interoperator

reliability (ICC=0.98; 95% CI=0.93–0.99; SEM <31.00 N/m; and MDC <85.93 N/m) were excellent. In brief, all the intraoperator and interoperator reliabilities were excellent for the gastrocnemius and the AT of the lower limbs.

Bland-Altman analysis

In Figure 1A–1F are the Bland-Altman plots of intraoperator and interoperator reliability of the LG, MG and AT, respectively. Almost all points are evenly distributed above and below the mean difference value in A, B, C and D, which shows no or less systematic bias in these measurements. The 95% limits of agreement (LoA) of A and B are –53.8 to 45.6 and –26.6 to 27.9; the 95% LoA of C and D are –36.7 to 34.9 and –12.2 to 13.1; and, the 95% LoA of E and F are –179.0 to 130.8 and –62.4 to 75.9. There was only one outlier in the Bland-Altman plots of intraoperator reliability of the LG and MG, and no outliers in the Bland-Altman plots of interoperator reliability of the LG and MG. By contrast, there was no outlier in the Bland-Altman plots of intraoperator reliability of the AT, and only one outlier in the Bland-Altman plots of interoperator reliability of the AT.

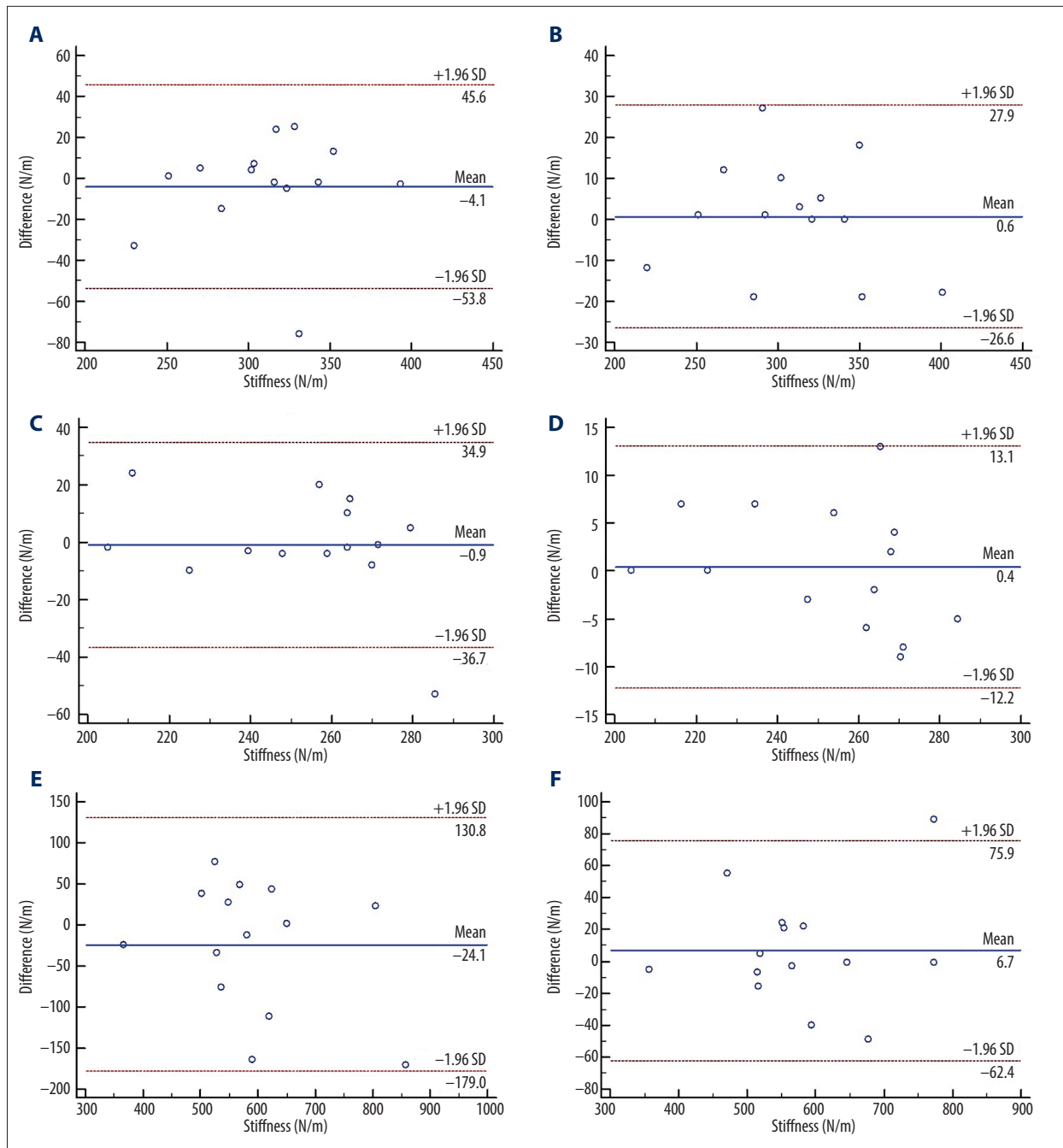


Figure 1. Bland and Altman plots of intraoperator and interoperator reliability of gastrocnemius and Achilles tendon stiffness. (A, C, E) Intra-operator reliability of LG, MG, and AT stiffness. (B, D, F) Inter-operator reliability of LG, MG, and AT stiffness.

Discussion

We found excellent intraoperator and interoperator reliability in the stiffness of the gastrocnemius and the AT using the MyotonPRO, as well as relatively low values of SEM and MDC. Our findings from this study support that MyotonPRO is reliable for evaluating stiffness of the medial and lateral heads of the gastrocnemius and the AT in subjects with SCI.

In the current study, our results showed that stiffness evaluated by MyotonPRO has a minimum value in intraoperator reliability at the MG (ICC=0.87, 95% CI: 0.61–0.96). Chuang et al. (2012) suggested that a value of ICC of at least 0.75 or greater indicated excellent intraoperator and interoperator reliability [26]. The closer the value of ICC is to 1, the higher the consistency of the two measurements [16]. Therefore, our results reflected excellent reliability of the MyotonPRO in assessment

of gastrocnemius and AT stiffness. The variation in range of reliability of the MyotonPRO in this study was consistent with one previous study. Fröhlich et al. (2014) reported excellent intraoperator reliability of the MyotonPRO among patients with chronic stroke with limited hypertonia. However, they did not evaluate interoperator reliability of the MyotonPRO [6]. Considering the possible explanations for the different intraoperator reliability compared with our study, we considered that it is related to the measuring region, measurement interval, and population. Fröhlich et al. (2014) evaluated MG stiffness at the proximal 30% between the superior border of the calcaneus and popliteal crease, and they measured twice using a 7-day measuring interval; further, they recruited patients with chronic stroke [6].

Results of some studies in healthy populations agree with our study findings. Stiffness of the LG and MG was measured in the middle of the gastrocnemius belly by Bizzini et al. (2003). They reported an ICC for the LG of 0.86 and an ICC for the MG of 0.80 using a myometer (Myoton-2) [27]. Taş et al. (2019) investigated the stiffness of the MG at dorsiflexion 0° and 10° of ankle joint and confirmed that reliabilities of the MG were excellent (ICC=0.87–0.98) [28]. Moreover, they reported that the SEMs of MG stiffness ranged from 15 to 31 N/m and the MDC of MG stiffness ranged from 78 to 85 N/m. In our study, SEMs of MG stiffness ranged from 6.18 to 9.83 N/m, and the MDC of MG stiffness ranged from 17.13 to 27.25 N/m. Variations in reliability of those studies may reflect the measured site of MG, measurement interval, and a different ankle position. Similarly excellent reliability of the gastrocnemius by SWE has been found in other studies. Saeki et al. (2017) demonstrated the reliability of the MG and LG in shear elastic modulus measurement with ultrasonic SWE [29]. They quantified the difference in intraoperator reliability at different ankle angles, indicating that LG and MG had higher intraoperative reliability in measuring the shear elastic modulus in the ankle dorsiflexed position. Intraoperator reliability of shear elastic modulus measurement of the LG and MG is higher at the ankle dorsiflexed position. Dubois et al. (2015) have demonstrated differences in reliability for SWE of LG and MG between the ankle at rest position and during passive stretching [30]. The reasons for the different intraoperator and interoperator reliability in those studies were the different ankle joint and muscle states. These cases demonstrated that it is necessary to pay attention to the corresponding joint position and the length of measured muscle when evaluating muscle stiffness.

In this research, the ICC values for intraoperator and interoperator reliability ranged from 0.89 to 0.98 in AT, with SEMs of AT stiffness ranging from 29.74 to 37.44 N/m, and MDCs of AT stiffness ranging from 82.44 to 103.78 N/m. In a clinical or scientific research environment, the value of SEM and MDC can be used to determine whether changes in a group or an individual are statistically significant [31,32]. Our study showed that

the contribution of real change to performance change is greater than that of random measurement error and the measurement of our data is reliable [33]. Those results were similar to our previous study. In our previous study, the ICCs of intraoperator and interoperator reliability in AT stiffness among healthy subjects ranged from 0.9 to 0.95, and the measured region was located at 4 cm above the insertion [14]. Similar findings were published in the literature for assessing intraoperator reliability among healthy subjects. Sahand et al. (2017) confirmed excellent same-day test-retest reliability of the MyotonPRO, with healthy subjects who were seated with hip and knee flexion of approximately 90°; they found an ICC of AT stiffness of 0.96 [34]. Taş et al. (2019) quantified the AT stiffness (measurement site: 2 cm above the calcaneal tuberosity) at 0° and 10° of ankle joint dorsiflexion with excellent interoperator and intraoperator reliability (ICC: 0.87–0.94) using the MyotonPRO, with a SEM less than 44 N/m and MDC less than 122 N/m [28]. In that study, the ICC values for intraoperator reliability (ICC=0.87–0.91) were relatively low compared with those of interoperator reliability (ICC=0.98). Although all ICC values exceeded 0.87, exercise and other external factors may have affected intraoperator reliability during the 5-day interval between the two measurements.

The Bland-Altman plot can be used to intuitively interpret measurement data and visualize any possible relationship between measurement error and true values, systematic bias and random error [35]. The Bland-Altman plots from our study data are presented in Figure 1, and they show the systematic error of our measurement data. Our results indicate that measurement tended to be overestimated when rater B evaluated LG and MG, and measurement tended to be overestimated when rater A was the second rater evaluating AT, but that is only displayed as an outlier value, and it was acceptable. As seen in Figure 1, the mean difference value of most stiffness data is toward 0, and the 95% LoA line is approximately symmetric around 0, thus confirming good intraoperator and interoperator reliability of the MyotonPRO. Although the mean difference values of some data differ from 0, the 95% LoA included in almost all measurements shows that the measurement was acceptable within the LoA [36]. In short, the MyotonPRO appears to be a reliable handheld device for evaluating gastrocnemius and AT stiffness in patients with SCI.

Limitation

There were several limitations to this study. Although the measurement regions were marked by the same experienced therapist, the same position cannot be accurately determined by two measurements without using a waterproof marker. Only two of the subjects were women, thus, sex-based differences in the muscle and tendon stiffness could not be evaluated. Further studies should concentrate on comparing gender differences in muscle and tendon stiffness in patients after SCI.

Conclusions

This study assessed intraoperator and interoperator reliability of the MyotonPRO when used for patients with SCI, and it confirmed the reliability of the MyotonPRO for measuring

muscle and tendon stiffness in this population. The standard error measurement (SEM) and the minimal detectable change (MDC) of stiffness measurements should be used in future clinical evaluations.

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