Original Article

Effect of high-intensity pulse irradiation with linear polarized near-infrared rays on muscle tone in patients with cerebrovascular disease: a randomized controlled trial

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Abstract. [Purpose] This study evaluated effects of a high-intensity linear polarized near-infrared ray irradiation for mitigation of muscle hypertonia. [Subjects] The subjects were 20 patients with cerebrovascular disease. [Methods] Subjects were randomly allocated to an intervention or control group. The intervention group received irradiation of the triceps surae. Passive range of motion and passive resistive joint torque of ankle dorsiflexion were measured before and after the intervention in knee extended and flexed positions. [Results] In the knee extended position, the mean changes in passive range of motion were 2.70° and −0.50° in the intervention and control groups, respectively, and the mean changes in passive resistive joint torque were −1.42 and −0.26 N·m in the intervention and control groups, respectively. In the knee flexed position, the mean changes in passive range of motion were 3.70° and 0.70° in the intervention and control groups, respectively, and the mean changes in passive resistive joint torque were −2.38 and −0.31 N·m in the intervention and control groups, respectively. In both knee positions, the mean changes in the two indices were greater in the intervention group than in the control group. [Conclusion] High-intensity linear polarized near-infrared ray irradiation increases passive range of motion and decreases passive resistive joint torque.
Key words: Infrared ray, Muscle tone, Cerebrovascular disease

(This article was submitted Aug. 20, 2015, and was accepted Sep. 17, 2015)

INTRODUCTION

Muscle tone influences various movements, and reduction of excessive muscle tone is an important treatment target for physical therapy. There are many therapeutic approaches for hypertonia, and a lot of research has been conducted on this topic. Phototherapy, such as laser therapy or linear polarized near-infrared ray (LPNR) irradiation, is one therapeutic approach that has been shown to be effective[1, 2]. The equipment required for LPNR irradiation is a phototherapy device that emits infrared rays at deep penetrating wavelengths (600–1,600 nm)[3–7]. LPNR irradiation is commonly used in various therapeutic scenarios because of its noninvasiveness, safety, and simplicity[2, 4–6, 8–10].

The depth of penetration by emitted rays in phototherapy generally depends on the intensity (output), and rays reach deeper regions as the intensity increases, but the burn risk also increases. The maximum output of most LPNR irradiation therapy equipment is about 2,000 mW[4, 5], and continuous irradiation at this intensity may cause burns. Thus, irradiation is typically applied intermittently, with repeated irradiation lasting several seconds followed by a rest interval[4, 5]. High-intensity LPNR (Hi-LPNR) irradiation therapy using equipment with a maximum output of 10 W has recently been reported[11]. Continuous irradiation at this output has a very high risk of burns. The burn risk is reduced and deep penetration at the high-intensity peak output is secured by applying pulse irradiation, which involves repeated irradiation for several tens of milliseconds or hundreds of microseconds followed by a rest interval[11–15]. These high-intensity phototherapy devices are already being used clinically, but reports on them are mainly limited to pain relief or treatment of paralisis[11–17].

We have previously reported in Japan the inhibitory effect of LPNR irradiation at an output of 1,440 mW on muscle tone in patients with cerebrovascular disease (CVD)[18]. The maximum output of Hi-LPNR is higher than that of LPNR; therefore, the effect on deep tissue may also be greater. An

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inhibitory effect of Hi-LPNR irradiation on muscle tone in patients with CVD is also expected, but no study has been performed to test this. Therefore, we performed a study to clarify the effect of Hi-LPNR irradiation on hypertonia in patients with CVD, and the findings of the study are reported in this paper.

SUBJECTS AND METHODS

The objective and methods were explained to all patients, and written informed consent was obtained. This study was approved by the ethics committee at Honjo General Hospital (approval number 20110907).

The study was conducted at Honjo General Hospital in Japan. The subjects were 20 patients with CVD and hypertonia of the triceps surae muscle on the paretic side. The inclusion criterion was a score ≥1 on at least one item of the Ankle Plantar Flexors Tone Scale (APTS)[19]. The APTS is a plantar flexor muscle tone evaluation index comprised of three items: stretch reflex, middle-range resistance, and final-range resistance. Each item is evaluated on a 5-point scale ranging from 0 to 4 (Appendix 1). The stretch reflex mainly reflects neurological elements constituting muscle tone, and middle- and final-range resistance mainly reflect non-neurological elements of muscle tone[19]. The exclusion criteria were previous surgical treatment or drug therapy for hypertonia, limited range of motion of the ankle joint on the paretic side with a cause other than hypertonia, and the presence of pain or another factor that could influence measurement. The same physical therapist performed all measurements. In addition, one of the two assistants of the physical therapist helped to retain the position of the lower limb during measurement, and they assisted with measurement.

The subjects were randomly allocated to an intervention group treated with Hi-LPNR irradiation or a control group without irradiation (10 patients each, Fig. 1). In the intervention group, the patients received 5-min Hi-LPNR irradiation while side lying with the paretic side up and mild flexion of the bilateral hip and knee joints. In the control group, the patients rested in the supine position for 5 min.

Hi-LPNR irradiation therapy was delivered using the Super Lizer PX Type 1 (Tokyo Iken, Tokyo, Japan). This equipment emits pulse irradiation (3-ms irradiation at 7-ms intervals) with a maximum output of 10 W. Several probes with a changeable irradiation caliper were available. A hand-held irradiation probe with a 20-mm diameter was used in this study. Although the maximum output is 10 W, the output was set at 8 W for this study, and the total irradiation time was 5 min. We determined the irradiation conditions after performing a preliminary investigation and confirming that irradiation under these conditions could be applied safely without adverse events.

Four sites on the origin side of the myotendinous junction of the triceps surae muscle on the paretic side were irradiated. These sites were selected based on a study using LPNR irradiation at 1,440 mW that some of us had previously performed[18], in which a muscle tone-inhibitory effect was noted in this region. Each site was consecutively irradiated for 3 s, and this procedure was repeated for 5 min. The tip
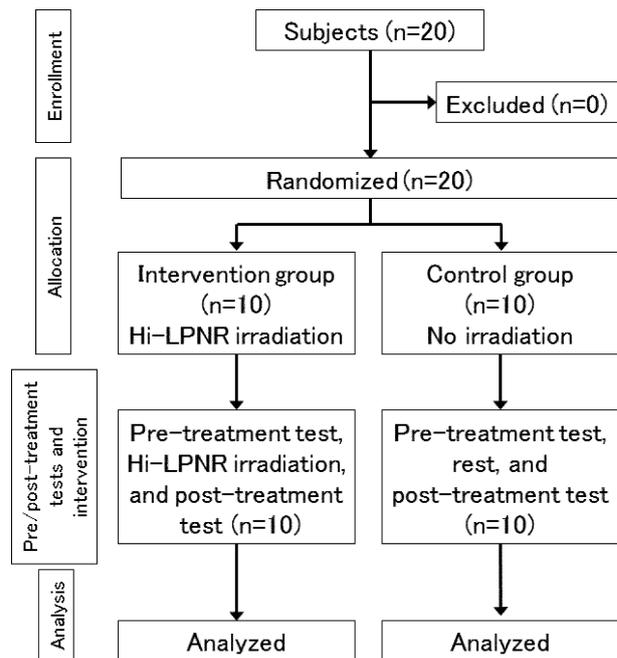

Fig. 1. Flow diagram of the intervention and control groups
Hi-LPNR: high-intensity polarized near-infrared ray

of the irradiation probe was lightly touched to the skin and rested there without excessive pressure. The myotendinous junction was confirmed by palpation and visual examination.

The outcome measures were passive range of motion of ankle dorsiflexion (PROM) and passive resistive joint torque of ankle dorsiflexion (PRJT), which were measured in the supine position. For PROM, a line perpendicular to the fibula was regarded as the stationary axis, and the 5th metatarsal bone was regarded as the migrating axis. The maximum dorsiflexion angle was measured using a goniometer with 1° increments. The fibular head, lateral malleolus, and head and base of the 5th metatarsal bone were drawn on the patient's skin with a marker as indices during measurement, and dorsiflexion was slowly applied. The change in PROM from before to after the intervention was calculated and analyzed.

PRJT was measured using a handheld dynamometer (HHD) (Power Track II, JTECH Medical, Salt Lake City, UT, USA). The center of the sensor pad was touched to the head of the second metatarsal bone, and the minimum force required to apply maximum passive dorsiflexion was measured using the HHD. The force was applied to produce dorsiflexion that was as slow as possible. The torque was calculated by multiplying the force measured by the HHD by the distance between the lower end of the medial malleolus, which was the axis of ankle plantar flexion, and the head of the second metatarsal bone. This value was regarded as the PRJT. The change in PRJT torque from before to after the intervention was calculated and analyzed.

PROM and PRJT were measured with the subjects in the supine position. The knee joint was placed in a position of maximum extension or 90° flexion. The order of the knee joint position and PROM and PRJT measurements was randomly set for each subject. Measurement was performed

immediately before and after irradiation in the intervention group, and immediately before and after resting in the control group.

In the intervention group, the presence or absence of such as things as redness and blisters at the irradiated site was examined by visual inspection. In addition, the subjects were interviewed to determine if they felt an excessive sensation of heat or other abnormalities. If redness, blisters, excessive sensation of heat, or other abnormalities were found, Hi-LPNR irradiation was discontinued.

The age, duration of illness, and PROM and PRJT before the intervention were compared between the two groups using the unpaired t-test; the gender distribution, paretic side, and diagnosis were compared between the two groups using the χ^2 test; and the APTS score was compared between the two groups using the Mann-Whitney test. The change in PROM and PRJT from before to after the intervention was compared between the two groups using the unpaired t-test to investigate the effect of Hi-LPNR.

In addition, the 95% confidence interval (CI) of the minimal detectable change (MDC_{95}) was calculated. MDC_{95} and the standard error of measurement (SEM) necessary to calculate the MDC_{95} were determined[20–22] with the equations below using test-retest data from a control group:

SEM = (standard deviation of the difference in the value between test and retest measurements)/$\sqrt{2}$

MDC_{95}= 1.96 × $\sqrt{2}$ × SEM.

When the knee was extended, the MDC_{95} in PROM was 3.36°, and that in PRJT was 1.44N·m. When the knee was flexed, the MDC_{95} in PROM was 2.45°, and that in PRJT was 1.07N·m. The effect of Hi-LPNR irradiation was investigated by comparing the average change in PROM and PRJT in each group with these MDC_{95} values. In addition, the number of subjects in whom the change exceeded the MDC_{95} was compared between the two groups using the χ^2 test.

The significance level was set at 5% in all tests. All analyses were performed using statistical analysis software (IBM SPSS Statistics, Version 23.0 J, IBM Japan, Tokyo, Japan).

RESULTS

Subject characteristics are shown in Table 1, the changes in PROM and PRJT from before to after the intervention are shown in Table 2, and the number of subjects with changes exceeding MDC_{95} is shown in Table 3.

There was no significant difference in age, gender, diagnosis, paretic side, duration of illness, or APTS score between the two groups (p>0.05; Table 1). No subjects met any of the exclusion criteria. In all subjects, side effects and other abnormalities did not occur. There were no subjects who discontinued Hi-LPNR irradiation. Under the irradiation conditions of the present study, adverse events were not observed, and this suggested that the intervention was safe.

In the knee extended position, the mean changes in PROM were 2.70° (95% CI: 0.95 −4.45°) and −0.50° (95% CI: −1.73–0.73°) in the intervention and control groups, respectively. The mean changes in PROM were significantly greater in the intervention group than in the control group (p=0.003). But the mean value of PROM was smaller than

the MDC_{95} in both groups (Table 2). The mean changes in PRJT were −1.42 N·m (95% CI: −1.83–1.01 N·m) and −0.26 N·m (95% CI: −0.79–0.26 N·m) in the intervention and control groups, respectively, and the change was significantly greater in the intervention group than in the control group (p=0.001). But the mean in PRJT was smaller than the MDC_{95} in both groups (Table 2). The change in PROM exceeded the MDC_{95} in four subjects in the intervention group and one subject in the control group (Table 3), but the difference was not significant between the groups (p=0.12). The change in PRJT exceeded the MDC_{95} in five subjects in the intervention group and one subject in the control group (Table 3), but the difference was not significant between the groups (p=0.051).

In the knee flexed position, the mean changes in PROM were 3.70° (95% CI: 1.82–5.58°) and 0.70° (95% CI: −0.20–1.60°) in the intervention and control groups, respectively, and the change was significantly greater in the intervention group than in the control group (p=0.004). The mean changes in PRJT were −2.38 N·m (95% CI: −3.15–-1.60 N·m) and −0.31N·m (95% CI: −0.70–0.08 N·m) in the intervention and control groups, respectively, and the change was significantly greater in the intervention group than in the control group (p<0.001). The mean changes in PROM and PRJT exceeded the MDC_{95} in the intervention group, but they were smaller than the MDC_{95} in the control group (Table 2). The change in PROM exceeded the MDC_{95} in six subjects in the intervention group and one subject in the control group (Table 3), and the difference was significant between the groups (p=0.019). The change in PRJT exceeded the MDC_{95} in nine subjects in the intervention group and one subject in the control group (Table 3), and the difference was significant between the groups (p<0.001).

DISCUSSION

The rays emitted by Hi-LPNR therapy equipment have characteristic wavelengths and intensities (output). Hi-LPNR therapy equipment emits complex rays of 600–1,600 nm[2, 7]. Rays with a wavelength shorter than 600 nm are likely to be absorbed by blood hemoglobin, and those with a wavelength longer than 1,600 nm are likely to be absorbed by water molecules. Accordingly, rays emitted by Hi-LPNR therapy equipment are unlikely to be absorbed by blood (hemoglobin and water molecules) or influenced by heat dispersion through blood flow and thus are superior in terms of heating the irradiated region. The origin of the myotendinous tendon junction of the triceps surae muscle, which was irradiated in this study, is present just under the skin, and Hi-LPNR may have reached the gastrocnemius and soleus muscle. However, there have been no reports of the depth of penetration of Hi-LPNR irradiation into the body, and the details remain to be investigated.

In general, polarized light includes linear, right-handed, and left-handed circularly polarized light, but the effects due to the presence or absence of each type of polarized light and the differences among the types of polarized lights have not been investigated. The influence of differences in polarized light on skin wound healing and spinal cord injury in animals has been reported[23–25], but there have been no reports

Table 1. Subject characteristics

	Total (n = 20)	Intervention (n = 10)	Control (n = 10)
Age (years)	77.7 (8.4) [73.7–81.6]	77.7 (8.5) [71.6–83.8]	77.6 (8.8) [71.3–83.9]
Gender (male/female)	11/9	4/6	7/3
Diagnosis			
Cerebral infarction	16	8	8
Intracerebral hemorrhage	4	2	2
Paretic side (right/left)	32/42	4/6	5/5
Duration of illness (d)	2,036.9 (3,369.5) [459.9–3,613.8]	3,127.8 (4,481.6) [−78.2–6,333.8]	945.9 (1,113.2) [149.6–1,742.2]
Ext			
APTS# score (0/1/2/3/4)			
SR	8/7/4/1/0	3/4/3/0/0	5/3/1/1/0
MR	5/10/4/1/0	2/6/2/0/0	3/4/2/1/0
FR	0/11/8/1/0	0/5/5/0/0	0/6/3/1/0
Baseline PROM# (°)	0.2 (3.9) [−1.7–2.0]	0.0 (4.0) [−2.9–2.9]	0.3 (3.9) [−2.5–3.1]
Baseline PRJT# (N·m)	5.8 (1.2) [5.3–6.4]	5.5 (1.1) [4.7–6.2]	6.2 (1.3) [5.3–7.2]
Flex			
APTS# score (0/1/2/3/4)			
SR	9/6/3/1/1	3/4/3/0/0	6/2/0/1/1
MR	9/9/2/0/0	4/6/0/0/0	5/3/2/0/0
FR	0/14/6/0/0	0/9/1/0/0	0/5/5/0/0
Baseline PROM# (°)	10.4 (6.7) [7.2–13.5]	12.1 (7.6) [6.7–17.6]	8.6 (5.5) [4.6–12.6]
Baseline PRJT# (N·m)	5.6 (1.3) [4.9–6.2]	5.1 (1.1) [4.4–5.9]	6.0 (1.4) [5.0–7.0]

Values are either n or mean (standard deviation) [95% confidence interval].
#Lower limb paretic side
APTS: Ankle Plantar Flexors Tone Scale; SR: stretch reflex; MR: middle range resistance; FR: final range resistance; Ext: knee extended position; Flex: knee flexed position; PROM: passive range of motion; PRJT: passive resistive joint torque; n.s.: not significant

Table 2. Change in passive range of motion and passive resistive joint torque and minimal detectable change at the 95% confidence level

		PROM (°)		PRJT (N·m)	
		Mean (SD) 95%CI	MDC$_{95}$†	Mean (SD) 95%CI	MDC$_{95}$†
Ext	Intervention	2.70 (2.45) 0.95 to 4.45	** 3.36	−1.42 (0.6) −1.83 to 1.01	** 1.44
	Control	−0.50 (1.72) −1.73 to 0.73		−0.26 (0.74) −0.79 to 0.26	
Flex	Intervention	3.70 (2.63) 1.82 to 5.58	** 2.45	−2.38 (1.08) −3.15 to −1.60	** 1.07
	Control	0.70 (1.25) −0.20 to 1.60		−0.31 (0.54) −0.70 to 0.08	

Ext: knee extended position; Flex: knee flexed position; PROM: passive range of motion; PRJT: passive resistive joint torque; CI: confidence interval
†MDC$_{95}$ was calculated using data from a control group.
**$p<0.001$

Table 3. Number of subjects that showed a change exceeding the minimal detectable change at the 95% confidence level

		PROM			PRJT		
		$\geq MDC_{95}$	$< MDC_{95}$		$\geq MDC_{95}$	$< MDC_{95}$	
Ext	Intervention	4	6	n.s.	5	5	n.s.
	Control	1	9		1	9	
Flex	Intervention	6	4	*	9	1	**
	Control	1	9		1	9	

MDC_{95}: Minimal detectable change at the 95% confidence level; PROM: passive range of motion; PRJT: passive resistive joint torque; Ext: knee extended position; Flex: knee flexed position, n.s.: not significant
*$p<0.05$, **$p<0.001$

on the effect of the presence or absence of polarization and differences among polarized lights on human muscle tone. We could not describe the effect of linearly polarized light on muscle tone, and it remains important to clarify this in detail.

The ankle plantar flexor muscle is comprised of biarticular muscles (gastrocnemius and plantaris muscles) and monoarticular muscles (the soleus, tibialis posterior, long fibular, and short fibular muscles). The main muscles are the gastrocnemius and soleus muscles, which account for 80% of the plantar flexion muscle force[26]. Accordingly, hypertonia of the gastrocnemius and soleus muscles may have a marked influence on overall plantar flexor muscle tone.

The gastrocnemius originates in the medial and lateral epicondyles of the femur, and the soleus muscle originates in the posterior tibial soleal line and fibular head. Both muscles become the Achilles tendon and end at the calcaneal tuberosity. The gastrocnemius is a biarticular muscle that crosses the knee and ankle joints, and the soleus muscle is a monoarticular muscle that crosses only the ankle joint. When the knee joint is extended with a fixed ankle joint position, the biarticular muscle is lengthened, but the monoarticular muscle length is not changed; therefore, the tone of the plantar flexors in this position reflects the tone of both the soleus and the gastrocnemius. On the other hand, when the knee joint is flexed, the tone of the plantar flexors mainly reflects the tone of the monoarticular muscle, because the biarticular muscle is relaxed.

In both knee positions, the mean changes in PROM and PRJT were greater in the intervention group than in the control group. In addition, in the intervention group, the mean changes in PROM and PRJT in the knee flexed position exceeded the MDC_{95}. Furthermore, the number of subjects with changes exceeding the MDC_{95} was significantly greater in the intervention group than in the control group. These findings suggest that Hi-LPNR irradiation applied to the posterior surface of the crus improved muscle extensibility and reduced the resistance to passive muscle stretch for the monoarticular plantar flexor muscles, mainly the soleus muscle.

The MDC represents the marginal field for which the change between two measured values in repeated measurement, such as test-retest, is due to measurement error, and the 95% CI of the MDC, MDC_{95}, is generally used[22]. Changes smaller than the MDC_{95} could be due to measurement error and therefore cannot be regarded as true changes[20]. Changes exceeding the MDC_{95} can be interpreted as true changes exceeding the error range, i.e., changes due to the effect of the intervention.

The main factor limiting ankle dorsiflexion is limited stretch of the ankle plantar flexor muscles, and PROM reflects the maximum stretch of the ankle plantar flexor muscles. In both knee positions, the mean change in PROM was significantly greater in the intervention group than in the control group. However, in the knee extended position, the mean change in PROM was smaller than the MDC_{95} in both groups, and there was no significant difference in the number of subjects exceeding the MDC_{95}. By contrast, in the knee flexed position, the mean change in PROM exceeded the MDC_{95} in the intervention group, and the number of subjects exceeding the MDC_{95} was significantly higher in the intervention group than in the control group. Therefore, we suggest that the increase in PROM in the knee flexed position in the intervention group was due to Hi-LPNR irradiation, but that the increase in PROM in the knee extended position was due to measurement error, and we therefore suggest that Hi-LPNR irradiation increased ankle plantar flexor muscle extensibility and increased PROM in the knee flexed position.

PRJT reflects the resistance to maximum passive muscle stretch. In both knee positions, the mean change in PRJT was significantly greater in the intervention group than in the control group. The mean change was greater than the MDC_{95} in the knee flexed position in the intervention group but smaller than the MDC_{95} in both knee positions in the control group, and the number of subjects with changes exceeding the MDC_{95} in the knee flexed position was greater in the intervention group than in the control group. These results suggest that Hi-LPNR irradiation increased ankle plantar flexor muscle extensibility and reduced resistance to maximum passive muscle stretch in the knee flexed position, decreasing PRJT.

Muscle tone involves a non-neural component that is based on the flexibility of fibrous tissue, such as muscle fibers and fascia, and a neural component that is based on reflex muscle contraction, such as the stretch reflex. In disorders of upper motor neurons, including CVD, the stretch reflex is enhanced due to impairment of the descending inhibitory system associated with central nervous system abnormality. Spasticity occurs due to an exaggerated stretch reflex resulting from upper motor neuron lesions and is considered velocity-dependent muscle hypertonia[27–29]. When spasticity

persists for a prolonged time without appropriate treatment, the frequency of muscle stretch decreases, and this leads to reduction of muscle fiber and fascial flexibility, which are non-neural components of muscle tone. The threshold of muscle spindles decreases with decreases in the non-neural component of muscle tone, thus increasing the stimulation of muscle spindles and enhancing the stretch reflex, leading to a vicious cycle of hypertonia. The neural and non-neural components of muscle tone are therefore different but closely associated with each other. In this study, PROM and PRJT were measured while the ankle plantar flexor muscles were slowly stretched. Thus, these measures may have captured mainly the non-neural component of muscle tone, but they would also have been influenced by the neural component if reflex muscle contraction occurred during measurement (i.e., during passive stretch). Therefore, PROM and PRJT were measured in the presence of both components of muscle tone. It is difficult to measure the muscle tone while strictly separating the neural and non-neural components in the procedure, and this is a limitation of this study.

As a muscle is heated, there is a reduction of stretch receptivity of muscle spindles and inhibition of muscle tone (Ib inhibition) caused by an increase in Golgi tendon organ activation-induced discharge by Ib fibers[30], suggesting that Hi-LPNR irradiation may reduce the stretch receptivity of muscle spindles and subsequently reduce the excitation of the secondary terminals, thus inhibiting the neural component of muscle tone. Heat stimulation also increases extensibility of muscle fibers and fascia[31]. It has been suggested that heat increases the flexibility of collagen in fasciae and tendons and the extensibility of muscle fibers, thus improving the non-neural component of muscle tone.

We acknowledge that this study had some limitations. The rater performing the measurements of PROM and PRJT and the Hi-LPNR irradiation was not blind to group allocation. In addition, the present study only included 20 subjects, and in the future, it will be necessary to increase the number of subjects. In conclusion, there was a significant difference in the changes in PROM and PRJT between the intervention and control group. PROM in a flexed knee position and PRJT in both a flexed and extended knee position changed more than the MDC_{95} in the intervention group. In conclusion, Hi-LPNR irradiation has an inhibitory effect on muscle tone in patients with CVD.

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Appendix 1. Ankle Plantar Flexors Tone Scale[19]

Stretch reflex

    0: No twitch.

    1: Twitch and no clonus.

    2: Mild clonus, persisting <3 s.

    3: Moderate clonus, persisting 3–10 s.

    4: Severe clonus, persisting >10 s.

Middle range resistance

    0: No resistance.

    1: Mild resistance, slight increase in resistance.

    2: Moderate resistance, greater increase in resistance.

    3: Severe resistance, considerable increase in resistance, but able to achieve passive movement.

    4: Passive movement is difficult.

Final range resistance

    0: No resistance.

    1: Mild resistance, slight increase in resistance.

    2: Moderate resistance, greater increase in resistance.

    3: Severe resistance, considerable increase in resistance, but able to maintain final position.

    4: Unable to maintain final position or passive movement is difficult.