Development and Preliminary Validation of a Pneumatic Focal Vibration System to the Mitigation of Post-Stroke Spasticity

Wei Li, Chong Li, Pan Liu, Yinbo Li, Yun Xiang, Tianyu Jia, Quan Xu, and Linhong Ji

***Abstract*—Some evidence has demonstrated that focal vibration (FV) plays an important role in the mitigation of spasticity. However, the research on developing the FV system to mitigate the spasticity effectively has been seldom reported. To relieve post-stroke spasticity, a new pneumatic FV system has been proposed in this paper. An image processing approach, in which the edge of vibration actuator was identified by the Canny edge detector, was utilized to quantify this system's parameters: the frequency ranging from 44 Hz to 128 Hz and the corresponding amplitude. Taking one FV protocol with the frequency of 87 Hz and the amplitude 0.28 mm of this system as an example, a clinical experiment was carried out. In the clinical experiment, FV was applied over the muscle belly of the antagonist of spastic muscle for twelve chronic spastic stroke patients. Spasticity was quantified by the muscle compliance and area under the curve for muscle (AUC_muscle). The result has demonstrated that, in the state of flexion of spastic muscle, the AUC_muscle and muscle compliance of the spastic muscle significantly increased immediately after FV compared with before-FV, illustrating the mitigation of the spasticity. This study will not only provide a potential tool to relieve post-stroke spasticity, but also contribute to improving the sensory and motor function of patients with other neurological diseases, e.g. spinal cord injury, multiple sclerosis, Parkinson and dystonia, etc.**

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***Index Terms*—Canny edge detector, focal vibration, muscle compliance, spasticity.**

I. Introduction

STROKE, as the leading cause of the adult disability, impairs patients' motor abilities and contributes to the long-term neurologic disability [1]. Post-stroke spasticity (PSS) is a common complication associated with the positive features of the upper motor neuron syndrome, which is characterized by a velocity-dependent increase in resistance to passive movements [2]. The existence of PSS may result in increased pain, functional limitations, reduced quality of life, high rehabilitation costs, as well as secondary complications including contractures and muscular imbalance (too tight for the muscles on one side of the joint and too weak for the muscles on the other side of the joint) [3], [4]. In addition to pharmacological interventions, there are many rehabilitation techniques to relieve PPS, such as motor training, sensory stimulations and non-invasive brain stimulations, etc. [5]. Focal vibration (FV), as one of sensory stimulations, has been proved effective on the mitigation of PSS [6].

Some research has focused on exploring the potential mechanism of FV on the mitigation of spasticity. It has been initially shown that the alleviating effect of FV on spasticity could be associated with the spinal mechanism of presynaptic inhibition, which originates from vibration-induced activation of the primary ending of the muscle spindle. For example, the reduction of spasticity has been presented with spinal reflexes, including H-reflex [7], F-wave [8], T-reflex [9], etc. In the past twenty years, more and more attention has been paid to investigate the potential mechanism of FV on the reduction of spasticity at the cortical level. Some studies have indicated that FV activates primary ending of the muscle spindle, thus causing alteration of corticospinal pathway to reduce spasticity at the cortical level [10]–[12]. Therefore, the mitigation of spasticity induced by FV is associated with the activation of primary ending of the muscle spindle, whether at the spinal level or at the cortical level.

Regarding frequency, human experiments have shown that most primary spindle endings in relaxed muscle respond in phase to vibration frequencies of up to 70-100 Hz, whilst the firing of primary spindle endings can decrease when vibration frequency reaches above 120 Hz [13]–[16]. Regarding amplitude, the firing threshold of muscle spindle primary endings went above 100 μm when the frequency changed from 40 Hz to 120 Hz [17]. Undue spread of vibration and withdrawal reactions were induced as the amplitude reached above 2 mm [18]. In addition, vibratory rehabilitation programmes used to effectively relieve spasticity are generally found with a frequency ranging from 60 Hz to 120 Hz and an amplitude ranging from 10 μm to 2 mm [6], [19]. Therefore, the new FV system with the frequency of 60-120 Hz and the amplitude of 100 μm to 2 mm can meet the clinical needs.

Currently, there were also some studies aiming at developing the FV system. These systems are driven by piezoceramic [20], pneumatic [21], electromagnetic [22], planar-coil [23] and shaft methods [24]. With a broad frequency range, these FV stimulators can lead to the firing of different primary mechanoreceptive afferents, like Merkel afferents, Ruffini afferents, Meissner afferents, Pacinian afferents and Ia afferents. These FV stimulators, which can be MR-compatible, were mainly used to study the patterns of cortical activation induced by the firing of different mechanoreceptive afferents following vibrotactile stimulations. However, reports of these stimulators carrying out in vivo experiments are sparse. In the clinical experiments, various focal vibratory devices are used. For example, some commercial vibration devices were used ranging from electromechanical system, e.g. CroSystem [12], [8], Thrive MD-01 [25]–[27], to air-pressure-driven system, e.g. VIBRA [28], [29], VISSMAN [30]. Vibrators driven by electromechanical systems generally have a limited frequency range, which may hinder their ability to perform individualized intervention to relief spasticity in the future. It was also difficult for the vibrator to adapt to the different muscles of the body and to be applied over the multiple muscles at the same time. For vibrators driven by air pressure, they can solve these existing problems of the electromechanical vibrators, but the price was very expensive and the device details was not described, which makes it difficult to homogenize the outcomes [6]. Moreover, the effectiveness of these pneumatic FV systems for the relief of SSP needs to be further confirmed. To be specific, two studies using VIBRA system have only demonstrated that FV combined with physiotherapy or robotic rehabilitation have a greater rehabilitation outcome of reducing spasticity than single physiotherapy or robotic rehabilitation [28], [29]. These may not be sufficient in proving that the VIBRA system has a good therapeutic effect on the PSS. Another study using VISSMAN system has found FV with the frequency of 300 Hz can decrease PSS [30]. High frequency (300 Hz) vibration can induce mainly the firing of mechanoreceptors specialized to receive tactile information (e.g. Meissner afferent and Pacinian afferent) [31] other than the firing of Ia afferent [15], [31]. The reducing effect that tactile mechanoreceptors have on PSS can be demonstrated further. In other studies, the vibration devices are created specifically for laboratory studies [11] or not be described [32]. Those details on vibration apparatuses in those selected studies are currently absent. These vibratory devices have not been validated by extensive clinical studies. The existence of these problems makes it difficult to realize a clear treatment protocol and dosage [6].

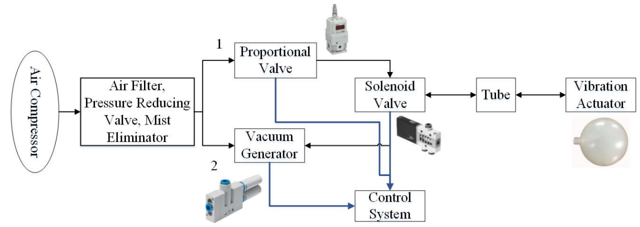

Fig. 1. The structural principle diagram of the pneumatic focal vibration system.

Besides, some researchers have explored the clinical effect of FV on the mitigation of spasticity. For example, some research has elucidated that the application of repetitive FV over the muscle belly of the upper-extremity can relief spasticity lasting for dozens of minutes, or several days, even more than one month. In those studies, the changes of spasticity were assessed by these indexes, such as a decrease in the modified Ashworth Score (MAS) of the spastic muscle [25], [26], [28], an increase of short intracortical inhibition (SICI) in the agonist spastic muscles [12], [29] and a prolongation of the cortical silent period (CSP) recorded from spastic muscle [11]. Several studies showed that the application of FV over calf muscles induced the reduction of ankle dorsiflexion angle and a decrease in MAS of spastic muscle, indicating that FV also can alleviate lower-limb spasticity [7], [33]. The quantification of spasticity was of great importance to assess the therapeutic interventions in the clinics. Myotonometer, as a new tool, has been used to evaluate the muscle spasticity for some patients with stroke [27], [34]–[36] and cerebral palsy [37]. Myotonometer measurements, which have the quantification of the displacement of muscle tissue with respect to perpendicular compression force, can reflect the changes of muscle viscoelastic properties and compliance. Myotonometer measurements also have a strong correlation with MAS scores [37].

Based on this, the objective of this study is to develop a new FV system and validate the effectiveness of the system on the mitigation of PSS. The FV system is driven by air pressure and have the advantage of being able to modulate the frequency of this system varies at least ranging from 50 Hz to 120 Hz. The frequency and amplitude of the FV system were measured based on the image processing, in which the edge of the vibration actuator was identified by the Canny edge detector and then was quantified by fast Fourier transformation (FFT). The effectiveness of FV system on the relief of spasticity for chronic stroke patients has been preliminarily validated by taking one FV treatment protocol (frequency: 87 Hz, amplitude: 0.28 mm) as an example. The relative change of muscle displacement and compliance between the spastic muscle and the antagonistic muscle was calculated to assess the reduction of spasticity.

II. Development of the Pneumatic FV System

A. The General Design Concept

As shown in Fig. 1, the pneumatic FV system consisted mainly of two parts: pneumatic driven system and vibration actuator. The pneumatic driven system consisted of these parts:

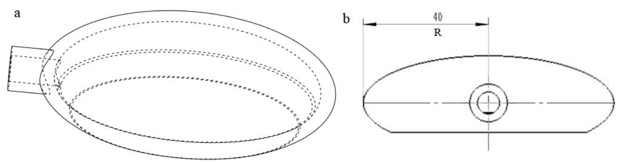

Fig. 2. The structural diagram of the vibration actuator:(a) The 3-dimensional diagram; (b) The front view (unit: mm).

air compressor, pneumatic triplet (air filter, pressure reducing valve and mist eliminator), proportional valve, solenoid valve, vacuum generator and tube. The vibration was achieved by blowing air into the vibration actuator and suctioning gas from the vibration actuator, as shown in Fig. 1. The gas from the air compressor was filtered, dried and depressurized by pneumatic triplet, and then divided into two branches:

(1) The branch one was responsible for blowing air to vibration actuator. After passing through the proportional valve, the air then flowed into the solenoid valve. When the way of the solenoid valve controlling the path between proportional valve and vibration actuator was open, the gas flowed out from the solenoid valve and then passed through the tube, and finally flowed into the vibration actuator to implement the blowing into the vibration actuator.

(2) The branch two was responsible for suctioning gas from the vibration actuator. The air flowed into the vacuum generator to create vacuum in the vacuum generator, and finally extracted from air having flowed into the vibration actuator when the way of the solenoid valve controlling the path between vibration actuator and vacuum generator was open.

In this way, the process of "one blow and one suction" made the vibration actuator vibrate. The structural diagram of vibration actuator was shown in Fig. 2. R indicated the actual diameter of vibration actuator (R=40 mm), as shown in Fig.2b. The vibration actuator was made of the rubber material through customized mold. The thickness between the upper (1 mm) and lower parts (3 mm) of the vibration actuator was designed different, so that the thinner side of the vibration actuator would produce stronger vibration. The vibration actuator was tied to the muscles with a bandage.

B. The Control System

The control principle of this pneumatic FV system was shown in Fig. 3a and the device was shown in Fig. 3b. The control system consisted of the input module, the power management module, the microcontroller unit (MCU), the programmable logic controller (PLC), the liquid crystal display (LCD), the digital toAnalog converter (DAC), the solenoid valve, and the proportional valve. The frequency was regulated by controlling the solenoid valve, whilst the amplitude was adjusted by controlling the proportional valve. The detailed control process is described as follows:

(1) The frequency regulation button transmitted the frequency input signal to the Personal Computer (PC) through the input module. The PC then controlled the Arduino UNO MCU. The frequency input signals was finally transmitted to the PLC amplifier to form the low or high level signals, which controlled the opening or closing frequency of the solenoid valve and vacuum generator. In this way, the frequency of "one blow and one suction" of vibration actuator was controlled. The frequency of vibration actuator was modulated by controlling the switching frequency of the solenoid valve.

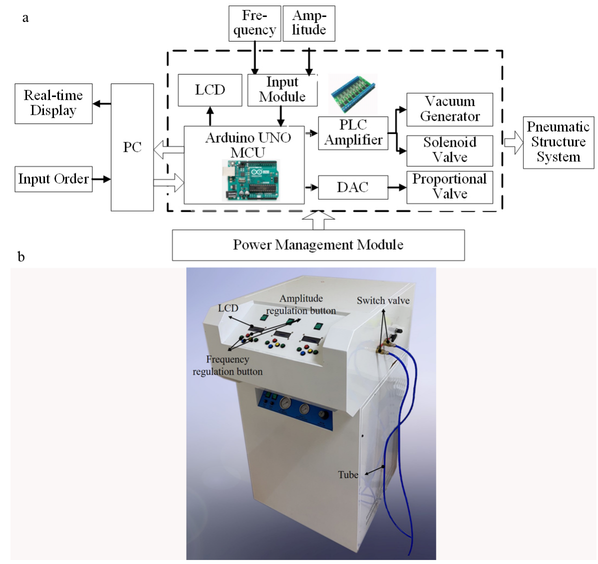

Fig. 3. The block diagram of control system (a) and the diagram of the device (b). Note: PC = Personal Computer, LCD = Liquid Crystal Display, MCU = Microcontroller Unit, PLC = Programmable Logic Controller, DAC = Digital toAnalog Converter.

(2) The amplitude regulation button transmitted the amplitude input signal to the Arduino UNO MCU through PC. The digital input signals of the amplitude with Pulse Width Modulation (PWM) signals were then converted into the voltage analog by the DAC module. The value of the air pressure flowing through the proportional valve was adjusted by controlling the input voltage value of the proportional valve, so as to modulate the amplitude of vibration actuator.

The control strategy above or connecting multiple vibration actuators with multi-way pneumatic quick fittings can be used to vibrate the multiple muscles of human body at the same time.

C. The Parameter Measurement

In order to measure the frequency and the amplitude of vibration actuator, an approach based on the image processing was proposed. Firstly, the movement of vibration actuator was captured by a high-speed camera. Secondly, the edge of vibration actuator was identified by the Canny edge detector and the trajectory of the edge was then obtained. Finally, the frequency and the amplitude of vibration actuator was quantified by fast Fourier transformation (FFT).

1) Imaging Capturing: A high-speed camera (Olympus i-SPEED TR, Tokyo, Japan) operating at 800 frames per second with a zoom lens (Navitar 12X Zoom, Rochester, NY, USA) with a resolution of 1280 ×800 (length × width), and a cold light source, were implemented to capture the movement of vibration actuator. The recorded video was then transmitted into a series of images, as shown in Fig. 4b. The magnification coefficient λ was calculated as follows.

$$\lambda = L/2R \tag{1}$$

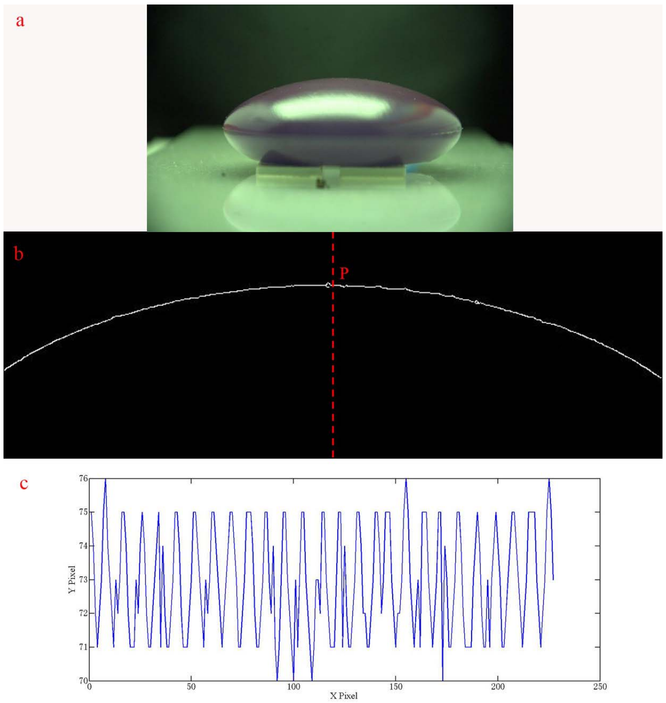

Fig. 4. The schematic diagram of the edge detection of vibration actuator: (a) The image originated from the conversion of the video captured by the high-speed camera; (b) The intercepted image from the converted images; (c) The motion trajectory of the pixel P during vibration.

where L stands for the diameter of vibration actuator in the transmitted image in Fig. 4a (L=140 mm). The R stands for the actual diameter of vibration actuator (Fig. 2b).

2) Image Processing: The Canny edge detector, which was first put forward in 1986, was one of the most common approaches to detect a wide range of edges in images [38]. The steps to detect the edges of actuator were illustrated as follows.

(1) Capture part of the actual image. The pixel coordinates of captured image were {(325, 200), (725, 250)};

(2) Gray image;

(3) Smooth the image using Gaussian filter and to reduce the influence of the noise;

(4) Calculate the gradient intensity and direction of each pixel in each image;

(5) Eliminate spurious response to edge detection using non-maximum suppression. The high threshold of 0.8 and the low threshold of 0.45 were set to determine the edge between the vibration actuator and the external environment;

(6) Apply the Hysteresis threshold method to detect the potential edge.

The edge detected was displayed in Fig. 4b. The width of the edge (L_{cut}) was 130 mm and the width of each pixel (d_{pixel}) is 130/400 mm. Considering that 800 frames per second were recorded for the high speed camera, the total number of images recorded during time, t, is $800*t$. The trajectory of the pixel P in Fig. 4b during vibration was, for example, shown in Fig. 4c.

3) The Determination of Parameters: The trajectory of pixel P (see Fig. 4c) was converted into the actual coordinate position based on the conversion factor K ($K = d_{pixel} * 1/\lambda$). To characterize the parameters of vibration actuator, FFT was implemented based on the actual trajectory of the edge of vibration actuator. The frequency-amplitude diagram of vibration actuator at different frequencies were shown in Fig. 5(a-c).

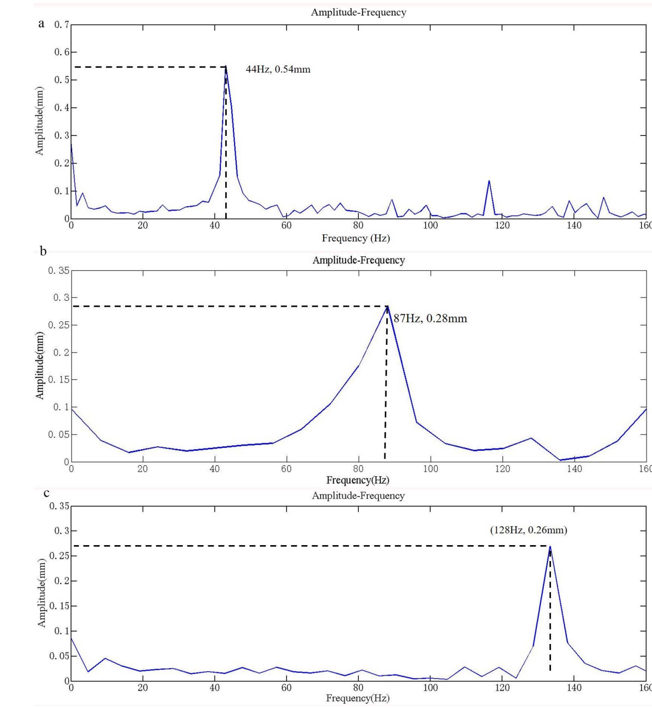

Fig. 5. The frequency-amplitude diagram of this system at the different frequencies based on FFT.

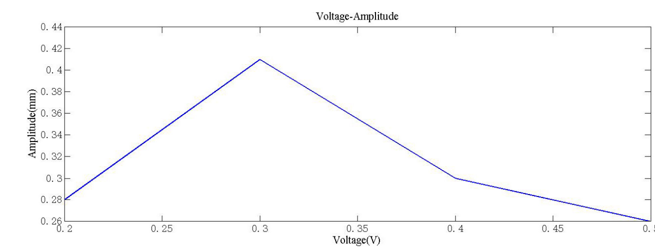

Fig. 6. The amplitude under different voltages when the frequency was set 85 Hz.

When the input value of frequency regulation button was 85 Hz, the variation range of amplitude under different voltage values was shown in Fig.6.

III. Preliminary Validation in Clinic Experiment

A. Participants

In this study, eight chronic stroke patients (47.5±17.6 years) were enrolled in Shenzhen Nanshan District People's Hospital and four chronic stroke patients (53.5 ±17.4) were enrolled in Beijing Rehabilitation Hospital Affiliated to Capital Medical University. Table I showed the clinical characteristics of the patients. The inclusion criteria for the participates were: 1) age from 18 to 80 years ago; 2) having cognition and being able to understand the request of the testers; 3) no history of the traumatic brain injury (TBI) and epilepsy; 4) more than 6 months post-stroke; 5) having a spasticity of the biceps brachii ranging from 1 to 3 on the MAS. The exclusion criteria

TABLE I
PATIENT CHARACTERISTICS

No.	Sex	Age	Lesion side	Lesion location	Time Post-stroke (months)	ADL	MAS
1	M	26	R	BG	12	88	1
2	M	31	R	BG	12	78	3
3	M	45	R	BG	6	44	2
4	M	27	R	BG, FL,PL,OL	24	96	1+
5	M	67	R	BG	48	30	3
6	M	55	R	BG	58	57	1+
7	M	47	R	BG, others	84	70	2
8	M	65	L	BG, PV,CS	12	49	1+
9	M	75	L	BG, others	29	10	1
10	M	34	L	OL, BG	44	10	2
11	M	58	L	BG	94	85	1
12	F	64	L	BG, LC	9	87	1

ADL=Activities of Daily Living, MAS=Modified Ashworth Scale, M=Male, F=Female, R=Right, L=Left, BG=Basal Ganglia, PV=Periventricular, CS=Centrum Semioval, LC=Lacunar, PL=Parietal Lobe, OL=Occipital Lobe, FL=Frontal Lobe

were: 1) concomitant neurodegenerative diseases; 2) severe visual, cognitive or language impairment; 3) several bone or joint disorders or changes in peripheral or central sensitivity; 4) serious complications of heart, lung, liver and kidney; 5) concomitant use of drugs for spasticity in the last 6 months. All the patients gave written consent before taking part in this study. The local ethics committees, namely Medical Ethics Committee of Shenzhen Nanshan People's Hospital and Medical Ethics Committee of Beijing Rehabilitation Hospital Affiliated to Capital Medical University, approved this study.

B. Experimental Setup

1) Muscle Displacement and Compliance Test: Based on the principle of the myotonometer [37], the muscle tone intelligence measure system (Hangzhou Ultimate Medical Technology Co., Ltd, China), was used. The system consisted of a testing handle and a operation panel. The system provided objective assessment of muscle spasticity by establishing the relationship between the external perpendicular compression pressure and muscle tissue displacement. Specifically, the depth of probe penetration increased when the probe of testing handle was pressed perpendicular to the long axis of muscle. As the outer sleeve remained static, the distance between the outer sleeve and the probe indicated the displacement of muscle tissue. The resistance of the muscle tissue to the probe was recorded from 0.25 kg to 2.0 kg at increments of 0.25 kg by the force sensor located in the handle whilst the issue displacement corresponded to the resistance one by one.

2) The Experiment Procedures: In this experiment, all the subjects were asked to be seated with upper-limb relaxed. One FV treatment protocol (frequency: 87Hz, amplitude: 0.28mm) was chosen and FV was applied over the muscle belly of the triceps based on those studies [29], [30], [33]. The triceps was the antagonist muscle of the spastic muscle for each stroke patients. The experiment was carried out according to the following phases: (1) before-FV, the muscle displacement of the biceps and the triceps in the affected limb of each patient was measured; (2) during-FV, the focal vibratory stimulation was applied for 3 sessions, with each session lasting about 3 minutes. A three-minute interval separated the sessions; (3) after-FV, the muscle displacement of the biceps and the triceps in the affected limb of each patient was measured immediately after three sessions of FV. During each test, the testing handle was pressed perpendicular to the long axis of muscle belly of the biceps and triceps in the two different states of elbow joint, including elbow joint in full extension and elbow joint in natural flexion. In this study, elbow flexion referred to elbow joint in natural flexion and elbow extension referred to elbow joint in full extension. Each test of muscle displacement and compliance was performed repeatedly for three times for all the patients.

C. Data Analysis

The displacement-force relation was generally nonlinear, which consisted of two segmental slopes induced by two different types of tissues, including subcutaneous tissue and muscle tissue [39]. Based on two previous studies [36], [37], muscle compliance and area under the curve for muscle (AUC_muscle), which were used to quantify the spasticity, were calculated at the force levels ranging from 1 kg to 2 kg. Muscle compliance referred to the slope of displacement-force and AUC_muscle referred to the sum of displacement-force. As for patients with PPS, the coexistence of spastic muscle over-activity and spastic antagonist muscle weakness can impair functional movement and even exacerbate spasticity [40]. Some rehabilitation techniques aiming at strengthening the weak muscle have been put forward, including the resistance training programs and the aquatic therapy [3]. Besides, the movement of the joint depended on the coordination of the agonist and antagonist muscles. Therefore, the normalized muscle compliance and AUC_muscle of the biceps during the elbow flexion or extension were calculated as follows.

$$\lambda_{\{ext,fle\}}^{AUC\_muscle} = \frac{AUC\_muscle_{\{ext,fle\}}^{biceps}}{AUC\_muscle_{\{ext,fle\}}^{biceps} + AUC\_muscle_{\{fle,ext\}}^{triceps}} \tag{2}$$

$$\lambda_{\{ext,fle\}}^{Compliance} = \frac{Compliance_{\{ext,fle\}}^{biceps}}{Compliance_{\{ext,fle\}}^{biceps} + Compliance_{\{fle,ext\}}^{triceps}} \tag{3}$$

where $\lambda_{\{ext,fle\}}^{Compliance}$ and $\lambda_{\{ext,fle\}}^{AUC\_muscle}$ indicated the normalized compliance and AUC_muscle of biceps muscle during the extension and flexion of the elbow joint, respectively.

D. Statistical Analysis

All the statistical analyses were carried out in SPSS Statistics 20.0. The paired-sample t-test was performed to determine whether FV led to the significant changes of the normalized compliance and the normalized AUC_muscle in the two states of elbow joint (flexion and extension) compared to before-FV.

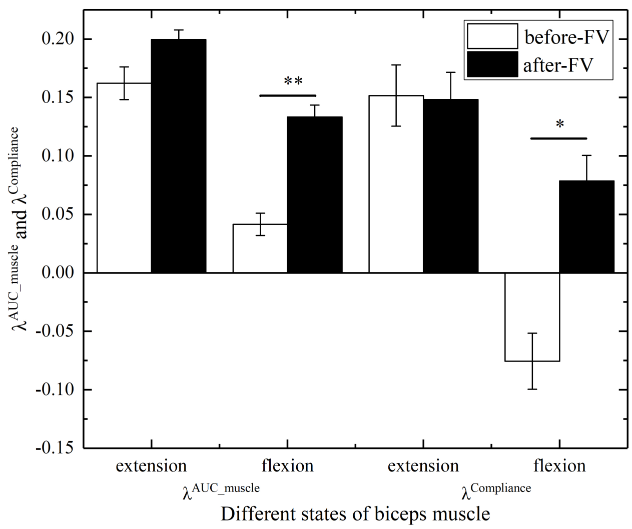

Fig. 7. $\lambda^{\text{AUC\_muscle}}$ and $\lambda^{\text{Compliance}}$ of the biceps during extension and flexion of elbow joint.

E. Results

The paired-sample t-test showed that the normalized AUC_muscle of the biceps during flexion of elbow joint ($\lambda_{\text{fle}}^{\text{AUC\_muscle}}$), had a significant increase after FV compared to before-FV (p=0.007), as shown in Fig. 7. The paired-sample t-test also showed that the normalized compliance of the biceps during flexion of elbow joint ($\lambda_{\text{fle}}^{\text{Compliance}}$), had a significant increase after FV compared to before-FV (p=0.028), as shown in Fig. 7. The paired-sample t-test indicated that $\lambda_{\text{ext}}^{\text{AUC\_muscle}}$ and $\lambda_{\text{ext}}^{\text{Compliance}}$ of biceps muscle had no significant change after FV compared to before-FV.

IV. Discussion

The present study has focused on the development of a new pneumatic FV system and the preliminary validation of this system to the mitigation of PSS. The new pneumatic FV system, in which the frequency ranged from 44 Hz to 128 Hz, has been developed. Taking one FV treatment protocol (frequency: 87 Hz, amplitude: 0.28 mm) of this system as an example, the clinical experiment has shown that this FV protocol, which was applied over the muscle belly the antagonist of spastic muscle of chronic spastic stroke patients, can lead to the increase of AUC_muscle and compliance, which reflects the reduction of spasticity.

A. The Pneumatic FV System

In our study, the frequency of the system ranges from 44 Hz to 128 Hz. The range of the system's amplitude depended on the preset frequency. For example, the amplitude ranges from 0.074 mm to 0.26 mm for the frequency at 128 Hz (Fig. 8) and the amplitude ranges from 0.26 mm to 0.41 mm for the frequency at 85 Hz (Fig. 9). The higher frequency this system is set at, the smaller the amplitude is, which corresponds to the characterization of vibration device. The range of the frequency and amplitude of this system can entrain muscle spindle Ia-afferent firing to finally reach the central nervous system by travelling along the proprioceptive pathway. Thereby, this system can recover the motor function

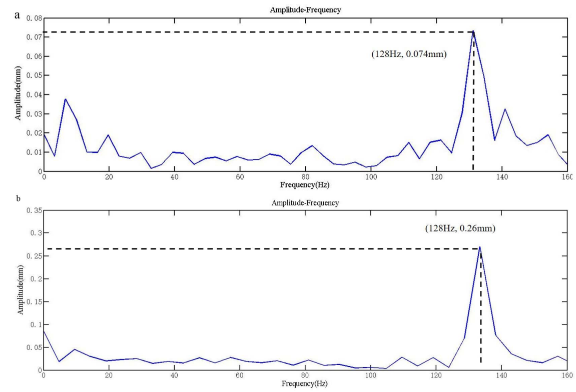

Fig. 8. The corresponding amplitude of this system on the frequency of 130Hz.

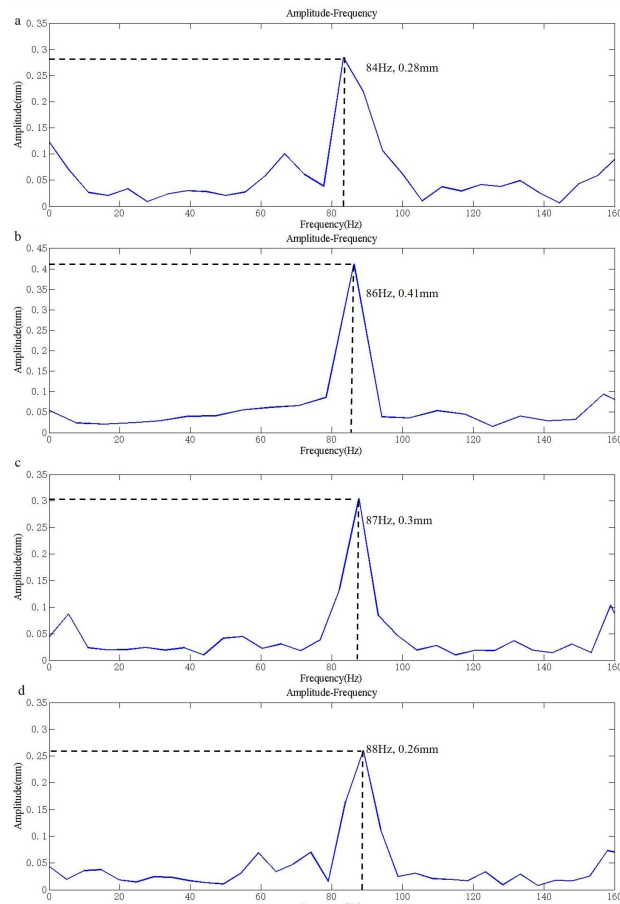

Fig. 9. The corresponding amplitude of this system on the preset Frequency of 85Hz.

for stroke patients, as well as relieve the spasticity for the spastic stroke patients [19]. According to Nurillo's study, this system can be also applied to the neurorehabilitation of these patients with other neurological diseases including spinal cord injury, multiple sclerosis, Parkinson.

The frequency fluctuates in a small range when the amplitude varies. For example, the frequency ranges from 84 Hz to 88 Hz if the frequency is set at 85 Hz, as shown in Fig.9. Several studies have confirmed that frequency ranging from 60 Hz to 120 Hz can enhance the excitability of the sensorimotor cortex compared to that below 60 Hz and above

120 Hz [15], [16]. Moreover, it is shown that the frequencies fluctuating in a small range around 80Hz have no difference in the number of the activation of the primary endings [13]. It was found that there is no significant difference in the muscle activity for the amplitude of between 0.2 mm and 0.3 mm [41]. Therefore, the small range fluctuation of the frequency and the amplitude does not affect the result of the present study. Besides, the frequency and amplitude of this system are generally set to a fixed value (87 Hz, 0.28 mm) in the clinical experiment. Therefore, this system can make the results of clinical experiment reliable.

B. The Changes of Muscle Tissue Displacement and Muscle Compliance Induced by FV

The present study found that FV significantly increased AUC_muscle and muscle compliance of the biceps. It meant that FV lead to a reduction of muscle resistance and an increase of tissue displacement of spastic muscle. Modifications of muscle mechanical properties have also been demonstrated in one previous study, which examined higher tissue displacement of chronic hypertonic stroke patients than that of healthy subjects [42]. Several studies have found that the displacement and the compliance of the spastic muscle are lower than that of non-spastic muscle at the contralateral side especially for chronic spastic stroke patients [34]–[36]. Moreover, two studies showed that the changes of muscle compliance had a strong correlation with the modified Ashworth Scale (MAS) for spastic stroke patients [42], as well as spastic cerebral palsy patients [37]. Furthermore, muscle tone, as well as muscle displacement and compliance, was significantly reduced after long-term rehabilitation therapies, such as robot-assisted training [34] and vibratory stimulation [27]. In this study, in order to minimize the influence of tissue displacement from the subcutaneous layer, muscle displacement is separated from the overall tissue displacement based on several studies [35], [36]. The increased muscle displacement after FV can reflect the degree of muscle deformation with respect to the perpendicular compressing force. It can, therefore, be associated with the changes of the component of muscle fiber types, fascicle length, pennation angle, and etc. During the development of spasticity following stroke, these parameters have been gradually altered by muscle atrophy, loss of sarcomeres, accumulation of intramuscular connective tissue, and an enhancement of intrinsic stiffness of muscle fibers [43], [44]. Muscle stiffness, which is described as the joint resistance torque with respect to angular deflection following conventional stretching, has also been used to characterize the changes of muscle tone [45]. Muscle stiffness consisted of the reflex and non-reflex (e.g. viscous and elastic component) stiffness. Although some differences existed between muscle stiffness and AUC_muscle, as well as between muscle stiffness and muscle compliance, their correlations have been confirmed [36], [42]. The increased AUC_muscle and muscle compliance can, therefore, reflect the mitigation of spasticity by the detection of the physiology changes of muscles.

In our study, one new FV system driven by air pressure has been developed. Compared with the existing electromechanical FV devices, this system has the advantage of modulating frequency from 44 Hz to 128 Hz and stimulating multiple muscles simultaneously by connecting multiple vibration actuators. Several recent studies have indicated that individual optimal frequency (IOF) in whole-body vibration can produce greater effects on the neuromuscular system [46], [47]. IOF can exist in FV. Concerning individualized treatment for PSS, our new system can be used to explore the IOF of PSS in order to maximize the outcome of the relief of spasticity. Compared with the existing pneumatic FV devices, the basic principles and technical specifications of our vibration apparatus in detail are described in detail, which will make it easy to homogenize the outcomes in future [6]. Our study has also validated the effect of this FV device on the mitigation of spasticity taking one FV protocol as an example. This study may provide a more direct evidence for this system than the two studies for VIBRA system [28], [29]. Based on those studies [8], [25]–[30], it is believed that this FV system relieve the spasticity by mainly activating those Ia afferents. The firing of Ia afferents responds to vibration frequency of 50-120 Hz. Therefore, this system in this study has great potential to relieve spasticity. Besides, compared with FV with the frequency of 300 Hz using VISSMAN system, this system with the frequency of 87 Hz to relieve PSS may be more convincing.

One limitation of this study is that the modulation of the amplitude of the pneumatic FV system depends on the preset frequency. This is challenging to ensure that the amplitude can be adjusted in the same range at the different frequencies. In the future, the closed-loop control schemes will be adopted. The pressure sensor will be used to feed back the pressure value of vibration actuator to adjust the proportional valve to solve the issue above. Another limitation of this study is that the sample size in the clinical experiment is small and the duration of the anti-spastic effect following this FV system has been not studied. Two studies have shown that the anti-spastic effect can remain at least 10 min following FV lasting for 5 min [11], [26]. It can be inferred that the anti-spastic effect can remain at least 10 min following FV intervention for 9 min. In future, a longitudinal study with a larger scale will be carried out to explore the long-term anti-spastic effect of this system. Besides, only one FV protocol was taken an example to explore the effect of this system on the mitigation of spasticity. This anti-spastic effects of FV of different frequencies and amplitudes will also be explored and compared in future research.

V. Conclusion

To summarize, a new pneumatic FV system has been developed. The vibration frequency and amplitude of this system can be adjusted, frequency ranging from 44Hz to 128Hz as the amplitude changes accordingly. Based on the changes of normalized AUC_muscle and muscle compliance, the clinical experiment has preliminarily validated that FV, which is applied over the muscle belly of the antagonist of the spastic muscle, has a short-term effect on the relief of the PSS taking one FV protocol with the frequency of 87 Hz and the amplitude of 0.28 mm. This study will not only provide a potential tool for the individualized mitigation of spasticity, but also contribute to homogenize the anti-spastic outcome to make the effective treatment protocol clear. In the future, this new pneumatic FV system may also be utilized to motor recovery of other neurological diseases including spinal cord injury, multiple sclerosis, Parkinson and dystonia.

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