Changes in Gait and Plantar Foot Loading upon Using Vibrotactile Wearable Biofeedback System in Patients with Stroke

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Abstract: Background: Patients with stroke walk with excessive foot inversion at the affected side, which may disturb their balance and gait. **Objectives**: This study aimed to investigate the effects of instant biofeedback of plantar force at the medial and lateral forefoot regions on gait and plantar foot loading in patients with stroke. **Methods**: A total of eight patients with hemiplegic stroke, who had flexible rearfoot varus deformity at the affected side, participated in this study. A vibrotactile biofeedback system was developed and evaluated. It analysed forces at the medial and lateral forefeet, and instantly provided vibration clues when the plantar force at medial forefoot was less than a threshold. Each subject’s three-dimensional gait parameters and plantar-pressure distribution during walking were measured under two experimental conditions (sequence randomized): with and without the device turned-on (Trial-registration number: ChiCTR-IPB-15006530& HKCTR-1853). **Results**: Providing biofeedback significantly reduced the foot inversion and increased the mid-stance foot-floor contact area and medial midfoot plantar pressure of the affected limb, bringing the values of these parameters closer to those of the unaffected-side. The biofeedback also significantly reduced the unaffected-side’s excessive knee flexion and hip abduction. **Conclusions**: There were signs of improved foot loading characteristics and gait upon provision of instant vibrotactile biofeedback of plantar force. The positive results of this study further support the development of wearable biofeedback devices for improving gait of patients with stroke.

Keywords: stroke; foot inversion; plantar pressure; instant biofeedback; gait training; smart wearable device

Introduction

Stroke is a leading cause of neurological impairment [1] and chronic motor disability [2] in adults. Motor impairments of lower limbs can lead to difficulty in locomotion and activities of daily living, and consequently influence an individual's quality of life [3]. People with stroke generally walk with higher gait asymmetry [4], energy consumption [5] and risk of fall [6]. Abnormal motion of the ankle-foot complex contributes to the deterioration of the overall balance performance and gait pattern [7]. Deformities at the ankle joint are common, due to the muscle spasticity [8] and muscle imbalance [9]. The foot at the affected side of people with stroke tends to be more plantar-flexed and inverted than people without stroke [10]. Recovery of walking ability by addressing the ankle-joint deformity helps patients with stroke to regain the independence in daily life, and is one of the main rehabilitation training goals [11].

Plantarflexion deformity can increase the chance of fall, as the feet tend to drag over the floor during swing phase [12]. Fortunately, ankle-foot orthoses have been used successfully to correct plantar-flexion deformity after stroke [13]. Correcting varus deformity has been more difficult, because of the lack of lever arm that provides sufficient corrective eversion moment at foot. Abnormally high degree of foot inversion during gait could put excessively more strains on muscles and tendons [14] and more plantar forces at the lateral side of paretic foot [15]. Such musculoskeletal overloading could lead to soft tissue damage and structural deformity at the foot, leading to foot pain [16]. Foot inversion also reduces the total contact area with ground during mid-stance and the propulsive force during push-off phases of the gait [17]. Foot pain together with the altered foot biomechanics could disturb gait and consequently predispose the individuals with higher risk of falls [18]. Previous studies have concluded that increased foot inversion is associated with decreased postural stability [19, 20], which is a crucial indicator of increased risk of falls [21]. Reducing the degree of abnormal foot inversion is required to relieve muscle stress and foot pain, which could improve walking performance and reduce risk of falls in patients with stroke [14].

Various interventions have been used to relieve varus deformity for patients with stroke, but with some limitations [9]. Local botulinum toxin injection has the limitations of high cost and transient nature that requires repetitive injections [22]. Patient's compliance of wearing ankle-foot orthosis has been low, thus leading to a high financial loss for society and a waste of therapeutic effort as reviewed in [23]. Physiotherapy which provides repetitive verbal reminders of putting the foot in a better position during gait requires intensive manpower [24].

Wearable biofeedback devices have great potential of facilitating home-based trainings in patients, which contribute to high level of continuity, adherence, and compliance rates of training in patients [25] and save the expertise human resources. Biofeedback devices, with the use of sensors (force sensors, accelerometers, gyroscopes and magnetometers) and feedback modalities (screens, speakers and vibrators) [26], were used in the elderly [27-29], healthy young adults [28-31], patients with vestibular disease [27, 32], patients with Parkinson's disease [33], and lower limb amputees [34, 35]. Regarding stroke patients, researchers have detected stance time using foot switches [36, 37], ground reaction forces using force sensors [33] and body sway using smartphones [38] and inertial motion sensors [33]. Upon giving some instant feedback based on the sensor measurements, some improvements in the amount of body sway [30, 35], symmetries in weight-bearing and stance/swing time between two legs [33, 34], as well as scores in standard clinical tests were noted [30]. However, there is a lack of comprehensive understanding on how biofeedback devices could influence the spatial-temporal, kinetic and kinematic gait parameters of stroke patients. In addition, little attempt has been made to address the negative effects of varus deformities on gait through biofeedback.

This paper aims to: (1) present a biofeedback system that reminds stroke patients with flexible foot varus deformity to increase loading at the medial aspect of the foot of the affected side during gait; and (2) report the effects of using such biofeedback system on gait parameters and plantar pressure distribution. It is hypothesized that instant vibrotactile biofeedback of plantar force at the medial and lateral forefoot could improve plantar loading at the medial aspect of the affected foot and the gait pattern of stroke patients with flexible foot varus deformity.

Materials and Methods

Subjects

Convenience sampling approach was used to recruit eight hemiplegic patients (seven males and one female) with an average age of 53.5 years, in this study (table 1). The causes of the stroke in these patients were ischemic in six and haemorrhage in two patients. The average duration since the onset of stroke was 3.8 years. Two subjects were hemiplegic at the left sides and the remaining six were at the right sides. All subjects were referred by a local Physiotherapy Clinic where they received trainings for treating dynamic balance disorder. They were unilateral hemiplegia caused by cerebral hemisphere stroke, living in a community-based setting, able to walk independently without walking assisting devices for more than 10 meters, and with good cooperation and compliance in gait analysis. All subjects were able to understand and follow the experimental instructions. They did not have fixed deformities over the ankle joint complex, but had rearfoot varus deformity at the affected side which could be corrected by external corrective forces, as evaluated by a Certified Orthotist following standard procedures specified in [39]. Subjects who had other peripheral or central nervous system dysfunctions, active inflammatory or pathologic changes in the joints of lower extremities in the previous 6 months, and active medical problems were not included in this study. All subjects have signed written-informed consents before participating in the study. Ethical approval was granted from the Human Subjects Ethics Sub-committee of The Hong Kong Polytechnic University (HSEARS20140211002). This study was registered on the Chinese Clinical Trial Registry (ChiCTR-IPB-15006530) and the Hong Kong Clinical Trial Registry (HKCTR-1853).

The Biofeedback System

The vibrotactile biofeedback system consisted of two separate components of 1) a plantar force acquisition unit (5.5cm×2.5cm×1.7cm) and 2) a vibration feedback unit (4.5cm×2.2cm×1.5cm) that were both attached to the subjects' affected side (figure 1). The plantar force acquisition unit consisted of two thin-film force sensors (A301, Tekscan Co., Ltd, USA), a microprocessor unit (ATMEGA328P, Atmel Co., Ltd, USA), a wireless transmitter module (HC-05, HC information Tech. Co., Ltd, China), and a rechargeable lithium-ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China). The vibration feedback unit consisted of one vibrator (XY-B1027-DX, Xiongying electronics Co., Ltd, China), a wireless receiver module (HC-05, HC information Tech. Co., Ltd, China), and a rechargeable lithium-ion battery (FLB-16340-880-PTD, UltraFire Co., Ltd, China).

The two thin-film force sensors (25.4mm×14mm×0.203mm, sensing area 9.53mm diameter each) were attached by adhesive tapes to the bottom of a piece of 2mm-thick flat insole, which was made of a medium firm (30-35 Shore A Hardness) ethylene-vinyl acetate (EVA, Foot Specialist Footcare & Products Co. Ltd, HK). The sensors were located at the first and fifth metatarsal heads of the affected side, verified by a certified orthotist, to evaluate the medial and lateral plantar force. One vibrator

(10mm diameter×2.7mm height) was fastened by an elastic strap at the subject's wrist of the affected side. The vibrator was set to produce full magnitude of vibration when the real-time forces measured at the first metatarsal head was less than 50% of that measured at the fifth metatarsal head at the same walking step. The vibrator was not activated in other conditions. Pilot studies showed that other ratios (25% and 100%) did not appear to provide appropriate reminder on foot inversion to subjects.

The plantar force acquisition unit analysed the force data at foot soles and delivered control signals to the vibration feedback unit via Bluetooth communication. The vibration frequency and strength of the vibrator were 220 Hz and 1 G, respectively, which were found to be highly recognizable by humans [40]. All subjects were assessed before the experiment to ensure that they could perceive the vibration of the vibrators. Both sampling frequency and transmission rate of the device were 10 Hz. The rechargeable batteries enabled the entire system to function for 24 hours continuously. The entire biofeedback system weighed less than 70 grams.

Experimental Design and Procedures

This study was conducted in a university locomotion laboratory. All subjects were explained how the biofeedback system functioned prior to the experiment. They were informed that the vibration of the vibrator corresponded to the excessive foot inversion at the affected lower limb. They were instructed to put more loading at the medial forefoot when the vibrator was activated. During the practicing period, the subjects were instructed to shift weight between the medial and lateral foot and experience the vibrations, to ensure that they understood the function of this system and were capable of using the feedback vibrations as a training aid. Subjects were given 10 minutes to get familiar with the new biofeedback system [41].

Gait analysis was then conducted over-ground on all subjects. Each subject was instructed to walk along a smooth, horizontal 7m-long walkway at a comfortable speed. The sequence of two testing conditions was randomly assigned to each subject: 1) with the biofeedback system turned-off; and 2) with the biofeedback system turned-on. Subjects were blinded from the experimental condition during the experiment. Same instructions were given to the subjects as to the actions they should take when there was a vibration feedback. Each testing condition was repeated 5 times consecutively for each subject. Between two conditions, each subject was given a 10-minute rest to eliminate the possible effect of fatigue. If subjects verbally reported any kinds of discomfort during the experiment, the experiment would be stopped with the situation being recorded. Two complete gait cycles in the middle of each walking trial (containing a total of 7-9 walking steps) were extracted to avoid the variable steps associated with initiation and termination of gait [42]. This strategy also enabled to collect data of one full gait cycle for both affected and unaffected sides, as well as the sufficient number of strides that are required to achieve high reliability when analysing gait parameters [43]. During the experiment, all subjects wore the same shoe model (TFGF81722/TFGF82722, TOREAD®, TOREAD Co., Ltd, China) provided by the researchers.

Outcome Measures

An in-shoe plantar pressure measurement system (novel pedar-x system, Pedar™, novel GmbH, Munich, DE), which was shown to have high repeatability [44] and validity [45], was sampling at 50 Hz and used to measure the plantar pressure distribution during walking in 2 experimental conditions. Before and after data collection of each subject, the insoles were checked using the Trublu® calibrating system to ascertain that all sensors produced accurate and reproducible absolute values [46]. The plantar foot was divided into six regions: medial forefoot, lateral forefoot, medial midfoot, lateral midfoot, medial rearfoot, and lateral rearfoot (figure 2). For all subjects, the forefoot, midfoot, and rearfoot regions comprised the first 35%, the following 35%, and the remaining 30% of the foot length, respectively.

An eight-camera three-dimensional (3D) motion capture system (Vicon Nexus 1.8.1, Vicon Nexus™, Vicon Motion Systems Ltd., UK), sampling at 100 Hz, was used to measure the 3D kinetic data in subjects during over-ground walking in 2 experimental conditions. A built-in lower limb marker set (Plug-in Gait Model) was adopted, in which 15 infra-red reflective markers were affixed to both sides at the heels, foot dorsum, lateral malleolus, lateral femoral condyles, middle of thighs/shanks, anterior superior iliac spines, and iliac crest. Spatial-temporal and kinematic data were measured and analysed using the Plug-in Gait Model in Vicon system. The gait data were low-pass filtered using a 4^{th} order Butterworth filter with a 6 Hz cut-off frequency.

Statistical Analysis

The parameters included for analysis were the average and peak plantar pressure parameters at each of the six plantar foot regions, total foot-floor contact area, stance time, swing time, stride time, walking speed, and peak lower limb joint angles during both stance and swing phases. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS, version 22.0, IBM Corporation, Armonk, NY, USA). Two-way repeated measures ANOVA was performed prior to examine the main effect of “interventions” (with vs. without biofeedback), the main effect of “limbs” (affected vs. unaffected side), and the interaction effect between two variables (interventions × limbs) in all measured parameters among all subjects. If significant interaction effect was found in ANOVA, pair-wise comparisons of “interventions” (with vs. without biofeedback) and “limbs” (affected vs. unaffected limb) were performed by using t-tests with Bonferroni corrections. The level of significance was set at 0.05. During data analysis, the person who analysed data did not know the content of each test condition, as conditions were coded.

Results

None of the subjects verbally reported any discomfort related to the use of the biofeedback during the experiment. The following shows the significant changes in gait variables and plantar pressure distribution upon using the biofeedback.

Changes in kinematic variables

Without the biofeedback, the peak foot inversion of the affected side during swing phase (angle 25.1 degrees) was 39.1%-significantly more than the unaffected side ($p=0.047$). Turning on the biofeedback system led to a significant 17.2% reduction of peak foot inversion ($p=0.012$) at the affected limb during swing phase (angle 20.8 degrees) (figure 3).

When the biofeedback system was turned off, the unaffected side had significantly more peak knee flexion ($p=0.047$) during swing phase and more peak hip abduction during both stance ($p=0.024$) and swing ($p=0.075$) phases than the affected side. Turning on the biofeedback device significantly reduced the unaffected-side peak knee flexion during swing phase ($p=0.009$) and peak hip abduction during stance phase ($p=0.017$). There was no longer significant difference in peak hip abductions between the 2 legs after turning on the device (figure 3).

Changes in plantar-pressure distribution

With the biofeedback system turned off, the total foot-floor contact area in mid-stance phase ($p=0.040$) and the peak plantar pressure at the medial midfoot ($p=0.034$) of the affected limb were significantly lower than those of the unaffected limb. When it was turned on, such contact area ($p=0.001$) and plantar pressure ($p=0.001$) at the affected limb were then significantly increased. There was no longer significant difference in total foot-floor contact area or peak plantar pressure at the medial midfoot between the 2 legs after turning on the device (figure 4&5).

Changes in kinematic variables and plantar-pressure distribution that happened at both the affected and unaffected sides

While turning on the biofeedback device did not significantly change the walking speeds, it significantly increased the stance ($p=0.003$) and stride ($p=0.001$) time, average plantar pressure at medial forefoot ($p=0.001$), peak ($p=0.001$) and average ($p=0.020$) plantar pressure at medial midfoot of both limbs (figure 4&5).

Discussion

This study developed a plantar-force based vibrotactile biofeedback and investigated the effects of its use on plantar foot loading and gait in hemiplegic stroke patients with flexible foot varus deformity. With no biofeedback, the foot inversion angle at the affected side was significantly higher than the unaffected side. The biofeedback device attempted to relieve foot varus by giving vibration clues when the medial side of the affected foot did not exert high enough forces during walking. This significantly reduced the maximum foot inversion of the affected side during swing phase. Significant increase in the plantar force at the medial forefoot during stance phase and total foot-floor contact area were then observed. This potentially improves postural balance [47], reduces chances of developing foot pain [14], and soft tissue injury [16].

It is interesting to note that while the device provided feedback on the weight bearing characteristics of the foot at the affected side, significant changes were observed at the unaffected side. Without turning-on the biofeedback device, subjects walked with significantly more peak hip abduction and knee flexion during swing phase at the unaffected side than the affected side, and these angles were higher than people without stroke [17]. Increasing hip abduction widened the base of support, which might compensate for the reduced walking balance caused by the abnormal orientation and loading of the feet at the affected side [17, 48]. Meanwhile, excessive knee flexion provides more foot clearance during swing phase at which the entire body weight is put against the opposite limb [17, 49, 50]. Turning on the device significantly reduced the unaffected-side knee flexion during swing phase and hip abduction during stance phases. Such reductions decreased the asymmetry between affected and unaffected legs. The improved symmetry of hip and knee joints during walking could improve the walking efficiency of patients of stroke [51].

The stance time of both limbs increased while walking speed did not have significant changes upon using the biofeedback device. The significantly increased stance time could reflect that subjects were more confident of bearing weight on their feet [52], indicating better walking capacity [53]. The biofeedback device did not compromise walking speed. This suggested that subjects did not need to walk more carefully and slowly when paying attention to the reminder signals from the device, which is consistent with a previous study identified retained beneficial effects of vibrotactile biofeedback when subjects performed dual cognitive tasks while receiving vibrotactile stimulations [54]. This also indicates that the changes in plantar pressure were not due to variations in walking speed.

In this study, the threshold ratio of provoking vibrotactile feedback was set at a level at which the plantar force at the medial forefoot reached 50% of that at the lateral forefoot. The threshold was chosen from a series of threshold ratios in pilot study, including 25%, 50% and 100%. It appeared that the ratio of 25% was too easy for the subjects to achieve, which lowered the value of using the device for gait training; while the ratio of 100% was too difficult for subjects to achieve in a limited training time period, leading to unstopped vibrations during walking. Subjects cannot benefit from the unstopped vibration, as no useful differentiated reminders were provided. It is worthwhile to involve more threshold ratios and further explore the best setting of the device in the future.

The clinical implication of this study is that a device measuring plantar forces and providing instant biofeedback has great potentials of improving gait in people with stroke. Subjects did not verbally report any discomfort upon using the biofeedback device in this study. Embedding thin-film force sensors into shoes/insoles and using appropriate feedback devices facilitate realization of home-based rehabilitation programs, which have high level of continuity, adherence, and compliance rates of training in patients [25, 55]. The nature of low interference with daily tasks of vibrotactile biofeedback [27] also allows the device to be used as a walking aid, which is capable of continuously monitoring the foot posture and walking ability, in both indoor and outdoor daily activities in the future.

This study investigated the immediate effect of this wearable vibrotactile biofeedback device on plantar loading and gait pattern in patients with chronic stroke. Future study shall investigate if such positive effects retained after long-term use, and in home-based settings. The evaluation of the applicability and repeatability of the device could be conducted in the future. The sample size of this study was rather small, while there are also some other published papers with small sample size demonstrated an effect of biofeedback devices [36, 56-59]. Future studies shall investigate the effect of such plantar force-based biofeedback device in larger samples who have poor walking ability.

Conclusions

Subjects in this study showed significant improvements in foot loading and gait upon using instant vibrotactile biofeedback regarding medical and lateral forefoot loadings. Instant vibrotactile biofeedback of plantar force at the medial and lateral forefoot significantly reduced the abnormally excessive foot inversion angle by more than 15%. This significantly increased foot-floor contact area and weight bearing over the medial aspect of the foot of the affected limb, which might help improve balance and walking capability. Improvements in gait patterns were also noted as the biofeedback significantly reduced the excessive hip abduction and knee flexion of the unaffected limb.

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Declaration of interest

The authors report no conflicts of interest.

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Table 1. Subject information

Subject	Age (years)	Gender	Weight (kg)	Height (m)	Causes of stroke	Duration after stroke (years)	Hemiplegic side
1	68	F	54.5	1.63	Ischemic	3	L
2	50	M	73.5	1.78	Ischemic	14	R
3	50	M	61.5	1.81	Ischemic	1	R
4	58	M	70.0	1.80	Hemorrhage	3	R
5	47	M	74.0	1.75	Ischemic	1	L
6	67	M	87.0	1.78	Ischemic	2	R
7	41	M	85.0	1.75	Hemorrhage	4	R
8	47	M	73.5	1.71	Ischemic	2	R

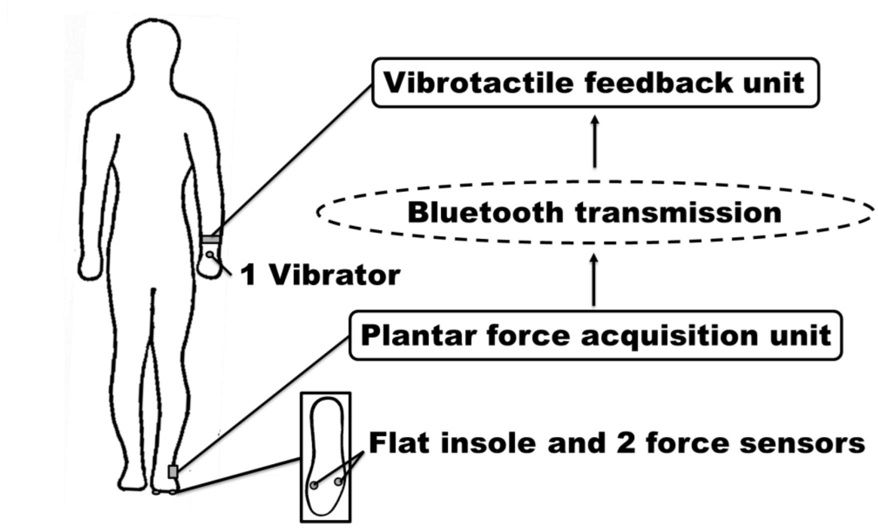

Figure 1. The vibrotactile system, consisted of a plantar force acquisition unit and a vibrotactile feedback unit wirelessly connected

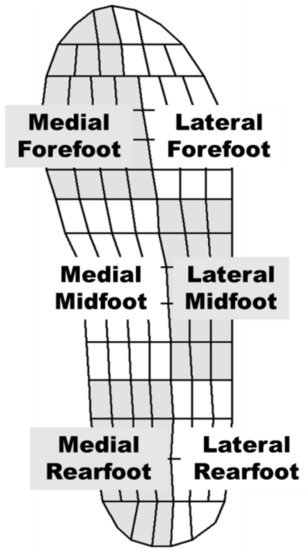

Figure 2. Foot regions: medial forefoot, lateral forefoot, medial midfoot, lateral midfoot, medial rearfoot, and lateral rearfoot

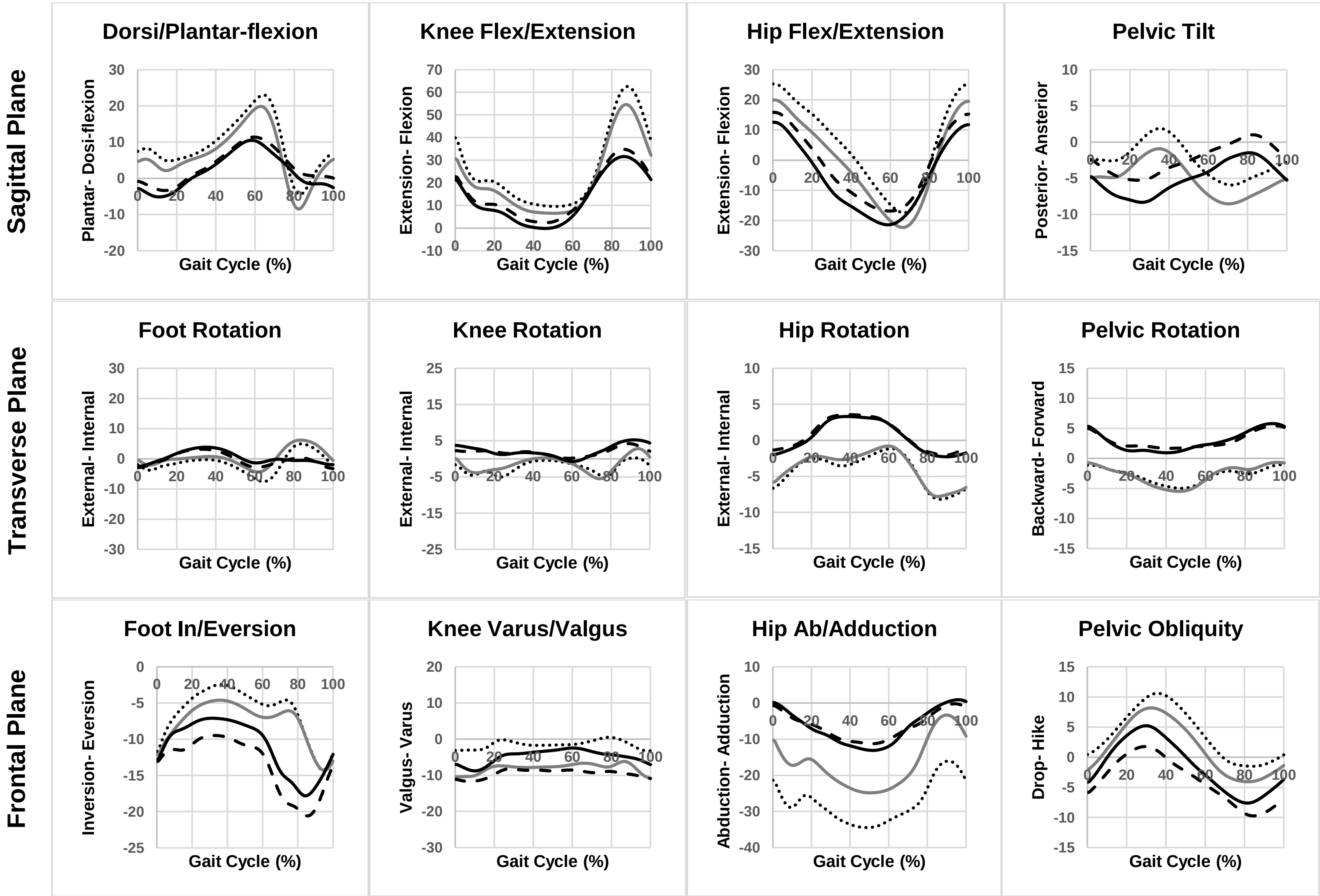

Figure 3. Three-dimensional kinetic data during walking with and without biofeedback system turned-on

Affected side-Without biofeedback   Affected side-With biofeedback   Unaffected side-Without biofeedback   Unaffected side-With biofeedback

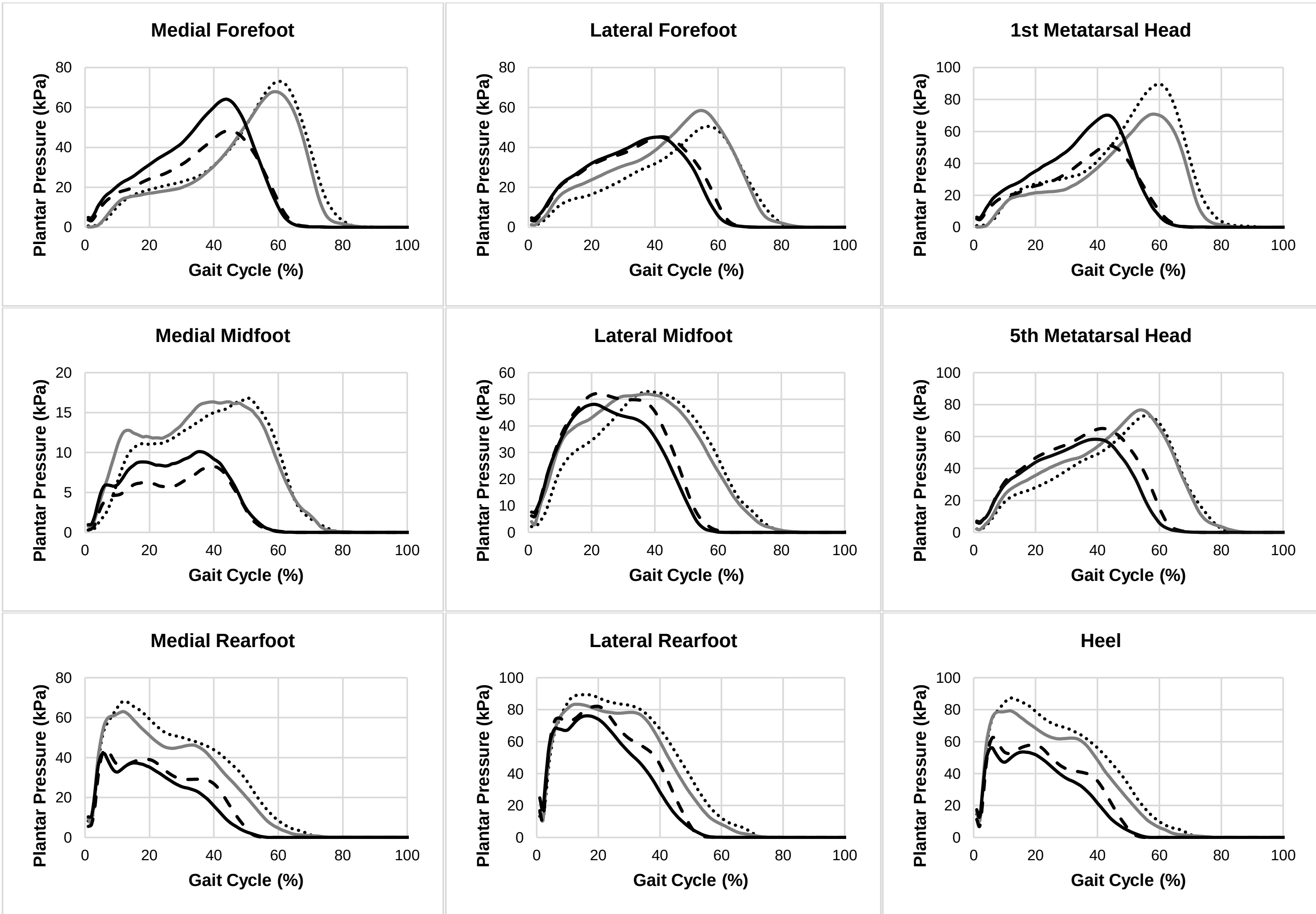

Figure 4. Regional plantar pressure pattern in patients with and without biofeedback system turned-on

Affected side-Without biofeedback   Affected side-With biofeedback   Unaffected side-Without biofeedback   Unaffected side-With biofeedback

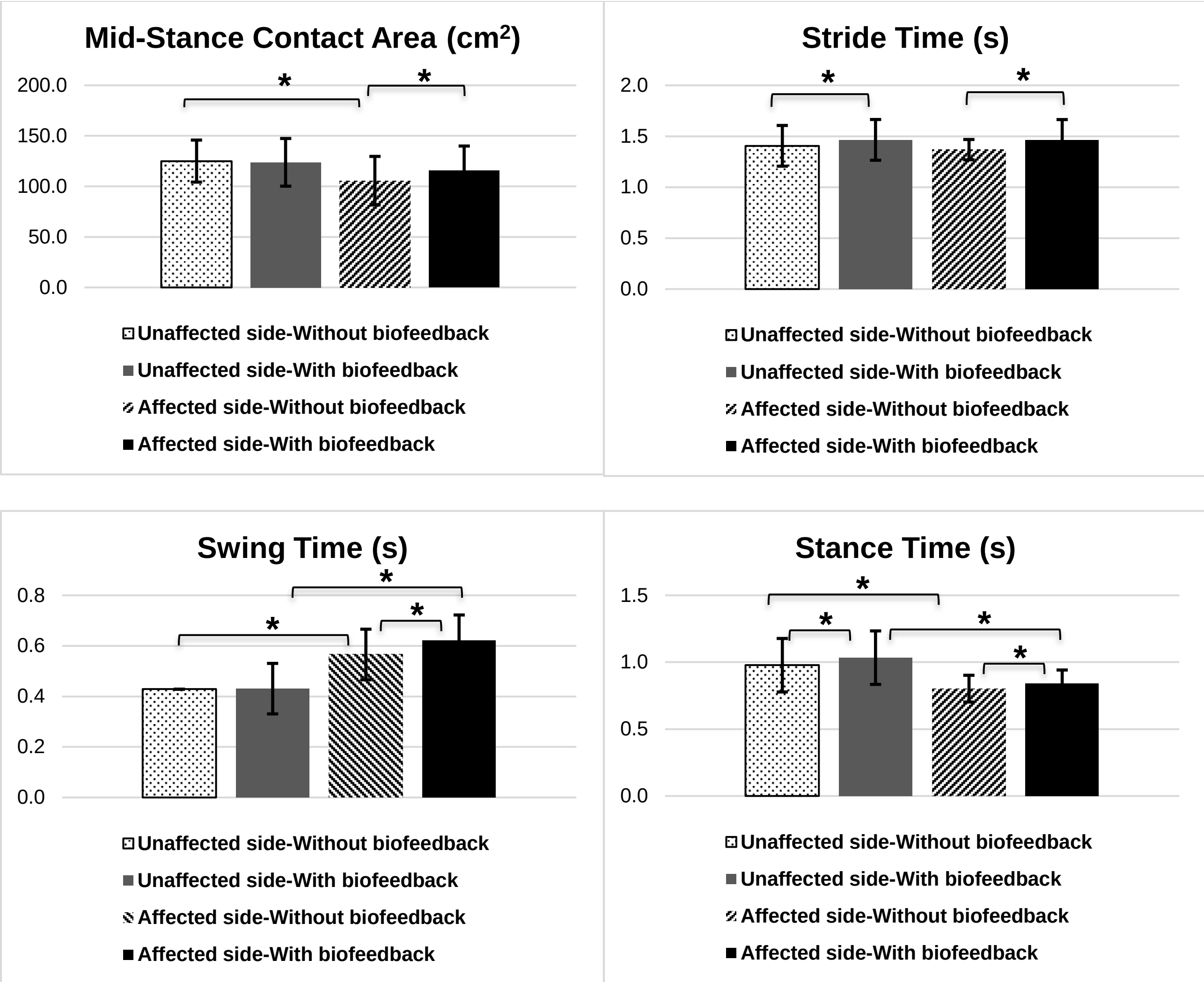

Figure 5. Contact area and temporal gait parameters in patients with and without biofeedback system turned-on

*：Significant difference existed.

Figure captions

Figure 1. The vibrotactile system, consisted of a plantar force acquisition unit and a vibrotactile feedback unit wirelessly connected.

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