

DEVELOPMENT REPORT

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Development of a vibratory cueing system using an implicit method to increase walking speed in patients with stroke: a proof-of-concept study



Kazuhiro Yasuda^{1*†}, Yuki Hayashi^{2†}, Anna Tawara³ and Hiroyasu Iwata²

Abstract

One of the main sequelae of stroke is dificulty walking, which is characterized by a decreased gait velocity and asymmetrical walking patterns. The purpose of this research was initially focused on developing a vibro-tactile cueing device that recognizes an implicit increase in cadence frequency. Subsequently, a proof-of-concept study with patients who had experienced stroke was conducted to examine the applicability of the system that had been developed. We applied Weber's law to provide an implicit method for increasing cueing frequency. This law involves the calculation of just-noticeable difference (JND) relative to a previous state. Throughout training with the proposed cueing device, patients marginally increased cadence, and their cadence and gait speeds were significantly increased post-test. Hip circumduction gait (i.e., abnormal gait patterns) did not change significantly throughout training. Notably, patients reported that they were unaware of any changes associated with the vibration stimulus. Our result demonstrates the immediate changes to cadence and gait speed that occurred through training with the proposed implicit cueing device. However, the result of this study is confined to immediate gait changes after training and utilized only a small sample of stroke patients. Thus, the limited volume of data obtained prevents rigorous analysis regarding the applicability of this training method. Nonetheless, these results are promising and provide a starting point from which to base larger studies.

Keywords: Stroke, Gait training, Cueing, Haptic device, Implicit motor learning

Introduction

In Japan, approximately 250,000 people annually experience a stroke, and several individuals require rehabilitation to regain independence [1]. One of the main sequelae of stroke is difficulty walking, which is characterized by decreased gait velocity and asymmetrical walking patterns [2, 3]. Therefore, gait training is a main focus of rehabilitation programs. Further, it has been reported

that increased walking speed contributes to improve quality of life (QOL) [4].

Gait rehabilitation research has been focused on the development of the cueing devices [7]. Systems with visual, audio, and vibratory cueing are well-known for assisting gait rehabilitation in patients with Parkinson's disease [5, 6]. These devices function by providing rhythmic stimulation to patients as biofeedback to alleviate gait freezing. This cueing method is also being currently used to explore the rehabilitative effects produced in patients that have experienced stroke [7–9]. A 2016 review article reported that cadence cueing has been applied to rehabilitate walking and that increasing the cueing frequency followed by the patient during walking rehabilitation

Full list of author information is available at the end of the article



^{*}Correspondence: kazuhiro-yasuda@aoni.waseda.jp

[†]Kazuhiro Yasuda and Yuki Hayashi contributed equally to this work

¹ Research Institute for Science and Engineering, Waseda University, 3-4-1 Okubo, Shinjuku-ku, Tokyo 169-8555, Japan

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sessions has improved walking speed significantly compared with other types of rehabilitative therapies [7].

Associated reaction is an unconscious, paretic, upperlimb muscle contraction that occurs throughout the duration of lower-limb exertion [10, 11]. This typical coordination problem is very likely to occur when patients who have experienced stroke intentionally speed up while walking. It presents a challenge for fast-gaitspeed rehabilitation implemented to avoid the deterioration of gait quality. As mentioned above, walking speed improvement in patients with stroke is more significant when a cueing system is used compared with other types walking rehabilitation. However, it is possible that the intentionally speed up while walking induced by the cueing system leads to associated unintended muscle contractions that could be detrimental, because the system requires a conscious walking pattern in patients with stroke.

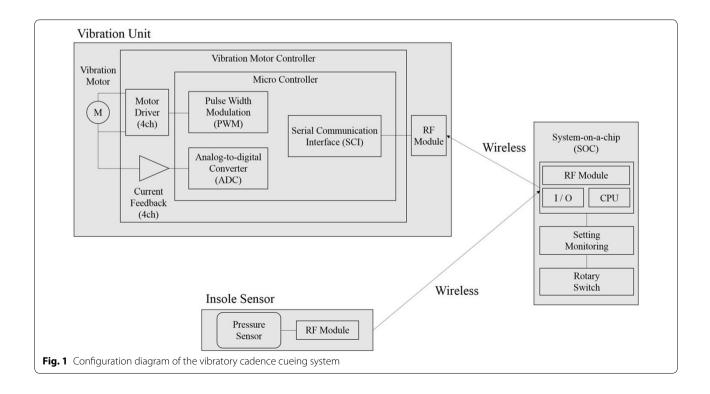
As mentioned above, since muscle tone is increased when patients intentionally make efforts to increase gait speed, there is a risk inducing abnormal gait patterns. Thus, the purpose of this research was initially aimed toward the development of a vibro-tactile device that recognizes an "implicit" increase in cadence frequency. Subsequently, we conducted a proof of concept study using patients with stroke to examine the applicability of the system.

Methods

System overview

Figure 1 depicts the configuration diagram used for developing the system. Two vibrators were deployed at bilateral sides of a pelvic belt. The vibro-tactile stimulus is provided by vibration motors (Z7AL2B1692082, Jinlong Machinery & Electronics, Inc. China) at 80 Hz on anterior superior iliac spine to perceive stimulus easily for patients. The interval of stimulation was set using personal computer software (Keil uVision5, Keil Software Inc., Germany) and was sent to a microcontroller (NRF 51, Nordic Semiconductor, USA). A rotatory switch on the NRF 51 enabled frequency changes while patients walked (Fig. 2). The vibration command was sent to another microcontroller (TMS320F270; Texas Instruments, USA) on the belt using wireless communication.

The patient walks while alternating vibration cues are given to the left and right sides of his/her waist. As stated in the introduction, the aim of the present study was to slightly alter the vibration tempo without inducing an abnormal muscular tone in the patients. A previous study has reported that Weber's law can be applied to the interval of stimulation [12]. Thus, we hypothesized that we could apply JND to alter cueing frequency (i.e., At every specified step, cueing frequency increases without the patient's awareness).



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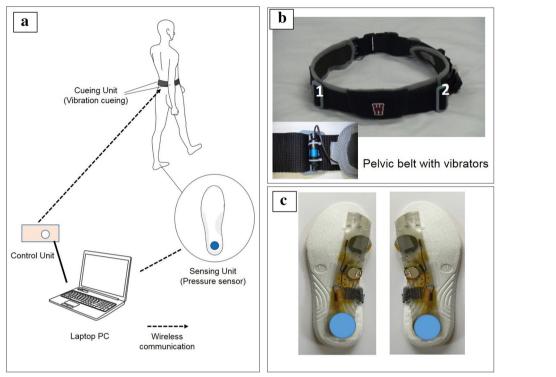


Fig. 2 Hardware of the vibratory cadence cueing system. The system shown in **a** consists of a belt with two left and right vibrators, a controller, PC and insole. Gait rhythm is cued by the vibrators, and frequency is modulated using the controller. The patient walks according to the left and right vibratory stimulation. In **b** vibrators are designed for placement on the left and right PSIS bony protuberances, and so the vibrations are easily felt. **c** Depicts how pressure sensors are placed on the heel of the insole, and sense heel strikes during walking

Method of implicit change of cadence-cueing frequency

We applied Weber's law [12] to determine the implicit method for increasing cueing frequency. This law involves the calculation of the just-noticeable difference (JND) relative to a previous state. For example, a value known as Weber's fraction represents the minimum difference ratio that can be realized. Weber's fraction w is calculated as follows:

$$w = \frac{\Delta R}{R},\tag{1}$$

where R is the value of previous state and ΔR is the JND value. Ideally, Weber's fraction is a constant. With respect to perception, Weber's fraction represents the smallest degree of change in stimulation that can be detected by an individual.

In our study, Weber's fraction represents the ratio of the minimal time interval of consecutive vibratory cues that can be perceived relative to a previous time interval. Figure 1b includes a basic illustration depicting increased cadence while walking. For each specified step number, n_{step} , the time interval of each cue decreases according to the following equation:

$$T_n = T_0 (1 - r)^n (2)$$

where T_0 is the specified initial time interval between each cue, n is the switched level set by the rotatory switch shown in Fig. 1, T_n is the time interval after setting by rotatory switch, and r is the ratio value determined according to the Weber's ratio W.

Determining the variables of cueing change

To apply our implicit method for increasing cueing cadence, the variable T_0 and r in Eq. (2) should be determined. Meanwhile, the switched level n was incremented by 1 for every n_{step} steps, and we conducted a verification test to determine this n_{step} variable. First, we set a 10 m walking distance using our cadence-cueing device. According to a previous study, the length of a step of a healthy individual is approximately 50–60 cm [13]. This means that it takes approximately 18–20 steps for a healthy individual to walk 10 m. We then decided that at least three cadence increases were required for each walk; therefore, n_{step} was set to 5.

Second, the appropriate initial time interval for each cue T_0 needed be determined based on the condition of each patient. Due to the asymmetry of a hemiplegic gait

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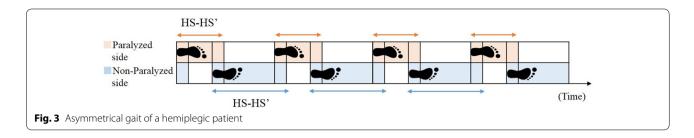


Table 1 Characteristics of patients participating in the study

Sex	Age	Brs.	Hypoesthesia	MMSE	Duration of time since the onset (months)
Male	69	III	Dull	27	<4
Male	79	V	Dull	28	< 3
Male	60	VI	Dull	30	<6

Brs. Brunstrom's recovery stage, MMSE Mini-Mental-State Examination Score

[3], we determined T_0 . The walking condition of a hemiplegic patient has been shown in Fig. 3. HS indicates heel strike at the non-paralyzed side, and HS' indicates heel strike at the paralyzed side. Thus, we defined $T_{HS-HS'}$ as the average time from HS to HS', while $T_{HS'-HS}$ is defined as the average time from HS' to HS'. T_0 was calculated from the average of the two values as follows:

$$T_0 = \frac{T_{HS-HS'} + T_{HS'-HS}}{2}. (3)$$

The timing of heel strikes was detected by an insole sensor as shown in Fig. 2c. It was comprised an NRF51 microcontroller and pressure sensors (FlexiForceSensorA401, Tekscan Inc., USA), which included the sensor deployed on the heel of the patient.

Finally, the value of the ratio, r, was determined using a test to verify Weber's fraction, which was performed on three patients that had experienced strokes. Each subject signed informed consents prior to testing, and basic information regarding these patients has been summarized in Table 1. The first value of r was set at 0.01. For each 5 steps taken, the time interval decreased according to specifications determined using Eq. (2) using this value for r. The patients were then asked whether they were able to feel frequency change after walking. If the patient did not recognize the change, 0.005 was added to r for the next trial. At the point where the frequency change was not recognized, the value of r was deemed to be Weber's fraction, and r was set to the value of the previous walk. Table 2 depicts descriptive statistics values

Table 2 Statistical analysis

Sample number	3
Standard deviation	0.013
95% confidence interval lower limit	0.040
Average	0.072
95% confidence interval upper limit	0.103

used for the test. To choose a value applicable to most patients, the 95% confidence interval lower limit value 0.04 was selected to be the r value used.

In summary, n_{step} was set at five to ensure that at least three cueing changes, T_0 were determined by measuring and averaging the heel strike patterns of patients before training. Further, r was set to 0.04, a value based on preliminary tests to verify Weber's fraction using the three patients who had experienced stroke.

Proof of concept study Objective

Our goal in developing this system was to decrease the time interval of cadence cueing to a point where it would not be recognized during the walking rehabilitation of patients. Thus, we expected the patient's walking speed to increase, without the patient noticing that stimuli had changed throughout the process of training. To evaluate these functions of our system, a proof of concept study was conducted using 6 patients that had experienced

Ethical approval and consent to participate in the study

All procedures were approved by the Waseda University Ethics Committee for Human Research. After a complete description of the procedures and purpose of the study had been given, written informed consent was obtained from all participants (Approval Number: 2015-087(2)).

Participants

stroke.

Table 3 shows the basic information and characteristics of the patients. Participants included six patients who had experienced stroke (mean age: 67.3 ± 5.5 years). Inclusion criteria were as follows: (a) Brunnstrom recovery stage

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Table 3 Basic characteristics of patients included in the pilot trial

sthesia MMSE Months past after the
onset (months)
m 28 <5
26 <2
22 <3
m Unavailable < 5
29 < 2
Unavailable < 1

Brs. Brunstrom's recovery stage [14], MMSE Mini-Mental-State Examination Score [15]

III (i.e., patients could initiate lower limb movements but were unable to control them well) or above, (b) ability to communicate well and sufficiently understand the instructions provided by the researcher (i.e., no dementia), and (c) patients could not have other medical conditions that may interfere with walking test performance and trial design.

Procedure

The test was conducted at the Tokyo General Hospital. In the pre-test phase, the patient was asked to walk twice for 10 m at a preferred speed. Meanwhile, the insole sensor was used to calculate the initial value, T_0 , using Eq. (3). In the training phase, the patient wore the pelvic belt and walked the 10 m course five times with the appropriate cueing cadence. During the patient's walk, we decreased the time interval of each cue every 5 steps by manipulating the rotatory switch. Finally, the post-test phase was conducted by asking the patient to walk for 10 m two separate times at his/her preferred speed without cueing, which was the same as for the pre-test. After the test, patients were asked whether they noticed any changes in stimuli.

Dependent variables

Cadence and walking speed were selected as indices for verifying the effect of cueing-training during the trial. Cadence was measured by an inertial-type gait analysis sensing system (RehaGait, Hosomed Gmbh, Germany) [16]. Walking speed was measured using a 10-m walking test [17], which is a typical method used for the evaluation in the context of clinical gait analysis. In addition, we measured the circumduction of the hip joint of the paralyzed side during the trial using RehaGait. This measurement shows the degree of compensation of movement utilized by patients. Lastly, the stance time ratio of the

paralyzed and non-paralyzed side was selected as an index value to evaluate gait asymmetry. This was defined as follows:

$$r_{stance} = \frac{t_{paralyzed}}{t_{healthy}},\tag{4}$$

where $t_{paralyzed}$ is the stance time of the paralyzed side, and $t_{healthy}$ is the stance time of non-paralyzed side. An r_{stance} of 1 indicates perfect stance symmetry for both sides. These indices were all measured by RehaGait.

Statistical analysis

The Friedman's test is an ideal statistic to use within a repeated measures type of experiment to determine whether a particular factor has an effect. Thus, the Friedman test followed by the Dunn's post hoc test was used to compare differences among three trials (i.e., pre-test, training and post-test). All tests were two-tailed and were considered significant if p-values were less than 0.05.

Results

The results of the study have been shown in Table 4, and individual data for cadence and walking speed were shown in Table 5.

Cadence

Average cadences at pre-test, during training, and post-test were 91.18, 99.72, and 101.68 steps/min, respectively. The cadence speeds were significantly increased both during training (p=0.0695) and post-test (p=0.0155) when compared to the pre-test (Fig. 4).

Walking speed

Average walking speeds measured pre-test, during training, and post-test were 0.737, 0.799, and 0.870 m/s, respectively. Walking speeds post-test were significantly increased relative to pre-test values (p = 0.0342) but during the training (p = 0.2331) increases were not significant (Fig. 5).

Circumduction of hip joint of paralyzed side

Figure 6 shows that the average circumduction of hip joint of paralyzed side during pre-test and training periods were 0.0404 and 0.0374 m. Thus, circumduction did not change significantly throughout training (p = 0.4142).

Stance time ratio of paralyzed and non-paralyzed sides

The average stance time ratio of paralyzed and non-paralyzed sides during pre-test and training periods were 0.987 and 0.980, respectively. No significant changes were observed in stance time ratios of paralyzed and

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Table 4 Comparison of specific tests at pre-training, training and post-training phases

Variable ^a	Pre (n = 6°)	Training (n=6)	Post (n = 6)	p-value ^b	
				Pre-tra	Pre-post
Cadence (steps/min)	95.07 (92.00–99.67)	104.46 (98.00–111.67)	107.45 (102.75–110.05)	0.0695 [†]	0.0155*
Walking speed (m/s)	0.739 (0.643-0.844)	0.732 (0.671 -1.009)	0.869 (0.798-1.030)	0.2331	0.0342*
Circumduction of hip joint of paralyzed side (m)	0.0399 (0.0334–0.0509)	0.0321 (0.0316–0.0489)	=	0.4142	=
Stance time ratio of paralyzed and non-paralyzed side (–)	0.992 (0.985–0.997)	0.986 (0.982–0.986)	-	1.00	_

a Median values (interquartile range)

Table 5 Individual data for cadence and walking speed at pre-training, training and post-training phases

	Pre	Training	Post
Cadence (steps/min)			
Patient A	103.47	108.20	108.89
Patient B	91.00	112.83	117.16
Patient C	61.27	65.91	65.90
Patient D	101.17	113.53	110.43
Patient E	95.18	100.71	106.01
Patient F	94.96	97.09	101.66
	Pre	Training	Post
Walking speed (m/s)			
Patient A	1.03	1.08	1.16
Patient B	0.61	0.68	0.83
Patient C	0.42	0.48	0.45
Patient D	0.87	1.08	1.07
Patient E	0.73	0.77	0.90
Patient F	0.74	0.66	0.78

non-paralyzed sides throughout training (p = 1.00) (Fig. 7).

Discussion

The purpose of this research was to develop a vibrotactile cueing device that is able to recognize implicit increases in cadence frequency and to conduct a proof-of-concept study using patients that had experienced stroke to examine the applicability of the developed system. The system developed here, through the provision of rhythmic stimulation, improved cadence in six stroke patients. Furthermore, walking speed, which is a criterion for complex gait evaluation, improved after training. Hip abduction, which is an index of abnormal gait, did not worsen from use of the system. Furthermore, patient did not notice any changes with respect to cadence or walking speed being provided rhythmically

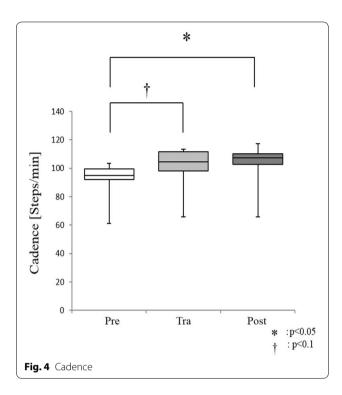
throughout tests. These results suggest the possibility that the proposed system may be used to allow walking speeds to improve in a natural manner (without the patient having to expend any effort increasing walking speed).

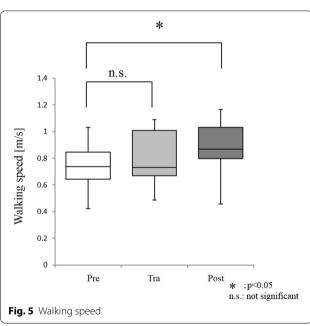
It has been reported that in general, the cadence of healthy individuals in normal walking is approximately 100–130 [18]. In the pre-test of this study, the walking cadence of patients was 91.18 which was lower than that of healthy individuals, and the cadences were 99.72 and 101.68 during training and post-training, respectively, indicating the improvement to the level of healthy individuals. Therefore, the improvement of cadence with this system may have demonstrated that the long-term training is valuable to be implemented. However, when focused on individual data, this system improved walking performances including cadence

 $^{^{}b}$ Dagger (†), P \leq 0.1; single asterisks, P \leq 0.05; (Friedman's test)

n = number of patients

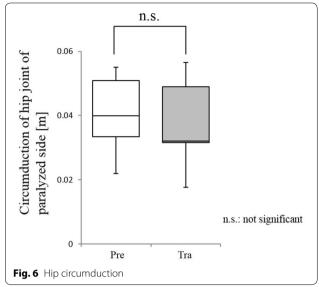
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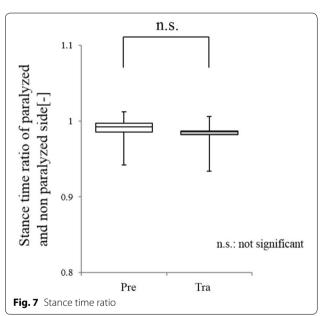




and gait velocity in most patients. However, as the decreased performance was noted in Patient F, suggesting that the effects of the system may vary from patient to patient.

Walking is typically disabled by stroke, and impaired ambulation reduces QOL [4]. Thus, improving walking speed is an important aspect of clinical treatment. However, excessive voluntary movement induces hip





abduction and other compensatory movements due to abnormal muscle tone development that occurs as a result of stroke [10, 11]. With the proposed system, conscious efforts exerted by patients are minimized and walking state is altered by making very fine changes to rhythmic stimulation patterns. Consequently, applying this technology may provide a cueing system applicable to stroke patients in clinical settings.

An experimental constraint of this research is that it is a proof of concept study, therefore, the sample size is small. In addition, verifying the influence of repeated practice in order to identify long-term changes will be required to produce a more complete determination of the usefulness of the system.

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One limitation of this study was the possible influence of order effect. Significant differences were observed in the cadence and gait velocity between the pre-test and post-test values. However, the cadence during training showed an improving trend that was not statistically significant compared to that in the post-test, and the gait velocity during training was not significantly different from that in post-test. These results may have been influenced by the habituation to walking through training. In subsequent experiments, the more robust design is needed to evaluate the effect, setting up a control group.

Conclusion

We have developed a device that has the capacity to improve cadence by implicitly changing gait rhythms. In a proof-of-concept study using stroke patients, cadence was improved without patients noticing, and walking speed improved after training with the system. There was also no worsening of hip abduction, which is a measure of compensatory movement that occurs when walking post-stroke. In addition, the patients were unaware improvements to cadence during training. The results of this proof-of-concept study suggest the possible application of the device developed here, but verification with a more robust study that includes a greater number of test subjects will be required before clinical application.

Abbreviations

QOL: quality of life; JND: just noticeable difference.

Acknowledgements

The authors express gratitude to Zenyuu Ogawa for assisting in hardware design.

Authors' contributions

KY performed the design of this study, acquisition and analysis of data, and drafted the manuscript. YH and AT made contributions to the development and analysis of the data. HI was involved in the conception of the system and design of the study. All authors read and approved the final manuscript.

Funding

This study was supported by the Japanese Society for the Promotion of Science (JSPS), Grant-in-Aid for Scientific Research (C) No. 17K01875, and Research Institute for Science and Engineering, Waseda University, Grant-in-Aid for Junior Researchers.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

Ethical approval was granted by the Ethics Committee of Waseda University.

Consent for publication

Written informed consent for the publication of clinical details and/or clinical images was obtained from all patients.

Competing interests

The authors declare that this research was conducted without any commercial or financial relationships which could be construed as a potential conflict of interest. The authors declare that they have no competing interests.

Author details

¹ Research Institute for Science and Engineering, Waseda University, 3-4-1 Okubo, Shinjuku-ku, Tokyo 169-8555, Japan. ² Graduate School of Creative Science and Engineering, Waseda University, 3-4-1 Okubo, Shinjuku-ku, Tokyo, Japan. ³ Department of Modern Mechanical Engineering, Waseda University, 3-4-1 Okubo, Shinjuku-ku, Tokyo, Japan.

Received: 1 October 2019 Accepted: 26 December 2019 Published online: 03 January 2020

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