ARTICLE





Immediate effects of lower limb loading exercise during stepping with and without augmented loading feedback on mobility of ambulatory individuals with spinal cord injury: a single-blinded, randomized, cross-over trial

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Abstract

Study design Single-blinded, randomized, cross-over design.

Objectives To compare the immediate effects of bodyweight shifting and lower limb loading (LLL) exercise during stepping with and without augmented loading feedback, followed by overground walking, on the mobility of ambulatory individuals with spinal cord injury (SCI).

Setting Academic laboratory center.

Methods Thirty participants with SCI were trained using a single intervention session consisting of repetitive bodyweight shifting and LLL exercises during stepping with or without external feedback (10 min/leg) followed by overground walking (10 min) with a 2-week washout period, in a random sequence. The timed up-and-go test (TUG) (primary outcome), 10-m walk test (10MWT), five times sit-to-stand test (FTSST), and maximal LLL were measured 1 day before and immediately after each training session.

Results Significant improvement was found following both training sessions, excepting the TUG and LLL of the less-affected leg, where improvement was found only after training using augmented feedback. Moreover, the improvement following the training with feedback was significantly greater than that after training without feedback. The mean (95% CI) between-group differences for the TUG = 1.9 [0.6–3.3]s, 10MWT = 0.1 [0.0–0.1]m/s, FTSST = 1.0 [1.5–4.8]s, LLL = 3.1 [1.5–4.8]–2.8 [0.8–4.9]%bodyweight, p < 0.05.

Conclusions The training programs immediately enhanced the mobility of ambulatory individuals with chronic SCI (post-injury time >6 years), particularly the training with augmented loading feedback. The findings offer another effective rehabilitation strategy that can be applied in various clinical and home-based settings.

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Introduction

Bilateral sensorimotor deteriorations following incomplete spinal cord injury (iSCI) impair bodyweight shifting and the

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weight-bearing or lower limb loading (LLL) ability of patients [1]. Insufficient LLL prevents effective contralateral leg swinging, which subsequently distorts the mobility of the affected individuals [2]. Inversely, asserting the maximum sustainable load on the stance limb is key in ensuring the movement stability and safety of the participating individuals [3]. Therefore, bodyweight shifting and LLL ability are commonly emphasized in rehabilitation practice through stepping training and overground walking [4, 5]. However, clear benefits of this training protocol have been reported only in individuals with brain lesions [4–6] and not in ambulatory individuals with iSCI.

Nonetheless, the sensorimotor impairments following iSCI may limit the ability of the individuals to utilize their intrinsic feedback for movement control and correction over trials, thus affecting the training outcomes [7]. Previous studies have cross-sectionally observed the benefits of external feedback on functional improvement in ambulatory individuals with iSCI [8, 9]. Some studies have further reported the effects of walking training using external feedback on normalizing gait patterns and mobility after iSCI [10, 11]. Nevertheless, training for entire walking tasks is highly demanding, limiting the participation of individuals with poor ambulatory ability. The training protocols also require complex and costly machinery-for example, instrumented kinematic real-time feedback and roboticassisted gait training equipment [11-15]—which limits clinical application of the protocols in general clinical settings.

The researchers hypothesized that a single intervention session of repetitive bodyweight shifting and LLL during stepping training, followed by overground walking training with an emphasis on LLL, would immediately enhance the mobility of ambulatory individuals with iSCI, particularly those who were trained with augmented loading feedback. Therefore, the present study compared the immediate effects between bodyweight shifting and LLL training with and without external feedback, followed by overground walking training on the mobility of ambulatory individuals with iSCI. The findings would offer another effective training strategy that can be applied in various clinical and home-based settings for individuals with various levels of ability.

Methods

Participants

This was a single-blinded, randomized, cross-over study that was conducted in an academic laboratory center from April 2017 to October 2018. Participants were communitydwelling individuals with iSCI with at least 18 years of age

with a body mass index of 18.5-29.9 kg/m² who had iSCI from traumatic causes or nonprogressive diseases. All of the participants were at a chronic stage of spinal cord injury (SCI) (post-injury time >12 months) and had the ability to walk independently, with or without a walking device, over at least 17 m (Functional Independent Measurement Locomotor Score of 5-7) [16, 17]. The exclusion criteria were as follows: conditions or disorders that could affect the individual's ability to participate in the study and/or their ambulatory ability, such as brain function disorders, color blindness, and visual deficits that were unable to be corrected using glasses or contact lenses, musculoskeletal pain (with an intensity of pain more than 5/10 on a numericalrating pain scale), deformity of the musculoskeletal system, inability to follow commands used in the study, and unstable medical conditions [8, 10].

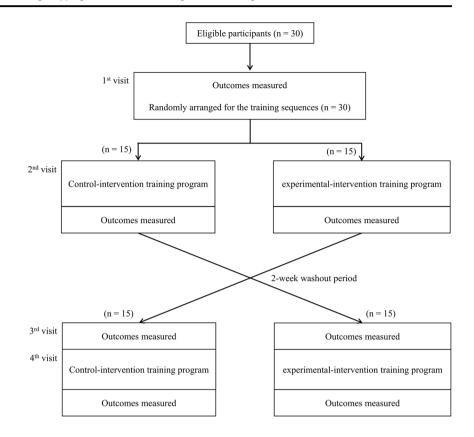
The study required at least 29 participants, according to the sample size calculation for a comparative study using the data from a pilot study (n = 15; unpublished data) with an effect size of 4.82 s ($\mu_1 = 2.1$ s, $\mu_2 = 6.92$ s) for a primary outcome of the study, namely the timed up-and-go test (TUG) with $\beta = 0.10$, $\alpha = 0.01$, and $\sigma^2 = 31.07$ (SD₁ = 5.72; SD₂ = 5.42).

Experimental protocols

A previous study applied a 2-week washout period [18], and the data from ten pilot participants indicated no significant carryover effects after 2 weeks (p > 0.10). Therefore, all participants involved in a control intervention program (bodyweight shifting and LLL training during stepping without external feedback and overground walking training), and an experimental intervention program (bodyweight shifting and LLL training during stepping with external feedback and overground walking training) with a 2-week washout period between the training programs.

Participants were involved in the study for four visits over 3 weeks (Fig. 1). On the first visit, the participants were interviewed and assessed for their demographics and SCI characteristics (interviewed for age, cause of SCI, and post-injury time; assessed for bodyweight, height, sensorimotor scores to determine level and severity of injury according to the criteria from the American Spinal Cord Injury Association (ASIA) Impairment Scale (AIS), and walking device used) [16]. Then, participants were assessed for the outcomes of the study. The findings on walking speed (<0.6 m/s or \ge 0.6 m/s) and AIS classification (C or D) were used to randomly arrange the participants for the training sequences (i.e., a control intervention program and experimental intervention program, using a blocked random allocation schedule via a Microsoft Excel program). The next day (second visit), participants were trained using the first program of their sequence by an experienced

Fig. 1 Participation flowchart.

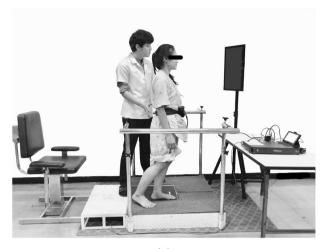


physiotherapist with assessment for the outcomes immediately following the training program. After a 2-week washout period, participants were assessed for the outcomes of the study on their third visit. During the fourth visit (the next day), they were trained using the second program, with assessment for the outcomes immediately following the training (Fig. 1). The details of the training protocols and outcome measures are as follows.

Training protocols

Control intervention program (Fig. 2a and Supplementary video 1): participants stood upright in a step-standing position while placing the leg being trained (stance leg) at the anterolateral direction to the non-trained (swing) leg [5]. Then they were instructed to shift their bodyweight onto the stance leg as much as possible and to step the contralateral leg forward, placing the foot on the floor at a distance of ~40% of the individual's height (this was suggested as a normal step length) [19], while minimizing the use of their upper extremities. The participants performed the same procedure when stepping backward [5, 19]. The training program started with the less-affected leg, as identified using the total sensorimotor scores according to the ASIA protocol [16], to promote the transferability of the training to the more affected foot, which was practiced subsequently [20]. Participants were encouraged to practice the task for each leg continuously for 10 min as long as they could do so without muscular fatigue. Thus, the program of bodyweight shifting and LLL training during stepping lasted 20 min (excluding resting periods). Subsequently, participants were trained to walk overground with an emphasis on LLL, with or without a walking device, according to their ability for 10 min to facilitate the transferability of the part-task (i.e., bodyweight shifting and LLL training during stepping) to the entire walking task. During training, the participants were allowed to take periods of rest as needed.

Experimental intervention program (Fig. 2b and Supplementary video 2): the participants were trained using the same protocols as those of the control intervention program but with visual feedback relating to the amount of LLL of the stance leg from a visual weight-taking machine (VWTM; patent application number: 1701004050) [5, 21]. The machine consists of a digital load cell (Model L6E3-C, 200 kg-3G, with a standard calibration method based on UKASLAB 14: 2006, accuracy up to 0.1 kg and measurement uncertainty of ± 0.082 kg), a display section, and a controller. While practicing the task, the participants were instructed to look at the display section notifying them of the amount of LLL on the stance leg through the number of lit bars (Fig. 2b). When the participants shifted their bodyweight onto the stance leg, the lit bars of the display section gradually illuminated the red, yellow, and green zones according to the amount of the participant's LLL. At





(b)

Fig. 2 Starting position of the training program. a Control intervention (lower limb loading without external feedback). b Experimental intervention (lower limb loading with external feedback).

every step, participants were instructed to shift their bodyweight onto the stance leg until the green zone was illuminated and a beep sounded to alert the participants and the therapist of the adequate amount of LLL on the stance limb (at least 80% of the participant's bodyweight) [22] and that they could swing their contralateral leg forward and backward. Similarly, participants practiced this task for 10 min on the less-affected leg, and 10 min on the more affected leg, followed by overground walking training with an emphasis on LLL ability for 10 min.

Outcome measures

Participants were assessed by a blinded and experienced assessor for the outcomes of the study, including the TUG (primary outcome), 10-m walk test (10MWT), five times sit-to-stand test (FTSST), and maximal LLL ability in a

random order 1 day prior to and immediately following each training session. The details of the tests are described below.

TUG: the participants were timed using a manual stopwatch while they stood up from a standard armchair, walked around a traffic cone that was located 3 m away from the chair, and returned to sit down on the chair at the fastest and safest speed with or without a walking device [23]. The average time required over the three trials was recorded.

10MWT: the participants were timed using a manual stopwatch while they walked over 4 m in the middle of the 10-m walkway at a comfortable, and fastest and safe speed with or without a walking device. The average time required over the three trials was recorded. The time was converted to a walking speed using the following formula: velocity (m/s) = distance (m)/time (s) [23-25].

FTSST: the participants were seated on a standard armless chair, with their back upright against the backrest of the chair, and their feet located on the floor with the heels slightly behind the knees. Participants were timed using a manual stopwatch while they completed five chair-rise cycles in the fastest and safest manner possible with or without using their hands. The average time used to complete the test over three trials was recorded [26].

LLL ability: this ability was assessed for both lower limbs in random order using a digital load cell of the VWTM [5, 6, 21] but without utilizing the display section. The participants were in the same starting positions as those used for the training procedure; participants were instructed to shift their bodyweight onto the leg being tested as much as possible before stepping the non-tested leg forward for five trials per leg. The first two trials served as familiarization sessions, and the data of the other three trials were reported in terms of percent of bodyweight [5].

During testing and training, participants were able to take a period of rest as required. They had a lightweight safety belt fastened around their waists, and an assessor was always nearby to ensure participant safety.

Statistical analysis

Descriptive statistics were used to explain the baseline demographics, SCI characteristics, and findings of the study. The carryover (or residual) effects of the intervention in the first sequence, which could persist and distort the outcomes of the second sequence, were assessed using the method proposed by Grizzle [27]. The method recommended that an independent sample *t*-test should be performed at a significant level greater than the traditional value of 0.05, such as 0.10 or 0.15. Thus, the study used a level of significance for carryover effects of p < 0.10, and if it was not significant, the data from both periods were

applied for analysis [27]. Given that the data were normally distributed, the dependent sample t-test was used to compare the different findings within the training programs. The independent sample *t*-test was employed to compare the magnitude of changes between the training protocols. The level of significance was set to p < 0.05.

Results

Participants (n = 30) with an average age of 53 years and average post-injury time of ~6 years were involved in the study. The majority had incomplete paraplegia (67%) and required a walking device on a daily basis (63%, Table 1). The total sensorimotor scores of the participants had a significant difference between the less and the more affected side (p < 0.05, Table 2).

There was no significant difference in participants' baseline data (p > 0.1, Table 3), suggesting no carryover effects between the training programs. Thus, the study reported the data of all the participants for each variable.

Table 1 Baseline characteristics of the participants.

Variable	Data $(n = 30)$
Demographics	
Age ^a , years	53.2 (11.8)
BMI ^a , kg m ^{-2}	24.3 (3.6)
Gender: male, n (%)	22 (73)
SCI characteristics	
Months post injury ^a	71.9 (74.5)
Level of injury: incomplete paraplegia, n (%)	20 (67)
AIS classification: D, n (%)	18 (60)
Using a walking device: yes, n (%)	19 (63)
Cane	5 (16)
Crutches	2 (7)
Walker	12 (40)

BMI body mass index, PIT post-injury time, AIS American Spinal Cord Injury Association Impairment Scale.

^aThe data are presented using mean ± standard deviation (SD).

Table 2 Sensorimotor scores of the participants.

Variable	More affected leg	Less-affected leg	p value ^a
Total sensory score	95.30 (14.73)	98.10 (15.23)	0.012*
Total motor score	37.97 (8.61)	41.87 (7.37)	< 0.001*
Lower limb score	15.93 (5.84)	19.40 (5.61)	<0.001*

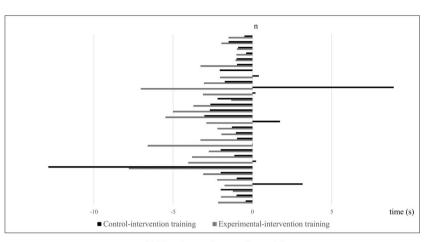
The data are presented using mean ± standard deviation (SD). Total sensory score: 0-112; total motor score: 0-50.

*Indicates significant differences.

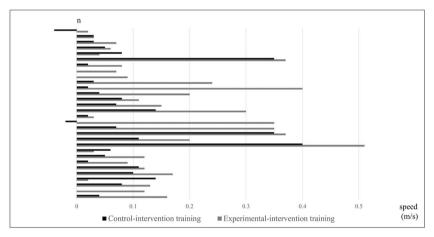
^aThe findings between the sides were compared using the dependent samples t-test.

Table 3 Findings of the study before and after the training programs $(n = 30)$.	after the training prog	grams $(n=30)$.							
Variable	Control intervention		p value ^c	Experimental intervention	ention	p value ^c	p value ^c Change data for		<i>p</i> value ^d
	Pretraining	Posttraining		Pretraining	Posttraining		Control	Experimental	
TUG (s) ^a	23.98 (13.44)	22.95 (12.46)	0.085	24.46 (13.55)	21.51 (12.54)	<0.001	1.03 (3.14)	2.94 (1.87)	0.006
Preferred speed (m/s) ^b	0.47 (0.4:0.8)	0.56(0.4:0.8)	<0.001	0.47 (0.4:0.7)	0.61 (0.5:0.9)	<0.001	0.05 (0.0:0.1)	0.12 (0.1:0.3)	0.002
Fastest speed (m/s) ^b	$0.56\ (0.4;\ 1.0)$	0.72 (0.5: 1.0)	<0.001	0.56 (0.4: 0.9)	0.72 (0.6: 1.1)	<0.001	0.08 (0.0:0.1)	0.13 (0.1:0.3)	0.001
FTSST (s) ^b	15.1 (12.4: 19.4)	13.6 (11.9: 18.0)	<0.001	15.6 (12.9: 19.0)	13.3 (11.2: 15.9) <0.001	<0.001	1.0 (0.7:2.2)	2.23 (1.1:3.9)	0.009
LLL—less-affected leg (%bodyweight) ^a	90.28 (8.53)	90.51 (6.50)	0.654	89.87 (8.43)	93.03 (5.46)	<0.001	0.24 (2.85)	3.37 (3.46)	<0.001
LLL-more affected leg (%bodyweight) ^b 83.29 (74.7: 91.0)	83.29 (74.7: 91.0)	85.23 (79.7: 95.0)	0.020	83.84 (74.6: 91.3)	83.84 (74.6: 91.3) 89.75 (80.2: 95.3) <0.001 1.79 (-1.0:5.9) 5.03 (3.2:6.9)	<0.001	1.79 (-1.0:5.9)	5.03 (3.2:6.9)	0.006
Control intervention training = bodyweight shifting and LLL training during stepping without external feedback followed by overground walking training; experimental intervention training = bodyweight shifting and LLL training during stepping with external feedback followed by overground walking training. TUG timed up-and-go test, <i>FTSST</i> five times sit-to-stand test, <i>LLL</i> lower limb loading. TUG timed up-and-go test, <i>FTSST</i> five times sit-to-stand test, <i>LLL</i> lower limb loading. ^a These data are normally distributed, and they are presented using mean (standard deviation). ^b These data are non-normal distribution, and they are presented using median (interquartile range, Q1:Q3). ^c values from the dependent samples <i>t</i> -test for the data with normally distributed, and from the Wilcoxon signed-rank test for the data with non-normal distribution.	t shifting and LLL trains stepping with extrant ext. Ines sit-to-stand test, <i>L</i> they are presented using they are presented using the the data with the test for the data with test for the data with the test for the data with test fo	raining during stepping w ternal feedback followed <i>LLL</i> lower limb loading. sing mean (standard devi d using median (interqua normally distributed, and h normally distributed, ar	y without e ved by ove ng. eviation). quartile ran und from th , and from	raining during stepping without external feedback followed by overground walking training; experiment ternal feedback followed by overground walking training. LLL lower limb loading. sing mean (standard deviation). d using median (interquartile range, Q1:Q3). normally distributed, and from the Wilcoxon signed-rank test for the data with non-normal distribution. h normally distributed, and from the Mann–Whitney U test for the data with non-normal distribution.	owed by overground ning. ank test for the data <i>U</i> test for the data w	walking tr with non-r ith non-no	aining; experiment tormal distribution	tal intervention tr	aining =

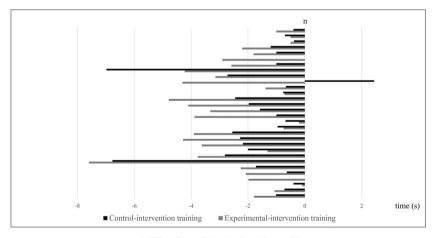
Fig. 3 Different findings between the training programs for every participant of three functional outcomes. a Timed up-and-go. b 10-m walk test (preferred walking speed). c Five times sit-to-stand test. Between-group difference



(a) Timed up-and-go test (seconds)



(b) 10-meter walk test (preferred speed, meters/second)



(c) Five times sit-to-stand test (seconds)

The findings suggested that both training programs significantly improved all the variables of the participants (Table 3, Fig. 3, and Supplementary Appendix 1), excepting the TUG and LLL of the less-affected leg following the control intervention training program. Moreover, the improvement after the experimental intervention program was significantly greater than that following the control intervention program (p < 0.05, Table 3, Fig. 3, and Supplementary Appendix 1).

Discussion

LLL ability of the stance limb during a single limb support period is crucial for movement stability and efficient walking [28, 29]. However, there is no clear evidence on the incorporation of this task in rehabilitation training for ambulatory individuals with iSCI. Thus, this study investigated the immediate effects of bodyweight shifting and LLL training with and without external feedback, followed by overground walking training on mobility, among independent ambulatory participants with iSCI using a singleblinded, randomized, cross-over design. The findings confirmed the benefit of the training program, particularly for the training using loading feedback, for ambulatory participants with chronic iSCI (Table 3, Fig. 3, and Supplementary Appendix 1).

The training programs required the participants to shift their bodyweight and increase LLL (e.g., minimizing the use of upper limbs while stepping the contralateral leg to place at an optimal step length [40% of the individual's height]) [19]. Thus, the repetitive loading exercises over 10 min offered a meaningful learning experience due to the effects of bodyweight shifting and joint approximation. Such a program facilitated the ability to control dynamic body balance and unload the contralateral leg. Increased LLL also facilitates joint receptors, mechanoreceptors within the static and dynamic structures, and muscular co-contraction for dynamic stabilization, prior to participants learning the entire walking task [30]. Then, overground walking training emphasizing LLL ability on the stance limb offered transferability of the part-task 20-min bodyweight shifting and loading exercise to a whole walking task. The load afferent during walking is a key input that modulates the translation from stance to swing during human locomotion [1]. Thus, the training program significantly enhanced LLL ability (p < 0.05, Table 3) that is associated with numerous factors needed for independent living, such as lower limb kinetics, kinematics, muscle strength, and perceptual apparatus [31, 32]. Consequently, participants showed significant improvement in their mobility after the training, particularly for the outcomes of the 10MWT and FTSST (p < p0.001, Table 3).

On the contrary, the TUG, a primary outcome of the study, comprises many sequential mobility tasks. The improvement of such a test may be more difficult than a single-task test, such as the 10MWT and FTSST. The augmented feedback during the training provided additional

useful information to help participants adequately control and modify their movements according to the task demands. The number of lit bars, or colors of the displayed section, of the VWTM in relation to LLL (Supplementary video 2) informed a proper amount of bodyweight shifting and LLL (at least 80% of their bodyweight) necessary for unloading and lengthening the step length of the contralateral leg [2]. Such information facilitated the participants to make maximum use of their stance limb, which inversely decreased the reliance on their upper limbs and overcame the learned non-use in the affected lower limbs or the leg being trained. As a result, the training using external feedback significantly increased LLL of the less-affected leg and improved a complex mobility test, namely the TUG; this improvement was not found after the control intervention training. In addition, the improvement following the experimental intervention training was significantly greater than that following the control intervention training (p < p)0.01, Table 3).

Previously, augmented feedback has been commonly applied in many individuals, but it has only recently been reported in ambulatory individuals with iSCI, mostly by way of using a costly and complex machine (e.g., treadmill or Lokomat) [8, 10–15]. The present findings additionally suggest the benefits of a simple and practical training program of bodyweight shifting and LLL training, particularly using augmented loading feedback, in individuals with iSCI with various levels of ability and long post-injury times (~6 years, Table 1) (Fig. 3 and Supplementary Appendix 1, and Table 1) and who have not received any particular routine training. Such feedback can be provided easily using a digital bathroom scale; thus, the program can be applied in various settings, such as hospitals, clinics, communities, and patients' homes.

Nonetheless, the findings have some noteworthy limitations. Participants were trained with emphasizing on the amount of LLL during stepping with or without external feedback, without an ordinary stepping training program. Therefore, the current findings cannot clearly confirm the superiority of the training program over the ordinary training. Moreover, the training effects were immediately measured in the participants at a chronic stage of SCI. Thus, the findings might not confirm the motor learning of these individuals. In addition, the findings were analyzed as a whole group of participants, who had different levels of lesion severity and walking ability. Furthermore, there is only little evidence regarding weight-bearing or LLL without clear evidence on a level clinical significance in ambulatory individuals with SCI. Therefore, there is a large room space for further exploration regarding LLL in ambulatory individuals with SCI to strengthen and thoroughly confirm the benefits of the LLL in these individuals.

Conclusion

A single session of repetitive bodyweight shifting and LLL exercises during stepping followed by overground walking training could improve the mobility of ambulatory individuals with chronic SCI (post-injury time >6 years), particularly those who were trained using additional loading feedback. Such feedback may be provided easily—for example, by using a digital bathroom scale—and thus the training programs can be applied for ambulatory individuals with SCI who face with a limit length of rehabilitation in various settings, including hospitals, clinics, communities, and patients' homes.

Data availability

All data generated and analyzed in this study are available from the corresponding author on request.

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Author contributions All authors were responsible for research conception and design, critical revision of the article for important intellectual content, provision of study materials, or patients. TN was additionally involved in the data acquisition, statistical analysis, and drafting a manuscript. PA was responsible on VWTM development and its function, and SA was also responsible for the project management, funding application, and finalizing the manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics This study had been approved by the Local Ethics Committee (HE601099). All participants provided a written informed consent document before participation in the study. We certified that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

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