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Article

The Effect of Virtual Reality Feedback Training Using Smart Insoles on Spasticity, Balance, and Gait in Chronic Stroke Patients

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Abstract: BACKGROUND: This study aimed to investigate the effects of a smart insole-based virtual reality program on balance and gait in patients with chronic stroke. The intention was to provide baseline data for an intervention program designed to improve balance and gait in chronic stroke patients within clinical practice. OBJECTIVE: Thirty-five chronic stroke patients were randomly divided into two groups: the experimental group, which received a smart insole-based virtual reality training program, and the control group, which received general physical therapy. **METHODS:** Prior to the initiation of this study, patients' balance ability was assessed using the Timed Up and Go (TUG) test, and Biorescue (Romberg OE, Romberg CE) was used for further evaluation. Affected step length, stride length, total double support, and cadence were measured to assess gait ability. **RESULT:** After the intervention, the experimental group showed a significant increase in TUG and Romberg test (OE, CE) values compared to the control group. Regarding gait ability, the experimental group showed significant increases in velocity, step length, and cadence post-intervention compared to pre-intervention scores, with differences significantly higher than those of the control group. **CONCULSION:** The conclusion of this study is that a virtual reality training program based on a smart insole is an effective intervention for chronic stroke patients and can serve as foundational data for clinical practice. It is also significant as an intervention method for chronic stroke patients who require long-term treatment.

Keywords: virtual reality; smart insole; balance; gait; chronic stroke

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1. Introduction

Stroke occurs when the blood vessels supplying the brain become blocked or rupture. It leads to extensive neurological deficits and severely affects motor function, impairing the ability to generate the necessary force to start and control movement, causing rapid muscle fatigue, and resulting in significant mobility limitations in the lower limbs [1]. Additionally, stroke is a condition that causes neurological dysfunction due to central nervous system damage, leading to impairments in motor function, body sensation, body perception, and cognitive abilities [2]. Over 60% of stroke patients experience functional impairments in the paralyzed arm, resulting in decreased coordination of the agonist and antagonist muscles around the shoulder and elbow joints due to changes in muscle length [3]. During task performance, the overuse of the non-paralyzed side reduces movement on the paralyzed side [4], causing the body's center of mass to shift towards the non-paralyzed side. This leads to asymmetrical weight-bearing and postural misalignment, thereby decreasing balance ability [5].

Recently, there has been increasing interest in evaluating gait in daily life rather than in laboratory environments, and in technologies that allow for easier real-time monitoring of gait variables. Technologies utilizing wearable devices, such as smartwatches and smart insoles, are representative of this trend. Among them, smart insoles are a type of smart gait equipment that refers to an integrated human gait data analysis system using artificial intelligence (AI) [6]. Smart insoles

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are wearable devices that collect foot pressure measurement data to calculate gait information (such as gait cycle time, swing phase, stance phase, center of pressure, speed, etc.) [7]. Smart insoles provide biomechanical information about the foot [8] and can potentially be used in rehabilitation medicine, sports injury detection, and athlete training through real-time data analysis [9].

Virtual reality training uses specialized equipment to replicate experiences similar to those encountered by the user, providing a simulation technique [10]. It can be broadly divided into non-immersive and fully immersive systems, based on the level of immersion [11]. Non-immersive virtual reality, which is the most commonly encountered in daily life, includes systems that interact with devices like smartphones, computers, and televisions, and typically use controllers such as a mouse or keyboard [12]. In contrast, fully immersive virtual reality uses head-mounted displays to replace real sensory information with computer-generated experiences, creating a more realistic simulation [13].

Virtual reality-based training has been shown to be effective in promoting neuroplasticity and helping individuals relearn motor patterns and skills [14]. Studies have demonstrated improvements in various measures, including the 10-Meter Walk Test, Timed Up and Go Test [15], stride time, and cadence [16]. Moreover, ongoing research has reported results from studies combining different interventions, such as treadmill training [17], robotic devices [18], and EMG [19]. However, there is still a lack of sufficient research on balance and gait training through virtual reality, particularly in terms of motor function, balance, and gait outcomes [20].

Although recent studies have explored the effectiveness of virtual reality intervention programs for stroke patients, there is a lack of research examining the impact of smart insole-based virtual reality programs. Therefore, this study aims to investigate the effects of smart insole-based virtual reality programs on the balance and gait of chronic stroke patients.

2. Materials and Methods

2.1. Participations

This study included 35 stroke patients, regardless of gender, who were hospitalized at B Hospital in Gyeonggi Province. The inclusion criteria for participants were as follows: First, participants must have had a stroke for at least six months and be capable of independent ambulation at a basic level. Second, they must have a Functional Ambulation Classification (FAC) score of 3 or lower. Third, participants should have scored 21 or higher on the Korean Mini-Mental State Examination, indicating sufficient communication skills. Fourth, they must not have had any allergic reactions to functional electrical stimulation. Lastly, participants should not have walking difficulties due to ankle joint contractures. The exclusion criteria were: Individuals with vestibular dysfunction or cerebellar disorders, those with visual or auditory impairments, patients who had undergone orthopedic surgery on their lower extremities, and individuals with cardiovascular or other neurological conditions affecting the lower limbs were excluded from the study.

2.2. Procedure

All participants were evaluated for balance and gait ability both prior to the intervention and after 4 weeks of treatment. Before the study began, the participants were provided with a detailed explanation of the experimental procedures. Participants were then randomly assigned to either the experimental group or the control group using a computer-generated random number table in a 1:1 ratio. Both groups participated in daily 30-minute sessions, five days a week. In addition to the intervention, both groups followed a standard rehabilitation program, which also consisted of 30-minute sessions, once a day, five days a week. This study was conducted after receiving the approval of the Institutional Bioethics Committee of the Gimcheon University. (Approval number GU-202207-HRa-05-02-P).

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2.3. Intervention

2.3.1. Smart Insole-Based Virtual Reality feedback Training(SIVRT) Group

In this study, the experimental group performed treadmill gait training while wearing an Oculus Rift and smart insoles (R-C-SPO-Pedisol250, Pedisol, Korea). The group engaged in real-time feedback virtual reality gait training on the treadmill (QUASAR MED, HP COSMOS, Deutschland) while using the Oculus Rift. During the training, participants received real-time feedback, which was displayed visually, based on data from the smart insoles. The feedback was activated after confirming the proper function of the sensors by pressing the calibration button while standing, before starting the gait training. The smart insole-based virtual reality training consisted of two sessions: a 15-minute walk through a tourist site while wearing the smart insoles and a 15-minute pre-recorded 3D city walk. Prior to the intervention, participants were given time to adjust to the Oculus device to ensure no issues arose during the sessions. The immersive virtual reality system provided an engaging environment through visual and auditory output delivered via the headset worn by the participants. Participants wore the smart insoles while using the virtual reality equipment and performed treadmill walking exercises. During these sessions, a physical therapist stood directly behind the participants to prevent falls and ensure safety.

2.3.2. Conservative Treatment (CON) Group

The control group (CON) engaged in strength training designed to activate and strengthen muscles involved in posture control. This included exercises targeting seven muscle groups in the legs: hip flexors, extensors, abductors, knee flexors, knee abductors, and ankle dorsiflexors [15]. Each exercise was performed in two sets of ten repetitions. The exercise routine consisted of the following: (1) torso lifts to strengthen the trunk and hip joints, (2) prone trunk lifts on a ball, (3) knee bending and straightening while seated on a therapeutic bench, (4) standing up from a kneeling position with support, and (5) standing on one leg while holding onto a wall for support.

2.4. Evaluation

2.4.1. Balance Test

The Timed Up and Go (TUG) test was utilized to assess the balance ability of stroke patients. The test begins with the participant seated in a chair with armrests. Upon command, they are instructed to stand, walk 3 meters to a designated turning point, and return to sit back in the chair. Before the test, participants were instructed to turn toward their unaffected side at the turning point. The test was repeated three times, and the average time was used for analysis. The intra-rater reliability was found to be r = .99, while the inter-rater reliability was r = .98 [21].

Balance was assessed using a balance measurement system (Biorescue, Marseille, France). The Center of Pressure (COP) was evaluated by having participants stand with their feet about 30 degrees apart, facing forward. After the tester demonstrated the procedure, participants were instructed to maintain a standing posture for one minute while the system recorded the COP movement. The Limits of Stability (LOS) were determined using the device's software, which calculated the total area traversed by the COP in the forward-backward, left-right, and diagonal directions. During the test, participants were required to keep their feet on the ground; if they lifted their feet, the measurements were restarted. In this study, the COP was used to measure balance ability while standing. The COP measurement reflects the average force at the pressure points in contact with the floor, indicating changes at the points where ground reaction forces are integrated. Additionally, the study included both the Romberg test with eyes open and the Romberg test with eyes closed [19].

2.4.2. Gait Analysis

Gait assessment was performed to evaluate the spatial-temporal walking characteristics of stroke patients using a gait analyzer (OptoGait, Microgate S.r.l, Italy, 2010). The system consists of two transmitting and receiving bars, each 4 meters long, and a webcam (Logitech Webcam Pro 9000).

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The bars are placed on the ground 1 meter apart, and within each bar, light-emitting diodes (LEDs) are positioned at 1 cm intervals. Communication between the bars occurs through continuous infrared signals sent from the transmitting bar to the receiving bar. Participants were asked to walk 10 meters at a comfortable pace on a flat surface, excluding the first and last 2 meters from the measurement. During the middle 6-meter segment, the gait analyzer detected the participant's footfalls, collecting data on various gait parameters. The spatial-temporal gait characteristics analyzed in this study included weight-bearing on the affected side, single support time on the affected side, double support time, step length, and walking velocity. To minimize inter-rater variability, all measurements were conducted by a single experienced physical therapist. The intra-rater reliability was r = .99, and the test-retest reliability ranged from r = .98 to .99. [22]

2.5. Data Analysis

The statistical analysis for this study was conducted using SPSS 22.0. Normality was tested using the Shapiro-Wilk test. Independent sample t-tests and Chi-square tests were performed to compare the general characteristics and baseline homogeneity between the two groups. Paired sample t-tests were conducted to compare the pre- and post-intervention dependent variables within each group. Independent sample t-tests were also used to compare the changes in dependent variables between the groups based on the intervention methods. All statistical significance levels (α) were set at .05 or below.

3. Results

3.1. General and Clinical Characteristics of the Patients

Both the virtual reality feedback training group using smart insoles and the treadmill walking training group, which served as the control group, were found to be homogeneous in terms of general characteristics (Table 1). Although a total of 45 participants were initially selected, 6 did not meet the selection criteria. During the 4-week period, 2 participants from the SIVRT group (n=17) and 2 participants from the control group (n=18) dropped out due to reasons such as transfer or reassignment. As a result, 35 participants completed the experiment.

Table 1. General Characteristics of Subjects.

	SIVRT group (n=17)	Control group (n=18)	t/x^2 (p)
Age (*year*)	53.35 ± 9.54	54.22 ± 7.61	-0.299(0.767)
Height (*cm*)	166.75 ± 4.09	167.43 ± 5.25	-0.425(0.673)
Weight (*kg*)	69.50 ± 10.23	72.23 ± 9.50	-0.819(0.418)
MMSE-K (*score*)	26.41 ± 0.51	26.72 ± 0.83	-1.330(0.193)
Gender(Male/Female)	10//7	12/6	0.230(0.631)
Stroke type (Hemorrhage / Infarction)	9/8	8/10	0.253(0.615)
Affected side (Right/Left)	6/11	10/8	1.446(0.229)

[*]p<0.05. [a]Mean ± SD, [b]Chi-square test. [c]Independent t-test. MMSE, mini-mental state examination. SIVRT group: smart insole-based virtual reality feedback training group.

3.2. Comparison of Composite Spasticity Score Between the Groups

The Composite Spasticity Score significantly increased in the SIVRT group, from 11.18±0.81 before treatment to 10.06±0.66 after treatment. Similarly, the control group showed a significant increase, from 11.28±0.83 before treatment to 10.67±0.69 after treatment. When comparing the two groups, the SIVRT group (change of -1.12) showed a significantly greater improvement in spasticity than the control group (change of -0.61) (p<.05) (Table 2).

Table 2. Comparison of Composite Spasticity Score between the SIVRT and control group.

Measures	SIVRT group (n=17)	Control group (n=18)	ES	t(p)
		Spasticity (score)		
Pre	11.18 ± 0.81	11.28 ± 0.83	0.1219422	-0.336(0.717)
post	10.06 ± 0.66	10.67 ± 0.69		
change	-1.12 ± 0.70	-0.61 ± 0.61	0.7767949	-2.296(0.028*)
t(p)	6.615(0.000*)	4.267(0.001*)		

*p<0.05. [a]Mean ± SD, [b]Independent t-test. [c]Paired t-test, SIVRT group: smart insole-based virtual reality feedback training group, ES: effect size f.

3.3. Comparison of Timed Up and Go and BioRescue Test Between the Groups

The TUG significantly increased in the SIVRT group, from 17.86±5.69 seconds before treatment to 14.46±3.82 seconds after treatment. Similarly, the control group showed a significant increase, from 18.32±4.63 seconds before treatment to 16.42±4.12 seconds after treatment. When comparing the two groups, the SIVRT group (change of -3.40 seconds) showed a significantly greater improvement in TUG than the control group (change of -1.90 seconds) (p<.05) (Table 3).

Table 3. Comparison of TUG and balance ability between the SIVRT and control group.

Measures	SIVRT group (n=17)	Control group (n=18)	ES	t(p)
		Timed up and go test (sec)		
Pre	17.86 ± 5.69	18.32 ± 4.63	0.08868072	-0.263(0.794)
post	14.46 ± 3.82	16.42 ±4.12		
change	-3.40 ± 2.63	-1.90 ± 0.90	0.7631389	-2.242(0.037*)
t(p)	5.339(0.000*)	8.944(0.000*)		
		Romberg`s eye open surface area (mm^2)		
Pre	130.76±39.81	126.01±31.00	0.1331354	0.396(0.695)
post	119.29±38.49	119.46±28.97		
change	-11.47±5.03	-6.54±5.10	0.9733233	-2.875(0.007*)
t(p)	9.409(0.000*)	5.453(0.000*)		
		Romberg`s eye open average speed (cm/s)		
Pre	1.03±0.27	1.08±0.28	0.1817881	-0.493(0.625)
post	0.81±0.15	0.96±0.21		
change	-0.22±0.14	-0.12±0.11	0.7943015	-2.338(0.026*)
t(p)	6.477(0.000*)	4.526(0.000*)		

*p<0.05. [a]Mean ± SD, [b]Independent t-test. [c]Paired t-test, SIVRT group: smart insole-based virtual reality feedback training group, ES: effect size f.

The REOSA significantly increased in the SIVRT group, from 130.76±39.81 mm^2 before treatment to 119.29±38.49 mm^2 after treatment. The control group also showed a significant increase, from 126.01±31.00 mm^2 before treatment to 119.46±28.97 mm^2 after treatment. When comparing the two groups, the SIVRT group (change of -11.47 mm^2) showed a significantly greater improvement in REOSA than the control group (change of -6.54 mm^2) (p<.05) (Table 3).

The REOAS significantly increased in the SIVRT group, from 1.03±0.27 cm/s before treatment to 0.81±0.15 cm/s after treatment. The control group also showed a significant increase, from 1.08±0.28 cm/s before treatment to 0.96±0.21 cm/s after treatment. When comparing the two groups, the SIVRT group (change of -0.22 cm/s) showed a significantly greater improvement in REOAS than the control group (change of -0.12 cm/s) (p<.05) (Table 3).

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3.4. Comparison of Gait Ability Between the Groups

The ASL significantly increased in the SIVRT group, from 37.01±6.56 cm before treatment to 40.50±5.26 cm after treatment. The control group also showed a significant increase, from 36.68±6.47 cm before treatment to 38.77±6.67 cm after treatment. When comparing the two groups, the SIVRT group (change of 3.48 cm) showed a significantly greater improvement in ASL than the control group (change of 2.09 cm) (p<.05) (Table 4).

Table 4. Comparison of gait ability between the SIVRT and control group.

Measures	SIVRT group (n=17)	Control group (n=18)	ES	t(p)
	Affected step length, (cm)			
Pre	37.01 ± 6.56	36.68 ± 6.47	0.05065113	0.152(0.880)
post	40.50 ± 5.26	38.77 ±6.67		
change	3.48 ± 2.05	2.09 ± 1.00	0.8618343	2.578(0.015*)
t(p)	-6.999(0.000*)	-8.838(0.000*)		
	Stride length (cm)			
Pre	66.60±7.02	64.04±8.08	0.3382405	0.997(0.326)
post	71.16±6.22	66.44±7.63		
change	4.57±2.78	2.40±2.94	0.7584446	2.239(0.032*)
t(p)	-6.766(0.000*)	-3.460(0.003*)		
	Total double support (%)			
Pre	33.61±2.03	33.35±1.57	0.1432795	0.414(0.682)
post	31.03±1.64	31.66±1.44		
change	-2.58±1.05	-1.69±1.01	0.8639148	-2.2543(0.016*)
t(p)	10.149(0.000*)	7.127(0.000*)		
	Cadence(step/sec)			
Pre	0.58±0.07	0.58±0.06	0	0.189(0.851)
post	0.62±0.07	0.60±0.06		
change	0.03±0.02	0.02±0.02	0.5	2.377(0.023*)
t(p)	-8.234(0.000*)	-5.398(0.000*)		

*p<0.05. [a]Mean ± SD, [b]Independent t-test. [c]Paired t-test, SIVRT group: smart insole-based virtual reality feedback training group, ES: effect size f.

The SL significantly increased in the SIVRT group, from 66.60±7.02 cm before treatment to 71.16±6.22 cm after treatment. The control group also showed a significant increase, from 64.04±8.08 cm before treatment to 66.44±7.63 cm after treatment. When comparing the two groups, the SIVRT group (change of 4.57 cm) showed a significantly greater improvement in SL than the control group (change of 2.40 cm) (p<.05) (Table 4).

The TDS significantly increased in the SIVRT group, from 33.61±2.03% before treatment to 31.03±1.64% after treatment. The control group also showed a significant increase, from 33.35±1.57% before treatment to 31.66±1.44% after treatment. When comparing the two groups, the SIVRT group (change of -2.58%) showed a significantly greater improvement in TDS than the control group (change of -1.69%) (p<.05) (Table 4).

Cadence significantly increased in the SIVRT group, from 0.58±0.07 steps/sec before treatment to 0.62±0.07 steps/sec after treatment. The control group also showed a significant increase, from 0.58±0.06 steps/sec before treatment to 0.60±0.06 steps/sec after treatment. When comparing the two groups, the SIVRT group (change of 0.03 steps/sec) showed a significantly greater improvement in cadence than the control group (change of 0.02 steps/sec) (p<.05) (Table 4).

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4. Discussion

Generally, the recovery of walking ability in stroke patients is one of the most important goals in rehabilitation, as impairments in walking ability affect patients' capacity to perform independent daily activities [23,24]. For effective walking training, it is essential to first control spasticity and balance.

In this study, we used a distributed practice training method consisting of 10 minutes of virtual reality application followed by 10 minutes of rest. This approach minimized muscle fatigue, a potential side effect for patients, and was thought to appropriately enhance attention and concentration, thereby improving the function of stroke patients. A randomized controlled trial was conducted to compare virtual reality feedback training using smart insoles with treadmill walking training in stroke patients. The results showed that the virtual reality feedback training group using smart insoles exhibited significant improvements in spasticity, balance, and walking ability compared to the treadmill walking training group.

Spasticity, characterized by an involuntary increase in muscle tone, limits joint range of motion and impairs functional performance, leading to contractures, soft tissue tightness, joint pain, and adverse effects on stroke rehabilitation [25]. The plantar flexor muscles, which are primarily recruited in standing posture, are essential for postural control and rehabilitation training [26,27]

A study by Jha et al. (2021) [28] reported that combining virtual reality gaming with physical therapy was not superior to physical therapy alone in improving gross motor function and daily living activities in children with bilateral spastic cerebral palsy. However, our study found that the virtual reality feedback training group using smart insoles showed a statistically significant improvement in spasticity compared to the treadmill walking training group.

This aligns with the study by Abd El-Kafy et al. (2022) [29], which reported that robot-mediated virtual reality game training effectively controlled upper limb muscle spasticity and improved motor function in chronic stroke patients. Similarly, Oh et al. (2019) [30] reported significant improvements in upper limb flexor spasticity after 4 weeks of joystick-based robot virtual reality intervention in stroke patients.

It is believed that the real-time visual feedback of the center of gravity movement transmitted to the smart insoles increased weight-bearing and movement on the affected side, enhancing ankle joint mobility and reducing spasticity in the ankle by lengthening the calf muscles. Additionally, the immersive virtual reality program induced realistic responses to virtual stimuli similar to actual walking, promoting functional ankle improvement through the influx of various sensory stimuli.

Our study also found that the virtual reality feedback training group using smart insoles showed a statistically significant improvement in balance compared to the treadmill walking training group. This is consistent with a case study by Kim et al. (2023) [31], which found that 8 weeks of real-time feedback virtual reality walking training, applied for 30 minutes, five times a week, improved balance and motor function in patients with traumatic brain injury. Song et al. (2004) [32] reported significant improvements in weight shifting and balance detection using visual feedback virtual reality training in healthy adults. Duque et al. (2013) [33] found significant improvements in balance in the elderly following a virtual reality training program. Anwar et al. (2021) [34] also reported that virtual reality training was more effective than conventional physical therapy in improving balance and lower limb function in stroke patients.

It is believed that the visual and auditory feedback received through the immersive virtual reality program enhanced the sensory aspect of balance, leading to improved balance ability. Additionally, sensory information from the feet via the smart insoles, along with visual and proprioceptive inputs from virtual reality, transmitted signals to the central nervous system and musculoskeletal system, enhancing physical responses and improving balance.

Our study also found that the virtual reality feedback training group using smart insoles showed a statistically significant improvement in balance compared to the treadmill walking training group. Several studies have reported improvements in balance and walking ability following virtual reality programs in brain injury patients [35–37]. Baram and Miller (2006) [38] reported improvements in walking ability in multiple sclerosis patients following virtual reality training utilizing visual

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feedback. Sana et al. (2023) [39] found that an 8-week program, with sessions three times a week for 30 minutes, improved balance and walking in stroke patients.

It is believed that the specific tasks repeated in virtual reality and treadmill training promoted automatic lower limb movements, while virtual reality enhanced attention and motivation towards the tasks, improving adherence to walking therapy [12]. Additionally, real-time feedback from virtual reality increased weight-bearing on the affected side, resulting in improved stride length, step length, walking speed, and cadence, thereby enhancing walking ability.

The limitations of this study include the small sample size, making it difficult to generalize the findings to all stroke patients. Additionally, there was no comparison with the effects of general treadmill training. Future research should recruit more participants to investigate the long-term effects of virtual reality feedback training using smart insoles. Comparative studies evaluating biomechanical factors such as joint angles, ground reaction forces, muscle activity, muscle fatigue, and energy consumption efficiency between virtual reality feedback training and general treadmill training in stroke patients are needed.

5. Conclusions

This study aims to investigate the effects of virtual reality training using a smart insole on the balance and gait abilities of stroke patients. The study involved 35 stroke patients, with 17 patients in the experimental group receiving virtual reality training based on a smart insole for 4 weeks, and 18 patients in the control group receiving traditional physical therapy. The experimental group showed greater improvements in balance and gait abilities compared to the control group. Currently, virtual reality exercise programs based on smart insoles are not widely used in stroke rehabilitation. Future research could significantly contribute to the development of such programs, potentially enhancing rehabilitation outcomes for stroke patients.

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Conflicts of Interest: The author declare no conflicts of interest.

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