Real-Time Tactile Biofeedback Device Use for Improving Balance Control of Pediatric Patients with Cerebral Palsy

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Research Article

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Abstract

Background.

This study aimed to develop a novel tactile biofeedback device, which tracks balance continuously and provides haptic biofeedback to its user through real-time vibration stimulus. The efficacy of the device on gait parameters was investigated in pediatric patients with cerebral palsy. Twelve children diagnosed with cerebral palsy and 12 age-matched healthy control subjects used the device during walking at a self-selected speed. The two group participants' lower extremity joint kinematics and spatial-temporal parameters were recorded with Xsens MVN during “with” and “without” biofeedback conditions.

Results.

The device did not disturb healthy gait. The integration of the real-time balance guidance through the device brought the gait parameters of the cerebral palsy patients closer to the gait parameters of the healthy control group. Pearson Correlation Coefficient and Root Mean Square Error techniques showed that biofeedback altered each gait parameter of the CP group when “with/without biofeedback” conditions were compared. The joints that diverged the most from the healthy control group trends were the ankle and pelvic joints. The extended stance percentage (without BF: 73.91% ± 10.42, with BF: 63.53% ± 2.99), step width (without BF: 0.20m ± 0.05, with BF: 0.18m ± 0.07), and step time (without BF: 1.55s ± 1.07, with BF: 0.73s ± 0.14) parameters decreased; similarly, cadence and walking speed increased when subjects were guided with biofeedback.

Conclusions.

Guidance with tactile biofeedback reduced the sternum sway, additionally, spatial-temporal parameters were regulated. Obtained results indicated that this wearable device can be integrated into the physical therapy and rehabilitation process of patients with balance and postural control impairments. The present findings contribute to a better understanding of the adaptation of innovative engineering applications with rehabilitation processes, which in turn could assist patients with balance impairments and facilitate their integration into society.

Background

The effectiveness of physical therapy and rehabilitation depends on its patient-specific design, the ability to keep the patient's performance at the optimal level during therapy, the patient's adaptation to treatment, the experience of the rehabilitation team, and the team's ability to monitor the physical development of the patient instantly and accurately. During conventional training practices, mental and psychological evaluation tools as well as physical examination findings or individuals’ subjective feedback does not provide quantitative assessment input. For this reason, it is very important to support
conventional physical therapy with innovative engineering applications. Biofeedback is one of these tools that favor motor control during static and dynamic tasks via augmenting motor information for improving patient motivation and adaptation.

Biofeedback is used to increase the motivation and performance of the individual during physical therapy [1]. It is a technique of providing instantaneous physiological data, as stimulated auditory, visual, or tactile feedback to enhance the efficiency of the activity by modifying the participant’s motivation, concentration, attention and to reduce anxiety and disruptive mental problems [2]. Biofeedback integrates information technology into physical therapy and rehabilitation; hence quantifiable information is obtained to design patient-specific physical therapy programs and therefore to acquire the best possible outcome. Additionally, the awareness of the immediate condition increases the learning ability, adaptability, and willingness to continue physical therapy of the patient [3].

Real-time movement, postural control, proprioception, and force produced by the body are typically involved in biomechanical biofeedback applications. Proprioception is the motion, equilibrium, and position sense of the body in space to stabilize the posture via biological information from various visual, vestibular, and proprioceptive inputs [4]. Static proprioceptive information involves the control of postural orientation; on the other hand, dynamic proprioceptive information involves the control of postural stability [5]. Accurate awareness of this information is required for maintaining an upright loading and sustaining normal ambulation. Organs such as the eye, inner ear, and body-position senses trigger impulses, which the brain interprets and coordinates. If one or more of the senses fail to transmit correct signals to the brain, the muscular system is unable to perform the intended movement. Struggling to maintain balance also makes it hard for the person to remain in a stable and upright position during walking, standing, and sitting activities.

Neuromuscular diseases cause physical limitations and mental disorders that the child must struggle with. Cerebral palsy (CP), a neuromuscular disease, is the most common neurological disorder in the world that permanently affects body movements and muscle coordination [6]. Population-based studies around the world report prevalence estimates of more than 4 CP per 1,000 live births or per child of a given age range [7–10]. CP is a major cause of motor deficits in children. Dynamic ankle equinus affects the position of the ankle during gait and causes pathological gait patterns in ambulatory children with CP that lead to plantar flexion contracture and shortening of the posterior muscle group. Statistics show how large a population is affected by neuromuscular diseases and how high the number of patients whose life standards can be improved with effective rehabilitation methods. Increasing efforts in the treatment of these diseases, which cause medical, physical, cognitive, social, and economic problems not only for the patient but also for the family and all caregivers, are promising. Neuromuscular training is aimed at developing the potential of the nervous system to produce rapid and optimal muscle contraction, improve coordination/balance, and relearn movement patterns and skills. Therefore, maximum efficiency is achieved with rehabilitation programs that are highly reproducible and designed for the needs and limitations of the person. Considering that the aim of treatment is to restructure the brain to compensate for the deficiencies of the body.
Tactile biofeedback has been integrated into physical therapy and rehabilitation programs of children and adult patients previously, hence its effect on balance control [11] and minimizing sway [12] has been reported. This manuscript proposed an innovative device, which serves both aims: it promotes physical activity adaptation of the patient and regulates gait through continuous and real-time balance control. Additionally, thanks to its compact and easy-to-wear design, patients who have balance and postural control impairments can practically use the device by themselves during the activities of daily living and outside of the physical therapy centers.

The aforementioned innovative wearable tactile biofeedback device provides haptic real-time balance control information to the patient with the intention of improving balance and facilitating postural control through achieving close-to-normal walking patterns. The efficacy of the device was validated through the biomechanical data collected from pediatric CP patients and healthy control participants during 10-meter walking tests with and without the device.

**Results**

Twelve CP patients and 12 healthy control subjects completed the data collection without any complications. Age, weight, and height were not significantly different among CP patients and healthy control participants. Spatial temporal parameters and lower extremity kinematic data were collected and compared for “without” and “with” biofeedback conditions for both groups (Table 2). The CP group was characterized by a longer stance percentage, lower cadence, shorter step length, and longer stride time when compared to the control group. Spatial-temporal parameters of control group participants were not significantly different for “with” and “without” biofeedback conditions (Raw data, which have been submitted as a supplementary file, can be reviewed).

**Table 2:** Mean (standard deviation) values of spatiotemporal parameters for CP and Control Groups

<table>
<thead>
<tr>
<th>Age (year)</th>
<th>CP GROUP</th>
<th>CONTROL GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>11.4 ± 3.6 years</td>
<td>14.9 ± 5.5</td>
</tr>
<tr>
<td>3 female, 9 male</td>
<td>7 male, 5 female</td>
<td></td>
</tr>
<tr>
<td>Height (cm)</td>
<td>138.9 ± 20.6</td>
<td>146.0 ± 21.2</td>
</tr>
<tr>
<td>24.6 ± 20.2</td>
<td>33.2 ± 20.6</td>
<td></td>
</tr>
</tbody>
</table>

**Table 1:** Participant physical and demographic information
Pearson Correlation Coefficient (PCC) and Root Mean Square Error (RMSE) techniques were used to evaluate the trajectory similarity of lower extremity joint trajectories of “with” and “without” biofeedback conditions. Larger differences in RMSE indicated a poor regression fit and a larger gap between the movement trajectories of conditions. Contrarily, smaller differences in RMSE indicated strong regression fit and similar movement trajectories.

The CP group participants had higher pelvic tilt and abnormal range of motion on pelvis rotation (with biofeedback CP- Control Group RMSE:14.25 and without biofeedback CP- Control Group RMSE: 17.44) in the sagittal plane during with and without biofeedback conditions. Balance control through tactile biofeedback guidance improved pelvic biomechanics and relatively higher symmetry was obtained with the control group. The pelvic obliquity of CP participants was significantly higher compared to the control group during both with and without biofeedback conditions. In the absence of biofeedback CP group participants presented a middle peak during late stance. Pelvic tilt and pelvis rotation revealed similar outcomes in CP group participants during “with” and “without” biofeedback conditions (Fig. 3). Hip flexion and extension angle revealed similar trajectories for CP patients for “with” and “without” biofeedback conditions and characterized with lower swing phase extension and longer stance phase, therefore increased double support percentage. CP patients reached lower knee flexion during “with” and “without” biofeedback conditions (Table 3).

Table 3: Gait Parameters: Trajectory Correlations

<table>
<thead>
<tr>
<th>Spatial-Temporal Parameters</th>
<th>CP Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Without biofeedback</td>
<td>With biofeedback</td>
</tr>
<tr>
<td>Stance (%)</td>
<td>73.91 ± 10.42</td>
<td>63.53 ± 2.99</td>
</tr>
<tr>
<td>Cadence (steps/min)</td>
<td>59.25 ± 40.91</td>
<td>65.63 ± 18.78</td>
</tr>
<tr>
<td>Walking Speed (m/s)</td>
<td>0.52 ± 0.37</td>
<td>0.61 ± 0.19</td>
</tr>
<tr>
<td>Step Length (m)</td>
<td>0.41 ± 0.11</td>
<td>0.49 ± 0.07</td>
</tr>
<tr>
<td>Step Width (m)</td>
<td>0.20 ± 0.05</td>
<td>0.18 ± 0.07</td>
</tr>
<tr>
<td>Step time (s)</td>
<td>1.55 ± 1.07</td>
<td>0.73 ± 0.14</td>
</tr>
</tbody>
</table>

Table 3: Gait Parameters: Trajectory Correlations

<table>
<thead>
<tr>
<th>Walking at Self-Selected Speed</th>
<th>Without biofeedback CP group</th>
<th>With biofeedback CP group with biofeedback</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle Angle (Dorsiflexion-Plantarflexion)</td>
<td>R² = 0.3948, RMSE: 16.99</td>
<td>R² = 0.519, RMSE: 15.24</td>
<td></td>
</tr>
<tr>
<td>Knee Angle (Flexion- extension)</td>
<td>R² = 0.5631, RMSE: 18.41</td>
<td>R² = 0.5025, RMSE: 12.70</td>
<td></td>
</tr>
<tr>
<td>Hip Angle (Flexion- extension)</td>
<td>R² = 0.7065, RMSE: 36.01</td>
<td>R² = 0.7082, RMSE: 26.68</td>
<td></td>
</tr>
<tr>
<td>Pelvis Angle (Pelvic tilt)</td>
<td>R² = 0.533, RMSE: 17.44</td>
<td>R² = 0.4964, RMSE: 14.25</td>
<td></td>
</tr>
</tbody>
</table>
Analysis of ankle kinematics of CP participants showed that biofeedback reduced the excessive plantarflexion at initial contact observed during “without” biofeedback condition when participants were guided with tactile biofeedback. Similarly, tactile biofeedback helped CP group participants to improve their dorsiflexion during the stance and swing phases (Fig. 4).

**Discussion**

Biofeedback is a method of providing real-time biological information to the patient by using auditory, visual, and tactile stimuli. Additionally, physicians and physiotherapists can utilize biofeedback mechanisms to regulate the gait pattern, correct balance/posture, and thus create personalized physical therapy and rehabilitation programs for the patients while regulating the physiological, kinetic, and kinematic variables. The primary aim of this study was to develop a novel tactile biofeedback device, which tracks balance continuously and provides haptic biofeedback to its user through real-time vibration stimulus. The efficacy of this device was investigated on the balance and postural control of CP patients during ambulation.

The goal of physical treatment and rehabilitation procedures is to strengthen the patient's cognitive awareness while also enhancing their mobility. The physical therapy and rehabilitation process as well as the accomplishments that can be made in the pediatric population as opposed to adults are distinct due to the benefit of neuroplasticity, which is high in the period of life from 2 to 20 years. This distinction, which makes it possible for children's physical and neurological processes to happen more quickly than those of adults, is extremely beneficial. Innovative engineering applications should be incorporated into physical therapy and rehabilitation processes to evaluate this process as effectively as possible. Only in this way can therapy programs with high repetition, personalized, and quantitative data-based evaluations of physical and neurological development be made.

The findings of this study coincide with the literature [11] that physical activity adaptation can be supported continuously with biofeedback for maintaining postural control/balance and regulating gait. Recent studies converge that biofeedback is a useful tool for maintaining participation, motivation, and global motor function domains of the participant [17, 18]. For this purpose, tactile biofeedback has been integrated into physical therapy and rehabilitation programs of children and adult patients previously, hence its effects on balance control [18] and minimizing sway [19] have been reported. The proposed innovative device, which serves both aims, promoted physical activity adaptation of the patient and regulated gait through continuous and real-time balance control and reduced the region where the body swayed. Contrarily, tactile biofeedback did not change or disturb the balance control of the healthy control group subjects.

The ability to maintain stability and balance is critical for neurological and orthopedic rehabilitation, as the goal is to achieve functional independence during ambulation. CP patients experience psychomotor problems and altered motor functions. The absence of gait symmetry, which is the ratio of kinetic and kinematic parameters between the right and left extremities, results in differences in muscle contraction,
balance, and biomechanical parameters during mobilization. Accurate awareness of static and dynamic proprioception is essential to maintain balance and sustain safe ambulation. Postural control and balance, which require complex synchronization of muscles and ligaments, are essential for optimal mobilization. Balance disorders cause irregular heart rate and center of mass pattern therefore, together with fatigue, are one of the main factors in the early termination of the performed activity. In this study, it has been shown that haptic biofeedback could be used as a tool to continuously guide the patient to facilitate balance and postural control during ambulation and the proposed wearable device could be integrated into the physical therapy and rehabilitation process of patients, who have balance and postural control impairments.

The main limitation of this study is the short adaptation period of the participants to the device and real-time tactile biofeedback guidance. Each participant was given the needed time to use the device and get familiar with the balance control mechanism through real-time tactile biofeedback. However, this procedure was not integrated into their conventional physical therapy routines for a certain amount of time to test the motor learning capabilities of the patients. Therefore, the effects of the device on long-term motor learning and motor adaptation perspectives were not investigated. Further aims are (1) to investigate the long-term efficacy of the device on motor learning and motor adaptation of the patients and (2) to develop a wireless and compact version of the device, which provides more comfortable and practical balance control and biofeedback guidance.

**Conclusions**

This study hypothesized that real-time balance biofeedback would improve postural control and gait parameters of patients with neuromuscular diseases. The novel balance control device did not disturb healthy gait but helped CP patients to regulate their lower extremity joints’ ROM and spatial-temporal parameters during walking at a self-selected speed. Physical activity adaptation, which is the optimal motor control response of the body to deliver performance, is a complicated process that involves various physiological systems, thus tactile biofeedback can optimize gait parameters during ambulation through sensory and proprioceptive guidance. The findings of this study indicated that physical activity adaptation can be supported continuously for maintaining postural control and balance to sustain optimal energy consumption and kinematic parameters.

**Materials And Methods**

**Participants**

Twelve patients (3 female, 9 male) between the ages of 9 and 16 (mean = 11.4 ± 3.6 years) diagnosed with CP participated in this cross-sectional study. Participants had a Gross Motor Functional Classification System (GMFCS) level of I-III and a Modified Ashworth Scale (MAS) score of 3 or below. Determination of the sample size was done with G-Power (GPower - Universität Düsseldorf) version 3.2.1 and 12 patients satisfied 0.80 power ratio and 0.8 effect size (10% standard deviation, 95% accuracy rate
(z = 1.96)). Included participants had no previous history of surgical intervention for spasticity. Participants were ambulatory with or without assistive devices, such as loft strand crutches or walkers, and had the ability to follow simple instructions, non-ambulatory children were excluded from the study.

Twelve (5 female, 7 male) age-matched control group participants (mean = 14.9 ± 5.5 years) were involved in the study. Selection criteria for the control group included no prior history of cardiovascular, neurological, or musculoskeletal disorders. They had normal body mass index, ROM, muscle strength and had no postural and motor deficits (Table 1). Ethics committee approval was obtained from the Institutional Review Board of Acibadem University (2017-19/24). Consent was obtained from the patients and their parent(s) prior to the investigation.

**Materials**

A novel real-time tactile biofeedback device was composed of a motion processor unit (MPU- 9-axis IMU with 3-axis accelerometer, 3-axis gyroscope, and 3-axis magnetometer), microprocessor and 4 vibration units, which were shielded in stereolithographic 3D printed cases (Autodesk Fusion 360 TM CAD, Formlabs Form 2®) (Fig. 1(a)). The vibration units were positioned between the user’s under-bust and natural waistline with an adjustable strap designed with the loop side of the Velcro material (Fig. 1(b)). Vibration units -for front-back- left-right directions, were located on the adjustable strap. The device is designed to be wearable, and the non-invasive belt is placed on the belly and the MPU is placed on the sternum (T8 level posteriorly) of the user. The vibration units and the MPU were controlled by Raspberry Pi (Raspberry Pi Foundation, https:www.raspberrypi.org).

The calibration of the device was performed while the participant was standing still in an anatomical position for 3 seconds at the beginning of data collection. Measured Euler angles were set as the initial orientation of the body and called the origin coordinates. The tactile biofeedback device assumed the axial body as a simple pendulum, the sternum being the bob, the amount that the pendulum bob swayed outside the pre-determined circular region, which is determined by the threshold value(s) in cardinal and/or quadrantal directions, the corresponding vibration unit(s) (one of the vibration units in the frontal plane (medial-lateral directions) and/or the combination of one of the vibration units in the sagittal plane) were activated and the number of balance loss is counted simultaneously. The threshold value, which can be assigned individually for each vibration unit, indicates the allowed sway area of the axial body. As the sway exceeds the specified threshold value(s), then the corresponding vibration unit(s) provides tactile biofeedback to the user until the balance is regained (Fig. 2).

The tactile biofeedback device was validated with Xsens MVN. The center of mass data was collected with Xsens MVN and tactile biofeedback device simultaneously. The accuracy rate of the tactile biofeedback device was compared with data collected with Xsens MVN. A high correlation was found between the results obtained from the tactile biofeedback device and the Xsens MVN (R = .9994, R² = .987, p < .05). The data were analyzed using the independent sample t-test. The results showed that there was no statistically significant difference between the sternum orientation data collected with Xsens MVN and the tactile biofeedback device (t = 1.91 < t 0.025,28 = 1.724; p > 0.05).
Xsens MVN is a commercial, inertial sensor-based, and portable motion capture system for full body motion capture. Seventeen wireless sensors, (MTw2, range of measurement of angular velocity: ±1200 °/s, sampling rate: 100 Hz) which comprise an accelerometer, gyroscope, and magnetometer, are attached to the key areas of the axial and appendicular body. The system allows spontaneous gait analysis and has been validated against optical motion capture systems [13–15]. The system was used to collect lower extremity joints’ kinematic data and spatial-temporal parameters.

**Experimental Design and Procedure**

A real-time tactile biofeedback device was developed by the authors [16] and used for two purposes in this study: (1) to track real-time balance during ambulation (2) to give haptic biofeedback to the user when the balance is lost to facilitate balance control. A standard testing protocol was developed, and the same methodology was followed for each participant. Before the experiment, CP patients and healthy control subjects were introduced to the tactile biofeedback device, informed about the purpose of the study, trained about the safety features of the device, and asked to stop the procedure anytime whenever they felt uncomfortable. Enough time was given to each participant to get familiar with the device and the balance control mechanism through real-time tactile biofeedback.

Data reduction was done with Xsens MVN Studio v.4.2.4. Continuous balance monitoring and haptic biofeedback guidance were done by the tactile biofeedback device. The threshold value for postural control was set to 10 degrees in four cardinal and four quadrantal directions. This threshold value was determined by the physical therapist and encircled the acceptable circular path that the sternum could sway during ambulation. As the sway region exceeded 10 degrees in any cardinal and/or quadrantal direction, then the corresponding vibration unit(s) was activated, and tactile biofeedback was provided to the participant. The aim was to facilitate balance and postural control through continuous and real-time guidance.

Lower extremity kinematic data were collected during a 10-meter walk test at a self-selected walking speed for 2 minutes while the participants were (with biofeedback condition) and were not (without biofeedback condition) guided with real-time biofeedback. Kinematic data were recorded for 2 minutes, and 5 consecutive strides were analyzed for each participant during “with” biofeedback and “without” biofeedback conditions. Data collection was done in a fully equipped gait analysis laboratory under doctor and physical therapist supervision. Data for “with” and “without” biofeedback conditions were collected consecutively and on the same day for each participant.

**Data processing and outcome measures**

Kinematic data were collected at 60 Hz by Xsens MVN and dominant side data have been analyzed. Lengths of lower limb segments were manually measured using the landmark locations as references, along with subject height, weight, and foot length. MATLAB (The MathWorks, Inc. USA) was used for data analysis. Pearson Correlation Coefficient (PCC) and Root Mean Square Error (RMSE) techniques were used to evaluate the difference between lower extremity joints’ angle trajectories in the sagittal plane.
Declarations

Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Acibadem University (protocol code: 10/05/2019-8251, 54022451-050.05.04; 30.04.2019).

Consent to participate: Informed consent was obtained from all individual participants and from their parents included in the study.

Availability of data and materials: The dataset, which contains raw data of healthy control participants and CP patients collected during “with” and “without” biofeedback conditions, is submitted as a supplementary file.

Competing Interests: The authors have no relevant financial or non-financial interests to disclose.

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Author's Contributions: Both authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Hande Argunsah and Begum Yalcin. The first draft of the manuscript was written by Begum Yalcin and Hande Argunsah approved the final version of the manuscript. Both authors read and approved the final manuscript.

References


Figures
Figure 1

(a) 3D printed cases (using stereolithography) of the vibration units (Autodesk Fusion 360 TM CAD (https://www.autodesk.com) Formlabs Form 2® (https://formlabs.com)), (b) Components of the wearable real-time tactile biofeedback device (MPU unit and 4 vibration units for front-back-left-right directions)
Figure 2

Tactile biofeedback device Logic Chart and Control Algorithm
Figure 3

Pelvis Kinematics
Figure 4

Kinematic Parameters: Ankle- Knee- Hip Joint Angles

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.
• CODESENSOR.txt
• FinalDataComprehensive.xlsx
• supplementaryfiles.pdf