Salient and placebo vibrotactile feedback are equally effective in reducing sway in bilateral vestibular loss patients

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1. Introduction

The vestibular labyrinths play a key role in posture and balance, retinal image stabilization and spatial orientation that all are affected in case of substantial vestibular deficits, and lead to a major handicap (oscillopsia, postural imbalance) in patients with a bilateral vestibular areflexia. Central compensation in combination with sensory substitution might reduce impairment, but is unlikely to restore full functionality. A potent aid for these patients might be an artificial labyrinth to restore the feedback of linear and angular accelerations of the head or body to the brain. Several researchers are currently engaged with the development of such a device. Some of them try to improve performance in posture and balance in humans using (non-implantable) sensory substitution—galvanic vestibular stimulation [1,2], auditory feedback [3], visual feedback [4], electrotactile stimulation of the tongue [5] or vibrotactile feedback to the trunk [6], while others try to restore image stabilization by implanting electrodes to restore the input to the brain in animals [6,7] or in humans [8].

Implantation of electrodes may be not the first option for patients as not everyone may want or need an implantable prosthesis [9], but even more because of the invasive aspect and the possible severe vegetative symptoms [10]. Sensory substitution prostheses for vestibular biofeedback can be developed in a fairly short time and reduction of sway (in both anteroposterior and mediolateral direction) is possible using biofeedback based on information about an individual’s posture. Several options for sensory substitution are available.

Galvanic vestibular stimulation (GVS) has been suggested to improve balance control [1,2] in case of labyrinthine deficits. However, habituation to galvanic stimuli is a major issue that reduces and changes the impact of GVS relatively fast [11]. Also,
many patients investigated in our clinic with GVS, report substantial nausea and pain in the skin under the electrodes in case of prolonged galvanic stimulation.

Auditory feedback [3,12–16] and visual feedback [4] could be used as well, although (1) visual and auditory inputs are already extensively used by patients with vestibular deficits, (2) these patients tend to rely even more on the primary function of the visual and auditory systems in challenging situations and (3) communication might be hindered.

Electrotactile [5,17–19] and vibrotactile [20–24] feedback systems also seem to be suitable for vestibular substitution. Electrotactile feedback through the tongue is an elegant method to improve posture and balance, as it is a fully head-based system and because a learning-effect of several hours after removal of the prosthesis has been shown [17]. Although, it has disadvantages in daily life, both esthetic and practical (talking and eating).

Vibrotactile feedback through the trunk, stimulating various cutaneous receptors [25,26], is a very intuitive approach and has been used in military applications for navigation in combat and as support orientation for blind people [27]. Therefore an ambulatory vibrotactile biofeedback (AVBF) system to reduce body sway and increase postural stability for patients with vestibular dysfunction was developed.

In this study we focus on the use of the AVBF system to increase postural stability in patients with severe bilateral vestibular losses. A description of the AVBF system will be given in this paper, along with a placebo-controlled evaluation of the effect of the AVBF system on static body sway and the optimal location of the sensor (trunk or head). To our knowledge, no studies on the placebo effects of biofeedback have been published.

2. Materials and methods
2.1. Ambulatory vibrotactile biofeedback (AVBF) system

The AVBF system, schematically shown in Fig. 1, consists of four major components:

1. A DynaPort MiniMod (McRoberts, 5.5 mg (1 mg = 1 cm2)) or a 0.30 resolution at a sample frequency of 50 Hz) virtual zero drift sensor, small and light weight (64 mm × 62 mm × 13 mm, 55 g), containing three orthogonal linear (piezo-) capacitive accelerometers, which can be mounted on the patients head or high on the trunk.

2. An elastic belt with 12 equally distributed actuators (ZURKNO32.V8, eccentric vibra-motors like applied in Nokia 3210 at 300 Hz and an amplitude of 0.5 mm [26]) around the waist mounted with a Velcro fastener.

3. An ATMEGA128 (Atmel) processor to translate sensor output into activation of correct actuators with a delay of <1 ms.

4. A LiPo battery pack (11.1 V, 3270 mAh) to supply power to all components, thus making the AVBF system an ambulatory, comfortable and simple system.

The battery pack and processor unit dimensions are 12 cm × 7 cm × 3 cm, weighing 330 and 240 g, respectively. The battery can power the processor, actuators and sensor for 72 h, and can be recharged within 8 h, making sure that patients can use the AVBF system for several days and recharge it overnight even without the explicit need of a spare battery.

A patient wearing the AVBF system can set a reference vector at any desired moment, simply by pressing a button on the processor unit. Setting this reference vector is necessary for the AVBF system to know its sensor orientation. Subsequently the processor calculates the vector difference between the reference vector and the current sensor orientation. This difference is the patient's tilt angle (size/angle and direction) and is translated into the activation of specific actuators. In normal mode, the patient's tilt magnitude and tilt direction are translated into the activation of a specific actuator. One actuator is activated in the direction of the patient's body tilt if it exceeds a tilt magnitude of 2°. In this way the AVBF system can code body tilt in any direction and the actuator which is activated above 2° of tilt indicates the tilt direction. When the patient correctly responds to the actuator, it will be deactivated when the tilt magnitude drops below 1.5°. The range between 1.5° and 2° was chosen to avoid abrupt changes in on and off switching of a specific actuator (in other words, hysteresis is induced). Thus, the dead zone has a size of 2°.

Two extra activation modes were implemented in the AVBF system as well to assess the placebo effect, which could be selected using a dedicated switch on the processor without having to set the reference vector. In full mode, if a patient's body tilt exceeds a tilt angle of 2° in any direction, all actuators are activated, thus only the patient's tilt magnitude, and not tilt direction, is translated into the activation of all 12 actuators. In this way, a patient knows his body tilt exceeds a certain limit, but he does not know in which direction. When the patient correctly corrects his body tilt back below 1.5°, all 12 actuators are deactivated. In random mode, the AVBF processor decides pseudo-randomly five times per second if an actuator will be switched on and if so, which one of the 12 actuators, thus neither the patient's tilt magnitude nor tilt direction are translated into the activation of a specific actuator. Even within the dead zone, an actuator is randomly switched on. Our patient's tended to test the AVBF system before every measurement and for that reason, in random mode the AVBF system functioned for the first 20 s as in normal mode.

2.2. Patients

10 patients (7 males, 3 females, age 45–76 years) participated in this placebo-controlled study to assess the effect of the AVBF system on postural stability (AVBF group). 10 additional patients (5 males, 5 females, age 40–65 years) participated to assess inter-individual and test–retest variability (reference group). All patients had severe balance problems with frequent falls (>5 times per year) and showed no responses to caloric stimulation (30 and 40 °C) of their lateral semicircular canals and reduced or zero gains (<0.2) at sinusoidal stimulation of the horizontal and vertical canals on rotary chair testing (0.1 Hz, Vmax = 60 °/s), pointing to a bilateral vestibular areflexia or severe bilateral vestibular hyporeflexia.

2.3. Procedure

The procedure for the AVBF group is schematically shown in Table 1. Each patient had 5 min to familiarize with the AVBF system. Thereafter each patient practiced with the AVBF system for 15 min to learn how to use the system and to experience the relation between trunk or head movement and actuators in both the normal mode and full mode. They were instructed to improve their balance using the vibrotactile feedback information, both on a firm surface as well as on a foam pad. Patients were informed about the application and evaluation of three activation modes. The feedback mechanism of the normal and full mode was explained in detail, whereas the patients were told that the third (random) mode was only slightly different from the normal mode and we tried to find the best out of the three modes to improve balance.

After practicing, body sway was assessed in all patients and performance was scored in seven different conditions:

- without biofeedback (1);
- with biofeedback on the waist and sensor on the trunk in normal (2), full (3) and random (4) mode;
- with biofeedback on the waist and sensor on the head in normal (5), full (6) and random (7) mode.

Body sway was assessed using a force platform. Patients were instructed to stand bare feet on a 6 cm thick foam pad (Airex balance-pad) as still as possible for 45 s with the feet at hip width and the arms hanging by the sides. The first 5 s were performed with eyes open, to identify the patient’s initial COP, followed by 40 s with eyes closed. Each condition was measured in two trials, resulting in 14 measurements per patient. Each measurement started 15 s after the AVBF system was correctly activated (which includes setting the reference vector) and the activation mode was selected. This way, the biofeedback during the measurement when the eyes were closed was truly random in random mode.

Patients in the reference group were instructed to stand bare feet on a 6 cm thick foam pad (Airex balance-pad) as still as possible for 45 s with the feet at hip width and the arms hanging by the sides. The first 5 s were performed with eyes open, to
identify the patient’s initial COP, followed by 40 s with eyes closed. All patients performed four trials.

2.4. Data and statistical analysis

The centre of pressure (COP) was sampled at 50 Hz, 16 bits, and related to the patient’s body length to calculate the body sway angle (bs = arctan[COP/(0.56 × body length)]). From bs swaypath, swayarea and mean sway (in both anteroposterior (AP) and mediolateral (ML) direction) were calculated per condition and averaged over the trials. In the reference group inter-individual variability and the test–retest variability (the latter defined as standard deviation relative to the average), also often referred to as intra-individual variation, were calculated. In the AVBF group Wilcoxon’s signed ranked test was used to determine the group effect of the AVBF system activated versus the condition with AVBF system deactivated. The changes in individual parameters were also determined per patient, relative to the condition without biofeedback (AVBF system deactivated). The level of significance in all tests applied was \( p < 0.05 \).

After having tested a patient, the patient was asked to rate the functionality of the AVBF system and its effect on balance on a scale from 0 to 10.

3. Results

In the reference group, the test–retest variability was on average 9% for swaypath (95% confidence interval (CI): 1–17%), 22% for swayarea (95% CI: 8–60%), 18% for mean AP sway (95% CI: 6–51%) and 21% for mean ML sway (95% CI: 6–67%). The inter-individual variability was 25% in swaypath, 45% in swayarea, 31% in mean AP sway and 35% in mean ML sway.

Because swaypath showed the smallest intra- and inter-individual variability in the reference group of the four measures used in this study for body sway assessment, swaypath was the only measure used for analysis in the AVBF group. A significant change in swaypath was identified when it exceeded 17%. The relative decreases in swaypath comparing the AVBF system activated with the AVBF system deactivated are shown in Fig. 2 and Table 2 also shows the significant swaypath changes.

With biofeedback on the waist and sensor on the trunk, a decrease in swaypath up to 39% was shown. A decrease in swaypath was shown in six patients in normal mode (7% on average), in eight patients in full mode (7% on average) and in nine patients in random mode (17% on average, significant). In one patient (no. 6) a significant decrease in swaypath (26%) was shown in normal mode. A significant decrease in body sway in full and random mode (24% and 31%, respectively) was also shown in this patient. In one patient (no. 10) a significant decrease in swaypath was shown in full and random mode (23% and 39%, respectively), not in normal mode (16%, just within the confidence interval). In both these patients (no. 10 and 6) the decrease in swaypath in random mode was larger, but not significant, than in full and normal mode.

Table 2

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Table 1

Schematic representation of the procedure followed.

| Surface Sensor location AVBF mode Condition |
|--------------------------------------------|------------------------------------------|
| Familiarization Practice                   |                                          |
| Body sway assessment                       |                                          |
| Firm                                       | Firm and foam                            |
| Trunk                                      | Trunk and head                           |
| Normal                                     | Normal and full                          |
| 1                                          | 2                                         |
| 2                                          | 3                                         |
| 3                                          | 4                                         |
| 4                                          | 5                                         |
| 5                                          | 6                                         |
| 6                                          | 7                                         |

Fig. 2. Relative decreases in swaypath using the AVBF system (on foam, eyes closed, feet at hip width and without footwear) in two (sensor location) conditions and in
With biofeedback on the waist and sensor on the head, a decrease in swaypath up to 51% was shown. A decrease in swaypath was shown in all 10 patients in normal mode (22% on average, significant), in eight patients in full mode (15% on average, significant) and in 10 patients in random mode (23% on average, significant). In four patients (no. 10, 6, 1 and 8) a significant decrease in swaypath was shown in normal mode. A significant decrease in swaypath in full and random mode was also shown in these patients. The decrease in swaypath in random mode was larger, but not significant, than in full mode.

Patient rated the functionality of the AVBF system and its effect on balance on average 6.5 (range 4–9).

4. Discussion

4.1. Vibrotactile biofeedback system outcome

We used swaypath as outcome parameter, because it showed the smallest intra- and inter-individual variability in our study and it was previously shown to be particularly valuable in clinical practice [28,29]. A significant decrease in swaypath was present in four of our patients with bilateral vestibular areflexia using vibrotactile biofeedback, in line with other studies showing that vestibular impaired patients are more stable using biofeedback in stance [3,5,12,13,16–20,22]. Moreover, using a reference group to quantify test–retest variability we were able to identify individual stance improvements.

4.2. Impact of feedback versus alerting

The comparison of the vibrotactile biofeedback system activated versus deactivated was performed in three activation modes (normal, full and random). Because balance improvements in normal mode were only observed when balance had also improved in full and random mode, the improvements were, at least partially, caused by other effects than biofeedback. These effects could be (1) training because it stimulates brain plasticity and improves motor performance [13,21], (2) the patient’s belief [30] or (3) increased alertness [3,12,21], as it continuously gives specific cues to reduce postural sway [24].

4.3. Sensor location

With biofeedback on the waist and sensor on the head four patients showed a significant improvement in swaypath (in all three activation modes), whereas with sensor on the trunk only one patient showed a significant improvement in swaypath in all three activation modes and another patient only in two activation modes. Thus the head seems to be the optimal location of the sensor. To our knowledge no studies on the optimal sensor location in biofeedback have been published [9], but improvements have been shown using a sensor on the trunk [3,12–16,20,21] as well as on the head [1,5,17–19,22,23]. Future studies are needed to examine the individual optimal sensor location.

4.4. Conclusions

Vibrotactile biofeedback reduces body sway in some patients with severe balance problems with frequent falls, indicating that the brain is able to include vibrotactile biofeedback in its predictive behaviour to avoid falls. But the major question is why? And is there any true effect of biofeedback beyond a placebo effect? Several work suggest that there is a fundamental effect, because biofeedback consistently increased postural stability, beyond the effects of practice alone [13,19,21]. Some critical remarks after evaluating our results obtained and exploring the literature can be made:

1. improvement of balance by biofeedback is shown in the minority of patients with balance problems–this study and [13]. The impact of biofeedback might vary among patients, because of differences in (1) the severity of the vestibular deficit and its effect on postural control, (2) the dependence on vestibular input for postural control compared to the other senses, (3) patient motivation and (4) the ability to learn how to switch to vibrotactile feedback of body sway and to interpret all sensory information to keep body sway within stability limits [24];
2. training to optimise use of biofeedback seems to be essential [12,13,18,19,21];
3. adaptation effects do occur and reduce the impact of feedback in time during use [13] but also prolong the impact after use [17]. This would suggest that repetitive applications of relatively short duration of vibrotactile biofeedback might improve balance and orientation and that continuous use of such a device might not be necessary;
4. the placebo effect might be substantial–this study and [21].

The even more important question is, if patient performance in daily life or quality of life will indeed increase by biofeedback. It will at least have a benefit in patient motivation to be more active, to train in challenging tasks and to learn more about postural sway and its dependence on daily life activities. Moreover, because there is a need for training and rehabilitation, biofeedback is a rewarding approach as it gives a positive feeling if no feedback has been given during a task. Therefore we continue the development and evaluation of a vibrotactile biofeedback system for a broad clinical application, but we are aware of the fact that our study suggests that the major AVBF application is related to support training and sensory substitution.

Conflict of interest

None.

References


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