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

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ABSTRACT

This study explores the effect of vibrotactile biofeedback on body sway in stance in patients with severe bilateral vestibular losses in a placebo-controlled study. A tilt sensor mounted on the head or trunk is used to detect head or body tilt and activates via a microprocessor 12 small vibrators that are placed around the waist with a mutual distance of 30°. Two positions of the tilt sensor (head and trunk) and three types of biofeedback (normal, full and random) were evaluated, besides no biofeedback. Body sway during stance was assessed in 10 patients with bilateral vestibular areflexia and performance was scored in the seven different conditions. Inter-individual and test–retest variability without biofeedback was assessed in 10 additional patients with bilateral vestibular areflexia. In six patients no significant change in body swaypath was observed using biofeedback. In four patients body swaypath decreased significantly using biofeedback and sensor on the head 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. The patients rated the functionality of the AVBF system and its effect on balance on average 6.5 on a scale from 0 to 10. Thus, body sway improved in 4 out of 10 patients using biofeedback, but the improvement with true biofeedback was only observed in those subjects where an improvement was present in placebo mode as well. The improvement was, at least partially, caused by other effects than biofeedback, like training, increased self-confidence or alertness.

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,

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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 prothesis 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 stance 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 cm/s^2) or 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* (ZUB.NO32.VIB, 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.

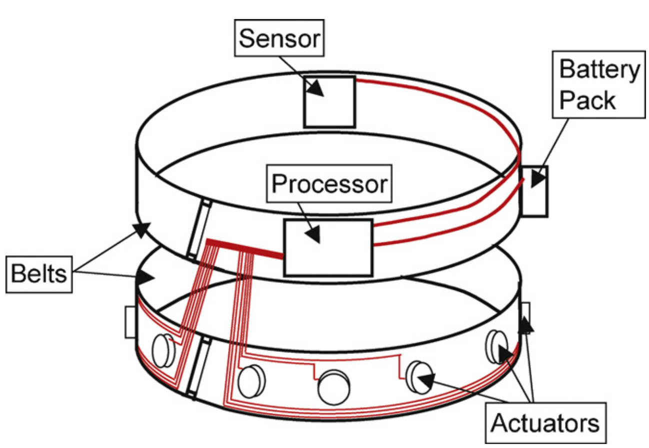

Fig. 1. Schematic overview of the ambulatory vibrotactile biofeedback (AVBF) system. Details are described in the text.

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 continuously, 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 a 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 corrects his body tilt back to 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 44 °C) of their lateral semicircular canals and reduced or zero gains (≤0.2) at sinusoidal stimulation of the horizontal and vertical canals on rotatory chair testing (0.1 Hz, V_{max} = 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 biofeedback 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