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The design and development of a production prototype Balance Belt

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Abstract— **This paper discusses the development of a balance device from lab to clinic/home use. An emerging practice among physical therapists in balance training and falls prevention addresses a major health problem in the United States: imbalance and its consequences. The annual cost for treating balance disorders exceeds $1 billion, not including the cost to treat falls. We aim to develop a non-invasive device worn around the waist. It detects when a person is tipping too far in any direction and vibrates on that side, signaling the wearer to stay within their limits of stability. Because this new technology gets a patient to a higher level of function in a shorter number of trials, it offers an opportunity to advance rehabilitation by enabling more effective outcomes for the same number of treatment sessions.**

I. Introduction

Falling and its consequences are a major healthcare problem in the United States. Two large groups of potential fallers that need balance rehabilitation are the prone-to-fall elderly and people with vestibular disorders. These two groups have a profound impact on healthcare costs. (1) Prone-to-fall elders. Because the ability to maintain one's balance diminishes with age, falling is a common occurrence among the elderly. In the US, more than one third of the 45 million adults over 65 report at least one fall each year [1], with over 7.5 million people 65 or over falling two or more times each year [2]. Falls are the leading cause of injury deaths among older adults [3]. The average cost to treat a significant fall injury for those over 72 is about $19,000 [4]. (2) Inner ear disease. Disorders of the inner ear's vestibular system also cause falls. An estimated 69 million individuals in the US will experience vestibular dysfunction at some time during their life [5]. The exact number of falls in this population is not known. In the US, the overall annual cost for treating individuals with balance disorders exceeds $1 billion, not including the cost of treating falls [6]. In 2000 the US healthcare system spent over $20 billion treating falls [7], estimated to grow to $50 billion by 2020 [8]. There is therefore a very strong motivation to treat imbalance and reduce the incidence of falls. Balance training and falls prevention is an emerging practice amongst physical therapists, and new technologies are being developed to aid therapists in the treatment of fall-prone individuals. Herein, we will describe how this existing research technology is being translated into a practical assistive device, called the Balance Belt.

The Balance Belt is a non-invasive device worn around the waist. It detects when a person is tipping too far in any direction and vibrates on that side, signaling the wearer to move in a given direction and return to an upright position within their limits of stability. This device will allow therapists to give their patients constant and accurate feedback of their body motion during rehab exercises and also, through its data collection capabilities, to document progress. Because the Balance Belt's new technology gets a patient to a higher level of training in a shorter number of trials, it offers an opportunity to advance the field by enabling more effective outcomes in the same number of treatment sessions (see Discussion). The goals of this paper are to provide an example of translational research, and the thought and research processes needed to go from bench to bedside with a balance assistive device.

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II. Transition from vest to belt

A. Overview

To transition from a device used to support research to a production prototype device required new experimental data and also engineering redesign. First, the baseline research device will be briefly described. Next, the experimental results that justify making a simpler device will be reviewed. Finally, the engineering redesign will be presented.

B. Description of baseline research device

The first generation design was a 4 kg. research vest, with a Linux-based, 300 MHz PC104 processor, a military grade inertial measurement unit (IMU) (Honeywell HG1920), and 48 tactile vibrators (Tactaid, Audiological Engineering, Somerville, MA) in 16 columns of 3 rows each. The unit cost was $60. The device uses a 6-degree of freedom motion sensor (3 linear accelerometers and 3 rate gyroscopes) that provides linear acceleration and angular rate information to an algorithm in order to estimate trunk tilt relative to the vertical. Motion sensors were mounted near the small of the back (near the vertical location of the center of mass) because pilot testing showed this location to give better performance during postural control tasks compared to head mounted sensors. The initial tilt estimation algorithm used Euler angle notation and a complementary digital filter [9]. The algorithm was subsequently improved by switching to quaternion notation and adding a Kalman filter to account for real instrument errors, thereby avoiding the "gimbal lock" (divide by zero) effect inherent in using Euler angles [10]. The device then feeds back this estimated tilt information to the subject via an array of tactile vibrators (tactors) that rings the torso [9, 11, 12]. The device displays both magnitude and direction of body tilt using a 16 column by 3 row array of tactors, and is held in contact using a wide elastic belt. Columns display tilt direction, while rows are used to display magnitude. During standing, only one tactor is activated at a time, and is driven by a continuous 250 Hz sinusoid. We form a signal magnitude by adding the tilt angle to one-half of the tilt rate, because this signal reflects the appropriate state variables needed to control the simplest model of posture – a single inverted pendulum. We call this the tilt signal (TS). TS = tilt angle + tilt rate/2. This combined signal is more effective than using tilt angle or tilt rate alone [13].

The magnitude of the tilt signal is displayed in a step-like fashion. The resolution for the display of tilt magnitude was determined using a dynamic manual control paradigm [14], and was set at four discrete levels (including a "null zone" of no tactor activation). The direction of the tilt signal is displayed by choosing which of the columns to activate. With 16 columns, the best spatial resolution is thus 22.5 degrees. The front and back columns are aligned along the anterior-posterior body axis. We can choose how many columns to use for a given experiment. For standing experiments 4 to 16 columns have been chosen. The column in which a tactor is activated is selected on the "nearest neighbor" principle. For walking only the columns on or near the right and left sides are activated. If the subject is ambulating normally, then the signal is set so that they get an alternating right-left pattern of vibration on just the lowest row of tactors. If the subject's mediolateral (M/L) tilt signal exceeds a threshold (typically set at 5 degrees) then all the tactors in a column are activated simultaneously. The objective is to give the subject a re-assuring stimulus under nominal locomotion, and to give them an alerting stimulus when their M/L tilt signal is off nominal, so they can correct during the next gait cycle.

The baseline research device (or devices similar to this design) has been used on over one hundred subjects in protocols that span five institutions, and has been validated in numerous published studies [9, 12-29]. The basic finding is that when the feedback contains information about a person's body motion, the amount of wavering is decreased when the feedback is on compared to the same situation when subject wears the device with the feedback turned off.

The HG1920 IMU is a tactical grade instrument (Gyro bias in the 1 to 10°/hr range, and accelerometer gain sensitivity in the 0.001g to 0.005g range) [11]. The drift in the tilt estimation algorithm was of the order of 0.1° over 10 hours. The IMU cost was $35,000.

C. Experimental results that enable device simplification

<u>Fewer tactile vibrators to signal tilt direction</u>. Using pseudorandom multidirectional perturbations [28], we varied the number of active tactor columns (4, 8, and 16) to evaluate the effects of spatial resolution upon postural control in eight vestibular-deficient subjects (51 years ± 10 years). Two uncorrelated pseudorandom, 5 state sequences were used to drive a high performance Balance Disturber (BALDER) platform's motion in the horizontal plane. One sequence drove the velocity in the x direction and the other sequence drove it in the y direction. The direction of body tilt (azimuth) was displayed by the appropriate tactor column using the "nearest neighbor" principle. A fourth configuration (4I) was treated as two separate single-axis systems, thus displaying anterior-posterior (A/P) tilt and M/L tilt information independently of each other. While all configurations significantly reduced root mean square body tilt, as compared to control conditions with no vibrotactile feedback, there was no significant difference that depended upon which of the 4 displays we used, with 4 columns working as well as 16 columns (Fig. 1). Thus we showed that only 4 columns along the cardinal body axes are needed to control body tilt in response to multi-directional, unpredictable motion inputs. This enabled us to reduce the total number of required vibrators by a factor of 4 [30].

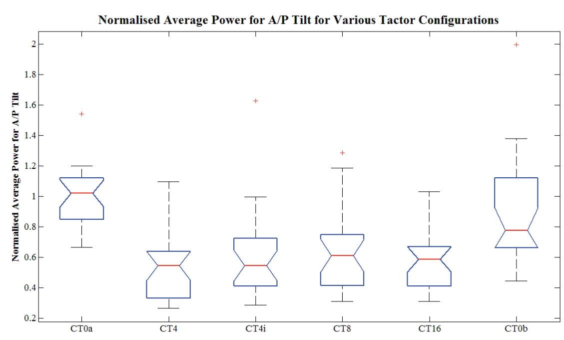

Fig. 1. Box plot of root mean tilt in response to pseudorandom perturbations for 6 tactile display conditions. CT0a and CT0b are with no feedback. CT4 and CT4i are with direction displayed in 90 deg increments. CT8 is with direction displayed in 45 deg increments, and CT16 is with the display set to 22.5 deg increments. The data for all configurations have been normalized on CT0a.

<u>Newer vibrators allow the use of fewer vibrators to signal tilt magnitude</u>. The original tactile vibrators (Tactaid) were only designed to use a 250 Hz sinusoid. Varying the amplitude of the signal into the tactor was not effective because we needed to use full amplitude so the all subjects could actually feel the vibration on their torso, so we signaled the

magnitude of body tilt by activating one of the three vibrators in a given column, a scheme we term "position-based coding". Pilot experiments revealed that actuating more than one tactor in column was not as effective as actuating only one tactor. A second feedback scheme, waveform-based coding, was developed using a new tactile vibrator (EAI C2, tactor - unit cost: $200) that provides a wider variety of signals, enabling tilt magnitude to be signaled with just one C2 tactor by using carefully selected states: no signal; a 250 Hz sinusoid; and a signal that has several periodic components. These states were determined by running human reaction time experiments using many candidate signals, until we found signals that give acceptably short reaction times in the 300 ms range. The reaction time experiment measures the time it takes for the subject to notice a change in the vibrotactile stimulus, and press a button with the finger. Thus, it is not the same as the short loop postural reflex reaction time. Using the best set of signals, we compared responses of the Tactaid vibrators to the C2 tactor using a standard test of balance function called the Sensory Organization Test (SOT). The SOT is a test developed by Neurocom International whose purpose is to vary the reliability of visual and proprioceptive information to subjects while they stand on a posture platform. In SOT 5 subjects stand with eyes closed on a moving platform in a protocol designed to make proprioceptive information from the feet and ankle joints unreliable in the pitch direction. In SOT 6, both the platform and a visual surround are moved as the subject pitches in a protocol designed to make both proprioceptive and visual information unreliable.

Two groups were studied: patients with diagnosed vestibular deficits (N=12, age=24±1.5), and healthy subjects with no history of balance disorder (N=8, age=53±10.5).

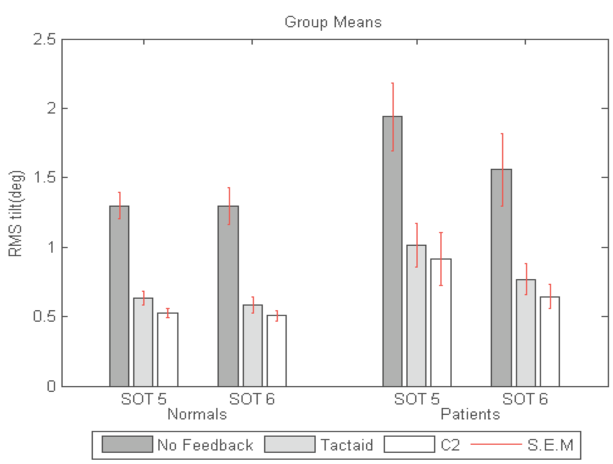

Fig. 2. Group tilt performance for SOT 5 and 6 for Normals and Patients. Mean root mean square (RMS) tilt for non-fall trials with feedback off (No Feedback), Feedback on with position-based display (Tactaid), and on with waveform-based display (C2). S.E.M = standard error of mean.

Results were gathered for root-mean-square (RMS) tilt and incidence of falls. Data were analyzed using ANOVA with repeated trials to compare the results with no feedback, with feedback using the Tactaid tactors, and with feedback using the C2 tactors. The results showed that waveform-based coding for magnitude of tilt performed as well as position-based coding in controlling body sway (Fig. 2) and reducing falls (Fig. 3). This allowed the number of tactors needed to display magnitude in any given direction to be decreased from three to one.

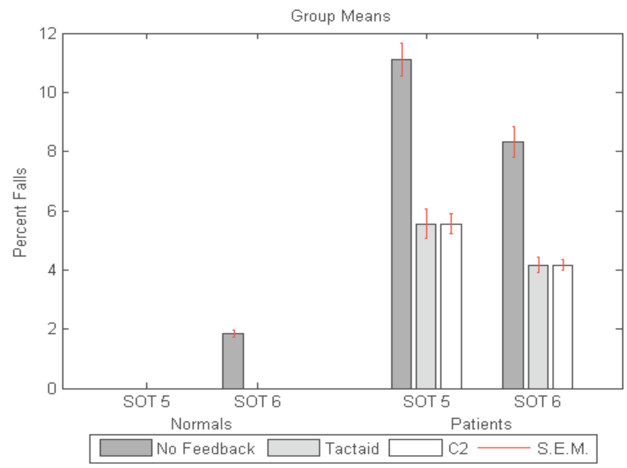

Fig. 3. Group falls performance for SOT 5 and 6 for Normals and Patients. Percent falls with feedback off, feedback on with position-based display (Tactaid), and on with waveform-based display (C2).

D. Engineering designs for production prototype

Simplified electronics test bed. In collaboration with Draper Laboratory, we then put the sensing and control electronics on a single printed circuit card. It had a PIC32 80 MHz microprocessor; an Analog Devices ADIS16350 IMU mounted on the card, and four C2 tactors driven by class D amplifiers. The ADIS1630 IMU had a unit cost of $455, and a drift rate in the order of 0.2 °/hr, after warm-up. The IMU and amplifiers communicate with the processor via a SPI bus. Wireless communication between the onboard electronics and a PC laptop is via Bluetooth allowing settings that are easily customized to the wearer. It runs the improved tilt algorithm with sufficient speed to provide 50 tilt estimates per second. Besides demonstrating proof of concept for a more compact design, many other electronic parts are now proven for use on the production prototype. Three of these devices are currently undergoing limited pilot testing at a Veteran's Administration falls prevention center (Fig.4).

Ergonomic belt design**.** A prototype ergonomic belt design based upon interviews with potential users has been fabricated. It is adjustable and elastic so that tree sizes fit the 98^{th} % of adults. It uses memory foam to couple the part of the belt that holds the motion instrumentation securely to the small of the back (near the center of mass) so it won't slip. The design has been made thin enough to be concealed under a blouse or shirt by distributing the electronics around the circumference of the belt.

Belt layout diagram. The physical layout of the belt that is shown in Fig. 5 illustrates the distribution of components along its length. Many of these components will be taken from the electronic test-bed, but the IMU is relocated off the printed circuit to reduce overall thickness (4.7 cm to 2.8 cm and will use a microprocessor with native floating point (Texas Instruments TMS320 series).

III. Discussion

A. What has been achieved in the transition?

The use of experimental data, newer technology, and an engineering redesign has resulted in a weight reduction from 4 kg to 0.7 kg, a reduction of tactile vibrators from 48 to 4, and a cost reduction of more than one order of magnitude. All of these improvements have helped remove barriers that prevent the use of vibrotactile tilt feedback by the balance rehabilitation community. The next steps are less expensive tactile vibrators, and limited clinical efficacy trials.

The development history gives some insight into the timing needed to make the transition. The baseline device was ready to take research data in 2002, and much of the research took place from 2004 to 2008. The simplified electronics test bed was developed in 2009-2010, with data accrual staring in 2011. A breadboard version of the TMS320 microprocessor is operational, and is presently being bench marked using the Kalman filter algorithm.

B. Role of technology in balance rehabilitation.

A recent issue of the Journal of Neurologic Physical Therapy was dedicated to new technologies and approaches for vestibular rehabilitation therapy. In an overview article for this issue, the editors recognized the opportunity [31] for the field to advance (e.g. have a better outcome using the same number of treatment sessions) by embracing these new technologies, including vestibular prostheses [32]. They specifically mention a noninvasive prosthesis that provides sensory substitution using vibrotactile tilt feedback, described elsewhere in the issue [29]. Use of better technology – like the Balance Belt – can improve the treatment of those needing balance or vestibular rehabilitation therapy in three significant ways. (1) The vibrotactile feedback that is provided during therapy sessions will help individuals sense the motion of their bodies better, and thus use this enhanced sensory input to more effectively control their sway and their sway variability during therapy sessions. (2) Unlike stationary devices that use force plate technology to provide patients with visual feedback of their body motion on a screen, the Balance Belt can be easily used during locomotion, and is portable for home visits. (3) The therapist may use the recording and data storage capability of the Balance Belt to gauge progress, share quantitative results among the therapist community and to document improvements to healthcare providers.

C. Potential for more cost effective balance rehabilitation.

Traditional balance rehabilitation trains subjects with balance and walking exercises.[33-36] In general, this approach requires the individual to change some of their stability limits while standing or walking, or helps them to "tune" extravestibular inputs to improve postural control. Providing people with additional sensory input to help them limit how much they sway appears to expedite the rehabilitation. Thus, the Balance Belt can help therapists deliver more effective and more rapid balance training. In a crossover design study (Fig. 6), nine subjects with unilateral vestibular loss practiced narrow gait with and without vibrotactile tilt feedback (using the prototype "vest"). After adjusting for the effects of practice, the use of feedback consistently increased postural stability (reduced mediolateral tilt) during tandem gait, beyond the effects achieved by practice alone. These data established use of the vibrotactile tilt feedback promoted patients to a higher level of training, in a shorter number of trials[21].

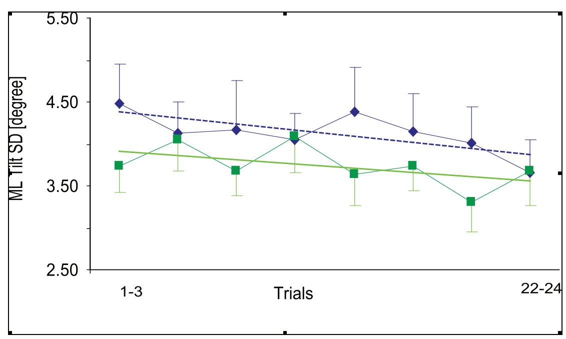

Fig. 6. Root mean square mediolateral tilt during 24 tandem walking trails with and without vibrotactile tilt (sway) feedback, for 9 unilateral vestibulopathic subjects. Blue diamonds show control (no feedback) and green squares show trials using feedback. Three neighboring trials were averaged to yield 8 points for all 24 trials. Error bars show 1 standard deviation. Linear trends in the data are shown by dashed blue line for the control condition, while the solid green line shows the tilt feedback trend.

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