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#### The Effect of Off Vertical Axis and Multiplanar Vestibular Rotational Stimulation on Balance Stability and Limits of Stability

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##### Abstract

***Background:*** Off vertical axis and multiplane whole body vestibular rotational therapy has received great attention by major network television and press subsequent to its utilization in the treatment of sports concussions and other traumatic brain injuries that result in neurological challenges to balance and gait. We desired to test the therapy in isolation from other therapies customarily used in a brain and vestibular rehabilitation center.

***Methods:*** Volunteer human subjects underwent postural evaluations to ascertain the characteristics of maintained head position/posture in the yaw and pitch planes. Based on this evaluation, normal human subjects were randomized to one of four groups based on head pitch and yaw. Each subject was then randomly assigned to a vestibular whole body rotational montage specific stimulation group. Immediate and time referenced pre and post-computerized dynamic posturographic measurements were compared.

***Conclusion:*** Vestibular activation in a multiplane whole body rotational devise has a modest but significant beneficial effect on the stability of the subjects as measured by the Stability Score and the Normalized 95% Confidence Ellipse Area. However, this beneficial effect appears to be temporary and disappears within one day. Neither the evaluation nor the stimulation had a significant effect on the limit of stability suggesting that the evaluation methodology adopted in this study was not sufficient to properly decide the direction and type of rotational stimulation and that this therapy is not a stand alone treatment. We recommend that this type of therapy not be utilized in isolation of other rehabilitation strategies.

**Keywords:** Posturography, Functional Neurology, Balance, Gait, Whole Body Rotation

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##### Introduction

We desired to study the effects of vestibular activation in a multiplane whole body computerized rotational chair. Specifically, we wanted to see if such stimulation would affect static balance and stance as well as the limit of postural stability. We have used off vertical axis rotation and multiplanar whole body stimulation combined with individualized brain and vestibular rehabilitation strategies in several hundred cases of traumatic brain injury with impressive outcomes of posture, balance and gait. Abnormalities of posture, balance and gait are commonly associated with traumatic brain injuries and other neurological syndromes that we see frequently. We wanted to test this modality of treatment in isolation from the other integrated treatment regimes we utilize to ascertain the consequences of the therapy. The evaluation of postural stability using computerized dynamic posturography (CDP) is an established functional diagnostic and treatment outcome-monitoring tool [1]. Because we have found that clinical applications of rotational multiplane therapy in concert with an intense multimodal brain and vestibular rehabilitation program have demonstrated posturographic changes, we elected to use CDP as a baseline and an outcomes measure in this study. Body sway increases with age and many neurological disorders and diseases are associated with pathology of balance and gait. Balance is an ability to maintain the line of gravity (vertical line from center of gravity) of a body within the base of support with minimal postural sway [2]. Sway is the horizontal movement of the center of gravity even when a person is standing still.

A certain amount of sway is essential and inevitable due to small perturbations within the body (e.g., breathing, shifting body weight for one foot to the other or from forefoot to rearfoot) or from external sources (e.g., air currents, floor vibration). Vestibular information is critical for the control of balance, posture, and eye movements and we desired to obtain baseline data and the characteristics of balance performance before and after whole body multiaxis rotational vestibular stimulation in a randomized controlled study of healthy human subjects. Elderly subjects demonstrate a higher degree of postural imbalance and use a hip strategy to maintain their balance while requiring a longer reaction time and a lower directional control in balance performance [3]. Our experimental model has been designed in concert with an understanding of a variety of strategies utilized in role activities. We have observed many different strategies that patients utilize to maintain balance in a variety of clinical scenarios. Almost all measures of balance are worse in elderly subjects compared with young controls [4], most likely as a result of biomechanical or central processing changes as opposed to diminished sensory or vestibular input. It appears that clinically significant balance impairment in the elderly may be the result of age-related disease rather than an inevitable consequence of aging and is therefore potentially treatable. Treatment of balance related pathology has a societal benefit of decreasing falls and increasing function and autonomy that is not limited to the elderly. Athletic performance and activities of daily living are in a large part associated with integrity of the systems that we desire to measure.

The contribution of sensory inputs to balance control differs considerably per individual and may be due to differences in the vestibular function related to the specific pathology or to differences in motor learning strategies in relation to daily life requirements [5]. These individual differences have resulted in specific rehabilitation strategies and treatments that are not similar between individual neurologically compromised patients. It is difficult for us to understand the value of the different contributing therapeutic applications we use as we have never used them in isolation of other therapies. We do know that it is important to evaluate both vestibulo-oculomotor and vestibulospinal pathways in patients with balance disorders. There is a significant correlation (p < 0.005) with a sensitivity and specificity of 95 percent and 90 percent, respectively, between the clinical assessment using CDP and the results of moving-platform posturography [6]. We use CDP regularly in clinical

applications and find that it has an ease of application with a richness of data for interpretation. Signals from vestibular receptors (semicircular canals and otoliths) are carried by the eighth nerve and distributed to the four nuclei of the vestibular nuclear complex (VNC). Otolith stimulation engages brainstem structures both within and outside of the vestibular nuclear complex, many of which project to the cerebellum [7]. While otoliths act as gravito-inertial force sensors and contribute to the perception of spatial orientation, patients with chronic utricular dysfunction can be identified with the use of difference angles (on-axis SVV - off-axis SVV) [8]. Functional canal and otolith vestibular impairment can be evaluated with vertical and off vertical axis rotation (OVAR) tests. We expect graviceptive moments of receptor activation coupled with angular and translator activation of the head and body when the subject is rotated in a multiplanar scenario. Deficits of vestibular function are involved in the delay of posturo-motor development as well as visual deficit and neurological impairment [9].

We desired to utilize diagnostic procedures in a therapeutic application to ascertain whether we could affect postural motor changes as measured with computerized dynamic posturography (CDP). Otolith-ocular responses can be investigated during off-vertical axis rotation. This stimulus induces nystagmus consisting of an exponentially decaying canalicular response, and an eye-velocity modulation and offset which arise from the excitation of the otoliths by the gravity vector, which lasts as long as the rotation continues [10]. We expected that the gravity vector might be changed after a rotation ceases and desired to test this vector with CDP. Constant velocity off-vertical axis rotation (OVAR) provides dynamic linear acceleration stimuli that can be used to assess otolith function [11]. Neurons with two-dimensional spatio-temporal properties to linear acceleration behave like one- dimensional rate sensors in that they encode the component of angular velocity (associated with a rotating linear acceleration vector) that is normal to their response plane. During off-vertical axis rotation (OVAR) otolith-sensitive neurons are activated by the gravity vector as it rotates relative to the head [12]. During passive whole-body motion in the dark, the motion perceived by subjects may or may not be veridical. We expect reflexive eye movements to be compensatory for the perceived motion, however for certain motions, the perceived motion and eye movements are incompatible [13]. This incompatibility has not been explained by basic differences in gain or time constants of decay but suggest that perceived motions are more compatible with eye movements in three dimensions than one-dimensional components indicate. We therefore decided to utilize CDP as an outcome measure rather than measurements of eye movements and perceived eye position and movements. Vestibular functional impairment leads to delayed posturomotor development if the impairment occurs before independent walking in children [14]. The interrelationship between vestibular functionality and posturomotor development led us to suggest that stimulation of the vestibular system might have a consequence in posturomotor expression. The caudal aspect of the parabrachial nucleus (PBN) contains neurons responsive to whole body, periodic rotational stimulation in alert monkeys while vestibulo-recipient caudal PBN units may detect potentially dangerous anomalies in control of postural stability during locomotion [15]. We desired to test whether whole body rotational stimulation might result in changes of postural stability in human subjects. The integration of neck proprioceptive and vestibular inputs underlies the generation of accurate postural and motor control, however the central mechanisms underlying the integration of these sensory inputs differs across species [16] with multimodal neuronal pools sensitive to neck proprioceptive and vestibular stimulation during passive body-under-head and whole-body rotation, respectively. We cannot rely on animal studies when dealing with human subjects who have compromise of postural and motor control. Reticular neurons take part in the neck tuning of vestibulospinal reflexes by transforming a head-driven sensory input into a body-centered postural response [17]. Vestibulospinal reflexes are elicited by head displacement and contribute to body stabilization owing to the integration of neck input by the cerebellar anterior vermis.

Due to this integration, the preferred direction of spinal motoneurons' responses to a tilt rotates by the same angle and by the same direction as the head over the body, which makes it dependent on the direction of body displacement rather than on head displacement. The responses of vestibulospinal neurons to whole body rotations in three dimensional space reflect a complex combination of static and dynamic vestibular inputs that may be required by postural reflexes that vary depending on head, trunk, and limb orientation, or on the frequency of stimulation [18]. Somatosensory reafferent inputs to the cerebellar vermis are activated in whole animal rotation and used to plastically modify the gain of the vestibulospinal reflex (VSR) when external forces produce changes in the final posture of the foot during animal tilt [19]. We expected modification of the VSR gain in our subjects and further expected that they might have Posturographic changes as a consequence of the gain change. We understand that sensory vestibular signals are transformed from head-in-space coordinates to trunk-in- space coordinates on many secondary vestibular neurons in the vestibular nuclei by the addition of inputs related to head rotation on the trunk. This coordinate transformation is presumably important for controlling postural reflexes and constructing a central percept of body orientation and movement in space [20].

The vestibulospinal (VS) reflexes elicited by animal rotation modify the activity of limb musculature, thus preserving balance and postural stability [21]. Periodic changes in the phase difference and gain ratio of the neck to the vestibular response may occur during dynamic displacement of the head over the body, depending on the stimulus direction resulting in prominent responses of P cells of the cerebellar vermis that may affect spatially organized postural responses by utilizing vestibular and reticular targets [22]. The conscious perception of passive horizontal rotations of the trunk, the head, or both depends on the interaction of canal and neck afferents such that the sensation of passive head rotation appears to be contaminated by an illusionary contribution from neck afferents that have parallels in postural reflexes as well as in neuronal responses that are known in the cat [23]. We desired to stimulate the vestibular system with multiplanar rotation to see if we would be able to change balance. The motor system that controls the neck musculature stabilizes the head to external perturbations or body movements, and generates both voluntary and orientating head movements. These movements are mediated by complex pathways involving the cerebral cortex and superior colliculus while stabilization is thought to be mediated by simple short-loop pathways that generate vestibulocollic (VCR) and cervicocollic (CCR) reflexes [24]. The VCR and CCR attempt to stabilize head position in space during whole body movements and are subserved by relatively direct, as well as indirect pathways linking vestibular nerve activity to cervical motor neurons [25,26]. Head stability is important during human balance corrections and the VCR modulates the amplitude of functionally stabilizing responses and damps mechanically induced instability of the head and neck [27]. Patients often time complain of stability problems when moving the head. The short-latency VCR is not suppressed by active head turns and its amplitude is not consistently modulated by the direction of head turns [28]. When the head rotates, VCR counteracts the rotation by causing contraction of the neck muscles that pull against the imposed motion [29]. We know that transient passive head rotations in PD (Parkinson's disease) patients are followed by an initial rapid rise in resistive torque representing reflexive head stabilization that normal subjects are able to suppress [30]. PD patients have gait instability and often have absent VCR [31], prompting us to investigate its stimulation in this investigation. Elderly subjects rely upon a combination of active trunk mechanics and vestibular integration in order to coordinate their head and trunk motion [32]. Rotation of the body and head in vertical planes of the VCR and of activation of vestibular neurons projecting to the neck tend to be antagonistic with the vector orientations usually opposite, and the response gains and phases similar in decerebrate cats [33].

We anticipated similar activities in humans, knowing that the CCR and VCR behave approximately linearly, both individually and in combination. Acting together, the two reflexes assist

each other in preventing oscillation of the head on a stationary body [34]. We postulated that multiplane rotational stimulation would have a definitive vestibular stimulation that would simulate natural activation by head and body rotations. Yaw head-movement kinematics are unaffected by changes in the head's inertia when the whole body is rotated. The VCR and CCR accommodate for changes in the head's inertia that produces forces on the neck when the body moves and stabilizing the head with respect to the trunk during whole body movements. Stiffness and VCR gain appear to be the primary contributors to the control of head stabilization in space. When angular velocities of the head and trunk in yaw and pitch are induced, the behavior of the head in yaw is found to change relatively little with added inertia while in pitch, increasing inertia accentuates phase shifts at higher frequencies [35]. We expected that whole body rotations in multiple planes at the same time might result in increasing balance performance. Incremental rotation axes for both pitch and yaw oscillations are functions of the pitch but not the yaw head positions, perhaps because of the head interface with the dens and occipital condyles during head oscillation with a contribution of the lower spine to pitch during locomotion [36]. Anteflexion and retroflexion of the head are among the main movements of the atlanto-occipital joint and head movements produce neck proprioceptive stimulation in the vestibular system [37] which we thought might be beneficial. Stabilization of the head is required for adequate motor performance, including maintaining balance while standing or walking, and for the adequate reception of sensory inputs such as visual and auditory information. The vestibular organs (semicircular canals, utriculus, sacculus), provide the most important input for the detection of head movement and their activation evokes the VCR which stabilizes head position in space [38]. Otolith and canal inputs are superposed when animals are rotated about roll and pitch axes from an upright position, insuring that these neurons respond over a broad frequency range from very low to high frequencies [39] and allow detection of linear acceleration generated by two different head conditions, dynamic linear translation and static tilt relative to gravity [40]. Otoliths also contribute to the perception of head rotation whole-body constant-velocity pitch rotations about an earth-horizontal, interaural axis because they sense the changes in direction of the gravity vector [41]. The convergence of canal and otolith inputs contribute mainly to vestibulospinal (VSP) reflexes by sending inputs to the neck and other muscles during head inclination [42] but also activate brain structures involved in movement disorders. For instance, activation of the sacculus evokes VCR activation of a multisensory cortical vestibular network within both hemispheres, including the posterior insular cortex, the middle and superior temporal gyri, and the inferior parietal cortex [43]. There are differences between responses to vertical and horizontal rotations [44] suggesting that we would need to rotate subjects in combined planes. The sensory signal from the semicircular canals in constant-velocity chair rotations undergoes neural processing to compute the percept of self-motion [45] an important contribution to human stabilization. We were interested to measure the consequences of this sensory signal specific to stabilization of balance and the limit of stability in our subjects. Sensory vestibular signals are transformed from head-in-space coordinates to trunk-in-space coordinates on many secondary vestibular neurons in the vestibular nuclei by the addition of inputs related to head rotation on the trunk [20]. Stability is dependent upon adaptation to body motions and adaptation to head movements performed during fast rotation during supine head-on-axis rotation is specific to the particular plane of the head movement [46].

Postural compensatory head pitch movements may be produced predominantly by the angular vestibulocollic reflex (aVCR) at low walking speeds and by the linear vestibulocollic reflex (1VCR) at the higher speeds [47]. During mixed angular head accelerations, the VCR may be partly accomplished by VSP and vestibulo-oculospinal (VOS) convergent neurons. For instance, stimulation of the anterior semicircular and/or posterior semicircular canal nerves in decerebrate cats evoke four types of collateral projections to the oculomotor complex and spinal cord; vestibulo-ocular, vestibulospinal, vestibulo-oculospinal, and vestibular neurons [48]. We wanted to see if such

stimulation in human subjects would evoke similar postural responses when they are accelerated in a variety of planes. Low acceleration anteroposterior movement in the standing position induces a body sway in proportion to the acceleration, pivoting on the ankle joint, while high acceleration increases body sway with the head-neck joint remaining locked upright [49]. The postural responses of the neck muscles suggest that the VCR might tonically activate them. Banovetz et al recorded electromyographic activity of dorsal neck muscles and neck torques to study VCR, CCR, and combined reflexes in cats during rotations about many axes. They characterized neck muscles by maximal activation direction vectors and found that all muscles were excited by the nose down phase of pitch rotation and by yaw and roll away from the side on which the muscle lay. All muscles responded as though they received convergent input from all three semicircular canals [50]. The spatial response properties of medial (MVST) and lateral (LVST) vestibulospinal tract neurons during whole body sinusoidal angular rotations of cats in various planes demonstrate a maximum activation direction vector (MAD) that maximally excites the neuron [51]. We wanted to stimulate human subjects in a combination of planes to attempt a similar maximized response. It is likely that activation of reticulospinal fibers, with their resultant motor consequences, are an important part of the neural substrate of the VCR [52]. Reticulospinal fibers make an important contribution to the horizontal VCR and in response to stimuli in vertical planes, the pontomedullary reticulospinal fibers depend on convergence of inputs within the neck with otolith reflexes [53]. Natural stimulation of the labyrinth of decerebrate cats in vertical planes evokes responses of pontomedullary reticulospinal neurons, the largest fraction of which project to the lumbar cord, playing a role in gravity-dependent postural reflexes of neck and limbs [54]. The effectiveness of vestibulospinal and reticulospinal fibers can be modified by spontaneous activity of neurons in the C3 ventral horn subsequent to sinusoidal vestibular stimulation of decerebrate paralyzed cats in multiple vertical planes [55].

Many neurological disorders that are associated with balance pathology involve the cerebellum. All cerebellar patients demonstrate impaired otolith-ocular responses and may demonstrate severe vestibular deficits [56]. Impairment of the corresponding otolith-spinal reflexes may contribute substantially to falls which pose an important problem to neurologists caring for patients with cerebellar disorders [57]. Cerebellar disease results in a higher sensitivity of anterior than posterior semicircular canal pathways, perhaps through loss of inhibition from the flocculus/paraflocculus complex on anterior canal secondary neurons in the vestibular nuclei [58]. We know that sustained centrifugation decreases gravitational modulation, reflecting a shift towards a more body centered frame of reference [59] and this is what we desired to explore.

Research Questions:

1. Does multiplanar whole body rotational stimulation affect static balance in the subjects considered?

If so:

* + How long does the effect last?
  + Is it dependent on the pitch/yaw evaluation of the subject?
  + Is it dependent on the pitch/yaw stimulation?

1. Does the multiplanar whole body rotational stimulation affect the limit of stability in the subjects considered?

If so:

* + How long does the effect last?
  + Is it dependent on the pitch/yaw evaluation of the subject?
  + Is it dependent on the pitch/yaw stimulation?

Methods: 1 Static Balance

This study was approved by our IRB and conducted in accordance with the Helsinki Declaration. 52 volunteer subjects without a history of neurological disease, vertigo, balance problems or head injuries were included in this study. The subject population was composed of 31 male and 21 females, aged 20 to 60 years old (age equals 29.9 ± 9.3 years; height equals 1.71 ± .08 m; weight equals 8.16 ± 15.5 kg). Participants were recruited from advertisements for research subjects and volunteered without reimbursement. All subjects underwent postural evaluations by a team of neurology residents skilled in postural observations and classification, to ascertain the characteristics of maintained head position/posture in the yaw and pitch planes. Based on this evaluation, the subject was assigned to one of four groups based on head pitch (positive if extended, negative if flexed) and yaw (positive to the right, negative to the left). Each subject was then randomly assigned to a stimulation group; the rotational stimulation could match both head rotations ( pitch and yaw), only one of them, or could be the opposite. Table 1 summarizes for each evaluation/stimulation, the number of subjects assigned to each group.

**Table 1. Number of subjects assigned to each group, based on evaluation and stimulation**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Evaluations** | | | | **Total** |
| - Pitch – Yaw (1) | + Pitch – Yaw (2) | - Pitch + Yaw (3) | + Pitch + Yaw (4) |
| **Stimulation** | Both matched (1) | 3 | 5 | 2 | 3 | 13 |
| Pitch opposite Yaw matched (2) | 3 | 2 | 3 | 6 | 14 |
| Pitch matched Yaw opposite (3) | 1 | 5 | 0 | 8 | 14 |
| Both opposite (4) | 1 | 2 | 1 | 7 | 11 |
| **Total** | | 8 | 14 | 6 | 24 | 52 |

Subjects underwent computer-controlled multi-axis vestibular chair (Gyrostim, UltraThera Technologies, Colorado Springs CO, USA) whole body rotations in randomized combinations Pitch and Yaw simultaneously over a 40 second profile at 90 deg/sec (15 RPM). The acceleration rates to 90 degrees per second as well as deceleration rates were linear and occurred in 1 second. We designed rotations that would represent all combinations of pitch and yaw as indicated in Table 1. To evaluate the effects over time the rotational stimulation could have on the balance of the subjects, each subject was tested using a dynamic computerized posturography system (CAPS™ Professional system (force platform and BalanceTRAK® software) – Vestibular Technologies, LLC – Cheyenne WY, U.S.A.).

The posturographic test battery included a standard modified Clinical Test of Sensory Integration in Balance (mCTSIB – Tests #1-4) [60-62] augmented with 4 additional static balance tests. These 4 additional tests were performed, similarly to the last of the mCTSIB test conditions, with the subjects standing on the perturbing foam cushion with their eyes closed, but instead of the head in a neutral position, the tests were performed with the head rotated volitionally and maximally to the patient’s comfort to the right (Right Yaw – Test #5), to the left (Left Yaw – Test #6) and with the head flexed (Test #7) and extended (Test #8). Each test lasted 20 seconds and was acquired with a sampling frequency of 64 Hz and a resolution of 20 bits. The entire test battery lasted approximately 5 minutes. Each subject performed the posturographic testing protocol four times: first just before the rotational stimulation to obtain a baseline reading (Time 1), then immediately afterward (Time 2), 1 day (Time 3) and finally one week (Time 4) later. Height-normalized posturographic measures provided by the BalanceTRAK® software for each test were used as outcomes. As the BalanceTRAK® software provides almost a hundred different measures, a choice had to be made as to which one to include in the analysis. It was decided to include a subset of posturographic measures of stability we believe are representative of those more commonly found in clinical and research applications. The following were therefore considered:

**Stability Score** (indicating in percentage the subject's ability to maintain balance during the test, with 0 being unable to maintain balance and 100 being perfectly still)

**Directionality** (indicating in percentage how the envelope of the Center of Pressure (CoP) path can be approximated by a circle, with 0 being a perfect circle and 100 being a line)

**Fatigue/Adaptation Ratio** (the percentage of change in the Stability Score between the first and second half of the test, indicating if the subject is getting worse (negative value indicating fatigue) or better (positive value indicating adaptation) during the test)

**Normalized Sway Area** (the area covered by the subject's CoP during the test normalized by dividing it by the square of the subject's height)

**Normalized Drift Velocity Vx** (the average velocity at which the CoP drifts in the mediolateral direction during the test, positive when drifting to the right and negative when drifting to the left, normalized by dividing it by the subject's height)

**Normalized Drift Velocity Vy** (the average velocity at which the CoP drifts in the antero- posterior direction during the test, positive when drifting forward and negative when drifting backward, normalized by dividing it by the subject's height)

**Normalized Average Velocity** (the average velocity at which the subject CoP moves during the test, normalized by dividing it by the subject's height; since the duration of the test is constant among all cases, it is equivalent to the normalized CoP path length)

**Normalized 95% Confidence Ellipse Area** (the area of the standard posturographic measure of the 95% CoP ellipse normalized by dividing it by the square of the subject's height).

The statistical data analysis was performed using the software IBM® SPSS® Statistics release

20.0.0. For all the statistical analyses a significance level of p<0.05 was considered. The normality was assessed visually, using the Q-Q plots, as well as numerically using the Kolmogorov-Smirnov

(with the Lilliefors Significance Correction) and the Shapiro-Wilk tests before further proceeding with the analysis. Data found to be not normally distributed were made normally distributed by taking the natural logarithm of each value. Since for each subject the eight posturographic measures considered were obtained for every one of the eight types of test and the four times considered, the resulting experimental design consisted in a 2 factors (test and time), within subject repeated measures and 2 4 levels factors (evaluation and stimulation groups) unbalanced (the groups did not have the same number of subjects) between subject design. Therefore, given the type of experimental design, General Linear Model (GLM) analysis with repeated measures and Type III sum of squares was used. The Mauchly's Test of Sphericity was used to evaluate the sphericity of each measure and the Greenhouse-Geisser and the Huynh-Feldt correction factors of the degrees of freedom were used in estimating the significance of the effects of the factors. When considering the repeated-measure time factor, simple contrast tests were performed to compare the posturographic measures of Time 2, 3 and 4 with those of Time 1 (baseline). When an effect due to either of the between subject factors (evaluation and stimulation) was found, a post-hoc analysis was conducted adjusting the significance to account for the multiple comparisons (Sidak and Tukey HSD).

To evaluate if the Rotational Whole Body stimulation had an effect on the posturographic results in general, or if there was an effect specific to the evaluation and stimulation groups, three analyses were performed: one investigating only the effect of time, one investigating if the effects of time were dependent on the examination groups the subjects belong to, and one investigating if the effects of time were dependent on the stimulation groups the subjects belong to. Given the uneven distribution of subjects among the evaluation and stimulation groups (Table 1), it was not possible to perform a single analysis with time, evaluation and stimulation as main factors.

##### Results

The Kolmogorov-Smirnov (with the Lilliefors Significance Correction) and the Shapiro-Wilk Tests of Normality both identified the Fatigue/Adaptation Ratio, Normalized Sway Area, Normalized Average Velocity and the Normalized 95% Confidence Ellipse Area as having a non normal distribution. The distributions were made normal by taking the natural logarithm of each value (in the case of the Fatigue/Adaptation Ratio, as some of the original values were negative, a constant value of 1 was added before transforming the data with the logarithm). Both Tests of Normality were then repeated to verify that the transformed variables were in fact distributed normally. The multivariate tests of the between subject factors for the two General Linear Model analyses failed to show a significant effect of either the evaluation (lowest p=0.116 (Hotelling's Trace) with an observed power at α=0.95 of 0.918) or stimulation (lowest p=0.385 (Pillai's Trace) with an observed power at α=0.95 of 0.801). After compensating for the lack of sphericity, the multivariate tests of the within subject time factor as well of the time\*evaluation and time\*stimulation effect showed a significant effect of time (highest p=0.019 (Pillai's Trace) with an observed power at α=0.95 of 0.983) and no significant effects of time\*evaluation (lowest p=0.082 (Hotelling's Trace) with an observed power at α=0.95 of

1.000) and time\*stimulation (lowest p=0.130 (Hotelling's Trace) with an observed power at α=0.95 of 0.999).

The univariate tests of the within subject effect of time showed an effect of time on the Stability Score (highest p=0.003 (Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.894), and the Normalized 95% Confidence Ellipse Area (highest p=0.014 (Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.772) and no significant effects of time\*evaluation and time\*stimulation. Contrast tests found a statistically significant difference between Time 1 (baseline pre Rotational stimulation) and Time 2 (immediately post Rotational stimulation) for the Stability Score (p=0.000 with an observed power at α=0.95 of 0.989) and the Normalized 95% Confidence

Ellipse Area (p=0.000 with an observed power at α=0.95 of 0.964). A difference between Time 1 and Time 2 was also found for the Normalized Sway Area (p=0.011 with an observed power at α=0.95 of 0.731) and Normalized Average Velocity (p=0.011with an observed power at α=0.95 of 0.735), as well as between Time 1 and Time 4 (one week post Rotational stimulation) for the Stability Score (p=0.015 with an observed power at α=0.95 of 0.695) and the Normalized Drift Velocity Vx (p=0.040 with an observed power at α=0.95 of 0.542). However, these differences failed to have an observed power greater than the conventionally accepted level of 0.80 [4] and therefore their significance is questionable.

Table 2 reports the estimates of the mean and its 95% confidence interval for the Stability Score, Normalized Sway Area, Normalized Average Velocity and the Normalized 95% Confidence Ellipse Area across all tests for the 4 times considered, and Figure 1-2 graphically illustrate the same values for the Stability Score and the Normalized 95% Confidence Ellipse Area respectively. Further pairwise comparisons adjusting the significance to account for the multiple comparisons (Sidak), found a statistically significant difference (p=0.021) between Time 1 (pre Rotational stimulation) and Time 2 (immediately post Rotational stimulation) only for Test #8 (Perturbed Stability Eyes Closed with Head Extended) for the Stability Score.

**Table 2. Estimates of the mean and its 95% confidence interval for the measures found to have a statistically significant difference between Time 1 and Time 2**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estimates | | | | | |
| Measure | Time | Mean | Std. Error | 95% Confidence Interval of the mean | |
| Lower Bound | Upper Bound |
| Stability Score | 1 | 80.3% | 0.5% | 79.3% | 81.3% |
| 2 | 81.5% | 0.5% | 80.6% | 82.5% |
| 3 | 80.6% | 0.6% | 79.4% | 81.8% |
| 4 | 81.3% | 0.5% | 80.3% | 82.2% |
| Normalized Sway Area (mm²/m²) | 1 | 520.4 | 24.2 | 474.2 | 571.2 |
| 2 | 485.3 | 25.0 | 437.8 | 538.1 |
| 3 | 519.1 | 28.3 | 465.4 | 578.9 |
| 4 | 515.8 | 25.8 | 466.5 | 570.3 |
| Normalized Average Velocity (mm/s\*m) | 1 | 16.7 | 0.5 | 15.7 | 17.7 |
| 2 | 16.1 | 0.5 | 15.0 | 17.2 |
| 3 | 16.4 | 0.6 | 15.3 | 17.5 |
| 4 | 16.3 | 0.5 | 15.3 | 17.4 |
| Normalized 95% Confidence Ellipse Area (mm²/m²) | 1 | 185.8 | 7.9 | 170.6 | 202.4 |
| 2 | 170.1 | 8.3 | 154.2 | 187.6 |
| 3 | 184.8 | 9.7 | 166.4 | 205.3 |
| 4 | 180.2 | 8.9 | 163.3 | 198.9 |

Stability Score

83.0%

82.5%

82.0%

81.5%

81.0%

80.5%

80.0%

79.5%

79.0%

1 2 3 4

Time (1 = Pre, 2 = Immediately Post, 3 = 1 day Post, 4 = 1 week Post)

Figure 1. Estimates of the mean and its 95% confidence interval for the Stability Score across all tests for the 4 times considered.

Normalized 95% Confidence Ellipse Area

210

200

190

180

Area (mm²/m²)

170

160

150

140

130

120

110

1 2 3 4

Time (1 = Pre, 2 = Immediately Post, 3 = 1 day Post, 4 = 1 week Post)

Figure 2. Estimates of the mean and its 95% confidence interval for the Normalized 95% Confidence Ellipse Area across all tests for the 4 times considered.

Methods: 2 Limit of stability

56 healthy (no history of neurological disease, vertigo or postural compromise) subjects, 33 males and 23 females, age 20 to 61 years old (age = 30.23±9.97 years; height = 1.72±0.08m; weight = 81.6±15.5kg) participated in the study. Participants were recruited from advertisements for research subjects and volunteered without reimbursement.

All subjects underwent postural evaluations by a team of neurology residents skilled in postural observations and classification, to ascertain the characteristics of maintained head position/posture in the yaw and pitch planes. Based on this evaluation, the subject was assigned to one of four groups based on head pitch (positive if extended, negative if flexed) and yaw (positive to the right, negative to the left). Each subject was then randomly assigned to a stimulation group; the rotational stimulation could match both head rotations (pitch and yaw), only one of them, or could be the opposite. Table 3 summarizes for each evaluation/stimulation, the number of subjects assigned to each group.

**Table 3. Number of subjects assigned to each group, based on evaluation and stimulation**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Evaluations** | | | | **Total** |
| - Pitch – Yaw (1) | + Pitch – Yaw (2) | - Pitch + Yaw (3) | + Pitch + Yaw (4) |
|  | Both matched (1) | 4 | 5 | 2 | 3 | 14 |
|  | Pitch |  |  |  |  |  |
|  | opposite  Yaw matched | 3 | 3 | 3 | 6 | 15 |
|  | (2) |  |  |  |  |  |
| **Stimulation** |  |  |  |  |  |  |
| Pitch |  |  |  |  |  |
|  | matched  Yaw opposite | 1 | 5 | 0 | 8 | 14 |
|  | (3) |  |  |  |  |  |
|  | Both opposite (4) | 1 | 2 | 1 | 9 | 13 |
| **Total** | | 9 | 15 | 6 | 26 | 56 |

Subjects underwent computer-controlled multi-axis vestibular chair (Gyrostim, UltraThera Technologies, Colorado Springs CO, USA) whole body rotations in randomized combinations Pitch and Yaw simultaneously over a 40 second profile at 90 deg/sec (15 RPM). The acceleration rates to 90 degrees per second as well as deceleration rates were linear and occurred in 1 second. We designed rotations that would represent all combinations of pitch and yaw as indicated in Table 3. To evaluate the effects over time the rotational stimulation could have on the balance of the subjects, each subject was tested using a dynamic computerized posturography system (CAPS™ Professional system (force platform and BalanceTRAK® software) – Vestibular Technologies, LLC – Cheyenne WY, U.S.A.). The posturographic test battery included a standard modified Clinical Test of Sensory Integration in Balance (mCTSIB – Tests #1-4) [60-62] augmented with 4 additional static balance tests. These 4 additional tests were performed, similarly to the last of the mCTSIB test conditions, with the subjects standing on the perturbing foam cushion with their eyes closed, but instead of the head in a neutral position, the tests were performed with the head rotated volitionally and maximally to the patient’s comfort to the right (Right Yaw – Test #5), to the left (Left Yaw – Test #6) and with the head flexed (Test #7) and extended (Test #8). Each test lasted 20 seconds and was acquired with a sampling frequency of 64 Hz and a resolution of 20 bits. The entire test battery lasted approximately 5 minutes. Each subject performed the posturographic testing protocol four times: first just before the rotational

stimulation to obtain a baseline reading (Time 1), then immediately afterward (Time 2), 1 day (Time 3) and finally one week (Time 4) later. Theoretical Limit of Stability normalized Limit of Stability measures provided by the BalanceTRAK® software for each test were used as outcomes. The following measures of the Limit of Stability were considered (refer to Figure 3 for the descriptive significance of the nomenclature):

**Ellipse\_Major\_Axis** (the major axis of the Limit of Stability ellipse)

**Ellipse\_Minor\_Axis** (the major; axis of the Limit of stability ellipse)

**Ellipse\_Angle** (the direction of the major axis of the ellipse - the angle is measured positive counterclockwise, with 0 being to the right of the subject and 90° being forward)

**LoS\_Bias** (the coordinates of the center of the Limit of Stability ellipse with respect to a Cartesian coordinate system centered in the starting position of the test (first point acquired during the test): the mediolateral (ML\_LoS\_Bias) and the antero-posterior (AP\_LoS\_Bias) coordinates respectively)

**LoS** (the four intersections of the Limit of Stability ellipse with the Cartesian coordinate system centered in the starting position of the test. They are expressed as percentage of the theoretical limit of stability: left (L\_LoS), right (R\_LoS), anterior (A\_LoS) and posterior (P\_LoS) interceptions respectively)

**Directionality** (the aspect ratio of the Limit of Stability ellipse; with 0% meaning the ellipse was a perfect circle, and 100% meaning the ellipse was a segment).



y

Limit of Stability Ellipse

A\_LoS

ML\_LoS\_Bias

R\_LoS

Angle

L\_LoS

x

P\_LoS

Starting position of the test

AP\_LoS\_Bias

Major Axis

Figure 3. Limit of Stability ellipse nomenclature.

Minor Axis

The statistical data analysis was performed using the software IBM® SPSS® Statistics release

20.0.0. For all the statistical analyses a significance level of p<0.05 was considered. The normality was assessed visually, using the Q-Q plots, as well as numerically using the Kolmogorov-Smirnov (with the Lilliefors Significance Correction) and the Shapiro-Wilk tests before further proceeding with the analysis. Data found to be not normally distributed were made normally distributed by taking the natural logarithm of each value. Since for each subject the ten Limit of Stability measures considered were obtained for the four times considered, the resulting experimental design consisted in a 1-factor (time), within-subject repeated measures and 2-4-levels-factors (evaluation and stimulation groups) unbalanced (the groups did not have the same number of subjects) between-subject design. Therefore, given the type of experimental design, General Linear Model (GLM) analysis with repeated measures and Type III sum of squares was used. The Mauchly's Test of Sphericity was used to evaluate the sphericity of each measure and the Greenhouse-Geisser and the Huynh-Feldt correction factors of the degrees of freedom were used in estimating the significance of the effects of the factors. When considering the repeated-measure time factor, simple contrast tests were performed to compare the LoS measures of Time 2, 3 and 4 with those of Time 1 (baseline). When an effect due to either of the between-subject factors (evaluation and stimulation) was found, a post-hoc analysis was conducted adjusting the significance to account for the multiple comparisons (Sidak and Tukey HSD). To evaluate if the Rotational stimulation had an effect on the LoS results in general, or if there was an effect specific to the evaluation and stimulation groups, three analyses were performed: one investigating only the effect of time, one investigating if the effects of time were dependent on the examination groups the subjects belong to, and one investigating if the effects of time were dependent on the stimulation groups the subjects belong to. Given the uneven distribution of subjects among the evaluation and stimulation groups (Table 1), it was not possible to perform a single analysis with time, evaluation and stimulation as main factors.

##### Results

The Kolmogorov-Smirnov (with the Lilliefors Significance Correction) and the Shapiro-Wilk Tests of Normality both confirmed all the measures considered were normally distributed. The multivariate tests of the between-subject factors for the two General Linear Model analyses failed to show a significant effect of either the evaluation (lowest p=0.062 ( Pillai's Trace) with an observed power at α=0.95 of 0.968) or stimulation (lowest p=0.411 (Hotelling's Trace) with an observed power at α=0.95 of 0.845). After compensating for the lack of sphericity, the multivariate tests of the within-subject time factor as well of the time\*evaluation and time\*stimulation effect showed a significant effect of time (p=0.000 (Pillai's Trace, Hotelling's Trace, Wilks' Lambda) with an observed power at α=0.95 of 0.999) and no significant effects of time\*evaluation (lowest p=0.707 (Hotelling's Trace) with an observed power at α=0.95 of 0.997) and time\*stimulation (lowest p=0.132 (Hotelling's Trace) with an observed power at α=0.95 of 1.000).

The univariate tests of the within-subject effect of time showed an effect of time on the Ellipse\_Major\_Axis (highest p=0.026 (Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.704), the Ellipse\_Angle (highest p=0.041 (Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.653),the AP\_LoS\_Bias (highest p=0.047 ( Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.640),the L\_LoS (highest p=0.014 (Greenhouse- Geisser) with an observed power at α=0.95 of 0.774), and the A\_LoS (highest p=0.012 (Greenhouse- Geisser) with an observed power at α=0.95 of 0.792). The only significant effect of the time\*stimulation interaction was found for the Ellipse\_Angle (highest p=0.031 (Greenhouse-Geisser correction) with an observed power at α=0.95 of 0.850). No significant effects of time\*evaluation was found. Contrast tests found a statistically significant difference between Time 1 (baseline

pre-Rotational stimulation) and Time 2 (immediately post-Rotational stimulation) for the Ellipse\_Major\_Axis (p=0.001 with an observed power at α=0.95 of 0.943), the L\_LoS (p=0.000 with an observed power at α=0.95 of 0.983) and the Directionality (p=0.002 with an observed power at α=0.95 of 0.902).

A difference between Time 1 and Time 2 was also found for the ML\_LoS\_Bias (p=0.011 with an observed power at α=0.95 of 0.734), as well as between Time 1 and Time 4 (one week post GyroStim stimulation) for the Ellipse\_Angle (p=0.016 with an observed power at α=0.95 of 0.688), the AP\_LoS\_Bias (p=0.013 with an observed power at α=0.95 of 0.710), A\_LoS (p=0.006 with an observed power at α=0.95 of 0.810). However, these differences, with the exception of the A\_LoS, failed to have an observed power greater than the conventionally accepted level of 0.80 [2] and therefore their significance is questionable. Post-hoc pairwise comparisons adjusting the significance to account for the multiple comparisons (Sidak) found for the time\*stimulation interaction a statistically significant difference only between Time 1 (baseline pre-GyroStim stimulation) and Time

2 (immediately post-GyroStim stimulation) for the Ellipse\_Angle (p=0.027) only for the “Both matched” stimulation group. Table 4 and Figure 4-6 report the estimates of the mean and its 95% confidence interval for the Ellipse\_Major\_Axis, the L\_LoS, and the Directionality for the 4 times considered.

**Table 4. Estimates of the mean and its 95% confidence interval for the Ellipse Major Axis, the L LoS, and the Directionality for the 4 times considered**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estimates | | | | | |
| Measure | Time | Mean | Std. Error | 95% Confidence Interval of the mean | |
| Lower Bound | Upper Bound |
| Ellipse\_Major\_Axis | 1 | 108.2% | 2.0% | 104.2% | 112.1% |
| 2 | 103.2% | 2.0% | 99.2% | 107.1% |
| 3 | 107.4% | 2.1% | 103.1% | 111.7% |
| 4 | 106.0% | 2.3% | 101.4% | 110.5% |
| L\_LoS | 1 | 95.6% | 2.0% | 91.5% | 99.7% |
| 2 | 87.0% | 1.9% | 83.1% | 90.9% |
| 3 | 89.7% | 3.0% | 83.7% | 95.6% |
| 4 | 90.2% | 2.8% | 84.6% | 95.8% |
| Directionality | 1 | 28.7% | 1.3% | 26.2% | 31.3% |
| 2 | 25.0% | 1.1% | 22.7% | 27.3% |
| 3 | 26.5% | 1.4% | 23.7% | 29.2% |
| 4 | 26.1% | 1.4% | 23.3% | 28.9% |

Ellipse\_Major\_Axis

115.0%

113.0%

111.0%

109.0%

107.0%

105.0%

103.0%

101.0%

99.0%

97.0%

95.0%

1 2 3 4

Time (1 = Pre, 2 = Immediately Post, 3 = 1 day Post, 4 = 1 week Post)

Figure 4. Estimates of the mean and its 95% confidence interval for the Ellipse Major Axis for the 4 times considered.

L\_LoS

100.0%

98.0%

96.0%

94.0%

92.0%

90.0%

88.0%

86.0%

84.0%

82.0%

80.0%

1 2 3 4

Time (1 = Pre, 2 = Immediately Post, 3 = 1 day Post, 4 = 1 week Post)

Figure 5. Estimates of the mean and its 95% confidence interval for the LLoS for the 4 times considered.

Directionality

32.0%

30.0%

28.0%

26.0%

24.0%

22.0%

20.0%

1 2 3 4

Time (1 = Pre, 2 = Immediately Post, 3 = 1 day Post, 4 = 1 week Post)

Figure 6. Estimates of the mean and its 95% confidence interval for the Directionality for the 4 times considered.

##### Discussion

The results indicate that vestibular activation in a multiplane whole body rotational devise has a modest but significant beneficial effect on the stability of the subjects as measured by the Stability Score (which increases, indicating a reduction in sway) and the Normalized 95% Confidence Ellipse Area (which decreases, consistently again with a reduction in the sway). However, this beneficial effect appears to be temporary and disappears within one day. No effect can be seen for all the other measures of stability. It appears the stimulation has a modest effect on the subjects' Limits of Stability. The main effects appear to be a significant decrease of the Left LoS, a reduction of the largest axis of the LoS Ellipse (i.e. a decrease in the subject's maximum LoS) and a reduction in the directionality. The last two results indicate that the subjects' LoS on average decreases but it becomes more uniform across all directions (the decrease in directionality means the LoS is less elliptical and more circular). This change might be a direct consequence of the decrease in the left LoS.

##### Conclusions

We have noted in several hundred cases that clinical applications of this therapy in concert with an intense multimodal brain and vestibular rehabilitation program have demonstrated posturographic changes that have been greater than those seen without inclusion of the multiplanar rotational therapy. The changes demonstrated have only been seen in clinical cases and not subjected to a controlled environmental research investigation. That in any case some small beneficial stability effects of the multiplane whole body vestibular stimulation was detected suggests that the stimulation is useful even when it is non-specific. With a different type of evaluation it might be possible to maximize the beneficial effects of a stimulation such as that provided by the therapy by more appropriately targeting the stimulation parameters. Doing so might also produce significant changes in the other posturographic measures for whose no significant change was found in this study. The fact that neither the evaluation nor the stimulation had a significant effect on the limit of stability suggests that the evaluation methodology adopted in this study was not sufficient to properly decide the direction and type of rotational stimulation and that this therapy is not a stand alone treatment. We were surprised with the outcomes of this study and recommend that this type of therapy not be utilized in isolation of other rehabilitation strategies. Further investigation to compare the consequences of a multimodal rehabilitation program with appropriate randomization of subjects to it will help us to further understand the consequences of such integration.

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