

A Noninvasive Palatal Device for Vestibular Imbalance

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ABSTRACT

Outcome Objectives:

- To demonstrate a hidden and non-invasive balance device for patients with inner-ear balance disorders.
- To determine the effect of alternative sensory feedback on imbalance and dizziness due to vestibular loss.

Methods - Eight patients with bilateral or unilateral vestibular dysfunction were recruited for an initial study on two testing sites. Each patient was fitted with a custom-made intraoral electronic balance aid called EquiCue™, a retainer-like device worn entirely inside the oral cavity and hidden behind the upper teeth. The device provides alternative sensory feedback by applying small electrical pulses on the palatal surface according to the direction and range of head tilting or movement. Balance performance in terms of equilibrium scores with or without wearing EquiCue™ was measured and compared in three sessions of training and balance tests using dynamic computerized posturography (DCP).

Results - It was repeatedly shown that patients with vestibular deficiency could balance on the DCP platforms like a normal person by using EquiCue™. The improvement was immediate, indicating that the device feedback recognized at the perceptual level could be integrated into the balancing mechanism of the body naturally. The device helped to relieve the symptom of dizziness as well. Patients who were already compensated could use EquiCue™ feedback to realign existing sensory information. In addition, maintaining balance with device induced secondary benefits to patients, including strengthening of core muscles, increased mental focus, and renewed confidence in life.

ACKNOWLEDGMENT

Funding for this project was provided by National Science Foundation under grant IIP-1353629.

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INTRODUCTION

Vestibular dysfunction is prevalent in the United States¹, and the associated dizziness and imbalance can be debilitating both physically and mentally with symptoms including tendency to fall, disorientation, and mental fog, etc. Various oto-neurological conditions can cause lost sense of balance, such as inner-ear disorders, aging, brain injuries, migraines, etc. Symptoms often get worse in busy places, where visual reference is misleading and/or proprioception may not be reliable. Loss of mobility further leads to secondary problems such as loss of body strength, anxieties, depression, and depersonalization that can severely impair life.

Vestibular rehabilitation therapies (VRT) may help patients to adapt to vestibular loss and compensate with other senses. However, vestibular sense cannot be fully substituted with vision and proprioception. While patients who respond to VRT may still live in constant physical and mental stress due to overreliance on vision and proprioception, those who fail to compensate are left with no options².

EquiCue™ intraoral balance aid is a hidden and noninvasive balance device from Innervo Technology. It provides an alternative way for the brain to “watch” the head movement so that appropriate motor functions can be triggered for balance of the entire body. The device presents feedback of head movement by applying small electrical pulses on the palatal surface. Initial patient trials were conducted to demonstrate the use of the device on patients and to study how alternative feedback from the device can be used to improve balance.

METHODS AND MATERIALS

Initial patient trials were conducted in two testing sites: Blue Ridge Physical Therapy (BRPT) and MU Balance Center with 4 patients recruited from each site. Each patient was fitted with a custom-made EquiCue™ in Session 1&2, followed by training and balance tests in Session 3-5. At BRPT, mCTSIB test was conducted on patients using a Balance Master, while at MU Balance Center, SOT test was performed on patients using a Smart EquiTest. In addition, MU patients went through dynamic gait exercises (1-7) to assess dizziness. Typically a patient had a baseline test without device at the beginning. After training with device for about 20 min, the patient was tested again for balance and dizziness with device.



Fig.1. EquiCue™ can be worn like a dental retainer onto the upper teeth. No surgery is ever needed, and it can be removed if not in use. Device settings can be adjusted using a wristwatch wirelessly.

RESULTS

Table 1. Patient Data. BR-2 lost contact with the clinic after device fitting was completed. BR-4 was excluded due to his neuropathy in the lower legs found during balance tests. MU-4 did not show any symptoms during tests, and her test results (only 1 session) are not included.

Patient #	Gender	Age	BVH/UVH (Yrs)	Diagnosis/Etiology	Other Problem	Imbalance	Dizziness	Patient Feedback
BR-1	F	48	BVH (28)	Gentamicin Stroke (L)	Head Tremor	Severe	Severe	Significant
BR-2	F	38	UVH (1)	Labyrinthitis (L)		Mild	Mild	Positive
BR-3	M	84	BVH (1)	Antibiotics	Heart & Urostomy	Walker	No	Negative
BR-4	M	83	BVH (12)	Idiopathic	Neuropathy	Mild	No	Negative
MU-2	M	28	UVH (<1)	Labyrinthitis (L)		Mild	Mild	Positive
MU-3	F	31	UVH (<1)	Multiple Sclerosis		Mild	Episodic	Significant
MU-4	F	36	BVH (3)	Idiopathic		Not shown	Not shown	Positive
MU-5	F	46	BVH(3)	Tumor removal		Severe	Severe	Significant

mCTSIB Test Results for BP Patients

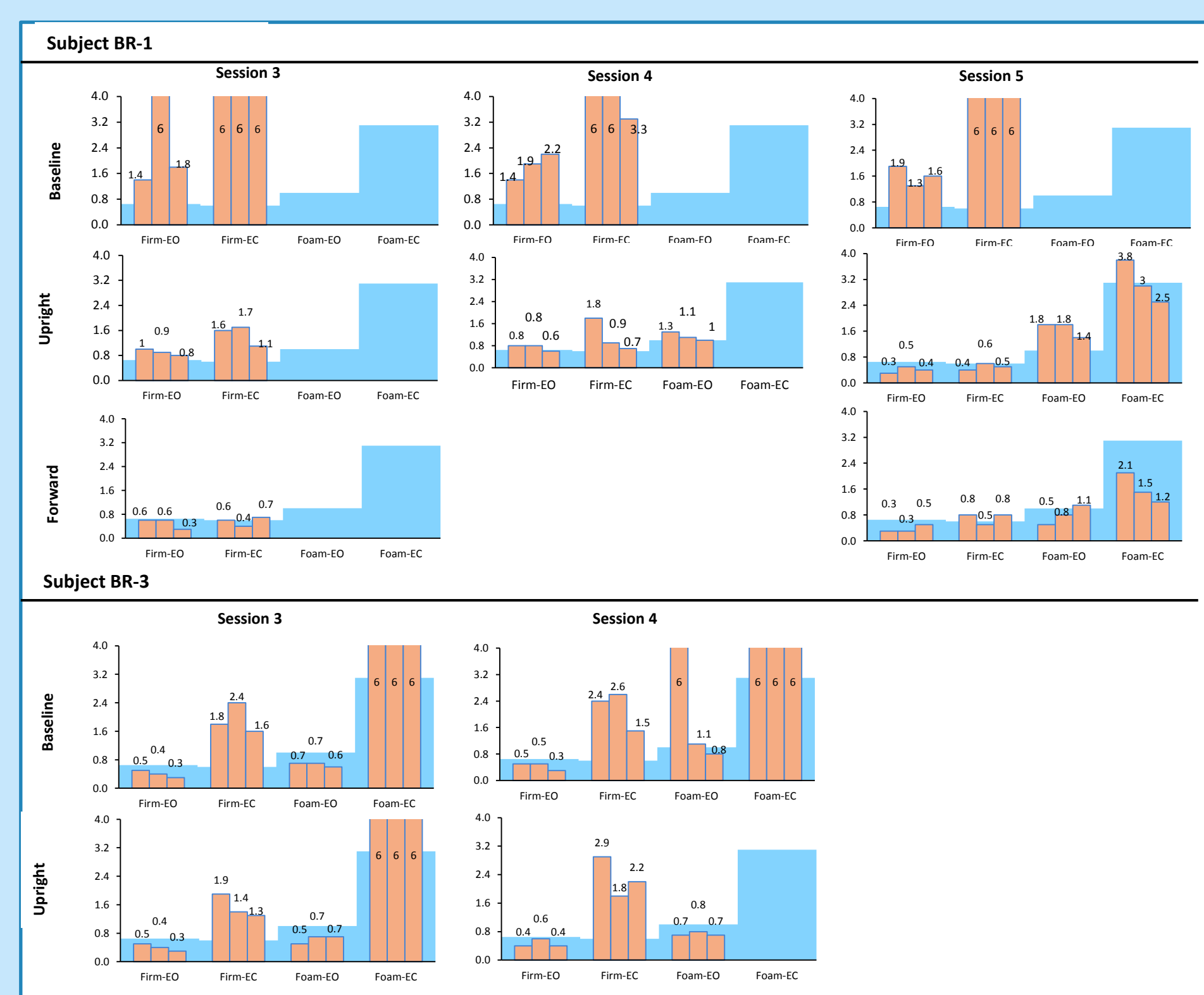


Fig.2. Mean COG sway velocities (unit: deg/s) for patient BR-1 and BR-3, with 3 trials for each condition (if performed). Blue areas indicate normal regions. Baseline – without device, upright – with device upright neutral position, forward – with device and neutral position tilted forward.

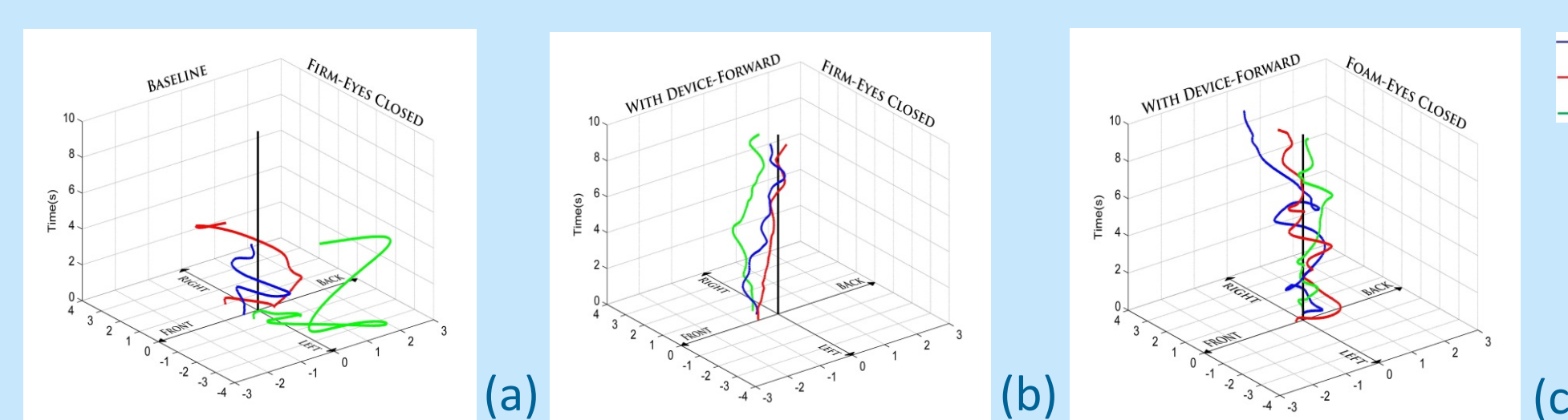


Fig.3. 3D Center of Gravity Path for BR-1 with eyes closed. (a) Firm surface, no device; (b) Firm surface, with device; (c) Foam surface, with device.

SOT Test Results for MU Patients

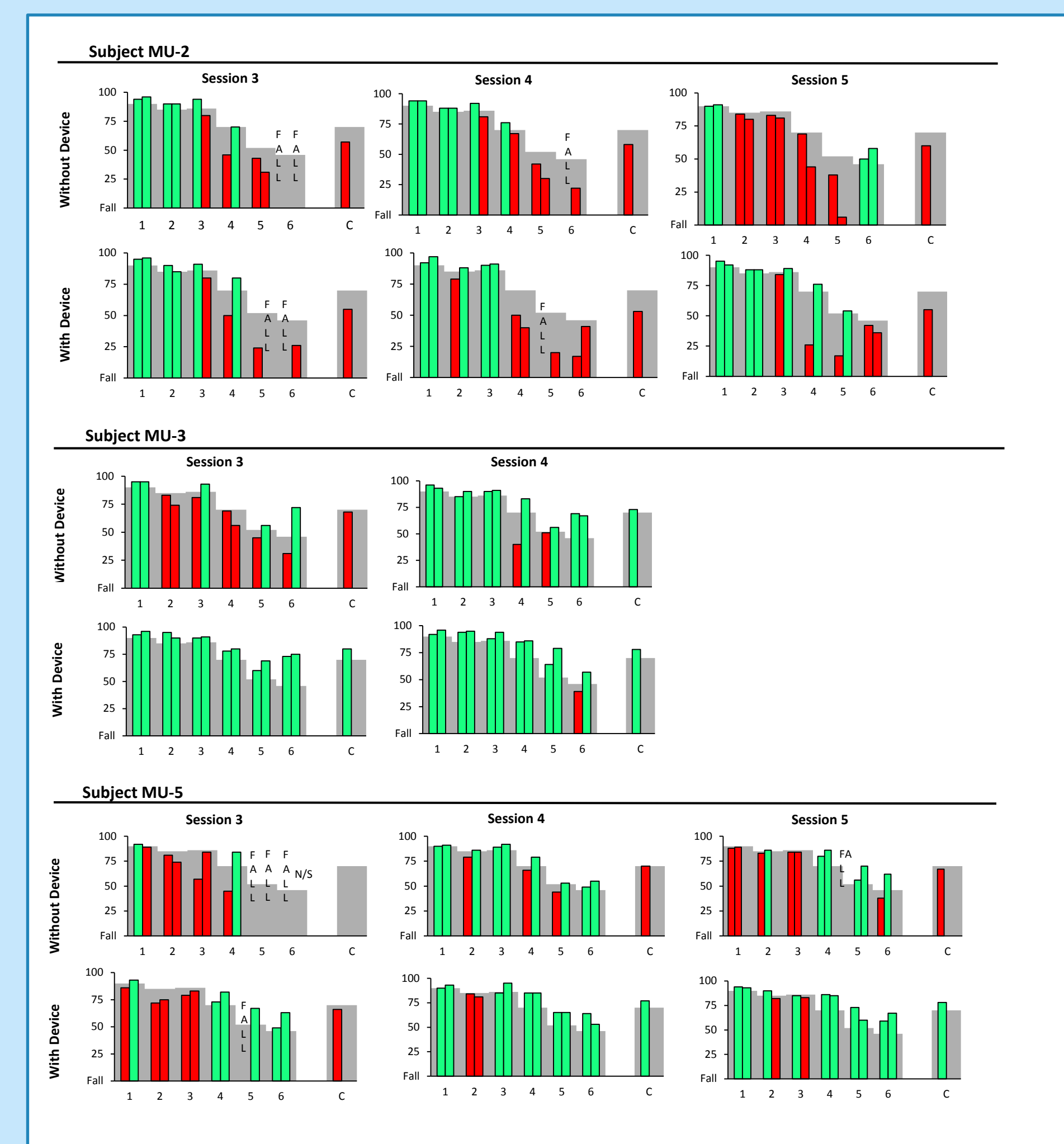


Fig.4. Equilibrium scores for MU patients (C – Composite Score). Two trials for each condition. 1, 2 –EO or EC, firm surface; 3, 4 –EO, sway ref'd visual or support; 5 –EC, sway ref'd support; 6 –EO, sway ref'd visual and support.

Relief of Dizziness

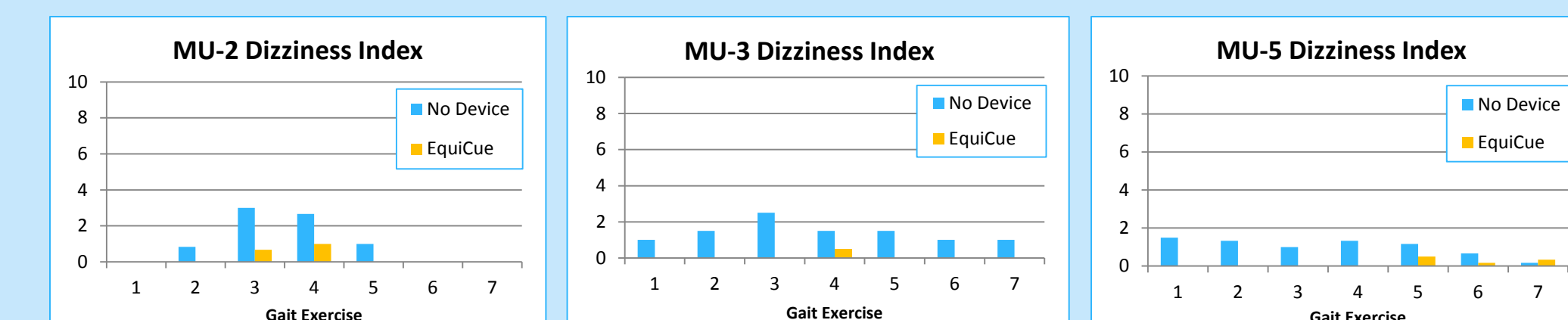


Fig.5. Average dizziness levels for walking: steadily (1), changing speed (2), horizontal (3) or vertical (4) head turns, pivotal turns (5), and obstacles (6, 7).

DISCUSSION

3 patients had dramatic immediate improvement in the balance tests. mCTSIB results indicated that patient BR-1 with severe imbalance could balance across testing conditions using EquiCue™, with sway velocities drastically reduced to normal. Patient MU-3 achieved normal equilibrium scores (high in the green) in all SOT conditions after wearing the device in Session 3. MU-5 who fell in condition 5 and 6 without device could balance like a normal person with device in Session 3.

Patient MU-2 appeared to be well compensated with existing senses, but could be tricked to imbalance by incorrect visual or somatosensory input with or without device. Nevertheless, his balance improved steadily to a point that he could achieve normal scores in condition 6 without device at the end of the test, suggesting that rehabilitative training with and without the device somehow helped him to realign the existing senses.

Fig.5 shows that the device relieved the symptom of dizziness during walking for all 3 dizzy patients tested (MU-4 did not have any dizziness in clinic). Secondary benefits of balancing using EquiCue™ were also reported from patients, including: tightening of the lower-back muscles, increased mental focus (which could suppress head tremors of BR-1), and renewed confidence in life for those with severe vestibular imbalance.

CONCLUSIONS

Initial patient trials revealed that EquiCue™ intraoral balance aid provided an alternative way for the brain to “watch” the head movement in order to maintain stability of a standing body which is inherently unstable. Though recognized at the perceptual level, it can be naturally integrated into the balancing mechanism of the human body for immediate improvement of balance performance. Regaining balance using EquiCue™ proved to be very beneficial to the physical and mental health of patients with vestibular deficiency.

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