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Controlling Motion Sickness and Spatial Disorientation and Enhancing Vestibular Rehabilitation with a User-Worn See-Through Display:

Triological Thesis

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Abstract

Objectives/Hypotheses—An eyewear mounted visual display (“User-worn see-through display”) projecting an artificial horizon aligned with the user's head and body position in space can prevent or lessen motion sickness in susceptible individuals when in a motion provocative environment as well as aid patients undergoing vestibular rehabilitation. In this project, a wearable display device, including software technology and hardware, was developed and a phase I feasibility study and phase II clinical trial for safety and efficacy were performed.

Study Design—Both phase I and phase II were prospective studies funded by the NIH. The phase II study used repeated measures for motion intolerant subjects and a randomized control group (display device/no display device) pre-post test design for patients in vestibular rehabilitation.

Methods—Following technology and display device development, 75 patients were evaluated by test and rating scales in the phase II study; 25 subjects with motion intolerance used the technology in the display device in provocative environments and completed subjective rating scales while 50 patients were evaluated before and after vestibular rehabilitation (25 using the display device and 25 in a control group) using established test measures.

Results—All patients with motion intolerance rated the technology as helpful for nine symptoms assessed, and 96% rated the display device as simple and easy to use. Duration of symptoms significantly decreased with use of the technology displayed. In patients undergoing vestibular rehabilitation, there were no significant differences in amount of change from pre- to post-therapy on objective balance tests between display device users and controls. However, those using the technology required significantly fewer rehabilitation sessions to achieve those outcomes than the control group.

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Conclusions—A user-worn see-through display, utilizing a visual fixation target coupled with a stable artificial horizon and aligned with user movement, has demonstrated substantial benefit for individuals susceptible to motion intolerance and spatial disorientation and those undergoing vestibular rehabilitation. The technology developed has applications in any environment where motion sensitivity affects human performance.

Keywords

Motion sickness; spatial disorientation; vestibular rehabilitation; artificial horizon; virtual reality; simulator sickness

Introduction

Motion Sickness / Spatial Disorientation

Motion sickness and spatial disorientation are acknowledged as wide spread problems, affecting a significant portion of world population. As much as 60% of the population is believed to have some motion intolerance. Motion sickness affects nearly one third of all people who travel by land, sea, or air (1). Individuals are affected daily by motion sickness and spatial disorientation while riding in automobiles, trains, buses, planes or other transport systems and as they participate in activities such as ocean cruising and deep sea fishing. The earliest occurrence undoubtedly coincided with the first attempts to improve mobility – probably a water craft. However, the Greeks provided the first written historical account of motion sickness. Cicero claimed he would rather be killed in battle than suffer the tortures of *nausea maris*. Motion sickness has even been used as a form of punishment. Admiral Lord Nelson reportedly never adapted to motion sickness. *Camel sickness* was reported to occur with Lawrence of Arabia while riding camels, and even General Carbuccia refused to use camels for Napoleon's army, because of the issues with motion (2). It is also known that some groups of people are more susceptible than others; for example, women as a group are more sensitive to motion than men by a ratio of about 5:3 (3) and the elderly, as a group, are more susceptible due to physical reasons related to age. Twin studies show a significant genetic contribution with heritability of propensity to motion sickness (4). It has been observed that poor ventilation, bad odors, smoking, eating large fatty meals and alcohol can make motion sickness more pronounced. Susceptibility to motion sickness begins at about age two, and for most will peak in adolescence and decline gradually, although many adults remain highly sensitive to any motion, particularly in the absence of a visual reference or in the presence of significant visual stimuli. In fact, a provocative visual stimulus has been shown to be the most influential cause of motion sickness symptoms (5, 6). Reading in a moving vehicle, abruptly moving the head or looking down while a vehicle is moving can also make symptoms worse. Fear, anxiety and other psychological factors can contribute to the onset of motion sickness. Some people (such as student pilots) with a history of motion sickness can get sick just thinking about an upcoming trip or flight.

For those who experience the symptoms, the result is often disabling, with nausea, vomiting, sweating, and unsteadiness, while feeling cold, clammy and disorientated. In addition, the term “sopite syndrome” was coined to refer to the apathy, passivity, and lack of concentration characteristic of motion sickness (7).

The prevalence of motion sickness can approach 100% in cruise ship passengers on rough seas (8). Seasickness, a common form of motion sickness, is frequent among naval personnel, where 60% to 90% percent of inexperienced sailors can suffer from seasickness, while up to 60% of experienced crew members have been affected (2). This becomes a major problem in modern seamanship in which small crews are responsible for the operation of sensitive and sophisticated equipment (9). During the invasion of Normandy, in World War II, the seas were reportedly very high causing the landing crafts to pitch and yaw, like a kite in a windstorm. The soldiers were lying and sitting in flat bottomed crafts and were using huge buckets for vomiting and urinating, which soon overflowed after boarding. As thousands of men were lying in the vomit, urine and rain they debarked in a state of terror, which was compounded by their symptoms of seasickness, and attempted to perform at a high level in order to survive in combat. Such acts required for survival can override even the most debilitating effects of motion sickness. On the other hand, there are volumes of data supporting the concept that motion sickness can have a severe effect on performance, permitting those affected to perform only the very basic tasks.

Spatial disorientation with motion sickness is also a significant problem in aviation. In motion provocative environments, spatial disorientation and motion sickness cause not only a loss in human performance (affecting cognitive and motor skills), but a loss of expensive aircraft and most importantly human life. Thousands of deaths have been attributed to aviation accidents caused by being spatially disoriented. One study has shown that almost 90-100% of professional aircrew have reported at least one incidence of spatial disorientation (SD) during their flying careers (10). SD accounted for 11% of USAF mishaps and a mishap fatality rate of 69%, with risk of SD significantly increased in helicopters and fighter/attack aircraft, particularly at night (11). The most frequently experienced SD episodes are “leans” (92%), loss of horizon due to atmospheric conditions (82%), misleading altitude cues (79%), sloping horizon (75%), and SD arising from distraction (66%) (12). In a review of aviation mishaps from 1987-1997, there was an average of one fatal SD accident every 11 days in the United States (13). The death of John F. Kennedy Jr. was an example of a spatial disorientation accident. Unknown to many were thirty other reported crashes that same day, with at least one other due to spatial disorientation. According to U.S. Federal Aviation Administration (FAA) statistics, SD and loss of situational awareness causes 15%-17% of fatal general aviation crashes annually. More significantly, 9 out of 10 SD mishaps result in a fatality (14). The Air Force Safety Center FY93—02 mishap analysis reported that Class A mishaps resulted in 243 destroyed aircraft, 310 fatalities, and an economic loss of \$6.23 billion. Airsickness has also been identified as a flight training issue. A motion sickness history questionnaire obtained from student pilots in the Air Force revealed an incidence of airsickness of 50% (15, 16). In a questionnaire to B-1 and B-52 bomber crewmembers, it was reported to be a frequent occurrence among non-pilots in both aircraft types, where experienced crewmembers were more likely to report an adverse impact on their duties (17).

Space motion sickness is experienced by 60%-80% of astronauts during the first 2-3 days in microgravity and by a similar proportion during their first few days after return to Earth (18). Up to 90% of astronauts experience spatial disorientation during reentry and landing of the shuttle, with prevalence proportional to the length of the mission (19). Exposure to

microgravity rearranges the relationships among signals from visual, skin, joint, muscle, and vestibular receptors. Congruence between vestibular signals and those from other receptors, as well as between the vestibular otolith and semicircular canal receptors, is disrupted by the absence of gravity. This lack of congruence between sensory exposure to provocative real or apparent motion leads to the progressive cardinal symptoms of terrestrial motion sickness. Space motion sickness may vary slightly with flushing more common than pallor, stomach awareness, malaise, loss of appetite, and sudden vomiting, often without prodromal nausea.

Simulator sickness is another example of motion sickness, and many military pilots have reported at least one symptom following simulator exposure (20, 21). In a study of Coast Guard aviators undergoing flight simulator testing, 64% reported adverse symptoms during the first simulator flight and 39% did so during the last flight (22). 36% of pilots reported motion sickness when training on a Blackhawk flight simulator (22).

More recently, simulator sickness in virtual environments (VE) has become an important issue. Virtual reality is already a popular technology for entertainment purposes, and both the U.S. Army and Navy are interested in the training applications of virtual environments (23, 24). However, some users of virtual environments experience discomfort during, and sometimes after, a session in a simulated environment, in equivalent fashion to simulator sickness already noted for flight and driving simulators.

Theory of Motion sickness / Seasickness / Air Sickness / Car Sickness / Space Sickness

Prior to the 1900s, there arose numerous theories regarding the cause of motion sickness. The earlier **Gut Theory** proposed that vomiting was a reflex response to irritation of the gastric mucosa. A more complex variation suggested that movements of the viscera caused abdominal contractions and over-stimulated the Pacinian corpuscles, consequently producing nausea and vomiting. Another variation proposed that visceral movements battered the liver, which consequently released too much bile into the small intestine and eventually caused emesis.

Vascular or Blood Theories fell into two categories: those that proposed a lack of blood flow to the brain (cerebral anemia) and those that proposed too much blood going to the brain (cerebral hyperemia). One theory suggested that vascular deficiency was due to the irritation of the eyes by perceived motion, which, by reflex action, produced spasm in the cerebral capillaries causing giddiness and vomiting. Other vascular theories argued that motion produced cerebral hyperemia, which destabilized brain cells in the vomiting center of the medulla oblongata.

Other early theories attributed motion intolerance problems to respiratory factors, shock to the central and autonomic nervous system, or infections. The vestibular and other sensory contributions came later, and were built upon some of the early work of Purkinje, Flourens, and Meniere (2).

Over stimulation of the semicircular canals theory evolved in the 1990s. This lost favor when it became clear that motion in the absence of vestibular stimulation could be as provocative as the primary sensory organs.

A **fluid shift theory** with assumptions of active or passive shifts in the body fluids to the central nervous system and vestibulo-auditory mechanisms was considered in space flight, but testing did not support the concept.

The **neural mismatch theory** suggested the problems to be in the central integrative mechanism, which is involved in interpreting the significance of the sensory environment. It was proposed that the conflict between visual or vestibular input systems or between separate components of the vestibular system is of secondary importance to mismatch occurring between ongoing sensory experience and long-term memory. The limbic system was suspected as perhaps being the neural mismatch center of the brain.

The **sensory conflict theory**, however, remains the most viable theory presently. Most investigators agree that it is not solely the movement or movement stimulus that results in motion sickness, but rather a conflict in movement information detected by the different sensory modalities of the inner ear, vision, and proprioception (25). A conflict of visual and vestibular (inner ear) information, as it relates to postural control and visual stabilization, is certainly a critical factor (see Appendix I for relevant references). Investigators now also agree that it is primarily an incongruence of visual and vestibular sensory information regarding movement and orientation that results in motion sickness. Incongruence between the semicircular canals and the otolithic organ input has also been implicated as the provocative stimulus in seasickness and in the onset of motion sickness associated with weightlessness. Another contributing factor which may trigger susceptibility to motion sickness may be the mass size differences of the utricular otoconia between the left and right sides in some people, as seen in fish (26).

Within the sensory conflict concept has arisen the 'incongruence in the visual system' theory, termed the **Velocity Storage Theory**. The vestibular nerve communicates head velocity, and estimates of angular displacements require further central nervous system processing (i.e. integration). There is some inconsistency between velocity-based ocular studies and displacement-based perceptual studies. Most oculographic studies of vestibular function are based on measurements of the slow phase velocity of the eye. If a monkey or man is rotated at constant velocity in the dark, the velocity of the slow phase of the nystagmus decays exponentially with a time constant of 15-20 s. Direct recordings of the vestibular nerve in monkeys have shown the head velocity signal, transmitted by the vestibular nerve, has a time constant of decay of only 7-10 s. The duration of the eye velocity curve (i.e. the nystagmus response) is therefore longer, outlasting the sensation or perception curve. The perception of angular velocity is based on signals subserved by the brainstem velocity storage system. Thus the head velocity signal appears to be stored in the brain and then released onto ocular motor neurons for the generation of nystagmus. Brainstem circuits in the vicinity of the vestibular nuclei, behaving as mathematical integrators, are thought to mediate this storage process. There is evidence that motion sickness is generated through this velocity storage and can be reduced by reducing the angular vestibular ocular reflex (aVOR) time constant (27). Others (28) support a multi-factor explanation of motion sickness, involving both sensory conflict and eye movement.

Vestibular Dysfunction

Postural control requires a complex interaction of visual and proprioceptive sensory inputs providing external orientation reference frames while the internal reference frame is provided by the vestibular system. An estimated 20% of the general population is affected by a vestibular disorder (29). Ninety million Americans will complain of dizziness at least once during their lifetime, and, of these, 80% will have a vestibular component. There are more than 10 million physician visits annually for dizziness or balance complaints (National Balance Centers/Vestibular Disorders Association), with a cost of >1 billion dollars/year. Persistent vestibular dysfunction can occur following a variety of insults to the vestibular system, including infections, ototoxicity, trauma, chronic ear pathology, tumors, Meniere's disease, surgery and other idiopathic causes. Acoustic tumor surgery and vestibular nerve section, performed for disabling vertigo in patients with Meniere's disease, usually result in rapid compensation. However some patients, particularly non-Meniere's disease patients, have a prolonged period of unsteadiness without compensation for a long period of time. The resulting disability can be devastating. It has also been shown that postural instability precedes motion sickness with provocative visual stimuli (30, 31). All these vestibular impairments cause disequilibrium, blurred vision, disorientation, and vertigo, which in turn cause dysfunction in many activities of daily living and in social interactions that traditional medical treatments may not address.

Current Treatment/Rehabilitation

Drug therapy has frequently been employed to control motion sickness and treat chronic dizziness. There have been a myriad of drugs used, including the H1 antihistamines (Meclizine, Diphenhydramine, Cetirizine, Loratadine, Desloratadine, Fexofenadine, and Pheniramine), central acting anticholinergics (Transdermal Scopolamine, Scopace), benzodiazepines (Diazepam, Clonazepam), anti-emetics (Promethazine, and Prochlorperazine, Droperidol, Diphenidol), and in some countries Cinnarizine (Stugeron). Cinnarizine is a calcium channel blocker not approved by The United States Food & Drug Administration. Other stimulants such as pemoline (Cylert), methylphenidate (Ritalin), and dextroamphetamine (Dexadrine) were also used in the past.

In general, drug therapy is often inadequate and too slow in acting for acute symptoms. All medications have had potential side effects such as drowsiness, inattentiveness, depression, decreased cognitive and motor skills, and they cannot be used in some industries or occupations. Long-term use of many of the drugs currently used to treat motion sickness or dizziness may also delay central compensatory capacities.

For example, Transdermal Scopolamine has been in wide use as a drug of choice for many to prevent seasickness. However, it has several drawbacks; it must be applied at least 4 to 6 hours before exposure to rough seas, about 10% of individuals who use it on a long-term basis experience allergic contact dermatitis, there is some evidence of decreased human performance on cognitive tasks when using the drug, and repeated use is associated with transient impaired near focusing and diminished visual acuity (32). It has also been demonstrated that the rate of habituation is slowed, indicating that if the central nervous

system is not challenged by disruption of normal activation, it does not produce the compensatory reactions that result in habituation (33).

Acupressure has also been used in the treatment of motion sickness. However results demonstrate that these alternative methods with pressure bands (“Sea Bands”) are no better than a placebo (34).

In the treatment of chronic balance disorders, only a small percentage of patients are appropriate for surgical or specific medical management. For some functional impairments caused by vestibular disorders, occupational therapy intervention may involve providing adaptive equipment, as well as teaching alternative strategies for performing activities of daily living, and psychological intervention for depression and anxiety (35). Organized vestibular rehabilitation therapy programs have been introduced primarily in the last few decades and typically include habituation exercises designed to facilitate central nervous system compensation by extinguishing pathologic responses to head motion, postural control exercises, and general conditioning activities (see Appendix I for relevant references). Compensation can be defined as functional recovery that counters asymmetrical, inaccurate, deficient, or contradictory sensory information from the vestibular, visual or proprioceptive systems. Research suggests that customized, supervised exercises facilitate recovery of postural stability, that vestibular rehabilitation can improve daily life function and that the benefits of organized vestibular rehabilitation therapy are widely accepted. Vestibular rehabilitation exercises offer an alternative to traditional pharmaceutical interventions, which may have harmful or debilitating side effects or interfere with those central nervous system compensatory functions. The benefits of vestibular rehabilitation have been evaluated in a variety of settings, and reviewed widely with many disorders (see Appendix I for relevant references). It has also been suggested that vestibular rehabilitation may be useful in motion sickness.

Basis for Development of a New Solution

The high prevalence of motion sickness in the normal population and in many industries associated with motion provocative environments, such as aviation and military settings, and the possibility that a visual aid may help to overcome these problems as well as speed up the compensation process in vestibular rehabilitation for patients with dizziness of other origins, provided the rationale for development of a device such as the eyewear mounted display (“user-worn see-through display”). The potential impact on health and well-being is broader than the individual. When flight or military personnel or others in commercial or public settings suffer symptoms of motion sickness or vestibular dysfunction, it can put the well-being and safety of others at risk as well.

It was the goal of the present study to produce and demonstrate the feasibility of a user-worn see-through display with software technology, to help overcome the symptoms of motion sickness / spatial disorientation and vestibular dysfunction, regardless of the etiology. The eyewear mounted display system, referred to as the “user-worn see-through display”, was expected to be useful in the rehabilitation recovery process, as an additional benefit.

According to the neural or sensory mismatch theory, motion sickness symptoms occur when vestibular, ocular, and proprioceptive receptors stimulated by motion produce signals that differ from those expected on the basis of past experience (2). The visual system, in particular, plays an important role in both the etiology and the prevention of motion sickness. For example, motion sickness incidence on the bridge of a ship, where sailors have a visual reference, is lower than below deck, despite the fact that motion on the bridge is more pronounced than below deck. Previous study results suggested that a projected horizon alleviated motion sickness aboard naval vessels, thus improving performance skills of sailors at sea (36). It was also demonstrated that visual information was more important than vestibular input in causing motion sickness when these stimuli are present in isolation (37). Money (38) reviewed the literature on the role of the visual system in motion sickness and concluded that appropriate use of visual information might reduce motion sickness up to 90%. Kennedy, Hettinger, & Lilienthal (39) suggest that vision plays an important role in both motion and simulator sickness. In fact, Kennedy and colleagues maintain that simulator sickness is primarily visually-induced (40). Courjon, et al. showed that vision was also important for compensation (41). If a cat was kept in the dark for a month after a neurectomy, nystagmus was apparent when the animal returned to the light. An animal kept in the light following the operation had resolved nystagmus by this time. Both of these early animal studies emphasized the importance of alternative sensory pathways in compensation from labyrinthine lesions. Rolnick and Bles (36) demonstrated that roll and pitch motion results in a deterioration in cognitive task performance and a decrement in well-being, and that the effect on performance was not related to the motion *per se*, but to the visual-vestibular conflict. Further, they demonstrated that the use of an artificial horizon would reduce these effects and prevent performance decrement at sea.

Caloric nystagmus routinely is suppressed by visual fixation (see Appendix I for relevant references). The degree of suppression of caloric nystagmus is influenced by the condition of visual fixation. Studies have shown that people are able to suppress caloric nystagmus with a visible target quite well, but can only partially suppress caloric nystagmus with an imaginary target and with after-image. Fixation overrides the vestibular stimulus and results in suppressing of post-rotational nystagmus. Foveal vision and not peripheral vision is responsible for the suppression of fixation. Other studies indicate that increased visual demand modifies the nystagmus waveform favorably (and possibly adaptively), producing a significant reduction in nystagmus intensity.

It has been shown that more rapid eye movements, indexed by higher frequency of optokinetic nystagmus (OKN), are related to the development of symptoms of motion sickness and gastric tachyarrhythmia (42). During fixation, optokinetic nystagmus is almost fully suppressed.

When subjects look at a target stabilized at the fovea presented against sinusoidal motion of an optokinetic stimulus field, optokinetic nystagmus (OKN) is suppressed. Optokinetic stimuli induce low velocity head movements in the direction of the stimulus with stepwise movements in the opposite direction. With motion stimuli, the head is well stabilized in space and moves to new positions in a stepwise manner, but in the absence of vision, the head is not able to maintain a stable position (43). Both visual field restriction and /or

fixation diminish circularvection, OKN, and motion sickness. Conditions involving both fixation and restricted field of view result in greater reductions in motion sickness than do either restriction alone (28).

Reflex head and eye movements were also observed in the guinea pig subjected to optokinetic stimulation and whole body oscillation in the yaw axis. With motion stimuli, the head remained well stabilized in space and moved to new positions in a stepwise fashion. In the absence of vision, the head was not able to be stabilized. During good stabilization, vestibular-ocular nystagmus does not occur (44). A recent study in humans with chronic vertigo used an interactive visual computer display to improve vestibulo-ocular reflex (VOR) gain and reduce symptoms (45). Fixation appears to “visually enhance” the VOR, depending on the magnitude of retinal error velocity that remains after vestibular eye movements have been generated (46). The vestibulo-ocular reflex responses can be drastically enhanced or suppressed according to mental task or attentional set. The common central processing of vestibular signals allows functional congruency between the various behavioral outputs (i.e. gaze stabilization by the VOR and the perception of self-motion in the external world).

While the VOR compensates for head movement by using inertial input from the vestibular apparatus, the optokinetic reflex works to maintain a stable retinal image through visual input. The optokinetic system uses visual information coming from the entire retina (not just the fovea) to detect if an image slip is occurring. If slippage occurs, a corrective optokinetic (OPK) eye movement is generated to compensate for it by moving the eye with equal gain in the opposite direction of the optical flow. Therefore, while both VOR and OPK reflexes serve the same general purpose and both are considered involuntary, the VOR uses vestibular input to generate oculomotor compensation commands while the OPK uses visual input to do the same. In fact, OPK stimuli can produce optokinetic nystagmus that appears similar to vestibular nystagmus, but while head rotation is required for vestibular nystagmus to occur, only a large-field moving image is required to produce optokinetic nystagmus.

Another type of eye-tracking response is smooth pursuit eye movement. Smooth pursuit, like the optokinetic system, uses visual input to generate eye movements, but instead of functioning to keep the entire retinal image from slipping, smooth pursuit moves the eye to keep only the image that is on the fovea stabilized (47). Smooth pursuit uses visual information of the foveal target to calculate its velocity so that the eyes can move accordingly.

Head movement activities alone are not sufficient to alter the VOR in the absence of the visual scene motion. Interaction with a computer-driven visual image appeared to improve vestibular function and reduce vertigo symptoms when used in an incremental adaptation rehabilitation approach.

When the target (foveal or full view) is stationary, movement of the head results in an equivalent movement of the target in the opposite direction relative to the head. When both the target and head move, the driving stimulus to the visual motor system is the angular velocity of the target relative to the head; that is the difference between the target velocity

relative to space and head angular velocity relative to space. In the absence of head movement, the eye movement response is under control of the closed-loop visual motor system; whereas if the head is rotated in the dark, the visual system is inoperative and the eye movement response is under control of the vestibular system.

Using the fundamentally known information regarding suppression of the stimulated vestibular system and abnormal ocular reflexes and applying the importance of visual information for enhancing proprioception, vestibular ocular reflex and gaze stabilization, hardware (i.e. a user-worn see-through display system) and software technology components were developed. The software technology and related visual symbology, as seen within the display, provides the user with 3-axial orientation, an artificial horizon with vertex in the center. An accelerometer (referred to as a “sensor”) is also mounted into the hardware component and measures many different movements of the head every second. As the user moves, the technology gives constant visual feedback information about the user movement, while always providing a fixed artificial horizon and vertex. It clearly aids proprioception by visual confirmation of head and body location and movement. It confirms what the inner ear and the proprioception have sensed when there is no or limited visual reference, such as in darkness, or the visual information is misleading. By visual fixation on a stable artificial horizon, at the intersection of the vertical line, suppression of the nystagmus associated with semicircular canal and / or otolithic stimulation will occur. Also with this fixation, the optokinetic nystagmus can be suppressed and the vestibular ocular reflex enhanced. In addition it was suspected that head stabilization would be enhanced with the technology. In a motion provocative environment the goal is to stabilize the abnormal response, correct the visual illusion and “assure the brain that the other sensory responses” are indeed accurate.

In a Phase I SBIR grant study, a prototype fully wearable see-through display (referred to as a “user-worn see-through display”) was developed and tested. This was followed by a Phase II SBIR grant study in which software technology, electronic, and hardware development was directed towards a) display device improvements and b) further clinical testing. The display device improvements included miniaturization of the computer system, power source enhancement and a better projection system (i.e. video engine) to display the symbology. Other improvements included: lessening the weight of the components so that the display device could be more easily utilized, lowering power consumption to provide longer lasting operation, integration of the see-through display and sensing device into one unit rather than two separate units, and development of a sensor, which was more affordable and fully functionally integrated within the display device; that is, to develop a clinically functional user-worn see-through display device. The technology which was displayed was then tested clinically in patients with motion sickness and in patients with vertigo or dizziness as a result of a vestibular dysfunction, regardless of the etiology. The latter group was assessed before and after use of the display device with objective measures of vestibular function and a measure of the functional impact of dizziness on daily life. The phase I and II display device development and clinical trials are described here.

Display Device Development

The first generation display device developed in Phase I used a hard hat with a hole cut in the top to mount and hold the positioning sensor (accelerometer), a headband component holding the see-through display, and a laptop computer for processing (Fig. 1). Over the next few generations of development, the computer became portable and was carried in a waist pack along with the power supply (Fig. 2). In the 3rd generation, the motion sensor (accelerometer) had been integrated into a different head-mounted see-through display (Fig. 3), eliminating the hard hat. Five wearable 3rd generation devices were subsequently produced to finish the Phase I clinical testing. The instrument consisted of a head-mounted display and required a VGA signal. The eyepiece had a resolution of 640×480 , and could be clipped on any eyeglasses. The VGA box, which drives the eyepiece, was portable but large and bulky. It was worn on the lower back, using a belt strap. An accelerometer (sensor) tracked head movements and was mounted on a visor. This was connected to a data-acquisition box, developed specifically by the engineering consultant to the project. The box captured the head movement data, processed the signal, and then displayed the movement in a graphic representation. To perform this task, the box had a 386 CPU-based PC-104 standard card and a VGA card. The software, developed in C-language, drives the VGA card to produce the image to display in the eyepiece. The program resides in non-volatile RAM. The box had two batteries, one to power the PC-104 cards (7.2V) and the second to power the sensor. The batteries last about 4 hours when fully charged.

For the Phase II study, five display device development tasks were specified in the project proposal:

1. Develop a positioning sensor that was free of electromagnetic interference: Several positioning sensor technologies were evaluated that included accelerometers, gyros, and motion sensor technologies. After the inertia cube sensor was chosen, the sensor (accelerometer) worked well with the embedded technology (FPGA/DSP).
2. Design a special processor board to interface with the sensor that was compact, had low power consumption, and interfaced to a box connected to the see-through lens: Two technologies were investigated: FPGA-based and DSP processor-based. However DSP processor-based board development was ultimately used, as the DSP processor chip, ASIC, consumes less than 50% of the power that the FPGA-based device consumption. Five units were assembled for testing with patients. Two display manufacturers were used: One display provided a color see-through display, but required designing and manufacturing of a special mounting apparatus. The other display provided monochrome display but had built-in mounting. Each had Lithium-Ion battery charging circuitry, were provided a 6V power supply for the sensor (accelerometer), and a power supply for the display in addition to the necessary circuitry for the actual signal collection, processing, and generation of meaningful output. The battery life was extended from 3 hours to 8 hours.
3. Design a compact box that was lightweight, wearable, and low in power consumption to provide extended battery life: Prototypes were developed which

housed the board and provided connections to a battery charger, sensor, and VGA display unit.

4. Develop interface for the video board: The LiteEye display integrated the controller in itself, so not much needed to be done with this display. Other manufacturers were prepared to share technical information once a significant-sized order was made.
5. Develop mounting headband that included both the see-through display viewing device and sensor, and could be easily mountable and worn by users: Generations 4 - 6 had further head mounting and display developments. Generation 4 is shown in Fig. 4. The 5th and 6th Generation display devices included development of two different eye display systems (Figs. 5 and 6, respectively). In addition, a compact box that was lightweight, wearable, and low in power consumption was developed in these latter two generations and is also depicted in Figure 5.

A demonstration illustrating the use of the technology and how it appears for individuals with motion sickness or vestibular dysfunction can be seen by viewing the simulation at www.advitech.net.

Preliminary Studies/Phase I

It was the stated goal of the this Phase I research to develop an eyewear-mounted visual display, using software symbology (called the “user-worn see-through display”) to project visual information about user movement and an artificial horizon as an effective alternative to control the symptoms of motion sickness and also to shorten the rehabilitative process in patients with dizziness. Specifically, it was intended that software development and electronic miniaturization would result in an eyewear mounted display device to be tested clinically in patients with motion sickness or vertigo or dizziness from other causes. Feasibility, ease of use, and preliminary data regarding safety and efficacy in reducing symptoms were to be assessed by means of questionnaire and rating scales. Such a display device was developed and clinical testing was completed on 41 patients. Feasibility and ease of use were assessed, and preliminary data were gathered regarding safety and efficacy in reducing severity of vertiginous episodes.

Institutional Review Board approval was obtained for the clinical portions of the study.

Subjects

A total of 41 patients were enrolled in the Phase I project, 7 using the prototype display device with helmet and laptop computer and 34 using a headband/visor and wearable display device package. There were 32 females (78%) and nine males (22%), ranging in age from 30 years to 80 years with a mean age of 52.2 years (SD=12.5). Twenty five patients had a history of motion sickness or movement-induced vertigo/dizziness. Other diagnoses included vestibular nerve section (8), tumor removal (3), central (3) and anxiety disorder (2).

Methods—After using the technology in the user-worn see-through display, patients completed a display device evaluation questionnaire asking them to rate ease of use (“simple

and easy”, “difficult but usable”, “difficult and not usable”) and comfort (“very comfortable”, “comfortable”, “uncomfortable”, “very uncomfortable”) of the wearable unit. Patients with motion sickness were asked to rate how helpful it was for each of 5 symptoms of motion sickness: cold clammy feeling, nausea, vomiting, awareness of movement, and general ill feeling. Those with vestibular dysfunction of other origins were asked to rate helpfulness on vertigo, unsteadiness, and lightheadedness or sensation of motion. Helpfulness was rated using a 5-point scale from “Extremely Helpful” to “Not at all Helpful”. The questionnaire also asked for comments and suggestions regarding use of the display device. Patients were asked to report anything that they considered an adverse effect or event. For those patients who underwent vestibular rehabilitation (as versus those with motion intolerance), the therapist also completed a questionnaire for each patient rating how helpful they felt the technology was for the patient’s vertigo, unsteadiness and lightheadedness symptoms, ease of use for the patient, ease of use for the therapist, and overall desirability of the device during rehabilitation for patients like the one being evaluated.

Data from the four data forms/questionnaires was entered into a computer database (Microsoft Access), and statistical software (SPSS for Windows) was used for all analyses. The criteria to determine that feasibility was demonstrated were: 1) Fewer than 30% of the subjects rate ease of use of the display device as ‘Difficult and not usable’; 2) More than 20% of the subjects rate the impact of the technology as at least moderately helpful for one or more symptoms; 3) Vestibular rehabilitation therapists, when involved, rate the technology as at least moderately helpful for one or more symptoms and desirable during therapy in more than 20% of the patients; and 4) serious adverse effects are reported in fewer than 10% of patients. These criteria were intended only to represent that it would appear both feasible and worthwhile to pursue further development and larger scale clinical trials.

Overall opinion was classified as Positive if the patient tried the display device and rated at least one category as positive. Opinion was classified as Negative if the patient tried the display device but discontinued its use without completing the patient evaluation form, made only negative comments, or found the device too complicated to use.

Results

Seven of the patients who agreed to participate took the display device home but did not test it, for a variety of reasons. In several cases this was because the dizziness or vertigo problem only occurred in particular situations (e.g. on a boat or airplane) and the patient was not able to test in that situation during the trial period. In two cases, electrical interference in the home prevented functioning of the display device. An additional eight patients tried to use the display device, but gave up because they found it too difficult, did not understand how to use it, or rated it negatively for other reasons. Overall, twenty six patients (63.4% of all subjects and 75% of all who tried to use it) wore the device and rated it positively, with 92% of these (56.1% of all) rating the helpfulness of the technology as at least ‘Moderately helpful’ for one or more symptoms of motion sickness or dizziness. This met the pre-stated criterion for feasibility to be demonstrated. There were twenty patients who had a diagnosis

of motion sickness or movement-induced symptoms, and for those patients who used the display device, 85% gave a positive rating for controlling their symptoms. The three patients who had a negative opinion expressed difficulty using the display device or they did not understand how to use the display device and did not use the display device regularly. Only 5 patients of the 26 who used it rated ease of use of the display device as 'Difficult but usable' and none rated it as 'Difficult and not usable'; again, meeting criterion for demonstrating feasibility of the display device. 46.2% of the 26 users rated comfort of the device as 'Very comfortable' or 'Comfortable'. There were no serious adverse effects reported. For those who were classified as 'Negative', nearly all comments had to do with inability to learn to use the device or its size and weight. Only one made a specific comment regarding inability to align the horizon with the visual cue. These results are shown, by individual patient, in Table I.

Seven patients used the technology during vestibular rehabilitation and had a therapist evaluation form completed. The therapist rated the desirability of use of the user-worn see-through display during vestibular rehabilitation as 'Extremely Desirable' in two patients and 'Quite Desirable' in the other five patients. Ease of use for the patient was rated as 'Simple and easy' for five of the seven patients and 'Difficult but usable' for the other two. Ease of use for the therapist was rated as 'Simple and easy' for four patients and 'Difficult but usable' for three patients.

In the early feasibility study, it appeared that patients who seemed to perform the poorest or did not benefit from the user-worn see-through display were those who had bi- or trifocal lenses, had poor computer skills or had panic and anxiety disorders.

Phase II Clinical Trial

Institutional Review Board approval was obtained for the clinical portions of the study.

Motion Intolerance Study

Methods

Subjects: Twenty five subjects with motion intolerance underwent trial use with the technology using the see-through display ("user-worn see-through display"). The seventeen women (68%) and eight men (32%) ranged in age from 18 to 62.8 years, with a mean age of 39.9 years (SD=12.8). All were in the 'White' racial category, and 36% were Hispanic or Latino. Most did not have other ear symptoms except one subject who also had a diagnosis of Meniere's disease. They all reported motion sickness when in a moving car or bus, and 72% indicated having symptoms when on a boat or airplane. Additionally, 36% noted symptoms on a moving train. The subjects indicated having had motion intolerance symptoms for an average of 9.7 years, with a large range from under one year to 20 years (many stated 'whole life'). They experienced a motion intolerance episode a median of ten times per month, ranging from twice a month to every day. More than half experienced severe or extremely severe nausea (52%) and inability to focus on a task (65%). Median ratings on these two symptoms were 'severe' (Table II). Median ratings for the other symptoms were in the 'moderate' range.

Materials: Subjects rated severity of symptoms before using the display device, including the symptoms of nausea, decreased cognitive ability, vomiting, unsteadiness, lack of concentration, and inability to focus on a task. They also completed a “Motion Intolerance Evaluation” questionnaire pre and post display device use. The pre-questionnaire asked them “When experiencing a typical episode of motion intolerance, how long does each of the following symptoms last?” This list of symptoms included: Cold “clammy” feeling, nausea, vomiting, awareness of movement, and general ill-feeling. Duration was indicated as hours, minutes, seconds, or ‘do not experience’. The post display device use questionnaire asked about duration of symptoms “When using the display device during a typical episode”. In addition, the post-questionnaire asked subjects to rate how helpful the display device was for each of the symptoms on a 5-point scale and whether they felt that the display device shortened the typical duration of their motion sickness symptoms, the ease of use of the display device and how comfortable it was to wear. They were also asked for comments or suggestions regarding the display device and to note any problems or adverse effects.

Procedures: After completing the pre-device use questionnaires, subjects were given basic instruction in use of the display device by the investigator. They then took the display device out of the clinic for use in situations that typically provoke their symptoms such as riding in the back seat of a car, in a plane or on a boat. Subjects were asked to spend as much time as possible (up to 4 hours) in symptom-provoking environments over a 3- to 4-week period. They were instructed to use the display device only in the presence of a companion who could act to safeguard them from the potential of losing balance and falling. After the trial period, the subjects completed the post-use questionnaire.

The criteria to determine that feasibility is demonstrated for the motion intolerance group as stated in the grant proposal were: 1) Fewer than 30% of the subjects rate ease of use of the display device as ‘Difficult and not usable’; 2) More than 20% of the subjects rate the impact of the display device as at least moderately helpful for one or more symptoms; and 3) Serious adverse effects are reported in fewer than 10% of patients.

Results—Table III shows the display device helpfulness ratings for six symptoms, including mean and median ratings as well as the percent of subjects who rated the display device according to helpfulness for each particular symptom.

Note that with the exception of one subject who rated the display device as not helpful for unsteadiness, all subjects felt it was helpful for all of these symptoms. Further, more than 70% rated it as quite or extremely helpful for each symptom, with 88% finding it quite or extremely helpful for lack of concentration during an episode of motion intolerance.

Additional motion intolerance symptoms were rated on the post-use Motion Intolerance Evaluation questionnaire. Table IV shows the distribution of these helpfulness ratings. No subjects rated the display device as ‘not at all’ helpful or even only ‘somewhat’ helpful for any of these three additional symptoms. And all but a small percentage found the display device ‘quite’ or ‘extremely’ helpful’.

Finally, the subjects were asked how long a typical episode of motion intolerance lasted prior to use of the display device and again with use of the display device. Many were unable to state “exact” durations, so the data were grouped as duration ‘none’ (no symptom), seconds, minutes, or hours. These data are summarized in Table V.

Prior to display device use, large percentages of subjects said that a typical episode lasted hours, and the remainder said minutes. A small percentage did not have one or more of the symptoms. With use of the display device during a typical episode, a large percentage of subjects said they did not have any of the symptoms. For example, although only 26% reported having no vomiting during an episode pre display device use, nearly all subjects said they had no vomiting with display device use (94.7%). Eighty nine percent (89%) had no cold “clammy” feeling when using the display device though only 17% lacked this symptom without display device use. Only a few subjects said they still had any symptom lasting an hour or more with use of the display device. Although many subjects still had “awareness of movement” with use of the display device (76.5%), the majority of these said it lasted only minutes (59%) or seconds (6%). Without the display device, awareness of movement was present in all subjects and 71% indicated that it lasted for hours, the remainder, minutes. A statistical test of these ordinal ratings showed statistically significant improvements in duration for all symptoms with use of the display device (see Table V).

In addition to these symptom ratings, all but one subject (i.e., 96%) rated the display device as “simple and easy to use”. The remaining subject rated it as “difficult but usable”. None rated it as “difficult and not usable”. Subjects rated the user-worn see-through display as “very comfortable to wear” (68%) or “comfortable” (32%). None rated it as “uncomfortable” or “very uncomfortable”.

Vestibular Rehabilitation Study

Methods

Subjects: Fifty subjects enrolling in a vestibular rehabilitation program were randomly assigned to use the technology with the see-through display (display device group) or not (control group). Table VI compares the demographics of the two groups. There were no statistically significant differences between the groups.

Materials: A patient data form was completed for each subject containing demographic, clinical history, and physical information. Pre- and post-rehabilitation, three assessments were performed:

Dizziness Handicap Inventory (DHI): This is a commonly used instrument to assess the functional impact of dizziness. The patient rates each of 25 items as ‘Yes’, ‘No’, or ‘Sometimes’. These answers are assigned values and a total score is obtained representing functional, emotional, and physical aspects of dizziness and unsteadiness.

Motion Sensitivity Quotient (MSQ): This test assesses the intensity and duration of symptoms with specific movements by the patient. The vestibular rehabilitation therapist evaluates sixteen movements. For each movement, intensity and duration

scores are added and a total score is computed. A formula is then used to calculate the MSQ.

Modified Clinical Test for Sensory Interaction in Balance (CTSIB): The CTSIB is performed by the therapist and assesses the patient's ability to use vestibular information in four static balance situations, including on a firm surface with eyes open and eyes closed and on a foam surface with eyes open and eyes closed. The time the patient is able to perform the task, up to 30 seconds, is recorded and the amount of sway and the patient's movement strategy are documented qualitatively.

In addition, a 'Patient' post-use questionnaire asked the display device group subjects to rate on a 5-point scale how helpful the display device was for each of three symptoms (spinning dizziness/vertigo, unsteadiness/imbalance, and lightheadedness). They rated the ease of use of the display device and how comfortable it was to wear. They were also asked for comments or suggestions regarding the display device and to note any problems or adverse effects.

A 'Therapist' post-use questionnaire asked the therapist to rate helpfulness of the display device for each of the three symptoms, ease of use of the display device, and how desirable the display device was for patients like the one being rated.

For both groups, the number of rehabilitation sessions was also recorded as the patient and therapist assessed each patient's individual needs and determined when to stop therapy.

Procedures: The patients were scheduled for vestibular rehabilitation in 30 to 60-minute sessions. For the display device group, the therapist instructed and supervised the patient in the use of the display device during what was otherwise a typical vestibular rehabilitation program. Specific goals for vestibular rehabilitation included: a) Improve balance, b) Reduce motion-provoked symptoms, c) Improve general conditioning through a more active lifestyle, d) Decrease the disability caused by dizziness or motion intolerance, and e) Speed recovery from an injury to the balance system. The vestibular rehabilitation program included a physical therapy evaluation (patient history, system evaluation, system integration, sensory organization, movement coordination, eye-head coordination, and motion sensitivity), visual sensitivity exercises, and balance retraining/compensation. Note: None of the rehab patients took the display device home, but only used it in the rehab environment.

Results

Assessments: Table VII provides the pre and post vestibular rehabilitation scores for the DHI, MSQ, and CTSIB for the display device and control groups.

Both groups improved significantly from pre to post on all three measures. The amount of change from pre to post did not differ significantly between groups. However, the number of sessions required to achieve these improvements was significantly fewer in the display device group (mean # visits = 4.2, SD=1.4) versus the control group (mean # visits = 6.0, SD=3.0) ($t=2.74$, $p=0.01$). Because the design of the study allowed patients to undergo as many sessions as necessary to achieve improvements, number of sessions required may be

the most direct measure of the difference the technology displayed in the user worn see-through display might make for vestibular rehabilitation.

Questionnaire: Table VIII shows the technology helpfulness patient and therapist ratings for three symptoms, showing the percent of subjects and therapists who rated the display device as of any help and as 'quite' or 'extremely' helpful for each particular symptom. Actual mean and median ratings can be found in Table IX).

Note that all subjects felt the display device was helpful for all of these symptoms. Further, more than half rated it as quite or extremely helpful for each symptom, with 75% finding it quite or extremely helpful for lightheadedness. The remainder of the subjects rated the display device as 'Moderately Helpful' for all symptoms, with the exception of three subjects (13%) who rated it as only somewhat helpful for unsteadiness.

The therapist also rated the helpfulness of the technology for each patient. In general, the therapist did not tend to rate the display device as helpful as did the patients. However, it was only rated as 'Not at all Helpful' for one subject on two of the three symptoms and was most often rated as 'Moderately Helpful'. The therapist also was asked for each subject how 'Desirable' the display device was for patients like the one being evaluated. In more than half of the subjects (61%), the therapist rated display device use as 'Quite' or 'Extremely' Desirable and never rated it as 'Not at all Desirable'.

In addition to these symptom ratings, subjects rated the display device as "simple and easy to use" (54%) or "difficult but usable" (46%). None rated it as "difficult and not usable". The therapist rated the display device as "simple and easy to use" for 48% of the patients and "difficult but usable" for 52%. Subjects rated the user –worn see-through display as "very comfortable to wear" (17%), "comfortable" (54%) or "uncomfortable" (29%). None rated it as "very uncomfortable".

Discussion

Visual fixation has been shown to suppress rotational or induced nystagmus. The importance of an actual visible target has been illustrated by patients who are able to suppress caloric nystagmus with a visible target very well, but can only partially suppress caloric nystagmus with an imaginary target or an afterimage. Prior studies also have shown optokinetic nystagmus suppression during fixation (44). An early study produced a model that accounts for the dominance of the visual system's response over the vestibular system's response at low frequencies (48). Fixation has also been shown to 'visually enhance' the VOR (46).

Gaze stabilization is improved when eye responses (OKN or VOR) are added to the head-related opto-collic or vestibulo-collic reflexes, especially during vestibular stimulation. In animals subjected to optokinetic stimulation and whole body oscillation in the yaw axis, the head was well-stabilized in space and moved to new positions in a stepwise manner, but in the absence of vision the head was not able to maintain a stable position (49).

Other studies have shown the benefits of using visual displays during vestibular rehabilitation. The observation that suppression of nystagmus reduced postural sway while standing on foam rubber is such an example (50).

Motion sickness / spatial disorientation and symptoms of dizziness are widespread, affecting all age groups and occurring in many career and social activities. It has been the goal of this study to develop and then evaluate an alternative method to prevent or combat the ill effects of motion sickness / spatial disorientation and enhance the balance response. Providing a visual artificial horizon with information about the user's head and body position in space with the use of a user-worn see-through display was theorized as a method to control or lessen the symptoms of motion sickness and prevent one from being spatially disoriented. It was also assumed that such technology would be of benefit in a vestibular rehabilitation environment.

Through NIH support, Phase I and II studies were conducted to first do a feasibility study of developing software technology to view through a see-through display device and obtaining preliminary test results in patients with any balance complaint. Secondly, the display device was modified extensively to become more miniaturized and efficient while continuing to evaluate patients with specific complaints of motion sickness as well as assess the technology with vestibular rehabilitation therapy. The results of the Phase I study showed that all of the criteria (i.e. regarding benefit confirmation, ease of use, and having few complications) for establishing feasibility were greatly surpassed. Eighty-five percent of all the patients with motion sickness or motion intolerance had positive responses when using the technology for controlling their symptom. Three patients in this group had trouble using the device due to technical reasons or did not understand how to use the device and therefore did not use it regularly. Of all the patients who wore the device and rated it positively, 92% rated the helpfulness of the technology as at least 'Moderately helpful' for one or more symptoms of motion sickness or dizziness.

In the Phase II study, all of the patients with motion intolerance or motion sickness rated the technology as helpful for all nine symptoms assessed, and 96% of patients rated the display device as simple and easy to use. When using the technology in the display device, the duration of symptoms was also significantly decreased. In patients undergoing vestibular rehabilitation, there were no significant differences in amount of change from pre to post-therapy on objective balance tests between display device users and controls. However, those using the technology in the display device required significantly fewer rehabilitation sessions to achieve those outcomes than the control group. Both patients and therapists perceived the technology in the user-worn see-through display to be helpful in the vestibular rehabilitation of patients with a variety of balance disorders. Ongoing and future studies will determine whether the device differs a great deal in effectiveness for patients with different etiologies of vestibular dysfunction or whether use earlier after onset of vestibular problems affects outcome.

The technology described here provides the user with some elemental benefits, including 3-axial orientation, and a stable artificial horizon with a vertex in the center. It helps determine head and body position in space (confirming location) and aids in suppression of the inner

ear responses when the otolith and semicircular canals have been stimulated, by visually fixing on the stable artificial horizon and vertex intersection. It also aids cervical proprioception by providing visual input about the head position. It confirms what the inner ear and the proprioception has sensed, when there is no visual reference or the visual information is misleading. The technology intent is to stabilize the abnormal response, correct any visual illusion and “assure the brain that the other normal sensory responses” are accurate. As a result of the fixation on a stable artificial horizon and vertex bar and using other visual information, the optokinetic reflex can also be stabilized and the vestibular ocular reflex can be enhanced. As the VOR is enhanced and proprioception is aided, head stabilization is enhanced.

This technology has shown significant benefit in a Phase II clinical study. It has dual use applications in other industries or environments where motion affects human performance, such as aviation where motion sickness and spatial disorientation continue to be problematic. Since completing the NIH studies reported here, follow-on studies in aviation have been performed in military and general aviation aircraft with the technology in a user-worn see-through display, but using different symbology with head or body movement. Also, when used in aviation, color directional indicators are used on the artificial horizon to indicate a normal or inverted flight status. A demonstration of the use in aviation can be seen by viewing the simulation at www.AdviTech.net. Brief experience has also been obtained in a simulator setting. All pilots voiced a positive opinion and none experienced simulator sickness. At the present time, the technology and the user worn see-through display device is being further modified and all the components miniaturized in preparation for further studies in aviation use, sponsored by the U.S. Air Force. Because of these potential military applications and the now ongoing evaluation sponsored by the Department of Defense, the device is subject to the International Traffic in Arms Regulations (ITAR) and more specific details of its function could not be described here.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
1st generation showing laptop computer, headband with see-through eye piece and helmet with positioning sensor (i.e. accelerometer) attached on top.

Figure 2.
Generation 2 of device development with helmet-mounted sensor and worn computer/
battery pack

Figure 3.
Generation 3 with the elimination of helmet and having mounting of positioning sensor (accelerometer) on headband.

Figure 4.
4th Generation of display device development, with head-mounted design.

Figure 5. 5th generation of display device with accelerometer in the mounting and also showing the lightweight, wearable power supply and computer for using the software technology.

Figure 6.
6th generation with the accelerometer incorporated in the mounting.

Table 1

Individual subject results from Phase I SBIR feasibility study

DIAGNOS	SEX	AGE	Overall opinion	Highest helpfulness rating	EASE	COMFORT	COMMENT
HELMET							
Motion sickness	Female	64	Positive	Extremely	Simple and easy	Uncomfortable	
Post VNS	Female	51	Positive	Somewhat	Difficult but usable	Uncomfortable	
Movement induced	Female	44	Positive	Quite	Simple and easy	Very uncomfortable	Hat was too heavy and did not fit my head
Movement induced	Female	38	Positive	Quite	Simple and easy	Very uncomfortable	It was letting me know I was not falling
S/P tumor removal	Female	57	Positive	Extremely	Simple and easy	Very comfortable	Stop dizziness, walk straight, hand writing
S/P tumor removal	Female	53	Positive	Extremely	Simple and easy	Uncomfortable	
Central	Female	75	Positive	Quite	Simple and easy	Comfortable	During therapy she had good response to wearing the unit, including better tolerance to head motion
HEADBAND							
Motion sickness	Male	40	Did not use	.	.	.	Did not have symptoms
Motion sickness	Female	44	Negative	.	.	.	Frustrated, difficulty keeping the horizon cue aligned horizontally
Motion sickness	Female	53	Did not use	.	.	.	Unable to test since problems were when flying - did not fly during trial period
Motion sickness	Female	70	Negative	.	.	.	Did not understand how to use the device
Motion sickness	Female	30	Negative	.	.	.	Difficulty with interference from the device
Motion sickness	Male	45	Did not use	.	.	.	Problems only on a boat, was unable to test on a boat
Motion sickness	Female	50	Did not use	.	.	.	Electrical interference in the home, no time to test in car
Motion sickness	Female	42	Positive	Extremely	Simple and easy	Comfortable	"This device was extremely helpful for motion sickness for me." (back seat of car, movies)
Motion sickness	Female	52	Positive	.	Difficult but usable	Comfortable	Wearing the 'headgear', rode 2 hours in S.U.V.'s 3rd seat and never developed motion sickness
Motion sickness	Female	37	Positive	Extremely	Simple and easy	Uncomfortable	I have used it at night and have been able to sleep much better without an attack
Movement induced	Male	52	Positive	Extremely	Difficult but usable	Comfortable	"This item was extremely beneficial for my hearing imbalance. I would purchase this equipment."
Motion sickness	Female	57	Positive	Extremely	Simple and easy	Comfortable	When I would begin to feel dizzy, the device would make me feel more stable
Motion sickness	Female	75	Positive	Moderately	Simple and easy	Uncomfortable	

DIAGNOS	SEX	AGE	Overall opinion	Highest helpfulness rating	EASE	COMFORT	COMMENT
Motion sickness	Female	40	Positive	Quite	Simple and easy	Comfortable	with use of the machine I was released from therapy early due to fast progressing
Motion sickness	Female	39	Positive	Extremely	Simple and easy	Comfortable	
Motion sickness	Male	34	Positive	Somewhat	Simple and easy	Uncomfortable	Allowed me to realize my head remains still
Movement induced	Female	44	Did not use	.	.	.	Had no time to test the device
Movement induced	Female	59	Positive	Extremely	Simple and easy	Comfortable	"Device has helped me. . .Much more able to cope with bouts of dizziness and no balance"
Movement induced	Female	55	Positive	Moderately	Simple and easy	Uncomfortable	"used for motion sickness in the car and it helped shorten the length of time of the symptoms."
Movement induced	Male	39	Positive	Quite	Simple and easy	Uncomfortable	air traffic controller. "When I put the HUD on in the office there was immediate relief."
Movement induced	Female	52	Positive	Extremely	Difficult but usable	Uncomfortable	The device appeared to release anxiety during use
Movement induced	Female	45	Positive	Extremely	Simple and easy	Uncomfortable	Benefited more when used during a lot of activity - shopping, walking
Anxiety disorder	Female	41	Did not use	.	.	.	Decided not to use, busy schedule, no time to wear it
Anxiety disorder	Male	60	Negative	.	.	.	Did not understand how to use the device
Post VNS	Female	57	Negative	.	.	.	Tried device but did not have much dizziness, felt impractical for her daily activities
Post VNS	Male	39	Negative	.	.	.	Having panic attacks, impatient, unable to use
Post VNS	Female	73	Negative	.	.	.	Unable to use machine, unable to learn process for wearing the unit
Post VNS	Female	62	Did not use	.	.	.	High voltage electrical interference near home, unable to use
Post VNS	Female	56	Positive	Extremely	Simple and easy	Very comfortable	"I used after surgery it was very helpful"
Post VNS	Female	65	Positive	Quite	Simple and easy	Comfortable	"Overall I feel that I improved very quickly with the help of this device."
Post VNS	Female	59	Positive	Quite	Difficult but usable	Very uncomfortable	Therapist rated 'Extremely Desirable' for patients like this one during vestibular rehab
Central	Female	80	Negative	.	.	.	Too complicated for patient to use (pt had blurred vision)
Central	Male	69	Positive	Extremely	Simple and easy	Very comfortable	Experienced relief from dizziness he had for over 5 years
S/P tumor removal	Male	42	Positive	Quite	Simple and easy	Uncomfortable	

Table II
Severity of motion sickness symptoms prior to use of eye display

Symptom	Mean *	Median *	Percent Severe or Extremely Severe **
Nausea	2.7	3.0	52.1%
Decreased Cognitive Ability	2.0	2.0	25.0%
Vomiting	2.1	2.0	31.6%
Unsteadiness	2.5	2.0	40.9%
Lack of Concentration	2.6	2.0	45.5%
Inability to Focus on a Task	3.0	3.0	65.2%

* 1=Mild, 2=Moderate, 3=Severe, 4=Extremely Severe

** Percentages based on only those answering the question; there were missing data for some items.

Table III
Device helpfulness ratings

Symptom	Mean [*]	Median [*]	Percent Any Help/Quite or Extremely Helpful ^{**}
Nausea	3.2	3.0	100% / 79.2%
Decreased Cognitive Ability	2.9	3.0	100% / 72.0%
Vomiting	3.1	3.0	100% / 70.0%
Unsteadiness	3.0	3.0	96% / 76.0%
Lack of Concentration	3.3	3.0	100% / 88.0%
Inability to Focus on a Task	3.1	3.0	100% / 75.0%

^{*} 0=Not at all Helpful, 1=Somewhat Helpful, 2=Helpful, 3=Quite Helpful, 4=Extremely Helpful

^{**} Percentages based on only those answering the question; there were missing data for some items.

Table IV

Distribution of Helpfulness ratings for additional symptoms

Symptom	Helpfulness Rating*				
	Extremely	Quite	Moderately	Somewhat	Not at All
Cold "clammy" feeling	60.0%	35.0%	5.0%	0.0%	0.0%
Awareness of movement	37.5%	50.0%	12.5%	0.0%	0.0%
General ill feeling	54.5%	36.4%	9.1%	0.0%	0.0%

* Percentages based on only those answering the question; there were missing data for some items.

Table V
Duration of symptoms during a typical episode without and with use of the device

Symptom	Percent of subjects*									
	Without Device (Pre)					With Device				
	None	Secs	Mins	Hrs		None	Secs	Mins	Hrs	
Cold “clammy” feeling	16.7%	0.0%	38.9%	44.4%		88.9%	0.0%	11.1%	0.0%	
Nausea	5.3%	0.0%	42.1%	52.6%		68.4%	0.0%	21.1%	10.5%	
Vomiting	26.3%	0.0%	36.8%	36.8%		94.7%	0.0%	5.3%	0.0%	
Awareness of Movement	0.0%	0.0%	29.4%	70.6%		23.5%	5.9%	58.8%	11.8%	
General ill feeling	5.9%	0.0%	29.4%	64.7%		64.7%	11.8%	17.6%	5.9%	

*. The improvements in duration rating were statistically significant for all symptoms (Wilcoxon Signed Ranks Test, all p's < .001 except Awareness of movement p < .002)

Table VI
Characteristics of the device and control groups

	Device (n=25)	Control (n=25)
Age: mean years (SD)	60.1 (11.7)	60.0 (14.5)
Sex: M/F %	48%/52%	36%/64%
Ethnicity [all were race = 'White']		
Hispanic/Latino	16%	20%
Not Hispanic/Latino	84%	80%
Diagnosis		
Labyrinthine dysfunction	48%	68%
Benign Positional Vertigo	12%	12%
Both of the above	16%	8%
Meniere's/endolymphatic hydrops	12%	12%
Post Vestibular nerve section	8%	0%
Motion intolerance	4%	0%
Duration of symptoms: mean mos. (SD)	28.6 (49.3)	29.2 (40.6)

Table VII
Test scores, mean (SD), before and after vestibular rehabilitation for the two study groups

	Device		Control	
	Pre	Post	Pre	Post
DHI*	41.8 (18.5)	10.6 (9.9)	50.1 (31.2)	24.5 (21.5)
MSQ*	26.5 (10.7)	4.5 (6.3)	34.9 (34.8)	13.4 (18.8)
CTSIB*	13.0 (2.7)	10.8 (1.7)	12.8 (2.7)	11.0 (2.2)

* Lower score is better performance

Table VIII
Device helpfulness of symptoms according to patient and therapist ratings*

Symptom	Patient Percent Any Help/Quite or Extremely Helpful**	Therapist Percent Any Help/Quite or Extremely Helpful**
Spinning Dizziness/Vertigo	100% / 60%	100% / 33%
Unsteadiness/Imbalance	100% / 52%	95% / 38%
Lightheadedness	100% / 75%	93% / 71%

* 1=Not at all Helpful, 2=Somewhat Helpful, 3=Moderately Helpful, 4=Quite Helpful, 5=Extremely Helpful

** Percentages based on only those answering the question; there were missing data for some items.

Table IX
Device helpfulness for symptoms according to patient and therapist ratings

Symptom	Patient		Therapist	
	Mean *	Median *	Mean *	Median *
Spinning Dizziness/Vertigo	3.8	4.0	3.3	3.0
Unsteadiness/Imbalance	3.5	4.0	3.3	3.0
Lightheadedness	4.0	4.0	3.8	4.0

* 1=Not at all Helpful, 2=Somewhat Helpful, 3=Helpful, 4=Quite Helpful, 5=Extremely Helpful

** Percentages based on only those answering the question; there were missing data for some items.