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Galvanic Vestibular Stimulation Headset balancing robust and simple administration with subject comfort: A Usability Analysis*

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Abstract— **The vestibular system is responsible for spatial orientation and stability. It can be stimulated with a weak electric current, a mechanism known as Galvanic Vestibular Stimulation (GVS). Typical GVS administration involves holding down electrodes on the mastoids either with a strap (or bandage) wrapped around the head or by positioning a self-adhesive electrode at the mastoid location. While the latter approach is simple to administer, it is limited to exposed skin application as hair impedes adhesion. The reduced access area limits total current delivery allowable due to increased skin sensation. Accordingly the former approach is more typically employed but leads to inconsistent and inaccurate electrode placement. As current flow pattern is directly influenced by electrode position, this results in inconsistent stimulation and replicability issues. The primary goal of this study was to test usability and comfort while developing a GVS-specific headset named "Mastoid Adjustable Robust Stimulation (MARS)" compared to a conventional elastic strap. We recruited 10 subjects, 5 operators and 5 wearers, and tested usability using the System Usability Scale (SUS) as well as comfort levels over a typical 20 minute stimulation session. Additional questions were answered by the operators and wearers on visual appeal, interference, slippage, and electrode placement. The results of this testing guided the development of a final version meeting our requirements of robustness, simple to administer, and subject comfort.**

Clinical Relevance—**This study introduces a headset for routine Bilateral-Bipolar GVS administration that is highly usable and ensures both flexible and consistent electrode application over typical approaches.**

I. Introduction

The vestibular system is composed of the semicircular canals that sense angular head velocity and the otolith organs that transduce linear acceleration and gravity. Together these are responsible for spatial orientation and postural stability. It is possible to stimulate the vestibular system by applying a weak electric current, a mechanism known as Galvanic Vestibular Stimulation (GVS). GVS is used to explore vestibular sensory signal processing in both healthy and diseased populations and to diagnose and treat vestibular syndromes [1].

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Various electrode montages are used for GVS. Bilateral-Bipolar GVS is one of the most common montages in which electrodes are placed on the mastoids for applying current to vestibular afferent neurons that extend into that region [2,3]. Bilateral-Bipolar GVS has been used for many applications, such as for treating bilateral vestibulopathy [4], improving motion perception in healthy subjects [5] and recalibrating pathological tilt of stroke patients [2]. Researchers working with GVS typically use two approaches to hold electrodes at the mastoid locations. The first involves using an elastic strap / bandage wrapped around the forehead and around the electrodes and in a way that does not constrain subject head movement [6]. Given that the mastoid locations are at a relative lower level, the strap is held at an angle from the axial plane at the level of the eyes (i.e. higher at the front and lower at the back). This results in the risk of the elastic strap lifting off the head (**Figure 1 A** and **B**). As a result, researchers have to balance wrapping the strap around the forehead at an optimal level that is low enough to prevent this from happening (balancing subject head curvature) while ensuring the mastoid electrode arrangement is not disturbed and does not shift superior from the desired locations. Additionally, they have to ensure that the strap is fastened tightly enough, balancing secure administration and the tension due to the tightness felt by the subject. Depending on the thickness and the type of the strap used, the final electrode position may be obscured to varying levels hampering consistent and repeatable electrode placement. The second approach uses hydrogel-based or pre-gelled self-adhesive electrodes that do not need a holding mechanism but require access to exposed skin to make reliable contact [7]. As the exposed areas are generally restricted for most subjects, these electrodes are typically small resulting in reduced electrode skin contact area. With contact area being a major factor in stimulation tolerability, the adhesive electrode approach limits researchers to low current intensity applications.

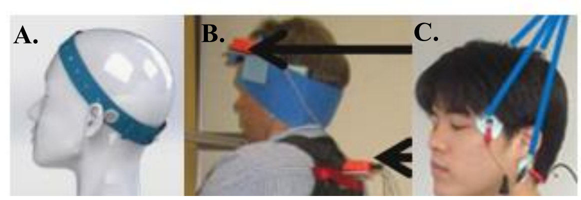

Figure 1: Typical approaches to hold GVS electrodes (Left: Elastic Strap; Middle: Bandage (Obtained from [6]); Right: Self-adhesive electrode (Obtained from [7])

Towards the goal of addressing these limitations, we first developed an initial prototype of a GVS-specific headset incorporating our “High-Definition (HD)” electrode approach [8]. This specific electrode material - conductive gel combination approach enables delivering high intensity current (upto 4 mA) using smaller area electrodes (~6 cm^2). We note the development of a four-pole (or four-electrode) GVS headset by Krebs et al. but with less emphasis on flexibility of mastoid electrode positioning and to accommodate larger range of head sizes [9]. The most important design inputs (or constraints) of this prototype involved: 1) ability to connect to two electrodes; 2) multiple mastoid electrode positioning options; 3) secure fit; 4) subject comfort; 5) easy to administer; 6) head size adjustable and 7) maintenance of scalp contact. Accordingly our solution included three main sections: forehead band, an adjustable slider, and a 3-position electrode loading section (**Figure 2**). We performed an usability analysis involving 10 participants (five ‘operators’ and five ‘wearers’) using the System Usability Scale (SUS) [10, 11] and updated the initial design based on the test results. We then repeated the usability analysis on the same participants using the revised design. We further posed additional questions to both operators and wearers (as appropriate) to gage headset robustness, comfort, interference to other accessories, and visual appeal during both rounds of testing.

II. Methods

<u>Headset Development</u> We pursued a typical iterative design workflow beginning with initial sketches realizing required design inputs. This was followed by 3D CAD modeling and 3D printing and associated machining to verify early concepts. These aforementioned steps were repeated until Headset

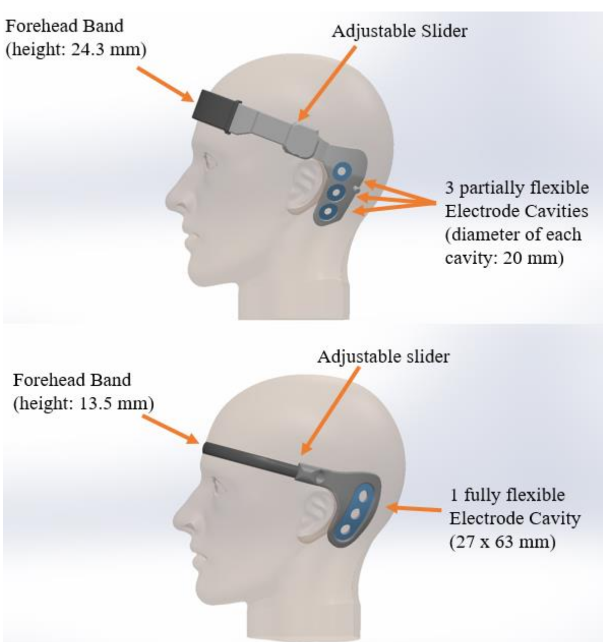

Figure 2. Functional elements of the GVS-specific headset (**Top:** Headset 1; **Bottom:** Headset 2). Each approach included 3 different electrode positions, a slider for adjusting to different head sizes and a forehead band. Headset 1 had a wider band and an independent cavity for each electrode surrounded by rigid material. Headset 2 had a narrower forehead band with one fully flexible cavity comprising of elasticized material with 3 openings.

designs were considered suitable to proceed to usability testing. All prototypes were printed using a Form 2 SLA printer (Formlabs, MA, USA) at a layer thickness of 100 microns. The final choice of materials along with comparison of relevant metrics to the conventional strap are noted below.

TABLE I. Weight, size, and material comparison across the different GVS headgear approaches

	Conventional Elastic Strap	**Headset 1**	**Headset 2**
Weight	17 g	136 g	74 g
Arc radius	N/A	61 mm	61 mm
Materials	Latex free Polyisoprene	Tough 2000	Tough 2000

<u>Usability Testing</u>
Each operator placed the elastic strap on one randomly assigned wearer and responded to the SUS survey (**Table II**). The final SUS scores were calculated from their responses using standard approaches [11]. Operators were also asked whether they agree or disagree with the statements, “The electrodes in this strap are accurately placed on the mastoids” and “The electrodes shift with head movement”. Wearers wore the strap for 20 minutes and reported the level of discomfort on their forehead, temples, mastoids, ears and overall discomfort every five minutes. They were asked if they agree or disagree with the statements, “This strap is visually appealing” and “My hair or head-worn accessories interfere with placement of this strap” (**Table II**). This procedure was repeated with the first GVS headset on the same subjects with the same questionnaires. Based on the results of the testing, we developed an improved GVS headset (**Figure 2**) and repeated the above tasks on the same subjects with the same questionnaires. The wearers’ head circumferences ranged from 54 cm to 59 cm.

TABLE II. System Usability Scale (SUS) used and additional questions posed to the operators and the wearers

<table>
<tr><td colspan="5">SUS for the Operators (1-strongly disagree, 5- strongly agree)</td></tr>
<tr><td colspan="2">I think that I would like to use the product frequently.</td><td colspan="3">I thought there was too much inconsistency in this product.</td></tr>
<tr><td colspan="2">I found the product unnecessarily complex.</td><td colspan="3">I would imagine that most people would learn to use this product very quickly.</td></tr>
<tr><td colspan="2">I thought the product was easy to use.</td><td colspan="3">I found the product cumbersome.</td></tr>
<tr><td colspan="2">I think that I would need the support of a technical person to be able to use the product.</td><td colspan="3">I felt very confident using the product.</td></tr>
<tr><td colspan="2">I found the various functions in the product were well integrated.</td><td colspan="3">I needed to learn a lot of things before I could get going with this product.</td></tr>
<tr><td colspan="5">Additional questions for Operators (1-strongly disagree, 5-strongly agree)</td></tr>
<tr><td colspan="2">The electrodes shift with head movement</td><td colspan="3">The electrodes are precisely placed on the mastoid</td></tr>
<tr><td colspan="5">Comfort Rating for Wearers (1-no discomfort, 5-extremely uncomfortable)</td></tr>
<tr><td>Mastoids</td><td>Ears</td><td>Forehead</td><td>Temples</td><td>Overall</td></tr>
<tr><td colspan="5">Additional Questions for Wearers (1-strongly disagree, 5-strongly agree)</td></tr>
<tr><td colspan="2">Bodily worn accessories (hearing aids, jewelry, eyeglasses, long hair etc.) interfere with holding mechanism.</td><td colspan="3">This device is visually appealing</td></tr>
</table>

III. RESULTS

We observed increases in both individual and total SUS scores going from elastic strap, Headset 1 to Headset 2. (**Figure 3 A**). As expected, the strap scored the lowest due to the need to adjust the angle of the strap and position of the electrode holders. Headset 1 had a slightly better usability score but due to its higher relative weight, bulkiness, and lack of flexibility, it was more difficult to position properly than Headset 2. As a result, Headset 1 received a lower usability

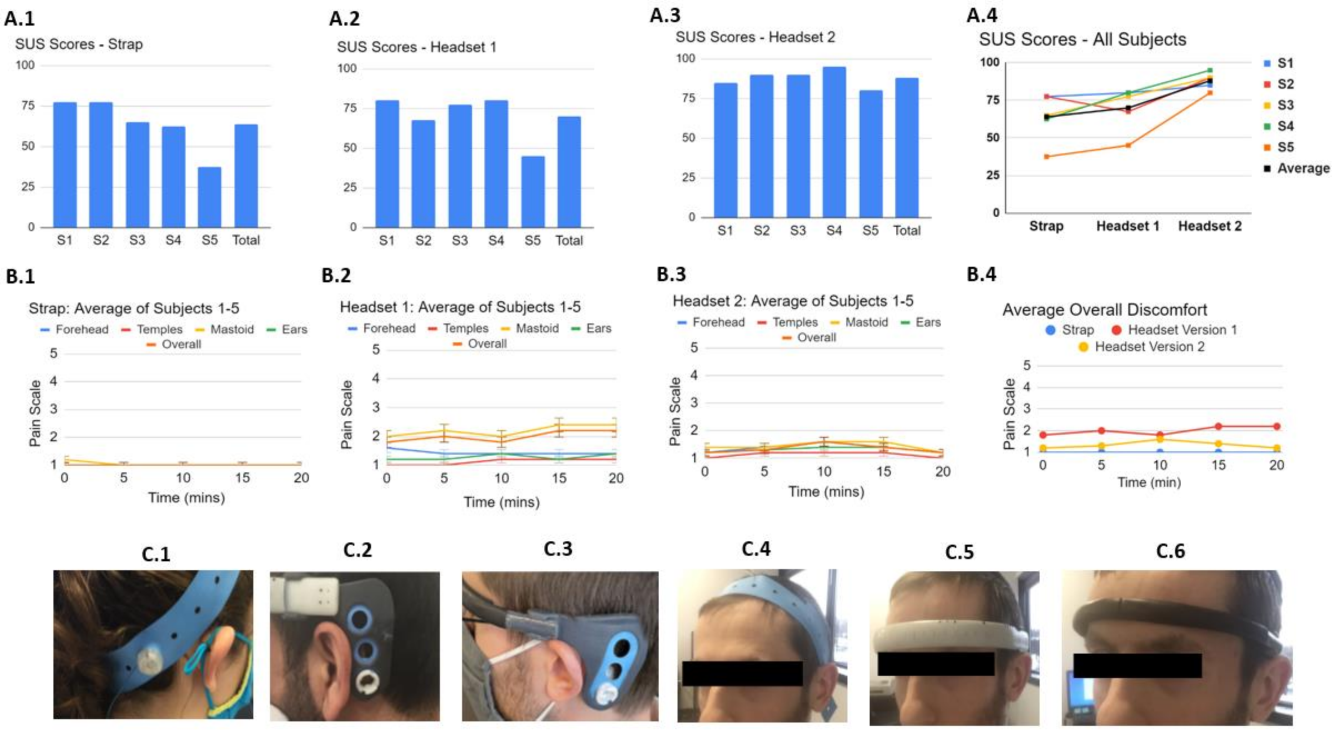

Figure 3. A.1-A.4. Individual and Total SUS scores. **B.1-B.4**. Individual and Average comfort ratings. **C.** Representative participant images showing the physical headgears tested**. C.1, C.4.** Elastic head strap. **C.2, C.5.** Headset Version 1. **C.3., C.6**. Headset Version 2.

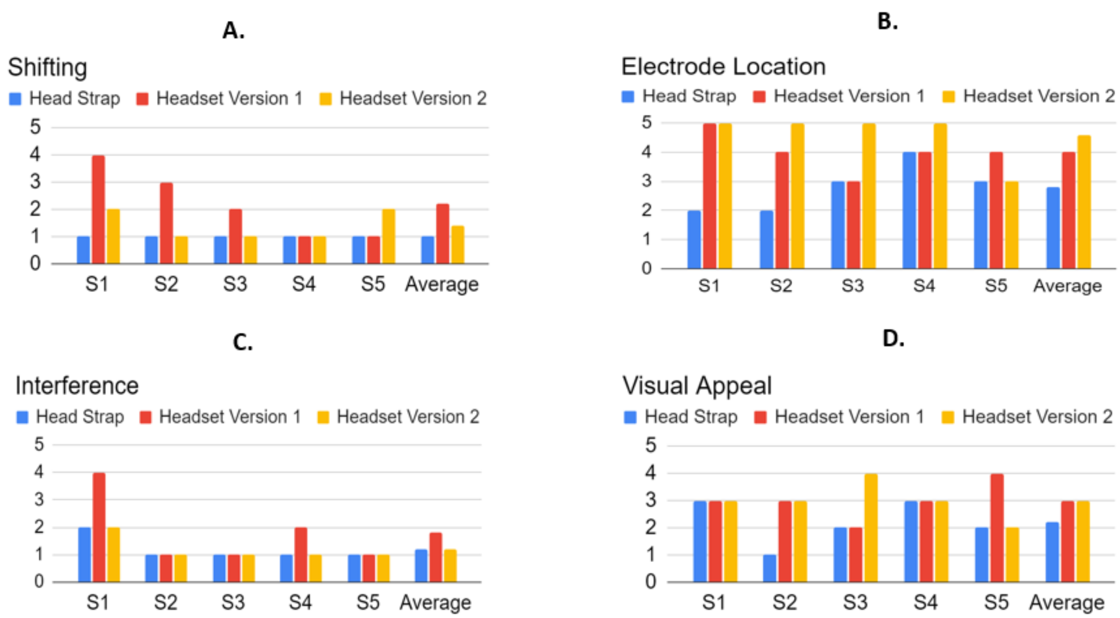

Figure 4: Individual and average ratings for additional questions posed to operators (headgear shift (A) and electrode location (B)) and wearers (interference (C) and visual appeal (D)). Note: While lower scores are desirable for headgear shift, higher scores are desirable for electrode location metric.

score. Headset 2 was deemed to have an optimal design/ features, weight, and flexibility resulting in the greatest usability score. The comfort ratings confirmed the expected ideal rating using the strap approach (pain scores of 0 and 1) as the inherent elasticized approach generates minimal pressure on the head (**Figure 3B.1**). Headset 1 indicated non-ideal pressure (mild discomfort) at the mastoid and ear regions over a 20 minute session (**Figure 3B.2**). Headset 1 was found to marginally shift over time primarily due to its weight and interfered with hair/ head-worn accessories (**Figure 4**). These drawbacks served as motivation behind the development of another headset. Upon repeating the usability evaluation with the revised headset, we observed close to outstanding usability (88) and comparable scalp comfort with respect to the strap (average score ~1). The usage of a single cavity comprising of an elasticized material with 3 slits **(Figure 2**) resulted in reduced scalp pressure due to the removal of the three fixed rigid material supports. This design change also helped reduce overall weight of the headgear and restricted shifting due to its weight. This naturally culminated in a much improved usability score. The narrower forehead band helped avoid interference with bodily worn accessories resulting in comparable interference ratings to the elastic strap. As expected, purely from the visual aesthetic standpoint, Headset 2 was rated exactly same as Headset 1, as the core design elements and finish was not altered. Headset 2 did however improve upon every other relevant metric over Headset 1 – i.e. lower interference, better (precise) electrode location, and lesser shifting while maintaining the same visual appeal.

IV. DISCUSSION

After reviewing thousands of studies, Bangor and colleagues found the mean SUS score to be a 70.5 with 25% of results to be above 77.8 [10]. Accordingly, the rubber strap had a usability score below average (64), Headset 1 slightly above average (71) and Headset 2 was rated in the top quartile (88). Furthermore, accuracy of electrode placement was found to be much higher with either headset. This was expected as the inherent "L-shaped" design wrapping around the ear provide much better access to the mastoid locations than the elastic strap. Additionally, as expected both headsets were rated to more visually appealing than the conventional strap due to the more finished appearance. While the impact of electrode shift has not been studied in GVS- whether it be clinically or via current flow simulation, it is rational to maintain consistent placement [12, 13]. The results of our study therefore motivate the adoption of Headset 2 for routine Bilateral-Bipolar GVS application over the elastic strap. The cost of slightly more scalp pressure is likely negligible for most participants. Additionally, subjects can be expected to habituate to the mild scalp pressure over multiple sessions. The concern with respect to marginal higher headgear shift (with head movement) is balanced with increased precision in positioning electrode over mastoids. Moreover, the headgear shift metric reflected the *in-session* shift from its original location (at the beginning of the session) over a 20 minute session. By design, the conventional strap approach results in holding the mastoid electrodes in a somewhat arbitrary fashion although guided by the experience of a trained GVS administrator. So while Headset 2 may result in a negligible headgear shift over time in-session, it presents potential for consistent and reproducible placement for a subject across multiple sessions. For instance, the operator may deem slot number 2 to the ideal placement for a particular subject in the first session. For subsequent sessions, the operator can simply repeat the same slot position for the subject. Taken together with the critical benefit of Headset 2 in ensuring no risk of lifting off (robustness), associated high SUS score, the potential benefit far outweigh the drawback. Moreover, given the potential for home self-administered GVS application in the future, the presented headset approach may pave the way for such a feasibility attempt. Finally, we note that while the proposed headset only presents a solution for a particular electrode placement, core design elements presented here (forehead band, adjustable slider, electrode cavity, etc.) can be extended for other placements. Accordingly, headset development incorporating electrodes on the forehead and temples should be attempted in the future.

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