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A non-invasive vestibular prosthesis by means of online, low-intensity noisy galvanic vestibular stimulation (nGVS)

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Chronic loss of vestibular sensation (bilateral vestibulopathy) results in sustained postural instability during standing and walking, especially in situations where other sensory sources are not available, e. g., while walking in darkness or on uneven ground [9]. Consequently, patients with limited vestibular feedback suffer from reduced mobility and live with an increased risk of falling [11]. Disturbed vestibular function is not limited to peripheral bilateral vestibulopathy (BVP) but can also be caused by central dysfunction in neurodegenerative disorders such as Parkinson's disease [8].

Current therapeutic options in vestibular hypofunction are mainly based on vestibular rehabilitation therapy with training of balance and eye-head coordination by physical therapists **(Fig. 1A)**. However, in most cases the training only results in partial relief of symptoms [10]. Two new therapeutic alternatives are currently under development that directly target vestibular dysfunctions. The first approach consists of a vestibular implant **(Fig. 1B)**, which has shown promising effects in alleviating postural symptoms and other signs of vestibular hypofunction in selected patients [1]. Nevertheless, the advantages of such an invasive vestibular implant must be carefully balanced against the surgical risks and potential side effects. The second new therapeutic approach aims to amplify residual vestibular function in patients through non-invasive noise stimulation of the vestibular periphery **(Fig. 1C)** [12].

Non-invasive noisy galvanic vestibular stimulation (nGVS) is a technique using the application of weak sensory noise through subthreshold electrical stimulation to enhance vestibular information processing **(Fig. 2)**. This method has been shown not only to facilitate residual vestibular perceptual and sensorimotor functions in patients with BVP, but also to stabilize their impaired balance capabilities during both static and dynamic postural tasks [4, 13, 14]. Additionally, nGVS has been shown to be effective in reducing body sway in patients with Parkinson's Disease (PD) [6, 15]. However, there is currently little evidence whether nGVS therapy also has a positive effect on the second significant functional domain of the vestibular system, i.e. gaze stabilization. Furthermore, the therapeutic effect of nGVS has been predominantly tested in short-term applications in laboratory settings. The feasibility and effectiveness of the approach in long-term use in everyday patient life remain unclear. These two unexplored aspects of the new treatment approach will be systematically investigated in this project. In the project presented here, the use of nGVS is intended to be extended beyond posture to other vestibular functional domains. Further, it is planned to transfer the therapeutic strategy from laboratory measures to the everyday use for patients.

Patients with chronic vestibular dysfunction face difficulty maintaining their gaze stable while walking and report image blurring and oscillopsia [2]. There is some evidence that nGVS can also improve vestibulo-ocular reflex function [3, 7]. However, whether and how these effects affect the impaired gaze regulation of patients during walking remains unclear. As part of the project, we systematically investigate the effect of nGVS on gaze stabilization. This involves examining both the interaction of the trunk, head, and eye (vestibulo-ocular reflex function) as well as the resulting visual performance (dynamic visual acuity) during locomotion with noisy or sham stimulation. The investigations will take place both in the laboratory on the treadmill and in the open field during natural locomotion under different lighting and surface conditions. Furthermore, a comprehensive

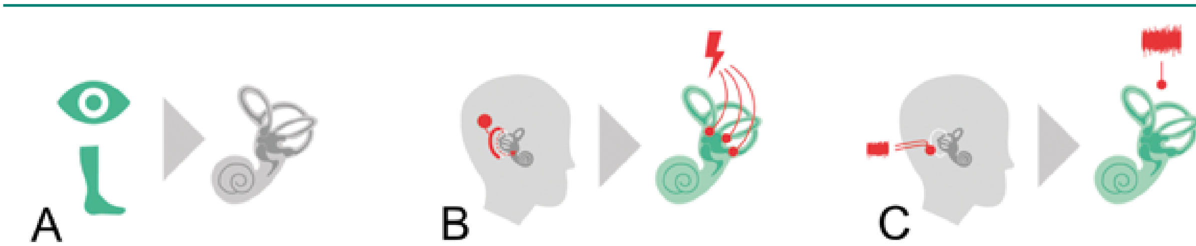

Figure 1. Vestibular hypofunction therapy approaches. **A** physical therapy, **B** invasive vestibular implant, and **C** noisy galvanic vestibular stimulation

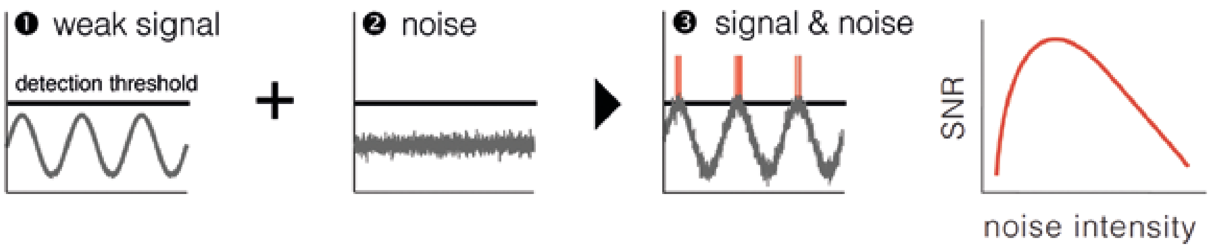

Figure 2. Schematic view on the mode of action of subthreshold noise on sensory functions (like nGVS for the vestibular system) based on the principle of stochastic resonance

assessment of the everyday effects of gaze dysregulation using questionnaires will be done.

In a second project phase, the translation of the treatment approach into everyday use will be attempted. Previous study results provide little evidence for long-lasting aftereffects of the stimulation [5]. Therefore, it is very likely that the stimulation will need to be administered continuously in order to effectively stabilize patients in postural tasks. For this purpose, a wearable stimulation device suitable for everyday use is being developed in the project with the support of an industry partner. The device must meet several requirements to get applicable in patients: One of the most important requirements is the wearability/ portability of the device and subsequently the energy efficiency. After the device has been developed, its effectiveness, practicability, and potential side effects of the treatment will be investigated in a small clinical study involving patients with BVP and patients with PD. The study participants will receive blinded and randomized nGVS treatment and sham treatment for one week each. The stimulation effect on mobility and gait function will be assessed using wearable mobility and gait sensors. The impact on gaze stabilization, quality of life, and the risk of falling will be systematically examined using questionnaires.

In conclusion, the presented research will enhance the knowledge on physiology behind the new therapy approach (nGVS). This holds true for effects on postural instability as well as effects on other domains (gaze stabilization). Additionally, within the project, initial steps will be taken towards a wearable stimulator as a therapeutic device for everyday use in patients with vestibular malfunction.

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