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Stefan Kampusch*, Eugenijus Kaniusas, Florian Thürk, Dorian Felten, Ibolya Hofmann and Jozsef C. Széles

Device development guided by user satisfaction survey on auricular vagus nerve stimulation

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Abstract: Development of wearable point-of-care medical devices faces many challenges. Besides technological and clinical issues, demands on robustness, miniaturization, and user interface design are of paramount importance. However, a systematic assessment of these non-functional but essential requirements is often impossible within the first product cycle. Later, surveys on user satisfaction with existing devices and user demands can offer significant input for device re-development and improvement. In this paper, we present a survey on satisfaction with and demands for a wearable medical device for percutaneous auricular vagus nerve stimulation (pVNS). We analyzed 36 responses from patients treated with pVNS and five responses from experienced physicians in order to devise a future concept of pVNS. Main shortcomings of a current pVNS device were identified to be lacking water resistance and mechanical robustness, both impairing daily activities. Painful sensation during pVNS application, unwanted side effects like skin irritations and strongly varying perception of the stimulation were reported. Results urge for more patient self-governance and an (automatic) adjustment of the stimulation to the current physiological state of the patient. Attained results support a strategic approach for future developments of pVNS towards personalized health care.

Keywords: auricular vagus nerve stimulation; medical device development; personalized healthcare; satisfaction; survey.

1 Introduction

Electrical stimulation of the vagus nerve is increasingly recognized as an effective treatment in a variety of disorders. Today, invasive stimulation techniques targeting the cervical vagus nerve are utilized, e.g. in the treatment of refractory epilepsy [1]. Remarkable results can be achieved, but the method comes with risks of major surgery and side effects. Recently, a more subtle stimulation method has been investigated, which aims at the modulation of the auricular branch of the vagus nerve in the ear [2]. The percutaneous auricular vagus nerve stimulation (pVNS) advantageously avoids risks/costs of surgery and allows for a selective stimulation of afferent nerve fibers [3]. pVNS is already in clinical use for $>$10 years mainly for pain management and the treatment of peripheral perfusion dysfunction.

Current single-use pVNS devices apply three needle electrodes in the auricle to stimulate afferent nerve fibers [2]. An additional reference electrode is required, which is affixed by an adhesive at the neck of the patient (see Figure 1A). Stimulation is performed continuously over several days and can be extended by changing the device each week. However, the current pVNS treatment is suboptimal. The implemented fixed stimulation pattern leads to undesired effects due to highly patient-specific reactions to pVNS. Recent studies indicate that the stimulation pattern affects therapeutic outcome and emphasises the need for a patient-specific stimulation pattern adjustment [3, 4]. Our personal communication with patients has also revealed deficiencies in wearability and operability of current pVNS devices.

For these reasons, we focus on the development of a novel personalized and body-worn pVNS device addressing these limitations, especially the high inter-patient variability. Focusing on personalized healthcare, it is essential to consider not only technological and clinical aspects during the early design phase, but also experiences and demands of users, i.e. patients and operators. In this context, patient surveys on satisfaction with medical devices, e.g. in the field of feedback controlled upper arm prostheses

***Corresponding author: Stefan Kampusch,** TU Wien, Institute of Electrodynamics, Microwave and Circuit Engineering, Research Group Biomedical Sensing, Gußhausstraße 27-29, A-1040 Vienna, E-mail: stefan.kampusch@tuwien.ac.at
Eugenijus Kaniusas and Florian Thürk: TU Wien, Institute of Electrodynamics, Microwave and Circuit Engineering, Research Group Biomedical Sensing, Gußhausstraße 27-29, A-1040 Vienna
Dorian Felten, Ibolya Hofmann and Jozsef C. Széles: Medical University Vienna, University Clinic for Surgery, Spitalgasse 23, A-1090 Vienna

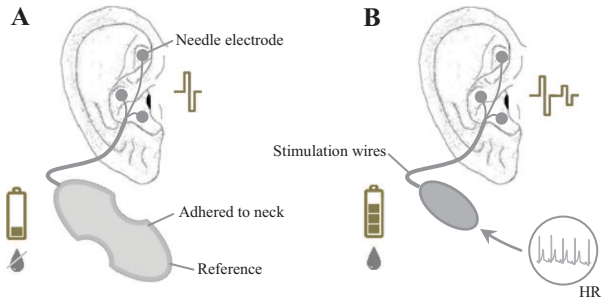

Figure 1: Schemes of body-worn medical devices for percutaneous auricular vagus nerve stimulation using three needle electrodes in the ear. (A) Current concept with simple and fixed stimulation parameters, limited battery life-time and adhesive reference electrode. (B) Future concept with individualized, feedback controlled stimulation parameters (e.g. by feedback of heart rate HR), extended battery life-time and watertight casing.

[5], can provide tremendous insight into current deficiencies of treatment while creating essential input for device development and improvement. Here a survey is presented with the major goal to identify aspects of improvement of current pVNS treatment in terms of improved stimulation methods as well as refined user interface, mechanical design, and application.

2 Method

The developed survey for patients (n = 40) and operators (n = 5, physicians) includes 61 questions on general data, satisfaction with current treatment, and demands for future treatment. Data on current treatment (Figure 1A) included satisfaction with pVNS treatment, effects and perception of treatment, and satisfaction with the device application. Data for future pVNS treatment (Figure 1B) was assessed, which concerned the device design, application and operation.

The respondent's statements were measured using single-choice or multiple-choice questions, five-level ordinal scales and five-level or ten-level interval scales. Open ended questions were used when closed questions could not account for the variety of expected responses. This also allows the respondents to bring in new ideas for development. The questions were designed for easy comprehension. Pretesting of the questionnaire was based on qualitative laboratory techniques. Single questions were evaluated by subject matter experts [6]. The completed questionnaire was evaluated in an expert review [7] and revised by a social scientist experienced in survey design. The questionnaire was filled by three users applying concurrent think aloud, follow-up probing and debriefing questions [8, 9].

Users were recruited from a special outpatient clinic at the Medical University Vienna, University Clinic for Surgery. Patients were included if they underwent at least one treatment with pVNS (P-Stim, Biegler GmbH, Austria). Surveys were distributed in paper form. All data processing and statistical analysis were performed using MATLAB R2014b (The Mathworks Inc., Natick, MA, USA). When appropriate, responses to interval scales are represented by mean ± standard deviation.

3 Results

From 40 questionnaires for patients 36 (90%) were completed and fulfilled the inclusion criterion. In addition, five questionnaires were completed by operators aged 32.25 ± 12.9 years (50% female) having experience with pVNS therapy of at least 6 months. Responding patients were aged 57.2 ± 17.4 years (25% female) and suffered from chronic lower extremity ulcers (41.7%), chronic pain (33.3%), neurological disorders (25%), acute pain (19.4%), peripheral arterial occlusive disease (8.3%) and other diseases (8.3%) with a history of the disease of 6.1 ± 6.4 years (the total range from 2 weeks to 28 years). Treatment durations of included patients range from 1 week up to 10 years. 48.6% of patients tried other therapies before pVNS treatment with a satisfaction rate of only 22.4%.

3.1 Satisfaction with therapy

Considering overall treatment satisfaction, 82.3% of patients are (very) satisfied, 17.6% sign for neutral and nobody is very dissatisfied or not satisfied. Patients report an improvement in life quality due to pVNS therapy of 1.7 ± 2.8 on a 10 point interval scale from very bad to very good.

Although satisfaction is high, 41.2% of all patients report unwanted side effects (at least once during treatment). This mainly accounts for skin irritation at neck (60%) and ear (26.7%), pain (26.7%), inflammation (20%), bleeding at ear (13.3%), and slight dizziness (13.3%).

Concerning activities of daily living (Figure 2), the device application dominantly influences personal hygiene and sleeping, where 31% and 21.4% of the patients report (very) negative influence, respectively.

Only 51.6%, 56.3% and 54.9% of all patients are (very) satisfied with the application of the needle electrodes, wires and the device itself, respectively (Figure 3).

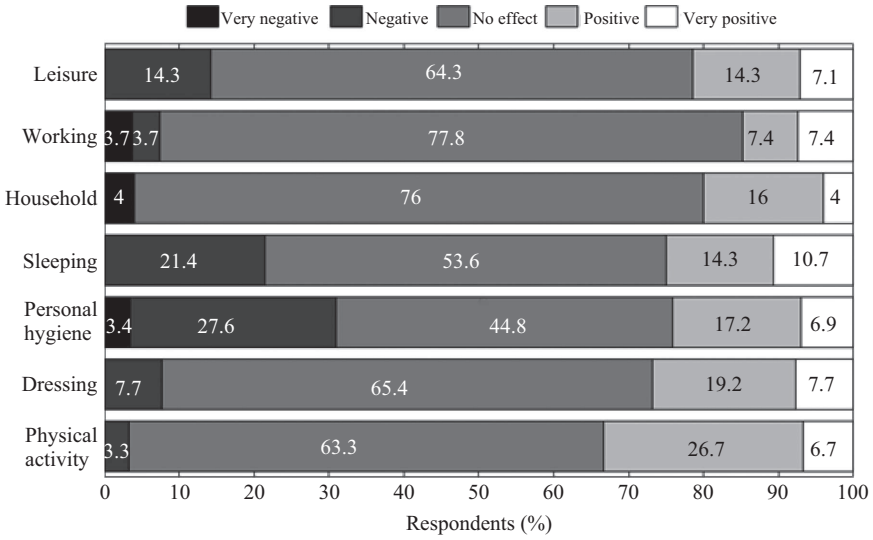

Figure 2: Influence through current pVNS application on patients' activities of daily living.

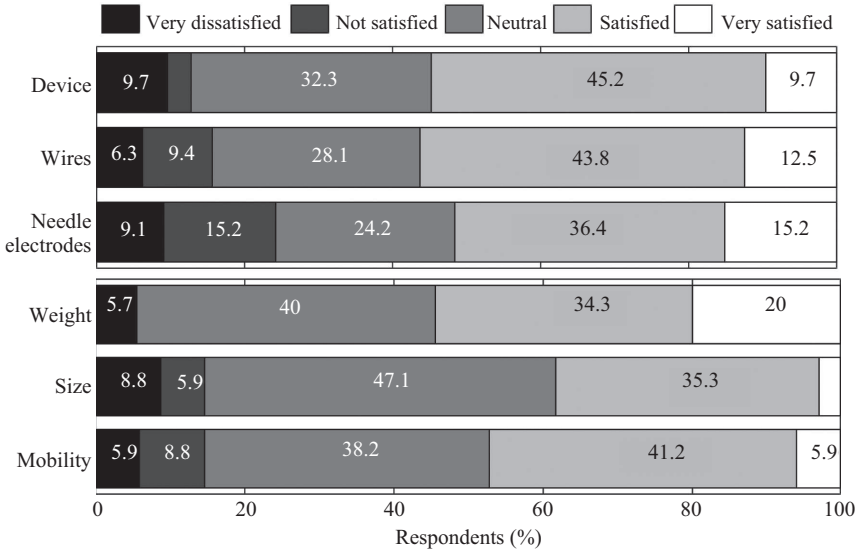

Figure 3: Patient satisfaction with the current pVNS device: device, wire, and needle mounting as well as weight and size of the device and mobility with the device.

Mechanical characteristics of the device seem to be satisfactory (Figure 3). Patients prove a good mobility with the applied device, 85.3% are neutral or (very) satisfied. Operators are most unsatisfied by the placement of the wires (too stiff) and the device with 33.3% each. Application of needles was reported to be painful on an interval scale from 0 to 10 (no pain to intolerable pain) with 3.5 ± 1.4 (Figure 4). On the same scale, patients perceive the initial stimulation amplitude as 4.7 ± 1.5 (Figure 4). Only 5.9% of all patients report a desirable comfortable feeling of stimulation. A largely varying perception was observed, which may influence therapeutic outcome heavily.

Concerning the therapy duration, a continuous stimulation over about 4 days is aimed at with the current pVNS device. Mean duration of the perception was answered to be 3.4 ± 0.9 days, whereas patients report a decrease in sensibility over longer periods of treatment. In 70.5% and 48.8% of all cases the device and the needles detached before 4 days at least once, respectively. In 25.7% of cases patients accidentally detached the device during activities of daily living.

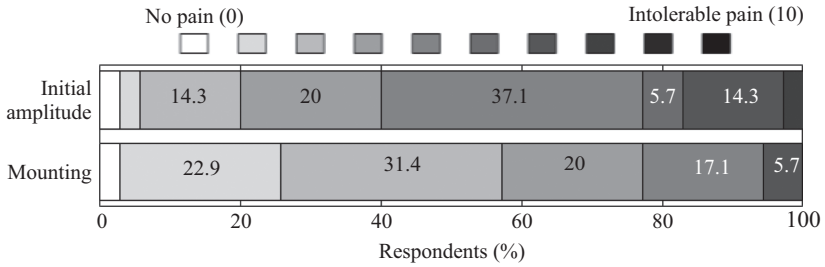

Figure 4: Pain perception of patients during device mounting prior to operation and perception of initial stimulation strength.

3.2 Demands for therapy

Patients and operators declared no clear preference concerning the mounting regions of the device. 80.5% of patients want the device fixed with an adhesive at a position near the ear (66.6%), in contrast to hanging it over the ear or the neck. Patients would also accept a placement on the chest, back or the upper arm. There is no clear preference of patients and operators concerning the shape of the device. One fundamental shortcoming of the current device was identified to be the missing robustness for water, since all patients and operators claim the need for the device to be watertight, and thus enable, e.g. showering.

Concerning the user interface, several possibilities of device operation were offered to patients and operators. 81.1% and 100% of all patients and operators, respectively, want to adjust the stimulation amplitude in accordance with the momentary perception. 84.4% of patients and 60% of operators want the stimulation amplitude to be adjustable by both patient and operator. There is no preference for any asked means of interaction with the device (e.g. by buttons). 40.5% and 72.2% of all patients want to disable or take off the device, respectively, in specific situations like showering or when they need to be concentrated, like during car driving.

An important boundary condition for an effective therapy is the required time interval between two pVNS applications, which depends strongly on the particular disease of the patient and is limited by battery lifetime of the device. On average, patients suggest a time interval between two consecutive treatments of 9.4 days with a range from 3 (wound treatment) up to 21 (chronic pain treatment) days. The device application should not exceed 24.0 min. Operators wish to have durations of 9.5 days between two applications and want a single application of the device not to take longer than 16.6 min.

With respect to new device developments towards patient-governed or automatic feedback-based control of stimulation parameters, it may be necessary to motivate the patient to perform additional measurements and/or to use or wear additional devices (e.g. to measure heart rate). Of all patients, 34.4% are willing to perform such additional measurements whereas 40.6% are likely willing, with the limitation of a maximum of 23.27 min per day. However, the motivation to continuously wear an additional device is lower, with 21.9% and 37.5% of all patients, respectively.

Open questions for potential improvements identified the following main shortcomings: limited battery life time, lacking resistance to water, missing flexible design with soft cables, and missing autonomy of the patient and operator (e.g. stimulation amplitude). On the other hand, patients and operators are attracted by the minimal-invasive nature of pVNS, as there are no pharmaceutical components involved and thus there are no pharmaceutical side effects.

4 Discussion

Although $>$80% of patients are satisfied with pVNS treatment, the given survey identified potential for its improvement.

From a technological point of view, attained results encourage further improvements for the device design (Figure 1B). Miniaturization seems not to be a relevant issue, as patients are happy with the current weight and size of the pVNS device. However, miniaturization may reduce disturbance during daily activities. The adhesive area of the device constitutes a major problem as it serves as the reference electrode for stimulation and its detachment is critical and terminates pVNS. The adhesive is also the main cause for unwanted side effects, namely skin irritation. Transferring the reference electrode from the neck to the ear (with an additional needle) or by using specific stimulation patterns (which do not need the reference electrode due to specific current steering concepts)

could account for these issues. The resulting requirements for the adhesive are then less restricting and a targeted extended wear time of about 10–14 days may be achieved. Concerning mechanical device design water tightness is crucial for wearing comfort.

From a biophysical and therapeutic point of view, it is necessary to enable the device to adjust its stimulation amplitude. The therapeutic concept of pVNS is based on the selective stimulation of thick afferent Aβ-fibers of the auricular vagus nerve [2]. For this, a tingling sensation of the stimulation is aimed at. As only 5.9% of all patients report a desirable comfortable sensation, the operator and patient need to adjust the stimulation amplitude. More than 20% of the patients feel the stimulation too intensive (Figure 4), thus personal adaptation of the strength will not only cause more specific fibre activation but will also reduce overstimulation, adaptation of perception, and energy consumption.

Concerning the operation of the device, the majority of patients and operators want to be able to switch/take off the device in certain situations, e.g. during showering or car driving. This may be a problem concerning therapeutic efficiency, as patients may reduce total stimulation time. Such feature is therefore debateable and might require fixed minimum stimulation duration per day. Interestingly, operators and patients tend towards more patient self-governance with the patient having the ability/responsibility to adjust stimulation parameters with respect to their health state. However, this is obviously not straight forward. Firstly, there is not enough data to identify specific parameters in the necessary granularity for an adjustment yet; secondly, patients would need certain knowledge about the function of the device. This emphasises the need for future development of automated feedback-controlled stimulation. The feedback may be implemented using different biophysical markers, from heart rate or heart rate variability to chemical markers.

From a methodological point of view, the survey may be biased by the selection of patients, as mainly patients with typically good compliance were selected. Thus, it may be difficult to draw conclusions for the whole population.

Our results show that surveys on user demands can provide essential input for device development. Based on the gathered data, mechanical device design, user interface design but also biophysical issues gained foundation and an optimized device development is promoted.

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Author's Statement

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