ADAPTIVE AURICULAR ELECTRICAL STIMULATION CONTROLLED BY VITAL BIOSIGNALS

Transition from Fixed to Adaptive and Synchronized Electrical Stimulation Controlled by Heart Rate Variability and Blood Perfusion

Eugenijus Kaniusas
Institute of Electrical Measurements and Circuit Design, Vienna University of Technology
Gusshausstrasse 27-29/E354, Vienna, Austria

Jozsef Constantin Szeles, Tilo Materna
Department of Surgery, University of Vienna, Vienna, Austria

Giedrius Varoneckas
Sleep Medicine Centre, Klaipeda University Hospital, Klaipeda, Lithuania

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Abstract: The auricular electrical punctual stimulation is usually applied for pain relief. The common application involves fixed stimulation parameters, which makes the simulation insensitive to prevailing pain or stress level and may lead to a disadvantageous over-stimulation. In order to address this issue, the given position paper presents an experimental background leading to a conceptual design of an adaptive and synchronized stimulation technique. Here parameters of the heart rate variability are used as stimulation biofeedback, while the stimulating signal is synchronized with cardiac or respiratory activity to boost stimulation effects.

1 INTRODUCTION

The auricular electrical punctual stimulation (P-Stim) is an electrical nerve stimulation technique, newly introduced by Dr. Szeles (Szeles, 2001a). The P-Stim is usually applied for acute and chronic pain relief. A reduction of pain perception and pain-relieving medications is attained (Szeles, 2001b; Sator-Katzenschlager, 2006; Likar, 2007), even with an induction of anaesthesia state (Litscher, 2007). Furthermore, reduction of body mass index (BMI) in obese patients (Szeles, 2001b), increase of blood flow velocity and oxygenation (Szeles, 2004) were reported during the P-Stim application. The advantages of the electrical stimulation over conventional (manual) acupuncture with respect to pain relief, well-being and sleep quality were documented in (Sator-Katzenschlager, 2004) for extended periods of time up to 3 months.

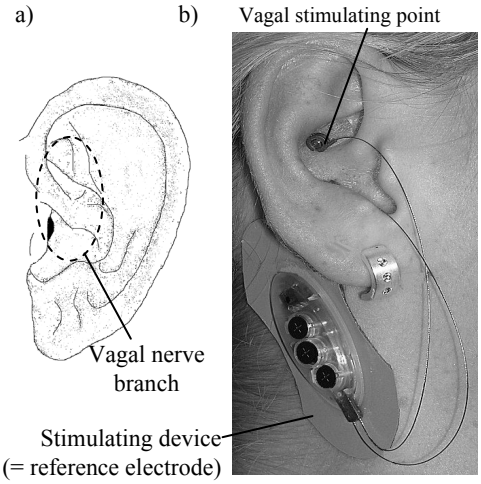

Figure 1: a) Ear with indicated approximate auricular branch of vagus nerve according to (Peuker, 2002; Gao, 2008). b) Electrical punctual stimulation of the auricular vagus nerve (P-Stim).

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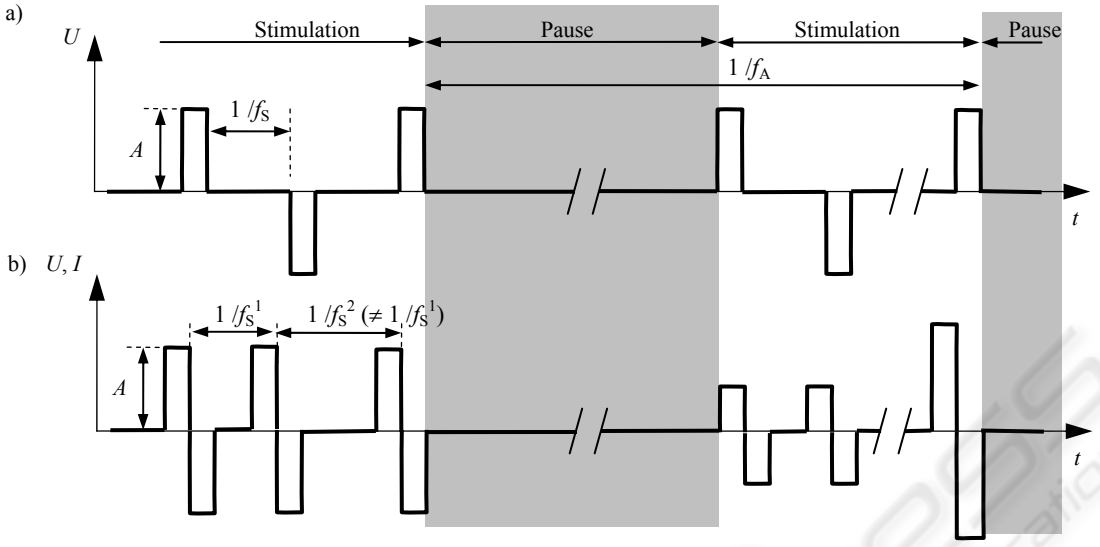

Figure 2: Stimulation waveforms of a fixed (a) and (b) adaptive electrical punctual stimulation.

The particular beneficial effects of the P-Stim are still under discussion, whereas a number of the following mechanisms seem to be involved. The electrical stimulation of the afferent nerve receptors may influence gate mechanisms in the central nervous system (CNS), preventing pain-related action impulses from reaching the CNS and avoiding the person's perception of pain. Furthermore, an indirect stimulation of pain receptors and activation of inhibitory pain control systems may be involved, as well as a stimulated release of neurotransmitters, e.g., endorphins and other endogenous opioids.

Though the efficiency of the P-Stim was subjectively proved in many cases and the P-Stim is already in clinical use, only recently some objective and statistical evidence was established on the stimulation effects. Given that an auricular branch of vagal nerve (Fig. 1a) is electrically stimulated by the P-Stim device (Fig. 1b), effects on the heart rate variability (HRV) were assessed in the time and spectral domain (Kaniusas, 2008; Gbaoui, 2008a) and in the state space (Gbaoui, 2008b) by our group. In addition, blood perfusion (BP) changes during stimulation were investigated (Kaniusas, 2008). In the latter studies optical plethysmography (OPG) served as biofeedback to derive the HRV and BP.

Here the suitability of the HRV and BP analysis is given by the fact that the stimulated afferent vagal nerve goes to the nucleus solitarius in the CNS, whereas the sinus node of the heart is controlled by the efferent vagus nerve from the nucleus ambiguous in the CNS. The node initiates heart contractions with particular rate dynamic and ejection strength, thus the HRV and BP being the appropriate parameters to register the stimulation effects.

The given position paper is intended to introduce a novel technology for an adaptive and synchronous P-Stim controlled by the HRV and BP. As a starting point, technical data and new experimental results concerning parasympathetic/sympathetic power in the HRV from the standard P-Stim are presented, which yield a substantial basis and arguments for the introduction of the adaptive stimulation.

2 ESTABLISHED STIMULATION

2.1 Methodology

The P-Stim was applied in supine position of three healthy volunteers: two men aged 41/29 with BMI 25/23 kg/m^2 and one female aged 19 with BMI of 20 kg/m^2. A precise positioning of the needle in the vicinity of the vagal nerve (Fig. 1) was facilitated by local conductivity measurements, for the local conductivity increases in the region of the nerve and its supporting blood vessels.

As demonstrated in Fig. 2a, the voltage U of the electrical stimulation comprises monophasic impulses with changing polarity, stimulation (=repetition) rate f_S of 1 Hz, amplitude A of 4 V and impulse duration of about 1 ms.

The duration of the recordings was about 15 min before, during, and after the stimulation, respectively. At least two recordings were performed per volunteer with a time-lag in-between of more

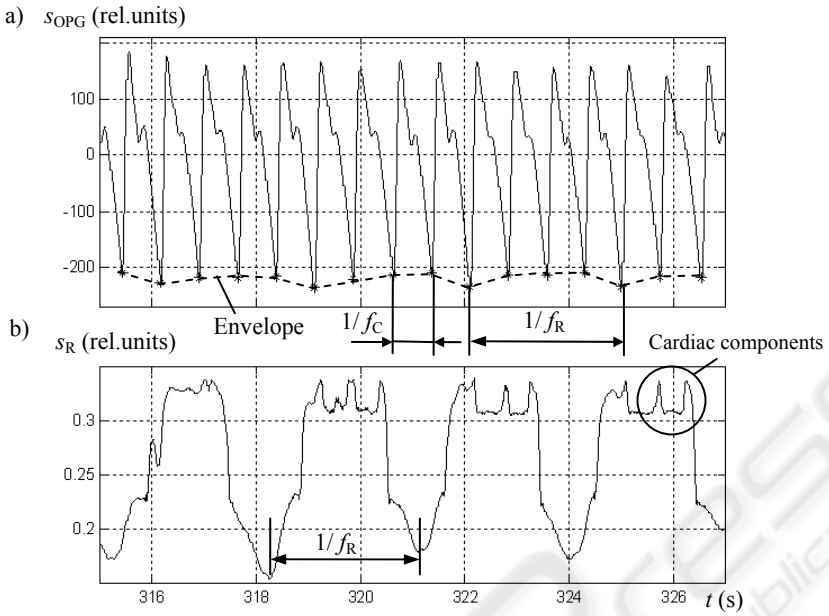

Figure 3: a) Optical plethysmography signal s_{OPG} with an estimated cardiac rate f_C from indicated systolic onset points (*) and an estimated respiratory rate f_R from the envelope. b) The corresponding respiration signal s_R from the chest skin curvature sensor.

than 10 days. It should be noted that the needles for stimulation were inserted about 5 min before the recording to avoid needle's positioning effects, i.e., to avoid temporal effects of manual acupuncture.

In parallel, the OPG signal s_{OPG} from the finger was assessed as biofeedback. Here the relatively high sampling rate of 2 kHz is needed for an accurate HRV analysis (Guidelines, 1996). A typical course of s_{OPG} is depicted in Fig. 3a.

The instantaneous heart rate f_C for the HRV analysis was estimated from s_{OPG}, as demonstrated in Fig. 3a, with artefacts and noisy segments being manually removed. The prominent minima in s_{OPG}, which correspond to the onset of the systole or blood ejection, were detected as fiducial points for the calculation of the instantaneous f_C.

The investigation of the resulting f_C sequence in the spectral domain comprised power in the established frequency ranges (Guidelines, 1996): low frequency range 0.04-0.15 Hz corresponding to sympathetic power P_{SYM} and high frequency range 0.15-0.4 Hz corresponding to parasympathetic power P_{PAR}. Both P_{SYM} and P_{PAR} were estimated for sequence windows of 300 s with 50 % overlap. It should be noted that there are controversial indications that P_{PAR} is also present in the low frequency range.

The BP is given by the course of s_{OPG} (Fig. 3a). In particular, the amplitude deflection of s_{OPG} within a single heart cycle corresponds approximately to both amount of blood ejected (=left ventricular stroke volume) and vesicular compliance.

The respiration reference s_R (Fig. 3b) was established by a skin curvature sensor on the chest, as described in (Pfützner, 2006; Kaniusas, 2004).

2.2 Results

2.2.1 Heart Rate Variability

Fig. 4b and Fig. 5b demonstrate a temporal increase of P_{PAR} during stimulation, which temporal activation is given in Fig. 4a and Fig. 5a. The relative increase of P_{PAR} among volunteers was about 20 %, which was observed in all sessions but one, probably because of a relatively high initial value of P_{PAR}. A temporal dip of P_{PAR} was often observed during the stimulation.

No unique tendencies were registered in the behaviour of P_{SYM}, as demonstrated in Fig. 4c and Fig. 5c. However, stress relaxation effects could be observed in some cases even in healthy volunteers. In Fig. 4b,c and Fig. 5b,c dashed ellipses mark the corresponding time intervals, where P_{PAR} increases and P_{SYM} concurrently decreases. In general, such changes of P_{PAR} and P_{SYM} tend to indicate ongoing restorative effects.

The stimulation effects on P_{PAR} were discussed in a wider context in (Kaniusas, 2008; Gbaoui, 2008a), considering additionally parameters in the

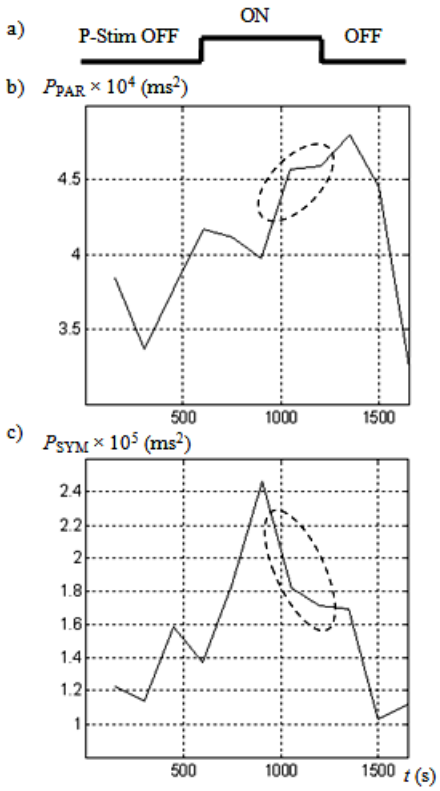

Figure 4: Effects on heart rate variability in the female subject. a) Temporal activation of the electrical stimulation (P-Stim OFF or P-Stim ON). b) The corresponding parasympathetic power P_{PAR}. c) The corresponding sympathetic power P_{SYM}.

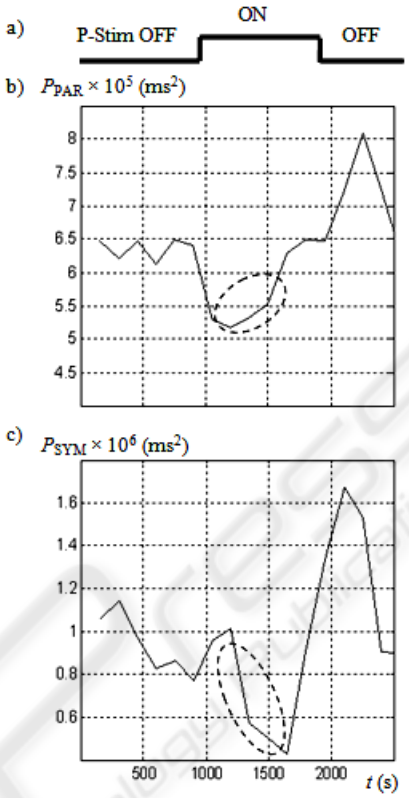

Figure 5: Effects on heart rate variability in a male subject. a) Temporal activation of the electrical stimulation (P-Stim OFF or P-Stim ON). b) The corresponding parasympathetic power P_{PAR}. c) The corresponding sympathetic power P_{SYM}.

time domain and state space. Aforementioned tendencies of P_{PAR} were also found in (Haker, 2000), even during non-electrical auricular stimulation by acupuncture needle.

In contrast to P_{PAR}, none of the mentioned studies indicate clear tendencies of P_{SYM}. This is likely to be attributed to the study enrolment of only healthy unstressed pain-free individuals in resting state, where potential changes or improvements of P_{SYM} are strongly restricted.

2.2.2 Blood Perfusion

The BP is given by the course of s_{OPG}, as show in Fig. 3a. It is important to observe that not only the instantaneous cardiac activity but also the respiration can be derived from s_{OPG}.

In particular, the systolic onset points, as marked by asterisks in Figure 3a, give a useful reference to heart excitation. These points are delayed by about 200 ms from the actual excitation of the heart ventricles (= R peaks in electrocardiography (ECG)) with the delay being nearly constant.

The respiratory cycle can be derived from s_{OPG}, as indicated by the envelope in Fig. 3a. Here the amplitude modulation of s_{OPG} results from the respiratory induced modulation of the left ventricular stroke volume which temporally increases during expiration. The simultaneously recorded respiration reference s_R (Fig. 3b) proves the respiratory related modulation of the s_{OPG} deflection.

3 PROPOSED STIMULATION

3.1 Rationale

Since the spectral HRV parameters are specifically influenced by the standard P-Stim application and the instant cardio-respiratory data can be derived from the BP, as shown above, a novel adaptive and synchronized P-Stim could be established.

A targeted control of the stimulation waveform (compare Fig. 2) is highly reasonable for avoiding over-stimulation and realising stimulation on-

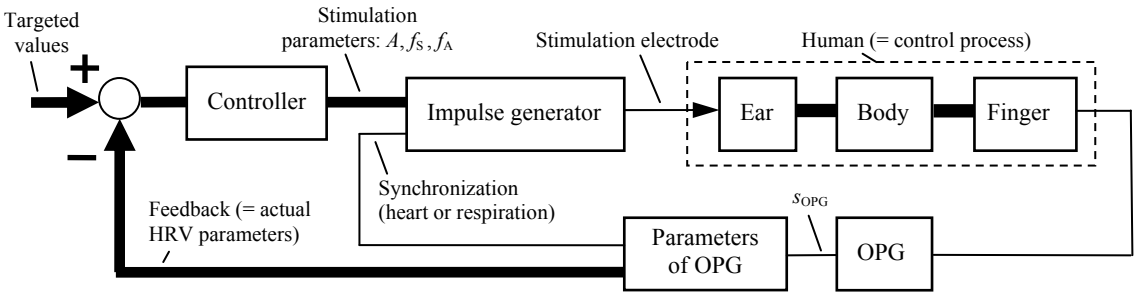

Figure 6: Control loop of the adaptive auricular stimulation with OPG as the optical plethysmography.

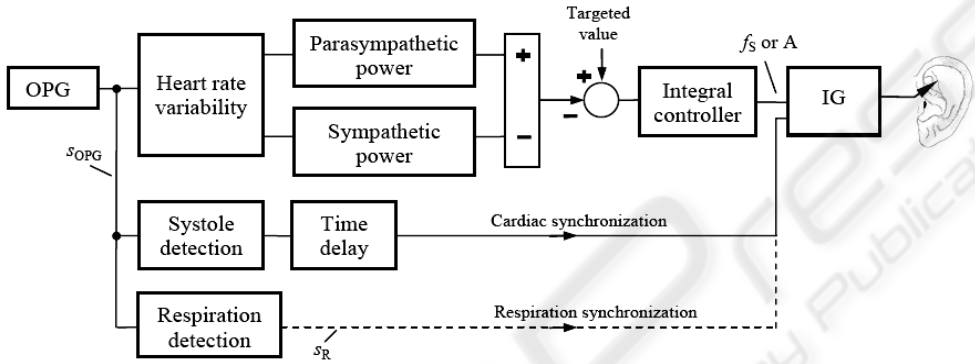

Figure 7: Establishment of biofeedback for controlling and synchronization purposes with IG as the impulse generator.

demand controlled by HRV parameters. In other words, if pain perception is already reduced, as detected by e.g., reduced stress and diminished P_{SYM}, then A, f_S (Fig. 2b) could be reduced as well. In addition, efficient energy use in the stimulation would be facilitated.

The synchronization of the stimulation waveform with the cardio-respiratory activity would allow a constructive interference of the stimulated pain-relieving effects and the residual body attempts. In particular, the cardiac synchronization would allow a timely activation of the gate mechanisms in the CNS or a timely and indirect stimulation of receptors (e.g., blood pressure), regulating vital body functions. The respiratory synchronization would help to interfere with body phenomena like respiratory sinus arrhythmia, yielding a forced increase of P_{PAR} in the expiration phase.

3.2 Realization

The proposed set-up is shown in Fig. 6. The input parameters A, f_S and the activation rate f_A of the impulse generator are adaptively adjusted according to the HRV parameters via a control loop. The cardio-respiratory synchronization signal for the impulse generator is also derived from s_{OPG}.

In particular, Fig. 7 suggests the difference P_{PAR} - P_{SYM} as a possible realization of the stimulation feedback, while the targeted value could be the pain intensity to be reduced. That is, the higher P_{PAR} and the lower P_{SYM} get in the course of the stimulation, the more strongly the pain has already been reduced. Similar behaviour of P_{PAR} and P_{SYM} during stimulation was already observed in Fig. 4 and Fig. 5. Obviously the ratio P_{PAR} / P_{SYM} could be used instead of the difference.

According to Fig. 7 an adaptive control of A and f_S is established, assuming that these parameters are directly interrelated with the stimulation strength. In an analogous way, a composition of bursts by controlling of f_A could be attained (compare Fig. 2). Here a proportional-integral controller or integral controller could be applied, for the human (Fig. 6) can be roughly approximated as a proportional control process with a single time constant (compare Fig. 4b). The time delay in Fig. 7 may be needed for synchronizing the stimulation pulses with a particular time instant in the heart cycle.

Fig. 2b exemplifies a possible adaptive controlling of the stimulation curve, while more efficient biphasic impulses are used (compare Fig. 2a). In addition, constant current stimulation would be preferred over voltage application, for the skin impedance is relatively low with electrode needles inserted and thus the risk of local tissue damage

though locally increased current density is low.

4 DISCUSSION

It is worth to note that the HRV is usually derived from the ECG (Guidelines, 1996). However, the P-Stim induced very strong artefacts in the ECG since the stimulation and the ECG have the same electrical origin. In contrast, the OPG with optical origin serves as a reliable biosignal, being independent of the P-Stim activation. However, the OPG conveys mechanical information on the systole-diastole cycle rather than electrical on the heart excitation (= origin for the HRV). In addition, the OPG exhibits relatively slow changes if compared to the ECG, for the pulse waves are much more inert than electrical heart excitation. The use of the OPG may have reduced an effective time resolution of f_C.

The time delay of about 200 ms between the systolic onset in the OPG and the R peak in the ECG depends on the speed of the heart excitation and mechanical vessel properties. Nevertheless, the delay can be assumed to be constant, if the respiratory induced blood pressure changes and thus arterial distension and stiffness changes can be neglected.

Lastly, the limitations of the presented experimental results should be mentioned. The observed effects, especially concerning P_{SYM}, are restricted by the fact that all volunteers were young pain-free healthy persons. Furthermore, the stimulation duration was relatively short: 15 min versus 4 hours (with 4 hours pause in-between) over at least seven days, as clinically applied and subjectively verified for being effective. The initial state of the volunteers, as their possible excitation at the beginning of the recording, and their mental activity changes during the investigation - both influencing the HRV - may have limited the range of potential changes or improvements of HRV parameters during the stimulation.

However, the provided experimental background leads to a comprehensible design of an adaptive and synchronized stimulation technique. This would allow a pain sensitive adjustment of the stimulating parameters avoiding over-stimulation and comforting the patients.

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