Objectivation of cerebral effects with a new continuous electrical auricular stimulation technique for pain management

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Aims: *The electrical point stimulation system (P-STIM®) reflects a new, miniaturized system for pain therapy through ear acupuncture. For this reason, ultrathin needles were applied at the ear. The needles stimulate the acupuncture areas at the ear using electrical impulses, which come from a little generator applied behind the acupunctured ear.*
Methods: *This study describes continuous, non-invasive measurements of near infrared spectroscopy (NIRS) and multidirectional transcranial Doppler sonography in two healthy females (aged 23 and 27 years) during stimulation with P-STIM®, for the first time.*
Results: *The results of the pilot measurements have shown that electrical point stimulation using the new electrical stimulation system on eye acupuncture points is able to modulate the mean blood flow velocity (v_m) of the supratrochlear artery. These effects were present using a stimulation frequency of 100 Hz. A lower increase in v_m was found in the middle cerebral artery. In addition, stimulus induced, quantifiable and reproducible alterations of the regional cerebral NIRS parameters were be detected.*
Conclusion: *For the first time, P-Stim® allows intermittent ear acupuncture stimulation for up to several days in combination with complete mobility for the patient.* [Neurol Res 2004; **26**: 797–800]

Keywords: Point stimulation; electro-acupuncture; ear acupuncture; electrical ear stimulation; pain; neuromonitoring

INTRODUCTION

Pain is the most common reason for ear acupuncture[1]. In recent times, investigation and quantification of the effects of acupuncture were done using modern biomedical methods. Evidence for measurable alterations in the brain using acupuncture stimulation can be found in previous reports by our research group[2–15].

A new method for pain treatment using ear acupuncture is the electrical point stimulation system P-STIM® (Biegler, Austria). Ultrathin permanent needles are applied to the ear. A generator, located behind the acupunctured ear, produces electrical stimulation impulses, which are transferred via the needles to the acupuncture areas (*Figure 1*). The ear is chosen because concentrations of free nerve ends/acupuncture points are located there[16]. In the past, traditional acupuncture and electro-acupuncture were characterized by the fact that these methods were confined to a clinic and/or the physicians practice. P-STIM® allows continuous, intermitting stimulation for up to several days combined with absolute mobility of the patient.

In this study, selective and specific effects of electrical point stimulation in the brain using P-STIM®, were investigated on healthy volunteers, using multidirectional transcranial Doppler sonography (TCD) and near infrared spectroscopy (NIRS). Simultaneous and continuous blood flow profiles in different cerebral vessels were monitored using TCD (compare *Figure 1*). Using NIRS, we registered changes of cerebral oxygen metabolism continuously after different stimulation frequencies.

MATERIALS AND METHODS

An expert in traditional Chinese acupuncture and ear acupuncture selected acupuncture points on the ear, for the eye and liver region (compare *Figure 1*). A position tape prepared previously with the P-STIM® application pointer was applied. This procedure was repeated until all the acupuncture points were marked. Then, the needles could be taken up by the application pointer and applied (*Figure 2*, lower left).

A physician adheres the actual device behind the acupunctured ear with the integrated adhesive electrode (compare *Figures 1* and *2*). Then, the wires are

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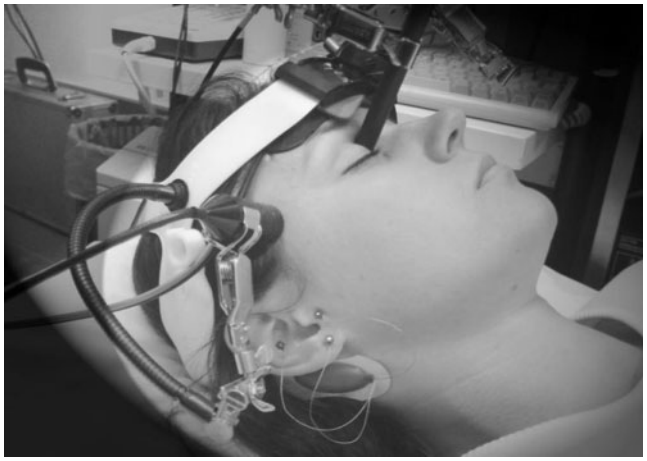

Figure 1: Electrical point stimulation. Pilot measurements at the Department of Biomedical Engineering and Research in Anaesthesia and Critical Care at the Medical University of Graz (with friendly approval of the volunteer)

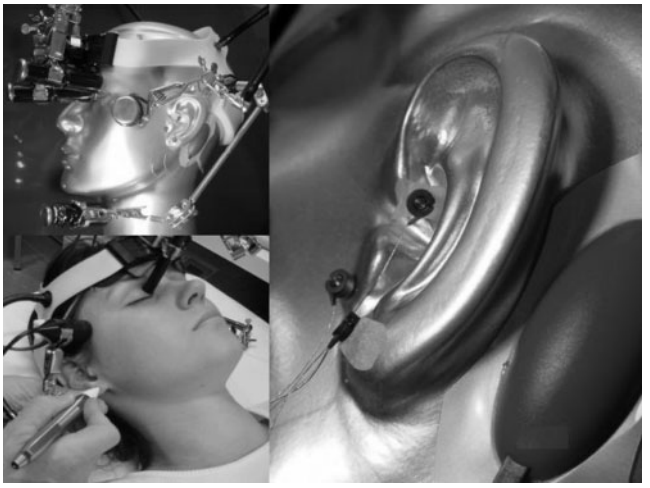

Figure 2: P-STIM® electrical point stimulation system and probe holder construction for the experimental transcranial ultrasound sonographic and near infrared spectroscopic investigations

connected to the permanent needles by snapping over the plastic rings (*Figure 2*, right) and are fastened with adhesive tape. Finally, P-STIM® is activated by removing the adhesive foils from the batteries and by opening the lid.

The stimulation patterns in *Table 1* were available.

For TCD-registrations, a special, multidirectional spectacle probe holder prototype was constructed (compare *Figures 1* and *2*, left). This allowed the continuous recording of cerebral blood flow velocities of the supratrochlear artery (STA) and the middle cerebral artery (MCA). The ultrasound signals were registered with the Multi-Dop T system from DWL Electronic Systems GmbH, Sipplingen, Germany. A 2 (MCA) and a 4 MHz (STA) probe were both used.

Table 1: Possible stimulation patterns with P-STIM®

Program	Stimulation pattern
P1: endless	15 minutes stimulation with 100 Hz/260 µS
	30 minutes pause
P2: four times	15 minutes stimulation with 100 Hz/260 µS
	30 minutes pause
	Four times
	3 hours stimulation with 1 Hz/20 mS
	3 hours pause
P3: four times	15 minutes stimulation with 100 Hz/260 µS
	30 minutes pause
	Four times
	10 minutes pause
	5 minutes stimulation with 50 Hz/260 µS
	30 minutes pause
	3 hours stimulation with 10 Hz/2 mS
	3 hours pause
	3 hours stimulation with 1 Hz/20 mS
	3 hours pause
P4: endless	15 minutes stimulation with 100 Hz/260 µS
	15 minutes pause
	15 minutes stimulation with 1 Hz/20 mS
	15 minutes pause

The lowest frequency value was used for the investigation of the vessels near the eye; the assessable signals were a maximum 20 mW/cm^2. Monitoring of the TCD signals from the STA was carried out using a scanning probe connected to a special holder at the median angle of the eye, which was positioned slightly medial and parietal and without pressure[17]. Using acoustic control, the angle and positioning of the probe was altered until the greatest signal amplitude was achieved. In addition, simultaneous and continuous alterations in blood flow velocity of the MCA were determined. The most important assessable parameters are alterations in the mean blood flow velocity (v_m). At the same time, different parameters of NIRS (NIRO 300, Hamamatsu Photonics, Hamamatsu, Japan) determined the regional cerebral oxygenation in frontal areas of the brain[3,7,10,12–15].

Two healthy volunteers aged 23 and 27 years took part in this investigation. They were positioned, relaxed on a bed during the investigation.

This study was performed with the approval of the Ethic Commission at the Medical University of Graz (13-016 ex 02/023 ''Punctual stimulation'').

RESULTS

Figure 3 shows the blood flow profiles in the right MCA and left STA of the 23-year-old female volunteer, before and during 100 Hz point stimulation with P-STIM®. According to multidirectional transcranial and orbital ultrasound scanning, the mean blood flow velocity in the MCA remained unchanged. However, in the STA, an increase in flow velocity of +4 cm/s occurred during point stimulation at this frequency. This change could not be documented at a stimulation frequency of 1 Hz. About 5 minutes after terminating electric stimulation, the initial results were achieved again.

NIRS initially showed a minor decrease in O_2Hb (oxyhemoglobin) in the second (27-year-old female)

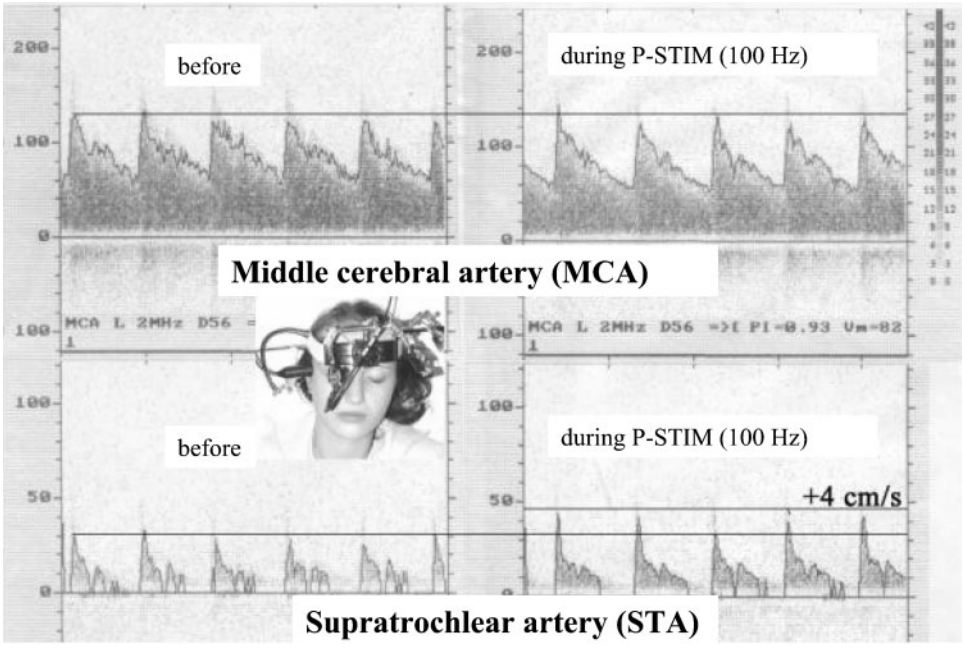

Figure 3: Multidirectional transcranial and orbital sonography investigations before and during the point stimulation (with friendly approval of the volunteer). Blood flow profiles of the MCA and the STA from a female, 23-year-old volunteer, before and during point stimulation. Observe the increase in blood flow velocity during stimulation using 100 Hz

volunteer during point stimulation of the ear at a stimulation frequency of 1 Hz. Immediately after stimulation, the O_2Hb values again reached their initial range. During electric ear stimulation with a frequency of 100 Hz, an obvious increase in O_2Hb was registered for this volunteer. This effect could again be observed in the same person after a delay of >30 minutes. In addition, a stimulation-induced influence on the NIRS parameters in the sense of an accumulation of the repeated stimulation of 100 Hz (compare *Figure 4*, middle and right) could be detected.

DISCUSSION

At the end of the 1950s, French physician Dr Paul Nogier further developed ear acupuncture. Nogier systematically proved that different regions of the ear and specific organs have definite functional relationships and dependencies. As a result of these relationships, using a needle on one or more ear acupuncture points can be performed to treat specific organs or organic functions; on the other hand, ear acupuncture points are also relevant for diagnostics in the field of auricular medicine. According to Nogier, a change in skin

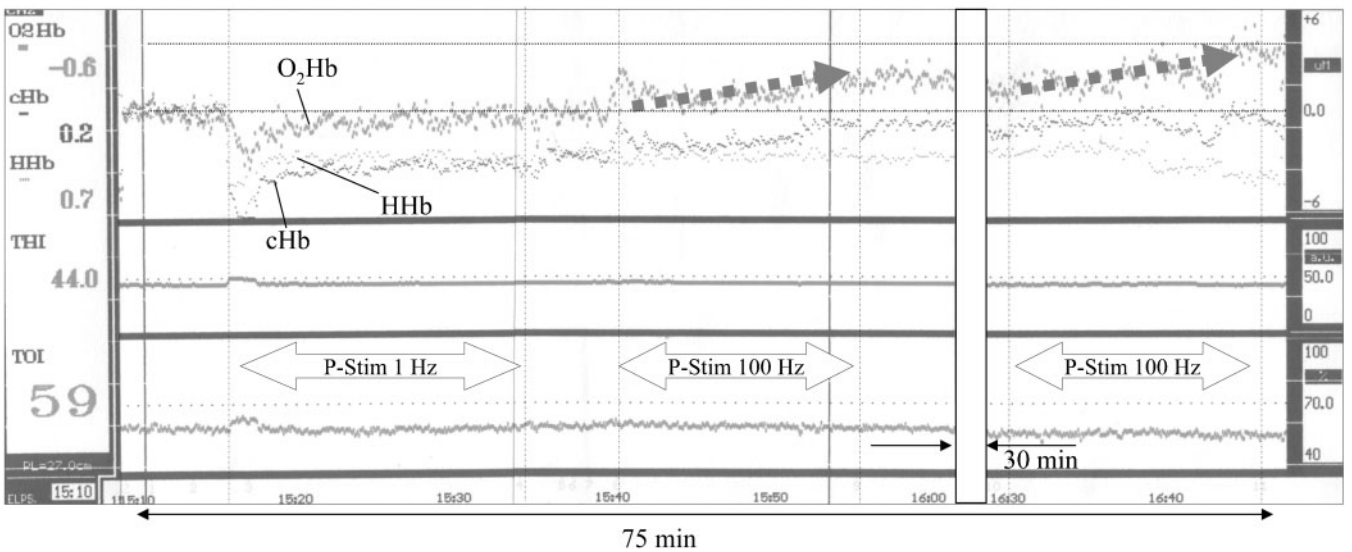

Figure 4: NIRS during point stimulation with P-STIM® at the ear of a 27-year-old female volunteer. Observe the reproducible increase in O_2Hb during the electrical stimulation with a frequency of 100 Hz (O_2Hb, oxyhemoglobin; cHB, total hemoglobin; HHb, deoxyhemoglobin; THI, tissue hemoglobin index; TOI, tissue oxygenation index)

resistance at certain areas of specific ear acupuncture points is present in particular organic diseases[16].

This study introduces a new, miniaturized system (P-STIM®) for continuous electric point stimulation of the ear. Based on measurement data from two healthy female volunteers using TCD and NIRS, the influence on cerebral function could be observed. As already mentioned above, electrical point stimulation allows continuous, intermitting electrical stimulation at ear acupuncture points for up to several days. During its use, the patient is guaranteed complete mobility, which is not the case when using other systems.

The auricular-stimulation method could be important in treating chronic pain. Moreover, this concept seems to be useful for treating addiction, allergies and special areas of anesthesiology[18–21].

The initial studies with point stimulation[18–21] used a P-STIM®, combined with reusable needles. Because of hygiene and discomfort during usage, we used one-use instruments and needles in this study.

The first interim results[18] of a clinical, point-stimulation study showed that a marked decrease in the VAS (Visual Analog Score) scale of pain occurred in 31 people who underwent electric stimulation. The average duration of stimulation was 36.6 hours at a treatment time of 18–72 hours. A significant decrease in the VAS scale during stimulation was observed in 67% of the patients and 29% of the patients reported a moderated reduction in pain. A relevant reduction in pain medication was observed in 70% of the patients. No accompanying medication was necessary in half of the patients treated. Almost all the patients reported an improvement in their general health situation.

The goal of a further clinical study was to test if the P-STIM® concept could be used to treat lumbago[19,20]. Here, ten patients suffering from chronic pain with a VAS score over 5, despite pain medication, were examined. In six patients there was a pain reduction of 50% and in two patients a reduction of 80% was achieved. Two patients terminated the study because of poor compliance. In 20% of the patients, all analgesic medication was stopped during the treatment with P-STIM®. A great improvement in mobility was achieved in all patients.

In conclusion, our study shows stimulation-related, quantifiable and reproducible alterations in cerebral parameters after point-stimulation in two female volunteers. Further studies are necessary in order to verify the results.

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