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Application of electrostimulation acupuncture (P-STIM) in clinical practice

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Acupuncture is one of the oldest types of therapy known to us for about five thousand years. It originated in Asia, specifically in China, was developed further and constituted a very essential part of medicine in that part of the world. In the West, acupuncture was virtually unknown until the year 1972. Professor Bischko was able to prove its mode of action using scientifically recognized methods of Western medicine.

When functional changes occur without identifiable morphological changes, then acupuncture may be used to achieve a complaint-free state. Acupuncture is an additional therapeutic method when tangible morphological changes have resulted from degeneration or trauma. The therapy leads to normalization of muscle tonus, improved blood circulation and pain reduction. This results in an improvement of the overall situation and chronicity is prevented or kept at bay.

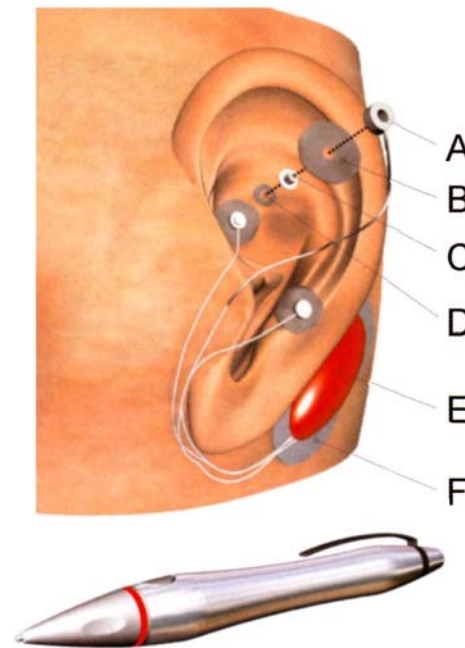
Electro-acupuncture is already used on a world-wide scale at present, but has found only limited application in auricular acupuncture, due to the currently relatively large sized equipment. For this reason, a miniature form of electro-acupuncture has been developed, in order to permit carrying out long term auricular acupuncture.

This aim has and is being realized in three phases: in the first phase, the prototype of the equipment has been developed, secondly, clinical testing on patients with adipositas and chronic pain is being carried out, and the third phase, is testing on patients with cervicobrachial syndrome (CBS) and bronchial asthma. The equipment is being developed to the stage of series production in parallel to the clinical studies.

The development and manufacture of this miniaturized equipment is based on the national and world-wide patents of the first author.

Micro point stimulation device.

The main component of the device is a micro controller (in further sequence a microchip), which allows continuous stimulation in conjunction with an integrated acupuncture needle. The dimensions of the equipment are 55 mm long (including



The applicator pen may be used for the determination of the acupuncture point and the application of the positioning plaster (D) as well as placement of the continuous stimulation needles (C).

integrated adhesive electrodes), 25 mm wide, with a weight of 7 g. The therapy unit is fixed behind the patient's earlobe. The micro controller incorporates a transducer which can regulate the magnitude of the end plate potential and thus generate and keep constant for a period of two days, a digital synthesis of the various wave shapes. The current is further regulated by means of integrated software in order to compensate any changes in skin resistance. For study-purpose devices, it is possible to ensure external micro controller programming of a new wave shape, using regulatory software and an external EPROM. At the same time, current strengths and wave shapes are adapted independently to the changes in skin resistance.

Point stimulation device(P-STIM)

- A current conducting plastic material
- B fixing plaster
- C continuous stimulation needle
- D positioning plaster
- E point stimulation unit with micro controller
- F integrated adhesive electrode

Studied patients: main focus on abdominal and accident surgery.

Between January and May 2000, 31 patients of a surgical unit with main focus on abdominal and accident surgery, were included in the study. The ratio male/female was 13/18, the average age of the patients was 45.7 ± 15.2 years. The frequency of operations was distributed as follows: Cholecystectomy (7), inguinal hernias (5), colorectal tumours (2), gastric banding (1), ligament plastic surgery of the knee (2), fractures of the extremities (8), hysterectomy (1), anal fistula (2). All patients had to sign a statement of consent prior to joining the study. Criteria for exclusion were: taking anticoagulants, active infectious diseases, endogenous depression, malign diseases, epilepsy, pacemaker or defibrillator, unclear compliance, severe heart disease with NYHA 3 to 4.

The patients were treated with the micro point stimulation device post-operatively within a few hours after transfer to the surgical general or accident ward.

This involved puncturing the earlobe of one side using sterile needles at 3 particular stimulation points: SHEN MEN (ear 55), GREY MATTER (ear 34) and a point corresponding to the region of the surgical wound. The duration of stimulation was adjusted individually according to the requirements of the patient, with an intended minimum application of 24 hours. A specially designed "case report form" (CRF), consisting of a visual analogue scale for pain perception (VAS score), was used for the evaluation of the success of the therapy and for recording the general condition of the patient. The CRF was filled in by the patient every 6 hours. The extent of consumption of analgesics was documented according to substance group in mg/24 hours.

Results. The duration of stimulation was 36.6 ± 13.4 hours (18-72 hours). 22 patients (71 percent) received acupuncture 3.04 ± 1.8 hours post-operatively and 9 patients (29 percent) were treated pre-operatively. The frequency of the ear points used was distributed as follows: SHEN MEN (55) = 100 percent, GREY MATTER (34) = 72 percent, POLSTER (ZHEN, OCCIPUT POINT) (29) = 27 percent, ORGAN DEPENDENT = 100 percent [CHE = 55, 34, gall bladder (96) or liver (76), hernias = 55, 34, abdomen (43), lumbago = 55, 34, LVC (lumbar vertebral column) or kidney (95), ligament plastic surgery = 55, 34 (or 29), knee (49)]. With 67.74 percent of the patients, a significant reduction of the VAS score could be observed during stimulation. Moderate pain reduction could nevertheless be observed with 29.03 percent of the patients (Fig. 2). A significant reduction of medication was observed in 70.6 percent of the cases. For half of the patients (16 patients = 49 percent) no analgesics were necessary, while for 30 percent of the patients only non-steroidal anti-rheumatics were required in combination with the stimulation therapy. All patients who were treated by means of electro-acupuncture, showed a significant improvement in the general personal and constitutional condition.

No side effects were observed during the treatment, which could be traced e.g. to the placement of needles.

Studied patients: main focus adipositas. During the course of the pilot study, altogether 9 patients were treated using the micro stimulation device. A total of 7 patients were part of the verum group (group 1) and 2 patients were part of the placebo group (group 2). All patients had a minimum therapy time of 10 weeks, one of the patients of the verum group had a therapy time of 20 weeks. The distribution of sexes in group 1 was 1:6 (m:f), there were only female patients in group 2. Average age at the time of admission was 42.6 ± 9 years (32-56 years) in group 1, and 37.5 ± 10.6 years (30-45 years) in group 2.

Conclusions:

a) Behaviour of body weight.

During the entire course of the treatment over a period of 10 weeks, an overall tendency towards a decrease in body weight was shown, which was more explicitly apparent in the verum group than in the placebo group. When the patients in group 1 had an average initial weight of 88.82 ± 13.6 kg (75.7 – 112.0 kg), then this was 85.9 ± 11.9 kg (74-105 kg) at the end of the therapy (10th week). In the placebo group the body weight of initially 82.9 ± 1.6 kg (81.8 – 84.1 kg) to finally $82. \pm 3.1$ kg (80.3 – 84.7 kg), only showed a minimal decrease.

b) Body-Mass-Index. Similar to the body weight, the Body-Mass-Index (BMI) shows an overall more distinct tendency towards a decrease in the verum group as compared to the placebo group. An average BMI of group 1 on admission of 32.7 ± 4.2 kg/m² (28.6-38.1 kg/m²), dropped to 31.2 ± 3.7 kg/m² (27–36.3 kg/m²) at the end of the ten week therapy period. In contrast, little change was observed in the placebo group: 32.95 ± 1.7 kg/m² (31.7-34.2 kg/m²) to 32.7 ± 3.6 kg/m² (30.2-35.3 kg/m²) towards the end of the therapy.

c) Mass of body fat. The absolute as well as the percentage proportion of fat mass decreased more after ten weeks of therapy, than could be observed in the placebo group:

	Fat mass (kg)	Fat mass (%)
Group1		
Admission	35.9 ± 6.4 (30.5-45.2)	40.3 ± 3.2 (35.0-44.0)
End	33.3 ± 5.5 (27-44)	38.6 ± 4.5 (30.0-44.0)
Group 2		
Admission	36.1 ± 1.3 (35.2-37.1)	43.5 ± 0.8 (42.9-44.1)
End	34.6 ± 1.9 (33.3-36.0)	42.0 ± 0.7 (41.5-42.5)

On the basis of the initial available interim results of the study, long term electro- acupuncture using a miniaturized acupuncture device, shows a distinct tendency towards an improvement of the relevant parameters for acute pre- and post-operative pain. A noticeable improvement in the general condition and quality of life of the patient as well as a reduction in consumption of pain-killing medication is observed. It should be noted that the use of the electro-acupuncture equipment, with its pain reducing effect and the simultaneous improvement of the general condition of the patient, could become relevant in daily clinical use. Besides this, it could be shown that a reduction of therapy costs could be achieved by using the device. Furthermore, new application possibilities may be developed with this equipment (e.g. adipositas). Double blind randomised studies approved by the ethics commission based on these results are thus in progress.

Literature from the author Dr. J.C. Sézles

