ORIGINAL CONTRIBUTION

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Effects of laserneedle acupuncture on olfactory sensitivity of healthy human subjects: a placebo-controlled, double-blinded, randomized trial*

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SUMMARY

The aims of the present study were to investigate the influence of laserneedle acupuncture on olfactory sensitivity and to examine whether the attitude towards laserneedle acupuncture affects the outcome. Olfaction was tested repeatedly on two days using the olfactory detection threshold subtest of the Sniffin' Sticks test battery in sixty-four healthy subjects of which 32 showed a positive attitude towards the effects of laserneedle acupuncture and 32 were sceptic about its effects. Testing was accomplished three times on day one (T1 = 0 min, T2 = 35 min, T3 = 105 min) without laserneedle acupuncture and on day two (T1 = 0 min, T2* = 35 min, T3* = 105 min) when the subjects were randomized in a non-stimulation (placebo) and a stimulation (laserneedle acupuncture) group. Stimulation or non-stimulation was conducted in a double-blinded design. Following laserneedle acupuncture a significant decrease in olfactory detection thresholds was observed at both, T2* and T3*, whereas no significant changes were found in the baseline or placebo group. Effects of laserneedle acupuncture on the olfactory detection threshold did not differ between sceptic and non-sceptic subjects. In conclusion, laserneedle acupuncture is an effective method to improve olfactory sensitivity after one session of stimulation for at least one hour, independently of the attitude of subjects towards the stimulation method.*

Key words: acupuncture, laserneedle acupuncture, attitude, expectancy, efficacy, olfaction, olfactory detection threshold, odor, n-butanol, Sniffin' Sticks, GERAC study

INTRODUCTION

The incidence of olfactory dysfunction is frequently underestimated. Over 79,000 patients suffering from olfactory dysfunction are annually treated in German hospitals [(1)]. Concerning the therapy of olfactory disorders, Doty and Mishra [(2)] concluded that only in some cases it is possible to improve olfactory function utilizing medical or surgical treatment. Another possibility is to treat patients using acupuncture. Of the 79,000 patients who are annually treated in German hospitals, 20% receive an acupuncture therapy [(1)]. Tanaka and Mukaino [(3)] reported that acupuncture of the ear increases olfactory sensitivity to an odorant. However, apart from this study and a few case reports there is no further evidence to support the effectiveness of acupuncture in the treatment of olfactory dysfunctions.

As an alternative to the classic acupuncture technique the so-called Laserneedle acupuncture® has been introduced in the 1990's. Contrary to the name, no needles are used to penetrate the skin. The "laserneedles" are blunt optical fibers which are sticked onto a certain acupuncture point. The laser beam causes a stimulation of the acupuncture point, which does neither cause any direct stimulation of nerves, nor any injury of the skin or the nerves, nor any other specific sensations [(4)]. On this account, the laserneedle stimulation allows double-blinded study designs including a real placebo method [(5)]. Regarding therapeutic effectiveness Litscher et al. [(6)] demonstrated that laserneedle acupuncture is at least equivalent to the classic needle acupuncture and partially even more effective than the traditional method.

The aim of this study was to investigate the effects of laserneedle acupuncture on human olfaction, specifically on olfactory sensitivity to the odorant n-butanol, in a double-blinded, placebo controlled, randomized study design. Since there is an indication that the attitude of subjects towards acupuncture as well as placebo effects influence the outcome [(7,8)], we balanced our study population regarding subjects who were sceptic and subjects who were not sceptic about the therapeutic effects of laserneedle acupuncture.

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MATERIALS AND METHODS

Subjects

Sixty-four healthy subjects (32 males, 32 females) participated in the study. Their age ranged from 21 to 40 years (mean age 27.9 years; SD 4.6 years). Age did not differ significantly between male and female subjects ($F(1,62) = 0.66$, n.s.). All subjects were non-smokers and were not taking any medication known to interfere with sensory perception [9,10]. Test subjects provided their written informed consent. The protocol was approved by the Medical Ethics Review Committee (IRB) of our institution and the study was conducted in accordance with the Declaration of Helsinki.

Regarding the expectancy of the subjects towards the efficacy of laserneedle acupuncture, the test persons were classified into non-sceptics and sceptics (32 subjects each) using the validated Holistic Complementary and Alternative Medicine Questionnaire [11] and additional direct interrogations to the attitude towards acupuncture and laserneedle acupuncture. Gender was uniformly distributed in both groups (16 female and 16 male non-sceptics, and 16 female and 16 male sceptics).

Subjects were interrogated for previous acupuncture treatment. Of the 64 subjects, 58 had not received any acupuncture in the past. Two subjects had received 1-2 acupuncture sessions more than 6 months prior to entering the study. Four subjects had received 4-10 acupuncture sessions (mean sessions 7.3, SD 3.2) more than 3 years prior to entering the study. Reasons for treatment (pelvic pain, back-ache, tensions, gastrointestinal disorders, withdrawal of smoking) did not interfere with the explorative effects of the present study. None of the subjects had had a laserneedle acupuncture session before. None of the subjects was ever treated for olfactory dysfunction.

Olfactory testing

Olfactory function was assessed by means of the olfactory detection threshold, a subtest of the Sniffin' Sticks (Burghart Instruments, Wedel, Germany) that is known to be highly reliable, even if repeated more than once per subject and over a long term period [12]. The Sniffin' Sticks are a test battery using pen-like devices for odor presentation (13,14) for measuring nasal chemosensory function. The olfactory detection threshold subtest consists of sixteen pens containing different dilutions of n-butanol (starting from a 4% n-butanol solution, dilution ratio 1:2 in deionized aqua conservata as diluent). Test scores vary between 1 (lowest sensitivity) and 16 (highest sensitivity) corresponding to the dilution steps of the sticks. It should be noted that low test scores correspond to a high detection threshold whereas high test scores indicate a low detection threshold. Details of the testing procedure are described elsewhere [13,14]. During the testing sessions the subjects had their eyes closed and wore photoresistable ceramic glasses so that a visual detection of the odor stick was impossible.

Laserneedle acupuncture

Stimulation was performed with a Laserneedle®-apparatus (Ronbar AG, Basel, Switzerland). The laserneedles emit red light of a wavelength of 685 nm. Stimulation was performed in the continuous wave mode. Including loss over the optical fibres the output power of the laserneedles at their distal end amounts to 30-40 mW. The energy transferred to the skin in a treatment of 25 minutes was up to approximately 70 J [4,5].

For safety purposes as well as to comply with the doubled-blinded study design, both, subjects and therapist, had to wear safety glasses. Subjects wore non-transparent glasses made of ceramic. The therapist used semi-transparent blue safety glasses with a filter function for red light in the wavelength of the laser.

We used a special acupuncture schema to impair the olfactory system (Bahr FR, personal communication). The laserneedles were affixed to the skin at the following acupoints:

- Hegu (Li 4): On the dorsum of the hand, between the 1st and 2nd metacarpal bones, approximately on the midpoint of the 2nd metacarpal bone [15].
- Yingxiang (Li 20): In the upper border of the nasolabial groove, besides the midpoint of the lateral border of the nasal alar wing, 0.5 cun from the nostril (1 cun is a chinese unit of measurement corresponding to the width of the patient's thumb) [15].
- Master Point of the Qi moving fluid: On the dorsum of the hand, on the basis of the 3rd metacarpal bone, distal to the processus styloideus ossis metacarpi III (Bahr FR, personal communication).

Hegu and Yingxiang were used on both sides of the body, the Master Point of the Qi moving fluid only on the dominant side depending on the handedness. Of the 64 subjects, 56 were right-handed and four were left-handed. Four subjects were bimanual. In these four subjects the Master Point of the Qi moving fluid was used on both sides.

For placebo treatment the laserneedles were attached to the acupoints in the same way as for laserneedle stimulation, but the laserneedle apparatus was not switched on. Not the acupuncture therapist but a scientist, who was aware of the randomization, switched the apparatus on while the subject and the therapist were not able to watch this. This scientist did not take part in any further investigations of the study.

Questionnaires and psychometric tests

Visual analogue scales [16] were used for psychometric ratings. Subjects rated their current state of hunger (0 = not hungry at all, 100 = very hungry), their desire for food (0 = very weak, 100 = very strong), and the fullness of their stomach (0 = not full at all, 100 = very full).

Subjects were interviewed if they had recognized anything unusual during acupuncture/placebo-acupuncture. If so, they had to state the period of time the sensation lasted and the kind of sensation they had noticed. They were also advised to rate the intensity (0 = very weak, 100 = very strong) and

painfulness of the stimulus (0 = very weak, 100 = very strong) on a visual analogue scale [16].

Concerning the expectancy of the subjects towards the efficacy of laserneedle acupuncture, the test persons had to complete the validated 11-item scale Holistic Complementary and Alternative Medicine Questionnaire (HCAMQ (11)). The HCAMQ acquires the attitude of the subjects towards complementary and alternative medicine (CAM) in general and the belief about holistic health (HH). Out of an 11-item scale a cumulative HCAMQ-score (min = 11, max = 66) is generated that can be subdivided into a CAM-subscore (min = 6, max = 36) and an HH-subscore (min = 5, max = 30). A lower score of the whole HCAMQ-score as well as of each subscore indicates a more positive attitude towards CAM and HH. For classification into sceptics and non-sceptics the subjects were asked whether they regarded laserneedle acupuncture as being an effective medical therapy using a six-point graduated forced choice questionnaire (three grades for a non-sceptical attitude and three grades for a sceptical attitude; 1-3 = strongly agree - mildly agree, 4-6 = mildly disagree - strongly disagree).

Depressive symptoms were assessed using the Beck Depression Inventory (BDI) (17). The BDI is a widely-used and well validated self-report inventory for the registration of the severity of depressive symptoms with scores ranging from 0 to 63. Scores of 0 to 9 are considered normal (18). None of our subjects had BDI scores of more than 9.

Experimental procedure

Subjects underwent two testing sessions on separate days with an interval of at least six days (range = 6 - 224 days; mean = 35.1 days; SEM 6.1 days). This time range was distributed equally between the groups of stimulation and non-stimulation ($range_{stimulation}$ = 6 – 224; $range_{non\text{-}stimulation}$ = 7 – 154; $mean_{stimulation}$ = 32.7 (SD 53.6); $mean_{non\text{-}stimulation}$ = 37.5 (SD 44.7); t(1,62) = 0.39, n.s.).

All subjects were tested individually in a ventilated, illuminated, and quiet room. Subjects were asked not to eat at all or drink caloric beverages or coffee during the testing sessions.

On day one, three olfactory detection threshold tests with n-butanol were conducted (T1 = 0 min, T2 = 35 min, T3 = 105 min) without any laserneedle stimulation. All 64 subjects underwent this so-called baseline investigation.

After the baseline investigation the subjects were randomized into two groups: 32 subjects (16 non-sceptics and 16 sceptics, 8 female and 8 male subjects each) to receive laserneedle stimulation and 32 subjects (16 non-sceptics and 16 sceptics, 8 female and 8 male subjects each) to receive placebo treatment (Figure 1a). Randomization was performed by a scientist who did not communicate with the test persons or the therapist using a computer program (LANEG Software, D. Schikora).

For each subject, the second testing session was scheduled approximately at the same time of day and subjects were advised to return in the same state of satiety as in the first testing session. On day two, three olfactory detection threshold tests with n-butanol were performed after the same periods of time (T1* = 0 min, T2* = 35 min, T3* = 105 min) (Figure 1b). After completion of the first threshold test, the acupoints were searched by pressure at the described locations.

Acupuncture points were considered to be found when the test person perceived a pressure pain. The skin was then cleaned with disinfection solution and the location of the acupoints was verified with the aid of a pen-like point-searching instrument (Silberbauer PS3, Blum, Germany). This instrument detects the skin resistance that is known to be lower at the acupoints [19]. Laserneedles were then directly attached to the defined acupoints. Thereupon subjects and the therapist put their glasses on. A third person switched the laserneedle apparatus on, or pretended to do so for placebo treatment, and left the room subsequently. After 25 minutes the second olfactory detection threshold test was performed (T2* = 35 min). Upon completion of the threshold test, the plug of the laserneedle apparatus was pulled. Subjects rested for further 60 minutes, followed by the last threshold test (T3* = 105 min).

Statistics

The SPSS program package (version 15.0 for Windows, SPSS Inc, Chicago, IL, USA) was used for statistical evaluation. Mean scores, standard deviations, and standard errors of mean were calculated. The following data were submitted to analyses

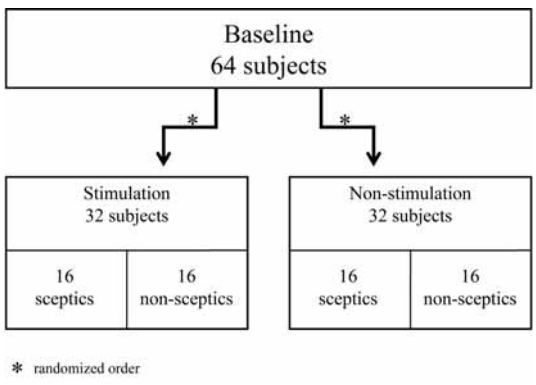

Figure 1a. Test procedure and classification of subjects

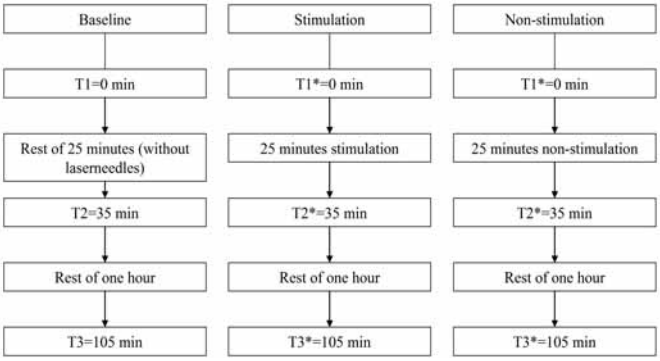

Figure 1b. Experimental procedure. Note that determining the olfactory detection threshold took about 5 - 10 minutes.

of variance (ANOVAs) using the general linear model: olfactory detection thresholds, BDI scores, age, ratings of the state of hunger, desire for food, fullness of the stomach, the HCAMQ-scores, the CAM- and the HH-subscores, and the scores referring to the attitude towards (laserneedle) acupuncture. For sensations during (non-) stimulation and the kind of the sensation, the intensity, and the painfulness of the felt sensations frequencies as well as ANOVAs using the general linear model were calculated. Where appropriate, degrees of freedom were adjusted using the Greenhouse-Geiser method. We looked for main effects as well as second-order interactions between these factors. Existing second-order interactions were corrected using the Bonferroni method. T-tests for independent samples were used to compare differences between olfactory detection thresholds (T2*-T1* and T3*-T1*) as well as differences of the time range between day one and day two of the stimulation and the non-stimulation group. The alpha level for all tests was set at 0.05.

RESULTS

Depressive symptoms

The subjects did not suffer from depressive symptoms (BDI score: $mean_{day1} = 1.8$ (SD 2.1), range $_{day1}$: 0-8; $mean_{day2} = 1.3$ (SD 1.7) range $_{day2}$: 0-6). Differences between days one and two were small, yet statistically significant ($F(1,63) = 10.41$, $p = 0.002$). Male and female subjects did not differ significantly with respect to the BDI score.

State of satiety

On both testing days, subjects described themselves as slightly hungry ($mean_{day1} = 30.2$ (SD 25.3), $mean_{day2} = 32.0$ (SD 23.2)), they had a low desire for food ($mean_{day1} = 25.6$ (SD 22.5), $mean_{day2} = 28.9$ (SD 21.4)), and they described their stomach as being moderately full ($mean_{day1} = 44.0$ (SD 21.4), $mean_{day2} = 46.7$ (SD 22.0)). Differences between the two testing days were statistically not significant ($F_{hunger}(1,63) = 0.61$, n.s., $F_{desire\ for\ food}(1,63) = 3.19$, n.s., $F_{filling\ state\ of\ the\ stomach}(1,63) = 1.28$, n.s.).

Expectancy

The attitude towards laserneedle acupuncture differed significantly between groups (laserneedle acupuncture: $mean_{non\text{-}sceptics} = 2.6$ (SD 0.5); $mean_{sceptics} = 4.9$ (SD 0.8); $F(1,62) = 196.9$, $p < 0.001$). The cumulative HCAMQ-score as well as the CAM- and the HH-subscores also differed significantly between the groups (cumulative HCAMQ-score: $mean_{non\text{-}sceptics} = 30.3$ (SD 5.3), $mean_{sceptics} = 38.1$ (SD 6.2), $F(1,62) = 28.9$, $p < 0.001$; CAM-subscore: $mean_{non\text{-}sceptics} = 20.6$ (SD 4.1), $mean_{sceptics} = 26.8$ (SD 4.8), $F(1,62) = 30.7$, $p < 0.001$; HH-subscore: $mean_{non\text{-}sceptics} = 9.8$ (SD 2.5), $mean_{sceptics} = 11.3$ (SD 2.4), $F(1,62) = 6.0$, $p = 0.017$).

Olfactory detection thresholds

The mean olfactory detection threshold for n-butanol in 64 subjects during the baseline measurement (day one) was 8.9 (SD 2.3) at T1 (0 min), 9.1 (SD 2.3) at T2 (35 min), and 9.2 (SD 2.3) at T3 (105 min) (Table 1). No significant differences were observed between the three time points ($F(2,126) = 1.07$, n.s.). Sceptics and non-sceptics did not differ significantly in their olfactory detection thresholds ($F(2,124) = 1.13$, n.s.) (Figure 3a). On the second testing day, the olfactory detection thresholds of the subjects who were assigned to the non-stimulation (placebo) group neither differed over time between T1* and T3* nor did they differ to the thresholds measured on day 1 (Table 2). This was also true if sceptics and non-sceptics were analyzed separately. Moreover, the comparison between sceptics and non-sceptics in the placebo group revealed no significant differences at any of the time-points (Tables 3a and 3b, Figure 3b).

On the contrary, significant effects were found in the stimulation (laserneedle acupuncture) group. Before the onset of laserneedle acupuncture (T1*), the mean olfactory detection thresholds did not differ significantly from the thresholds measured on day 1. Directly after stimulation (T2*) and one hour later (T3*) significantly lower olfactory thresholds were investigated. Mean olfactory detection thresholds were 8.8 (SD 2.2) at T1*, 12.1 (SD 2.6) at T2* and 12.5 (SD 2.1) at T3* (Table 2).

Table 1. Olfactory detection thresholds of n-butanol investigated on day one (baseline investigation, n = 64, T1 = 0 min, T2 = 35 min, T3 = 105 min).

Day 1	Attitude	Mean	SD	n
Olfactory Threshold at T1 (0 min)	Non-sceptics	9.21	2.30	32
	Sceptics	8.67	2.40	32
	Total	8.94	2.35	64
Olfactory Threshold at T2 (35 min)	Non-sceptics	9.36	2.50	32
	Sceptics	8.90	2.10	32
	Total	9.13	2.30	64
Olfactory Threshold at T3 (105 min)	Non-sceptics	9.66	2.50	32
	Sceptics	8.71	2.02	32
	Total	9.18	2.30	64

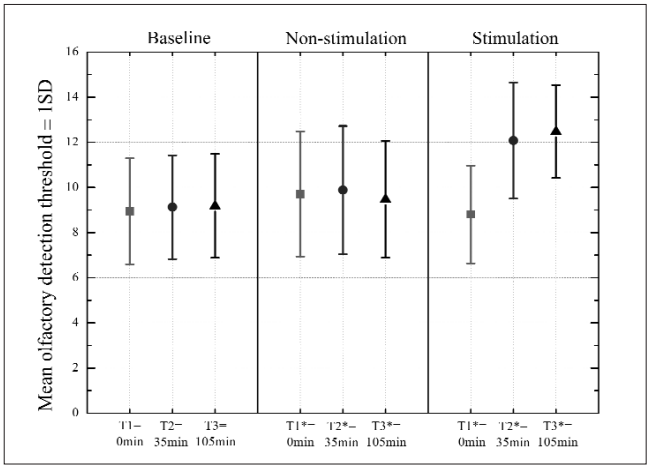

Figure 2. Means of olfactory detection thresholds depending on the condition (baseline: n = 64, non-stimulation: n = 32, stimulation: n = 32). In the stimulation group the significant differences are illustrated between T1* and T2* and T1* and T3*, whereas no difference between T2* and T3* is seen).

Table 2. Olfactory detection thresholds of n-butanol investigated on day two (non-stimulation (n = 32), stimulation (n = 32), T1* = 0 min, T2* = 35 min, T3* = 105 min).

Day 2	Condition	Mean	SD	n
Olfactory Threshold	Non-Stimulation	9.71	2.77	32
at T1* (0 min)	Stimulation	8.81	2.16	32
	Total	9.26	2.51	64
Olfactory Threshold	Non-Stimulation	9.88	2.84	32
at T2* (35 min)	Stimulation	12.08	2.57	32
	Total	10.98	2.91	64
Olfactory Threshold	Non-Stimulation	9.48	2.59	32
at T3* (105 min)	Stimulation	12.48	2.06	32
	Total	10.98	2.77	64

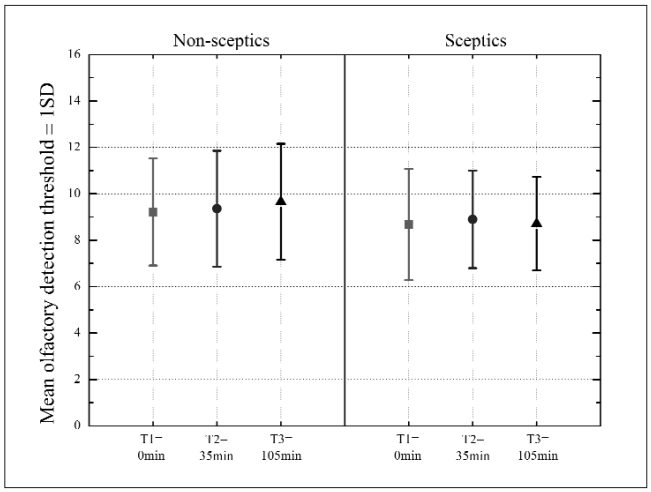

Figure 3a. Means of olfactory detection thresholds depending on the attitude on day one (non-sceptics: n = 32, sceptics: n = 32).

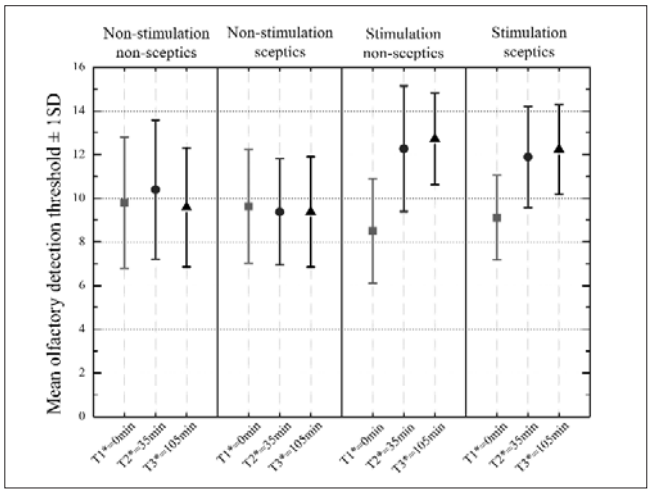

Figure 3b. Means of olfactory detection thresholds depending on the attitude on day two (non-stimulation, non-sceptics: n = 16, non-stimulation, sceptics: n = 16, stimulation, non-sceptics: n = 16, stimulation, sceptics: n = 16).

Table 3a. Olfactory detection thresholds of n-butanol investigated on day two (non-stimulation (n = 16), stimulation (n = 16), non-sceptics (n = 32), T1* = 0 min, T2* = 35 min, T3* = 105 min).

Non-sceptics	Condition	Mean	SD	n
Olfactory Threshold	Non-Stimulation	9.80	3.01	16
at T1* (0 min)	Stimulation	8.50	2.39	16
	Total	9.15	2.75	32
Olfactory Threshold	Non-Stimulation	10.39	3.19	16
at T2* (35 min)	Stimulation	12.27	2.87	16
	Total	11.33	3.13	32
Olfactory Threshold	Non-Stimulation	9.58	2.73	16
at T3* (105 min)	Stimulation	12.72	2.10	16
	Total	11.15	2.88	32

Table 3b. Olfactory detection thresholds of n-butanol investigated on day two (non-stimulation (n = 16), stimulation (n = 16), sceptics (n = 32), T1* = 0 min, T2* = 35 min, T3* = 105 min).

Sceptics	Condition	Mean	SD	n
Olfactory Threshold	Non-Stimulation	9.63	2.61	16
at T1* (0 min)	Stimulation	9.11	1.94	16
	Total	9.37	2.27	32
Olfactory Threshold	Non-Stimulation	9.38	2.43	16
at T2* (35 min)	Stimulation	11.89	2.32	16
	Total	10.63	2.66	32
Olfactory Threshold	Non-Stimulation	9.38	2.53	16
at T3* (105 min)	Stimulation	12.23	2.05	16
	Total	10.81	2.69	32

Differences between time-points were significant ($F(2,62) = 66.34$, $p < 0.001$; T1* vs T2*: $p < 0.001$; T1* vs T3*: $p < 0.001$). Differences between T2* and T3* were not significant (Figure 2).

This was also the case when sceptic and non-sceptic subjects in the stimulation group were analyzed separately (Tables 3a and 3b, Figure 3b). In both groups, laserneedle acupuncture led to significantly lower olfactory thresholds over time (non-sceptics: $F(2,30) = 39.0$, $p < 0.001$; T1* vs T2*: $p < 0.001$; T1* vs T3*: $p < 0.001$; sceptics: $F(2,30) = 28.43$, $p < 0.001$; T1* vs T2*: $p < 0.001$; T1* vs T3*: $p < 0.001$). Differences between T2* and T3* were not significant in both, sceptic and non-sceptic subjects. The olfactory thresholds of the sceptic subjects did not significantly differ from that of the non-sceptic subjects at any time-point.

The comparison of the differences of the olfactory detection thresholds at T2*-T1* and T3*-T1* of the non-stimulation (placebo) group with that of the stimulation (laserneedle acupuncture) group revealed a significant result (T2*-T1*: $t(1,62) = 6.49$, $p < 0.001$; T3*-T1*: $t(1,62) = 9.36$, $p < 0.001$). Thus laserneedle acupuncture significantly effected olfactory detection thresholds measured directly after stimulation (T2*) and one hour later (T3*).

Olfactory detection thresholds did not differ between male and female subjects. This was true at all time-points and for both over-all and sub-group analyses ($F_{day1}(2,124) = 0.91$, n.s., $F_{non\text{-}stimulation}(1.6,48.0) = 0.79$, n. s., $F_{stimulation}(2,60) = 0.11$, n.s.).

Reported sensations during laserneedle stimulation / non-stimulation

21 of the 64 subjects (32.8%) reported sensations during treatment on day two. Sensations were perceived both, by subjects in the stimulation and the non-stimulation group. Perceived sensations were of rather weak intensity (mean = 28.7; SD = 22.3) and low painfulness (mean = 9.5; SD = 16.5).

In the group of stimulation (laserneedle acupuncture), nine of the 32 subjects (28.1%) reported sensations during treatment (prickle, warmth, pain or vertigo). In the group of non-stimulation (placebo) 12, of the 32 subjects (37.5%) reported sensations during treatment (prickle, warmth, or pain) (Figure 4). Neither the overall frequency of reported sensations, nor the frequency of particular sensations or the reported intensity or painfulness differed significantly between the stimulation and the non-stimulation group. Likewise, the reported sensations did not differ significantly between non-sceptic and sceptic subjects.

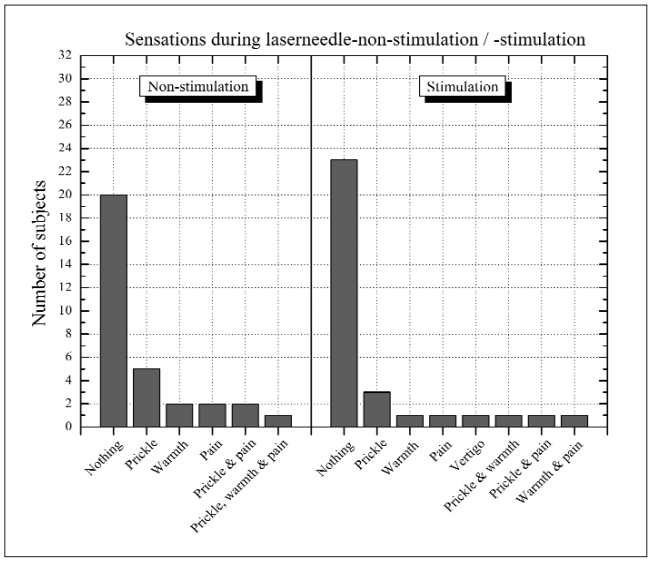

Figure 4. Frequencies of sensations during non-stimulation/stimulation with laserneedles (non-stimulation: n = 32, stimulation: n = 32).

DISCUSSION

In this study we were able to demonstrate that laserneedle acupuncture has specific effects on the human olfactory system. In detail, laserneedle stimulation decreases olfactory detection thresholds, i.e. lower concentrations of an odorant can be detected. Importantly, our results show that the effect of laserneedle stimulation on the olfactory system is not a placebo effect, and is independent from the expectancy of subjects towards laserneedle acupuncture. Olfactory detection thresholds were not affected by placebo stimulation, and laserneedle stimulation was equally effective in subjects who were sceptic of the therapy as in subjects who had a positive attitude towards the therapy.

The mechanism of the effect of laserneedle acupuncture is not yet explained in detail, but it is known that laser light has effects on biochemical processes. By affecting particularly lower skin layers, laser light is absorbed for example by cytochromes and porphyrins. Photochemical reactions stimulating the respiratory chain lead to a phosphorylation of ADP and therefore to a higher membrane potential [20]. On account of that, we presume that the effect of laserneedle-acupuncture we found in our study is also a biochemical one, which probably affects special regions of the CNS depending on the special combination of acupuncture points and the connected meridians known from the traditional Chinese medicine. Unfortunately, the functions of the meridians are not completely understood until today. The effect of laserneedle acupuncture of the utilized special combination of acupoints on olfactory sensitivity could possibly be explained by a decrease in olfactory mucosa swelling. This may lead to a higher air flow in the nose and due to this to a higher number of molecules reaching the olfactory receptors.

In previous studies laserneedle acupuncture has been compared to classic acupuncture, acupressure, or acupuncture of non-meridian placebo-points [6,21,22]. In our study we validated the effectiveness of laserneedle acupuncture in comparison to placebo in a double-blinded, placebo-controlled, randomized design.

The effect of laserneedle stimulation on the olfactory detection thresholds was already detectable at the end of the stimulation period, i.e. after 25 minutes. The effect lasted at least until the end of our observation period, i.e. 70 minutes after the end of stimulation. Thresholds did not differ significantly between these two time-points. Our study design did not allow to determine how long the effect of laserneedle stimulation persisted, and whether it was increasing, decreasing, or stable over the next hours and days. This will be the subject of further studies.

Our results confirm and expand the results of Tanaka and Mukaino [3] who reported decreased olfactory detection thresholds after acupuncture of the ear. In contrast to Tanaka and Mukaino [3], however, our method allowed a double-blinded, randomized study design with an effective placebo method.

Our observation that non-sceptics and sceptics did not differ in their reaction to acupuncture supports the findings of Pariente et al. [23] who also showed that expectancy does not influence the effect of acupuncture. Our data also shed new light on the results of the nationwide “German Acupuncture Trials” (GERAC). In this study both, verum acupuncture (acupuncture of real acupuncture points) and sham acupuncture (acupuncture of defined non-meridian acupuncture points), were effective in the treatment of migraine [7]. Our results contradict the speculations that the results of the sham group were due to “a positive expectancy of the patients” [24] or “a powerful placebo effect” [7]. Instead, our results support the statement of Thalmann [25]. This author criticized that the sham acupuncture of the GERAC study was suboptimal because the acupuncture points for the sham acupuncture were chosen in the so-called “Head’s zones”. These zones constitute a cuta-

neous projection area of the viscera in the way that stimulation in a certain Head's zone leads to a reflex circuit which affects also distant viscera. Taking this into consideration, it seems possible that sham acupuncture can result in a reduction of pain through the visceral nerve of the related organ, and may be similarly effective as real acupuncture for pain reduction as long as the stimulation points of both methods lie within the same Head's zone.

Furthermore, our data support the assumption that laserneedle acupuncture has few if any significant side effects. Subjects who received laserneedle stimulation reported sensations (prickle, warmth, pain, vertigo) with the same frequency and perceived intensity as subjects in the placebo group. These findings support the results of Litscher and Schikora [5], allowing effective double-blinded study designs since the subjects have no means to identify whether they receive real laserneedle stimulation or not.

It is not clear from our study whether acupuncture may be an effective treatment in olfactory dysfunction. However, our study delivers sound evidence that acupuncture can have specific effects on the olfactory system, and therefore provides a rationale to investigate the therapeutic efficiency of acupuncture in patients with olfactory dysfunctions.

In conclusion, the results of this study show that laserneedle acupuncture is an effective method to decrease olfactory detection thresholds, i.e. to improve the olfactory perception after one session of stimulation for at least one hour. Moreover, these results also support the assumption that acupuncture is effective in general, as we were able to show that the effects of acupuncture are not due to a placebo effect, and were independent from the attitude or expectancy towards the method.

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