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# Review of transcutaneous electrical acupoint stimulation and related devices

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**Abstract**

A review was undertaken of the operation process and development of transcutaneous electrical acupoint stimulation (TEAS) and related devices for TEAS, with the aim to offer a reference for developing an international standard for the basic safety and essential performance of the devices. The articles related to TEAS and instruction of devices for TEAS were searched using the EMBASE, MEDLINE, and Web of Science databases with the time period from inception to July 18, 2023. In the absence of a parameter description of the stimulators, a multimeter was used to measure the output voltage, resistance, and current. Thirty-two related devices for TEAS were obtained. The safety parameters of most devices were neither clearly defined, nor standardized, and in some cases were missing. There was a noticeable disparity in the upper safety limits of the output current among the devices. The sizes of the skin electrode pads as well as the lengths of the electrode connecting wires of most devices were not clearly indicated. Acupoints on different parts of the human body, including the upper limbs, head, auricle, chest, abdomen, trunk, and lower limbs, required different maximum tolerable current intensities and current densities. It is important to indicate comprehensive output/safety parameters and essential performance for devices for TEAS to meet the need of global distribution, achieve precise stimulation parameters at different acupoints across the human body, and allay any safety concern of national therapeutic device authorities, the regulators, manufacturers, and end users.

**Keywords:** Transcutaneous electrical acupoint stimulation; Acupoint; Device for transcutaneous electrical acupoint stimulation; Basic safety; Essential performance

## 1. Introduction

Acupuncture is the vanguard in the internationalization of traditional Chinese medicine. It has been adopted and practiced in 196 countries or regions around the world.[1] Transcutaneous electrical acupoint stimulation (TEAS) is a novel acupuncture application. However, the overall condition of related devices for TEAS remains unknown. The increasing interest and application of TEAS, as well as the growing expectations and concerns by end-users regarding the safety and performance of TEAS, necessitate an international standard for the operation and development of related devices that pertain to transcutaneous electrical acupoint stimulators. This study aims to review the operational process and the potential for further development of TEAS and related devices.

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## 2. Methods

### 2.1. Literature and instruction review

Predefined strategies were used to search the EMBASE, PubMed, and Web of Science with the time period from their inception to July 18, 2023, for related publication or devices pertaining to transcutaneous electrical acupoint stimulators. The search terms for the screening of eligible studies or products included “transcutaneous electrical acupoint stimulation” or “transcutaneous electrical acupoint stimulators” or “transcutaneous electrical stimulators for acupoints” or “transcutaneous electrical nerve stimulators with acupoints” or “device for transcutaneous electrical acupoint stimulation,” and a combination of free-text terms and controlled vocabulary was adopted to facilitate the literature search. Three rounds (the first round from November 23, 2021, to March 15, 2022; the second from March 16 to March 25 in 2022; and the third from July 1 to December 31 in 2022) of investigation were carried out based on international expert consultation meetings to gain the knowledge about the development of transcutaneous electrical acupoint stimulators internationally. The available parameters of different stimulators were recorded.

### 2.2. Measurement of the output parameters of related devices pertaining to transcutaneous electrical acupoint stimulators

A multimeter (FLUKE-15B+; Anhui Shifu Instrument Co, Ltd, Wuhu, Anhui Province, China) was used to measure the output voltage, resistance, and current of the transcutaneous electrical acupoint stimulators that lacked listing the specifications of the parameters in the instruction manual. An oscilloscope (TEKTRONIX TBS1102X, TEKTRONIX [China] Co, Ltd, Shanghai, China) was employed to display the pulse waveform and energy scope in the absence of related information.



## 3. Results

### 3.1. Overall condition of related devices pertaining to transcutaneous electrical acupoint stimulators around the globe

The 3 rounds of investigation identified 32 related devices for TEAS (Table 1) produced by 27 manufacturers from 10 countries: China, Japan, Germany, Australia, the United Kingdom, Poland, Finland, the Netherlands, Canada, and the United States. The parameters of the different stimulators (Table 1) varied concerning the different manufacturers and the country.

### 3.2. Safety parameters

**3.2.1. Safety of TEAS in the clinical application** A total of 1254 articles were retrieved from the 3 databases, including product manuals and device research articles, of which 151 that were duplicate articles were deleted. After intensive reading, 48 articles were selected for review, including 32 device descriptions, 15 clinical research reports, and 1 animal experiment research report. Figure 1 illustrates the article screening scheme in this study.

TEAS is a noninvasive treatment method and has been widely recognized for its clinical efficacy.[2] Compared with conventional acupuncture therapy, TEAS demonstrates a high level of safety.

*3.2.1.1. Acupoints on the upper and lower limbs*

Chao et al[3] performed TEAS at bilateral Hegu (LI4) and Sanyinjiao (SP6) at a frequency of 100 Hz with a burst frequency of 2 Hz during the first stage of labor during parturition. They reported a reduction in the visual analog scale (VAS) score by ≥3 compared with the placebo intervention (a very low electrical stimulation with less than 5 mA only and no burst frequency of 2 Hz) and also found an increase in the operative delivery rate. Neither group reported an adverse event.

Mucuk et al[4] performed TEAS at bilateral Hegu (LI4) in the women during the active phase of labor and assessed the effects of TEAS on labor pain (VAS) and adrenocorticotropic hormone and cortisol levels. The results showed that TEAS lowered the adrenocorticotropic hormone and cortisol levels and VAS score compared with the control group (no intervention). There were no adverse events for either group.

Wang et al[5] systematically evaluated the VAS score in 1019 patients in 12 randomized controlled trials that employed TEAS at acupoints Hegu (LI4), Neiguan (PC6), Zusanli (ST36), Tianzhu (BL10), Fengchi (GB20), and Baihui (DU20) on the limbs, neck, and head for managing postoperative pain. The results found that TEAS significantly decreased the VAS scores of the patients undergoing open and minimally invasive surgeries; reduced the incidence of postoperative pain, dizziness, nausea, and vomiting and the number of postoperative analgesic medications ingested; and accelerated postoperative recovery. The results demonstrated TEAS was a safe nonpharmacological therapy for preventing and treating postoperative pain.

Li et al[6] performed TEAS at bilateral Zusanli (ST36) in the women 5 hours after the cesarean section and twice daily from days 1 to 3 postoperation. The sham group received TEAS at bilateral points 10–15 cm down and 3–4 cm lateral to Zusanli (ST36). The study reported that TEAS promoted postoperative recovery, by facilitating gastrointestinal motility and alleviating symptoms related to upper gastrointestinal motility. This meant that patients had a reduction in the time taken to resume semifluid, a decrease in the total score of loss of appetite, and diminution in the incidence of belching during days 1 to 3 postoperation when compared with the sham group. Neither group reported adverse event.

Zhao et al[7] administered TEAS at the acupoints Hegu (LI4), Yuji (LU10), Zusanli (ST36), and Chengshan (BL57) in the patients with muscle spasms after brain injury. The results showed that TEAS at 100 Hz decreased wrist spasticity at weeks 2, 3, and 4 of treatment and 1 month after treatment compared with TEAS at 2 Hz or the sham group. This study concluded that TEAS at 100 Hz was a safe and effective treatment method for relieving muscle spasms after brain injury. There were no adverse events reported during treatment and follow-up period.

*3.2.1.2. Acupoints on the head and auricle*

Zhang et al[8] conducted a randomized controlled trial on the clinical efficacy and safety of transcutaneous electrical cranial-auricular stimulation (TECAS) and escitalopram in the treatment of mild to moderate depression. They found that TEAS applied at the acupoints Baihui (DU20), Yintang (EX-HN3), the auricular sites designated for the liver ($CO_{12}$), and heart ($CO_{15}$) was equivalent to escitalopram in alleviating depression and related symptoms. They also reported that TEAS had special efficacy in reducing trauma-related depression, with higher safety and acceptability than escitalopram. Moreover, the overall incidence of adverse events in the TECAS group was much lower than that in the escitalopram group. Specifically, the 5 most frequent adverse events that occurred in the escitalopram group were somnolence, nausea, dizziness, palpitation, and decreased appetite, and the TECAS group experienced dramatically lower incidence of somnolence, nausea, dizziness, decreased appetite, insomnia, tiredness, and dry mouth.

*3.2.1.3. Acupoints on the abdomen, trunk, and lower limbs*

Jin et al[9] performed TEAS at Guanyuan (RN4), bilateral Shenshu (BL23), and left Zusanli (ST36) in the men with asthenozoospermia and concluded that TEAS was effective for treating asthenozoospermia by improving sperm motility and vitality. Liu et al[10] performed TEAS at the Huato-Jiaji (T10-L3) and Ciliao (BL32) acupoints in the women with labor pain at a frequency of 100 Hz with a burst frequency of 2 Hz. They reported that TEAS significantly reduced VAS score compared with the control group (not receiving any analgesia). There were no adverse effects reported in the 2 studies.

**3.2.2. Current status of related devices pertaining to transcutaneous electrical acupoint stimulators** Most of transcutaneous electrical acupoint stimulators did not report comprehensive parameters of stimulation (Table 1). The above studies showed that TEAS had some unique advantages in terms of safety in clinical application, whereas the safety parameter ranges of the stimulators were vague and limited to the scale and quality of the clinical study. A clear and objective perception remains to be determined regarding the safety of transcutaneous electrical acupoint stimulators in clinical application. This study extracted and summarized the safety parameters of 32 transcutaneous acupoint electrical stimulators (Table 1) on the basis of available studies, market research, and stimulator manuals. The safety parameters of most stimulators were neither clearly defined, nor standardized, or in some cases not mentioned. For example, the upper safety limit of the output current was not clearly defined. The upper safety limits of the output current varied among different stimulators. The sizes of the skin electrode pads as well as the electrode connecting

**Table 1**

**Safety parameters of related devices for TEAS.**

| No. | Model | Stimulation location | Power supply | Input power | Output pulse waveform | Output power | Output pulse frequency | Output voltage peak | Output current limit | Output pulse width | The most energy of a pulse | Skin electrode | Output deviation | Current density | Electrode connection wire length | Cross section area of electrode connecting wire | Electrode area |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | NET-1000 | Auricle | NS | NS | NS | NS | 0.5–100 Hz | NS | 0–600 mA | NS | NS | NS | NS | NS | NS | NS | NS |
| 2 | NET-2000 | Auricle | NS | NS | NS | NS | 0.5–100 Hz | NS | 0–600 mA | NS | NS | NS | NS | NS | NS | NS | NS |
| 3 | Tinnoff | Auricle | NS | NS | NS | NS | | NS | | NS | NS | NS | NS | NS | NS | NS | NS |
| 4 | TENSTem dental | Auricle | NS | NS | NS | NS | 0.5–120 Hz | NS | 0–35 mA | 70–500 μs | NS | NS | NS | NS | NS | NS | NS |
| 5 | Twister | Auricle | NS | NS | NS | NS | | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 6 | ES-420 | Auricle | NS | NS | NS | NS | 1–200 Hz | NS | 0–99 mA | 50–250 μs | NS | NS | NS | NS | NS | NS | NS |
| 7 | S88X GRASS stimulator | Auricle | NS | NS | NS | NS | 0.1–1000 Hz | NS | | 10–99 μs | NS | NS | NS | NS | NS | NS | NS |
| 8 | V-TENS plus | Auricle | NS | NS | NS | NS | 2–200 Hz, 8000–12,000 Hz | NS | 0–50 mA | 2–250 μs 5–40 μs | NS | NS | NS | NS | NS | NS | NS |
| 9 | EMS7500 | Auricle | NS | NS | NS | NS | 2–120 Hz | NS | 100 mA | 50–300 μs | NS | NS | NS | NS | NS | NS | NS |
| 10 | S20 | Auricle | NS | NS | NS | NS | | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 11 | DoloBravo | Auricle | NS | NS | NS | NS | 1–200 Hz | NS | 0–90 mA | 50–450 μs | NS | NS | NS | NS | NS | NS | NS |
| 12 | IMER Systems | Auricle | NS | NS | NS | NS | | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 13 | SDZ-II | Auricle | NS | NS | NS | NS | 1–100 Hz | NS | ≤10 mA | NS | NS | NS | NS | NS | NS | NS | NS |
| 14 | CM02 | Auricle | NS | NS | NS | NS | | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 15 | NEMOS | Auricle | NS | NS | NS | NS | 25 Hz | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 16 | VITOS | Auricle | NS | NS | NS | NS | 25 Hz | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 17 | SDZ-IIB | Auricle and head | DC 9 V or power supply adaptor (input AC 220 V/ 50 Hz, output DC 9 V) | 5.0 VA | Asymmetric bidirectional pulse | Maximum output power 0.3 VA (250 Ω) | 1–100 Hz (adjustable) | NS | ≤10 mA (250 Ω) | 0.2 ms ± 30% | | 50 × 50 mm | NS | NS | NS | NS | NS |
| 18 | SDZ-III | Nonauricle and nonhead | DC 9 V or power supply adaptor (input AC 220 V/ 50 Hz, output DC 9 V) | 10.0 VA | Asymmetric bidirectional pulse | 0.3 VA (250 Ω) | 1–100 Hz | NS | ≤10 mA (250 Ω) | 0.2 ms ± 30% (EMC testing basic performance) | | 50 × 50 mm | NS | NS | NS | NS | NS |
| 19 | SDZ-V | Nonauricle and nonhead | DC 9 V or power supply adaptor (input AC 220 V/ 50 Hz, output DC 9 V) | 10.0 VA | Asymmetric bidirectional pulse | 0.3 VA (250 Ω) | 1–100 Hz | NS | ≤10 mA (250 Ω) | 0.2 ms ± 30 (EMC testing basic performance) | | NS | NS | NS | NS | NS | NS |
| 20 | HANS-200A | Nonauricle and nonhead | NS | NS | Symmetrical bidirectional pulse | NS | 2–100 Hz | NS | ≤40 mA, correct to 1 mA | NS | NS | NS | NS | NS | NS | NS | NS |

*Continued next page*

**Table 1** (Continued)

| No. | Model | Stimulation location | Power supply | Input power | Output pulse waveform | Output power | Output pulse frequency | Output voltage peak | Output current limit | Output pulse width | The most energy of a pulse | Skin electrode | Output deviation | Current density | Electrode connection wire length | Cross section area of electrode connecting wire | Electrode area |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 21 | JS-502A | Nonauricle and nonhead | DC 9 V battery | NS | Symmetrical bidirectional pulse | NS | 2/100, 2, 15, 40, 100 Hz | <500 V during open circuit measurement | ≤50 mA (500 Ω) deviation less than ±20% | NS | When loaded with a resistance of 500 Ω, the maximum energy of a single pulse is not more than 300 mJ | NS | Discrete increments of no more than 1 V or 1 mA per increment, with a minimum output of no more than 2% of the maximum output | Possibly exceed 2 mA (r.m.s.)/cm$^2$ | No shorter than 1 m | No less than 0.05 mm$^2$ | No less than 9 cm$^2$ |
| 22 | SP-502-A | | DC 9 V battery | NS | Symmetrical bidirectional pulse | NS | NS | NS | Rated current 50 mA | NS | NS | NS | NS | NS | NS | NS | NS |
| 23 | XS-99806 | Nonauricle and nonhead | AC 220 V ± 22 V, 50 Hz ± 1 Hz | <50 VA | Bidirectional symmetrical narrow Square wave | NS | 2, 10, 50, 100, cycling | ≤150 V | ≤10 mA (500 Ω) allowed error ±10% | 0.4–0.6 ms | The maximum output energy of a single pulse is not more than 150 mJ. | NS | NS | NS | NS | NS | NS |
| 24 | DJT-D10 | Auricle and nonauricle | AC 220 V 50 Hz | NS | NS | NS | <350 ± 15% Hz | NS | NS | 200 ± 15% μs | NS | NS | NS | NS | NS | NS | NS |
| 25 | QZT-9E | Auricle, nonauricle, nonhead | DC4.5 ± 0.5 V | NS | Asymmetrical pulse | 1.1 VA (500 Ω) | 3–2000 Hz | ≤60 $V_{p\text{-}p}$ | ≤10 mA (500 Ω), error less than ±10% | NS | NS | The reference electrode (holding electrode) has a length of 15 mm, a diameter of 4 mm, and a detection electrode length of 17 mm | NS | NS | 1.52 m | 3 mm in diameter | 2 mm in diameter for the detection electrode |

Continued next page

**Table 1** *(Continued)*

| No. | Model | Stimulation location | Power supply | Input power | Output pulse waveform | Output power | Output pulse frequency | Output voltage peak | Output current limit | Output pulse width | The most energy of a pulse | Skin electrode | Output deviation | Current density | Electrode connection wire length | Cross section area of electrode connecting wire | Electrode area |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 26 | MH-1 | Auricle | DC 6 V | NS | NS | maximum power 6VmA (at least 6kΩ) | 1–100 Hz | NS | ≤1 mA (at least 6 KΩ) | NS | NS | NS | NS | NS | 1.52 m | 3 mm in diameter | 7 mm in diameter for the clip contact surface |
| 27 | MH-II | Auricle | DC 3 V | NS | NS | NS | 1–100 Hz | NS | ≤1 mA | NS | NS | The reference electrode (handheld electrode) is 9.1 cm long and 5 mm in diameter; the detection electrode is 4.5 cm long | NS | NS | NS | 3 mm in diameter | 2.2 mm in diameter for the detection electrode |
| 28 | SZF | Auricle | DC 5 V | NS | NS | NS | NS | Rated voltage 3.3 V, constant pressure 80–90 g | ≤30 μA | NS | ≤100 mJ | NS | NS | NS | NS | NS | More than 3 $cm^2$ |
| 29 | XS-100A | Auricle | DC 6 V (4 AG3 1.5 V button cell) | NS | NS | NS | NS | NS | Quiescent current (no signal) ≤10 mA working current ≤20 mA Detection resistance Rx maximum sensitivity 10 M | NS | NS | NS | NS | NS | NS | NS | NS |
| 30 | SNH-138 | | DC 9 V | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS | NS |
| 31 | NDK (Osaka) | | Battery-driven | NS | NS | NS | 50 Hz | NS | NS | 50 μs | NS | NS | NS | NS | NS | NS | NS |
| 32 | AcuHealth Professional 900 — Search mode | Auricle and head | 0.15–4 V | NS | NS | NS | 200–2000 Hz | NS | NS | 0.3–3.6 ms | NS | NS | NS | NS | NS | NS | NS |
| | Stimulation mode | | 0–8.8 V | NS | NS | NS | 2.5 Hz | NS | Minimum current 6–8 mA (10–100kΩ) Maximum current 85–600 mA (100kΩ) | 300–330 ms | NS | NS | NS | NS | NS | NS | NS |

NS, not stated; r.m.s., root mean square; TEAS, transcutaneous electrical acupoint stimulation.

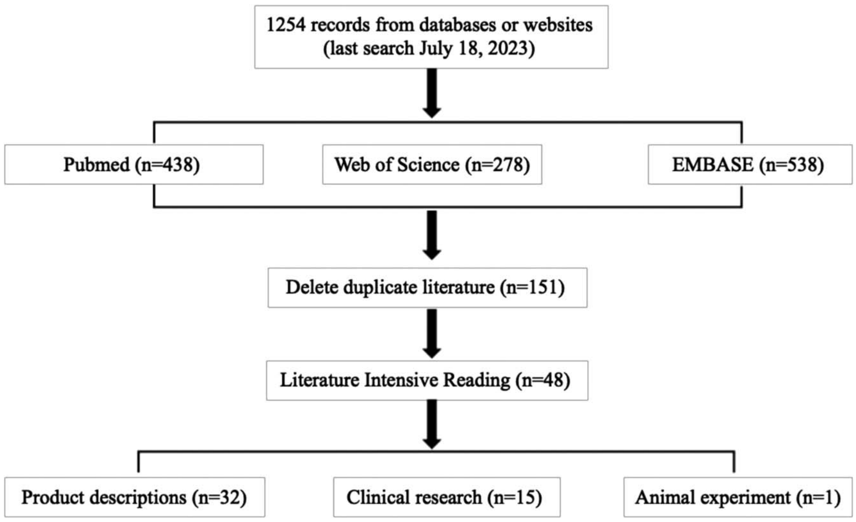


**Figure 1.** Literature screening scheme of transcutaneous electrical acupoint stimulation and related devices for TEAS. TEAS, transcutaneous electrical acupoint stimulation.

wires of most of stimulators were not clearly indicated. The above problems can impede the application of transcutaneous electrical acupoint stimulators, which will not enhance the trust of consumers or expand the use of these devices in the international market. It is necessary to clarify the safety parameters, standardize the production process, and expand the international market share of transcutaneous electrical acupoint stimulators.

There are a diverse range of transcutaneous electrical acupoint stimulators circulating in the market, and their safety parameter ranges lack unified criteria. Although efficacy is important for a medical device, safety is a primary condition for it to gain consumer trust and be widely promoted in the market.

### 3.3. Essential performance

#### 3.3.1. Selection of parameters to achieve precise stimulation for diseases or conditions

As an important device for clinical and basic research, transcutaneous electrical acupoint stimulators have been widely recognized in the industry for their therapeutic effect. The operation parameters are important indicators for evaluating the performance of the stimulators.

By reviewing the available studies, we summarized the therapeutic parameters of transcutaneous electrical acupoint stimulators. The stimulators achieved satisfactory clinical efficacy in the treatment of various conditions including postoperative neuralgia, infertility, insomnia, hypertension, respiratory diseases, and other neurological-endocrine disorders,[11–31] which is shown in Table 2. Acupoints on the chest, abdomen, trunk, upper limbs, and lower limbs were often used for clinical diagnosis and treatment of diseases. Danzhong (RN17) on the chest and Dingchuan (EX-B1) on the back were often stimulated for treating chest disorders. Hegu (LI4) and Neiguan (PC6) on the upper limbs, as well as Zusanli (ST36), Yinlingquan (SP9), and Yanglingquan (GB34) on the lower limbs, were often stimulated for treating neuralgia. Zhongwan (RN12) and Guanyuan (RN4) on the abdomen were frequently selected for treating infertility.

Transcutaneous electrical acupoint simulators were often applied with the pulse widths of 100 and 200 μs, frequencies of 2 Hz, 100 Hz, and alternating 2/100 Hz, with current intensities of 5–20 mA. According to the reviewed studies, different parameters produce different effectiveness. Some studies compared the therapeutic effects of transcutaneous acupoint electrical stimulators operated with different parameters. Frequency affected the efficacy of TEAS, which might be related to neural effects. Qu et al[20] reported that compared with the TEAS at 2 or 100 Hz, the alternating frequency of 2/100 Hz significantly elevated the level of neuropeptide Y in the follicular fluid, thereby improving the effect of external fertilization. Wang et al[29] concluded that auricular concha transcutaneous electrostimulation at 20 Hz effectively moderated epileptic seizures. Under fixed stimulation frequencies of 2 and 100 Hz, auricular concha transcutaneous electrostimulation for 30 seconds and 30 minutes exerted definite effects on epilepsy in rats.

TEAS has demonstrated high efficiency, affordability, and safety in treating brain disorders such as depression and mild cognitive impairment, as well as infertility, insomnia, and respiratory diseases. Wang et al[30] conducted TEAS at bilateral auricular acupoints sites $CO_{15}$ and $CO_{10}$ with the frequency of 20/100 Hz and current intensity of 0.6–1 mA, which significantly improved the cognitive functions. Zhao et al[27] found that the electrical stimulation at Baihui (DU20) and Yintang (DU29) on the head and auricular acupoints for the liver ($CO_{12}$) and heart ($CO_{15}$) at the alternative frequency of 4/20 Hz and current intensity of 0.5–2.0 mA significantly reduced the Pittsburgh Sleep Quality Index and Hamilton Depression Scale-17 scores and alleviated insomnia symptoms in depressed patients. Zhang et al[28] performed TEAS for 30 minutes per session with a low current intensity (3 mA in the upper limbs and 5 mA in the lower limbs) in the first week and a current intensity of 10–15 mA in the following weeks for the children with autism. They reported a significant improvement in the control of emotional response for fear or anxiety and an increase in the level/consistency of intellective relations and general impressions using the Childhood Autism Rating Scale, as well as the sensory and related factors in the Autism Behavior Checklist.

TEAS has also demonstrated definite therapeutic effects regarding analgesia after birthing, joint replacement surgery, ureteroscopic lithotripsy, and laparoscopic surgery.[16,18,32,33] Li et al[15] used a transcutaneous acupoint electrical stimulator to stimulate Yinlingquan (SP9) and Yanglingquan (GB34) in a parallel randomized clinical

**Table 2**

**Stimulation parameters of TEAS in treating various diseases or conditions.**

| No. | Author | Stimulus intensity | Pulse width | Frequency | Disease | Acupoint | Stimulation length per session |
|---|---|---|---|---|---|---|---|
| 1 | Wang et al[11] | Individually adapted stimulus intensity | 0–100 µs | 100 Hz | High-normal blood pressure | Hegu (LI4), Quchi (LI11), Zusanli (ST36), and Taichong (LR3) | 15 min |
| 2 | Ngai et al[12] | NS | 200 µs | 2 Hz | COPD | Dingchuan (EX-B1) | 45 min |
| 3 | Tu et al[13] | 5–10 mA for upper limbs; 10–30 mA for lower limbs and trunk | NS | 2/100 Hz | Postoperative analgesia after ureteroscopic lithotripsy | Shenshu (BL23) and Yinlingquan (SP9) | 30 min |
| 4 | Yu et al[14] | 6–9 mA | 0.2 ms/0.6 ms | 2/100 Hz | Neuropathic pain | Yanglingquan (GB34), Shuigou (GV26), Zusanli (ST36) | 30 min |
| 5 | Li et al[15] | A strong but comfortable current | 200 µs | Group 1: 5 Hz<br>Group 2: 100 Hz<br>Group 3: 5/100 Hz | Acute pain after the total knee arthroplasty | Yinlingquan (SP9), Yanglingquan (GB34) | 30 min |
| 6 | Sun et al[16] | A maximum current tolerated | 0.2 ms/0.6 ms | 2/100 Hz | Pain after laparoscopic surgery | Hegu (LI4), Neiguan (P6) | 30 min |
| 7 | Fatemeh et al[17] | 500 µA | NS | 2.5 Hz | Fatigue in hemodialysis patients | Zusanli (ST36), Sanyinjiao (SP6), Hegu (LI4) | 50s |
| 8 | Lu et al[18] | The maximal tolerance to the "Teh Chi" sensations of heaviness, numbness, and swelling at the point of stimulation | NS | 2/10 Hz | Chronic pain after mastectomy | Neiguan (PC6), Danzhong (CV17) | 30 min |
| 9 | Ma et al[19] | 10–15 mA | NS | 2/100 Hz | Withdrawal syndrome in heroin addicts | Hegu (LI-4), Laogong (PC-8) Neiguan (PC-6), Waiguan (SJ-5) | 30 min |
| 10 | Qu et al[20] | NS | NS | Group 1: 2 Hz<br>Group 2: 100 Hz<br>Group 3: 2/100 Hz | Patients with bilateral tubal blockage who were referred for IVF | Xuehai (SP10), Diji (SP8), LR3 (Taichong), Zusanli (ST36), Zigong (EX-CA1), Guanyuan (RN4), Neiguan (PC6), Zhongwan (RN12) | 30 min |
| 11 | Shuai et al[21] | 9–25 mA | NS | 2 Hz | Recurrent implantation failure | NS | 30 min |
| 12 | Bai[22] | 15–20 mA | NS | 30/60 Hz | Maternal gastrointestinal function recovery | Zusanli (ST36), Dubi (ST35) | 30 min |
| 13 | Dong et al[23] | Prefer patients to feel comfortable | NS | 2 Hz | Insomnia | Sanyinjiao (SP06), Neiguan (PC6), Shenmai (BL62), Zhaohai (KI6) | 20 min |
| 14 | Chen et al[24] | 5 mA | NS | 2/100 Hz | Early functional rehabilitation after total knee arthroplasty | Zusanli (ST36), Xuehai (SP10), Liangqiu (ST34), Yinlingquan (SP9), Yanglingquan (GB34), Weizhong (BL40) | 30 min |
| 15 | Cao et al[25] | 7–15 mA | NS | 10 Hz | Delirium after total hip Joint replacement in the elderly | Neiguan (PC6), Hegu (LI4) | 30 min |
| 16 | Xia et al[26] | The current intensity is tolerable by the patient | 200 µs | 100 Hz | Apoplexy | Jianyu (LI15), Quchi (LI11), Shousanli (LI10), Waiguan (SJ5) | 20 min |
| 17 | Zhao et al[27] | 0.5–2.0 mA | 200 µs | 4/20 Hz | Depressive disorder with insomnia | Baihui (GV20), Yintang (GV29), ear acupoints liver ($CO_{12}$), and heart ($CO_{15}$) | 30 min |
| 18 | Zhang et al[28] | 3–15 mA | 0.3 ms | 2/15 Hz | Autism | LI 4 (Hegu), PC6 (Neiguan), ST 36 (Zusanli), SP6 (Sanyinjiao) | 30 min |
| 19 | Wang et al[29] | 1 mA | NS | 2 Hz<br>20 Hz<br>100 Hz | Epilepsy | NS | 30s group<br>5 min group<br>10 min group<br>30 min group |
| 20 | Wang et al[30] | 0.6–1.0 mA | NS | 2/100 Hz | Mild cognitive impairment | Heart (concha, $CO_{15}$) and Kidney ($CO_{10}$) | 30 min |
| 21 | Feng et al[31] | The stimulation intensity was set to 10 mA, The current was increased to 15–20 mA if the woman could tolerate it and feel comfortable | NS | 2 Hz | Infertility | Diji (SP8), Guilai (ST29), Zigong (NR19), and Xuehai (SP10), Zusanli (ST36), Taixi (KI3), Shenshu (BL23), Guanyuan (RN4), Zhongwan (NR12) | 30 min |

COPD, chronic obstructive pulmonary disease; IVF, in vitro fertilization; NS, not stated; TEAS, transcutaneous electrical acupoint stimulation.

trial for the treatment of acute pain after total knee joint replacement. The study indicated that the combined stimulation at 5 Hz/100 Hz was more conducive to relieving acute pain after surgery than stimulation at single frequencies. Yu et al[14] concluded that TEAS with the frequency of 2 Hz and current intensity of 6–9 mA at Yanglingquan (GB34), Shuigou (DU26), and Zusanli (ST36) significantly attenuated the mechanical allodynia and thermal hyperalgesia in a rat model for chronic constriction injury.

Shuai et al[21] conducted TEAS (9–25 mA, 2 Hz) at the acupoints Sanyinjiao (SP6), Zhongji (RN3), Guanyuan (RN4), and Zigong (EX-CA1) for 30 minutes, which significantly improved the clinical outcomes of subsequent in vitro fertilization cycles among women who had experienced recurrent implantation failure. Feng et al[31] found that TEAS can enhance endometrial receptivity by stimulating Diji (SP8), Guilai (ST29), Zigong (RN19), and Xuehai (SP10) at the frequency of 2 Hz and current intensity of 10–20 mA before embryo transfer and stimulating Zusanli (ST36), Taixi (KI3), Shenshu (BL23), Guanyuan (RN4), and Zhongwan (RN12) after embryo transfer. The results indicated that the treatment significantly improved the clinical pregnancy rate, embryo transfer success rate, and live birth rate.

Ngai et al[12] pointed out that the TEAS at Dingchuan (EX-B1) at a frequency of 2 Hz and a pulse width of 200 μs improved the forced expiratory volume within 1 second ($FEV_1$), which might be related to bronchodilation induced by β-endorphin elevation.

According to the studies above, the current intensity of TEAS performed by different research teams spanned a wide range. The maximum acceptable current intensity for participants was mainly determined under the premise of comfort. Considering the thickness and structure of muscles in different parts of the body, different stimulation parameters were formulated. For example, Tu et al[13] employed the current intensity of 5–10 mA at the acupoints on the upper limbs and 10–30 mA at the acupoints on the lower limbs and trunk and defined the effect of acupoint stimulation based on the sensation of "De Qi." Table 2 shows the summary for the parameters of TEAS for treating diseases or conditions.

***3.3.2. Steady output parameters and precise acupoint stimulation*** Essential performance refers to steady output parameters needed and precise stimulation at acupoints at different parts of the human body. Different electrode design and sizes are required for exact stimulation of acupoints across the various parts of the body. The essential performance of TEAS is mainly related to the stability of the output current and the electrode shape and size at stimulated acupoints. An international standard should be developed to improve the quality of TEAS and ensure stable output and precise stimulation at different acupoints sites.

According to the available parameters of transcutaneous electrical acupoint stimulators circulating in the market, the outputs in pulse width, frequency, and current intensity present with deviations of 15%–30%, 15%, and 10%–30%, respectively. It is suggested that the deviations should be less than 10% to ensure precise output of pulse width, frequency, and current intensity.

Precise stimulation is a necessary aspect of any therapeutic response. Because the structures and distribution of acupoints vary in different parts of the human body, electrodes should be designed using different shapes and sizes to ensure optimum configuration between the electrodes and acupoints so as to achieve a therapeutic effect. Due to the close distribution of acupoints on the head and ears, the shapes and sizes of electrodes should be designed based on those of the acupoint surface. The contact areas of electrodes used to stimulate acupoints on the head, auricle, and other parts (such as the neck, chest, stomach, upper limbs, lower limbs, and trunk) should not exceed 16, 0.08, and 32 $cm^2$, respectively. According to the investigation results, the contact areas of the electrodes for stimulating acupoints on the neck, chest, stomach, upper limbs, lower limbs, and trunk did not exceed 32 $cm^2$. Considering the close distribution of cranial acupoints, smaller contact areas of the electrodes for stimulating cranial acupoints are recommended for precise stimulation. The investigation results showed that the contact area of the electrodes for stimulating cranial acupoints was 16 $cm^2$ at most when the hair was shaved.

The adhesive force of electrodes should not be less than 105% of the gravity of the electrode connecting wire. Because the position of electrical stimulation is often affected by wires, the length of the wire should be controlled within a suitable range. Most manuals did not indicate the length of the electric wire. Through measurement and practice, it is recommended to keep the wire length as 1.5 m, which is suitable for stimulating all acupoints across the human body. Due to the complex structure of the ear, it is necessary to design an electrical stimulator with a specific structure. Considering that the auricular structure is not a flat surface, particular electrodes are needed for proper electrical stimulation at local auricular acupoints. The maximum length of the electrode should be within 3 mm to stimulate auricular acupoints at the helix, antihelix, tragus, and medial side of the antitragus and scapha. The length of the electrode should be within 7 and 9 mm to stimulate auricular acupoints at the triangular fossa and cymba concha, respectively. The length of the arm to which the electrode is attached should be 5 mm more than that of the clips at the tragus to stimulate the auricular acupoints at the cymba concha. The length of the electrode should be 11 mm for the coupling with the cavum concha.

Consensus should be reached regarding all of these parameters, including the deviations of output parameters (pulse width, frequency, and current intensity), the electrode contact area, the adhesive force of the electrode, and the lengths of the wire and electrode, so as to maintain steady output parameters and precise acupoint stimulation.

## 4. Discussion

### *4.1. Differences between TEAS and transcutaneous electrical nerve stimulation*

TEAS is different from transcutaneous electrical nerve stimulation (TENS) in the following 4 aspects.

First, there is definition difference between acupoint and nerve. A nerve is an enclosed, cable-like bundle of axons. An acupoint involves different tissues, including the skin, vessel, muscle, sinew, and bone membrane.

Second, the mechanism is different. TENS exerts local effect. It originates from the gate control theory proposed by the British physiologist Patrick David Wall and the Canadian neurophysiologist R. Melzack in 1965. This theory posits a pain-modulating system in which a neural gate is present in the spinal cord that can open and close to modulate the perception of pain.

TEAS is often particular for a distal effect, brain-modulating effect, and a systemic effect.

(1) Distal effect. TEAS applied on the hind limbs promotes gastrointestinal movement and secretion through first the integrated reflex of the upper spinal cord center via the unmyelinated afferent fibers and then through the parasympathetic vagal efferent fibers.
(2) Brain-modulating effect. TEAS can increase focal cerebral blood flow perfusion and kinetic energy in the left frontal lobe, Broca's, and Wernicke's regions. Jia et al[34] observed decreased focal cerebral blood flow perfusion and kinetic energy in the left frontal lobe, Broca's, and Wernicke's regions in the children with autism before TEAS, which were increased during TEAS at bilateral Hegu (LI4), Quchi (LI11), Zusanli (ST36), and Sanyinjiao (SP6).

(3) Systemic effect. According to Han's study,[35] TEAS at Hegu (LI4) can produce a systematic analgesic effect by altering the pain thresholds of different sites in normal people. During the first 30 minutes, the pain threshold slowly increased, indicating that the analgesic effect gradually strengthened. The analgesic effect remained at a high level during the period of 30–50 minutes during TEAS. The pain threshold slowly decreased after needle extraction at the TEAS end (50 minutes) and did not fully recover to the initial level at the time point of 80 minutes.

Third, TEAS is particular for the effects on the physiological and biochemical indicators. Arginine-vasopressin and oxytocin (OXT) produced in the brain play a vital role in social behaviors and cognition. Reduction in OXT was observed in autistic children.[36] Zhang et al[28] performed a prospective single-blind controlled study on TEAS in children with autism and found that TEAS at Hegu (LI4) and Neiguan (PC6) on one side and at Zusanli (ST36) and Sanyinjiao (SP6) on the other side increased the plasma arginine-vasopressin level and prevented a reduction in plasma OXT level in the children with autism.

TEAS can improve sperm motility and vitality.[9] Compared with the baseline, 2 Hz TEAS significantly increased sperm motility and the percentage of grade a + b sperms in the patients with asthenozoospermia. In contrast, 100 Hz TEAS improved not only sperm motility and the percentage of grade a + b sperms, but also the percentage of grade a sperms. In addition, TEAS can promote the incretion of cytokines related to embryo implantation.[37]

Fourth, the stimulation magnitude is different. TENS can often cause local muscle vibration. In addition to local muscle vibration, TEAS is particular in inducing a sensation radiating to the big toe until the involuntary movement of the lower limb occurred and the muscles twitched for 3 times.

### 4.2. Prospects

An international standard involving the safety parameters and essential performance of related devices pertaining to transcutaneous electrical acupoint stimulators should be developed to enhance the safety, ensure the quality, maximize the market acceptance and recognition, and minimize any potential international trade barriers. This standard will benefit major manufacturers such as Wuxi Shenpingxintai Medical Technology Co, Ltd (China), Auri-Stim Medical, Inc (USA), Acuhealth Professional 900 (Australia), NDK (Osaka, Japan), NEMOS (Germany), Body Clock Health Care Ltd (UK), and Tinnoff Inc (Finland). It will facilitate global trade procedures and service; increase market acceptance, recognition, and circulation; and decrease international market conflicts. Furthermore, it will benefit small and middle-sized manufacturers including Suzhou Medical Equipment Factory Nanjing (China), Xiaosong Medical Device Institute (China), Astro-Med, Inc (USA), Schwa-medico BV (the Netherlands), Ito Co., Ltd (Japan), Roscoe Medical (UK), and MTR GmbH (Germany) by improving the quality of the stimulators for meeting market need and reducing potential complaints from consumers.

The standard will serve the government authorities such as the National Administration of Traditional Chinese Medicine and the Standardization Administration of China, as well as the Standardization Administration of South Korea, Japan, and Australia, in regard to supervising and controlling the quality of transcutaneous electrical acupoint stimulators. There will be referential standards for the management and production of authorities including State Administration of Market Regulation and Certification and Accreditation Administration of China and all manufacturers.

The standard will ensure the safety, quality, and clinical effect of TEAS and improve willingness of consumers to purchase transcutaneous electrical acupoint stimulators. Accordingly, the salary and welfare of engineers and workers will be improved. Academic and research institutions, such as China Academy of Chinese Medical Sciences, Korea Institute of Oriental Medicine, and University of Technology Sydney, will be interested in further research on TEAS.

Transcutaneous electrical acupoint stimulators play an important role in senior-aged care. According to the Demographic Dictionary compiled by the International Union for the Scientific Study of Population, when the proportion of people older than 60 years in a country or region reaches or exceeds 10% of the total population, or the proportion of people older than 65 years reaches or exceeds 7% of the total population, its population is called an "elderly" population, and such a society is called an "aging society." The proportion of people 65 years or older reaching 14% indicates a deeply aging society and that reaching 20% indicates a super-aging society. At present, many countries in the world have entered the aging society, including European countries such as Italy, Germany, Bulgaria, Finland, Portugal, Croatia, Greece, Latvia, Sweden, and Norway, as well as Asian countries such as Japan, China, South Korea, and Singapore. TEAS can be performed at corresponding acupoints for managing senile diseases or syndromes such as stroke-related motor disorder[38] and sense dysfunction, perioperative pain,[39] chronic pain,[40] cancer pain,[41] gastrointestinal dysfunction,[42] cognitive impairment,[30] and fatigue.[43]

Transcutaneous electrical acupoint stimulators play an important role in the field of digital medicine. The digital economy, also known as the information economy, refers to the market that exists on the Internet. The upgrading network infrastructure and information tools such as smartphones, as well as the emerging information technologies such as the Internet, cloud computing, blockchain, and the Internet of Things, continuously enhance the quantity, quality, and speed of big data processing and promote the transition from industrial economy to information economy, knowledge economy, and smart economy. China is a leader in the digital economy. As of December 2022, China has had 1.067 billion Internet users, with an Internet coverage rate of 75.6%, forming the world's largest and most vibrant digital society. With the comprehensive integration of digital technology into social interaction and production, digital life has increasingly become an important way of life, and the strong creativity of digital technology in empowering life is constantly highlighted. The overall scale of China's digital healthcare market has increased from 31.2 billion CNY in 2015 to 179.2 billion CNY in 2022, with a composite annual growth rate of 28.3%. It is expected to reach 425.6 billion CNY by 2025.

After falling ill, people no longer need to physically seek external medical treatment, but can use simple and lightweight medical equipment to self-test basic health indicators at home. Patients can connect doctors through computer terminals, transmit test data, have video conversations with doctors, and complete the entire outpatient process. When traveling to other places and experiencing emergencies, people no longer need to conduct lengthy medical history inquiries. They only need to present a personal medical card, and all cases and allergies from birth to present are recorded at a glance. All of this is not a bridge in science fiction, but a vision for the development of telemedicine across the world. Transcutaneous electrical acupoint stimulators, as noninvasive devices, can be used by the individual themselves at home under the guidance of doctors. The stimulators can fundamentally address the long-standing livelihood problem of difficulty in seeking medical treatment due to uneven distribution of medical workforce.

According to the in-depth research report on global and China's transcutaneous electrical acupoint stimulator industry in 2020 released by Beijing Newsijie International Information Consulting Co, Ltd, the global market scale exceeded US $500 million in 2019, in the commercial market of China, Japan, South Korea, Germany, United Kingdom, and Italy.

Transcutaneous electrical acupoint stimulators have broad prospects considering the basic safety and essential performance as a medical device. From the perspective of application scope, transcutaneous electrical acupoint stimulators include 2 types that can be used at medical sites and at home. TEAS is recommended and prescribed by doctors in hospitals and clinics. Potential users are required to have the guidance from the doctor when they use a stimulator at home, which require stable output, safe maximum tolerable current intensity, and precise stimulation at acupoints. It is necessary to establish an international standard to ensure the basic safety and essential performance and will promote the production and circulation of transcutaneous electrical acupoint stimulators in the market. Moreover, it is meaningful for improving the product quality, expanding trade transparency, simplifying global trade procedures and services, promoting market circulation, and decreasing international market conflicts.

## 5. Conclusion

It is important to indicate comprehensive output/safety parameters and essential performance of devices for TEAS to meet the need of global circulation, achieve precise stimulation at different acupoints of the human body, and address the safety concerns of the regulators, manufacturers, and end users.

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## Statement of ethics

None.

## Conflict of interest statement

No conflict of interest has been declared by the authors.

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## Data availability statement

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

## Author contributions

All authors: Contributed to the design of this study; Lei Wang: Designed, drafted this article, and investigated the development of the related devices for TEAS; Xinjiang Zhang, Bowen Feng, Shuai Zhang and Yanfeng Zheng: Performed literature search; Chen Xin, Jinling Zhang and Liang Li: Gave suggestion in the design of this study; Chong Su: Guided the measurement of the output voltage, resistance, and current; Fang Wang and Mozheng Wu: Modified the manuscript in English expression and grammar; Yuqi Liu: Guided the section of prospects of this article; Chris Zaslawski: Investigated the development of the transcutaneous electrical acupoint stimulators in Australia and edited and polished the manuscript in English expression and grammar; Peijing Rong: Conceptualized, designed, reviewed, funded, and administered this study and project.

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