Randomised Controlled Trial

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Effect of transcutaneous electrical nerve stimulation on neuro-sensory disturbance after orthognathic surgery: a randomized clinical trial

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Background: The present study aims to determine the effect of Transcutaneous Electrical Nerve Stimulation (TENS) on neuro-sensory disturbance after orthognathic surgery.

Materials and methods: In a randomized clinical trial, the participants via split-mouth sampling were randomly divided into two intervention ($n = 27$) and control ($n = 27$) groups. In the intervention group, participants received TENS physiotherapy. TENS physiotherapy was performed on the day after surgery, 1, 2, 3, and 4 weeks after surgery, along with prescriptions for the use of painkillers. On the control group, no physical therapy was performed and the patients only used painkillers (immediately after the operation). Paresthesia was evaluated using the 2-point discrimination (TPD) test and the semi-quantitative sensory-neural disorders test called brush stroke 6 months after the surgical procedures. Self-reported sensory-neural disorders were measured and reported for each patient before and 6 months after surgery using the visual analog scale (VAS).

Results: A total of 54 patients participated in this study. The mean TPD score in the TENS group and the control group 6 months after the operation were 5.76 (SD = 0.73) and 6.14 (SD = 0.54), respectively ($P = 0.003$). The mean VAS score in the TENS group and the control group 6 months after the operation was 6.48 (SD = 0.50) and 5.80 (SD = 0.63), respectively ($P = 0.005$). Also, 66.7 and 38.9% in the TENS and control groups, respectively, performed the brush stroke test correctly ($P = 0.007$).

Conclusion: In sum, the benefits of TENS physiotherapy can be effective in reducing complications such as pain in dental surgery treatments or orthognathic surgeries.

Keywords: orthognathic surgery, sensation disorders, transcutaneous electrical nerve stimulation

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HIGHLIGHTS

- The mean TPD score in the TENS group and the control group 6 months after the operation were 5.76 (SD = 0.73) and 6.14 (SD = 0.54), respectively, ($P = 0.003$).
- The mean VAS score in the TENS group and the control group 6 months after the operation was 6.48 (SD = 0.50) and 5.80 (SD = 0.63), respectively, ($P = 0.005$).
- Also, 66.7 and 38.9% in the TENS and control groups, respectively, performed the brush stroke test correctly ($P = 0.007$).
- In sum, the benefits of TENS physiotherapy can be effective in reducing complications such as pain in dental surgery treatments or orthognathic surgeries.

Introduction

Dentofacial anomalies result from defects in the growth and development of the craniofacial complex in the maxilla, mandible, or both. In these patients, deformities occur symmetrically or asymmetrically, either genetically or acquired. Orthognathic surgery (orthosurgery) is one of the methods of correcting abnormalities of the jaw and face. The most common surgical technique includes sagittal split osteotomy, which is performed in

prognathic, retrognathic, and mandibular asymmetry correction surgeries[1].

One of the side effects of split osteotomy surgery is sensory and nerve disorders that result from the manipulation of the neurovascular nerve bundle and cause a temporary disorder in the inferior alveolar nerve and mental nerve. Various degrees of inferior alveolar nerve and mental foramen disorders have been reported in the lower lip, chin, labial mucosa, and skin of the mandible and the lower jaw teeth[2–7]. Trauma to the peripheral nerve may cause damage that varies from the destruction of sensation to minor changes in sensation and may last for days or permanently. The return of sensory disorders depends on the degree of damage, the situation, and the capacity of the person for recovery[8].

Sensory and neurological disorders are seen as the most common complications of orthosurgery in 9–84.6% of patients[9]. Some factors affect the occurrence of these disorders, such as the age of the patient, fixation method, type of surgical procedures, inappropriate splints, the number of mandibular movements, the surgeon's experience, and the position of the inferior alveolar nerve[10]. On the other hand, parameters such as the direction of movement of the mandible (forward or backward); the number of mandibular movements, improper osteotomy, manipulation of the lower alveolar nerve during surgery[11]; the simultaneity of third molar surgery or the use of hard fixation instead of intermaxillary fixation[12] and the increasing age of patients[13] are related to the increase in neuro-sensory disorders following orthognathic surgeries.

Some medicinal and nonmedicinal methods have been used to reduce the severity and complications associated with oral, jaw, and facial surgeries such as pain, swelling, and trismus[14]. Transcutaneous Electrical Nerve Stimulation (TENS) is one of the electrotherapy methods that relieve almost any type of pain, but the TENS device is mostly used to treat acute and chronic pain. TENS leaves its effects by blocking and preventing pain messages from being sent to the brain and relieves the patient's pain. TENS electrodes cause a sensation of vibration in the tissues that cause pain and thus play a role in pain relief. TENS technique activates the pain prevention systems in the central nervous system by applying electric currents at different frequencies using surface electrodes placed on the skin and activating the complex nerve network and exerting its analgesic effects. This method is simple, cheap, and easier to use, and it can be used together with pharmaceutical agents to control and reduce pain after surgical treatments[15,16]. On the other hand, TENS has been found to reduce peripheral and central pain, and the areas of the spine and brain root that produce serotonin, opioid, and muscarinic receptors are activated through TENS. In the areas of TENS application, opioid, and alpha-2 receptors peripherally participate in the relief goals caused by TENS[17]. A study demonstrated that employing TENS effectively lessens pain following third molar surgery[18]. The outcomes of a different study indicated that utilizing TENS on a weekly basis enhances oral function following orthognathic surgery[19]. Little research has been done on the effects of TENS in the recovery of complications related to orthognathic surgery, but it seems that the use of this technique has been effective in reducing these complications[20]. With regard to this matter, the objective of this study is to explore the impact of TENS on neuro-sensory disruption following orthognathic surgery.

Methods

Study design and setting

This study is a randomized clinical trial that examines the effect of TENS on sensory-neural changes after orthognathic surgery in line with CONSORT criteria[21] (Fig. 1). Overall, 54 individuals were randomly selected for this study, with one half of their faces designated as the TENS group and the other half as the control group. The samples were collected from the population of patients referred to a department of oral and maxillofacial surgery affiliated to Shahid Beheshti University of Medical Sciences in Iran.

Ethics consideration

The ethics committee of Shahid Beheshti University of Medical Sciences has given its approval to this study (IR.SBMU.DRC.REC.1400.100). Also, this study was registered in the Iranian Registry of Clinical Trials Database (IRCT20210224050492N1). The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time.

Participants

The samples examined in the research included patients receiving orthosurgery treatments. The sampling method in the research was random. Split-mouth sampling was employed to distribute the samples, with one side of the face being in the control group and the other side receiving TENS treatment. The study inclusion criteria included patients over 18 years of age with class 3 skeletal deformity and in need of bimaxillary orthognathic surgery treatment, whose treatment plan was maxilla advancement and mandibular setback (maximum 4 mm). The exclusion criteria of the study included patients with a history of facial trauma and Close or ORIF treatment of fractures, patients with a history of pathological lesions in the mandible or maxilla, patients with the need for resurgery after orthosurgery, patients who had a bad spill during surgery, patients who got an infection after surgery and needed drug treatment and I&D, patients who were not the same on both sides due to the treatment plan during the mandibular osteotomy surgery, patients with a history of brain or neurological problems and a history of base skull surgeries, patients with a history of taking drugs due to mental problems, and patients who needed IMF after surgery.

Sample size

The sampling method employed was simple random, and the allocation of samples followed a split-mouth design, where one side of the face was assigned to the control group, while the other side received TENS treatment. The sample size was measured using the following equation:

$$N = \frac{(r+1)\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2 \delta^2}{rd^2}$$

The CI in this study was 95%, and the power of the study was considered 80%. According to the study of Arabion *et al.*[22], the SD was considered to be 1.66 and the measurement error was considered to be 0.9. The number of patients needed for the research was determined based on the above equation to be 54.

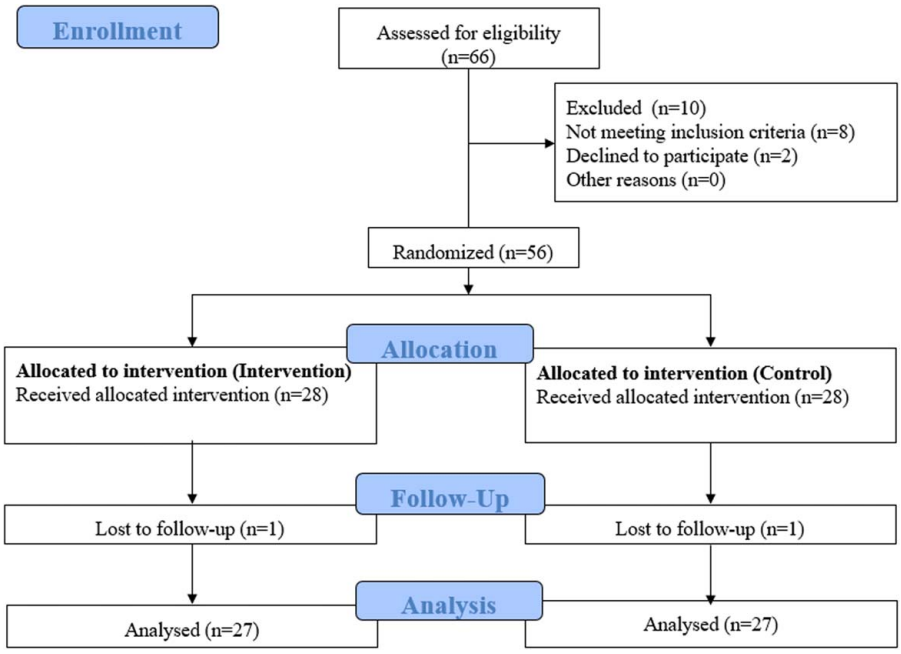

Figure 1. Flow diagram of participants.

Intervention

All patients received a single dose of Ibuprofen (400 mg, Daana Pharm Company) 1 h before surgery. The facial hair of the male patients was shaved by the researcher for adequate electrode fixation. The complexity and difficulty of the surgical work was considered during the surgery. Orthosurgery treatments were performed using conventional and standard methods (Lefort I osteotomy in the maxilla and sagittal split osteotomy using the Dal point method in the lateral and shortcut in the medial mandible). The fixation method was a plate with four holes in the midbody of each side, with four monocortical screws and no IMF after surgery. On one side of the randomly selected patients, TENS physiotherapy was performed with EM 80 Beurer digital TENS/EMS device. TENS intervention was performed in standard parameters with frequency (4 Hz), period of 220 ms, and duration of stimulation (30 min). Two electrodes of the device were placed on the skin in the surgical area (mental area skin and mandibular parasite) and stimulations were performed. TENS physiotherapy was performed on the day after surgery 1, 2, 3, and 4 weeks after surgery, along with prescriptions for the use of painkillers (a single dose of Ibuprofen (400 mg, Daana Pharm Company)). On the control side, no physical therapy was performed and the patients only used painkillers (immediately after the operation) (a single dose of Ibuprofen (400 mg, Daana Pharm Company)).

Paresthesia was evaluated using the 2-point discrimination (TPD) test and the semi-quantitative sensory-neural disorders test called brush stroke 6 months after the surgical procedures. The TPD test was performed as a fixed 2-point test in horizontal and vertical directions in the mental area, while the patient's eyes are closed. If the patient had different TPD test results in horizontal and vertical directions, the average TPD values were used for statistical analysis. A Brush stroke test was also performed in the mental area and anterior and posterior directions using fine toothbrushes. The patients' responses to this test were recorded and the brush tests were performed in two sessions and on two different days by two examiners. If the patients had different answers, the third test was performed by an independent examiner. Self-reported sensory-neural disorders were measured and reported for each patient before and 6 months after surgery using the visual analog scale (VAS). The neuro-sensory disorders of the patients were recorded by an oral and maxillofacial surgeon and the patients were divided into two groups based on the symptoms of paresthesia and hypostasis. Also, the variables of age, sex, and mechanism related to the injury were included as primary variables, and recovery rate and paresthesia rate based on the results of two-part discrimination tests, brush stroke, and VAS were included as outcome variables.

Anesthesia method

The anesthesia method was the same for all participants using a hybrid technique. The anesthesia process includes basic standard monitoring including (blood pressure and heart rate (Bp-HR), electrocardiography (ECG), end-tidal carbon dioxide ($EtCO_2$), oxygen saturation (SPO_2)), normal saline before injecting drugs, pretreatment with Midazolam (0.2 mg/kg; 5 min before giving anesthetic drugs), Fentanyl (2 μg/kg; at the same time as Midazolam), Propofol (2 mg/kg), and Atracurium besilate (0.5 mg/kg) for muscle relaxation. Ninety seconds before Intubation, 1 mg/kg of Lidocaine was injected, then the patients were intubated through the nasal passage. Maintenance of anesthesia was conducted using isoflurane (1-1.2 MAC). At the end of the surgery, the patients were taken out of the tracheal tube using Atropine (0.02 mg/kg) and Neostigmine Reverse (0.05 mg/kg) and after breathing returned and the train-of-four (TOF) ratio (TOFR) ≥ 0.9 and the patients were transferred to the recovery room. All patients were kept in recovery for 2 h and their vital signs were evaluated.

Statistical analysis

The data were examined using SPSS software (version 25.0, SPSS Inc.). The frequency and percentage of Brush stroke test results in two control and TENS groups were calculated and analyzed using the χ^2 test. Also, the mean and SD of the results of the TPD test, as well as the degree of improvement of sensory-neural disorders of the patients were calculated using VAS and statistically analyzed using the independent *t*-test. The correlation of variables with each other was also evaluated with the Pearson correlation coefficient test. A significance level of 0.05 was considered.

Results

A total of 54 patients participated in this study. Half of the face of 54 people was considered as the TENS group and the other half as the control group. The average age of the participants was 27.3 (SD = 4.9). Among the participants, 52.8% were female. No damage was done to the main nerves such as the mental nerve and the alveolar nerve during the patients' surgery.

As shown in Table 1, the mean TPD score in the TENS group and the control group 6 months after the operation were 5.76 (SD = 0.73) and 6.14 (SD = 0.54), respectively, and they had a significant difference from each other ($P = 0.003$). The mean VAS score in the TENS group and the control group 6 months after the operation was 6.48 (SD = 0.50) and 5.80 (SD = 0.63), respectively, which had a significant difference from each other ($P = 0.005$). Also, 66.7% and 38.9% in the TENS and control groups, respectively, performed the brush stroke test correctly, and there was a significant difference between them ($P = 0.007$).

As shown in Table 2, there was no significant relationship between age factor, mean PTD score, and mean VAS score.

It is important to highlight that patients did not experience any significant complications following the TENS intervention.

Discussion

Nowadays, many people come to receive orthognathic surgery treatments and the results of this surgery are both improved and predictable. However, there have been some concerns about the rapid rehabilitation of patients in the postsurgery periods, and the necessity of oral function recovery of patients is felt more than ever. Permanent sensory disorders of the inferior alveolar nerve are one of the common complications of orthognathic surgeries[23]. Increasing the amount of nerve regeneration helps patients to carry out their daily activities without any problems. The present study was conducted to evaluate the improvement of sensory-neural changes in orthognathic surgery patients after TENS physiotherapy. TENS is an objective method of stimulation; however, it can also be used to directly activate nerves. Evoked potentials are neural responses time-locked to a stimulus. They are objective markers of clinically relevant abnormalities in sensory or motor systems, used in clinical and research settings[24]. Also, The Contact Heat Evoked Potential Stimulator (CHEPS) can stimulate heat-sensitive receptors expressed by Aδ and C fibers and record resulting evoked potentials[25]. Based on evidence, the utilization of somatosensory evoked potentials (SEPs) of the trigeminal nerve via electroencephalography (EEG) has proven to be instrumental in evaluating anesthesia. By monitoring SEPs through EEG, anesthesiologists can assess the impact of anesthesia on the trigeminal nerve's sensory pathways. This approach provides valuable insights into the patient's neurological response to anesthesia, aiding in maintaining optimal anesthetic levels during surgical procedures. Monitoring SEPs of the trigeminal nerve can help ensure that the patient remains appropriately anesthetized throughout the operation, contributing to both the anesthesia's efficacy and the patient's safety. Overall, the assessment of anesthesia by observing SEPs of the trigeminal nerve by EEG is a valuable tool in optimizing anesthesia management and ensuring patient well-being during surgical interventions[26–28].

Table 1

Paresthesia, self-reported sensory-neural disorders, and brush stroke test of patients after 6 months (*N* = 54).

	Groups		
	Intervention	Control	*P*
TPD	5.76 (SD = 0.73)	6.14 (SD = 0.54)	0.003[a]
VAS	6.48 (SD = 0.50)	5.80 (SD = 0.63)	0.005[a]
Brush stroke			
True	36 (66.7)	21 (38.9)	0.007[b]
False	18 (33.3)	33 (61.1)	

Values are given as a mean for continuous variables and frequency and percentage for categorical variables.
[a]*P*-value was obtained with an independent *t*-test.
[b]*P*-value was obtained with a χ^2 test.

Table 2

Relationship between age, paresthesia, and self-reported sensory-neural disorders (*N* = 54).

	Age	TPD	VAS
Age	1		
TPD	0.003	1	
VAS	0.082	0.09	1

P-value was obtained with the Pearson correlation coefficient test.

According to the results of the present research, the mean TPD scores in the TENS areas were significantly lower than the control. The average degree of recovery of sensory-neural disorders of patients in the area under TENS application was significantly higher than in the control areas. Therefore, TENS physiotherapy has had significant effects in improving sensory-neural disorders of patients undergoing orthognathic treatments. Based on the results of the present research, TENS physiotherapy can be used as a cheap, noninvasive, and safe method without specific side effects to reduce the side effects of orthognathic surgeries and improve sensory-neural changes. One of the advantages of the TENS method is the possibility of relieving pain following surgery and reducing the use of additional painkillers, which can reduce the effects and side effects of these drugs. Another advantage of the TENS device is that the patient can use this tool at home. According to the results of the brush stroke test, TENS group patients recognized the correct directions of toothbrush movements better than the control group, and there were significant differences between the two groups. Therefore, TENS physiotherapy has brought significant and better performance in the brush stroke test.

Arabion *et al.*[22] investigated the effects of physiotherapy with the TENS technique on the intensity of post-treatment pain in the

extraction areas of impacted third molars and reported the average pain levels in the TENS group were significantly lower than the control group. Cebi *et al*. also investigated the effects of TENS physiotherapy in reducing pain after surgery of latent third molars and showed that there were significant differences in terms of VAS values at different times between the routine and TENS treatment groups. In this study, TENS physiotherapy reduced pain through the activation of the complex nerve network, and this method was also very effective in reducing pain following third molar surgery[29]. On the other hand, Rezazadeh *et al*.[30] investigated the effects of TENS physiotherapy and low-power laser radiation in drug-resistant temporomandibular disorders and showed that TENS physiotherapy had more effects in reducing pain in the follow-up period. In the study of Bjordal *et al*.[15], the effects of TENS physiotherapy in reducing the consumption of painkillers were investigated in a systematic review and it was found that TENS physiotherapy along with strong current intensity and less had significant effects in reducing the consumption of painkillers to reduce pain after treatment. These findings indicate the reduction of pain levels after TENS physiotherapy.

Cacho *et al*. investigated the results of the weekly application of TENS in the recovery of oral function after orthognathic applications and reported a significant and greater improvement in the TENS group compared to the placebo group. Researchers associated these results with muscle relaxation in the TENS process[19]. de Oliveira *et al*. investigated the effects of using acupuncture along with TENS and laser acupuncture on the return of the sense of touch as well as the pain levels of patients undergoing orthognathic surgery treatments and did not observe significant differences between the two groups in terms of DTP test results in the buccal mucosa area[31]. However, in the present study, significant differences were observed in terms of the results of the two-point discrimination test between the control and TENS groups.

Limitations

One of the limitations of this study was the simultaneous consideration of the intervention and control groups in one person. Considering the opposite side of the face in physiotherapy as a control group can be criticized to some extent, because a person's understanding of side effects such as sensory-neural changes, complaints, and pain may be evaluated unequally in these conditions. Considering the concept of individual and separate, using the opposite side of the face as the control group is not fully consistent with the mechanism of action of physiotherapy because both control methods and TENS involve the same central mechanisms. Therefore, stimulation of one part of the face is probably effective on the other side of the face and can reduce the amount and intensity of the effects of physiotherapy, which may have a negative impact on external validity and reduce generalizability.

Recommendations for future research

Based on the results and limitations of the study, it is necessary to use research designs with different people in the test and control groups, so that no intervention is done in the control group. Also, TENS physiotherapy should be performed on both sides of the patient's face with high and low frequencies, and in this way, treatment results can be compared in different people.

Conclusions

In conclusion, according to the significant increase in the degree of recovery of sensory-neural changes in the areas under TENS physiotherapy compared to the control group and the increase in DTP test scores in this method, it seems that there are significant differences in terms of its effectiveness compared to the control method in clinical conditions. Also, the benefits of TENS physiotherapy can be effective in reducing complications such as pain in dental surgery treatments or orthognathic surgeries.

Ethical approval

The ethics committee of Shahid Beheshti University of Medical Sciences has given its approval to this study (IR.SBMU.DRC.REC.1400.100). Also, this study was registered in the Iranian Registry of Clinical Trials Database (IRCT20210224050492N1). The participants gave informed consent after being informed of the current study's goals. It was made clear to participants that they could leave the study at any time.

Consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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Author contribution

All authors contributed in study concept and design, data acquisition, data interpretation, drafting the manuscript, revision of the manuscript, the final version of the manuscript is approved.

Conflicts of interest disclosure

The authors declare no conflict of interest.

Research registration unique identifying number (UIN)

We could not register our manuscript in the Research Registry UIN: www.researchregistry.com due to internet access restrictions and international sanctions. we live in Iran. We hardly even meet the basic needs of our daily life. We do not receive any funding for our research and we cannot pay for our research. Please excuse us from registering this manuscript in the Research Registry UIN: www.researchregistry.com

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Data availability statement

The datasets generated and analyzed during the current study are available from the corresponding author on reason-able request.

Provenance and peer review

Not commissioned, externally peer reviewed.

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