Randomised Controlled Trial

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Effect of transcutaneous electrical nerve stimulation on maximum mouth opening after orthognathic surgery: a randomised controlled trial

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Background: The present study aims to determine the effect of transcutaneous electrical nerve stimulation (TENS) on maximum mouth opening (MMO) after orthognathic surgery.

Materials and methods: This study is a randomised clinical trial. The samples of this study were class III patients who are candidates for Le Fort I osteotomy surgery for maxillary advancement and bilateral sagittal split osteotomy (BSSO) for mandibular setback surgery due to the lack of maxilla growth and mandibular prognathism using the Dalpont method. On the day following surgery, the intervention group received TENS physiotherapy and instructions to take analgesics. In the control group, patients only received analgesics. MMO was measured in both groups using a digital caliper preoperatively, 1 month, and 6 months postoperatively.

Results: A total of 82 patients participated in this study, who were divided into two groups of 41, intervention and control. The difference in the mean MMO in different periods after surgery of the intervention group ($F = 59733.350$, $P < 0.001$) and the control group ($F = 32.480$, $P < 0.001$) was significant. The pattern of MMO increase over time was not the same in the two groups. There was a steeper slope in the increase of MMO in the intervention group than in the control group.

Conclusion: It can be concluded from the results of this study, that the use of TENS after orthognathic surgery can be effective along with analgesics in reducing pain intensity and, subsequently, recovery in MMO in the short term.

Keywords: dental caries, dental, maximum mouth opening, orthognathic surgery, transcutaneous electrical nerve stimulation

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Introduction

Disharmony between the face and the dental bone structure, known as dentofacial deformities, may occur at a variable velocity depending on genetic or acquired causes[1]. These patients are observed with various irregularities in the face and dental bone structure, such as hyperplasia, hypoplasia, and deformity of the maxilla, mandible, or chin[2]. Disturbances in beauty, psychol ogy, and various oral functions such as speech, chewing, and digestion are negative consequences of these deformities[3]. Also, evidence shows the negative impact of these untreated anomalies on self-esteem, self-confidence, and mental health[4,5]. Furthermore, the mentioned consequences can reduce the quality of life. In this regard, many studies have determined a lower level of quality of life for patients with dentofacial deformities[6–8]. However, with the help of appropriate treatment procedures, positive changes can be made in the esthetic and functional aspects of the lives of these patients[3,9].

Several treatments have been proposed to correct dentofacial deformities. The gold standard for the treatment of moderate-to-severe cases of these deformities is a combination of orthodontic treatment and orthognathic surgery[10,11]. Orthognathic surgery is a common treatment for dentofacial deformities[2,3]. Correction using orthognathic surgery can vary according to the severity of the problem, from only moving a group of teeth to changing the position of the mandible and maxilla[12]. The main indications for using this therapeutic procedure include

functional problems, malocclusion, pain-related issues such as temporomandibular disorders (TMD), and cosmetic problems[13]. The most used techniques of this surgery are Le Fort I osteotomy, bilateral sagittal split osteotomy (BSSO), and bimaxillary osteotomy (BIMAX), which can be combined with an osseous genioplasty[2,14]. Technical and scientific advances have made these osteotomies to be considered safe and acceptable to the general population[9,13]. However, as with other surgeries, the occurrence of various complications to varying degrees is inevitable. In general, complications associated with orthog nathic surgery may occur postoperatively or intraoperatively regardless of the surgeon's experience. Among the intraoperative complications, we can mention hemorrhage, iatrogenic dental injuries, and bad splits. Consequences such as temporary sensory impairment, infections, issues related to fixation hardware, ske letal relapse, nasal deformities, dental problems, excessive post operative swelling, and TMD are potential complications of surgery[15].

TMD is a group of pathologies involving the temporomandibular joint and muscles, which are classified as myogenic, arthrogenic, mixed, and joint-related disorders[16]. The occurrence of this complication can cause a decrease of more than 50% of the maximum mouth opening (MMO), which causes disturbances in nutrition and the recovery process of patients[17]. In this regard, several studies showed that within 1 month after orthognathic surgery, the amount of MMO decreased significantly[18–20]. In order to reduce such a complication and increase the quality of life of patients, thermotherapy, a soft diet, use of analgesics and anti-inflammatories, and physical therapy are usually recommended[21].

The new technique of pain relief after orthognathic surgery is the use of transcutaneous electrical nerve stimulation (TENS). TENS units consist of adhesive electrodes that are placed on the skin in the painful area to apply electrical stimulation[22]. Available evidence suggests that TENS reduces the ability to transmit pain to the spinal cord and brain and stimulates the production of natural pain relievers[23,24,25].

Aim

Despite the positive effects of using TENS in reducing acute and chronic pain, there is a lack of studies on the effect of TENS on the recovery of MMO after orthognathic surgery. Therefore, the present study aims to determine the effect of TENS on MMO after orthognathic surgery.

Methods

Study design

This randomised clinical trial investigates the effect of TENS on MMO after orthognathic surgery in a hospital affiliated with Shahid Beheshti University of medical science. The study adhered to CONSORT criteria[26] (Supplementary File 1, Supplemental Digital Content 1, http://links.lww.com/MS9/A608).

Ethics consideration

Approval for this study was obtained from the ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.DRC.REC.1400.174), and the study was duly registered in the Iranian Registry of Clinical Trials Database (IRCT20211205053279N2). Before participation, informed consent was obtained from all participants, accompanied by a comprehensive explanation of the study objectives. Participants were explicitly informed of their right to withdraw from the study at any point in time.

HIGHLIGHTS

- The difference in the mean MMO in different periods after surgery of the intervention group ($F = 59733.350$, $P < 0.001$) and the control group ($F = 32.480$, $P < 0.001$) was significant.
- The pattern of MMO increase over time was not the same in the two groups.
- There was a steeper slope in the increase of MMO in the intervention group than in the control group.
- It can be concluded from the results of this study, the use of TENS after orthognathic surgery can be more effective than analgesics in reducing the intensity of pain and, subsequently, recovery in MMO in the short term.

Participants

The samples of this study were class III patients who are candidates for Le Fort I osteotomy surgery for maxillary advancement and BSSO for mandibular setback surgery due to the lack of maxilla growth and mandibular prognathism using the Dalpont method. Sampling and allocation of patients into two groups were done by the random block method, classified according to age and sex. The study inclusion criteria included class III patients who are candidates for Lefort I osteotomy surgery for maxillary advancement and BSSO for mandibular setback surgery due to the lack of maxilla growth and mandibular prognathism using the Dalpont method. The exclusion criteria of the study included the presence of pathological lesions around the surgical area, limitation in jaw movements, drug use due to mental problems, fracture scar in the jaw area, previous jaw surgery, maxillary advancement, and mandibular setback rate above 5 mm, surgery longer than 6 h, Bad Split and accidents at work, simultaneous genioplasty, requiring resurgery after ortho-surgery, presence of a pacemaker, presence of epilepsy, and history of CVA.

Sample size

The sample size was obtained by considering the first-type error of 0.05 and the second-type error of 0.2, with the test power of 80%, and extracting information from the study of Rezendeh *et al*.[27]. The number of samples for each group was 41 patients and a total of 82 patients.

Intervention

All patients undergo Le Fort I osteotomy surgery for maxillary advancement and BSSO for mandibular setback surgery with the Dalpont method. The maxilla fixation method will be done by four L-shaped plates with four holes and mandible fixation by three screws. Also, the protocol for prescribing dexamethasone is 8 mg intravenously three times a day on the first day after the operation, 8 mg intravenously twice a day on the second day after the operation, and stopping it on the third day. Preoperatively,

1 month, and 6 months postoperatively, anterior-posterior cephalometric radiography, lateral cephalometric and orthopantomagram were performed for all patients. The postoperative X-ray confirmed that the temporomandibular joint is in its normal position.

On the day following surgery, the intervention group received TENS physiotherapy and instructions to take analgesics. Paracetamol (1 g, intravenously, three times a day) was used for postsurgery pain relief. The method of using the device was explained to the patients. The method of using TENS in patients is shown in Figure 1. The electrodes of the device were placed on the healthy skin in the surgical area bilaterally. Stimulations with high and low frequencies were initiated at standard parameters in terms of frequency, duration, and pulse width. TENS with a frequency of 150 Hz, a pulse width of 20 μs, and a pulse intensity of 10–30 mA were adjusted according to the tolerance threshold of each individual. The pulses were Quadratic Biphasic Symmetrical and the modulation was up to 50% of the frequency variation and the time of each session was 45 min. This physical therapy was done for 1 month, three sessions a week[28]. In the control group, patients only received analgesics. Other treatment protocols for patients undergoing orthognathic surgery were performed in the same way in both groups. MMO was measured in both groups using a digital caliper preoperatively, 1 month, and 6 months postoperatively.

Statistical analysis

The data were examined using SPSS software (version 25.0, SPSS Inc.). Descriptive statistics, including means with SD or frequencies with percentages, were employed for continuous and categorical variables, respectively. The normal distribution of variables was assessed utilizing the Shapiro–Wilk test. Due to the normal distribution of the data, the χ^2 test was used to compare the distribution of sex in the group, and the independent *t*-test was used to compare the age and maximum mouth opening at different measurement times of the two groups. Two-factor repeated measures ANOVA was used to investigate the effect of time and type of intervention and their mutual effect on the MMO. Mauchly's test was also used to check the assumption of the sphericity of the data. Due to the nonestablishment of this default, Greenhouse–Geisser correction was used to calculate probability values. A significance level of 0.05 was considered.

Results

A total of 82 patients participated in this study, who were divided into two groups of 41, intervention and control (Fig. 2). Among the participants, 54.9% were women. Also, the mean age in the intervention and control groups was 25.63 (SD = 2.98) and 25.12 (SD = 3.91), respectively. There was no significant difference between sex and age in the two groups ($P > 0.05$).

As shown in Table 1, the mean MMO of patients preoperatively in the intervention and control groups was 20.63 (SD = 1.74) and 21.05 (SD = 2.20), respectively. There was no significant difference in preoperatively MMO between the intervention and control groups (t = 0.945, $P = 0.374$). The mean MMO of patients in one month after surgery in the intervention and control groups was 28.95 (SD = 1.49) and 24.93 (SD = 1.88), respectively. There was a significant difference in the mean MMO between the two groups 1 month after surgery (t = –10.684, $P < 0.001$). Also, the mean MMO of patients in six month after surgery in the intervention and control groups was 44.71 (SD = 1.40) and 44.02 (SD = 2.17), respectively. There was no significant difference between the two groups in the average MMO 6 months after surgery (t = –1.691, $P = 0.095$). The difference in the mean MMO in different periods after surgery of the intervention group (F = 59733.350, $P < 0.001$) and the control group (F = 32.480, $P < 0.001$) was significant (Fig. 3).

The pattern of MMO increase over time was not the same in the two groups. There was a steeper slope in the increase of MMO in the intervention group than in the control group. Although the MMO in the two groups was finally at the same level 6 months after surgery.

Discussion

Various causes can cause a patient's MMO to decrease, the normal range is usually considered to be between 40 and 60 mm,

Figure 1. The method of using TENS in patients.

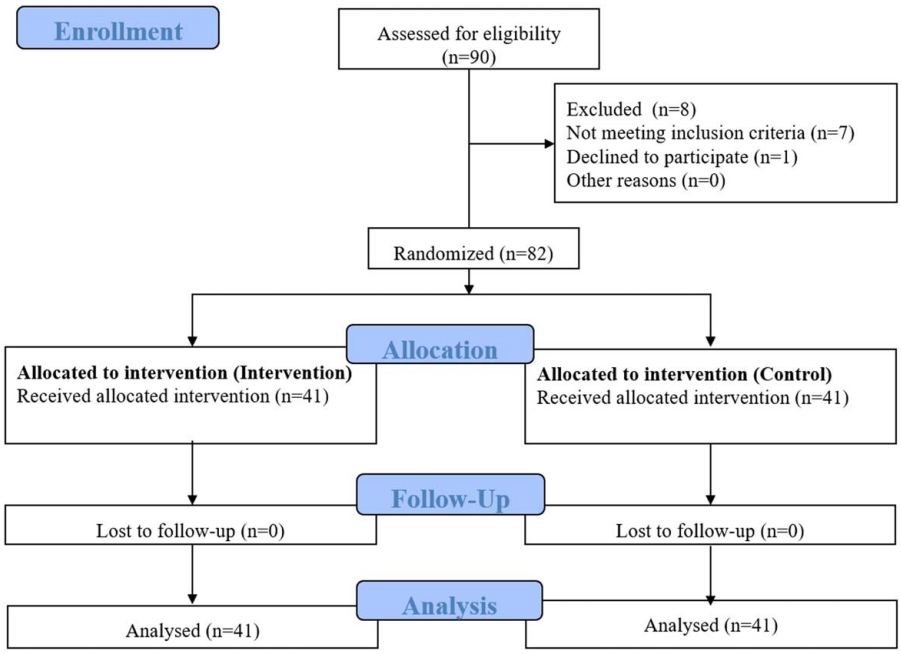

Figure 2. Flow diagram of participants.

such as infection, trauma, tumors, drugs, chemotherapy and radiotherapy, congenital problems, dental treatments, and TMD[21]. Correcting the maxilla and mandible through orthognathic surgery requires extensive manipulation of the masticatory muscles, and the inability to open the mouth is one of its common consequences[29]. Decreased range of mouth opening after orthognathic surgery can be associated with facial edema, decreased muscle strength, and pain[19,20,28]. In addition to phar maceutical methods for postoperative pain control, non pharmacological treatments are also used, such as TENS[30]. The available evidence indicates the effect of TENS on pain control in various conditions such as musculoskeletal pain, labor pain, dysmenorrhea, fibromyalgia, multiple sclerosis, poststroke pain, procedural pain, and postoperative pain[31].

In this regard, the results of this study showed that TENS can cause faster recovery of MMO in the short term (1 month) by controlling acute pain after orthognathic surgery. The study of Cacho *et al*.[17], consistent with the results of the present study, showed that the weekly use of TENS in the first month after orthognathic surgery can contribute to the improvement of jaw opening by achieving muscle relaxation. In addition, several studies conducted in Iran and Brazil emphasized that the use of TENS can reduce the pain intensity of TMD or jaw corrective surgeries and improve masticatory muscle activity[32–35].

In general, this study found that despite TENS having a faster effect on mouth-opening rehabilitation than analgesics, there was no significant difference between the two modalities in the long term. In order for the results to be more reliable, it is recommended that future studies be conducted using a placebo-controlled randomised clinical trial with a larger sample size. Also, enabling a longer follow-up helps to more accurately assess the effect and durability of the treatment. However, it is suggested to use of TENS in health care facilities to reduce the need for high doses of analgesics and earlier effectiveness.

Limitations

We can mention the small sample size and not very long follow-up as the limitations of this design. The small sample size reduces the reliability of this study and the lack of longer follow-up has limited the accurate evaluation of treatment persistence.

Table 1

MMO in patients ($N = 82$)

	Groups			
	Intervention ($N = 41$)	**Control ($N = 41$)**	***t***	***P***
Preoperatively MMO	20.63 (SD = 1.74)	21.05 (SD = 2.20)	0.945	0.374[a]
MMO 1 months after surgery	28.95 (SD = 1.49)	24.93 (SD = 1.88)	−10.684	< 0.001[a]
MMO 6 months after surgery	44.71 (SD = 1.40)	44.02 (SD = 2.17)	−1.691	0.095[a]
F	59733.350	32.480		
P	< 0.001[b]	< 0.001[b]		

Values are given as a mean for continuous variables.
[a]*P*-value was obtained with an independent *t*-test.
[b]*P*-value was obtained with a repeated measure ANOVA test.

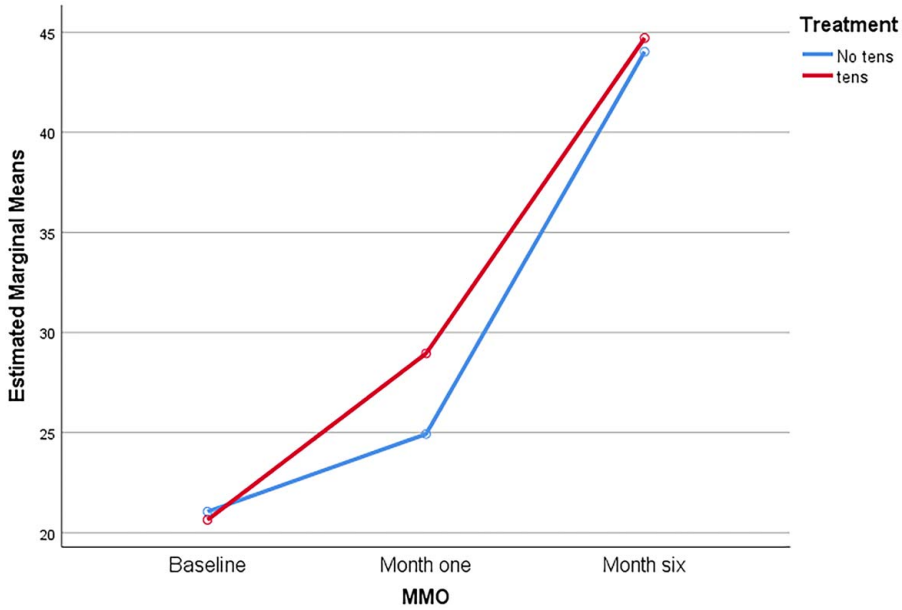

Figure 3. Effect of TENS on MMO in the preoperatively, 1 month, and 6 month after orthognathic surgery.

Recommendations for future research

It is recommended to conduct future studies with a larger sample size and with a placebo-controlled randomised clinical trial method so that the results have more reliability. Studies with a longer follow-up period bring the possibility of evaluating the durability of the treatment.

Conclusion

It can be concluded from the results of this study, that the use of TENS after orthognathic surgery can be effective along with analgesics in reducing pain intensity and, subsequently, recovery in MMO in the short term. However, in the longer term, both modalities have a similar effect on MMO. Therefore, TENS can be considered a suitable modality for faster initial progression of MMO and for reducing the need for high doses of analgesics.

Ethical approval

The ethics committee of Shahid Beheshti University of Medical Sciences has given its approval to this study (IR.SBMU.DRC.REC.1400.174). Also, this study was registered in the Iranian Registry of Clinical Trials Database (IRCT20211205053279N2). 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 have agreed on the final version of this manuscript. Those listed as authors are qualified for authorship according to the following criteria: They have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; been involved in drafting the manuscript or revising it critically for important intellectual content; and have given final approval of the version to be published. Each author participated sufficiently in the work, has taken public responsibility for appropriate portions of the content, and has agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflicts of interest disclosure

The authors declare no conflicts 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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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. https://irct.behdasht.gov.ir/trial/62254.

Trial Id: 62254.

Iranian Registry of Clinical Trials Database (IRCT20211205053279N2).

Guarantor

Rmyar Farzan.

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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