STUDY PROTOCOL

Use of transcutaneous electrical nerve stimulation (TENS) for the recovery of oral function after orthognathic surgery

NCT ID not yet assigned

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ABSTRACT:

Oral functions of patients are markedly diminished immediately after orthognathic surgery, and novel approaches are needed to accelerate their recovery. The aim of this study will be to examine the usefulness of weekly applications of transcutaneous electrical nerve stimulation (TENS) for this purpose, based on evidence of its effectiveness in other types of patients with muscle alterations. Maximum jaw opening, bite force, pain, and facial inflammation will be compared between patients receiving TENS and those receiving sham-TENS for 30 min at baseline and weekly over a four-week period after orthognathic surgery and will be also compared between before and after each procedure.

MATERIAL

The sample will be made up of a sufficient number of patients according to the calculation of the sample size who will undergo bimaxillary surgery or mandibular surgery divided between experimental (TENS group) and control groups (sham-TENS).

Participants will be selected by non-probabilistic sampling of consecutive patients until the estimated sample size is reached. All patients have a skeletal and facial deformity amenable to surgery after a pre-surgical orthodontic period, and they will have to signed their informed consent after receiving an information sheet on the study.

This study was approved by the ethics committee of the hospital (San Carlos Hospital, Madrid, Spain).

Inclusion criterion:
- programing of bimaxillary or mandibular orthognathic surgery by the same surgeon in order to avoid inter-operator variability.
- no surgery for temporomandibular disorders or more complex syndromes,
- no presence of muscle or nervous disorders or receipt of medication for such disorders

Exclusion criterion:
- the impossibility to attend follow-up appointments
- the refusal of informed consent.

The sample size will be estimated to obtain a statistical power of 80% with an alpha error of 0.05 and 95% confidence interval to detect a difference in jaw opening ≥ 2.5 mm.

Patients will be randomly assigned to the experimental group for TENS application or the control group for sham-TENS and will be blinded to their group assignation, as was the researcher responsible for data analyses (single-blind randomized clinical trial).

METHOD

TENS procedure

An Enraf Nonius® S82 model TENS device will be used, with a maximum frequency of 220 Hz and an intensity range of 0 to 99.5 mA.

TENS electrodes will be placed bilaterally on mandibular elevator muscles, on the superficial masseter muscle above the gonial angle, and bilaterally on the anterior temporal muscle, following the manufacturer's instructions. The device will be applied in an identical manner to all patients in both groups and kept in position for the same time period (30 min); however, the device will be not switched on for the control group.

The stimulation intensity will be adjusted for those in the experimental group to the maximum that did not cause discomfort or areas of contraction, maintaining this stimulation intensity and frequency throughout the 30-min session.

Each participant will experience a weekly TENS or sham-TENS session on the same day of the week during a four-week period; appointments will be scheduled so as to minimize any possible interaction among study participants.

Study variables

Data will be gathered from all patients on jaw opening, bite force, inflammation, and pain before surgery and at 7, 14, 21, and 28 days post-surgery, conducting measurements both before and after the TENS/sham-TENS session.

Maximum Jaw Opening will be evaluated with patients seated vertically upright in the dental chair, using a digital dental caliber (Model R 100110, Mestra®) to measure the maximum opening from the incisal margin of upper central incisors to the incisal margin of lower incisors, adding the amount (in mm) of overbite or subtracting the amount (in mm) of open bite in occlusion.

Bite force will be measured using Dental Prescale Fuji® film, which is formed by microcapsules that generate a chemical reaction under pressure, staining the contact area with a color density corresponding to the pressure applied.

A sheet of the film will be placed between the occlusal surfaces of the two arches, and the patient will be asked to bite as strongly as possible for 5 sec. This procedure will be repeated three times, selecting the sheet with the best-defined tooth print to be photographed with a Canon® EOS 500 camera (RAW format, F32, and annular Flash) at the minimum distance permitted by the 75-macro lens.

The image will be processed in a Mac® computer to obtain the color value according to the Cie L*a*b* (CIELAB) scale, which gives the color a numerical value.

The corresponding pressure units (Megapascals, MPa) will be calculated according to Dental Prescale specifications, and the bite force (in Newtons [N]) will be obtained by using the following formula:

$$\text{Bite Force} = \text{Bite Pressure (MPa)} \times \text{mm}^2 \text{ print surface.}$$

Pain perceived by patients while autonomously opening and closing their jaws will be evaluated using a visual analog scale (VAS).

Facial inflammation will be measured (in mm) with patients seated upright in the dental chair, using a soft ruler to obtain a horizontal measurement from the lower border of the earlobe to the corner of the mouth and a vertical measurement from the gonial angle to the outer canthus of the eye. The soft ruler will be adapted to the contour of the patient's face without exerting any pressure.

All of the above measurements provided numeric values for treatment as continuous quantitative variables.