Protocol: In-person randomized control trial of the incidence of postoperative hypoesthesia among bilateral sagittal split osteotomy patients treated with ultrasonic vs. reciprocating saw instrumentation.

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Research Strategy Overview

The aim of this prospective study is to analyze the postoperative paresthesias experienced in patients who undergo bilateral sagittal split osteotomies (BSSO) using an ultrasonic saw, versus a reciprocating saw. A matched-pair (with-in person) RCT design will be used, wherein each mandibular side (right versus left) in each patient will be randomized to be treated with either reciprocating saw (RemB) or Sonopet ultrasonic device (Sonopet IQ Hp). Patients included in the study are ages 15-45 scheduled to undergo BSSO surgery at the University of California, San Francisco. The orthognathic surgeries will be performed at UCSF Parnassus Moffitt-Long Hospital and UCSF Medical Center at Mission Bay, Benioff Children's Hospital. Follow-up appointments will be conducted at 513 Parnassus Ave, S738, Oral and Maxillofacial Surgery (OMFS) Faculty Practice Clinic.

One side of the patient’s mandible will be instrumented with either the Stryker Sonopet ultrasonic saw or traditional reciprocating saw, while the other side will receive the remaining intervention (determined via randomization on the day of surgery). Patient paresthesias will then be analyzed on each side for 3 months postoperatively (at postoperative days: 1, 7, 14, 28, and 84). Sensory examinations will be carried out by blinded examiners using von Frey hairs and two-point discrimination testing. Patients will also subjectively rate their sensation on each side. The results will then be analyzed to determine if patient paresthesias, including the severity and duration, differed depending on which instrument was used, the ultrasonic or reciprocating saw.

Study procedures

Treatment:

On the day of surgery, a randomization process (using randomization blocks of 8, using sealedenvelope.com with a predetermined seed) will determine which mandibular side receives which intervention (Sonopet ultrasonic saw or reciprocating saw), as well as which side is operated on by Dr. Soheil Saghezchi, DDS, MD, with the remaining side being operated on by the senior resident involved with the case. Given the supervision of the attending surgeon, the senior resident has the appropriate skills to perform the equivalent procedure on the contralateral side. Given that the two osteotomy instruments are physically different, the provider delivering the treatment cannot be blinded. It will be documented in the operative report if the patient received any other interventions, such as LeFort I osteotomy or genioplasty, and if any direct manipulation of the inferior alveolar nerve occurred (for instance if the nerve was gently freed from the proximal mandibular segment, if the nerve was not directly visualized, etc.).

Data Collection:

Patient sensation in the V3 distribution will be analyzed on each side at one week preoperatively (baseline) and at five different postoperative timepoints: 1 day, 1 week, 2 weeks, 4 weeks, and 3 months. Patients are already and consistently under OMFS care at these timepoints (whether as an inpatient or at a clinic visit) thereby collecting this data will be at minimal inconvenience to the patient. Sensation will be evaluated with patients completing a Medical Research Council Scale questionnaire, along with residents testing sensation with von Frey hairs (at a region 1 cm below corresponding lower lip) and two-point discrimination tests with calipers (on corresponding lower lip).

The patient, as well as the resident evaluating the patient, will be blinded to which side received which intervention. Patient's medical records will not indicate which side was operated on with which osteotomy instrument, and the evaluating resident will be a different provider than the senior resident who delivered the treatment. To assess efficacy of observer blinding, the observing resident will guess at the time of sensory measurement which side of the patient was operated on using the ultrasonic saw. Also to verify measurement accuracy, a second observer (Dr. Saghezchi) will reexamine the patient and verify the von Frey hair and two point discrimination findings that the resident collected at each visit.

Patient’s age, gender, race/ethnicity, and intraoperative complications relating to osteotomy will also be recorded. Also, medication history (steroids, analgesics, psychiatric/neuroepileptic, etc...) will be recorded at each visit.

Statistics

Outcome operationalization:

For more practical clinical a\ined as a lower lip two point discrimination test >15mm, or patient's inability to sense third hair or thicker in the von Frey hair series.

Primary analysis:

Effect measure (Odds Ratio) of the intervention on neurosensory deficit at 3 months will be calculated in both an Intention to Treat (ITT) and Per Protocol (PP) analysis using conditional logistic regression models (an extension of McNemar's test). If the treatment and intervention arms are perfectly balanced and matched, age and gender will not be used as covariates. However, effect measure modification (interaction) of these and other covariates (e.g. gender, age, specific medications) will be explored. Likely, very few patients will undergo unexpected intraoperative manipulation of the inferior alveolar nerve. These patients will be omitted from analysis, unless they represent >10% of the sample size, in which case, we will include the patients and adjust for them as a covariate in the conditional logistic regression.

Secondary analyses:

A subgroup time-to-recovery analysis will also be performed among those patients exhibiting neurosensory deficit in post-operative day 1. This analysis will be a survival analysis with follow-up period from day 1 to 3 months, with "failure event" being recovery of neurosensory deficit. If too few recoveries occur prior to 3 month visit, we will again use conditional logistic regression test instead. [Update: This analyses was not ultimately done due to small sample size at completion of study.]

Quality Control / Interim Analysis

For the first six months, all investigators and an on-field data collecting resident will meet monthly to discuss and assess challenges, progress, harms, and benefit. Any initial reports of deviation/adverse event/breaks in confidentiality will be reviewed immediately by the principal investigator and out-report in accordance with the UCSF post-approval reporting requirements. Thereafter, the research team will reconvene at a minimum of every three months. An unblinded interim analysis of efficacy and effect measure will be performed by the analytic investigator at 1 year (or at 25 patients, whichever is sooner) to assess for termination of trial due to unexpectedly strong benefit or harm.

Human Subjects

Patients will be identified from the UCSF Moffitt-Long and Mission Bay Benioff Children's hospital operating room schedules for Dr. Saghezchi, and those scheduled for BSSO surgery who meet the inclusion criteria will be approached for enrollment in the study. All patients scheduled for BSSO surgery with Dr. Saghezchi will be approached for enrollment in the study. Exclusion criteria will be an age of over 45, and any preexisting mandibular sensory derangements. This study will aim to include 50 patient participants.

At each patient's presurgical clinic appointment, which occurs one week before their scheduled surgery date, they will be approached for enrollment by a resident. The resident will explain the study and emphasize that whether they decide to enroll or not will not affect their scheduled surgery date. It will be explained that on the day of surgery, randomization will decide which mandibular side will be instrumented with the Sonopet ultrasonic saw, with the remaining side receiving treatment with the traditional reciprocating saw. Both of these methods are an accepted and standard level of care for BSSO patients, commonly used in academic institutions across the country. We will then analyze their V3 paresthesias on each side at various timepoints postoperatively. Dr. Saghezchi will see the patient next and will further answer any questions they have about the study. If the patient, or their legal guardian if they are under the age of 18, agree to be involved in the study they will then sign a paper consent form explicitly documenting this. Less than one hour- roughly 10 additional minutes will be added to each follow up appointment (5 in total) time to thoroughly assess their sensory function on each mandibular side.

Data will be stored immediately on collection using the secure and HIPAA-compliant online web application, REDCap. Sepehr Hashemi will serve as data manager, programmer, analyst, and quality control coordinator. All patient records will be accessed from UCSF campus computers, therefore no PHI will be saved on personal computers or stored for later use. Any identifiable data collected for recruitment purposes (i.e. during patient approach and while gathering informed consent) will be discarded via shredder machine the same day should the patient not be interested in participating in the study. Only necessary information for the study will be kept regarding patients who do choose to participate in the study.