The Effect of Temporal Muscle Suspension on the Risk of Temporal Hollowing: A Prospective Randomized Clinical Trial

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The pterional approach to the cranio-facial region is an often-used approach by neurosurgeons. This surgical approach is used for access to intra-cranial abnormalities (ie. Tumors, trauma, or vascular insults). Temporal hollowing is a common complication that that can affect the patient both physically and emotionally. In an aesthetic region, it can represent a stigma of disease that prevents the patient from moving on with the normalcy of their disease-free lives. The hollowing generally occurs within 6 months from the index surgery. Currently the exact mechanism or incidence of this complication is not very well described.

The purpose of this prospective study is see if traditional techniques to the closure and temporal muscle suspension (TMS) after the pterional approach will show any differences in post-operative temporal hollowing (TH).

1. Objectives

The primary objective is to identify which patients undergoing a traditional pterional approach with 2 different surgical techniques for TMS will develop TH. Pre and post-operative CT scans will be reviewed and analysis with previously proven metrics will be performed.

2. Background

Surgical Details/Anatomy

The pterional approach is an indicated neurosurgical approach commonly used for anterior circular aneurysms, suprasellar lesions, and medial sphenoid wing tumors (1,2). A curvilinear incision from the midline widows peak and extending laterally to 1 cm anterior to the tragus of the ear, terminating within a skin crease, with preservation of the superficial temporal artery if possible. The temporalis fascia is encountered and divided. Either the entire temporalis muscle can be elevated or a cuff of temporalis muscle can be left on the cranium to facilitate closure and suspend the temporalis muscle. Subperiosteal dissection of the muscle is performed and the craniotomies are then accomplished.

Reconstruction of the pterional approach can be accomplished with bony fixation of the bone flap. However, the TMS can be performed by:

1. Resuspension of the temporalis muscle to the cuff of muscle left on the temporal crest or
2. Suturing the temporalis muscle directly to one of the bone plates that is used to for fixation.

Current Literature

The TH can occur either due to direct injury to the muscle, atrophy from denervation or even loss of vascular supply (3). Modern neurosurgical techniques have led to great improvements of surgical and functional outcomes, however less attention has been paid to the post-operative complications of scarring and soft tissue deformities (4). There have been several techniques and alterations to the traditional pterional approach to overcome some of the surgical drawbacks such as TH. The most common published is the use of a minipterional (MPT) approach (5). However, the minimalist approach has been debated regarding its effectiveness due to the narrowing of the visual field and restricted maneuverability (6). In the Johns Hopkins experience a retrospective review performed by Huang et al. found the MPT a suitable alternative approach without suboptimal visualization and no instances of improper vascular clip applications (7). They also described limited temporal wasting in 96% of their patients. The obvious limitations to this study and much of the studies in the literature are that they are retrospective in design. Additionally, the primary objective of that study was to evaluate the safety and efficacy of a minimalist approach. To their credit the temporal hollowing was addressed with a placement of an artificial implant. To date there has not been a prospective study regarding the reconstructive placement of the bone flap and temporalis muscle after a pterional approach to the cranium. Elucidation of a surgical cause of TH may lead to a decrease in secondary surgeries and the inherit risks that are associated.

3. Study Procedures

This study will include all patients under the care of John Weingart MD who qualify for a pterional approach for management of their neurosurgical disease. A pre-operative CT scan will be performed using the Gordon/Stryker Maxillofacial protocol, which is performed as part of the patients routine workup. If

the patient agrees to take part in the study, the patient will be randomized into 1 of 2 groups (randomization will take place by a coin flip).

Group Heads: Traditional pterional approach with a muscle cuff left for TMS

Group Tails: Traditional pterional approach with TMS performed with a bone plate.

All patients will be assigned a confidential experimental number which will be linked to their MRN. The linking database identifying patients with their alphanumeric code will be stored on a single computer that is password protected. The password will only be given to the Co-Investigators on this IRB application.

Routine follow up will be performed at 1 week from surgery, 1 month, and lastly 6 months from surgery where a routine post-operative CT Scan will be performed.

Photographs will be taken on the lateral head for comparison. All identifying markers (eyes,nose, and lips, or skin lesions/tattoos) will be removed for privacy. All other care and services will be as per routine.

There will be no extra research procedures performed or asked of the patient.

Demographic data including age, gender, indication for surgery, length of surgical time, and complications will be recorded.

a. **Study Duration**
    a. The duration of the study will conclude 6 months after the last patient is enrolled. The study does not alter the normal amount of post-operative visits that are considered routine.
b. **Blinding, including justification for blinding or not blinding the trial, if applicable.**
    There will be no blinding of the study as the operating surgeon will need to know which operation to perform.
c. **Justification of why participants will not receive routine care or will have current therapy stopped.**
    a. All patients enrolled will receive routine care
d. **Justification for inclusion of a placebo or non-treatment group.**
    a. There will be no role for a placebo group or a non-treatment group, as standard of care is some form of TMS
e. **Definition of treatment failure or participant removal criteria.**
    a. Participant removal will be initiated if they are unwilling to follow up in a routine fashion as outlined in the study protocol.

f. **Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.**

a. All patients under the care of Dr. John Weingart will receive routine care and followup. This includes management of all surgical complications. There is no alteration of their routine care when the study ends or is prematurely ended.

4. Inclusion/Exclusion Criteria

This study will include all patients over the age of 18 years who qualify for a pterional approach for their neurosurgical pathology. This will be determined by a clinical exam and plan by Dr. John Weingart.

We will not include patients from protected populations, such as inmates or children. Patients will not be excluded on the basis of pregnancy.

5. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used. **N/A**

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed. **N/A**

c. Justification and safety information if non-FDA approved drugs without an IND will be administered. **N/A**

6. Study Statistics

a. Primary outcome variable.

The primary end point and outcome variable will the CT quantitative evaluation of TH. The pre and post operative CT scans will be analyzed by the same volume dimensional analysis which has been previously standardized by the lead authors' prior study on TH and cranioplasties (8). Percent change and volume analysis as compared to the non operated temporal region in a two dimensional and three dimensional view will be the primary outcome variable.

b. Secondary outcome variables.

Secondary variables will include patient satisfaction for aesthetic results. Patients will be asked to rate their satisfaction of their aesthetic result on a scale from 1 to 10.

c. Statistical plan including sample size justification and interim data analysis.
A sample size of 30 patients was calculated (alpha error of .05 and a statistical power of 0.80) in order to detect a significant difference in post-operative TH in the 2 different surgical techniques. A paired Student t-test will be used to compare the degree of TH on the control side with the operated side. For the categorical data, a Fisher test and chi square test will be utilized. Differences less than 0.05 will be considered significant.

d. Early stopping rules.
The study will be stopped early is patients with a certain type of TMS have favorable results.

7. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.
1. There are no added risks to this study

b. Steps taken to minimize the risks. **N/A**

c. Plan for reporting unanticipated problems or study deviations.
d. Legal risks such as the risks that would be associated with breach of confidentiality.
e. Financial risks to the participants**. N/A**

8. Benefits

There are no added benefits to the patient. TH is a known sequela and complication from the pterional surgical approach. The benefit to society maybe great. If one type of TMS proves to limit the incidence of TH that could decrease the need for further corrective secondary surgeries.

8. Payment and Remuneration

There will be no payment or remuneration for patients.

Costs: There will be no associated costs for patients

References

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