Comparison of Operating Room Time Length with the Use of Virtual Surgical Planning Versus Conventional Treatment of Mandible Fractures

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Protocol Title:	Comparison of Operating Room Time Length with the Use of Virtual Surgical Planning Versus Conventional Treatment of Mandible Fractures
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Population:	All patients presenting with diagnosed mandible fracture at Memorial Hermann Hospital
Number of Sites:	Memorial Hermann Hospital
Study Duration:	Between November 2019 and November 2021 (until adequate data is obtained for significant statistical analysis)
Subject Duration:	From the initial preoperative evaluation to end of treatment which is 2 months

General Information

Patients at Memorial Hermann Hospital who have an isolated mandibular fracture and who are appropriately consented will partake in this study. They will be split evenly into 2 groups which are virtual surgical planning (VSP) and the conventional surgery. The conventional surgery involves having medical grade CT in order to assess the mandible fracture and having an open reduction and internal fixation of the fracture. The reconstruction plate will be bent intra-operatively. VSP patients will also receive the medical grade CT and also receive intraoral scans for aid in assessing occlusion. 3D models of the patient's jaws will be made and set into the proper occlusion. A reconstruction plate will be bent before the surgery using these models to be used at the time of surgery. Advancements in VSP technology increasingly demonstrate improvements in operative efficiency and reduce operating time. Pre-surgical planning and fabricated guides can potentially improve intraoperative efficiency, postoperative outcomes, and minimize complications. Additionally, use of this technology may permit a reduction of operating costs associated with longer operating room and anesthesia times in conventional treatments. Another challenge presented with VSP is turn over time from the actual planning and fabrication of splints or anatomical models to having them ready for surgery. This can take between one to two weeks and delay treatment for acute trauma cases.

Objectives

Objective of this randomized controlled study is to compare operating room time between conventional treatment techniques (without VSP) versus use of VSP and surgically-guided techniques. Surgically-guided techniques will include use of an occlusal splint (from digital intraoral scanner), and a 3D printed anatomical model for adaptation of pre-bent titanium plates. Additionally we will determine if remotely printing anatomical guides and splints is feasible and can decrease turn over time for VSP.

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
To compare OR time between conventional treatment techniques (without VSP) vs use of VSP and surgically guided techniques	ORIF time, which is defined as starting after the dissection is complete and fractures are reduced until final screws are placed. Ideally the dissection, reduction, closure	To compare whether or not the intervention (VSP) yielded decrease OR time

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	should not change from the control to the treatment	
Secondary		
To compare and contrast the effect of any other variables that might have an effect on the overall result	Age, gender, fracture pattern, Type of archbars, fit guides, type of approach, Surgical revisions, infections, mouth opening, Hardware failure defined as plate fracture or screw loosening	Age, gender, and fracture pattern is basic data needed to analyze results. The rest of the endpoints are important because they might possibly have an effect on the primary objective.

Background Information

Mandibular fractures are the second most common facial bone fracture [1] due to its prominent position in the maxillofacial region and the mandible's relative lack of structural support. The most common cause of injury is low impact blunt trauma, including motor vehicle accidents (MVCs), physical assault, and sports injuries [1, 2]. Advancement in mandibular reconstruction increasingly allow for interventions that result in reduction of facial deformities [3]. With the application of virtual surgical planning (VSP), the planning process has become more precise, reducing the number of intra- and postoperative complications [4-16].

Complex mandibular fractures often require open treatment with internal fixation of the mandibular segments, and maxillomandibular fixation for proper healing. Treatment and surgical approaches vary with fracture patterns, location, degree of bony displacement, and involvement of dental structures. Greatly displaced fractures, fractures in difficult anatomical locations, and loss of dental landmarks (occlusion) can pose a challenge for the reconstructing surgeon. [1, 3, 4]. Successful management of these complex fractures requires careful consideration of these factors. Such challenges may include achieving an accurate reduction of the fragments and placing a stable reconstruction plate for the purpose of re-establishing the original shape of the mandible. In order to help overcome these challenges, VSP has been utilized for the reconstruction of traumatic facial injuries, including the repair of complex mandible fractures. Three-dimensional modeling of maxillofacial injuries facilitates precise intraoperative reduction of displaced bone fragments, while CAD/CAM technology produces occlusal splints that allow superior restoration of facial symmetry, appearance, and function to those fitted intra-operatively [5].

The advent of VSP allows surgeons to increase surgical precision while reducing operating time. In addition to shortening OR time, surgical reconstruction of the mandible using VSP and pre-bent hardware demonstrates successful restoration of orofacial contour and function [4, 7, 8, 10, 14]. Today, there are numerous publications on the use of VSP and 3D imaging methods to fabricate occlusal splints and anatomical models to facilitate adaptation of a pre-bent reconstruction plate for mandibular reconstruction [4-23]. Furthermore, these studies have demonstrated reduction in operating time and had minimal intraoperative plate manipulation [4-16].

Excellent results have been shown for VSP on mandibular reconstruction with assistance from an intraoral scanner for modeling generated occlusal splints and pre-bent fixation plates. This randomized control study will attempt to determine whether there is reduction in operating time, costs, and post-operative complications. This treatment modality may potentially allow for increased accuracy, efficiency, and outcome in this surgical setting. A reduced time in the operating room could potentially lead to better outcomes for the patient while decreasing overall treatment cost. Hence, a decreased operating time, anesthesia time, and hospitalization could thereby, potentially, justify the additional preoperative costs that come with computer assisted surgical planning. Furthermore we will determine the effectiveness of remote 3D printing guides and models to decrease the turn over time of VSP.

Study Design

- In this randomized controlled study, we will evaluate patients from the University of Texas Health Science Center at Houston, Department of Oral & Maxillofacial Surgery treatment facility at Memorial Hermann Hospital

- from a patient population that undergoes mandibular trauma via open reduction internal fixation (ORIF) via intraoral or extraoral approach, using an intra-oral scanner, VSP® 3D Systems, and Stryker Anatomical Models.

- The study population will be composed of patients presenting with mandible fractures to Memorial Hermann Texas Medical Center in Houston, Texas from November 2019 to November 2021 (until adequate data is obtained for significant statistical analysis).
- Recruited and consented patients will be asked to attend the follow up appointments, for permission to review their records, to answer additional questionnaires, and have additional measurements/formal exam taken.
- Subjects will be re-evaluated at 3 within 6 weeks to assess the patient's mandible fracture healing via panorex or maxillofacial CT (follow ups: 1 week, 3 weeks +/- 1 week, 6 weeks +/- 1 week)
- Patients will be recruited from the Memorial Hermann Hospital when assessed and scheduled for mandibular reconstruction via open reduction internal fixation with VSP, fabrication of occlusal splint (from intraoral scanner), and 3D printed anatomical model for adaptation of pre-bent reconstruction plate.
- The study design would implement a randomized non-blinded clinical trial. Randomization will be performed by having sealed envelopes at the time of enrollment with either "original" or "VSP" written on cards.
- Both groups of patients will be treated by a team of oral and maxillofacial surgery residents and attending surgeons.
- The patients will be divided into two groups, the treatment group and control group. Records for both groups will be evaluated by the investigators and the patients will be asked to follow up in the OMFS Clinic at Memorial Hermann and treated by the Oral & Maxillofacial Surgery service.
    - The treatment group corresponds to patients undergoing mandibular reconstruction via open reduction internal fixation (intraoral or extraoral approach) utilizing virtual surgical planning via 3D Systems, bite registration and fabrication of occlusal splint via intraoral digital scanner, and mandibular hardware
    - The control group will include patients that undergo mandibular reconstruction via open reduction internal fixation (intraoral or extraoral approach) in standard fashion (without virtual surgical planning assistance and occlusal splint)

Study Population

Our study population consists of all patients with complex mandible fractures presenting to the University of Texas Health Science Center at Houston, Department of Oral & Maxillofacial Surgery facility at Memorial Hermann Hospital between October 2019 and October 2021 (until adequate data is obtained for significant statistical analysis).

- We anticipate recruitment of approximately 50 patients (25 patients for each control and treatment group) from Memorial Hermann Hospital. The control group will undergo mandibular fixation via standard open reduction internal fixation techniques. The VSP group will undergo mandibular fixation with standard open reduction internal fixation techniques and utilization of intraoperative occlusal splint, Virtual Surgical Planning via 3D Systems, and Stryker Anatomical Models.
- Inclusion criteria:
    - Patient consent
    - Male or female; 18 years or older
    - Complex mandible fracture (at least two fractures) that require ORIF of at least one fracture.
- Exclusion criteria:
    - Patient refusal to participate in study
    - Infected mandible fracture
    - Closed reduction treatment of mandible fracture
    - Fractures older than 2-3 weeks at the time of treatment
    -
    - Other etiologies than trauma of the mandibular fracture or pathologic fracture secondary to benign or malignant pathology that may require resection
    - Pregnant patients will NOT be excluded from the study
    - Co-morbidities (auto-immune disease, osteoporosis, titanium or metal allergy, uncontrolled diabetes (A1c greater than 8)

Patient would be enrolled upon evaluation and consent for mandibular reconstruction at the University of Texas Health Science Center at Houston, Department of Oral & Maxillofacial Surgery treatment facility at Memorial Hermann Hospital - Texas Medical Center

Study Procedures

- No additional time will be required from participants than the time required for the normal care, treatments, or management. Patients will not be charged anything additional to participate in the study and will also not receive any compensation.
- Patients will have post-operative CT scan to ensure adequate reduction and fixation of fractures
- Patients will be re-evaluated at 3 follow up visits within 6 weeks to determine mandible fracture healing.
    - Post-op (prior to discharge), 1 week, 3 weeks +/- 1 week, 6 weeks +/- 1 week
- Collected data will include:
    - Age, gender, operating time (ORIF time, total operating time), fracture pattern
        - ORIF time will be defined as starting after the dissection is complete and fractures are reduced until final screws are placed.
        - Ideally the dissection, reduction, closure should not change from the control to the treatment
    - Accuracy of fracture reduction
    - Type of archbars, fit of guides, type of approach
    - Surgical revisions, infections, mouth opening
    - Hardware failure defined as plate fracture or screw loosening
- Once data is collected, variability will be calculated within individual test results.

Data & Safety Monitoring

- Adverse events
    - Expected adverse events: pain, infection, bleeding, swelling, trismus, possible nerve damage, damage to adjacent structures
    - Unexpected adverse events: repeat fractures, trauma post-surgery, plate fractures, loose screws, mal-unions, non-unions, poor cosmetic outcome, delayed healing
    - Potential serious adverse events: sepsis from infection, osteomyelitis
- Unanticipated problems will be discussed amongst investigators.
- Methods of measuring results will be discussed amongst investigators and standardized so that measurements remain consistent from investigator to investigator.
- The research team will periodically review its protocols to ensure maximal patient safety and data validity.

Statistics

- Generalized linear model will be used to identify data distribution differences between the two study groups.
- This data will be recorded using a standardized data sheet to be shared within the department.
- Power analysis was performed for an f-test, and to show a large effect size (f=0.4) between the groups will require:
    - n = 25 patients/group to achieve a power of 0.8 and a significant level of 0.05.
- **ANOVA-based power analysis figures require:**
    - n = 26 patients/group for a large effect size
    - n = 64 patients/group for a medium effect size
    - n = 393 patients/group for a small effect size

Ethics

- A written informed consent will be obtained from the adult subject. This site has submitted the consent documents for CPHS review.
- IRB approval will be sought from CPHS (Committee for the Protection of Human Subjects).
- Treatment and clinical management will not be affected by this study. The surgical procedure investigated in this study is considered standard of care.
- Informed consent for the review of records and permission to conduct additional questionnaires and measurements at each follow up appointment will be obtained from each patient prior to commencing the study.
- To protect the privacy of subjects, only members of the research staff including the attending doctors, residents, will have access to patient health information

Data Handling & Record Keeping

- Data collected electronically through the medical record system and recorded on the data sheets attached to this protocol. Access to source documents will be per respective EHR guidelines on computers that are encrypted, and password protected. The data sheets, including consents, will be kept with the principal investigator in a locked cabinet. The patients will also receive a copy of their consent forms. HIPAA compliance guidelines will always be used.
- Human subjects will not be directly identifiable, but only identifiable in the study database through identifying information (Hospital MRN)
- Age of patient will be recorded to replace birth date. Only specific disease information, sex, and age as potential identifier will be used. No identifiable patient name, number or birth date will be used in this study and subsequent publications.
- The study data will be saved on the HIPAA compliant University of Texas Secured Cloud Service (Secure Share).

Quality Control & Assurance

- The investigators will use the same methods and supplies in completing physical examinations, including inspection, palpation, sensation, and range of motion, and post-operative complications and to record data consistently.
- The investigators will record the ORIF time (defined above) and total operating time
- Results will be verified against known sample for testing validity.
- There are no plans for third party monitoring.

Publication Plan

- Research will be submitted to multiple scientific, medical, dental, and OMFS journals for publication consideration.
- The results will not be returned to research subjects.

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