

**University of Kansas Medical Center**  
**RESEARCH PROTOCOL INVOLVING HUMAN SUBJECTS**

**Version date:** 10/30/19

**Principal Investigator:** Dr Clinton Humphrey

**Study Title:** Management of Subcondylar Mandible Fractures. A Survey of Oral Maxillofacial, Plastic and Facial Plastic Surgeons.

**Co- Investigator(s):** Dr J David Kriet, Dr. Richard Davila

---

**I. Purpose, Background and Rationale**

**A. Aim and Hypotheses**

We hypothesize that there is a wide variance in surgical approach preference when repairing mandibular condylar/subcondylar fractures amongst surgeons who perform these procedures. This variance may show different patterns when looking at practice type, experience, and/or specialty (Oral Maxillofacial Surgeons, Plastic Surgeons, Facial Plastic Surgeons). The aim of this study is clarifying what the current practice patterns are for repair of these fractures amongst these surgeons. Additionally, we want to identify if there is a discrepancy in management of these fractures amongst specialists. And lastly, we hope to better understand if there is any individual preference for any one surgical approach and if so, what are the perceived benefits of these.

**B. Background and Significance**

1. Mandibular condylar/subcondylar fractures are common with the literature reporting an incidence of 30-50% amongst mandibular fractures. Sequela from these fractures if not treated appropriately can include malocclusion, infection, chronic pain, TMJ related problems and permanent facial deformity<sup>1</sup>. The treatment for these fractures can range from conservative management with a soft diet, and close monitoring to operative open reduction and internal fixation of fracture fragments through introral and/or external facial/neck incisions. Criteria for proceeding with operative repair vs conservative management is clearly stated in the maxillofacial literature. However, when operative repair is indicated there are several approaches described to access this region of the mandible, each with its own strengths, risks and benefits. These surgical approaches include: closed incision-less reduction, intra-oral and external facial approaches with open reduction and internal fixation. While there are studies describing outcomes for each individual approach there is no consensus on which

approach is better and/or appropriate in any given scenario. The decision has often been based on personal experience and anecdotal reported benefits to any given approach. With this survey study we look to elucidate practice patterns in repair of these fractures amongst specialists in Otolaryngology, Plastic Surgery and Oral Maxillofacial Surgery. We also look to assess barriers in utilization of any and all of these approaches as well as the perceived benefits and weaknesses of all of these.

## 1. Literature Review:

- Langdon, J., Patel, M., & Brennan, P. (2010). *Operative Oral and Maxillofacial Surgery Second edition*. Chapter 55. Mandibular Fractures. CRC Press
- Bayat, M., Parvin, M., & Meybodi, A. A. (2016). Mandibular subcondylar fractures: a review on treatment strategies. *Electronic physician*, 8(10), 3144.
  - Author reviews the approaches commonly used for repair of subcondylar fractures and argues that endoscopic assisted approaches are a safe alternative.
- Ellis III, E., McFadden, D., Simon, P., & Throckmorton, G. (2000). Surgical complications with open treatment of mandibular condylar process fractures. *Journal of oral and maxillofacial surgery*, 58(9), 950-958.
  - Author describes a cohort of patients at his institution repaired via an open approach and describes his outcomes and rate of complications.
- Strohl, A. M., & Kellman, R. M. (2017). Current management of subcondylar fracture of the mandible, including endoscopic repair. *Facial Plastic Surgery Clinics*, 25(4), 577-580
  - Author discuss the current controversy in management of subcondylar fractures and describes the multiple approaches used for the management of these fractures.
- Epidemiology and treatment outcome of surgically treated mandibular condyle fractures. A five years retrospective study. *J Craniomaxillofac Surg*. 2014;42:879-884
  - Author describes his experience utilizing the two open approaches to treat subcondylar fractures, with good results, and minimal complications
- Ellis III, E., Simon, P., & Throckmorton, G. S. (2000). Occlusal results after open or closed treatment of fractures of the mandibular condylar process. *Journal of oral and maxillofacial surgery*, 58(3), 260-268.
  - Author describes the post-operative results in occlusion when utilizing open vs closed approaches for subcondylar fractures. He concluded open approaches lead to improved post-operative dental occlusion.

## **C. Rationale**

Understanding current national trends in management of subcondylar fractures and in particular the approaches most commonly utilized can help us understand if there are gaps in knowledge, barriers to access or lack of training in any particular approach. Results may help identify discrepancies amongst providers and help training programs address these deficiencies while training young surgeons and/or provide more access to courses training in these techniques.

## **II. Research Plan and Design**

### **A. Study Objectives:**

- i. Primary outcome:
  - To assess practice trends with regards to the use of closed, open and/or endoscopic approaches when repairing condylar/subcondylar fractures amongst specialists in Otolaryngology, Plastic Surgery, and Oral Maxillofacial Surgery.
- ii. Secondary outcomes:
  - To determine perceived benefits and risks of utilizing a closed, open and/or endoscopic approach when repairing condylar/subcondylar fractures.
  - Identify any barriers in adopting any particular approach within a surgical specialty, as well as amongst specialties

### **B. Study Type and Design:**

A questionnaire would be sent to members the American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS), American Society of Maxillofacial Surgeons (ASMS) and American Association of Oral and Maxillofacial Surgeons (AAOMS). The questionnaire will be made and sent through the RedCap KUMC, responses will be completely anonymous.

### **C. Subject Criteria (See Vulnerable Populations appendix, if applicable):**

1. Inclusion criteria: Participants must be active members of one of the following medical societies: American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS), American Society of Maxillofacial Surgeons (ASMS) and American Association of Oral and Maxillofacial Surgeons (AAOMS).
2. Exclusion criteria: Those not members of the aforementioned societies
3. Withdrawal/Termination criteria: Only completed surveys will be used for statistical analysis.

### **E. Specific methods and techniques used throughout the study**

1. Laboratory tests N/A
2. Study Procedures:  
Online Survey – Sample document attached
3. Timeline:  
Duration of study is expected to last 6 months between data collection, analysis and write-up of paper.

**F. Risk/benefit assessment:**

1. Physical risk **None**
2. Psychological risk **None**
3. Social risk **None**
4. Economic risk **None**
5. Potential benefit of participating in the study **None**

**G. Location where study will be performed:** Survey will be done online through the RedCap KUMC survey tool

**H. Collaboration (with another institution, if applicable):** N/A

**I. Single IRB Review for a Multi-site study (if applicable):** N/A

**J. Community-Based Participatory Research (if applicable)** N/A

**K. Personnel who will conduct the study, including:**

1. Indicate, by title, who will be present during study procedure(s):  
Dr Richard Davila MD , Dr Clinton Humphrey, Dr J David Kriet.
2. Primary responsibility for the following activities, for example:
  - a. Determining eligibility: Dr. Davila
  - b. Obtaining informed consent: Dr. Davila
  - c. Providing on-going information to the study sponsor and the IRB:  
d. Dr. Davila
  - e. Maintaining participant's research records: N/A
  - f. Completing physical examination: N/A
  - g. Taking vital signs, height, weight: N/A
  - h. Drawing / collecting laboratory specimens: N/A
  - i. Performing / conducting tests, procedures, interventions, questionnaires:  
N/A
  - j. Completing study data forms: Dr. Davila
  - k. Managing study database: Dr. Davila

**L. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan**  
N/A

**III. Subject Participation**

**A. Recruitment:**

Recruitment will be done through active members email server for the following organizations: American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS), American Society of Maxillofacial Surgeons (ASMS) and American Association of Oral and Maxillofacial Surgeons (AAOMS)

**B. Screening Interview/questionnaire: N/A**

**C. Informed consent process and timing of obtaining of consent**

Consent letter will be included as first page in survey.

**D. Costs to Subjects: None**

**E. How new information will be conveyed to the study subject and how it will be documented: N/A**

**F. Payment, including a prorated plan for payment: N/A**

**G. Payment for a research-related injury: N/A**

**IV. Data Collection and Protection**

**A. Data Management and Security:**

All data collection will be done via an anonymous survey performed on the KUMC REDCap platform, utilizing their online survey tool. Data sets will be collected automatically and immediately stored in the REDcap (research electronic data capture) web-based clinical databases storing application which is password protected secured via our KUMC firewall and per our institution IT departments security infrastructures.

**B. Sample / Specimen Collection: N/A**

**C. Tissue Banking Considerations: N/A**

**D. Procedures to protect subject confidentiality:**

Data sets will be collected automatically and immediately stored in the REDcap (research electronic data capture) web-based clinical databases storing application

which is password protected secured via our KUMC firewall and per our institution IT departments security infrastructures.

#### **E. Quality Assurance / Monitoring**

Individual responses will be tracked and duplicated will be able to be identified and removed with verification of specific internet protocol (IP) address verification

#### **V. Data Analysis and Reporting**

**A. Statistical and Data Analysis:** We plan on performing chi square and Fisher's exact testing for binomial comparison between groups – by each group analyzed being each respective society - American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS), American Society of Maxillofacial Surgeons (ASMS) and American Association of Oral and Maxillofacial Surgeons (AAOMS).

**B. Duration of study:** Expected to last 3 months between data collection and analysis. We plan on performing chi square and Fisher's exact testing for binomial comparison between groups – by each group analyzed being each respective society - American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS), American Society of Maxillofacial Surgeons (ASMS) and American Association of Oral and Maxillofacial Surgeons (AAOMS).

**C. Outcome:** We expect >15% response rate prior to 90 days window from the time of survey distribution.

**D. Study results to participants:** Results will be given to participants through publication of results. There will not be individual results distribution.

**E. Publication Plan:** Results will plan to be published before the end of the year to JAMA Facial Plastics or active periodical from the American Academy of Facial Plastic and Reconstructive Surgeons (AAFPRS)

#### **Bibliography / References / Literature Cited**

1. Langdon, J., Patel, M., & Brennan, P. (2010). *Operative Oral and Maxillofacial Surgery Second edition*. CRC Press
2. Bayat, M., Parvin, M., & Meybodi, A. A. (2016). Mandibular subcondylar fractures: a review on treatment strategies. *Electronic physician*, 8(10), 3144.
3. Ellis III, E., McFadden, D., Simon, P., & Throckmorton, G. (2000). Surgical complications with open treatment of mandibular condylar process fractures. *Journal of oral and maxillofacial surgery*, 58(9), 950-958.

4. Ellis III, E., Simon, P., & Throckmorton, G. S. (2000). Occlusal results after open or closed treatment of fractures of the mandibular condylar process. *Journal of oral and maxillofacial surgery*, 58(3), 260-268.

## **APPENDIX I: VULNERABLE POPULATIONS**

N/A