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**A Comparison of Stryker Hybrid Arch Bars
versus Erich Arch Bars for Maxillomandibular
Fixation of Mandibular Fractures:
A Prospective Randomized Study**

Investigators:

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Schema:

Consecutive patients presenting to Grady Memorial Hospital with mandibular fractures will be evaluated for recruitment in this pilot study. Patients requiring either open reduction and internal fixation (ORIF) or closed reduction (CR) will be included in the study.

The choice of surgical method (ORIF versus CR) will be determined by the patient preference in conjunction with the attending surgeons expert opinion. The surgical procedure for closed treatment is a simple and standardized procedure involving placement of arch bars and maxillomandibular fixation (MMF) for a period of 4-6 weeks. The surgical procedure for ORIF will involve the placement of arch bars intraoperatively, exposure of fractures by intraoral or transcutaneous incisions, intraoperative MMF and ORIF. All procedures will be done under a general anesthesia. All eligible subjects will be initially stratified to ORIF or CR. Subjects within each group will then be randomized to either Stryker Hybrid arch bars or Erich arch bars (control). In all groups the arch bars will be left in place for six weeks. Stryker Hybrid arch bars will be placed according to the manufactures instruction using a minimum of four locking screws per arch. Erich arch bars will be placed using a combination of 24 and 25 gauge wire as is the historical technique. Arch bar removal is a simple procedure that will be completed under local anesthesia in the outpatient clinic.

The primary predictor variable is the type of archbar (Stryker Hybrid versus Erich). The primary outcome variable is time required to place the arch bars. Secondary outcomes include union (nonunion, fibrous union, malunion), complications, hospital charges and need for additional procedures

Introduction:

Mandible fractures are commonly a result of maxillofacial trauma and account for the majority of facial fractures. The majority of fractures are treated with either ORIF or CR. Erich arch bars are the most commonly used type of MMF and are considered the gold standard. However, the application of Erich arch bars is time-consuming and requires the presence of teeth. Intermaxillary fixation screws and IVY loops are alternative approaches that may also be used. The hybrid arch bar system developed by Stryker is unique in that the bars are secured to the underlying alveolar bone with self-drilling locking screws rather than the teeth. This potentially reduces the time required to place the arch bars as well as the need for teeth.

There are no studies comparing Stryker Hybrid arch bars to traditional methods of MMF.

Objectives

- 1) Is there a difference in the application time when comparing Stryker hybrid arch bars to Erich arch bars for the ORIF or CR of mandibular fractures?
- 2) Is there any difference in overall surgical time, postoperative length of stay, hospital charges, fracture healing or complications when comparing Stryker hybrid arch bars to Erich arch bars for the ORIF or CR of mandibular fractures?

Patient Selection

Patients presenting to Grady Memorial Hospital will be eligible for inclusion in the study.

Inclusion Criteria:

- 1) Mandible fracture involving subcondyle, ramus, angle, body, parasymphysis and symphysis
- 2) Age 18 years - 90 years
- 3) Ability to give informed consent
- 4) Minimum 6 weeks follow-up
- 5) Pre and post-operative panoramic xrays

Exclusion Criteria:

- 1) Comminuted fractures
- 2) Infected fractures
- 3) Previously treated fractures
- 4) Complete edentulism
- 5) Gun shot wounds
- 6) Pregnancy or breast feeding

Informed consent will be obtained on all patients. Any patient who declines to participate in this study will be treated in an identical fashion to those who enroll in this study other than the type of intra-operative MMF will be determined by the attending surgeon rather than randomized.

Pretreatment Evaluation

All patients will have a history and physical examination as part of their admission to Grady Memorial Hospital. All patients will have a panorex xray or maxillofacial CT scan to assess the severity and location of mandible fractures and other facial fractures, as is the standard of care. In addition to routine blood tests (complete blood count and metabolic panel), patients reporting diabetes in their history will have a hemoglobin A1c drawn. Patients reporting human immunodeficiency virus infection in their history will have a CD4 count drawn unless they have recent result (CD4 count within 6 months) or

refuse. This will allow the level of immunocompetence in patients with known diabetes or HIV to be evaluated and additional medical care (additional antibiotics, antifungals, opportunistic infection prophylaxis, strict blood glucose control etc.) to be provided as the standard of care.

Registration and Randomization

Eligible patients will be offered the opportunity to enroll in the study when they are first consulted by the oral and maxillofacial surgery service. Consent will be obtained by one of the study investigators. Subjects will then be randomized to either Stryker hybrid arch bars or Erich archbars group using sealed envelopes that have been prepared by the study statistician.

Sample size

No prior studies exist to guide sample size calculations. It is anticipated that this pilot study will include a total of 40 subjects in the CR arms and 60 subjects in the ORIF arms. This study will allow for a drop out rate 30% for the outcome variables which is consistent with the patient population based on prior studies.

Therapy

In the ORIF group, thirty patients will be randomized to each arm of the study (30 Stryker hybrid arch bars and 30 Erich arch bars). In the CR group, twenty subjects will be randomized to each arm of the study (20 Stryker hybrid arch bars and 20 Erich arch bars). A number of different resident surgeons will perform the surgical treatment including the application of MMF. All residents will complete Stryker clinical skills training and will be standardized as the application process and technique for both arch bar systems. For all study subjects, time will be recorded from start to completion of maxillary and mandibular arch bar placement, and from insertion of throat pack to removal of throat pack. This will be measured using two different electronic timers to record the respective times. All arch bars will be left in place (ORIF and CR) for a period of 6 weeks. Patients will be discharged from the hospital as soon as possible after medically stable from surgery. Patients will be seen for follow up routinely for a minimum of 6 weeks postoperatively to ensure appropriate healing.

Patient Assessment

Patients will be assessed during surgery and in the postoperative period while in the hospital. After discharge, patients will be followed routinely to ensure complete bony consolidation of the fracture and at 4 to 12 weeks postoperatively. The primary

outcome variable is application time for placement of arch bars. Secondary outcomes include intra-operative surgical time length of stay after surgical procedure, length of stay, hospital charges, fracture healing and complications.

All data will be collected by the PI or CI during the initial admission for surgery to repair the fracture or at the one week and 6 week follow-up appointments. All data will be recorded on a standard data collection sheet. Subjects will not have any questionnaires or surveys to complete. Demographic, preoperative, operative and postoperative variables will be recorded and analyzed. Demographic data includes age, sex and race. Preoperative variables include medical history (DM and HIV), social history, fracture location, number of fractures, time from injury to surgery and antibiotic use. Operative variables include time for arch bar application, surgical time and surgical approach. Post operative variables include fracture healing, follow-up, complications and hospital charges. It is anticipated that the study will conclude at 24 months. All subjects will be paid \$50 at the 4 to 12 week follow-up visit.

Data Collection

A data collection sheet will be used to record demographic, preoperative, operative and postoperative variables. A separate copy of the data collection sheet is attached. All data collection sheets (unscrubbed and scrubbed) will be kept in a locked office. All data will be entered into a computer and this will be both password protected and secured in a locked office.

Data Safety Monitoring Plan

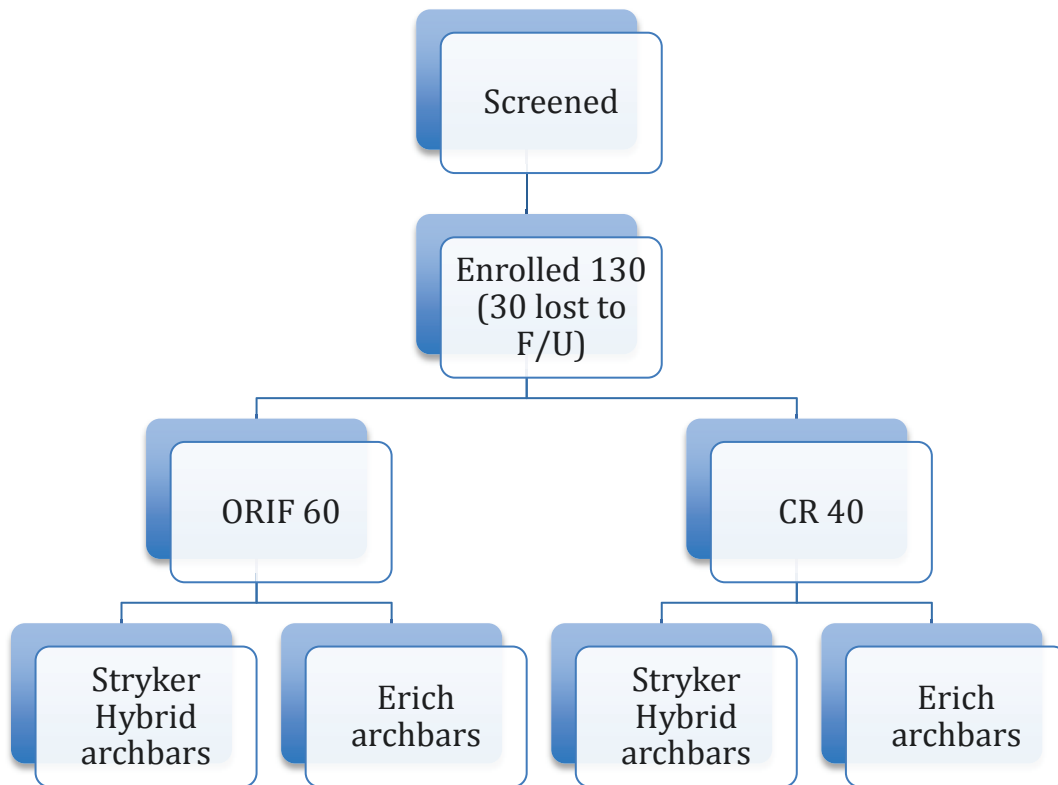
The use of either Erich arch bars or Stryker Hybrid arch bars are both FDA approved and used in clinical practice routinely to immobilize the jaws due to fracture. They can immobilize the jaw for 4 to 6 weeks to allowing healing when open surgery is not indicated or wanted by the patient. They can also immobilize the jaw temporarily during surgery to allow the surgical placement of titanium plates and screws to repair the fracture. There are no anticipated risks for subjects recruited to this study. However to ensure safety of subjects the investigators have appointed Dr Guillermo Umpierrez MD as the medical monitor. The medical monitor responsibilities include

- Pre-investigation discussion to verify understanding of the protocol, DSMB and IRB requirements.
- Ensure that eligibility and exclusion criteria are adhered to ensure the appropriate risk/benefit ratio for subjects.
- Ensure written consent is obtained for each subject

- Ensure that subjects are 18 yrs of age, non-pregnant and not actively seeking to become pregnant, not breast feeding and are not disadvantaged populations.
- Ensure that data on adverse outcomes is recorded appropriately in the surgical operative report and during the follow-up visits.
- Provision for subject withdrawal and documentation for reasons of discontinuation.
- Ensure that data is entered in real time to provide electronic access on a monthly basis.
- Three Monthly conference with the investigators.
- Review subject records periodically to ensure that data is accurate and legible. Of particular importance will be recognizing any data omission, missing visits or examinations, drop-out subjects and reasons for withdrawal and satisfactory completion of informed consent.
- A written record of the teleconference and any site visits will be kept as well as any corrective action recommended by the monitor.

Bibliography

1. West GH, Griggs JA, Chandran R, Precheur HV, Buchanan W, Caloss R. Treatment outcomes with the use of maxillomandibular fixation screws in the management of mandible fractures. J Oral Maxillofac Surg. 2014 Jan;72(1):112-20.
2. Bell RB, Wilson DM. Is the use of arch bars or interdental wire fixation necessary for successful outcomes in the open reduction and internal fixation of mandibular angle fractures? J Oral Maxillofac Surg. 2008 Oct;66(10):2116-22.
3. Thor A, Andersson L. Interdental wiring in jaw fractures: Effects on teeth and surrounding tissues after a one-year followup. Br J Oral Maxillofac Surg 2001 Oct;39(5):398-401.



Budget

1) Research Coordinator 0.3 FTE

- Prepare and submit IRB application
- Follow subjects and ensure adequate F/U
- Data entry
- Record Data on site
- Issue Reimbursement to subjects

30% of 1 FTE (\$46000) for 2 yrs
plus fringe 26.5% \$34,914

2) Subject Reimbursement (100) \$5000

3) Redcap data base (electronic)

- Setup
- Annual fees

\$2500

4) Data analysis and randomization \$3000

5) Salary Support

- Gary Bouloux MD, DDS 1% effort \$5000

6) Indirect 39% \$19661

TOTAL \$70075