Union Rate of Transverse Tibia Fracture

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Union Rates g of Transverse Tibia Fractures Managed with Internal Fracture Compression Through an Intramedullary Rod Compared to Standard "Backslapping"

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Introduction

When compared to other fracture patterns, transverse fractures of the tibial shaft have historically been associated with an increased incidence of delayed union and nonunion when stabilized with intramedullary rods, perhaps due to the decreased cortical surface area available for healing.[1-4] As a result, some authors have recommended that simple transverse fractures of the tibial shaft be managed with plate fixation and compression of the fracture using an articulated dynamic tensioner.[5] Open plating of the tibia requires a large incision which may be at an increased risk for soft tissue complications, particularly when operating through a high-energy injured soft tissue envelope. Furthermore, intramedullary rodding of the tibia is currently regarded as the gold standard for surgical management of tibia fractures, including transverse fractures, and as such compression plating is not considered a reasonable option unless other mitigating circumstances exist.[1]

In recent years, technological advances in the design of intramedullary rods allow intraoperative, controlled compression of fractures with internal devices built in to the rod. This type of controlled compression may be beneficial when compared to traditional "backslapping" techniques, in which the amount of compression cannot be controlled or "dialed" in. After internal compression, static or dynamic locking of the rod can be accomplished as is routine when rodding typical long bone fractures. This advance poses a potential advantage when managing transverse fractures, the one fracture type most amenable to intraoperative compression to facilitate rapid bony healing.

The literature regarding intramedullary rodding of transverse tibia fractures is limited, and no literature exists comparing controlled internal compression with traditional methods of dynamic rodding or backslapping. The purpose of this analysis is to prospectively assess a consecutive cohort of patients with transverse tibial shaft fractures treated with intramedullary rodding and compressed with one of three methods: dynamic locking alone, backslapping followed by dynamic locking locking, or controlled internal

fracture compression with modern nails followed by static locking.

Primary Hypothesis:

Our hypothesis is that internal, controlled transverse fracture compression with modern intramedullary rod treatment of transverse tibial shaft fractures will be associated with an increased rate and time to union compared to the traditional methods of dynamic locking and backslapping.

Methods:

Inclusion Criteria

1. Skeletal Maturity
2. Closed or open diaphyseal (shaft) tibia fracture that is axially stable and will tolerate compression without shortening.
3. Treatment with Intramedullary Rod.
4. Fracture compression using one of three methods:
    a. Dynamic locking.
    b. Backslapping with dynamic locking.
    c. Internal rod compression with static locking.
5. Complete inpatient and outpatient medical records and operative notes.
6. Complete radiographic and clinical follow-up for minimum one year.

Exclusion Criteria

1. Skeletally immature.
2. Metabolic Bone Disease
3. Immunosuppression
4. Pathological Fracture (Tumor, Pre-existing Infection)
5. Pre-existing Infection
6. Soft-tissue coverage not obtained within two weeks from time of injury.
7. Use of Negative Pressure Dressing to definitively manage wound.
8. Use of external or implantable bone growth stimulator.

9. Unable to Full Weight Bear immediately post-operative.

Data Points:

1. Age
2. Sex
3. Medical Comorbidity
4. Smoking Status (Yes or No)
5. Closed or Open fracture:
    a. Wound Size (surface area)
    b. Wound type (Gustilo Anderson and OTA)
6. Number of Surgical Debridements
7. Time to definitive closure.
8. Soft Tissue Reconstructive Procedure
9. Compartment Syndrome (Yes or No)
10. Fasciotomy (Yes or No)
11. Treatment Method:
    a. Dynamic locking.
    b. Backslapping with dynamic locking.
    c. Internal rod compression with static locking.
12. Union (Yes or No)
13. Time to union (months).
14. Implant complications (Rod or Screw Breaking)
15. Loss of reduction and healing alignment on orthogonal radiographs.
16. Need for subsequent secondary treatment:
    a. Superficial Infection (Antibiotic Treatment)
    b. Deep Infection (Surgical Treatment)
    c. Delayed Union (Exchange rodding, Bone grafting)
    d. Nonunion (Exchange rodding, Bone grafting)

Methodology:

This study will be a prospective analysis of patients with transverse tibial shaft fractures (OTA 42-A3 classification) treated with an intramedullary rod. Patients will be enrolled at a single facility (Harborview Medical Center-HMC). Patients who meet inclusion criteria will be assigned to one of the three treatment groups based on the night of presentation. Currently there are three teams that manage the trauma call at HMC (Red, Green, Blue) and alternate on a strict 1 in 3 rotation schedule. Patients that present on a night when the Red Team is on call will be treated as Group A (dynamic locking). Patients that present on a night when the Green Team is on call will be treated as Group B (backslapping with dynamic locking). Patients that present on a night when the Blue Team is on call will be treated as Group C (internal rod compression). All three methods of treatment are considered acceptable current standards of practice in the orthopedic trauma community on a local and national level. All patients will be treated similarly with respect to:

1. Open wound management
2. Immediate post-operative full weight bearing.
3. Follow-up at 6 weeks, 12 weeks, 24 weeks and 52 weeks.
    a. Radiographic
    b. Clinical

Union will be determined according to the modified Hammer criteria,[6] with union considered to have occurred with bridging cortical bone on 3 or 4 cortices using orthogonal radiographic views.

Risks

There is no risk to the patient as all three treatment methods are current standard of practice both nationally and locally. All patient identifiers will be kept private. All data will be stored on a password protected database available only to the study team.

Benefits

The study performed will provide information regarding the optimal treatment strategy for transverse tibia fractures, and what the expected time to union is when using internal

compression. This information is of benefit to patients, particularly when being counseled by surgeons regarding how long they can expect before obtaining radiographic union, and what the potential reoperation rate would be.

Procedures to Ensure Confidentiality

No patient identifiers will be used during the formal study. Identifiers such as name and medical record numbers will be used to identify patients with a transverse tibia fracture, and will be stored on a password protected departmental network in a master file. Data files will be listed with subject number.

Statistical Analysis Plan

Descriptive statistics will be presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Statistical analysis of categorical variables utilized Fischer's exact test with descriptive statistics reported as frequencies and percentages. For continuous variables, a Mann-Whitney U test was utilized with descriptive statistics reported as means and ranges. Significance set at p value less than or equal to 0.05. All statistical analyses were performed using IBM SPSS version 22 (Chicago, IL, 2013).

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