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Original Research Article

Assessing Outcome of Unreamed Interlocking Intramedullary Nailing in Open Tibial Shaft Fractures- An Observational Study

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Abstract:
Background: Open tibial shaft fractures remain a significant challenge due to high complication risks such as infection, non-union, and malalignment. Unreamed interlocking intramedullary nailing has been proposed as a safe and effective management strategy, particularly in severe injuries.
Aim: To evaluate the outcomes of unreamed interlocking intramedullary nailing in open tibial shaft fractures and analyze associations with demographic and clinical variables.
Methodology: A prospective observational study was conducted at Department of Orthopedics, Adesh Medical College and Hospital, Haryana, India, from July 2023 to September 2024, including 30 patients with open tibial shaft fractures up to Gustilo-Anderson Type IIIB. Patients underwent unreamed interlocking nailing, with outcomes assessed through clinical and radiological parameters. Statistical analysis was performed using chi-square and ANOVA tests.
Results: The distribution included 8 Type II, 17 Type IIIA, and 5 Type IIIB fractures. No significant associations were found between fracture severity and sex (p=0.42), age (p=0.84), fracture pattern (p=0.53), or time to injury (p=0.47). Functional outcomes reflected earlier intervention for severe fractures. Additional procedures showed no significant association with fracture type (p=0.26).
Conclusion: Unreamed interlocking nailing is a reliable method for managing open tibial shaft fractures, offering stability, reduced complications, and favorable recovery, independent of demographic factors or fracture morphology.
Keywords: Fracture Outcomes, Functional Recovery, Gustilo-Anderson, Open Tibial Fracture, Unreamed Intramedullary Nailing.

Introduction

The tibia, as the most commonly fractured long bone of the lower extremity, often experiences high-energy injuries from road traffic accidents, falls from height, and industrial injuries [1]. Open fractures of the tibial shaft are particularly complex from a clinical perspective due to the combination of bone injury, soft tissue injury, and contamination [2]. Open tibial shaft fractures confer a higher risk of complicating conditions such as infection, delayed union, non-union, and malunion than closed fractures. This risk is largely attributable to the soft tissue envelope and disrupted vascularity. Therefore, management of open tibial fractures must balance stabilization of the skeleton with preservation of the soft tissue envelope in order to give the best patient outcomes with lowest morbidity [3].

Traditionally, open tibial shaft fractures were treated non-operatively with traction and cast immobilization, while recent developments in surgical techniques and implant technology have resulted in operative methods [4]. Of the operative methods, intramedullary nailing (IMN) is the procedure of choice since it offers biomechanical advantages for the treatment of tibial fractures by utilizing load-sharing fixation, encouraging early mobilization, and maintaining the periosteal vascular supply. Intramedullary nailing of tibial fractures may be completed with or without reaming of the medullary canal. Reamed intramedullary nailing can result in improved mechanical stability and increases the area of contact between the nail and endosteal surface, but can result in complications associated with open fractures such as disruption of the endosteal blood supply and increased thermal necrosis or fat embolism risk [5]. Therefore, unreamed interlocking intramedullary nailing has become an accepted modality for the treatment of open tibial shaft fractures, particularly in patients with significant soft tissue compromise.

Unreamed interlocking nails aim to produce sufficient stability while minimizing preparation of the medullary canal [6]. Unreamed interlocking nails preserve the endosteal blood supply to promote biological fracture healing and limit the risk of trauma to the bone and surrounding soft tissues [7]. Interlocking screws offer both axial and rotational stability, which is particularly important in open fractures, where the presence of fragmented or comminuted cortical bone may pose a risk to stability. Clinical studies have indicated that unreamed nailing provides satisfactory union rates, infection rates, and functional outcomes as compared to conventional reamed techniques, especially in open fractures such as Gustilo-Anderson type II and III fractures [8]. The minimally invasive nature of unreamed nailing limits surgical time, blood loss, and risk of iatrogenic injury, all the more important in the setting of polytrauma patients.

While unreamed interlocking nailing has become widespread, there remains controversy and debate surrounding its efficacy for use in the acute setting of severe open fractures, particularly when the fracture is grossly contaminated or has segmental bone loss [9]. Pertinent complications such as delayed union, nonunion, and malalignment have provided impetus to consider careful patient selection, surgical technique, and an algorithmic structuring of postoperative care. Recent studies have discussed the importance of early debridement, adequate antibiotic prophylaxis, and timely stabilization of the fracture to minimize the risk of infection and allow for healing [10]. Functional outcomes of patients, such as the return to normal activities in addition to pain and long-term function of the limb, remain an important end point to directly assess the clinical efficacy of unreamed interlocking nailing of open tibial fractures.

In this regard, observational studies offer valuable real-world evidence about the outcomes of unreamed interlocking intramedullary nails in open tibial shaft fractures, particularly in the areas of fracture union, complications, and functional recovery across a variety of patients and clinical settings [11]. Documenting clinical outcomes in a systematic manner helps refine surgical procedures, recognize risk factors for poor outcomes, and contribute to evidence-based practice in trauma patients. The present observational study aims to determine the outcomes of unreamed interlocking intramedullary nailing of open tibial shaft fractures treated at our institution, with specific focus on fracture healing, infections, and functional recovery [12]. This study will inform the discussion around the safety, efficacy and feasibility of this technique, contributing to the discussion regarding the optimal management of open tibial fractures.

The clinical outcomes of unreamed interlocking nailing in patients with open tibial fractures is important to improve patient care, assist with surgical decision-making, and reduce long-term morbidity. The high incidence of tibial fractures in both developing and developed nations, along with significant effects on patient quality of life, means that research in this area remains a priority. The results of this study are expected to guide trauma surgeons, enhance care for patients, and support the consilidation of treatment protocols in patients with open tibial shaft fractures.

Materials and Methods

This study was designed as a prospective observational study conducted in the Department of Orthopedics, Adesh Medical College and Hospital, Haryana, India from July 2023 to September 2024. The study aimed to evaluate the outcomes of unreamed intramedullary interlocking nailing in patients presenting with open tibial shaft fractures.

Study Population: The study population comprised all patients presenting to the outpatient department (OPD) and emergency department with open tibial shaft fractures (up to Gustilo Anderson Type IIIB). The patients were treated with unreamed interlocking nailing following detailed assessment and fulfillment of inclusion criteria.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Patients with open fractures of the tibial shaft (up to Grade IIIB of Gustilo Anderson classification).
- Age range: 18–60 years.
- Patients who provided written informed consent for participation in the study.

Exclusion Criteria

- Children with tibial fractures involving open growth plates.
- Patients with osteoporosis or established nonunion.
- Pathological fractures of the tibia.
- Polytrauma patients with extensive injuries to other body regions.
- Patients with closed tibial fractures.
- Refusal to consent for participation

Sample Size: As this was an observational study, all eligible patients meeting the inclusion and exclusion criteria and presenting during the study period were included. Data were collected continuously over the 15-month study period.

Ethical Considerations

- Ethical approval was obtained from the institutional ethics committee.
- Written and informed consent was taken from every participant or their legal guardian after explaining the study's purpose, methodology, potential risks, and benefits.
- Data confidentiality and privacy were maintained throughout the study.

Data Collection: Data were collected using a combination of primary sources (clinical examination and patient interviews) and secondary sources (medical records, imaging studies, and previous literature). A structured evaluation form was used to standardize the data collection process.

1. **Demographic Data:** Age, sex, occupation, and mode of injury.
2. **Clinical Parameters:**
   - Gustilo-Anderson classification of fractures.
   - Associated injuries and comorbidities.
3. **Surgical Procedure:** Detailed documentation of unreamed interlocking nailing.
4. **Postoperative Parameters:** Follow-up evaluations, functional outcomes, and complications.

Preoperative Management

- Patients were assessed clinically and radiologically upon presentation.
- Sterile dressing was applied to open wounds, and the affected limb was immobilized using a POP slab or Thomas splint.
- Patients underwent thorough debridement based on the Gustilo-Anderson fracture type. The wound was managed with either primary closure, delayed closure, or skin grafting as needed.
- Appropriate investigations, including X-rays, blood tests, and microbiological studies, were performed before surgery.

Surgical Technique

- A vertical patellar tendon-splitting incision (~5 cm) was made to access the proximal tibia.
- The correct point of insertion was identified just distal to the tibial plateau, medial to the midline of the bone.
- A curved bone awl was used to create an entry portal into the proximal metaphyseal cancellous bone, ensuring alignment with the medullary canal.
- Nail insertion: The unreamed nail was inserted across the fracture site. The diameter of the nail was chosen based on the tibial isthmus measurement.
- Interlocking: Both proximal and distal locking screws were inserted to stabilize the construct.

Evaluation of Outcomes

➢ **Functional outcomes were assessed using validated criteria:**

- Klemm and Borner's Criteria (1986): Evaluates knee and ankle motion, muscle atrophy, and radiographic alignment.

➢ **Yokoyama's Modification of Ketenjian and Shelton Criteria:**

Assesses joint motion, pain, gait, and swelling.

➢ **AO Classification**

- Radiological outcomes were evaluated for fracture union, alignment, and implant integrity.
- Complications: Infection, nonunion, malunion, implant failure, and the need for secondary surgeries were recorded.

Data Analysis

- Data were compiled and analyzed using SPSS software (Version 27).
- Qualitative variables (e.g., fracture type, complications) were expressed as percentages.
- Quantitative variables (e.g., time to union, range of motion) were summarized as means with standard deviations.

➢ Statistical significance was tested using:

- Chi-square tests for categorical variables.
- T-tests or ANOVA for continuous variables.
- Graphical representations included bar charts, pie diagrams, and scatter plots for better visualization of results.

Result

Comparison of Ga with Demographic Data

Table 1: Classification by sex

Gustilo-Anderson Type	Female	Male	Total
Type 2	4	4	8
Type 3A	9	8	17
Type 3B	1	4	5
Total	14	16	30

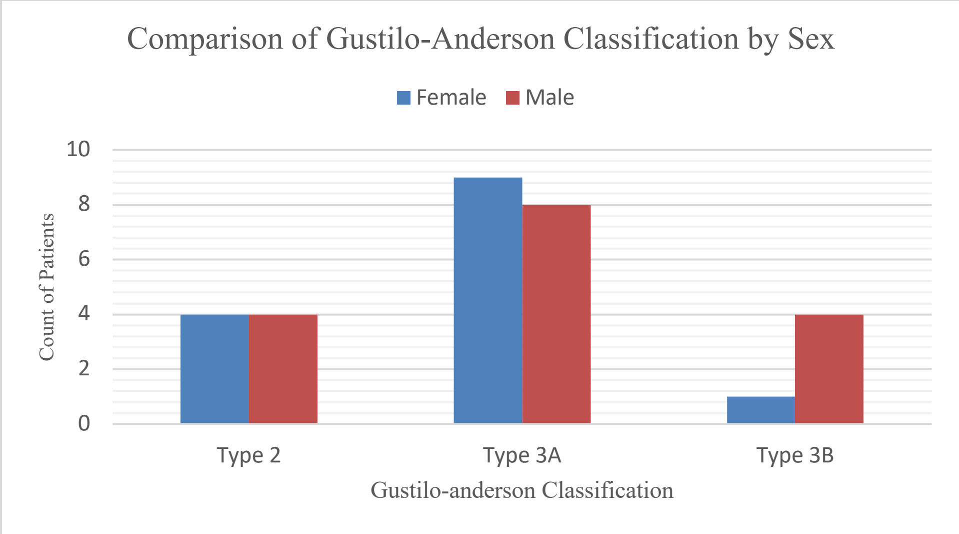

Figure 1: Classification by Sex

➢ **Table 1: Classification by Sex**

This table classifies patients based on their sex (Female/Male) and their Gustilo-Anderson classification:

- Type 2: 4 females, 4 males
- Type 3A: 9 females, 8 males
- Type 3B: 1 female, 4 males
- Statistical Test: Chi-Square Test of Independence, Chi-Square Statistic: 1.73
- p-value: 0.42

There is no statistically significant association between sex and the Gustilo Anderson classification, as the p-value (0.42) is greater than 0.05. The distribution of males and females is relatively balanced across the categories, indicating that sex does not play a significant role in determining the severity of the fractures as per this classification

Table 2: Comparison by Age

Gustilo-Anderson Type	**Count**	**Mean Age**	**Std Dev**	**Min**	**25%**	**50% (Median)**	**75%**	**Max**
Type 2	8	43	6.954879	31	39.5	43	47.5	53
Type 3A	17	44.88	11.60217	27	43	48	53	68
Type 3B	5	46.6	9.2358	36	42	43	53	59

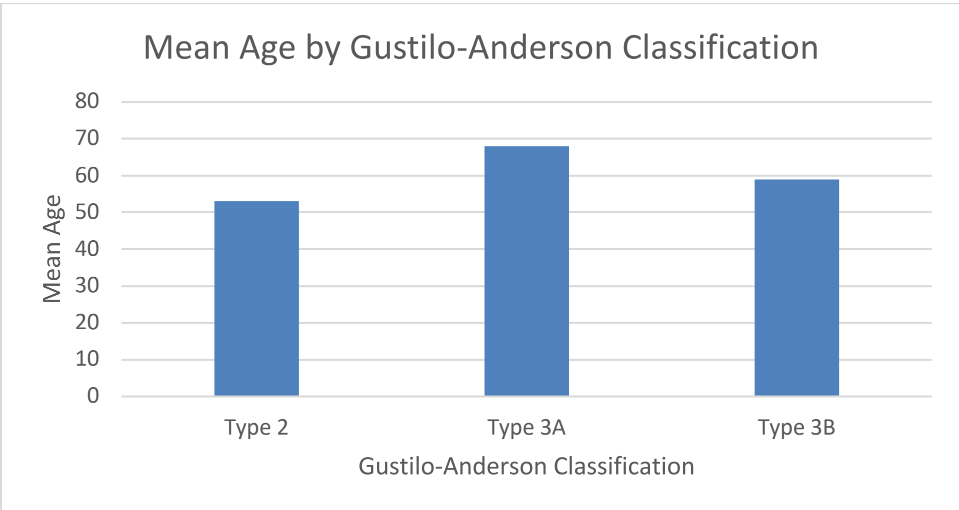

Figure 2: Comparison by Age

➢ **Table 2: Comparison by Age**

This table compares the age of patients across the Gustilo-Anderson classifications, presenting the mean, standard deviation, and range:

- Type 2: Mean age = 43 years, SD = 6.95
- Type 3A: Mean age = 44.88 years, SD = 11.60
- Type 3B: Mean age = 46.6 years, SD = 9.24
- Statistical Test: One-way ANOVA or T-Test (if comparing two groups) can be applied to the means of age for different Gustilo-Anderson classifications.
- F-Statistic: 0.18
- p-value: 0.84
- The mean age does not differ significantly across the Gustilo-Anderson classifications, as indicated by the high p-value (0.84). This suggests that age is not a determinant of the fracture severity in this study.

Table 3: Comparison by Fracture Pattern

Gustilo Anderson	Comminuted	Oblique	Segmental	Spiral	Transverse	Wedge (Spiral/Bending)	Total
Type 2	1	3	0	2	0	2	8
Type 3A	2	1	1	4	4	5	17
Type 3B	0	1	0	1	0	3	5
Total	3	5	1	7	4	10	30

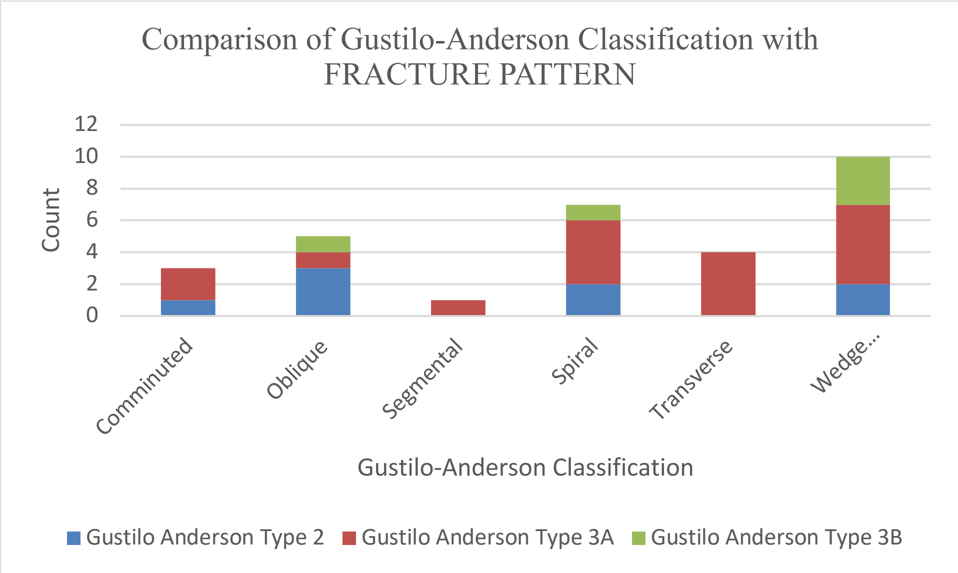

Figure 3: Comparison by Fracture Pattern

- Type 2: Most common patterns are oblique (3) and wedge (2).
- Type 3A: Fracture patterns are diverse, with wedge (5) and spiral (4) being more frequent.
- Type 3B: Patterns include wedge (3) and spiral (1).

➢ **Statistical Analysis**

- **Chi-Square Statistic:** 9.07
- **p-value:** 0.53

➢ **Interpretation**

The p-value (0.53) suggests no statistically significant association between fracture pattern and Gustilo-Anderson classification. This indicates that fracture patterns are distributed across classifications without a clear relationship.

Table 4: Time to Injury

Gustilo-Anderson Type	2 Day	4 Days	5 Days	8–24 Hours	<8 Hours	Total
Type 2	0	1	1	1	5	8
Type 3A	1	0	0	1	15	17
Type 3B	0	0	0	0	5	5
Total	1	1	1	2	25	30

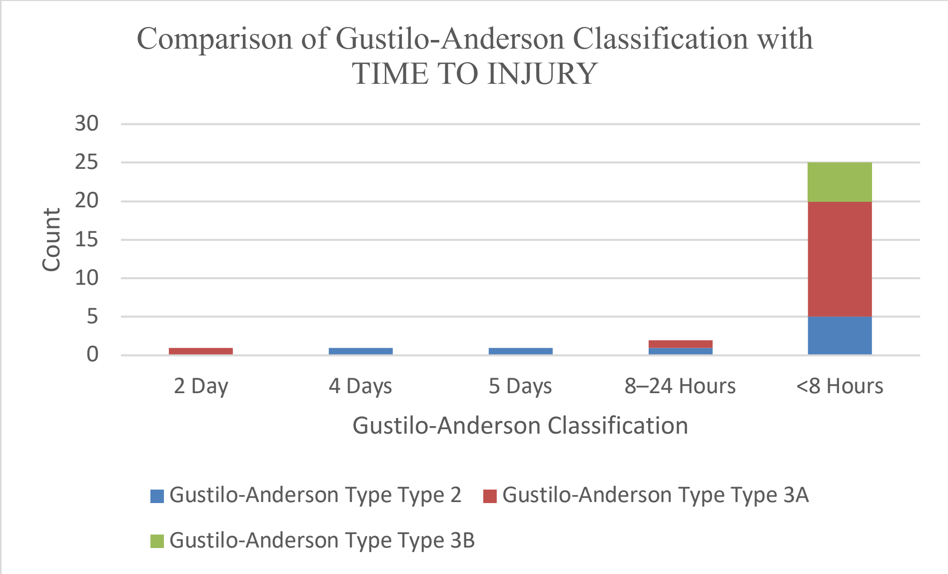

Figure 4: Time to Injury

➢ **Data Overview**

- **Type 2:** Majority of patients (5) reported injury within less than 8 hours.
- **Type 3A:** Most injuries (15) occurred within less than 8 hours.
- **Type 3B:** All injuries (5) occurred within less than 8 hours.

➢ **Statistical Analysis**

- **Chi-Square Statistic: 7.65**
- **p-value: 0.47**

➢ **Interpretation**

The p-value (0.47) indicates no statistically significant association between the time to injury and Gustilo-Anderson classification. This suggests that the severity of fractures is not influenced by the elapsed time to injury in this cohort.

Table 5: Chi Square Analysis

Variable	Chi-Square Statistic	p-value	Degrees of Freedom
Sex	1.733	0.42	2
Occupation	11.375	0.497	12
Mode of Injury	1.412	0.494	2
Side	5.931	0.052	2

From the statistical analysis:

➢ **Sex:**

- **Chi-square statistic: 1.73**
- **p-value**: 0.42

o Interpretation: There is no statistically significant association between Gustilo-Anderson classification and the sex of patients, as the p-value is greater than 0.05.

➢ **Occupation:**

- **Chi-square statistic: 11.38**
- **p-value**: 0.50
- **Interpretation**: There is no statistically significant association between

Gustilo-Anderson classification and the occupation of patients, as the p-value is greater than 0.05.

➢ **Mode of Injury:**

- **Chi-square statistic:** 1.41
- **p-value:** 0.49
- **Interpretation:** There is no statistically significant association between Gustilo-Anderson classification and mode of injury, as the p-value is greater than 0.05.

➢ **Side (Right/Left):**

- **Chi-square statistic:** 5.93
- **p-value:** 0.05
- **Interpretation**: The p-value is borderline significant. This suggests a potential association between Gustilo-Anderson classification and the side of injury, warranting further investigation.

Comparison Of Ga with Functional Out Come

Table 6: Duration B/W Trauma and Surgery			
Gustilo-Anderson Type	**1 Day**	**4 Days**	**Total**
Type 2	1	1	
Type 3A	2	0	
Total			

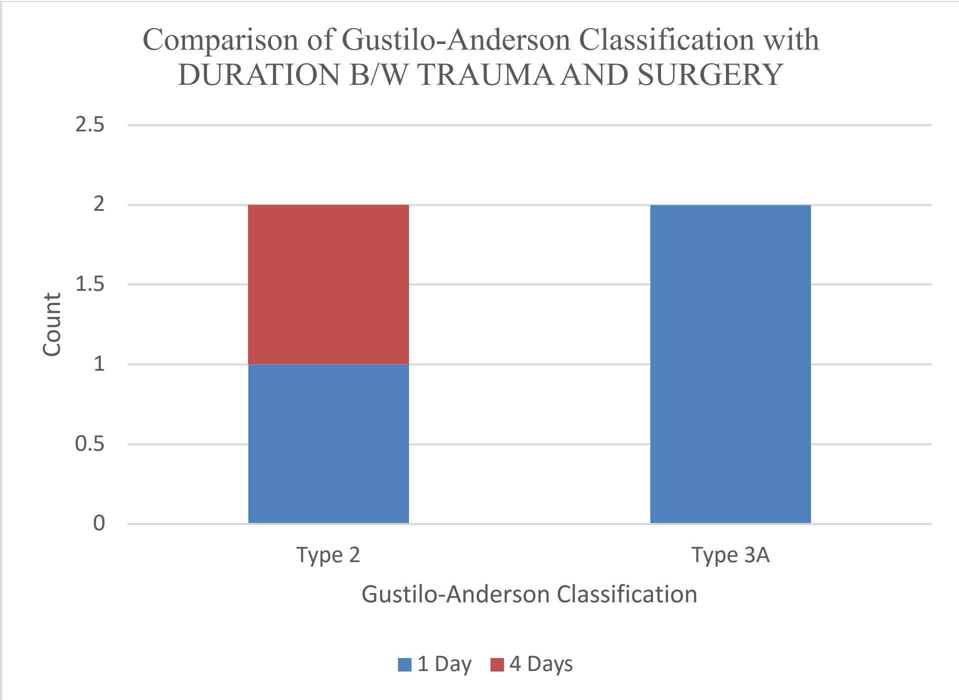

Figure 6: Duration B/W Trauma and Surgery

➢ **Statistical Analysis**

- **Type** 2: Mean = 2.5 days, SD = 2.12
- **Type** 3A: Mean = 1.0 day, SD = 0.0

➢ **T-Test:**

- **T-Statistic**: Not available due to computational limitations (insufficient variability in Type 3A group).
- **p-value:** Not available.

➢ **Interpretation**

The lack of variability in the Type 3A group (SD = 0) made statistical comparisons unreliable. However, descriptively, patients with Type 2 fractures had longer times between trauma and surgery (mean = 2.5 days) than those with Type 3A fractures (mean = 1.0 day).

Table 7: Additional Procedure					
Gustilo-Anderson Type	**Clavicle Brace**	**Closed Reduction**	**CRIF with K-Wire and POP Cast**	**ORIF with Plate**	**Total**
Type 2	1	1	0	0	2
Type 3A	0	0	1	1	2
Total	1	1	1	1	4

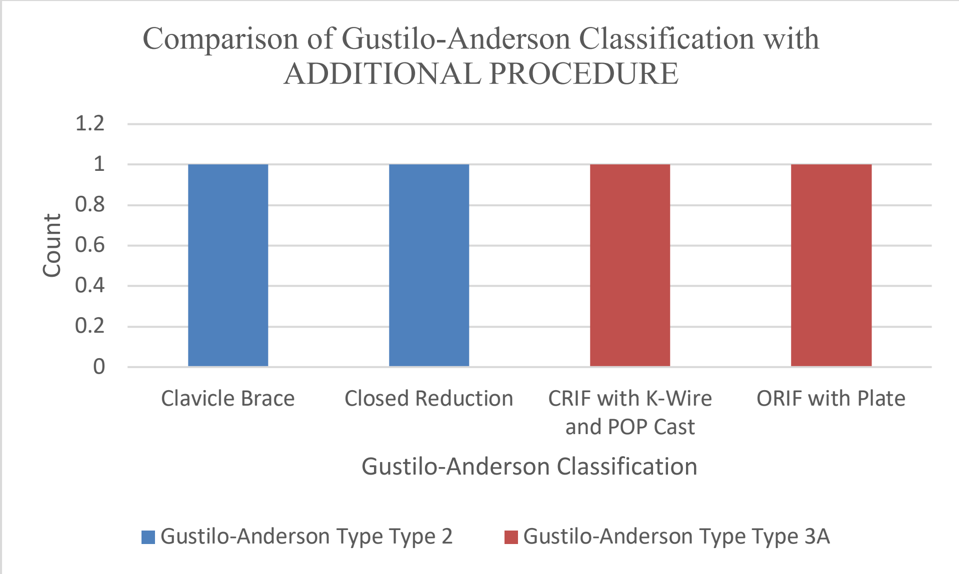

Figure 7: Additional Procedure

Statistical Analysis

- **Chi-Square Statistic:** 4.00
- **p-value:** 0.26

Interpretation

The p-value (0.26) suggests no significant association between additional procedures and Gustilo-Anderson classification. This indicates that the requirement for specific procedures is not significantly influenced by fracture severity.

Discussion

The current study was to evaluate the relationships among the outcomes and demographic factors of open tibial shaft fractures classified through the Gustilo Anderson (GA) classification system. Of the 30 subjects, the distribution of GA types were 8 for Type 2, 17 for Type 3A, and 5 for Type 3B. Gender was not significantly associated with GA classification (p = 0.42) suggesting fracture severity was not impacted by gender. This is consistent with findings from Alam et al. (2021) [12] reporting a predominance of males (73.2%) in a larger cohort study with 56 subjects and was also not significantly different with regard to fracture severity or outcomes in gender. Khan et al. (2021)[13] showed results of their studies that open tibial fractures were more common in males (81.7%), however, gender was not a significant factor with regard to fracture healing or infection rates.

The distribution of age in our study indicated a mean age of 43 years, 44.88 years, and 46.6 years for Type 2, 3A, and 3B fractures, respectively, which were all not statistically different (p = 0.84). The results are in agreement with those reported by Khan et al. (2021), in which the mean age of the patients was 32.8 ± 8.9 years and found no significant association between age and fracture severity. Conversely, the larger multicenter SPRINT trial (Bhandari et al., 2008) [14], involving 1,226 patients, found an average age of 39.5 years and again fracture severity and outcomes showed no significant dependence on age.

Regarding fracture pattern, our study observed oblique and wedge types as common in Type 2 fractures, wedge and spiral in Type 3A, and wedge predominance in Type 3B. No significant association with GA classification was found (p = 0.53). This heterogeneity in fracture morphology is supported by Khan et al. (2021), where transverse (28.3%), oblique (36.7%), spiral (13.3%), and comminuted (21.7%) patterns were documented without clear correlation to GA severity. Similarly, Alam et al. (2021) found that most fractures were AO Type A (83.9%), regardless of demographic or injury-related variables.

In terms of time to presentation, our study found that the majority of patients presented within 8 hours across all GA types, with no significant difference (p = 0.47). Khan et al. (2021) also emphasized that early intervention (within 12 hours) was common in their series and was associated with favorable union rates of 83.3%. The SPRINT trial (Bhandari et al., 2008) confirmed that early standardized perioperative care, particularly prompt debridement and antibiotic administration, was critical for minimizing complications, although fracture severity itself was not dependent on presentation time.

Functional outcomes in our study showed earlier surgery for more severe fractures (Type 3A: mean 1 day) compared to less severe ones (Type 2: mean 2.5 days). Although not statistically analyzed due to sample size, this trend reflects clinical prioritization of severe fractures. Similar results were reported by Alam et al. (2021), where all fractures were managed surgically within 7 days of injury, with excellent outcomes in 48.2% and good outcomes in 25% of cases according to Johner and Wruh's criteria.

Our study found no significant association between GA classification and additional procedures (p = 0.26). This is consistent with Khan et al. (2021), who reported low rates of reoperation, with delayed union in 15% and non-union in only 1.7% of cases. By contrast, the SPRINT trial highlighted higher reoperation rates in unreamed nailing compared to reamed, particularly in closed fractures (17% vs. 11%; p = 0.03), though no difference was found for open fractures. These findings suggest that while fracture severity may not directly dictate the need for additional procedures, surgical technique (reamed vs. unreamed) may influence long-term outcomes in certain subgroups.

Infection control also varied across studies. While our study did not specifically evaluate infection rates, Khan et al. (2021) documented infections in 13.3% of patients undergoing unreamed nailing, whereas Alam et al. (2021) reported fewer complications overall, with only 5% poor outcomes. The SPRINT trial corroborated that infection rates were comparable between reamed and unreamed groups for open fractures, reinforcing that fracture management strategy rather than GA severity influences this outcome.

Our findings resonate with the broader literature in demonstrating that demographic variables such as sex and age, as well as fracture morphology and time to injury, are not strongly predictive of GA severity or outcomes. Functional outcomes and complication risks appear more influenced by surgical decision-making and perioperative care. The consistent observation across studies that individualized management outweighs demographic predictors underscores the need for tailored treatment protocols in open tibial shaft fractures.

Conclusion

The present study demonstrated that unreamed interlocking intramedullary nailing provides a reliable method for the management of open tibial shaft fractures across varying Gustilo-Anderson types. Demographic factors such as age, sex, and occupation showed no significant association with fracture severity, indicating that these variables do not strongly influence outcomes. Similarly, fracture patterns and time to injury did not correlate significantly with classification, highlighting the heterogeneity of these injuries. Functional outcomes reflected timely surgical intervention, with more severe fractures often prioritized for earlier management. Additional procedures were not significantly associated with fracture type, suggesting that clinical judgment plays a greater role than severity alone. Overall, the findings support unreamed interlocking nailing as a safe and effective option, reinforcing its role in optimizing stability, minimizing complications, and promoting favorable recovery in open tibial fractures.

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