ORIGINAL RESEARCH

# Managing Pin Tracts in Open Tibial Fractures: The Role of Medical Waste Rubber Bung

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**Objective:** This study aims to assess the effect of using medical waste rubber bung (MWRB) for pin-tract management in patients with open tibial fractures treated with external fixators (EFs).

**Methods:** A retrospective analysis of 91 patients with open tibial fractures admitted to our hospital over a three-year period was conducted to compare and statistically characterize overall PTI incidence, PTI rate across five different pin-tract locations, time (days) to the first occurrence of infection, and Checketts-Otterburn classification.

**Results:** Among the enrolled 91 patients, 88 met the criteria. After excluding deaths and losses to follow-up, they were divided into two study groups, with no significant difference in overall PTI incidence. Group A exhibited a significantly lower rate of severe infection and prolonged time to initial infection compared to Group B (both P < 0.05). Group A also had a significantly lower rate of PTI at the tibial telangiectasia than Group B.

**Conclusion:** The study underscores that compression in EF management is necessary to significantly reduce the incidence of severe PTIs, especially in the tibial metaphysis, and to delay the onset of initial infection among patients with open tibial fractures. **Keywords:** compression, external fixator, medical waste rubber bung, open tibial fracture, pin site infection, pin-tract infection

#### Introduction

An open tibial fracture represents a type of fracture where the fractured bone directly communicates with the external environment through a skin wound. These fractures are clinically prevalent due to the tibia's limited soft tissue coverage, which is a key factor predisposing to such injuries.<sup>1</sup> External fixator (EF) remains a routine option for initial stabilization of these fractures, especially in Gustilo type III open fractures with severe soft tissue injury, edema, or blisters. Depending on soft tissue condition and fracture type, external fixation can be either temporary (two-stage treatment) or terminal (single-stage treatment). Axial EFs (eg, hybrid fixators) offer biomechanical advantages through dynamic compression via the elastic Kirshner needle, enabling early partial weight-bearing and improved tolerance in proximal tibial applications compared to traditional circular fixators. For complex intra-articular fractures (AO type 43-C), delayed conversion to internal fixation may be pursued when soft tissue conditions permit. Options include open reduction internal fixation (ORIF) for anatomically reconstructing articular surfaces in low-energy closed fractures or high-energy fractures with good soft tissue condition (AO type 43-B/C), albeit with infection risks from extensive dissection, minimally invasive plate osteosynthesis (MIPO)<sup>2</sup> for indirect reduction in compromised soft tissue scenarios with minor fracture displacement (eg, AO type 43-B1/C1), though the precision of articular surface reduction may be limited, and intramedullary nailing (primarily for mid-shaft tibial fractures) with limited articular fixation capacity.<sup>3</sup> A study has shown that the rate of serious complications was significantly higher in the external fixation group (EF) than in the internal fixation group (ORIF/MIPO), emphasizing the critical importance of biomechanical optimization to reduce risks when employing external fixation systems.<sup>4</sup>

1455

While EF use reduces infection risks compared to internal fixation techniques and facilitates wound management, it introduces the critical challenge of pin-tract infection (PTI). Reported rates of PTI associated with EFs vary widely, ranging from 3% to over 80%.<sup>5</sup> PTI can lead to increased pain, pin loosening, delayed patient mobilization, and severe complications such as osteomyelitis and septicemia, which impede rehabilitation and escalate healthcare costs.<sup>6</sup> A variety of techniques and approaches have been proposed to mitigate the occurrence of PTI, focusing on pin design optimization, refinement of surgical techniques, and enhancement of pin-tract care protocols.<sup>7,8</sup>

The design of pins emphasizes the selection of materials and the application of specialized coatings. To date, a variety of pin materials and coatings have been engineered for implant use, encompassing titanium, copper, silver, hydroxyapatite, nitric oxide, chlorhexidine, iodine, and antibiotic formulations. While these engineered materials and coatings are attractive due to their antibacterial properties and efficacy, existing evidence is insufficient to conclusively show their effectiveness in lowering infection rates associated with EF pins.<sup>8,9</sup> Adhering to proper surgical techniques is crucial for preventing PTI and relevant complications. Evidence-based intraoperative precautions, including minimalistic skin incisions minimally exceeding pin diameter, drill sleeve utilization for soft tissue preservation, controlled drilling parameters to prevent thermal osteonecrosis, and thoughtful pin placement, are systematically recognized as effective strategies for mitigating PTI.<sup>10–13</sup> Numerous protocols for postoperative pin-tract care have been proposed and exhibit substantial institutional variability, including use of specific cleaning solutions, frequency of cleansing, application of dressings, pin-tract massage, allowances for showering and bathing, crust management, and compression techniques. However, a unified standard for optimal pin-tract care has yet to be established.<sup>7,14</sup>

Despite the absence of advanced pin materials and specialized coatings at our hospital, we adhere to stringent insertion techniques and principles for EF application, and maintain a rigorous pin-tract care regimen, as outlined by Bible & Mir.<sup>2</sup> Nonetheless, the occurrence of PTI remains prevalent, leading to heightened patient anxiety, depression, and overall distress. This necessitates exploration of alternative interventions to combat PTI within resource-constrained settings. We propose a novel application of medical waste rubber bungs (MWRBs), sterilized and high-durability elastomers originally designed for medical safety and environmental protection, as convenient, cost-effective, and accessible devices for pin-tract management, which is particularly well-suited to our context. Engineered with high-strength, corrosion-resistant needle materials and coating technology to improve sealing performance and reduce friction, MWRBs combine mechanical stability and durability with sustainable design principles. This study investigates their efficacy in PTI prevention through controlled circumferential compression, hypothesizing that this intervention reduces infection severity and delays onset compared to standard care.

# **Materials and Methods**

#### Study Design and Patient Enrollment

Between January 2019 and December 2022, a total of 91 patients presenting with open tibial fractures were admitted to our hospital, where they received treatment utilizing EFs. A retrospective analysis was conducted to compare the outcomes between patients undergoing pin-tract compression using MWRB and those receiving standard fixation without MWRB. All PTIs were meticulously monitored, and a comprehensive evaluation of the clinical efficacy and technical feasibility of MWRB application was performed. Ethical approval was granted by the Ethics Committee of Changde Hospital, Xiangya School of Medicine, Central South University (The First People's Hospital of Changde City) (Approval No. 2024–285-01), with written informed consent secured from all participants involved in the study.

# Inclusion and Exclusion Criteria

The inclusion criteria were defined to include patients with open tibial fractures requiring the application of EFs. The exclusion criteria were specified as follows: (1) Patients previously identified with infections necessitating extended antibiotic therapy. (2) Patients presenting with immune dysfunction. (3) Patients with immune system disorders requiring long-term administration of immunosuppressants or hormonal treatments.



Figure I The MWRB. (a) Longitudinal plane. (b) Transverse plane.

#### Surgical Procedures and Principles of EF Application

For patients admitted with open tibial fractures, emergency surgical interventions using EFs were performed in strict accordance with the established principles of EF application, as referenced by Bible & Mir.<sup>2</sup> The specific surgical procedures included: (1) Piercing the skin at a diameter equivalent to that of the pin. (2) Inserting the pin to a precisely determined location. (3) Puncturing the MWRB (Figure 1). (4) Advancing the MWRB onto the pin and securing it at the designated level on the connecting rod. (5) Mounting the connecting rods applying clamps. (6) Tending to the pin tract and encircling the pin with sterile pre-cut gauze segments. (7) Lowering the rubber bung to apply mild compression and securing it with sterile gauze (Figure 2). The pins, crafted from stainless steel, were supplied by Shanghai EK Medical Equipment Co., Ltd. The MWRB used in the study is typically made of disposable latex or synthetic materials (such as silicone) that meet medical waste management practices and have tensile strength and biocompatibility. Reasons for choosing these disposable materials are as follows: Single-use can eliminate cross-contamination, especially in cases of open fractures (Gustilo II–III) or soft tissue injury, and can effectively reduce the risk of PTIs and wound complications. Inherent flexibility permits dynamic wound dressing, allowing surgeons to modulate compression forces during temporary external fixation and subsequent dressing. Furthermore, these medical-grade constructs are in line with the classification standards of medical waste, enabling unified postoperative management.

#### **Postoperative Management**

An iodine complex solution was irrigated for pin-tract nursing, followed by coverage with sterile dry gauze. Pin-tract cleansing was scheduled on a weekly basis for stable bone-pin interfaces, with a frequency increase to daily when encountering significant drainage or upon suspicion of infection. Gauze dressings were replaced promptly upon saturation. In cases of infection, crusts were meticulously removed to promote unobstructed drainage; however, if no infection was present, they were preserved. Systemic antibiotic therapy was initiated for all instances of open tibial fractures, with discontinuation occurring 48 hours post-wound closure.<sup>15</sup> PTI management adhered to the established Checketts-Otterburn classification system<sup>8</sup> (Table 1).

#### Observation Items and Methods

The general information of the patients was recorded, encompassing demographics and clinical parameters such as gender, age, underlying diseases, smoking history, time elapsed from injury to the completion of emergency surgery



Figure 2 The operational procedures of using MWRB are demonstrated by these pictures right here. (a) Piercing the skin at a diameter equivalent to that of the pin. (b) Inserting the pin to a precisely determined location. (c) Puncturing the MWRB. (d) Advancing the MWRB onto the pin and securing it at the designated level on the connecting rod. (e) Mounting the connecting rods applying clamps. (f and g) Tending to the pin tract and encircling the pin with sterile pre-cut gauze segments. (h) Lowering the rubber bung to apply mild compression and securing it with sterile gauze.

(hours), Gustilo-Anderson classification,<sup>16</sup> pin-tract locations, intraoperative tourniquet use, and follow-up duration (days). Comparative analysis was performed on overall PTI incidence, PTI rate across five different pin-tract locations, time to the first occurrence of infection (days), and Checketts-Otterburn classification.<sup>8</sup> Pin tracts were monitored throughout in-hospital care and subsequent post-discharge follow-ups were conducted via outpatient visits, telephonic consultations, and WeChat-based digital messaging. To ensure diagnostic objectivity, all PTI determinations were ascertained by an independent, unbiased observer following the established clinical criteria.

#### Statistical Analysis

Statistical analyses were performed utilizing SPSS version 21.0 for Windows. Numerical data were presented as mean  $\pm$  standard deviation (SD) or median with interquartile ranges, with analyses conducted using the Student's *t*-test for parametric distributions or the rank sum test for non-parametric distributions. Categorical variables were assessed using the Chi-square test. Statistical significance was set at the threshold of P < 0.05.

 Table I Checketts-Otterburn Grading System for the Level of Pin-Tract Infection

Grade	Appearance	Treatment
	Minor infection	
I	Slight redness, little discharge	Improved pin-tract care
2	Redness of the skin, discharge, pain and tenderness in the soft tissue	Improved pin-tract care, oral antibiotics
3	Grade 2 but not improved with antibiotics	Affected pin or pins resisted and external fixation continued
	Major infection	
4	Severe soft tissue infection involving several pins, sometimes with associated loosening of the pin	External fixation must be abandoned
5	Grade 4 but also involvement of the bone; also visible in radiographs External fixation must be abandoned	External fixation must be abandoned
6	The infection occurs after fixation removal. The pin track heals initially but will break down and discharge at intervals Radiograph shows new bone formation and sometimes sequestrum	Curettage of the pin track

#### Results

During the study period (January 2019-December 2022), 91 cases of open tibial fractures managed with EFs were initially enrolled, with 88 patients fulfilling the inclusion criteria. Patients were categorized into two cohorts: Group A, comprising 46 patients who received MWRB for pin-tract compression, and Group B, consisting of 42 patients who underwent standard care without MWRB. In Group A, follow-up data for one patient were unobtainable. For Group B, follow-up was not possible for one patient, and two patients expired (Figure 3).



Figure 3 Distribution of study subjects from enrollment to the end of the study.

The baseline characteristics of the patients are presented in Tables 2 and 3. No statistically significant disparities were observed between the groups in gender, age, underlying diseases, smoking history, time elapsed from injury to the completion of emergency surgery (hours), Gustilo-Anderson classification, pin-tract locations, intraoperative tourniquet use, or follow-up duration (days).

Upon completion of the follow-up period, 14 cases of PTI were observed in Group A, compared to 20 cases in Group B. No statistically significant difference was noted between the two groups. The overall PTI incidence was 31.1% for Group A and 51.3% for Group B. According to the Checketts-Otterburn classification, Group A comprised eight Grade 1, three Grade 2, one Grade 3, and two Grade 4 cases. Group B included three Grade 1, seven Grade 2, two Grade 3, six Grade 4, and two Grade 5 cases. Specifically, Group A had 12 minor infection cases (Grades 1 to 3) and two major infection cases (Grades 4 to 6), whereas Group B had 12 minor and eight major infection cases (Figure 4). The rate of major infections was 4.4% for Group A and 20.5% for Group B. A statistically significant difference in the prevalence of major infections was observed between the two groups (P = 0.023 < 0.05). The time to the first occurrence of infection was significantly longer in Group A compared to Group B, with a statistically significant difference between the groups (P = 0.001 < 0.05, Table 4). Table 5 presents a comparison of infections across five distinct pin-tract locations between the two groups. It was observed that Group A had a lower rate of PTIs at the tibial metaphysis compared to Group B, and the difference was statistically significant (P = 0.01 < 0.05).

Group	Cases	Ge	ender	Age (years)	Unde	rlying Disea	se	Smoking History		Time Elapsed from Injury to the	Gustilo-Anderson Classification				
		Male	Female		High Blood Pressure	Diabetes	Gout	Yes	No	Completion of Emergency Surgery (hours)	I	II	IIIA	IIIB	IIIC
A B	45 39	28 25	17 14	51.0±11.4 53.4±10.3	5 3	3 2	I I	12 16	33 23	9.29±2.49 9.15±2.67	2 3	 9	16 13	9 9	7 5
Test value		χ²=	=0.032	t=-0.991		χ <sup>2</sup> =0.104		χ <sup>2</sup> =1.938		t=0.240		χ <sup>2</sup> =0.054			
P value		0	.859	0.325		0.949		0.164		0.811		0.816			

Table 2 Comparison of the General Data of Patients with Open Tibial Fractures Between the Two Groups

**Table 3** Comparison of the General Data of Patients with Open Tibial Fractures Between the Two Groups for Pin-Tract Location andPostoperative Tourniquet Use

Group		Pin-Tract Location					erative niquet se	Follow-Up Duration (days)
	Femoral Metaphysis	Tibial Metaphysis	The Medial Surface of the Tibial Shaft	The Lateral Surface of the Tibial sHaft	Calcaneus	Yes	No	
A B	18	63 57	50 46	18	36 32	11	34 25	P25=14, P50=265, P75=407 P25=14, P50=273, P75=405
Test value	χ <sup>2</sup> =0.212						.311	Z=-0.448
P value	0.995						252	0.654



Figure 4 Representative images of pin-tract infection in our cases. a-c Minor infection. (a) Grade 1: Slight redness, little discharge. (b) Grade 2: Redness of the skin, discharge, pain and tenderness in the soft tissue. (c) Grade 3: Grade 2 but not improved with antibiotics. (d and e) Major infection. (d) Grade 4: Severe soft tissue infection involving several pins, sometimes with associated loosening of the pin. (e) Grade 5: Grade 4 but also involvement of the bone; also visible in radiographs. External fixation must be abandoned.

# Discussion

EFs are an essential orthopedic tool in the management of open tibial fractures, yet their prolonged application is associated with significant morbidity, particularly regarding device-related complications.<sup>17</sup> PTI emerges as the most frequently encountered complication, with its clinical significance extending beyond transient patient pain and discomfort to potentially severe sequelae such as osteomyelitis if the soft tissue condition is poor or the fixation time is prolonged.<sup>18</sup> In addition to PTI, other complications include nonunion (7.44%), loss of reduction (3.19%), and soft tissue necrosis (as high as 30% in Gustilo Type III open fractures). Orthopedic clinicians continue to grapple with this unresolved challenge

Group	Cases	<b>Overall Incidence of</b>	Time to the First	Checketts-Otterburn Classification							
		Pin-Tract Infections	Occurrence of Infection (days)	Mi	Minor Infection		Major Infection				
				Grade I	Grade 2	Grade 3	Grade 4	Grade 5	Grade 6		
A B	45 39	14 20	120.5±61.77 52.15±30.16	8 3	3 7	1 2	2 6	0 2	0 0		
Test value		χ <sup>2</sup> =3.528	t=3.833	$\chi^2$ =4.776, $\chi^2$ =0.172, $\chi^2$ =5.144, $\chi^2$ =1.230							
P value		0.06	0.001	0.029, 0.678, 0.023, 0.267							

Table 4 Comparison of the Follow-Up Results Between the Two Groups

Group	Number	Incidence of Pin-Tract Infections					
Femoral metaphysis							
A	18	6					
В	14	8					
Test value							
P value	0.283						
Tibial metaphysis							
A	63	12					
В	57	23					
Test value	χ <sup>2</sup> =6.574						
P value	0.01						
The medial surface of the tibial shaft							
A	50	4					
В	46	6					
Test value	χ <sup>2</sup> =0.224						
P value	0.636						
The lateral surface of the tibia	l shaft						
A	18	5					
В	15	7					
Test value							
P value	0.300						
Calcaneus							
A	36	4					
В	32	9					
Test value	χ <sup>2</sup> =3.171						
P value	0.075						

 Table 5
 Comparison of the Infections Across Five Different Pin-Tract Locations Between the Two Groups

and face controversies regarding optimal prevention strategies, despite extensive scholarly attention focused on the design of pins, surgical techniques, and postoperative pin-tract care.<sup>8</sup> While no consensus has been reached, numerous valuable suggestions have been proposed that hold promise for PTI mitigation in our field. Yet, integrating these novel devices from the literature into our clinical practice remains elusive. Consequently, we have been compelled to devise our own preventative approach for PTI integrating biomechanical stability assessments with microbiologically-informed wound care strategies. The present study systematically evaluates and confirms the clinical efficacy and practicality of our proposed method, aiming to contribute novel insights into this critically important yet understandardized area.

Our research introduces an uncomplicated and accessible method for pin-tract compression using MWRB, building upon established pin-tract care protocols and consensus statements for the utilization of compression-based management. These viewpoints emphasize the critical role of controlled mechanical compression in mitigating PTI, a complication arising from excessive skin movement surrounding the pin, creating a "tenting" effect, fluid buildup at the bone-tissue junction, and subsequent bacterial colonization. Concurrently, modest compression around the pin-tract aids in preventing tenting, excessive skin-pin interface micromotion, and hematoma formation.<sup>7</sup> Paley<sup>19</sup> employed a surgical scrub sponge at the pin-tract to prevent PTI, and concluded that the surgical scrub sponge offered an efficacious compression approach, reducing the incidence of PTI. Dayton et al<sup>20</sup> presented a case report, introducing a pin-tract compression technique employing a cord lock to preempt potential complications. Davies et al<sup>21</sup> conducted a comparison between two

protocols regarding the operative techniques and pin-tract care for EFs, revealing that the PTI rate was lower in Group B, utilizing occlusive pressure dressings, as opposed to Group A, which followed local standard pin-tract care practices. While our study shares similarities with that of Davies, it presents additional evidence and novel findings. Our results extend these observations by demonstrating that Group A not only exhibited a statistically reduced rate of major PTIs (P = 0.023), but also experienced a prolonged interval until the first infection event (P = 0.001). The findings indicate that employing MWRB for pin-tract compression significantly reduces the incidence of major infections and delays the onset of PTI. Utilizing MWRB for compression ensures that the gauze is firmly positioned at the skin-pin interface. Firstly, this method protects and isolates the skin-pin interface from the external environment. Secondly, the gauze's absorbency facilitates the removal of seepage around the skin-pin interface, preventing hematoma formation. Notably, seepage at the skin-pin interface provides a nutrient-rich medium conducive to bacterial proliferation, as highlighted by Clasper et al.<sup>22</sup> Thirdly, the application of mild compression reduces skin-pin motion and tension, thereby stabilizing the interface, alleviating pin-tract mechanical irritation, and decreasing PTI incidence.

Additionally, this study scrutinized PTI incidence in relation to different pin placements for open tibial fractures. A statistically significant difference in PTI rates between Group A (19.0%) and Group B (40.4%) was observed in the metaphyseal region of the tibia, with a *P*-value of 0.01, revealing a critical spatial determinant of PTI risk. The tibial metaphysis's inherent vulnerability stems from its cancellous bone composition, which offers reduced pullout resistance against the pin, leading to less stable skin-pin interfaces and a heightened susceptibility to PTI. The application of targeted compression counteracts this biomechanical disadvantage by enhancing the stability around the skin-pin interface and mitigating sliding, thus reducing PTI incidence. Consequently, careful consideration must be given to the pin's location and placement. It is advisable to avoid pin insertion into the tibial metaphysis whenever feasible, given its increased infection risk compared to alternative placements. Furthermore, the observed spatial susceptibility highlights an urgent need for biomechanically optimized fixation hardware, specifically calling for innovations in pin design that enhance cortical bone engagement and rotational stability. This geographical analysis not only informs immediate surgical decision-making, but also establishes a framework for future research into topography-specific infection prevention strategies.

# Limitations

Our study encounters several inherent limitations. Firstly, the constraints of our study's retrospective cohort design cannot be overlooked. Secondly, the limited sample size, particularly regarding the femoral metaphysis, tibial shaft, and calcaneus regions, raises concerns about the precision of our findings. Thirdly, variations in follow-up duration are observed, notably among patients with pin insertion into the femoral metaphysis who typically undergo temporary fixations followed by early removal, resulting in abbreviated follow-up periods. Lastly, the determination of the time to initial infection onset is heavily reliant on patient-reported descriptions, which, in some instances, lack the requisite specificity.

# Conclusion

The study underscores the necessity of pin-tract compression in the management of EFs for open tibial fractures. Implementing MWRB for this purpose is a cost-effective, accessible, and efficacious strategy that significantly diminishes the prevalence of severe PTI, particularly in the tibial metaphysis, and postpones the onset of initial infection. In the future, integration with biomechanical optimization of pin design (such as enhancing metaphyseal anti-withdrawal force) and smart dressings (real-time monitoring of infection) could revolutionize external fixation care, and multi-center studies are also needed to validate the efficacy of these hybrid strategies.

# **Abbreviations**

PTI, Pin-tract infection; MWRB, Medical waste rubber bung; EF, External fixator; ORIF, Open reduction internal fixation; MIPO, Minimally invasive plate osteosynthesis; SD, standard deviation.

# **Data Sharing Statement**

All data generated or analyzed during this study are included in this published article.

# **Ethics Approval and Consent to Participate**

This study protocol was complied with the Declaration of Helsinki and approved by the ethics board of Changde Hospital, Xiangya School of Medicine, Central South University (The first people's hospital of Changde city) (No. 2024-285-01) and written informed consent was secured from each participant involved in the study.

# **Author Contribution**

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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# Disclosure

The authors declare no competing interests in this work.

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