Heliyon 10 (2024) e33589

Contents lists available at ScienceDirect

Heliyon

journal homepage: www.cell.com/heliyon

Research article

Comparing clinical outcomes of patients with severe lower limb trauma undergoing orthoplastic and orthopedic surgeries: A long-term study protocol

Zhao Yang [a,1], Chao Xu [b,c,1], Yonggang Zhu [d,1], Yanchen Tan [e], Hao Hu [e], Peng Fang [f], Di Cui [f], Guangyue Zhao [d,*], Danmin Miao [f,**], Lei Shang [c,***]

[a] *Air Force Health Service Training Base, Air Force Military Medical University, No. 169 Changle Xi Road, Xi'an, Shaanxi, 710032, PR China*
[b] *Department of Knee Joint Surgery, Honghui Hospital, Xi'an Jiaotong University, Xi'an, Shaanxi, 710054, PR China*
[c] *Department of Health Statistics,Faculty of Preventive Medicine, Air Force Military Medical University, No. 169 Changle Xi Road, Xi'an, Shaanxi, 710032, PR China*
[d] *Department of Orthopeadic Surgery, Xi'an People's Hospital, No.155 Hangtian Dong Road, Xi'an, Shaanxi, 710199, PR China*
[e] *Student Brigade of Basic Medical College, Air Force Military Medical University, No. 169 Changle Xi Road, Xi'an, Shaanxi, 710032, PR China*
[f] *Department of Military Medical Psychology, Air Force Military Medical University, No. 169 Changle Xi Road, Xi'an, Shaanxim, 710032, PR China*

A R T I C L E I N F O

Keywords:
Orthoplastic surgery
Severe lower limb injury
Orthopedics
Physical and psychological status

A B S T R A C T

This long-term study protocol aims to compare the clinical outcomes of patients with severe lower limb trauma undergoing orthoplastic and orthopedic surgeries, focusing on their physical and psychological status. Patients with lower limb injuries and open fractures have been recruited since October 2019 and will be followed up until October 2024. The patients will be divided into two groups: (1) Orthoplastic group, where single-stage debridement, fixation, and soft tissue repair will be performed, and (2) Orthopedic group, where soft tissue repair will be done in a delayed-stage. The follow-up period will be one year, during which clinical data, limb function recovery, psychological scores, and health-related quality of life (HRQOL) will be evaluated to assess postoperative recovery and clinical outcomes. Additional clinical data, such as socio-demographic information, baseline features, Enneking score, Visual Analogue Scale (VAS) score, two-point discrimination score, and blood test parameters will also be collected. The 36-Item Short Form Health Survey (SF-36) will be used to evaluate HRQOL, while the Post-traumatic Stress Disorder Checklist (PCL) will assess the severity of self-reported post-traumatic stress disorder. The results of this study will provide valuable insights into prognostically relevant targets and contribute to improving the management and outcomes of patients with lower limb injuries and open fractures, who often face challenges related to limb disability and potential amputation postoperatively, significantly impacting their psychological and physical well-being.

* Corresponding author. Department of Orthopeadic Surgery, Xi'an People's Hospital. No.155 Hangtian Dong Road, Xi'an, Shaanxi province, 710199, PR China.
** Corresponding author. Department of Military Medical Psychology, Air Force Military Medical University, No. 169 Changle Xi Road, Xi'an, Shaanxi province, 710032, PR China.
*** Corresponding author.
E-mail addresses: zhaogyue@163.com (G. Zhao), miaodanmin@126.com (D. Miao), shanglei@fmmu.edu.cn (L. Shang).
[1] These authors contributed equally to this work.

https://doi.org/10.1016/j.heliyon.2024.e33589
Received 20 December 2022; Received in revised form 12 June 2024; Accepted 24 June 2024
Available online 24 June 2024

1. Introduction

Severe traumatic injuries resulting in significant soft tissue defects and vascular impairment pose formidable challenges for reconstructive surgeons. An open fracture, characterized by a bony fracture accompanied by a soft tissue wound that is exposed to the external environment, is widely acknowledged as a hazardous scenario with potential complications such as deep infection, chronic osteomyelitis, nonunion, and the risk of limb loss or fatality [1]. Among long bone fractures, fractures of the tibia are the most commonly encountered. One of the largest scale epidemiological studies in the Royal Infirmary of Edinburgh reviewing 2386 open fractures reported that tibial were one of the commonest types in adults [2,3]. Open fractures involving extensive soft tissue defects can pose a significant threat to an individual's life [4,5]. Although numerous therapeutic approaches and management standards have been proposed for lower limb open fractures [6–8], preserving limb function has emerged as a paramount focus for surgeons [9]. Furthermore, patients who have suffered severe lower limb injuries often experience profound psychological distress, with prevalence rates ranging from 42 % to 48 % [10].

During World Wars I and II, physicians observed improved outcomes by combining antibiotics, wound debridement, early bone stabilization, and soft tissue healing for severe injuries. The use of external fixators in definitive management is no longer the primary approach [11]. A study comparing open tibial fractures found no difference in nonunion and infection rates between external and internal fixation methods. However, this widely accepted treatment method significantly prolongs operative time and increases expenses. Additionally, delays in debridement and inadequate initial treatment have been frequently reported [12]. These limitations result in unpredictable limb function outcomes and contribute to significant psychological distress [11,13].

Gustilo and Anderson classified open fractures into types I, II and III in 1976, and further refined type III into three subtypes(IIIA, IIIB and IIIC) in 1984 according to the soft tissue defect, degree of contamination and state of blood flow. As severe open fractures (referred to as Gustilo IIIb or IIIc injuries) often lead to large soft tissue defects and high risk of infection, various methods and standards have been used for the salvage treatment, however, it is still a huge challenge for reconstructive surgeons as the essence of traditional orthopedic surgery is repeated debridement, simple external bone fixation and negative pressure aspiration of soft tissue defect [5,7]. Recently, the British Association of Plastic, Reconstructive, and Aesthetic Surgeons (BAPRAS) and the British Orthopaedic Association (BOA) have been collaborating to enhance the care of patients with severe open fractures of the lower limb [8]. The importance of promptly addressing soft tissue cover, particularly in grade III injuries, was highlighted by Godina in 1986 [6]. Studies have shown that orthoplastic surgery offers several advantages over orthopedic surgery, including reduced flap failure, lower infection rates, and faster bone healing and hospital stays [6,12]. Consequently, orthoplastic surgery has the potential to achieve better clinical outcomes compared to orthopedics as benefited from the joint care by orthopedic trauma surgeons and plastic surgeons with experience in limb reconstruction [14]. Moreover, the management of severe open fractures has significantly improved, such as advancements in wound care, tissue engineering, and evidence-based treatment strategies, internal fixation techniques have gradually been employed in grade-IIIB injuries [15,16]. This surgical approach holds the potential to facilitate the functional recovery of limbs in patients with severe lower limb trauma.

In summary, the collaboration between BAPRAS and BOA, along with the adoption of orthoplastic surgery techniques, aims to enhance patient outcomes, promote better limb functionality, and optimize the management of severe open fractures of the lower limb.

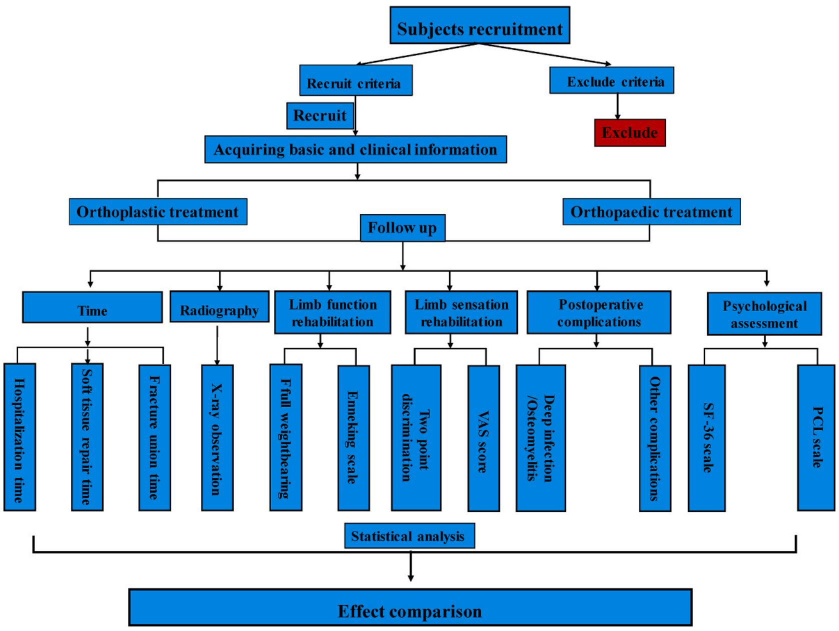

Fig. 1. Flowchart of the study process.

Currently in China, there is a lack of relevant studies that have specifically evaluated the prognosis of patients who undergo orthoplastic treatment, including their physical function and psychological well-being. Similar to most developing countries in the world, orthopedics remains the primary approach for managing severe lower limb trauma in mainland China. However, it is worth noting that a considerable number of Chinese surgeons in orthopedic departments possess the skills to perform both fixation and microsurgery [17].This is obviously different from the practice of developed countries in the world.

Findings of previous researches on severe open fractures of lower limb were relatively limited by the sample size or the lack of psychological assessment indicators. In this study, we aim to develop a prospective clinical trial to investigate the disparities in clinical outcomes between single-stage orthoplastic reconstruction and the definitive orthopedic fixation approach for patients with open fractures of lower limb, which classified as Gustilo-Anderson (GA) grades IIIB and IIIC. All participants in the study will undergo a comprehensive set of assessments to evaluate limb function and psychological well-being. The study protocol will compare the clinical outcomes, including the recovery of limb function, psychological scores, and health-related quality of life (HRQOL), between patients with severe lower limb trauma who undergo orthoplastic and orthopedic surgeries. This is the first time the study was carried out in China.The findings from this research will not only contribute significantly to the selection of relevant prognostic indicators but also have the potential to improve the overall management and outcomes for these patients.

2. Methods and analysis

This study was conducted as a non-randomized controlled study, adhering to ethical principles and requirements. The study process is illustrated in Fig. 1, demonstrating the flowchart of the study design. Prior to participation, all subjects and their families were provided with detailed information regarding the advantages and disadvantages of the two surgical methods. Based on the subjects' preferences, they were assigned to either the Orthoplastic group or the Orthopedic group.

The Orthoplastic group underwent a single-stage procedure involving debridement, fixation, and soft tissue repair. In contrast, the Orthopedic group underwent a delayed-stage approach, where soft tissue repair was conducted at a later time point.

2.1. Study subjects

All study participants will be required to provide written informed consent after receiving comprehensive information about the study procedure and its details. The recruitment of patients will be conducted over a period of 5 years, from October 2019 to October 2024, and a follow-up period of 1 year will be implemented.

The inclusion criteria for the study are as follows: Lower limb injuries, including both bone fractures and severe soft tissue injuries, primarily Gustilo-Anderson grades IIIB and IIIC according to Gustilo's criteria [5]. Subjects aged between 16 and 79 years. The exclusion criteria for the study are as follows: history of mental illness (history of psychiatric disorders such as mania, schizophrenia, etc); subjects with a history of central nervous system (CNS) diseases (such as encephalitis, brain tumour, etc); unconscious subjects at the time of admission (such as in coma, etc); subjects with a history of lower limb disorders (such as the anterior or posterior cruciate ligament injury of the knee, traumatic arthritis of the knee, etc).

The primary outcome is the recovery of limb function. Psychological disorder and HRQOL are secondary outcomes. Efficacy index between two groups is formulated as follows: $n_1 = n_2 = 2[\frac{(u\alpha+u\beta)}{\delta/\sigma}]^2 + \frac{1}{4}u\alpha^2$ (n: sample size; u: mean value; σ: standard deviation), $\delta = u_1 - u_2$, $\alpha = 0.05$, $\beta = 0.8$, $u\alpha = 1.96$, $u\beta = 0.84$ [18]. To ensure statistical validity, a sample size of 26 patients will be included in each group. Considering a drop-out rate of 10 % among the enrolled subjects and accounting for the number of cases, the final sample size will be adjusted to 30 individuals for each group. Patients in each group will be given full informed consent especially the potential prognostic variables to ensure their decision-making. For the grade IIIC injury, the vascular reconstruction was accomplished first, and the protocol followed was the same.

2.2. Orthoplastic group

Upon admission to the emergency department of our hospital, patients with lower limb trauma will receive life-support treatments as needed for temporary stabilization. Once transferred to the orthopedics department, orthoplastic surgery will be initiated promptly. For patients with grade-IIIB injuries, radical debridement and transitional fixation will be performed. Alongside debridement, a thorough wound lavage will be conducted. Skeletal stabilization will be achieved using a transitional plate, external fixation, or a combination of both. Importantly, instead of employing negative-pressure wound therapy, soft tissue defects will be addressed simultaneously by covering them with an engineered vascular muscle flap and a split-thickness skin graft or a local flap. In cases of grade-IIIC injuries, vascular reconstruction will be prioritized before proceeding with the same protocol. For certain patients with bone defects, Masqualet or bone shortening methods will be utilized. Additionally, delayed bone grafting will be carried out after a period of 6–8 weeks.

2.3. Orthopedics group

Patients do not accept or their general condition does not tolerate radical orthoplastic surgery will be assigned to orthopedics group. They will undergo temporary stabilization of lower limb trauma through life-support treatments, following the same protocol as before. For patients with grade-IIIB injuries, radical debridement and transitional fixation will be performed. Soft tissue defects will initially be covered by negative-pressure wound therapy, which will be maintained for 3–7 days until the general and local conditions stabilize. Subsequently, soft tissue defects will be addressed by using an engineered vascular muscle flap with a split-thickness skin graft or a local flap. In cases of grade-IIIC injuries, vascular reconstruction will be prioritized, followed by the same protocol. The main distinction in the orthopedics group lies in the delayed soft tissue coverage. This means that definitive skeletal fixation and soft tissue coverage will be carried out in a multi-stage process.

2.4. Postoperative rehabilitation

The postoperative rehabilitation process will be consistent for both groups. Intravenous antibiotics, specifically cefoperazone sodium and metronidazole, will be administered for the initial five days. Subsequent antibiotic treatments will be adjusted based on the culture results obtained from skin grafting. All patients will be encouraged to perform joint movements while in bed and will receive postoperative anticoagulant, anticonvulsant, and anti-infective therapy to promote the survival of the skin flap.

Partial weight-bearing will be allowed once early bony stability is achieved, typically around 12 weeks postoperatively. The removal of external fixation devices will be scheduled at an average of 4 months after the operation. Patients who have been discharged will be scheduled for timely follow-up appointments in our orthopedic department.

2.5. Clinical assessments

Patient demographic characteristics, including sex, age, level of education, history of smoking and drinking, occupation, comorbidities, and Gustilo open fracture classification system, will be recorded for all patients. In addition, the following clinical features will be collected:

Time interval between injury and admission at our hospital. Preoperative preparation time (since the first admission).Waiting time for emergency operation. Blood loss during the emergency operation. Volume of infused blood during the emergency operation. Time interval between admission and soft tissue coverage. Duration of soft tissue healing. Length of stay in the hospital. The number of additional operations on the bone. Duration of radiographic signs of bone healing. The time required for full weight-bearing. Total cost of hospitalization. Other details including early antibiotic use, intravenous prophylactic antibiotics, timing of irrigation and debridement, debridement success, culture data, and resuscitation details including the type and timing of resuscitation fluids will also be recorded. These assessments will provide valuable information for evaluating patient outcomes and determining the effectiveness of the treatment approach.

2.6. Follow-up

All subjects in both groups will undergo four interviews following the repair of critical soft tissues: at the first postoperative day, at the 3rd month, at the 6th month, and at the 12th month after the operation. The follow-up period will last for one year. Patients will return to our hospital for scheduled appointments, and the same procedures will be conducted throughout the follow-up period. All follow-up results will be recorded.

2.7. Recovery of limb function

X-ray examinations of fracture healing will be performed using a Philips Practix 360 Mobile X-ray System (Philips Healthcare, Amsterdam, the Netherlands). The Enneking scoring system will be utilized to evaluate the recovery of lower limb function post-operation [14,19]. The time required for radiologic evaluation of fracture healing and full weight-bearing will be documented. Other details such as rehabilitation protocols, compliance, and deviations will be documented, as these factors can significantly affect patient outcomes and the study's findings.

2.8. Rehabilitation of limb sensation

The Visual Analogue Scale (VAS) scoring and two-point discrimination test will be carried out to assess limb sensation.

2.9. Postoperative complications

Postoperative complications will primarily be related to deep infection/osteomyelitis. If clinical suspicion arises, skin and bone tissue cultures will be obtained, and routine blood tests will be conducted to detect high-sensitivity C-reactive protein (hs-CRP) levels and erythrocyte sedimentation rates (ESR). Positron emission tomography-computed tomography (PET-CT) scans will be performed for diagnosing osteomyelitis. Other complications, such as flap failure, nonunion, and activity limitations, will also be included in the assessment.

2.10. Psychological assessment

For psychological assessment, the 36-Item Short Form Health Survey (SF-36) will be utilized to evaluate the Health-Related Quality of Life (HRQOL) of the patients. Additionally, the Post-traumatic Stress Disorder Checklist (PCL) will be administered to assess the severity of self-reported post-traumatic stress disorder (PTSD). These surveys will be repeated four times following the repair of soft tissue at specific intervals: the first postoperative day, the 3rd month, the 6th month, and the 12th month post-operation.

All subjects will be interviewed and examined by a surgeon responsible for the entire medical process. Data will be collected by a member of our team and recorded in an evidence-based case report form. The surgeon is also responsible for addressing missing data following best practices. A supervising professor overseeing our orthopedic team will verify the accuracy and reliability of the outcomes.

2.11. Statistical analysis

The data will be collected precisely considering the potential for numerous publications and the need for methodological and statistical support. These data will be analyzed by SPSS 18.0 software (IBM, Armonk, NY, USA). $P < 0.05$ will be considered statistically significant.

Appropriate statistical methods were used for accounting potential treatment group differences. The normally distributed quantitative data (age, time interval between injury and admission at our hospital, preoperative preparation time, waiting time for emergency operating, blood loss during emergency operation, volume of infused blood, time interval between admission and soft tissue coverage, duration of soft tissue healing, the length of stay in hospital, VAS score, Enneking score, two-point discrimination, the number of additional operations on bone, duration of radiographic signs of bone healing, time required for full weight-bearing, total cost of hospitalization, SF-36 score, PCL score) will express as mean ± standard error, and Student's *t*-test will be applied to test the difference between the two groups; if the data are skewed, they will be presented as median (middle value) and interquartile range (IQR; upper quartile-lower quartile), and those data will be analyzed by the Mann-Whitney *U* test.

Categorical variables (sex, level of education, history of smoking and drinking, occupation, comorbidities, Gustilo open fracture classification system, complications) will be expressed as n(%), and Fisher's exact test will be utilized to compare the differences between the two groups. The relative risk for the deep infection/osteomyelitis will be presented with 95 % confidence interval (95 % CI).

2.12. Socio-demographic and clinical data

The distribution of socio-demographic and clinical data within the groups and subgroups will be evaluated. Our hypothesis is that the type of surgery (orthopedic and orthoplastic procedures) may influence the outcomes.

For normally distributed quantitative data (such as age, time interval between injury and admission, preoperative preparation time, waiting time for emergency operation, blood loss during emergency operation, volume of infused blood, duration of soft tissue healing, length of hospital stay, VAS score, Enneking score, two-point discrimination, number of additional operations on bone, duration of radiographic signs of bone healing, time required for full weight-bearing, total cost of hospitalization, SF-36 score, PCL score), mean values will be presented with the standard error of the mean (SEM), and Student's t-test will be used to assess our hypothesis. If the data are skewed or contain influential outliers, they will be presented as median (middle value) and interquartile range (IQR, upper quartile-lower quartile), and analyzed using the Mann-Whitney *U* test.

Fisher's exact test will be employed to compare differences among categorical variables (such as sex, level of education, history of smoking and drinking, occupation, comorbidities, Gustilo open fracture classification system, complications). The relative risk for deep infection/osteomyelitis will be reported with a 95 % confidence interval (95 % CI).

Considering factors such as resource constraints and team availability, the delay in treatment and the reasons for the delay will be addressed and analyzed.

3. Discussion

Psychological distress is a recognized consequence of severe lower-limb injuries. Numerous studies have primarily focused on the physical health outcomes of severe open fractures in the upper and lower extremities. However, to date, there is a lack of comprehensive reports addressing the evaluation of physical, psychological, and Health-Related Quality of Life (HRQOL) outcomes in these patients.

Patients with severe open fractures of the upper and lower extremities often encounter significant challenges in limb reconstruction, with the success of these efforts heavily reliant on adequate soft tissue coverage. The British Association of Plastic, Reconstructive and Aesthetic Surgeons has emphasized the importance of early soft-tissue coverage (within 72 h) in severe open tibial fractures, as it has been associated with improved outcomes in terms of hospital stay duration and infection rates [20].

Moreover, Gopal et al. [11] have demonstrated satisfactory outcomes through an aggressive combined approach involving both orthopedic and plastic surgical interventions for severe injuries. Previous studies have also revealed the effectiveness of this approach in managing severe open fractures, particularly in the case of tibial fractures. It is worth noting that this approach is considered radical, and there have been concerns about the safety of immediate soft tissue coverage. However, the results have consistently shown satisfactory rates of bone union and low infection rates [21–23].

Despite the evident advantages of orthoplastic surgery, it continues to face significant challenges on a global scale. Currently, traditional orthopedic approaches with delayed wound closure are widely practiced in China, presenting a significant challenge for orthopedic surgeons in managing severe lower limb injuries. It is worth noting that, unlike in other countries, China does not have dedicated orthoplastic centers. However, many orthopedic surgeons in China possess the skills and expertise not only in fractures but also in soft tissue reconstruction. On the other hand, decision-making for patients who could potentially undergo either a single-stage fix-and-flap procedure or a multi-stage approach tend to be complex. The qualitative factors influencing these decisions, such as patient preferences, surgeon expertise, and institutional protocols need to delve into.

In this research, we aimed to address this gap by conducting a prospective clinical trial that follows the same aggressive orthoplastic approach as Gopal et al. [11], who achieved satisfactory outcomes. Our study involved radical and thorough debridement performed by experienced and qualified senior surgeons. We ensure that the case report form captures a wide range of information, from demographics to wound characteristics, implant types, and complications. By effectively analyzing the orthoplastic approach, we sought to contribute to the body of knowledge on managing severe lower limb injuries in the Chinese context.

Functional recovery is one of the key indicators in limb reconstruction. X-ray examination plays a crucial role in assessing the status of bone healing. It provides valuable information on bone mineral density, malunion and nonunion, as well as the integrity of fixation. Furthermore, X-ray imaging can indirectly indicate the presence of bone infection [19].

To evaluate limb sensation rehabilitation, the Visual Analogue Scale (VAS) score and two-point discrimination in the injury zone have proven to be helpful. The VAS score was initially introduced by Bond et al. as a subjective measure of pain intensity [24]. Even after 50 years, it remains one of the most effective approaches to quantify the subjective experience of pain intensity [25]. Additionally, the two-point discrimination test is commonly used in clinical practice [26].

Post-traumatic infection is a common occurrence in cases of open lower limb fractures. However, conventional blood test parameters such as white blood cell count, erythrocyte sedimentation rate (ESR), and high-sensitivity C-reactive protein (hs-CRP) level are not reliable indicators for detecting infection [27]. Radiographic signs, including periosteal elevation, cortical disruption, medullary involvement, and osteolysis, can be indicative of osteomyelitis. Although plain radiography has been used for early diagnosis, it remains an indirect method for detecting osteomyelitis. Recent studies have demonstrated that positron emission tomography-computed tomography (PET-CT) is highly accurate in assessing osteomyelitis [28].

A significant clinical outcome of the orthoplastic approach for severe open tibial fractures has been reported in a multi-center, prospective cohort study [14]. It is important to note that patients who have experienced major trauma may face long-term limitations in terms of functional abilities and work productivity. Furthermore, studies have indicated that patients with moderate to severe injuries may also experience significant psychological disorders [10,29,30].

The SF-36 questionnaire is widely used as a generic instrument to assess health-related quality of life. It was standardized in 1990 and is a self-report measure of functional health and well-being [31,32]. The questionnaire consists of eight scales that provide two summary measures: physical health and mental health. The physical health measure includes scales for physical functioning (10 items), role-physical (4 items), bodily pain (2 items), and general health (5 items). The mental health measure includes scales for vitality (4 items), social functioning (2 items), role-emotional (3 items), and mental health (5 items) [32].

The Post-traumatic Stress Disorder Checklist (PCL) is commonly used to assess PTSD symptoms [33]. It has been shown to have excellent psychometric properties, including strong internal consistency, test-retest reliability, convergent and discriminant validity, structural validity, diagnostic utility, and sensitivity to clinical change [34,35].

Composite outcome that combines several factors, such as revision surgery, infection, late amputation, and flap failure will be sufficiently considered. Survival analysis to assess the impact of prolonged hospitalization on psychological and physical recovery will also be conducted. This analysis will provide valuable insights into the long-term consequences of open fractures. However, it is important to note that the sample size of this study is relatively limited.

3.1. Limitation

The limitation of this study is that our study was being conducted only at a single center. And the sample size of this study is relatively limited. Therefore, based on the results of this study, we will further conduct a multi-center randomized controlled study to increase the significance of the research results.

4. Conclusion

In conclusion, the results of this clinical trial will contribute to the evaluation of the orthoplastic approach in the treatment of severe lower limb injuries. The findings will be valuable in identifying relevant prognostic factors and improving the management and outcomes for patients with these injuries. The study has the potential to make a significant impact on the field and provide valuable insights for clinicians and researchers working in the area of severe lower limb injury management.

4.1. Study status

This study protocol represents the initial version of the research plan, and recruitment for the study began in October 2019. The anticipated completion of the recruitment phase is estimated to be around 2024.

Study registration

This study has been registered at Chinese Clinical Trial Registry, http://www.chictr.org.cn/index.aspx (ID: ChiCTR1900025815; Date of registration: September 9th, 2019).

Funding

This study was supported by National Natural Science Foundation of China (No.81902185), China Postdoctoral Science Foundation (No.2020M673661), the Key Research and Development Program of Shaanxi Province (No.2023YBSF-464 and No.2021SF-175),the Academic Boost Plan of Xijing hospital (No.XJZT18D37) and Research Incubation Fund of Xi'an People's Hospital (No.LH-9).

Availability of data and materials

This study is registered at http://www.chictr.org.cn/index.aspx (ChiCTR1900025815). The datasets supporting the conclusions of this study will available after we update the information.

Ethic approval and consent to participate

The experiment conformed to the principles of the Declaration of Helsinki and was approved by the ethics committee of the first affiliated hospital (Xijing Hospital) of Air Force Military Medical University (KY20192067–F-1).They obtained informed consent of participants, as required for protection of human participants. Consent will be obtained from minor(s) in addition to parental/guardian consent.

Data availability statement

The data associated with our study will be deposited into a publicly available repository (http://www.chictr.org.cn/index.aspx) after the last follow-up of all subjects have been accomplished.

CRediT authorship contribution statement

Zhao Yang: Writing – original draft, Resources, Methodology, Investigation, Funding acquisition. **Chao Xu:** Methodology, Investigation, Funding acquisition, Formal analysis, Data curation. **Yonggang Zhu:** Project administration, Methodology, Investigation. **Yanchen Tan:** Writing – original draft, Software, Project administration, Methodology. **Hao Hu:** Software, Resources, Data curation. **Peng Fang:** Project administration, Investigation, Conceptualization. **Di Cui:** Software, Investigation. **Guangyue Zhao:** Writing – review & editing, Visualization, Validation, Supervision, Methodology, Conceptualization. **Danmin Miao:** Writing – review & editing, Visualization, Validation, Supervision, Conceptualization. **Lei Shang:** Writing – review & editing, Visualization, Validation, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

Not Applicable.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e33589.

References

[1] World Health Organization (WHO), World Report on Road Traffic Injury Prevention, WHO, Geneva, Switzerland, 2004.
[2] M.C.-B. Charles, E.B. Kate, D.C. Nicholas, D.D. Andrew, The epidemiology of open fractures in adults. A 15-year review, Injury 43 (6) (2006) 891–897.
[3] J.A. Mathews, J. Ward, T.W. Chapman, U.M. Khan, M.B. Kelly, Single-stage orthoplastic reconstruction of Gustilo-Anderson Grade III open tibial fractures greatly reduces infection rates, Injury 46 (11) (2015) 2263–2266.
[4] R.B. Gustilo, J.T. Anderson, Prevention of infection in the treatment of one thousand and twenty-five open fractures of long bones: retrospective and prospective analyses, J. Bone Jt. Surg. Am. Vol. 58 (4) (1976) 453–458.
[5] R.B. Gustilo, R.M. Mendoza, D.N. Williams, Problems in the management of type III (severe) open fractures: a new classification of type III open fractures, J. Trauma 24 (8) (1984) 742–746.
[6] M. Godina, Early microsurgical reconstruction of complex trauma of the extremities, Plast. Reconstr. Surg. 78 (3) (1986) 285–292.
[7] S.B. Naique, M. Pearse, J. Nanchahal, Management of severe open tibial fractures: the need for combined orthopaedic and plastic surgical treatment in specialist centres, The Journal of bone and joint surgery British 88 (3) (2006) 351–357.
[8] N. J, N. S, K. U, M. C, B. S, S. F, et al., Standards for the Management of Open Fractures of the Lower Limb, RSM Press, London, 2009.
[9] ST. Jr. Hansen, The type-IIIC tibial fracture. Salvage or amputation, J. Bone Jt. Surg. Am. Vol. 69 (6) (1987) 799–800.

[10] M.L. McCarthy, E.J. MacKenzie, D. Edwin, M.J. Bosse, R.C. Castillo, A. Starr, Psychological distress associated with severe lower-limb injury, J. Bone Jt. Surg. Am. Vol. 85 (9) (2003) 1689–1697.
[11] J. Conroy, M. Agarwal, P.V. Giannoudis, S.J.E. Matthews, Early internal fixation and soft tissue cover of severe open tibial pilon fractures, Int. Orthop. 27 (6) (2003) 343–347.
[12] S. Gopal, S. Majumder, A.G. Batchelor, S.L. Knight, P. De Boer, R.M. Smith, Fix and flap: the radical orthopaedic and plastic treatment of severe open fractures of the tibia, The Journal of bone and joint surgery British 82 (7) (2000) 959–966.
[13] A.K. Chad, C.R. Jessica, J.T. David, J.S. Andrew, J.S. Daniel, C.W. Joseph, Late amputation may not reduce complications or improve mental health in combat-related, lower extremity limb salvage patients, Injury 46 (8) (2015) 1527–1532.
[14] F. Boriani, A. Ul Haq, T. Baldini, R. Urso, D. Granchi, N. Baldini, et al., Orthoplastic surgical collaboration is required to optimise the treatment of severe limb injuries: a multi-centre, prospective cohort study, J. Plast. Reconstr. Aesthetic Surg. : JPRAS 70 (6) (2017) 715–722.
[15] Y.K. Tu, C.H. Lin, J.I. Su, D.T. Hsu, R.J. Chen, Unreamed interlocking nail versus external fixator for open type III tibia fractures, J. Trauma 39 (2) (1995) 361–367.
[16] J.F. Keating, P.J. O'Brien, P.A. Blachut, R.N. Meek, H.M. Broekhuyse, Locking intramedullary nailing with and without reaming for open fractures of the tibial shaft. A prospective, randomized study, J. Bone Jt. Surg. Am. Vol. 79 (3) (1997) 334–341.
[17] Y. Zhao, X. Chao, Z. Yong-Gang, L. Jun, W. Zi-Xiang, Z. Ji-Wei, X. Bao-Bao, M. Dan-Min, S. Lei, Z. Guang-Yue, Radical treatment of severe open fractures of extremities by orthoplastic surgery: a 10-year retrospective study, J. Orthop. Surg. Res. 16 (1) (2021) 340.
[18] S. Zhenqiu, X. Yongyong, Y. Yan, W. Tong, L. Hongbo, M. Jun, Medical Statistics, People's Medical Publishing House Press, Beijing, 2020.
[19] W.F. Enneking, W. Dunham, M.C. Gebhardt, M. Malawar, D.J. Pritchard, A system for the functional evaluation of reconstructive procedures after surgical treatment of tumors of the musculoskeletal system, Clin. Orthop. Relat. Res. (286) (1993) 241–246.
[20] I. Poudel, C. Tejpal, H. Rashid, N. Jahan, Major adverse cardiovascular events: an inevitable outcome of ST-elevation myocardial infarction? A literature review, Cureus 11 (7) (2019) e5280.
[21] G. Cierny 3rd, H.S. Byrd, R.E. Jones, Primary versus delayed soft tissue coverage for severe open tibial fractures. A comparison of results, Clin. Orthop. Relat. Res. (178) (1983) 54–63.
[22] R. Gg, H. R, A. G, Primary or delayed closure for open tibial fractures, J. Bone Joint Surg. 72-B (1990) 125–128.
[23] H.S. Jr, Hansen & swinotowski, in: Open Fractures in Orthopaedic Trauma Protocols, Raven Press, New York, 1993.
[24] M.R. Bond, I. Pilowsky, Subjective assessment of pain and its relationship to the administration of analgesics in patients with advanced cancer, J. Psychosom. Res. 10 (2) (1966) 203–208.
[25] H. Breivik, Fifty years on the Visual Analogue Scale (VAS) for pain-intensity is still good for acute pain. But multidimensional assessment is needed for chronic pain, Scandinavian journal of pain 11 (2016) 150–152.
[26] T. Wolny, P. Linek, Reliability of two-point discrimination test in carpal tunnel syndrome patients, Physiotherapy theory and practice 35 (4) (2019) 348–354.
[27] D.P. Lew, F.A. Waldvogel, Osteomyelitis. Lancet (London, England) 364 (9431) (2004) 369–379.
[28] N. Maffulli, R. Papalia, B. Zampogna, G. Torre, E. Albo, V. Denaro, The management of osteomyelitis in the adult, Surgeon : journal of the Royal Colleges of Surgeons of Edinburgh and Ireland 14 (6) (2016) 345–360.
[29] T.L. Holbrook, J.P. Anderson, W.J. Sieber, D. Browner, D.B. Hoyt, Outcome after major trauma: 12-month and 18-month follow-up results from the Trauma Recovery Project, J. Trauma 46 (5) (1999) 765–771.
[30] J.L. Butcher, E.J. MacKenzie, B. Cushing, G. Jurkovich, J. Morris, A. Burgess, et al., Long-term outcomes after lower extremity trauma, J. Trauma 41 (1) (1996) 4–9.
[31] E.M. Andresen, Measures of general health status, in: E.M. Andresen (Ed.), Assessing the Health Status of Older Adults, Springer Publishing Co, New York, NY, 1997, pp. 41–91.
[32] X.L. Lv, Y.H. Jiang, Y.H. Sun, C.Z. Ren, C.Y. Sun, L. Sun, et al., Short form 36-Item Health Survey test result on the empty nest elderly in China: a meta-analysis, Arch. Gerontol. Geriatr. 56 (2) (2013) 291–297.
[33] J.D. Elhai, P.A. Palmieri, The factor structure of posttraumatic stress disorder: a literature update, critique of methodology, and agenda for future research, J. Anxiety Disord. 25 (6) (2011) 849–854.
[34] F.W. Weathers, Posttraumatic stress disorder checklist, in: G. Reyes, J.D. Elhai, J.D. Ford (Eds.), Encyclopedia of Psychological Trauma, Wiley, Hoboken, NJ, 2008, pp. 491–494.
[35] C.A. Blevins, F.W. Weathers, M.T. Davis, T.K. Witte, J.L. Domino, The posttraumatic stress disorder checklist for DSM-5 (PCL-5): development and initial psychometric evaluation, J. Trauma Stress 28 (6) (2015) 489–498.