Open Journal of Orthopedics, 2024, 14, 149-172
https://www.scirp.org/journal/ojo
ISSN Online: 2164-3016
ISSN Print: 2164-3008

Functional Outcomes of Adult Tibia Shaft Fractures Treated with Solid Intramedullary Nails versus Hollow Nails: A Systematic Review

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How to cite this paper: Abu, K.A., Hammond, B., Bukari, M.I.S., Vormawor, K.K., Awoonor-Williams, R., Anyitey-Kokor, D., Baidoo, P.K. and Konadu-Yeboah, D. (2024) Functional Outcomes of Adult Tibia Shaft Fractures Treated with Solid Intramedullary Nails versus Hollow Nails: A Systematic Review. *Open Journal of Orthopedics*, **14**, 149-172.
https://doi.org/10.4236/ojo.2024.143016

Received: February 22, 2024
Accepted: March 25, 2024
Published: March 28, 2024

Abstract

Introduction: The management of fractures of the tibia shaft is an important aspect of orthopaedic care, and the selection of the surgical method for fixation can substantially impact patient outcomes. The current review aims to compare the outcomes of adult tibia fractures treated with solid nails to those treated with hollow nails. **Methods:** A search on Scopus, PubMed, and Cochrane Library, using three keywords (Outcome, Tibia shaft fractures, Nail) was conducted in April 2023. Results were compiled and two independent reviewers screened and selected eligible articles After removing duplicates, titles and abstracts were read to exclude ineligible studies. Full-text articles of the remaining papers were read to select eligible studies which were further critically appraised to ascertain their methodological quality. The data extracted from the selected papers were synthesized using a combination of pooling of results, tests of statistical difference (t-test and chi-square) and narrative synthesis methods. **Results:** A total of 2295 articles were obtained from the databases and citation searching. A total of 9 papers were identified as eligible and included in the review. Findings revealed that there is no statistical difference in the outcomes of tibia fractures treated with either solid or hollow nail groups such as duration of surgery ($p = 0.541$), rate of delayed and non-union ($p = 0.342$), and rate of surgical site infections ($p = 0.395$). **Conclusion:** Intramedullary nailing of tibia shaft fractures with either solid or hollow nails have similar functional outcomes.

Keywords

Tibia Shaft Fractures, Functional Outcome, SIGN Nail, Hollow Nail

1. Introduction

1.1. Background of Study

Musculoskeletal trauma is a significant global burden, particularly in low and middle-income countries (LMICs). The prevalence of musculoskeletal trauma in LMICs ranges from 779 to 1574 per 100,000 person-years, according to Cordero *et al.* [1]. Studies by Court-Brown and Caesar, Larsen *et al.* and Weiss *et al.* (2008) have reported an incidence of 16.9 to 22.0 cases per 100,000 person-years in Western European countries [2] [3] [4]. This data emphasizes that LMICs bear a considerably higher burden of musculoskeletal trauma compared to their Western counterparts. In Sub-Saharan Africa, tibia shaft fractures have been found to comprise a substantial proportion of all long bone fractures seen in trauma centres. Reports from studies have indicated that these fractures make up 13.5% to 41.4% of all long bone fractures in the region [5] [6] [7]. It is also noteworthy that the median age of patients presenting with tibia shaft fractures in these countries is 40 years [5]. This finding reveals that these injuries affect individuals in their productive years, potentially hindering their ability to participate in the workforce and contribute to the economic prosperity of LMICs.

The impact extends beyond the individual level, affecting families, communities, and the overall socioeconomic landscape [8]. The incapacitation resulting from these fractures leads to a significant loss of productivity, income, and economic potential. The burden on healthcare systems in LMICs is exacerbated by the need for immediate and long-term medical care, including surgical interventions, rehabilitation, and ongoing management of complications [9] [10]. The consequences of tibia shaft fractures extend beyond the immediate healthcare costs. In LMICs, where access to healthcare services may be limited and financial resources are constrained, the economic impact becomes even more pronounced [11] [12]. Limited access to specialized care, including orthopaedic surgeons and rehabilitation facilities, can result in suboptimal treatment outcomes, prolonged disability, and increased burden on the affected individuals and their families [13]. Moreover, the indirect costs associated with tibia shaft fractures in LMICs are substantial. These include transportation expenses for seeking medical care, loss of income due to temporary or permanent disability, and additional expenditures for assistive devices such as crutches or wheelchairs [14] [15]. For individuals already living in poverty, these expenses can push them further into economic hardship, perpetuating a cycle of poverty and limited opportunities.

The treatment of tibia shaft fractures in skeletally mature patients has evolved over time, with reamed locked intramedullary nailing emerging as the gold standard. This surgical fixation method offers several advantages, including faster mobilization and shorter time to union [16]. The history of tibia intramedullary nails dates to the 1900s when an ivory rod was first used as a primitive form of fixation. Since then, significant advancements have been made, leading to the development of locked hollow and solid reamed nails [17]. Rosa *et al.* explained that the similarity in modulus of elasticity between Titanium and bone reduces stress shielding, a phenomenon where the implant absorbs most of the mechanical load, leading to bone resorption and potential complications [17]. By using Titanium nails, surgeons aim to minimize stress shielding and promote better load sharing between the implant and bone, which can contribute to improved fracture healing and long-term outcomes [18].

These characteristics are important for implant longevity and reduced risk of adverse reactions within the body [19] [20]. Furthermore, Titanium's lower density compared to stainless steel contributes to lighter implants, which can enhance patient comfort and reduce the load burden on the affected limb during the healing process [21]. Stainless steel nails have also demonstrated satisfactory clinical outcomes and have been widely utilized in many healthcare settings [21] [22]. However, the stiffness of stainless steel relative to bone and its potential for stress shielding has led to the exploration of alternative materials like Titanium, aiming to further optimize treatment outcomes [23]. While Titanium is favoured for its biomechanical properties and closer match to bone's elasticity, stainless steel remains a viable option that has stood the test of time and continues to be widely used in clinical practice [24] [25].

It is important to note that the selection of the implant material is just one aspect of the overall management of tibia shaft fractures. Factors such as surgical technique, appropriate patient selection, postoperative care, and rehabilitation protocols also play critical roles in achieving optimal outcomes [26]. A multidisciplinary approach involving orthopaedic surgeons, nurses, physiotherapists, and other healthcare professionals is necessary to ensure comprehensive and individualized care for patients with tibia shaft fractures.

Reamed locked intramedullary nailing with hollow nails has become the established and widely adopted option for the treatment of tibia shaft fractures in most regions around the globe. This surgical technique, which involves the insertion of a hollow nail into the intramedullary canal of the tibia, provides excellent stability and facilitates early mobilization [27] [28]. However, it is important to acknowledge that not all healthcare settings have access to advanced resources such as fluoroscopy and image intensifiers, especially in low-resourced countries.

Recognizing the need for an effective and accessible solution, the Surgical Implant Generation Network (SIGN) was established in 1999. The primary objective of SIGN was to develop a solid locked, reamed intramedullary nail specifically designed for the tibia. This innovation aimed to address the challenges faced by low-resourced countries in providing adequate fracture treatment options [29]. The SIGN nail system has gained significant recognition and acceptance in regions where resources are limited [30]. One notable advantage of the

SIGN nail system is its design which allows for usage without the need for fluoroscopy. In third-world countries where image intensifiers are not always available or accessible, this characteristic of the SIGN nails greatly enhances their appeal [31] [32].

1.2. Problem Statement

Biomechanical research plays a crucial role in advancing the field of Orthopaedic surgery and fracture management. One area of interest in this realm is the comparison between solid and hollow nails for the treatment of tibia shaft fractures. Solid nails, as supported by biomechanical studies, have demonstrated superior stability when compared to their hollow counterparts [33]. The biomechanical stability provided by solid nails can be attributed to their structural integrity and resistance to deformation. The solid design offers increased rigidity, preventing excessive motion at the fracture site and promoting optimal healing conditions [34]. In contrast, hollow nails may be more prone to bending or collapsing under mechanical loads, compromising the stability of the fracture fixation construct [35]. Considering the biomechanical and infection-related advantages, the question arises: Why are hollow nails still commonly used, particularly in resource-limited countries where cost-effectiveness is a significant factor in healthcare delivery?

In low-resource settings, where healthcare budgets are constrained and financial considerations heavily influence decision-making, the cost of surgical implants and instruments plays a crucial role [36]. The affordability of solid nails makes them a viable option for healthcare providers who are faced with limited resources and financial constraints. By opting for cheaper solid nails like the SIGN nail, healthcare facilities can allocate their funds to other essential aspects of patient care, such as medications, diagnostics, and postoperative rehabilitation. However, it is important to approach this cost-driven decision with caution. While solid nails may offer economic advantages, it is crucial to weigh these benefits against the potential compromises in biomechanical stability and infection resistance. It is essential to strike a balance between cost-effectiveness and optimal patient outcomes. This requires a comprehensive evaluation of the available resources, infrastructure, and long-term implications of the chosen treatment strategy. In recent years, there has been a growing recognition of the importance of providing sustainable and cost-effective healthcare solutions in resource-limited countries [37]. Various initiatives and organizations have aimed to bridge the gap by developing affordable and context-specific medical devices. These efforts have resulted in the introduction of alternative implant options, including solid nails (SIGN nails) that are specifically designed to meet the needs of low-resourced settings [38].

The treatment of tibia shaft fractures is a critical aspect of orthopaedic care, and the choice of implant for surgical fixation method significantly impacts patient outcomes. The existing literature provides a diverse range of reports on the outcomes associated with the use of these different nail types in tibia fracture management [30] [39]. Consequently, there is a pressing need for a systematic review that can comprehensively analyse the available evidence and guide clinical practice, particularly in countries such as Ghana where both solid and hollow nails are currently utilized.

1.3. Objectives

The study aimed to compare the outcomes of adult tibia fractures treated with solid SIGN nail to those treated with hollow nails. The specific objectives are to determine:

- A difference in the average duration of surgery when tibia fractures are fixed with hollow nails compare to fixation with solid nails.
- A difference in the rate of surgical site infection between tibia fractures fixed with hollow nails compared to those fixed with solid nails in literature.
- A statistical difference in the non-union and delayed rates between tibia fractures fixed with hollow nails and those fixed with solid nails in literature.

1.4. Research Questions

- Is there a difference in the average duration of surgery when tibia fractures are fixed with hollow nails compare to fixation with solid nails?
- Is there a difference in the rate of surgical site infection between tibia fractures fixed with hollow nails compared to those fixed with solid nails in literature?
- Is there a statistical difference in the non-union and delayed rates between tibia fractures fixed with hollow nails and those fixed with solid nails in the literature?

1.5. Hypothesis

There is no statistical difference between the outcomes of tibia nailing with conventional hollow nails and tibia nailing with solid nails, in adults with tibia shaft fractures.

2. Methodology

2.1. Protocol in the Systematic Review

In other to conduct this review with rigour and transparency and maintain quality and reliability the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were used [40].

PRISMA-P, an extension of the PRISMA guidelines, focuses specifically on systematic review protocols. It provides a comprehensive checklist of items that should be incorporated into a systematic review protocol, ensuring that the entire review process is conducted in a meticulous and transparent manner [41]. By adhering to the PRISMA-P guidelines, we ensured that the systematic review protocols contain all the necessary components to maintain rigour and transparency.

Eligibility criteria for inclusion were based on the Population, Intervention, Comparison, and Outcome (PICO) framework. By explicitly stating the criteria for study selection, the protocol minimized potential bias and ensured that relevant studies were included while maintaining consistency and transparency.

2.2. Search Strategy

From 1st April 2023 to 31st May 2023 a systematic review was performed using three prominent biomedical databases: Scopus, PubMed, and Cochrane Library. These databases were specifically chosen due to their extensive coverage of diverse healthcare topics, making them highly comprehensive [42]. The review considered all relevant publications from the year 2000 onwards. The search process adhered to the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) procedure, as described by Moher *et al.* [41].

To facilitate the identification of relevant papers, a set of three keyword groups (Outcomes, Tibia shaft fractures, Nail) was employed during the search process. In order to capture a wide range of related terms, synonyms for these keywords were obtained using a thesaurus. The search was conducted using Boolean operators, namely "AND" and "OR" in conjunction with the keywords across the selected databases. The utilization of keywords occurred as follows:

Outcomes

"Functional outcomes" OR "Function*" OR "Use*" OR "Useful outcomes" OR "practical outcomes" OR "Operat*" OR "outcome*"

Tibia shaft fractures

"Tibia shaft fracture*" OR "Tibia fracture*" OR "Tibia shaft crack*" OR "Tibia crack*" OR "Tibia shaft discont*" OR "Tibia discont*" OR "Tibia shaft fragment*" OR "Tibia fragment*"

Nail

"Solid nail*" OR "SIGN nail*" OR "Hollow nail*" OR "Standard nail*" OR "intramedullary nail*"

A search of the gray literature was conducted in addition by going through the WHO registry, book of abstracts from various orthopaedic conferences as well as the Openmed and BASE databases.

Study selection

After retrieving studies through the search, they were gathered and organized using the Rayyan tool for systematic reviews. This marked the primary stage of screening and sorting out the collected studies. The review process involved two independent reviewers who assessed the titles and abstracts of the studies in this stage. Disagreements between the reviewers were resolved by consulting a third reviewer (**Figure 1**). The secondary stage aimed to determine the relevance and suitability of the remaining studies for inclusion in the review. Full texts of articles retrieved were read during this stage to access their eligibility (**Table 1**). The selection of studies was based on specific eligibility criteria, which were as follows:

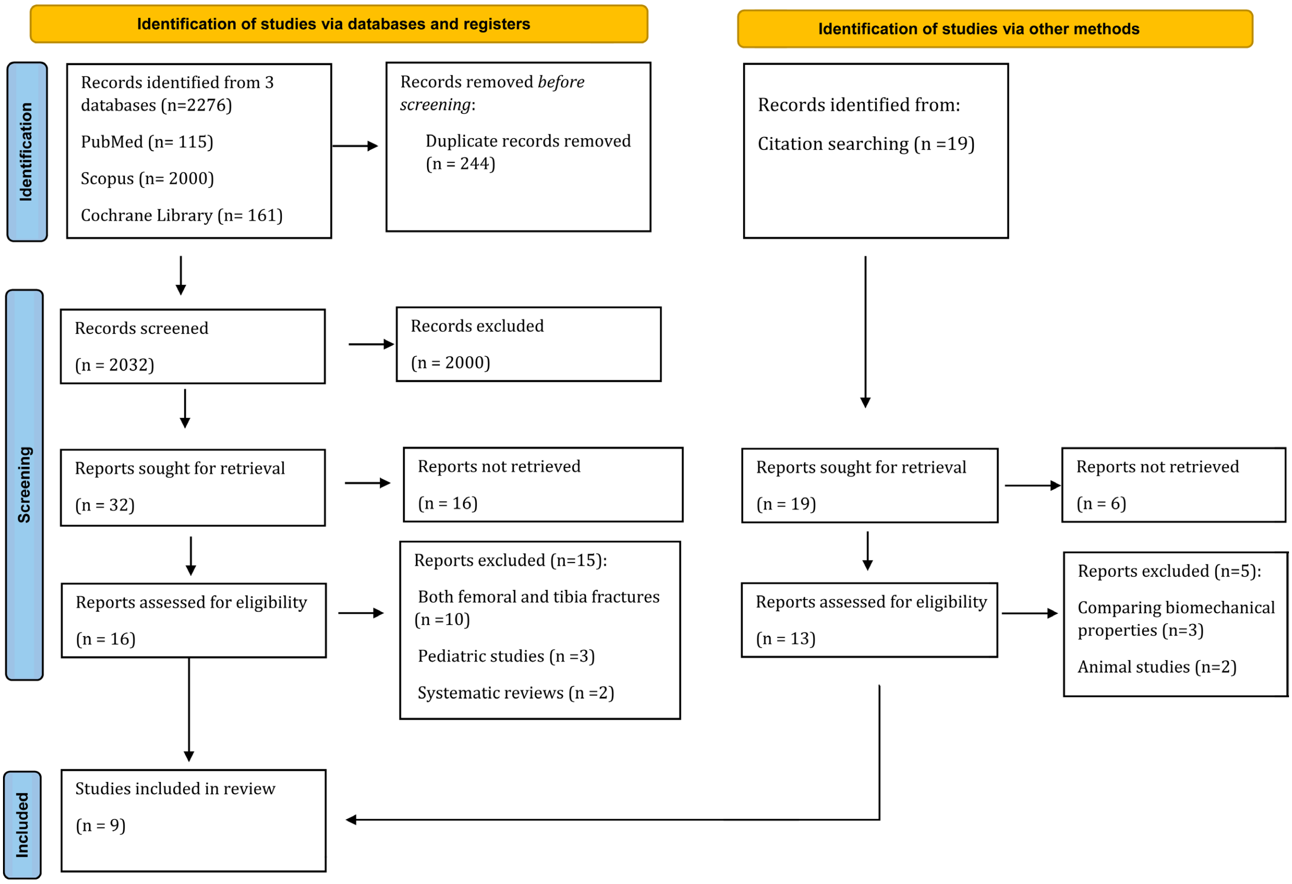

Figure 1. Identification of studies via databases and registers.

Table 1. Eligibility criteria for study selection.

PICO	Inclusion Criteria	Exclusion Criteria
Population	• Studies with skeletally mature populations (16 years) with tibia shaft fractures treated with solid/hollow nails.	• Studies with skeletally immature population (<16 years).
Intervention	• Tibia nailing with solid locked, intramedullary nails.	• Tibia nailing with solid unlocked intramedullary nails. • Tibia nailing with polymethylmethacrylate (PMMA) nails.
Comparison	• Tibia nailing with hollow locked nails.	• Tibia nailing with hollow unlocked nails.
Outcomes	• average duration of surgery (minutes). • rate of surgical site infection after treatment. • delayed union rates after fixation. • Non-union rates after surgery.	• Anterior knee pain rates after surgery.

2.3. Data Extraction and Analysis

The review process followed the guidance provided by the Centre for Reviews and Dissemination in order to ensure a systematic and rigorous approach [43]. Two independent researchers conducted the data extraction and analysis in accordance with these guidelines. The data extracted from the selected papers were synthesized using a combination of pooling of results, tests of statistical difference (t-test for normally distributed data and chi-square for categorical data) and narrative synthesis methods. The resulting findings were then summarized and presented based on the outcomes observed in fractures treated with SIGN nails in comparison to those treated with hollow nails.

The following data were extracted from each study:

1) Study design.

2) Sample size.

3) Setting and population.

4) Classification of fractures.

5) Type of nail used.

6) Findings on the duration of surgery, union rates and surgical site infections.

2.4. Critical Appraisal of Studies

Studies used in the reviews comprised both non-randomized and randomized trials. The non-randomized trials were critically appraised using the Methodological Index for Non-Randomized Studies (MINORS) tool.

The MINORS tool includes a set of items that assess the methodological aspects of non-randomized studies. These items cover eight domains: study aim, inclusion of consecutive patients, prospective data collection, endpoints appropriate to the study aim, unbiased assessment of the study endpoint, follow-up period appropriate to the study aim, loss to follow-up less than 5%, and prospective calculation of the study size. Each item is scored on a 0 - 2 scale, with 0 indicating that the item is not reported, 1 indicating that the item is reported but inadequate, and 2 indicating that the item is reported adequately. In addition to the MINORS checklist, the tool includes four additional items for assessing the reporting quality of the study. These items evaluate the clarity of the study objectives, the description of patient characteristics, the interventions or exposures, and the outcomes. Each item is scored on a 0 - 2 scale, similar to the checklist items.

Below are the scores from the assessment of the six non-randomized controlled trials (**Table 2**):

Table 2. MINORS score for non-randomized trials.

Study	Methodological items												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Khan *et al.* (2013)	2	2	2	2	1	2	2	1	0	1	0	0	15
Shah *et al.* (2004)	2	2	1	2	1	2	2	0	0	1	1	0	14
Nambiar *et al.* (2018)	2	2	2	2	1	2	2	1	0	1	1	0	16
Acharya *et al.* (2019)	2	2	2	2	2	2	2	2	1	2	2	1	22
Mathur *et al.* (2020)	2	2	0	1	1	1	2	2	2	1	1	1	16
Deleanu *et al.* (2014)	2	2	1	1	2	2	2	1	1	2	2	2	20

Methodologic items are as follows: 1) a clearly stated aim; 2) inclusion of consecutive patients; 3) prospective collection of data; 4) endpoints appropriate to the aim of the study; 5) unbiased assessment of the study endpoint; 6) follow-up period appropriate to the aim of the study; 7) loss to follow-up, which is less than 5%; 8) prospective calculation of the study size; 9) an adequate control group; 10) contemporary groups; 11) baseline equivalence of groups; and 12) adequate statistical analyses [44].

Three out of the six non-randomized trials did not report an adequate control group. Half of the non-randomized trials also failed to provide adequate statistical analysis. Other parameters were mainly reported adequately by the non-randomized controlled trials.

The randomized trial was assessed as follows (**Table 3**).

3. Results

3.1. Search Statistics and Analysis

The initial search on the databases yielded a total of 2276 papers, and an additional 19 papers were found through citation searching. Among them, 244 papers were identified as duplicates and subsequently removed, leaving 2051 papers for further evaluation. The screening process consisted of two steps: primary screening and secondary screening. During the primary screening, the titles and abstracts of the studies were reviewed to determine their relevance for inclusion in the review. In cases where the titles were not sufficient to determine the focus of the study, the abstracts were examined to ascertain the study's scope. Following the primary screening, 2003 papers were excluded from further consideration. The remaining 48 papers underwent secondary screening, where they were assessed based on the predefined inclusion and exclusion criteria for the review. As a result of the secondary screening, a total of 9 studies were identified as meeting the eligibility criteria for inclusion in the review.

3.2. Characteristics of Included Studies

Studies were conducted in 5 countries: Nepal, Pakistan, Romania, Tanzania, and India. Three (3) studies were conducted in Nepal [30] [39] [45]. One study was conducted in Pakistan [46]. Three studies were conducted in India [47] [48] [49].

Table 3. Methodological assessment of randomized trial.

Study	Risk of bias						
	Random sequence generation	**Allocation concealment**	**Blinding of participants and personnel**	**Blinding of outcomes assessment**	**Incomplete outcome data**	**Selective reporting**	**Other bias**
Maharjan *et al.* (2021)	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear risk	Unclear risk
Haonga *et al.* (2019)	Low risk	Low risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
Sathis (2017)	Low risk	Low risk	Low risk	Unclear risk	Unclear risk	Low risk	Low risk

The remaining two studies were from Romania, and Tanzania respectively [50] [51]. Shah *et al.* and Mathur *et al.* did not clearly state the study design used in the study so extracting this information was not possible [39] [48]. Maharjan *et al.* employed a parallel design randomized trial, Acharya *et al.* conducted a retrospective observational study, and Deleanu *et al.* employed a prospective observational design [30] [45] [50]. Haonga *et al.* and Sathis conducted a prospective randomized control study [51] [49]. Khan *et al.* was a case series, and Nambiar *et al.* (2018) employed a prospective study design [46] [47].

A total of 507 participants were involved in all studies with studies involving both genders. The mean ages of participants ranged from 26 to 36.4 years. Six (6) studies used participants with both closed and open fractures of the tibia [30] [45] [46] [47] [49] [50]. Three studies used participants with only open fractures [39] [51] [48]. Eight studies employed the Gustilo-Anderson classification system for open fractures [30] [39] [45]-[50]. Open fractures in studies by Khan *et al.*, Deleanu *et al.* and Nambiar *et al.* were Gustilo I and II [46] [47] [50]. Maharjan *et al.* used participants with Gustilo I open fractures, Acharya *et al.*, Mathur *et al.* and Sathis used participants with Gustillo I, II and IIIa, Shah *et al.* used participants with Gustilo I, II, IIIa and IIIb fractures [30] [45] [48] [49]. Two studies compared the usage of both solid SIGN nail and conventional hollow nail [30] [49]. One compared the solid SIGN nail with external fixator [51]. Two studies involved only hollow nails [47] [48] while three (3) studies used only the solid SIGN nail [39] [45] [46]. Deleanu *et al.* compared reamed and unreamed IM locked nailing however, the unreamed group was operated on with SIGN nail and the reamed were treated with a hollow nail [50].

3.3. Surgical Procedure and Duration

Studies by Maharjan *et al.* and Nambiar *et al.* presented details of the surgical procedures each used as operative interventions [30] [47].

According to Maharjan *et al.*, surgeries were conducted on supine patients using a trans patellar approach, and tourniquets were not used during reaming [30]. One group received a hollow tibial interlocking nail, while the other group received a solid SIGN nail. The mean (SD) time for the surgery in minutes were 94.8 (14.57) for the hollow nail group and 82.0 (12.36) for the solid nail group [30].

Nambiar *et al.* using hollow nail reported that, in the operating room, with appropriate anaesthesia and sterile precautions in place, the surgical area was prepared and covered. The average duration of surgery was 82 minutes, ranging from 70 - 92 minutes [47].

Deleanu *et al.* also reported that the surgeries were performed by six orthopaedic surgeons and participants were operated using the transtendinous approach. The average length of surgery was reduced for the SIGN group, with a mean duration of 43 mins (SD 18), in contrast to 55 mins (SD 27) for the hollow nail group [50].

Test of Statistical Difference

Compiling findings from the review, the mean duration of surgery gathered from each review is presented in **Table 4.** An independent sample t-test revealed that the difference in means of the two groups were not statistically significant.

3.4. Surgical Site Infection (SSI)

Seven studies reported on rates of surgical site infections comprising superficial and deep infections [30] [39] [45] [47] [48] [49] [50]. In one (1) instance of solid SIGN nailing, there was a deep surgical site infection that persisted for three (3) months, necessitating debridement and the administration of intravenous (IV) antibiotics [30]. Nambiar *et al.* recorded two (2) cases of superficial infection (5.71%) [47]. Finally, two cases of superficial infections were reported by Shah *et al.* in Grade II open fractures, which were effectively managed using antibiotics [39]. In the case of a Grade IIIB fracture, there was 1 instance of a deep infection, which was resolved through a series of debridement procedures and antibiotic therapy [39]. According to Acharya *et al.*, superficial wound infection necessitating a prolonged course of suitable intravenous antibiotics for healing was observed in three patients (2.9%) with Gustilo Anderson type IIIA open fractures [45]. Deleanu *et al.* reported no SSI in both solid and hollow nail groups, however Mathur *et al.* recorded 4 cases of infection [48] [50]. Sathis also recorded 4 cases of SSI in the solid nail group and 3 cases in the hollow nail group [49].

Test of Statistical Difference

The proportion of SSI cases reported by studies in both groups was pooled for a test of statistical difference with chi-square. The statistical analysis reported that the difference between the rate of SSI in both groups is not statistically significant (Refer to **Table 5**).

3.5. Union

After surgical intervention, follow-ups were conducted in all studies to study the outcomes of participants such as duration of union [30] [39] [45]-[51]. Maharjan *et al.* adopted the radiological union score for tibia (RUST) in assessing union [30]. Solid SIGN nail group had a higher RUST score than the hollow nail group. The score in the order of 6 weeks, 12 weeks, 24 weeks, and 52 weeks were

Table 4. Test of statistical difference between duration of surgery.

Author (Year) - Nail group	Mean duration of surgery (mins)	t-value(p-value)
Maharjan *et al.* (2021) - Solid	82	
- Hollow	94.8	
Nambiar *et al.* (2018) - Hollow	82	−0.704 (0.541)
Deleanu *et al.* (2014) - Solid	43	
- Hollow	55	

Table 5. Test of statistical difference between rates of SSI.

Author (Year) – Nail group	Proportion (%)	Chi-square (p-value)
Shah *et al.* (2004) - Solid	8.3	
Nambiar *et al.* (2018) - Hollow	5.7	
Maharjan *et al.* (2021) - Solid	3.3	
- Hollow	0	
Acharya *et al.* (2019) - Solid	2.9	7.333 (0.395)
Deleanu *et al.* (2014) - Solid	0	
- Hollow	0	
Mathur *et al.* (2020) - Hollow	20.0	
Sathis (2017) - Solid	5.6	
- Hollow	4.2	

5.5, 6.7, 10.1 and 11.7 for the SIGN nail group. In the same order of weeks, the scores were 5.3, 6.4, 9.9 and 11.3 for the hollow nail group [30].

Nambiar *et al.*: Among their patients, the highest proportion, that is 31.43% (n = 11), displayed indications of radiological union within a timeframe ranging from 18 weeks to 19 weeks (with an average of 18.2 weeks). There were no direct reports of delayed and/or non-union among participants, however, the range of union time varied between 14 and 22 weeks [47].

Khan *et al.* described union between 7 to 9 months as delayed, and fractures which were not united after 9 months as non-union. They reported the mean duration of union was 163 ± 30.6 days (23.3 weeks). In the evaluation of radiological union, 66% of patients displayed the presence of bridging callus at the fracture site after 3 months. After 6 months, a union was observed in 82% of patients. By 9 months, 14% of patients exhibited homogenous bone at the fracture site, while 78% of patients displayed extensive bone trabeculae spanning the fracture, making the fracture line difficult to discern. Out of the total, 82% of patients (41 patients) achieved union within 6 months, while 10% (5 patients) experienced delayed union, and 8% (4 patients) encountered non-union. The overall union rate was, however, 92% [46].

Shah *et al.* also defined delayed union as lack of significant union within 6 months postoperatively and non-union as having no signs of union after 8 months. Radiographic evidence of union was also defined by the presence of bridging callus and clinical union by the ability to support body weight without walking aids [39]. They reported that within 6 months, a total of 31 fractures (86.1%) successfully achieved union, with an average time of 22 weeks. Out of all cases, there were four instances of delayed union and one case of non-union. Among the delayed unions, three eventually united within 8 months without any intervention, while one required bone grafting at the 6 months and achieved healing by 9 months. Similarly, the non-union case was also treated with bone grafting, resulting in eventual healing and a positive outcome. Regarding the severity grading, grade I fractures had a mean time to union of 24 weeks, grade II fractures took approximately 20 weeks, and grade III fractures required 32 weeks. Interestingly, there was no correlation observed between the severity of open fractures (grade I-IIIA) and the time taken to achieve union (P = 0.02). However, more complex grade IIIB fractures exhibited a longer union time compared to other grades. [39].

Delayed union was observed in 6 cases, accounting for 5.8% of the total, while there were no instances of non-union reported by Acharya *et al.* [45]. All patients in the intramedullary nail group demonstrated indications of bone union, with 8% of patients experiencing delayed union, according to Haonga *et al.* [51]. Mathur *et al.* recorded only 1 case of delayed union [48]. Sathis also recorded 1 case of delayed union in the hollow nail group and no case of either delayed or non-union in the solid nail group [49].

Deleanu *et al* recorded a single case of non-union each in both groups, which were managed through the use of exchange nailing and autologous bone grafting [50].

Test of Statistical Difference

Seven studies reported directly on the rate of delayed and non-union among participants [39] [45] [46] [48] [49] [50] [51]. Reports from these studies were pooled and added for each nail group. A chi-square test to ascertain the statistical difference revealed that the difference in the rates of delayed and non-union was not statistically significant. (Refer to **Table 6**).

4. Discussion

The current review aimed to compare the functional outcomes of adult tibia diaphyseal fractures treated with solid SIGN nails to that of hollow nails. Nambiar *et al.*, Deleanu *et al.* and Maharjan *et al.* reported different durations of surgery for both two groups of interest (groups treated with solid nails and those with hollow nails) [30] [47] [50]. The mean duration of surgery reported by

Table 6. Test of statistical difference in rate of delayed and non-union.

Author (Year) - Nail group	Proportion of delayed + non-union (%)	Chi-square (p-value)
Khan *et al.* (2013) - Solid	18.0	
Shah *et al.* (2004) - Solid	13.8	
Haonga *et al.* (2019) - Solid	8.0	
Acharya *et al.* (2019) - Solid	5.8	
Deleanu *et al.* (2014) - Solid	2.3	9.0 (0.342)
- Hollow	2.2	
Sathis (2017) - Solid	0	
- Hollow	1.4	
Mathur *et al.* (2020) - Hollow	5	

Table 7. Summary of study characteristics.

Author (Year)	Study design	Sample size	Setting and Population	Classification of fractures	Type of nail used	Summary of results
Maharjan *et al.* (2021)	Randomized trial	60 participants	Adults with fracture of leg presenting within one year to a university based tertiary hospital in Nepal.	Closed and Gustilo grade I	Both solid and hollow	-One case of deep infection was recorded. -Longer duration of surgery in hollow nail group -SIGN nailing had a higher RUST score compared to hollow nailing.
Khan *et al.* (2013)	Case series	50 participants	Patients who reported in 2 weeks at the Department of Orthopaedic and Spine Surgery, Ghurki Trust Teaching Hospital, Lahore Medical and Dental College, Lahore.	Closed and Gustilo grade I and II	Solid	-58% of the patients achieved full weight-bearing independently within 3 months. - Mean duration of union was 163 ± 30.6 days (23.3 weeks) - Two (2) cases of interlocking screws breakage.
Shah *et al.* (2003)	Not stated	32 participants	Open fractures of the tibia treated at a hospital in Nepal between March 2000 and April 2002.	Gustilo grade I, II, IIIa and IIIb	Solid	- Two (2) cases of superficial infections in grade II and one (1) deep infection in grade IIIb - A total of 31 fractures. (86.1%) successfully achieved union within 6 months. - Three (3) cases of malunion.
Nambiar *et al.* (2018)	Prospective study	35 participants	Patients with tibial diaphyseal fractures treated with intramedullary interlocking nail at Sree Balaji Medical College and Hospital, India.	Closed and Gustilo grade I and II	Hollow	-Average duration of surgery was 82 minutes, ranging from 70 - 92 minutes. - Two (2) cases of superficial infection. - The highest proportion, that is 31.43% (n = 11), displayed indications of radiological union within a timeframe ranging from 18 weeks to 19 weeks (with an average of 18.2 weeks).
Acharya *et al.* (2019)	Retrospective observational study	104 participants	Patients with tibial diaphyseal fractures treated with SIGN nail at Department of Orthopedics and Trauma Surgery, Patan Hospital (PH), Patan Academy of Health Sciences (PAHS), Lalitpur, Nepal.	Closed and Gustilo grade I, II and IIIa	Solid	- Six (6) cases (5.8%) of delayed union and zero non-union. - Three patients (2.9%) who had Gustilo Anderson type IIIA open fractures experienced a superficial wound infection, which needed an extended duration of suitable intravenous antibiotics for recovery.

Continued

Deleanu *et al.* (2014)	Prospective observational design	84 participants	Patients with recent open and closed tibial shaft fractures treated with reamed or unreamed intramedullary locked nail fixation at a tertiary hospital in Romania.	Closed and Gustilo grade I and II	Both solid and hollow	- The mean duration of surgery was shorter for the SIGN nail group with 43 min (SD 18) compared to 55 (SD 27) in the hollow nail group. - In both groups, one case of non-union was observed, and they were treated using exchange nailing and autologous bone grafting. There were no reports of delayed union. - No cases of SSI were reported.
Sathis (2017)	Prospective randomized control study	72 participants	Adult patients with tibia shaft fractures treated with intramedullary nailing at the trauma unit of a tertiary teaching hospital attached to Kannur Medical College, India.	Closed and Gustilo grade I, II and IIIa	Both solid and hollow	- One case of delayed union in the hollow nail group and no cases in the solid nail group. - Four (4) cases of SSI in the solid nail group and three (3) cases in the hollow nail group.
Haonga *et al.* (2019)	Prospective randomized control study	50 participants	Patients presenting with open diaphyseal tibial fracture at Muhimbili Orthopaedic Institute (MOI) in Dar es Salaam, Tanzania.	AO/OTA Type 42 open fractures	Solid	- All patients in the intramedullary nail group demonstrated indications of bone union, with 8% of patients experiencing delayed union ($p = 0.05$).
Mathur *et al.* (2020)	Not stated	20 participants	Patients having compound tibial shaft fracture at the Department of Orthopaedics at Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, India.	Gustilo grade I, II and IIIa	Hollow	- One (1) case of delayed union. - Four (4) cases of infection.

Nambiar *et al.* of a hollow nail group was similar (82mins) to the duration reported by Maharjan *et al.* of the solid nail group [47] [30]. However, Deleanu *et al.* reported durations that were very different from the former studies (43 mins and 55 mins) [50]. The reported durations in two studies fell within the range commonly reported in the literature for tibial fracture surgeries, which generally falls between 60 mins to 120 mins [52] [53]. Findings indicated that there was no statistically significant difference in the mean duration of surgery between the two groups. Existing literature on surgical duration has shown mixed results across various surgical procedures and patient populations. Some studies have reported statistically significant differences in tibial shaft fracture surgical duration between different groups [54] [55]. Other studies have reported findings similar to the current study, where no statistically significant difference in surgical duration was observed between different groups [56] [57]. It is important to note that several factors can influence the duration of surgery. The complexity of the procedure, the surgeon's experience, the patient's comorbidities, and the availability of surgical equipment and resources are just a few examples [58] [59] [60]. The existing literature suggests that these factors can contribute to variations in surgical duration across different studies and patient populations. Considering these factors, the current findings of no statistically significant difference in surgical duration between the two groups should be interpreted cautiously. It is worth considering the limitations of the current review in comparison to the existing literature. The review process itself introduces potential biases, as the compilation of findings from multiple reviews may not fully capture the nuances and variability across individual studies. Additionally, the specific patient populations, surgical procedures, and methodologies employed in the reviewed studies may differ from those in existing literature, limiting direct comparisons.

The review presented the incidence of surgical site infections in both solid SIGN and hollow nail groups. However, no case of deep surgical site infections was reported by the studies with the hollow nail group [30] [47]. On the other hand, there were cases of superficial surgical site infections in both groups [39] [47]. Animal studies by Melcher *et al.* and Horn *et al.* reported an infection rate for the hollow nail group to be almost double that of the solid nail group [61] [62]. This has led to the assumption that the dead space and greater implant surface of the solid nail play a role in resisting bacterial infections because bacterial adhesion to a surface is important in causing infections [61] [62] [63]. The findings of the review however are inconsistent with earlier studies considering the fact that there were fewer infections reported in the hollow nail groups. It's important to note that these findings are limited to the specific studies mentioned and may not provide a comprehensive understanding of the overall risk of surgical site infections in tibial fracture surgeries. Additionally, factors such as patient characteristics, surgical techniques, infection prevention measures, and adherence to sterile protocols can all influence the occurrence of infections [64]. Therefore, a thorough analysis of multiple studies is necessary to draw definitive conclusions regarding the association between nail type and surgical site infection rates in tibial fracture surgeries. The finding that the rate of SSI in tibia shaft fracture treatment is not statistically significant between the groups using the SIGN and hollow nail techniques is an important result. This finding suggests that both treatment approaches may have similar infection rates and can be considered viable options for managing tibia shaft fractures. Surgical site infection is a significant concern in orthopaedic surgery, as it can lead to prolonged hospitalization, increased healthcare costs, and potentially adverse outcomes for patients [65]. Therefore, numerous studies have investigated infection rates and compared different surgical techniques to identify the most effective approaches for managing tibia shaft fractures [54] [66] [67] [68]. The finding in question suggests that when pooling the results from studies utilizing both the SIGN and hollow nail techniques, there is no statistically significant difference in the rate of

SSIs between the two groups. However, it is crucial to note the limitations of the present analysis. Factors such as the heterogeneity of the included studies, variations in surgical protocols, patient populations, and follow-up durations can influence the overall findings [69] [70].

Comparing the timeframes and union rates between the hollow and solid nail groups, it was observed that most of the hollow nail group achieved union earlier (around 5 months) than the majority of the solid nail group (around 6 months). However, the difference in time to achieve union between the two groups was not statistically analysed in the given studies. Considering the average duration of union of about 6 months (approximately 24 weeks), the RUST scores reported by Maharjan *et al.* also indicated very good scores for both groups [30]. The scores were slightly different with the solid nail group having a 10.1 score and the hollow nail group with 9.9. In as much as these scores do not represent the full union of fractures, they were very close and indicate that both groups achieved significant union of fractures around that timeframe. There were different operational definitions for union, delayed union and non-union as described by different studies, however, consistent with Nork *et al.* and P. Ashok Reddy, the duration of union was reported around between 20 - 24 weeks [71] [72]. It is also worth noting that various factors can influence the time to achieve union, including fracture severity patient characteristics, surgical techniques, and the postoperative care [73]. Therefore, a holistic assessment of multiple studies is necessary to draw definitive conclusions regarding the association between nail type and time to achieve union in tibial fracture surgeries. The findings of the review indicate that there is no statistically significant difference in the rates of delayed and non-union between the two nail groups. This suggests that both types of nails are equally effective in promoting bone healing in tibia shaft fractures. Consistent with the findings of the study, a systematic review and metanalysis by Xin *et al.* compared various types of intramedullary nailing and reported no significant difference in the rates of delayed and non-union between reamed and unreamed nailing groups [74]. The lack of statistical significance in the rates of delayed and non-union between the SIGN nail and hollow nail groups suggests that other factors, such as patient characteristics, fracture patterns, surgical technique, and postoperative management, may play a more significant role in the outcome of tibia shaft fracture treatment [33] [75]. It is important to note that while the review's findings indicate no statistical difference, it does not necessarily mean that there is no clinical difference between the two nail groups. Other factors, such as the ease of surgical technique, implant cost, and surgeon's experience, may still influence the choice of nail type in clinical practice [76] [77] [58]. Further research and larger studies may provide additional insights into these aspects.

5. Limitations of Study

- The study included articles published in only the English language and may have missed articles in other languages.

- Most of the studies used were not comparative studies, hence the inability to accurately state definitive conclusions and estimate effect sizes.
- Three out of the six non-randomized trials did not report an adequate control group.
- Half of the non-randomized trials also failed to provide adequate statistical analysis.

6. Conclusions

The current review compared the functional outcomes of adult tibia diaphyseal fractures treated with solid SIGN nails to those treated with hollow nails. The duration of surgery and incidence of surgical site infections were assessed, as well as time to achieve union, rates of delayed and non-union. The findings of the included studies were analysed and compared to the broader literature.

The review found that the duration of surgery varied between studies but fell within the commonly reported range for tibial fracture surgeries. The review suggests that the incidence of infections may be influenced by various factors and further analysis of multiple studies is needed. Similarly, there were variations in the reports of rates of SSI, delayed and non-union. However, there was no statistical difference in the various reports by studies. However, when assessing these outcomes, it is important to consider multiple factors, such as surgical techniques, patient characteristics, and postoperative care.

Further research and analysis of multiple studies are necessary to draw definite conclusions and better understand the association between nail type and outcomes in tibial fracture surgeries. In addition, future studies should have a clearly defined control group for adequate comparative analysis and provide a comprehensive comparative analysis of the data.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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