Clinical/Basic Science Research Article

Intramedullary nailing versus external fixation for open tibia fractures in Tanzania: a cost analysis

Heather J. Roberts, MD[a,*], Claire A. Donnelley, MD[a], Billy T. Haonga, MD[b], Erik Kramer, MD[c],
Edmund N. Eliezer, MD[b], Saam Morshed, MD, PhD[a], David Shearer, MD, MPH[a]

Abstract

Objectives: Open tibia fractures pose a clinical and economic burden that is disproportionately borne by low-income countries. A randomized trial conducted by our group showed no difference in infection and nonunion comparing 2 treatments: external fixation (EF) and intramedullary nailing (IMN). Secondary outcomes favored IMN. In the absence of clear clinical superiority, we sought to compare costs between EF and IMN.

Design: Secondary cost analysis.

Setting: Single institution in Tanzania.

Patients/Participants: Adult patients with acute diaphyseal open tibia fractures who participated in a previous randomized controlled trial.

Intervention: SIGN IMN versus monoplanar EF.

Main Outcome Measurements: Direct costs of initial surgery and hospitalization and subsequent reoperation: implant, instrumentation, medications, disposable supplies, and personnel costs.

Indirect costs from lost productivity of patient and caregiver.

Societal (total) costs: sum of direct and indirect costs.

All costs were reported in 2018 USD.

Results: Two hundred eighteen patients were included (110 IMN, 108 EF). From a payer perspective, costs were \$365.83 (95% CI: \$332.75–405.76) for IMN compared with \$331.25 (\$301.01–363.14) for EF, whereas from a societal perspective, costs were \$2664.59 (\$1711.22–3955.25) for IMN and \$2560.81 (\$1700.54–3715.09) for EF. The largest drivers of cost were reoperation and lost productivity. Accounting for uncertainty in multiple variables, probabilistic sensitivity analysis demonstrated that EF was less costly than IMN from the societal perspective in only 55% of simulations.

Conclusions: Intramedullary nail fixation compared with external fixation of open tibia fractures in a resource-constrained setting is not associated with increased cost from a societal perspective.

Keywords: cost analysis, low-income country, open fracture, orthopaedic trauma

1. Introduction

The incidence of open tibia fractures is rising in developing countries, largely due to increasing road traffic and associated injuries.[1,2] Open tibia fractures are a surgical emergency, with appropriate management including early antibiotic prophylaxis, surgical wound debridement, and fracture stabilization.[3] Even with appropriate management, deep infection occurs in up to 40% of cases and is strongly associated with the development of chronic osteomyelitis, nonunion, and the need for amputation.[4–6] These complications have been shown to have a greater negative effect on quality of life than myocardial infarction, stroke, or end-stage arthritis.[7]

While both intramedullary nailing (IMN) and external fixation (EF) are acceptable treatment options for definitive fixation of open tibia fractures,[8] outcome studies tend to favor IMN, with a recent meta-analysis demonstrating reduced malunion and need for reoperation following IMN.[9] Our group previously conducted a randomized controlled trial comparing IMN to EF for open tibial shaft fractures in Tanzania.[10] This trial demonstrated no difference between groups in the primary outcomes of infection or nonunion. Secondary outcomes, including health-related quality of life, alignment, and radiographic healing at 6 weeks, favored IMN.

DS serves on the Board of Directors of SIGN Fracture Care International, the non-profit company that designed and manufactured the implant used in the clinical trial from which this study is derived. In that capacity he receives no royalties or other compensation.

No funding was received for this study.

This work has not been previously presented or published.

The authors have no conflicts of interest to disclose.

This article was partially funded by an OTA Award, based on the merit of the submission.

[a] Department of Orthopaedic Surgery, Institute for Global Orthopaedics and Traumatology, University of California San Francisco, San Francisco, CA, [b] Muhimbili Orthopaedic Institute, Dar es Salaam, Tanzania, [c] Yale University School of Medicine, New Haven, CT

[*] Corresponding author. Address: University of California San Francisco, San Francisco, CA 94147; e-mail: address: Heather.Roberts@ucsf.edu (H. Roberts).

OTAI (2021) e146

Received: 1 June 2020 / Accepted: 20 June 2021

http://dx.doi.org/10.1097/OI9.0000000000000146

However, the cost difference between IMN and EF is not well established, particularly in a low-resource setting. The choice of treatment strategy may be influenced by implant cost. Orthopaedic surgeons in Africa, South America, and Asia are more likely to choose EF over IMN compared with counterparts in North America, Europe, or Australia.[9] A recent survey of orthopaedic trauma surgeons in Latin America suggested that implant cost is a driver of treatment choice.[11] In addition, direct costs due to recurrent hospitalizations and need for multiple surgeries, as well as indirect costs due to loss of productivity for patients and family members, are substantial.[1,12]

In the absence of clear clinical superiority, and given the economic impact of open tibia fractures in resource-austere settings, we sought to compare costs between EF and IMN in Tanzania.

2. Methods

This secondary analysis utilized data collected in a prior randomized controlled trial conducted at a tertiary referral hospital in Dar es Salaam, Tanzania from December 2015 to March 2017.[10] Patients age ≥18 years of age with an AO/Orthopaedic Trauma Association type 42 open tibia fracture who presented within 24 hours of injury were randomized to treatment with an intramedullary nail or an external fixator. Patients requiring flap coverage (Gustilo-Anderson type IIIB) or with vascular injury (Gustilo-Anderson type IIIC) were excluded. Enrolled patients were followed at 2, 6, 12, 26, and 52 weeks postoperatively. For the purposes of this study, only patients with follow-up at 52 weeks were included. Baseline and postoperative employment were collected.

All patients received intravenous ceftriaxone at the time of hospital presentation. All patients were managed with irrigation and debridement followed by bony stabilization. Intraoperative fluoroscopy was not used for any case. The intramedullary implants used in this study were hand-reamed solid interlocking nails (SIGN Fracture Care International, Richland, Washington). The external fixators used in this study involved 2 Schanz pins in the proximal segment and 2 in the distal segment, each connected to a single stainless steel bar with pin-to-bar clamps (Samay Surgical, Gujarat, India). External fixators were removed in clinic at regularly scheduled postoperative visits.

The clinical trial was approved by the University of California, San Francisco and the Tanzanian National Institutes of Medical Research ethical review committees.

2.1. Direct medical costs

Direct medical costs included costs of personnel, supplies, medications, and implants. To estimate personnel costs associated with the operative procedure, the surgical time was recorded for all patients in the clinical trial. The cost per minute of surgical time was estimated using data from a prior study of intramedullary nailing for femoral shaft fractures that used a rigorous time and motion analysis to directly observe personnel time and disposable supplies for each case.[13] The procedure was divided into intraoperative time, defined as the time from patient entry to the operating room to patient exit from the operating room, and combined preoperative and postoperative time, defined as the time spent in the preoperative or postoperative area before and after the procedure. Each member of the medical team was classified into 1 of 7 categories: attending anesthesiologist, nurse anesthetist, attending surgeon, resident physician, nurse, radiology technician, or hospital assistant. A trained research assistant recorded the amount of time each personnel type spent in each phase of the procedure. Person-hours for each personnel type were summed for each phase. It was assumed that the personnel involved were the same for IMN of a femoral shaft fracture, IMN of an open tibia fracture, and EF of an open tibia fracture. Further, it was assumed that the personnel and time involved in the preoperative and postoperative time were similar across all procedures. Finally, person-hours for the intraoperative phase were scaled by average intraoperative time from the femur cases to each of the open tibia fracture treatments (SIGN-IMN and EF).

Personnel costs associated with the ward were determined directly from the clinical trial. Daily ward personnel costs were calculated separately for day shift (6A-6P) and night shift (6P-6A) due to different staffing structures. Average staff for each shift was divided by the number of patients present on the ward to generate staff person-hours spent per patient for each shift. Hospital overhead costs were calculated using the patient-day equivalent method, which uses annual hospital expenditures for administrative and ancillary staff to estimate costs per patient adjusted for length of stay.[14]

It was assumed that nonimplant disposable supplies and medications used for SIGN-IMN or EF of an open tibia fracture did not differ substantially from those used for IMN of a femur fracture. The quantities of nonimplant disposable supplies and medications used intraoperatively for femur IMN were directly observed and recorded by study staff. Associated costs were obtained from the hospital invoice list.

For each implant type, both production costs and hospital charges were determined. Production costs are used to calculate costs from a societal perspective, while hospital charges are used to calculate costs from a payer perspective. SIGN Fracture Care International (SIGN) is a nonprofit company that donates implants to hospitals in low- and middle-income countries, and use of the SIGN nail does not require fluoroscopy or power drills.[15] Therefore, the full manufacturing cost of the SIGN nail was used to calculate cost from a societal perspective; this production cost was obtained from the SIGN directly. From a payer perspective, the cost of the SIGN nail was near zero and included minimal costs related to shipping. This cost reflects hospital charges for the SIGN nail and was obtained from the hospital invoice list. The cost of the external fixator from both payer and societal perspective was assumed to be equal and was estimated using hospital charges. In addition, because the hospital reuses the same external fixator on subsequent patients after removal up to 3 times per set, external fixator implant costs for a single set (1 bar, 4 clamps, and 4 Schanz pins) were divided by the number of uses to determine per patient costs. The actual number of uses for each set was not recorded, but we assumed 3 uses per set based on the hospital guidelines. Instrumentation costs were assumed to be nondifferential between intramedullary nailing and external fixation, and were based on a 10-year lifespan with 300 cases performed per year using each set.

Reoperation costs were not directly recorded and are estimated from other studies that suggest that total costs of treatment for open tibia fractures complicated by infection or nonunion are 2 to 6.5 times the total costs of treatment for open tibia fractures without complications.[16–18] Reoperation costs were based off index operation costs for SIGN-IMN regardless of the initial group to which patients were randomized, as it was assumed that reoperation costs would not depend on index treatment and would not differ substantially between groups.

2.2. Indirect costs

Indirect costs result from lost productivity of the patient and caregivers due to the injury. Costs associated with lost productivity of the patient were calculated for patients who reported employment prior to injury; those with either formal or informal employment were included for this analysis. Employment was scored as a binary value at each follow-up time point. Using midpoints between follow-up visits before and after the follow-up time point, lost productivity was calculated as the sum of weeks with reported unemployment, with a maximum of 52 weeks.

Indirect costs associated with caregiver lost productivity were inferred from the prospective study of patients with femur fractures.[19] In Tanzania, patient family members or other caregivers provide important care to hospitalized patients, including provision of food, assistance with bathing and toileting, and other tasks. Caregivers were interviewed during the patients' hospitalizations. Number of visits, duration of visit, and time spent traveling to and from the hospital were recorded. Caregiver hours were assumed to be similar between patients with open tibia fractures and patients with femoral shaft fractures, and to be linearly associated with the length of the hospital stay.

The costs associated with lost productivity of patients and caregivers were calculated using a standardized wage for Tanzania, adjusted using purchasing power parity to 2018 USD.

2.3. Economic model

A simple decision tree was designed to capture direct and indirect costs associated with SIGN-IMN versus EF for adult patients with Gustilo-Anderson type I to IIIA open tibia fractures. Patients could enter into 1 of 3 outcome states: uncomplicated union, aseptic nonunion, or deep infection with or without nonunion (Fig. 1). Probabilities of outcome states for each treatment group and for undergoing reoperation were based on results from the randomized open tibia study. The time horizon for the model was 1 year; therefore, no discounting was applied. The model was run using TreeAge Pro 2019 (TreeAge Software, Williamstown, Massachusetts). All costs are adjusted for inflation and converted to 2018 USD.

The model was run from the payer and the societal perspective. In the clinical trial, many patients who were indicated for reoperation by an independent adjudication committee never underwent reoperation during the study follow-up period. Therefore, the model was run from each perspective for 2 scenarios: the actual reoperation rate observed in the study, and the indicated reoperation rate based on the adjudication committee. All patients who developed aseptic nonunion or deep infection were considered indicated for reoperation.

Finally, to estimate the cost differences between IMN and EF in places where the SIGN nail is not available, the model was run from both payer and societal perspectives substituting the SIGN implant costs with those of a tibial IMN provided by Samay Surgical, the same company that made the external fixator used in this study. Based on company price listings, these costs are estimated to be $31. Implant costs from the payer and societal perspectives were assumed to be equal. All other model inputs, such as surgical time, complication rates, and return to work, were assumed to be equal to SIGN-IMN in this scenario.

For cost of reoperation, a uniform distribution ranging from 2 to 6.5-fold the cost of the index operation was used. For outcome probabilities, a beta distribution was used. For all other cost inputs, a gamma distribution was used. To account for uncertainty in model parameters, probabilistic sensitivity analyses with 10,000 iterations were performed for each of the above 4 scenarios. One-way sensitivity analyses were performed to evaluate the influence of implant cost.

3. Results

A total of 221 patients from the randomized open tibia study reached 1 year follow-up, of whom 3 died from causes unrelated to their injury and were excluded from these analyses. One hundred ten patients were randomized to SIGN-IMN and 108 to EF. The majority of patients in both groups were male, in the third and fourth decades of life, reported working in the informal

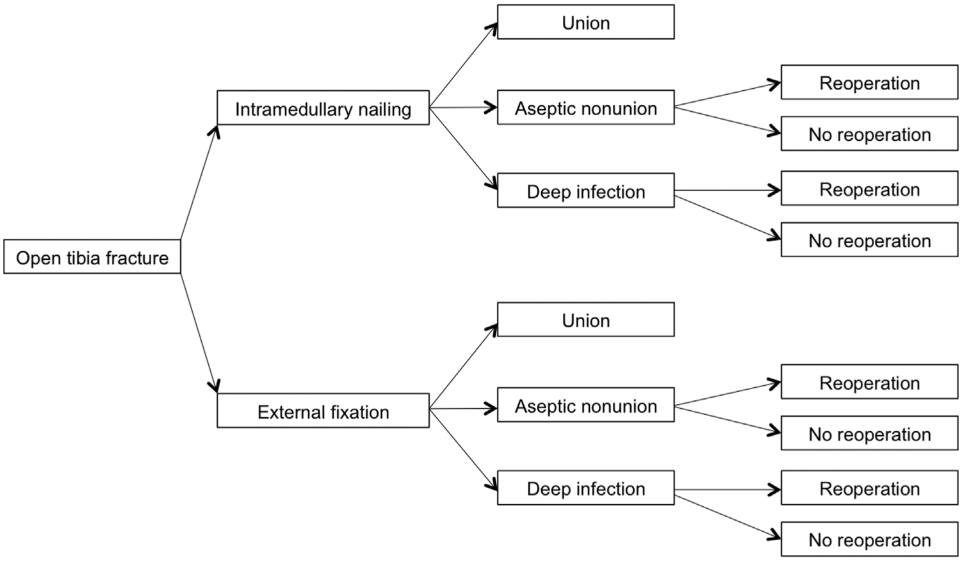

Figure 1. Cost analysis decision tree.

Table 1

Patient characteristics

	Intramedullary nailing (n=110)	External fixation (n=108)
Age (years), mean ± SD	33.4 ± 11.9	31.7 ± 9.6
Male sex, n (%)	97 (88.1)	89 (82.4)
No formal employment, n (%)	90 (81.8)	80 (74.1)
Mechanism of injury, n (%)		
Road traffic injury	103 (93.6)	102 (94.4)
Car	13 (11.8)	19 (17.6)
Motorbike	47 (42.7)	38 (35.2)
Pedestrian	42 (38.2)	43 (39.8)
Bicycle	1 (0.9)	2 (1.9)
Other	7 (6.4)	5 (4.6)
Current smoker, n (%)	16 (14.5)	24 (22.2)
Current alcohol use, n (%)	45 (40.9)	35 (32.4)
Body mass index, mean ± SD	25.2 ± 5.2	24.7 ± 4.6
Diabetes mellitus, n (%)	7 (6.4)	1 (0.9)
No medical insurance, n (%)	87 (79.1)	90 (83.3)
OTA classification, n (%)		
Type A	36 (32.7)	35 (32.4)
Type B	33 (30.0)	28 (26.0)
Type C	9 (8.2)	8 (7.4)
Wound length (cm), mean ± SD	3.7 ± 2.7	3.7 ± 2.4

sector prior to injury, and were injured in a road traffic injury (Table 1). Hospital length of stay averaged 3.7 days for the EF group and 3.1 days for the IMN group ($P = .16$).

The probability of each outcome state (union, aseptic nonunion, and deep infection) did not differ significantly between treatment groups (Table 2). While all patients with aseptic nonunion or deep infection were indicated to undergo reoperation, only a minority underwent reoperation. Probability of returning to work differed across treatment groups and outcome states, with highest rate of return to work among patients with uncomplicated union (Fig. 2). Costs associated with EF and SIGN-IMN, and associated data sources, are displayed in Table 3.

Outputs of the model are displayed in Table 4. When viewed from a payer perspective, such that indirect costs were not included and implant costs were equal to hospital charges, the cost of SIGN-IMN was significantly greater than the cost of EF when the actual reoperation cost was considered, by an average of $34.57 with a selection frequency for external fixation of 97.6%. One-way sensitivity analysis indicated that the threshold implant cost of EF assuming three uses per set was $45.94 for it to be less costly than SIGN-IMN. Only twelve of 41 patients with an indication for reoperation underwent reoperation. When the indicated reoperation rate was considered, the cost of SIGN-IMN was less than the cost of EF by an average of $20.68, and probabilistic sensitivity analysis favored SIGN-IMN over EF in 83.9% of iterations. One-way sensitivity analysis indicated that the threshold implant cost of IMN was $24.60 for it to be less costly than EF.

Table 2

Outcome and reoperation characteristics

	Intramedullary nailing (n=110)	External fixation (n=108)	*P* value
Operation duration (min), mean ± SD	102.4 ± 92.7	60.6 ± 23.4	<.0001
Hospital length of stay (d), mean ± SD	3.1 ± 1.6	3.7 ± 4.1	.15
Outcome, n (%)			.35
Union	91 (82.7)	86 (79.6)	
Aseptic nonunion	4 (3.6)	9 (8.3)	
Deep infection, with or without nonunion	15 (13.6)	13 (12.0)	
Actual reoperation, n (%)			.65
For aseptic nonunion	1 of 4 (25.0)	1 of 9 (11.1)	
For infection	2 of 15 (13.3)	1 of 13 (7.7)	

When viewed from a societal perspective, such that indirect costs and implant production costs were included, the cost of EF was lower than the cost of SIGN-IMN. When the actual reoperation rate was considered, the average difference in costs was $105.76, and probabilistic sensitivity analysis favored EF in 54.9% of iterations. When the indicated reoperation rate was considered, the difference in costs was $23.83, and probabilistic sensitivity analysis favored EF in 50.3% of iterations. This cost difference of $23.83 amounts to 0.76% of the standardized Tanzanian annual wage in 2018. To put this in the context of United States income, the same percentage of $63,179, the average US annual income in 2018, is $479.

When comparing analysis results using the Samay Surgical IMN (SS-IMN) in place of the SIGN nail, and assuming all other variables to be equal, the cost associated with SS-IMN compared with EF was higher from the payer perspective and lower from the societal perspective. From the payer perspective, SS-IMN on average cost $66.05 more than EF, with a selection frequency for EF of 99.96%. From the societal perspective, SS- IMN was on average $35.57 less costly than EF, with a selection frequency of 52.8%. From the societal perspective, SS-IMN is preferred over EF if the rate of aseptic nonunion after IMN is <7.5% as determined using one-way sensitivity analysis.

4. Discussion

This study is the first to our knowledge that compares costs of EF to IMN for the management of open tibial shaft fractures in a high volume, resource-austere setting. Our results show that from the payer perspective, there was a small cost saving associated with EF, but from a societal perspective there was no significant difference in cost between EF and SIGN-IMN. This suggests that cost alone should not be a reason to choose EF over SIGN-IMN for open tibia fractures in a low-resource setting.

Open tibia fractures are costly injuries regardless of treatment strategy. A 2017 study in England of open lower limb fractures, over half of which were open tibia fractures, demonstrated an average direct cost of inpatient treatment of £19,200 per patient.[20] Costs associated with operative time were the largest proportion of inpatient costs, which is consistent with the influence of operative length on cost found in our study. Here, the operative length for an IMN was 102 minutes compared with 60 minutes for EF; from operative length alone, this resulted in an average $53 excess in cost for SIGN-IMN relative to EF. As a result, when viewed from a payer perspective, EF was less expensive than SIGN-IMN despite the subsidized cost of the SIGN nail when the actual reoperation rate was considered.

Complications after open tibia fracture significantly increase cost. In a study of open and closed tibia fractures, rate of infection at 2 year follow-up was between 7% and 12%, with a 5-fold increase in direct health care costs for patients with infection compared with those without.[21] For patients with open tibia fractures requiring a free flap, infection is associated with

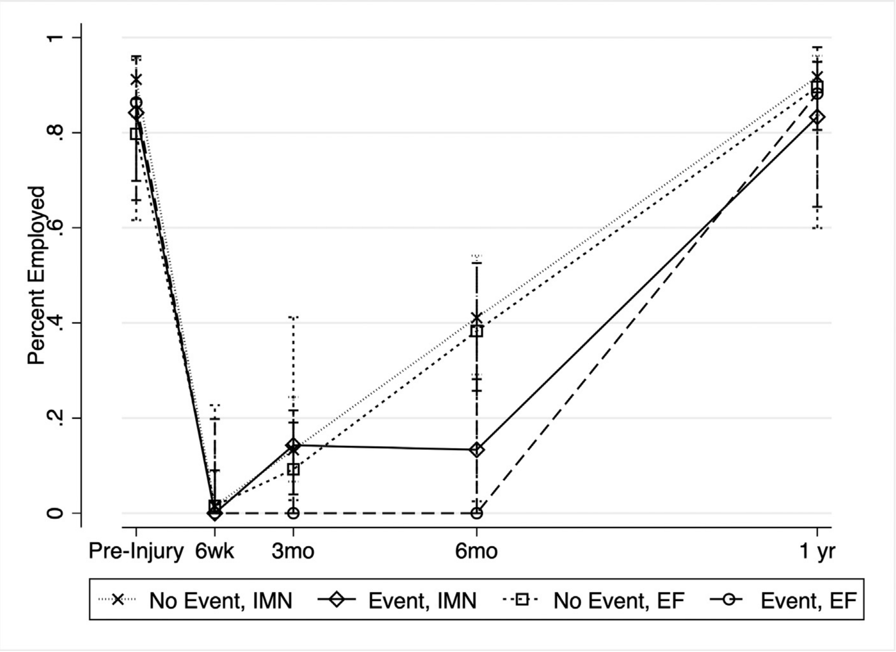

Figure 2. Percent employment over time by treatment group and outcome.

a 1.6-fold increase in direct costs of care.[22] A study in Belgium found a deep infection rate of 13.7% after open tibia fractures and a 5-fold increase in direct health care costs.[17] Nonunion has been shown to affect 20% to 30% of open tibia fractures[16,17] and lead to more than double the direct health care costs over 2 years.[16] These complication rates are comparable to those found in our study, with an overall 12% rate of deep infection and 6% rate of aseptic nonunion. In our model, rate of aseptic nonunion after a non-donated IMN, such as the Samay Surgical IMN, would have to be below 7.5% to be less costly than EF from a societal perspective. Similarly, direct costs of health care for patients who developed aseptic nonunion or deep infection were significantly higher than those who went on to uncomplicated union. When indicated reoperations were considered, estimated direct costs were over 5-fold higher for patients who developed complications compared with those who did not.

Direct health care costs do not consider lost employment of open tibia fracture patients, which poses a burden to not only the patient but also society. Six months after surgery, 40% of patients who had uncomplicated unions had returned to work, while employment for patients with aseptic nonunion or infection was below 20%. For the young, active population primarily affected by musculoskeletal trauma in low-resource settings, who also often serve as income earners for their family, this productivity loss may be financially devastating. A retrospective comparison of casting to IMN for open tibia fractures demonstrated lower

Table 3

Model cost parameters and data sources

	SIGN intramedullary nail: base case ± standard error (2018 USD)	External fixator: base case ± standard error (2018 USD)	Data sources
Direct costs			
Nonimplant supplies and medications	35 ± 2	35 ± 2	Kramer 2016 [13]
Operative procedure personnel	195 ± 10	142 ± 4	Kramer 2016 [13], Haonga 2020 [10]
Ward personnel	83 ± 4	101 ± 12	Haonga 2020 [10], MOI
Instrumentation	0.30	0.30	SIGN, MOI
Implant: production	168	34*	SIGN, MOI
Implant: hospital charge	0.70	34*	SIGN, MOI
Reoperation: multiplier for cost relative to index hospitalization	2–6.5	2–6.5	Antonova 2013 [16], Hoekstra 2017 [17], Metsemakers 2017 [18]
Indirect costs			
Lost productivity: union	2047 ± 696	2096 ± 637	Haonga 2020 [10]
Lost productivity: aseptic nonunion	2637 ± 244	2476 ± 206	Haonga 2020 [10]
Lost productivity: deep infection	2141 ± 637	2531 ± 218	Haonga 2020 [10]
Caregiver lost productivity	30 ± 3	36 ± 5	Kramer 2016 [13], Haonga 2020 [10]

* Represents cost for one use of external fixator parts.

Table 4

Model results

	External fixation: mean (95% confidence interval), 2018 USD	SIGN intramedullary nail: mean (95% confidence interval), 2018 USD	Samay surgical intramedullary nail: mean (95% confidence interval), 2018 USD
Payer perspective			
Actual reoperation rate	331.25 (301.01–363.14)	365.83 (332.75–405.76)	399.68 (364.91–442.62)
Indicated reoperation rate	589.27 (423.68–817.59)	568.49 (423.86–777.29)	
Societal perspective			
Actual reoperation rate	2560.81 (1700.54–3715.09)	2664.59 (1711.22–3955.25)	2511.95 (1549.28–3812.45)
Indicated reoperation rate	2955.90 (2034.19–4120.97)	2974.91 (1982.40–4319.84)	

direct costs of casting but longer average time off work (15 versus 24 months, respectively), resulting in comparable societal costs of the 2 treatment strategies. This emphasizes the value of considering the societal perspective in cost analysis.

The SIGN nail is unique because it is donated to hospitals in low-resource settings, and payers are responsible for a minimal cost. Therefore, SIGN nails are less costly than external fixators when viewed from a payer perspective. While the higher cost—the production cost—is considered in the societal perspective, total costs of EF and IMN did not significantly differ when viewed from this perspective, with selection frequencies that were virtually evenly split between these 2 options. This is largely due to the societal costs of complications and reoperations. From a societal perspective, reoperation for complication was associated with a 2-fold increase in cost compared with an uncomplicated postoperative course. Furthermore, the large uncertainty associated with cost of reoperation was much greater than the difference in implant production costs between IMN and EF.

For sites that do not have access to the SIGN nail, implant costs of nondonated tibial nails such as the Samay Surgical nail may be less than implant costs of external fixation. However, increased operative time of IMN compared with EF adds to direct cost, leading to increased costs of the SS-IMN from a payer perspective. Considering the societal perspective, where production costs are included, SS-IMN is least costly, suggesting that IMN is a viable option in places where donated implants are not available. This assumes that outcomes after SS-IMN are similar to those after SIGN-IMN.

Many patients in this study who were indicated for reoperation did not undergo reoperation, which decreased the apparent cost of complications compared with the cost had all indicated reoperations been performed. A cost-effectiveness analysis that incorporates quality-adjusted life years would better capture the reduced health-related quality of life of patients with untreated complications after open tibia fracture. In particular, deficits in health-related quality of life would be best captured with an extended time horizon that considers long-term outcomes after open tibia fracture.

A major limitation in this cost analysis is the paucity of data regarding costs associated with reoperation, particularly in a low-resource setting. Reoperation costs were both a major driver of total costs and a primary contributor to uncertainty in the cost analysis. Therefore, future studies that provide more precise estimates for reoperation costs are needed to better assess the optimal treatment strategy for open tibia fractures. The costs of operative time, disposable supply costs, and caregiver burden were extrapolated from a separate study of femoral shaft fractures, which introduces uncertainty associated with the assumptions that these metrics are similar in patients with femoral shaft and tibial shaft fractures. Additionally, these disposable supply costs were assumed to be equivalent between groups, which does not affect the outcome of the analysis but does illustrate the relatively small contribution of these costs to the overall costs. While patient employment and caregiver hours were considered in indirect costs, other indirect costs such as transportation to and from clinic visits were not captured. These costs may substantially differ in areas where the SIGN nail is not available, patients must pay for their implants, or where wages are different, which would impact costs associated with lost employment. Additionally, while these results are useful in understanding the cost differences between EF and IMN, a cost-effectiveness analysis that incorporates health-related quality of life and patient satisfaction would provide a more complete assessment of these treatment options. Finally, this study included a 1-year rather than lifetime time horizon, and long-term outcome and resource utilization after EF or IMN of open tibia fractures in this setting are unknown.

Based on the small differences in cost between IMN and EF from both societal and payer perspectives, cost does not appear to be a strong justification to choose one treatment over the other for open tibia fractures in a low-income setting. Future studies should incorporate both cost and clinical benefit for each treatment over a longer horizon.

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