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ORIGINAL ARTICLE • LOWER LIMB - FRACTURES

Long-term outcomes after high-energy open tibial fractures: Is a salvaged limb superior to prosthesis in terms of physical function and quality of life?

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Abstract

Purpose The aim of this study was to describe complication rates and long-term functional outcomes among patients with amputated versus reconstructed limb after high-energy open tibial fractures.

Methods Patients treated operatively for a high-energy open tibial fracture, classified as Gustilo–Anderson (GA) grade 3, at our hospital in the time period 2004–2013 were invited to a clinical and radiographic follow-up at minimum 2 years after injury. Eighty-two patients with 87 GA grade 3 fractures were included. There were 39 type GA 3A, 34 GA 3B, and 14 GA 3C.

Results The GA 3A reconstruction group had the lowest complication rate and the best long-term outcome scores at mean 5 years (range 2–8 years) after injury. Within the group of GA 3B and 3C fractures, we found no significant differences in long-term outcomes among patients with reconstructed versus amputated limbs. The mean physical component summary score of the SF-36 in the reconstruction versus amputation group was 54.2 (95% CI 46.3–62.1) versus 47.7 (95% CI 32.6–62.2), respectively ($p=0.524$), while the mean mental component summary score was 63.7 (95% CI 50.6–71.8) versus 59.2 (95% CI 48.8–68.0), respectively ($p=0.603$). On the 6-minute walk test, the reconstruction group walked on average 493 m (95% CI 447–535 m) versus 449 m (95% CI 384–518 m) in the amputation group. The return to work rate was 73% (16 of 22) in the reconstruction group versus 50% (7 of 14) in the amputation group ($p=0.166$). The mean patient satisfaction score (VAS 0–100) was 67 (95% CI 67–77) in the reconstruction group versus 65 (95% CI 51–76) in the amputation group ($p=0.795$). Regardless of the treatment strategy, the complication rate was high.

Conclusions Amputation should be considered as a viable treatment option, equal to limb salvage, after high-energy open tibial fracture with severe vascular damage or soft tissue loss.

Keywords Lower leg trauma · Bone fracture · Soft tissue damage · Surgery · Functional outcome

Introduction

High-energy open tibial fractures are challenging to treat. While the Gustilo–Anderson (GA) grade 3A fractures in general regain good function, the complication rates are high for type 3B and 3C fractures, which are associated with more severe soft tissue loss and/or arterial injury requiring repair [1]. Malunions, nonunions, deep infections and amputations occur frequently, and multiple surgeries over long periods of time are often required to obtain bone and soft tissue healing. The functional results after limb salvage are often disappointing [2–5], and the continuous progress in prosthetic technology actualises the ongoing debate on which treatment strategy yields better results; limb salvage or early amputation [6–23].

At the time of injury, the majority of patients will prefer limb salvage [8, 9], but interestingly, after the treatment and rehabilitation period, some wished they had opted for an initial amputation [10, 12]. It has been shown that patients undergoing limb salvage have longer hospital stays and longer rehabilitation times, as well as more re-hospitalisations and additional surgeries [9, 10, 12, 14, 16, 22]. This

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is mainly due to postoperative complications, which in turn may lead to secondary amputations. Despite this, the total average lifetime costs for limb salvage patients are reported to be significantly lower than for amputees, because of the long-term costs associated with prosthetic purchase and maintenance [24, 25].

There is a lack of knowledge as to whether limb salvage is superior to modern prosthetic replacement in terms of health-related factors, such as physical function, activity level, self-reported pain, mental health status, quality of life and return to work [2–5]. More knowledge on long-term outcomes is needed to improve surgical decision-making and optimise treatment for these patients. Thus, the aim of this study was to describe the complication rates and long-term functional outcomes among patients with amputated versus reconstructed limb after high-energy open tibial fractures.

Materials and methods

Patient inclusion

At our hospital, 145 patients were treated operatively for a high-energy open tibial fracture (AO/OTA 41A-43C, GA 3A, B or C) [1, 26] in the time period 2004–2013 and were eligible for the present study. The patients were identified from our local fracture database, where all treated fractures are registered continuously and coded according to the GA and AO/OTA classification system. We excluded 25 patients due to severe comorbidity ($n=1$), mental impairment ($n=1$), living abroad ($n=11$) or age below 15 years ($n=2$). In addition, 10 patients had died. Thus, 120 patients were invited to a clinical and radiographic follow-up at minimum 2 years after injury. Of these, 82 patients accepted, while 38 patients declined to participate. In total, 5 patients had bilateral open tibial fractures, giving a total of 87 GA 3-fractures; 39 type GA 3A, 34 GA 3B and 14 GA 3C. The decision to amputate or try limb salvage was left to the treating surgeon, in conjunction with the patient if possible.

Data collection and outcome measurements

The follow-up examinations were arranged during two time periods, in 2012 (54 patients) and 2016 (28 patients). The follow-up examination was organised as a 60-min individual consultation with the physician, including radiographs of the injured leg(s) and physical testing by a physiotherapist/research nurse. Information about injury mechanism, Injury Severity Score (ISS), initial treatment, time to fracture union, complications and final treatment was extracted from the patient medical records. As our hospital is a tertiary referral centre, medical records from the patient's local hospital were obtained if the patient had some of the follow-ups there ($n=7$). Based on standard radiographic follow-ups, the time to fracture union was determined according to the Radiographic union scale in tibial fractures (RUST) [27].

All patients were asked to fill out the Short Form 36 (SF-36) version 1.2 [28] to assess the health-related quality of life by measuring physical function, social function, role limitations due to emotional problems, role limitation due to physical problems, vitality (energy and fatigue), bodily pain, mental health and general health perception [29]. Each dimension was scored individually on a scale from 0 to 100, where a higher score indicates better health [30, 31]. To assess objective physical function, we chose the 6-minute walk test, which is a well-known and standardised test measuring functional capacity [32]. Furthermore, we recorded employment status before and after injury. Patient satisfaction with the treatment result at the time of consultation was measured using a visual analogue scale (VAS 0–100 mm). In addition, the patients with a reconstructed limb were asked whether they would undergo limb salvage again versus initial amputation.

In total, 5 of the 82 included patients were not able to meet for the follow-up examination, but all answered the mailed SF-36 questionnaire. In addition, 2 of the amputated patients with bilateral injuries were unable to walk (used wheelchair) and were therefore not included for the 6-minute walk test.

Statistical analysis

All data were analysed using the statistical software SPSS (version 23, Chicago, IL, USA). The individual SF-36 questionnaires were scored using the scoring manual developed by the Medical Outcome Trust [33]. Descriptive data are presented as percentages and means with standard deviation or range. When comparing data between groups, the Chi-square test was used for categorical variables and bootstrap for continuous variables. Analyses based on bootstrap replications were considered superior to normal Student's *T* test, as the data were not normally distributed [34]. For the bootstrap replications, we used 10,000 samples and bias-corrected and accelerated (BCa) bootstrap. Seed for Mersenne Twister was set to 3. A p value <0.05 was considered statistically significant.

Ethical approval

The study was approved by the Regional Committee for Medical and Health Research ethics, Region South-East Norway. Written informed consent was obtained from all study participants.

Results

Of the 82 patients, 66 (80%) were males and 16 (20%) females. The mean age at injury was 41 years (range 15–82). The mean follow-up time after injury was 65 months (range 29–106). The most frequent injury mechanisms were motorcycle accident ($n=23$), motor vehicle accident ($n=16$) and pedestrian hit by car ($n=16$). More than half of the patients ($n=52$) had severe associated injuries (ISS > 15), classified as polytrauma patients. As a result of the high-energy open tibial fractures, 70 limbs in 66 patients were reconstructed, while 17 limbs in 16 patients had to undergo amputation (Table 1). None of the 39 GA 3A fractures were treated with amputation. Demographic data for the patient groups treated with reconstruction versus amputation are shown in Table 2.

The level of amputation after GA 3B or 3C fractures was trans-tibial ($n=5$), trans-femoral ($n=11$), or knee disarticulation ($n=1$). The average time to initial amputation was 2 days (range 0–8) after injury, while 2 patients had secondary amputations after 131 and 803 days (due to limb salvage failure). In the reconstructed limbs ($n=70$), the most frequent procedure for final fracture fixation after initial stabilisation was intramedullary nailing ($n=29$), followed by circular external fixation (Ilizarov or Taylor spatial frame) ($n=28$), and open reduction and internal fixation ($n=11$), whereas 2 cases were stabilized with a unilateral external fixation and a cast. The average time to fracture union was 51 weeks (range 11–273). Of the reconstructed legs ($n=70$), 38 needed soft tissue reconstruction to cover the injured area, either a split skin graft ($n=13$), or a free flap ($n=13$) or pedicled flap ($n=12$). Complications that required additional surgeries after initial reconstruction or amputation are listed in Table 3.

Among the GA 3B and 3C fractures, there were no statistically significant differences in self-reported quality of life between patients with reconstructed versus amputated limbs at the time of consultation (Table 4). They scored almost equally on the items bodily pain, mental health and social function. The amputation group, however, scored slightly better on general health and vitality (energy/less fatigue), although not statistically significant, while the reconstruction group scored slightly better on physical function and reported less role limitations due to emotional and physical problems. The GA 3A reconstruction group had the highest physical and mental component summary scores, although there were no statistically significant differences between the groups (compared to the GA 3B/C amputation group; $p=0.298$ for the physical score and $p=0.152$ for the mental score).

Table 1 Gustilo–Anderson classification of the 87 fractures (in 82 patients) treated with reconstruction versus amputation

Classification	Reconstruction	Amputation
Gustilo grade 3A	39 (35)	0 (0)
Gustilo grade 3B	30 (30)	4 (4)
Gustilo grade 3C	1 (1)	13 (12)
Total	70 (66)	17 (16)

On the 6-minute walk test, the GA 3A reconstruction group ($n=33$ patients) had the longest walking distance with an average of 515 m (95% CI 461–564 m). Comparing the reconstructed and amputated GA 3B and 3C fractures, the reconstruction group ($n=30$ patients) walked on average 493 m (95% CI 447–535 m) versus 449 m (95% CI 384–518 m) in the amputation group ($n=12$ patients). This yielded no significant difference (44 m, 95% CI–40–122 m, $p=0.286$).

Among the patients with GA 3B or 3C fractures who were working prior to injury, the return to work rate was 50% (7 of 14) in the amputation group versus 73% (16 of 22) in the reconstruction group ($p=0.166$), while the return to work rate in the GA 3A reconstruction group was 65% (20 of 31). Changes in employment status before versus after injury are presented in Fig. 1, showing a general decrease (30%) in patients having a physically demanding job and a marked increase (25%) in patients on sick leave, across all three groups.

Regarding patient satisfaction with the result at the time of consultation, measured on a VAS scale (score 0–100 mm), the GA 3A reconstruction group ($n=33$ patients) had the highest score of 75 (95% CI 68–81). Of the GA 3B and 3C fractures, the patients with reconstructed limb ($n=30$ patients) scored 67 (95% CI 56–77) versus 65 (95% CI 51–76) for the amputees ($n=14$ patients); there was no significant difference (score of 2, 95% CI − 13 to 18, $p=0.795$). However, there were 2 patients in the reconstruction group who would prefer an initial amputation if they could choose the treatment again.

Discussion

To our knowledge, this is the first study to investigate long-term outcomes in patients with reconstructed versus amputated limbs after high-energy open tibial fractures, including an objective evaluation of physical function as a part of the clinical examination in addition to patient-reported outcomes and radiological assessments. We found no statistically significant differences between the patients with amputated versus reconstructed limbs after GA 3B or 3C fractures in terms of self-reported quality of life, walking capacity, employment status, and patient satisfaction at mean 5 years after injury.

Table 2 Demographic data of the 82 patients, according to treatment groups after high-energy open tibial fractures (GA 3A, B and C)

Group	Patients (*n*)	Mean age (year, range)	Sex (% male)	ISS > 15 (%)	Follow-up (months, range)
GA 3A reconstruction	35	39 (15–67)	77	74	71 (33–106)
GA 3B/C reconstruction	31	41 (15–82)	81	58	62 (29–100)
GA 3B/C amputation	16	48 (23–69)	87	50	58 (32–98)
Overall	82	41 (15–82)	80	63	65 (29–106)

Table 3 Complications that required additional surgeries after the 87 high-energy open tibial fractures (GA 3A, B and C) treated with reconstruction and amputation

Complications	GA 3A reconstruction ($n=39$)	GA 3B/C reconstruction ($n=31$)	GA 3B/C amputation ($n=17$)
Removal of internal osteosynthesis material	7	8	–
Nonunion	2	4	1
Deep infection	1	7	6
Flap or skin graft necrosis	–	7	1
Compartment syndrome	6	7	1
Secondary amputation (> 7 days)	–	–	2
Below-knee to above-knee amputation	–	–	2
Malunion	1	2	–
Autologous bone grafting	1	1	–
Tenotomy	2	–	–
Exostosis	1	–	–
Pes equinus	–	1	–
Total	21	37	13

Table 4 The SF-36 score for each of the 8 items in patients with reconstructed versus amputated limb after GA 3A, B and C fractures

SF-36	GA 3A reconstruction ($n=35$)	GA 3B/C reconstruction ($n=31$)	GA 3B/C amputation ($n=15$)	GA 3B/C reconstruction versus amputation	
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	Diff. (95% CI)	*p* value
Physical function	68.6 (61.2–75.6)	63.1 (55.0–70.2)	50.3 (33.5–66.0)	12.7 (− 3.5 to 29.1)	0.165
Role physical	45.0 (32.0–58.6)	46.0 (32.1–59.6)	26.7 (12.5–42.5)	19.3 (− 2.1 to 39.9)	0.085
Bodily pain	57.8 (49.3–66.3)	47.3 (38.2–56.2)	45.8 (32.7–58.5)	1.5 (− 14.4 to 17.9)	0.852
General health	66.3 (59.7–73.0)	60.2 (53.1–67.1)	68.1 (56.5–78.1)	− 7.9 (− 19.5 to 4.3)	0.210
Vitality/energy	58.9 (51.9–66.0)	46.9 (40.7–53.1)	57.3 (47.8–66.3)	− 10.4 (− 20.9 to 0.6)	0.072
Social function	77.2 (68.7–85.2)	70.0 (59.7–79.0)	65.9 (49.9–79.9)	4.1 (− 12.3 to 21.0)	0.640
Role emotional	70.5 (57.0–82.9)	65.6 (50.6–79.4)	44.5 (25.7–63.3)	21.1 (− 4.0 to 45.0)	0.099
Mental health	76.9 (71.0–82.3)	72.4 (64.0–80.1)	69.1 (59.7–77.6)	3.3 (− 9.3 to 16.0)	0.604
PCS	59.4 (48.2–68.0)	54.1 (46.3–62.1)	47.7 (32.6–62.2)	6.4 (− 12.5 to 26.9)	0.524
MCS	70.9 (61.8–77.2)	63.7 (50.6–71.8)	59.2 (48.8–68.0)	4.5 (− 13.8 to 21.3)	0.603

There was one patient in the amputation group with not completed data

PCS physical component summary score, *MCS* mental component summary score

We included all GA grade 3 (A, B and C) fractures in the study, as high-energy open tibial fracture is a relatively rare injury and more knowledge on long-term outcomes is needed, regardless of the severity of the fracture. However, when comparing long-term outcomes in patients with amputated versus reconstructed limbs, we included only the GA 3B and 3C fractures, as amputation may only be necessary for GA 3A fractures in cases of severe and late

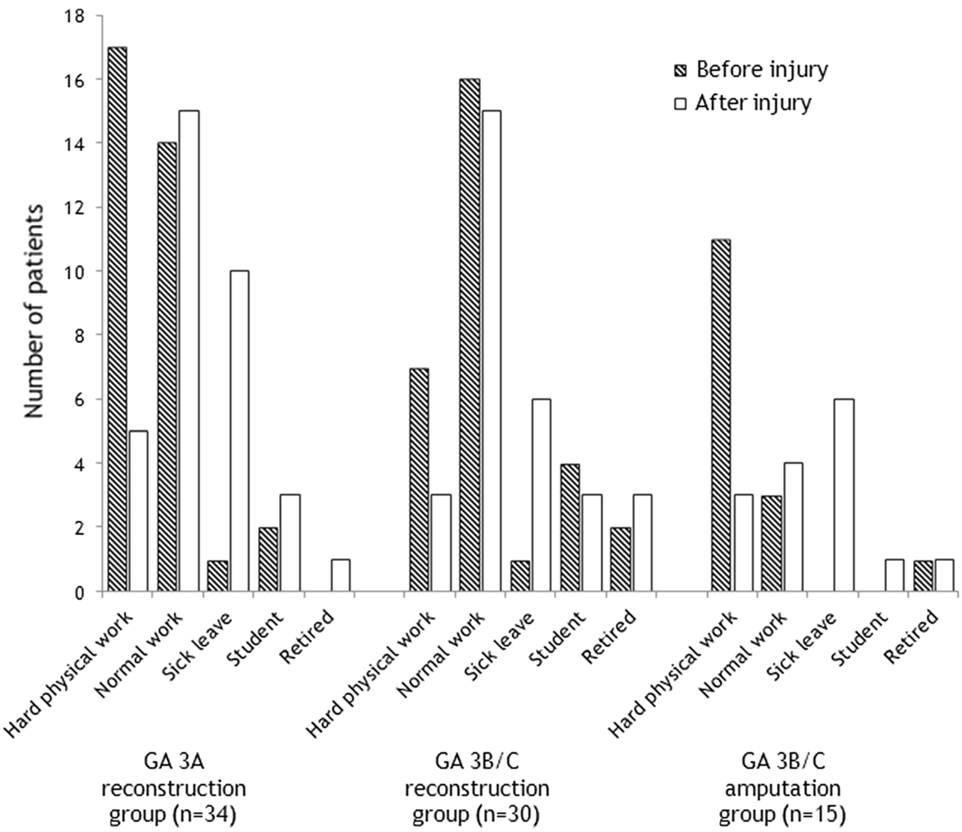

Fig. 1 The working situation before versus after injury presented as the number of patients with amputated versus reconstructed limb after GA 3A, B and C fractures. Note: there was one patient in each group with uncompleted data

complications. And, as expected, we found that the GA 3A reconstruction group had the lowest complication rate and the best long-term outcome scores.

We included both initial and secondary amputations in the GA 3B/C amputation group, as well as below-knee and above-knee amputations, because neither timing nor level of amputation has shown to influence the long-term outcomes [11]. We also included both unilateral and bilateral injuries, as it has been reported that patients with bilateral injuries have outcomes comparable with those with unilateral injuries [11]. The amputation rate in the GA 3C fracture group was higher in the present study than previously reported (93% vs. 61–78%) [9, 14, 17, 20, 35]. This can be related to the type of injury mechanism, as all our GA 3C fractures were severe crush injuries, and 10 of the 14 cases required immediate amputation. Furthermore, we had a lower amputation rate among GA 3B fractures (12% versus 17–24%) [9, 14, 17, 20, 35]. Thus, the GA 3B/C reconstruction group consisted mainly of GA 3B fractures, while the majority of the GA 3B/C amputation group was GA 3C fractures. Regardless of the type of fracture and treatment strategy, the number of clinical complications was high. Comparisons with previous studies reporting clinical complications should be performed with caution due to small data sets and inconsistent definitions and diagnostic criteria used.

A high-energy open tibial fracture will have long-term physical and psychological consequences for the patient, regardless of the type of fracture and treatment strategy [2–5]. Concerning the GA 3B and 3C type fractures, we found no statistically significant differences between patients with amputated versus reconstructed limbs in any of the items of the SF-36 questionnaire. Previous studies have reported a summary score of the physical versus psychological components of the questionnaire only, not specific scores for each of the 8 items. A meta-analysis found no difference between the reconstruction and amputation groups in the physical component score, but the reconstruction group had a significantly better psychological component score [2]. In more recent studies, no differences have been detected between the two groups at all [19, 23]. However, among US military service members, better physical function was reported in the amputation group than in the reconstruction group [11]. This is most likely due to early and specialised rehabilitation with weight-bearing as soon as there is sufficient wound-healing among amputees, while patients with a reconstructed limb were not allowed weight-bearing before fracture union, causing a prolonged rehabilitation.

This is the first study measuring physical function objectively in this patient group, using the 6-minute walk test. We found no statistically significant difference in walking distance among GA 3B and 3C fracture patients with reconstructed versus amputated limbs. In previous studies, physical function has mostly been reported through quality of life questionnaires (e.g. SF-36, SIP, SMFA, or Eq-5d) with inconclusive results [6–23]. However, some studies have asked the patients more specific questions about activities such as walking distance and stairs climbing [7, 12, 14, 15, 22]. While the amputees often have better scores reported 2–3 years after the time of injury, the reconstruction group has reported better function in the longer term. At mean 3 years after injury, more patients with a reconstructed versus amputated limb reported problems with performance of recreational (85% vs. 50%, $p \leq 0.05$) and occupational (36% vs. 19%, $p \leq 0.05$) activities [22], whereas at mean 7 years after injury, patients with a reconstructed limb reported a median walking distance of 12 km (range 0.3–40) versus 5.25 km (range 0.2–17.5, $p < 0.018$) among amputees [14].

Among patients with GA 3B or 3C fractures who were working prior to injury, we found a return-to-work rate of 50% in the amputation group versus 73% in the reconstruction group. When interpreting these results, we should keep in mind that a higher percentage of the amputees, although not statistically significant, defined their job prior to injury as "physically demanding" (based on time of walking, standing, using stairs and inclines, kneeling, lifting, etc.). This was also the case in the GA 3A reconstruction group with a return-to-work rate of 65%. In the LEAP cohort, physically demanding work prior to injury was associated with significantly lower return-to-work rates [36]. It seems like return-to-work rate is more associated with the type of work prior to injury than the type of fracture and treatment strategy [6, 7, 9–11, 36]. Furthermore, we found a clear change in employment status among patients who returned to work, in particular among the amputees. As found in other studies, it seems like the amputees return faster, but need to modify their work more than the patients with a reconstructed limb [12–14, 20, 22, 37].

Regarding patient satisfaction with treatment results after GA 3B and 3C fractures, the amputation and reconstruction groups were equally satisfied at mean 5 years after injury. This is in line with a previous study reporting that 83% ($n = 15$) in the amputation group versus 86% ($n = 32$) in the reconstruction group were satisfied with the long-term results of treatment [15]. A study from the LEAP cohort reported that at 2 years after injury, patient satisfaction was associated with return to work, better self-reported physical function, absence of depression, and lower pain intensity [38]. Thus, it is reasonable to believe that patient satisfaction is related to overall health status. Results from previous studies using the VAS score to measure overall health status at mean 3 years after injury are in line with ours [22, 23]. Regarding patient preferences, we found that 2 of the 31 patients in the reconstruction group after GA 3B or 3C fractures would prefer initial amputation if they could choose the treatment again. This finding confirms previous studies reporting that the majority of patients prefer limb salvage at the time of injury [9, 10, 12, 20].

In the present study, all follow-up data were obtained in person through a standardised examination performed by only a few investigators. The examinations included well-known and validated outcome measurements, and physical function was measured objectively. However, our study has several limitations that should be considered when interpreting the results. First, as severe open tibial fractures are relatively rare injuries, we had a limited number of patients included in each group. It might be that higher statistical power would give more statistically significant results. Second, using a retrospective observational study design, we cannot draw direct conclusions and causalities between treatment strategy and long-term outcomes. There might be underlying factors, crucial for surgical decision-making at the time of injury, which may differentiate the reconstruction and amputation groups, in addition to soft tissue loss and vascular injuries. Several studies have also reported that different injury and patient characteristics have been associated with certain outcomes, such as quality of life and return to work, regardless of treatment strategy [6, 18, 36].

However, the groups were comparable in terms of sex, age, ISS, and injury mechanism, as the majority of patients in each group were young men involved in severe traffic accidents (Table 2). A potential methodological limitation in the present study is that the time of follow-up varied between 2 and 8 years after injury. It seems reasonable to expect some improvement in function over time due to physical and mental adaptation. In general, it is suggested that patients with amputated limbs recover more quickly, while patients with reconstructed limbs continue to recover over a longer time period [2–5]. However, there is also a risk of function worsening. More importantly, all patients in our study had completed the rehabilitation period at the time of follow-up, and the mean follow-up time did not differ between groups (Table 2).

It should also be mentioned that we had a response rate of 68%, which is in accordance with previous studies [11, 19]. Demographically, there were no significant differences between the included patients and those who declined to participate in the study ($n = 38$, 89% male, mean age 38 years, and 72% polytrauma patients). However, there is always a risk of selection bias, and we do not know the reasons for declining to participate. Finally, the degree to which our results can be generalised is uncertain, as we do not know to what extent the outcomes have been influenced by the expertise of the physicians and other caregivers locally at the hospital.

Conclusions

The GA 3A reconstruction group had the lowest complication rate and the best long-term outcome scores at mean 5 years after injury. Within the group of GA 3B and 3C fractures, we found no statistically significant differences between patients with reconstructed versus amputated limbs in terms of self-reported quality of life, walking capacity, employment status, and patient satisfaction. Regardless of the treatment strategy, the complication rate was high.

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Author's contribution CF, JCJ, JEM, GF, FF, GSA and TB contributed to study conception, design, and methodology. CF, JCJ and TB coordinated the study, performed the clinical assessments, and analyzed the data. CF and TB wrote the first draft of the paper, and all authors contributed to the final manuscript.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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