

RQ [##]: [Should return to work status be utilised as a primary outcome measure in open fractures?]

Section 1: Background (<300 words).

Return to work (RTW) is a commonly reported outcome measure after traumatic injuries, especially in younger populations because employment and income are particularly essential for people of working age. Recovery after orthopaedic trauma is known to be a multifaceted process, which includes returning to work and social activities at a level considered acceptable by the individual. Thus, patient satisfaction has been shown to be directly associated with RTW, better self-reported physical function, absence of depression, and lower pain intensity.

However, RTW rates after complex orthopaedic injuries are generally low. As part of the recovery process, which includes RTW, the adoption of specific and comprehensive rehabilitation programs has been recommended, addressing physical, cognitive, and psychological recovery, including multidisciplinary rehabilitation in the hospital and after discharge, aiming to address the biopsychosocial domains of recovery.

Regardless of the rehabilitation program, some studies have indicated that the RTW rate is more associated with the type of work performed before the injury than with the type of fracture and the treatment strategy. In fact, lower RTW rates are observed in physically demanding professions.

Ultimately, RTW assessment as a recovery tool becomes important not only in the social and psycho-emotional sense, but also economically, since in high-income countries only 60% of patients who suffer open tibial fractures fully return to work one year after the injury.

Section 2: Data extraction table.

S. no	Author, year of publication, Country	Study Design	Sample Size	Study population (Inclusion and exclusion criteria)	Groups compared	Results
1	Fioravanti et al., 2018, France	Retrospective comparative study; level IV	51 patients: 27 conservative/limb salvage; 24 amputation	Adults >18 years treated in Marseille trauma centres for severe open lower-limb trauma involving the tibia, Gustilo IIIB or IIIC, with minimum 2-year follow-up. Exclusions: difficulty understanding/expressing responses, central motor sequelae, bilateral amputation, non-consolidated contralateral lower-limb fracture, or new lower-limb fracture.	Lower-limb salvage/conservative treatment vs amputation.	Hospital stay, infection, and surgical revision rates were significantly lower after amputation. Functional parameters and overall quality of life favoured amputation, except return to work, which was not improved. No significant difference in SF-36 mental component.
2	Schade et al., 2025, Malawi	Economic analysis / cost-utility analysis nested in a multicentre	287 participants recruited: 224 tertiary/central hospital; 63 district hospital. Main model: 253	Adults ≥18 years with AO/OTA 42 open tibia fractures treated at 6 hospitals in Malawi.	Treatment-setting strategies: POP in district or central hospital,	At 1 year, 42% were working vs 89% pre-

		prospective cohort study	with 1-year follow-up (140 Gustilo I/II; 113 Gustilo III)	Exclusions: unable to consent or complete patient-reported outcome questionnaires. Rare/non-standard treatment modalities and missing length of stay excluded from modelling.	intramedullary nail, external fixation, and amputation; analysed by Gustilo grade.	injury. Median monthly household income decreased from US\$60 to US\$40. Societal costs ranged widely; for Gustilo III, posterior median societal costs reached US\$2,428 for IM nail in central hospital. Open tibia fractures imposed major patient, health-system and societal costs.
3	Flores et al., 2024, United States	Secondary analysis of the pilot Gentamicin Open Tibia randomized trial	100 adults with open tibial shaft fractures; 78 no adverse event; 22 adverse events (FRI and/or non-union); 80% 1-year follow-up	Adults enrolled in the pGO-Tibia trial at Muhimbili Orthopaedic Institute, Dar es Salaam, with open tibial shaft fractures. Patients were	Adverse event (FRI and/or non-union) vs no adverse event; economic impact and return-to-work outcomes.	Only half returned to work by 1 year. RTW was lower with adverse

				randomized to local gentamicin vs saline placebo in the original trial and followed for 1 year.		events (27% vs 73%; p=0.028); adjusted hazard of RTW was 77% lower with an adverse event. Lost productivity was nearly double with adverse events; total mean indirect cost was US\$2,385 with AE vs US\$1,190 without AE.
4	Lindahl and Juneja, 2023, Denmark	Longitudinal observational study	201 baseline interviews; 164 completed 6-month follow-up; RTW analysis n=162	Patients aged 18-64 years hospitalized in 5 Danish hospitals with simple, compound or multiple fractures after an accident. Exclusions: spinal cord injury, internal-organ injury, Glasgow Coma Scale ≤ 13 , and early retirement before accident.	Patients grouped by expectations and later outcomes; predictors of short-term and long-term sick leave/RTW.	Patient expectations during admission did not predict short-term or long-term sick leave. RTW prevalence was 48.1% within 3

						months and 63.5% within 6 months; 36.4% remained on sick leave at 6 months. Self-rated health and SMFA bother index predicted sick leave.
5	Sethuraman et al., 2021, India	Retrospective cohort study; therapeutic level II	78 adults: 20 above-knee amputation; 16 below-knee amputation; 42 limb salvage	Adults >18 years with severe open tibial fracture, GHOISS >13, follow-up >12 months, treatment complete/fracture union. Exclusions: initial management outside the institution, cognitive deficit, and bilateral limb-threatening injury.	Limb salvage vs below-knee amputation vs above-knee amputation.	Salvage yielded better function and quality of life than BKA and AKA (LEFS 51 vs 39 vs 31; SF-12 PCS 48 vs 40 vs 34). Upfront and secondary costs were higher for salvage, but salvage patients were more likely to return to work

						at 36 months than BKA patients. Authors favoured aggressive salvage in this developing-country context.
6	Belangero et al., 2022, Brazil	Seven-hospital prospective observational study	72 treated; 57 followed for 120 days; 48 completed SF-12	Adults ≥ 18 years with isolated open tibial shaft fracture in 7 hospitals in Brazil and Argentina, no previous treatment, able to consent. Exclusions: pathological fracture, polytrauma, prior fracture sequelae in same bone, metabolic bone disease, incomplete history, treatment at non-study hospital, unreliable neurological/psychiatric evaluation, or limited freedom.	No randomized comparison; outcomes assessed by RTW status, SF-12, bone healing and gait at 120 days.	At 120 days, 70.6% returned to work and 61.4% had bone healing. RTW was influenced by age, antibiotic therapy, definitive treatment type and infection. RTW correlated strongly with gait status and SF-12 physical component

						score; younger age, absence of infection and ability to run favoured RTW.
7	Frisvoll et al., 2019, Norway	Retrospective cohort with long-term clinical/radiographic follow-up	82 patients / 87 GA grade III open tibial fractures: 70 reconstructed limbs in 66 patients; 17 amputated limbs in 16 patients. GA 3B/C comparison: 31 reconstruction vs 16 amputation	Patients treated operatively for high-energy GA grade III open tibial fractures at Oslo University Hospital from 2004-2013, invited to follow-up minimum 2 years after injury.	Reconstruction/limb salvage vs amputation, with main comparison focused on GA 3B/C fractures.	Mean follow-up 65 months. In GA 3B/C injuries, no significant difference between reconstruction and amputation in SF-36, 6-minute walk, satisfaction or RTW. RTW was 73% (16/22) after reconstruction vs 50% (7/14) after amputation (p=0.166). GA 3A reconstruction had best

						outcomes; complication rates were high.
8	Cross et al., 2012, United States	Retrospective military cohort	115 soldiers / 127 type III open tibia fractures; 83 salvaged limbs; amputees Return to duty (RTD) rate analysed separately	Battle-wounded soldiers with Gustilo-Anderson type III open tibia fractures from 2003-2007 treated definitively in a U.S. military medical centre. Exclusions: incomplete medical record (n=6) and deaths (n=2).	RTD after limb salvage vs amputation; analysis by injury and treatment characteristics.	Overall RTD rate was 18.3% (21/115). Salvaged extremities RTD 20.5%; isolated salvaged fractures RTD 22.4%; amputees RTD 12.5%. Older age and higher rank increased likelihood of RTD. No type IIIC or bilateral open tibia fracture returned to duty.
9	Ganta et al., 2024, United States	Retrospective chart review; therapeutic level III	168 identified; 150 included after excluding retired/unemployed/never-RTW patients. RTW	Consecutive patients undergoing operative repair of tibial shaft fractures. Excluded:	Early vs average vs delayed RTW after tibial shaft fracture surgery.	Mean RTW time was 4.17 +/- 2.06 months.

			groups: early ≤ 90 days n=39; average 91-180 days n=85; late ≥ 180 days n=26	retired (n=10), unemployed (n=4), or unable to RTW and receiving disability insurance at minimum 6- month follow-up (n=4).		Delayed RTW was associated with high- energy injury, open fracture, initial external fixation, labour- intensive job and postoperative non-weight- bearing. Closed fracture reduced risk of delayed RTW (p=0.004).
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Section 3: Results summary write-up (upto 500 words).

Document is attached (**Summary of the included studies**).

Section 4: Discussion (<1000 words).

This review suggests that return to work (RTW) is a highly relevant and patient-centered outcome after open fractures, but the current literature remains too heterogeneous to support its use as a primary outcome measure in open fractures. In all the evidence included, RTW captured an important dimension of recovery that was not fully reflected by radiographic consolidation, functional scores, infection status, or treatment success. In several studies, patients achieved fracture consolidation or acceptable limb-related functional scores but still experienced delayed occupational reintegration, income loss, or inability to resume previous functions. This supports the view that RTW should be considered a central domain of recovery after treatment of open fractures, particularly in working-age adults.

Most of the available evidence has focused on open tibial fractures, especially Gustilo-Anderson grade III injuries. This is clinically understandable because open tibial fractures combine severe soft tissue damage, prolonged rehabilitation, risk of infection, risk of non-union, and high socioeconomic consequences. However, this anatomical concentration limits generalization to other open fractures, including pelvic, femoral, upper limb, and polytrauma-associated injuries. Available studies also differed substantially in study design, injury severity, treatment approach, follow-up duration, and definition of return to work. Some studies reported return to work in a binary fashion, while others assessed time to return to work, return to service, sick leave, productivity loss, or economic burden. These differences prevented a meaningful pooled analysis and highlight the need for standardized definitions of return to work.

Despite these limitations, consistent signals emerged. Complications such as fracture-related infection, non-union, reoperation, and delayed healing were repeatedly associated with poorer occupational outcomes. Secondary analysis of the pGO-Tibia study in Tanzania showed that adverse events sharply reduced return to work and nearly doubled productivity losses, demonstrating that complications have consequences beyond clinical failure. Similarly, economic analysis from Malawi showed large reductions in employment and household income one year after open tibial fracture, emphasizing that open fractures can be financially catastrophic

in resource-limited settings. These findings suggest that return to work (RTW) is not merely a social outcome, but an integrated measure of biological recovery, functional capacity, access to rehabilitation, and economic resilience.

The relationship between limb preservation and amputation was more complex. Some studies reported better functional or occupational outcomes after preservation, while others found no clear superiority over amputation in the most severe injuries. This likely reflects an indication bias, because patients undergoing amputation often present with more severe vascular, soft tissue, or neuromuscular injuries. However, the findings reinforce that success should not be judged solely by limb preservation. A preserved limb that remains painful, infected, weak, or unable to sustain employment may not represent a successful patient-centered outcome. On the other hand, selected amputees can regain function and social participation when rehabilitation and prosthetic support are adequate. Therefore, RTW can help capture the value of treatment in ways that traditional surgical outcomes fail to do.

Several prognostic factors have been associated with late or inconclusive return to work (RTW), including advanced age, greater injury severity, open fracture, external fixation or staged treatment, infection, impaired gait, poorer physical health scores, manual labour, and socioeconomic vulnerability. These findings are consistent with a biopsychosocial model of recovery. RTW depends not only on fracture consolidation and soft tissue healing, but also on pain, mental health, patient expectations, workplace demands, compensation systems, rehabilitation quality, transportation, and employer flexibility. Therefore, future studies should avoid treating RTW as a simple binary orthopaedic outcome and should prospectively collect occupational context.

The methodological quality of the evidence was limited. Most studies consisted of observational, retrospective, or secondary analyses, with small samples, incomplete follow-up, variable adjustment for confounding factors, and inconsistent measurement of return to work. Only a minority consisted of prospective multicentre studies. The risk of bias was driven primarily by confounding factors, selection bias, missing data, and limitations in outcome measurement. These issues are especially important because return to work is strongly influenced by initial employment, type of work, injury severity, access to medical care, and social security systems. Without careful adjustment, comparisons between treatments may overestimate or underestimate the true effect of the surgical strategy on work recovery.

Overall, return to work should not replace conventional clinical outcomes such as consolidation, infection, reoperation, function, pain, and quality of life. However, evidence supports the inclusion of return to work as a key secondary outcome and, in selected pragmatic trials or cost-effectiveness studies of working-age adults with open fractures, as a patient-centered primary or co-primary outcome. Future research should utilize a standard set of essential outcomes for RTW, define pre-injury work and labour demands, distinguish

full RTW from modified RTW, record time to RTW, and capture lost productivity and economic consequences for families. This standardization would allow RTW to become a robust and clinically significant measure of recovery after open fractures.

Section 5: Risk of bias of included studies.

	Confounding/ selection	Exposure/ intervention	Missing data	Outcome measurement	Selective reporting	Overall
Fioravanti 2018	⬤	⬢	?	?	?	⬤
Schade 2025	?	⬢	?	⬢	?	?
Flores 2024	?	⬢	?	⬢	?	?
Lindahl 2023	?	⬢	?	?	?	?
Sethuraman 2021	⬤	⬢	?	?	?	⬤
Belangero 2022	?	⬢	?	⬢	?	?
Frisvoll 2019	⬤	⬢	?	?	?	⬤
Brenneman 1997	⬤	⬢	⬤	?	?	⬤
Cross 2012	?	⬢	?	⬢	?	?
Ganta 2024	⬤	⬢	⬤	?	?	⬤

⬤ = High risk

⬢ = Low risk

⬤ = Unclear risk

Section 5: Response/Recommendation (1-2 lines as a conclusion and recommendation statement for the question).

Return to work should be included as a secondary outcome, not replacing conventional clinical outcomes, and as a primary or co-primary patient-cantered outcome in cost-effectiveness studies and selected pragmatic trials with working-age adults with open fractures.

Section 6: Level/ strength of Evidence.

All included studies present either some concerns or serious concerns, with a very low level of evidence. This is an interesting gap in the literature, which allows the Consensus to propose RTW as a primary outcome measure based on the creation of a reproducible patient-reported outcome measure.