

RQ [02]: Should Patient-Reported Outcome Measures (PROMs) Be Prioritised Over Clinical Metrics in Assessing the Success of Limb Salvage Following Severe Open Lower Limb Injuries?

SECTION 1: BACKGROUND

‘Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’ (World Health Organisation [WHO], 1948). This is a simple yet a significant and complete fact that can be extrapolated to Open injuries as well.

Successful limb salvage following severe open lower limb injuries has traditionally been evaluated using surgeon-reported clinical outcomes such as fracture union, infection eradication, limb survival, range of motion, alignment, and reoperation rates. While these metrics remain important indicators of technical success, they may not fully reflect the patient's experience of recovery, functional independence, psychosocial wellbeing, return to work, or overall quality of life.

Over the past two decades, increasing emphasis has been placed on patient-centred healthcare and value-based outcome assessment. Patient-reported outcome measures (PROMs) have emerged as important tools for evaluating treatment success from the patient's perspective. Instruments such as EQ-5D, SF-36, Disability Rating Index (DRI), Wales Lower Limb Trauma Recovery (WaLLTR) Scale, and Short Musculoskeletal Function Assessment (SMFA) have been increasingly used in trauma research.

Several studies have demonstrated some to significant mismatch between clinical outcomes and patient-perceived recovery. Patients achieving fracture union and limb preservation may continue to report significant pain, disability, psychological distress, and reduced quality of life. Conversely, some patients undergoing amputation may report quality-of-life outcomes comparable to or better than those following complex limb salvage.

Despite increasing recognition of PROMs, uncertainty remains regarding whether they should be prioritised over traditional clinical metrics when determining the success of limb salvage. Establishing consensus on this issue has important implications for clinical decision-making, research methodology, healthcare policy, and future outcome reporting standards.

SECTION 2: DATA EXTRACTION TABLE

S.No	Author, Year	Study Design	Sample Size	Population	Outcomes Evaluated	Key Findings
1	Hoogendoorn et al., 2001	Comparative Cohort Study	64 patients	Gustilo Grade III open tibial fractures	Functional outcome, QoL, impairment scores	Quality of life similar between salvage and amputation despite major differences in physical impairment.
2	Giannoudis et al., 2009	Cross-sectional Cohort Study	130 patients	Full spectrum of	EQ-5D quality of life assessment	Injury severity significantly affected long-term

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				tibial injuries		quality of life; functional deficits persisted despite successful treatment.
3	Penn-Barwell et al., 2015	Cohort Study	30 limb salvage patients compared with amputees	Severe open tibial fractures	SF-36 outcomes	Similar medium-term quality-of-life outcomes between salvage and amputation groups.
4	Trickett et al., 2020	PROM Development and Validation Study	204 patients	Open tibial fractures	WaLLTR Scale development	Developed first patient-derived trauma-specific recovery instrument reflecting patient priorities.
5	Pallister et al., 2021	Prospective Longitudinal Cohort	68 patients	Open lower limb fractures	Functional recovery measures and PROMs	Patient perception of recovery closely paralleled combined functional outcomes.
6	Parikh et al., 2020	Prospective Cohort Study	182 patients	Type II, IIIA and IIIB open tibial fractures	Time to union, hospital stay, treatment duration, operations, admissions, LEFS	GHS significantly correlated with all clinical outcomes and LEFS functional outcome score. Demonstrated ability to predict both objective treatment metrics and patient-centred functional recovery.
7	Schade et al., 2019	Systematic Review	18 studies	Open tibia fractures in LMICs	PROMs, disability and quality of life	Highlighted growing importance of PROMs and significant gaps in outcome reporting.
8	Berner et al., 2024	International Multicentre Cohort Study	92 patients	Open lower limb fractures	SF-12, EQ-5D	Significant reduction in quality of life following

S.No	Author, Year (QUINTET Study)	Study Design	Sample Size	Population	Outcomes Evaluated	Key Findings
9	Rajasekaran et al.	Validation Study	Open lower limb injuries	Limb salvage versus amputation	GHOISS scoring system	injury with incomplete recovery at 12 months. GHOISS predicts salvageability effectively provides reliable discrimination between limbs suitable for salvage and those better treated by primary amputation, underscoring the importance of integrating injury severity with patient-centred outcome assessment.

SECTION 3: RESULTS SUMMARY

Eight key studies evaluating outcomes after severe open lower limb trauma were included. The evidence consistently demonstrated that traditional clinical outcomes such as fracture union, infection eradication, limb preservation, and range of motion do not fully reflect patient-perceived recovery.

Multiple studies identified persistent deficits in quality of life despite technically successful limb reconstruction. The QUINTET study demonstrated substantial deterioration in patient-

reported quality of life following open fractures, with only partial recovery at one year. Similar findings were reported by Giannoudis et al., who observed persistent impairment years after injury.

Comparative studies evaluating limb salvage versus amputation demonstrated that physical impairment measures and clinical outcomes often differed substantially while overall quality-of-life outcomes remained similar. These findings suggest that surgeon-reported measures alone may inadequately represent treatment success.

The development of trauma-specific PROMs such as the WaLLTR Scale further emphasises the importance of assessing recovery through patient-derived domains including independence, confidence, social reintegration, emotional wellbeing, and participation.

Prognostic tools used during limb salvage decision-making, including injury severity indices such as the Ganga Hospital Open Injury Severity Score (GHOISS), are valuable in predicting salvageability and guiding early treatment decisions. Nevertheless, the ultimate success of limb salvage should be determined not solely by limb survival but by the patient's long-term functional and quality-of-life outcomes. Rajasekaran et al. demonstrated that GHOISS provides reliable discrimination between limbs suitable for salvage and those better treated by primary amputation, underscoring the importance of integrating injury severity with patient-centred outcome assessment.

An important contribution was made by Parikh et al. (2020), who demonstrated that the Ganga Hospital Score correlated significantly with time to union, length of treatment, hospital stay, number of operations, admissions, and Lower Extremity Functional Score (LEFS). The study highlighted that injury severity influences not only objective treatment burden but also eventual patient-reported functional outcomes. The authors proposed predictive models that could estimate both clinical and functional recovery following severe open tibial fractures.

Collectively, the evidence supports the incorporation of PROMs as a central component of outcome assessment following limb salvage.

SECTION 4: DISCUSSION

The concept of successful limb salvage has evolved substantially over recent decades. Historically, success was defined by limb preservation, fracture union, and avoidance of infection. Modern trauma care increasingly recognises that these outcomes represent only one component of recovery.

Patients deserve, need and value outcomes that extend beyond radiographic healing. The ability to walk independently, return to work, participate in social activities, maintain psychological wellbeing, and achieve an acceptable quality of life are often more meaningful and desirable than objective clinical measures alone.

PROMs offer several advantages. They capture domains that cannot be assessed through physical examination or radiographic evaluation. They provide insight into pain, disability, emotional health, social participation, and overall wellbeing. Furthermore, they align closely with contemporary principles of patient-centred care.

However, PROMs should not completely replace traditional clinical metrics. Objective measures remain essential for evaluating complications, comparing treatment strategies, monitoring quality of care, and guiding resource allocation. Union, infection, alignment, and limb viability continue to represent critical treatment targets which have to definitely be met.

The available evidence therefore supports a balanced framework in which PROMs are prioritised as co-primary outcomes alongside clinical metrics rather than considered a replacement. Success should ultimately be defined by both technical achievement and patient-perceived recovery.

Future research should focus on developing a standardised core outcome set incorporating validated PROMs, functional assessments, return-to-work measures, and traditional clinical outcomes.

SECTION 5: RISK OF BIAS OF INCLUDED STUDIES

Overall Risk of Bias: MODERATE

Justification:

- Majority of included studies are observational cohort studies.
- Few randomised or comparative trials directly address the research question.
- Consistent findings across multiple independent cohorts.
- Use of validated PROM instruments.
- Heterogeneity in outcome measures and follow-up periods.
- Limited long-term prospective comparative data.

SECTION 6: **RECOMMENDATION**

PROMs should be considered a mandatory and prioritised component of outcome assessment following limb salvage. However, they should complement rather than replace objective clinical metrics. An approach integrating patient-reported outcomes, functional performance measures, and traditional clinical outcomes is recommended.

SECTION 7: LEVEL / STRENGTH OF EVIDENCE

Strength of Recommendation: STRONG

Quality of Evidence: MODERATE

Justification:

The recommendation is supported by multiple prospective cohort studies, comparative outcome studies, systematic reviews, and validated PROM development studies demonstrating consistent findings across different populations and healthcare systems. However, the predominance of observational evidence, heterogeneity of PROM instruments, and lack of large randomised comparative studies prevent classification as high-level evidence.

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