LETTER TO THE EDITOR

Casting out the truth: why ITT alone fails in trials that compare surgery to casting

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Randomisation and intention-to-treat (ITT) analysis are pillars of trial methodology – and for many questions they are rightly so. But when the interventions under study are epistemologically dissimilar, ITT stops answering the clinical question clinicians and patients actually care about. In trials that compare a discrete, one-off surgical procedure to a prolonged therapeutic pathway of casting, the standard ITT framework produces a categorical mismatch: it analyses *assignment* rather than *completed treatment*. That mismatch is not a minor technicality – it is a fundamental design error.

Surgery is, by definition, a delivered intervention: a patient in the operative arm receives the procedure (a discrete act, measured once). Casting is different. Cast treatment is a pathway – eight to ten weeks of immobilisation, serial reviews, and an outcome only realised if the pathway is completed without salvage surgery. Patients who abandon casting or convert to surgery within that pathway have not, in any meaningful sense, been treated with 'casting to completion'. Yet ITT routinely retains these non-completers in the casting arm and counts their outcomes against conservative care. The result is a mixed, heterogeneous 'casting' group composed of true cast completers and a distinct population of failures who were salvaged by surgery. Comparing that mixed group to a homogeneous surgical cohort is comparing apples to half-apples.

This is not a semantic quibble. The difference matters clinically. Trials that report no long-term difference between arms under ITT can still mask a clear superiority of *completed* casting for the subset of fractures that remain stable in cast. Conversely, early functional advantages for surgery, commonly measured at three months, are confounded by the asymmetry in time-to-intervention (one hour vs weeks in cast) and by inclusion of cast failures in the conservative arm. In short, the analysis answers the question: 'What happens if we randomise patients to a policy of casting versus surgery?', which is not the question clinicians need: 'What are the outcomes when casting is carried through to completion versus when surgery is performed?'

If our objective is to judge the comparative efficacy of the interventions themselves, the trial design and reporting must reflect that objective. I therefore propose the following practical standards for fracture trials that compare casting with operative fixation:

- Define 'casting to completion' a priori. Specify objective criteria (duration of immobilisation, radiographic parameters, no unplanned surgery within X weeks) so that per-protocol denominators are clear.
- Report the three clinical pathways separately: a) cast completers, b) cast failures converted to surgery, and c) primary surgery. Present outcomes for each pathway alongside ITT results.
- Prespecify and publish per-protocol and as-treated analyses in the primary manuscript (not buried as supplementary exploratory tables).
- Report crossover counts and reasons, time-to-surgery, and time-in-cast (median, IQR). Present time-to-event curves for reoperation and union where appropriate.
- Stratify or adjust for fracture stability (or present subgroup analyses), because the decision boundary between casting and surgery is biologically and mechanically meaningful.

These steps do not reject ITT; they complement it. ITT will continue to inform policy about assignment strategies and real-world implementation. But it must not be allowed to masquerade as the sole answer to the question of treatment efficacy when the interventions themselves are asymmetrical.

If we fail to align trial design, analysis, and the clinical question, we risk endorsing a policy of routine fixation on the basis of statistical neatness rather than therapeutic truth – a particularly costly mistake in resource-limited settings. Trialists, editors and reviewers should insist that trials comparing discrete interventions to prolonged therapeutic pathways present analyses that reveal, not obscure, what actually works for patients.