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What Counts as a Healed Wound A Critical Review of Outcome Definitions in Ayurvedic Wound Care Research

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Abstract

Wound improvement can mean less pain, a smaller area, improved granulation or complete closure. These outcomes are related but do not justify the same treatment claim. This critical narrative review examines selected Ayurvedic wound studies alongside regulatory guidance and wound measurement research. A clean wound dressing trial used a multidomain assessment tool over a short observation period, whereas a chronic ulcer trial assessed a different clinical population and treatment package. Such studies cannot be interpreted through a single undifferentiated label of healing. We distinguish intermediate changes from complete closure, time to closure and sustained closure. Percentage area reduction requires a reproducible measurement method and cannot establish closure by itself. Researchers should prespecify an outcome that matches the proposed claim, define the index wound, document background care and retain participants with unhealed wounds in the analysis. Clear endpoint definitions would improve clinical interpretation without dismissing partial improvement that matters to patients.

Keywords

Wound healing; Ayurveda; complete closure; wound area; outcome definition; clinical trials

Introduction

A wound can become smaller and remain open. It can become less painful without closing faster. A dressing can improve comfort while producing a similar healing result to a comparator. Each finding has clinical value, but the conclusions need to match the outcome measured.

This distinction is relevant to Ayurvedic wound research because interventions include cleansing agents, oils, dressings and multimodal care. A trial of Jatyadi, *Madhughrita* and honey tulle investigated clean wounds using a multidomain wound assessment tool.[1] A separate multicentre study examined herbal sprays in diabetic and

varicose ulcers.[2] Their populations and treatment contexts differ. A common word such as healing should not conceal those differences.

Review approach

Targeted searches of PubMed and PMC indexed literature and official guidance were conducted on 19 and 20 November 2026 using Ayurvedic wound care, Jatyadi, wound closure, area measurement and clinical trial endpoints. Selected clinical studies were examined for outcome interpretation. FDA wound product guidance provided an external reference for distinguishing wound care and wound healing claims. This is a narrative methodological review, not a systematic estimate of treatment effectiveness.

Sources were organised by the question they could answer: direct clinical evidence, formulation or measurement evidence, and general methodological guidance. Clinical reports were interpreted within their population, comparator and follow up; laboratory findings were used only for the measured property. Proposed explanations and research priorities are identified as interpretation rather than established treatment effects. The synthesis does not claim comprehensive retrieval, duplicate independent screening or a formal risk of bias assessment. Consequently, the examples support a critical argument but cannot determine the frequency of a reporting problem or a pooled estimate of benefit.

Table 1 Selected evidence and its interpretation

Source	Design or material	Direct contribution	Boundary of inference
Prasannan and colleagues[1]	Three arm study in clean wounds	Uses a wound assessment tool and evaluates dressing performance over ten days.	Does not establish effectiveness for every chronic ulcer or later recurrence.
Tamoli and colleagues[2]	Multicentre study of diabetic and varicose ulcers	Examines combined cleansing and dressing products using scores and photographs.	The design does not isolate every ingredient or background care component.
FDA guidance[3]	Wound product development guidance	Distinguishes closure and other wound care outcomes.	Provides a methodological reference rather than an Indian legal requirement.

Match the endpoint to the claim

FDA guidance distinguishes complete closure from other wound care outcomes and describes closure in terms of epithelialisation without drainage or dressing requirements, with confirmation at subsequent assessment.[3] The guidance concerns product development in a particular regulatory setting; it is used here for conceptual clarity rather than presented as an Indian legal requirement.

A study designed to reduce pain can use pain as its primary outcome. A study claiming accelerated closure needs a defined closure event and an appropriate observation period. Reduction in slough or an improved composite score can support a more limited conclusion. The problem arises when an intermediate endpoint is described as proof of complete healing.

Area reduction and measurement error

Percentage area reduction is calculated relative to the baseline area. The numerator and denominator must therefore use a consistent method. A change from a length by width estimate to traced planimetry can produce an apparent difference that partly reflects measurement. Research comparing wound measurement approaches shows that wound boundary interpretation and observer technique affect the result.[4]

An irregular wound is not necessarily rectangular. Reporting length multiplied by width as an estimated area can be acceptable when the method is explicit, but the result should not be confused with exact planimetry. Depth and undermining add information that a surface area does not capture. A photograph without a scale cannot retrospectively supply these measurements.

Table 2 Outcomes and the claims they support

Outcome	Interpretation	Claim not established alone
Pain reduction	Symptom improvement	Faster closure
Improved wound score	Change in the scored domains	Complete healing
Percentage area reduction	Surface size change by a defined method	Closure or durable recovery
Complete closure	Prespecified epithelialisation endpoint	Freedom from later recurrence
Time to closure	Speed of reaching the endpoint	Better quality of healing
Sustained closure	Closure maintained during follow up	Permanent cure

Lessons from selected Ayurvedic studies

The tulle trial assessed 45 participants across three groups over a short treatment period using the Bates Jensen tool and a dressing assessment form.[1] Its design allows discussion of wound condition and dressing performance within that context. It should not be used to establish efficacy for every chronic ulcer or to infer a long term recurrence benefit.

The herbal spray study enrolled patients with diabetic and varicose ulcers and used clinical scoring and photographs.[2] These wound aetiologies require careful description of background care and subgroup interpretation. A study of a combined cleansing and dressing intervention also cannot isolate the effect of one ingredient without an appropriate comparison.

Animal wound experiments can investigate biological responses, including histological change.[5] Such evidence should remain a separate layer of the review. An experimental wound model does not reproduce every vascular, neuropathic or mechanical factor present in a prolonged human ulcer.

Designing a clinically interpretable study

The protocol should identify the index wound when a participant has several wounds. It should define the baseline measurement, debridement timing and observation schedule. Otherwise, the endpoint can change meaning during follow up. Background care and rescue treatment must also be documented because they can influence both closure and symptoms.

Participants whose wounds remain open should not disappear from the conclusion. A time to event analysis needs an explicit approach to those who have not reached closure at the endpoint or who are lost to follow up. The statistical method should follow the actual design, rather than treating every unhealed wound as if an unknown closure date were known.

Table 3 Endpoint specification before recruitment

Decision	Information to prespecify
Population	Wound aetiology, chronicity and clinically relevant eligibility
Index wound	Selection rule if several wounds are present
Primary outcome	Exact definition and assessment method
Measurement	Instrument, calibration and assessor training
Background treatment	Dressing, debridement and aetiology appropriate care
Follow up	Confirmation of closure and assessment after closure
Missing outcomes	Reasons and planned analysis

Healing describes several different processes

A wound outcome should identify the aspect of recovery that changed. Surface contraction, epithelial coverage, exudate, pain and the condition of surrounding skin can follow different trajectories. An intervention might improve dressing comfort while leaving closure time unchanged. Another might reduce the open surface without resolving the underlying reason for ulceration. These are not interchangeable findings. A useful review separates them before discussing effectiveness. Otherwise, a favourable change in any one domain can be promoted into a general claim that the wound healed, even when an open area or another clinically important problem remains.

Composite assessment tools can capture several domains efficiently, but the total needs interpretation. The same total improvement could arise from reduced exudate in one participant and a smaller wound in another. Item level results can clarify which changes contributed. A lower composite score is therefore evidence of improvement on that instrument, not automatic proof of complete closure. The tulle trial's use of the Bates Jensen assessment and a dressing performance form illustrates that wound condition and dressing experience can be evaluated separately.[1] Both matter, but they support different statements about the intervention.

The endpoint should also reflect wound aetiology. A clean acute wound, a diabetes related foot ulcer and a venous ulcer do not have identical natural histories or background care needs. A result in one group should not be extended to another through the common label wound. The herbal spray study included diabetic and varicose ulcers, making aetiology and treatment context particularly important to interpretation.[2] Future syntheses should organise these populations separately unless there is a justified reason to combine them. Clinical similarity should be examined before statistical pooling is considered.

Defining complete and sustained closure

Complete closure requires more than a smaller opening or a dry surface. The FDA product development guidance uses a definition involving epithelial coverage without drainage or dressing requirements, confirmed at two visits two weeks apart.[3] Its specific regulatory setting should remain clear. The methodological lesson is that closure needs an observable definition and confirmation. A single favourable photograph cannot establish every component. The assessment should identify who judged the endpoint, what information was available and whether uncertainty was resolved through further observation rather than assumed away.

Sustained closure is a further outcome. A wound can close and later reopen, so the observation period after initial closure determines what can be claimed about durability. The reason for reopening also matters, but it should not erase the event from the record. A study should distinguish initial closure, maintenance of closure and recurrence according to prespecified definitions. Reporting only the most favourable appearance can conceal a less stable course. This review does not propose one follow up duration for every wound type; it recommends a duration justified by the clinical objective and the expected risk of recurrence.

Time to closure needs a defined starting point. It might begin at randomisation, the first application or another specified clinical event. Those choices affect comparison, especially when preparation or debridement occurs before treatment. The actual closure time is often known only between visits. A participant with an open wound at one visit and a closed wound at the next did not necessarily close on the latter date. The analysis should explain how this interval is handled. Reporting an exact day without acknowledging the observation schedule can imply a level of precision the data do not contain.

Partial area reduction has value and limits

Early size change can provide useful prognostic information. Sheehan and colleagues examined four week area change as a predictor of later closure in a prospective diabetic foot ulcer trial population.[6] That study supports a relationship under its conditions. It does not make partial reduction equivalent to healing, establish a universal threshold across wound types or prove that an intervention causing an early change will improve every later outcome. Prediction and causal treatment effect are different questions. A review should preserve that distinction when discussing area reduction as an intermediate endpoint.

Percentage reduction depends strongly on baseline measurement. For a small initial wound, a modest absolute difference can create a large percentage change. For an irregular wound, the selected boundary can influence both baseline and follow up estimates. Reports should therefore provide absolute area alongside percentage change and identify the measurement method. A claim such as ninety percent improvement is incomplete unless readers know which dimension or score changed, over what period and by which method. A percentage should not combine length, width and depth informally without a stated and justified calculation.

Area and depth should remain separate when they represent different aspects of the lesion. A reduced surface can coexist with persistent depth or undermining. Multiplying a few maximum dimensions does not necessarily provide true wound volume. If a rectangular approximation is used, it should be labelled as an estimate. Measurement research demonstrates that boundary interpretation and analysis technique can affect the result.[4] Consistency is therefore necessary, but consistent use of an approximate method does not transform the approximation into an exact representation of complex anatomy.

Baseline preparation and the index wound

A wound measured before debridement may appear larger afterwards because devitalised tissue or an obscured margin has been removed. This does not necessarily indicate deterioration. The timing of measurement in relation to cleansing and debridement should be consistent and explicit. If baseline and follow up use different preparation conditions, an apparent change may partly reflect observation rather than biology. The protocol should identify the clinical sequence and preserve relevant images or measurements. Retrospective interpretation is much weaker when the preparation steps were not recorded at the time.

When participants have multiple wounds, the study needs an index wound rule or an analysis that accounts for clustering. Selecting whichever lesion improves most after treatment creates bias. A prespecified rule can consider a clinically justified feature, but it should be applied before the outcome is known. If several wounds are analysed, they are not independent participants. Their outcomes may share the same vascular, metabolic and care environment. The statistical plan should reflect that relationship. A large count of wounds cannot simply be presented as the same amount of independent evidence as an equally large count of people.

The anatomical site also affects interpretation. A dorsal foot lesion differs mechanically from a plantar ulcer, and the same dressing may be exposed to different pressures and movement. Site, chronicity, prior treatment and baseline condition should therefore be reported in enough detail to judge applicability. A prolonged ulcer is not fully characterised by duration alone. The clinical record should identify what was assessed about its cause and relevant barriers to healing. Missing vascular, neurological or infection information cannot be supplied retrospectively by a photograph or by an assumption that every foot ulcer in a person with diabetes has the same mechanism.

Background care is part of the causal question

An adjunctive topical intervention should be evaluated within clearly described background care. The IWGDF wound healing guidance frames additional interventions in relation to best standard care, including attention to relevant local and underlying factors.[7] In a trial, those factors should be documented for both groups. The presence of a novel product does not make cleansing, pressure management or other concurrent care analytically invisible. If the groups receive different care packages, the result concerns those packages. It cannot isolate the topical ingredient merely because that ingredient is the most distinctive feature of the report.

The comparison treatment should also be clinically appropriate and fully described. A study can produce a favourable contrast against a weak or inconsistently delivered comparator without establishing superiority to contemporary care. Reviewers should examine the actual comparator rather than accept the term conventional treatment as a sufficient description. Changes in background treatment during follow up should remain visible. A participant who receives an additional procedure or rescue intervention may still contribute valuable outcome data, but attribution needs to reflect what occurred. The analysis should prespecify how such events are handled rather than exclude them only when inconvenient.

Adherence affects both groups. A dressing dispensed is not necessarily a dressing used as intended, and instructions about mechanical protection may not be followed consistently. Practical barriers, discomfort and access to supplies can influence the result. Recording actual use helps distinguish product performance from implementation problems. A pragmatic strategy trial may intentionally include these realities, but its conclusion should then concern effectiveness in that setting. A tightly controlled explanatory trial answers a narrower question. Neither design is inherently more valuable; each requires a clear account of what the comparison can establish.

Patient relevant outcomes beyond closure

Closure is important, but it does not capture every burden of wound care. Pain during dressing change, leakage, odour, treatment time and ability to walk or work can affect daily life. A trial can legitimately examine these outcomes alongside healing. They should be measured with defined methods and reported without implying that symptom relief proves closure. The tulle study's attention to application, removal and comfort shows why dressing performance deserves explicit assessment.[1] A product may have a useful role because it is easier to manage even when a study does not establish faster complete healing.

Infection and other complications require clinical definitions separate from appearance. Less slough or a cleaner looking surface does not by itself prove that an infection has resolved. Similarly, a photograph cannot exclude deeper involvement. The protocol should identify the assessment process and the role of relevant clinical investigations when indicated. This review does not supply a diagnostic algorithm or treatment regimen. It emphasises that a healing claim should not be used to imply unmeasured resolution of every associated problem. Clinical findings should be reported at the level actually assessed.

Treatment burden and harms should also be considered together. Frequent supervised applications may create travel and time costs, while a convenient home regimen may shift responsibility to the participant. Both can affect adherence and acceptability. A complete outcome account should include withdrawals and reasons, not only observations among completers. If a wound remains open but becomes easier to manage, that is a limited but potentially meaningful benefit. If a wound becomes smaller while treatment causes substantial discomfort, the trade off should remain visible rather than disappearing behind a favourable percentage reduction.

Analysis of unhealed and missing outcomes

Participants with unhealed wounds at the observation endpoint are part of the result. They should not be assigned invented closure dates or omitted from the headline conclusion. Time to event methods can handle some forms of incomplete observation, but their assumptions need attention. Loss to follow up may be related to deterioration, treatment burden or care elsewhere. Assuming that such loss is unrelated to prognosis can be unrealistic. The report should describe reasons and consider appropriate sensitivity analyses, with the method chosen before inspecting which approach produces the most favourable result.

A landmark closure proportion and a time to closure analysis answer related but different questions. The former asks how many wounds have closed by a specified time; the latter examines the timing of the event across follow up. Both need clear handling of additional procedures, amputation, death or other events relevant to the population. These outcomes should not be treated as ordinary missing measurements without explanation. The appropriate strategy depends on the study objective. A small exploratory study may present descriptive results transparently rather than fit an unstable complex model that its data cannot support.

Between group estimates should include uncertainty and clinically interpretable units. A significant within group change does not prove superiority to another group. The clean wound tulle study reported comparable between group results while identifying differences in aspects of dressing performance.[1] That distinction deserves preservation in a review. Selectively quoting favourable within group values would distort the comparison. The same principle applies to animal experiments: histological or contraction findings can inform biological hypotheses, but they should not be pooled conceptually with human closure outcomes as if all represented the same endpoint.[5]

A more useful framework for future wound reviews

Future reviews should begin by classifying the claim each study can support: wound condition, symptom control, dressing performance, partial reduction, complete closure or durability. The population, background care and measurement method should then determine whether findings can be compared. This approach avoids dismissing partial improvement while preventing it from carrying a claim it cannot support. It also identifies precise research gaps. If several studies measure scores but none confirms closure, the next priority is not another unqualified statement that a product promotes healing; it is a study designed around a defined clinically meaningful endpoint.

The proposed framework remains methodological rather than a validated core outcome set. Its strength is that it makes the evidential chain reviewable. Readers should be able to move from the stated treatment claim to the endpoint definition, the measurement record and the analysis. Where that chain is incomplete, the conclusion should narrow accordingly. Wound research becomes more credible when improvement is described accurately, including the residual problem and the care still required. This is especially important in chronic ulcers, where a visually encouraging course and complete durable recovery can remain substantially different outcomes.

Publication figures should reflect the endpoint definition used in the analysis. If the final image shows a residual open area, the caption should preserve that fact even when the size reduction is substantial. A measurement record can support a quantitative statement; appearance alone cannot provide the missing final dimensions. Keeping figure language aligned with the clinical record prevents an encouraging partial response from being presented as a closure event that was never documented.

Background care and reporting affect the meaning of healing

The IWGDF offloading guideline identifies mechanical tissue stress as an important determinant of healing in diabetes related foot ulcers.[8] Consequently, improvement during an Ayurvedic wound intervention should be interpreted alongside the offloading approach where relevant, as well as the other care already described. A topical product study cannot attribute the whole healing trajectory to that product when important cointerventions differ between groups or are undocumented.

TIDieR provides a structure for describing both the intervention and how it was delivered.[9] In wound research this includes application frequency, dressing changes, permitted background treatment and modifications over time. The same level of detail is needed for the comparator. If the wound deteriorates and rescue treatment is introduced, the event and the subsequent course should be reported rather than allowing the treatment change to disappear within a final size measurement.

CONSORT 2025 supports transparent participant flow and prespecified outcomes, while CONSORT Harms provides a parallel framework for adverse event collection and reporting.[10,11] In a healing trial, infection, deterioration, discontinuation and other clinically important events should be considered alongside closure and its durability. This does not require combining all outcomes into a single score. It requires a coherent account of who was followed, what happened to the wound and what care was needed during observation.

Discussion

Outcome precision improves rather than diminishes the value of partial improvement. A smaller residual wound can be an encouraging result while still requiring further treatment. Honest separation of these states prevents overstatement and allows the next study to ask a more useful question.

This review is selective and does not compare all available interventions. The proposed endpoint matrix is not a validated core outcome set. Its practical implication is that researchers should decide what the trial is intended to demonstrate and collect the measurements necessary for that claim.

Conclusion

Ayurvedic wound studies should distinguish wound condition, partial size reduction, complete closure and sustained closure. The measurement method and background care belong in the interpretation. A clear endpoint protects both the clinical value of an improvement and the credibility of the conclusion.

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