RQ 15 : Is there a role for pulsatile lavage during debridement of open injuries?

Section 1: Background

Irrigation and debridement are accepted cornerstones of open injury management, but the optimal method of fluid delivery has long been controversial. Earlier experimental and narrative literature suggested that pulsatile systems might better remove bacteria and particulate matter, especially from irregular wound surfaces while simultaneously raising concerns that higher-pressure delivery could damage soft tissue and bone, seed contaminants, and potentially impair healing. [5, 4, 6]

The modern clinical evidence base is dominated by the FLOW study which demonstrated that pressure did not improve patient-important outcomes, while detergent additive harmed outcomes relative to saline. Consequently, later reviews consequently shifted toward recommending very-low-pressure/gravity delivered normal saline as the default strategy, with no routine indication for more forceful pulsatile delivery. [1, 8, 7]

However, important unknowns remain as almost all the available direct clinical data concern adult open fractures rather than the broader spectrum of open injuries. Furthermore, no uploaded comparative clinical study separately analyzed antibiotic use as an outcome, and direct patient-level data on tissue damage caused by pulsatile lavage remain lacking. These gaps are central when translating the evidence into a consensus statement. [1, 2, 4]

Section 2: Data extraction

Only three studies identified in the literature search directly compared lavage strategies with extractable effect estimates or comparative performance data. The remaining relevant papers only provide protocol, narrative, biologic, or consensus context.

Core comparative evidence

Uploaded paper	Study design	Population	Sample size	Intervention details	Comparator	Outcomes measured	Key results and effect sizes	Limitations	Risk of bias
A Trial of Wound Irrigation in the Initial Management of Open Fracture Wounds	International blinded RCT, 2×3 factorial	Adults ≥18 years with open extremity fracture requiring operative fixation	2,551 randomized; 2,447 analyzed; ~90% with 12-month follow-up	High-pressure >20 psi, low-pressure 5–10 psi, very-low-pressure/ gravity 1–2 psi; castile soap 0.45% vs normal saline; minimum 3 L for grade I and 6 L for grade II/III	Pressure groups vs each other; soap vs saline	Primary: reoperation within 12 months for infection, wound-healing problem, or bone-healing problem. Secondary: nonoperative infectio	Reoperation: 13.2% high, 12.7% low, 13.7% very low; no pressure benefit. HRs: low vs high 0.92 (0.70–1.20), high vs very low 1.02 (0.78–1.33),	Surgeons could not be fully blinded; composite endpoint; open-fracture population only; sensitivity analysis weakened certainty around soap finding if losses to follow-up were	Low overall, with minor concerns for performance bias/attrition

Uploaded paper	Study design	Population	Sample size	Intervention details	Comparator	Outcomes measured	Key results and effect sizes	Limitations	Risk of bias
						n, wound-healing, bone-healing problems	low vs very low 0.93 (0.71–1.23). Soap worse than saline: 14.8% vs 11.6%, HR 1.32 (1.06–1.66). No significant secondary-outcome differences by pressure. Antibiotic use standardized, but not analyzed as a comparative outcome. [1]	distributed unfavorably	
FLOW Investigators. Fluid Lavage of Open Wounds (FLOW): A Multicenter, Blinded, Factorial Pilot Trial	Multicenter blinded pilot RCT, 2×2 factorial	Skeletally mature patients with open appendicular fractures, Gustilo I–IIIb	111 randomized; 89 completed 1-year follow-up	Low-pressure pulsatile 6–10 psi vs high-pressure pulsatile 25–30 psi; castile soap 80 mL of 17% solution per 3 L	Low vs high pressure; soap vs saline	Primary: reoperation for infection, wound-healing problem, or nonunion. Secondary: all infectio	Soap vs saline: 23% vs 24%, HR 0.91 (0.42–2.00), not significant. Low vs high pressure: 19%	Pilot study, underpowered, wide CIs, ~20% attrition, cointerventions not protocolized	Moderate risk / some concerns

Uploaded paper	Study design	Population	Sample size	Intervention details	Comparator	Outcomes measured	Key results and effect sizes	Limitations	Risk of bias
Comparing Alternative Irrigating Solutions and Pressures in Patients With Open Fractures.				saline vs normal saline; minimum 3 L for type I and 6 L for type II or higher		ns, wound-healing problems, nonunion, EQ-5D, SF-12	vs 28%, HR 0.55 (0.24–1.27), not significant. No significant functional differences. Tissue damage and antibiotic use were not measured as comparative outcomes. [2]		
Comparing the speed of irrigation between pulsatile lavage versus gravity irrigation: an ex-vivo experimental investigation.	Ex-vivo experimental study	No patients; 3-L saline bags tested in simulated OR setup	3 flow cycles per method-height combination	Gravity 1–2 psi; low-pressure pulsatile 5–10 psi; high-pressure pulsatile 20+ psi; tested at 6 ft and 9 ft bag height	Method and height comparisons	Irrigation time per 3 L; gross cost comparison	At 6 ft: gravity 142 s, high-pressure 189 s, low-pressure 324 s; at 9 ft: gravity 114 s, high-pressure 186 s, low-pressure 347 s; all $p<0.001$. Pulsatile systems cost ~3.3× gravity.	Ex vivo only; no wound bed, tissue interaction, or patient outcomes; very small run count	High risk for clinical applicability / very serious indirectness

Uploaded paper	Study design	Population	Sample size	Intervention details	Comparator	Outcomes measured	Key results and effect sizes	Limitations	Risk of bias
							No infection, wound healing, or reoperation outcomes. [3]		

Contextual and supporting uploaded evidence

Uploaded paper	Study design	Population	Sample size	Pulsatile lavage details	Comparator / outcomes	Key message for this question	Limitations	Risk of bias
FLOW Investigators. Fluid Lavage of Open Wounds (FLOW): design and rationale for a large, multicenter collaborative 2 × 3 factorial trial.	Trial protocol / rationale paper	Planned adults with open extremity fractures	Planned n=2,280	Planned gravity vs low vs high pressure; soap vs saline	Planned reoperation, function, QoL	Summarizes rationale that higher pressure may improve debris/bacteria removal but may damage bone, seed bacteria deeper, and reduce fracture-healing strength; no outcome data reported. [4]	Protocol only; relies on preclinical and prior literature	Not applicable for treatment effect
Irrigation of the wounds in open fractures.	Narrative review/annotation	Human, animal, and in vitro irrigation studies	Not systematic	Describes low-pressure methods and pulsed systems that often operate at 50–80 psi	Infection, bacterial clearance, debris removal, bone/so	Recommends normal saline routinely; finds high-pressure evidence inconclus	Narrative review; secondary-source evidence; methods not systematic	High

Uploaded paper	Study design	Population	Sample size	Pulsatile lavage details	Comparator / outcomes	Key message for this question	Limitations	Risk of bias
					ft-tissue damage	ive and associated with concerns over soft-tissue and bone damage and bacterial propagation. Notes lack of direct clinical evidence for delayed fracture healing. [5]		
Acute Management of Open Fractures: An Evidence-Based Review	Narrative review	Adults and children with open fractures	NA	Reviews low- vs high-pressure pulsatile techniques	Infection, wound/bone healing	States concern that high pressure may damage bone/soft tissue and push contaminants deeper; notes the pilot FLOW trial suggested, but did not prove, an advantage for lower pressure. [6]	Predates definitive FLOW RCT; narrative review	High
Open fractures: evidence-based best practices.	Narrative review / meeting proceedings	Open fracture and FRI prevention literature	NA	Synthesizes FLOW pressure and solution data	Reoperation, wound/bone healing, infection	Interprets FLOW as showing no pressure advantage and higher reoperati	Secondary synthesis, not systematic	High, but anchored to high-quality RCT

Uploaded paper	Study design	Population	Sample size	Pulsatile lavage details	Comparator / outcomes	Key message for this question	Limitations	Risk of bias
						on with castile soap, supporting very-low-pressure normal saline as an acceptable low-cost option. [7]		
Surgical timing for open fractures.	Narrative review	Open fractures	NA	Reviews pressure/solution/volume evidence	Reoperation, infection, wound management	Explicitly recommends very-low-pressure/ gravity irrigation with normal saline, stating FLOW resolved the pressure question; volume remains uncertain. [8]	Narrative review	High
The Contaminated High-Energy Open Fracture: A Protocol to Prevent and Treat Inflammatory Mediator Storm–Induced Soft-	Conceptual/ protocol article	High-energy contaminated open fractures	No comparative cohort	Discusses pressure lavage conceptually; proposes Versajet hydrosurgery plus TNP	Contaminant removal, tissue preservation	Argues pressure lavage was once viewed favorably but later evidence questioned it; suggests high-pressure pulsation may drive contaminants deeper. [9]	Opinion/protocol, no comparative patient outcomes	High / very low certainty

Uploaded paper	Study design	Population	Sample size	Pulsatile lavage details	Comparator / outcomes	Key message for this question	Limitations	Risk of bias
Tissue Compartment Syndrome								
The classification and principles of management of wounds in trauma.	Narrative trauma review	Traumatic wounds including open fractures	NA	Describes pulsed lavage and low-pressure approaches	Debris clearance, tissue injury	Notes pulsed lavage may help access wound crevices, but cites review evidence that bulb or elevated-bag irrigation is comparable and that excessive pressure may damage tissues and seed bacteria deeper; favors low-pressure systems. [10]	Narrative secondary review	High
Prevention and Treatment of Surgical Site Infections in Orthopaedic Surgery: An Italian Delphi Consensus on Risk Stratific	Modified Delphi consensus with narrative review	Orthopaedic SSI/PJI/FRI experts	10 experts, 12 statements	Technical consensus favored low-pressure irrigation, especially in traumatic surgery	Consensus statements, not patient outcomes	Supports low-pressure technique, but the document is broader than acute open injuries and also prefers antiseptic agents based on expert opinion	Expert opinion; indirect population and intervention; clinical trials lacking	High / very low certainty for current question

Uploaded paper	Study design	Population	Sample size	Pulsatile lavage details	Comparator / outcomes	Key message for this question	Limitations	Risk of bias
ation and Wound Irrigation Strategies						and translational evidence rather than direct comparative trials. [11]		

Section 3: Results

The available literature consistently supports irrigation as part of debridement, but it does not support the proposition that pulsatile delivery improves clinical outcomes over simpler very-low-pressure approaches. The definitive FLOW RCT demonstarted that the differences in irrigation pressure did not translate into lower 12-month reoperation, reduced risk of infection, or better wound/bone healing. This neutral result was seen despite a large sample, broad international recruitment, blinded outcome adjudication, and clinically relevant endpoints. [1]

The FLOW pilot study previosuly had reached a similar conclusion. It suggested, but did not prove, that lower-pressure pulsatile irrigation might be preferable to higher-pressure pulsatile irrigation. Because the confidence intervals were wide and the study was a pilot, the correct interpretation is not that low-pressure pulsatile lavage is superior, but that higher pressure lacked convincing benefit and may be unnecessary. [2]

Across the narrative reviews identified, the evidence is clear. Early reviews framed pulsatile lavage as a plausible means to improve bacterial removal and access wound recesses. However, the same literature repeatedly described experimental concerns over bone surface injury, soft-tissue trauma, bacterial propulsion deeper into tissue planes, and impaired fracture healing, particularly with older “high-pressure” devices operating far above the thresholds tested in FLOW. These concerns remained largely indirect because clinical harm outcomes were not robustly evaluated clinically. [5, 6, 10]

Subsequent reviews, written after FLOW was completed, are notably more definitive. Both the 2020 and 2024 review papers interpret the evidence as favoring very-low-pressure/gravity normal saline because it achieves comparable clinical outcomes at lower complexity and cost. The ex-vivo study by Mundy, et al [3] reinforces that practical conclusion by confirming gravity irrigation is faster and less expensive than pulsatile systems, although that study cannot speak to infection or healing. [8, 7]

None of the identified comparative clinical studies demonstrated that pulsatile lavage reduced infection rate, wound-healing complications, nonunion, or reoperation when compared with lower-pressure or gravity delivery strategies. Furthermore, none of these studies analyzed antibiotic use as an outcome. Objective clinical evidence on tissue damage from pulsatile systems is also absent; that concern remains supported mainly by experimental and secondary-source literature. [1, 2, 4]

Section 4: Discussion

This evidence base supports a judicious but strong conclusion: pulsatile lavage should not be regarded as the default or evidence-based superior method of irrigating open injuries during debridement. The strongest clinical evidence demonstrates equivalence across pressure strategies in open extremity fractures, with no measurable advantage for higher-pressure pulsatile delivery. Consequently, the burden of proof has shifted whether a pulsatile device can demonstrate any additional value. The available literature does not demonstrate that added value. [1, 7]

A practical nuance is important to recognize. The direct RCT evidence addresses pressure category, but does not consider every conceivable technical use of a pulsatile device. Surgeons may still find pulsatile instruments useful in selected situations where directed flow into deep recesses, undercut surfaces, or irregular trajectories is technically helpful. That procedural convenience is acknowledged in the trauma review literature. However, such a role is operational, not outcome-proven. It does not justify a recommendation for routine pulsatile use, and it certainly does not justify high-pressure pulsation. [10,5]

Another nuance is that the historic "high-pressure" literature often involved devices operating around 50–80 psi, whereas the FLOW high-pressure arm was defined as >20 psi. That means the most definitive clinical trial does not directly answer whether very-high-pressure legacy pulsatile systems are harmful; rather, it indicates that at commonly used modern pressure ranges, raising pressure above very-low or low pressure does not improve clinically important outcomes. When this neutral clinical evidence is read alongside the experimental harm concerns summarized in the available reviews, it becomes clear that there is no justification to favor high pressure lavage. [5, 1]

The irrigation fluid also matters, even though this is not the main issue addressed here. Anglen [12] reported that irrigation of open fracture wounds with an antibiotic solution offered no advantages over the use of a non-sterile castile soap solution, and suggested it may increase the risk of wound-healing problems. However, the FLOW trial, the same definitive trial that neutralized the pressure question, later observed harm with castile soap relative to saline. This strengthens the broader debridement message that simple normal saline remains the default irrigant in open fracture surgery, and more recent reviews consistently echo that conclusion. The 2026 Delphi paper is broader and leans toward antiseptic irrigation in selected orthopedic infection settings, but it explicitly rests on expert consensus and translational evidence, not on robust acute open-fracture RCT data. Its applicability to the current question is therefore limited and should not outweigh the conclusions based on the FLOW trial. [1, 8, 7, 11]

The main limitation of the available evidence base is population scope. The consensus question is framed as "open injuries," but the direct comparative clinical evidence is almost exclusively focused on open extremity fractures. Evidence for isolated contaminated lacerations, degloving injuries without fracture, ballistic soft-tissue wounds, pediatric open injuries, hand/toe open fractures, and IIIC vascular injuries is sparse or absent in the available literature. This limitation argues against an absolute statement that pulsatile lavage has "no role" in any open injury. A more defensible consensus formulation is that pulsatile lavage has no proven routine role and no demonstrated outcome advantage, while a selective technical role at low pressure remains plausible but unproven. [1, 2, 4]

Finally, the evidence has additional meaningful systems implications. If clinical outcomes are similar, then speed, simplicity, device availability, and cost become relevant. The ex-vivo study by Mundy, et al [3] suggests gravity is faster and cheaper than pulsatile irrigation. In resource-constrained settings, that finding strengthens the case for very-low-pressure/gravity saline as the default method, particularly when recent reviews have already interpreted FLOW in that direction. [3, 8, 7]

Section 5: Risk of bias of included studies

Source type	Overall appraisal
FLOW definitive RCT	Low risk of bias; strongest direct evidence, despite unavoidable surgeon unblinding and modest attrition [1]
FLOW pilot RCT	Moderate risk / some concerns due underpowering, wider imprecision, and greater attrition [2]
Ex-vivo efficiency study	High risk for clinical applicability because it is indirect and does not measure patient outcomes [3]
Protocol/design paper	Not applicable for comparative effect estimation [4]
Narrative reviews / conceptual articles / Delphi consensus	High risk of selection and interpretation bias for treatment effect estimation; useful only as contextual or biologic support [5, 6, 7, 8, 9, 10, 11]

GRADE-style assessment

Outcome	Evidence base	Certainty	Judgment
Reoperation / infection / wound or bone healing for pulsatile vs very-low-pressure/gravity irrigation in open extremity fractures	One large low-risk RCT plus one small pilot RCT	Moderate	Downgraded for indirectness to the broader “open injuries” question; otherwise, the evidence is robust and favors no clinically important advantage for pulsatile/high-pressure strategies
Tissue damage / bacterial propulsion / healing harm from higher-pressure pulsatile lavage	Experimental data summarized in reviews and protocol papers	Low	Serious indirectness and reliance on animal/in vitro/secondary-source evidence
Operative efficiency and cost	One ex-vivo study	Low	Serious indirectness despite consistent practical signal favoring gravity
Antibiotic use as a comparative outcome	No direct comparative study outcome data	Very low / insufficient	Outcome largely unreported or only standardized as cointervention

Section 5: Response / recommendation

Routine pulsatile lavage is not recommended during the debridement of open extremity injuries/fractures because it has not been shown to reduce infection, wound-healing complications, nonunion, or reoperation frequency compared with very-low-pressure/gravity normal saline irrigation. High-pressure pulsatile lavage should be particularly avoided as a routine default. [1, 5]

Section 6: Level/strength of evidence: MODERATE.

The strongest justification for this conclusion is that a large, well-conducted RCT (FLOW trial) reported no clinically meaningful benefit of pulsatile/high-pressure strategies over very-low-pressure/gravity irrigation in open extremity fractures, and later secondary papers uniformly interpret the evidence in that direction. The level of evidence is downgraded from "High" to "Moderate" because the consensus question ("open injuries") is broader than the directly studied population ("open extremity fractures") and because the available data on harms remain indirect. [1, 8, 7]

References

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