

Evidence Summary

Intraoperative Antiseptic Lavage

SIMINI PROTECT LAVAGE

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Intraoperative Evaluation Framework and References

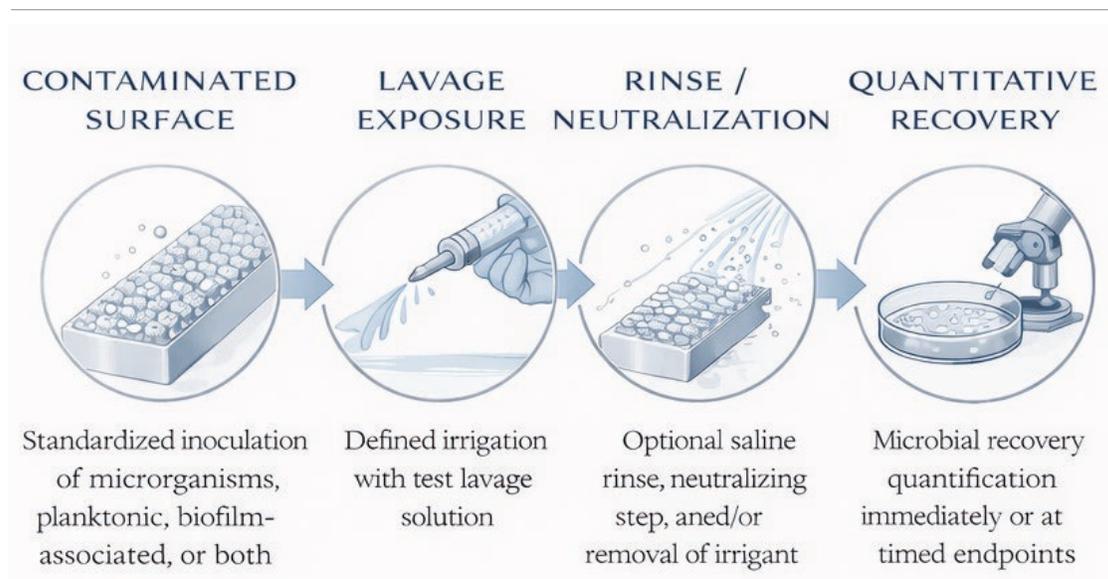


Figure 1. Intraoperative evaluation framework schematic

Schematic overview of a controlled intraoperative lavage evaluation workflow. This schematic is provided for orientation only; specific protocols, dwell times, substrates, and recovery methods vary by study and are detailed in the cited source publications.

References

- [1] Hamad CD, et al. Comparing the in vitro efficacy of commonly used surgical irrigants for the treatment of implant-associated infections. *J Bone Joint Surg Am.* 2025.
- [2] Seta J, et al. Efficacy of Commercially Available Irrigation Solutions on Removal of Staphylococcus Aureus and Biofilm From Porous Titanium Implants: An In Vitro Study. *J Arthroplasty.* 2024.
- [3] O'Donnell J, et al. Efficacy of Common Antiseptic Solutions Against Clinically Relevant Planktonic Microorganisms. *Orthopedics* 2022.
- [4] Kia C, et al. Effectiveness of topical adjuvants in reducing biofilm formation on orthopedic implants: an in vitro analysis. *J Shoulder Elbow Surg.* 2021
- [5] Powell J, et al. Effect of Commercially Available Wound Irrigation Solutions on Uninfected Host Tissue in a Murine Model. *Arthroplasty Today* 2024
- [6] Forzisi I, et al. Use of Simini Protect Lavage as an Adjuvant in the Antiseptic Protocol for Revision Surgeries Involving Total Hip Replacement. *VCOT Open* 2025
- [7] **Unpublished Data:** Texas Tech University: Unpublished preclinical murine surgical wound model evaluating bacterial recovery following saline and antiseptic irrigation.

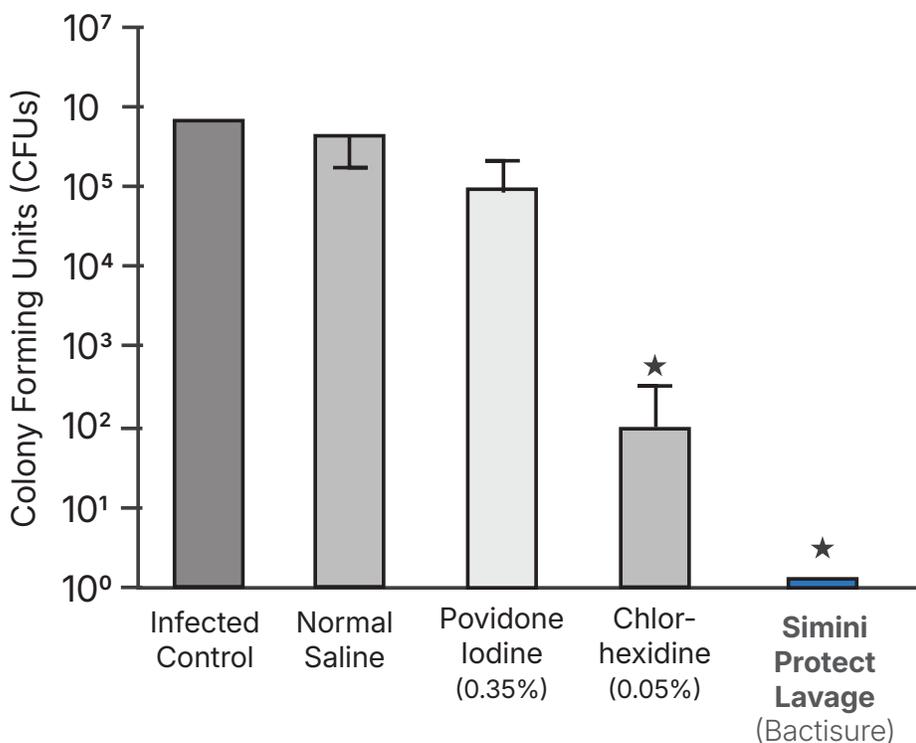
Planktonic Microorganism Reductions

— comparison with saline, povidone iodine and chlorhexidine

Figure 2. Log-transformed CFU recovery of planktonic *Staphylococcus aureus* following fixed-dwell exposure to surgical irrigants.

Planktonic *Staphylococcus aureus* was exposed to multiple irrigation solutions under standardized dwell conditions, followed by neutralization and quantitative CFU recovery. Data represent immediate post-exposure bacterial burden as measured in vitro.

Orientation note: This figure reports log-transformed recoverable bacterial burden following exposure. Lower values indicate lower recoverable bacterial burden.



Statistical annotation: The asterisk denotes a statistically significant difference as defined in the source publication. Details of statistical comparisons and thresholds are reported by the original authors.

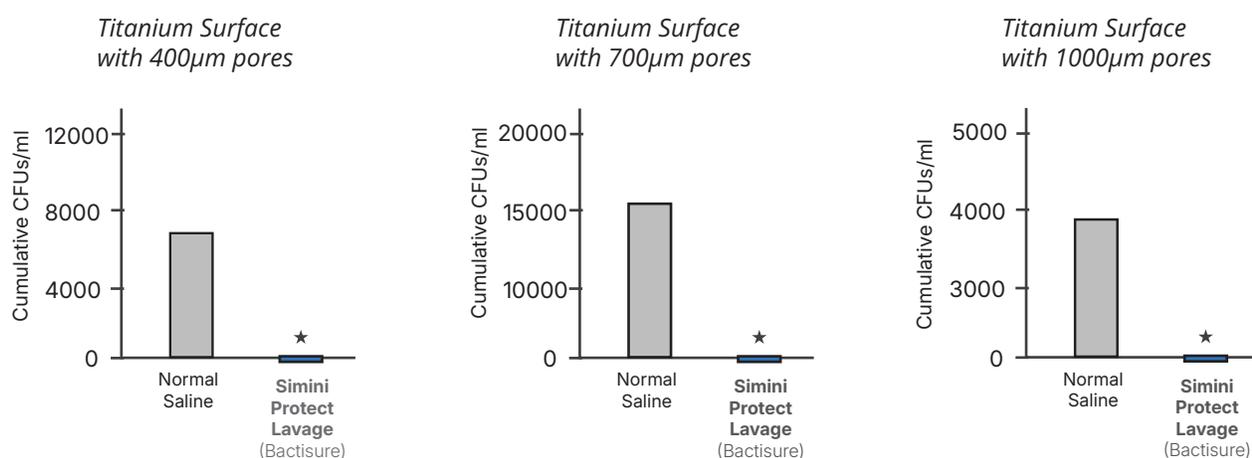
Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

Acute porous titanium model — saline control versus Simini Protect Lavage

Figure 3. Recoverable *Staphylococcus aureus* following saline and antiseptic irrigation on porous titanium substrates under acute in vitro conditions.

Porous titanium substrates with defined pore sizes were inoculated with *Staphylococcus aureus* and irrigated with saline or Simini Protect Lavage using a brief, 15-second exposure under controlled acute in vitro conditions. Recoverable bacterial burden was quantified following irrigation and sequential sonication, as described in the source publication. Results are presented by substrate pore size to illustrate measured recoverable bacterial burden following short-duration irrigation in this model.

Orientation note: Values represent cumulative recoverable bacterial burden following irrigation and recovery procedures. Lower values indicate lower recoverable burden.



Statistical annotation: The asterisk denotes a statistically significant difference as defined in the source publication. Details of statistical comparisons and thresholds are reported by the original authors.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

Planktonic Microorganism Reductions

— comparison with povidone iodine and chlorhexidine

Figure 4. Planktonic microorganism log reduction following timed exposure to common surgical irrigants.

Planktonic suspensions of clinically relevant microorganisms were exposed to saline, povidone-iodine, chlorhexidine-based irrigation, or Simini Protect Lavage for a fixed duration under controlled in vitro conditions. Bacterial recovery was quantified immediately following exposure and neutralization using colony-forming unit (CFU) enumeration. Conditions and statistical analyses are reported in the source publication.

Orientation note: This figure reports bacterial reduction relative to baseline. Higher values indicate greater reduction.

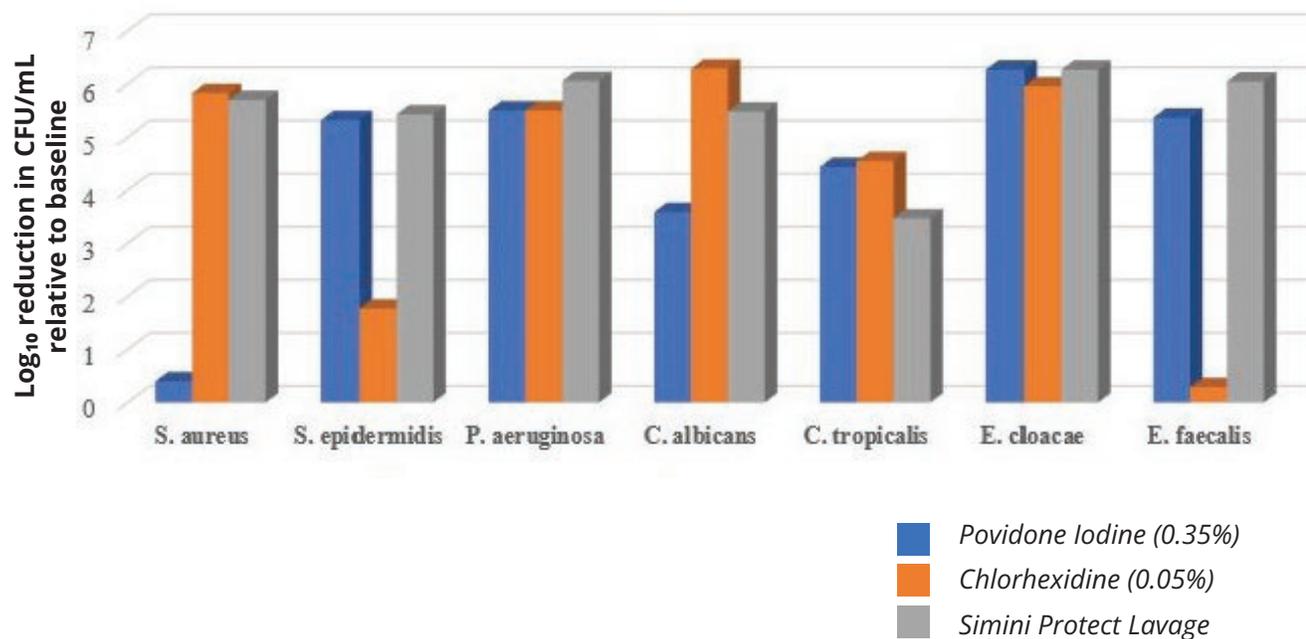


Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

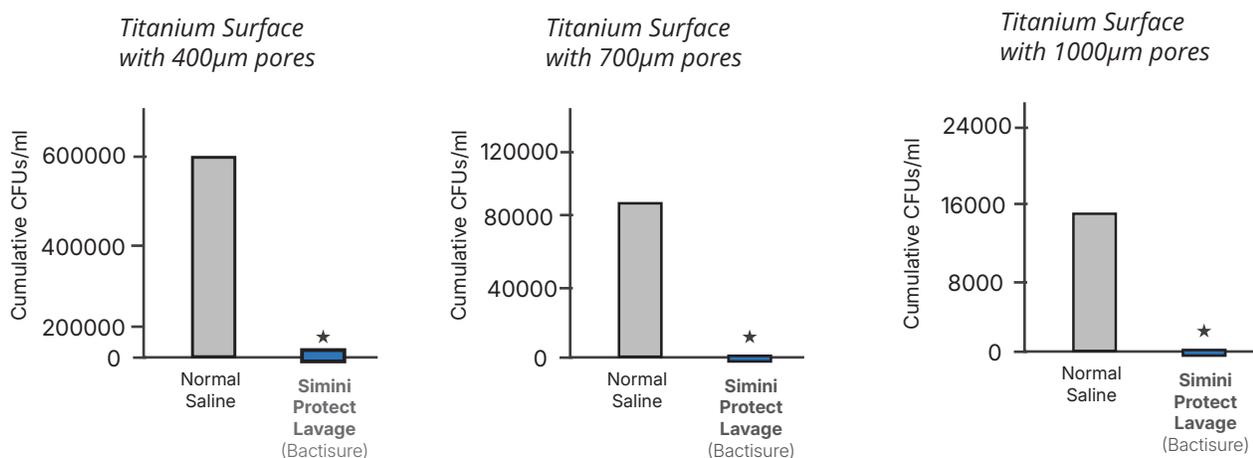
Biofilm-associated Staphylococcus aureus

— porous titanium substrates

Figure 5. Biofilm-associated Staphylococcus aureus recovery on porous titanium implants following lavage exposure.

Porous titanium substrates with defined pore sizes were inoculated with Staphylococcus aureus and irrigated with normal saline or Simini Protect Lavage using a 15-second pulse irrigation exposure, consistent with the acute in vitro model described in the source publication. Recoverable bacterial burden was quantified following irrigation and sequential sonication. Results are presented by substrate pore size to illustrate measured recoverable bacterial burden following short-duration irrigation in this acute model.

Orientation note: Values represent recoverable biofilm-associated bacterial burden following exposure and recovery procedures. Lower values indicate lower measured biofilm-associated recovery.



Statistical note: Statistical comparisons and significance thresholds are reported as defined in the source publication.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

Biofilm-associated bacterial recovery on orthopedic implant metals following antiseptic lavage

Table 1. Percent recoverable biofilm-associated bacteria remaining on orthopedic implant metals following lavage exposure at 48 hours.

Biofilms formed by *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Cutibacterium acnes* on commonly used orthopedic implant metals were exposed to saline, povidone-iodine, chlorhexidine-based irrigation, or Simini Protect Lavage under controlled in vitro conditions. Biofilm-associated bacterial burden was quantified as percent colony-forming units (CFUs) remaining relative to untreated controls, adjusted for metal substrate. Results are presented by bacterial species to illustrate organism-specific differences in recoverable biofilm following lavage exposure.

Orientation note: Values represent percent recoverable biofilm remaining relative to untreated controls. Lower percentages indicate greater reduction in biofilm-associated bacteria.

	Antiseptic Solution	% CFU Remaining	P-value
All Bacteria	Povidone Iodine (0.35%)	8.13%	<0.001
	Chlorhexidine (0.05%)	9.80%	0.002
	Simini Protect Lavage	5.31%	N/A
C. Acnes	Povidone Iodine (0.35%)	9.55%	<0.001
	Chlorhexidine (0.05%)	9.06%	<0.001
	Simini Protect Lavage	5.61%	N/A
S. Aureus	Povidone Iodine (0.35%)	6.36%	0.068
	Chlorhexidine (0.05%)	12.47%	0.017
	Simini Protect Lavage	4.42%	N/A
S. Epidermidis	Povidone Iodine (0.35%)	8.49%	0.007
	Chlorhexidine (0.05%)	7.86%	0.009
	Simini Protect Lavage	5.89%	N/A

Statistical note: P-values reflect statistical comparisons between each listed irrigant and Simini Protect Lavage, as defined in the source publication. Statistical methodology and comparator definitions are reported by the original authors.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

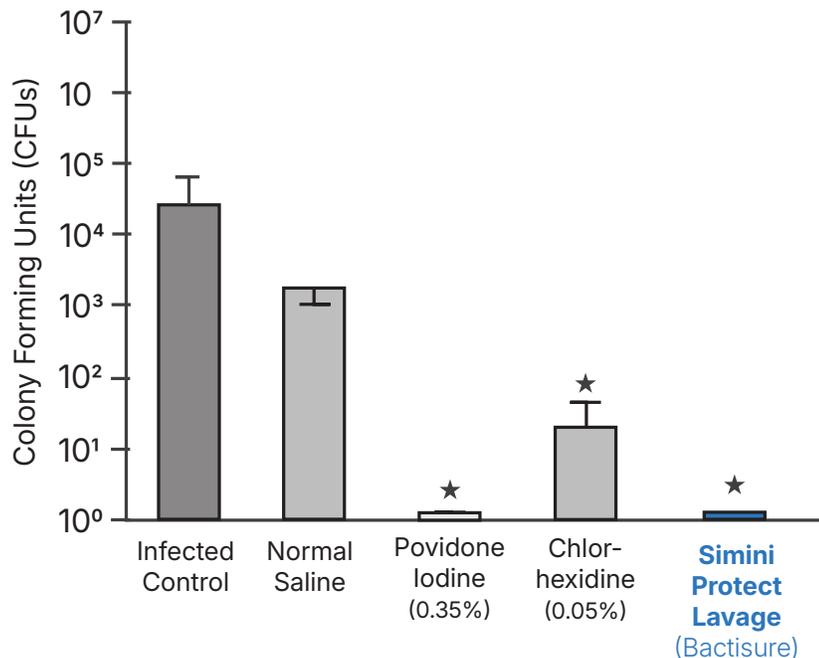
Biofilm-associated Staphylococcus aureus

— matched irrigant dwell conditions

Figure 6. Biofilm-associated Staphylococcus aureus recovery following matched-dwell irrigant exposure.

Established Staphylococcus aureus biofilms grown on titanium alloy substrates were exposed to surgical irrigants using a standardized 5-minute dwell time under controlled in vitro conditions. Recoverable biofilm-associated bacterial burden was quantified following irrigation, sonication, and colony-forming unit (CFU) enumeration. Bars represent mean CFUs with standard deviation, as reported in the source publication.

Orientation note: Planktonic killing assays using the same dwell time are reported separately in the source publication, allowing comparison of irrigant efficacy across microbial states. Lower values indicate lower recoverable biofilm-associated bacterial burden.



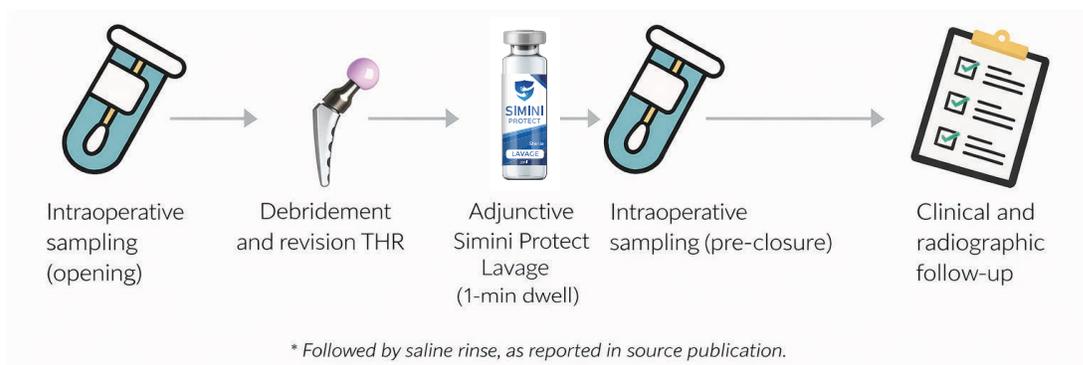
Statistical annotation: The asterisk denotes a statistically significant difference relative to infected control, as defined in the source publication.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

Clinical outcomes in revision total hip replacement — canine case series

Figure 7. Clinical outcomes following revision total hip replacement with adjunctive Simini Protect Lavage in canine patients.

Revision total hip replacement procedures were performed using Simini Protect Lavage as an adjunct to standard surgical debridement, antiseptic irrigation, and antimicrobial protocols. The figure presents a schematic of the intraoperative workflow alongside descriptively reported clinical outcomes, including implant retention and clinical and radiographic follow-up, as reported in the source publication.



Outcome Measure	Reported Result
Total revision THRs	36
Use of Simini Protect Lavage	Adjunctive; intraoperative
Implant retention at final follow-up	35 / 36
Number of patients requiring explant	1
Clinical or radiographic signs of infection at final follow-up	Absent in 35 / 36 cases
Minimum follow-up duration	≥1 year

Orientation note: Results are reported descriptively from a retrospective case series without a control group. Outcomes reflect the combined surgical, antimicrobial, and adjunctive lavage protocol used by the authors.

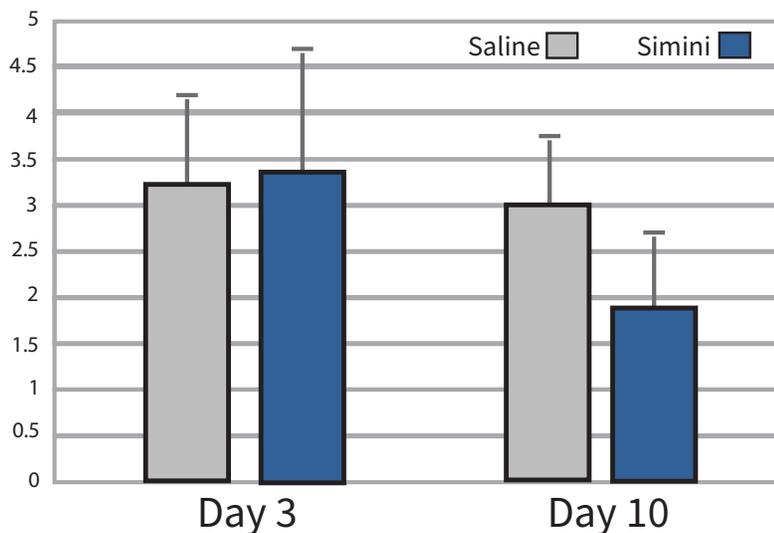
Tissue response to antiseptic lavage — non-infected murine model

Figure 8. Histologic inflammation scores following single, short-duration antiseptic lavage exposure in a non-infected murine wound model.

Full-thickness murine skin wounds were exposed intraoperatively to commercially available irrigation solutions, including Simini Protect Lavage (Bactisure), under manufacturer-directed exposure durations, followed by saline rinse. Local inflammatory response was assessed histologically at 3 and 10 days post-exposure using a standardized grading scale. Results are presented as mean inflammation scores with standard deviation.

No statistically significant differences in inflammation were observed between antiseptic irrigation solutions and normal saline at either time point.

Orientation note: Lower scores indicate less histologic inflammation.



Statistical annotation: Statistical comparisons and significance thresholds are reported as defined in the source publication.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

Tissue response to antiseptic lavage

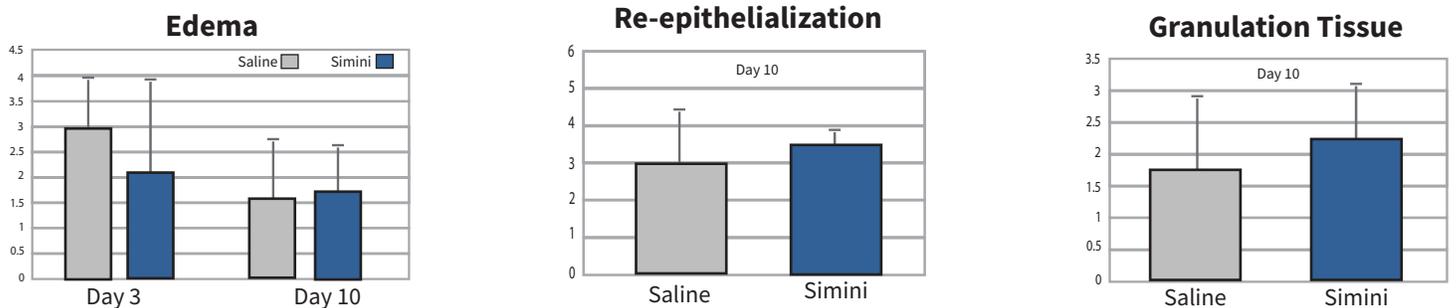
— wound healing parameters in a non-infected murine model

Figure 9. Wound healing–related histologic parameters following single, short-duration antiseptic lavage exposure in a non-infected murine wound model.

Full-thickness murine skin wounds were exposed intraoperatively to commercially available irrigation solutions, including Simini Protect Lavage (Bactisure), under manufacturer-directed exposure durations, followed by saline rinse. Histologic wound healing parameters—including edema, granulation tissue formation, and re-epithelialization—were assessed at defined post-exposure time points using standardized grading criteria. Results are presented as mean scores with standard deviation, as reported in the source publication.

No statistically significant differences in wound healing parameters were observed between antiseptic irrigation solutions and normal saline at any assessed time point.

Orientation note: Lower scores indicate more favorable wound healing characteristics.



Statistical annotation: Statistical comparisons and significance thresholds are reported as defined in the source publication.

Figure note: Simini Protect Lavage and Bactisure refer to the identical fluid. The product name used reflects the terminology in the source publication.

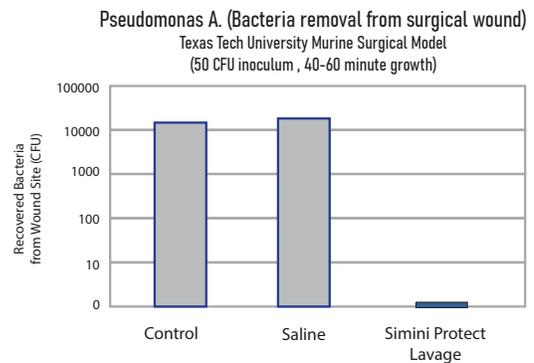
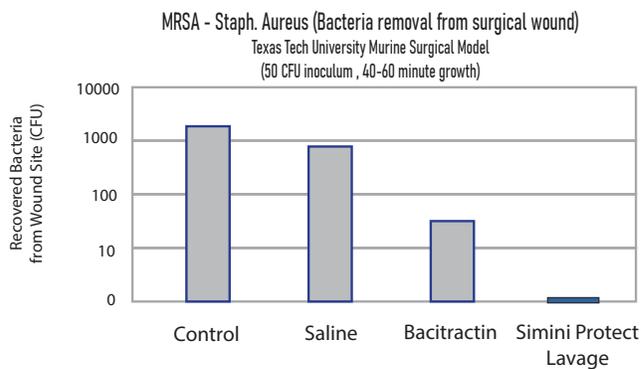
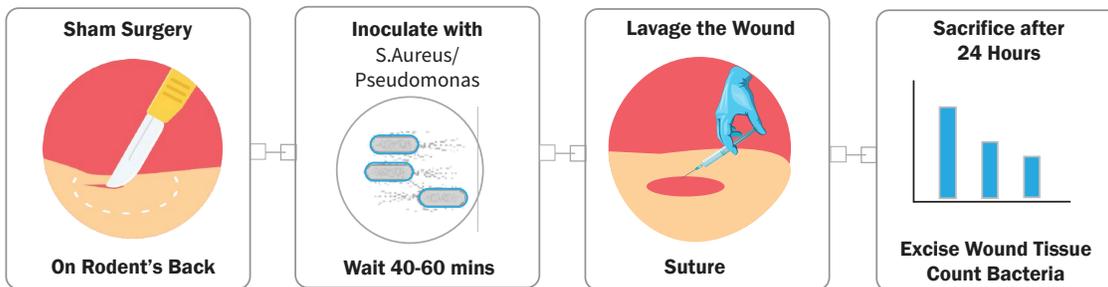
Preclinical murine surgical wound model

— bacterial recovery following saline or antiseptic irrigation

Appendix Figure A1. Unpublished preclinical murine surgical wound model — study design and quantitative bacterial recovery

Full-thickness dorsal wounds were created in rodents, inoculated with *Staphylococcus aureus* or *Pseudomonas aeruginosa*, and allowed to incubate for 40–60 minutes prior to wound closure. Wounds were irrigated intraoperatively with either normal saline or Simini Protect Lavage according to the study protocol. Animals were sacrificed at 24 hours, and excised wound tissue was processed for quantitative bacterial recovery.

Bar charts depict recoverable bacterial burden from wound tissue for each organism under control, saline, and Simini Protect Lavage conditions, as measured in colony-forming units (CFUs). Data are shown descriptively as reported by the study investigators.



Orientation note: Lower values indicate lower recoverable bacterial burden.

Disclosure: The data presented in this appendix derive from an unpublished preclinical murine study conducted at Texas Tech University. These findings have not undergone peer review and are presented for transparency and contextual completeness only.