CLINCH: Supplementary Test Plan and Study Matrix

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Purpose

This supplement enumerates validation studies and bench tests required to establish safety, performance, and repeatability of the Laminar-Shear Biogel Closure System (CLINCH). Each study defines objectives, methods, variables, instruments, endpoints, and pass/fail criteria. Targets align with known skin mechanics, hydration/temperature effects, tissue orientation, and hydrogel adhesion [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, **?**, 11, 12, 13].

1 Global Test Matrix

2 Study Protocols

S1. Impulse–Depth Calibration (bench, then ex vivo)

Objective: Map tangential impulse (0.01 −-0.06 N s) and normal pressure (10 −-70 kPa) to realized shear depth (50 −-150 µm) across hydration/temperature.
Substrates: Layered skin analog then porcine skin.
Controls: IPA-prepped vs. no-prep; ambient setpoints 22 °C, RH 40%.
Instruments: High-speed motion/force logging; OCT or confocal microscopy for depth.
Endpoints: Depth (median, IQR); visible bleeding (rate).
Pass: ≥95% of taps within 50 −-150 µm; 0% visible bleeding at spec settings.
Rationale: Depth safety relative to microvasculature [10, **?**]; hydration/temperature effects [1, 2, 3].

S2. Adhesion & Flexion Durability

Objective: Verify lap-shear and cyclic durability with lattice seal.
Gels: Low-modulus (1 kPa to 10 kPa) and high-modulus (up to 50 kPa) formulations (e.g., chitosan, PEG–alginate).
Methods: Lap-shear to skin analog; flexion rig with ±10% strain, 1000 cycles.
Endpoints: Lap-shear ≥20 kPa; edge gapping <0.3 mm.
Rationale: Adhesive mechanics and modulus matching [8, 9].

Table 1: Study overview and primary endpoints

ID	Study	Primary endpoints
S1	Impulse–Depth Calibration	Shear depth (µm) vs. impulse/pressure; epidermal-only confirmation (no bleeding)
S2	Adhesion & Flex Durability	Lap-shear (kPa); edge gapping (mm) after 1000 flex cycles at ±10% strain
S3	Timing Sensitivity	Seal integrity vs. gel deposition delay (0.5–5 s)
S4	Orientation (Langer Lines)	Dehiscence/gapping vs. parallel vs. perpendicular orientation
S5	Hair/Surface Condition	Failure rate and adhesion vs. clipped/unclipped; IPA vs. no prep; moisturized vs. clean
S6	Thermal/Hydration Envelope	Performance across 18 °C to 30 °C, RH 20 % to 70 %
S7	Microvascular Safety	OCT/dermoscopy confirmation of epidermal-only shear; no capillary disruption
S8	Biogel Biocompatibility	Irritation/sensitization screens; ISO 10993-relevant cutaneous endpoints
S9	High-Tension Sites	Performance with high-modulus gel and denser lattice at high-tension locations
S10	Sterility/Bioburden	Pad cover sterility, process bioburden checks; post-use contamination
S11	Usability/Timing	Time-to-gel and adherence to SOP windows (sub-3 s)
S12	Failure Modes & Margins	Worst-case testing for overshoot, delayed gel, misalignment

S3. Timing Sensitivity (gel deposition delay)

Objective: Quantify seal degradation vs. delay: 0.5, 1, 2, 3, 5 s post-shear.
Endpoints: Gap (mm), leak/burst pressure change.
Pass: No significant degradation $\leq$3 s; performance drop documented beyond 3 s.
Rationale: Skin elastic recovery timescale [4, 3].

S4. Orientation vs. Langer Lines

Objective: Compare closure aligned with vs. across tension lines.
Endpoints: Dehiscence rate, gap after flex cycles.
Rationale: Orientation reduces opening stress [5].

S5. Hair & Surface Condition

Objective: Evaluate hair and skin film effects. Groups: clipped (<0.3 mm) vs. unclipped; IPA vs. no-prep; moisturizer applied 1 h prior vs. none.
Endpoints: Failure rate (missed shear, poor adhesion), lap-shear, gap.
Rationale: Hair/contact mechanics and lipid films alter friction [14, 6, 7].

S6. Thermal/Hydration Envelope

Objective: Validate performance across 18 °C to 30 °C and RH 20 % to 70 %.
Endpoints: Depth control, lap-shear, gap.
Pass: Maintain S1/S2 criteria within 20 24, RH 30 % to 50 %; characterize drift at edges.
Rationale: SC mechanics vs. hydration/temp [1, 2, 3].

S7. Microvascular Safety (imaging)

Objective: Confirm epidermal-only shear; no capillary disruption.
Methods: OCT/dermoscopy; optional laser Doppler or capillaroscopy.
Endpoints: No intradermal bleeding; depth within 50 −-150 µm.
Rationale: Papillary plexus depth; epidermal target [10, **?**].

S8. Biogel Biocompatibility (ISO-relevant)

Objective: Screen irritation/sensitization and local tissue response for selected gels.
Methods: In vitro cytotoxicity; ex vivo skin; small-animal cutaneous patch (if required).
Endpoints: Irritation scores, histology; accept vs. ISO cutoffs.
Rationale: Established safety of chitosan and alginate/PEG-based blends [11, 12, 13].

S9. High-Tension Sites

Objective: Validate performance at high-tension locations (e.g., joints).
Methods: Use high-modulus gel and increased lattice crosslink density.
Endpoints: Dehiscence rate, gap under dynamic strain.
Rationale: Modulus matching and architecture improve durability [8, 9].

S10. Sterility & Bioburden

Objective: Verify pad cover sterility and post-use bioburden.
Methods: Standard plate counts/swabs; accelerated aging (if applicable).
Endpoints: CFU thresholds met; no detectable cross-contamination.

S11. Usability & Timing (human factors)

Objective: Measure time-to-gel and adherence to sub-3 s window across operators.
Methods: Simulated closures with task analysis; log timestamps.
Endpoints: % closures meeting timing SOP; learning curve.

S12. Failure Modes & Margins

Objective: Stress test worst cases: over-impulse, under-pressure, delayed gel (5 s), misalignment to Langer lines.
Endpoints: Failure signatures; margin-to-failure quantified for each factor.

Metric	Minimum Acceptance
Shear depth control	$\geq$95% within 50 −-150 µm (no bleeding)
Lap-shear strength	$\geq$20 kPa (analog) at 22 °C, RH 30–50% [8, 9]
Edge gapping	<0.3 mm after 1000 flex cycles at ±10% strain
Timing robustness	No significant degradation $\leq$3 s; documented drop >3 s [4, 3]
Orientation benefit	Reduced dehiscence/gap when aligned with Langer lines [5]

3 Acceptance Criteria Summary

4 Statistics & Sample Size Notes

For S1/S2, plan $n \geq 10$ samples per condition; repeated-measures ANOVA (or mixed models) across impulse/pressure and environment factors. Power analysis to detect a 20 µm shift in depth and 5 kPa in lap-shear at $\alpha = 0.05$, power 0.8. For usability (S11), aim $n \geq 12$ operators and report learning curves.

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