

# Accelerating Perfusion in Chronic and Diabetic Wounds

## A Closed-Loop Isothermal Regulation System via a Flexible Additively Manufactured Matrix

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### Background

**The Clinical Problem:** In patients with diabetes, impaired blood circulation reduces oxygen delivery to tissues. This causes a significantly **lower wound-bed temperature**, which stalls cellular repair and leads to severe chronic wounds. Essential healing processes function most efficiently when tissue temperature remains within the physiological range of 37–39°C.

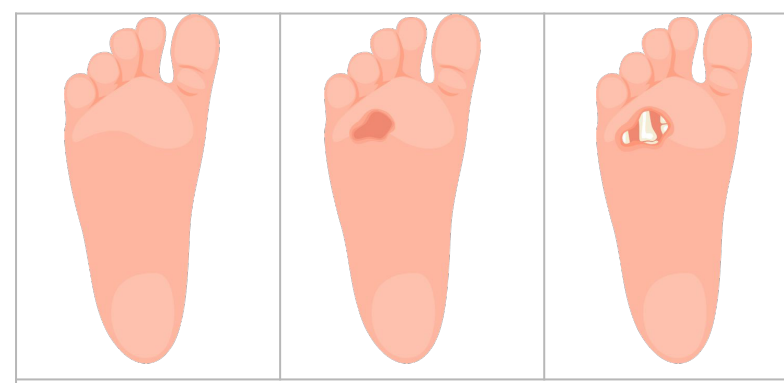


Figure 1: The progression of impaired circulation leading to diabetic ulcers and abscesses. (Source: vesvocre/Envato Elements)

**The Technological Gap:** Modern wound dressings are **purely passive systems**. They can protect a wound or retain moisture, but they **do not regulate temperature**.

**The Engineering Solution:** Maintaining a stable thermal environment accelerates tissue perfusion. Advances in flexible resistive heating and **closed-loop feedback systems** now enable the creation of **isothermal wound environments** using additively manufactured, highly accessible hardware.

### Thermal Physiology

Adequate blood flow is critical during the **acute inflammatory phase** (days 1 through 4) of the wound-healing timeline. During this crucial window, the body relies on rapid circulation to deliver immune cells, to the injured tissue. In diabetic patients, underlying **vascular disease impairs this circulation**, which stalls the healing timeline and increases the risk of **chronic wounds**.

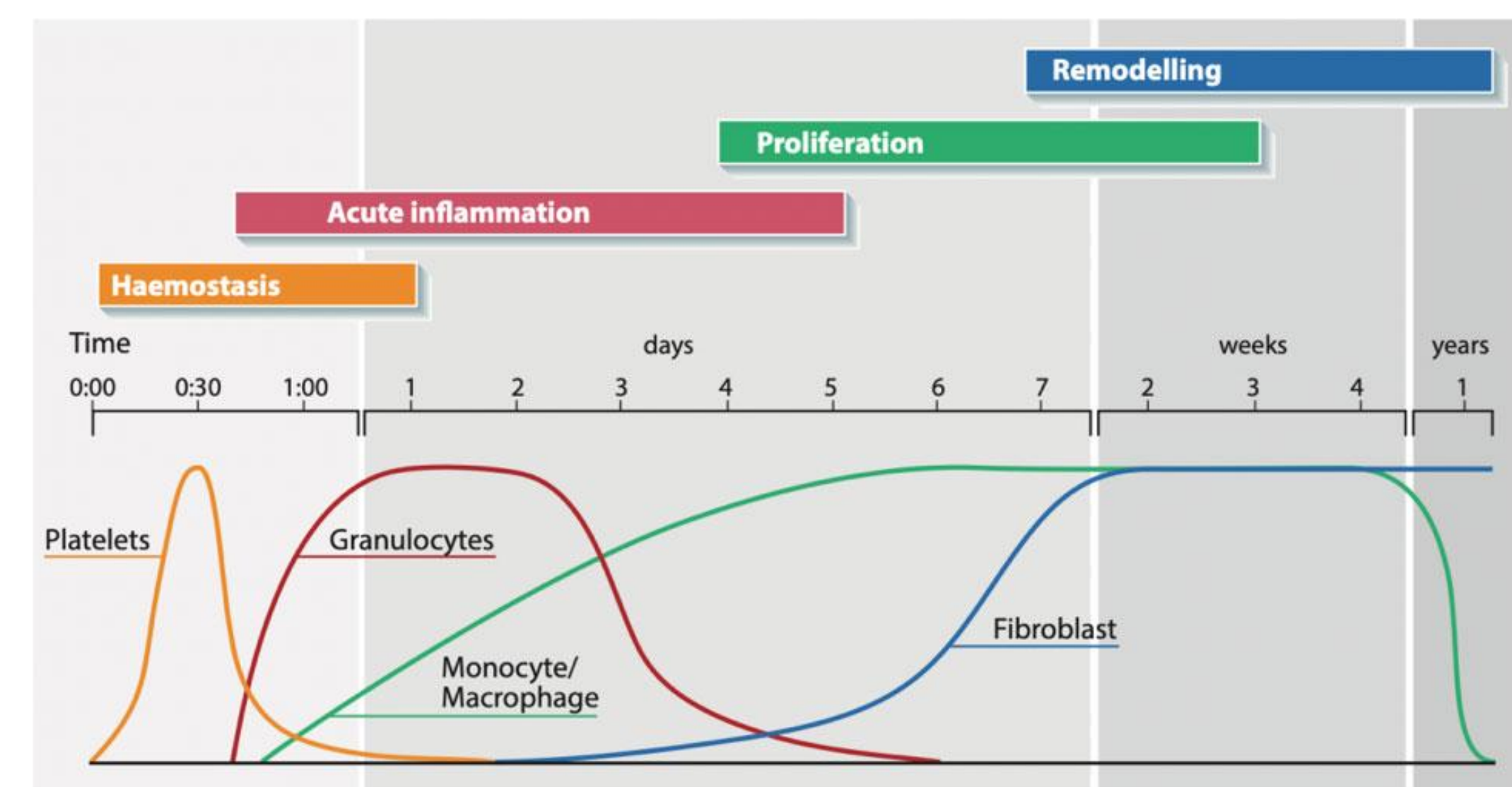


Figure 2: The critical 4-day window where impaired circulation delays the arrival of essential immune cells. (Source: RCEMLearning, 2018)

### Therapeutic Vasodilation

To counteract this deficit, targeted heat is used to induce **vasodilation**. As localized tissue temperature rises toward a physiological ideal of **38°C**, active vasodilator tone increases, **substantially increasing skin blood flow**. This thermal intervention artificially **restores healthy circulation**, ensuring that vital oxygen, nutrients, and cellular repair mechanisms reach the wound bed when they are most needed.

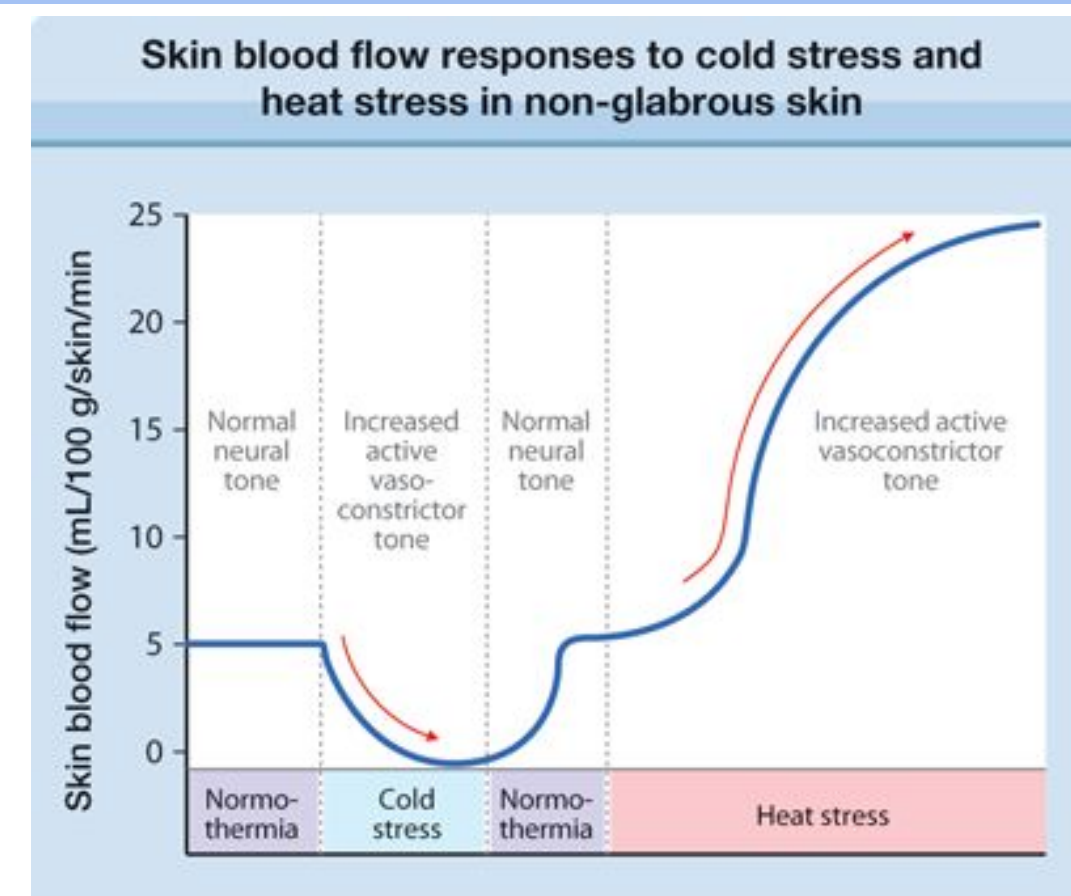


Figure 3: Heat drives vasodilation and skin blood flow. (Source: Goldsmith LA, et al. Fitzpatrick's Dermatology, 8th Ed.)

### Methodology

**Gelatin-based hydrogels** were employed to replicate the mechanical and hydration properties of human skin. Uniform **6 mm circular wounds** were created using a biopsy punch to ensure consistency.

Three experimental groups were tested:

**Group 1: [Control]** Standard dressing with no thermal regulation.

**Group 2: [Passive Insulated]** Dressing designed to retain heat but without active heat.

**Group 3: [Active Isothermal Regulation]** Heating to maintain **38°C ± 0.5°C**.

All samples were maintained under **reduced ambient temperature conditions (24°C)**, designed to simulate impaired diabetic healing environments.

Over a **4-day experimental period**, data collected included:

- Daily wound images
- Continuous temperature and weight recordings
- Wound area measurements using **ImageJ software analysis**

### Engineering Objectives & Goals

The primary objective of this project is to design and experimentally validate a **low-cost, closed-loop resistive heating system** capable of maintaining a stable, **isothermal wound-bed environment**. Specific engineering goals include:

- **Hardware Integration:** Engineering a flexible, **additively manufactured** smart bandage using bio-safe TPU and surface-mount circuitry.
- **Algorithmic Control:** Achieving precise thermal regulation of **38.0°C ± 0.5°C** using a microcontroller and Pulse Width Modulation (PWM).
- **Thermal Validation:** Quantifying heat transfer and thermal penetration using a standardized **“Phantom Skin” gelatin wound model**.
- **Safety Verification:** Provide continuous therapeutic heat while preventing dangerous temperature spikes above the 40.0°C safety threshold.

#### Design Criteria

To successfully accelerate perfusion without endangering neuropathic tissue, the prototype was required to meet the following parameters:

- **Isothermal Precision:** Must maintain a continuous, regulated temperature of exactly 38°C across the wound bed without dangerous fluctuations.
- **Closed-Loop Intelligence:** Must utilize real-time thermal feedback to autonomously cut or supply power, eliminating human error.
- **Bio-Mechanical Flexibility:** The matrix must bend and stretch with human skin and joints to prevent secondary friction ulcers.
- **Biocompatibility:** All patient-facing materials must be non-toxic and skin-safe (utilizing ISO 10993 certified 85A TPU).

#### System Constraints

The development of this solution was restricted by several real-world and physical limitations:

- **Economic Accessibility:** To reach vulnerable populations, the total manufacturing cost per unit was constrained to under \$15.00.
- **Power Limitations:** To eliminate shock hazards, the system had to operate entirely on a low-voltage (3.7V) wearable power source.
- **Form Factor:** The entire circuit had to be miniaturized to remain thin enough to be worn comfortably under standard clothing.
- **Computational Capacity:** The safety logic had to be optimized to run entirely on an ATtiny85 microcontroller with only 8KB of programmable flash memory.



Figure 4: From 3D model to assembled ThermaAid active thermal matrix. The bio-safe TPU enclosure houses the electronics components demonstrating the low-profile, wearable form factor constraint.

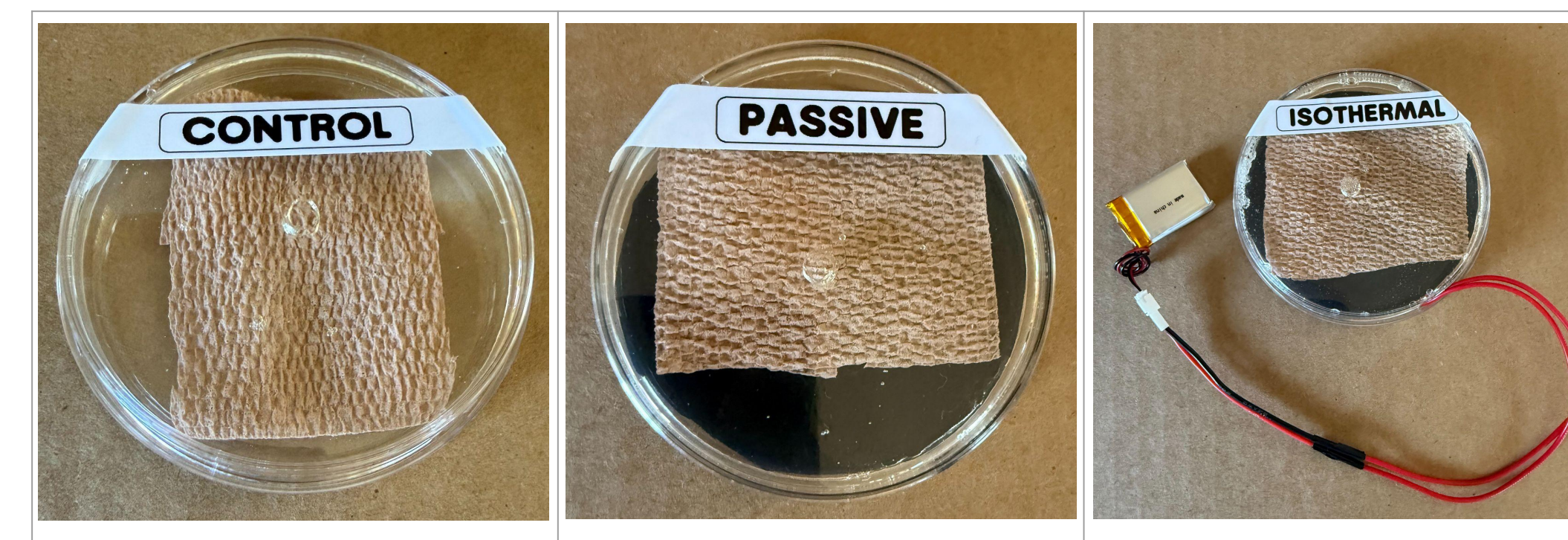


Figure 5: Thermal validation using a standardized “Phantom Skin” gelatin wound model. The experimental setup compares an unregulated control, a passive insulating dressing, and the active closed-loop isothermal system.

### Circuit Design & Experimental Setup

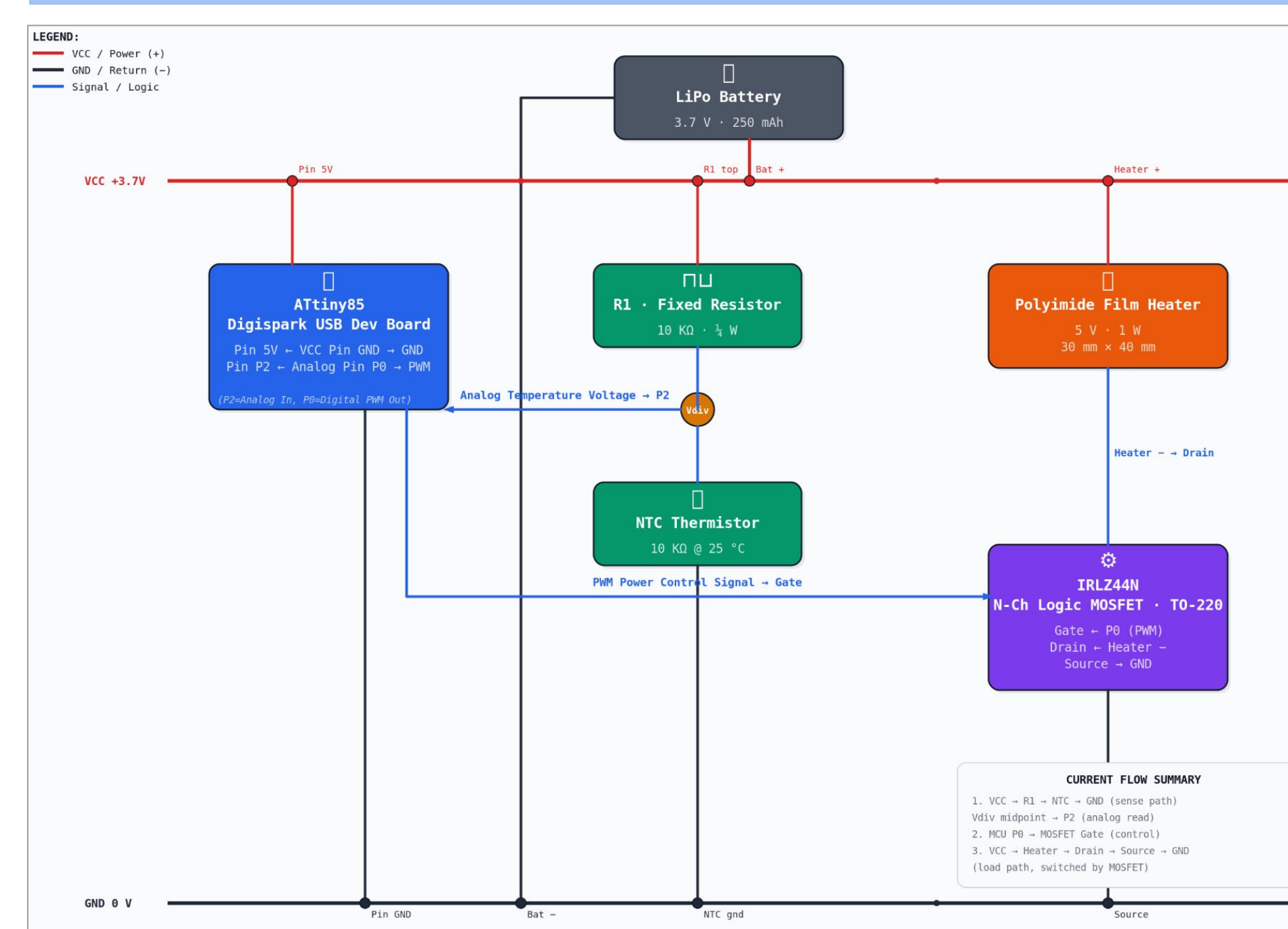


Figure 6: Infrared surface thermometer confirming the active thermal matrix successfully maintained within the therapeutic zone.

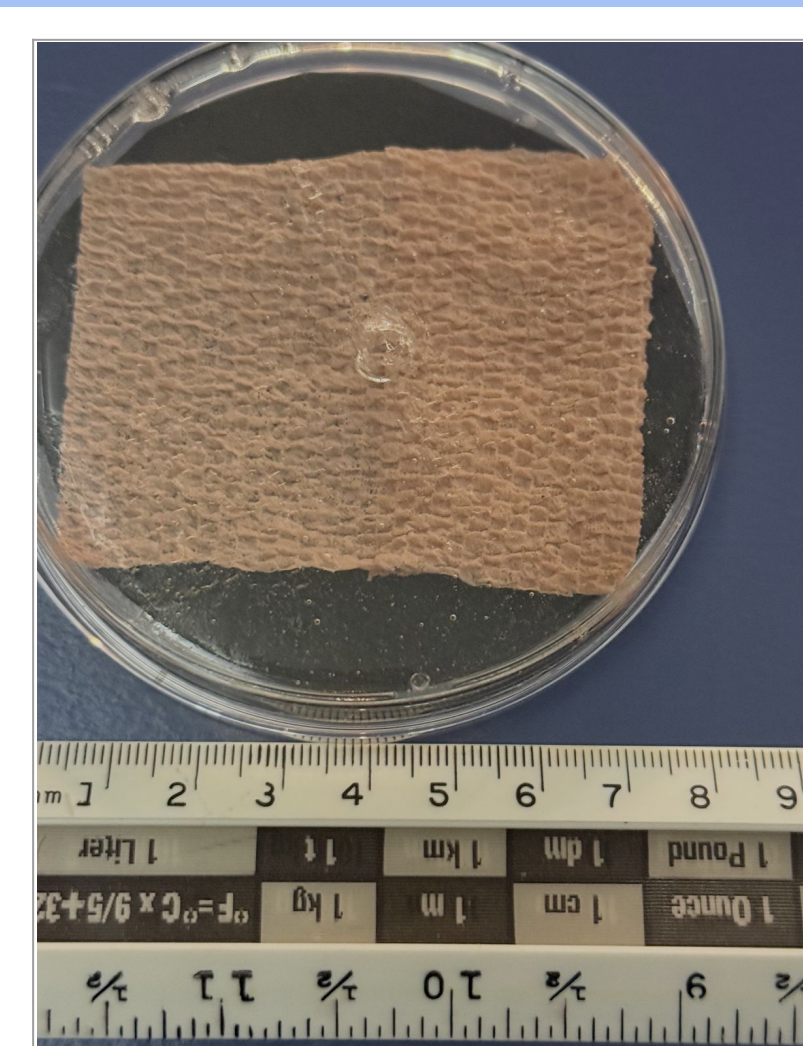


Figure 7: Gelatin wound model with scale reference, prepared for daily area analysis via ImageJ software.

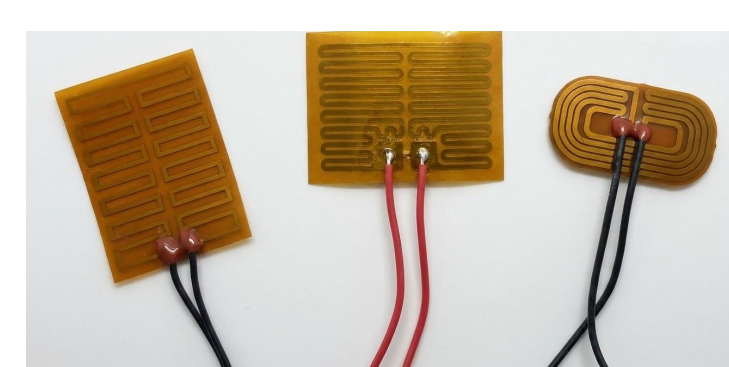


Figure 8: Digital quantification of wound closure, utilizing ImageJ software to precisely measure the defect area over the 4-day trial.

### Iterative Design

**Challenge 1: [Thermal Runaway]** Early 4.2W and 2.8W heaters generated unsafe, unstable heat.

**The Fix:** Downscaled to a 5V 1W Polyimide film heater for a precise, manageable thermal climb.



**Challenge 2: [Substrate Failure]** Initial gelatin “Phantom Skin” models melted under continuous heat.

**The Fix:** Iteratively adjusted the hydrogel concentration to increase thermal resistance for multi-day testing.



**Challenge 3: [Non-Uniform Heating]** Infrared testing revealed severe “hot spots” and rapid rear heat dissipation.

**The Fix:** Integrated a high-density EVA foam insulation layer to force a uniform, downward isothermal distribution.



### Conclusions

Experimental validation of the thermal matrix yielded the following key findings:

- **Isothermal Stability:** Maintained a 38°C ± 0.5°C wound-bed environment.
- **Accelerated Closure:** Achieved 3.5x faster simulated wound closure than the unheated control.
- **Accessibility:** Demonstrated low-cost, scalable components for advanced chronic wound therapy.

### Limitations

While demonstrating significant therapeutic potential, this study acknowledges the following constraints:

- **Model Constraints:** Hydrogels simulate mechanics but lack living biological responses like angiogenesis.
- **Statistical Power:** Small sample size (n=3) limits statistical inference; however, the day-over-day trends suggest a robust effect warranting further investigation with larger cohorts.

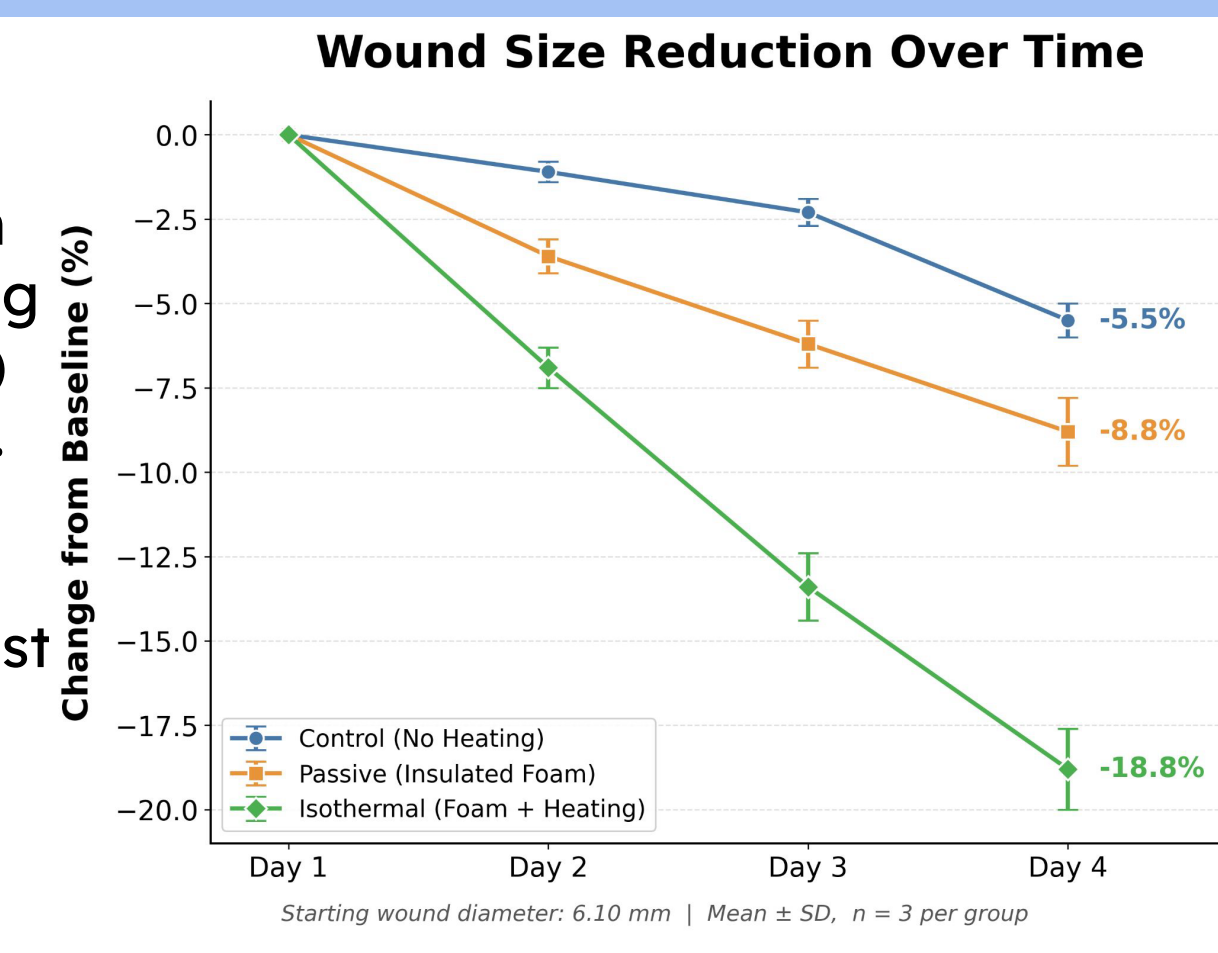
### Future Plans

Future research will expand and improve the system through:

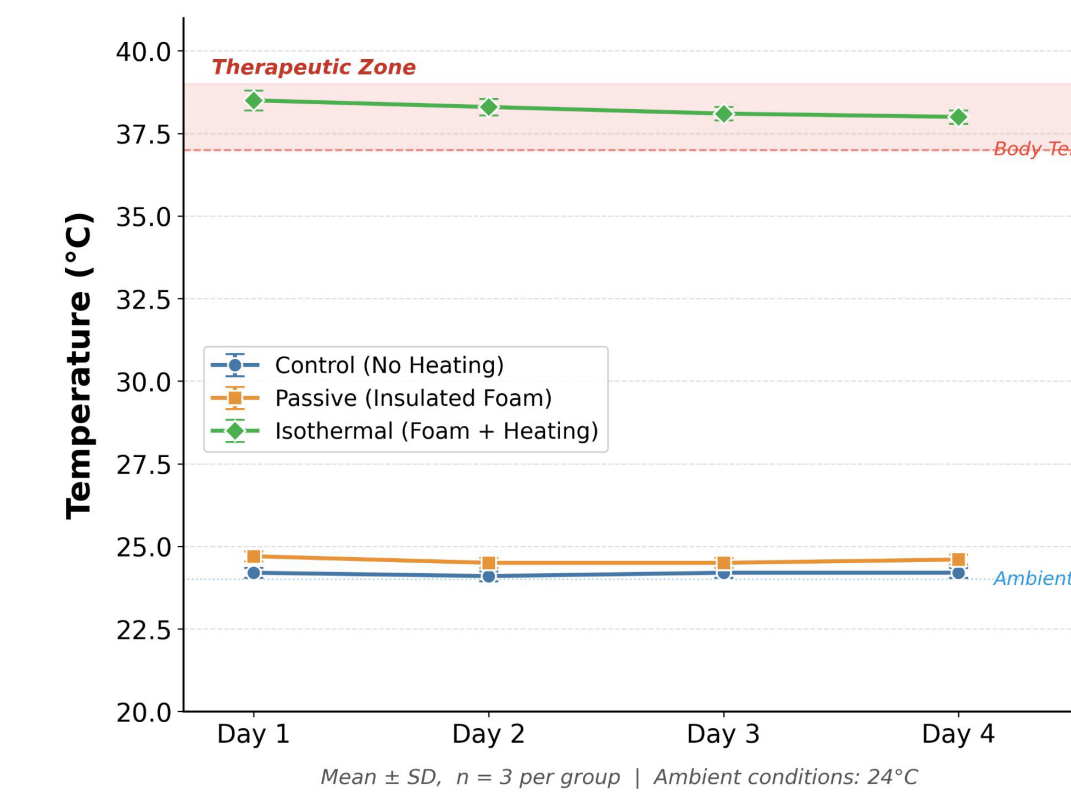
- **Biological Models:** Testing with living tissue models.
- **Extended Timelines:** Conducting longer-duration experiments.
- **System Upgrades:** Integrating wireless monitoring.
- **Human Trials:** Preparing for clinical feasibility testing.

### Results & Thermal Validation

**Wound Size Reduction:** By Day 4, the isothermal system achieved an **18.8% reduction in wound area**, outperforming both passive insulation (8.8%) and unheated controls (5.5%). The isothermal group showed **consistent day-over-day acceleration**, with the steepest decline occurring between Days 2 and 3, suggesting a compounding therapeutic effect.

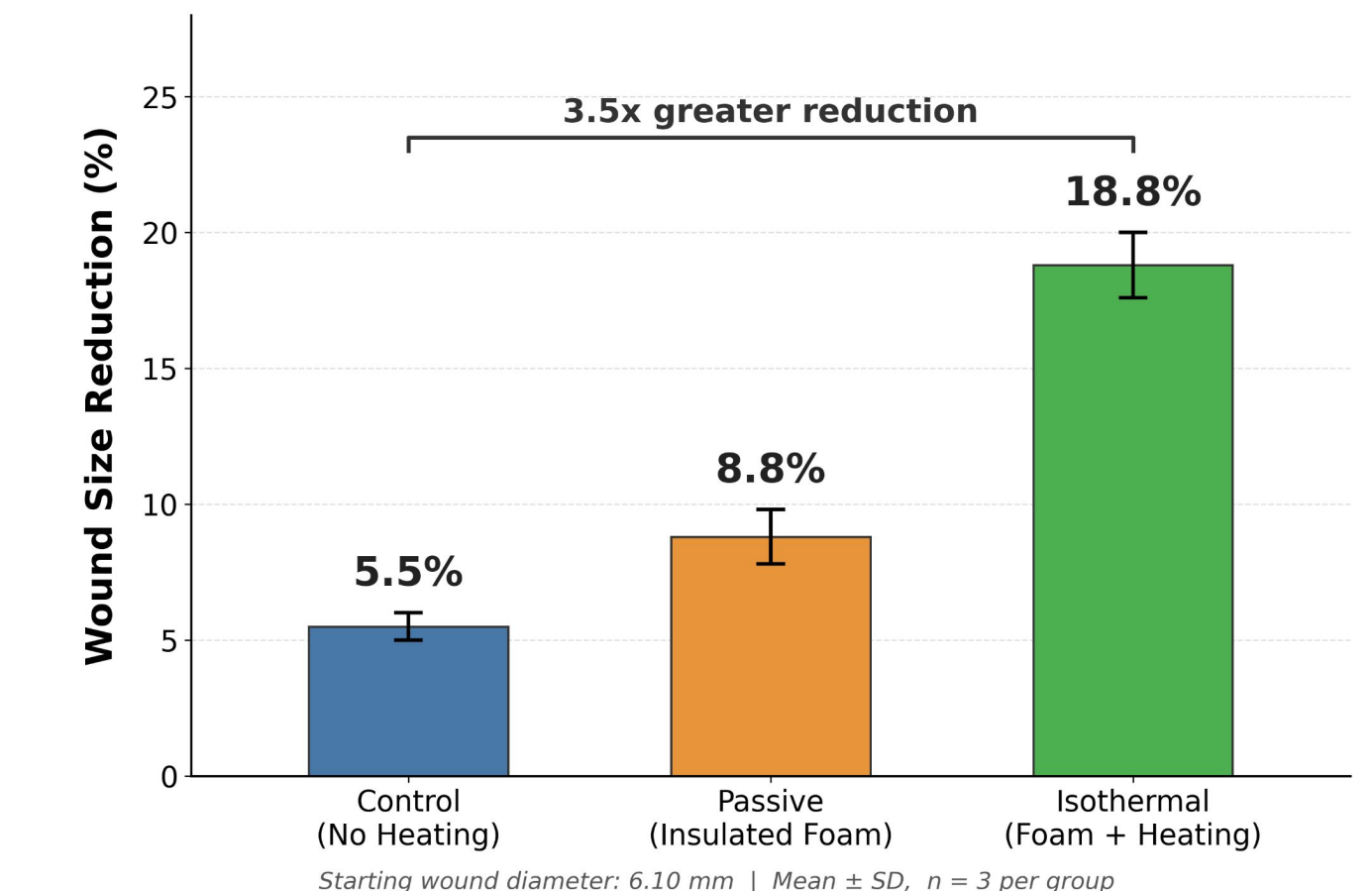


#### Surface Temperature Maintenance

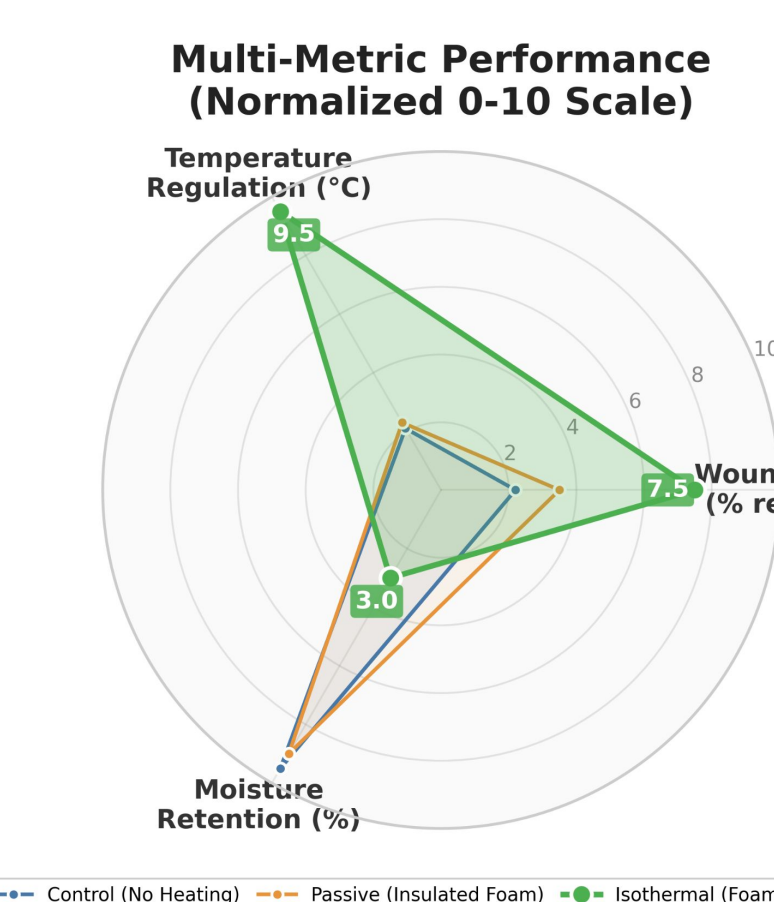


**Thermal Maintenance:** The active system successfully **maintained the target therapeutic temperature within ±0.5°C across all four days**. In contrast, passive and control dressings failed to elevate the wound bed above ambient room temperature (24°C). This 14°C differential is critical: enzymatic activity and cellular metabolism required for tissue repair function optimally within the 37–39°C range.

#### Total Wound Healing After 4 Days



**Overall Healing Efficacy:** Over the full 4-day trial, the active isothermal system drove an 18.8% total reduction in wound size, accelerating simulated healing by 3.5x compared to the unheated control group. This result is consistent with the thermal mechanism underlying the design: **sustained heat at 38°C accelerates hydrogel matrix remodeling and moisture transport**, mirroring the enhanced tissue dynamics predicted by established wound-healing literature.



**Holistic Performance:** The isothermal system dominates in thermoregulation (9.5/10) and wound closure (7.5/10), the two metrics most linked to clinical outcomes. The tradeoff is moisture retention (3.0/10). Active heating at 38°C accelerates evaporative loss from the hydrogel. Critically, this is an artifact of the gelatin model: in living tissue, perfusion continuously resupplies interstitial fluid. The net therapeutic profile remains vastly superior to passive or unheated approaches.

### Bibliography

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