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Life-Support Biofoam: Self-Expanding Polymer Systems for Non-Compressible Hemorrhage Control

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ABSTRACT

Background. Non-compressible torso hemorrhage (NCTH) is a leading cause of potentially survivable death in trauma and combat casualty care, unreachable by tourniquets or direct pressure. **Objective.** To review the scientific basis of self-expanding life-support biofoam—two liquid components reacting in situ to tamponade intracavitary bleeding—and to define its translational and regulatory pathway. **Methods.** Narrative review of the DARPA Wound Stasis program and peer-reviewed swine studies of self-expanding polyurethane foam, with extraction of survival and blood-loss outcomes and engineering parameters. **Results.** In lethal hepatoportal-injury swine models, foam administration raised survival from roughly 8% to over 70% at three hours and markedly reduced blood loss, while remaining removable at laparotomy. Expansion pressure and exotherm are the principal safety parameters. **Conclusion.** Biofoam is a high-value bridge intervention for NCTH; field use requires controlled-expansion engineering, human safety evidence and doctrinal integration.

Keywords: non-compressible hemorrhage; self-expanding foam; hemostasis; combat casualty care; polyurethane; damage control; biomaterials

1. Introduction

Hemorrhage accounts for the majority of potentially survivable battlefield deaths, and a large fraction originates from non-compressible sites within the torso [1]. Bridging the interval between point of injury and surgical care motivated injectable, self-expanding hemostatic foams capable of stabilising intracavitary bleeding [2].

2. Mechanism of Intracavitary Tamponade

Life-support biofoam is delivered as two liquid precursors that mix and polymerise within the abdominal cavity, expanding to conform to viscera and applying distributed pressure opposing bleeding. Unlike topical dressings, which need an accessible wound surface, in-situ foams act volumetrically, raising intracavitary pressure to slow flow from multiple or inaccessible sources while forming a

removable solid mass for surgical extraction [2,3].

3. Preclinical Evidence

The DARPA Wound Stasis System program produced a self-expanding polyurethane foam evaluated in swine models of lethal hepatoportal injury. Administration significantly improved survival and reduced blood loss versus standard resuscitation, while remaining removable at laparotomy [2,4]. Subsequent work characterised dose, expansion dynamics and tissue effects, identifying expansion pressure and exotherm as the principal safety parameters [3,5].

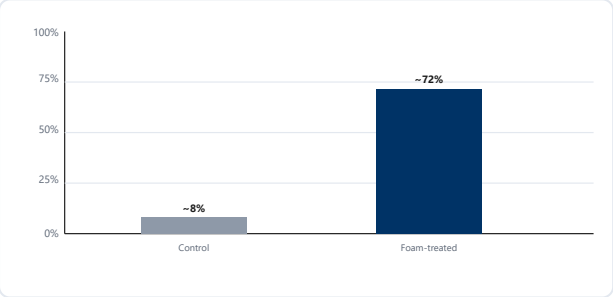


Figure 1. Three-hour survival in a swine model of lethal Grade V hepatoportal injury: standard care versus self-expanding foam, approximate values reported by Rago et al. and Duggan et al. [2,4]. Animal model; not human outcomes.

Table 1. Design parameters and rationale for life-support biofoam.

Parameter	Design target	Rationale
Expansion ratio	Controlled, cavity-filling	Tamponade without ischemic over-pressure
Set time	Seconds	Rapid point-of-injury stabilisation
Removability	Single cohesive mass	Atraumatic surgical extraction
Exotherm	Minimised	Avoid thermal tissue injury
Shelf stability	Two-component, field-stable	Austere storage and transport

4. Engineering Trade-offs

The central tension is between sufficient tamponade pressure and the risk of visceral ischemia or compartment effects. Polymer chemistry must balance rapid set time against a controlled, low exotherm; expansion must fill the cavity yet be bounded to limit peak pressure (Figure 2). Biocompatibility, sterilisation, field-stable packaging and reliable mixing under austere conditions are additional constraints [3,5].

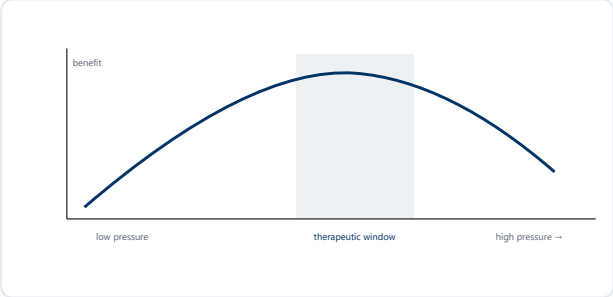


Figure 2. Schematic dose-response: hemostatic benefit rises with expansion pressure then falls as ischemia and compartment effects dominate, defining a therapeutic window. Conceptual, derived from the safety discussion in [3,5].

5. Clinical Translation and Limitations

Evidence to date is predominantly preclinical; human use requires demonstration of safety, defined indications within damage-control resuscitation, training for correct administration, and clear surgical removal protocols. Foam is an adjunct that buys time to definitive surgery, not a substitute, and inappropriate use could exacerbate injury. Regulatory clearance as a

combination product and integration into Tactical Combat Casualty Care guidelines are prerequisites [6].

6. Discussion

The translational risk profile is dominated by the pressure–ischemia trade-off and by removal logistics in resource-limited surgical settings. Reported survival gains are striking but derive from controlled animal injuries; human anatomy, mixed-injury patterns and evacuation timelines will modulate real benefit.

7. Conclusion

Self-expanding biofoam addresses a genuine and lethal gap in NCTH management, supported by strong preclinical survival data. Covenant Aegis treats it as a bridge intervention whose path to field use runs through controlled-expansion engineering, rigorous safety evaluation and doctrinal integration.

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9. Epidemiology of Non-Compressible Hemorrhage

Analyses of combat fatality data found that roughly 90% of potentially survivable battlefield deaths were due to hemorrhage, the majority from non-compressible truncal sources beyond the reach of tourniquets [A1]. Civilian trauma shows an analogous pattern, with truncal hemorrhage a leading cause of early preventable death. This epidemiology defines the unmet need that bridge interventions such as life-support biofoam address during the pre-surgical interval.

Table A1. Hemorrhage-control options by anatomical accessibility.

Site	Standard control	Gap
Extremity	Tourniquet	Well addressed
Junctional	Junctional tourniquet	Partially addressed
Truncal (NCTH)	Surgery only	Bridge needed

10. Polymer Chemistry

The DARPA Wound Stasis foam is a two-component polyurethane: a polyol and an isocyanate that react on mixing to form a polymer while CO_2 generated in situ drives expansion [A2]. Key tunable variables are reaction (set) time, expansion ratio, and the exotherm of the curing reaction. The design objective is fast set with controlled expansion and minimal heat release to

avoid thermal injury, while yielding a cohesive solid that can be extracted intact at laparotomy [A3].

11. Hemodynamics of Tamponade

Foam acts by raising intra-abdominal pressure to oppose bleeding from multiple or inaccessible sources. The therapeutic principle mirrors controlled, permissive resuscitation: enough pressure to reduce hemorrhage without provoking organ ischemia or abdominal compartment syndrome. Figure A1 illustrates modelled blood loss versus time with and without foam, reflecting the survival data of Section 3.

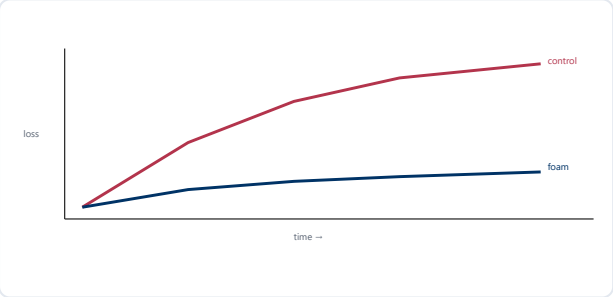


Figure A1. Schematic cumulative blood loss: foam tamponade flattens the loss curve relative to untreated control, consistent with reported survival benefit [A2,A3]. Conceptual, animal-model-derived.

12. Biocompatibility and Removal

A foam left in the peritoneal cavity must be biologically tolerated for the bridge interval and removable as a single mass without lacerating viscera. Preclinical work reported high removal rates with limited adherent injury, but human peritoneal anatomy, adhesions and mixed injuries may complicate extraction [A3,A4]. Sterilisation, particulate shedding and long-term biocompatibility are additional evaluation requirements for any combination-product clearance.

13. Doctrine and Logistics

Field utility depends on doctrine as much as chemistry. Tactical Combat Casualty Care guidelines define when and by whom interventions are applied [A5]. Biofoam requires trained administration, defined indications within damage-control resuscitation, weight and thermal stability for austere transport, and a clear hand-off protocol to the receiving surgical team. It is explicitly a bridge to surgery, not a definitive treatment.

14. Regulatory Pathway and Limitations

As a drug–device combination acting structurally and pharmacologically, biofoam faces a demanding clearance pathway requiring human safety data, defined indications and post-market surveillance. The principal limitations are the pressure–ischemia therapeutic window, removal logistics, and the gap between controlled animal injuries and the heterogeneous, multi-system injuries seen clinically. Misapplication could worsen outcomes, underscoring the need for training and strict indications.

15. Future Directions

Research directions include pressure-self-limiting formulations, radiopaque markers

to guide surgical removal, biodegradable variants that reduce extraction burden, and adjunctive hemostatic agents incorporated into the polymer. First-in-human studies under trauma-research protocols are the necessary next step.

Extended References

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