Next Generation Dressing for Burn and Soft Tissue Injuries

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Research was conducted in compliance with the Animal Welfare Act, the implementing Animal Welfare Regulations, and the principles of the Guide for Care and Use of Laboratory Animals, National Research Council. The facility's Institutional Animal Care and Use Committee approved all research conducted in this study. The facility where this research was conducted is fully accredited by AAALAC.

Scope of Military and Civilian Burn Injuries

Every year in the United States more than

- ~500k people received medical treatment for burn injuries
- 40,000 required hospitalization

Associated costs

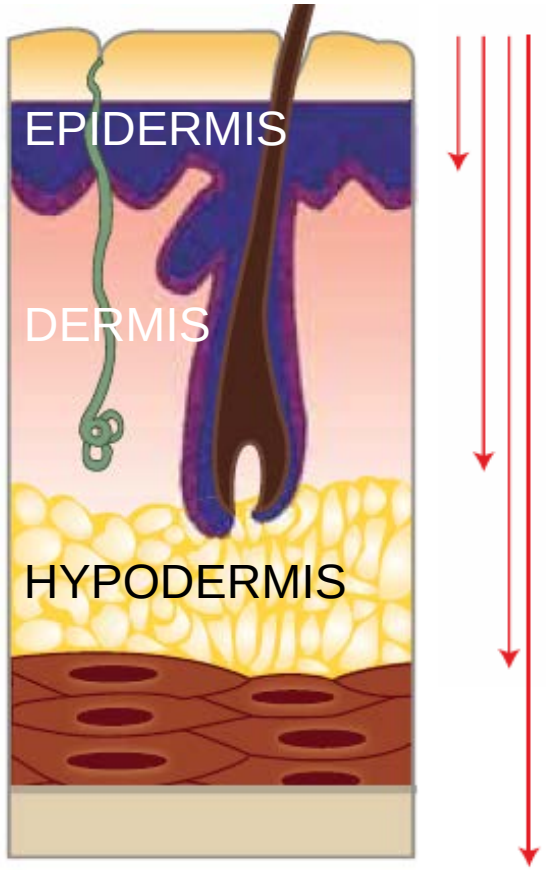
- Burns: $10 billion
- Skin scarring: $12 billion

Military Setting

- Burn Injuries Account for **8-11%** of Combat Casualties

J Trauma Acute Care Surg., 2012,73 (S5), S409-4016 ; Burn Incidence and Treatment in the United States: 2016 http://www.ameriburn.org/resources_factsheet.php.

Classifications, Treatments, and Risks for Burn Wounds



Classifications	Standard of Care
Superficial	Clean Dressing
Superficial Partial-Thickness	Wet Debridement, Clean Dressing
Deep Partial-Thickness	Sharp Debridement, Temporary Coverage, Grafting
Full-Thickness	

Chan RK, *et al.*, Stem Cells Int. 2012

Combat Burn Injuries

Burn Injuries Account for 8-11% of Combat Casualties (CCs)

Small Burns (<20% TBSA) are 80% of the CCs

Treated Role I-III and remain in theater w/o evacuation

Accomplished by having:
1) Field deployable device to assess burns
2) Deployable therapies for burns
   a) Conversion Inhibitors
   b) Infection Prevention and Management
   c) Non-Surgical Debridement
   d) Temporary Coverage
   e) Resuscitation

In theater RTD

Large Burns (>20% TBSA) are 20% of the CCs

Evacuated to Role IV (USAISR)

Accomplished by having:
1) Improved skin substitutes
2) Temporary coverings
3) Autograft sparring

Delayed RTD

J Trauma Acute Care Surg., 2012,73 (S5), S409-4016 ; Burn Incidence and Treatment in the United States: 2016 http://www.ameriburn.org/resources_factsheet.php.

Severe Burn Capability Gaps

Accurately assess burn injuries to enable providers at point of need to sustain Warfighter and unit lethality, appropriately allocate resources, and prevent unnecessary evacuations

- Field deployable toolset for rapidly assessing burn injury depth and total body surface area (TBSA) by non-skilled providers to inform evacuation and RTD decisions
- Decision support tool with risk assessment algorithms to predict ability to return to duty following burns to inform medical evacuation decisions

Minimize morbidity in burn wound casualties to reduce the need for evacuation and increase RTD in Warfighters with superficial partial-thickness or <20% TBSA deep partial-thickness burns following injury

- Advanced toolset to enable rapid recovery of skin function following superficial partial thickness or <20% TBSA deep partial-thickness burn injury
- Acute therapeutic to prevent burn wound conversion/progression
- A field deployable system for non-surgical debridement
- Treatment capabilities for wounds caused by emerging weapons systems (e.g. ionizing/nonionizing radiation)

Burn Injury Gaps

With current focus on Prolonged Field Care (PFC) and anticipation of conflicts with near-peer adversaries, focus has shifted to solutions that can be employed farther forward in the continuum of care.

- Technology to assess burns and/or wound status
- Burn conversion/progression prevention
- Infection prevention and management
- Non-surgical debridement
- Temporary coverage of wounds

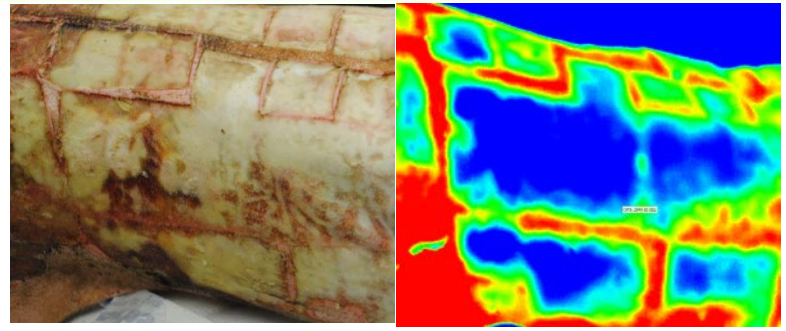



Identify materiel solutions to improve survival and recovery after combat-related burn injury that will result in decreased hospitalization time, quicker return to duty, and improved cosmetic and functional outcomes.

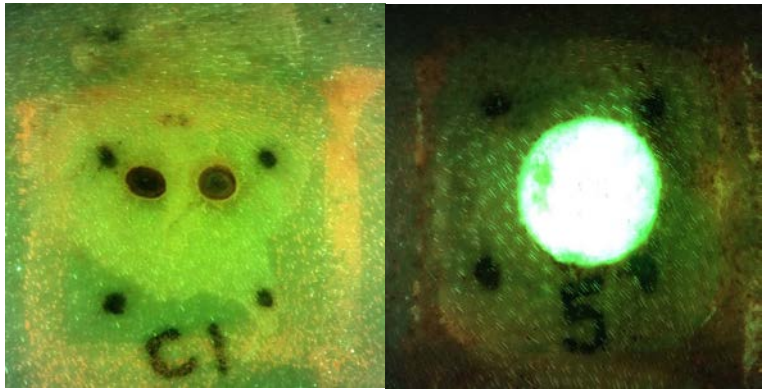
Technology to Assess Burns and/or Wound Status

- **Objective:** Provide capability to rapidly assess burn injuries to inform evacuation and RTD decisions
- **Approaches:**
  - Evaluate existing non-invasive imaging devices to assess burn wound depth, size, and/or wound status
  - Develop decision support tools to predict RTD and inform evacuation based on patient status and injury characteristics
- **Operational Impact:** Allows expeditionary medical providers at point of need the ability to sustain warfighter and unit lethality to prevent unnecessary evacuations

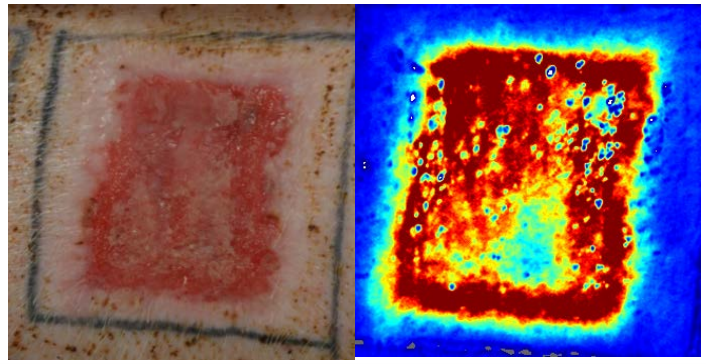
FLIR



MolecuLight



Laser Doppler/ Speckle

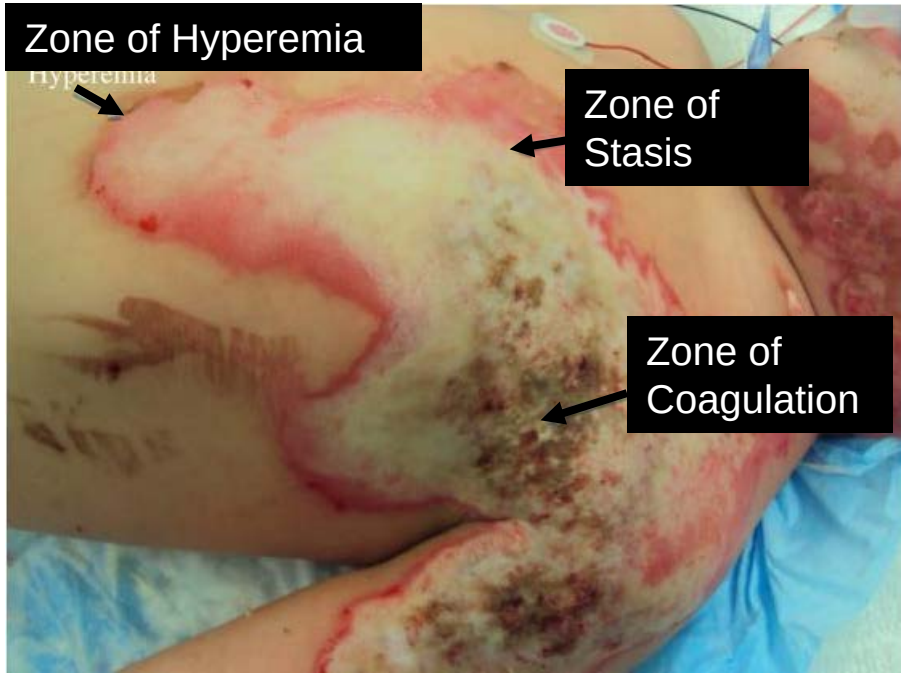


Burn Conversion/Progression Prevention

- **Objective:** Investigate point of injury treatments which can be deployed at Role 1-3 in order to prevent burn progression

- **Approaches:**
  - Develop preclinical model of burn conversion/progression
  - Identify and evaluate potential therapies to prevent progression of partial thickness to full thickness burns

- **Operational Impact:** Preventing progression will reduce burn wound severity which will expedite RTD, lessen evacuations, and maintain unit power



Lateral + Vertical Progression

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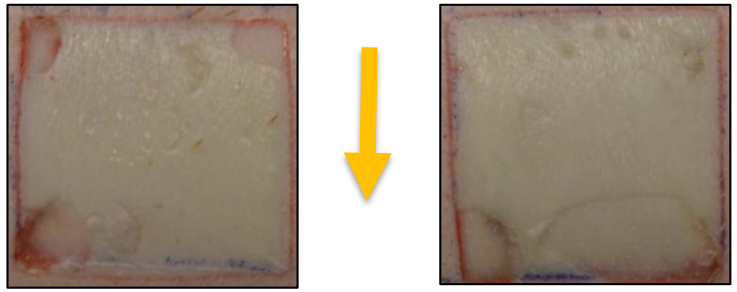
Full-Thickness Injury

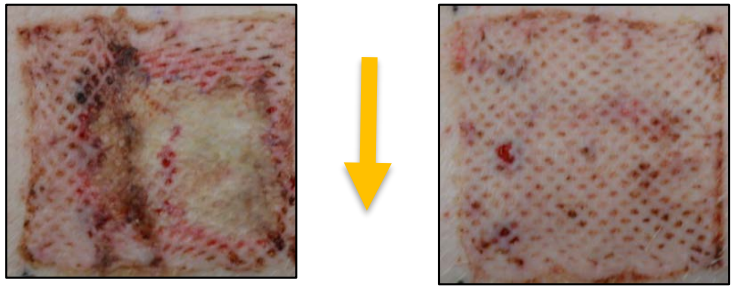
Infection Prevention and Management

- **Objective:** Provide technology to prevent infection of burn wounds
- **Approaches:**
  - Evaluate existing COTS products in preclinical models of infected burn wounds
  - Identify and evaluate novel therapies to prevent infection of partial thickness to full thickness burns
- **Operational Impact:** Preventing infection will reduce burn wound severity which will expedite RTD, lessen evacuations, and preserve the fighting force

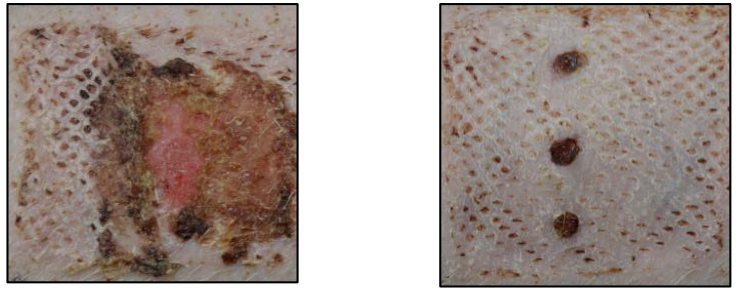
Day 4 after Burn



Day 7 after SOC (E&G)



Day 14 after SOC



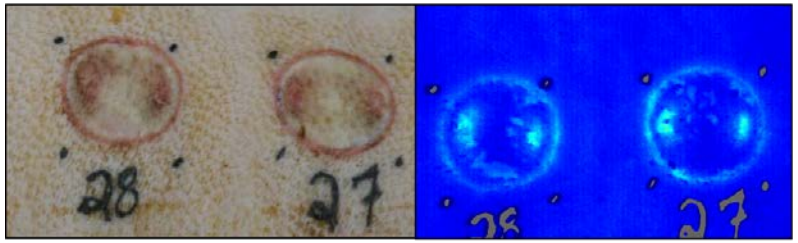
Graft Failure **Graft Success**

Non-Surgical Debridement

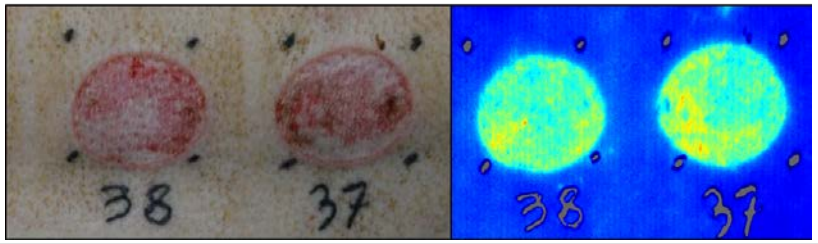
- **Objective:** Provide a field deployable therapy for non-surgical debridement of partial thickness burns
- **Approaches:**
  - Identify optimal non-surgical debridement therapies for burn wounds
  - Demonstrate safety, feasibility, and therapeutic efficacy of NSD therapies in preclinical models
- **Operational Impact:** The ability to remove non-viable tissue by non-skilled providers will expedite RTD, lessen evacuations, and maintain unit power by reducing SOC requirements and healing times

Application of NSD Therapies

No Treatment



SN514 – 48 Hr Treatment

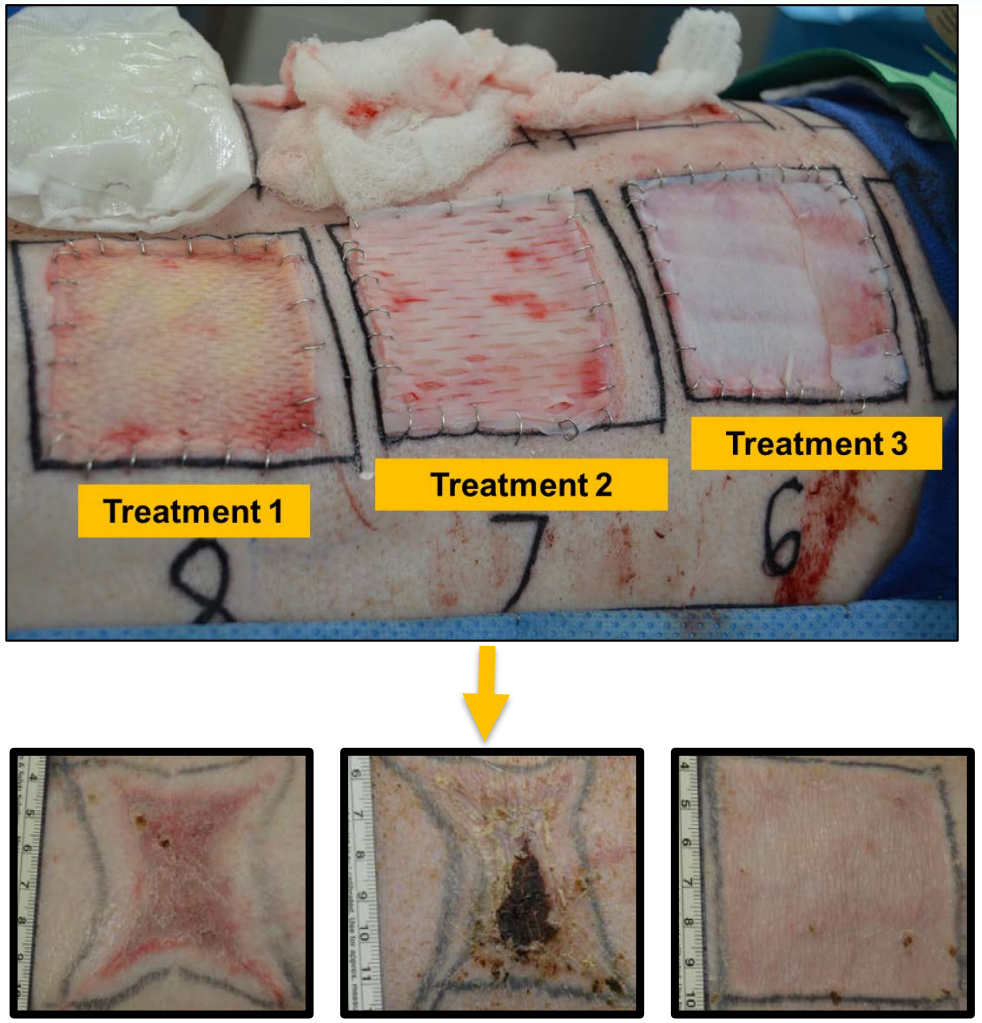


Temporary Coverage of Wounds

- **Objective:** Provide a field deployable therapy to initiate healing and wound closure of partial thickness burns

- **Approaches:**
  - Identify optimal technologies for early intervention to provide barrier function
  - Demonstrate safety, feasibility, and therapeutic efficacy of therapies in preclinical models

- **Operational Impact:** The ability to provide temporary coverage of burns by non-skilled providers will expedite RTD, lessen evacuations, and maintain unit power



Criteria for Development of POI Products for Wound Healing

- Ease of use (self-buddy-care application)
- Readiness of application (prep time, no additional processing)
- Multiple functionality (treats burn and other soft tissue wounds)
- Frequency of treatment (single/multiple applications)
- FDA status (approved/path identified)
- Size/weight/packaging (appropriate for field use)
- Prevents infection (contains antimicrobial activity)
- Monitor wound status without dressing removal (allows imaging)
- Product stability (temperature requirements)
- Safety (no contraindications)
- Manages pain (contains analgesic)
- Cost

Battlefield Burn Wound Treatment Summary

1. Portable wound imaging
2. Point of Injury antimicrobial wound dressing.
3. Biocompatible dressings for the delivery of antimicrobials, immunomodulators and/or analgesics to burn wounds.

1. Non-surgical debridement for improved burn wound healing
2. Decellularized matrices for treatment of deep partial- and full- thickness
3. Enhanced skin substitutes
4. AI assisted prediction of wound healing, graft success, infection and sepsis in burn patients.

1. Pulse dye and CO_2 lasers for the treatment of hypertrophic burn scars.
2. Stem cell based treatments of hypertrophic scars

Role 4 Wound Products to the Battlefield

Must move treatments that are currently only used at Role 4 to Role 1&2 with the long-term goal of POI

Treatment Goals to Reduce Wound Morbidity Summary

- Identify and triage injury severity
- Prevent infection

- Limit burn wound progression
- Nonsurgical wound debridement
- Permanent wound coverage
- Pain management

- Hand-held burn wound assessment and imaging
- Broad spectrum antimicrobial wound dressings, biodegradable matrices
- Metabolic and immune modulation
- Enzyme-based debridement
- Skin substitutes, bio-absorbable wound treatments
- Non-opioid analgesics, topical applications

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