Presented to
Biomedical Technology Forum
By
Dr. James R. Stewart
Sr. Scientist, Clinical and Rehabilitative Medicine Research Program
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Environmental Hazards
- Heat and Cold
- Altitude
- Toxic Industrial Chemicals & Materials

Chemical/Biological Warfare Threats
- Bacterial Threats
- Viral Threats
- Toxin Threats
- Nerve Agents
- Vesicant Agents
- Blood Agents

Endemic Disease Threats
- Parasitic Diseases
- Bacterial Diseases
- Viral Diseases

Combat Injuries
- Hemorrhage
- Head Trauma
- Blast Injury

Operational Stressors
- Sleep Deprivation
- Traumatic Stress and Situational Stressors
- Physical Work Load
- Cognitive Burden & Operational Complexity

Systems Hazards
- Laser
- Blast
- Biomechanical Insults and Stresses
- Noise

Difficulties of Medical Command, Control, Communications, Computer, Intelligence, Surveillance and Reconnaissance (C4ISR)
Working Together
- Joint programs
- Service collaboration

Contemporary Health Threats
- Blast Injury
- Post Traumatic Stress Disorder (PTSD)
- Traumatic Brain Injury (TBI)
- Restoration and rehabilitation of Wounded Warriors

Help Reset the Force
- Improved laboratory techniques (high performance computing, etc.)
- Systems biology
- Collaborative interdisciplinary research teams
(1) Basic Research, (2) Applied Research, and (3) Advanced Technology Development to prove tech-base concepts for medical products (drugs, biologics & devices) and information.

CHEMICAL & BIOLOGICAL DEFENSE PARTNERSHIP SUPPORT DIRECTORATE (PSD)
LTC Nick Koterski

Interface with Defense Threat Reduction Agency (DTRA)

- Medical Biological Defense Research Program (MBDRP)
  Managed by DTRA
  - Vaccines and pre-treatments
  - Small molecule therapeutics
  - Next generation diagnostics
  - Animal model development
  - Broad-spectrum therapeutics

- Medical Chemical Defense Research Program (MCCDRP)
  Managed by DTRA
  - Nerve agent pre-treatments
  - Therapeutics for nerve agents
  - Therapeutics for vesicant injury
  - Diagnostic assays/technologies

BLAST INJURY COORDINATING OFFICE – Mr. Mike Leggeri

- History:
  - Directed by Congress in FY06 National Defense Authorization Act
  - Established by DoD Directive 6025.21E
  - Secretary of the Army is Executive Agent
  - USAMRMC is program coordinator

- Mission:
  Coordinate DoD medical research programs focused on the prevention, mitigation, and treatment of blast injuries.

- Key Accomplishments:
  - ID knowledge gaps to focus blast injury research programs across DoD, federal agencies, academia, and industry
  - Developed funding requirements
  - Established the Joint Trauma Analysis and Prevention of Injury in Combat (JTAPIC) Program - provides a coordinated approach to improve tactics, techniques, procedures, & materiel solutions to prevent blast injuries
  - Strengthened collaboration between medical researchers and materiel developers to provide improved individual and combat vehicle blast protection systems

Example of Tissue Regeneration

Product: Extract of pig bladder for promoting healing and tissue regeneration.
PI: Dr. Stephen Badylak, University of Pittsburgh

ARMED FORCES INSTITUTE OF REGENERATIVE MEDICINE (AFIRM)
COL Bob Vandre

- A virtual organization of 27 universities and 230 scientists working with the US Army Institute of Surgical Research under a five-year cooperative agreement
- Expected to make major advances in the ability to understand and control the cellular response in wound repair and organ/tissue regeneration as well as designing and engineering new biomaterial scaffolds to guide the regeneration process
- Expected that this institute will be able to translate some of its technologies into patients within the five-year period

Research Funds from DoD
Research Funds from Many Sources
Research Funds from Army, Navy, Air Force, NIH, and VA

Before Right middle finger during an early stage of regrowth after an August 2005 accident cut off the tip.
After four months of healing.

PI: Dr. Stephen Badylak, University of Pittsburgh

Dr. James Stewart (301-619-9810)/james.stewart@us.army.mil
Discover, develop, and translate regenerative medicine technologies having both near term and far-term translation potential.

To provide cutting-edge medical capabilities to heal and reset our warriors who have catastrophic traumatic injuries and disabilities.
All major scientific approaches to tissue regeneration are utilized in the development of regenerative therapies for the wounded service member.

Cell-based therapy

Bioactives

Cell-Scaffold Hybrid

Scaffold
Representative Technologies: Biomimetic, resorbable tissue scaffolds

Nerve, Bone, Other Connective and Soft Tissue
Goal: Because severely burned patients need skin and need it fast, development based on ink jet printer technology device to “print” skin directly on burns is underway.

The system will include a scanner to determine the size and depth of the burn.

PI: James Yoo
Goal: Injectable and/or implantable soft tissue substitute resulting in sustained shape and volume over time to provide precise shape of facial features after craniofacial injury.

Based upon biomaterial scaffolds comprised of silk, collagen, and hyaluronic acids, along with autologous cellular elements.

First clinical trial will be an initial study on the use of autologous adipose derived stem cells in a lipoaspirate scaffold. During the coming year, we will determine the optimal combination of biomaterials for the clinical therapy.

PI: Peter Rubin

Athymic mice sacrificed 6 weeks after injection with lipoaspirate mixed with GFP labeled ASCs (n=6). Tissues formed subcutaneously were exposed, excised and measured with water displacement method. A. lipoaspirates mixed with 2x10⁶ ASCs. B. lipoaspirates alone C. Tissues harvested after 6 weeks. Left: lipoaspirates with ASCs, Right: lipoaspirate without ASCs.
1. Hand transplants (accelerated with Congressional Special Interest funding)
2. Face transplants
3. Use of porcine extracellular matrix to regenerate limb muscle form and function (accelerated with JIEDDO/OTT funding)
4. Engineered Skin Substitute (ESS) to treat >50% TBSA burns
5. Autologous skin cell spraying to treat burn injuries with less scarring (ReCell®)
6. Autologous fat injections to reduce severity of burn scarring (AFT)
7. Skin graft stretching to reduce degree of scarring
8. Segmental nerve gap regeneration using a novel nerve scaffold biomaterial (2010 new start)
9. Safety and efficacy of allogeneic skin substitute for burn coverage (2010 new start)
10. Bandage for Improved healing and scar reduction (2010 new start)

OTT* contributions (2010 new starts) to AFIRM investigators
   - Autologous skin cell spraying to repair excessive scars
   - Nanoscale Ca PO4 scaffolds for craniomaxillofacial repairs
   - Allogeneic Cultured Human Dermal Fibroblasts injections to remodel facial scars

BTI**
   - Autologous Adipose Derived Stem Cells For Soft Tissue Reconstruction After Facial Trauma

*Office of Technology Transition
** Biotechnology Initiative
Goal: Protocol for treatment of forearm or hand loss by transplantation with local immunomodulation

Status: Enrollment at approved sites is currently underway

PI- Andy Lee, U. Pitt
CT scan showing 10% increase in quadriceps mass (red circled area) at 4 months post surgery.

Novel application of extracellular matrix to encourage regeneration of large muscle
PI: S. Badylak, U. Pitt
ReCell Skin Cell Spray

• A regenerative device that uses patient’s own cells to treat burns, wounds and chronic skin defects.

• Goal: FDA approval & the first Class I efficacy data w/ long-term outcome data

PI- J. Holmes,
Wake Forest and Avita Medical

Avita Medical has received approval from the FDA to begin its US clinical trial for ReCell spray-on skin. The company claims it to be the first regenerative device enabling surgeons to treat burns, wounds and chronic skin defects using the patient’s own cells (December 2009 Press Release)
A small sample of a patient’s skin is digested and seeded onto a resorbable matrix, then treated to grow into a full thickness sheet of engineered skin.

PI: S. Boyce, Cincinnati Children’s Hospital
PI: Sang-jin Lee

**Goal:** *in vitro* tissue expander system that permits a rapid increase in surface dimensions of donor skin while maintaining tissue viability for subsequent skin transplantation. This system was successfully tested and validated on human skin samples.

Consistently able to double the surface area of donor skin within 2 weeks while maintaining cell viability and showed viable graft take, in animals, when implanted on a recipient dermal bed.

Completed design and built a clinically applicable bioreactor system.

Defined clinical trial strategy.
Preliminary Pilot trial in humans post-abdominal surgery (n=9) show safety and dramatic efficacy of stress-shielding device.
USAMRMC Medical R&T
Good Ideas to Fielded Medical Policies, Information, and Products

Integrated Defense Acquisition, Technology, & Logistics Life Cycle Management Framework

USAMRMC

GOOD IDEAS
- Private Industry
- Academia
- Entrepreneurs
- Innovations
- “Salesmen”
- Congress
- DOD/Services
- Military Leaders
- Soldiers
- Families
- Others

RECEPTOR SITES
- New Idea Website¹
  - Standing BAA
    (Broad Agency Announcement)²
- Special CSI
  Solicitations³,⁴
- HQ Program Staff
- Other Command Personnel

EVALUATION & RESEARCH
- Program Reviews
- Peer Review
- Knowledge of Other Service and Agency Programs
- Intramural
  Research Programs
- Extramural
  Research Programs

POLICY & DECISIONS
- DOD
- MHS
- Army
- OTSG
- MEDCOM
- Defense Centers of Excellence
- Services

FEEDBACK

KNOWLEDGE GAP BRIDGING REQUEST

CONSENSUS

INPUT

IMPROVEMENT

EVIDENCE

KNOWLEDGE GAP BRIDGING REQUEST

• Program Reviews
• Peer Review
• Knowledge of Other Service and Agency Programs

• Intramural Research Programs
• Extramural Research Programs

AFIRM - http://www.afirm.mil/

Grants announcements- http://grants.gov


Federal contract solicitations- https://www.fbo.gov/


TATRC- http://www.tatrc.org/