Novel Off-The-Shelf Conduits For Use With Military Vascular Injuries: The Humacyte Graft

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Disclosures

- No financial conflicts of interest to disclose

42-Year Perspective

Vietnam (1972) to Afghanistan (2014): The state of military trauma care and research, past to present

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What has been learned?

Wounded: 52,311
Deaths: 6,850
defense.gov/news/casualty

Epidemiologic Research

The Epidemiology of Vascular Injury in the Wars in Iraq and Afghanistan


Epidemiologic Research

Rate of Wartime Vascular Injury

Extremity Injury

- 70-80% of vascular trauma occurs in the extremities
- Autologous vein conduit of choice when possible/available
- Experience highlights scenarios when vein is not possible/feasible
- Need for alternative conduit for expedited reconstruction
IN THE LAB, ON THE BATTLEFIELD

Extreme Limb Salvage Efforts

Scenarios of Abbreviated Operating (No case > 1 hour)

FOB Shank (OEF) FOB Jalalabad (OEF)

National Investment Applied to Priority Gaps

DoD Combat Casualty Care Research Program

• Gap-driven (top-down), programmed, life-cycle research & development to deliver knowledge & materiel solutions to those injured in combat

• Research, development & acquisition of an autologous, ‘off the shelf’ vascular conduit to improve capability in settings of extreme limb salvage and or abbreviated operating...

Approximate $200M annual spanning all topics of trauma care
Leverage Capability & Expertise from Civilian Sector

- Human aortic (organ donor pool) smooth muscle cells - isolated, screened & banked

Research Gap

**Autologous Vascular Conduit**

- Polyglycolic acid (PGA) polymer scaffold on which smooth muscle cells placed - degrades

**Human Acellular Vessels**

- Cells used to grow bioengineered vessels in bioreactor
- Decellularization of graft
- Acellular bioengineered vascular graft/conduit

**Studied in Established Military Research Model**

Hemorrhagic shock worsens neuromuscular recovery in a porcine model of hind limb vascular injury and ischemia-reperfusion

- Humacyte conduit in iliac artery position
- Compared to ePTFE
- 4 week outcomes

Patency

- Humacyte
- PTFE

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<th>12</th>
<th>14</th>
<th>21</th>
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<td>Patency (%)</td>
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<td>80</td>
<td>60</td>
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**Clinical Study of Humacyte Human Acellular Vessels**

- Received FDA approval for IND (2013) to conduct US clinical trial to assess safety & efficacy of the graft as dialysis conduit
- To date, 80 human implants worldwide (60 dialysis access / 20 lower extremity occlusive disease)
- Plans in 2016 for study of the conduit in US including arterial reconstruction & a DoD-sponsored study in vascular trauma

**DoD Research Program**

- Resolving gaps in vascular injury & military trauma care
- Leverage private & federal equity/ expertise

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**Histology**

- Humacyte
- Artery

- PTFE
- Artery