Laboratory Evaluation of Battlefield Tourniquets in Human Volunteers

Thomas J. Walters, Ph.D., David G. Baer, Ph.D., SFC
Dominique Greydanus, Joseph C. Wenke, Ph.D.
Background

- Army One-Handed Tourniquet (OHT)
  - Effective on arm
  - Ineffective on large legs
    - Wenke et al (in press)
- Good start-not the final solution

Significant Events

- **Aug 21-22, 2003**
  - ATACCC Tourniquet panel underscores need for battlefield tourniquet
  - Outlines appropriate tourniquet requirements and testing requirements
- **Oct 30, 2003**
  - Ad hoc committee drafts requirements for tourniquets to be tested
- **Feb 15, 2004**
  - Request for Information-CBD
- **April 15, 2004**
  - Letters of intent
- **July 1, 2004**
  - Provide 10 tourniquets to USAISR
- **Aug 11, 2004**
  - Testing completed
Combat Tourniquet Requirements

- Complete occlusion of arterial blood flow in thigh
  - Thigh circumference – 95% male soldier (26.7 cm)
- Capable of easy release and re-application
- Application time = 60 seconds
- Cost (predicted) < $25
- Weight: < 8 oz. (250 g)
- Simplicity of application
  - Tactical environment (dark, cold, hot, wet, sand, mud, ice)
  - Minimal familiarization
- No assembly; No batteries
- Width: >1”
- Self life of 10 yr
<table>
<thead>
<tr>
<th>No.</th>
<th>Product Name</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M.A.T.</td>
<td>Bio Cybernetics International</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1815 Wright Avenue</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LaVerne, CA 91750</td>
</tr>
<tr>
<td>2</td>
<td>C.A.T.S.</td>
<td>Combat Application Tourniquets</td>
</tr>
<tr>
<td>3</td>
<td>E.M.T.</td>
<td>Delfi Medical Innovations Inc</td>
</tr>
<tr>
<td>4</td>
<td>L.R.T.</td>
<td>Hammerhead, LLC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100 Overlook Center</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suite 102</td>
</tr>
<tr>
<td>5</td>
<td>Hemodyne</td>
<td>Hemodyne Inc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>800 East Leigh Street Suite 112</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Richmond, VA 23219</td>
</tr>
<tr>
<td>6</td>
<td>LBT*</td>
<td>London Bridge Trading Company, Ltd.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3509 Virginia Beach, Virginia</td>
</tr>
<tr>
<td>7</td>
<td>S.A.T.S.</td>
<td>Marketing Tactics, LLC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4459 Danielson Drive</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lake Worth, FL 33467</td>
</tr>
<tr>
<td>8</td>
<td>S.O.F.T.-T.</td>
<td>Tactical Medical Solutions LLC</td>
</tr>
<tr>
<td></td>
<td>(special operation forces tactical tourniquet)</td>
<td>Raeford, NC USA</td>
</tr>
</tbody>
</table>

Did not meet specified requirements-not tested
Emergency Military Tourniquet EMT (215 g)

Last Resort Tourniquet LRT (183 g)

Special Applications Tourniquet System SATS (136 g)

Mechanical Advantage Tourniquet MAT (145 g)
Experiment I
Endpoints

- Arterial Occlusion
  - Doppler auscultation-posterior tibial artery
  - Continuous auditory feedback
  - Self-tighten to one of the following:
    - Cessation of Doppler
    - Limit of tolerable pain
    - Limit of ability to tighten

- Pain
  - Analog pain scale (0-10)

- Instructed on how to apply each tourniquet
  - Instructions provided by each manufacturer
Doppler Auscultation to Determine Tourniquet Effectiveness
Tourniquet Pain

Wong-Baker FACES Pain Rating Scale
Experiment I
Subject Characteristics

- N = 18 (male = 16/female = 2)
- Age (yr) = 35.3 ± 7.3 (23/47)
- Wt. (Kg) = 83.4 ± 10.7 (65/103)
- Leg Circumference (cm)
  - 59.5 ± 4.6 (51.5/67.5)
  - (μ = 59.5 /θ = 59.9)
  - θ 59.6 (51.7/67.9)\(^1\)

\(^1\)Gordon CC et al. 1988.
Limb Circumference (cm): Comparison to Army Norms*


*United States Army Institute of Surgical Research
Experiment I
Design: Randomized Cross-over

Example:

<table>
<thead>
<tr>
<th></th>
<th>Subject 1</th>
<th></th>
<th>Subject 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Leg (R/L)</td>
<td>Tourniquet #</td>
<td>Leg (R/L)</td>
<td>Tourniquet #</td>
</tr>
<tr>
<td>1</td>
<td>R</td>
<td>1</td>
<td>L</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>L</td>
<td>4</td>
<td>R</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>R</td>
<td>2</td>
<td>L</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>L</td>
<td>6</td>
<td>R</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>R</td>
<td>3</td>
<td>L</td>
<td>7</td>
</tr>
<tr>
<td>6</td>
<td>L</td>
<td>7</td>
<td>R</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>R</td>
<td>5</td>
<td>L</td>
<td>6</td>
</tr>
</tbody>
</table>
## Experiment I Results

<table>
<thead>
<tr>
<th></th>
<th>MAT</th>
<th>CAT</th>
<th>EMT</th>
<th>LRT</th>
<th>H-Dyne</th>
<th>SATS</th>
<th>SOFTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent Effective</td>
<td>82</td>
<td>100</td>
<td>100</td>
<td>71</td>
<td>22</td>
<td>39</td>
<td>100</td>
</tr>
<tr>
<td>Pain (circum)</td>
<td>2.9</td>
<td>3.1</td>
<td>2.6</td>
<td>3.7</td>
<td>3.6</td>
<td>3.1</td>
<td>3.5</td>
</tr>
<tr>
<td>Pain (pinch)</td>
<td>3.7</td>
<td>0.4</td>
<td>0.0</td>
<td>2.9</td>
<td>1.2</td>
<td>0.9</td>
<td>2.2</td>
</tr>
<tr>
<td>Malfunction/ Break</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*United States Army Institute of Surgical Research*
Pain (Arm)

Circumferential

Pinching

United States Army Institute of Surgical Research
# Experiment II

## Design: Randomized Cross-over

Example:

<table>
<thead>
<tr>
<th>Tourniquet #</th>
<th>Tourniquet #</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

Self-applied to non-dominant arm
## Experiment II Results

<table>
<thead>
<tr>
<th></th>
<th>MAT</th>
<th>CAT</th>
<th>EMT</th>
<th>SOFTT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent Effective</td>
<td>75</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Pain (circum)</td>
<td>2.7</td>
<td>1.0</td>
<td>0.3*</td>
<td>1.2</td>
</tr>
<tr>
<td>Pain (pinch)</td>
<td>6.2</td>
<td>0.1*</td>
<td>0.1*</td>
<td>2.3</td>
</tr>
<tr>
<td>Malfunction/Break</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* United States Army Institute of Surgical Research
Subject Characteristics
Only Successful Tourniquets from Experiment I

- N = 12 (male = 10/female = 2)
- Age (yr) = 35.5 ± 7.9 (22/47)
- Wt. (Kg) = 85.5 ± 13.9 (65/103)
- Arm Circumference (cm)
  - 34.0 ± 4.2 (28.5/42.5)
  - (? = 34.7 /? = 30.6)
  - ? 33.4 (29.2/38.1)

Successes

Emergency Military Tourniquet
EMT

Combat Application Tourniquet
C-A-T

Special Operation Forces Tactical Tourniquet
SOFTT

United States Army Institute of Surgical Research
<table>
<thead>
<tr>
<th>Name</th>
<th>Wt (g)</th>
<th>L (cm)</th>
<th>W(cm)</th>
<th>H(cm)</th>
<th>LxWxH(cm³)</th>
<th>Max Circ. (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMT</td>
<td>215</td>
<td>10.3</td>
<td>6.9</td>
<td>6.9</td>
<td>491</td>
<td>88.9</td>
</tr>
<tr>
<td>CAT</td>
<td>59</td>
<td>18.3</td>
<td>4.8</td>
<td>3.1</td>
<td>266</td>
<td>77.5</td>
</tr>
<tr>
<td>SOFTT</td>
<td>160</td>
<td>17.4</td>
<td>5.1</td>
<td>8.4</td>
<td>746</td>
<td>92.7</td>
</tr>
</tbody>
</table>
Pros
- Safety-Proven
- Easily applied
  - One-handed
  - Trapped Limb

Cons
- Puncture
- Shelf-life
- Cost?
Pros
- Wt/size
- Easily applied
  - One-handed
  - Trapped Limb
- Circumferential force evenly distributed

Cons
- Safety-width
- Tightening-180° increments
- Velcro
Pros
- Easily applied
  - One-handed
  - Trapped Limb

Cons
- Safety-
  - Width
  - Tightening-180° increments
- Very small excursion
- Pinches
What next?

- Field testing
  - Army
  - Navy
  - SOF
Acknowledgment

- Funding
  - Office of Naval Research
  - USAMMDA

- Technical Assistance
  - Ms. Heather Wynne
  - Ms. Angel Torres
# Weight and Dimensions

<table>
<thead>
<tr>
<th>No.</th>
<th>Name</th>
<th>Wt (g)</th>
<th>L (cm)</th>
<th>W(cm)</th>
<th>H(cm)</th>
<th>LxWxH(cm³)</th>
<th>Max Circ. (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MAT</td>
<td>145</td>
<td>12.1</td>
<td>10.4</td>
<td>7.2</td>
<td>912</td>
<td>87.6</td>
</tr>
<tr>
<td>2</td>
<td>CAT</td>
<td>59</td>
<td>18.3</td>
<td>4.8</td>
<td>3.1</td>
<td>265</td>
<td>77.5</td>
</tr>
<tr>
<td>3</td>
<td>EMT</td>
<td>215</td>
<td>10.3</td>
<td>6.9</td>
<td>6.9</td>
<td>490</td>
<td>88.9</td>
</tr>
<tr>
<td>4</td>
<td>LRT</td>
<td>183</td>
<td>10.9</td>
<td>6.0</td>
<td>6.3</td>
<td>410</td>
<td>76.2</td>
</tr>
<tr>
<td>5</td>
<td>H-Dyne</td>
<td>174</td>
<td>25.0</td>
<td>4.8</td>
<td>5.8</td>
<td>692</td>
<td>82.6</td>
</tr>
<tr>
<td>6</td>
<td>LBT</td>
<td>260</td>
<td>14.7</td>
<td>5.5</td>
<td>4.9</td>
<td>400</td>
<td>88.9</td>
</tr>
<tr>
<td>7</td>
<td>SATS</td>
<td>136</td>
<td>16.5</td>
<td>4.8</td>
<td>5.7</td>
<td>447</td>
<td>121.9</td>
</tr>
<tr>
<td>8</td>
<td>SOFTT</td>
<td>160</td>
<td>17.4</td>
<td>5.1</td>
<td>8.4</td>
<td>745</td>
<td>92.7</td>
</tr>
</tbody>
</table>
Why is it so hard to stop bleeding in the thigh?

Arterial Occlusion Pressure vs. Tourniquet Width/Limb Circumference

- 1” tourniquet width/28” thigh
- 1” tourniquet width/20” thigh
- 2” tourniquet width/20” thigh
- Or
- 1” tourniquet with/10” arm