Increasing Confidence in Performance of Non-Pneumatic Limb Tourniquets

Cassy Robinson, National Institute of Standards and Technology

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Nonpneumatic Tourniquet Examples

(a) Strap and windlass
(Source: www.scorpionsurvival.com)

(b) Elastic
Source: www.medtree.co.uk

(c) Ratcheting
Source: www.chinookmed.com

Certain commercial products, organizations and websites are identified. Such identification is not intended to imply recommendation or endorsement by NIST nor is it intended to imply that the products or organizations identified are necessarily the best available for the purpose.

Why a Tourniquet Standard?

- Uncontrolled hemorrhage is the single most preventable cause of death after traumatic injury (Hegvik, JR, et al. J Am Coll Surg 2017)
- Public safety personnel now carry or have access to nonpneumatic limb tourniquets
- Increasing demand has incentivized companies to produce and sell tourniquets with little or no efficacy testing
- Reported incidents of tourniquets failing when used
- Reports of counterfeit tourniquets being sold
- End users identified the need for a standard

Source: www.post-gazette.com

Addressing the Need

- ASTM E54 Committee on Homeland Security Applications
  - ASTM task group kickoff in January 2017
  - Task group members include end users, manufacturers, testing and certification experts, researchers, Red Cross, federal agency personnel, stakeholder organizations
- Starting point: understanding end user needs and requirements

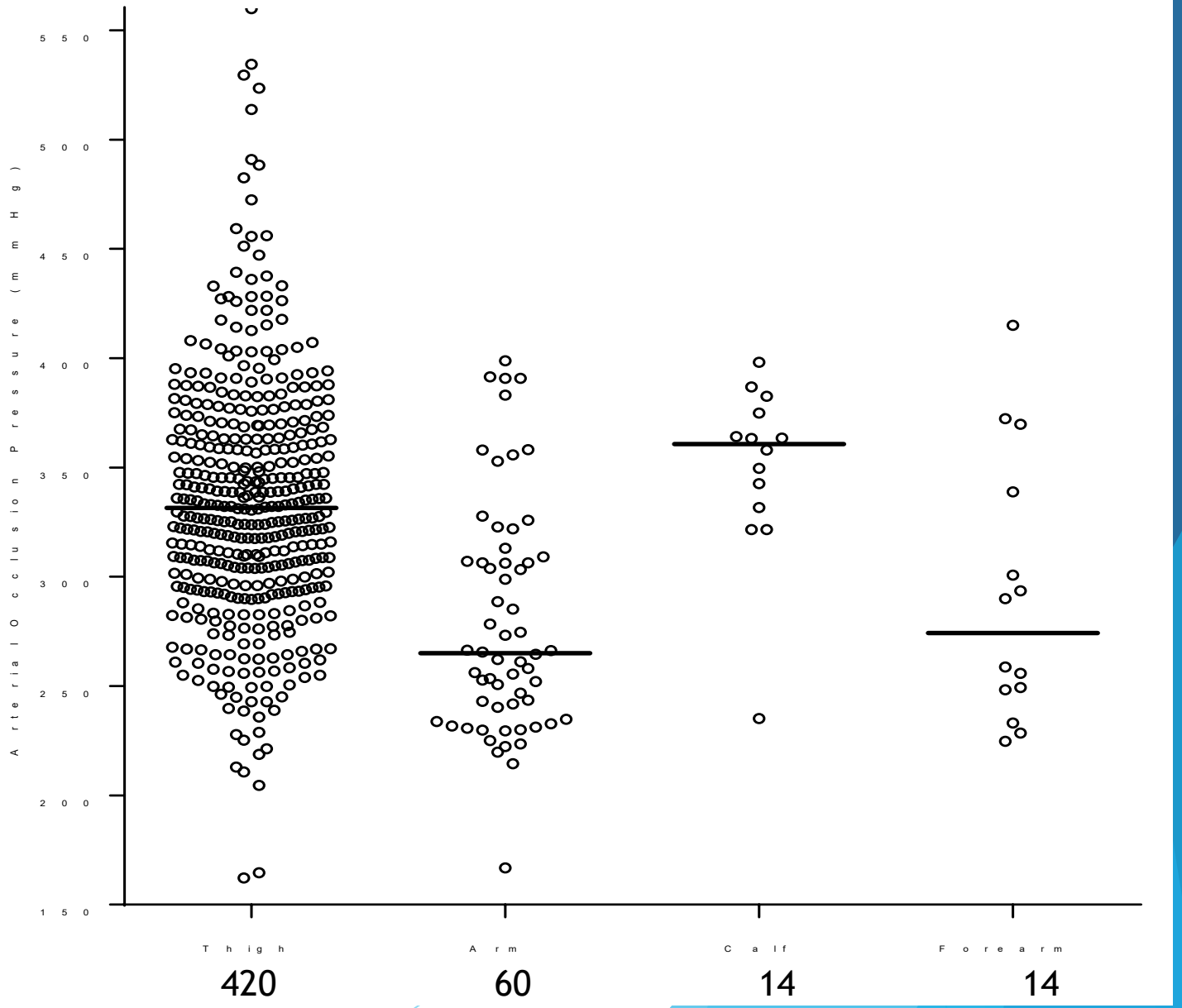
End User Requirements

Performance Requirements	Application Criteria
• Complete occlusion of arterial blood flow in arm or leg without slipping or loosening of the applied tourniquet • Sizing to accommodate adults or children • Durability under typical storage and use conditions	• Capable of easy release and re-application • Application time ≤ 60 seconds • Simplicity and ease of application in the tactical environment • Minimal familiarization required for correct application • One-handed self application • Application on an entrapped limb

Setting Occlusion Pressure

- Research by Dr. Piper Wall
- Testing using 1 ½ inch wide non-elastic ratchet tourniquet

Source: www.thetacticalmedic.com/



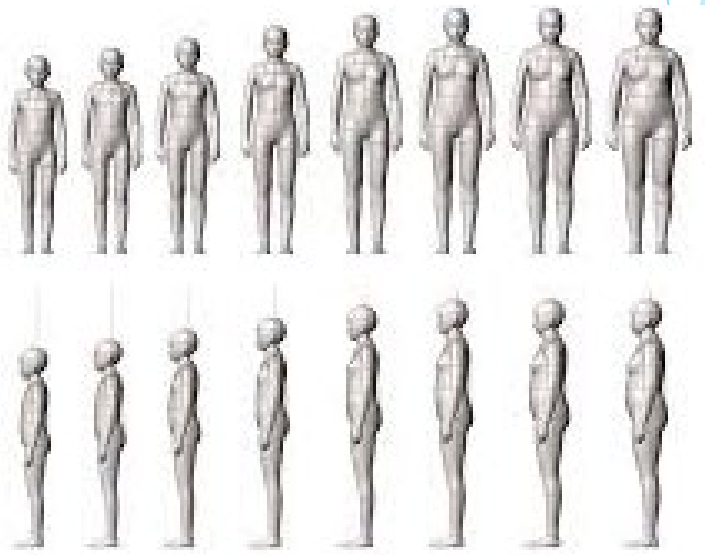
Setting Occlusion Pressure (Continued)

Maximum maintainable pressure recommendation for 1 ½ inch wide nonelastic strap tourniquets = 505 mm Hg

- Numbers used for pressure recommendation
  - 95th percentile for thigh completion pressure: 428 mm Hg
  - 5th percentile for thigh pressure increase from occlusion to completion pressure: 35 mm Hg
  - High side maximal pressure loss not related to muscle tension change: 87 mm Hg
  - Average pressure increase during transportation: 25 mm Hg
- 428 – 35 + 87 + 25 = 505 mm Hg to reach and maintain thigh arterial occlusion for most adults from tourniquet application to ER arrival

Sizing to Accommodate Child or Adult

- Attempting to accommodate all limb sizes within in the US population was not practical
- Reasonable size range (minimum and maximum) selected based on review of ASTM standards baselining body measurements in apparel for children, youth, and adult males and females:
  - Minimum circumference of 6.125 inches, based on a school-age girl's mid-arm
  - Maximum circumference of 27.75 inches, based on an adult male's mid-thigh circumference



Source: www.alvanon.com

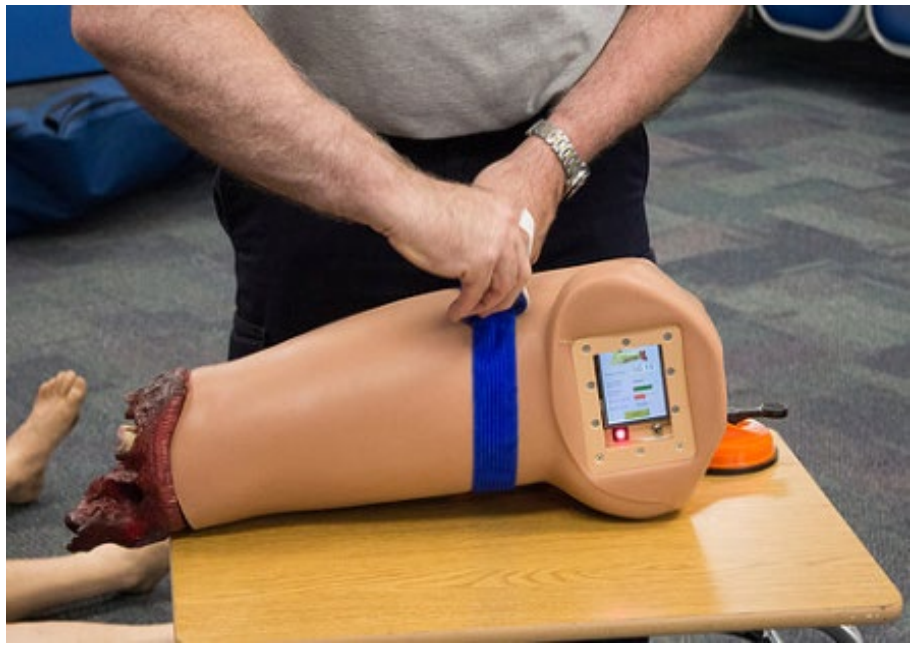
Durability Requirements: Conditioning Prior to Testing

- Tourniquets must be able to survive expected storage or application conditions

Test Item	Number of Replicates	Conditioning Procedures
1	3	Controlled ambient conditions for at least 12 hours
2	3	High Temperature (method 501.6, procedure I)
3	3	Low Temperature (method 502.6, procedure I)
4	3	Solar (method 505.6, procedure II)
5	3	Fully submersed in simulated blood for 15 minutes + 30 seconds
6	3	Sand and Dust (method 510.6, procedures I and II)
7	3 Marine-grade only	Mil Std 810G, 509.6 salt fog
8	3 Marine-grade only	ASTM G155, Practice for Operating Xenon Arc Light Apparatus for Exposure of Non-Metallic Materials

Test Fixture: Considering Options

- Human: Not feasible
- Surrogates:

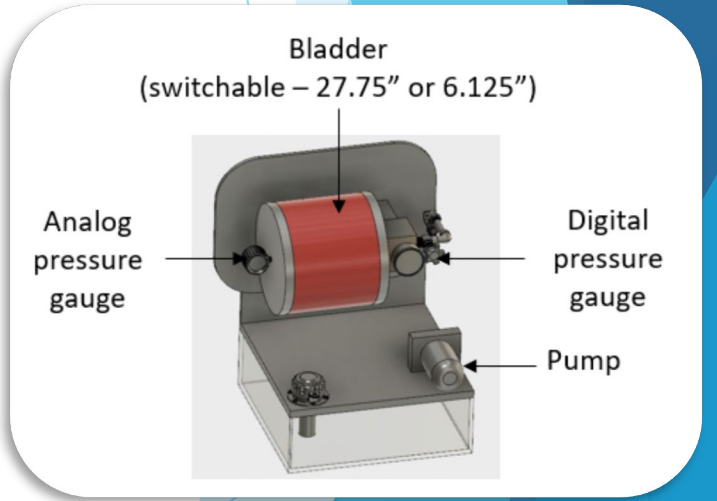
HapMed Instrumented Trainer	SynDaver Synthetic Human
	
Cons: • Intended use is training, not testing • Cannot be calibrated • Not able to achieve size range	Cons: • Cost-prohibitive for this purpose • Cannot be calibrated • Not able to achieve size range

Test Fixture: Developing New Fixture

Test fixture requirements:

1. Must not leak any fluid medium
2. Must return to its original shape when the tourniquet is removed
3. Must be capable of measuring occlusion pressures from 200 mmHg to 600 mmHg
4. Must be capable of being calibrated to ensure accurate test results
5. Must be capable of accepting/testing tourniquets covered in simulated blood or tourniquets at temperatures between -51°C (-60°F) and 71°C (160°F)
6. Must be independent of the strap width
7. Must be capable of being fabricated in two extreme sizes for simulating limb circumferences of 6.125 in to 27.75 in, respectively

Prototype



Test Fixture: Developing New Fixture (Continued)

- Task Group had no funding to develop new fixture
- Irregular Warfare Technical Support Directorate agreed to fund development
  - Posted Broad Agency Announcement in January 2019 and 2021
  - Vendor selected in March 2022
  - Development has begun
  - Expected completion of 3 prototypes in November 2022

Test Method Development: 2 Tests

- Test for application, achieving and maintaining max pressure for specified time
  - Pre-condition tourniquets
  - Apply to test fixture, small circumference
  - Measure pressure while applied for 5 minutes
  - Repeat using large circumference test fixture
- Test for one-handed operation
  - Applies to tourniquets for which one-handed operation is claimed by the manufacturer

Source: www.emsworld.com

Source: www.amazon.co.uk

Next Steps

Target Date	Activity
April 2022	Begin test fixture development
June 2022	Re-engage task group to: • Complete test methods • Draft specification (performance requirements) • Consider verification program
November 2022	Complete test fixture development and validation
December 2022	Complete development of test methods and specification and submit for balloting
January – March 2023	Balloting process
April – May 2023	Publish standards

Acknowledgements

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ASTM E54 Committee

Tourniquets Task Group Members

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Contact information:

Cassy Robinson, casandra.robinson@nist.gov