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Applying Risk Analysis to Acceptance Testing of Combat Helmets

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Background

- **DOT&E test protocols for Personal Protective Equipment establish consistent test procedures, statistical analysis methodologies, and performance criteria.**
  - Apply to First Article Tests (FAT) and Lot Acceptance Tests (LAT)
  - Specify the number of articles tested, the statistical measures of merit, and the criteria for acceptance
- **In 2013 the DoD Inspector General's office published a technical assessment of the Advanced Combat Helmet that included a review of the DOT&E-approved helmet test protocols (FAT and LAT)**
- **In 2013 to 2014, the National Research Council (NRC) reviewed the helmet test protocols and published a Review of the DoD Test Protocols for Combat Helmets**

Motivation: Concerns & Recommendations

Test protocols should account for real or potential variations in helmet performance across helmet sizes and test conditions.

- *We recommend that DOT&E and PEO Soldier describe the method of identifying and addressing statistically significant differences in performance due to environmental conditions, helmet sizes, shot locations, and different vendor designs for all FAT results under the DOT&E helmet test protocol.*
  - ACH Technical Assessment, DoD Inspector General

- *The Office of the Director, Operational Test and Evaluation, should revise the current protocols to implement them separately by helmet size.*
  - Review of DoD Test Protocols for Combat Helmets, NRC

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 PEO – Program Executive Office   ACH – Advanced Combat Helmet   FAT – First Article Test

Motivation: Concerns & Recommendations

Test protocols should use test data to set acceptance criteria.

- *We recommend that DOT&E and PEO Soldier fully characterize the performance of all helmet designs included in the combat helmet test protocols. Performance characterization should consider threat, historical test data, prototype test data, and manufacturing capabilities. Based on helmet performance characterizations, DOT&E and PEO Soldier should determine if modification to the FAT and LAT protocols are appropriate.*
  - ACH Technical Assessment, DoD Inspector General

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ACH – Advanced Combat Helmet   FAT – First Article Test   LAT – Lot Acceptance Test

Motivation: Concerns & Recommendations

Test protocols should use test data to set acceptance criteria.

- *If there is a scientific basis to link brain injury with performance metrics (such as penetration frequency and backface deformation), the Director of Operational Test and Evaluation (DOT&E) should use this information to set the appropriate standard for performance metrics in the test protocols. In the absence of such a scientific basis, DOT&E should develop a plan that provides assurance that it leads to the production of helmets that are at least as penetration-resistant as currently fielded helmets.*

- *Available backface deformation (BFD) data should be used to develop data-based limits against which to compare future BFD data, as a replacement for the current legacy ad hoc limits.*
  – Review of DoD Test Protocols for Combat Helmets, NRC

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Outline

- **Introduction to Combat Helmet Testing**
- **Resistance to Penetration**
  - Treating multiple conditions with a binomial response
- **Backface Transient Deformation**
  - Treating multiple conditions with a continuous response
- **Characterization Testing**
  - Matching acceptance criteria to test data

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First Article and Lot Acceptance Test Design

- **Testing is Destructive and Expensive**
  - Can only test a small fraction of the helmets
  - Want to test as few helmets as possible, while maintaining reasonable levels of risk

- **Traditional Statistical Errors**
  - Want to reject combat helmets that do not meet desired protection levels
  - Want to accept helmets that meet desired protection levels
    - » Need to field combat helmets
    - » Multiple qualified designs with similar performance lowers cost and reduces time to fielding
    - » In the long run, decreasing the risk of rejecting good helmets should prevent increases in weight and cost

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Helmet Test Metrics and Statistical Measures

- **Probability of no Penetration, P(nP)**
  – Binary outcome, Binomial
  – Lower Confidence Limit

- **Ballistic Transient Deformation (BTD)**
  – In stopping high-energy ballistic threats the helmet deforms and can impact the head, potentially with enough energy to injure the wearer
    » Current upper limits on the BTDs measured in the clay-filled headform are not based on medical data
  – Continuous metric, Distribution close to normal
  – Upper Tolerance Limit
  – Calculated for each of five shot locations

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First Article Test – Overview
Advanced Combat Helmet and other Aramid-Based Helmets

- **9 mm on the Shell**
  - 4 Sizes, 4 Environments, 5 Shot Locations
  - 48 Helmets, 5 Shots per Helmet, 240 Shots
    - » 3 Shots on each combination of size, environment, and shot location

	Ambient					Hot					Cold					Seawater				
Small	F	B	Cr	R	L	L	R	B	R	Cr	Cr	F	B	R	L	B	L	F	R	Cr
	L	R	Cr	B	F	Cr	R	B	F	L	L	R	B	F	Cr	Cr	R	F	L	B
	B	R	F	L	Cr	F	R	L	Cr	B	F	B	R	L	Cr	L	F	R	Cr	B
Medium	Cr	L	F	R	B	B	Cr	L	R	F	Cr	L	R	B	F	B	Cr	R	F	L
	R	L	B	Cr	F	R	Cr	F	B	L	B	R	L	Cr	F	R	B	Cr	L	F
	F	Cr	B	L	R	L	B	F	Cr	R	F	Cr	L	R	B	F	L	Cr	B	R
Large	L	Cr	R	F	B	Cr	B	R	L	F	F	R	Cr	B	L	L	R	F	Cr	B
	B	F	R	Cr	L	F	L	R	B	Cr	L	B	Cr	R	F	B	Cr	F	R	L
	Cr	F	L	B	R	R	L	Cr	F	B	R	Cr	B	L	F	Cr	L	B	F	R
Extra-Large	R	B	L	F	Cr	B	R	Cr	L	R	F	L	B	Cr	R	R	F	B	L	Cr
	B	L	Cr	F	R	L	Cr	F	B	R	Cr	B	L	F	R	L	Cr	R	B	F
	R	F	Cr	L	B	R	B	F	Cr	L	R	F	L	B	Cr	F	B	R	Cr	L

Cr - Crown, L - Left, R - Right, B - Back, F - Front

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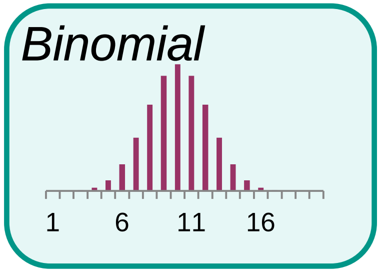
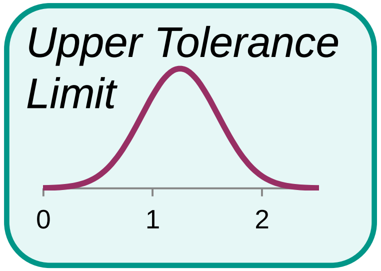
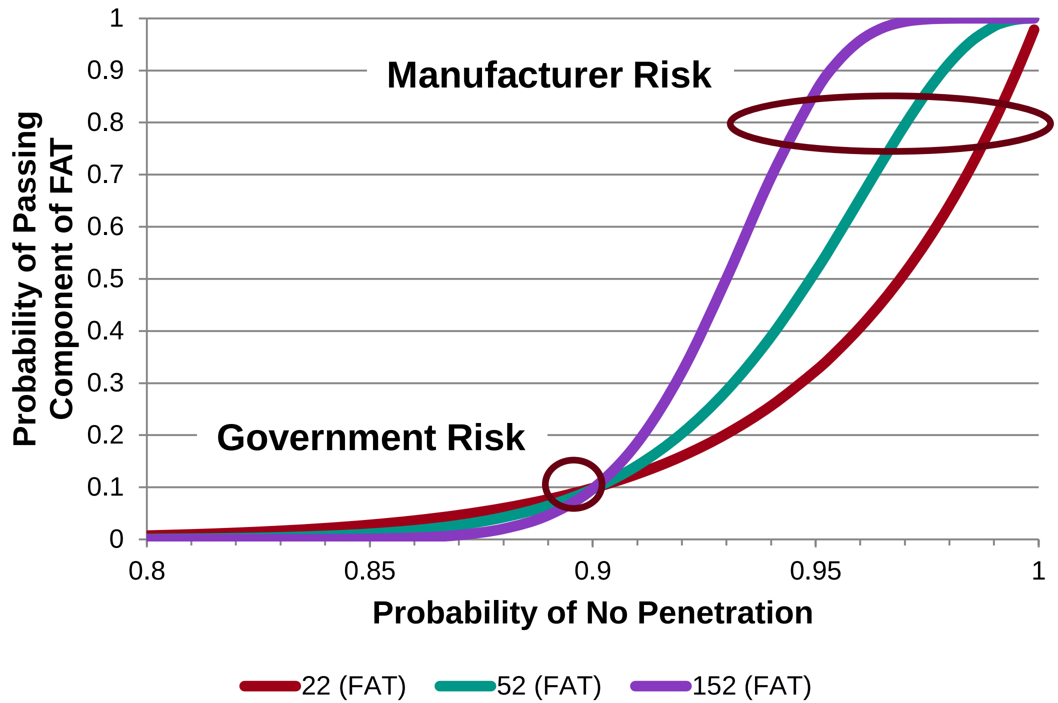
Government and Manufacturer's Risks
Operating Characteristic (OC) Curves



P(nP)



BTD



OC curves quantify the risks to the government and the manufacturers

– Always have a trade-off between risks and test size

Challenge: *How to achieve reasonable government risk across multiple factors without an unreasonable increase in test size or manufacturer risk?*

 BTD – Ballistic Transient Deformation FAT – First Article Test P(nP) – Probability of No Penetration

Outline

- **Introduction to Combat Helmet Testing**

➢ **Resistance to Penetration**
  – Treating multiple conditions with a binomial response

- **Backface Transient Deformation**
  – Treating multiple conditions with a continuous response

- **Characterization Testing**
  – Matching acceptance criteria to test data

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Hierarchical Pass/Fail Criteria for a Binomial Metric

Specify the number of allowed penetrations for:

- The full aggregated FAT test matrix
- Each individual helmet size, environmental condition, and shot location
- Could extend framework to interactions between the factors (e.g., helmet size by shot location)

Select the numbers of allowed penetrations such that:

- Aggregate criterion specifies the performance needed to pass the full set of resistance to penetration criteria
- If a failure occurs for an individual condition, then the failure is statistically significant and the failure can be attributed to that condition.

In other words, a failure for the individual conditions is rare when performance is uniform across the test factors

Aggregate	Size & Environment	Location	Allowed Penetrations			
			Total	Size	Environment	Location
97/90	90/90	86/90	3 in 240	2 in 60	2 in 60	2 in 48

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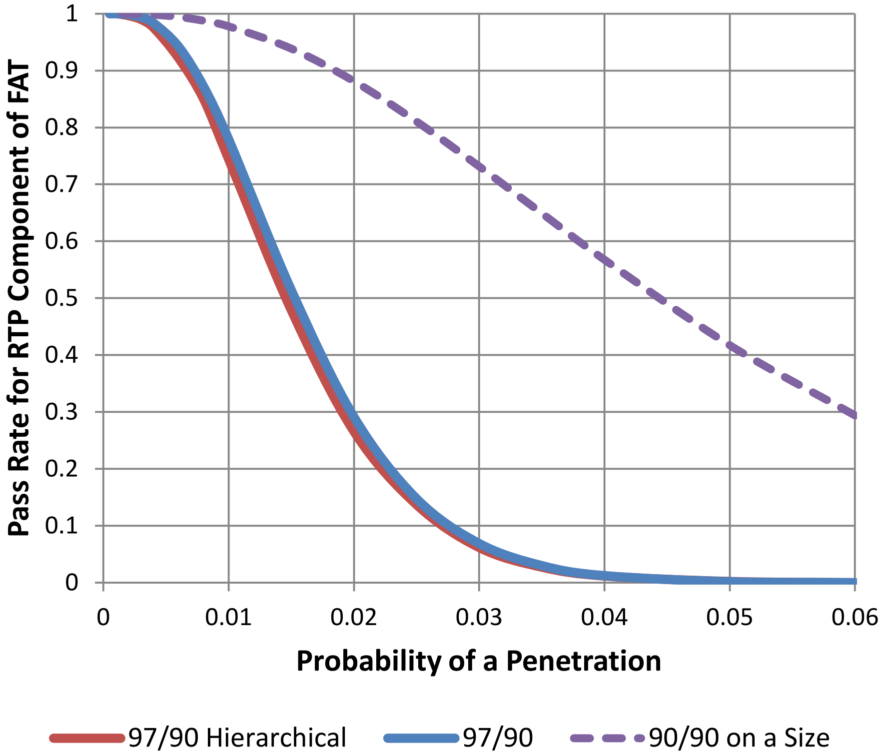
 FAT – First Article Test

Hierarchical Pass/Fail Criteria for a Binomial Metric

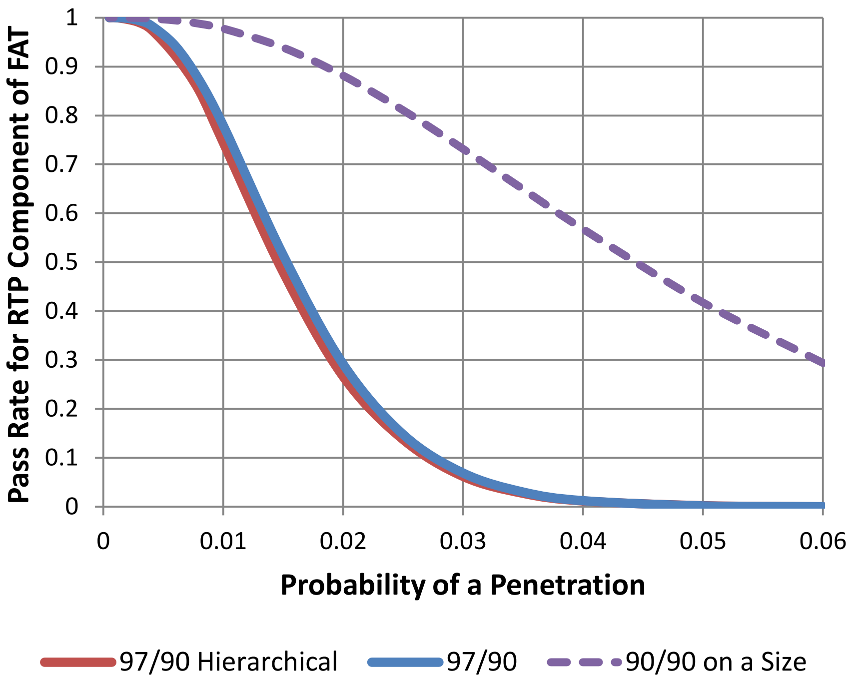


Aggregate	Size & Environment	Location
Lower Confidence Limit		
97/90	90/90	86/90
Allowed Penetrations		
3	2	2

	# Groups	# per Group	Reject at	Exact Fisher
Size	4	60	3	0.060
Environment	4	60	3	0.060
Location	5	48	3	0.038
Total Shots	--	240	4	--

 FAT – First Article Test RTP – Resistance to Penetration

Hierarchical Pass/Fail Criteria for a Binomial Metric



Aggregate	Size & Environment	Location
Lower Confidence Limit		
97/90	90/90	86/90
Allowed Penetrations		
3	2	2

When performance is similar across the test factors

The government risk on the individual conditions and the manufacturer's risk from the aggregate condition can be used to select a test size.

There is an explicit trade-off between:

- Criteria for individual conditions
- Number of conditions
- Manufacturer's risk for aggregate performance
- Test size

When performance is not similar across the test factors

The individual criterion for one (or multiple) test factors might control both government and manufacture's risks and can be used to select the test size.

 FAT – First Article Test RTP – Resistance to Penetration

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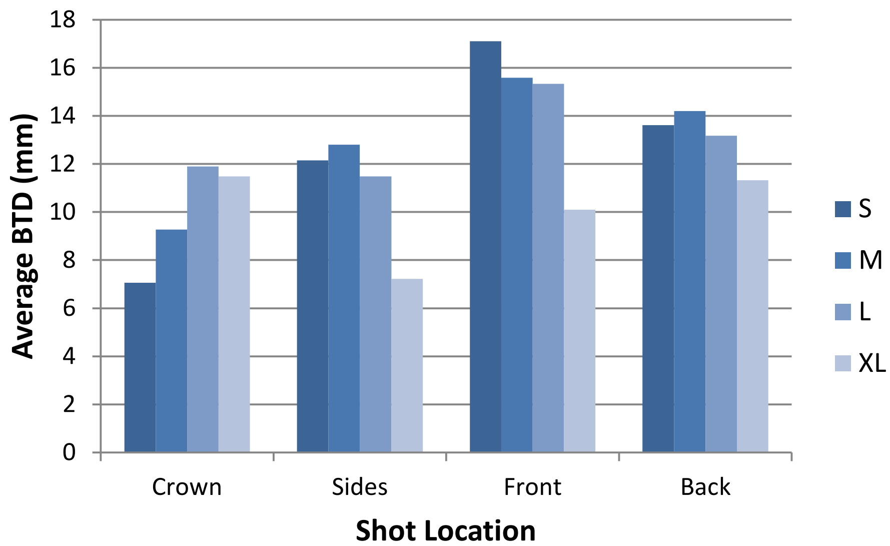
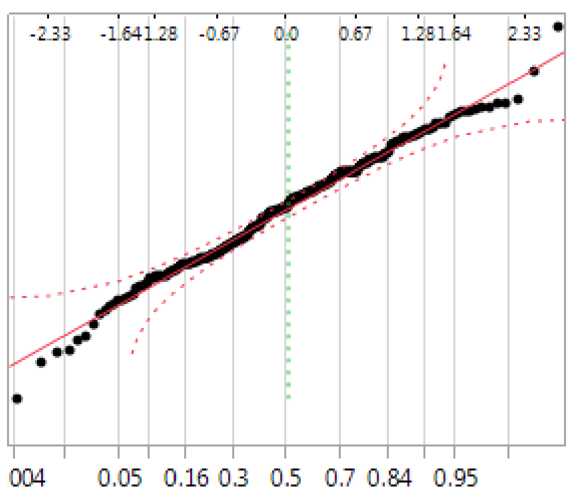
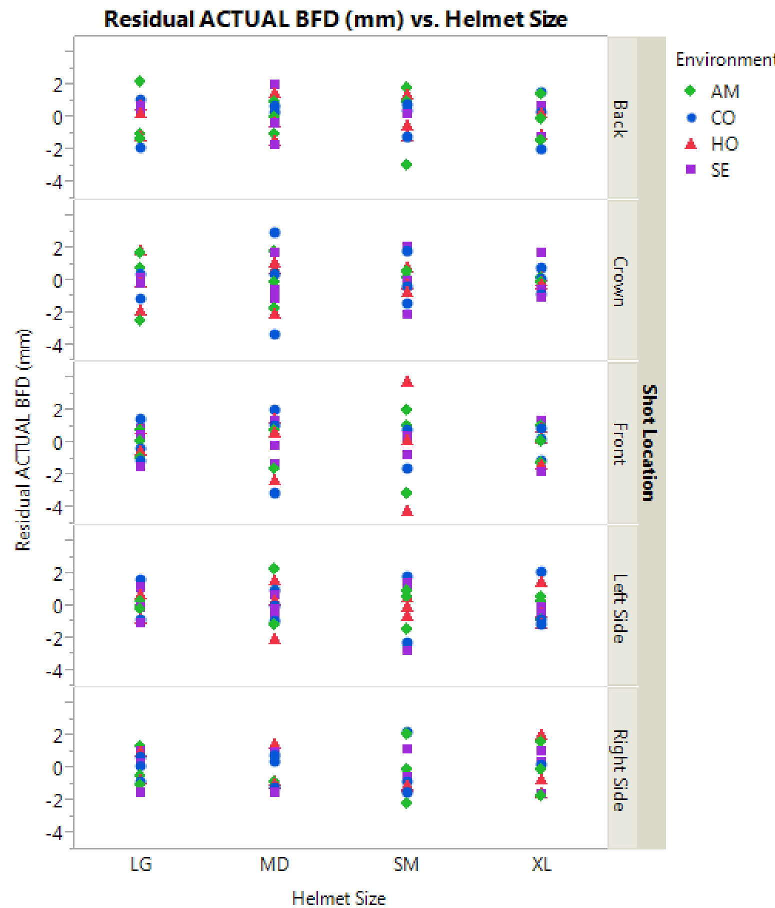
Typical BTD Data from an Aramid-Based Helmet (Data Set 2)







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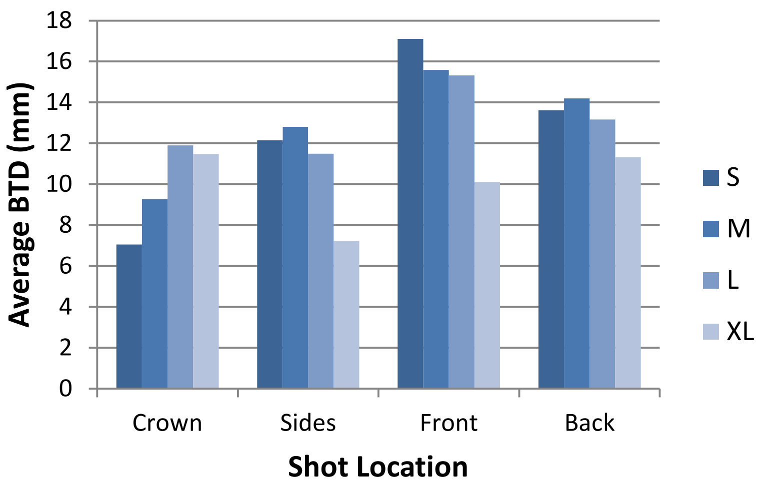
 BTD – Ballistic Transient Deformation

Acceptance Criteria for the BTD



	Ambient	Hot	Cold	Seawater
SM	3 helmets 5 shots each	…	…	…
MD	…	…	…	…
LG	…	…	…	…
XL	…	…	…	…

240 shots total

160 degrees of freedom for the pure error

Score every combination of helmet size and shot location

- 12 shots each
- Pass rate dominated by 1 or 2 size-location combinations

Binomial

- Allow 0 over for an 82/90 LCL
- Allow 1 over for a 71/90 LCL

UTL with multiple estimates of the standard deviation

- $\mathrm{UTL} = \overline{\mathrm{BTD}} + ks$
- k = 1.966 for a 90/90 UTL

UTL with a single estimate of the standard deviation (pure error)

- k = 1.673 for a 90/90 UTL

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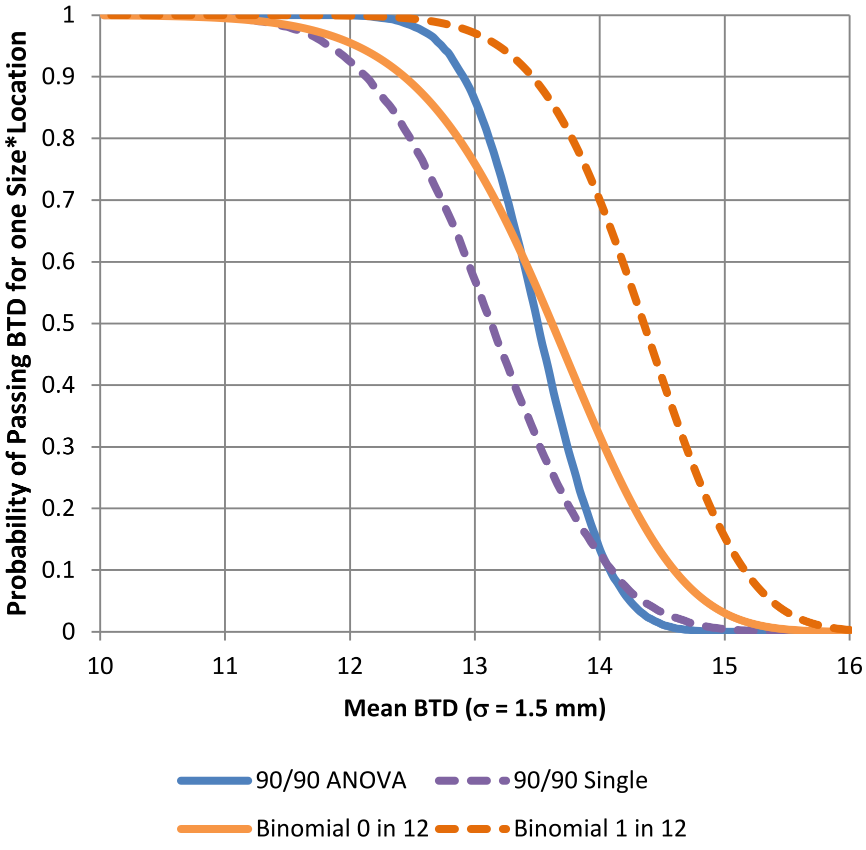
 BTD – Ballistic Transient Deformation UTL – Upper Tolerance Limit

Acceptance Criteria for the BTD



Score every combination of helmet size and shot location

- 12 shots each
- Pass rate dominated by 1 or 2 size-location combinations

Some increase in power using UTL instead of binomial

Significant increase in power using pure error estimate to calculate the UTLs

Test can best distinguish current performance from degraded performance using the UTL and the pure error estimate

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 BTD – Ballistic Transient Deformation UTL – Upper Tolerance Limit ANOVA – Analysis of Variance

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Approach

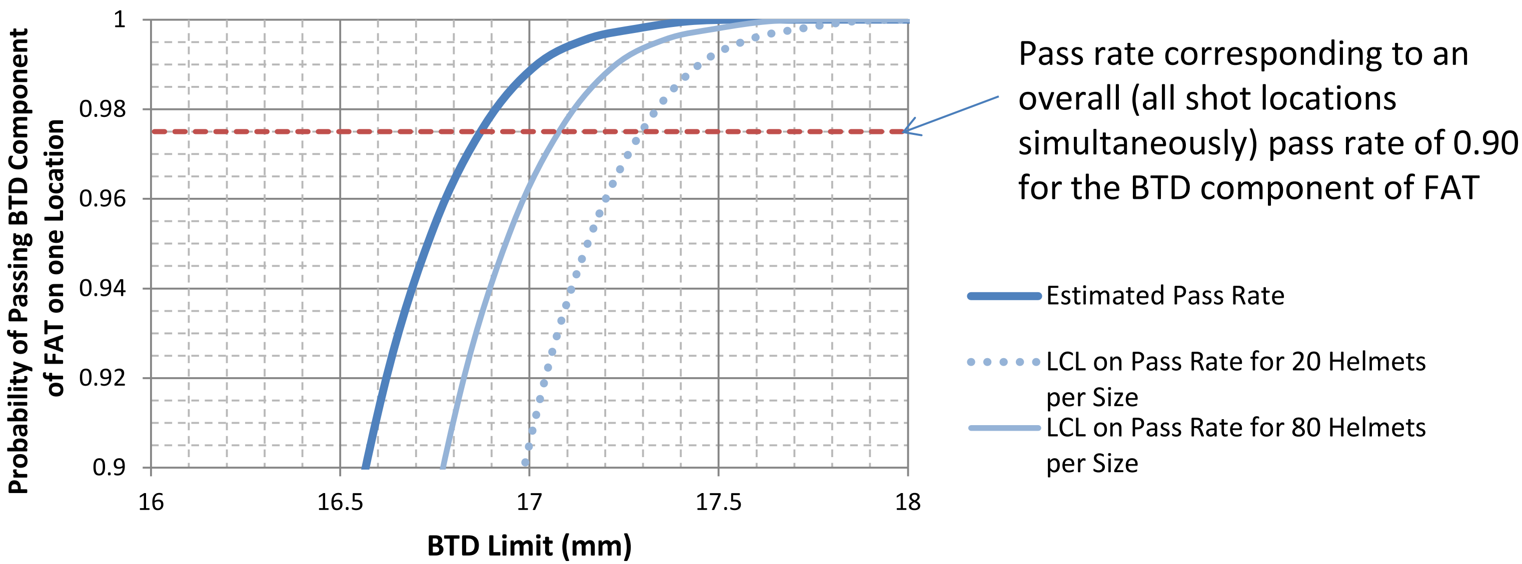
- **Use characterization data to set new BTD limits for each of the four shot locations (crown, sides, front, back)**
- **Set new BTD limits at some percentile of the BTD distribution (i.e., some number of standard deviations above the mean)**
- **Ensure that the manufacturer's risk for FAT is close enough to the characterization data**
- **Conduct enough characterization testing to control the risks of setting BTD limits either too low or too high**

What percentile should the new limits be set to?

How close should the data be to the manufacturer's risk point?

 BTD – Ballistic Transient Deformation FAT – First Article Test

Approach



Propose setting the BTD limit for the worst case helmet size on each shot location so that:

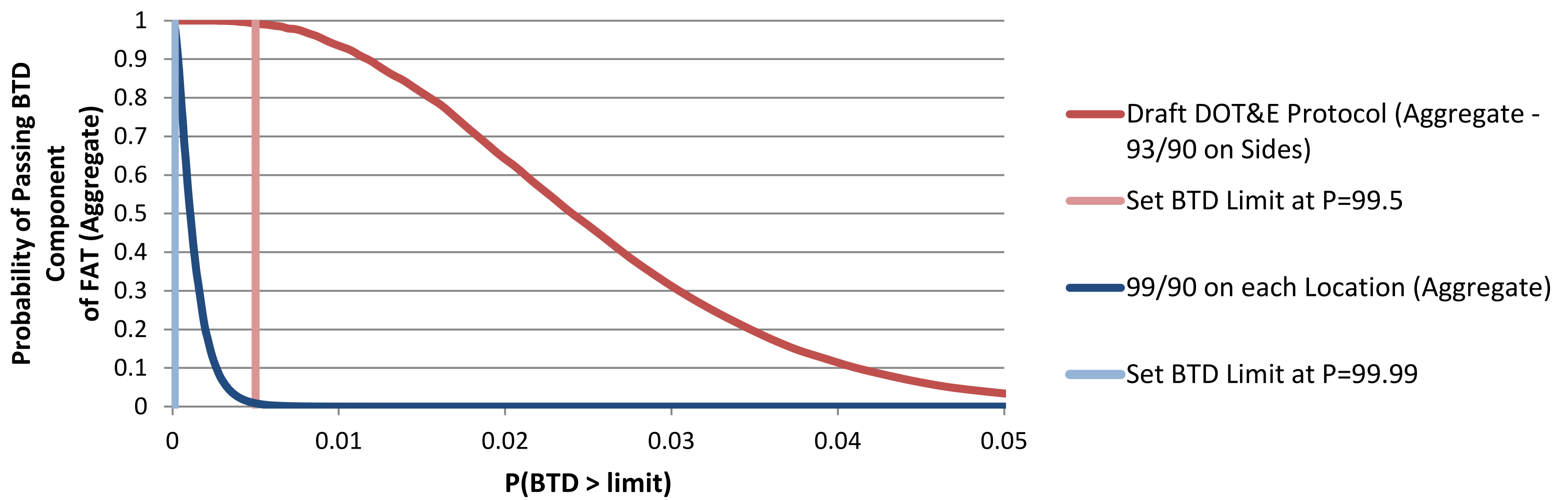
- Each shot location has an equal risk of failing FAT (same percentile for all shot locations)
  - → *Use pass rate for all locations simultaneously to determine manufacturer's risk*
- The Lower Confidence Limit (LCL) on the pass rate for the BTD component of FAT (all shot locations simultaneously) is 0.90 with 90 percent confidence.
- The manufacturer's risk for the BTD component of FAT is close to the data
  - The larger the characterization test, the closer the BTD limits can be set to the desired percentile.

 BTD – Ballistic Transient Deformation FAT – First Article Test

Percentile for the BTD Limits

The FAT criteria and the BTD limits must be selected together.

Higher BTD limits require a higher UTL percentile to match the manufacturer's risk point to the data[1]



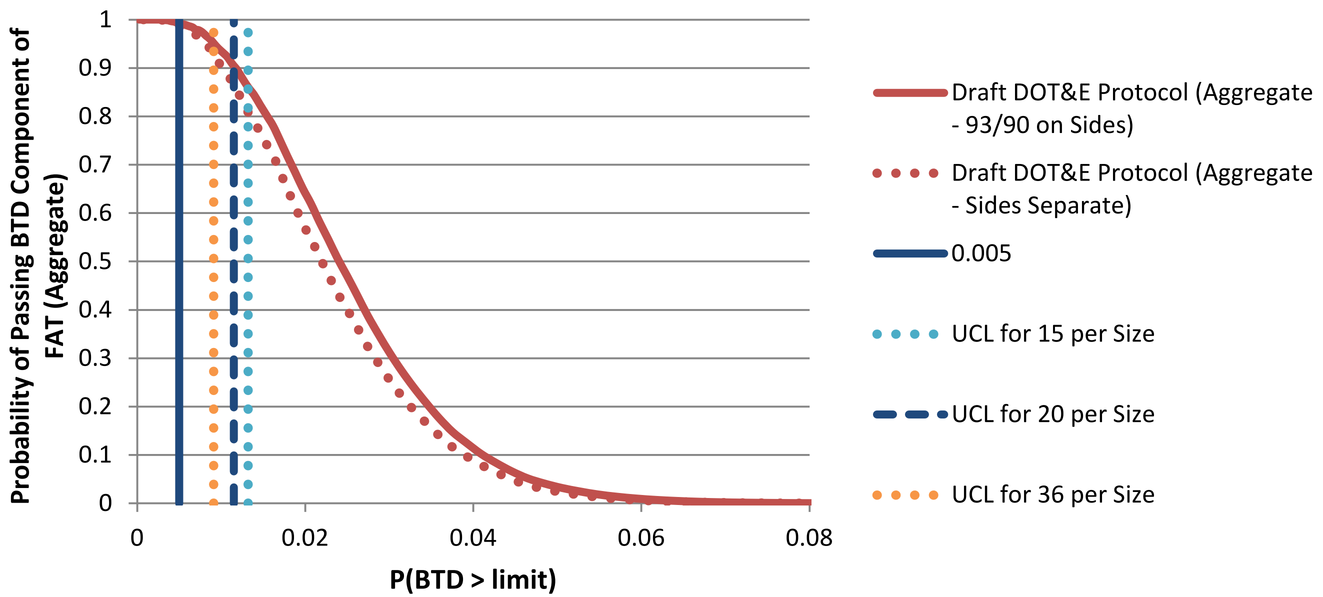
BTD Limit (Percentile)	P(BTD > limit)[3]	UTL on each Location	Manufacturer's Risk Point (Aggregate)[3]	k-value	Example Location 1	Example Location 2
0.995	0.005	90/90[2]	0.012	1.673	17.3 mm	15.6 mm
0.9999	0.0001	99/90	0.0003	2.749	18.8 mm	17.5 mm

[1] Both the draft DOT&E protocol and the example 99/90 FAT have 48-helmets. The 99/90 FAT has a higher k-value.
[2] 93/90 on sides if right and left can be combined
[3] These are only examples – closer matches between P(BTD>limit) and the manufacturer's risk point are possible but require a larger characterization test to avoid overestimating the BTD performance.

 BTD – Ballistic Transient Deformation FAT – First Article Test UTL – Upper Tolerance Limit

Characterization Test Size

A larger characterization test decreases the risk of overestimating the BTD performance and allows the manufacturer's risk point to be set closer to the data.



As the size of the characterization test increases, the BTD is better characterized

- The upper confidence limit (UCL) on the true number of BTDs above the new limit decreases.
- The lower confidence limit on the predicted FAT pass rate increases.
- The manufacturer's risk point can be set closer to the data

 BTD – Ballistic Transient Deformation FAT – First Article Test

Other Challenges

- **Lack of medical data on which to base BTD limits**
- **Single-size test headform**
  - Better to have multiple-size headforms for multiple helmet sizes
  - Anthropometric for best comparison among designs
- **Applying statistical framework to other elements of personal protective equipment**
  - For example, the Enhanced Combat Helmet has only two shots per helmet
- **Test threats**
  - Which direct- and indirect-fire threats are the most operationally relevant?
- **Variability in the test procedures**
  - Need to continue to identify and control sources of variation in the test

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