Total Inward Leakage – An Assessment of Variation in Implementation of Anthropometric Marking and Measurement Techniques

Quiring, A.; Parham, M.; Simmonds, E.
Scott Safety, Monroe, NC
aquiring@tycoint.com
AIHce 2011 – Portland, Oregon, May 17th, 2011
Introduction – What is TIL?

- In October, 2009 NIOSH proposed “Total Inward Leakage Requirements for Respirators” (TIL) rulemaking to address fit of air-purifying half-facepiece particulate respirators
- TIL measures total % leakage through filter, through facepiece to face seal, using a Condensation Nuclei Counter (CNC) in an ambient atmosphere
- TIL level is defined as 1%, Protection Factor of 100
  - TIL = 100/FF, assuming that measured Fit Factor is equivalent to Protection Factor
  - the level of fit testing performance specified by the OSHA
  - TIL will not be equivalent to Assigned Protection Factor (APF)
- Goals of “Total Inward Leakage Requirements for Respirators”
  - Highly effective model (>80%) would almost always pass
  - Less effective models (<60%) should almost always fail
- NIOSH proposed a 35-member panel, using Bivariate Panel and excluding outliers from Principle Component Analysis (PCA) Panel with a pass rate of 74%
- Requires manufacturers to identify the intended user populations
Background – TIL
NIOSH Benchmark Study

- NIOSH NPPTL conducted Benchmark Testing
  - 57 Filtering Facepiece Respirators, 43 Elastomeric Half Masks, 1 Quarter Mask
  - Entire panel of 25 Subjects per model
  - Three donnings per respirator per subject
  - 8250 Fit Factor Points

- Findings
  - Wide variability in fitting characteristics of half-mask respirators
  - Statistical differences between elastomeric & FFRs
  - Easier for user to obtain OSHA-required FF wearing an elastomeric

- Recommendation
  - TIL performance requirement is necessary step in respirator certification for particulate respirators


© 2011 Scott Safety
**Background – Bivariate Panel**

LANL 25-Member Panel for Half-Mask Respirators

<table>
<thead>
<tr>
<th>Lip Length (mm)</th>
<th>34.5</th>
<th>43.5</th>
<th>52.5</th>
<th>61.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>133.5</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>123.5</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>113.5</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>103.5</td>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>93.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- NIOSH Bivariate Panel is designed to more accurately represent shifting demographic of US worker population
- 10 cells, 25 subjects with at least 2 subjects per cell intended to match the distribution of defined population
- Utilized facial width & facial length for half-mask and full facepiece

**NIOSH Bivariate Panel**

<table>
<thead>
<tr>
<th>Face Width (mm)</th>
<th>134.5</th>
<th>146.5</th>
<th>158.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>138.5</td>
<td>#6</td>
<td>#9</td>
<td>#10</td>
</tr>
<tr>
<td>128.5</td>
<td>#7</td>
<td>#8</td>
<td></td>
</tr>
<tr>
<td>118.5</td>
<td>#3</td>
<td>#4</td>
<td>#5</td>
</tr>
<tr>
<td>108.5</td>
<td>#3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>98.5</td>
<td>#1</td>
<td>#2</td>
<td></td>
</tr>
</tbody>
</table>

**Bivariate Distribution against LANL Panel**

Background – Principle Component Analysis Panel

- Principle Component Analysis derives two new variables based on linear combinations of 10 different anthropometric measurements.
- Two principle components (eigenvectors) are described as PC1, the overall size of the face (Small – Large) and PC2, the shape of the face (Small face with short, wide nose to a Long face with a long, narrow nose).
- PCA Panel excludes extreme facial features, accommodates 95% of US Civilian Worker Population, including 95.2% Male and 97.6% Females.

Situation/Problem

- Specialized training from subject matter experts was required
- Time, expense to conduct pilot study, full study
- Limited and biased population sample available for study
  - No random selection
  - Limited in geographical and individual diversity (age, gender, racial and ethnic bias in sample)
  - Overrepresentation of skilled panel subjects
- Had to develop methods of describing facial sizes/shapes and amending current product offering's guidance
  - Specify which sizes will accommodate which portion of the population
- Accuracy/Allowable measurement error for anthropometric measurements difficult to meet
- Concern that panel placement error may contribute to poor fit, problems in certification with subject accommodation in crossover sizes and requirements for panel-specific pass
- ANSI Z88 guidance on fit and comfort for size selection
- Had to overcome legacy error in LANL panel placement with skilled subjects
Objective

- Original experimental design was a **BHAG = Big Hairy Auspicious Goal**
  - Observed need for Training by Subject Matter Experts, Pilot Study
  - Sought to control measurement, human error
  - 3D scanning equipment
  - 100 randomly selected subjects
  - 3 replicates
  - Issue with local participants and representation of US civilian worker population

- Pilot Study was initiated to assess variability in anthropometric landmarking and measurement for facial dimensions described in the Principle Component Analysis (PCA) panel and NIOSH's Bivariate Panel
  - Error Contribution to PC1, PC2 by facial dimension during Training
  - Measurement Systems analysis of Pilot Study – total sample, by subject, by measurer
  - Interobserver, intraobserver error during measurement system analysis/gage repeatability & reproducibility
    - Gage R&R study on each measurement
  - Panel to panel placement variability & effect on QNFT result
    - Attribute agreement analysis on panel assignment
    - 95% Confident Interval errors for subject placement on bivariate test panel
    - Capability, Probability plots by panel assignment and by Half-Mask size to achieve overall FF of 100
Training - Anthrotech

• Anthropometric Landmarking and Measurement Training provided by Anthrotech
  • 2 days classroom and hands-on training
• Landmarks and measurements to support a TIL study recommended by Dr. Bruce Bradtmiller and Dr. Ziqing Zhuang
  • Landmarks - alare, cheilion, frontotemporale, glabella, gonion, orbitale, opisthocranion, menton, nasal root point, pronasale, sellion, subnasale, tragion, zygion, zygofrontale
• Anthropometric Measurements – head circumference, head length, head breadth, minimum frontal breadth, maximum frontal breadth, bizygomatic breadth (or face width), bigonial breadth, interpupillary breadth, nose protrusion, subnasale-sellion length, menton-sellion length (or face length), nasal root breadth, nose breadth, lip length

Images Shown Courtesy of Anthrotech
Observations from Training

- We looked at error contribution to the PC1 (Facial Size) and PC2 (Facial Shape) calculations based on anthropometric measurement error observed during our training and made a Pareto of results.
- The estimate is made by multiplying the derivative with respect to the specific measurement times its standard deviation.

For the error Pareto, example calculation:

Bigonial Breadth Error Contribution
dPC1 / dBigonial Breadth = 0.37272

Standard Deviation of Bigonial Breadth average within subjects = 1.36 mm, Square root of the sum of squares PC1 measurement errors (all ten measurements) = 2.33

Error contribution (Bigonial Breadth) = (0.37272 * 1.36 / 2.33)^2 => 0.34156
Observations from Training

- Training and hands-on work with subjects helped identify measurements that require the most attention to minimize PC1 and PC2 error and therefore panel determination error
  - Bigonial Breadth
  - Face Width
  - Minimum Frontal Breadth
  - Nose Protrusion
  - Subnasale-Sellion Length
  - Face Length
- Most erroneous measurements were those most important to LANL panel placement as well
Methods – Experimental Design for Pilot Study

• 25 Subjects – unfortunately no random selection/broad distribution of half mask LANL panel subject pool
• Photo of subject, voluntary participation, compensation on completion, questionnaire establishing subject population characteristics
• 2 trials / different days, 2-D anthropometric landmarks and measurement
• 3 measurers in random order - Same landmark/data recorder/fit test technician for each trial
• Same calibrated calipers for each measurement – sliding, spreading and steel tape
• Landmarking and Anthropometric Measurement conducted per Anthrotech Training and landmark/measurement test protocol and handbooks
• Calculated PC1, PC2 and placement on PCA, Bivariate, LANL panels
• Recommended of size based on Bivariate Panel
• Did not exclude PCA Panel placement determined to be “off-panel”
• QNFT on each size on Portacount per OSHA 1910.134 exercise protocol, Pass/Fail = 100 FF for APF of 10
  – Normal Breathing, Deep Breathing, Head Side to Side, Head Up & Down, Bend Over, Recite the Rainbow Passage, Grimace (15 seconds-excluded), Normal Breathing
  – Donning, Negative Pressure Leak Test and Positive Pressure Leak Test
Subject Population

Gender - % Subject Population

- 40% Female
- 60% Male

Ethnicity - % Subject Population

- Asian 12%
- African/American 12%
- Hispanic 2%
- White/Caucasian 4%
- American Indian 4%
- Alaskan Native 4%
- Other 84%

Age Range - % Subject Population

- 18-29 44%
- 30-44 40%
- 45-65 8%
- 65+ 8%
Results – Measurement Normality
Ex: Facial Width (Bizygomatic Breadth)

Normality Check - Total Sample, By Subject, By Panel Cell, By Measurers on each Measurement

By Measurer

Total Sample

© 2011 Scott Safety
Results – Measurement Normality
Ex: Facial Length (Menton-Sellion)

Normality Check - Total Sample, By Subject, By Panel Cell, By Measurers on each Measurement

Summary for Face Length
Measurer = John M.

Summary for Face Length
Measurer = Dan S.

Summary for Face Length
Measurer = Bill S.

Summary for Face Length
Landmark = Ethan V.

By Measurer

Total Sample

Anderson-Darling Normality Test

Mean 120.34
SD 9.44
Skewness -0.877906
Kurtosis 0.877906
N 204

95% Confidence Interval for Mean
119.09 121.70
95% Confidence Interval for Median
120.64 123.09
95% Confidence Interval for SD
0.64 10.46

Probability Plot of Face Length
Normal + 95% CI

Mean 120.4
SD 9.46
N 204
AD 2.323
P-Value < 0.005
Results - Gage R&R Study
Bizygomatic Breadth (Facial Width)

Gage R&R Study - ANOVA Method
Gage R&R for Face Width

Gage name: Spreading Calipers
Date of study: May 2011
Reported by: 
Tolerance: 12
Misc: 

Two-Way ANOVA Table With Interaction

<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>24</td>
<td>8663.16</td>
<td>369.298</td>
<td>152.131</td>
<td>0.000</td>
</tr>
<tr>
<td>Measurer</td>
<td>2</td>
<td>34.81</td>
<td>17.407</td>
<td>7.171</td>
<td>0.002</td>
</tr>
<tr>
<td>Subject * Measurer</td>
<td>48</td>
<td>116.52</td>
<td>2.427</td>
<td>2.890</td>
<td>0.000</td>
</tr>
<tr>
<td>Repeatability</td>
<td>75</td>
<td>63.00</td>
<td>0.840</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>149</td>
<td>9077.49</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Alpha to remove interaction term = 0.25

Gage R&R

<table>
<thead>
<tr>
<th>Source</th>
<th>%Contribution of VarComp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gage R&amp;R</td>
<td>1.9333</td>
</tr>
<tr>
<td>Repeatability</td>
<td>0.8400</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>1.0933</td>
</tr>
<tr>
<td>Measurer</td>
<td>0.2996</td>
</tr>
<tr>
<td>Mearurer*Subject</td>
<td>0.7937</td>
</tr>
<tr>
<td>Part-To-Part</td>
<td>61.1451</td>
</tr>
<tr>
<td>Total Variation</td>
<td>63.0785</td>
</tr>
</tbody>
</table>

Process tolerance = 12

<table>
<thead>
<tr>
<th>Source</th>
<th>Study Var</th>
<th>%Study Var</th>
<th>%Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gage R&amp;R</td>
<td>1.39044</td>
<td>8.3427</td>
<td>17.51</td>
</tr>
<tr>
<td>Repeatability</td>
<td>0.91652</td>
<td>5.4991</td>
<td>11.54</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>1.04563</td>
<td>6.2738</td>
<td>13.17</td>
</tr>
<tr>
<td>Measurer</td>
<td>0.54734</td>
<td>3.2841</td>
<td>6.89</td>
</tr>
<tr>
<td>Measurer*Subject</td>
<td>0.89093</td>
<td>5.3456</td>
<td>11.22</td>
</tr>
<tr>
<td>Part-To-Part</td>
<td>7.81954</td>
<td>46.9172</td>
<td>98.46</td>
</tr>
<tr>
<td>Total Variation</td>
<td>7.94220</td>
<td>47.6532</td>
<td>100.00</td>
</tr>
</tbody>
</table>

Number of Distinct Categories = 7
Results - Gage R&R Study
Menton-Sellion (Facial Length)

Gage R&R Study - ANOVA Method
Gage R&R for Face Length
Gage name: Menton-Sellion
Date of study: May 2011
Reported by: [Name]
Tolerance: 10 mm
Misc:

Two-Way ANOVA Table With Interaction
<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>24</td>
<td>11956.1</td>
<td>498.171</td>
<td>110.201</td>
<td>0.000</td>
</tr>
<tr>
<td>Measurer</td>
<td>2</td>
<td>43.7</td>
<td>21.840</td>
<td>4.831</td>
<td>0.012</td>
</tr>
<tr>
<td>Subject * Measurer</td>
<td>48</td>
<td>217.0</td>
<td>4.521</td>
<td>0.929</td>
<td>0.603</td>
</tr>
<tr>
<td>Total</td>
<td>75</td>
<td>365.0</td>
<td>4.867</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alpha to remove interaction term = 0.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Two-Way ANOVA Table Without Interaction
<table>
<thead>
<tr>
<th>Source</th>
<th>DF</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject</td>
<td>24</td>
<td>11956.1</td>
<td>498.171</td>
<td>105.286</td>
<td>0.000</td>
</tr>
<tr>
<td>Measurer</td>
<td>2</td>
<td>43.7</td>
<td>21.840</td>
<td>4.616</td>
<td>0.012</td>
</tr>
<tr>
<td>Repeatability</td>
<td>123</td>
<td>582.0</td>
<td>4.732</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>149</td>
<td>12581.8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Gage R&R

<table>
<thead>
<tr>
<th>Source</th>
<th>% Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gage R&amp;R</td>
<td>5.0738</td>
</tr>
<tr>
<td>Repeatability</td>
<td>4.7316</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>0.3422</td>
</tr>
<tr>
<td>Measurer</td>
<td>0.3422</td>
</tr>
<tr>
<td>Part-To-Part</td>
<td>82.2398</td>
</tr>
<tr>
<td>Total Variation</td>
<td>87.3136</td>
</tr>
<tr>
<td>Process tolerance = 10</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source</th>
<th>StdDev (SD)</th>
<th>%Study Var</th>
<th>%Study Var</th>
<th>%Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Gage R&amp;R</td>
<td>2.25250</td>
<td>13.5150</td>
<td>24.11</td>
<td>135.15</td>
</tr>
<tr>
<td>Repeatability</td>
<td>2.17522</td>
<td>13.0513</td>
<td>23.28</td>
<td>130.51</td>
</tr>
<tr>
<td>Reproducibility</td>
<td>0.58495</td>
<td>3.5097</td>
<td>6.26</td>
<td>35.10</td>
</tr>
<tr>
<td>Measurer</td>
<td>0.58495</td>
<td>3.5097</td>
<td>6.26</td>
<td>35.10</td>
</tr>
<tr>
<td>Part-To-Part</td>
<td>9.06862</td>
<td>54.4117</td>
<td>97.05</td>
<td>544.12</td>
</tr>
<tr>
<td>Total Variation</td>
<td>9.34417</td>
<td>56.0650</td>
<td>100.00</td>
<td>560.65</td>
</tr>
</tbody>
</table>

Number of Distinct Categories = 5
**Results – 95% Confidence Interval Error for Bivariate Panel Placement**

**Ho:** accuracy and quality of anthropometric data collected will affect validity of fit test panel placement

**Ha:** data collected will not affect validity of fit test panel placement

- Could impact fit test panel placement and ultimately certification
- Attempted to control bias with one landmarker throughout study
- Values of three measurers were averaged, still had a large number of panel reassignments

![Graph showing NIOSH-NPPTL Bi-Variate Test Panel with data points and error bars representing face length and width measurements.](image-url)

Acceptable error was NOT controlled based on accuracy between 1-3 mm, depending on dimension measured*, based on standard practice in anthropometric field.**

*(Zhuang and Bradtmiller, 2005; Anthrotech, 2004)

**(Gordon et al., 1989)
Results – Attribute Agreement Analysis on Panel Assignment

Within Appraisers
Assessment Agreement

Appraiser  # Inspected  # Matched  Percent  95 % CI
Dan S.     25          18        72.00 (50.61, 87.93)
Ed S.      25          16        64.00 (42.52, 82.03)
John M.    25          14        56.00 (34.93, 75.60)

# Matched: Appraiser agrees with him/herself across trials.

Each Appraiser vs Standard
Assessment Agreement

Appraiser  # Inspected  # Matched  Percent  95 % CI
Dan S.     25          16        64.00 (42.52, 82.03)
Ed S.      25          15        60.00 (38.67, 78.87)
John M.    25          10        40.00 (21.13, 61.33)

Between Appraisers
Assessment Agreement

# Inspected  # Matched  Percent  95 % CI
25          7          28.00 (12.07, 49.39)

# Matched: All appraisers' assessments agree with each other.

All Appraisers vs Standard
Assessment Agreement

# Inspected  # Matched  Percent  95 % CI
25          7          28.00 (12.07, 49.39)

# Matched: All appraisers' assessments agree with the known standard.

• Conducted attribute analysis of bivariate panel assignment.
• Used the average measurement across both trials and measurements to determine the panel assignment "standard" for each subject.
• Overall the reproducibility and repeatability is not acceptable.

© 2011 Scott Safety
**Results – Fit Data**

- Distribution non-normal, non-linear relationship observed between Fit and Facial Dimensions.
- Distribution of all fit data and most subcategories (mask and panel) is a geometric mean or Square Root of Overall Fit Factor (FF of 100 = transformed FF of 10).
- Capability analysis demonstrates <4% subjects would be <100FF.
  - Confirmed pass rate of 96% for population.

**Probability Plot of Sqrt(Overall FF)**

- **Normal**:
  - Mean: 138.0
  - SD: 69.46
  - N: 100
  - AD: 0.421
  - P-Value: 0.317

**Process Capability of Sqrt(Overall FF)**

- **LSL**: 10
- **Target**: *
- **USL**: *
- **Sample Mean**: 138.048
- **Sample N**: 100
- **StDev(Overall)**: 69.463

**Observed Performance**
- % < LSL: *
- % > USL: *
- % Total: 4.00

**Exp. Overall Performance**
- % < LSL: 3.26
- % > USL: *
- % Total: 3.26

© 2011 Scott Safety
Results – Fit Test Data
Capability, Probability Plots by Panel Assignment

Capability Histograms of Sort(Overall FF) by Bivariate Panel Assignment

Probability Plots of Sort(Overall FF) by Bivariate Panel Assignment

© 2011 Scott Safety
Results – Fit Tests
Capability, Probability by Half Mask Size

- Identified minor issues with mask accommodation for subjects from this population in smaller panels, but there is a strong correlation between negative leak checks and pass rate for FF of 100
- Positive leak check works well but has a higher false positive rate
- Half Mask fits too well with this subject pool to make a prediction that it would not be certified according to the NIOSH TIL Draft Concept due to panel assignment error
Results – Boot-strapping
Simulation of Bivariate Panel Assignment

Bivariate Panel Assignment frequency for Monroe Subjects
Boot-strap simulation of 240 panel assignments of the 25 member subject pool
Results – Bootstrapping

Distribution of Panel Subjects by Measurer and Simulation

Comparison of Panel Distribution

- Simulated Panel Distribution (240 measurements of 25 subjects)
- Dan S. Panel (2 measurements of 25 subjects)
- Ed S. Panel (2 measurements of 25 subjects)
- John M. Panel (2 measurements of 25 subjects)

Bivariate Panel Assignment

© 2011 Scott Safety
Results – Bootstrapping
Stability for Panel Determination – Mode
Lessons Learned/Discussion

- Measurements identified as largest potential for error in PC1 and PC2 calculation were those most important to Bivariate Panel placement
- Measurement techniques employed are acceptable as a gage for measuring differences across the subject population (% study < 30) but unacceptable for determining panel placement (% tolerance > 30).
  - Supported by Gage R&R, Attribute Agreement Analysis
  - For face width there is no significant difference between repeatability and reproducibility
  - For face length there is significant contribution from repeatability which is indicative of landmarking error due to the difficult to place menton landmark
- No correlation between bivariate panel assignment and fit factor when donning and mask sizing are followed
  - Panel specific pass criteria are not appropriate given the limited panel size proposed for TIL
  - Use of panels helps to introduce sufficient subject pool variance for overall pass/fail criteria but panel assignment is not exact enough to establish panel specific pass/fail criteria
  - Families of respirators can be certified against a fit-test panel – recommend that NIOSH not specify which portion of the panel each individual size must fit
Recommendations for Further Research

- Undertake “BHAG” Study, highlight which facial features have biggest impact on fit
- Analysis of placement of landmarks as potential source of error
- Effort to reduce human error in landmark placement and anthropometric dimension requirements
  - Anthrotech recommends tolerance limits for intra- and interobserver differences in repeat measurements of the same variable
  - Field Editing – identify errors vs. min/max, subject measurements checked for consistency via regression analysis
  - Post-hoc Editing – identify high/low values for inspection, compare measured with predicted value from regression, flag outliers
  - Practice, Practice, Practice on a variety of facial sizes, shapes
- 3D Scanning to validate placement of landmarks trial to trial
- Create a population sample that is reflective of race/ethnic, age and gender diversity of desired population in accordance with ISO, use random sampling and expand into other geographical regions
- Further simulations & Boot-strapping – apply the same analysis to observed fit factor variation
- Look at various types of half-mask respirators (highly effective/less effective)
References


QUESTIONS?

Sincere thanks to Michael Parham and Edward Simmonds for assistance in Experimental Design and Data Analysis.

Thanks to the APR Engineering team at Scott Safety - Dan Symons, John Mouser, Edward Simmonds, Jeremy Maness, Paul Schneider and Ethan Voss for gathering the experimental data for this study. Thanks to the Scott Safety employees for willing and enthusiastic participation.

Special thanks to Dr. Bruce Bradtmiller and Belva Hodge from Anthrotech for on-site training and inspiration for this pilot study.