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

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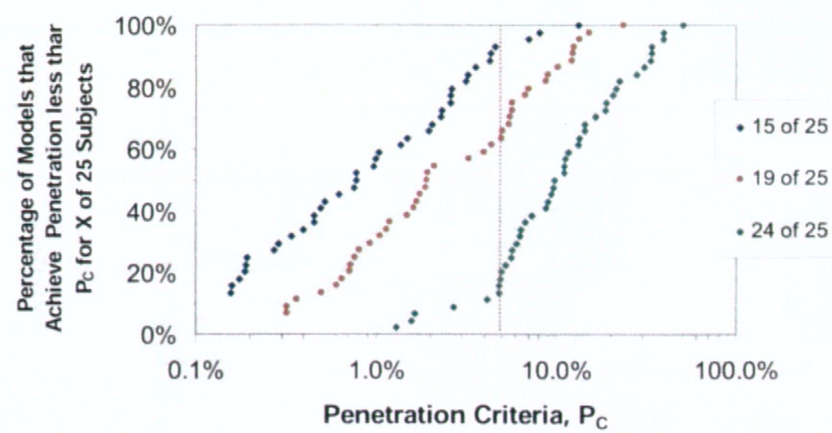
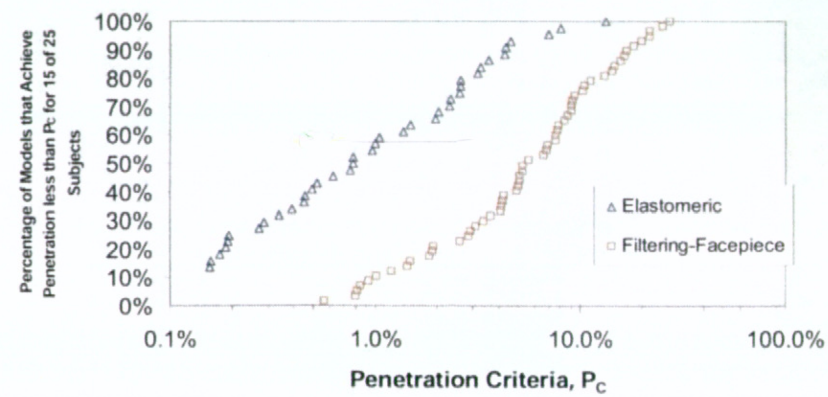
Introduction – What is TIL?

- 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

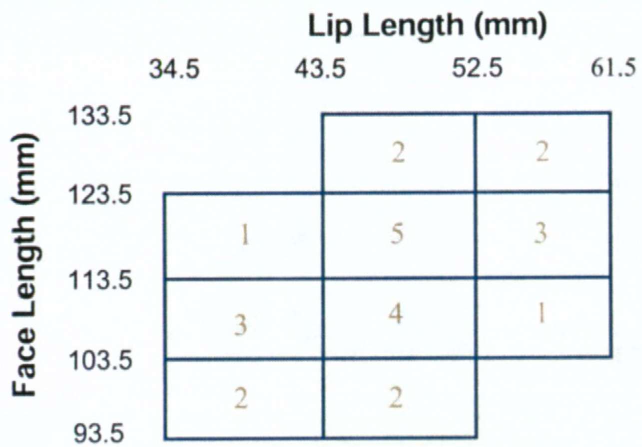




Graphs from NIOSH/NPPTL Presentation at Public Meeting, June 26, 2007. *Proposed TIL Testing in NIOSH Certification Benchmark Testing* by William Newcomb

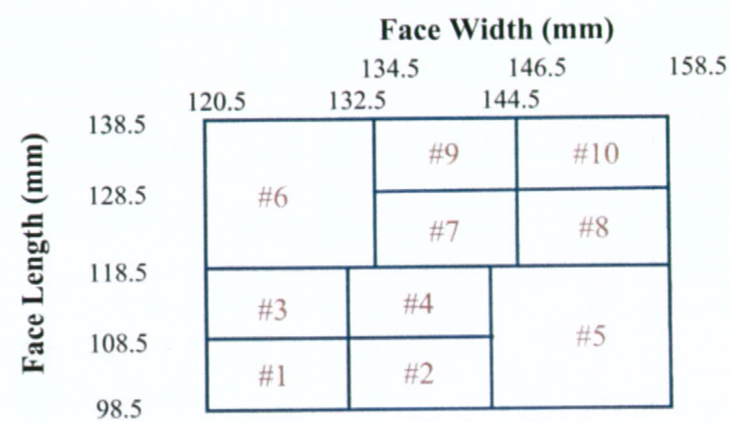
Background – Bivariate Panel

LANL 25-Member Panel for Half-Mask Respirators

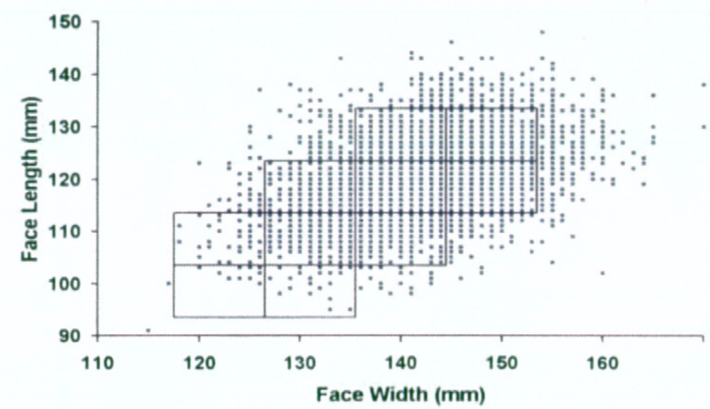


- NIOSH Bivariate Panel is designed to more accurately represent shifting demographic of US worker population
- 10 cells, 25 subjects with at least 2 subjects per cell intended to match the distribution of defined population
- Utilized facial width & facial length for half-mask and full facepiece

NIOSH Bivariate Panel



Bivariate Distribution against LANL Panel



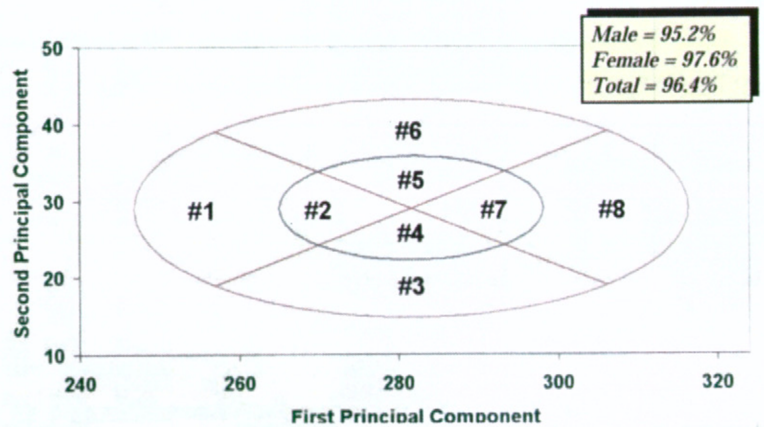
Images from NIOSH NPPTL Public Meeting, June 26, 2007. *Anthropometrics Research to Develop Respirator Fit Test Panels*, Ziqing Zhuang, Ph.D.

Background – Principle Component Analysis Panel

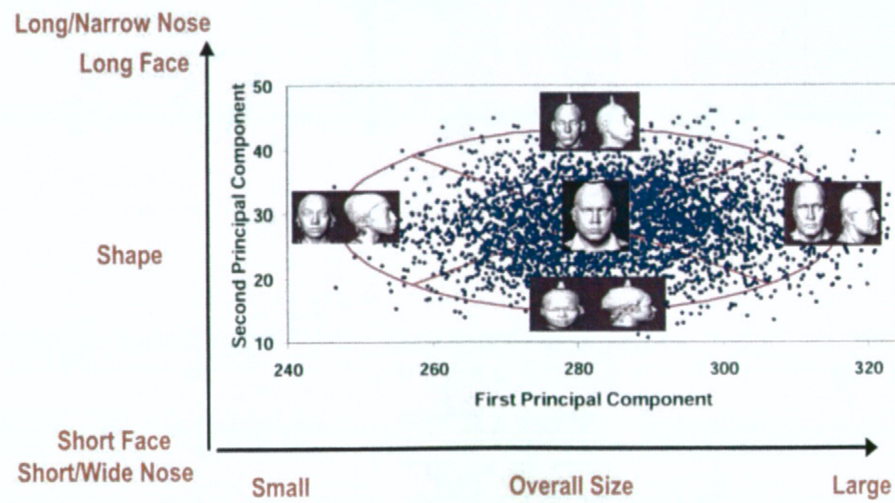
- Principle Component Analysis derives two new variables based on linear combinations of 10 different anthropometric measurements
- Two principle components (eigenvectors) are described as PC1, the overall size of the face (Small – Large) and PC2, the shape of the face (Small face with short, wide nose 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

Images from NIOSH NPPTL Public Meeting, June 26, 2007. *Anthropometrics Research to Develop Respirator Fit Test Panels*, Ziqing Zhuang, Ph.D.

NIOSH PCA Panel



Facial Shape Trends



Situation/Problem

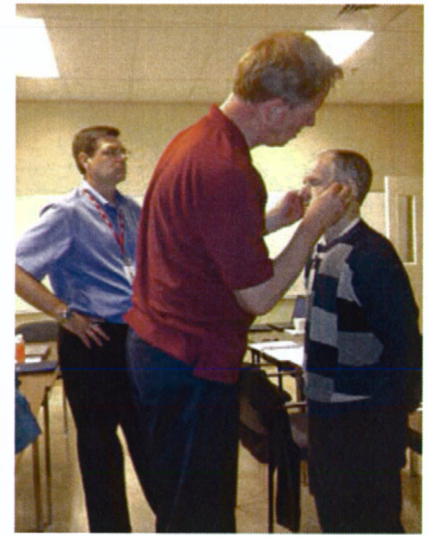
- Specialized training from subject matter experts was required
- Time, expense to conduct pilot study, full study
- Limited and biased population sample available for study
  - No random selection
  - Limited in geographical and individual diversity (age, gender, racial and ethnic bias in sample)
  - 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

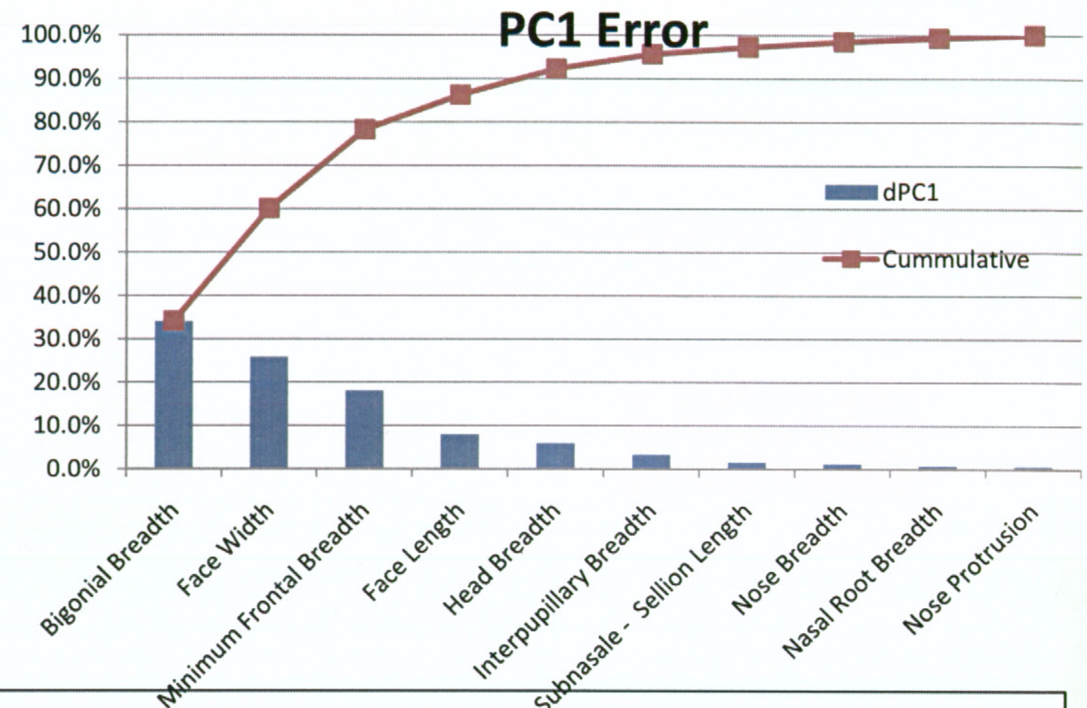
- Anthropometric Landmarking and Measurement Training provided by Anthrotech
  - 2 days classroom and hands-on training
- Landmarks and measurements to support a TIL study recommended by Dr. Bruce Bradtmiller and Dr. Ziqing Zhuang
  - Landmarks - alare, cheilion, frontotemporale, glabella, gonion, oribitale, 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:

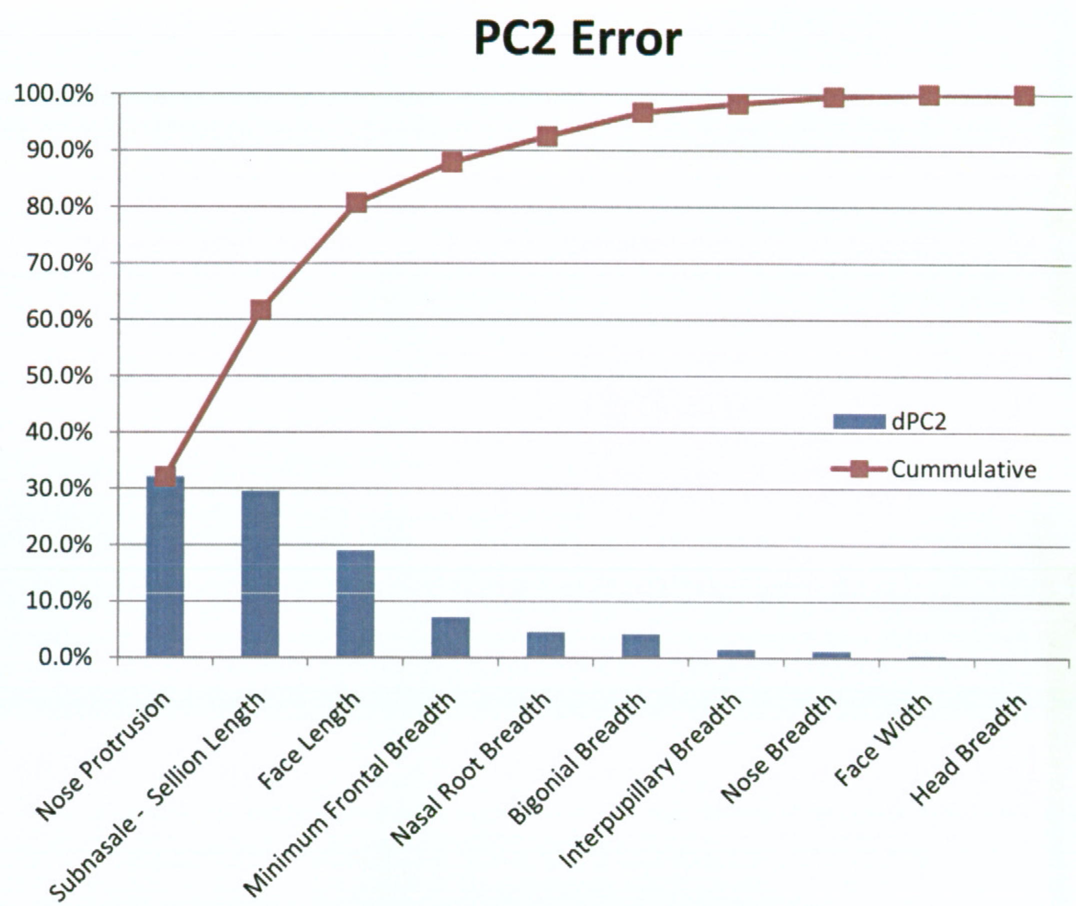
Bigonial Breadth Error Contribution
dPC1 / dBigonial Breadth = 0.37272

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

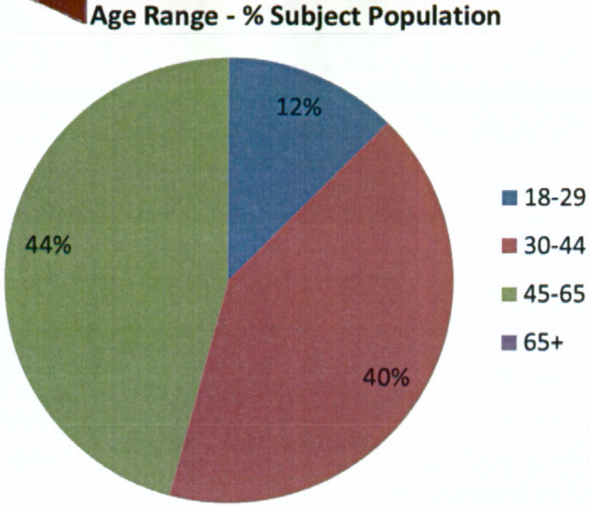


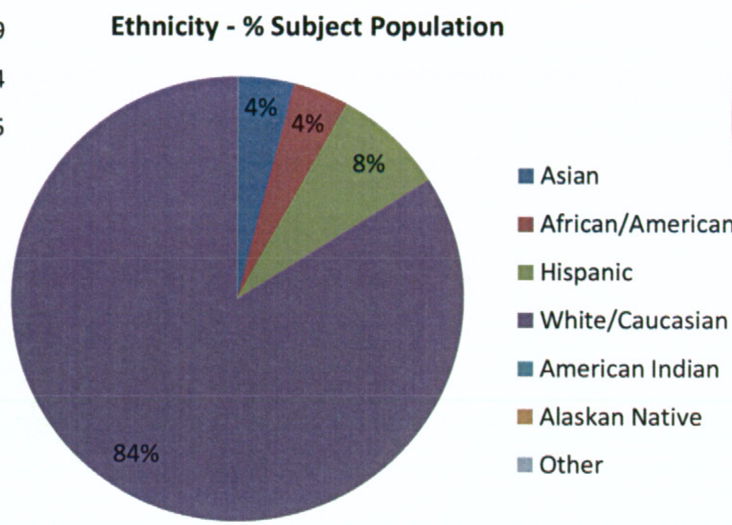
Methods – Experimental Design for Pilot Study

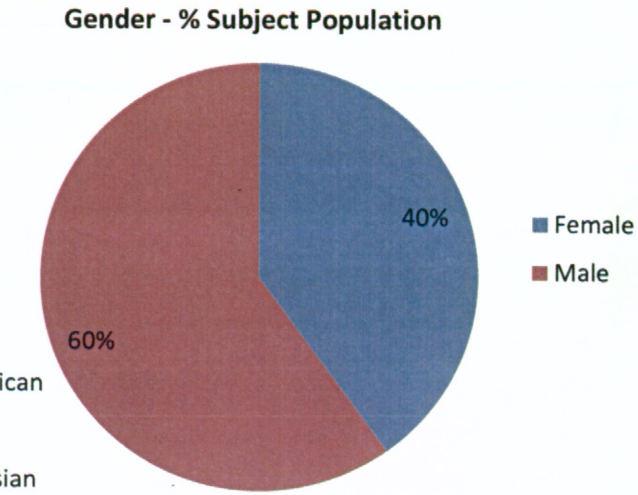
- 25 Subjects – unfortunately no random selection/broad distribution of half mask LANL panel subject pool
- Photo of subject, voluntary participation, compensation on completion, questionnaire establishing subject population characteristics
- 2 trials / different days, 2-D anthropometric landmarks and 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

Subjects

Subject Population





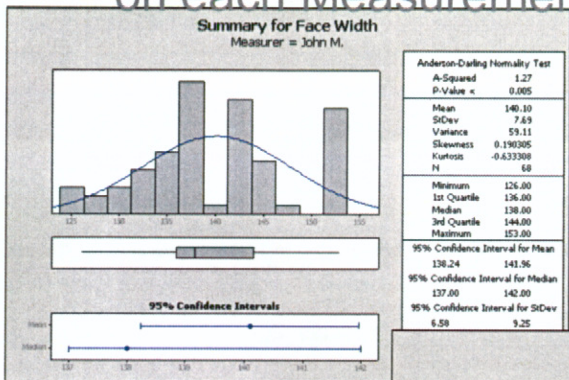


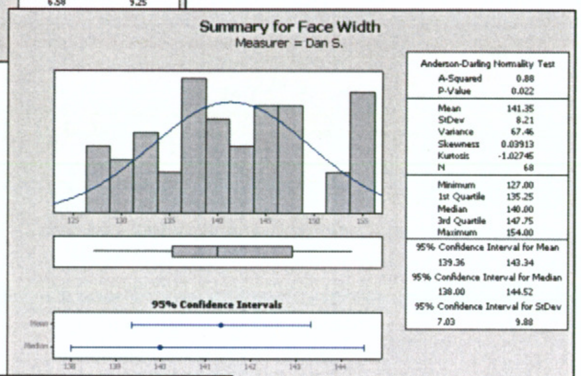
- Age, Gender and Racial/Ethnic Category population description lacking
- ISO 15535 General Requirements for Establishing an Anthropometric Database recommends n = (1.96 x CV/a)^2, where n is the sample size per cell, CV is the coefficient of variation for a specific measurement (standard deviation / mean x 100) and a is the level of precision required for 95 percent confidence limits*
- No inferences can be made from this data to a target population such as US civilian workers

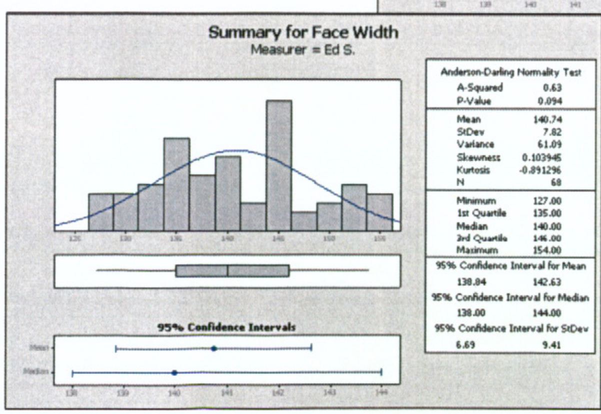
*Anthrotech 2004

Results – Measurement Normality
Ex: Facial Width (Bizygomatic Breadth)

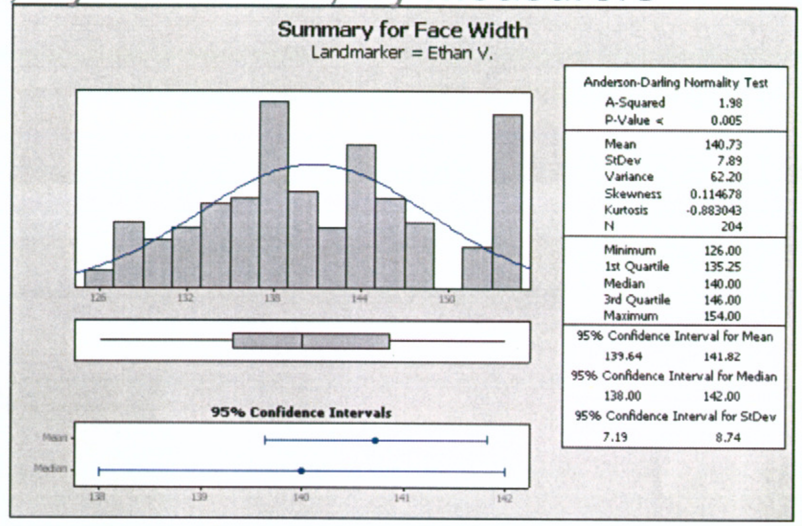
Normality Check - Total Sample, By Subject, By Panel Cell, By Measurers on each Measurement



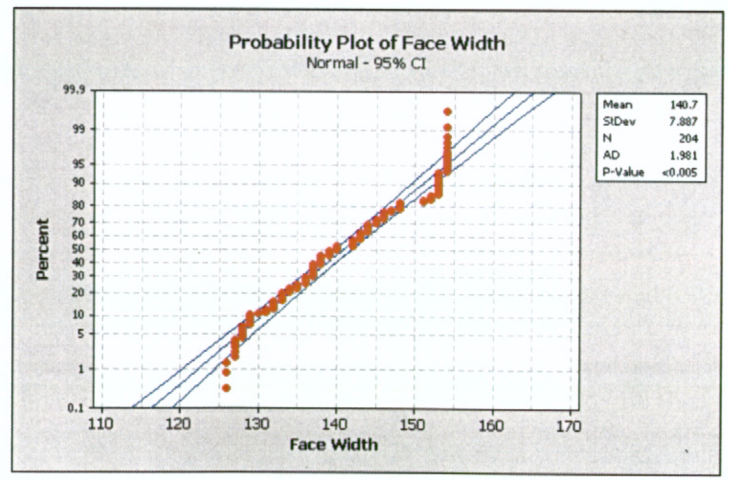




By Measurer

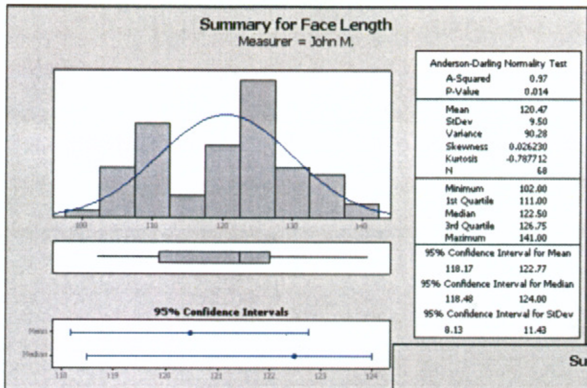


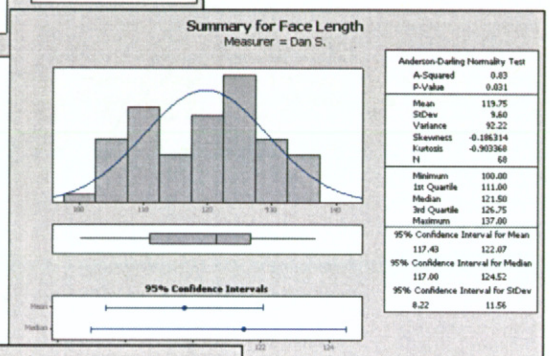
Total Sample



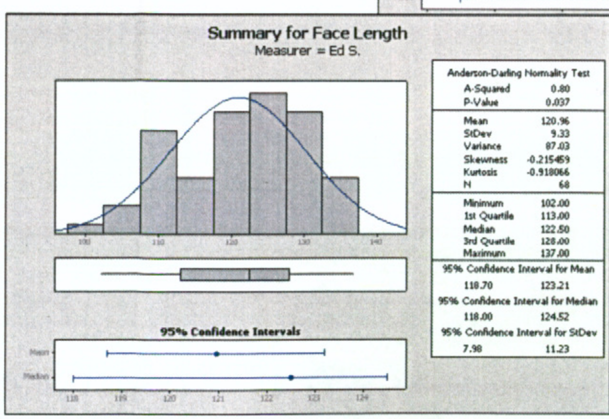
Results – Measurement Normality
Ex: Facial Length (Menton-Sellion)

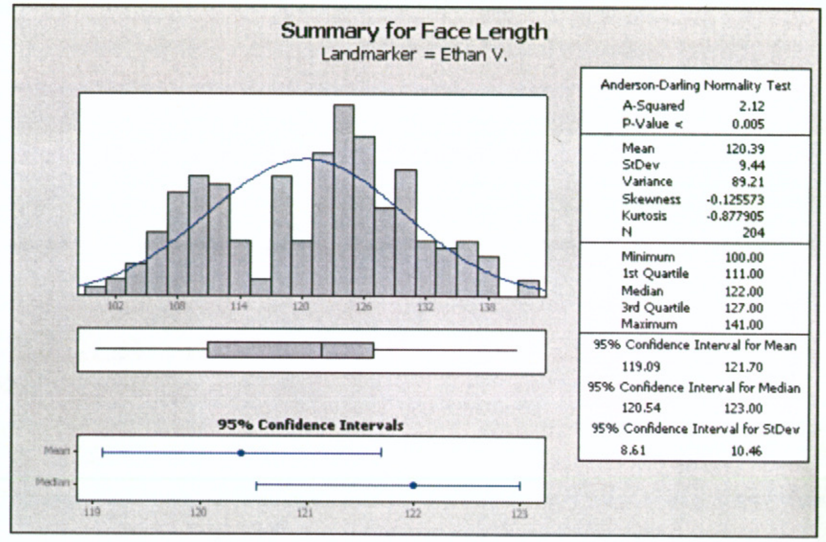
Normality Check - Total Sample, By Subject, By Panel Cell, By Measurers on each Measurement



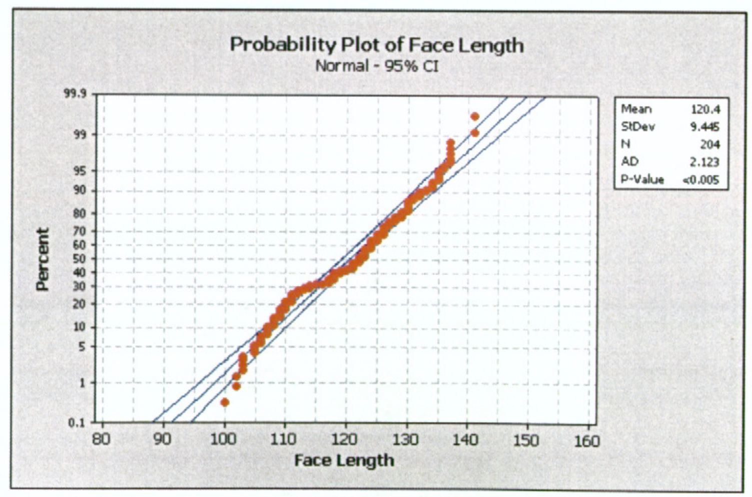


By Measurer





Total Sample



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

Source	DF	SS	MS	F	P
Subject	24	8863.16	369.298	152.131	0.000
Measurer	2	34.81	17.407	7.171	0.002
Subject * Measurer	48	116.52	2.427	2.890	0.000
Repeatability	75	63.00	0.840		
Total	149	9077.49			

Alpha to remove interaction term = 0.25

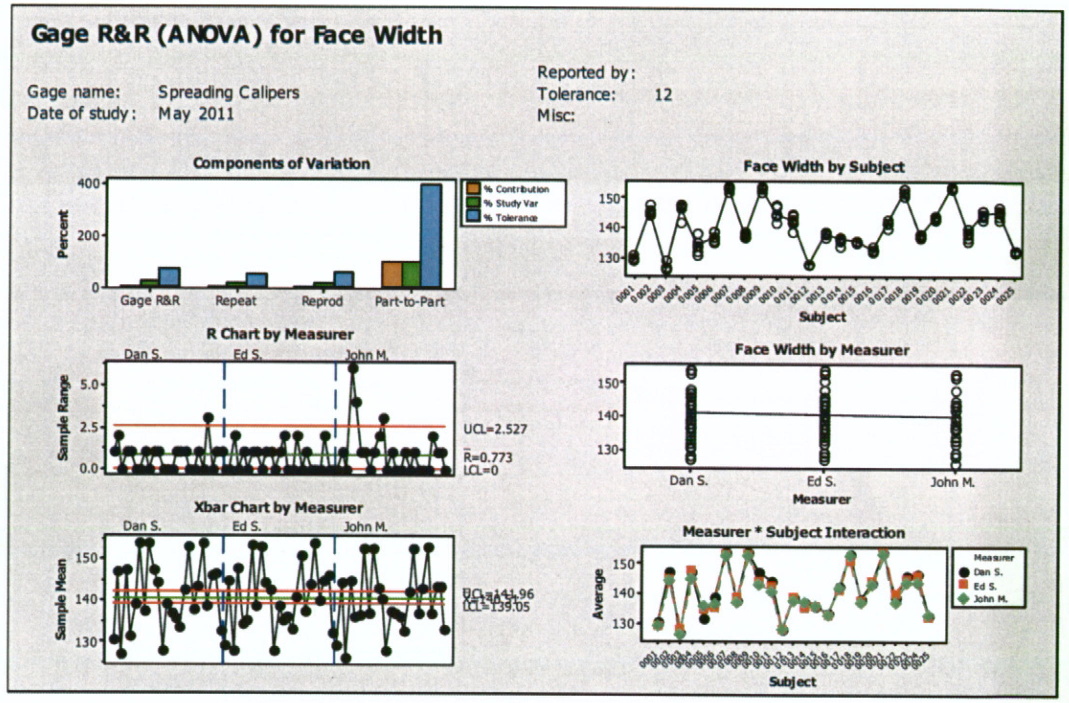
Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	1.9333	3.06
Repeatability	0.8400	1.33
Reproducibility	1.0933	1.73
Measurer	0.2996	0.47
Measurer*Subject	0.7937	1.26
Part-To-Part	61.1451	96.94
Total Variation	63.0785	100.00

Process tolerance = 12

Source	StdDev (SD)	Study Var (6 * SD)	%Study Var (%SV)	%Tolerance (SV/Toler)
Total Gage R&R	1.39044	8.3427	17.51	69.52
Repeatability	0.91652	5.4991	11.54	45.83
Reproducibility	1.04563	6.2738	13.17	52.28
Measurer	0.54734	3.2841	6.89	27.37
Measurer*Subject	0.89093	5.3456	11.22	44.55
Part-To-Part	7.81954	46.9172	98.46	390.98
Total Variation	7.94220	47.6532	100.00	397.11

Number of Distinct Categories = 7



Results - Gage R&R Study
Menton-Sellion (Facial Length)

SCOTT SAFETY

Gage R&R Study - ANOVA Method

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Gage R&R for Face Length
Gage name:
Date of study:    May 2011
Reported by:
Tolerance:        10 mm
Misc:
```

Two-Way ANOVA Table With Interaction

Source	DF	SS	MS	F	P
Subject	24	11956.1	498.171	110.201	0.000
Measurer	2	43.7	21.840	4.831	0.012
Subject * Measurer	48	217.0	4.521	0.929	0.603
Repeatability	75	365.0	4.867		
Total	149	12581.8			

Alpha to remove interaction term = 0.25

Two-Way ANOVA Table Without Interaction

Source	DF	SS	MS	F	P
Subject	24	11956.1	498.171	105.286	0.000
Measurer	2	43.7	21.840	4.616	0.012
Repeatability	123	582.0	4.732		
Total	149	12581.8			

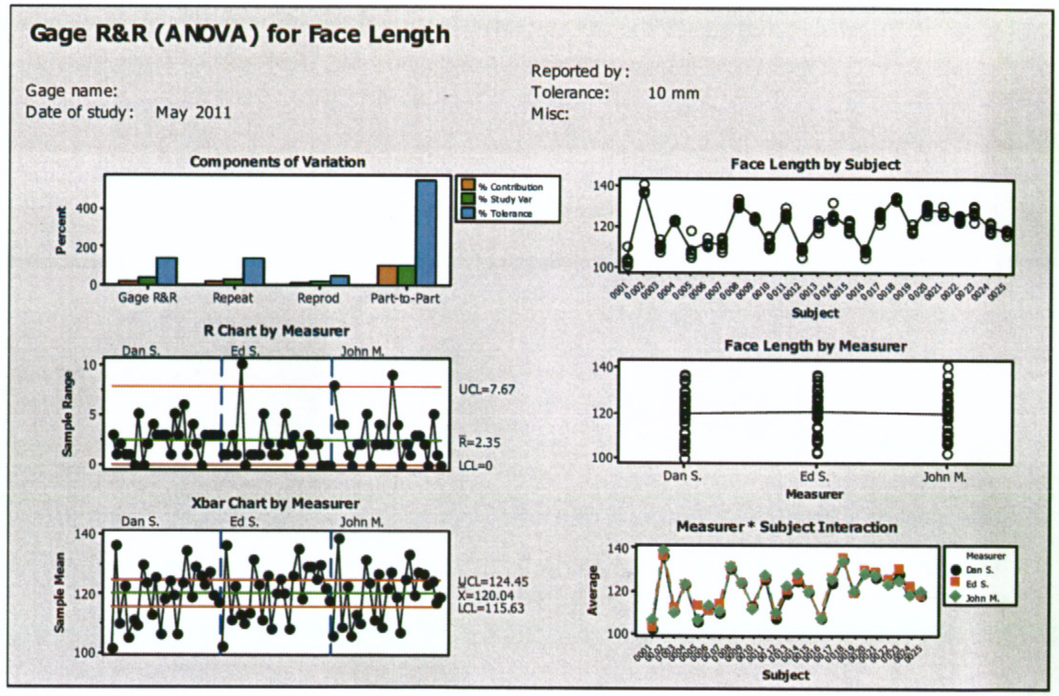
Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	5.0738	5.81
Repeatability	4.7316	5.42
Reproducibility	0.3422	0.39
Measurer	0.3422	0.39
Part-To-Part	82.2398	94.19
Total Variation	87.3136	100.00

Process tolerance = 10

Source	StdDev (SD)	Study Var (6 * SD)	%Study Var (%SV)	%Tolerance (SV/Toler)
Total Gage R&R	2.25250	13.5150	24.11	135.15
Repeatability	2.17522	13.0513	23.28	130.51
Reproducibility	0.58495	3.5097	6.26	35.10
Measurer	0.58495	3.5097	6.26	35.10
Part-To-Part	9.06862	54.4117	97.05	544.12
Total Variation	9.34417	56.0650	100.00	560.65

Number of Distinct Categories = 5

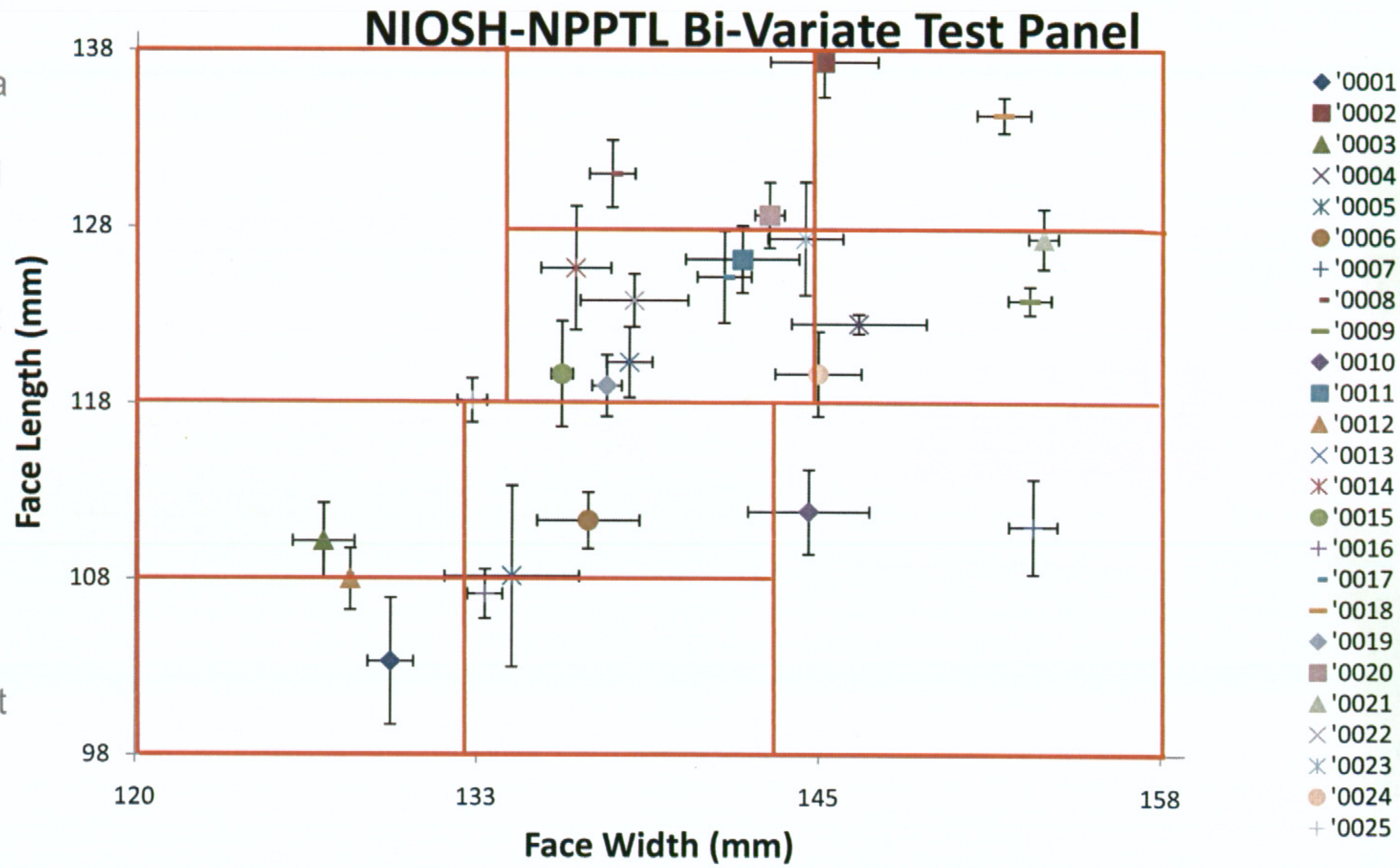


Results – 95% Confidence Interval Error for Bivariate Panel Placement

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



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

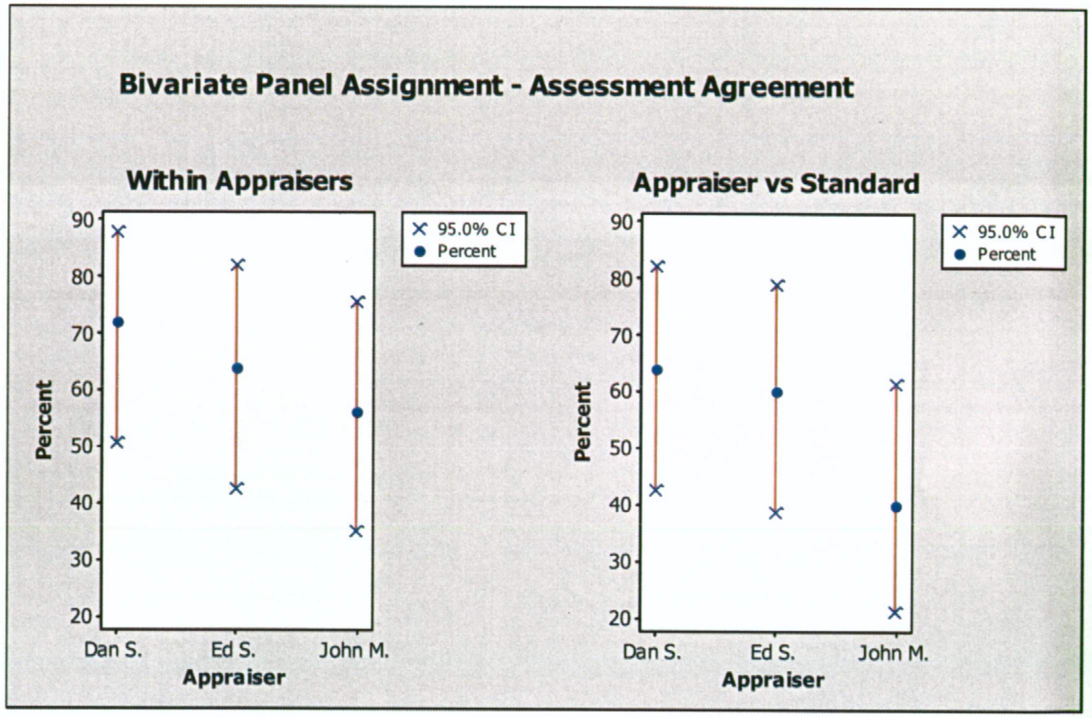
# Inspected	# Matched	Percent	95 % CI
25	7	28.00	(12.07, 49.39)

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)

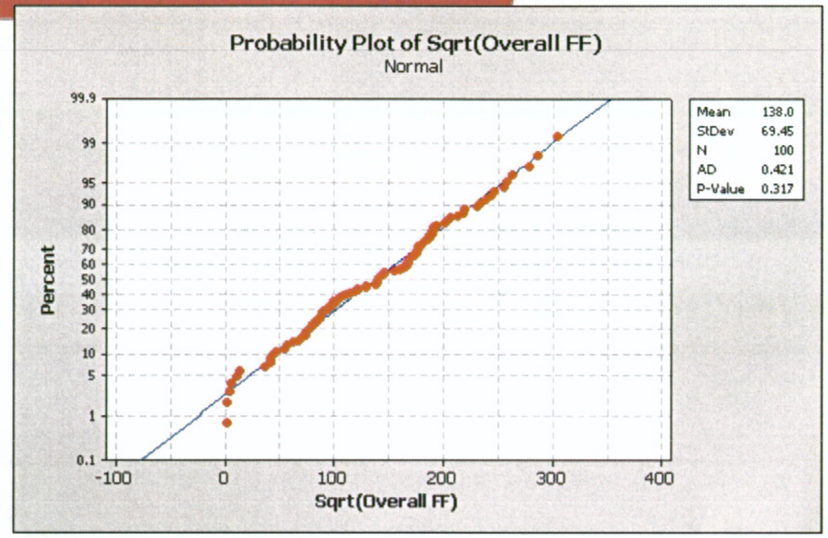
Matched: All appraisers' assessments agree with the known standard.

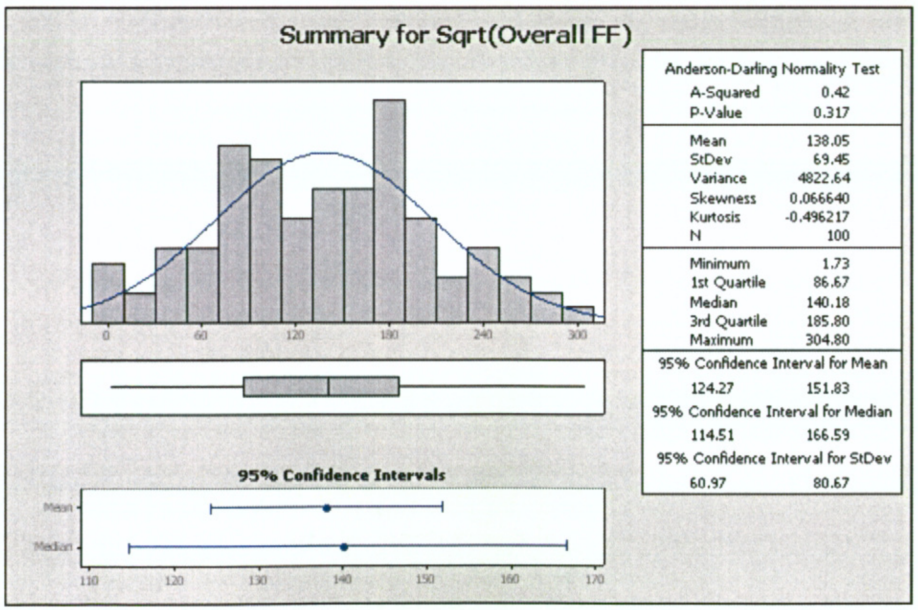


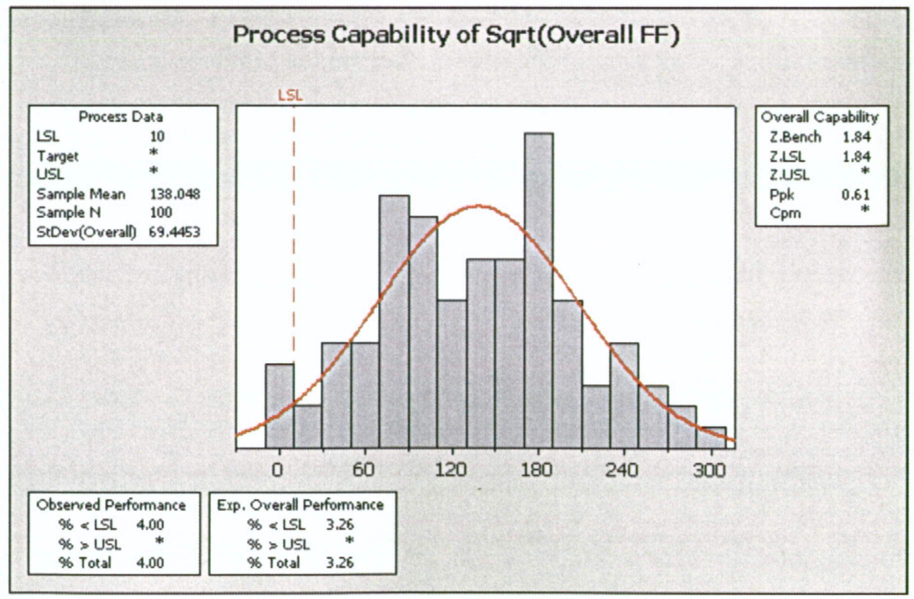
- Conducted attribute analysis of bivariate panel assignment.
- Used the average measurement across both trials and measurements to determine the panel assignment "standard" for each subject.
- Overall the reproducibility and repeatability is not acceptable.

Results – Fit Data

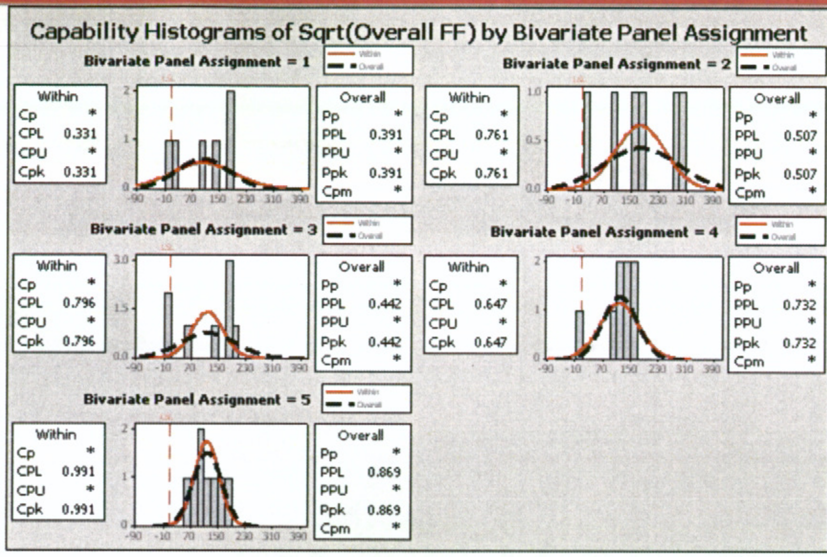
- Distribution non-normal, non-linear relationship observed between Fit and Facial Dimensions
- Distribution of all fit data and most subcategories (mask and panel) is a geometric mean or Square Root of Overall Fit Factor (FF of 100 = transformed FF of 10)
- Capability analysis demonstrates <4% subjects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

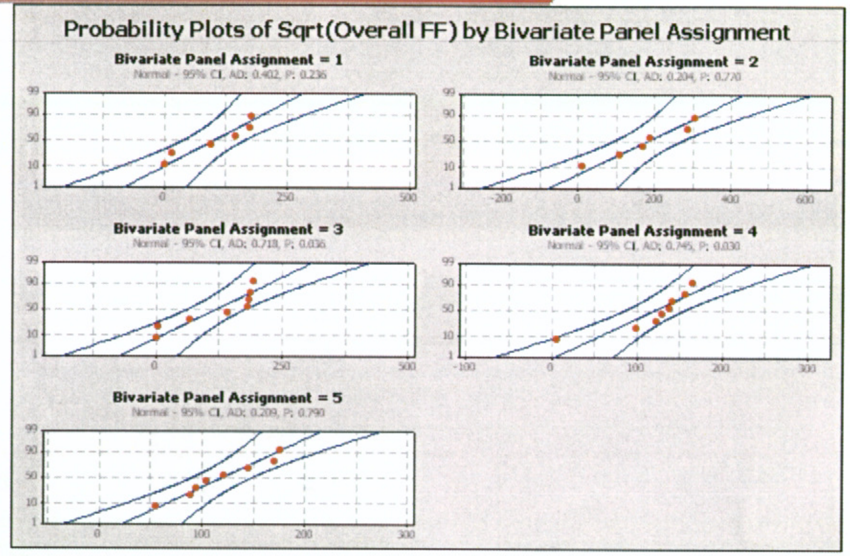


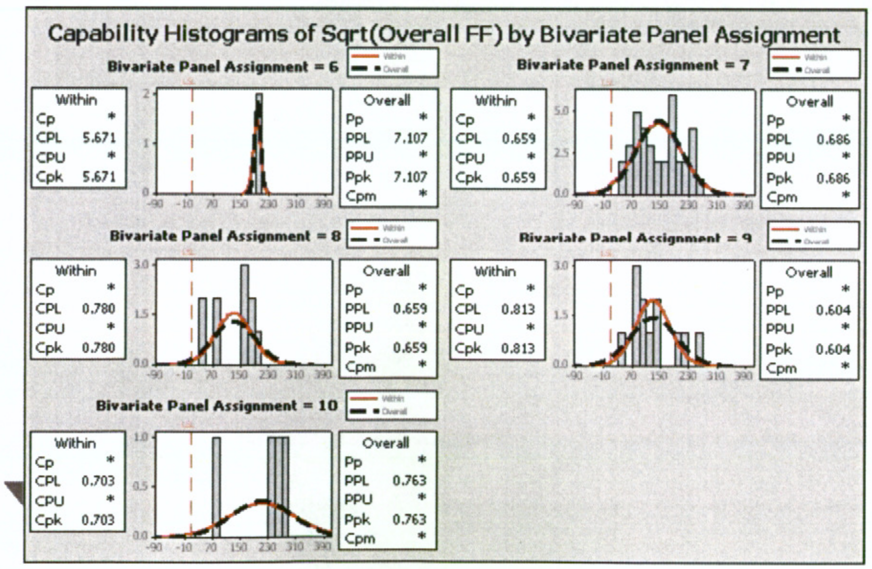


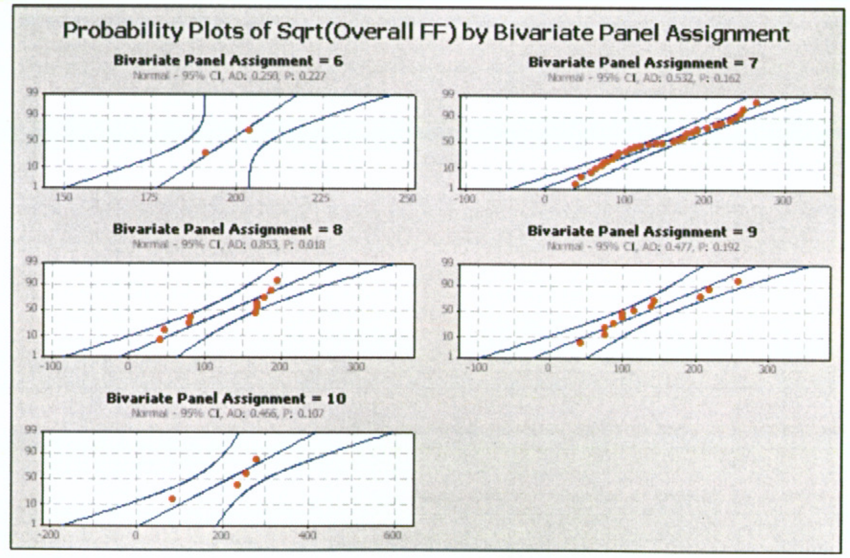


Results – Fit Test Data
Capability, Probability Plots by Panel Assignment

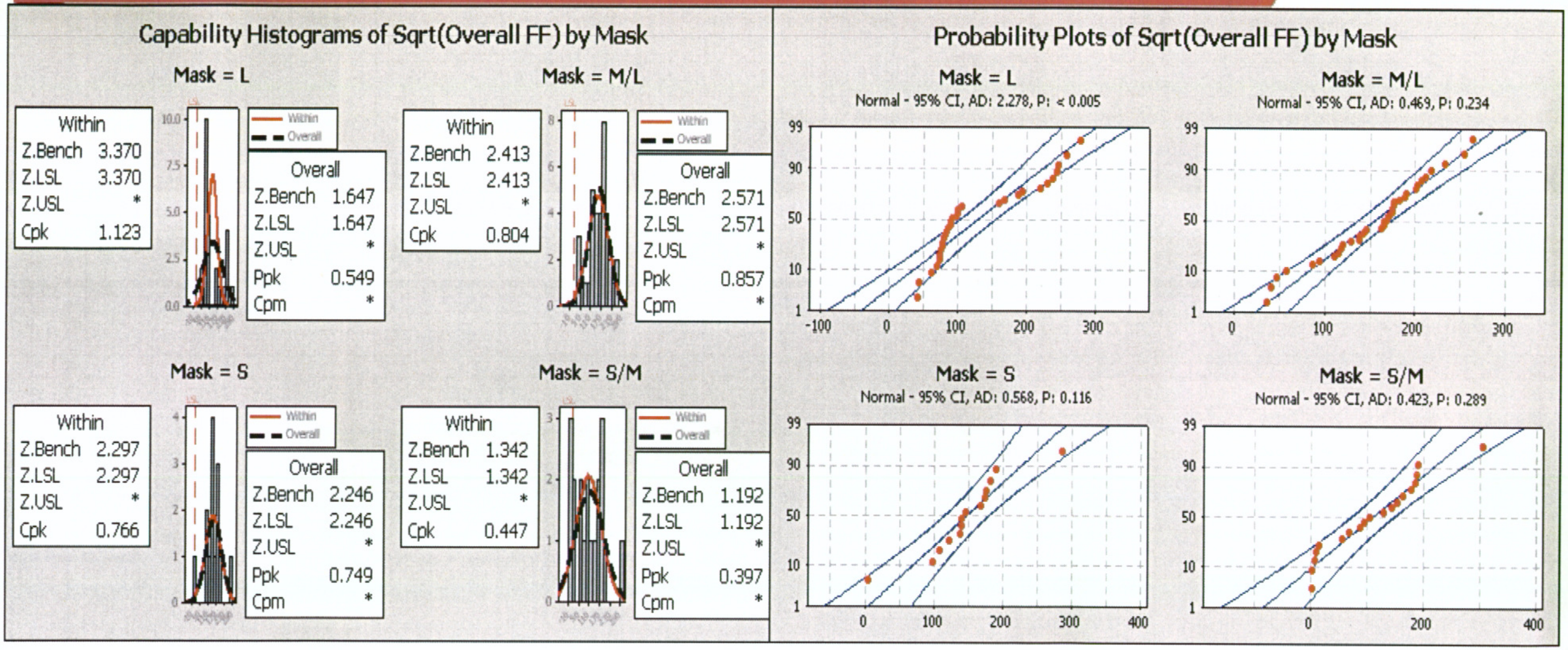






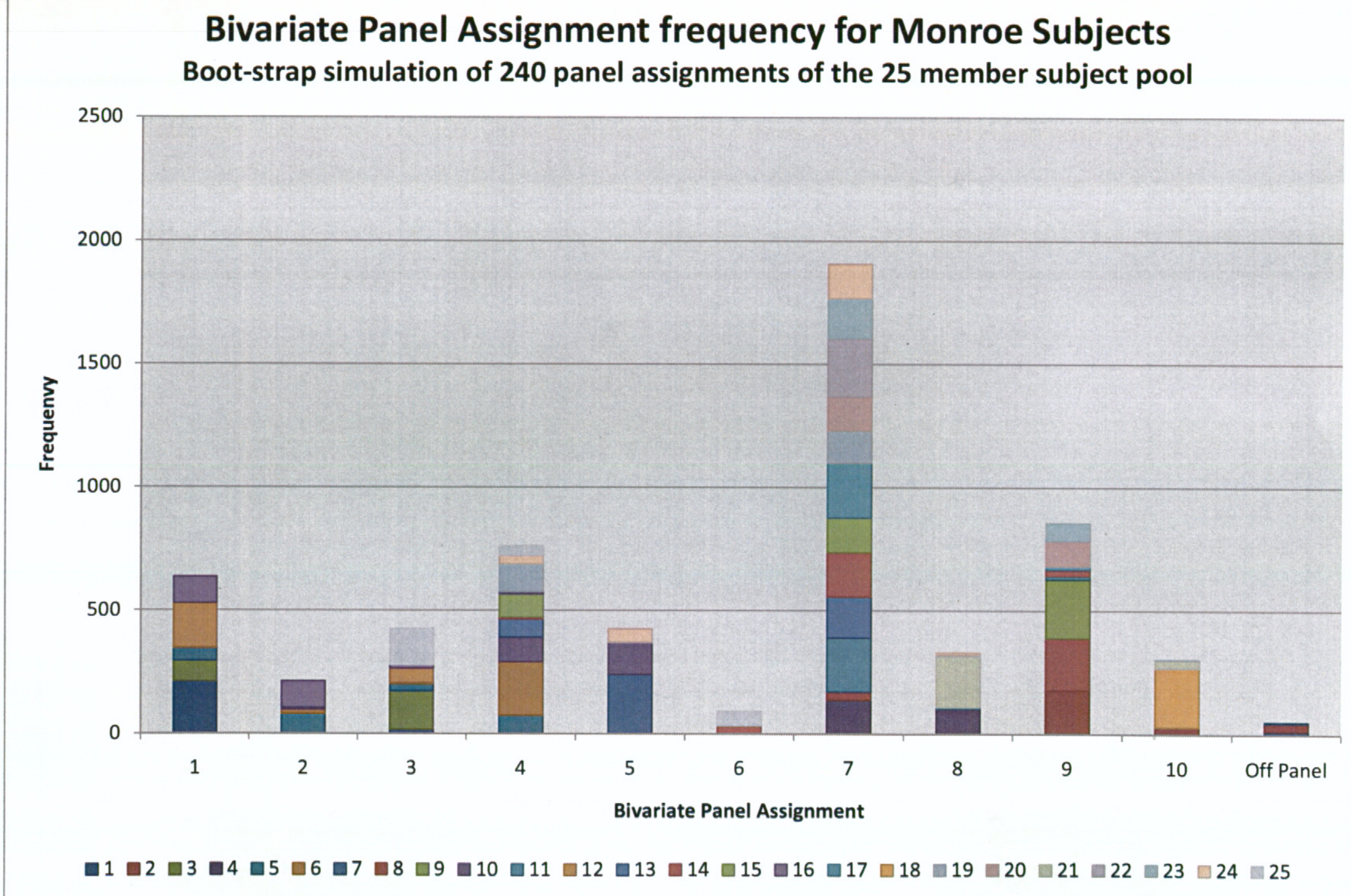


Results – Fit Tests
Capability, Probability by Half Mask Size

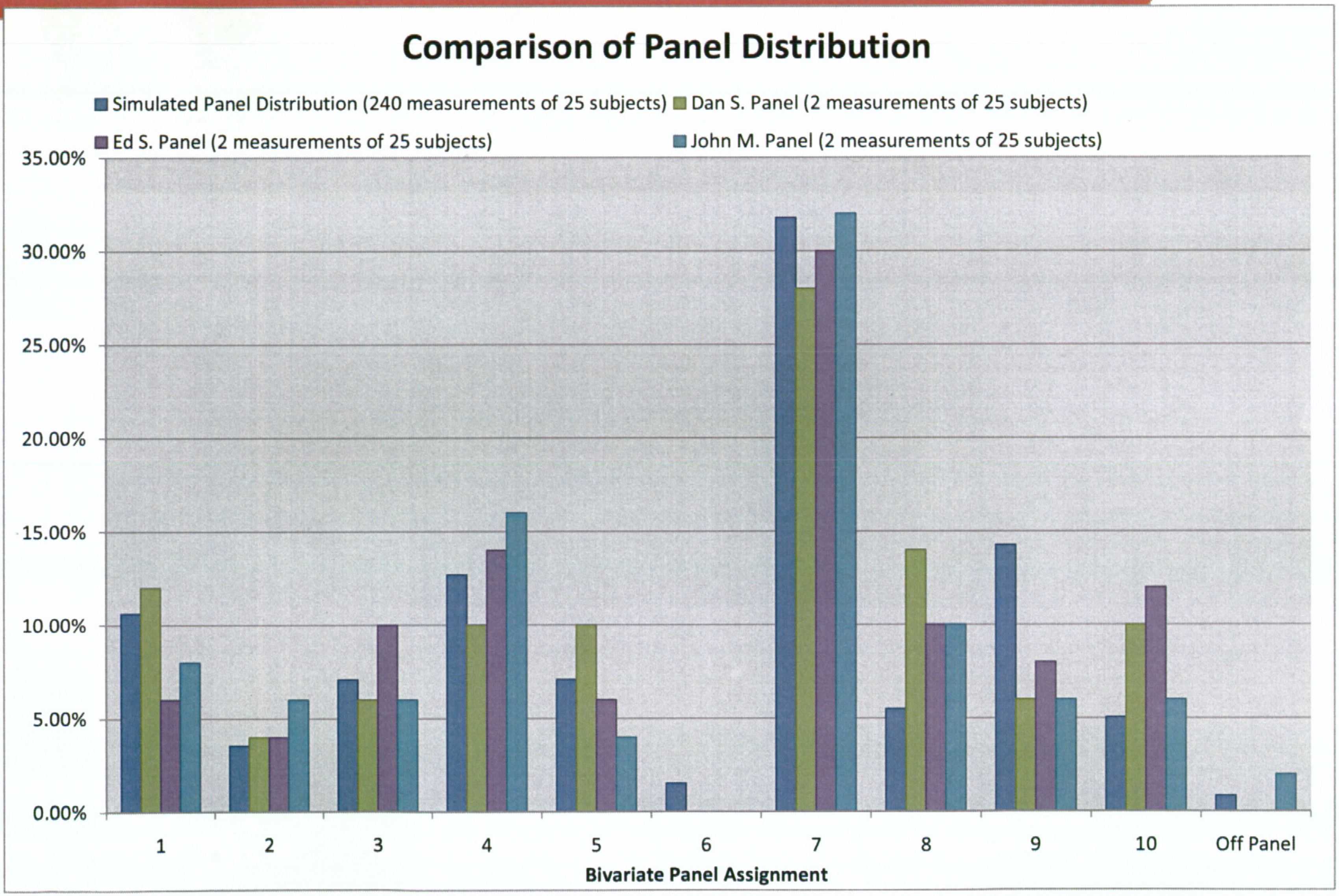


- Identified minor issues with mask accommodation for subjects from this population in smaller panels, but there is a strong correlation between negative leak checks and pass rate for FF of 100
- Positive leak check works well but has a higher false positive rate
- Half Mask fits too well with this subject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

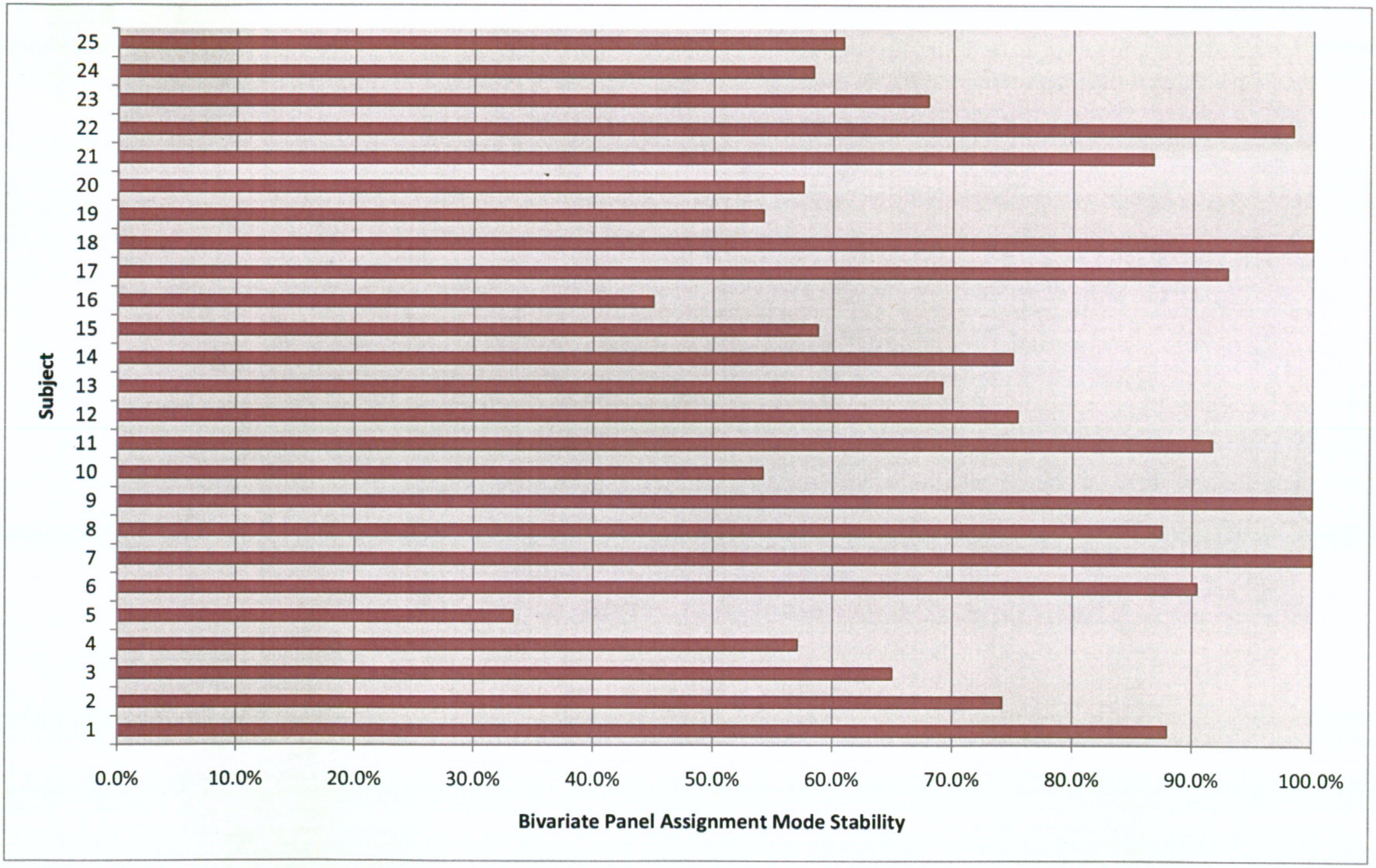
Results – Boot-strapping
Simulation of Bivariate Panel Assignment



Results – Boot –strapping
Distribution of Panel Subjects by Measurer and Simulation



Results – Boot-strapping
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)

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QUESTIONS?

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