

Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part II – One Year Assessment of Fit Changes

Ziqing Zhuang¹, Andy Palmiero², Stacey Benson¹, Michael Bergman², Raymond Roberge¹ and Jessica Williams¹

¹NIOSH/NPPTL, Pittsburgh, PA ²URS Corp., Pittsburgh, PA

Objectives

- The objectives of this study are to assess changes in respirator fit and facial dimensions as a function of time for a representative sample of subjects wearing filtering facepiece respirators (FFRs) (Figure 1) and to investigate factors (e.g., weight change) that affect change in fit.



Figure 1. Examples of FFR

Background

- Over three million American workers are required to wear respirators and receive annual fit tests in accordance with the 1998 Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134.
- Four commenters were considered in establishing the OSHA annual fit test requirement:
 - Texas Chemical Council: found that virtually no individuals fail fit tests a year after initial test.
 - Exxon Company: < 1% annual fit test failure rate.
 - Lord Corporation: < 1-3% annual fit test failure rate.
 - Hoffmann-La Roche: 7% switch to different sizes and/or models after 2 years.
- The National Institute for Occupational Safety and Health completed the first year of its three year study to assess changes in respirator fit and facial dimensions as a function of time to improve the scientific basis for the periodicity of fit testing.
- A representative sample of 229 subjects was initially enrolled in the study with 199 subjects continuing to participate. The results of the first year of testing including baseline, 6 month and 12 month evaluations, are presented.

Materials and Methods

- Subjects were trained to don and doff FFRs using standardized videos.
- Inward leakage (IL) was measured with the TSI PORTACOUNT® instrument during five – exercise fit tests. Filter penetration was measured to calculate face seal leakage (FSL).
- The study included only subjects who (a) passed one of the first three fit tests and (b) demonstrated, through a series of nine donnings, that they achieved adequate fit. A subject was considered to have achieved adequate fit if 90th percentile FSL was 5% or less.
- On each subsequent visit, subjects repeated the series of nine five-exercise fit tests for their specific style, model and size respirators.
- Three-dimensional (3-D) scans of subjects were captured; height, weight and 13 facial dimensions were measured using traditional measurement techniques (Figures 2-3).

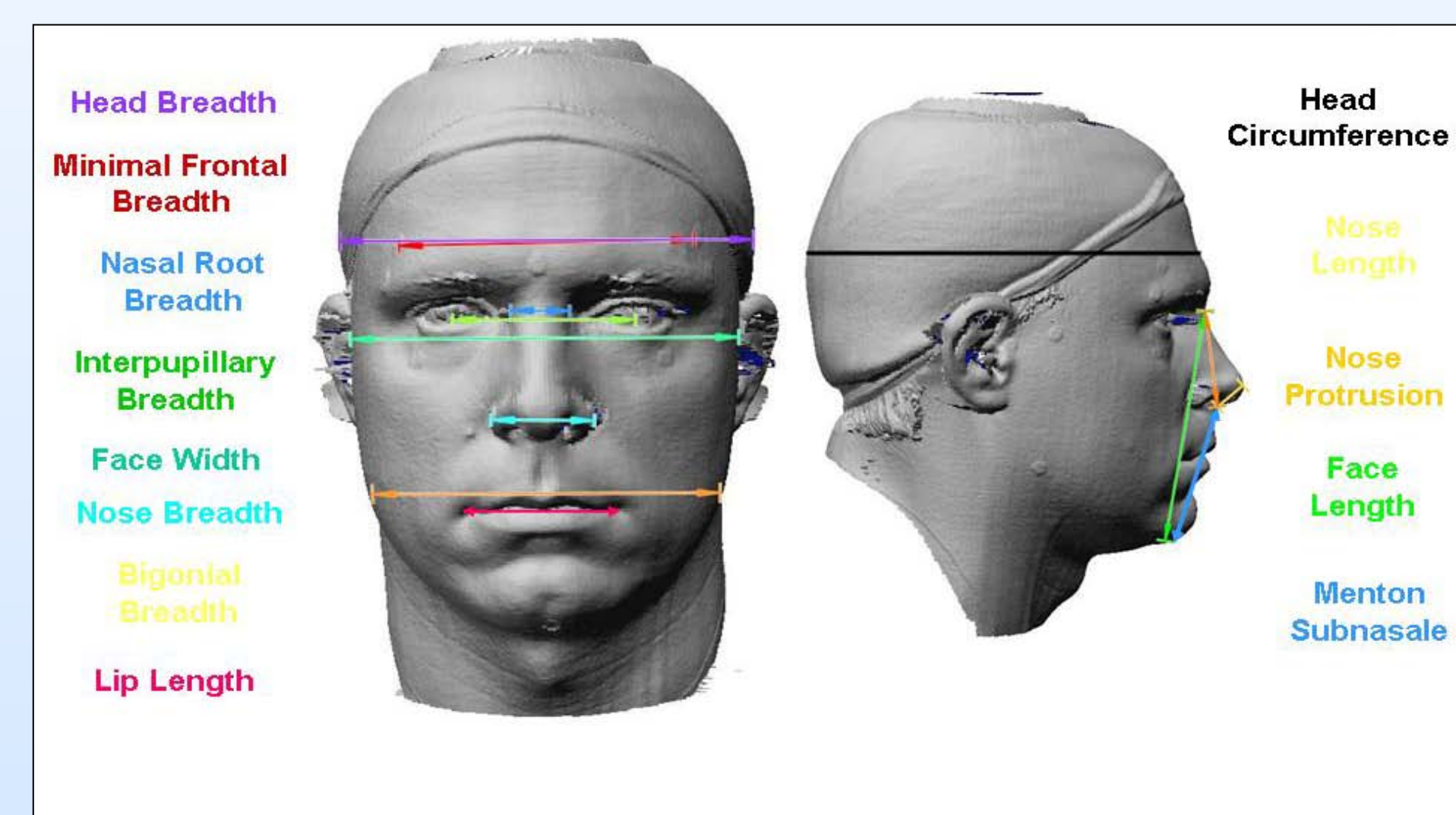


Figure 2. The 13 Traditional Facial Measurements



Figure 3. The 3dMDcranial5 System

Results

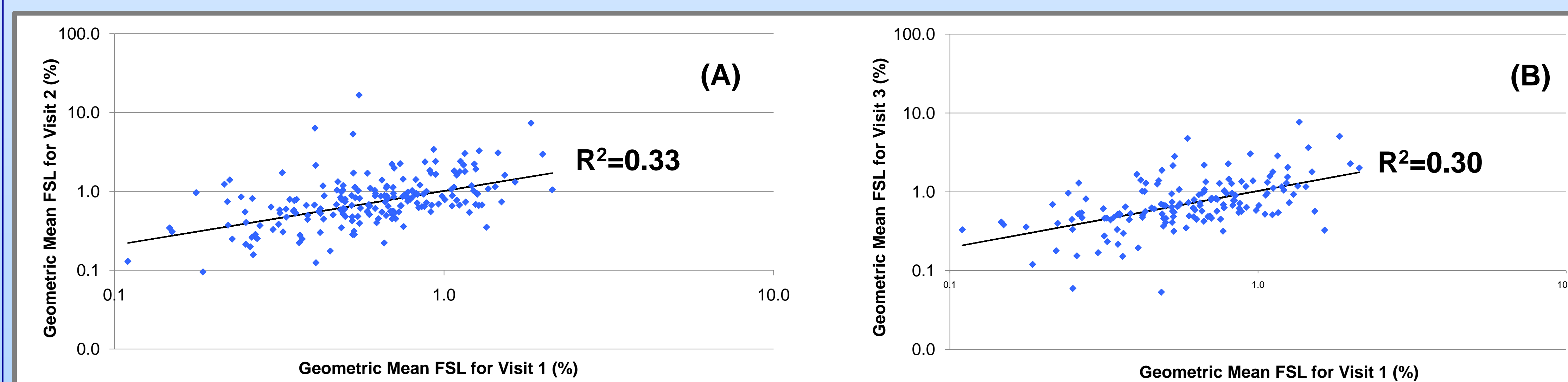


Figure 4. (A) Plot of Geometric Mean (GM) FSL for Visit 1 (baseline) against GM FSL for Visit 2 (6 mo.); (B) Plot of GM FSL for Visit 1 (baseline) against GM FSL for Visit 3 (1 yr.)

Table 1. (A) Changes in weight and FSL for subjects whose fit became unacceptable on either the 6 month visit (V1) or 1 year visit (V2); and (B) those who maintained an acceptable fit for both visits

(A) Unacceptable						(B) Acceptable					
	n	Mean	SD	Min	Max		n	Mean	SD	Min	Max
Weight V1 (lb)	32	197.3	51.1	131.6	311.3	Weight V1 (lb)	167	180.4	39.9	98.4	305.6
Δ Weight (V2 - V1) (lb)	32	-1.0	11.7	-30.4	18.9	Δ Weight (V2 - V1) (lb)	166	2.7	10.2	-30.6	46.7
Δ Weight (V3 - V1) (lb)	23	-6.7	22.9	-92.3	33.9	Δ Weight (V3 - V1) (lb)	131	0.7	12.3	-36.7	45.6
FSL V1 (%)	32	0.9	0.4	0.3	2.0	FSL V1 (%)	167	0.6	0.3	0.1	2.1
Δ FSL (V2 - V1) (%)	32	1.7	3.0	-0.6	16.0	Δ FSL (V2 - V1) (%)	167	0.1	0.4	-1.1	1.7
ΔFSL (V3 - V1) (%)	23	1.3	1.6	-0.4	6.3	ΔFSL (V3 - V1) (%)	132	0.1	0.4	-1.3	1.5

Results Continued

- The mean FSL for Visit 1 was 0.69% (SD=0.36) with a range of 0.11% to 2.13%. The mean change in FSL between Visits 1 (baseline) and 2 (six months later) was 0.36% (SD=1.39), and between Visits 1 and 3 (one year later) was 0.25% (SD=0.82).
- For Visit 2, 11.1% of the subjects had unacceptable fit (90th percentile FSL > 5%). For Visit 3, 10.3% of the subjects had unacceptable fit. Six subjects had an unacceptable fit for both their 6 month and 12 month visits.

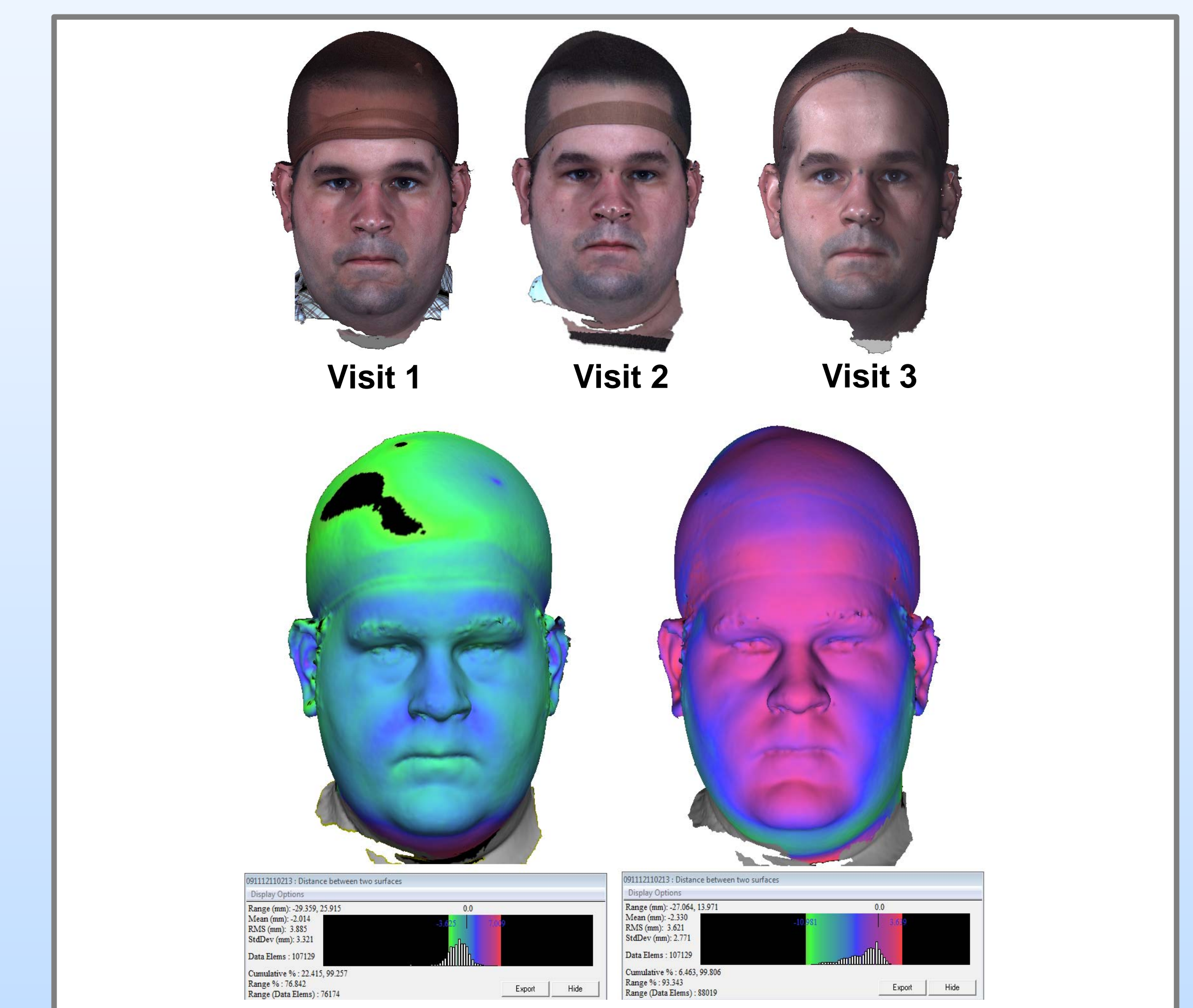


Figure 5. 3-D Scan data showing facial changes associated with changes in weight. At bottom left, the subject lost 26.0 lbs between baseline and the 6 month visit. At bottom right, the subject lost 92.3 lbs between baseline and 12 month visit.

Conclusions

- These preliminary results demonstrate that ~11% of subjects tested experienced a significant change in fit during the first year, but additional work is needed to understand the cause of those changes.

Future Directions

- Complete second year of data collection with the remaining 199 subjects.
- Conduct an elastomeric pilot study with 10 subjects in conjunction with the overall study.
- Assess 3-D data to determine ability to capture changes in facial characteristics over time.

Disclaimer: The findings and conclusions in this poster have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.