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Effect of Upper Strap Downward Displacement on N95 Filtering Facepiece Respirator Fit Factors: A Pilot Study

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Abstract

Fifteen subjects underwent three replicates of quantitative respirator fit-testing with N95 filtering facepiece respirators that were donned with the upper strap high on the occiput, as per the manufacturers' donning instructions. Each fit-test was immediately followed by repeat fit-testing with the upper strap downwardly displaced to the level of the ear sulcus to determine any change in fit factors that might occur with upper strap downward slippage. A total of 35/45 (78%) initial fit-tests had a passing score (fit factor ≥100) with the top strap high on the occiput and 33/35 (94%) of these passed subsequent fit-testing after the top strap was displaced downward to the ear sulcus. Geometric mean fit factors for the initial passed fit-tests, and following downward strap displacement, were 217±1.6 and 207±1.9, respectively ($p = 0.64$). Downward displacement of the top strap did not significantly impact fit factors of N95 FFRs that had previously passed fit-testing.

Keywords

displacement; fit factors; N95 filtering facepiece respirators; top strap

INTRODUCTION

The proper fit of respiratory protective devices is essential to minimize inward leakage of airborne contaminants (e.g., particulates, pathogenic microorganisms, and so on) into the

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wearer's breathing zone. One popular method of quantitative respirator fit-testing to determine the adequacy of respirator fit utilizes condensation nuclei or particle counting technology to make optical density measurements of ambient particles and particles within the respirator dead space. The ratio of measured ambient particles to particles in the respirator dead space is termed the fit factor.[1]

Passing an Occupational Safety and Health Administration (OSHA) quantitative fit-test for a filtering facepiece respirator (FFR) requires a fit factor of ≥100, indicating that ≤1 in 100 particles is entering the FFR wearer's breathing zone.[1] FFR fit is dependent, in significant measure, upon the adequacy of the seal at the face/respirator interface that is itself substantially reliant upon the restorative forces developed in response to stretching of its tethering devices (e.g., straps, bands) during donning.[2]

Proper donning, in turn, is considered an important initial step in ensuring a proper fit.[3–5] OSHA-respiratory protection programs are required to use National Institute for Occupational Safety and Health (NIOSH)-certified respirators and wearers should follow manufacturers' donning instructions.[6] Typically, for class N95 FFRs, the most commonly used negative pressure respirators in U.S. industry and healthcare,[4] proper donning involves the lower strap being worn around the neck and below the ears, and for the top strap to sit above the ears and high on the head (i.e., crown), with avoidance of passage over the ears.[3,4,7] For persons with long hair, the lower strap should be placed under (not over) the hair.[3] When properly positioned, the upper strap's angle and longer trajectory result in the majority of developed force being applied to the upper region of the maxilla and the nasal prominence,[8] and the bottom strap ensures that the device is drawn down and over the jawbone.[9] Although the upper strap may remain stationary during the relatively short time (~12 min) required for a quantitative respirator fit-test,[1] downward slippage of the top strap off the crown of the head is likely a relatively frequent occurrence with normal use.[2] Though little supportive scientific data are available, it is currently assumed that upper strap repositioning, due to downward slippage, will lead to a negative impact on fit and, by extension, on the protection afforded the wearer.

This study was undertaken by the National Personal Protective Technology Laboratory of NIOSH to determine if downward displacement of the top strap of N95 FFRs results in any significant change in fit factors of subjects initially passing a quantitative respirator fit-test. Our null hypothesis was that downward displacement of the upper strap of N95 FFRs would result in no significant change in fit factors. These data could be useful to regulatory bodies, respirator manufacturers, researchers, and respiratory protection program managers.

MATERIALS AND METHODS

Fifteen subjects (six men, nine women), mean age 37.3±11.3 years (range 21–54 years) were recruited for the study, all of whom were experienced in the use of N95 FFRs. The subjects' anthropometric facial measurements were used to determine their place in the NIOSH bivariate fit-test panel[10] (Figure 1). The study was approved by the NIOSH Human Subjects Review Board and all subjects provided written and verbal consent. Subjects were studied over three contiguous sessions, each of which consisted of wearing one of three samples of the same model of a randomly assigned N95 FFR from either of two manufacturers (3M, St. Paul, Minn.; Moldex, Culver City, Calif.). The N95 FFR models, size, and number of assigned subjects included four molded, cup-shaped models (regular size 3M 1860 [n = 1]; standard size 3M 8210 [n = 1]; medium/large size Moldex 2200 [n = 3]; small size Moldex 2201 [n = 4]), and one trifold model in one-size-fits-most-faces 3M 1870 [n=6]. The constituent strap materials of the N95 FFRs were one piece polyisoprene bands (3M 1870, Moldex 2200, Moldex 2201), braided polyester containing four thin polyisoprene bands running in parallel (3M 1860), and one piece thermoplastic bands (3M 8210).

As per OSHA guidance,[(1)] the N95 FFRs were donned in accordance with the manufacturers' donning instructions that included the lower strap behind the neck and below the ears, and the top strap high on the head (crown) and above the ears (Figure 2a). The three 3M models had deformable nasal bars that the subjects molded to the contour of the nose after donning. Positive and negative user seal checks were then carried out to evaluate the seal of the N95 FFR to the face.[(1)] A 3-min period of acclimatization was then followed by subjects undergoing fit-testing with the Portacount Plus Fit Tester (TSI, Shoreview, Minn.) while performing a modified quantitative fit-test protocol that consists of seated subjects completing a series of five 50-sec duration fit-test exercises (i.e., normal breathing, deep breathing, breathing while moving the head from side to side, breathing while moving the head up and down, and a return to normal breath). Immediately upon completion of the initial fit-test, the N95 FFR remained stationary and its upper strap was lowered by the fit-test technician to the level of the auricular (ear) sulcus (Figure 2b). No further adjustments to the N95 FFR were made and the fit-test was repeated. Subjects underwent an initial fit-test and a post-strap displacement fit-test on each of three samples of a randomly assigned model of N95 FFR (15 subjects × 3 N95 FFRs samples × 2 upper strap locations = 90 quantitative fit-tests).

Statistical Analysis

Fit factors were first log-transformed because they are typically log-normally distributed.[(11)] The log transformed geometric mean (GM) fit factors for the initial fit-tests and post-displacement fit-tests were compared with a paired t-test. A two-sided $p < 0.05$ was considered statistically significant. A post hoc power analysis was carried out to determine if the subject numbers were sufficient to allow the detection of a difference of 60 in mean fit factors. All data analyses were conducted using SAS software (Version 9.3; SAS Institute, Inc., Cary, N.C.).

RESULTS

The GM fit factor for the initial 45 quantitative respirator fit-tests was 154 with a geometric standard deviation (GSD) of 2.3 and for the 45 strap downward displacement fit-tests was 164 (2.2) ($p = 0.58$). The 45 fit factors for strap displacement fit-tests plotted against the fit factors for the initial fit-tests indicate a positive linear trend slope of 1.0056 with an R-squared value of 0.6697 (Figure 3). A total of 35/45 (78%) initial fit-tests had a passing score (i.e., fit factor ≥ 100) with a GM fit factor of 217(1.6). Upon repeat fit-testing with upper strap downward displacement, 33/35 (94%) of the initially passed fit-tests again passed fit-testing with a GM fit factor of 207 (1.9) (p = 0.64). The two fit-test failures, one each of models 3M 1870 and Moldex 2201, had initial fit factors of 165 and 204 and post-strap displacement fit factors of 97 and 13, respectively. There were no significant differences noted in fit factors of FFRs with and without pliable nasal bars on the initial fit-tests (p = 0.38) or on the downward strap displacement fit-tests (p = 0.62). A significant difference (p = 0.01) in the mean fit factor for the tri-fold model of N95 FFR (278) compared with the cup-shaped models of N95 FFRs (204) on the initial passed fit-tests did not persist on the downward displacement fit-tests (p = 0.21).

DISCUSSION

Our data demonstrate that there was no significant difference in the GM fit factors of the initial 45 fit-tests and 45 post-displacement fit-tests (p = 0.58) and that there was a positive linear correlation of these same data (R-squared = 0.6697) (Figure 3) indicating a moderately strong strength of association. Our study findings further show that, for initially passed fit-tests, the downward displacement of the upper strap of various models of N95 FFR did not result in a significant difference in GM fit factors (p = 0.64); 94% of immediately antecedent passed quantitative respirator fit-tests subsequently passed fit-testing with the upper strap downwardly displaced. However, the finding that the statistically significant difference in fit factors (p = 0.01) on initially passed fit-tests between the trifold FFR and the cup-shaped FFRs did not carry over to the strap downward displacement fit-tests (p = 0.21) suggests that FFR style may influence the effects of top strap position.

A larger study will be necessary to determine differential effects of FFR style on strap repositioning. The two post-downward displacement fit-test failures that had initially passed fit-testing in the present study were a petite 48-year-old woman (48.5 kg, 1.56 meters height, BMI 19.9, Panel 1 in the NIOSH bivariate panel) and a morbidly obese 21-year-old woman (114.2 kg, 1.6 meters height, BMI 44.6, Panel #4 in the NIOSH bivariate panel). Neither of these individuals had any facial scarring, deformity, or abnormal dentition. It is recognized that a great deal of variability exists in repeat fit factor testing of human subjects.[(12)] Discounting initial improper placement, downward displacement of the upper strap of FFRs occurs commonly[(2)] for a variety of reasons that may include decreased friction between the hair and the straps (e.g., natural oiliness of some hair, hair moisture [e.g., sweat], use of hair products [e.g., hair conditioners], composition of FFR straps [e.g., polyisoprene bands create more friction with hair that may allow them to retain their position better than braided straps]), head motion, speech, and so on.

It is perhaps not totally surprising that downward displacement of the upper strap did not significantly affect passage of a fit-test in the current study, given that the oblique circumference of the skull at the crown of the head (where the upper strap is positioned during donning) and at the level just inferior to the occipital protuberance (the most distal position that occurs with upper strap slippage) has been shown to differ by only 2.4 mm in one study of Caucasian adult men and women.[(13)] This scant difference in donned strap length would likely have minimal impact on the restorative forces that are required to properly seat the N95 FFR to the face.[2]

Our study findings have some potentially noteworthy ramifications because of the importance currently ascribed to proper positioning of the upper strap of N95 FFRs.[4] For example, improper strap placement has been observed commonly in healthcare workers treating patients with tuberculosis.[14,15] In a study of 533 individuals performing post-hurricane Katrina mold remediation of damaged structures, Cummings et al.[3] noted incorrect placement of straps on more than half the subjects (fit-testing was not carried out). Conversely, in an analysis of five standard steps to maximize N95 FFR seal integrity (i.e., strap integrity check, correct strapping, correct adjustment at bridge of nose, positive pressure check, negative pressure check), only correct strapping and correct adjustment at bridge of nose were identified as predictive ($p \leq 0.01$ for both steps) of achieving an adequate seal, as determined by qualitative respirator fit-testing.[16] Our data indicate that upper strap downward displacement has little negative impact on fit factors of N95 FFRs that have initially passed respirator quantitative fit-testing. These data should lead to a reevaluation of current instructions about the absolute necessity of upper strap placement at the crown of the head and spur additional related research to validate these findings.

Limitations of the current study include the relatively small numbers of subjects ($n = 15$) tested. However a total of 90 fit-tests were performed, and a post hoc power analysis indicated that our sample size was sufficient to detect a difference in mean fit factors of 60 with 99% assurance. Some N95 FFR models (i.e., 3M 1860, 3M 8210) were tested by only one subject each, thereby limiting an in-depth evaluation of those models. A study examining larger numbers of each tested model of N95 FFRs would possibly elucidate findings that might have been too under-powered to detect. We did not perform standard OSHA fit-testing because we used a modified fit-test procedure. However, the modified procedure omits only two OSHA-measured parameters (i.e., talking, bending over) and modified fit-tests have been used in previous N95 FFR studies.[17–20]

CONCLUSION

Slippage of the upper strap from the occiput to the level of the ear sulcus, as occurs not infrequently with normal use, has little negative impact on fit factors of N95 FFRs that have previously passed respirator quantitative fit-testing. The study data do not allow us to reject the null hypothesis. In a preponderance of instances (94%), lowering the upper strap apparently did not affect strap tension to the degree that it significantly impacted the seal of the N95 FFR to the face. Given that government agencies (e.g., Centers for Disease Control and Prevention [CDC], OSHA, and so on) and respirator manufacturers provide donning instructions signifying the necessity of N95 FFR upper strap placement high on the occiput for maximal protection, the current study's findings should spur additional research to validate these data.

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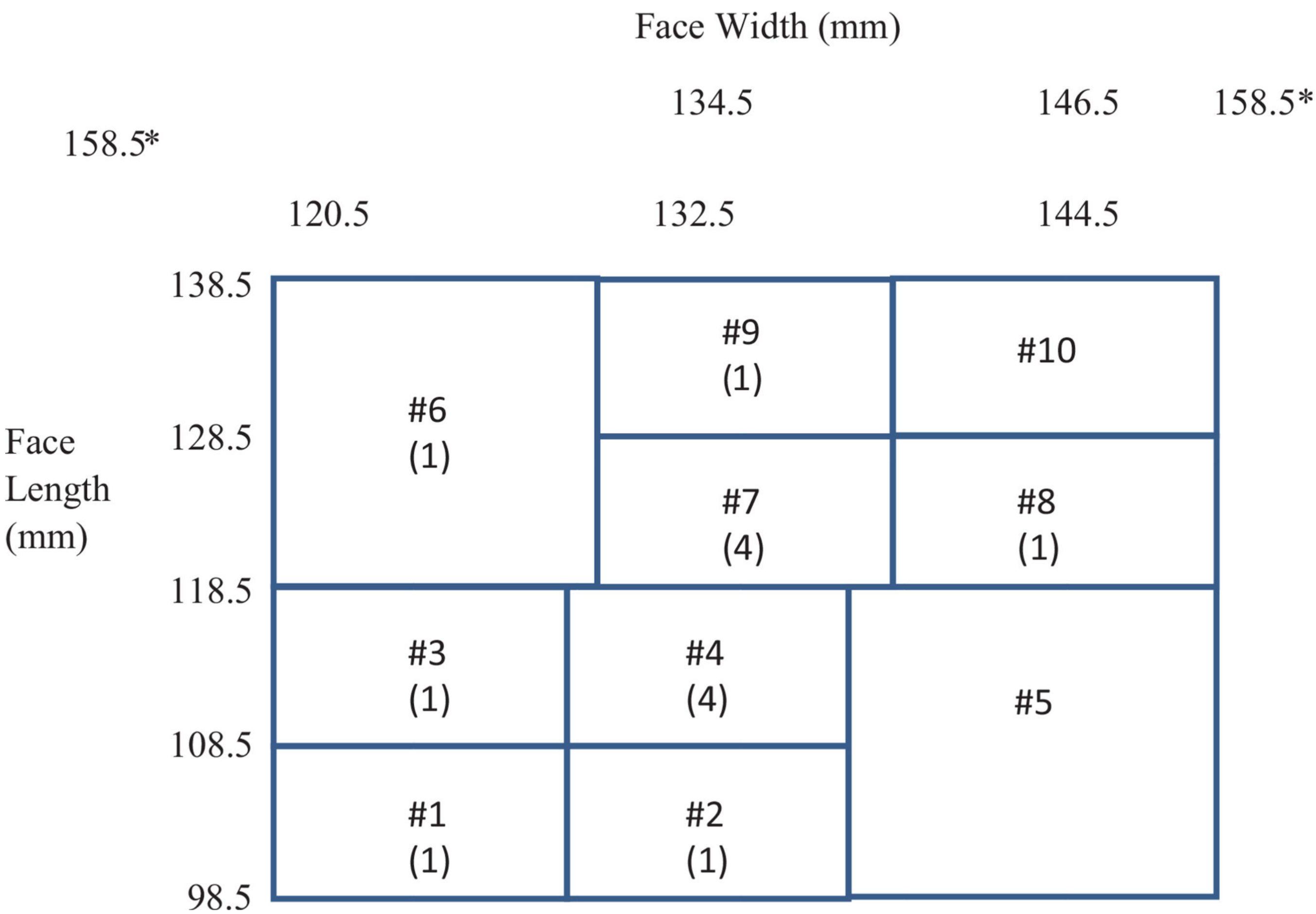

FIGURE 1.

Distribution of study subjects in the National Institute for Occupational Safety and Health (NIOSH) bivariate respirator fit-test panel. (color figure available online)

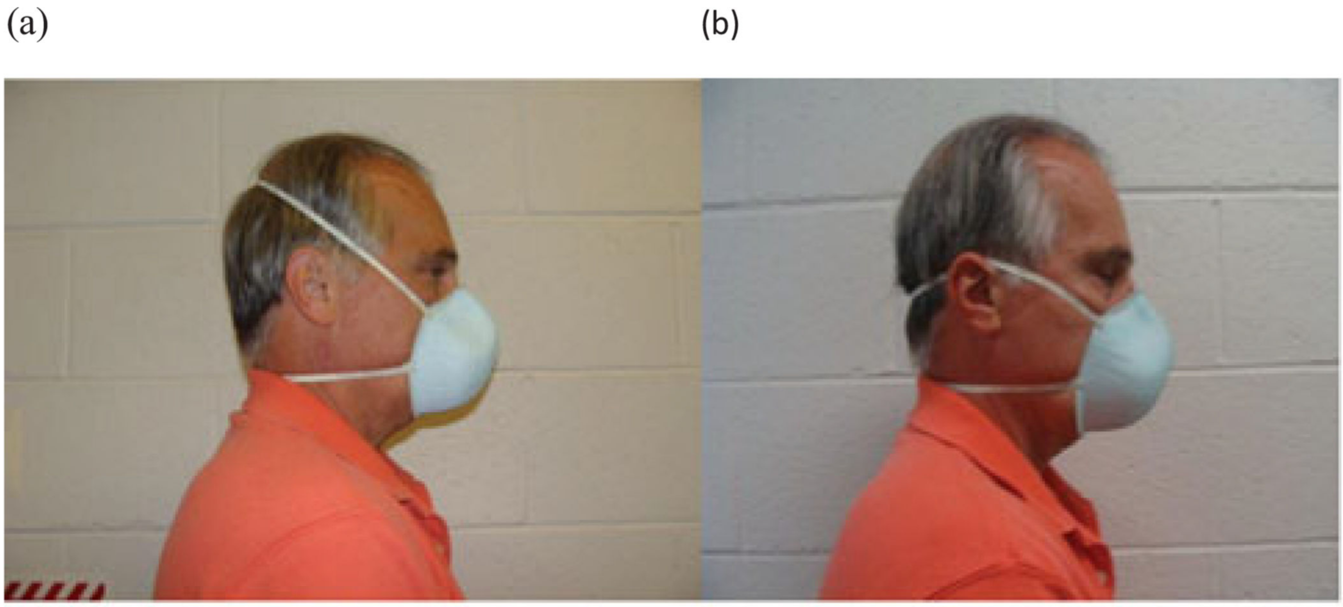

FIGURE 2.
N95 filtering facepiece respirator with top strap high on the occiput (a) and with the top strap displaced downward to the ear sulcus (b). (color figure available online)

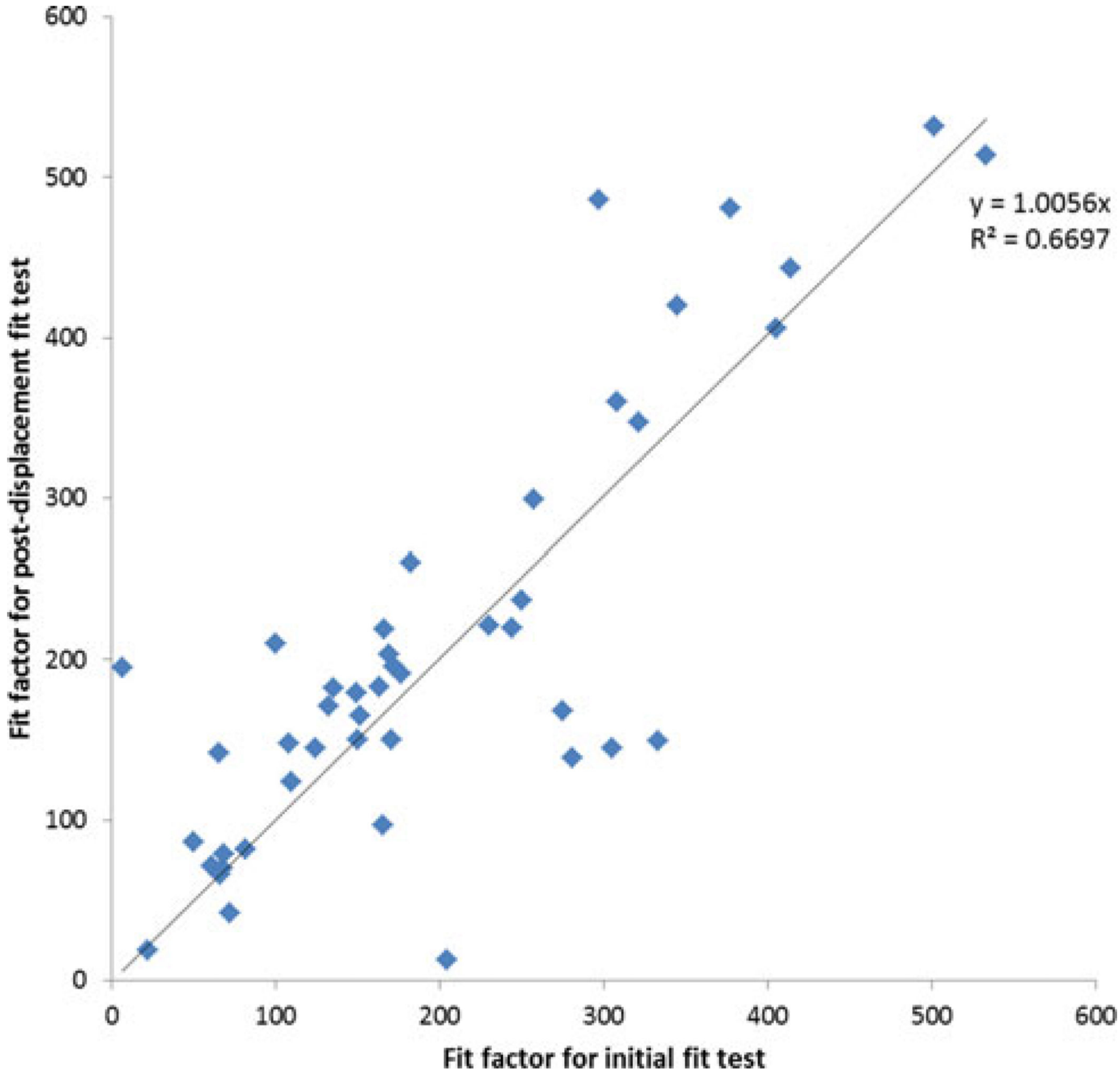

FIGURE 3.

Scatter plot of 45 fit factors for post-strap displacement fit-tests plotted against fit factors for the initial 45 fit-tests. The solid line represents a linear trend with intercept set to 0. (color figure available online)