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Evaluation of Rigidity of Surgical N95 Respirators Using a Manikin-System: A Pilot Study

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Abstract

Background—Surgical N95 respirators are devices certified by the National Institute for Occupational Safety and Health (NIOSH) and also cleared by the Food and Drug Administration (FDA) as a medical device. They are commonly used in healthcare settings to provide protection from infectious aerosols, as well as, bodily fluid sprays and splashes. It is hypothesized based on design, some models may change their shape significantly (i.e., collapse) during heavy breathing, which may allow the device to touch the wearer's face. Concerns have been raised that droplets of infectious biological fluids may reach the inner layer of surgical N95 respirators leading to the transfer of microorganisms to the oronasal facial region upon collapse. Unfortunately, little data currently exists on respirator rigidity testing or its relation to efficacy. The objective of this study was to develop and optimize a manikin-based test system to evaluate respirator rigidity.

Methods—Six surgical N95 models of three different designs (cup-shaped, flat fold and trifold) were tested at two different environmental conditions on the NIOSH medium headform. Rigidity evaluation was performed at 50% relative humidity (RH) and 22°C, and at ~100% RH and 33°C at 40, 50, and 60 L/min breathing flow rates. Facial contact secondary to shape change was assessed by coating the inner layer of the surgical N95 respirators with a fluorescent tracer and its transfer to the manikin face.

Results—The results showed that the cup-shaped models were rigid and resistant to shape change at both environmental conditions and all flow rates. In contrast, the flat fold models and trifold models showed significant changes with rigidity, at higher breathing flow rates and higher RH and temperature conditions. The flat fold models showed transfer of the fluorescent tracer to the manikin face at higher RH and breathing rates, confirming a change in rigidity.

Conclusions—The results from the study suggest that the manikin-based test system designed for the purposes of this study can be used to evaluate respirator rigidity.

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Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. Mention of company names or products does not constitute endorsement by NIOSH.

Keywords

surgical N95 respirator; rigidity; fluorescence tracer; fluid penetration

INTRODUCTION

Surgical N95 respirators are devices certified by the National Institute for Occupational Safety and Health (NIOSH) and also cleared by the Food and Drug Administration (FDA) as medical devices for use as surgical masks (SMs). They are used in healthcare settings to reduce inhalation of infectious aerosols as well as for protection from sprays and splashes of bodily fluids. For instance, surgeons and operating room personnel may wear surgical N95 respirators to prevent personal oral and nasal microorganisms from falling into the sterile surgical field as well as to maintain protection against intraoperative blood and fluid splatter.

A recent study evaluated the fluid resistance of surgical N95 respirators and other devices when exposed to synthetic blood (Rengasamy, Sbarra, Nwoko, & Shaffer, 2015). In this study, a synthetic blood was used to evaluate fluid penetration at 450 and 635 cm/sec velocities as described by the ASTM F1862 test method and the results confirmed that surgical N95 respirators were resistant as expected (Rengasamy et al., 2015). However, the ASTM F1862 test method allows the failure of three samples out of 32 samples tested for each surgical N95 respirator model for FDA clearance, so sample-to-sample variation can occur. Recent studies on resistance to penetration using synthetic blood targeted at the face/mask interface area (90° angle to the ASTM F1862 direction) showed diffusion through the sides of the mask (manuscript submitted to American Journal of Infection Control). This suggests that splashes and sprays of biological fluid on the faceseal area can diffuse inside the respirator. Furthermore, numerical simulations have shown that migration of liquids from the outer surface of the respirator to the inner surface is theoretically possible due to diffusion and capillary action (Li & Li, 2005).

One concern is that variations in respirator shape could make some devices more susceptible to biological fluids reaching the facial skin in the oronasal region, ultimately increasing the risk of disease transmission. Many surgical N95 respirators have a rigid structural design (cup-shaped or trifold) that prevents the inner surface of the respirator from coming in contact with the user’s face (Coffey et al., 2004; Niezgoda, Kim, Roberge, & Benson, 2013; Zhuang, Coffey, & Ann, 2005). On the other hand, some designs such as the flat fold models appear less rigid and may allow the inner surface of the respirator to touch the face during breathing. In this scenario, the user may be exposed to biological secretions that reach the inner surface of the mask. For instance, a previous study showed SMs collapsing and sticking to the face of test subjects (Ray et al., 2012) suggesting that facial contact could also occur with flat fold respirators. Unfortunately, little data exists on respirator rigidity and which environmental factors and design considerations make devices more likely to collapse. This information is needed by safety professionals seeking to select respirators for healthcare workers and for organizations such as the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) recommending design characteristics. For example, during the recent Ebola epidemic WHO recommended

that workers *"Use a fluid-resistant medical or surgical mask with a structured design that does not collapse against the mouth (e.g. duckbill or cup-shape)"* (WHO, 2016).

Surgical N95 respirators of different designs are used in healthcare. Some structural designs such as flat fold models may collapse against the mouth and transfer infectious organisms to user's face. It is hypothesized that the internal surface of flat fold respirator models might touch a user's face when a significant change in rigidity occurs during heavy breathing. The objective of this study was to develop and optimize a manikin-based test system to study respirator rigidity.

MATERIALS AND METHODS

Materials

Six models of surgical N95 filtering facepiece respirators were evaluated for rigidity at two different relative humidity (RH) and temperature conditions (~22°C, ~50% RH, and ~33°C, ~100% RH). The designs tested include: two cup-shaped respirators, two flat fold respirators, a trifold style respirator, and a pleated trifold respirator model. Table I includes the list of respirators by model, design, and manufacturer.

Apparatus

All testing was conducted using a medium sized headform in a laboratory setting. The NIOSH advanced headform is built with synthetic casing that mimics the skin and tissue depth of a real human head (Bergman et al., 2014). The synthetic skin offers a good sealing surface for the respirator to provide good contact and fit. The test operator took effort to place the respirator in its original configuration on to the manikin face and sealed it well by adjusting the straps. The headform was placed inside a Plexiglas® chamber and a breathing tube (22 mm ID) was inserted from the inside of the mouth, out of the midback of the head and connected to an isolated artificial lung outside of the chamber. Testing was conducted so temperature and humidity conditions could be controlled (Figure 1). Heated and humidified air was supplied to the manikin by passing compressed air through a 2000 ml Erlenmeyer flask containing ~1000 ml water at ~100°C. A breathing simulator (Model: BRSS, Koken Ltd., Japan) was connected to an artificial lung and then to the Erlenmeyer flask. The humidity system was stationed between the artificial lung and the headform. The RH of exhaled air mimicked human breathing air. Inhaled air was cycled directly back to the artificial lung creating a closed loop system. The experiments were done under sinusoidal breathing flow rates at 40, 50, and 60 L/min.

Fluorescent Tracer

Only the faceseal area of a correctly donned respirator will contact the wearer's face while the inner surface of the respirator is not expected to touch the facial skin. It is hypothesized that the internal surface of some respirator models might touch a user's face when a significant change in rigidity occurs during heavy breathing. To study the rigidity of a respirator, it is necessary to develop a test method to determine the respirator inner surface (concave side) contact to face. This was achieved using a fluorescent tracer (Glo-Germ™, Germ Moab, UT) coated on the concave side of a respirator donned on a manikin face.

The fluorescent tracer is expected to transfer to the manikin face during a significant contact. The fluorescent tracer on the manikin face can be visualized using a black light, based on manufacturer guidelines, which indicates highest luminescence occurs when the fluorochrome is excited by long-wave ultraviolet light.

The drying process ensured that the fluorescence was not accidentally transferred to the face of the headform during the standard donning process. Fluorescence transfer from the respirator to the breathing manikin at 40, 50, and 60 L/min flow rates was evaluated at two different exposure conditions (50% RH and 22°C, and 100% RH and 33°C). During heavy breathing, the inner surface of the respirator is likely to contact the manikin face and transfer the fluorescent tracer.

Test Procedure

Respirator shape change as well as fluorescence tracer transfer from respirator to manikin face were evaluated at two different atmospheric conditions. A good seal between the manikin face and the respirator is important for the evaluation of shape change. The synthetic skin of manikin offered flexibility to adjust the respirator and secure it properly to give a better seal. The test operator carefully adjusted the placement of the respirator on the manikin face to give a good seal with minimum leaks. In the first series of tests, samples were evaluated at laboratory temperature (22°C) and relative humidity (50% RH). Each respirator with dried fluorescent tracer was placed on the manikin inside the testing chamber. Laboratory air was used during inhalation, while heated (33–35°C) and humidified air (~100% RH) was used during exhalation to mimic exhaled air of human subjects. Manikin breathing at ≤40 L/min did not show major change with the shape of the respirators. Further tests were done at 50 L/min to understand if higher flow rates show any shape change. Each test lasted 20 minutes and five tests were conducted for each respirator model. The shape change during the test was evaluated for five samples of each of the six surgical N95 respirator models. After each test, the respirator was carefully removed and the face of the headform was examined for any fluorescence. The shape change results were visually ranked as ‘no change’, ‘minor change’ or ‘major change’ as designated by “No”, “Possibly” or “Yes”, respectively (Table II and Table III).

In the second series of tests, the test chamber was kept at 33°C and ~100% RH (higher temperature and RH) to simulate environmental conditions that were experienced by healthcare workers in West Africa during the Ebola epidemic (CDC, 2015). Each respirator coated with the fluorescent tracer was donned on the headform in the test chamber at higher temperature and RH. After 15 min equilibration, the test was conducted for 20 minutes. Three samples of each respirator model were tested at 40, 50, and 60 L/min breathing rates. At the end of each test, each respirator was carefully removed from the face of the headform and was evaluated for fluorescent tracer transfer. The face of the headform was cleaned with a gauze material immersed in detergent solution followed by a gauze with water and then dried with a cloth in between use before initiating the next sample test.

RESULTS AND DISCUSSION

Table II shows the rigidity results for six respirator models tested at laboratory temperature and RH (~22°C, ~50%) at a breathing flow rate of 50 L/min. The two cup-shaped surgical N95 models (3M 1860 and Gerson 1730) did not show any bend in the shape of the respirator during breathing condition. On the other hand, the two flat fold surgical N95 respirators (Kimberly Clark and Sperian) models expanded partially outward during exhalation and showed minimum shrinking during inhalation. One of the trifold models (3M 1870/1870+) behaved similar to the cup-shaped models with no shape change. In contrast, the other pleated trifold model (Alpha ProTech 695) showed minor changes in rigidity during breathing at room temperature and RH similar to the flat fold models. The experiments also evaluated whether the inner surface of respirators touched the manikin face during breathing conditions. Tests at 50 L/min breathing flow conditions showed some fluorescence at faceseal area, but no fluorescence on other areas of the manikin face.

Table III shows the rigidity of the respirators at higher temperature and RH conditions (~33°C,~100% RH) at breathing flow rates 40, 50, and 60 L/min. The cup-shaped designs were consistently stable and resistant to shape change when challenged at all three breathing flow rates tested. On the other hand, several samples of flat fold and trifold models showed shape change to varying degrees. Many respirator samples showed shape change with increasing breathing flow rate (Table III) indicating that breathing flow rate is a major determinant of shape change. Figure 1a shows a typical flat fold respirator positioned on the headform at no breathing condition. The respirator showed significant expansion (Figure 1b) during exhalation at a breathing rate of 60 L/min. During inhalation, considerable shrinking of the device was noticed as shown in Figure 1c, in response to the negative pressure created inside the mask. Similar changes in shape were also observed with trifold design models (Sperian and Alpha ProTech).

The effect of temperature and RH on respirator shape change of flat fold and trifold designs was evaluated. Five samples per design were evaluated at laboratory temperature and RH while three samples per design at higher temperature and RH. In spite of the difference, only three samples showed shape change at laboratory temperature and RH compared to seven samples at higher temperature and RH at 50 L/min flow rate. The results indicate that higher RH and temperature may induce respirator pliability followed by significant shape change as well as the transfer of the fluorescent tracer from the inner surface of the respirator to the face of the manikin during breathing. Results showed significant fluorescence transfer at higher temperature, RH, and 60 L/min breathing flow rate with the flat fold Kimberly Clark design (Figure 2b (top right). In addition to faceseal contact area, facial areas near the upper and lower lips also showed significant amounts of fluorescence. It appears that the contact of the respirator at the faceseal area extends toward the center during breathing. Results with additional respirator samples showed different amounts of fluorescence transfer to the faceseal area and other facial surfaces as shown in Figure 2c and 2d (bottom left and right, respectively) indicating the variability between experiments.

The design of a respirator appears to influence the rigidity significantly. Of the three different shapes of respirators tested in this study, the cup-shaped designs showed very

little structural change at 50% RH and 50 L/min or ~100% RH and 60 L/min test conditions. This indicates the hemisphere shaped respirator designs might offer maximum resistance to shape change during heavy breathing. On the other hand, the bi-fold and trifold designs, which are flexible, appear to undergo shape change during heavy breathing conditions. With a shape change, the higher RH appears to favor the transfer of fluorescence to the face. The fiber material and packing density are also important factors contributing to the rigidity of respirators. Overall, the observation that respirators can collapse and touch the face is supported by this study and previous observations (Canini et al., 2010; Roberge, Kim, & Benson, 2012). For example, Roberge et al. concluded masks may stick to the facial skin at high humidity and temperature levels, upon assessing the physiological, thermal, and subjective responses from participants wearing SMs (Roberge et al., 2012). In this study, subjects first walked at low to moderate work rates continuously for 1 hour without a SM followed by the same activity wearing a SM. The respiratory rate of the subjects increased with time, and about 11% complained about the SM sticking to their face during inhalation.

Limitations of this study may include test conditions and sample sizes. Environmental conditions described in the study may not represent the worst-case RH and temperature field conditions that are thought to influence the rigidity of respirators. This issue can partly be addressed using a manikin that mimics hyperhidrosis at higher RH and temperature. In this study, rigidity was evaluated with three or five samples at two different exposure conditions. Additional samples of respirators should be tested to understand the significance of the results. Future laboratory studies should be conducted to validate the findings obtained in the present study. Additionally human subject testing is recommended to understand the influence of respiratory rate on rigidity of respirators.

CONCLUSIONS

A novel test system was developed using the medium sized NIOSH advanced headform and optimized to evaluate respirator rigidity. Six surgical N95 respirator models with three different designs tested in our study showed variations of rigidity between designs. The cup-shaped designs showed no shape change at laboratory temperature and RH as well as relatively higher temperature and RH and 40, 50, and 60 L/min breathing flow rates. On the other hand, the flat fold and trifold designs showed significant shape changes at higher temperature and RH conditions compared to laboratory temperature and RH conditions. The fluorescence probe coated on the inner side of the flat fold surgical N95 respirator was transferred to the manikin face at a higher temperature and RH indicating the possibility of infectious fluid splash reaching the facial skin of users. For the purposes of this study, fluorescent tracers were used primarily as a tool in which there is generally a low burden of evidence, and the study results are defined by investigator observed tracer transfer. The manikin-based test system developed for this study can be used to effectively evaluate rigidity of respirators.

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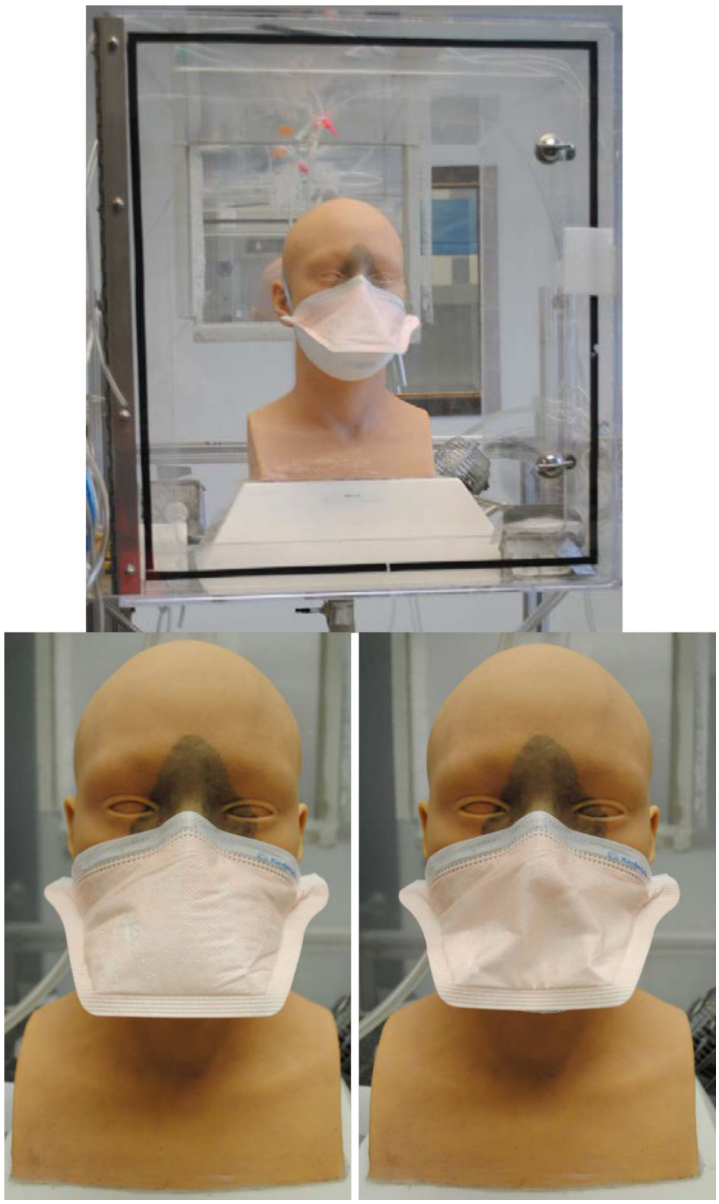

Figure 1.

a. A flat fold respirator (Kimberly Clark 46727) mounted on a headform at no breathing condition inside the test chamber (Top).

Figure 1b. Exhalation (Bottom Left) and Figure 1c. Inhalation (Bottom Right) at 60 L/min breathing flow rate.

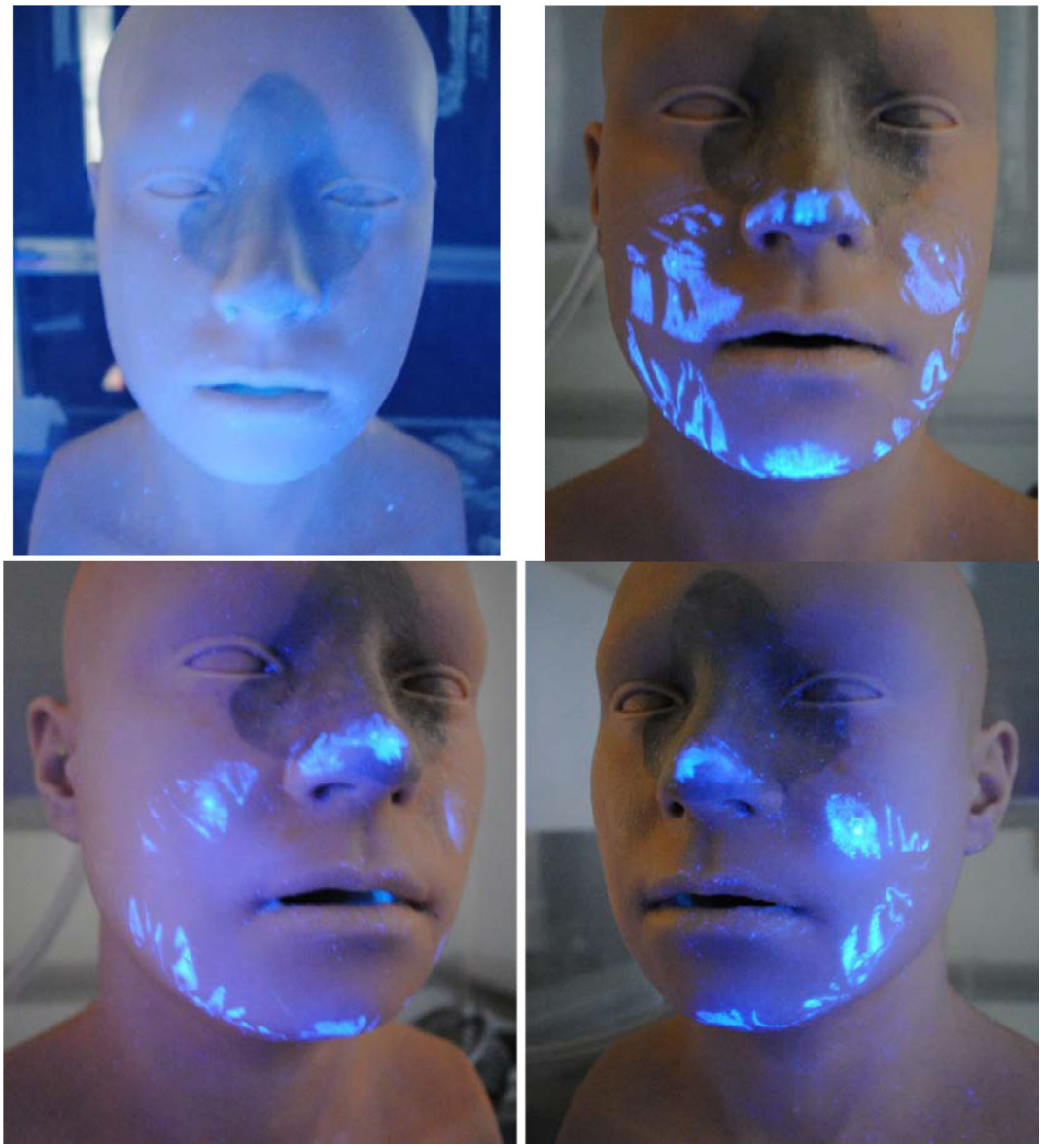

Figure 2:
Fluorescence transfer from inner side of a flat fold surgical N95 respirator to the face of the manikin head at 60 L/min breathing flow rate. a) Control, no breathing at 22°C and ~50% RH (Top Left); b), c) and d) typical fluorescent tracer transfer from respirator shape change at 32°C and ~100% RH (Top Right, Bottom Left and Bottom Right).

Table I.

Surgical N95 Respirator Model, Design, and Manufacturer Samples

Model	Design	Manufacturer
3M 1860	Cup-shaped	3M Company, Minneapolis, MN
Gerson 1730	Cup-shaped	Louis M. Gerson Co., Middleboro, MA
Kimberly-Clark 46727	Flat fold	Kimberly-Clark, Roswell, GA
Sperian One-Fit HC-NB295F	Flat fold	Sperian Respiratory Protection USA, LLC., Santa Ana, CA
3M 1870/1870+	Trifold	3M Company, Minneapolis, MN
Alpha Pro Tech 695	Pleated/Trifold	Alpha Pro Tech, Inc., Salt Lake City, UT

Table II.

Shape Change of Surgical N95 Respirators Using a Medium Headform at 22°C and 50% RH, and a Breathing Flow Rate of 50 L/min

PPE Model	Sample #				
	1	2	3	4	5
3M 1860	No	No	No	No	No
Gerson 1730	No	No	No	No	No
Kmberly Clark 46727	No	No	No	Possibly	No
Sperian One-Fit HC-NB295F	No	Possibly	No	No	No
3M 1870/1870+	No	No	No	No	No
Alpha ProTech 695	No	No	Possibly	No	No

Note: Shape change observed was insignificant, minor and major as represented by “No”, “Possibly” and “Yes”, respectively.

Table III.

Shape Change of Surgical N95 Respirators Using a Medium Headform at 32°C, and ~100% RH, at 40, 50, and 60 L/min Breathing Flow Rates

PPE Model	Breathing Flow Rate	Sample #		
		1	2	3
3M 1860	40	No	No	No
	50	No	No	No
	60	No	No	No
Gerson 1730	40	No	No	No
	50	No	No	No
	60	No	No	No
Kimberly Clark 46727	40	No	No	Possibly
	50	Possibly	Yes	Possibly
	60	Yes	No	Yes
Sperian One-Fit HC-NB295F	40	No	No	No
	50	No	No	No
	60	Yes	Yes	No
3M 1870	40	No	Yes	Possibly
	50	Yes	Yes	No
	60	Yes	Possibly	Yes
Alpha ProTech 695	40	No	No	No
	50	Yes	Yes	No
	60	Yes	No	Yes

Note: Shape change observed was insignificant, minor and major as represented by “No”, “Possibly” and “Yes”, respectively.