Development of Computational Models to Advance the Review of Respirators and Gowns

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Abstract

Computational modeling for single-use personal protective equipment (PPE), such as surgical N95 respirators and gowns, is lacking given the products are disposed after one use. With a replenished stock of PPE after the initial scarcity of PPE supplies due to the COVID-19 pandemic and the introduction of decontamination methods for disposable PPE, novel regulatory science considerations for product testing are warranted. A computational model describing the impact of textile/material characteristics and mechanical stress on surgical N95 respirator/mask performance would provide a cost-effective freeware tool for PPE medical device stakeholders to examine product performance. The goal of this effort is to use experimental data, from FDA and collaborators at CDC/NIOSH/NPPTL, along with published data to construct a 'risk' calculator that provides investigators insight into product performance and supports public health countermeasures.

Several standards are used for testing PPE, including those recognized by FDA and/or CDC/NIOSH/NPPTL: ASTM F2100 (standard specifications for performance of medical face masks) and ASTP 0059 (standard specification of the mask materials) recommended by CDC; testing recommended by the FDA includes ASTM F2101 (bacterial filtration efficiency), ASTM D737 (air penetration test), and a modified version of ASTM F1862 (resistance to penetration by blood). These PPE test parameters combined with material characteristics (thickness, porosity, weight, tensile strength, and fluid resistance) will be used to establish empirical relationships between mask characteristics and filtration efficiency using multiple linear regression. These regression models will serve as a starting point and validation method for models generated for decontaminated PPE. With refinement and optimization of the computational models to represent PPE efficacy before and after decontamination and stress/strain testing, a graphics user interface (GUI) will be constructed to allow for user input of test and material parameters resulting in an output of PPE viability based on these computational models. The 'risk' calculator produced from this work could expedite testing and provide a publicly available tool to evaluate PPE material performance.

Introduction

As a result of the pandemic and the importance of minimizing the risk of COVID-19 spread, public awareness of mask and the use of personal protective equipment (PPE) increased significantly and rapidly. Delays in the manufacture and supply-chain shortages in materials critical to PPE items, exposed vulnerabilities in U.S. public health, safety, and preparedness as well as gaps in regulatory assessment. This unprecedented need for N95 respirators and surgical masks, showcased the importance of PPE on a national scale.

U.S. medical countermeasures (MCM) require PPE in domestic and international efforts for public-service personnel and national safety Resulting from the current pandemic, streamlining emergency readiness through coordination between government agencies and private entities, is a national priority. To meet this public priority, the FDA will be testing PPE materials to include the repertoire of FDA reviewed, N95 surgical masks and respirators, previously complicated by supply chain demands during the pandemic.

The goal for this project is to create and advance our 'PPE Risk Calculator'—a computational tool developed with data from PPE testing, using current and improved test standards.

Materials and Methods

Standard	Description	Used by
ASTM F2100	Standard specifications for performance of medical face masks	CDC
ASTP 0059	Standard specifications of the mask materials	CDC
ASTM F2101	Bacterial Filtration Efficiency	Both
ASTM D737	Air penetration test	Both
ASTM F1862	Resistance to penetration by blood	Both

Table 1. Five standards that are used to test surgical N95 respirators and their effectiveness.

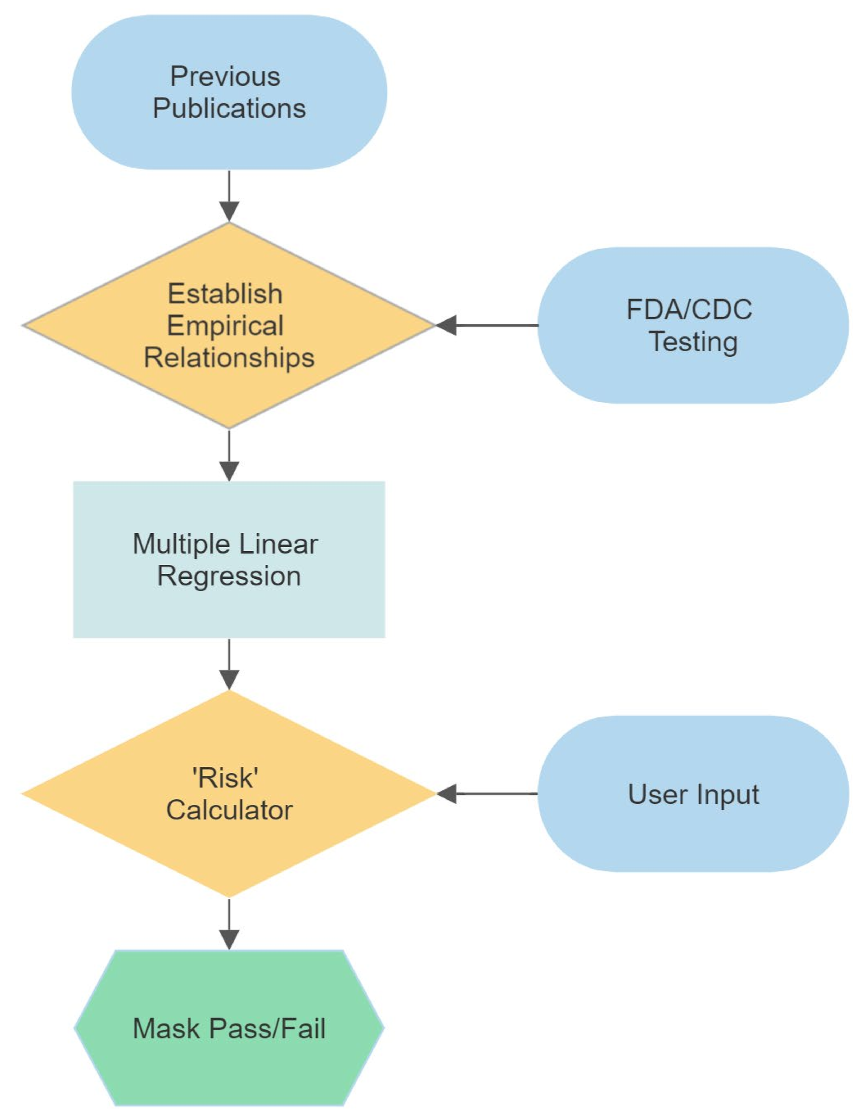

Figure 1. Workflow towards the development of the PPE 'Risk' Calculator.

Results and Discussion

- Leonas and Jones (2003) compares % bacterial filtration efficiency (BFE) of six different commercial surgical face masks (3 three-ply and 3 molded) and measured Thickness of the mask, weight per unit area, average pore diameter, and the largest pore diameter (Table 2). Measurement of material properties conformed to ASTM standards.
- Monjezi and Jaamati (2021) establishes relationships between physical properties of the fibrous medium its affect on work of breathing (WOB) and particle filtration efficiency (PFE).
- Our correlation plot was created using Leonas and Jones' data and findings; material characteristics were compared with each other and % BFE for preliminary relationship analysis (Figure 2).
- Our early linear models based on Leonas and Jones' data show a positive relationship between thickness vs. BFE, while negative relationships were established between weight, poremean, and poremax vs. BFE (Figure 3).

Results and Discussion

Mask	Thickness mm	Weight gm/m²	Pore mean µm	Pore max µm	*S. aureus* % BFE	*E. coli* % BFE
1	0.3345	66.908	23.97	41.74	91.09	98.53
2	0.2339	58.657	19.29	43.27	88.18	97.26
3	0.4417	95.775	16.90	27.19	92.19	99.34
4	0.6137	140.828	35.06	87.74	90.72	99.10
5	0.3607	145.460	51.00	146.60	84.82	95.74
6	0.4742	164.405	31.72	92.12	86.40	99.73

Table 2. Six surgical face masks and their material characteristics measured by Leonas *and Jones* and the mask's corresponding % BFE with *S. aureus* and *E. coli.*

Figure 2. Correlation plots between each mask parameter in Table 2. Circles correspond with their numeric value and represent the strength and type of relationship that exists between variables; larger equates to a stronger relationship and color represents positive or negative correlation.

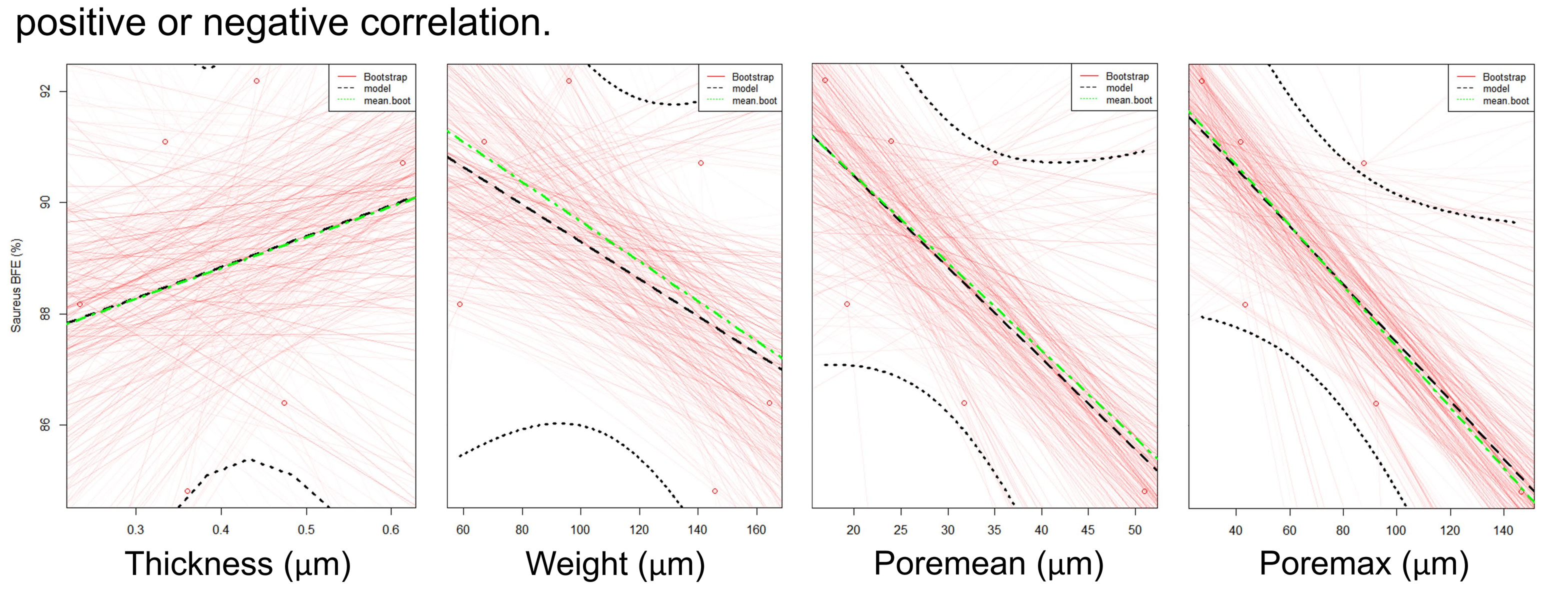

Figure 3. Graphs of linear models representing each material characteristic vs. *S. Aureus* % BFE from Table 1. Red lines show 1000 iterations of bootstrapping by resampling. Black dotted lines represent linear regression equation and confidence intervals.

- Collaborative efforts from CDC/NIOSH/NPPTL and the FDA comprise testing N95 BFE according to ASTM standards while measuring important face mask material characteristics identified by the preliminary models.
- Measurement of tensile strength and liquid resistance will inform additional models representing mask performance.
- With the establishment of a final multiple linear regression model representing mask material characteristics vs. mask performance, a GUI created through Rshiny will serve as the PPE 'Risk' Calculator.
- Users may enter information regarding the established mask characteristics to generate a predictive mask performance rating – which may pass or fail the specified threshold of the ASTM standards.
- Once the N95 respirator multiple linear regression model is established, similar efforts will be made to establish relationships of medical gown materials and their respective performance.
- Replicated methods for decontaminated PPE are being performed as well; these data will add to the validation of the previous models as well as be stand-alone models for decontamination methods vs. PPE material characteristics.

Conclusion

- The pandemic highlighted the importance of PPE testing, production, and regulation.
- Early linear models from previous publications involving mask material properties vs. mask performance indicated thickness and pore size are important.
- Using the early models as guidance, ongoing and future testing by FDA and CDC/NIOSH/NPPTL comprise measuring similar parameters to further refine our models.
- A final PPE 'Risk' Calculator will be created to provide a mask's performance rating based on user input mask parameters.
- The outcome of this work will support FDA efforts on product assessment, assist with regulatory science priorities important to MCMi, and provide the 'PPE Risk Calculator' as freeware, a publicly accessible tool, to assess PPE material efficacy for PPE medical device stakeholders.

References

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