

FITRA: ADDRESSING THE PROBLEM OF INADEQUATE N95 RESPIRATOR FIT

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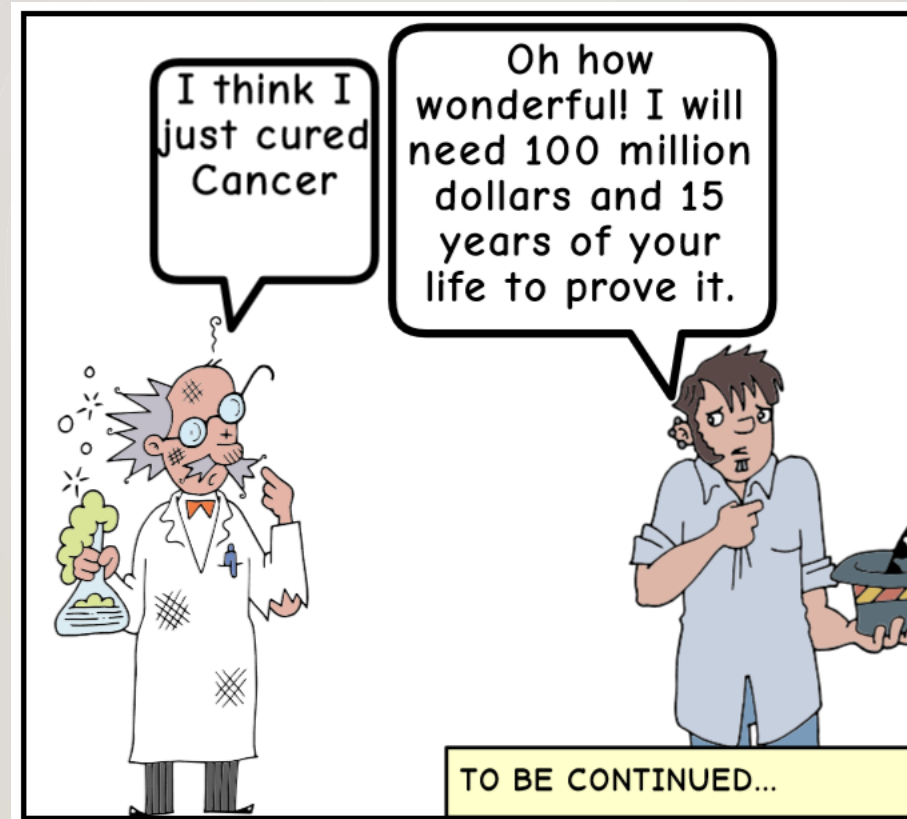
MARCH 16TH 2020 MY LIFE CHANGED



COVID-19 INCREASED THE NEED FOR N95 RESPIRATORS BEYOND THE SUPPLY CHAIN'S REACH

- NIOSH/CDC
 - Responded quickly to make a list of recommended products
 - This list largely allows for respirators that were already in the system as certified but might be from other parts of industry and not typically used in healthcare.
- Hospitals/EMS
 - Supply Chains could not keep up with demand for standard equipment
 - Facilities looked for the guidance from CDC and other agencies and found the list
 - https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html
 - This link includes all “NIOSH-APPROVED” N95 Respirators

REGULATORY JOKE REGULATORY PEOPLE DON'T LAUGH



WINDOW INTO MY SYSTEM

- 4500+ employees who are fit for PPE annually
- 84 ICU beds across 8 specialty ICUs
- 2200 RNs and 160 RCPs
- I managed 9 PAPR units for the entire system until the end of August when we received a large order from Germany
- Employee Health is a department of 7
- April 2020 we had 1 TSI PortaCount
- July we were up to 4 PortaCounts running fulltime
- The EHS team was now more than 40 staff
- Between March 16th and April 9th we created 86 guidance documents for our clinical areas

THE PROBLEM WITH FIT

- OSHA 29CFR1910.134 Makes employers responsible for ensuring proper fitting PPE
 - As a result of Quantitative Fit protocols being the minority strategy poor fitting respirators are being widely used
 - There is a significant difference in the HCW infection rate at my institution when compared to those using Qualitative methods
- Testing showed that around 90% of N95's tested may not be appropriate in the Clinical Setting
 - The respirators have disclaimers on their labeling stating that they are not tested for the clinical environment and are not tested for bacteria or virus protection
 - Fit needs to be improved to makes these respirators truly safe for frontline workers exposed to SARS CoV-2
 - We observed 173 failed Quantitative Fit Tests with Approved Listed N95 models

SOUND THE ALARM

- July 7th I received MAKERITE 9500's for testing
- 0 out of 62 faces passed quantitative fit protocol
- I was concerned about a manufacturing issue or counterfeit product
- July 10th I reported this to FDA through MedWatch and contacted MAKERITE
- Within a week I met with CAL-OSHA to explain our findings and seek guidance
- I was referred to NIOSH Deputy Director at that time and began monthly meetings
- The MAKERITE masks were not counterfeit and were not adulterated in anyway. They met all the standards and design outputs from the manufacturer

WHO'S IN CHARGE HERE?

- CDC makes recommendations to the public and works along side industry to share resources and move quickly
- NIOSH governs the requirements for manufacturers to make specific products and then has a process for validating submitted designs at there testing site
- OSHA is responsible for the regulations and laws that protect employees and sets the requirements for employers, they also police employers for following regs
- States often have their own ie CAL-OSHA
- FDA validates data submitted by manufacturers for med devices/drugs/and biologics
- They ensure that products are not adulterated or misbranded, these two words are actually the basis for the entire FD&C act
- They are expensive and slow but have deep expertise
- So who can I call!!!!

WHAT TO DO?

- The masks simply did not fit because there are no strict requirements for fit at this time. There is no procedure at NIOSH to validate fit design outputs with any quantitative testing at this time
- So we chose to implement our own internal process for approving respirators based on Quantitative Testing
- Many of our friends and neighbors were not able to make the same choices due to the dire situation with mask availability and the staffing shortages were crippling to operations
- At the end of August we had a HCW infection rate of 0.27% in my building
- Our friends and neighbors were hovering between 5-7.5% positivity

LIMITED OPTIONS

- Once we had kicked off the new protocol for fit we struggled to find respirators that passed
- Even supplies acquired by the state were not meeting our standards and it was an incredible challenge to source masks at this time.
- We opted for a mask that was controversial with CDC as it had an exhalation valve on the front
- The BYD Care N95 was delivered and distributed out of the port of LA in the 10's of millions
- Our team was able to source the 3M 8511 in a large quantity in August and allowed us to keep our preferred products only for the COVID units

MATH TO THE RESCUE

- We felt an incredible push to find interim solutions to the poor fitting masks
- My friends were literally getting sick in EMS and in other hospitals and we had to do something
- Step 1
 - Assemble interested folks good at the maths and the beep boops
- Burhan, Darryl, Mark
 - Beep Boop experts

WHO CAN HELP US

- Bellus3D had an app out that was providing files for a small fee that could be 3D printed and that custom fit individual faces
- This product was great and could have been useful for small teams but for 1000's of employees it was an operational nightmare
- We needed a more broadly useful product that could be used on multiple faces
- Enter Burhan and his maths with curves
- The rest of the team was ready to print and test prototypes till we had something that worked

THE TEAM



Mark Roden, PhD



Daniel Stemen, MSRS



Darryl Hwang, PhD



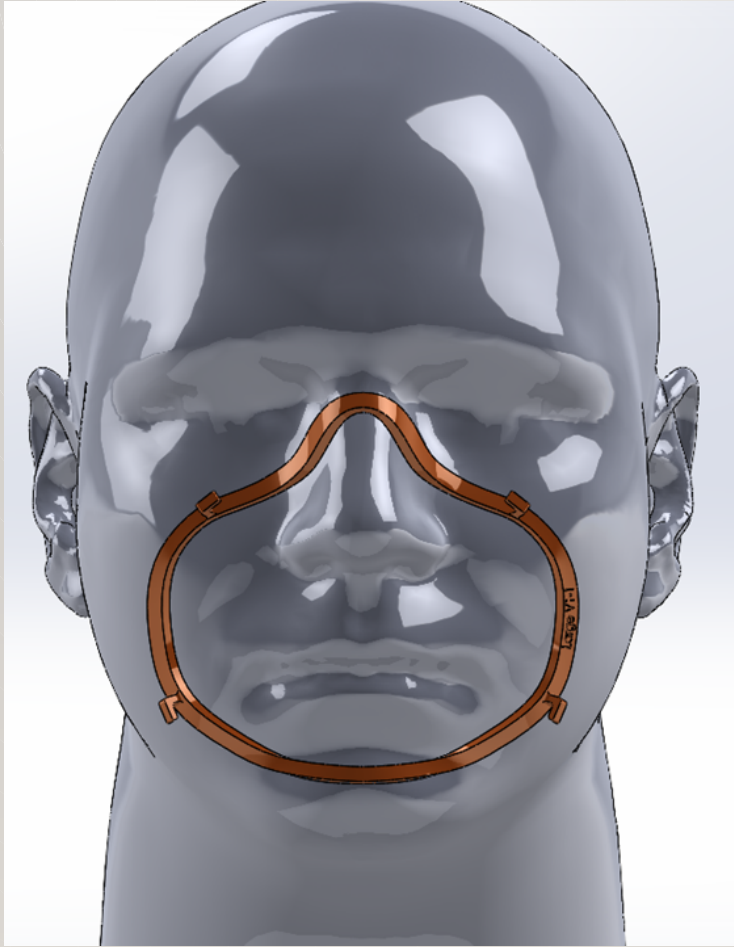
Burhan Qaddoumi



Patrick Campbell, MSME



Jamie Waters

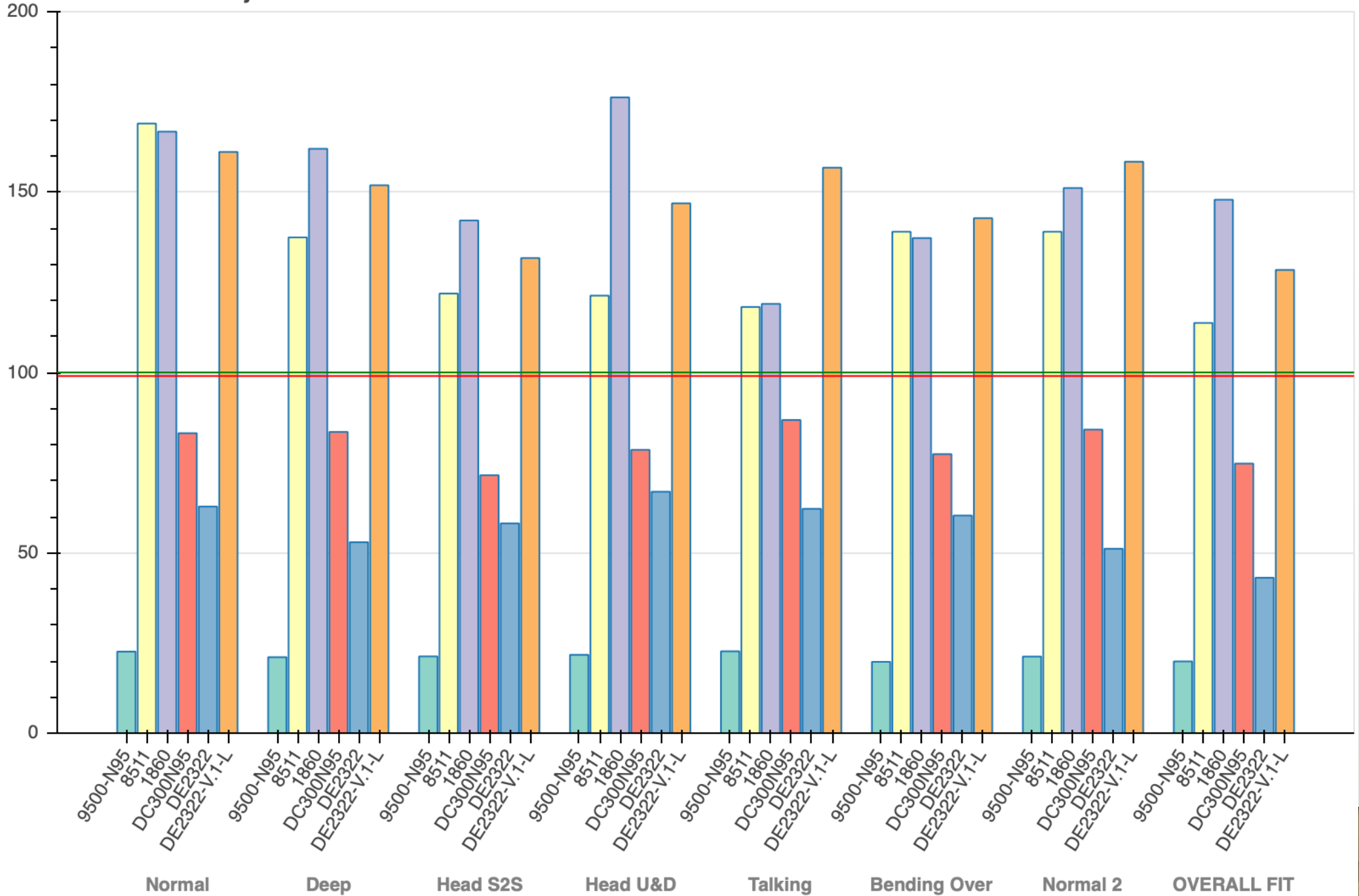


LETS TEST IT



Sum of mean	Column Labels					
Row Labels	1860	8511	9500-N95	DC300N95	DE2322	DE2322-V.1-L
Normal	166.75	169.00	22.60	83.15	62.81	161.12
Deep	162.00	137.43	21.06	83.50	52.93	151.88
Side to Side	142.13	121.86	21.28	71.50	58.15	131.71
Up and Down	176.25	121.29	21.71	78.54	66.93	146.88
Talking	119.00	118.14	22.69	86.81	62.19	156.76
Bending over	137.25	139.00	19.76	77.35	60.33	142.76
Normal 2	151.13	139.00	21.24	84.15	51.11	158.41
OverallFitFactor	147.88	113.71	19.88	74.73	43.07	128.41

Fitment Results by Mask Model



LET'S TELL PEOPLE AND PUT IT ON THEIR FACES

- CAL-OSHA said slow your roll without an approval this causes regulatory issues
- CDC said there is no pathway at NIOSH for respirator accessories unless they are submitted with the mask at the time of approval
- NIOSH was very empathetic and very helpful in all our conversations including sharing their proposed rules and looking at our data to be used in the pool of evidence to bolster support for rule changes
- Some of the faculty used fit assist devices in our OR's to better protect themselves while using microscopes and other devices where PAPRs interrupted normal workflow

WE WROTE IT DOWN

JOEM/JOEM-21-8883; Total nos of Pages: 6;

JOEM-21-8883

FAST TRACK ARTICLE

Frame to Improve the Fit of N95 Filtering Face Mask Respirators

Daniel Stemen, BS RCP, RRT-ACCS, Marshall Ge, MD, Darryl Hwang, PhD, Burhan Qaddoumi, BS, Mark Roden, PhD, Neha Nanda, MD FSHEA, and Elisabeth Ference, MD MPH

Objective: Test a device that can improve upon the seal of filtering face mask respirators (FFRs). **Methods:** A 3-D prototype for a fit improvement frame (FIF) was created and quantitative fit testing was performed for FFRs with and without the FIF. **Results:** Thirty eight volunteers underwent fit testing. The overall fit pass rate was 100% for the 3M model 1860 masks, 50% for the 3M model 1860 masks, 13% for the BYD CARE model DE2322, and 7% for the Honeywell DC300N95. When using the FIF the overall passing rate increase to 87% for the DE2322 + FIF ($P < 0.01$) and for the DC300N95 + FIF the passing rate increase to 73% ($P < 0.01$) **Conclusion:** The FIF is effective in improving the mask fit of a common flat fold N95 masks and potentially other N95 masks.

Keywords: filtering face mask respirators, frame, N95, personal protective equipment, quantitative fit testing

masks became tantamount to safety at healthcare institutions. State governments nationwide urgently needed to aid in securing new supplies of N95 masks, and quickly signed contracts with providers of N95 or equivalent masks.^{12,13} Due to the rush to procure N95s, there have been concerns regarding deficient quality and unverified certification processes for some respirators being introduced to US healthcare facilities.¹⁴

In the United States, N95 respirators must meet standards described in US 42 CFR part 84 and are regulated by the National Institute of Occupational Safety and Health (NIOSH) and the Food and Drug Administration (FDA). Analogous standards can be found in other countries, with the KN95 mask conforming to GB2626–2006 in China and the FFP2 mask following EN149:2001 across Europe. The NIOSH standard testing procedure (STP-0059) for

WE ARE STILL TRYING

- NIOSH/CDC is still working permanent solutions
- Proposed new rule was published in the Federal Register in 2021
- Public comment has been heard and there has been consistent support for changes particularly in support of Quantitative methods as a new standard or requirement.
- NIOSH released new guidance docs June 29th 2022 I hope we are weeks/months away from changing the requirements for manufacturers permanently

QUESTIONS?

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