A New Fully-reusable, Affordable, Comfortable Mask Design With Superior Filtration and Fit for Use During Respirator Shortages and Pandemics

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BACKGROUND

Face masks have now become a part of our daily routine. At the start of the COVID-19 pandemic, shortages in medical masks and other personal protective equipment (PPE) quickly ensued [21]. Despite producing 20 million face masks per day (half of the world's total production), China could not even meet its own demands [1]. During a pandemic or outbreak, masks benefit not only the health care community but also the population at large. This is in part due to masks being the main protection available when there are no drugs or vaccine, as well as when the mode of transmission is not fully elucidated [22]. In response to the shortages in medical-grade masks, governments began to restrict public access to them, including surgical masks and FDA-regulated respirators such as the N95. However, research shows that wearing a mask helps in reducing transmission of SARS-CoV-2 even within the general community [8]. In fact, a person infected with SARS-CoV-2 wearing a face mask exhales three times fewer viral particles than a symptomatic individual without a mask [22]. In response to the current pandemic, agencies including CDC, WHO, and ECDC have recommended face masks for the general population in crowded settings, and more routinely for higher risk groups such as the elderly, pregnant, and those with underlying health conditions [22]. However, with compliance directly linked to success in containing or limiting the spread of the virus, many US state governments and other parts of the world began mandating the use of face masks in public to increase compliance [21]. In order to meet such requirements with the limitations in access to medical grade masks, cloth masks have quickly become the norm for the general public.

There are now innumerable options available for face masks within the general population, including differences in style, fabric type, price, durability, reusability, etc. However, almost all of these options have not been formally tested. There are multiple factors that determine if a mask is truly effective. The ideal mask has fabric with high filtration efficiency, good breathability, and minimal air leak [23, 27]. It should also be comfortable to wear, be easy to don and doff, not hinder communication, and be reusable [25]. High filtration efficiency is often tested with a particle counter. To determine potential efficacy against SARS-CoV-2, filtering down to at least 0.3 microns is preferred, as this virus is on average 0.25-0.5 microns in diameter [38].

Breathability is also an important aspect to mask design. If a mask makes breathing significantly more difficult, compliance with wearing the mask will decline significantly [31]. Most studies testing breathability rely on measuring airflow resistance, or pressure drop across the material [23]. One way to improve breathability and reduce the change in pressure across the mask is to increase the surface area of the fabric, or make the mask bigger [34]. While many studies objectively measured breathability by calculating the change in pressure across the fabric, another study reported that compliance is not directly related to the measured resistance, suggesting that measuring breathability subjectively would be sufficient [31].

Another classification for masks is in determining if it is a face mask versus a respirator. The term "face mask" is generally used when referring to a mask that only factors in filtration without taking into account air leak. A "respirator" is regulated and has a tight seal against the face in addition to high filtration efficiency, making it a better option when filtering aerosolized particles. In fact, air leak such as that found with standard surgical masks and other masks with the ear loop [30] can decrease filtration efficiency by more than 50% [29, 31, 32, 35]. The most common example of a medical grade respirator is the FDA-regulated one-time use N95 mask. To determine if the respirator has a good fit, a test is completed to determine if air leak is present around the edge of the mask. This can be performed with either a qualitative or quantitative test [22]. While quantitative methods are more reliable, they are less available. Therefore, the qualitative testing is what is typically used to determine if an N95 can be appropriately worn by a health care worker.

Despite restrictions on access to medical grade face masks and respirators, there have been massive shortages of masks for health care workers (HCW). Traditional supply chains cannot meet the demand for respirators even with restricted access [15]. To help mitigate the shortages, many strategies have been pursued, including methods to reuse the N95 masks, employment of non-standard reusable elastomeric respirators, and testing of various materials to be used as filters alone or in combination to protect disposable respirators such as the N95. Such studies have concluded that despite attempting multiple methods for preserving the N95 during disinfection, no method was proven effective in real life after one round of disinfection [9, 11, 27].

Review of the literature shows that until this current pandemic, research on reusable masks in the medical field has not been routinely investigated since the 1960's, when disposable masks came into market [22, 27, 38]. Of note, this is despite disposable masks being unavailable in many areas of the world with limited resources [38].

There are newer studies recently conducted on cloth masks, comparing various styles and materials. In comparing filtration efficiency, it is first important to understand fabric composition. Fabrics are either woven or nonwoven. Woven fabrics (including cotton and other common household items) tend to have significant variation in width and shape, making them harder to compare and provide reliable data on filtration [38]. Nonwoven fabrics are not made with interloping yarn, but instead in a 3D configuration with small pore size, low resistance, and a larger surface area, increasing the chance of trapping particles [34]. Overall, the majority of studies find that nonwoven cloth options have filtration efficiencies far superior to woven and knitted options. However, common materials with higher filtration abilities were typically unable to be washed for reuse without resulting malformation, including felt, static dust cloth, leather, various filters, and cleaning cloth [33].

Some of the recent studies on cloth masks also evaluated breathability. Many of these studies found that options with high filtration tended to have poor breathability. This was especially true with multi-layered masks [16, 34]. One exception was using a vacuum bag or HEPA as a filter. This was found to have high filtration and good breathability in a few studies [16, 34], though another study reported decreased breathability [10]. However, a vacuum bag or HEPA filter cannot be reliably reused or washed, making the mask not fully reusable.

Even fewer studies measured fit. This is most likely because it is the hardest factor to achieve successfully. In fact, to be FDA-approved, there are rigorous tests that must be passed in order to qualify as a true respirator [28]. One type of respirator that was evaluated for fit factor is the elastomeric half face mask respirator (EHFR). This mask is traditionally used in other occupational settings, such as in construction to filter dust and other harsh chemicals [15]. They also require filter cartridges, which are available in different styles and filtration abilities [40]. With shortages in medical masks and N95s, the EHFR models were then tested to be used within the hospital setting. Some benefits to the EHFR include a better seal than the N95 [7] and reusability [25]. In fact, cost comparison for stockpiling in preparation for a pandemic is significantly better than that for N95, costing on average almost ten times less [25]. However, there are also several drawbacks with using an EHFR as a respirator. While it can have a better seal on the face, several users reported skin breakdown after prolonged use, as well as more difficulties with communication, breathing, and cleaning [7, 14]. Also, an EHFR is not designed to filter exhaled breaths, only inhaled, requiring modification of the design to prevent potential contamination from the user into the air [20]. Without such modification, this contamination could result in spread of infection if the user is infected. Another disadvantage is the need for filter cartridge replacement, with unclear recommendations as to how often it should be changed [5, 7]. In addition, users find the EHFR cumbersome to carry around in between uses, as it is much larger and cannot fit in a standard pocket [25]. Finally, cleaning and disinfecting an EHFR is not standardized across styles of EHFR masks, is time-consuming and complex, requiring an additional 16 minutes after each use [4, 6, 19, 25]. In fact, a study reported that, of HCW using EHFR respirators, while >90% reported their respirator as "clean," only 52% disinfected according to guidelines provided, and only 9% cleaned them with soap and water prior to disinfecting, per manufacturer's recommendations [13]. This indicates that the EHFR respirator may instead become a fomite, potentially spreading the infection it is meant to prevent.

One theoretical benefit of cloth masks over disposable face masks and respirators is their reusability (and therefore, affordability). Many of these masks claim to be reusable, though the ones with higher filtration abilities require disposable filters to be continually replaced. New reusable mask designs have been proposed to help meet such demands. One group recently developed a washable nanofiber mask, claiming the mask to be fully washable. However, while better than most available cloth masks, it filters only 80% of 0.6 micron particles [1, 24]. To adequately protect against viruses as small as SARS-CoV-2, a mask should filter to at least 0.3 microns. In addition, there is no data on fit testing. Another mask now available on the market is the O2 Nano Mask. This mask is also washable, but requires a filter replacement. It claims to filter >99% of particles, but such particles are 2.5 microns or greater [26]. It does not report how well it filters down to 0.3 microns, making it less reliable as protection against SARS-CoV-2. The O2 Nano mask does not provide fit testing data, either. Prior to the current pandemic, a plastic mask was developed, referred to as the Tobobo mask. It is a plastic mask that is trimmed to the person's face shape that can filter down to 0.3 microns via a replaceable HEPA filter. A published study on this mask suggests fit testing be required since only 73% of its subjects passed a fit test after reporting a good seal [3]. In addition, the same study suggested further testing be performed across other races, as face shape varies significantly between different ethnic groups. A couple other published studies report recent development of reusable 3D masks with better filtration [27, 32]. However, these masks have not yet been fit tested. In addition, reports show they not only require disposable components, but also potential for skin lesions along the nose with prolonged use.

In summary, research shows that while there are several promising candidates for a reusable respirator, they each have drawbacks, making them a less favorable candidate for use during pandemics and respirator shortages.

RESEARCH IDEA/PRIMARY STUDY AIM:

With this need in mind, the primary investigator, Dr. Nordell, has developed a machine-washable mask which shows potential to be significantly more effective than other masks on the market. The Nordell mask uses a fabric that is machine washable, without need for a filter or replaceable component. This fabric, Evolon-100 or E-100, is a microfilament fabric produced by a private company outside of the USA (and is therefore not yet FDA approved) [12]. Review of current literature shows only one published report using this material, and it was for constructing a wearable health monitoring device with fabric electrode conduction [17].

Unofficial data shows the Nordell mask passes the N95 fit test before and after multiple washes on the majority of individuals tested, and the material used in the design filters 93-96% of 0.3 micron particles. For reference, the N95 mask used in the hospital (whenever concern for potential exposure to COVID-19 or similar contagion exists) filters 95% of 0.3 micron particles when factoring in air leak, assessed with the "fit test." Voluntary survey of users also shows it is more comfortable than other masks, including the N95, and the mask is also reported to be breathable even after prolonged use.

The Nordell mask design addresses every factor in respirator design [25]. The design intentionally used a pleat design to increase the effective mask surface area while decreasing the seal perimeter, resulting in increased air flow, lower pressure drop, and increased filtration efficiency [18]. We propose that it has a higher filtration ability than other washable fabrics tested, filtering at least 93% of 0.3 micron particles. It also helps prevent air leak, a large factor limiting efficacy of most non-standard masks. It is easy to don and doff, and it is very easy to clean and disinfect. This material can be washed multiple times in a standard washing machine without reducing its effectiveness. And finally, it is very affordable, with materials for one mask costing less than $1.50. All materials used beyond this specific fabric are easily purchased on the internet or in a fabric store.

My mask design (and design subtypes) will be formally tested to determine both their filtration ability as well as their ability to reduce air leak around the mask. Filtration will be tested using a particle counter that detects particles down to 0.3 microns. Specifically, we will be using the Grainger 23V750 particle counter. Ambient air testing will be completed to determine baseline comparison [2]. At least 8 measurements of each subtype will be performed to assure statistical significance [2]. Filtration will be tested against ambient air as well as in front of forced air from a stationary fan. Air speed will be measured with an anemometer and compared to average speeds reported for coughing and forced exhalation: human ventilation at rest is about 6 LPM, while increased several fold with activity [21, 37]. Of note, we will also test subtypes with one layer of E-100 fabric with an overlying decorative cotton layer, as the general public appears more compliant with personalized mask styles, and therefore would potentially prefer this alternative when comparing style versus function.

To determine the best method for washing/decontamination, we will test masks prior to washing as well as at various settings on a standard washing machine (see specific subtypes below). This data will then be compared to that of our standard medical grade N95 mask as well as to standard hospital grade surgical masks. I will also compare it to the more common non-medical masks currently being produced for the general population. We will determine breathability and comfort via a questionnaire given to a group of voluntary health care workers.

For fit testing, we will use the standard method used for N95 fit testing at Mayo Clinic – qualitative fit testing. We will recruit at least 40 MCHS HCW volunteers, allowing for improved statistical significance [37]. Demographics will be recorded including: sex, race, age, occupation, BMI, smoking status, and facial characteristics [36, 39]. Inclusion criteria will be passing an N95 fit test within the past year. Exclusion criteria will include history of uncontrolled asthma, pneumonia, or hypertension, recent respiratory illness within the prior 2 weeks, as well as presence of facial hair, specifically a beard. Facial hair is a known interference with adequate respirator fit, and therefore a contraindication [1]. Consent will be obtained at least verbally, as this is a minimal risk project without need to review patient records. Statistical analysis will then be completed.

The same recruited volunteers will also complete an electronic survey, rating comfort, communicability, sense of protection, perceived resistance to breathing (see below). Statistical analysis will then be completed on this data.

[redacted]

<u>Nordell mask design subtypes for filtration testing, fit-testing, and subjective questionnaire (breathability and comfort)</u>

<u>PART ONE - FILTRATION</u>

**Note: all masks that are washed will be washed with gentle soap, specifically All Free & Clear with Oxi. No liquid fabric softener will be used. No fabric softener.*

1) Double layer E-100, adult, after washing in machine 50 times, normal dryer temp until dry
    a. Sanitize cycle
        i. Ambient air
    b. If decreased filtration from baseline, will try Cold water, delicate cycle, air dry
        i. Ambient air
2) Single layer E-100 plus cotton print, adult, after washing in machine 50 times, normal dryer temp
    a. Sanitize cycle
        i. Ambient air
    b. If decreased filtration from baseline, will try Cold water, delicate cycle, air dry
        i. Ambient air
3) Double layer cotton mask washed 10x
4) Blue surgical mask available online and in stores, unused
5) Purple surgical mask provided by MCHS-Mankato to employees and patients, unused
6) KN95 available in stores and online, unused
7) NIOSH-approved 3M N95, unused

<u>PART TWO – FIT TESTING/AIR LEAK</u>

<u>Ideal demographics for voluntary subjects</u>:

1) Health care worker having passed N95 fit test within the past year
2) No recent history of hypertension, pneumonia, or uncontrolled asthma

3) No facial hair, specifically no beard
4) No respiratory illness within the 2 weeks prior to testing
5) Not pregnant
6) Both genders
7) Wide range of ages 18+
8) Wide representation of race/ethnicity
9) Spectrum of occupations (i.e. physician, RN, RT, etc)
10) Wide range of BMI (will ask for height and weight to calculate BMI)

<u>Qualitative fit testing</u>: [39]
Will perform exact procedure used at MCHS-Mankato for annual N95 fit testing for HCW personnel.
For each subject:

1) Don N95, perform user seal check, wait 5 minutes.
2) Perform fit test with N95 control using Bitrix solution:
    a. Normal breathing
    b. Deep breathing
    c. Turn head side to side
    d. Turn head up and down
    e. Talking
    f. Grimacing
    g. Bending over
    h. Normal breathing again
3) If fails N95 fit test, still proceed.
    a. Will allow for collection of data comparing if fit of Nordell mask is better than fit with N95.
4) Wait at least 5 minutes, and until no taste of Bitrix.
5) Don Nordell mask (ideally the mask after being washed 50 times on sanitize cycle), perform user seal check, wait 5 minutes.
6) Perform fit test with Nordell mask using Bitrix solution:
    a. Normal breathing
    b. Deep breathing
    c. Turn head side to side
    d. Turn head up and down
    e. Talking
    f. Grimacing
    g. Bending over
    h. Normal breathing again
7) Wait at least 5 minutes, and until no taste of Bitrix.
8) Perform 2nd fit test with N95 control using Bitrix solution:
    a. Normal breathing
    b. Deep breathing
    c. Turn head side to side
    d. Turn head up and down
    e. Talking
    f. Grimacing

   g. Bending over
   h. Normal breathing again

9) Wait at least 5 minutes, and until no taste of Bitrix.
10) Perform 3rd fit test with N95 control using Bitrix solution:
   a. Normal breathing
   b. Deep breathing
   c. Turn head side to side
   d. Turn head up and down
   e. Talking
   f. Grimacing
   g. Bending over
   h. Normal breathing again

PART THREE – COMFORT AND BREATHABILITY

Questionnaire components:

1) Smoking status
2) Height and weight
3) Rate comfort on a scale from 1-5
4) Rate communicability on a scale from 1-5
5) Rate sense of protection on a scale from 1-5
6) Rate perceived resistance to breathing on a scale from 1-5
7) Determine preferred mask – Nordell mask vs N95 vs others

Upon completion of my research, we hope to demonstrate that the Nordell mask is a superior alternative in multiple settings, including hospitals in developing countries with little or no N95 mask access, non-hospital settings such as nursing homes (where there has been a significantly higher rate of COVID-19 transmission and death), businesses and schools, churches and other religious settings, as well as for other members of the general population, including those with high risk for COVID-related complications.

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