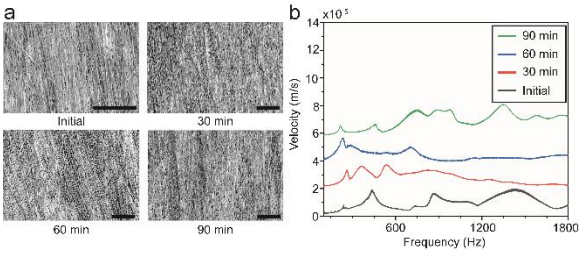
Biodegradable Piezoelectric Surgical Mask | Team Name: PiezoMembrane

Statement of purpose: Due to the rise of the Covid-19 pandemic, we have quickly realized how unprepared we are for a healthcare crisis. As cases for virus grew, the production of the mask was unable to meet the demands of the hospitals and the public. To provide the numerous masks to the public, the FDA Emergency Use Authorization has allowed the FDA to allow unapproved medical products that do not pass the original biocompatibility requirements. This has led to more landfill with plastics that take centuries to decay as well as pollution in or oceans. With our reusable and biodegradable piezoelectric bioactive surgical mask, we can solve these problems and lead a more environmentally friendly future in the mask industry.

Methods: The piezoelectric film, which is used as the filter in the mas, was prepared by electrospinning a 4% w/v solution of PLLA dissolved in a 1:4 mixture of N,N – Dimethylformamide (DMF), and dichloromethane (DCM). The solution is pumped at a constant rate of 2ml/hr through a 21-gauge needle with a 14kV (kilovolts) applied to it. This electrified solution is then sprayed at a grounded aluminum drum rotating at speeds from 500 – 4,500 rpm. This results in a nanofiber mat of PLLA with varying degrees of alignment based on rotating drum speed. These fibrous mats were then annealed at 105°C and 160°C for 10hr and allowed to cool to room temperature. Finally, the films were cut at a 45° angle relative to the oriented direction to harvest the shear piezoelectric signal of the film. The filtering layer is then sandwiched between biodegradable medical polymer layers (PLA, PLGA, etc.), which act as supporting layers by ultrasonic welding and an impulse heat sealer. The ear loops are also made from biodegradable polymers (PLA, PLGA, etc.) and are ultrasonically welded to the respirator. The masks were then tested for reusability using an autoclave by running (3) 30-minute cycles. Our respirators were tested using the TSI8130A instrument under flowrates of 32L/min and 85L/min under NIOSH protocols.

Results: The masks displayed reusability of up to three times after being sterilized (Figure shown). The masks also showed an acceptable pressure drop value: 350 Pa at 85 LPM). The trapping efficiency of the masks is at 91%.

Conclusions: Our PLLA piezoelectric mats have shown 91% trapping efficiency and reusability after 3 sterilization cycles. The piezoelectricity and pores size of the PLLA nanofiber film can be tuned by engineering the electrospinning parameters (e.g., electric field, drum rotation speed), as reported in our previous work[1]. The pressure drop can also be optimized to reach similar levels to N95 masks. Our research with this PLLA piezoelectric mat also shows that after the lifetime of the mask, it can be biodegraded which provides it an edge to current surgical masks.



Technology: Our product is reusable and biodegradable, and we hope to address the rising demand of surgical masks with this product in an environmentally friendly manner. Our mask has 91% filtration efficiency and is effective even after (3) 30-minute autoclave sterilization cycles.

Market: As covid-19 cases continue to increase, the demand for PPE, specifically masks, increases. N95 mask production has increased from 45 million units monthly in January 2020 to 180 million at the end of 2020 (Statista). The face masks market is projected to reach $5.2 billion by 2025 compared to the $3.5 billion in 2019 globally. It is projected to grow to $900 million for North America[2].

Commercialization Strategy: For the first phase of the commercialization, FDA regulation is not needed mas our masks will only be sold to the public and not healthcare settings. After selling our product to the public, we will get FDA approval for our masks and sell directly to hospitals and other medical clinics. Our value propositions are that our surgical masks are reusable and biodegradable. Manufacturing will be done in-house with materials sourced from wholesalers abroad. Main point of sale will be via our online website along with sales representative reaching out to hospitals/clinics for multi-year contracts. As for public sales, a subscription plan will be employed to keep customers coming back. Initial funding for the company will come from SBIR/STTR grants as well as angel and private investors. Exit strategy is to eventually offer an IPO and use our PLLA piezoelectric material to create other filtration and biomaterial products.

References:

1. Curry, Eli J., et al. "Biodegradable nanofiber-based piezoelectric transducer." Proceedings of the National Academy of Sciences 117.1 (2020): 214-220.
2. BCC Publishing Staff. (2021, Feburary). Face Mask Equipment: Global Market Data (Report Code: IAS172A). *BCC Research*. Retrieved Fevburary 13, 2021 from: https://www.bccresearch.com/