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THE PROCESS IMPLEMENTATION OF MICRO MANUFACTURED SLA PRINTED NASOPHARYNGEAL SWABS

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ABSTRACT

We illustrate SLA 3d-printing printing methods to produce COVID-19 nasopharyngeal testing swabs, proving that they can be produced in a manner that is safe and clean for the users. 3D printing is an effective and efficient tool that can be used for a wide variety of applications, especially for a quick turn around in response to a shortage, and specifically for this application, this method was created in response to the swab shortage in early summer 2020.

Keywords: COVID-19, NP Swabs, 3D Printing

1. INTRODUCTION

According to the U.S. Center for Disease Control (CDC) there have been over 180 million reported tests for SARS-CoV-2 (COVID-19) as of November 27, 2020 [1]. With the rate of the pandemic increasing, daily testing is also increasing across the country with Minnesota seeing upwards of 50,000 tests per day (11/27/20) [2]. While there are multiple methods of acquiring samples to test for COVID-19, in most cases sample material is collected using a nasopharyngeal swab. It is unknown precisely what percentage of current tests are collected using this method, but it can be concluded that the vast majority of the reported tests in Minnesota have been acquired using nasopharyngeal swabs [3].

It is well documented that the COVID-19 pandemic has caused significant supply chain complications, and there were early shortages of nasopharyngeal swabs used for COVID-19 testing especially in early Summer of 2020 [4-5]. To address this concern, designs for 3D printed, biocompatible nasopharyngeal (NP) swabs have been successfully clinically evaluated for use in COVID-19 testing [6-7].

The use of 3D printing for medical applications has become more widespread especially in medical uses, like planning procedures and creating small medical devices [8]. Specifically, stereolithographic printing is commonly used in dentistry to create surgical guides to place an implant, patterns for casting, full dentures, and permanent crowns [9-10]. That being said, documentation for micromanufacturing methods of this 3D printed design is lacking.

In this paper, we present a micromanufacturing process for 3D printed nasopharyngeal swabs for use in COVID-19 testing and compare the cost and time against other NP swabs. Our methodology is targeted for universities or small centers who already have access to SLA 3D printing, and they would be able to supply swabs in case of a shortage due to increased testing.

2. MATERIALS AND METHODS

The 3D printed swab design used by our group is the same design presented by Ford, et al [6]. The 3D printing process and development of the micro manufacturing methodology was done by the University of Minnesota (UMN) Earl E. Bakken Medical Devices Center (B-MDC) in conjunction with the UMN 3D Bioprinting Facility.

2.1 Equipment

As presented in work by Ford, et al., we used a Formlabs Form 3B printer to produce batches of the NP swabs. This printer utilizes stereolithography to produce parts from a large number of various polymer resin bases. For our purposes, we used the Formlabs Surgical Guide resin which is autoclavable and biocompatible [11]. Additionally, we used the Form Wash and Form Cure machines which are integral pieces of post processing methodology. We also used a standard biosafety cabinet and autoclave for final packaging and cleaning. Lastly, a MTS Criterion Universal Tester was used for performing the three point flex test.

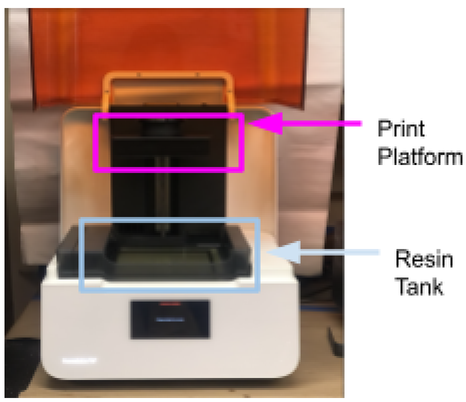

FIGURE 1: FORM 3B PRINTER AND ITS COMPONENTS.

2.2 Manufacturing Processes

To ensure patient safety and usability, two main goals were identified and met throughout the manufacturing process. First, the swabs were to be clear of debris. Second, the swabs were to be sterile. These goals were set to ensure safety of the patient during the nasal swab test.

2.2.1 Swabs Clear of Debris

To ensure a swab was clear of debris, a sterile environment was created for this manufacturing process. The Form printers were moved to a separate lab where hair nets, masks, and gloves were required before entering. Eating and drinking was not allowed in this lab. Often, 3D printers were in an environment that is high-traffic and not meant for sterile manufacturing, so it was important to create clean conditions for this process. Additionally, the Form Wash and Form Cure machines were also placed inside this lab. After the swabs are printed on the Form 3B printer, the swabs are moved to the Form Wash machine. The Form Wash machine stirs Isopropyl Alcohol (IPA) to dissolve uncured resin as well as remove any debris from the swabs. After the Form Wash step, the swabs are placed in a holding rack (also made from surgical guide) and then placed in the Form Cure machine or the curing step of the process.

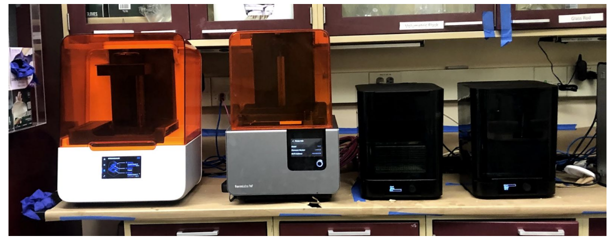

FIGURE 2: PRINTING SET UP. FROM LEFT TO RIGHT: FORM 3B PRINTER, FORM 2 PRINTER, FORM WASH, AND FORM CURE.

2.2.2 Sterility of Swabs

The swabs were then packaged in autoclavable pouches from PlastCare USA, following standard biosafety cabinet procedures. At this step, each swab passed its first quality control check point. They were each inspected by the naked eye before packaging for any deformities such as debris on the swab, excessive bend (>10 degrees of bend), cracks, misprints, flash on shaft/handle, or tacky finish. To ensure the sterility of the swabs, the swabs were autoclaved 121°C, 14 psi, for 15 minutes. Autoclaving was completed at the glasswashing core facility of the Masonic Cancer Research Building at the University of Minnesota.

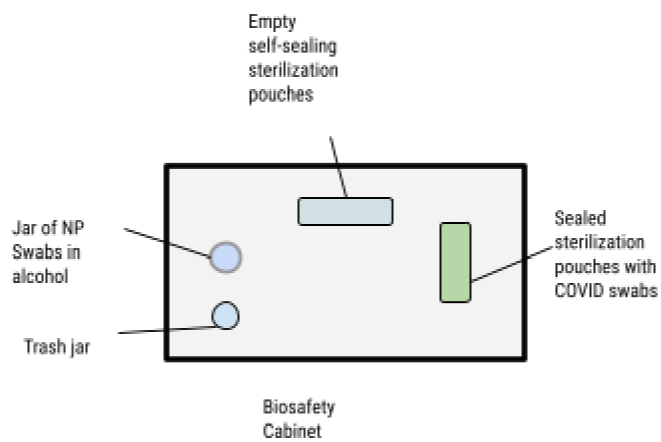

FIGURE 3: BIOSAFETY CABINET SET UP.

FIGURE 4: INDIVIDUAL AUTOCLAVE POUCHES.

To manufacture the swabs, the following steps were taken. After every step was completed, it was dated in a production batch number form to keep track of each batch of swabs produced. If any swabs were unusable, a note was made in the production batch number form.

1. *Print the swabs:* Load the swab STL file onto Preform, and make sure that the special "SG Covid Swab" setting is on. Send it to the Form 3B printer, and print. Make a note of completion on the production batch number form.
2. *Wash the swabs:* Once the print is complete, move the swabs (while still on the print platform) onto the Form Wash. Turn on the wash for 20 minutes. Make a note of completion on the production batch number form.
3. *Cure the swabs:* After the wash step is complete, remove the swabs from the print platform, and place them onto the curing rack. Place the cure rack inside the Form Cure, and cure at 70°C for 30 min. Make a note of this on the production batch number form.
    a. Set aside three swabs after this step for the three point flex test.
4. *Package and Autoclave Swabs:* After curing all the swabs, individually package the swabs into the autoclave pouches. While packaging, the swabs were individually checked, by the naked eye, for any deformations. Autoclave the swabs. Make a note of this on the production batch number form.

3. RESULTS AND DISCUSSION

For the three point flex test, the MTS Universal Tester applies a load, and then measures the extension of the swab. The swabs were extremely elastic, so it allowed for high deformation. Often the swabs would bend so far that the ends of the swab would touch the upper supports, which indicated the end of the test.

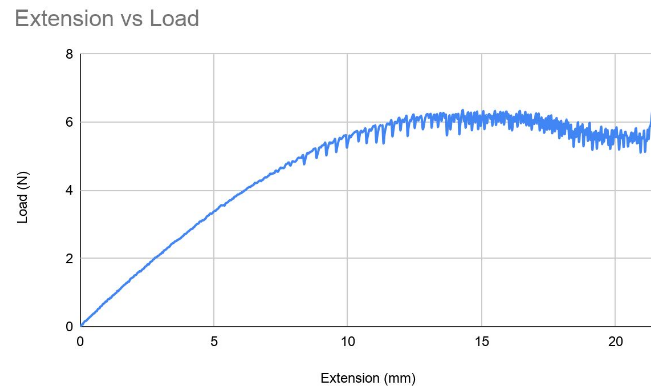

FIGURE 5: GRAPH OF EXTENSION OF THE SWABS VS LOAD.

Above is a graph of extension vs load of a swab on the three point flex test. Ultimate stress is the maximum load the swab can withstand before necking. The graph shows a max load of about 6.2 N. Further work will be able to determine upper and lower bounds of the 3 point bend test.

All of the materials and machine time per batch of swabs are priced below. Each batch prints 342 swabs.

Materials - Swabs	Cost	Cost/Swab Batch
Surgical Guide	$249.00	$15.56
Tank 3B	$149.00	$2.33
IPA (wash)	$298.70	$16.24
Self Sealing Auoclave Baggi	$15.49	$26.33
Materials - Curing Jigs	**Cost**	**Cost/Swab Batch**
Form 2 TL Tank	$99.00	$26.40
Surgical Guide	$249.00	$28.22
IPA (wash)	$298.70	$34.33
Machine time	**Cost**	**Cost/Swab Batch**
Form 3B	$3,999.00	$35.20
Form 2	$3,500.00	$18.67
Wash	$499.00	$4.80
Cure (swabs)	$699.00	$14.00
Cure (rack and stand)	$699.00	$4.48
Total		Per Swab Batch
Materials	$10,754.89	$226.57
Number of swabs per batch		349
Material Cost per swab		**$0.65**

FIGURE 6: TABLE OF THE COSTS OF THE MATERIALS TO BUILD THE SWABS.

Each swab costs $0.65, the labor to create one batch of swab amounts to three hours, and there is machine time of about 12 hours. There are not much data on the supply chain of NP swabs and how the demand impacted the pricing of the swabs in spring of 2020, however, as of February 2021, the market has caught up to the demand, and 500 NP swabs for $169.00 (about $0.34 per swab) can be ordered on Amazon.

4. CONCLUSION

Our micromanufacturing methodology done within the B-MDC shows that it is feasible for dentistry clinics or universities to 3D print their own NP swabs in response to a national shortage. While we recognize that there is likely no cost saving to the micromanufacturing process, we believe that our setup provides a safe, reliable, feasible alternative in the event of supply chain issues with traditional NP swabs. It is possible to ensure a high quality print and safe use by choosing a safe material, ensuring a clean work environment, and keeping clear documentation of the batches.

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REFERENCES

[1] "CDC COVID Data Tracker," Center for Disease Control, 2020. [Online]. Available: https://covid.cdc.gov/covid-data-tracker/#testing_positivity7day. [Accessed: 30-Nov-2020].

[2] "Daily Testing Trends in the US - Johns Hopkins," Johns Hopkins, 2020. [Online]. Available: https://coronavirus.jhu.edu/testing/individual-states. [Accessed: 25-Nov-2020].

[3] C. Richert, "Coronavirus Testing Delays Fueled By Swab Shortage : Shots - Health News : NPR," Minnesota Public Radio, 2020. [Online]. Available: https://www.npr.org/sections/health-shots/2020/03/18/817801222/testing-swabs-run-in-short-supply-as-makers-try-to-speed-up-production. [Accessed: 30-Nov-2020].

[4] "COVID-19 Supply Chain Issues | CIDRAP," UMN Center for Infectious Disease Research and Policy, 2020. [Online]. Available: https://www.cidrap.umn.edu/covid-19/supply-chain-issues. [Accessed: 30-Nov-2020].

[5] S. Pfeiffer, M. Anderson, and B. Van Woerkom, "Why Is There A Coronavirus Test Shortage? One Reason: We Don't Have Enough Swabs : NPR," National Public Radio, 2020. [Online]. Available: https://www.npr.org/2020/05/12/853930147/despite-early-warnings-u-s-took-months-to-expand-swab-production-for-covid-19-te. [Accessed: 30-Nov-2020].

[6] J. Ford, T. Goldstein, S. Trahan, A. Neuwirth, K. Tatoris, and S. Decker, "A 3D-printed nasopharyngeal swab for COVID-19 diagnostic testing," 3D Print. Med., vol. 6, no. 1, p. 21, Dec. 2020.

[7] S. J. Decker et al., "3D Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for COVID-19 testing," Clin. Infect. Dis., Sep. 2020.

[8] Aimar, Anna, et al. "The Role of 3D Printing in Medical Applications: A State of the Art." Molecular Biotechnology, vol. 3, no. 1, 2019 Mar. 2021, doi:10.1155/2019/5340616.

[9] Whitley D 3rd, Eidson RS, Rudek I, Bencharit S. In-office fabrication of dental implant surgical guides using desktop stereolithographic printing and implant treatment planning software: A clinical report. J Prosthet Dent. 2017 Sep;118(3):256-263. doi: 10.1016/j.prosdent.2016.10.017. Epub 2017 Feb 20. PMID: 28222882.

[10] "Form 3B: Industrial-Quality Dental 3D Printer." *Formlabs*, dental.formlabs.com/products/form-3b/.

[11] "Using Surgical Guide Resin Form 3B." *Form Labs*, Formlabs , support.formlabs.com/s/article/Using-Surgical-Guide-Resin?language=en_US.