Design of a 'Go / No-Go' Gauge to Qualitatively Assess Nasal Swab Maneuverability & Flexibility

Purpose

The Veterans Health Administration (in conjunction with the 'Covid-19 Rapid Response MoU Team') is evaluating the safety and functionality of a variety of commercially available 3D printed nasopharyngeal (NP) swabs for their use in acquiring samples to test for the SARS-CoV-2 virus. As part of our risk assessment, we are considering bending flexibility and general maneuverability to be important factors in whether the swab can safely reach the sampling location without breaking. The 'Go / No-Go' gauge was created to complement the more quantitative results from the mechanical bending test and dimensional analysis report and provide a 'sanity check' that the swab has appropriate geometric and mechanical characteristics to meet this requirement. The gauge is <u>not</u> intended to be an absolute indicator for the safety of a swab, but rather to provide feedback on the swab design's mechanical & dimensional properties in a form that is more obviously related to its clinical application than a mechanical testing machine. Data obtained from the gauge is intended to be followed up with a formal clinical trial during less critical times to establish safety and efficacy more rigorously.

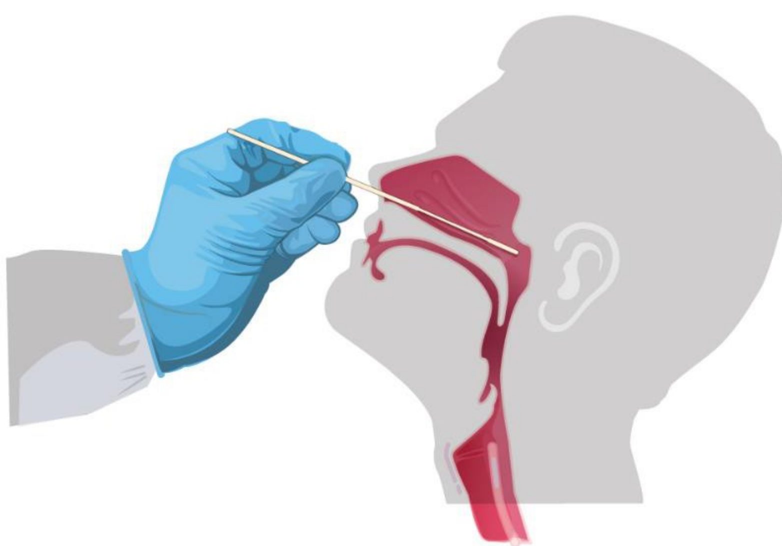

Figure 1: Swab at the Nasopharyngeal Sampling Site (cdc.gov)

Methods

Design Goals and Scope

Our main concern in designing a gauge to assess the ability of nasal swabs to safely reach an intended sampling site was to make the design complex enough to be representative of a nasal cavity, but not overly specific to any one person's nasal geometry or needlessly complicated. Another consideration was that the gauge should be easily reproduced without highly specialized equipment so that the model could be made publicly available for community use and continued feedback.

It was decided that the gauge should adhere realistically to the anatomical geometry of the nasal cavity. Although the ideal gauge would match a human nasal cavity in both geometry and tissue characteristics, the latter was decided to be too time and resource-intensive given the complexity of matching the mechanical properties of tissue, cartilage, and bone, and the current limitations of fabrication technologies most commonly at hand. Therefore, we decided to design the gauge to be 3D printed from an easily accessible rigid material, with the intention that it could be more widely utilized if made publicly available while retaining the necessary geometric complexity.

Nasal Cavity Geometric Analysis

An attempt was made to consider the mechanical constraints of a nasal cavity with a deviated septum or otherwise uncommon geometry while not being so difficult to pass through that it was unrepresentative of a typical case. This was achieved in two ways. To characterize the geometry of a 'standard' nasal cavity, existing data from a 2020 Nature Scientific Reports paper was utilized (Brüning et al., 2020). In this work, a statistically averaged geometry of the nasal cavity was calculated based on CT data from 25 subjects, and an .stl surface model of the averaged geometry was made publicly available under a Creative Commons Attribution License.

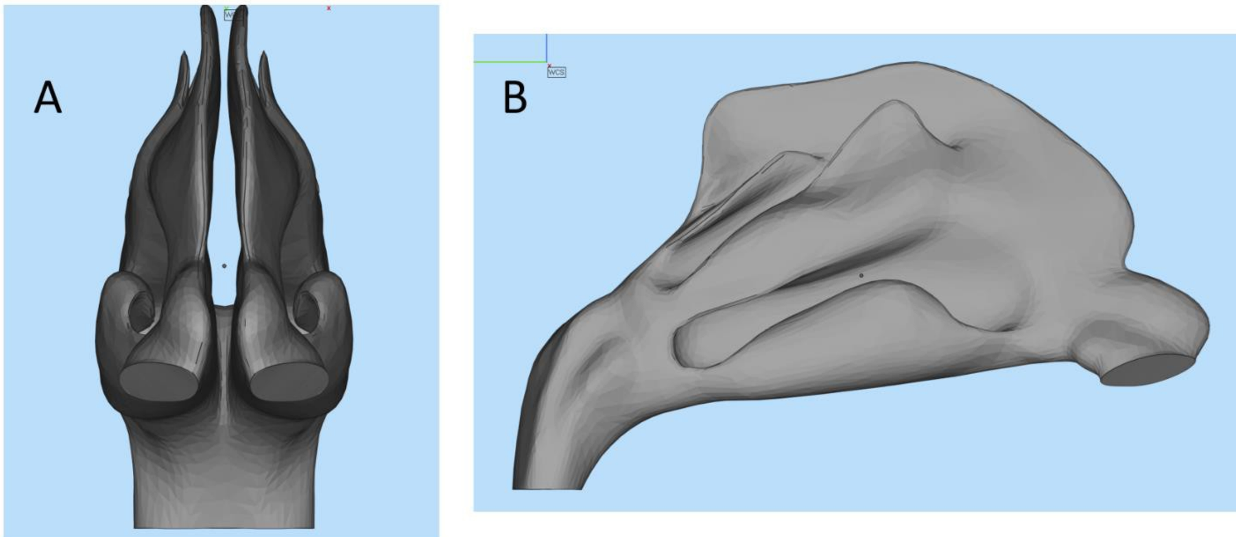

Figure 2: Anterior (A) and Lateral (B) Views of Geometrically Averaged Surface Model by Brüning et al.

To assess a ‘worst-case’ geometry for navigating a swab to the NP sampling site, local CT data was gathered from four subjects. Nasal cavities were segmented and split symmetrically into eight (left and right) cavities. Each section was then 3D printed in a rigid transparent material using polyjet technology.

A wire was used to trace the approximate path a nasopharyngeal swab would take to reach the NP sampling site. A worst-case and best-case bending scenario was chosen from the eight nasal cavity samples by first maximizing, and then minimizing, the bend curvature represented by the wire in each of the eight nasal cavity models. A digital image was captured for each scenario, along with a grid to provide a scaling reference. This facilitated transferring the wire course from each of the worst-case and best-case bending scenarios into a digital representation.

The images of each section were imported into SOLIDWORKS and scaled according to the reference length on the grid. A curve, based on a circular arc tangent to two straight lines, was then drawn to closely match the path of the wire, from which the radius and angle of curvature were extracted, as shown in Figure 3.

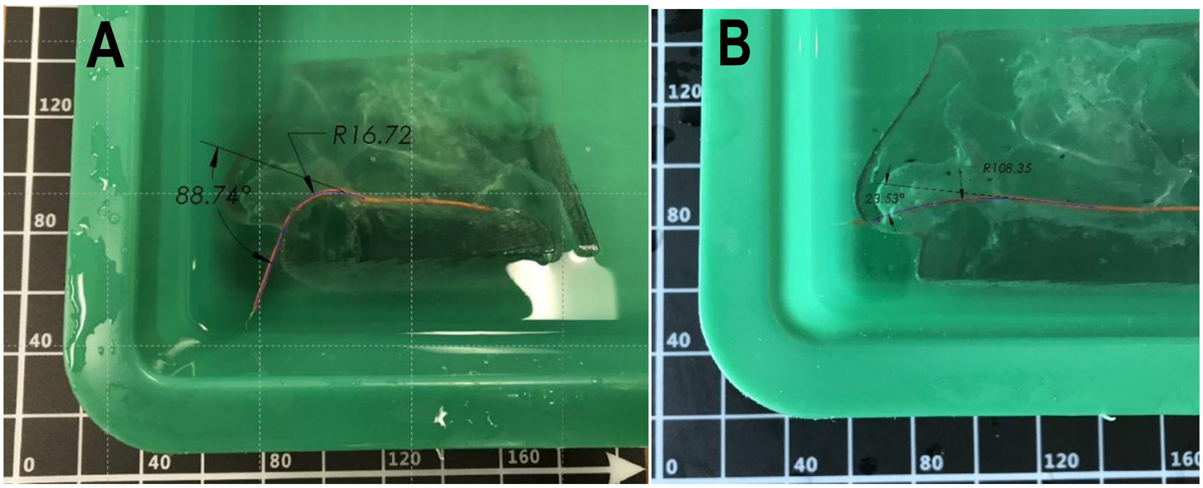

Figure 3: 3D Printed Nasal Cavity with Wire Inserted Mimicking (A) the Worst-Case Curvature and (B) the Best-Case Curvature Required to Reach the Nasopharynx

The results of analyzing the eight sections are shown in Table 1.

Table 1:

Path Traced	Mean Angle of Curvature (deg)	Mean Radius of Curvature (mm)
Worst-Case	74 ± 14	15 ± 3
Best-Case	22 ± 9	80 ± 60

Design Process

Ultimately, the final model synthesized a hybrid of the geometrically averaged model by Brüning et al., worst-case results found from the 3D printed nasal cavity models, as well as feedback from test swabbers and clinical experts with direct clinical experience in nasal swabbing for Covid-19.

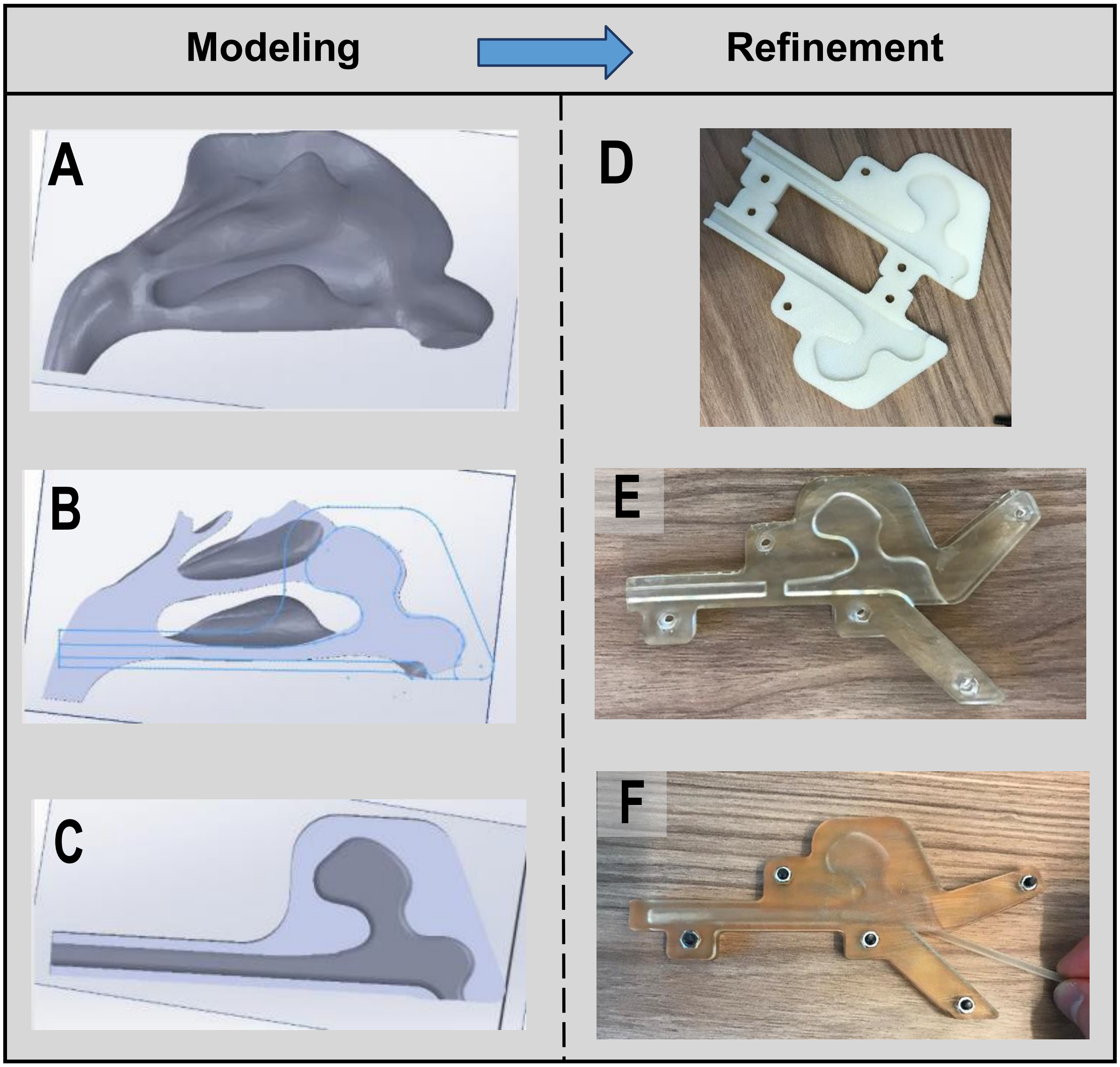

Figure 4: Schematic Depicting Development of the 'Go No-Go Gauge' Design

The design process is detailed in Figure 4. Sagittal cut planes were taken of the Brüning et al. *(4A)* model until an outline of the cavity could be sketched in SOLIDWORKS. Some adaptations were made in the entry region to account for results from the worst-case bending scenario test, creating a curvature angle of 90° with a radius of 12 mm *(4B)*, although the bend angle was later decreased as it was perceived as too unrealistic by test swabbers. Because of the natural compliance of tissue in the nasal cavity, the diameter of the channel below the inferior turbinate needed to be widened to reflect that tissue will deflect when the nasal swab is inserted. Based on feedback from test swabbers, a diameter of 5 mm was ultimately chosen *(4C)*. Because it is often difficult to clean support material when 3D printing narrow internal geometries, the model was printed in halves with holes so that the halves could be held together with M3- sized fasteners or glue. With this addition, the separate sections can be rapidly printed flat on the print bed of FDM or SLA-type printers with little to no support required *(4D)*. Feedback from experienced test swabbers indicated that the gauge was too difficult to be realistic. To address this concern, the nostril opening was widened considerably, and the angle of curvature was substantially reduced from 90° to 45°. Another point of feedback was that the bending of the swab occurred most severely before entering deep into the nasal cavity and could be exacerbated by the angle the swabber is approaching at. Typical protocols call for the patient to sit in a chair and tilt their head back 70º; however, this protocol could not always be achieved if, for instance, the patient was seated inside a tall vehicle during the procedure, with the swabber reaching through the window. For this reason, flanges were added as indicators that the swab could enter the patient's nose from a reasonably achievable range of angles. Additionally, blockages were created to make two separate gauges, one which indicated the NP sampling site, and the other which indicated the mid-turbinate (MT) site *(4E)*. Additional testing and feedback found the upper flange to cause an unreasonably severe bending angle, so the angle was decreased from 45° from horizontal to 10° from horizontal *(4F)*.

References

Brüning, J., Hildebrandt, T., Heppt, W., Schmidt, N., Lamecker, H., Szengel, A., Amiridze, N., Ramm, H., Bindernagel, M., Zachow, S., & Goubergrits, L. (2020). Characterization of the Airflow within an Average Geometry of the Healthy Human Nasal Cavity. *Scientific Reports*, *10*(1), 3755. https://doi.org/10.1038/s41598-020-60755-3

Callahan, C. J., Lee, R., Zulauf, K. E., Tamburello, L., Smith, K. P., Previtera, J., Cheng, A., Green, A., Azim, A. A., Yano, A., Doraiswami, N., Kirby, J. E., & Arnaout, R. A. (2020). Open Development and Clinical Validation Of Multiple 3D-Printed Nasopharyngeal Collection Swabs: Rapid Resolution of a Critical COVID-19 Testing Bottleneck. *Journal of Clinical Microbiology*, JCM.00876-20. https://doi.org/10.1128/JCM.00876-20