

Summary of Nasal Swab Maneuverability & Flexibility ‘Go/No-Go’ Gauge

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Background

Nasopharyngeal (NP) swabs are an important part of the diagnostic testing procedures for the SARS-CoV-2 virus which causes the current pandemic Coronavirus disease (COVID-19). The expanded demand for testing has increased the need for swabs and 3D printing has emerged as a method to meet the demand. There are a variety of 3D printed swabs currently available with different designs and printing methods. Veterans Health Administration (VHA) is evaluating the safety and functionality of a variety of commercially available 3D printed NP swabs for their use in acquiring samples for Covid-19 diagnostic tests.

Purpose

This protocol assesses the bending flexibility and general maneuverability of the swabs. In ideal clinical and anatomical conditions there is limited bending required to perform a swab; however, there is an expected amount of bending for the swab when used during typical clinical procedures. Due to the depth of insertion into the nose, a broken swab could cause serious injury to the patient and require significant additional resources to extract the broken piece(s). A simple ‘Go / No-Go’ gauge test was devised to provide a quick check for swabs to ensure they have the required geometric and mechanical characteristics to perform their intended function. The gauge is not intended to be an absolute indicator of a safe or unsafe sampling swab. Rather, it is meant to provide feedback on the swab design’s mechanical properties in a form that more directly simulates its clinical application (compared to lab bench testing). These data will supplement additional quantitative mechanical bending tests performed by VHA laboratories. Data obtained from the gauge is intended to be followed up with a formal clinical trial to establish safety and efficacy more rigorously.

Summary

Computed tomography (CT) models of 5 subjects and data from scientific literature (Brüning et al., 2020) were used to establish a worst-case bend in the nasal cavity. This was designed, optimized and replicated in 3D printable form. The gauge can be used by inserting the NP swab fully, then bending the handle downwards to touch the bottom flange and upwards to touch the top flange. Swabs that break during this test do not meet the criteria for use in patients.

