

3-D printed nasal swabs work as well as commercial swabs for COVID-19 diagnostic testing

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First author Summer Decker, PhD, directs the USF Health Radiology-Tampa General Hospital Division of 3D Clinical Applications, which creates and prints 3D anatomical models for surgeons and other clinicians and designs medical devices. Credit: USF HealthlUniversity of South Florida



As COVID-19 quickly spread worldwide this spring, shortages of supplies, including the nasopharyngeal (nasal) swabs used to collect viral samples, limited diagnostic testing.

Now, a multisite clinical trial led by the University of South Florida Health (USF Health) Morsani College of Medicine and its primary hospital affiliate Tampa General Hospital (TGH) provides the first evidence that 3-D-printed alternative nasal swabs work as well, and safely, as the standard synthetic flocked nasal swabs.

The results were published online Sept. 10 in *Clinical Infectious Diseases*. A commentary accompanying the paper cites the authors' timely, collaborative response to supply chain disruptions affecting testing capacity early in the pandemic.

Seeking a solution to an unprecedented demand for nasal swabs at their own institution and others, USF Health researchers in the Departments of Radiology and Infectious Diseases reached out to colleagues at TGH; Northwell Health, New York's largest health care provider; and leading 3-D-printer manufacturer Formlabs. Working around the clock, this multidisciplinary team rapidly designed, tested and produced a 3-D printed nasal swab prototype as a replacement for commercially-made flocked <u>nasal swabs</u>. Bench testing (24-hour, 3-day, and leeching) using <u>respiratory syncytial virus</u> as a proxy for SARS-CoV-2, as well as local clinical validation of the final prototype (fabricated with FDA-approved nontoxic, surgical grade materials), was successfully completed in mid-March 2020.

The larger-scale clinical trial began in late March at three sites: TGH, Northwell Health, and Philadelphia-based Thomas Jefferson University Hospital. (Other sites joined later.)

Although USF Health held a provisional patent on the concept and



design of the new 3-D printed swab, they freely shared the information with hospitals, clinics, governments and international agencies experiencing supply chain shortages. Since the first batches of 3-D printed swabs were processed, tens of millions of the USF Healthinvented devices have been used in 22 countries, said lead author Summer Decker, Ph.D., an associate professor of radiology at the USF Health Morsani College of Medicine. Dr. Decker directs the USF Health Radiology-TGH Division of 3-D Clinical Applications, a group with expertise in creating and printing 3-D anatomical models for surgeons and other clinicians as well as designing medical devices.

"In the midst of a pandemic, our team of experts representing academic medicine, health care delivery systems, and the medical device industry put aside boundaries to quickly work together toward a common purpose," Dr. Decker said. "It's rewarding that the novel design for a 3-D swab we created has been adopted around the world, equipping more providers to diagnose COVID-19 and hopefully help prevent its spread."





The 3D printed nasal swabs invented by USF Health to address COVID-19 diagnostic testing shortages are in use around the world. The swabs were specifically designed for patients using FDA-approved surgical grade material. Credit: USF HealthlUniversity of South Florida

The gold standard for diagnosing respiratory infections is to look for viral genetic material found in mucosal fluid collected with a long, slender swab inserted into the patient's nose and back of the throat. The nasal swab is put into a plastic tube with chemicals that stabilize the sample until the virus-specific genetic material can be extracted and amplified by polymerase chain reaction (PCR) in a diagnostics laboratory. Conventional swabs feature a bushy tip coated with nylon



flock; the USF Health doctors designed a tip with a 3-D printed textured pattern able to capture a sufficient sample for COVID testing while keeping patient safety and comfort in mind.

The clinical trial fully tested the safety and effectiveness of this 3-D printed swab in 291 symptomatic adults undergoing COVID-19 screening at the TGH, Northwell Health and Thomas Jefferson University Hospital sites. The 3-D printed nasal swab was compared to the standard synthetic nasal swab across three SARS-CoV-2 testing platforms FDA-authorized for emergency use—a modified version of the Center for Disease Control and Prevention's real-time reverse transcriptase PCR diagnostic panel, and two commercial molecular diagnostic tests.

"This trial provided the first rigorous head-to-head comparison to make sure that the 3-D swab performed as well as the standard," said principal investigator Kami Kim, MD, professor and division director for infectious disease at the USF Health Morsani College of Medicine. "Across all three platforms used in our study, we demonstrated that the commercial swab and the 3-D printed swab were comparable for accurate detection of COVID-19 infection."

For both swabs, the only adverse patient reaction documented during the trial was a few instances of slight nasal bleeding. The cost of materials per 3-D printed nasal swab ranges from 26-to 46-cents, while commercial swabs cost about \$1 each, the authors reported.

Given the ongoing need for widespread COVID-19 testing, the study authors concluded that 3-D printing technology offers a viable, costefficient option to address swab supply shortages, particularly when local hospitals or other clinical sites already have 3-D printing labs equipped to print and process the devices.



Frank Rybicki, MD, Ph.D., vice chair of operations and quality at the University of Cincinnati College of Medicine's Department of Radiology, wrote a commentary on 3-D printing in medicine to accompany the *Clinical Infectious Diseases* paper. The article frames the contributions of Decker et. al. in the context of the larger 3-D manufacturing community.

"Among all parts 3-D printed during COVID-19, nasopharyngeal swabs have received the most attention, with participants ranging from humanitarians to charlatans," Dr. Rybicki wrote in his summary. "The authors should be congratulated for staying on the right side of the curve, and for their perseverance, leadership, scientific rigor, and good will."

More information: Summer J Decker et al, 3D Printed Alternative to the Standard Synthetic Flocked Nasopharyngeal Swabs Used for COVID-19 testing, *Clinical Infectious Diseases* (2020). DOI: 10.1093/cid/ciaa1366

Provided by University of South Florida

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