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DEVELOPMENT OF AN OROPHARYNGEAL SWAB ASSEMBLY

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ABSTRACT

Oropharyngeal (OP) swabbing is a clinical specimen collection method to diagnose the presence of viral infection in the respiratory tract. During the Covid-19 pandemic, OP swab sampling plays an important role in the disease diagnosis. With its advantages in direct visualization of the swab site and less training requirement on medical professionals, OP swab is massively used for COVID-19 specimen collection in many countries. However, patients may demonstrate less tolerance for the OP swabbing by gagging or closing their mouths, which puts the swab tip in contact with the oral palate or tongue and results in defective sampling. Gagging and other involuntary reactions increase the risk to medical workers who are in direct contact with the patients. To solve these issues, this research presents a novel OP swab assembly which can assist adult patients to collect OP swab specimen by themselves or facilitate adults to collect specimens for their children or disable family members. The OP swab assembly has features to mitigate discomforts in the swab procedures as so to reduce involuntary reactions, minimizing specimen contamination. It also has features to keep the mouth open and constrain the motion of the swab tip in the effective sampling area, furtherly ensuring the high quality of the specimen. Experiments were conducted on a standard adult human skull mannequin by using the presented OP swab assembly. The results demonstrated the feasibility and effectiveness of self-collection for OP swabs using the presented assembly and method.

Keywords: Covid-19, OP swab, self-collected, specimen sampling

1. INTRODUCTION

COVID-19 (coronavirus) pandemic has affected almost all countries around the world, which significantly and negatively impacts all the people's lives [1, 2]. As of mid-November 2020, more than eleven million cases of COVID-19 infections had been reported worldwide, and over 52 million people have died from the disease, causing a devastating disruption to public health, food system and the workforce [3-5]. Lack of effective medication and deployment of vaccine, current control programs mostly rely on a combination of massive testing, quarantine, and social distancing [6, 7]. Many researchers indicate that early diagnosis of the disease is important to configure a timely treatment and appropriate infection control. However, although FDA allows more private laboratories to have more flexibility to expand testing platforms, the overall testing capacity remains below the levels needed [8, 9]. Expanding testing capacity faces many barriers, such as supply chain constraints for specimen collection devices, high infection risk to medical professionals, and overload of work for medical professionals doing the specimen collection [10, 12].

Currently, the most common specimen collection methods for the diagnosis of COVID-19 and other respiratory diseases are nasopharyngeal (NP) and oropharyngeal (OP) swabbing. Many researchers found that NP swab specimens are more sensitive than OP swab specimens in COVID-19 diagnosis [13]. However, as a specialized device, the NP swab kit has strict component performance requirements for flexibility, which contributed to shortages and interruptions in the supply chain at the beginning of the pandemic [14]. Moreover, without direct visualization on the swab spot, NP swab highly relies on medical workers' experience and usually creates some unbearable discomforts due to over-insertion. The OP method is relatively convenient for medical professionals to operate because the larger oral cavity allows for visual verification of the sampling site and requires less professional training for medical workers [15]. However, patients may demonstrate less tolerance of the discomforts by gagging or closing their mouths, which puts the swab tip in contact with the oral palate or tongue and results in defective sampling [16]. Gagging and other involuntary patient reactions can create many droplets, increasing the airborne transmission of the disease to medical workers [17, 18].

To address the issues in current specimen collection in COVID-19, engineers and medical workers are making efforts to

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seek solutions. Some added patient plastic mouth shields or used a transparent isolation box during the sampling procedure to protect medical workers [19, 20]. Although these adaptations can reduce the risk of contracting the disease, medical workers remain vulnerable in the contagious environment. Moreover, it still lacks strategies to reduce the contamination of the specimen, increase the quality of the specimen, and minimize patients' discomfort. Rutgers Clinical Genomic Laboratory and Yale School of Public Health have each developed a method to use saliva to test for COVID-19 diagnosis and both obtained an emergency-use authorization from the FDA [21, 22]. However, the methods still need further improvement on the approach of reducing the interference from salivary enzymes in the specimen before they could be used for massive testing [23, 24].

Unlike the above-mentioned strategies, this study presents a novel OP swab assembly, which facilitates the swab tip to accurately reach the targeted swab sites with reduced discomfort, minimized specimen contamination, and enhanced efficiency. With these advantages, adult and teenage patients even can self-collect the specimen at home, and the collection of specimens for children and disabled people can be efficiently and effectively conducted by adult family members who have less or even no medical training. This can significantly reduce medical workers' workload, increase the testing capacity and reduce exposure to the contagious environment. This paper mainly introduces the advanced structure of the OP swab assembly and its functional analysis. Experiments are conducted on a standard human skull mannequin to demonstrate the functionality and effectiveness of the proposed assembly and its operation method.

2. METHOD

With the proposed swab assembly, it is expected the users can do OP swab by themselves without any visualization to the swab sites, making OP swab self-collection feasible and effective. This section will illustrate the design requirements, the structure of the swab assembly, its operation procedure, and the design analysis.

2.1 Design requirements

According to CDC's specimen collection guidelines, the effective site of the OP swab is the posterior pharynx and tonsillar area. In the operation, the swab tip should not touch the tongue, teeth, and gums, avoiding specimen contamination [25-27]; thus, a tongue depressor is usually used to depress the tongue. The current operation is as shown in Figure 1. The posterior pharynx is in an arch shape for a regular adult. Studying these swab procedures inspires us to set the design requirement for the swab. Here we set the target swab site as a circle with 20 mm in diameter as shown in Figure 2. The first requirement is to constrain the swab tip in this circle range, which is approximated to cover most of the posterior pharynx and the edge of the tonsils. The second requirement is to reduce patients' discomfort and maintain an open mouth status in the whole sampling processing. The third requirement is to have straightforward instruction for the operation.

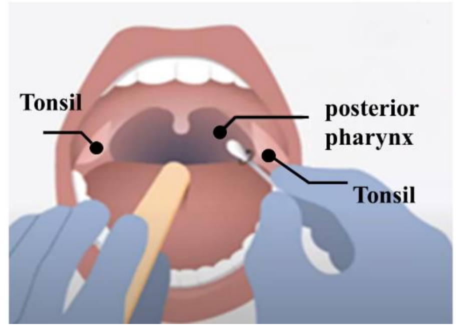


FIGURE 1: CURRENT OP SWAB OPERATION

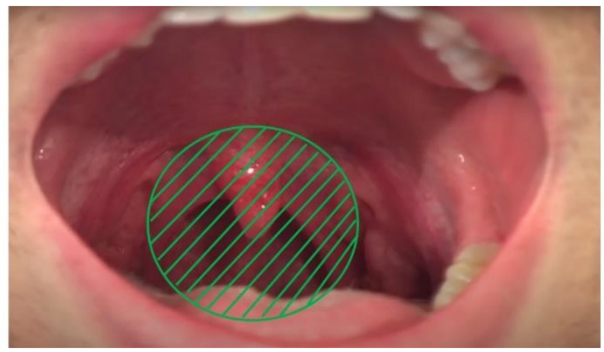


FIGURE 2: TARGETED SWAB SITE (EFFECTIVE RANGE)

2.2 Structure of the OP swab assembly

The structure of the OP swab assembly is as shown in Figure 3. The whole assembly consists of a swab holder, a standard swab, and a limit device. The swab holder is used to support the swab and prevent the contact of the swab with the oral cavity. The swab holder has many featured designs including member cover, mouth cover, wall cover, teeth slot, and shaped aperture (Figure 3). At the front side of the swab holder, there is a shaped aperture on the cover member, which allows the swab to be slide in or out and pivoted to rub the targeted swab site. The shaped aperture has an important function to limit the swab tip within the effective swab range during the operation procedures. Behind the cover member, a mouth cover was attached, which touches the lips to provide a fixture function. Behind the mouth cover is provided a wall cover, extending around the opening in the mouth cover to keep the mouth open and prevent contamination from saliva. At the top and bottom portions of the wall cover, there are some teeth slots, with which the patients can engage with their teeth to position the swab holder in the mouth, as well as creates a biting registry to reduce discomforts and minimize the involuntary reactions. The feature of the teeth slots is inspired by the orthodontic treatment in which biting registry is an effective way to mitigate pain and discomforts [28]. Extended from the wall cover is a tongue inhibitor that has the function to depress the tongue, avoiding contamination from the tongue if involuntary reaction occurs due to discomfort. The swab is standard and made with dacron or rayon swab wrapped around a plastic shaft. A limit device is designed with a clip feature that could grip the shaft of the swab to limit the insertion depth, giving patients' intuition about the depth under a non-visualization environment and preventing injury from over-depth insertion. This limit device will be developed with different lengths so that it will be suitable for a wide population based on the information of age, race, and gender. One end of the limit device will match the breaking-off point of the shaft of the swab, as shown in Figure 4. This is to facilitate the breaking to stock the specimen in a medical container (e.g. tube) after the sampling.

The self-collected OP swab assembly is economical and easy to manufacture. The volume of the swab assembly is approximately 23.4 cm^3 and can be further reduced by using a hollow structure.

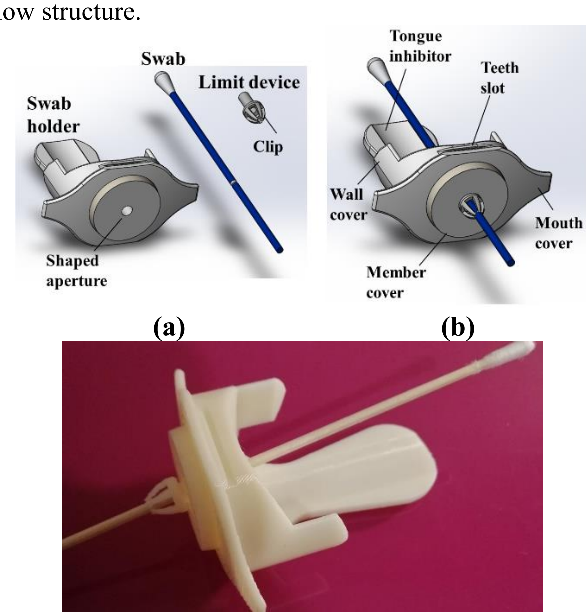


FIGURE 3: STRUCTURE OF THE SWAB ASSEMBLY: a) EXPANDED VIEW; b) ASSEMBLY VIEW; c) PROTOTYPE

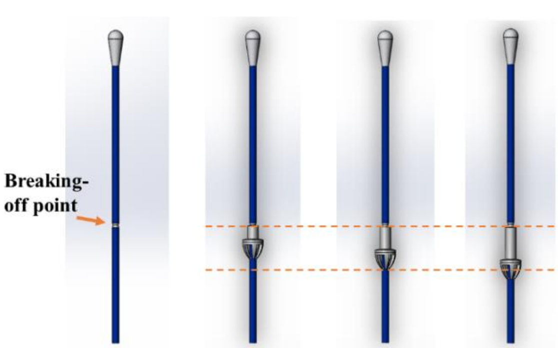


FIGURE 4: DIFFERENT LENGTHS OF LIMIT DEVIC

The swab holder, the standard swab, and the limit device will be packed in separate bags. Before sampling, the users can open the bags and assemble the pieces by themselves. The presented assembling procedures are as shown in Figure 5: a) the shaft of the swab needs to be inserted through the shaped aperture from the inside of the holder, and the limit device is moved towards the shaft from outside of the holder for a docking; b) the end of the limit device reaches the breaking point of the shaft; c) Verification of the completion of the assembling is conducted by sliding in or out the swab shaft.

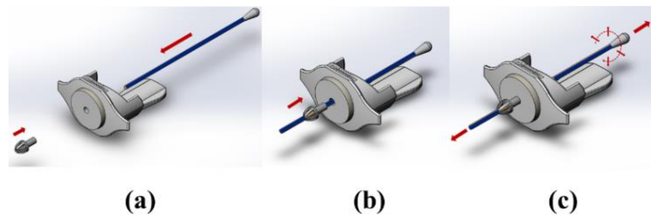


FIGURE 5: STEPS TO ASSEMBLE

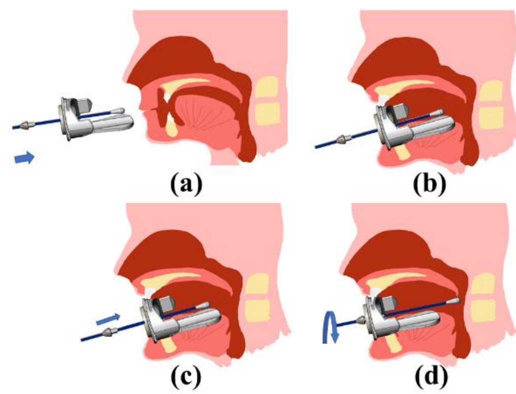
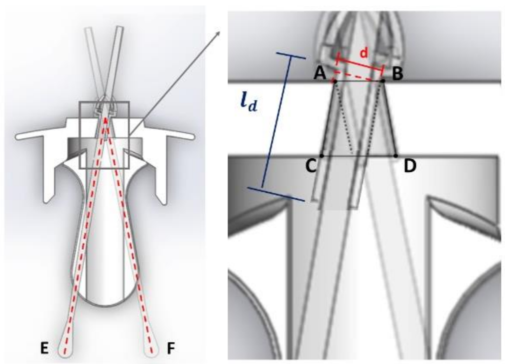


FIGURE 6: PROCEDURES TO SWAB

After the assembling, the users can start to operate the swab following swab procedures as: a) the user opens his/her mouth and insert the whole assembly into the mouth (Note: the swab tip needs to be near the shaped aperture in this procedure); b) The user adjusts the assembly into a proper position, puts the tongue below the tongue inhibitor and bites the teeth slots; c) The user inserts the swab shaft to make the swab tip reach the posterior pharynx site based on depth provided by the limit device and self-intuition; d) Once the swab site is reached, the user can swab the area with a pivotal motion which is limited and determined by engagement of the surface of the limit device and that of the shaped aperture. The whole operation is as shown in Figure 6.

2.3 Analysis

To make the swabbing procedure convenient and easy to operate by the users, the shaped aperture is designed with a truncated cone shape which allows sliding and rotating the swab shaft in a controlled and efficient manner. In this section, we will analyze the kinematics to pursue the dimensions of the shaped aperture given the size of the limit device and the thickness of the member cover of the swab holder have been set. Figure 7 shows the swab tip reaches extreme positions in the 2D cross-section view. The distance between Point E and F determines the diameter of the targeted swab site (l_{EF}). We label the points with features as shown in Figure 7. Therefore, the purpose of the kinematics to find the expressions of cone top surface diameter (l_{AB}) and base diameter (l_{CD}) in terms of the diameter of the limit device (d), the diameter of the targeted swab site (l_{EF}), the swab effective length (l_{OE} or l_{OF})and the thickness of the truncated cone (h).



(a) **(b)**

FIGURE 7: CROSS SECTION VIEW OF SWAB ASSEMBLY: a) FULL CROSS SECTION VIEW; b) DETAIL VIEW OF APERTURE

Taking the features from Figure 7, we can extract a geometrical model shown in Figure 8.

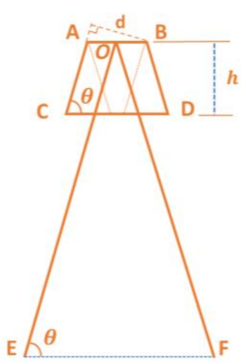


FIGURE 8: GEOMETRICAL MODEL OF THE APERTURE AND SWAB

The base slope angle θ can be obtained from the geometrical model in Figure 8 as follows

$$\theta = \arcsin(2l_{OE}/l_{EF}) \quad (1)$$

To make the swab rod reach the extreme points, the limited device should be tilted by a certain degree and touch point A and point B at this moment. Thus, l_{AB}, the diameter of the upper circle of the truncated cone shape aperture, can be obtained with Eq. (2) as follows

$$l_{AB} = \frac{d}{\sin\theta} \quad (2)$$

Therefore, the base diameter l_{CD} can be obtained through the isosceles trapezoid shape relationship as follows.

$$l_{CD} = \frac{d}{\sin\theta} + 2h \times \tan\theta \quad (3)$$

By arranging (1), (2), and (3), dimensions of the truncated cone shape aperture can be obtained as follows.

$$l_{AB} = \frac{d}{\cos(\arcsin(2l_{OE}/l_{EF}))} \quad (4)$$

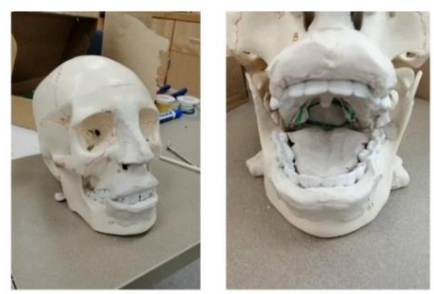
$$l_{CD} = \frac{d}{\cos(\arcsin(2l_{OE}/l_{EF}))} + 2 * h * \tan(\arcsin(\frac{2l_{OE}}{l_{EF}})) \quad (5)$$

The human oral structure varies from person to person in size. l_{EF} here is set as 20 mm to adapt to most adults' throat. Adjusting the parameters of the shaped aperture (l_{AB}, l_{CD} and h) and the limited device(d and l_d) could make this assembly be standardized according to patients' age, weight, and genders.

3. EXPERIMENTS AND RESULTS

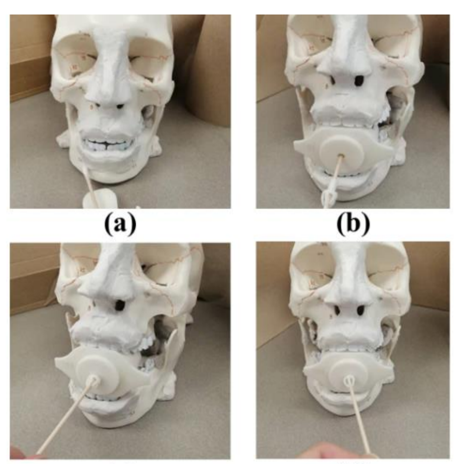
3.1 Experiment Descriptions

To evaluate the presented swab assembly and the procedures, we simulate the OP swab on a standard human adult skull mannequin, as shown in Figure 9 (a). We use clay to make an oral structure inside of the head skull, and we drew the effective swabbing range (targeted swab site) on the posterior oropharynx area of the model (shown in Figure 9 (b)).



(a) **(b)**

FIGURE 9 THE MODEL OF THE HEAD SKULL



(a) **(b)** **(c)** **(d)**

FIGURE 10: SWAB PRACTICE

Then we follow the procedures presented in Section 2.2 to open the mouth of the mannequin, insert the assembly, adjust for biting registry, depress the tongue, insert the shaft of the swab, and pivot the shaft for swabbing. The operation was conducted without any visualization on the swab site, largely mimicking specimen self-collection. The whole procedures are as shown in Figure 10. The swab tip was dipped into the ink with a blue color different from the color drawn for the targeted swab site. The comparison between the actual swab range and the targeted site will be used to evaluate the effectiveness of the proposed assembly and swabbing method. The swabbing procedures were simulated 10 times.

3.2 Experiment results

As can be seen in Figure 11, the actual swab range is within the targeted swab site. There is no ink beyond the range of the targeted swab site; and no ink is founded on the gum, tongue, or teeth. This indicates the swab tip is always rubbing around the area of the posterior pharynx and tonsillar edge. The results demonstrate the feasibility and effectiveness of self-collection with the presented OP swab assembly and method.

FIGURE 11: SWAB TRAJECTORY

4. CONCLUSION AND DISCUSSION

To increase the testing capacity for current COVID-19 and other future respiratory diseases or influenzas, this paper presents a novel OP swab assembly and a relevant method for specimen collection. The structure of the swab assembly contains several features to facilitate standard OP swab sampling and avoid contamination from the oral surface other than the targeted swab site. It also has a feature to create a biting registry to minimize patients' discomfort in the swab procedures. An analysis was conducted on the shaped aperture to ensure the motion trajectory of the swab tip is located within the expected range. Experiments of swabbing simulation were conducted on a standard adult human skull mannequin under the condition of non-visualization of the swab site. Results show the trajectories of the swab tip during the swabbing procedure were located within the targeted swab site and there was no touch on the oral surface other than the targeted swab site, which demonstrates the feasibility and effectiveness of the proposed OP swab assembly and method.

Moreover, the OP swab assembly also has an advantage in production cost. The volume of the OP swab assembly is around 10 cubic centimeters and can be further shrunk down. Using proper material and an optimized manufacturing method, the manufacturing cost could go down to a couple of cents per unit at a large production scale.

Future work will add more features to minimize discomforts. Practical experiments on human subjects will also be conducted to further verify its effectiveness. We will also seek solutions to minimize its cost by reducing the materials and simplify the manufacturing process.

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