INTRODUCTION

The novel coronavirus pandemic resulting in coronavirus disease 2019 (COVID-19) has led to a dramatic change in surgical practices across the world. Otolaryngologists in particular have a high risk for exposure to aerosolized virus particles when performing airway and endonasal surgeries. Early reports from Wuhan, China, demonstrated this increased risk to surgeons and operating room personnel when these surgeries were performed on infected patients. Because middle ear and mastoid mucosa are continuous extensions of respiratory epithelium, the potential risks of exposure to COVID-19 remain a serious concern for ear surgeons.

Currently, many hospitals across the United States are limiting surgical interventions to those patients with acute, life-threatening conditions such as cancer or trauma. Unfortunately, due to extended delays and prolonged access to care for non-COVID-19–related pathologies, surgeries that were once considered elective have now become increasingly more urgent to address as diseases progress. Cholesteatoma, a condition that requires surgical extirpation and for which no reasonable medical alternatives exist, is one example of a common pathology – of which is continued growth that can adversely affect treatment outcomes.

Currently, recommendations for personal protective equipment (PPE) mandate utilizing either an N-95 respirator with a face shield or a powered, air-purifying respirator (PAPR) for most otolaryngologic surgeries. Recently, the COVID-19 Airway Management Isolation Chamber (CAMIC) was developed by our group as adjunctive PPE that functions as a self-contained negative pressure system to enhance safe management of the airway.

This study will provide an overview of an otologic modification to the CAMIC (CAMIC-Ear) for a patient that required urgent ear surgery during the COVID-19 pandemic.

METHODS

The Walter Reed National Military Medical Center (Bethesda, MD) Institutional Review Board provided oversight and approval for this initial proof of concept project (WRNMMC-EDO-2020-0471). An emergency-use authorization has been approved by the Food and Drug Administration (#PEUA200438) to include detailed assembly and disassembly instructions for the CAMIC design. Preliminary, ex vivo data in a separate multi-institutional study to evaluate the original CAMIC design was performed. Assessments for aerosol and particle leak were obtained utilizing industrial-grade condensation particle counters for a smoke model (for ultrafine particles) and a nebulizer model (for microdroplets and aerosol particles). Our group found the CAMIC contained the particulate within the system despite this fenestration. With this preliminary data, we modified the CAMIC to a patient that required urgent ear surgery during the COVID-19 pandemic.
The frame can be readily disassembled and sterilized using a low-temperature (< 55°C) gas plasma sterilizer system with hydrogen peroxide vapor such as the STERRAD 100 (ASP, Irvine, CA) and repackaged for use in the operating room. After the patient is intubated, prepped, and draped, the CAMIC-Ear frame is steriley placed around the head, neck, and shoulders of the patient and secured using a sterile suction hose fastened around the operative table. A transverse arm board is placed at the head of the operative table to increase space for the frame. Suction is attached and distributed via the frame at its two ports. A microscope drape (Carl Zeiss, OPMI Drape, Germany) is attached in the usual fashion to the microscope but then reversed over the CAMIC frame to complete the self-contained environment, and two sterile bags are attached to the microscope hand controls (see Fig. 2). Two cutouts just large enough to allow one’s forearms to pass through are made for the surgeon’s hands, and one is made for the scrub technician to facilitate the passing of instruments.

RESULTS

A single patient with mesotympanic cholesteatoma and unsafe ear requiring urgent surgery was consented for tympanoplasty and possible mastoidectomy. The patient had been identified to have cholesteatoma 6 months earlier but was unable to have surgery due to a change in the military duty station and had developed worsening otorrhea and hearing loss. Consent for the procedure, including use of the CAMIC-Ear and intraoperative photography, was obtained from the patient. Same-day COVID-19 testing is not available at our facility; therefore, preoperative COVID-19 testing was performed 2 days prior to surgery, and the patient tested negative. The operating room staff wore N-95 masks for the duration of the case.

An endoscopic-assisted tympanoplasty for removal of the cholesteatoma was performed in the standard fashion. A mastoidectomy was not required for complete disease removal. The procedure was performed without complication, and the patient was discharged home the same day. The CAMIC-Ear was considered ergonomically satisfactory by the operating surgeon and scrub technician.

DISCUSSION

The global coronavirus pandemic has drastically altered the timeline for which elective and nonurgent surgeries are performed. Most otologic surgery is considered routine and nonurgent, although notable exceptions exist, including unsafe cholesteatoma, complications of acute otitis media and mastoiditis, and large lateral skull base tumors causing brainstem compression. Concerns about coronavirus aerosolization exist due to the prominent use of the high-powered otologic drill and the fact that the middle ear cleft is directly connected to the nasopharynx via the Eustachian tube (the site considered the highest concentration for coronavirus inoculation).\(^5\)

Utilization of proper PPE is critical to protect the surgeon and operating room staff. However, use of a microscope with a face shield or PAPR is cumbersome.
We have developed the CAMIC-Ear as an adjunctive PPE device that may circumvent the needs for a face shield or PAPR and can be utilized to facilitate both otomicroscopy and endoscopic ear surgery. The hollow PVC frame with attached suction creates an isolation chamber for the operative field that contains and evacuates potentially infective particles.

Although rapid widespread COVID-19 and antibody testing for patients and operative room staff would be ideal, this is not currently feasible or available at most institutions. Moreover, false-negative rates for certain tests remain a concern. Therefore, it is incumbent to treat all patients as potential asymptomatic carriers for COVID-19, necessitating the continued use of proper PPE.

**CONCLUSION**

The CAMIC-Ear system serves as an adjunct PPE device, supports safe and effective ear surgery, and can be readily used for endoscopic and microscopic techniques.

**ACKNOWLEDGMENT**

The contents of this publication are the sole responsibility of the authors and do not necessarily reflect the views, opinions, or policies of the Uniformed Services University of the Health Sciences (USUHS), the Department of Defense (DoD), or the Departments of the Army, Navy, or Air Force. Mentions of trade names, commercial products, or organizations does not imply endorsement by the U.S. Government.

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