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#### SPECIAL ISSUE

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# Is the ultrasonic scalpel recommended in head and neck surgery during the COVID-19 pandemic? State-of-the-art review

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#### Abstract

**Background:** Guidelines for ultrasonic devices use are imperative because infectious aerosols arising from airway procedures were a key etiologic factor in prior coronavirus outbreaks. This manuscript aims to summarize the available recommendations and the most relevant concepts about the use of ultrasonic scalpel during the SARS-CoV-2 pandemic.

**Methods:** Literature review of manuscripts with patients, animal models, or in vitro studies where the ultrasonic scalpel was used and the plume produced was analyzed in a quantitative and/ or qualitative way.

**Discussion:** Activated devices with tissue produce a biphasic bioaerosol composed (size 68.3-994 nm) of tissue particles, blood, intact and no viable cells, and carcinogenic or irritant hydrocarbons (benzene, ethylbenzene, styrene, toluene, heptene, and methylpropene).

**Conclusion:** It is imperative to use an active smoke evacuator, to avoid ultrasonic scalpel use in COVID-19 positive patients and in upper airway surgery, as well as to follow the protection recommendations of the guidelines for management this type of patients.

The authors belong to the Task Force COVID-19 of the Young-Otolaryngologists of the International Federations of Oto-rhino-laryngological Societies (YO-IFOS).

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#### K E Y W O R D S

aerosol, SARS-CoV-2, surgical smoke, ultrasonic scalpel, virus transmission

#### **1** | INTRODUCTION

Since its declaration as a Public Health Emergency of International Concern on January 30, 2020 by the World Health Organization,<sup>1</sup> the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has represented a major challenge for health-care systems worldwide. Several scientific reports about its epidemiology, clinical course, laboratory testing, treating support, or management guidelines, have been published.<sup>2-4</sup> In this sense, surgical procedures increase demands on an already taxed system through the consumption of a large amount of personal protective equipment, use of inpatient beds post-operatively, and elevated risk of transmission of SARS-CoV-2 to other patients and staff.

The Centers for Disease Control and Prevention recommended cancelation of all elective and non-urgent procedures and subsequent guidelines were released by the American College of Surgeons and the American Academy of Otolaryngology-Head and Neck Surgery, to provide only "time-sensitive" or "emergent" care.<sup>5,6,7(p19)</sup> These recommendations are based on the pragmatic aspects of surgery, being ultimately the responsibility of the surgeon to define what is an "elective" and "urgent" surgery.

Even in urgent or elective surgery, current guidelines recommend avoiding surgical techniques which might spread viral particles. Ultrasonic energy devices are commonly used in head and neck surgery and they represent an alternative to the scalpel, electrosurgery, or laser.<sup>8-11</sup> Bloodborne transmission has not been documented in SARS-CoV-2. However, aerosolization of blood through the use of this type of instruments has been reported.<sup>12</sup> They can easily produce a lowtemperature aerosol that cannot effectively deactivate the cellular components of virus in patients. In previous studies, activated corynebacterium, papillomavirus, and HIV DNA have been detected in surgical smoke, reporting the theoretical possibility of contagions related to exposure.<sup>13-15</sup>

One study found that after using ultrasonic equipment in laparoscopic surgery for 10 minutes, the particle concentration of the plume was significantly higher than in traditional open surgery.<sup>16</sup> Despite the fact that these data are positive, given the type of surgery in which this type of scalpel is commonly used on the head and neck area, there is some controversy regarding it.<sup>17,18</sup> The health effects of aerosols created by ultrasonic devices are not well documented, but considering the high viral titers in nasal mucosal, oral, pharyngeal, and pulmonary secretions, any operation that involves these surfaces is of high risk to the entire operating room personnel.<sup>12</sup>

Although there are several publications that contain guidelines for aerosols reduction during anesthesia, management of the airway, endoscopy, or tracheostomy,<sup>4,12,19,20</sup> awareness of best practices using ultrasonic devices is imperative because infectious aerosols arising from airway procedures were a key etiologic factor in prior coronavirus outbreaks.<sup>21</sup> The aim of this study is to summarize the available recommendations and the most relevant concepts about the technique during the SARS-CoV-2 pandemic.

#### 2 | METHODS

This literature review is an initiative of the Young Otolaryngologist Group of the International Federation of Otolaryngologic Societies (YO-IFOS), which is composed of European, American, Asian, and African otolaryngologists.

Although this is not a systematic review, we took a systematic approach for the search strategy in peer reviewed journals based on the recommendations of the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement,<sup>22</sup> which was carried out during the month of April 2020 (Figure 1). The criteria for considering studies for this systematic review were based on population, intervention, comparison, outcome time, and setting (PICOTS) framework.<sup>23</sup>

- Participants: Patients, animal models, or in vitro studies.
- Intervention: use of ultrasonic scalpel as a cutting or sealing method for surgery (open and/or endoscopic).
- Comparison: The presence of a control group with another type of scalpel was evaluated. Its absence did not constitute an exclusion criterion.
- Outcome: Quantitative and/ or qualitative analysis of the ultrasonic scalpel aerosol.
- Time: Studies were considered in which the aerosol was evaluated at the time of use of the device, as well as by subsequent cultures.
- Setting: laboratory or operating rooms were considered.

Different indexed databases (PubMed, the Cochrane Library, Scielo, and Web of Science) were used with the following keywords and their combinations: *aerosol, smoke, ultrasonic scalpel, SARS-CoV-2, transmission, COVID, Coronavirus, virus, head neck,* and complemented

FIGURE 1 Flow chart of the search strategy based on the PRISMA Statement and critical analysis of the literature



with free text terms. Eligibility criteria regarding the type of study, language, or publication date were not applied with the objective of including all possible articles in this review. Furthermore, manual review of selected articles references in order to identify paper not found with the search strategy was carried out. From this review of the available literature, conducted by two authors (M.M.Y and C.C.E), a critical analysis of the published content and summary of the data of the selected research was performed.

### 3 | DISCUSSION

#### 3.1 | Virus transmission

The coronavirus disease 19 (COVID-19) is an infection caused by the SARS-CoV-2, a highly contagious and pathogenic viral. The entry mechanism of a coronavirus depends upon cellular proteases which include, human airway trypsin-like protease (HAT), cathepsins, and transmembrane protease serine 2 (TMPRSS2) that split the spike protein and establish further penetration changes.<sup>24</sup> Person-to-person transmission occurs primarily via direct contact or through droplets spread by coughing or sneezing from an infected individual as well as a contact transmission (oral, nasal, and eye mucous membranes).<sup>25</sup> Although fecal-oral spread has also been confirmed.<sup>4</sup> In a small study conducted on pregnant women in their third trimester who were confirmed to be infected with the coronavirus, there was no evidence that there is transmission from mother to child.<sup>26</sup> SARS-coronavirus require binding between the receptor-binding domain of virus spikes and the angiotensin-converting enzyme 2 (ACE2).<sup>27</sup>

Aerosolized COVID-19 particles less than 5  $\mu$ m, produced during various procedures, may remain airborne for up to 3 hours and may survive on surfaces for much

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longer.<sup>28,29,30(p1)</sup> SARS-CoV has been measured in air samples within 1 m of an infected patient in 11 samples over 8 hours suggesting a high risk for airborne transmission. Specifically, the SARS-CoV-2 is more stable on plastic and stainless steel than on copper and cardboard, and viable virus can be detectable up to 72 hours after application to these surfaces.<sup>30(p1)</sup>

#### 3.2 The ultrasonic scalpel

The ultrasonic scalpel (US) unites the ability to cut and coagulate in the same surgical device. The equipment consists of a generator, a hand-piece (housing the acoustic mount and ultrasonic transducer, which is composed of piezoelectric crystals sandwiched between metal cylinders), and specific inserts.<sup>31</sup> The mechanism of action is based on transforming electrical energy into mechanical movement of 55.5 kHz frequency. These vibrations are transmitted along the handpiece to the instrument tip where they cause longitudinal displacements of 80 µm. This movement causes the blade to denature protein in the tissue to form a sticky coagulum of partly denatured proteins.<sup>32</sup>

The effects of the US on tissues differ greatly according to its mode of action. Three main mechanisms are in operation to varying degrees: cavitation, heat generation, and protein denaturation. The process of cavitation arises from the creation, expansion, and implosion of cavities in liquids.<sup>33,34</sup> Mechanical oscillations of the instrument tip cause internal tissue pressures to rise and fall rapidly. Once the cellular pressure falls below the vapor pressure of cellular fluid, vapor-filled cavities form within the cells. It is the force generated by the expansion and contraction of these that result in tissue dissection. The pressure exerted on the tissue by the blade surface collapses blood vessels and allows the coagulum to form a hemostatic seal, controlling bleeding by coaptive coagulation at low temperatures, ranging from 50°C to 100°C. By contrast, electrosurgery and laser coagulate by burning (obliterative coagulation) at higher temperatures (150°C-400°C).

#### 3.3 Aerosolization

Aerosol formation during procedures may be divided into patient induced or mechanically induced, as is the case with US. Aerosol particle size is inversely related to air speed and thus an aerosol generating procedure is any procedure capable of generating increased air velocities within the airway.<sup>35</sup> These procedures are associated with the possibility of increasing the risk of SARS-CoV transmission among health-care workers.<sup>36</sup>

The interaction of ultrasonically activated devices with tissue produces a biphasic bioaerosol composed of tissue particles and a blood aerosol. This atomization that creates a mist has long been noted but few studies evaluated or explored it.<sup>37-40</sup> It has been seen reported that the aerosols caused by this type of devices can be found more than 40 cm from their production area and for more than 1 minute in suspension, with various factors influencing their dispersion pattern and quantity (eg, type of scalpel tip or material being acted on). Fatty tissue generated 10 to 20 times more particles than lean tissue, probably due to its higher water content. Another study exhaustively evaluated the use of the ultrasound scalpel in muscle tissue, finding two large populations of particles (>500 nm and >500 nm), with mean size of 68.3 and 994 nm and a concentration of  $6.10 \times 10^5$  and  $1.48 \times 10^3$ /cm<sup>3</sup>, respectively.<sup>38</sup> As for its action in bloody surgical fields, this type of devices produce a spray with a particle counts ranged of up to 500 000 particles of blood/L.<sup>37</sup>

The US is said by the manufacturer to produce a vapor, not smoke, and the process has been described as lowtemperature vaporization. This is concerning because cool aerosols in general have a higher chance of carrying infectious and viable material than do higher temperature aerosols.41 The composition of particles created by the scalpel is morphologically intact and no viable cells and carcinogenic or irritant hydrocarbons (benzene, ethylbenzene, styrene, toluene, heptene, and methylpropene) were identified in one or more samples.31,42

In determining health hazards from inhaled aerosol particles, the respirable material that penetrates is of primary importance. Classifying aerosols by their initial size is relevant in relation to their dispersal patterns, but it is also important to classify aerosols according to where they deposit in the respiratory tract because pathogenesis can be influenced by whether a virus deposits in the upper or lower respiratory tract.<sup>43</sup> Dispersal and deposition depend on a variety of factors, and there is no exact cutoff for small and large droplets. Some authors use  $\leq 5 \,\mu m$  in diameter as a cutoff for small droplets, while another possible cutoff between aerosol types is 20  $\mu$ m, since aerosols  $\leq$ 20  $\mu$ m in diameter can desiccate to form droplet nuclei, and aerosols  $\geq 20 \ \mu m$  do not deposit substantially in the lower respiratory tract.44

The absence of evidence suggesting harm from inhalation of ultrasonic surgical smoke does not mean it is therefore safe. The possibility of disease transmission through surgical smokes exists, even though currently documented cases of pathogen transmission are rare.<sup>41</sup> The few existing data on the aerosolization of US (Table 1), together with studies on SARS-CoV-2 transmission and viability over time, suggest a considerably increased risk of disease transmission if this type of device is used in infected patients.37

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Composition	<ul> <li>Tissue particles (two populations: &lt;500 nm and &gt;500 nm)</li> <li>Blood aerosol</li> <li>Intact and no viable cells, tumor cells in cancer resection.</li> <li>Carcinogenic or irritant hydrocarbons (benzene, ethylbenzene, styrene, toluene, heptene, and methylpropene)</li> </ul>
Characteristics	<ul> <li>Various names: Aerosol, spray, plume or mist</li> <li>Supposedly no smoke (low-temperature vaporization) → ↑ infectious and viable material</li> </ul>
Sizes	<ul> <li>Variation between studies. It depends on the type of tip or material.</li> <li>Mean size by population:</li> <li>&lt;500 nm: 68.3 nm</li> <li>&gt;500 nm: 994 nm</li> </ul>
Quantity	<ul> <li>Depends on the material composition where it acts (↑ water → ↑ quantity):</li> <li>Fatty tissue generated 10 to 20 times more particles than lean tissue</li> <li>Blood: 500000 particles/ L</li> <li>Mean concentration by population:</li> <li>&lt;500 nm: 6.10 × 10<sup>5</sup> cm<sup>3</sup></li> <li>&gt;500 nm: 1.48 × 10<sup>3</sup>/cm<sup>3</sup></li> </ul>
Distance	>40 cm
Suspension duration	> 1 min (without evacuation methods)
Scatter pattern	<ul> <li>Depends on:</li> <li>Type of scalpel tip (circumferentially, 120° arch)</li> <li>Material composition where it acts (↑ water → ↑ dispersion)</li> <li>Ventilation conditions</li> </ul>
Recommendations	<ul> <li>Active used of smoke evacuator</li> <li>Avoid the use of ultrasonic scalpel in COVID-19 positive patients</li> <li>Avoid the use of ultrasonic scalpel in upper airway surgery (↑ asymptomatic rate)</li> <li>Follow the recommendations of the guidelines for management this type of patients (FFP3, ocular protection, PPE)</li> </ul>

# TABLE 1 Main characteristics of the aerosol produced by ultrasonic scalpel

### 4 | IMPLICATIONS FOR PRACTICE

Because of the fact that almost 80% of SARS-CoV-2 positive patients are asymptomatic,<sup>45</sup> some clinical guidelines advocate that all patients should be assumed to be infective.<sup>46</sup> The availability of reliable testing for SARS-CoV-2 will be an important step forward in the future to distinguish between infected and noninfected patients. Until then, aerosol generating procedures require special attention in every patient with unclear infection status. Even then, it is noteworthy that the sensitivity of current available test is 72%,<sup>47</sup> and they are highly dependent on the technique followed to recollect the sample.<sup>48</sup>

Reducing aerosol formation to a minimum should be a priority, avoiding the use of the US or excessive water cooling for handpieces, saws, high speed drills, and piezoelectric devices in all cases where it is possible and especially when working on the upper airway.<sup>12,49</sup> The risks posed by the aerosol generated from the US compared to that of laser and electrocautery is not known, and may be greater due to the larger size of particles generated and because it is a cooler aerosol and therefore may contain more biologically viable particles (Table 1).

Likewise, the number of staff members in the operating room should be limited to a minimum. The operating room should be equipped with adequate ventilation and a negative pressure system. Besides eye protection and gloves, facial mask and respirators of a high protection level (FFP3/N99/equivalent) and as well as waterproof gowns should be used.<sup>12,49</sup> Finally, the minimal existing reports suggest that the local exhaust ventilation smoke-evacuation system dramatically reduced particle concentration exposure.<sup>37,38,41</sup> Therefore, an exquisite vacuum from the field while using this type of device is recommended.

### 5 | CONCLUSION

The first reported physician fatality related to COVID-19 in Wuhan, China, was an otolaryngology physician on January 25, 2020.<sup>50</sup> Health-care personnel that manage patients with diseases of the aerodigestive tract (otolaryngologists, maxillofacials, anesthetist, dentists, head and neck surgeons, gastroenterologists, pneumonologists, respiratory therapists, speech therapists, and infectious disease physicians or ophthalmologists) are the health-care workers most susceptible to infection (risk ratio of 2.13).<sup>51</sup>

There is a particular need for protective measures in these professional groups, both at the current time of the pandemic and the possible de-escalation of containment measures. Currently, there is no specific information regarding SARS-CoV-2, aerosolization with ultrasonic devices, and its infective capacity. Aerosol-generating medical procedures are increasingly being recognized as important sources for nosocomial transmission of emerging viruses.<sup>35,36</sup> Therefore, all procedures that have the potential to aerosolize aerodigestive secretions, such as nasolaryngoscopy, endotracheal intubation, non-invasive

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ventilation, tracheostomy, upper airway surgery, transnasal endoscopic surgery, and high-speed handpieces or ultrasonic instruments, increase the risk of infection and should be avoided or employed only when mandatory. There is no information regarding any potential risk for electrocautery smoke or transoral laser resection generated smoke but it would be reasonable to take appropriate precautions in these settings too.

It is important to recognize the range of aerosol generating procedures and the circumstances under which they might be performed on infected patients. In order to associate certain aerosol-generating medical procedures with nosocomial virus transmission, researchers need to test whether certain procedures generate aerosols with infectious virus, either through hospital sampling or laboratory procedures.<sup>35</sup> The ambiguity with which procedures and viruses require additional protective measures during these procedures may lead to breaches in protocol. Likewise, proper patient triage and diagnosis are the first steps to ensuring that precautions are undertaken when performing it.

Overall, more research and communication about the risks of certain viruses and aerosol-generating medical procedures, as well as additional research to determine when smoke evacuation systems need to be used, are necessary to resolve the uncertainty surrounding their role in nosocomial virus transmission.

#### **CONFLICT OF INTEREST**

There was no conflict of interest and authors have nothing to declare. This research does not involve human participants.

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