

News Release

Title

Made in Nagoya; Endoscopic mask called “e-mask” for preventing droplets during the COVID-19 pandemic

Development and implementation of device for safe endoscopic procedure towards new normal, with/post COVID-19

~ Demonstration of prevention of droplets and patients’ safety through visual experiments and clinical trials ~

Key Points

- Development, sale, and implementation of the endoscopic mask called “e-mask” that prevents droplets spread during endoscopic procedures.
- The effectiveness of e-mask in preventing droplets was confirmed with a droplet visualization and simulation experiment.
- Based on clinical trial, the patients’ safety of e-mask was confirmed
- The e-mask was made up based on surgical mask, which enable to provide mass-production with low cost for daily use.
- E-mask that was beneficial to reduce the dispersal enables us to do safer endoscopic style in new normal, with/post COVID-19.

Summary 1

Research and development team of e-mask (Assistant Professor **Takayasu Ito**, Assistant Professor **Shotaro Okachi**, Designated Lecturer **Kazuhide Sato**, and Professor **Makoto Ishii** in the department of respiratory medicine, Nagoya University Graduate School of Medicine) demonstrated the effectivity and safety of e-mask for preventing dispersal droplets during bronchoscopy.

Assistant Professor **Takayasu Ito (first author)** in the department of respiratory medicine, Nagoya University Graduate School of Medicine, Assistant Professor **Shotaro Okachi (co-first author)** in the department of respiratory medicine, Nagoya University Graduate School of Medicine, Designated Lecturer **Kazuhide Sato (corresponding author)** in the department of respiratory medicine, Institute for Advanced Research, Nagoya University Graduate School of Medicine, Graduate student **Hirotohi Yasui** in the department of respiratory medicine, Nagoya University Graduate School of Medicine, Professor **Topouzis Fengshi Chen-Yoshikawa** in Department of Thoracic Surgery, Nagoya University Graduate School of

Medicine, Hospital professors **Masahiko Ando** in the Center for Advanced Medicine Clinical Research, Nagoya University Hospital, Executive board of World Association for Bronchology and Interventional Pulmonology (WABIP) **Hideo Saka** in the Department of Respiratory Medicine, Matsunami General Hospital, successfully developed the mask preventing droplets spread during endoscopy such as bronchoscopy, along the industry-academia collaboration. We could provide e-mask for patients through visual experiments and clinical trial. The mask is a surgical mask with a designed fold, and a slit for the endoscope and suction tube. The mask is now on sale as “Kenz e-mask”. The e-mask was awarded by 4th Japan Open Innovation Award, Minister of Health, Labor and Welfare Award, Cabinet Office, Government of Japan.

In order to verify the effectiveness of this mask in preventing droplets, a high-sensitivity particle visualization experiment was conducted with the cooperation of Shin Nippon Air Conditioning Co., Ltd., and the mask clearly reduced the spread of droplets. Furthermore, to be application to clinical practice, we confirmed patients’ safety of wearing e-mask during bronchoscopy with clinical trials. This mask is designed based on surgical masks commonly used in daily life, disposable, low-cost, disposable, and easy to use with mass production. We believe this mask reduces the risk of infection in endoscopy procedures, not only to the healthcare providers but also to the patients, therefore, e-mask provides newly safer endoscopic style towards new normal, with/post COVID-19.

This research was supported by the Yahoo! Foundation, the Nagoya University DEAN’s Fund, Unit B3 of the Research University Enhancement Program of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), R2 National University Innovation Creation Supporting FUND, and was published in the journal of *Respirology* (2022).

Summary 2

Research Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2), which is the causative agent for the ongoing COVID-19 pandemic, has spread worldwide since 2020. In addition to dealing with infected patients, asymptomatic patients have been reported in medical practice, and even if the PCR testing of SARS-CoV-2 is performed, the result has the possibility of false negative. Therefore, it is necessary to always take measures to prevent infection. Bronchoscopy is important to provide definite diagnosis and therapy of various respiratory disease such as lung cancers, and pneumonias. Although topical use of lidocaine or sedatives during bronchoscopy should be offered to patients who undergo bronchoscopy to prevent excessive coughing and provide patient comfort, they cannot completely stop the cough reflex. Additionally, bronchoscopy is a high infection risk procedure since patients’ droplets scatter around during

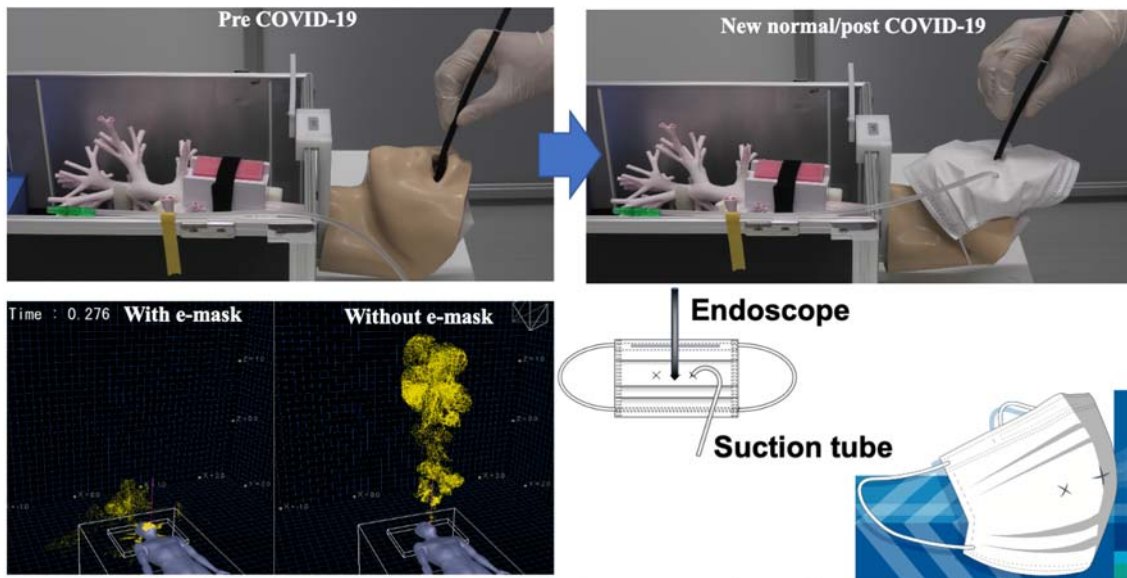
inserting the endoscope into the airway. Therefore, the protective equipment during endoscopic procedures should be considered not only for healthcare workers (with PPE such as N95 masks, face shields, gowns, and gloves) but also for patients. Moreover, airborne particles during bronchoscopy do cause the environmental infectious pollutions, which is transmitted through contact surfaces (e.g., endoscopic system, walls, medical equipment). This may increase the infection risk. Accordingly, patients who undergo endoscopy are under the infection risk, same as the healthcare workers.

Research Results

This research group and the mask manufacturer headquartered in Nagoya City have jointly developed a mask for endoscopy as an industry-academia collaboration project. To visualize and evaluate the effectiveness of preventing droplets, we conducted droplets-visualization experiment using the acrylic box, and high-sensitivity particle visualization (ViEST). The ViEST can visualize floating fine particles with a specialized light source and ultra-sensitive camera. Our results revealed that more than ten thousand times of airborne particles were generated without e-mask compared to with e-mask. Moreover, e-mask can significantly reduce exposure pollution to the environment during bronchoscopy using simulation of the spread of small airborne particles with or without the e-mask.

To evaluate the operability of the bronchoscope with the e-mask, we compared the operation time with or without e-mask. No significant difference between the two groups was detected in the trial.

Additionally, we compared patients who underwent bronchoscopy with the e-mask in comparison to who underwent bronchoscopy without the e-mask (historical control group) using propensity score matching, because it was difficult to perform bronchoscopy without e-mask during COVID-19 pandemic. While wearing e-mask was a significant factor affecting the elevation of end-tidal carbon dioxide (EtCO₂), we considered that wearing e-mask was safe because this EtCO₂ elevation during bronchoscopy can be recovered to baseline levels after the procedure.



Proposal of newly medical style for preventing dispersal infection associated with endoscopic procedure in new normal or post COVID-19

Research Summary and Future Perspective

We are planning to propose our result to the Japan Society for Respiratory Endoscopy and the Japanese Respiratory Society and launch it to make a guideline for bronchoscopy.

We expected that our mask can be used in daily clinic and be widely applicable for preventing dispersal infection associated with the procedure.

Technical Terms

Bronchoscope: The device with a thin and soft tube with a diameter of about 3-6mm to look into the trachea and bronchi leading to the lungs deep in the chest. It has the same structure as a gastroscope, but much thinner. It is an important instrument for patients suffering from diseases of respiratory (such as trachea, bronchi, and lungs), and is used to observe the inside of the trachea and bronchi, collect tissue and cells for accurate diagnosis (bronchoscopy), and treat diseases that cause narrowing of the trachea and bronchi (bronchoscopic treatment).

PCR (polymerase chain reaction) test: a fast, highly accurate way to diagnose certain infectious diseases and genetic changes.

Droplets and aerosols: Droplets are the fine scattering drop of water that with cough or sneeze. In general, aerosols are the particles smaller than droplets and drifting through the air. Infection occurs when droplets or aerosols containing pathogens are inhaled or adhere to mucous membranes.

Publication

Takayasu Ito^{1*}, Shotaro Okachi^{1*}, Kazuhide Sato^{1,2,3#}, Hirotohi Yasui¹, Noriaki Fukatsu², Masahiko Ando⁴,
Toyofumi Fengshi Chen-Yoshikawa⁵, Hideo Saka⁶

*These authors are equally contributed to this work.

¹ Department of Respiratory Medicine, Nagoya University Graduate School of Medicine

² Nagoya University Institute for Advanced Research, Advanced Analytical and Diagnostic Imaging Center (AADIC)/Medical Engineering Unit (MEU), B3 Unit

³ FOREST-Souhatsu, CREST, JST

⁴ Center for Advanced Medicine and Clinical Research, Nagoya University Hospital

⁵ Department of Thoracic Surgery, Nagoya University Graduate School of Medicine

⁶ Department of Respiratory Medicine, Matsunami General Hospital

DOI: 10.1111/resp.14321

<https://doi.org/10.1111/resp.14321>

Japanese ver.

https://www.med.nagoya-u.ac.jp/medical_J/research/pdf/Res_220704.pdf