

**Interference between Simulation Education and
Anesthesiology and Intensive Care Therapy under Extreme Circumstances**

Ph.D. thesis

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1 Introduction

Simulation education has become a fundamental part of graduate and postgraduate medical training and has played an increasingly important role in additional medical education as well. Laboratory work and the practicing of manual skills are inevitable and crucial segments of the teaching of theoretical subjects as. The fact that the practical part of clinical subjects is largely based on case presentations and patient examination has developed through the history of the medical profession, however, nowadays, with the rapid advancement of teaching methodologies medical training cannot entirely rely on methods that mainly require direct patient care experience.

In Hungary, the beginning of the 2010s witnessed the initiation and spreading of a professional project that was mainly based on using simulation equipment. Support from university leaderships and close collaboration with supervisory boards of national health care institutions resulted in the development of a network that incorporates medical faculties and teaching hospitals of Hungarian universities. The establishment of simulation education centers has been of vital importance in Hungary as such a network significantly contributes to the teaching of standardized practical skills and knowledge opening up possibilities for on-line, 'real-time' distance learning as well. The professional consortium has around twenty locations (3 university-level and 16 county-level teaching hospitals) that offer standardized equipment and consequently, standardized graduate and post-graduate training facilities along observing professional guidelines at a national level.

Professional training programs are built upon clinical subject requirements as defined by medical faculties of the country; the Hungarian Medical Simulation Society that has been established focuses on securing the future of such training programs and works towards developing and facilitating cooperation at national and international levels. It is important to emphasize, however, that medical simulation assisted education does not and cannot substitute direct patient care experience in the teaching of clinical subjects. Although the equipment and devices used are the same, the possibilities offered by simulation devices are never the same as those witnessed through real life situations; therefore, this type of education can only serve as a bridge between theoretical knowledge,

and applied, practical skills acquisition. Besides acquiring practical skills, it is also essential to witness communication challenges, to learn various communication strategies and skills that are commonly encountered in provider-patient interactions; simulation education provides a safe and sufficient practice environment for the teaching of medical communication as well.

Taking a closer look at the relationship between anesthesia and simulation education, the counter-dependence and interference is apparent. Technical advancement in anesthesiology has derived from a need for different types of narcosis which points to the fact that it is very often the clinical needs that open the door to novel methods for the testing of which simulation education can provide a safe and standardized environment. Unusual, unexpected situations that require an immediate, adequate and often novel response and solution can be viewed as extreme circumstances, in which, lack of experience together with inadequate availability or substandard quality of available equipment, or both, may significantly hinder or delay adequate response. The papers that form the backbone of the present study have mostly been based on ideas and hypotheses triggered by the challenges posed by the current pandemic.

The challenges created by the COVID-19 (Corona Virus Disease-19) pandemic have given rise to a professional 'race' to develop and advance medical equipment and devices that has led to the development of improvised anesthesiology workstations and oxygen therapy equipment. Throughout the history of anesthesiology and intensive care therapy it has often been a non-directly related medical field that provided solutions to special challenges and problems. The advancement of 3D technology has had a marked impact on medical sciences. Novel procedures have been expected to yield immediate results, to be more efficacious, and more cost-effective. Simulation centers are able to provide the adequate background for testing novel equipment or their prototypes at different levels of development. As our access to personal protective gear and equipment currently used in health care has been quite limited, our team embarked upon the idea to test other, similar but more cost-effective sample products in education instead of original, manufactured, internationally certified protective equipment. Our primary aim was to test equipment that can protect the face and airways from virus transmission.

One of the biggest challenges faced by health care systems today amidst the COVID-19 pandemic is the airway management and oxygen therapy for patients with

known or unknown COVID-19 status. As a result of advances in video and fiber optic technologies, VL procedures have become first line recommendations in several COVID-19 airway management protocols, e.g. -American Society of Anesthesiologists (ASA), Difficult Airway Society (DSA).

Uncertainty and lack of certain skills required by novel procedures necessitate the regular and comprehensive practice of complex patient care procedures, if possible, in a life-like, realistic, simulation environment. It is crucial to practice the identification, comprehension and solution of arising problems prior to encountering them in a real, emergency care setting. Models, tools and devices designed and manufactured with Additive Manufacturing (AM) technology for use in health care do always have to undergo thorough scientific investigation as they can only be applied and used subsequent to ethics committee approval and authorization.

2 Aims and objectives

2.1 A national survey of videolaryngoscopes and alternative intubation devices in Hungary

Our study aimed to examine the availability of and access to videolaryngoscopes (VL) in Hungary. Respondents' professional status, and the progressivity of their workplace in terms of patient care were also analyzed. Our results in connection with VL access and availability were compared with international results found in the literature. Besides general opinion our study surveyed the popularity of VL as well. Our survey included questions about initiation to the procedure, availability of related training, frequency of practice sessions and participation requirements as determined by institutions and departments. Subsequent to evaluating currently available data and assessing directions for future development, our further aim was to devise professional plans for the future taking into consideration needs and requirements of the health care profession in Hungary.

Our hypotheses were the following:

- Medical professionals whose work includes airway provision are fully knowledgeable about various types of VL.
- VL devices are less commonly used in routine everyday practice; they are mainly used as an alternative method of airway management.
- Colleagues do feel the need for training focusing on the use of VL devices.

2.2 Comparison of VividTrac®, Airtraq®, KingVision®, Macintosh Laryngoscopes and a Custom-Made Videolaryngoscope for normal airways in mannequins by novices

Our study investigated the efficacy of certain VL devices compared with traditional, direct laryngoscopy in normal airway management, in a simulation environment with volunteers who had no routine or prior experience in airway management. Upon performing the various airway management types, we analyzed technical performance and success rate besides the objective assessment of complications. We also evaluated general conditions of the simulated airway management as our further goal was to define

future directions for research, development and education. Through analyzing the simulation environment and the airway management devices used, our prior aim was to search for and outline directions for skills development training of methods that are applicable under extreme circumstances.

Our hypotheses were the following:

- Upon analyzing normal airway management maneuvers performed by novices using different VL devices, traditional, direct laryngoscopy will prove to be less successful compared to indirect (ID) laryngoscopy
- A more successful airway management technique with the use of VL can be taught and mastered faster when teaching students.

2.3 An Overview on Personal Protective Equipment (PPE) Fabricated with Additive Manufacturing Technologies

After a short introduction to AM technologies, the present paper intends to provide an outline of the current national and international situation surrounding the manufacturing and further development of personal protective equipment (PPE) that could potentially provide additional protection against the virus for medical personnel involved in airway management during the pandemic. We searched for available production technologies, defined potential dangers and performed risk assessment analyses based on objective parameters. Subsequent to the manufacturing of open source (OS) models, face shields, face masks and protective goggles, consumer and quality control examinations were carried out. Novel ideas were tested through prototypes. We determined long-term developmental and research goals with regard to the manufacturing and application of PPE that can be printed via 3D technology under extreme circumstances.

Our hypotheses were the following:

- The further development of OS, widely available face masks, face shields and goggles that can be printed with 3D technology necessitates the continuous consideration of practical aspects.

- From among AM technologies, Fused filament Fabrication (FFF) and Selective Laser Sintering (SLS) technologies are well applicable in the development and small series production of PPE in emergency situations.
- Disinfection procedures, as defined by guidelines, have no negative impact upon mechanical and optic features, consequently, 3D printed protective equipment are reusable.

3 Materials and methods

3.1 A national survey of videolaryngoscopes and alternative intubation devices in Hungary

Prior to this study, permission was first obtained from the Ethics Committees of the Medical Research Council of Hungary (National Healthcare Services Center, Ministry of Human Capacities of Hungary, 28230-2//2018/EKU).

The survey was designed as a Google form by the author and the survey was conducted between 01.01.2018 and 31.12.2018. We aimed to reach all the 1567 anesthesiologists of Hungary. A link was distributed electronically with the help of the Hungarian Society of Anesthesiology and Intensive Therapy, and the participants were requested to complete the survey online. Informed consent regarding participation and publishing was obtained from the participants through a question incorporated into the questionnaire. The survey asked for single and individual responses from all the anonymous responders. The study presumed that the connection between the patient and the device used for airway management is the anesthesiologist. Therefore, in the current study, the participating anesthesiologists were asked to answer as individuals in contrast to similar previous studies in which departments or hospitals were the respondents. We intend to emphasize here that not all the aforementioned devices are classic videolaryngoscopes.

Data were first exported as a Microsoft Excel 2013 (Microsoft Corporation, Redmond, WA, USA) spreadsheet, and then the Statistical Package for the Social Sciences (SPSS) Statistics software, version 25.0 (IBM Corporation, Armonk, NY, USA) was used for further analysis. Data are presented as the mean and standard deviation (SD) or as raw numbers (n) and percentages (%).

3.2. Comparison of VividTrac®, Airtraq®, KingVision®, Macintosh

Laryngoscopes and a Custom-Made Videolaryngoscope for normal airways in mannequins by novices

Prior to this study, permission was first obtained from the Institutional Scientific and Human Research Ethics Committee of the University of Pécs (5825/2016).

Volunteer students studying general medicine at the Medical School, University of Pécs were recruited into the study. As an inclusion criterion students were required to have no previous experience of advanced-level airway management. Subsequent to sample size estimations, a total of fifty students were included into the study, they were randomly allocated into small groups (n=5). The study was conducted at the Medical Simulation Education Center of the Medical School, University of Pécs. The following devices were used: Direct laryngoscope (Macintosh), VividTrac®(VT), Custommade improvised laryngoscope, King Vision®, Airtraq®(AT).

For the ID and VT, we used a PC to display real-time videos during the study. For the AT, we attached the original, universal, smartphone adapter (Prodol, Vizcaya, Spain) and a smartphone to the scope for the same purpose. VividVision® and Airtraq Mobile® software were used for the VT and AT, respectively. Each endotracheal intubation was performed with a standard 7.5-mm internal diameter, cuffed, plastic endotracheal tube (Mallinckrodt®, Covidien, Dublin, Ireland). Demonstrations, training and evaluations were all performed on the Laerdal® Airway Management Trainer (Laerdal®, Stavanger, Norway).

In the scenario, full head reclamation was allowed and each participant received 15 min. of standardized training on each device and in each study setting. Optimization maneuvers, the use of stylets and an estimation of the Percent of Glottic Opening (POGO) score were also explained and practiced under the supervision of experienced investigators. The importance and the mechanism of dental injury were also explained and highlighted. Participants were asked to complete endotracheal intubations with all devices in all scenarios in a random order. The primary outcome was successful endotracheal intubation. Secondary outcomes included the time to successful

endotracheal intubation, the time needed for achieving the best glottis view, tube insertion time, the best POGO achieved, the number of intubation attempts, the occurrence of esophageal intubations, the occurrence of dental trauma and the need for optimization maneuvers.

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Following the completion of a scenario, the students were asked to grade each device based on the ease of technical use (1 = easy, and 5 = difficult), the ease of physical use (1 = easy, and 5 = difficult) and the willingness to reuse (1 = would never use device again, and 5 = would use device again) in the relevant scenario; they were discouraged from giving an overall ranking.

The analyses were conducted by Statistical Package for the Social Sciences (SPSS) Statistics software, version 22.0 (IBM Corporation, Armonk, NY, USA). Continuous and ordinal data are presented as the median and interquartile range (IQR), and the categorical data are presented as raw numbers and as frequencies. Non-parametric tests were used as the data distribution was not normal based on Kolmogorov-Smirnov and Shapiro-Wilk tests. The Kruskal-Wallis one-way analysis of

variance (ANOVA) with post-hoc Dunn's test was used to assess pair-wise differences between the devices for the following variables: laryngoscopy time (LT), tube insertion time (TIT), intubation time (IT), POGO score, ease of technical use, ease of physical use and willingness to reuse. Chi-square tests were used to evaluate differences between the devices for the rate of successful tracheal intubation, esophageal intubation, dental injury and bougie and stylet usage. Values of $P < 0.05$ were considered as significant.

3.3. An Overview on Personal Protective Equipment (PPE) Fabricated with Additive Manufacturing Technologies

No Ethics Committee approval was required for the study.

To evaluate the feasibility of different 3D printing technologies, specimens and model equipment were printed. Based on previous studies, it has been observed that for medical device development and small-series production, the most frequently used technologies worldwide are FFF and SLS 3D printing. For the FFF 3D printing, a Craftunike Craftbot 2 Plus with Craftware™ slicing software and polylactic acid (PLA, distributed and manufactured by Herz Hungária Ltd., Üllő, Hungary) was used for the estimation and production of PPE. The devices and polylactic acid (PLA) test specimens were printed with a 0.6 mm nozzle diameter and 400 μm layer height for the face shields and a 0.4 mm nozzle diameter and 200 μm layer height in all other cases. The printing speed was set to 60 mm/s, and the infill density was 100%. For estimating the productivity and for manufacturing test bars made of polyamide (PA) (PA2200—Varinex Ltd., Budapest, Hungary), an EOS Formiga P110 was used. The layer height was set to 100 μm resolution. The printing speed was 5 sec/layer. The room temperature was set to 24 °C. According to international standards, 5 pieces of test bars were printed for each test. All test specimens were measured in the “X” printing orientation. In the development process of the face masks, a ZA-22 “THIXO BODY” (Alvin Ltd., Budakeszi, Hungary) two-compound silicone mixture was molded. For transparent parts of goggles and face shields, 0.3 mm thick polymethyl methacrylate (PMMA) sheets (distributed by AkaDekor Ltd., Pécs, Hungary) were applied. In order to assess the mechanical properties of the objects, based on international standards, all the tests of the materials were performed on test specimens without disinfection, after 5 and 10

disinfection cycles, respectively. As a disinfection agent, the commonly used solution of tetra-acetyl-ethylene-diamine (TAED) and sodium-perborate solution (commercially available as Sekusept™— EcoLab Hungary Ltd., Budapest, Hungary) 2 m/m% solution were used. Based on the local and international medical protocols, one disinfection cycle was set for 1 h, and all the test specimens were submerged in the agent at room temperature (24 °C).

As a dynamic mechanical test, Charpy impact test (ISO 179-1) was used on the unnotched specimens with a size of 80 × 10 × 4 mm. For the static mechanical analysis, a 3-point bending test (ISO-178) and tensile strength test (ISO-527-2) were performed. The 3-point bending test was carried out on the specimens with a size of 80 × 10 × 4 mm, and tensile strength tests are specified as B1. A flex resistance test of the ZA-22 silicone materials was carried out according to the ISO 32.100 standard using a Zwick/Roell (Senselektro Ltd., Budapest, Hungary) e/m actuator. The size of the test specimen was 70 × 45 × 1 mm, and the number of cycles were: 1000, 2000, 3000, 4000 and 5000 on all disinfected and non-disinfected samples. Shore A hardness measurements were performed on silicone test specimens. All test bars were laid on the printing bed with the largest surface facing downwards. All test specimens were measured in the “X” printing orientation. The room temperature was set to 22.6 °C, while the relative humidity was 49.5%. According to international standards, 5 pieces of test bars were printed for each test. The broken surfaces of the test specimens were examined using scanning electron microscopy (SEM-JSM-6300, Jeol, Japan) at 10× and 60× magnification. Gold sheeting was applied to the test bars. After a flex resistance test, the surface of the silicone samples was examined with a König digital microscope with 60× magnification. For the statistical analysis, OriginPro 2018 software was used.

To determine the effect of disinfection procedures on the transparency of PMMA sheets, spectrophotometry measurements were performed on test samples of 0.3 mm thick and 50 × 30 mm size samples using Secoman Anthelie Advanced 2 spectrophotometry device (Secomam, Ales, France). The change of intensity was measured, between 300 and 900 nm wavelengths, on non-disinfected and disinfected test specimens. All measurements were repeated 5 times.

According to publicly available materials and sources, three different types of PPE have been manufactured by 3D printing communities to date, mainly with FFF technology. Since biological agents transferred by droplets can easily enter the human body through mucous membranes, safety goggles can be used to specifically protect viral penetration through the eye. To protect the face from aerosol-based biological threats such as SARS-CoV-2, face masks can be used effectively. These equipment are especially useful for all healthcare professionals who might come into contact with the virus. Protective half masks are important in filtering the air, thereby, reducing the risk of exposure to airborne diseases and aerosol-based microorganisms. Therefore, they can be useful at all levels of the healthcare system. The effectiveness of half masks mainly depends on the type of the incorporated filter and the fitting parameters of the masks to the face. Further protection can be achieved by applying face shields, either in combination with other PPEs or solely for non-medical purposes. Three main models of the aforementioned PPEs were examined, with regard to the production time, costs and practical aspects. The following open-source (OS) models were examined: a half mask (“OS Half Mask” in the Supplementary Material; “NHS COVID MASK REMIX” by user wayneuk on Thingiverse), a face protection shield (“OS Shield” in the Supplementary Material; “PRUSA RC 2” by Prusa Research a.s.), and safety goggles (“OS Safety Goggles” in the Supplementary Material; “COVID-19 coronavirus goggle” by user jim0089 on Thingiverse).

In this study, the OS models were modified using different CAD software solutions (Autodesk Inventor 2020™, San Rafael, USA; Rhino 6™ (Rhinoceros McNeel, Barcelona, Spain); Fusion 360™, Autodesk, San Rafael, USA). Based on the findings and practical aspects, the research team created models that are cost-effective, easy to print and assemble, and adaptable to special or unique needs; these models can potentially increase the effectiveness and protection level each device can offer. The novel models are referred to as V.2.0.

Statistical analyses were performed using the OriginPro 2018 (OriginLab Corporation, One Roundhouse Plaza, Suite 303, Northampton, MA, Software. Twosample T tests were carried out for the comparison of individual measurement data. Values of $P < 0.05$ were considered as statistically significant.

4. Results

4.1. A national survey of videolaryngoscopes and alternative intubation devices in Hungary

In total, 324 completed forms were returned without duplicates. Response rate was 21%. The mean age of respondents was 43 years; males were slightly overrepresented (58%). The majority of respondents (80%) were specialists with the majority involved in anesthesia (68%). Different levels of patient care were equally represented with the exception of the private sector. Approximately 78% of respondents reported being involved in the education of trainees at least once a month.

Two hundred and ten (65%) respondents provided positive information on the availability of any type of VL at one anesthesia workstation at least at their main workplace. Nineteen anesthesiologists (6%) reported having definite access to VL but were unable to name the exact location (clinical area) of the device. Regarding immediate availability, the most well supplied clinical areas were surgery (n = 115, 36%), the intensive care units (n = 98, 30%) and traumatology departments (n = 90, 28%).

The poorest availabilities were reported in the pediatric (n = 21, 7%), emergency (n = 23, 7%) and ear-nose-throat (n = 34, 11%) departments. The overall, average, immediate availability rate was 18%. When the time window for availability was increased to 'within ten minutes', the overall, average, availability rate increased by 5% to 23%. By increasing the time window, the best supplied clinical areas remained the same, however, the order changed as follows: intensive care units (n = 143, 44%), surgery (n = 116, 36%) and traumatology departments (n = 98, 30%). None of the respondents reported availability of the following video laryngoscopes: the AP Venner, Bullard, Coopdech, C-Trach, Levitan, Shikani, Upsherscope and Wuscope.

Forty-five (14%) respondents claimed they were not familiar with any of the devices included in this survey. The ten most well-known devices are shown in [Fig 2](#). Regarding the real clinical availability of certain video laryngoscopes the survey showed that only three devices reached at least a 5% positive response rate. KingVision was the most

available video laryngoscope in clinical practice with 24% (n = 79), while the McGrath Mac (n = 36, 11%) and Airtraq (n = 28, 9%) were also among the top three most commonly used video laryngoscopes (Fig 5.). Fifty-three (16%) respondents reported the following: “A video laryngoscope is available, but I am not sure about the brand.”

One hundred and four respondents (32%) said that they had never ever used any video laryngoscope in a clinical setting. Only 39% (n = 126) confirmed that they used VL at least once per month. The KingVision, Airtraq and MacGrath Mac were the top video laryngoscopes used at least once in patient care according to the responding Hungarian anesthesiologists.

The vast majority of users preferred to use VL in “predicted” (n = 151, 47%) and “unexpected” (n = 119, 37%) difficult airway scenarios. The most common indications for VL were the following: “difficulties visualizing the vocal cords appropriately” (n = 303, 94%), “suspected or definitive cervical spine injury” (n = 252, 78%) and “difficulties in endotracheal tube placement even though the vocal cords are fully visible” (n = 153, 47%). Only 11% (n = 37) used VL for “routine” airway management, and 28% (n = 90) used VL for teaching purposes. Fibroscopy was the most popular clinical alternative to VL (n = 281, 87%), while direct laryngoscopy (n = 142, 44%) was the second most common, followed by the use of a laryngeal mask (n = 115, 36%).

The most well-known methods for selecting a videolaryngoscope were the following: short clinical trial (n = 67), decision of the department leader (n = 65) and market price (n = 54). The majority of users (n = 218, 67%) received some type of training regarding VL. However, training was reported to be mainly on voluntary (n = 187) and rarely on a compulsory (n = 31) basis. Forty-one (13%) anesthesiologists used VL without any prior training. The overall experience was positive. Apart from those who reported a lack of experience (n = 74, 23%), 98% (n = 246) considered VL beneficial. However, the vast majority of the latter group (n = 210, 65%) found VL useful only in “special circumstances”.

4.2. Comparison of VividTrac®, Airtraq®, KingVision®, Macintosh Laryngoscopes and a Custom-Made Videolaryngoscope for normal airways in mannequins by novices

Fifty voluntary medical students without prior experience in advanced airway management were recruited. All students provided written informed consent prior to participation. No significant difference was observed in the tracheal intubation success rate between the devices throughout this scenario. The overall longest IT was associated with the ID, and commercial VLs were faster than DL. Participants achieved better POGO scores with all VLs than with the DL. On comparing VLs relative to POGO scores, the ID was found to be inferior ($P < 0.05$), but the VT proved to be far superior to DL and ID ($P < 0.05$). All commercial VLs received better ease of use scores than DL and ID ($P < 0.05$). The scores with regard to willingness to reuse were significantly better for KV and VT than for the DL.

4.3. An Overview on Personal Protective Equipment (PPE) Fabricated with Additive Manufacturing Technologies

According to data, PLA showed significantly lower resistance against dynamic forces than PA. Before disinfection, the mean value of impact strength was $57.95 \text{ kJ/m}^2 \pm 10.55 \text{ kJ/m}^2$ for SLS test bars and $19.44 \text{ kJ/m}^2 \pm 1.52 \text{ kJ/m}^2$ for PLA test specimens. The results of the static mechanical tests revealed that there was no significant difference in tensile strength: PLA had a mean value of $57.60 \text{ MP} \pm 1.22 \text{ MPa}$, while the mean value for PA test bars was defined as $46.40 \text{ MP} \pm 1.04 \text{ MPa}$. The three-point bending and tensile tests showed significantly higher values for the FFF technology, with a remarkable elastic modulus of $3.06 \text{ GPa} \pm 0.12 \text{ GPa}$ on the three-point bending and $3.34 \text{ GPa} \pm 0.03 \text{ GPa}$ on the tensile test, while the SLS technology had mean values of $1.3 \text{ GPa} \pm 0.05 \text{ GPa}$ on the three-point bending and $1.68 \text{ GPa} \pm 0.05 \text{ GPa}$ on the tensile test. These results could be explained by the ISO-178-1 international standard where the measurement ends at a 10% deflection. Neither the PA nor the PLA test bars broke at this rate which implies a higher elasticity; this allowed for a more precise calculation of the value of flexural stress at the standard deflection value. For PPE, dynamic forces are more relevant than other forces. During their routine, everyday use, PPE can be easily dropped or they may hit other objects; therefore, they have to be more resistant than other materials against such effect.

According to our data, after submerging test specimens in the Sekusept solution for 5 and 10 disinfection cycles, no significant change was observed in the mechanical parameters. More surprisingly, in the case of polyamide, a small elevation of the elastic modulus was observed with the mean value of $1.32 \text{ GPa} \pm 0.05 \text{ GPa}$, as well as in the case of PLA with the mean value of $3.06 \text{ GPa} \pm 0.04 \text{ GPa}$. The tensile elongation of PA also showed a slight increase, with the maximum value of $14\% \pm 0.45\%$.

To determine the usability of ZA-22 silicone mold as an insulating layer in PPE, flex resistance tests and Shore A hardness tests were performed. An interesting result was that the surface analyses of the samples showed 0 degree of change (no change) in all cases both before and after disinfection procedures. There was no significant change on Shore A hardness tests in samples with and without disinfection; the values varied between 18.92 ± 0.18 and 20.4 ± 0.58 .

Although several papers have described the layer-based structural characteristics of FFF 3D printing technology, examinations of PA structures created with SLS technology have mainly focused on the granule and the in-production states of melting [17,54–57]. In the case of PPE fabrication, the surface of the product is crucial for determining the survivability of different biological agents. According to available evidence, the transmission of SARS-CoV-2 between people takes place via respiratory droplets of sizes $>5\text{--}10 \mu\text{m}$, while the size of the virus is approximately 120 nm [31,58–60]. Airborne transmission refers to the conveyance of pathogens via droplet nuclei which have a diameter below $5 \mu\text{m}$ and spread over 1 m in air. SARS-CoV-2 transmission conceivably takes place in special circumstances such as during aerosol-generating medical procedures [59]. Therefore, the $15\text{--}150 \mu\text{m}$ pores of the SLS products without further coating, impregnation, lamination or other surface treatment methods can serve as environments where SARS-CoV-2 can survive (Figure 5) without proper disinfection measures; consequently, clinically used PPE tends to be highly contaminated with pathogens [13,47,61,62]. However, the virulent SARS-CoV-2 titer significantly decreases hourly, and decontamination by standard disinfection techniques such as sodium hypochlorite or detergents further decreases the possibility of spreading and could offer potential solution to preventing infection through PPE [27,62]. Since there is no effective treatment or vaccination against COVID-19, disease prevention is the highest priority,

therefore, the standard disinfection methods should be further investigated and riskstratified including the aforementioned materials and reusable PPE.

Regarding face shields and goggles, visibility is a key factor. Consequently, the light intensity passing through PMMA sheets is essential for the proper use of these PPEs. Medical personnel and other healthcare staff must be able to see through them clearly, thus, disinfection methods should not affect vision. Spectrophotometry measurements revealed that 5 or even 10 disinfection cycles did not decrease the light intensity significantly. Nonetheless, a slight increase (1–2%) could be observed.

In this study, OS models were modified using different CAD software solutions (AutodeskInventor 2020™, San Rafael, USA; Rhino 6™ (Rhinoceros McNeel, Barcelona, Spain); Fusion 360™, Autodesk, San Rafael, USA). Based on the findings and taking into consideration various practical aspects, the research team created models that are cost-effective, easy to print and assemble and adaptable to special or unique needs, and thus, can potentially increase the effectiveness and protection features of each device. The novel models are referred to as V.2.0.

Shield V.2.0: The part of the model where the transparent polymer (PMMA) shield can be fitted is elongated to cover and protect a large area of the face. The overall size of the model was decreased compared with the earlier model which reduced printing time using FFF technology from 100 to 38 min. per piece. The new model allows a markedly higher productivity with SLS technology as 41 pieces can be printed in a full chamber. It was also important to design a head cover part to prevent contamination of the top of the head.

Face Mask V.2.0: In general, using half-face masks are of pivotal importance in the prevention of COVID-19. The available OS models generally seek certifications based on the level of protection they can offer (e.g., FFP or N levels). To receive a certification, one of the major criteria is how well the mask fits to the face and nose, since a good fit ensures that virus particles cannot enter the airway system. To improve the face fitting in the V.2.0 model, a silicone layer was designed to reduce air leakage. This silicone layer was easily molded by an FFF 3D-printed mold tool. As the flex resistance test revealed, the use of silicone is a durable and long-lasting solution, and silicone can be disinfected without affecting its mechanical stability. Since a proper and easily changeable filter

holder is a crucial safety feature of a mask, our team had to find a solution to this problem as well. To prevent air leakage and increase safety, an O-ring was designed that can be inserted into the connector part. FFF printing technology helped reduce the material weight per piece from 120g to 70 g and the production price from 0.73 to 0.43 Euros. A silicone layer is applicable to SLS models as well.

Safety Goggles V2.0: Two main modifications have been made to the new model. With the aim to provide a wider angle for peripheral vision, two side openings were designed to the goggles that can be covered with transparent polymer sheets. Changing the transparent sheet is easy and fast making the disinfection process also easier. The nose fitting was also redesigned to enable parallel use of goggles with a face mask. In terms of manufacturing, the use of SLS 3D printing technology is recommended (Figure 9). Spectrophotometry measurements confirmed that PMAA sheets can provide a suitable solution as the transparent part of the goggles and the disinfection cycles have no effect on the visibility or mechanical properties.

5 Summary

5.1. A national survey on videolaryngoscopes and alternative intubation devices in Hungary

Our aim was to examine the use of VL devices in routine practice in Hungary with special focus on availability, related training, usage skills and patterns of use in Hungary. To the best of our knowledge, the present study has been the first such survey in Hungary to date. Despite several limitations, our result provide useful insights that are elaborated in more detail below. Challenges posed by the COVID-19 pandemic have brought VL devices into the focus of attention; therefore, our study may provide useful guidance and up-to-date information for ongoing or future training programs and development projects. The survey intended to elicit responses from colleagues working at anesthesiology and intensive care units as opposed to other surveys asking for the opinion of various institutions and departments within health care. One of the major results of our study was that according to 65% of respondents VL was available at a workstation of the institute they worked at. Despite the fact that the individual, personal responses could not be directly compared with data provided by hospitals, based on data presented above the availability of VL devices in Hungary correspond to data reported in the UK between 2010 and 2017. It was an interesting finding that KingVision is the most commonly available VL, a brand that is rarely, if at all used in the UK. Despite an increasing number of VL technology available, it is clear to see that many of these are infrequently used. The choice in Hungary largely depends on the decision of the departmental leadership and/or the market price. It is important to underline the fact that the availability of VL devices should go hand in hand with a unified and harmonized training program to ensure that colleagues involved can use these devices safely and adequately. Therefore, we intend to stress the importance of the development and implementation of a uniform training program in order to ensure that VL devices used provide the greatest potential benefit for patients.

5.2. Comparison of VividTrac®, Airtraq®, KingVision®, Macintosh Laryngoscope and a Custom-Made Videolaryngoscope for normal airways in mannequins by novices

Prior to discussing and summarizing our results we consider it important to mention that the medical students recruited performed intubations on intubation mannequins and had only a short 15 min. training prior to their airway management attempts. Consequently, the validity and direct applicability of our results and conclusions to clinical practice is cannot be claimed with certainty. Dental injury occurring during intubations was recorded with a yes/no answers only; we did not record the exact rate of occurrence and the exact force causing these injuries. Nonetheless, we would like to highlight the high number of successful first attempts (90%) and short ITs that are 25 sec. shorter than ITs reported by other European studies. The aforementioned rates are an excellent result considering the fact that volunteer students had had only 15 min. prior training.

It is a well-known fact that even well-acquired and retained manual skills may decay with time; therefore, our observations may prove beneficial in the design and implementation of airway management training programs targeting medical students and beginner colleagues.

Our findings have shown that in the case of videolaryngoscopes available on the market LT and IT were shorter than in the case of DL, thus DL seems to have underperformed. Or data are in line with earlier data presented in studies with simulators and patient care data. The use of VLS available on the market have significantly improved POGO scores compared to DL, however, compared to ID they did not. The aforementioned advantage of VL has been reported by several earlier studies the results of which are in line with our findings.

Several considerations may influence the choice among similar intubation devices in clinical practice including the experience of the physician and other subjective factors. Medical students involved in our study found VL easier than DL. When asked, they mostly preferred KV and VT devices, and reported they would be willing to use these devices again. This finding does also correspond with results of other previous studies. Our study has been the first to report that during normal airway management performed

by novices on mannequins VT and KV outperformed both DL technology and specially designed laryngoscopes in all parameters analyzed. Upon comparing VL devices, our study has been the first to examine intubation success rate in a simulation environment. Comparing different types of VL device, we found that novices recruited into our study without any prior experience or routine in airway management performed better using VT in all parameters analyzed upon normal airway management as compared to other types of device.

5.3. An Overview on Personal Protective Equipment (PPE) Fabricated with Additive Manufacturing Technologies

AM technologies have had a significant impact on the development and manufacturing of personal protective equipment worldwide. FFF and SLS printers have played an important role in this process, mainly, due to their special features and the materials used for printing. PLA can be used for printing face protecting shields as a result of the cost- effectiveness and widespread availability of the tools and equipment needed. In case of supply shortage that may occur due to the COVID-19 pandemic, FFF technology can provide a temporary solution for the manufacturing of PPE, especially, through methods described above that are well-applicable for the printing of functional 3D parts. In the clinical use of 3D printed PPE, in order to reduce the risk of the transmission of the SARS-CoV-2 virus, abiding by disinfection procedures as described in professional guidelines is of crucial importance. Alcohol-based surface disinfectants that are widely used and ethylene-oxide may prove cost-effective and efficient.

Our study has proved that the widely available and cost-effective solution of tetraacetylene-diamine (TAED) and sodium-perborate (Sekusept™ - EcoLab Hungary Ltd., Budapest, Hungary), can be effectively used on polyamide PLA and ZA-22 silicon materials used in devices protecting against SARS-CoV-2 transmission without affecting the mechanical and structural integrity of 3D-printed or molded parts. Spectrophotometry examination subsequent to disinfection revealed that transparency remained unchanged even after multiple treatments. 3D-printed PPE is reusable with an adequate disinfection protocol and thus can play a crucial role in the protection of staff involved in airway management during the COVID-19 pandemic. It is important to note, that most such devices have not been licensed by the Food and Drug Administration (FDA) or the

European Community (EC), therefore, possible users need to be aware of the consequences and potential dangers involved in using unauthorized and unsupervised devices.

Tests we have developed may provide useful guidance for the cost-effective manufacturing and quality control of personal protective equipment. We intend to underline that personal protective equipment manufactured using AM technology need to undergo further preclinical and clinical testing. Our study has revealed that AM technologies are well-applicable in states of emergency or in case of supply shortages for the development of small series production of PPE. However, these technologies are not yet adequate for large-scale production in terms of productivity or cost-effectiveness.

The above clearly demonstrates interferences between simulation education and anesthesia and intensive care, opening up seemingly endless possibilities for cooperation. The present study discussed special airway management procedures and the significance of additive production technologies in the manufacturing of personal protective equipment in response to extreme circumstances and the state of emergency caused by the current pandemic.

6 Novel findings

- Upon evaluating the applicability of VL we concluded that VL airway management technology is available for approximately two-thirds of Hungarian anesthesiologists. Our study has found that the majority of colleagues are aware of the advantages offered by VL, nonetheless, they resort to using VL as an alternative solution in the case of difficult airways.
- Analyzing VL use in Hungary, we have found that most colleagues use VL without any prior training. Therefore, we do believe that the design and implementation of specialized training would be of pivotal importance.
- Evaluation of airway management maneuvers on normal airways as performed by novices using different VL devices has led us to the conclusion that VL devices yield better results when used by unexperienced, unskilled providers compared to DL. VL devices are novel, promising, affordable alternatives that may even become safe, first line options in airway management in the future.
- VL devices can be used effectively in the teaching of students as these devices have proved to be more effective in all parameters examined compared to DL even after a short training time. The effectiveness of ID does not exceed that of direct laryngoscopy; it is not recommended for clinical use without further detailed analyses.
- AT and VT devices that have been first examined by our team according to the literature proved more effective in several aspects compared to traditional airway management devices during normal airway management maneuvers performed by novices.
- The examination of AM technologies verified our initial hypothesis that 3D printing technologies may prove useful in facilitating protective measures introduced during the COVID19 pandemic as they can play a role in PPE development and small series production. Compared with other manufacturing technologies, e.g. injection molding, they require less time for development and manufacturing as there is no need for tool design. As a result, production costs may also decrease even in the case of small series production.

- Our study has proved that the plans and suggestions presented and outlined above may potentially enhance the efficacy of personal protection equipment with further modifications as required based on experience through routine usage.

The end product is easily modifiable, it can be redesigned and manufactured as dictated by changing needs.

- Our study has been the first to show that disinfection procedures, as set in guidelines, can be performed on the materials mentioned without any changes to the mechanical properties or applicability. As a result, it can be stated that 3D-printed PPE offers an environment-friendly, practical and reusable solution.
- We have outlined and discussed that FFF and SLS AM technologies are reliable but can only provide temporary, short-term solutions to issues concerning the manufacturing personal protective equipment. We would like to emphasize that these technologies should primarily be used in the absence of other manufacturing technologies, in the case of supply shortages, under extreme circumstances or states of emergency.