First robotic tracheal intubations in humans using the Kepler intubation system

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Background. Intubation is one of the most important anaesthetic skills. We developed a robotic intubation system (Kepler intubation system, KIS) for oral tracheal intubation.

Methods. In this pilot study, 12 patients were enrolled after approval of the local Ethics board and written informed consent. The KIS consists of four main components: a ThrustMaster T.Flight Hotas X joystick (Guillemot Inc., New York, NY, USA), a JACO robotic arm (Kinova Rehab, Montreal, QC, Canada), a Pentax AWS video laryngoscope (Ambu A/S, Ballerup, Denmark), and a software control system. The joystick allows simulation of the wrist or arm movements of a human operator. The success rate of intubation and intubation times were measured.

Results. Eleven men and one woman aged 66 yr were included in this study. Intubation was successful in all but one patient using KIS at a total time of [median (inter-quartile range; range)] 93 (87, 109; 76, 153) s; in one patient, fogging of the video laryngoscope prevented intubation using KIS.

Conclusions. We present the first human testing of a robotic intubation system for oral tracheal intubation. The success rate was high at 91%. Future studies are needed to assess the performance and safety of such a system.

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Tracheal intubation is one of the most commonly performed procedures in anaesthesia. Whereas tracheal intubation can be easy in the hands of the skilled operator in the perfect conditions of the operating theatre, it can be more difficult in suboptimal conditions, such as the emergency department, or in the hands of the less skilled, occasional operator. In addition, our patient population has a higher incidence of morbidly obese patients who present specific problems during intubation. Different operator-related factors might also play a role, physical differences, such as arm length or height, and arm strength, might have an influence on the individual skill set. Tracheal intubations, commonly performed with high success rates in anaesthesia departments, can be associated with lower success rates in emergency departments, where intubation success rates can be as low as 70% of the time at the first attempt and 89% at the second attempt.

Robots have long found their way into surgery (e.g. DaVinci robotic system), allowing operating robotic arms with little force and possible higher precision, but less so in anaesthesia. A study conducted by Tighe and colleagues demonstrated the use of a surgical robot to assist in airway management in two cases of mannequin intubation; however, the expense of such a system prohibits its widespread adoption for this application. We have developed a specific robotic intubation system (Kepler intubation system, KIS) and successfully tested it in airway mannequins, including semi-automated operation.

This article presents a pilot study of its evaluation in humans.

Methods
In this pilot study, 12 patients were enrolled after approval of the local Ethics board and obtaining written informed consent. Patients whose airway was assessed as ‘difficult’ during preoperative assessment (Mallampati >1, mouth opening <4 cm, thyromental distance <7 cm, and limited neck movement) or patients with a history of difficult intubation and those with an ASA classification >II were excluded. A remotely controlled robotic system was used to intubate using a standard video laryngoscope. The KIS consists of four main components (Fig. 1): a ThrustMaster T.Flight Hotas X joystick (Guillemot Inc., New York, NY, USA),
Fig 1 Illustration of the KIS. The system consists of: a ThrustMaster T.Flight Hotas X joystick (Guillemot Inc.), a JACO robotic arm (Kinova Rehab), a Pentax AWS video laryngoscope (Ambu A/S), and a software control system. An assistant is needed to open the mouth while performing robotic intubation.

Fig 2 A screenshot of the KIS 'cockpit', installed on a portable laptop. There are two live feeds (left: live feed from a videolaryngoscope, right: live feed from a webcam). In the middle, there is a graphical/numerical representation of the time with the time starting at 0 and change of colour at 2 and 3 min of time and acoustic alarms at 2 and 3 min. There is also a window indicating the type of arm speed chosen (low, middle, high).
a JACO robotic arm (Kinova Rehab, Montreal, QC, Canada), a Pentax AWS video laryngoscope (Ambu A/S, Ballerup, Denmark), and a software control system (ITAG laboratory, Montreal, Canada). The software control system was developed in C sharp (Microsoft Corporation, Redmond, WA, USA) and the graphical user interface was developed in LabVIEW (National Instruments, Austin, TX, USA). The robotic arm can be operated in three different speeds (low, medium, and high, where high speed is used to put the arm from the resting position over the patient, medium used to descend the video laryngoscope towards the mouth, and low used to manipulate the video laryngoscope within the patient’s mouth and throat). A commercial webcam (Microsoft Corporation) can be positioned laterally to the patient and attached using a flexible arm on the side of the operating table, providing a live-video feed of the video laryngoscope during intubation. The interface of this system is the KIS® Intubation Cockpit (Fig. 2). The tracheal tube was attached into the groove of the Pentax video laryngoscope in a standard fashion without sticking the tip out. Anti-fogging liquid was administered onto the tip of the fibreoptic cable and the video laryngoscope was also pre-heated during 5 min to minimize the risk of fogging during intubation.

In the preoperative assessment area, all patients’ airways were evaluated by the same research assistant. The following parameters were determined: Mallampati, mouth opening as inter-incisive distance, thyromental distance, neck and larynx mobility, and presence of retrognatism (i.e. recessed jaw).

The KIS was attached at the head of the operating table using an extension and fixed using commercial clamps on the base of the table to avoid any movement during its use (Fig. 3). Before intubation, the KIS was set up in the resting position allowing facial mask ventilation and easy access to the patient. Once the patient was placed on the operating table, two i.v. lines were installed, one for administration of total i.v. anaesthesia (TIVA) using propofol, remifentanil, and rocuronium and the other for fluid administration. Standard monitoring consisted of five-lead ECG, peripheral pulse oximetry, bispectral index (BIS) monitoring, and non-invasive arterial pressure monitoring. Depending on the type of surgery, invasive arterial pressure monitoring was added.

Directly behind the head of the operating table, on the left side, a mobile cart with the KIS control centre (joystick and laptop) was positioned. Video-feeds from the video laryngoscope and webcam were displayed on the screen of the laptop (ASUS 19 in, ASUS Company, USA) and simultaneously on two large video screens on either a mobile screen of the operating theatre or a screen attached to the wall of the operating theatre. All screens were visible to the operator of the KIS, who performed all robotic intubations (T.M.H.). The operator had performed more than 100 robotic intubations in a standard airway mannequin before this pilot study. A timer was also displayed in the intubation cockpit, with visual and audible alarms at 2 and 3 min after the start of the intubation process. Three minutes were regarded as the cut-off time to change to manual intubation using a standard laryngoscope.

The head of the patient was positioned in a neutral position on a gelled pillow. The webcam was positioned on the right side of the patient at the middle of the mouth; at the left side of the table, an assistant was positioned who performed the mouth opening, placing one hand on each side of the mouth.

All patients were preoxygenated for at least 5 min using a facial mask with $F_{O_2}$ of 100%.

Then, TIVA was started using remifentanil 0.5 $\mu$g kg$^{-1}$ min$^{-1}$ for 2 min, remifentanil 0.2 $\mu$g kg$^{-1}$ min$^{-1}$ for 1 min, followed by remifentanil 0.1 $\mu$g kg$^{-1}$ min$^{-1}$. Once the infusion rate changed to 0.1 $\mu$g kg$^{-1}$ min$^{-1}$, 2 mg kg$^{-1}$ of propofol was injected, followed by an infusion of 200 $\mu$g kg$^{-1}$ min$^{-1}$, which was then adjusted to maintain a BIS of 45. If BIS did not descend below 60 after the propofol bolus, an additional dose of 0.5 mg kg$^{-1}$ of propofol was injected. Once BIS was below 85 and no spontaneous respiration detected, mask ventilation was started manually using 100% oxygen. Once mask ventilation produced end-tidal CO$_2$ waves indicating sufficient ventilation, rocuronium 0.9 mg kg$^{-1}$ was injected and the intubation process started 2 min later, once train-of-four monitoring of the adductor pollicis showed no twitch response. Once neuromuscular block completed, the mouth was opened by the assistant to the left side of the patient while the KIS operator moved the laryngoscope into place using the KIS control centre.

The two handles of the joystick allow similar movements as are possible by the human wrist and arm when using the video laryngoscope manually (Fig. 4). All movements of the wrist, flexion, extension, ulnar, radial deviation, and pronation and supination are assigned to specific buttons or movements of the handles of the joystick. Equally, the robotic arm can be moved forward, backwards, and up and down.
The video laryngoscope was moved with the blade in a vertical position into the mouth; based on preliminary airway mannequin testing, the entry point was aimed to be as close to the upper palate as possible. The laryngoscope was then inserted further using three-dimensional movements by using the joystick handles. A combination of these three movements was used to manipulate the Pentax’s crosshair overlying the vocal cords; once this position was achieved, the attached tracheal tube (TT size 7.0) was then pushed forward into the trachea by the KIS operator. The ventilator tubes were then connected to the tracheal tube and ventilation was confirmed via end-tidal CO2 tracing and artificial ventilation commenced. Then, the video laryngoscope was removed using the KIS.

As a primary outcome, the success rate at first attempt was measured. An intubation attempt was defined as the introduction of the laryngoscope into the patient’s mouth and its removal regardless of whether the tracheal tube was inserted. As a secondary outcome, the time from entering the mouth to insertion of the tracheal tube through the vocal cords was determined. If intubation was not performed robotically within 3 min, it was regarded as a failed attempt. The incidence of mucosal damage, peripheral oxygen desaturation <95%, dental injury, and oesophageal intubation were noted from the beginning of the intubation process to the discharge from the postanaesthesia care unit. An independent observer assessed these outcomes.

Once the mask ventilation was interrupted and the intubation process started, three different times were measured by an independent observer: positioning time, intubation time, and extraction time. The positioning time was defined as the time to move the robotic arm from the resting position to the mouth, with the tip of the video laryngoscope at the entry of the mouth. The intubation time was defined as the interval from the insertion of the video laryngoscope into the mouth to connection of the tube to the ventilator. The extraction time was defined as the interval from the connection of the tube to the ventilator to the extraction of the laryngoscope from the mouth.

A sample size of 12 patients was used to perform this feasibility study based on the published minimal sample size for pilot studies.5

| Table 1 Airway assessment. Data are presented as values |
|---------------------------------|-----------------|
| **Airway assessment (n=12)**    |                 |
| Mallampati                      | 1/2/3           |
| Thyromental distance            | ≤ 6.5 cm 1      |
|                                 | > 6.5 cm 11     |
| Mouth opening                   | 4 cm 1          |
|                                 | > 4 cm 11       |
| Upper teeth protrusion          | Yes/No 1/11     |
| Neck mobility                   | Normal/abnormal 12/0 |
| Larynx mobility                 | Normal/abnormal 12/0 |
We successfully used a robotic intubation system, remotely controlling a standard video laryngoscope using a commercial joystick. Using the KIS, tracheal intubation was successful in 11 out of 12 patients within 100 s; in one patient, fogging prevented a successful KIS use.

Several studies have looked at the learning curve of anaesthesia residents to achieve acceptable success rates when performing tracheal intubation. Kapacz and colleagues\(^7\) stated that a 90.8% of success rate can be achieved after 45 attempts. Konrad and colleagues\(^5\) determined a significantly higher number of attempts of 57 tracheal intubations to achieve success rates of 90%, and de Oliveira Filho\(^6\) determined a pooled success rate of 85% after 43 tracheal intubation attempts. These studies have been performed with anaesthesia residents; however, similar learning curves can be determined for staff experienced in direct laryngoscopy when acquiring skills for using video laryngoscopes for tracheal intubation.\(^9\)–\(^11\) Within the limitation of this small-scale pilot study, a success rate of 91% for the first 12 attempts is a clinically very favourable rate. Our study did not show any significant learning curve in terms of success rate because of the already high initial rate, whereas Konrad and colleagues\(^7\) showed a significant learning curve for the success rate during the first 20 attempts reaching ~65% after 20 attempts. Because of the small number of patients in this pilot study, we did not find any significant improvement in the time it took to perform the intubation. A significantly bigger number of patients are needed to evaluate this question.

The Pentax AWS video laryngoscope was specifically chosen for this project since it offers two features: there are two additional ports on the transparent blade, one for suction and the other for attaching a standard tracheal tube; it also features a crosshair, which, once placed in the area of the vocal cords, is supposed to indicate proper positioning of the scope for easy advancement of the tracheal tube into the trachea. In contrast to the other video laryngoscope, such as the widely popular Glidescope (Verathon, USA), there is no need for a stylet, and insertion of the tracheal tube can be achieved by simply pushing the tube forward using the groove on the blade as a rail. Several studies have determined the success rate of intubation with the Pentax video laryngoscope in non-difficult airways and determined success rates between 98% and 100% and mean intubation times of ~20 s. Intubation times were defined as the time to insert the blade into the mouth until passage of the tracheal tube is completed.\(^12\)–\(^14\) This definition corresponds to what we defined as ‘intubation time’ which was 57 s in the present study. In order to put this difference in perspective, one has to take into account the early stage of development of the system, the pilot nature of the study, the limited number of patients, and similar developments of robotic systems in medicine. This time difference is comparable with similar time differences when surgery moved from open techniques to endoscopic and robotic...
It is interesting to note that intubation times in the present study were significantly faster than those in a previous mannequin study where fibreoptic intubations were performed using a multipurpose surgical robot. In one patient, intubation using KIS was not successful because of fogging of the Pentax video laryngoscope. Fogging has been described as rare or more common using this type of video laryngoscope. As recommended by the manufacturer, preheating of the laryngoscope and application of antifogging liquid was performed before each intubation attempt in this study. Another limitation of this type of laryngoscope is that the maximum width of the blade is 2.5 cm; this might create problems in patients with limited mouth opening, who in this pilot study were excluded.

The controller used by the KIS is a standard gaming joystick with the possibility to programme up to 12 buttons and five axles. All movements carried out by the wrist or arm of a human being when holding the laryngoscope can be simulated. The operator (T.M.H.) had familiarized himself with these movements and operational modes of the joystick in extensive mannequin training. At present, there is no force feedback integrated into the system and all movements need to be directed by a human being using the joystick. However, the ultimate goal is to fully automate the intubation process. The first step towards this goal is to automate the navigation of the blade of the video laryngoscope through the mouth and pharynx, avoiding damage to the teeth and tissue. At this point, the operator could easily align the video laryngoscope with the trachea and manually insert the tube. The KIS is designed to also allow for remote intubations and could be used as part of a telemedical system.

There are several limitations to this study. This study was designed as a pilot study focusing on measuring the success rate and intubation times in a small number of patients. More patients are needed to evaluate its performance and safety. The KIS is a prototype with future technical focus being placed on making the system smaller, portable, and semiautomatic.

We present the first robotic intubation system for oral tracheal intubation tested in humans. These first tests revealed a good success rate within reasonable time frames. Future studies are needed to evaluate the performance and safety of the system.

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**Declaration of interest**

T.M.H. is the inventor and patent holder of the Kepler intubation system and stands to benefit financially.

**References**