INTRODUCTION

With over 150 thousand new cases per year worldwide, laryngeal cancer remains a widespread tumor entity.\(^1\) Radio(chemo)therapy and surgical resection are considered as the standard treatment modality. For early staged laryngeal cancer (T1-T2) in particular, transoral laser microsurgery (TLM) has been accepted as the favorite surgical strategy due to its minimally invasive approach and favorable long-term results. In cases that are not accessible by TLM, therapeutic options are limited to open partial laryngectomy or radiation.\(^2\) TLM as the standard therapy modality for laryngeal cancer offers several advantages over open partial laryngectomy, including shorter hospitalization times and superior functional outcome as well as shorter treatment time and laryngeal preservation over radiotherapy.\(^3,4\) There are currently two transoral robot-assisted surgery (TORS) systems clinically approved for head and neck surgery: the DaVinci system (Intuitive Surgical, Sunnyvale, CA) and the Flex system (Medrobotics, Raynham, MA). Both systems have been described to be suitable for the therapy of supraglottic pathologies.\(^5,6\) However, the treatment of glottic cancers with both TORS systems has only been described in a limited number of case reports with variable success rates.\(^7,8\)

A major problem of both TLM and conventional TORS is the difficulty of treating the larynx in cases with hindered accessibility. In TLM, the laser beam requires a straight line of sight on the surgical field. The widely used DaVinci Si and Xi systems (Intuitive Surgical) only operate with rigid surgical instruments and endoscopes. In order to obtain a satisfying view of the vocal cords, both surgical techniques demand a high grade of cervical spine extension due to the nonlinear anatomical

Adding Flexible Instrumentation to a Curved Videolaryngoscope: A Novel Tool for Laryngeal Surgery

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OBJECTIVES: Transoral surgery of the larynx with rigid instruments is not always possible. This may result in insufficient therapy or in an increased need for open surgery. For these patients, alternative surgical systems are needed. Here, we demonstrate a curved prototype for laryngeal surgery equipped with flexible instruments.

STUDY DESIGN: Pre-clinical user study in an ex vivo porcine laryngeal model.

METHODS: The prototype was built from established medical devices, namely a hyperangulated videolaryngoscope and modified flexible instruments as well as three-dimensional printed parts. Feasibility of laryngeal manipulation was evaluated in a user study (n = 19) with a porcine ex vivo laryngeal model. Using three different visualization technologies, the participants performed various fine motor tasks and rated the usability of the system on a 5-point Likert scale.

RESULTS: Exposure, accessibility, and manipulation of important laryngeal structures were always possible using the new prototype. The participants needed considerably less time (mean, 96.4 seconds ± 6.4 seconds vs. 111.5 seconds ± 4.5 seconds, P = .018), reported significantly better general impression (mean score 3.0 vs. 3.8, P = .041) and significantly lower user head and neck strain (2.6 vs. 1.7, P = .022) using a 40-inch television screen as compared to a standard videolaryngoscope monitor.

CONCLUSION: The results indicate that our curved prototype and large monitor visualization may provide a cost-effective minimally invasive alternative for difficult laryngeal exposure. Its special advantages include avoiding the need for a straight line of sight and a simple and cost-effective construction. The system could be further improved through advances in camera chip technology and smaller instruments.

KEY WORDS: Flexible instruments, curved, video laryngoscope, laryngeal surgery, TORS.

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conditions of the laryngopharyngeal region. It is estimated that approximately 20% of performed interventions are partially or completely unsuitable for transoral surgery due to altered cervical spine anatomy, intensive trismus, or scarring after previous radiation.9–13

The Flex system (Medrobotics) can potentially bypass this problem by using a computer-assisted flexible endoscope that adapts to the nonlinear anatomy of the oropharynx.14 Likewise, the new single port (SP) version of Da Vinci (Intuitive Surgical) allows a certain movement of the instruments through two distal joggle joints in the robotic arms. First clinical reports of those (semi-)flexible TORS system have led to good results in the treatment of the tongue base and the hypopharynx.15,16 In contrast to the possible advantages, the high acquisition costs, a relatively elaborate handling, and the decreased haptic and tactile feedback contribute to the fact that TORS has not yet been further established in clinical routine.17,18

To be able to assess the actual advantages of robot-assisted surgery in the head and neck area, there is a need for unbiased randomized clinical studies that evaluate the treatment of the (supra)glottic carcinoma over conventional TLM.11,19,20 With the knowledge about the problems and advantages of the different systems for transoral glottic surgery, the following beneficial features can be filtered out: 1) curved rigid retractor, 2) easy positioning of the camera even with difficult laryngopharyngeal anatomy, 3) a satisfying view of the vocal cord plane, and 4) the use of fully flexible surgical instruments. Many of these desired features match with a curved blade videolaryngoscope because it is used on a daily basis for intubation in the field of anesthesiology and emergency rescue. Various manufacturers have specialized in the development of videolaryngoscopes, including the King Vision (Ambu, Copenhagen, Denmark), McGrath MAC (Medtronic, Dublin, Ireland), and the C-MAC videolaryngoscope (Karl Storz, Tuttingen, Germany) with the hyper-angledated D-blade, which was designed for intubation in patients with difficult anatomical airway conditions. They offer a simpler, faster, and optimal visibility of the vocal cords compared to the conventional Macintosh laryngoscope.21,22 The aim of the following user study is to examine whether surgical manipulation of the larynx is possible with a modified videolaryngoscope prototype in a porcine ex vivo laryngeal model. Furthermore, we hypothesize that the standard monitor of the videolaryngoscope as used for intubation is not suitable in a surgical setting due to its limited display diameter.

MATERIAL AND METHODS

Experimental Setup

Two domestic pig laryngeal specimens with surrounding structures (epiglottis, tongue, trachea, esophagus) were taken to a surgical setting. In order to simulate the anatomy of a patient lying supine, the laryngeal model was clamped in a custom-made frame as previously described.23 The surgical system was attached to a horizontal operating rod, which was fastened by two height-adjustable rods, and the view was adjusted on vocal folds level. The instruments were then introduced (Fig. 1A).

Description of the Nonlinear Laryngeal Surgical System

The system (Fig. 1B) is based on the C-MAC videolaryngoscope 8403 HX (Karl Storz) with an increasingly elliptical curved blade (D-blade), one LED light, and a video chip with a resolution of 640 × 480 pixels. Two working channels are attached for flexible surgical instruments to both sides of the blade, which are made of low-friction polytetrafluoroethylene (PTFE). With custom-build rapid prototyping parts, the PTFE tubes are attached to the videolaryngoscope in its catheter guide (Fig. 2). A standard metal crossbar is connected to the surgical table. The system can be attached to the crossbar using further custom-build and three-dimensional (3D) printed parts. This bracket is tailored to the shaft of the videolaryngoscope.

Instrumentation

To follow the shape of the nonlinear surgical system, fully flexible surgical instruments are required. We used the manually operated endoscopic tool DiLumen graspers (Lumendi, Westport, CT), which were originally developed for tissue manipulation in the digestive tract. The instruments were shortened to a length of 55 cm by the manufacturer to better suit the use in the head and neck area. The flexible instruments have a diameter of 6 mm and can be tilt up to 90° (polar angle) and 360° (azimuthal angle), which result in spherical shell workspace. The gripper jaws of the biopsy forceps are 6 mm long and show an opening angle of 60° (Fig. 3A,B). A commercially available instrument holder enables fixation and therefore bimanual handling of the flexible instruments.

Monitors

The videolaryngoscope is typically used with its standard monitor 8403 ZK (Karl Storz), with display measurements of 150 mm × 94 mm and a resolution of 1200 × 800 pixels (Fig. 3C). It has a standard high-definition multimedia interface (HDMI) output, through which the input signal of the video chip can be transmitted distortion-free to various other monitors. Besides the 1) default monitor, two additional visualization systems were tested: 2) a virtual reality headset as a 2D head-mounted display (PS VR, Sony Computer Entertainment, Tokyo, Japan) (Fig. 3D). To be in working order, a PlayStation 4, PlayStation Camera, and a processor box (Sony Computer Entertainment) is required. The test persons performed an eye distance measurement to adjust the 5.7-inch display with a display resolution of 960 × 1080 pixels per eye. Nine positional LEDs of the head-mounted display are tracked by the camera, which allow registration of the head movements. The adjusted settings gave the viewer a 100°-wide detail view of the whole image, which could be shifted by head movements to the left and right. The study director was also able to follow and control the...
camera image on an external monitor. 3) A 40-inch monitor (SMART Signage DE40A LED, Samsung, Seoul, South Korea) was used, which was mounted to an adjustable stand at eye level at a distance of 2 m of the participants (Fig. 3E). Its display resolution is 1920 × 1080 pixels.

Porcine Larynx Model

A domestic porcine larynx was used to simulate the highly specialized functional qualities of the human larynx (Fig. 4). Due to large anatomical and biomechanical similarities, such as structure and stiffness of the vocal cords, porcine models are an ideal choice for preclinical

Fig. 1. (A) The Storz C-MAC videolaryngoscope (Karl Storz, Tuttlingen, Germany) D-BLADE with attached working channels and inserted flexible surgical instruments. The experimental setup simulates a surgical table with crossbar, to which the prototype is fixed with a custom-built and 3D-printed bracket. (B) The C-MAC videolaryngoscope (Karl Storz, Tuttlingen, Germany) with attached instruments is directed at the vocal folds of the porcine larynx. 3D = three-dimensional. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

Fig. 2. The custom-build rapid prototyping parts attaching the PTFE tubes to the videolaryngoscope in its catheter guide (A–E). The inner diameter of the pipe sections is 8.2 mm; the wall thickness is 1 mm. The solid printed cylinder has a diameter of 6.1 mm and can be inserted into the catheter guide of the videolaryngoscope. It is longer than the tube section, which results in a firm locking of the whole part in the curved guide. The parts were CAD-designed and 3D-printed with polylactide (A, B). PTFE = polytetrafluorethylene; 3D = three-dimensional. [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]
Nevertheless, the porcine larynx model shows some minor differences: paired interarytenoid cartilage projecting far into the lumen of the larynx, a broader epiglottis at the front of the ring cartilage, and an existent intralaryngeal fat pad for functional swallowing. In contrast to the human larynx, the porcine vestibular folds reach far into the lumen and contribute to voice formation through their collagen structure and their capability of vibrating.26 Despite these minor deviations, the porcine model offers suitable anatomical and biomechanical similarities to the human larynx, which allows for preclinical testing of laryngeal surgery methods.

Group of Subjects and Performed Tasks of the User Study

The participants (n = 19) were medical students in the clinical part of their studies with no previous experience in robotic surgery. The design of the experiment was
based on previous studies in the minimally invasive surgery literature and was divided into a fine motor coordination skills test and a Likert scale satisfaction survey. The fine motor coordination skills test for each monitor included three tasks: 1) grasping of laryngeal structures with the flexible instrument (vocal cords, vestibular folds, anterior commissure, ventral subglottis, postcricoid region); 2) grasping a vocal cord with both flexible instruments in order to simulate vocal cord excision; and 3) removing a rubber-ring (diameter 9 mm) with the flexible instruments, which was positioned in the glottic area. Required times were documented. To prevent sequence effects, the monitor sequence was permuted randomly. Subsequently participants were asked to perform an instrument change simulation by fully removing and reinserting the flexible instrument into the surgical system. In the subsequent user satisfaction survey, the subjects were asked to answer a questionnaire regarding the satisfaction (e.g., image quality, depth perception of structures) and potential problems (e.g., exertion of the eyes, head and neck strain) to compare the different monitors. The questionnaire was rated on a 5-point Likert scale.

**Statistics**

Statistical analysis and intergroup comparisons were evaluated with version 25 of the Statistical Package for the Social Sciences (IBM Corp., Armonk, NY). Due to the pilot study on a new prototype, a power analysis was waived. Required times were normally distributed with the exception of the group using the C-MAC standard monitor (Karl Storz) and the first monitor in the sequence of use as assessed by the Shapiro–Wilk test ($\alpha = .05$). The subjects required times were analyzed using an analysis of variance with repeated measurements and Bonferroni-adjusted post-hoc analysis. The Likert rating scale items were evaluated using the Kruskal-Wallis nonparametric test and Dunn-Bonferroni post-hoc test. If not stated otherwise, results are reported as mean ± standard error of the mean, whereas statistical significance was assumed for a $P$ value below .05.

**RESULTS**

All 19 participants completed the fine motor skills test and the satisfaction survey. Visualization and accessibility of laryngeal structures of interest (vocal cords, vestibular folds, anterior commissure, ventral subglottis) were achieved by all participants. The participants demonstrated a considerably faster performance using the 40-inch external screen than using the C-MAC standard monitor (Karl Storz) in the overall fine motor skills test (mean, 96.4 seconds ± 6.4 seconds vs. 111.5 seconds ± 4.5 seconds, $P = .18$), although the results were not statistically different (Fig. 5A). This also applies for each of its subtasks: 1) grasping of laryngeal landmarks, 2) bimanual manipulating of one vocal cord, and 3) foreign body retrieval (Table I). Comparing the required times by sequences of monitor use, a significant learning effect could be determined. The required time was significantly faster from the first to the second attempt (mean, 117.0 seconds ± 5.8 seconds vs. 97.7 seconds ± 5.0 seconds; $P = .013$) (Fig. 5B). The exchange of the flexible instrument was always possible with an average duration of 35.6 seconds (standard deviation = 16 seconds).
TABLE I. Required Average Time of the Fine Motor Skills Tests Tasks by Monitor Type.*

<table>
<thead>
<tr>
<th>Monitor Type</th>
<th>Grasping of Laryngeal Landmarks (s)</th>
<th>Bimanual Manipulation of the Vocal Fold (s)</th>
<th>Foreign Body Retrieve (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head-mounted display</td>
<td>68.4 ± 18.2</td>
<td>25.3 ± 13.6</td>
<td>9.6 ± 5.8</td>
</tr>
<tr>
<td>Standard monitor</td>
<td>74.2 ± 14.1</td>
<td>27.7 ± 10.3</td>
<td>9.7 ± 6.4</td>
</tr>
<tr>
<td>40-inch external monitor</td>
<td>63.8 ± 17.4</td>
<td>23.5 ± 10.7</td>
<td>9.1 ± 6.2</td>
</tr>
</tbody>
</table>

Mean and standard deviation are illustrated.
s = seconds.

*Grasping of laryngeal landmarks, bimanual manipulation of the vocal fold and foreign body retrieve (n = 19).

Fig. 6. Questionnaire data regarding the satisfaction among the different monitors in a 5-point Likert scale. (A) rating of various surgical items by monitor type and (B) rating of potential problems by monitor type. Mean ± standard error of the mean is illustrated.

Fig. 7. Monitor preferences. (A) Subjects’ monitor preference, with which they would perform laryngeal manipulations. (B) Subjects named their monitor preference regardless of the current image quality.
The results of the satisfaction survey are shown in Fig. 6. In six out of nine items regarding the monitor suitability for transoral laryngeal surgery, the 40-inch external monitor was preferred. The participants reported significantly better general impression (mean score 3.0 vs. 3.79, P = .041) and significantly lower head and neck strain (mean score 2.63 vs. 1.74, P = .022) using the 40-inch monitor than the C-MAC (Karl Storz) monitor. Furthermore, exertion of the eyes was significantly reduced by using the 40-inch external monitor (mean score 1.74) as compared to head-mounted display (mean score 2.63, P = .026) or the C-MAC monitor (Karl Storz) (mean score 2.74, P = .005). Out of the evaluated displays, the 40-inch external monitor was preferred by 11 of 19 participants (57.9%) for laryngeal surgery. If the subjects were disregarding the image quality in their decision, only nine of 19 (47.4%) preferred to use the 40-inch external monitor, whereas 13 of 19 (86.4%) would use the head-mounted display as first choice (Fig. 7).

**DISCUSSION**

The practical application of our novel surgical prototype in an ex vivo laryngeal model was confirmed in a user study including a custom designed fine motor skills test and a user questionnaire. The manipulation of all major laryngeal landmarks was feasible with the system. The subjects demonstrated the fastest and most satisfying results when the surgical field was visualized by a large external monitor. The standard small diameter videolaryngoscopic monitor seems to be less suitable for surgical purposes.

The choice of available videolaryngoscopes is wide, and they have become indispensable in the daily routine of anesthesia and emergency medicine. Various studies show an overall better glottic view with the D-Blade (Cormack–Lehane classification) than the regular curved Macintosh blades, even within a complex anatomy of the neck. This was confirmed by our own results; the subjects rated the items “image quality” and “depth perception” between “appropriate” and “good” in the satisfaction survey when using a 40-inch external monitor. However, to the authors’ knowledge, none of the videolaryngoscopes have yet been modified for surgical purposes.

Although the 150 mm × 94 mm standard videolaryngoscope monitor is suitable for intubation, it has not been evaluated if its screen size and display resolution is adequate for surgical purposes. In our setting, we found both objective and subjective limitations for the use of the standard monitor of the videolaryngoscope, such as longer operative times, significantly higher head and neck strain, and a worse general impression compared to a 40-inch external monitor. This observation emphasizes the need for high-quality camera and visualization when performing surgery in delicate locations, for example, the larynx. Similar results were obtained from the DaVinci system (Intuitive Surgical), when other research groups found faster operating times and better experience with improved 3D visualization as compared to 2D screens. When available by the manufacturer, such 3D technology will be integrated in our present system. At this stage, the use of a head-mounted display would be very interesting because it is the only tested monitor that can also display stereoscopic images.

The presented prototype will have to be compared to the current standard treatment methods, including TLM and TORS. In our department, TLM is the treatment of choice for low-stage tumors. However, there are some limitations that make the use of TLM not appropriate for every patient. Namely, laryngeal target exposure through the oral-oropharyngeal corridor and the need for a straight line of sight are not possible in every patient due to decreased mouth opening or limited extension of the cervical spine. TORS represented by the DaVinci system (Si, Xi; Intuitive Surgical) has similar problems due to its rigid instruments mounted on the robotic arm, which can hardly traverse the limited nonlinear space of the pharynx down to the vocal folds when anatomy is complex or altered by pathologic findings. Previous studies especially have described the visualization of the anterior commissure as highly challenging in laryngeal surgery with TORS. This problem has been addressed by new developments in the field of TORS, for example, the Flex system (Medrobotics). However, even with this new system, the accessibility to the vocal cords has been challenging. With our prototype, we were able to demonstrate the feasibility of visualization and accessibility of important laryngeal landmarks such as the anterior commissure in the porcine model.

There is currently only a small selection of fully flexible surgical instruments commercially available, which are suitable for microsurgery of the larynx. At a gripper jaw length of 6 mm, the surgical tools in our experiments are quite similar sized as the Medrobotics Flex Needle Driver and Monopolar Scissors that are already being used for laryngeal surgery on a regular basis. On the other hand, the rigid microlaryngoscopic instruments regularly used in our clinic (LaryngoFIT, Kleinsasser, STORZ) have a gripper jaw length of only about 3.5 mm. Depending on the intervention, the ideal instrument size is a compromise between the required gripping force, the size of the anatomical structures, and the required surgical delicacy. For the classic excision after (early staged) laryngeal carcinoma, the dimensions of the used DiLumen instruments (Lumeni) seem to be acceptable to us, whereas finer instruments should be used, for example, for laryngeal microflap surgery.

Additionally, TORS systems show a high financial burden for the involved departments, which stands against a broader application in clinical routine until today. According to calculations by Dombree et al., the cost of a laryngectomy in Belgium is about 90% higher (3581 vs. 6767 EUR) if a robot-assisted operation is performed as compared to conventional TLM. Our prototype has the potential to become a cost-effective alternative by the modification of already existing videolaryngoscopes and the use of disposable parts. In summary, the advantages of our prototype include the easy handling, the economic efficiency, and the absence of a straight line of sight or rigid surgical instruments.

A limitation of the novel prototype is the current image quality of the C-MAC videolaryngoscope (Karl
Storz) (640 × 480 pixels). Although adequate for intubation, it is not completely satisfactory for surgical purposes in terms of detailed identification of anatomical structures. In addition, once adjusted to the vocal cord level, the camera image can only be moved by repositioning the entire system. On the other hand, this may not be necessary for manipulation in a confined area, such as the vocal folds. We are aware of the fact that the laser tool is the main cutting tool in TLM. However, until recently, we were not able to equip our system with a functional laser beam. Currently, various options are being developed. The prototype of an integrated laser tool has been recently described by us, which may also be applicable for the system presented in this article.34 Taking into account the differences between the porcine and human larynx, as well as the rather small group size, level of training of study participants, and prototype stage of the surgical system, there still is a strong need for further development, including body donor studies. However, in the future, the system has the potential to be used in a clinical setting with a confined indication.

CONCLUSION

In the current study, a nonlinear surgical system prototype was tested for visualization and accessibility of laryngeal landmarks in a porcine ex vivo model. The results indicate that the system in conjunction with a 40-inch external monitor could become an alternative to currently available transoral surgery systems for the surgery of the larynx. Its special advantages include avoiding the straight line of sight, a simple construction, and the cost-effectiveness. Nevertheless, the system could be further improved through advances in camera technology. A small monitor that is close to the site might not be needed. The significant learning curve of the study participants, regardless of the type of monitor, confirms the feasibility of laryngeal manipulation with the surgical system in a porcine model even for participants without prior knowledge of assisted surgery.

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BIBLIOGRAPHY