Demonstration of nasopharyngeal surgery with a single port operator-controlled flexible endoscope system

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ABSTRACT: *Background.* Nasopharyngeal surgery is commonly performed with a rigid endoscope using a transnasal or transoral approach. Here, we demonstrate a flexible single port computer-assisted endoscopic system enabling easy transoral access to the nasopharynx.

Methods. Transoral nasopharyngeal surgery was performed in human cadavers ($n = 8$) using the Flex System (Medrobotics, Raynham, MA). Learning curves were evaluated based on the time necessary for reaching the Eustachian tube. Mock surgical procedures were performed with compatible flexible instruments.

Results. Nasopharyngeal surgery is feasible with the Flex System with a nontraumatic approach. The inbuilt HD digital camera enables high-quality visualization of the nasopharynx. The design of the flexible compatible tools adequately meets the requirements for surgical procedures in the nasopharynx.

Conclusion. The single port operator-controlled flexible endoscope system is a feasible way to approach the nasopharynx for surgical manipulation. Further clinical studies as well as development of supplemental tools are in progress. *Head Neck* **00:** 000–000, 2014

KEY WORDS: nasopharynx, flexible endoscope, camera, transoral robotic surgery (TORS), retractor

INTRODUCTION

Since transoral robot-assisted surgery (TORS) has been approved by the Food and Drug Administration in 2009, multiple indications in the head and neck region have been identified, and new applications are continuously added to the list.[1] Especially in countries where laryngeal laser surgery is less well established, TORS of the pharynx and larynx is now regularly applied with great success.[2] Advantages of robot-assisted surgery include refined precision and improved visualization of the surgical field as compared to standard microscopic surgery as well as decreased morbidity as compared to open cervical approaches.[3,4] However, until today, robot-assisted surgery of the nasopharynx has not been adequately addressed. There are few publications on nasopharyngeal TORS, which are, without exception, based on the da Vinci system by Intuitive Surgical (Sunnyvale, CA). Complete successful nasopharyngectomy by TORS was first described by Ozer and Waltonen[5] in a single cadaver study. Dallan et al[6] then compared the complete transoral approach with a combined transnasal/transoral approach with the transnasal placement of the optic system in 2 cadavers. Complete nasopharyngectomy was feasible for both approaches, with the latter avoiding palatal splitting. Recently, Tsang et al[7] described a lateral palatal flap in 2 cadavers, which increases visualization of the lateral wall of the nasopharynx during TORS. Two publications by Wei et al[8] and Yin Tsang et al[9] described removal of a nasopharyngeal tumor by TORS in 1 clinical patient each. The latter surgical procedure was supported by an additional transnasally introduced endoscope for better visualization of the upper nasopharynx. All these approaches were limited either by their morbidity in terms of palatal splitting or by their limited visualization of the surgical field.

Here, we present a new approach to the nasopharynx taking advantage of a flexible single port computer-assisted endoscopic system (Flex System; Medrobotics, Raynham, MA). The system is currently being developed for a variety of transoral surgical approaches in the head and neck region, and detailed technical descriptions are available in the literature.[10,11] Recently, the potential of the Flex System was successfully tested for the transoral approach to the larynx.[12] In the present study, the advantages and limitations of skull base nasopharyngeal surgery using the Flex System are investigated in a preclinical cadaver study.

MATERIALS AND METHODS

Description of the flexible endoscopic system

The Flex System consists of an operational tower with 3D-joystick and touch screen graphic user interface, a framework for stabilization of compatible flexible instruments as well as the flexible endoscope itself, which is

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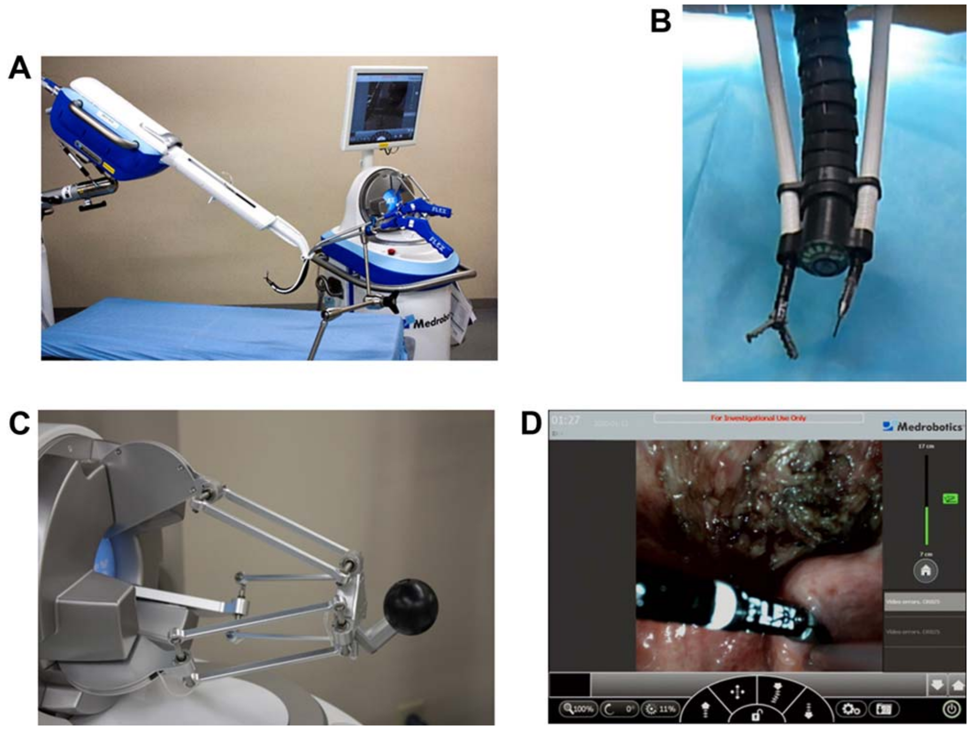

FIGURE 1. (A) Setup of the Flex System, including an operational tower with 3D-joystick and touch screen graphic user interaction device, a framework for stabilization of compatible flexible instruments, as well as the Flex endoscope itself, which is mounted over the surgical table. (B) The camera system and 6 light-emitting diode (LED) lights are located in the distal tip of the endoscope. Two separate working channels for delivery of flexible instruments are attached at both sides. (C) The endoscope is maneuvered by the surgeon using a 3D-joystick. (D) The touch screen display allows for high-quality intraoperative visualization. Moving modalities of the endoscope are selected by buttons at the bottom of the screen. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com]

mounted over the surgical table (Figure 1A). In contrast to common line-of-sight laser surgery and currently available robotic systems, the tip of the Flex System endoscope can be maneuvered freely in a 3D space and has a flexibility of 180 degrees. Six light-emitting diode (LED) light sources and a high-definition (HD) digital camera are inbuilt in the tip of the flexible endoscope, and 2 flexible working channels are attached to each side (Figure 1B). An additional lens washer system is included in a third working channel located in the inner lumen of the endoscope, displaying a maximal diameter of 17 mm at the tip. When the endoscope has been placed in the surgical field, various compatible flexible instruments are introduced into the working channels, where they can extend 2 cm beyond the distal tip of the endoscope showing good triangulation (Figure 1B). Changing of instruments required a maximum of 1 minute. Compatible flexible instruments include grasper, Maryland dissector, needle holder, laser guide, monopolar spatula, and monopolar needle knife. As previously described, the endoscope shaft itself is moved by the surgeon using a 3D-joystick (Figure 1C).[12] A touch screen at the patient's head displays the intraoperative pictures delivered by the HD digital camera in the endoscope tip. Figure 1D shows a representative screenshot. On the bottom center section of the screen, the surgeon selects from various driving modes for the endoscope, including advance steer, fine mode, retract, and automatic retraction. A green indicator bar on the right side of the screen shows the distance traveled by the endoscope with a maximum length of 17 cm.

Cadaver studies

For preclinical evaluation of the Flex System, 8 adult fresh frozen human cadavers were placed in the supine position on the operating table without the use of headpins. Each cadaver consisted of a head and neck attached to the upper torso, and all relevant anatomy was found to be intact without any obvious malignancies upon inspection. As previously described, the flexible endoscope was mounted to the surgical table rails and arranged to approach the oral cavity from the caudal direction.[13] The soft palate was moved in an anterior position by 2 simple suction hoses, which were introduced transnasally. After insertion of the retractor, the surgeon moved the tip of the flexible endoscope forward in an S-shaped curve toward the nasopharynx with a 3D-joystick device (Figure 2A and 2b). The surgeon was located at the head of the cadaver, maintaining control of the surgical procedure at all times. Compatible flexible endoscopic instruments were inserted into the 2 accessory working channels, once the flexible endoscope had been maneuvered and docked into the right position. All important landmarks of the nasopharynx were reached by flexible tools. The duration from first

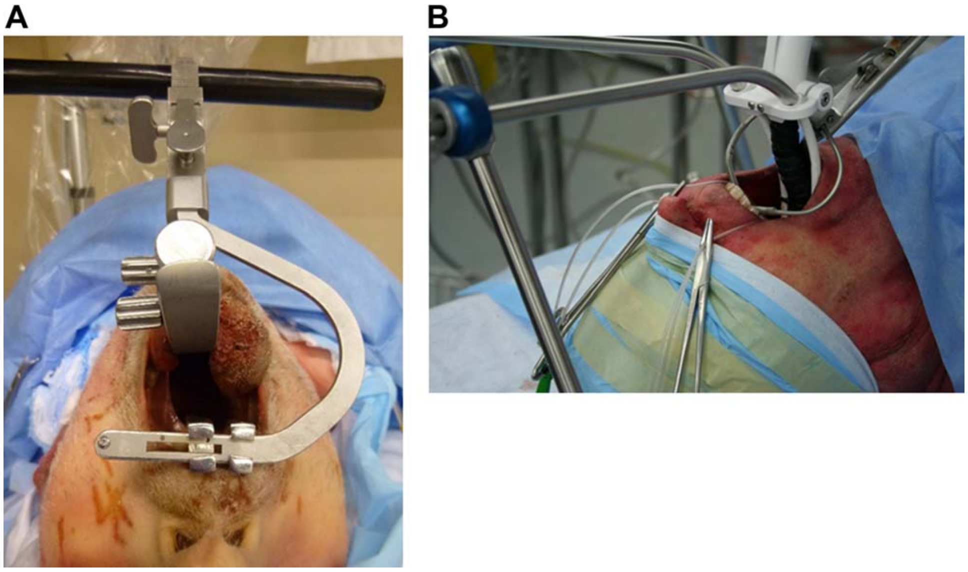

FIGURE 2. (A) The retractor allows for sufficient exposure of the oral cavity and retraction of the tongue. (B) The tip of the endoscope is introduced into the oral cavity from a caudal approach while flexible instruments are introduced from a cranial position. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com]

introduction of the flexible endoscope tip into the oral cavity until touching of the torus of the Eustachian tube by a compatible flexible grasper was measured 5 times each in 3 cadavers. Lateral resection of the nasopharynx was then performed using the Flex System endoscope and compatible flexible instruments.

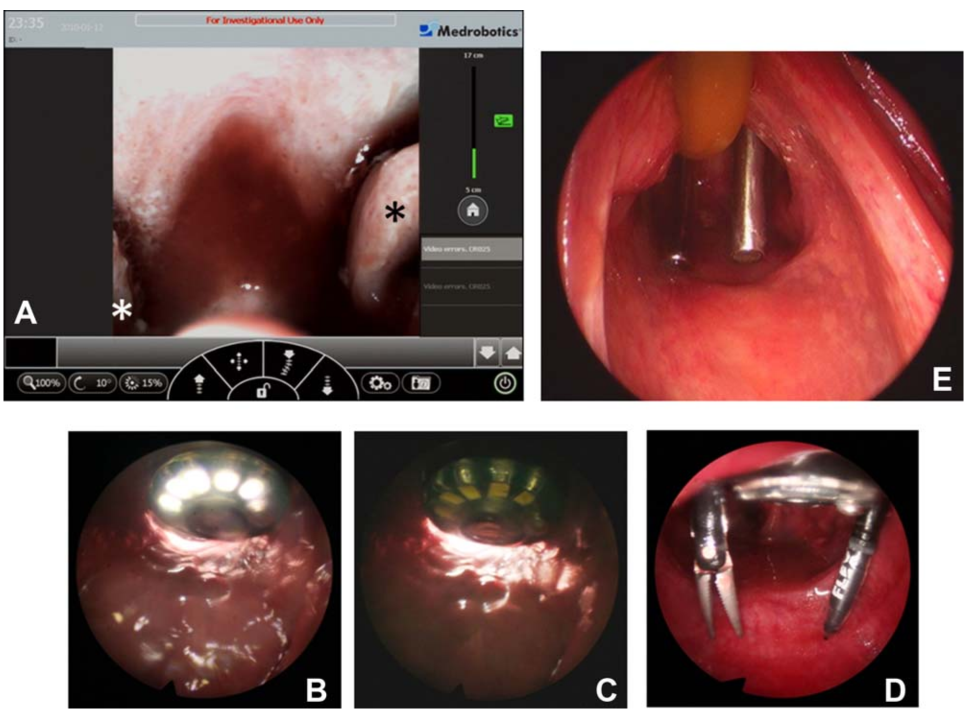

FIGURE 3. (A) Intraoperative visualization and access of the nasopharynx, as seen by the endoscope camera system. The torus (*) and opening of the Eustachian tube is seen on both sides. (B) The distal tip of the Flex endoscope in the nasopharynx with turned on light-emitting diode (LED) lights, as seen with a transnasal endoscope. (C) The tip of the endoscope with an additional light source behind the endoscope. (D) A compatible flexible Maryland dissector and monopolar needle knife are guided into the nasopharynx by the docked endoscope tip. (E) The transnasal approach with rigid tools was conducted for comparison. Access to the anatomic landmarks of the nasopharynx was evaluated by an additional transoral camera. The rigid 30° endoscope, the rigid suction device, and a yellow rubber tube for palatal elevation are seen in the nasopharynx. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com]

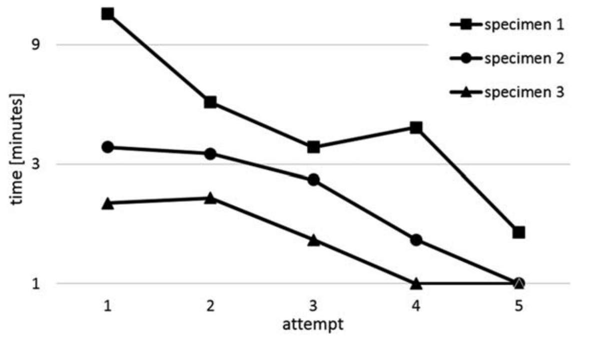

FIGURE 4. Reaching the torus of the Eustachian tube with the flexible instruments of the endoscope system was executed 5 times each in 3 specimens. In all experiments, the time was reduced significantly with repeated attempts.

RESULTS

Cadaver studies

In the present study, the transoral approach of the Flex System endoscope allowed for adequate visualization and access of the nasopharynx (Figure 2A and 2B). Important landmarks of the nasopharynx, which were in reach of the compatible flexible instruments, included the left and right Eustachian tube, lateral and posterior wall of the nasopharynx, as well as posterior nares (Figure 3A). For clarification, the location of the flexible endoscopic tip in the nasopharynx was visualized by a 30° endoscope introduced through the nasal cavity. Figure 3B displays the tip of the endoscope with the LED lights turned on and the HD digital camera in the central position. Again, for demonstration, the endoscope is shown with the LED lights turned off in Figure 3C. An additional light source behind the endoscope demonstrates the extra space between the endoscope and the posterior wall of the nasopharynx in the center of the photograph. Next, the endoscope was docked and compatible flexible instruments were introduced into the 2 flexible working channels attached to the side of the endoscope. Figure 3D shows a Maryland dissector and monopolar needle knife touching the posterior wall of the nasopharynx, as seen by the additional transnasal endoscope. The transnasal endoscope was only used for demonstrational reasons, and it was removed before performing the surgical procedures described below.

Next, the flexible endoscope was compared with a currently applied standard approach to the nasopharynx using rigid instruments. To this end, a rigid 30° endoscope and a rigid suction device were introduced transnasally. Access to the nasopharynx was evaluated by an additional external camera, which was introduced transorally (Figure 3E). Visualization of the nasopharynx was comparable with the rigid endoscope. However, access to the anatomic landmarks in the nasopharynx (eg, the torus of the Eustachian tube and the lower dorsal wall of the nasopharynx), was limited with the rigid tools as compared with the flexible tools.

The duration from first introduction of the endoscope tip into the oral cavity until touching of the torus of the Eustachian tube by a compatible flexible grasper was measured 5 times each in 3 cadavers. In all cases, a steep learning curve was observed reducing the time required by up to 7-fold (Figure 4).

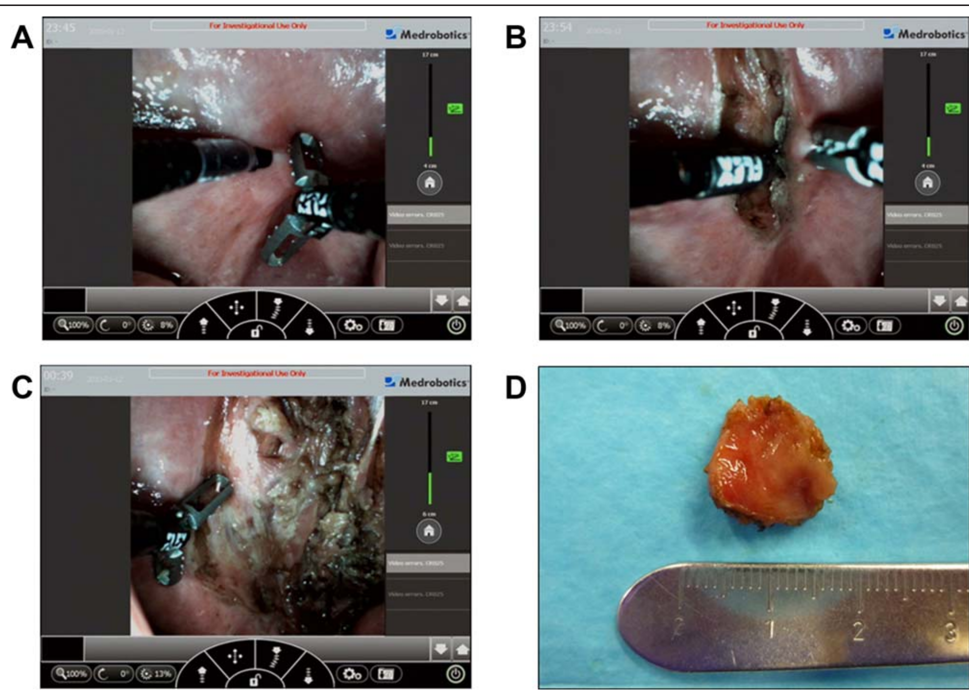

FIGURE 5. (A–C) A mock procedure of the nasopharynx was performed using the Flex System. (D) The lateral part of the nasopharyngeal wall was resected en bloc. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com]

Next, a mock surgical procedure was performed using only the Flex Scope visualization system and compatible flexible instruments. A lateral pharyngectomy was performed with the grasper instrument and monopolar spatula. First, the midline incision was conducted holding the left nasopharynx with the grasper (Figure 5A). The mucosa was then lifted with the monopolar spatula (Figure 5B). For the lateral incision, compatible flexible instruments were exchanged from side to side, which took less than 1 minute (Figure 5C). The resected tissue is shown in Figure 5D.

DISCUSSION

Common surgical approaches to the nasopharynx are not satisfying because of limited access or due to increased morbidity by using a transpalatal approach.[14–16] Until today, only few studies with small cohorts have addressed the potential of TORS in surgical manipulation of the nasopharynx using currently approved robotic systems.[5–9] However, none was able to avoid splitting of the soft palate in order to gain appropriate access to the nasopharynx. Here, we present a new approach to the nasopharynx taking advantage of a single port operator-controlled computer-assisted flexible endoscope system. With the preclinical prototype of the Flex System, good visualization of the nasopharynx is achieved without splitting of the palate, and all relevant anatomic landmarks of the nasopharynx were shown to be in reach of the flexible instruments. The set of compatible flexible instruments, which is currently investigational for use in the flexible endoscopic system, includes grasper, Maryland dissector, needle holder, laser guide, monopolar spatula, and monopolar needle knife. All flexible instruments have a diameter of 3.5 mm and are very user friendly, whereas the accuracy and size of the instruments are appropriate for surgical procedures in the nasopharynx. Recently, the camera system in the tip of the endoscope has been upgraded to a full HD digital camera resulting in an increased visualization quality, as compared to previous studies.[12] The current equipment, therefore, allows for comfortable and safe surgical manipulation of the nasopharynx, as demonstrated in Figure 5. Consequently, the Flex System will be implemented into clinical routine in the near future. Indications for TORS of the nasopharynx may include small to medium size malignancies and juvenile nasopharyngeal angiofibromas after catheter embolization.[17]

Although, a significant share of these patients could be treated with standard rigid endoscopes, there is a potential benefit for postradiation patients with limitations of oral opening and velopharyngeal pliability or for patients with decreased reclination of the cervical spine. In these patient groups, the flexible endoscope technique could be far superior. Additional instruments, such as a suction device, could be inserted into the operation field through both nostrils.

This transoral approach to the nasopharynx can potentially be extended in order to reach the anterior region of the upper cervical spine (ie, transodontoid approach), which is frequently necessary for pathologies that cannot be accessed from a dorsal approach. Possibly, the immense morbidity caused by the surgical approach could be minimized as compared to currently used techniques.[18] However, appropriate instruments for bony work are not yet available and will need extra developmental effort because of the flexible nature of the instruments.

CONCLUSION

In the present study, the new investigational single port flexible endoscope system underlines its potential for clinical surgery of the nasopharynx. Because of the flexible tip in combination with a series of compatible flexible tools and a high-quality HD digital camera system, visualization and surgical access within the nasopharynx are feasible without splitting of the soft palate. Clinical implementation of the Flex System will profit from extension of the compatible instrument collection and further refinement of the system.

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