Application of a computer-assisted flexible endoscope system for transoral surgery of the hypopharynx and upper esophagus

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Abstract Zenker's diverticulum is a common pathology in the transition zone of the posterior hypopharynx and esophagus. Surgical treatment is routinely performed by ENT and general surgeons. Besides the traditional open transcervical diverticulectomy, the introduction of transoral rigid treatment led to a paradigm change and is now the preferred treatment option for patients who are fit for general anesthesia. The implementation of interventional flexible endoscopy has opened another new micro-invasive approach for patients with high morbidity. Here, we present the potential utilization of a flexible, single port, robot-assisted, and physician-controlled endoscope system to facilitate transoral surgical access to the hypopharynx and upper esophagus. Transoral surgery of the hypopharynx and upper esophagus was performed in human cadavers ($n = 5$) using the Flex System (Medrobotics, Raynham, USA). Anatomical landmarks were identified, and posterior cricothyroid myotomy was performed with compatible flexible instruments in all cases. The approach to the hypopharynx and upper esophagus using the Flex system is feasible in a cadaveric model. Myotomy with a flexible tool and needle knife (from the perspective of treatment of Zenker´s diverticulum) was successful in all cases. Visualization of the surgical site with the system's HD camera is suitable and the flexible instruments meet the special needs of a micro-invasive transoral approach. Zenker´s diverticulum can be potentially treated with a transoral minimally invasive approach using a computer-assisted flexible endoscope system. This setup could be of advantage in patients with reduced mobility of the cervical spine to prevent open transcervical surgery. In our study, the Flex system enabled advanced visualization of the surgical site and extended intervention options, compared to standard flexible endoscopic treatment. However, general anesthesia is mandatory for the presented approach. Application in live patients with actual pathologies of the hypopharynx and upper esophagus will have to prove suitability for the treatment of Zenker's diverticulum. Further development of the system could include improved instrumentation and an adoption by other disciplines with challenging anatomy such as colorectal surgery.

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Introduction

Zenker's diverticulum is the most common acquired pouch of the hypopharynx and esophagus with a reported lifetime prevalence of 0.01–0.11% [1]. As soon as the diverticulum becomes symptomatic, surgical treatment is the accepted gold standard, routinely performed by general and head and neck surgeons. However, the surgical modality of choice is highly debated to date. The classic open transcervical approach is performed via left neck access and consecutive diverticulectomy combined with a cricopharyngeal myotomy [2]. In some cases, an additional diverticulopexy is performed by stitching up the residual pouch to the prevertebral fascia. Myotomy and diverticulectomy are commonly performed with electrocautery or stapling devices. After the first endoscopic approaches, performed by Dohlman and Mattsson in 1960 [3], and crucial advancements of endoscopic surgery and minimally invasive technologies in the 1990s, the increased establishment of transoral endoscopic diverticulum treatment consolidated the paradigm change. In 1993, Collard et al. introduced a transoral rigid endoscopic technique to treat Zenker's diverticulum by dissecting the septum dividing the diverticulum from the esophageal lumen with a linear stapling device [4]. Two years later, several groups began to promote a flexible endoscopic treatment, which used electrocautery for dissection of the diverticulum's septum [5, 6]. Over the last two decades, various authors steadily expanded the repertoire of possible dissection tools for transoral diverticulotomy including the conventional high-frequency needle, scissors and forceps cautery [7, 8], laser devices [9], and the Harmonic Scalpel® [10]. Special clipping and stitching devices can be utilized to reunite the lumina of the esophagus and the detached diverticulum [11, 12]. In consequence, the plentitude of available techniques did not lead to a clear improvement of patient care, but started a vivid discussion about the best treatment modality, which is held until today. Without analyzing the value of every single modality, many authors regard the size of the diverticulum as a crucial aspect. At our facility, rigid transoral laser or stapler diverticulotomy is preferred for all cases where possible, while the open approach is reserved for revision surgery and exceptionally large diverticula as well as diverticula that cannot be visualized by rigid endoscopy. A notable advantage of the rigid endoscopic approach is the option to perform a primary mucosal suture. Whether this method has the potential to reduce incidence of mediastinitis after Zenker's diverticulum treatment is subject to an ongoing investigation at our facility (unpublished results). Some authors prefer an open surgery technique even for younger, healthy patients with small-sized diverticula, due to higher long-term success rates [13, 14]. On the other hand, the transoral approach with flexible instruments creates a therapeutic alternative for older patients with small-sized diverticula, who are unable to undergo open surgery or general anesthesia [15, 16]. The latest meta-analyses see a benefit for endoscopic treatment due to shorter procedure length and hospitalization, lower complication rates, and earlier regular food uptake [17], compared to open surgery resulting in lower recurrence rate with a success rate of up to 90% [18]. Interestingly, while the number of adverse events and complications for endoscopic treatment decreases with a growing number of cases, the recurrence rate increases, stating a similar pooled success rate of 91% for endoscopic treatment in another major meta-analysis [19]. Mediastinitis, perforation of the pharyngeal wall, and injury to the recurrent laryngeal nerve are reported main complications following open surgery, while general infections and perforation of the pharyngeal wall are listed for endoscopy [20]. However, the lack of randomized and controlled trials is impeding a final recommendation of one or another technique, and the right choice depends on the patients individual demands, the surgeons expertise, and local preferences [18]. In a recent review, Bencini et al. discussed the potential benefits of robot-assisted techniques in esophageal surgery including diverticulum treatment [21]. The application of transoral robot-assisted surgery (TORS) for the treatment of benign and malignant pathologies of the oropharynx is broadly accepted and routinely performed at some facilities [22–24]. However, expanding the application of TORS towards the larynx and hypopharynx has been limited due to the restricted accessibility with rigid instruments [25]. In contrast, the Flex system with its flexible construction has overcome the classical philosophy for a 'straight line of sight' approach to this curvilinear anatomy. Consequently, the feasibility was demonstrated for surgery of the glottis and the nasopharynx in cadaveric models [26, 27]. Based on the data of the first clinical phase I trial (NCT02262247) including 80 patients, the Flex system has reached CE-mark in 2014 and approval by the FDA in 2015.

Here, we present the application of a novel computer-assisted operator controlled flexible endoscope system (Flex system) for treatment of upper esophageal diverticula in a cadaveric model.

Materials and methods

Flexible endoscope details

First introduced in 2012 [28], the Flex System (Medrobotics, Raynham, USA) was designed to overcome the limitations of large and rigid instruments with its flexible endoscope construction. Featuring a surgeon control unit with a touch screen monitor and a base module for attachment of the flexible endoscope (Fig. 1), the system covers a three-dimensional working space of 180° at a maximum reach of 17 cm. Operation of the computer-assisted endoscope is performed by a 3D joystick, controlled by the surgeon seated at the patient's head. The instruments are introduced through two working channels attached to the endoscope and driven independently by the hand of the surgeon without computed assistance. The distal tip of the endoscope measures 15×17 mm in total. A variety of compatible flexible surgical instruments are available, e.g. fenestrated grasper, Maryland dissector, monopolar needle or spatula cautery, cautery scissors, and universal laser holder; changing of instruments takes less than 1 min. Visualization of

Fig. 1 Flex system setup featuring a HD-monitor control unit with a joystick for basic positioning and forwarding of the endoscope, and a base module, where the endoscope attaches. The endoscope is driven computer assisted by joystick, while the flexible instruments are manipulated independently by the hand of the surgeon

the surgical site is performed by a 2D-HD digital camera connected to the touch screen monitor in the control unit. Important information, such as the current extension of the endoscope or relevant setting modes, is displayed on the same screen.

Retractor

To optimize access to the hypopharynx, a newly designed retractor was applied in the current experimental setting. As previously published, the retractor takes advantage of a curved blade design enabling extra retraction of the base of tongue [29]. Precise adjustments of pitch and angle of the lingual blade allow an additional redressment of the larynx in the postcricoid region, opening a wide view on the hypopharynx and access to the upper esophagus.

Cadaver studies

Five adult human fresh frozen cadavers were used to examine potential applications and possible limitations of the Flex system in surgery of the hypopharynx and upper esophagus in a simulated surgical setting. Specimens were placed on the surgical table with the head reclined and the surgeon being placed at the cadaver's head. The endoscope system was placed over the cadaver's body with the control unit next to the surgeon. After positioning of the retractor under direct sight, the endoscope was introduced transorally and guided towards the hypopharynx. Anatomic landmarks of the pharynx, larynx, hypopharynx, and esophagus were identified with the flexible endoscope before starting the respective procedure. The endoscope was locked when visualization of the surgical field appeared to be appropriate. Instruments were inserted through the working channels attached to each side of the endoscope to begin the surgical procedure.

Results

Diverticulotomy

For the surgical procedure, the flexible endoscope system was installed as described above. The endoscope was led into the hypopharynx and locked in position before the flexible instruments were inserted. The hypopharyngeal mucosa was stretched using a Maryland dissector to identify the upper esophageal sphincter. None of the specimens presented with a hypopharyngeal or esophageal diverticulum. Therefore, in all cases, a mock surgical procedure was performed in form of a median myotomy of the upper esophageal sphincter muscle, including the covering mucosa. A nasogastric tube was inserted before performing the procedure.

Handling of the flexible endoscope system

In the pre-clinical cadaver setting, the Flex system enabled good visualization of the hypopharynx, including the piriform sinuses, the postcricoid region (Fig. 2) and the lateral and posterior pharyngeal transition zones towards the esophagus. Instruments satisfactorily reached into the upper esophagus for inspection of the mucosa (Fig. 3a). Visualization quality of the 2D-HD camera on the tip of the endoscope and display on the HD monitor of the control unit was adequate. Steering characteristics of the flexible instruments were satisfactory, and the upper parts of the esophagus could be reached up to 2 cm beyond the upper esophageal sphincter muscle, including the lateral, anterior, and posterior walls (Fig. 3b). In the respective cases, a nasogastric tube could be positioned and safely forwarded into the esophagus by the use of the flexible instruments. Here, the endoscopic view was helpful and facilitated introduction (Fig. 4a). In all cases, a controlled myotomy of the upper esophageal sphincter muscle was feasible (Fig. 4b, c). The monopolar needle knife enabled targeted and complete dissection of the muscle fibers (Fig. 4d).

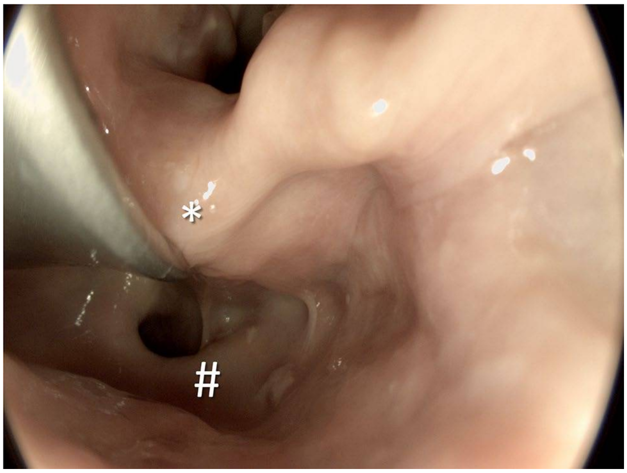

Fig. 2 Lingual blade of the Flex Retractor landing dorsal to the laryngeal access, enabling visualization of the hypopharynx, the upper esophageal sphincter muscle, and the upper esophagus (*asterisk* postcricoid region, *hash* upper esophagus sphincter)

Discussion

Feasibility of flexible endoscopic surgery

In all cases of this study, approach and intervention in the hypopharynx and upper esophagus were feasible in terms of visualization, accessibility, and technical success. This may give the prospect of a possible transfer to surgical treatment of Zenker's diverticulum and other pathologies of the hypopharynx and upper esophagus with the Flex system, as far as they can be reached. Surgical tissue control with the flexible instruments was satisfactory. Auxiliary actions, such as the introduction of a nasogastric tube, were enabled by the specific construction, despite the limited action scope in the hypopharynx. Transoral robot-assisted treatment of Zenker's diverticulum has never been reported, and despite an increasing acceptance of TORS, none of the available systems has been tested for the transoral treatment of pathologies in the hypopharynx and upper esophagus. Even though interventions with the Flex system are always performed under general anesthesia, the flexible construction offers a treatment alternative especially for patients with reduced cervical spine mobility [23] or osteophytic narrowing of the prevertebral space. In consequence, open surgery may be prevented in this particular patient group, leading to reduced morbidity and reduced overall hospital stay.

Variety of treatment options

Until today, there is no generally agreed gold standard for the treatment of Zenker's diverticulum [30]. Some authors see equal efficacy of all treatment modalities. Others use the size of the diverticulum and the patient's age as a basis for choosing the ideal approach. At our facility, an open approach is only used for exceptionally large diverticula and recurrence surgery or when visualization via a rigid endoscopy is technically impossible. Some facilities promote open surgery for small diverticula in healthy patients to reach a higher long-term success [31]. Other authors are more rigid and regard a diverticulum smaller than 3 cm as a formal contraindication for transoral treatment, as the septum of the diverticulum may be too short for sufficient stapling [32]. However, transoral laser surgery could be a suitable option in these cases. Significantly shorter perioperative times and a reduced total hospital stay endorse the role of transoral endoscopic treatment for older patients with high morbidity [33]. The flexible endoscopic approach under sedation has been shown to be a safe and successful treatment alternative to the rigid alternative in patients who have general anesthetic risks [34, 35].

Advantages and disadvantages of the flexible endoscope system

The flex system offers a good visualization of the surgical site in the transition zone of the hypopharynx and esophagus. Interestingly, the compatible flexible instruments

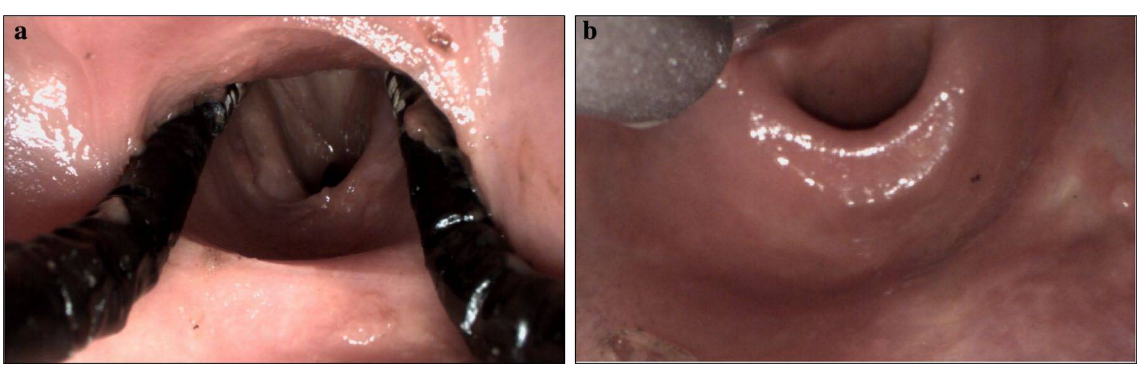

Fig. 3 **a** Flexible instruments reaching into the upper esophagus. **b** Upper esophageal sphincter muscle can be identified and exposed

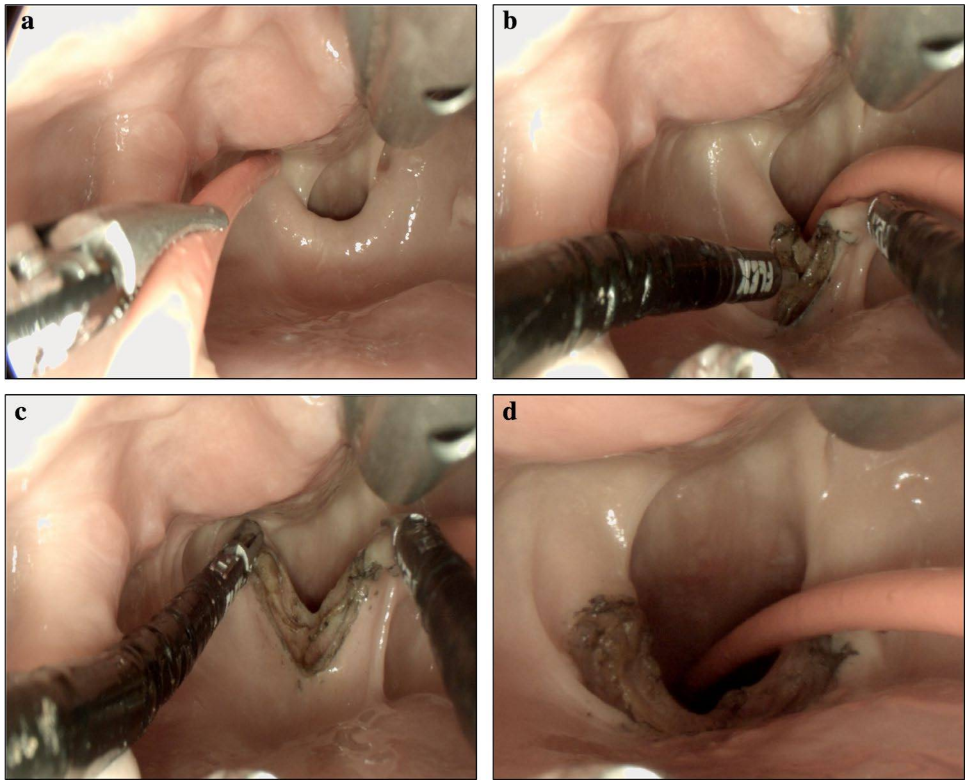

Fig. 4 **a** Endoscope-assisted introduction of a nasogastric feeding tube was safe and sufficient. **b** Performance of a median myotomy of the upper esophageal sphincter muscle. **c** Controlled dissection was possible, leading to an **d** obvious extension of the esophageal lumen

promise better haptic and tactile feedback characteristics than other robotic systems, e.g. the DaVinci system [36]. Other research groups have shown that the monopolar needle knife, which is the favored cutting device in the Flex system, produces similar results as a laser device [37, 38]. In line with these findings, the needle knife is reported to be a good compromise of cutting precision and coagulation zone [39].

The flexible system overcomes the demand for a straight line of sight endoscope and may have advantages in terms of access, using the available laryngeal retractors, even compared with open approaches. Compared to standard flexible endoscopic treatment, the working channels and suitable tools of the Flex system enable suturing of the mucosa. While stapling devices only allow suturing in predefined directions and range, normally by dissecting the diverticulum´s septum and closing the resulting defects in one operation, the flexible tools allow an individual treatment including closure of smaller perforations or defects. This might additionally reduce the incidence of mediastinitis and enable immediate postoperative oral ingestion with relatively low cost and high individuality. On the other hand, the use of a computer-assisted system is always associated with an increased setup time. In our hands, the time span can be reduced by sufficient training of the surgical team [40].

With a reported average myotomy length of 2–6 cm [41], the system reach will not enable sufficient treatment of all diverticula, so far. The reach of 2 cm in our study refers to the maximum instrument extension over the endoscope's tip. This gives the prospect of an extended reach, if the endoscope itself can be placed deeper in the hypopharynx, e.g. through advanced retractor placement, enabling treatment of larger diverticula.

A common disadvantage of all computer- or robot-assisted surgical systems is the financial burden, which is not adequately reimbursed in most health insurance systems and a main disadvantage compared with standard flexible endoscopic treatment [36]. Furthermore, the benefits of a flexible approach and instrumentation with the Flex system come with the demand on general anesthesia as in open surgery, diminishing the applicability in unfit patients with high morbidity, compared to standard flexible endoscopic treatment. The adoption of TORS-systems into clinical routine is, therefore, only granted, if a clear patient benefit is visible.

Conclusion

Until today, the benefits of robot-assisted surgery could not be delivered to the hypopharynx and upper esophagus. In the present cadaver study, the flexible endoscope system is a feasible option for surgical access to the hypopharynx and upper esophagus, giving the prospect of potential treatment of Zenker's diverticula. Open surgery and conventional endoscopic techniques enable treatment of most pathologies, but a definite advantage of one specific technique versus another remains open, and even major randomized trials do not answer that question. However, the flexible construction and the advanced versatility of compatible instruments offer additional advances especially for patients with decreased mobility of the cervical spine. In summary, optimized visualization, haptic feedback, and tissue control confront higher cost, setup time, and the limited reach on the esophagus. These advantages and disadvantages demand a restriction on selected patients, so that this innovative technique is not available for every patient. Further investigations are required to prove the reliability of the system and evaluate its performance and efficiency for routine clinical application.

Compliance with ethical standards

Ethical approval For the presented study, human cadavers were utilized. All specimens used were voluntary body donors. All procedures performed in studies involving human cadavers were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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Conflict of interest The authors have published on the Flex system (Medrobotics) before. The authors took part as investigators in the clinical study evaluating the Flex system without receiving financial compensation. A fee was payed per case. The authors have received travel expenses for cadaver labs with the Flex system. Permission was obtained from the respective manufacturers for publication of all figures.

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