

Transoral surgery using a novel single-port flexible endoscope system

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Abstract The transoral resection of pharyngeal and laryngeal tumors is challenging due to their location in a narrow anatomic space. In this study, the visualization and resection in the area of the pharynx and larynx using a novel computer-assisted flexible endoscopic robotic system are evaluated. The Medrobotics® Flex® System (Medrobotics Corp., Raynham, MA, USA) is an operator-controlled flexible endoscope robotic system that includes a flexible endoscope and computer-assisted controllers, with two accessory channels for the use of compatible, 3.5 mm flexible instruments. In six human cadavers, four basic procedures (tonsillectomy, base of tongue resection, hemi-epiglottectomy and resection of false vocal cords) were performed bilaterally by two surgeons. Success in appropriate visualization of the target structure and resection was documented. The driving and resection time was determined for each procedure. An appropriate exposure and resection within the pharynx and larynx was achieved in all cases. Both surgeons experienced a learning curve in driving the system and performing the procedures. The Medrobotics Flex® system is a promising tool for transoral resections within the pharynx and larynx. Good

visualization, access, and resectability are hereby clear advantages of the system compared to commonly used systems.

Keywords Head and neck cancer · Minimally invasive surgery · Transoral surgery · Endoscopic surgery · TORS

Introduction

Squamous cell carcinoma of the head and neck (HNSCC) is the sixth most common cancer worldwide and fifth most common cause of malignancy-related mortality [1, 2]. Treatment options for HNSCC include surgery, radiation, chemotherapy or a combination of these modalities. Traditionally, radical open surgical approaches with wide excisions to assure clear margins were the standard in the treatment of early and late tumor stages, causing high morbidity in the patients as well as overtreatment in many. To improve functional and cosmetic results in HNSCC patients, less invasive surgical methods were established within the last decades e.g., transoral surgery. Several decades ago transoral laser microsurgery (TLM) was established, showing satisfying oncological results with better functional outcomes [3–6] compared to open approaches. Although becoming a standard procedure in most parts of Europe, TLM never gained much popularity in North America. In recent years, transoral robotic surgery (TORS) was introduced and was rapidly adopted especially in North America and Asia. The most commonly used robotic system nowadays to perform TORS is the da Vinci Si robotic system (Intuitive Surgical®, Sunnyvale, CA, USA). TORS has shown to achieve acceptable functional and oncological results in the treatment of patients with

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pharyngeal and supraglottic tumors [7–9]. However, as a system developed to be used in various surgical disciplines (urology, gynecology etc.), the da Vinci system has tremendous shortcomings for TORS and procedures in the head and neck region as instruments are bulky and rigid, and lack tactile feedback; even very experienced TORS surgeons would appreciate smaller and more flexible tools to navigate through the narrow anatomic spaces within the upper aerodigestive tract, ideally in the form of a single-port system.

The Medrobotics Flex[®] System (Medrobotics Corp., Raynham, MA, USA) is an operator-controlled flexible endoscope that includes an endoscope and computer-assisted controllers, with two accessory channels for the use of compatible, third party 3.5 mm flexible instruments [10, 11]. This system is particularly designed to enable surgical procedures, which require a nonlinear advancement of surgical instruments, like in transoral surgery.

The present human cadaver study evaluates the feasibility of the Medrobotics[®] Flex[®] System in visualization and ease of surgical access of various sites in the pharynx and larynx for surgical resections.

Materials and methods

Medrobotics Flex[®] System

The Medrobotics[®] Flex[®] System (Medrobotics[®], Raynham, MA, USA) is an operator-controlled computer-assisted flexible endoscope system, consisting of numerous articulated segments allowing for a free three-dimensional and nonlinear movement of the system. The endoscope is comprised of two segments, an inner and outer segment, which are arranged in a concentric mechanical assembly to form a scope guide. Each set can be placed into a semi-rigid or a flexible state by adjusting the tension on the cables running through the segments. The distal and leading linkage, which is controlled by the surgeon using a 3-D joystick-like controller, embodies a digital camera providing HD vision, six LED lamps, a lens washer, two external and one internal accessory channel. The endoscope is equipped with two accessory channels for introducing 3.5 mm flexible instruments (Design Standards Corporation, Charleston, NH, USA). The surgeon drives the endoscope under visual control by means of a monitor on the Flex Console. The Medrobotics Flex[®] System consists of five components: the Flex console which houses the surgeon's control handle and a touch screen visual display included in the touch screen monitor; the Flex Base, a reusable assembly that translates electronic signals

from the console into mechanical motions; the Flex Scope, a sterile, disposable for transfer of mechanical motions from the Flex Base to the scope; the table mounted stand as support for the Flex Base and Flex Scope and the Flex Cart (Fig. 1a).

The compatible 3.5 mm flexible tools for surgical manipulation are manufactured by Design Standards Corporation (Charlestown, NH) (Fig. 1b).

Cadavers

Using six fresh frozen adult cadavers in accordance with institutional protocols, we investigated the feasibility and learning curves for using the Medrobotics[®] Flex[®] System for performing four basic head and neck procedures: tonsillectomy, resection of the base of tongue, hemi-epiglottectomy and resection of the false vocal cords. One of the cadavers was female, five were male 1:5, mean age was 65.2 years and showed partial or full dentation. Each specimen consisted of a head and neck attached to the entire upper torso. All relevant anatomy superior to the cricoid cartilage was found intact without obvious anomalies upon prior inspection.

System set-up

The cadavers were placed in a supine position on the operating table. An endotracheal tube was inserted transnasally to mimic real-life conditions. The robot was mounted to the surgical table rails and arranged to approach the oral cavity (Fig. 2a, b).

Each procedure was performed using the McIvor mouth gag (NovoSurgical, Oak Brook, USA) with different sized blades. A 3.5-mm grasper was used for tissue retraction and manipulation, and a 3.5-mm cauterizing instrument (needle knife) for resection.

Procedures

The surgical procedures were performed bilaterally in each cadaver with alternating surgeons. In each cadaver, the procedure on one side was performed by a well-experienced endoscopic surgeon (T.W), and on the other side by an otolaryngology resident (M.M). Driving and resection time was determined for each procedure. The procedure was successfully performed when the target structure was reached and resected (tonsillectomy, base of tongue resection, hemi-epiglottectomy and resection of false vocal cords). Learning curves were evaluated for both surgeons for each procedure type.

Fig. 1 a Medrobotics Flex[®] System. The system consists of five components: the Flex Console which houses the surgeons control handle and a touch screen visual display and the touch screen monitor; the Flex Base, a reusable assembly that translates electronic signals from the console into mechanical motions; the Flex Scope, a sterile, disposable for transfer of mechanical motions from the base to the endoscope; the table mounted stand as support for the base and disposable and the Flex Cart. **b** Photograph of the distal tip of the flexible endoscope system with the HD camera, LED lamps and flexible 3.5-mm instruments inserted through the two accessory channels, and of flexible instrument control for 3.5-mm flexible instruments with distal wristed end-effectors

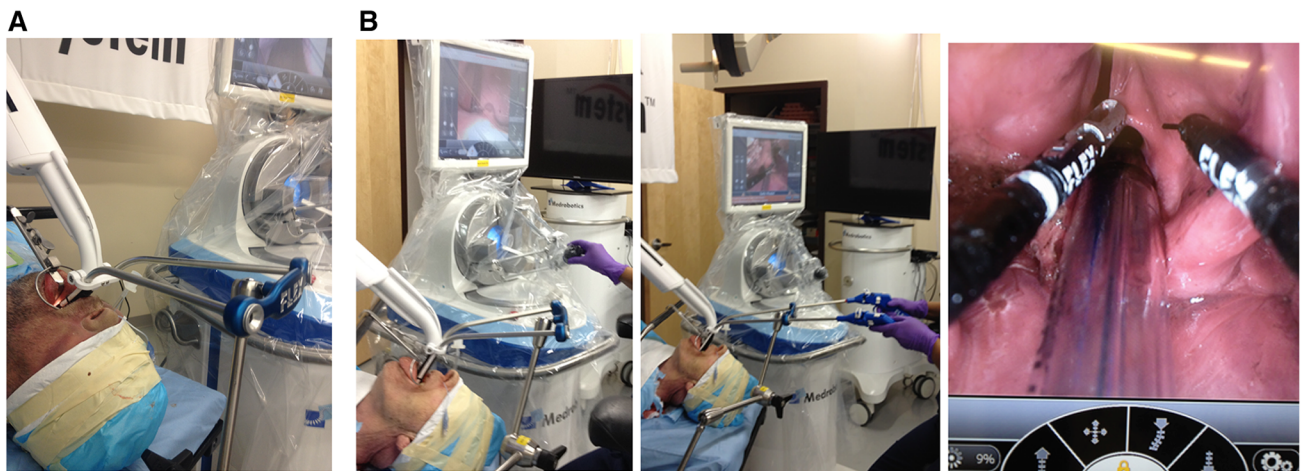


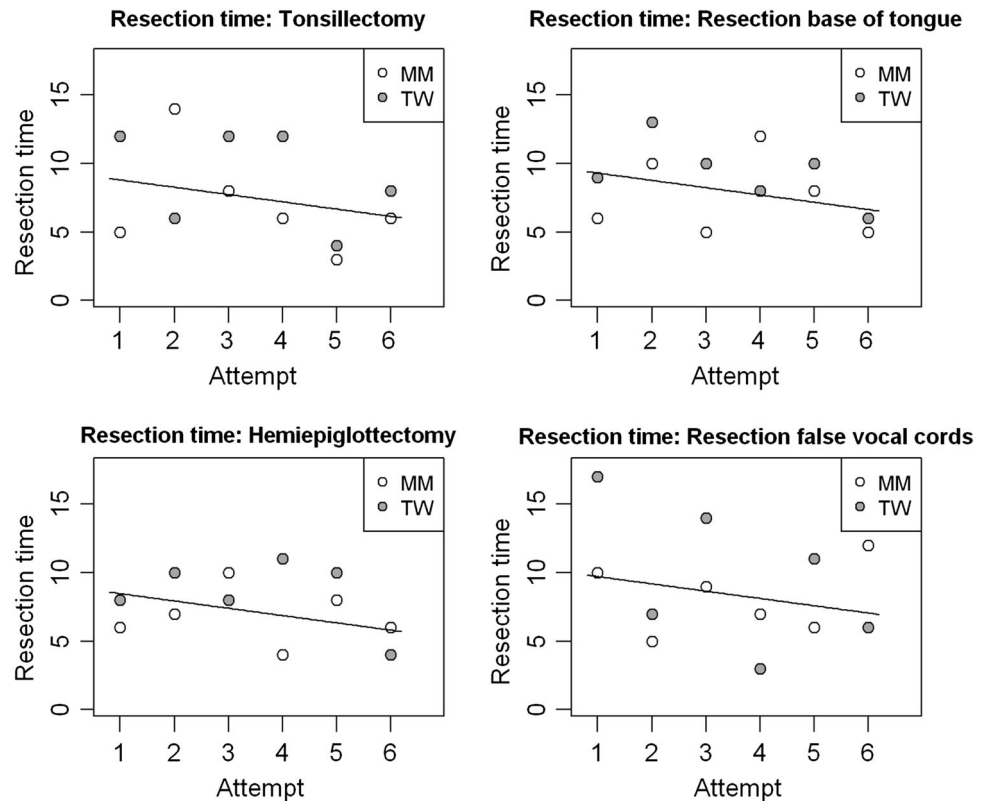
Fig. 2 a Medrobotics Flex[®] System mounted onto the caudal end of the operation table directed cranially to reach the mouth of the patient. **b** As the system is inserted transorally, a video monitor offers visual feedback to the surgeon while driving the system

Statistical analysis

To analyze the driving and resection time, a simple linear regression model to estimate the average improvement

with each additional attempt and test for statistically significant trends while taking into account the correlation between driving times in procedures performed by the same surgeon was used.

Fig. 3 Learning curve of the two surgeons for performing tonsillectomies, base of tongue resections, hemi-epiglottectomies and resection of false vocal cords using the Medrobotics Flex[®] System. An estimate variable “attempt” gives the change in minutes for the driving time with the experience of each additional attempt averaged across operations and operators. A *negative value* indicates that resection time decreased on average as experience was gained. The model was able to detect the improvement in resection time as statistically significant ($p = 0.045$)



Results

Application of the Medrobotics Flex[®] System

Duration of system set-up

The time to set up the system by two people was determined twice. The overall time for setting up the system completely under appropriate sterile conditions was 16 min in the first attempt and reduced to 9 min in the second attempt done 24 h later. These durations include the draping time and the time to position the device in its final position on the operating table.

Driving time and learning curves

All four procedures were performed by two surgeons in six fresh frozen adult cadavers as described above. Driving time was determined driving the endoscope after placing the retractor to docking the endoscope system in its final position with appropriate visualization of the targeted structure. The average time for exposure of the tonsil region was 2 ± 1 min, of the base of tongue was 2 ± 0.7 min, of the epiglottis was 1.4 ± 0.5 min and the supraglottis was 3.8 ± 1.9 min. A learning curve was observed for both surgeons in driving the Flex[®] System; however, the results showed no statistical significant difference. All attempts in visualizing the target structure were successful (Fig. 3).

Procedure time and learning curves

The procedures were performed using a 3.5-mm grasper for tissue retraction and manipulation and a 3.5-mm cauterizing instrument (needle knife) for resection. All mentioned procedures were performed successfully in all six specimens. In every surgical procedure, the instruments were passed through the accessory channels without any difficulty. The average procedure time for performing tonsillectomies was 8 ± 3.6 min, for base of tongue resections was 8.5 ± 2.6 min, for hemi-epiglottectomies was 7.7 ± 2.3 min and resection of false vocal cords was 8.9 ± 4.1 min. Although the number of attempts per procedure was little, a positive learning curve was observed for both surgeons in performing all four procedures (Fig. 3). An improvement in resection times during the different attempts (12 per procedure) could be shown ($p = 0.045$). There was no significant difference in timings of both surgeons as well as their respective learning curves.

Discussion

Minimally invasive surgical techniques in the treatment of HNSCC have been developed with the desire for better functional and cosmetic results compared to radical open approaches without sacrificing oncological safety [12–14]. Transoral surgery in the form of TLM has been widely

used for decades in most parts of Europe and specialized centers in North America and Asia in the treatment of pharyngeal and laryngeal tumors. Limitations of this method include the resection in only a unilateral direction not allowing for resection around corners without manipulating the tissue. TORS has rapidly gained popularity as a minimally invasive surgical technique especially in North America. The three-dimensional, magnified view with the ability to manipulate the instruments in seven degrees of freedom, are hereby clear advantages of the system in resecting within the pharynx. However, many experienced TORS surgeons have concluded that an adequate surgical access of areas within the pharynx and larynx outside the oropharynx is still difficult to achieve using the da Vinci system, as instruments are still relatively large and rigid. Especially, adequate exposure of target structures distally from the base of tongue remains challenging.

Transoral head and neck surgery would profit from a system providing access to deep anatomical structures within the pharynx and especially larynx by conforming to the given anatomy without causing trauma to surrounding tissue. In addition, the ability to introduce multiple instruments along this predefined path to reach the surgical site of interest would be greatly beneficial.

The Medrobotics® Flex® System addresses the limitations of current robot and laser technology by providing an operator-controlled flexible endoscope system, which can be maneuvered in a nonlinear fashion to targets within the pharynx and larynx. Further, the system allows for introduction of flexible instruments along the same path to perform surgery.

The results of our small cadaver study demonstrate that this highly flexible endoscope system is a viable tool in performing transoral tonsillectomies, base of tongue resections, hemi-epiglottectomies and resections of false vocal cords. These procedures were selected to demonstrate feasibility of using the Medrobotics® Flex® system in basic head and neck procedures. Further studies will attempt to undertake more involved procedures.

The procedures were completed in an adequate time frame by both, the well-experienced and resident surgeon, with positive learning curves.

Set-up time of the system for beginners is very short compared to times reported for setting up the da Vinci system [15–17].

All attempted procedures could be completed without difficulties. Multiple instruments were introduced without any difficulties and could be manipulated without causing in situ collision. A haptic feedback while performing the procedure similar to performing endoscopic head and neck surgery is provided. For resection, we used a monopolar needle knife, but laser fibers are being currently developed to be compatible with this novel system.

In the present study, feasibility in visualization and performing common surgical procedures in different sites within the pharynx and larynx using the Medrobotics Flex® system was demonstrated.

Obviously the results presented in this work may only be considered preliminary and do not allow making observations on e.g., haemostasis, post-operative morbidity and functional and oncological outcome. All these aspects need to be targeted in successive animal models and later in clinical studies.

Conflict of interest M.M's travel expenses for performing the three-day cadaver study were financed by Medrobotics® Corporation.

References

- Parkin DM, Bray F, Ferlay J, Pisani P (2002) Global cancer statistics. *CA Cancer J Clin* 2005(55):74–108
- Fremgen AM, Bland KI, McGinnis LS Jr et al (1999) Clinical highlights from the national cancer data base. *CA Cancer J Clin* 1999(49):145–158
- Werner JA, Dunne AA, Folz BJ, Lippert BM (2002) Transoral laser microsurgery in carcinomas of the oral cavity, pharynx, and larynx. *Cancer Control* 9(5):379–386
- Köllisch M, Werner JA, Lippert BM, Rudert H (1995) Functional results following partial supraglottic resection. Comparison of conventional surgery vs. transoral laser microsurgery. *Adv Otorhinolaryngol* 49:237–240
- Iro H, Waldfahrer F, Gewalt K, Zenk J, Altendorf-Hofmann A (1995) Enoral/transoral surgery of malignancies of the oral cavity and the oropharynx. *Adv Otorhinolaryngol* 49:191–195
- Suárez C, Rodrigo JP, Silver CE, Hartl DM, Takes RP, Rinaldo A, Strojjan P, Ferlito A (2012) Laser surgery for early to moderately advanced glottic, supraglottic, and hypopharyngeal cancers. *Head Neck* 34(7):1028–1035
- Hans S, Delas B, Gorphe P, Ménard M, Brasnu D (2012) Transoral robotic surgery in head and neck cancer. *Eur Ann Otorhinolaryngol Head Neck Dis* 129(1):32–37
- Park YM, Kim WS, Byeon HK, Lee SY, Kim SH (2013) Oncological and functional outcomes of transoral robotic surgery for oropharyngeal cancer. *Br J Oral Maxillofac Surg* 51(5):408
- Weinstein GS, Quon H, Newman HJ, Chalian JA, Malloy K, Lin A, Desai A, Livolsi VA, Montone KT, Cohen KR, O'Malley BW (2012) Transoral robotic surgery alone for oropharyngeal cancer: an analysis of local control. *Arch Otolaryngol Head Neck Surg* 138(7):628–634
- Johnson PJ, Rivera Serrano CM, Castro M, Kuenzler R, Choset H, Tully S, Duvvuri U (2013) Demonstration of transoral surgery in cadaveric specimens with the medrobotics flex system. *Laryngoscope*. 123(5):1168–1172
- Neuzil P, Cerny S, Kralovec S, Svanidze O, Bohuslavsek J, Plasil P, Jehlicka P, Holy F, Petru J, Kuenzler R, Sediva L (2013) Single-site access robot-assisted epicardial mapping with a snake robot: preparation and first clinical experience. *J Robot Surg* 7(2):103–111 (Epub 2012 Mar 13)
- Canis M, Ihler F, Wolff HA, Christiansen H, Matthias C, Steiner W (2013) Oncologic and functional results after transoral laser microsurgery of tongue base carcinoma. *Eur Arch Otorhinolaryngol* 270(3):1075–1083

13. Roh JL, Kim DH, Park CI (2008) Voice, swallowing and quality of life in patients after transoral laser surgery for supraglottic carcinoma. *J Surg Oncol* 98(3):184–189
14. Steiner W, Fierek O, Ambrosch P, Hommerich CP, Kron M (2003) Transoral laser microsurgery for squamous cell carcinoma of the base of the tongue. *Arch Otolaryngol Head Neck Surg* 129(1):36–43
15. Paleri V, Rees G, Arullendran P et al (2005) Sentinel node biopsy in squamous cell cancer of the oral cavity and oral pharynx: a diagnostic meta-analysis. *Head Neck* 27(9):739–747
16. Blanco RG, Fakhry C, Ha PK, Ryniak K, Messing B, Califano JA, Saunders JR (2013) Transoral robotic surgery experience in 44 cases. *J Laparoendosc Adv Surg Tech A* 23(11):900–907
17. Hans S, Badoual C, Gorphe P, Brasnu D (2012) Transoral robotic surgery for head and neck carcinomas. *Eur Arch Otorhinolaryngol* 269(8):1979–1984