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LARYNGOLOGY

Transoral robotic surgery (TORS) with the Medrobotics Flex™ System: first surgical application on humans

M. Remacle · V. M. N. Prasad · G. Lawson · L. Plisson · V. Bachy · S. Van der Vorst

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Abstract Head and neck surgery can be fraught with difficulties in accessing the pharynx and larynx. Minimally invasive surgery has developed with the recent advances in technology. Currently, we have a variety of high-definition multichannel videoendoscopes and robots in our armamentarium. We present our experience in a new robotic surgical system—'The Medrobotics Flex™ System' at our tertiary referral unit. We aimed to assess the safety, functionality and ease of use of this new device in this prospective study. Thus far, this is the first study in live human subjects who have undergone surgery for the following conditions: (1) obstructive sleep apnoea involving the base of tongue, the tonsil and the velum; (2) vocal fold polyp; (3) carcinoma of the lateral edge of the tongue. There were no complications in our series and the system provided good visualisation and access to these subsites without compromising safety or success. In summary, we found the Medrobotics Flex™ System to have certain other advantages including ease of set up and use besides being reliable and safe.

Keywords Robot · TORS · Head and neck surgery

Introduction

Surgery in the head and neck can be fraught with challenges and difficulties in accessing certain sites and subsites. Modern technology has made access easier and evaluation clearer using better fibreoptics and microscopes. There are, however, still certain areas which despite these innovations in technology continue to prove to be difficult to visualize, access and operate in without the need for more radical approaches surgically.

Minimally invasive throat surgery routinely consists of the insertion of a laryngoscope for access and exposure to the oropharynx while long, rigid surgical instruments are manipulated within the confines of the laryngoscope. In order for the otolaryngologist to successfully monitor and treat subjects with conditions in the oropharynx and hypopharynx, a method of visual inspection and tissue resection is required. Current options to access and visualize the oropharynx and hypopharynx are limited to the shortcomings of currently available videoendoscopes which include but are not limited to the lack of accessory channels or of a shortage of multiple accessory channels, rigidity to support instrument articulation and manipulation, vision being limited to the line of sight, instrument handle support and instrument manipulation being restricted to working within the long, crowded, narrow channel of a laryngoscope. At present, flexible videoendoscopes are used to view and examine the oropharynx, biopsy suspicious lesions and growths and perform minor surgical procedures. In suspension laryngoscopy, vision is also limited to the line of sight and instrument manipulation is restricted to working within the long, crowded, narrow confines of the laryngoscope [1, 2].

The introduction of the 'robot' has made some strides in reducing these challenges and its use in carefully selected tongue base, tonsillar and certain laryngeal and hypopharyngeal cases has shown great success. The Medrobotics Flex™ System (Medrobotics Corp., Raynham, MA) is an operator-controlled computer-assisted flexible endoscope

M. Remacle · V. M. N. Prasad (✉) · G. Lawson · L. Plisson · V. Bachy · S. Van der Vorst
Department of ORL-Head and Neck Surgery, Louvain University Hospital of Mont-Godinne, Avenue Docteur G. Therasse, 1, 5530 Yvoir, Belgium
e-mail: vyasprasad@gmail.com

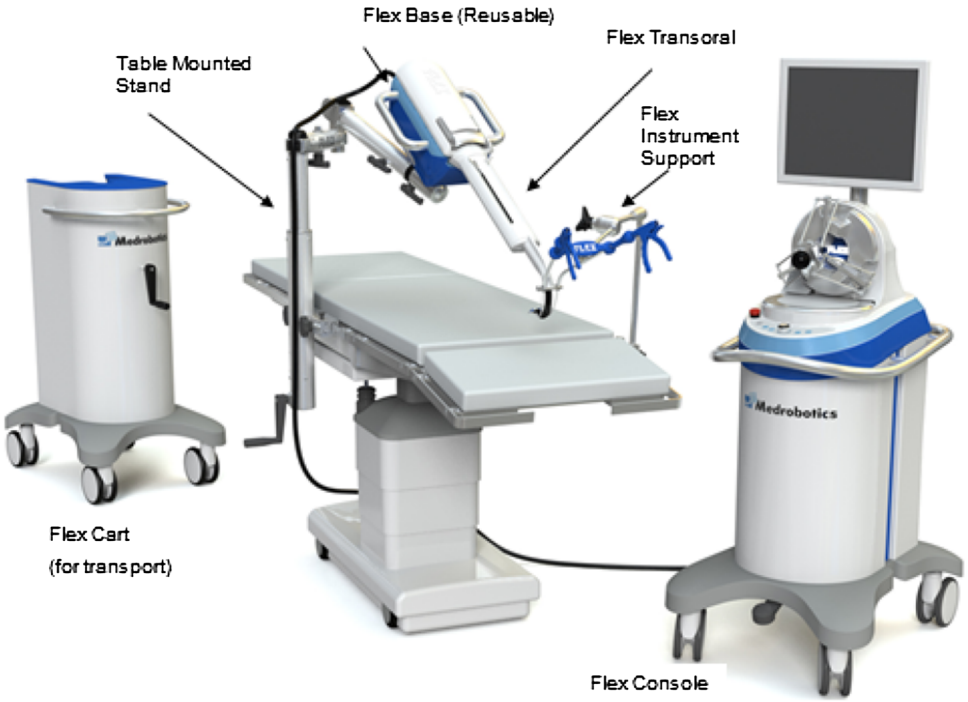

Fig. 1 Medrobotics Flex™ System

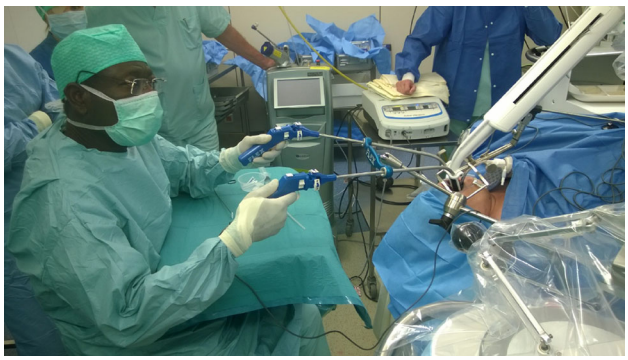

Fig. 2 Surgeon in position for operating after setting of the flex system

that utilizes similar technology, with the additional benefit of remote manipulation by the user. The centre of the Flex™ System technology is the articulated segments. The segments incorporate features that provide a single point of articulation between adjacent segments while controlling rotation and lateral motion. The articulation of the outer segments is achieved by varying the forces of the three outer segment cables enabling the endoscope to traverse and maintain its position in three-dimensional space without external support (Fig. 1).

The endoscope is comprised of two sets of segments, inner and outer which are arranged in a concentric mechanical assembly to form the endoscope. 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 outer segments also have the ability to be articulated by varying the tension to the outer segment cables when a portion of the outer segments are extended beyond the distal end of the inner segments. This method of steering is consistent with existing steerable catheter and endoscope technologies. By employing a "follow-the-leader" movement strategy with these two alternating states (semi-rigid or flexible), the endoscope can be manipulated into any shape bounded by the sum of the movement of the individual joints (Fig. 2).

The endoscope contains two internal lumens, which are defined by counterpart features in each of the segments of the inner and outer sets. The first lumen provides a pathway for the electrical connections from the Flex™ base to the distally mounted complementary metal–oxide–semiconductor (CMOS) camera and light emitting diode (LED) illumination lamps. The second lumen provides a pathway for the irrigation tubing which carries fluid to the lens washer nozzle located at the distal tip of the endoscope.

The Flex™ System also offers two External Accessory Channels that lead from the proximally located rigid metal accessory guides to the distal end of the endoscope allowing for compatible flexible instrument exchange during the procedure. These external accessory channels consist of flexible guide tubes which terminate at the distal end of the endoscope to laterally positioned ports. These ports present the accessories to the operative field within the field of view of the distally mounted camera. Proximally, the flexible guide tubes are housed in rigid metal accessory guides which provide accessory port access and instrument handle support to the user.

In summary, the Flex^{TM} System consists of five primary components: (1) the Flex^{TM} Console which houses the 'Surgeon Controller', a touch screen visual display, surgeon's workspace with a membrane key pad, the main system electronics, and an emergency stop button; (2) the Flex^{TM} Base which is a reusable electro-mechanical assembly that translates signals from the Flex^{TM} Console into mechanical motions, which in turn are transferred to the Flex^{TM} Disposable; (3) the Flex^{TM} Disposable which is a sterile, one time use disposable plastic housing that contains capstans and other mechanical components that transfer mechanical motions from the Flex^{TM} Base to the scope, (4) the Table Mounted Stand (TMS) is an adjustable support stand for the Flex^{TM} Base and Flex^{TM} Disposable. The TMS attaches to the surgical table side rails and allows the surgeon to position the Flex^{TM} Base in the position required to access the oral cavity, and (5) the Flex^{TM} Cart which allows for safe transport and transfer of the Table Mounted Stand (TMS) and Flex^{TM} Base to and from the surgical table and provides storage of the TMS, Flex^{TM} Base, and System Cable.

Debate surrounds the use of the term 'robot' in the surgical realm. While the robot is clearly defined by the Robotic Industries Association (RIA) as a reprogrammable, multifunctional manipulator, the Medrobotics Flex^{TM} System may be deemed more a manipulator than a true 'robot' as it is not pre-programmed to perform its tasks.

We present three cases performed at our tertiary centre using the Medrobotics Flex^{TM} System. As far as we are aware, there are no reports on an earlier safe use and application in live human subjects [3].

Objectives

The primary objective of this paper is to report our first three cases of an ongoing prospective study for assessing the safety and performance of the Medrobotics Flex^{TM} System for access and visualization of the oropharynx and hypopharynx when used for transoral surgical treatments. The secondary objective was to assess the safety of the system through 48-h post-treatment. Finally, the tertiary objectives were to confirm the clinical performance and safety of the Flex^{TM} System, identifying new or changed product risk, assessing if identified risk remained at an acceptable safety level, detecting emerging risks based on factual evidence and identifying new product opportunities for development and/or improvement.

Materials and methods

We present three separate cases of adults referred to our tertiary referral centre for management of various conditions in the head and neck. Our choice of patients was focused on firstly testing the safety and capability of performing common ear, nose and throat (ENT) procedures using this novel system and secondly, in relation to Case 1, i.e. tongue base resection, to assess the improved access the system provided compared to currently available 'non-robotic' techniques. All three cases presented underwent surgery using the Medrobotics Flex^{TM} System. All operations were performed with full and informed consent and in keeping with our local Ethics Committee protocols.

Case 1

A 49-year-old lady with a background history of severe snoring, day time somnolence and an Apnoea-Hypopnoea Index (AHI) of 15.3 presented to our Ear, Nose and Throat (ENT) service. She underwent a sleep nasendoscopy where she was found to have inferior turbinate hypertrophy bilaterally, a deviated nasal septum, velopharyngeal and tongue base collapse as well as desaturations during the course of the procedure. She was also discovered to have enlargement of her tonsils, the left being slightly larger.

She was counselled and appropriately listed for surgical treatment of her obstructive sleep and snoring symptoms. She underwent bilateral tonsillectomy, uvulopalatoplasty, cauterization of inferior turbinates and robot-assisted resection of the tongue base.

The procedures were performed under general anaesthesia with a standard oro-tracheal intubation. The tonsillectomy was performed in a standard manner on the right side utilizing bipolar diathermy for dissection and haemostasis while the left side was dissected using a CO_2 laser fibre. The intention of using different modalities to dissect the tonsils in different ways was to prove that the new system was equally safe to traditional methods. The tonsillectomy proceeded uneventfully. Inferior turbinectomy was performed in a standard manner using a monopolar needle electrode and visualized using a 30-degree endoscope.

Tongue base resection was then performed with modification in the position of the gag with increased tongue protrusion to allow access to the base. This procedure was performed using the Medrobotics Flex^{TM} System. Lingual tonsillar ablation was performed thereafter using monopolar cautery under robotic guidance.

The patient made a steady recovery with no complications. She was discharged several days after and was followed-up routinely in our outpatient clinic.

Case 2

A 62-year-old patient presented for symptoms of dysphonia and was diagnosed with an anterior polypoidal lesion on

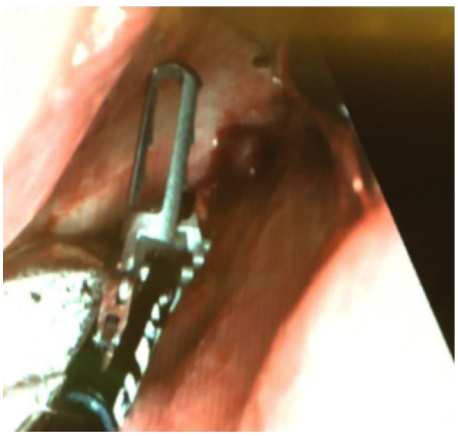

Fig. 3 Ablation of an angiectatic polyp (case 2)—Maryland and needle monocautery

the right vocal cord. She underwent a microlaryngoscopy and excisional biopsy (MLB).

The procedure was performed under a general anaesthetic. The polyp was excised under direct laryngoscopic visualization using the Medrobotics Flex^{TM} System. The procedure was performed using cold steel and a fine monopolar cautery needle designed specifically for both cutting and coagulation purposes with the Medrobotics Flex^{TM} System (Fig. 3).

The patient was discharged the same day with no sequelae post-operatively and was reviewed routinely in the outpatient setting.

Case 3

A 34-year-old man presented with a keratotic looking lesion in the left lateral border of the tongue close to the glosso-tonsillar sulcus. He was asymptomatic except for an irritation in his throat when swallowing. A full diagnostic work-up was performed to outrule any sinister pathology after a thorough ENT examination. This included PET scanning which demonstrated increased uptake in the same area of the tongue as the lesion, a sub-centimeter lymph node in the left upper neck (level II) and the left nasopharynx. Endoscopic evaluation and biopsy of the left lateral border of the tongue and Eustachian tube under general anaesthesia showed no malignant pathology.

The patient was recommended an excisional biopsy of the tongue lesion thereafter for the complete assessment and removal of the lesion utilizing the Medrobotics Flex^{TM} System. The lesion was excised using monopolar cautery. Sentinel node biopsy of the left lateral node was performed as well. The patient made an uneventful recovery and was discharged shortly after (Fig. 4).

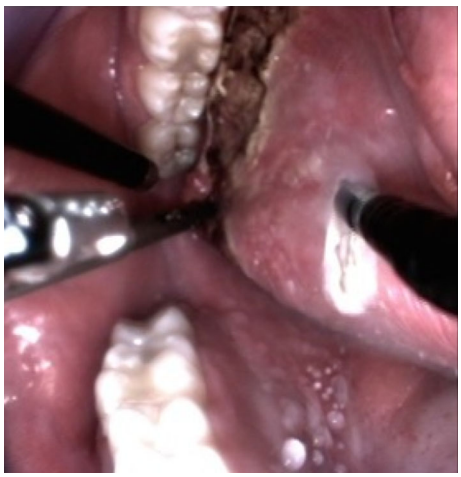

Fig. 4 Ablaltion of carcinoma of the lateral edge of the tongue—monocautery blade

Discussion

We present our experience in three separate cases of the use of the Medrobotics Flex^{TM} System for surgery of the ENT/Head and Neck. All three cases were performed by the same senior surgical colleagues (MR, GL) under general anaesthesia and with full informed consent.

While the Flex^{TM} System provides similar vision and illumination capabilities of other flexible and rigid endoscopes, it allows the surgeon a single-site minimally invasive approach to navigate and access difficult to reach areas of the oropharynx and hypopharynx utilizing high-definition vision. The Flex^{TM} System also provides the option of a semi-rigid state for better instrument purchase and offers two external accessory channels. The two external accessory channels provide instrument handle support which allows the surgeon to perform two-handed procedures when using compatible flexible endoscopic instruments. Additional benefits of the Flex^{TM} System include remote single-hand manipulation by the user, accessory channels for compatible flexible instruments, and a High-Definition (HD) Vision system.

This system is currently under development and is being trialled by several international centres with the intention to have a user-friendly semi-robotic system that allows for better access, visualization, haptic feedback, simplicity of set-up and use as well as safety—while also remaining affordable. In time, HD 3-D (high-definition three-dimensional) visualization will be available too. This system has advantages over its peer in that it is simpler to use, more mobile, easy to set up and at present less expensive [4]. It has been specifically designed for the use primarily in the head and neck and as such is a tool that has been adapted for the otolaryngologist and not vice versa. Accordingly,

the position of the surgeon is at the head of the patient and access to the larynx directly is therefore possible. As such, lesions of the larynx which may be more difficult to access due to anatomical restrictions can be considered. Also, present tools in robotic surgery for ablation and cautery include mainly monopolar cautery, bipolar (e.g. Maryland) and harmonic instrumentation but with the development of the Flex^{TM} System, a variety of modalities other than the aforementioned such as: (1) CO_2 laser wave guide and (2) Thulium laser can be employed.

Conclusion

Our experience of the Flex^{TM} System has been encouraging. The access provided, safety and ease of use were all equal to if not better than traditional systems in use. There were neither adverse, serious adverse or unanticipated adverse device effects nor treatment emergent adverse events. In conclusion, we found the robot to be easy to use, allowing for access in more difficult areas of the upper aerodigestive tract and safe.

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