HEAD AND NECK

Flexible transoral robotic surgery: the Italian experience

Chirurgia robotica transorale flessibile: l'esperienza italiana

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SUMMARY

Objective. This prospective, non-randomised study documents our initial experience using the Flex® Surgical System for transoral surgery in Italy.

Methods. All patients who underwent transoral robotic surgery using the Medrobotics® Flex® Robotic System (Raynham, MA, USA) between March 2018 and April 2019 were reviewed. Rates of successful surgery, surgical time and complications were evaluated. 43 surgical procedures were performed in the study. The average age was 62.56 years (range 36-90 years). The Flex® system was used successfully in surgery of the base of the tongue, palatine tonsils, supraglottis, hypopharynx and glottis, which was the most frequent target.

Results. All procedures were successfully completed. There were no intraoperative or serious postoperative complications, with no cases of intraoperative haemorrhage.

Conclusions. This is the first study in Italy evaluating the use of the Flex® system to safely resect lesions in the oral cavity, larynx and pharynx.

KEY WORDS: larynx, pharynx, transoral surgery, flexible endoscope

RIASSUNTO

Obiettivo. Questo studio prospettico, non randomizzato, documenta l'esperienza iniziale con il sistema chirurgico Flex® nella chirurgia transorale in Italia tra Marzo 2018 ed Aprile 2019.

Metodi. Sono state eseguite 43 procedure chirurgiche su 41 pazienti con età media di 62,56 anni (intervallo 36-90 anni). Sono stati valutati i tassi di successo dell'intervento chirurgico, il tempo chirurgico e le complicanze. Il sistema Flex® è stato utilizzato nella chirurgia della base della lingua, delle tonsille palatine, della regione sovraglottica, dell'ipofaringe e della glottide: quest'ultimo è stato il target chirurgico più frequente.

Risultati. Tutte le procedure sono state completate con successo. Non ci sono state complicanze intraoperatorie e postoperatorie gravi, nè casi di emorragia.

Conclusioni. Questo è il primo studio in Italia in cui viene utilizzato il sistema Flex® per la resezione di lesioni faringee e laringee e ne documenta l'affidabilità e la sicurezza.

PAROLE CHIAVE: *laringe, faringe, chirurgia transorale, endoscopio flessibile*

Introduction

In recent decades, transoral surgery for tumours of the upper aerodigestive tract has become a standard procedure for treating different pathologies in this region at the early and/or intermediate stages, although sometimes there may be procedural difficulties depending on anatomical variations of the patient [1]. Over the years, transoral laser microsurgery (TLM) has been proven to be effective in treating neoplasms of the upper aerodigestive tract, especially of the larynx, while achieving satisfactory oncological results and with better functionality compared to open reconstructive approaches. However, some hypopharyngeal and laryngeal lesions remain difficult to visualise and treat through a transoral, surgical approach [2,3].

Transoral robotic surgery (TORS) is a recent approach in managing pharyngeal and supraglottic neoplasms. The use of 3D HD angled endoscopes combined with robotic arms allows better exposure, visualisation and evaluation of anatomical regions that are otherwise difficult to manage with TLM [4]. The most commonly used robotic system in head and neck surgery is the da Vinci Si® HD (Intuitive Surgical®, Sunnyvale, CA, USA), through which surgeons are able to perform procedures in the pharyngeal region [5], at the base of the tongue and in some laryngeal sites, mainly in the supraglottic region [6]. However, there are some limitations which are mainly caused by the conflict between rigid robotic arms that may result in obstruction at the surgical site and limitation of movement. Unlike this well-known system, which was originally designed for surgery within larger cavities (such as abdominal and pelvic surgery), a new flexible robotic system – the Flex® Robotic System (Medrobotics®, Raynham, MA, USA) – has been developed to expand the field of TORS by responding specifically to the unmet needs of minimally invasive surgery of the upper aerodigestive tract [7]. This is a hybrid technology, combining the flexibility of an endoscope to gain access to the surgical site and capable of becoming rigid to perform the procedure. This technology is described as a hybrid because, on one hand, it uses the characteristics of flexible endoscopy, offering 102° of freedom in angular motion, and, on the other, is capable of navigating in non-linear spaces and becoming rigid near the surgical site [8,9]. After demonstrating feasibility and safety with successful cadaver dissections, the system obtained the CE Mark in March 2014 and the first patients were treated clinically in Europe beginning in July 2014 [10,11]. The surgical site is visualised using a 3D video camera incorporated into the distal end of the flexible endoscopic arm. The robotic arm has two accessory instrument channels for the delivery of 3.5-mm flexible instruments and, recently, 2-mm flexible instruments for laryngeal microsurgery. These instruments provide haptic feedback and allow the surgeon to have full control of the tip of the instrument. The system consists of two components: the 1) Flex® Cart, which carries the Flex® base, the Flex® Scope, and 2) the Flex® Console which has a 2D touchscreen and physician controller. The flexible robotic arm is controlled by the physician controller and a 2D touchscreen monitor. A reusable 3DHD camera and light source consisting of four LED lights are mounted on the tip of the flexible robotic arm. Thanks to a 3D monitor and passive 3D glasses, all of the room is able to follow the surgical procedure in real time [12].

There are numerous studies in literature in which Flex technology has been applied in the pharyngeal and supraglottic regions [13-15]. However, clinical work on the glottic plane as the surgical target is limited [16]. The development of new, laryngeal robotic arm, flexible micro-instruments and curved laryngeal blades as a component of the Flex® Retractor System allows surgeons to easily reach the glottic plane with excellent exposure and to operate safely. The purpose of this study is to evaluate the flexible robotic system in laryngeal transoral robotic surgery of the head and neck. We demonstrate our experience with the Flex® Robotic System on the glottic region as this anatomy has not been the focus of previous clinical studies.

Materials and methods

From March 2018 to April 2019, a prospective, non-randomised study, approved by the local ethics committee, was carried out at our Department to assess the safety, efficacy and potential of the flexible robotic system in the treatment of laryngeal lesions. A total of 41 patients were enrolled and treated. The average patient age was 62.56 (range 36-90) and, of these, 28 patients were men and 13 patients were women.

A total of 43 surgical procedures were performed because in 2 cases two separate procedures were performed (in the first, two laryngeal neoformations and, in the second, a laryngeal neoformation and a pharyngeal neoformation) (Tab. I). Six procedures (13.95%) were performed for a pharyngeal lesion, and 37 (86.05%) for laryngeal lesions (Tab. II). All patients underwent a pre-operative visit and fibre-optic laryngoscopy with NBI. All patients spent one night in hospital. A new dedicated retractor was used in all procedures (Flex® Retractor System: Medrobotics). Positioning of the retractor was video-assisted using a GlideScope® Core (Verathon) portable video laryngoscope supplied by our anaesthetists. Nasotracheal intubation was chosen in all procedures; in our opinion, this allows better exposure and less obstruction of the surgical field using a 5-mm armored endotracheal tube. All procedures were performed by the same surgeon and nursing team. Each procedure required the use of two Flex® Instruments. Either a Flex® Monopolar Maryland Dissector, a Flex® Fenestrated Grasper or a Micro Flex® Triangle Grasper were selected as a grasping and retraction instrument. A Flex® Monopolar Needle Knife or a Flex® Monopolar Spatula was used as a cutting tool in 40 procedures (93%). In 3 of the laryngeal procedures (7%), however, a Micro Flex® Sickle Knife, a cold cutting instrument, was preferred. In all operations, a suction tube for smoke evacuation was connected to the Flex® Retractor and a second operator helped the surgeon with the suction and traction of tissues using an external rigid double-edged curved laryngeal suction unit.

Table I. In 41 patients, 43 surgical procedures were performed.

Patient no.	Sex	Age, Y	Malignant/benign (M/B)	Histology	Surgical procedure	Site	Subsite
1	M	64	B	Laryngocele	Resection	L	Vestibule
2	M	70	B	Dysplasia	Type II cordectomy	L	Vocal fold
3	M	63	B	Synechia	Resection	L	Vocal fold
4	M	64	B	Cyst	Resection	O	Tonsil
5	M	65	B	Dysplasia	Type III cordectomy	L	Vocal fold
6	M	58	B	Laryngocele	Resection	L	Vestibule
7	M	71	M	SCC pT1a	Type Va cordectomy	L	Vocal fold
8	M	72	M	SCC pT1a	Type III cordectomy	L	Vocal fold
9	M	57	B	Dysplasia	Type I cordectomy	L	Vocal fold
10	M	64	B	Synechia	Resection	L	Infraglottic cavity
11	F	68	M	SCC pT1a	Type III cordectomy	L	Vocal fold
12	F	56	B	Cyst	Resection	O	Base of tongue
13	F	60	B	Cyst	Resection	L	Epiglottis
14	F	62	B	Cyst	Resection	O	Base of tongue
15	F	45	B	Reinke oedema	Resection	L	Vocal fold
16	M	64	B	Mucosal flap	Resection	L	Vestibule
16 BIS	M	64	B	Sovraglottic obstruction	Epiglottectomy	L	Epiglottis
17	M	66	M	SCC pT1a	Type Va cordectomy	L	Vocal fold
18	M	70	B	Papilloma	Resection	L	Infraglottic cavity
19	M	71	M	SCC pT1b	Type VI cordectomy	L	Vocal fold
20	M	65	M	SCC pT1a	Type III cordectomy	L	Vocal fold
21	M	56	B	Cyst	Resection	L	Epiglottis
22	M	90	M	SCC pT1	Bot resection	O	Base of tongue
23	M	62	B	Taratoma	Tonsillectomy	O	Tonsil
24	F	67	B	Polyp	Resection	L	Vocal fold
25	M	70	M	SCC pT1a	Type IV cordectomy	L	Vocal fold
26	F	65	B	Cyst	Resection	L	Vocal fold
27	F	58	B	Cyst	Resection	L	Vestibule
28	M	66	B	Laryngocele	Resection	L	Vestibule
29	F	36	B	Cyst	Resection	L	Vocal fold
30	F	46	B	Cyst	Resection	L	Vocal fold
31	F	69	M	SCC pT1a	Type III cordectomy	L	Vocal fold
32	M	71	M	Mixed tumour T1	Epiglottectomy	L	Epiglottis
33	M	69	M	SCC pT1a	Type iii cordectomy	L	Vocal fold
34	F	58	B	Laryngocele	Resection	L	Vestibule
35	M	43	M	SCC pT1a N2	Epiglottectomy + snd	L	Epiglottis
36	M	41	M	SCC pT1	Epiglottectomy	L	Epiglottis
37	F	52	B	Cyst	Resection	L	Vocal fold
38	M	74	B	Cyst	Resection	O	Tonsil
38 BIS	M	74	B	Cyst	Resection	L	Vestibule
39	M	71	B	Dysplasia	Type III cordectomy	L	Vocal fold
40	M	70	B	Dysplasia	Type III cordectomy	L	Vocal fold
41	M	56	B	Reinke edema	Resection	L	Vocal fold

Table II. Surgical subsites.

Surgical subsite	N	Tot
Pharynx		6
Tonsil	3	
Base of tongue	3	
Larynx		37
Epiglottis	6	
Vestibule	7	
Vocal fold	22	
Infraglottic cavity	2	
	Tot	43

Table III. Benign lesions. Anatomical subsites and histologies.

Surgical subsite	N	Tot	Histology
Pharynx		5	
Tonsil	3		Cyst (2), Taratoma (1)
Base of tongue	2		Cyst (2)
Larynx		20	
Epiglottis	3		Cyst (2), Sovraglottic obstriction (1)
Vestibule	7		Laryngocele (4), Mucosal flap (1), Cyst (2)
Vocal fold	8		Synechia (1), Reinke edema (2), Polyp (1), Cyst (4),
Infraglottic cavity	2		Synechia(1), Papilloma(1)
	Tot	25	

Setup time, retractor positioning time, surgical procedure time and resection time were calculated during surgery. Access to the surgical site and exposure were evaluated with a score from 1 to 5 (1 = impossible to expose, 5 = easy to expose). The score was given by the single operator.

The following aspects were investigated:

Postoperative pain at 24 h and 48 h was rated on a scale of 0 to 10 (0 = no pain, 10 = severe pain) and the presence of intraoperative complications, postoperative complications (0-7 days following surgery) and surgical outcomes (> 7 days) were also evaluated.

All patients underwent endoscopic examinations on the first, seventh and fourteenth day following surgery.

Patients who had malignant lesions (13; 30%) or dysplasia (5; 11.6%) followed the standard follow-up protocol as per institutional guidelines.

Results

The average setup time was 15.07 minutes (range 7-40), demonstrating a quick learning curve, as the first case setup time was 40 minutes and the most recent cases ranged between 7-15 minutes. The average retractor positioning time was 10.82 minutes (range 4-26). Exposure was possible in 100% of cases and the procedure was successfully completed in all patients without the need for conversion to another type of transoral surgery (TOLS: Trans Oral Laryngeal Surgery, TOUSS: Trans Oral UltraSonic Surgery). The mean time for the surgical procedure was 32.78 minutes (range 15-75). The mean resection time was 24.74 minutes (range 4-55). The mean exposure score was 3.42 (range 2-5). There were no cases where the exposure score was 1 or where a site could not be exposed.

There were 25 (58.14%) benign lesions, of which 5 (20%) were pharyngeal and 20 (80%) were laryngeal. The anatomical subsites of the two surgical targets and histologies are shown in Table III.

There were 5 dysplastic lesions (11.6%), of which 3 were SIN I (60%), 1 was SIN II (20%) and 1 was SIN III (20%). The margins were negative in two cases. In one case, the deep margin was close and, after two months of follow-up and NBI examinations, due to the presence of pseudo-granulomatous tissue in the surgical site, we preferred to opt for TOLS revision surgery, with negative resection margins. (Tab. IV).

There were 13 malignant lesions (30%), of which 1 (7.7%) was pharyngeal and 12 (92.3%) were laryngeal. Specifically, the pharyngeal lesion involved the base of the tongue, while the laryngeal lesions were localised in 3 (25%) cases in the supraglottic region and in 9 (75%) cases in the glottic plane. In 12 cases, the histology was squamous cell carcinoma (92.3%); in a single case, the histological diagnosis was a mixed tumour (7.7%). Resection margins were negative in 11 (84.6%) cases. Margins were close in 2 cases (15.4%). In one case, the patient underwent TOLS revision surgery one month after the first operation due to persistence of pathology, although the margins were negative at the histological examination. In one case, a contralateral neck dissection to the lesion was carried out for N+ on one

Table IV. Dysplastic lesions.

Surgical subsite	N	Tot	Histology
Larynx		5	
Vocal fold	5		SIN I (3), SIN II (1), SIN III (1)
	Tot	5	

Table V. Malignant lesions. Staging, grading, location of lesions.

Surgical subsite	N	Tot	Histology
Pharynx		1	
Base of tongue	1		SCC pT1 G1 HPV-
Larynx		12	
Vocal fold	9		SCC pT1a G1 (8), SCC pT1b G1 (1)
Epiglottis	3		SCC pT1 G1 (1), SCC pT1 G2 (1), Mixed tumour pT1 G2 (1)
	Tot	13	

patient that had already been treated with neck dissection at another centre. No patients underwent postoperative adjuvant therapy. All patients (100%) are currently free of disease. The duration of follow-up ranges from 1 month to 11 months. Staging, grading, location of lesions and type of transoral surgery are shown in Table V.

All procedures were successfully completed. There were no intraoperative complications. In one case, postoperative arytenoid oedema appeared (one day following the surgery), which was resolved after 12 hours of corticosteroid therapy.

At one-month follow-up, we found a granuloma in two patients: in the 1st case the granuloma appeared in the paracommissural area and in the 2nd case in the posterior area; both were treated with medical therapy. In one case, we found the appearance of para-commissural leukoplakia near the resection margin, NBI negative, and not in progression. The postoperative pain score at 24 h and 48 h was 2.88 and 0.77 of 10, respectively. All patients who underwent transoral surgery only were discharged on the first day following the surgery with an indication for complete vocal rest and hyaluronic acid therapy. No patients were prescribed antibiotic or anti-inflammatory treatment.

Discussion

The most commonly used system for TORS in the United States today is the da Vinci Si® HD (Intuitive Surgical®, Sunnyvale, CA, USA), which has been used since 2005 and was approved by the Food and Drug Administration (FDA) in 2009 [17]. Over the years, this system has allowed progress in transoral and conservative surgery of the aerodigestive tract; however, multiple rigid arms limit access to some hypopharyngeal-laryngeal regions that cannot be exposed through line of sight [18].

The Flex® Robotic System (Medrobotics, Raynham, MA, USA) is a hybrid approach specifically designed for head and neck surgery. Animal and cadaveric studies have vali-

dated the feasibility of using the Flex Robotic System in various head and neck procedures [8,9]. Lerner et al. [19] demonstrated the possibility of transoral surgical access to the oropharynx and hypopharynx without risks or complications. Additionally, others have demonstrated the feasibility of performing supraglottic laryngectomy, total laryngectomy, removal of a Zenker's diverticulum, thyroid lobectomy, dissection of the neck, removal of the submandibular gland, cranial base surgery and nasopharyngeal surgery [20,21].

In the literature, there are fewer publications on the Flex® Robotic System compared to the da Vinci® system. This is due to the recent introduction of the Flex® Robotic system in transoral surgery.

The Flex® Robotic System obtained the European CE Mark (Conformité Européenne) in March 2014 and FDA clearance in July 2015 to allow the use in the oropharynx, hypopharynx and larynx in adults (aged ≥ 22 years). More recently, the CE Mark approval (2016) and FDA clearance (2017) also provides for transanal surgical procedures in the anus, rectum and distal colon.

The most significant experience in Europe is that of the University of Essen. In a prospective study (N = 40), Mattheis et al. demonstrated important surgical results using the Flex system. They showed that 95% of T1 and T2 carcinomas of the oropharynx, hypopharynx and supraglottis in their cohort were accessible, allowing for an oncologically correct resection with no major complications [15]. Lang et al. also demonstrated excellent exposure of the oropharynx and the supraglottic larynx, noting that in 75 of 80 patients with lesions in these locations, exposure and resection was possible. Additionally, they showed that there is a reasonable setup time between 9 and 12.4 minutes, demonstrating a shorter setup time with the Flex® Robotic system than that of the da Vinci system [12]. These studies have demonstrated the feasibility of using this technology in TORS; however, further studies are needed to support these results in the long term.

The American experience has also shown similar and comparable results. In a multicentre study, Persky et al. successfully used the Flex® system in 66 of 70 cases, demonstrating that it can be used to perform complex pharyngeal and laryngeal surgical procedures. In this study, the Flex® Robotic System was used both for transoral surgical procedures (tonsils) and for procedures with indications similar to those of TOLS surgery. It was concluded that flexible robotic surgery provides better visualisation of the surgical site and greater precision than classic transoral surgery and allows, with respect to TOLS, three-handed surgery (second operator) and the ability to modify both the visual and the cutting angle with a simple wrist movement. In this study, however, the failures on the glottic plane are

highlighted: 2 of 4 procedures were not completed (50%). Although the number of patients that underwent surgery in these centres on this subsite is too low, the Authors conclude that anatomical variants (such as macroglossia or laryngeal anteriorisation), trismus and radiations could make exposure a challenge [14].

Therefore, in the literature, the surgical targets where this surgery was evaluated were the pharynx and the supraglottic region. There are few experiences on the glottic region. For around 6 months, our multi-specialty department has had the new hyper curved blades that allow excellent exposure of the glottis using the Flex® Retractor System. Most of the interventions we carried out were due to vocal cord lesions. We did not find any complications for either benign lesions or malignant lesions, and functional and oncological outcomes were good. In fact, only one patient needed revision surgery for recurrence. Although follow-up is less than one year, all patients are currently free of disease. We think that, while the superiority of robotic surgery vs. TOLS regarding the supraglottic region is now a fact, in terms of handling, exposure, visualisation and surgical duration in the glottic region, TOLS has been the standard in terms of surgical precision. The Flex® technology is constantly evolving, and dedicated engineers bring monthly innovations to our attention. We believe that within a few years the Flex® system will achieve the same performance as TOLS on the glottic plane. We will add a fact to this consideration: in our experience, more than 90% of patients were treated with a monopolar cutting instrument. On the first day following surgery, fibrin at the surgical site was almost nonexistent. This meant no endoscopic medications were required, even when surgery was performed on anterior commissural neoformations. CO_2 laser cutting tools are also compatible with the Flex® system, but we have no experience with these.

Nasotracheal intubation is very useful because it leaves the oral cavity free and the tube runs down against the rear wall of the pharynx; accordingly, it is less of an obstruction to movement of the flexible arm.

The 3D view is good, although the monitor needs to be in the same line of sight as that of the operator. In our opinion, the da Vinci® system has a good 3D camera that allows better view of anatomical structures. It is questionable whether this type of magnification is indispensable for this surgery. Surgery is a single-operator procedure; a second operator sits beside the surgeon and uses a dedicated suction device that allows the suction of secretions and smoke and helps surgical micro-instruments with tissue traction.

Setup times are very fast and in line with other international experiences. The choice of the retractor blade is fundamental; this is guided by the shape of the patient's neck and

aerodigestive tract, the surgical site and the experience of the operator. It would be useful if the different centres that use this technology will follow a standardised algorithm in the future.

It would also be interesting to find relevant parameters and create a score to identify patients that are difficult to expose. In our experience, all the patients were exposed and patients with an exposure score of 2 would have been difficult to expose even with TOLS surgery.

The haptic feedback of the instruments is very accurate and it is possible to recognise the consistency and tension of different tissues.

In their work, Friedrich et al. [22] concluded that the flexible instruments of the Flex® Robotic System allow better haptic feedback than the da Vinci® system due to the direct transmission of the force of the Flex® Instruments compared to the electromechanical transformation of the da Vinci® system. In addition, flexible microinstruments have a moderate force and grip that allow space to be made between tissues to reach the surgical targets, inspect anatomical structures such as the pyriform sinuses and move the tracheal tube. The use and manageability of these instruments is very instinctive, and the learning curve to use them is quick.

Another advantage, in our opinion, is the rapid repositioning of the Flex® Scope and microsurgical instruments. In our experience, two patients were each treated for two different lesions at different anatomical sites. In both cases, it was not necessary to reposition the retractor and the transition from one site to the other was immediate, using the Flex® Physician Controller. In addition, the times to reverse (swap) the position of the microlaryngeal instruments are very fast.

Conclusions

The Flex® Robotic System is a safe instrument that consistently provides good surgical exposure to treat benign and malignant lesions of the upper aerodigestive tract. Further technological innovations will be needed for better surgical precision, especially in the field of phonosurgery, and to better treat more extensive lesions. Choosing the correct retractor blade for each individual patient remains fundamental to the outcome of the surgery. The increasing number of ORL centres that utilise the Flex® Robotic System will allow more experiences to be shared and will be useful for development purposes.

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