Journal of Robotic Surgery (2022) 16:527–536
https://doi.org/10.1007/s11701-021-01270-z

ORIGINAL ARTICLE

Trans-oral robotic surgery for head and neck cancers using the Medrobotics Flex® system: the Adelaide cohort

Oladejo Olaleye[1] · Bola Jeong[1] · Michael Switajewski[2] · Eng H. Ooi[3] · Suren Krishnan[2] · Andrew Foreman[2] · John-Charles Hodge[2]

Received: 18 April 2021 / Accepted: 14 June 2021 / Published online: 7 July 2021

Abstract

Trans-oral robotic surgery for head and neck cancers can be performed using rigid, multi-port robots with linear access but the Medrobotics Flex® system offers an alternative as it is endo-luminal, single-port, and uses flexible instruments. To assess the utility of the Medrobotics Flex® system for head and neck cancer (HNC) resections. A retrospective review of all HNC resections done over a 2.5-year period (Jan 2017–July 2019) at the Memorial Hospital, using the Flex® system. Data collected include patient demographics, tumour site, tumour stage, p16 status, smoking history, surgery performed, histologic margins, complications, overall survival, recurrence, and adjuvant treatments received. There were 49 head and neck cancer cases in total done using the Medrobotics Flex® system. Median age 60 years, with M:F ratio 3.5:1. *Outcomes:* oropharyngeal cancers (82%), p16 positive (89%), overall survival (94%), local recurrence (6%), and adjuvant treatment (84%). Cancer procedures done included lateral oropharyngectomy (43%), tongue base mucosectomy (27%), tongue base resection (18%), and others (12%) which include a single case each of supraglottic laryngectomy, hypopharyngeal tumour resection, partial pharyngectomy, partial glossectomy, and vocal cord tumour resection. Clear margins were related to tumour T stage and achieved for T1 tonsil cancer (75%), T2 tonsil cancer (70%), T3 tonsil cancer (50%), T1 tongue base cancer (80%), and T2 tongue base cancer (66.7%). Median operating time with neck dissection was 2 h 40 min, whilst median length of hospital stay was 1 day (IQR 1–7 days). Complications included a single case each of secondary haemorrhage (managed conservatively), oro-cervical fistula, wound infection, tongue numbness, and a medical event. There was no primary haemorrhage and no mortality. The Medrobotics Flex® system is a safe and reliable tool for head and neck cancer surgery.

Keywords Trans-oral · Robotic · Surgery · FLEX · Medrobotics · Cancer, head and neck

Introduction

Trans-oral robotic surgery (TORS) has been shown to be an effective approach in treating cancers of the head and neck area including oropharynx, posterior oral cavity, hypopharynx, and larynx. TORS was first approved by the FDA in America for small-volume oropharyngeal cancer resections following the landmark work done by Weinstein et al. [1] using the first commercially available robot (Da Vinci, Intuitive Surgical, Inc,. Sunnyvale, CA). The Da Vinci robot is a multi-port, linear system using 3-D endoscopes and endo-wristed robotic arms. It allows high-definition visualisation of the operating field with good oncologic outcomes published worldwide for appropriately selected oropharyngeal cancers, comparable with chemo-radiation. There has been an evolution in TORS in recent years with newer robots now commercially available including both rigid and flexible systems.

The Flex® robotic system (Medrobotics Corp., Raynham, MA) is the first flexible system specifically designed for use in head and neck surgery and has received FDA clearance for trans-oral surgery. It is a novel single-port platform that is available as an alternative to rigid multi-port robotic technology. It is endo-luminal and, given its flexible construct, is

✉ Oladejo Olaleye
dejolaleye@yahoo.com

[1] Department of Otolaryngology, Head and Neck Surgery, Royal Adelaide Hospital, Adelaide, SA 5000, Australia

[2] Department of Otolaryngology, Head and Neck Surgery, Memorial Hospital, Adelaide, SA 5000, Australia

[3] Otolaryngology, Head and Neck Surgery, Flinders Medical Centre, College of Medicine and Public Health, Flinders University, Bedford Park, Adelaide, SA 5042, Australia

readily deployed round the contours of the upper aerodigestive tract. It has been utilised effectively by TORS surgeons in the USA and Europe for cancer surgery.

The head and neck surgeons in Adelaide have extensive experience in TORS as the department was the first to adopt its use in Australia, with our first TORS performed in August 2008. TORS is now employed in the treatment of oropharyngeal cancers across Australia. The unit was the first in Australia to publish its results on the use of the Flex® robotic system on 20 head and neck cases which included 11 procedures for cancers [2]. We demonstrated this to be a safe, reliable tool for TORS. The aim of this paper is to evaluate the utility of the Flex® robotic system for cancer resections with presentation of the Adelaide surgical experience and oncologic outcomes.

Methods

All trans-oral surgery procedures were performed using the Flex® robotic system (Medrobotics Corp., Raynham, MA). Standard operating procedures were employed as described in our previous paper [2]. Pre-operative assessments were carried out to establish suitability for TORS including tumour stage, pre-operative scans, mouth opening, mallampatti classification, retrognathia, neck extension, and medical co-morbidities. Every patient also had a pre-TORS panendoscopy under general anaesthetic to fully assess clinical tumour characteristics, extent, mouth access, and nodal disease. Intra-operatively, either the FLEX retractor or Boyle–Davis gag was used for stabilisation and hemostasis achieved using vessel ligaclips or electrocautery. A hemostatic agent (Purastat® 3-D Matrix Medical Technology; or SURGIFLO® Hemostatic matrix Ethicon) was applied topically to the surgical bed at the end.

Data were prospectively collected on all consecutive cases including demographic data, co-morbidities, anatomic site of tumour, TNM tumour stage, p16 status, type of TORS procedure, peri-operative complications, length of hospital stay, any requirement for post-operative adjuvant treatment, cancer recurrence, and disease-free survival. Data were entered into an Excel spreadsheet and variables analysed. The analysis was separated into benign and cancer groups. Consent was obtained from all patients prior to their TORS and ethical approval from the CALHN research ethics committee to analyse data (Ref 13,407).

Medrobotics Flex® set-up experience

Intra-operative set-up was straightforward with assistance from the company representatives who were present for all cases. The Flex® robot was easy to move and transfer easily between theatres as required. It therefore does not need to be stationed permanently in a single theatre or take up space. The Flex® is positioned next to the operating theatre couch, with the flexible trans-oral component perpendicular to the oral cavity and supported using the Flex® retractor and rigid instrument supports. The Boyle-Davis gag was used as an alternative retraction system, stabilised on Draffin rods, in a similar fashion to a tonsillectomy set-up. The Flex® retractor is advantageous in achieving optimal positioning and tumour access as it has unique mobility in both the longitudinal and axial rotational planes (Fig. 1). It also has a range of different tongue retractor sizes with some shaped to allow controlled tongue base prolapse and visibility. Docking is complete once the robot is satisfactorily positioned in the oropharynx with high-definition 3-D views and magnification optimal for surgery achieved using the Flex® console. Instruments are passed through the ports on both sides of the rigid supports and allow for triangulation, wristed articulation, continuous rotation, static locking in fixed positions, and some tactile feedback (Fig. 2). The main operating surgeon sits at the patient's head end and operates using the wristed Flex® instruments in a laparoscopic fashion (Fig. 2). The surgeon's assistant helps with retraction and suctioning of the operative field as required. In an emergency the Flex® robot is easily withdrawn from the operative field. The instruments are retrieved from the ports, and the control lever on the robot is pulled unlocking the flexible cart from suspension and removed quickly.

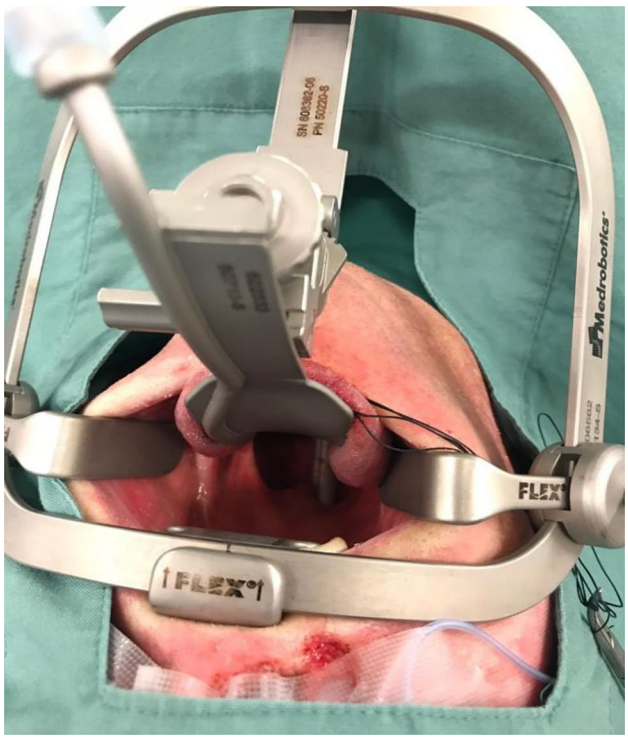

Fig. 1 FLEX retractor system with multi-adjustment feature

Fig. 2 TORS surgeon located at patient head end with HD magnification of oropharynx

Average set-up time of the FLEX system just before surgery was 30 min during which the system was adequately positioned next to the operating table after anaesthetic procedures and intubation was complete. In this time, the FLEX console is draped with sterile drapes, the FLEX retractor is inserted, and the FLEX cart is gently lowered into the oral cavity and secured on stabilisation. The average time for FLEX resections is 2 h 40 min which includes the time taken for neck dissections. Trans-oral resections alone of the oropharynx plus hemostasis take 45 min. The neck dissections done in the traditional open fashion without robotics, usually take an average of 1.5–2.5 h depending on the extent of nodal disease.

In terms of peri-operative complications, there was no primary haemorrhage in our Adelaide cohort. Within 30 days of TORS, there was a single case each of secondary haemorrhage (managed conservatively), wound infection, oro-cervical fistula, and numbness at the tip of tongue from retraction (Table 2). There was one cardio-respiratory reversible event, and in one case of a vocal cord resection, the TORS was converted to a laser resection. There are strategies employed in our unit to reduce the risk of bleeding or fistula formation [3] in oropharyngectomies for malignancy. Selective arterial ligation of the facial, lingual, and ascending pharyngeal arteries occurs in all cases undergoing a neck dissection. At the end of every TORS, we apply hemostatic agents like purastat or surgiflow topically to the oropharyngectomy bed. A digastric flap is also routinely used after the neck dissection to seal the commonest site of fistulisation in level Ib.

Post-resection, meticulous review of the resected specimen by all the TORS surgeons is undertaken to check completeness of cancer resection macroscopically and determine if any further margins should be taken (Fig. 3). The resected specimen is properly orientated with stitches placed on labelled margins as appropriate on a background of the anatomic picture (Fig. 4). This is then reviewed with the head and neck pathologist in a quality-assured process and subsequently discussed at the head and neck multidisciplinary cancer board meeting.

Results

There were 49 head and neck cancer cases performed using the Medrobotics Flex® system between January 2017 and August 2019. Age range was 38–85 years. Median age was 60.5 years (IQR 51–66 years). There were 38 males and 11 females with M:F ratio 3.5:1.

The range of oncologic procedures is listed in Table 1. This included lateral oropharyngectomy (43%), tongue base mucosectomy (27%), tongue base resection (18%), and others (12%) which include a single case each of supraglottic laryngectomy, hypopharyngeal tumour resection, partial pharyngectomy, partial glossectomy, and vocal cord tumour resection (Table 1).

Fig. 3 Meticulous assessment of the resected cancer specimen for macroscopic clearance

Table 1 Surgical procedures performed using the FLEX robot

	TORS procedure	Number of cases
Cancer surgery	Lateral oropharyngectomy	21
	Tongue base mucosectomy	13
	Tongue base resection	9
	Supraglottic laryngectomy	1
	Hypopharyngeal cancer resection	1
	Partial pharyngectomy	1
	Vocal cord tumour resection	1
	Partial glossectomy	1
	Retropharyngeal lymph-node excision	1
Benign Surgery	Lingual tonsillectomy	10
	Tonsillectomy	6
	Uvulopalatoplasty	4
	Vallecular cyst excision	3
	Epiglottic cyst excision	1
	Vocal process lesion excision	1
	Adenoidectomy	1

Median operating time was 2 h 40 min (IQR 75 min–4 h 18 min). Simultaneous neck dissections were performed in 30 cancer cases which are included in the operating time. Trans-oral resections alone of the oropharynx plus hemostasis take 45 min. The neck dissections done in the traditional open fashion without robotics usually take an average of 1.5–2.5 h depending on the extent of nodal disease.

Median length of hospital stay was 1 day (IQR 1–7 days) and range was 1–18 days. TNM classification and margin clearance is shown in Tables 2, 3.

Outcomes

The majority of head and neck cancers that had oncologic resection using the Medrobotics Flex® system were oropharyngeal cancers (82%) with p16 positivity shown in 89% of cases. Overall survival in this cohort of patients was 94% calculated from date of cancer diagnosis to either death or if they were still alive at the fixed date for analysis (25/11/2019).

6% of patients had local cancer recurrence and 84% of all patients required adjuvant treatment (Table 4).

Neck dissections

As part of the cancer management protocols, standard neck dissections were performed in 30/47 cases (64%) that had simultaneous resection of their primary tumours using the FLEX system. The neck dissections were performed open with utility neck incisions and clearance of levels 1–4 neck nodes. These were performed for both N0 and N + neck status. A level 5 neck dissection was added if there was evidence of nodal disease extending beyond the posterior border of the sternocleidomastoid muscle or muscle invasion. Modified radical neck dissections with resection of

Table 2 Tumour T stage and margin clearance using the FLEX system

TORS with FLEX	Tumour TNM8 T-staging	Frequency	Margin status Clear—*N* (%)
Lateral Oropharyngectomy (N-21)	T1	8	6 (75%)
	T2	10	7 (70%)
	T3	2	1 (50%)
	T4	1	0 (0%)
Tongue base resection (N-9)	T1	5	4 (80%)
	T2	3	2 (66.7%)
	T3	0	–
	T4	1	0 (0%)
Tongue base mucosectomy (N-12)	T0	12	5/12 (42%) cancer primary found 3/5 (60%) clear margin
Supraglottic laryngectomy (debulking)	T4	1	0 (0%)
Hypopharyngeal cancer resection	T2	1	1 (100%)
Partial pharyngectomy	T2	1	0 (0%)
Vocal cord tumour resection	T1	1	1 (100%)
Partial glossectomy	T2	1	1 (100%)

the sternocleidomastoid muscle, spinal accessory nerve, or internal jugular vein were undertaken if there was tumour involvement of any of these structures. The FLEX system was not used for any neck dissections. Our group does not use the daVinci robot for neck dissections either.

Routine intra-operative ligation of relevant blood vessels in the neck was performed to reduce the risk of post-operative bleeding. Ligaclips were applied to lingual, facial, and ascending pharyngeal arteries during the neck dissection phase which was done immediately after the trans-oral cancer resections under the same general anaesthetic. In appropriate small-volume cases, a modified submandibular gland resection with preservation of the deep lobe was done to reduce communication with the oropharynx. We also routinely performed a digastric muscle flap to reduce the risk of oro-cervical fistula formation. The anterior belly of digastric muscle is released from its attachment at the undersurface of the anterior mandible, and reversed on its sling to cover the level 1b neck area. The edges of the muscle are stitched with vicryl 3.0 stitches to surrounding tissue including the posterior belly of digastric. Tissel glue is then applied topically to provide a durable seal.

Tumour staging and margin clearance

The majority of cancer cases in this cohort were oropharyngeal cancers. Of the 47 cancer resections performed with the FLEX system, there were 21 lateral oropharyngectomy, 11 tongue base mucosectomy, 10 tongue base resections, and 5 other non-oropharyngeal cases.

Every cancer case was reviewed by the multidisciplinary cancer team prior to treatment. To increase the chances of oncologic clearance, endoscopic appearance, cross-sectional imaging with MRI scans were assessed to check the volume of disease, extension to tongue base midline, invasion of surrounding structures like the medial pterygoid muscle, prevertebral fascia, and mandible. The majority of tumours selected for TORS were therefore small-volume cancers T1 and T2 which were HPV positive with a view to avoiding triple modality treatment if no adverse histologic factors such as extracapsular spread were identified on histology.

Tumour size as recorded using T stage showed that margin clearance was more likely with small-volume tumours T1 and T2 when compared to T3 and T4 tumours (although limited numbers) (Tables 2, 3). Clear margins were achieved in lateral oropharyngectomy for tonsil cancers in 75% (T1), 70% (T2), 50% (T3), and 0% (single T4). Similarly, for tongue base resections, margin clearance was achieved in 80% (T1), 66.7% (T2), and 0% (single T4).

The FLEX system was also used to perform non-oropharyngeal resections and achieved clear margins in the single T1/2 cases done in subsites including hypopharyngeal cancer resection, vocal cord tumour resection, and partial glossectomy. (Tables 2, 3). There was a single supraglottic laryngectomy performed on a bulky T4 tumour with the aim of debulking. Resection was difficult due to access and tumour bulk but beneficial as it defined the narrow base and allowed a smaller field of radiation. Proceeding with immediate treatment with chemoradiotherapy would have run the risk of precipitating airway obstruction.

Table 3 TNM classification of tonsil cancers, p16 status, and margin outcome following TORS lateral oropharyngectomy using the FLEX system

Tonsil cancers—lateral oropharyngectomy	TNM 8 stage	p16 status	Margin status	Age	Gender
1	T1N0M0	Negative	Clear	55	F
2	T1N0M0	Positive	Clear	63	F
3	T1N0M0	Negative	Clear	65	M
4	T1N0M0	Negative	Clear	76	F
5	T1N1M0	Positive	Clear	51	M
6	T1N1M0	Positive	Clear	62	M
7	T1N1M0	Positive	Involved	58	M
8	T1N1M0	Positive	Involved	72	M
9	T2N0M0	Positive	Clear	58	F
10	T2N0M0	Positive	Clear	74	M
11	T2N1M0	Positive	Involved	38	M
12	T2N1M0	Positive	Clear	43	M
13	T2N1M0	Positive	Involved	78	M
14	T2N1M0	Positive	Clear	64	M
15	T2N1M0	Positive	Clear	61	M
16	T2N1M0	Positive	Clear	67	M
17	T2N1M0	Positive	Involved	72	M
18	T2N2M0	Positive	Clear	85	F
19	T3N1M0	Positive	Clear	67	M
20	T3N1M1	Positive	Involved	59	M
21	T4N2M1	Positive	Involved	58	M
Tongue base resections					
1	T1N0M0	Negative	Clear	55	F
2	T1N0M0	Negative	Clear	65	M
3	T1N0M0	Negative	Clear	76	F
4	T1N1M0	Positive	Clear	63	F
5	T1N1M0	Positive	Involved	50	M
6	T2N1M0	Positive	Clear	64	M
7	T2N1M0	Positive	Clear	57	M
8	T2N1M0	Positive	Involved	78	M
9	T4N2M1	Positive	Involved	58	M

Table 4 Post-operative complications within 30 days of TORS with FLEX and outcomes (*N*-49)

Complication	Frequency
Primary haemorrhage	0
Secondary haemorrhage	1
Oro-cervical fistula	1
Wound infection	1
Numbness at tip of tongue	1
Medical event	1
Transferred to laser resection (vocal cord)	1
Outcomes	%
Oropharyngeal cancers	82%
p 16 positive Oropharyngeal cancers	89%
Overall survival at 2 years	94%
Local cancer recurrence	6%
Adjuvant treatment	84%

Management of unknown primary cancers and tongue base mucosectomy

Tongue base mucosectomies were performed using the FLEX system in the management of 12 unknown primary cancers in cases where there were no clinically obvious lesions and no radiologic abnormality identified on MRI or PETCT scans. In the 12 cases of unknown primary cancers, there was identification of the cancer primary in 5/12 cases (42%) using FLEX robotic tongue base mucosectomies. 3 out of the 5 positive mucosectomies had clear margins. Both cases with involved mucosectomy margins had adjuvant radiotherapy, but one patient had a completion oropharyngectomy prior to radiotherapy.

Complications

There was no primary haemorrhage and no mortality following use of the FLEX system for head and neck cancers. Complications included a single case of secondary haemorrhage which occurred over 48 h after surgery and was managed conservatively. This is a 1/49 (2%) postoperative secondary bleed rate. There was also a case of oro-cervical fistula managed over 2 weeks with antibiotics, nil by mouth (nasogastric feeding), and wound dressings. There was a case of wound infection following a neck dissection managed with antibiotics and dressings within the first week of surgery. Tongue numbness was reported by a patient and it resolved within 5 days of surgery. There was a medical event which was a reversible cardio-respiratory event in the first few hours following TORS due to pre-existing co-morbidities. (Table 4).

84% of patients in this cohort had adjuvant treatment following surgery with radiation ± chemotherapy as per standard of care. If there were clear margins obtained for small-volume cancers and no adverse histologic features like extracapsular spread in the neck dissection specimens, then conservative surveillance was adopted. However, if there were any concerning histologic features, the patients proceeded to radiotherapy ± chemotherapy. Two patients declined any adjuvant treatment.

Second primary malignancies were recorded in 4/49 patients (8%) during the 2.5 years of follow-up. These included large cell carcinoma of the lung, squamous cell carcinoma of the lung, parotid squamous cell carcinoma, and renal cell carcinoma.

Discussion

Trans-oral robotic surgery (TORS) now has a defined and evolving role in head and neck cancer surgery. The improvements in robotic technology and the advancements in our understanding of tumour biology, diagnostic imaging, and algorithms for patient selection have translated to better outcomes for our patients with head and neck cancers. TORS is superior to standard procedures requiring mandibulotomy (jaw split) for access to the oropharynx as it utilises the natural oral cavity orifice. TORS reduces the inherent morbidity associated with open surgery for cancers, reduces length of hospital stay, and improves the quality of life outcomes. High-risk human papillomaviruses (HPV) are causal for a subset of oropharyngeal squamous cell carcinomas (OPSCC) as shown by strong laboratory and epidemiologic literature [4, 5]. HPV confers a prognostic value in OPSCC, with improved survival documented in HPV-OPSCC compared to HPV negative OPSCC [6]. Surgically, TORS has been demonstrated in recent literature since its FDA approval for T1-2 oropharyngeal cancers, and comparable oncologic outcomes to chemo-radiation [1]. TORS has the potential to reduce the recognised toxicity of chemo-radiation for head and neck cancer patients especially in patients with small-volume disease and non-aggressive tumour biology. There are on-going surgical clinical trials examining the potential for de-intensification treatments in human papillomavirus-associated oropharyngeal cancers. The PATHOS UK multicentre trial will assess unimodality TORS, as well as cases requiring adjuvant treatment in varying de-intensification protocols. TORS wherever available should now form part of the repertoire for the management of oropharyngeal cancers by multidisciplinary teams.

The newer robotic platforms that address the limitations to surgery have added a spectrum of capability that enhance access, anatomic visualisation, instrument manoeuvrability, and tissue handling. The rigid, multiport robotic systems like the pioneering Da Vinci platform (Intuitive Surgical, Inc., Sunnyvale, CA), with an established record for head and neck cancers, have now been joined by the Vesius® robot (Cambridge Medical Robots) with a multi-port, linear, rigid system with limited experience in head and neck. These all grapple with the line of sight and access issues especially along the trajectory towards the hypopharynx and larynx.

The Flex® system (Medrobotics Corp., Raynham, MA) is the first FDA approved and commercially available flexible robot specifically for head and neck cancer surgery. The unique features of the Flex® robot include the flexible system that allows access along the contours of the upper aerodigestive tract. It provides access to the oropharynx and difficult-to-reach anatomic subsites like the hypopharynx and larynx. Whereas trismus or reduced cervical movements have been relative contra-indications to robotic surgery, the single-port flexible construct means that these cases are now viable. It provides an endo-luminal, high-definition 3-D view of the operating field. It provides some gross and minute tactile feedback to the surgeon. It is less expensive than the leading multi-port rigid system. It has also been adopted by other surgical specialities such as gynaecology and general surgery.

In our cohort in Adelaide, we used the Flex® robot to perform both benign and cancer surgery in the head and neck area. Cancer surgery was mainly for oropharyngeal squamous cell carcinomas and included lateral oropharyngectomy, tongue base cancer resections, and tongue base mucosectomy for cancers of unknown primary, as shown in Table 1. We also explored operating on different anatomic subsites aside the oropharynx and performed one case each of supraglottic laryngectomy, partial pharyngectomy,

hypopharyngeal cancer resection, partial glossectomy, and resection of a vocal cord tumour.

The Essen surgical group who are a regional training centre for Europe have demonstrated the utility of the FLEX system in hypopharyngeal and laryngeal tumour resections [7] and recently presented their outcomes at the World Conference of Robotic Surgery (2020) on 157 patients, including supraglottic (61), glottis (26), hypopharynx (21), oropharynx (49), and oral cavity (1). The FLEX system provided adequate access to these difficult-to-reach areas using direct vision or rigid robots. They used the C02 laser fibre (Lumenis® Acupulse® DUO, Lumenis Ltd, Yokneam, Israel) and reported post-operative bleeding in 3 cancer cases (2%) and a single intra-operative bleed requiring a lateral pharyngotomy for hemostasis. Our Adelaide post-operative bleed rate of 1/49 cases (2%) is comparable.

Cancer outcomes

The majority of cancer cases treated in our cohort (89%) were HPV-positive oropharyngeal squamous cell carcinomas (HPV-OPSCC). These were treated with TORS lateral oropharyngectomy using the Flex® robot, neck dissections and adjuvant treatment as required, based on histopathologic findings of primary tumour and neck disease. Patients with HPV-OPSCC constitute a unique group of patients who are often younger than HPV negative OPSCC, without significant smoking history and who respond better to current treatments. There are on-going clinical trials to assess de-escalating treatment doses in HPV-OPSCC without impacting on the good survival outcomes. There is a subset of these patients who will benefit from surgery alone and avoid toxic side-effects of chemo-radiation altogether. These are small-volume tumours with no aggressive pathologic features like extracapsular spread, perineural, or lymphovascular invasion in nodal disease. This is the subject of clinical trials like the PATHOS UK trial [8] and the Flex® robot offers another surgical option alongside rigid robots and trans-oral laser in these cases.

Immediately following TORS, our surgeons carefully examine the resected specimen for any macroscopic evidence of margin involvement of both the mucosa and stroma (Fig. 3). We find this a very important step in ensuring surgical clearance. Margin status is a significant factor in determining disease-specific survival and cancer recurrence. Extra margins are therefore taken at the time of surgery for any margins considered close by our team of surgeons. For oropharyngectomy, we utilise the pathologic categories of surgical clearance from tumour edge: >2 mm (clear), <2 mm (close), and tumour abutting margin (involved). In our cancer cohort, the resected specimens are appropriately labelled, with silk stitches placed at margins in relation to the relevant anatomy and sent for histopathologic examination in formalin.

In our cancer series, we achieved clear margins in 75% of T1 tonsil and 70% of T2 tonsil cancer resections with lateral oropharyngectomy done with the FLEX system. Similarly, in tongue base resections, we had clear margins in the early stage tumours with 80% clear margins in T1 tongue base cancers and 66.7% in T2 tongue base cancers. We had limited numbers of advanced oropharyngeal cancers T3/4; however, margin control was less with increasing tumour T stage. Patients who had involved resection margins had a re-resection with TORS and then adjuvant radiotherapy. This approach ensured that these patients avoided chemotherapy. 84% of our cohort required post-operative adjuvant treatment with radiotherapy $\pm$ chemotherapy depending on the pathologic features discussed by the cancer multidisciplinary team. Some patients with either unknown primary cancers or early stage disease and no adverse histologic features had only TORS and neck dissections as their single modality of treatment. The small group of patients who had triple modality treatment with TORS and chemo-radiation had large volume tumours with aggressive pathologic features including extracapsular spread in the neck nodes. Overall survival of 94% at 2 years was documented in our cohort. Local cancer recurrence rate was 6%. These oncologic outcomes are comparable with results achieved using rigid robotic systems for TORS as well as the Flex® robot [9]. TORS tongue base mucosectomy has also been shown to be a useful diagnostic surgery for unknown primary cancers as shown in our series and corroborated in the literature [10]. In this study, the FLEX achieved 42% identification of the unknown primary cancer on tongue base mucosectomy and 60% clear margins.

Limitations and challenges

There is a learning curve for surgeons using the Flex® robot for trans-oral cancer surgery. This is not dissimilar to the expected learning on rigid systems. Our surgeons in Adelaide are established trans-oral surgeons who are experienced in using the da Vinci robot which facilitated the transition to oncologic surgery using the Flex® robot. Medrobotics have addressed the training needs by establishing a cadaveric course for registrars and fellows. Our unit is the regional training centre for Pan-Asia. The head and neck fellowship at the RAH also incorporated clinical exposure to the Flex® robot and accreditation on a cadaveric course specific for fellows and Consultants new to the flexible system.

At present, the high-definition optics for head and neck surgery are achieved with magnification on the Flex® robot and the use of 3-D glasses [11]. These optics are constantly being improved with each robot revision, as well

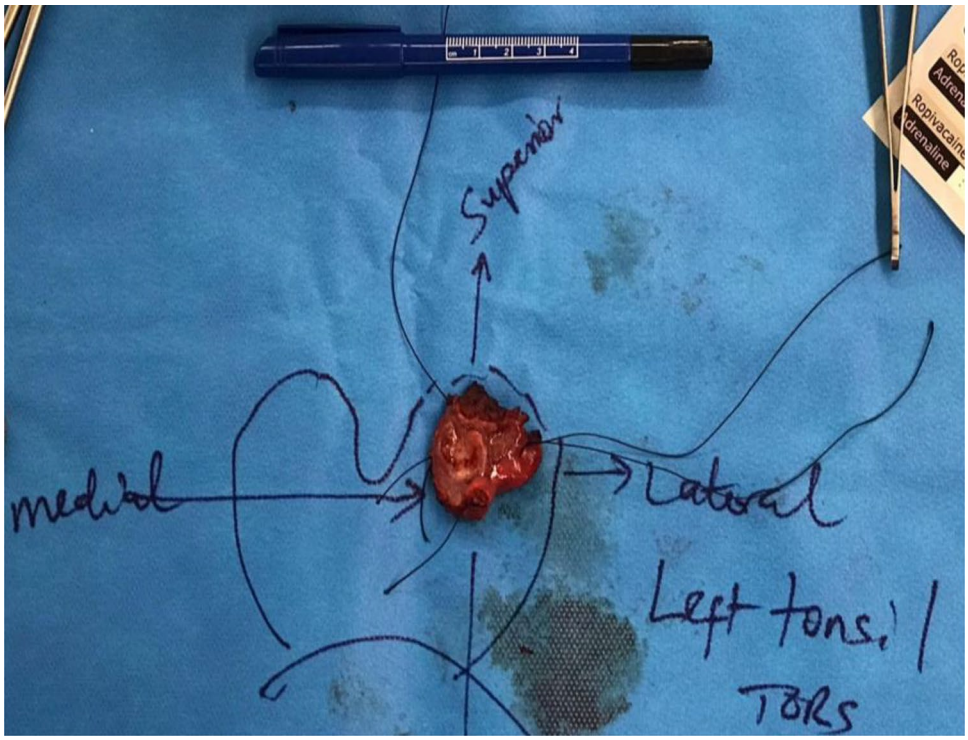

Fig. 4 Post-TORS tumour orientation and assessment of a left oropharyngectomy for clearance or macroscopically close margins

as reducing the occasional interference observed on the monitor when cautery occurs in close proximity to the retractor.

Difficulties with distal access have driven the development of a Flex® laryngeal drive with smaller, larynx-specific endo-wristed instruments. This will facilitate laryngeal and hypopharyngeal surgery. The challenge though is in developing shared airway management strategies with the anaesthetists whilst maintaining the balance for surgical exposure, manoeuvrability, and preventing airway fires.

A laryngeal procedure was converted to a trans-oral laser case due to space and manoeuvrability issues. The supraglottic laryngectomy was equally challenging as this was a debulking procedure in a large volume tumour with limited oral access. The tumour could not be treated with chemo-radiation upfront as there was a significant risk of developing airway obstruction from oedema. The FLEX-assisted debulking ensured expedient and safe treatment with chemo-radiation, without the need for a tracheostomy tube.

The limitation that mouth opening presents is also important. Every TORS cases is assessed under general anaesthetic before the planned procedure to ensure that adequate access to the tumour can be achieved. A lack of good oral cavity access contributed to abandoning a planned TORS case using the Flex® robot in our series. The use of the multi-directional Flex® retractor has been excellent for manipulating tissues to achieve good access in our experience.

Comparison with linear rigid robotic platforms

The FLEX system when compared with the daVinci robot (aside consumables) is cheaper to procure at a cost approximately £650,000 as opposed to £1.5–£2.5million depending on the make of the daVinci robot (Si, Xi or single-port). The required theatre operating sets are similar and consist of tonsillectomy instruments and hemostatic equipment. Set-up time is the same for both systems consisting of patient positioning and robot deployment but with the FLEX operating arms requiring stabilisation. Retraction can be achieved by simply using the Boyle–Davis gag stabilised on Draffin rods as is usually done for tonsillectomy. Alternatively, the custom-designed FLEX retractor can be purchased separately or the FK retractors used in most TORS centres. Draping and theatre consumables are similar. Both the FLEX system and daVinci provide 3-D visualisation; however, the FLEX relies on 3-D goggles and the optics are not as sharp as the daVinci robot console. The FLEX system provides tactile and haptic feedback during procedures given the laparoscopic nature of trans-oral surgery using the system compared to daVinci which provides much less haptic feedback given the separation of the console from the operating field. Manoeuvrability is equally effective in both the FLEX and daVinci systems, and tissue dissection and hemostasis can be achieved with either diathermy or hand-held ligaclips. Both the flexible and rigid trans-oral robotic systems provide good access to the oropharynx with completeness of resections especially

of small-volume tumours. Cancers of the larynx, hypopharynx, and more distal tongue base remain challenging, but the FLEX system is able to reach further than the daVinci in these areas as it can contour itself around the anatomy and can be deployed in patients with relatively limited mouth opening.

The future of head and neck cancer surgery is promising with the additional use of the Flex® robot in our repertoire for trans-oral surgery. There will be greater scope for more complex laryngeal and hypopharyngeal surgery with the new flexible laryngeal drive, optics, and laser utility. Increasingly, there are extended gastroenterology applications being developed for the Flex® robot. This extends its multispecialty appeal to head and neck, gynaecology, and gastroenterology. We have demonstrated that the Flex® robot can be used for head and neck cancer surgery and is a safe, flexible system for trans-oral surgery.

Conclusions

The Medrobotics Flex® robot is uniquely endo-luminal, flexible, and well adapted to the upper aerodigestive tract. It is FDA approved and we have shown in our Adelaide cohort that it can be used to perform head and neck cancer procedures safely with good oncologic and post-operative outcomes.

Acknowledgements We are deeply grateful to Leanne Scott and Sandra Allen for their assistance in collation of the required data from appropriate records as per protocols.

Data availability Data and materials are available if required.

Declarations

Conflict of interest There are no conflicts of interest to declare for authors O.O, B.J, M.S, O.E, and A.F. Educational grants were received by JC.H, S.K from Medrobotics.

Ethical approval Ethical approval for this study was obtained from the CALHN research ethics committee to analyse data (Ref 13407) and we certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional—Royal Adelaide ENT and CALHN Research Ethics Committee) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study analysing their data on use of the FLEX system.

Informed consent Appropriate consent has been obtained from participants for the procedure and data for research as well as publications.

References

1. Weinstein GS, O'Malley BW Jr, Magnuson JS et al (2012) Transoral robotic surgery: a multicenter study to assess feasibility, safety, and surgical margins. Laryngoscope 122:1701–1707
2. Sethi N, Gouzos M, Padhye V, Ooi EH, Foreman A, Krishnan S, Hodge JC (2020) Transoral robotic surgery using the Medrobotic Flex® system: the Adelaide experience. J Robot Surg 14(1):109–113
3. Krishnan G, David R, Gouzos M, Foreman A, KrishnanS HJC (2018) Evolution of neck dissections performed in conjunction with transoral robotic surgery lateral oropharyngectomy. Aust J Otolaryngol 1:6
4. Chaturvedi AK, Anderson WF, Lortet-Tieulent J, Curado MP, Ferlay J, Franceschi S, Rosenberg PS, Bray F, Gillison ML (2013) Worldwide trends in incidence rates for oral cavity and oropharyngeal cancers. J Clin Oncol 31(36):4550–4559
5. D'Souza G, Kreimer AR, Viscidi R et al (2007) Case-control study of human papillomavirus and oropharyngeal cancer. N Engl J Med 356:1944–1956
6. Ang KK, Harris J, Wheeler R, Weber R, Rosenthal DI, Nguyen-Tân PF, Westra WH, Chung CH, Jordan RC, Lu C, Kim H, Axelrod R, Silverman CC, Redmond KP, Gillison ML (2010) Human papillomavirus and survival of patients with oropharyngeal cancer. N Engl J Med 363(1):24–35
7. Lang S, Hussain T, Holtmann L, Hasskamp P, Mattheis S (2020) TORS using the medrobotics system: bleeding experience and management. Oral Presentation, World Conference on Robotic Surgery
8. Owadally W, Hurt C, Timmins H, Parsons E, Townsend S, Patterson J, Hutcheson K, Powell N, Beasley M, Palaniappan N, Robinson M, Jones T, Evans M (2015) PATHOS: a phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV) positive oropharyngeal cancer. BMC Cancer 15:602
9. Mattheis S, Hasskamp P, Holtmann L, Schäfer C, Geisthoff U, Dominas N, Lang S (2017) Flex Robotic System in transoral robotic surgery: the first 40 patients. Head Neck 39(3):471–475
10. Ofo E, Spiers H, Kim D, Duvvuri U (2018) Transoral robotic surgery and the unknown primary. ORL J Otorhinolaryngol Relat Spec 80(3–4):148–155. https://doi.org/10.1159/000490596
11. Wagner OJ, Hagen M, Kurmann A, Horgan S, Candinas D, Vorburger SA (2012) Three—dimentional vision enhances task performance independently of the surgical method. Surg Endosc 26(10):2961–2968