清水　顕、伊藤博之、鈴木衛	FKWOリトラクターを使用した経口的ロボット支援手術（TORS）シミュレーション	耳鼻咽喉科展望	57	365-368	2014
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Case Report

Magnifying Endoscopy with Narrow Band Imaging to Determine the Extent of Resection in Transoral Robotic Surgery of Oropharyngeal Cancer

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Transoral robotic surgery (TORS) is a less invasive treatment that is becoming popular all over the world. One of the most important factors for achieving success in TORS is the ability to determine the extent of resection during the procedure as the extent of resection in the laryngopharynx not only affects oncological outcomes but also directly affects swallowing and voice functions. Magnifying endoscopy with narrow band imaging (ME-NBI) is an innovative optical technology that provides high-resolution images and is useful in detecting early superficial pharyngeal cancers, which are difficult to detect by standard endoscopy. A 55-year-old male with superficial oropharyngeal cancer has been successfully treated by combining MB-NBI with TORS and MB-NBI was useful in determining the extent of resection. ME-NBI with TORS will make it possible to achieve a higher ratio of minimally invasive treatment in pharyngeal cancer.

1. Introduction

Transoral robotic surgery (TORS) [1–3] is a less invasive treatment that is becoming popular all over the world. TORS has great advantages over the conventional open surgery, especially in functional outcomes such as swallowing and use of voice, and is creating a paradigm shift in the treatment strategy of laryngopharyngeal cancer.

One of the most important factors for achieving success in TORS is the ability to determine the extent of resection during the procedure as the extent of resection in the laryngopharynx not only affects oncological outcomes but also directly affects swallowing and voice functions.

Narrow band imaging (NBI) is an innovative optical technology that can increase contrast of the precise morphological changes in the mucosal surface. We [4–6] have previously reported that magnifying gastrointestinal endoscopy with NBI function (ME-NBI) provides high-resolution images and is useful in detecting early superficial pharyngeal cancers, which are difficult to detect by standard endoscopy.

In this report, we present the first case of oropharyngeal cancer that has been successfully treated by combining MB-NBI with TORS in order to estimate the precise extent of the tumor and to determine the extent of resection during the procedure.

2. Case Presentation

A superficial tumor lesion in the tongue base was found in a 55-year-old male during upper gastrointestinal endoscopy with a ME-NBI (GIF-H260Z, Olympus, Tokyo, Japan) as a follow-up examination after endoscopic treatment of

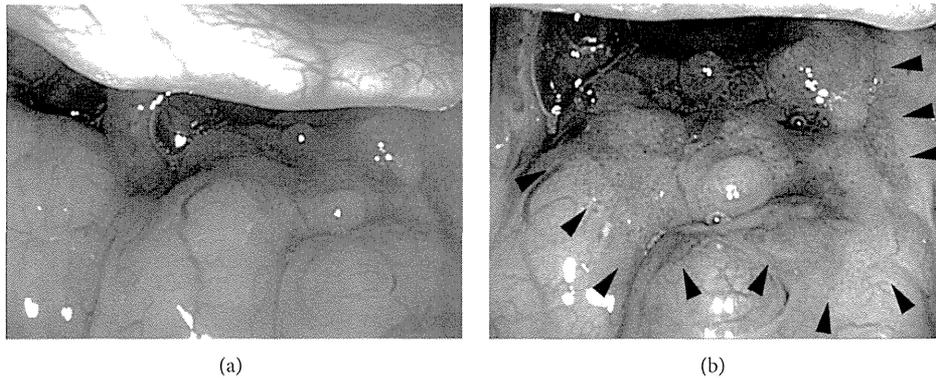(a)   (b)

FIGURE 1: Preoperative endoscopic findings in the superficial tongue base cancer with an otolaryngological videoendoscope with NBI (ENF-type VQ). The lesion in the tongue base is hardly recognizable under white light (a). NBI visualizes the lesion as a brownish area with scattered brownish dots (arrow heads).

esophageal cancer. A pathological diagnosis of the biopsy specimen revealed squamous cell carcinoma and he was referred to the Department of Otolaryngology.

The superficial cancer lesion, about 1.5 cm in diameter, was identified in the left side of the tongue base with an otolaryngological videoendoscope with NBI (ENF-type VQ) (Figure 1). NBI clearly visualized the lesion as a brownish area with scattered brownish dots whereas the lesion was hardly recognizable under white light. The cancer lesion was not recognizable by computed tomography (CT), magnetic resonance imaging (MRI), or positron emission tomography (PET). Neither neck lymph node metastasis nor distant metastasis was found on CT, MRI, or PET. The lesion was clinically diagnosed as T1N0M0.

Tongue base resection with TORS was performed under general anesthesia by cooperating with gastroenterologists. Following transnasal intubation, the FK-WO laryngoscope was inserted to visualize the surgical field. ME-NBI was then inserted transorally and the lesion was observed to confirm a boundary (Figure 2). The main tumor was slightly elevated, with a flat lesion spread surrounding the elevated area. ME-NBI visualized the flat lesion as a brownish area with scattered dots of abnormal vessels, which were invisible in white light. The boundary of the tumor was easily traceable with ME-NBI. The extent of the lesion was confirmed by iodine staining. Then, marking dots were made surrounding the boundary of the lesion with an electric needle knife (Figure 3). An incision line at the lower boundary of the lesion was made with the electric needle knife and the procedure was switched to TORS. The horizontal safety margin was about 5 mm.

The da Vinci S surgical system (Intuitive Surgical Inc., Sunnyvale, CA, USA) with three arms was used for the TORS procedure. The tumor was resected with two instrument hands, 8 mm Maryland dissector, and 8 mm monopolar cautery under the vision of the 3D endoscope (Figure 3). The resection started from the superior side and a branch of the lingual artery was ligated with clips. The depth of the tongue base resection was about 5 mm as the tumor was superficial, and the procedure was completed after confirming a negative margin in the frozen sections. No

neck dissection was performed. The fasting period was 2 days following the surgery. The pathological diagnosis was squamous cell carcinoma with subepithelial invasion, and the size was 18 mm in diameter. The final diagnosis was pT1 and the pathological margin was negative.

The patient is eating a normal diet and has no evidence of local recurrence or metastasis 6 months after the surgery.

3. Discussion

This is the first report on combining ME-NBI with TORS in treatment of pharyngeal cancer.

NBI is an optical image enhancement technology installed in endoscopy systems that can display the mucosal surface layer in high contrast, especially hemoglobin-rich areas such as blood vessels. Combined with magnifying endoscopy, NBI can capture the microvascular pattern on the lining of the digestive tract [7]. ME-NBI has the capabilities of both standard video endoscopy and adjustable image magnification over a continuous range up to a magnification factor of 80 [6]. It provides higher resolution images with higher contrast compared to endoscopes with NBI used in otolaryngology, such as ENF-VQ and ENF-VH (Olympus Medical Systems, Tokyo, Japan), and enables detection of early superficial laryngopharyngeal cancers, which are difficult to detect by standard endoscopy or the type of nonmagnifying endoscopy with NBI used in otolaryngology. In this case, combining ME-NBI with TORS made it possible to estimate the horizontal extent of the superficial lesion precisely, which was beneficial in determining the extent of resection.

There are two advantages in using ME-NBI for TORS. One is that the combination facilitates early diagnosis and less invasive treatment of pharyngeal cancer. An increasing number of superficial pharyngeal cancers are expected to be discovered with the increasing use of ME-NBI [8]. The concept of the superficial cancer came from the digestive tract, such as esophagus and stomach. The superficial cancers of esophagus and stomach are usually treated with either endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) using a gastrointestinal endoscope.
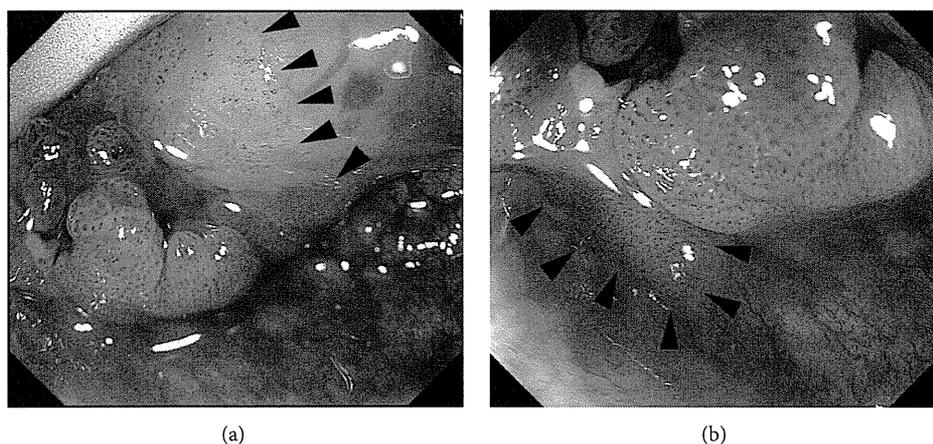
FIGURE 2: Intraoperative evaluation of the extent of the lesion with ME-NBI in the medial superior (a) and inferior (b) borders of the tumor located in the left side of the tongue base. The quality of the image is better than that of the otolaryngological videoendoscope (Figure 1) and the boundary (arrow heads) of the superficial cancer is easily traceable.
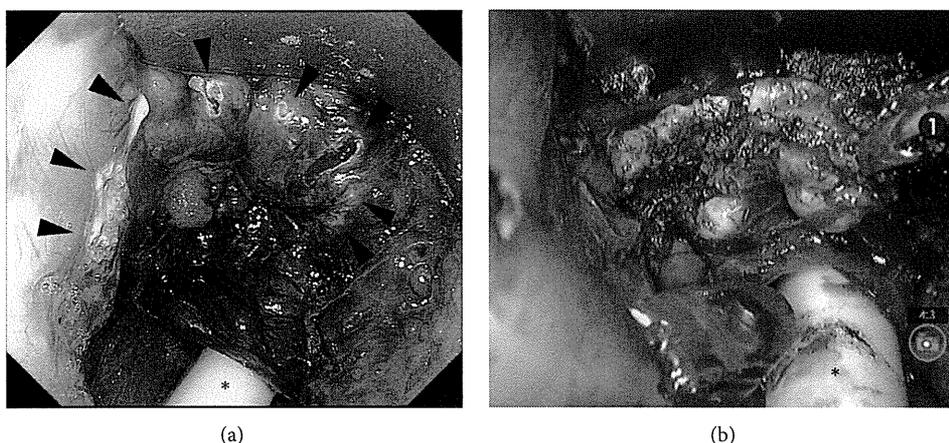

FIGURE 3: Marking dots (arrow heads) were made to indicate resection based on the findings by ME-NBI (a) and the TORS procedure with the da Vinci S surgical system (b). *: intubation tube.

These superficial lesions in the laryngopharynx can be treated with TORS and ME-NBI will be essential during the TORS procedure because we need to "see" the lesion during the surgery. Early diagnosis of pharyngeal cancer with ME-NBI and less invasive treatment for such lesions with TORS combined with ME-NBI will contribute to progress in the treatment of pharyngeal cancer.

The other advantage of the ME-NBI TORS combination is associated with invasive cancer lesions. When observed with ME-NBI, many invasive cancers have superficial lesions surrounding invasive lesions. It is generally accepted that the safety margin needed for the resection of superficial lesion is less than that for the resection of invasive cancer in the upper digestive tract. The safety margin needed for the resection of superficial lesion is about 2 mm [9] to 5 mm [10] whereas that of invasive cancer is 10 to 15 mm. The boundary of a superficial lesion can be easily identified with ME-NBI, so the combination of ME-NBI with TORS will be beneficial in avoiding excessive resection, especially for the superficial part of the invasive cancer, thus resulting in better functional outcomes, such as swallowing and voice function.

The limitation of ME-NBI is that ME-NBI is not useful for examining deeper tissue beneath the epithelium. Frozen section may not be necessary for checking the horizontal margin of the tumor, but it is still necessary for checking the vertical margin.

4. Conclusions

The reported case of oropharyngeal cancer was successfully treated by combining MB-NBI with TORS and MB-NBI was useful in determining the extent of resection. ME-NBI with TORS will make it possible to achieve a higher ratio of minimally invasive treatment in pharyngeal cancer. Further study is needed to validate the benefit of combining ME-NBI with TORS.
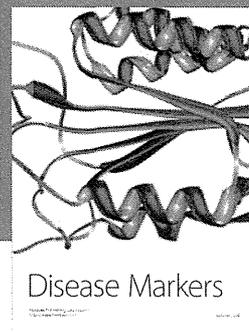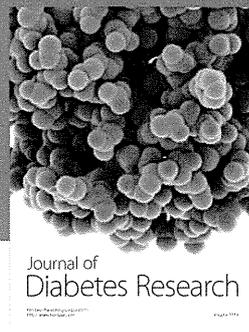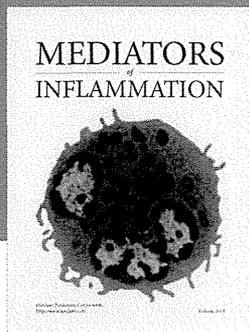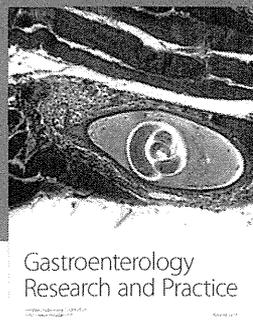
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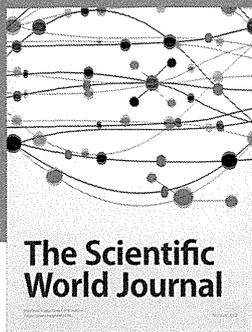
The authors declare that there is no conflict of interests regarding the publication of this paper.

Acknowledgment

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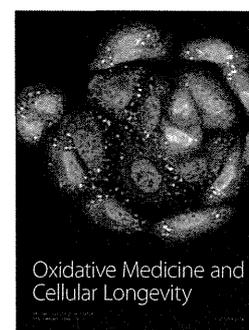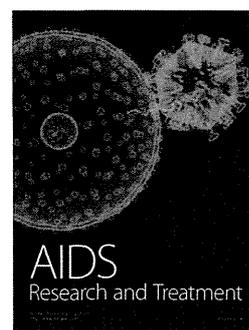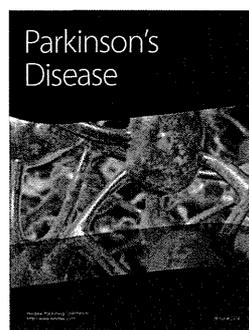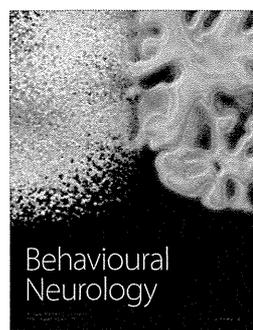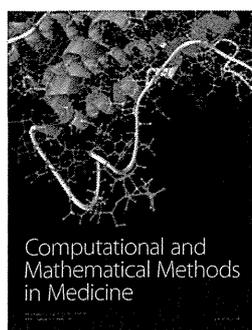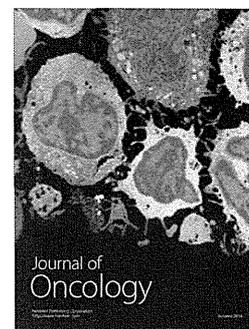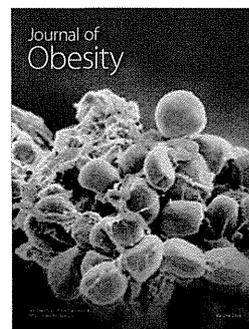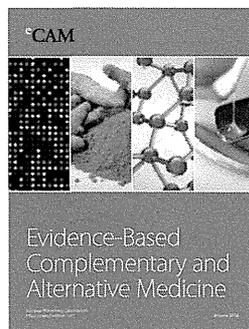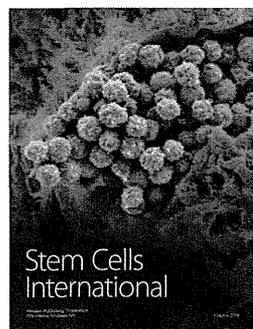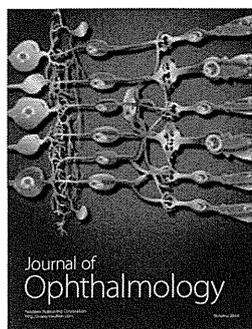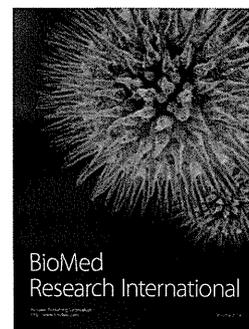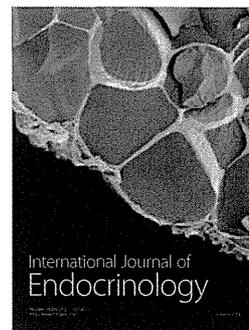
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Magnifying Endoscope With NBI to Predict the Depth of Invasion in Laryngo-Pharyngeal Cancer

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Tomomasa Hayashi, MD, PhD; Makiko Funakoshi, MD; Ikuo Aoyama, MD; Shigeru Hirano, MD, PhD;
Morimasa Kitamura, MD, PhD; Seiji Ishikawa, MD, PhD; Yo Kishimoto, MD, PhD; Mami Morita, MD;
Patnarin Mahattanasakul, MD; Satoshi Morita, PhD; Juichi Ito, MD, PhD

Objectives/Hypothesis: To examine if macroscopic classification with a magnifying gastrointestinal endoscope with narrow band imaging (ME-NBI) is useful in predicting pathological depth of tumor invasion in laryngo-pharyngeal cancer.
Study Design: Retrospective study.
Methods: Preoperative endoscopy reports and postoperative pathological reports on 139 laryngo-pharyngeal cancer lesions were retrospectively reviewed, and the association between macroscopic findings in the lesions and the depth of tumor invasion was analyzed statistically.
Results: The ratios of lesions macroscopically classified as 0-I (superficial and protruding), 0-IIa (slightly elevated), 0-IIb (true flat), 0-IIc (slightly depressed), and 0-III (superficial and excavated) in the preoperative endoscopy reports were 3%, 25%, 71%, 1%, and 0%, respectively. Regarding the depth of tumor invasion in the postoperative pathological reports, the ratios of lesions classified as EP (carcinoma in situ), SEP (tumor invades subepithelial layer), and MP (tumor invades muscularis propria) were 73%, 26%, and 1%, respectively. The ratios of subepithelial invasion or muscular invasion in 0-I, 0-IIa, and 0-IIb were 100%, 54%, and 14%, respectively, and showed significant difference ($P < 0.0001$). Only one of 139 lesions invaded the muscular propria.
Conclusions: This study is the first one to show that macroscopic findings by ME-NBI predict the depth of tumor invasion in superficial laryngo-pharyngeal cancer. It was indicated that there is a little chance of muscular invasion if the lesion is endoscopically diagnosed as 0-I or 0-II. A new T stage classification based on the depth of tumor invasion may be needed in order to adapt the classification to include transoral surgery.
Key Words: Magnifying endoscopy, narrow band imaging, endoscopic laryngo-pharyngeal surgery, transoral robotic surgery, TNM classification.
Level of Evidence: 4

Laryngoscope, 00:000–000, 2014

INTRODUCTION

Transoral surgery is a less invasive treatment that is becoming a major strategy in the treatment for laryngo-pharyngeal cancer. Since the 1990s, transoral laser microsurgery (TLM) has been recognized as an organ preservation strategy that reportedly has good oncological control and functional results,[1] although it has not been widely used because of its technical difficulty. Recently, transoral robotic surgery (TORS) is becoming popular as a new treatment modality for laryngo-pharyngeal cancer, and surgical robots are widely used in the United States.[1] To date, several methods have been reported as less invasive transoral surgical approaches, such as TLM, TORS,[2–4] and transoral videolaryngoscopic surgery.[1] These surgical methods have great advantages over the conventional open surgery, especially in functional outcomes such as swallowing and use of voice, and are creating a paradigm shift in the treatment strategy for laryngo-pharyngeal cancer.

One of the most important factors for achieving success in transoral surgery is the ability to determine properly whether there is indication for transoral surgery and especially the ability to estimate the depth of tumor invasion precisely at the preoperative examination. Cancer lesions that invade bone or cartilage are contraindications for this technique. In addition, the preoperative estimation of the depth of tumor invasion strongly influences functional outcomes, such as swallowing and use of voice, whereas the extent of resection in the laryngo-pharynx directly affects swallowing and
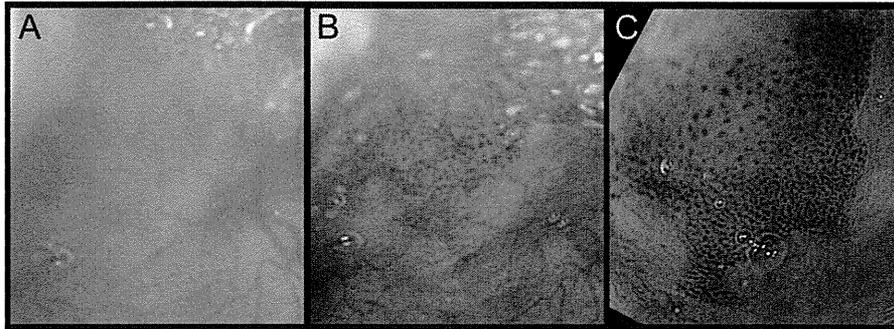
Fig. 1. The same superficial cancer lesion in the hypopharynx observed by endoscope for otolaryngology (ENF type VQ) with white light (A), endoscope for otolaryngology (ENF type VQ) with NBI (B), and magnifying endoscope for upper gastrointestinal tract (GIF TYPE H260Z) with NBI (C). (A) The lesion cannot be identified by ENT endoscope with white light. (B) The lesion can be identified by ENT endoscope with NBI, although the contrast is poor. (C) The lesion is clearly identified as a brownish area with scattered dots of abnormal vessels, and the margin of the lesion is easily traceable. ENT = ear, nose, and throat; NBI = narrow band imaging.

voice functions. Although computed tomography and magnetic resonance imaging are widely accepted as useful modalities for estimating the extent of tumor growth, different preoperative invasion staging techniques may help estimating the depth of tumor invasion more accurately. Therefore, developing a method to predict the depth of tumor invasion is needed in transoral surgery.

Narrow band imaging (NBI) is an innovative optical technology that can increase contrast of the precise morphological changes in the mucosal surface. When combined with magnifying endoscopy, NBI clearly visualizes microvascular structures.[5] In the head and neck region, we have previously reported that magnifying gastrointestinal endoscopy with NBI function (ME-NBI) provides high-resolution images and is useful in detecting early superficial laryngo-pharyngeal cancers, which are difficult to detect by standard endoscopy.[6–8] In addition to the detection, ME-NBI is useful in predicting the depth of tumor invasion in the upper gastrointestinal tract.[9] For example, esophageal cancer is classified in detail in terms of macroscopic morphology and the pathological depth of tumor invasion according to the Japanese Classification of Esophageal Cancer (10th edition),[10] and correlations between endoscopic findings and the depth of tumor invasion have been reported.[11] Nevertheless, although Kikuchi et al.[12] reported correlation between microvascular characteristics and the depth of tumor invasion in superficial pharyngeal cancer, no reports have been published regarding the correlation between macroscopic findings and the depth of tumor invasion in head and neck cancer.

Since 2007, the departments of otolaryngology head and neck surgery and gastroenterology and hepatology in our university hospital have been collaborating and have been screening the laryngo-pharyngeal region of all patients who have a history of esophageal cancer or head and neck cancer by using ME-NBI. Detected lesions were macroscopically classified and were then biopsied. If a lesion was diagnosed as superficial cancer, it was treated by either endoscopic submucosal dissection (ESD)[13,14] or endoscopic laryngo-pharyngeal surgery (ELPS), which was developed to treat laryngo-pharyngeal superficial cancer.[15]

The purpose of this study is to examine if the preoperative macroscopic classification with ME-NBI is useful in predicting pathological depth of tumor invasion in laryngo-pharyngeal cancer. Endoscopic report data on the screening and postoperative pathological results were retrospectively reviewed, and the correlation between the macroscopic endoscopic classification and the pathological depth of tumor invasion was statistically analyzed.

MATERIALS AND METHODS

Patients and Lesions

During the period from February 2007 to January 2014, 176 consecutive laryngo-pharyngeal lesions in 106 patients were treated with ELPS or ESD under general anesthesia at Kyoto University Hospital, Japan. Among them, 139 fresh lesions of carcinoma in situ or squamous cell carcinoma in 91 patients who had no history of radiation therapy to the neck or surgery to the same site are included in this study. The 15 patients excluded from the study include four patients with a history of surgery on the same site, four with a history of neck radiation, one with a spindle cell carcinoma, and six with nonmalignant lesions.

Patients were predominantly male (86 cases, 95%) and the median age was 67 years (range 33–85 years). Written informed consent for the treatment was obtained from all patients; and this study was approved by the institutional review board of the Graduate School of Medicine, Kyoto University.

Macroscopic Classification by Magnifying Endoscopy With Narrow Band Imaging

All procedures were performed using a ME-NBI (GIF TYPE H260Z, Q240Z, or Q260J; Olympus Medical Systems, Tokyo, Japan), as reported previously.[5] In short, each patient was sedated with 35-mg pethidine hydrochloride before the examination. A nonmagnifying observation with NBI was performed to identify abnormal mucosal areas. If abnormal mucosal areas (e.g., well demarcated brownish lesions) were identified, photographs of the nonmagnified NBI view were taken. Subsequently, the lesion and surrounding normal mucosa was observed under magnification. ME-NBI has the capabilities of both standard video endoscopy and adjustable image magnification over a continuous range up to a magnification factor of 80, and it provides higher resolution images with higher
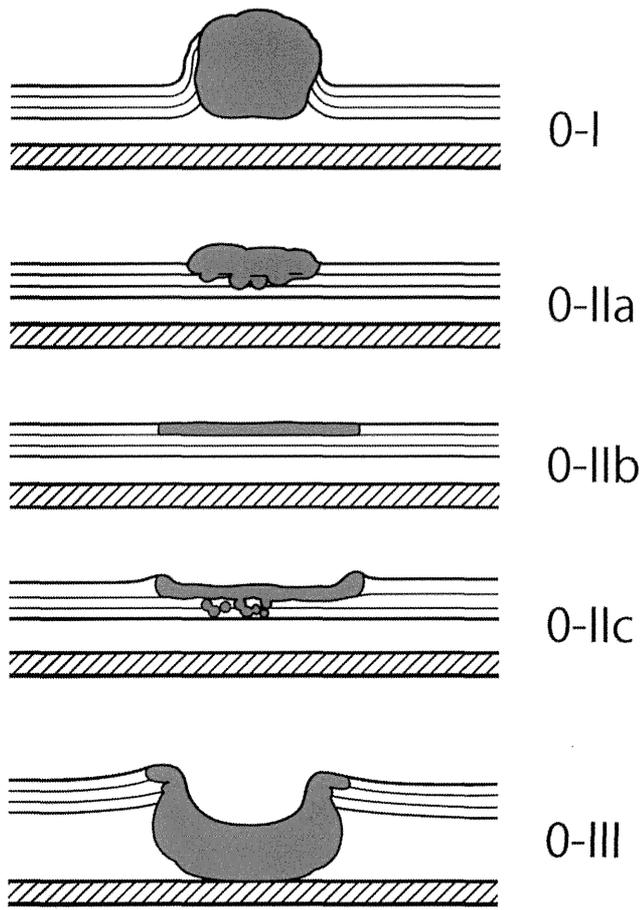
0-I

0-IIa

0-IIb

0-IIc

0-III

Fig. 2. Schematic view of the macroscopic classification of superficial esophageal cancer in the Japan Classification of Esophageal Cancer (10th edition), modified from reference 10. This classification is applied for head and neck cancer in the General Rules for Clinical Studies on Head and Neck Cancer (5th edition) of the Japan Society for Head and Neck Cancer[17] and used for this study. 0-I (superficial and protruding type: more than 1 mm in height), 0-IIa (slightly elevated type: less than 1 mm in height), 0-IIb (flat type), 0-IIc (slightly depressed type: less than 0.5 mm in depth), 0-III (superficial and excavated type). [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

contrast compared to endoscopes with NBI used in otolaryngology, such as ENF-VQ and ENF-VH (Olympus Medical Systems) (Fig. 1).

If scattered brownish dots were observed within the lesion under ME-NBI, the lesion was clinically diagnosed as malignant, as has previously been reported for lesions in the esophagus.[16] Biopsy was performed to pathologically confirm the malignancy after the observation.

Macroscopic morphology of the lesion was classified quickly after the examination and reported in accordance with both the Japanese Classification of Esophageal Cancer (10th edition)[10] and the General Rules for Clinical Studies on Head and Neck Cancer (5th edition) of the Japan Society for Head and Neck Cancer[17] by at least two experienced gastroenterologists who had no information regarding the pathology. According to the Japanese Classification of Esophageal Cancer (10th edition),[10] superficial cancer is defined as a lesion with no invasion to the muscularis propria, and tumors in which invasion is diagnosed to extend to the muscularis propria or beyond are

classified as advanced type. The superficial type has the prefix 0 and is classified into 0-I (superficial and protruding type), 0-II (superficial and flat type), or 0-III (superficial and excavated type). Type 0-II (superficial and flat type) is classified into 0-IIa (slightly elevated type: less than 1 mm in height), 0-IIb (true flat type), and 0-IIc (slightly depressed type). The utility and clinical relevance of the Japanese endoscopic classification of superficial neoplastic lesions of the gastrointestinal (GI) tract, including esophagus, stomach, and colon, were explored by an international group of endoscopists, surgeons, and pathologists in an intensive workshop in Paris in 2002, and the results[9] were published in 2003. This endoscopic classification of the GI tract is globally accepted and is also called the Paris endoscopic classification.[9] Clinically, the height and depth of a lesion are evaluated by placing a single cup of the opened biopsy forceps (approximately 1.2 mm in height) next to the lesion as a calibrating gauge. Lesions protruding above the level of the cup are classified as 0-I; and protruding lesions that have a thick pedicle with a broad base[18] and restricted mobility are classified as type 1, an invasive tumor. Lesions that are depressed by more than half the level of a single cup are classified as 0-III. Entirely flat lesions with neither protrusion nor depression observed with ME-NBI are classified as 0-IIb. The 0-IIb lesions are detectable only with NBI. This classification has been applied for head and neck cancer by the Japan Society for Head and Neck Cancer as the General Rules for Clinical Studies on Head and Neck Cancer (5th edition).[17] Schema views of each of the subtypes of the superficial cancer are shown in Figure 2.

Surgical Procedure

If the lesion was clinically diagnosed as superficial cancer, ELPS or ESD was indicated as a minimally invasive treatment under general anesthesia. ELPS was developed to treat laryngopharyngeal superficial cancer. The concept of ELPS is the same as that of ESD in that both are performed as en bloc resection of a cancer lesion following submucosal injection, but it differs from ESD in that the resection procedure is performed by a head and neck surgeon with both hands (Supp. Fig. S1). After starting the use of ELPS in August 2009, all lesions have generally been treated with ELPS except those that invaded the cervical esophagus beyond the entrance of the esophagus. In brief, a curved rigid laryngoscope (Nagashima Medical Instruments Company, Ltd, Tokyo, Japan) was inserted to provide a working space in the pharyngeal lumen, and a ME-NBI was inserted transorally by a gastroenterologist to visualize the surgical field (Supp. Fig. S2). The extent of the lesion and the exact margins were determined by NBI and iodine staining. A mixed solution of epinephrine (0.02 mg/mL) and saline was injected into the subepithelial layer beneath the lesion in order to lift the lesion above the surrounding mucosa and to create a safety space. Specially designed curved forceps[13] (Nagashima Medical Instruments Company, Ltd, Tokyo, Japan) and a curved electrosurgical needle knife (Olympus Medical Systems) were orally inserted and the tumor was resected. Thirty-five lesions were treated with ESD, and 104 lesions were treated with ELPS in this study.

Pathology and Evaluation of the Invasion of the Tumor

All resected specimens were cut into longitudinal slices 2 mm in width after fixation. The slices were embedded in paraffin and stained with hematoxylin-eosin. All specimens were microscopically evaluated according to the World Health Organization Classification. T staging was performed according to the Union for International Cancer Control tumor-node-

Esophageal cancer

EP   LPM   MM   SM   (T2)

Epithelium
Lamina propria mucosa
Muscularis mucosa

Muscularis propria

Laryngo-pharyngeal cancer

EP   SEP   MP
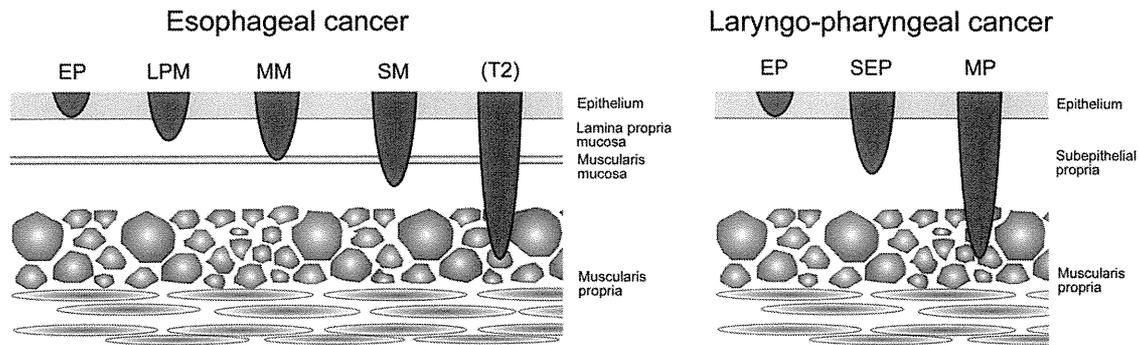
Epithelium

Subepithelial propria

Muscularis propria

Fig. 3. Schematic view of the pathological classification for the superficial cancer of the esophageal cancer and the head and neck cancer, in the Japan Classification of Esophageal Cancer (10th edition)[10] and the General Rules for Clinical Studies on Head and Neck Cancer (5th edition) of the Japan Society for Head and Neck Cancer,[17] respectively, modified from reference 10.
In the esophageal cancer, superficial cancers are classified as EP (carcinoma in situ), LPM (tumor invades lamina propria mucosa), MM (tumor invades muscularis mucosa), and tumor invades submucosa (T1b), depending on the depth of tumor invasion. In the laryngo-pharynx, because muscularis mucosa is absent in the laryngo-pharynx, the lesion was classified as EP (carcinoma in situ), SEP (tumor invades subepithelial layer), and MP (tumor invades muscularis propria).[17] [Color figure can be viewed in the online issue, which is available at www.laryngoscope.com.]

metastasis (UICC/TNM) classification (7th edition) of the head and neck cancer.[19]

Evaluation of the invasion of the tumor was also made according to the General Rules for Clinical Studies of Head and Neck Cancer (5th edition) by the Japan Society for Head and Neck Cancer[17] and the Japanese Classification of Esophageal Cancer by the Japan Esophageal Society (10th edition).[10]

In the esophageal cancer, superficial cancers are pathologically classified as EP (carcinoma in situ), LPM (tumor invades lamina propria mucosa), MM (tumor invades muscularis mucosa), and tumor invades submucosa (T1b), depending on the depth of tumor invasion.[10] In the laryngo-pharynx, because muscularis mucosa is absent in the laryngo-pharynx, the lesion was classified into EP (carcinoma in situ), SEP (tumor invades subepithelial layer) and MP (tumor invades muscularis propria), according to the General Rules for Clinical Studies on Head and Neck Cancer by the Japan Society for Head and Neck Cancer (5th edition).[17] In this study, all lesions were classified as EP, SEP, or MP in accordance with the rule by the Japan Society for Head and Neck Cancer.[17] Schematic views of pathological classi-

fication of the depth of tumor invasion in the esophageal cancer and head and neck cancer are shown in Figure 3.

Data Analysis

Macroscopic classification with a ME-NBI, pathological classification regarding the depth of tumor invasion, lymphatic invasion, vessel invasion, and recurrence was reviewed. The association between macroscopic classification (0-I /0-IIa/0-IIb) and the depth of tumor invasion (EP/SEP + MP) was statistically analyzed using the Cochran–Mantel–Haenszel test (degree of freedom = 1). Because of the small sample size (N = 1), 0-IIc was excluded from the statistical analysis. SAS for Windows 9.3 (SAS Institute Inc., Cary, NC) was used for the analysis.

RESULTS

Lesion characteristics are shown in Table I. Of the 139 lesions resected, the total number of lesions in the oropharynx, hypopharynx, and larynx was 41 (30%), 95 (68%), and three (2%), respectively. In the oropharynx, the numbers of lesions in the anterior, posterior, superior, and lateral walls were five (12%), 19 (46%), nine (22%), and eight (20%), respectively. In the hypopharynx, the numbers of lesions in the piriform sinus, postcricoid, and posterior walls were 76 (80%), three (3%), and 16 (17%), respectively. In the larynx, all lesions were in the supraglottic area. Regarding the T classification, 101 lesions were pathologically diagnosed as Tis, 16 lesions as T1, 18 lesions as T2, and four lesions as T3.

Macroscopic classification, pathological classification regarding the depth of tumor invasion, lymphatic invasion, vessel invasion, and the number of recurrences are shown in Table II. The numbers of lesions classified macroscopically as 0-I, 0-IIa, 0-IIb, 0-IIc, and 0-III were 4 (3%), 35 (25%), 99 (71%), one (1%), and 0(0%), respectively. Representative images of each subtype are shown in Figure 4. Regarding the depth of tumor invasion, the numbers of lesion classified as EP, SEP, and MP were 101 (73%), 37 (26%), and one (1%), respectively.

In the 0-I lesions, all lesions showed subepithelial invasion (SEP). In the 0-IIa lesions, 18 lesions (51%) were SEP;

TABLE I.
Lesion Characteristics.

Origin	Subsite	
Oropharynx	Anterior wall	5
	Posterior wall	19
	Superior wall	9
	Lateral wall	8
Hypopharynx	Piriform sinus	76
	Post cricoid	3
	Posterior wall	16
Larynx	Supraglottic	3

T stage	
Tis	101
T1	16
T2	18
T3	4

TABLE II.
Macroscopic Classification by Magnifying Endoscope, Pathological Classification Regarding the Depth of Tumor Invasion, Lymphatic Invasion, and Vessel Invasion.

Preoperative Macroscopic Classification	Number of Lesions	Pathology				
		Depth of Tumor Invasion				
		EP	SEP	MP	ℓy (+)	v (+)
0-I	4	0	4	0	0	0
0-IIa	35	16	18	1	2	1
0-IIb	99	85	14	0	0	0
0-IIc	1	0	1	0	1	0
0-III	0	0	0	0	0	0

Preoperative Macroscopic Classification	Ratio of SEP + MP*
0-I	100%
0-IIa	54%
0-IIb	14%

*The ratios of SEP + MP in 0-I, 0-IIa, and 0-IIb showed significant difference ($P < 0.0001$; Cochran–Mantel–Haenszel test: degree of freedom = 1).

one lesion (3%) was MP; and vessel invasion was observed in three lesions (9%). In the 0-IIb lesions, most lesions (86%) were EP and there was no vessel invasion. Only one lesion was classified as 0-IIc; and the lesion was pathologically classified as SEP with lymphatic duct invasion.

The ratios of subepithelial invasion or muscular invasion (SEP + MP) in 0-I, 0-IIa, and 0-IIb were 100%, 54%, and 14%, respectively, and showed significant difference ($P < 0.0001$).

DISCUSSION

The present study showed strong correlation between macroscopic classification by ME-NBI and pathological depth of tumor invasion. This is the first report to show that macroscopic findings by ME-NBI predict the depth of tumor invasion in superficial laryngo-pharyngeal cancer.

Correlations between endoscopic macroscopic type and invasion depth have been reported for superficial esophageal squamous cell carcinoma and early gastric and early colorectal adenocarcinomas in the Paris endoscopic classification,[9] which was made based on the Japanese endoscopic classification of superficial neoplastic lesions of the GI tract. In the multicenter analysis of superficial esophageal squamous cell carcinoma conducted in Japan on the basis of 2,418 patients from 143 institutions,[20] the total risk for submucosal invasion is high (90%) in type 0-I lesions. The highest risk occurs in type 0-I and in type 0-III lesions, and the lowest risk is in type 0-IIb lesions. Ratios of invasion deeper than EP in 0-I, 0-IIa, 0-IIb, and 0-IIc were 99% (259/262), 89% (270/303), 47% (104/221), and 80% (567/707), respectively. In our study, the highest risk for subepithelial invasion occurred in type 0-I (100%); and the lowest risk was in type 0-IIb lesions (14%), which were similar to the results in esophageal cancer.

The major difference between our study and the report on esophageal cancer is the overall ratio of submucosal (muscularis propria) invasion in 0-I and 0-II lesions. The overall ratio of invasion to muscularis propria in 0-I and 0-II lesions in our study was only one of 139 lesions, whereas it was 52% in esophageal cancer.[20] We suggest that one reason for this discrepancy may be associated with the different populations. For example, in our study there was just one 0-IIc lesion, but the ratio of 0-IIc in esophageal cancer was 47%. Although it is unclear if the population difference is due to a natural characteristic of laryngo-pharyngeal cancer or to an institutional bias, the results indicate that there is a little chance of muscular invasion in the laryngo-pharyngeal cancer as long as the lesions are diagnosed as 0-I and 0-II.

Finally, the correlation between macroscopic morphological classification and the depth of tumor invasion shown in this study may contribute to modify the T stage classification in head and neck cancer. The T stage classification of head and neck cancer, especially in the pharynx, is based on the diameter of the tumor. This is probably because radiotherapy or open neck surgery are two standard modalities, and the volume or the area of the tumor are important for them. The T staging system is the gold standard in evaluating a primary lesion and its prognostic importance is widely accepted. However, the limitation of the current T staging system is becoming evident with the development of new treatments and diagnostic modalities. For example, NBI enables detection of superficial pharyngeal cancer lesions that are barely visible by conventional methods, and excellent long-term oncological outcome for endoscopic resection of such lesions is reported with the 5-year cause-specific survival rate of 97%.[13] According to the current T staging system, a pharyngeal superficial cancer with micro invasion, such as SEP, is diagnosed as T3 when it is
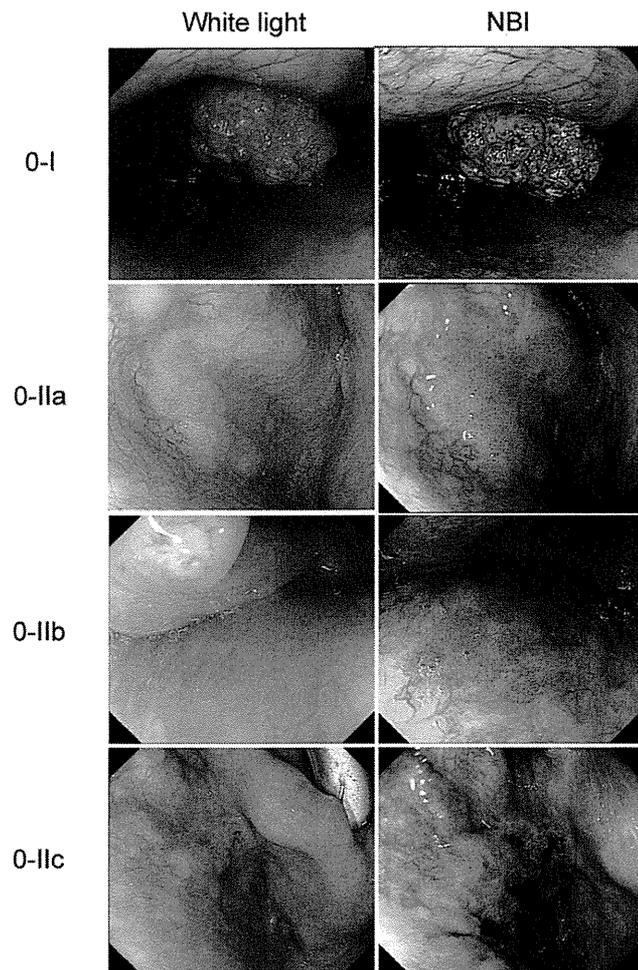
White light   NBI

0-I

0-IIa

0-IIb

0-IIc

Fig. 4. Representative endoscopic images of each macroscopic subtype by magnifying endoscope for upper gastrointestinal endoscope with NBI (GIF TYPE H260Z). NBI = narrow band imaging.

was a retrospective study. A prospective, randomized, controlled multi-institutional trial should be conducted in the future to validate the results.

CONCLUSION

This study is the first to show that macroscopic findings by ME-NBI predict the depth of tumor invasion in superficial laryngo-pharyngeal cancer. The highest risk for subepithelial invasion was present in type 0-I (100%), and the lowest risk was in type 0-IIb lesions (14%). Only one out of 139 lesions of 0-I and 0-II invaded muscular propria; and it was indicated that there is a little chance of muscular invasion in the laryngo-pharyngeal cancer as long as the lesions are diagnosed as 0-I and 0-II.

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more than 4 cm in diameter or when it invades to the entrance of the esophagus, although it is a superficial lesion with excellent prognosis. In esophageal cancer, transoral endoscopic resection is a standard treatment, and T stage classification is based on the depth of tumor invasion because the depth is an important factor in determining whether there is indication for endoscopic treatment. Indeed, in esophageal cancer,[10] EP, LPM, and MM lesions are classified as T1a; a SM lesion is classified as T1b; and a lesion with invasion to the muscularis propria is classified as T2. Faced with the paradigm shift in treatment modality from open surgery to transoral surgery, it may be necessary to adapt a change in T stage modification based on the depth of tumor invasion in the laryngo-pharyngeal cancer. The findings shown in this study will help to develop the new T stage classification based on the depth of tumor invasion.

There are two limitations in this study. One is the small number of invasive lesions. There was no 0-III lesion in the study because 0-III lesions were primarily treated with radiation or concurrent chemoradiotherapy, and pathological information other than biopsy results was not obtained. The other limitation is that the study

論　　　説

耳鼻咽喉科におけるロボット支援手術の現状と今後の展望

楯谷　一郎・伊藤　壽一

Robotic surgery in otolaryngology
—present and future—

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Robotic surgery is ushering in a new era in surgery by offering patients better outcomes and has already become one of standard modalities in urology and gynecology. In the otolaryngological field, after the FDA clearance in 2009, transoral robotic surgery (TORS) has now been widely adopted by head and neck surgeons for treatment of benign and malignant conditions of the pharynx and larynx. TORS has also been adopted for treatment of parapharyngeal tumors, sleep apnea, recurrent nasopharyngeal cancer, retropharyngeal node metastasis. Another use of surgical robots in otolaryngology is thyroidectomy and neck surgery. Robotic thyroidectomy has been developed mainly by Korean surgeons and the technique evolved into robotic neck dissection. Despite the 2nd biggest market of surgical robots in the world, the access to surgical robot for otolaryngology is very limited in Japan because da Vinci has not been approved for otolaryngological field by pharmaceuticals and medical devices agency (PMDA) yet. Multi-institutional clinical study of TORS is currently conducted in order to clear PMDA. The limitations and future directions of surgical robots in otolaryngology are also discussed.

Keywords : robotic surgery, da Vinci surgical system, transoral robotic surgery, robotic thyroidectomy

はじめに

　手術支援ロボットはナビゲーション手術装置，内視鏡下手術の補助装置として 1980 年代に開発されたが，その後 Zeus などを経て，da Vinci surgical system（以下ダビンチ）が登場し，第一世代の普及機として広く使用されつつある[1]．すでに世界で 3000 台以上納入され，泌尿器科など一部の領域ではすでに標準治療となっており，本邦においても泌尿器科領域において前立腺癌手術が保険収載されている．耳鼻咽喉科領域においては 2009 年に経口的ロボット支援手術が FDA（Food and Drug Administration）により承認されたのを皮切りに世界的に普及しつつあり，また頸部手術においても手術支援ロボットが導入されているが，本邦では耳鼻咽喉科領域は医薬品医療機器等法（旧薬事法）上の適応外の状態である．本稿ではダビンチを用いたロボット支援手術の国内外における現状について概説し，耳鼻咽喉科領域におけるロボット手術の今後の展望について論じてみたい．

手術支援ロボット　ダビンチ

　ダビンチは能動的に動くものではなく，術者の操作を忠実に再現する，いわゆる "マスタースレイブ型" のロボットである．ビジョンカート，サージャンコンソール，ペイシェントカートの 3 つから構成されており，ビジョンカートがロボットの目，サージャンコンソールがコク

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ピット，ペイシェンカートが手術操作を行うロボット本体に相当する（図1）．カートは4本のアームをもっており，1本が3D内視鏡カメラ用アーム，残りの3本に鉗子を装着して手術操作にあたる．3本の鉗子のうち1本は組織を牽引したまま保持するいわゆる鉤引きの役割を担い，残りの2本で実際の手術操作を行う．この鉗子は7つの自由度をもっており，自在な方向に向きを変えることが可能である．術者はサージャンコンソールに座って3Dモニターを見ながら4本のアームを操作する．内視鏡には拡大機能があり，最大15倍までズームが可能である．操作においては親指と人差し指でマスターコントローラに挿入し，指や腕を動かすと，タイムラグなくその動きを忠実にロボットアームが再現する．ダビンチにはモーションスケール機能が備わっており，マスターコントローラでの動きを2：1，3：1，あるいは5：1に縮小してアームに伝えることができる．またフィルター機能により術者の手ぶれは補正される．これらの機能により，内視鏡下手術に比べてより繊細で安定した手術操作を行うことが可能であり，ロボット支援手術は内視鏡下手術に比べて習得が早いことが報告されている[2]．

ダビンチは1999年1月にヨーロッパでCEマークを取得したのを皮切りに2000年7月に一般消化器外科領域が米国のFDAで承認され，以後2005年5月までに胸部外科，泌尿器科，心臓血管外科，婦人科，小児外科領域がFDAで承認された．その後耳鼻咽喉科領域では2009年12月に経口的ロボット支援手術がFDAの承認を得ている．ダビンチの販売台数は年々増加しており，2013年12月時点において世界で3000台が納入されている．その内訳をみると，米国で約2000台，ヨーロッパで500台弱，アジアで300台弱が納入されている．日本には2012年，2013年に多くの施設で納入され，160台が納入されているが，これは米国に次いで世界第二の保有数である．

一般臨床においてダビンチはとくに泌尿器科領域，婦人科領域において急速に普及している．前立腺癌手術においては従来尿失禁，性機能障害が問題となっていたが，ロボット支援手術がこれらの機能温存に有用であることもあり，現在米国で行われている前立腺摘出術の9割がダビンチを用いて施行されている．このようにロボット支援手術は開発・普及段階ではなく，一部の領域ではすでに標準治療となっている．耳鼻咽喉科・頭頸部外科領域において，手術支援ロボットは経口的手術と甲状腺を
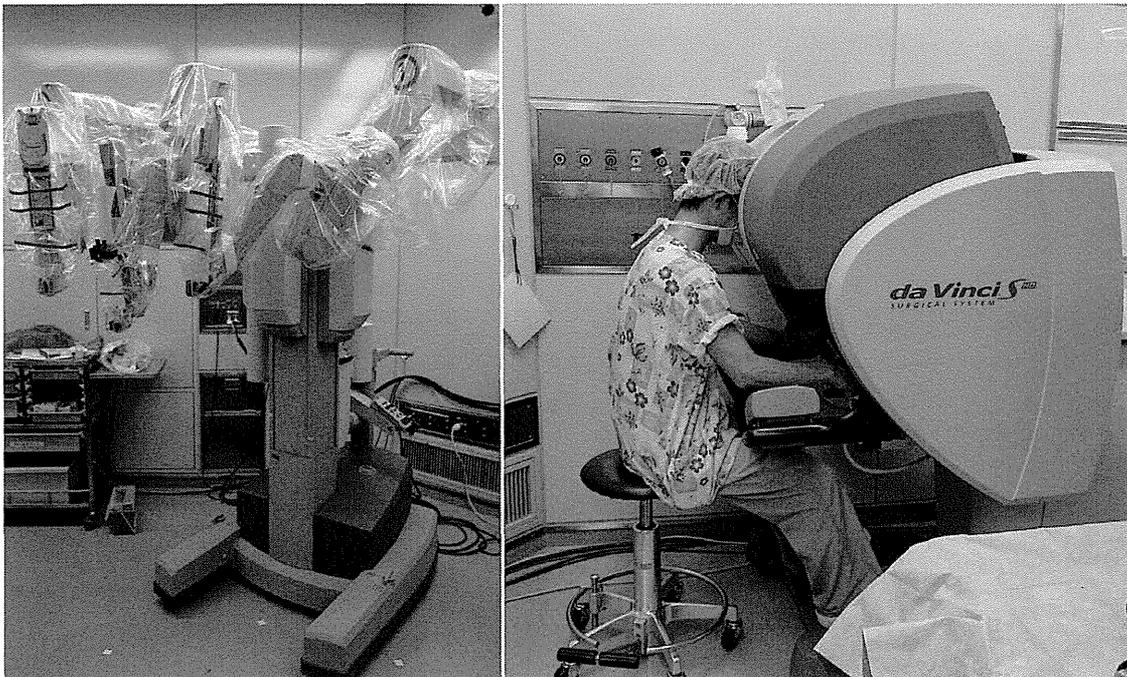

図1　ダビンチS　サージカルシステム
ペイシェントカート（左）とサージャンコンソール（右）

中心とした頸部領域における手術において使用されている．以下に各術式の概要ならびに現状について述べる．

経口的ロボット支援手術

咽喉頭癌治療は嚥下・発声機能と密接に関係している．日本頭頸部癌学会の頭頸部癌診療ガイドライン（2013年版）[3]や米国の代表的なガイドラインである頭頸部癌NCCN ガイドライン（2014 年版）[4]において，咽喉頭癌に対する標準治療としては手術治療と（化学）放射線治療は並列で記載されている．近年は臓器温存の観点から手術療法よりも放射線治療あるいは化学放射線療法を行う施設が増えてきているが，照射後に永続的な唾液腺分泌低下や嚥下機能低下をきたし，臓器が温存されても生涯にわたり口渇や摂食障害に悩むケースが少なくない．実際，Machtay ら[5]の 230 例の解析では頭頸部癌に化学放射線療法を行った患者の 13% が治療後 2 年経過しても経管栄養を要していたと報告されている．一方，1990 年前後より Steiner[6]によって腫瘍を顕微鏡下にレーザー切除する経口的レーザー手術（Transoral laser microsurgery）が始められ，局所制御のみならず嚥下機能においても良好な成績が報告された．しかし，顕微鏡下の経口的内視鏡手術では，一度に直視できる視野や器具の可動域が狭いため大きな病変の切除が技術的に困難などの問題点があり，広く普及するには至らなかった．

経口的ロボット支援手術（TORS：transoral robotic surgery）は経口的レーザー手術の欠点を克服する手法として，ペンシルバニア大学の Weinstein らのグループ[7]~[10]により開発された．これは 3D 内視鏡アームとロボットアームを経口的に挿入して病変を切除する手法である（図 2）．本術式用に開発された FK-WO リトラクターにより喉頭や舌組織を適切に展開し，3D 内視鏡を病変部近くまで挿入することで術野に近接した鮮明な 3D 画像を得ることができ，さらに自在に先端が曲がるロボットアームにより従来では切除が困難であった咽喉頭癌病変の切除が可能となった．通常のロボット支援手術では内視鏡アームに加えて 3 本のアームで手術を行うが，TORS においてはスペースの問題のため 2 本のアームで手術操作を行う．他領域では主に直径 8 mm のアームが使用されているが，TORS においては 5 mm のアームが使用されており，一方にメリーランド鉗子，もう一方にバイポーラを接続して施行されている．
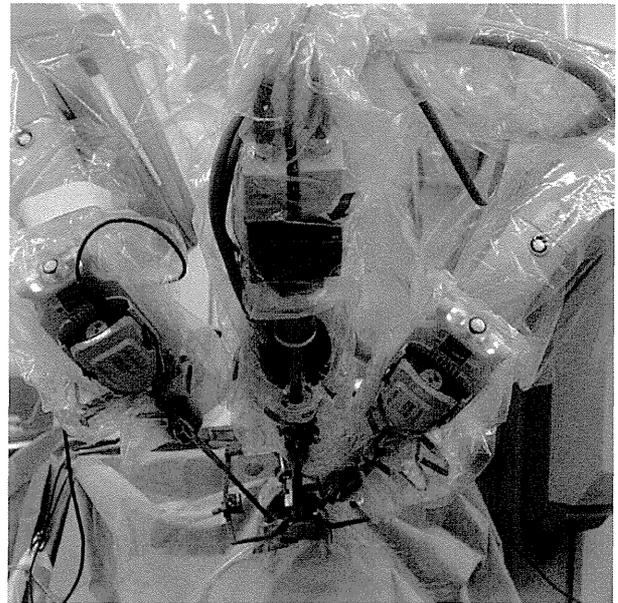
経口的ロボット支援手術の主対象は中・下咽頭癌，声

図 2　経口的ロボット支援手術
経口的に 1 本の 3D 内視鏡アームと 2 本の鉗子用アームを挿入して手術操作を行う．

門上癌の T1，T2 病変であり，早期中咽頭癌を対象とした二つのメタアナリシス[11][12]では 2 年生存率は約 90%（約500 例）[11]，1 年以上の胃瘻利用率は 5%（206 論文）[12]と，非常に良好な成績が報告されている．また中咽頭癌に対する化学放射線治療の治療成績は HPV 陽性か否かで大きく異なることが知られているが，興味深いことに Cohen ら[13]が経口的ロボット支援手術を行った 50 例の検討では，HPV 陽性例と陰性例の 2 年疾患特異的生存率はともに約 90% 以上と良好であり，予後に有意差を認めなかったと報告されている．従来では経口的切除の適応にならなかった大きな病変もより安全に切除することが可能であり，T3 や T4 病変の切除報告例[14]も出てきている．当初は中咽頭癌が主対象であったが，下咽頭癌に対する報告例[15][16]も増えてきている．また，（化学）放射線治療に比べて入院期間が短く，治療後の嚥下機能が良好であり，また唾液分泌低下・味覚障害などの後遺症が皆無である，などのメリットを有する．米国では術後 1〜4 日で退院しており[17]，ランニングコスト等の問題はあるが，2〜3 ヵ月の治療期間を要する（化学）放射線治療に比べ医療経済的なメリットも期待できる．

経口的ロボット支援手術は 2009 年に FDA で初めて認可された後，2011 年に EU，カナダ，オーストラリア，

韓国，中国で承認されており，2012年12月の時点で全世界において4000例（累計）が施行されている．最新の頭頸部癌NCCNガイドライン（2014年版）[4]においてもロボット支援手術について記載されており，また経口的ロボット支援手術やいわゆるラリンゴマイクロサージェリーを含む経口的内視鏡手術（endoscpic resection）についてもその扱いが大きくなってきている．経口的ロボット支援手術の登場により，咽喉頭癌に対する治療戦略は（化学）放射線治療への流れから経口的ロボット支援手術を中心とした積極的な経口的切除術へとパラダイムシフトが起こりつつある．

　経口的ロボット支援手術の適応は上記以外の癌病変や良性疾患にも広がってきている．経口的ロボット支援手術は原発不明癌の原発巣探索に応用されており，Patelら[18]は原発不明の頸部リンパ節転移47例に対して同側の扁桃摘出術，舌根粘膜摘除術を行った結果，72％で原発巣を同定できたと報告としている．また，（化学）放射線治療後の喉頭癌再発例に対し，Lawsonら[19]は経口的ロボット支援手術下に喉頭全摘を行うtransoral robotic surgery total laryngectomy（TORS-TL）を報告している．これはやや大きめに気管切開の皮膚切開を置き，切開部から可及的に頭側に向かって気管・喉頭の剥離を進めたのち，経口的ロボット支援手術により経口的に披裂部と喉頭蓋谷の粘膜切開を行って喉頭を口から摘出し，さらに経口的に粘膜縫合を行うというものである．頸部操作の一部が盲目的になるため，その適応には意見の分かれるところであるが，最小限の粘膜切開，皮膚切開で手術を行うため組織の血流を最大限に保存でき，化学放射線治療の既往例でも瘻孔をきたすリスクが低いとしている．さらに上咽頭癌の化学放射線治療後再発例に対し，ロボット補助下の上咽頭癌病変切除も台湾や香港を中心に施行されている[20][21]．アプローチとしては軟口蓋を切除して経口的に上咽頭にアプローチする方法や，経鼻腔・経上顎洞的に上咽頭にアプローチする方法が報告されている．その他，副咽頭間隙腫瘍[22][23]や咽頭後リンパ節[24][25]に対する経口的ロボット支援手術や，良性疾患に関しては閉塞性睡眠時無呼吸症候群に対する舌根切除術[26][27]などが報告されている．

　ロボット支援手術を行う際，腹部外科，胸部外科，泌尿器科，婦人科の各領域ではいずれも体壁に小孔をあけて術野にアプローチする必要があるが，咽喉頭領域は経口的にアプローチできるため皮膚に切開を加える必要が

なく，また可動域の広いロボットアームを用いることで解剖学的に狭い咽喉頭領域でも安全かつ確実な操作が可能である．経口的ロボット支援手術は手術支援ロボットのもっとも良い適応の一つであるといえる．本術式は，患者のQOL向上の面から，また入院期間短縮など医療経済の面からも咽喉頭癌に対する本邦での癌治療戦略を大きく変えるものであり，早期の保険収載が必要とされる．

頸部領域のロボット支援手術

　頸部領域において手術支援ロボットが最初に導入されたのは甲状腺手術である．以前より甲状腺に対する鏡視下手術としてさまざまな術式[28]〜[30]が報告されていたが，Kangらは腋窩に皮膚切開を置いて手術支援ロボットの補助下に甲状腺手術を行うrobotic thyroidectomyを報告した[31][32]．これは腋窩の皮膚切開部から胸鎖乳突筋前面の皮下を広く剥離し，胸鎖乳突筋の胸骨枝と鎖骨枝の間を剥離して甲状腺にアプローチする術式である．頸部や胸部に皮膚切開を置くことなく甲状腺手術を行うことが可能であるが，剥離面積が広く低侵襲とはいえないこと，また郭清操作において鎖骨上の操作が困難であるという問題点があった．Terrisら[33]はこれらの問題点を改良した術式として耳介周囲に切開を置くフェイスリフト切開により，頭側から甲状腺にアプローチするrobotic facelift thyroidectomyを報告した．さらに延世大学のKohらのグループ[34]〜[36]はこれを発展させ，フェイスリフト切開あるいは耳後部切開により手術支援ロボットの補助下に頸部郭清術を行うrobotic neck dissection（図3）を報告している．Robotic neck dissectionでは耳後部切開から胸鎖乳突筋周囲の皮下を大きく剥離し，レベルIbの一部とII，III，Va領域の郭清を肉眼的に行った後，レベルIab，IV，Vbの郭清をロボット支援手術下に行う．耳後部の切開をヘアラインの後方で尾側に切り下げることで，術後は皮膚切開線が完全に毛髪に隠れた状態となるため，審美的に非常に優れている．内頸静脈周囲の郭清が鈍的にならざるを得ないという問題点があるものの，胸鎖乳突筋の頭側から尾側まで剥離の方向と郭清の方向が一致しているという点で理にかなった方法である．現在ではこのアプローチと経口的ロボット支援手術を組み合わせ，ロボット支援下に再建手術を行った報告も出てきている[37][38]．すなわち原発巣は経口的ロボット支援手術で摘出し，耳後部切開によりロボット支援下頸部郭清

術を行った後，遊離皮弁と粘膜の縫合を経口的ロボット支援手術により内腔側から行うというもので，一部の症例では血管吻合も手術支援ロボットにより行われている．甲状腺あるいは頸部のロボット支援手術については韓国から非常に多くの報告がなされているが，肥満がある場合には手技的に困難という問題があることもあり，欧米での報告はそれほど多くなく，FDA でも頸部手術・甲状腺手術は未だ承認されていない．
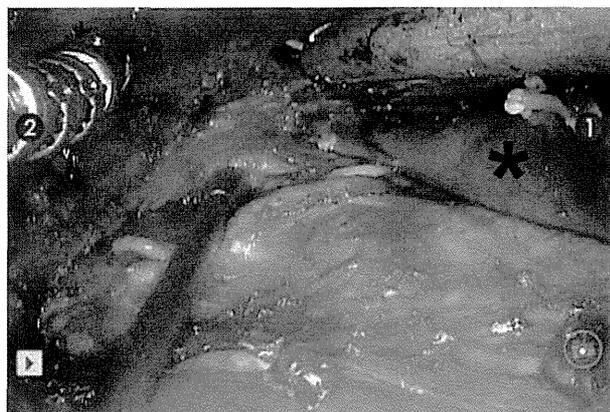

図3　耳後部切開によるロボット支援頸部郭清術（左側）
レベルⅣ郭清終了後．左耳後部の皮膚切開部から 3D 内視鏡アームと 3 本のロボットアームを挿入し，尾側を観察している．（＊：左内頸静脈）
（延世大学 Koh 先生のご厚意による）

国内におけるロボット支援手術の現状

前述のとおりわが国は世界第二のダビンチ保有国であるにもかかわらず，実地臨床での利用は大変遅れている．一般に，医療機器を通常の保険診療で使用するためには，1）医薬品医療機器等法上の承認，2）保険収載，の二つのハードルを越えることが必要である．国内においてダビンチは一般消化器外科，胸部外科，泌尿器科，婦人科の各領域において 2009 年に薬事承認され，その後 2012 年に泌尿器科領域において前立腺悪性腫瘍手術における内視鏡手術用支援機器加算として保険収載されている．消化器外科，呼吸器外科，婦人科領域においては保険収載されたものはなく，現在各領域において保険収載を目指した多施設臨床試験が先進医療 B として行われ，あるいは準備されつつある．耳鼻咽喉科領域は未だ薬事未承認であり，国内耳鼻咽喉科においてロボット支援手術の実施経験をもっているのは京都大学[39]，東京医科大学[40]，鳥取大学[41] の 3 大学のみである．そこで現在，経口的ロボット支援手術の公知申請（適応拡大）を目的として，厚生労働省科学研究費補助金事業「咽喉頭癌に対する経口的ロボット支援手術の安全性・有効性に関する多施設臨床試験」として臨床試験が行われている（図 4）．本臨床試験は京都大学病院臨床研究総合センターの支援の下に，京都大学，東京医科大学，鳥取大学の 3 大学による多施設臨床試験として国際的な治験ルールである ICH-GCP に則り実施されている．対象症例は中・下咽頭癌並びに声門上癌の Tis，T1，T2 症例であり，2014 年 2 月より京都大学において先行試験が開始され，現在
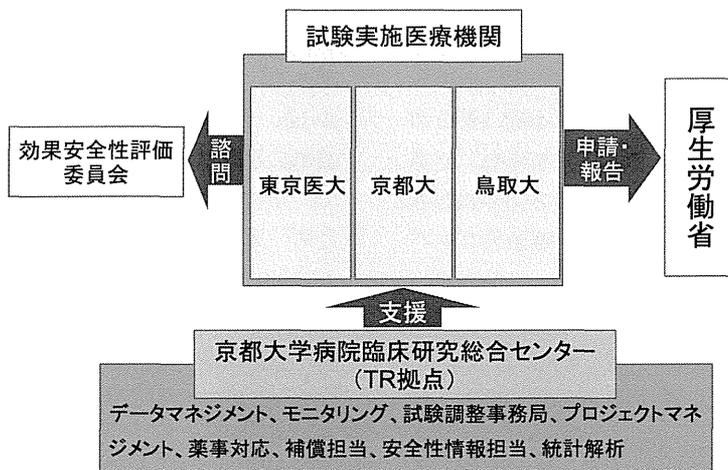

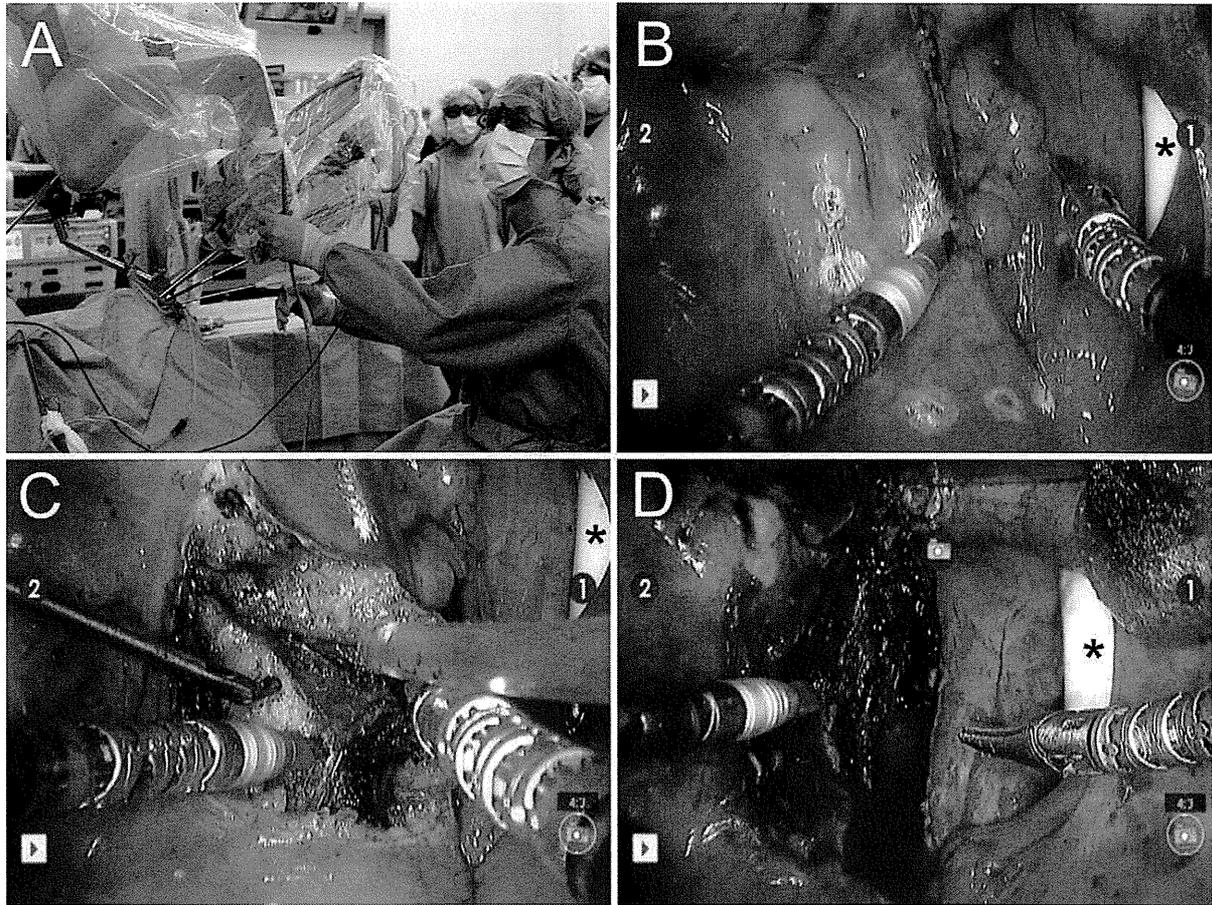**図4**　咽喉頭癌に対する経口的ロボット支援手術の安全性・有効性に関する多施設臨床試験（試験実施体制）

図5　中咽頭癌に対する経口的ロボット支援手術による左拡大扁摘術
　　　A：助手は患者の傍に座り，3Dモニターを観察しながら手術操作を補助する．B：外側は下顎翼突縫線，内側は中咽頭後壁に切開
　　　線を置く．C・D：左口蓋扁桃を咽頭収縮筋で包み，副咽頭間隙の脂肪を温存しつつ一塊として摘出する．（＊：経鼻挿管チューブ）

まで5例が実施されている（図5）．間もなく東京医科大学，鳥取大学においても試験開始予定であり，2017年3月までに計20例を実施し，そのデータにより公知申請が行われる予定である．

　2014年10月に京都大学の「咽喉頭癌に対する経口的ロボット支援手術法」が関西圏の国家戦略特区プロジェクトとして認定された．行政の後押しを得てできるだけ早期に適応拡大を達成したいと考えている．

今後の展望

　ダビンチが世界的に普及した現在，手術支援ロボットとダビンチはほぼ同義になっている．ダビンチは初代ダビンチ，ダビンチS，ダビンチSiを経て，2014年4月にダビンチXiが発売されている．Xiではオーバーヘッ

ドブームや新設計アームにより，アームの取り回しが改善し，アームの交換が容易になっているなど，徐々にバージョンアップされている．しかし，ダビンチそのものが世界的な普及機としては第一世代であり，依然として改善すべき余地を多く残している．徐々に小型化されてはいるものの，ダビンチの本体は非常に大きく，取り回しがしにくい．とくにロボットの鉗子はスタンダードが直径8 mm，経口的ロボット支援手術や小児外科用の細径のものでも直径5 mmと太く，経口的ロボット支援手術においても声門部の操作は困難である．また触覚機能がないため，視覚情報のみに頼らざるを得ない．慣れてくればアームで対象を推した際の移動距離（視覚情報）で対象物の硬さをある程度類推することが可能であり，助手が鉗子を挿入して対象物に触れることでも補うことが

可能であるため，それほど違和感なく手術を遂行できる[42]が，次世代の手術支援ロボットでは触覚を含めたより多くの情報のフィードバックが求められるであろう．

　以上を鑑みると，今後手術支援ロボットが向くべき方向性としては「小型化」，「触覚機能」「ナビゲーション機能」の３点かと思われる．小型化への選択肢の一つとしては複数のアームを利用するのではなく，１本のアーム（ポート）で複数のデバイスを操作できるのが望ましいと思われるが，Intuitive Surgical 社が開発した da Vinci Sp Single Port Robotic Surgical System が 2014 年 4 月にアメリカで FDA の承認を得ている．ポート自体の直径が 2.5 cm とかなり大きいため，耳鼻咽喉科領域に応用するメリットは今のところないが，今後縮小化すれば鼻科，耳科領域に応用可能となろう．またアーム自体が軟性であるスネークロボット[43]や触覚フィードバックを備えたロボット[44]なども開発されつつある．ナビゲーションシステムについては，術前の CT から 3D 画像を再構築し，その画像をロボット支援手術中に術者が見ているサージャンコンソールの 3D モニター上に同期して映し出す console-integrated real-time 3D image overlay navigation が Furukawa ら[45]により泌尿器科領域で臨床応用され，その有用性が報告されている．一方，耳鼻咽喉科領域においては Lalich ら[46]がダビンチの鉗子の先端に繊細な鎌状メスや探索子を接続することで喉頭微細手術への応用を試みている．またわれわれは経口的ロボット支援手術における Narrow Band Imaging（NBI）拡大内視鏡併用の有用性を確認しており[39]，ダビンチと NBI 機能の統合も今後の展望として考えられる．鼻内内視鏡手術への応用に向けた手術支援ロボットについてはすでに複数の施設から報告があり[47]，最少で直径 3 mm のデバイスが報告されている．側頭骨外科への応用を目指した取り組み[48]もなされている．

おわりに

　外科手術の歴史は医療機器の歴史と密接に関係している．1960 年代には手術用顕微鏡が開発され，それにより側頭骨外科，音声外科が大きく発展した．その後 1980 年代には内視鏡が広く普及し始め，現在では鼻副鼻腔手術といえば鼻内内視鏡手術のことをイメージするまでになっている．手術支援ロボットは 2000 年代になって本格的に発展・普及し始めてきたが，今後はロボットの時代である．内視鏡手術を行うには「孔」をあける必要がある他領域に比べ，最初から「孔」があいており，その奥に狭い空間が存在している耳鼻咽喉科領域は，安定した手術操作ができるロボットのメリットが生きる，もっとも良い適応であると考えている．現在はデバイスの大きさの問題があり，経口的アプローチ以外は困難であるが，今後デバイスが小型化されれば耳科手術，鼻科手術にも本格的に応用され普及していくのはほぼ確実であろう．

　わが国特有のデバイスラグの問題により，残念ながら本邦はロボット支援手術の流れに大きく遅れており，ダビンチが耳鼻咽喉科領域へ適応拡大されるのは早くても 2017 年である．FDA での承認から 8 年後となり，その時点からダビンチに関して海外に追いつくのは非常に難しいと言わざるを得ない．しかしその一方，ダビンチは世界的な普及機としてはまだ第一世代であり，手術支援ロボットの分野は今後まだまだ発展する余地を残している．幸いなことにわが国には優れた技術をもった企業が数多くあり，実際ダビンチにも日本の企業の技術が多く使用されている．また，幸か不幸かデバイスラグの問題により，transoral videolaryngoscopic surgery（TOVS）[49][50]や endoscopic laryngo-pharyngeal surgery（ELPS）[51][52]などわが国独自の術式が咽喉頭癌手術において開発され，手術支援ロボットを使わない経口的鏡視下手術として海外でも注目されている．一刻も早く耳鼻咽喉科領域においても適応拡大がなされ，同じ土俵に立つことができれば，手術支援ロボットの第二世代・第三世代においてわが国独自の経験や技術を組み込んだ医療技術を開発・発信することが可能と考える．優れた手術支援ロボットが医師と企業の協力の下で開発され，本邦から世界に普及していくことを念じてやまない．

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