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Original research article

Applying the technology ORBEYE™ exoscope in transoral exoscopic laryngeal surgery: single centre prospective study

Richard Holý [1, 2 a] *, Tomáš Filipovský [1, 2 a], Eva Lukavcová [1], David Kalfeřt [3, 4], Pavol Praženica [5], Petra Dytrych [6, 7], Jiří Hložek [1, 2], Jan Rotnágl [1, 2], Daniel Kovář [1, 2], Jaromír Astl [1, 2]

[1] *Military University Hospital Prague, Department of Otorhinolaryngology and Maxillofacial Surgery, Prague, Czech Republic*
[2] *Charles University, Third Faculty of Medicine, Prague, Czech Republic*
[3] *University Hospital Motol, Department of Otorhinolaryngology and Head and Neck Surgery, Prague, Czech Republic*
[4] *Charles University, First Faculty of Medicine, Prague, Czech Republic*
[5] *University Hospital Limerick, Department of Otolaryngology Head & Neck Surgery, Limerick, Ireland*
[6] *University Hospital Motol, Department of Ear, Nose and Throat, Prague, Czech Republic*
[7] *Charles University, Second Faculty of Medicine, Prague, Czech Republic*

Abstract
Introduction: ORBEYE™ exoscope offers superior visualization with clearer imaging compared to standard methods and supports narrow band imaging (NBI). ORBEYE™ provides better visualization of tissue structures, thus increasing the accuracy of the surgical procedure. The systematic use of ORBEYE™ in transoral exoscopic laryngeal surgery (TOLES) is rarely documented. This study evaluates the sensitivity and specificity of TOLES using ORBEYE™ with white light and NBI modalities.
Methods: Between 8/2021 and 8/2024, 84 patients underwent TOLES using ORBEYE™ with white light and NBI modes. All surgeries were performed in a specialized setting with consistent preoperative and intraoperative imaging protocols.
Results: TOLES using ORBEYE™ was successfully performed in all 84 patients. A statistically significant dependence ($p < 0.001$) was observed between preoperative/perioperative (TOLES) findings and definitive histology for both white light and NBI modalities. ORBEYE™ facilitated detailed imaging of tissue structures and allowed targeted biopsies.
Conclusion: TOLES with perioperative NBI/white light endoscopy achieved a high correlation between pre-histopathological diagnoses and final histopathological results. ORBEYE™ exoscope provides three-dimensional 4K resolution, superior imaging, and improved ergonomics for the surgeon, reducing workload and increasing efficiency. It delivered more efficient surgical team collaboration and experience sharing. The integration of NBI into the TOLES system facilitated accurate navigation and targeting of the biopsy, helping to establish correct definitive diagnosis. TOLES showed more accurate scoring of perioperative NBI findings.

Keywords: Endoscopy; Histopathological results; Laryngeal tumor; Narrow band imaging; ORBEYE; Transoral exoscopic laryngeal surgery

Highlights:
- Prospective study included 84 patients who underwent TOLES using ORBEYE™.
- Compared pre/perioperative (TOLES) white light/NBI endoscopy to histopathological results.
- Statistically significant correlation ($p < 0.001$) for pre/perioperative endoscopy.
- TOLES is a good method for improving the diagnostics of laryngeal lesions.
- ORBEYE™ exoscope facilitated detailed imaging of tissue structures.

Introduction

The ORBEYE™ exoscope (OLYMPUS) has been used in surgical practice since 2017. This technology offers 4K resolution and three-dimensional (3D) imaging (Takahashi et al., 2018). The ORBEYE™ 3D 4K exoscope is an innovative solution for visualizing the surgical field with a clearer visualisation compared to standard imaging. The ORBEYE™ exoscope allows accurate display of anatomical details of tissues. The imaging is virtually lag-free and gives the possibility of up to 26× zoom. The surgical field is displayed on a 55-inch TV monitor in 4K resolution using 3D glasses. The system allows switching between white light and Narrow Band Imaging (NBI) modes. The exoscope is

* **Corresponding author:** Richard Holý, Military University Hospital Prague, Department of Otorhinolaryngology and Maxillofacial Surgery 3rd Faculty of Medicine Charles University and Military University Hospital Prague, U Vojenské nemocnice 1200, 169 02 Prague 6, Czech Republic; e-mail: richard.holy@uvn.cz; http://doi.org/10.32725/jab.2025.010
[a] These authors contributed equally to this research.

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equipped with autofocusing to maintain constant sharpness of the operating field. The technology also offers an optical transfocator function that allows the image to be zoomed in and out. The digital transfocator provides rapid additional image magnification (Amoo et al., 2021; Filipovský et al., 2023, 2024; Göttsche et al., 2022; Rotermund et al., 2021).

Up to now, the use of ORBEYE™ has been reported primarily in neurosurgery (Amoo et al., 2021). The use of exoscope technology in otorhinolaryngology has rarely been reported in the literature (Carlucci et al., 2012; Chebib et al., 2022; Colombo et al., 2021; Kanzaki et al., 2021; Okamoto et al., 2022). Its use in ear surgery, pediatric otorhinolaryngology, and thyroid surgery has been mentioned (Chebib et al., 2022; Colombo et al., 2021; Kanzaki et al., 2021; Okamoto et al., 2022). In 2024, Filipovský et al. (2024) reported the use of the ORBEYE™ exoscope in otorhinolaryngology and thyroid surgery.

Systematic use of ORBEYE™ in transoral exoscopic laryngeal surgery (TOLES) has rarely been reported in the literature (Filipovský et al., 2023, 2024).

Transoral laser microsurgery: the available surgical approach of transoral laser microsurgery (TOLMS) with ORBEYE™ has been commonly used at our department so far. In TOLMS, a conventional microscope is used, and a rigid endoscope can also be used. The 30-degree rigid endoscope is available at our department. When connected to a video chain (Olympus Visera 4K UHD), it can be switched between white light/Narrow band imaging modes.

We published TOLMS and its surgical results in 2023 (Filipovský et al., 2023). We are now using TOLES, so far in parallel with the legacy TOLMS system. The use of exolaryngoscopy was first described by Italian authors Carlucci et al. in 2012. The TOLES system uses a new innovation in laryngeal surgery, the ORBEYE™ exoscope, which replaces the conventional microscope. The exoscope is set above the tube instead of the conventional microscope (Fig. 1). Exoscope: the extracorporeal optical system is positioned approx. 20–30 centimeters from the surgical field. Under exoscopic control, it is possible to use the same instruments through the laryngoscope (Carlucci et al., 2012). Unfortunately, the ORBEYE™ system cannot yet be connected to a CO_2 laser.

The aim of this study was to evaluate the sensitivity and specificity of TOLES using ORBEYE™, using both the white light and NBI modalities.

Materials and methods

This single-centre prospective study was approved by the local Ethics Committee – Reference Number 108/17–29/2022. All patients signed an informed consent form. Over three years, 8/2021–8/2024, 84 patients with laryngeal lesions were included. The group consisted of 31 females and 53 males. The mean age in the group was 57 years (range 24–94 years).

We cross tabulated flexible preoperative endoscopy/transoral exoscopic laryngeal surgery (TOLES) (both modalities white light and NBI) and prehistological working diagnosis, to the results of laryngeal histopathologic outcomes. We used the NBI classification by Ni et al., with the following categorisation: Ni I, II, III – benign lesions, Ni IV – typical view for papilloma, and Ni V – malignant lesions (Filipovský et al., 2023; Lukes et al., 2014; Ni et al., 2011).

All surgeries were performed by senior surgeons (co-authors) at the Military University Hospital Prague.

Fig. 1. The use of ORBEYE™ exoscope in transoral exoscopic laryngeal surgery (TOLES) (from the first author's archive)

Inclusion criteria:
- Age over 18 years.
- Pathological preoperative laryngeal lesions.
- Applying transoral laser exoscopic surgery with ORBEYE™ (OME – V200 by Olympus) including NBI mode.

Exclusion criteria:
- Age below 18 years.
- Non-pathological preoperative laryngeal findings.
- Lack of perioperative Narrow Band Imaging (NBI) mode.

Investigation algorithm:
1. Flexible preoperative NBI endoscopy (Olympus Exera II); white light endoscopy and NBI classification: vascularity grading scale according to Filipovský et al. (2023), Lukes et al. (2014), and Ni et al. (2011). On NBI examination, the grade IV finding was considered suspicious for papilloma. On NBI examination, a grade V finding was considered suspicious for malignancy. On white light examination, clinical findings of "suspicious" and "very suspicious" were used as suspicious for malignancy for statistical evaluation – Table 1 (Filipovský et al., 2023).
2. Perioperative transoral laser exoscopic surgery (TOLES) with ORBEYE™ including narrow band imaging mode and white light mode. NBI classification: scale for vascularization evaluation according to Ni et al. (2011). On the NBI examination, a grade IV finding was considered suspicious for papilloma. On the NBI examination, a grade V finding was considered suspicious for malignancy. White light: for statistical evaluation, the clinical findings of "suspicious" and "very suspicious" were used as suspicious of malignancy – Table 1 (Filipovský et al., 2023).
3. Collection of histopathological samples.
4. Determination of working diagnoses: benign or premalignant or malignant mucosal laryngeal pathologies.

5. Comparison of histopathological results with the working diagnoses.

Statistical analysis was performed using IBM SPSS Statistics (version 22.0; SPSS, IBM, Armonk, NY, USA) and MedCalc Software Ltd. Diagnostic test evaluation calculator was used – https://www.medcalc.org/calc/diagnostic_test.php (Version 20.211; accessed January 9, 2023).

Results

TOLES using ORBEYE™ was successfully performed in all 84 patients.

a) White light mode

Data analysis of TOLES using ORBEYE™ exoscope and white light mode:

- Preoperatively (flexible preoperative endoscopy), 48 (57.1%) cases were classified non-suspicious, 19 (22.6%) cases were suspicious, and 17 (20.2%) cases were very suspicious by white light.
- Perioperatively (TOLES), 54 (64.3%) cases were classified as non-suspicious, 15 (17.9%) cases were suspicious, and 15 (17.9%) cases were very suspicious by white light.

Data analysis showed a statistically significant dependence ($p < 0.001$) between preoperative flexible endoscopy using white light and final histopathological results.

Data analysis suggested a statistically significant dependence ($p < 0.001$) between perioperative TOLES using white light and final histopathological results (Table 1).

b) NBI mode

Data analysis of TOLES using ORBEYE™ exoscope and NBI mode:

- Preoperatively (flexible preoperative endoscopy), 7 (8.3%) cases were classified Grade I, 27 (32.1%) cases were classified Grade II, 25 (29.8%) cases were classified Grade III, 17 (20.2%) cases were classified Grade IV, and 8 (9.5%) cases were classified V using NBI.
- Perioperatively (TOLES), 4 (4.8%) cases were classified Grade I, 30 (35.7%) cases were classified Grade II, 27 (32.1%) cases were classified Grade III, 14 (16.7%) cases were classified Grade IV, and 9 (10.7%) cases were classified V using NBI.

Data analysis showed dependence ($p < 0.001$) between preoperative flexible endoscopy using NBI mode and final histopathological results.

Data analysis suggested a statistically significant dependence ($p < 0.001$) between perioperative TOLES using NBI mode and final histopathological results (Table 2).

Table 1. Cross tabulation – definitive histopathological results vs preoperative/perioperative (TOLES) white light mode

White light evaluation		Definitive histopathological results					
		Benign		Malignant		Total	
		Count	Row *N* %	Count	Row *N* %	Count	Row *N* %
Preoperative	non-suspicious	48	100.0%	0	0.0%	48	100.0%
	suspicious	18	94.7%	1	5.3%	19	100.0%
p-value < 0.001	very suspicious	7	41.2%	10	58.8%	17	100.0%
Perioperative (TOLES)	non-suspicious	54	100.0%	0	0.0%	54	100.0%
	suspicious	14	93.3%	1	6.7%	15	100.0%
p-value < 0.001	very suspicious	5	33.3%	10	66.7%	15	100.0%

Table 2. Cross tabulation – definitive histopathological results vs preoperative/perioperative (TOLES) NBI mode

NBI evaluation		Definitive histopathological results					
		Benign		Malignant		Total	
		Count	Row *N* %	Count	Row *N* %	Count	Row *N* %
Preoperative	I	7	100.0%	0	0.0%	7	100.0%
	II	26	96.3%	1	3.7%	27	100.0%
	III	23	92.0%	2	8.0%	25	100.0%
p-value < 0.001	IV	17	100.0%	0	0.0%	17	100.0%
	V	0	0.0%	8	100.0%	8	100.0%
Perioperative (TOLES)	I	4	100.0%	0	0.0%	4	100.0%
	II	30	100.0%	0	0.0%	30	100.0%
	III	24	88.9%	3	11.1%	27	100.0%
p-value < 0.001	IV	14	100.0%	0	0.0%	14	100.0%
	V	1	11.1%	8	88.9%	9	100.0%

The definitive histopathological findings detected 73 (86.9%) benign and 11 (13.1%) malignant laryngeal lesions.

The diagnostic success rate of white light and NBI for malignancy detection in relation to the time of performance was calculated using Confusion Matrix Analysis and is described in Table 3.

The sensitivity and specificity for the preoperatively performed white light examination were 100.00% and 65.75%, respectively. For the preoperatively performed NBI examination they were 72.73% and 100.00%, respectively. The sensitivity and specificity for the perioperative white light examination were 100.00% and 73.97%, respectively. For the perioperatively performed NBI examination they were 72.73% and 98.63%, respectively (Table 3).

Table 3. The diagnostic success rate of NBI and white light for malignancy detection in relation to the time of performance

Light mode (flexible endoscopy)	White light preoperative		NBI preoperative	
Statistic	Value	95% CI	Value	95% CI
Sensitivity	100.00%	71.51% to 100.00%	72.73%	39.03% to 93.98%
Specificity	65.75%	53.72% to 76.47%	100.00%	95.07% to 100.00%
Positive likelihood ratio	2.92	2.12 to 4.01		
Negative likelihood ratio	0.00		0.27	0.10 to 0.72
Disease prevalence (*)	13.10%	6.72% to 22.22%	13.10%	6.72% to 22.22%
Positive predictive value (*)	30.56%	24.25% to 37.68%	100.00%	63.06% to 100.00%
Negative predictive value (*)	100.00%	92.60% to 100.00%	96.05%	90.26% to 98.46%
Accuracy (*)	70.24%	59.27% to 79.73%	96.43%	89.92% to 99.26%
Light mode (TOLES)	White light perioperative		NBI perioperative	
Statistic	Value	95% CI	Value	95% CI
Sensitivity	100.00%	71.51% to 100.00%	72.73%	39.03% to 93.98%
Specificity	73.97%	62.38% to 83.55%	98.63%	92.60% to 99.97%
Positive likelihood ratio	3.84	2.61 to 5.66	53.09	7.33 to 384.48
Negative likelihood ratio	0.00		0.28	0.11 to 0.73
Disease prevalence (*)	13.10%	6.72% to 22.22%	13.10%	6.72% to 22.22%
Positive predictive value (*)	36.67%	28.23% to 46.01%	88.89%	52.49% to 98.30%
Negative predictive value (*)	100.00%	93.40% to 100.00%	96.00%	90.14% to 98.44%
Accuracy (*)	77.38%	66.95% to 85.80%	95.24%	88.25% to 98.69%

Note: (*) These values are dependent on disease prevalence [confidence intervals (CI)]

Discussion

The first use of exolaryngoscopy was described in 2012 (Carlucci et al., 2012). The use of exoscopic techniques including the ORBEYE™ system in Otorhinolaryngology and Head & Neck surgery has been described in several studies. The systematic use of the ORBEYE™ exoscope in laryngeal surgery (TOLES) has not been published so far. Recently, Filipovský et al. (2024) reported on the use of the ORBEYE™ exoscope in laryngeal surgery in the Czech Republic.

Japanese authors published a case report on the use of the ORBEYE™ exoscope. They performed successful transoral laser surgery of congenital pyriform sinus fistula in a child (Okamoto et al., 2022).

Several (mainly Italian) studies have been reported in the literature addressing the use and feasibility of laryngeal surgery using other exoscopic systems (e.g., VITOM® 3D-HD) in TOLES (Cantarella and Pignataro, 2024; Carobbio et al., 2021; De Virgilio et al., 2022; Marchi et al., 2024; Piazza et al., 2024). The Italian authors reported that when comparing the use of TOLES (using the VITOM® 3D-HD exoscope) and TOLMS methods, no significant differences were found when evaluating the duration of surgery, positive margins, or complications. Assessment of ergonomics during surgery showed less biomechanical overload with TOLES compared to TOLMS. Exoscopic technology finds application in transoral laser-assisted laryngeal surgery where it facilitates minimally invasive procedures by combining shared high-quality and magnified images with 3D visual perception. The advantages of TOLES are higher didactic value, better digital light control through small aperture laryngoscopes, improved binocular vision, and increased surgical performance using multi-sight techniques. However, these advantages are difficult to quantify (Piazza et al., 2024). Exoscopic surgery has progressively evolved, and TOLES represents one of the most promising applications of this new technology in the field of transoral resection of laryngeal lesions. Exoscopy is a promising alternative to traditional microscopic techniques (Piazza et al., 2024).

Carobbio et al. (2021) reported that the exoscopic surgical setting (VITOM® 3D-HD) was a convincing alternative to traditional TOLMS for early to intermediate pharyngo-laryngeal neoplasms. It is a natural evolution of the traditional technique (Carobbio et al., 2021). Marchi et al. (2024) compared TOLES and TOLMS groups in laryngeal carcinomas. No significant differences were observed between the two subgroups.

The University of Washington quality of life questionnaires and dysphonia assessment using the Voice Handicap Index-10 were used.

Another Italian study reported the use of the exoscope in phonosurgery. It describes the advantages of the system, especially in the era of the Covid-19 pandemic. It was pointed out that it was not necessary to place the surgeon's eyes on the ocular, and surgeons could wear full-face cover (Cantarella and Pignataro, 2024).

Our experience with TOLES using ORBEYE™ exoscope is as follows: accurate display of multiple anatomical details and tissue structure and the use of a 3D 4K imaging chain. Imaging was delay-free up to 26× magnification. The system offers white light mode switching/NBI modus. The system provides a comfortable upright position of the surgeon's body, ocular lens-free surgery, and flexible adjustment of the exoscope arm position. In laryngeal surgery, this technology, along with the use of the NBI modus, increases the accuracy of navigated biopsy or tissue resection. The technology supports the participation of the complete surgical team and the sharing of experiences with other team members during surgery (Filipovský et al., 2023, 2024).

We compared data from this study (TOLES) for NBI findings of Ni II+III preoperatively/perioperatively versus definitive histopathological findings. We found that preoperative "incorrect" assessment of Ni II+III findings was present in 3 of 52 (5.8%) subjects. In those, SCC of the larynx was detected in the final result. Perioperatively (TOLES), this "incorrect" assessment was found in 3 of 57 subjects (5.3%). In those, SCC of the larynx was found in the final outcome.

In contrast, in our previous study (TOLMS) in 2023 (Filipovsky et al., 2023), this "incorrect" assessment of NBI Ni II+III findings was found in 3 of 44 (6.8%) (preoperative endoscopy) and 3 of 46 (6.5%) (TOLMS). The assessment was based on a comparison of NBI findings with the final histopathological result.

When analyzing Ni IV laryngeal NBI findings in this TOLES study, we detected the following results in preoperative endoscopy: from the 17 cases included in Ni IV, 15 cases (i.e., 88.2%) were confirmed as papilloma on histopathological examination, 2 (i.e., 11.8%) corresponded to benign lesions, and none were malignant.

The perioperative (TOLES) evaluation of Ni IV findings revealed the following results: from the 14 Ni IV findings, 13 cases (92.9%) corresponded to histopathological findings of papilloma, 1 case (7.1%) corresponded to histopathological findings of benign lesions, and none (0%) corresponded to histopathological findings of malignant lesion.

We conducted new and detailed analysis of previous TOLMS study data from 2023 concerning NBI findings of Ni IV (Filipovský et al., 2023). We detected the following results in preoperative endoscopy: from the 12 Ni IV findings, 9 cases (75%) corresponded to histopathological findings of papilloma, 2 (16.7%) corresponded to the histopathological finding of a benign lesion, and 1 case (8,3%) corresponded to the histopathological finding of a malignant lesion.

The perioperative (TOLMS) evaluation of the Ni IV finding revealed the following results: from the 11 Ni IV findings, 9 cases (81.8%) corresponded to histopathological findings of papilloma, 2 (18.2%) corresponded to the histopathological finding of a benign lesion, and none (0%) corresponded to the histopathological finding of a malignant lesion.

The above analysis shows that the "correct" evaluation of NBI Ni IV findings is more accurate with TOLES (93%) compared to conventional TOLMS (82%).

However, it should be noted that the limitation of NBI classification should also be taken into account. When comparing the analysis of other aspects of TOLES and TOLMS surgical procedures (Filipovský et al., 2023) at our institution, it can be concluded that both methods are comparable. The sensitivity/specificity of TOLES versus TOLMS was similar: TOLES white light mode 100%/74% versus TOLMS white light mode 100%/64%; TOLES NBI mode 73%/99% versus TOLMS NBI mode 77%/96% (Filipovský et al., 2023).

Regarding limitations, we suggest that more studies should be performed to objectively compare both TOLES and TOLMS methods and to confirm the results regarding TOLES using the ORBEYE™ exoscope (De Virgilio et al., 2022; Filipovský et al., 2023, 2024; Jurovčík et al., 2024; Piazza et al., 2024). The next expected step could be to link TOLES using artificial intelligence – AI (Filipovský et al., 2023).

AI and selectively applied optical biopsy methods can improve diagnostic accuracy in endoscopy and reduce the time delay for early detection and treatment of laryngeal cancer (Hu et al., 2025).

Another limitation of TOLES with the ORBEYE™ exoscope might be the high cost of the whole equipment and the impossibility of connecting a CO_2 laser.

Conclusion

The use of TOLES with perioperative NBI/white light endoscopy indicated very significant dependence ($p < 0.001$) between the pre-histological working diagnosis and the final histopathological results. The ORBEYE™ exoscope provides high resolution and imaging of laryngeal tissues in TOLES. The advantages of the ORBEYE™ system are the natural position of the surgeon's body during surgery, lens-free surgery, and unlimited operating space. The system allows the entire surgical team to participate in the surgical procedures and pass on their experience to other colleagues. 4K 3D resolution and the use of NBI mode in TOLES enables targeted, navigated peri-operative biopsies. TOLES showed more accurate scoring of perioperative NBI findings than TOLMS.

Author contributions

All authors contributed to the conception and design of the study. All authors have read and agreed to the published version of the manuscript. All authors gave their consent for publication. Conceptualization, *R.H., T.F., E. L., P.D., D.Ka.* and *J.A.*; validation, *J.R. D.Ka., P.P., J.H., E.L., P.D., J.R.* and *R.H.*; investigation, *R.H. T.F., E.L.* and *D.Ko.*; resources, *R.H., T.F., D.Ka., P.P., E.L., D.Ko.* and *J.A.*; data curation, *T.F., R.H., D.Ka., J.H., P.D.* and *J.R.*; formal analysis, *R.H., J.H., D.Ko., D.Ka.* and *J.R.*; writing – original draft preparation, *R.H., T.F., P.P.* and *D.Ka.*; writing – review and editing, *R.H., T.F., D.Ko., P.P., P.D.* and *D.Ka.*; visualization, *R.H., P.D., E.L., D.Ko., J.H., J.R.* and *T.F.*; supervision, *R.H., T.F.* and *J.A.*; project administration, *R.H., J.A.* and *T.F.*; funding acquisition, *R.H.* and *J.A.*

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Ethical aspects and conflict of interest
The authors have no conflict of interest to declare.

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