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Preclinical implementation of a steerable, Da Vinci Xi® compatible CO_2-laser fibre carrier for transoral robotic surgery (TORS): A cadaveric feasibility study

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Abstract

Introduction: Monopolar electrocautery is the most common dissection and coagulation tool during transoral robotic surgery (TORS) but causes significant collateral tissue damage as opposed to CO_2 laser. We aimed at combining both modalities in one robotic instrument arm.

Methods: We developed a steerable CO_2-laser fibre carrier serving as an add-on to the existing Endowrist® monopolar spatula of the Da Vinci Xi. Feasibility and safety were assessed in a preclinical setting.

Results: One radical tonsillectomy with monopolar cautery and three with the instrument prototype were performed in two cadavers by two surgeons. No serious prototype-related intra-operative difficulties were observed. Safe and efficient switching between energy sources proved possible in all simulated intra-operative bleeding events. Prototype use allowed for the identification of the majority of key anatomical structures and was scored favourably on NASA-TLX questionnaires.

Discussion: The reported prototype successfully combines the advantages of CO_2-laser with the advantages of TORS

KEYWORDS
Da Vinci Xi system, feasibility, head and neck cancer, laser surgery, TORS, transoral robotic surgery

1 | INTRODUCTION

Introduced in 2006, transoral robotic surgery (TORS) is established as a treatment option with good oncological and functional outcomes for selected malignancies in the upper aero-digestive tract.[1–6] Moreover, primary TORS is a more cost-effective treatment modality than primary radio(chemo)therapy in early stage oropharyngeal cancer.[7–9] The most used robotic system, Da Vinci (Intuitive Surgical Inc.), provides the surgeon with a three-dimensional view of the operating field and with excellent dexterity, thanks to the combination of endo-wristed instruments with seven degrees of freedom (DOF) and the elimination of physiological tremor.[10] In this way, TORS enables the surgeon to adhere to the oncological principle of en-bloc tumour resection, avoiding piecemeal resection, thus facilitating histopathological assessment of the tumour and surgical margins. This is in contrast to the piecemeal resection that results from the longer existing and competing technique of transoral laser microsurgery (TLM). During TLM, tumours are removed through a narrow laryngo- or oropharyngoscope under a microscopic view by a micromanipulator-controlled CO_2-laser fixed to the microscope, resulting in a tangential-only cutting plane ('line-of-sight' issue).[11]

Electrocautery is incorporated in the da Vinci system as a monopolar spatula or monopolar scissors, mounted on one of the robotic arms, and is the most commonly used surgical cutting and

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haemostatic tool for TORS. However, when compared to a CO_2-laser, monopolar cautery causes significantly more collateral tissue damage as well as specimen coagulation, which complicates margin assessment,[12,13] besides a well-known and cumbersome 'tissue coagulate sticking' to the spatula tip, which frequently has to be removed intra-operatively, in order to be able to perform fine dissection. CO_2-laser initially could not be used in TORS as it needed to be fixed to a microscope, but since the introduction of flexible hollow wave guides, this technology can be added to the robotic technology. Advantages over electrocautery are (1) a more precise cutting, (2) effective haemostasis of vessels of 0.5 mm or less, (3) lymphatic sealing by laser, preventing tumour spread and (4) a reduced thermal injury resulting in less postoperative oedema.[11,14] The feasibility of adding flexible CO_2-laser technology to the da Vinci platform was first demonstrated in 2007 in cadaver and animal models by Solares et al., followed by human use in 2007.[14,15] To date, however, the only commercially available solution to introduce and manipulate the CO_2-laser fibre during TORS consists of a drop-in guide which can be grabbed by the robotic needle driver.[16] This device is not very popular, as the drop-in guide cannot be combined with the Da Vinci monopolar spatula (while occupying its robotic arm). Consequently, when the surgeon is confronted with bleeding from vessels with a diameter of more than 0.5 mm during CO_2-laser TORS, haemostasis relies on the assistant surgeon at the head of the table by means of for example, a suction cautery device or haemostatic clips, which can be especially difficult when bleeding arises deep in the aerodigestive tract (e.g. hypopharyngeal location). An alternative, but time consuming option is to interrupt the surgery and switch the needle driver for a monopolar spatula. Moreover, the drop-in guide—needle driver combination is not suitable for blunt dissection, which is an essential feature of the monopolar spatula during TORS. Taking these limitations of the current CO_2-laser application for TORS into account, we developed a controllable add-on CO_2-laser fibre carrier, which is compatible with the existing Da Vinci Xi Endowrist® monopolar spatula and which is the first in its kind. This solution theoretically combines the coagulation advantages of the monopolar spatula with the superior cutting properties and minimal collateral damage to the surrounding healthy tissue of the CO_2-laser fibre. This paper reports on a preclinical cadaveric feasibility study that assesses performance and safety of the developed prototype during TORS radical tonsillectomy.

2 | MATERIALS AND METHODS

2.1 | Instrument development and design

We identified an existing need for a modular device combining a CO_2-laser fibre with the existing Da Vinci Xi Endowrist® monopolar spatula, together with an intuitive control to switch quickly between both laser and monopolar energy modalities and without having to reload the robotic arm. As such, the objective was to augment an existing single-function instrument (monopolar spatula) to a multi-function instrument, including a CO_2-laser fibre. As a start, surgeons and engineers worked closely together to conduct a workflow analysis of TORS. A number of relevant TORS interventions were organized by the surgeons and attended by the engineers. A Workflow Integration Matrix (WIM)[17] was constructed, including a detailed scenario of a TORS intervention broken down into logical steps as well as a detailed risk analysis. From this analysis the requirements with respect to the instrument's functioning and its integration in a clinical setting were formalized. After these initial steps, surgeons and engineers collaborated closely in instrument development, including conceptual design with definition of requirements and possible constraints upon the instrument, finally leading to an instrument concept which was prototyped. The prototype is designed as a Da Vinci Xi compatible add-on, which can be installed on the monopolar spatula in the operating room immediately before surgery and removed after surgery. Its modular design includes a segment which is slid over the shaft of the monopolar spatula, containing a McKibben pneumatic muscle and return spring, which are both fastened to the CO_2-laser fibre and controlling a bi-directional axial translation (retraction and protraction) of the fibre relative to the monopolar spatula tip upon contraction and relaxation of the McKibben muscle respectively. A two DOF 'tip guide', made of PerFORM™, a proprietary polymer patented by Materialise NV characterized by excellent friction and stiffness properties, is secured on the distal tip of the monopolar spatula with a set screw, and steers the distal part of the CO_2-laser fibre, allowing for smooth re- and protraction during TORS (Figure 1). As such, no definitive modifications to the Da Vinci instruments are necessary, which is an important feature of this design, as the robotic platform is shared between many surgical specialties. Additionally, the 'add-on' principle of the prototype avoids interference with robotic instrument cleaning and sterilization. Moreover, the prototype parts are suitable for ethylene oxide sterilization and can be constructed as a disposable solution.

The bi-directional translation is controlled by a foot pedal which allows switching between three different positions of the laser fibre tip relative to the monopolar spatula tip:

1. Fully retracted position: the laser fibre tip is retracted to a position well behind the monopolar spatula tip, allowing the monopolar spatula to be used for cutting/cauterization and/or blunt dissection.
2. The intermediate position: the laser fibre tip is protracted to a position 2 mm behind the monopolar spatula tip, allowing to use the laser fibre for cutting. As CO_2-laser fibre cutting properties are optimal when the distance between the laser fibre tip and the tissue is approximately 2 mm, gently touching the tissue during surgery with the spatula tip automatically indicates the optimal distance between laser tip and tissue. After all, the monopolar spatula gives better visual feedback during surgery compared to the very thin and almost transparent laser fibre. Even with the three-dimensional view of the robot, it is not easy for the surgeon to have an accurate intra-operative estimation of the distance

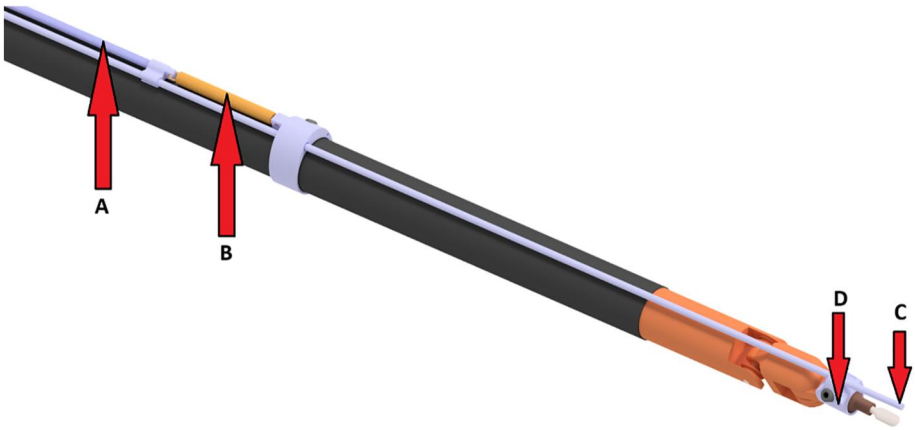

FIGURE 1 Initial instrument conceptual design, which allows for combining the Da Vinci Xi Endowrist® monopolar spatula with the CO_2-laser fibre integrated into a modular add-on. The McKibben muscle/return spring complex is fastened to the CO_2-laser fibre and controls the retraction and protraction of the laser fibre relative to the monopolar spatula tip. A 'tip guide' facilitates the distal part of the CO_2-laser fibre and allows for smooth retraction and protraction (A = McKibben muscle, B = return spring, C = CO_2-laser fibre, D = tip guide, DOF = degree of freedom)

between laser tip and tissue. As such, this configuration is considered very helpful to maintain the optimal laser tip-tissue distance during surgery. This configuration is ideal when operating with a straight monopolar spatula; bending the distal tip of the monopolar spatula during surgery will inevitably lead to changes in the relative distance between laser tip and spatula tip, nullifying the above mentioned advantage of this configuration.

3. Fully protracted position: the laser fibre tip is protracted to a position well in front of the monopolar spatula tip, allowing to use the laser fibre during extreme positions of the spatula tip.

Thereafter, surgeons and engineers set up relevant pre-clinical experiments using a Da Vinci Xi, CO_2-laser fibre and the instrument prototype to retrieve missing information and to verify and validate the developed technology. These preclinical experiments, which focused on installation of the instrument in the operating room setting, movements in free space, switching between laser fibre and monopolar cautery and applying laser and monopolar energy on natural tissue (chicken breast) identified shortcomings in the initial prototype, leading to improvements and evolution towards an updated prototype which was deemed ready for a feasibility study on a cadaveric model.

2.2 | Preclinical feasibility study on a cadaveric model

The feasibility and safety of the instrument prototype were tested in a preclinical setting in two male human fresh-frozen cadavers at the ORSI academy for robotic surgical training (Melle, Belgium). The patient cart of the Da Vinci Xi robot (Intuitive Surgical Inc.) was positioned on the cadaver's left side and was equipped with a 0° robotic camera placed in the midline (arm 3), an 8 mm EndoWrist® Maryland atraumatic forceps (arm 2 for a right-sided procedure or arm 4 for a left-sided procedure) and the EndoWrist® monopolar spatula combined with the instrument prototype in the remaining (third) arm. Arm 1 was kept in a stowed position. Opposed to the Maryland forceps and the robotic camera, which are both introduced through an 8 mm trocar, the increased diameter of the monopolar spatula/CO_2-laser complex necessitated introduction through a 12 mm trocar equipped with a custom-made 3D printed reducer, made out of polyamide. The instrument prototype's CO_2-laser wave guide (Lumenis) is a hollow glass waveguide with an internal core of 500 μm and outer diameter of 1040 μm. The inner surface is coated with a metallic silver layer and innermost silver iodide layer acting as a reflective mirror. The glass tube has an external biocompatible coating.[18] The fibre was connected to the CO_2-laser energy source (AcuPulse Duo) and laser settings were: superpulse mode, 7–15 W, continuous delivery. A Feyh–Kastenbauer retractor (Gyrus ACMI) was used to achieve transoral exposure. An assisting surgeon was seated at the head of the cadaver with a Yankauer suction device in order to evacuate smoke, assist with dissection and control the pro- and retraction of the laser fibre by pushing the foot-pedal switch on command of the surgeon seated at the console. The TORS procedure performed in the cadaveric model was a radical tonsillectomy as described by Weinstein et al.[19] In the first cadaver, a radical tonsillectomy was performed with the classic monopolar spatula at one side and with the monopolar spatula/CO_2-laser combination at the contralateral side by the same (junior) surgeon (JM). In the second cadaver, a radical tonsillectomy was bilaterally performed with the experimental set-up, one side by a senior surgeon (VVP) and the other side by a junior surgeon (JM). Every TORS procedure was objectively quantified by a third observer (EVP, TV, MO) by means of time registration, peroperative identification of key anatomical structures (pterygoid muscle, styloglossal and stylopharyngeal muscles, pharyngeal constrictor muscle, descending palatine artery, tonsillar branch of facial artery) and registration of peroperative difficulties. Difficulties which were encountered intra-operatively were quantified as modest (prolonging surgery without procedure

interruption), moderate (procedure interruption without potentially negative consequences for the patient) and severe (definitive device failure with potentially negative consequences for the patient and/or definitive interruption of the procedure). The switching process between CO_2-laser and monopolar spatula was evaluated intra-operatively by simulation of five to six bleeding events initiated at random points in time by the main surgeon. On his command, the assistant surgeon retracted the laser fibre and the monopolar spatula was used to coagulate the simulated bleeding focus. Times between the given command and the application of monopolar energy/declared stop of bleeding were registered. In order to measure the impact of the prototype-use on the surgeon's workload and performance, the NASA-Task Load Index (NASA-TLX) was completed by both surgeons for every procedure. The NASA-TLX is a tool for measuring and conducting a subjective mental workload assessment and rates performance across six dimensions: mental demand, physical demand, temporal demand, effort, performance and frustration level.[20] This validated tool has been used across professions, including healthcare, to quantify the demand on users and has been adapted for surgery.[21,22] The surgeons were asked to rate their score on an interval scale ranging from low (1) to high (20), with higher scores representing higher demands. The collected data were analysed by descriptive statistics. Laser-cautery switching times were compared between procedures using the nonparametric Kruskal–Wallis test. Prior, non-normal distribution of registered switching times was confirmed with a Shapiro–Wilk normality test.

3 | RESULTS

3.1 | Time registration of TORS procedures: single monopolar versus prototype

Total operative time for the classic radical tonsillectomy with monopolar cautery performed by the junior surgeon was 12 min 58 s. Registered times for the prototype radical tonsillectomies were 40 min 21 s (junior surgeon, first attempt), 15 min 9 s (junior surgeon, second attempt) and 17 min 39 s (senior surgeon, first attempt). These times suggest a quick adaptation of both surgeons to prototype use during TORS with resulting good performance. However, it needs to be taken into account that modest difficulties related to the switching-process negatively influenced duration of the first procedure performed by the prototype (cfr infra).

3.2 | Peroperative difficulties

Modest peroperative difficulties related to the exposure and/or robot were: interference of the monopolar spatula with the mandible ($n = 2$) and 'chopsticking' of the instrument arms ($n = 1$). Two modest recurrent difficulties related to the instrument prototype were identified, both influencing the switching–process between laser-fibre and monopolar spatula. First, the bi-directional axial translation of the laser fibre proved not possible when the monopolar spatula tip was in a significantly deviated position relative to the neutral position, due to friction of the bent laser fibre in the distal 2DOF guide ('tip ring'). Growing experience by the surgeon during the experiments learned that straightening the monopolar spatula tip before inducing re-or protraction of the laser fibre solved this issue. Second, switching between retracted/protracted positions by pushing the foot pedal took time to get accustomed to by the assistant surgeon during the first procedure, as he did not have unambiguous visual feedback on the fibre's tip position relative to the monopolar spatula tip. Both difficulties related to the switching process negatively influenced surgical time and switching times during the first procedure performed using the prototype. One moderate peroperative difficulty related to the robot was failure of a component of the distal tip of the Endowrist® monopolar spatula which was not noticed at the time of applying the add-on laser fibre before starting the surgery; this only became clear after starting the surgery, observing a free and uncontrolled rotation of the distal spatula tip, the fibre connector and the fibre. This did not make the manipulation impossible, but surely contributed to the longer duration of the first add-on surgery. The monopolar spatula was therefore renewed for the following procedures. Three modest peroperative difficulties related to the prototype were encountered: in 2 different procedures, the laser fibre slipped out of the 'tip ring' during extreme positions of the monopolar spatula while having the laser in fully retracted, inactive position, necessitating a short intervention interruption and manual replacement of the laser fibre through the tip ring. Additionally, during the first prototype procedure, the laser fibre migrated towards a position too much anteriorly relative to the monopolar spatula tip when being in the fully protracted position. Both difficulties were due to insufficient fixation of the add-on on the shaft of the monopolar spatula. This necessitated a short intervention interruption during which the add-on's position on the shaft was adjusted and fixed more tightly. No serious intra-operative difficulties related to the prototype and leading to definitive failure of the instrument or potentially negative consequences for a patient were observed during the reported experiments.

3.3 | Switching between CO_2-laser and monopolar cautery

Safe and efficient switching between energy sources by successfully retracting the laser fibre and subsequently applying monopolar energy until declared stop of the imaginary bleeding proved possible in all 17 simulated intra-operative bleeding events. Mean and median switching times were 8 and 6 s respectively (range 3–22 s, SD 5.6 s). Mean switching time was significantly longer during the first prototype-radical tonsillectomy (13.9 s) compared to the second procedure (7.3 s) and third procedure (6.6 s) (Kruskal–Wallis test, $p = 0.032$). The significantly longer switching times during the first procedure can be explained by the intra-operative difficulties influencing the switching process (cfr supra).

3.4 | Identification of key anatomical structures

Key anatomical structures were all identified during the classic radical tonsillectomy with monopolar spatula and during one radical tonsillectomy performed by the instrument prototype. During the remaining two prototype radical tonsillectomies, four out of six anatomical landmarks were identified, with the missed key structures being pterygoid muscles and tonsillar branch of the facial artery in one case and pterygoid muscles and descending palatine artery in the other.

3.5 | Results of NASA-TLX questionnaires: single monopolar versus prototype

Table 1 depicts the results of NASA-TLX questionnaires for different procedures and different surgeons. Scores on mental, physical and temporal demand as well as on performance were favourable after all prototype procedures. Especially performance was scored very well (2-3-3 vs. 5 for the classic TORS procedure) and was related to the high surgeon's satisfaction with the surgical result. Scores on effort and frustration were higher during the first prototype procedure, due to the abovementioned issues of suboptimal switching between laser and monopolar, but normalized during the second and third prototype procedure.

4 | DISCUSSION

Currently, monopolar energy remains the most widely used dissection and coagulation tool during TORS.[11] However, as electrocautery is widely recognized to cause significant collateral tissue damage when compared to CO_2-laser, implementation of CO_2-laser technology during TORS could be of substantial benefit. It has been shown by Liboon et al. on oral mucosa of swines that the acute width of injury for incisions is greater with monopolar electrocautery than with CO_2-laser. Moreover, the CO_2-laser was considered to provide the best combination of ease of use, haemostasis of small vessels and lack of tissue injury in comparison to scalpel and electrocautery.[13] Comparing human tongue tissue samples that were resected using a CO_2-laser or an electrotome, Matsumoto et al. observed a similar frequency of thermal denaturation patterns (carbonization, vacuolar degeneration and elongation of nuclei) between the different modalities, but the range of thermal artefacts caused by the CO_2-laser (269 μm, SD = 38.72) in pulse wave mode was significantly smaller than the range of artefacts caused by the electrotome (373 μm, SD = 56.77, $p < 0.001$).[23] This is explained by the fact that the thermal energy of the CO_2-laser is absorbed strongly by water, resulting in heating of a concentrated area very near to the incision. The electrotome's heat, on the other hand, is spread more evenly in the surrounding tissues in all directions.[23] As a result, the CO_2-laser is considered superior to the electrotome for tumour resections, as the fine tissue cutting and reduced thermal artefacts in CO_2-laser resected specimens facilitate margin assessment.[10,15,23,24] The abovementioned beneficial cutting properties of the CO_2-laser were confirmed to be applicable for the flexible CO_2-laser waveguide in a TORS-specific setting by Hoffman et al., who compared different resection tools (flexible CO_2-laser, flexible Tm:YAG laser, monopolar blade and radiofrequency needle) compatible with the Da Vinci robotic platform and suitable for TORS, in an animal model (porcine tongue). On histopathologic evaluation, the CO_2-laser had smaller coagulation zones compared to monopolar (100–500 vs. 150–750 μm). Moreover, upon subjective evaluation of instrument performance by two head and neck surgeons, the CO_2-laser exhibited excellent performance with less bleeding, no tissue sticking on the instrument (due to non-contact resection) and minimal coagulation beyond the application site when compared to monopolar cautery. Moreover, it proved to be most time efficient.[12] After the introduction of hollow wave guides, different authors implemented CO_2-laser technology during TORS procedures, illustrating feasibility and safety in a preclinical[14] and clinical setting in which malignant tumours in the oropharynx, supraglottic larynx and hypopharynx were addressed by the integrated combination of CO_2-laser and robotic technology.[14–16,18,24–26] The histologic observation of minimal thermal damage to surrounding tissues related to the use of a (flexible) CO_2-laser may lead to substantial advantages for patients. This

TABLE 1 Table depicting the results of NASA-TLX questionnaires for different procedures and different surgeons

	Classic TORS	1st Junior	1st Senior	2nd Junior
Mental demand (How mentally demanding was the task?)	3	6	3	5
Physical demand (How physically demanding was the task?)	3	3	3	4
Temporal demand (How hurried or rushed was the pace of the task?)	1	1	3	1
Performance (How successful were you in accomplishing what you were asked to do?)	5	2	3	3
Effort (How hard did you have to work to accomplish your level of performance?)	5	15	3	5
Frustration (How insecure, discouraged, irritated, stressed and annoyed were you?)	3	13	3	3

Note: Column 1 represents the scores given after classic TORS radical tonsillectomy with the monopolar spatula. Columns 2-3-4 represent the scores given by different surgeons after TORS radical tonsillectomy with the instrument's prototype. Scale 0–20, with higher scores representing higher demands.

Abbreviations: NASA-TLX, NASA-Task Load Index; TORS, transoral robotic surgery.

hypothesis is supported by the findings of Ansarin et al., who published a retrospective comparison of the author's first 10 patients treated with TLM and first 10 treated with electrocautery-TORS for cT1-T3 supraglottic cancer: TLM proved superior in terms of margin evaluability, postoperative pain, and length of tubefeeding.[10] Although different operating techniques are compared (TLM vs. TORS) which have proven to result in comparable oncological outcomes,[27] the main difference is the energy source used for tumour resection (CO_2-laser vs. electrocautery) and one can postulate the use of electrocautery negatively impacted postoperative pain and functionality. With the integration of CO_2-laser technology into the Da Vinci system, it seemed therefore likely that these reported disadvantages of TORS could be minimized. Indeed, in a non-randomized prospective study, comparing flexible CO_2-laser with monopolar cautery in TORS base of tongue surgery for obstructive sleep apnoea, the use of CO_2-laser resulted in a shorter length of hospitalization, a shorter duration until start of oral intake and less postoperative pain. Additional advantages of CO_2-laser TORS were less intra-operative bleeding that required cauterization and shorter robot operating time compared to electrocautery, as the monopolar spatula tip had to be cleaned almost every —three to four cuts.[28] Similar findings were reported by Benazzo et al. in a retrospective review and comparison of efficacy in the treatment of patients affected by cT1–T2 oropharyngeal and supraglottic squamous cell carcinomas treated with electrocautery versus YAG-and CO_2-laser fibres: a considerable difference was observed in overall functional parameters with shorter hospitalization and quicker tracheostomy and nasogastric tube removal in the laser-treated group. Moreover, close or positive margins were significantly more frequent in electrocautery TORS, confirming the easier margin assessment after laser-TORS.[24] Taking the abovementioned elements into account, our instrument concept indeed is likely to combine the best of both worlds: the superior cutting properties with minimal collateral damage of the CO_2-laser combined with the advantages related to the TORS-approach, which offers improved surgeon control and precision and enhanced manoeuvrability of the laser beam allowing for multiplanar tissue transection at any angle, as opposed to traditional TLM with a straight laser beam and resulting tangential only cutting plane.[14] In contrast to the commercially available CO_2-laser fibre drop-in guide manipulated by the robotic needle driver, our innovative prototype of a steerable CO_2-laser fibre carrier allows for dynamic switching between CO_2-laser and monopolar energy and as such utilizes the advantages of laser- and electrocautery-TORS to the full extent, including the use of the monopolar spatula as a blunt dissection tool and as a powerful coagulation instrument for vessels too large for laser coagulation (Figures 2 and 3). In this preclinical study, we confirmed feasibility of the prototype application during TORS radical tonsillectomy in a cadaveric model. No serious intra-operative difficulties related to the prototype and leading to definitive failure of the instrument or potentially negative consequences for a patient were observed. Surgery durations illustrated a quick adaptation to the prototype during TORS by both surgeons with ultimately comparable surgical times between prototype TORS and classic TORS. Switching between CO_2-laser and monopolar energy (including retracting the laser fibre and applying monopolar energy) proved to be efficient without failures and with a consistent short switching time after a quick adaptation by the surgeon limited to the first procedure. Thanks to the combination of the precise cutting with the CO_2-laser and absence of carbonization/crusting at the instrument tip on one hand and the possibility of blunt dissection with the monopolar spatula tip with the laser fibre in retracted position on the other hand, key anatomical landmarks could easily be identified when using the prototype. This user-friendliness translated into favourable scores on the NASA-TLX questionnaires.

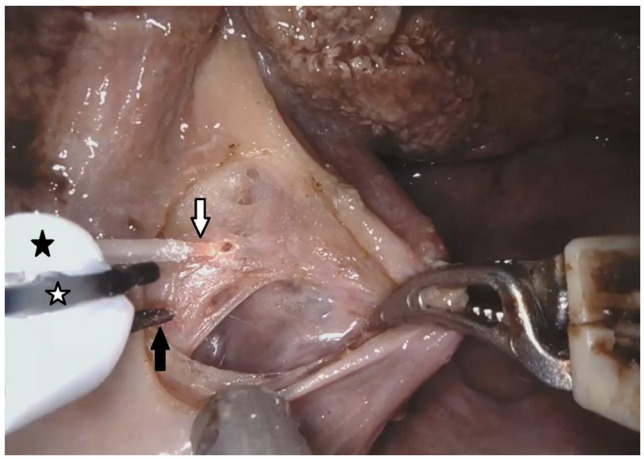

FIGURE 2 Intra-operative view during left radical tonsillectomy in a human cadaver. The CO_2-laser fibre is in its fully protracted position and is used for parapharyngeal laser dissection, deep of the pharyngeal constrictor muscle. The white arrow indicates the laser fibre, the black arrow the monopolar spatula tip, the black star the tip ring which carries the laser fibre and the white star an electromagnetic tracker used for experimental workspace measurement. Note the absence of crusting on the laser fibre and monopolar spatula tip

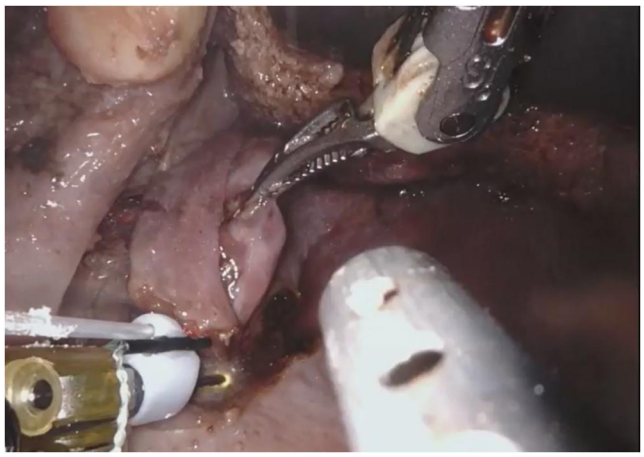

FIGURE 3 Intra-operative view during left radical tonsillectomy in a human cadaver. The CO_2-laser fibre is now in its fully retracted position while the monopolar spatula is used for coagulation of a simulated bleeding focus

However, some disadvantages of the instrument prototype could be identified. Although the CO_2-laser fibre proved strong enough to resist the bending forces applied on the fibre during extreme positions of the monopolar spatula's distal tip and kept performing satisfactory throughout all monopolar spatula positions, the bi-axial translation proved not possible when the monopolar spatula tip was in a significantly deviated position relative to the neutral position, due to friction of the bent laser fibre in the tip guide. As such, it proved necessary to straighten the monopolar spatula tip before inducing re-or protraction of the laser fibre. Second, depending on the position of the monopolar spatula's distal tip, the distance between the laser fibre tip and spatula tip fluctuated (e.g. bending the spatula tip will lead to less protraction). This fluctuating distance between the spatula tip and laser fibre tip on one hand and the necessity of keeping a constant distance between the laser fibre tip and the tissue on the other hand, forces the surgeon to control the robotic instrument arm focused on the laser tip and not on the monopolar spatula tip, which could be confusing. However, this issue was not reported as problematic by both surgeons performing TORS procedures in this feasibility study. Third, switching between the retracted/protracted positions of the laser fibre by pushing the foot pedal took some time to get accustomed to by the assistant surgeon during the first procedure, as he had no clear indication on the current fibre position and needed to rely on the commands of the main surgeon for controlling the position of the laser fibre relative to the monopolar spatula. It proved not always easy for the assistant surgeon to get visual feedback on the fibre's position on the vision cart's screen. Integrating a visual feedback mechanism into the switching pedal which confirms the fibre's position could solve this issue. Finally, the extra foot switch controlling the laser energy source proved difficult to integrate in the Da Vinci surgeon's console.

Moreover, some limitations related to the study design need to be mentioned. First, the prototype was only tested during radical tonsillectomy. Future studies assessing the safety and feasibility of an updated prototype during transoral robotic laryngeal and hypopharyngeal surgery are warranted. Second, the simulation of bleeding events can be considered unrealistic for some reasons. First, as the main surgeon himself declares a bleeding event to occur, it can be assumed that his reaction time is shorter when compared to a situation in which a real bleeding event would occur 'out of the blue', positively influencing the switching times between modalities. Additionally, as active bleeding will negatively affect coagulation properties, the application of monopolar energy does not necessarily translate into actual stopping of the bleeding event. As such, these 'imaginary bleeding events' are only a simplistic way to measure switching times, not coagulation properties. Further validation of the instrument's prototype in a more realistic living animal model is necessary.

This preclinical study indicates that the proposed innovative solution combining CO_2-laser technology with robotic technology has the potential for significant advantages during TORS compared to the currently available system, so further optimization of the prototype and subsequent prospective validation of feasibility and safety of the updated instrument in a clinical TORS model is warranted. Moreover, pre-clinical investigation of this instrument in surgical settings other than TORS which could also benefit of combining the advantages of robot-assisted surgery with the advantages of CO_2-laser (e.g., endometriosis surgery), will be considered.

5 | CONCLUSION

In this preclinical study, we confirmed feasibility and safety of a steerable CO_2-laser fibre carrier which is compatible with the Da Vinci Endowrist® monopolar spatula during TORS radical tonsillectomy in a cadaveric model. In contrast to the commercially available CO_2-laser fibre drop-in guide manipulated by the robotic needle driver, the current prototype allows for dynamic and swift switching between CO_2-laser and monopolar energy and as such successfully combines the advantages of CO_2-laser technology (superior cutting properties with minimal collateral tissue damage) with the advantages of TORS (improved surgeon control and precision and enhanced manoeuvrability of the laser beam allowing for multiplanar tissue transection), while maintaining the monopolar spatula as a blunt dissection tool and as a powerful coagulation instrument for vessels too large for laser coagulation.

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CONFLICT OF INTEREST

The authors declare to have no financial or personal interest in relation to the content of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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