Design Requirements of Robotic Systems for Assisting Percutaneous Tracheostomy: a Scoping Review and Development Framework

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Design Requirements of Robotic Systems for Assisting Percutaneous Tracheostomy: a Scoping Review and Development Framework

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***Abstract*—Percutaneous dilatational tracheostomy (PDT) is a common procedure for patients managed in Intensive Care Units (ICUs). PDT has equivalent complication rates to surgical tracheostomy but can be performed at the ICU bedside, eliminating delays in the procedure. However, PDT complications associated with initial needle insertion into the trachea still exist and can cause severe consequences such as pneumothorax, major haemorrhage, and death. Robotic technology is a powerful adjunct to assist manual surgery, improving procedural safety and accuracy. Whilst robotic surgery of the airway has become established, there is limited research and guidance regarding robotics to assist tracheostomy insertions. This study aims to identify design requirements that map clinical needs to design details and motivate the development of a scientific design framework in robotic tracheostomy. A literature search in Google Scholar, PubMed, and Web of Science on topics relevant to robotic tracheostomy was conducted. Clinical requirements were evaluated by distributing an online questionnaire to professional clinicians. Thirteen eligible studies were presented, from which 36 design requirements in four categories were collected. We present a design framework to inform the development of robotic tracheostomy with key requirements validated for suitability by relevant healthcare professionals.**

***Index Terms*—Tracheostomy, Robot, Design, Requirement, Review**

I. Introduction

TRACHEOSTOMY is one of the most frequently performed procedures for patients managed in Intensive Care Units (ICU) who require mechanical ventilation with a history of over 2000 years [1], [2]. Placement of tracheostomy is classically indicated by symptoms related to airway obstruction, although the commonest indication is to facilitate weaning from invasive ventilation [3]–[5]. Tracheostomy can contribute many benefits for ICU patients, including decreased ICU length of stay and improved long-term survival [6]. It can be performed using an open surgical technique (Open Tracheostomy–OT) or using a needle/wire/dilator approach (Percutaneous Dilatational Tracheostomy–PDT).

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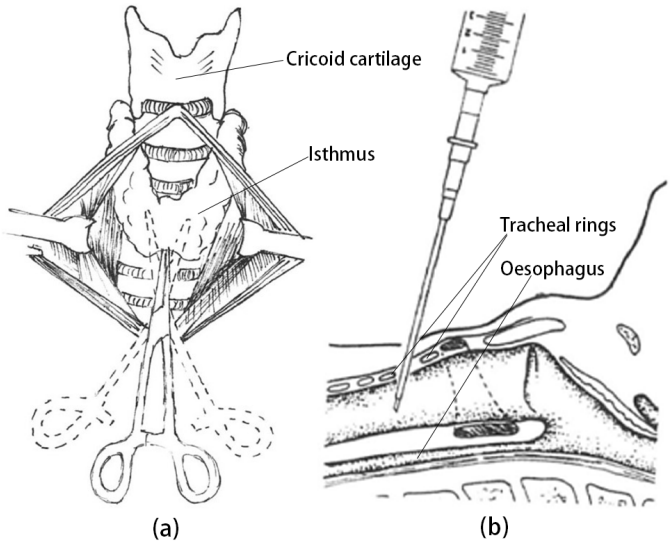

Fig. 1. (a) In OT, an incision is created and tracheal rings are exposed. (b) In PDT, the trachea is punctured with an intravenous catheter. Then the needle is withdrawn while the catheter in place allows the passage of guidewire [7].

The incision for performing OT lies between the cricoid cartilage and the sternal notch. Dissection of the neck tissue exposes the trachea, which is opened under direct vision before inserting the tracheostomy tube into the stoma [7], as shown in Fig. 1(a). The tube keeps the stoma patent and allows connection to oxygen and a source of ventilation. Although direct exposure to the trachea provides a good visualization of surgical sites and tissues, it also leads to some complications. Studies conducted by Klotz *et al.* and Hoseini *et al.* show the rate of inflammation reaches 22.2% [8] and haemorrhage rates to be 33.6% [9]. As an alternative approach, PDT is illustrated in Fig. 1(b). Instead of large-scale dissection on the neck, clinicians only need to create a small skin incision, followed by blunt dissection and needle puncture of the trachea. A guidewire and dilators expand the site until it allows the passage of the tracheostomy tube [3]. Studies conducted by Rashid and Higgins have shown lower overall complication rates and shorter operation time of PDT compared with OT [10], [11]. Significantly, PDT can be performed at the bedside. This almost eliminates the logistical delays associated with coordinating an OT with the surgical and anaesthesiology

teams, patient availability (due to critical illness treatments) and operating theatre availability. PDT reduces the surgery cost but also significantly shortens ICU length of stay compared to OT [12]. As for tracheostomy practice in the UK, a survey amongst ICU clinicians in 2008 showed the preference for PDT over OT and demonstrated its advantages [13].

Nevertheless, PDT does have some complications that may cause adverse consequences. The PDT technique relies on accurate initial needle insertion into the trachea. This is most commonly achieved by palpation of the surface landmarks alone. Misdirection of the PDT needle risks damage to the adjacent structures of the neck, which can lead to bleeding, pneumothorax injury to the trachea, oesophagus, thyroid gland, pleura or lung parenchyma [14]–[19]. Due to the patient's underlying critical illness, complications can rapidly become life-threatening. PDT needle puncture must not just enter the trachea but enter at a precise location between the second and third tracheal rings on the anterior surface. A cadaver study determined the puncture when experienced operators used a palpation-only technique, and the number of successful cases of accurate catheter placement was 9/20 [20]. Two visualization techniques, bronchoscope and ultrasound, are commonly used for guidance, but neither overcomes all challenges. Bronchoscopy provides a direct vision of the surgical site from inside the trachea but only confirms the final puncture, offering no navigation assistance during needle insertion through the tissues [21]. The air-filled trachea does not transmit ultrasound and, combined with the limited access at the front of the neck, limits ultrasound to the pre-procedural vessel and depth identification only [22]. Performing a precise puncture is essential in reducing procedural and post-procedural complications such as tube displacement, which may be influenced by poorly inserted tubes [23].

Clinical experiences also play a critical role in risks associated with PDT. The long learning curve of PDT may lead to relatively high risk until clinicians have mastery of the procedure after performing perhaps up to 70 procedures [24]. Some complications can be attributed to the dilation procedure, such as posterior trachea wall injury and longer surgical time [25], [26]. An experienced team is needed to minimize the probability of human errors, which increases the cost and required resources. Therefore, if a safer and easier PDT is to be achieved, assistance and improvements in the procedure need to be developed.

Robots have proved to be capable of providing excellent assistance during minimally invasive surgery (MIS) such as laparoscopy, gynaecology and urology [27]. Robot-assisted gastronomy, a type of MIS, reduces average hospital stay by four days compared with the traditional technique [28] while robotic esophagectomy also shortens the hospital stay by one day compared with the manual approach [29]. Therefore designing a robotic system for semi-automated tracheostomy may be feasible and capable of improving the effectiveness of PDT by improving the accuracy of needle puncture, reducing the complications associated with the puncture, dilation and optimal tube placement, which will reduce later complications. We did a literature search on Google Scholar and PubMed using "tracheostomy robots" as keywords, but only a few relevant studies were identified [30], [31] Specific procedural clinical needs and associated technical specifications were not described. To the best of our knowledge, methods adopted to design and evaluate tracheostomy robots are still being explored. These concepts are essential for the future application of robotics in tracheostomy since they can provide supportive references about how to develop an effective robot with satisfying performance and how to set up evaluation parameters to test the design.

Although various robotic systems have been introduced in different surgeries, research that includes the specific mapping between clinical needs and design specifications is absent. As tracheostomy robotics is a new concept [31], it will be extremely beneficial for designers if comprehensive descriptions of what exactly the challenges are to be solved in tracheostomy by robots are presented. Therefore this research aims to identify the clinical needs and technical design requirements derived from surgical challenges in PDT. We first identify specifications for converting clinical needs into design parameters from published works related to this area. Then by obtaining clinical needs and evaluations of the requirements from experienced clinicians, we address each requirement to the specific surgical problem, validating the results and design framework. The results of this research shall provide a systematic overview and guidelines on how to develop new robotic systems that can perform PDT effectively and safely.

II. Methodology

A. Literature search

A scientific literature search was conducted to identify potential design specifications for robotic tracheostomy. Since the number of previously published works directly relevant to developing tracheostomy robots is limited, we searched the areas related to tracheostomy from which potentially useful information was extracted. Design requirements were captured from the following areas: (1) existing prototypes of tracheostomy robots, (2) surgical systems used in relevant surgeries such as transoral robotic surgery (TORS) and MIS, and (3) design specifications and considerations for general surgical robotics.

PubMed, Web of Science and Google Scholar were used for searching pertinent studies. Additionally, we scanned the bibliographies of retrieved articles to expand the search range. A combination of the following keywords and terms was applied:

- Surgical robots, system, technology
- Tracheostomy, percutaneous
- Design, requirements, specification, consideration, evaluation

One exact search term used was (percutaneous AND (tracheostomy OR tracheotomy) AND (robot* OR surgical* system OR surgical* technology) AND (design OR speci* OR require* OR consideration OR evaluation)).

B. Eligibility criteria

We first examined the studies obtained from the aforementioned sources by their titles and abstracts. Possibly pertinent

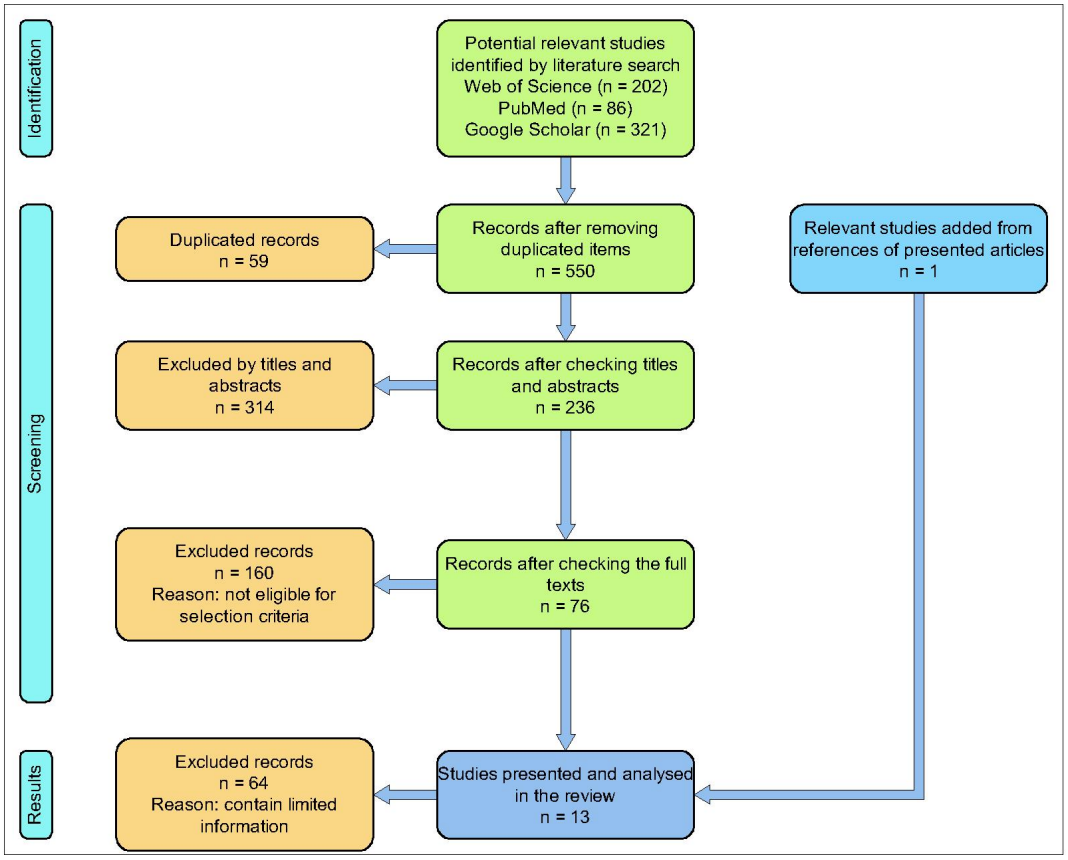

Fig. 2. Flowchart of literature search and selection.

articles were assessed by checking the full text, especially the design methodology and discussion sections. Those passing this screening stage should contain useful information regarding the development of surgical robotics or improving PDT procedures. Papers that only contain limited information regarding design requirements were excluded from presenting in the review. Articles that fulfil the following criteria were used to develop the list of design requirements:

- Directly related to the development and evaluation of robotic tracheostomy.
- Identified some design specifications for surgical systems used in related areas, which could be applied to robotic tracheostomy.
- Demonstrated methods that contributed to lower complication rates or easier PDT procedures and may be applied to robotic tracheostomy.
- English-written articles published from 1st January 1990 to 1st October 2022 since the area of surgical robotics emerged in the mid-1980s.

C. Evaluation of Results

After retrieving all possible design requirements, they were classified into three categories: safety, functionality and usability. Those eligible for multiple categories were categorized into one with the most relevance.

Requirements associated with the nature of PDT and specific clinical needs were assessed to check their necessity for exactly mapping the design to procedural challenges. Professional healthcare staff with related experience were invited through an online questionnaire to evaluate the findings. Other requirements are evaluated using a five-point Likert scale by engineers with experience in mechanical design and mechatronics.

Some design requirements were converted into quantified terms to better measure the performance of tracheostomy robots. We searched the literature to capture the quantitative terms that could better establish designers' understanding of the qualitative statements.

1) Ethics: According to the regulation of research ethics in the Faculty of Science and Engineering at the University of Manchester (UoM) and the results of the UoM ethics assessment, ethical approval was not required to undertake this questionnaire. All responses were anonymised and did not include any sensitive or personal data.

2) Questionnaire design: An online questionnaire to assess the significance of clinical requirements was conducted through Qualtrics. It was distributed through professional networks by email, targeting clinicians with experience relevant to the PDT procedure. Eligible participants should satisfy at least one of the following criteria:

- Have experience in directly performing PDT procedures
- Have experience assisting PDT procedures (e.g., operating a bronchoscope or performing anaesthesia)
- Have experience teaching or supervising PDT procedures

TABLE I
SUMMARY OF IDENTIFIED STUDIES

Author & Year [Ref]	Description	Objective	Features & Design requirements
Calmet *et al.* 2022 [32]	Design and modelling of a device used for tracheostomy	Reduce the risk of infection from aerosols	1. Work under the worst-case scenarios 2. Simple to manufacture 3. Economical 4. Limit the spread of aerosols 5. Allow unhindered access and no collision with operators 6. Compatible with various patients 7. Compact size
Korb *et al.* 2003 [33]	Risk & practicality analysis	Provide guidelines for the implementation of surgical robots	1. Different means to perform a required function 2. Redundant design 3. Graceful degradation 4. Model the interaction among systems, environment and user 5. Ease of operation 6. User-friendly interface 7. Meet safety requirements
Xiao *et al.* 2020 [31]	Tracheostomy robot design	Develop a surgical robot for translaryngeal PDT	1. Locate the puncture position 2. Flexible structure 3. Allow airflow into and out of the trachea 4. Maintain stability during puncture 5. Provide visual feedback 6. Exert sufficient force
Poon *et al.* 2018 [34]	Overview robots for TORS and present a prototype	Analyse existing systems and highlight future robots	1. Enhanced visualization 2. Sufficient flexibility and manoeuvrability 3. Provide haptic feedback 4. Leader-follower control system 5. Reduce the learning curve 6. Modularity design 7. Compact size 8. Flexible manipulator 9. Allow good visualization of the surgical site 10. Cost-effective 11. Trajectory planning & navigation 12. Intuitive software framework
O'toole *et al.* 2010 [35]	Design and evaluation method of surgical robots	Establish the evaluation criteria for surgical robotics	1. Fulfil clinical needs 2. Meet safety requirements 3. Redundant design 4. Risk identification and control 5. Compatible with the environment and surgical tools 6. Cost-effective 7. User-friendly interface 8. Intuitive software and interface 9. Easy for sterilisation 10. Compact size 11. Reduce operation time and learning curve
Abdelaal *et al.* 2020 [36]	Overview recent work in surgical robotics	Develop design requirements, challenges and future perspective	1. Reduce operation time 2. Provide haptic feedback 3. Easy to set up and exchange instruments 4. Small footprint and weight 5. Data integration 6. Sufficient stability 7. Flexible and dexterous surgical tools 8. Unhindered access 9. Exert sufficient force 10. High movement resolution 11. Provide visualization 12. Teleoperation or performing some tasks autonomously 13. Hardware and software redundancies 14. Risk control
Kapsalyamov *et al.* 2019 [37]	Design of a robot for MIS	Provide tissue-robot interaction and assist MIS safely	1. Compact size and lightweight 2. High precision and accuracy 3. Compliant manipulation 4. Sufficient workspace 5. Compatible with the environment 6. Meet safety requirements
Georgilas *et al.* 2018 [38]	Design requirements for robots for fracture surgery	Capture user needs as requirements for robot design and test	1. Enable visualization of surgical sites 2. Exert sufficient force 3. Sufficient workspace 4. Intuitive graphical user interface 5. Compatible in any operating room 6. Preoperative planning 7. User-friendly system 8. Not traumatic for the patient 9. Conform to the regulations 10. Portable 11. Unhindered access to the surgical field.
Rosen *et al.* 2017 [39]	Design of a robot for MIS	Provide full functionality for skull base surgery and neurosurgery	1. Highly dexterous motion 2. Provide visualization 3. Easy exchange of instruments 4. Meet velocity and acceleration requirements 5. Flexible structure
Sang *et al.* 2011 [40]	Control of a MIS robot	Develop control component for a surgical system	1. Exert sufficient force 2. Rapid instrument changing 3. Backdrivability 4. Teleoperated system 5. Provide visual feedback 6. Stability and transparency
Kuo *et al.* 2012 [41]	Review on robotic systems for MIS	Develop design goals, requirements and preferences for MIS robot	1. No collision with the patient's body 2. High precision 3. Meet safety requirements 4. Ergonomic design 5. Enhance surgical dexterity 6. Compact extracorporeal workspace 7. Backdrivability 8. Good isotropy over the entire workspace 9. Redundant design
Diaz *et al.* 2017 [42]	Review clinical needs and technical requirements of surgical robots	Address technical, logistic, economic and safety issues in robot design	1. Cost-effective 2. Reduce intervention time 3. Easy to set-up 4. Small footprint 5. Data integration 6. Improve decision-making 7. Minimised size and mass 8. Sufficient workspace 9. High resolution 10. Good platform stability 11. Sufficient output force 12. Force feedback 13. Flexibility and manoeuvrability 14. Ergonomic design
Zhu *et al.* 2021 [43]	Review of recent progress and expected features for future surgical robots	Envision new characteristics of next-generation MIS robots	1. Flexibility and steerability 2. Sufficient workspace 3. Constrained dimension of the manipulator 4. Precise movement 5. Good stability 6. Cost-effective 7. Long durability 8. Easy maintenance process 9. Small footprint 10. Collect real-time information from human 12. Perform some procedures autonomously 13. Sufficient and continuous force exertion

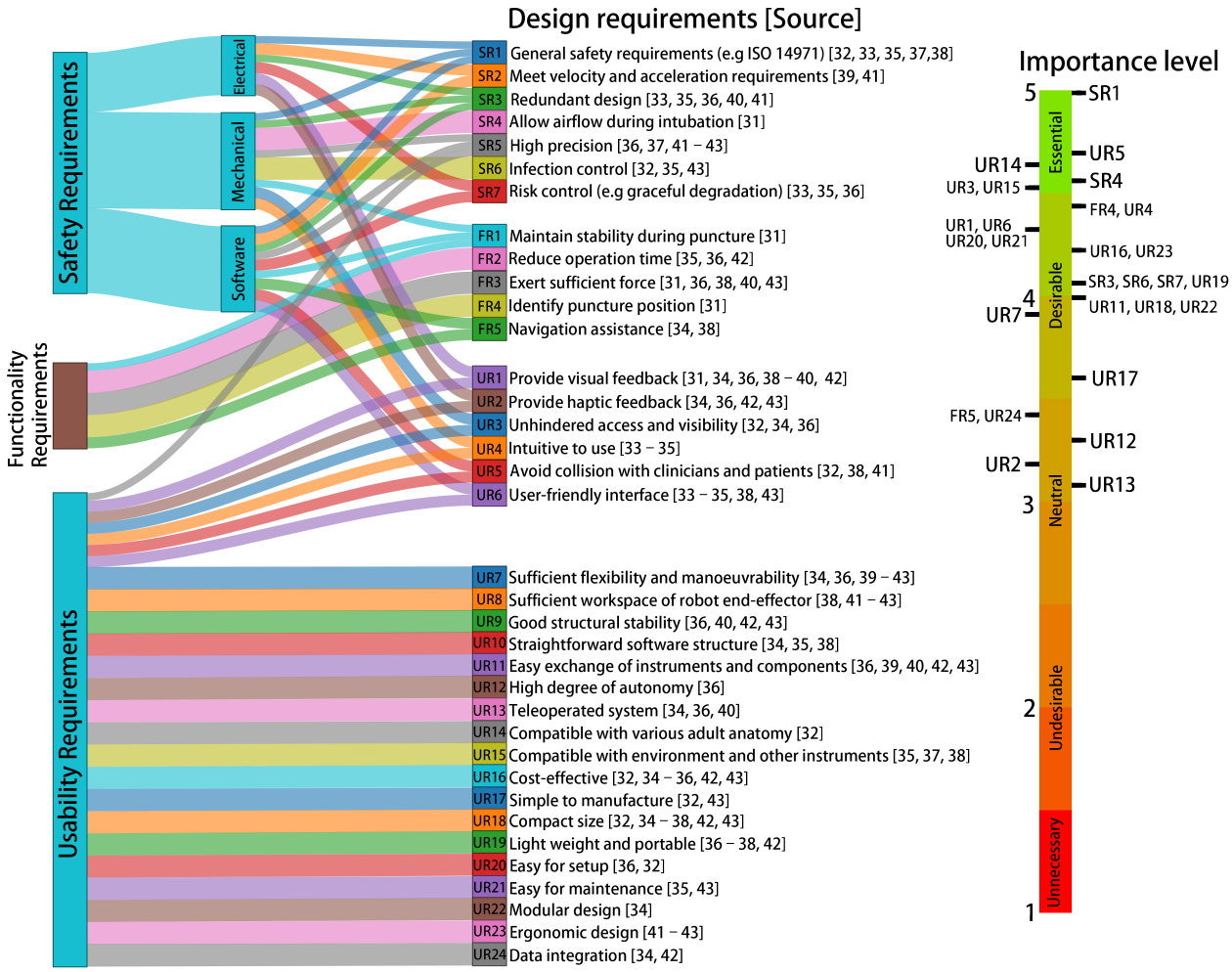

Fig. 3. Overview of the design requirements extracted from literature and their importance levels. The importance level is calculated by averaging the ranking scores provided by all survey participants.

The questionnaire consists of three sections: the first section asks for the length of working experience with tracheostomy and specifies the expertise related to PDT; the second section asks the participants to rank the clinical requirements identified by the literature review using a five-point Likert scale; the third section asks clinicians to identify potential areas of improvement of current procedure and specific needs that tracheostomy robots should fulfil. The importance level of each clinical requirement was calculated by averaging the ranking values collected from the second section.

For the evaluation of non-clinical-related requirements, interviews were conducted to obtain ranking results using a five-point Likert scale. Participants with relevant experience in mechanical design and mechatronics were invited.

III. Results

At the initial search stage, 609 articles were collected from the aforementioned sources. There were 236 articles selected for full-text assessment after screening titles and abstracts for relevance. Thirteen studies met the selection criteria and were used to extract possible design requirements, whereas 224 were excluded as they either were not eligible for the aforementioned criteria or only contained limited information relevant to design specifications. The process of the literature search is illustrated in Fig. 2.

Topics of all the selected studies are listed as follows:

- Development of a tracheostomy robot prototype [31]
- Design of other devices related to tracheostomy [32]
- Development of robots for MISs [37], [39], [40]
- Reviews of surgical robots [34], [36], [42]
- Design specifications of surgical robots [33], [35], [38], [41], [43]

A summary, including brief descriptions and requirements collected from each study, is shown in Table I. After synthesizing all the information, 36 potential design requirements were developed and listed in Fig. 3 and Table II. Seven (19.4%) were classified as safety requirements that dominate the overall risk level of robot-assisted PDT. Five (13.9%) functionality requirements were identified describing the objectives tracheostomy robots need to achieve, and the rest (n=24, 66.7%) were categorized into usability requirements that illustrate miscellaneous characteristics.

Fifteen completed online questionnaires were received from Oct 2022 to Jan 2023. The average working experience of participants on tracheostomy was 13.9 years, and all had

expertise in directly performing PDT. The importance levels of all clinical requirements are illustrated in Fig. 3. Twenty-seven (75%) clinical requirements were evaluated for their significance level. All terms reached at least level 3 and thus should be recommended for robot development. Five of the 27 features were considered essential and should be achieved during the design stage, and 15 were highly desirable and could improve the outcome of PDT significantly. Nine (25%) non-clinical-related requirements were evaluated by eight mechanical engineers with an average relevant working experience of 8.3 years.

TABLE II
LIST OF DESIGN REQUIREMENTS AND IMPORTANCE LEVELS

Requirements	Importance (1–5)
Safety Requirements (SR)	
SR1: Meet general safety requirements	5*
SR2: Meet velocity and acceleration requirements	4.24*
SR3: Redundant design	4.05
SR4: Allow airflow during intubation	4.63
SR5: High precision	4.42*
SR6: Infection control	4.05
SR7: Risk control	4.11
Functionality Requirements (FR)	
FR1: Maintain stability during puncture	4.32*
FR2: Reduce operation time	4.14*
FR3: Exert sufficient force	4.53*
FR4: Identify puncture position	4.47
FR5: Navigation assistance	3.42
Usability Requirements (UR)	
UR1: Provide visual feedback	4.37
UR2: Provide haptic feedback	3.22
UR3: Unhindered access and visibility	4.58
UR4: Intuitive to use	4.42
UR5: Avoid collision with operators or patients	4.74
UR6: User-friendly interface	4.32
UR7: Sufficient flexibility and manoeuvrability	3.89
UR8: Sufficient workspace for end-effector	3.95*
UR9: Good structural stability	4.00*
UR10: Straightforward software structure	3.51*
UR11: Easy exchange of instruments	4.00
UR12: High level of autonomy	3.33
UR13: Teleoperated system	3.11
UR14: Compatible with various adult patients	4.68
UR15: Compatible with the environment	4.58
UR16: Cost-effective	4.26
UR17: Simple to manufacture	3.61
UR18: Compact size	4.00
UR19: Lightweight and portable	4.05
UR20: Easy for setup	4.32
UR21: Easy for maintenance	4.32
UR22: Modular design	3.95
UR23: Ergonomic design	4.26
UR24: Data integration	3.21

The importance level is calculated by averaging the ranking scores provided by all survey participants. Numbers with '*' come from the evaluation based on the engineering point of view of 8 designers.

IV. DISCUSSIONS

Our study has examined and refined key clinical and design requirements for robot-assisted PDT using a comprehensive literature review and an expert panel of experienced health-care providers, being unique in understanding robotic PDT's design. Results of the literature review illustrate an increasing trend of applying robotic PDT by identifying several recent studies relevant to this area, leading to the demand for a guideline that maps clinical needs to design details. Although the sample size of questionnaire participants is relatively small, according to Guest *et al.*, a minimum of 8 experts is needed to obtain a reliable, representative conclusion [44]. Therefore ranking results from the questionnaire can be considered adequate to capture the design requirements of tracheostomy robots.

A conceptual sequence of a robot-assisted PDT procedure based on the requirements summarized in Table II is illustrated in Fig. 4. We envisage a semi-autonomous mode in which the robot performs the key procedures, including puncture and dilation, while a human supervisor assists the whole procedure and completes the remaining tasks. First, the system identifies the puncture position using sensing techniques and moves the manipulator above the patient's neck. Having obtained the desired position and orientation, the robot manipulator performs the puncture followed by the dilation, which should be more accurate and safer than those undertaken manually. Second, the robot manipulator disengages and move back to the safe position away from the patient, while the insertion of the tracheostomy tube is completed manually. A bronchoscopist is needed during the procedure to confirm each step's accuracy and complete tasks such as inserting the guidewire and tracheostomy tube.

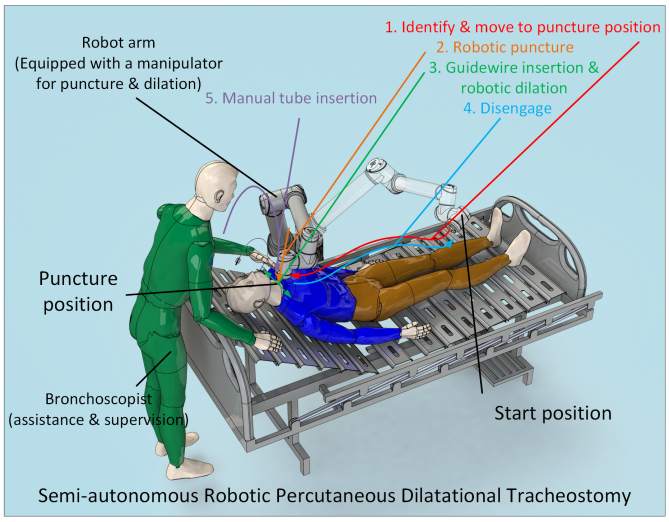

Fig. 4. A potential workflow of a semi-autonomous robotic PDT.

A. Safety Requirements

To obtain clinical acceptance of a new surgical robot, it must demonstrate at least the equivalent performance level in terms of efficiency and safety compared with manually-performed surgeries. While one objective is improving outcomes by reducing perioperative risks, factors that significantly affect overall safety should be emphasized and fulfilled at the design stage.

SR1: The system must meet general safety requirements

Tracheostomy robots must fulfil the general safety level by passing specific tests like other medical devices and surgical instruments for different surgeries. A few international standards exist that set safety requirements and risk management to evaluate safety for all kinds of medical robots. The following

standards apply to tracheostomy robots: ISO 14971, IEC 80601-2-77 and IEC/TR 60601-4-1. These standards define the materials, design guidelines and evaluation methods for surgical devices installed on the robotic systems, methods of identifying and evaluating the potential risks of applying tracheostomy robots and standards for sterilisation. These should be taken into consideration when developing the mechanical structure of the robot end-effector for performing PDT.

SR2: The locomotion of the robot end-effector must meet velocity and acceleration requirements

SR5: The end-effector must move with high precision

To prevent imprecise puncture on nearby tissues, including the thyroid, tracheal rings and gaps other than the one between the first and second rings, the needle must move with high resolution. The movement of the robot body should be smooth and avoid excessive velocity and acceleration, which reduces the risk of bringing damage to the patient. According to the requirements of other robotic systems used for MIS, such as the STRAS built by Donno *et al.* for endoluminal surgery [45] and Roboscope for endoscopic surgery [39], 50 mm/s for velocity and 200 mm/s^2 could be reasonable upper limits for tracheostomy robots when the manipulator is nearby the patient's neck or performing in-vivo tasks.

The resolution of robots depends on the procedure they are applied to, such as 30 μm in neurosurgery [46] and 2 mm in cholecystectomy [47], and it should be sufficiently small to avoid damaging the nearby tissues. Since the average inter-ring distance around the PDT puncture position is 1.52mm [48], the movement resolution of the end-effector could be around 1 mm to prevent accidental hits on the tracheal ring during the puncture.

SR3: The design of robots should acquire degrees of redundancy to prevent possible malfunctioning

SR7: Robots should be capable of controlling risks and dealing with potential hazards

A couple of safety-oriented measures can be taken to enhance the system's reliability and address underlying hazards from errors made during the procedure or malfunctioning. To prevent any uncontrolled or unwanted movement, a fail-safe architecture can be applied to robot control, allowing the system to detect any error condition and immediately stop all movements in an emergency [49]. Alternatively, fault-tolerant control can be used to address both external hardware errors and logical faults in the programs [50]. In this case, the system continues normal functionality despite a malfunction [51]. For better risk identification and management, logfiles and watchdogs can be implemented in the control system to supervise the operation and respond to abnormal actions [52].

Hardware and software redundancy is needed during the design process to ensure a single point of failure does not harm the patient or the user [53]. Implementing more technical functionalities than required allows for substitution among components for the same objective, maintaining the functionality even when facing subsystem malfunctioning.

SR4: The use of robots should not negatively affect the ventilation condition during PDT

Current robot prototypes all follow the translaryngeal tracheostomy (TLT) concept in which the robot end-effector is inserted transorally, reaches the location of tracheal rings, and punctures from inside the trachea. This concept remains controversial regarding performance in real surgeries because of not only the limited number of prototypes but also the relatively rare application of the TLT method. Puncturing from inside the trachea could realise several advantages, such as preventing posterior tracheal wall injury and combining the functions of a bronchoscope and introducer needle. However, there exist several barriers while one significant problem is improving the ventilation condition of patients. The mechanical structure of the translaryngeal robot becomes an occlusion inside the trachea and makes it more difficult for patients to be ventilated appropriately. Since the technology of TORS is advancing, the feasibility of transoral robotic PDT may increase.

SR6: The system design should reflect considerations of maintaining good infection control

Due to the healthcare-associated hazards from patients, medical equipment and clinicians, there exists a strict protocol for infection control of both disposable and reusable surgical instruments. As stated in several standards such as ISO 13402, ISO 7151 and ISO 7741, reusable surgical instruments must pass the test of autoclaving before applying to actual surgeries. To improve the outcome of sterilisation, the robot design should satisfy the following: (1) Withstand multiple sterilisations, (2) have a removable end-effector for sterilization, while the rest part is covered with a disposable drape [54]. Additionally, the geometry of the end-effector should allow comprehensive access by steam or other cleaning products during autoclaving by being easy to disassemble and comprised of heat-resistant components.

The spread of the COVID-19 pandemic has also brought new safety requirements to PDT procedures. Since tracheostomy is an aerosol-generating procedure, healthcare workers are at risk of infection during insertion and subsequent care [55]. The action of surgical robots should reduce the generation of airborne particles by finishing the insertion of the tracheostomy tube rapidly and facilitating stable gas exchange during the procedure [56], [57].

B. Functionality requirements

Robotic systems should achieve certain perioperative tasks at a satisfactory level to improve the overall efficiency of PDT. Functionality requirements serve as instructions for what robots should accomplish and what actions to prevent. Five statements were proposed based on results from the literature review and clinical feedback recorded in questionnaires.

FR1: The introducer needle must maintain good stability in the presence of disturbances during puncture

FR4: Robots should precisely identify the puncture position

Two of the greatest challenges of current PDT procedures are the precise incision of the introducer needle and locating the puncture site. The current procedure to locate the tracheal rings relies on palpation, which has some limitations. Anatomical landmarks are sometimes difficult to identify because of obesity and fat pretracheal tissues. The use of a

bronchoscope inevitably affects the ventilation of the patient, which must continue throughout the procedure. Therefore, the PDT procedure must be prompt to minimise the duration of bronchoscope insertion.

Ideally, the puncture should be performed along the midline of the trachea while the incision should lie at the 12'o clock location as seen from the cross-section. The atypical placement of PDT may predispose to re-insertion difficulties and recurrent bleeding [23]. It is difficult for clinicians to puncture at the exact position every time, particularly when the insertion is based on a palpating-only technique. However, with appropriate sensing and control, robots may achieve automated and precise punctures to significantly enhance overall safety by preventing damage caused by the needle. The objective of the sensing system is to obtain the appropriate position for the puncture and the orientation that a midline puncture should follow. Potential sensing techniques to be implemented include: 1. real-time ultrasound, a method already applied to assist PDT; 2. electromagnetic tracking, already used in other MISs such as endoscopic surgeries [58] and neurosurgeries [59].

The robotic system should attenuate or reject the effects of external disturbances (e.g., displacements of the base platform and robot interaction with the workspace) on the end-effector trajectory. Furthermore, the end-effector stability can be defined as a non-increasing positioning error smaller than 1 mm in both the lateral and tracheal midline direction to prevent damaging the tracheal rings and posterior tracheal wall, which is sufficient for safe operation as the inter-ring distance is 1.52 mm [48], and the average radius of the trachea is 8–9.5 mm [60].

FR2: The system should not prolong the procedure to a clinically significant degree

As one of the most critical evaluation criteria directly related to overall performance, reasonable operation time plays an important role in raising the quality of robot-assisted PDT. The operation time fluctuates depending on clinicians' experience, calculation methods, and techniques, which may vary from 3 to 25 minutes [61]–[65]. Considering the operation time as the duration from the insertion of the introducer needle to the end of tracheostomy intubation, a robot-assisted PDT should be completed in less than 5 minutes to demonstrate its superiority compared with manual PDT, in which the majority of operation durations fluctuate around 8 minutes.

FR3: The end-effector must output sufficient force for puncture and dilation

The average dilation forces measured with the Griggs method for expanding pretracheal tissues and trachea are 31.6N and 44.4N, respectively, while the force for tracheal destruction is 87.7N [66]. The puncture force used in [31] as a design parameter is much less than that for dilation. To prevent damage caused by excessive force, a limit of maximum allowable output force should be enforced. Therefore, using the values measured in [66] as guidance, the robot end-effector should exert at least 10N during puncture and 45N during dilation but not exceed 70N to avoid tracheal ring collapse.

FR5: Navigation assistance should be provided for robot locomotion during the surgery

In MIS, surgeons have to cope with two main challenges, orientation and precise tool guidance, with fairly small errors because of the compact dimension of the surgical site and nearby delicate tissues [67]. For PDT, the position error should be smaller than the interval between tracheal rings, which is 1.52mm [48]. Otherwise, the introducer needle may hit the tracheal rings. Precise control of the locomotion of surgical instruments is essential to mitigate clinical-related complications during PDT. With the navigation assistance provided by robots on which sharp tools are mounted and manipulated, errors from hand tremors can be attenuated. Furthermore, operators can designate position and orientation commands with precision reinforced by control algorithms. For example, the vector-field inequalities method developed by Marinho *et al.* allows the robot to prevent collisions with surrounding tissues using dynamic active constraints [68].

C. Usability requirements

Several factors play a paramount role in the wide acceptance of clinicians for a new medical device. On the one hand, the mechanical structure of tracheostomy robots needs to be specially designed to map the design features to clinical needs. Regarding surgical robotics as an interdisciplinary area, clinical perspectives must be considered to ensure satisfying performance when used by non-engineering users. On the other hand, the control system of tracheostomy robots, just like other surgical robots, relies heavily on the real-time information collected from patients and input commands from operators. The success of achieving high precision, smooth movement, and minimal risks to patients require feedback data and the application of effective control algorithms. Since various surgeries and scenarios are associated with different specifications, a list of components for control systems used in robot-assisted PDT needs to be established.

UR1: Visual information of instruments and the surgical site should be collected for control and guidance

UR2: Haptic data should be captured for feedback control and guidance

The benefits of visualization brought by bronchoscope have been well studied by several pieces of research. Its major advantage is the direct visualization of the surgical site and verified satisfactory placement of the needle, dilator and tracheostomy tube [21], [69]. Therefore the real-time visual information of instrument position and nearby tissue is essential for robot-assisted PDT. Furthermore, the collected visual data can be used as feedback inputs for robot control to enhance overall performance.

Many prototypes have been introduced and proved haptic feedback helpful during the surgery. Results from a survey by Keohn and Kuchenbecker [70] illustrated a clear preference for receiving feedback data on tool vibration among surgeons and non-surgeons who also regard haptic information as useful during surgery. The review completed by Amirabdollahian *et al.* in 2018 also demonstrated the scope and need for new developments in haptic augmentation for robot-assisted surgery to improve patient care and robotic surgical technology further [71]. Therefore, for robotic PDT to be semi-autonomous, in which robots either automate subtasks like

puncture and dilation or are teleoperated by human operators using feedback data, controlling the contact force and feeding it back to the operator through haptics can become extremely useful for high-precision interaction and smooth movement.

UR3: The robot must allow good visibility and unhindered access for operators

UR5: The movement of robots must not collide with operators or patients

UR15: The system must compatibly fit in the ICU without any inference with the surroundings or other instruments

Depending on the settings of different ICUs, the installation location of tracheostomy robots varies. Crowded with equipment and intensivists, the robot's locomotion range must be constrained but sufficient to carry out tasks from any installation location. The movement of the tracheostomy robot must be smooth and controlled within a certain range to avoid interference with other instruments in the ICU, patients and clinicians. Since the whole procedure requires human supervision, even if it is completed autonomously by robots, clear vision and unhindered access to the surgical site should always be maintained. In this case, immediate actions can be taken by the supervisor while facing an emergency, guaranteeing patient safety and the reliability of robot assistance. Therefore, robot structures including the manipulator and the base platform, should not be too bulky to block the direct visualization of the surgical site.

UR4: The robot operation must be intuitive and easy for clinicians to obtain full mastery

UR6: The control console should have a user-friendly interface

A user-centred design should be followed when developing the mechanical structure of surgical robots. Since robotic tracheostomy is an emerging area, any new technology raises several important issues related to users' familiarity with the new device: skill development, teaching, and translation into the actual surgical mission [72]. Regarding the non-engineering users, procedures requiring manual control directly on the hardware should be straightforward to shorten the learning curve and reduce the focus clinicians put on control rather than patients. The hardware mechanism should not be excessively complicated so that users can obtain mastery of the robot more easily.

The design of the user console should strengthen the capability of human-machine interactions by transmitting more sophisticated commands and easing the operator's comfort during the control process. Human operators are largely involved in robot control in the early development stage of robotic PDT, giving position and orientation commands for robot movement. With the rapid development of biotechnology and sensing techniques, various input formats can be potential candidates for robot manipulation other than the traditional control through a joystick, keyboard and buttons. Input methods should be compatible with the nature of PDT and prevent drawing excessive attention from the procedure. The interface could improve the usability and efficiency of the whole system since it makes interacting with the robot easier for non-engineering professionals. Also, the interface could be simplified after robots are able to automate more subtasks.

For the design of the user interface, Prohorenko *et al.* [73] proposed a generalized framework architecture for the software translating between surgeons' requests into automated procedure execution. Shown in Fig. 5, the typical software structure consists of the following distinguished layers [73]:

(1) Presentation layer modules containing user-oriented functionality and responsible for implementing user interaction with the system;

(2) Service layer modules that provide interaction among layers and between external clients and system functionality;

(3) Domain logic layer modules implementing the rules of the application domain;

(4) Control and data access layer modules to establish interaction with hardware and access to data both in storage systems and from other services;

(5) Cross-cutting modules with specific functionality accessible from modules in any layer.

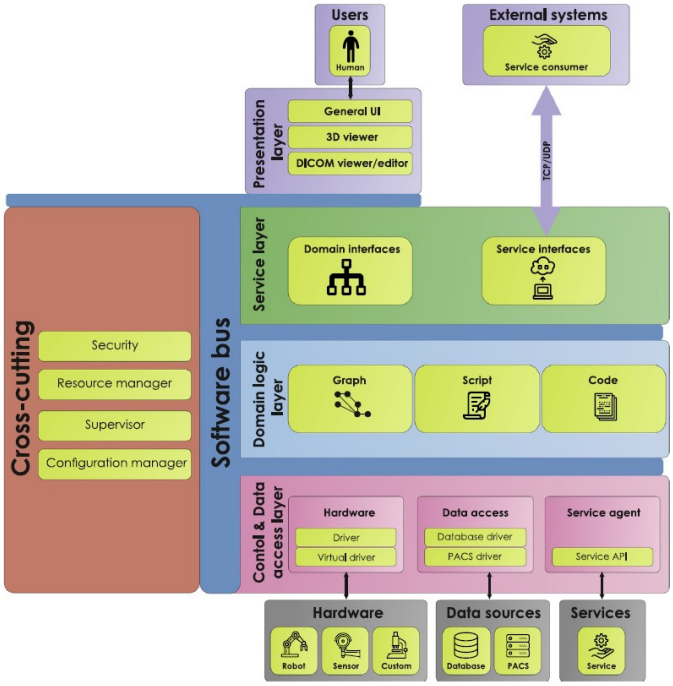

Fig. 5. The architecture of a layered system of surgeon-robot interaction software [73].

UR7: The robot end-effector must have sufficient flexibility and manoeuvrability

The robot end-effector must be able to fit different anatomy while considering the depth and orientation of the trachea relative to the skin surface. Therefore, the movement of the tracheostomy robot should be flexible enough to achieve the required orientation and position while using compliant mechanisms or active compliance through impedance control. Existing tracheostomy robot prototypes employ compliant mechanisms by using soft materials, as they provide conformity and safe interaction with the human body [74]. Robots with soft mechanisms can manipulate, palpate and dislocate organs with excellent dexterity and adaptability to different

tissue conditions [75], which can maintain high performance in the confined in-vivo workspace and carry out tasks at locations where rigid robots cannot reach. However, the underlying challenges of applying soft robotics include difficulty in precisely measuring the state of the soft mechanism [76] and lack of actuation methods [77], and increase in the complexity of implementing soft mechanisms, all of which need to be addressed to guarantee the surgical outcome.

UR8: The workspace of robot end-effector should cover the necessary volume to perform PDT

The installation location of tracheostomy robots may vary according to the settings in various ICUs, but end-effector movement should always cover the region nearby the patient's neck. Therefore design redundancy of the robot workspace, which means the workspace is always larger than the required volume, should be taken into consideration while determining the movement range.

UR9: The system must have good structural stability against disturbance

Two components are crucial when analysing the system performance: closed-loop stability and control robustness. An appropriately designed robotic platform should offer enhanced dexterity and manipulability while ensuring closed-loop stability and improving motion accuracy [78]. Additionally, errors from operators, including hand tremors and misoperation, also contribute to the inaccuracy and non-smoothness of robot movement. Filtering algorithms can be applied to the robot control system to attenuate the vibrations. Effects caused by disturbances should be mitigated by applying control algorithms, such as a disturbance rejection scheme [79], fuzzy PID control [80], or H_∞ control [81]. Communication delays of feedback data and lengthy response time can also cause the instability of robot control systems, while solutions should be taken to address those problems [82].

UR10: The software design structures should be straightforward to modify

For easier debugging and adding new functions, the software design of tracheostomy robots should be straightforward, with easy identification of key components and structures. Component-based software engineering can be applied by following three themes: (1) develop software from pre-produced parts, (2) reuse software in other applications, and (3) be able to maintain and customize the software to generate new functions and features [83], [84]. Each component has a well-defined interface and data structure for observing and controlling internal behaviour [85]. The complexity c of the software structure can be evaluated by calculating [86]

$$c = \ell \cdot (f_{\text{in}} \cdot f_{\text{out}})^2, \tag{1}$$

where ℓ is the length, $f_{\text{in}} \cdot f_{\text{out}}$ represents the total possible combinations of an input source f_{in} to an output destination f_{out}. The complexity of the software structure is reduced when (1) is minimized.

UR11: Instruments and components mounted on tracheostomy robots should be easy and rapid to exchange

During the preparation and operation, various components, such as surgical instruments and parts for replacement, need to be installed on the robot platform for executing different tasks. The unavailability of instruments is recognised to cause delays and stress in the operating room, which can lead to additional risks for the patients [87]. The reduced frequency and duration for instrument replacement will accelerate the procedure and decrease the risks associated with repetitive changing tools. Easily exchanging components also allows for easier maintenance and sterilization.

UR12: The robot control should reach a high level of autonomy and automate some subtasks

UR13: The system should support teleoperated modes for operation

The International Organization for Standardisation (ISO) framework defines the six-stage classification for evaluating the autonomous capabilities of surgeries and surgical robots. With the Level of Autonomy (LoA) ascending, the percentage of human involvement and the occupation of resources will decrease [88], while the uncertainty and technical challenges will rise.

Current PDT procedures are at LoA 0 without any robotic assistance. The potential LoAs of robotic PDT are defined as follows:

- LoA 1: The robot is remotely teleoperated, or robots assist in identifying the puncture position, or the on-site operator controls the robot to complete the puncture and dilation.
- LoA 2: Robots identify the puncture position and perform the puncture and dilation. The operator participates in the puncture position identification and completes the intubation.
- LoA 3: Robots identify the puncture position and complete the puncture, dilation and intubation. The operator supervises the whole procedure and only gives starting commands for each step.

Existing robots for MIS have achieved the stage of LoA 2, where robots can carry out subtasks without human control or interference. This stage is feasible for robots to automate critical procedures like puncture and dilation and help identify the puncture position.

The commanding method of tracheostomy robots remains debatable because of the limited number of prototypes. Potential approaches include teleoperation, on-site control and semi-autonomous control. One of the greatest benefits of using remote teleoperation is that it allows the user to give and receive commands in an easily interpreted, learned, and understood manner since individuals may prefer carrying out robot control through the joystick or keyboard [89]. However, the lack of on-site supervision and technical challenges associated with the feedback data may lead to potential hazards such as delayed response to malfunctioning, especially in the case of remote teleoperation. Thus, remote teleoperation is an important but not essential feature of tracheostomy robots.

UR14: The system must be capable of performing PDT on various adult patients

One significant feature of successful commercialised surgical robots is their wide application to patients with diverse physical conditions. The range of eligible patients to use robots should be sufficiently large to acquire wide acceptance of clinicians and patients. Therefore, during the design process, the individual diversity of patients and its impact on robot

functionality must be considered. As for PDT, different dimensions of the trachea, obesity and anatomical characteristics at the surgical site are factors that noticeably influence the outcome of surgery. Hardware design of the tracheostomy robot should enhance the eligibility of patients suitable for robotic PDT and guarantee equally satisfactory performance under various conditions.

UR16: Costs of robot-assisted PDT must be economic-viable

UR17: Components of the robot should have simple structures and be easy to manufacture

Many surgical robots' practical implementations are limited by the high cost of initial installation and continued maintenance [90]. To increase the popularity of robot-assisted PDT, robots should be cost-effective, and their presence should cut down the budget compared with traditional procedures. The occupation of ICU resources, intensivists, and disposable tracheostomy kits are all significant components of the overall cost. Robots can address them by accelerating the operation time, shortening hospital stays, adopting reusable tools, reducing the number of clinicians required and being cheap to manufacture and maintain. The mechanical design does not have to be overcomplicated, which increases the cost of manufacturing and makes it more sophisticated to carry out sterilization and routine check.

UR18: The system should have compact footprints

UR19: The robot should be lightweight and portable

The mechanical design of tracheostomy robots should be environment-friendly, which means their appearance and mechanical features must fit the nature of their work location. Considering the limited space around the ICU bed where tracheostomy robots are to be installed, their dimensions should be compact to allocate more room for other necessary equipment. The robot is only involved during the PDT, and will not necessarily remain within the ICU, so the total mass of the robotic system should be sufficiently small for easy transportation before and after the procedure.

UR20: The installation process of the tracheostomy robot should be easy and quick

UR21: Components of the hardware must be easy to maintain

Some research about commercialised surgical robots has demonstrated their drawbacks regarding the installation and maintenance process. Although the acceptance of robot-assisted surgery is growing, the installation and recurring costs remain high [91], [92]. If setup and uninstallation procedures are simplified, it is undoubted that the associated capital investments will drop to a great extent. Intuitive setup and disassembly sequences may even allow clinicians rather than engineers to take charge of the device, improving reliability, especially when engineers are unavailable.

UR22: Modular design should be applied so that the systems comprise independent modules

Combined with the current trend toward open and modular "plug and play" of different subsystems of medical devices, a modular human-robot system design with versatile access to cooperative functions with varying degrees of automation on demand is desirable [93], [94]. Various subsystems of tracheostomy robots, including the end-effector, user console, controller and actuators, can become independent modules to allow rapid exchange without disassembling the whole device. During the early design stage, additional interfaces should be set to install more modules in the system to achieve more functionalities without redesigning the base structure.

UR23: The design of the mechanical structure should follow the instructions of ergonomics

The hardware design, especially parts directly interacting with users, needs to adopt the instructions from ergonomics. Complex machines and the interposition of bulky mechanical interfaces between operators and patients facilitate the demand for such a concept under which devices are designed to provide a comfortable user experience and increased efficiency as well as safety [95]. The ergonomic hardware console shall allow surgeons to conduct operations comfortably with a shortened learning curve and reduced labour intensity [96].

UR24: Data of anatomical information should be integrated into the system and can be retrieved during the procedure

Surgical robots are complex platforms and may capture large amounts of unique data from the procedure that can be used to develop artificial intelligence solutions benefiting from computer-assisted interventions [97]. Additionally, various patients' preprocedural and perioperative anatomical data can be collected to train the machine learning model for automated tasks or display the relevant information to surgeons for assistance. Thus an interface that allows surgeons to check surgical data can be implemented on the user console, while a dataset containing all vital information shall be established.

D. Potential Benefits and Drawbacks

The potential benefits of adopting robotic technologies to assist PDT procedures are summarised as follows:

- Improved precision: by implementing sensing techniques and feedback controllers, PDT puncture could be completed more accurately and dilation could be done with less probability of encountering relevant complications. This is the key important clinical need for tracheostomy robots.
- Shortened learning curves: robots can automate the puncture and dilation processes, reducing the complexity of the whole procedure and making it easier and faster for operators to obtain mastery of PDT techniques since they only need to deal with the simpler tasks.
- Cost reduction: replacing single-use PDT kits with sterilisable robot components and easing the procedure could reduce the overall cost thanks to reusable instruments and shortened training process. Furthermore, considering the daily cost of intensive care is £2871 in the UK [98], robotic techniques can potentially reduce the total cost by shortening the ICU stay.

The application of robot assistance also brings additional problems to be addressed:

- Fitting the current workflow: additional training programs are needed for clinicians to get familiar with the new technique, increasing the initial implementation costs and affecting the clinicians' acceptance of robotic PDT.
- High initial investments: the initial investments for adopting robotic technologies are higher than current PDT kits.

Long-term financial benefits may limit the application in more medical centres.

E. Technical Challenges

Several technical challenges arise and are summarised as follows:

• Lack of suitable sensing technique: current visualisation techniques, bronchoscopy and ultrasound, cannot be directly applied for robot sensing. Modifications or alternative solutions are needed to guarantee precision especially when robots automate some tasks.

• Need for a robot end-effector design: robotic PDT can be performed either in the translaryngeal or the traditional outside-in way. Compared with directly using current surgical instruments, a specially-designed end-effector may shorten the operation time and reduce the risks whatever the method chosen. Lacking available products, designers have to develop the mechanical structure from scratch.

• Lack of evaluation metrics: a comprehensive evaluation is necessary to assess robotic PDT's performance and economic viability. Systematic evaluation metrics must be developed to quantify the traditional PDT and robotic approach under the same standard for easier comparisons.

F. Strengths and Limitations

Specific requirements for the design progress cover all critical subsystems, including mechanical structure, control system, user interface and design methodology, all of which will serve as general guidelines while developing each component. Limitations exist due to the limited number of prototypes; therefore, robotic tracheostomy remains an unexplored area lacking decisive outcomes. Since relevant previous work is insufficient to demonstrate the development path for future design, rather than directly from robotics in tracheostomy, the results of our study mostly came from studies containing inspiring and potentially helpful information. Although clinicians evaluated the statements, results are not definitive and may change as the knowledge grows along with design progress.

V. Conclusion

This paper collected design specifications and requirements for applying robot-assisted technology to PDT from previous studies about PDT procedures, relevant assistive devices and existing surgical robots in related areas. Clinicians proposed and validated essential functionalities of tracheostomy robots, which clearly defined what robotic systems need to achieve to prevail over manual procedures and summarised, for the first time, the potentially valuable information for developing robotic tracheostomy. Derived chiefly based on the perspective of the engineering side, results and statements shall complement clinical knowledge, making the early exploration of robot-assisted PDT obtain more feasible solutions. Acting as guidance for designers, the requirements will help enhance the practicality and clinical acceptance of disruptive prototypes of tracheostomy robotic systems.

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