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Robotic control of a traditional flexible endoscope for therapy

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Abstract In therapeutic flexible endoscopy a team of physician and assistant(s) is required to control all independent translations and rotations of the flexible endoscope and its instruments. As a consequence the physician lacks valuable force feedback information on tissue interaction, communication errors easily occur, and procedures are not cost-effective. Current tools are not suitable for performing therapeutic procedures in an intuitive and user-friendly way by one person. A shift from more invasive surgical procedures that require external incisions to endoluminal procedures that use the natural body openings could be expected if enabling techniques were available. This paper describes the design and evaluation of a robotic system which interacts with traditional flexible endoscopes to perform therapeutic procedures that require advanced maneuverability. The physician uses one multi-degree-of-freedom input device to control camera steering as well as shaft manipulation of the motorized flexible endoscope, while the other hand is able to manipulate instruments. We identified critical use aspects that need to be addressed in the robotic setup. A proof-of-principle setup was built and evaluated to judge the usability of our system. Results show that robotic endoscope control increases efficiency and satisfaction. Participants valued its intuitiveness, its accuracy, the feeling of being in control, and its single-person setup. Future work will concentrate on the design of a system that is fully functional and takes safety, cleanability, and easy positioning close to the patient into account.

Keywords Robotics · Flexible endoscopy · Multi-degree-of-freedom input device · Surgery

Introduction

In flexible endoscopy the interior surfaces of the gastrointestinal, reproductive, and respiratory tracts are assessed. The physician uses a flexible endoscope with a camera at the steerable distal tip that is introduced into the natural body openings. Instruments can be inserted into the endoscope. These protrude from the tip and enable interventions such as resecting small polyps.

Current commercially available flexible endoscopes and their instruments have limited capacity to execute procedures that require advanced maneuverability. Technological improvements could enable a shift from more invasive surgical procedures that require external incisions to endoluminal procedures that use the natural body openings (mouth, anus, ureter, or vagina) as access points [1]. At present, these endoluminal surgical procedures, like resection of large mucosal lesions, are not generally adopted by physicians. The concept of natural orifice

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Fig. 1 Therapeutic procedure with flexible instruments

transluminal endoscopic surgery (NOTES) that requires even more dexterity is still in its infancy because of the lack of sophisticated user-friendly tools [2, 3].

No revolutionary changes have occurred in endoscope handling technology during the last five decades. At present there are no flexible endoscopes available that can be controlled in an intuitive and user-friendly way by one person [4]. With the addition of instruments in therapeutics, a team is required to control all independent translations and rotations (degrees of freedom) of the tools, as shown in Fig. 1.

It is expected that endoluminal surgical procedures would be generally adopted by physicians if the enabling technology were available [5, 6]. Robotic technology has the potential to support physicians in easily and safely manipulating flexible endoscopes and their instruments. Computer techniques, like motion scaling and tremor filtering, can be implemented. As shown for robotizing rigid instruments [7], robotizing flexible instruments is the next logical step in improving the patient's well-being and the physician's work comfort and capabilities [8, 9]. We propose a robotic system that interacts with a traditional flexible endoscope. In this way current endoscope qualities, like cleanability and good image quality, are maintained and costs related to replacement of endoscopic equipment are prevented.

Previous work [10] concentrated on redesign of the control section to obtain single-person endoscope steering for diagnosis. With the addition of instruments in therapy, single-person control can only be obtained if the flexible endoscope can be operated with one hand and the instruments with the other. The robotic steering module [10] that actuates left–right and up–down of the distal tip is combined with a robotic shaft manipulation module that actuates the axial and rotational movements of the flexible shaft of the endoscope. The physician uses one multi-degree-of-freedom (multi-DOF) input device to steer, advance, rotate, and maintain the position of the motorized flexible endoscope, while the other hand is able to manipulate instruments. Fig. 2 indicates the motorized and manually operated degrees of freedom of the robotic traditional flexible endoscope for therapeutic procedures and shows how displacements of the input controller, represented by a pen, are linked to endoscope movements to obtain intuitive manipulation.

Robotic control is not intended for endoscope movement in diagnosis that requires precise interpretation of the interaction forces between endoscope and lumen [4], but it enables the physician to intuitively manipulate the tip of the endoscope in the operating area. It creates a stable endoscopic platform without the need of an assistant and allows for small precise robotic movements of the distal tip when the spatial range of the instruments is too small.

The Endodrive® (ECE Medical Products, Erlangen, Germany) is the first and only known commercially available system for electro-mechanical support of shaft manipulation of traditional endoscopes. The system allows positioning and driving of the endoscope shaft forwards and backwards by means of drive rolls and a foot pedal. It assists in inspection and leaves both hands free for operation of the navigation wheels of the endoscope and for instrument manipulation. Rotation of the shaft should be done manually. Kume et al. [11] have developed an endoscopic operation robot for steering, advancing, rotating, and stabilizing a standard endoscope. It is controlled bimanually by means of two joysticks. Although the study suggests the possibility of clinical application of the system, it is far from being ready for clinical implementation. The Invendoscope® (Invendo Medical, Kissing, Germany) consists of a dedicated single-use flexible endoscope that is actuated by an insertion module equipped with gearwheels. Tip steering as well as shaft translation is actuated. Rotation of the shaft is not actuated [12].

All these systems have been mainly developed to assist in navigating the lumen in diagnostic procedures. A system that assists in performing advanced therapeutic procedures by robotizing all degrees of freedom of a flexible endoscope, and that is steered with one hand, does not exist. The remainder of this paper discusses the design and evaluation of such a robotic flexible endoscope, but first the current problem area is researched.

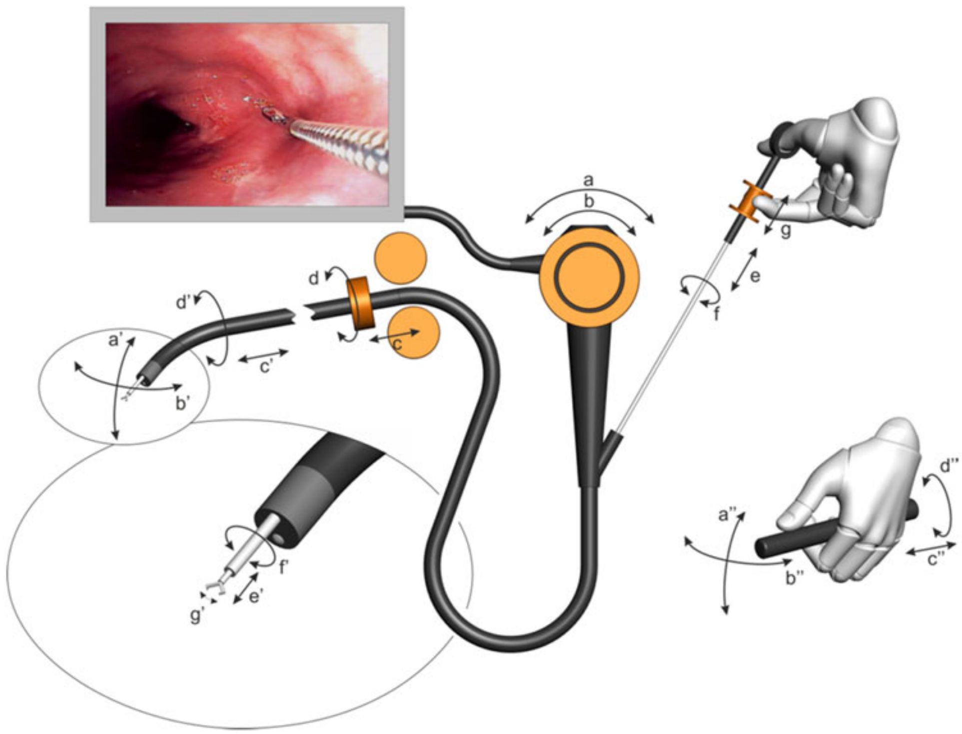


Fig. 2 Degrees of freedom of robotic flexible endoscope for therapeutics: *a* robotic up-down, *b* robotic left–right, *c* robotic in–out, *d* robotic (counter) clockwise rotation, *e* manual in–out instrument, *f* manual (counter)clockwise rotation instrument, *g* manual grasp instrument

Current user interface shortcomings

The main usability problems are related to the control section at the proximal end of the flexible endoscope. Often the physician uses both hands for the control section, while assistants manipulate the shaft and instruments according to spoken instructions, as already shown in Fig. 1 [13]. The drawback of this workflow is that the physician lacks valuable force feedback information on tissue interaction, communication errors easily occur, and a team is required to perform the procedure.

Current applications of endoluminal surgery are only performed by very technically skilled clinical experts using traditional endoscopes. Most of them are able to perform single-handed (left-hand) endoscope tip steering [4]. The right hand alternately controls the shaft of the endoscope and the instrument that protrudes through the working channel, so even with a very skilled endoscopist all degrees of freedom of the endoscope and the applied instruments are not constantly under control.

In current practice bimanual action is required to steer the distal tip of the endoscope and to advance and rotate the shaft. Bimanual coordination of hand movements virtually always requires training. It is a high-level capability that requires intense coupling of the motor areas of both hemispheres of the brain [14]. Steering all four degrees of freedom of the endoscope with one hand is expected to be more intuitive and less mentally demanding.

It can thus be concluded that current endoscope handling is not ergonomic, user-friendly, or intuitive. The next section discusses opportunities and considerations for a robotic flexible endoscope.

Design directions

Endoscope advancement up to the operating area will only be supported by the robotic steering module [10], so during the procedure when the shaft of the flexible endoscope is already positioned in the patient and the therapeutic area has been reached, the robotic shaft manipulation module will be brought into position and it will be coupled to the endoscope. The complete procedure of coupling or decoupling an endoscope should not take more than a few seconds.

A multi-DOF joystick with a stylus pen could be an appropriate device to enable single-handed control and intuitive coupling between the motion of the input device and the 4-DOF motion (steering and shaft manipulation) of the endoscope. Incremental position control is the most intuitive transfer function in tasks that require accurate manipulation in a limited workspace and should be implemented for tip as well as shaft control [15]. Hand movement can be coupled to endoscope movement by pressing a hold-to-run button. It prevents unintended movements of the endoscope, allows repositioning of the stylus pen to a comfortable position, and locks the endoscope into position when the input device is (unintentionally) released.

Single-handed endoscope control allows instrument manipulation with the other hand. However, an assistant is not made superfluous by the introduction of a robotic flexible endoscope. Instruments need to be unpacked, positioned in the working channel, and often more than one degree of freedom needs to be operated during the procedure. If the physician only needs assistance occasionally during the procedure, one person should be capable of assisting the physician as well as managing all non-therapeutic actions, like preparation of the room, test equipment, check the availability of accessories, collect specimens obtained during the procedure, and monitor the patient [13].

Force feedback is particularly important when advancing the endoscope through the lumen in diagnosis. During interventions, endoscope displacements are limited and interaction of the endoscopic tip with tissue is avoided. Providing force feedback information is not essential in robotic manipulation of the shaft in therapy. The instruments in the robotic setup are manually operated by the physician, so direct force feedback information between instrument and tissue is available.

The instrument channel of an endoscope is situated at the 5 o'clock position with reference to the visual field. To perform therapy, one of the most important factors is that the point of interest should be in a proper position relative to where the instrument protrudes from the endoscope. To capture, e.g., a polyp, an attempt should be made to bring it into the 5 o'clock position to facilitate snare placement. This can usually be accomplished by rotation of the shaft of the endoscope [16]. Our robotic setup should be able to achieve (counter)clockwise rotation of −180° up to 180° measured from the neutral position.

Although high interaction forces between tissue and flexible endoscope are not expected, for safety purposes the actuation principle should allow translation and rotation of the endoscope when forces reach a critical level. Korman et al. [17] have studied the applied axial and torque forces exerted by endoscopists during a colonoscopy procedure. Since patient pain, instrument damage, and perforation of the lumen are related to the forces applied by the endoscope, these values should not be exceeded and should possibly be reduced if experiments indicate that less force is sufficient in endoluminal therapy.

With regard to other performance parameters of the actuation mechanism, like speed and accuracy, assumptions were made since no data was available from the literature. The most important performance parameters and other important design requirements are summarized in Table 1. All values need to be validated in experiments.

Table 1 Requirements for electro-mechanical shaft actuation

Coupling and decoupling of shaft	<10 s
Degrees of freedom of shaft actuation	2 DOF: in–out translation, (counter)clockwise rotation
Input controller	Single-handed 4-DOF control of tip steering and shaft manipulation
Push–pull force on shaft	60 N
Push–pull range	−150 mm/+150 mm
Push–pull accuracy	±1 mm
Push–pull max. speed	50 mm/s
(Counter) clockwise torque on shaft	1.5 Nm
(Counter) clockwise range	−180°/+180°
(Counter) clockwise accuracy	±1°
(Counter) clockwise rotational speed	90°/s

These critical design requirements are addressed in a basic proof-of-principle setup as discussed in the next section. It was built to test at an early stage the suitability of our actuation mechanism for shaft manipulation and to test the usability of a standard multi-DOF input controller for single-handed endoscope control.

Design proof-of-principle

Figure 3 shows two pictures of the actuation mechanism for robotic shaft translation and rotation.

The endoscope shaft is clamped between two wheels that are pretensioned with a spring. The shaft can be installed and removed at any time during the procedure by pushing a lever down. The lever is linked to the top wheel that moves up to create space. Wheels are preferred above all other solutions due to their greater simplicity. One motor actuates the bottom wheel for translational movements along the shaft axis. The upper wheel rotates freely. Another motor rotates the frame on which the wheels are positioned. Since the shaft is securely clamped between the wheels, axial rotation is achieved when the frame including the wheels is turned. Two DC servo motors (Maxon, Sachseln, Switzerland) were selected for translational and rotational actuation. The motors are controlled by Elmo Whistle servo amplifiers (Elmo Motion Control, Petach-Tikva, Israel). The set-points for the two degrees of freedom are generated by a laptop computer. The software is written in Python.

Except for the rotational range of motion, performance of the actuation mechanism is in accordance with the

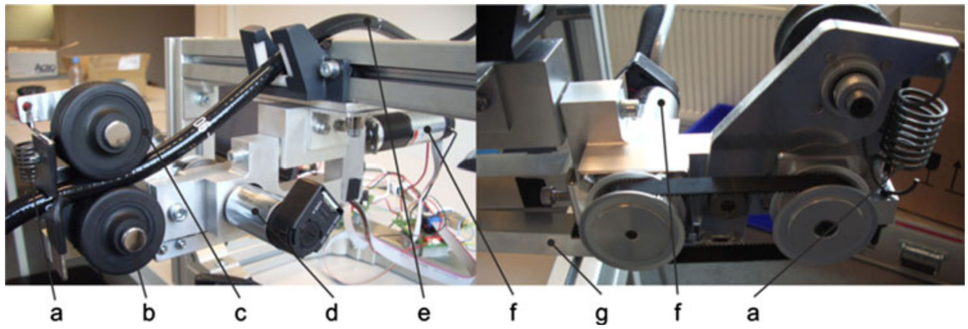


Fig. 3 Actuation mechanism for shaft manipulation: *a* spring, *b* bottom wheel, *c* upper wheel, *d* motor translation, *e* flexible endoscope, *f* motor rotation, *g* lever

requirements indicated in Table 1. The range of motion is limited to −90°/+90°, since introducing a larger stroke would require a much more complex design and has been estimated to be used rarely in therapy. This assumption is tested in our experiment.

A Phantom Omni® haptic device (Sensable Technologies, Woburn, MA, USA) is used as input controller to steer shaft manipulation as well as tip movement. Figure 2 already showed how endoscope movements are linked to stylus displacements in our setup. Incremental position control has been implemented as a transfer function between user input and end effector displacement. The gain (or scaling factor) of both motors is adaptable to vary the accuracy of endoscope manipulation.

Evaluation proof-of-principle

This section describes the experiment conducted to determine the feasibility of the robotic endoscope. We compared the usability of conventional steering with robotic steering in tasks that require advanced endoscope maneuverability.

Experimental setup

Figure 4 depicts the complete setup used in this experiment to assess the intuitiveness and user-friendliness of robotic flexible endoscopy. Besides the robotic shaft manipulation module, the robotic steering module [10] is implemented in the setup.

We tested three setups. In the first setup participants perform conventional endoscope operation while an assistant controls the instrument. This setup is used as a reference for robotic flexible endoscopy. The second setup allows single-handed robotic steering and shaft control (4-DOF) and manual instrument control with the other hand (1-DOF, grasping), as shown in Fig. 4. The third setup consists of the robotic steering module [10] and a Phantom Omni® controller to obtain 2-DOF single-handed tip steering. The shaft is manually operated with the other hand (2-DOF translation and rotation) and the instrument by an assistant (1-DOF, grasping). The last setup was added to evaluate the influence of bimanual endoscope control by the physician.

The 12 participants (aged 19–50 years, two women and ten men) were engineers ($n = 9$) and supporting staff

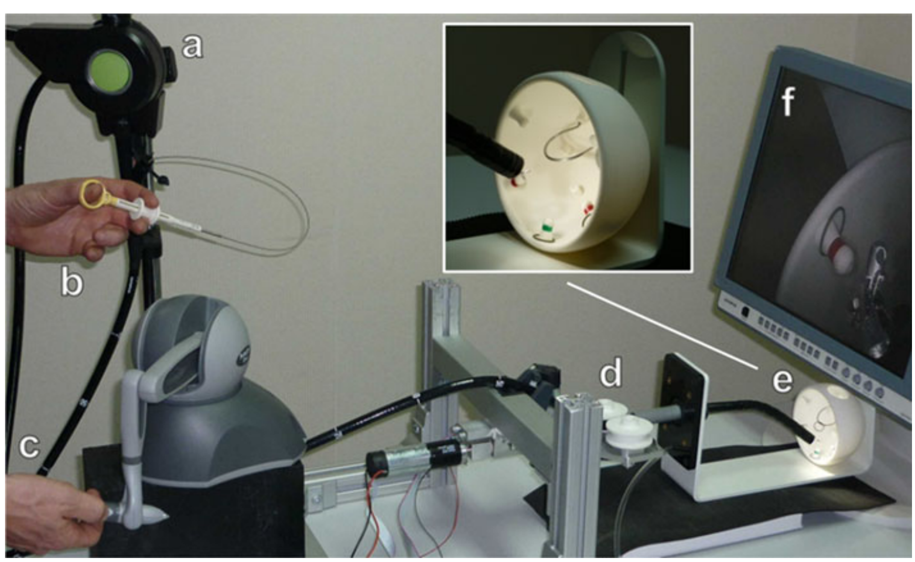


Fig. 4 Robotic control flexible endoscope: *a* traditional endoscope with driving means for tip steering [10], *b* manual instrument control, *c* multi-DOF controller for tip steering and shaft control, *d* driving means for shaft actuation, *e* training model, *f* monitor

($n = 3$) of DEMCON Advanced Mechatronics, without medical background, without experience in endoscope handling, and without experience in controlling one of the robotic setups. The absence of experience enabled testing of intuitiveness. Participants were asked to perform two tasks which required difficult endoscope maneuvering and which simulated clinical tasks in existing therapy, like performing a polypectomy. First, participants had to pick up an O-ring from a pawn with a grasper and place it on a designated pawn. Second, a ring had to be guided from one end of a tortuous wire loop to the other end. The instrument protruded about 2 cm from the tip of the endoscope and instrument manipulation was limited to opening and closing the grasper. Figure 4 shows a close-up of the training model which was developed for this experiment.

Each of the six possible sequences of the three setups was performed equally often to correct for learning effects and fatigue. Each setup was introduced with a short demonstration and the opportunity to ask for advice on usage. Subsequently, the participants were allowed to practice task 1 as well as task 2 once before its evaluation was started.

Our focus was to test the control usability of the robotic endoscope. Usability is defined by the International Standardization Organization (ISO) as "the extent to which a product can be used by specific users to achieve goals with effectiveness, efficiency, and satisfaction in a specified context of use" [18]. In the current experiment the following dependent variables were measured:

- Tasks completed (effectiveness)
- Time required for tasks (efficiency)
- Workload analysis based on a modified NASA Task Load Index, measuring mental and physical demand [19] (efficiency)
- Rank interfaces to preference (satisfaction).

Results and discussion

The quantitative results and the comments that were made indicate that robotics enhances flexible endoscope control by novices in therapeutic tasks. According to the participants, traditional steering "requires constantly thinking about what to do", "the degrees of freedom are not intuitive", and "the navigation wheels for tip control are frustrating". These and other qualitative results are discussed in the remainder of this section. First, the quantitative results of the experiment will be discussed. Table 2 shows median scores and their ranges on the outcome measures.

The low sample size ($n = 12$), the large variation in individual scores, and the absence of normal data distributions on these measures across the three set-ups made us decide to base the analyses on ranked data using non-parametric tests. Separate Friedman's ANOVAs were conducted to compare the three setups. In the case of a significant effect, Wilcoxon signed-rank tests were conducted to compare the scores between two setups. A Bonferroni correction was applied to control for chance capitalization, resulting in a 0.0167 level of significance for the contrast analyses. Overall significance level was $p = 0.05$.

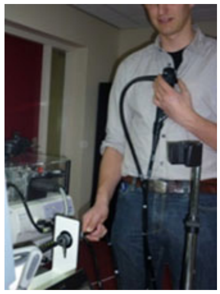
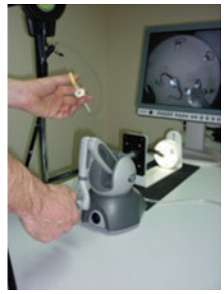
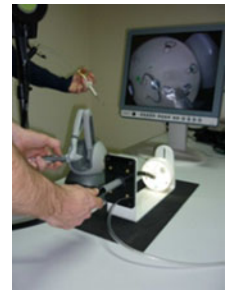
Performance of the participants in task 1 differed across the three set-ups: χ^2 ($N = 12$, 2) = 8.17, $p = 0.017$. Post-hoc analyses indicated that performance on the single-handed robotic setup was significantly better than performance on the conventional setup: $Z = 2.43$, $p = 0.015$. Participants also performed better on the bimanual setup than on the conventional setup: $Z = 2.75$, $p = 0.006$. No significant difference in performance was found between the two robotic setups: $Z = 0.43$, $p = 0.666$.

In addition, the performance scores in task 2 differed significantly across the three setups: χ^2 ($N = 12$, 2) = 9.50, $p = 0.009$. However, post-hoc analyses only showed a significant difference in performance between the single-handed and conventional setups: $Z = 2.51$, $p = 0.012$. No significant differences were found between the bimanual and conventional setups: $Z = 1.26$, $p = 0.209$, and among the robotic setups: $Z = 1.78$, $p = 0.077$.

The perceived workload differed significantly across the three setups: χ^2 ($N = 12$, 2) = 20.47, $p = 0.001$. Participants experienced the workload in the single-handed setup as lower than in the conventional setup: $Z = 3.06$, $p = 0.209$. This was also true for comparing the bimanual setup against the conventional setup: $Z = 3.08$, $p = 0.002$. In addition, the difference between the two robotic setups approached significance: $Z = 2.35$, $p = 0.019$, suggesting that the perceived workload was lower for the single-handed setup than for the bimanual setup.

The results show that robotic control significantly improves efficiency and satisfaction in simulated clinical tasks performed by novices. All participants were able to complete the tasks with all setups, so improved effectiveness is not demonstrated in this experiment. The results of the bimanual robotic setup show no significant differences compared with the single-handed setup. One participant preferred the bimanual robotic setup, because the rotational range of the single-handed robotic setup is limited to −90°/+90°, whereas in manual shaft rotation the range is limited by human capabilities. All other participants preferred the single-handed setup. Participants valued its intuitiveness, its accuracy, the feeling of being in control, and its single-person setup. Additionally, about 50 % of the participants indeed complained about the bimanual robotic setup being more mentally demanding. Some of them constantly

Table 2 Quantitative results experiment

Setup	1. Conventional	2. Robotic (single-handed)	3. Robotic (bimanual)
			
Tip steering	Left hand	Right hand	Left hand
Shaft manipulation	Right hand	Right hand	Right hand
Instrument control	Assistant (not visible)	Left hand	Assistant
Time for task 1 (s)[a]	356 (186–720)	149 (78–370)	158 (84–450)
Time for task 2 (s)[a]	183 (77–310)	84 (47–279)	98 (70–312)
Workload (on scale of 1–5)[a]	4 (2.40–4.80)	2.10 (1.40–2.60)	2.40 (1.60–3.40)
Preference (*n*, 1/2/3)	0/1/11	11/1/0	1/10/1

[a] Values are represented as median (range)

switched between tip steering and shaft manipulation during the procedure. However, in the bimanual robotic setup the degrees of freedom were better decoupled than in the single-handed robotic setup. Although participants were instructed how to realize independent endoscope movements, intended translations and rotations often led to small noticeable endoscope movements in other directions. "I like the single-handed robotic setup very much, but it can be optimized by better decoupled steering of all displacements and rotations" was one of the remarks that indicates that improvements can be made in single-handed multi-DOF control. Two rotational degrees of freedom of the Phantom Omni® input controller are not in use in our setup. Bowman [20] suggests that redundant degrees of freedom should be constrained; using haptic restrictions is a known method [21]. However, a Phantom Omni® is a cost-effective haptic device with force feedback only on the translational movements, not on the rotations. We were therefore not able to easily restrict the redundant rotational movements. Future work could focus on improving performance by using a more sophisticated haptic device that provides force feedback on all degrees of freedom. In this way additional forces can be created that restrict haptic device movements to the kinematics of the robotic endoscope.

What participants missed in all setups was independent axial rotation of the grasper to orient it to grasp a ring. Instrument rotation can be realized by rotating the shaft of the endoscope that holds the instrument. However, when the tip is bent, rotating the shaft will result in translational camera movements. Only in the 4-DOF robotic setup could this be automatically compensated for by actuating tip steering in the opposite direction. To take advantage of axial rotation of the grasper, the rotational range of motion of the shaft (and as a consequence the grasper) should be enlarged from $-90°/+90°$ to at least $-180°/+180°$. Additionally, as discussed in the design directions section, this larger range of rotation will be helpful in therapy to orient the point of interest in a proper position relative to where the instrument protrudes from the endoscope.

Conclusions and future work

The positive reviews, the quantitative results of the tests, and the opportunities to implement intelligent algorithms justify our focus on development of the single-handed robotic setup. The proof-of-principle system demonstrated its usability. However, it is not ready to be implemented in the current clinical workflow. Currently, work concentrates on the design of a system that is fully functional. The main design issues that will be addressed are:

- Size and positioning

In the clinical setup the shaft manipulation module needs to be positioned as close as possible to the patient to minimize loss of shaft length and limit buckling effects of the shaft outside the patient's body. Nevertheless, for safety purposes some distance is required to prevent physical contact between robotic module and patient. A distance of 25–30 cm, as used in manual manipulation and seen in the comparable systems discussed, seems appropriate. Most endoscopists place the patient in the left lateral position. Patient repositioning (to right lateral, supine, or even prone position) may be necessary to optimize visibility and access to the operating area. In order to facilitate robotic shaft manipulation under these conditions the robotic module needs to be small and its position needs to be easily adaptable without retracting the endoscope from the patient.

- Disinfection

Even in the case of non-sterile endoluminal interventions, all parts that can potentially be touched by the therapist or the patient should be clean to prevent cross-contamination. Use of disposable parts (including plastic bags) that separate the clean from the contaminated world (e.g. actuation mechanism) is a known method. By taking these measures, provided that the endoscope and instruments are sterile, the system could potentially be used in interventions that require sterility, like in NOTES [2]. Additionally, the lay-out of the system has to be suitable for handling a polluted endoscope.

In future experiments the new design needs to be tested by clinical experts. First, a laboratory experiment, like the one discussed in this paper, should be performed by physicians to assess the usability of the system. Second, in-vivo (animal) tests should be executed to evaluate the efficacy and accuracy of robotic interventional endoscopy. Finally, the clinical usability and efficacy need to be tested by physicians on candidates for this procedure. The results of the experiments will be used to refine our robotic system and ultimately provide a tool for performing advanced therapeutic procedures in an intuitive and user-friendly way by one person.

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Conflict of interest None.

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