Integration of robotic in the reprocessing and transfer of endoscopes

Authors

Hans Dieter Allescher[1], Florian Voigt[2], Martin Mangold[1], Sami Haddadin[2]

Institutions

1 Klinikum Garmisch-Partenkirchen, Teaching Hospital of the Ludwig Maximilians University Munich, Munich, Germany

2 Chair of Robotics Science and Systems Intelligence, Technical University of Munich, Munich, Germany

submitted 1.6.2021

accepted after revision 26.11.2021

published online 18.7.2022

Bibliography

Endosc Int Open 2022; 10: E1022–E1028

DOI 10.1055/a-1789-0532

ISSN 2364-3722

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Corresponding author

Prof. Dr. Hans-Dieter Allescher, Center for Internal Medicine, Klinikum Garmisch-Partenkirchen, Teaching Hospital of the Ludwig Maximilians University Munich, Auenstr. 6, D-82467 Garmisch-Partenkirchen, Germany

Fax: +49-8821 1562

hans.allescher@klinikum-gap.de

ABSTRACT

Background and study aims Optimal hygiene is crucial for patients undergoing flexible endoscopy. Reprocessing is currently influenced by manual procedures performed by endoscopy staff. To overcome this limitation, we designed and evaluated the integration of robotic application for an automated endoscope processing pathway.

Methods We used an endoscope reprocessing pass through machine with drying cabinet and a Franka Emika Panda robot. The robot was programmed to interact with its environment in a compliant way, guaranteeing desired contact force thresholds and therefore ensuring safety of both robot and medical equipment.

Results In an initial phase we tested the robots' ability to handle a modified tray holding an endoscope as well as certain challenges (correct positioning, connection of tubing, undesired collisions). We added another Panda robot arm resulting in a device featuring two independent manipulators and tested the accuracy of each individual step.

We evaluated 50 consecutive processing and transfer procedures, simulating the average daily throughput of an endoscopic unit. The endoscopes were removed in adapted tray using a specially designed lifting device and placed in an endoscope storage and venting cabinet. The mean time for the handling of the scope was 104.2 ± 1.2 seconds and an accuracy of 100 % (0 failures in 50 attempts) was achieved.

Conclusions To the best of our knowledge, this is the first description and evaluation of an automated compliant robotic assistance in the processing of endoscopes. Further development could help to overcome shortcomings of the man handled endoscope processing and could lead to reproducible, standardized and certified endoscope processing.

Introduction

Optimal hygiene is crucial for patients undergoing flexible endoscopy. Several outbreaks of serious infections following endoscopic procedures have raised considerable concerns about the cleaning process for flexible endoscopes [1–4]. These infections involved highly resistant bacteria as well as transmission of bacterial within a single patient as well as from one patient to another [5]. Several factors such as design and the layout of flexible endoscopes have been advocated as possible mechanisms contributing to the transmission process [4, 6, 7]. As an important mechanism, insufficient drying before storage was identified as a possible reason for contamination and strict adherence to reprocessing procedures ended the

outbreak [1]. In addition, strict adherence to a fully completed and error-free cycle is of central importance for the cleaning result. Hygiene and the cleaning of gastrointestinal endoscopes has been identified as the major problem in further development of flexible endoscopy [8].

Thus, several recommendations were defined and published, which should be strictly followed to achieve an optimal result [9–11].

However, even after strict training programs and adherence to the cleaning protocols, there were still some endoscopes that did not pass the hygiene controls. In addition to general problems in the organization or layout of the reprocessing area, one possible factor is the human factor, which cannot be fully controlled. Failures in the application of the various steps in the endoscope handling by the cleaning personal as well as handling problems constitute an additional factor that could cause hygiene problems. The limitation of the variable human factor also impairs the certification of a processing pathway.

This study was initiated to investigate the use of robotic automation in reprocessing of endoscopic equipment, thus eliminating the human factor and possible human failures for the processing pathway. It also aimed to examine whether use of robotics could be implemented under routine conditions for processing, storage, and transfer of the endoscopes and to establish a certified processing workflow.

Methods

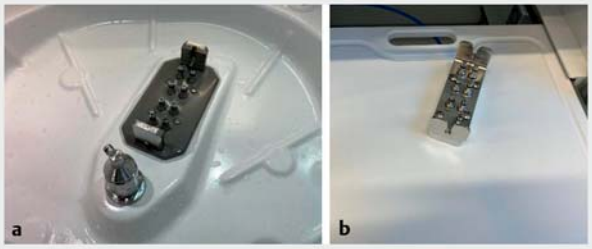
The studies were performed in the Endoscopy Department of the Center for Internal Medicine of the Clinic Garmisch-Partenkirchen at the BG Murnau in collaboration with the Chair of Robotics Science and Systems Intelligence of the Technical University of Munich.

Ethics and regulatory aspects

The study was approved by the institutional review board (IRB) and the Hygiene Department of the Clinic Garmisch-Partenkirchen. The study was reported to and approved by the local ethics committee. In this phase of the study, no human or patient interaction was planned. All experiments were performed with equipment not intended for use with patients at the current stage. The local Hygiene Department and the local authorities were informed of the study and approved the use of the technical equipment. All hygiene tests were performed by an independent external hygiene provider.

Equipment for endoscope processing and storage

For the purpose of endoscope processing, a commercially available automated endoscope washer-disinfector (EWD) pass-through machine (Cantel, Advantage Plus Pass thru Cantel, PC Heerlen, Netherlands) and drying and storage cabinet (Endostore Neo, Cantel, PC Heerlen, Netherlands) were used. An endoscope washer-disinfector (EWD) is intended for cleaning and disinfection of flexible thermolabile endoscopes and their endoscope components within a closed system according to EN ISO 15883-4. The EWD has the advantage that only a single endoscope is processed in an individual cleaning chamber and each endoscope is placed in a single tray. The tray can be used for the transfer and all connections for flushing and venting. The individual endoscope channels are established with a connecting device and secured with a lever to ensure tight connections (▶ **Fig. 1a** and ▶ **Fig. 1b**).



▶ **Fig. 1** Connecting devices in the **a** automated endoscope reprocessing machine and **b** the drying cabinet where the tray has to be placed and connected with a lever to allow secure connection with all individual pipes.

Once placed in the processing tray and connected to the individual lines, the endoscope stays in this tray during processing, drying, and storage, and transport back to the procedure room until the next use. Thus, the endoscope itself does not have to be handled directly. The endoscopes were cleaned using Proteazone (Proteazone, Cantel, PC Herrlen, Netherlands) and a per-acidic acid-based disinfectant (Rapacide, Cantel, PC Heerlen, Netherlands).

Special adaptation for robotics

The endoscope tray and the hand grip on each side of the tray were modified for accurate positioning of the lifting device (Plastic tray, Cantel, PC Heerlen, Netherlands). A special lifting device was designed, using an aluminum rod and hooks printed via a 3D-printer (Ultimaker 3, Ultimaker Netherlands) using PLA filament (BASF Ultrafuse, BASF Germany).

For the robotic application, a robotic arm (Panda, Franka Emika, GmbH, Germany) was used with a lifting ability of approximately 3 to 5 kg. In the first and second phases, the experiments were carried out with a single robotic arm; in the third routine phase, two robotic arms were used to increase flexibility and versatility. In addition, one arm was placed on a linear unit, which allowed for vertical movement of the Panda robot.

The robotic system was first set up and tested under lab conditions (Chair of Robotics Science and Systems Intelligence, Technical University of Munich) to grab, lift and position the processing tray. The Panda robot was controlled using impedance control [12], which lets the robots end-effector behave like a spring-damper system. This allows for compliant manipulation, such as desired contacts and contact forces or compliance when running into obstacles. Due to the torque sensors in its joints, the Panda robot is able to sense external forces acting upon the robot. With this, the robot can perform safe Human-Robot-Interactions. In order to calculate the external forces correctly, the weight of tray and endoscope is determined via gravity compensation. Both robot and linear unit

were controlled via C++ and Python and communication was implemented via UDP and TCP protocols. For C++, the Franka control interface (FCI) was used with open-source code available online (https://frankaemika.github.io/docs/).

At this stage, safety features such as collision recognition and avoidance, emergency stopping, and error recovery were included in the system. Also, compliant manipulation parameters such as stiffness and desired contact forces were adapted to the handling process.

For testing under laboratory conditions, a conventional gastroscope not in use in patients (GIF-Q-145, Olympus, Germany) was used. For routine use, a conventional standard gastroscope was used. The tests were performed in the Endoscopy Department of the Clinic Garmisch-Partenkirchen, Germany after the regular working hours of the endoscopy unit to avoid interference with the endoscopic program in patients.

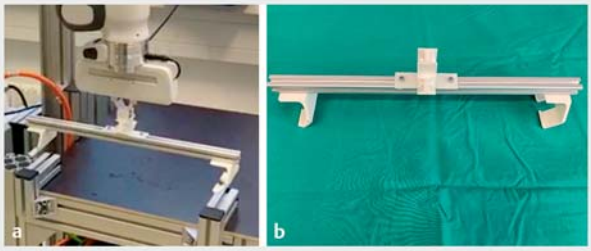
Integration of the robotic system into the routine cleaning process

The robotic system was transferred to the clean side of the endoscope processing area. The robotic system was tested and evaluated, and its stability was further improved. A second robot arm placed on a mobile platform on the opposite of the first arm was introduced to increase the flexibility of the system. This allowed for simultaneous processing of the storage cabinet and the EWD unit and also, the effective overall workspace was increased, as both robot arms were able to collaborate. This meant that all shelves of the cabinet could be handled, and the system featured improved speed and performance.

In the final step, the complete transfer process of the tray with the cleaned endoscope from the EWD to the cabinet was tested in consecutive tests. Errors and adequate handling (correct shelve, connection of all lines) were recorded. Consecutive test runs were carried out and evaluated using 50 consecutive trial runs.

Reprocessing of the scope

Endoscope processing was subdivided in small individual steps in order to plan future integration of robotic assistance. These steps included: 1) leakage test, immersion of the endoscope in the pre-cleaning solution, manual cleaning and flushing; 2) transfer of the scope to the endoscope washer disinfector machine (EWD); 3) washing/cleaning cycle in the EWD; 4) transfer of the cleaned endoscope to a drying and storage cabinet; and 5) transfer of the endoscope from the storage cabinet to the transport box). In the current project, steps 1 and 2 were performed by a nurse whereas the last two steps were performed by the robot. Manual cleaning of the used scope was performed according to guidelines and recommendations from the manufacturer. Then the digitally registered endoscopes were transferred to the pass-through EWD, connected and the reprocessing was started by the nurse.



▶ **Fig. 2** Adaptation of the processing tray and the lifting device.

Hygiene testing

Hygiene testing of all scopes was performed according to the standardized procedures of our institution and the German guidelines [11] and all scopes were randomly tested for possible contamination [13].

Results

Adaptation of the cleaning process

For use of the Panda robot arm, a special plastic-based processing tray was used in order to save weight and improve safety of the handling properties. The standard metal tray has flexible hand grips and was replaced by a plastic tray with fixed hand grips and that weighed less.

A special grabbing and lifting device for the robotic arm was designed and printed with an Ultimaker-3 3D-printer using PLA filament (▶ **Fig. 2a**, ▶ **Fig. 2b**). The fixed hand grip on each side of the tray allowed accurate positioning of the lifting device.

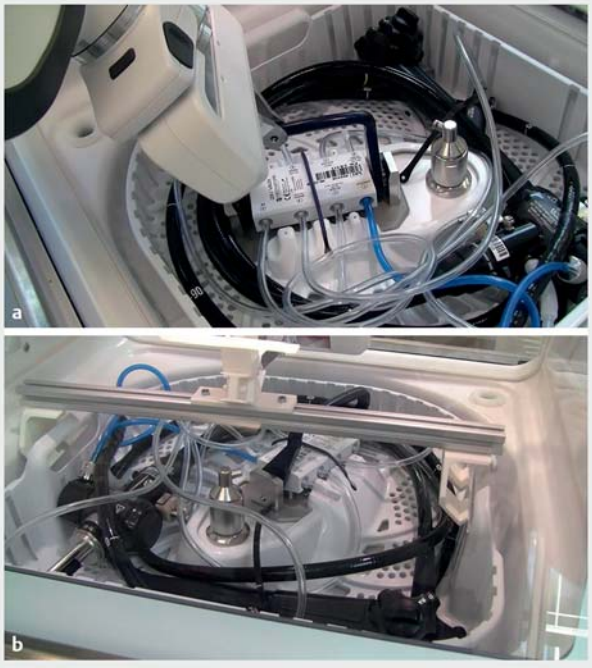
The robotic system was first applied and configured under lab conditions to grab, lift and position to special cleaning try with high accuracy. In the lab test, an accuracy of 100 % with 50/50 successful attempts could be achieved.

Special features designed to avoid damage of the endoscope, equipment (EWD, storage cabinet) and humans or foreign bodies were established. There was a special algorithm for forced feedback control to avoid action against a given resistance. Status light to indicate robotic activity and control to check for correct positioning of the endoscope and the robot arm as well as for possible interference which human were included as safety features. Interference with the robotic arm leads to an immediate stop of the robotic movement.

Testing in the endoscopy unit: field test

After these transfer routines were achieved in a save and routine fashion with 100 % accuracy, the system was checked in a field test in the clean side of the endoscope reprocessing room. Fine-tuning of the parameters for the application of the robotic system to open the lever in the EWD, grab and remove the tray and place it at a given location took place.

At the end of the reprocessing cycle, the endoscope positioned in the tray was removed on the clean side of the reprocessing room by the Franka Emika Panda robot. The robot first opened the lever which connects the individual lines to the

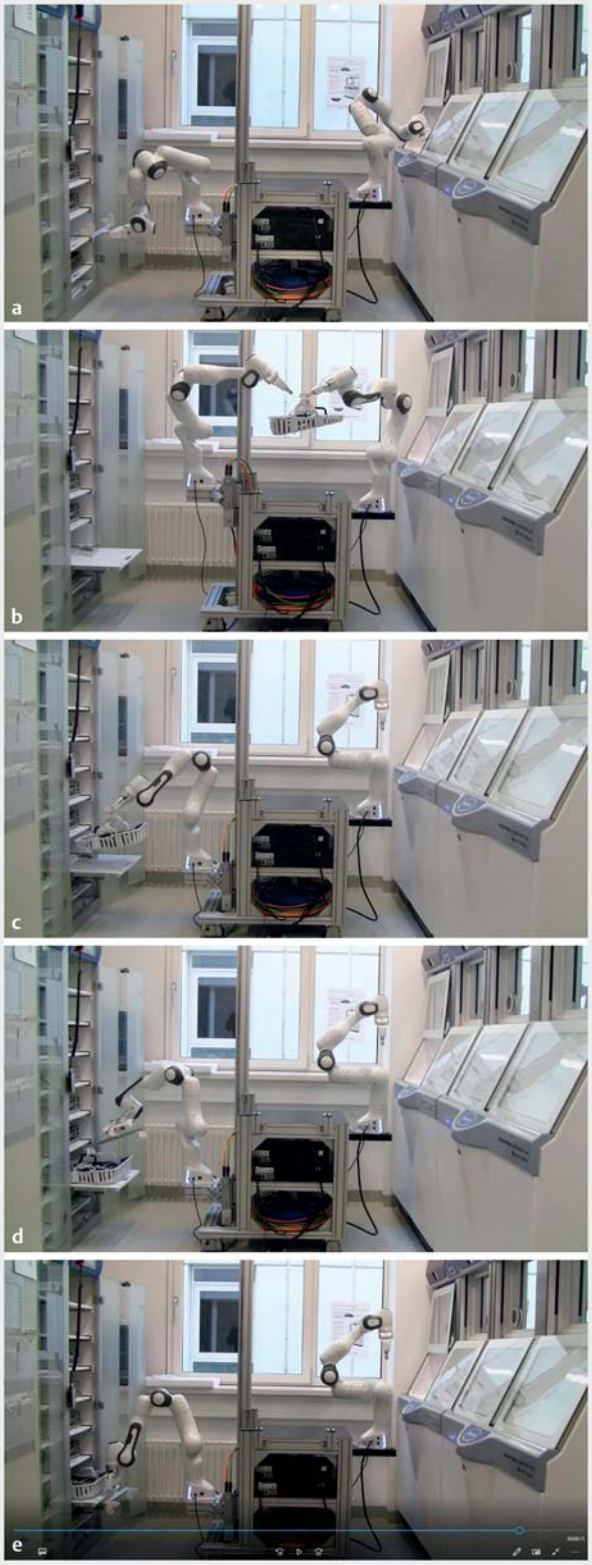


▶ **Fig. 3** Preparatory steps for the removal of the adapted tray with the processed endoscope from the EWD. **a** Lifting of the lever to separate the individually connected lines **b** removal of the tray with the special lifting device.

channels of the endoscope. It then removed the tray using a specially designed lifting device and placed it in a venting and storage cabinet (▶ **Fig. 2**). The robot was programmed to interact with its environment in a compliant way, guaranteeing desired contact force thresholds and therefore ensuring safety of both robot and medical equipment. Based on a given drawer number, the target position of the endoscope within the storage cabinet was calculated. The robot was mounted on a linear unit, by which the height of the robots' base could be controlled. During insertion, the robots compliant control ensured connection of the individual tubing for venting of the individual endoscopic channels, while preventing damage (▶ **Fig. 3**, ▶ **Video 1**, ▶ **Video 2**). Upon touch panel request, the processed endoscopes could then be delivered into a plastic transport box by the robot.

After adapting programming routines, the robot achieved an accuracy and reproducibility of 100 % (50 attempts, 50 successful transfers, no failure, no damage or loss of the tray or the endoscope).

During the field test, the robotic device had to be modified and a second robotic arm was included in the system. The second arm was mounted on a mobile platform, which could be moved in vertical direction up and down to reach all shelves of the storage cabinet. To work with two robotic arms, the grabbing device had to be modified to allow transfer from one arm the other. In the final field test, the robotic arm safely and accurately removed the processing tray and transferred it to the correct position of the storage cabinet and connected the individ-



▶ **Fig. 4** Sequential images of the automated process with dual robotic arm system. **a** The left arm is preparing the venting cabinet, the right arm is opening the lever in the EWD to allow the removal of the tray. **b** Removal of the tray with the right arm and transferring it directly to the left arm. **c** Placement of the tray in the desired shelves **d** Closure of the lever for connection of the individual venting lines. **e** Closure of the shelve. The complete process and the individual components are shown in a supplementary video.

▶ **Fig. 5** **a** Transfer of the endoscope from the storage cabinet **b** Opening of the lever to disconnect the individual venting lines. **c** Total view of the clean side with the autonomous trolly and the sterile plastic box for the endoscopic tray. **d** Collision detection of the system to avoid interference.

ual venting lines to the trays (▶ **Fig. 4**, ▶ **Video 3**). Again 100 % accuracy of the endoscopes (50 of 50 attempts) was achieved.

The average transfer time for the complete transfer was 104.2 ± 1.2 seconds. The variation is due to correction routines carried out by the robotic system. Still images showing the complete as well as the individual processes, such as closing the lever and removing the trays, are shown and complete videos of this processes are attached in the supplementary material.

Security controls such as manual (n = 10) or physical interference (n = 10) with the tray or blocking the robotic workspace (n = 10) were performed and lead to immediate stop of the robotic movements (▶ **Video 4**).

As the final step, we tested transfer of the endoscope on demand from the storage cabinet to the plastic transport box on the transport trolly. The desired endoscope could be indicated with a button control and the robot arm delivered the scope to the container on the transport trolly (▶ **Fig. 5**). After the learning period, the controlled pathway again achieved an accuracy of 100 % (50 transfers of 50 attempts) and the average time for the transfer of the scope was 32.0 sec.

The different times for the individual procedure steps by a nurse were analyzed with individual recordings of the procedure steps. The average time for a nurse to perform a transfer from the EWD to the storage cabinet was 46.0 ± 4.1 sec, which was composed of 25.8 ± 4.9 sec for hand disinfection and 20.1 ± 4.6 sec for the transfer endoscope tray and connecting the lines (n = 9). The average time for a nurse to perform the transfer from the storage cabinet to the transport box was 41.0 ± 6.6 sec, which was composed of 26.8 ± 4.2 sec for hand disinfection and 14.1 ± 2.7 sec for the transfer of the endoscope tray to the transport box (n = 9).

Concepts and visions (ROBERTA)

The final concept is that the clean side of the reprocessing room is completely autonomous and free of human interaction. The whole process is carried out by the robotic system. The system is connected to the EWD, the storage cabinet and an outgoing communication interface for personnel. The system is provided with information from the EWD regarding the cleaning cycle and an assignment to store a tray is added to the execution queue on successfully finishing the reprocessing cycle. The robotic system then removes the clean endoscopes and places them in the venting and storage cabinet.

Once in the digitized storage cabinet, the endoscope can be requested either via a button at the entrance or as a future application via voice control, either at the entrance or the procedure room. The robotic system then removes the endoscope from the storage cabinet and places it in a special endoscope transportation box. A mobile transportation unit can then deliver the box with the reprocessed endoscope to the procedure room.

Thus, robotic-assisted endoscopic reprocessing and transfer (ROBERTA) technology can be implemented and used to standardize processing and handling of the reprocessed endoscopes and accessories. The same technology could be used to supply procedure rooms with endoscopy devices, special medication or accessories or other material.

Discussion

Processing of flexible endoscopes is a crucial factor for the safety of patients undergoing endoscopy. There are several detailed recommendations for processing of flexible endoscopes [14, 15]. Attempts to optimize optimal reprocessing conditions have been further emphasized by reports on transmission of pathogens, especially multi resistant bacteria [1, 3].

All these recommendations are limited by the fact that the human factor cannot be eliminated, and possible handling or procedural errors could affect the results of the optimal cleaning cycle. As in the surgical environment, non-adherence to the sterilization and reprocessing recommendation can be linked to possible transmission of pathogens [16]. In addition, certification of the processing pathway is always limited by the involvement of the human interface and possible manual variations

VIDEO

▶ **Video 1** Detail of the disconnection of the individual lines by lifting the lever in the EWD.

VIDEO

▶ **Video 2** Detail of the removal of the tray containing the cleaned endoscope from the EWD.

VIDEO

▶ **Video 3** Complete process of the transfer of the endoscope from the EWD to the drying and storage cabinet.

VIDEO

▶ **Video 4** Security measures for physical interferences (collision control).

and errors. In order to establish a standardized and certified processing procedure a controlled and reproducible pathway is required.

Contamination of the scope by the staff, placement of the scope in an unclean area, and cross-contamination with other scopes cannot be excluded or controlled for. Therefore, additional safety measures have to be undertaken such as video surveillance or regular audits have been suggested [8]. It is crucial to solve these problems as otherwise, requirements such as single-use endoscopes [17] or sterilization of the endoscopes will be required for interventional endoscopic procedures [18].

Another option to improve endoscopic processing would be to exclude the human factor and make the process accessible for a standardization, digital control and finally a certification of the reprocessing cycle. As a first step we used an advanced single endoscope endoscope washer disinfector machine and combined it with an automated robotic device, which allows a standardized process from the successful reprocessing of the scope to the storage cabinet and finally to the delivery of the scope to the endoscopy procedure room.

We divided the reprocessing procedure into five individual working steps. From these steps, the final steps (transfer from the EWD to the storage cabinet and transfer from the storage cabinet to the transport box) were then subjected to a robotic assisted training. The first two steps (precleaning and brushing, manual cleaning, and placement of the endoscope in the EWD) can so far not be automated with the current status of our robotic device.

However, when processing of an endoscope in the EWD is started, the further process located on the clean side of the passage through EWD is standardized. A robotic device can safely and in a standardized fashion remove the scope from the EWD with the specialized tray. It can transfer the tray to another robotic arm which can place the tray with the scope in a microprocessor-controlled fashion in the storage cabinet. It can then deliver the scope upon demand from the storage cabinet to a clean box on a trolly which can be used to transport the endoscope back to the procedure room. Eventually, this step can also be automated in the future. Thus, there would be no need for human staff to enter the clean processing area eliminating possible cross contamination or irregularities in the handling process of the cleaned endoscopes. Furthermore, a digital log file is generated from the beginning of the proces-

sing cycle to the final delivery of the scope for the next procedure.

The hygiene controls showed no abnormalities and the system can now be used under routine conditions. The robotic device for endoscope reprocessing and transfer (ROBERTA) could improve processing and workflow. Integration into the workflow could further improve the quality and safety of endoscopic procedures.

Conclusions

We believe we have established and evaluated the first application and implementation of a robotic device in clinical endoscope processing. This concept could provide the basis for a certified cleaning process of endoscopes and the concept could be expanded to supply of materials.

Acknowledgements

The authors thank Dr. Chris Fulghum and Prof. Dr. John Clarke for proofreading the manuscript. The authors acknowledge the work of the staff of the Department of Robotics Science and System intelligence, Technical University of Munich as well as the endoscopy staff and hygiene personal at the endoscopy unit in the Clinic Garmisch-Partenkirchen.

Competing interests

S.H. holds shares from Franka Emika GmbH, Germany

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