Design and control of a novel gastroscope intervention mechanism with circumferentially pneumatic-driven clamping function

Yanmin Li1,2, Hao Liu1,2*, Siwen Hao1, Hongyi Li1, Jianda Han1,2, Yunsheng Yang3*

1State Key Laboratory of Robotics, Shenyang Institute of Automation, Chinese Academy of Sciences, Shenyang, People’s Republic of China
2University of Chinese Academy of Sciences, Beijing, People’s Republic of China
3Department of Gastroenterology and Hepatology, Chinese PLA General Hospital, Beijing, People’s Republic of China

*Correspondence to: H. Liu and Y. Yang, Shenyang Institute of Automation, Chinese Academy of Sciences, No. 114 Nanta Street, Shenhe District, Shenyang 110016, People’s Republic of China. E-mail: liuhao@sia.cn

Abstract

Background  Robot-assisted manipulation is promising for solving problems such as understaffing and the risk of infection in gastrointestinal endoscopy. However, the commonly used friction rollers in few existing systems have a potential risk of deforming flexible endoscopes for non-uniform clamping.

Methods  This paper presents a robotic system for a standard flexible endoscope and focuses on a novel gastroscope intervention mechanism (GIM), which provides circumferentially uniform clamping with an airbag. The GIM works with a relay-on mechanism in a way similar to manual operation. The shear stiffness of airbag and the critical slipping force (CSF) were analysed to determine the parameters of the airbag. A fuzzy PID controller was employed to realize a fast response and high accuracy of pneumatic actuation. Experiments were performed to evaluate the accuracy, stiffness and CSF. In vitro and in vivo animal experiments were also carried out.

Results  The GIM realized an accuracy of 0.025 ± 0.2 mm and −0.03 ± 0.25° for push–pull and rotation without delivery resistance. Under < 10 N delivery resistance, the error caused by the airbag stiffness was < 0.24 mm. A quadratic polynomial could be used to describe the relationship between the CSF and pneumatic pressure.

Conclusions  The novel GIM could effectively deliver gastrosopes. The pneumatic-driven clamping method proposed could protect the gastroscope by circumferentially uniform clamping force and the CSF could be properly controlled to guarantee operating safety. Copyright © 2016 John Wiley & Sons, Ltd.

Keywords  gastroscope intervention mechanism; circumferential clamping; critical slipping force; shear stiffness; fuzzy PID control

Introduction

The flexible endoscope is a routine and reliable diagnostic tool for gastrointestinal (GI) disease. Its role has now been extended to complex intraluminal therapeutic procedures, such as Endoscopic Submucosal Dissection (ESD),
Endoscopic Mucosal Resection (EMR) and Endoscopic Retrograde Cholangiopancreatography (ERCP) (1–3), for quick recovery and minimal trauma. Generally, the endoscopist holds the handle and manually operates the shaft during traditional endoscopy. The endoscopists, however, have to undertake a heavy workload by holding the endoscope and the large patient population adds to their burden. Besides, the endoscopists are exposed to the digestive pollutant or even X-ray radiation in certain situations, such as ERCP surgery. Moreover, the operation of the flexible endoscope within the digestive tract requires the endoscopist to be well trained. A robotic assistant system is promising to overcome these limitations.

A wireless capsule endoscope (CE) and modified colonoscopes have been developed. CE is currently a fairly good supplement to traditional flexible endoscopes (4). Commercially available CEs, such as the PillCam Series, MiroCam, Endocapsule and MOM, are mostly used for GI screening. Several FDA-approved sensing capsules aid in the diagnosis of pH, pressure and temperature-sensitive GI pathologies. However, CEs are limited for therapy or diagnosis by their capabilities. Aiming at the potentials of looping and perforation during colonoscopy, some institutions have focused on improving the structure of the colonoscope. The Invendoscope (Invendo Medical, Germany) driving unit has eight driving wheels rolled on the inner side of an inverted sleeve with the sleeve rolled inside out, drawing the colonoscope deeper into the colon (5). The Endotics System (Era Endoscopy srl, Italy) achieves its probe locomotion in a worm-like fashion by two champers located in the proximal and distal part of the tip (6). The Aer-O-Scope (GI View Ltd, Israel) has an electro-optical capsule embedded in the front of a lightweight balloon vehicle and is inflated by CO2 to propel the balloon, which glides along the slippery colon walls (7). The Sightline ColonoSight (CS) colonoscope (Stryker GI, USA) employs an air pressure-powered engine located close to the tip to help propel the colonoscope proximally in the colon (8). In these systems, particular scopes were used. However, at present the standard and expensive flexible endoscope is still indispensable for gastroscopy or colonoscopy. Adoption of the above-mentioned robotic flexible endoscope system would significantly increase the expenditure of hospitals and treatment cost of patients. It can be foreseen that the standard GI endoscopes will continue to be used clinically for years.

Until now, only a few research groups have developed robotic systems for the manipulation of standard GI endoscopes, which consist mainly of gastroscopes and colonoscopes. Although gastroscopy is different from colonoscopy in the inspection area, the basic manipulation requirement is the same, including pushing–pulling, rotation and turning of knobs. Kume et al. (9) developed an endoscopic operation robot (EOR) which extends and retracts the endoscope by moving the control section via a separate timing belt and pulley transmission. The EOR is so bloated and far from clinical application. Researchers from the University of Twente (10) proposed a robotic system for manipulating a traditional flexible endoscope. They divided the endoscope manipulation into two parts: a robotic steering module, which actuates up–down and left–right of the distal tip and robotic shaft manipulation module for shaft translation and rotation. Loss of shaft length in their system may result in incomplete examination. They also tried to use an interface in the form of a grip, which allows the users to steer the colonoscope intuitively (11). The Endodrive (ECE Medical Products, Germany) allows driving of the endoscope shaft forwards and backwards; the other operations still need manual operation. From the systems mentioned above, we find that friction rollers were adopted owing to their simple structure and potential low cost. The rollers, however, clamp the endoscope shaft from opposite directions and exert an uneven force on the shaft of the flexible endoscope. Compared with the above-mentioned traditional friction roller mechanisms, the Invendoscope (5) adds a pair of clamping forces vertically; however, an uneven grasping force still exists. As is well known, flexible endoscopes are re-usable and costly medical devices which need significantly better protection during robotic manipulation.

We proposed a robotic system for manipulation of flexible endoscope. In this study, we used the gastroscope as design object for preliminary trials and focused on developing a novel gastroscope intervention mechanism (GIM), which could protect the gastroscope with a circumferentially uniform force.

This paper is structured as follows. In the Materials and methods section, the overall robotic system for the flexible endoscope and the novel circumferential clamping concept is described. The critical slipping force and shear stiffness of the GIM are analysed. Fuzzy PID control was utilized to improve the performance of pneumatic system. In vitro and in vivo experiments were designed to evaluate the performance of the GIM. Subsequently, the calculated and experimental results are presented. The next section discusses the accuracy, safe intervention and noise and analyses the influence of oesophageal mucus and airbag shear stiffness on the system. The final section concludes and suggests possible future work.

**Materials and methods**

The design, analysis and experiment protocol of the GIM is presented in this section. First, the overall flexible endoscope robotic system is described. Second, the novel circumferential clamping concept is presented, including
A novel GIM with circumferentially pneumatic-driven clamping function

the working principle, mechanical structure and relay delivery mechanism. Third, the CSF is analysed. Then, the shear stiffness of airbag is modelled to determine the parameters of the airbag. Besides, fuzzy PID control was introduced to accelerate response time and improve the accuracy of pneumatic actuation. Finally, the in vitro and in vivo experiments were performed.

The overall robotic system for flexible endoscope

The robotic system for flexible endoscope intervention and manipulation is shown in Figure 1. In consideration of manual manipulation of the flexible endoscope, we divide the system into two parts, the delivery arm (DA) and the operation arm (OA). The DA adjusts the position and orientation of the endoscope relative to the patient mouth and inserts, withdraws and rotates the endoscope like the clinician’s right hand. The control section of the endoscope installed on the OA follows the translation and rotation of the endoscope tip. The OA also twists the large and small knobs, controls the gas/water insufflation and suction and implement functions such as taking a picture or switching to narrow band imaging, similar the clinician’s left hand. The drive unit of the knobs could be designed to connect with a disposable dedicated interface to the navigation wheels of each individual type of standard endoscope. The endoscopists could sit nearby or in a remote room, operating the robot by steering the joystick. Synchronous translation and rotation between OA and DA are designed to avoid potential damage owing to the pull or twist of the shaft. Following the translation could also minimize loss of shaft length and limit buckling effects of the shaft outside the patient’s body.

This study aimed to design a mechanism for shaft translation and rotation (a and b in Figure 1) which could protect the gastroscope better with a circumferential clamping force. The requirements for GIM are summarized in Table 1.

Novel circumferential clamping concept

The circumferential clamping concept is described from three aspects: working principle; mechanical structure; and movement pattern.

Working principle for circumferential clamping

Figure 2a indicates that the roller-pair delivery mechanisms exert a bidirectional clamping force on the scope. The uneven load may deform the scope; In the long run, it potentially destroys the scopes and reduces their lifetime. Figure 2b shows our novel circumferential clamping concept, which applies uniform pneumatic pressure around the gastroscope. This could better protect the gastroscope; the reasons are detailed as follows.

The friction rollers clamp the gastroscope in such a way that there is a small contact area. The contact pressure is unevenly distributed and achieves its maximum value at the centre of the contact area. Thus, the gastroscope tends to deform to an oval shape, as shown in Figure 2a. The pneumatic circumferential clamping we propose, however, uses an airbag to surround and hold the gastroscope.

Besides, the transmission force along the axial direction of the gastroscope is offered by the friction force between the gastroscope and the clamping mechanism. The interaction force between the gastroscope and the airbag at the moment of sliding is named the critical slipping force (CSF). It is equal to the maximal static friction force, which is the product of the clamping force and the friction coefficient. The clamping force is the integral of pressure on the contact area, and the friction coefficient is a constant of the material chosen, according to Coulomb’s friction law. The CSF could be used to evaluate the transmission ability of the delivery mechanism. Obviously the GIM has a much larger contact area, so it has a larger

Table 1. Actuation requirements of GIM

<table>
<thead>
<tr>
<th>Degrees of freedom</th>
<th>±0.5 mm</th>
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</thead>
<tbody>
<tr>
<td>Push–pull accuracy</td>
<td>6 mm/s</td>
</tr>
<tr>
<td>(Counter) clockwise</td>
<td>±0.5°</td>
</tr>
<tr>
<td>max. rotational speed</td>
<td>75°/s</td>
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</table>

Figure 1. Overall robotic system for flexible endoscope intervention and manipulation. Once the joystick is pushed forward or pulled backward (a), the DA inserts or retracts the shaft (a) while the OA follows the shaft motion (a). The left or right swing of the joystick (b) controls the handle rotation (b) and handle rotation (b). The bar with four directions (c and d) controls the distal orientations (bending c up and down and d left and right) by rotating the large and small knobs (c and d). Program buttons are used for functions such as water, gas, suction, taking a picture and so on.
transmission ability under the same clamping pressure as the friction rollers. Greater transmission ability under lower pressure is needed to protect the gastroscope during robotic interventions.

Mechanical structure of the airbag

The mechanical structure of the airbag is shown in Figure 3. A silicone tube was placed into the metallic shell and fixed at both ends with two covers. This assembly formed an airbag between the silicone tube and the metallic shell. The screw hole on the shell was used to inflate and deflate the airbag. The air pressure could be changed to control the clamping force exerted on the gastroscope. The silicone tube was chosen for its biocompatibility, softness to protect coat of gastroscope, easy deformation upon air pressure and large friction coefficient for enough transmission force.

A low-cost quick mechanical connector was designed as a carrier for the airbag. The connector, including the airbag, was designed to be disposable, which contributes to convenient sterilization. It also facilitates the clamping of gastrosopes of different sizes and even for other flexible medical instruments, such as colonoscopes and cardiovascular catheters.

Relay delivery mechanism

The GIM we designed has two degrees of freedom (DOFs), pushing–pulling and rotating. The relay pattern was chosen because of the technical requirements of airbag grasping. It delivers the gastroscope in a way similar to that of clinicians’ manual operation (12). During gastroscopy, the clinicians move their hands in a relay pattern. Two airbags were used to realize the operation. Figure 4 shows one stroke of translation and rotation, which consists of four steps; they are both reciprocating motions.

Critical slipping force

As mentioned above, the CSF is the most important parameter to evaluate the transmission capacity of the system. It must be large enough to deliver the gastroscope reliably. Moreover, it could be used as the guideline for safe delivery. Dynamic slipping could be achieved intentionally to restrict the maximum contact force and avoid damaging soft tissues. The CSF is greatly dependent on the normal clamping force, \( F_n \), which is determined by pneumatic pressure. \( F_n \) could be written as:

\[
F_n = \pi D_a L_c P_a
\]

where the air pressure within the airbag is \( P_a \), the external diameter of gastroscope is \( D_a \) and the contact length of the airbag is \( L_c \). Then, the CSF \( F_c \) is:

\[
F_c = \mu F_n = CF_c P_a = CF_c (P_a)
\]

where \( \mu \) is the static friction coefficient between the airbag and the gastroscope. \( C \) is the product of \( \mu \), \( \pi \) and \( D_a \) and \( C \) is a constant if the gastroscope is selected. The contact length \( L_c \) increases with \( P_a \); thus, the critical friction force is positively correlated with the air pressure.
Airbag shear stiffness

During the intervention of the gastroscope with GIM, the friction force between the airbag and the gastroscope will stretch the silicone tube, owing to its elasticity. This would affect the delivery accuracy. The shear stiffness of the airbag plays an important role in this deformation. This section analyses the airbag shear stiffness at different pressures.

As shown in Figure 5a, the silicone tube was stretched to clamp the gastroscope with circumferential force. The axial cross-section of the silicone tube was simplified to an isosceles trapezium, as shown in Figure 5b. The deformable silicone is divided into three parts: \( L_{v1} \), \( L_{v2} \) and \( L_c \). When the GIM drives the gastroscope to the right, the \( L_c \) attached to the gastroscope has a monolithic left movement under the reversed friction force. Its length is supposed to be unchanged. The force of the air pressure applied on the \( L_c \) is vertical to the inner surface of the silicone tube. Thus, the shear strain of the \( L_c \) is small enough to be ignored. The \( L_{v2} \) is prolonged and the \( L_{v1} \) shortens, as shown in Figure 5c. The small gap between the gastroscope and the silicone tube results in a slightly initial tension strain. Little movement of \( L_c \) (<0.005 mm) will make \( L_{v1} \) shorter than its initial length and eliminate the tension force of \( L_{v1} \) onto \( L_c \). So, only the \( L_{v2} \) applies a pulling force onto \( L_c \). For further development of the model, the delivery is simplified as a quasi-static state.
Thus, the inertia of the gastroscope can be ignored. Besides, the medical silicone tube is supposed to be incompressible and isotropic.

The shear stiffness, $K$, could be written as:

$$K = \frac{F_g}{x}$$  \hspace{1cm} (3)

where $F_g$ is the transmission force and $x$ is the axial deformation of the airbag.

$$F_g = E \varepsilon S \cos \theta$$  \hspace{1cm} (4)

where $E$ is the elastic modulus of the medical silicone tube, which is obtained by the uniaxial tension experiment (13) and equals 3.16 MPa. $S$ is the radial cross-sectional area of the silicone tube; $\varepsilon$ is the strain of $L_{v2}$; and $\theta$ is the angle between the $L_{v2}$ and the $L_c$, as shown in Figure 5c.

The above variables satisfy the following geometric constraints:

$$\begin{cases}
S = S_0/(1 + \varepsilon) \\
S_0 = \pi \left( (r + d)^2 - r^2 \right) \\
\varepsilon = (L_{v2} - L_{v20})/L_{v20} \\
L_{v2} = \sqrt{h^2 + (L + x)^2} \\
L_{v20} = \sqrt{h^2 + L^2} \\
\theta = \arctan \left( \frac{h}{L + x} \right)
\end{cases}$$  \hspace{1cm} (5)

where $S_0$ is the initial sectional area of the silicone tube. The silicone tube is supposed to be incompressible; thus, the sectional area is inversely proportional to its length. $d$ and $r$ are the thickness and inner radius of the silicone tube; $L_{v2}$ is the length of the prolonged part; $L_{v20}$ is the initial length of the $L_{v2}$; $h$ is the gap between the gastroscope and the silicone tube; the diameter $D$ of the tested gastroscope is 10.6 mm; $L$ is the projection of $L_{v20}$ onto the $x$ axis; and $L_0$ is the initial length of the silicone tube.

We expect that the influence of elasticity of the airbag to the delivery accuracy is $< 0.25$ mm. With regard to gastroscope transmission forces during gastroscopy, no data were available from the literature. A push–pull gauge was pushed by a professional endoscopist to estimate the maximal intervention force during gastroscopy; the measured result was about 10 N. So, the shear stiffness should be $> 40$ N/mm. The parameters of the airbag, such as initial length, thickness and inner diameter, were calculated to satisfy the requirement of stiffness. Finite element analysis was done to obtain the contact length between the airbag and the gastroscope with different parameters. The parameters of the silicone tube are set as follows: elastic modulus ($E$) = 3.16 MPa; Poisson ratio ($\lambda$) = 0.35; load is evenly distributing. The relationship between stiffness and the three parameters of the airbag can be calculated using equations 3, 4 and 5.

**Fuzzy PID control of the pneumatic actuation**

Clamping of the gastroscope is implemented by pneumatic pressure. The pneumatic actuator exhibits highly non-linear characteristics, due to the compressibility of air, and a dead band of the spool movement in the valve (14). A combination of conventional PID controller with fuzzy logic inference has been proved to be efficient for the pneumatic system (15–17). A hybrid fuzzy PID controller similar to that in (17) was employed to obtain a fast response and a tiny steady-state error. The air circuit is shown in Figure 6. The mobile and static airbags were coordinated to realize translation and rotation by intermittent aeration and deflation. The aeration procedure is our control object.

First, the supply pressure and valves should be designated. An air pipe with an external diameter of 4 mm and an inner diameter of 2 mm was chosen. The lengths of $L_{et}$ and $L_{ta}$ were 2000 and 400 mm, respectively. The volume of the inflated air circuit was 0.0076 l along with the airbag, whose volume was $5 \times 10^{-5}$ l. The desired inflation time was $< 0.1$ s. So, the rate of flow should be $> 0.076$ l/s. The electric–pneumatic regulator ITV 0030 (SMC Corp., Japan) with a flow of 0.1 l/s was chosen. The three-port solenoid valve SY513-5DZD was chosen, whose sonic conductance, $C$, was 19 l/s (MPa). The sonic conductance is an important parameter describing...
the flow capacity of pneumatic components. The valve used can realize a 1.9 l/s rate of flow under 0.1 MPa differential pressure, which guarantees the required flow rate. To guarantee the flow of the regulator, the supplied air pressure was 0.6 MPa.

Then, the working process of the fuzzy PID control was as follows. The error $P_e$ between the reference input $P_r$ and the feedback output $P_f$ determines whether PID or fuzzy controller will be chosen. When the error $P_e > E_0$, the fuzzy controller was used to get a fast response. The fuzzy controller divides the output into four cases, according to the $P_e$: (a) when the output pressure is far lower than the reference ($P_e < E_{nib}$), the controller output $U$ gets its maximal value; (b) when the measured pressure is increasing closer to the reference ($E_{nib} < P_e < -E_0$), $U$ decreases linearly; (c) when the pressure exceeds the reference ($E_0 < P_e < E_{pb}$), $U$ decreases linearly to the minimum; (d) when the pressure is extremely large ($P_e > E_{pb}$), $U$ equals the minimal value. When the air pressure is close to the reference ($|P_e| < E_0$), the controller is switched to PID to improve the accuracy. Taking into account fast calculation and simple realization, we designed a one-dimensional fuzzy controller. The air pressure error, $P_e$, and the control voltage of electric–pneumatic regulator serve as the input and output linguistic variables. The classification parameters $E_0$, $E_{nib}$ and $E_{pb}$ and the PID parameters $K_p$, $K_i$ and $K_d$ are set by experience and tuned according to the experimental results. Obviously, the parameters satisfy the formula: $E_{nib} < -E_0 < 0 < E_0 < E_{pb}$.

**Experimental set-up and protocol**

In order to determine the performance of the GIM, five experiments were constructed. The *in vitro* experiment, the first one, was performed to evaluate the insertion performance of the GIM. The second one measured the axial and radial accuracy. The CSF and airbag shear stiffness were measured in the next experiment. Then, the response of the pneumatic system was tested. Finally, an *in vivo* animal experiment was performed.

**In vitro experiments**

Figure 7b shows the assembly of the GIM. The whole size and weight of the GIM, along with the nylon shell, were 136.75 mm (length) × 100.5 mm (width) × 118.28 mm (height), and 0.868 kg, respectively. The GIM was mounted on a supporting arm. A human phantom was used to test its performance, as shown in Figure 7a. Motors 1 and 2 were the driving source of radial and axial motion, respectively. Motor 1 was connected via gears with the shell of the mobile airbag. Motor 2 was connected via gears and a synchronous belt with the lead screw on which the airbag was installed. The supporting arm, fixed onto a trolley, could adjust the pose of the GIM relative to the phantom’s mouth.

Insertion experiments were conducted to compare the performance between the robot-assisted operating method and the conventional manually operating method. Ten unskilled roboticists were asked to insert the gastroscope from the entrance of the oesophagus to the pylorus, while the insertion time was recorded. Five insertion trials of each method was performed by every subject. For each method, they were given instructions together. In order to avoid the learning effect of one method onto the other, the order of the robotic-assisted operation and the manual operation was set alternately. In the robotic method, the subject controlled the translation and rotation of the gastroscope, using the GIM, by stepping on pedals. The knobs on the control section were still manually operated.

**Accuracy evaluation**

A 10.5 mm diameter rigid nylon rod was employed in place of a generic gastroscope to avoid the measurement errors introduced by the bending and flexible characteristics of the gastroscope. Two experiment set-ups were built to evaluate the actuating accuracy and velocity of the GIM.
for axial and radial motion. The translation of 18 mm and rotation of 90° experiments were repeated 10 times. The velocities were the mean values of the displacement or angle and recorded time.

A laser displacement sensor with 50 μm resolution was used to measure the accuracy of pushing–pulling. Installed on the end of the nylon rod was a 130 mm nylon plate, which could reflect the laser launched from the displacement sensor. The GIM and displacement sensor were both fixed on an optical experimental platform to ensure that the laser ray and the nylon rod were parallel. A DAQ card was used to sample the position signals from the displacement sensor. The axial motion procedure was performed over a 180 mm range, with increments of 18 mm. Measurement accuracy was evaluated by the mean error and the standard deviation (SD) of the error in the measured positions.

The accuracy of radial position measurements were evaluated using an absolute rotary encoder with 19-bit resolution. To decrease the measurement error, the axis of the nylon rod was set to be concentric with the rotary encoder. Accuracy was evaluated by obtaining measurements at 180° increments over 1800°, and then calculating the mean error and SD of the measured angles.

**Measurement of the CSF and airbag shear stiffness**

We replaced the gastroscope with a gastroscope insertion tube with a nylon rod glued inside, to eliminate its axial deformation during loading. The tube was clamped by an airbag spliced on a linear motor platform, as shown in Figure 8. A force sensor (LSB200 FSH00103, Futek Advanced Sensor Technology Inc., USA) with non-linearity of 0.1% of rated output, mounted on the linear motor, was used to exert delivery resistance on the insertion tube. Amplified force signals were sampled by a DAQ card (USB6221, National Instruments Corp., USA). The air pressure was adjusted by the electric–pneumatic regulator. The advanced velocity was 100 μm/s. The recorded maximum was the CSF during loading. The slope of measured force with the motor displacement before sliding was the shear stiffness of airbag. The loading force was recorded at air pressure in the range 0–0.06 MPa, with 0.01 MPa increments. Experiments at each air pressure were repeated 10 times.

During gastroscopy, bodily fluids inevitably influence the friction coefficient between the gastroscope and the GIM. The gastroscope insertion tube was inserted into the fresh oesophagi of pigs to be attached with mucus. Then the insertion tube was placed in the clamping mechanism to measure the CSF. The CSF was measured with air pressure increased from 0 to 0.5 MPa, with 0.1 MPa intervals.

**Pneumatic response experiment**

The pneumatic pressure of the airbag was recorded under fuzzy PID control, simple PID control and open-loop control mode. Reference inputs were set 0.05 MPa.

**In vivo animal experiment**

After the in vitro tests, in vivo animal experiments were carried out. The GIM was installed onto a passive mechanical arm and the arm was locked; the experimental platform is shown in Figure 9. The procedures were performed on a male pig of approximately 25 kg in the Olympus laboratory. The pig was fasted for 72 h before the experiment. Zoletil 50 (0.03 ml/kg), atropine (1 ml/25–40 kg) and Lumiplanning (2 ml/25–40 kg) were used as the pre-operative anaesthetic. During the experiment, the pig was anaesthetized by isoflurane. The experiment was approved by the Animal Ethics Committee.

**Results**

In this section, the calculation results of stiffness are first listed to confirm the parameters of the airbag. Then the experimental results of the performance evaluation are presented.

**Parameters of the airbag**

The air pressure used in calculation was referred to the endoscopic air pumps. The maximal pressures generated by the endoscopic light source air pumps were ca. 0.05 MPa (18). Compared with the endoscopic air circuit, the air of the GIM works outside the patient, so we set the maximal air pressure at 0.06 MPa, which is a little larger than that of the endoscopic air pumps.

The relationship between shear stiffness and the initial length of airbag is shown in Figure 10. The shear stiffness was found to be independent of the initial length of the airbag. Given the contact area and size of the clamping mechanism, the length was chosen as 20 mm.
The shear stiffness varies with the inner diameter and thickness of the silicone tube. The stiffness was calculated with increasing inner diameter in the range 10.8–11.6 mm, with 0.2 mm increments, and thickness in the range 0.6–1.4 mm at 0.2 mm increments. By analysing the calculated relationship between shear stiffness and thickness and inner diameter shown in Figure 11, 0.03 MPa was chosen to provide enough shear stiffness (40 N/mm). So, the inner diameter should be < 11.0 mm and the thickness should be > 1 mm, according to Figure 11c. We set the inner diameter at 11.0 mm because that smaller diameter may influence the free push in–out of the gastroscope in the airbag without air pressure. The thickness was selected as 1.0 mm; this was because that thicker silicone tube took a higher air pressure to provide same clamping force, compared with the thinner one, for higher elastic stiffness.

In vitro experiment

The gastroscope intervention was successfully implemented on the human phantom. The experimental results of insertion time are shown in Figure 12. They were compared using a repeated-measures analysis of variance (ANOVA). For the robotic method, significant effects were found for trial \([F (4, 45) = 2.78; p < 0.05]\). There were no significant differences found between the trials of the conventional method. The robotic method had a significantly higher average insertion time than the conventional method by comparing the insertion time of the last trial of each method (i.e. trial 5 for each method), using ANOVA \([F (1,18) = 22; p < 0.001]\), 269 and 118 s, respectively.

Delivery accuracy

The measured positions of translation and rotation are shown in Figure 13. Table 2 lists the accuracy and velocities of the GIM. The performances of its counterparts were also listed for comparison. The listed parameters of Ruiter’s device is its design requirement. The accuracy of other mechanisms was evaluated by the SDs of the measured results. The maximal speed of Ruiter’s device and the mean speed of other devices are also shown in Table 2. The mean errors of measured translation and rotation were 0.025 mm and –0.03°, respectively.

Critical slipping force

The measured CSFs under different air pressures are shown in Figure 14. The transmission forces without
Figure 11. Shear stiffness of airbag with thickness and inner diameter of silicone tube; the value of the plane is 40 N/mm

Figure 12. Results of In vitro experiments: the subjects are significantly faster when using the conventional method compared with the GIM; error bars indicate SE

Figure 13. Measured rotation angle with reference 180° and displacement with reference 18 mm
oesophageal mucus were significantly higher than those with it.

Shear stiffness of the airbag

The calculated delivery resistance with deformation of airbag and one set of data of 10 measured forces with deformation are both shown in Figure 15. The force is nearly proportional to the deformation, which means that the stiffness is almost a constant at the same pneumatic pressure. All of the 10 experimental results at each air pressure were fitted to linear models. The average fitting stiffness and $R^2$ and fitting results of calculation are shown in Table 3.

![Figure 14. Critical slipping force, with or without oesophageal mucus attached, and air pressure](image)

![Figure 15. Calculated and experimental relationships between the transmission force and airbag deformation; the slope of the curve is the shear stiffness of the airbag](image)
Response of the pneumatic actuation

The sampled air pressure is shown in Figure 16. The fuzzy PID controller reduced the aeration time from 350 to 102 ms with a reference pressure of 0.05 MPa compared with the PID controller. It also decreased the steady state error significantly, owing to the open loop.

**In vivo animal experiment**

During the *in vivo* experiment, the endoscopist successfully inserted the gastroscope into the porcine oesophagus and stomach.

**Discussion**

The GIM could fit flexible endoscopes of different sizes, provide adequate transmission force at lower clamping pressure and protect the gastroscope better.

![Figure 16. Air pressure varying with time under reference of 0.05 MPa](image)

Table 3. Fitting results of calculated and experimental results of airbag shear stiffness

<table>
<thead>
<tr>
<th>Air pressure (MPa)</th>
<th>Calculated results</th>
<th>Experimental results</th>
<th>Deviation of stiffness (%)</th>
</tr>
</thead>
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<td></td>
<td>Stiffness (N/mm)</td>
<td>Fitting R²</td>
<td>Average stiffness (N/mm)</td>
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<td>0.05</td>
<td>53.18</td>
<td>0.9986</td>
<td>52.98</td>
</tr>
<tr>
<td>0.06</td>
<td>58.27</td>
<td>0.9986</td>
<td>57.95</td>
</tr>
</tbody>
</table>

Insertion time of *In vitro* experiment

Two methods for gastroscope intervention were compared, using an insertion experiment. It was found that the insertion time for the robotic method was significantly longer than that of the conventional method. This was probably due to the slow insertion speed of the GIM, which was limited by the reciprocating motion and the short stroke for light-duty design. The speed could be promoted by increasing the stroke in future studies; however, the shaft length outside the patient would lengthen. These two parameters should be balanced according to application requirements; there is a trade-off. Figure 12 indicates that the completion time for each trial decreased for the robotic method, probably due to learning effects.

Delivery accuracy and velocity compared with its counterparts

Table 2 indicates that our GIM had better accuracy than its counterparts. The velocity of the friction wheel mechanism was larger than that of the stepping mechanism. This was because of the limitations of small stroke length and reciprocating motion.

CSF for safe intervention

Figure 14 shows that the CSF without oesophageal mucus attached to the gastroscope increased with the air pressure. These forces could be fitted with the quadratic polynomial:

\[ F_s = \alpha P^2 + \beta P + \gamma \]  

where \( F_s \) denotes the critical slipping force, \( P \) denotes the air pressure and \( \alpha, \beta \) and \( \gamma \) are fitting constants. The \( R^2 \) of the fitting curve was 0.9994. The polynomial fitting coefficients were \( \alpha = 4025, \beta = 56.68 \) and \( \gamma = 3.14 \).

The fitting result indicates that the contact length in equation 2 is nearly proportional to the air pressure. According to equation 6, we can change the CSF conveniently by adjusting the pneumatic pressure. Different CSFs can be set at different intervention positions, according to the safety guidelines. The clamping force of the friction roller mechanism could also be regulated by adding a grasp DOF; however, this method would inevitably enlarge the size and complexity of the mechanism.

A large interaction force between the gastroscope and the GI tissue is the main reason for tissue damage. A great many experiments should be performed to measure the relationship between proximal intervention force and distal interaction force. The CSF could be set based on this relationship to keep the distal interaction force within safe limits.

![Figure 14](image)

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levels. These measurements will be performed in later studies.

**Influence of oesophageal mucus on CSF**

Oesophageal mucus lubricated the gastroscope and significantly decreased the friction coefficient, as shown in Figure 14. The critical slipping force has no obviously positive relationship with the air pressure. The CSF cannot be controlled by adjusting the air pressure for the lubrication supplied by oesophageal mucus. Besides, the CSF with oesophageal mucus showed much bigger fluctuation than that without oesophageal mucus attached. The main reason for this is that the amount of oesophagus liquids adhering to the gastroscope varies in different tests. Moreover, much higher air pressure is required to implement gastroscopy intervention. We therefore suggest that a wiper be set at the end of the GIM to remove oesophageal mucus during retraction and eliminate the uncertainty of transmission force caused by it; in (22) a wiper was used, supporting this idea.

**Influence of airbag shear stiffness on delivery accuracy**

The shear stiffness of the airbag inevitably influences intervention accuracy. The stiffness increases with the air pressure, as shown in Figure 15. This means that the airbag aerated to a higher air pressure has less impact on gastroscopy intervention with the same transmission force. The deviation between theoretical and experimental results tends to decrease with the air pressure, because low pressure may not generate enough uniform deformation of the airbag to clamp the gastroscope. The deviation shrinks to 11.29% and $<4\%$ when the air pressure increases to 0.03 and $\geq0.04$ MPa.

The influence of airbag stiffness on the accuracy of the GIM can be evaluated quantitatively. The air pressure should be set to $>0.03$ MPa to provide enough transmission force, according to Table 3; so the influence of the shear stiffness on delivery accuracy is $<0.24$ mm with delivery resistance $<10$ N.

**Noise during endoscopy**

The noise during robotic intervention of the gastroscope with GIM was tested by a sound level meter (WS1361, Wensn-Tech Co. Ltd, China). The noise reaches its peak at about 61.5 dB during acceleration of the motor, while the noise of the GIM is submerged by the noise of the inner gas circuit in the gastroscope and the workstation; we do not anticipate that it will disturb the work of the clinicians.

**Conclusion**

This paper presents a novel device for the protection of flexible gastroscopes, with circumferentially uniform clamping force during interventions. Compared with the traditional friction roller mechanisms, our GIM has significantly larger transmission ability under the same clamping pressure. The GIM realized accuracy of 0.025 $\pm$ 0.2 mm and $-0.03 \pm 0.25^\circ$, for push–pull and rotation, respectively, without delivery resistance. With $<10$ N delivery resistance, the error caused by airbag stiffness was $<0.24$ mm. Moreover, the operation safety could be guaranteed by adjusting the CSF with the pneumatic pressure. The GIM is the core component of the robotic gastroscopy system. Implementing the standard gastroscope as an operation object makes the robotic system easier for clinicians to accept. In the future, the GIM will be integrated into a slave manipulator. A master controller will be developed to construct the overall robotic gastroscope system.

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