

Evaluation of the tip-bending response in clinically used endoscopes

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Background and study aims: Endoscopic interventions require accurate and precise control of the endoscope tip. The endoscope tip response depends on a cable pulling system, which is known to deliver a significantly nonlinear response that eventually reduces control. It is unknown whether the current technique of endoscope tip control is adequate for a future of high precision procedures, steerable accessories, and add-on robotics. The aim of this study was to determine the status of the tip response of endoscopes used in clinical practice.

Materials and methods: We evaluated 20 flexible colonoscopes and five gastroscopes, used in the endoscopy departments of a Dutch university hospital and two Dutch teaching hospitals, in a bench top setup. First, maximal tip bending was determined manually. Next, the endoscope navigation wheels were rotated individually in a motor setup. Tip angulation was recorded with a USB

camera. Cable slackness was derived from the resulting hysteresis plot.

Results: Only two of the 20 colonoscopes (10%) and none of the five gastroscopes reached the maximal tip angulation specified by the manufacturer. Four colonoscopes (20%) and none of the gastroscopes demonstrated the recommended cable tension. Eight colonoscopes (40%) had undergone a maintenance check 1 month before the measurements were made. The tip responses of these eight colonoscopies did not differ significantly from the tip responses of the other colonoscopes.

Conclusion: This study suggests that the majority of clinically used endoscopes are not optimally tuned to reach maximal bending angles and demonstrate adequate tip responses. We suggest a brief check before procedures to predict difficulties with bending angles and tip responses.

Introduction

Flexible endoscopy depends to a high degree on steering the endoscope tip in the desired direction. This is important for scope introduction, mucosal inspection, and interventional procedures. Unfortunately, control of the endoscope is difficult. Even fully trained endoscopists are not able to complete colonic intubation in up to 25% of procedures (depending on the clinical setting and indication) [1–3]. Also, adenoma miss rates with current colonoscopic techniques are high, with up to 27% of adenomas missed in a back-to-back study [4]. We suspect that these inadequate outcomes, which are clinically important, are caused by difficulties with tip control.

Endoscopic tip steering is based on a cable pulling system (► **Fig. 1**) [5]. This system of traction cables enables a high degree of flexibility of the endoscope shaft. Flexibility is needed to move through the tortuous and confined environment

of the bowel. However, cable-actuated systems are prone to a significant nonlinear response, with backlash, cable slackening, and eventually reduced control [6]. Whereas too little cable tension causes delays and unresponsive tip bending, too much cable tension increases friction and reduces predictability of the response.

Endoscopists currently combine tactile assessment of the tension on the navigation wheel with visualization of the endoscopic image to determine the endoscope tip response. This manual feedback loop is a direct and stable compensation mechanism. The question arises as to whether the current physician-dependent feedback method is adequate for future requirements. The need for tip control has increased with the development of high precision procedures, such as peroral endoscopic myotomy (POEM), endoscopic submucosal dissection (ESD), and (hybrid) natural orifice transluminal endoscopic surgery (NOTES) [7–9]. Additional challenges derive from the

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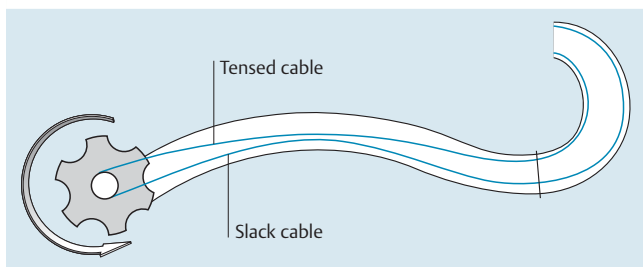


Fig. 1 A set of antagonist cables running from the navigation wheel (left) to the bent tip (right).

need to control steerable accessories and robotic systems that function as add-ons to flexible endoscopes [10,11]. These systems may also depend on traction cables; they are not equipped with manual user feedback [12].

Solutions are available to cope with the nonlinear effects of cable pulling systems; these include cable pre-tension mechanisms that add external sensors registering true vs. predicted tip position and software compensation algorithms that predict tip response [5]. We surveyed the current status of the endoscope tip response to learn how to deal with these issues in robot-assisted endoscope steering.

Materials and methods

Included endoscopes

Included in the study were 20 colonoscopes and five gastroscopes from three Dutch hospitals (Table 1). As standard procedure, the scopes are checked once or twice per year, with additional maintenance provided upon a physician's request. Used service agencies are Olympus Nederland (Zoeterwoude, the Netherlands), SurgiTec (Didam, the Netherlands) and Rescope (Nijmegen, the Netherlands). These maintenance checks include at least tuning of the bending angles and cable tension. Maximal tip angulation is evaluated by manually rotating the wheel in each direction and reading the bending angle from an angle specification sheet. Cable tension is determined to be optimal when the tip (visibly) responds to wheel rotation while the shaft is in a looped position. Colonoscopes are positioned with the shaft in a loop of 360 degrees (O-loop). Gastrosopes are positioned with the shaft in a loop of 180 degrees (U-loop).

Eight colonoscopes from one of the hospitals had undergone their yearly maintenance checks 1 month before the hysteresis measurements. Unfortunately, records of the last maintenance checks of the other scopes were not available. Records of the number of procedures in which each endoscope had been used since the last maintenance were not available for any endoscope.

Setup

First, maximal tip angulation was evaluated for each direction with an angle specification sheet provided by Olympus Nederland. The tip was maximally rotated by hand. Then, the endoscope was positioned in a bench setup that recorded the tip position while the navigation wheel was rotated. The endoscopic shaft was placed in loop position, as is done during maintenance. Tip responses when the small and large wheels were rotated were individually recorded, resulting in a total of two measurements per endoscope.

The endoscope navigation wheels were actuated by a remote drive unit connected to two DC servo motors (EC-max 40, 70 W; Maxon Motor, Sachseln, Switzerland) via two sets of pre-tensed antagonist Nokon Bowden cables (Carl Stahl, Süßen, Germany) [13]. It can be argued that a setup with flexible Bowden cables increased the nonlinear response of the endoscope. However, preliminary bench tests revealed that this setup did not significantly affect measurements in comparison with a complex setup without flexible transmission. On the contrary, this setup was easy to use in different hospital room settings and required no modifications to the endoscopes.

The endoscope navigation wheels were rotated in alternating up-and-down or left-and-right bending directions. Colonoscope wheels were rotated 10 times back and forth. Each time, the rotation angle was increased, up to a maximum of 115 degrees. Gastroscope wheels were rotated to 90 degrees in six rounds. The endoscope tip position was recorded with a camera (Chameleon CMLN-13S2M; Point Grey Research, Richmond, British Columbia, Canada) at a rate of 60 frames per second. Image recognition software written with IEP (Interactive Editor for Python, version 3.2, 2012) detected the tip position. Tip position was registered as the x-coordinate of the detected tip in a 1280×960-pixel image frame. The resulting data were post-processed with Matlab, version R2013b (MathWorks; Natick, Massachusetts, USA). The endoscopic tip was placed above the table to be free of friction. A light studio setup was used to prevent shadow formation (Fig. 2).

Evaluation parameters

The tip response was determined by using maximal bending angles and cable slackness. The tip bending response is described in a hysteresis plot (Fig. 3). When the endoscope shaft is in a straight position, the cables lie relatively loose in their guiding tubes (Fig. 3, point I, neutral position). Wheel rotation first tenses the cable before the tip starts to bend in the corresponding direction (Fig. 3, point II, start of tip bending). The amount of wheel rotation needed to start tip bending represents the *cable slackness*. Rotating the wheel in the opposite direction causes cable relaxation (Fig. 3, point III). The amount of wheel rotation needed to start tip straightening represents the *virtual play* (Fig. 3, points III and IV). After the tip is straight, further wheel rotation pulls the antagonist cable to bend the tip in the opposite direction (Fig. 3, point V, pulling the antagonist cable).

Table 1 Endoscopes used for evaluation and validation.

	Colonoscope 190 series		Colonoscope 180 series			Colonoscope 160 series		Gastrosopes		
Type	CF-HQ190L	PCF-H190L	CF-H180AL	CF-Q180AL	CF-H180DL	Q160DL	Q160ZL	GIF-H190	GIF-1TQ160	GIF-H180
Measured endoscopes, n	8	1	2	6	2	1	Validation scope	3	2	Validation scope



Fig. 2 In-hospital example of setup for hysteresis measurement: 1, motor module; 2, computer; 3, remote drive unit connected to the navigation wheels of a conventional endoscope; 4, camera capturing images of the endoscope tip; 5, light studio to prevent shadow formation from the hovering tip.

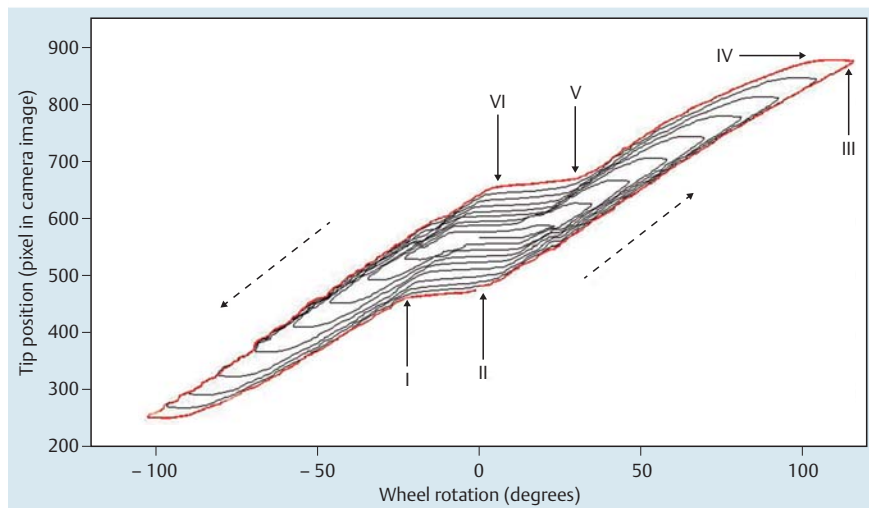


Fig. 3 Nonlinearity in the endoscope tip response. The tip is angulated in alternating up-and-down directions, with increasing bending angles. I. Cable pulling starts in neutral position. II. Tip starts bending. III. Tensed cable is released. IV. Tip starts to relax and return to straight position. V. Pulling the antagonist cable. VI. Tip follows the antagonist cable.

Looping of the endoscope shaft results in stretching and shortening of the path of the antagonist cable, which increases tension on the cables. The settings recommended by the manufacturer¹ for endoscope cable tension are such that a colonoscope with its shaft in a 360-degree loop and a gastroscope with its shaft in a 180-degree loop have no cable slackness. Therefore, a straight tip responds immediately to navigation wheel rotation. There is no plateau between points I and II or between points V and VI in the hysteresis plot.

In this study, cable slackness was calculated as the maximal width of the hysteresis plot (● Fig. 4, section B) minus the average widths of the virtual play in up/right and down/left pulling cables (● Fig. 4, sections A and B). Therefore, cables are considered to be well tuned when the slackness is 0 or lower.

¹ Expert maintenance technician from Olympus Nederland, Zoeterwoude, the Netherlands.

Setup validation

One colonoscope (CF-Q160ZL) and one gastroscope (GIF-H180) were repeatedly measured with different cable tensions to confirm the hypothesis that hysteresis width represents cable tension. An expert repair and maintenance mechanic from Olympus Nederland gradually adjusted the cable tension from loose to optimal (as prescribed by the manufacturer). From the hysteresis plots, we were able to confirm that in loop configurations, a plateau was not present for well-tensed cables but appeared as the cables slackened (● Fig. 5).

Accuracy

Repeated measurements of one colonoscope revealed accuracy of the evaluation system. A well-tensed CF-H180AL colonoscope was repositioned and reconnected to simulate five full cycles of large and small wheel measurements in a looped configuration.

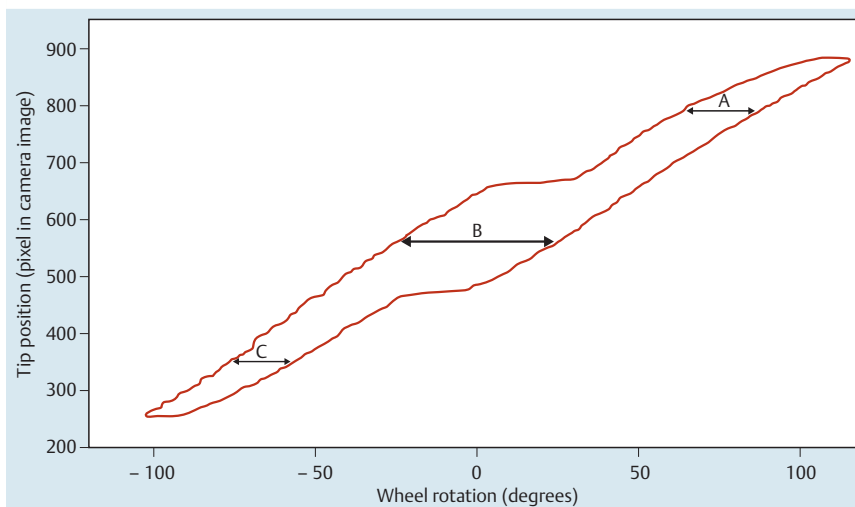


Fig. 4 Parameters describing nonlinearity: A, virtual play up/right cables; B, cable slackness; C, virtual play down/left cables.

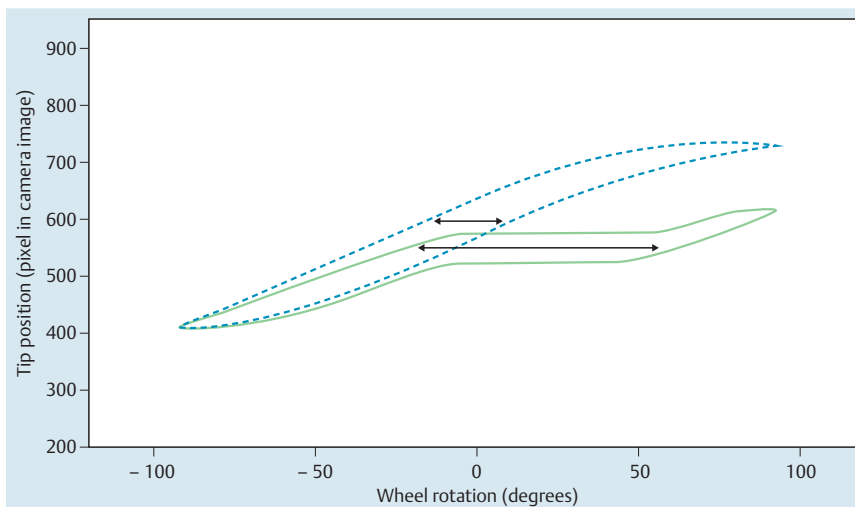


Fig. 5 Hysteresis plot of a gastroscope with well-tensed (dotted lines) and loose (solid lines) cables. The maximal width is increased with loose cables.

The greatest variance for endoscope repositioning was 1.7 degrees (Table 2).

A second set of five measurements included changes in the camera position because an identical camera position cannot be guaranteed when the setup is moved to another hospital. The endoscope was placed in a straight position to simulate the possibility of poor cable tension in the evaluated endoscopes. The variance in hysteresis width to consider with changes in camera position in a setting of poor cable tension is 3 degrees.

Statistical analysis

Statistical analysis was done, where applicable, with Wilcoxon's signed rank test and a significance level of $P=0.05$. Data are represented as median with interquartile range (IQR).

Results

Only two of the 20 colonoscopes reached the maximal angulation for all bending directions as prescribed by the manufacturer (including a maximal deviation of 10 degrees). None of the five gastroscopes reached the maximal angulation. Overall, the maximal colonoscope angles deviated at a median of 20 degrees (IQR 10–20) and at a maximum of 50 degrees from the manufacturer's prescribed settings (Table 3). Gastroscope angles deviated at a

median of 13 degrees (IQR 8–13) and at a maximum of 25 degrees from the manufacturer's prescribed settings (Table 3). Cable slackness of the validation colonoscope with optimal cable tension was –11 degrees for the large wheel and –14 degrees for the small wheel. Cable slackness of the gastroscope was –4 degrees for both wheels.

Only three colonoscopes and none of the gastroscopes showed cable slackness below 0 degrees in both cable sets when in loop configuration (Table 4). Four colonoscopes showed appropriate cable tension in one of the two cable sets. In the remaining colonoscope cable sets, cable slackness ranged from a minimum of 5 to a maximum of 46 degrees. For gastroscopes, these values ranged from 8 to 30 degrees. No correlation was found between the maximal tip angulation and the wheel rotation needed to start tip bending in all directions in both the colonoscopes and the gastroscopes.

Eight colonoscopes from one hospital had undergone their yearly maintenance check 1 month before the hysteresis measurements. Their tip responses did not differ significantly from the tip responses of the other colonoscopes, for both cable sets.

Table 2 Validation measurements of cable slackness.

		Average, degrees	Variance, degrees
Endoscope repositioning (n = 5)	Looped, large wheel	-12	1.7
	Looped, small wheel	-19	0.8
Camera repositioning (n = 5)	Straight, large wheel	36.5	3.0

Table 3 Maximal tip bending angles: prescribed manufacturer settings vs. clinical equipment.

	Colonoscope (n = 20), degrees		Gastroscope (n = 5), degrees	
	Prescribed	Measured	Prescribed	Measured
Up	180	165 (155–165)	210	195 (190–195)
Down	180	155 (150–155)	90	80 (70–80)
Left	160	145 (139–145)	100	85 (85–85)
Right	160	143 (130–143)	100	90 (90–90)

Discussion

In this study, we assessed endoscope tip response when the navigation wheels of clinically used flexible colonoscopes and gastroscopes were rotated. We anticipate that current cable-driven endoscopes may not be able to deliver the response that is required for innovative therapies and add-on control methods. This study confirms that tip bending is frequently limited in clinically used endoscopes. As a general rule, endoscopists refer equipment for maintenance when technical issues arise. However, this survey strikingly shows that an angulation deficiency of 50 degrees was not enough to send the endoscope back for repairs. The authors assume that tip bending of 160 instead of 180 degrees might limit inspection behind bowel folds or retroflexion when it is needed. We expect that with experience, endoscopists develop methods of torquing and manipulation that enable them to reach clear clinical end points, such as cecum intubation and polyp removal. Nevertheless, our main concern is that inadequate tip response delays procedures and reduces wall inspection. Unfortunately, it is difficult to estimate the clinical effect of limited tip bending. There is no objective method for registering the number of endoscopic procedures that are prematurely ended or lengthened because of an inadequate endoscope tip response.

In this study, the slackness of most endoscope cables was greater than what the manufacturer recommended. Although slack cables increase scope flexibility, greater wheel rotation is required before the endoscope tip starts to bend. An endoscopist can tell when the tip starts to bend by the increased tension on the wheel. However, control can be hindered when such a large wheel motion is required that the fingers driving the wheel must be repositioned. Also, large differences among endoscopes reduce the predictability of responses, especially when an operator is learning to control the instrument.

There are two possible explanations for the poor tip response of the endoscopes that had undergone maintenance 1 month before this evaluation. Either the maintenance was unsuccessful in checking and tuning the cables and tip, or 1 month of use was enough to reduce cable status. A long-term analysis would be able to demonstrate the decline of cable status during clinical use and the effect of maintenance on functional status.

With regard to adding motor-driven accessories and remote control, this short inventory shows that there is already a large degree of nonlinearity of the tip response. Adding cable-driven systems will increase nonlinearity, and tip position errors will grow.

Table 4 Cable slackness values of the validation and hospital endoscopes in loop configuration.

Scope	Large wheel	Small wheel
Validation scopes		
Colonoscope CF-Q160ZL	-11	-14
Gastroscope GIF-H180	-4	-4
Colonoscopes with all cables well tensed		
CF-Q180AL	-14	-17
CF-H180AL ^{1,2}	-4	-18
CF-Q160DL	-3	-4
Colonoscopes with one good cable set		
CF-HQ190L ^{1,2}	-7	4
CF-Q180AL ²	9	-3
CF-H180DL ¹	12	-16
XCF-Q180AYL	13	-9
Colonoscopes with all cables too slack		
CF-HQ190L	5	19
CF-HQ190L ¹	5	6
CF-H180DL ¹	10	19
CF-Q180AL	12	18
CF-Q180AL	14	18
CF-H180AL ¹	18	25
H190L	20	15
Q190L	20	22
Q190L	26	22
CF-Q180AL	29	27
CF-HQ190L ¹	33	46
CF-HQ190L	34	42
CF-HQ190L ¹	44	41
Gastroscopes with all cables too slack		
GIF-H180	9	8
GIF-H190	13	15
GIF-ITQ160	15	29
GIF-ITQ160	22	15
GIF-H190	30	22

Values represent the maximal hysteresis width minus the average widths of the virtual play in up/right and down/left pulling cables. Cables are considered well tensed when slackness is 0 or lower.

¹ Endoscope received yearly maintenance check 1 month before hysteresis measurements.

² Endoscope reached maximal bending angles in all directions.

Compensation methods should be highly adaptive to different endoscopes and their configuration. Another strategy could be the use of non-cable-driven endoscopes. Promising alternatives currently under investigation are magnet- [14] and sleeve-controlled camera navigation [15,16]. However, these are experi-

mental designs not yet ready to be tested as cost-effective, safe, and user-friendly diagnostic procedures.

In current daily practice, we suggest a brief check before procedures to predict problems of large angulations and inaccurate tip responses. The maximal tip angulation serves as one method to quickly assess the endoscope cable status. A second method is to visually determine the response while rotating the navigation wheels of an endoscope in loop configuration. This takes slightly more time but may be worthwhile before the initiation of challenging procedures in which a quick tip response is necessary.

Conclusion

This study shows that a substantial percentage of the endoscopes used in daily clinical practice are not optimally tuned to reach maximal bending angles and demonstrate adequate tip responses. We suggest a short pre-procedural check to predict problems with large angulations and inaccurate tip responses. A long-term analysis would be able to demonstrate the decline of cable status during clinical use and the effect of maintenance on functional status.

Competing interests: None

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