Published in final edited form as:

Gastrointest Endosc. 2012 October ; 76(4): 867–872. doi:10.1016/j.gie.2012.05.030.

Segmental increases in force application during colonoscope insertion: quantitative analysis using force monitoring technology

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Abstract

Background—Colonoscopy is a frequently performed procedure that requires extensive training and a high skill level.

Objective—Quantification of forces applied to the external portion of the colonoscope insertion tube during the insertion phase of colonoscopy.

Design—Observational cohort study of 7 expert and 9 trainee endoscopists for analysis of colonic segment force application in 49 patients. Forces were measured by using the colonoscopy force monitor, which is a wireless, handheld device that attaches to the insertion tube of the colonoscope.

Setting—Academic gastroenterology training programs.

Patients—Patients undergoing routine screening or diagnostic colonoscopy with complete segment force recordings.

Main Outcome Measurements—Axial and radial force and examination time.

Results—Both axial and radial force increased significantly as the colonoscope was advanced from the rectum to the cecum. Analysis of variance demonstrated highly significant operator-independent differences between segments of the colon (zones) in all axial and radial forces except

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DISCLOSURE: The following author disclosed financial relationships relevant to this publication: Dr Korman: consultant and patent coholder, Artann Labs. The other authors disclosed no financial relationships relevant to this publication. Supported by grant NIDDK 2R44 DK068936-02A1.

Presented at Digestive Disease Week, 2010, New Orleans, Louisiana (*Gastrointest Endosc* 2010;71:AB214-15).

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average torque. Expert and trainee endoscopists differed only in the magnitude of counterclockwise force, average push/pull force rate used, and examination time.

Limitations—Small study, observational design, effect of prototype device on insertion tube manipulation.

Conclusion—Axial and radial forces used to advance the colonoscope increase through the segments of the colon and are operator independent.

Colonoscopy is a frequently performed medical procedure. Standards for training and quality strive to ensure that endoscopists perform colonoscopy in a safe and effective manner.¹⁻⁴ Colonoscopy force monitoring technology measures the forces applied by the endoscopist to the external portion of the insertion tube.^{5,6} Recent studies demonstrated significant variation among endoscopists in the pattern of force application.⁶

Indeed, experienced endoscopists recognize that manipulation of the colonoscope differs depending on which segment of colon is being traversed.⁷ Force monitoring technology could improve methods of instrument manipulation. This analysis was designed to characterize the pattern of insertion forces by segment as the colonoscope is advanced.

METHODS

Study design and protocol

This was an observational cohort study designed to assess colonoscopic force application as the instrument is advanced to the cecum. Experts were board certified in gastroenterology and had performed more than 2500 colonoscopies. Trainee endoscopists were first-, second-, and third-year fellows in an accredited training program. The clinical protocol was approved by the institutional review boards. Seven expert and 13 trainee endoscopists were recruited at 4 training centers (VA Medical Center, Georgetown University Medical Center, Washington, DC; University of Pennsylvania, Philadelphia, Pa; and Montefiore Medical Center, Bronx, NY) participated. Patients between the ages of 30 and 75 who were American Society of Anesthesiologists class 2 or lower and presenting for screening or diagnostic colonoscopy between August 2010 and March 2011 were considered for inclusion. Each endoscopist was asked to perform a maximum of 5 procedures with the colonoscopy force monitor (CFM). The study was closed once the defined number of cases was performed or the study duration achieved. Informed consent was obtained from all patients undergoing colonoscopy with the CFM and the procedure being performed by using standard methods for colonoscope insertion and withdrawal. Olympus CF and PCF-160 (Olympus America, Center Valley, Pa) or Pentax 3872 series (Pentax Medical, Montvale, NJ) colonoscopes were used. Patients received either conscious sedation or monitored anesthesia with propofol. During each procedure, the endoscopist was asked to identify the approximate location of the instrument tip each time a new segment was entered. The endoscopist was blinded to the force display. Informed consent was obtained from 96 patients and 76 had uninterrupted force recordings. Forty-nine patients had complete force recordings for insertion with well-documented tip location. Twenty-seven patients were excluded from this analysis because of force recording failure, absence of tip documentation, interrupted data transmission, or incomplete examination.

CFM system

The CFM system comprises 3 components: (1) a hand-held wireless colonoscope attachment (Fig. 1); (2) a docking station; and (3) a computer with Bluetooth Wireless communication. The endoscopist attaches the CFM to the external portion of the instrument insertion tube and manipulates the colonoscope in his or her usual fashion, and the measured push/pull and

torque force are recorded. The endoscopist can reposition the CFM by activating the grip release mechanism, sliding the device along the shaft, and then reactivating the grip mechanism to close the device over the colonoscope shaft. The CFM underwent standard high-level disinfection immediately after each procedure. The CFM system software collects and records data and displays the results of the measurements.

Parameter calculations and statistical analysis

Ten parameters were calculated to characterize each examination. These included push/pull and rotational forces and time derivatives of force and examination time.⁶ The colon was divided into 3 zones: zone A extended from the rectum to the descending colon; zone B from the descending colon to the transverse colon; and zone C from the transverse colon to the cecum. To determine whether there were differences by zone, mean force parameters and examination times were compared by using analysis of variance and 2-sample *t* tests. Linear mixed models were specified to analyze the differences between the zones incorporating operator-level characteristics with random intercepts. All statistical analyses were conducted by using SAS software version 9.1.3 (SAS Institute Inc, Cary, NC). A *P* value <.05 was considered statistically significant.

RESULTS

Complete zone force recordings were available for the 7 expert and 9 trainee endoscopists for 49 patients for a total of 147 zone measurements. Table 1 provides the demographic and procedural characteristics of these 49 patients. Table 2 provides the descriptive statistics for calculated force parameters by zone. All of the force measurements were significantly different except for average torque (Table 3). Maximum push, pull, and clockwise and counterclockwise torque increased as the instrument was advanced from zone A to zone C. Measurements for all 3 zones were significantly different from each other according to multiple comparisons by Tukey tests.

To determine whether there were differences between attending and trainee endoscopists cumulative force measurement data were compared (Table 4). Only maximum counterclockwise torque, average push and push/pull rates, and examination time were significantly different.

Finally, to control for operator variation, a mixed-model analysis was performed (Table 5). The variation between operators is estimated by including the operator as a random effect. Operator variation accounts for only 32% of the total variance in maximum push. Similar but lower percentages of the total variance among operators are also noted for maximum pull, clockwise and counterclockwise torque, and examination time. After adjusting for operator-level differences, it is evident that measurements in zone C are significantly different from measurements in zone A and zone B. Significant differences were obtained for maximum pull and clockwise and counterclockwise torque force parameters. The model demonstrated no difference between expert and trainee level forces, but expert zone examination time was significantly lower by 63.9 seconds compared with that of trainee zone.

DISCUSSION

This study quantifies significant increases in peak and average forces as the instrument is advanced to the cecum. The operator advances more forcefully and more slowly in all directions. The increase in force and time as the instrument is advanced may be explained by the greater resistance and contact surface area because more colon is pleated over the instrument. The mixed-model analysis suggests that a significant component of the increase

in force is independent of the individual operator and a function of the characteristics of the individual patient. The study also suggests the presence of differences between expert and trainee endoscopists in how effectively force is used to advance the instrument.

Endoscopists are taught and develop techniques to maneuver the colonoscope so that mucosal inspection is optimal, patients are comfortable, and complication risk is minimized.⁷ In theory, the need for pain medication and the risk of perforation could be decreased by minimizing the force needed to advance the instrument. Thus, force feedback combined with normative references could improve performance and training by identifying optimal methods of instrument insertion. For example, the differences between experts and trainees seen in Table 4 suggest that the longer examination time may be the result of less forceful counterclockwise torque and a lower rate of push/pull force application. Identification of more effective maneuvers in certain anatomic locations or in the presence of loop formation by combining force measurement with other tools⁸ could accelerate skill acquisition and define better methods of loop management.

The current exploratory study is too limited in sample size to identify a standard for force application. In addition, the small number of cases and the use of a prototype device limited the ability to isolate other factors such as instrument type and procedure difficulty as factors in force application. Despite these limitations, it is likely that a less forceful technique could reduce the pain associated with endoscopy and events such as perforation and splenic injury. That perforation frequency could be decreased is evidenced by the significant variation in published perforation rates,⁹ suggesting that operator rather than patient differences may be the critical factor in colonic injury. Because pain is the result of activation of stretch receptors and pain sensors,¹⁰ a decrease in force is also likely to decrease patient discomfort. The finding that force is lowest in the sigmoid colon and that this is often the most painful part of colonoscopy and most frequent site of perforation suggests a more complex relationship between force, pain, and injury.^{11–17}

Current standards for skill development, instrument design, and procedure quality are time to cecum, withdrawal time, and polyp detection rates.^{18–22} Individual perforation rates are not used because they are low-frequency events. Pain as a quality measure is limited by variability in patient nociceptive thresholds, anatomy, and anesthesia.^{23–25} Force monitoring may provide another measure of skill development and quality. Finally, force monitoring could be used as a more objective measure of the impact of new instrument design such as tip angulation and flexural rigidity. Recent design changes suggest that colonoscopy performance can be improved by alterations in instrument characteristics.^{26–28} Furthermore, modified instruments and techniques could be matched to patient characteristics such as tissue elasticity, age, adhesions, and tortuosity to improve performance and safety.

CONCLUSION

This study demonstrated that endoscopists increase force as they advance the colonoscope to the cecum. The increase in force as the instrument is inserted is independent of the operator, level of experience, and patient characteristics. The significant variation in force suggests that lower forces could be used to achieve the same performance outcome. Finally, the current study supports the concept that force monitoring could provide important feedback for training, quality assurance, and instrument design.

Acknowledgments

The authors thank the trainees, nursing, and technical staff at the participating institutions.

Abbreviation

CFM colonoscopy force monitor

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Take-home Message

- Axial and radial force applied to the colonoscope insertion tube increases as the instrument is advanced from the rectum to the cecum. There is very little difference between experts and trainees with regard to the magnitude of the force applied, but trainees take longer to move through segments.
- Force-monitoring technology quantifies the relative contribution of operator variation and patient/instrument characteristics to the magnitude of the force used.

Figure 1. Colonoscopy force monitor (A) in closed position and (B) with insertion tube attached.

TABLE 1

Demographic and procedural characteristics

	No.	Mean (SD)
Age, y	49	54.3 (12.5)
Time to cecum, min	45	9.5 (4.9)
Total examination time, min	45	17.1 (7.2)
Fentanyl, μg	21	100.7 (53.0)
Midazolam, mg	21	5.0 (4.7)
Propofol, mg	27	332.4 (172.4)

SD, Standard deviation.

TABLE 2

Descriptive statistics for zone force parameters

Parameter	No.	Mean (SD)	Min	Max
Max push, N	147	18.59 (10.56)	2.6	56.7
Max pull, N	147	-13.74 (8.29)	-39.2	-0.7
Max clockwise torque, N · m	147	0.45 (0.21)	0.1	1.0
Max counterclockwise torque, N · m	146	-0.47 (0.24)	-1.3	-0.05
Average push, N	147	4.96 (1.86)	1.7	11.5
Average pull, N	147	-3.75 (1.75)	-13.0	-1.0
Average torque, N · m	147	0.13 (0.04)	0.06	0.27
Average push/pull rate, N/s	147	0.46 (0.10)	0.32	0.91
Average torque rate, N/s	147	0.02 (0.004)	0.01	0.03
Examination time, s	147	190.50 (186.51)	5.00	1073.0

SD, Standard deviation; *Min*, minimum; *Max*, maximum.

TABLE 3

Force parameters by zone

Parameter	Zone A		Zone B		Zone C		ANOVA <i>P</i> value
	Mean	SD	Mean	SD	Mean	SD	
Max push, N	11.78	5.67	16.31	6.9	27.67	11.07	<.0001
Max pull, N	-9.17	6.29	-13.74	8.47	-18.3	7.41	<.0001
Max clockwise torque, N · m	0.34	0.17	0.45	0.18	0.57	0.21	<.0001
Max counterclockwise torque, N · m	-0.33 *	0.17	-0.44	0.21	-0.63	0.24	<.0001
Avg push, N	3.71	1.2	5.16	1.63	6.02	1.89	<.0001
Avg pull, N	-3.11	1.62	-4.16	2.22	-3.99	1.06	.0059
Avg torque, N · m	0.12	0.03	0.14	0.05	0.14	0.04	.1020
Avg push/pull rate, N/s	0.41	0.08	0.47	0.08	0.5	0.1	<.0001
Avg torque rate, N/s	0.0182	0	0.0176	0	0.0151	0	<.0001
Examination time, s	138.06	151.57	116.63	91.87	316.8	223	<.0001

SD, Standard deviation; ANOVA, analysis of variance; Max, maximum; Avg, average.

* Force data were available for all 3 zones for 49 patients except for 1 patient; maximum counterclockwise torque data for zone A were missing.

TABLE 4

Force parameters by experience level

	Expert		Trainee		<i>t</i> test	
	Mean	SD	Mean	SD	<i>P</i> value	
Max push, N	20.1	11.8	17.4	9.4	.1266	
Max pull, N	-13.8	8.5	-13.7	8.2	.9301	
Max clock torque, N · m	0.4	0.2	0.5	0.2	.4412	
Max counter torque, N · m	-0.4	0.2	-0.5	0.3	.0415 *	
Average push, N	5.3	2.2	4.7	1.5	.0454 *	
Average pull, N	-3.7	1.5	-3.8	1.9	.8323	
Avg torque, N · m	0.13	0.04	0.14	0.04	.1240	
Avg push/pull rate, N/s	0.48	0.11	0.44	0.08	.0209 *	
Avg torque rate, N/s	0.017	0.0047	0.017	0.0032	.8455	
Examination time, s	154.6	150.7	217.5	206.2	.0343 *	

SD, Standard deviation; *Max*, maximum; *Avg*, average.

* Significant at <.05.

TABLE 5

Mixed-effects model

Fixed effects					
	Max push estimate (SE)	Max pull estimate (SE)	Max clockwise torque estimate (SE)	Max counterclockwise torque estimate (SE)	Examination time estimate (SE)
Intercept	26.4 (2.0) *	-17.6 (1.8) *	0.6 (0.04) *	-0.7 (0.04) *	344 (27.8) *
Level: expert	2.5 (2.7)	-0.7 (2.4)	-0.02 (0.07)	0.08 (0.06)	-63.9 (31.6) *
Zone A	-15.9 (1.4) *	9.1 (1.3) *	-0.2 (0.03) *	0.3 (0.04) *	-178.7 (32.2) *
Zone B	-11.4 (1.4) *	4.6 (1.3) *	-0.1 (0.03) *	0.2 (0.04) *	-200.2 (32.2) *
Random effects					
	Variance	Variance	Variance	Variance	Variance
Operator level	22.3 *	16.7 *	0.01 *	0.01 *	945.4
Residual	48.1 *	41.9 *	0.03 *	0.03 *	25387 *

Max, Maximum; SE, standard error.

* Significant at <.05.