Quantitative Analysis of Force Application During Colonoscopy: “May the Force be with You”

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Disclosure

Issued US Patents: 6,981,945, D612,045; Colonoscope handgrip with force and torque monitor: A. Sarvazyan, L. Korman, S. Tsuryupa


Principal Clinical Investigator: SBIR NIDDK 2R44 DK068936-02A1
Skillful Colonoscopy

Proficiency, facility, or dexterity that is acquired or developed through training and experience.
Lord Kelvin

"When you measure what you are speaking about and express it in numbers, you know something about it, but when you cannot express it in numbers your knowledge is of a meager and unsatisfactory kind... " 
Perforation

• **Colonoscopies:** 116,000

• **Perforations:** number = 37 (0.03%)  
  rate = 1 per 3189

• **Patient Age:** mean = 69.4 yrs  
  median = 75 yrs

• **Procedure:** diagnostic = 24 (65%)  
  therapeutic = 13 (35%)

Pain

Cost of UnskilledColonoscopy

• Perforation:
  Total Medicare Colonoscopies (1999) = 2,239,638
  Estimated Perforations (0.1%) = 2,240
  Cost/Complication = $30,000
  Total Cost = $672,000,000

• Pain Management:
  MAC anesthesia Medicare: $4 billion/year
Maneuvering

Courtesy Prof. C. Williams
Loop Configuration

N = 79%

Alpha

Reverse Alpha

Counter Clockwise Spiral
Loop Configuration

Deep Transverse Loop

Gamma Loop and Transverse Loop

Reverse Splenic Flexure Loop
Force control and loop management are basis for skill and training

- The application of force to the colon could be painful
- Significant force is applied during colonoscopy at specific locations
- Sedation/analgesia is required
- Forces are not characterized
- No current means for quantitative assessment
- Cadaver perforation: 2.7-9.0 kg

NIDDK NIH SBIR Supported Project

• **Phase I**: CFM feasibility grant proposal: Design of CFM prototype device

• **Phase II**: CFM validation grant proposal: Testing of CFM concept

• **Phase II Extension**: Advance the CFM to the pre-manufacturing level; further define CFM technology efficacy, safety and intended use, complete clinical studies required for the PMA application processes; and prepare regulatory submission for market clearance of the CFM technology.
The CFM continually measures, displays and stores the push/pull, clockwise and counter-clockwise torque applied to the insertion tube of the colonoscope.
CFM™: Technology

Issued US Patents:
6,981,945; D612,045

Patent Pending:
Serial # 12/558,737
Serial # 12/558,837
Serial # 61/242,107
CFM™ : Functionality Features

• Maintains a conventional hand position over the shaft of the endoscope
• Engages and disengages rapidly to facilitate movement along the shaft
• Able to advance, withdraw, rotate and grip the scope to facilitate completion of the procedure with minimal distraction
• Sustains high level disinfection without change in sensing properties
• Produces easily interpretable computer representations of force and force direction
Clinical Studies

• Observational study of 6 expert endoscopists in 30 patients undergoing routine ambulatory endoscopy (5 cases per operator)
• CFM measurement of radial and axial force
• Comparison among endoscopists
• Classification of endoscopists
• CFM performance feedback

Studies performed at Chevy Chase Endoscopy Center under WIRB® approved protocol, registered at the www.clinicaltrials.gov
Typical CFM™ Record

The endoscopist applies very different forces to move through different parts of the colon.
Operator-dependent differences in applied force and torque

The average push/pull force and clockwise/counter-clockwise torque displays differences in technique of individual endoscopists (6 operators, 5 cases each)
Operator-dependent differences in rates of applied force and torque

The average time derivative of force and torque displays differences in technique of individual endoscopists (6 operators performed 5 cases each)
### Colonoscopy Parameters

<table>
<thead>
<tr>
<th>Parameter no.</th>
<th>Parameter name, units</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Maximum push force, N</td>
<td>Averaged for 5 readings</td>
</tr>
<tr>
<td>2</td>
<td>Maximum pull force, N</td>
<td>Averaged for 5 readings</td>
</tr>
<tr>
<td>3</td>
<td>Maximum torque clockwise, N·m</td>
<td>Averaged for 5 readings</td>
</tr>
<tr>
<td>4</td>
<td>Maximum torque counterclockwise, N·m</td>
<td>Averaged for 5 readings</td>
</tr>
<tr>
<td>5</td>
<td>Mean push/pull force rate (average force rate), N/s</td>
<td>Data with force time derivative &gt; 0</td>
</tr>
<tr>
<td>6</td>
<td>Mean torque rate (average torque rate), N·m/s</td>
<td>Data with torque time derivative &gt; 0</td>
</tr>
<tr>
<td>7</td>
<td>Examination time, s</td>
<td>Net colonoscope insertion tube manipulation time</td>
</tr>
</tbody>
</table>
**ANOVA among Experienced Endoscopists**

Highly significant differences among endoscopists.

**TABLE 2. One-way analysis of variance for 7 parameters with a Bonferroni correction for post hoc analysis**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Max push</th>
<th>Max pull</th>
<th>Max torque clockwise</th>
<th>Max torque counterclockwise</th>
<th>Push/pull rate</th>
<th>Torque rate</th>
<th>Exam time</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P$ value* (Bonferroni)</td>
<td>.016</td>
<td>.012</td>
<td>.41</td>
<td>.14</td>
<td>.001</td>
<td>.001</td>
<td>.002</td>
</tr>
</tbody>
</table>

*Max, Maximum; Exam, examination.*

*P < .05 indicates a significant difference among endoscopists.*
Endoscopists signature techniques grouped on the basis of the CFM records

Based on the cluster analysis of the CFM data expert endoscopists are separated into distinct groups according to their technique.
Ordinal Scale of Individual Techniques

<table>
<thead>
<tr>
<th>Cluster number</th>
<th>Max Push</th>
<th>Max clockwise torque</th>
<th>Avg Push</th>
<th>Avg counter-clockwise torque</th>
<th>Avg Pull</th>
<th>Avg push/pull force rate</th>
<th>Max Pull</th>
<th>Avg torque</th>
<th>Avg torque rate</th>
<th>Avg push-torque vector</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low</td>
<td>Low</td>
<td>Med</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Med</td>
<td>Low</td>
<td>Med</td>
<td>Long</td>
</tr>
<tr>
<td>3</td>
<td>Med</td>
<td>Med</td>
<td>Med</td>
<td>Med</td>
<td>Med</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Short</td>
</tr>
</tbody>
</table>

Each colonoscopy examination is characterized by multiple CFM recorded parameters. For each parameter levels of Low, Medium and High are based on relation to average force for each parameter.
Force Distribution

Zone 1: Rectum - Descending

Zone 2: Descending-Transverse

Zone 3: Transverse - Cecum
Force Distribution

Max Push Force

Avg Push Force

Avg Push/Pull Force Rate
Force Distribution
CFM™: Current Studies

- Evaluation of Handheld Colonoscopy Force Monitor by Expert and Trainee Endoscopists in the Performance of Colonoscopy

- Multicenter Study: Washington VA, University of Pennsylvania, Georgetown University, Montefiore Medical Center.

- Aim: to evaluate the role of experience on the pattern of forces used to perform colonoscopy using a device that monitors the amount of force applied to the shaft of a standard colonoscope during colonoscopy.

- Eight expert endoscopists, twenty trainees
CFM-02 Training Study

- Maximum pull force, N
- Average push force, N
- Average push/pull force rate, N/s
- Examination time, s

Comparisons between Conscious Sedation and Propofol.
Goals

- More Uniform Training
- Improved Continuing Education
- Improved Instrumentation
  - Reduction in Pain
  - Reduced Anesthesia
  - Reduction in Complications
CFM™: Characterizing the colonoscopy technique

- CFM continuous force monitoring can characterize and classify endoscopy techniques
- CFM reveals unique signatures for an endoscopist through the combination of recorded manipulations and forces
- CFM can be used to develop training methods based on best practices of expert endoscopists
- CFM can be used to assess trainees technique and monitor their training progress
- CFM can be used to correlate force measures with: instrument type and design, i.e. diameter, stiffness, frequency of use.
The CFM™ Workstation Prototype

Post procedure case review: Correlation of force and video
“May The Force or The Schwartz Be With You!”

Obi-Wan Kenobi: Star Wars 1977

Yoghurt: Spaceballs 1987