

Over-the-Scope (OTS)-Clips Can be Fired Safely Over a Guidewire: Proof of Concept in an Ex-vivo Porcine Model

Colin G. DeLong, MD, Alexander T. Liu, MD, and Eric M. Pauli, MD
Division of Minimally-Invasive and Bariatric Surgery
Penn State Milton S. Hershey Medical Center

Background

- **Problem:** Over-the-scope (OTS)-clips can be used for full-thickness gastrointestinal tract defects, but deployment can be difficult:
  - (OTS)-clips perform best when fired in an "end-on" position
    - Scope, clip, tissue aligned on one axis
  - OTS-clip deployment also requires successful fistula identification
- **New Concept:** cannulating defect with guidewire, backloading endoscope over wire, firing OTS-clip over tissue/wire, removing wire through the endoscope

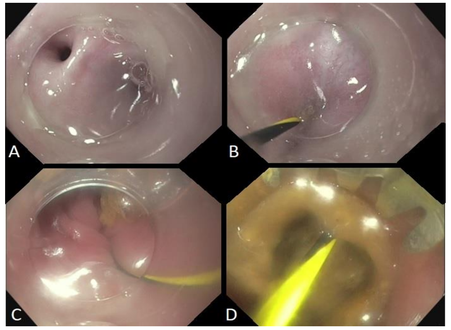


Figure 1

- **Example:** Here, a colovaginal fistula is identified from the vaginal side **(Figure 1A)** and cannulated **(1B)**. The wire is identified in colon **(1C)**, and the guidewire is used to position the OTS-clip over the colonic defect **(1D)**.
- **Question:** Can this technique be performed safely without risk of wire entrapment within the deployed clip?

Methods

- Ex-vivo fresh porcine foregut model
- 3-mm diameter full-thickness defects made with biopsy punch **(Figure 2A)**
- Wire threaded through defect, endoscope backloaded onto wire **(2B)**
- OTS-Clip (OVESCO, Tuebingen, Germany) fired over **(2C)**
- Guidewire pulled back through the endoscope and clip **(2D)**
- Wire removal difficult graded using 5-point Likert scale **(Figure 3)**

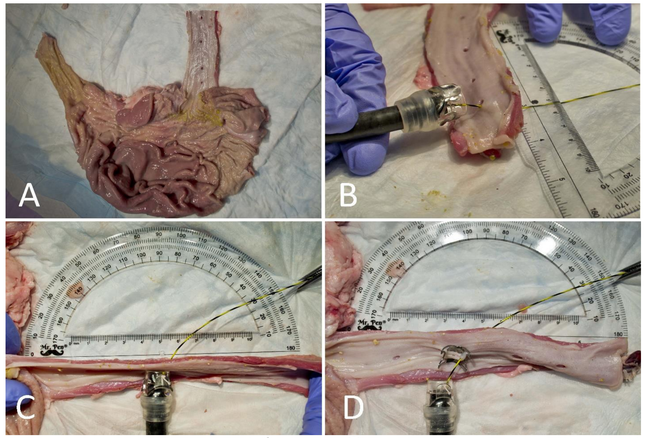


Figure 2

Difficulty of Wire Removal Scale
1: No difficulty – wire slides with no resistance
2: Mild difficulty – small amount of resistance is noted, but wire can be slid in continuous motion
3: Moderate difficulty – more resistance is noted, requiring wire to be pulled in noncontinuous motion
4: Extreme difficulty – significant resistance is noted, and significant manipulation of the wire is required to remove
5: Impossible – wire is trapped and unable to be advanced or withdrawn

Figure 3

- 216 unique combinations of firings including:
  - 9 OTS-clip types: 10/3A, 10/3 T, 11/6A, 11/6 T, 12/6 A, 12/6T, 12/6 GC, 14/6A, 14/6T
  - 2 wire types: .035' monofilament, .035' braided
  - 4 wire angles: 0°, 30°, 60°, 90°
  - 3 tissue locations: esophagus, stomach, duodenum

Results

- Total Number of Attempts: 216
- Mean Likert Score (all attempts): 1.24
- Likert Score Breakdown
  - 1: No difficulty = 174 (80.6%)
  - 2: Mild difficulty = 35 (16.2%)
  - 3: Moderate difficulty = 5 (2.3%)
  - 4: Extreme difficulty = 2 (0.9%)
  - 5: Impossible = 0 (0%)

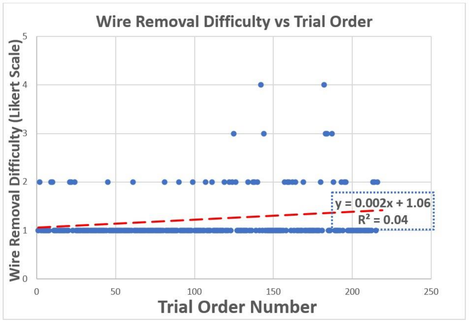


Figure 4

- Removal difficulty by subgroup:
  - Significant difference in OTS-clip size (p = 0.001)
    - 10/3: 1.40 ± 0.7
    - 11/6: 1/13 ± 0.3
    - 12/6: 1/33 ± 0.6
    - 14/6: 1.04 ± 0.2
  - Significant difference in trial order **(Figure 4)**
  - No difference (p > 0.05) in:
    - Clip teeth type
    - Wire type
    - Tissue location
    - Angle

Conclusion

- No clinically significant wire entrapments occurred. The wire could have been removed endoscopically in all cases.
- The few difficult wire removals were likely related to wire damage from reuse, which would not occur in a clinical setting.
- This technique can be employed to facilitate OTS-clip closure when "end-on" positioning or fistula identification are difficult.
- Further clinical study in human patients is indicated before wide clinical implementation.

PennState Health
Milton S. Hershey Medical Center