Developing A Smaller And More Dexterous Distal Tip for Disposable Endoscopes

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BACKGROUND

MOTIVATION

- In 2012 worldwide [1]:
  Gastric Cancer (GC) is 2nd leading cancer-related deaths in the world:
  952,000 new cases of GC
  723,000 GC-related deaths
- 70% of all cases occur in low-and-middle income (LMI) countries

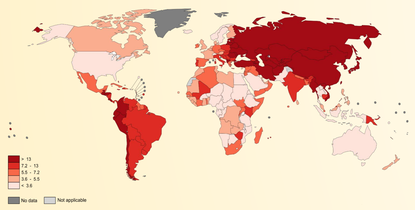


Figure 1: Distribution of male deaths in the world due to gastric cancer in 2012

TRADITIONAL ENDOSCOPE

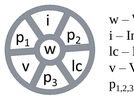
- Cost[2]: $66,000 (avg.); $104,000 (high)
- LMI countries can rarely afford the economic costs and lack the resources for endoscopy
- Unintuitive and requires hours of training
- Takes long time to clean or repair
- Not portable, bulky tower unit

Figure 2: Endoscopic tower unit and endoscope

DISPOSABLE ENDOSCOPE SOLUTION (DEIPA)

Multi-Lumen Catheter

FABRICATION COST: < 25 USD

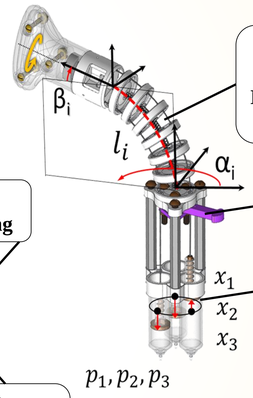


w – Wire Rope (spine)
i – Insufflation Lumen
lc – Lens Cleaning Lumen
v – Video Lumen
$p_{1,2,3}$ – Bellow Line Pressure

Lens Cleaning

HD Camera with LED Lighting

Off-the-shelf Bellows



Continuum Actuation Manipulator Handle (Nitinol Wires)

Position Locking Mechanism

Syringe Piston Fluid Actuators

Battery Pack

Wi-Fi Image Transmission Module

LIMITATIONS

- Off-the-shelf bellows limit angular range of motion, preventing retroflexion from being achieved
- End-effector tip diameter is bigger than traditional endoscope
- Difficult to maneuver in narrow areas and smaller patients

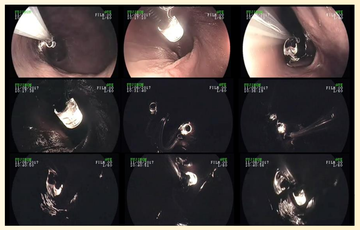


Figure 3: DEIPA probing through upper gastrointestinal tract (UGI) of human cadaver

DESIGN AND DEVELOPMENT

OBJECTIVES

1) Develop an end effector with a much smaller diameter
2) Fabricate bellows that can achieve retroflexion (180º range of motion) to visualize 100% of stomach tissue ***(Fig. 4d)***

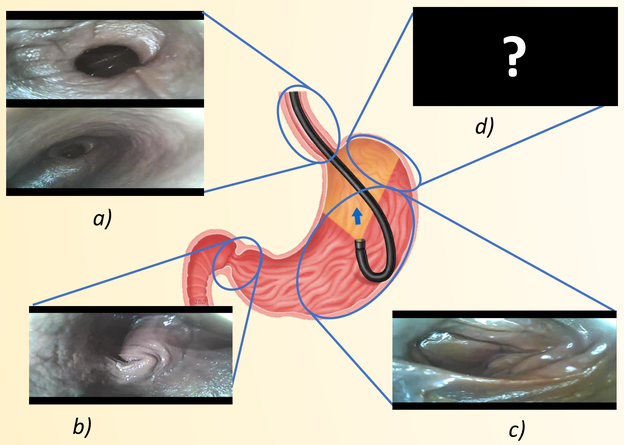


Figure 4: *Endoscope performing retroflexion;*
a) *Esophagus and Esophageal Sphincter*
b) *Pyloric Sphincter (opening to duodenum)*
c) *Greater and Lesser Curvature of stomach*
d) *GI Junction (lacking visualization)*
**images taken from August 2017 human cadaver trial*

METHOD

1) 3D CAD software used to create bellow model for molding ***(Fig.5)***
2) Formlabs Form 2 3D printer (resolution 0.25mm) was used to print the mold ***(Fig. 6)***
3) Prepared Shore A-30 silicone rubber compound (Polycraft GP-3481-F Silicon)
4) Injected viscous silicone rubber compound into mold and allowed for curing and drying for 12 hours

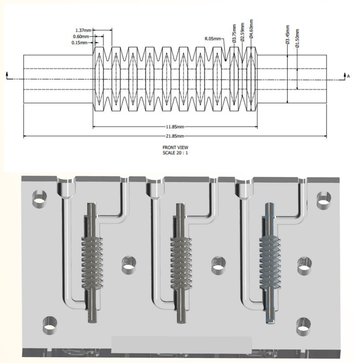


Figure 5: *CAD modeling of molding pieces*
(top) 2D drawing of bellow
(bottom) 3D CAD assembly of mold layout

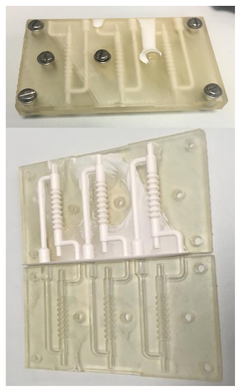


Figure 6: *Injection mold of bellow using silicon compound*

RESULTS

- The new end-effector tip retains an outside diameter of 8.3mm compared to 14mm for the original
- Higher range of motion is achieved by the new end-effector tip ***(Fig. 8)***
- Silicone material can withstand significant pressure despite extremely thin wall thickness

Figure 7: *Three new bellows next to current bellow superimposed on British penny*

Figure 8: *New bellow end-effector approaching retroflexion configuration*

Figure 9: *New end-effector tip compared to current tip*

CONCLUSION

- Significantly smaller bellows were successfully and feasibly developed
- The new end-effector tip achieved retroflexion
- Maneuverability is significantly increased

Future Work:

- Embedding camera for in-vivo clinical trials
- Load cycle and stiffness testing
- Testing various silicon compound materials

REFERENCES

[1] Campisano, F, Gramuglia, F, Dawson, IR et al. (7 more authors) (2017) Gastric Cancer Screening in Low-Income Countries: System Design, Fabrication, and Analysis for an Ultralow-Cost Endoscopy Procedure. IEEE Robotics & Automation Magazine, 24 (2). pp. 73-81. ISSN 1070-9932

[2] Leiby, Casie. "Purchasing Insight: Endoscopic Surgery Video System." *Cost of Scopes I Purchasing Insight for Endoscopic Surgery Video Systems I MD Buyline*, Md Buyline, www.mdbuyline.com/research-library/articles/purchasing-insight-endoscopic-surgery-video-system/.

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