

DISLODGE MENT RESISTANT ENDOSCOPIC DISSECTING CAP



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Abstract

- Gastrointestinal diseases are commonly treated through endoscopic procedures
- Endoscopic caps can improve efficiency of procedure, but often dislodge
- The goal of this project is to design an endoscopic cap which resists dislodgement
- The design utilizes multiple internal flaps which restrict displacement of the cap
- Future work will enhance the design, change materials and make the cap reusable

Background and Impact

Background

- The client performs endoscopies to view the human gastrointestinal tract
- Current caps dislodge during nearly every procedure
- Dislodgement during procedure increases length of surgery
- Caps are generally less than 12 millimeters in diameter



Figure 1: Endoscopic cap in use [1]

Problem Statement

The goal of this project is to develop a dislodgement resistant cap for endoscopic procedures.

Endoscopy Background

- Endoscope consists of thin flexible tube with a camera attached to the end
- Enters in mouth and travels down esophagus
- Various tools passed through the endoscope to collect tissue samples and treat problems



Figure 2: View from endoscope with cap attachment [2]

Impact

- Design allows for endoscopies to proceed without the dislodgement of the cap, more efficiently diagnosing and treating conditions

Design Criteria

- Cap must withstand typical surgical movements without dislodgement and be easily attached and detached by the user.
- Cap must be made of transparent and colorless biocompatible material
- Material must operate in conditions of 37 degrees Celsius and a pH of 2
- Cap must fit on the 9.9 mm diameter endoscope and extend ~4 mm outward.
- Must not alter the endoscope

Final Design and Prototype

Two Part Cap Design

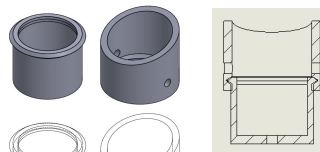


Figure 3: Silicone bottom section (left) and Polycarbonate section (right)

Dislodgement Resistant Design:

- The bottom silicone section has a ridge on the top exterior surface and four flaps on the bottom interior surface
- The flaps fold up when the endoscope is inserted and prevent the cap from completely dislodging during surgical procedures
- The top polycarbonate section has a beveled end, drainage holes and a channel on the bottom of the interior surface
- The ridge and channel of the sections align to keep cap together

Figure 4: Internal section of SolidWorks assembly for the two endoscopic cap sections

3D Printed Prototype



Figure 5: 3D printed endoscopic cap prototype on endoscope

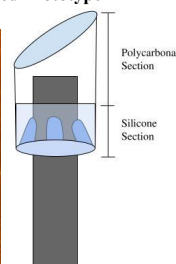


Figure 6: Model of interaction between internal flaps and endoscope

Cap - Endoscope Attachment:

- The endoscope used by the client is a EVIS EXERA III Olympus gastroscope with a diameter of 9.9 mm for the distal end
- The silicone section of the endoscopic cap has an internal diameter of 10 mm with the internal flaps having a thickness of 1.25 mm
- The elasticity of the silicone allows the cap to stretch when the endoscope is inserted
- For the cap to completely dislodge, the internal flaps would need to fold in on themselves to allow the endoscope to move backwards through the cap.

Assembly/Fabrication:

- Created a SolidWorks model of the silicone and polycarbonate sections for 3D printing
- Printed using FormLabs Elastic and Biomed Clear resins
- Polycarbonate section has an interior channel and the silicone section has an exterior ridge so the two pieces can lock together without the use of glue
- The bottom of the silicone section has 4 interior flaps that fold up when the endoscope is inserted into the cap
- The flaps allow the cap to stay in place throughout the endoscopic procedure

Testing and Results

- Caps were placed on gastroscope and maneuvered down esophagus and into stomach, then back up through the esophagus
 - Combination of lateral movement and twisting was used to best emulate surgery conditions, with movements kept as similar as possible between tests
- | Hospital Caps: | | New Cap Design | |
|---|---------------------------------------|--------------------------------------|-------------------------------------|
| ○ Resin/Silicon: dislodged in 2 of 3 trials | ○ Silicon: dislodged in 3 of 4 trials | ○ Medium: dislodged in 1 of 6 trials | ○ Small: dislodged in 0 of 3 trials |

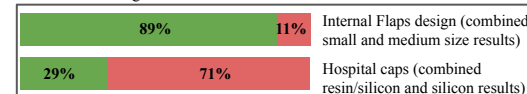


Figure 7: Chart of dislodgement testing data

Conclusion

- Using a two proportion z test with pooled trials from new and old designs, a p value of 0.0067 rejects the null and support the claim that the new cap is more resistant to dislodgement. [3]

Discussion and Future Work

Strengths of Design

- Design overall resisted displacement
- Caps fit well and were easily detached
- No tape or glue was required

Weaknesses of Design

- Polycarbonate section not clear
- Not reusable
- Cap sections can separate

Future Work

- Change material of cap to ensure biocompatibility and enhanced viewing field
- Create a reusable design
- Print cap using dissolvable supports

Acknowledgements

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References

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