Development of a safer endoscope to prevent infection transmission between patients

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Outline

- Endoscopes
- ERCPs and the Superbug
  - 3D Printing Endoscopes
  - Distal End Caps
- Esophageal Damage During Cardiac Ablations
  - Esophageal Deflection Device
  - Thermal Sensing
- Device Commercialization
- Summary
An endoscope is a Medical device with a light source attached which is used to look inside a body cavity or organ.

https://www.youtube.com/watch?v=Zxrykg-9bok
Parts of an Endoscope

Duodenoscopes

- ERCPs – endoscopic retrograde cholangiopancreatography

Medical Problem:
The Superbug: Antibiotic Resistant Bacteria
Duodenoscopes

- Superbug – CRE – Led to multiple deaths in the U.S.
Proposed Solution for contamination problem

• Disposable endoscope using 3-D printing
3D Printing

- 3D printing technology is a form of additive manufacturing, where an object is developed layer by layer allowing for complex, customizable structures

-makerbot replicator
-formlab form 2
-stratasys connex
3D Printed Endoscope Structures and Overtubes

Multiple designs have been created to allow for proper balance of flexibility and rigidity.
Manipulating an Endoscope

Pulley mechanisms have been incorporated to manipulated endoscope distal end
3D Printed Endoscope and Overtube Structures

Designs can fit multiple types of procedures having varying design requirements.
Targeting the Problem: Elevator Design

Taking advantage of 3D printers ability to construct complex geometries, the end can be printed to include the elevator...
Distal End 3D printed Elevator
Distal End 3D printed Elevator

3D printing structure can be influenced by printer/material type as well as the orientation that it is printed.
Medical Problem:
Esophageal Damage during Cardiac Ablation
Medical Problem: Esophageal Damage during Cardiac Ablation

- Procedure performed by Cardiac Electrophysiologist on Atrial Fib patients
- ~1 million procedures/year
- ~15% of procedures likely to have esophageal damage
- Damage, in extreme cases can lead to death.
Esophageal Deflection Device
First Prototype

Existing Esophageal Overtube
CAD Model
3D Print
Esophageal Deflection Device
First Prototype
Esophageal Deflection Device

**Overtube Device**
- Domed tip
- Curved Deflection
- Bellowed Design
- Handle w/ holes to view indicators

**Insertion Device**
- Indicators of extraction
- Handle

**3D Printed Components**
Finite Element Analysis of Esophageal Deflection Device
Uniaxial Testing of 3D Printed Photopolymer

3D Printed Coupons

MTS Criterion Tester

Extension rate @ 0.05mm/s

Uniaxial Tests - TangoBlack+

- Horizontal Coupons
- Vertical Coupons

Stress (σ) [MPa]

Extension Ratio (λ)
Finite Element Analysis of Esophageal Deflection Device

Model Parameters

Boundary Conditions
- 6 DOF Constraints on EDD arm Elements
- Solid 8-node brick
- Rigid wall movement
- Top Stationary Wall and Bottom Wall moving upward

Material Models
- 2-parameter Mooney Rivlin Stress and Force detection
- von Mises stress and plate force measured
Ex Vivo Testing

- Ex vivo tests illustrate that the device will also be affected by surrounding tissues
- It is important to also include esophageal tissue in future FEA models
Temperature Sensor Embedding...
Ex Vivo Testing for Heat Flow and Temperature Monitoring
Summary

- There is a wide variety of 3D printing technology that can be deployed to create medical devices
- 3D printing can be used to construct complex endoscope geometry both for the endoscope arm and the distal end
- Endoscope elevator mechanism can be 3D printed allowing for easy disposability preventing spread of infection / bacteria
- Distal end caps can be developed to redirect the view and working channel of a forward viewing scope.
Summary of Esophageal Deflection Device

- Medical doctors can provide rapid feedback to design by utilizing 3D printers / rapid prototyping.
- 3D printing has been used to develop a properly dimensioned and properly stiff endoscope-like esophageal deflection device.
- Disposability increases the value of such devices by preventing the possibility of spreading infectious diseases.
- Simulation, bench, and ex vivo tests can all aid in the medical device rapid development process.
Commercialization Activities

- Working with the Office of Innovation and Commercialization to patent devices – Esophageal Deflection Device PCT 3/8/18
- Working with Institute for the Global Entrepreneur’s technology accelerator and consulting groups defining regulatory and reimbursement pathways
Thank you