Design of Esophageal Stent with Decreased Migration

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SCOPE — Senior Capstone Program in Engineering

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Goals

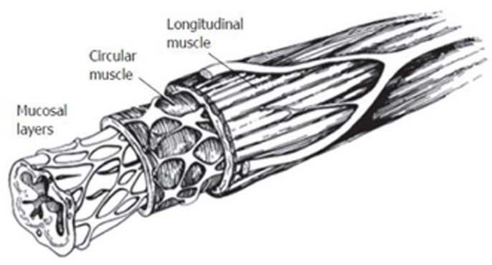
1. Design a stent or stent-like device that
   a. Separates the esophageal lumen from the biological tissue
   b. Decreases stent migration

2. Develop testing methods to validate stent designs

Background

The Esophagus

Lumen – canal of the esophagus
Mucosa – protective mucus layer of stratified cells
Submucosa – layer of mucus secreting glandular cells
Muscularis Externa – 2 layers consisting of circular and longitudinal muscles



Esophageal Disorders

Esophageal cancer - Tumors occlude the lumen and prevent swallowing

Esophageal perforations - holes in the esophagus

Tracheo-esophageal fistulas - a hole between the esophagus to the trachea, causing aspiration

Benign strictures - scar tissue, often caused by acid reflux

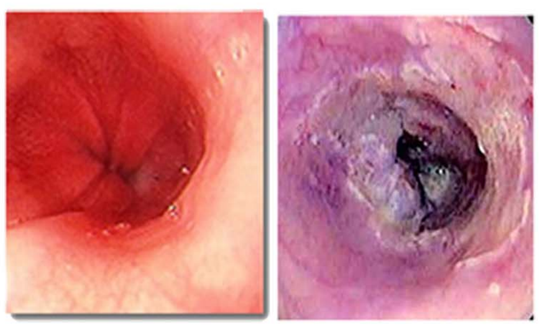
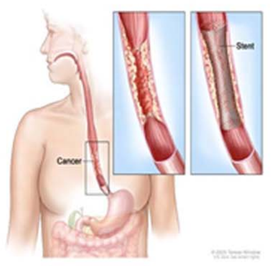


Image of a healthy vs an occluded esophagus

Why Stents?

Palliative care for inoperable cancers
Allows for normal swallowing



Normal usage of a stent

Types of Stents

Bare metal | Partially Covered | Fully Covered | Plastic

Problems with Current Stents

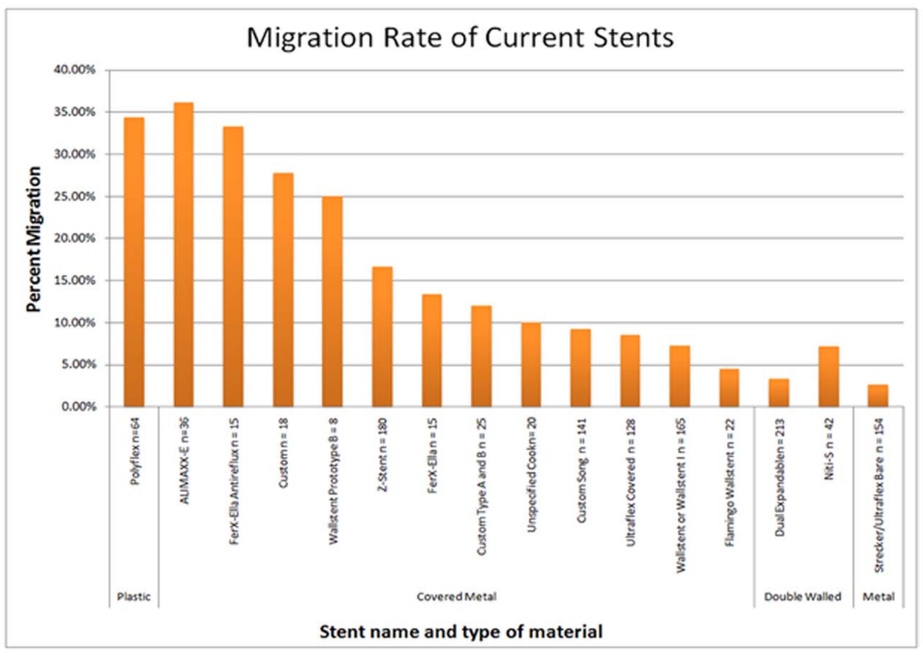
Stent migration into lower GI tract - occurs up to 35% of cases for some stents

Esophageal perforation due to stent - increases risk of infection and further complications

Inaccurate deployment of stent - could require additional procedures to correct positioning

Injury during removal - no esophageal stent is currently indicated for removal. However, certain cases require removal.

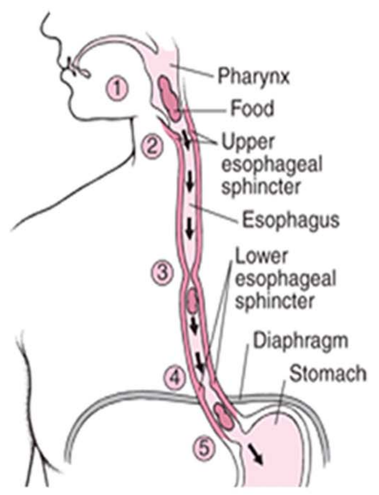
A migrated stent in the lower GI tract

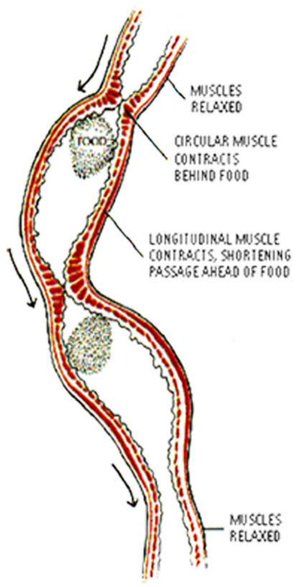


Mechanisms of Stent Migration

Basics of Swallowing

(1) Food is masticated into a bolus.
(2) The bolus moves past the upper esophageal sphincter.
(3) Peristalsis then carries the bolus down the esophagus.
(4) The lower esophageal sphincter opens to allow the food into the stomach.
(5) The bolus is digested in the stomach.





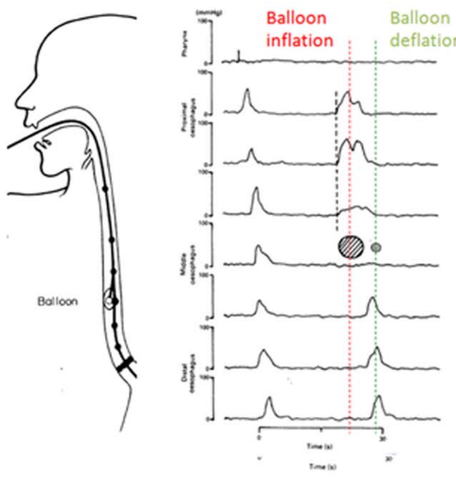
Primary Peristalsis

Consists of involuntary muscle movements
Longitudinal muscles contract ahead of the bolus (distal)
Increases the diameter of the lumen and the concentrates circular muscles around the bolus
The circular muscles contract above the bolus
Completely occludes the lumen and pushes it down into the wider lumen further down
The peristaltic wave moves at a velocity independent of the bolus

Secondary peristalsis

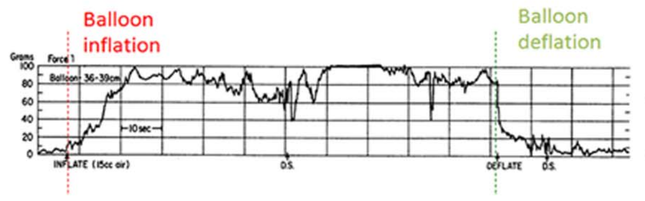
A natural reflex of the circular muscles to accommodate leftover food passed over by the peristaltic wave.
Depends on continual distention of the esophageal tissue.
Independent of any neuronal activity and can be induced *ex vivo*.

Esophageal Propulsive Force (EPF)



The esophageal propulsive force (EPF) is a stronger, sustained muscular reaction to an immovable bolus.

Results from distentions larger than those resulting in secondary peristalsis
Consists of a single, sustained force by the circular muscles
The force exerted is significantly larger than that resulting from primary or secondary peristalsis
Could contribute significantly to stent migration

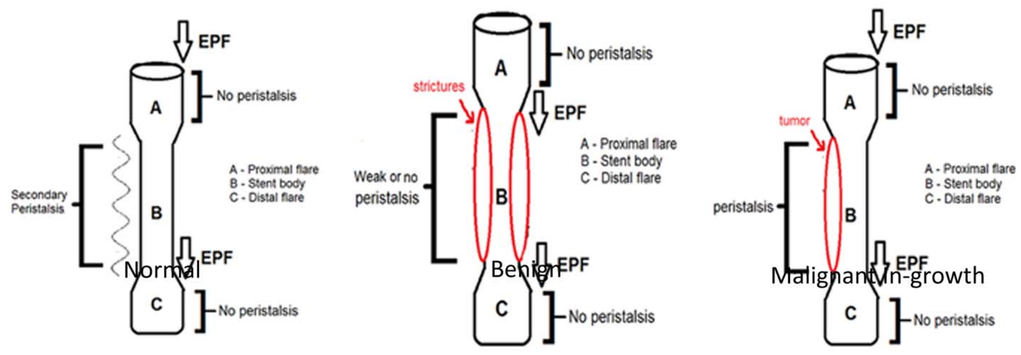


This image shows a peristaltic wave moving down the esophagus towards the stomach (vertical axis) while also showing the movement of the peristaltic wave in time (horizontal axis). Note that the there are no peristaltic waves immediately above or below the bolus. The peristaltic wave appears trapped proximal to the bolus. Once the balloon is deflated (30s), the peristaltic wave continues down the esophagus.

	Distension Diameter (mm)	Distension Duration (sec)	Force of Contraction (g)	Type of Contraction	Location
Secondary Peristalsis	≤ 21.2	< 5	40-100	Peristaltic wave	Proximal to obstruction
Esophageal Propulsive Force	≥ 26.6	>10	4-200	Sustained contraction	Proximal to obstruction

Distention thresholds to induce secondary peristalsis (motor threshold), patient discomfort (sensation threshold), and maximum tolerated sensation

Possible Esophageal Responses to Stent Placement



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