Design of an Anti-Migratory Esophageal Stent

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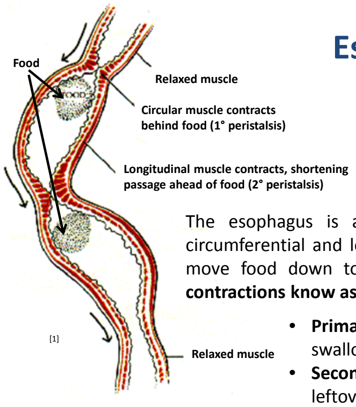
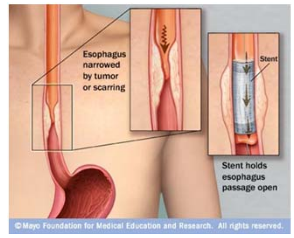
Esophageal Physiology & Applications of Stents



The esophagus is a **highly dynamic system** composed of circumferential and longitudinal muscles that work together to move food down to the stomach via **involuntary wave-like contractions know as *peristalsis***.

- **Primary** peristalsis begins immediately after swallowing
- **Secondary** peristalsis is a local reflex to remove leftover food or stomach reflex



[2]

Esophageal stents are **widely used to treat narrowing of the esophagus and to provide structure during surgical reconstruction** due to:

- tumors
- refractory strictures
- fistulas
- perforations

The stent provides mechanical support to the esophageal wall while keeping the lumen open for proper passage of food.

Even though the use of stents does improve patient health and quality of life, a subset of patients experience complications – the most of common of which is **displacement of the stent from its original location within the esophagus**, or migration.

Migration Rates for Boston Scientific Stents

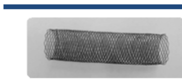
2-19%	Ultraflex†‡ Conio, *et al.* 2007	 [3]
6%	Wallflex†‡ van Boeckel, *et al.* 2010	 [4]
22%	Polyflex‡ Conigliaro, *et al.* 2007	 [5]

† Partially covered, ‡ Malignant strictures

While Boston Scientific's contribution to the advancement of stent technology has been outstanding, continued **innovation to even further reduce potential of stent migration both holds tremendous market opportunity** as well as **closely follows Boston Scientific's aim of improving patient health and care using minimally invasive solutions.**

Evolution of Stent Design and Related Tradeoffs

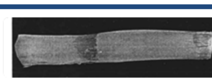
Wire-mesh tubes



Uncovered Stent, [6]

Stents made of expandable tubes of **wire mesh** exhibited low migration rates. However, tissue would grow through these uncovered metal stents to re-occlude the lumen.

Polymer **Stent Covering**



Early covered Stent, [7]

Metal stents were covered with polymer coatings to reduce re-occlusion. However, they are associated with higher migration rates.

Flared Geometry

Partially covered stent with flares , [8]

To reduce migration, **uncoated, flared ends** were introduced to coated stents. However, stent migration remains a problem.

Polymer Innovation: **Biodegradability**

SX Ella BD Stent ,[9]

Biodegradable stents rely on ingrowth to temporarily prevent occlusion, but are effective for only short time frames.

Metal double-walled stent [10]

Uncovered stent, [6]

Historically, stents that do not migrate are difficult to remove and often re-occlude. Conversely, removable stents exhibit high migration rates. However, increasing treatment of benign strictures has produced growing demand for effective, removable stents that do not migrate.

To prevent migration while allowing removal, new stent designs must achieve a complex balance between anti-migratory function and removability.

SX Ella BD Stent, [9]

Anti-Migratory
anchorage provided by tissue ingrowth

Removability
coverings and biodegradable materials

Project Goal: Design a stent or stent-like device that **imperviously separates the lumen from tissue and decreases migration**

The **2009-2010 Boston Scientific SCOPE team produced proof-of-concept designs** and results indicating their potential for future development. **This year, the SCOPE team set the following three aims:**

1. **Specify Designs** for the concepts developed by the 2009-2010 SCOPE team
2. Test the anti-migration **functionality** of the designs
3. Assess the **feasibility** of integrating the designs into current stent technology

2010-2011 Accomplishments:

1. Specified design parameters for proposed designs
2. Developed and validated tests for functionality & feasibility
3. Prototyped proposed designs
4. Used prototypes to perform functionality & feasibility testing
5. Made recommendations to Boston Scientific

Boston Scientific

FRANKLIN W. OLIN COLLEGE OF ENGINEERING 1997

SCOPE Senior Consulting Program for Engineering

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