Esophageal Stents

What, Why, When and How?

Motility Noon Conference

Bill Kessler

February 1, 2017

Disclosure

• Research support from Merit Medical, Inc.

Objectives

- Background
- Indications
- Techniques
- ...and

- --- What?
- --- Why?
- --- When? How?
- --- What's next???

What (Who) is (a) stent?

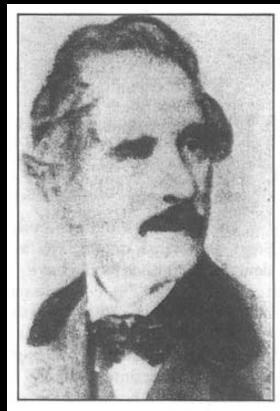
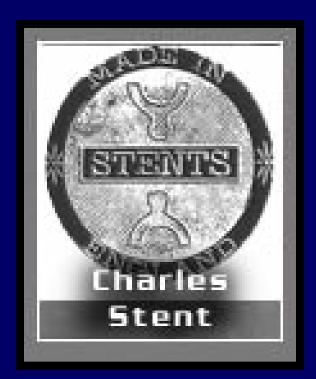


Fig. 1. Charles Stent, 1807-1885.

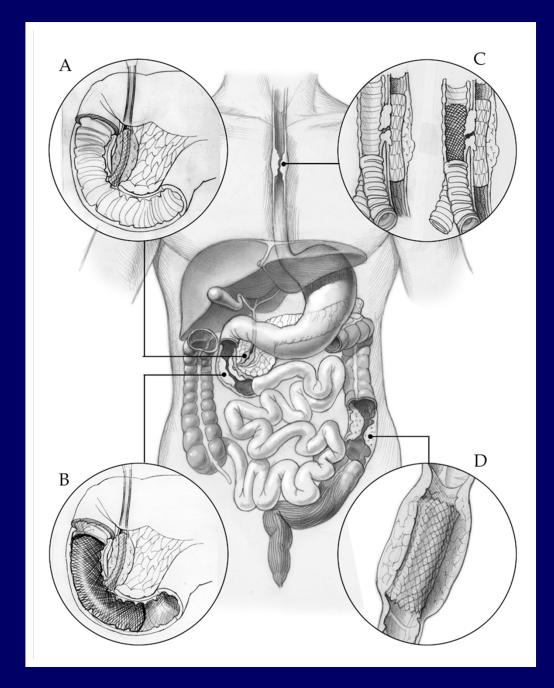


History of Stent Development

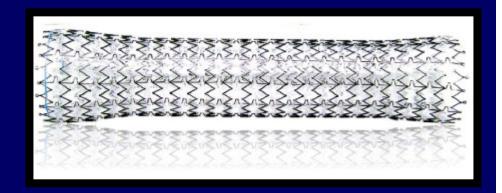
- 1859 Dentist Charles T Stent developed dental splint and commercialized the device in 1869
- 1964 Charles Dotter first used coaxial tubes for gradual intraluminal stenting
- 1986 First human use of Wallstent® by Puel
- 1989 1st use of SEMS esophageal stent

History of Stents Continued

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1997 Bioabsorbable Esophageal stent
2008 SX Ella BD Stent Commercially Available
2013 Niti-S TTS (Through the Scope) stent
2016 Extracellular Matrix + stent
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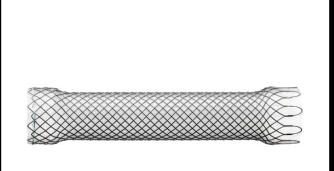


WHAT?









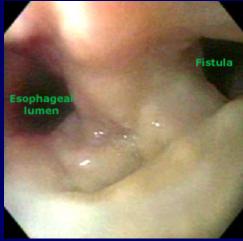


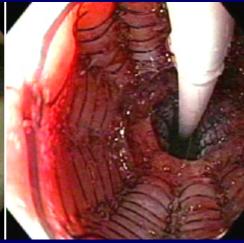




WHY? (Indications)

- Malignant
 - Locally unresectable
 - Widely Metastatic
 - Poor surgical candidate
 - Poor functional status
 - Preoperative





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- Benign (OFF LABEL)
 - Tracheo-EsophagealFistula
 - Anastamotic Leak
 - Esophagectomy
 - Bariatric (fistula)
 - Esophageal Perforation
 - Boerhaave
 - latrogenic
 - Foreign body (EoE)
 - Benign Stricture
- Extraesophageal CA (extrinsic)

Dysphagia Score: Mellow and Pinkas

- 0 = able to eat normal diet / no dysphagia.
- 1 = able to swallow some solid foods
- 2 = able to swallow only semi solid foods
- 3 = able to swallow liquids only
- 4 = unable to swallow anything / total dysphagia

A CONTROLLED TRIAL OF AN EXPANSILE METAL STENT FOR PALLIATION OF ESOPHAGEAL OBSTRUCTION DUE TO INOPERABLE CANCER

KLAUS KNYRIM, M.D., HANS-JOACHIM WAGNER, M.D., NORBERT BETHGE, M.D., MICHAEL KEYMLING, M.D., AND NIMISH VAKIL, M.D.

- 50% of circumference
- 50% incurable disease
- Most rapidly rising CA

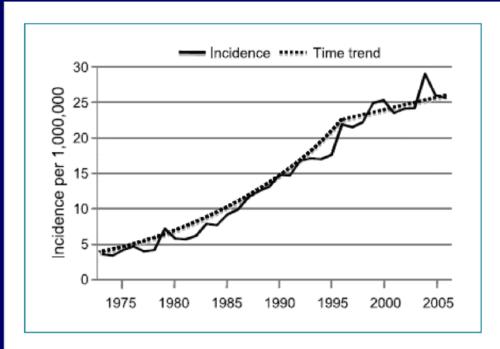


Figure 1. Overall incidence trend in esophageal adenocarcinoma (1973-2006).

Palliation for Malignant Dysphagia



- Wilson Cook
- General Anesthesia
- Balloon dilation 20 mm
- 16 mm Prosthesis



- Wallstent
- MAC sedation
- Max dilation 10 mm
- 16 mm diameter

Results

Table 3. Complications and Recurrent Dysphagia.

	PLASTIC	METAL
	Prosthesis	STENT
EVENT	(N = 21)	(N = 21)

no. of patients (%)

Control of the second	0 (10)	
Complication	9 (43)	0*
Perforation	3 (14)	0
Aspiration pneumonia	1 (5)	0
Migration of device	5 (24)	0
Recurrent dysphagia	7	7†
Food-bolus impaction	1	3
Migration of device	5	0
Tumor ingrowth	0	3
Tumor overgrowth	0	2
Tracheoesophageal fistula	1	2

Table 4. Reinterventions.*

	PLASTIC PROSTHESIS	METAL STENT
VARIABLE	(N = 21)	(N = 21)
Procedure (no. of patients)		
Percutaneous endoscopic gas- trostomy	3	0
Placement of a new prosthesis	2	3
Laser therapy	5	10
Retrieval of prosthesis	3	0
Laparotomy	1	0
Placement of a chest tube	1	0
Endoscopic disimpaction	2	3
Emergency bronchoscopy	1	0
Rate of reintervention	0.9 ± 0.3	0.8 ± 0.3
Duration of hospitalization for treatment of recurrent dys- phagia and complications (days)	3.4±0.6	1.9±0.7
Total hospital stay after place- ment of prosthesis (days)	12.5±2.1	5.4±1.0†

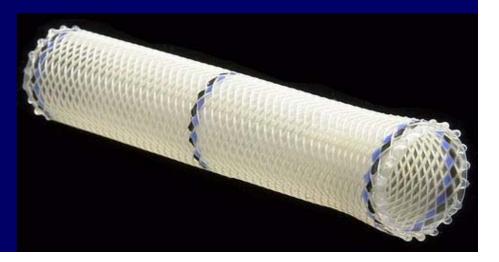
Manufacturer and product name	Material and design	Outer diameter (mm)	Length (cm)	Introducer diameter (mm)
Boston Scientific				
Polyflex Esophageal Stent*	Polyester/silicone	16 (proximal flare, 20) 18 (proximal flare, 23) 21 (proximal flare, 25)	9, 12, 15	12, 14
Ultraflex Esophageal NG Stent System (covered)**	Nitinol (polyurethane)	18 (proximal flare, 23) 23 (proximal flare, 28)	10 (covered portion, 7) 12 (covered portion, 9) 15 (covered portion, 12)	6
Ultraflex Esophageal NG Stent System (noncovered)**	Nitinol	18 (proximal flare, 23)	7, 10, 12, 15	6
WallFlex Partially Covered Esophageal Stent [†]	Nitinol (silicone-coated, wire-braided, removal suture)	18 (proximal flare, 23) 23 (proximal flare, 28)	10 (covered portion, 7) 12 (covered portion, 9) 15 (covered portion, 12)	6
WallFlex Fully Covered Esophageal Stent	Nitinol (silicone-coated, wire-braided, removal suture)	18 (proximal flare, 25) 23 (proximal flare, 28)	10, 12, 15	6
Cook Medical				
Esophageal Z-Stent with Dua Anti-Reflux Valve [‡]	Stainless steel (polyurethane coating)	18 (proximal flare, 25)	8, 10, 12, 14	10
Evolution Esophageal Fully Covered Controlled-Release Stent ⁹	Nitinol (internal and external silicone coating)	18 (flange, 23) 20 (flange, 25)	8, 10, 12	8

Evolution Esophageal Partially Covered Controlled-Release Stent ⁹	Nitinol (internal and external silicone coating)	20 (flange, 25)	8, 10, 12.5, 15	8
EndoChoice				
Bonastent Esophageal Stent	Nitinol (silicone coating)	18	6, 8, 10, 12, 14, 16	6
Merit Medical Endotek				
Alimaxx-ES Fully Covered Esophageal Stent	Nitinol (covered with polyurethane)	12, 14, 16, 18, 22	7, 10, 12	5.3
Taewoong Medical Co				
Niti-S Esophageal Double Stent	Inner, covered layer: polyurethane; outer, uncovered layer: nitinol wire	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	Inner layer, 6; outer layer, 1.5 Inner layer, 8; outer layer, 2.5 Inner layer, 10; outer layer, 3.5 Inner layer, 12; outer layer, 4.5 Inner layer, 15; outer layer, 7	5.8, 6.5
Niti-S Esophageal Covered Stent (fully covered) [§]	Nitinol (completely covered with polyurethane)	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	6, 8, 10, 12, 15	5.8, 6.5
Niti-S Esophageal Covered Stent (antireflux)	Nitinol (covered with polyurethane) and a polytetrafluoroethylene antireflux skirt [¥]	16 (ends, 24) 18 (ends, 26) 20 (ends, 28)	6, 8, 10, 12, 15	5.8, 6.5
SV Ella Esonh Stont	Surgical suture			

SX-Ella Esoph Stent	Surgical suture	
Saito et al	Poly-L-lactic acid	

Potential Benefits of SEPS

- FDA Approved for benign and malignant stricture
- Less tissue in-growth
 - —Complete sealing 33-100%
 - -migration 30%
- Less stricture formation
- Increased radial expansion
- Removable

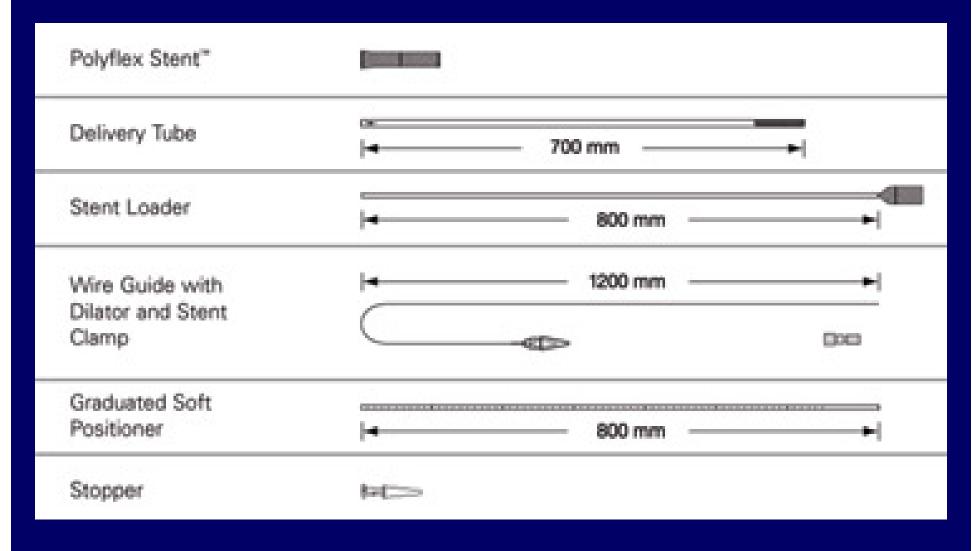


Polyflex

- Fully covered, silicone reinforced ends, proximal flare
- Radiographic and Endoscopic markings



Polyflex Continued...



Polyflex self-expanding, removable plastic stents: assessment of treatment efficacy and safety in a variety of benign and malignant conditions of the esophagus

M. Karbowski · D. Schembre · R. Kozarek ·

K. Ayub · D. Low

Table 1 Stents: application and complications

Pathologic condition	Patients (n)	Stents placed (n)	Stents removed (n)	Mean duration (weeks) n (range)	Complications
Malignant fistula	3	5	4	7 (3-10)	2 failures to occlude requiring surgery
Benign fistula	2	2	1	1	1 migration, 1 mucosal herniation
Perforation	3	3	1	7	1 migration
Radiation stricture	2	2	2	3 (3-4)	1 TE fistula
Anastomotic stricture	5	8	8	10 (2-38)	4 migrations
Caustic stricture	1	1	0	Never removed	N/A
Refractory reflux stricture	4	5	4	5 (2-6)	1 migration, 1 pain requiring removal
Anastomotic leak	1	1	1	7	N/A
Autoimmune esophagitis	1	2	1	6	N/A
Post-Nissen gas bloat	1	1	1	0	1 migration
Malignant stricture	7	7	3	3 (2-4)	1 migration, 1 tumor overgrowth

TE tracheoesophageal fistula; N/A not applicable

Summary of Study

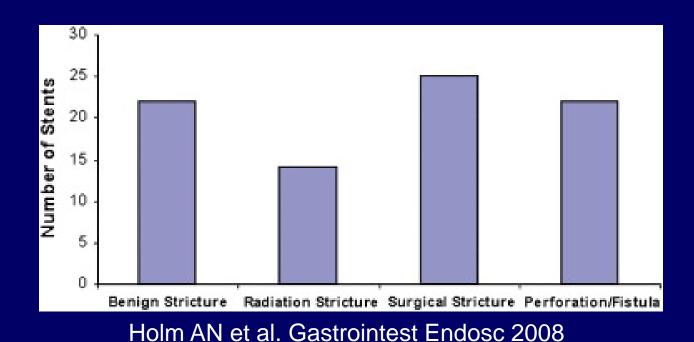
- 30 patients
- Left in place 52 days (mean)
- 30% migration rate (1/2 clipped)
- 30% Immediate pain (1 removed)
- 90% improvement
- 47% Required reintervention post removal

How about benign conditions?

- 15 Patients with benign strictures
- All stented with Polyflex
- Single migration
- Remainder with improvement in dysphagia
- 80% long term (22 months)

Self-expanding plastic stents in treatment of benign esophageal conditions

- 83/84 stents successfully placed (airway)
- 77/83 (92%) with initial improvement



Immediate Complications

Complication	# Procedures
Chest Pain	23 (27%)
Nausea/Vom	8 (9.5%)
Airway Comp	3* (3.6%)
Dysphonia	2 (2.4%)
Perforation	1 (1.2%)

* Unplanned brief hospital stay In 22 procedures (26%)

Migration

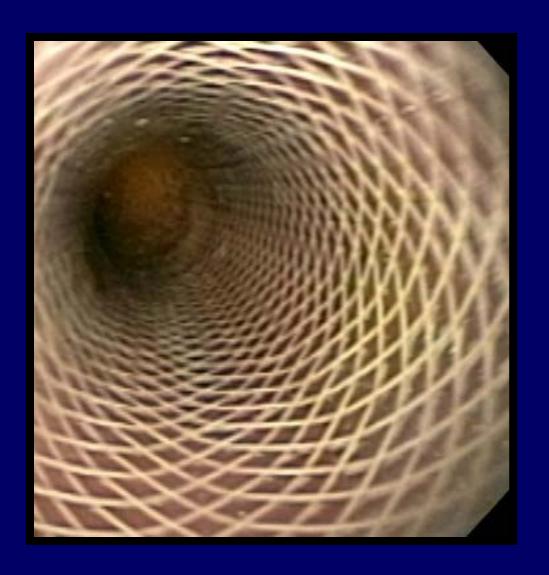
Location	Frequency (%)	Indication	Frequency (%)
Proximal	30/44 (68)	Benign Stricture	18/22 (82)
Mid	3/10 (30)	Anast. Stricture	18/25 (72)
Distal	19/27 (70.4)	Leak/ Fistula	13/22 (59)
		Radiation	4/14 (29)

Long Term Results

- 5/83 (6%) with long term improvement
- No difference in;
 - Indication
 - Location
 - Size of stent

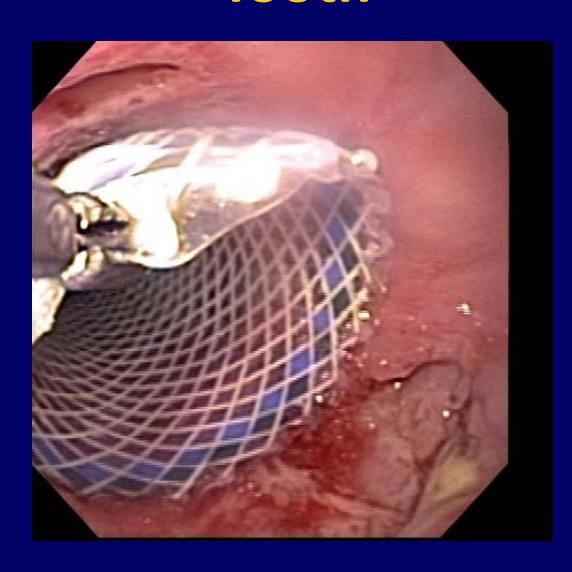
Esophageal Leak post Heller Myotomy



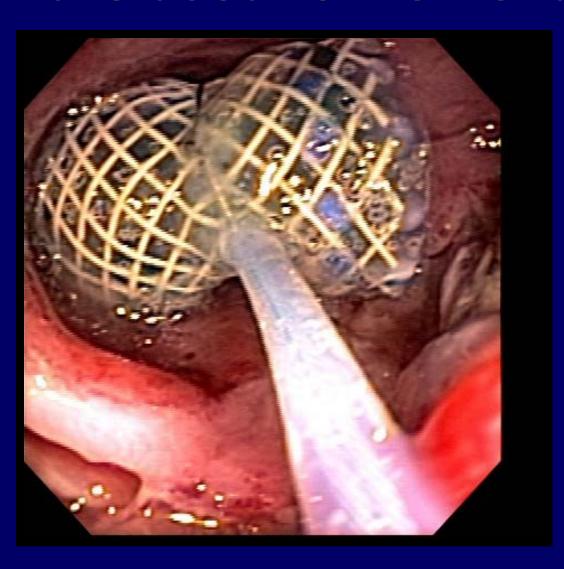




Unsuccessful Removal with Rat Tooth



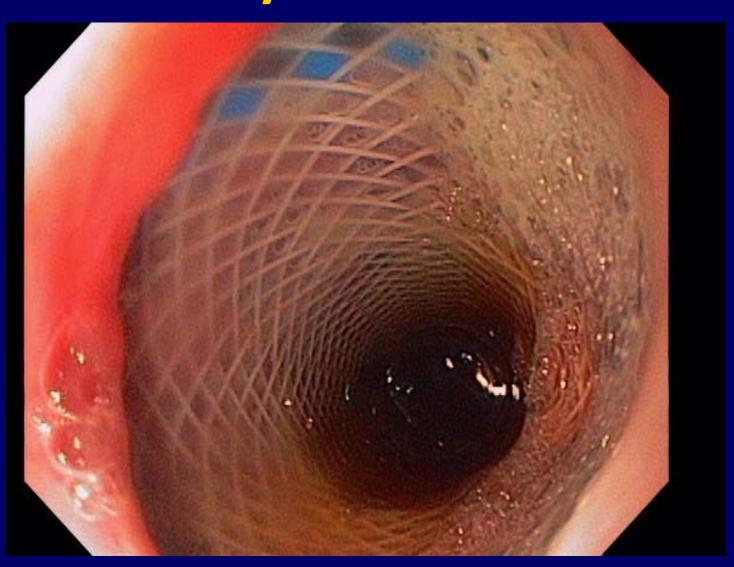
Snare used for removal



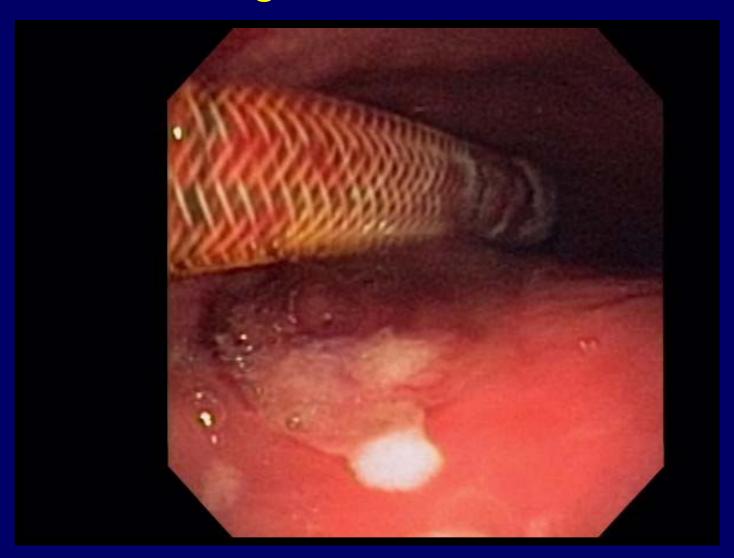
69 yo male with refractory stricture



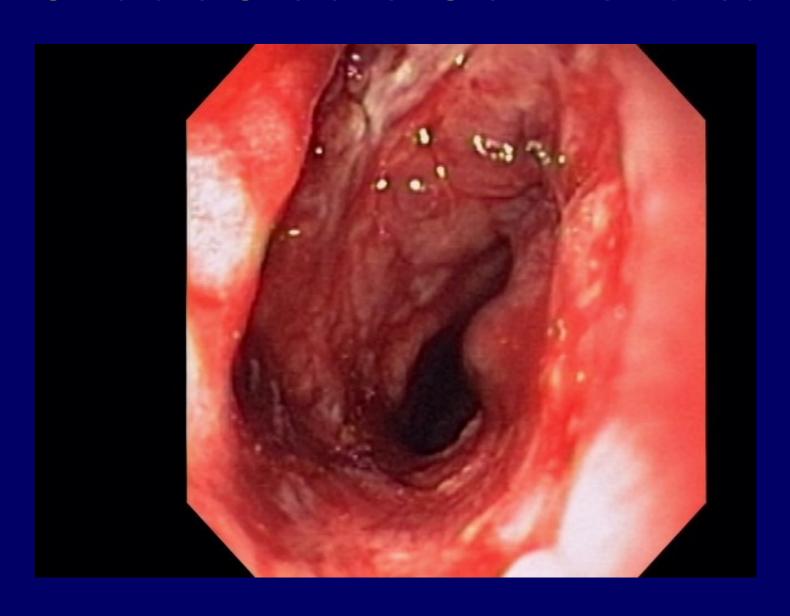
Dilated 24→39 Fr 18 mm Polyflex Stent Placed



Migrated SEPS



Stricture Site after Stent Removed



Recurrence of symptoms a few weeks later...

Sex: Age:

02/11/2008 11:57:46

CVP:4 D.F:1 ม:7 G:N

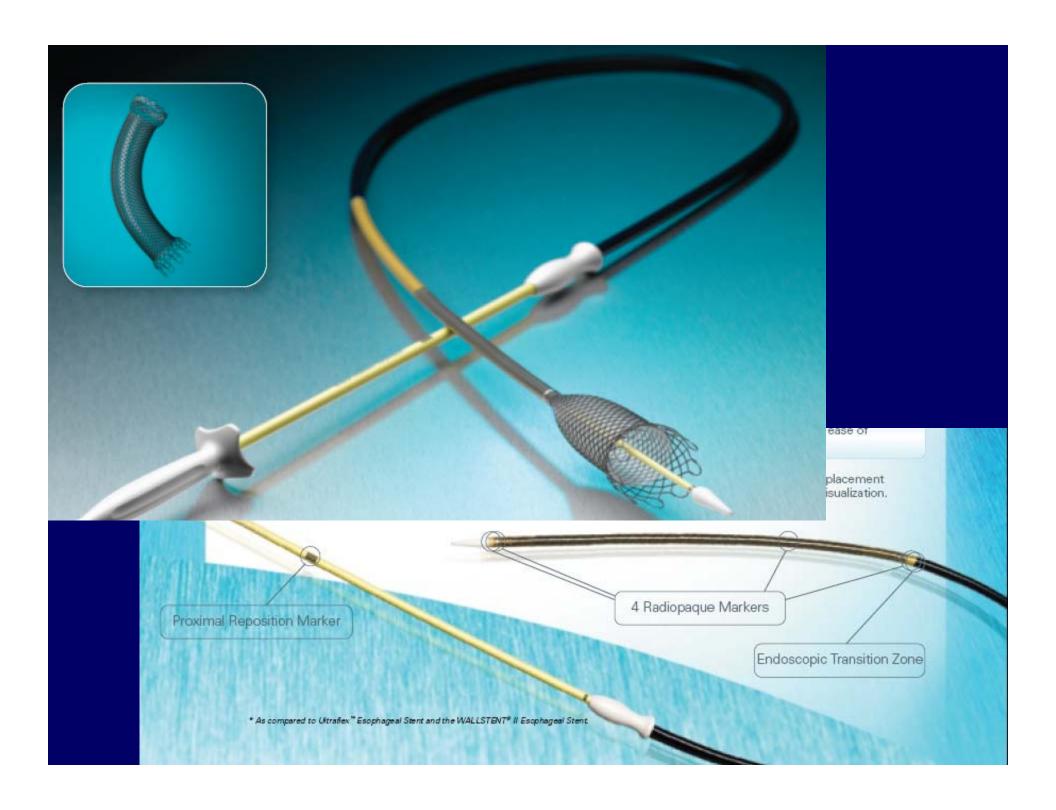
Physician: Comment: Sex: Age:

02/11/2008 11:58:18

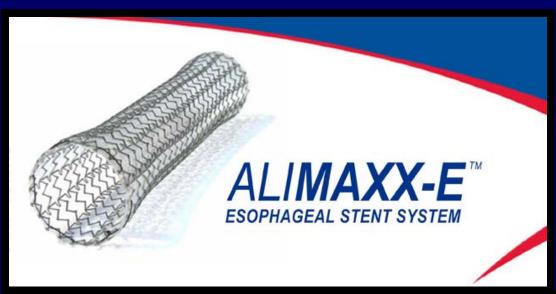
CVP:5 D.F:1 h:7 Cr:N

Physician: Comment:





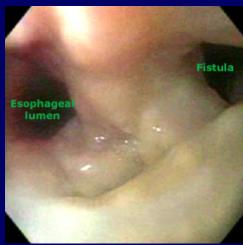
Alimaxx E Stent

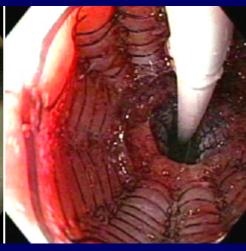




Esophageal Stent Indications

- Malignant
 - Locally unresectable
 - Widely Metastatic
 - Poor surgical candidate
 - Poor functional status



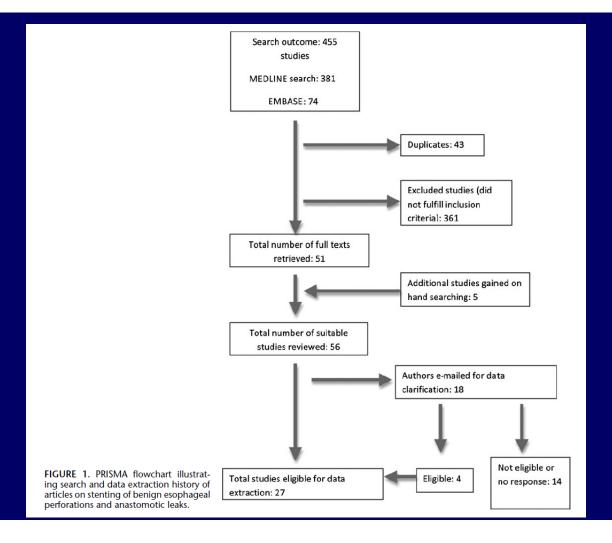


BV Dasari Ann Surg 2014 RK Freeman Ann Thorac Surg 2015

- Benign (Off label)
 - Tracheo-EsophagealFistula
 - Anastamotic Leak
 - Esophagectomy
 - Bariatric (fistula)
 - Esophageal Perforation
 - Boerhaave
 - latrogenic
 - Foreign body (EoE)
 - Benign Stricture
- Extraesophageal CA (extrinsic)

The Role of Esophageal Stents in the Management of Esophageal Anastomotic Leaks and Benign Esophageal Perforations

Bobby V.M. Dasari, MRCS,* David Neely, MRCS,* Andrew Kennedy, FRCS,* Gary Spence, FRCS,† Paul Rice, FRCR,‡ Eamon Mackle, FRCS,‡ and Emmanuel Epanomeritakis, FRCS‡



300 patients: 404 Stents (1/3 FCSEPS only)

Ann Surg 2014;259:852-60

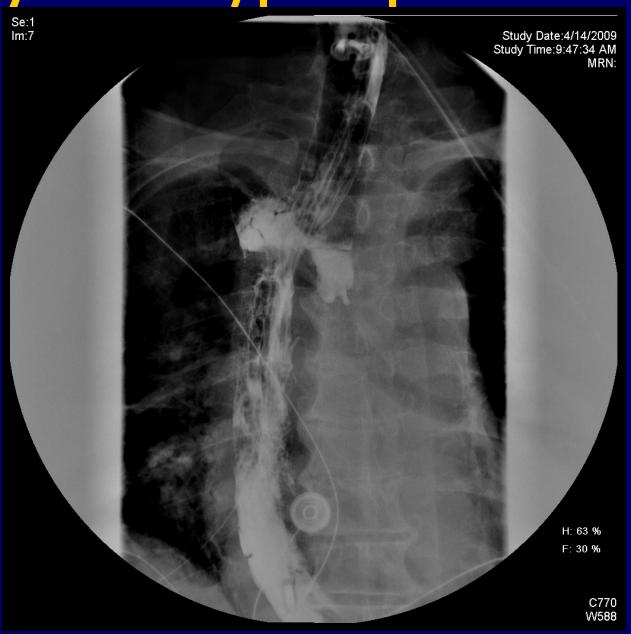
Primary Outcomes:

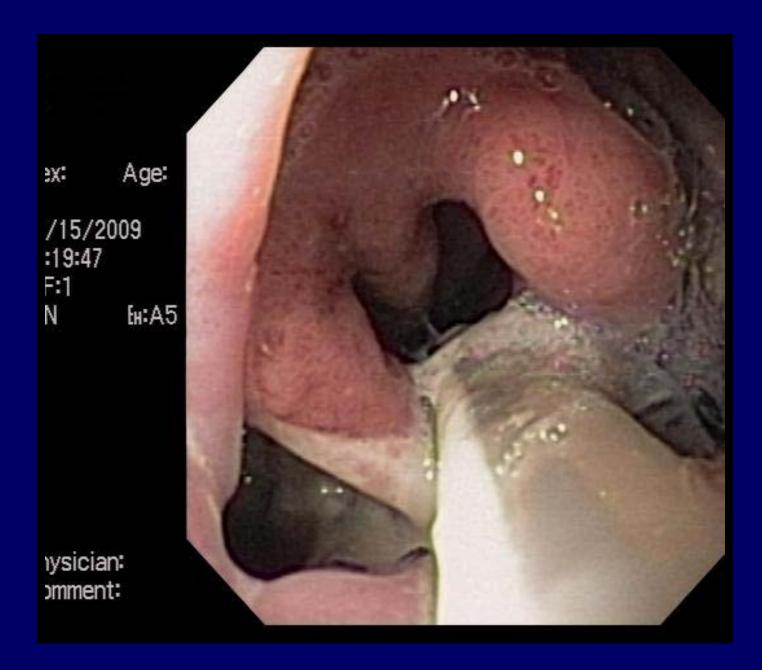
- 91% Technical Success (Metal higher*)
- 81% Clinic Success healing +/- stent

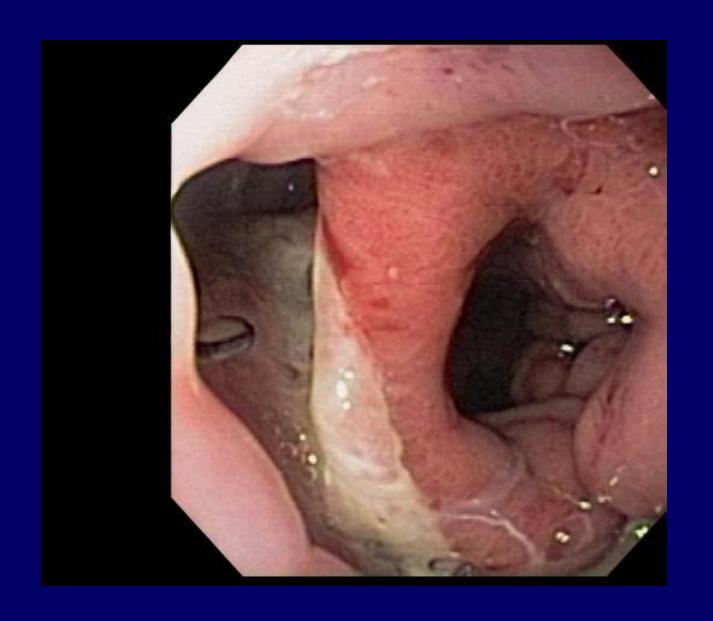
Secondary Outcomes:

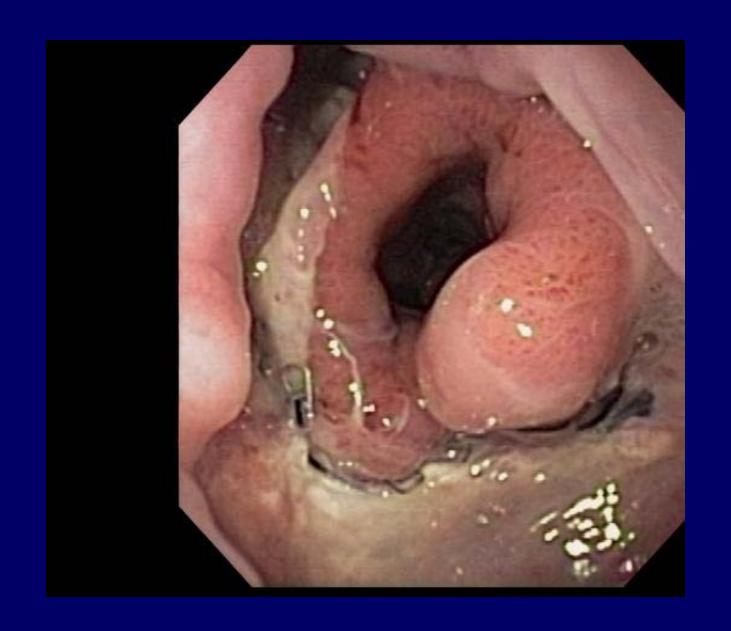
- Migration: 27% Plastic vs. 11% Metal
- Reintervention:
 - Endoscopic: 22% Plastic vs. 5% Metal
 - Surgical: 6% Plastic vs. 15% Metal
- Stricture rate: 0.3% Plastic, 3% Metal

48 yo male s/p esoph-x with leak

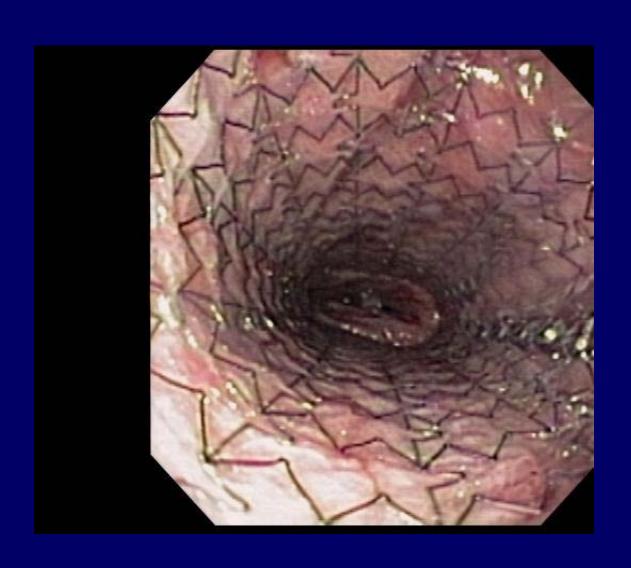








Leak covered with SEMS



Stent Removal





When?

How soon should the stent go in?

When should it come out?

Self-expandable metal stents for the treatment of benign upper GI leaks and perforations

- Retrospective review, single institution
- 88 patients
- 65% post-operative fistula
- 15% iatrogenic perforation
- PC SEMS (Ultraflex, Boston Scientific)

Findings

- Timing is important for perforation
 - -100% closure if immediate (<24 hrs)
 - -50% closure if delayed
- Is patient infected?
 - —Non-infectious 100%
 - —Infectious 75% ***drain if present
- Leak closure overall 78%
- Stricture 21% and migration 11%
- Stent removal in 97.8%

IUH "Level-One" Program

- Multidisciplinary Team: Esophageal Emergency
- 30 Month Review
- Referrals from 45 Hospital
- Mean Distance : 56 miles (1-163)
- 80% by ambulance, 20% by air
- 89% perforation (suspected, diagnosed)
- 89% of perforations non-contained

IUH "Level One" Program Etiology of perforation

Boerhaave syndrome	32 (45%)
latrogenic	26 (37%)
Other	13 (18%)
Coughing	2
Gastric volvulus	2
Malignancy	1
Caustic ingestion	1
Foreign body ingestion	1
Osteophyte erosion into esophagus	1
Bronchoesophageal fistula	1
Unknown	4

Ceppa D Esophageal Emergency Program (Submitted)

Results

	Supportive Care (n=5)	Endoscopic Intervention (n=8)	Surgery (n=25)	
Leak				
Contained	3	0	1	
Non-contained	2	8	24	
Location of leak				
Cervical	0	0	1	
Thoracic	3	8	14	
Abdominal	2	0	10	
Time from perforation to arrival				
<24hrs	4	7	25	
<u>></u> 24hrs	1	1	0	
Pittsburgh Severity Score	2.0	6.1	5.1	p<0.01

	Supportive Care (n=5)	Endoscopic Intervention (n=8)	Surgery (n=25)	
Re-intervention required	1 (20%)	4 (50%)	8 (32%)	NS
Any complication	1 (20%)	5 (62%)	14 (56%)	NS
Respiratory complication	1 (20%)	5 (62.5%)	10 (40%)	NS
Pneumonia	0	3	2	
Atelectasis	0	0	1	
Pulmonary embolus	0	1	0	
Ventilation >48hrs	0	1	6	
Unplanned reintubation	0	0	2	
Tracheostomy	0	0	6	
Other	1	1	4	
Cardiac complication	0 (0%)	2 (25%)	6 (24%)	NS
Myocardial infarction	0	1	0	
Atrial arrhythmia	0	1	5	
Congestive heart failure	0	0	1	
Other	0	0	0	
Acute kidney injury	0 (0%)	1 (12.5%)	1 (4%)	NS
Sepsis	0 (0%)	3 (37.5%)	4 (16%)	NS
Other	0	2	6	NS
Mean hospital length of stay (days)	3	14	13	p<0.01
30-day mortality	0	1 (12.5%)	2 (8%)	NS

Boerhaave's Syndrome

- 1724 Dr. Hermann Boerhaave describes
- Large meal + emetic-induced vomiting
- 90% food or alcohol related
- Men>Women, 40-60 yo
- 90% distal esophagus
- Lack of serosal layer
- Mortality up to 75%

Findings in Boerhaave's Syndrome

- Mackler triad (seen in 50%)
 - Vomiting
 - Acute chest pain
 - Sub cutaneous air
- Hamman sign (precordial crunch)

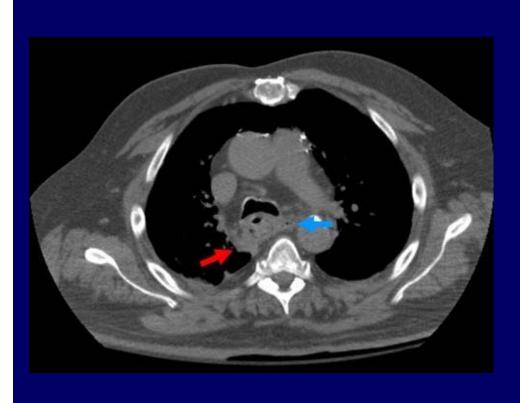
Imaging

- CXR (90% sensitive)
- Esophagram
 - Water soluble (60-75% sensitivity)
 - Barium (90% sensitivity but mediastinitis concern)
- - Mediastinal air
- -- Periesophageal fluid
- Extraluminal contrast
 Pleural effusion
- Endoscopy is not typically helpful

Esophagram









Stenting of Esophageal Perforation in the Setting of Esoinophilic Esophagitis

John W. Jacobs Jr. · Hala Fatima · Gregory A. Cote · William R. Kessler

- 32/36 yo males
- EoE
- Perforation during EGD
- PCSEMS placed
- 1 of 2 followed long term



What if? (Potential Complications)

- Airway Compression
- Fistulization
 - Vascular Structures (Aorta)
 - Airway
- Migration with SBO
- Esophageal Necrosis
- Stent Fracture/Degradation
- "Stuck Stent"

Informed Consent

- 0.5-2% Stent Related Mortality
- Off Label Use of FCSEMS for Benign Indication
- Diet
- Aspiration Risk (DD PPI, HOB elevation)
- Need for Repeat Procedures
- Chest Pain

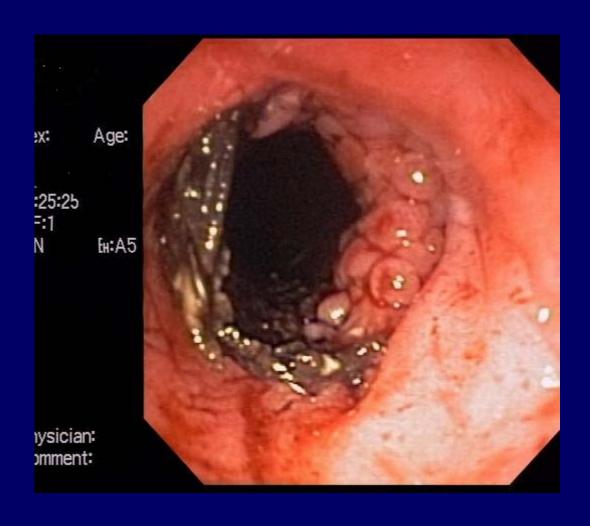
WHEN (to remove)?

- Typically 4-8 weeks
 - Monitor for embedding;
 - Q 4 weeks for Partially covered SEMS
 - Q 6 weeks for SEPS/Fully covered SEMS
- Prolonged Stenting Times (8-16 weeks)
 - Ischemic Injury
 - Strictures <6-12 months after injury
 - Strictures > 5 cm in length

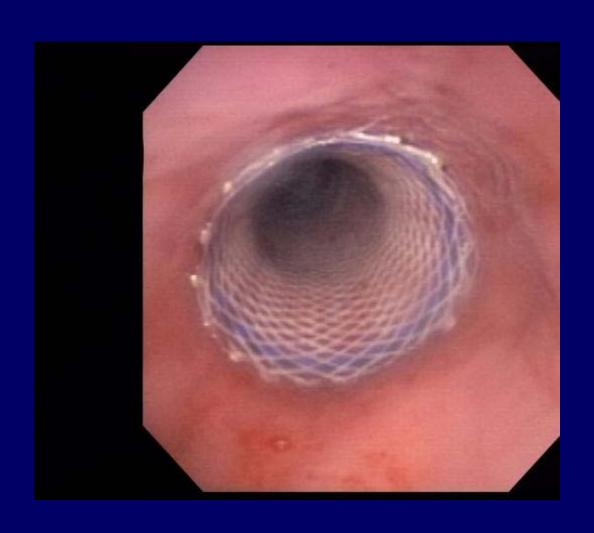
Trends: SEPS with SEMS

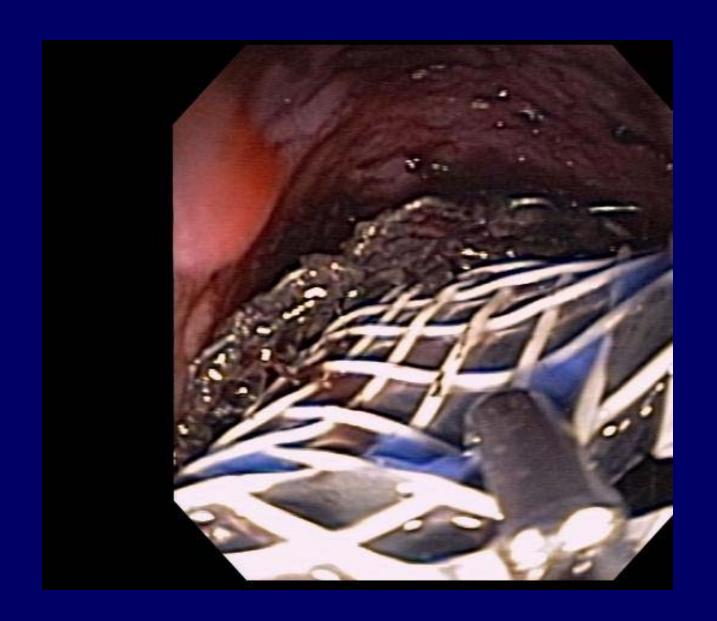
- PC SEMS 8-10 weeks + SEPS 10 days
 - -Swinnen J et al. GIE 2011;73:890-9
- PC SEMS + SEPS 7-14 days
 - —Hirdes MMC et al. Endoscopy 2011;43:156-9
 - –4 perforations with removal (median 29 days)

SEMS 5 months after deployment

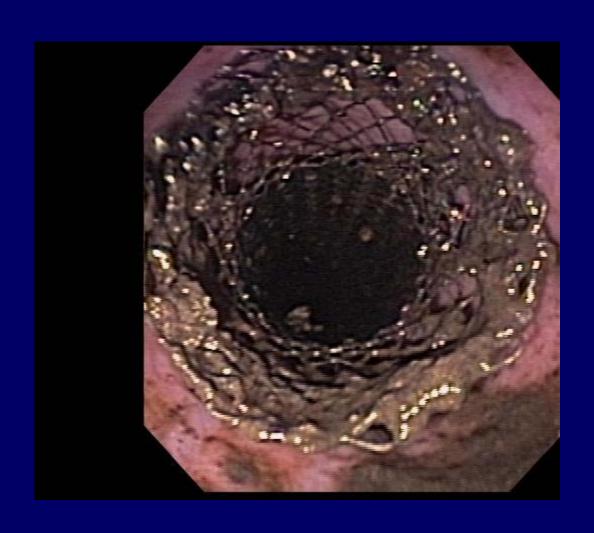


SEPS inside SEMS

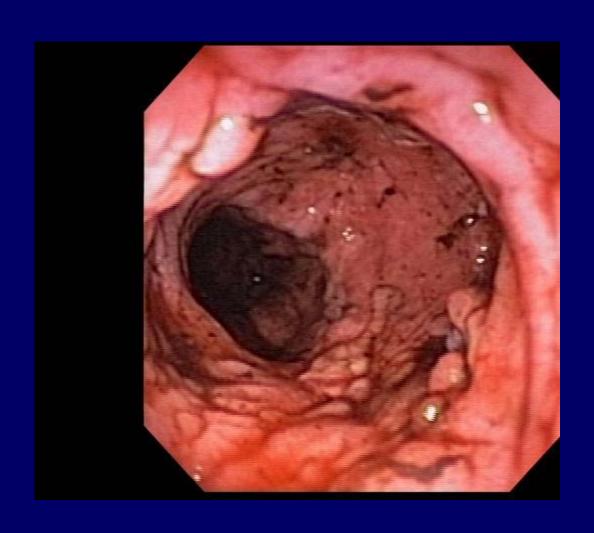




After SEPS removed



Both Stents removed – leak healed





An Assessment of the Optimal Time for Removal of Esophageal Stents Used in the Treatment of an Esophageal Anastomotic Leak or Perforation

Richard K. Freeman, MD, MBA, Anthony J. Ascioti, MD, Megan Dake, PA-C, and Raja S. Mahidhara, MD

Department of Thoracic and Cardiovascular Surgery, St. Vincent Hospital, Indianapolis, Indiana

Variable	An astomotic Leak (n = 45)	Perforation (n = 117)
Age, y (mean ± SD)	61 ± 19	59 ± 23
Range	(44-73)	(19-89)
Nitinol stent	19 (42%)	29 (25%)
Plastic stent	26 (58%)	88 (75%)
Preoperative chemotherapy and/or radiation therapy	38 (84%)	•••
Mediastinitis	7 (16%)	38 (32%)
Sepsis	1 (2%)	16 (14%)
Etiology of acute perforation		
Spontaneous		39
Foreign body removal		29
Esophageal dilatation		29
Endoscopy with biopsy		6
Transesophageal echo		6
Endoscopic ultrasound		3
Endoscopic antireflux procedure		3

Variable	Anastomotic Leak	Perforation
Resolution of leak	43 (96%)	111 (95%)
Stent removal, days (mean \pm SD)	12 ± 11	19 ± 16
Range	6-39	7-51
Hospital length of stay, days (mean \pm SD)	9 ± 6	8 ± 11
Range	3-29	5-31

Timing of Removal Continued...

Table 3. Morbidity and Mortality After Esophageal Stent Placement								
	A	nastomotic Leak		Perforation				
Variable	<2 wk (n = 29)	>2 wk (n = 16)	p Value	<4 wk (n = 96)	>4 wk (n = 21)	p Value		
Migration	4 (14%)	7 (44%)	0.04	9 (9%)	9 (43%)	0.0007		
Dysphagia	5 (17%)	8 (50%)	0.04	4 (4%)	6 (29%)	0.0022		
Hemorrhage	0	1 (6%)	0.4	0	2 (10%)	0.03		
Stent fracture	3 (10%)	6 (38%)	0.05	5 (5%)	7 (33%)	0.001		
Airway compromise	1 (3%)	2 (13%)	0.3	3 (3%)	2 (10%)	0.2		
Respiratory failure	2 (7%)	3 (19%)	0.2	3 (3%)	4 (19%)	0.2		
Pneumonia	2 (7%)	2 (13%)	0.2	3 (3%)	4 (19%)	0.1		
DVT	1 (3%)	2 (13%)	0.3	2 (2%)	2 (10%)	0.1		
Myocardial infarction	0	0		1 (1%)	0	0.2		
Mortality	0	0	0.3	2 (7%)	2 (10%)	0.3		

HOW?



Migration Prevention?



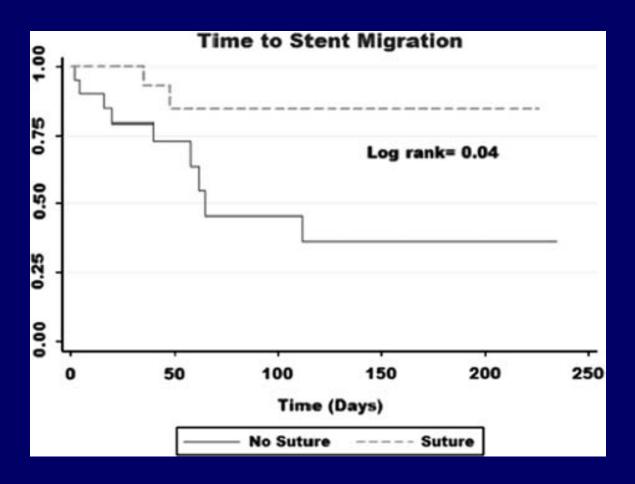


Migration Prevention

- OTS Clips: Animal data
 - Similar force required to remove as sutures
- Clips: 44 Patients (50% strictures)
 - 55% vs 13% migration
 - Avg 2.4 clips-- 12 with retained clip
- Suture: 37 Patients
 - 55% vs 11.7% migration

Hebuterne X Surg Endosc 2012 26(1)53-9 Surg Endosc 2015 29(11)3367-72 Sethi A J Clin Gastroenterol 2015 49:57-60

Sutures to Prevent Migration



Sethi A J Clin Gastroenterol 2015 49:57-60

What's next?

- Valved Esophageal Stent
- Biodegradable esophageal stent
- Regenerative stent

Valved Stent

- Anti-Reflux Valve
- Wind Sock
- Current Study

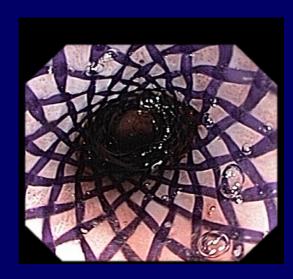


Why Biodegradable?

- FCSEPS and FCSEMS migrate
- PCSEMS pose difficulty in removing
- No need to remove

How do they work?

- Woven polydioxanone monofilament
- Degrades by hydrolysis, accelerated by \downarrow pH
- Strength maintained for 1 month
- Disintegrates in 3 months





Retrospective Study of BD Stents

Benign Strictures

- 10 pts (17 stents)
- Median F/U 3+ years
- Dilation Interval (days)
 - Pre: 34 (12-67)
 - Post: 149 (60-244)*
- No migration
- One SAE (sepsis)
- 2/10 required SEMS

Malignant Strictures

- 10 pts (11 stents)
- Planned XRT/CTX +/- EsophX
- Median Survival 36 weeks
- Only 1 patient went to OR
- Stent Patency Period (month)
 - -6.5(4.5-9)
 - 5/10 required SEMS (4.5)
 - 1 alive at completion (2 yrs)

New Frontier?

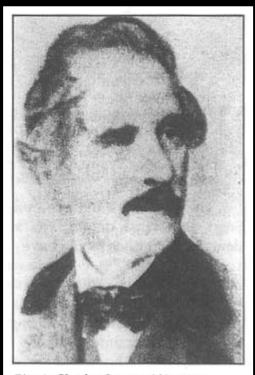


Fig. 1. Charles Stent, 1807-1885.



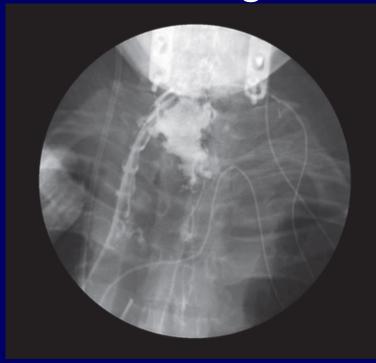
In-vivo oesophageal regeneration in a human being by use of a non-biological scaffold and extracellular matrix



Kulwinder S Dua, Walter J Hogan, Abdul A Aadam, Mario Gasparri

- 24 yo quadraplegic male s/p MVA 5 years prior
- Large paraspinal abscess C4-T11
- Retrograde endoscopy with Alimaxx-bridge





KS Dua Lancet 2016

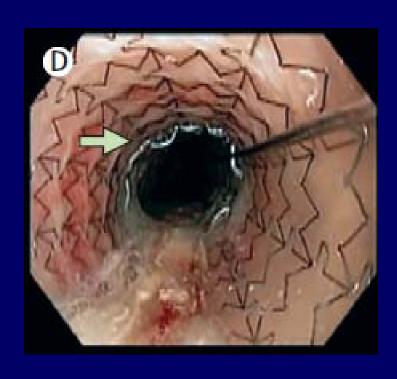
3 weeks later....persistent leak

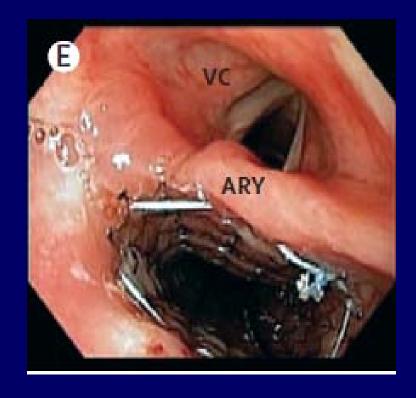
- Sternocleidomastoid Incision
- AlloDerm (regenerative tissue matrix), sutured
- Platelet-rich plasma (PRP)+Thrombin+CaCl
- SCM incision closed



- Esophogram negative
- 4 weeks later dysphagia...stent bridge

Telescoping stents

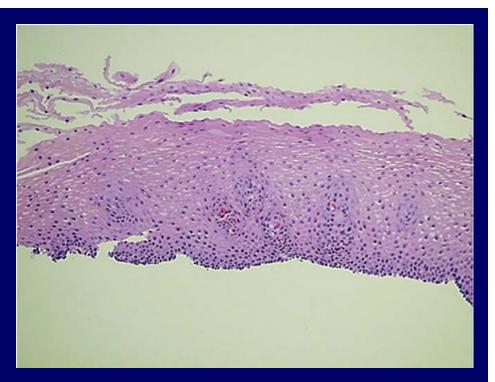




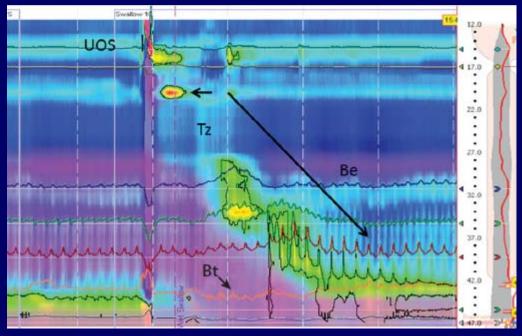
Follow Up

- Planned removal at 12 weeks
- Returns with dysphagia at 2 years
- APC fails
- FCSEPS for 2 weeks
- Follow up to 4 years...









Summary

- Stents are useful in a variety of indications
- Stents have significant potential complications
- Know what stent you want/need
- Stents may evolve further in the near future

Thank You!