ENDOLUMINAL TREATMENT OF OBESITY

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- America spends as much as $147 billion annually on the direct and indirect costs of obesity.

Why Care?
Health Risks Associated with Obesity

- Coronary artery disease
- Hypertension
- Type II diabetes mellitus
- Asthma
- Hypoventilation syndrome
- Obstructive sleep apnea
- GERD
- Esophagitis
- Fatty liver
- Cholelithiasis
- NASH
- Cirrhosis
- Stress urinary incontinence
- Venous stasis/superficial phlebitis
- DVT/PE
- Hernias (inguinal, ventral, umbilical, incisional)
- PCOS
- Cancer (colon, prostate, breast, uterine)
- Cellulitis, panniculitis, post-op wound infections
- DJD, OA
- Psuedotumor cerebri
- Depression

Objectives

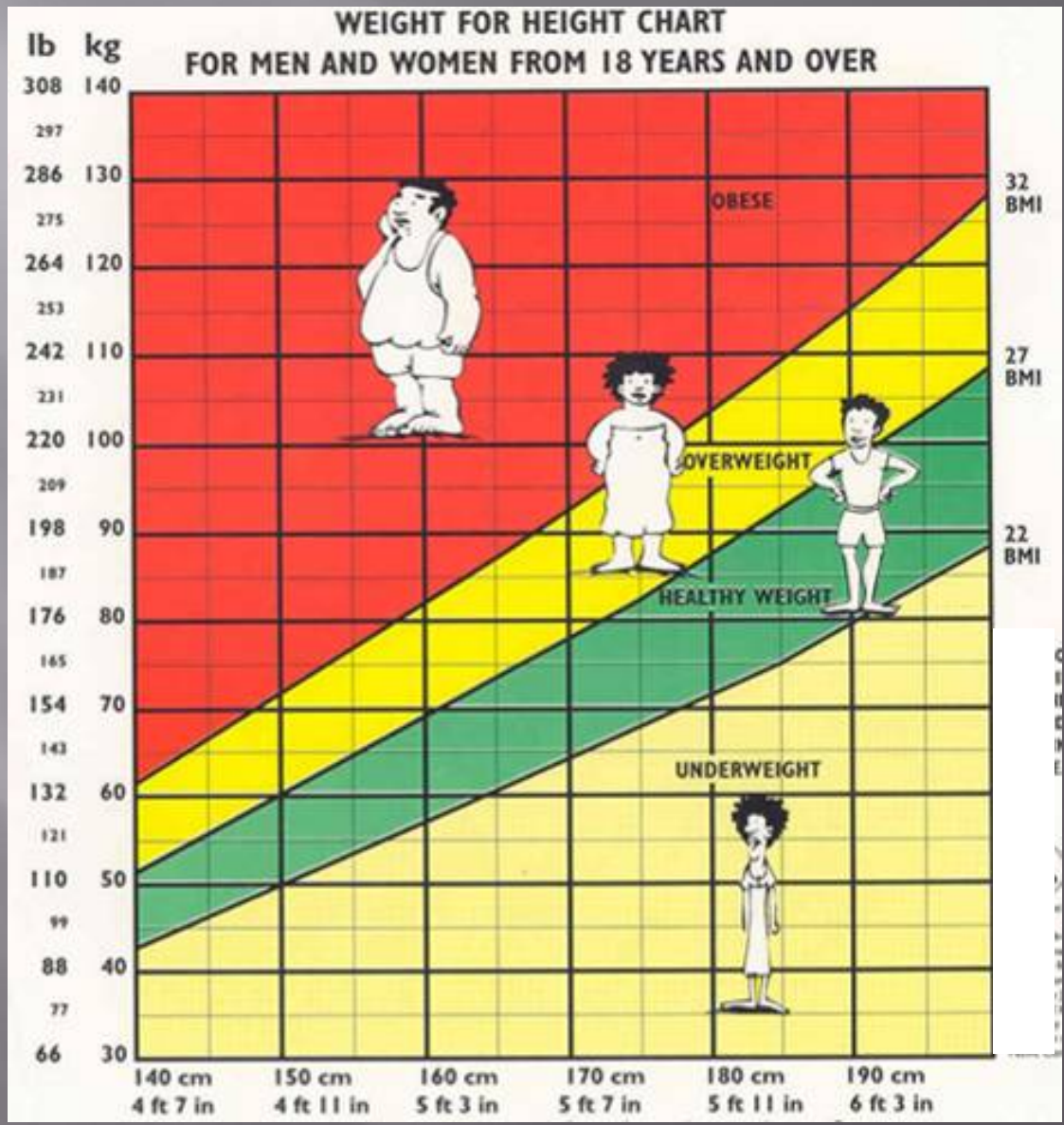
- Review obesity related terms
- Revisit past and present surgical options
- Discuss endoluminal approaches to obesity

Body Mass Index (BMI)

$$\text{Wgt (kg)}/(\text{Ht(m)})^2$$

or

$$\text{lbs/in}^2 \times 703$$

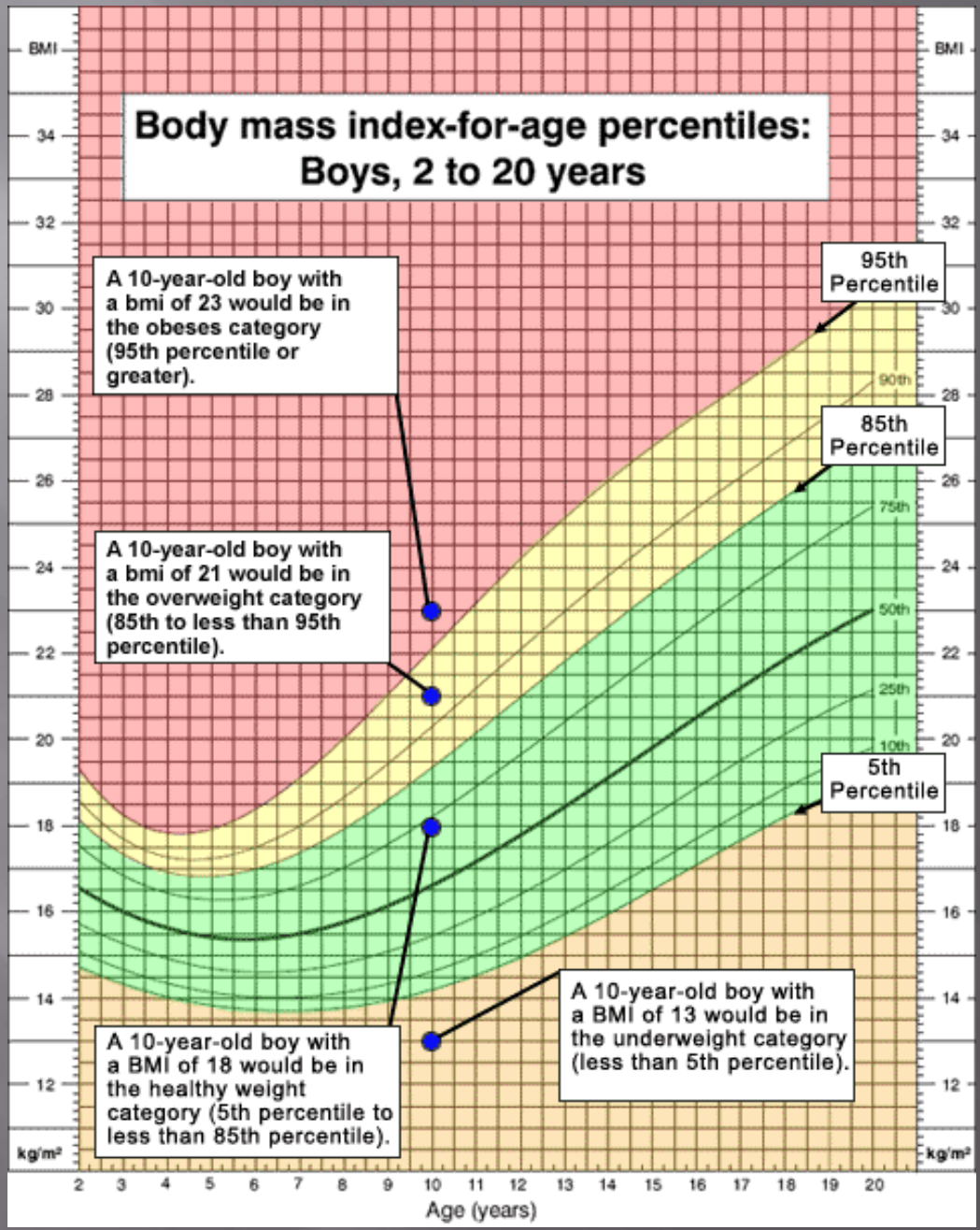

WEIGHT FOR HEIGHT CHART
FOR MEN AND WOMEN FROM 18 YEARS AND OVER
lb
kg
308
297
286
275
264
253
242
231
220
209
198
187
176
165
154
143
132
121
110
99
88
77
66
140
130
120
110
100
90
80
70
60
50
40
30
OBESE
OVERWEIGHT
HEALTHY WEIGHT
UNDERWEIGHT
32 BMI
27 BMI
22 BMI
140 cm 4 ft 7 in
150 cm 4 ft 11 in
160 cm 5 ft 3 in
170 cm 5 ft 7 in
180 cm 5 ft 11 in
190 cm 6 ft 3 in

BMI	Classification
< 18.5	Underweight
< 16	Severe thinness
16 – 16.9	Moderate thinness
17 – 18.4	Mild thinness
18.5 – 24.9	Healthy weight
25.0 – 29.9	Overweight
30.0 - 34.9	Class I obesity
35.0 – 39.9	Class II obesity
40 – 49.9	Class III obesity (extreme or morbid)
>50	Class IV obesity (super morbid)

World Health Organization 2004

Obesity in Children

- Underweight = below 5th percentile
- Healthy weight – 5th to 85th percentile
- Overweight – 85th -95th percentile
- Obese – above 95th percentile


Body mass index-for-age percentiles:
Boys, 2 to 20 years
BMI
kg/m²
Age (years)
95th Percentile
90th
85th Percentile
75th
50th
25th
10th
5th Percentile
A 10-year-old boy with a bmi of 23 would be in the obeses category (95th percentile or greater).
A 10-year-old boy with a bmi of 21 would be in the overweight category (85th to less than 95th percentile).
A 10-year-old boy with a BMI of 18 would be in the healthy weight category (5th percentile to less than 85th percentile).
A 10-year-old boy with a BMI of 13 would be in the underweight category (less than 5th percentile).

Terms

- Excessive Weight
  - Patient's weight – weight of an individual of same height with a BMI of 25
- Percentage of excess weight loss (%EWL)
- Weight lost/Excessive weight x 100

Terms

- Example:
  - Initially a patient is 70 in. tall and 279 lbs (BMI = 40)
  - He loses 52 lbs
  - To have a BMI of 25 at 70 in, one most weight 175 lbs.
  - Excessive wgt = 279 – 175 = 104
  - %EWL = 52/104 x 100 = 50%

Case

- A 30 year old woman is referred for obesity treatment after failing diet and lifestyle modification.
- Body Mass Index (BMI) 48.2
- 61 inches, 255 lbs

Bariatric surgery is the most effective weight loss intervention for the obese patient

Indications for Surgery (NIH)

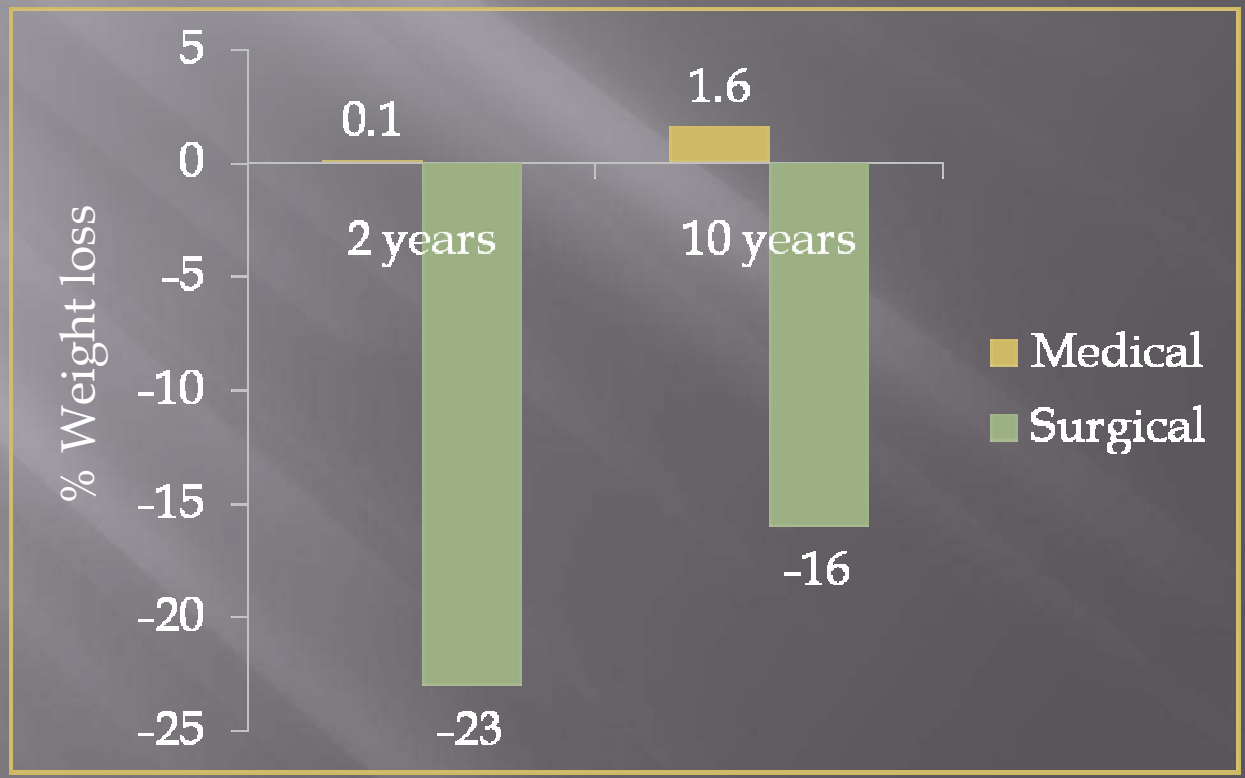
- Be well informed and motivated
- BMI > 40 or
- BMI >35 with serious comorbidities (i.e. DM, OSA, obesity related cardiomyopathy, or severe DJD)
- Have acceptable risk of surgery
- Failed previous nonsurgical weight loss

Surgical Options

- Restrictive
  - Vertical banded gastroplasty (VBG)
  - Laparoscopic adjustable gastric band
  - Sleeve gastrectomy
- Malabsorptive
  - Jejunoileal bypass
  - Biliopancreatic diversion (BPD)
  - Biliopancreatic diversion with duodenal switch (BPD-DS)
- Combined restrictive and malabsorptive
  - Roux-en-Y gastric bypass

Surgery Works!
SOS Trial

6328 patients



Sjostrom,L et al. NEJM 2007;357:741

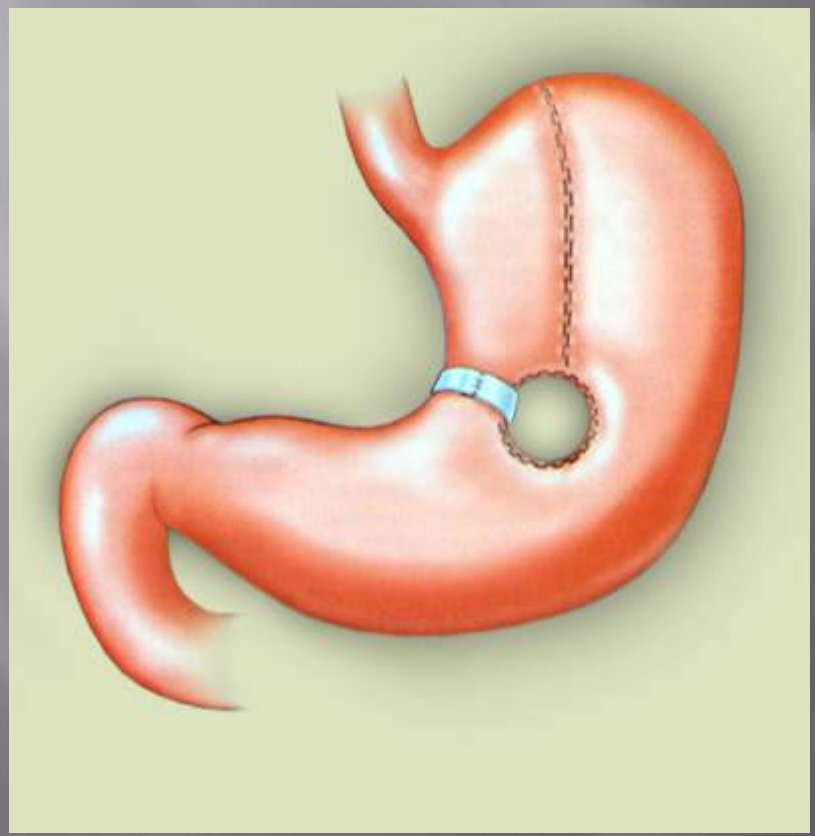
Surgery Works!
SOS Trial

29% REDUCED RISK OF DEATH

Sjostrom,L et al. NEJM 2007;357:741

VBG

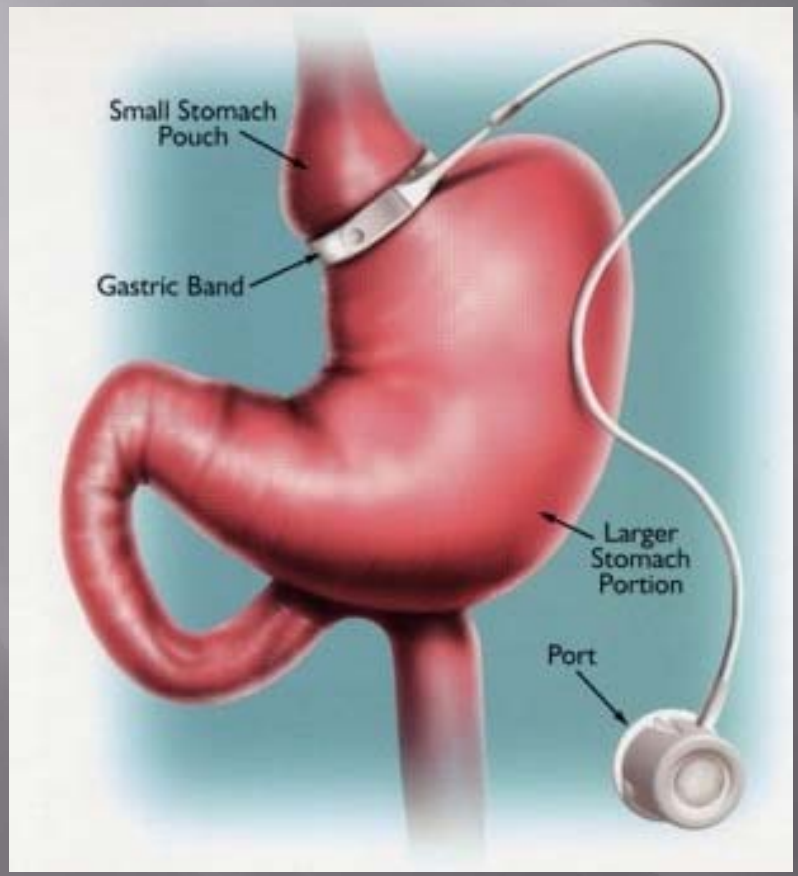
Complication rate requiring revision 20 – 56%.



- Staple line disruption
- Stoma stenosis
- Band erosion
- Band disruption
- Pouch dilation
- Vomiting
- GERD
- Poor results for "Sweet Tooth"

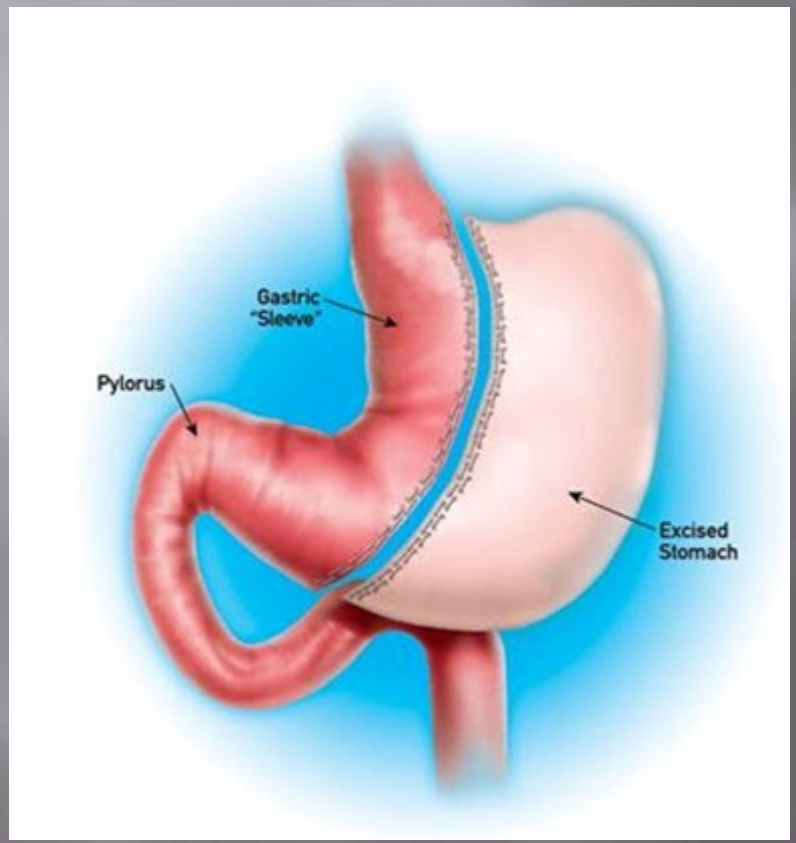
Lap Band

Lowest mortality rate among bariatric surgeries (< 0.5%)



- Acute stoma obstruction
- Infection
- Gastric perforation
- Hemorrhage
- Gastroparesis
- Band erosion, slippage, prolapse
- Port/tubing malfunction/leakage
- Pouch/esophageal dilation
- Esophagitis

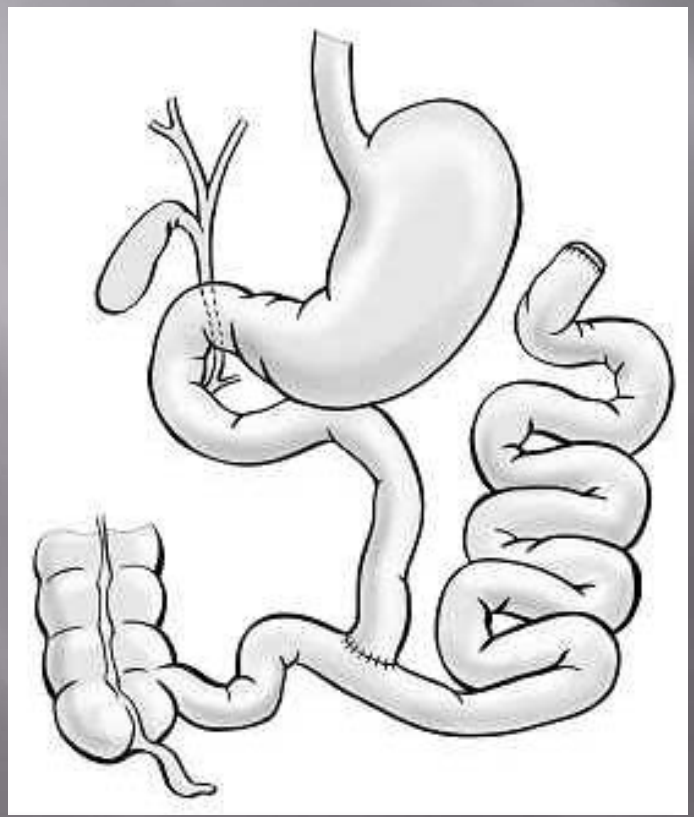
Sleeve gastrectomy



- Better weight loss and hunger control than lap band
- Ghrelin suppression
- Leak
- Suture disruption
- Bleeding

Jejunoileal Bypass

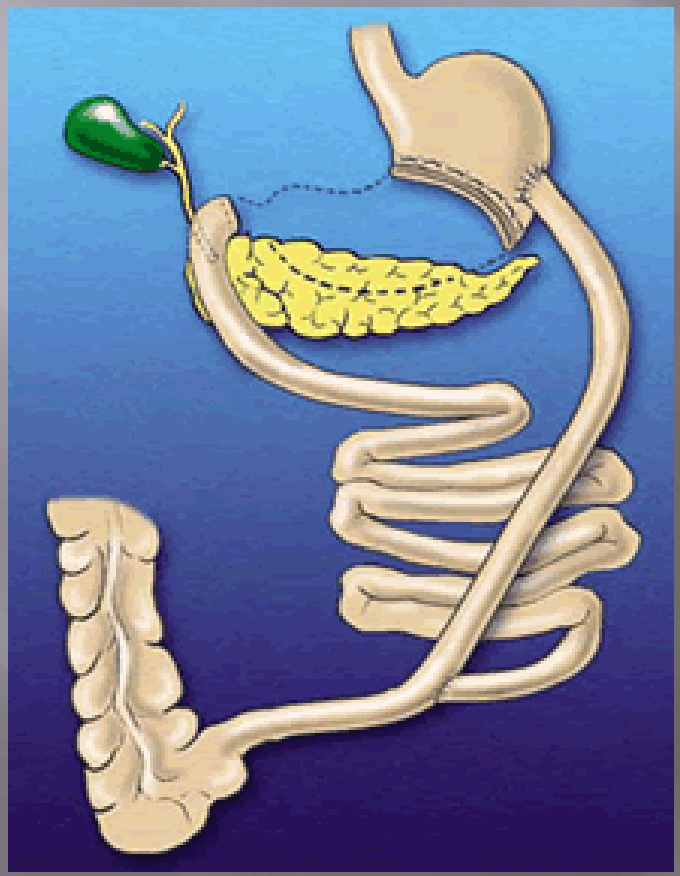
One of the first bariatric operations



- Liver failure 30%
- Death
- Diarrhea
- Electrolyte imbalances
- Oxalate renal stones
- Vitamin deficiencies
- Malnutrition
- Arthritis

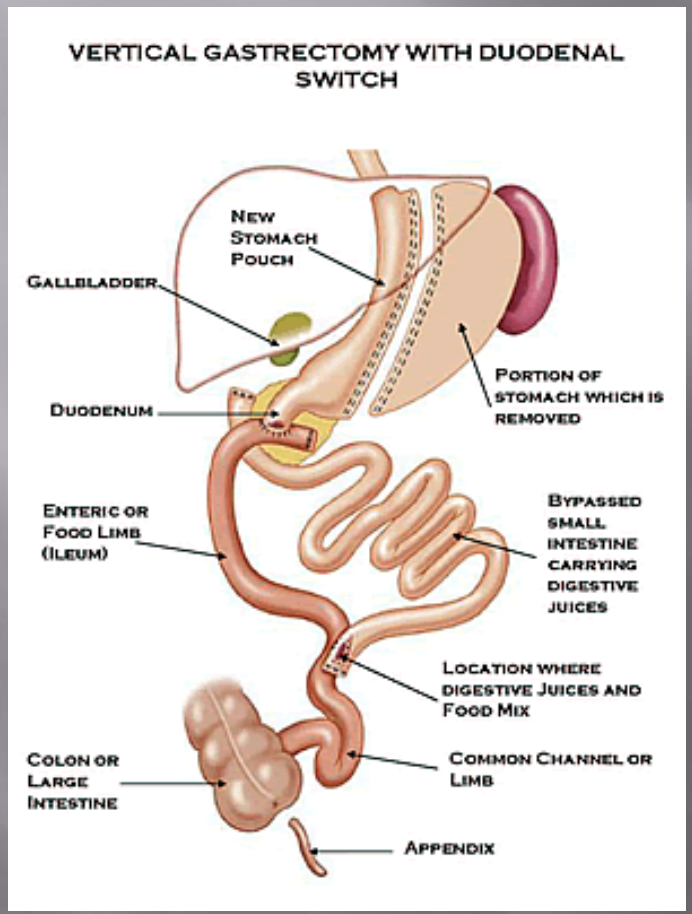
Biliopancreatic diversion

Introduced as a solution to high rates of liver failure with jejunoileal bypass



- Protein malabsorption
- Anemia
- Metabolic bone disease
- Vitamin Deficiencies
- Diarrhea
- Stoma ulcers

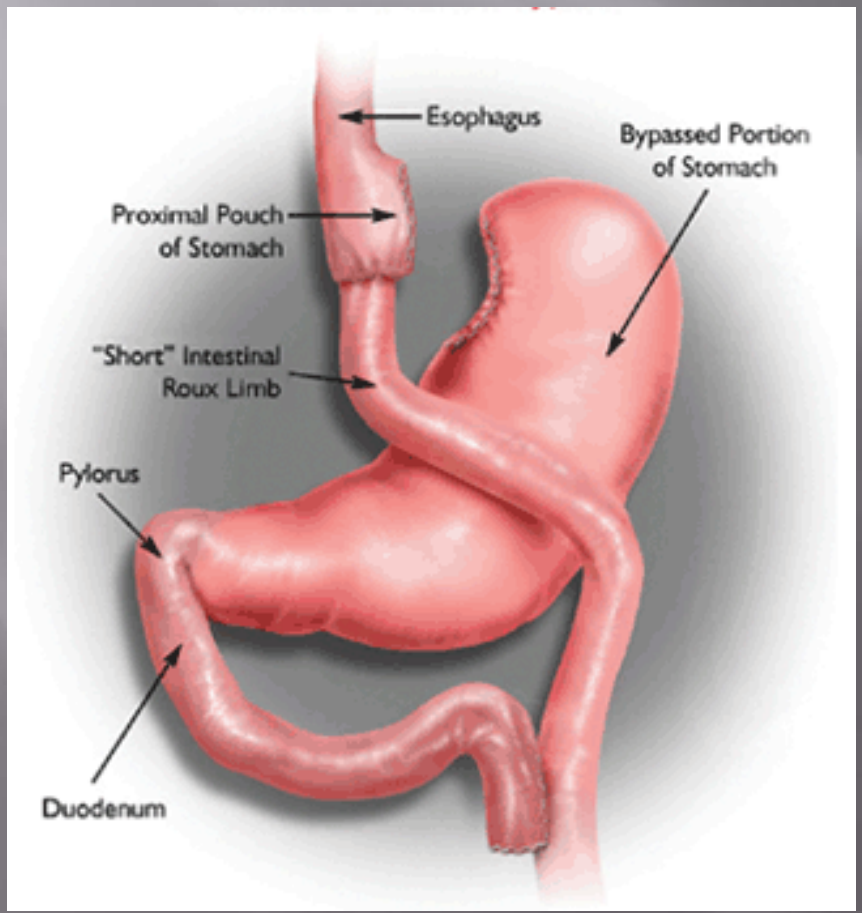
BPD - Duodenal Switch



- Partial sleeve gastrectomy
- Pylorus sparing
- Complex procedure
- Similar complications to BPD

Roux-en-Y Gastric Bypass

- **Most common bariatric procedure performed in the U.S.**



- PE/DVT
- Leaks up to 5%
- Bleeding
- Gastric remnant distension – rupture
- Infection
- Stoma stenosis
- Marginal Ulcers
- Gall stones
- Incisional/Internal hernias
- Dumping
- Vitamin/mineral deficiencies

Endoluminal Bariatric Procedures

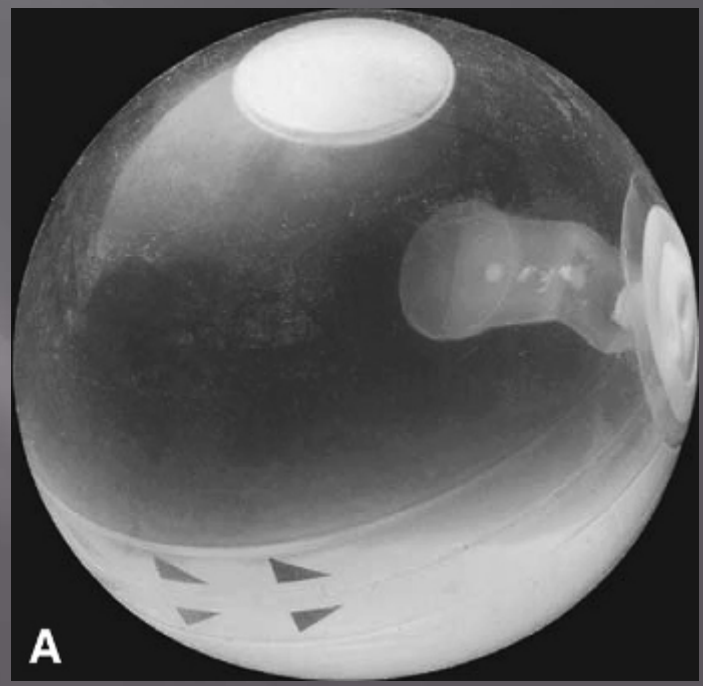
- Compared to the laparoscopic bariatric surgery, the ideal endoluminal procedure would be:
  - Incisionless
  - Outpatient
  - Safer
  - Durable
  - More cost effective
  - Potentially offered to older, sicker patients, or those with milder obesity (BMI 30-35)

Endoluminal Obesity Options

- Intragastric balloon
- Gastric Restriction
  - Endoluminal vertical gastroplasty (EndoCinch)
  - Transoral gastroplasty (TOGA)
- Duodenojejunal bypass sleeve

Intragastric Balloon

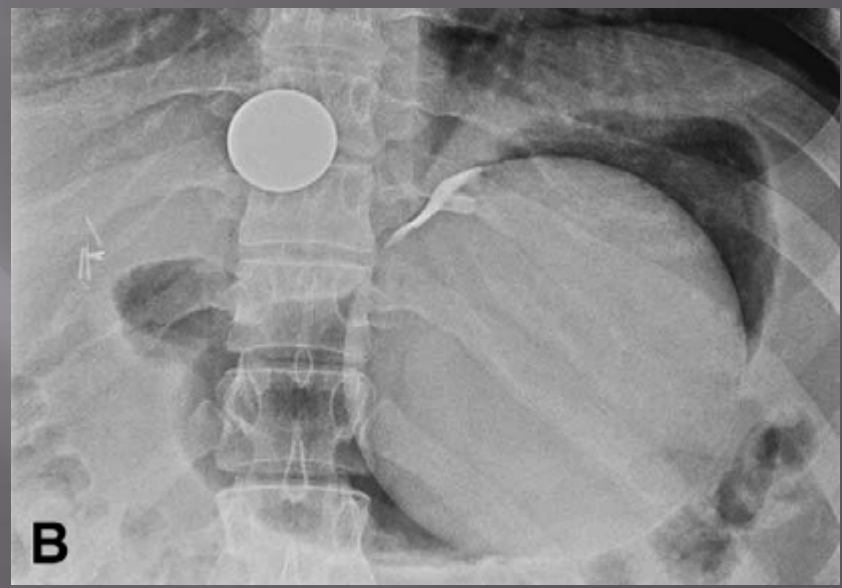
- One of the earliest endoluminal concepts to treat obesity
- Restrictive device
- Deployed into stomach under direct visualization
- Inflated with 500 to 700cc of saline/methylene blue



BioEnterics Intragastric Balloon (BIB)

Intragastric Balloon

- May be deflated and removed using a needle and snare or basket
- Complications include nausea, vomiting, erosion, ulceration, perforation, aspiration



Intragastric Balloon

- Retrospective analysis
- 2515 patients; mean BMI 44.8
- 2 unsuccessful placements (0.08%)
- 6-month follow-up %EWL 33.9 +/- 18.7
- Improvement/Resolution
  - DM – 86.9%
  - HTN – 93.7%
- Complications (2.8%)
  - 5 (0.19%) gastric perforations with 2 deaths

Genco A, Bruni T, Doldi SB, et al. Obes Surg 2005;15:1161-4.

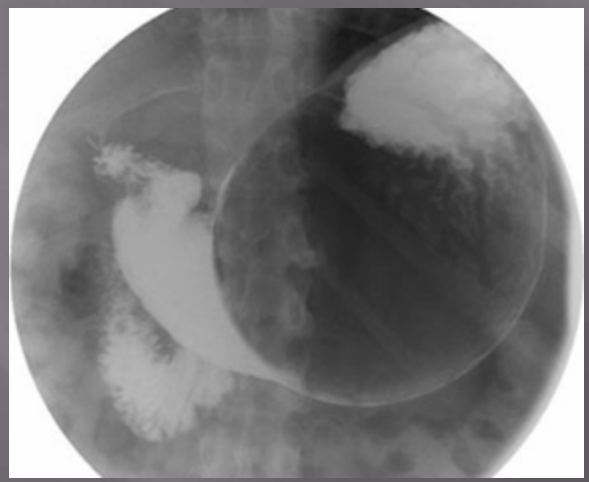
Intragastric Balloon

- 26 high risk "super-obese"
- Mean BMI 65.3 +/- 9.8
- At least 3 medical comorbidities
- Turned down for surgery with plans to undergo surgery as second stage
- 6-month follow up %EWL 22.4 +/- 14.5
- Improvement/resolution
  - DM – 81%
  - HTN – 83%
- Complication – 1 patient died within 24 hours from aspiration

Spyropoulos C, Katsakoulis E, Mead N, et al. Surg Obes Relat Dis 2007;3:78-83.

Intragastric Balloon

- Often removed after 6 months
- Used successfully as a primer for more definitive bariatric surgery
- Not currently approved in the U.S.



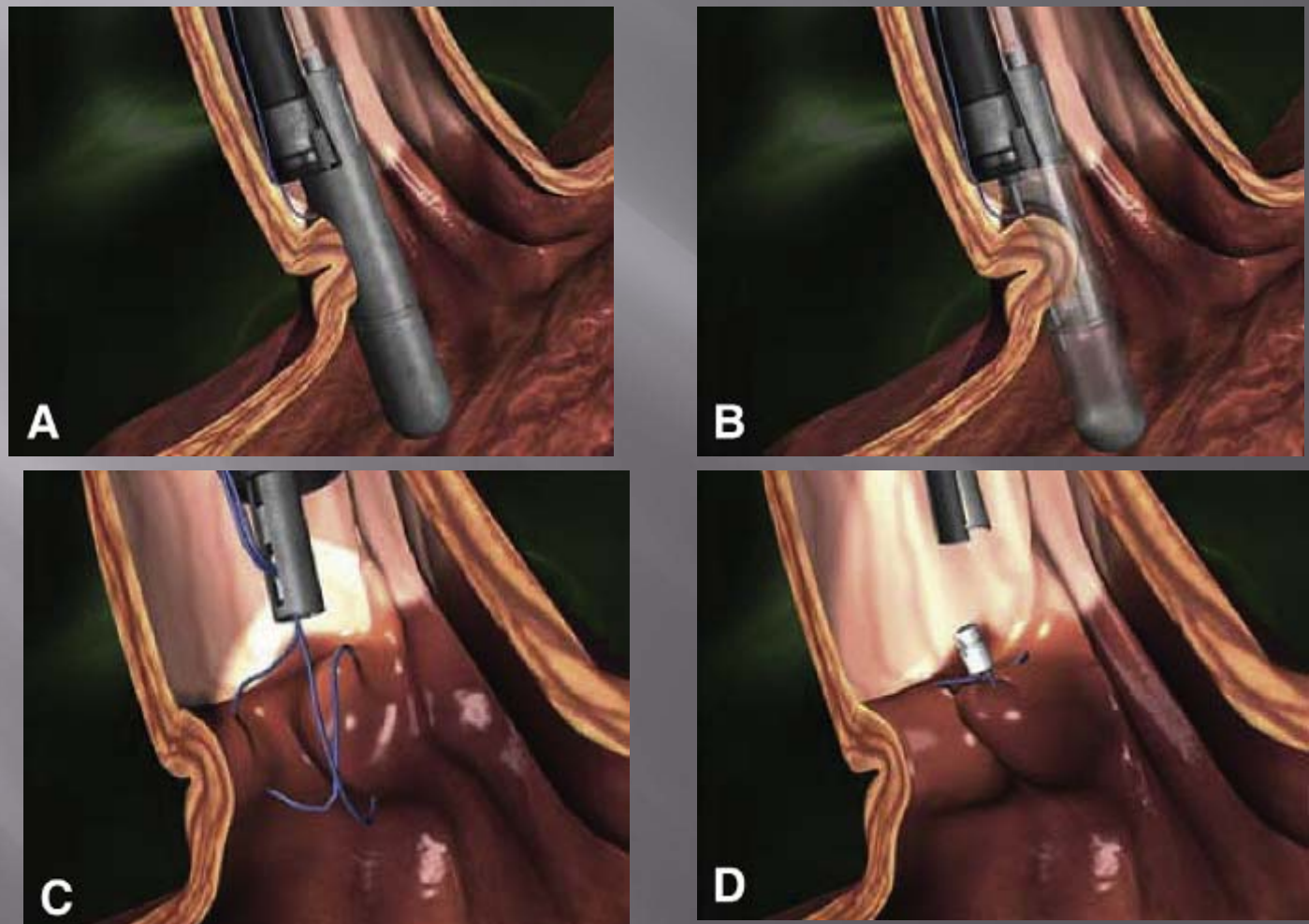
Suturing/Stapling Devices

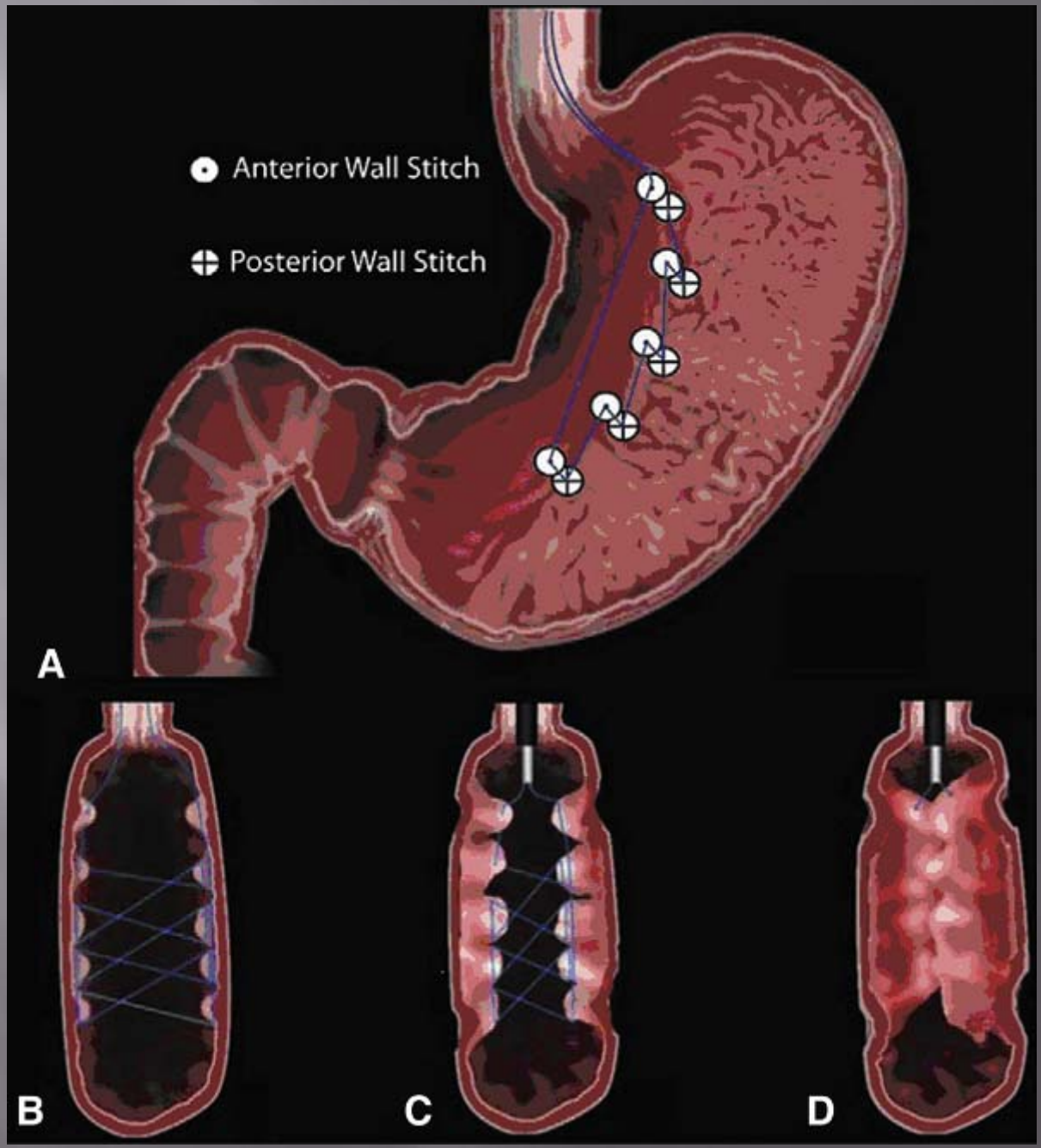
- Endoluminal Vertical Gastroplasty (EndoCinch)
- Transoral Gastroplasty (TOGA)

EndoCinch

- Initially for the treatment of GERD
  - Lacks durability
  - Often incomplete control of reflux

Endoluminal Vertical Gastroplasty (EndoCinch)




Anterior Wall Stitch
Posterior Wall Stitch
A
B
C
D

EndoCinch for Obesity

- 64 patients
- Seven sutures deployed from the proximal fundus to the distal body
- Procedure time 45 minutes
- %EWL
  - 1 month – 21.1%
  - 12 months – 58.1%

Fogel R, De Fogel J, Bonilla Y, et al. Gastrointest Endosc 2008;68:51-8.

EndoCinch for Obesity

- 14 patients required repeat EGD within the first year
- 11 of those did NOT require repeat intervention
- Minimal complications

- Need long term outcomes

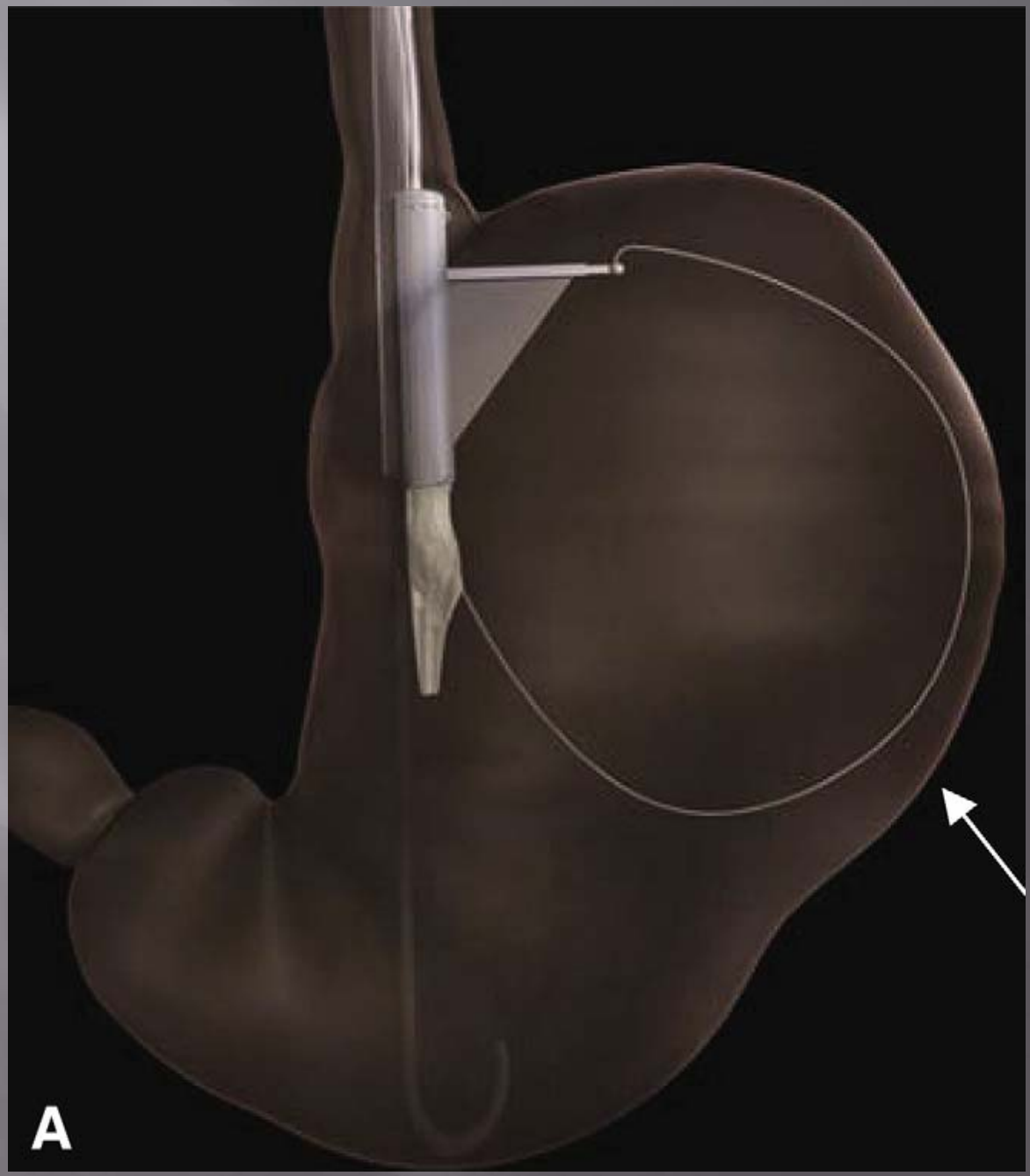
Fogel R, De Fogel J, Bonilla Y, et al. Gastrointest Endosc 2008;68:51-8.

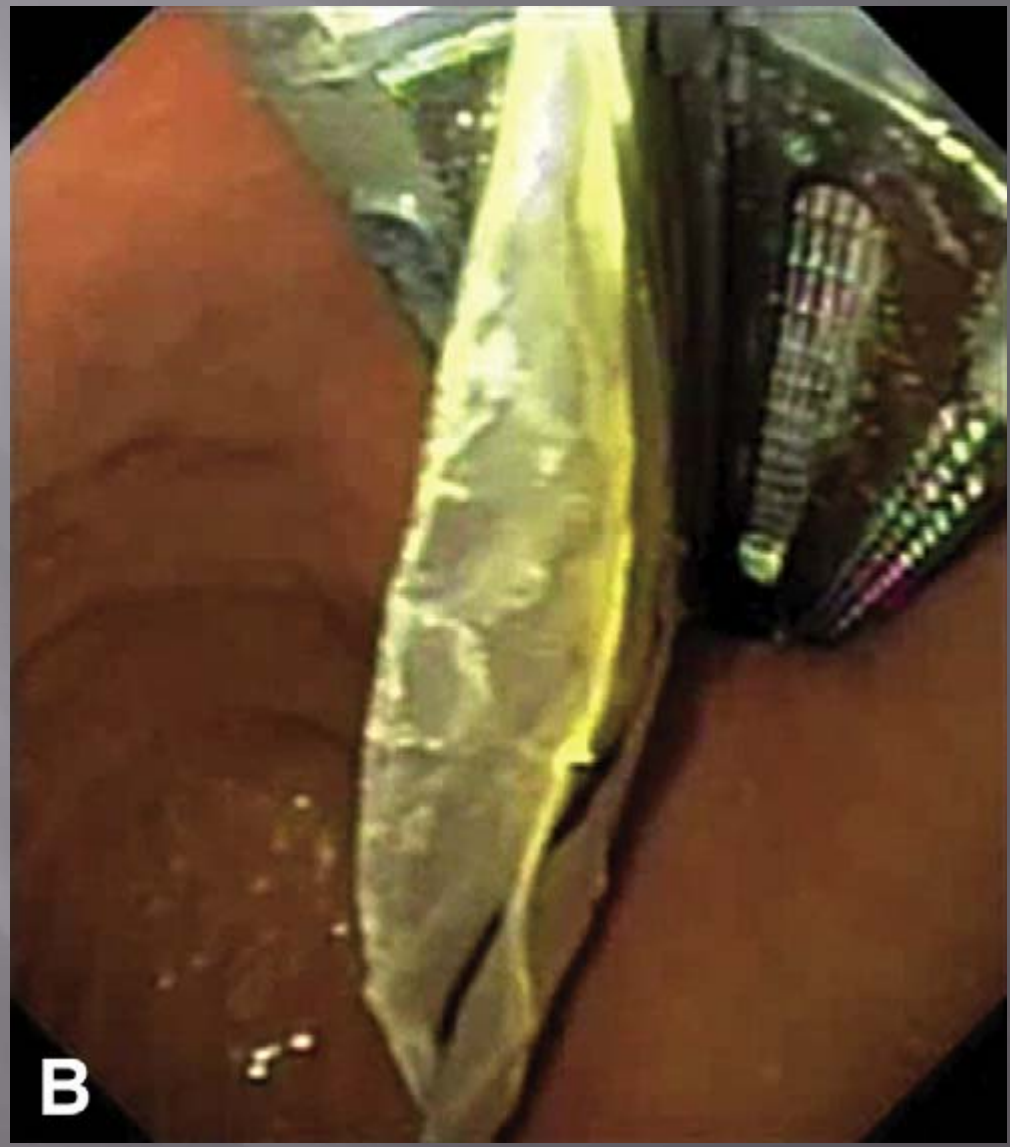
EndoCinch for Obesity

- Davol is initiating a randomized, multicenter trial in the U.S.

Transoral Gastroplasty (TOGA)

- www.satietyinc.com/toga-clinical-trial/overview/


A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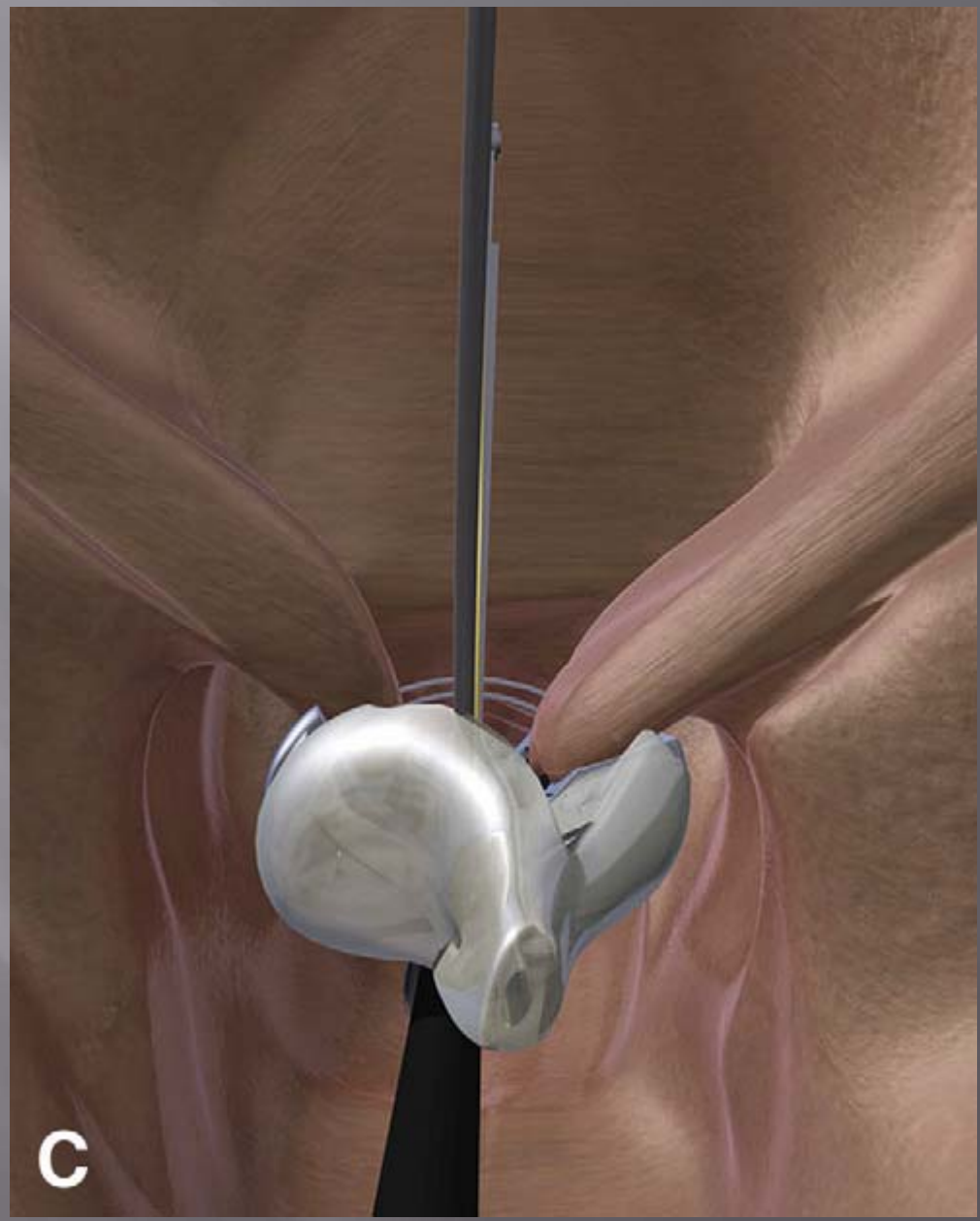
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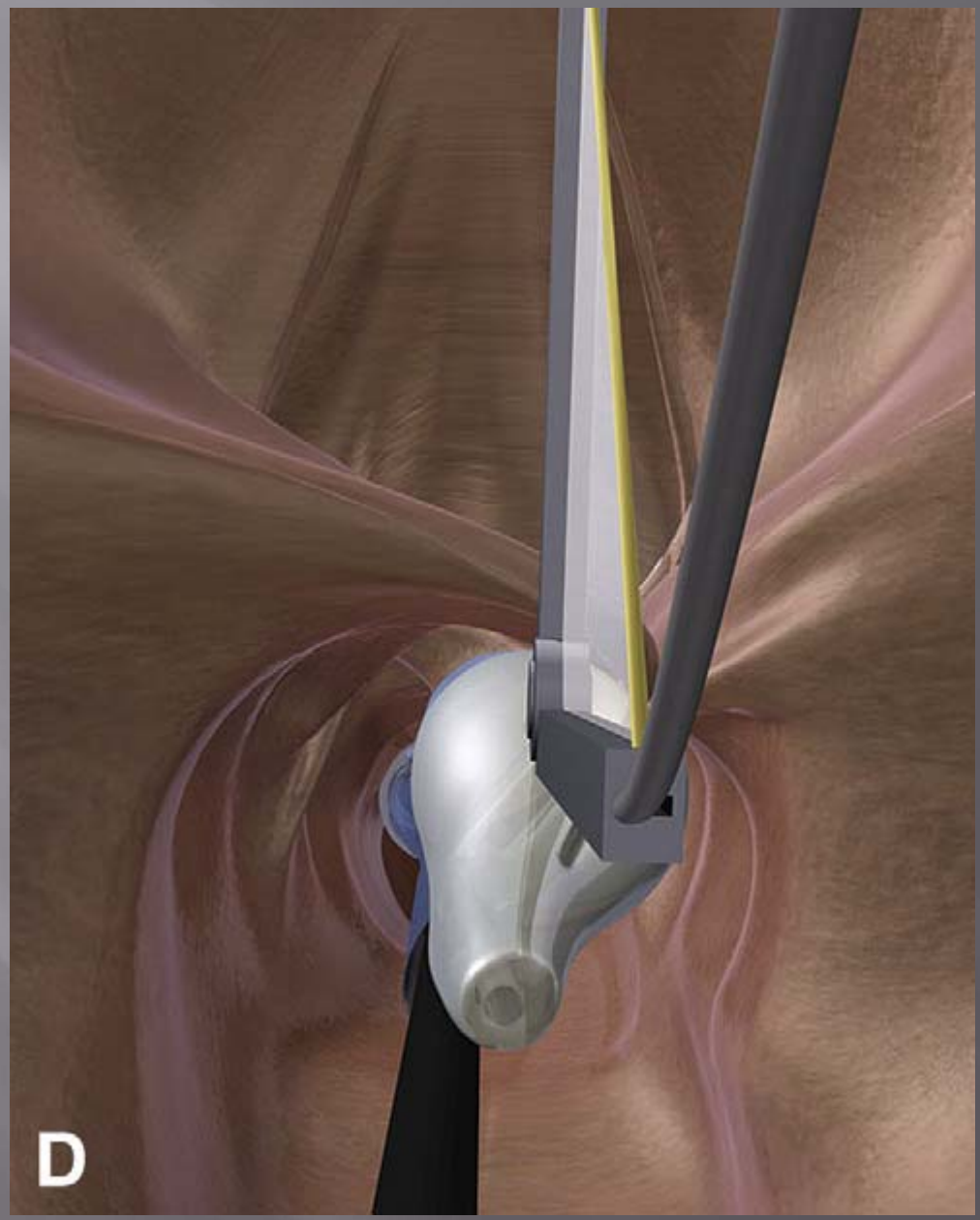
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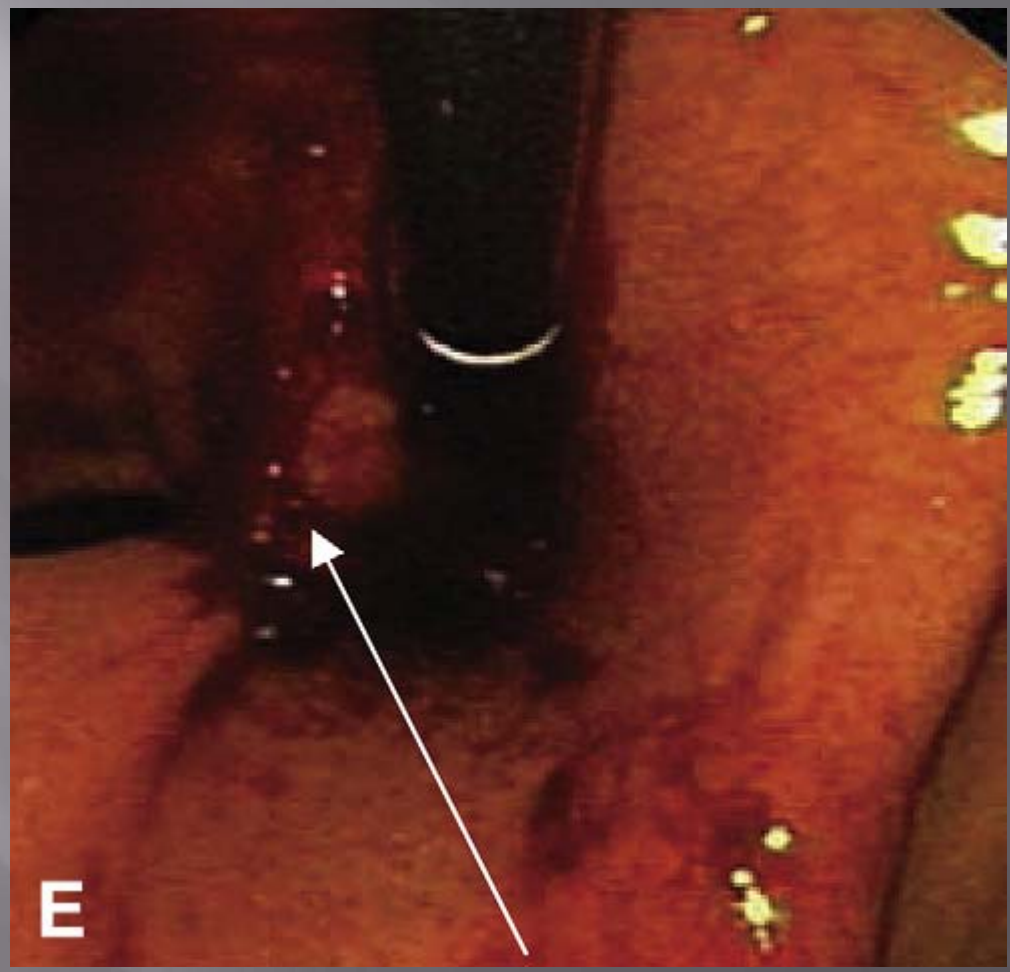

E

TOGA

- Procedure time – 2 hours
- Transmural tissue apposition (?more durable)
- Sleeve length – 8cm from GEJ
- Luminal diameter of 20mm reduced to 12mm using the TOGA restrictor to pleat the gastric folds as needed

TOGA

- Feasibility trial, Belgium
- 11 patients
- Mean BMI > 41.6
- 9 patients had an intact staple line at discharge
- 7 intact at 6 months
- %EWL = 46.0% at 6 months (24 kg)
- No significant complications

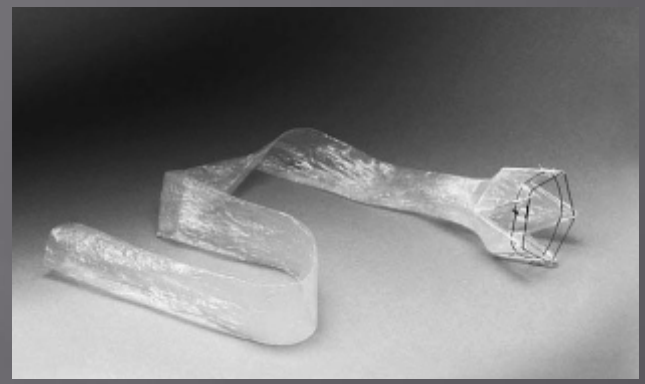
Moreno C, et al. Endoscopy 2008;40:406-13.

TOGA

- Randomized, sham-controlled trial is ongoing in the U.S.

Duodenojejunal Bypass Sleeve (DJBS)

- First endoluminal device to bypass the proximal small bowel
- Self-expanding 60 cm plastic sleeve
- Wire-guided delivery under fluoroscopy
- Anchor is deployed into the duodenal bulb to hold the device in place



- www.gidynamics.com/delivery-method-endobarrier-gastrointestinal-liner

DJBS

- 12 patients
- Mean delivery time 26.6 minutes
- Sleeve remained in place in 10 patients for 12 weeks and was successfully removed
  - Mean removal time 43.3 min
  - 2 patients with refractory abdominal pain required early removal
- Mean %EWL 23.6 at 12 weeks
- Complications –
  - 1 minor oropharyngeal tear
  - 1 minor esophageal mucosal tear

Rodriguez-Grunert L, et al. Surg Obes Relat Dis 2008;4:55-9.

DJBS

- 25 experimental patients vs. 14 controls
- 80% kept sleeve in place x 12 weeks
- %EWL – 22 (DJBS) vs. 5 (controls)
- Complications
  - 3 upper gi bleeds
  - 1 anchor migration
  - 1 stent obstruction

Tarnoff M, et al. Surg Endosc 2009;23:650-6.

Case Resolution

- Pt underwent first TOGA procedure in U.S. at Washington University in St. Louis, MO

- http://daveproject.org/ViewFilms.cfm?Film_id=856

Summary

- Surgery is currently the best treatment for obesity, but it is not without complications
- Endoluminal approaches to obesity are being developed and may be available in the future