Research

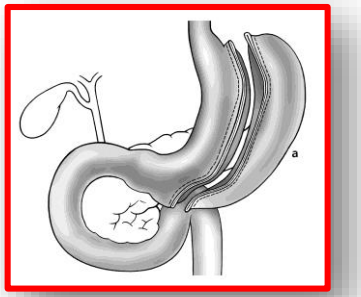
JAMA | Original Investigation

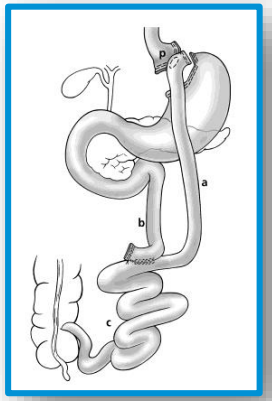
Effect of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass on Weight Loss in Patients With Morbid Obesity

The SM-BOSS Randomized Clinical Trial

Ralph Peterli, MD; Bettina Karin Wölnerhanssen, MD; Thomas Peters, MD; Diana Vetter, MD; Dino Kröll, MD; Yves Borbély, MD; Bernd Schultes, MD; Christoph Beglinger, MD; Jürgen Drewe, MD, MSc; Marc Schiesser, MD; Philipp Nett, MD; Marco Bueter, MD, PhD

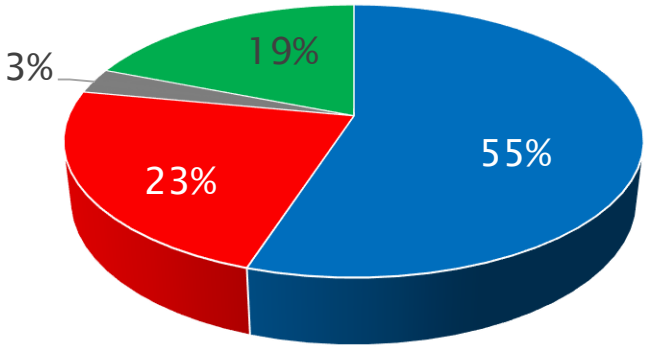
JAMA. 2018;319(3):255-265. doi:10.1001/jama.2017.20897





Disclosure

- consultant to Ethicon Endosurgery
- case mix disclosure



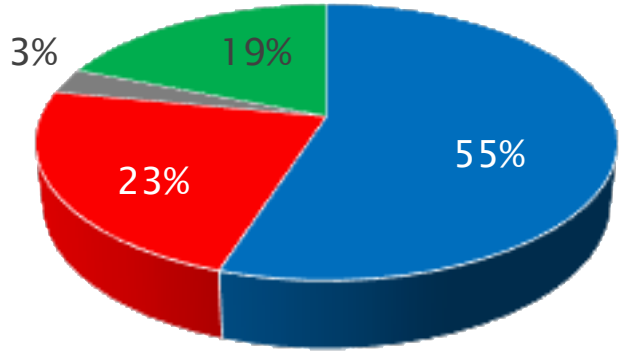
LRYGB sleeve BPD revisions

OAGB (“miniBP”), SADI: 0%

Disclosure

- consultant to Ethicon Endosurgery

- case mix disclosure



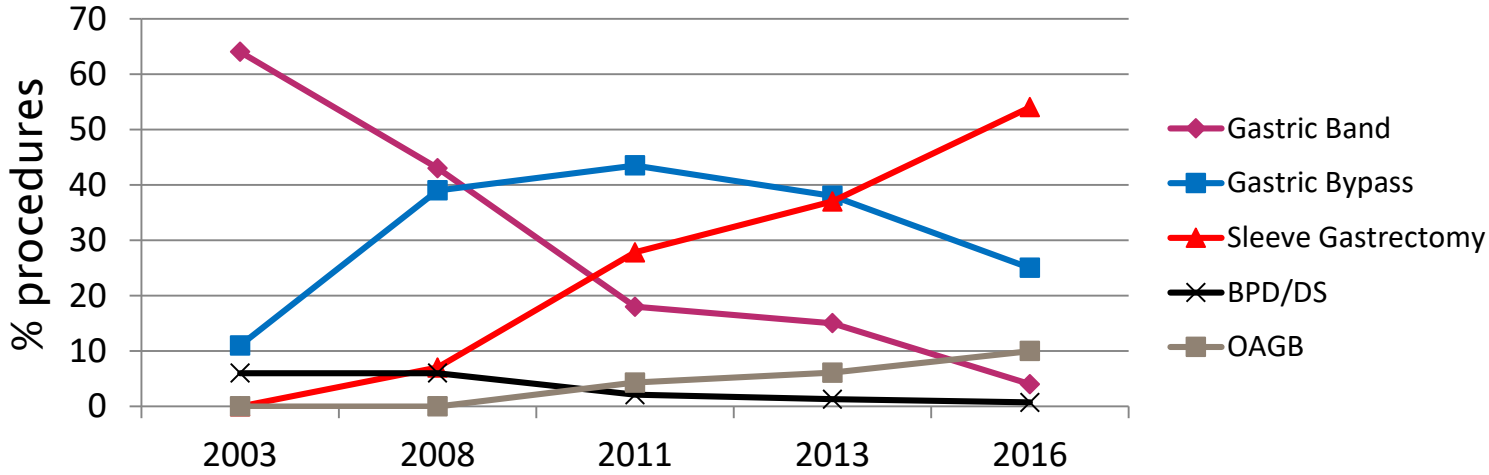
LRYGB sleeve BPD revisions

OAGB (“miniBP”), SADI: 0%

BACKGROUND

procedures worldwide/europe

world:	N=	146‘000	344‘000	340‘000	469‘000	686’000
europe:	N=	33‘000	67‘000	113‘000	125‘000	217’300

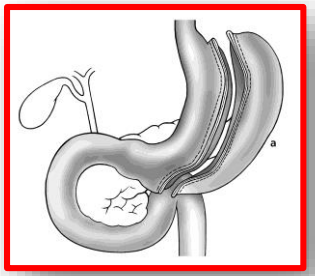


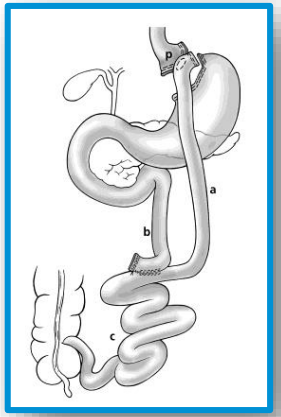
Angrisani, Obes Surg 2018

OBJECTIVE

SM-BOSS

Is sleeve as effective and safe as bypass at 5 years





METHODS

SM-BOSS

- randomized clinical trial

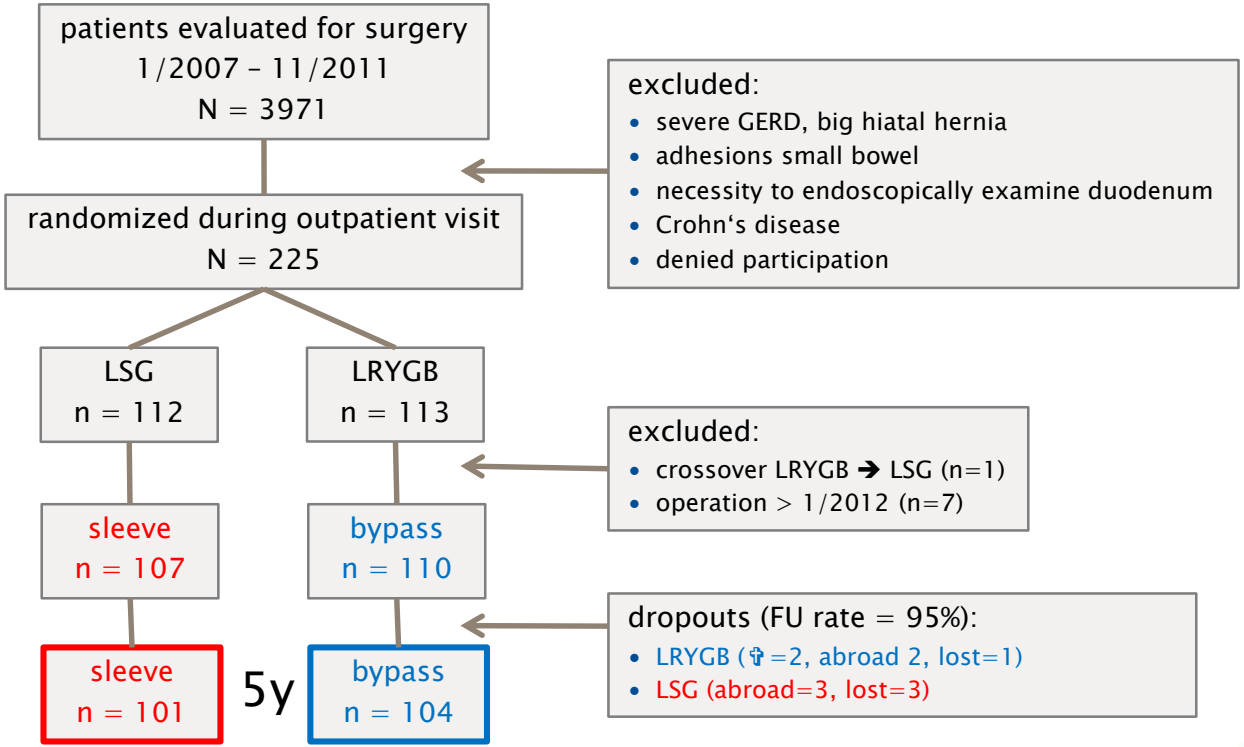
- multicentre:
  - Claraspital Basel, Bern, Zürich, St.Gallen

- endpoints:
  - primary: weight loss (excess BMI loss) at 5 y
  - secondary: reduction of co-morbidity
    QoL
    safety
    metabolic effects (gut hormones, adipokines, bile acids, …)
    (Peterli, Ann Surg 09, Obes Surg 12, Wölnerhanssen SOARD 11, Steiner Obesity 13)

- support:
  - Swiss National Science Foundation
  - Ethicon Endosurgery, USA

Patients

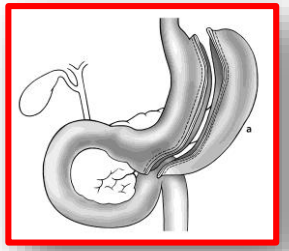
SM-BOSS



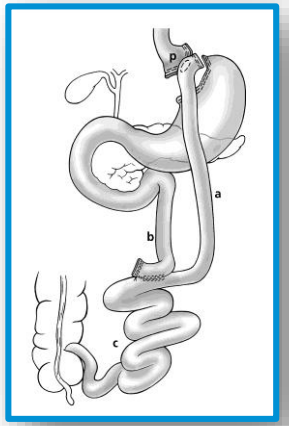
Operation Techniques

SM-BOSS

- sleeve:
  - 35 F bougie
  - 3-6cm prepyloric to angle of His
  - suturing of stapler line

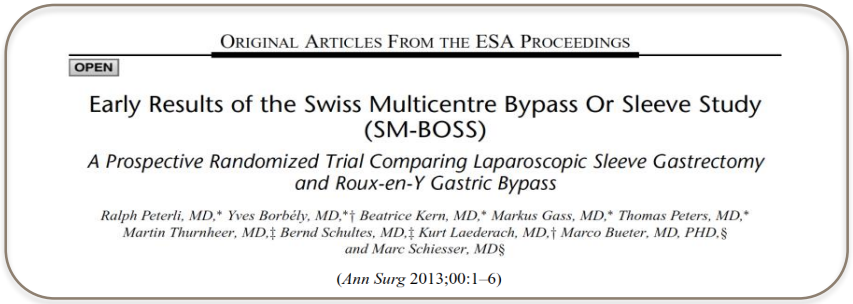


- bypass:
  - 150cm alimentary limb, antecolic
  - 50cm bilio-pancreatic limb
  - circular or linear technique
  - defects closed in circular, not in linear technique



SM-BOSS

previous results



ORIGINAL ARTICLES FROM THE ESA PROCEEDINGS

OPEN

Early Results of the Swiss Multicentre Bypass Or Sleeve Study (SM-BOSS)

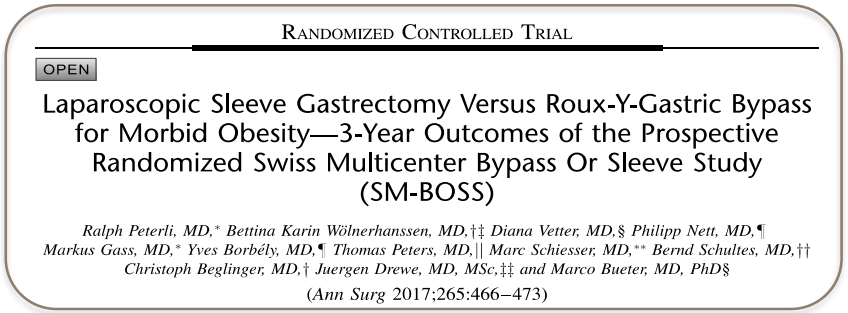
A Prospective Randomized Trial Comparing Laparoscopic Sleeve Gastrectomy and Roux-en-Y Gastric Bypass

Ralph Peterli, MD, Yves Borbély, MD,*† Beatrice Kern, MD,* Markus Gass, MD,* Thomas Peters, MD,* Martin Thurnheer, MD,‡ Bernd Schultes, MD,‡ Kurt Laederach, MD,† Marco Bueter, MD, PHD,§ and Marc Schiesser, MD§*

(*Ann Surg* 2013;00:1–6)

early (1 year):

- sleeve faster, (safer); equal weight loss



RANDOMIZED CONTROLLED TRIAL

OPEN

Laparoscopic Sleeve Gastrectomy Versus Roux-Y-Gastric Bypass for Morbid Obesity—3-Year Outcomes of the Prospective Randomized Swiss Multicenter Bypass Or Sleeve Study (SM-BOSS)

Ralph Peterli, MD, Bettina Karin Wölnerhanssen, MD,†‡ Diana Vetter, MD,§ Philipp Nett, MD,¶ Markus Gass, MD,* Yves Borbély, MD,¶ Thomas Peters, MD,|| Marc Schiesser, MD,** Bernd Schultes, MD,†† Christoph Beglinger, MD,† Juergen Drewe, MD, MSc,‡‡ and Marco Bueter, MD, PhD§*

(*Ann Surg* 2017;265:466–473)

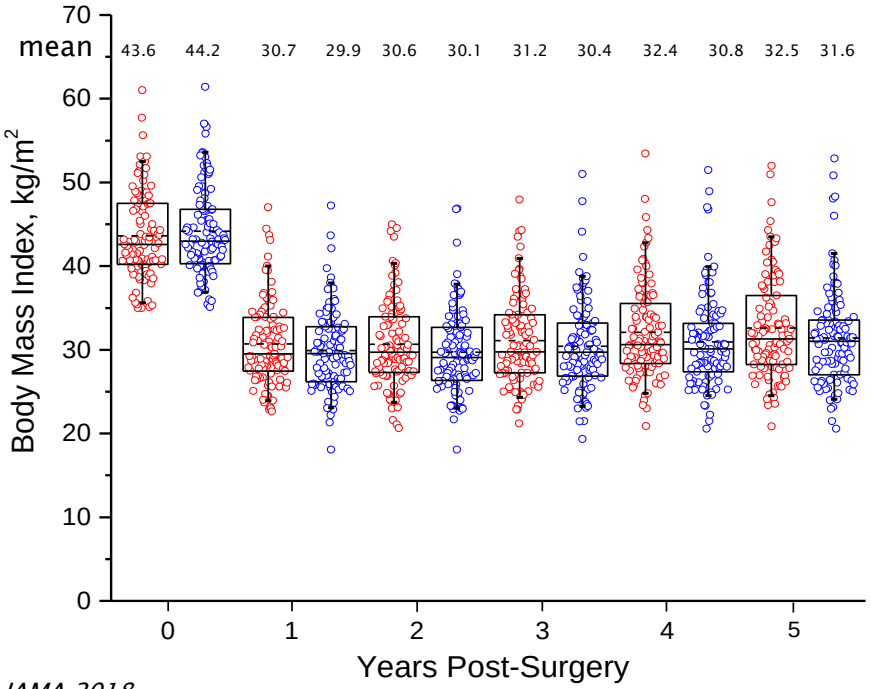
3 years:

- equal weight loss, complications, QoL, co-morbitiy
- except GERD, dyslipedemia: bypass better

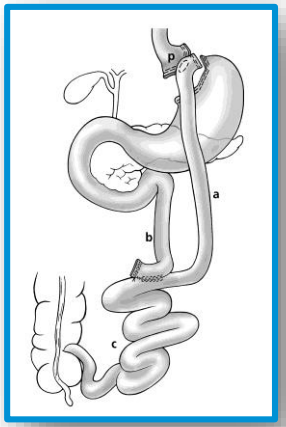
5-YEAR RESULTS Weight loss (BMI)

SM-BOSS

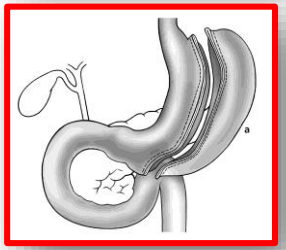
- N = 217 (FU rate 95%)



Peterli, JAMA 2018



−36.6 kg

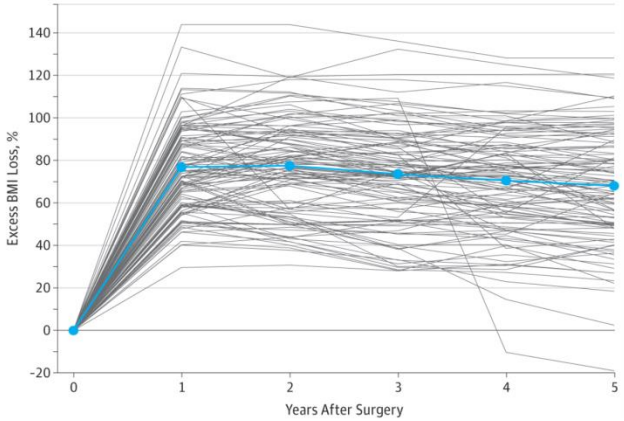


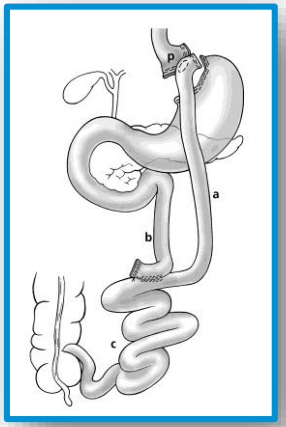
−33.0 kg

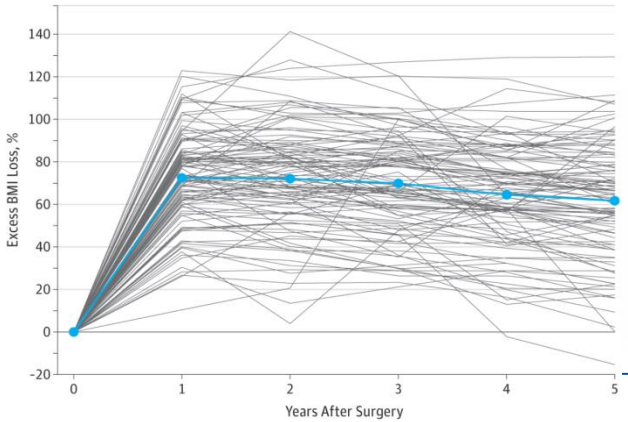
Δ = 3.6 kg

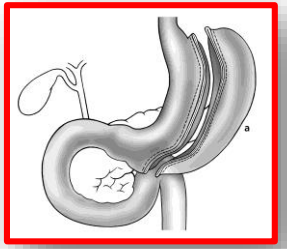
stClaraspital
In besten Händen.

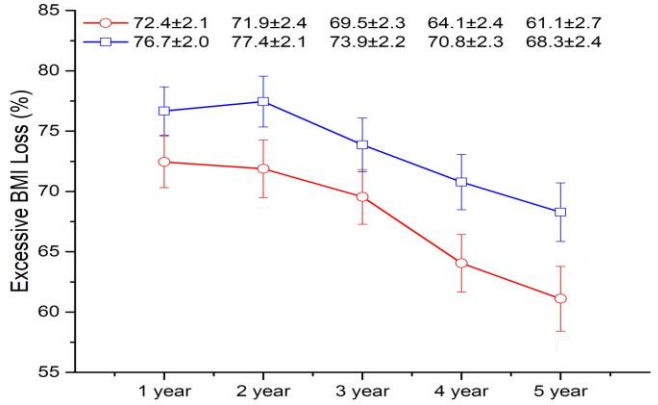
5-YEAR RESULTS Excess BMI loss *SM-BOSS*











Peterli, JAMA 2018

stClaraspital
In besten Händen.

Weight loss

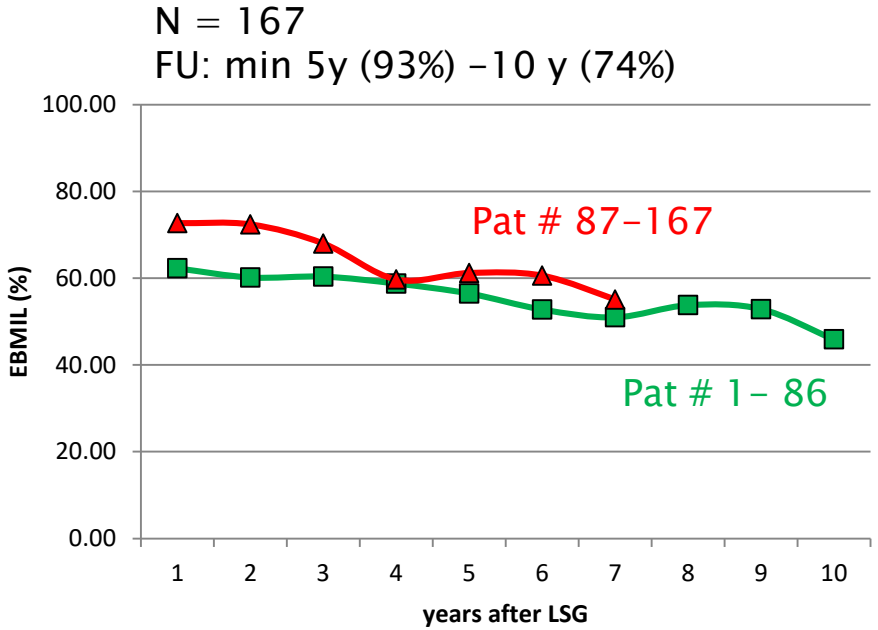
Literature RCT

Author	Journal	Year	N		FU years	FU-rate %	reported as	Mean weight loss		p
			sleeve	bypass				sleeve	bypass	
Karamanakos	Ann Surg	08	16	16	1	100	% EWL	69.7	60.5	0.04
Kehagias	Obes Surg	11	30	30	3	95	% EWL	68.5	62.1	n.s.
Schauer *(Stampede)*	NEJM	14	49	49	3	98	Δ Baseline [%]	−21.1	−24.5	0.06
	NEJM	17	47	49	5	96	% EBMIL	61	68	0.02
Zang	Obes Surg	14	32	32	5	96	% EWL	63.2	76.2	0.02
Ignat	BJS	17	37	29	5	66	% EWL	65.1	74.8	0.02
Salminen *(Sleevepass)*	JAMA	18	98	95	5	80	% EWL	49	57	n.s.
Peterli *(SM-BOSS)*	Ann Surg	17	104	107	3	97	% EBMIL	70	74	n.s.
	JAMA	18	101	104	5	95	% EBMIL	61.1	68.3	n.s.

Long-term Weight loss

sleeve

- durable ?



Author	Year	N	FU (years)	FU (rate, %)	% EWL
Rawlins	12	49	5	100	86
Prager	16	53	10	96	53
Himpens	16	65	11	59	63
Gadiot	16	276	5-8	50(?)	54
Kowalewski	18	100	8	79	51
Claraspital	*18*	*167*	*8.3*	*82*	*59*

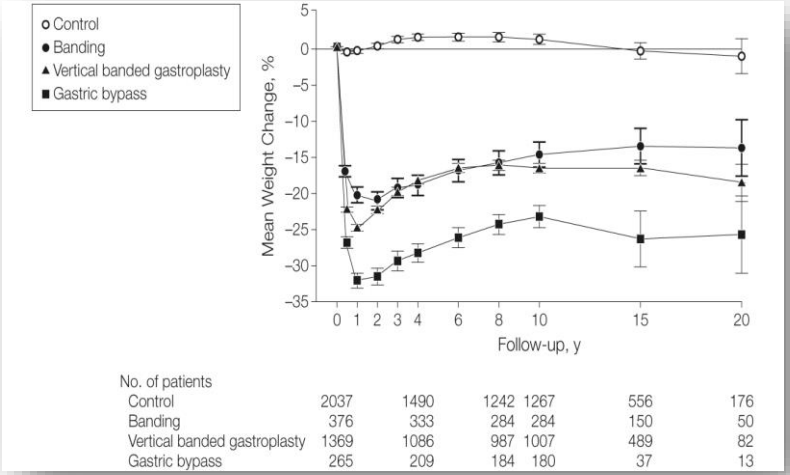
Kraljevic & Peterli, submitted

Long-term Weight loss *bypass*

- durable

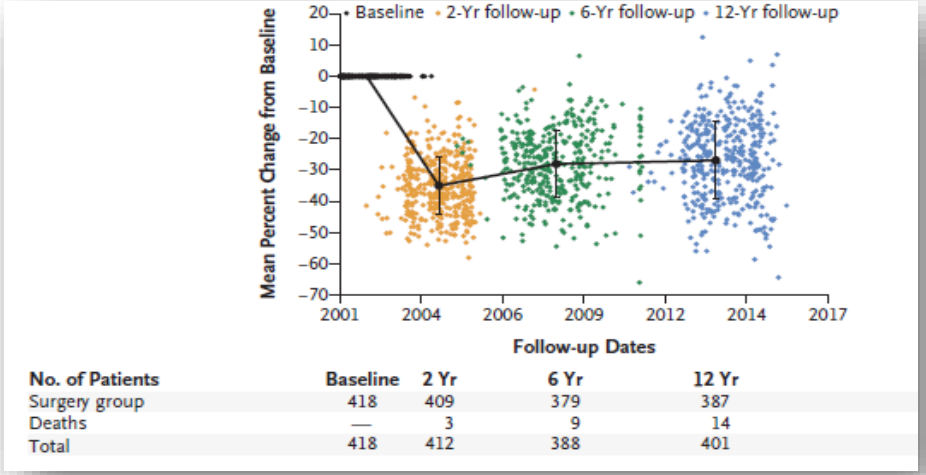
  SOS trial

Utah, USA: 12 y post bypass, 97% FU rate



No. of patients						
Control	2037	1490	1242	1267	556	176
Banding	376	333	284	284	150	50
Vertical banded gastroplasty	1369	1086	987	1007	489	82
Gastric bypass	265	209	184	180	37	13

Sjöström, JAMA 2014

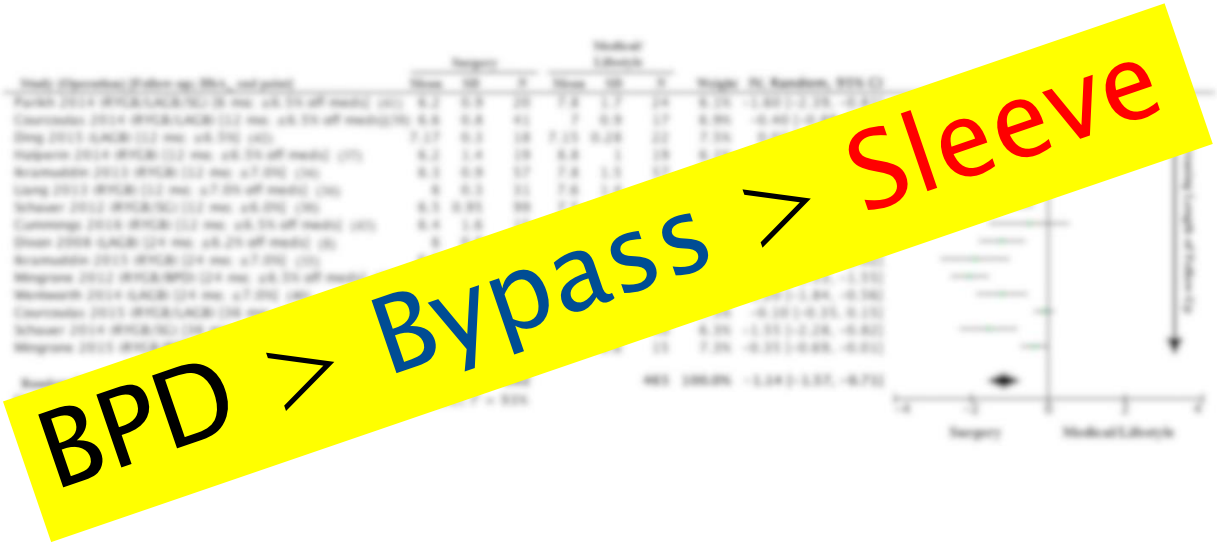


No. of Patients	Baseline	2 Yr	6 Yr	12 Yr
Surgery group	418	409	379	387
Deaths	—	3	9	14
Total	418	412	388	401

Adams, NEJM 2017

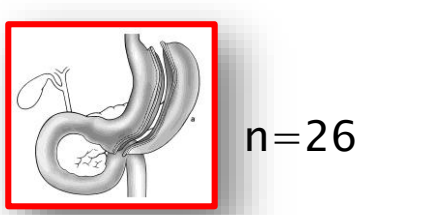
Weight loss

long term (literature)

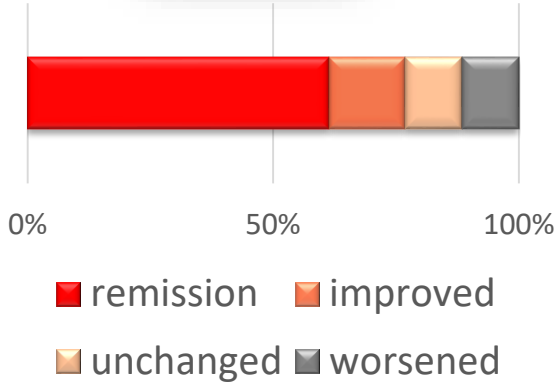


Osland, Surg Laparosc Endosc Percutan Tech 2017; Buchwald, Am J Med 2009

5-YEAR RESULTS Diabetes *SM-BOSS*

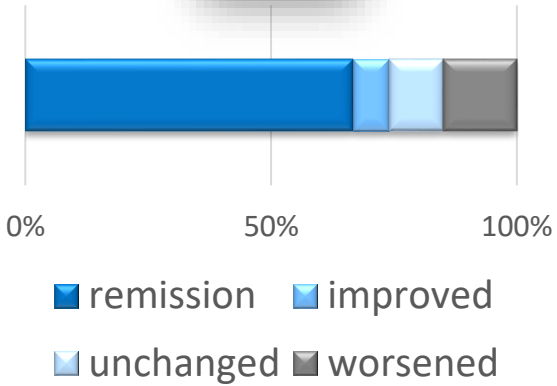


n=26



n.s.

n=28

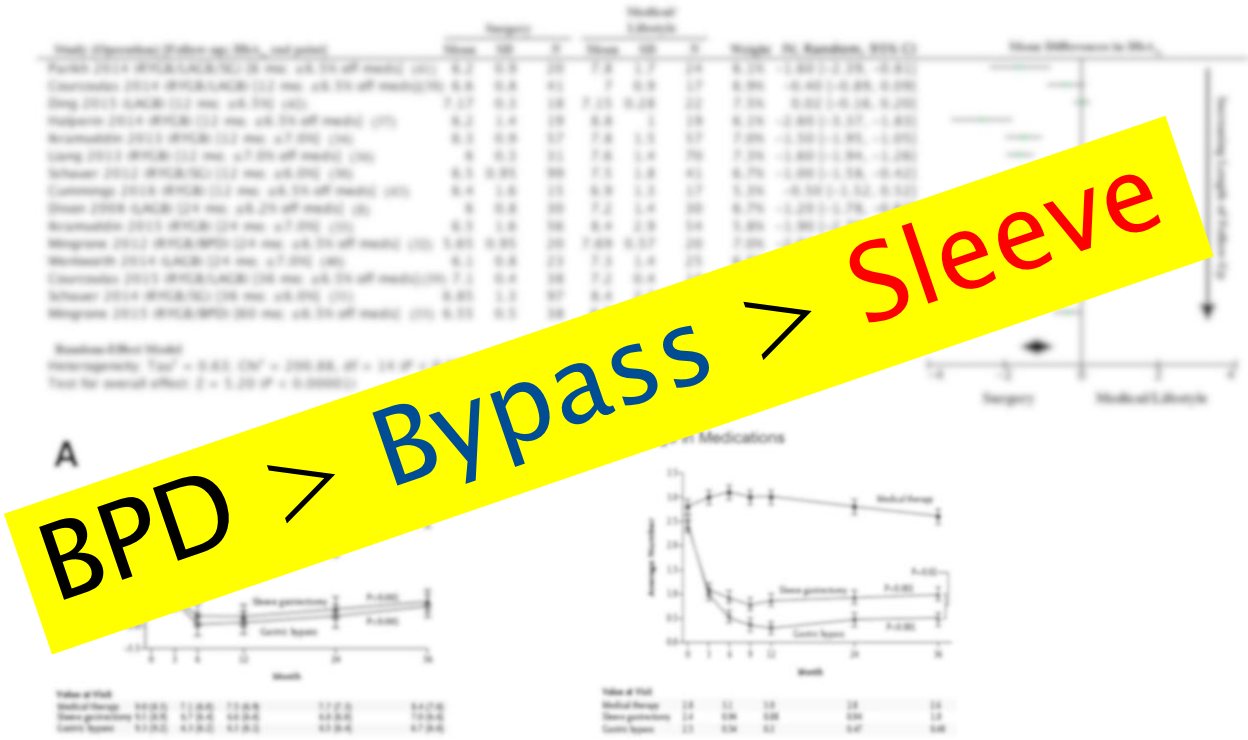


- Gluc 6.4 ±0.42 5.8 ±0.31 (p=0.21)
- HbA1c 6.2 ±0.17 5.9 ±0.16 (p=0.09)

Peterli, JAMA 2018

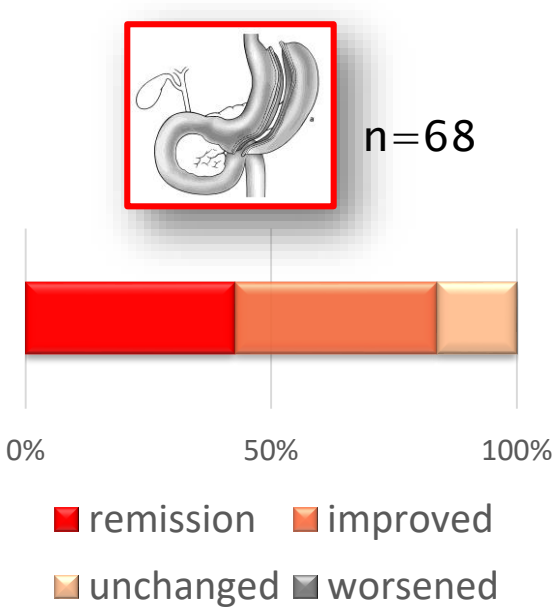
Diabetes

Literature

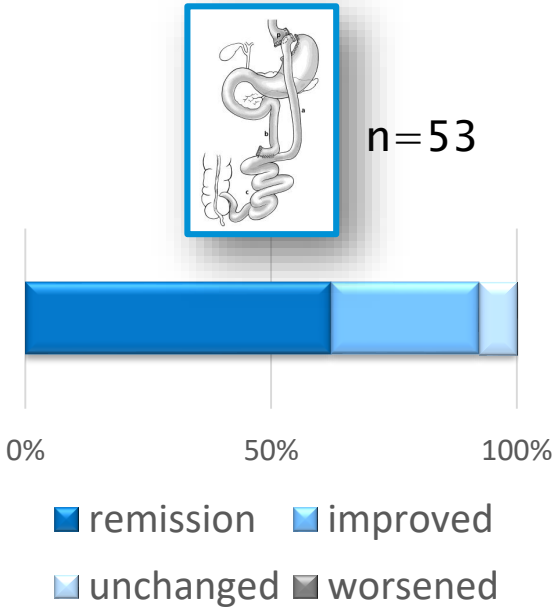


Schauer, NEJM 2017 & Diabetes care 2016; Müller, Ann Surg 2015, Buchwald, Am J Med 2009

5-YEAR RESULTS Dyslipidaemia *SM-BOSS*



p=0.09*



• LDL	3.0 ±0.12	2.62 ±0.08	(p=0.008)
• Chol/HDL q	3.3 ±0.13	3.0 ±0.09	(p=0.02)

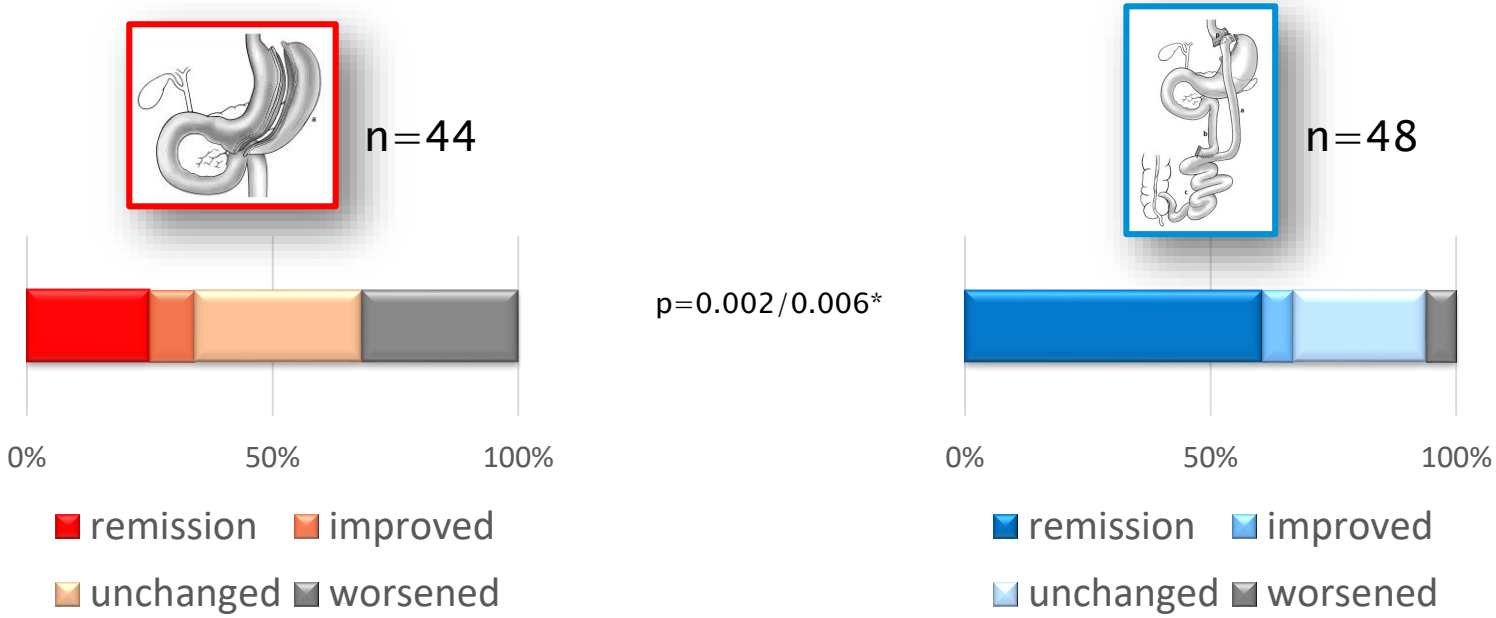
Peterli, JAMA 2018

* after adjustment for multiple comparisons

stClaraspital
In besten Händen.

5-YEAR RESULTS GERD

SM-BOSS



- new onset GERD: 31.6% vs 10.7% (p=0.01)

Peterli, JAMA 2018

* after adjustment for multiple comparisons

COMPLICATIONS up to 3 years *SM-BOSS*

TABLE 4. Complications (1 Month to 3 Yrs)

Complication	LSG (n = 107)		LRYGB (n = 110)	*P* Values LSG Vs. LRYGB
Conservative treatment				
General complications				
Total	9		11	0.67
Peptic ulcer	0		1	
Stricture	0		1	
Kidney stones	2		1	
Other	7		8	
Deficiencies				
Total: patients with ≥1 micronutrient deficiency	39	=	45	0.59
Vit. D	34		26	
Vit. B12	39		45	
Iron	24		29	
Zink	16		20	
Folate	10		5	
Protein	0		1	
Operative treatment				
Total	9		16	0.15
Conversion to LRYGB for GERD	2		NA	
Choleystectomy for newly acquired gallstones	4		6	
Revision for small bowel obstruction	0		2	
Internal hernia	0		3	
Insufficient weight loss	2		1	
Other (umbilical hernia, Meckel diverticulum, gastroduodenoscopy, abdominal lavage, etc.)	1		4	

The reoperation rate was slightly higher in the LRYGB group. There was no statistically significant difference between the 2 groups.

Peterli, Ann Surg 2017

COMPLICATIONS up to 5 years *SM-BOSS*

Complication necessitating reoperation/endoscopic intervention	sleeve n = 101	bypass n = 104	p
• GERD	9 LRYGB	0	0.02
• insufficient weight loss	3 lap. BPD-DS 2 LRYGB	1 banded bypass 1 pouch resizing	0.12
• small bowel obstruction	0	2	0.5
• internal hernia	0	9	0.03
• severe dumping	0	1 banded bypass 1 Apollo 1 reversion	0.25
• incisional hernia	1	1	1
• laparoscopy for gastroscopy	NA	1	
• **total >30d**	**15**	**18**	**0.23**
• ***all reoperations/interventions (early* & late)***	***16***	***23***	***0.25***

Peterli, JAMA 2018

** Peterli, Ann Surg 2013*

Surgery for *GERD & Stenosis & HH after sleeve*

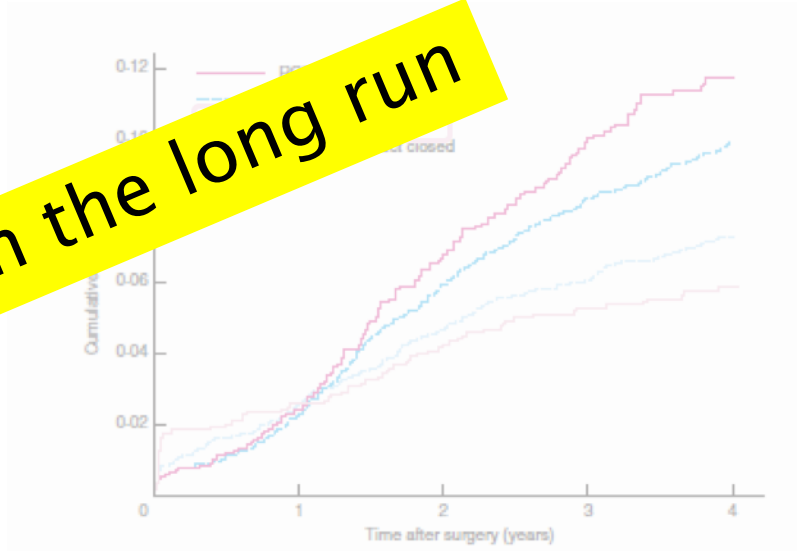
Author	Year	N	FU years	reop %	type	%	t postop m
Prager	16	53	10	11	bypass BPD-DS	95 5	36
Himpens	16	110	12	4	bypass hiatoplasty	50 50	
Gadiot	16	276	5-8	(15)	bypass	100	
Claraspital	*18*	*167*	*8.3*	*6.5*	*bypass* *hiatoplasty*	*82* *18*	*60* *48*

- Barrett‘s oesophagus
  - 17% in asymptomatic pts >4y postop *
  - 12% 5 y postop #

** Genco, SOARD 2017; # Felsenreich & Prager, Obes Surg 2017*

Surgery for *internal hernia after bypass*

today < 5 % in the long run

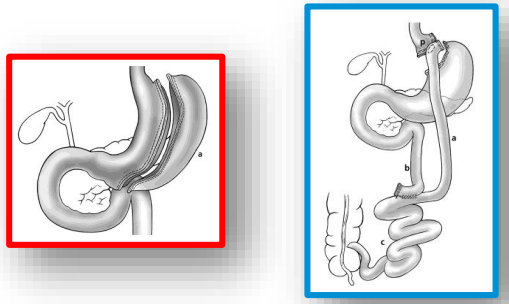


Aghajani & Gislason, Surg Endosc 2017

Stenberg, BJS 2017

SUMMARY

SM-BOSS



- sleeve vs bypass at 5 years (95% of 217 pts):
  - weight loss not sign. different* (61 vs 68% EBMIL)
  - co-morbidities:
    - T2DM: remission: 62 vs 68% (underpowered)
    - dyslipidaemia: bypass ±better (p=0.09*)
    - GERD: bypass better (remission 25 vs 60.4%; de novo: 31.6 vs 10.7%)
  - QoL improved markedly with both procedures
  - number of complications necessitating reoperation/intervention:
    - 15.8 vs 22.1%

Peterli et al., JAMA 2018

*after adjustment for multiple comparisons

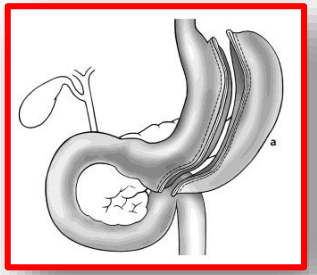
CONCLUSION 1

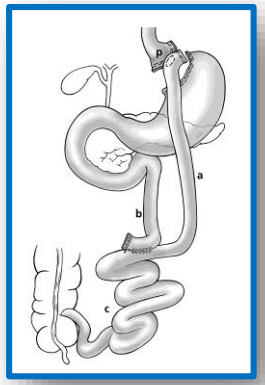
SM-BOSS

- rapid switch from bypass to sleeve ≠ misadventure
  - but: weight loss with longer FU?

- metabolic effect equal?

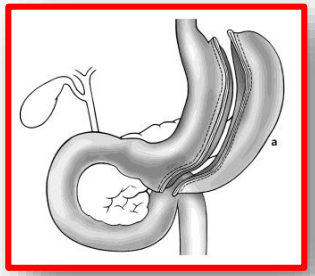
- safety:
  - sleeve: GERD, Barrett
  - bypass: internal hernia, severe dumping

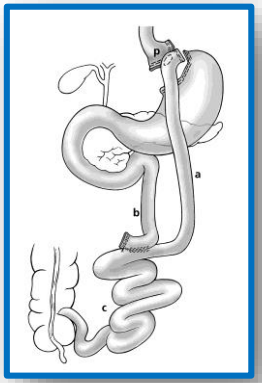




CONCLUSION 2

- good candidate for sleeve:
  - very high BMI
  - necessity of endoscopic access
  - extensive previous surgery (expected adhesions), big hernias
  - Crohn's disease
  - professional driver (fear of dumping)
  - elderly patient
- good candidate for bypass:
  - GERD, large hiatal hernia
  - esophageal motility disorder
  - T2DM, dyslipidemia
- patient selection & information important





stClaraspital
In besten Händen.