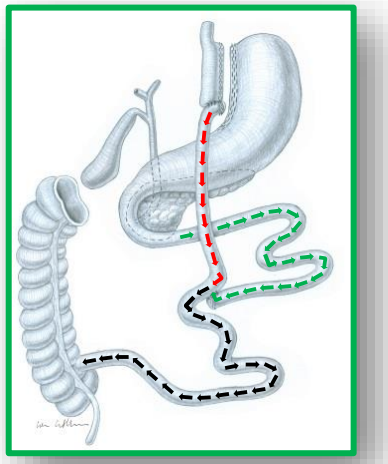
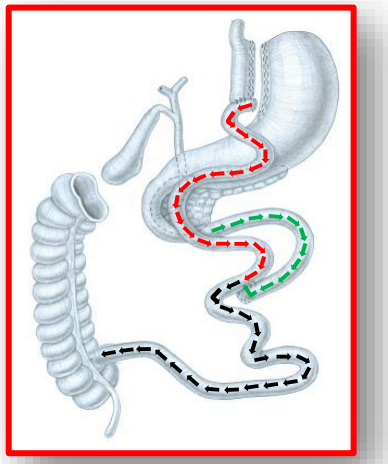
SLIM-Trial 1-Year Results: Limb Lengths in Gastric Bypass



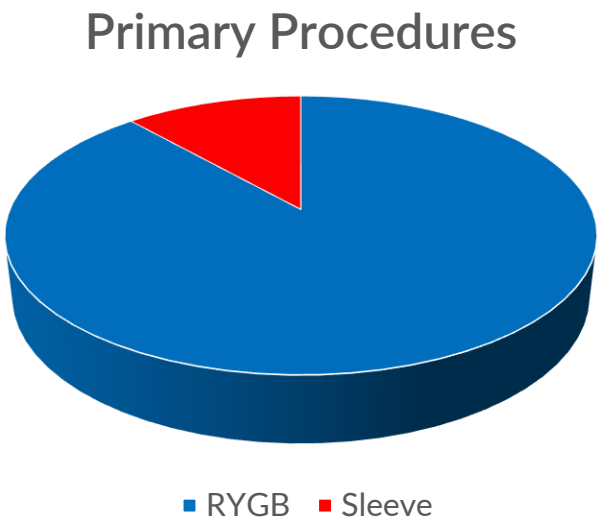
vs

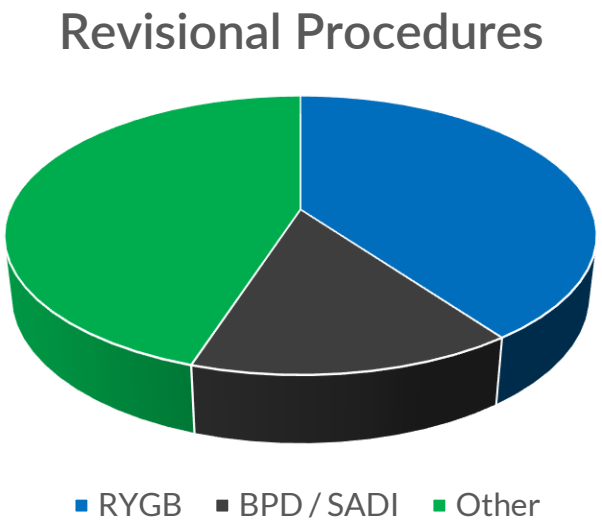


Prof. Ralph Peterli
Department of Clinical Research University of Basel, Switzerland
Senior Consultant Visceral Surgery: ViszeraMed Zürich & Spital Männedorf

DISCLOSURES

- Research grants: Swiss National Science Foundation, Johnson & Johnson, Hirzbrunnen Foundation NovoNordisk, UKBB, Novartis
- Lecture/consulting fees: Johnson & Johnson, Viatris, Falk Foundation, NovoNordisk, Lilly, Medtronic
- Case mix disclosure





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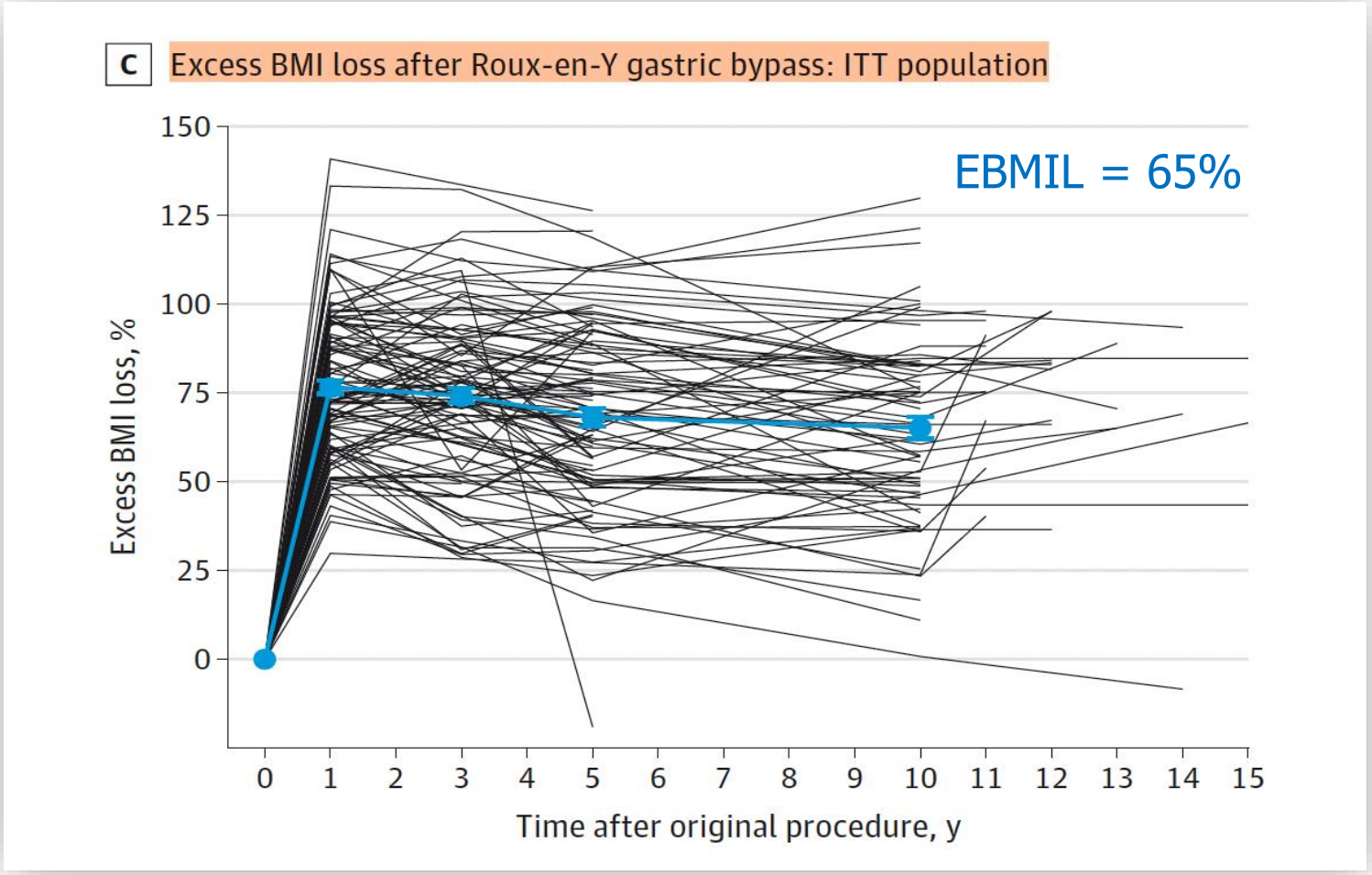
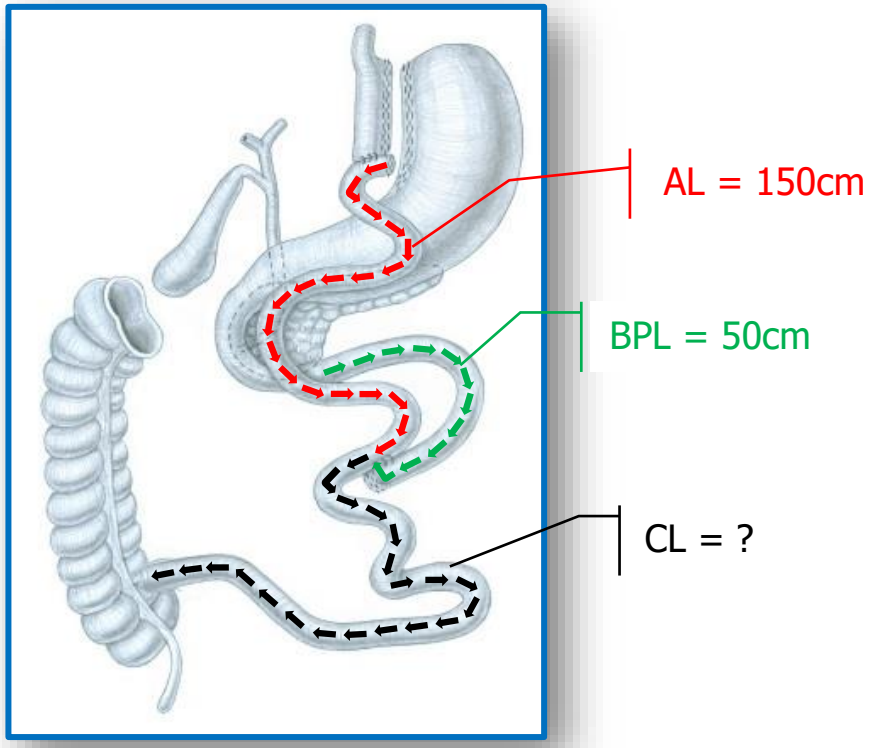
Variety of Weight loss Results

in highly standardized Gastric Bypass

- SM-BOSS → Sleeve vs Gastric Bypass (110 vs 107 patients) > 10y

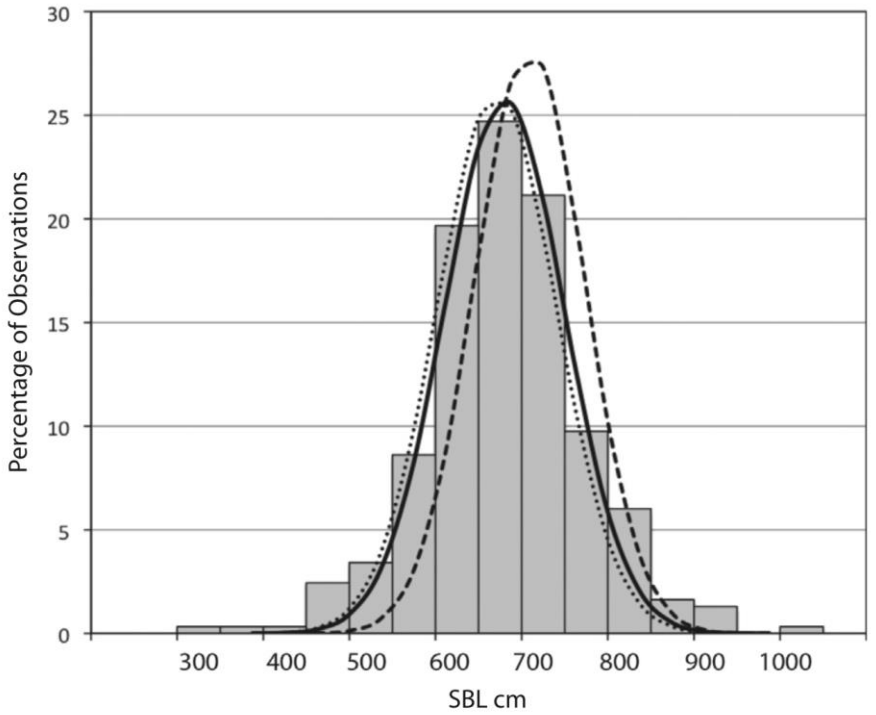




Variety of Total Small Bowel Length

- N = 443: 690 ± 94cm (350 – 1050cm) *
  - Correlates with height (not weight)
  - Male > female (730cm vs 680cm, p<0.0001)
  - Depends on measuring method:
    - Open: with/without ruler
    - Laparoscopy: measure band, marked forceps (5 or 10cm)
    - With/without tension

- Personal experience
  - Open BPD-DS (10cm with ruler)
    - N=120
    - 600cm (350 – 1300cm)
  - LRYGB, LBPD-DS etc.
    - Laparoscopy: 5cm steps
      = best reproducibility



*Tacchino, SOARD 2014

Possibilities to increase effectivity in RYGB

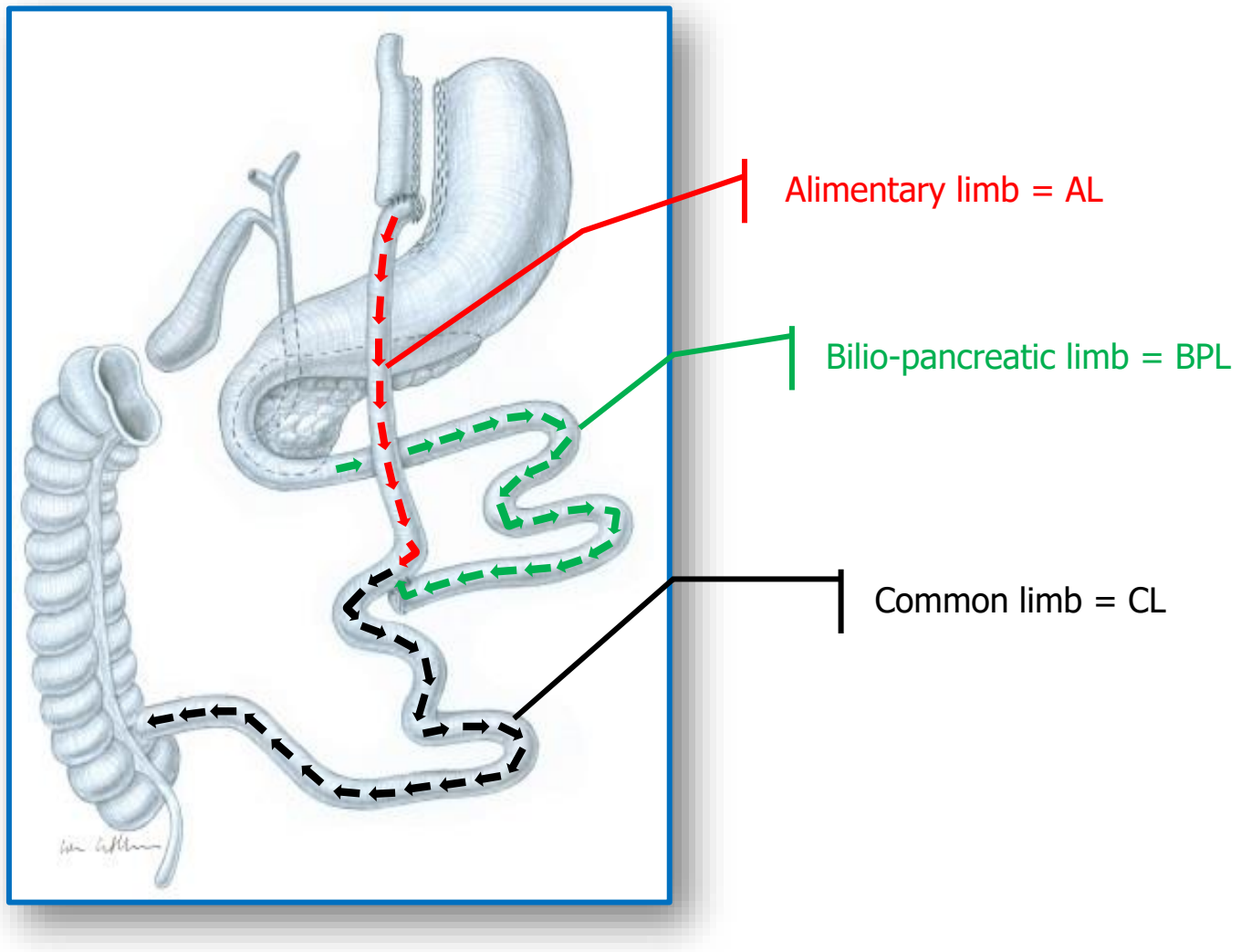
1. Lengthening of alimentary limb (AL)
2. Shortening of common limb (CL)
3. Lengthening of bilio-pancreatic limb (BPL)

The length of one limb:

- Influences the length of the other(s)
- Its effect cannot be analysed without knowledge of the other two

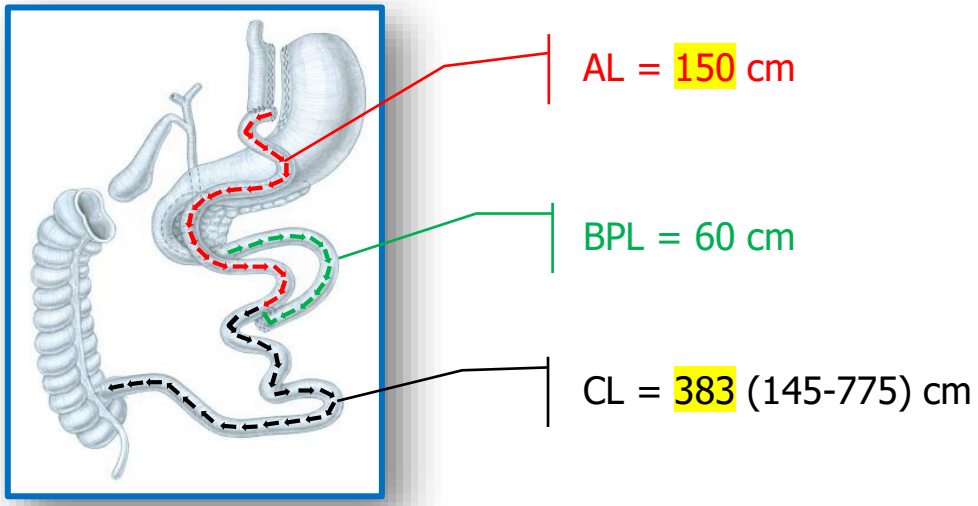
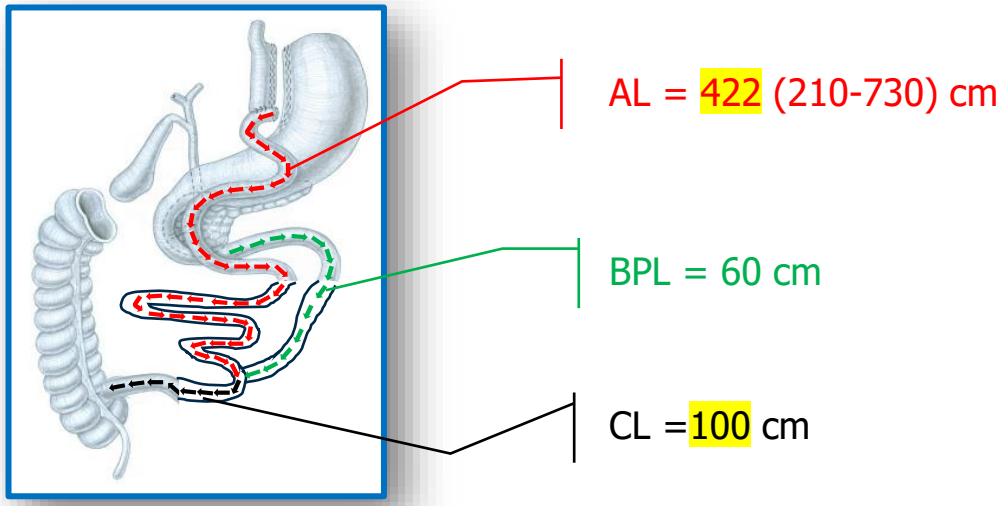
- Consequence: Total bowel length has to be known

AL & CL = total alimentary limb (TAL)



1. Increasing the length of the alimentary limb (AL) in RYGB

DUCATI Trial: RCT, N=444

	Standard-LRYGB	VLRL-LRYGB
	 AL = 150 cm; BPL = 60 cm; CL = 383 (145-775) cm	 AL = 422 (210-730) cm; BPL = 60 cm; CL =100 cm
• % EWL 3y	77%	85% *(p=0.04)*
• T2DM remission	49%	72% *(p=0.04)*
• Complications	9%	16%
– Malabsorption	0.9%	3.6% *(p=0.056)* ➡ bowel adjustment

- Conclusion: Lengthening of AL does (not) work
  Risk of liver damage ↑ *Moolenaar L, J Clin Gastroenterol 2022*

1. Total alimentary limb (TAL = AL & CL)

- Metaanalysis
  - N = 21 trials (12 primary RYGB, 2 RCT)
  - >4760 pts
- Results:
  - Better weight loss if TAL leads to longer BPL
  - Shorter CL:
    - More deficiencies
    - Lengthening in 3 – 64% due to malabsorption
- Conclusion:
  In primary RYGB:
  - TAL = 400cm and CL 200cm = safe & effective

  In revisional RYGB:
  - TAL may be shorter (min 300cm?)

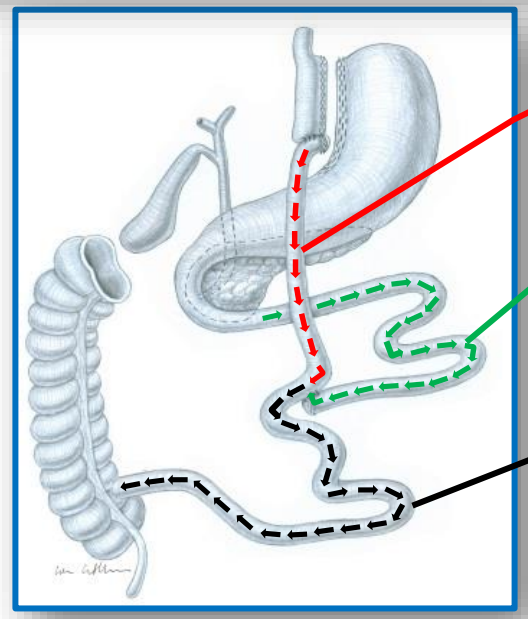
Surgery for Obesity and Related Diseases 18 (2022) 555–564

The role of total alimentary limb length in Roux-en-Y gastric bypass: a systematic review

Alice Wang, M.D., M.H.S.[a], Lauren Poliakin, M.D.[a], Naresh Sundaresan, M.D.[a], Vilok Vijayanagar, D.O.[b], Alexander Abdurakhmanov, M.D.[a], Kyle J. Thompson, Ph.D.[b], Iain H. Mckillop, Ph.D.[b], Selwan Barbat, M.D.[a], Roc Bauman, M.D.[a], Keith S. Gersin, M.D.[a], Timothy S. Kuwada, M.D.[a], Abdelrahman Nimeri, M.D., F.A.C.S., F.A.S.M.B.S.[a,*]

[a]*Atrium Health Weight Management, Section of Bariatric & Metabolic Surgery, Department of Surgery, Carolinas Medical Center, Atrium Health, Charlotte, North Carolina*

[b]*Division of Research, Department of Surgery, Carolinas Medical Center, Atrium Health, Charlotte, North Carolina*



Alimentary limb = AL

Bilio-pancreatic limb = BPL

Common limb = CL

2. Changing Common limb length

- Metaanalysis (N = 13 trials, 1934 pts)
- CL 75cm – 600cm

- Results:
  - △ in CL does not change weight loss
  - Shorter CL: better metabolic effect
  - But more deficiencies
    - Up to 48% protein deficiency in distal bypass

- Conclusion:
  - Common limb > 400cm = safe & effective
    - Reasonable weight loss
    - Positive impacts on metabolic outcomes
    - Without severe nutritional deficiencies
  - Surgeons must consider
    - Measuring TBL in all/selected patients
    - CL in revisional cases

REVIEW ARTICLE

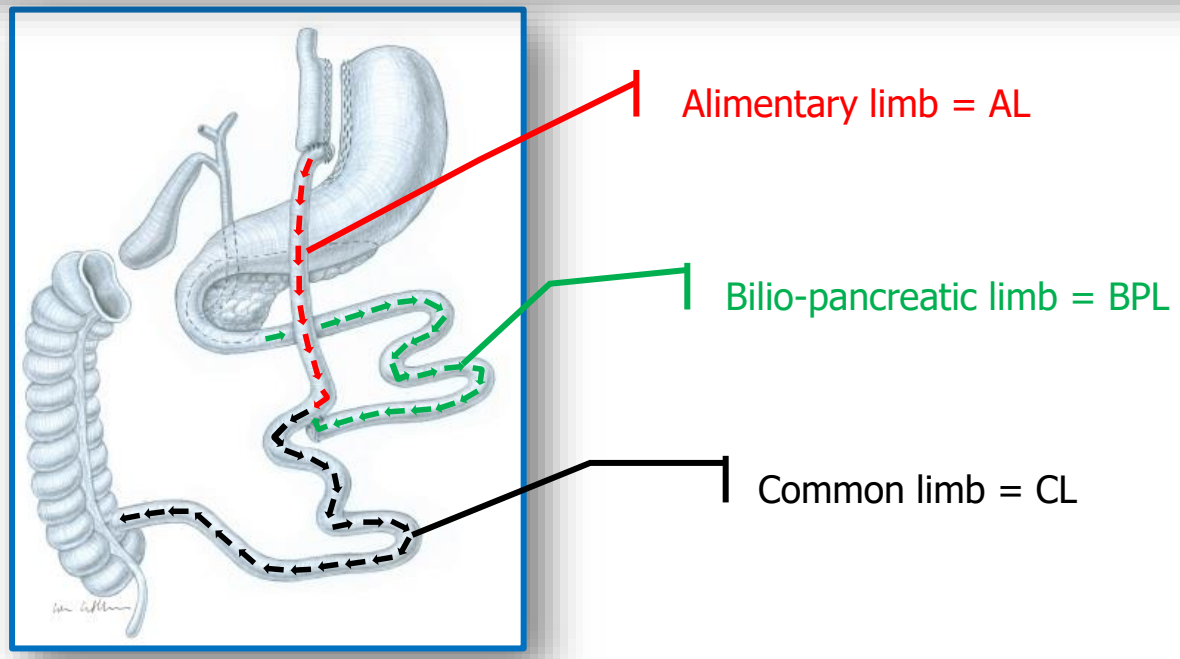
Royal Australasian College of Surgeons

Accepted for publication 27 November 2022.

Optimal common limb length in Roux-en-Y gastric bypass surgery: is it important for an ideal outcome? – a systematic review

Amy Hort,*† Qiuye Cheng,*‡ Tia Morosin,* Peter Yoon* and Michael Talbot‡

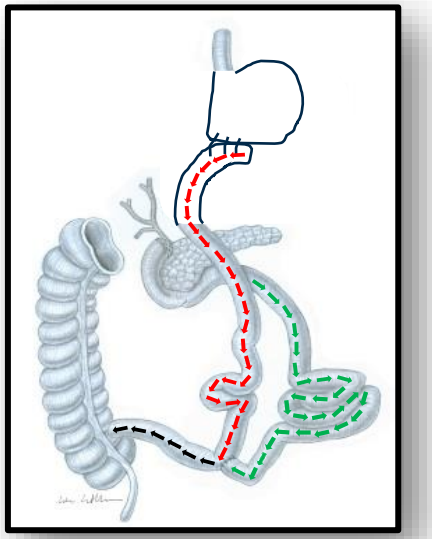
*Department of Surgery, Westmead Hospital, Sydney, New South Wales, Australia
†Department of Surgery, The School of Medicine, The University of Sydney, Sydney, New South Wales, Australia and
‡UNSW St George and Sutherland Clinical School, Sydney, New South Wales, Australia



3. Increasing the BPL

Bilio-pancreatic Diversion

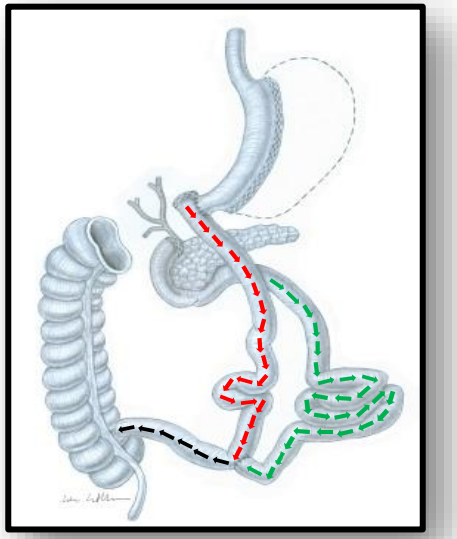
- Maximum weight loss (78% excess BMI loss >10 y) *
- Highest rate of diabetes remission (95%) *



Scopinaro

- BPL = TBL – AL (250cm)
- CL: 50-75cm

Scopinaro, Obes Surg & WJS 1991-2017



Marceau

- BPL = TBL – 250cm (age>50: 350)
- CL: 100cm

Marceau, Obes Surg 1995-2015, Peterli Obes Surg 2007

Hess

- BPL = 50% TBL
- AL = 40%; CL 10% (75-100cm)

Hess Obes Surg 2005

RCT #1: Long BPL vs Short BPL

Elegance Trial

- BMI 43 / 45
- FU 91% at 4y

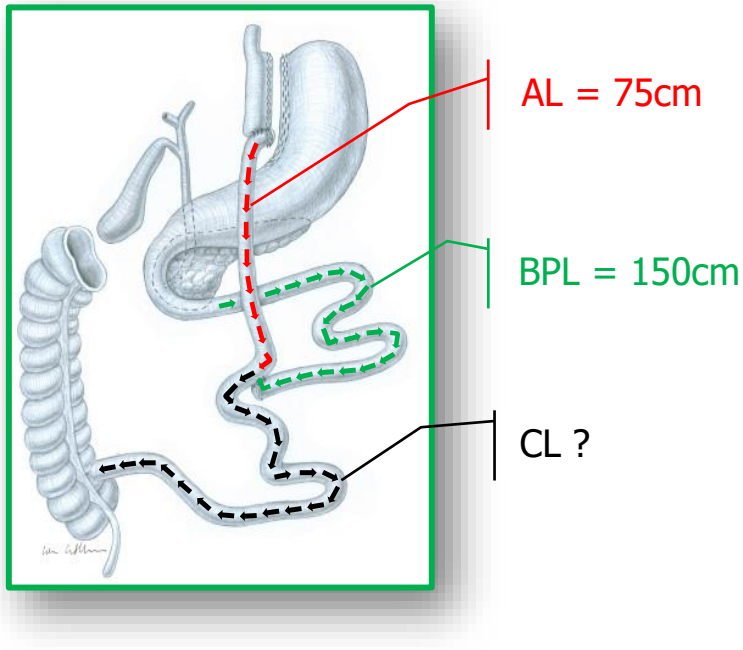
- %TWL (=primary endpoint)
  - 1y 33 / 31 (p=0.042)
  - 4y 30 / 27 (p=0.15)

- %EWL:
  - 1y 81 / 71 (p=0.007)
  - 4y 72 / 64 (p<0.05)

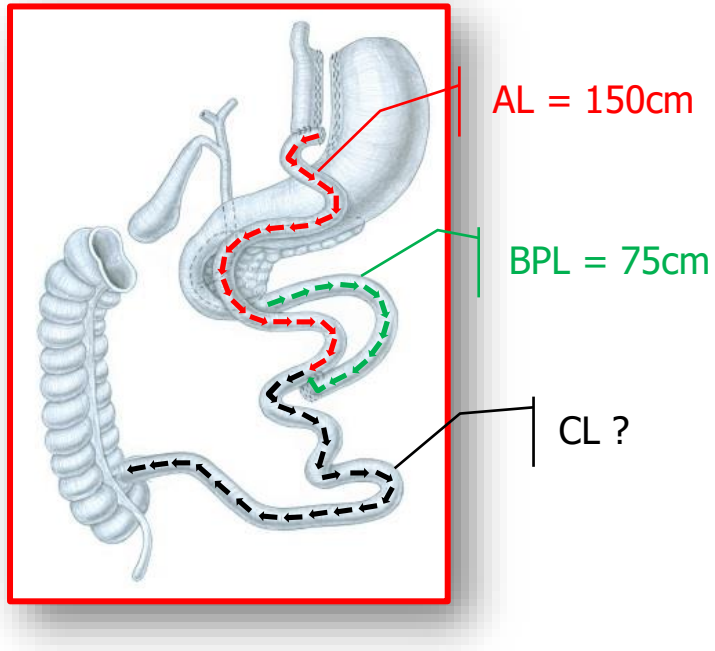
- Co-morbidities
  - T2DM, HAT no difference
  - Dyslipidemia: 95 / 83 % (p=0.02)

- Complications
  - early: 10 / 5 % (n.s.)
  - late: 28 / 30 % (deficiencies not mentioned!)

Long BPL: n = 67

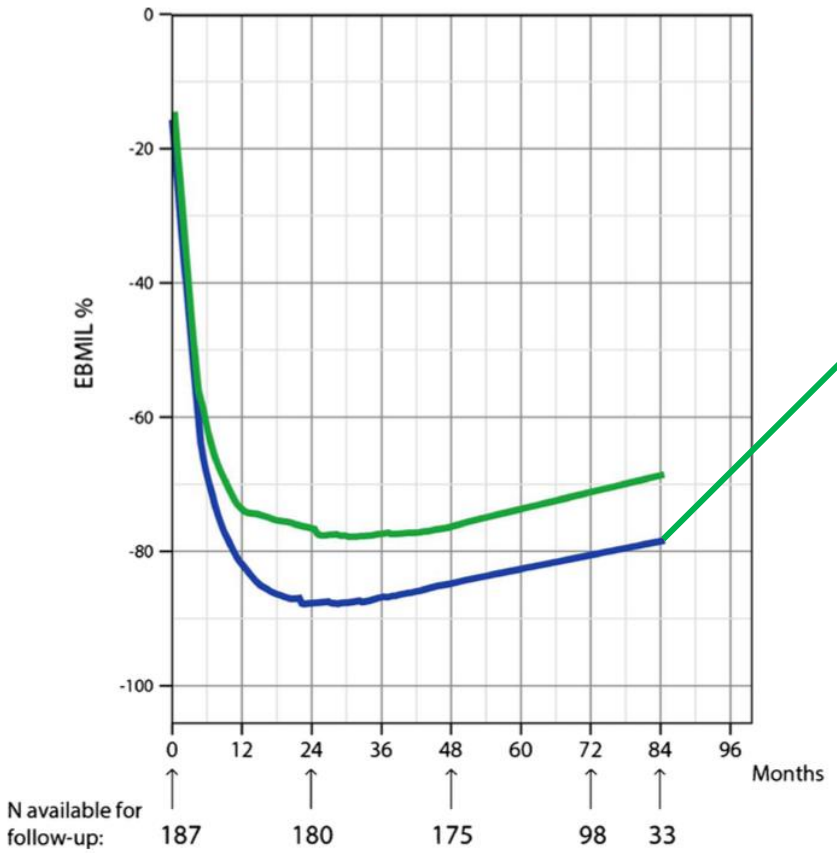


Short BPL: n = 74

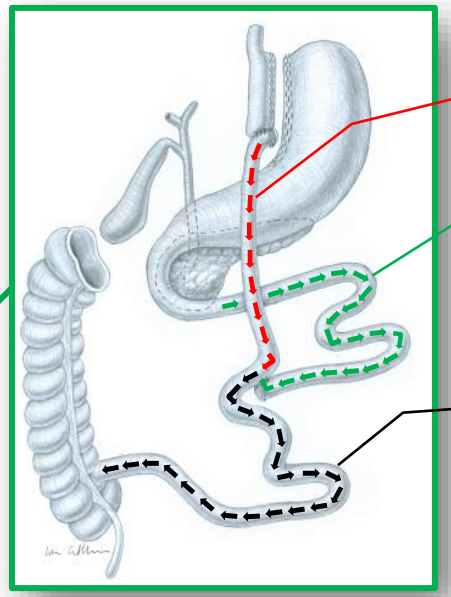


RCT #2: Long BPL vs Short BPL

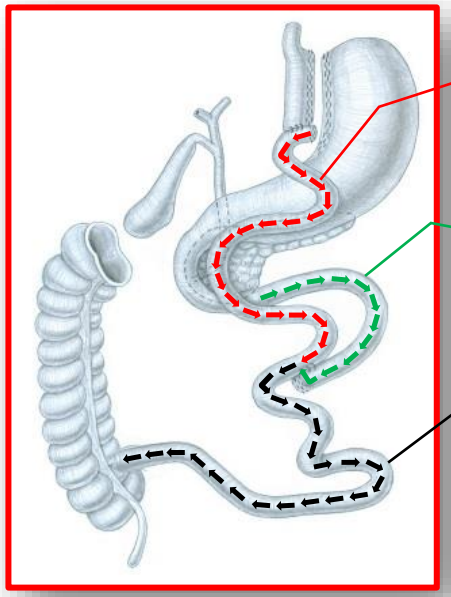
- BMI 44
- FU 85% at 5y



Long BPL: n = 94



Short BPL: n = 93



Nergaard & Gislason, Obes Surg 2014

RCT #2: Long BPL vs Short BPL

- Co-morbidities: no difference
- Deficiencies:

Table 4 Nutritional parameters outside reference values, number of patients (%)

	Before surgery	3 to 9 years after surgery ($n = 177$), median follow-up 71.8 months (36–93)		
	All patients ($n = 187$)	Long BP-limb ($n = 87$)	Long A-limb ($n = 86$)	p Value
Albumin	7 (3.7 %)	23 (26.4 %)	18 (20.9 %)	0.394
Vitamin B-12	12 (6.4 %)	24 (26.4 %)	16 (18.6 %)	0.161
Vitamin D	57 (30.5 %)	39 (44.8 %)	18 (20.9 %)	<0.001
PTH	1 (0.5 %)	15 (17.2 %)	3 (3.5 %)	0.003
Iron	2 (6.4 %)	32 (36.8 %)	13 (15.1 %)	<0.001
Ferritin	11 (5.9 %)	58 (66.7 %)	45 (52.3 %)	0.055
Haemoglobin	2 (1.1 %)	53 (60.9 %)	37 (43.0 %)	0.019
Iron and ferritin	0 (0 %)	20 (23.0 %)	12 (14.0 %)	0.126
Iron and ferritin and haemoglobin	0 (0 %)	15 (17.2 %)	10 (11.6 %)	0.185

Values given are number of patients and %; p values indicate difference in prevalence between the two arms of the study; $p < 0.05$ is taken to indicate statistical significance

Nergaard & Gislason, Obes Surg 2014

3. Modification of BPL in RYGB

- Metaanalysis

ELSEVIER

Surgery for Obesity and Related Diseases xxx (xxxx) xxx

SURGERY FOR OBESITY AND RELATED DISEASES

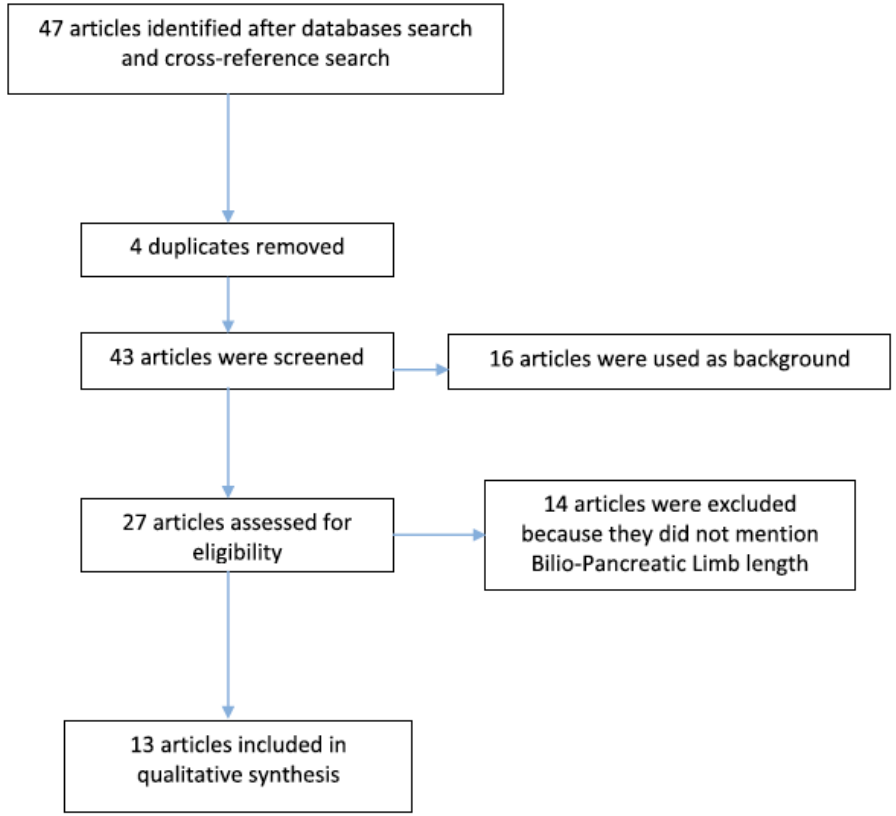
Original article

The importance of the biliopancreatic limb length in gastric bypass: A systematic review

Luis F. Zorrilla-Nunez, M.D., Anthony Campbell, M.S., Giulio Giambartolomei, M.D., Emanuele Lo Menzo, M.D., Ph.D., F.A.C.S., F.A.S.M.B.S., Samuel Szomstein, M.D., F.A.C.S., F.A.S.M.B.S., Raul J. Rosenthal, M.D., F.A.C.S., F.A.S.M.B.S.*

The Bariatric & Metabolic Institute, Section of Minimally Invasive Surgery, Cleveland Clinic Florida, Weston, Florida

Received 30 May 2018; received in revised form 26 September 2018; accepted 15 October 2018; Available online xxx



3. Modification of BPL in RYGB

- Weight loss and diabetes remission

Authors	Weight Loss Short Limb	Weight Loss Long Limb	Diabetes Short Limb	Diabetes Long Limb	Follow-Up, mo
Brolin et al. [14]	BMI 63.4 to >43	BMI 61.6 to >37	43% resolved/47% improved	43% resolved/47% improved	48
Maclean et al. [15]	BMI 65.1 to >39.8	BMI 63.1 to >33–36	N/A	N/A	75
Feng et al. [16]	66.3% EWL	58.2% EWL	N/A	N/A	12
Inabnet et al. [17]	83% EWL	65% EWL	N/A	N/A	24
Leifsson and Gislason [18]	N/A	93% EWL	N/A	N/A	18
Pinheiro et al. [22]	70% EWL	74% EWL	98% improved	95.50% improved	48
Nora et al. [19]	N/A	69.6 EBMIL	N/A	92.6% resolved	12
K. Dogan	52.2% EWL	61.7% EWL	N/A	N/A	6
Nergaard et al. [20]	67.1% EBMIL	78.4% EBMIL	74% resolvedNo difference	74% resolvedNo difference	7 yr
Homan et al. [23]	33.3%–34.1% TWL	34% TWL	N/A	N/A	12
Kaska et al. [24]	Loss of BMI −27.7%	Loss of BMI −38.4%	74.5% Hb <6	95.2% Hb <6	24
Ramos et al. [25]	79.9 ± 19.4% EWL	77.9 ± 21.6% EWL	83% controlled	84% controlled	25
Guimarães et al. [21]	87.6 ± 1.21% EWL	90.7 ± 3.2% EWL	6.1 ± .1%	5.92 ± 0.2%	26

EBMIL = excess body mass index loss; EWL = excess weight loss; BMI = body mass index; TWL = total weight loss; Hb = hemoglobin A1C; N/A = not applicable.

3. Modification of BPL in RYGB

- Weight loss and diabetes remission

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Kaska et al. [24]	MI −27.7%	Loss of BMI −38.4%	74.5% Hb <6	95.2% Hb <6	24
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Guimarães et al. [21]	87.6 ± 1.21% EWL	90.7 ± 3.2% EWL	6.1 ± .1%	5.92 ± 0.2%	26

EBMIL = excess body mass index loss; EWL = excess weight loss; BMI = body mass index; TWL = total weight loss; Hb = hemoglobin A1C; N/A = not applicable.

No trial measured total bowel length

Dutch registry Trial

Modification of BPL in RYGB

- N > 5000
- PS matching:
  - Age
  - BMI
  - Sex
  - ASA-score
  - Comorbidities

- Results 5y:

* 1y: GERD better with long AL

- No information on:
  - Nutritional issues

Table 2 Primary and secondary outcomes for long and short BPL at 5 years in matched patients

Weight loss outcomes	Weight loss at 5 years N = 2,528	Short BPL (< 100 cm) N = 1,264	Long BPL (≥ 100 cm) N = 1,264	OR (95% CI)	β (95% CI)	*P*-value
≥ 25% TWL (yes/no, %)		63.9	67.9	1.19 (1.01 – 1.41)		0.04
%TWL (%)		28.4	29.7		1.26 (0.53 – 1.99)	<0.001
%EWL (%)		69.9	73.2		3.29 (1.45 – 5.13)	<0.001
Δ BMI (kg/m^2)		12.5	13.1		0.55 (0.19 – 0.91)	0.003
Comorbidity	Improvement at 5 years (%)					
	n	Short BPL (< 100 cm)	Long BPL (≥ 100 cm)			
Diabetes mellitus	659	81.8	90.4	2.17 (1.31 – 3.60)		0.002
Hypertension	1,059	72.5	79.3	1.45 (1.06 – 1.99)		0.02
Dyslipidemia	578	73.6	74.2	1.02 (0.66 – 1.56)		0.94
OSAS	423	85.4	92.1	2.00 (0.94 – 4.26)		0.07
GERD	315	90.0	78.6	0.37 (0.13 – 1.12)		0.08
Musculoskeletal pain	1,425	60.3	58.1	0.92 (0.66 – 1.27)		0.60

*

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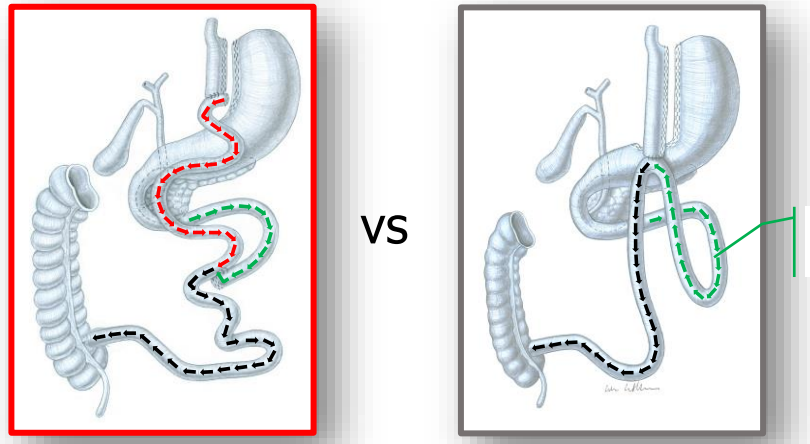
Bruinsma, Nienhujs, Liem, Greve et al, Obes Surg 2024

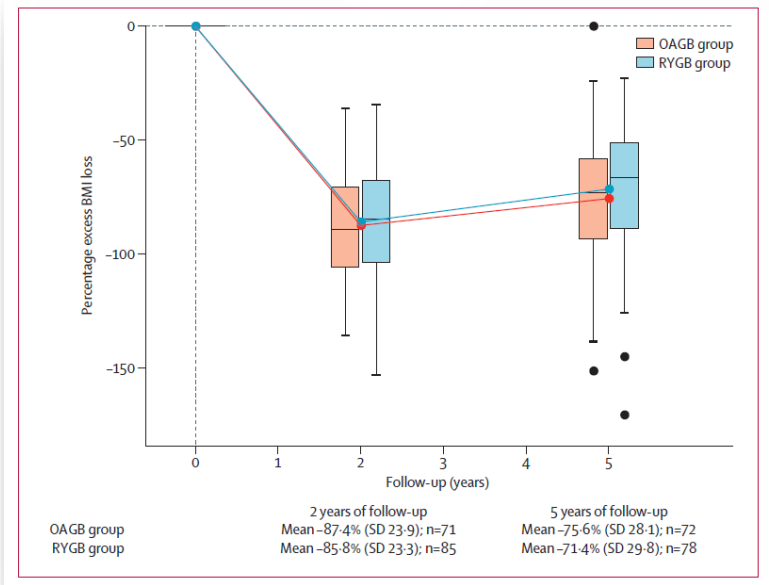
Bilio-pancreatic limb length in OAGB

Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass at 5 years (YOMEGA): a prospective, open-label, non-inferiority, randomised extension study

Maud Robert, Tigran Poghosyan, Delphine Maucort-Boulch, Alexandre Filippello, Robert Caiazzo, Adrien Sterkers, Lita Khamphommala, Fabian Reche, Vincent Malherbe, Adriana Torcivia, Toufic Saber, Dominique Delaunay, Carole Langlois-Jacques, Augustin Suffisseau, Sylvie Bin, Emmanuel Disse, François Pattou

- Design:
  - Multicentre RCT, non inferiority
  - Primary endpoint: % excess BMI loss
  - 127 OAGB (200cm BPL) vs 121 RYGB (150cm AL, 50cm BPL)
- Results: (pp population)
  - FU rate 68%
  - % excess BMI loss: 75.6 vs 71.4
  - GERD: 41% vs 18% (6/127 conversion to RYGB)
  - Co-morbidities: no difference
  - Nutritional status no difference (at 2y FU: OAGB more SAE)

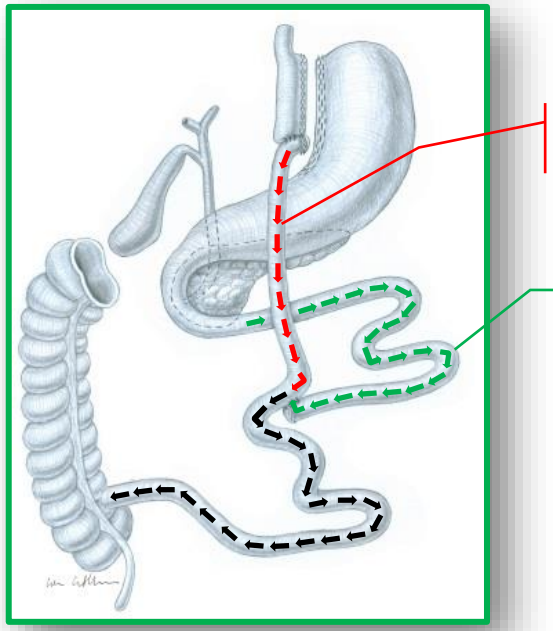




Robert, Lancet Diabetes Endocrinol, 2024

Swiss Multicenter RCT on Different Limb Lengths in Gastric Bypass Surgery (SLIM)

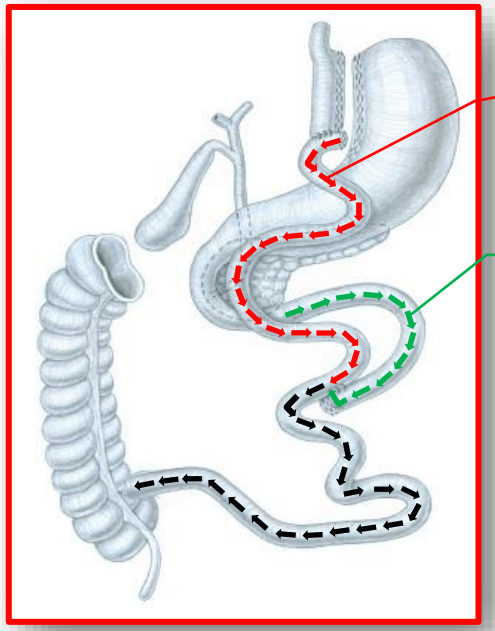
Long BPL RYGB



AL = 80 cm

BPL = 180 cm

Short BPL RYGB



AL = 180 cm

BPL = 80 cm

ViszeraMed Einfach.Exzellent.Versorgt.

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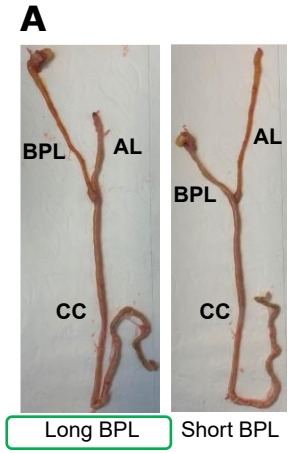
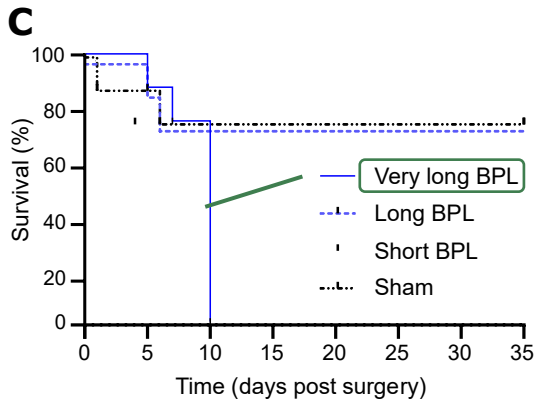
Mouse Model:

longer BPL

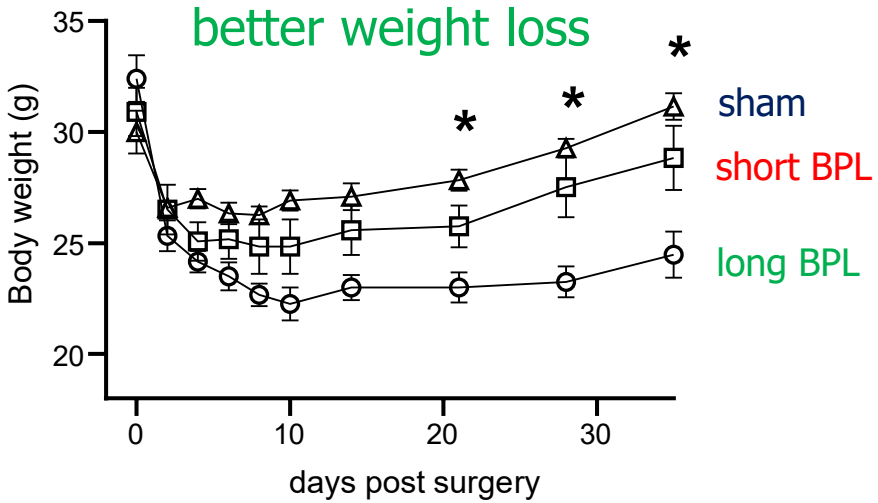
- Groups
  - Sham
  - Short BPL
  - Long BPL
  - Very long BPL

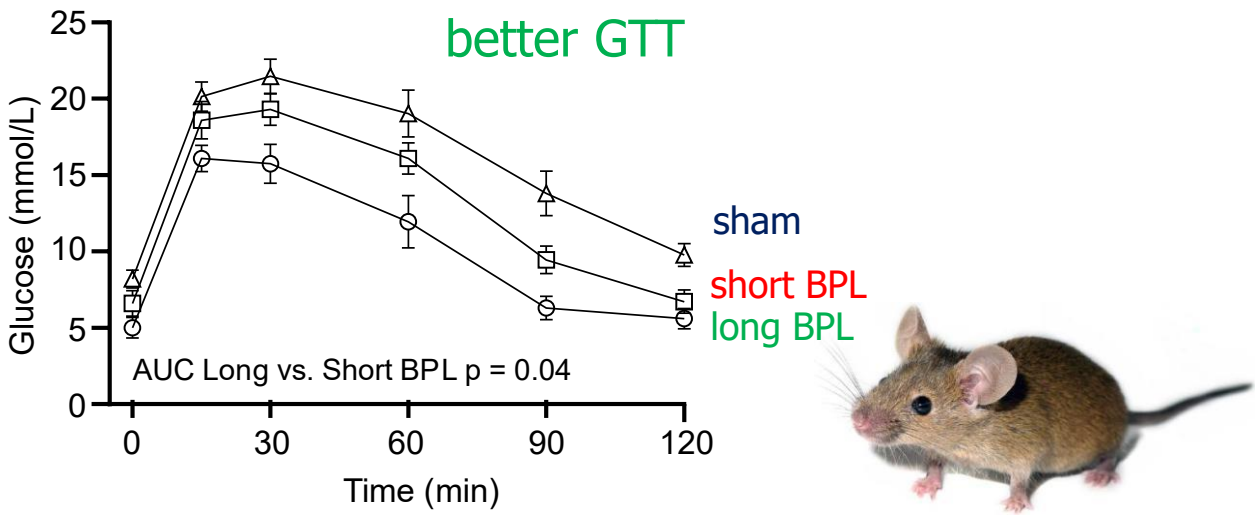


  - Very long BPL:
    - Starvation



  - Long BPL:





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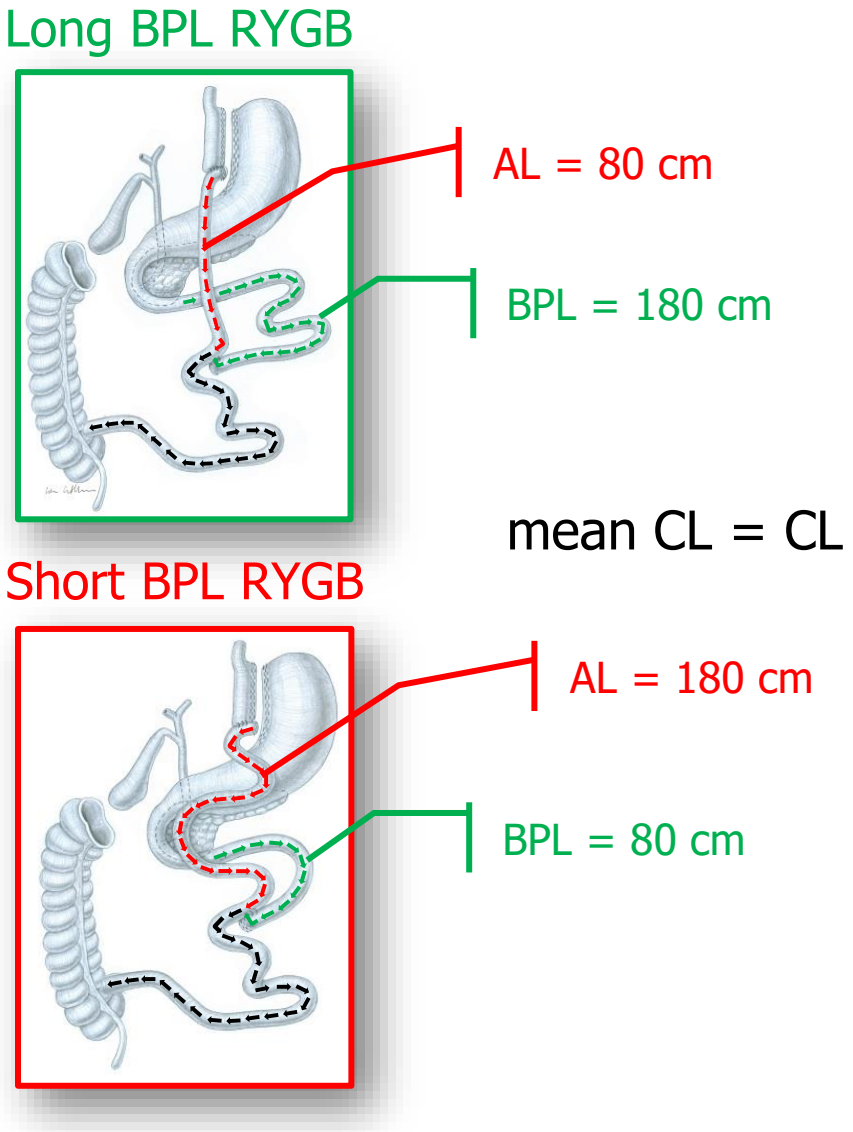
Swiss Multicenter RCT on Different Limb Lengths in Gastric Bypass Surgery (SLIM)

- RCT
  - 15 Swiss centers & Turku University, Finland
  - N = 800
  - Double blinded (patient & observer)
  - Total bowel length measured
  - Recruitment of main trial closed Jan.15, 2024

- Outcomes:
  - Composite primary outcome:
    - % weight loss (superiority) & deficiency rate (non-inferiority) at 5 y
  - Secondary outcomes:
    - Effectivity (Remission of comorbidities, QoL)
    - Safety
    - Influence of all limbs on all outcomes in subgroup analysis
    - Part II (Clarunis) impact on body composition and bone metabolism
    - Part III (Clarunis, Zürich) mechanistic studies
    - .....



Swiss National Science Foundation

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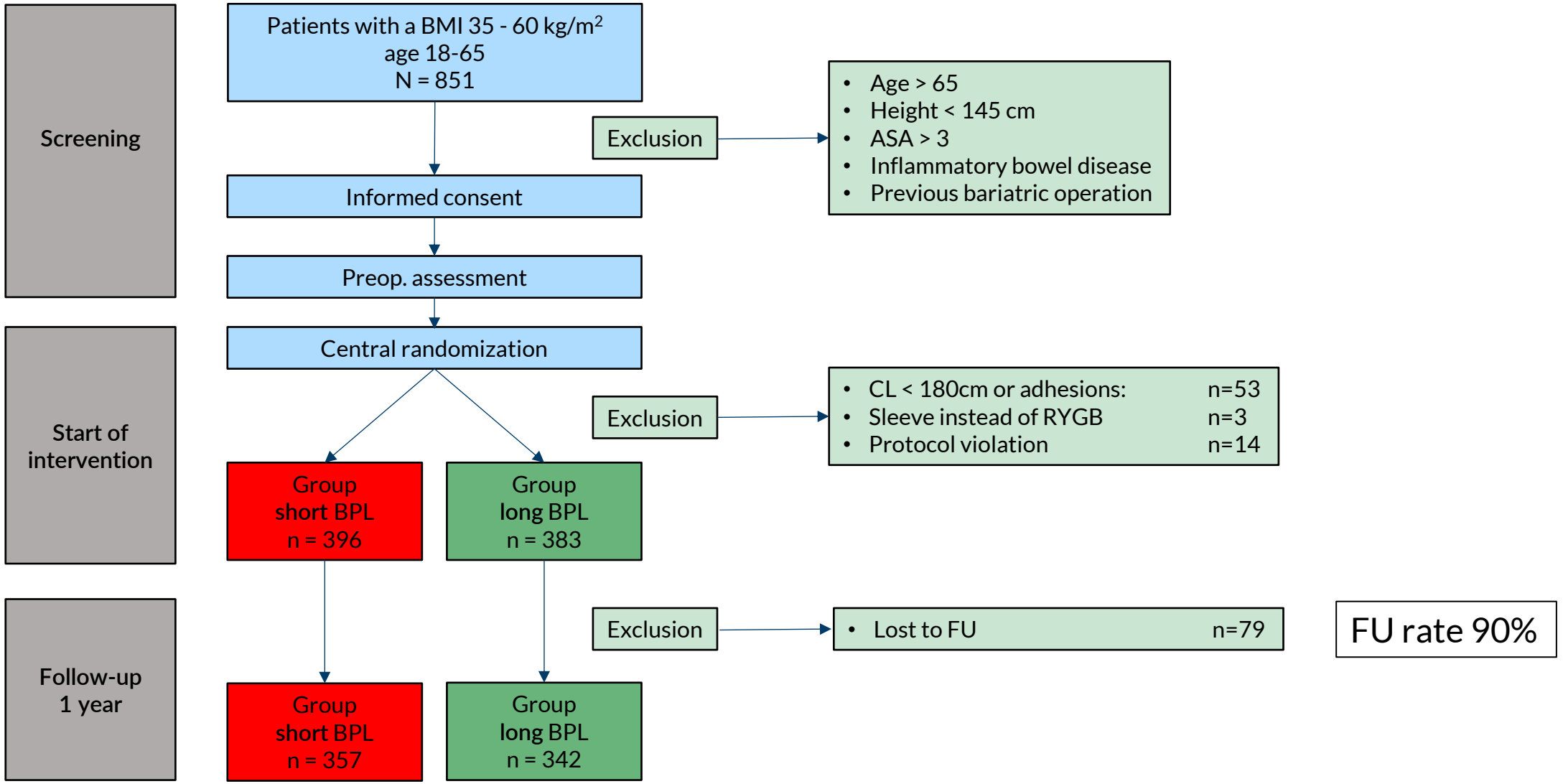
Kraljevic & Peterli, Trials 2021

Study Flow Chart



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Peterli, Suter, Salminen, Kraljevic , Büter, unpublished

SLIM Trial *Baseline Characteristics*

	Short BPL (n=396)	Long BPL (n=383)
Female (%)	74	70
Age (y)	41.4 ± 11.6	41.3 ± 10.5
Weight	120.3 ± 20.0	119.5 ± 18.2
BMI (kg/m^2)	42.7 ± 5.1	42.3 ± 5.0
Waist circonference (cm)	123.3 ± 15.4	123.8 ± 14.5
T2 Diabetes (n, %) • Insulin dependent	57 (14.4) (3.6)	77 (22.8) (3.9)
Dyslipidemia	228 (58.3)	224 (58.8)
Hypertension	168 (42.2)	153 (39.9)
OSAS	145 (37.0)	142 (37.3)
GERD	178 (44.9)	173 (45.2)

SLIM Trial

Intraoperative Parameters

	Short BPL (n=396)	Long BPL (n=383)	p
Access (%)			ns
• Open	0	0	
• Laparoscopic	93.1	93.7	
• Robotic	6.9	6.3	
• Conversion	0	0.3	
Gastroenterostomy (%)			ns
• Hand sewn	14.2	15.5	
• Linear	46.3	44.3	
• Circular	39.5	40.2	
Roux limb (%)			ns
• Antecolic	73	73	
• Retrocolic	27	27	

SLIM Trial

Intraoperative Parameters

	Short BPL (n=396)	Long BPL (n=383)	p
Duration (min.)			ns
• Total	125.1 ± 34.9	130.1 ± 38.9	
• Additional operation (CE, HH repair...)	20.8 ± 19.6	20.3 ± 16.7	
• Small bowel measurement	13.8 ± 10.6	13.4 ± 8.0	
Surgeon experience (%)			ns
• Experienced	47.2	42.5	
• 51 – 100 cases	34.9	37.5	
• 0 – 50 cases	17.9	20.1	
• > 50% = teaching operations			

SLIM Trial

Intraoperative Parameters

- Total bowel length measurement
  - Technique:
    - Measure band: 30%
    - Marked forceps 10cm: 10%
    - Marked forceps 5cm: 60%
  - Duration: <14 min
  - Associated complications: 19/779 (2.4%)
    - 2 perforations, 17 serosal lesions
    - 12/19 (63.2%) with measure band!
  - Complete measurement:
    - Complete: 93.4%
    - Incomplete: 6.6%
  - Total small bowel length: 653 ± 113 cm
    - Min 300 cm
    - Max 1050 cm

SLIM Trial

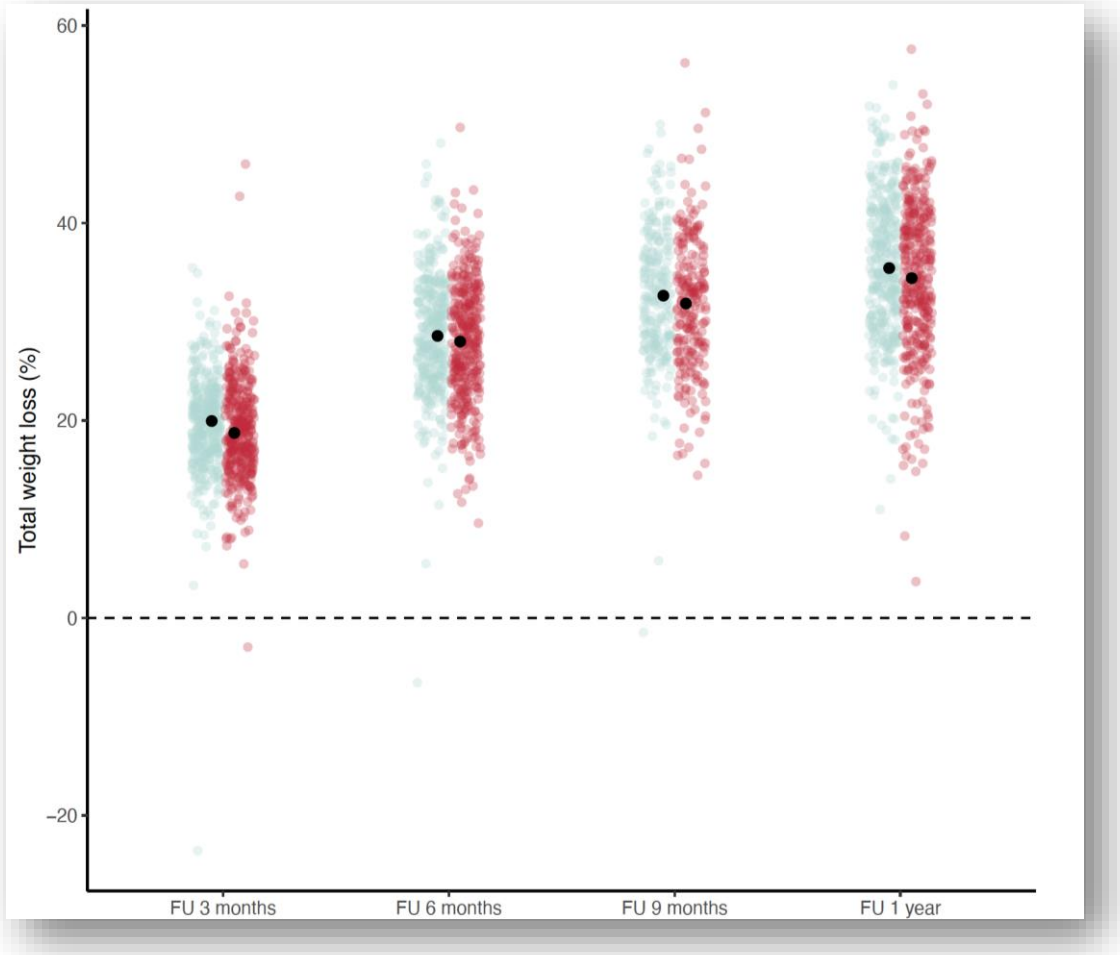
Early Morbidity

Complications	Short BPL (n=396)	Long BPL (n=383)
• Clavien-Dindo III (n, %)	9 (2.2)	10 (2.6)
• Clavien-Dindo IV (n, %)	1 (0.2)	1 (0.2)
• Clavien-Dindo V (n, %)	0	0

1 Year Results

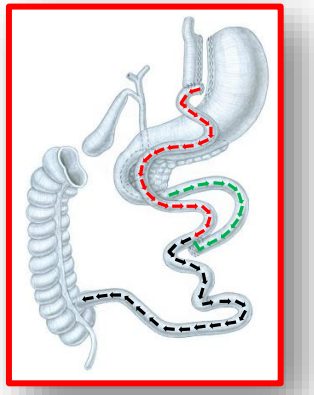
Weight loss

- % WL



Long BPL RYGB

35.4 %
(30.7, 41.0)



Short BPL RYGB

34.4 %
(29.4, 39.9)

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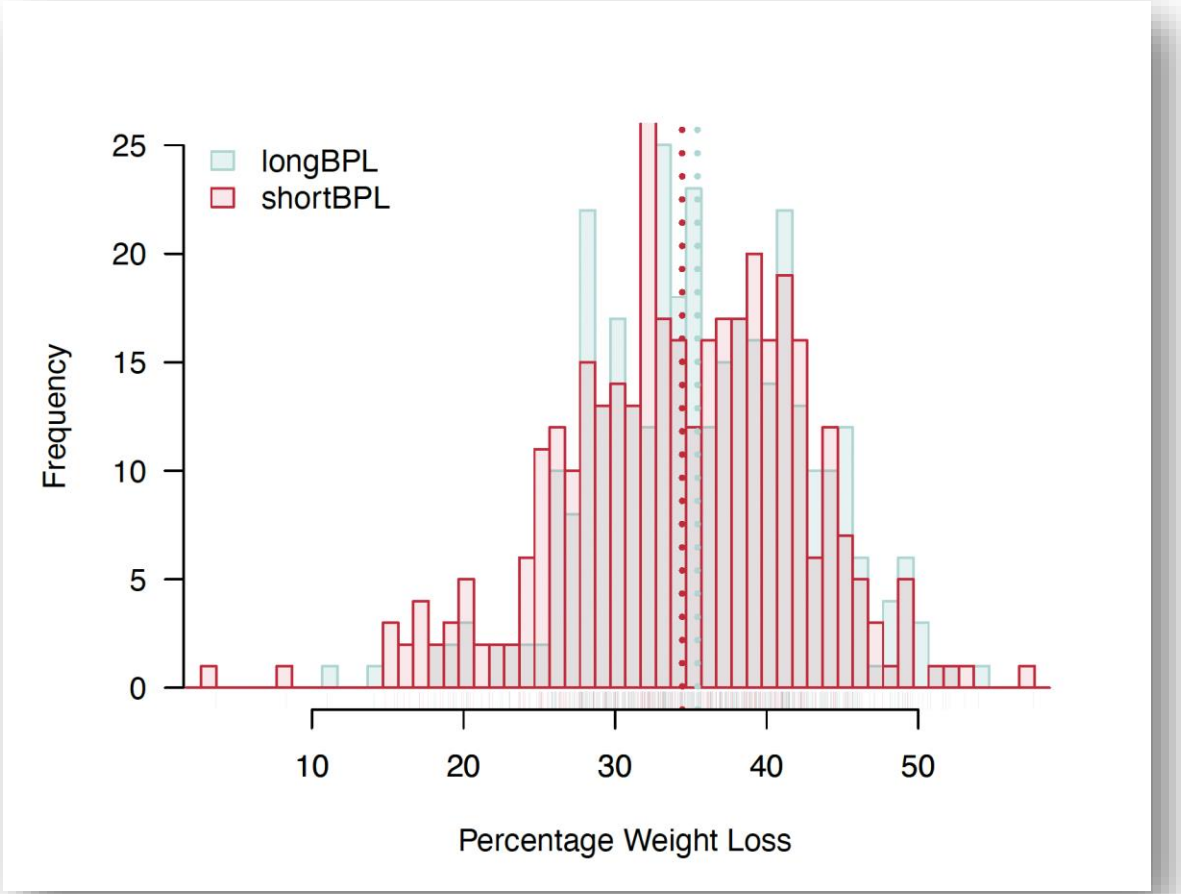
1 Year Results *Weight loss*

- % WL



Long BPL RYGB

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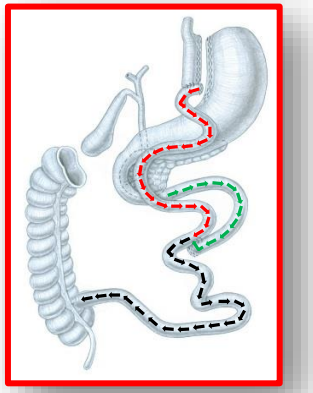


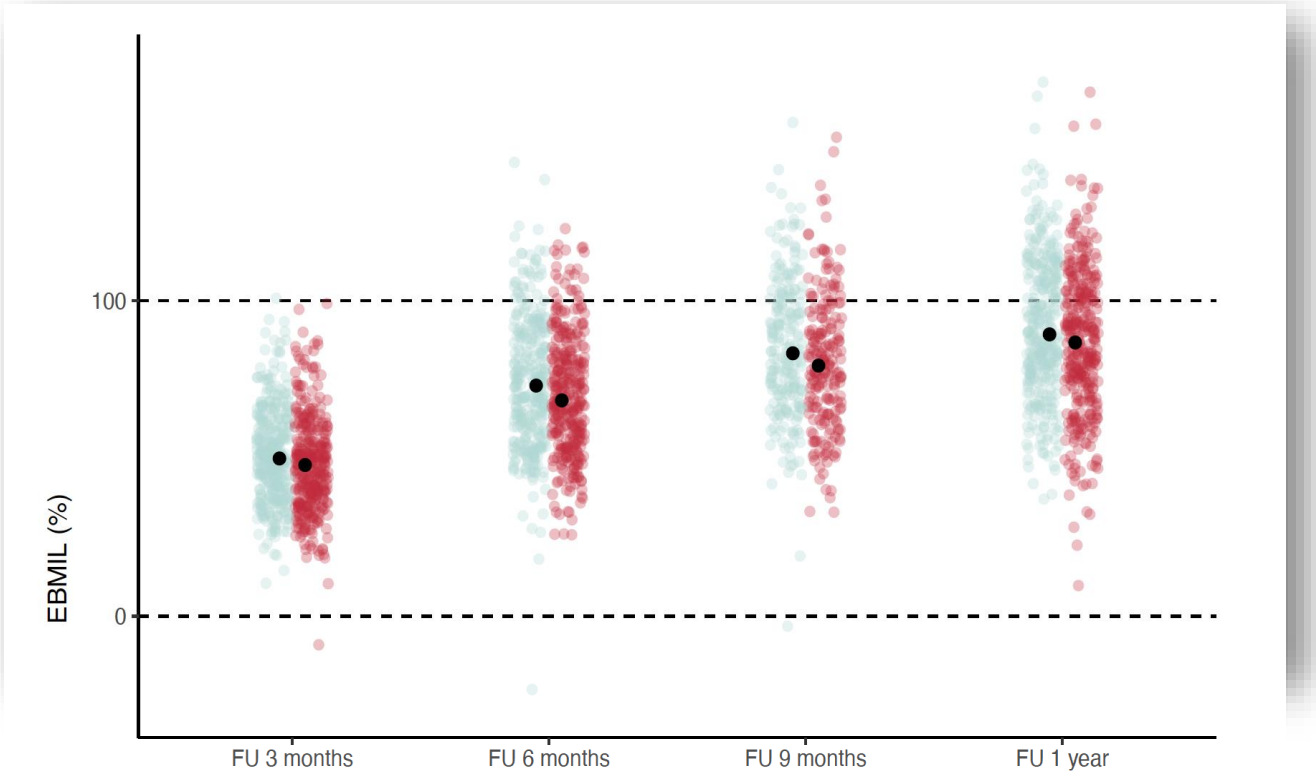
Short BPL RYGB

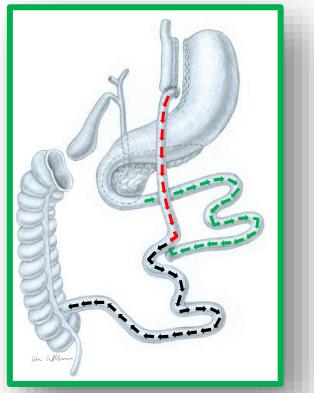
34.4 %
(29.4, 39.9)

1 Year Results

Weight loss

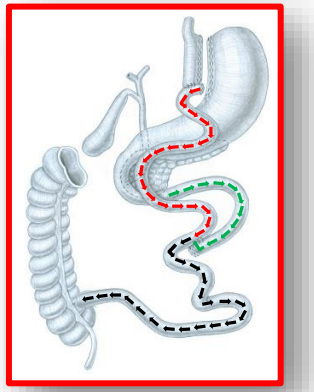
- % EBMI loss





Long BPL RYGB

~ 88 %



Short BPL RYGB

~ 84 %

1 Year Results

Nutritional Deficiencies

Deficiencies (%)	Short BPL (n=368)	Long BPL (n=349)
• 3 months	49.0	52.2
• 6 months	48.6	54.3
• 9 months	38.7	47.5
• 12 months	42.9	47.5
Any patient with event up to 12 months	69.8	72.0

Non-inferiority margin of 0.1 (10%)

1 Year Results

Nutritional Deficiencies

Type of deficiency (%)	Short BPL (n=368)	Long BPL (n=349)
• Anemia	11.1	14.8
• Iron	17.8	20.9
• Folate	13.2	19.2
• Zinc	23.5	30.8
• Albumin	2.6	4.4
• Vit. A	16.3	22
• Vit. B1	0.8	0.8
• Vit. B6	2.6	3.8
• Vit. B12	20.2	18.1
• Vit. D	48.8	50.5

Non-inferiority margin of 0.1 (10%)

1 Year Results *Morbidity*

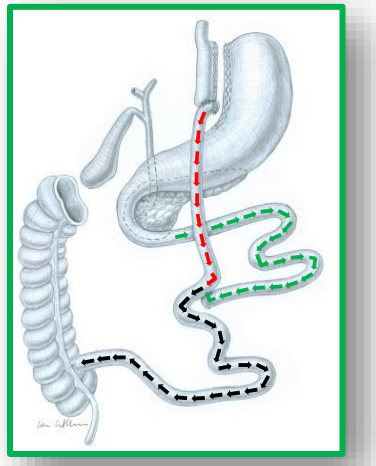
Reoperations	Short BPL (n=396)	Long BPL (n=383)
Early (<30d)	10 (2.5)	11 (2.9)
6 months	3 (0.8)	13 (3.4)
9 months	11 (2.8)	6 (1.6)
1 year	14 (3.5)	13 (3.4)
Total	38 (9.6)	43 (11)

Summary

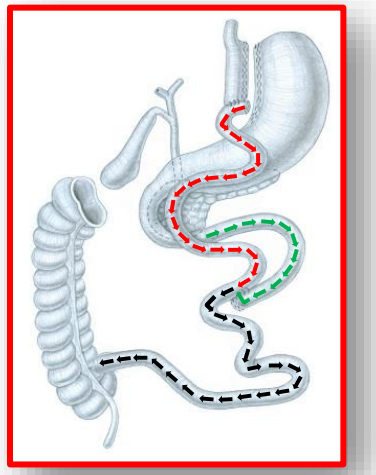
1-Year Results of SLIM Trial

- Total small bowel length varies
  - SLIM: 653 ± 113 cm (min 300 cm, max 1050 cm)
- Small bowel measurement:
  - >93 % possible
  - Takes < 14 min.
  - 1 additional trocar
  - Low risk (2/779 perforations)
- % WL similar (35.4 % vs 34.4 %)
- Nutritional deficiencies similar (72.0 % vs 69.8 %)

Long BPL RYGB



Short BPL RYGB



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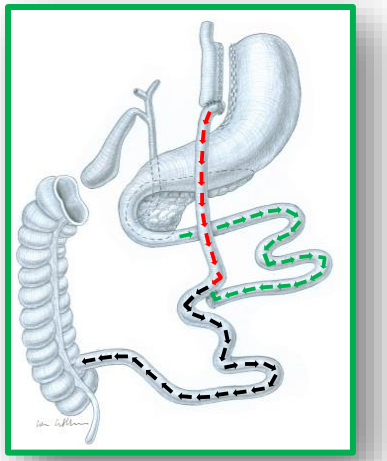
Conclusion

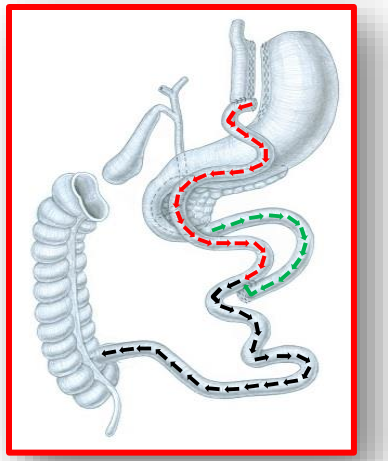
1-Year Results of SLIM Trial

- Today: ideal length of AL / BPL and CL not known
  - Tailored to the total bowel length?
  - Tailored to initial BMI, other parameters?
  - BPL always 150-200 cm?
  - SLIM trial will be able to analyse all segments involved

- Longer BPL may lead to:
  - Improved weight loss
  - Better metabolic effect (T2DM, dyslipidemia) ?
  - BUT: more deficiencies ?
    - up to 1 year no



vs



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