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Society of Bariatric and Metabolic Surgeons of Kazakhstan

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"Acid and Bile Reflux Esophagitis Prevention by Modified Fundoplication of the Excluded Stomach in One-Anastomosis Gastric Bypass: A Randomized Controlled Trial"

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No dislosure

Obesity Surgery
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ORIGINAL CONTRIBUTIONS

A Randomized Controlled Trial of Acid and Bile Reflux Esophagitis Prevention by Modified Fundoplication of the Excluded Stomach in One-Anastomosis Gastric Bypass: 1-Year Results of the FundoRing Trial

Oral Ospanov[1,2] · Galymzhan Yeleuov[1] · J. N. Buchwald[3] · Nurlan Zharov[1] · Bakhtiyar Yelembayev[2] · Kassymkhan Sultanov[4]

Received: 19 February 2023 / Revised: 14 April 2023 / Accepted: 19 April 2023

Abstract

Background The advantages and disadvantages of one-anastomosis gastric bypass (OAGB) with primary modified fundoplication using the excluded stomach ("FundoRing") is unclear. We aimed to assess the impact of this operation in a randomized controlled trial (RCT) and answer the next questions: (1) What the impact of wrapping the fundus of the excluded part of the stomach in OAGB on protection in the experimental group against developing de novo reflux esophagitis? (2) If preoperative RE could be improved in the experimental group? (3) Can preoperative acid reflux as measured by PH impedance, be treated by the addition of the "FundoRing"?

Methods The study design was a single-center prospective, interventional, open-label (no masking) RCT (FundoRing Trial) with 1-year follow-up. Endpoints were body mass index (BMI, kg/m^2) and acid and bile RE assessed endoscopically by Los Angeles (LA) classification and 24-h pH impedance monitoring. Complications were graded by Clavien-Dindo classification (CDC).

Results One hundred patients ($n=50$ FundoRingOAGB (f-OAGB) vs $n=50$ standard OAGB (s-OAGB)) with complete follow-up data were included in the study. During OAGB procedures, patients with hiatal hernia underwent cruroplasty (29/50 f-OAGB; 24/50 s-OAGB). There were no leaks, bleeding, or deaths in either group. At 1 year, BMI in the f-OAGB group was 25.3 ± 2.77 (19–30) vs 26.48 ± 2.8 (21–34) s-OAGB group ($p=0.03$). In f-OAGB vs s-OAGB groups, respectively, acid RE was seen in 1 vs 12 patients ($p=0.001$) and bile RE in 0 vs 4 patients ($p<0.05$).

Conclusion Routine use of a modified fundoplication of the OAGB-excluded stomach to treat patients with obesity decreased acid and prevented bile reflux esophagitis significantly more effectively than standard OAGB at 1 year in a randomized controlled trial.

Trial Registration **ClinicalTrials.gov Identifier:** NCT04834635.

Keywords Obesity · Bariatric surgery · Acid and bile reflux esophagitis · One-anastomosis gastric bypass · Fundoplication · FundoRingOAGB · Modified fundoplication of the OAGB-excluded stomach

Key Points
- Modified fundoplication of the OAGB used excluded stomach treats obesity and reflux esophagitis.
- Wrapping fundus of the excluded stomach in OAGB protected developing de novo reflux esophagitis.
- Primary fundoplication of the OAGB used excluded stomach prevented bile reflux esophagitis.
- Primary FundoRingOAGB used excluded stomach should be used routinely in each case of OAGB.

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Introduction

A randomized controlled trial (RCT) comparison of Roux-en-Y gastric bypass (RYGB) and one-anastomosis gastric bypass (OAGB), the YOMEGA Trial, demonstrated the non-inferiority of OAGB weight loss and metabolic outcome improvement at 2-year follow-up [1]. While OAGB has shown overall efficacy and safety, the procedure has been associated with a higher incidence of biliary reflux [2, 3]. Medical treatment-resistant biliary reflux has an incidence

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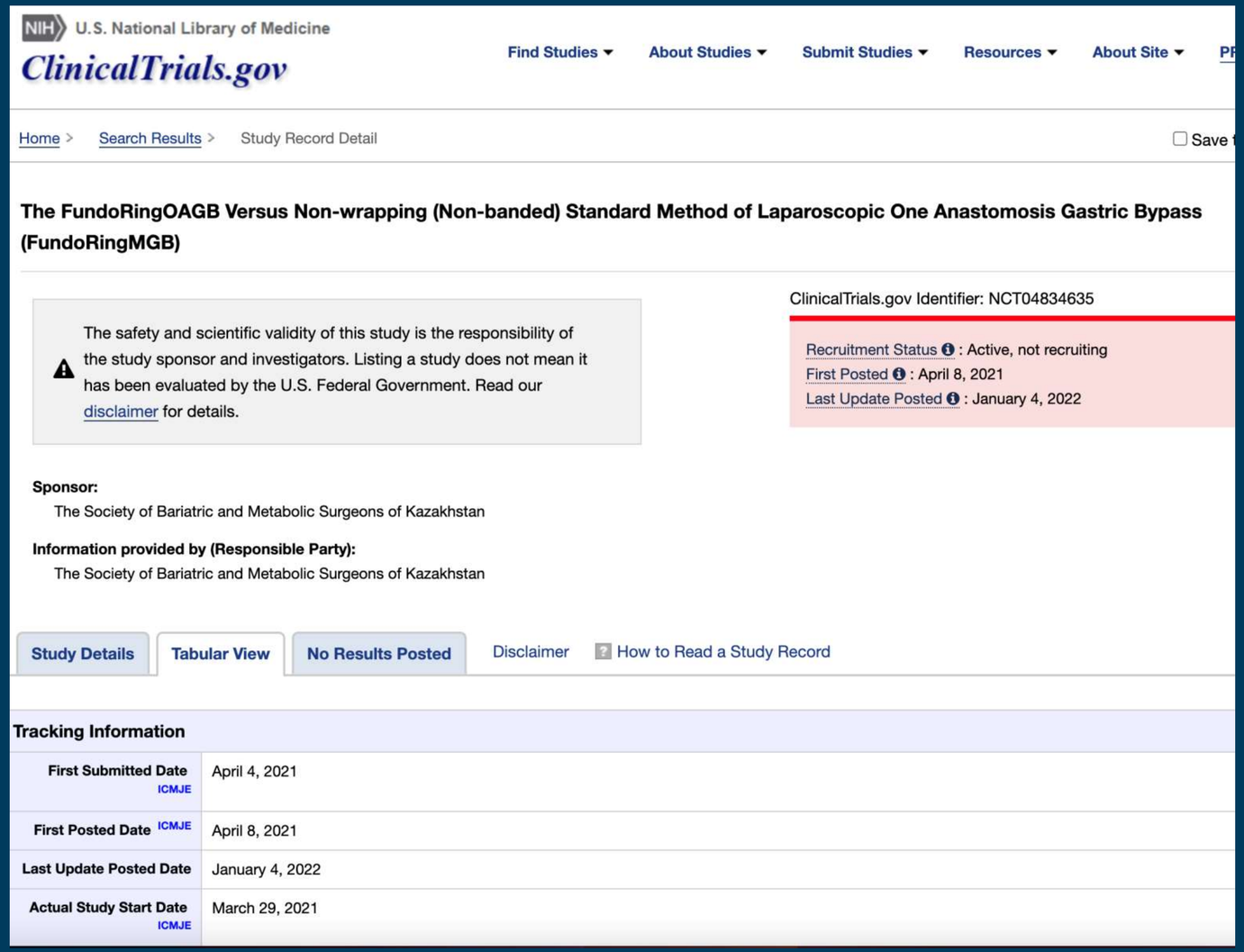
The FundoRingOAGB versus non-wrapping (non-banded) standard method of laparoscopic one anastomosis gastric bypass. Available from: https://clinicaltrials.gov/ct2/show/NCT04834635



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The FundoRingOAGB Versus Non-wrapping (Non-banded) Standard Method of Laparoscopic One Anastomosis Gastric Bypass (FundoRingMGB)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04834635

Recruitment Status : Active, not recruiting
First Posted : April 8, 2021
Last Update Posted : January 4, 2022

Sponsor:
The Society of Bariatric and Metabolic Surgeons of Kazakhstan

Information provided by (Responsible Party):
The Society of Bariatric and Metabolic Surgeons of Kazakhstan

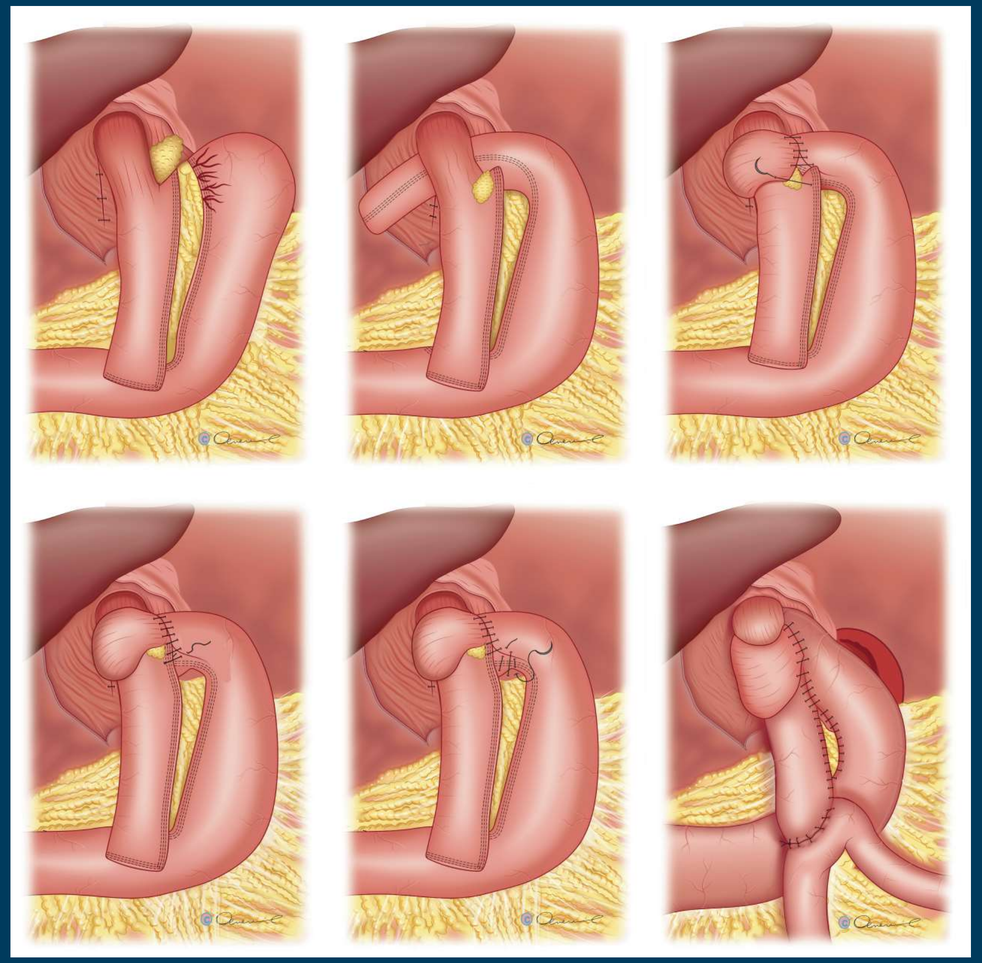
Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Tracking Information

First Submitted Date ICMJE	April 4, 2021
First Posted Date ICMJE	April 8, 2021
Last Update Posted Date	January 4, 2022
Actual Study Start Date ICMJE	March 29, 2021

Modified Fundoplication of the Excluded Stomach in OAGB - FundoRingOAGB

What is a concept?

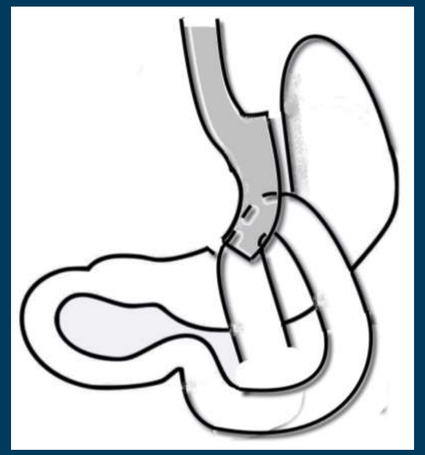


Ospanov O. The Surgical Technique of Primary Modifies Fundoplication Using the Excluded Stomach with Simultaneous Gastric Bypass. Obes Surg. 2023 Apr;33(4):1311-1313. doi: 10.1007/s11695-023-06505-6. Epub 2023 Feb 17. PMID: 36800158.

1. Concept of FundoRingOAGB

- **Primary fundoplication (Simultaneous)**

is easier and safer in OAGB than during revision surgery



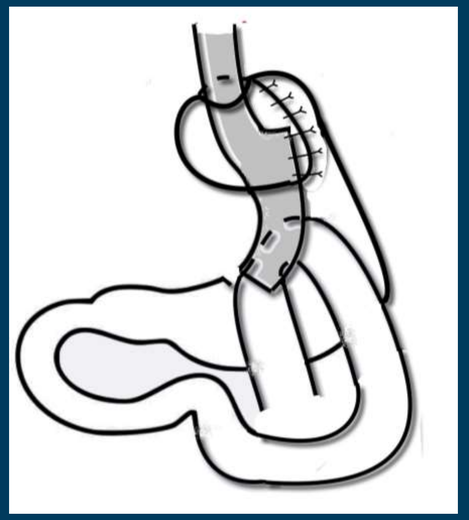
VS

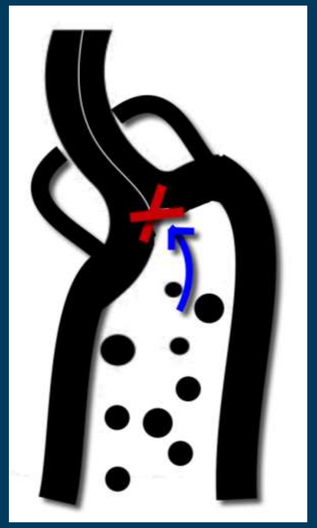
2. Concept of FundoRingOAGB

- **Reinforced anti reflux mechanism:**

- The large length (5-6 cm) of the fundoplication wrap. 2/3 of wrap positioned on abdominal part of esophagus and 1/3 wrap on the pouch

- **Double calibration**





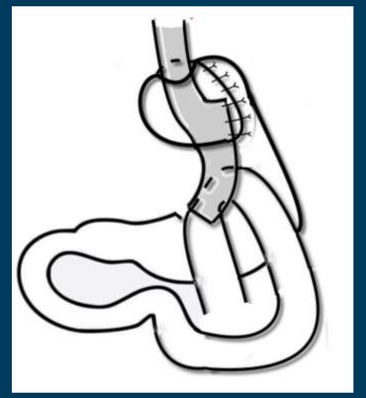
3. Concept of FundoRingOAGB

- **“Gastric Banding”**

1/3 of fundoplication positioned on upper part of the pouch.

Double calibrated wrap: first at 1 o`clock and second at 3-4 o`clock creates a fundoplication Ring - FundoRing.

FundoRing **FobiRing**



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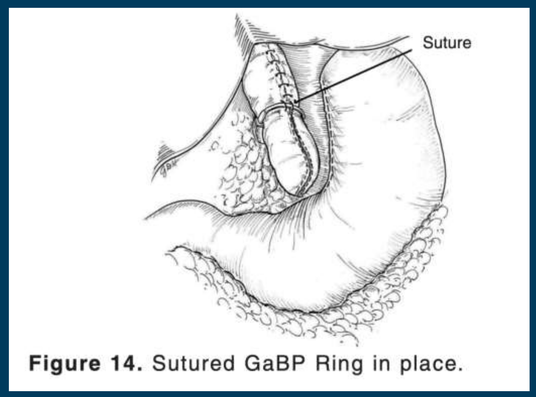


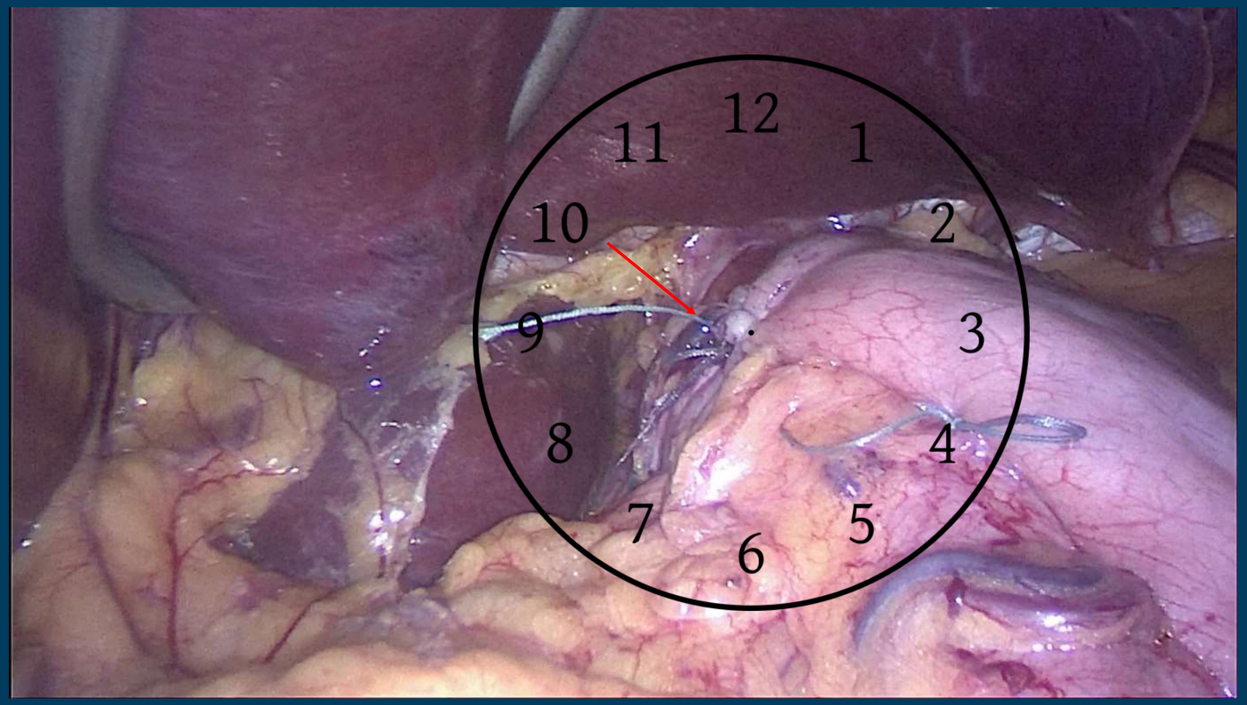
Figure 14. Sutured GaBP Ring in place.

Material: living autologous tissues
Width: 4-6 cm
Elasticity: high
Probability of gastric wall decubitus: none
Insertion site: abdominal oesophagus and upper gastric pouch

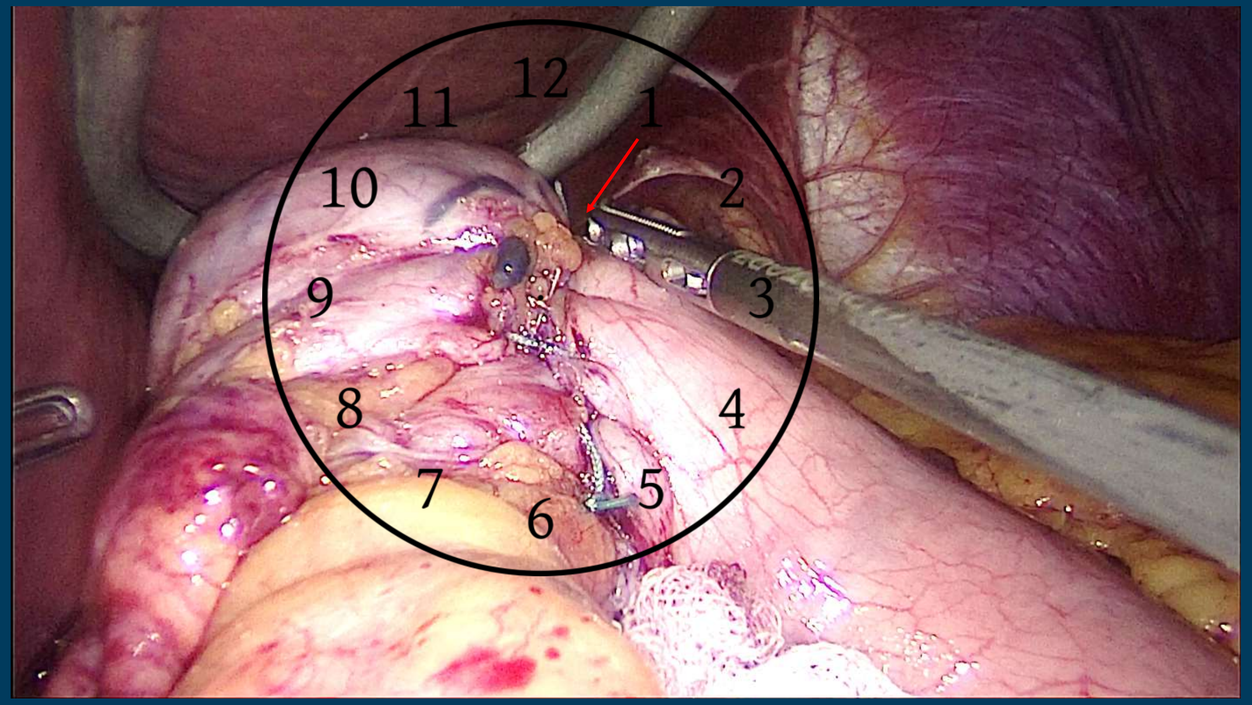
First calibration (suturing) at 1 o`clock

- The fundoplication wrap according to Nissen is formed at 10 o'clock of the conventional dial (take tissue in equal distance from the greater curvature of the stomach!)

- FundoRing formed matching to the stapler line on the pouch! In addition, in this way it closes the weak points of the pouch.



Nissen fundoplication

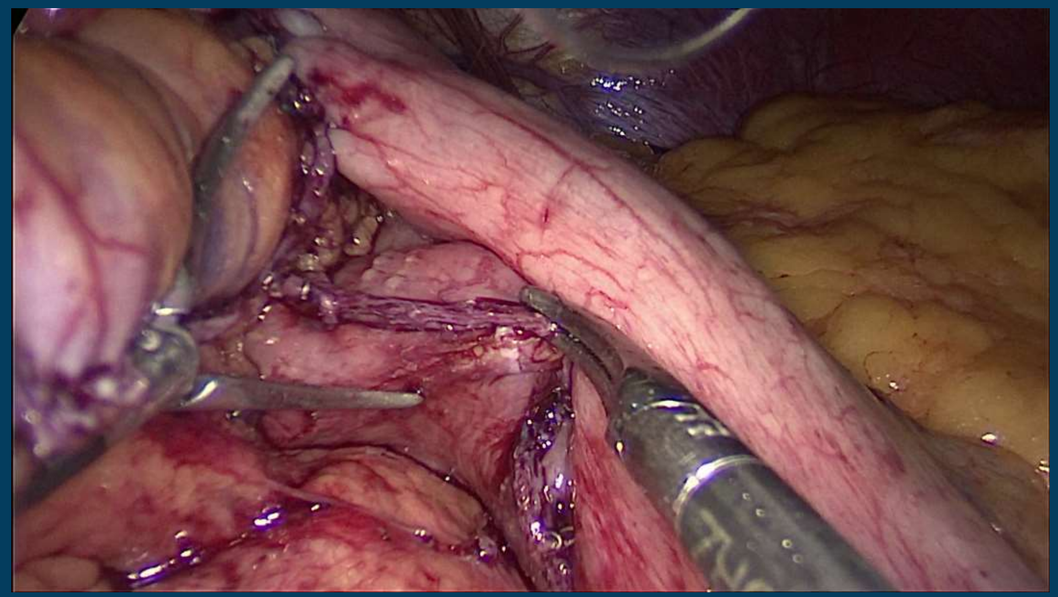


FundoRingOAGB

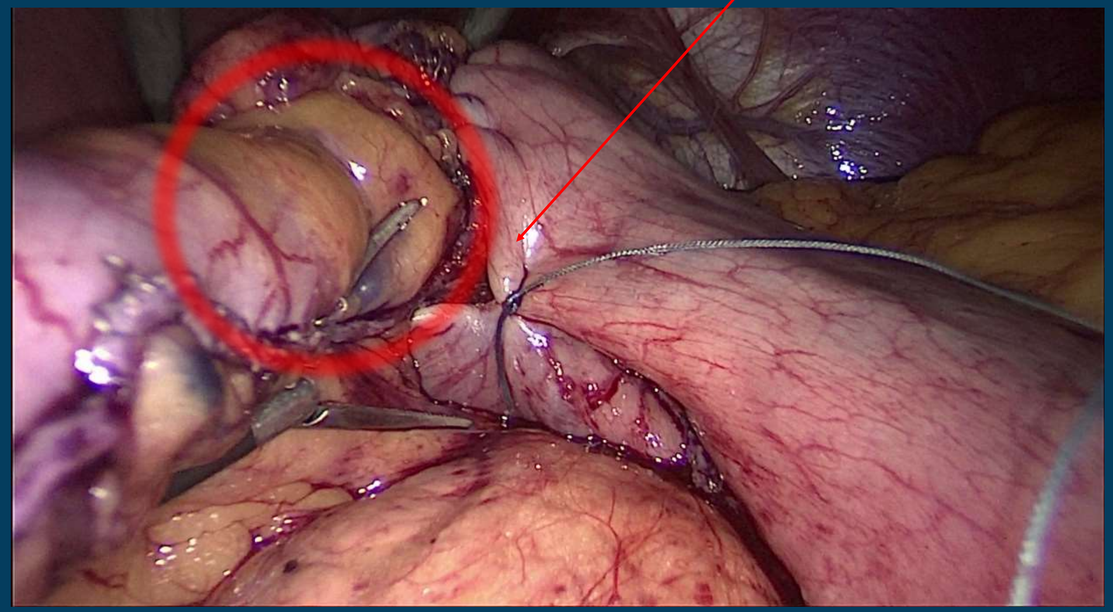
Second calibration at 3-4 o`clock creates a fundoplication ring (Most important difference from Nissen)

- The anterior and posterior walls of the excluded part of the stomach are sutured together. Finally forming a "living ring" FundoRing.

Calibration of wrap tension from the “greater curvature” side

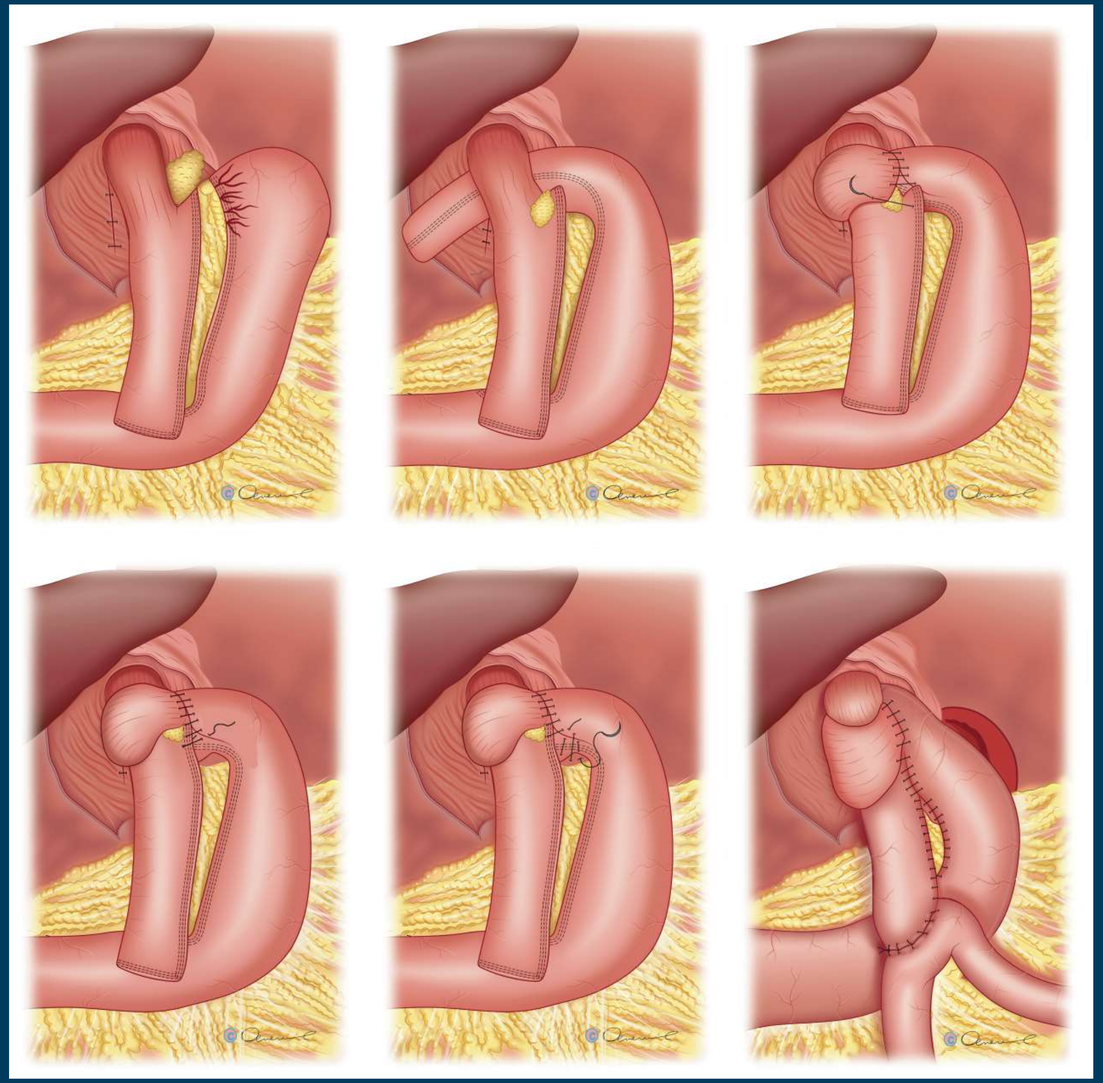


Fundoplication ring



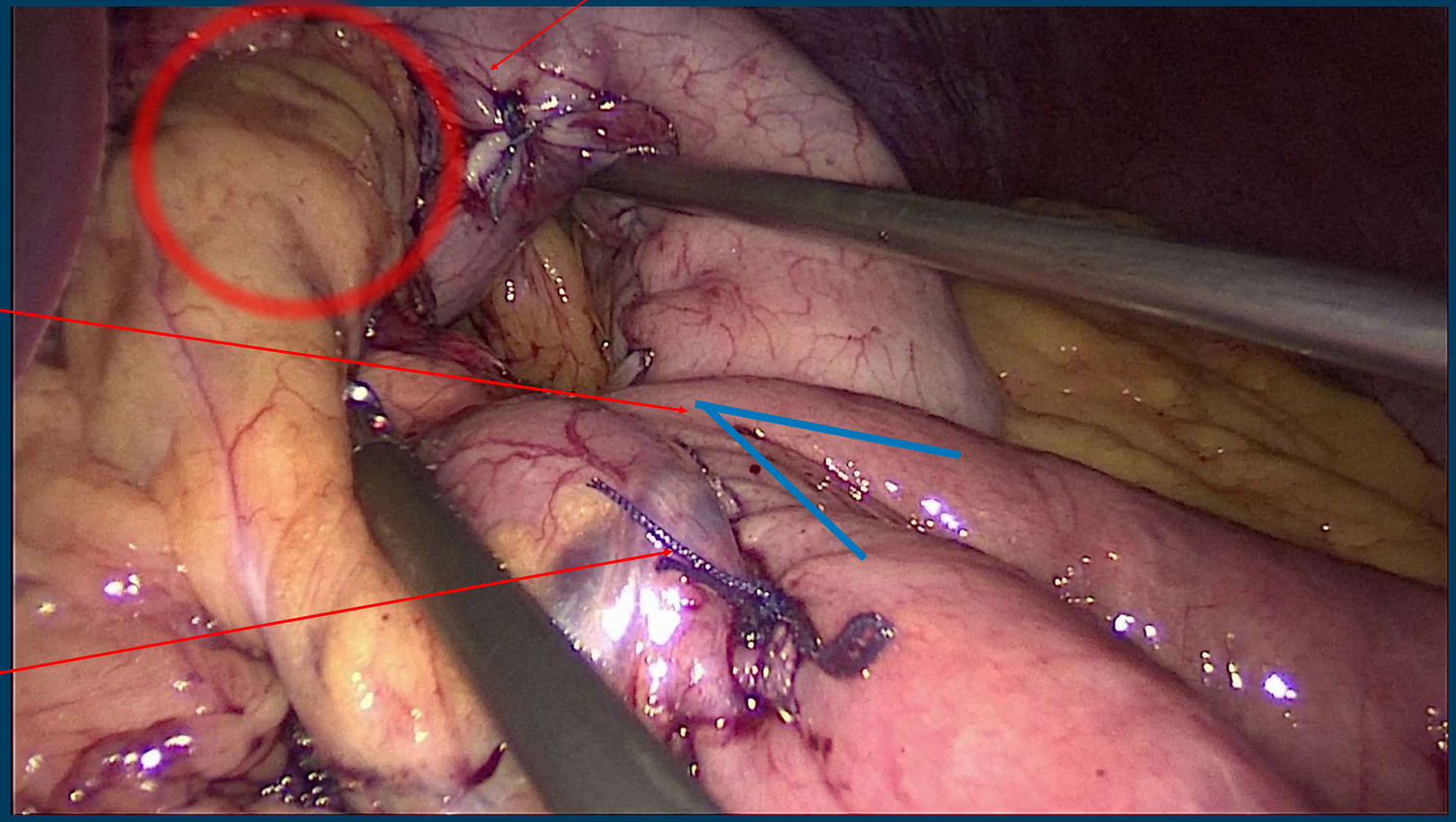
Key Points of FundoRingOAGB

- The large length (5-6 cm) of the fundoplication wrap.
- The suture of fundoplication wraps must orient to the stapler suture line on the gastric pouch.
- Double calibrated wrap: first at 1 o`clock and second at 3-4 o`clock creates a fundoplication ring.



Completion of FundoRingOAGB according to our method with an additional standard antireflux “spur”

- FundoRing
- Antireflux spur
- GEA



Methods

The study design - single-center prospective, interventional, open-label (no masking) RCT.
f-OAGB experimental procedure (n = 50) vs s-OAGB control group (n = 50)
1-year follow-up.

Endpoints:

Body mass index (BMI, kg/m2)

Acid RE endoscopically by Los Angeles (LA) classification and 24-h pH impedance monitoring

Bile RE

Obesity Surgery
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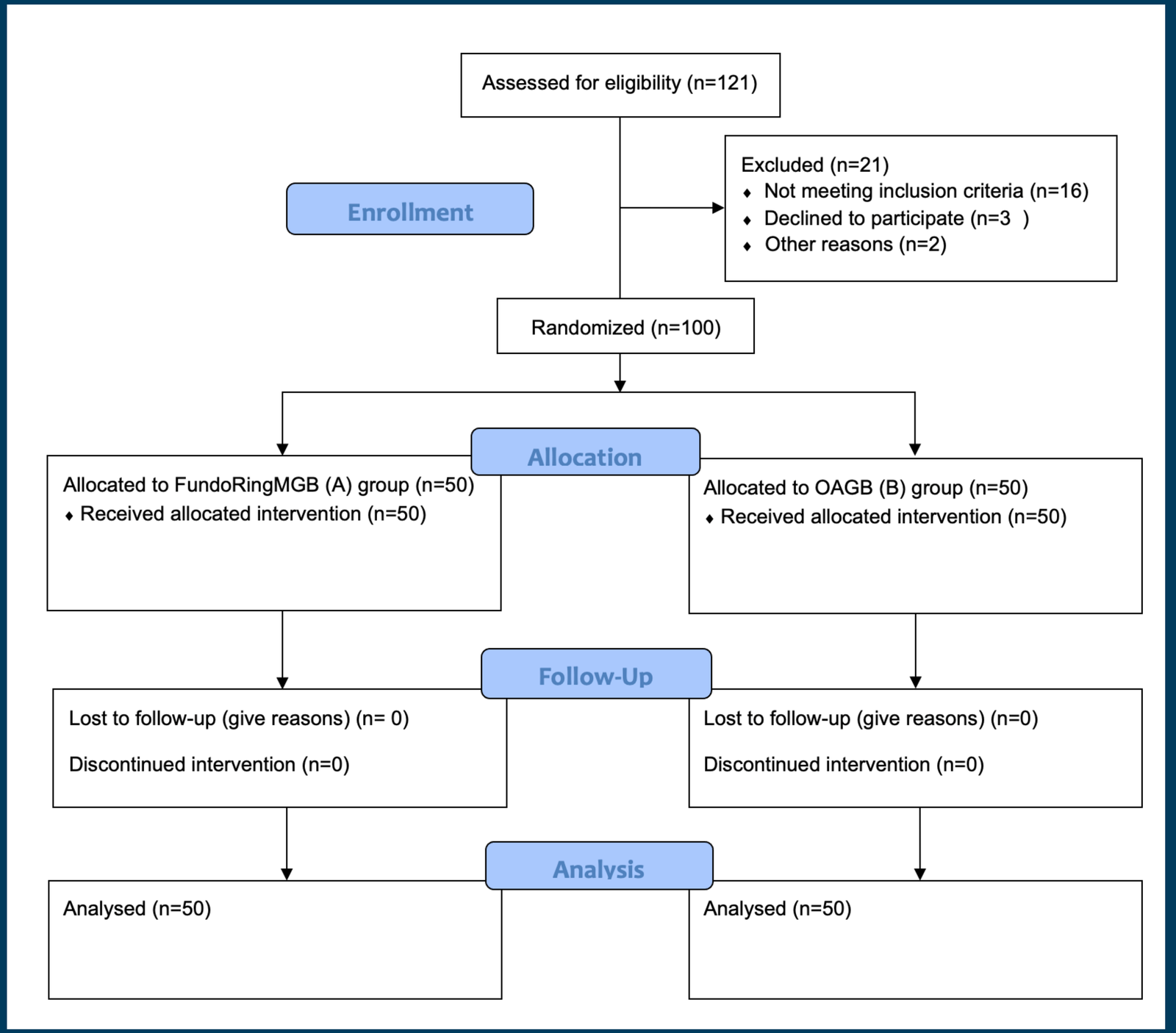
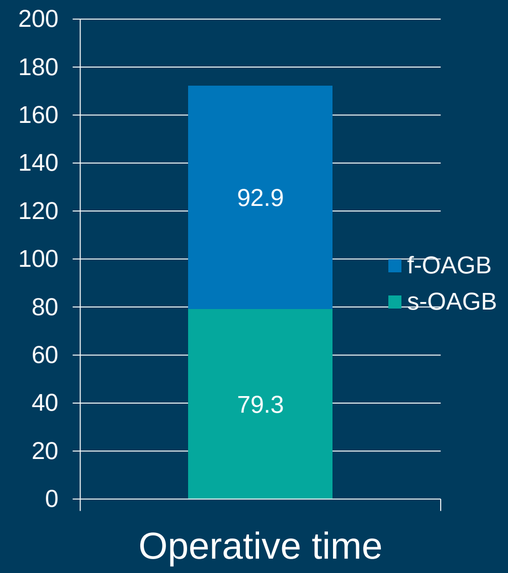
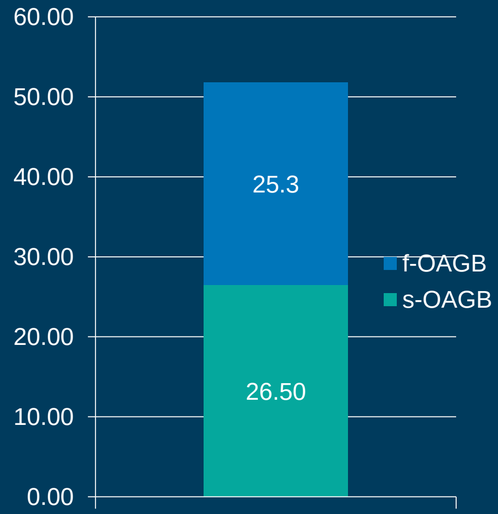

Assessed for eligibility (n=121)
Enrollment
Excluded (n=21)
♦ Not meeting inclusion criteria (n=16)
♦ Declined to participate (n=3)
♦ Other reasons (n=2)
Randomized (n=100)
Allocation
Allocated to FundoRingMGB (A) group (n=50)
♦ Received allocated intervention (n=50)
Allocated to OAGB (B) group (n=50)
♦ Received allocated intervention (n=50)
Follow-Up
Lost to follow-up (give reasons) (n= 0)
Discontinued intervention (n=0)
Lost to follow-up (give reasons) (n=0)
Discontinued intervention (n=0)
Analysis
Analysed (n=50)
Analysed (n=50)

Table 1. Baseline characteristics, operative and hospital duration, and 1-year change in body mass index after FundoRing (f-OAGB) vs Standard OAGB (s-OAGB)

	f-OAGB (n=50) mean±SD (range)	s-OAGB (n=50) mean±SD (range)	*P-value
Age (years)	40.3±10.3 (20-64)	39.2±8.6 (19-53)	0.57
Sex (female/male)	45/5	44/6	—
Weight (kg)	110.4±19.1 (75-160)	113.0±21.0 (78-178)	0.46
Height (cm)	1.7±0.6	1.7±0.8	0.8
BMI (kg/m^2)	40.6±5.9 (31-53)	40.9±6.2 (32-56)	0.96
Average operative time (min)	92.9±10.9	79.3±15.5	0.0001
Median length of hospital stay (days)	3.2±0.75	3.2±0.71	0.78
BMI (kg/m^2) at 1 year follow-up	25.3±2.8 (19-30)	26.5±2.8 (21-34)	0.03
Change in BMI (kg/m^2) (95% CI)	15.3 (13.47)	14.4 (12.46)	—



Operative time



BMI af 1 year

Table 2. Proportion of patients with hiatal hernia in the FundoRing (f-OAGB) vs Standard OAGB (s-OAGB) groups

	f-OAGB (n=50)				s-OAGB (n=50)			
	Small HH (≤ 2 cm)	Moderate HH (>2 – ≤4 cm)	Large HH (>4 – ≤5 cm)	Total	Small HH (≤2 cm)	Moderate HH (>2 – ≤4 cm)	Large HH (>4 – ≤5 cm)	Total
Preoperatively diagnosed GERD	13	5	1	19	10	6	1	17
Intraoperatively diagnosed HH without preop-erative GERD	4	6	0	10	5	2	0	7
Total	17	11	1	29/50	15	8	1	24/50

Table 3. Patients with endoscopically diagnosed acid/bile reflux esophagitis at 1-year postoperative FundoRing (f-OAGB) vs Standard OAGB (s-OAGB) using the Los Angeles Classification System

	f-OAGB (n=50)		s-OAGB (n=50)		P-value† x^2
Name of Subgroup	Baseline	≥12 mo. (A)	Baseline	≥12 mo. (B)	≥12 mo. A vs B
1.Preop no acid RE (n)	31/50	30/50	33/50	29/50	
1.1. De novo acid RE (n):	-	0/31	-	4/33	0.045; x^2=4.0
LA grade A	-	0		3	
LA grade B	-	0		1	
1.2. De novo bile RE (n):	-	0/31	-	1/33	
LA grade A		0		1	
LA grade B		0		0	
LA grade C		0		0	
2.Preop acid RE (n)	19/50	1/50	17/50	8/50	
2.1. permanent acid RE (n):	19	1/19	17	8/17	0.0038 x^2=8.35
LA grade A	11	1	12	7	
LA grade B	8	0	5	1	
LA grade C	0	0	0	0	
2.2. De novo bile RE (n):	-	0/50	-	3/50	
LA grade A	-		-	1	
LA grade B	-		-	1	
LA grade C	-		-	1	
Totally N De novo bile RE	-	0/50	-	4/50	0.039 x^2=4.25

Table 4. Patients with preoperatively diagnosed distal acid reflux esophagitis based on pH-impedance monitoring at 1 year after FundoRing (f-OAGB) vs Standard OAGB (s-OAGB)

	f-OAGB (n=19) mean±SD			s-OAGB (n=17) mean±SD		
	Baseline	≥12 mo.	*P-value	Baseline	≥12 mo.	*P-value
% Total time pH <4 min	6.2±4.0	1.55±1.34	0.001	6.1±5.5	5.0±4.7	ns
% Upright time pH <4 min	9.3±8.0	2.4±2.2	0.001	9.0±7.2	8.0±5.1	ns
% Recumbent time pH <4 min	4.0±3.7	0.9±1.0	0.001	4.0±2.3	4.0±0.8	ns
Number of reflux episodes	55.0±21.0	19.0±13.0	0.01	57.0±24.0	47.0±17.0	ns
Number of reflux episodes with pH <4 for ≥5 min	4.6±3.9	1.0±1.2	0.01	4.8±5.0	4.4±0.3	ns
Longest single acid exposure episode min	32.6±19.1	6.4±7.1	0.0001	32.4±24.0	23.1±8.45	0.0013
DeMeester score	18.0±9.3	3.7±1.4	0.001	19.0±5.0	17.3±4.4	0.14

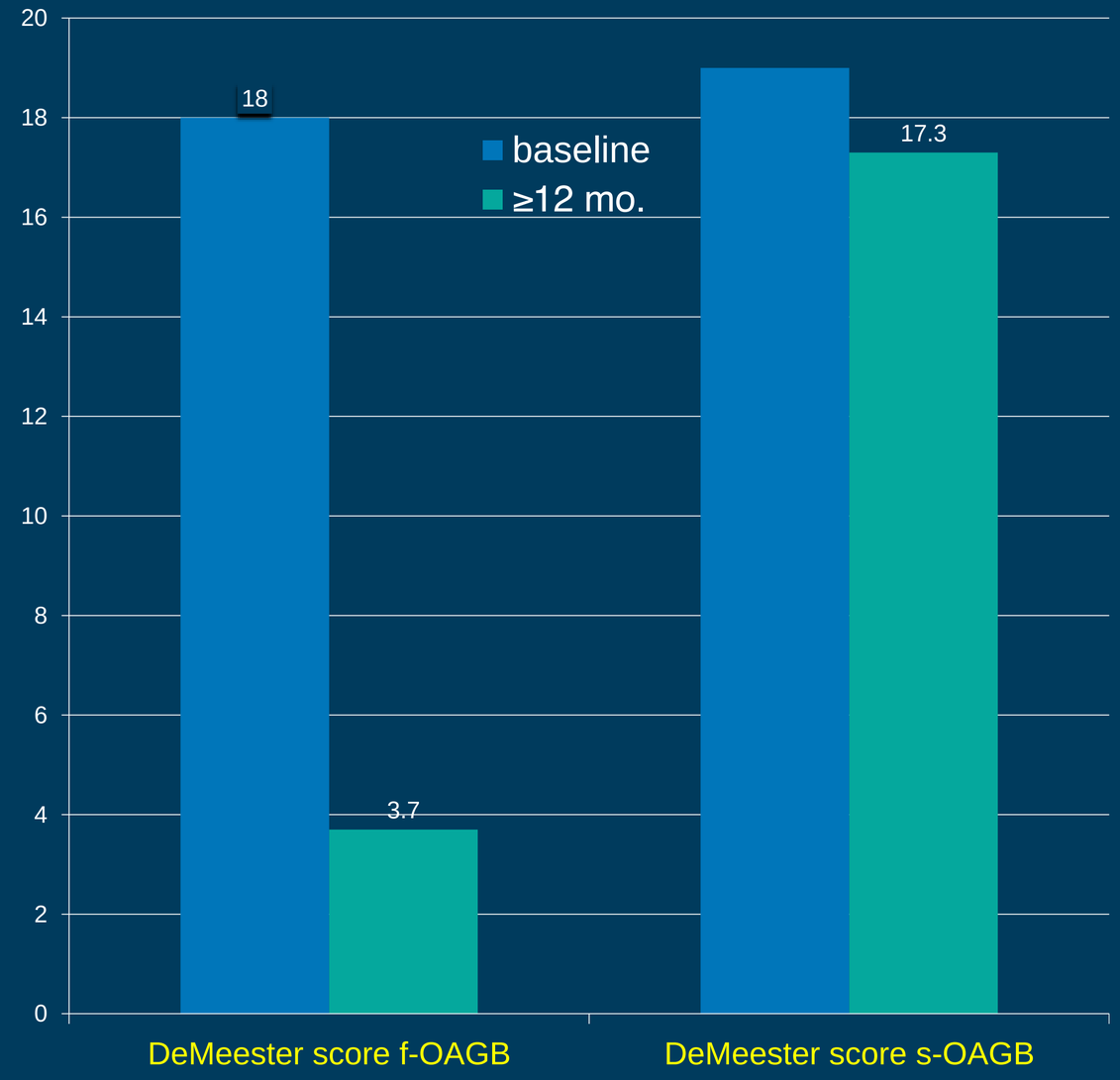


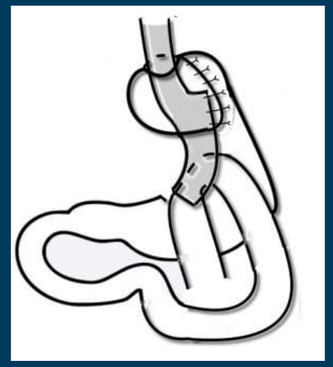
Table 5. Complications (CDC) of the FundoRing (f-OAGB) vs Standard OAGB (s-OAGB) through 1 year

	f-OAGB (n=50)	s-OAGB (n=50)	P-value
Total complications	5/50	12/50	0,06 x^2=3,47
Vomiting/food intolerance (CDC I)	5/50	4/50	0.72; x^2=0.12
De novo acid reflux esophagitis (CDC I)	0/31	4/33	0.045; x^2=4.0
Total bile reflux:	0/50	4/50	0.04; x^2=1.16
Bile reflux (CDC I)	0	3	–
Bile reflux conversion OAGB to RYGB (CDC IIIb) at 13 mo.	0	1	–

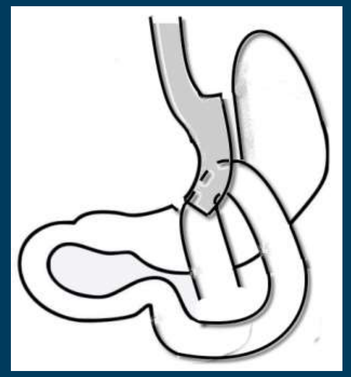
Conclusion:

FundoRingOAGB:

- treats obesity and reflux esophagitis
- protected developing de novo reflux esophagitis
- prevented bile reflux esophagitis
- should be used routinely in each case of OAGB



FundoRingOAGB



Standard OAGB

Thank you for your attention!