Session III. 비만에 대한 기술 기반 중재
(technology-based interventions)

체중 감량을 위한 새로운 장치들

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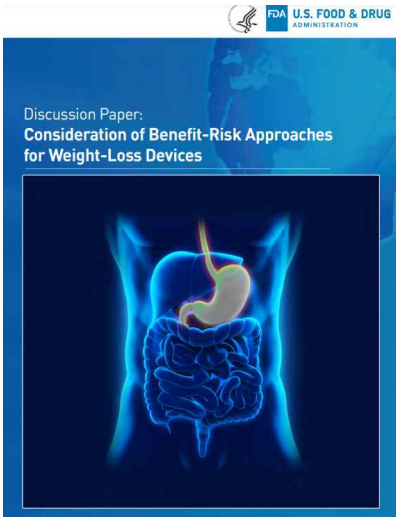
체중 감량을 위한 새로운 장치들

Table 1. FDA approved devices intended for weight loss (*in reverse chronological order*)

Device Name	Device Type	Marketing Application	Date Approved
Transpyloric Shuttle	Intragastric implant	P180024	April 16, 2019
Obalon Balloon System	Intragastric implant	P160001	September 8, 2016
AspireAssist	Aspiration therapy system	P150024	June 14, 2016
Orbera Intragastric Balloon System	Intragastric implant	P140008	August 5, 2015
ReShape Integrated Dual Balloon System*	Intragastric implant	P140012	July 28, 2015
MAESTRO Rechargeable System**,#	Neuromodulator	P130019	January 14, 2015
REALIZE Adjustable Gastric Band*	Restrictive band	P070009	September 28, 2007
LAP-BAND Adjustable Gastric Banding System	Restrictive band	P000008	June 5, 2001
Garren Gastric Bubble*	Intragastric implant	P840025	September 17, 1985

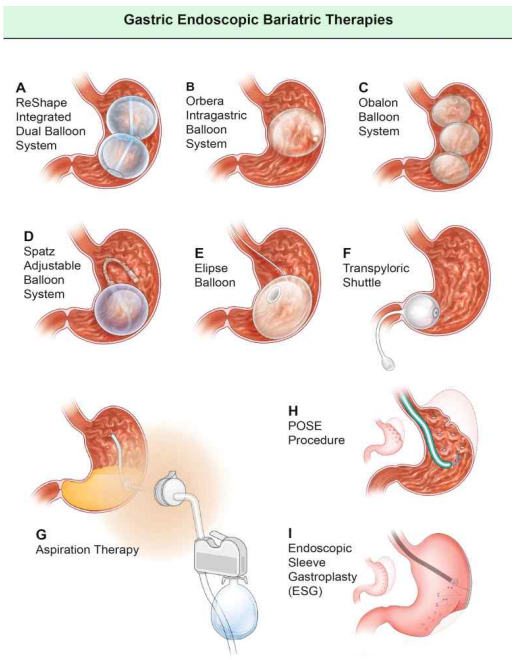
* voluntarily removed from the market; ** no longer commercially distributed; # also known as ReShape vBloc



FDA approved devices

Weight-Loss Devices : three types

- Gastric Band
  - Lap-Band Adjustable Gastric Banding System
- Gastric Balloon Systems
  - ORBERA Intragastric Balloon System
  - Obalon Balloon System
  - TransPyloric Shuttle/TransPyloric Shuttle Delivery Device
  - Spatz3 Adjustable Balloon System
- Endoscopic suturing devices for altering gastric anatomy
  - Apollo Endoscopic Sleeve Gastroplasty and Revise Systems



Sullivan, Shelby et al. "Endoscopic Bariatric and Metabolic Therapies: New and Emerging Technologies." *Gastroenterology* vol. 152,7 (2017): 1791-1801.

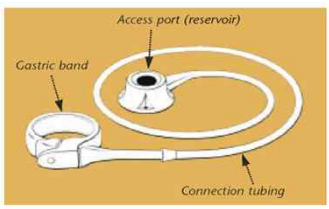
FDA approved devices

Weight-Management Devices : two types

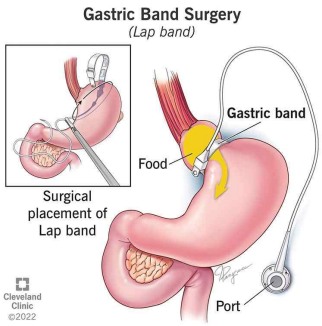
- Oral Removable Palatal Space Occupying Device
  - Sensor Monitored Alimentary Restriction Therapy (SMART) Device
- Ingested, Transient, Space Occupying Device
  - Plenity

1. Gastric Band

- **Lap-Band Adjustable Gastric Banding System (LAP-BAND®)**
- Surgically implanted device
  - the band is placed around the upper part of the stomach
  - leaving only a small portion available for food



The LAP-BAND Adjustable Gastric Banding System



1. Gastric Band

- The system helps the patient eat less by
  - limiting the amount of food that can be eaten at one time
  - increasing the time it takes for food to be digested

- Long-term (no maximum duration specified by FDA)

1. Gastric Band

Table 2. Weight, blood pressure, eating questionnaire baseline and yearly outcomes data for 5 years

	Baseline	*1 year*	*2 year*	*3 year*	*4 year*	*5 year*
No. of subjects	149	140	132	125	105	108
% EWL[a]	—	65.0 ± 29.8	70.7 ± 32.0	67.7 ± 38.7	65.8 ± 39.7	62.7 ± 41
% Achieving ⩾ 30% % EWL[b]	—	84.6%	85.9%	81.3	78.1%	76.9%
Weight (kg)[a]	98.16 ± 11.1	79.2 ± 11.1	77.8 ± 12.2	78.4 ± 12.2	78.8 ± 12.6	79.4 ± 12.4
BMI (kg m^{-2})[a]	35.6 ± 2.5	28.8 ± 3.2	28.2 ± 3.3	28.5 ± 3.9	28.7 ± 4.2	29.0 ± 4.5
% Weight loss[a]	—	18.4 ± 8.4	20.0 ± 9.2	19.0 ± 10.8	18.8 ± 11.6	17.9 ± 12.1
Waist circumference (cm)[a]	105.5 ± 11.2	89.9 ± 10.7	90.2v11.2	90.9 ± 11.2	89.2 ± 11.6	90.2 ± 11.9
Blood pressure						
Systolic BP (mm Hg)[a]	127.6 ± 12.9	119.5 ± 15.5	121.8 ± 13.8	120.4 ± 14.7	119.5 ± 13.5	121.5 ± 13.5
Diastolic BP (mm Hg)[a]	78.2 ± 9.8	76.0 ± 9.0	77.4 ± 9.3	77.0 ± 9.5	78.8 ± 9.3	80.3 ± 10.2
Three factor eating questionnaire						
No. of subjects	149	144	135	126	104	104
Cognitive restraint[a]	10.4 ± 4.4	15.4 ± 3.9	14.7 ± 3.8	14.5 ± 3.9	14.9 ± 3.9	14.7 ± 4.1
Disinhibition[a]	9.6 ± 3.6	5.4 ± 3.3	4.8 ± 3.5	4.9 ± 3.5	4.8 ± 3.4	4.4 ± 3.2
Hunger[a]	7.1 ± 3.6	2.6 ± 2.8	2.5 ± 2.7	2.5 ± 2.7	2.7 ± 3.2	2.4 ± 2.9
Binge-eating disorder (QEWP-R)						
No. of subjects	149	142	134	125	104	100
N (%) with disorder[c]	20 (13.4)	0	1 (0.7)	1 (0.8)	1 (1)	4 (4)

Abbreviations: BMI, body mass index; BP, blood pressure; EWL, excess weight loss; QEWP-R, Questionnaire on Eating and Weight Patterns-Revised. [a]*P*-values for continuous variables based on paired *t*-test or Wilcoxon signed rank test based on *P*-value for normality test. [b]The proportion of responders significantly (exact 95% binomial confidence interval) exceeded 60% at each yearly follow-up. [c]*P*-values based on change from baseline by McNemar test. All dark shaded data differs significantly from baseline data with a *P*-value < 0.001 and lighter shaded < 0.05. There was no significant change in mean diastolic blood pressure throughout the study.

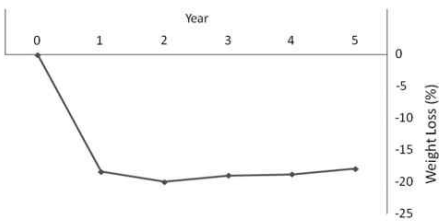


Figure 1. Weight trajectory over the 5 years for completer.

Dixon, J B et al. "LAP-BAND for BMI 30-40: 5-year health outcomes from the multicenter pivotal study." *International journal of obesity (2005)* vol. 40,2 (2016): 291-8.

1. Gastric Band

- **Most AEs were of gastrointestinal origin**
  - Nausea and vomiting
  - Heartburn (gastroesophageal reflux)
  - Abdominal pain

1. Gastric Band

Complications

- Proximal gastric enlargement
- band erosion or migration
- system leaks

Table 4 Device-related complications

Complication	*n* (%)
Slippage/prolapse	134 (4.52)
Port-related problems[a]	99 (3.34)
Band-related problems[b]	49 (1.65)
Band erosion	7 (0.24)

[a] Includes leak, abscess, disconnection, port infection, migration, or ulceration

[b] Includes band intolerance or removal, leak or perforation, device-related obstruction, or device-related malfunction

Carelli, Allison M et al. "Safety of the laparoscopic adjustable gastric band: 7-year data from a U.S. center of excellence." *Surgical endoscopy* vol. 24,8 (2010): 1819-23.

2. Gastric Balloon Systems

- inflatable balloons are placed in the stomach to take up space and delay gastric emptying.

Fig 1. (A) Orbera (http://apolloendo.com), (B) ReShape Duo,™ (C) Obalon (http://www.obalon.com), (D) Spatz3,™ (E) Elipse,™ (F) Heliosphere BAG,™ (G) End-ball (http://www.endalis.com).

Cho, Joon Hyun et al. "The Clinical and Metabolic Effects of Intragastric Balloon on Morbid Obesity and Its Related Comorbidities."
Clinical endoscopy vol. 54,1 (2021): 9-16.

2. Gastric Balloon Systems

Contraindications

- have had prior gastrointestinal or bariatric surgery
- already have an intragastric balloon
- have inflammatory and other pathophysiological conditions of the GI tract
- have a history of structural or functional disorders of the stomach including, gastroparesis, gastric ulcer, chronic gastritis, gastric varices, hiatal hernia (> 2cm), cancer or any other disorder of the stomach.
- have allergies to products
- have alcoholism or drug addiction
- are pregnant or breast-feeding

2. Gastric Balloon Systems

Severe adverse events

- esophageal tear
- esophageal perforation
- aspiration pneumonia
- bleeding gastric ulcer
- gastric perforation

Table 3. Common Non-SAE in Intragastric Balloon US Pivotal Trials

Adverse event	ReShape (%)	Orbera (%)	Obalon (%)
Vomiting	86.7	86.8	17.3
Nausea	61.0	75.6	56.0
Abdominal pain	54.5	57.5	72.6
Gastric ulcer	35.2[a]	0	0.9
Dyspepsia	17.8	21.3	16.9[c]
Eructation	16.7	24.4	9.2
Abdominal discomfort	13.3	6.3	0
Abdominal distension	11.0	17.5	14.6
Erosive gastritis	9.1	0.6	7.1[b]
GERD	6.8	30.0	(see dyspepsia)
Erosive esophagitis	0.4	0.6	1.8
Constipation	5.3	0	2.7
Diarrhea	3.0	13.1	8.3

GERD, gastroesophageal reflux disease; SAE, serious adverse event.
[a]After design modification of the distal tip of the ReShape Balloon, the ulcer rate decreased to 10%.
[b]Composite of erythema, erosion, inflammation, or polyp.
[c]Composite of dyspepsia and GERD.

2. Gastric Balloon Systems

Complications

- balloon migration
- intestinal obstruction
- gastric ulcer
- gastric perforation

2-1. ORBERA Intragastric Balloon System

- Placed and removed by endoscopically
  (while the patient is under mild sedation)
- silicone sphere, filled with 400–700 mL of saline

- Maximal implantation time : 6mo

2-1. ORBERA Intragastric Balloon System

Table 1. Prospective, Randomized Controlled Trials of Intragastric Balloons

IGB device	Study	Country	IGB implant time (wk)	Number of subjects		%EWL	%TBWL	BMI loss (kg/m^2)	*p*-value
				n (total)	Study arm				
Orbera	Genco et al. (2006)[39]	Italy	12	32	16 (IGB + diet) 16 (sham + diet)	34.0±4.8 2.1±1.0	NR	5.8±0.5 0.4±0.2	<0.001 (%EWL)
Orbera	Konop-ko-Zubrzy-cka et al. (2009)[40]	Poland	24	36	21 (IGB) 15 (diet + exercises)	NR	12.3 2.3	NR	<0.001
Orbera	Peker et al. (2011)[44]	Turkey	24	32	16 (IGB) 16 (laparoscopic band)	39.3 32.3	NR	NR	0.189
Orbera	Farina et al. (2012)[41]	Italy	24	50	30 (IGB + diet + exercise) 20 (sibutramine + diet + exercise)	NR	14.5±1.2 9.1±1.5	NR	<0.05
Orbera	Lee et al. (2012)[42]	Singapore	24	18	8 (IGB + diet + exercise) 10 (sham + diet + exercise)	NR	NR	1.69±0.89 0.54±0.54	<0.001
Orbera	Fuller et al. (2013)[43]	Australia	24	66	31 (IGB + behavioral modification) 35 (behavioral modification alone)	50.3 16.9	14.2 4.8	5.1 1.7	<0.001 (%EWL)

Cho, Joon Hyun et al. "The Clinical and Metabolic Effects of Intragastric Balloon on Morbid Obesity and Its Related Comorbidities." *Clinical endoscopy* vol. 54,1 (2021): 9-16.

2-2. Obalon Balloon System

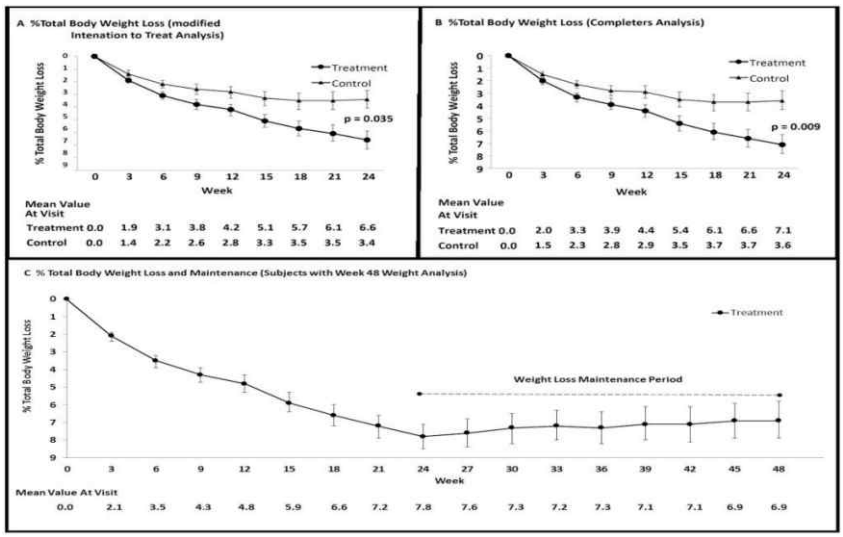
- Swallowable capsule that is attached to a thin (1 mm) inflation catheter
- Once in place, the capsule opens and the balloon is filled with air via the inflation catheter
- Thin polymer ellipse filled with 250 mL of a nitrogen mix gas

2-2. Obalon Balloon System

- The correct position of the capsule is confirmed with fluoroscopy
- 3 balloons administered over 9- to12-week period

- Maximal implantation time : 6mo
  - all balloons removed 6mo after first balloon placed
  - removed with an endoscopic procedure

2-2. Obalon Balloon System



Sullivan, Shelby et al. "Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss." *Surgery for obesity and related diseases : official journal of the American Society for Bariatric Surgery* vol. 14,12 (2018): 1876-1889

2-2. Obalon Balloon System

Table 4. GI-System Device Related Adverse Events Occurring in 10% or More of Subjects treated (Safety Population, n=336)

Device Related Adverse Event	Events	Subjects (%) N=336	Mild* #Events/ %Events	Moderate** #Events/ %Events	Severe*** #Events/ %Events	Onset**** (Days)	Event Duration (Days) #Events (% of Events)
Abdominal Pain	494	244 (72.6%)	414 (83.8%)	79 (16.0%)	1 (0.2%)	Median: 0 Mean: 10 Range: 0-112	0-7: 323 (65.4%) 8-14: 37 (7.5%) >14: 134 (27.1%)
Nausea	311	188 (56.0%)	261 (83.9%)	50 (16.1%)	0 (0.0%)	Median: 0 Mean: 11 Range: 0-90	0-7: 225 (72.3%) 8-14: 25 (8.0%) >14: 61 (19.6%)
Vomiting	71	58 (17.3%)	56 (78.9%)	15 (21.1%)	0 (0.0%)	Median: 1 Mean: 14 Range: 0-134	0-7: 59 (83.1%) 8-14: 5 (7.0%) >14: 7 (9.9%)
Indigestion/ Heartburn	69	57 (17.0%)	48 (69.6%)	20 (30.4%)	0 (0.0%)	Median: 5 Mean: 15 Range: 0-67	0-7: 22 (31.9%) 8-14: 4 (5.8%) >14: 43 (62.3%)
Bloating	54	49 (14.6%)	49 (90.7%)	5 (9.3%)	0 (0.0%)	Median: 2 Mean: 14 Range: 0-61	0-7: 22 (40.7%) 8-14: 3 (5.6%) >14: 29 (53.7%)

**Mild: Subject has an awareness of signs or symptoms, which are easily tolerated and causing no loss of time from normal daily activities; symptoms do not require prescription medications, other than those previously specified; actions taken are limited to clinical observations or diagnostic tests.*

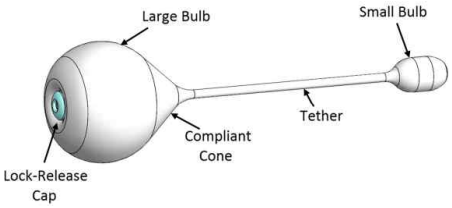
*** Moderate: Subject is experiencing transient periods of discomfort, interfering with normal daily activities; actions taken may include prescription medications beyond what is pre-specified; actions taken do not require hospitalization or invasive interventions.*

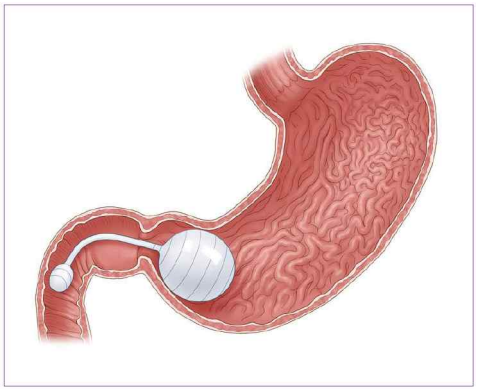
**** Severe: Subject is experiencing non-transient discomfort inhibiting performance of normal daily activities; actions taken require hospitalization or invasive interventions.*

***** Onset: Number of days from the time of balloon administration or removal that the Adverse Event began.*

2-3. TransPyloric Shuttle/ TransPyloric Shuttle Delivery Device

- smooth large bulb connected to a smaller bulb by a flexible silicone tether
- using the TPS Delivery Device
- Maximal implantation time : 12mo





2-3. TransPyloric Shuttle/ TransPyloric Shuttle Delivery Device

Table 8. %TBWL at 12 Months – PP Population

%TBWL12M	TPS (N=168)	Control (N=89)	Difference TPS-Control	p-value
LS* Mean (SE) 95% C.I.	9.5 (0.7) 8.2 to 10.8	2.8 (0.9) 1.1 to 4.5	6.7 (1.1) 4.5 to 8.8	< 0.0001

**Least Squares mean*

Table 9. Proportion of Subjects in the TPS Group Achieving ≥ 5% TBWL

	TPS (n=168)	p-value*
Proportion of subjects with ≥ 5% TBWL at 12-Months 95% C.I.	66.8% 59.3 to 74.3	< 0.0001

** p-value for the hypothesis that the proportion is equal to 0.5.*

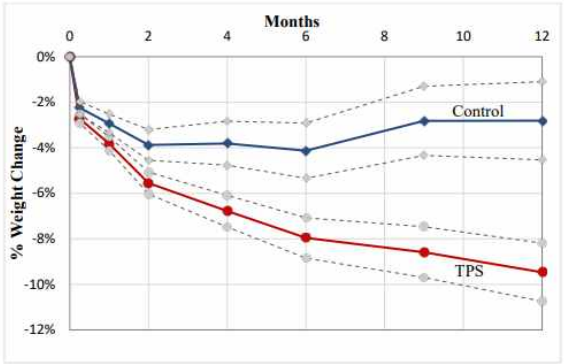


Figure 5. TPS and Control Group Weight Loss Over Time (PP Population)
(Solid lines are mean % weight change, and the dotted lines represent the 95% confidence interval for the means)

2-3. TransPyloric Sh…
TransPyloric Sh

Table 2. Device or Procedure-Related Serious Adverse Events

SAEs by MedDRA Categorization	# of Events	Subjects % (n/N)	Time to Onset (Days)	Device Removed Due to SAE
Esophageal rupture*	1	0.47% (1/213)	0	NA
Pneumothorax*	1	0.47% (1/213)	0	NA
Upper abdominal pain	1	0.49% (1/203)	2	Yes
Gastric ulcer**	1	0.49% (1/203)	119	Yes
Vomiting**	1	0.49% (1/203)	189	Yes
Device impaction **	4	1.97% (4/203)	Mean (SD): 195 (95) Range: 119-261	Yes

**Pneumothorax was due to the esophageal rupture, which occurred in the same subject.*
***Overlapping events. Device impaction included the patient with gastric ulcer (1) and the patient with vomiting (1).*

Table 4. Summary of Onset and Duration of Device-Related GI Events occurring in ≥ 10% of TPS Subjects (Safety Population)

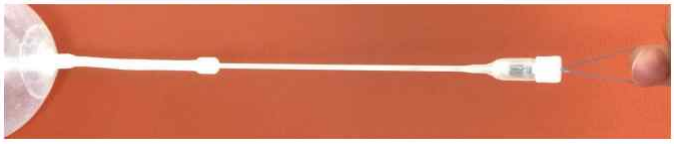
MedDRA Preferred Term	TPS Subjects (N=203)	# Events	Event Severity Rating			Days to Onset Median, Mean and Range		Median Duration (Days)	Subjects with Event Onset ≤ 3 Days n/N (%)
			Mild # Events (%)	Mod. # Events (%)	Severe # Events (%)				
Nausea	128 (63.1%)	243	133 (54.7%)	93 (38.3%)	17 (7.0%)	Median: Mean: Range:	29.0 82.8 0-355	3.0	89/128 (69.5%)
Abdominal pain upper	127 (62.6%)	221	112 (50.7%)	86 (38.9%)	23 (10.4%)	Median: Mean: Range:	17.0 66.2 0-349	5.0	88/127 (69.3%)
Vomiting	118 (58.1%)	252	138 (54.8%)	92 (36.5%)	22 (8.7%)	Median: Mean: Range:	74.0 105.1 0-376	2.0	54/118 (45.8%)
Dyspepsia	111 (54.7%)	174	83 (47.7%)	65 (37.4%)	26 (14.9%)	Median: Mean: Range:	15.5 59.5 0-363	13.0	67/111 (60.4%)
Diarrhea	77 (37.9%)	126	59 (46.8%)	47 (37.3%)	20 (15.9%)	Median: Mean: Range:	52.0 86.5 0-350	3.5	22/77 (28.6%)
Abdominal distension	75 (37.0%)	110	83 (75.5%)	23 (20.9%)	4 (3.6%)	Median: Mean: Range:	33.0 67.4 0-327	7.0	24/75 (32.0%)
Gastro-esophageal reflux	70 (34.5%)	97	56 (57.7%)	31 (32.0%)	10 (10.3%)	Median: Mean: Range:	42.0 82.6 0-363	12.0	25/70 (35.7%)
Eructation	67 (33.0%)	81	68 (84.0%)	13 (16.0%)	0 (0.0%)	Median: Mean: Range:	27.0 77.8 0-324	73.0	20/67 (29.9%)
Gastritis erosive	27 (13.3%)	36	30 (83.3%)	6 (16.7%)	0 (0.0%)	Median: Mean: Range:	196.0 231.8 46-398	147.5	1/27 (3.7%)
Gastric mucosa erythema	23 (11.3%)	26	20 (76.9%)	6 (23.1%)	0 (0.0%)	Median: Mean: Range:	70.0 130.4 46-356	138.0	0/23 (0.0%)
Gastric ulcer	21 (10.3%)	23	11 (47.8%)	9 (39.1%)	3 (13.0%)	Median: Mean: Range:	273.0 270.7 119-373	68.0	0/21 (0.0%)

2-4. Spatz3 Adjustable Balloon System

- Placed and removed by endoscopically
- Silicone, single adjustable balloon filled with 400–800 mL of saline
- Adjustable Balloon volume can be increased or decreased during the period

- Maximal implantation time : 8mo

Figure 5: Inflation Tube partially stretched



2-4. Spatz3 Adjustable Balloon System

Table 2 Results of entire group

	Mean	Range	*P* value	95% CI
Mean wt loss	16.3 kg	(− 2.1–55.2)	< 0.0001	14.8–17.8 kg
Mean %TBWL	16.3%	(− 2.0–49.0)	< 0.0001	15.0–17.7%
Mean %EWL	67.4%	(− 6.1–264.9)	< 0.0001	60.2–74.6%

Table 6 IGB responders

Study [Ref #]	Spatz3 [this review]	Spatz3 [27]	[a, b]FDA Orbera [7]	[a, b] FDA Reshape [6]	[a]Mathus-Vliegen Orbera [28]	[a]Negrin Dastis Orbera [29]	[a, b] Courcoulas Orbera [3]	Kathani Orbera [30]
# pts in study	165	227	160	164	43	100	255	173
Achieve > 10% TBWL or 25% EWL	88.5%	83.3%	46.4%	48%	75%	63%	45.6%	24%

Usuy, Eduardo, and Jeffrey Brooks. "Response Rates with the Spatz3 Adjustable Balloon." *Obesity surgery* vol. 28,5 (2018): 1271-1276.a

2-4. Spatz3 Adjustab

Table 14: Spatz3 Adjustable Balloon adverse event complaints reported through OUS clinical product surveillance between August 30, 2012 and March 15, 2021

	Aug 2012 to Mar 2021		March 2020 to March 2021	
# of balloons	**76,000**		**12,614**	
Event	**Count**	**† Rate (%)**	**Count**	**† Rate (%)**
Serious Adverse Events				
Deflation & Migration with bowel Obstructed	23	0.030	0	0.000
Ulcer	22	0.029	0	0.000
Stomach Perforation	19	0.025	1	0.008
Death*	7	0.009	0	0.000
Esophageal Perforation	3	0.004	0	0.000
Dehydration	2	0.003	0	0.000
Gastric outlet obstruction	2	0.003	0	0.000
Gastritis	1	0.001	0	0.000
Allergic Reaction	1	0.001	0	0.000
Bowel Perforation	1	0.001	0	0.000
Bleeding	1	0.001	0	0.000
Device Failures leading to inability to Implant				
Inflation tube tear	181	0.238	10	0.079
Hole in the Balloon Prior/during Implantation	28	0.037	7	0.055
Procedure usability complications***	12	0.016	2	0.016
Use errors	6	0.008	1	0.008
Valve Disconnected	3	0.004	0	0.000
Inflation tube too long	1	0.001	0	0.000
Extension tube leak	1	0.001	0	0.000
Defective valve	1	0.001	0	0.000
Device Failures leading to inability to Adjust				
Procedure usability complications	9	0.012	0	0.000
Valve Disconnected	2	0.003	0	0.000
Inflation tube knotted	2	0.003	0	0.000
Broken Funnel	1	0.001	1	0.008
Cap nylon loop tear	1	0.001	0	0.000
White catheter broke	4	0.005	0	0.000
Device Failures during treatment phase				
Balloon Deflations for all reasons	1668	2.195	38	0.301
Deflation from Balloon Bond failure****	628	0.826	2	0.016
Deflation with insufficient information to determine cause	400	0.526	10	0.079
Deflation & passage in the stool	260	0.342	3	0.024
Deflation caused by fungal infection	222	0.292	8	0.063
Deflation caused by Cap Failure	44	0.058	13	0.103
Deflation caused by Balloon microholes	37	0.049	2	0.016
Spontaneous Hyperinflation	32	0.042	2	0.016
Deflation caused by Balloon Burst	31	0.041	0	0.000
Deflation & Migration with bowel Obstructed	23	0.030	0	0.000
Deflation & balloon vomited	18	0.024	0	0.000

2-5. Elipse

- not FDA-approved
- Spherical balloon made of a film, filled with 550 mL of saline
- The correct position of the capsule is confirmed with fluoroscopy
- Valve release at 4mo with complete deflation and passage of the balloon through the GI tract

3. Endoscopic suturing devices for altering gastric anatomy - Apollo Endoscopic Sleeve Gastroplasty and Revise Systems

- Endoscopic suturing device
- Reducing stomach volume through endoscopic sleeve gastroplasty

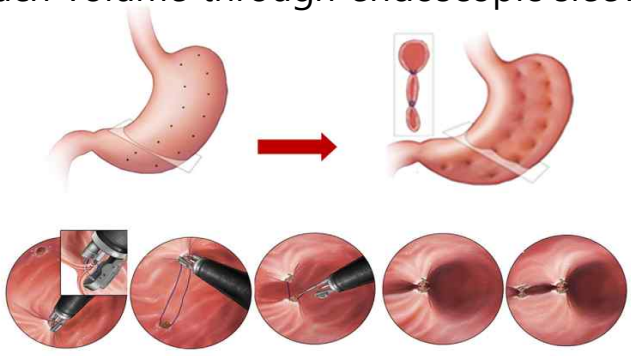


Figure 3. Suturing sequence for the creation of the endoscopic sleeve gastroplasty.

Abu Dayyeh, Barham K et al. "Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity." *Gastrointestinal endoscopy* vol. 78,3 (2013): 530-5.

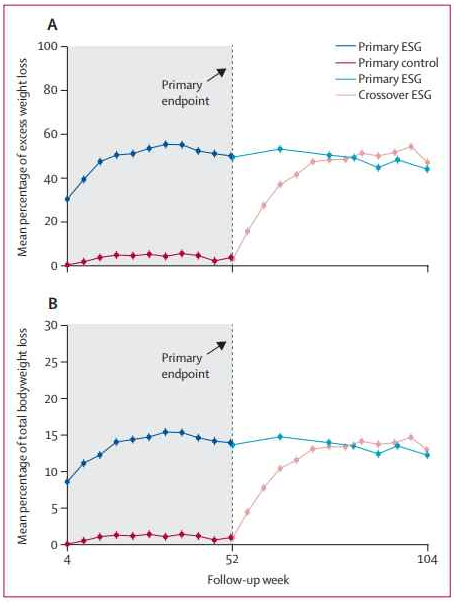


Figure 2: **Mean percentage of excess weight loss (A) and percentage of total bodyweight loss (B) by study group over time from initial treatment**
Error bars are 95% CI. After the conclusion of the 52-week visit, participants in the control group who met predefined criteria were eligible for crossover ESG. ESG=endoscopic sleeve gastroplasty.

levices for altering gastric anatomy eeve Gastroplasty and Revise Systems

	ESG (primary)	Control	Rate difference*	p value†	ESG (primary and crossover)
Diabetes					
Improving	92% (12/13; 65 to 100)	15% (4/27; 5 to 33)	−77·5 (10·1; −91·4 to −47·4)	<0·0001	93% (25/27; 76 to 99)
Worsening	0% (0/13; 0 to 27)	44% (12/27; 28 to 63)	44·4 (9·6; 16·1 to 60·2)	0·0041	0% (0/27; 0 to 15)
Hyperlipidaemia					
Improving	40% (6/15; 20 to 64)	32% (8/25; 17 to 52)	8·0 (15·7; −37 to −22)	0·61	30% (7/23; 10 to 15)
Worsening	27% (4/15; 11 to 52)	28% (7/25; 14 to 48)	1·3 (14·9; −28 to 28)	0·93	30% (7/23; 10 to 15)
Hypertension					
Improving	67% (24/36; 50 to 80)	40% (19/48; 27 to 54)	−27·1 (10·6; −46·1 to 5·5)	0·014	60% (39/65; 48 to 71)
Worsening	6% (2/36; 1 to 19)	23% (11/48; 13 to 37)	17·4 (7·2; 1·5 to 30·7)	0·029	9% (6/65; 4 to 19)
Metabolic syndrome					
Improving	83% (24/29; 65 to 93)	35% (10/29; 20 to 53)	−48·3 (11·3; −67·0 to −23·3)	0·0002	83% (35/42; 69 to 92)
Worsening	0% (0/29; 0 to 14)	38% (11/29; 23 to 56)	37·9 (9·0; 17·2 to 53·7)	0·0002	5% (2/42; 1 to 17)
Effect on multiple comorbid conditions					
Improved at least 1 condition	41 (80%; n=51)	28 (45%; n=62)	..	..	70 (78%; n=90)
Worsened at least 1 condition	6 (12%; n=51)	31 (50%; n=62)	..	..	15 (17%; n=90)

Data are rate (n/N; 95% CI), rate difference (SE; 95% CI) or n (%; N). ESG=endoscopic sleeve gastroplasty. A negative rate difference indicates that the ESG rate was greater than the control rate. *Mean difference was calculated as the difference between the rate for the control group minus ESG group. †The p value was determined with an independent samples proportions test to evaluate differences between two rates.

Table 2: **Comorbidity 52-week change from baseline for randomly assigned participants**

3. Endoscopic suturing devices for altering gastric anatomy - Apollo Endoscopic Sleeve Gastroplasty and Revise Systems

TABLE 3. Morbidity after primary endoscopic sleeve gastroplasty in 1000 patients who underwent the procedure at our center

Morbidity	No. of patients (%)
Fever with no procedure-related collection	5 (.5)
Perigastric collection with bilateral pleural effusion*	2 (.2)
Perigastric collection with left-sided pleural effusion†	2 (.2)
Blood loss‡	7 (.4)
Severe abdominal pain/nausea§	
Readmission + conservative management	5 (.5)
Readmission + reversal of endoscopic sleeve gastroplasty	3 (.3)

*Managed with CT-guided drainage of perigastric and left pleural collections.
†One patient underwent percutaneous US-guided pleural drainage with conservative management of the perigastric collection, and the other was managed conservatively with broad-spectrum antibiotics only.
‡Two patients underwent blood transfusion and 5 received rehydration.
§Pain resolved spontaneously in 5 patients, and 3 requested removal of sutures.

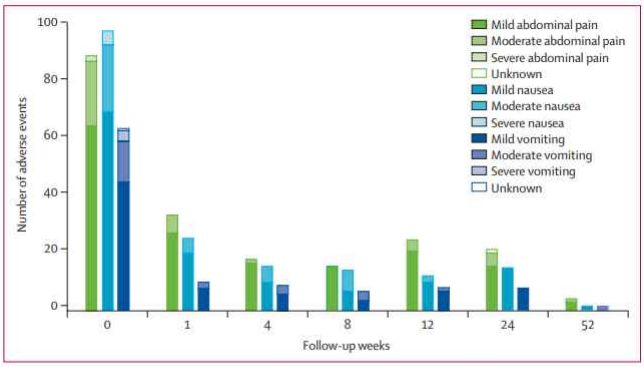


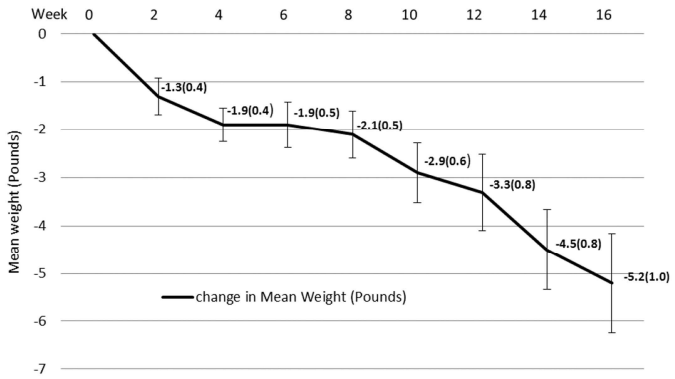
Figure 3: **Prevalent adverse events (device-related or procedure-related) associated with accommodative symptoms by severity and time from the ESG procedure**
The graph includes adverse events occurring after both primary and crossover ESG. ESG=endoscopic sleeve gastroplasty.

4. Oral Removable Palatal Space Occupying Device

- **Sensor Monitored Alimentary Restriction Therapy (SMART) Device**
- SmartByte™
  - a non-invasive, removable medical device (only placed when eating)
  - fitted to each individual
  - worn in the upper palate while eating
  - to limit bite size and slow the intake of food, thereby reducing the amount of food

4. Oral Removable Palatal Space Occupying Device

Trajectory of mean weight loss over the course of the study for the per protocol population



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4. Oral Removable Palatal Space Occupying Device

- **No serious adverse events** were associated with use of the device
- Being possibly related to the device
  - hard palate abrasion
  - tongue laceration
  - transient choking on food
  - gag reflex on insertion
  - mouth soreness
  - gum irritation

5. Ingested, Transient, Space Occupying Device

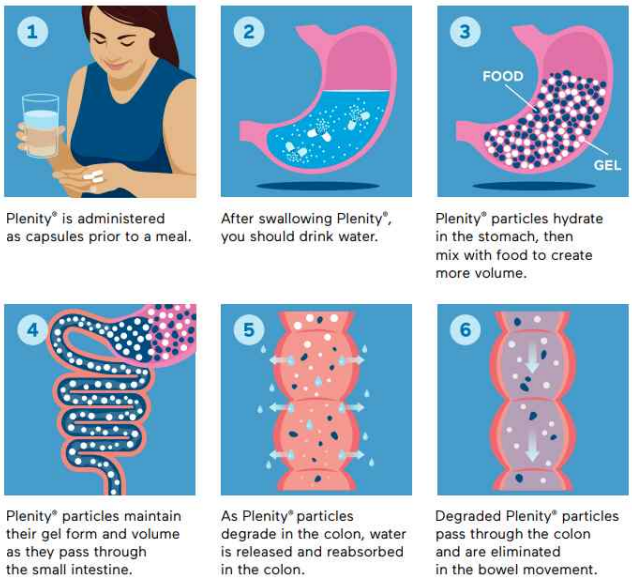
- **Plenity®**

- cellulose and citric acid
- with water twice a day,
  20-30 minutes before lunch and dinner

- Swallow 3 capsules with water
- After taking the capsules, drink 2 additional glasses of water
  (8 fl oz/250 mL each)
- Wait 20-30 minutes to begin the meal

- If a pre-meal dose is missed, instruct the patient to take Plenity
  during or immediately after that meal.

Plenity®



Plenity® is administered as capsules prior to a meal.

After swallowing Plenity®, you should drink water.

Plenity® particles hydrate in the stomach, then mix with food to create more volume.

Plenity® particles maintain their gel form and volume as they pass through the small intestine.

As Plenity® particles degrade in the colon, water is released and reabsorbed in the colon.

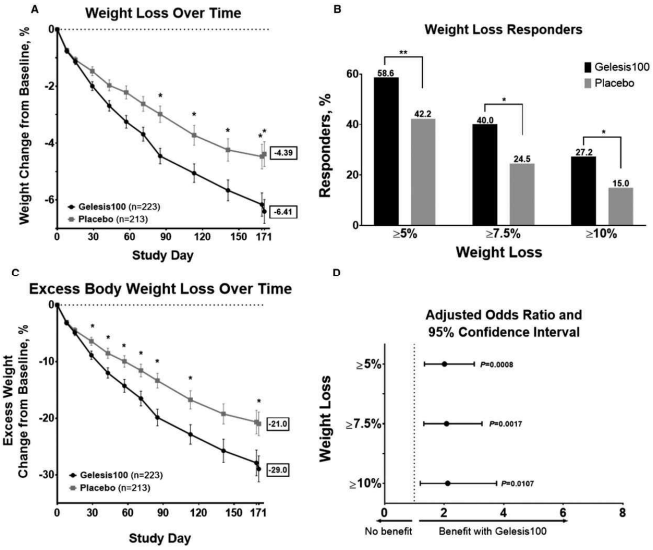
Degraded Plenity® particles pass through the colon and are eliminated in the bowel movement.

Plenity®

Contraindication

- are pregnant
- have had allergic reactions to cellulose, citric acid, sodium stearyl fumarate, gelatin, or titanium dioxide

Plenity®



Greenway, Frank L et al. "A Randomized, Double-Blind, Placebo-Controlled Study of Gelesis100: A Novel Nonsystemic Oral Hydrogel for Weight Loss." *Obesity (Silver Spring, Md.)* vol. 27,2 (2019): 205-216.

감사합니다.