

# Gastric Balloon for Weight Loss

*Karol A Gutowski, MD, FACS*

*Hot Topics*

plastic  
surgery  
THE MEETING



# Disclosures

None related to this topic

Will use brand names due to lack of distinguishing generic names

# Presentation Level of Evidence

## **Levels of Evidence and Qualifying Studies (Therapeutic Studies):**

- I** High-quality, multi-centered or single-centered, randomized controlled trial with adequate power ( $N \geq 100$ ); or a systematic review of these studies
- II** Lesser-quality, randomized controlled trial; prospective cohort study; or systematic review of these studies
- III** Retrospective comparative study; case-control study; or a systematic review of these studies
- IV** Case series
- V** Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

# Gastric Balloon FDA Approvals

- ReShape Dual Balloon 2015
- Orbera Balloon System 2015
- Obalon Balloon System 2016

## **Non-Balloon Devices**

- Lap-Band Adjustable Gastric Band 2001
- Maestro Electrical Stimulation System 2015
- AspireAssist Gastric Emptying System 2016

# Status of Product

## **Obalon Balloon System**

- Obalon Therapeutics
- FDA approved September 2016
- Cost for 3 balloons: \$2600
- Cost to patient: \$6,000 to \$10,000
- > 10,000 patients treated worldwide

## **Indications**

- Temporary weight loss for up to 6 months
- BMI 30 to 40 kg/m<sup>2</sup>
- Used with moderate intensity diet & exercise program

# Liquid vs Gas Filler Gastric Balloons

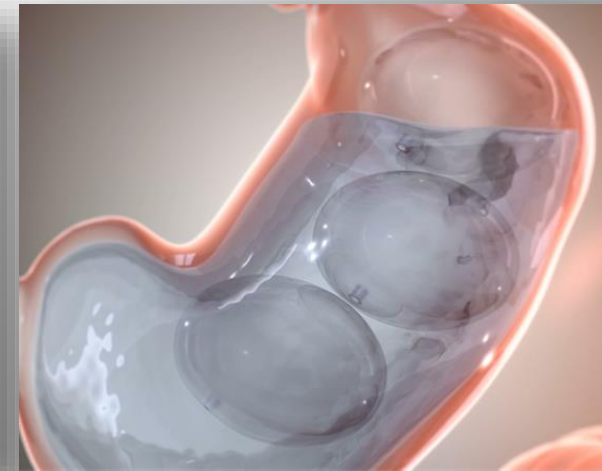
## Liquid-Filled Balloons

Orbera® Liquid  
Filled Balloon  
1989 Patent Filed  
2015 FDA-approved

ReShape Duo® Liquid  
Filled Balloon  
2007 Patent Filed  
2015 FDA-approved

## Gas-Filled 3-Balloon System

Obalon® Gas Filled  
3-Balloon System  
2011 Patent Filed  
2016 FDA-approved



# Liquid-Filled vs Gas-Filled Balloons

Attribute	Liquid Filled Balloon Systems	Gas-Filled 3- Balloon System
Device Placement	Endoscopy under general anesthesia	Swallowable, no anesthesia or sedation
Material and Filling Agent	Silicone rubber Saline and methylene blue dye	Multi-layer, non-porous, nylon polyethylene polymer filled with a proprietary nitrogen gas mix
Balloon Volume	Range 400-900 cc	750 cc total volume 250 cc per balloon
Progressive Volume Over Time	No, total volume added during the initial placement	Yes, three balloons added gradually during the first 3 months of the 6-month treatment
Total Weight (g)	Weight >400-900 g	Weight <10 g, (~ 3g per balloon)
Balloon residence location in the stomach	Antrum (bottom)	Fundus (top)
Removal	Endoscopy under general anesthesia	Endoscopy under light, conscious sedation (intubation not required)

# Approval Study

- 419 subjects
- 387 able to swallow device
  - 198 balloon device vs 189 sham control device
  - All had diet & exercise counseling
- Results
  - Balloon                      14 lbs                      6.6% of body weight
  - Control                        7 lbs                         3.4% of body weight
- Common adverse events
  - Abdominal pain & nausea x 1-2 weeks
  - 0.9% gastric ulcers
  - 3.0% early removal due to non-serious adverse events

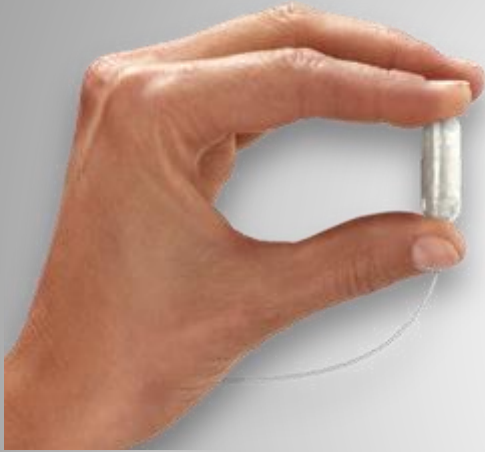


# Balloon Placement Process

- 1<sup>st</sup> balloon, then at least 2 weeks apart
  - 2<sup>nd</sup> Balloon 3 to 4 weeks later
  - 3<sup>rd</sup> balloon 9 to 12 weeks later
- Supervised diet & exercise program
  - Monthly meetings
- Endoscopic removal at 6 months



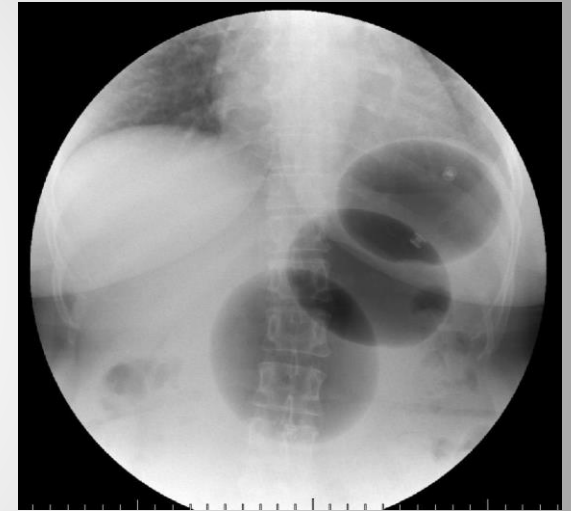
# Gas-Filled Balloon Placement



Swallowable  
Balloon Capsule



Inflation System



Fluoroscopic  
Confirmation

# Behavior Modification Program

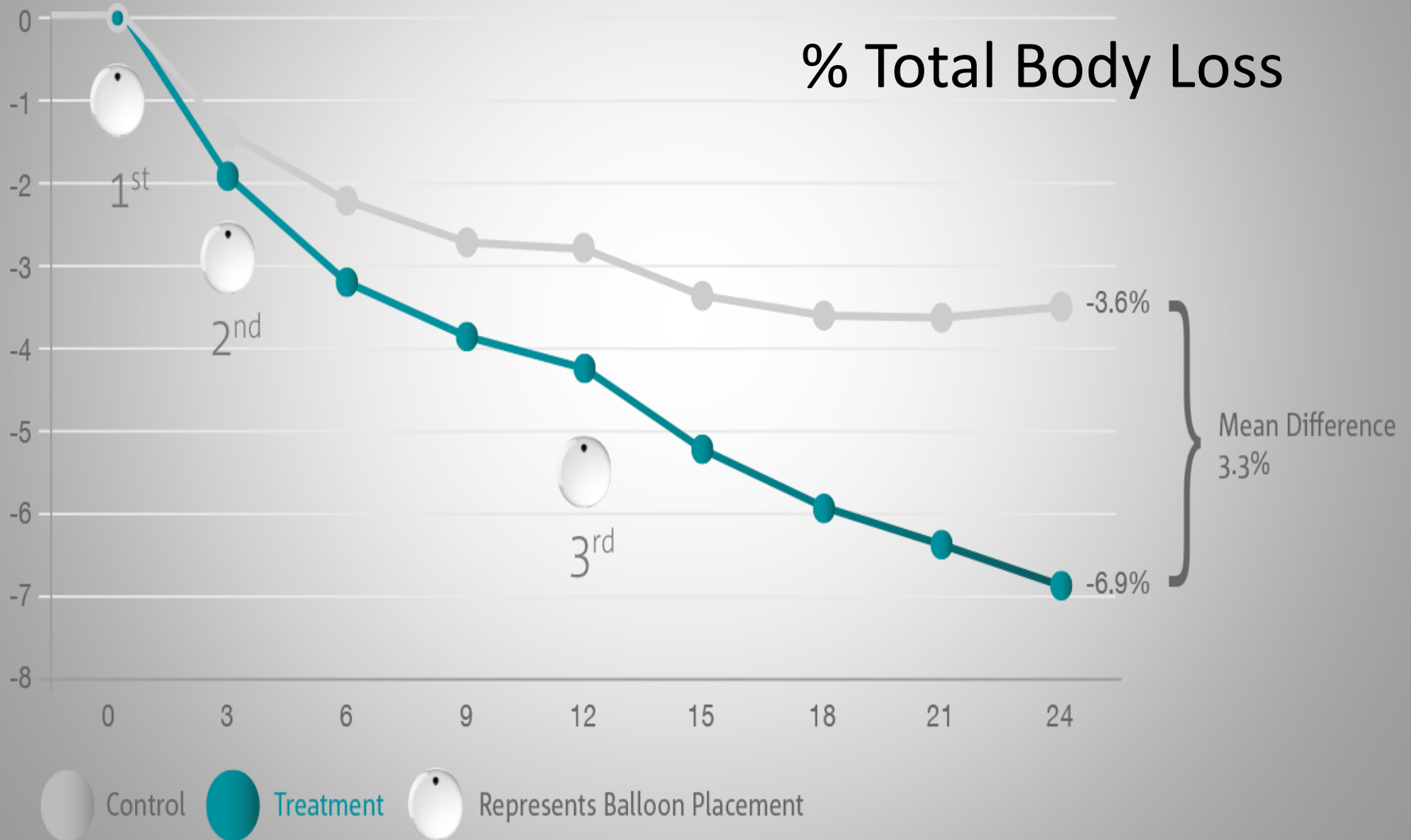
- Balloons are a tool to facilitate weight loss
- Patients follow supervised program
  - Nutrition & exercise
  - Managing goals and barriers
  - Customized by the practice
    - In-house registered dietitian, contract out, virtual platforms
- Weight loss maintenance is dependent on patients continuing learned habits after balloons are removed



# Endoscopic Balloon Removal



# Balloon vs Control Results

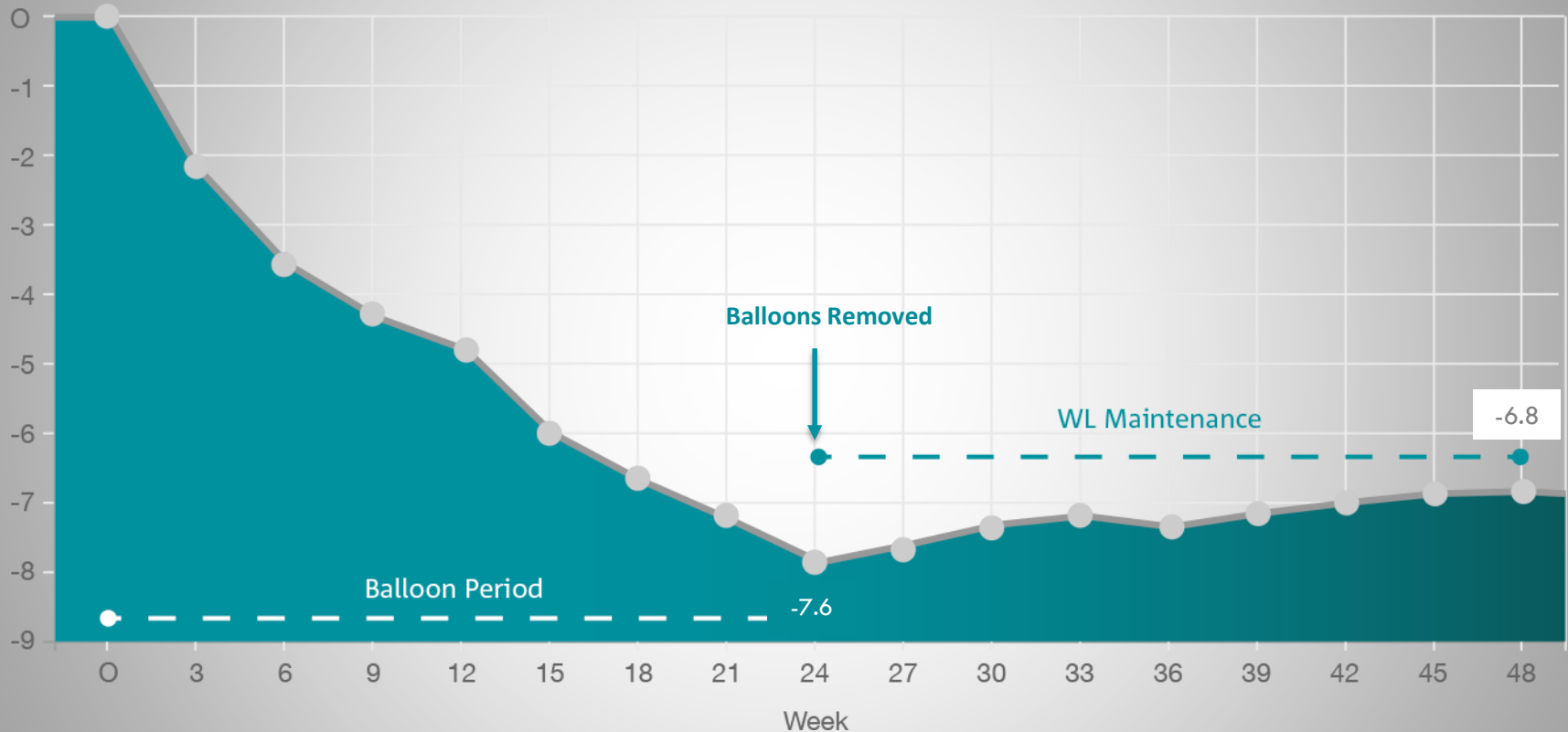


# Balloon Group Stratified Weight Loss

≥ %Total Body Loss	Number of Subjects
<b>5%</b>	<b>120 / 185 (64.9%)</b>
6%	98 / 185 (53.0%)
7%	81 / 185 (43.8%)
8%	68 / 185 (36.8%)
9%	55 / 185 (29.7%)
<b>10%</b>	<b>49 / 185 (26.5%)</b>

**2/3 lost at least 5% body weight**

# Weight Loss Maintenance After Removal



**Average 89% of weight loss maintained  
6 months after balloon removal**

# Why Market to Plastic Surgeons?

- Need fluoroscopy & table (Used about \$10-20K)
  - Radiology regulations, hospital privileges, etc
- Need dietician support
- Need gastroenterologist to remove balloons
  - Included in patient package price





# Plastic Surgeons & Self Pay Patients

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- Self financed patients have better weight loss outcomes with compared to insured patients
- Plastic surgeons charge on the higher end
- Additional service for aesthetic patients
- Bundle with other body contouring treatments

# Liquid Filled Balloon Deaths

- **5 reported deaths since 2016**
  - All deaths within 1 month of placement
  - NO root cause available
- **2 additional deaths** associated with fluid filled balloons
  - Gastric perforation
  - Esophageal perforation



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ADMINISTRATION

# Summary

- Role of Plastic Surgeons in weight loss
  - Are we qualified?
- Medical liability issues
- Cost for 20 lb weight loss
- Long term efficacy?
  - FDA mandated post-approval trial soon

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