Update on new devices for bariatric procedures

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Lyon (France)
Lyon (France) April 24-25, 2015: Vth International symposium on non invasive bariatric techniques
Disclosures

None
Background (1)

- Although expanding, the array of bariatric techniques does not meet the current needs; we have to implement less aggressive procedures.
- Yet innovation is risky, expensive and meets ethical challenges.
- Should minimally invasive procedures take over? When? How?
- Is metabolic surgery a priority in this respect?
Background (2): definition of new bariatric technologies: a frame/suggesting combinations

1. Surgical novelties: new concepts (stimulation)/ new operations (LGCP, SGIT)/ new approaches (SILS, robotic)/ 3-D imagery

2. Endoscopy: new balloons/ gastric partitioning/ Metabolic field (EDJS, duodenal resurfacing)

3. Adjacent fields++: patient monitoring (smartsensing, daily activities expenditure)/ biology (microbiota, brown tissue)/ « coaching tools » (vibrating platforms, US)
Should they take over? The low BMI issue (obesity class I - IFSO 2014 statement !?)

- Not enough resources for spreading surgery, otherwise disregarded by a majority of patients
- Futile quarrels (Omega loop vs Roux-en-Y? hiatal hernia repair?)
- Surgical discrepancies point to the direction of less aggressive procedures
Weight Loss and Weight Regain, typical trajectory: the SOS Study

![Graph showing weight changes over time for different procedures: controls, banding, vertical-banded gastroplasty, and gastric bypass.](image)

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<th>Procedure</th>
<th>No. Examined</th>
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<th>Year 2</th>
<th>Year 3</th>
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Weight Loss standard trajectory (Post-op)

**Fig. 1** Cross-sectional vs. longitudinal depiction of weight loss outcomes.  

- **a** The traditional depiction of weight loss results after bariatric surgery. The *triangles* represent the average %EWL computed over all patients within each yearlong period (as well as 3 months).  
- **b** Individual patient weight loss plots
Discrepancies: Atypical trajectories, a concept that applies to any kind of bariatric procedures

A closer look: Analysis at short intervals in minimally invasive techniques: HA injections vs balloons + crossover, with 2 years FU
1. Conditions have been listed
2. Science has been built
3. What is ready but requires additional studies? What is not ready but should be a priority?
4. Facing the criticism of those in favor of « surgery for everyone »!
5. Steps and goals
When?

- **1. Conditions** (Ibrahim, 2013): any of the following event will kill a start-up:
  - **Ideas and prototypes**: The market has not been clearly identified, or is too small; the device is too complex, or too expensive for its application.
  - **Development and regulatory process**: Investors do not want to finance delays; regulatory bodies request additional trials; clinical results do not pass reimbursement thresholds; physicians do not want to change their habits, or patient access is barred.
  - **Marketing and sales**: The adoption takes longer than anticipated; training for experienced physician is complicated; the start-up is bought by a major company in order to kill competition.
2. Science has been built/is being built:
   two very recent examples
   - Fasting and meal-suppressed ghrelin level before and after intragastric balloons and balloon-induced weight-loss *Mathus-Vliegen 2013, Obes Surg*
   - Endoscopic duodenal-jejunal bypass liner rapidly improves type 2 diabetes *Greve 2013, Obes Surg*
When?

3. What is ready but requires additional studies?
Endotube, endoplication, endoaspirer

4. What is not but could become a priority?
Endo-rings, endo-stapling, duodenal resurfacing

5. Steps and goals
Concept similarities/ ethical frame
Ethical frame

- American Society for Metabolic and Bariatric Surgery position statement on emerging endosurgical interventions for treatment of obesity, SOARD, 2009; 5: 297-298

- Limitation to clinical trials, and peer-reviewed protocols for now
Concept similarities, e.g. anti-reflux (plication/injections)

**EndoCinch® System (BARD)**

- **Description**
  - Plication results from suction
  - Several sutures

- **Technique**
  - Creation of 2 to 6 folds from lower esophagus to the upper part of the great curvature


Endo-stapling/ VBG-like technique: TOGA System
X-Ray 3 months
Gastric partition


Transoral rotational esophagogastric fundoplication: technical, anatomical, and safety considerations

Reginald C. W. Bell · Guy-Bernard Cadière
Endo-malabsorption
Minimally invasive banding
HA Injection beneath the GE Junction
TERIS Endoscopic ring
HourGlass Technologies developed an incision-free weight-loss procedure for morbidly obese patients. The left figure represents a stomach after the HourGlass procedure has been performed, featuring the same restrictive anatomy that is present with surgical gastric banding, as seen on the right.
Endoplication: Apollo System
Endoplication: USGI System
Endoplication: USGI System

- Multiple Instruments
- Multiple Operating Channels
- Independent 4-Way Steering
- Endoscope Port
- Steering controls
- Instrument Ports
- Insufflato-controlled CO₂ Delivery
Should they take over? How??

Solution n°1:
Blend of new and old/ concept similarities. Making use of adjacent technologies.

Solution n°2:
Breakthrough from another field (e.g. brown adipose tissue/microbiota): not likely soon.

Solution n°3 (++)
One good shot is enough! One of the available tools? Three bets…
Three bets: 1. New balloons

Obalon® is about to change the way you think about weight loss.
Swallowable balloons

- Placement without endoscopy
- 1-2 additional balloons
- Endoscopy for removal
- Balloon removal by 12 weeks
New balloons: Spatz 3
New balloons: THE ELIPSE™ is swallowed and naturally excreted

- Same proven mechanism of action as endoscopically-administered IGBs
- Made entirely from thin, flexible materials intended to avoid GI tract obstruction (<10% compressed volume of BIB)
- Provided to patients in a capsule for easy swallowing
- Swallowed and filled during a 20 minute, in-office procedure without anesthesia or sedation
- Release valve opens at 3-months allowing immediate device drainage and natural passage at home; lost to follow up not a concern
Three bets: 2. Plication
Laparoscopic Gastric Vertical Plication (Talebpour)
Three bets: 3. The metabolic asset, Sleeve EndobARRIER
Less faith, leading to...
Additional bets? ASPIRE System
Super-Obese Trial Czech Republic, BMI 71
Additional bets? NOTES EUS-guided gastrojejunal anastomosis

Lumen apposition stent

Binmoeller KF Endoscopy 2011;43; 337-42
Additional bets? Gelesis

Capsules are taken orally prior to a meal and contain small particles that expand ~100 times when hydrated in the stomach and small intestine. Among 125 subjects the average reductions in body weight by group at the end of treatment were as follows: 6.1 percent for 2.25g of Gelesis100, 4.5 percent for 3.75g of Gelesis100 and 4.1 percent for placebo.
Smartsensing technologies: a connected T-shirt for post-op and long-term monitoring
Conclusion (1): A bariatric schedule

- Minimally invasive techniques are not ready for prime time... But:
- They are already being successful as re-do procedures
- A time-frame for step-strategies can be defined
- **Warning:** re-do after endoscopic techniques might be more difficult than anticipated
Combination may be the essence: e.g. what should not have been done?? BIB

2 years after plication
Conclusion (2): A bariatric schedule: the « One good shot » theory

- One success could change our vision,
- Sparkle the whole minimally invasive field,
- And attract investors, as well as getting major companies to step up
- IFSO New Technologies Committee (T Horbach, JD): surveillance and suggestions for companies