Bariatric endoscopic procedures & metabolic surgery

Presenters: Dr Adrian Sartoretto & Dr Georgia Rigas

Acknowledgement of Country

The RACGP would like to acknowledge the traditional owners of the lands on which this webinar is being broadcast and we pay our respects to the elders, past and present.
**Presenters**

**Dr Georgia Rigas** is a Fellow of the RACGP and also Chair of the RACGP Specific Interests Obesity Management Network. She is also the senior Bariatric Medical Practitioner at Australia’s first accredited Bariatric Centre of Excellence at St George Private Hospital, Sydney.

Dr Rigas is recognised as a “SCOPE-certified Obesity Doctor” by the World Obesity Federation and serves on a number of medical advisory committees—both nationally and internationally.

**Dr Adrian Sartoretto** is a Gastroenterologist & Hepatologist with a subspecialty interest in Bariatric Endoscopy. Dr Sartoretto has been a Clinical Lecturer with the University of Sydney since 2012.

He joined The BMI Clinic in 2016 and took on a leadership role, greatly expanding the multidisciplinary team and developing a unique, comprehensive lifestyle program to complement bariatric endoscopic interventions.

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**Learning Objectives**

- Describe the metabolic mechanism of action underpinning bariatric metabolic surgery
- Describe recent bariatric endoscopic therapies which have been developed
- Provide aftercare to patients who have undergone bariatric endoscopy or metabolic surgery
- Identify red flag symptoms to look out for in patients who have undergone bariatric endoscopy or surgery, which warrant urgent referral back to hospital/clinic of origin
What do we know thus far?

Many patients want and expect weight loss guidance from Health Care Professionals. (1)
Having the conversation and formally diagnosing and documenting overweight or obesity strongly predicts treatment plan in place subsequent weight loss. (2)
People with obesity are on a weight gain trajectory
BMI is genetically predetermined & genetics play an important role

What do we know thus far?

Body weight is vigorously defended

As one loses weight:
- ↓leptin
- ↓insulin
- ↓CCK

1) Hunger hormones:
- ↑Ghrelin increased appetite
- ↑GIP increased fat storage

2) Reduced energy expenditure
Hunger is not the only trigger for eating:

What do we know thus far? Clinically meaningful weight loss

5–10% weight loss is clinically meaningful

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**Therapeutic Spectrum for Obesity**

- **Risk**
  - Lifestyle = Nutritious Intake & Physical Activity
  - Lifestyle + Medication
  - Lifestyle + Very Low Energy Diet
  - Lifestyle + Endoscopic Bariatric Therapies
  - Lifestyle + Bariatric Metabolic Surgery

- **Efficacy**

**Bariatric Metabolic Surgery**

Dr Georgia Rigas BScMed MBBS FRACGP
General Practitioner | RACGP SI Obesity Management Network Chair
Senior Bariatric Medical Practitioner
Polling questions: Bariatric surgery in Australia

Whilst recognising that not all patients with obesity want or need bariatric metabolic surgery,…..

Q1: What percentage of patients who meet the NHMRC guidelines criteria actually have bariatric surgery per year?
   a. 0-5%
   b. 6-10%
   c. 11-20%
   d. 21-30%
   e. 31-40%

Q2: What percentage of bariatric metabolic surgery is performed in public hospitals?
   a. 0-5%
   b. 6-10%
   c. 11-20%
   d. 21-30%
   e. 31-40%

Q3: Do you think bariatric metabolic surgery makes people lose weight?
   a. Yes
   b. No

To find out what obesity management services are available in your State or Territory, please direct all email enquiries to: gpsi@racgp.org.au

Bariatric Surgery is cost effective

Practice point

- Bariatric surgery, when indicated, should be included as part of an overall clinical pathway for adult weight management that is delivered by a multidisciplinary team (including surgeons, dietitians, nurses, psychologists and physicians) and includes planning for continuing follow-up.

And variations thereof...

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Healthy Profession, Healthy Australia.
**Surgery as a therapeutic tool**

View Bariatric metabolic surgery as an **enabler** for lifestyle modification:
- Reduced hunger/ increased satiety
- Effectively reduce main meal portions
- Malabsorption of micro (LGBP) or macro nutrients (BPD)

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**So how does bariatric metabolic surgery work?**

I think you should be more explicit here in step two.
Recap: as one loses weight
downward arrows:
- Leptin
- Insulin
- CCK

1) Hunger hormones
- Ghrelin: increased appetite
- GIP: increased fat storage

2) Reduced energy expenditure

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Restoration of euglycaemia & Reversal of lipotoxicity
Enhanced response of incretins
Restoration of insulin sensitivity
Altered bile acid signalling
Altered microbiome
Diminished ghrelin secretion

Bariatric metabolic operations compared

<table>
<thead>
<tr>
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<th>Hormonal Effects</th>
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<td><strong>Band</strong></td>
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</table>
**Swedish Obese Subjects (SOS) trial: Prospective controlled intervention study of bariatric surgery**

![Graph showing weight change over time](image)


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**Safe but not without risk**

Bariatric metabolic surgery is as safe as an elective laparoscopic cholecystectomy *

Revisional surgery may be required:

- LABG: Gastric pouch dilation, band erosion, leaks to band system, weight regain, gallstones
- LSG : GORD, staple-line leak, abdominal pain, gallstones, nutritional deficiency, weight regain
- LGBP: Abdominal pain, staple-line leak, stomach ulcer, intestinal obstruction, gallstones, nutritional deficiency, weight regain

When to refer

BMI 40 (= Class III obesity, previously called *morbid* obesity)
BMI 35 + medical comorbidity/ complication of obesity
BMI 30 + poorly controlled diabetes*
Willing to engage in lifelong care*
Previous attempts to lose weight
Acceptable operative risks

NH&MRC Guidelines 2013

Contraindications

- Non-stabilised medical disorders
- Active cancer
- Patient not willing to commit to the postop care plan^*
- Unable to provide consent
- ?over 65yo
- Relative C/I: Untreated or non-stabilised psychological disorders*

* "Treatment should be started before surgery" NHMRC Guidelines, 2013
Polling Question
Who should you refer to?

FEATURES OF CLUSTER GROUP (1):
Offer quickest turn around
Cheapest
Hosts lovely GP luncheons/ dinners
Personal friend of yours

FEATURES OF CLUSTER GROUP (2):
Had a multi disciplinary team in the practice
Has extensive experience
Has an academic post ie teaches students

FEATURES OF CLUSTER GROUP (3):
Has good bedside manner
Has a friendly telephone receptionist
Takes phone calls from GPs with queries

Who to refer to?

• Extensive experience: high volume center
  – Shown to have ↓ postoperative complications*
• Offer a variety of operations = tailor to patient’s health profile
• Multidisciplinary team

*N.T. Nguyen et al, Annals of Surgery, 2004
Bariatric surgery - complications

Early: <30 days
- Perforation
- GIT Hemorrhage
- Gut ischaemia
- Band slippage
- Band erosion

Late: >30 days
- Perforation
- GIT Hemorrhage
- Anastomotic leaks
- Strictures
- Reflux
- Gut ischaemia


Importance of Aftercare

- Achieve optimal benefit from therapy
- Delivery of education and support
- Prevention or early diagnosis of complications

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Routine minimal daily nutrient supplementation post operatively

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<th>Nutrient marker</th>
<th>Before surgery</th>
<th>In 1st year: every 3–6 months</th>
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<tr>
<td>Copper</td>
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</table>

*Including folic acid 400ug, copper 2mg, iron and thiamine

*Carbonate requires acid for absorption

*In cases of severe vitamin D malabsorption, oral doses may need to be as high as 50,000 units 1 to 3 times weekly to daily

*Usually 350-1000ug orally or may need IM/intranasally
Abdominal Pain

Any pt who has lost weight:
  – Could be gallstones; arrange abdominal ultrasound +/-HIDA
LAGB pt:
  – Could be a slipped or strangulated band->need to come to clinic ASAP for review
LSG:
  – Could be a leak -> need to come to clinic ASAP for review
RYGBP:
  – Could be small bowel obstruction: urgent referral to surgical clinic or ED-> the bowel could become necrotic within 24-48 hours
Bypass (RYGBP or omega):
  – Could be stomal ulcer->refer back to surgeon to perform a gastroscopy

CHRONIC DISEASE MODEL OF CARE
Comorbidity & complications of obesity need regular review
eg Diabetes remission—may relapse

Take home messages:
1. Diabetic patients still require routine surveillance, even if in remission
2. Relapse is a normal expectation of dealing with a chronic disease
**Bone Health**

- Important for all bariatric procedures
- Test for: Ca, Mg, PO4, vit D, PTH*
- Baseline bone DEXA scan and in other patients identified as high risk; repeat DEXA at 2-5 years*
- Gastric bypass: supplement with calcium & vitamin D for life; others prn

*AACE/TOS Bariatric Surgery guidelines, 2013

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**Anemia**

Iron deficiency:
- exclude other common causes
- ↓ red meat intake- may need supplementation
- bypass will need supps (stores deplete with time)

Vitamin B12:
- important to measure Active B12
- needs replacing with bypass,
- sometimes needs replacing with LSG too
Occasionally bariatric patients at risk of thiamine (vitamin B1) deficiency

Potential causes:
- Gastric resection procedures (sleeve, bypass operations)
- Prolonged vomiting
- Excessive alcohol intake
- Lowered acid environment in sleeve and bypass may be an issue

Refer to hospital for treatment-iv thiamine

Fat soluble vitamins

Definitely monitor in SAGB (omega loop bypass) SADI & BPD
- Vitamins A,D,E,&K
- Measure at least 6 months
- Oral supplements
Emotional Support

- Mental well being improves for most, not all
- Surgery may interfere with hedonistic pathways
- Alcoholism- esp RYGBP^  
- Higher incidence of relationship breakdowns
- RYGBP: sl ↑ risk of accidental & non accidental death* 
- Body image disorders eg loose skin
- Weight regain-> reinforces “failure” shame/guilt

^ W.C. King et al JAMA 2012  
* J Bhatti et al JAMA Surgery 2015

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GORD/Reflux

LAGB:
- Could be a slipped or overtight band->need to come to clinic ASAP for review (if possible arrange a barium swallow)

LSG:
- Expected, will need PPI +/-H2 rec antagonist  
- If intractable->may need to be converted to RYGBP

Bypass (RYGBP or omega):
- Could be stomal ulcer->refer back to surgical clinic to perform a gastroscopy

SAGB (omega loop bypass):
- At risk of bile reflux -> refer back to surgical clinic

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“Inadequate” weight loss

- NO such thing as “failure”; should be viewed as partial responders to Rx
- Look beyond the kilos on the scale
- Shift the emphasis to:
  1. Improved weight related comorbidities
  2. Improved fitness
  3. Improved function
  4. Improved QOL

Should we worry about weight regain?

- How much wt regain is too much?
- ?10% of their nadir weight *
- ? Worsening of associated co-morbidities

* Karmali et al Obesity Surgery 2013;23 p 1922
**Red Flag symptoms**

- Protracted vomiting- think B1&EUC
- Dehydration
- Abdominal pain
- Neurological symptoms
- Significant GORD
- Recurrent chest infections/pneumonia
- Nutritional deficiencies
- Patient is *considering* pregnancy
- If in doubt-> refer back

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**Summary: Role of GP**

- reinforce healthy eating behaviour
- reinforce healthy lifestyle habits
- monitoring and reviewing nutritional status
- compliance with vitamins and supplements
- referral to relevant specialists and health professionals
- regular follow-up: adopt a chronic disease model of care
Therapeutic Spectrum for Obesity

**Therapeutic Spectrum for Obesity**

- **Diet & Exercise**
  - 5 - 7% TBWL
  - Regain in 6 – 12 months

- **Drugs**
  - 4 – 10% TBWL
  - Regain when ceased

- **EBT**

- **Surgery**
  - High risk of morbidity, reoperation and nutritional deficiency
  - 3 - 5 day inpatient stay
  - Sleeve (VSG)
    - TBWL 25%
    - EWL 50 – 60%
  - RYGB
    - TBWL 30%
    - EWL 60 – 80%
Role of Endoscopic Bariatric Therapies

Prospective thresholds for EBTs have been set jointly by ASMBS and ASGE

Goal of all EBTs is to offer
- Clinically meaningful weight loss
  - EWL >25% (and TBWL >10%) at 12 months
- Lower risk
- Lower requirement for resources
- Improved patient acceptance

May be used as:
- Primary therapy
- Adjunctive (Bridging) therapy
- Revisional therapy

EBTs and Lifestyle Intervention

ALL EBTs to date demonstrate a positive correlation between efficacy and frequency/intensity of lifestyle interventions (dietetic, exercise and behavioural)
- EBTs should be considered amplifiers of lifestyle change

It is recommended that all EBTs are accompanied by a multiphase lifestyle intervention that is:

- Intensive (≥ 12 contacts within the first 6 months) before moving into a lower intensity maintenance phase
- Comprehensive- including dietary, behavioural and exercise interventions
- Last a period of at least 12 months
Modes of action

Gastric therapies
- Slowing of gastric emptying
- Restriction
- Aspiration

Small bowel therapies
- Malabsorption
- Changes in bile salt metabolism/absorption
- GI hormone changes (GLP1)
- ? Microbiome

Mechanism of Intragastric Balloon Therapy

Reduced appetite, early & prolonged satiety
- Delayed gastric emptying
- Restrictive component (with preferential fundal filling)
- Intragastric weight

Behavioural effects
- Punitive effects of over- or rapid-eating
- Punitive effects of poor food choices (esp. high fat content)
**Typical Clinical Course**

Honeymoon period (6 hours)
Adaptation Period
- 3 – 5 days (peak by day 3)
- Colicky pain
- Nausea +/- Vomiting
- Reflux
- Lethargy

Symptoms after week 1 should never be considered “normal”
- Acute post prandial symptoms typically result from hyperphagia, tachyphagia
- Other causes may include: gastric accretion, antral impaction, hyperinflation, ulceration, pancreatitis, cholelithiasis

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**Gastric Balloon Patient Selection**

Eligibility
- Age < 70yrs
- BMI ≥ 27 kg/m²
- (Eradicate H pylori)

Contraindications
- History of gastric surgery (including fundoplication)
- Hiatus hernia > 5cm
- Active peptic ulcer disease
- Vascular lesions (eg GAVE)
- Strictures (eg oesophageal)
- Pregnancy and breastfeeding
- Regular use of NSAIDs

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**Orbera**

First of the modern “Large volume” IGBs
- Spherical shape
- Fixed volume
- 6 month implantation time
- TBWL 12 – 15% at 12 months

**Spatz 3**

Third generation adjustable balloon
- Twelve month dwell time
- Only available adjustable balloon
  - TBWL 17 – 19%
  - Advantage in improving early tolerability and balloon retention by downward adjustment
  - Advantage in improved weight loss and response rates
  - Increased risk of gastric ulceration (2 – 5%)

**RACGP | Specific Interests**
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Healthy Practice. Healthy Australia.
Safety

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<td>1020</td>
<td>41,863</td>
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<td>164 (.5%)</td>
<td>5 (.5%)</td>
<td>205 (.5%)</td>
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<td>146 (.5%)</td>
<td>4 (.4%)</td>
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<td>52 (5.1%)</td>
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<td>0 (0%)</td>
<td>2 (.01%)</td>
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<tr>
<td>Total</td>
<td>650 (2%)</td>
<td>84 (8.2%)</td>
<td>734 (2.5%)</td>
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SD = standard deviation; IGB = intragastric balloons; TBW = total body weight; BMI = body mass index.
\(^{1}\)Treated by balloon removal.
\(^{2}\)Treated conservatively.
\(^{3}\)Treated surgically.

Neto et al Brazilian Consensus Guidelines on IGB SOARD 2017

Intolerance: 7–10% Orbera; 1-3 % Sp3

Ulcer: 1:250 (Sp3 5.7%, but 90% did not require IGB removal)

Perforation: 1:2500

Migration: 1:500, but 75% resolve spontaneously (1:1600 risk of surgery for SBO)

Death: 1: 10,000
**Abdominal Pain**

**Thorough history and examination**
- Exclude NSAIDs, ensure PPI adherence, diet history, weight loss history, GI bleeding
- Beware the panicked patient with severe apprehension for abdominal exam
  - Often a sign of antral impaction and severe gastric distention (NBM + CT + NGT)
- Ensure IGB in LUQ

**Approach should be standardized**
- NBM or CF diet (+/- enzymes)
- Lipase (+/- amylase)
- FBC, LFT, EUC, CMP, CRP
- CT if clinical concern for perf; US if suspect cholelithiasis
- Liaise early with bariatric Endoscopist

Cause of pain should be resolved within 1 week of onset; if ongoing, urgent endoscopy is warranted
ESG
Endoscopic Sleeve Gastroplasty (ESG)
- Incisionless transoral endoscopic procedure
- Developed at the Mayo Clinic in 2012
- Running sutures are applied along the greater curvature of the stomach to reduce gastric volume
- Able to be performed as a day only procedure
- No implanted device
- No device retrieval

ESG - Indications and contraindications

• Eligibility:
  • BMI $\geq 30$ kg/m$^2$
  • Declines conventional bariatric surgical intervention

• Contraindications:
  • Family history of gastric malignancy
  • Active $H$ pylori infection
  • Active gastric ulceration
  • Requirement for gastric surveillance (eg Gastric intestinal metaplasia or atrophic gastritis)
  • Decompensated organ failure
  • Known vascular anomalies (mucosal or abdominal)
  • Obligate therapeutic anticoagulation
  • Pregnancy or lactation
**ESG – Published Results**

- TBWL 14-16% at 6 months\(^1,2\)
- TBWL approximates 20% at 24 months\(^1,2\)
- Reported complication rate of ~ 1%
  - Most commonly peri-gastric inflammatory collection
- Sustained significant improvements in HbA1c, WC, Systolic BP, TG and ALT in one series\(^1\)
- Weight loss is related to intensity of lifestyle intervention\(^3\)

<table>
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<th>Ref.</th>
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<td>Spain</td>
<td>154</td>
<td>15.8</td>
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<td>U.S.</td>
<td>91</td>
<td>14.4</td>
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<td>Multicentre study (Spain: Madrid, USA: Mayo, Weill-Cornell)</td>
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</table>

1. Sharaiha et al Clinical Gastroenterology & Hepatology 2017  
2. Lopez-Nava et al Obesity Surgery 2017  

**Our Experience**

- Consecutive ESG patients from three centres:  
  - Australia: The BMI Clinic  
  - The US: Johns Hopkins and UT Health  
- Study period Feb 2016 to May 2017  
- N = 112; average BMI 37.9 kg/m\(^2\)  
- 10 patients with previous IGB experience

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**Percent ≥ 10% TBWL at 24 months**

- Per Protocol: 84%
- ITT: 53%
Predictors of Outcome

Predictors include:

Positive
- Baseline BMI
- Male sex
- Allied Health follow up

Negative
- Gastric Balloon Experience

ESG and Conventional Surgery

No RCT data, but...

Endoscopic Sleeve Gastroplasty, Laparoscopic Sleeve Gastrectomy, and Laparoscopic Band for Weight Loss: How Do They Compare?

Aleksey A. Novikov • Chegeveara Afaneh • Monica Saumoy • Viviana Parra • Alpama Shukla • Gregory F. Dakin • Alfons Pomp • Enad Dawod • Shawn Shah • Louis J. Aronne • Reem Z. Sharaiha
Study Summary

- 12 month retrospective cohort study of 278 patients; included initial experience with ESG
  - LSG 120 pts; ave BMI 47.2 kg/m²
  - ESG 91 pts; ave BMI 38.6 kg/m²
  - LAGB 67 pts; ave BMI 45.0 kg/m²

- 12 month TBWL%:
  - LSG 29.3% vs ESG 17.6% vs LAGB 13.3%
  - When analysed by BMI 30 - 40 kg/m², no significant difference in weight loss between interventions

- However, much lower morbidity with ESG
  - LSG 9.17% vs ESG 2.20% vs LAGB 8.97%

- Average inpatient stay (days)
  - LSG 3.09 vs ESG 0.32 vs LAGB 1.66

Weight Loss

[Graph showing BMI and %TBWL over 12 months for LSG, LAGB, and ESG]
Emerging and Investigational Therapies

Aspire Assist

- Venting Gastrostomy tube
  - 20 min procedure; fully reversible
  - Allows removal of approx. 30% of ingested calories following each meal (after 20 mins)
- EWL 37.2% +/- 26.7% (PP) at 12 months
  - 15-21% TBWL
  - Ongoing weight loss at 2 years
  - Weight loss in excess of aspirated calories
- Common side effect of granulation tissue. Electrolyte abnormality uncommon.
TransPyloric Shuttle

- Slows gastric emptying
- Very well tolerated
- Under investigation in US (RCT) and Australia (Single Arm)
  - Feasibility study published 2014 of 20 patients with ongoing weight loss throughout study period (6 months). EWL 41% TBWL 14.5%
  - Complicated by ulcers in 10% (2 pts)
- 12 month (or longer?) residence

POSE

- “Primary Obesity Surgery, Endoluminal”
- Gastric plication focussed on fundus (and distal body)
- Failed to meet primary endpoint in pivotal trial 4.94±7.04% TBWL (although 13.04±1.4% in Europe)
  - Likely owing to flawed study design (allowed cross-over if failed to lose adequate weight; low intensity lifestyle intervention)
- Offered in Europe and Middle East
**EndoBarrier**

- 60cm Duodenal liner
  - Purportedly induces malabsorption by preventing ingested food from mixing with bile and pancreatic juices, and limiting contact with small intestine
  - Likely also GI hormonal changes owing to altered GI nutrient sensing
  - Complicated by ~2% risk of hepatic abscess
    - Anchor design issues; ? Role of PPI.
- Poor weight loss (<10% TBWL) but impressive improvements in HbA1c
- No longer TGA approved
  - Likely to be redesigned and released

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**Fractyl- Duodenal Mucosal Resurfacing**

Cauterises 10 – 15cm duodenal mucosa
- Injects fluid to act as safety buffer to prevent full thickness burns & strictures
- Circulates hot water via balloon to effect cuffs of mucosal burns

First in Man results
- Baseline early G1 obese HbA1c 9.6±1.4%
- Absolute reduction of 1.2±0.3% was seen in HbA1c at 6 months
- Minimal weight loss of roughly 3%TBWL at 6 months
- 2 strictures; treated with balloon dilatation
**Incisionless Anastomosis System- GI Windows**

Magnets aligned from prox. jejunum and distal ileum under fluoroscopy
- Magnets induce pressure necrosis and fistula formation, creating a bidirectional “bypass”

First in Man, 10 subjects (mean BMI 41kg/m²)
- 10.6% TBWL at 6 months
- 4/10 had DM2 at baseline (HbA1c 7.8%) and experienced a -1.8% reduction (despite reducing or stopping all anti-diabetic meds)
- Resolved prediabetes within 6 months
- Overnight observation, discharged 24 hours and no complications*

**Future Directions**

- Improved devices and techniques
  - Durability, safety, device delivery & retrieval, efficacy
- Combination therapy with pharmacologic agents to augment efficacy and/or stabilise weight
- EBTs in combination (eg IGB and EndoBarrier) or in series (eg multiple IGBs)
- Conventional bariatric surgery augmented with EBT (eg LSG + Fractyl/GI Windows)
Summary

- EBTs represent effective therapies positioned between pharmacotherapy and conventional surgery
- Adjunctive lifestyle intervention is critical for short and long term efficacy
- May be used as primary interventions or as bridging procedures
- Numerous therapies are available or are under investigation
  - Represents a potential paradigm shift in bariatric care
- Liaise with Bariatric Endoscopist if any concerns

Q&A