Latest Advances in Weight Loss Surgery
Disclosure

- Medtronic - Speaker/Research Grant
- Gore - Education Grant/Speaker
- Teleflex - Consultant
- Da Vinci - Proctor
- Mederi - Speaker
- Novadaq - Advisory Board
- Levita Magnetics - Advisory Board
Comprehensive Obesity Treatment
At DUHS there are 9 different centers or clinics that provide weight management services, located in 7 different locations.

Duke Lifestyle Medicine Clinic
Endocrinology, Metabolism, and Nutrition
Lifestyle & Disease Management Center
A coordinated and comprehensive Weight Management Center that spans the entire continuum of services.

Weight Management Center

Alignment of vision with 2015 Clinical Enterprise Strategic Plan

- Clinical Quality
- Patient-Centered Care
- Integration/Coordination of Care
- Strategic Growth
- Innovation
- Population Health
Comprehensive Weight Management Services Large Group

- Sarah Armstrong, M.D. – Duke Healthy Lifestyles
- Mitch Babb – Vice President, DRH
- Andrea Coviello, M.D. – Endocrinology
- Kathleen Galbraith – President, DRH
- Derrick Keddington – Administrative Fellow, DUH
- Pamela Keels – Senior Business Manager, Department of Surgery
- Brian King – Strategic Planning, DUHS
- Andrea Layton – Administrative Director, DRaH
- Andrew Muir, M.D. – Gastroenterology
- Thaddeus Murray – Strategic Planning, PDC
- Neha Pagidipati, M.D. – Cardiology
- Adam Perlman, M.D. – AVP, Health and Wellness
- Joseph Piccirilli – Administrator, Metabolic and Weight Loss Surgery, DRH
- Dana Portenier, M.D. – Metabolic and Weight Loss Surgery
- John Ragsdale III, M.D. – Community and Family Medicine
- Devdutta Sangvai, M.D. – Family Medicine, Medical Director of DukeWELL
- Stuart Smith – Associate Vice President, DUHS
- Michael Spiritos, M.D. – Chief Medical Officer, DRaH
- Jenny Tong, M.D. – Endocrinology
- Kathleen Worrell – Strategic Planning, PDC
- Will Yancy, M.D. – Diet and Fitness Center
- David Zaas, M.D. – President, DRaH
- Nancy Zucker, PhD – Duke Center for Eating Disorders
**Proposed Patient Flow:**
- Multiple entry points
- Centralized intake
- Right balance of patient preference and guided decision-making
- Standardized H&P, Labs/Testing during initial appointment
- Keep patients within DUHS
Indications

- Based upon 1991 NIH Guidelines
- Late June or July multiple surgical and endocrine societies are meeting to take a fresh look at these guidelines
Procedure Advances
**How many bariatric surgeries are taking place?**

The fast growth in weight-loss surgeries has ended. Though numbers are not available beyond 2009, most in the field believe the number of procedures is going down.

<table>
<thead>
<tr>
<th>Year</th>
<th>Percent change</th>
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<tbody>
<tr>
<td>1992</td>
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<td>1994</td>
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<td>4%</td>
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<td>2006</td>
<td>15%</td>
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<td>2007</td>
<td>7%</td>
</tr>
<tr>
<td>2008</td>
<td>0%</td>
</tr>
<tr>
<td>2009</td>
<td></td>
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</table>

**Source:** American Society for Metabolic & Bariatric Surgery

Published April 23, 2012, in American Medical News. www.amednews.com
Filling the Gap
How many bariatric surgeries are taking place?
The fast growth in weight-loss surgeries has ended. Though numbers are not available beyond 2009, most in the field believe the number of procedures is going down.
The Gap
Less invasive, lower risk alternative
Right-fitting your patients for success

vBloc® Therapy, delivered via the Maestro® System, is:
- Non-anatomy altering
- Customizable, adjustable and reversible to accommodate your patients' varied lifestyles.

Patients who underwent vBloc Therapy experienced 28% Excess Weight Loss (EWL) in the first twelve months.¹

Allows patients to safely lose weight by helping them feel less hungry and still able to eat a normal variety of foods.

The Maestro® System is a neurometabolic device that blocks the nerve signals between the stomach and the brain, effectively controlling appetite.

vBloc® Therapy, delivered via the Maestro® System, is FDA approved for weight loss in adults with a Body Mass Index of 40-45 kg/m² or 35-39.9 kg/m² (with a related health condition). Individuals should have first tried to lose weight by diet and exercise in a supervised program within the last 5 years before receiving the Maestro® System.
Overall Efficacy: vBloc® Therapy EWL Results

Clinically significant weight loss, 28% EWL at 12 months*
Sustainable weight loss across all trials up to 36 months
Over 50% of vBloc patients achieved +20% EWL*

Follow-up Visit (Months)

<table>
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<th></th>
<th>0</th>
<th>3</th>
<th>6</th>
<th>12</th>
<th>18</th>
<th>24</th>
<th>36</th>
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<tbody>
<tr>
<td>VBLOC-DM2</td>
<td>28</td>
<td>26</td>
<td>25</td>
<td>26</td>
<td>24</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>EMPOWER (treatment group with &gt;9 hours of use)</td>
<td>79</td>
<td>77</td>
<td>78</td>
<td>79</td>
<td>67</td>
<td>60</td>
<td></td>
</tr>
<tr>
<td>ReCharge</td>
<td>117</td>
<td>117</td>
<td>109</td>
<td>119</td>
<td>94</td>
<td>87</td>
<td></td>
</tr>
</tbody>
</table>
Role of the Vagus Nerve

Targeting neurometabolic pathways

20% MOTOR
Vagus Nerve fibers send instructions from the brain to the gut

- Gastric acid secretion
- Digestive enzyme secretion
- Gastric capacity/motility
- Glucose regulation

80% SENSORY
Vagus Nerve fibers send instructions from the gut to the brain

- Satiety (Hunger)
- Satiation (Fullness)
- Energy metabolism
- Blood pressure regulation
**Procedure: Implanting the Leads & Placing the Neuroregulator**

- Leads implanted laparoscopically
- Electrodes placed around vagus nerve
- Electrical impulses applied to Vagus Nerve
Intragastric Balloons

- 2 FDA Approved Devices in the US today
- Stay in the Stomach for 6 months
- Most programs are combining with a 12 month medical weight loss program
ORBERA™ provided 3.1x weight loss vs. diet & exercise alone

Mean EWL at 6 months: 38%
The first week with ORBERA™ will be challenging

Patients should expect to feel sick for the first 3-5 days. In some patients, symptoms may last up to two weeks.

Medications will be prescribed to help address the symptoms and our support team is available to help as needed.

### Frequent Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>% of Subjects</th>
<th>Severity: n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td>Nausea</td>
<td>86.9%</td>
<td>73/139 (52.5%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>75.6%</td>
<td>54/121 (44.6%)</td>
</tr>
<tr>
<td>Abdominal pain (general)</td>
<td>57.5%</td>
<td>44/92 (47.8%)</td>
</tr>
<tr>
<td>Gastroesophageal reflux disease</td>
<td>30.0%</td>
<td>31/48 (64.6%)</td>
</tr>
</tbody>
</table>
Magnets
Over a 12 week period, B-CAPLET™ patients take 5 caplets at meal time, forming a large artificial bezoar, filling 80% of the stomach.
Reversibility

- A Degaussing machine de-magnetizes magnets in stomach.
- Peristalsis breaks up demagnetized artificial Bezoar.
- De-magnetized caplets pass through intestines and are defecated.
- Patient can be re-treated
Caplets before peristalsis shapes the artificial bezoar
Peristalsis forms caplets into a bezoar, conforming to the shape of the stomach but reducing the stomach lumen, x-ray at 34 days
Conclusion

- We don't have a handle on the obesity epidemic
- Need to develop comprehensive solutions
- While surgery is safer than no treatment need to continue to improve the safety profile
- Need to find effective nonsurgical means to durably treat obesity