HEALING ALL PEOPLE WITH COMPASSION, FAITH AND EXCELLENCE
Surgical Therapy for the Treatment of Metabolic Syndrome

Bryan K. Thomas, MD
C. Kenneth Mitchell, Jr., MD, FACS, FASMBS
December 3, 2016.
Our Team - Proven Performance

• Roper St. Francis Bariatric and Metabolic Services
  • Designated an ASMBS Bariatric Surgery Center of Excellence® in 2011 and re-designated in 2015
  • Designated BlueCross BlueShield Center of Distinction for Bariatric Surgery in 2013, currently undergoing recertification
  • Designated a Certified Bariatric Center by Cigna in 2012
  • Aetna Institute of Quality for Bariatric Surgery in 2014
  • Awarded Disease-Specific Care Certification by the Joint Commission in March 2013
Our Team - Complete Patient Support

Charles (Ken) Mitchell M.D.
Bariatric Surgery
Medical Director
Established Bariatric Program in 2011  >2,400 cases

Bryan Thomas M.D.
Bariatric and General Surgery
Trained in advanced laparoscopic and minimally invasive surgery
>1500 cases

Suzanne E. Livengood-Britt, PA-C, MPAS
Physician Assistant

Jessica Raux, PA-C
Physician Assistant

Ginny Ledbetter, RN
Clinical Manager

Debbie Olin, RN
Office Nurse

Terri Southard
Licensed Professional Counselor

Michael Johnson
Practice Manager

Alexis Appel, RD
Registered Dietitian

Jillian Morgan, RD
Registered Dietician

Cassi Dawson
Medical Assistant

Sarah Greene
Bariatric Program Specialist

Ieshia Head
Bariatric Program Specialist
Our Team - Case Volume Since 2011

- Number bariatric cases: 1058
- Lap RNY: 662 (62.6%)
- Sleeve Gastrectomy: 146 (13.8%)
- Lap Band: 82 (7.7%)
- Revision: 53 (5.0%)
- LAGB Removal/Revision: 34 (3.2%)
- Other: 77 (7.3%)
- Open RNY: 4 (0.4%)

<table>
<thead>
<tr>
<th>Co-Morbidity</th>
<th>At 6 Months:</th>
<th>At 12 Months:</th>
<th>At 2 Years:</th>
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<tbody>
<tr>
<td>Sleep Apnea</td>
<td>32.1</td>
<td>46.8</td>
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<td>Hyperlipidemia</td>
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<td>Hypertension</td>
<td>34.2</td>
<td>38.1</td>
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<td>Diabetes</td>
<td>67.7</td>
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</table>
MBSAQIP Quality Data

**Safety Data**

<table>
<thead>
<tr>
<th>Complications</th>
<th>Count/Total (%)</th>
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<tr>
<td>Staple Line Leak</td>
<td>0/1058 (0.0%)</td>
</tr>
<tr>
<td>Mortality</td>
<td>0/1058 (0.0%)</td>
</tr>
<tr>
<td>&gt; 30-day LOS</td>
<td>1/1058 (0.09%)</td>
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<tr>
<td>D/C to NHP or Inpatient Rehab</td>
<td>2/1058 (0.18%)</td>
</tr>
<tr>
<td>Convert from Lap to Open</td>
<td>14/1058 (1.3%)</td>
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Data Range: 3/2012 – 6/2016
## Laparoscopic Sleeve Gastrectomy

<table>
<thead>
<tr>
<th></th>
<th>Total Cases</th>
<th>Observed Events</th>
<th>Obs. Rate</th>
<th>Pred** Rate</th>
<th>Expected Rate</th>
<th>Odds Ratio</th>
<th>C.I.*** Lower</th>
<th>C.I.*** Upper</th>
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<th>Decile</th>
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<tbody>
<tr>
<td>LSG Mortality</td>
<td>33</td>
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<td>1.40%</td>
<td>1.81%</td>
<td>0.77</td>
<td>0.21</td>
<td>2.88</td>
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<tr>
<td>LSG All Occurrences Mortality</td>
<td>33</td>
<td>0</td>
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<td>4.22%</td>
<td>5.33%</td>
<td>0.78</td>
<td>0.37</td>
<td>1.65</td>
<td>No</td>
<td>2</td>
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<tr>
<td>LSG Leak</td>
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<td>0</td>
<td>0.00%</td>
<td>0.25%</td>
<td>0.25%</td>
<td>0.99</td>
<td>0.44</td>
<td>2.19</td>
<td>No</td>
<td>7</td>
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<tr>
<td>LSG Bleeding</td>
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<td>0</td>
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<td>0.67%</td>
<td>0.72%</td>
<td>0.93</td>
<td>0.31</td>
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<td>No</td>
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<tr>
<td>LSG SSI</td>
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<td>0.25%</td>
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<td>LSG Related Readmission</td>
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<td>0.00%</td>
<td>2.62%</td>
<td>3.16%</td>
<td>0.82</td>
<td>0.35</td>
<td>1.94</td>
<td>No</td>
<td>2</td>
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Data Range: 3/2012 – 6/2016
<table>
<thead>
<tr>
<th></th>
<th>Total</th>
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<th>Outlier</th>
<th>Decile</th>
<th>Comment*</th>
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<tbody>
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<td>LRYGB Morbidity</td>
<td>120</td>
<td>5</td>
<td>4.17%</td>
<td>3.90%</td>
<td>3.31%</td>
<td>1.19</td>
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<td>120</td>
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<td>10.56%</td>
<td>9.89%</td>
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<td>2.50%</td>
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<td>2.19%</td>
<td>1.98%</td>
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<td>0.83%</td>
<td>1.37%</td>
<td>2.26%</td>
<td>0.60</td>
<td>0.19</td>
<td>1.91</td>
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<tr>
<td>LRYGB Related Intervention</td>
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<td>0.85%</td>
<td>2.01%</td>
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<td>8.33%</td>
<td>7.11%</td>
<td>5.24%</td>
<td>1.39</td>
<td>0.79</td>
<td>2.43</td>
<td>No</td>
<td>9</td>
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</tbody>
</table>
Total Pounds Lost: **54,796 lbs** =

24.5 Tons = 7,123 Gallons of Gasoline = 67,399 lbs of Coal =

Enough Energy to Power a 60-watt light bulb for 155,255 days or walk across England 7,123 times

Enough Energy to brew every cup of coffee served by Starbucks in the USA for one day

Total Loss in Fat Mass: **43,312 lbs (79.04%)**
Recent Accomplishments....

• Were able to remove the bariatric coverage limit to allow life-long follow up and care of our RSFH teammates with our multidisciplinary approach (team).
  • Presented a strong case demonstrating both safety and efficacy

• So why are we not utilizing this therapy for the majority of our morbidly obese patients?
  • Physicians and patients continue to push for less invasive treatments with equal efficacy
Balloon Band

- Minimally invasive outpatient procedure
- No permanent anatomical changes
- Lower complication rate than any bariatric procedures
- Patient eats normal food
- Durable life-long therapy

vBloc

- Minimally invasive outpatient procedure
- No permanent anatomical changes
- Lower complication rate than any bariatric procedures
- Patient eats normal food
- Durable life-long therapy
• FDA Approved Long-Term Surgical Weight Loss Solution

• Patient Eligibility
  • BMI of 35 – 39.9 with health-related conditions
  • BMI of 40 – 45

• ~700 Implanted Devices Worldwide

• Two+ Year Clinical Data Highlights Leader in Safety

(1) Center for Disease Control (CDC)
Neurometabolic Therapy
- 2 leads connected to the vagus nerve to block hunger signals between brain + stomach

Customizable for every Patient
- Therapy delivered up to 18 hours per day
- Can adjust level of blocking intensity

Recharged wirelessly by patient

Can be turned on and off or removed
## SIGNIFICANT Reduction In Co-morbidity Risk

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>1 Year Follow-up</th>
<th>Health Improvement Observed</th>
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<tbody>
<tr>
<td></td>
<td>Outcomes with 10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total Body Weight</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Loss</td>
<td></td>
</tr>
<tr>
<td><strong>HbA1c (%) (Diabetes Trial)</strong></td>
<td>-1.0</td>
<td>Clinically significant improvement in diabetic health</td>
</tr>
<tr>
<td><strong>Waist Circumference (reduction in inches)</strong></td>
<td>-7”</td>
<td>Reduction of abdominal fat, the fat associated with CV disease</td>
</tr>
<tr>
<td><strong>Triglycerides (mg/dL)</strong></td>
<td>-41</td>
<td></td>
</tr>
<tr>
<td><strong>Total Cholesterol (mg/dL)</strong></td>
<td>-15</td>
<td>Drop in “bad” cholesterol</td>
</tr>
<tr>
<td><strong>LDL (mg/dL)</strong></td>
<td>-9</td>
<td></td>
</tr>
<tr>
<td><strong>HDL (mg/dL)</strong></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td><strong>Heart Rate (bpm)</strong></td>
<td>-6</td>
<td>Overall improvement in cardiovascular health</td>
</tr>
<tr>
<td><strong>Diastolic BP (mmHg)</strong></td>
<td>-6</td>
<td></td>
</tr>
<tr>
<td><strong>Systolic BP (mmHg)</strong></td>
<td>-9</td>
<td></td>
</tr>
</tbody>
</table>
• vBloc® patients achieved an average 10% reduction in BMI from a starting BMI of 41.

| Starting BMI (kg/m²) | Reduction in BMI
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>5 %</td>
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<tr>
<td>30</td>
<td>69.35</td>
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<tr>
<td>31</td>
<td>130.67</td>
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<td>32</td>
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<td>37</td>
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<td>44</td>
<td>7,221.58</td>
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<tr>
<td>45</td>
<td>10,030.69</td>
</tr>
</tbody>
</table>

vBloc Complication Rate At 12 Months Is Lower Than Other Bariatric Surgery Options


Why is Obesity Such a Problem?

C. Kenneth Mitchell, JR, MD, FACS, FASMBS
December 3, 2016.
Goal Today is:

- To establish sustainable cultural change regarding the treatment of obesity
- Utilize a scientifically-based philosophical approach
- Emphasizing prevention and evidence based treatment models
• Early on, Obesity was thought to be a “surgical” disease.

• Bariatric surgery created more problems for the PCP and the patient than it addressed positively.
• Treatment of a nonsurgical, lifelong disease via a “surgical” approach left patients stranded and PCP’s frustrated, bouncing between providers
  – General Surgery
  – GI
  – Behavioral medicine
  – Endocrinology
  – ER Physicians
• PCPs felt they were doing their patients a disservice by recommending bariatric surgery in this environment.

• As bariatric surgeons, we had to clean up our act
  – Implement the multi-disciplinary treatment model
    • Cardiac Disease Treatment Model
    • Cancer Center Treatment Model
  – Focus on Quality Outcomes to regain the confidence of the patients and providers.
Step #1

Define Obesity Correctly
Definition of Metabolic Syndrome

- Need to meet at least 3 of the following:
  - Increased waistline c/w obesity
  - Hypertension
  - Hyperglycemia/Diabetes
  - Elevated Triglycerides
  - Decreased HDL

- “Metabolic” refers to the biochemical processes involved in the body’s normal functioning
Definition of Obesity

- NIH – “a BMI of 30 or above”
- BMI = Mass/Height x Height
- Dwayne “The Rock” Johnson
  - 6’ 5”, 262 pounds
  - BMI = 31.1
  - Is he “obese”? 
• Harvard T.H. Chan School of Public Health
  – “..having too much body fat.”
• Merriam Webster
  – “a condition characterized by the excessive accumulation and storage of fat in the body.”
• Mayo Clinic
  – “a complex disorder involving an excess amount of body fat.”
• Wikipedia
  – “a medical condition in which excess body fat has accumulated to the extent that it may have a negative effect on health.”
Step #2

Properly understand the mechanism of the disease of Obesity
• Weight can be reliably controlled by voluntarily adjusting energy balance through diet and exercise.

FALSE
Two Models

**Classical Model**
- Purposeful behavior *drives* the physiology of energy balance regulation
  - Increased calorie intake drives weight gain
  - All calories have similar effects
  - Calories burned during physical activity drive weight loss

**Newly Proposed Model**
- The physiologic regulation of energy balance *drives* behavior
  - Changes in the modern diet alters physiology
  - The chemical nature of the calories is critical
  - Re-regulation of abnormal physiology is essential to success
Fat Mass Set Point

Body Fat Mass Set Point
Body Fat Mass Set Point

- Abnormal Dietary Constituents
- Unhealthy Muscle
- Stress
- Sleep Deprivation
- Disrupted Circadian Rhythms
- Weight Gain Inducing Medications
Fat Mass Set Point

Body Fat Mass Set Point

- Abnormal Dietary Constituents
- Unhealthy Muscle
- Stress
- Sleep Deprivation
- Disrupted Circadian Rhythms
- Weight Gain Inducing Medications

After Years of Exposure
FIGURE 1. Body fat mass, a close correlate of body weight, is tightly regulated by several regions of the brain in response to a series of physiological feedback loops from other metabolically active tissues.
Step #3

We are not measuring the effectiveness of our treatment objectively
• Types of weight loss programs
  • Weight Watchers
  • Nutri-Systems
  • Jenny Craig
• All based on losing pounds!
• Is that the best way for the morbidly obese patient to improve their health?
What Weighs More?

• A Pound of Muscle?
• A Pound of Water?
• A Pound of Fat?

• THEY ALL WEIGH A POUND!

• If you could choose which one to lose, which would you choose?
Body Composition

• It is not important **WHAT YOU WEIGH**, but more important what your body **IS MADE OF**

• Example
  • Two people, each weighs 250 pounds
  • One is 50% body fat
  • The other is 20% body fat

• Do they look different?

• Increased body fat = more co-morbidities
Step #4

We are not utilizing prevention or treatment to the extent we should be
Prevention

• Should screen for obesity by obtaining body composition just as we screen for other diseases:
  – Colon Cancer
  – Breast Cancer
  – Prostate Cancer

• Early detection can lead to effective treatment prior to the development of numerous co-morbidities.
Treatment

• Should be based on the premise that as the disease process increases in severity, treatment options should escalate in like fashion

• Can’t treat Stage IV breast cancer in the same fashion as Stage I breast cancer or you are doomed to fail
  – Biggest Loser from the NY Times
  – Weight Watchers for the 350 pound patient with a body fat >50%
Questions?