



# Trends-in-Medicine

June 2008

by Lynne Peterson

## SUMMARY

Obesity procedures were predicted to increase an average of 11% in 2008 over 2007. ♦ Gastric sleeves are catching on very quickly, and they are likely to cause total gastric band usage over the next year to *decline*, while gastric bypass procedures are expected to grow slightly. ♦ Bariatric surgeons are happy with, and loyal to, Allergan's Lap-Band, but many are getting trained on J&J's Realize because they have seen – or expect – patient demand for Realize as a result of J&J's direct-to-consumer advertising. Thus, Lap-Band sales are likely to be hit by both sleeves and Realize. ♦ Gastric bypass safety is improving, and long-term complications of bands are increasing. ♦ Data are building that obesity surgery can cause significant remissions in diabetes, but data from large, randomized clinical trials are needed, including how long the effect lasts. Insurance coverage for bariatric procedures to treat diabetes in overweight but not obese patients is unlikely in the next 5 years. ♦ Sources were dubious about the outlook for EnteroMedics' VBLOC, an electrical vagus nerve block system.

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## Trends-in-Medicine

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## AMERICAN SOCIETY FOR METABOLIC AND BARIATRIC SURGERY (ASMBS)

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More than 20 bariatric surgeons and bariatric center nurses were interviewed at ASMBS about trends in bariatric surgery. Many said gastric sleeves are affecting use of banding devices. They predicted that their use of laparoscopic adjustable gastric bands (LAGBs) this year would be flat to down as a result of gastric sleeves.

The hot procedure at ASMBS was the laparoscopic sleeve gastrectomy, a restrictive surgery in which a line of staples are placed vertically in the stomach, leaving a cylindrical or sleeve-shaped stomach. Originally, sleeve gastrectomies were used in super-obese patients (BMI >50) to get their size down sufficiently to make them better candidates for gastric bypass (most often Roux-en-Y) surgery, but increasingly bariatric surgeons are using it in less obese patients as a stand-alone procedure. The gastric sleeve is an irreversible surgical procedure, but it can be converted to a gastric bypass if complications develop. Even though there is no company or specific device driving the sleeve trend, it is catching on very quickly. Almost every surgeon questioned said he is either already doing gastric sleeves or plans to start soon. Surgeons simply use staples which are sold by several companies, including J&J/Ethicon and Covidien.

Overall, on average, these sources estimated that procedure volume would increase 11% in 2008 vs. 2007. Gastric sleeve use would double to 20% of procedures. Gastric bypass would increase 5% to 40% of procedures. Adjustable gastric bands would decrease 6% to 40% of procedures.

Procedure Outlook

Procedure	Market share 2007	Market share 2008	Procedure volume change
Adjustable gastric band	47%	40%	Down 6%
Gastric bypass	42%	40%	Up 5%
Sleeve gastrectomy	11%	20%	Up 105%
Total procedures	100%	100%	Up 11%

More than 178,000 bariatric procedures are done annually in the U.S., and 10%-15% of the cases at major centers are now revisions of previous surgeries due to complications, a patient's failure to lose at least 50% of excess weight, or weight regain. Although bariatric surgery procedures are growing, they are still <2% of the eligible patients with insurance coverage who could benefit, and ~0.7% of all eligible patients.

### Why aren't more eligible people getting bariatric surgery?

Dr. James Maher of Virginia Commonwealth University said, "Many of our patients feel the currently available treatments are too invasive. Certainly, the gastric band is less invasive than gastric bypass, but at least in this country it looks like it may be less effective...I think there is room for improvement in our therapy for people who need surgical weight reduction."

#### ASMBS Members Procedure Preferences

Measurement	Laparoscopic			
	Bypass	Band	Gastric Sleeve	Duodenal switch
<b>If BMI were 35-44.9</b>				
With diabetes	57.4%	N/A	N/A	N/A
Without diabetes	27.8%	45.4%	25.9%	0
<b>If BMI were 45-54.9</b>				
With diabetes	71.3%	14.8%	9.3%	4.6%
Without diabetes	60.2%	26.9%	10.2%	2.8%
<b>If BMI were ≥55</b>				
With diabetes	68.5%	8.3%	6.5%	16.7%
Without diabetes	65%			13.5%

Researchers from Johns Hopkins presented a poster on the findings of their survey of 108 ASMBS members asking what bariatric procedure they would choose for themselves if they had diabetes and a BMI of 35-44.9. They found that ASMBS members preferred bypass for diabetes and for high BMI.

### LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING

#### ALLERGAN's Lap-Band and JOHNSON & JOHNSON/ETHICON's Realize

The results with an ideal band – and neither Lap-Band nor Realize are considered ideal – were described as:

- No more hunger – physical or emotional.
- No cravings.
- Ability to eat a variety of foods.
- Small meals are satisfying.
- No maladaptive eating.
- Resolution of all co-morbidities.
- 100% excess weight loss (EWL).
- Able to maintain ideal weight long term.
- No need for frequent adjustments in the long-run.

Doctors are generally very pleased with the results of banding. The key emphasis was on safety; mortality is lower with bands than with gastric bypass, though the mortality rate with bypass has been steadily improving and is now  $\leq 1\%$ .

From 10%-25% of bariatric surgery patients will need a provisional or salvage operation, according to Dr. David Provost of the University of Texas Southwestern Medical Center in Dallas. The role of laparoscopic adjustable gastric bands for these patients remains controversial, but Dr. Provost argued

#### Bariatric Procedures

Procedure	How it works	Excess weight loss (EWL)	Revisions	Advantages	Disadvantages
<b>Restrictive procedures</b>					
Vertical banded gastroplasty (VBG)	Upper part of the stomach is partitioned by a line of staples	No longer done in U.S. 1 year: 68.2%	79% at Mayo Clinic	Simple, low leak rate, minimal nutrient absorption	Solid food difficult to swallow, not much weight loss, high revision rate over time, erosion of the band
Laparoscopic adjustable gastric banding (J&J's Realize, Allergan's Lap-Band)	Adjustable silicone ring makes a pouch at top of stomach	3 months: 15%-20% 1 year: 40%-53% 2 years: 45%-58% 3 years: 49%	30%-50%	Adjustable, no dissection of the stomach, no change in hormonal secretion, short surgical time, very low mortality	Multiple office visits required for adjustments, malfunctions, slippage and erosion increasing over time, vomiting
Sleeve gastrectomy	Vertical staples reduce size of stomach, leaving a tube shape	18 months: 55%-64%	N/A	Simple procedure, normal intestinal absorption, can do in super-obese, can re-do other procedures, has hormonal action	Leakage, lack of 5-year data, long staple line creating a leak potential
Intragastric balloon (Allergan's BIB)	Balloon inflated in stomach to reduce functional size	Not FDA-approved, "not very good"	N/A	Simple procedure	Bowel obstructions
<b>Malabsorptive procedures</b>					
Original gastric bypass	Stomach is stapled horizontally into a smaller pouch	Rarely done today	N/A	N/A	Caused dumping syndrome
Roux-en-Y gastric bypass	Small stomach pouch created and attached directly to small intestine, bypassed duodenum	Most common bypass procedure 5 years: 50%-75%	5%-23%	Long-term follow-up	Dumping side effect, not good for super-obese, mortality ~4%
Biliopancreatic diversion with duodenal switch (BPD-DS)	Combines a reduction in stomach size with bypass of some of the small intestine	1 year: 70%	N/A	Good long-term weight loss, particularly in super-obese	Higher complication rate than gastric bypass or banding

that a band is a safe and effective option for patients who regain weight following a variety of bariatric procedures.

The key issues with gastric bands appear to be:

- Gastric sleeves are slowing or decreasing use of bands.
- Patient compliance with adjustments can be problematic.
- Long-term efficacy is proving disappointing. Efficacy appears to wane (perhaps because of compliance issues) by 3 years.
- Performing adjustments under fluoroscopy is gaining popularity, but manual palpation remains the primary method.
- Weight loss is significantly less with bands than with gastric bypass, but band safety is perceived as better than bypass.
- The complication rate is increasing over time.

Researchers from Hennepin County Medical Center in Minneapolis presented a poster on a retrospective analysis of their experience with 252 Lap-Band patients. They found the EWL was lower than expected, and a large standard deviation suggested that patient-specific factors play large roles in the success of any surgery. They also reported that follow-up compliance dropped to about 57% at 18 months and 55% at 36 months. EWL was 26.8% at 6 months, 35.5% at 12 months, 4.0% at 18 months, 7.2% at 24 months, and 34.5% at 36 months. The complication rate was 15% (43 events in 38 patients): 9 slipped bands, 5 cholelithiasis, 4 tubing fractures, 4 band fractures, and 4 port rotations, but no deaths. Re-operations were required in 22 patients (40% of these for mechanical malfunction).

#### Co-morbidity Results with Lap-Bands

Measurement	Resolved	Improved	Worsened
GERD	42%	10%	8%
Hypertension	19%	12%	8%
Type 2 diabetes	19%	29%	0
Urinary incontinence	19%	14%	0
Depression	14%	9%	7%
Obstructive sleep apnea	11%	28%	0
Asthma	9%	34%	6%
Osteoarthritis	9%	30%	5%

#### Bands vs. Bypass

Measurement	Band n=100	Bypass n=100	p-value
All complications <30 days	8%	11%	Nss, 0.63
Early complications >30 days	<b>3 patients:</b> wound infection, trocar site bleeding, urinary retention	<b>6 patients:</b> wound infection, G-J bleed, LUQ abscess, pneumonia	Nss, 0.49
Late complications	5%	3%	---
Re-operation	<b>7 patients:</b> mostly device complications like port malfunction, band erosion, or port erosion	<b>1 patient:</b> bowel obstruction	Nss, 0.06 "strong trend"
EWL at 1 year	41%	64%	<0.01
BMI change	Down 10	Down 15.5	<0.01
Type 2 diabetes at 1 year	38% reduction	71% reduction	---

Researchers from the University of California, San Francisco, matched 100 bypass patients to 100 band patients by BMI, gender, race, age, and diabetic status. They reported laparoscopic gastric bypass is as safe as laparoscopic adjustable gastric bands but provides superior weight loss.

Physician comments on bands included:

- *Texas*: "It is now very difficult to keep patients coming to the office for (band) adjustments with the current gas prices. On the other hand, people say these (bands) work because people have to come to the office for adjustments...It seems in the long term that gastric bypass and banding have similar weight loss results."
- *Louisiana*: "We used to tell (gastric band) patients they would lose 10-15 pounds the first month, but now that we are seeing more patients with lower BMI, we say 1-2 pounds per week, with >1 pound per week considered 'exceptional.'"
- *New York #1*: "Slippage is the No. 1 complication with gastric bands...We do our adjustments in the office without fluoroscopy...I've punctured a few ports...(But) most complications are very fixable. They are rarely fatal or urgent. Of all the Lap-Bands I've taken care of, we had one urgent removal from a patient with gastric prolapse and massive chest pain after eating that would not go away."
- *Connecticut*: "I think a lot of patients with a band look for a magic sledgehammer that whacks them over the head when they choose the wrong foods. Bands don't do that. They take away hunger."
- *Pennsylvania*: "From 10%-20% of patients post-operatively either don't lose as much weight as they want or regain weight. Ten percent of bypass and 25% of banding patients fail to maintain at least a 5% reduction in body weight."
- *New York #2*: "Remission of diabetes is less with banding than with bypass."

- “I went from 100% bypass to 85% bands...Once you do a couple of bands, those patients send you more patients, and the practice builds up pretty fast. I let my patients tell me what they want to do.”
- *California*: “The only reason I do bands is because patients ask for them. Yes, it is a less severe operation, but I see so many people having trouble with compliance with bands. The bands are more frustrating for them with the adjustments and trying to find the sweet spot, and they can cheat. Patient demand has forced me to do bands. I was very enthusiastic about the band in the beginning, but now, after 7 years, I’m less happy with the results.”
- “After 7 years, I don’t see a difference between the band and bypass...but if I can be safer, why not do a band...I have to have a good reason not to do a band.”
- *New York #3*: “I will choose the safer operation, which is the band.”

### Lap-Band vs. Realize

In order to use either Realize or Lap-Band, a physician must go through a short training course (one day for experienced Lap-Band surgeons starting Realize). There is already a backlog for J&J’s training program, and several doctors, particularly in smaller bariatric practices, said they have been unable to get on the training schedule yet, but they still expect to get trained in the future.

Lap-Band vs. Realize

Measurement	Lap-Band	Realize
List price	Realize is slightly less expensive but a lot of negotiations and bundling are occurring, obscuring final pricing	
Port	Has a “click” to it	Flatter, no click, easier to adjust
Port placement	4 sutures	Port applier, no sutures
Width	19 cm	23 cm
Pressure	Low	Very low
Marketing	Website not as interactive as Realize	My Success online program for patients
Shape	Pre-curved	Straight
Unbuckle design	Yes	No
Maximum volume	10-14 cc	9 cc
EWL	43%-62% at 1 year	41.1% at 3 years

The key differences between Lap-Band and Realize are:

- **Shape** – possible advantage to Lap-Band.
- **Width** – possible advantage to Realize.
- **Pressure** – Realize uses higher pressure, which several (but not all) doctors described as an advantage.
- **Port application** – possible advantage to Realize because its port applier requires no stitches, but Allergan reportedly is working on a similar device.

- **Website** – possible advantage to Realize. J&J’s My Success website garnered high praise from doctors. However, Allergan reportedly is about to upgrade its website with more interactivity.
- **Price** – Realize may be a little cheaper on the list price, but so much negotiating is going on that final prices are probably very close.

### How will doctors choose between Lap-Band and Realize?

Several doctors said it depends on patient demand. Some doctors have already had patients coming in asking for Realize, and that is likely to increase since J&J began a direct-to-consumer marketing campaign about a week before ASMBS. Most bariatric surgeons questioned said they plan to get trained on Realize, particularly so they can offer it to patients who ask for it.

Surgeon comments included:

- “We started doing Realize to offer patients what they want...People will come and ask for it...I tell them we have two (bands) with the same concept but different technology.”
- *Tennessee*: “We just started doing Realize. We get patients asking for Realize, so we offer it. If patients want it, they can have it.”
- “I’ve only used Lap-Band. I have a lot of experience with that, and the company has been very supportive. There is no patient demand for Realize yet.”
- “I prefer Lap-Band because it is a high pressure band, and it has a physiological curve, but there are good results with both.”
- *Colorado*: “I just trained on Realize and will do a group of patients to see how they do. The platform is good and makes sense. It is a different philosophy, but the studies show it is relatively equivalent. It’s a Ford vs. a Toyota thing. I’ll let the patient choose, but personally I have a lot of experience with Allergan’s Lap-Band, and Allergan has done a good job of supporting surgeons...Allergan now realizes it has to up its game with the J&J entry.”
- “I took the Realize course. There is no functional difference in the two bands. We are an Ethicon hospital, and we are re-negotiating our contract right now...J&J is not discounting Realize, but it will bundle it...I’m not anxious to replace the Lap-Band because I’ve had good experience with that, and it is extraordinarily safe. I told the hospital administration I may need both as J&J’s advertising campaign will lead to people asking for Realize. I want to be able to offer it. I just had my first patient ask about Realize. I give equal time to the two bands in my patient discussions...The Realize size may decrease slippage, but it really needs to be properly positioned...Realize will compete more effectively against Lap-Band with its second generation device. Now, it will be an uphill battle.”

- *New York #1*: “I haven’t had any demand for Realize yet.”
- *Ohio*: “I will start Realize and compare it in my hands (to Lap-Band)...The motivational aspects of the Realize website are unique.”
- “We’ve seen patients with a Realize who had it implanted elsewhere, and we will start doing Realize ourselves.”
- *California*: “I will train on Realize, but I won’t use it in the next year unless patients ask for it.”
- *New York #2*: “I’ve done both Lap-Band and Realize. What I use in the future will depend partly on patient choice. If a patient verbalizes a preference, we will respect that because both are suitable. Some support group patients ask about the differences, and I say it is a choice between a Cadillac and a Lincoln – both are impressive. But price could literally drive choice if one is offered \$1,000 less than the other, that would be enough to drive choice.”

### Band adjustments

The advantage of bands – adjustability – is also one of the biggest negatives. Typically, both Lap-Band and Realize are generally adjusted every 4-8 weeks, and compliance with the frequent office visits required is <60% by Year 3. In addition to the travel and time involved, those visits cost patients from \$100-\$300 each (without insurance coverage). Then, there are the support group meetings.

**Band Adjustment Approaches**

Issue	Fluoroscopy	Palpation
Location	Usually hospital- or ASC-based but can be office-based	Usually office-based
Fill schedule	Depends on fluoroscopy results	Usually a fixed schedule
Physician/technician safety	Radiation exposure needs to be monitored	No issue
Number of adjustments needed	Fewer	---

Adjusting the bands can be a bit of an art. Most bariatric surgeons use only palpation and patient status reports to determine when a band needs filling, but interest in fluoroscopy-directed adjustments is growing. At one session, about 10% of the audience indicated they were using fluoroscopy.

Several speakers argued that fluoroscopy is a more accurate way to adjust bands, but they admitted that it is also more expensive, particularly for a private practice, more time consuming, and requires manpower to support it. Palpation can be done in the office but it is a “blind stick.”

*Asked if fluoroscopy-guided adjustments give better weight loss and require less frequent adjustments than palpation, Dr. Greg Schroder of Richmond VA said, “It depends on the type of band you are using. If you are doing palpation, especially with Realize, there is a limit of 4 cc that you can put in with the first adjustment, and we find we are putting in more fluid with fluoroscopy. There is a suggestion that fluoroscopy-based adjustments do get the patient to the sweet spot quicker. In our experience, we have had tremendous success using fluoroscopy guidance, with small adjustments in the office under palpation.”*

Dr. Matthew Kroh of the Cleveland Clinic argued that routine fluoroscopic imaging provides clinically important information that affects band management (and adjustments), “Routine fluoroscopy altered (our) management in 12% of patients and identified 3 (asymptomatic) malpositioned bands ...12% of patients who would have undergone a fill based on symptoms alone were not filled based on fluoroscopic findings ...And some non-randomized studies suggest better weight loss may be achieved with fluoroscopic imaging.”

### Band efficacy

Dr. Richard Flint of Brigham & Women’s Hospital presented the results of a two-part retrospective study of treatment failure with LAGB vs. laparoscopic gastric bypass, which showed significantly better efficacy (excess weight loss) with gastric bypass. He pointed out that it is critical to account for drop-outs when comparing the two procedures.

Using a last observation carried forward (LOCF) approach, he computed mean EWL at 1, 2, and 3 years. Then, in the second part of the study with increased follow-up, statistical modeling was used to account for missing data. He found bypass and bands were comparable in weight loss at 3 years if treatment failures are ignored, but bypass was significantly better when treatment failures were included.

**Gastric Bands vs. Gastric Bypass (by LOCF)**

Issue	Gastric bypass	Gastric band	p-value
Baseline BMI	47.7	45.6	<.001
<b>Part I</b>			
EWL without failures	Bypass showed significantly more weight loss after 1 year, bypass still statistically significant at 2 years, not significant at 3 years		<.05 in Year 1 and Year 2, Nss in Year 3
EWL with failures	Peak at 1 year	Peak at 1 year; significantly less than bypass in Year 1-2-3	<.05 in all 3 years
<b>Part II</b>			
EWL without statistical modeling	Bypass better than band at Years 1-2-3, but lines <i>beginning to converge</i> and possibility of similar efficacy over longer time		<.05 in all 3 years
EWL with statistical modeling	Band plateaus after ~2 years and is significantly worse than bypass, which is <i>maintained</i> over time		<.05 in all 3 years

### Bands in young patients

Dr. Hermann Nehoda of Austria reported on a retrospective study that found disappointing mid-term gastric band results in 41 morbidly obese young patients (under age 25). He said, "When banding was introduced 12 years ago, the early results were excellent and very promising – with low early morbidity, almost no mortality, and good weight loss. But with young patients, our results showed bands were very successful in the first 4 years...Thereafter, BMI slowly increases, and weight loss is unsatisfactory in many patients."

Dr. Nehoda said 46% of these patients required re-operations, and the complication rate was 52%: 27% pouch dilatation, 10% leaking, 5% band migration, 5% perforation of the esophagus, and 5% port disconnection. Of the 11 pouch dilatations, 3 had the band removed, and 8 had a band revision. Overall, the failure rate was 40%, and a fair outcome was achieved in 4% of patients, good in 28%, very good in 20%, and excellent in 8%.

In conclusion, Dr. Nehoda said, "If you take the high complication rate and unsatisfactory weight loss after >4 years, the most important reason for poor results were complications and re-operations...The long-term results are not as promising as expected when LAGB was introduced. LAGB will probably remain the procedure of choice for many patients, but the main complaints are dilatation and band migration."

### Truncal vagotomy plus gastric band

Dr. Luigi Angrisani of Naples, Italy, presented interim results of a prospective randomized trial comparing LAGB ± vagotomy (vagal nerve severing or removal) in 50 patients with a BMI of 35-45. It showed no statistically significant advantage to the addition of vagotomy in terms of weight loss, but patients did require fewer band adjustments with a vagotomy. The side effects from vagotomy were belching (95.25% at 3 months), bloating, diarrhea, and dumping; but most of these side effects disappeared within 18 months.

LAGB ± Vagotomy

Measurement	LAGB n=25	LAGB + truncal vagotomy n=23
EWL at 12 months	33%	30% (Nss)
Patients not requiring adjustment at 6 months	25%	50%
Patients not requiring adjustment at 12 months	8%	35%

### SLEEVE GASTRECTOMY

Sleeve gastrectomies are gaining in popularity as primary procedures, and there was high attendance at all the talks on this, but there are several unresolved issues with this procedure, including:

- **Bougie size.** Initially, a 60 bougie was used, but most experts are now using smaller bougies. The question is

Sleeve Gastrectomy vs. Gastric Band

Measurement	Sleeve Gastrectomy	Gastric Band
Complications	More surgical-related (bleeding), dehydration	More late
EWL at 1 year	25 kg/m <sup>2</sup>	15.5 kg/m <sup>2</sup>
EWL at 3 years	27 kg/m <sup>2</sup>	18 kg/m <sup>2</sup>
Peri-operative mortality	0.39%	N/A
Efficacy	33%-83% EWL	Less
Durability	3-5 years	Comparable
Adjustments necessary	No	Yes
Reflux post-procedure	Higher initially, but <5% at 3 years	Not much initially, but >20% at 3 years
Hospital length of stay	Slightly longer	Shortest
Effect on ghrelin	Removed completely	None
Loss of appetite	Yes	No
Dietary restrictions	No	Yes

how small is small enough. Some experts argued that 32 is best, but others said that 40 is fine. One expert noted that a slightly larger bougie allows room for a re-do if necessary later. Dr. Michel Gagner of Mt. Sinai Medical Center in Miami said, "I started with a 60 bougie and then went to 50 and then 40...My thinking is that I'd rather have a sleeve I can re-sleeve than a sleeve that is too narrow and then there is no material to work with...The difference between 32 and 40 is small."

- **Pylorus distance.** Experts also didn't agree on how far the sleeve should be from the pylorus. Some place it 2 cm from the pylorus, and others prefer an 8 cm distance. Dr. Eldo Frezza of Texas Tech University said, "I personally do 8 cm from the pylorus; others do 2 cm."
- **Lack of long-term data.**

Dr. Phil Schauer, director of the Bariatric and Metabolic Institute at the Cleveland Clinic and a past president of ASMBS, cited several advantages to sleeve gastrectomy: low mortality, reduced technical challenges, reduced major complications, short operating time, minimal nutritional complications, weight loss similar to bypass, no adjustments necessary, and no device complications. Another expert added some other advantages: little/no dumping syndrome, no intestinal bypass, no internal obstruction, no anemia, no vitamin deficiencies (except B-12), and fewer dietary restrictions. The disadvantages of the sleeve include a potential for leaks (though less than with bypass), not easily reversible, and no long-term data yet.

Dr. Raul Rosenthal of the Cleveland Clinic Florida predicted that the sleeve gastrectomy was going to "inundate our market." Another speaker said the gastric sleeve has twice the EWL as the intragastric balloon (which is not yet approved in the U.S.) and twice the weight loss of the gastric band at 12 months. He said there is less feeling of hunger at 1 year with the sleeve than with banding.

Dr. Paul Cirangle of San Francisco said the number of gastric sleeves he has been doing has significantly increased over time, and he expects to do ~400 this year, which is about 50% of his total procedure volume. Since 2002, he's done ~1,000 patients, mostly men, with an average BMI of 45.7. Operating time has decreased to about 55-65 minutes. He's found the resolution of co-morbidities is very similar to the results with gastric bypass: 83% diabetes, 79% hypertension, 76% GERD, 67% joint pain, 93% sleep apnea. His complication rate with the sleeve was 9 patients (0.9%) vs. no leaks with bypass, bleeding 0.4%, readmission 2.2%, death 0.1% (a leak cared for outside his facility), and pulmonary embolism (0.15%).

Physician comments on sleeves included:

- *Texas*: "The gastric sleeve is not a difficult procedure and can be done by anyone anywhere."
- *New York #1*: "I don't do many sleeves because my partners each had a leak, and one patient died. I'm hearing more and more reports of leaks and deaths not being reported."
- *Colorado*: "I just started sleeves, but the jury is still out."
- "I do some sleeves, but they aren't affecting my band use. I offer sleeves when the patient is not a good band candidate and not a good bypass candidate."
- *Ohio*: "There is no CPT code yet for sleeves, and reimbursement is a challenge. We have a fair number who pay cash. Medicare doesn't reimburse yet, and private insurance varies. But we are now at the turning point with sleeves. There is now a critical mass of studies. The operating cost is comparable to a band, but in the long run a sleeve is cheaper because there are no adjustments, and ~10% of bands slip and require re-operation. Sleeve leakage is ~1%."
- "Cash patients will find gastric sleeves the cheapest because there is no device, no adjustments, etc. And the hospital price point should be lower, making the sleeve the most economic for patients with no insurance or who have insurance and still want to pay cash."
- "I haven't done any sleeves yet, but I took training, and I will start."

Swedish researchers presented a poster on the initial results of the first 23 of 79 consecutive gastric sleeves in self-pay patients with BMI 30-35 at a private hospital. Average length of stay was 2 days, operating time was 90 minutes (though it is now down to ~70 minutes), and EWL was 100%. Most co-morbidities were improved or resolved at 6 months. Two patients required re-operation due to bleeding, one needed a transfusion due to a drop in hematocrit, there was one patient with protracted port pain, and one patient with a port wound infection.

### OBESITY SURGERY IN LOWER BMI PATIENTS TO TREAT DIABETES AND OTHER CO-MORBIDITIES

Bariatric surgeons at ASMBS were enthusiastic about data suggesting that obesity surgery (gastric banding and bypass) can cause a remission of Type 2 – and even some insulin-dependent – diabetes. However, the vast majority of the diabetic population has a BMI <35, so this would mean expanding the indications for bariatric surgery to a less overweight population (BMI 30-35), and non-surgeon experts were not optimistic that bariatric surgery will become an insurance-covered procedure for this group of patients in the near future. They predicted that coverage for diabetes in BMI 30-35 is likely to require large, long-term trials, and other medical specialties will fight the proposal.

Medical costs attributable to obesity are \$45 billion a year, Eric Finkelstein PhD, director of the Public Health Economics Program at RTI International, estimated. He pointed out that obesity treatments are being held to a different standard than other medical procedures – that they have to be proven to save money, not just be cost-effective in terms of quality of adjusted life year (QALY) saved. "If the high cost of obesity is the reason for government intervention, then you should only implement cost-savings interventions, and the reality is that cost-savings interventions in obesity are pretty tough to come by and highly unlikely."

Dr. Schauer added, "A health economics study of the cost-effectiveness of obesity operations over 2.5-4 years will be published soon in the *American Journal of Managed Care*, and this will be important. The results show that there are cost savings in that period and beyond."

Dr. Brent O'Connell, former medical director for Highmark Blue Shield (Pennsylvania), said the insurance industry is happy that bariatric surgeons have reduced the complication rate for obesity surgery, but he predicted that it will be more than five years before obesity surgery will be reimbursed as a treatment for co-morbid conditions like diabetes. He said, "They (insurers) won't extend coverage readily if you just have diabetes and want the surgery to do away with the diabetes."

Dr. O'Connell said bariatric surgeons face some formidable adversaries in the diabetes coverage fight, "You have to convince the American Diabetes Association (ADA) that obesity surgery is important in diabetes...(and) the Endocrine Society support is needed...The Endocrine Society is who insurers will consult...The ADA, for all the good work it does, is a fund-raising machine. It is big business. The bariatric profession doesn't have such an organization yet...You need lobbyists, organizations, and bariatric surgeons to participate. You need a voice, and you don't have a voice for the most part."

He also warned that more data, especially from large, randomized trials, will be needed and should get started soon, "There is a general rule in the insurance industry: If there are

a lot of people with a disease, you need large, long, well-controlled studies. That is what you need to start working on. You need evidence-based support, but there is no quick take-off here. It will take a period of time, probably a minimum of five years to get the energy or momentum to get diabetes listed as a coverage for bariatric surgery.”

Surgeons did not like the idea of new, large trials. A California surgeon said, “I cure more diabetes in southern California than all of the endocrinologists on the east coast of this country combined...We have data. It may not be randomized because we can't do that because our patients want surgery...For you to say to us that you need more data – for the ADA and endocrinologists, who are afraid we are taking their patients away – just doesn't jive.” Dr. O'Connell responded, “It may not seem to jive, but I want you to understand the reality of the situation you are facing...You need to understand you have a formidable adversary in the Endocrine Society. They are consultants to every insurance company out there...Every insurance company has an endocrinologist as a consultant...The data they are asking for is not whether bariatric surgery works. We know it works. The data you need to establish is whether doing some kind of bariatric procedure on someone who has normal BMI and diabetes has a positive outcome – that the diabetes stays away for whatever period of time you want to talk about. If you don't have documented outcomes, since they (the insurance companies) only have a patient 3-4-5 years, they won't foot the bill for someone else to benefit from.”

The ongoing STAMPEDE trial, sponsored by J&J, may provide some data, but not everything Dr. O'Connell believes is needed. STAMPEDE is comparing medical therapy alone vs. medical therapy plus bariatric surgery (either Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy) in patients with Type 2 diabetes and BMI 30-40. The study will examine the short- and long-term effects of each intervention on biochemical resolution of diabetes, diabetic complications, and end-organ damage.

Dr. O'Connell also warned bariatric surgeons not to try sneaking procedures by insurance companies, “Coverage without review: this is coverage under the radar. Sometimes plans look at this as bordering on illegal behavior, so don't get sucked into this. Don't get sucked into doing anything foolish. You can do off-label things and have other arrangements for coverage – like government-sponsored cancer clinical trials. If you can get a government agency to do a clinical trial, many plans will cover that.”

*Can obesity surgery be approved without large studies based on common use, like TENS units or chiropractic care?* Dr. O'Connell said that would take a very long time, “This (approach) is a slow process,

very slow, going plan by plan by plan. You just may make it doing this, but it is a long, tedious process.”

*Are states likely to mandate that insurance companies cover obesity surgery for diabetes?* Dr. O'Connell said that is possible in Massachusetts and California but unlikely in other states.

*Will payors sponsor a trial?* Dr. O'Connell suggested it was possible but unlikely, “The federal government can run a trial project on that...but on the commercial side, it is very difficult to do that.”

Dr. O'Connell summed up his view of the obesity/diabetes landscape using an airplane analogy: “There is turbulence ahead. It will be the payors and ADA...There are many diversions (necessity, convenience)...It will be a long trip (no preventive benefit). It will be a high cost trip and will take five years of very good data. You have worrisome flight controllers, which is the Endocrine Society, which will not be terribly cooperative with you because they have a vested interest...You have a potential water landing.”

### Centers for Medicare and Medicaid Services (CMS)

On May 19, 2008, CMS initiated a National Coverage Analysis (NCA) to see if there is sufficient scientific evidence to support a National Coverage Decision (NCD) for bariatric surgery performed to treat diabetes in patients with lower BMIs (30-35). During the public comment period, which ended May 18, 2008, major medical societies, including ASMBS, recommended against it. A CMS decision on the NCA is expected this fall, but an announcement that an NCD is being initiated is not expected. Experts were dubious that Medicare would decide to start an NCD.

### Employer viewpoint

Tom O'Brien, director of obesity marketing for Johnson & Johnson/Ethicon Endo-Surgery, said 8% of employees are morbidly obese, 30% are either obese or morbidly obese, 34% are overweight (BMI 25-30), and 30% are normal. He said that in the U.S., 45% of employees have bariatric surgery

### Direct and Indirect Costs to Employers of Obesity

Measurement	Morbidly obese (BMI >40)	Obese (BMI 35-40)	Overweight (BMI 30-35)	Normal (BMI 25-30)
NIH guidelines for bariatric surgery	Recommended	Recommended if co-morbid conditions	No coverage	No coverage
Employees	8%	30%	34%	30%
Work days lost (indirect costs)	5.3 days/year	5.0 days/year	N/A	4.2 days/year
Direct costs per employee	>\$4,300/year	\$2,700/year	~ \$1,600/year	~ \$500/year
Population	5 million	15 million	40 million	90 million
Tolerable mortality from bariatric surgery	<1%	<0.5%	0	0
Intervention cost	\$25,000	\$16,000	\$10,000	\$3,000



coverage, with the number increasing, “73% of the largest companies offer bariatric surgery coverage. Why cover it? Because large companies tend to have longer employee tenure, they work in a competitive environment, and take a much longer view. The largest employers who can take an economic look at it have, and they are deciding to cover. It is the smaller companies that face different cash flow issues.”

O’Brien explained that bariatric coverage saves companies money: “To a company like J&J (with self-funded medical coverage) with 120,000 employees, the indirect costs in lost productivity is 38,000 missed days...or \$5 million in lost productivity” plus \$137 million in direct costs.” He said an ROI analysis of actual claims data at J&J showed that bariatric surgery paid for itself in 2-4 years. Among patients with diabetes, he said the payout can be as short as 18 months.

### Effect of gastric banding on co-morbidities

Researchers from the Northwest Weight Loss Surgery in Everett WA reported on short-term results of LAGB in 118 low BMI (30-35) patients, an off-label use of the band. They concluded that “a significant segment of obese population in the U.S. has been denied access to this procedure...LAGB results in significant weight loss at 6 months and 1 year that is associated with the improvement and resolution of many obesity-related co-morbidities. Further study may prompt a re-evaluation of these recommendations (NIH guidelines).”

LAGB in Low BMI Patients

Measurement	6 months n=106	12 months n=79
EWL	49.5%	69.5%
Weight loss	11.0 kg	15.2 kg
Complications	6.8%	
<b>Improvement in co-morbid conditions at 12 months</b>		
Type 2 diabetes	100%	
Insulin-dependent diabetes	100%	
Hypertension	75%	
Obstructive sleep apnea	67%	
GERD	68%	
Joint Pain	77%	
Depression	68%	
Stress urinary incontinence	67%	
Low back pain	72%	
Asthma	75%	

### NEW OBESITY THERAPIES IN DEVELOPMENT

Dr. Scott Shikora of California reviewed new technologies on the horizon. He pointed out that with the current options most eligible patients are not getting a procedure, “What is coming may be safer and have fewer issues than what we have today. Fewer than 1% of eligible patients are undergoing bariatric surgery (today). Many patients and perhaps many of you out there who might refer patients are not interested in what we are offering. You and they are looking for something safer,

and that is where new technologies are headed...Patients are not busting down our doors for the operations because many people are fearful of the side effects and food intolerance issues.”

### Intragastric balloons: ALLERGAN’s BIB

Early balloons had complications including pressure ulceration/perforation and rupture with intestinal obstruction. The FDA pulled single-layer balloons from the market, but newer balloons are in use in Europe, and likely to come to the U.S. Dr. Shikora said, “(Single-layer balloons) went the way of other bad ideas. But the concept of a balloon itself is not a bad idea. It is the design that was bad. Allergan’s BIB balloon is double-layered and round, so there are no edges to cause erosions, ulcers, and bleeding. The weight loss (~26%) is reasonable and may be a reasonable first-stage for the super-obese, high risk patients. There is modest weight loss, but this is not a long-term solution. Generally, the balloons stay in ~6 months.”

Italian researchers reported on a laparoscopic gastric sleeve vs. BIB. They said weight loss and decrease in co-morbidities was comparable at 6 months. A researcher said, “When you take the balloon out, patients slowly regain weight and the co-morbidity reappears...The balloon is a good first stage to prepare a patient for surgical procedures. In patients with a lower BMI, long-term use might be possible.” He predicted that a U.S. trial would begin later this year.

### New gastric bands

- **ALLERGAN/ENDOART’s FloWatch Telemetric Gastric Band.** This is a watch motor-driven band that eliminates the port and port-related complications. The band is tightened wirelessly. Dr. Shikora said, “If this ever comes to fruition, it would make bands more popular, take away pain, inaccuracy, etc. I was told it will be around very soon.”
- **HELIOSCOPE’s Heliogast.** This French band is sold in Europe. A user said it is very good. The company reportedly is trying to decide if it will bring Heliogast to the U.S.

### Natural orifice totally endoscopic surgery (NOTES)

Endoscopic gastric partitioning and/or bypass can be done to correct prior procedures or as a new procedure, such as placing endoscopic stents or sleeves. Endoscopic stapling, partitioning, or anastomoses are being explored. Dr. Shikora said, “It is an early frontier but exciting.”

- **J&J’s Spiderman** goes down the mouth.
- **USGI MEDICAL’s Transport** allows the use of 3 instruments through the endoscope. Dr. Shikora said, “There is not a lot of literature on (Transport) yet...It is a work in progress. It is FDA-approved, but time will tell.”

- **ENDOGASTRIC SOLUTIONS' Stomaphyx** “pleats” the stomach endoscopically. Dr. Shikora said, “I’m guardedly optimistic. I think we would use this as a stop gap to get the patient into a better state of mind and then work with the patient to be more compliant and maybe you could salvage some people. But if this eliminated the 20% of revisions, maybe there is something to it.”
- **GI DYNAMICS' EndoBarrier.** This 60 cm impermeable endoscopic gastric sleeve is put into the GI tract to separate food from the small intestine. It is anchored in the duodenum, creating a duodenal-jejunal bypass. In pigs, researchers found a smaller sleeve decreased normal weight loss, and a longer sleeve caused pigs to lose weight. In a small (12-patient) study in Brazil, patients achieved weight loss and “dramatic” improvement in diabetes. Currently ~100 patients have been done worldwide, and the major problem has been that some devices migrate and have to be removed, but so far the removals have not involved major complications. EWL was ~26%. There was one esophageal perforation, but once the device is in place Dr. Shikora says there have been no problems with it.

#### Single port surgery: CAMBRIDGEENDO's Autonomy Laparo-Angle

The idea behind this technology is to give surgeons complete wrist-like maneuverability in a hand-held, 5 mm laparoscopic device. The single point of entry is the belly button.

#### Neuromodulation – stimulation or blocking

Dr. Shikora called this a very hot area. A generator is used to deliver an electrical pulse to target tissue in the GI tract for either blocking or enhancing. It is *not* gastric pacing. Dr. Shikora said, “It is hard to say if these will work.”

Among the companies working on devices are:

- **Cyberonics** – vagal nerve stimulation.
- **Leptos Biomedical** – sympathetic nerve stimulation.
- **Intrapace** – intragastric stimulation.
- **MetaStim** – implantable intestinal stimulation.
- **Medtronic's IGS** – a pocket-watch-sized, implantable gastric device that stimulates the stomach with a continuous electrical current. The lead is implanted in the wall of the stomach in a procedure that takes less than an hour, and there is no change in GI anatomy or function. It is reversible, adjustable, and safe. So far about 800 patients worldwide have been implanted. Average EWL so far has been ~25% (~35% in responders). Dr. Shikora said, “These are not bypass results, but it doesn't have the bypass risks. At about one year the batteries ran down, and patients regained weight. When the batteries were replaced, the patients lost weight again. There are now data out to 10 years, and patients who respond have kept their weight off. There have been no deaths or serious complications...The problem is it did not work consistently...It is extremely safe vs. gastric bypass or banding, but it is not consistently effective. Some patients responded, but many did not...And we never targeted how it worked, which physiologic function directly causes the weight loss...Medtronic has backburnered this.”
- **Metacure's Tantalus** – implantable gastric stimulation that is activated when a patient eats. It involves more leads (6) than IGS. When a patient eats, the device recognizes food and fires. In pilot trials, there was ~20%-25% EWL in 1 year, but they also had non-responders. Dr. Shikora said, “Like IGS, it had some responders, but it also had non-responders, for many of the same reasons ...I don't know if this is still being studied. The project may have been stopped.”
- **EnteroMedics' VBLOC** – intra-abdominal vagal nerve block. A higher frequency current (5000 Hz) is delivered directly to the vagus nerve with the sole function of shutting the nerve off. There have been no complications and no major problems, with a reduction in food intake.

#### New surgeries for diabetes:

- **Duodenal exclusion** – This was pioneered in Brazil. Patients rarely lose much weight, but there is a profound improvement in diabetes.
- **Betastim's duodenal electrical stimulation** – Electrodes are implanted into the anterior wall of the duodenum. In an animal model, there was a dramatic reduction in sugar and insulin when this device was activated. No data have been published yet, but Dr. Shikora called it “very exciting work” and “incredibly safe.” Human trials are expected to begin in Europe this summer. Dr. Shikora said, “I think this will also cause weight loss, but the intent of the entire project is diabetes (reduction).”

#### VAGAL BLOCKING: ENTEROMEDICS' VBLOC Maestro

EMPOWER, the PMA trial of VBLOC, is on schedule to complete enrollment this month. This is a 15-center (13 in U.S., 2 in Australia), 300-patient study. The primary endpoint is EWL with the device on vs. with the device off; the secondary endpoint is the percentage of patients with ≥25% EWL. A subset of patients is diabetic.

Electrodes are positioned at the anterior and posterior vagus nerve, and the regulator is implanted along the rib cage. Patients then wear an external device belt during waking hours. The 5000 Hz device is intermittently turned on, causing a functional vagotomy. In the trial, all patients are having a device implanted. In the first year, 200 will have it turned to the on position, and 100 to the off position. At the end of one year, the device will be turned on in all patients. This is a five year trial, but the company expects to file for FDA approval on one-year data.

Katherine Tweden PhD, an EnteroMedics' scientist, described the preclinical data on VBLOC. She said that data on blocking from 1-12 weeks in more than 50 juvenile pigs were submitted to the FDA. Glucoregulation, heart rate, and blood pressure were all unimpaired, normal microstructure was maintained at the nerve level, and digestive enzymes were down-regulated. Rodent data demonstrated complete and reversible vagal block, "As soon as we turn off the block, the animals are fully recovered by 10 minutes."

Prof. James Toouli of Australia described the experience with the first 38 patients in Australia, Mexico City, and Norway. He said, "The electrodes need to be very precisely implanted so they don't tilt... We thought the (first device) was very nice and very clever, but it was quite large, and the patients didn't really like it. So, it has gone through some very positive changes for the patient... When there is a fully implantable component, when it becomes even smaller, we may have something that will be very readily acceptable (to patients)."

Dr. Toouli said that at 6 months there was no change in the percentage of carbohydrates consumed. However, patients consistently felt earlier fullness when the system was working, and there was a significant reduction in hunger between meals. He added, "It does affect pancreatic function... It does do what it is meant to do... but none of the patients get steatorrhea (non-solid stools)... so we must be blocking enough to have an effect but not enough to produce an abnormality." At 12 months, the interim results in these patients continue to be promising.

Preliminary VBLOC Results

Measurement	Number of patients	EWL
3 months	26	17%
6 months	28	21.4%
9 months	17	27.4%
12 months	12	29.1%

A nurse from Australia who has worked with VBLOC for more than 2 years said patient response to VBLOC has been mixed, some good and some "not too good." She said patients generally report: Reduced hunger and appetite, some report a constant feeling of "fullness," satisfaction with food, control over food and becoming a "normal eater," a lack of obsession with food. She described the best candidates as patients who accept they need help, have succeeded/complied with a diet, and have internal motivation and a willingness to respond to new cues. Poorer candidates are emotional eaters, know-it-alls, patients with "magic bullet" expectations, patients who expect rapid weight loss, and patients with the notion that bypass/band is the only solution."

Some of the reasons the nurse said patients *may like* VBLOC are:

- No limit to dietary choices.
- Lack of alteration of anatomy/absorption.

- Feeling of "wellness" instead of ill health feelings related to restrictive procedures.
- It is a positive procedure, which avoids punitive outcomes associated with restrictive procedures.
- Opportunity to learn new eating behaviors.

She also cited some things patients *don't* like about VBLOC:

- It is not restrictive, so it won't help emotional eaters.
- They have to wear an external device – which leads to compliance issues. "The device sometimes can be cumbersome... particularly as patients lose weight and become more conscious of their body."
- The rate of weight loss may be too slow.
- Side effects can be an issue, including retrosternal pain, bloating ( $\pm$  nausea), and discomfort from the neuro-regulator under the skin, which might catch when they move.

At a symposium sponsored by EnteroMedics, Virginia bariatric surgeon Dr. Maher, who has been doing VBLOC for 6 months, discussed where VBLOC might fit into a bariatric practice. He said, "How can I have perspective on something we've done for 6 months? Perspective is something we've done for 5-10 years... Every bariatric procedure looks good for two years... I've done (many types of procedures) over 28 years of practice and 6 years of residency... I've seen procedures come and go. So far, there is one that has stood the test of time – gastric bypass. Lap-Band looks pretty good now, but there is still no really long-term follow-up... It is too soon to say what role this (VBLOC) will have... It could be the best thing since sliced bread, or it could fail... Potentially, it is more physiologic... and it looks pretty safe. It is easy to expose the vagus nerves, even in very heavy males. It is less easy to place the electrodes, but that could be overcome... It is good for pregnancy, illnesses like cancer, Crohn's, etc., necessitating improved nutrition... I don't know how this will turn out. It is a very exciting procedure to be associated with."

*Asked about non-responders*, Dr. Toouli said, "There have been non-responders. In the initial patients there were 5-6 non-responders, and I honestly can't say why... Emotional eaters, etc., we believe were the problem... I think after a while there were some patients who really didn't like wearing an external device, and then they become non-responders. It works, but they just don't like wearing a device... I think ultimately it will be the fully implantable device that will make it acceptable... If you give patients a choice (with an external device), that is probably not a good thing, that probably increases the non-responders. Patients who need bariatric surgery need the choice to eat taken away from them... The device is largish at the moment, but it is getting smaller." An investigator from Mexico added, "Hopefully, we will have a good size that gets rid of the problems soon."

**MISCELLANEOUS****COVIDIEN**

Tyco International spun off Tyco Healthcare, and it was renamed Covidien. Bariatric surgeons had high praise for the new company. Among the comments were:

- “Covidien is more focused now, and it has an alliance with Allergan to sell Lap-Band, which is good.”
- “There has been a huge positive difference since the company became Covidien. It’s given them an agility they didn’t have. Before, they couldn’t make fast changes as part of a huge conglomerate. Today, they can. And they are hiring good people. The relationship with Tyco is also a positive. Covidien is coming on strong, the products are good, and it is a much better competitor to J&J than it was.”
- “Covidien being a stand-alone is very positive for the bariatric industry. They have specialized reps for our needs. Now they have reps we know who are familiar with us and are there to work with us.”

the operating room time increased initially, and then decreased to previous levels, and PACU time was unchanged. Asked if he is still using the Da Vinci for bariatric surgery, he said he initially used it for all bands, but now he uses it only selectively – for patients with hiatal hernia, reach issues, or thick abdominal walls.”

**INTUITIVE SURGICAL’S Da Vinci**

Intuitive had a booth at ASMBS and was showing the Da Vinci. Bariatric surgeons were interested in it, and a few said they are already using it for bariatric procedures, primarily gastric bypass, and one surgeon said he is using it for gastric bands as well. However, doctors pointed out that Da Vinci is just too expensive for their hospital to purchase one just for bariatric surgery. A California doctor said, “I tried the robot, and it was not worth the effort. The biggest application is to help the surgeon with the (physical) work.” A Maryland doctor said, “We have two robots at our hospital, but we haven’t used either of them for bariatric surgery yet.”

A speaker presented a retrospective review of Da Vinci procedures at Stanford from July to December 2005: 21 robotic procedures, 78 stapled bypasses, 36 hand sewn bypasses. He said there was no statistically significant difference in complications, mortality, procedure time, or length of stay; but the cost of the robotic procedure was significantly higher ( $p < .007$ ). He concluded, “In my brief experience, especially in high BMI, the physical strain on the surgeon is removed. The benefit to the patient is hard to assess; there is not much benefit to the patient.”

**Procedure Costs in a Bariatric Surgery Practice**

Measurement	Average cost
Robotic surgery	\$82,000
Stapled bypass	\$66,000
Hand sewn bypass	\$69,000

Dr. Michael Johnell of Colorado presented a poster with initial data on the use of the Da Vinci in Lap-Band surgery at his center. During 2006 and 2007, his center used the Da Vinci in 174 of 216 cases, concluding it is safe and effective. He said