Implantable Gastric Stimulation for the Treatment of Obesity in Adults: A Systematic Review

Blair Monell
Pacific University
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Abstract
Background: The problem of obesity in the adult population requires the exploration and development of new, safe effective therapies to combat increasing girth. Implantable gastric electrical stimulation (GES) offers a novel, minimally invasive surgical approach to promote weight loss. This report utilizes the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool to review and evaluate current literature exploring GES as a safe and effective therapy for reducing obesity in adults.

Method: An exhaustive search of available medical literature was conducted in the PubMed, Medline, Evidence-Based Medicine Reviews Multifile, Web of Science, and CINHAL databases.

Results: Three studies were reviewed for the primary endpoint of percentage of excess weight loss (EWL) and secondary endpoint of device safety. GRADE results revealed moderate levels of evidence for both of these endpoints. A small subset of adult patients experienced weight loss ranging between 5-17% EWL while other patients experienced weight gain.

Conclusion: Use of a gastric electrical stimulation device fails to produce any significant weight loss in obese individuals when compared to traditional lifestyle changes of diet and exercise. Implantable GES for weight loss in obese adults is not recommended.

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Implantable Gastric Stimulation for the Treatment of Obesity in Adults: A Systematic Review

Blair Monell

A course paper presented to the College of Health Professions in partial fulfillment of the requirements of the degree of Master of Science

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# TABLE OF CONTENTS

**INTRODUCTION** .............................................................................................................5  
  Background ...............................................................................................................5  
  Purpose of the Study .............................................................................................8  
**METHOD** .........................................................................................................................8  
**RESULTS** ........................................................................................................................9  
**DISCUSSION**.................................................................................................................14  
**REFERENCES** ..............................................................................................................22  
**APPENDIXES** ..................................................................................................................25  
  A. Table 1: Body Mass Index (BMI) Classification ...................................................26  
  B. Figure 1: Intra-operative view of implantable GES device during laparotomy with electrodes attached to the proximal antrum .................................................27  
  C. Figure 2: Transcend gastric electrical stimulation device and its anatomical placement .................................................................................................................28  
  D. Figure 3: Tantulus™ Gastric Electrical Stimulation Device ........................................29  
  E. Table 2: GRADE Quality of Studies ....................................................................30
INTRODUCTION

Background

Obesity is a growing pandemic, tipping scales across the globe. The most current statistics from the International Association for the Study of Obesity (IASO, 2010) estimate that worldwide over 475 million people are obese. The Centers for Disease Control and Prevention (CDC, 2010) report that in the United States approximately 72.5 million adults are obese. This translates into greater than one in three American adults having a body mass index (BMI) > 30 kg/m² (Bray, 2011; Flegal, Carroll, Ogden, & Curtin, 2010; Appendix A, Table 1).

Obesity takes its toll both directly through economic costs and rising rates of morbidity and mortality and indirectly through non-tangible drains on society. The annual medical burden of obesity is estimated to be $147 billion per year with a per capita spending 42% higher than for someone of normal weight (Finkelstein, Trogdon, Cohen, & Dietz, 2009). The IASO (2010) reports that increased BMI has been strongly linked as a risk factor for the development of type II diabetes, hypertension, coronary-heart disease, and other co-morbidities such as various cancers, gall-bladder disease, fatty liver, sleep apnea and osteoarthritis. The organization also reports that annually, obesity is responsible for an estimated 2.8 million unnecessary deaths in the US. Obesity is now considered to be at least equal to smoking as a preventable cause of premature death (Monash University, 2009). In the Framingham Study, obese middle aged adults lived on average six to seven years less than those with BMI ≤ 24.9 kg/m² (Bray, 2011). Conversely, by maintaining a healthy BMI of less than 30 kg/m² a
middle aged adult would gain about two years of life expectancy (Prospective Studies Collaboration, 2009). Obesity also indirectly puts a strain on social resources by forcing numerous infrastructure changes including but not limited to wider transportation seats, reinforced hospital beds and larger wheelchairs. Furthermore, income lost from absenteeism, decreased productivity and illness is often overlooked when evaluating the overall negative impact of obesity within America (IASO, 2010). In 2004, disability attributable to obesity was calculated at over 36 million disability-adjusted life years (IASO, 2010). It is clear that the socioeconomic hardships stemming from obesity require immediate attention.

Despite available anti-obesity treatment options such as behavioral, pharmaceutical or surgical interventions, rates of obesity have increased 1.1 percentage points since 2007 (CDC, 2010). Conservative lifestyle alterations such as diet and exercise are proving to be insufficient in combating obesity, so long-term maintenance of weight loss remains uncommon (Hogan, Gallagher, Kennelly, Baird, & Winter, 2009). Furthermore, systematic reviews of oral weight loss drugs show poor compliance and minimal weight loss after one year of treatment (Hogan et al., 2009). Finally, while surgical interventions are moderately successful, currently <1% of patients who qualify for bariatric surgery will undergo it (Shikora, 2004). Obstacles to bariatric operations include large financial cost and patient fear of perioperative and long-term complications. Morbidly obese individuals are often coupled with multiple comorbidities making them high-risk surgical candidates. The death rate for bariatric procedures ranges between 0.2%-1% with a ten-fold major complication rate of about 10-
20% (Shikora, 2004). The continuing trend toward an increasing adult BMI reflects an urgent need for more affordable, more effective and overall safer bariatric treatment alternatives.

One such promising alternative is the implantable gastric stimulation device. Shown to be effective in animal trials as well as some small human trials, this bariatric surgery is being touted as the safest and simplest operation currently available (Bohdjalian et al., 2006; Greenway & Zheng, 2007). Unlike other obesity surgeries, gastric electrical stimulation (GES) does not rely on manipulation and rearrangement of the patient’s anatomy to promote malabsorption or create restrictive conditions in order to achieve weight loss. Instead, GES applies a small electric current to stimulate the stomach and induce early satiety while reducing appetite (Hogan et al., 2009). The GES device consists of an electrical pulse generator similar to a cardiac pacemaker and bipolar leads (Shikora et al., 2004; Appendix B, Figure 1). A minimally invasive laparoscopic technique implants these electrode leads in the gastric muscular wall, while the generator is implanted subcutaneously along the anterior abdomen (Sanmiguel et al., 2009). Post-operatively, the device is turned on and rhythmic imperceptible contractions commence. Variations among devices exist, as currently there is no standardized anatomic position for lead placement nor is there a uniform recommendation for stimulation voltage, pulse width, pulse frequency, or duty cycle.

A systematic review of GES as a treatment for morbid obesity was performed in 2006 (Medical Advisory Secretariat, 2006). The authors found the
quality of evidence to be low and gave a weak recommendation for using GES to treat morbid obesity in adults. At that time, no randomized clinical trials had been published in full. Since 2006, new literature has emerged further evaluating this unique approach as a treatment for adult obesity.

Purpose of the Study

The purpose of this paper is to perform a systematic review of the most recent literature published after 2006, to evaluate the safety and efficacy of implantable gastric stimulation to reduce obesity in adult patients. The literature will be evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool developed by the GRADE Working Group.

METHOD

An extensive literature search was performed using PubMed, Medline, Evidence-Based Medicine Reviews Multifile, Web of Science and CINHAL. These databases were accessed through the Pacific University Library system. The following keywords were searched individually and in combination: gastric electrical stimulation, gastric pacing, adult, obesity and weight loss. The search was limited to human subjects, the English language and articles published after 2006. The initial results included 37 articles of which duplicates, descriptive reviews and letters to the editor were excluded. This resulted in 26 articles to review. Articles which did not examine weight loss as a primary outcome of interest, studies that included participants with poorly controlled diabetes, or studies with participants who had failed previous bariatric surgery were excluded.
This left three relevant articles which met inclusion criteria and were assessed in the final analysis.

RESULTS

The first study reviewed was performed by Shikora et al. (2009) who conducted a large, randomized, placebo-controlled, double-blind, multi-center study known as the SHAPE trial, with a primary outcome of evaluating the difference in the percentage of excess weight loss (EWL) between control and treatment groups. The SHAPE trial was sponsored by Medtronic/Transneuronix, the manufacturers of the Transcend implantable GES device (Shikora et al., 2009). Enrollment criteria were limited to adult participants (18-65 years old) with a BMI of 35-55 kg/m² and who have successfully passed a BaroScreen screening algorithm. This algorithm was developed by Medtronic of Minneapolis, MN using data gathered from previous gastric stimulation clinical studies as a predictive tool to estimate potential weight loss with implantable GES treatment. Only candidates with a predicted loss of \( \geq 15\% \) excess body weight within one year were considered eligible for enrollment in the trial. Exclusion criteria included pregnancy, lactation, previous gastrointestinal (GI) bariatric surgery, previous operations of any type on the stomach, the presence of other electrostimulation devices, GI motility disorders, peptic ulcer disease, behavioral issues that would have excluded them from conventional bariatric surgery, binge eaters, and clinically important co-morbid diseases such as poorly controlled diabetes.

In all, 190 patients underwent implantation with the Transcend gastric stimulation device (Shikora et al., 2009; Appendix C, Figure 2). Two weeks after
implantation, randomization occurred. At this point one half of the study population had their stimulation device turned on while the other half was kept inactive. “All subjects were instructed to consume a diet with a 500-kcal/d deficit and were required to attend monthly support group meetings” (Shikora, et al. 2009, p. 445). After 12 months of treatment there was no statistically significant difference in the percentage of excess weight loss between the treatment and control groups. Additionally, there were no statistically significant between-group differences at any month during the trial. At the conclusion of the 12 month period the control group lost 11.7% ± 16.9% of their excess weight and the treatment group lost 11.8% ± 17.6% of their excess weight. The authors concluded that no clinically or statistically significant difference for the primary outcome of weight loss was found between the two groups in the study. They go on to state that these findings are consistent with those achieved in earlier trials evaluating implantable GES for the treatment of obesity in adults (Shikora et al., 2009).

Beyond evaluating the efficacy of GES as a treatment for obesity, a secondary outcome of the SHAPE trial assessed the safety of the device. Of the 190 subjects, 26 (13.7%) experienced one or more endoscopy-detected gastric lumen lead penetrations during the laparoscopic implantation. None of these perforations led to consequences such as gastric leak, infection, or bleeding. Additional complications included two lead dislodgments and one patient who developed a pocket infection. Also, at the conclusion of the study it was discovered that 22 devices were noted to have a low battery capacity. Despite
these incidents, no deaths or major complications occurred. Given these results, the authors concluded that implantable gastric stimulation is a less complex procedure than current bariatric operations.

The second study reviewed also evaluated weight loss and safety outcomes of GES. Performed by Champion, Williams, Champion, Gianos, and Carrasquilla (2006), a small, nonrandomized, open-label FDA clinical trial evaluated the safety and efficacy of GES in low BMI patients. The primary outcome of interest was 10% total body weight loss within the 2-year follow-up period. Secondary outcomes included monitoring of adverse outcomes and change in waist circumference. Inclusion criteria were adult patients, a BMI between 30-35 kg/m², passing a BaroScreen algorithm, passing a binge eating questionnaire, and a psychological evaluation. No exclusion criteria were reported.

In all, 24 patients at two geographic sites underwent laparoscopic implantation of the Transcend gastric stimulation device (Champion, Williams, Champion, Gianos, & Carrasquilla, 2006). Two weeks after surgery all of the devices were activated. The participants were instructed on a 500-calorie energy-deficient diet and exercise program. Follow-up findings and outcomes at six months were reported. The mean percentage of EWL at six months for the combined 24 patients was 5.9% total. A subset of nine patients had an EWL of at least 10% (mean 20.1% EWL). In total, 14 patients lost weight (mean 13.9% EWL) and 10 patients gained weight (mean 8.2% estimated weight gain). There were no deaths or serious adverse events reported by the authors. Adverse
events reported for more than 5% of subjects included abdominal pain (20.8% incidence), incisional site pain (16.7%), stomach lumen penetration at implant (16.7%), generalized pain (12.5%), fever (8.3%) and flatulence (8.3%). The only statistically significant outcome reported in the study, was a mean waist circumference decrease of 5.8%. The authors concluded that gastric stimulation appears to be safe for weight loss in a low BMI population. Since only approximately one-third of the patients experienced an EWL exceeding 10% at six months, the authors felt further exploration of GES is warranted.

The third and final study reviewed was by Bohdjalian et al. (2006) which explored the effect GES had on several outcomes. The article described a small, prospective, non-randomized, open-label, single-center trial which evaluated changes in body weight in morbidly obese human subjects, gastric stimulation device safety, and the effect of GES on both eating behavior and blood pressure. The participants were followed over a 20 week period with an additional extension period up to 52 weeks. Inclusion criteria consisted of adult patients between 18-50 years of age, a BMI between 35-50 kg/m² which had been stable for three months, five years of obesity history and energy expenditure > 1200 kcal/day. Participants were excluded from the study if they had had a previously placed permanent electro-stimulation device, undergone previous bariatric surgery, were found to have unstable weight (± 1 BMI unit) during the four week screening period, were currently taking antidepressant drugs, had an eating disorder, had endocrine-related obesity, had taken weight-loss medication within the last three months, suffered from motility disorders of the GI tract, had an
alcohol or drug abuse problem, or suffered from any psychopathological
diseases.

In all, 12 morbidly obese, non-diabetic subjects were included in the
Bohdjalian et al. (2006) study and were laparoscopically implanted with the
Tantalus™ System (Appendix D, Figure 3). After a six week stabilization period
following device implantation, all devices were activated. While the participants
were not required to follow a specific diet, a dietician did provide information
about the caloric content of foods and education about a healthy diet. The
authors reported that at 20 weeks a statistically significant body weight decrease
from 128.8 kg ± 5.2 kg to 119.9 kg ± 5.9 kg corresponding to an EWL of 17.6% ±
4.3% occurred. At 28 weeks, three patients had dropped out of the study. In the
remaining nine subjects a further decrease to 112.4 kg ± 3.8 kg was observed,
corresponding to an excess weight loss of 26.6% ± 8.5%. At the conclusion of
the study, after a 52-week period and one further drop out, a total EWL of 30.5%
± 8.5% was documented in the remaining eight participants. The authors
concluded that weight loss achieved via gastric stimulation is comparable to
gastric banding over a 52 week period but inferior to gastric bypass and other
malabsorptive procedures. It was the authors’ opinion that these results for
weight loss encourage further studies so that GES may eventually be included
among the options for the treatment of obesity.

Secondary outcomes of the study included the effect implantable GES had
on blood pressure (BP) and eating behavior. Device safety was also examined
(Bohdjalian et al., 2006). In regards to blood pressure, the authors found a
statistically significant decrease at week 20 and again at one year follow-up readings. The mean BP of 10 participants decreased from 142mmHg + 6.1 / 91mmHg + 3.2 to 125.5mmHg + 4.0 / 83mmHg + 2.6 at week 20 and the mean BP of eight participants was 128.8mmHg + 3.8 / 86.3mmHg + 3.6 at one year. In regards to eating behavior, the authors state “subjects showed a significant reduction in the score for hunger, while the score for cognitive control increased significantly” (Bohdjalian et al., 2006, p. 631). Safety concerns associated with the device or procedure were minimal. There were five documented lead failures in four patients and one intra-operative gastric penetration. One serious adverse event related to the surgery, was the development of severe rhabdomyolysis and blood loss in combination with pulmonary insufficiency on the day of implantation leading to prolonged hospitalization. Though attributed to the procedure, the events resolved without sequelae and the participant was able to complete the study. No other safety concerns related to the device or its implantation were cited. Altogether, the authors concluded, “that the device and its implantation appear to be safe and well-tolerated” (Bohdjalian et al., 2006, p. 632).

**DISCUSSION**

A need to develop efficient and effective alternatives to bariatric surgery exists if there is any hope of reversing rising obesity trends in the US. Gastric electrical stimulation offers a novel approach to treating obesity in adults. The procedure is minimally invasive, reversible and does not alter existing GI anatomy. Review of the evidence revealed that a small subset of obese adults treated with an implantable gastric stimulation device successfully achieved
between 5% and 17% excess weight loss at the conclusion of the studies. However, this EWL range is similar to that achieved by diet and exercise alone in the SHAPE trial (Shikora et al., 2009). Furthermore, some patients either failed to lose weight or gained weight after implantation with GES (Champion et al., 2006). The GES devices appear to be both safe to implement and well tolerated without any reported deaths and few serious adverse effects. While these results seem promising, there were several important methodological flaws in the three studies reviewed.

The randomized controlled trial (RCT) performed by Shikora et al. (2009) is the first of its kind to explore, in a double-blind, placebo-controlled fashion, the applications of GES in obese subjects. Overall, the study was of excellent quality with only a small number of drawbacks. Limitations to this study consist of applicability to all adult populations, possible device battery failure and potential publication bias. Of the 190 study participants 81.6% were of Caucasian race and 87.4% were female. It is possible that the primary outcome of weight loss would be different when evaluated in other ethnicities or in equal gender proportions. Secondly, at the conclusion of the 12 month trial period it was discovered that 22 participants had devices which read “low battery capacity.” All of these subjects were allocated to the treatment group which means that for an unspecified period of time some of the device batteries were exhausted. It is unknown whether these participants may have achieved greater weight loss had gastric stimulation been occurring as intended. The authors did not re-evaluate the raw data after excluding these 22 subjects from statistical analysis. Lastly,
the SHAPE trial was sponsored by Medtronic/Transneuronix, the manufacturers of the Transcend device (Shikora et al., 2009). This sponsor compiled the raw data, analyzed the data, and produced data summaries which have the potential of researcher bias. However, the data was available to all authors upon request and the final report was reviewed and approved by all co-authors (Shikora et al., 2009).

Limitations to the Champion et al. (2006) study included a small sample size of 24 subjects, diminished applicability of GES for males as 87.5% (21 of the participants) were female and selection bias. The patients self-selected to participate in this open-label, non-randomized, and un-blinded study. Also beyond asserting that the patients were similar with regards to age, baseline weight and BMI, no further comorbidities were addressed by the authors. Another limitation included the short follow-up period. The primary outcome was to address total body weight loss after two years yet the trial was stopped early for unstated reasons and only data at the six month endpoint is reported. Moreover, three out of the 24 patients were dropped from the study prior the six-month visit and their final weights were not obtained. Finally, the authors did not supply raw data for the changes in waist circumference which was the only statistically significant finding in the study. Instead, the authors generalize that “the mean waist circumference decreased 5.8%” (Champion et al., 2006, p. 444).

Limitations to the third and final study by Bohdjalian et al. (2006) included a small sample size of 12, the short amount of time that all participants were being stimulated and evaluated, and a large loss to follow up at the 52 week
mark. The authors go on to state “the study was further limited by the absence of subject and investigator blinding, a control group or the use of a cross-over design” (Bohdjalian et al., 2006, p. 633). Moreover, the authors did not publish any raw data. They instead reported their results in terms of mean values which shows potential publication bias. Finally, it is unclear whether the observed blood pressure decrease is inferred by the authors to be a direct outcome from the gastric stimulation device or if is secondary to weight loss.

To evaluate the evidence presented by these three articles in an explicit, comprehensive and systematic fashion we employed the GRADE system, developed by the GRADE Working Group, which rates both the quality of evidence and the strength of recommendation (Guyatt et al., 2008). Quality of evidence is classified as either high, moderate, low, or very low. High quality evidence means that further research is very unlikely to change the confidence in the estimate of effect. Moderate quality signifies that further research is likely to impact confidence in the estimate and may change the estimate while low quality signifies that further research is very likely to impact confidence in the estimate and is likely to change the estimate. Very low quality of evidence means that any estimate of effect is very uncertain (Guyatt et al., 2008, p. 926). Randomized controlled trials begin as high quality of evidence but can be downgraded based on study limitations, inconsistency of results, indirectness of evidence, imprecision in estimates, or high likelihood of publication bias. On the other hand, observational studies start as low quality of evidence but can be upgraded if the magnitude of the treatment effect is large, if there is evidence of a dose-response
A second purpose of the GRADE tool is to evaluate the strength of the recommendation. A strong recommendation is made when it is very certain that the desirable effects of an intervention outweigh risks and burdens. Strong recommendations imply that virtually all informed patients will make the same choice. A weak recommendation is given when risks and burdens are balanced against desired effects or when there is appreciable uncertainty about the magnitude of benefits and risks. Weak recommendations imply that patient values and preferences play a crucial role in individual decisions (Guyatt et al., 2008).

After applying GRADE to the three articles evaluating weight loss in obese adult patients using gastric electrical stimulation, the GRADE for this outcome is moderate and the strength of the recommendation is weak (Appendix E, Table 2). The single RCT performed by Shikora et al. (2009) was a well designed, precise study that produced results consistent with previous reports. Although there were limitations noted in the study, it was not felt that these limitations were significant enough to warrant downgrading the GRADE score of this RCT from high. The two observational studies however, were of low quality and unable to be upgraded. The patients had self-selected to participate in the open-label, non-randomized and un-blinded studies. The sample sizes were small (n=36) and there was a large loss to follow up in both studies. No large magnitude of effect or dose-response gradient could be inferred from the results, thus the quality of
evidence could not be upgraded. The poor quality of the two observational studies combined with the existence of only one high quality RCT necessitates an overall GRADE of moderate for the body of evidence supporting the outcome of weight loss via GES.

Applying the GRADE tool to evaluate gastric electrical stimulation device safety reveals that the quality of evidence is also moderate. Between the one RCT and the two observational studies, few serious adverse events were reported. This is consistent with previous findings that after implantation in over 800 patients worldwide, “the operative procedure is relatively safe, simple, and devoid of any long-term nutritional or metabolic derangements” (Shikora et al., 2009, p. 35). The RCT cannot be downgraded due to poor study quality, inconsistency, indirectness, imprecision, or publication bias, therefore, it remains at a GRADE of high. Conversely, the observational studies cannot have increased GRADE because there is no proof of a large magnitude of effect, a dose-response relationship, or the identification of any confounders responsible for the treatment effect so they remain low. Consequently, for the body of evidence supporting the outcome of GES device safety, an overall GRADE of moderate is reached.

The overall GRADE of evidence for using an implantable gastric stimulation device to safely promote weight loss is moderate. At this time, there is only enough evidence to justify a weak recommendation for using GES to treat obesity in adults. Each study only saw a fraction of their participants lose weight and the SHAPE trial found no difference in weight loss between the control and
treatment groups. Across all three trials, several individuals saw either no weight loss or had weight gain at the end of the study period. Despite being safe and minimally effective for weight loss in a handful of study participants, the extent of EWL with GES is significantly below the effectiveness that bariatric surgeons have come to expect. Current bariatric surgery techniques such as lap banding, gastric sleeves, or Roux-en-Y procedures, on average, have a >50% EWL (Lanthaler et al., 2010; Schouten, Wiryasaputra, van Dielen, van Gemert, & Greve, 2010; Welch et al., 2011). In light of this standard, the results gleaned from the three studies reviewed are disappointing. Since the evidence implies some uncertainty about the benefits of implanting a gastric stimulation device for weight loss in obese individuals, it is suggested that clinicians continue to advise lifestyle changes, pharmacotherapy, or standard surgical approaches for weight loss.

There are several factors revolving around GES which demand further exploration. For example, while it is hypothesized that GES functions by reducing appetite and increasing satiety, the exact mechanism of action remains unknown. Several study participants described increased feelings of fullness with GES, therefore, further evaluation of this type of device and its application towards reducing BMI should be pursued. Furthermore, technical aspects of both the Transcend and the Tantulus devices need to be improved upon. Creation of standard settings for electrical stimulation as well as standard lead placement sites on the gastric mucosa may improve results and reduce variability between
study populations. It is likely that as additional RCT are performed and GES parameters are developed, EWL results beyond 17% could be seen.
References


### APPENDIX A

#### Table 1: Body Mass Index (BMI) Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal weight</td>
<td>≥ 18.5 – 24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥ 25.0 – 29.9</td>
</tr>
<tr>
<td>Obese Class I</td>
<td>≥ 30.0 – 34.9</td>
</tr>
<tr>
<td>Obese Class II</td>
<td>≥ 35.0–39.9</td>
</tr>
<tr>
<td>Obese Class III (severe/extreme/morbid obesity)</td>
<td>≥ 40.0</td>
</tr>
</tbody>
</table>
Figure 1. Intra-operative view of implantable GES device during laparotomy with electrodes attached to the proximal antrum

Figure 2. Transcend gastric electrical stimulation device and its anatomical placement

Figure 3. Tantulus™ Gastric Electrical Stimulation Device

Reprinted with kind permission from Springer Science and Business Media: Obesity Surgery Journal, One-Year Experience with Tantulus: a New Surgical Approach to Treat Morbid Obesity, 16, 2006, 627-634, Bohdjalian et al., Figure 1.
## APPENDIX E

### Table 2: GRADE Quality of Studies

<table>
<thead>
<tr>
<th>Comparison</th>
<th>Outcome</th>
<th>Quantity and type of evidence</th>
<th>Findings</th>
<th>Starting grade</th>
<th>Decrease GRADE</th>
<th>Increase GRADE</th>
<th>Grade of Evidence for Outcome</th>
<th>Overall GRADE of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Implantable Gastric Stimulation</strong></td>
<td>Weight Loss</td>
<td>1 RCT 2 Case series</td>
<td>Equivalent weight loss</td>
<td>High</td>
<td>0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0</td>
<td>High</td>
<td>Moderate</td>
</tr>
<tr>
<td><strong>Device vs Standard Therapy</strong></td>
<td>Safety</td>
<td>1 RCT 2 Case series</td>
<td>No serious adverse events</td>
<td>High</td>
<td>0 0 0 0 0 0 0 0</td>
<td>0 0 0 0 0</td>
<td>High</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

- **Study Quality**: 0
- **Consistency**: 0
- **Directness**: 0
- **Precision**: 0
- **Publication Bias**: 0
- **Large Magnitude**: 0
- **Dose-Response**: 0
- **Confounders**: 0