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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

Transcend® Implantable Gastric Stimulator (IGS) for the treatment of morbid obesity

July 2005
(Updated June 2006)



ASERNIP(S)

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**



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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



Name of Technology:

Transcend® Implantable Gastric Stimulator (IGS) for the treatment of morbid obesity.

Purpose and Target Group:

The Transcend® Implantable Gastric Stimulator (IGS) system is designed to induce early satiety and weight loss in the morbidly obese without altering gastrointestinal anatomy. It is indicated in the treatment of those with a BMI of 35-55 who have failed to achieve sustained weight loss through diet and exercise, and who are likely to respond well to a postoperative regimen of nutritional counselling and education (Shikora 2004). Typically implanted through minimally invasive laparoscopy, the IGS offers an alternative to the more invasive bariatric surgical procedures of gastric banding, Roux-Y gastric bypass, and biliopancreatic diversion (Shikora 2004). It may therefore be a useful weight loss option for obese groups at high risk for invasive bariatric surgery, groups unresponsive to diet and lifestyle approaches alone, as well as for obese patients desiring a less invasive surgical approach.

Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

Note: D'Argent (2002) makes reference to prospective clinical trials (sponsored by Transneuronix Inc.) currently being carried out in Australia. No specific details are given, however.

The Transcend® IGS is not listed or registered in the Australian Register of Therapeutic Goods (ARTG).

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
Italy		✓	
Austria		✓	
Sweden		✓	
Germany		✓	
Belgium		✓	
France		✓	
USA	✓		



Impact Summary:

Background

Obesity is defined by the World Health Organization as a body mass index (BMI) of $\geq 30 \text{ kg/m}^2$ (Australian Institute of Health and Welfare 2003). Equal only to tobacco as the highest contributor to the burden of disease in Australia, obesity remains a leading risk factor in the development of serious chronic illnesses, including type 2 diabetes, cardiovascular disease, cancer and depression (Catford & Caterson 2003; Cameron *et al.* 2003). Morbid obesity, defined as a BMI of $\geq 40 \text{ kg/m}^2$, poses a particularly high health risk, shortening the average life expectancy by as much as 10 to 15 years and greatly reducing quality of life (Linz 2003).

Lifestyle efforts to promote healthy eating and physical activity remain the staple means of preventing and treating the onset of obesity in the population as a whole. Medical interventions involving diets, and pharmaceutical and behavioural therapy have similarly become a major treatment option for the overweight and obese. In recent years, bariatric surgery has evolved as a further option in achieving and maintaining significant weight loss, particularly in groups unresponsive to these traditional lifestyle and medical interventions.

At present, bariatric surgery relies on malabsorption and gastric restriction to achieve weight loss. While techniques such as gastric banding, Roux-Y gastric bypass, and biliopancreatic diversion are effective in achieving rapid, maintainable weight loss in obese patients (as much as a 40 to 70% loss of excess weight (EWL)), the risks of death (1% of all patients die), unpleasant side-effects (such as chronic vomiting) and complications (10 to 20% of patients experience complications which require corrective surgery) continue to be prohibitive issues for the majority of obese individuals who would otherwise be eligible for surgery (Greenstein & Belachew 2002; Knapp 2004; Shikora 2004; Connor 2005).

The concept of gastric 'pacing' for weight loss therapy was initially introduced by Dr. Valerio Cigaina, who was responsible for establishing the IGS prototype and pioneering animal and human studies into gastric pacing (Cigaina 2002). By delivering small, programmable electrical pulses to the stomach wall, it is hypothesised that the IGS stimulates weight loss by inducing early satiety (Chen 2004). The exact mechanism of this process is yet to be scientifically established. However, the IGS relies solely on satiety signals for weight loss, so the appropriate behavioural responses to appetite are more important to the long-term success of IGS treatment than for other bariatric operations.

The IGS system incorporates the 24-gram stimulator, a gastric stimulation lead and an external programming wand (Young 2004; Aigner *et al.* 2004). The lead is typically implanted in the stomach wall through laparoscopy (with lead placement monitored by gastroscopy), and the stimulator is implanted in a subcutaneous pocket on the abdominal wall (D'Argent 2002). After allowing a one-month postoperative period of healing, the IGS is activated and patients are initially required to attend regular follow-ups for monitoring (D'Argent 2002).



Clinical Need and Burden of Disease

Obesity has become a major health issue in Australia, with as much as 60% of the Australian adult population and 27% of children aged 7 to 11 presently classified as obese or overweight (Catford & Caterson 2003; Cameron *et al.* 2003). Contributing to 10% of the total burden of disease in Australia, obesity, unhealthy diets and sedentary lifestyles are equal only to tobacco as the highest risk factors for serious chronic illness (Catford & Caterson, 2003; Cameron *et al.* 2003). In addition to the adverse impact of obesity on physical health and well-being, the psychological and social costs of obesity for individuals, families and the health sector are also taking on increasing significance.

Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System

Since the initial human trials with the IGS prototype in 1995, there have been nearly 700 IGS systems implanted worldwide, mostly through clinical studies (Young 2004). Produced by U.S. company Transneuronix Inc., the IGS received CE Mark approval in Europe in 2001, where it is now commercially available and conforms to the health, safety and environmental standards of the CE Mark.

(<http://www.gastricpacer.com/eng/notevisitatore.html>; <http://www.newapproach.org/>).

Only a limited number of institutions and specialists are using this technique commercially in Europe at present, and the IGS is not covered under either public or private health insurance schemes. In Italy, Dr. Cigaina and a team of technicians and specialists are active in performing the procedure for private patients (<http://www.gastricpacer.com/eng/costi.html>). The Polyclinique de Rillieux (France) has also been involved in the European round of clinical trials, and may be a likely institution to perform this procedure commercially. Additionally, Professor Karl Miller of Krankenhaus Hallein has published a case report on the implantation of four patients commercially in Austria (Miller 2002).

The IGS is currently listed as an investigational device by the FDA, and is consequently only employed for the purposes of research in the U.S. (<http://www.gastricpacer.com/eng/notevisitatore.html>). It is predicted that FDA approval for commercial manufacture may be achieved in 12 to 18 months, following the successful completion of upcoming U.S. clinical trials (Connor 2005). At present, at least seven institutions throughout the U.S. are actively involved in clinical trials.

The anticipated commercial release of the IGS system in the U.S. will have to contend with two other gastric pacing devices on the market. The first of these devices is the Medtronic Enterra® Therapy System, a gastric electrical stimulator (GES) approved by the FDA in 2000 for commercial production as a humanitarian device with limited use in the treatment of the condition gastroparesis (Connor 2005) but not presently used for obesity. Another device,



currently in the initial stages of design, is being developed by IntraPace. The company proposes that this gastric pacemaker can be endoscopically – as opposed to laparoscopically – implanted for the treatment of obesity, thus minimising the time and risks involved in implantation (Connor 2005; <http://www.biobn.com/index.cfm?Page=viewnews&NewsID=0002209968>). The potential impact this may have on the diffusion and use of the Transcend® IGS is yet to be commented upon in the literature.

Existing Comparators

- Invasive bariatric surgery (gastric banding, Roux-Y gastric bypass, and biliopancreatic diversion)
- Medical weight loss techniques (low kilojoule diets, pharmaceutical therapies)
- Lifestyle modifications (balanced diets, physical activity, behavioural therapies)

Estimated Cost Impact

The IGS is presently priced at about €5000 or US\$6000 (Knapp 2004); however the cost impact of implantation is not widely published. Currently, the cost of implanting the Enterra® Therapy System in the U.S. is approximately US\$24 000 per patient per year (Friedman 2002). Given the similarities between Enterra® and the Transcend® devices in terms of size, placement and the surgical procedure involved in implantation, it is reasonable to assume this might also represent the initial cost of implanting the Transcend® IGS in the U.S. Compared to the Roux-Y gastric bypass and gastric banding (which cost up to US\$40 000 and US\$30 000 respectively) gastric stimulation implants appear to be a cheaper procedure (Knapp 2004). Moreover, because the minimally-invasive nature of IGS implantation markedly reduces the risk of complications associated with other bariatric techniques, it is possible that this cost may be further offset in the long-term by savings from reduced hospital stay.

Costs associated with this new product in Australia are not currently available. However, the reimbursement fee as stated in the Medicare Benefits Schedule for gastric bypass is currently \$887.05 (Medicare Benefits Schedule item number 30512) (<http://www.health.gov.au>). This fee may be an indication of the likely reimbursement cost of implanting the IGS system if it becomes an established and routine procedure in Australia. According to the Health Insurance Commission, a total of 178 claims were processed between July 2003 and June 2004 for gastric bypass procedures (<http://www.hic.gov.au/>).



Efficacy and Safety Issues

List of Studies Found

Total number of studies	11
Randomised controlled trials	2 (Plus one U.S. RCT currently in the initial stages of development)
Case series studies	8 (11 articles)
Case reports	1

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from two randomised controlled trials and two case series (six articles) have been selected for inclusion in this summary. The case series were included for their long follow-up periods, comprehensiveness and multicentre spread.

In the U.S. O-01 RCT (n=103), patients in the device OFF group had their devices activated after six months, and all patients were subsequently followed up as a single group. The study reported no statistically significant difference in excess weight loss (EWL) between groups initially assigned to device ON or device OFF during the randomisation period. However, this may have been due to some confounding factors. Shikora (2004) comments that many patients 'tested' the status of their devices by overeating, due to the initial blinding of stimulation status. Binge eaters and those unresponsive to satiety signals were also not excluded from the study (Shikora 2004). The study reported clinically significant weight loss (>5%) in 24/103 (23%) patients at 12 months (Shikora 2004). The mean EWL for this subset of patients was 10.3% (Shikora 2004). At 29 months follow-up, 69 patients had withdrawn from the trial, and the mean EWL for the remaining 34 patients was 20%.

IGS tended not to achieve superior weight loss in comparison to traditional surgical techniques. A small RCT by Wolff *et al* (2002) reported a mean weight loss of 18 kg (range 12-34 kg) at six months for the gastric banding patient group, compared to 13 kg (range 0-23 kg) for the gastric pacing group.

The preliminary results of the non-randomised multicentre European 'Laparoscopic Obesity Stimulation Study' (LOSS) trial (involving 69 patients) reported significant increases in weight loss for the first 10 months of stimulation, after which %EWL began to level out (De Luca *et al* 2004, Favretti *et al* 2004, and Aigner *et al* (date unknown)). The mean %EWL at six months was 17.8[2.0] (n=51), which increased to 21.0[2.6] at 10 months (n=43), and levelled out to 21.0[3.8] at 15 months (n=20) (De Luca *et al* 2004, Favretti *et al* 2004, Aigner *et al*). A subset of 19 patients from the Vicenza trial had their appetite and satiety scores evaluated. In this Vicenza subset, 13/20 (65%) patients reported decreased appetite before meals and 17/20 (85%) reported an increase in satiety between meals at 10 months follow-up (Favretti *et al*. 2004).



Cigaina (2002) reported on the long-term weight loss efficacy of IGS in three study cohorts from the initial human trials of 1995/96 (n=4), 1998 (n=10) and 2000 (n=10). In the 1995/96 cohort, Cigaina (2002) observed a slight decrease in mean excess body mass lost (%EBL) from 28.6[46.8] at month 15 to 23.7[39.0] at month 30. Significant weight loss was observed in the first six months among the 1998 cohort, with mean %EBL increasing from 7.3[5.2] at month one, to 18.8[11.8] at six months (Cigaina 2002). At 12 months, mean %EBL was 24.1[10.7] (Cigaina 2002). After a small decrease at 24 months (mean %EBL of 22.3±16.4), %EBL had increased to 28.5[20.3] at month 30 (Cigaina 2002). For the 2000 cohort, mean %EBL increased from 5.4[3.6] in the first month, to 14.6[6.7] at three months (Cigaina 2002). From month six to 12, %EBL rapidly increased from 23.5[11.7] to 33.5[23.3] (Cigaina 2002).

The major factors affecting the efficacy of IGS include lead complications and psychological variables, such as behavioural and dietary responses to appetite signals. Lead complications were extremely common in the earlier studies, but improved after minor surgical and technical modifications. Cigaina (2002) reported a lead dislodgement rate of 53% (eight of the initial 15 patients) and a 50% (2/4) lead fracture rate in the 1995-96 cohort. After surgical modifications were made to improve the security of lead placement, the dislodgement rate dropped to zero in the subsequent nine patients. The introduction of a dedicated lead also reduced the fracture rate to 5% (1/20) in the 1998 and 2000 cohorts (Cigaina 2002). Shikora (2004) reported a similar trend in the O-01 study, with 17 dislodgements out of the first 41 leads (41%). After subsequent leads were sutured and/or anchored in place, only three leads (4.8%) out of a further 62 implantations became dislodged. D'Argent (2002) encountered lead dislodgement in three out of 12 patients (25%), which was diagnosed after the patients reported 'abnormal feelings'. Wolff *et al.* (2002) reported electrode dislodgement in 1/13 (8%) patients, which penetrated the stomach six months post-implantation. The authors attributed this to lead tension and inadequate securing of the electrode cable (Wolff *et al.* 2002). For the most part, fractures and dislodgements lead to a loss or impairment of therapeutic effect, some patient discomfort, and in all cases required additional surgery to remove and/or replace electrode cables.

Unlike other bariatric techniques, the IGS creates no mechanical or physical barrier to overeating. Due to the reliance of IGS on behavioural responses to satiety signals, psychological factors can therefore affect weight loss outcomes. This is demonstrated by the O-01 study in particular. Not only did many patients deliberately overeat during the randomisation process, but likely non-responders, such as binge eaters, were not excluded from the study. In order to ensure long-term effectiveness Shikora (2004) suggests that behavioural weight loss techniques be provided as an adjuvant therapy some time post-implantation. For this reason, individuals with untreated binge eating disorders may not be suitable candidates for IGS.

The included studies indicate a positive short- and long-term safety profile, with no deaths or serious complications. Cigaina (2002) reported 11 lead perforations of the lumen out of 24 patients (46%). Adverse consequences were prevented by immediate identification of lead



perforations, demonstrating the need for gastroscopy during lead implantation (Cigaina 2002). Seven intra-operative lead penetrations out of 69 patients (10%) were identified by gastroscopy in the LOSS case series (De Luca *et al* 2004; Favretti *et al* 2004; Aigner *et al* date unknown). No complications were encountered, and the leads were immediately repositioned intraoperatively (De Luca *et al* 2004; Favretti *et al* 2004; Aigner *et al* date unknown).

Cigaina (2002) reported that patients with comorbid gallstones at the time of implantation went on to develop colicky pain two years later. The author (Cigaina 2002) speculated that gastric stimulation could create a new bile precipitation set-point by altering the liver exocrine physiology. Alternatively, Cigaina (2002) also hypothesised that these patients may have had gallstones prior to implantation, and that their large body mass merely prevented them from being detected prior to implantation.

No further adverse effects were noted in any of the studies, and no deaths were recorded. In addition to weight loss, other benefits of IGS were also noted in some studies, particularly for conditions related to obesity. Cigaina (2002) reported that ‘almost all’ patients with gastroesophageal reflux disease (GORD) experienced symptom relief a few days after IGS implantation. Insulin resistance in diabetics was also reduced following gastric stimulation, with the mean Homeostatic Model Assessment – Insulin Resistance (HOMA-IR) index decreasing from 4.35 ± 10.9 pre-implantation to 2.98 ± 0.55 at seven months post-implantation (Cigaina, 2002). Favretti *et al* (2004) noted that one patient with co-morbid hypertension was able to discontinue their medication four months after implantation.

2006 update

Safety and efficacy

A search of relevant databases, online journals and the Internet was conducted in May 2006, following the recommendation in July 2005 that Transcend be monitored for assessment in 12 months time. Two new sources of evidence on the safety and efficacy of this intervention were located in the literature.

Total number of studies	2
Case series	2

Utilising the Baroscreen algorithm (to identify patients likely to respond to IGS treatment) developed by Transneuronix Inc., 24 patients were screen from a pool of 48 patients in a FDA trial to receive the Transcend IGS over a period of 6 months for the treatment of obesity (Champion *et al.* 2006). Three (3/24) (12.5%) patients were explanted prior to the final examination due to noncompliance with the clinical protocols



for visits and monitoring. One explant took place at 6 months upon the request of the patient who require magnetic resonance imaging for shoulder surgery. This patient achieved an excess weight loss (EWL) of 6% prior to removal of transcend. The other two patients were explanted due to failure of keeping postoperative appointments and complete testing protocols, both patients gained weight prior to explant (2.8% and 14.9%). No deaths of serious adverse events were related to the device. The mean overall EWL at 6 months for the entire group was 5.9%, while a subset of 9/24 (37.5%) patients had EWL of at least 10% (mean EWL = 20.1%). The authors reported that 14 patients lost weight (mean EWL = 13.9%), while 10 patients gained weight (mean = 8.2%). The mean percentage of change in waist circumference was 5.8% ($p = 0.0009$) (Champion *et al.* 2006).

Meanwhile, the LOSS trial in Europe ($n = 91$) achieved preliminary results for mean EWL of 20% 12 months post-implantation and approximately 25% 24 months post-implantation (Miller *et al.* 2006). Limiting the analysis to a subset of patients screened with the Baroscreen algorithm, a mean EWL of 31.4% was achieved, significantly greater compared to patients who were not selected with Baroscreen (15% EWL) ($p < 0.01$). The authors reported no deaths or severe peri/post-operative complications (Miller *et al.* 2006).

2006 Recommendation

The use of gastric electrical stimulation for the treatment of obesity offers a potentially safe and effective alternative for patients who are not suited for surgery. Current evidence suggests that patient selection is an important determinant of treatment success; however weight loss appears to be slower compared to traditional surgical techniques (gastric banding etc.). At the time of writing, final results from the randomized controlled trial in the United States (O-01 RCT) and the European trial (LOSS trial) has not been published. Based on the evidence available, it is proposed that this technology is monitored until the publication of RCT results.

Horizon Scanning Report

Full Health Technology Assessment

Monitor

Archive

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Ethical Issues: No issues were identified from the retrieved material.

Cultural or Religious Considerations: No issues were identified from the retrieved material.

Other Issues

It should be noted that all research by Dr. Cigaina presents possible issues of bias due to the author's strong involvement in the conceptual and commercial development of the IGS system and surgical treatment. All major trials involved partial or full funding from Transneuronix Inc., the manufacturer and distributor of the Transcend® IGS system.

HealthPACT recommendation:

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor | <input type="checkbox"/> Archive |



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Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in February 2005.

Search terms used were: 'Transneuronix Inc. transcend implantable gastric stimulator'; 'implantable gastric stimulat*'; 'gastric electrical stimulat*'; 'gastric pacing'; 'gastric pacemaker'; 'implantable medical device'; 'obesity [prevalence/epidemiology]'; 'Medtronic enterra implantable gastric stimulator'.

This Horizon Scanning Prioritising Summary was prepared by Ms Pauline McLoughlin from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (HealthPACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).