



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Transoral gastroplasty (TOGA® System) for obesity**

**September 2010**



**ASERNIP/S**

**Australian  
Safety  
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# PRIORITISING SUMMARY

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**REGISTER ID** S000120

**NAME OF TECHNOLOGY** TRANSORAL GASTROPLASTY (TOGA® SYSTEM)

**PURPOSE AND TARGET GROUP** TO FACILITATE WEIGHT LOSS IN MORBIDLY OBESE PATIENTS

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input type="checkbox"/> Yet to emerge              | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental               | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input checked="" type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established         |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Belgium	✓	✓	
Italy	✓	✓	
Mexico	✓		
United States	✓		

## IMPACT SUMMARY

Transoral gastroplasty (TOGA® system) is a new minimally invasive procedure, utilising the concept of natural orifice transluminal endoscopic surgery (NOTES), for the treatment of obesity.

## BACKGROUND

Obesity is a growing epidemic, having dramatically increased in prevalence in the last few decades, particularly in Western countries. Clinical studies have shown that obesity is associated with a range of potentially debilitating illnesses such as heart disease, diabetes, hypertension, and dyslipidaemia (Chiellini et al 2010). In addition, obesity also

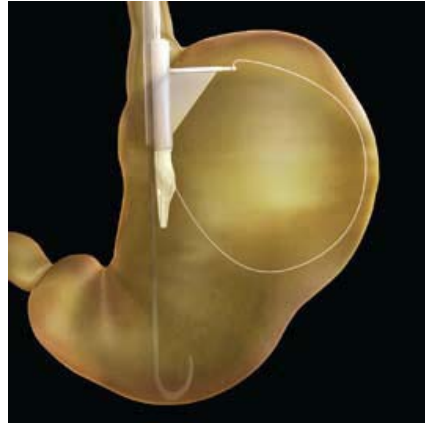
increases the risk of death from cancer and is also associated with a decrease in life expectancy (Moreno et al 2008). It is therefore not surprising that the treatment of obesity has garnered considerable attention.

Numerous strategies have been employed in the treatment of obesity, including dietary modifications, behavioural therapy and pharmacotherapy. Although there is some evidence that these treatment options can reduce the risk of obesity-related diseases, studies have shown that for the majority of obese patients, weight loss is often followed by a slow, inevitable climb back to their original weight (in some cases exceeding baseline weight) (Moreno et al 2008). For caloric restriction programs, only 25% of patients are successful in maintaining weight loss after 4 years with the condition that the programs were run well enough to maintain high participation rates for at least one year (Martin and Hunter 1995).

Extreme forms of obesity are not likely to respond to dietary, behavioural or pharmacological treatment. Bariatric surgery therefore has emerged as the most effective treatment for these patients. In fact, the US National Institutes of Health (NIH) and the Australian National Health and Medical Research Council (NHMRC) have stated that bariatric surgery is the most effective treatment for morbid obesity that is capable of inducing long-term weight reduction and is statistically associated with decreased comorbidity for the majority of patients (National Institutes of Health 1992, NHMRC 2003). At the time of writing, vertical banded gastroplasty and gastric banding are the most common restrictive bariatric procedures worldwide. Both procedures attempt to limit food intake by causing the patient to feel full earlier. These procedures can be performed via laparotomy or minilaparotomy (Deviere et al 2008).

Clinical experience has shown that a characteristic feature of obese patients is their susceptibility to develop parietal complications after surgery, such as incisional hernia, wound infection, fistula or anastomotic leak (Nguyen and Wilson 2007). In addition, only a small proportion of obese patients actually undergo bariatric surgery. In the United States, only 1% of patients who meet NIH guidelines for weight loss surgery actually undergo bariatric surgery (Fogel et al 2008). Therefore, there are strong incentives to develop new procedures that can be utilised in a greater proportion of morbidly obese patients. These reasons, along with strong patient preference for less invasive procedures, have led to the development of transoral techniques for endoluminal restrictive surgery.

**Figure 1: TOGA system (www.medgadget.com)**



The transoral gastroplasty or TOGA® system (Satiety Inc., Palo Alto, CA, United States) consists of a set of flexible stapling devices that are utilised to create a restrictive gastric pouch or sleeve that induces the feeling of satiety after a small meal. This procedure is performed under general anaesthesia and patients are required to stay in hospital for at least one night for monitoring.

#### **CLINICAL NEED AND BURDEN OF DISEASE**

In Australia, the proportion of adults considered overweight or obese has increased substantially from 52% to 62% in men and from 37% to 45% in women between 1994/1995 to 2004/2005; highlighting the rapid growth of this disease (Australian Bureau of Statistics 2007). If overweight individuals are excluded, approximately 3.24 million Australians are considered obese (15.1% of all males and 16.8% of all females) (Australian Bureau of Statistics 2007).

For older Australians (>55 years old), the prevalence of obesity has increased markedly in the last two decades. The Australian Institute of Health and Welfare reported a three-fold increase in obese older Australians; from 310,000 in 1980 to 940,000 in 2000. Since older individuals are already at a greater risk of developing chronic diseases such as type II diabetes, coronary heart disease, stroke, certain cancers, osteoarthritis and kidney disease; the additional health implications of obesity can severely affect their quality of life.

The increasing number of obese older Australians will also have substantial repercussions towards healthcare costs, the wellbeing of carers, and the ability of aged care services to meet the needs of the older generation (Australian Institute of Health and Welfare: Obesity trends in older Australians 2004). International studies to assess the economic costs of excess body weight, including data from Australia, have shown that between 2% to 7% of total healthcare costs may be directly attributable to overweight and/or obesity (WHO 2000). In 2005, the estimated total financial cost of obesity in Australia was \$3.767 billion. The direct cost to the health system was \$873 million, while productivity costs were \$1.7 billion, and carer cost was \$804 million. Deadweight loss from transfers

(lost tax revenue, welfare, government payments: \$358 million) and other indirect costs were approximately \$40 million (Access Economics 2006).

### **DIFFUSION**

At the time of writing, TOGA was not TGA approved for use within Australia. Within the United States, TOGA is considered experimental and is only available through participation in a clinical trial for FDA approval (Clinical trials 2010). TOGA has CE mark approval and is in limited use throughout Europe.

### **COMPARATORS**

The selection of bariatric surgical treatment is determined by patient characteristics and surgeon preference. Some of the main bariatric procedures currently utilised are adjustable gastric banding, Roux-en-Y gastric bypass, biliopancreatic diversion with duodenal switch and sleeve gastrectomy (NIDDK 2009).

### **SAFETY AND EFFECTIVENESS ISSUES**

Three case series studies were selected for inclusion in this summary (Moreno et al 2008, Deviere et al 2008, Chiellini et al 2010).

Deviere et al (2008) evaluated the safety and feasibility of TOGA in 21 morbidly obese patients who fulfilled the United States NIH treatment criteria for the treatment of obesity. This prospective, single arm trial employed clear inclusion and exclusion criteria during the selection process. Patients were only allowed to consume thin liquids for the first 2 weeks post-treatment, with thicker liquids allowed at 2 weeks and pureed foods at 3 weeks. All patients were allowed to resume a solid food diet 4 weeks after treatment but were counseled to adhere to a low calorie diet. However, the actual caloric intake recommended was not stated in this study. Statistical tests were utilised to detect significant changes (body mass index (BMI), weight etc.). Patients were followed-up for 6 months.

Moreno et al (2008) reported the first human multicentre trial on TOGA, where 11 patients were prospectively enrolled utilising clear inclusion and exclusion criteria. As with most bariatric procedures, patients were required to follow a pre-set diet. Statistical tests were utilised to identify significant differences. In the first 2 weeks after the procedure, patients consumed only thin liquids, with thicker liquids allowed at 2 weeks and pureed food at 3 weeks. Solid foods were permitted from 4 weeks onwards. However, specific daily caloric intake guides were not presented in this study. Patients were assessed at 1 day and 1 week post-treatment for safety outcomes only. Later, at 1, 3 and 6 months post-treatment, patients were assessed to determine the efficacy of TOGA in terms of weight loss and weight loss maintenance. One patient was lost to follow-up at 6 months.

Chiellini et al (2010) examined 9 glucose normo-tolerant obese patients at baseline and at 3 months after undergoing the TOGA procedure. The primary aim of this study was to evaluate the effect of TOGA on insulin sensitivity and secretion. No inclusion or exclusion criteria were reported. In addition, there was insufficient detail to determine if

patients were subjected to a strict diet after the procedure. Statistical tests were utilised to examine the results of the oral glucose tolerance test (OGTT).

### *Safety*

Of the 2 studies reporting safety outcomes (Deviere et al 2008, Moreno et al 2008), both reported no serious adverse events during the TOGA procedure.

One study (Deviere et al 2008) noted that the most commonly reported procedure- or device-related adverse events were pain (16 patients, 76%), vomiting (7 patients, 33%), nausea (6 patients, 28.5%) and transient dysphagia (6 patients, 28.5%). Other isolated adverse events included temporomandibular dysfunction (1 patient, 4.8%) which persisted for 7 days and superficial phlebitis (data not reported) (Deviere et al 2008).

Similarly, Moreno et al (2008) reported that pain, specifically transient epigastric pain, was the most common procedure-related adverse event (11 patients, 100%). Other adverse events included throat pain (3 patients, 27.3%), esophagitis (2 patients, 18.2%), nausea (2 patients, 18.2%), mild dysphagia (3 patients, 27.3%), superficial phlebitis (1 patient, 9%) and worsening cervical pain (1 patient, 9%). All cases either spontaneously resolved or were treated medically (Moreno et al 2008).

### *Efficacy*

Deviere et al (2008) stated that 18/21 patients (85.7%) received two stapled sleeves. One patient received a single sleeve while 2 other patients had a partial sleeve due to technical difficulties during the TOGA procedure. The proximal staple line gap (between the angle of His and proximal staple line) or mid gap (between the proximal and distal staple lines) was observed endoscopically or on barium swallow in 11 patients prior to discharge (8 had fully intact sleeves, 2 had partial sleeves). At 6 months follow-up, staple line gaps were visible endoscopically or on barium swallow in 13 patients. Of these, 3 (23%) had incomplete distal sleeves while 5 (38.5%) had fully intact sleeves and stable lines; no results were provided for the remaining 5 patients. At 1, 3 and 6 months, mean % excess weight loss was 16.2%, 22.6% and 24.4%, respectively. Absolute mean weight loss was 8.0kg, 11.1kg and 12.0kg at 1, 3 and 6 months, respectively. The average BMI decreased significantly from 43.3 kg/m<sup>2</sup> pretreatment to 38.5 kg/m<sup>2</sup> at 6 months (P<0.0001).

Moreno et al (2008) observed mean weight loss of 9.9kg, 17.5kg and 24.0kg at 1, 3 and 6 months, respectively. The results demonstrated that the decrease in weight from 119.8kg to 109.9kg (1 month), 102.3kg (3 months) and 95.8kg (6 months) were statistically significant (P<0.01 for all time points). Mean BMI decreased from 41.6kg/m<sup>2</sup> to 38.1kg/m<sup>2</sup>, 35.4kg/m<sup>2</sup> and 33.1kg/m<sup>2</sup> at 1, 3 and 6 months, respectively (P<0.01 for all time points). At 3 months, 2 patients received additional restrictions (presumably with TOGA) due to insufficient weight loss (Moreno et al 2008). It is unclear if these patients were excluded from the analysis, which presents an element of potential bias within this study.

Quality of life measures specifically Short Form (SF)-36, which measures overall quality of life, and Impact of Weight on Quality of Life (IWQOL)-Lite, which measures quality

of life specific to obesity, indicated that patients experienced considerable improvements (Deviere et al 2008). Six of the eight SF-36 components were significantly improved (physical functioning, role physical, bodily pain, general health, vitality, social functioning;  $P < 0.05$  each). Meanwhile, every component of the IWQOL-Lite surgery significantly improved ( $P < 0.05$ ). Similarly, SF-36 and IWQOL-Lite outcomes in Moreno et al (2008) demonstrated significant improvement in all components.

In the study that evaluated insulin sensitivity and secretion post-TOGA (Chiellini et al 2010), significant reductions in weight (116.74kg to 98.1kg;  $P = 0.008$ ) and BMI ( $42.49\text{kg/m}^2$  to  $35.65\text{kg/m}^2$ ;  $P = 0.008$ ) were observed after TOGA. In addition, there was a significant decrease in fat mass (57.22kg to 41.46kg;  $P = 0.008$ ) and fat-free mass (59.52kg to 56.67kg;  $P = 0.048$ ). Analysis of OGTT data revealed that insulin levels were significantly lower at fast ( $P = 0.045$ ) and 120 minutes ( $P = 0.032$ ). Meanwhile, c-peptide levels were significantly lower at 120 minutes ( $P = 0.031$ ) and 150 minutes ( $P = 0.039$ ). However, glucose levels remained constant. Examination of insulin secretion rate revealed that it decreased significantly 3 months after TOGA (235.05 to 124.77  $\text{nmol/min/m}^2$ ;  $P = 0.021$ ). Meanwhile, insulin sensitivity significantly increased from 348.45 to 421.18  $\text{ml/min/m}^2$  after the procedure ( $P = 0.038$ ) (Chiellini et al 2010).

Further analysis by Chellini et al (2010) suggests that the decrease in insulin secretion was dependent on the decrease in BMI after TOGA as the change in insulin secretion only correlated significantly with change in BMI ( $r = 0.667$ ;  $P = 0.049$ ).

#### **COST IMPACT**

There is no cost information on the TOGA system available in the literature. Based on the limited evidence available, it is difficult to determine if any cost savings can be realised from shorter patient hospital stays and lower complication rates.

#### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

#### **OTHER ISSUES**

Two of the included studies (Deviere et al 2008, Moreno et al 2008) received support from the manufacturer of the TOGA system, Satiety Inc. (Palo Alto, California). In addition, two of the authors in Deviere et al (2008) were co-inventors of the device and founders of the company.

#### **SUMMARY OF FINDINGS**

All three retrieved studies were supportive of the TOGA system. The procedure was associated with significant weight loss and BMI reduction, at least up to 6 months. There is also some evidence that insulin sensitivity improves after TOGA, along with a decrease in insulin secretion. Overall, it appears that patients were very satisfied with the TOGA procedure and almost all components of the SF-36 and IWQOL registered significant improvements.

## HEALTHPACT ASSESSMENT

Based on the evidence available, there is a general consensus from the very limited data that TOGA is at least feasible and can lead to considerable weight loss in morbidly obese patients. Due to its potential, it is recommended that TOGA be monitored for 12 months along with all other NOTES bariatric procedures.

## NUMBER OF STUDIES INCLUDED

Total number of studies	3
Level IV evidence	3

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#### **SEARCH CRITERIA TO BE USED**

Transoral gastroplasty  
TOGA

#### **HEALTH PACT DECISION**

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

#### **PRIORITY RATING**

- High**                       **Medium**                       **Low**