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Australia and New Zealand Horizon Scanning Network

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Horizon scanning technology prioritising summary

StomaphyX™

April 2010



ASERNIP/S

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



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PRIORITISING SUMMARY

REGISTER ID S000110

NAME OF TECHNOLOGY STOMAPHYX™

PURPOSE AND TARGET GROUP REVISIONAL BARIATRIC SURGERY IN OBESE PATIENTS

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" 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 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
United States		✓	
Europe*		✓	

*Information on specific countries not located.

IMPACT SUMMARY

StomaphyX (EndoGastric Solutions, Washington, United States) is a novel single-use surgical device utilised for tissue approximation and ligation in the gastrointestinal tract. Its applications include revision bariatric surgery and repair of gastric leaks.

BACKGROUND

First line treatment against obesity encompasses a range of strategies, including increased physical activity, dietary adjustment and behaviour modification. Research has shown that this is effective for individuals who are mildly overweight. However individuals who are morbidly obese are less likely to succeed with these strategies and are more likely to require surgical intervention to permanently correct their weight and improve associated

comorbid conditions. As obesity has become more prevalent in society, it has inadvertently led to a surge in the popularity of bariatric procedures. Observers have noted that the demand for bariatric surgery is likely to continue to increase in the next decade (Hallowell et al 2009). As a result of this, surgeons are now encountering a new challenge, the rise of revision bariatric surgery.

Various factors can contribute to the failure of primary bariatric surgery, such as postoperative complications (e.g. motility problems, acid secretion problems) and inadequate long-term weight control (Gumbs et al 2007). Revision surgery can potentially be technically challenging and associated with high risk as patients may present with uncorrected serious comorbidities. In addition, there is the possibility that patients may have extensive abdominal adhesions, ulcers, inflammation, bowel obstructions, metabolic disturbances and other severe physiological problems attributed to primary surgery (Hallowell et al 2009). These factors will contribute to postoperative complications and therefore lead to undesirable outcomes after revision surgery (Sugerman and Wolper 1984, Cates et al 1990, Roller and Provost 2006, Gagner et al 2007). Trials evaluating the safety and efficacy of revision bariatric surgery procedures remain limited. To date, researchers have proposed and tested several approaches for revision bariatric surgery, including laparoscopic techniques and gastric banding (Bessler et al 2005). However, there is insufficient evidence at the time of writing to suggest if any one technique is superior to the others (Gumbs et al 2007).

The StomphyX is a natural orifice transluminal surgical (NOTES) device developed for transoral tissue approximation (connection) and ligation within the gastrointestinal tract using SerosaFuse™ fasteners. These propopylene H fasteners are capable of creating full-thickness, serosal-to-serosal tissue approximations. To date, StomaphyX has been utilised to reduce the volume of the small stomach pouch created during primary bariatric procedures such as Roux-en-Y or gastric bypass surgery which may have stretched over time (Mikami et al 2010) and for repair of gastric leaks during reoperation (Overcash 2008).

CLINICAL NEED AND BURDEN OF DISEASE

The Australian National Health Survey reported that 32.6% of adults were overweight while 16.4% of adults were obese in 2004-2005 (Australian National Health Survey 2004-2005). The prevalence of overweight and obesity has increased substantially from 29.5% to 32.6% in adults between 1995 and 2004-2005 (Australian National Health Survey 2004-2005). However, it should be noted that since this was derived from self-reported data, this information may be underestimating the actual prevalence of obesity in Australia.

It is not surprising that the international obesity epidemic has led to a marked increase in bariatric surgery cases worldwide. However, it is a well known fact that not all patients who undergo surgery will achieve or maintain long-term weight loss. For some, revision surgery is an attractive option. Evidence from some case series studies have indicate that revision surgeries are performed in 5% to 56% of patients who have previously

undergone primary bariatric surgery (Buckwalter et al 1985, van Gemert et al 1998, Nessel et al 2007).

DIFFUSION

The StomaphyX was approved by the FDA in April 2007 and is CE Mark approved in Europe. However, there are no clear indications regarding the speed of diffusion of StomaphyX in the United States and Europe. Nevertheless, as with many NOTES procedures, there is potential for rapid diffusion due to worldwide patient preference for minimally invasive surgery.

At the time of writing, two ongoing clinical trials on StomaphyX were identified (ClinicalTrials 2010):

- Evaluation of the Safety and Effectiveness of Stomaphyx for Transoral Incisionless Reduction of the Enlarged Gastric Pouch and Stoma (ClinicalTrials.gov identifier: NCT01025076). Expected study completion date: February 2010.
- StomaphyX versus Sham for Revisional Surgery in Post-Roux-en-Y Patients to Reduce Regained Weight (ClinicalTrials.gov identifier: NCT00939055). Expected study completion date: July 2011.

COMPARATORS

The comparators to StomyphyX includes all other devices and procedures currently being investigated for gastric bypass revision, including adjustable gastric banding, laparoscopic sleeve gastrectomy and the emerging transoral ROSE (Restorative Obesity Surgery) procedure.

SAFETY AND EFFECTIVENESS ISSUES

Study descriptions

Two clinical studies on StomaphyX were identified and retrieved for inclusion in this summary.

The prospective case series study by Mikami et al (2010) discussed their experience on the use of StomaphyX to decrease the size of gastric pouches after Roux-en-Y gastric bypass. All patients (n=39, mean age: 47.8 years, 36 females) were at least 2 years from their original gastric bypass surgery and had gained at least 10% of their lowest nadir weight. The average body mass index (BMI) and weight prior to the StomaphyX procedure was 39.8 (range 22.7 to 63.2) kg/m² and 108.0kg (range 65.90 to 172.2 kg), respectively. An average of 17 fasteners (range: 12 to 41) were placed with StomaphyX during the procedure. All patients were instructed to maintain a liquid diet for 2 weeks, followed by six small meals per day after 2 weeks. Postoperative assessment included length of hospital stay, weight loss at 2 weeks and 1, 2, 3, 6 and 12 months, complications and other unexpected changes.

The case reports by Overcash (2008) documented the use of StomaphyX for the repair of gastric leaks after revision Roux-en-Y surgery in two patients. The first patient (age: 58 years, female) experienced increasing abdominal pain 12 days after revision surgery and experienced fever of 38.9°C. Computed tomography scans revealed a leak from the gastric pouch, conservative therapy with maximal nutritional support was not effective (no healing of leak after 4 months). The second patient (age: 42 years, male) underwent revision surgery (vertical sleeve and duodenal switch) 10 years after original Roux-en-Y surgery. A leak developed immediately along the staple line of the vertical sleeve and did not close despite conservative therapy and nutritional support after 6 weeks (Overcash 2008).

Safety and Effectiveness

Mikami et al (2010) reported that 37 patients were treated as outpatients while 2 patients were kept overnight due to their procedures being done late in the afternoon. Average procedural duration was 35 minutes (range: 16 to 62 minutes). At 2 weeks, average weight loss was 3.8kg (7.4% excess body weight loss [EBWL]; n=39), at 1 month it was 6.4kg (10.6% EBWL; n=34), at 2 months it was 6.7kg (13.1% EBWL; n=26), at 3 months it was 6.7kg (13.1% EBWL; n=15), at 6 months it was 8.7kg (17.0% EBWL; n=14) and at 1 year it was 10.0kg (19.5% EBWL; n=6). No major adverse events were observed. The authors reported that 87.2% (34/39) of patients experienced sore throats lasting less than 48 hours while 76.9% (30/39) experienced epigastric pain that lasted several days. All patients described a feeling of increased early satiety 2 weeks after the procedure. Unexpected results were noted in 11 patients after the StomyphyX procedure. Eight patients with a history of gastric oesophageal reflux experienced improvement of their symptoms at their 1-month visit. This effect has been noticed in other plication procedures and the formation of pleats near the gastroesophageal junction may have increased the robustness of the oesophageal valve. Meanwhile, 3 patients with late dumping syndrome after their original gastric bypass had their postprandial diarrhoea resolved (Mikami et al 2010).

Overcash (2008) stated that the first patient received 9 fasteners and the procedure lasted 30 minutes. No perioperative or postoperative complications were observed. Endoscopic assessment revealed that the leak was reduced by at least 70% and rapidly closed within a few days (not quantified). The patient was released 4 days after the procedure and remained on a liquid diet for 1 to 2 weeks. At 6 months, there was no evidence of a leak or fistula. The second patient underwent the same procedure as the first patient, total procedure time was 30 minutes as well and resulted in the placement of 6 fasteners and a tissue shield over the leak. No complications were observed. Endoscopic examination at 3 months revealed no evidence of a leak or fistula. Both patients returned to normal diet and lifestyle within 60 days (Overcash 2008).

COST IMPACT

The cost effectiveness of endoluminal techniques like Stomaphyx has not been determined. If this technique is successful in minimising complication rates associated with revision bariatric surgery, it may result in substantial long-term cost savings. The cost of the StomaphyX procedure ranges from USD\$8,500 to \$12,500 and varies based on location and expertise (Consumer guide to bariatric surgery 2010).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

A brief search revealed that the lead author of one of the papers, Dr. Mikami, receives (or used to receive) teaching and speaking honorarium from Endogastric Solutions (Endocrine Today 2007). Meanwhile, the case reports by Overcash (2008) acknowledged professional assistance from an employee of EndoGastric Solutions with the preparation of the final manuscript and its submission.

SUMMARY OF FINDINGS

There is some evidence that StomaphyX can lead to EBWL and resolve complications like gastric leaks after revision bariatric surgery. However, the evidence to date is severely limited by small sample sizes, no comparative data and substantial follow-up losses. In addition to this, there is considerable variation in weight loss between patients, with some losing only 2kg after 3 months (Mikami et al 2010), suggesting that there is need to improve patient selection for this procedure. Long-term comparative results are necessary before any firm conclusions can be made regarding the effectiveness of StomaphyX.

HEALTHPACT ACTION

Considering the limited evidence available, it is difficult to make any conclusive statements regarding the effectiveness of StomaphyX. However, preliminary evidence indicates that it has the potential to address the escalating need for revision bariatric surgery worldwide. It is recommended that StomaphyX and all other NOTES techniques for revision bariatric surgery be monitored for 24 months to gather additional data and to observe the diffusion of NOTES in bariatric surgery.

NUMBER OF STUDIES INCLUDED

Total number of studies	2
Level IV intervention evidence	1
Case report	1

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SEARCH CRITERIA TO BE USED

StomaphyX, Natural orifice bariatric surgery.