



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Polypropylene mesh for postoperative hernia prophylaxis in open bariatric surgery

February 2007



**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.

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PRIORITISING SUMMARY

REGISTER ID: S000011

NAME OF TECHNOLOGY: POLYPROPYLENE MESH FOR POSTOPERATIVE HERNIA PROPHYLAXIS IN OPEN BARIATRIC SURGERY

PURPOSE AND TARGET GROUP: PROPHYLACTIC USE OF POLYPROPYLENE MESH DURING WOUND CLOSURE IN PATIENTS UNDERGOING ROUX-EN-Y GASTRIC BYPASS (OR OTHER OPEN BARIATRIC PROCEDURES) FOR MORBID OBESITY TO REDUCE THE RISK OF POSTOPERATIVE HERNIA.

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

- | | | |
|----------------------------------------------------|-------------|-----|
| <input type="checkbox"/> Yes | ARTG number | N/A |
| <input type="checkbox"/> No | | |
| <input checked="" type="checkbox"/> Not applicable | | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Poland		✓	

IMPACT SUMMARY:

This prioritising summary investigates the prophylactic use of polypropylene mesh during wound closure in patients undergoing open bariatric procedures (e.g. Roux-en-Y gastric bypass) for morbid obesity for the prevention of postoperative hernia.

BACKGROUND

Obesity is a medical disorder associated with increased morbidity and mortality, and is the most obvious manifestation of the global epidemic of sedentary lifestyles and excessive energy intake. The surgical treatment of obesity (bariatric surgery) is a rapidly growing area of surgical practice in Australia (O'Brien et al 2004). Bariatric procedures result in reduced calorie intake by combining intake restriction and a moderate degree of malabsorption. In general, surgery is indicated for patients with a body mass index (BMI) > 40 or with a BMI > 35 with serious medical co-morbidities, although it is increasingly being used in patients with BMIs lower than this (NHMRC 2003).

There are currently four major procedures in use for obesity surgery: laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion and vertical banded gastroplasty (VBG). All four procedures induce significant weight loss and a reduction in many obesity related co-morbidities (NHMRC, 2003). There is variation in preferred procedure between countries, however in Australia, LAGB is the procedure of choice in more than 90% of cases, with RYGB making up most of the rest (O'Brien et al. 2004).

The popularity of laparoscopic bariatric surgery is gradually rising as it is less invasive and generally safer; however open bariatric surgery is still widely used. One of the main disadvantages of open bariatric surgery is an unacceptable rate of incisional hernia, with occurrence rates of 25% (Sugerman et al. 1996) and up to 51% in super obese patients (Arribas et al. 2004). In an effort to reduce the incidence of postoperative incisional hernia, prosthetic meshes have been utilised in high-risk patients undergoing open bariatric surgery. This summary will discuss the current evidence available on the safety and efficacy of prophylactic meshes in preventing incisional hernias following open bariatric surgery.

CLINICAL NEED AND BURDEN OF DISEASE

In Australia, the prevalence of obesity has more than doubled in the past 20 years (Cameron et al 2003). It has been estimated that 20% of Australian adults (an estimated 2.6 million people) are obese and have a BMI greater than 30 kg/m² (AIHW 2004). Surgery is recommended as the most effective treatment available for selected patients with morbid obesity (NHMRC 2003). According to the AIHW National Hospital Morbidity Database, 192 gastric bypass procedures were performed in 2004-05.

Abdominal wall closure is one of the major problems associated with open bariatric surgery. Wound failure remains one of the most frequent problems related to RYGB (Strzelczyk et al 2002). The incidence of wound dehiscence and post operative hernia following bariatric procedures is reported to be as high as 25%, much higher than in other elective procedures (Pans et al 1998). If this is extrapolated to the Australian context, approximately 50 patients undergoing gastric bypass surgery could have suffered post operative hernias in 2004-05.

DIFFUSION

If proven to be effective, the addition of a polypropylene mesh during open bariatric surgery may be widely accepted as a precautionary step. It is not clear if this slight addition to open bariatric surgery has been practised in Australia. However, the rising incidence of obesity and therefore the increasing need for bariatric surgery provides a strong incentive to adopt surgical modifications that can reduce the incidence of incisional hernias in patients, who for various reasons, are required to undergo open bariatric surgery.

COMPARATORS

Previously, retention sutures have been utilised to reduce the risk of postoperative hernias (Strzelczyk et al. 2002). A range of other methods have been investigated, such as the use of absorbable polyglactin meshes (Pans et al. 1998). However the optimal means of abdominal wound closure has not been established.

SAFETY AND EFFECTIVENESS ISSUES

In 2002, Strzelczyk et al. reported the results of a non-randomised study on the prophylactic use of polypropylene mesh in 60 consecutive patients undergoing Roux-en-Y gastric bypass (RYGB). Patients were divided into three groups; group 1 (n = 12) consisted of patients who received mesh during the surgery, group 2 (n = 9) consisted of patients who developed hernia post-surgery and group 3 (n = 39) consisted of patients with neither mesh nor post-operative hernia. The mesh patients (group 1) were significantly more obese compared to patients in group 2 and group 3, while their BMI was significantly greater than patients in group 3. Therefore, of the 48 patients who underwent standard wound closure, incisional hernia was found in 9 cases (20%), while none of the patients with the inserted mesh (n = 12) developed hernia following surgery. The length of hospital stay in the mesh group (14.4 days) was similar to that in the non-mesh group (11.9 days) and shorter than in patients with hernia occurrence (27.8 days). Mesh insertion was complicated with wound fluid discharge in three patients. In one of these patients, small pieces of mesh were removed for treatment of the wound (Strzelczyk et al. 2002).

A clinical trial published in 2006 by Strzelczyk et al. randomised 74 patients undergoing RYGB to wound closure with (n=36) and without polypropylene mesh (n=38). Patients were followed up for at least six months. The authors reported that hernias developed in 8 patients (21%) in the non-mesh group, while no patients from the mesh group developed hernias. The length of hospital stay was not significantly different between the mesh (8.4 days) and non-mesh (10.3 days) groups. No serious complications were observed in either group. The incidence of seromas and minor wound leakage was similar in both groups, with 14% in the mesh group and 11% in the non-mesh group.

Both of the studies which examined the use of polypropylene mesh in wound closure of open bariatric surgery found that the use of mesh prevented hernia development in patients undergoing open bariatric surgery for obesity. In addition to this, the use of the mesh did not result in prolonged hospital stay, and hence did not incur a large increase in cost. The randomised trial by Strzelczyk et al. (2006) observed that patients who developed hernias were found in both ends of the bodyweight distribution (BMI 36.2 to 65.8 kg/m²) which indicates that the incidence of hernia following open bariatric surgery is difficult to predict. It is important to note that in both studies the length of follow up was relatively short and may not have been sufficient to detect complications related to the utilisation of the mesh. Previous studies have shown that enterocutaneous fistulas can occur more than 3 years after mesh insertion and has been reported to occur 14 year post-surgery (Strzelczyk et al. 2002). This highlights the need for larger, long-term trials to assess the safety of mesh insertion for the prevention of incisional hernias following open bariatric surgery.

COST IMPACT

No data exists regarding the costs of the polypropylene mesh used in the included studies or the cost of the additional time taken to insert it during wound closure. In relation to the gastric bypass procedures, an MSAC report costed gastric bypass at just over \$8000 per procedure and gastric banding at just over \$9000 per procedure (MSAC 2003). These costs do not take into account costs of complications associated with the surgery if they arise. The Medicare Benefits Schedule reimbursement fees for procedures related to bariatric surgery are listed in Table 1:

Table 1 Medical Benefits Schedule of fees for procedures related to bariatric surgery (Medicare Australia 2006)

Category	Item Number	Benefit (AUD)	Number of Claims (July 2005 to June 2006)
Initiation and management of anaesthesia for gastric reduction or gastroplasty for the treatment of morbid obesity.	20791	\$175.00	5930
Gastric reduction or gastroplasty by any method for morbid obesity.	30511	\$750.70	6080
Gastric bypass for morbid obesity by any method including anastomosis.	30512	\$923.80	239
Surgical reversal of morbid obesity by any method of procedure to which item 30511 or 30512 applies.	30514	\$1360.05	721

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES No issues were identified from the retrieved material.

HEALTHPACT CONCLUSION

Based on the included studies (1 randomised control trial and 1 case series study by the same author), the use of polypropylene mesh appears to reduce the risk of postoperative hernia in gastric bypass surgery. HealthPACT has recommended that further assessment of this technology is no longer warranted.

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

SOURCES OF FURTHER INFORMATION:

Gutiérrez de la Peña C, Medina Achirica C, Domínguez-Adame E, Medina Diez J. Primary closure of laparotomies with high risk of incisional hernia using prosthetic material: analysis of usefulness. *Hernia* 2003; 7(3):134–136.

Talbot ML, Jorgensen JO, Loi KW. Difficulties in provision of bariatric surgical services to the morbidly obese. *Medical Journal of Australia* 2005; 182(7): 344-347.

LIST OF STUDIES INCLUDED

Total number of studies 2
Level II and IV intervention evidence.

SEARCH CRITERIA TO BE USED:

Surgical Mesh*
Polypropylene
Hernia, Ventral/prevention & control*
Polypropylenes/therapeutic use*
Obesity, Morbid/surgery*

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