NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic mobilisation of the greater omentum for breast reconstruction

The aim of breast reconstruction is to restore the shape of the breast after surgery, usually because of cancer. The greater omentum is a sheet of fat tissue that is attached to the stomach and part of the intestines, and can be used to reconstruct the breast. In this procedure, the greater omentum is released from its surrounding tissue and is drawn through to the chest wall, using special instruments inserted through a number of small incisions ('keyhole' surgery).

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in July 2007.

Procedure name

- Laparoscopic mobilisation of the greater omentum for breast reconstruction

Specialty societies

- Association of Laparoscopic Surgeons of Great Britain and Ireland
- British Association of Aesthetic Plastic Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Association of Surgical Oncology

Description

Indications

Breast reconstruction

The most common reason for breast reconstruction is previous surgery for breast cancer. More rarely, breast surgery may have been carried out prophylactically because of a strong family history of breast cancer. Part of the breast may be removed during surgery (also called lumpectomy, or breast-conserving surgery) or the whole of the breast (mastectomy). In addition, axillary lymph node clearance may be performed. The aim of breast reconstruction is to create a new breast that is similar in size, shape and texture to the one that was removed. It can be done at the same time as the breast surgery or at a later date.

Current treatment and alternatives

Several techniques are used for breast reconstruction. They involve the use of prosthetic material (implant) alone, autologous tissue (i.e. from elsewhere in the body, usually the abdomen, buttocks or back), or a combination of the two. When prosthetic material is used alone, an implant is placed under the skin or muscle. Tissue expansion is sometimes used and can avoid the need for more extensive surgery. This involves placing an expandable implant under the chest muscle. The implant is expanded over a few months by regularly injecting saline into it through a valve just under the skin. Once the tissue has expanded, the implant can be removed and replaced with a permanent implant. However, in women previously treated with radiotherapy (as is necessary for certain types and stages of breast cancer) the skin may lose its natural elasticity, which may limit the possibility of using breast implants.

Autologous tissue for implant may take the form of either a free flap or a ‘pedicled’ (or ‘mobilised’) flap. A pedicled flap is one in which the ‘native’ blood supply is preserved.

A free flap reconstruction involves removing skin, fat and sometimes muscle from the lower abdomen or buttock and grafting it to the breast area. Microsurgery is used to create a new blood supply. A number of different types of free flaps are used for breast reconstruction, including the transverse rectus abdominis muscle (TRAM) flap, a deep inferior epigastric perforator (DIEP) flap, superficial inferior epigastric artery (SIEA) flap, superficial gluteal artery perforator (SGAP) flap and inferior gluteal artery perforator (IGAP) flap.

Pedicled flap reconstruction involves subcutaneous channelling of skin, muscle and fat from the back or abdomen through to the chest. The flap of tissue remains connected to its original blood supply. In a latissimus dorsi flap reconstruction, a flap of fat and skin is tunnelled from the back to the breast area, under the skin just below the armpit. The flap stays connected to the latissimus dorsi muscle in the back. If there is not enough tissue to create a

whole breast, an implant may also be used. Although the flap is usually harvested by open surgery, endoscopic techniques have recently been developed. In a pedicled TRAM flap reconstruction, a flap of fat, muscle and skin is tunnelled upwards from the abdomen and positioned on the chest wall to create the shape of a breast. The flap is conventionally harvested via an incision across the abdomen. The greater omentum has also been used as a pedicled or free flap which are conventionally harvested by open surgery (laparotomy).

What the procedure involves

Breast reconstruction with a laparoscopically harvested omental flap is usually done at the same time as mastectomy or breast-conserving surgery. Under general anaesthesia, the peritoneal cavity is insufflated with carbon dioxide. A number of small incisions are made to provide access for the laparoscope and surgical instruments. The greater omentum is detached from the colon and stomach.

When a pedicled flap is used, the greater omentum remains connected to the terminal branch of the right gastroepiploic artery. A skin-sparing mastectomy or breast-conserving surgery is then performed, together with axillary lymph node clearance as required. A subcutaneous tunnel is created from the inframammary skin fold towards the xiphoid process of the sternum. An incision is made at the linea alba to allow communication with the abdominal cavity. Forceps are inserted into the abdominal cavity and used to draw out the greater omentum, through the tunnel.

When a free flap is used, the roots of the right gastroepiploic vein and artery are clipped and resected. The flap is removed through a small incision in the right lower abdominal wall and inserted via the mastectomy wound. Microsurgery is used to perform anastomosis of the epiploic artery to the internal mammary artery.

With both pedicled and free flaps, the greater omentum is fixed to the major pectoral muscle with staples or sutures, and the mastectomy incision is closed. A gravity drain is placed within the mastectomy compartment.

Efficacy

In one case series, the omental flap was found to be inadequate in volume in 11% (5/44) of women. A lattisimus dorsi myoflap was combined with the omental flap in these patients. Cosmetic results were reported to be mostly satisfactory, the reconstructed breast being soft in texture and natural in appearance. No size reduction of the reconstructed breast was noted during follow-up (median 25 months).

In a second case series, the omental flap was inadequate in 20% (2/10) of women and an implant was also used. None of the women reported dissatisfaction with the cosmetic result.

Safety

In the case series of 44 women, 4 (9%) had wound or graft infections, which were treated conservatively; 1 woman (2%) had a 'minor' vascular injury and 1 (2%) developed an epigastric hernia. No patients had local or systemic recurrence of breast cancer after a median follow-up of 25 months.

In the case series of 10 women, 1 reported epigastric pain, which persisted for 4 months (resolved with medication). One patient had partial necrosis of an areolar graft implanted during the same operation. The report stated that there were no cases of abdominal wall herniation. No patients had local or systemic recurrence of breast cancer by the end of follow-up (period not stated).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic mobilisation of the greater omentum for use in breast reconstruction. Searches were conducted via the following databases, covering the period from their commencement to 04/07/2007: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix B for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good-quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial or laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients having breast reconstruction after partial or full mastectomy
Intervention/test	Laparoscopic mobilisation of the greater omentum
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on two case series and three case reports, including a total of 58 patients.[1–5]

No other studies were identified that were considered to be relevant to the procedure.

Existing reviews on this procedure

No published systematic reviews with meta-analysis or evidence-based guidelines were identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix A details the recommendations made in each published piece of guidance listed below.

Clinical guidelines

'Familial breast cancer: the classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care'. *NICE clinical guideline* no. 41 (2006). Available from: http://www.nice.org.uk/guidance/CG41

'Advanced breast cancer: diagnosis and treatment'. *NICE clinical guideline* in progress (expected date of issue January 2009)

'Early breast cancer: diagnosis and treatment'. *NICE clinical guideline* in progress (expected date of issue January 2009)

Cancer service guidance

'Improving outcomes in breast cancer – manual update'. *Cancer service guidance* (2002). Available from: www.nice.org.uk/csgbc

Table 2 Summary of key efficacy and safety findings on laparoscopic mobilisation of the greater omentum for breast reconstruction

Abbreviations used:			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Zaha H (2006)[1] Case series Japan Study period: 2002–2005 n = 44 Population: Women with stage 0, I or II breast cancer undergoing nipple-sparing mastectomy (n = 21) or breast-conservation surgery (n = 23). Mean age: 47.2 years (range 27–67) Tumour size: • Diffuse ductal carcinoma in situ = 14% (6/44) • T1 = 4% (2/44) • T2 = 82% (36/44) Indications: For breast-conserving surgery, reconstruction was used when a 30% or wider region of the breast tissue was resected, or the cosmetic result was poor because of the tumour location in the lower medial region. Patients in whom tumour invasion of the nipple was suspected and who had a past history of upper abdominal laparotomy were excluded. Patients undergoing nipple-sparing mastectomy but requiring a large breast reconstruction were usually excluded. Technique: Immediate breast reconstruction; laparoscopically harvested omental flaps: 40 pedicled, 4 free Median follow-up: 25 months (range 4–48) Conflict of interest: None stated	All omental flaps were harvested laparoscopically within 1 hour, without need for conversion to open surgery. In 11% (5/44) of women, the omental flap size was found to be inadequate during the procedure and was combined with a latissimus dorsi myoflap. “Cosmetic results were mostly satisfactory, with a soft breast that was natural in appearance. Donor-site scars were minimal.” No size reduction of the reconstructed breast was noted during the follow-up period. Concomitant postoperative radiotherapy was performed in 12 patients, but no change was noted in the reconstructed breast.	**Complications:** • ‘Minor’ vascular injury = 2% (1/44) • Wound and graft infections that could be treated conservatively = 9% (4/44) • Epigastric hernia (because of excessive extension of the subcutaneous tunnel for a large volume of the greater omentum) = 2% (1/44) There was no total graft loss. In 4 patients, minor deformity of the reconstructed breast occurred through postoperative complications. No patients had had local or systemic recurrence by the end of follow-up.	Patient selection not described. The authors state that they currently use a free omental flap when the omental volume is large. The authors state that the biggest disadvantage of omental flaps is that preoperative estimation of the omental volume is not possible. The volume may be insufficient when the breast to be reconstructed is large. The study reported that 12.5% of women had an inadequate omental flap size, but stated this as being 5/44 women, which is 11%.

Abbreviations used:			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Cothier-Savey I (2001)[2] Case series France Study period: 1998–1999 n = 10 Population: Women undergoing breast reconstruction with a laparoscopically harvested pedicled omental flap Mean age: 48 years (range 35–57) Indications: In 9 patients, the indication was immediate breast reconstruction after skin-sparing mastectomy. One patient had an ulcerated, budding tumour invading the chest wall. None of the patients had abdominal contraindications to omental flap harvesting (such as a history of multiple abdominal surgical procedures). Technique: Pedicled omental flaps were used. In 2 patients, same-stage implant insertion was performed. Meshed, split-thickness skin grafting was also performed in the patient with an extensive chest wall defect. Follow-up: Not stated Conflict of interest: None stated	The omental flap size was found to be inadequate during the procedure in 20% (2/10) of patients, and an implant was inserted under the omental flap. (One of these patients had a small greater omentum because of previous radiation therapy for Hodgkin's disease. The other patient had relatively large breasts despite normal body weight.) Hospital stay ranged from 4 to 7 days. Appearance of the breast (evaluated by two plastic surgeons who compared preoperative and postoperative photographs): • Very satisfactory = 60% (6/10) • Satisfactory = 20% (2/10) • Fair = 20% (2/10) None of the patients reported dissatisfaction with the cosmetic result. Breast contour was more satisfactory in patients with small or medium breasts. Patients described a stone-hard consistency at around 2 months' follow-up. The change was transient and by 4 months the greater omentum was again pliable and similar in consistency to the other breast.	Report states that the postoperative course was uneventful in every case. Bowel function resumed within 24 hours. "Some dyspepsia and gastralgia were noted during the first 2 months. These symptoms abated spontaneously in every case" (rates not reported). One patient reported persistent epigastric pain after the 4th month (resolved with medication). In the patient who had meshed split-thickness skin grafting, substantial drainage from the wound occurred until the 15th day after the operation. Exudation was minimal in the other 9 patients. One patient developed partial necrosis of an areolar graft implanted during the same operation (paper does not state whether this was an autograft). The necrosis healed with local wound care after excision of the necrotic area. There were no cases of abdominal wall herniation. No patients had had local or systemic recurrence by the end of follow-up.	Patient selection not described. The authors state that the major drawback of omental flap reconstruction is that there is no reliable means of predicting the size of the greater omentum before the procedure. Operating time decreased from 3 hours in the first patients to less than 1.5 hours. The authors attributed this partly to the learning curve and partly to the use of a harmonic scalpel in later procedures. The authors state that the technique is highly sophisticated and has a number of risks, including injury to vital organs.

Abbreviations used:			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Gomez Jimenez A (2002)[3] Case reports Canada Study period: 1999–2001 n = 2 Population: Women undergoing breast reconstruction with a laparoscopically harvested omental flap Ages: 36 and 56 years Indications: One patient had Poland's syndrome and presented with chest deformity caused by capsular contracture after previous breast reconstruction; the other patient had skin-sparing mastectomy for breast cancer, followed by immediate breast reconstruction. Technique: Free omental flap, without using any synthetic material. Follow-up: 6–18 months (including two additional patients with greater omentum harvesting by laparotomy) Conflict of interest: None stated	In the first patient, greater omentum weighed 325 g. A second procedure was performed 1 month later to reposition the nipple–areola complex and to lift the contralateral breast to achieve symmetry. In the second patient, greater omentum weighed 458 g. Reconstruction of the nipple–areola complex and contralateral breast lifting were done in the same surgical procedure. "Good results were achieved during the follow-up period, which ranged from 6 to 18 months. The reconstructed breast was stable, had good projection and remained similar in size and shape to the contralateral breast. The reconstructed breast remained soft, supple and with normal feel to palpation; any sagging of the breast appeared natural."	"There was no clinical evidence of fat necrosis or microcalcification and/or macrocalcification in the mammography."	The article also discusses two other women who had breast reconstruction with greater omentum that was harvested by laparotomy. The results for all four patients were reported together. Harvesting by laparotomy was chosen because of an abdominal adhesion from previous surgery in one patient and because of extreme obesity in the other patient. The authors noted difficulty in assessing omental volume preoperatively, and that there is a risk of iatrogenic abdominal injuries at the time of harvest.

Abbreviations used:			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Kamei Y (2003)[4] Case report Japan Study period: not stated n = 1 Population: A woman referred for breast reconstruction after prior surgery to remove a phyllode tumour of the left breast Age: 18 years Technique: Skin expansion was initially performed, as reconstruction by an endoscopically harvested latissimus dorsi muscle flap was originally planned. Once the skin expansion was complete, the patient requested that an omental flap be used instead. The omental flap was harvested by endoscopic surgery and transferred to the chest wall / breast cavity after removal of the tissue expander. Follow-up: Not stated Conflict of interest: None stated	"The final shape and size of the breast was excellent."	"The postoperative course was uneventful. The patient experienced only slight pain and demonstrated a rapid recovery."	Non English language paper (Japanese). Information from English abstract only.

Abbreviations used:			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Bufo AJ (1997) Case report USA Study period: not stated n = 1 Population: Adolescent girl undergoing chest-wall and breast reconstruction 7 years after radiotherapy and left chest-well resection for Ewing's sarcoma. Age: 17 years Technique: Two subcutaneous saline tissue expanders were inserted in the area of the chest-wall depression and removed three months later. Pedicled omental flap was used to complete the chest and breast reconstruction. Follow-up: 1 year Conflict of interest: None stated	Patient was reported as being satisfied with the cosmetic results of the surgery approximately 1 year after the operation.	"The patient's postoperative course was unremarkable… and has no evidence of an incisional hernia or other complications approximately 1 year after her operation."	

Validity and generalisability of the studies

- There were no randomised controlled trials against comparators such as implants and/or other types of flap.
- The aim of the procedure is cosmetic – safety considerations are therefore important.
- Two of the five reports were from Japan and the results may not be readily generalisable to the UK population.
- The five reports included a total of 51 pedicled omental flap reconstructions and 7 free omental flap reconstructions.
- Most of the procedures described were skin-sparing mastectomies followed by immediate reconstruction.

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr P Harris, Mr J Kenealy, Mr M Keshtgar, Mr N Parkhouse, Mr J Winstanley

- Two Specialist Advisers described the procedure as definitely novel and of uncertain safety and efficacy. One described it as established practice and no longer new and one described it as a minor variation on an existing procedure, which is unlikely to affect that procedure's safety and efficacy.
- Appropriate comparators include open mobilisation of the greater omentum for breast reconstruction, free or pedicled TRAM, DIEP, SIEA, SGAP, IGAP and latissimus dorsi flap reconstructions.
- This is not a widely practiced procedure (fewer than 10% of specialists are engaged in this area of work).
- One Specialist Adviser noted that few specialists would use this for primary breast reconstruction but most would occasionally use the greater omentum for chest wall reconstruction where other options are not available.
- The omental volume cannot be assessed before surgery and may be inadequate to reconstruct a large breast.
- Reported adverse events include partial flap necrosis, vascular injury, wound and graft infection, epigastric hernia and small omental flap (inadequate for full reconstruction).
- Additional theoretical adverse events include vascular damage leading to total flap loss, damage to intra-abdominal organs during harvest, referred pain (through autonomic nervous system), impact on future abdominal surgery or lack of greater omentum to defend against intra-abdominal sepsis, and possible risk of seeding tumour cells into the peritoneal cavity.
- There are no reported data with long-term follow-up.
- Key efficacy outcomes include: tumour control at the site of mastectomy and lack of peritoneal deposit, cosmetic outcome evaluated by

independent observers, evaluation of patient satisfaction, short- and long-term morbidity.

- Training in laparoscopic surgery and breast surgery skills are required to perform the procedure.
- The procedure should be undertaken within the context of a multidisciplinary breast practice.
- There is uncertainty about the long-term effects of loss of intraperitoneal omentum.
- Appropriate outcome measures for audit include the need for an additional implant, conversion to open surgery, operative time, length of hospital stay, the need for revision procedures, local and distant control, short- and long-term cosmesis, effects of postoperative radiotherapy, psychological impact, patient satisfaction, and disease-free survival.
- The greater omentum would not currently be viewed as first choice for an autogenous reconstruction.
- One Specialist Adviser stated that this procedure is unlikely to replace established techniques but it may have a place in the full armamentarium of techniques available, particularly when the usual donor flaps are inadequate.
- Three Specialist Advisers considered that the potential impact of this procedure on the NHS to be minor; another considered it to be moderate, in terms of numbers of patients and use of resources.

Issues for consideration by IPAC

- None other than those described above.

References

1. Zaha H, Inamine S, Naito T et al. (2006) Laparoscopically harvested omental flap for immediate breast reconstruction. *American Journal of Surgery* 192: 556–8.
2. Cothier-Savey I, Tamtawi B, Dohnt F et al. (2001) Immediate breast reconstruction using a laparoscopically harvested omental flap. *Plastic and Reconstructive Surgery* 107: 1156–63.
3. Gomez Jimenez A, St. Germain P, Sirois M et al. (2002) Free omental flap for skin-sparing breast reconstruction harvested laparoscopically. *Plastic and Reconstructive Surgery* 110: 545–51.
4. Kamei Y, Torii S, Toriyama K et al. (2003) Breast reconstruction using omentum harvested by endoscopic surgery: a case report. *Japanese Journal of Plastic and Reconstructive Surgery* 46: 509–13.

Appendix A: Related published NICE guidance for laparoscopic mobilisation of the greater omentum for breast reconstruction

Guidance programme	Recommendation
Interventional procedures	None applicable
Technology appraisals	None applicable
Clinical guidelines	**CG41 Familial breast cancer** 1.4.12.9 All women considering bilateral risk-reducing mastectomy should be able to discuss their breast reconstruction options (immediate and delayed) with a member of a surgical team with specialist oncoplastic or breast reconstructive skills. 1.4.12.10 A surgical team with specialist oncoplastic/breast reconstructive skills should carry out risk-reducing mastectomy and/or reconstruction.
Cancer service guidance	**Improving outcomes in breast cancer** Prophylactic mastectomy should be available for women at high risk who request it. Such women should have counselling before any decision is made on surgery, and should be given opportunities to discuss all aspects of the operation, including reconstruction. Surgeons should discuss breast reconstruction with all patients. Reconstruction should be available at the initial surgical operation. If this cannot be provided within 1 month of diagnosis, women should be offered a choice between routine surgery with delayed reconstruction (if desired), or waiting longer for initial surgery. When women choose the latter option, the reason for the delay should be recorded. The proportion of each type of operation done will reflect local differences in case-mix and women's preferences. Surgeons should have the technical skills to support a full range of choices. Suitable patients should be offered breast conserving surgery. Breast reconstruction should be available at the time of, or after, mastectomy, provided either by a plastic surgeon or a breast surgeon trained in the appropriate techniques.
Public health	None applicable

Appendix B: Literature search for laparoscopic mobilisation of the greater omentum for breast reconstruction

Database	Date searched	Version searched
Cochrane Library	03/07/2007	Issue 2, 2007
CRD databases (DARE & HTA)	03/07/2007	Issue 2, 2007
Embase	03/07/2007	1980 to 2007 Week 26
Medline	03/07/2007	1950 to June Week 3 2007
PreMedline	03/07/2007	July 02, 2007
CINAHL	03/07/2007	1982 to June Week 5 2007
British Library Inside Conferences	03/07/2007	-
NRR	03/07/2007	2007, Issue 2
Controlled Trials Registry	03/07/2007	-

Search strategy used in Medline

The search strategy was adapted for use in the databases above

1	Mastectomy/
2	mastectomy.tw.
3	Breast/
4	Mammaplasty/
5	(breast$ adj3 reconstruct$).tw.
6	(breast$ adj3 conserv$ adj3 surgery).tw.
7	or/1-6
8	Omentum/
9	(omentum or omental).tw.
10	((o adj3 majus) or epiploon).tw.
11	(deep adj3 inferior adj3 epigastric adj3 perforator).tw.
12	DIEP.tw.
13	(superficial adj3 inferior adj3 epigastric adj3 artery).tw.
14	SIEA.tw.
15	Surgical Flaps/
16	flap$.tw.
17	or/8-16

18	exp Laparoscopy/
19	exp Laparoscopes/
20	exp Surgical Procedures, Minimally Invasive/
21	laparoscop$.tw.
22	endoscop$.tw.
23	percutan$.tw.
24	or/18-23
25	7 and 17 and 24
26	Animals/
27	Humans/
28	26 not (26 and 27)
29	25 not 28