



ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

SUBMISSION TO THE HEALTH SELECT COMMITTEE ON THE PETITION 2011 / 102
CARMEL BERRY AND CHARLOTTE KORTE REGARDING SURGICAL MESH

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Introduction

The Royal Australasian College of Surgeons (the College) is the leading advocate for surgical standards, professionalism and surgical education in New Zealand and Australia.

The College is a not-for-profit organisation that represents more than 7000 surgeons and 1300 surgical trainees and international medical graduates across New Zealand and Australia. It also supports healthcare and surgical education in the Asia-Pacific region and is a substantial funder of surgical research. The College provides training in nine surgical specialties, cardiothoracic surgery, general surgery, neurosurgery, orthopaedic surgery, otolaryngology head and neck surgery, paediatric surgery, plastic and reconstructive surgery, urology and vascular surgery.

The College plays an active role in the setting of standards of surgical care, the training of surgeons and their participation in continuing medical education throughout their lifetime of surgical practice. As part of its commitment to standards and professionalism the College strives to take informed and principled positions on issues associated with the delivery of health services. The use of surgical mesh is one such issue.

Background

Surgical mesh is a broad term encompassing a variety of surgical implants used in the repair of structural defects, usually occurring as a consequence of defective supporting fascial or fibrous tissue. While the mesh may be constructed from a range of absorbable or non-absorbable materials, either harvested from biological materials or by synthetic manufacture, most concern appears to be related to the use of synthetic non-absorbable meshes constructed of polypropylene, polyester or polytetrafluoroethylene (PTFE).

Biological meshes have been produced as an alternative to synthetic mesh. Biological absorbable meshes have limited data available, have durability issues, significant complication rates and are very expensive. Even when used in the presence of a contaminated field their efficacy is questionable. The use of biological meshes for abdominal wall hernia repair was the subject of an evidence-based report produced by ACC in July 2013. Biologic mesh consists of an extracellular collagen matrix and the commercially available ones are derived from human and porcine dermis, small intestinal mucosa and bovine pericardium. The rate of hernia recurrence after the use of biological mesh appears to be similar to that of synthetic mesh but the research evidence for the use of biological mesh is sparse.¹ Biological mesh is more expensive than synthetic mesh and there are concerns relating to disease transmission by biological materials.

Further comment on surgical mesh in this submission is limited to the synthetic non-absorbable meshes.

Synthetic non-absorbable surgical meshes have been widely used by General Surgeons, Paediatric Surgeons, Urologists, and Plastic and Reconstructive Surgeons for more than thirty years in the repair of hernias (cavity wall defects) involving the abdomen and chest. When mesh reinforcement is required to repair a hernia of the groin or abdominal wall, a synthetic non-absorbable mesh is the standard of care. The use of surgical mesh in these situations has been

¹ Evidence-based report. Biological mesh for abdominal wall hernia repair. Mark Ayson. July 2013 Accident Compensation Corporation publication.

associated with a lower risk of hernia recurrence than where techniques without mesh have been employed. There has been no increase in other symptoms such as local discomfort by the use of these meshes. Meshes have also been used (but less commonly) in complex breast reconstruction surgery. While the use of any artificial or synthetic implant is associated with a slightly greater risk of infection, the overall benefits arising through the use of mesh in these clinical situations have been confirmed through its extensive use over many years.

Given the successful use of surgical mesh in the repair of cavity wall defects the indications for its use have been extended into other areas of surgery. Its use in surgery for female urinary stress incontinence has been associated with a number of complications and concerns in respect to this specific use have triggered the Health Select Committee investigation. It is also used in procedures such as abdominosacrocolpopexy and rectopexy to correct vaginal or rectal prolapse. While these procedures have permitted sometimes difficult conditions to be better managed, resulting in improved comfort for most patients, there has been a higher incidence of local complications including discomfort and implant extrusion.

Informed Consent and the Use of Surgical Mesh

Patients should be well informed of the risks outlined above (along with other significant risks attributable to the planned surgery and anaesthetic) as part of the consent process as they consider whether surgery is the best option in their situation.

There is an expectation that patients will be provided with a general overview of the benefits and the risks of the potential care options available to them. Surgeons should assist patients in their selection of the form of treatment most appropriate to their particular situation. Where any form of surgery is planned information should be provided to the patient in respect to the anticipated benefits of the intervention along with the potential risks associated with the procedure. The need to substitute foreign materials to replace or augment a patient's natural tissues during any operation should be discussed in general terms (and there might, in some situations, be the need to discuss the specific structure or technology of the proposed implant). Discussion is expected to be more specific where the proposed procedure is more controversial or of higher risk.

When consenting a patient for hernia repair the risk/benefit of non-operative management must be also discussed. The consequences of non-operative management may be ongoing pain, bowel obstruction, intestinal strangulation and even death.

The College's Code of Conduct requires that surgeons fully inform the patient and obtain consent prior to employing a new intervention, technique or prosthesis. The Code of Conduct also requires surgeons to ensure consent has been obtained from the patient (or guardian) before elective operations are undertaken and wherever possible in emergency situations.

Given the vast range of surgical procedures available to assist in patient care and the continually evolving technology, the College does not provide specific consent advice or training to Fellows on each procedure. With the rapidity of the increase in medical knowledge, advances in technology and the development of highly individualised packets of care available to meet specific patient requirements, being appropriately informed on these aspects of continuing education through the lifetime of surgical practice must remain the responsibility of each individual surgeon.

The introduction of new technologies and treatments is dependent upon research, audit and the publishing of supportive peer-reviewed articles demonstrating efficacy without undue risk, and practitioners ensuring they have acquired the appropriate levels of knowledge and skill. This is most satisfactorily monitored through the robust credentialing of practitioners and their working environment expected as part of each practitioner's employment or right of access to surgical facilities.

The College does facilitate the distribution of patient information pamphlets which provide some written information and illustrations in respect to a range of surgical procedures. Although this covers only a proportion of surgical procedures, a pamphlet entitled "Surgery to Repair Hernia" is available providing information in respect to hernia repair and the use of surgical mesh in that operation.

The Urological Society of Australasia, many of whose members are also Fellows of the College, has a patient information brochure on the "Treatment of Urinary Incontinence" that describes the use of transvaginal tape (ie. mesh) for the surgical management of incontinence.

Surgical Mesh Usage Amongst Surgical Specialties

The College has consulted with each of its nine specialties and can provide the following information on the use of mesh by each of those specialties:

Cardiothoracic surgery

The use of synthetic non-absorbable mesh is rare.

Neurosurgery

The use of synthetic non-absorbable mesh is rare.

Vascular surgery

The use of synthetic non-absorbable mesh is rare.

Orthopaedic surgery

The use of synthetic non-absorbable mesh is rare.

Paediatric surgery

Synthetic non-absorbable mesh is occasionally used for repair of congenital diaphragmatic hernia and exomphalos major (congenital abdominal wall defect). For each of these conditions various options are available including the use of surgical mesh, biological mesh and muscle flaps.

Otolaryngology, Head and Neck Surgery

Absorbable mesh is used occasionally for chylous leaks after neck dissection.

Plastic & Reconstructive Surgery

In plastic surgery synthetic non-absorbable mesh is commonly used for abdominal wall repair, either primarily or secondarily directly related to flap donor sites. Mesh is also used for difficult abdominal and chest wall hernias. Synthetic mesh can also be used as part of breast reconstruction where sometimes a biological "mesh" (acellular dermal matrix) is also used for similar situations.

Urology

In urological patients with stress urinary incontinence synthetic non-absorbable mesh is used for mid-urethral slings. Mesh is also being used for sacrocolpopexy (repair of pelvic organ prolapse) and the morbidity directly related to mesh in these circumstances is reported to be minimal. Since the early 2000's urologists have been using midurethral slings made of polypropylene mesh, and they continue to do so. The vaginal erosion rate in the urological literature is around 2 to 5%. Paediatric urologists are using mesh for diaphragmatic agenesis and large omphaloceles (refer to Paediatric Surgery above).

General surgery

In General Surgery the use of synthetic non-absorbable mesh is primarily related to the surgical repair of abdominal wall and groin hernias and for the repair of rectal prolapse (ventral rectopexy).

Mesh Usage in Specific Procedures

Abdominal Wall And Groin Hernia Repair

The New Zealand Association of General Surgeons (NZAGS) has released a position statement on mesh hernia repair. This applies only to ventral and groin hernia repair and it does not apply to mesh pelvic reinforcement. The following is an extract from that position statement.

The use of mesh in General Surgery to repair hernias of the groin or the abdominal wall is

well established internationally and is considered the procedure of choice.² For ventral hernias with fascial defects greater than 2cm in diameter mesh must be used to reinforce the tissue repair.³ If not the hernia recurrence rate without mesh is unacceptably high. For groin hernia repair most surgeons worldwide use mesh for the repair.

The use of mesh for abdominal and groin hernia repair is safe. Chronic pain may occur after hernia repair in less than 10% of patients. However, it is important to remember that chronic pain after groin hernia repair is higher for patients having non-mesh repair compared to mesh repair.⁴ Mesh infection after abdominal hernia repair is uncommon, less than 1%.⁵ For laparoscopic inguinal hernia repair it is even lower.

The use of surgical mesh is an important part of the curriculum for general surgical training and NZ general surgeons have extensive experience in the use of mesh for hernia repair.

The good results of mesh hernia repair in general surgery should not be bought into disrepute by categorising all mesh repairs as the same.

Ventral Rectopexy

In 2014, Mr Rowan Collinson MBChB, FRACS (A General Surgeon with a subspecialty interest in colorectal surgery, from Auckland District Health Board) released a "Discussion Paper on Mesh-related Complications following Ventral Mesh Rectopexy" used for the treatment of rectal prolapse. He commented:

Ventral Mesh Rectopexy (VMR) is currently most frequently performed with a synthetic mesh sutured to the anterior rectal wall and sacral promontory, and to the vagina in some cases. Biologic mesh usage is less common, primarily due to uncertainty around the durability of the result. Concerns around pelvic placement of synthetic mesh have made preoperative discussions more complex, partly due to a lack of clarity in our own data as to the risks posed to the patient by synthetic mesh.

The publication of a report into the safety and effectiveness of transvaginal tape placement for pelvic organ prolapse (POP) by the US FDA in 2011 brought this issue into bold relief. On the basis of this report, it is estimated that this type of gynaecological surgery activity has decreased by 40-50% in the US. Several products have been withdrawn from the market. On the FDA website, the report is summarised by two main points:

- *serious complications associated with surgical mesh for transvaginal repair of POP are not rare; and*
- *it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair*

The report itself includes the following observations about safety:

- *Mesh-associated complications are not rare. The most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion. Based on data from 110 studies including 11,785 women, approximately 10% of women undergoing transvaginal POP repair with mesh experienced mesh erosion within 12 months of surgery.*
- *More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room. Some women required two to three additional surgeries.*
- *Mesh contraction, causing vaginal shortening, tightening, and/or vaginal pain in association with transvaginal POP repair with mesh, is increasingly reported in the literature.*

² Den Hartog D et al. Open surgical procedures for incisional hernias. *Cochrane Database Syst Rev.* 2008 Jul 16;(3):CD006438

³ Bittner R et al. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)—Part 1. *Surg Endosc* (2014) 28:2–29

⁴ Simons MP et al. European Hernia Society guidelines on the treatment of inguinal hernia in adult patients. *Hernia* (2009) 13:343–403

⁵ Aufenacker TJ et al. Systematic review and meta-analysis of the effectiveness of antibiotic prophylaxis in prevention of wound infection after mesh repair of abdominal wall hernia. *Br J Surg* 2006 Jan;93(1):5-10.

- Transvaginal surgery with mesh to correct vaginal apical prolapse is associated with a higher rate of complication requiring reoperation and reoperation for any reason compared to traditional vaginal surgery or sacral colpopexy.
- Abdominal POP surgery using mesh (sacral colpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with the median vaginal mesh erosion rate reported at 4% within 23 months of surgery.

It is the final point of course that leads onto the discussion around VMR. A balanced Australasian (RANZCOG) perspective on the FDA report can found at http://www.ranzcog.edu.au/editions/doc_view/1024-28-transvaginal-mesh.html.

Where does this leave VMR? What can we tell our patients about mesh safety? The evidence base in this area is limited, and because mesh-related complications are uncommon, the answer only lies in pooled data, of variable quality. Three systematic reviews are available and can give an indication of the magnitude of the problem.

Samaranayake et al in 2010 reported a systematic review of 728 patients across 12 case series.⁶ The techniques included some patients who had both anterior and posterior mobilisation. Median followup of the purely VMR cases was 15 months. Four mesh-related complications were noted – one death due to mesh-related septicaemia, one posterior vaginal wall erosion, and two mesh detachments.

Smart et al in 2013 reported a systematic review of thirteen VMR case series, with a total of 866 patients.⁷ In eleven of the studies (767 patients) synthetic mesh was used. In the other two, biologic mesh was used, in 99 patients. Median follow up in the synthetic group was 38 months (range 7 – 74), and was 12 months in the biologic group. Five mesh-related complications were reported in the synthetic group, with one each of erosion into small bowel, vagina, rectum and ‘mesh rejection’ and de novo dyspareunia. Four patients had their mesh removed. In the biologic group, there were no mesh-related complications. There was no difference in the recurrence rate (3.7% versus 4%).

Gouvas et al 2014 have as an ‘Accepted Article’, a further systematic review of VMR for overt rectal prolapse and obstructed defaecation syndrom.⁸ Twenty-three studies are included, with a total of 1460 patients. Synthetic mesh was used in 1316 patients. Median length of follow up is not clearly stated. Two bowel erosions with mesh were noted in 192 patients (1%). Two vaginal erosions were noted in 78 patients (2.6%). There are methodological flaws in this study, in particular where there may have been double-counted patients included where there are several publications from a single centre.

Also published in 2014, a consensus statement has been produced in an effort to standardise the approach to VMR⁹. It quotes a synthetic mesh erosion rate of 2-3%, although this figure is not referenced.

Finally, The Pelvic Floor Society subgroup of the ACPGBI have recently published ‘Update on Use of Surgical Mesh or Implant in LVMR’. The full update is found at http://eepurl.com/3_KuP. It includes the statement -

⁶ Samaranayake CB, Luo C, Plank AW, Merrie AEH, Plank LD, Bissett IP. Systematic review on ventral rectopexy for rectal prolapse and intussusception. *Colorectal Disease*. 2010;12(6):504-

⁷ Smart NJ, Pathak S, Boorman P, Daniels IR. Synthetic or biological mesh use in laparoscopic ventral mesh rectopexy – a systematic review. *Colorectal Disease*. 2013;15(6):650-

⁸ Gouvas N, Georgiou PA, Agalianos C, Tan E, Tekkis P, Dervenis C, et al. Ventral Colporectopexy For Overt Rectal Prolapse And Obstructed Defaecation Syndrome: A Systematic Review. *Colorectal Disease*. 2014:n/a-n/a.

⁹ Mercer-Jones MA, D'Hoore A, Dixon AR, Lehur P, Lindsey I, Mellgren A, et al. Consensus on ventral rectopexy: report of a panel of experts. *Colorectal Disease*. 2014;16(2):82-8.

'It is The Pelvic Floor Society's view that LVMR when performed correctly is a safe and effective operation with low mortality (0.09%) and morbidity. Mesh erosion rates are low (2.4%) but sometimes requires revision surgery. The latter when performed properly is associated with normalization of function. Biological implants have an erosion rate of 1%.'

When discussing mesh type, it goes on to specify –

Mesh erosion is a function of the "honesty of reporting" as well as mesh material, suture type and length of follow-up. Current data would suggest that the median time to erosion is two years for synthetic mesh and 10 months for biologic implants. The risks with "standard" polypropylene approximate to 1.8% @ median 8 yrs FU, polyester 6.5% @ 4yrs, titanium coated LMW polypropylene 0.2% @ 3 yrs. Erosion is unrelated to age, menopausal status, hysterectomy or smoking and occurs equally in both external and internal prolapse patient groups. The use of a non-absorbable suture e.g. Ethibond may be a predisposing factor and should now be avoided (particularly with synthetic mesh and any vaginal stitches). To date there have been no recorded complications in men.

While many of us would agree in principle with several of these statements, unfortunately none of the quoted figures are referenced, and I have been unable to find them to date.

In summary, when the two good quality systematic reviews (5,6) are considered, the risk of a mesh-related complication with synthetic mesh in VMR would seem to be in the 0.5 - 1% range. The other un-referenced data above put that figure at 2 - 3%.

Summary

The Royal Australasian College of Surgeons acknowledges that the use of synthetic non-absorbable mesh for the treatment of urogynaecological conditions carries with it a relatively high complication risk particularly because of erosion of the vaginal wall. It should be noted that synthetic non-absorbable surgical meshes have been widely used by General Surgeons, Paediatric Surgeons, Urologists, and Plastic and Reconstructive Surgeons for more than thirty years in the repair of hernias (cavity wall defects) involving the abdomen and chest. The use of surgical mesh in these situations has been associated with a lower risk of hernia recurrence than where techniques without mesh have been employed. There is little evidence to suggest that substituting synthetic non-absorbable surgical mesh with biologic materials offers any advantage in these circumstances.

- The College would support the recommendation that surgeons should undertake caution when placing mesh devices near hollow viscera where erosion might occur.
- The College would support ongoing audit and research into the safety of surgical mesh devices used in New Zealand.
- The College would support patients making claims to ACC for treatment injury following mesh related adverse events.
- The College would support the ongoing education of surgeons on the use of surgical mesh in all surgical sites.
- The College believes that it would be inappropriate for surgeons using mesh in situations other than urogynaecological surgery to be credentialled along lines proposed by the Urogynaecological Society of Australasia and it would also be inappropriate to use the Urogynaecological Society pelvic floor database to record surgery and any complications related to sites distant from the pelvic floor if that database was limited to only members of that society.¹⁰

¹⁰ Interim Report on the Petition 2011/102 of Carmel Berry and Charlotte Korte. NZ House of Representatives Health Committee 2014.

- The College would support the listing of mesh devices on the PHARMAC Hospital Medicines List (HML) and would support the monitoring of adverse events by Medsafe.

Thank you for considering the College's comments in relation to this matter.

Nigel Willis FRACS
Chair, New Zealand National Board