UROGYNAECOLOGICAL SOCIETY OF AUSTRALASIA

MODEL OF CARE FOR ABDOMINAL SACROCOLPOPEXY

This model of care is a consensus statement developed by the Urogynaecological Society of Australasia (UGSA) for use by surgeons credentialled to perform sacrocolpopexy (SCP). SCP is a procedure that suspends the vaginal apex to the anterior longitudinal ligament of the sacrum using a mesh/graft with possible incorporation into the fibromuscular layer of the anterior and/or posterior vaginal walls[1]. This model of care will provide best practice guidelines on which patients should be offered SCP. It also contains advice on consent processes and documentation for use in SCP and the processes for auditing SCP outcomes. This document will also be of assistance to women considering their treatment options for pelvic organ prolapse, and to states, territories, and private health service providers where sacrocolpopexy is performed.
In summary, this model of care aims to ensure high-quality care, patient safety, and positive outcomes for individuals seeking this surgical intervention.

Clinical assessment and patient selection

Assessment includes obtaining a detailed history with particular emphasis on any symptoms associated with prolapse, especially bothersome vaginal bulge, urinary, bowel, and coital symptoms. A detailed general and pelvic examination should be conducted. It is important for the clinician to identify all the vaginal support defects accurately so that they can be corrected at the time of surgery. The patient should be examined for signs of stress incontinence with the prolapse present and reduced and for any anorectal pathology, including rectal prolapse.

Urodynamic studies should be made available to patients with associated urinary symptoms but, in particular, for women with stress urinary incontinence or those wishing to investigate occult stress urinary incontinence. Imaging of the pelvis including the pelvic floor and anorectal physiological testing are recommended, as indicated.

Indications

SCP is indicated for patients with symptomatic and significant prolapse of the vaginal vault or multicompartment prolapse. Typically, these women have had a previous uterectomy (hysterectomy) and on examination have prolapse of a POP-Q stage 2 or greater according to the International Continence Society (ICS)/International Urogynaecological Association Pelvic Organ Prolapse Quantification System (IUGA) classification [2].

Contraindications

General Contraindications to SCP

- Sacral abnormalities (e.g. sacral agenesis, sacral meningomyelocele)
- Inability to safely access the anterior longitudinal ligament on the sacral promontory at time of surgery
- Current anticoagulation medication that has not been appropriately ceased prior to surgery (salicylic acid is not a contraindication to surgery)

Contraindications to SCP when using Mesh

- Recognised intraoperative bowel perforation
- Active inflammatory bowel disease
- Current pelvic or vaginal sepsis

Contraindications to Laparoscopic SCP and Robotic SCP

- Any contraindication to laparoscopy or robot-assisted laparoscopy

Counselling

As outlined in the Australian Commission on Safety and Quality in Health Care's (the Commission) Care Pathway for the Management of Pelvic Organ Prolapse, there are a number of non-surgical and surgical options for advanced pelvic organ prolapse. These include vaginal support pessaries and vaginal suture suspension or obliterative procedures. These need to be discussed in terms of advantages and disadvantages and written information supplied, such as the Commission's document Treatment Options for Pelvic Organ Prolapse. In most series, SCP is associated with longer operative times but greater long-term durability and vaginal length [3]. This would be most appropriate for women who wish to optimise coital function.

Consent to SCP

A template consent document is provided in Appendix 1. Additional information on gaining informed consent, shared decision making and providing person-centred care can be found on the Commission's Partnering with Consumers website.

Types of mesh/graft

A variety of synthetic meshes, and biological grafts have been described for SCP. The largest body of evidence exists for synthetic mesh including in the Cochrane collaboration and the International Consultation on Incontinence[4], [5].

From a regulatory point of view, where possible, mesh approved (on label) for SCP should be the mesh of choice. Mesh approved for hernia should only be used off label for SCP if on label mesh SCP mesh is unavailable and only with approval of the patient, hospital and medical indemnity insurer. Alternatives to synthetic mesh include autologous fascia lata and rectus sheath fascia, however long term evidence is limited in terms of success and durability compared to mesh[6,7,8]. Non-autologous biological grafts for SCP have been utilised particularly in the context of concomitant rectopexy[9].

Route/ Variations

Minimally invasive/laparoscopic/robotic-assisted

There are no differences in the primary outcomes for different routes for SCP. However, the laparoscopic approach is associated with shorter operating time compared to the robotic approach and shorter inpatient stay than the open approach [6]

In circumstances where a desire for uterine preservation is present, the procedure can be modified to allow uterine suspension using a mesh/graft to the sacral promontory by attachment to the anterior and/or posterior cervix and vagina. Sacral hysteropexy utilising mesh or graft has been described in women wishing uterine conservation however, the limited data are inconclusive of any benefit when compared to alternative uterus-preserving vaginal interventions[6].

SCP has also been described in conjunction with uterectomy (hysterectomy) or subtotal uterectomy (hysterectomy) to treat advanced uterine prolapse of stage 2 or greater [10-12]. In 2022 the International Consultation on Incontinence (ICI) on surgical management of prolapse, recommend not performing total uterectomy (hysterectomy) at the time of SCP due to high mesh exposure rates[13,14].
The rate of mesh exposure is significantly higher with concomitant total uterectomy (hysterectomy) compared to subtotal uterectomy (hysterectomy) [15,16].

Pelvic organ prolapse is usually multicompartment and surgery to address all defects may include additional paravaginal and vaginal surgery.

Fixation to vagina

There are several studies that have addressed the optimal type of suture material to attach the graft or mesh to the vagina. Evidence suggests

delayed absorbable sutures are non-inferior to permanent sutures with the benefit of avoiding suture erosion [17].

Sacral promontory fixation

Various methods of attaching the mesh/graft onto the sacral promontory have been reported. These include sutures, bone anchors, staples, and helical tacks. There is a lack of research comparing the various methods of fixation of the prosthesis onto the sacral promontory. Evidence reports tackers and permanent sutures have similar efficacy outcomes, but tackers may be associated with increased intensity of postoperative back pain[18].

Credentialling

The Royal Australia & New Zealand College of Obstetricians & Gynaecologists' clinical guidance statement provides evidence-based summary for Sacrocolpopexy and credentialling. Sacrocolpopexy is a complex operation requiring both advanced laparoscopic and reconstructive pelvic surgery skills. Only surgeons competent in these operative techniques should undertake this surgery. Guidelines for the privileging and credentialing of surgeons planning to implement or continue the use of SCP have also been published by the American Urogynecologic Society (AUGS) [19]

Audit

The Australian Pelvic Floor Procedure Registry (APFPR) and Urogynaecological Society of Australasia (UGSA) databases currently collects pre, intra and post-operative data and validated patient-reported outcome measures on prosthesis related stress urinary incontinence and pelvic organ prolapse procedures including sacrocolpopexy. The UGSA Advisory Board recommends that surgeons use these databases to audit their SCP procedures. More information on the importance and use of Clinical Quality Registries can be found on the Commission's website.

Abdominal Sacrocolpopexy Providers

As a resource for referring doctors, patients and hospitals

UGSA has surveyed their membership. This link contains the information on those members who confirm that they perform Abdominal Sacrocolpopexy.

References

1. Developed by the Joint Writing Group of the American Urogynecologic S, the International Urogynecological A (2020) Joint report on terminology for

surgical procedures to treat pelvic organ prolapse. Int Urogynecol J 31 (3):429-463. doi:10.1007/s00192-020-04236-1
2. Bump RC, Mattiasson A, Bo K, Brubaker LP, DeLancey JO, Klarskov P, Shull BL, Smith AR (1996) The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 175 (1):10-17. doi:10.1016/s0002-9378(96)70243-0
3. Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J (2016) Surgery for women with apical vaginal prolapse. Cochrane Database Syst Rev 10 (10):CD012376. doi:10.1002/14651858.CD012376
4. Barber MD, Maher C (2013) Apical prolapse. Int Urogynecol J 24 (11):1815-1833. doi:10.1007/s00192-013-2172-1
5. Cardozo L, Rovner, E, Wagg, A, Wein, A, Abrams, P (2023) Internationa Consultation on Incontinence - International Continence Society. 7th Edition edn.,
6. Maher C, Yeung E, Haya N, Christmann-Schmid C, Mowat A, Chen Z, Baessler K (2023) Surgery for women with apical vaginal prolapse. Cochrane Database Syst Rev 7 (7):CD012376. doi:10.1002/14651858.CD012376.pub2
7. Wang R, Reagan K, Boyd S, Tulikangas P (2022) Sacrocolpopexy using autologous rectus fascia: Cohort study of long-term outcomes and complications. BJOG 129 (9):1600-1606. doi:10.1111/1471-0528.17107
8. Patel S, Chaus FM, Funk JT, Twiss CO (2022) Total Autologous Fascia Lata Sacrocolpopexy for Treatment of Pelvic Organ Prolapse: Experience in Thirty-Four Patients. Urology 170:73-77. doi:10.1016/j.urology.2022.08.038
9. Quiroz LH, Gutman RE, Shippey S, Cundiff GW, Sanses T, Blomquist JL, Handa VL (2008) Abdominal sacrocolpopexy: anatomic outcomes and complications with Pelvicol, autologous and synthetic graft materials. Am J Obstet Gynecol 198 (5):557 e551-555. doi:10.1016/j.ajog.2008.01.050
10. Miklos JR, Kohli N, Lucente V, Saye WB (1998) Site-specific fascial defects in the diagnosis and surgical management of enterocele. Am J Obstet Gynecol 179 (6 Pt 1):1418-1422; discussion 1822-1413. doi:10.1016/s0002-9378(98)70004-3
11. Cosson M, Rajabally R, Bogaert E, Querleu D, Crepin G (2002) Laparoscopic sacrocolpopexy, hysterectomy, and burch colposuspension: feasibility and short-term complications of 77 procedures. JSLS 6 (2):115-119
12. Rozet F, Mandron E, Arroyo C, Andrews H, Cathelineau X, Mombet A, Cathala N, Vallancien G (2005) Laparoscopic sacral colpopexy approach for genito-urinary prolapse: experience with 363 cases. Eur Urol 47 (2):230-236. doi:10.1016/j.eururo.2004.08.014
13. de Tayrac R, Antosh DD, Baessler K, Cheon C, Deffieux X, Gutman R, Lee J, Nager C, Schizas A, Sung V, Maher C (2022) Summary: 2021 International Consultation on Incontinence Evidence-Based Surgical Pathway for Pelvic Organ Prolapse. J Clin Med 11 (20). doi:10.3390/jcm11206106

14. Bretschneider CE, Myers ER, Geller EJ, Kenton KS, Henley BR, Matthews CA (2024) Long-Term Mesh Exposure 5 Years Following Minimally Invasive Total Hysterectomy and Sacrocolpopexy. Int Urogynecol J 35 (4):901-907. doi:10.1007/s00192-024-05769-5
15. Matthews CA, Myers EM, Henley BR, Kenton K, Weaver E, Wu JM, Geller EJ (2023) Long-term mesh exposure after minimally invasive total hysterectomy and sacrocolpopexy. Int Urogynecol J 34 (1):291-296. doi:10.1007/s00192-022-05388-y
16. Costantini E, Brubaker L, Cervigni M, Matthews CA, O'Reilly BA, Rizk D, Giannitsas K, Maher CF (2016) Sacrocolpopexy for pelvic organ prolapse: evidence-based review and recommendations. Eur J Obstet Gynecol Reprod Biol 205:60-65. doi:10.1016/j.ejogrb.2016.07.503
17. Matthews CA, Geller EJ, Henley BR, Kenton K, Myers EM, Dieter AA, Parnell B, Lewicky-Gaupp C, Mueller MG, Wu JM (2020) Permanent Compared With Absorbable Suture for Vaginal Mesh Fixation During Total Hysterectomy and Sacrocolpopexy: A Randomized Controlled Trial. Obstet Gynecol 136 (2):355-364. doi:10.1097/AOG.0000000000003884
18. Vieillefosse S, Thubert T, Dache A, Hermieu JF, Deffieux X (2015) Satisfaction, quality of life and lumbar pain following laparoscopic sacrocolpopexy: suture vs. tackers. Eur J Obstet Gynecol Reprod Biol 187:51-56. doi:10.1016/j.ejogrb.2015.02.014
19. American Urogynecologic Society's Guidelines Development C (2013) Guidelines for privileging and credentialing physicians for sacrocolpopexy for pelvic organ prolapse. Female Pelvic Med Reconstr Surg 19 (2):62-65. doi:10.1097/SPV.0b013e318289c018

Document Contributors

Authors

Mugdha Kulkarni
Anna Rosamilia
Marcus Carey
Alexandra Mowat

Document approved by UGSA Advisory Board Members (2022-2023)

Marcus Carey
Alexandra Mowat
Lin Li Ow
Ruchi Singh
Timothy Dawson
Lucy Bates
Fiona Bach
Bernadette Brown

UROGYNAECOLOGICAL SOCIETY OF AUSTRALASIA

Appendix 1.

Patient Information and Informed Consent Form

Name of Surgery: Open, laparoscopic or robotic sacrocolpopexy using an off-label synthetic mesh for pelvic organ prolapse

Your Surgeon: .....

Introduction

You and your surgeon have discussed and agreed upon the appropriate surgical approach (open, laparoscopic or robotic) sacrocolpopexy operation using synthetic mesh for pelvic organ prolapse. In Australia, there are no TGA (Therapeutic Goods Administration) registered meshes for sacrocolpopexy and only off label meshes used to treat hernia are available for sacrocolpopexy.

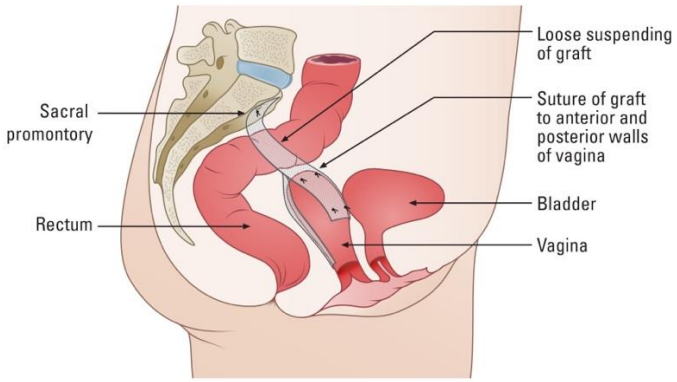
This information document has been given to you to allow you to decide whether you would like to go ahead with open, laparoscopic or robot-assisted laparoscopic sacrocolpopexy operation using off-label synthetic mesh. It is up to you to decide if you would like to have this surgery, and you should only have this surgery if you want to. Before you make this decision, please read this form carefully. Ask your surgeon to explain anything you do not understand. You are also encouraged to seek an opinion from another doctor and speak with your GP or friends or family members about the recommended surgery.

If you decide to go ahead with an open, laparoscopic or robot-assisted laparoscopic sacrocolpopexy operation using synthetic mesh, you will be asked to sign this form in order to show that you understand what is involved in having this surgery. By signing it you are telling us that you:

- Understand what you have read or have had translated to you using appropriate interpreter/communication assistance.
- Voluntarily consent to undergo sacrocolpopexy using off-label synthetic mesh
- Have been informed of risks, benefits, possible complications and alternative options.

You will be given a copy of this Consent Form to keep. You will also be provided with a copy of the company's synthetic mesh product information brochure.

What does surgery using synthetic mesh involve?
The surgery is performed under general anaesthetic (you are completely asleep). Surgery can be performed by open, laparoscopy or robot-assisted laparoscopy approaches. Laparoscopy or robot-assisted laparoscopy is often referred to as key-hole surgery [16]. During surgery, your bladder and rectum are carefully separated from the upper part of your vagina and a ligament on the front part of your tailbone (sacrum) is accessed. The synthetic mesh is put into your abdomen and is attached with stitches to the upper part of your vagina and the ligament on your sacrum. This has the result of suspending your upper vagina from your sacrum. The mesh is then covered over by tissue called peritoneum to prevent bowel sticking to the mesh. The diagram below shows the placement of the synthetic mesh onto the upper vagina and sacrum.



At the end of the procedure, a cystoscopy (camera inserted into your bladder) will be done to exclude injury to the bladder, urethra and ureter. A catheter will be placed into your bladder to drain urine and will be removed the following day.

For some women, your surgeon will ask permission to take clinical videography of the surgery to be used in scientific presentations, scientific publication or clinical teaching. Any images obtained will be de-identified – that is all personal information that might identify you will be removed.

You can choose to have clinical videography of your surgery or not, it does not have any effect on what type of procedures you have done or if it will be done.

What are the risks of surgery?
There are risks associated with the type of operation and you should discuss these with your surgeon. These risks include general risks associated with any surgical procedure and risks specific to pelvic floor surgery using synthetic mesh.

The general risks involved with having any surgery include:

- adverse reactions to the anaesthetic
- excessive bleeding,
- infection
- potential for blood clots.

Antibiotic are given during surgery and continued after your operation to reduce the risk of infection. Medication (e.g. enoxaparin) to thin your blood is given during surgery and while you are in hospital to reduce your risk of developing blood clots. It is very uncommon to experience serious bleeding or need a blood transfusion but there is still a small risk that it could happen.

Generally, there is improved sexual function after prolapse surgery. However, about 2% of women experience painful intercourse after surgery and this may require minor corrective surgery or the use of vaginal dilators.

Occasionally, bladder problems can occur after surgery (e.g., difficulty with bladder emptying, cystitis (inflammation of the bladder) or urinary leakage) but these problems usually settle soon after surgery, typically within 12 weeks. If persisting urinary incontinence (leaking of urine) remains a problem, then further surgery or medication may be required.

Pain may occur immediately after surgery, but this generally settles after a few days or weeks. It is rare for women to experience long-term pain following prolapse surgery.

Rare complications from prolapse surgery may include injury to a nearby structure (e.g. bowel, bladder, ureter, nerve). Usually, your surgeon will inspect the bladder with a cystoscope (a telescope-like camera) at the completion of surgery to exclude any bladder or ureter injury. Rare long-term complications after open, laparoscopic, or robot-assisted laparoscopic prolapse surgery include bowel obstruction from adhesions and abdominal hernia. Further surgery may be necessary if a complication occurs. Table 1 below lists the risks and or adverse events that can occur.

Table 1: Mesh Sacrocolpopexy Complications

Medical term	**Definition**
Common (more than 1 in 100 women who have this surgery)	
Bruising	Damage of small blood vessels

Pain	Unpleasant physical sensation
Urinary Tract Infection	Symptomatic and/or the adverse physiologic effects of bacterial overgrowth within the urinary tract
Haematoma	A collection of blood that has leaked outside of the blood vessel
Paraesthesia	Numbness or altered sensation related to nerves
Nerve pain	Unpleasant physical sensation related to nerves
Recurrence of prolapse	Resurgence of uterovaginal or vaginal vault prolapse regardless of compartment
Vaginal Mesh extrusion or erosion	Exposure of mesh into the vagina In some studies, this risk is increased if total hysterectomy is performed concomitantly (at that same time).
Uncommon (more than 1 in 1,000 women who have had this surgery)	
Mesh extrusion or erosion	Erosion of mesh into the bladder or bowel
Haemorrhage	Excessive bleeding
Damage to internal organs	Damage to organs including bowel, bladder and ureters, the lining around them and structures adjacent to surgical site
Donor site muscle herniation	Abnormal donor site muscle (or other tissue) protrusion which may or may not lead to a bulge
Surgical site infections	Symptomatic and/or the adverse physiologic effects of bacterial overgrowth on tissue
Rare (more than 1 in 10,000 women who have had this surgery)	
Serious adverse event	a. led to death b. led to serious deterioration in the health of the participant, that either resulted in: • a life-threatening illness or injury, or • a permanent impairment of a body structure or a body function, or • in-patient or prolonged hospitalisation, or

	• medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function

Recovery time and instructions following surgery

Women stay in hospital for one, two or three nights.

It is MOST important to rest after the operation and allow the area to heal.

You will be seen by your surgeon 6 weeks following surgery to check for any problems. Typically, you will also have a review with your surgeon 1-year following surgery.

Generally, it is recommended to:

- Completely restrict your level of physical activity for two weeks.
- From two to four weeks do light activity only.
- Avoid heavy lifting (nothing heavier than 5 kg) for 4 weeks, including small children.
- Abstain from sexual intercourse for 6 weeks.
- Avoid playing sport and impact exercises such as jogging or jumping for 6 weeks.

Pain relief

- If you experience pain after leaving hospital, we suggest that you take pain control medication as prescribed on the packaging or instructions and as required until pain resolves.
- Make sure you take some time each day to rest.

Maintain good bowel habits

- Try do drink approximately 2.5 litres of fluids each day.
- Maintain a healthy diet.
- Use Movicol or similar preparations (available at the chemist or supermarket) if required to maintain regular bowel function and to keep your bowel motions soft.

Some vaginal loss may occur after you leave hospital, but this should be minimal and light pink, and may last for three weeks. You must seek urgent

medical attention if you experience ongoing, heavy vaginal bleeding at any time after surgery.

Any stitches that you still have in when you go home will dissolve in about 10 days (but possibly up to three weeks). These do not need to be removed.

Are there any benefits of using Synthetic Mesh?

Research shows that sacrocolpopexy using mesh has better outcomes than alternative non-mesh operations. Placing the mesh directly into the abdomen using laparoscopic or robot-assisted laparoscopic surgery avoids vaginal incisions and reduces the risks of mesh-related problems that have been seen when mesh is placed through the vaginal opening ("trans-vaginal mesh").

What are the alternatives to using Synthetic Mesh?

You can choose to have no treatment. You can choose to try pelvic floor muscle training or placement of a vaginal pessary.

If you decide to have prolapse surgery, instead of using synthetic mesh, you can choose to use your own tissue taken from a 3-4 cm cut in your thigh. This tissue is called fascia lata. However, there is not a lot of information about the long-term success of this new approach to sacrocolpopexy. Other alternative operations include vaginal surgery, and non-mesh open, laparoscopic and robot-assisted procedures.

UROGYNAECOLOGICAL SOCIETY OF AUSTRALASIA

Appendix 1.

Consent Form - *Adult providing own consent*

Treatment: Abdominal Sacrocolpopexy Using Synthetic Mesh

Surgeon …….

Declaration by Patient

I have read the Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of having Synthetic Mesh used to treat my prolapse.

I understand that the Synthetic Mesh used to treat my prolapse will be an off-label use of mesh as there is no TGA approved mesh for sacrocolpopexy in Australia.

I give permission for my surgeon to enter information to a database concerning my disease and treatment. I understand that such information will remain confidential.

□ YES □ NO

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to the treatment as described and understand that I am free to have alternative treatments, withdrawal of my consent, or have no treatment for my prolapse

I understand that any de-identified video images may be used for scientific presentation, scientific publication and clinical teaching.
I give consent to be filmed if selected for the purposes of scientific presentations, scientific publication or clinical teaching.

□ YES □ NO

I agree for my GP to be notified about the proposed treatment and for my records to be uploaded in confidential databases such as 'My Health Record'

I understand that I will be given a signed copy of this document to keep.

Name of Patient (please	_____
Signature _____	Date _____

Declaration by the surgeon

I have given an explanation of the proposed treatment and risks and I believe that the participant has understood that explanation.

Name of Surgeon (please print)	_____
Signature _____	Date _____

Clinical contact person

Name	……
Position	Treating surgeon
Telephone	……..
Emergency Contact	……
Email	……