CATEGORY: BEST PRACTICE STATEMENT

Power morcellation at Minimally Invasive Procedures

This statement has been developed by the AGES Society and reviewed by the RANZCOG-AGES Endoscopic Surgery Advisory Committee (ESAC). It was subsequently reviewed by the Women's Health Committee and approved by the RANZCOG Council and Board.

A list of Women's Health Committee membership (Appendix A) and Endoscopic Surgery Advisory Committee membership (Appendix B) is provided.

Disclosure statements have been received from all members of this committee.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: June 2014
Current: November 2022
Review due: November 2027

Objectives:

To provide advice on the use of power morcellators for removal of tissues.

Target audience:

Health professionals who use power morcellators, and patients undergoing procedures that use power morcellators.

Values:

The evidence was reviewed and applied to local factors relating to Australia and New Zealand.

Background:

This statement was first developed by the AGES Society and ratified by the AGES Board in May 2014, March 2017 and most recently reviewed in November 2021.

Funding:

The development and review of this statement was funded by the AGES Society and RANZCOG.

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1. Plain language summary

At times, organs or tissues that are to be taken out during minimally invasive surgery need to be cut up into smaller pieces in order to allow removal through a small abdominal incision or a via a vaginal colpotomy. This statement provides guidance for gynaecologists, when using power morcellation, to reduce the risk of injury to patients or the spread of unrecognised abnormalities/ the "seeding" of benign or malignant tissue throughout the peritoneal cavity.

2. Summary of recommendations

Recommendation 1	Grade
Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options.	Consensus-based recommendation
Recommendation 2	**Grade**
Morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy (including atypical endometrial hyperplasia).	Consensus-based recommendation
Recommendation 3	**Grade**
Practitioners performing power morcellation should be adequately trained, skilled and credentialed for the use of power morcellators and in-bag containment systems, by the local credentialing committee.	Consensus-based recommendation
Good Practice Note	
In minimally invasive procedures, where tissue extraction is facilitated by a power morcellator, an in-bag containment system should be used.	

3. Introduction

Minimally invasive gynaecologic surgeries (MIGS), including laparoscopic abdominal, endoscopic, robotic, and vaginal procedures, offer patients the benefits of quicker recovery, less postoperative pain, less risk of postoperative complications (inherent risks of laparotomy). Furthermore, less invasive procedures, such as myomectomies, have also allowed for uterine preservation in settings that traditionally would have resulted in a hysterectomy and loss of fertility.

By their nature, these MIGS may at times require the morcellation, drainage or deflation of abdominal or pelvic masses to permit their extraction through the vaginal or abdominal wall incisions. Morcellation may be defined as the division of a large specimen into smaller fragments to allow their removal from the peritoneal cavity via small incisions. Morcellation may be performed manually with the scalpel or scissors, by using techniques such as bivalving or coring (hand morcellation).

Alternatively, morcellation may be performed electromechanically, that utilises devices specifically designed for power morcellation. The term 'power morcellation' in this statement is taken to encapsulate all terms relating to electromechanical morcellation.

Gynaecologists recognise that tissue extraction by power morcellation may be associated with a number of risks:

1. Patient injury: other tissue, such as bowel, other pelvic organs or blood vessels intended to be retained in the body may be inadvertently injured during the morcellation process. The efficiency of power morcellation poses a specific hazard in this setting.
2. Dissemination: fragments of tissue generated by the morcellation process may disseminate throughout the peritoneal cavity. Tissue dissemination has been reported for both benign disease (e.g., leiomyomas, endometriosis) and malignancy (e.g., leiomyosacrcoma) and may have a detrimental effect on prognosis and/or increase the need for adjuvant treatment. There is concern that power morcellators may increase the risk of dissemination by creating a larger volume of smaller tissue fragments.
3. Pathology: the smaller size of the tissue fragments and the associated loss of anatomical relationships within the specimen, may complicate the histological diagnosis. Concerns have been expressed that power morcellation may yield a larger volume of small and dissociated fragments than hand morcellation, which may further complicate analysis.

4. Discussion and recommendations

4.1 Risks of Tissue Extraction

This statement addresses each of the defined risks of tissue extraction by power morcellation as follows:

4.1.1 Patient Injury

Hand morcellation is a core gynaecological technique that is generally acquired during membership and fellowship training. However, power morcellation is an advanced surgical technique. Local credentialing bodies need to be satisfied that specialists using such devices have received appropriate training and education in the use of such devices. In general, the use of such devices is restricted to practitioners at AGES-RANZCOG Level 5 and above.

The following precautions should be applied when using a morcellator:

1. No suspicion of premalignancy or malignancy on preoperative or intraoperative assessment
2. Maintain the tip of the instrument in view at all times
3. Maintain control of the specimen at all times
4. Feed the specimen into the morcellator in a controlled manner
5. Minimise spillage of specimen fragments wherever possible
6. Post-morcellation retrieval of all macroscopic fragments.

4.1.2 Dissemination

The dissemination of both benign and malignant disease cannot be completely prevented if a decision is made to morcellate a specimen. However, appropriate steps may be taken to minimise this risk:

4.1.2.1 Case Selection

Patients requiring a hysterectomy or removal of an abdominopelvic mass represent a heterogeneous group, each with inherent risk factors. As such, it is not possible to distill the assessment of any patient to a simple decision matrix, and careful case selection is essential if manual or powered morcellation is a consideration. This assessment is inherent to the core knowledge of a specialist in obstetrics and gynaecology.

4.1.2.2 Preoperative Assessment

Patients should have an appropriate history and examination performed, specifically to assess the risk of malignancy. Routine preoperative investigations should include a cervical screening test and an ultrasound. Further investigations must be targeted to the type of pathology and may include blood tests, such as tumour markers, endometrial sampling and/or extended imaging.

4.1.2.3 Consent

Patients must be engaged in the discussion of the risks and benefits of the route of any proposed surgical procedure, including the mechanism of tissue extraction. This discussion should include the risks, benefits and likely outcomes of alternative management options.

4.1.2.4 Intraoperative Assessment

Clinical intraoperative assessment of a pelvic mass is difficult and inaccurate. In the event of possible malignancy it may be appropriate to abandon the procedure, seek the advice of a gynaecological oncologist intraoperatively or avoid techniques that may increase the risk of dissemination, such as morcellation.

4.1.2.5 Minimisation of specimen spillage

Small pieces of fibroid ("fibroid chips") are generated with both hand and power morcellation. Options to minimize the potential risks of tumour spread and abdominal fibroid seeding during morcellation should be considered. These include removal of all visible fibroid pieces at the end of morcellation. Consideration should also be given to a larger extraction-site incision (mini-laparotomy). In MIGS where tissue extraction is facilitated by a power morcellator, an in-bag containment system should be used.

Recommendation 1	Grade
Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options.	Consensus-based recommendation
Recommendation 2	**Grade**
Morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy (including atypical endometrial hyperplasia).	Consensus-based recommendation

4.2 Pathological assessment

The postoperative histopathological diagnosis of a morcellated specimen may be compromised. It is recommended that members seek the opinion of a gynaecological oncologist and specialised pathologist in the diagnosis of any gynaecological malignancy, whether expected or unexpected.

4.3 Specific Consideration: Leiomyosarcoma

In April 2014, the United States Food and Drug Administration (FDA) issued an FDA Safety Communication regarding power morcellation in hysterectomy and myomectomy, followed by a Safety Alert on laparoscopic power morcellators from the Australian Therapeutic Goods Administration (TGA). These alerts reacted to reports of adverse patient outcomes in patients with fibroids related to the potential for the devices to spread malignant cells in patients with previously undetected malignancy.

The specific problem posed by the diagnosis of uterine sarcoma, is that there are no reliable pre-operative diagnostic tools to differentiate malignant mesenchymal tumours of the uterus, from their benign counterparts.

Local gynaecological units are encouraged to develop their own clinical protocols, based on the availability of local resources and expertise.

The incidence of leiomyosarcoma (LMS) is 0.36–1.8 per 100,000 woman-years.[1, 2] The risk of diagnosing LMS after surgery for presumed fibroid is estimated to be between 0.01% - 0.08%. [3]

Reported demographic risk factors for LMS include:

- Age (mean age of diagnosis: 60)
- Menopausal status
- African American ethnic background
- Current or prior tamoxifen exposure
- History of pelvic Irradiation
- Hereditary Leiomyomatosis, retinoblastoma syndrome, Li Fraumeni syndrome and Renal Cell Carcinoma (HLRCC) syndrome
- Survivors of childhood retinoblastoma.

In the clinical assessment, practitioners should be alert to the possibility of malignancy, if:

- Rapidly expanding mass
- Post-menopausal bleeding or variants of abnormal uterine bleeding, in premenopausal women with an unusual pattern
- Ascites
- Lymphadenopathy
- Evidence of secondary spread.

A cervical screening test should be taken and endometrial assessment be performed by imaging and / or endometrial sampling prior to engaging in any invasive procedure if there is a history of abnormal uterine bleeding.

Patients should have preoperative imaging by ultrasound or MRI, with reference to local guidelines. Risk factors for LMS include:

- Large size or large interval growth
- Tissue signal heterogeneity
- Central necrosis
- Ill-defined margins
- Ascites
- Metastases

With the exception of the last two elements, it is recognised that risk stratification using these features have a significant overlap with degenerating fibroids. There are no established tumour markers for LMS, though there may be an elevation in LDH, related to an increased cell turnover.

Recommendation 3	Grade
Practitioners performing power morcellation should be adequately trained, skilled and credentialed for the use of power morcellators and in-bag containment systems, by the local credentialing committee.	Consensus-based recommendation
Good Practice Note	
In minimally invasive procedures, where tissue extraction is facilitated by a power morcellator, an in-bag containment system should be used.	

5. Conclusion

It is recognised that the recommended measures will not completely preclude the occurrence of an unsuspected malignancy at myomectomy or hysterectomy. If the diagnosis is made postoperatively, early consultation with a gynaecological oncologist is mandatory.

6. References

1. Toro JR, Travis LB, Wu HJ, Zhu K, Fletcher CD, Devesa SS. Incidence patterns of soft tissue sarcomas, regardless of primary site, in the surveillance, epidemiology and end results program, 1978-2001: An analysis of 26,758 cases. Int J Cancer. 2006;119(12):2922-30.
2. Roberts ME, Aynardi JT, Chu CS. Uterine leiomyosarcoma: A review of the literature and update on management options. Gynecologic oncology. 2018;151(3):562-72.
3. Hartmann KE FC, Surawicz T, Krishnaswami S, Andrews J C, Wilson J E, Velez-Edwards D, Kugley S, Sathe N A. Management of Uterine Fibroids [Internet]. Rockville Agency for Healthcare Research and Quality (US); 2017.

7. Other suggested reading

1. American College of Obstetricans and Gynecologists. Power Morcellation and Occult Malignancy in Gynecologic Surgery: A Special Report. May 2014.
2. American College of Obstetricans and Gynecologists Committee Opinion Number 822 2021 (Replaces Committee Opinion No. 770, March 2017). Uterine Morcellation for Presumed Leiomyomas. March 2019.
3. AAGL Advancing Minimally Invasive Gynecology Worldwide. AAGL Practice Report: Morcellation During Uterine Tissue Extraction. May 2014.
4. AAGL Tissue Extraction Task Force. Morcellation During Uterine Tissue Extraction: An Update. May/June 2018.
5. Use of Electric Power Morcellation and Prevalence of Underlying Cancer in Women Who Undergo Myomectomy. [Erratum appears in JAMA Oncol. 2015 Apr;1(1):110; PMID: 26182314] Wright JD; Tergas AI; Cui R; Burke WM; Hou JY; Ananth CV; Chen L; Richards C; Neugut AI; Hershman DL. JAMA Oncology. 1(1):69-77, 2015 Apr.
6. Trends in Use and Outcomes of Women Undergoing Hysterectomy With Electric Power Morcellation. Wright JD; Chen L; Burke WM; Hou JY; Tergas AI; Ananth CV; Hershman DL. JAMA. 316(8):877-8, 2016 Aug 23-30.
7. What is the Future of Open Intraperitoneal Power-Morcellation of Fibroids?. [Review] Parker WH; Pritts EA; Olive DL. Clinical Obstetrics & Gynecology. 59(1):73-84, 2016 May.
8. U.S. Food and Drug Administration (FDA) Safety Communication update. Perform Only Contained Morcellation When Laparoscopic Power Morcellation Is Appropriate, published 29 December 2020. https://www.fda.gov/medical-devices/safety-communications/update-perform-only-contained-morcellation-when-laparoscopic-power-morcellation-appropriate-fda

8. Links to other College statements

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)
https://www.ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%20General/Evidence-based-medicine,-Obstetrics-and-Gynaecology-(C-Gen-15)-Review-March-2016.pdf?ext=.pdf

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Dr Scott White	Chair
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Anna Clare	Deputy Chair, Obstetrics
Associate Professor Amanda Henry	Member and Councillor
Dr Samantha Scherman	Member and Councillor
Dr Marilla Druitt	Member and Councillor
Dr Frank O'Keeffe	Member and Councillor
Dr Kasia Siwicki	Member and Councillor
Dr Jessica Caudwell-Hall	Member and Councillor
Dr Sue Belgrave	Member and Councillor
Dr Marilyn Clarke	Aboriginal and Torres Strait Islander Representative
Professor Kirsten Black	SRHSIG Chair
Dr Nisha Khot	Member and SIMG Representative
Dr Judith Gardiner	Diplomate Representative
Dr Angela Brown	Midwifery Representative, Australia
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Leigh Toomey	Community Representative
Dr Rania Abdou	Trainee Representative
Dr Philip Suisted	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Steve Resnick	Co-opted member

The Women's Health Committee acknowledges the significant contribution of the RANZCOG Endoscopic Surgical Advisory Committee (ESAC) (Appendix B) and previous ESAC members who contributed to the statement update: Professor Jason Abbott, Professor Michael Permezel, Dr Martin Ritossa and Dr John Tait.

Appendix B Endoscopic Surgical Advisory Committee Membership

Name	Position on Committee
Dr Marilla Druitt	Chair, Representative RANZCOG
Dr Michael Wynn-Williams	Deputy Chair, Representative AGES (NZ)
Professor Yee Leung	Representative RANZCOG
Dr Stephen Lyons	President, AGES
Dr Philip Suisted	Representative RANZCOG (NZ)
Dr Rachel Green	Representative AGES
Dr Gary Swift	Representative RANZCOG
Dr Helen Green	Representative AGES

Appendix C Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in June 2014 by AGES and was most recently reviewed by the RANZCOG Women's Health Committee in March 2017. The RANZCOG-AGES Endoscopic Surgery Advisory Committee (ESAC) carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all members prior to reviewing this statement.
- Structured clinical questions were developed and agreed upon.
- An updated literature search to answer the clinical questions was undertaken.
- At the March 2022 committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix B part iii).

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of the Women's Health Committee. A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Women's Health Committee members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall level of evidence and grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines. Level of evidence reflects the best study types for the specific type of question. The most appropriate study design to answer each type of clinical question (intervention, diagnostic accuracy, aetiology or prognosis) is level II evidence. Level I studies are systematic reviews of the appropriate level II studies in each case. Study designs that are progressively less robust for answering each type of question are shown at levels III and IV.

Where no robust evidence was available but there was sufficient consensus within the Women's Health Committee, consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s), but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix D Full Disclaimer

Purpose
This Statement has been developed to provide general advice to practitioners about women's health issues concerning tissue extraction at minimally invasive gynaecological surgery, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any person. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person with a breech presentation at term and the particular circumstances of each case.

Quality of information
The information available in tissue extraction at minimally invasive gynaecological surgery is intended as a guide and provided for information purposes only. The information is based on the Australian/New Zealand context using the best available evidence and information at the time of preparation. While the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) had endeavoured to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available. The use of this information is entirely at your own risk and responsibility.

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