

Vaginal 'rejuvenation' and cosmetic vaginal procedures

This statement has been developed and reviewed by the Women's Health Committee and approved by the RANZCOG Board and Council.

A list of Women's Health Committee Members can be found in <u>Appendix A</u>.

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: July 2008

Current: March 2019 Review due: March 2022 Background: This statement was first developed by Women's Health Committee in July 2008 and most recently reviewed in March 2019.

Funding: The development and review of this statement was funded by RANZCOG.

Surgical or laser techniques which claim to improve the appearance of the female genital tract such as "vaginal rejuvenation", "revirgination", "designer vaginoplasty", "G spot amplification" and techniques for vaginal atrophy are relatively new, poorly understood and backed by limited clinical evidence.

The American College of Obstetricians and Gynecologists (ACOG) Committee on Gynecologic Practice and the Society of Obstetricians and Gynaecologists of Canada have produced documents discouraging the practice of female genital cosmetic procedures which do not include medically-indicated reconstructions. ^{1, 2} Gynaecological conditions that merit surgery include genital prolapse, reconstructive surgery following female genital mutilation and labioplasties for medical indications. Medical practitioners performing any vaginal surgery should be appropriately trained.

"Vaginal rejuvenation", refers to devices that deliver thermal energy to the vaginal mucosa and are marketed for the treatment of vaginal menopausal symptoms, sexual dysfunction and urinary incontinence. These devices include CO2 and Erbium lasers, and radiofrequency ablation that are not supported with Medicare reimbursement and not approved by the Food and Drug Administration (FDA) in the USA for these indications. In Australia, only the Erbium laser has approval from the Therapeutic Goods Administration (TGA) for the treatment of vaginal atrophy and was approved in 2017 under an "application without audit" review process. Recently, the FDA in America declared that these devices were associated with serious adverse events including vaginal pain, burning, dyspareunia and chronic pain and lack adequate supporting efficacy data⁴. Until the indications for treatment and the safety and efficacy profile of these treatments are established against standard therapies, vaginal laser treatments should be conducted under the guidance and supervision of local ethics committee.

Obstetricians and gynaecologists should have a role in educating women that there is a large number of variations in the appearance of normal female external genitalia and that there are normal physiological changes over time, especially following childbirth and menopause. Patients requesting procedures other than for gynaecological conditions should be assessed thoroughly and the reasons for such a request assessed carefully. Sexual counselling is also recommended for patients requesting surgery that is purported to enhance gratification. The College is particularly concerned that such surgery may exploit vulnerable women. Doctors who perform these procedures should not promote or advertise that these surgeries enhance sexual function.

The College strongly discourages the performance of any surgical or laser procedure that lacks current peer reviewed scientific evidence other than in the context of an appropriately constructed clinical trial.

The College urges caution in accepting financial incentives from manufactures of commercial products including flights and accommodation to attend information sessions. Any sponsorship places medical practitioners at risk of a perceived conflict of interest and may contravene local hospital protocols.

At present, there is no evidence that these procedures are effective, enhance sexual function or improve self-image. The risks of potential complications such as scarring, adhesions, permanent disfigurement, infection, dyspareunia and altered sexual sensations should be discussed in detail with women seeking such treatments.³

References

- Vaginal "rejuvenation" and cosmetic vaginal procedures, ACOG Committee Opinion No. 376.
 American College of Obstetricians and Gynecologists. Obstet Gynecol 2007; 110: 737-738.
- 2. Shaw D, Lefebvre G, Bouchard C etal. Female genital cosmetic surgery. J Obstet Gynaecol Can. 2013;35:1108-14
- 3. Singh A, Swift S, Khullar V, Digesu A. Laser vaginal rejuvenation: not ready for prime time. Int Urogynecol J. 2015;26:163-164.
- 4. FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication 2018 [Available from: https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm

Links to other College statements

Evidence-based Medicine, Obstetrics and Gynaecology (C-Gen 15)

Patient information

A range of RANZCOG Patient Information Pamphlets can be ordered via:

http://www.ranzcog.edu.au/publication/womens-health-publications/patient-information pamphlets.html

Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee	
Professor Yee Leung	Chair and Board Member	
Dr Gillian Gibson	Deputy Chair, Gynaecology	
	Deputy Chair, Obstetrics and	
Dr Scott White	Subspecialties Representative	
Associate Professor Ian Pettigrew	Member and EAC Representative	
Dr Kristy Milward	Member and Councillor	
Dr Will Milford	Member and Councillor	
Dr Frank O'Keeffe	Member and Councillor	
Professor Sue Walker	Member	
Dr Roy Watson	Member and Councillor	
Dr Susan Fleming	Member and Councillor	
Dr Sue Belgrave	Member and Councillor	
Dr Marilyn Clarke	ATSI Representative	
Associate Professor Kirsten Black	Member	
Dr Thangeswaran Rudra	Member	
Dr Nisha Khot	Member and SIMG Representative	
Dr Judith Gardiner	Diplomate Representative	
Dr Angela Brown	Midwifery Representative	
Ms Ann Jorgensen Community Representative		
Dr Rebecca Mackenzie-Proctor	Trainee Representative	
Prof Caroline De Costa	Co-opted member (ANZJOG member)	
Dr Christine Sammartino	Observer	

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

i. Steps in developing and updating this statement

This statement was originally developed in July 2008 and was most recently reviewed in March 2019. The Women's Health Committee 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 November 2018 face-to-face 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 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. 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	А	Body of evidence can be trusted to guide practice
	В	Body of evidence can be trusted to guide practice in most situations
	С	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 C Full Disclaimer

This information is intended to provide general advice to practitioners, 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 patient.

This information has been prepared having regard to general circumstances. 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 patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours 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.