

# CATEGORY: BEST PRACTICE STATEMENT Use of Lasers in Obstetrics and Gynaecology

Consensus statement of the Royal Australian & New Zealand College of Obstetricians & Gynaecologists (RANZCOG) and the Australian Gynaecological Endoscopy & Surgery Society (AGES)

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 and Endoscopic Surgery Advisory Committee membership respectively, 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 2002 Current: November 2021 Review due: November 2026

**Objectives:** To provide advice on the use of lasers by RANZCOG Fellows and trainees.

Target audience: All health practitioners using lasers in obstetrics and gynaecology.

**Background:** This statement was first developed by Women's Health Committee in July 2002 to provide advice on the use of lasers.

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



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## 1. Plain language summary

Lasers are used to treat gynaecological conditions such as genital warts, pre-cancerous conditions of the lower genital tract, pelvic endometriosis, polycystic ovaries, and heavy menstrual bleeding. They are also used in obstetrics to help manage complications in twin pregnancies.

Any person using laser must have undergone appropriate training and credentialling and should inform patients about the potential risks and benefits of laser treatment.

# 2. Summary of recommendations

Recommendation 1	Grade
Lower genital tract pre-cancer and condylomata can be treated by excisional or ablative techniques depending on pathology, patient and resource factors. $^{\underline{1}}$	Evidence based recommendation Level C
Recommendation 2	Grade
There is insufficient evidence to support the routine use of vaginal laser therapy in the treatment of urogenital atrophy, urinary incontinence or sexual dysfunction $\frac{2-6}{2}$	Evidence based recommendation Level C
Recommendation 3	Grade
If vaginal laser therapy is offered in the treatment of urogenital atrophy or stress urinary incontinence, it should be in the context of a clinical trial [RCOG, SOGC, ISSVD, ICS, AUGS] <sup>4-10</sup>	Consensus-based recommendation
Recommendation 4	Grade
There is insufficient evidence to show that routine laser therapy is superior to any other energy source in minimally invasive gynaecologic surgery	Consensus-based recommendation
Recommendation 5	Grade
Laser photocoagulation is the therapy of choice when twin-twin transfusion syndrome requires definitive treatment. $\frac{11-13}{}$	Evidence based recommendation Level A
Recommendation 6	Grade
Prior to performing laser surgery those performing procedures should be	Consensus-based

### 3. Introduction

Lasers can be used in several clinical settings in obstetric and gynaecological surgery but at present have a limited clinical role. All practitioners should consider the adequacy of their own training and the evidence supporting the use of these devices before committing resources to this technology.



# 4. Clinical use in Obstetrics and Gynaecology

### 4.1 Gynaecology

### 4.1.1 Treatment of lower genital tract pre-cancer and condylomata

Lower genital tract pre-cancer and condylomata can be treated by excisional or ablative techniques. Excisional techniques include carbon dioxide (CO<sub>2</sub>) laser conisation, loop electrosurgical excision procedure (LEEP) or scalpel excision. Ablative techniques include CO<sub>2</sub> laser vaporisation, radical diathermy, or coagulation. The choice of excisional or ablative technique is related to the underlying condition, the extent of the lesion(s), patient factors and availability of resources.

There is insufficient evidence to show that laser therapy is superior to any other treatment modality in the routine management of lower genital tract pre-cancer and condylomas<sup>1</sup>.

Recommendation 1	Grade
Lower genital tract pre-cancer and condylomata can be treated by excisional	Evidence based
or ablative techniques depending on pathology, patient and resource factors. $^{1}$	recommendation
	Level C

### 4.1.2 Treatment of non-lesional vaginal conditions

In Australia, the CO<sub>2</sub> or Er:YAG laser has not been approved for use in treating urogenital atrophy symptoms (vaginal rejuvenation) because there has not been enough high-quality research evidence supporting its benefit, or short and long term safety.  $^2$ 

In the USA, the Food and Drug Administration (FDA) has issued a statement on deceptive health claims and significant risks related to the use of laser therapy for "vaginal rejuvenation" (<u>https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-safeguard-womens-health-deceptive-health-claims</u>). <sup>3</sup>

The International Society for the Study of Vulvovaginal Disease and the International Continence Society Best Practice document does not recommend the routine treatment of vulvovaginal atrophy, urinary incontinence, vulvodynia and lichen sclerosus by laser therapy.  $\frac{4}{2}$ 

The Royal College of Obstetricians & Gynaecologists do not recommend the routine treatment of urogenital atrophy or stress urinary incontinence by laser therapy.  $\frac{5}{2}$ 

Recommendation 2	Grade
There is insufficient evidence to support the routine use of vaginal laser	Evidence based
therapy in the treatment of urogenital atrophy, urinary incontinence or	recommendation
sexual dysfunction. $2-6$	Level C
Recommendation 3	Grade
If vaginal laser therapy is offered in the treatment of urogenital atrophy or	Consensus-based
stress urinary incontinence, it should be in the context of a clinical trial	recommendation

\* The Royal College of Obstetricians and Gynaecologists (RCOG); The Society of Obstetricians and Gynaecologists of Canada (SOGC); The International Society for the Vulvovaginal Disease (ISSVD); International Continence Society (ICS); American Urogynecologic Society (AUGS).



#### 4.1.3 Minimally invasive surgery

A number of different types of laser have been used in minimally invasive surgery. This includes neodymium– yttrium-aluminium-garnet (Nd-YAG) laser for hysteroscopic surgery, and CO<sub>2</sub> laser for laparoscopic surgery, however there is insufficient evidence to support its routine use in minimally invasive gynaecologic surgery. With the advancements in new technologies, alternative energy sources and modalities are available for use in minimally invasive surgery.

Recommendation 4	Grade
There is insufficient evidence to show that routine laser therapy is superior to	Consensus based
any other energy source in minimally invasive gynaecologic surgery	recommendation

### 4.2 Obstetrics

Laser photocoagulation has been used successfully in the treatment of twin- twin transfusion syndrome, with a survival of at least one fetus in 75-90 per cent of cases. The laser of choice is either the neodymium–yttrium-aluminium-garnet (Nd-YAG) or a Diode Pumped Solid State Laser (Diode Laser) with a wavelength of 400-600nm.<sup>11-13</sup>

Laser photocoagulation is the therapy of choice when twin-twin transfusion syndrome requires definitive treatment.

Recommendation 5	Grade
	Evidence based recommendation Level A

### 4.3 Training

# 4.3.1 4.3.1 Those performing laser surgery must be familiar with the use of lasers in medical settings.

- The physics, effects and safety aspects of lasers in surgery (an accredited biomedical engineer should guide this part of the course); and
- The clinical aspects of lasers in gynaecology which should cover the application and techniques for using lasers in one or more of the settings outlined in the <u>Introduction</u>.
- 4.3.2 Attend a number of theatre/outpatient sessions observing the use of laser in an operative setting.

# 4.3.3 Where possible, invite a preceptor to observe the first few cases in the clinician's hospital environment.

Once these criteria have been fulfilled, credentialing in one or more of the clinical settings should be issued by the hospital before the clinician commences laser surgery as an independent operator. (See RANZCOG statement <u>WPI 23</u> Credentialing in Obstetrics and Gynaecology).



Recommendation 6	Grade
Prior to performing laser surgery those performing procedures should be	Consensus-based
specifically credentialed to undertake laser surgery by the relevant	recommendation
hospitals credentialing process. (See <u>WPI 23</u> Credentialing in Obstetrics	
and Gynaecology)	

## 5. References

1. Martin-Hirsch PP, Paraskevaidis E, Bryant A, Dickinson HO, Keep SL. Surgery for cervical intraepithelial neoplasia. The Cochrane database of systematic reviews. 2010(6):Cd001318.

2. Li FG, Deans R, Nesbitt-Hawes E, Budden AK, McCormack L, Maheux-Lacroix S, et al. Fractionated Laser for Vaginal Atrophy Symptoms: A Randomized, Double-Blind Placebo Controlled Study. Journal of minimally invasive gynecology. 2020;27(7):S69.

3. ISSVD/ICS comments on the FDA communication on the use of energy-based devices to perform vaginal 'rejuvenation' or vaginal cosmetic procedures: International Society for the Study of Vulvovaginal Disease and International Continence Society; 2018. Available from: <u>https://www.issvd.org/issvd-ics-</u> comments-on-the-fda-communication-on-the-use-of-energy-based-devices-to-perform-vaginal-rejuvenationor-vaginal-cosmetic-procedures/.

4. Preti M, Vieira-Baptista P, Digesu GA, Bretschneider CE, Damaser M, Demirkesen O, et al. The Clinical Role of LASER for Vulvar and Vaginal Treatments in Gynecology and Female Urology: An ICS/ISSVD Best Practice Consensus Document. J Low Genit Tract Dis. 2019;23(2):151-60.

Excellence NIfHaC. Transvaginal laser therapy for stress urinary incontinence [Internet]. London: NICE;
2021.

6. Excellence NIfHaC. Transvaginal laser therapy for urogenital atrophy[Online]. London: NICE; 2021.

7. Walter J-E, Larochelle A. No. 358-Intravaginal Laser for Genitourinary Syndrome of Menopause and Stress Urinary Incontinence. Journal of Obstetrics and Gynaecology Canada. 2018;40(4):503-11.

8. Alshiek J, Garcia B, Minassian V, Iglesia CB, Clark A, Sokol ER, et al. Vaginal Energy-Based Devices. Female pelvic medicine & reconstructive surgery. 2020;26(5).

9. Paraiso MFR, Ferrando CA, Sokol ER, Rardin CR, Matthews CA, Karram MM, et al. A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VeLVET Trial. Menopause. 2020;27(1):50-6.

10. Mension E, Alonso I, Tortajada M, Matas I, Gómez S, Ribera L, et al. Vaginal laser therapy for genitourinary syndrome of menopause - systematic review. Maturitas. 2021.

11. Walker SP, Cole SA, Edwards AG. Twin-to-twin transfusion syndrome: is the future getting brighter? Aust N Z J Obstet Gynaecol. 2007;47(3):158-68.

12. Van Der Veeken L, Couck I, Van Der Merwe J, De Catte L, Devlieger R, Deprest J, et al. Laser for twinto-twin transfusion syndrome: a guide for endoscopic surgeons. Facts Views Vis Obgyn. 2019;11(3):197-205.

13. Akkermans J, Peeters SH, Klumper FJ, Lopriore E, Middeldorp JM, Oepkes D. Twenty-Five Years of Fetoscopic Laser Coagulation in Twin-Twin Transfusion Syndrome: A Systematic Review. Fetal Diagn Ther. 2015;38(4):241-53.



## 6. Other suggested reading

- 1. Standards Australia. Guide to the safe use of lasers in health care. AS/NZS 4173:2004. Available at: http://infostore.saiglobal.com/store/details.aspx?ProductID=378218
- 2. For links to Federal, State and Territory Acts and Regulations relating to legislation on the use of lasers, please refer to Radiation Protection Regulations and Standards in Australia and New Zealand at: http://www.arpansa.gov.au/radiationprotection/links.cfm

# 7. Links to other College statements

<u>Guidelines for training in advanced endoscopic surgery and endometrial ablations</u> (C-Trg 1) <u>Guidelines for performing gynaecological endoscopic procedures</u> (C-Trg 2) <u>Evidence-based Medicine, Obstetrics and Gynaecology</u> (C-Gen 15) <u>Credentialing in Obstetrics and Gynaecology</u> (WPI 23)



# Appendices

### Appendix A: Committee membership

### Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair and Board Member
Dr Gillian Gibson	Deputy Chair, Gynaecology
Dr Scott White	Deputy Chair, Obstetrics
Dr Jared Watts	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, Australia
Ms Adrienne Priday	Midwifery Representative, New Zealand
Ms Ann Jorgensen	Community Representative
Dr Ashleigh Seiler	Trainee Representative
Dr Leigh Duncan	Māori Representative
Prof Caroline De Costa	Co-opted member (ANZJOG member)
Dr Christine Sammartino	Observer

### Endoscopic Surgery Advisory Committee (RANZCOG/AGES) Membership

Name	Position on Committee
Professor Jason Abbott	Chair, Representative AGES
Dr Stephen Lyons	Deputy Chair, Representative RANZCOG
Prof Yee Chit Leung	Representative RANZCOG
Dr Martin Gerard Ritossa	Representative AGES
Professor Michael Permezel	Representative RANZCOG
Dr John Tait	Representative RANZCOG
Dr Stuart Salfinger	President AGES
Dr Vijay Roach	President RANZCOG



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

Steps in developing and updating this statement

i.

This statement was developed in July 2016. 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 September 2021 teleconference 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	A	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 D Full Disclaimer

#### Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning use of lasers in obstetrics and gynaecology 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 and the particular circumstances of each case.

#### Quality of information

The information available in use of lasers in Obstetrics and Gynaecology 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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Version	Date of Version	Pages revised / Brief Explanation of Revision
v1.1	Jul / 2002	AGES (author)
v2.1	Mar / 2005	AGES (Dr J Tsaltas)/ WHC
v3.1	Jul / 2007	AGES (Dr J Tsaltas)/ WHC
v4.1	Jul / 2010	AGES (Dr J Tsaltas)/ WHC
v5.1	Nov / 2013	WHC (A/Prof P Duggan)
v6.1	Mar / 2018	Endoscopic Surgery Advisory Committee (ESAC)
Policy Version:		Version 7.1 (2021) amended 2022

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