Statement

Permanent Female Contraception by Filshie Clip tubal occlusion

The interim update to this statement has been developed and reviewed by the Women's Health Committee and the RANZCOG Council.

A list of Women's Health Committee Members can be found in Appendix A.

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: November 2007
Current: November 2014
Review due: November 2019
Interim review undertaken: July 2023

Objectives: To provide advice on methods available for permanent female contraception, particularly by Filshie clip tubal occlusion.
Target audience: All registered health professionals providing gynaecological care, and patients.
Values: The evidence was reviewed by the Women's Health Committee (RANZCOG), and applied to local factors relating to Australia and New Zealand.
Background: This statement was first developed by Women's Health Committee in November 2007 and reviewed in November 2014. It was most recently reviewed by the Endoscopic Surgery Advisory Committee and approved by the Women's Health Committee in July 2023 (interim review).
Funding: The development and review of this statement was funded by RANZCOG.

Contents

1. Plain language summary

There is a range of methods available for permanent female contraception that involve either occlusion or transection of the fallopian tubes. A tubal occlusion can be performed laparoscopically or at open abdominal surgery (usually caesarean section), or hysteroscopically (e.g. Essure procedure). The most common method of female tubal occlusion in Australia and New Zealand is the Filshie clip system which has been available since 1982. During this procedure non absorbable titanium and silicone rubber clips are applied by either a disposable single use applicator or a reusable applicator which requires regular recalibration.

Although this statement applies predominantly to laparoscopic Filshie clip tubal occlusion, it is recognised that in some instances Filshie clips will be applied at caesarean section. This statement does not relate directly to that technique. It must be recognised that Filshie clips applied at caesarean section have a higher rate of failure.

2. Discussion and Good Practice points

2.1 What is the suggested technique for application of the Filshie clip to the tube?

- Uterine manipulator in position.
- Entry technique for laparoscopy, as per RANZCOG/AGES Consensus Guidelines for performing gynaecological endoscopic procedures (C-Trg 2).
- Multiple puncture laparoscopy.
- Identify the ovarian and round ligaments and the fallopian tubes by visualising their fimbrial ends.
- Apply the clip to the tube, ensuring the jaws of the clip completely enclose the tube. The manufacturer's guidelines currently recommend placement of the clip on the isthmic portion of the tube.
- After releasing the clip, ensure the tube has not been transected, the upper arm of the clip is flat and locked under the nose of the lower jaw, and that the tube is still completely enclosed.
- Repeat the procedure on the other side.
- It may be useful to document correct application of the Filshie clip by image capture device, if available.

2.2 What are the minimum equipment requirements?

The procedure may be performed by either a disposable/ single-use or reusable applicator. Poorly serviced applicators can result in a loss of calibration which can lead to incorrect closure of the Filshie clip and possible failed tubal occlusion.

If using a reusable applicator it is strongly recommended that:

- Filshie clip applicators be serviced and recalibrated by their manufacturer or their appointed agent in line with the manufacturer's guidelines.
- Prior to using a reusable applicator it is good practice to ensure that the applicator is assembled correctly and tested with the pressure gauge to ensure correct calibration.

2.3 What are the main reasons for legal claims against medical practitioners resulting from a failed tubal occlusion?

Failed tubal occlusion has historically been a frequent source of legal claims against medical practitioners. The basis for such claims has been due to an alleged failure by the medical practitioner to:

- Time the procedure so that the patient is not pregnant, or exclude a pregnancy prior to performing the procedure;
- Warn of possible contraception failure;
- Perform the appropriate technique;
- Diagnose a pregnancy that occurs after a failed contraception; and
- Diagnose an ectopic pregnancy.

Another basis for claims has been inadvertent injury at laparoscopy. Therefore, it is vital that practitioners are skilled in carrying out the procedure.

2.4 Good Practice Points

I. Ensure a detailed history is taken about previous gynaecological procedures.
II. Ensure other contraceptive alternatives are discussed with the patient, including other safe long term methods of contraception.
III. The risk of the development of some ovarian carcinomas from the Fallopian tubes left in situ should be discussed with the patient, as well as consideration of permanent contraception by bilateral salpingectomy instead of tubal occlusion (see below).
IV. Provide printed material such as the RANZCOG brochure on tubal occlusion.
V. Discuss the risk of failure (for Filshie clips it is generally considered about 1 in 300) and record this discussion in the patient's file.
VI. Ensure the appropriate patient consent form/ is correctly completed. It is good practice to include reference to the various discussions in the patient's file and in a letter to the referring doctor.
VII. Ensure that the patient is aware that should a pregnancy occur, there is an increased risk of ectopic pregnancy. If a pregnancy occurs, ectopic pregnancy should be excluded as early as possible using appropriate diagnostic tests.
VIII. The date of the patient's last menstrual period should be recorded. It is recommended that the procedure be performed in the early to mid-follicular phase of the cycle unless other contraception is being used. A pregnancy test should be performed prior to the procedure if necessary.
IX. The surgical unit at which the procedure is done is responsible for ensuring that equipment is serviced and that calibration gauges are available. It is the unit's responsibility to ensure that equipment is correctly calibrated. Fellows should satisfy themselves that the unit has conducted appropriate servicing and calibration.
X. Note any intraoperative difficulties. If initial application is not ideal, a second clip may be applied. If image capture equipment is available, take adequate photographs to show that the clip has been correctly applied.
XI. If there is any doubt about either of the clip applications, or if one or both tubes can not be visualised, discuss the situation with the patient post-operatively.
XII. If in doubt, advise the patient to use alternative contraception until tubal occlusion has been confirmed with hysterosalpingogram or hysterosalpingo contrast sonogram.
XIII. Uterine curettings are not required but if any have been obtained they should be submitted to pathology and the histology reviewed.

2.5 Salpingectomy versus tubal Occlusion

There is growing evidence that high-grade serous tumours of the ovary and peritoneal surface epithelium (the most common histologic sub-type of epithelial ovarian cancer) may originate in the fallopian tubes. Furthermore, there is no known benefit for retaining fallopian tubes in the post-reproductive period, and removal of the fallopian tubes does not appear impact on ovarian function (RANZCOG Clinical Guidance Statement: Managing the adnexa at the time of hysterectomy for benign gynaecological disease C-Gyn 25). Hence, bilateral salpingectomy should be discussed with the patient during the informed consent process for Filshie clip tubal occlusion.

Although the removal of the fallopian tubes does not appear to increase surgical complications when performed with oophorectomy, there may be an increased risk of other complications when compared to tubal occlusive procedures. This, and the possible need for extra laparoscopy port sites when performing salpingectomy, should also be discussed with the patient.

3. Suggested reading

Lyneham R. A review of the Filshie system in Australia and New Zealand, O&G 2003; 5 (3): 194-195.
Filshie M G. Female sterilization, O&G 2000; 2 (1): 43-49.

Woodhouse D. Filshie clips safety alert update. O&G 1999;1 (1): 42-43.

4. Links to other College statements

Consent and provision of information to patients in Australia regarding proposed treatment (C-Gen 02a)

Consent and provision of information to patients in New Zealand regarding proposed treatment (C-Gen 02b)

RANZCOG/AGES Guidelines for performing gynaecological endoscopic procedures (C-Trg 2)

Managing the adnexa at the time of hysterectomy for benign gynaecological disease (C-Gyn 25).

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

5. Patient information

The pamphlet on Contraception methods and a range of other RANZCOG Patient Information Pamphlets can be viewed at: https://ranzcog.edu.au/resource-hub/?resource_audience=for-public
and ordered via:
https://ranzcog.zhpro.com.au/DSF/SmartStore.aspx?6xni2of2cF3ZE6Vkp5312HLCKdyzRw/RlmVRsVdzDflA7ud2OCsqiD4C7i9UTKPF#!/Storefront

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 contribution of the Endoscopic Surgery Advisory Committee (ESAC) in reviewing this statement.

Appendix B: RANZCOG-AGES Endoscopic Surgery Advisory Committee Membership

Name	Position on Committee
Dr Michael Wyn-Williams	Chair and AGES Member
Dr Marilla Druitt	Deputy Chair and RANZCOG Member
Dr Tal Jacobson	AGES Member
Professor Yee Leung	RANZCOG Member
Dr Stephen Lyons	AGES Member
A/Professor Emma Readman	AGES Member
Dr Phil Suisted	RANZCOG Member
Dr Gary Swift	RANZCOG Member
Dr Katy Culliney	STAG representative
Dr Rachel Green	AGES President
Dr Ben Bopp	RANZCOG President
Ms Vase Jovanoska	RANZCOG CEO
Ms Mary Sparksman	AGES General Manager

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

i. Steps in developing and updating this statement

This statement was first developed by Women's Health Committee in November 2007 and reviewed in November 2014. It was most recently reviewed by the Endoscopic Surgery Advisory Committee in May 2023. The Endoscopic Surgery Advisory Committee members advised that the statement is complete and remains current and recommended the statement for Women's Health Committee review. It was approved by RANZCOG Council (interim review) in July 2023. 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.
- Review of the statement content, with minor updates to hyperlinks and syntax changes agreed.
- The statement title was updated from Female Sterilisation by Filshie Clip occlusion. The term 'sterilisation' was replaced with 'permanent female contraception' throughout the statement.
- Updated statement recommended for RANZCOG Council approval.

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

There are no evidence-based recommendations in this statement.

Appendix D Full Disclaimer

Purpose

This Statement has been developed to provide general advice to practitioners about women's health issues concerning permanent female contraception by Filshie Clip tubal occlusion 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 this statement 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) have 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
v1.0	Nov / 2007	RANZCOG Women's Health Committee
v2.0	Nov / 2014	RANZCOG Women's Health Committee
V2.1	July / 2023	AGES-RANZCOG Endoscopic Surgery Advisory Committee / RANZCOG Women's Health Committee

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Policy Approved by:	RANZCOG Council
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