

REVIEW

Failed sterilisation: evidence-based review and medico-legal ramifications

Introduction

Sterilisation is one of the most common procedures in the world. Around 50,000 female sterilisations are performed every year in the UK,¹ although there is a suggestion of a worldwide downward trend in sterilisation procedures.^{2,3} Surgical techniques used in female sterilisation are designed to prevent pregnancy by occluding tubal patency through mechanical device application, electrocautery or by tubal excision and separation. These are shown in Table 1. Laparoscopic tubal occlusion by clip or ring is the preferred method of female sterilisation in the UK, and has replaced the earlier preference for tubal electrocautery. Laparoscopic sterilisation using the Filshie clip is the principal method in Europe, Canada and Australia and is becoming popular in the USA since licensing in 1996.⁴

Conception occurring after sterilisation is termed failed sterilisation, and can occur several years after the procedure; one case was described after an interval of 23 years.⁵

Complications can occur during sterilisation. The complication rate of interval laparoscopic sterilisation in one large multicentre study was 4.5 per 1000, with vascular or bowel injury, or inability to complete sterilisation laparoscopically, cited as the main reasons for conversion to laparotomy.⁶ Other complications include intractable localised pelvic pain, mesosalpingeal tears, tubal transection, tubal torsion and necrosis, tubo-ovarian abscess, uterine perforation, thermal bowel injury by electrocoagulation, pelvic or wound infection, delayed migration of Filshie clips (urethra, rectum, vagina), psychological symptoms and regret.⁷ Mortality attributed to the sterilisation procedure is extremely low, and has been estimated to vary from 1 to 2 per 100,000 for procedures performed in the United States, to 4 per 100,000 in developing countries, and is consequent to operative and anaesthetic related complications. Of significance, sterilisation decreases the risk of ovarian cancer but increases the risk of subsequent hysterectomy and ectopic pregnancy.⁸

Identification and assessment of evidence

The Cochrane library, Cochrane Controlled Trials Register Issue 1, 2003, Royal College of Obstetricians and Gynaecologists (RCOG, UK), American College of Obstetricians

and Gynaecologists (ACOG, USA), were searched for relevant randomised controlled trials, systematic reviews, meta-analyses and evidence-based guidelines relating to sterilisation. A search was also carried out of MEDLINE 1966–2003. The searches were performed using the relevant MeSH terms including: sterilisation, tubal; sterilisation; sterilisation sexual; surgical instruments; electrocautery; cautery; liability, legal; jurisprudence; malpractice; medical errors; treatment failure; risk factors. Other non-MEDLINE referenced information sources (published articles, conference proceedings) were also retrieved for analysis. Overall, the majority of publications were retrospective observational studies, case reports and reviews, with a paucity of prospective controlled trials or meta-analyses.⁹

Legal precedence

The psychological and physical morbidity following failed sterilisation often leads to litigation.¹⁰ A gynaecologist has a duty to inform women of the risk of failure, to carry out the operation in accordance with accepted good medical practice and to avoid foreseeable complications. Women who have undergone *sterilisation performed negligently* are entitled to recover damages according to:

1. Wrongful conception: In addition, an action in contract may also arise if the sterilisation procedure was performed outside the NHS in the private sector.
2. Negligence: A breach of duty arises when an operation is not carried out in accordance with practice accepted as proper by a reasonable body of gynaecologists (Bolam test). Negligence also occurs when there is omission in appropriate pre-operative counselling.
3. Wrongful birth: The negligent act deprived the mother of the possibility to prevent the conception of a disabled child or to have a lawful abortion.

Women are entitled to recover general damages for pain and suffering during pregnancy and delivery, and loss of earnings during pregnancy. However, a recent judgement held that the costs of bringing up a healthy child, or loss of earnings because of child-rearing responsibilities, are not recoverable (*McFarlane v Tayside Health Board* 2000).

Table 1. Female surgical sterilisation techniques.

Method	Techniques	Comments
Tying of tube with suture material and cutting it	Pomeroy—a free tie is placed around a loop of tube which is then excised Fimbriectomy Salpingectomy	Usually performed at mini-laparotomy, but can be performed laparoscopically
Mechanical occlusion	Filshie clip Hulka–Clemens clip Falope ring (silicone rubber band) Silastic ring	Less of the tube is damaged increasing the chance of reversibility
Coagulation-induced tubal closure	Unipolar diathermy Bipolar diathermy	Not recommended as the first line method in the UK by the RCOG

Although, a case for compensation for the costs of bringing up a healthy child was upheld in the case where the mother was disabled (*Rees v Darlington Memorial Hospital NHS Trust* 2002) as this parent was not in the same position as able-bodied parents.

Compensation that is limited to the special upbringing costs associated with rearing a child with a serious disability is allowed (*Parkinson v St James's & Seacroft University Hospital Trust* 2001, *Salih v Enfield Health Authority* 1991). Both parents can claim for shock and distress on discovering the child's condition as disabled, and the increased stress in bringing up the child. They can claim for lost earnings for bringing up the child, which they would not have lost had the child been healthy (*McLelland v Greater Glasgow Health Board* 2001). Furthermore, parents that chose sterilisation to avoid the risk of a child with congenital abnormalities can recover the costs associated with the child's disabilities, even though the disabilities had not been caused by the clinician's negligent sterilisation.

Sterilisation failure

Sterilisation failure varies according to the woman's characteristics, operator experience, sterilisation technique and method of sterilisation chosen.⁹ Sterilisation failure rates are often calculated as crude rates or Pearl index (failure rates per 100 women years) and rarely quoted as cumulative probabilities of pregnancy from operation. The latter index is the preferred terminology as the probability calculation utilises life table analysis and allows for both loss to follow up and time interval from sterilisation. Two well-designed studies from the United States and Canada have set a benchmark in sterilisation failure research.

The US multicentre CREST study (Collaborative Review of Sterilisation) recruited 10,685 women undergoing sterilisation between 1978 and 1987 and prospectively

followed up the cohort for up to 14 years.^{11–13} Silicone rubber band was the most common technique (31%), followed by bipolar coagulation (21%), postpartum partial salpingectomy (15%), Hulka clip application (15%), unipolar coagulation (13%) and interval partial salpingectomy (4%); the Filshie clip was not licensed by the US FDA until 1996 and was therefore excluded from the study. The overall 10-year cumulative probability of pregnancy was 18.5 per 1000 procedures (1.85%).

The Canadian study was a retrospective analysis of the Quebec health insurance database of 311,960 female sterilisations from 1980 to 1999.¹⁴ The 10-year cumulative probability of pregnancy was 8.4 per 1000 procedures (0.84%), considerably lower than the US study. The authors suggest this is due to the principal use of the Filshie clip in Canada for female sterilisation, which is considered a more effective method.

The RCOG has recently updated the 1 in 200 (0.5%) lifetime risk of pregnancy failure quoted to women by stating that the risk of failure at 10 years is 2–3 per 1000 procedures when using the Filshie clip.¹ However, upon examining those studies that are well-designed, prospective and recently published, the failure rate for Filshie clip has a wide range of between 1.1 and 19.3 per 1000 procedures.

Often there is a combination of *direct* or *indirect* factors that contribute to sterilisation failure. However, precise knowledge of these factors, particularly the time interval from operation and the exact mechanism of failure, is absent in most publications, and even in cases proceeding to litigation. The few studies that have rigorously assessed these elements are listed in Table 2. Accurate collation of this information would be useful in developing strategies to reduce the failure rate as well as to distinguish negligent from non-negligent cases. Of significance, an early study showed that the overall 10-year failure rate for Filshie clip sterilisations was 0.56% in 10,000 women, but fell significantly to 0.2% when cases caused by operator error were excluded.⁴

Table 2. Mechanism of sterilisation failure *versus* sterilisation method *versus* time interval from procedure.

Fault	Mechanism of sterilisation failure				Reference
	Wrong structure 'sterilised'	Incomplete tubal occlusion and/or patent lumen	Tubo-peritoneal fistula formation	Spontaneous recanalisation	
	Operator fault	Likely to be due to operator fault	Not due to operator fault	Not due to operator fault	
Ring	1/5 cases (<1 year)			4/5 cases (<1 year)	38
	1/3 cases (20 months)				15
Hulka clip		2/2 cases (<6 months)			49
	9/19 cases (mean 8 months)		3/19 cases (mean 8 months)	4/19 cases (mean 8 months)	53
Filshie clip		1 case (<1 year)			38
		3/17 cases (<2 years) 'despite locked-in-place and correctly applied clips'			29
	6/7 cases (<1 year)				17
	1/3 cases (9 months)				15
	5/30 cases (6 months)				22
	1/8 cases (<2 years)				80
	1/1 case (10 months)				81
	5/14 cases (mean 14.6 months)	1 case spontaneous opening of clip			35
		8/14 cases (mean 12.5 months)			Femcare personal communication
		1/14 cases (14 months) by mixed applicator			Femcare personal communication
Fimbriectomy				9 cases (<18 months)	38
				1/4 cases (time unknown)	82
Snare resection				4/4 cases (time unknown)	83
			2/6 cases		38
Pomeroy			2/3 cases		38
				1/3 cases	38
				1 case (4 months)	45
			3/4 cases (1.5–4 years)		49
Unipolar			2/6 cases (mean 11 months)		53
			3 cases (>2 years)	3/6 cases (mean 11 months)	38
Bipolar		1/2 cases (6 months)	1/2 cases (8 months)		49
	1 case (<1 year)	9 cases (<1 year)			38
			5/17 cases (14–44 months)		28

Direct factors contributing to sterilisation failure

Timing

During postpartum or post-abortion period

Sterilisation can be performed in the postpartum period (combined with caesarean section or via mini-laparotomy) or post-abortion. However, this period is associated with higher rates of failure and regret by the woman,^{15,16} and this should be incorporated into the counselling and documentation prior to the procedure. In terms of postpartum sterilisation, salpingectomy and Filshie clip have similar rates of failure (7.5 and 8.8 per 1000, respectively).^{11,15}

Pregnant at the time of the sterilisation (luteal pregnancy)

Studies have identified luteal pregnancy occurring in 0.32% to 0.6% of sterilisation cases.^{11,15,17} Routine pre-operative same-day pregnancy testing should be done for all cases,¹ and has been shown to reduce the incidence of luteal phase pregnancies.¹⁸ Although tubal occlusion can be performed at any time within the menstrual cycle, the woman should be advised to use effective contraception before and after the procedure, and up to her next (postprocedure) period in order to avoid luteal phase pregnancy. This advice also applies when an intrauterine device is removed at the time of sterilisation, especially at mid-cycle or luteal phase.

Method failure

A meta-analysis has shown no significant difference in failure rate or operative morbidity between mini-laparotomy and laparoscopy methods of tubal sterilisation.¹⁹ Overall, the failure rates for each method (clip, ring, electrocautery) in recent studies approximate to each other.^{4,11,12,15,17,20–33} Significantly, the US CREST showed that bipolar compared with unipolar electrocautery decreased the risk of thermal bowel injury but increased the risk of pregnancy failure and ectopic pregnancy.^{12,30}

Factors dependent on operator error

Sterilisation method failure due to absent or incomplete tubal occlusion most commonly arises through operator error at the time of initial sterilisation. Operator error can occur at six stages:

Fault in localising the correct sterilisation site

This involves anatomical misplacement of the sterilisation device away from the optimal mid-isthmic tubal site

(1 to 3 cm from the uterine cornu) or mistaken 'sterilisation' of an adjacent structure (e.g. the round ligament or a fold of peritoneum between the round ligament and tube).²⁶ If electrocautery is used, at least 3 cm of the mid to distal portion of the isthmic part of the tube should be coagulated with sparing of at least 2 cm of the proximal tubal stump to reduce failure through cornual fistula formation.^{1,28} At least 25 W of unipolar cutting current (rather than coagulating waveform) should be used to achieve complete tubal desiccation³⁴; without transecting the tube through excess electrocautery.

Deviation from the recommended technique for each sterilisation method

The Filshie clip should be applied in a manner to completely encapsulate the tube and lumen, be fully locked with the upper jaw compressed, completely flattened and its end adequately secured under the latch which 'locks' the clip jaw (Fig. 1). The clip should flatten the whole tube portion within the clip without leaving any unflattened tubal 'knuckles' and without transecting the tube. Finally, the clip should sit perpendicular to the long axis of the tube,²⁶ facilitated by stretching the isthmic portion with hinge placed on the anti-mesenteric aspect of the tube.

There is only one published case of failed sterilisation, which proposes Filshie clip under-closure as the most likely mechanism of sterilisation failure. Therefore, this cause of failure should be considered rare.³⁵ Filshie clip under-closure is considered to arise by operator fault in most cases.

Failure in the systematic approach to check the sterilisation method

Upon completing the sterilisation procedure, it is imperative that the operator check that the tubal fimbriae are seen and followed back to tubal isthmus, and that the correct tubal isthmic portion was 'sterilised'. Evidence of the checking procedure, may be considered as proof that all necessary precautions were undertaken by the operator as recommended by both the manufacturer and good clinical practice guidelines. Although not a legal requirement in the UK, we recommend:

- Taking clinical photographs or operative videos of the sterilised structures identifying them as fallopian tubes. However, photographs may be unhelpful in confidently excluding other negligent causes of incomplete tubal occlusion, for example, protruding knuckle of tube, inadequate locking of clip jaws, clip under-closure, or tubal transection (partial or complete) (see below).
- Presence of second operating surgeon for counter-checking. A recent study involving 1094 sterilisations from 1988 to 1989 showed that Registrars had a 1.3%

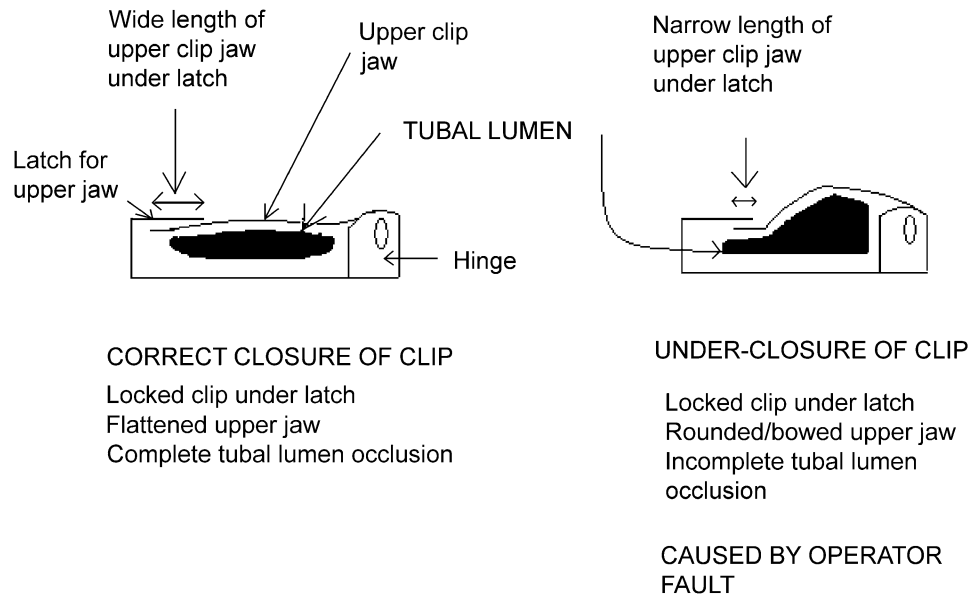


Fig. 1. Filshie clip under-closure due to operator fault. Despite the clip appearing locked, on closer inspection the upper jaw of the clip will be noted to be incompletely compressed, rounded rather than flattened, and the end insufficiently secured under the latch for the upper jaw. Most causes of clip under-closure are due to operator fault.

failure rate, Consultants 1.9% and when both a Consultant and a Registrar performed the procedure a failure rate of 0.7% was recorded.¹⁷ A medical witness to concur the sterilisation procedure is a legal requirement in some countries.³⁶

Complete or partial tubal transection of the tube

Improper use of the clip (clip over-closure) or diathermy (excess) may lead to tubal transection (partial or complete) and subsequent sterilisation failure through luminal regeneration (i.e. tubal fistula or recanalisation). In such cases, a complete salpingectomy is required to ensure successful sterilisation. Correct use of clip or diathermy is unlikely to transect the tube.²⁶

Applying two clips to each tube

Applying two mechanical clips adjacent to each other on the tube does not decrease the failure rate, but may even increase it if they are applied too closely together.^{26,37,38}

Improper maintenance of mechanical occlusion device applicator

It is a legal requirement that device applicators are well maintained and adequately checked to ensure optimum function. In the case of the Filshie clip, both the manufacturer (Femcare, UK, <http://www.femcare.co.uk>) and MDA strongly recommend that all single Filshie clip applicators

are serviced and readjusted at least once a year or after every 100 procedures. Furthermore, a closing checking gauge should be used prior to every sterilisation procedure to ensure that the applicator functions correctly.

Factors independent of operator error

Spontaneous tubal lumen regeneration

Numerous reports have described tubal lumen regeneration following electrocautery, Falope ring and tubal excision methods, but none have been reported following Filshie or Hulka clips. Those studies that have confirmed tubal lumen regeneration as the actual mechanism of sterilisation of failure are shown in Table 2. However, occurrence of tubal lumen regeneration post-sterilisation exceeds the actual pregnancy occurrence at that time.³⁹ Tubal lumen regeneration occurs through two possible mechanisms:

- Tubo-peritoneal fistula formation, which may be associated with endosalpingiosis, necrosis or tubal atrophy;
- Spontaneous tubal reapproximation associated with tubal reanastomosis and recanalisation.

Mechanical tubal occlusive methods have lower rates of tubo-peritoneal fistula formation than coagulation-based techniques.^{40–42} This may be because mechanical occlusion methods destroy much less tube (approximately 4 mm for clips and 2 cm for rings) than electrocoagulation methods (3–4 cm). However, the exact aetiology of tubal lumen regeneration remains unclear. Other factors such as individual's tubal 'healing' response, pre-existing proliferative

tubal disease, degree of tubal avascularity and interval from operation are likely to modify tubal lumen regeneration ability.^{28,40,43–46} Presently, there is no evidence to suggest that operator fault in sterilisation technique predisposes to tubal lumen regeneration, and therefore this mechanism of sterilisation failure would be considered non-negligent and independent of operator error.

Mechanical failure of occlusion device

Mechanical tubal occlusive device manufacturers for Filshie clip, Hulka clip and Falope ring have not reported spontaneous mechanical failure as a possibility for sterilisation failure, and this concurs with an absence of such cases in the published literature. Nevertheless, there remains at least a theoretical possibility of mechanical material failure, and manufacturers like Femcare offer an examination of the Filshie clips in failed sterilisation to exclude the possibility of this failure mechanism (Femcare, personal communication).

Indirect factors predisposing to sterilisation failure

Tubal patency occurring despite correctly applied sterilisation technique

There is evidence that anatomical tubal patency can occur following a correctly undertaken sterilisation, and has been reported following electrocautery, Falope ring, Hulka clip and partial salpingectomy methods.^{44,47–49} In addition, persisting tubal patency has been described as the mechanism of sterilisation following correctly applied Filshie clips in three cases of Filshie clip failure (Table 2).²⁹

However, persisting anatomical tubal patency does not necessarily imply sterilisation failure, as tubal patency rates of 1–2% at three months and 16% at five years have been noted following correctly applied tubal ligation, with the actual pregnancy occurrence of 1–2% over this time period.⁴⁴ There are three possible mechanisms of tubal patency following correctly undertaken sterilisation:

- *A partially non-occluded segment of tubal lumen has formed within the clip.* This tubal 'knuckle', with a patent lumen, can exist within the completely flattened tube portion inside the clip identifiable only at microscopy. Alternatively, the tubal 'knuckle' may be macroscopically visible as an uncompressed tubal portion. The latter description indicates a negligent sterilisation, as the surgeon should have identified the tubal knuckle at final checking and taken additional precautions to ensure tubal occlusion.
- *Incomplete tubal luminal occlusion by electrocautery desiccation,* despite external appearances suggestive of a satisfactorily diathermised tube. A study has shown that

the use of a current meter (indirectly measuring tubal impedance) may be more sensitive than visual tubal assessment (blanching, swelling or collapse) or a defined coagulation time in predicting complete tubal desiccation. However, this is not yet a legal requirement for electrocautery sterilisation.³⁴

- *Pre-existing utero-tubal structural abnormalities* such as accessory fallopian tube, uterine didelphys⁵⁰ and utero-tubal fistulas.

Woman's age and interval from procedure

A failure-free interval from sterilisation does not guarantee continued success. The longitudinal analysis in the CREST,¹¹ Quebec¹⁴ and Brazil⁵¹ studies show that the greater the time elapsed between surgery, and the younger the age the sterilisation was performed, the higher the cumulative pregnancy failure rate will be. Importantly, most pregnancies after failed sterilisation tend to occur within one to two years. The 1st, 5th and 15th year cumulative probability of pregnancy in the Quebec study were 3/1000, 7/1000 and 9/1000, respectively.³³ In the Brazil study, the cumulative failure rate was 5.4/1000 at 12 months, increasing to 10.4/1000 at 48 months. These data concur with an earlier (1968–1974) large UK prospective study that estimated that of every 1000 women undergoing tubal sterilisation, about 4 would have experienced a pregnancy after one year, 8 after four years and 10 after seven years.⁵²

The synergy effect of age with sterilisation method is illustrated by the CREST's 10-year cumulative probabilities of pregnancy in those cases with young age (below 28 years) and bipolar coagulation (54.3/1000) and young age and clip application (52.1/1000). These rates are higher than the failure rates for each individual method (24.8/1000 for bipolar, 36.5/1000 for clip, 18.5/1000 for all methods and all ages). Furthermore, from the Quebec study, the cumulative risk of sterilisation failure stabilises earlier for the older age group, which has a lower peak than for the younger age group. This results in gradient and plateau

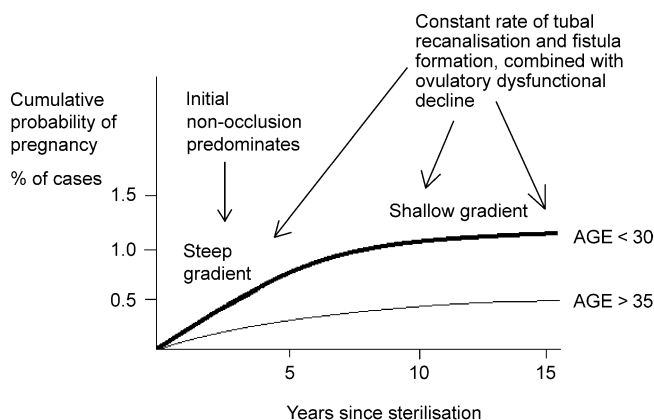


Fig. 2. Clinicopathological mechanisms proposed in sterilisation failure.

differences between the two curves shown in Fig. 2. The gradient is steeper in early years because of combined effects of tubal non-occlusion and tubal lumen regeneration, but in later years the effects of tubal lumen regenerating, increasing age and ovarian failure predominate.

Inadequate practitioner or operating centre experience

The substantial variation in failed sterilisation across centres using the same methods indicates that operating centre experience and practitioner expertise impact on rates of sterilisation failure. The CREST study showed failure rates of 7.1 to 78.0 per 1000 for the Hulka clip and 0 to 42.5 per 1000 for the silicone ring—all dependent upon the operating centres being surveyed.¹¹ Higher failure rates were more common in centres performing fewer annual procedures.

Other groups have shown improper application of the occlusive devices by inexperienced surgeons as a constant factor in sterilisation failure.^{32,53,54} Studies have shown that surgeons consider diathermy to be superior to mechanical tubal occlusion techniques as it allows easier inspection⁵⁵ of the sterilisation procedure,^{56–60} and that Filshie clips are easier to apply than Falope rings³¹ or Hulka clips.²⁴ This indicates that operator preference is likely to have an impact on method-related failure rates.

Pre-existing gynaecological pathology

Pre-existing gynaecological pathology predisposes to sterilisation failure (e.g. pre-existing tubal disease, history of abdominal or pelvic surgery, history of pelvic inflammatory disease increasing the risk of ectopic pregnancy,³⁰ pregnancy or postpartum state (discussed earlier), obesity, prior use of an intrauterine contraceptive device, previous induced abortion, congenital uterine anomalies, fibroids, endometriosis, endosalpingoblastosis and adenomyosis).^{41,58,61–64} The myth that sterilisation protects against pelvic inflammatory disease has recently been challenged.⁶⁵

Following complicated sterilisation, good clinical practice (rather than a legal requirement) dictates testing of tubal patency.^{32,48,66–68} However, a negative dye spill post-sterilisation HSG does not completely preclude the possibility of pregnancy at a later stage.⁶⁹

How to determine the mechanism of sterilisation failure?

A systematic investigative approach is required, and at a minimum should include:

- The use of accurate pregnancy dating, last menstrual period and operative interval to determine if the woman was pregnant before the operation.

- A perpendicular lateral end-on X-ray view of the Filshie or Hulka clip. This is best achieved with the aid of an image intensifier and optimising the woman's position. This will easily identify open clips, and for those clips that appear locked, precise measurements of the clip jaws can be made to determine whether the clip was correctly closed at initial application (Fig. 1).
- Clinical inspection of the pelvis and utero-tubal anatomy at laparoscopy or laparotomy to exclude wrong structures being clipped, missing or open clips or tubal lumen regeneration.
- Testing of tubal patency by X-ray hysterosalpingography, or tubal dye insufflation.
- Tubal histopathology, ideally with clip or ring preserved *in situ* on salpingectomy specimen. A new technique of embedding and sectioning permits sections to be made while the metal clips are *in situ*.⁷⁰

A simple lateral and antero-posterior pelvic X-ray can often identify clips or rings that are missing, have markedly ectopic locations or are incorrectly locked or open, and may be a useful adjunct before embarking on the systematic approach described above. No studies have yet examined a potential role for computed tomography or magnetic resonance imaging for non-invasive evaluation of failed sterilisation.

Manufacturers of the Filshie clip (Femcare) also provide an investigation service for any case of Filshie clip failure, anywhere in the world, to determine if either material, hinge or lock failure [under-closure and over-closure (Fig. 1)] may have been contributory to the failure mechanism.

Missing Filshie clips, clip migration and dropped 'lost' Filshie clips: management issues

Good clinical practice dictates that proof of tubal occlusion (X-ray HSG or tubal dye insufflation or histology of salpingectomy) should be undertaken once missing clips are identified, not only when examining failed sterilisation cases, but also at laparoscopy or laparotomy for other reasons.^{26,71} However, missing clips do not necessarily indicate failed application or imminent pregnancy failure, as over time there is a tendency for clips to migrate and even be expelled without resulting in clinical morbidity.^{27,31,72}

It is estimated that over 25% of women will experience a migration of one or more Filshie clips.⁷² The tissue between the Filshie clip jaws normally undergoes avascular necrosis and fibrosis, leaving two healed stumps, which tend to separate, permitting clip displacement.

Filshie clips may be inadvertently dropped during laparoscopic sterilisation. If possible, the clip should be laparoscopically removed upon completion of the sterilisation procedure. However, if the clip is unretrievable, either open

or closed, it should be left. Performing a laparotomy would subject the woman to greater operative morbidity risk than leaving the lost clip in the abdomen. To date, there have been no reports of any serious morbidity or mortality consequent to a lost clip. Women should be informed of the lost clip and reassured accordingly.²⁶

Proposed clinicopathological mechanism of sterilisation failure

Based on the data depicted in Table 2, and review of world literature, evidence for sterilisation failure reveals distinct trends:

- When considering all cases of failed sterilisation for all methods, initial tubal non-occlusion through operator error is the most common mechanism of failure.
- A greater proportion of early (within one year from operation) than late (after one year from operation) sterilisation failures are due to initial tubal non-occlusion. In contrast, a greater proportion of late compared with early sterilisation failures arise as a result of tubal lumen regeneration (tubal fistula formation or tubal recanalisation).
- Ectopic pregnancy is more likely to occur in cases with: late compared with early sterilisation failure; when electrocautery compared with mechanical occlusion is used; there is pre-existing pelvic inflammatory disease. The CREST study showed that for all methods combined, the risk of ectopic pregnancy was significantly higher after three years (5.3 vs 2.0 per 1000 procedures). A closer analysis shows that the 10-year ectopic pregnancy probabilities per 1000 procedures were highest for bipolar coagulation (17.1), Hulka clip (8.5), interval partial salpingectomy (7.5), Silicone ring (7.3) and unipolar coagulation (1.8).
- Mechanical clip occlusion methods are observed to have lower rates of tubo-peritoneal fistula formation than coagulation-based techniques.
- The evidence suggests a minimal interval of one year between electrocautery and evidence of functional tubo-peritoneal fistula.^{73,74} This evidence may also be applicable to mechanical occlusion- and excision-based sterilisation methods.

These trends can be inter-related in the form of a unifying clinicopathological mechanism. We propose that initial tubal non-occlusion is more likely to lead to early sterilisation failure (within one year), and as it is less likely to damage the tube, the resulting pregnancy is more likely to be intrauterine than ectopic. Conversely, late sterilisation failure arising from tubal recanalisation or fistula formation is more likely to result in an abnormal lumen predisposing to a decreased risk of pregnancy, but should it occur there would be an increased risk of ectopic pregnancy. This is graphically illustrated in Fig. 2.

Can the clinicopathological mechanism also apply to sterilisation reversal?

The factors that predispose to sterilisation failure are usually identical to those that favour successful reversal of sterilisation. This provides further evidence of a unifying mechanism of tubal function and regenerative capacity based on the extent of initial tubal damage and time-dependent transformation. Sterilisation reversal success is more likely: when the time interval from original sterilisation is shorter, in younger women and when mechanical occlusion compared with electrocautery was used at original sterilisation.^{14,75} Histological findings that correlate with reduced reanastomotic success rate over time are the gradual appearance of proximal luminal dilatation, plical attenuation, chronic inflammatory infiltrates with pseudopolyp formation and plical thickening in the distal segment of the tube, which have also been identified in failed sterilisation cases.^{49,76,77} Sterilisation reversal achieves pregnancy rates of only 35–50% despite tubal patency rates approaching 90%,^{78,79} suggesting that additional complex male and female factors being necessary for conception to occur in addition to operator technical skill in re-establishing tubal patency.

Medico-legal checklist for non-negligent sterilisation

This expands on the RCOG-based recommendations¹ and uses information listed in this review.

1. Clear contemporaneous documentation within notes.
 2. Pre-operative checklist.
- Appropriate medical history and clinical examination
 - The reason for the sterilisation should be stated
 - Adequate counselling and informed consent: failure rate advised as 1 in 200 lifetime risk (increased at postpartum or post-abortion) or 2–3/1000 over 10 years for Filshie clip; failure can occur anytime after the procedure; failure may be ectopic pregnancy; permanent non-reversible procedure; sterilisation performed by laparoscopic mechanical clip or ring method (primary method of sterilisation in the UK); need for contraception before and after operation; risk of operative complications (e.g. laparotomy); increased risk of hysterectomy but decreased risk of ovarian and breast cancer; no disturbance of menses if performed after 30 years age; alternative long term contraceptive methods (e.g. Mirena Coil and vasectomy) must be discussed
 - Providing the woman with a written patient information leaflet on sterilisation
 - Increased operative risk (specifically laparotomy) to women with coexistent medical disorders (e.g. obesity) or prior abdominal surgery

- In women under the age of 30 years, or those without children who request sterilisation, the sterilisation decision should be sanctioned by a consultant who has talked with the woman.

3. Immediate pre-operative.

- Assessment for risk of pregnancy before sterilisation—routine use of urine pregnancy test, last menstrual period, contraception used during cycle
- Validate consent for sterilisation to continue.

4. Operator.

Performed by an experienced operator (RCOG level II accredited or competent through operative experience of at least 25 correctly undertaken supervised laparoscopic sterilisations); capable of performing at least two methods of sterilisation.

5. Sterilisation technique.

- Filshie clip: using a well-maintained Filshie clip applicator, with prior closure gauge checking, clip applied on the correct structure, at tubal mid-isthmic site, with perpendicular clip alignment, complete tubal lumen encapsulation without protruding tubal knuckle or tubal transection, correctly flattened upper clip jaw with its end sufficiently locked under the latch for the upper jaw (Fig. 1).
- Electrocautery: duration, number and length of tubal areas targeted, and type of electrocautery current used (should be at least three areas, cutting waveform, 25 W); should occlude mid to distal portion of isthmic part of the tube, at least 2 cm from the cornu.
- Checking procedure: clear documentation of checking of structure/site/application as being correct after the procedure performed by visual inspection and instrumental manipulation of the fallopian tube. Clearly focussed photographs of the clips on the fallopian tubes would be useful but currently not a legal requirement in the UK.

6. Postprocedure.

- Woman is informed of the method of sterilisation, confirmed in GP discharge letter, and need for contraceptive precautions until next menstrual cycle.
- Any technically difficult cases or doubts of sterilisation success should be referred for tubal patency testing.

Conclusions

We have proposed a clinicopathological mechanism of sterilisation failure. Current evidence suggests that if sterilisation failure occurs before one year, pregnancy is due to

operator fault because of tubal non-occlusion, and the pregnancy is more likely to be intrauterine. Conversely, sterilisation failure after one year is more likely due to natural tubal lumen regeneration through tubal recanalisation or fistula formation and the pregnancy is more likely to be an ectopic pregnancy. The RCOG working group recommendation for a national register of sterilisation failure should help to clarify long term failure rates and enhance good medical practice. Expansion of this data set is urgently required, which we have commenced in our institution. This includes histopathological and radiological expertise. This should include precise knowledge of the method of sterilisation, time interval to failure and mechanism of sterilisation failure (especially the contribution of operator fault). These factors may show obvious trends relating to early/late sterilisation failure and help to validate the proposed clinicopathological mechanism. Furthermore, this article provides practical advice on how to perform laparoscopic sterilisation safely, how to minimise failure and manage failed sterilisation medico-legally.

Conflict of interest

None declared.

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