

# Failure and Regret After Laparoscopic Filshie Clip Sterilization Under Local Anesthetic

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**OBJECTIVE:** To estimate the failure, regret, and reversal rates 5 or more years after laparoscopic Filshie clip sterilization using local anesthesia.

**METHODS:** A total of 1,101 women underwent Filshie clip sterilization between 1983 and 2002. They completed follow-up questionnaires that were analyzed for the following outcomes: failed sterilization, regret after the operation, and sterilization reversal.

**RESULTS:** Two hundred thirty-three of 968 (24%) eligible women sent the questionnaire had moved from their last known address. Of the remaining 735 women, 573 (78%) completed the questionnaire: 223 (39%) 5–6 years after the operation, 175 (30%) after 7–9 years, and 175 (30%) after 10–15 years. One pregnancy occurred 10 months after surgery, and one woman had the procedure repeated when unilateral tubal patency was identified by hysterosalpingography 3 weeks after surgery. Twenty-four (4%) women regretted having the operation; 7 (1.2%) women had a reversal operation, and all subsequently conceived.

**CONCLUSION:** Failure after tubal sterilization using Filshie clips is less than 1:500 operations. Patient selection and surgeons' experience may have influenced these results. Regret occurred in a small proportion.

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**LEVEL OF EVIDENCE: III**

At the introduction of laparoscopic sterilization under local anesthetic in a private nonprofit clinic in 1983, a prospective continuing audit was planned as part of patient care and general governance of the clinic. Given the anticipated difficulties with a retrospective survey of the relatively young and potentially mobile patient population involved, we reasoned that a prospective study might reduce bias in data collection and enhance the proportion of women who provide follow-up data. The observations were recorded to assess any effect on menstrual function, regret at being sterilized, request for reversal of the operation, and any subsequent planned and unplanned pregnancies.

The Royal College of Obstetricians and Gynaecologists (RCOG) Guideline on male and female sterilization, published in 2004,<sup>1</sup> concluded that it would be good practice to conduct a retrospective audit of surgeons' outcomes if more than one pregnancy occurred after sterilization procedures. We therefore had initiated our audit before there had been any failed sterilizations. The objective of our study was to estimate the failure, regret, and reversal rates 5 or more years after laparoscopic Filshie clip sterilization using local anesthesia.

## MATERIALS AND METHODS

Women were self-selected for operation and referred to the clinic by their General Practitioner; the majority were self-funding. At the outset, women were counseled and examined, usually by the gynecologist who would operate, as subsequently recommended

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by the RCOG.<sup>1</sup> A list of exclusion criteria was defined to which there was strict adherence. Exclusions included unusually anxious women, body weight more than 76 kg, a history of bleeding diathesis, diabetes mellitus, grand mal epilepsy, cardiac or chronic pulmonary disease, previous lower midline abdominal surgical incision, pelvic surgery, or pelvic peritonitis. Demographic details and operative findings and outcomes were recorded for all women.

Of the four gynecologic surgeons, three were consultants, and one was a senior registrar who performed 26 operations before appointment to a consultant position elsewhere. A middle-grade anesthetist was present at each operating session and provided premedication, local anesthetic injections into the abdominal wall before the surgical procedure, and when necessary postoperative analgesia. Emergency services were available using the hospital cardiac arrest team.

The operative technique changed little during 1983–2002 study period, with all women managed as day-cases on a Saturday morning. The technique has been described previously.<sup>2</sup> Unless rejected by the patient, the majority were given oral premedication, most commonly aspirin with papaveretum or diclofenac (808 cases) or intravenous midazolam or pethidine (289 cases). Operative anesthesia was provided by 20–30 mL 1% lidocaine with epinephrine (1:200,000) injected at sites identified by the surgeon in the subumbilical and suprapubic regions, ensuring that the infiltration reached the peritoneal layer. After distension of the abdomen with 1–3 L nitrous oxide, a 7-mm laparoscope was used for all procedures. A Filshie clip<sup>3</sup> was applied to each Fallopian tube as a routine, with an additional clip if the surgeon was concerned about the application of the first clip on either side. During the course of the study, 3–5 mL of 1% lidocaine was dripped under direct vision onto each Fallopian tube at the proposed site of clip application. The analgesic benefit of this procedure was convincingly established through a randomized controlled trial.<sup>4</sup> At the end of the operation, any surgical difficulty was recorded; if there were concerns about the adequacy of tubal occlusion, hysterosalpingography was performed before recommending abandoning alternative contraception.

All women signed a consent form before the operation was performed. With the patient's approval, her partner was also asked to sign his agreement with her decision. After the operation, the patient was asked to return an early recovery questionnaire detailing postoperative progress, and she was also advised that a further questionnaire enquir-

ing about subsequent health would be sent. This approach to follow-up was established before the introduction of current guidelines adopted by research ethics committees in the United Kingdom. Even so, the principles contained in the Declaration of Helsinki were adopted and procedures were used to maintain the confidentiality of the patient. In 1991, the early recovery questionnaire included a written request for the patient to indicate whether she was agreeable to being contacted in future. Before 1991, questionnaires were sent only to women who had returned the early recovery questionnaire and whose partner had signed his agreement to the operation. Only one questionnaire was sent to each woman, at a variable time after sterilization. We did not ask whether information could be requested from General Practitioners when personal contact failed, and as a consequence, we had no way of obtaining further information from nonresponders to our questionnaire.

In the follow-up questionnaire, women were asked if, following sterilization, they

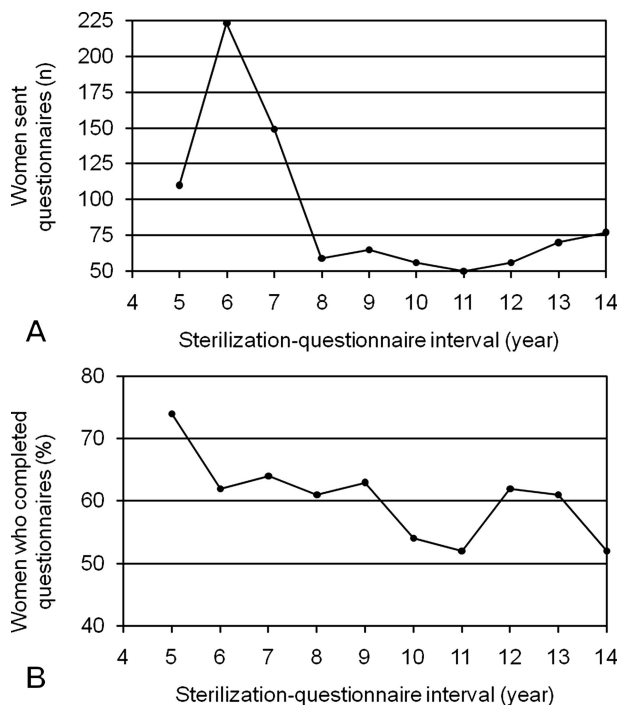
- regretted being sterilized,
- had undergone sterilization reversal,
- had been pregnant since the sterilization,
- wished to make further free-hand comments.

Statistical analyses were performed with  $\chi^2$  test,  $\chi^2$  test for trend,<sup>5</sup> and odds ratios (ORs) with 95% confidence intervals (CIs) using binomial distribution and GraphPad Prism 3 (GraphPad Software Inc., San Diego, CA).

## RESULTS

A total of 1,101 women underwent the operation between 1983 and 2002, with the four surgeons each performing 26, 163, 374, and 538 operations, respectively; 15 anesthetists managed between five and 324 women each. There was no requirement for emergency intervention under general anesthesia, and no major early or long-term morbidity was identified. The hospital cardiac arrest team was never required. The operation was not completed for six women (0.5%) because of difficulties with pain or nonnegotiable pelvic adhesions encountered during the operation. Three women were advised to undergo a hysterosalpingogram 3 weeks after surgery when adhesions compromised the views of the pelvis: Successful bilateral tubal occlusion was confirmed in two, and one patient required a second operation under general anesthetic because of inadequate occlusion on one side. One thousand fifteen (92%) women completed and returned the early recovery questionnaire;





**Fig. 1.** Response rate for questionnaire completion related to the interval since sterilization. **A.** The number of women sent questionnaires. **B.** The percentage of women who completed the questionnaires.

MacKenzie. *Filshie Clip Sterilization Failure. Obstet Gynecol* 2009.

968 of these women were eligible for inclusion in the long-term study.

Figure 1 illustrates the numbers of women and the intervals between surgery and questionnaire completion, with the percentage response rates for each year after sterilization. The decline in response rate seen with the increased interval between sterilization and follow-up was not significant (Chi<sup>2</sup> test for trend 2.481, *df* 1, *P* = .12). Table 1 documents the characteristics of all women at the time of operation separately, identifying those who were sent a follow-up questionnaire and those responding: 233 had moved from their last known address. Of the remaining 735, 573 (78%) provided long-term follow-up data, and a response was not provided by 163. Of the 573 completed questionnaires, 223 (39%) were completed 5–6 years after the operation, 175 (30%) were completed after 7–9 years, and 171 (30%) were completed after 10–15 years (Table 2).

One woman who conceived 10 months after her sterilization was reported to us by her General Practitioner. She was 42 years old when sterilized in May 1994 and she conceived in March 1995, miscarrying during the first trimester. At the time of surgery,

adhesions were noted which obscured the lateral end of her left Fallopian tube, but the surgeon concluded he had achieved satisfactory clip placement. The reason for the failure could not be established because the patient declined further investigation or repeat surgery, and her partner subsequently had a vasectomy performed by the clinic. This respondent also reported this failure when completing her questionnaire 6 years after sterilization. We were not advised of any other failures. This gives a failure rate of 0.175%, with 95% CI 0.004–0.968% (exact binomial distribution).

Twenty-four of the 573 women (4.2%, 95% CI 2.5%, 5.8%) reported some regrets after being sterilized: details at the time of the operation for these women are shown in Table 2 together with their ages at the time of questionnaire completion. We did not ask at what stage after sterilization their regret surfaced; 4% expressed regret 5–6 years and 7–9 years after sterilization compared with 5.0% 10–15 years after sterilization. In addition to the five women listed in Table 2 who had a reversal of sterilization, two further women had the operation reversed without expressing regret, one because of the death of one of her children and the other because of a new relationship. All seven women undergoing a reversal operation conceived, six delivering a live baby and one experiencing a confirmed spontaneous abortion at 10 weeks of gestation.

## DISCUSSION

The rate of patient response to follow-up questionnaires is consistent with that reported in similar studies.<sup>6,7</sup> Demographic characteristics and the proportion in whom technical difficulty was experienced during the operation were similar in those followed up and the remaining women, apart from the larger proportion of married women among those followed up. This was doubtless due to the initial policy of restricting questionnaire follow-up to women whose partners had signed their agreement to the operation, obviously leading to a smaller proportion of single and previously married women being audited in the early years. One might speculate that regret and sterilization reversal would be higher in the unmarried or previously married population. However, although we have no reason to anticipate that the low incidence of failed sterilization would be different when follow-up data were not available, we cannot rule out the possibility of failure to ascertain cases.

The 1996 collaborative review of sterilization (CREST),<sup>7</sup> studying 10,685 women prospectively who were sterilized between 1978 and 1986 in nine med-



**Table 1. Details at the Time of Surgery According to Completion of Follow-up Questionnaires**

	No Follow-up Data Available					Follow-up Data Available (n=573)	P
	All Women (N=1,101)	Not Circulated (n=133)	Moved Away (n=232)	No Response (n=163)	Total (n=528)		
Age (y)							.10*
20–29	78 (7)	7 (5)	25 (11)	15 (9)	47 (9)	31 (5)	
30–39	705 (64)	80 (60)	152 (66)	102 (63)	334 (63)	371 (65)	
40–49	315 (29)	45 (34)	54 (23)	46 (28)	146 (27)	170 (30)	
Not recorded	2 (0)	1 (1)	1 (0)	0 (0)	1 (0)	1 (0)	
Civil state							<.001*†
Married	933 (85)	69 (52)	201 (87)	136 (83)	406 (77)	527 (92)	
Previously married	112 (10)	57 (43)	19 (8)	11 (7)	87 (16)	25 (4)	
Single	56 (5)	7 (5)	12 (5)	16 (10)	35 (7)	21 (4)	
Number of children							.03*
0	126 (11)	18 (14)	28 (12)	22 (13)	68 (13)	58 (10)	
1	92 (8)	16 (12)	17 (7)	16 (10)	49 (9)	43 (8)	
2	542 (49)	57 (43)	122 (53)	81 (50)	260 (49)	282 (49)	
More than 2	341 (31)	42 (32)	65 (28)	44 (27)	151 (31)	190 (32)	
Aged less than 2 y	195 (18)	15 (11)	44 (19)	38 (23)	97 (18)	98 (17)	.64‡
Difficult operation	25 (2)	4 (3)	6 (3)	5 (3)	15 (3)	11 (2)	0.33‡

Data are n (%). P values come from comparison of follow-up with no follow-up.

\* From  $\chi^2$  test for trend.

† Artifact of follow-up policy (see text).

‡ From  $\chi^2$  test.

ical centers in the United States provided follow-up data on 71% women 5 years after operation and 58% after 8–14 years. This report suggested that the spring-loaded clip was one of the least reliable methods, with a failure rate in 414 women aged 34–44 years at sterilization of 1.0% at 5 years, rising to 1.8% by 10 years. A retrospective study<sup>8</sup> of women sterilized during 1980–1999 in Quebec reported a failure rate of 0.7% within 5 years of the operation, rising to 0.9% within 15 years. Numbers and proportions of the sterilization techniques used were not reported, although few were performed using the spring-loaded clip, and the Filshie clip was the preferred option. The authors acknowledged that their identification strategy might have underestimated the true failure rate. Taking the rates reported at face value, for the 417 women aged 34–44 years in our study, there should have been at least three to five failures. A retrospective postal survey<sup>9</sup> in Western Australia relying on the gynecologists' memory of failures with the Filshie clip reported a rate around 2–3 per 1,000 operations. This accords more with our findings, but the methodology used is open to serious challenge.

Why the discrepancy between our prospectively collected results and those from the United States and Canada? Our selection criteria could be relevant, as could the surgical technique in our study, although abdominal distension is restricted to reduce patient discomfort using local anesthetic. In consequence,

visualization of the pelvic organs can be more difficult than with general anesthesia, with three patients requiring hystero-graphic reassurance of adequate tubal occlusion before abandoning alternative birth control. Although not reported in the U.S.<sup>7</sup> and Canadian<sup>8</sup> studies, general and regional anesthesia was most probably used, and the surgery was in teaching centers where surgeons might have been marginally less experienced; details were not provided about the seniority of the surgeons involved. Greater experience of the surgeons in our study might have been relevant despite the increased operative demands required with local anesthesia. The most likely explanation, however, is the design of the Filshie clip, with the silicon inserts that expand to accommodate the space left through shrinkage of the compressed Fallopian tube after clip application. This clip was not available for use in the CREST study, where many of the failures were late, between 1 and 10 years after surgery, which supports this theory. As Varma and Gupta<sup>10</sup> have suggested, failures of sterilization identified after the first 12 months are more likely to represent recanalization than malpositioning of the occluding clip. Denominator data in the Quebec<sup>8</sup> study for the method of sterilization used in the successful as well as the failed cases might help to address this possibility.

Regret after female sterilization has been reported by 2–26% women undergoing the operation<sup>11</sup> and has



**Table 2. Women Expressing Regret and Having Reversal of Sterilization**

Age (y) at		Marital Status at Sterilization	Presterilization Contraception	Number of Children	Sterilization Reversal*
Sterilization	Follow-up				
24	38	Married	Combined pill	2	Yes
27	40	Married	Combined pill	1	
30	43	Married	Combined pill	2	
30	38	Married	Combined pill	3	
30	37	Married	Combined pill	2	
30	35	Married	Condom	3 <sup>†</sup>	
30	35	Married	Condom	2	
31	42	Married	Progestin-only pill	2 <sup>†</sup>	Yes
31	40	Married	Diaphragm	2 <sup>†</sup>	
31	39	Single	Intrauterine device	2 <sup>†</sup>	Yes
31	37	Married	Combined pill	3	Yes
32	43	Married	Condom	3	
32	38	Previously married	Condom	2	
33	43	Married	Progestin only pill	2	Yes
34	47	Married	Condom	2	
34	40	Married	Combined pill	2	
35	41	Married	Combined pill	2	
37	49	Married	Progestin-only pill	3 <sup>†</sup>	
37	44	Married	Abstinence	2	
38	48	Married	Progestin-only pill	3 <sup>†</sup>	
38	45	Married	Condom	3	
40	47	Married	Condom	1	
42	48	Married	Condom	2	
44	50	Married	Not recorded	3	

\* Two women had sterilization reversal without previous regret (see text).

† Youngest child aged younger than 2 years.

been reported as three times more common for women aged 30 years and younger at sterilization compared with older women.<sup>12</sup> The regret rate was 7% in the CREST study,<sup>7</sup> in which 88% women had delivered at least two children compared with 4% and 82%, respectively, in our study. The retrospective study from Quebec<sup>8</sup> did not report on regret rates or parity but noted that 1.8% of the population had undergone sterilization reversal, similar to the 1.2% in our study but higher than the 0.2% reported in the CREST study. The majority of studies assessing frequency of sterilization reversal report rates of approximately 1–2%.<sup>13</sup> Aside from differential ascertainment, the explanation for these differences is likely to be economic: Reversals in Quebec were provided cost-free, whereas in the United States they were unlikely to be funded by insurance. In the United Kingdom, funding for the operation by the National Health Service was withdrawn during the early 1990s and thereafter private insurance policies were unlikely to cover the costs. Nevertheless, it was reassuring to note the high conception (100%) and delivery (86%) rates after reversal in our study, contrasting with the 61% conception and 48% delivery rates reported in Quebec. Success rates be-

tween 25% and 82% are commonly quoted.<sup>14,15</sup> It is tempting to speculate that our reported success is related to the limited tubal damage caused by the Filshie clip, as others have suggested; however, large prospective studies are required to prove this hypothesis.

Our study enhances the evidence on which the 2004 RCOG Guideline<sup>1</sup> was based, that the Filshie clip is capable of being considerably more effective than the variety of methods in the CREST study<sup>7</sup> (which by 10 years averaged 17 failures per 1,000 operations). Our rate of one to two failures per 1,000 sterilizations (one conception ascertained and one preemptive early reoperation in 1,101 sterilizations) is compatible with the two to three per 1,000 in the retrospective study of 30,000 cases by Kovacs et al,<sup>9</sup> which seems to be the main evidence base for the RCOG. The 4% expressing regret, although at the lower end of the reported range, nevertheless highlights the inability of careful counseling by the referring General Practitioner and the gynecologist or predictors such as young age to eliminate this outcome.

## REFERENCES

1. Male and female sterilisation. In: Clinical Governance and Standards Department of the RCOG. Evidence based Clinical Guideline Number 4. (UK): RCOG Press; 2004. p. 1–122.



2. MacKenzie IZ, Turner E, O'Sullivan GM, Guillebaud J. Two hundred out-patient laparoscopic clip sterilizations using local anaesthesia. *Br J Obstet Gynaecol* 1987;94:449-53.
3. Filshie GM, Casey D, Pogmore JR, Dutton AG, Symonds EM, Peake AB. The titanium/silicone rubber clip for female sterilization. *Br J Obstet Gynaecol* 1981;88:655-62.
4. Garwood S, Reeder M, MacKenzie IZ, Guillebaud J. Tubal surface lidocaine mediates pre-emptive analgesia in awake laparoscopic sterilization: a prospective, randomized clinical trial. *Am J Obstet Gynecol* 2002;186:383-8.
5. Altman DG. *Practical statistics for medical research*. 1st ed. London (UK): Chapman & Hall; 1991.
6. Frank P, Ferry S, Moorhead T, Hannaford P. Use of a postal questionnaire to estimate the likely under-diagnosis of asthma-like illness in adults. *Br J Gen Pract* 1996;46:295-7.
7. Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. *Am J Obstet Gynecol* 1996;174:1161-8.
8. Trussell J, Guilbert E, Hedley A. Sterilization failure, sterilization reversal, and pregnancy after sterilization reversal in Quebec. *Obstet Gynecol* 2003;101:677-84.
9. Kovacs GT, Krins AJ. Female sterilisations with Filshie clips: what is the risk of failure? A retrospective survey of 30,000 applications. *J Fam Plann Reprod Health Care* 2002;28:34-5.
10. Varma R, Gupta JK. Predicting negligence in female sterilization failure using time interval to sterilization failure: analysis of 131 cases. *Hum Reprod* 2007;22:2437-43.
11. Chi IC, Jones DB. Incidence, risk factors, and prevention of poststerilization regret in women: an updated international review from an epidemiological perspective. *Obstet Gynecol Surv* 1994;49:722-32.
12. Hillis SD, Marchbanks PA, Tylor LR, Peterson HB. Poststerilization regret: findings from the United States Collaborative Review of Sterilization. *Obstet Gynecol* 1999;93:889-95.
13. Van Voorhis BJ. Comparison of tubal ligation reversal procedures. *Clin Obstet Gynecol* 2000;43:641-9.
14. Reversal of Filshie clip female sterilisation. In: Phillips JM, editor. *Second World Congress of Endoscopic Female Sterilisation*. Williamsburg (VA); 1988.
15. Nwagbara PN, Stibbe HM, Browning AJ, Tonks AM. Reversal of female sterilisation experience in a district general hospital. *J Obstet Gynaecol* 1997;17:293-7.



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