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Contemporary hysteroscopic methods for female sterilization

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ABSTRACT

A permanent contraceptive method that avoids abdominal incisions and general anesthetic should be safer than sterilization by laparoscopy or laparotomy. In theory, the transcervical route ought to be ideal for female sterilization. However, past attempts have not seen widespread success, and contemporary efforts demonstrate that challenges to the creation of an ideal transcervical sterilization technique continue to exist. After 6 years of use, clinical data and real-world experience indicate that the Essure permanent birth control system is a viable option. Efficacy of 99.74% has been demonstrated. Adverse effects and risks are low. Patient satisfaction is high. Successful placement is observed in worldwide marketing. It can be placed in the office setting, which offsets the relatively high cost of the device. Recent data suggest that patients and surgeons are choosing hysteroscopic sterilization over laparoscopic and postpartum sterilization. Adiana emerged in 2009 as a second hysteroscopic sterilization option. Challenges continue to exist for transcervical sterilization. Compliance with post-procedure confirmation imaging is not universal. Real-world contraception failures are seen in a setting of protocol non-compliance. However, extrapolation of the failure rates in real-world use seems to be comparable with other laparoscopic and abdominal sterilization methods.

1. Introduction

Female sterilization is the single most prevalent method of contraception in the world [1]. United Nations data for 2007 show that of the 1.1 billion partnered women practicing contraception, 20% were using female sterilization. The next most prevalent modern methods were intrauterine devices (16%), oral contraceptives (9%), condoms (6%), male sterilization (3%), and injectable hormones (3%). Permanent female contraception routinely entails exposing women to abdominal incisions, and thus to the related risks of surgery and anesthesia. Although they are generally extremely safe, the traditional methods for sterilization in women carry risks for major complications, including mortality [2]. A permanent contraceptive method that avoids abdominal incisions and general anesthesia should be safer than sterilization by laparoscopy or laparotomy. In theory, the transcervical route ought to be ideal for female sterilization. However, past attempts have not seen widespread success, and contemporary efforts demonstrate the challenges remaining for an optimal method to accomplish tubal occlusion transcervically.

1.1. History: Electrosurgical energy

Cooper [3] presented a detailed history of transcervical sterilization in 1992. First attempted in the 1920s [4], hysteroscopic application of electrocautery to cause infertility saw a resurgence in the 1970s. Quinones et al. [5] performed over 1200 hysteroscopic sterilizations with tubal endocoagulation and observed a bilateral occlusion rate of 80%. No pregnancies occurred after 1 year of observation in 513 patients whose hysterosalpingogram had shown bilateral occlusion. However, of 423 patients monitored for 5 years in whom the hysterosalpingogram had demonstrated occlusion, 3.8% eventually became pregnant [3]. A subsequent collaborative series showed a 3.2% pregnancy rate among patients with a hysterosalpingogram showing occlusion, and a 3.2% major complication rate, including a death after bowel injury [6].

1.2. History: Mechanical devices

Many mechanical devices for tubal occlusion have been proposed or tried in animals and humans, with limited success. Tube-occluding substances have included hydrogel/nylon (P-block) [7]; silicone Ovabloc [8]; polyethylene [9]; nylon [10]; and polytetrafluoroethylene [11].

1.3. History: Chemical

Quinacrine hydrochloride has been studied extensively. Quinacrine can be instilled blindly or hysteroscopically. It causes inflammation and subsequent scar tissue formation within the fallopian tubes. Over 100 000 quinacrine sterilization procedures have been performed worldwide, but the technique is marred in controversy [12].

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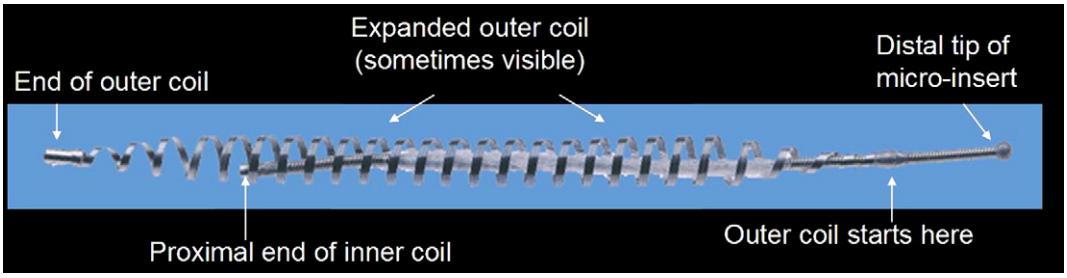

Fig. 1. Essure design.

1.4. Lessons from the past

Many of these methods are available options for women worldwide. However, none sees widespread use. Kerin [13] cites improvements in the design and application of fallopian tube cannulation devices used for infertility treatments as the foundation for the creation of successful transcervical sterilization techniques. Catheter technology has advanced adequately to be able to reliably negotiate an occluding substance into the fallopian tubes. Cooper [3] identifies that, in the past, mechanical devices failed because they migrated or were expelled too frequently. He emphasizes that in order to anchor an implant for tubal occlusion, one must take advantage of the less-compliant uterine portion of the fallopian tube. Some past failures occurred because the implanted medium did not result in complete tubal occlusion. Some devices were temporary; others did not adhere closely enough to the tubal endothelium to provide adequate occlusion.

2. Essure system

The Essure Permanent Birth Control system (Conceptus; Mountain View, CA, USA) was marketed first in Australia and Singapore. Approval by the European Union followed in 2001, and by the United States Food and Drug Administration late in 2002. It is now also available across North, Central, and South America, and in parts of Asia and the Middle East.

2.1. Design

The micro-insert is made of a flexible stainless steel inner coil, surrounded by a dynamic outer coil composed of nickel titanium (Nitinol). Polyethylene terephthalate (PET) fibers run along and through the inner coil. (Fig. 1) In its expanded form, the implant is about 4 cm long and up to 2 mm in diameter. The disposable delivery system includes a nitinol delivery wire, a release catheter, a hydrophilic delivery catheter, and a handle with mechanisms to retract the release catheter and the delivery catheter. The materials that compose the micro-insert have a long history of use in medical and surgical devices. For example, Dacron (Invista; Charlotte, NC, USA), a polyester made of PET fibers, has been used in suture, grafts, and stents for about 40 years. Tubal occlusion occurs because of tissue reaction toward the presence of the PET fibers. The stainless steel-nickel titanium coil serves as an anchor within the utero-tubal junction, which keeps the PET fibers in the proper location for tissue in-growth to occur following placement. The PET fibers elicit a benign local inflammatory response, which peaks between 2 and 3 weeks after placement. This inflammatory response gradually resolves over a 10-week period.

2.2. Placement

Placement of the Essure micro-coils requires a rigid hysteroscope with a 5-Fr operating channel. Most commercially available hysteroscopes have a 5.5 mm outer diameter operating sheath with inflow and outflow ports for a fluid distending medium. Warmed normal saline is typically used for distension. After performing diagnostic hysteroscopy, and confirming that bilateral placement is possible, the catheter is introduced under direct visualization into a fallopian tube. Delivery and release catheters are retracted, and the coil expands to anchor itself in the tube. After detaching the implant from a guide wire, the micro-coil spans the utero–tubal junction. Part of the micro-coil trails into the uterine cavity, and the rest of the coil remains within the fallopian tube (Fig. 2).

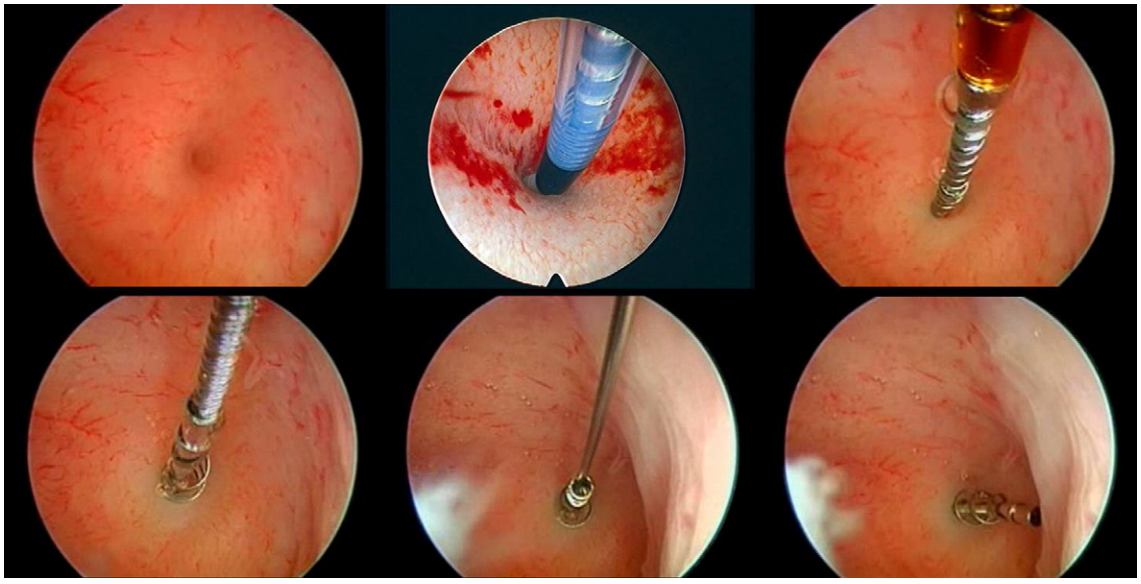

Fig. 2. Placement procedure.