

Essure

A Hysteroscopic Approach to female sterilization

Sara Barton
Reproductive Choice Elective
January 21, 2005

Female Sterilization

- ▶ Chosen by 28% of women who use contraception
- ▶ Most used method for definite contraception in the United States
- ▶ > 10 million procedures performed
- ▶ Covered by insurance
- ▶ Safe and effective
- ▶ Options include: laparotomy, laparoscopy and transcervical
 - majority of sterilization procedures in the US involve laparoscopy performed under general anesthesia
 - risks associated with general anesthesia
 - vascular damage, injury to the bowel, bladder, or uterus, or unintended laparotomy.
 - postoperative pain

What is Essure

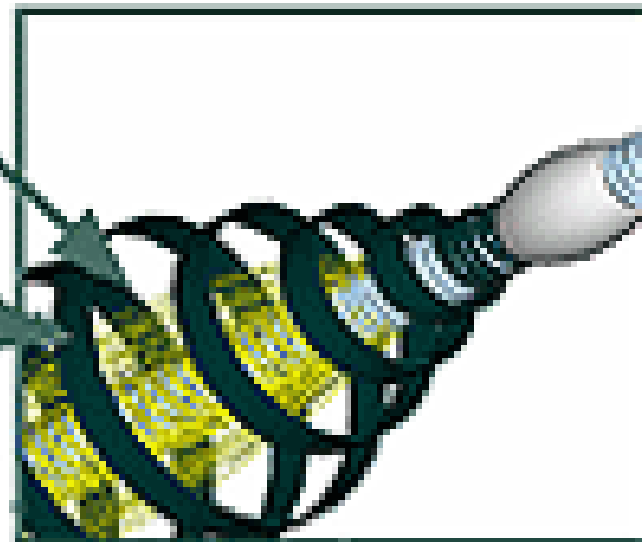
- ▶ Hysteroscopic approach to place micro-inserts into the fallopian tubes
- ▶ Tissue growth in and around the inserts blocks the fallopian tubes achieving tubal occlusion
- ▶ Permanent protection against pregnancy
- ▶ FDA approved in November 2002

Essure System Overview: Micro-insert Design

Fibers (PET)

Dynamic Expanding
Superelastic Outer Coil

Wound Down Diameter 0.8 mm
Expanded Diameter 1.5 - 2.0 mm



Micro-Insert Length = 4cm



Steps to Essure Placement

1. Paracervical block is administered, hysteroscope with attached camera is inserted through the cervix into the uterus.
2. Catheter is passed through the hysteroscope and directed to the ostium of the fallopian tube
3. Micro-insert is positioned in the proximal portion of the fallopian tube and then detached
4. Catheter is removed
5. Over the next 3 months, fibers in the insert cause a tissue response and tissue ingrowth occludes the fallopian tubes
6. HSG is done after 3 months to confirm occlusion and location

Mechanism of Action

- ▶ Micro-insert is flexible and dynamic and accounts for differences in women.
- ▶ The diameter of the micro insert is larger trailing into the uterus than within the tubal lumen. This difference in the diameters is intended to prevent migration toward the peritoneal cavity.
- ▶ The PET fibers elicit tissue in-growth. The PET fiber mesh and the micro-insert act as scaffolding into which the tissue grows, anchoring the micro-insert within the fallopian tube and occluding the tube, resulting in sterilization.

Benefits

- ▶ No general anesthesia required
- ▶ No incisions required
- ▶ Speed of procedure
- ▶ May be performed as an outpatient
- ▶ Quick recovery
- ▶ Effective

Considerations

- ▶ Patients must use another form of birth control for at least three months after the procedure
- ▶ Removal requires surgery
- ▶ Reversal is not achievable-IVF only option to conceive
- ▶ Not all women will achieve successful placement of both micro-inserts
- ▶ Physician learning curve

Phase IA: Peri-Hysterectomy Study

► Objectives

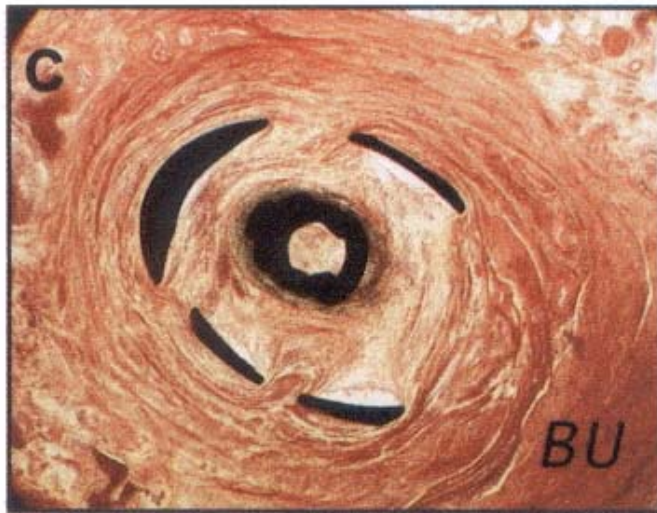
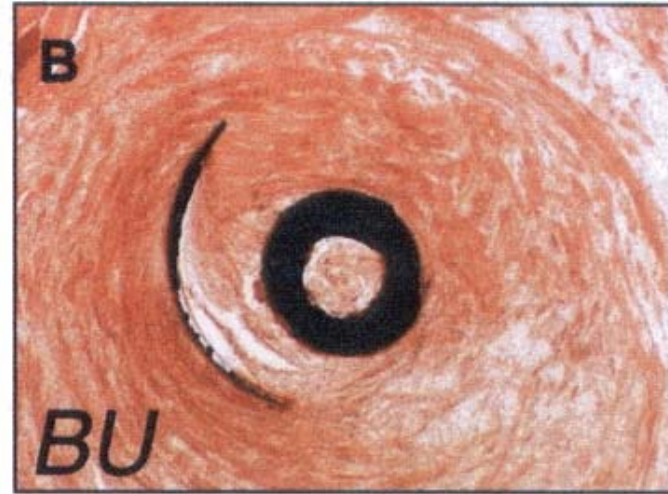
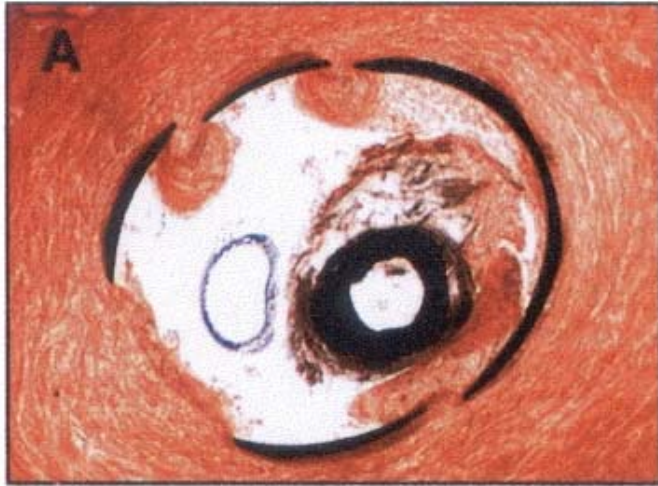
- evaluate the feasibility of micro-insert placement
- to evaluate placement techniques and delivery system
- to assess acute tubal occlusion.

► Results

- preliminary evidence regarding the safety of the placement procedure, the ability of the device to acutely anchor in the fallopian tube as well as the immediate space filling design of the device to occlude the fallopian tube.

Phase 1B: Pre-hysterectomy patients

- ▶ 49 pre-hysterectomy patients
- ▶ Device worn for a range of 1 day to 7 months, with the majority of patients wearing the devices for 10-12 weeks
- ▶ Essure device elicited both a fibrotic and an inflammatory response, leading to tissue ingrowth.
- ▶ The tissue response was localized to the region of the tube where the device was placed and did not involve the serosal surface.
- ▶ Normal tubal architecture was seen 5 millimeters distal to the device.



Phase II and Pivotal Trials

- ▶ The purpose of the Phase II study was to gather safety and effectiveness data for the first time in the intended patient population
- ▶ The primary endpoints of the Pivotal Trial were pregnancy prevention, safety of the placement procedure, and safety of long-term use

Micro-insert Placement Status

	Phase II	Pivotal
Bilateral placement	88% (n=200)	90% (n=466)*
Unilateral placement	3% (n=6)	2% (n=10)
No placement	9% (n=21)	8% (n=42)
Procedure time	18 minutes	13 minutes
Good or excellent tolerance of the procedure	89%	88%

* 2 participants had uni-cornuate uteri and had placement in the one tube

Reasons for failure of placement

- ▶ 4 % of the women had pre-existing tubal occlusion
- ▶ The majority of the failed placements were related to anatomic issues
 - stenotic tube
 - tube that is too far lateral to enter
 - scarring of the tube, preventing entry to the ostium

Phase II and Pivotal Results

- ▶ Hysterosalpingogram three months later to evaluate micro-insert position and tubal occlusion.
- ▶ Bilateral occlusion was demonstrated in 96% of women with bilateral placement in both the phase II and pivotal trials.
- ▶ Bilateral occlusion at six to seven months was 100% for both the phase II and pivotal trials.

Effectiveness

- ▶ Combined total of 745 women aged 21-45 years have shown

NO PREGNANCIES

in women relying on Essure for contraception

- ▶ Clinical data has proven 99.8% effective at 2 years of follow-up

Adverse Effects

- ▶ Failure to place 2 micro-inserts at first procedure (14%)
- ▶ Initial tubal patency (3.5%)
- ▶ Expulsion (2.2%)
- ▶ Perforation (1.8%)
- ▶ Unsatisfactory device location (0.6%)

Adverse Effects continued

▶ Procedure Side Effects

- Cramping (29.6%)
- Pain (12.9%)
- Nausea/Vomiting (10.8%)
- Dizziness (8.8%)
- Bleeding/Spotting (6.8%)

▶ Side effects occurring over first year

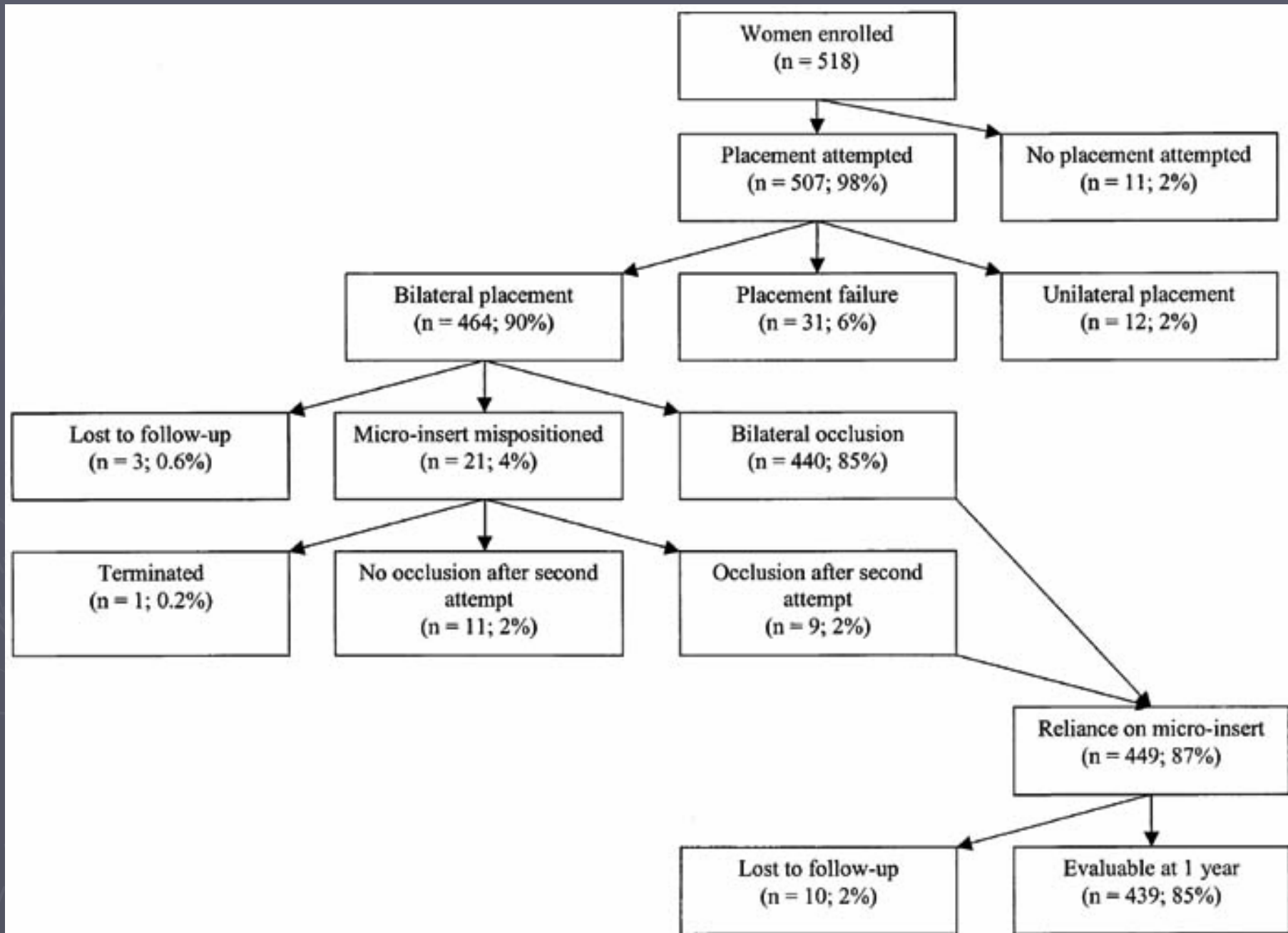
- Back pain (9.0%)
- Abdominal pain (3.8%)
- Dyspareunia (3.6%)

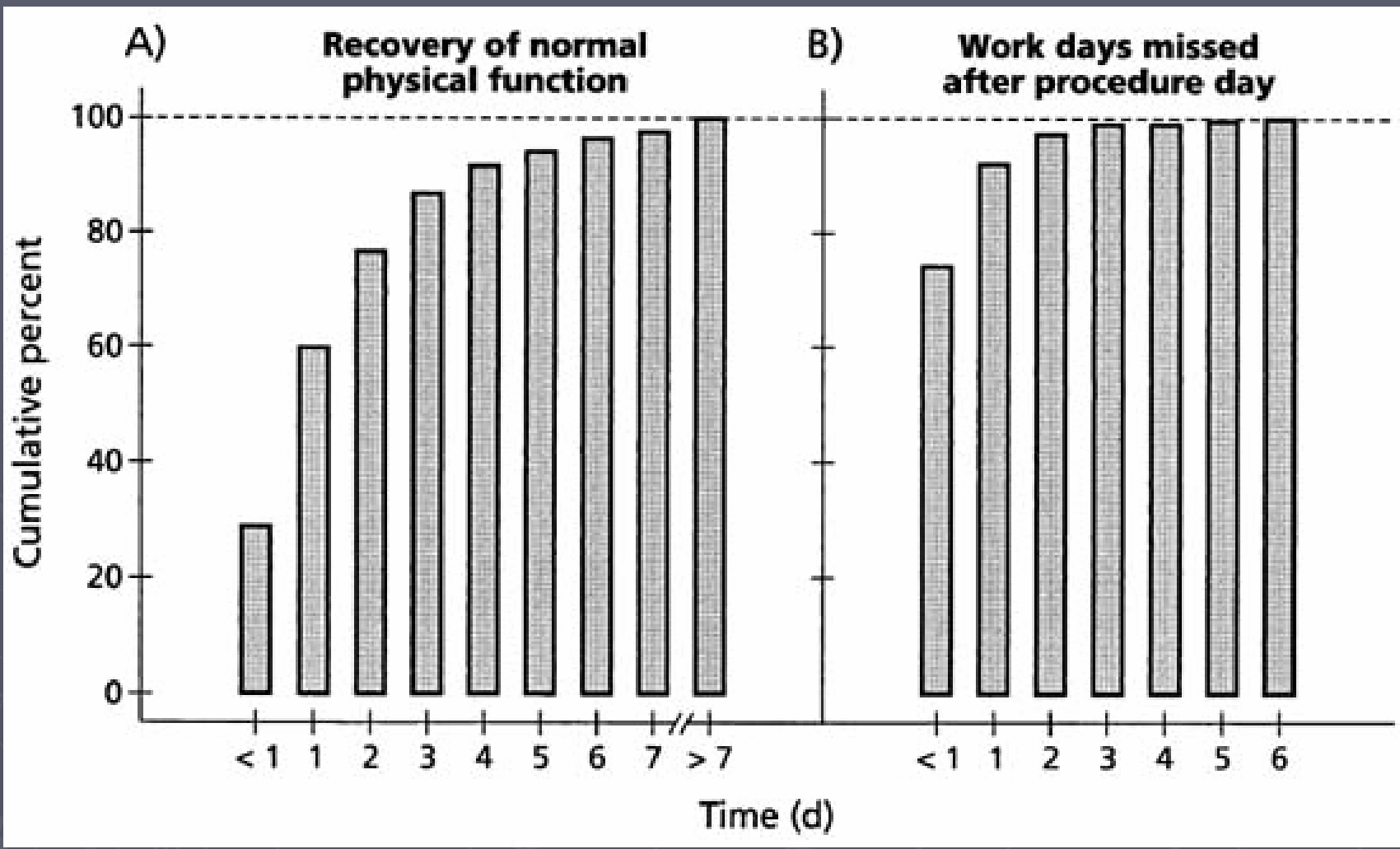
Human Reproduction, 2003

- ▶ 227 previously fertile women
- ▶ Successful bilateral **micro-insert** placement was achieved in 88% of women.
- ▶ 90% rated tolerance of the **device** placement procedure as good to excellent.
- ▶ Majority discharged in an ambulatory state within 1-2 h.
- ▶ Adverse events occurred in 7% of the women, but none was serious.
- ▶ Correct **device** placement was confirmed in 97% of cases at 3 months.
- ▶ Over 24 months follow-up, 98% of study participants rated their tolerance of the micro-insert as very good to excellent.
- ▶ **6015 woman-months of exposure to intercourse, no pregnancies have been recorded**

Obstetrics and Gynecology, 2003

- ▶ 518 previously fertile women seeking sterilization
- ▶ Microinsert placement was attempted in 507 women.
- ▶ Bilateral placement of the microinsert was achieved in 464 (92%) of 507 women.
- ▶ 88% rated tolerance of device placement procedure as good to excellent.
- ▶ Average time to discharge was 80 minutes.
- ▶ Quick return of function
- ▶ Three months after placement, correct microinsert placement and tubal occlusion were confirmed in 96% and 92% of cases, respectively.
- ▶ Comfort was rated as good to excellent by 99% of women at all follow-up visits.
- ▶ **After 9620 woman-months of exposure to intercourse, no pregnancies have been recorded.**





Phase III clinical trial

- ▶ **CONCLUSION:** This study demonstrates that hysteroscopic interval tubal sterilization with microinserts is well tolerated and results in rapid recovery, high patient satisfaction, and effective permanent contraception.

Fertility and Sterility

July 2004, Spain

- ▶ Successful placement was achieved in 81 patients (95%)
- ▶ Mean time elapsed between the start of hysteroscopy, placement of devices, and removal of optics was 9 minutes (range, 1–35 minutes)
- ▶ No intraoperative or postoperative complications were detected.
- ▶ 75 (93%) had abdominal x-ray performed at the third month; bilateral correct placement was confirmed in all of them.

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