

# Success of Essure® Micro-inserts in the Treatment of Hydrosalpinx Prior to In Vitro Fertilization (IVF) and Frozen Embryo Transfer (FET) Pregnancy Outcomes

John E. Nichols, Piedmont Reproductive Endocrinology Group, Greenville, SC  
Jennifer R. West, Conceptus Incorporated, Mountain View, CA

## Objective

Investigate pregnancy outcomes in women with hydrosalpinges treated with Essure® micro-inserts prior to IVF and FET.

## Design

Prospective, single arm, clinical study. This study examined an off-label use of the Essure procedure.

## Background

- Patients with hydrosalpinges undergoing IVF experience approximately one-half the pregnancy rate of patients who do not have hydrosalpinges.
- Salpingectomy performed for hydrosalpinx prior to IVF improves subsequent pregnancy, implantation and live birth rates.
- Current data are insufficient to permit recommendation of other treatment alternatives such as transvaginal aspiration of hydrosalpinx fluid or proximal tubal ligation.

## Materials & Methods

Six women ages 34-41 with unilateral (N=1; prior LSO) or bilateral hydrosalpinges (N=5) diagnosed by HSG (hysterosalpingogram) scheduled to undergo IVF or FET following tubal occlusion by the Essure micro-insert during the time period 2005 – 2008.

**Six (6) infertile patients: age ranged from 34 to 41 years old (mean 37.5, median 38.5):**

- 4 patients with bilateral hydrosalpinx, normal uterine cavity
- 1 patient with right hydrosalpinx (prior LSO – ruptured appendix), normal uterus
- 1 patient with bilateral hydrosalpinx, fibroid uterus, history of myomectomy X 3

**All devices placed by same physician:**

- 4 performed in office setting with paracervical block, NSAIDs
  - One patient required two separate procedures
- 2 performed in out-patient surgery center with IV sedation due to insurance coverage issues
- Confirmation test performed 3 months after placement noted bilateral tubal occlusion in all 6 patients

## Results

Age	Parity	D3 FSH	AFC	IVF cycles	FET	Outcome
41	G2P1Ab1		8.6	1		Singleton
34	G0	5.9	11	1		Singleton
39	G7P1Ab3E3	3.9		1 (Trisomy 13)	1 (Twins)	Singleton
34	G0	4.8	18	1 (Negative)	4 frozen embryos	Gestational carrier
37	G0	5.2	6	1 (Negative)		Donor egg?
40	G0	6.9		4 (1 <sup>st</sup> and 2 <sup>nd</sup> cycle – negative; 3 <sup>rd</sup> cycle – twins (lost both); 4 <sup>th</sup> cycle – chemical pregnancy)		Adoption?

Essure placements were performed by one physician in an office setting using local anesthetic (N=4) or in an out-patient surgery center with conscious sedation (N=2). Five patients had bilateral successful placement on first attempt. One patient had unilateral placement on first attempt and one month later underwent a successful second placement procedure. Tubal occlusion was confirmed by HSG in all patients. Three patients became pregnant on their first IVF treatment cycle; two delivered full-term without complications and one had a fetal demise at 8 weeks due to trisomy 13. Subsequently she conceived on a FET with twins and then had an uneventful fetal demise of one twin; the other was delivered at term without complications.

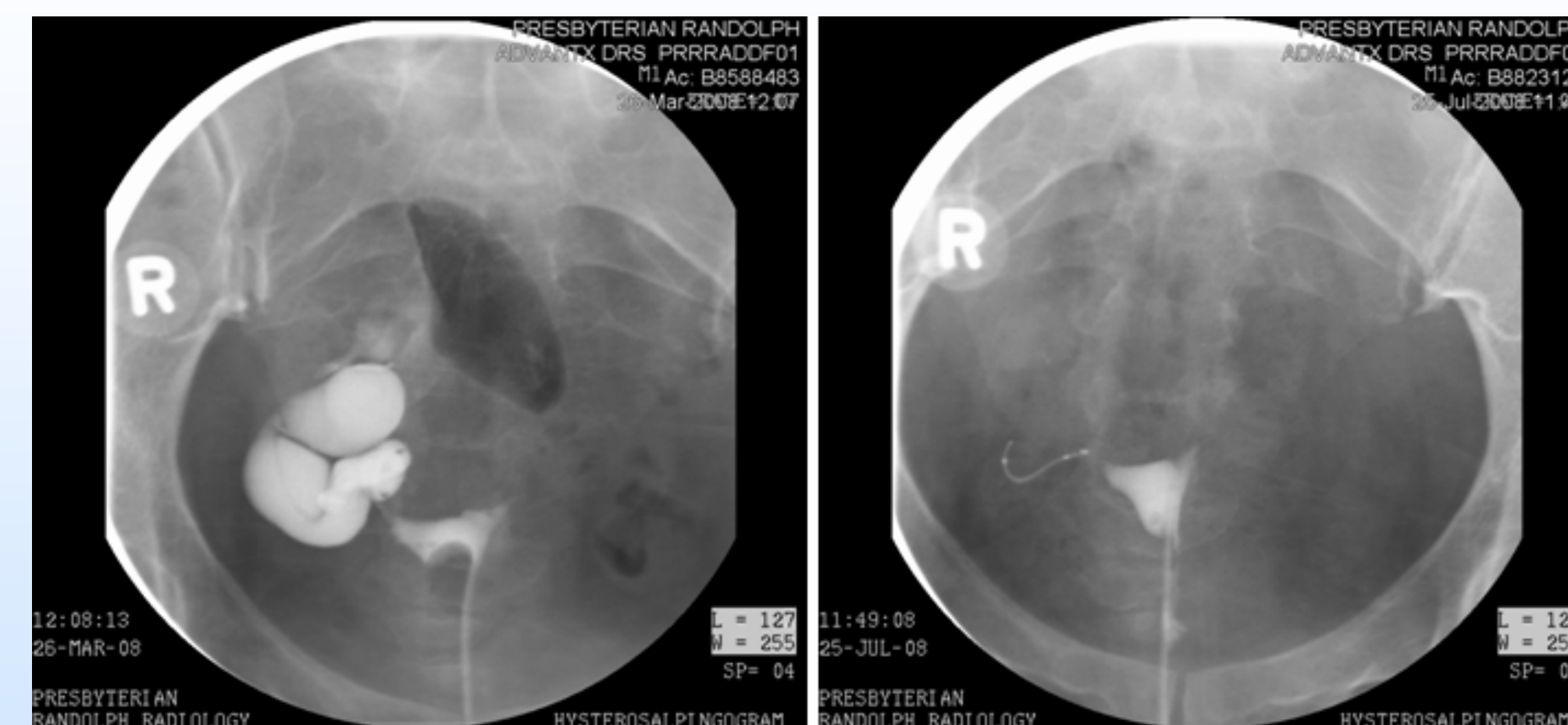


Figure 1: HSG of Unilateral Hydrosalpinx before (L) and after (R) Essure micro-insert placement.

## Results (continued)

One patient (age 40) underwent four IVF cycles; the first two cycles were unsuccessful, the third cycle resulted in a twin pregnancy that miscarried at 6 weeks and her last cycle resulted in a chemical pregnancy. The patient is now pursuing adoption. One patient (age 37 with prior LSO) discontinued treatment after an unsuccessful IVF cycle due to poor ovarian stimulation response. The sixth patient (age 34 with recurrent fibroids) had a single unsuccessful IVF cycle but has four frozen embryos available and is now pursuing a gestational carrier.

## Conclusion

Essure placement for hydrosalpinx prior to IVF-ET results in excellent pregnancy rates and outcomes:

- 4/6 patients conceived (66.6% pregnancy rate).
- 3/6 patients delivered, (50% live birth rate), with no pregnancy complications.
- Mean age 37.5 years old.

Placement of the Essure micro-inserts in patients with hydrosalpinges provides a minimally invasive option for proximal tubal occlusion prior to IVF and FET and appears to result in excellent pregnancy rates and outcomes. There were no complications related to Essure.

## References

- Rosenfield, et al. *Fert Steril* 2005;83:1547-50. Proximal occlusion of hydrosalpinx by hysteroscopic placement of microinsert before in vitro fertilization-embryo transfer.
- Kerin, et al. *Fert Steril* 2007;87:1212e1-4. Successful pregnancy outcome with the use of in vitro fertilization after Essure hysteroscopic sterilization.
- Galen, *Fert Steril* 2007;88 (Suppl 1). Utilization of the Essure micro-insert for the treatment of hydrosalpinx prior to in vitro fertilization.
- Hitkari, et al. *Fert Steril* 2007;88:1663-36. Essure treatment of hydrosalpinges.
- Mijatovic, et al. *Fert Steril* 2009. Essure hysteroscopic tubal occlusion device for the treatment of hydrosalpinx prior to in vitro fertilization-embryo transfer in patients with a contraindication for laparoscopy.