

# Can laparoscopic removal of Essure device before embryo transfer correct poor reproductive outcome pattern in IVF?

## A case report

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### Summary

**Objective:** This report describes a successful surgical approach to multiple in vitro fertilization (IVF) failures in the setting of hydrosalpinges, which had been previously treated with Essure inserts. **Materials and Methods:** A non-smoking 33-year-old Caucasian G2 P0020 (body mass index: BMI = 22) attended for second opinion. Her history was significant for bilateral hydrosalpinges having been noted on hysterosalpingogram two years earlier. This was managed by hysteroscopic placement of Essure inserts bilaterally. One year later, and now with Essure in situ, the patient completed three IVF cycles elsewhere. Her first and third IVF attempts resulted in biochemical pregnancy, while human chorionic gonadotropin (hCG) was negative after the second cycle. Upon presentation at the authors' center and before beginning a fourth IVF cycle, further testing and surgical removal of the Essure devices was recommended. **Results:** Repeat hysteroscopy was unremarkable; laparoscopic bilateral salpingectomy and extirpation of Essure implants was accomplished without difficulty. Following menses, the patient initiated IVF with three embryos transferred. At day 60, a single intrauterine pregnancy was identified with positive cardiac activity (rate >100/min). Her obstetrical course was uneventful; a healthy 4,195 gram male infant was delivered (breech) by Cesarean at 40 weeks' gestation. **Conclusion:** Essure inserts comprise inner fibers of polyethylene terephthalate, a stainless steel coil, and a nickel-titanium coil. The product received FDA approval as a contraceptive in 2002 although its use for hydrosalpinx remains off-label. While successful outcomes with IVF following Essure placement have been reported, this is the first description of pregnancy and delivery from IVF after Essure removal. Essure may be considered for sterilization when laparoscopy is contraindicated, but experience with its use specifically for treating hydrosalpinges before IVF is limited. This observed association between prior poor IVF outcomes and Essure with subsequent delivery after surgical Essure removal is the first of its kind to be reported, and warrants further investigation.

**Key words:** Essure; Hydrosalpinx; IVF; Recurrent miscarriage; Laparoscopy.

### Introduction

Hydrosalpinx identified during the evaluation prior to in vitro fertilization (IVF) represents a significant finding [1]. Most research to date has recommended surgical correction of such tubal pathology before embryo transfer [1,2]. There is now general consensus that surgical treatment should be considered for all women with hydrosalpinges before IVF treatment. Room for debate does exist, however, on how best to carry out such surgery. A recent comprehensive review on this topic [3] concluded that laparoscopic tubal occlusion or laparoscopic salpingectomy appropriate interventions are to improve IVF pregnancy rates in women with hydrosalpinges. It should be noted that simple proximal tubal occlusion has been recognized as an effective alternative to salpingectomy, if the latter were technically difficult or impossible to complete for other reasons [4]. Because proximal tubal occlusion can also be achieved by the non-incisional hysteroscopic insertion of metallic microinserts (Essure), this non-laparoscopic approach has attracted considerable attention. Early papers describing abdominal opera-

tions for correction of hydrosalpinx before IVF were all predicated on the understanding that pre-IVF patients are willing and able to undergo laparoscopy, yet this may not always be the case. Indeed, hysteroscopic management brings several advantages over laparoscopy by eliminating the need for abdominal access [5,6], reducing overall cost [7-9], and minimizing anesthesia requirements [10]. These characteristics have enabled a small but growing experience with Essure placement specifically for proximal tubal occlusion for women with hydrosalpinx before IVF. Thus far, all such publications have been favorable [11-17]. In this report, we describe IVF preceded by the surgical removal of Essure implants where multiple poor outcomes had occurred with Essure *in situ*. After three failed IVF attempts, our patient conceived on her fourth IVF cycle and delivered once the Essure devices were excised.

### Case Report

A healthy, non-smoking 33 year-old Caucasian G2 P0020 with regular menses attended for reproductive endocrinology consultation and second opinion. Physical examination was unremarkable and BMI was 22kg/m<sup>2</sup>. Past medical history was significant

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for bilateral hydrosalpinges which were noted on hysterosalpingogram performed two years before initial consult with the present authors. The patient subsequently underwent a laparotomy for bilateral ovarian cysts, but the fallopian tubes were apparently not accessible. The patient had been advised that communicating hydrosalpinges required treatment before IVF, and was offered an office hysteroscopy procedure (Essure) as a non-laparoscopic way to resolve the tubal fluid.

The patient underwent bilateral Essure placement and tolerated the procedure well. The patient then waited one year and had a repeat hysterosalpingogram, which confirmed bilateral proximal tubal occlusion secondary to the device placement. Next, the patient embarked three fresh IVF cycles. All three of these attempts were completed at the same institution with similar monitoring practices and identical ovulation induction regimes. The patient's response to controlled ovarian hyperstimulation was adequate and there were no complications. Evaluation of the male partner at the present center agreed with the previous assessments and confirmed normal semen parameters.

The first and third IVF attempts resulted in biochemical pregnancy (not requiring D&C), although serum hCG was zero following the second IVF cycle. Luteal phase support remained unchanged for the three IVF cycles. There were no frozen surplus embryos available from any of these IVF treatments.

Upon presentation at our unit and before beginning a fourth (fresh) IVF cycle, further testing and surgical removal of the implants was discussed. An autoimmune panel and thrombophilia testing did not reveal any abnormality, and karyotypes on both partners were also normal. Repeat hysteroscopy was unremarkable; laparoscopic bilateral salpingectomy and extirpation of Essure implants was accomplished without difficulty (Figure 1). Following menses, the patient initiated IVF with three embryos transferred. Transvaginal ultrasound performed on day 60 revealed a single intrauterine pregnancy with positive cardiac activity (144/min). The patient's obstetrical course was uneventful and a healthy male infant (birth weight 4,195 g) was delivered by Cesarean for breech presentation at 40 weeks' gestation. The placenta was delivered without difficulty. Mother and baby continue to do well.

## Discussion

The presence of fluid-filled tubes is a reliable marker of pelvic pathology, as hydrosalpinx fluid is now recognized as antagonistic to embryo implantation [18, 19]. Subsequent research has found IVF pregnancy rates in the presence of hydrosalpinx fluid reduced by up to 50% compared to age-matched women without this finding [20]. This adverse effect of communicating hydrosalpinges on embryo survival and/or implantation rates in IVF has been reported by numerous investigators [21-24], supporting the recommendation to take surgical action before IVF. For most IVF patients, salpingectomy or proximal tubal occlusion by laparoscopy is the operation usually recommended to address the hydrosalpinx problem [2,25]. However for patients who are poor candidates for laparoscopy, a non-abdominal approach to achieve tubal occlusion before IVF was needed.

The arrival of the Essure device, a non-incisional procedure for tubal sterilization which is performed hysteroscopically in an office setting, drew interest as one

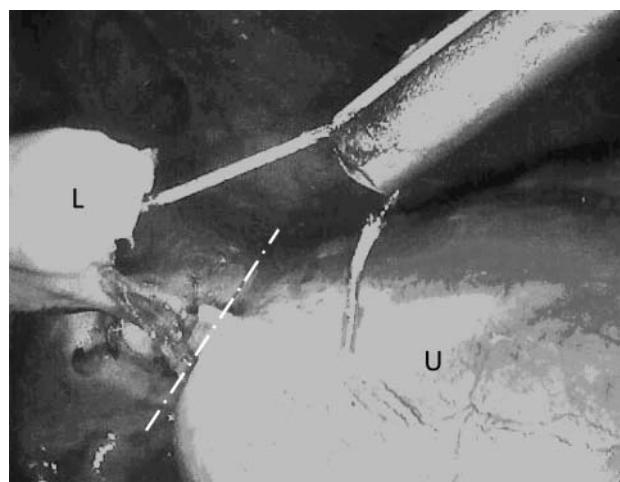


Figure 1. — Left Fallopian tube (L) divided near the uterotubal junction (dashed line), with removal of the Essure device using a five-mm laparoscopic grasper. The same approach was used for the contralateral tube. Interior and exterior contours of the uterus (U) were normal.

way to fill this niche [5]. Clinical investigation of Essure began in 1996, and it received FDA approval for use in permanent sterilization in 2002 [15]. Although the product was approved for a contraceptive indication rather than to treat hydrosalpinx before IVF, Essure has consistently provided satisfactory results in this off-label application [11-17].

One of the first studies to detail post-Essure intrauterine cavity status [13] used a second-look hysteroscopy design, with repeat hysteroscopy between four and 43 months after initial Essure placement. The investigators reported data on 22 patients, and complete tissue encapsulation of both micro-inserts had already occurred in 17% of cases when reexamined within 12 months or less. Among study patients reevaluated 13-43 months post-Essure insertion, complete encapsulation was noted in 25% [13]. Several investigators have offered support for exclusive use of Essure specifically to correct retrograde flux of hydrosalpinx fluid before IVF [11-17].

Despite promising early results with Essure placement before embryo transfer, the approach has not been systematically reviewed and remains off-label. Indeed, the 2010 Cochrane review [3] found that surgical treatment should be considered for all women with hydrosalpinges before undergoing IVF treatment, with an emphasis on laparoscopic tubal occlusion or laparoscopic salpingectomy to improve pregnancy rates with IVF for women with hydrosalpinges. With regard to postoperative intrauterine inflammatory mediators impacting endometrial receptivity and embryo implantation, more data are needed to establish what difference may exist after laparoscopic vs. hysteroscopic interventions.

Against this background, the present case is the first report to describe unsatisfactory IVF outcomes in association with proper placement of Essure inserts for management of hydrosalpinx. Because Essure is a permanent sterilization method, the product is not supposed to be removed and guidelines for surgical extirpation of the device are currently lacking. While it is encouraging that others have shown this off-label use of Essure can lead to pregnancy and delivery [11-17], for the present patient, delivery was possible only after laparoscopic removal of Essure and salpingectomy. Indeed, except for these surgical tubal manipulations, no other aspect of IVF treatment changed for the present patient when her first three cycles are compared to the fourth successful attempt. Because hysterosalpingogram and hysteroscopy were normal following Essure insertion, the authors' suspicion for improper placement of the device or reflux of tubal fluid was low. Nevertheless, the present case frames this key question: is it possible that even in the setting of good placement technique and complete device engraftment and encapsulation, can the Essure device exert some type of inflammatory endometrial contraceptive effect sufficient to antagonize embryo implantation? The current report offers a crucial counterpoint to the emerging literature on Essure, and suggests that laparoscopic removal of Essure microinserts before embryo transfer can correct a recurrent poor outcome pattern in IVF.

## Conclusions

Given that the extant literature on using Essure for hydrosalpinx before IVF has been, until now, uniformly reassuring, the present patient's disappointing IVF results all occurring with Essure implants *in situ* were surprising. Fortunately laparoscopy was not contraindicated in this case, and surgical removal of both Essure implants could be achieved without complication. Had the present patient been unable or unwilling to undergo abdominal surgery, our therapeutic options would have been limited to surrogacy or to repeat her embryo transfer (a fourth time) with Essure implants still present—neither were attractive alternatives on this occasion. Based on the new findings presented here, we believe that IVF patient counseling should discuss the potential impact on IVF outcome when Essure is used for this off-label indication. Further clinical experience will be welcome as IVF outcomes following Essure use for this indication continue to be monitored.

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SAS and ACP were consultants associated with the case, and RDS was principal surgeon. ESS conceived of the project and developed the manuscript. All authors read and approved the final submission.

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