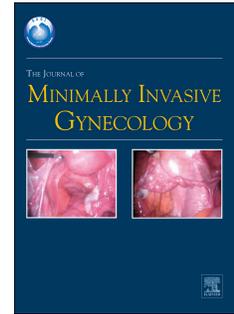


# Accepted Manuscript

Essure Surgical Removal and Subsequent Symptom Resolution: Case series and follow-up survey

Luiz Gustavo O. Brito, M.D, M.Sc, Ph.D, Sarah L. Cohen, M.D., M.P.H, Emily R. Goggins, B.A, Karen C. Wang, M.D, Jon I. Einarsson, M.D, Ph.D, M.P.H



PII: S1553-4650(15)00282-4

DOI: [10.1016/j.jmig.2015.03.018](https://doi.org/10.1016/j.jmig.2015.03.018)

Reference: JMIG 2534

To appear in: *The Journal of Minimally Invasive Gynecology*

Received Date: 27 February 2015

Revised Date: 27 March 2015

Accepted Date: 31 March 2015

Please cite this article as: Brito LGO, Cohen SL, Goggins ER, Wang KC, Einarsson JI, Essure Surgical Removal and Subsequent Symptom Resolution: Case series and follow-up survey, *The Journal of Minimally Invasive Gynecology* (2015), doi: 10.1016/j.jmig.2015.03.018.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

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3 Luiz Gustavo O. Brito, M.D, M.Sc, Ph.D, Sarah L. Cohen, M.D., M.P.H, Emily R.

4 Goggins B.A, Karen C. Wang, M.D and Jon I. Einarsson, M.D, Ph.D, M.P.H\*

5

6 Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Harvard

7 Medical School, Boston, Massachusetts (all authors)

8

9 **Corresponding author:**

10 Jon I. Einarsson, MD, Department of Obstetrics and Gynecology, Brigham and

11 Women's Hospital, 75 Francis St, ASB 1-3, Boston, MA 02115

12 E-mail: [jeinarsson@partners.org](mailto:jeinarsson@partners.org)

13

14 **Disclosures:** none declared

15

16 **Abstract**

17 Transcervical sterilization is a minimally invasive option for permanent contraception

18 with high reported rates of patient satisfaction. A small percentage of women

19 subsequently choose to have the tubal inserts removed due to regret or perceived side-

20 effects. There is limited information regarding improvement in symptom profile

21 following surgical removal of the tubal inserts. We present a retrospective case series

22 of 11 women who underwent surgical removal of Essure by hysteroscopy,

23 salpingectomy and/or hysterectomy. The predominant symptom upon presentation

24 was pain (n=10; 90.91%), as well as bleeding (n=6; 54.54%) and/or dyspareunia

25 (n=5; 45.45%). After surgical removal, the majority of patients (n=8; 72.72%)

26 reported an improvement of their symptoms. However, three (27.27%) patients  
27 continued to have persistent symptoms after surgery. Prior to surgical removal of  
28 Essure, it is important to thoroughly discuss with patients the risk for ongoing  
29 symptoms.

30

31 **Keywords:** Essure; survey; postoperative status; salpingectomy; hysterectomy; pelvic  
32 pain

33

### 34 **Introduction**

35

36 Essure ® (Bayer AG, Leverkusen, Germany) is a sterilization device which  
37 consists of an expanding micro-insert that is inserted into the cornual section of the  
38 fallopian tube during hysteroscopy.(1) The initial 5-year-placement success rates by  
39 tubal occlusion range from 84%-99.8% (2) and the US Food and Drug Administration  
40 (FDA) approved its use in the United States in 2002.

41 One important risk of the procedure is the chance of regret which is reported  
42 to be as high as 5.5% (3). Some patients present after Essure placement requesting  
43 removal of these devices due to complaints of pain, identification of a misplaced  
44 insert, the desire for fertility or presumed allergic reaction. The removal can be  
45 classified into two broad categories: hysteroscopic removal (typically preferred for  
46 the cases inserted less than 12 weeks) and laparoscopic extraction (in patients whose  
47 devices are outside the window for hysteroscopic removal or if the insert has  
48 perforated into the abdominal cavity) (4).

49 There is scant literature regarding outcomes of women who undergo Essure  
50 implant removal. Therefore, the primary objective of this study was to survey women  
51 regarding symptom resolution following removal of Essure devices.

52

53 **Methods**

54

55 This retrospective case series included women who sought surgical  
56 management for the removal of Essure between September 2012 and July 2014 with  
57 the Division of Minimally Invasive Gynecologic Surgery at Brigham and Women's  
58 Hospital in Boston, MA. The project was approved by the Partners Institutional  
59 Review Board. Women who underwent Essure removal due to desire for future  
60 pregnancy or sterilization regret were excluded.

61 The following demographic data were abstracted from the medical record:  
62 age, race, body mass index (BMI), parity, comorbidities, clinical symptoms after  
63 Essure placement, duration of symptoms, type of surgery, operative time, length of  
64 hospital stay and time from surgery to questionnaire response. An eight-question  
65 survey consisting of multiple choice and open-ended questions was created for this  
66 study. The survey addressed patients' feelings about removal of Essure implants and  
67 the surgery itself, family and/or partner support and symptom improvement after  
68 surgery.

69 Through review of surgical records, patients were identified as meeting the  
70 inclusion criteria for this study. These patients received an introductory letter with an  
71 explanation of the study and instructions for participation. Patients who chose to  
72 participate were mailed a paper version of the survey which included a REDCap  
73 (Nashville, TN, USA) online participation link (5). Descriptive analysis was  
74 performed with the use of Microsoft Excel (Redmond, WA, USA).

75

76 **Results**

77 Based on a review of surgical records, 11 patients were identified that met  
78 inclusion criteria. All patients invited to participate completed the survey (Table 1).  
79 The median age of the participants was 35 years (range 25-44) and majority of the  
80 women were caucasian (n=9; 81.8%). Median BMI was 24.7 (18.7-35) and median  
81 parity was 3 (2-7). Of the 11 patients, five reported a history of chronic pelvic pain.

82 The median timeframe between removal of the Essure implant and  
83 administration of the survey was five (range 1-23) months. Patients reported  
84 symptoms after Essure placement for a median of two (0.5-9) years. The most  
85 common surgery performed for removal of Essure devices was bilateral  
86 salpingectomy (n=7/63.6%), followed by total laparoscopic hysterectomy and  
87 bilateral salpingectomy (n=4/36.4%). One patient initially had undergone bilateral  
88 salpingectomy then seven months later underwent a laparoscopic hysterectomy due to  
89 persistence of pelvic pain. Only one Essure removal was done hysteroscopically.  
90 Median operative time was 60 (35-140) minutes and majority of the patients were  
91 discharged home the same day (n=9; 81.8 %).

92 Table 2 shows the results of the survey answered by the patients who  
93 underwent Essure removal. A majority of patient had symptoms of pelvic pain  
94 (n=10;90.9%), abnormal bleeding (n=6;54.5%) and pain during intercourse  
95 (n=5;45.4%) which were thought to be related to the Essure devices. Most patients  
96 reported physician agreement with the decision to remove Esssure implants (n=8;  
97 72.7%) as well as sufficient parental and partner support (n=7; 63.6%) regarding their  
98 decision.

99 After surgery, most of the patients (n=8; 72.72%) reported an improvement in  
100 all domains which were queried (pelvic pain, daily activities, sexual life, quality of  
101 life, healing and recovery), as seen in Figure 1. However, three patients reported

102 ongoing symptoms after surgery and two reported worsening symptoms of pain and  
103 dyspareunia.

104

## 105 **Discussion**

106 In this case series, most patients experienced improvement of symptoms  
107 following surgical removal of Essure via salpingectomy and/or hysterectomy. This  
108 study differs from previous studies on this topic (6, 7) as it surveyed patients' feelings  
109 during the postoperative period following surgery for symptoms that they believed to  
110 be Essure-related. Usually, satisfaction indexes after placing Essure are high and  
111 patients are happy with their decision (6, 7). However, it is also well established that  
112 Essure placement can be associated with side-effects after placement.

113 Pain was the most commonly reported symptom in our patient cohort. Pelvic  
114 pain may develop after hysteroscopic sterilization (incidence of 8.1%), with fifty  
115 percent of these cases resolving in 3 months (8). One of the first reports for Essure  
116 removal due to pain showed resolution of the symptoms with two weeks of removal  
117 (9). It is important to note that the causal relationship between Essure placement and  
118 symptoms of pain cannot be validated by a retrospective study design. Moreover, five  
119 of the patients in this study had preexisting chronic pelvic pain, which confounds pain  
120 reported after Essure placement. It has been reported that patients with previous  
121 chronic pelvic pain are more likely to report both acute and chronic pain after  
122 hysteroscopic sterilization (8).

123 An analysis of the Manufacturer and User Facility Device Experience  
124 (MAUDE) database has found 63 records for this device from 2001 to 2010 (10).  
125 Twenty of these cases were related to allergic dermatitis due to nickel  
126 hypersensitivity. In our case series, there were three (27.27%) cases associated with

127 allergic reaction. One of these cases is not entirely thought to be associated with the  
128 device, since this patient was diagnosed with Hodgkins lymphoma concurrent to  
129 symptom development. Bleeding was another commonly reported issue during this  
130 survey. This was not a complaint found in a recent systematic review about Essure  
131 complications, however (11).

132 A unique aspect of this report is the exploration of patients' feelings regarding  
133 having to undergo surgery as well as their fears. Patients presented mixed feelings  
134 (happy and sad) about undergoing surgery. This is an important issue, because it has  
135 been demonstrated that patient perception is directly correlated with both their  
136 postoperative status and with physicians' communication. Limitations include the  
137 retrospective study design and small number of cases (12).

138 The majority of patients in this series who underwent surgery for symptoms  
139 related to Essure experienced improvement. However, a small percentage continued  
140 to have symptoms. It is an important part of the informed consent to discuss with  
141 patients the risk of ongoing symptoms prior to performing Essure implant removal.

142

### 143 **Acknowledgments**

144

145 We would like to thank Sao Paulo Research Foundation (FAPESP) grant n. 13/25956-  
146 0, which sponsored Dr. Brito's post-doctoral research fellowship.

147

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- 182

183 **Figure 1. Rating of how important the following factors have improved after**  
184 **removing Essure due to symptoms (n=11)**

**Table 1. Patient baseline characteristics**

	Age	Race	Parity	BMI (kg/m <sup>2</sup> )	Comorbidities	Duration of symptoms*
1	35	White	3	24.7	Asthma, chronic low back pain	5
2	44	White	3	35	Migraine, chronic low back pain	9
3	28	Declined	2	24.7	Constipation, chronic low back pain	7
4	35	White	7	19.7	Chronic low back pain	2
5	41	White	2	26.6	Chronic headache	5
6	42	White	5	32.8	Diabetes, hypertension, depression	2
7	44	White	2	21.5	Constipation, chronic low back pain, asthma	2
8	25	White	2	21.3	None	1
9	30	White	4	25.3	None	0.5
10	34	Black	4	21.6	Joint pain, Chronic headache	1
11	40	White	2	18.7	None	0.5

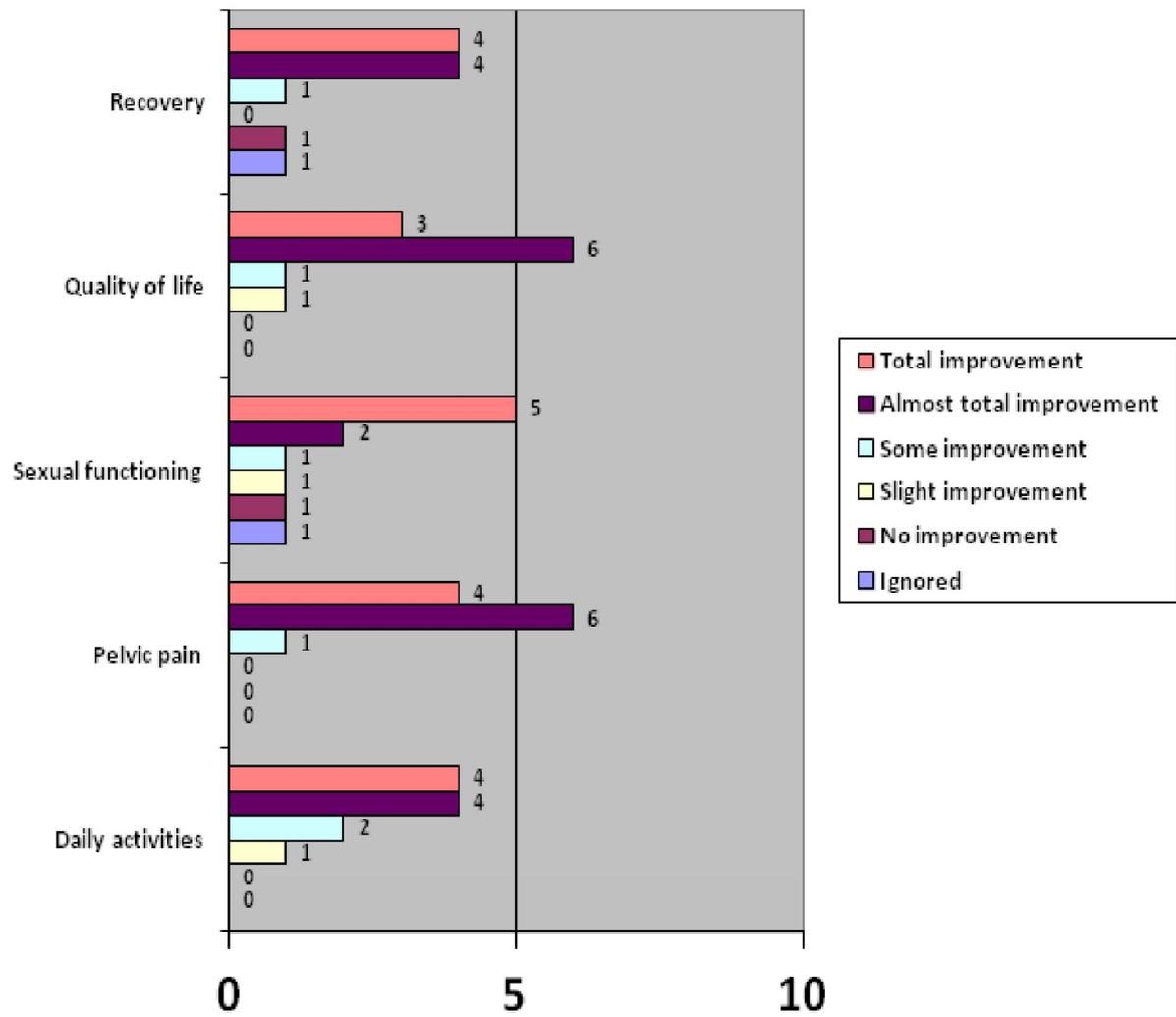
\* in years, until surgery date

**Table 2. Survey questions sent by survey to patients that performed Essure removal due to symptoms (n=11)**

<b>What were your symptoms before removing Essure? *</b>	<b>n</b>
Pain	10
Allergic reaction	3
Pain with intercourse	5
Bleeding	6
Other	7
<b>What did you feel when he/she said your would have to operate/remove Essure? *</b>	<b>n</b>
Happy, because I would solve this problem	6
Happy, because my life was horrible at that point	6
Happy, because I would have to take out my uterus (for hysterectomy patients)	0
Sad , because I did not want to do another procedure	4
Sad, because I would have to take out my uterus (for hysterectomy patients)	3
Other	3
<b>What did your partner and family think about your choice? Did they support you?</b>	<b>Total</b>
Both gave all support	7
My partner gave all support; my family did not/was not involved with my decision	3
My family gave all support; my partner did not/was not involved with my decision	0
None had influence towards my decision	1
Other	0

<b>Did you have any fears concerning the procedure? *</b>	<b>n</b>
No, I did not; I was confident about my doctor's ability.	4
No, I did not; I was certain that my symptoms were related with Essure	4
Yes, I did; I was afraid of not relieving my symptoms	4
Yes, I did; I was afraid of having problems regarding the procedure	5
Yes, I did; I was - afraid of worsening my situation	1
Other	3
<b>Did you have any new symptoms after surgery?</b>	<b>Total</b>
Yes	3
No	8
<b>Did you have any symptoms that worsened after surgery?</b>	<b>Total</b>
Yes	2
No	9

\*More than one response





<http://www.AAGL.org/jmig-22-5-JMIG-D-15-00135>

ACCEPTED MANUSCRIPT

**Precis**

Essure removal by surgery improved pain in most of patients

ACCEPTED MANUSCRIPT