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Original article

Essure removal for device-attributed symptoms: quality of life evaluation before and after surgical removal

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1 **ABSTRACT**

2 **Introduction:** Increasing reports of adverse effects have raised concerns about the Essure
3 hysteroscopic sterilization method. Women suffering alleged complications of the Essure
4 device often seek surgical removal. This study evaluated the quality of life (QoL) and
5 postoperative outcomes in women undergoing Essure removal.

6 **Material and methods:** This observational case series included 95 women. Removal was
7 performed by laparoscopic salpingectomy-cornuectomy, or hysterectomy with bilateral
8 salpingectomy. QoL was assessed preoperatively and three months postoperatively by SF-
9 36 questionnaires [correlated physical health score (PCS) and mental health scores (MCS)].
10 Symptoms evolution was collected at three months, and complications at one month.

11 **Results:** 64 laparoscopic salpingectomy-cornuectomies, 33 laparoscopic hysterectomies,
12 and eight vaginal hysterectomies were performed. Four intraoperative complications
13 occurred (one conversion from cornuectomy to laparoscopic hysterectomy, one skin burn,
14 two bladder injuries). Seven postoperative complications occurred (Clavien Dindo, grade 1 or
15 2). All components of the preoperative QoL scores were lower than those of the general
16 population. PCS scores were lower preoperatively than postoperatively [37.6 versus 50.7;
17 $p < 0.001$]. MCS scores were lower preoperatively than postoperatively [29 versus 52.4;
18 $p < 0.001$]. 71% of patients showed an improvement of at least 10% in both PCS and MCS
19 scores. Systemic and gynecologic symptoms were more frequent before than after surgery
20 (98% versus 50%; $p < 0.001$ and 77% vs 20%; $p < 0.001$ respectively).

21 **Conclusions:** Patients seeking Essure removal had an impaired preoperative QoL. They
22 experienced a significant QoL improvement at three months post-operation. These findings
23 will help clinicians to inform patients about their expected postoperative functional status and
24 QoL.

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29 **INTRODUCTION**

30 Essure (Bayer AG, Leverkusen, Germany) is a female sterilization method marketed since
31 2002. The Essure device is introduced into the proximal part of each fallopian tube via
32 hysteroscopy. It is made of a metal alloy of nickel and titanium outer coil and a 316 L
33 stainless steel inner coil wrapped into polyethylene terephthalate fibres [1]. Premarketing
34 studies considered Essure to be a safe and effective sterilization method. The overall
35 complication rate following Essure placement was low and tolerance at one year was
36 considered very good for 98% of patients [2,3]. However, in recent years, reports and
37 complaints of its alleged adverse effects have been forwarded to public health agencies.
38 These adverse events included gynecologic or/and systemic symptoms [4-6]. Although no
39 causal association between Essure and the reported symptoms has been established, there
40 is growing attention on the adverse effects that could be attributed to the Essure devices.
41 Safety concerns and ensuing has led to the Essure method being withdrawn from clinical
42 practice by the manufacturers. The women who believe their quality of life (QoL) has been
43 negatively impacted by their Essure inserts often request surgical removal. Even if it appears
44 that the withdrawal of the devices resolves symptoms for many patients, there is a lack of
45 data regarding postoperative outcomes and accurate QoL measurement [7-9].

46 The aim of the study was to assess the QoL of patients requesting surgical removal
47 due to adverse effects attributed to the Essure device both before the procedure and at three
48 months post-operation. The secondary objectives were to describe the symptoms presented
49 by the patients and the morbidity of the surgical procedures.

50

51 **MATERIAL AND METHODS**

52 Study Design

53 This retrospective observational case series was conducted at two academic tertiary care
54 centers (Montpellier and Marseille) between February 2017 and March 2018. It was a before-
55 and-after design that included female patients who underwent Essure removal because of
56 suspected adverse effects of the device. Exclusion criteria were failure to perform a complete

57 removal of the Essure and second surgery to remove fragments left behind from a previous
58 procedure. The following information was collected during preoperative clinics: demographic
59 data, medical history, clinical symptoms attributed to the Essure device, time between
60 Essure sterilization and early symptoms, time between the beginning of symptoms and
61 surgical removal. Follow-up visits were scheduled at one month and three months post-
62 operation. The evolution of symptoms was collected during the follow-up visit at three months
63 based on clinical reports and a dedicated questionnaire. Informed consent was obtained from
64 all participants. Ethics approval was obtained (2018_IRB-MTP_06-05). This study was
65 registered at ClinicalTrial.gov (NCT 03401437).

66 Surgical removal

67 The Essure position was determined by a preoperative ultrasound exam, or alternatively by
68 an X-ray or an MRI. Essure removal techniques included salpingectomy, salpingectomy with
69 cornuectomy, or hysterectomy depending on the Essure device position, associated clinical
70 conditions, and patients' choice. Salpingectomy +/- cornuectomy were performed by
71 laparoscopy. Hysterectomy with salpingectomy were performed by laparoscopy or using a
72 vaginal approach. An intraoperative X-ray of the retrieved Essure devices or a postoperative
73 X-ray of the patient was performed in order to ensure that the Essure device was totally
74 removed. Information about the operative findings, removal techniques, and intraoperative
75 and postoperative complications at one month were collected [10].

76 QoL assessment

77 Health-related QoL was assessed using SF-36 questionnaires both preoperatively and three
78 months postoperatively. In cases where patients did not attend the follow-up clinics at three
79 months, postoperative questionnaires were returned by mail. The SF-36 is a health-related
80 QoL instrument also validated in French-language format [11-13]. This form includes 36
81 items and covers eight different domains of health-related functions, which reflect the
82 patient's perception of their general health symptoms, restrictions on activities, and
83 participation: physical functioning, role limitations due to physical health problems, bodily
84 pain, general health perceptions, vitality, social functioning, role limitations related to

85 emotional problems, and mental health. A linear transformation was performed on a 0 to 100
86 scale (the lower the score, the worse the status). The physical component summary (PCS)
87 and mental component summary (MCS) were calculated by aggregating the eight previous
88 scales.

89 Anxiety and depression evaluation

90 The Hospital Anxiety and Depression Scale (HADS) is among the most widely used brief
91 screening instruments available for identifying cases of emotional disorders. The HADS was
92 submitted twice: preoperatively and three months postoperatively. The scale was designed to
93 be useful in general hospital or outpatient clinical settings where patients often present with
94 multiple physical complaints or conditions that may co-exist with emotional disorders [14].
95 This instrument discriminates between anxiety and depressive disorders with two distinct
96 seven-item subscales assessing anxiety and depression (HADS-A and HADS-D). The
97 possible sum score of each subscale ranges from 0 to 21, with each item scoring 0 to 3
98 points. A high summated score represents high levels of problems. In this study, a score ≥ 11
99 was used as the definition of an emotional disorder [14].

100 Statistical Analysis

101 Categorical data were described by frequency and percentage, and continuous data were
102 described by mean \pm SD or median (Interquartile Range). The McNemar test was used to
103 compare the proportions of symptoms before and after the intervention. The Wilcoxon
104 signed-rank test was used to compare preoperative and postoperative values of the different
105 SF-36 dimensions. The Z-score test was used to compare the means of the different SF-36
106 dimensions of our study population and the values in general population [12]. A p-value of
107 less than 0.05 was considered statistically significant. All analyses were performed using
108 SAS version 9.4 (SAS Institute, Cary, North Carolina).

109

110 **RESULTS**

111 During the study period, 97 patients underwent surgical Essure removal. A complete removal
112 could not be achieved in two cases. Sixty-five patients from Montpellier and 30 patients from

113 Marseille were included. Demographics and clinical characteristics are presented in Table 1.
114 The median time between Essure placement and the beginning of symptoms was five
115 months (IQR 1–12). The median time between the beginning of symptoms and surgical
116 removal was 44 months (IQR 22–72).

117 Symptom assessment

118 Seventy patients (73.7%) presented preoperatively with systemic symptoms associated with
119 gynecologic symptoms. Twenty-four patients (25.3%) had only systemic symptoms, and one
120 patient had only gynecologic symptoms. Twenty-five patients did not attend the three-month
121 follow-up visit. The percentage of patients with systemic symptoms was significantly lower
122 after Essure removal than beforehand [35/70 (50%) versus 69/70 (98%); $p < 0.001$]. The
123 percentage of patients with gynecologic symptoms was significantly lower after Essure
124 removal than beforehand [14/70 (20%) versus 54/70 (77%); $p < 0.001$] (Table 2).

125 Surgical removal

126 Sixty-four patients underwent laparoscopic salpingectomy with or without cornuectomy and
127 31 patients underwent total hysterectomy with salpingectomy. There was no case of blood
128 transfusion. Procedure characteristics are detailed in Table 3. 4/95 (4.2%) intraoperative
129 surgical complications occurred: one case of conversion from cornuectomy to hysterectomy
130 for bleeding, one case of skin burns due to the endoscope light, two cases of bladder injury
131 during hysterectomy. All patients attended the follow-up consultation at one month. During
132 the one-month postoperative period, 7/95 (7.2%) complications occurred: five Clavien Dindo
133 Grade 1 complications and one Grade 2 complication (hyperthermia and digestive disorder
134 requiring antibiotic therapy).

135 SF-36 QoL assessment

136 There were 12 patients lost to follow-up at three months. All components of the preoperative
137 SF-36 score were lower than those of the general population of the same age. These
138 outcomes are detailed in Table 4 and illustrated in Appendix A. All component of the score
139 were significantly improved at three months following surgical Essure removal (Table 5).
140 Preoperative and postoperative outcomes (PCS and MCS) were not associated with criteria

141 such as age, type of symptoms, type of procedure (i.e. salpingectomy-cornuectomy vs
142 hysterectomy) or length of Essure placement (data not presented).
143 The relative variations of PCS and MCS were calculated for each patient and are displayed
144 in the Figure. We defined improvement as a positive relative variation of at least 10%. An
145 improvement was observed in 67/83 patients (80%) for PCS and 69/83 patients (83%) for
146 MCS. 59 patients (71%) patients showed an improvement in both PCS and MCS. 24 patients
147 (29%) showed no improvement in at least one of the two scores, and among these, 18
148 patients (22%) showed a negative relative variation (i.e., worsening) in at least one of the two
149 scores. Three patients showed a worsening of both scores (Appendix B).

150 HADS assessment

151 Data were available at baseline and at three months post-operation for 67 patients. There
152 was a higher percentage of patients with anxiety disorder before Essure removal than after
153 [33/67 (49%) versus 11/67 (16%); $p < 0.001$]. There was a higher percentage of patients with
154 major depression before Essure removal than after [22/67 (33%) versus 3/67 (4%); $p < 0.001$].

155

156 **DISCUSSION**

157 The hysteroscopic tubal implant sterilization by Essure was widely chosen in western
158 countries because it was effective, as well as less invasive and less expensive than
159 laparoscopic tubal ligation. Some of these women later requested removal of the Essure
160 devices due to attributed adverse effects. This study reveals that prior to surgical removal,
161 these patients had a lower QoL compared to the general population of women in the same
162 age group. Three months after removal, QoL improved up to a level similar to the general
163 population.

164 During the first decade following its market release, the safety profile of the Essure
165 system appeared to be good [2,3]. In 2013, the number of voluntary patient-reported adverse
166 events submitted to the Manufacturer and User Facility Device Experience database rose
167 sharply. Consequently, the FDA re-examined the evidence and updated the device label,
168 including information about the risks of chronic pain and device migration [4,15]. Since the

169 FDA warnings, available evidence has been reassuring [16,17]. A recent cohort study found
170 no difference in clinical outcomes at one and three years between women who underwent
171 hysteroscopic versus laparoscopic sterilization [18]. Future research should explore clinical
172 profile and characteristics of the sub-group of patients reporting impaired QoL after Essure
173 placement.

174 The present study population did not appear to have unusual characteristics that
175 would suggest a specific clinical profile at risk of adverse effects due to Essure. The median
176 time between early symptoms and removal of the Essure device was close to four years,
177 even if symptoms started most often in the first year after insertion. The recent media
178 exposure may have influenced removal demands, whereas unexplained symptoms started
179 long before in these women [19,20].

180 Participants had an impaired preoperative QoL according to all areas of measurement
181 of the SF-36 questionnaire. This altered preoperative QoL and the postoperative
182 improvement was further supported by the evolution of the HADS scores [21]. The fact that
183 postoperative SF-36 scores were at a similar level to the general population average is
184 strongly in favor of the positive impact of surgical Essure removal for this population.
185 However, a proportion of participants (29%) were not improved. Given the broad range of
186 preoperative symptoms, it can be hypothesized that these patients had QoL impairment due
187 to other causes.

188 Unsurprisingly, removal procedures can cause surgical complications. There is no
189 international consensus about the most appropriate procedure for Essure removal. In this
190 study, patients were operated according to the principles of the French college of
191 gynecologists, which recommend a conservative treatment whenever possible and an En
192 bloc technique to limit the risk of fragmentation or incomplete removal [22]. The morbidity of
193 hysterectomies should not be neglected, as illustrated in this study [23]. The role of the
194 surgeon is to inform about potential surgical complications and the possible absence of QoL
195 improvement. It is important to cautiously address removal requests, taking into account the

196 preoperative QoL. Thus, candidates with preserved QoL are likely to undergo unnecessary
197 procedures, opening the path to possible litigations.

198 Another study recently assessed QoL before and after surgical removal in a
199 population of 80 women presenting symptoms attributed to Essure [24]. Postoperative
200 evaluation at 3 months revealed an improved QoL, as measured by SF-12 questionnaires
201 and a visual analogue scale. These outcomes maintained at six months. The percentage of
202 women who experienced no improvement in terms of QoL was not provided. This apparent
203 efficacy of Essure removal in a specific population of women presenting new or worsening
204 symptoms after placement of Essure is in keeping with two retrospective studies that
205 reported complete relief of symptoms after device removal in 39.8% and 72.2% of cases
206 [7,9]. Nonetheless, patients should be informed about the possibility of no improvement in
207 terms of QoL after surgery.

208 A strength of the present study was the QoL evaluation using an objective and
209 validated questionnaire. This assessment tool allowed comparisons with women of the same
210 age from the French general population. Furthermore, this is the largest series to date with a
211 three-month follow-up. The one-group design is the main limitation. It is reasonable to
212 assume that surgical Essure removal effects were associated with a placebo effect [25].
213 However, this placebo effect is difficult to estimate given the lack of data in a similar context
214 [26]. An ideal measure to counterbalance this bias would have been to add a placebo control
215 arm. This option was not possible due to ethical concerns. Another limitation is that a variety
216 of removal procedures were undertaken in this study. Thus, hysterectomy is known to
217 improve QoL for patients who present with dysmenorrhea in the same age group [27].
218 However, a majority of patients underwent a surgical treatment conservative of the uterus
219 and QoL improvement occurred regardless of the surgical approach. Finally, the number of
220 patients who did not attend clinical follow-up was not negligible. Nevertheless, in this young
221 working population, this is common and probably due to substantial clinical improvement.
222 Therefore, we think that the potential attrition bias would reinforce our conclusion.

223

224 **CONCLUSION**

225 Patients undergoing surgical removal of Essure devices for alleged related symptoms had a
226 lower QoL preoperatively compared to the general population. These outcomes suggest that
227 Essure removal has a restorative role in terms of QoL 3 months after surgery. Patients
228 should be informed about risks of surgical morbidity. To ensure that the benefit felt after
229 surgery persists, a longer-term follow-up will be of interest.

230

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234

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309

310 **FIGURE LEGEND:**

311 **Figure:** Evolution of SF-36 score between preoperative and postoperative assessment:
 312 distribution of patients for physical component summary (PCS) and mental component
 313 summary (MCS); n=83 patients

314

315 **TABLES:**

316 **Table 1:** Patients characteristics and medical history before Essure placement (n=95)

Characteristics		Preoperative values (n=95)
Age, years, median (IQR)		46 (42-49)
BMI, median (IQR)		23.9 (21-28)
Parity, median		2
Smokers, n (%)		24 (28.6)
Postmenopausal statut, n (%)		8 (8.6)
Past medical history before Essure placement, n (%)		
	Rheumatologic	16 (18.4)
	Neurologic – dysesthesia	7 (8.05)
	Thyroid	6 (6.9)
	Psychiatrics	3 (3.5)
	Cardiologic	2 (2.3)
	Dermatologic or allergic	2 (2.3)
	Ophthalmologic	1 (1.1)

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320 **Table 2:**

321 Symptoms presented before and 3 months after Essure removal: n (percentage)

	Symptoms	Preoperative n =95	Postoperative n=70
Gynecologic	pelvic pain	56 (58.9)	7 (10.0)
	abnormal menstrual bleeding	52 (54.7)	8 (11.4)
	dyspareunia	17 (18.1)	3 (4.3)
Systemic	asthenia	77 (81.1)	8 (11.4)
	joint pain	61 (64.2)	9 (12.9)
	back pain	47 (49.5)	10 (14.3)
	muscular pain	36 (37.9)	4 (5.7)
	ENT disorders	35 (36.8)	5 (7.1)
	memory disorder	33 (34.7)	5 (7.1)
	visual impairment	33 (34.7)	7 (10.0)
	neurological	28 (29.5)	2 (2.9)
	digestive disorder	27 (28.4)	11 (15.7)
	dermatologic	23 (24.2)	1 (1.4)
	urinary	18 (18.9)	2 (2.9)
	cardiologic disorder	18 (18.9)	1 (1.4)
	weight increase	18 (18.9)	3 (4.3)
	respiratory disorder	15 (15.8)	3 (4.3)
	hair loss	10 (10.6)	2 (2.9)
allergic	10 (10.5)	4 (5.7)	

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328 **Table 3:**

329 Procedure characteristics and operative time (n=95)

330

	n (%)	Outpatient (n)	Mean operative time (min)
Salpingectomy with cornuectomy	60 (63.1)	35	111
Salpingectomy only	4 (4.2)	4	51
Laparoscopic hysterectomy with salpingectomy	23 (24.2)	6	103
Vaginal hysterectomy with salpingectomy	8 (8.4)	0	170

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347 **Table 4:**

348 Quality of life assessment (SF-36): comparison of general population vs study population
 349 preoperatively and 3 months postoperatively. Result are presented as mean +/- SD

350

	GENERAL POPULATION	PREOPERATIVE n=95	POSTOPERATIVE n=83
Physical Functioning	86.2 +/- 19.1	62.8 +/- 26.0 **	86.5 +/- 18.7 NS
Role limitations due to Physical health problems	85.5 +/- 29.4	20.8 +/- 30.2 **	77.4 +/- 35.5 **
Bodily Pain	72.0 +/- 23.9	30.3 +/- 17.1 **	66.9 +/- 22.3 **
General Health perceptions	69.1 +/- 18.6	39.5 +/- 20.0 **	67.3 +/- 19.9 *
Vitality	58.9 +/- 17.8	21.7 +/- 16.2 **	61.9 +/- 21.9 **
Social Functioning	79.8 +/- 21.4	36.4 +/- 22.5 **	76.8 +/- 23.6 **
Role limitations related to Emotional problems	83.4 +/-31.2	27.0 +/- 36.2 **	83.9 +/- 33.9 NS
Mental Health	64.8 +/- 16.7	41.4 +/- 18.6 **	70.8 +/- 19.3 *

351 Comparison versus general population were tested using the Z-score test. NS p-value >
 352 0.05; * p-value in [0.01-0.05]; ** p-value <0.0001.

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361 **Table 5:** Quality of life assessment (SF-36): Comparison preoperative versus postoperative
 362 scores at 3 months. Result are presented as median (interquartile range)

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	PREOPERATIVE n=95	POSTOPERATIVE n=83	DELTA
Physical component summary	37.6 (32-44)	50.70 (45-55) *	10.8 (5-18)
Mental component summary	29 (23-36)	52.39 (44-56) *	20.3 (12-28)
Physical Functioning	70 (45-85)	95 (80-100) *	20 (5-35)
Role limitations due to Physical health problems	0 (0-25)	100 (50-100) *	75 (0-100)
Bodily Pain	31 (22-41)	72 (51-84) *	40 (21-52)
General Health perceptions	40 (25-57)	70 (57-82) *	25 (10-42)
Vitality	20 (10-30)	65 (50-80) *	45 (15-60)
Social Functioning	37.5 (25-50)	87.5 (62,5-100) *	37.5 (12,5-62,5)
Role limitations related to Emotional problems	0 (0-33)	100 (100-100) *	66.7 (0-100)
Mental Health	40 (28-52)	75 (60-84) *	28 (26-44)

364 * p-Values <0.001 (Wilcoxon signed-rank test comparing postoperative versus preoperative)

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