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## Quality of life after laparoscopic removal of Essure<sup>®</sup> sterilization devices



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### ABSTRACT

**Objective(s):** To assess changes in quality of life after laparoscopic removal of Essure<sup>®</sup> sterilization devices (Bayer AG, Leverkusen, Germany).

**Study Design:** In this prospective observational study in an academic research hospital, 80 women with new or worsening symptoms since placement of Essure<sup>®</sup> sterilization devices undergoing subsequent surgical removal were included. Laparoscopic removal of Essure<sup>®</sup> devices and salpingectomy with or without cornual excision were performed. Concomitant uterine procedures could be associated where indicated for gynaecological complaints. Comparison using the T student test for coupled series was done in this before-and-after study.

**Results:** Health related quality of life (HRQL) was the primary outcome measured by the Short Form 12 (SF-12) questionnaire and a global 10 cm visual analogue scale (VAS). Secondary outcomes included assessment of pain, using continuous (VAS) and ordinal scales (Modified McGill Pain Questionnaire), menstrual bleeding (pictorial blood loss assessment chart (PBAC) score) and surgical feasibility and safety. There was a significant improvement in quality of life in both mental and physical health aspects of the SF-12 (34.02 (+/-1.19) vs. 49.61 (+/-1.42,  $P < .0001$ ) and 36.55 (+/-0.99) vs. 43.32 (+/-1.18,  $P < .0001$ ) respectively) as well as global VAS assessment (+2.91 (SD +/-0.27)) at the end of the first post-operative month. These improvements were maintained at three and six months. Mean pain decreased at one month following surgery compared to baseline (VAS 3.6 (+/-0.36) to 1.4 (+/-0.25),  $P < .0001$  and McGill pain score 18.70 (+/-1.88) to 4.73 (+/-0.90),  $P < .0001$ ). Improvements of a similar magnitude were observed when analysis was restricted to the 47 women without concomitant uterine surgery. No significant changes in bleeding were seen following of Essure<sup>®</sup> device removal. Planned procedures were all successfully completed.

**Conclusion:** Laparoscopic removal of Essure<sup>®</sup> devices in symptomatic women is technically successful and associated with short and medium-term improvement in quality of life as well as reduction in pelvic pain.

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### Introduction

Safety concerns and ensuing, high profile campaigns by patient groups has led to hysteroscopic sterilization using the Essure<sup>®</sup> method (Bayer AG, Leverkusen, Germany) being withdrawn from clinical practice by the manufacturers [1,2]. As a consequence, increasing numbers of women are requesting removal of Essure<sup>®</sup>

devices primarily because of symptoms attributed to the devices [3]. Symptoms are thought to arise directly from the presence of the foreign bodies within the uterus, whether optimally or suboptimally sited, or indirectly from components of the devices; metals (nickel, titanium and stainless steel) and polyethylene terephthalate (PET) fibers [1,4–6]. The main presentation relates to pelvic pain but other gynaecological symptoms reported include abnormal uterine bleeding (AUB) and menopausal symptoms. In addition, a broad range of non-specific symptoms, such as persistent asthenia, heart palpitations, tinnitus, pruritus, joint and/or muscular pain, rashes and digestive disorders have been reported [3].

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Whether all such symptoms are caused by correctly placed Essure<sup>®</sup> devices is contentious but individual or combinations of symptoms can impact adversely on health-related quality of life. Data pertaining to surgical removal of devices are scarce, restricted to small retrospective studies. However, these reports suggest that surgical removal of the Essure<sup>®</sup> devices may improve symptomatology [3–7] and the French College of Gynecology and Obstetrics (CNGOF) [8] has recently issued guidance recommending specialist referral to discuss device removal in symptomatic women.

We conducted a prospective observational study to evaluate the efficacy of laparoscopic surgical removal of Essure<sup>®</sup> devices in alleviating presenting symptoms and improving quality of life.

## Material and methods

A single centre, prospective study of women undergoing surgical removal of Essure<sup>®</sup> devices was conducted at the University Hospital of Lyon (HFME, Lyon, France) from 1 October 2017 to 30 August 2018. This study received permission from the Civil Hospices de Lyon Ethics Committee and is registered under clinicaltrials.gov identifier: NCT03281564. All women presenting with new, persistent and treatment-resistant complaints (non-specific gynaecological or extra-gynaecological symptoms such as pelvic pain, abnormal uterine bleeding (AUB), persistent asthenia, heart palpitations, tinnitus, pruritus, joint and/or muscular pain, rashes and digestive disorders) since their Essure<sup>®</sup> procedure were invited to participate in the study. Consenting women agreed to provide baseline and post-surgical removal follow up data relating to symptoms including pain and bleeding as well as their impact upon health-related quality of life (HRQL).

### Patient reported outcome measures (PROMs)

The primary objective was to evaluate the degree of improvement in short and medium-term HRQL at one, three and six months after laparoscopic removal of Essure<sup>®</sup> devices. HRQL was assessed using the validated Short Form 12 (SF-12) questionnaire [9,10], a generic assessment tool measuring physical and mental health status. The mean HRQL as measured using the SF-12 is 50 in both domains in the general population; the higher the score, the better the quality of life. In addition, a 10-cm continuous Visual Analogue Scale (VAS) was used to evaluate global HRQL. Women were asked to mark the scale in response to the question: “how do you feel now compared with before surgery?”; at one end of the spectrum was “a lot worse” and at the other end “a lot better” and this scale was anchored in the middle (at 5 cm) with the statement “No change”.

Pain was evaluated with a 10 cm-VAS and also using the modified French version of the McGill pain questionnaire (QDSA – Questionnaire Douleur de Saint-Antoine) [11–13]. In the short form

of the QDSA there are 16 items and the higher the pain score the more intense the pain. Overall pain scores can range from 0 to 64 comprising of a sensory component (score 0–36) and an affective component (score 0–28). A semi-objective measurement of the amount of menstrual bleeding was obtained using the pictorial blood assessment chart (PBAC) [14].

### Surgical approach and outcomes

A pre-operative ultrasound was performed to verify correct tubal position of the Essure<sup>®</sup> implants and the absence of uterine anomalies. In the case that the implants could not be visualized, a computed axial tomography (CT) or a magnetic resonance imaging (MRI) scan was performed. Laparoscopic surgical removal of Essure<sup>®</sup> devices were performed by three expert surgeons (GC, KLBC, GL) under general anaesthesia in an ambulatory setting. A 1–2 cm longitudinal incision was made over the proximal fallopian tube using monopolar scissors until the tubal lumen containing the Essure<sup>®</sup> device was visualised [15,16]

*Tubal incision and soft traction* [15]. The device was gently grasped using atraumatic forceps and pulled from within the utero-tubal lumen by systematically ‘walking’ the device out, being careful to avoid elongating and uncoiling the micro-insert from the application of excessive traction. A salpingectomy was then performed [16,17].

*Mini-cornuectomy* [18]. The device was gently grasped and elevated using atraumatic forceps and monopolar scissors were then used to make a small, circular cornual incision. This allowed the proximal aspect of the device to be identified and removed without traction, minimising the risk of inadvertent device fracture. The salpingectomy was then completed [16,17].

In both cases, the removed Essure<sup>®</sup> devices were inspected on a surgical drape to check that the device had been fully removed. This was confirmed by visualising both the distal spherical and proximal rectangular ends of the intact Essure<sup>®</sup> microinsert, taking particular care to reassemble the device in the presence of fracturing (Fig. 1). If device fractures occurred during of the microinsert removal, a laparoscopic peritoneal washing was performed followed by an abdominal and pelvic x-ray in the post-operative room.

Concomitant endometrial ablation was performed in some women complaining of heavy menstrual bleeding. In addition, laparoscopic myomectomy or hysterectomy was performed in some women where bleeding or pain symptoms were associated with an ultrasonic diagnosis of symptomatic fibroids and / or adenomyosis. In case of ultrasonic discovery of non-symptomatic small fibroids or non-symptomatic adenomyosis, Essure<sup>®</sup> removal alone was performed.

Surgeons rated the complexity of removal of the Essure device using a 10 cm-VAS ranging from “easy” to “difficult” immediately



Fig. 1. Complete removal of the Essure<sup>®</sup> device confirmed by visualising both the distal spherical and proximal rectangular ends of the microinsert.

after surgery. The duration of surgery and the peri-operative and post-operative complications, using the Clavien-Dindo classification [19], a validated, surgical complication scoring system, were also reported.

### Statistical analysis

Patient characteristics, type of symptoms and surgical data were described. Continuous data were presented means and standard deviations. Categorical and dichotomous data were presented as percentages. The average of the quality of life, pain and bleeding scores, before and after surgery, were compared using the T student test for coupled series.

## Results

### Surgical outcomes

Patient characteristics and intraoperative data are presented in Table 1. In total, 80 women underwent laparoscopic removal of their Essure<sup>®</sup> devices; in 21 women this was carried out by tubal incision and traction and in the remaining 59 women using a mini-cornuectomy. During the same surgery, but following the removal of Essure<sup>®</sup> devices, 33/80 women underwent additional uterine procedures: 23 radiofrequency global endometrial ablations (NovaSure<sup>®</sup> device, Hologic, MA, USA); five laparoscopic myomectomies and five laparoscopic hysterectomies. In all 80 surgeries, complete removal of the Essure<sup>®</sup> devices was possible but there were six (28.5%) device fractures associated with the tubal incision and traction approach in contrast to no fractures when the mini-cornuectomy technique was adopted. No persistent intra-abdominal fragment was identified on the post-operative radiography confirming the complete removal of the device in all cases of fracture.

There was no significant difference in the mean time required to remove an Essure device from a fallopian tube according to the technique used (incision and traction (9.5 min (+/- 1.03) per device vs. mini-cornuectomy (10.4 min (+/- 1.2) per device, P=0.53). The majority of procedures were considered by the surgeons to be simple. This included seven cases where an incorrectly sited Essure<sup>®</sup> device was identified: four simple tubal perforations (device attached to the tube) and three complex tubular perforations where the device was found located in the epiploen (two cases) and in the fringes of the caecal fat (one case). However, operators described significantly more technical difficulties removing the Essure<sup>®</sup> devices by the tubal incision and traction technique compared with the mini-cornuectomy technique (5/21 (23.8% 95% CI 5.5%–42%) vs. 6/59 (10.1% 95% CI 2.4%–17.8%), p=0.07). There was one Clavien-Dindo Grade 3 perioperative complication consisting of an intestinal injury sustained during the placement of the primary umbilical trocar. This was promptly recognised and immediately repaired during surgery without the need for a laparotomy. There were two Clavien-Dindo grade 2 postoperative complications: two cases of urinary infections. All women were discharged home the same day except for eight women: seven of them had undergone concomitant laparoscopic myomectomy or hysterectomy and the one with the intestinal injury was discharged home on the third post-operative day.

### Patient outcomes

Outcome questionnaires were completed for 80 (100%), 75 (93.7%) and 73 (91.2%) at one, three and six months time points respectively. There was a significant improvement in quality of life as measured by the SF-12 at the end of the first post-operative month in both the mental and physical health scores compared with baseline (34.02 (+/-1.19) vs. 49.61 (+/-1.42), p < 0.0001 and 36.55 (+/-0.99) vs. 43.32 (+/-1.18, p < 0.0001 respectively)). This

**Table 1**

Patient characteristics and intraoperative data.

|                                                                                                            | All patients<br>(N = 80) |
|------------------------------------------------------------------------------------------------------------|--------------------------|
| Mean (range) BMI (kg/m <sup>2</sup> )                                                                      | 25.4 (21.1–29.3)         |
| Mean (range) age (years)                                                                                   | 45 (35–54)               |
| Mean (range) length of time between Essure placement and removal (months)                                  | 45.3 (8–122)             |
| Mean (range) time between Essure placement and first symptoms (months)                                     | 5.6 (2–19)               |
| History of nickel allergy (n)                                                                              | 6 (7.5%)                 |
| History of pain syndromes (n):                                                                             | 13 (16.25%)              |
| -fibromyalgia                                                                                              | 3 (3.75%)                |
| -autoimmune disease (rheumatoid arthritis or spondyloarthritis or lupus or digestive inflammatory disease) | 4 (5%)                   |
| -back pain                                                                                                 | 6 (7.5%)                 |
| Ultrasonic pre-operative findings                                                                          | 42 (52.5%)               |
| -adenomyosis with heavy bleeding and/or cyclic pain                                                        | 28 (35%)                 |
| - non-symptomatic adenomyosis                                                                              | 5 (6.25%)                |
| -fibroids with heavy bleeding and/or cyclic pain                                                           | 5 (6.25%)                |
| -non-symptomatic fibroids                                                                                  | 4 (5%)                   |
| Surgical technique                                                                                         | 21 (26.3%)               |
| Tubal incision and soft traction                                                                           | 59 (73.7%)               |
| Mini-cornuectomy                                                                                           |                          |
| Mean (SD) Essure <sup>®</sup> removal duration (minutes):                                                  | 10.21 (+/-1.07)          |
| Right side                                                                                                 | 10.56 (+/-0.76)          |
| Left side                                                                                                  |                          |
| Complications                                                                                              | 1 (1.2%) <sup>1</sup>    |
| Peri-operative                                                                                             | 2 (2.5%) <sup>2</sup>    |
| Post-operative                                                                                             |                          |
| Hospital stay (days)                                                                                       | 72 (90%)                 |
| 1                                                                                                          | 3 (3.75%) <sup>3</sup>   |
| 2                                                                                                          | 5 (6.25%) <sup>3</sup>   |
| >2                                                                                                         |                          |

BMI, body mass index. SD, standard deviation.

<sup>1</sup> One case of intestinal injury during primary open trocar insertion immediately repaired through the umbilical incision (Clavien-Dindo grade 3) [18].

<sup>2</sup> Two cases of urinary tract infection treated with antibiotics (Clavien-Dindo grade 2) [18].

<sup>3</sup> Concomitant hysterectomy / myomectomy. One intestinal injury.

**Table 2**  
Quality of life before and after Essure<sup>®</sup> device removal n = 80 (Data are expressed means and standard deviations).

|                                                   | Pre-surgery     | Post-surgery                         |                              |                              |
|---------------------------------------------------|-----------------|--------------------------------------|------------------------------|------------------------------|
|                                                   | Baseline        | One month (n = 80)                   | Three months (n = 75)        | Six months (n = 73)          |
| SF-12 questionnaire:                              |                 |                                      |                              |                              |
| Mental health score                               | 34.02 (+/-1.19) | 49.61 <sup>*</sup> (+/-1.42) p<.0001 | 53.36 <sup>*</sup> (+/-1.36) | 50.19 <sup>*</sup> (+/-2.47) |
| p value                                           |                 | 43.32 <sup>*</sup> (+/-1.18)         | p<.0001                      | p= 0.01                      |
| Physical health score                             | 36.55 (+/-0.99) | p<.0001                              | 44.63 <sup>*</sup> (+/-1.79) | 48.56 <sup>*</sup> (+/-2.41) |
| p value                                           |                 |                                      | p<.0001                      | p= 0.003                     |
| Global improvement of quality of life (10 cm VAS) | -               | 2.91 (+/-0.27)                       | 3.25 (+/- 0.36)              | 3.28 (+/-0.89)               |
| Global pain (10 cm VAS)                           | 3.6 (+/-0.36)   | 1.4 <sup>*</sup> (+/-0.25)           | 0.8 <sup>*</sup> (+/-0.21)   | 1.5 (+/- 0.68)               |
| p value                                           |                 | p<.0001                              | p<.0001                      | p= 0.18                      |
| McGill pain score                                 | 18.70 (+/-1.88) | 4.73 <sup>*</sup> (+/-0.90)          | 1.90 <sup>*</sup> (+/-0.62)  | 3.0 <sup>*</sup> (+/-1.73)   |
| p value                                           |                 | p<.0001                              | p<.0001                      | p= 0.003                     |
| Sensory component                                 | 9.78 (+/-0.94)  | 3.04 <sup>*</sup> (+/-0.54)          | 1.65 <sup>*</sup> (+/-0.49)  | 2.25 <sup>*</sup> (+/-1.23)  |
| p value                                           |                 | p<.0001                              | p<.0001                      | p= 0.008                     |
| Affective component                               | 8.91 (+/-1.04)  | 1.68 <sup>*</sup> (+/-0.44)          | 0.25 <sup>*</sup> (+/-0.16)  | 0.75 <sup>*</sup> (+/-0.5)   |
| p value                                           |                 | p<.0001                              | p<.0001                      | p= 0.003                     |
| Pictorial blood assessment chart                  | 302.7 (+/-53.1) | 176.1 (+/-49.1)                      | 124.1 (+/-44.8)              | 247.0 (+/-65.5)              |
| p value                                           |                 | p= 0.06                              | p= 0.08                      | p= 0.83                      |

VAS = visual assessment scale.

\* Statistically significant result (P < 0.05 - post-operative data were compared to pre-operative, baseline data with the student t-test for coupled series).

improvement in HRQL was maintained at three and six months post intervention (Table 2). There was a 58% improvement in global quality of life at one month following surgery as measured on a VAS (mean improvement +2.91 (SD +/-0.27)). This average global improvement increased to 65% at three and six months (Table 2). In the 47 patients with exclusive Essure<sup>®</sup> removal (i.e. no associated uterine procedures), global improvement of quality of life at one month was of a similar magnitude at 63% although this reduced slightly to a 50% improvement at 6 months post-surgery. Quality of life data are presented in Tables 2–4.

The estimated pain with the 10 cm-VAS index and with the McGill questionnaire (both in the sensorial and affective components) significantly decreased in the first post-operative month. Mean pain as measured by the global VAS reduced from 3.6 (+/-0.36) to 1.4 (+/-0.25), p < 0.0001 and from a mean overall score of 18.70 (+/-1.88) down to 4.73 (+/-0.90), p < 0.0001 according to the McGill pain score. Moreover, this lower level of pain was maintained at three months post intervention. At six months pain remained significantly reduced according to the McGill pain score although the decrease from baseline in pain intensity was non-significant as measured by the VAS (Table 2). A

similar pattern in terms of the changes in magnitude of pain post-surgery was observed in the 47 women without uterine surgery (Table 3).

There was a non-statistically significant decrease in bleeding at all time points post intervention, as assessed using the PBAC score (Table 2). However, when concomitant surgical procedures to treat heavy menstrual bleeding (i.e. hysterectomy, myomectomy and radiofrequency global endometrial ablation) were excluded, Essure<sup>®</sup> removal was associated with a non-significant increase in the amount of bleeding (Table 3). In case of Essure<sup>®</sup> removal with concomitant surgical procedures, there was a statistically significant decrease in the amount of bleeding at three and six months (Table 4).

### Comment

Laparoscopic surgical removal of Essure<sup>®</sup> sterilization devices appears to be a safe, successful and ambulatory procedure associated with rapid improvement in HRQL and pelvic pain, which is sustained up to six months. No reduction in the amount of menstrual bleeding attributable to removal of the Essure<sup>®</sup> devices

**Table 3**  
Quality of life before and after Essure<sup>®</sup> device removal without associated procedures n = 47 (Data are expressed means and standard deviations).

|                                                   | Pre-surgery     | Post-surgery                 |                              |                              |
|---------------------------------------------------|-----------------|------------------------------|------------------------------|------------------------------|
|                                                   | Baseline        | One month (n = 47)           | Three months (n = 45)        | Six months (n = 43)          |
| SF-12 questionnaire:                              |                 |                              |                              |                              |
| Mental health score                               | 34.02 (+/-1.50) | 48.89 <sup>*</sup> (+/-1.87) | 52.78 <sup>*</sup> (+/-1.69) | 50.60 <sup>*</sup> (+/-2.56) |
| p value                                           |                 | p<.0001                      | p<.0001                      | p= 0.049                     |
| Physical health score                             | 36.34 (+/-1.28) | 44.04 <sup>*</sup> (+/-1.31) | 45.30 <sup>*</sup> (+/-2.46) | 48.73 <sup>*</sup> (+/-2.48) |
| p value                                           |                 | p= 0.0002                    | p<.0001                      | p= 0.003                     |
| Global improvement of quality of life (10 cm VAS) | -               | 3.16 (+/-0.28)               | 3.83 (+/-0.3)                | 2.77 (+/-1.19)               |
| Global pain (10 cm VAS)                           | 3.37 (+/-0.42)  | 1.86 <sup>*</sup> (+/-0.36)  | 1.16 <sup>*</sup> (+/-0.33)  | 1.76 (+/- 0.90)              |
| p value                                           |                 | p= 0.01                      | p=0.008                      | p= 0.37                      |
| McGill pain score                                 | 17.42 (+/-2.23) | 6.27 <sup>*</sup> (+/-1.39)  | 2.11 <sup>*</sup> (+/-0.65)  | 3.66 <sup>*</sup> (+/-2.27)  |
| p value                                           |                 | p<.0001                      | p= 0.0005                    | p= 0.02                      |
| Sensory component                                 | 9.0 (+/-1.09)   | 3.86 <sup>*</sup> (+/-0.83)  | 1.94 <sup>*</sup> (+/-0.59)  | 2.66 <sup>*</sup> (+/-1.61)  |
| p value                                           |                 | p<.0001                      | p= 0.0003                    | p=0.04                       |
| Affective component                               | 8.42 (+/-1.27)  | 2.41 <sup>*</sup> (+/-0.69)  | 0.16 <sup>*</sup> (+/-0.12)  | 1.0 <sup>*</sup> (+/-0.66)   |
| p value                                           |                 | p<.0001                      | p= 0.002                     | p= 0.02                      |
| Pictorial blood assessment chart                  | 140.3 (+/-28.9) | 243.0 (+/-71.6)              | 190.2 (+/-75.2)              | 238.5 (+/-73.6)              |
| p value                                           |                 | p=0.09                       | p=0.55                       | p= 0.83                      |

VAS = visual assessment scale.

\* Statistically significant result (P < 0.05 - post-operative data were compared to pre-operative, baseline data with the student t-test for coupled series).

**Table 4**

Quality of life before and after Essure<sup>®</sup> device removal with associated procedures (endometrial ablation and hysterectomy) n = 28 (Data are expressed means and standard deviations).

|                                                   | Pre-surgery     | Post-surgery                 |                              |                             |
|---------------------------------------------------|-----------------|------------------------------|------------------------------|-----------------------------|
|                                                   | Baseline        | One month<br>(n = 28)        | Three months<br>(n = 25)     | Six months<br>(n = 25)      |
| SF-12 questionnaire:                              |                 |                              |                              |                             |
| Mental health score                               | 34.02 (+/-2.01) | 50.75 <sup>*</sup> (+/-2.18) | 54.40 <sup>*</sup> (+/-2.14) | 48.98 (+/-2.43)             |
| p value                                           | 36.94 (+/-1.58) | p<.0001                      | p<.0001                      | p= 0.17                     |
| Physical health score                             |                 | 42.18 (+/-2.28)              | 44.39 <sup>*</sup> (+/-2.46) | 48.07 (+/-2.34)             |
| p value                                           |                 | p= 0.06                      | p= 0.001                     | p= 0.48                     |
| Global improvement of quality of life (10 cm VAS) | -               | 2.48 (+/-0.58)               | 2.64 (+/-0.67)               | 4.63 (+/-0.18)              |
| Global pain (10 cm VAS)                           | 4.19 (+/-0.65)  | 0.80 <sup>*</sup> (+/-0.26)  | 0.26 <sup>*</sup> (+/-0.08)  | 1.06 (+/- 0.86)             |
| p value                                           |                 | p= 0.0002                    | p=0.002                      | p= 0.21                     |
| McGill pain score                                 | 20.92 (+/-3.40) | 2.52 <sup>*</sup> (+/-0.74)  | 1.53 <sup>*</sup> (+/-1.12)  | 1.32 (+/-1.0)               |
| p value                                           | 11.14 (+/-1.74) | p<.0001                      | p= 0.0002                    | p=0.15                      |
| Sensory component                                 | 9.77 (+/-1.27)  | 1.88 <sup>*</sup> (+/-0.51)  | 1.20 <sup>*</sup> (+/-0.79)  | 1.02 (+/-0.60)              |
| p value                                           |                 | p<.0001                      | p= 0.0003                    | p=0.08                      |
| Affective component                               |                 | 0.64 <sup>*</sup> (+/-0.32)  | 0.33 <sup>*</sup> (+/-0.33)  | 0.3 (+/-0.1)                |
| p value                                           |                 | p<.0001                      | p= 0.0006                    | p= 0.21                     |
| Pictorial blood assessment chart                  | 492.1 (+/-81.4) | 54.5 (+/-17.5)               | 39.4 <sup>*</sup> (+/-19.9)  | 38.5 <sup>*</sup> (+/-19.9) |
| p value                                           |                 | p=0.25                       | p= 0.02                      | p= 0.03                     |

VAS = visual assessment scale.

<sup>\*</sup> Statistically significant result (P < 0.05 - post-operative data were compared to pre-operative, baseline data with the student *t*-test for coupled series).

was observed. Essure<sup>®</sup> removal alone seems enough to improve quality of life, but concomitant procedures as hysterectomy or endometrial ablation should be needed if the patients complaint with important menstrual bleeding.

Criteria based upon the symptom chronology, severity and response to medical treatments in the absence of other explanatory pathologies, have been suggested to assist the clinician and the patient when deciding whether to undergo removal of Essure<sup>®</sup> devices [18]. Furthermore, in the absence of abnormally sited Essure<sup>®</sup> devices, the varied and often non-specific nature of women's presenting symptoms make it difficult for the clinician to formulate effective management plans. The apparent efficacy of surgically removing Essure<sup>®</sup> devices reported here are in keeping with two retrospective studies that reported complete relief of symptoms after device removal in 39.8% and 72.2% [3,7,20]. Failure to eradicate symptoms reflects the generic nature of the symptomatology and suggests that persisting symptoms may not be related to the Essure<sup>®</sup> device [3].

This study described two surgical approaches for removing Essure<sup>®</sup> devices from the fallopian tubes. Both techniques were highly feasible but mini-cornuectomy was considered subjectively easier to perform than conventional tubal incision and soft traction. Furthermore, the latter technique was associated with device fractures in 28.5% of cases presumably because of difficulty in controlling tensile pressures when applying traction on the fragile devices. Thus, mini-cornuectomy seems the preferable technique because potential problems arising from fragmentation and retention of components of the devices within the peritoneal cavity are avoided [18]. Only the removed Essure<sup>®</sup> devices need to be inspected on a surgical drape to confirm they have been fully removed (Fig. 1). Therefore, pelvic x-ray and removed Essure<sup>®</sup> devices x-ray are unnecessary.

Strengths of our study include its prospective design, novelty and good rates of follow up in both the short term, allowing assessment of the rapidity of symptom resolution post-surgery but also in the medium term to see if early effects are sustained. Patient centred symptomatic outcomes were collected in addition to evaluating surgical endpoints. The limited data that are available pertaining to the removal of Essure<sup>®</sup> devices concentrate upon technical aspects of the surgery or patient symptoms [3,4]. However, one of the problems assessing the effectiveness of removing these contentious devices is that the presenting

symptoms are not restricted to pelvic pain or uterine bleeding but are often multiple and diverse. It was for this reason that we chose HRQL with validated questionnaires as our primary outcome in order to better understand the effect of surgery upon overall patient wellbeing.

Limitations of the current study include its relatively small sample and follow up limited to six months. Although 33 (40%) women in our cohort underwent a concomitant uterine procedure, endometrial ablation for heavy menstrual bleeding accounted for 70% of these additional interventions and only five (6%) women had a hysterectomy. Moreover, when analysis was restricted to the 47 women exclusively undergoing laparoscopic removal of Essure<sup>®</sup> devices, the magnitude and direction of clinical outcomes did not materially change. Thus, these consistent findings imply that the clinical improvement in HRQL and alleviation of pelvic pain relate to surgical removal of the Essure<sup>®</sup> devices.

The findings from this study that day-case removal of Essure<sup>®</sup> devices is not only simple and safe but also is associated with rapid improvement in HRQL and alleviation of pelvic pain symptoms should further reassure clinicians that this management strategy can be supported. Whilst longer-term outcome data and a randomizing management with a control group are needed to validate our findings, these data, along with others [3,20], can be used to help counsel women about the likely outcomes although they should be made aware of the ongoing uncertainties.

#### Disclosure statement

The authors declare they have no conflict of interest to disclose.

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