# Comparison of The Effect of a Hysteroscopic Niche Resection and LNG-IUD on Niche Related Postmenstrual Spotting: An Interventional Study

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## Abstract

***Background:*** **Caesarean deliveries are regarded as one of the most prevalent surgical procedures, constituting one-third of all births globally. In a few cases, the scar on the uterus from a caesarean section doesn't heal fully, which leads to the formation of the uterine niche. This can cause irregular uterine bleeding, dysmenorrhea, and secondary infertility.** ***Aim:*** **To improve women's physical health by reducing cesarean section long term complication such as niche related postmenstrual spotting and bleeding by using different modalities of interventions. Objectives: To evaluate the efficacy of hysteroscopic niche excision versus LNG-IUD in mitigating niche-related postmenstrual spotting at six months post-treatment.** ***Subjects and methods:*** **his study was performed in the Department of Obstetrics & Gynecology at Suez Canal University Hospital from December 2021 to June 2023, involving 56 women presenting with postmenstrual spotting and diagnosed with a niche. Participants will be randomly assigned to either the hysteroscopy group or the LNG-IUD group following the fulfilment of inclusion criteria and will be monitored for 6 months post-treatment.** ***Results:*** **Fifty of the fifty-six eligible patients were included, with twenty-five patients in each group completing the six-month follow-up. The LNG-IUD group demonstrated markedly superior outcomes in all menstrual and bleeding characteristics, which were considerably lower than those in the hysteroscopy group, with a p-value of less than 0.0001.The efficacy rate improved over a period of 6 months following the implantation of the LNG-IUD (from 60% to 88%; P value < 0.006), whereas no trend change was noted in the hysteroscopy group.** ***Conclusion:*** **the LNG-IUD demonstrates superior efficacy in addressing postmenstrual spotting from the 6$^{th}$ month onwards compared to hysteroscopic niche excision in patients with a symptomatic niche, while incurring fewer direct expenses.**

**Keywords**: *Uterine cesarean scar niche, Hysteroscopy niche excision, Levonorgestrel-releasing intrauterine device, Postmenstrual bleeding.*

## Introduction

Over the past three decades, the number of caesarean sections (CS) has increased to a level that is higher than what is regarded to be best. The rate of this operation around the world has doubled in the last 10 years, reaching 21%. It goes up by 4% every year [(1).] More than half of deliveries in middle-income nations like Egypt are now by caesarean section [(2)].

The scar that forms in the uterus after each caesarean section is the result. Some patients' uterine scars don't heal completely following a caesarean section, which causes the uterine niche to form. Most of the minor niches don't cause any problems, but the big caesarean scar niches in women who aren't pregnant can induce caesarean scar syndrome, which shows up as abnormal uterine bleeding,

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painful periods, and secondary infertility [3].

Healthcare professionals have known for a long time that caesarean deliveries might cause long-term health problems. This may be because of a problem with the scar from the uterine caesarean section. Sono-hysterography shows that it is a breach of the myometrial integrity at the caesarean scar site, with a minimum depth of 2 mm. There are many ways to make a diagnosis, including magnetic resonance imaging and hysteroscopy [4].

A pouch or "isthmocele" in the caesarean section scar is thought to be the source of postmenstrual spotting. This bag lets blood that has been stuck in the scar slowly leak out in the days after menstruation (5).

There have been both surgical and non-surgical treatments for spotting symptoms that come with caesarean scar abnormalities (6). Transvaginal, laparoscopic, and hysteroscopic niche resections are all surgical options. Hysteroscopic niche resection is the best minimally invasive method for people with a small caesarean scar defect and myometrial thickness greater than 2.5 mm [7].

Non-surgical methods include hormonal medications that are given all the time or on a schedule, as well as a Levonorgestrel-releasing intrauterine device (52 mg) [8]. LNG-IUS (52 mg) has been shown to work to reduce menstrual blood loss and dysmenorrhea by stopping the growth of the endometrium through the action of levonorgestrel [9].

Research assessing the impact of hormonal therapy on LNG-IUD is few; nevertheless, a prior study suggested a beneficial effect of LNG-IUD in the management of patients with post-menstrual spotting [10].

The objective of this study is to examine the efficacy of hysteroscopic niche excision with LNG-IUD in diminishing niche-related postmenstrual spotting.

## Aim of the work

To improve women's physical health by reducing cesarean section long term complications such as niche related postmenstrual spotting and bleeding by using different modalities of interventions.

## Objectives:

1- To assess of menstrual characteristics and complications before and after treatment.

2- To evaluate the efficacy of hysteroscopic niche excision versus LNG-IUD in mitigating niche-related postmenstrual spotting at six months post-treatment.

3- To assess the relation between menstruation satisfaction and characteristics of bleeding/menstruation among study groups after each intervention.

## Patients and Methods

**Type of study:** A randomized control trail.

**Study setting**: The study was conducted in the department of Obstetrics & Gynecology, Suez Canal University hospital.

**Study Population:** Women of childbearing period presenting at the outpatient clinic of the Department of Obstetrics and Gynecology complaining of postmenstrual spotting and diagnosed with uterine caesarean scar defect (niche) from December 2021 to June 2023.

**Criteria for inclusion:**

Women aged 20 to 45 years with a history of at least one previous caesarean section, who had postmenstrual spotting for a minimum of 2 days and demonstrated a

niche on Sono-hysterography, were deemed eligible to participate in our study.

**Criteria for exclusion:**

-Planning for conception within one year.

- Irregularities in the menstrual cycle preceding the last caesarean delivery,

- Coagulopathy

- Uterine cavity length is either below 6 cm or beyond 10 cm - Hormone therapy administration

- Additional gynaecological conditions that may lead to irregular uterine bleeding encompass uterine fibroids, endometrial hyperplasia, and pregnancy.

- Prior history of hysteroscopic resection or placement of a levonorgestrel-releasing intrauterine device (LNG-IUD).

The analyzed population was divided into two cohorts: one cohort had hysteroscopic niche excision, while the other cohort received the insertion of a 52 mg LNG-IUD. In the hysteroscopic cohort, the residual myometrium thickness (RMT) should not fall below 2.2 mm to prevent bladder injury and uterine perforation.

A total of 56 participants were included; 28 received an LNG-IUD implantation, while the other 28 underwent hysteroscopic niche excision.

The patients were randomly assigned in a 1:1 ratio to either the hysteroscopic niche resection group or the LNG-IUD group by centralized systematic randomization using the web-based REDCap (Research Electronic Data Capture) system. 22.

The second group who underwent hysteroscopic niche resection of niche was advised to use barrier contraceptive method for 1 year.

**All patients were subjected to the following:**

- Thorough medical history: age, parity, obstetric history, detailed menstrual history pre- and post-operative, previous surgery, chronic illness, past history of any operation, number of Caesarean sections and timing of last CS.
- Physical examination: general, abdominal and pelvic examination.
- Investigations:
  - Radiology: sonohystrography and trans-vaginal US for site of the niche, size of the niche, thickness of myometrium at scar site and depth of niche.
  - Laboratory: Baseline hormonal profile, complete blood picture, liver, kidney function test and coagulation profile.

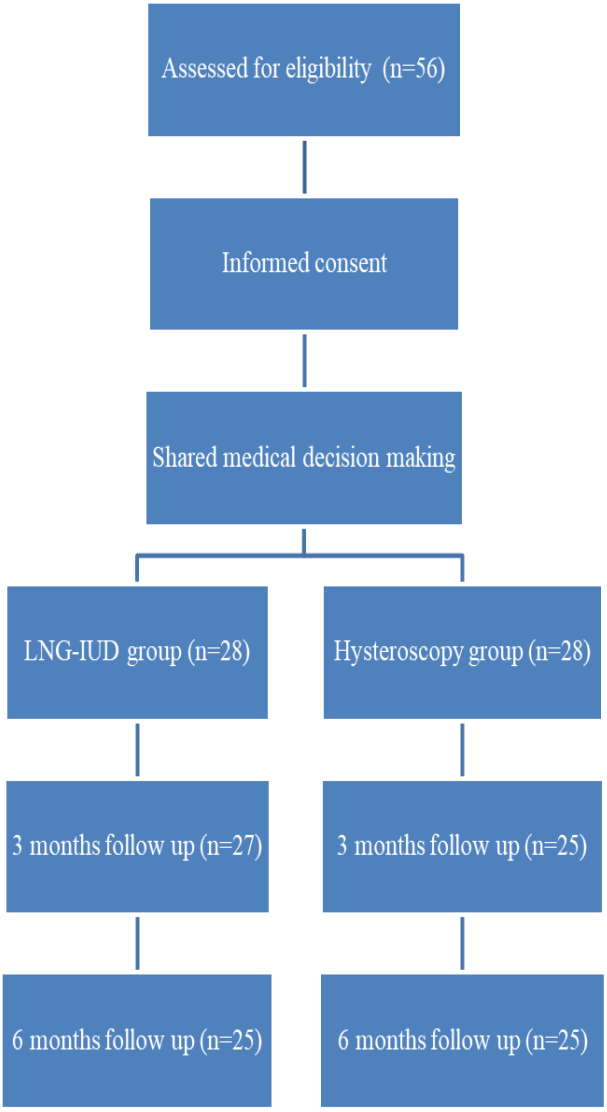


Figure 1: Flow diagram of the study.

**The Procedure:**

**In Group (A): the "LNG-IUD (52 mg)" group, the LNG-IUD was implanted in the outpatient clinic.** Following the evaluation of uterine dimensions and orientation, cervical disinfecting was performed, and the length of the uterine cavity was measured, which should range from 6 to 10 cm. The accurate placement of the LNG-IUD was verified using transvaginal ultrasonography.

**In Group (B): the "Hysteroscopic resection of niche" group, sonohysterography was initially conducted using a Mindray ultrasound machine, model DC-30, 240-270V 50/60Hz, 630VA (Mindray, China)**, as a standard diagnostic procedure to ascertain the source of the haemorrhage. Prior to study enrolment, the niche was assessed by transvaginal sonography and saline infusion sonography in the sagittal plane, where the greatest niche was observable, and in the transverse plane, where the niche was maximised, specifically with the thinnest remaining myometrium. The depth, remaining myometrium, and morphology of the niche were recorded.

To ensure inclusion, a niche must possess a minimum depth of 2 mm, and the residual myometrium should measure no less than 2.2 mm in one plane to avert uterine perforation or bladder damage. [11]

Operative hysteroscopy was conducted utilizing a 9 mm resectoscope (Karl Storz GmbH & Co.), employing bipolar electrical current and sodium chloride as a distension medium at a pressure of 100-120 mm Hg. All procedures were conducted under visual inspection. Upon identifying the niche location, a cutting loop was employed to excise the flap of fibrotic tissue situated beneath the pouch-like defect, extending from the defect's boundary to the endocervix, while adjusting the technique based on the defect's site until the underlying myometrial tissue became apparent. The pouch's residue was cauterized using a 3 mm roller-ball as necessary. Patients were monitored postoperatively for a minimum of 3 hours

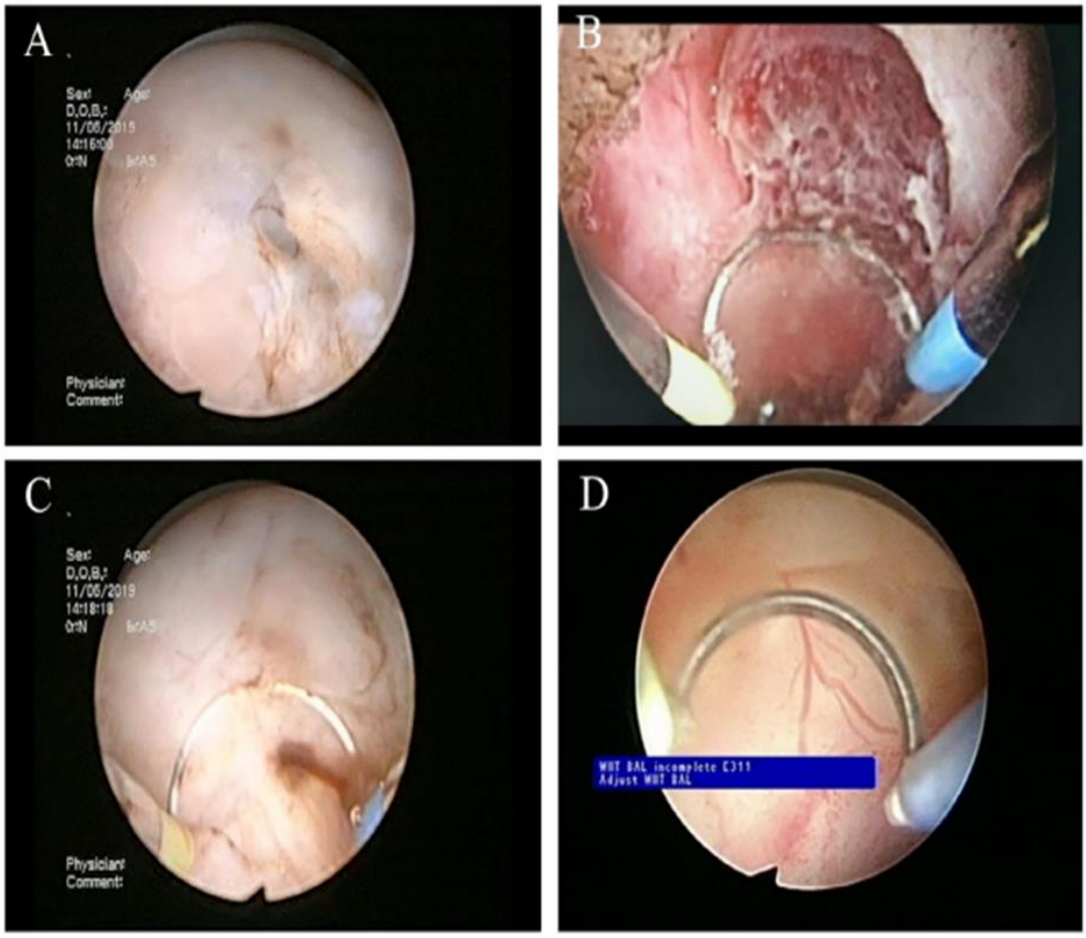


Figure 2: Intraoperative pictures showing niche features during hysteroscopic corrective operation (A. Cystic patterns B. Polypoid forms C. Lateral branches D. Aberrant blood vessels).

**Statistical analysis of the data**

- Data was coded and entered Microsoft Excel 365. All statistical analyses were performed using the Statistical Package for Social Science (SPSS) version (25).
- Descriptive statistics were applied in numerical form (mean, SD or percentages) to describe the quantitative variables.
- Diagrammatic and tabular forms were used -when appropriate- to describe the qualitative variables.
- Data presentations were performed via tables and graphs. Qualitative data were presented as numbers and percentages while quantitative data as mean ± Standard Deviation.

- Chi square and Fisher's exact tests were used for qualitative variables. - P value of <0.05 was considered statistically significant.

## Results

The study included 56 women suffering from post CS uterine niche attended to SCU teaching hospital; 28 of them had LNG-IUD inserted and another 28 patients underwent hysteroscopic niche resection.
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Table 1 illustrates demographic data of the study participants. Over all these features were matched between both groups. Their mean age was 28.6 ±3.4 years old, with an average BMI of 25.1±1.9 Kg/m$^2$. Mean parity and previous CS number were 2.8 and 1.8, successively. The mean time since last CS was 18.1 months. There is no significant difference between both groups regarding any of these characteristic

**Table 1: Comparison of demographic characteristics of the study groups**

| | LNG-IUD (N = 25) | Hysteroscopy (N = 25) | Total (N = 50) | P value |
|---|---|---|---|---|
| Age (years) | 28.6 ± 3.4 | 28.6 ± 3.3 | 28.6 ± 3.4 | 0.9 |
| BMI (kg/m2) | 25.2 ± 1.8 | 25 ± 2 | 25.1 ± 1.9 | 0.7 |
| Parity | 2.8 ± 0.8 | 2.8 ± 0.8 | 2.8 ± 0.8 | - |
| Previous CS (months) | 1.9 ± 0.7 | 1.8 ± 0.6 | 1.8 ± 0.6 | 0.6 |
| Time since last CS (months) | 17.9 ± 4.4 | 18.3 ± 3.5 | 18.1 ± 3.9 | 0.7 |

Table 2 illustrates the number and percent of previous CS. Most patients had two previous CS, while least commonly was three previous CS. No statistically significant difference was found between both groups.

**Table 2. comparison of previous CS frequency among the study groups**

| | LNG-IUD (N = 25) | Hysteroscopy (N = 25) | Total (N = 50) | P value |
|---|---|---|---|---|
| Previous one | 7 (28) | 7 (28) | 14 (28) | |
| Previous two | 13 (52) | 15 (60) | 28 (56) | 0.7 |
| Previous three | 5 (20) | 3 (12) | 8 (16) | |

Table 3 shows a comparison of the study outcome measures at baseline between both groups. It is evident that the mean menstruation duration, spotting days, total bleeding days and intermenstrual spotting did not differ significantly between both groups. Regarding medical cost, the LNG-IUD group spent remarkably less than the other group.

**Table 3: comparison of bleeding/menstruation history of the study groups at baseline**

| | LNG-IUD (N = 25) | Hysteroscopy (N = 25) | Total (N = 50) | P value |
|---|---|---|---|---|
| Menstruation duration (days) | 5.9 ± 0.8 | 5.8 ± 0.8 | 5.8 ± 0.8 | 0.7 |
| Spotting days | 6 ± 1.2 | 6.2 ± 1.3 | 6.1 ± 1.2 | 0.7 |
| Total bleeding days | 12 ± 1.7 | 12 ± 1.7 | 12 ± 1.7 | 0.9 |
| Inter-menstrual spotting n (%) | 6 (24) | 5 (20) | 17 (34) | 0.5 |
| Menstruation satisfaction | 1.9 ± 0.6 | 2 ± 0.4 | 1.9 ± 0.5 | 0.8 |
| Medical cost (EGP) | 1492 ± 51 | 5508 ± 400 | 3500 ± 2047 | <0.001** |

Table 4 shows a comparison of the study outcome measures after six months' follow up between both groups. We noticed that LNG-IUD group continued to witness better results with statistically significant difference regarding all menstruation and bleeding features. Also, the former group had a much better effectiveness rate (88%), and much lower mean medical cost (502 EGP). However, seven patients from LNG-IUD group experienced amenorrhea, while no one from hysteroscopy had it with statistically significant difference in favor of hysteroscopy group.

**Table 4: Comparison of bleeding/menstruation history between both methods after 6 months of intervention**

| | LNG-IUD (N = 25) | Hysteroscopy (N = 25) | Total (N = 50) | P value |
|---|---|---|---|---|
| Menstruation duration (days) | 2.5 ± 1.7 | 5.6 ± 0.8 | 4.1 ± 2 | <0.001** |
| Spotting days | 1.3 ± 1.2 | 3.5 ± 0.7 | 2.4 ± 1.5 | <0.001** |
| Total bleeding days | 4 ± 3 | 9.2 ± 1 | 6.6 ± 3.4 | <0.001** |
| Amenorrhea n (%) | 7 (28) | 0 (0) | 7 (14) | 0.005* |
| Effectiveness rate | 88% (22/25) | 52% (13/25) | 76% (38/50) | <0.006* |
| Medical cost (EGP) | 502 ± 68 | 550 ± 35 | 526 ± 59 | <0.003** |

Table 5 illustrates the mean difference in change from the start of study up to six months of follow up. In general, both groups witnessed clinical improvement in menstruation duration, spotting days and total bleeding days. All these differences were statistically significant except in hysteroscopy group the change in menstruation duration didn't show a statistically significant difference. Also, the mean difference of change in these parameters during the follow up period was higher in LNG-IUD group in comparison to hysteroscopy group.

**Table 5: Comparison of characteristics of bleeding/menstruation history of the study groups at baseline and after six months for each method of intervention.**

| | Baseline | 6th month | Mean difference | P value |
|---|---|---|---|---|
| LNG-IUD | | | | |
| Menstruation duration (days) | 5.9 ± 0.8 | 2.5 ± 1.7 | 3.3 ± 1.5 | <0.001** |
| Spotting days | 6 ± 1.2 | 1.3 ± 1.2 | 4.7 ± 1.4 | <0.001** |
| Total bleeding days | 12 ± 1.7 | 4 ± 3 | 8 ± 2.8 | <0.001** |
| Hysteroscopy | | | | |
| Menstruation duration (days) | 5.8 ± 0.8 | 5.6 ± 0.8 | 0.1 ± 0.8 | 0.3 |
| Spotting days | 6.2 ± 1.3 | 3.5 ± 0.7 | 2.6 ± 1.1 | <0.001** |
| Total bleeding days | 12 ± 1.7 | 9.2 ± 1 | 2.8 ± 1.5 | <0.001** |

Table 6 demonstrates the correlation between menstruation satisfaction and each of the following: menstruation duration, spotting days and total bleeding days. There was a strongly negative and significant correlation between each of the parameters mentioned and menstruation satisfaction. In other words, the shorter menstruation duration, spotting days and total bleeding days, the greater the satisfaction and it showed better results in LNG-IUD group with statistically significant difference.

| Table 6: Significant correlation between menstruation satisfaction and characteristics of bleeding/menstruation among study groups | | |
|---|---|---|
| Variables | r | P value |
| Menstruation duration | | |
| LNG-IUD | - 0.7 | <0.001** |
| Hysteroscopy | 0.05 | 0.8 |
| Spotting days | | |
| LNG-IUD | - 0.6 | 0.002** |
| Hysteroscopy | - 0.1 | 0.4 |
| Total bleeding days | | |
| LNG-IUD | - 0.7 | <0.001** |
| hysteroscopy | 0.05 | 0.8 |

## Discussion:

The baseline characteristics of women in both groups at the study's inception were comparable in terms of personal data, with a mean age of 28.6 years and a mean BMI of 25.1. No substantial difference existed between the two groups concerning any of these traits. He et al. (2021) also discovered in their investigation that both groups exhibited no statistically significant differences in baseline age or BMI [4].

Concerning the obstetric factors assessed for each study participant, no statistically significant variations were seen between the two groups in terms of parity, number of prior caesarean sections, and duration since the last caesarean section in months. The mean parity and number of previous caesarean sections were 2.8 and 1.8, respectively. The average duration since the last CS was 18.1 months. There is no substantial disparity between the two groups about any of these features. The similarity of these characteristics diminishes the likelihood of bias in a comparable study; J. Zhang et al. (2023) corroborated these findings.

This investigation revealed that the characteristics of the uterus and niche were similar in both groups for the uterine axis, with more than half of the participants exhibiting an AVU uterus [12]. Regarding the niche dimensions, no statistically significant difference was seen between the two groups. The mean residual myometrial thickness (RMT) was found to be similar across the two groups, without statistical significance, contrary to the findings of He et al. (2021), which indicated a reduced RMT in the LNG-IUD group [4].

After a six-month follow-up, the LNG-IUD group had superior outcomes with statistically significant differences in all menstrual and bleeding characteristics. The total number of spotting days exhibited a statistically significant difference, with a Mean ± SD of 1.3 ± 1.2 in the LNG group compared to 3.5 ± 0.7 in the hysteroscopy group, yielding a p-value < 0.001. Furthermore, the total bleeding days were significantly lower in the LNG group, with a Mean ± SD of 4 ± 3 versus 9.2 ± 1 in the hysteroscopy group, also with a p-value < 0.001. In contrast to the outcomes of this present study and prior prospective cohort studies, A study conducted by J. Zhang et al. in 2023 found no significant difference in postmenstrual spotting at the 6-month follow-up between those receiving LNG-IUS placement and those undergoing

hysteroscopic niche excision (P=.370). A markedly greater enhancement in spotting was noted in the LNG-IUS group at 9 months (P=.002) [12].

The efficacy rate was superior in the LNG-IUD group, around 88%, compared to 52% in the hysteroscopic group. This is similar to the findings presented by He et al., 2021[4].

The efficacy rate after three months was determined to be 83.33% (30/36) in the LNG-IUD group compared to 71.05% (27/38) in the hysteroscopic group, with a p-value of 0.21. Additionally, concerning medical expenses, the results of this study indicated that the LNG group exhibited a lower average medical cost, consistent with the findings reported by He et al., 2021, and J. Zhang et al., 2023 [4] [12].

## Conclusion:

This study found that LNG-IUD is superior to hysteroscopic niche resection in shortening niche related postmenstrual spotting from the 3rd month onwards, with lower direct medical costs and extra contraception benefit.

## Recommendations:

• LNG-IUD is better than hysteroscopic niche resection at stopping postmenstrual spotting related to the niche from the 3rd month onwards. It also has lower direct medical costs and an extra benefit of contraception.

• Another benefit of the LNG-IUD is that it can be used regardless of the thickness of the remaining myometrium.

• Large-scale studies are needed to find out how safe the technique is and what long-term effects it has on patients' lives.

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