

# Microinsert Nonincisional Hysteroscopic Sterilization

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**OBJECTIVE:** To assess the safety, effectiveness, and reliability of a tubal occlusion microinsert for permanent contraception, as well as to document patient recovery from the placement procedure and overall patient satisfaction.

**METHODS:** A cohort of 518 previously fertile women seeking sterilization participated in this prospective, phase III, international, multicenter trial. Microinsert placement was attempted in 507 women. Microinserts were placed bilaterally into the proximal fallopian tube lumens under hysteroscopic visualization in outpatient procedures.

**RESULTS:** Bilateral placement of the microinsert was achieved in 464 (92%) of 507 women. The most common reasons for failure to achieve satisfactory placement were tubal obstruction and stenosis or difficult access to the proximal tubal lumen. More than half of the women rated the average pain during the procedure as either mild or none, and 88% rated tolerance of device placement procedure as good to excellent. Average time to discharge was 80 minutes. Sixty percent of women returned to normal function within 1 day or less, and 92% missed 1 day or less of work. Three months after placement, correct microinsert placement and tubal occlusion were confirmed in 96% and 92% of cases, respectively. Comfort was rated as good to excellent by 99% of women at all follow-up visits. Ultimately, 449 of 518 women (87%) could rely on the micro-

insert for permanent contraception. After 9620 woman-months of exposure to intercourse, no pregnancies have been recorded.

**CONCLUSION:** This study demonstrates that hysteroscopic interval tubal sterilization with microinserts is well tolerated and results in rapid recovery, high patient satisfaction, and effective permanent contraception. (Obstet Gynecol 2003;102:59–67. © 2003 by The American College of Obstetricians and Gynecologists.)

The majority of interval sterilization procedures in the United States and other developed countries involve laparoscopy performed under general anesthesia in a day surgery setting.<sup>1</sup> In the United States, an estimated 89% of interval tubal sterilizations are currently performed laparoscopically.<sup>1</sup> Conventional incisional approaches to interval sterilization, such as laparoscopy and minilaparotomy, carry risks associated with general anesthesia and on rare occasions can result in vascular damage, injury to the bowel, bladder, or uterus, or unintended laparotomy.<sup>2</sup> In addition, laparoscopic tubal sterilization might be associated with considerable postoperative pain.<sup>3,4</sup>

A transcervical route offers an attractive alternative to a transabdominal approach, eliminating the need for incisional surgery and general anesthesia. The transcervical approach might lessen postoperative pain and allow faster recovery and resumption of normal activities. However, development of a safe and effective transcervical method of sterilization has proven difficult, as it requires both a safe mode of delivery and a reliable method of tubal occlusion.<sup>5</sup> Tubal occlusion via a trans-

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cervical route has been attempted with electrocoagulation, sclerosing substances or tissue adhesives, and mechanical occlusive devices or plugs to block the oviduct, but no method has been widely adopted owing to safety or effectiveness limitations.<sup>6</sup>

Based on modifications of tubal cannulation technology, an occlusive approach with a dynamically expanding microinsert (Essure Permanent Birth Control System, Conceptus Inc., San Carlos, CA) was recently approved by the United States Food and Drug Administration. The microinsert, designed to be placed through a hysteroscope into the proximal section of the fallopian tube,<sup>7</sup> is the first such device for hysteroscopic tubal sterilization ever approved by the Food and Drug Administration. Early reports of clinical use have been encouraging.<sup>8</sup> A prospective, international, phase II clinical trial demonstrated that the Essure hysteroscopic sterilization procedure was associated with rapid patient recovery without unacceptable postprocedure pain and with high long-term patient tolerability and satisfaction, as well as effective permanent contraception.<sup>9</sup>

In this report, results are presented from a phase III, prospective, multicenter, international trial with the objective of assessing the safety, effectiveness, and reliability of the microinsert. Findings on patient recovery after device placement, overall satisfaction, microinsert wearing comfort, and return of patients to normal activities and work are also reported.

## MATERIALS AND METHODS

This phase III study, which enrolled women between May 2000 and February 2001, was an international, multicenter, single-arm clinical trial enrolling previously fertile women of childbearing age seeking permanent birth control. Twenty investigators from 13 clinical sites located in the United States (eight sites, 320 women), Australia (two sites, 133 women), Spain (one site, 37 women), the United Kingdom (one site, 14 women), and Belgium (one site, 14 women) participated. All investigational sites conducted the study according to similar protocols and obtained approval from their respective institutional review boards or ethics committees before study commencement.

The study was designed to assess 1) the safety and tolerance of the microinsert placement procedure, 2) patient recovery after the procedure, 3) patient experience and satisfaction during the first 15 months after microinsert placement, and 4) effectiveness at preventing pregnancy during the first year after discontinuation of alternative contraception, which generally occurred 3 months after device placement. Women participating in this study are to be followed for an additional 4 years to



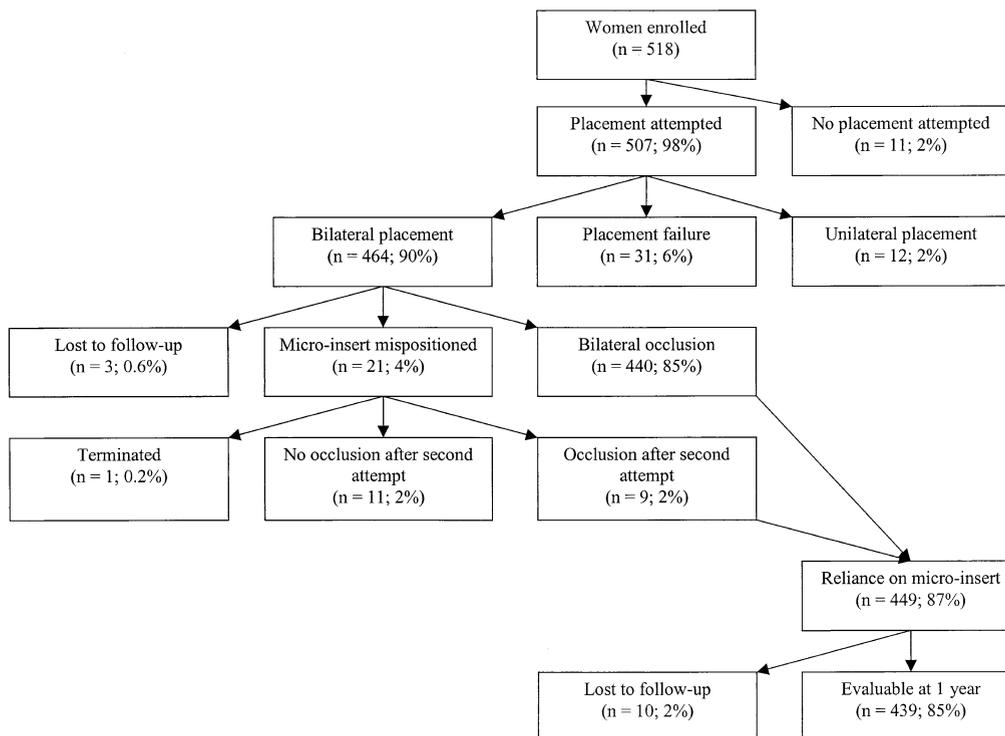
**Figure 1.** A) Fully-expanded microinsert ex vivo and B) microinsert delivery system loaded in hysteroscope before insertion.

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obtain data on 5-year safety, effectiveness, and reliability of the microinsert.

Women 21–40 years and 90–300 lb body weight seeking permanent contraception who were engaged in a monogamous relationship and willing to use a temporary contraceptive method for the first 3 months after device placement were eligible to participate in the study. Participants also were required to have regular menses the 2 months before the microinsert placement procedure, at least one live birth, and a minimum of 4–8 coital acts per cycle. Exclusion criteria included a history of chronic pelvic pain, severe dysmenorrhea, severe dyspareunia, or any chronic pain in the previous 12 months. Also excluded were women with tubal, ovarian, or endometrial pathology and women with a prior history of infertility treatment. Those women who met the selection criteria gave their written, informed consent before undergoing pelvic examinations and screening for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* infection.

The microinsert, previously known as STOP (Selective Tubal Occlusion Procedure), consists of a flexible stainless steel inner coil, a dynamic outer coil made of nickel titanium alloy (Nitinol), and a layer of polyethylene terephthalate fibers running along and through the inner coil (Figure 1A). Over a 3-month period, the polyethylene terephthalate fibers elicit a benign localized tissue in-growth from the surrounding tubal wall into and around the device to occlude the tubal lumen completely.<sup>10</sup> The microinsert is delivered transcervically through a 5-Fr (1.7 mm internal diameter) operative channel of a 5-mm outer diameter hysteroscope of varying manufacture (Figure 1B).<sup>8</sup> Optimal positioning of the insert in the fallopian tube occurs when 5–10 mm of the



**Figure 2.** Disposition of study participants. Bilateral occlusion was not hysterosalpingogram-confirmed in three patients. Cooper. *Hysteroscopic Sterilization. Obstet Gynecol* 2003.

proximal end of the microinsert is visible at the ostium. When released from the delivery catheter, the outer coil of the microinsert expands to span the intramural and proximal isthmic portions of the fallopian tube. This expansion serves to anchor the microinsert in the tubal lumen. Permanent retention of the microinsert in the proximal tube is achieved upon subsequent fibrous tissue in-growth.

A negative urine pregnancy test was required within 24 hours before the procedure, and participants were instructed to continue or begin temporary alternative contraception, such as barrier methods or oral contraceptives, for the first 3 months after microinsert placement. Whenever possible, the procedure was performed during days 7–14 of the proliferative phase of the menstrual cycle to enhance visualization of the fallopian tubal ostia. Preoperative analgesia, if given, consisted of a nonsteroidal antiinflammatory drug given 30–60 minutes before the procedure. Women received local anesthesia (paracervical block), with intravenous sedation added as necessary. Physiologic saline irrigation was used to distend the uterine cavity, as well as to simultaneously provide forward vision for safe introduction of the hysteroscope; mechanical dilation of the cervix was avoided if possible. Standard fluid absorption monitoring procedures were followed. If uterine pathology was

identified that prohibited access or visualization of either tubal ostium, then the device placement procedure was terminated. The endoscopic image of the uterine cavity displayed on a video monitor allowed the women to visualize their fallopian tube openings and the entire procedure. The objective of the procedure was bilateral microinsert placement. A pelvic x-ray was conducted within 24 hours after device placement to serve as a baseline evaluation of device location.

Women completed a self-administered pain assessment questionnaire daily during the first week after microinsert placement. At 1 week postprocedure, patients completed another questionnaire detailing the occurrence of any bleeding or other symptoms, as well as perceptions and satisfaction with the placement procedure. Participants were also contacted by telephone at 1 week postprocedure to assess recovery and document adverse events. Women kept daily diaries for 6 months and recorded menstrual bleeding, sexual intercourse events, any untoward symptoms experienced, and medications taken. Further office or telephone patient follow-up was scheduled for 3, 6, 12, 18, 24, 36, 48, and 60 months after discontinuation of alternative contraception to record effectiveness of pregnancy prevention, sole reliance on the microinsert for contraception, microinsert retention, adverse events or unusual symptoms,

**Table 1.** Patient Demographics

Characteristic	n	Mean	SD
Age	518	31.9	4.6
Weight (lb)	511*	159.9	37.3
Height (in)	508*	64.5	2.6
Cycle length (d)	512*	28.1	2.6
Gravidity	518	3.0	1.5
Parity	518	2.3	1.0

SD = standard deviation.

\* Observations missing for some women.

patient comfort and satisfaction, and intrauterine procedures or surgery.

Three months after microinsert placement, participants underwent a mandatory hysterosalpingogram to evaluate device location and fallopian tube occlusion. A patient was always counseled that microinserts should not be relied on for contraception until she had undergone the 3-month hysterosalpingogram. Given satisfactory device location and tubal occlusion, participants were advised that they could rely on the microinserts for permanent birth control and were instructed to cease alternative contraception.

Data analysis was conducted using SAS 8.0 statistical software (SAS Institute, Cary, NC), including the PROC MIXED procedure and GLIMMIX macro, and the WinBUGS 1.3 program (MRC Biostatistics Unit and Imperial College School of Medicine at St Mary's, London, UK). Factors that affected microinsert placement rate and procedure duration were estimated with both fixed and hierarchical random effects logistic regression modeling.<sup>11</sup> Factors studied included patient-, treatment-, and center-based covariates. The effect of by-center variation was modeled with a hierarchical model, with physician as a random effect. In the absence of significant by-physician variation, fixed-effects estimates and confidence interval (CI) results were reported. Since there were zero failures, effectiveness rates and corre-

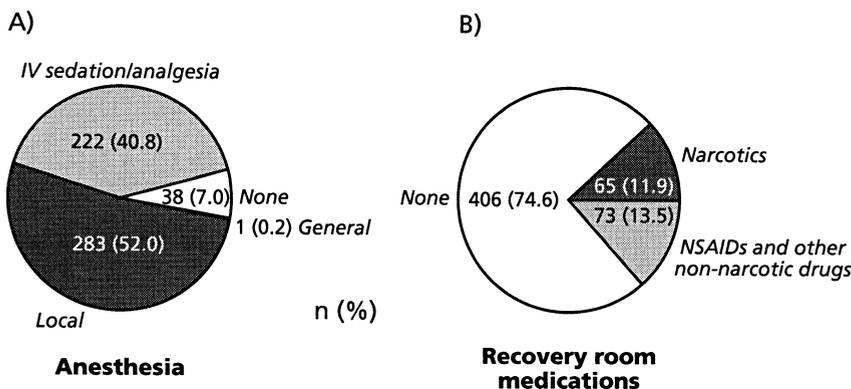
sponding exact CI were determined with standard formulas appropriate for zero numerator problems.<sup>12</sup>

## RESULTS

Of the 518 women enrolled in the study, microinsert placement was attempted in 507 (Figure 2). Microinsert placement was not attempted in 11 women because of endometrium or uterine polyps blocking the ostia in six women, inability to visualize the fallopian tubes for unspecified reasons in three women, cervical stenosis in one woman, and inability to reach the ostia in an obese woman. The demographic characteristics of the enrolled patients are presented in Table 1. There were no significant differences in any of the evaluated demographic characteristics among women in whom a successful placement was achieved versus those with unsuccessful placement attempts versus those in whom placement was not attempted.

In 84% of the 544 total procedures (sum of primary procedure in 518 women plus secondary placement procedures plus procedures to replace expelled microinserts), women received an oral nonsteroidal antiinflammatory drug before the procedure. General anesthesia was used in only one case, local anesthesia only with or without intravenous sedation was used in 505 procedures (93%), and no anesthesia other than oral nonsteroidal antiinflammatory drug was used in 38 of 544 procedures (7%) (Figure 3A).

Bilateral placement of the microinsert was ultimately achieved in 464 of 507 women (92%; 95% CI 89%, 94%). Bilateral placement was accomplished with one procedure in 446 women and in an additional 18 women during a second placement procedure. Unilateral placement was achieved in 12 women, including two with unicornuate uteri. Of the 41 of 507 women (8%) with bilateral tubes in whom bilateral placement was not achieved, 15 were found to have previously undetected



**Figure 3.** A) Predominant type of anesthesia used during the microinsert placement procedure and B) type of medications used during postprocedure recovery. IV = intravenous; NSAIDs = nonsteroidal antiinflammatory drugs.

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**Table 2.** Reasons for Failure of Bilateral Microinsert Placement

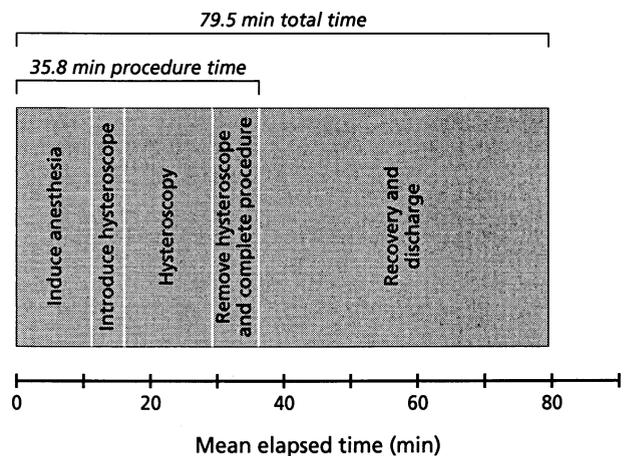
Reason	n*	%
<b>Anatomic</b>		
Blocked/stenotic tubes	39	43
Visual field obscured by endometrium	15	16
No visible ostium/scarring	3	3
Uterine adhesions	3	3
Lateral tube	3	3
Other anatomic	3	3
Uterine pathology (polyps)	2	2
Obesity	2	2
Subtotal	70	77
<b>Procedure-related</b>		
Impaired visualization	4	4
Tubal spasm	10	11
Other <sup>†</sup>	5	5
Subtotal	19	21
Microinsert related or indeterminate	2	2
<b>Total</b>	<b>91</b>	<b>100</b>

\* Bilateral placement was not achieved in 72 women on the first attempt; more than one reason contributed to failure in some women. Eight women failed a second placement attempt, three (38%) because of blocked/stenotic tubes, three (38%) because of lateral tube, and two (25%) because of obesity.

<sup>†</sup> Bent device tip, endometrial reaction to saline, pain, painful vulvar lesion, and hysteroscope malfunction.

proximal tubal occlusion of one or both fallopian tubes on follow-up hysterosalpingogram. With exclusion of these 15 women, the overall bilateral microinsert placement rate in women in whom placement was attempted and was possible was 94% (464 of 494). The reasons for bilateral microinsert placement failure are detailed in Table 2. Anatomic impediments accounted for 78% of the failures.

Using several different statistical approaches, we extensively evaluated the potential effect of patient- and physician-related variables on the odds of bilateral placement during one or more placement procedures. There was mild variation in placement rates across physicians, but this variation disappeared after excluding women with unicornuate uterus and proximal tubal occlusion. Use of nonsteroidal antiinflammatory drugs before the procedure was associated with an increased placement success rate (odds ratio: 2.6; 95% CI 1.1, 5.8). No other patient or study center differences could be identified that were predictive of device placement outcome. Obesity and prior abdominal surgery, both relative contraindications to laparoscopy, were not associated with increased failure rates. Of 125 women with body mass index greater than 30, bilateral placement was achieved in 120, a 96% rate. Of the 93 women with prior abdominal surgery, microinsert bilateral placement was successful in 91 women, a 98% rate. Prior physician experience in the phase II trial had a modest, nonsignificant effect on increasing placement rates.



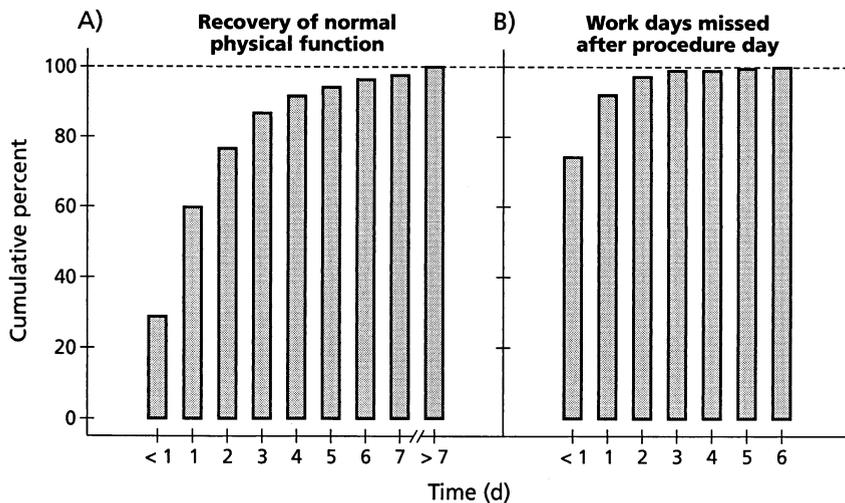
**Figure 4.** Procedure and recovery time for microinsert placement.

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The level of hysteroscopy experience of the participating gynecologists ranged from the performance of infrequent, diagnostic hysteroscopy to routine, operative hysteroscopy. Of the 20 investigators, 14 had no prior experience with the microinsert. Procedure time decreased rapidly over the first five cases and slowly thereafter. Bilateral placement rates did not improve substantially in relation to increased experience with the device. Even physicians with relatively little experience achieved high success rates. When asked to rate the hysteroscopic procedure in comparison with a laparoscopic sterilization, eight of ten investigators rated the level of difficulty of the device placement procedure as very simple, simple, or moderately simple. Two respondents classified the procedure as moderately difficult.

Total procedure time compared favorably to reported average length of laparoscopic sterilization procedures,<sup>13,14</sup> and patient recovery was rapid and uncomplicated. Total procedure time averaged 36 minutes, with mean hysteroscopy time of 13 minutes (Figure 4). Women spent an average of 44 minutes in the recovery room. The average time from procedure room entry to discharge from the facility was 80 minutes. During the outpatient recovery period, three quarters of women did not require any medication, whereas 12% received narcotic-containing medication (Figure 3B).

Recovery was categorized as uneventful in 58% ( $n = 316$ ) of procedures. In the other 228 procedures, women reported a variety of symptoms. Cramping (30%) was the most common postoperative symptom, followed by pain (13%) and nausea (9%). Of those experiencing symptoms, complete resolution before discharge was attained in 56%. Of those symptoms that had not resolved by the time of discharge, most involved cramping



**Figure 5.** Cumulative percentage of patients A) returning to normal activities within the indicated number of days or fewer and B) missing the indicated number of days from work or fewer.

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or bleeding. In general, symptoms during recovery were similar to those typically seen after a diagnostic hysteroscopic procedure, namely mild uterine cramping and light bleeding.<sup>15</sup>

Adverse events diagnosed on the day of the procedure occurred in 17 women (3.1%). All women recovered fully, and all but one were discharged on the day of the procedure. Three patients experienced a vasovagal response, and two developed hypervolemia from the uterine distention fluid. One patient was hospitalized overnight for observation after severe vomiting due to an adverse reaction to pain medication, but she required no other intervention.

Almost two thirds of the participants (65%, 338 women) rated the average pain during the procedure as either mild or none. Only 4% (21 women) rated the average procedural pain as severe. At discharge, more than three quarters (79%, 412 women) rated the average pain as mild or none. Tolerance of the placement procedure was rated as good, very good, or excellent by 88% (434) of the women. As shown in Figure 3B, three quarters of the women required no pain medication in the recovery room. Moreover, at the time of discharge, 72% of women did not request a prescription for analgesic drugs.

After the procedure, bleeding stopped in a mean of 3 days. Bleeding persisted to day 7 in 19% of women. Bleeding was characterized as primarily spotting or light.

On the first day after the procedure, one third of women reported pain during household tasks, childcare, walking, getting in or out of the car, and sleeping. On subsequent days, pain was seldom reported, and the pain that was reported was primarily the same or less than that experienced during a normal menstrual cycle. Recovery of normal physical functioning was rapid (Figure

5A). Sixty percent of women reported a return to normal function within 1 day or less, and more than three quarters had resumed normal activities by day 2. Almost three quarters of those working missed less than 1 day of work after the procedure day, and 92% missed no more than 1 day (Figure 5B).

After the procedure, persistent changes in menstrual pattern were rarely reported, and no clear pattern of change was evident, with an approximately equal number of reports of both increased and decreased menstrual flow. At 1 year postprocedure, 2.2% of women (ten of 455) reported heavier than usual menstrual flow, whereas 1.5% (seven of 455) reported less than usual menstrual flow. Half of the reported spotting episodes did not require sanitary protection. Over the course of the first 6 months after the procedure, the average number of days in which sanitary protection was needed for spotting decreased from 3.3 to 0.5. No woman reported persistent pain.

A total of 456 of the 464 women with bilateral placement completed the 3-month post-device placement visit, which included the performance of a hysterosalpingogram. Satisfactorily located microinserts were observed in 437 of 456 women (96%) and bilateral tubal occlusion in 421 of 456 women (92%). All 16 women who had tubal patency at the 3-month hysterosalpingogram had bilateral occlusion as determined by repeat hysterosalpingogram at 6 months. Nine women with microinsert expulsion because of too proximal placement of the device in the fallopian tube underwent a second placement procedure. Bilateral microinsert placement was successful in all nine women, and all showed evidence of tubal occlusion on hysterosalpingogram 3 months after the placement procedure. Therefore, of the women with bilateral placement completing the 3-month

**Table 3.** Adverse Events Preventing Reliance on Microinsert After Bilateral Placement

Adverse event	<i>n</i>	%	Suspected cause	Management
Expulsion	14	3.0	Proximal placement in 13 cases and placement into endometrial tissue in one	Nine successfully underwent second microinsert placement procedure; four laparoscopic sterilization; and one laparotomy due to preexisting Crohn disease
Perforation	4	0.9	Two cases each of preexisting tubal occlusion and poorly identified ostium	Laparoscopic sterilization in three cases; repeat microinsert placement requested in one
Proximal location and perforation	1	0.2	Proximal placement on one side and difficult placement contralaterally	Proximal microinsert removed hysteroscopically during laparoscopic sterilization
Proximal location	2	0.4	One case each of proximal placement and hydrosalpinx	Awaiting women's decision to undergo laparoscopic sterilization
Total	21	4.5		

visit, 446 of 456 (98%) were ultimately found to have microinserts in satisfactory location and bilateral occlusion. Overall, a total of 449 of 507 women (89%) in whom microinsert placement was attempted were able to rely on the microinsert for permanent contraception because of successful bilateral placement. With respect to all women enrolled in the study, including those in whom microinsert placement was not attempted, the reliance rate was 87% (449 of 518) (Figure 2). In those women with successful bilateral placement, the reliance rate was 97% (449 of 464).

Adverse events preventing reliance on the microinsert after bilateral placement was attempted are detailed in Table 3. None of the adverse events occurred in women with properly placed microinserts. Microinsert expulsions resulting from improper placement accounted for two thirds of the adverse events.

Patient satisfaction remained high throughout the follow-up period. Comfort was rated as good to excellent by 99% of women at all follow-up visits. Over 98% were satisfied or very satisfied at all follow-up visits.

Because patients were counseled that microinserts can provide permanent contraception only when they are placed bilaterally and tubal occlusion and satisfactory microinsert location are verified by hysterosalpingogram, effectiveness rate calculations were restricted to cases of successful bilateral placement. As of January 8, 2003, 449 women with bilateral placements (Figure 2) had contributed 9620 women-months of effectiveness follow-up time, with a mean follow-up of 21.4 months. To date there have been no pregnancies. The effectiveness rate during the first year of follow-up, based on 5305 women-months of follow-up, was 100% (95% CI 99.32%, 100%). Combined with 2327 women-months of first-year follow-up among 194 women in the phase II trial, the effectiveness rate was 100% (95% CI 99.53%, 100%).

## DISCUSSION

This study demonstrates that hysteroscopic interval tubal sterilization with microinserts is well tolerated and results in rapid recovery, high patient satisfaction, and effective permanent contraception. This approach, therefore, offers an attractive alternative to standard laparoscopic approaches.

The lack of need for general anesthesia, an incision, and postoperative narcotics allowed the procedure and recovery period to be brief. Average total time to discharge was 80 minutes.

The absence of severe pain associated with the procedure was noteworthy. More than half of the women rated the average pain during the procedure as either mild or none. More than two thirds rated the postprocedure pain during recovery as mild or none. Accordingly, only 12% of patients received narcotic-containing analgesics after the procedure.

In contrast, postoperative pain after surgical tubal sterilization, which can involve the abdomen, shoulder and throat, can be a substantial problem.<sup>3,4</sup> Postoperative pain can delay discharge of patients from the hospital and their return to normal activity. Laparoscopic tubal sterilization typically requires 3–5 hours of hospital recovery time,<sup>13,16–20</sup> an average of 4–6 days after the day of surgery before returning to regular activities,<sup>3,19</sup> and an average of 3 days before returning to work.<sup>19</sup> To decrease postoperative pain after laparoscopic surgery for tubal sterilization, a variety of regimens involving local anesthesia and/or oral analgesics have been tested, but none has been proven totally efficacious.<sup>14,17,18,20–24</sup> Women undergoing surgical tubal sterilization often require narcotic-containing analgesia.<sup>3</sup> Pain and narcotic analgesia are common causes of postoperative nausea and vomiting.<sup>22</sup> In a study of postoperative pain after tubal ligation surgery, the 83% of women who took more

than 3 days to return to regular activity reported that pain and fatigue were the main reasons for the delay.<sup>3</sup>

The majority of women undergoing hysteroscopic sterilization with microinserts were rapidly ambulatory and able to be discharged quickly. They were also able to return to normal activities and work in 1 day or less.

Women reported high satisfaction at the time of the procedure and throughout the follow-up period. Postoperative bleeding was mild, resolved quickly, and did not appear to exceed that observed in a standard diagnostic hysteroscopy. Minimal persistent changes in menstrual function were reported, and there were no reports of persistent pelvic pain. At 1 week after the procedure, 83.3% of study participants indicated that they would definitely recommend the procedure to a friend.

Also of significant note in this study is that women with a relative contraindication for laparoscopic tubal sterilization, such as those with obesity or prior abdominal or pelvic surgery, had very high bilateral placement rates. Other women who would likely be poor candidates for incisional surgery, such as those under a warfarin regimen or with multiple sclerosis, also had successful microinsert placement in the study.

Starting 3 months after the microinsert placements, 96% of the women with successful bilateral placement had achieved hysterosalpingogram evidence of tubal occlusion and were able to discontinue other forms of contraception. The remaining 4% of women required an additional 3 months before tubal occlusion could be confirmed.

Tubal occlusion with a laparoscopic approach is highly effective in preventing pregnancy.<sup>25</sup> The findings of this and a previous study suggest that hysteroscopic tubal sterilization accomplished with the microinsert is a comparatively effective method for permanent contraception. In the present study, no pregnancies occurred during the 9620 woman-months of follow-up. Combined with similar results from a phase II study,<sup>9</sup> the observed 1-year effectiveness rate was 100% (lower end of 95% CI, 99.5%). This rate compares favorably to success rates reported for laparoscopic approaches after a comparable follow-up period.<sup>26</sup> Women in this study will be followed for 5 years to assess long-term effectiveness.

A limitation of this hysteroscopic sterilization procedure is that in as many as 10% of women it may not be possible to place the microinserts bilaterally because of anatomic hurdles or unsuspected intrauterine or tubal pathology.<sup>6</sup> Bilateral placement of the microinsert was ultimately achieved in 464 (92%) of 507 women in whom placement was attempted and usually required only one procedure. The most common causes for placement failure were stenotic or previously occluded tubes. The second most common anatomic cause was compromise

of the visual field by thickened endometrium. Improved visualization of the tubal ostia can usually be achieved if the procedure is performed during the proliferative phase of the menstrual cycle.<sup>6</sup> Tubal spasm also prevented successful microinsert placement in a number of cases. Uterotubal spasm is sometimes found at the time of hysteroscopy, and in the majority of cases the etiology remains unclear.<sup>6</sup>

The primary reason for the inability to rely on the microinserts once they are placed was expulsion. A total of 14 misplaced microinserts were expelled. All but one had been placed too proximally in the fallopian tube; the other had been placed in endometrial tissue. Expelled microinserts are easily diagnosed radiographically. Trial protocol did not allow the removal of misplaced microinserts at the time of the procedure, and that undoubtedly increased the number of expulsions. However, with Food and Drug Administration approval came product labeling that allows for removal of microinserts that have 18 or more coils trailing into the uterine cavity, and this should significantly reduce the risk of expulsions in the routine clinical setting. In the present trial, it was demonstrated that expelled microinserts can be successfully replaced. Successful bilateral placement was achieved in all nine women who had an expelled microinsert replaced, and all were ultimately able to rely on the microinsert for permanent contraception. No properly placed microinsert has been expelled. Accurate microinsert placement in the narrow diameter of the intramural portion of the fallopian tube and subsequent fibrous tissue ingrowth promotes firm anchoring of the microinsert.

Four cases of perforation—diagnosed either at the time of the microinsert placement procedure or the subsequent hysterosalpingogram—have also prevented the microinserts from serving as reliable permanent contraception. No clinical adverse events were detectable from either the expulsions or perforations.

Women need to be adequately counseled that successful bilateral placement may not be possible in all cases because of anatomic impediments and visualization difficulties. However, this fact must be weighed against the potentially serious risks, side effects, and longer recovery time of laparoscopic tubal sterilization procedures.

Adequate hysteroscopic skills are essential to cannulate and manipulate the microinsert within the tubal lumen, but nine of ten participating physicians reported that the placement procedure was either simple or moderately simple. All obtained proficiency in the procedure rapidly. If desired, video documentation of the placement procedure is possible.

This study extends the findings of previous studies of the microinsert. On the basis of the evidence, this ap-

proach offers an effective method with decided advantages for the patient in terms of avoiding morbidity associated with general anesthesia and abdominal incision and for speeding recovery. This study has also demonstrated that patients are highly satisfied with both the procedure and the subsequent permanent contraception afforded by the microinsert.

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