

PN-AMS-554  
89879

A COMPARATIVE STUDY OF INTRAUTERINE DEVICES,  
TCu 380A VERSUS LIPPES LOOP D  
IN LIMA, PERU

*Prepared for:*  
*Dr. Manuel Acosta*  
*Maternidad de Lima*

*Center: 101*  
*Study: 552*

---

*Clinical Trials Division*  
*Family Health International*  
*Research Triangle Park, NC 27709*  
*USA*

*November 1993*

## FHI Staff Responsible for Document

**Document title:** A Comparative Study of Intrauterine Devices, TCU 380A versus Lippes Loop D in Lima, Peru

**Date issued:** November 5, 1993

The following FHI staff are responsible for the integrity and analysis of the data included in this document:

**Clinical:** *Gaston Farr*  
Gaston Farr  
Associate Director

**Data:** *Carolyn Reusché for Amy Burdan*  
Amy Burdan  
Medical Writer

**Medical Writer:** *Carolyn Reusché*  
Carolyn Reusché  
Medical Writer

**Biostatistician:** *Ramesh Amatya*  
Ramesh Amatya  
Biostatistician

**CT Director:** *Laneta J. Dorflinger*  
Laneta Dorflinger  
Director, Clinical Trials

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	MATERIALS AND METHODS .....	1
	Study Objective .....	1
	Study Design .....	1
	Study Products .....	1
	Selection Criteria .....	2
	Admission Procedures .....	2
	Data Analysis .....	3
III.	RESULTS .....	4
	Subject Population .....	4
	Baseline Measures .....	4
	Pre-existing Conditions .....	5
	Insertion-Related Problems .....	5
	Complications Reported During Follow-up .....	5
	Subject Discontinuation .....	6
IV.	DISCUSSION AND SUMMARY .....	8
V.	DATA QUALITY STATEMENT .....	10
VI.	ACKNOWLEDGEMENT .....	11
VII.	REFERENCES .....	12
Table I	Patient Characteristics at Admission .....	13
Table II	Reproductive History at Admission .....	14
Table III	Special Study Questions Asked at Admission .....	15
Table IV	Complications and Complaints Reported During the Study .....	16
Table V	Participant Status at Twelve Months .....	17
Table VI	Gross Cumulative Life-table Discontinuation Rates Per 100 Women .....	18

## **I. INTRODUCTION**

The intrauterine device (IUD) is a popular and highly tested method of contraception. About 85 million women worldwide use IUDs. The current generation of IUDs is safe and about 99 percent effective over one year of use. To further evaluate IUD use, Dr. Manuel Acosta of Peru, in collaboration with Family Health International, conducted a study in 1987 comparing the Copper T 380A (TCu 380A) to the locally used Lippes Loop D IUD at the family planning clinic, Maternidad de Lima. This study was part of Family Health International's (FHI) Phase III multicenter clinical trial which compared the clinical performance and contraceptive effectiveness of the TCu 380A and the Lippes Loop D.

## **II. MATERIALS AND METHODS**

### *Study Objective*

The major objective of this trial was to evaluate the use of the TCu 380A among women in particular geographic locations. The TCu 380A has been extensively tested in order to verify its efficacy and safety. The factors evaluated in this trial were complications and complaints, participant's status after twelve months of use, and gross cumulative life-table termination rates over a twelve-month follow-up period.

### *Study Design*

In this study, the TCu 380A IUD and the Lippes Loop D IUD were randomly assigned to volunteer participants according to sealed random allocation envelopes pre-printed at FHI. At the time of each woman's admission to the study, the envelope corresponding to her assigned patient order number (PON) was opened, indicating the IUD to be inserted. If a woman was inadvertently admitted and discovered to have an exclusion condition, she was discontinued from the study and the PON was not reused. The next available PON was assigned to the next woman using the appropriate random allocation envelope.

The protocol, fact sheet, and volunteer agreement form used in the study were approved by FHI's Protection of Human Subjects Committee before study initiation.

### *Study Products*

The TCu 380A is a T-shaped IUD made of polyethylene with barium sulfate for x-ray detectability. It has two 33 mm<sup>2</sup> solid copper sleeves on each transverse arm and 314 mm of copper wire wound tightly around the vertical stem. The increased copper surface area has been shown to improve the efficacy of the TCu 380A over the Lippes Loop and other IUDs [1]. The device is 32 mm wide and 36 mm long with a plastic ball at the bottom of the

vertical stem to guard against cervical penetration. A polyethylene filament is tied through the ball and provides two marker threads. At the time of this study the approved lifespan was four years, however, studies conducted by the Population Council have demonstrated an extended lifespan of at least eight years.

The Lippes Loop IUD, formed in a double S-shape of polyethylene with barium sulfate, is available in four sizes; size D was used in this study. The Lippes Loop D IUDs are used with a push-out inserter, unlike the withdrawal inserter used with the TCU 380A. The length of the Lippes Loop D IUD increases after it has been drawn into the inserter barrel and released. After its release, the measurement of size D is 30 mm in width and 36 mm in length. The marker strings on the Lippes Loop IUDs differ in color according to their size; size D uses white marker strings.

### *Selection Criteria*

Women 18 to 40 years old who were healthy, sexually active, parity of one or more,  $\geq 42$  days postpartum, freely consenting to participate in the study, could conveniently return for follow-up, and were willing to rely solely on the IUD for contraception were admitted into the trial. Women were to be excluded if there was evidence of pregnancy, current sexually transmitted (STD) or pelvic inflammatory diseases (PID). In addition, women were excluded if they had undiagnosed vaginal bleeding, allergy to copper, or a history or evidence of clinically significant gastrointestinal or renal disease. Candidates were also to be excluded if they had an abnormal Pap smear three months or less prior to admission into the study.

### *Admission Procedures*

At the initial visit, women were screened for study eligibility using predetermined screening criteria. The screening process included taking a medical history and performing a pelvic examination. The risks and benefits of study participation were explained to each woman. All participants gave informed consent before admission and agreed to return to the clinic for follow-up visits.

### *Follow-up Procedures*

The subjects were requested to return for follow-up visits at 1, 3, 6, and 12 months after IUD insertion or at any time complications occurred. At the follow-up visits, pelvic examinations were performed and appropriate treatment if necessary, was provided; the data collected were documented on the case record form (CRF) by clinic staff.

Women were terminated from the study if pregnancy occurred, if their IUD was partially or totally expelled, or if their IUD was removed for any reason. Study devices that were

expelled or displaced after insertion were not to be reinserted. Depending upon the physician's judgment, a woman's IUD could be left in place at the end of the study period in accordance with the approved life span for the IUDs, and the woman was to be followed-up according to standard medical practices. However, events (e.g. pregnancy) noted at the routine follow-up visits after study completion were not reported to FHI.

### *Data Analysis*

Data were sent to FHI for processing and analysis. Differences in incidence of complications and complaints between the two groups at insertion and at follow-up were tested using Fisher's exact test. Comparison of important study events were made on the basis of pregnancy, expulsion, bleeding and/or pain, and other specific removal rates.

Pregnancies were classified as accidental if a woman became pregnant with the IUD in situ during her 12-month study period. When both conception and expulsion were reported for the same woman, accidental pregnancy is defined as:

- all conceptions occurring after insertion of the IUD and prior to removal for any reason, or prior to an expulsion noticed by the wearer, or
- all conceptions associated with an expulsion not noticed by the wearer, or
- all conceptions associated with a perforation of the uterus.

This does not include conceptions prior to insertion, after a noticed expulsion, or after the IUD was removed for whatever reason [2]. The estimated date of discontinuation for complete or partial expulsions was to be calculated as the midpoint between the date of last follow-up and the visit at which the expulsion was reported.

The life-table method was used to calculate all termination rates. Single decrement gross life-table rates were compared using the log rank statistic which permits the overall comparison of cumulative life table event rates. To assess participant's status at twelve months, a woman was considered discontinued if she became pregnant, her IUD was expelled or displaced, or her IUD was removed for any reason within 12 months postinsertion. A woman was classified as continuing at 12 months if she did not discontinue from the study and she returned for a visit at  $\geq 9$  months postinsertion. All remaining woman were considered lost to follow-up.

Statistical significance was set at  $p \leq 0.05$  for comparing complications and complaints, and for discontinuation rates. As a multicenter study, statistical power was not predetermined for each individual study, but was calculated after the results were analyzed.

### III. RESULTS

#### *Subject Population*

Three hundred women were enrolled over a seventeen-month period beginning in December 1985. By random allocation, 153 women received the TCu 380A IUD and 147 women received the Lippes Loop IUD. There were six random allocation errors: 5 subjects should have received the Lippes Loop D instead of the TCu 380A, and one received the Lippes Loop D instead of the TCu 380A. There were a total of nine interval protocol violations which included one postpartum woman who had the IUD inserted 32 days after delivery, one at 34 days, one at 39 days, and three women at 41 days after delivery. Three post-abortion subjects had their IUDs inserted at 25, 32, and 40 days after the abortion. Eleven women did not meet the age criteria. Two subjects were 16 and 17 years old, and nine subjects were older than 40 years. These were considered to be protocol violations but were allowed to continue participation in the study in the groups corresponding to the IUD they received. Further analysis was done on the data set with the protocol violations removed, but no significant differences were noted.

#### *Baseline Measures*

The mean age  $\pm$  standard deviation (SD) of the women in the TCu 380A IUD group was  $27.6 \pm 6.3$  years and  $27.0 \pm 5.8$  years for the Lippes Loop D IUD group (Table I). The reproductive history for the women is detailed in Table II. All the women had at least one live birth prior to study admission. The mean  $\pm$  SD for the total number of live births was  $2.7 \pm 2.0$  for the TCu 380A IUD group and  $2.6 \pm 1.9$  for the Lippes Loop D IUD group. More than 70% of the women in both groups reported using no contraceptive method during the month prior to study enrollment. When a method was used, the most frequent choice was an IUD, oral contraceptives, or condoms.

The subjects were asked special study questions at admission, and the results are tabulated for the combined groups in Table III. The majority of the subjects lived within 20 km of the center, 1 subject (0.3%) lived near the center, 138 (46.0%) lived from 1-10 km from the center, and 115 (38.3%) lived from 11-20 km from the center. Thirty-three (11.0%) women lived from 21-50 km from the center, 2 (0.7%) lived more than 51 km from the center, and 11 (3.7%) women did not specify the distance to their homes.

Almost all of the women in the combined groups were less than 170 cm tall: 49 (16.3%) were less than 149 cm, 159 (53%) were between 150-159 cm tall, and 86 (28.7%) were between 160-169 cm tall. Three subjects (1.0%) were 170 cm or taller, and three (1.0%) did not specify their height.

Almost all of the women in the study weighed less than 70 kg: 82 (27.3%) weighed less than 50 kg, 175 (58.3%) weighed between 51-60 kg, and 35 (11.7%) weighed between 61-70 kg.

Seven (2.3%) women weighed between 71-80 kg, and one (0.3%) woman weighed 81 or more kg.

### *Pre-existing Conditions*

A few pre-existing conditions were reported. In the TCU 380A IUD group, 11 subjects had an unspecified inflammation or infection, nine subjects had vaginitis, one had mild condyloma, one had mild adnexal inflammation, one had an unspecified degree of pelvic inflammatory disease, and one had mild trichomoniasis. In addition, one subject had mild vulvitis. In the Lippes Loop D IUD group, 14 subjects had an unspecified inflammation or infection, five subjects had vaginitis, one had moderate cervicitis, one had moderate adnexal inflammation. Five of the above subjects were excluded from analysis because of pre-existing conditions, (one cervicitis, two adnexal inflammations, one unspecified PID, and one mild trichomoniasis.

### *Insertion-Related Problems*

There were minor complications or complaints reported at insertion (Table IV). Thirty-six (23.5%) of the TCU 380A group and 29 (19.7%) of the Lippes Loop D group reported mild pelvic pain, and 8 (5.1%) of the TCU 380A group and 13 (8.8%) of the Lippes Loop D group reported moderate pelvic pain. There were 10 (6.5%) cervical lacerations not requiring treatment in the TCU 380A group, and 12 (8.2%) in the Lippes Loop D group. Three (2.0%) of the TCU 380A insertions and 1 (0.7%) of the Lippes Loop D insertions required dilation. One insertion in the TCU 380A group failed due to cervical adhesion, and the subject withdrew from the study.

In addition, one subject from the TCU 380A IUD group was diaphoretic, and in the Lippes Loop group, one subject had syncope and one was diaphoretic. All three conditions were probable reactions to IUD insertion. None of these conditions were considered by the attending physician to preclude use of the study IUDs.

### *Complications Reported During Follow-up*

One hundred forty-seven (96.7%) of the subjects in the TCU 380A and 143 (97.3%) of the Lippes Loop D group returned for at least one follow-up visit. All complications and complaints reported during the study are listed in Table IV. Pelvic pain was the most frequent intermenstrual problem reported, 47 (32.0%) women in the TCU 380A IUD group and 43 (30.1%) women in the Lippes Loop D IUD group. Dysmenorrhea was reported by 26 (17.7%) women in the TCU 380A IUD group and by 21 (14.7%) women in the Lippes Loop D IUD group. Five (3.4%) subjects of the TCU 380A IUD group and 6 (4.2%) of the Lippes Loop D IUD group reported intermenstrual spotting. In addition, 3 (2.0%) subjects of the

TCu 380A IUD group and 5 (3.5%) subjects of the Lippes Loop D IUD group reported intermenstrual bleeding.

Table IV also includes reports for PID, and other inflammations or infections. Eleven (7.5%) women in the TCu 380A IUD group and 10 (7.0%) women in the Lippes Loop D IUD group were diagnosed with PID. In addition, one (0.7%) woman in the TCu 380A IUD group was diagnosed with endometritis.

There were a large number of other inflammations and infections reported; however, the differences in the number of reports between the two IUD groups were not statistically significant. In the TCu 380A IUD group, 32 (21.8%) women were diagnosed with vaginitis (including moniliasis and colpitis) and 7 (4.8%) with trichomoniasis. In the Lippes Loop D IUD group 31 (21.1%) women were diagnosed with vaginitis (including moniliasis and colpitis) and 9 (6.3%) with trichomoniasis. In the TCu 380A IUD group, 6 (4.1%) women presented with leukorrhea, 4 (2.7%) were diagnosed with cervicitis, and 7 (4.8%) were diagnosed with miscellaneous infections. In the Lippes Loop D IUD group, 1 (0.7%) woman presented with leukorrhea, 2 (1.4%) were diagnosed with cervicitis, and 6 (4.1%) were diagnosed with miscellaneous infections, which included Bartholinitis, and urinary tract infection.

There was one adverse experience in each IUD group requiring hospitalization. One of the subjects in the TCu 380A IUD group who had been diagnosed with PID was hospitalized for a pelvic abscess and was under medication for 10 days. She did not return for her second follow-up visit, but went to another clinic and had the IUD removed because she wanted another child. In the Lippes Loop D IUD group, one subject began to bleed vaginally after IUD insertion, which required hospitalization. The IUD was removed, and curettage was performed.

### *Subject Discontinuation*

One hundred fifteen (75.2%) of the TCu 380A group and 108 (73.5%) of the Lippes Loop D group completed the study through the 12-month follow-up visit. Table V summarizes the women's status at the end of twelve months of use and Table VI presents the 12-month gross cumulative life-table discontinuation rates for these termination events. Evaluations of performance were made on the basis of various termination rates and continuation rates, with a focus on the accidental pregnancy and expulsion rates. Other termination reasons included planning a pregnancy and removals for other personal reasons. The differences in life-table rates between the two groups for the terminations reasons listed above were not statistically significant.

There were two accidental pregnancies (1.3%) in the TCu 380A IUD group yielding a 12-month life-table rate of 1.4 per 100 women. One of these two subjects was diagnosed as being pregnant approximately six weeks after insertion, with the IUD in situ. She had a

menstrual period four weeks after IUD insertion, and one follow-up visit without signs or symptoms of pregnancy. At a gestational age of 13 weeks, the pregnancy was confirmed, and the doctor speculated that the failure was due to the size of the IUD. The follow-up form does not indicate that the IUD was removed, but that the subject continued with the pregnancy; the pregnancy outcome was not reported. The other subject in the TCu 380A IUD group became pregnant after an unnoticed expulsion; the estimated date of expulsion, based on the mid-point date of the follow-up interval was two days after the last menstrual period onset date. The estimated date of conception was approximately two weeks later; the pregnancy outcome was not reported. There were three accidental pregnancies (2.0%) in the Lippes Loop D IUD group yielding a 12-month life-table rate of 2.5 per 100 women. One subject was diagnosed as being pregnant approximately eight months after insertion, with the IUD in situ. The gestational age was eight weeks at the time of IUD removal; the pregnancy outcome was not reported. The second Lippes Loop D IUD subject was diagnosed as being pregnant approximately ten months after insertion, with the IUD in situ. It was an ectopic pregnancy; the IUD was removed and a laparotomy was performed at eight weeks' gestation. The third Lippes Loop D IUD subject was diagnosed as being pregnant approximately five months after insertion, with the IUD in situ. The investigator noted that "failure was due to small size of device." The gestational age was seven weeks at the time of IUD removal; the pregnancy outcome was not reported.

There were a total of eight IUD expulsions or displacements in the study: 2 (1.3%) in the TCu 380A IUD group and 6 (4.1%) in the Lippes Loop D IUD group. The 12-month gross life-table expulsion rates were 1.5 per 100 women for the TCu 380A IUD group and 4.8 per 100 women for the Lippes Loop D IUD group. This difference was not statistically significant. One patient of the TCu 380A IUD group became pregnant after the IUD was expelled (pregnancy was confirmed after the IUD was expelled).

Removals for bleeding and/or pain included four women (2.6%) in the TCu 380A IUD group and six women (4.1%) in the Lippes Loop D IUD group. The life-table rates for removal due to bleeding and/or pain for the TCu 380A and Lippes Loop D IUD users were 3.0 per 100 women and 4.7 per 100 women, respectively.

Five women (3.3%) in the TCu 380A IUD group and one woman (0.7%) in the Lippes Loop D IUD group were discontinued from the study for a medical reason. PON 12 (TCu380A) had cervical adhesions, PON 17 (TCu380A) had bilateral adnexitis, PON 45 (TCu380A) had persistent cervicitis, PON 75 (TCu380A) had pelvic inflammation, and PON 195 (TCu380A) and PON 297 (Lippes Loop D) had persistent urinary infections. The 12-month gross cumulative life-table removal rates for other medical reasons were 4.0 per 100 women for the TCu 380A IUD group and 0.8 for the Lippes Loop D IUD group.

There were a small number of women who requested IUD removal in order to plan a pregnancy. One (0.6%) woman in the TCu 380A IUD group, and 4 (2.7%) in the Lippes Loop D IUD group requested removal for this reason, with a 12-month gross cumulative life-

table rate of 0.7 per 100 women for the TCu 380A group and 3.4 per 100 women for the Lippes Loop D IUD group.

Only one woman had her IUD removed because of other personal reasons. This subject was in the TCu 380A IUD group and requested removal because she no longer needed contraception. The 12-month gross cumulative life-table removal rate for this reason was 0.7 per 100 women for the TCu 380A IUD group and 0.0 per 100 women for the Lippes Loop D IUD group.

#### IV. DISCUSSION AND SUMMARY

From December 18, 1985 to May 30, 1987, IUDs were inserted in 300 women in a 17-month comparative clinical trial conducted at the family planning clinic, Maternidad de Lima, Peru. This study was designed to assess the contraceptive safety and efficacy between two different types of IUDs. By random allocation, 153 women received the TCu 380A IUD and 147 received the Lippes Loop D IUD. A total of 25 protocol violations occurred: nine interval violations, eleven age violations, and five subjects were excluded for pre-existing conditions. In addition, there were six random allocation errors. However, all of the protocol violations and random allocation error subjects continued in the study and were included in the analysis. Subsequent analysis of the data when excluding these protocol violations did not alter the final results of the trial. About 97% of the women in both IUD study groups returned for at least one follow-up visit.

Participants in the two groups were similar with respect to selected socio-demographic characteristics and reproductive history. The main complication reported at insertion was mild pelvic pain. In addition, 6.5% insertions in the TCu380A group experienced cervical lacerations, and 8.2% in the Lippes Loop D group.

During follow-up, the most frequently reported menstrual complaints for both groups were dysmenorrhea and intermenstrual pelvic pain. The most frequently reported inflammations or infections were vaginitis, including moniliasis, and trichomoniasis. The difference between the IUD groups was not found to be statistically significant. Two adverse experiences requiring hospitalization and IUD removal were reported: a TCu 380A subject was diagnosed with PID and a Lippes Loop subject was diagnosed with a vaginal hemorrhage.

The Lippes Loop D IUD group had three accidental pregnancies while there were two accidental pregnancies in the TCu 380A IUD group. The three pregnancies in the Lippes Loop D IUD group and one of the pregnancies in the TCu 380A IUD group were due to device failures in situ, and the other pregnancy in the TCu 380A IUD group was due to an unnoticed expulsion. Of the women enrolled in the study, 75.2% of the TCu 380A IUD group and 73.5% of the Lippes Loop D IUD group decided to continue wearing the IUD after the study had ended at 12 months. No significant overall differences between the two study IUDs were observed in the incidence of terminations or complications. Given the final

sample size and the pregnancies reported at this center, the power to detect a statistically significant difference in pregnancies of 1.7% and 2.8% between these two study groups at twelve months was low, <10% (alpha = 0.05).

A larger than expected number of infections/inflammations, including pelvic inflammatory disease, was reported among this study population. Selection criteria for this trial excluded potential subjects who were at risk of vaginal and reproductive tract infections because of the high risk of developing pelvic inflammatory disease. The fact that approximately 8% of the women in this trial developed PID, and that many experienced infections such as vaginitis, trichomoniasis, and leukorrhea suggests that this population must be carefully screened when an IUD is being considered as a contraceptive option.

Because of this center's sample size in this study, statistically significant differences in accidental pregnancy and expulsion/displacement rates between the two IUDs were unlikely to be seen. However, some trends were noted that, with sufficient data, may provide enough information for programmatic decisions. The general direction of the lower accidental pregnancy rate with the TCU 380 A IUD is consistent with other studies which have shown the TCU 380A IUD to be more effective in preventing pregnancy than the Lippes Loop IUDs [3]. Furthermore, rates for expulsion/displacement were approximately three times greater in the Lippes Loop D IUD group. This difference may be clinically important when considering costs of reinsertion of expelled IUDs and the risk of unplanned pregnancy due to unawareness that the IUD had been expelled.

## **V. DATA QUALITY STATEMENT**

The overall conduct of this study was fair. Admissions were completed over a 17-month period. Four physicians performed the IUD insertions, but due to misunderstandings of the protocol requirements, twenty five protocol violations occurred (age, interval status, and pre-existing conditions), as well as six random allocation errors. Special emphasis was made on the signing of consent forms and on instructing the patients on the IUD fact sheet. More attention to detail should have been made towards follow-up of the subjects; the clinic was recommended to use a follow-up log book. While patient records were available in the hospital, they were sometimes difficult to locate. Although forms were conscientiously completed and great attention was paid to answering queries and correcting data problems, data cleaning was a slow process, partly due to the mail strike in Lima at the time.

**Note:** This statement is provided to the investigator to help him set the study's results in the proper context. The quality of the data collected may affect the validity of the stated results.

## **VI. ACKNOWLEDGEMENT**

Support for this work was provided by FHI with funds from the U.S. Agency for International Development. FHI is an international not-for-profit organization based in Research Triangle Park, North Carolina that conducts research and provides technical assistance in health, family planning, STDs, and AIDS. Views expressed in this report do not necessarily reflect those of USAID.

The following staff of FHI should be acknowledged for their participation with this study and with the writing of the consultant report: Carolyn Reusché, Amy Burdan, Ramesh Amatya, and Gaston Farr. We would also like to thank I-cheng Chi, MD, Rosalie Dominik, MPH, Laneta Dorflinger, PhD, John Lewis, Howard Miller, MD, Thomas Petrick, MD, and David Sokal, MD for reviewing this report.

## **VII. REFERENCES**

1. Sivin I, Schmidt F. Effectiveness of IUDs: a review. *Contraception* 1987;36(1):55-84.
2. Teitze C, Lewit S. Evaluation of intrauterine devices: ninth progress report of the Cooperative Statistical Program. *Stud Family Plann* 1970;55:1-40.
3. Rivera R, Farr G, Chi I-C. *The Copper IUD--Safe and Effective. The International Experience of Family Health International.* Research Triangle Park, NC: Family Health International; 1993.

**Table I**  
**Patient Characteristics at Admission**

Characteristics	TCu 380A (N=153)		Lippes Loop D (N=147)	
	No.	%	No.	%
<u>Age in Years Completed</u>				
< 20	10	6.5	14	9.5
20-24	55	35.9	45	30.6
25-29	40	26.1	45	30.6
30-34	24	15.7	25	17.0
35-39	17	11.1	16	10.9
40+	7	4.6	2	1.4
Mean (S.D.)	27.6	(6.3)	27.0	(5.8)
<u>Education in School Years Completed</u>				
0	2	1.3	4	2.7
1-3	11	7.2	9	6.1
4-6	32	20.9	43	29.3
7-9	44	28.8	31	21.1
10-12	52	34.0	49	33.3
13+	12	7.8	8	5.4
Unspecified	0	0.0	3	2.0
Mean (S.D.)	12	(5.0)	8.5	(3.4)
Median	8.7		8.5	

**Table II**  
**Reproductive History at Admission**

Characteristic	TCu 380A (N=153)		Lippes Loop D (N=147)	
	No.	%	No.	%
<u>Total Live Births</u>				
1-2	89	58.2	89	60.5
3-4	39	25.9	33	22.4
5-6	16	10.4	20	13.6
7-8	7	4.6	2	1.4
9+	2	1.3	3	2.0
Mean (S.D)	2.7	(2.0)	2.6	(1.9)
Median	2.2		2.1	
<u>Contraceptive Method Used in Past Month</u>				
None	110	71.9	114	77.6
IUD	15	9.8	12	8.2
Oral Pill	15	9.8	10	6.8
Condom	5	3.3	5	3.4
Withdrawal/Rhythm	3	2.0	2	1.4
Injectable	3	2.0	2	1.4
Foam/Diaphragm/Jelly	1	0.7	1	0.7
Abstinence	1	0.7	1	0.7
<u>Patient Category</u>				
Interval	148	96.7	143	97.3
Postpartum	3	2.0	3	2.0
Post-abortion	2	1.3	1	0.7

**Table III**  
**Special Study Questions Asked at Admission**

Questions at Admission	No.	Groups Combined (N=300) %
<u>Distance From the Center (km)</u>		
<0	1	0.3
1-10	138	46.0
11-20	115	38.3
21-50	33	11.0
51+	2	0.7
unspecified	11	3.7
<u>Woman's Height (cm)</u>		
<149	49	16.3
150-159	159	53.0
160-169	86	28.7
170+	3	1.0
unspecified	3	1.0
<u>Woman's Weight (kg)</u>		
<50	82	27.3
51-60	175	58.3
61-70	35	11.7
71-80	7	2.3
81+	1	0.3

**Table IV**  
**Complications and Complaints Reported During the Study**

Complications/Complaint	TCu 380A		Lippes Loop D	
	No.	%	No.	%
<b>Total Women at Insertion</b>	<b>153</b>	<b>100.0</b>	<b>147</b>	<b>100.0</b>
<u>Pre-existing conditions:</u>				
Vaginitis	9	5.9	5	3.4
Mild Condyloma	1	0.7	0	0.0
Mod. Cervicitis	0	0.0	1	0.7
Mild Adnexitis	1	0.7	0	0.0
Mod. Adnexitis	0	0.0	1	0.7
Unspecified PID	1	0.7	0	0.0
Mild Trichomoniasis (STD)	1	0.7	0	0.0
Mild Vulvitis	1	0.7	0	0.0
<u>Insertion-related Problems:</u>				
Mild Pelvic Pain	36	23.5	29	19.7
Moderate Pelvic Pain	8	5.1	13	8.8
Unspec. Inflammation/Infection	11	7.2	14	9.5
Cervical Laceration (no treatment)	10	6.5	12	8.2
Dilation	3	2.0	1	0.7
Syncope	0	0.0	1	0.7
Diaphoresis	1	0.7	1	0.7
Failed Insertion	1	0.7	0	0.0
<u>Abnormalities:</u>				
Cystocele	1	0.7	1	0.7
Septic Abortion	0	0.0	1	0.7
Ovarian Cyst	1	0.7	1	0.7
Cervical Erosion	0	0.0	1	0.7
<b>Total Women ever Followed-up</b>	<b>147</b>	<b>96.7</b>	<b>143</b>	<b>97.3</b>
<u>Menstrual Problems:</u>				
Dysmenonhea	26	17.7	21	14.7
<u>Intermenstrual:</u>				
Pelvic Pain	47	32.0	43	30.1
Spotting	5	3.4	6	4.2
Bleeding	3	2.0	5	3.5
<u>PID:</u>				
Adnexitis	7	4.8	7	4.9
Anatomically Unspecified	4	2.7	3	2.1
Endometritis	1	0.7	0	0.0
<u>Other Inflammations or Infections:</u>				
Vaginitis <sup>1</sup>	32	21.8	31	21.1
Trichomoniasis (STD)	7	4.8	9	6.3
Leukorrhea	6	4.1	1	0.7
Cervicitis <sup>2</sup>	4	2.7	2	1.4
Miscellaneous	7	4.8	6	4.1
<u>Hospitalizations:</u>	1	0.7	1	0.7

<sup>1</sup> Includes moniliasis.

<sup>2</sup> Includes cervical erosion and ectropion.

**Table V**  
**Participant Status at Twelve Months**

Status	TCu 380A (N=153)		Lippes Loop D (N=147)	
	No.	% <sup>1</sup>	No.	% <sup>1</sup>
Continuing <sup>2</sup>	115	75.2	108	73.5
Accidental Pregnancy	2	1.3	3	2.0
Expulsion/ Displacement	2	1.3	6	4.1
<u>Removals for:</u>				
Planning Pregnancy	1	0.6	4	2.7
Other Medical Reasons	5	3.3	1	0.7
Bleeding/Pain	4	2.6	6	4.1
Personal Reasons	1	0.6	0	0.0
Lost to Follow-up	23	15.0	19	12.9

<sup>1</sup> Percentages may not total 100 due to rounding.

<sup>2</sup> At 12 months, a woman was considered "discontinued" if she became pregnant, her IUD was expelled or displaced, or her IUD was removed for any reason. A woman was classified as "continuing" at 12 months if she did not discontinue from the study and she returned for a visit at  $\geq 9$  months within 12 months since insertion. All remaining woman were considered "lost to follow-up".

Table VI

## Gross Cumulative Life-table Discontinuation Rates Per 100 Women

Discontinuation <sup>1</sup> Type and Period	TCu 380A			Lippes Loop D		
	At Risk (N)	Rate per 100 women	(S.E.)	At Risk (N)	Rate per 100 women	(S.E.)
<b>Accidental Pregnancy</b>						
3 months	140.5	0.7	(0.7)	133.5	0.0	(0.0)
6 months	131.0	1.4	(1.0)	119.5	0.8	(0.8)
12 months	97.0	1.4	(1.0)	93.0	2.5	(1.4)
<b>Expulsion/Displacement</b>						
3 months	140.5	0.7	(0.7)	134.0	1.4	(1.0)
6 months	130.5	0.7	(0.7)	119.5	3.0	(1.5)
12 months	97.0	1.5	(1.1)	93.5	4.8	(2.0)
<b>Bleeding/Pain</b>						
3 months	140.5	0.7	(0.7)	133.5	2.1	(1.2)
6 months	131.0	2.2	(1.2)	120.0	3.7	(1.6)
12 months	97.0	3.0	(1.5)	93.5	4.7	(1.9)
<b>Other Medical Reasons</b>						
3 months	140.5	0.7	(0.7)	133.5	0.0	(0.0)
6 months	131.0	2.2	(1.2)	120.0	0.8	(0.8)
12 months	97.5	4.0	(1.8)	93.0	0.8	(0.8)
<b>Personal Reasons</b>						
3 months	140.5	0.0	(0.0)	133.5	0.0	(0.0)
6 months	130.5	0.7	(0.7)	119.5	0.0	(0.0)
12 months	97.0	0.7	(0.7)	93.0	0.0	(0.0)
<b>Planning Pregnancy</b>						
3 months	140.5	0.0	(0.0)	134.0	0.7	(0.7)
6 months	131.0	0.7	(0.7)	120.0	2.4	(1.3)
12 months	97.0	0.7	(0.7)	93.5	3.4	(1.7)
<b>Total Discontinuation Rate</b>						
3 months	140.5	2.7	(1.4)	134.5	4.2	(1.7)
6 months	132.5	7.7	(2.2)	121.0	10.2	(2.6)
12 months	97.5	11.0	(2.7)	94.5	15.3	(3.2)
<b>Continuation Rate</b>						
3 months		97.3	(1.4)		95.8	(1.7)
6 months		92.3	(2.2)		89.8	(2.6)
12 months		89.0	(2.7)		84.7	(3.2)

<sup>1</sup> Lost to follow-up cases are censored by the life-table procedure.