

A COMPARATIVE STUDY OF THE  
TCu 380A IUD AND THE TCu 200 IUD  
AT TWO STUDY SITES IN KARACHI, PAKISTAN

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April 1991

## Introduction

A study comparing the Copper T 380A (TCu 380A) intrauterine device (IUD) and the Copper T 200 (TCu 200) IUD was conducted between April 1986 and January 1989 by the National Research Institute of Fertility Control (NRIFC), Karachi, Pakistan. The study was conducted at two Family Welfare Centers in Karachi, Malir and Khokharapar, with 150 patients at each study site. The purpose of this study was to evaluate the relative safety and efficacy of the TCu 380A IUD compared to the locally available TCu 200 IUD. The factors evaluated were complications and complaints, participant's status after twelve months of use, and gross cumulative life-table event and continuation rates over a twelve-month follow-up period.

## Materials and Methods

### *Study Products*

The TCu 200 is a T-shaped IUD made of polyethylene with barium sulfate added for visibility on x-ray. It is wound with copper wire on the stem, providing a surface area of 200 mm<sup>2</sup>. The cross arm is 32 mm in width and the vertical arm is 36 mm in length. The proximal end of the IUD stem is provided with two threads of polyethylene to serve as markers. It has an approved lifespan of four years.

The TCu 380A is also a T-shaped device made of polyethylene with barium sulfate. It has two 33 mm<sup>2</sup> solid copper sleeves on each transverse arm and 314 mm<sup>2</sup> of copper wire wound tightly around the vertical stem. This increased copper surface area, the most found on any commercially available copper IUD, is expected to improve the efficacy of the TCu 380A over the standard TCu 200 IUD. The device is also 32 mm wide and 36 mm long but has a plastic ball at the

bottom of the vertical stem to guard against cervical penetration. A polyethylene filament is tied through the ball which provides two threads to serve as markers. An expanded lifespan of six years for the IUD has been demonstrated by studies done by the World Health Organization. At the time of this study however, the U.S. Food and Drug Administration approved life-span for this device was four years.

### *Selection Criteria*

Women 18 to 40 years old who were healthy, sexually active, seeking intrauterine contraception,  $\geq 40$  days postpartum and willing to rely solely on the IUD for contraception were admitted into the trial. Other criteria for inclusion were that general and pelvic examinations, including Pap smear, were normal and the women had no active sexually transmitted diseases, undiagnosed vaginal bleeding, or allergy to copper. Candidates for this study were excluded if they had a history of ectopic pregnancy, an abnormal pap smear (3 months or less prior to study), and history or evidence of clinically significant gastrointestinal or renal disease.

Three hundred women were enrolled between April 1986 and December 1987. In order to recruit 300 patients, patient enrollment was split between two NRIFC Family Welfare Centers in Karachi approximately 5 km apart, Malir and Khokharapar, with 150 patients to be admitted at each clinic. The same study protocol was followed at each of the two sites. Computer-generated random assignments of study IUDs corresponding to Patient Order Numbers 1-150 were used at Khokharapar and those for Patient Order Numbers 151-300 were used at Malir.

### *Enrollment*

Insertions were performed by the Lady Health Visitor (LHV) at each clinic, who is trained at a paramedic level with some midwifery skills. There was one motivator at each clinic to assist with follow-up and to track defaulters. One study physician provided follow-up care at both clinics. All women gave informed consent before admission and agreed to return to the clinic for follow-up visits.

### *Follow-up and Termination Procedures*

Patients were requested to return for follow-up at 1, 3, 6 and 12 months after insertion of their IUD or at any time complications occurred. 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 partially or totally expelled after insertion were not to be reinserted and these patients were discontinued from the study. Patients lost to follow-up were regarded as discontinuers at the time of their last recorded follow-up visit.

### *Data Analysis*

Data were recorded on standard case report forms by clinic staff and sent to FHI for processing and analysis. Differences in categorical data were assessed using the chi-square test of significance and comparisons of means using the t-test. Rates of discontinuation for specific reason were calculated using the life-table method. Single decrement gross life-table rates were compared between the two groups using the log rank statistic which permits the overall comparison of cumulative life-table event rates. Patients lost to follow-up were censored from by the life-table procedure at the follow-up interval in

which they no longer provided data to the study. They are not included as continuers in termination or continuation rates. Statistical significance was set at  $p < 0.05$ . For this study, the power to detect a four percent difference in the two groups is less than 40 percent for the number of patients admitted.

Although the study was conducted at two sites in Karchi, this report will focus on a pooled analysis of the results. Selected data for the two study sites will be presented in separate tables. By random allocation, 151 women received the TCu 380A IUD and 149 the TCu 200 IUD.

#### Patient Characteristics.

One woman, a TCu 380A patient at Khokharapar, was 39 days postpartum and is excluded from this analysis as a protocol violation. Selected sociodemographic characteristics for 150 TCu 380A and 149 TCu 200 acceptors are presented in Table I. Mean age was 28.2 years for women in the TCu 380A group and 27.1 years in the TCu 200 group (difference not significant). There was no significant difference in the mean number of live births for the two study groups (4.7 for the TCu 380A group and 4.4 for the TCu 200 group). Over 59 percent of the women in both study groups reported using no contraceptive method prior to admission into the study. When reported, the most frequently used methods had been IUDs and withdrawal/rhythm. There was no significant difference in previous contraceptive use among these women.

Patients at the Khokharapar study site were found to be dissimilar in age and parity distributions (Table Ia). Women in the TCu 200 group at this site were younger ( $X^2=8.82$ ,  $p=0.032$ ) and had had fewer live births than women in the TCu 380A group ( $X^2=22.84$ ,  $p<0.001$ ). There was no significant difference in previous

contraceptive use for both groups of women at this study site. Women at the Malir study site were similar along each of the three sociodemographic characteristics analyzed (Table Ib).

## Results

### *Complications/Complaints at Insertion*

Complications and complaints reported during the study period in the pooled study are summarized in Table II. Forty-five women (30.0%) in the TCu 380A group and 42 (28.2%) in the TCu 200 group were reported to have experienced cervical lacerations during IUD insertion. However, most of these were reported at one site (Malir) due to concerns about incidental bleeding observed at or during insertion (Table IIb). Over 70 percent of the reports were attributed to the inserter device. These events were not considered serious by the attending physician, or to require treatment. Mild pelvic pain was reported by 57 women (38.0%) in the TCu 380A group and by 59 women (39.6%) in the TCu 200 group. Most reports of pelvic pain at IUD insertion (83 out of 116) were from the Malir clinic cohort (Table IIb). No statistically significant differences between the two study groups were detected when comparing insertion-related complications and complaints either for pooled data or at the individual sites. No failed insertions were reported during the study.

All 150 women in the TCu 380A group and 146 (98.0%) in the TCu 200 group returned for at least one follow-up visit. Table II presents pooled data on bleeding/pain complaints ever reported during follow-up. Twenty-one women in the TCu 380A group (14.0%) and 12 women (8.2%) in the TCu 200 group reported intermenstrual spotting. Intermenstrual bleeding was reported for 65 (43.3%) TCu 380A users and 59 (40.4%) TCu 200 users (difference not significant).

Dysmenorrhea was reported by 79 women (52.7%) in the TCu 380A group and by 69 women (47.3%) in the TCu 200 group (difference not significant). TCu 380A users reported significantly more cases of intermenstrual pelvic pain than did TCu 200 users ( $X^2=7.01$ ,  $p=0.03$ ). Most of the reports of menstrual problems, primarily dysmenorrhea (110 of 148) or intermenstrual pelvic pain (100 of 124), were from the Malir clinic cohort (Table IIb). Differences between IUD study groups in the number of menstrual complaints at either site were not significantly different, except for reports of intermenstrual pelvic pain (Tables IIa and IIb).

One case of trichomonas was reported among TCu 380A users (Table II). A total of 51 women (17.0%) were diagnosed with other inflammations or infections during follow-up: six cases (4.0%) of vaginitis in the TCu 380A group and seven (4.8%) in the TCu 200 group; 18 cases (12.0%) of cervicitis in the TCu 380A group and 20 (13.7%) in the TCu 200 group. No statistically significant differences between the two groups were noted for either of these conditions. Reports of inflammation or infections were evenly distributed between the two study sites (Tables IIa and IIb).

#### *Termination Events*

Table III summarizes patient status for the pooled study at the end of twelve months of use and Table IV presents pooled gross cumulative life-table rates for these termination events. Pertinent terminations (those which are related to efficacy and acceptability of the IUD) include accidental pregnancy, expulsion, removal for bleeding or pain and removals for other medical reasons. Other medical reasons included: uterine perforation, infection, cervical erosion, and other medical events. Non-pertinent termination reasons include: planned

pregnancy or removals for other personal reasons (e.g. husband's objections or moving). Total terminations included all reasons for discontinuation from the study.

Three accidental pregnancies were reported in the TCU 200 group, yielding a twelve-month gross life-table rate of 2.4 per 100 women. One user (Khokharapar) became pregnant approximately nine months after insertion; the estimated gestational age was six weeks when the pregnancy was confirmed and the IUD removed. The outcome of the pregnancy was a live birth. A second TCU 200 user (Khokharapar) became pregnant approximately seven months postinsertion; the estimated gestational age was 12 weeks when the IUD was removed. This patient experienced a spontaneous abortion at approximately 24 weeks gestation. The third TCU 200 user (Malir) became pregnant approximately two months postinsertion; the estimated gestational age was six weeks and the IUD was not removed. The patient aborted at eight weeks gestation. No pregnancies were reported among TCU 380A users. Rates were not significantly different for both the pooled (Table IV) and individual study sites (Tables IVa and IVb).

IUDs were expelled or displaced in two TCU 380A users (1.3%) and four TCU 200 users (2.7%) by twelve months postinsertion (Table III). The twelve-month gross life-table expulsion rates were 1.4 per 100 women for the TCU 380A group and 6.2 per 100 women for the TCU 200 group (Table IV). The difference in these rates was not statistically significant, nor for expulsion rates at each study site (Tables IVa and IVb).

A total of 15 TCu 380A users (10.07%) had their IUDs removed for bleeding and pain, yielding a 12-month life-table rate of 11.6 per 100 women. Twelve removals occurred in the TCu 200 group (8.1%), yielding a twelve-month life-table rate of 10.7 per 100 women for the TCu 200 group. This difference was not statistically significant. The number of removals for bleeding/pain were roughly the same at both study sites (Table IIIa and IIIb), although life-table rates were slightly lower at Khokharapar (Table IVa) than at Malir (Table IVb). Differences between study groups removal rates were not statistically significant at either study site.

Two women in the TCu 380A group (1.3%) and one woman in the TCu 200 group (0.7%) requested removal of their devices in order to become pregnant. One request was from a woman attending the Khokharapar study site, while the other two were from women attending the Malir study site. In each case, request for removal of their study IUD occurred sometime after the women had completing the 12-month follow-up period. As a result, these removals do not appear in the 12-month life-table rates.

Twelve women in the TCu 380A groups (8.0%) and eight women in the TCu 200 group (4.0%) requested removal of their IUDs for personal reasons by the 12-month visit (Table III). The basis for these requests varied and included: patient moving, husband or mother-in-law objections, and the husband being out of the country for an extended period of time. The twelve-month life-table rates for removal due to personal reasons were 9.4 per 100 women in the TCu 380A group and 6.6 per 100 women in the TCu 200 group. This difference in pooled life-table rates was not statistically significant (Table IV). Most of the removals (14 of 20) for personal reasons occurred at the Khokharapar study site (Table IIIa).

In the pooled dataset, two women in the TCU 380A group (1.3%) and two in the TCU 200 group (1.4%) had their IUDs removed for non IUD-related other medical reasons by the end of the 12-month follow-up period. Reasons for the two TCU 380A removals were: prior to kidney surgery (6 months postinsertion) and for tubal ligation (9 months). One TCU 200 user had her IUD removed prior to surgery for gallstones (10 months postinsertion) and the other prior to hospitalization for treatment of ovarian cancer (2 months). The 12-month life-table removal rates for other medical reasons were 2.4 per 100 women in the TCU 380A group and 1.7 per 100 women in the TCU 200 group. This difference was not found to be statistically significant. The two TCU 380A removals occurred at the Khokharapar site (Table IIIa) and the two TCU 200 removals occurred at the Malir site (Table IIIb).

A total of 31 women in the TCU 380A study group and 32 women in the TCU 200 groups were discontinued from the trial during the 12-month study period (including three women lost to follow-up). This yielded a 12-month total termination life-table rate of 22.9 per 100 women in the TCU 380A group and 24.8 per 100 women in the TCU 200 group. This difference was not statistically significant. At the Khokharapar clinic, 21 TCU 380A users and 20 TCU 200 users had been discontinued from the study by the end of 12 months; life-table rates were 31.6 pr 100 women and 26.2 per 100 women, respectively (difference not sitatistically significant). Ten women in the TCU 380A group and 13 in the TCU 200 group at the Malir clinic had been discontinued by the end of the 12 month follow-up period. Twelve-month total termination life-table rates were 14.3 and 22.4 per 100 women, respectively (difference not significant).

Pooled continuation rates (Table V) are defined as 100 minus the total termination rate and indicate that user had not been terminated from the trial by the specified follow-up period. At twelve months these rates were 77.1 per 100 women in the TCu 380A group and 75.2 per 100 women in the TCu 200 group. The difference between these rates was not statistically significant. Follow-up status (Table V) is defined as the percentage of women not previously terminated who returned for a follow-up visit. These percentages were at or above 80% for both groups over the duration of the study. Three women, all TCu 200 users, never returned for a follow-up visit after their admission into the study, but are included in the continuation rates until censored by the life-table procedure (Table III).

Twelve-month continuation rates at the Khokharapar clinic (Table Vb) were 68.4 per 100 TCu 380A women and 72.8 per 100 TCu 200 women (difference not significant). At the Malir clinic (Table Va) these rates were 85.7 per 100 women in the TCu 380A group and 77.6 per 100 women in the TCu 200 (difference not significant). Follow-up percentages were similar at both clinics because social workers at both sites make home visits to patients late for follow-up.

### **Summary**

From April 1986 through December 1987, IUDs were inserted in 300 women participating in a clinical trial coordinated by the National Research Institute of Fertility Control in Karachi, Pakistan. The study was conducted at two NRIFC Family Welfare Centers located in Karachi, Malir and Khokharapar, with 150 women enrolled at each site to facilitate recruitment of 300 patients. By the process of random allocation, 151 women had a TCu 380A IUD and 149 a TCu 200 IUD inserted. One woman in the TCu 380A group was excluded from analysis because

her IUD was inserted less than 40 after pregnancy end in violation of the inclusion criteria for study participation. The two study groups were similar with respect to other sociodemographic characteristics.

While women at the Malir study site were found to be similar across sociodemographic characteristics, women at the Khokharapar study site were not. At this site, women in the TCu 200 group were both younger and of lower parity than their TCu 380A counterparts. Since randomization was based on a computer-generated program at FHI, it is unclear why this may have occurred. One possibility may be that the randomization procedure was programmed for 300 patients at one site, not for 150 each for two sites. Prior to initiation of the study it was decided that 150 patients would be recruited at each of the two study sites. Randomization of patients was then split in half with IUD assignments for PONs 1-150 reserved for the Khokharapar study site and IUD assignments for PONs 151-300 for the Malir study site. Failure to account for two study sites in randomizing patients to one of the two study groups may bias group characteristics when individual study sites are analyzed.

Most of the 300 IUD insertions at the two clinics were performed by Lady Health Visitors (LHV) who had paramedic training. Insertion-related complaints included reports of cervical laceration and mild pelvic pain. The number of cervical lacerations reported in this study was unexpected. Surprisingly, all but four of the reports were from the clinic at Malir. Inquiries by FHI study staff suggest that there was a tendency by LHVs at Malir to diagnose cervical laceration anytime bleeding or spotting occurred at IUD insertion. LHVs at this site expressed concern that this bleeding was due to tissue trauma during the insertion procedure and reported such cases as cervical laceration. Thus, many

of the lacerations reported in this study may be a reflection of the initial bleeding associated with IUD use and not to cervical laceration; the true incidence of cervical laceration may be less than suggested by the pooled data.

All of the women in the TCU 380A group and 98.0 percent women in the TCU 200 group returned for at least one follow-up visit during the study. High follow-up was due to home visits by social workers from the clinic if the study patient was two weeks late to remind her that she was scheduled for a follow-up visit.

The most frequently reported menstrual complaints by either group were for dysmenorrhea or intermenstrual pelvic pain. However, there were no significant differences between the two IUD groups in the overall incidence of these two events. TCU 380A users reported significantly more cases of intermenstrual bleeding than TCU 200 users. However, the number of cases reported for this complaint was low for both study groups (19 and 6 cases, respectively). Few women experienced inflammation or infection during the trial. When reports did occur, these were mainly for cervicitis. The difference between each study group in the number of reports of inflammations or infections was not significant.

Almost all of the reports of IUD-related menstrual problems during the study were from the Malir study cohort. There seemed to be a tendency of study staff at the Malir clinic to be more sensitive to patient reports of menstrual complaints than were staff at the Khokharapar clinic. As a result, the incidence of IUD-related menstrual complaints reported during this study, primarily those for dysmenorrhea or intermenstrual pelvic pain, must be

evaluated accordingly.

The most frequently reported termination events up to 12 months postinsertion were removals for bleeding/pain. Pooled removal rates for bleeding and pain were similar for both IUD study groups. The second most frequently reported events were requests for removal due to personal reasons, including moving from the area, family objections (husband's or mother-in-law's) to IUD use, and separation due to the husband being out of the country for an extended period of time. Three accidental pregnancies were reported (all TCu 200 users) and expulsion rates were not found to be high. There were no differences between IUD study groups in total termination rates for either the pooled or individual site data. Approximately 30 percent of the women discontinued IUD use before the study was completed, with 12-month continuation rates of 77.1 per 100 women for TCu 380A users and 75.2 per 100 women for TCu 200 users. These rates suggest that both IUDs were acceptable contraceptive methods for this population of users after 12 months of use. Continuation rates were slightly higher at the Malir site, compared to the those reported for the Khokharapra site.

While no significant overall differences between the two study IUDs were observed in the incidence of terminations or complications, the power to detect a statistically significant difference was low in this study. The reliance on two investigative sites to recruit 300 study patients also resulted in center effects. There was a bias in reporting insertion-related cervical laceration and postinsertion menstrual complaints at one of the two participating study clinics (Malir). In addition, women in the two study groups at one of the study sites (Khokharapar) were not similar in age and parity distributions. Lastly, slightly over 30 percent of the patients did not complete the twelve months of

study participation, making it difficult to assess 12-month experience. As a result, caution must be used when interpreting the pooled results from this trial.

Although these data cannot be considered definitive, this study does suggest that the TCU 380A is no different in terms of safety and effectiveness, for this population of users, than the TCU 200. Safety issues could not be assessed accurately by this study because of reporting discrepancies between the Malir and Khokharapar study clinics concerning menstrual complaints and due to the high discontinuation rates for both IUD study groups. However, unlike the TCU 200, the TCU 380A does offer the benefit of a longer IUD lifespan. The TCU 380A was recently approved for use in the United States for up to six years. A longer potential lifespan would allow for fewer requests for replacement over time, longer contraceptive protection, and for a longer time span between births. This would suggest that the TCU 380A should receive further consideration for use in Pakistan family planning programs.

**Table I**

**Selected Sociodemographic Characteristics  
Comparative Study of the TCU 380A vs. the TCU 200 IUD  
Karachi, Pakistan**

| Characteristics                                     | TCu 380A<br>(N=150) |      | TCu 200<br>(N=149) |      |
|---|---------------------|------|--------------------|------|
|   | No.                 | %    | No.                | %    |
| <b>Age (years)</b>                                  |                     |      |                    |      |
| <24   | 41                  | 27.3 | 45                 | 30.2 |
| 25-29   | 56                  | 37.3 | 64                 | 43.0 |
| 30-34   | 34                  | 22.7 | 31                 | 20.8 |
| 35+   | 19                  | 12.7 | 9                  | 6.0  |
| Mean $\pm$ SD                                       | 28.2 $\pm$ 4.7      |      | 27.1 $\pm$ 3.8     |      |
| <b>Total Number of Live Births*</b>                 |                     |      |                    |      |
| <2  | 27                  | 18.0 | 21                 | 14.1 |
| 3   | 18                  | 12.0 | 42                 | 28.2 |
| 4   | 32                  | 21.3 | 24                 | 16.1 |
| 5   | 25                  | 16.7 | 27                 | 18.1 |
| 6   | 24                  | 16.0 | 13                 | 8.7  |
| 7   | 12                  | 8.0  | 8                  | 5.4  |
| 8+  | 12                  | 8.0  | 14                 | 9.4  |
| Median  | 4.7                 |      | 4.4                |      |
| <b>Use of a Contraceptive<br/>in the Past Month</b> |                     |      |                    |      |
| None  | 104                 | 69.3 | 102                | 68.5 |
| Condoms   | 23                  | 15.3 | 28                 | 18.8 |
| IUD   | 19                  | 12.7 | 12                 | 8.1  |
| Other*  | 4                   | 2.7  | 7                  | 4.6  |

\*Statistically significant,  $\chi^2=15.79$ ,  $p=0.015$ .

\*\*Includes withdrawal/rhythm, foam/diaphragm/jelly, orals, injectables.

Table Ia

Selected Sociodemographic Characteristics  
Comparative Study of the TCu 380A vs. the TCu 200 IUD  
Khokharapar Study Site, Pakistan

| Characteristics                                     | TCu 380A<br>(N=74) |      | TCu 200<br>(N=75) |      |
|---|--------------------|------|-------------------|------|
|   | No.                | %    | No.               | %    |
| <b>Age (years)*</b>                                 |                    |      |                   |      |
| <24   | 20                 | 27.1 | 29                | 38.7 |
| 25-29   | 27                 | 36.5 | 31                | 41.3 |
| 30-34   | 18                 | 24.3 | 14                | 18.7 |
| 35+   | 9                  | 12.1 | 1                 | 1.3  |
| Mean $\pm$ SD                                       | 28.8 $\pm$ 4.5     |      | 26.5 $\pm$ 3.2    |      |
| <b>Total Number of Live Births**</b>                |                    |      |                   |      |
| <2  | 10                 | 13.6 | 9                 | 12.0 |
| 3   | 6                  | 8.1  | 24                | 32.0 |
| 4   | 15                 | 20.3 | 14                | 18.6 |
| 5   | 12                 | 16.2 | 18                | 24.0 |
| 6   | 16                 | 21.6 | 5                 | 6.7  |
| 7+  | 15                 | 20.2 | 5                 | 6.7  |
| Median  | 5.0                |      | 3.8               |      |
| <b>Use of a Contraceptive<br/>in the Past Month</b> |                    |      |                   |      |
| None  | 51                 | 68.9 | 58                | 77.3 |
| Condoms   | 3                  | 4.1  | 2                 | 2.7  |
| IUD   | 18                 | 24.3 | 10                | 13.3 |
| Other***  | 2                  | 2.7  | 5                 | 6.7  |

\*Statistically significant,  $\chi^2=18.82$ ,  $p=0.032$ .

\*\*Statistically significant,  $\chi^2=22.84$ ,  $p=0.001$ .

\*\*\*Includes withdrawal/rhythm, foam/diaphragm/jelly, orals, injectables.

**Table Ib**

**Selected Sociodemographic Characteristics  
Comparative Study of the TCU 380A vs. the TCU 200 IUD  
Malir Study Site, Pakistan**

| Characteristics*                                    | TCu 380A<br>(N=76) |      | TCu 200<br>(N=74) |      |
|---|--------------------|------|-------------------|------|
|   | No.                | %    | No.               | %    |
| <b>Age (years)</b>                                  |                    |      |                   |      |
| <24   | 21                 | 27.6 | 16                | 21.7 |
| 25-29   | 29                 | 38.2 | 33                | 44.6 |
| 30-34   | 16                 | 21.1 | 17                | 23.0 |
| 35+   | 10                 | 13.1 | 8                 | 10.7 |
| Mean $\pm$ SD                                       | 27.6 $\pm$ 4.9     |      | 27.7 $\pm$ 4.2    |      |
| <b>Total Number of Live Births</b>                  |                    |      |                   |      |
| <2  | 17                 | 22.4 | 12                | 16.3 |
| 3   | 12                 | 15.8 | 18                | 24.3 |
| 4   | 17                 | 22.4 | 10                | 13.5 |
| 5   | 13                 | 17.1 | 9                 | 12.2 |
| 6   | 8                  | 10.5 | 8                 | 10.8 |
| 7+  | 9                  | 11.8 | 17                | 22.9 |
| Median  | 4.0                |      | 4.2               |      |
| <b>Use of a Contraceptive<br/>in the Past Month</b> |                    |      |                   |      |
| None  | 53                 | 69.7 | 44                | 59.5 |
| Condoms   | 20                 | 26.3 | 26                | 35.1 |
| IUD   | 1                  | 1.3  | 2                 | 2.7  |
| Other*  | 2                  | 2.7  | 2                 | 2.7  |

\*No statistically significant differences were detected.

\*\*Includes withdrawal/rhythm, foam/diaphragm/jelly, orals, injectables.

Table II

Complications/Complaints Reported at Insertion and Follow-up\*  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Karachi, Pakistan

| Complication/Complaint          | TCu 380A     |      | TCu 200      |      |
|---------------------------------|--------------|------|--------------|------|
|                                 | No.          | %    | No.          | %    |
| <b>Total Women at insertion</b> | <b>N=150</b> |      | <b>N=149</b> |      |
| Cervical Laceration (due to)    |              |      |              |      |
| No laceration                   | 105          | 69.9 | 107          | 71.8 |
| Sound                           | 10           | 6.7  | 11           | 7.4  |
| Inserter                        | 33           | 22.0 | 29           | 19.5 |
| Device                          | 1            | 0.7  | 2            | 1.3  |
| Not determined                  | 1            | 0.7  | 0            | -    |
| Pelvic Pain                     |              |      |              |      |
| None                            | 88           | 58.7 | 89           | 59.7 |
| Mild                            | 57           | 38.0 | 59           | 39.6 |
| Moderate                        | 5            | 3.3  | 1            | 0.7  |
| <b>Total Women Followed-up</b>  | <b>N=150</b> |      | <b>N=146</b> |      |
| Menstrual Complaints            |              |      |              |      |
| Dysmenorrhea                    | 79           | 52.7 | 69           | 47.3 |
| Intermenstrual:                 |              |      |              |      |
| Pelvic Pain                     | 65           | 43.3 | 59           | 40.4 |
| Spotting                        | 21           | 14.0 | 12           | 8.2  |
| Bleeding**                      | 19           | 12.7 | 6            | 4.1  |
| Sexually Transmitted Disease    |              |      |              |      |
| Trichomonas                     | 0            | -    | 1            | 0.7  |
| Other Inflammation/Infection    |              |      |              |      |
| Vaginitis***                    | 6            | 4.0  | 7            | 4.8  |
| Cervicitis****                  | 18           | 12.0 | 20           | 13.7 |

- \* More than one event may be recorded for a woman.  
 \*\* Statistically significant ( $X^2=7.01$ ,  $p=0.03$ ).  
 \*\*\* Includes cervical erosion and ectropion.  
 \*\*\*\* Includes candidiasis and colpitis.

Table IIa

Complications/Complaints Reported at Insertion and Follow-up\*  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Khokharapar Study Site, Pakistan

| Complication/Complaint          | TCu 380A    |      | TCu 200     |      |
|---------------------------------|-------------|------|-------------|------|
|                                 | No.         | %    | No.         | %    |
| <b>Total Women at insertion</b> | <b>N=74</b> |      | <b>N=75</b> |      |
| Cervical Laceration (due to)    |             |      |             |      |
| No laceration                   | 72          | 97.2 | 73          | 97.3 |
| Sound                           | 1           | 1.4  | 0           | -    |
| Inserter                        | 0           | -    | 2           | 2.7  |
| Device                          | 0           | -    | 0           | -    |
| Not determined                  | 1           | 1.4  | 0           | -    |
| Pelvic Pain                     |             |      |             |      |
| None                            | 57          | 77.0 | 55          | 73.3 |
| Mild                            | 14          | 18.9 | 19          | 25.3 |
| Moderate                        | 3           | 4.1  | 1           | 1.3  |
| <b>Total Women Followed-up</b>  | <b>N=74</b> |      | <b>N=73</b> |      |
| Menstrual Complaints            |             |      |             |      |
| Dysmenorrhea                    | 24          | 32.4 | 14          | 19.2 |
| Intermenstrual:                 |             |      |             |      |
| Pelvic Pain                     | 13          | 17.6 | 11          | 15.1 |
| Spotting                        | 6           | 8.1  | 1           | 1.4  |
| Bleeding**                      | 8           | 10.8 | 2           | 2.7  |
| Sexually Transmitted Disease    |             |      |             |      |
| Trichomonas                     | 0           | -    | 0           | -    |
| Other Inflammation/Infection    |             |      |             |      |
| Vaginitis***                    | 4           | 5.4  | 5           | 6.8  |
| Cervicitis****                  | 11          | 14.9 | 7           | 9.6  |

\* More than one event may be recorded for a woman.

\*\* Statistically significant by Fisher's Exact Test (p=0.042).

\*\*\* Includes cervical erosion and ectropion.

\*\*\*\* Includes candidiasis and colpitis.

**Table IIb**

Complications/Complaints Reported at Insertion and Follow-up\*  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Malir Study Site, Pakistan

| Complication/Complaint          | TCu 380A    |      | TCu 200     |      |
|---------------------------------|-------------|------|-------------|------|
|                                 | No.         | %    | No.         | %    |
| <b>Total Women at insertion</b> | <b>N=76</b> |      | <b>N=74</b> |      |
| Cervical Laceration (due to)    |             |      |             |      |
| No laceration                   | 33          | 43.4 | 34          | 45.9 |
| Sound                           | 9           | 11.9 | 11          | 14.9 |
| Inserter                        | 33          | 43.4 | 27          | 36.5 |
| Device                          | 1           | 1.3  | 2           | 2.7  |
| Not determined                  | 0           | -    | 0           | -    |
| Pelvic Pain                     |             |      |             |      |
| None                            | 31          | 40.8 | 34          | 45.9 |
| Mild                            | 43          | 56.6 | 40          | 54.1 |
| Moderate                        | 2           | 2.6  | 0           | -    |
| <b>Total Women Followed-up</b>  | <b>N=76</b> |      | <b>N=73</b> |      |
| Menstrual Complaints            |             |      |             |      |
| Dysmenorrhea                    | 55          | 72.4 | 55          | 75.3 |
| Intermenstrual:                 |             |      |             |      |
| Pelvic Pain                     | 52          | 68.4 | 48          | 65.8 |
| Spotting                        | 15          | 19.7 | 11          | 15.1 |
| Bleeding**                      | 11          | 14.5 | 4           | 5.5  |
| Sexually Transmitted Disease    |             |      |             |      |
| Trichomonas                     | 0           | -    | 1           | 1.4  |
| Other Inflammation/Infection    |             |      |             |      |
| Vaginitis***                    | 2           | 2.6  | 2           | 2.7  |
| Cervicitis****                  | 7           | 9.2  | 13          | 17.8 |

- \* More than one event may be recorded for a woman.  
 \*\* Statistically significant by Fisher's Exact test (p=0.043).  
 \*\*\* Includes cervical erosion and ectropion.  
 \*\*\*\* Includes candidiasis and colpitis.

**Table III**

Participant Status After Twelve Months of Use  
Comparative Study of the TCU 380A vs. TCU 200 IUDs  
Karachi, Pakistan

| Characteristics                           | TCu 380A<br>(N=150) |                | TCu 200<br>(N=149) |      |
|---|---------------------|----------------|--------------------|------|
|   | No.                 | % <sup>1</sup> | No.                | %    |
| <b>Continuing</b>                         | 119                 | 79.3           | 117                | 78.5 |
| <b>Accidental Pregnancy</b>               | 0                   | -              | 3                  | 2.1  |
| <b>Expulsion</b>                          | 2                   | 1.3            | 4                  | 2.7  |
| <b>Removal:</b>                           |                     |                |                    |      |
| Pain/bleeding                             | 15                  | 10.0           | 12                 | 8.1  |
| Planned pregnancy                         | 0                   | -              | 0                  | -    |
| Personal reasons                          |                     |                |                    |      |
| Woman moved                               | 2                   | 1.3            | 3                  | 2.1  |
| Husband objected                          | 5                   | 3.3            | 0                  | -    |
| Husband abroad                            | 3                   | 2.0            | 3                  | 2.1  |
| Mother-in-law objected                    | 1                   | 0.7            | 1                  | 0.7  |
| Other                                     | 1                   | 0.7            | 1                  | 0.7  |
| Other Medical                             | 2                   | 1.3            | 2                  | 1.4  |
| <b>Not Followed-up</b>                    | 0                   | -              | 3                  | 2.1  |
| <b>Total Discontinuations<sup>2</sup></b> | 31                  | 20.7           | 32                 | 21.5 |

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

<sup>2</sup> Includes lost to follow-up.

**Table IIIa**

Participant Status After Twelve Months of Use  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Khokharapar Study Site, Pakistan

| Characteristics                           | TCu 380A<br>(N=74) |                | TCu 200<br>(N=75) |      |
|---|--------------------|----------------|-------------------|------|
|   | No.                | % <sup>1</sup> | No.               | %    |
| <b>Continuing</b>                         | 53                 | 71.6           | 55                | 73.3 |
| <b>Accidental Pregnancy</b>               | 0                  | -              | 2                 | 2.7  |
| <b>Expulsion</b>                          | 1                  | 1.4            | 2                 | 2.7  |
| <b>Removal:</b>                           |                    |                |                   |      |
| Pain/bleeding                             | 9                  | 12.2           | 6                 | 8.0  |
| Planned pregnancy                         | 0                  | -              | 0                 | -    |
| Personal reasons                          |                    |                |                   |      |
| Woman moved                               | 2                  | 2.7            | 2                 | 2.7  |
| Husband objected                          | 4                  | 5.4            | 0                 | -    |
| Husband abroad                            | 1                  | 1.4            | 3                 | 4.0  |
| Mother-in-law objected                    | 1                  | 1.4            | 1                 | 1.3  |
| Other                                     | 1                  | 1.4            | 1                 | 1.3  |
| Other Medical                             | 2                  | 2.7            | 0                 | -    |
| <b>Not Followed-up</b>                    | 0                  | -              | 2                 | 2.7  |
| <b>Total Discontinuations<sup>2</sup></b> | 10                 | 13.2           | 13                | 17.6 |

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

<sup>2</sup> Includes lost to follow-up.

Table IIIb

Participant Status At Twelve Months of Use  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Malir Study Clinic, Pakistan

| Characteristics                     | TCu 380A<br>(N=76) |                | TCu 200<br>(N=74) |      |
|-------------------------------------|--------------------|----------------|-------------------|------|
|                                     | No.                | % <sup>1</sup> | No.               | %    |
| Continuing                          | 66                 | 86.8           | 61                | 82.4 |
| Accidental Pregnancy                | 0                  | -              | 1                 | 1.4  |
| Expulsion                           | 1                  | 1.3            | 2                 | 2.7  |
| <b>Removal:</b>                     |                    |                |                   |      |
| Pain/bleeding                       | 6                  | 7.9            | 6                 | 8.1  |
| Planned pregnancy                   | 0                  | -              | 0                 | -    |
| Personal reasons                    |                    |                |                   |      |
| Woman moved                         | 0                  | -              | 1                 | 1.4  |
| Husband objected                    | 1                  | 1.3            | 0                 | -    |
| Husband abroad                      | 2                  | 2.6            | 0                 | -    |
| Mother-in-law objected              | 0                  | -              | 0                 | -    |
| Other                               | 0                  | -              | 0                 | -    |
| Other Medical                       | 0                  | -              | 2                 | 2.7  |
| Not Followed-up                     | 0                  | -              | 1                 | 1.4  |
| Total Discontinuations <sup>2</sup> | 21                 | 28.4           | 20                | 26.7 |

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

<sup>2</sup> Includes lost to follow-up.

**Table IV**

Gross-Cumulative life-table Events Per 100 Women  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Karachi, Pakistan

| Termination<br>Type and Period                | TCu 380A<br>Rate S.E. <sup>1</sup> | TCu 200<br>Rate S.E. |
|---|------------------------------------|----------------------|
| <b>Accidental Pregnancy</b>                   |                                    |                      |
| 3 months                                      | 0.0 ± 0.0                          | 0.7 ± 0.7            |
| 6 months                                      | 0.0 ± 0.0                          | 1.5 ± 1.0            |
| 12 months                                     | 0.0 ± 0.0                          | 2.4 ± 1.4            |
| <b>Expulsion/Displacement</b>                 |                                    |                      |
| 3 months                                      | 1.4 ± 1.0                          | 1.5 ± 1.0            |
| 6 months                                      | 1.4 ± 1.0                          | 1.5 ± 1.0            |
| 12 months                                     | 1.4 ± 1.0                          | 6.2 ± 2.3            |
| <b>Removal for Bleeding/Pain</b>              |                                    |                      |
| 3 months                                      | 4.7 ± 1.8                          | 3.5 ± 1.5            |
| 6 months                                      | 8.4 ± 2.3                          | 7.2 ± 2.2            |
| 12 months                                     | 11.6 ± 2.7                         | 10.7 ± 2.7           |
| <b>Removal for other<br/>medical reasons</b>  |                                    |                      |
| 3 months                                      | 0.0 ± 0.0                          | 0.7 ± 0.7            |
| 6 months                                      | 1.5 ± 1.1                          | 0.7 ± 0.7            |
| 12 months                                     | 2.4 ± 1.4                          | 1.7 ± 1.2            |
| <b>Removal for other<br/>personal reasons</b> |                                    |                      |
| 3 months                                      | 2.1 ± 1.2                          | 1.5 ± 1.0            |
| 6 months                                      | 4.3 ± 1.7                          | 1.5 ± 1.0            |
| 12 months                                     | 9.4 ± 2.6                          | 6.6 ± 2.3            |
| <b>Total Terminations<sup>2</sup></b>         |                                    |                      |
| 3 months                                      | 8.0 ± 2.2                          | 7.6 ± 2.2            |
| 6 months                                      | 14.8 ± 2.9                         | 11.8 ± 2.7           |
| 12 months                                     | 22.9 ± 3.5                         | 24.8 ± 3.7           |

<sup>1</sup> Standard Error; no statistically significant differences were detected by log-rank method. Lost to follow-up cases censored by the life-table procedure.

<sup>2</sup> Includes all terminations.

**Table IVa**

Gross-Cumulative life-table Events Per 100 Women  
Comparative Study of the TCu 380A vs. TCu 200 IUDs  
Khokharapar Study Site, Pakistan

| Termination<br>Type and Period                | TCu 380A   |                   | TCu 200    |      |
|---|------------|-------------------|------------|------|
|   | Rate       | S.E. <sup>1</sup> | Rate       | S.E. |
| <b>Accidental Pregnancy</b>                   |            |                   |            |      |
| 3 months                                      | 0.0 ± 0.0  |                   | 0.0 ± 0.0  |      |
| 6 months                                      | 0.0 ± 0.0  |                   | 1.6 ± 1.6  |      |
| 12 months                                     | 0.0 ± 0.0  |                   | 3.5 ± 2.4  |      |
| <b>Expulsion/Displacement</b>                 |            |                   |            |      |
| 3 months                                      | 1.4 ± 1.0  |                   | 1.5 ± 1.0  |      |
| 6 months                                      | 1.4 ± 1.0  |                   | 1.5 ± 1.0  |      |
| 12 months                                     | 1.4 ± 1.0  |                   | 6.2 ± 2.3  |      |
| <b>Removal for Bleeding/Pain</b>              |            |                   |            |      |
| 3 months                                      | 6.9 ± 3.0  |                   | 5.5 ± 2.7  |      |
| 6 months                                      | 13.0 ± 4.1 |                   | 9.9 ± 3.5  |      |
| 12 months                                     | 14.8 ± 4.3 |                   | 11.6 ± 3.9 |      |
| <b>Removal for other<br/>medical reasons</b>  |            |                   |            |      |
| 3 months                                      | 0.0 ± 0.0  |                   | 0.0 ± 0.0  |      |
| 6 months                                      | 3.4 ± 2.3  |                   | 0.0 ± 0.0  |      |
| 12 months                                     | 5.2 ± 2.9  |                   | 0.0 ± 0.0  |      |
| <b>Removal for other<br/>personal reasons</b> |            |                   |            |      |
| 3 months                                      | 4.3 ± 2.4  |                   | 1.4 ± 1.4  |      |
| 6 months                                      | 9.0 ± 3.5  |                   | 1.4 ± 1.4  |      |
| 12 months                                     | 14.2 ± 4.4 |                   | 11.5 ± 4.1 |      |
| <b>Total Terminations<sup>2</sup></b>         |            |                   |            |      |
| 3 months                                      | 12.2 ± 3.8 |                   | 8.3 ± 3.2  |      |
| 6 months                                      | 24.6 ± 5.0 |                   | 13.8 ± 4.1 |      |
| 12 months                                     | 31.6 ± 5.5 |                   | 26.2 ± 5.3 |      |

<sup>1</sup> Standard Error; no statistically significant differences were detected by log-rank method. Lost to follow-up cases censored by the life-table procedure.

<sup>2</sup> Includes all terminations.

**Table IVb**

Gross-Cumulative life-table Events Per 100 Women  
 Comparative Study of the TCU 380A vs. TCU 200 IUDs  
 Malir Study Site, Pakistan

| Termination<br>Type and Period                | TCu 380A |                   | TCu 200 |       |
|---|----------|-------------------|---------|-------|
|   | Rate     | S.E. <sup>1</sup> | Rate    | S.E.  |
| <b>Accidental Pregnancy</b>                   |          |                   |         |       |
| 3 months                                      | 0.0      | ± 0.0             | 1.4     | ± 1.4 |
| 6 months                                      | 0.0      | ± 0.0             | 1.4     | ± 1.4 |
| 12 months                                     | 0.0      | ± 0.0             | 1.4     | ± 1.4 |
| <b>Expulsion/Displacement</b>                 |          |                   |         |       |
| 3 months                                      | 1.3      | ± 1.3             | 1.5     | ± 1.5 |
| 6 months                                      | 1.3      | ± 1.3             | 1.5     | ± 1.5 |
| 12 months                                     | 1.3      | ± 1.3             | 8.6     | ± 3.7 |
| <b>Removal for Bleeding/Pain</b>              |          |                   |         |       |
| 3 months                                      | 2.7      | ± 1.9             | 1.4     | ± 1.4 |
| 6 months                                      | 4.0      | ± 2.3             | 4.4     | ± 2.5 |
| 12 months                                     | 8.6      | ± 3.4             | 9.6     | ± 3.8 |
| <b>Removal for other<br/>medical reasons</b>  |          |                   |         |       |
| 3 months                                      | 0.0      | ± 0.0             | 1.4     | ± 1.4 |
| 6 months                                      | 0.0      | ± 0.0             | 1.4     | ± 1.4 |
| 12 months                                     | 0.0      | ± 0.0             | 3.3     | ± 2.3 |
| <b>Removal for other<br/>personal reasons</b> |          |                   |         |       |
| 3 months                                      | 0.0      | ± 0.0             | 1.5     | ± 1.5 |
| 6 months                                      | 0.0      | ± 0.0             | 1.5     | ± 1.5 |
| 12 months                                     | 5.0      | ± 2.8             | 1.5     | ± 1.5 |
| <b>Total Terminations<sup>2</sup></b>         |          |                   |         |       |
| 3 months                                      | 3.9      | ± 2.2             | 7.0     | ± 3.0 |
| 6 months                                      | 5.3      | ± 2.6             | 9.8     | ± 3.5 |
| 12 months                                     | 14.3     | ± 4.2             | 22.4    | ± 5.1 |

<sup>1</sup> Standard Error; no statistically significant differences were detected by log-rank method. Lost to follow-up cases censored by the life-table procedure.

<sup>2</sup> Includes all terminations.

**Table V**

Rate of Continuation and Follow-up Percentage  
Comparative Study of the TCU 380A vs. TCU 200 IUDs  
Karachi, Pakistan

| Termination<br>Type and Period                  | TCu 380A | TCu 200 |
|---|----------|---------|
| <b>Continuation Life-table Rate<sup>1</sup></b> |          |         |
| 3 months  | 92.0     | 92.4    |
| 6 months  | 85.2     | 88.2    |
| 12 months                                       | 77.1     | 75.2    |
| <b>Follow-up Percentage<sup>2</sup></b>         |          |         |
| 3 months  | 100.0    | 95.8    |
| 6 months  | 97.7     | 95.5    |
| 12 months                                       | 85.5     | 83.6    |

<sup>1</sup> The continuation rate is defined as 100 minus the total termination life-table rate (refer to Table IV). Three cases lost to follow-up are censored by the life-table procedure at the interval in which they no longer have data.

<sup>2</sup> The percentage of women returning for follow-up who have not been previously terminated.

**Table Va**

Rate of Continuation and Follow-up Percentage  
Comparative Study of the TCU 380A vs. TCU 200 IUDs  
Khokharapar Study Site, Pakistan

| Termination<br>Type and Period                  | TCu 380A | TCu 200 |
|---|----------|---------|
| <b>Continuation Life-table Rate<sup>1</sup></b> |          |         |
| 3 months  | 87.8     | 91.7    |
| 6 months  | 75.4     | 86.2    |
| 12 months                                       | 68.4     | 72.8    |
| <b>Follow-up Percentage<sup>2</sup></b>         |          |         |
| 3 months  | 100.0    | 95.8    |
| 6 months  | 98.3     | 95.4    |
| 12 months                                       | 92.2     | 83.9    |

<sup>1</sup> The continuation rate is defined as 100 minus the total termination rate (refer to Table IV). Two cases lost to follow-up are censored by the life-table procedure at the interval in which they no longer have data.

<sup>2</sup> The percentage of women returning for follow-up who have not been previously terminated.

**Table Vb**

Rate of Continuation and Follow-up Percentage  
Comparative Study of the TCU 380A vs. TCU 200 IUDs  
Malir Study Site, Pakistan

| Termination Type and Period                     | TCu 380A | TCu 200 |
|---|----------|---------|
| <b>Continuation Life-table Rate<sup>1</sup></b> |          |         |
| 3 months  | 96.1     | 93.0    |
| 6 months  | 94.7     | 90.2    |
| 12 months                                       | 85.7     | 77.6    |
| <b>Follow-up Percentage<sup>2</sup></b>         |          |         |
| 3 months  | 100.0    | 95.8    |
| 6 months  | 97.3     | 95.6    |
| 12 months                                       | 80.3     | 83.3    |

<sup>1</sup> The continuation rate is defined as 100 minus the total termination rate (refer to Table IV). One case lost to follow-up was censored by the life-table procedure at the interval in which the patient no longer provided data.

<sup>2</sup> The percentage of women returning for follow-up who have not been previously terminated.

### Data Quality Statement

The progress of this study was slow and admissions took 21 months to complete and the recruitment period of twelve months was extended to accommodate the slow process. Informed consent procedures were followed and there were no random allocation errors. Data quality was good and there were few women lost to follow-up.

One protocol violation occurred during the admission process: a woman in the TCU 380A group did not meet the interval status criteria; her IUD was inserted at 39 after her pregnancy ended. This patient was not included in the final dataset. The two clinics periodically checked the follow-up log book against the forms to verify that all women returned for their scheduled follow-up visit. When a patient was at least two weeks late for a scheduled visit, a social worker went to her home and requested that the patient return for a visit. Follow-up was high throughout the life of the study owing to the active efforts of study staff to remain in contact with study patients.

The two study groups at the Khokharapar clinic were not similar in age or parity. This may have been the result of dividing randomization cards generated for a 300-case study into two 150-case studies. Furthermore, the number of reports of cervical laceration and pelvic pain at the time of IUD insertion must also be evaluated in context of reports that LHV's were likely to report these events anytime bleeding or pain occurred. Most of these events were reported by LHV's at the Malir Family Welfare Center. LHV's at this site were concerned that these bleeding were an indication of tissue trauma. Once this issue was clarified, reports of cervical laceration decreased during later recruitment. Similarly, menstrual complaints ever reported at follow-up were also much higher for the Malir cohort than for the Khokharapar cohort. As a result, pooled study data on insertion-related events or IUD-related menstrual problems must be interpreted with caution since center bias is present in the data.

Pursuant to the protocol, this Consultant Report only analyzed events occurring within the twelve month study period. Terminations that occurred after twelve months were not analyzed and the women were considered as continuing with the IUD. Thirteen terminations in the TCU 380A group and 14 in the TCU 200 group were reported during the 13-24 month interval. These terminations included: four expulsions in the TCU 200 group, four for bleeding and/or pain in the TCU 380A group and two in the TCU 200 group, four for other medical reasons in the TCU 380A group, two for planning a pregnancy in the TCU 380A group and one in the TCU 200 group, and three women for personal reasons in the TCU 380A group and seven in the TCU 200 group.

**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.