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A Clinical Comparison of Two
Progestogen-Only Oral Contraceptives
in Zimbabwe

Prepared for
Zimbabwe National Family Planning Council
Centers: 4011, 4012, 4013
Study: 8877

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I. Introduction

A comparative study of two progestogen-only oral contraceptives (OCs) was conducted at seven Zimbabwe National Family Planning Council (ZNFPC) clinics. The seven-center study was centrally coordinated at the ZNFPC headquarters in Harare, Zimbabwe. The objectives of this study were to compare and evaluate the effectiveness, side effects, and continuation rates of two pills, Ovrette (Wyeth) and Micronovum (Ortho), in breastfeeding women.

Studies have shown that lactation may be impaired by combined estrogen-progestogen oral contraceptives, including those with relatively low doses of estrogen. Progestogen-only OCs offer an alternative to combination OCs for lactating women who desire steroidal contraception. Progestogen-only OCs may minimize a reduction in milk volume and in length of lactation, and may have a lower incidence and lesser severity of non-menstrual estrogen-related side effects associated with combined OCs. Progestogen-only OCs have been associated with disrupted menstrual cycles--with a higher incidence of both intermenstrual bleeding and amenorrhea.

II. Study Design

Oral Contraceptive Evaluated

Each of the OCs administered in this study was provided in 28 day packs of 28 active steroid tablets. Ovrette has a composition of 75 mcg of the progestin, norgestrel, and Micronovum has a composition of 35 mcg of the progestin, norethisterone.

Study Procedure

Each woman admitted to the study had to meet the following criteria: be between the ages of 18 and 35 years old; be sexually active; have fully established breastfeeding prior to admission; be in good health; rely exclusively upon the pills as her only method of contraception throughout the course of the study unless advised otherwise by the investigator; give informed consent, and be followed up for at least 6 months.

Normal clinical criteria for contraindications to OC use were followed. In addition, women with any of the following conditions were excluded from the study: currently pregnant; history or evidence of thromboembolic disorders; significant cardiovascular disease; diabetes; renal dysfunction; epilepsy; hypertension; migraine; severe liver disorders; breast cancer; undiagnosed vaginal bleeding; or chronic use of medications, such as antibiotics and barbiturates, which could reduce pill effectiveness.

A total of 1165 women were admitted to the study from November 1985 through September 1988. Women admitted to the study were randomly allocated to receive either Ovrette or Micronovum according to preprinted sealed envelopes opened at the time of admission; 583 women were assigned Ovrette and 582 women were assigned Micronovum. Two women were inadvertently given Ovrette instead of Micronovum; one woman was inadvertently given Micronovum instead of Ovrette. These women were allowed to remain in the study in the groups to which they were inadvertently assigned.

Follow-up visits were scheduled at 1, 3, and 6 months after admission to the study. Only the first follow-up visit is recorded for the 50 women admitted at the Torwood clinic due to a misunderstanding of the follow-up schedule by the nurse. Nineteen women were not included in the analysis due to protocol violations; 9 of these women were over the age of 35 and 4 women were under the age of 18, 4 women were not breastfeeding at admission, 1 woman took the pills less than one month, and 1 woman never began pill use. Of the 1146 women included in the analysis, 955 were interval patients (\geq 42 days since termination of last pregnancy) and 191 were postpartum patients (<42 days since termination of last pregnancy). The study was not blinded, because an evaluation of the products as they appear on the market was desired.

Data from this study were recorded by the clinic staff on standard forms and were sent to Family Health International (FHI) for processing and analysis.

III. Results

Sociodemographic Characteristics

Selected patient characteristics are presented by pill group in Table I. The mean age of the Ovrette group was 24.6 years and of the Micronovum group, 24.4 years. The mean education level was 8.6 years for Ovrette users and 8.5 for Micronovum users. The mean total live births was 2.3 for the Ovrette users and 2.2 for the Micronovum group. These differences were not statistically significant ($p > .05$).

Contraceptive Practices

Three hundred forty-six women (60.4%) from the Ovrette group and 333 women (58.1%) from the Micronovum group reported having used no contraception in the past (see Data Quality Statement). Two hundred ninety-one women (50.8%) in the Ovrette group and 282 women (49.2%) in the Micronovum group reported ever having used oral contraceptives prior to the study.

Complaints at Admission

None of the women reported a pre-existing medical condition at admission. Seventy-three women (12.7%) in the Ovrette group and 105 women (18.3%) in the Micronovum group reported one or more menstrual complaints (Table II). This difference is statistically significant ($p < .05$). The most frequently reported menstrual complaint in both groups was amenorrhea; reported by 49 women (8.6%) in the Ovrette group and 68 women (11.9%) in the Micronovum group. This difference is not statistically significant ($p > .05$). Two hundred forty women (41.9%) in the Ovrette group and 236 women (41.2%) in the Micronovum group reported one or more other minor physical complaints (Table II). Headache was the most frequently reported physical complaint; by 129 women (22.5%) in the Ovrette group and 120 women (20.9%) in the Micronovum group.

Regularity of Use

Information on regularity of use was collected at 1, 3, and 6 months after beginning oral contraceptive use. Compliance was assessed by self-report and from the date the last pill was taken prior to the date of follow-up visit.

Follow-up visit data indicated that of the 949 women ever followed up, 29 women (6.2%) in the Ovrette group and 14 women (2.9%) in the Micronovum group missed more than one pill at some time during the study. Information on regularity of pill use was not available for 3 women (0.6%) in the Ovrette group and 5 women (1.0%) in the Micronovum group.

Side Effects

Of the 949 women who returned for at least one follow-up visit, 8 reported serious complications (Table III). Two women in the Ovrette group reported severe headaches. One of these women reported the complaint at her three month follow-up visit but remained in the study; the other woman reported the complaint at her one month follow-up visit and discontinued because of the severity of the headaches. Two women complained of severe leg pain in the Ovrette group. One of these women reported the complaint at her one month follow-up visit. She was diagnosed with thrombophlebitis but remained in the study. The other woman reported leg pain at her two month follow-up visit. She was discontinued from the study the next month because she missed more than three pills. One woman in the Ovrette group reported a combination of headaches and vision problems at her one month follow-up visit but remained in the study with no further complaints of this nature. No Adverse Experience Reports were filed for these patients.

One woman in the Micronovum group reported shortness of breath at her two month follow-up visit. She was diagnosed with malaria and treated with medication. She remained in the study. Another woman in the Micronovum group reported malaria at her four month follow-up visit. She was discontinued from the study at a later date because she stopped taking the pills for 3 months. Another

woman in the Micronovum group reported dysuria at a 6 month follow-up visit. Medication was prescribed for this condition and she completed the study. No Adverse Experience Reports were filed for these patients.

Table III also lists minor medical complaints reported at follow-up by 38 women (8.1%) in the Ovrette group and 43 women (9.0%) in the Micronovum group.

A summary of menstrual complaints ever reported throughout the follow-up period is shown in Table IV. Two hundred thirty-five women (50.1%) in the Ovrette group and 229 women (47.7%) in the Micronovum group reported one or more menstrual complaints throughout the study period. One hundred forty-eight women (31.5%) in the Ovrette group and 165 women (34.4%) in the Micronovum group reported amenorrhea as the most common menstrual complaint at follow-up visits. One hundred seven women (22.8%) in the Ovrette group and 83 women (17.3%) in the Micronovum group reported intermenstrual bleeding at follow-up visits. No information on menstrual complaints since admission was available for four women in the Ovrette group and five women in the Micronovum group.

A summary of typical pill-related problems and complaints ever reported at all follow-up visits is presented in Table V, and a summary of the changes in severity of complaints is reported in Table VI. A total of 230 women (49.0%) in the Ovrette group and 195 women (40.6%) in the Micronovum group reported one or more pill-related complaints (Table V); this difference is statistically significant ($p < .05$). Overall, the largest increases in severity of complaints were for headaches and nausea for both Ovrette and Micronovum users (Table VI). Information on changes in complaints since admission was not available for four women in the Ovrette group and five women in the Micronovum group.

Discontinuation Rates and Reasons

A summary of all reasons for discontinuation is presented in Table VII. Seventy-nine women (16.8%) in the Ovrette group and 68 women (14.2%) in the Micronovum group discontinued during the study period. The reasons provided most often by both groups were for other personal reasons such as forgetfulness in taking the pill, desire to change contraceptive method because the baby had stopped breastfeeding or for reasons unrelated to the method such as moving/travel. No accidental pregnancies were reported in either group.

Lost to follow-up and total discontinuation percentages, along with woman months of use are presented in Table VIII. The lost to follow-up percentages at 6 months for the two groups were 51.1 for Ovrette users and 50.1 for Micronovum users. The 6 month total discontinuation percentages (including lost to follow-up) were 63.2 for the Ovrette group and 59.7 for the Micronovum group. Gross cumulative life table discontinuation rates are presented in Table IX.

IV. Summary

A study of two low dose oral contraceptives, Ovrette and Micronovum, was conducted at seven Zimbabwe National Family Planning Council (ZNFPC) clinics in Zimbabwe. The objectives of this study were to compare and evaluate the effectiveness, side effects, and continuation rates of the aforementioned oral contraceptives. This report includes an analysis of 1146 women; 955 were interval patients (≥ 42 days since last pregnancy termination) and 191 were postpartum patients (< 42 days since termination of last pregnancy). Follow-up visits were scheduled at 1, 3, and 6 months after admission.

The lost to follow-up percentages at 6 months were 51.1 for Ovrette and 50.1 for Micronovum users. The 6 month total discontinuation percentages (including women lost to follow-up) were 63.2 and 59.7 for the Ovrette and Micronovum groups, respectively. Their reasons for termination were generally for personal reasons and reasons unrelated to the contraceptive method. No accidental pregnancies were reported in either group.

Table I
Selected Sociodemographic Characteristics

Characteristic	Ovrette (N=573)		Micronovum (N=573)	
	No.	% ^a	No.	% ^a
Age (years)				
Less than 20	88	15.4	72	12.6
20-24	234	40.8	273	47.6
25-29	186	32.5	172	30.0
30-34	60	10.5	56	9.8
35	5	0.9	0	0.0
Mean	24.6		24.4	
Education (years)				
None	10	1.7	14	2.4
1-6	110	19.2	112	19.6
7-12	410	71.6	403	70.4
13+	43	7.5	44	7.7
Mean	8.6		8.5	
Total live births				
1	192	33.5	204	35.6
2	176	30.7	172	30.0
3	106	18.5	98	17.1
4	58	10.1	65	11.3
5	19	3.3	24	4.2
6+	22	3.8	10	1.7
Mean	2.3		2.2	
Contraceptive method used one month prior to admission or conception				
None	346	60.4	333	58.1
Oral contraceptives	202	35.3	215	37.5
Condoms	9	1.6	8	1.4
Injectables	7	1.2	4	0.7
Withdrawal/Rhythm	4	0.7	7	1.2
IUD	4	0.7	4	0.7
Foam/Diaphragm/Jelly	1	0.2	1	0.2
Other barrier methods	0	0.0	1	0.2

^a Percentages may not always add to 100 due to rounding errors; this holds true for all subsequent tables in this report.
N represents the total number of women included in the analysis.

Table II
Complaints at Admission

Complaints	Ovrette (N=573)		Micronovum (N=573)	
	No.	%	No.	%
Intermenstrual bleeding				
None	569	99.3	565	98.6
Staining/Spotting	2	0.3	2	0.3
Moderate	2	0.3	6	1.0
Primary Other Menstrual Complaints ¹				
None	503	87.8	476	83.1
Amenorrhea	49	8.6	68	11.9
Dysmenorrhea	20	3.5	27	4.7
Scanty menses	1	0.2	2	0.3
Total women with one or more menstrual/bleeding complaints*	73	12.7	105	18.3
Other complaints reported in past month ¹				
Headaches	129	22.5	120	20.9
Vaginal discharge	85	14.9	94	16.4
Breast discomfort	32	5.6	32	5.6
Dizziness	30	5.2	26	4.6
Nausea	18	3.1	19	3.3
Vomiting	1	0.2	6	1.0
Total women with one or more complaints	240	41.9	236	41.2

N represents the number of women in the analysis.

¹Multiple complaints may be reported per woman for this category.

*p<.05

Table III

Medical Complaints Since Admission

Characteristic	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Serious complications				
Severe headaches	2	0.4	0	0.0
Severe leg pain	1	0.2	0	0.0
Thrombophlebitis	1	0.2	0	0.0
Combination (headaches and vision problems)	1	0.2	0	0.0
Malaria	0	0.0	2	0.4
Dysuria	0	0.0	1	0.2
Total women with serious complications	5	1.0	3	0.6
Minor medical complaints				
Weight gain	5	1.0	4	0.8
Weight loss	1	0.2	2	0.4
Increased appetite	5	1.0	2	0.4
Loss of appetite	0	0.0	1	0.2
Bloating	1	0.2	1	0.2
Weakness	1	0.2	4	0.8
Skin problems	0	0.0	2	0.4
Abdominal pain	8	1.7	6	1.3
Dysuria	0	0.0	1	0.2
Diarrhea	0	0.0	2	0.4
Constipation	0	0.0	2	0.4
Feels hot in abdomen after sex	0	0.0	1	0.2
Blurred vision	3	0.6	0	0.0
Edema	0	0.0	1	0.2
Breast pain	1	0.2	3	0.6
Cracked nipples	1	0.2	0	0.0
Galactorrhea	1	0.2	0	0.0
Reduced milk production	5	1.1	4	0.8
Itching nipples	0	0.0	1	0.2
Itching breasts	0	0.0	1	0.2
Heart palpitations	1	0.2	0	0.0
Chest pain	0	0.0	2	0.4
Back pain	3	0.6	2	0.4
Nosebleed	1	0.2	0	0.0
Loss of libido	2	0.4	0	0.0
Combination: loss of sex drive and profuse discharge	1	0.2	0	0.0

(cont.)

Table III (cont.)

Medical Complaints Since Admission

Characteristic	Ovrette (No.=469)		Micronovum (No.=480)	
	No.	%	No.	%
Combination: reduced lactation and abdominal pain	1	0.2	0	0.0
Combination: reduced lactation and diminished discharge	1	0.2	0	0.0
Combination: backaches, discharge, dysuria, dyspareunia	1	0.2	0	0.0
Combination: joint and abdominal pain	1	0.2	0	0.0
Combination: breasts swelling and itching over entire body	1	0.2	0	0.0
Combination: diarrhea and swelling of feet and legs	1	0.2	0	0.0
Combination: depression and abdominal cramps	0	0.0	1	0.2
Combination: drying up of milk and loose stools	0	0.0	1	0.2
Combination: dry vagina and bloated abdomen	0	0.0	1	0.2
Combination: abdominal pain and backache	0	0.0	1	0.2
Combination: breast pain and swelling	0	0.0	1	0.2
Unspecified*	4	0.9	5	1.0
Total women with one or more minor medical complaints	38	8.1	43	9.0

N represents number of women ever followed up.

*Information not available

Table IV
Menstrual Complaints Ever Reported Since Admission

Complaint	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Intermenstrual bleeding ¹				
None	358	76.3	392	81.7
Staining/spotting	42	9.0	26	5.4
Moderate	60	12.8	50	10.4
Severe (clots)	5	1.1	7	1.5
Unspecified*	4	0.9	5	1.0
Primary other menstrual complaint ²				
None	288	61.4	295	61.5
Amenorrhea	148	31.5	165	34.4
Intermenstrual pelvic discomfort or cramps	12	2.6	10	2.1
Dysmenorrhea	9	1.9	8	1.7
Menorrhagia	5	1.1	0	0.0
Scanty menses	6	1.3	4	0.8
Prolonged bleeding	6	1.3	0	0.0
Prolonged spotting	1	0.2	0	0.0
Polymenorrhea	1	0.2	1	0.2
Irregular menses	1	0.2	0	0.0
Combination: cramps and amenorrhea	1	0.2	0	0.0
Abdominal discomfort ⁺	0	0.0	1	0.2
Backache ⁺	0	0.0	1	0.2
Unspecified*	4	0.9	5	1.0
Total women with one or more menstrual/bleeding complaints	235	50.1	229	47.7

N represents number of women ever followed up.

¹Most severe complaint ever reported

²Multiple complaints may be reported per woman for this category.

⁺Coded by investigator as menstrual complaint

*Information not available

Table V
Other Complaints Ever Reported Since Admission

Complaint	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Headaches	137	29.2	102	21.3
Vaginal discharge	77	16.4	68	14.1
Nausea	61	13.1	52	10.8
Dizziness	43	9.2	33	6.9
Breast discomfort	43	9.1	39	8.1
Vomiting	12	2.5	6	1.2
Unspecified*	4	0.9	5	1.0
Total women with one or more complaints ⁺	230	49.0	195	40.6

N represents number of women ever followed up.

Multiple symptoms may be reported per woman.

*Information not available

⁺p<.05

Table VI¹

Changes in Severity of Complaints Since Admission

Changes in Complaints	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Intermenstrual bleeding				
Never reported	356	75.9	385	80.2
No change	0	0.0	1	0.2
Decrease	2	0.4	7	1.5
Increase	107	22.8	82	17.1
New reports*	105	22.4	82	17.1
Unspecified*	4	0.9	5	1.0
Nausea				
Never reported	392	83.6	411	85.6
No change	5	1.1	3	0.6
Decrease	12	2.6	12	2.5
Increase	56	11.9	49	10.2
New reports*	56	11.9	48	10.0
Unspecified*	4	0.9	5	1.0
Vomiting				
Never reported	452	96.4	465	96.9
No change	0	0.0	0	0.0
Decrease	1	0.2	4	0.8
Increase	12	2.6	6	1.3
New reports*	12	2.6	6	1.3
Unspecified*	4	0.9	5	1.0
Headaches				
Never reported	268	57.1	304	63.3
No change	41	8.7	29	6.0
Decrease	62	13.2	70	14.6
Increase	94	20.0	72	15.0
New reports*	89	19.0	70	14.6
Unspecified*	4	0.9	5	1.0
Dizziness				
Never reported	402	85.7	426	88.8
No change	7	1.5	4	0.8
Decrease	20	4.3	16	3.3
Increase	36	7.7	29	6.0
New reports*	36	7.7	29	6.0
Unspecified*	4	0.9	5	1.0

(cont.)

Table VI (cont.)

Changes in Severity of Complaints Since Admission

Changes in Complaints	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Vaginal discharge				
Never reported	357	76.1	363	75.6
No change	37	7.9	35	7.3
Decrease	31	6.6	45	9.4
Increase	40	8.5	32	6.7
New reports*	38	8.1	31	6.5
Unspecified*	4	0.9	5	1.0
Breast discomfort				
Never reported	406	86.6	413	86.0
No change	12	2.6	8	1.7
Decrease	16	3.4	23	4.8
Increase	31	6.6	31	6.5
New reports*	30	6.3	31	6.5
Unspecified*	4	0.9	5	1.0

N represents the number of women ever followed up.

*Information not available

New reports are complaints reported during the follow-up period by women who did not report the complaint at admission

N.B. Since the time periods for reporting a complaint since admission (e.g. 3 months from the 3 to 6 months follow-up visit) were longer than the time period to report a complaint at admission (1 month prior to admission), there is a bias toward and increased reporting of complaints since admission.

¹Reports of complaints were ranked by severity, with the most severe complaint ever reported throughout the study being given priority. For example, if a woman reported experiencing breast discomfort "sometimes" at admission, "often" at her first follow-up, "none" at her second follow-up, and "sometimes" at her last follow-up, then the most severe report (here, "often") would be recorded. As represented in this table, the report would be an increase in severity of complaint since admission. A decrease would only be reported if a complaint at admission was the most severe report of that complaint throughout the study.

Table VII
Reasons for Discontinuation

Complaint	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Menstrual Problems				
Spotting	1	0.2	0	0.0
Breakthrough bleeding	5	1.1	0	0.0
Heavy bleeding	3	0.6	0	0.0
Prolonged bleeding	3	0.6	1	0.2
Combination: cramps and intermenstrual bleeding	1	0.2	0	0.0
Side Effects				
Weight loss	0	0.0	1	0.2
Weight gain	0	0.0	1	0.2
Headaches	3	0.6	0	0.0
Dizziness	1	0.2	0	0.0
Breast pain	1	0.2	1	0.2
Combination: nausea, vomiting, headaches, breast discomfort	1	0.2	0	0.0
Combination: headaches, dizziness, blurred vision	1	0.2	0	0.0
Combination: vomiting, joint pain, abdominal pain, dizziness	1	0.2	0	0.0
Combination: dizziness, nausea	1	0.2	0	0.0
Other Medical				
Abdominal pain	1	0.2	1	0.2
Chest pain	0	0.0	1	0.2
Leg pain (phlebitis)	1	0.2	0	0.0
Decrease in milk supply	1	0.2	1	0.2
Constipation	0	0.2	1	0.2
Other Personal				
Fears method	1	0.2	1	0.2
Forgetfulness	10	2.1	1	0.2
Husband objects	1	0.2	6	1.2
Frigidity	1	0.2	0	0.0
Desires change	8	1.7	16	3.3
Not needed	2	0.4	1	0.2
Baby died	1	0.2	1	0.2

(cont.)

Table VII (cont.)

Reasons for Discontinuation

Complaint	Ovrette (N=469)		Micronovum (N=480)	
	No.	%	No.	%
Method unrelated				
Relative ill	0	0.0	1	0.2
Moving/travel	10	2.1	14	2.9
Disinterest in study	12	2.6	14	2.9
Job obligation	1	0.2	1	0.2
Center choice	0	0.0	1	0.2
Resupply elsewhere	1	0.2	2	0.4
Dislikes visits	0	0.0	1	0.2
Patient hospitalized (hemorrhoid removal)	1	0.2	0	0.0
Patient hospitalized (car accident)	1	0.2	0	0.0
Patient hospitalized (snake bite)	1	0.2	0	0.0
Patient hospitalized (backache)	1	0.2	0	0.0
Patient hospitalized (D and C)	1	0.2	0	0.0
Patient hospitalized (unspecified operation)	1	0.2	0	0.0
Total discontinuations	79	16.8	68	14.2

N represents number of women ever followed up.

Table VIII

Lost To Follow-up And Total Discontinuation Percentages

Event	Ovrette (N=573)	Micronovum (N=573)
Lost to follow-up percentage ¹		
1 month	18.2	16.2
3 month	29.3	27.1
6 month	51.1	50.1
Total discontinuation percentage ²		
1 month	18.8	16.6
3 month	36.3	31.6
6 month	63.2	59.7
Woman-months		
1 month	509.0	515.5
3 month	1287.5	1338.0
6 month	2097.0	2211.5

¹Percentage of women lost to follow-up among the total number who entered the study.

²Percentage of women not returning to the clinic among the total number who entered the study (including lost to follow-up).

Table IX

Gross Cumulative Life Table Discontinuation Rates

Event	Ovrette (N=573)		Micronovum (N=573)	
	At Risk	Rate \pm S.E.	At Risk	Rate \pm S.E.
Menstrual problems				
1 month	504.0	0.6 \pm 0.3	510.5	0.0 \pm 0.0
3 month	360.5	2.4 \pm 0.7	383.0	0.0 \pm 0.0
6 month	196.0	3.5 \pm 1.0	216.5	0.3 \pm 0.3
Side effects				
1 month	504.5	0.8 \pm 0.4	510.5	0.0 \pm 0.0
3 month	359.5	1.5 \pm 0.6	383.0	0.5 \pm 0.3
6 month	195.5	1.8 \pm 0.7	216.5	0.5 \pm 0.3
Other medical reasons				
1 month	503.	0.2 \pm 0.2	511.0	0.2 \pm 0.2
3 month	359.5	0.4 \pm 0.3	384.0	0.7 \pm 0.4
6 month	195.5	0.8 \pm 0.4	216.5	1.3 \pm 0.6
Other personal reasons				
1 month	503.5	0.4 \pm 0.3	513.0	1.0 \pm 0.4
3 month	361.5	2.2 \pm 0.7	387.0	3.9 \pm 0.9
6 month	197.0	6.8 \pm 1.4	217.5	5.4 \pm 1.2
Method unrelated reasons				
1 month	504.0	0.6 \pm 0.3	512.5	0.8 \pm 0.4
3 month	360.0	4.1 \pm 1.0	386.0	3.5 \pm 0.9
6 month	196.0	7.1 \pm 1.4	217.5	7.5 \pm 1.4
Method related reasons				
1 month	506.0	1.4 \pm 0.5	510.5	0.0 \pm 0.0
3 month	360.5	3.9 \pm 0.9	383.0	0.5 \pm 0.3
6 month	196.0	5.3 \pm 1.2	216.5	1.1 \pm 0.5

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Data Quality Statement

Item 13 on the admission form is designed to report the contraceptive method used mainly in the month prior to admission or in the month before conception for postpartum cases. However, in this study the question was often interpreted as: method mainly used in the past versus in the past month or in the month before conception. Therefore, for this study Table I presents a summary of the primary contraceptive practices used by the women in the past. The predominant method used in both groups was oral contraceptives, by 202 women (35.3%) in the Ovrette group and 215 women (37.5%) in the Micronovum group. However, these numbers vary from the percentages given for Item 25 which reports previous use of oral contraceptives; in this study 282 women (49.2%) in the Ovrette group and 291 women (50.7%) reported ever having used oral contraceptives prior to the study. Because of the discrepancies in these percentages, caution should be used in any interpretation of these responses.

The results reported in this study should be interpreted in relation to the following considerations. The lost to follow-up percentages for this study at 51.1 for the Ovrette group and 50.1 for the Micronovum group at 6 months were high. Ten Patient Order Numbers were inadvertently omitted from the site and it is possible that randomization procedures were compromised due to this error. There were protocol violations that resulted in

exclusion of 19 patients from the study. Fifty women admitted at the Torwood Clinic only had one follow-up due to a misunderstanding of the follow-up schedule by the nurse at the clinic. These factors result in questionable data quality for the study.