

A CLINICAL TRIAL ON THE USE OF MARGULIES SPIRAL (I.U.D.) AMONGST 200 WOMEN IN SINGAPORE

By A. C. Sinha, M.M.S.A., M.R.C.O.G., F.I.C.S.

(Consultant Obstetrician and Gynaecologist, Gleneagles Hospital & Mount Alvernia Hospital, Singapore.
Vice-President, Family Planning Association of Singapore)

I must thank the Family Planning Association of Singapore for giving me this opportunity of presenting some experiences with the Margulies Spiral as an effective means of fertility control over a period of 17 months in Singapore.

Forty years ago Grafenberg first introduced his intra-uterine rings as a method of fertility control which was later condemned by the leading Gynaecologists of the day; yet today in 1965 a very similar method is being advocated in the shape of various intra uterine devices as an effective and safe method of overcoming our ever increasing menace of population Explosion.

The reasons for such revival of a method which was condemned as being unphysiological, dangerous and fraught with complications, lies in our clearer understanding of the physiology of the genital tract; a greater knowledge of human tissue reactions between various types of foreign bodies; an era of antibiotics which has revolutionised control of infections and the final dissatisfaction that every type of contraceptive method has its own limitations and objections.

Grafenberg in his first report of 600 cases presented an incredibly low failure rate of 1.6% which has not been bettered by any other methods in use except "Oral".

A review of the literature shows that foreign bodies have been introduced into the Corpus Uteri for two main reasons; either to prevent pregnancy or to interrupt pregnancy. A third reason for such insertion in the past had been for therapatic purposes in the treatment of dysmenorrhoea, hypoplasia and infertility. Our current interest lies in its value as an effective means of planning future pregnancies.

Following the introduction of the Grafenberg ring and its subsequent falling into disrepute a complete void appears in the medical literature from the year 1934 until 1948 when Halton and others published their experiences with the use of coarse silk worm gut rolled into a coil for intra-uterine insertion.

In a series of 266 patients they recorded an amazingly low pregnancy rate of .9 per 100 "Exposure Years".

Oppenheimer and Ishihama in 1959 published a further series of cases by which time intra-uterine devices as a means of fertility control had begun to attract the eye of human fancy. Oppenheimer used silk worm gut ring instead of silver whilst Ishihama favoured the much widely publicised "Ohta ring" in Japan made of plastic material, though the original consisted of metal spiral supported by a central gold disc.

In a series of 329 women Oppenheimer introduced 866 rings between 1930-1957 with the following results:—

1. Inflammation and infection rate—Nil
2. Pregnancy rate 2.4%
3. Expulsion rate a) 9 cases complete
 b) 21 cases incomplete } 9%
4. Removal—Conception interval = 2-4 months.

Ishihama recorded a failure rate of 3.5% in 20,000 cases. Oppenheimer made the following observations:—

1. The ring once inserted could be left in situ for 1-2 years followed by removal and re-insertion.

2. It did not predispose to sterility for on subsequent removal patients conceived just as easily.
3. The failure rate was better than that of all other methods in use.
4. It was useful where other methods had failed or were objectionable.
5. It did not predispose to abortions or foetal deformities when conception arose with I.U.D. in situ.

Armstrong & Anderson (1959) reported a case of normal pregnancy following on an Ohta ring which had been left in situ for 5 years and expelled along with the chorion at delivery.

Freedman (1953) reported a similar case of a woman who delivered a healthy live infant 2 years and 8 months following the insertion of her golden wedding ring into her cervix.

The next important milestone in the use of intra-uterine devices was reached when *Hall & Stone (1962)* after studying the defects of the Grafenberg ring concluded that the ill effects lay not in the principle of the method employed but rather on the material used in its manufacture. Hall employed stainless steel in the hope that it would minimise tissue reaction. His results on 128 patients between 1949 and 1960 proved to be highly satisfactory e.g.

1. Spontaneous Expulsion occurred in 7 cases i.e. 5.5%
2. Dysmenorrhoea — Nil
3. Infection — Mainly local with no pelvic involvement as judged clinically.
4. Meno-Metrorrhagia — 5 cases.
5. Neoplasm — No cases of malignancy were reported in the series.

The commonest symptom was abdominal cramps and was confined to within the first 48 hours of insertion. Furthermore in 13 cases of contemplated pregnancies the "removal conception" interval was on an average of 3 months. Although the use of I.U.D. as a contraceptive method is now accepted universally the modes operandi is still much in the realm of specula-

tion. Amongst the many suggestions offered in its explanation few bear critical and scientific analysis e.g.

- a) Chronic endometrites.
- b) Impediment to sperm migration.
- c) Suppression of ovulation.
- d) Interference with nidation of the fertilised ova.

The first three have been refuted by workers, whose reports are found in the transactions of the second International Conference on I.U.D. held in New York in 1964. Whilst on the more plausible theory of interference with the nidation of the fertilised ova opinion is somewhat divided. Although there is no impediment to sperm migration in utero and fallopian tubes, the presence of the I.U.D. is said to maintain a state of irritability of the uterine myometrium causing a possible displacement of the fertilised ovum before it is able to secure for itself a bed for nidation.

However once nidated, the I.U.D. has no further influence in its ultimate growth and expansion. Meanwhile Margulies in 1958 in an attempt to produce an inexpensive reliable, inert and free from tissue reaction I.U.D. used a plastic material e.g. polyethelene impregnated with 5%Ba. Salt to permit X Ray visualisation.

Lippes produced a double "S" loop which differed basically in its shape and configuration from that of the Margulies type but shared in common in having a tail piece which dangled in the vagina. This tail piece marked a departure from the orthodox types of rings used in the past which were entirely uterine; in contrast the current ones are utero-cervico-vaginal.

The purpose of the tail piece has been to facilitate identification and subsequent removal.

These plastic devices are usually inserted with the aid of an introducer which should not require any dilatation of the cervix greater than that of Hegars No. 4.

This avoids administering an anaesthetic for the necessary insertion. Although the I.U.D. is still in its experimental stage, it has already established itself as an effective means of fertility control with numerous studies being undertaken to evaluate its efficacy and mode of action e.g.

1. Clinical studies to establish the efficacy of the method.
2. Physiological studies to establish the modus operandi.
3. Bacteriological studies to assess infection.
4. Cyto-histological studies to detect tissue changes and reactions.
5. Hormonal studies in relation to effects on ovulation, fertilization and menstruation.

REPORT

I shall now report on a clinical survey in the use of the Margulies Spiral as an effective means of fertility control in Singapore. Two hundred patients have been fitted with the Margulies Spiral over a period of 17 months commencing from 4 October 1963. These were cases referred by the Singapore F.P.A. under whose auspices this trial has been held. All insertions were made in the non-pregnant state as and when referred, though all efforts were made to induce them to attend within a week of their menstrual cycle.

Table I shows the monthly analysis of the 200 cases included in this trial in order of insertion.

TABLE I

Month	No. of Cases
1963 October	13
November	13
December	14
1964 January	15
February	18
March	22
April	27
May	30
June	13
July	0
August	0
September	4
October	18
November	13
Total:	200

One of the cases, No. 78, had to be withdrawn from the trial as the patient refused to return for re-insertion of the I.U.D. after an

initial unsuccessful attempt making a total of 199 cases in the trial. These 199 cases were exposed to a total of 2123 "woman-, months".

These 199 cases have been further subdivided in relation to age distribution and parity (Table II & III).

TABLE II

Age distribution	No. of Cases
25 years and under	21
26 years and up to 30 years	71
31 years and up to 35 years	71
36 years and up to 40 years	32
40 years and above	0
Total:	195

N.B. In 4 cases age was unrecorded.

The youngest age recorded in this series was 20 years with 3 pregnancies and the eldest 40 years with 8 pregnancies.

The average age group was 31 years for the entire trial. Nearly one third of the patients were in the 36 years and over age sector, with high parity incidence which will be significant, when studying the spontaneous primary expulsion rate in this series e.g. 72% amongst women of gravide 5 and over (see Table IV).

Distribution of cases in relation to parity:—

TABLE III

Gravida	No. of Cases
1	2
2	7
3	15
4	22
5	30
6	42
7	31
8	16
9	12
10	9
11	7
12	4
13	1
14	0
15	1
Total:	199

Amongst these 199 cases a total of 1236 pregnancies were recorded between them, including abortion and still births giving an average parity rate of 6.2 pregnancies per case, indica-

ting the high parity rate in the trial. The number of cases of pregnancies of 5 and over were 153; about 77% of the total number entering the trial.

From this selection it will be seen that most of the patients in the trial belonged to the high parity and age group with an average of 6.2 pregnancies and 31 years of age per case.

Two sizes of Margulies Spirals were used "V" and "VJ" types; the latter being the junior size and were supplied free of charge through the kind offices of the Ortho Pharmaceutical Research Laboratories to whom I am most grateful.

89 cases were fitted with the "VJ" Spiral and 110 cases with the "V" Spiral. Most of the patients referred to were also victims of various degrees of utero-vaginal prolapses, Cervical Hypertrophy and Erosions, Chronic cystic Cervicitis, rendering the use of diaphragms unsatisfactory whilst several were intolerant to "Orals". 114 cases or 58% showed some degree of Gynaecological abnormalities which needed urgent attention.

This in short presents the type of cases subjected to this I.U.D. trial, which may be considered severe when assessing results.

I shall discuss the clinical aspects of the trial under the following:—

1. Abdominal discomfort and pain.
2. Expulsion of the device.
3. Pregnancy.
4. Infection (as assessed clinically).
5. Dysmenorrhoea.
6. Meno-Metrorrhagia.

I. *Abdominal pain and discomfort*

With the exception of a few cases who experienced only vague abdominal discomfort no single patient complained of abdominal pain or cramps in strict conformity with the connotation of the term.

Hall & Stone recorded abdominal cramps restricted to the first 48 hours only, however it must be remembered they used stainless steel rings which will not be as resilient and light as the Margulies spiral or the Lippes loop. The most severe forms of uterine cramps that I have seen, have been associated with the "Ohta ring".

II. *Expulsion of I.U.D.*

The natural tendency for the human body is to expel any foreign material in its system

and I.U.D. is no exception. Such extrusions may occur via sinus tracks, facial planes aided by muscle action and even tubal peristalsis and uterine activity will expel foreign materials used in tubal plastic operations unless anchored.

These I.U.D. expulsions can be divided into two categories:—

1. Spontaneous expulsions either
 - a) primary
 - or b) secondary
 - or c) tertiary
2. Voluntary expulsions where the device has to be removed intentionally for some reason or other.

There were 25 spontaneous primary expulsions and 3 voluntary ones (see Table IV) in this study making a total of 28 expulsions. Amongst these 28 spontaneous expulsions, three were habitual ejectors, two were expelled within 48 hours and on re-insertions have retained them till now indicating faulty technique, and two cases expelled the junior type of spiral on first insertion but on subsequent re-insertion with the larger spiral retained it, suggesting *faulty judgement*. Hence the three causes of failures unrelated to the device will be:—

1. Habitual ejectors
2. Faulty technique
3. Faulty judgement.

A habitual ejector is defined as one who will not retain the I.U.D. in her uterus in spite of three repeated re-insertions and so have been advised to switch over to other types of contraceptive measures. There were three such "habitual ejectors" in this series. The expulsion rate in my series is as follows: (Table IV).

TABLE IV
CASES WITH PRIMARY EXPULSION
OF THE I.U.D.

A. **Voluntary Expulsion**

Case No. 19 = removed by doctor at K.K. Hosp.

Case No. 22 = removed at husband's request

Case No. 159 = removed at request of Dr. Fox as patient mentally unfit

Total No. of voluntary Expulsion - 3

B. Spontaneous Primary Expulsion

Total No. of Expulsions	-	25
<i>Habitual ejectors</i>	-	3
No. 52 (Vj-V-V.)	gravida	7
No. 132 (Vj-Vj-V)	gravida	4
No. 196 (V-V-V.)	gravida	7
<i>Faulty Technique</i>	-	2
No. 157 expelled 2nd. day, re-inserted, now 9/12		
No. 173 expelled 2nd. day, re-inserted, now 4/12		
<i>Faulty Judgement</i>	-	2
No. 57 exp. 7th day Vj. re-inserted V. retained		
No. 23 exp. 2nd. day Vj. refused re-insertion		

C. Associated with Menorrhagia

No. 79 exp. 16th day following continued haemorrhage.		
No. 188 exp. 9th day of haemorrhage.		

PRIMARY EXPULSION RATE

(a) Gross.	-	-	= 12.56%
(b) Corrected	-	-	= 9.2%

Christopher Tietze at the second International Conference of I.U.D. reported an Expulsion Rate of:—

3.8% for the plastic Brimberg Bow.

9% for either the spiral or the loop. over a large series of trials conducted by various workers in different lands.

Twenty one secondary insertions were undertaken with 8 failures which included the three "habitual ejectors" giving a secondary expulsion rate of:—

a) Gross	38%
b) Corrected	27.8%

Only six of these failures returned for a third insertion, half of whom have retained them till now.

The Tertiary Rate may therefore be expressed as 50% of tertiary insertions and as they also represent "habitual ejectors"—1.5% of the total cases subjected to this trial fall into the category of Habitual Ejectors—(See Table V).

TABLE V

I. Cases with Secondary Expulsion of I.U.D.

No. of secondary insertions	-	21
Case No. 3, 5, 19, 40, 44, 52, 53, 57, 69, 98, 101, 111, 112, 113, 125, 132, 157, 168, 173, 196 & 15.		
No. of secondary Expulsions	-	8
Case No. 5, 15, 40, 52, 53, 69, 132 & 196.		

It includes three cases of Habitual Ejectors

SECONDARY EXPULSION RATE

(a) Gross	-	-	38%
(b) Corrected	$\frac{5}{18} \times 100 =$		27.8%

II. Cases with Tertiary Expulsion of I.U.D.

No. of tertiary insertions	-	6
Case No. 15, 40, 52, 69, 132, 196.		
No. of tertiary Expulsion (Habitual ejectors)	-	3

TERTIARY EXPULSION

RATE	-	-	50%
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On further scrutiny they were found to belong to the high parity group, except case No. 132 (Gravida 4) and were advised to have a tubal ligation done.

The 25 cases of Primary Spontaneous Expulsions were further studied in relation to:—

- Parity (Table VI)
- Type of spiral used (Table VII)
- Menstrual cycle (Table VIII)
- Insertion expulsion interval (Table IX).

TABLE VI
CASES OF EXPULSION OF I.U.D.
IN RELATION TO PARITY

Case No.	Gravida	
3	5	
5	7	
11	6	18 cases or 72% have a parity of 5 and over.
15	6	
23	6	
35	3	
40	5	
52	7	
53	4	
57	7	
69	4	
79	6	
91	7	
98	3	
101	5	
111	8	
112	7	
113	4	
125	3	
138	5	
157	9	
168	7	
173	6	
188	4	
196	7	

Type of Spiral used

TABLE VII
EXPULSION OF I.U.D. IN RELATION
TO TYPE OF SPIRAL

Case No.	Spiral	Case No.	Spiral
3	Vj.	98	V.
5	V.	101	V.
11	Vj.	111	V.
15	Vj.	112	Vj.
23	Vj.	113	Vj.
35	Vj.	125	V.
40	Vj.	138	V.
53	Vj.	157	V.
52	Vj.	168	Vj.
57	Vj.	173	V.
69	V.	188	V.
79	V.	196	V.
91	V.		

There were: 12 Expulsion with Vj. Spiral
13 Expulsion with V. Spiral

One hundred and fifty three or 77% of cases in this trial had five or more pregnancies each (Table III). and 18 cases of primary spontaneous expulsion or 72% belonged to this group, indicating that "high parity" is an aetiological factor in spontaneous primary expulsions.

The standard criteria used in the insertion of the two types of spirals were based on:—

1. size of the uterus as judged clinically.
2. the actual size of the utero-cervical cavity as measured by the Margulies uterine marker.

Unless the uterus was clinically enlarged, a size of the utero-cervical cavity up to 6 cm +1 was fitted with the "VJ" spiral; and cavities of 6 cm +2 and over with the "V" spiral. From table VII it can be seen that the number of expulsions were about equal using either size of spirals without any statistical significance.

Twenty one cases of primary expulsion were studied in its relationship to the menstrual cycle and 14 cases or 66.7% were expelled during a period with a further 10% occurring within a week either before or after. Only one device was expelled in mid-cycle whilst in 2 cases the I.U.D. was expelled following continual menorrhagia, the one on the ninth day, and other on the sixteenth day following insertion.

Thirteen cases or 61.8% of the expulsions occurred within the first 8 weeks. The average for the whole clinical trial was within 12 weeks. Excluding Case No. 57, 79 and 188, the earliest expulsion occurred within 2 weeks of insertion and the longest interval was 64 weeks in Case No. 3.

Two patients expelled the device after a period of 32 weeks following insertion.

PREGNANCY RATE

TABLE X

I.U.D. cases associated with Pregnancy

No. of cases pregnant with I.U.D. in	-	8
Case 44 =	pregnant at insertion	
Case 45 =	„ after 1 cycle	
Case 60 =	„ after 11 cycles	
Case 87 =	„ after 5 cycles	
Case 90 =	„ after 4 cycles	
Case 108 =	„ after 2 cycles	
Case 132 =	„ at insertion	
Case 157 =	„ after 11 cycles	

(following 2nd insertion)

TABLE VIII

L.U.D. Expulsion in relation to menstrual cycle

Total No. of cases - - - - 21

Before period	During period	After period
No. 40 - 2 days	No. 3 - 2nd day	No. 15 - 2 days
No. 138 - 1 day	No. 5 - 2nd „	No. 101 - 4 days
	No. 11 - 2nd „	
	No. 35 - 2nd „	
	No. 52 - 3rd „	
	No. 53 - last „	
	No. 57 - 4th „	No. 91 - mid-cycle
	No. 69 - last „	
	No. 98 - last „	
	No. 111 - 4th „	
	No. 112 - 2nd „	
	No. 113 - 2nd „	
	No. 125 - 3rd „	
	No. 168 - 1st „	
Expulsion before period	— 2 cases — 9.5%	
Expulsion during period	— 14 cases — 66.7%	
Expulsion within 7 days of a period	— 2 cases — 9.5%	
Expulsion during mid-cycle	— 1 case — 4.8%	
Expulsion following continued haemorrhage	— 2 cases — 9.5%	

TABLE IX

Primary Insertion-Expulsion Interval

Total No. of Cases - - - - 21

Case	Insert.-Exp. Interv.	Case	Insert.-Exp. Interv.
3	— 64 wks.	91	— 6 wks.
5	— 11 „	98	— 8 „
11	— 2 „	101	— 4 „
15	— 16 „	111	— 6 „
35	— 32 „	112	— 4 „
40	— 6 „	113	— 32 „
52	— 8 „	125	— 16 „
53	— 6 „	138	— 6 „
57	— 1 „	168	— 12 „
69	— 15 „	188	— 1+ „
79	— 2+ „		

Average Insertion-Expulsion Interval =

$$\left. \begin{array}{l} \text{Total No. of weeks} \\ \text{Total No. of cases} \end{array} \right\} = 12 \text{ weeks per case}$$

13 cases or 61.8% of expulsions occurred within the first 8 weeks.

TABLE X (continued).

Pregnancy Rate

Gross rate	-	-	-	4%
Corrected rate	-	$\frac{6}{197} \times 100 =$		3%
Case No. 45—Spiral Vj.—trimmed 4 beads				
Case No. 50—Spiral Vj.—trimmed 4 beads				
Case No. 87—Spiral Vj.—trimmed 6 beads				
Case No. 90—Spiral Vj.—trimmed 4 beads				
Case No. 108—Spiral V.—trimmed 7 beads				
Case No. 157—Spiral V.—trimmed 7 beads				

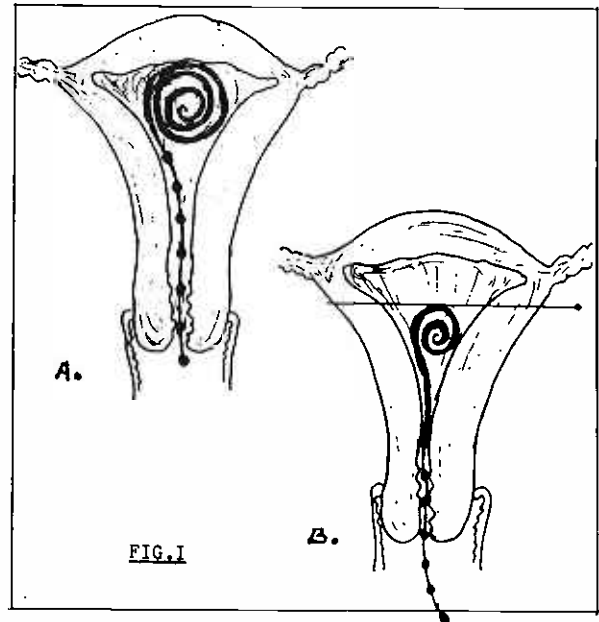
Pregnancy in the presence of intrauterine foreign bodies has been reported from time to time and as early as the 18th century. Similarly in any trial of a comparable size with I.U.D. there will always be a small failure rate due to superimposed pregnancy and this has been placed at 2.6% by Christopher Tietze in 16,734 cases spread over a total of 132,400 exposure months from 38 institutions. In my series there were 8 cases with superimposed pregnancy with the I.U.D. amongst 199 women giving a pregnancy rate of 4%. However as in two of these cases subsequent examinations revealed a state of pregnancy at the time of primary insertion, the actual pregnancies rate in this trial is 3%.

Furthermore from Table X one will notice that pregnancy can occur at any time in the post insertion period commencing from as early as the first cycle to almost a year after. The classical case of Armstrong and Anderson revealed a pregnancy, 5 years following the insertion of an Ohta ring. Although the length of time the I.U.D. has been in bears no relationship to a superimposed pregnancy, yet the degree to which the spiral has descended in the uterine cavity does have a bearing. A glance at Table X will show that in every case of superimposed pregnancy 4 or more beads were trimmed and in fact in two cases 7 beads had been trimmed following extrusion at the external Os.

In Fig. IA. the Margulies spiral is diagrammatically represented as filling the entire uterine cavity when properly inserted whilst in Fig. I.B a similar spiral with 4 beads protruding through the external os is seen with the main body of the spiral situated well below the uterine fundus.

This descent gives sufficient room for the fertilised ovum to implant in the upper Uterine segment with subsequent development of a pregnancy.

This suggestion may throw some light on the possible modes operandi of the I.U.D. as a means of preventing pregnancy in that the uterine motility keeps the device in a state of continual motion preventing the midation of the ovum at its intended site. The researches of Behrman at the University of Michigan in this field may throw further interesting light.

**IV. Infection**

No cases of infection were recorded in this series of 199 cases as judged clinically by a raised temperature and pulse rate, lower abdominal pain. Every case with I.U.D. was asked to return between the 2nd and 3rd day of insertion to have the beads trimmed when a full clinical examination was made to evaluate pelvic infection. Owing to lack of facilities no bacteriological studies were undertaken in this series.

V. Dysmenorrhoea

No cases of dysmenorrhoea were recorded arising directly as a result of the I.U.D. insertion

VI. Meno-Metrorrhagia

Every case in this study had some degree of vaginal bleeding ranging from that of staining to actual blood loss for about 5 days whilst in about one third of the cases it persisted up to 7 days.

Two cases No. 19 and 188 had vaginal bleeding which was particularly heavy and continued to the 16th, 19th day respectively

followed by ultimate expulsion of the spiral. Thirty six cases or 18% had definite heavy period for the first two cycles after which it reverted back to normal. There were no cases of inter-menstrual bleeding in this series.

CONCLUSIONS

In conclusion, whilst the I.U.D. marks a departure from the Orthodox method of fertility control, it has nevertheless proved itself highly satisfactory with a failure rate well below that seen with the usual conventional method of contraception except the "orals".

SUMMARY

1. Two hundred women were fitted with the Margulies spiral under the auspices of the Family Planning Association of Singapore, with a view to studying its effect on fertility control commencing from 4th October 1963 for a period of 17 months.
2. One case was withdrawn from the trial making a total of 199 cases.
3. Two types of spirals were used, the V and Vj type. 89 cases were fitted with the Vj spiral and 110 cases with the V spiral.
4. The average age in this trial was 31 years with a parity 6.2 pregnancies per case.
5. There were 3 Voluntary and 25 Primary Spontaneous Expulsions.
6. The Spontaneous Primary expulsion rate was:—
 - a) Gross = 12.56%
 - b) Corrected 9.2%
7. The spontaneous secondary expulsion rate was:—
 - a) Gross = 38% of reinsertions.
 - b) Corrected 27.8% of "
8. The spontaneous Tertiary expulsion rate was 50% of all tertiary reinsertions.
9. 1.5% of the total number of cases fell into the category of "Habitual Ejectors".
10. The expulsion rate in relation to the type of spiral used showed no significant differences.
11. 66.7% of spontaneous primary expulsions occurred during the menstrual phase with a further 9.5% before and 9.5% after within one week of a cycle.
12. The average primary insertion expulsion interval was 12 weeks, although 61.8% of the expulsions occurred during the first eight weeks.
13. The gross pregnancy rate was 4% but after deleting 2 cases which were subsequently found to be pregnant at time of primary insertion, the pregnancy rate was reduced to 3%. In every case where pregnancy occurred with the device in, at least 4 beads had been trimmed. One case had 6 and two cases had 7 beads trimmed suggesting that descent of the spiral in utero enabled the fertilised ovum to implant itself without any interference at its normal site within the upper uterine segment.

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