CLINICAL TRIAL OF A NEW INTRA-UTERINE CONTRACEPTIVE DEVICE, THE COILED LOOP (C. L.)

by

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The variation in size, configuration and compositional makeup of of intra-uterine devices currently used during the last 6 years are of considerable interest and significance.

Most ingenious of these were the variety of configurations made of the new plastics, molded in the from of spirals, coils and loops. The malleability of the plastic material is so regulated that the device can be threaded into a curvilinear small bore introducer to permit painless introduction. The extent to which configuration, size and composition contribute to the effectiveness of these contraceptive devices is undoubtedly depending on the degree to which these variables contribute to the elemination of side effects and the occasional failure with pregnancy resulting.

The purpose of this study is to present our clinical experience with a new design of intra-uterine contraceptive device, The Coiled Loop.

THE COILED LOOP

Fig. I showes the coiled loop and its the inserter which are made of polyethelene containing barium salt.It is curved in a flat plane in the shape of a large S continuing into a smaller coil wound in the opposite direction of the upper part (S). Thus the number of horizontal portions are 3. The length when straightened is 108 mm, the width at the upper end 24 mm., the diameter of the coil 14 mm, and the height is 27 mm. The end of the coil has a perforation through which passes the midportion of a 150 mm long 000 monifilament of polyethelene.

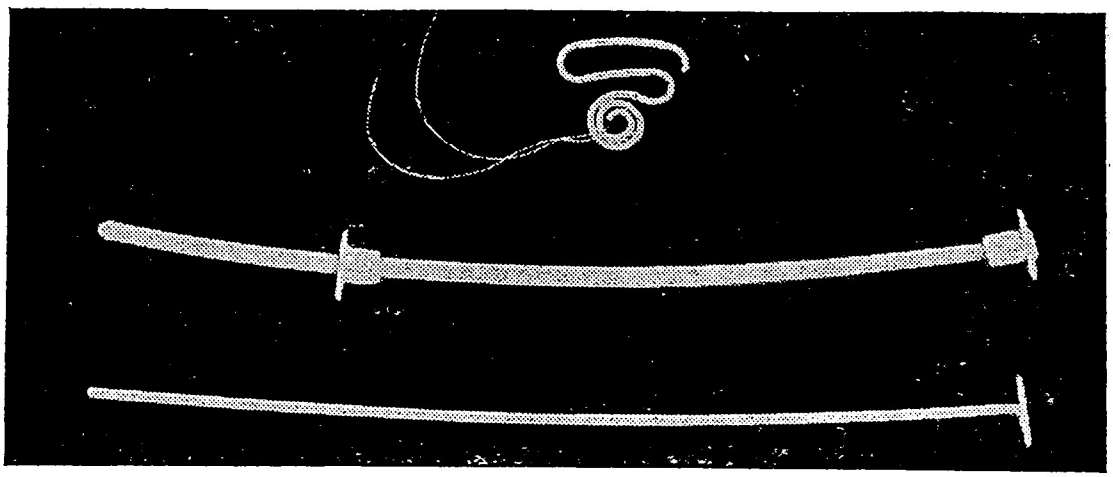


Fig. 1.—Coiled loop and Inserter.

This is threaded in a double strand in such a way that no free end remains in the uterine cavity. To prevent slipping of the thread both ends are run through the hole and round the coiled end.

The inserter is oval in cross section. The upper end has bilateral side slits to allow easy recoiling of the straightened coiled loop during its introduction into the uterine cavity. Fig. 3. The plunger is of teflon and is longer by 3 mm than the length of the tube to allow easy pushing of the lower end of the coil high up in the uterine cavity. A flange can be adjusted to indicate the portion which should get inside the uterus, and the plane which the loop will assume when extruded into the uterine cavity.

MATERIAL FOR THE STUDY

Two groups of women were choosen for the study in three family planning centres. Each group consisted of 417 women. To one group Loop size 30 mm was applied and to the other group the new device was used. They were followed for periods ranging from 2 to 8 months, with a total number of months of use for each group women-2094 months.

History and pelvic examination were carefully done and patients with contraindications (Fibroid, acute and subacute pelvic inflammatory diseases, and veginitis) were excluded from the study. We use for disinfection of the device and inserters diluted **dettol** solution or cetavilon 10%.

The loaded inserter is then introduced into uterine cavity until the flange reaches the extermal as. It is then rotated as indicated by the flamge 90° and the plunger is then pushed so that the device is delivered in the frontal plane. The throad outside the cervix is cut off allowing about 15 mm to remain visible.

RESULTS

A total of 417 coiled loops have been inserted to one group of women. To another group, 417 Lippes Loops size 30 mm were applied for comparitive study in the same monthes of exposure. We used Lippes Loop (Fig. 2) because of their availability in our country and their relatively superior results compared to other devices as reported by different authers[1,2,3,4,5]

Analysis of the side effects reported showed the following : (See table). For comparative purposes we call the women using the Lippes Loop group L. and those using the new device coiled loop group CL.

BLEEDING

35%of both groups L & CL suffered from bleeding after insertion for a period varing from 4-12 days in group L and 1-7 days in group CL. In all cases where the loop was inserted during the phase of lactation amenorrhea the bleeding was minimal and did not last more than one or 2 days.

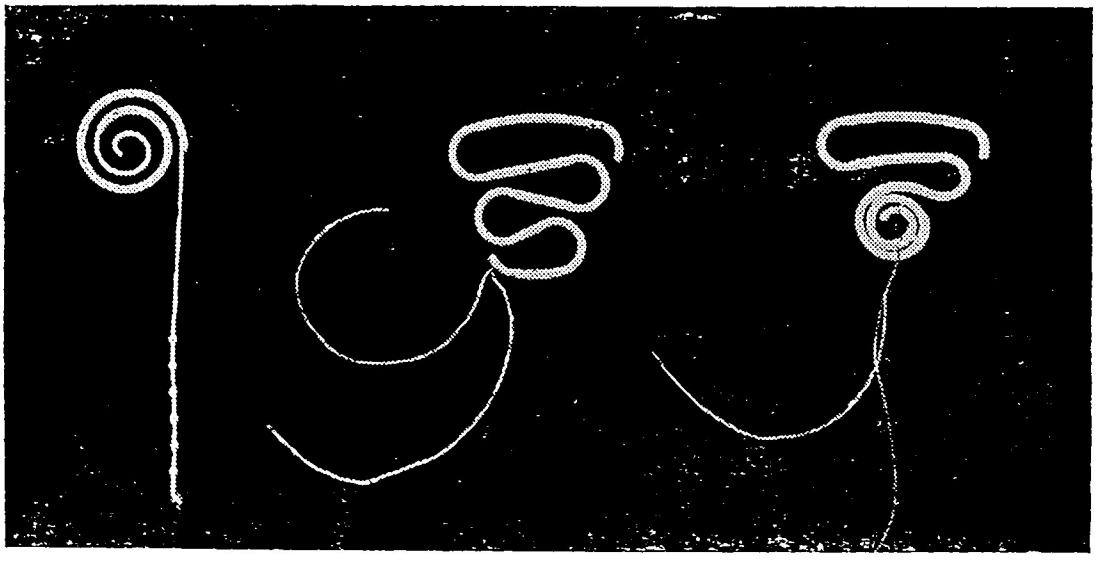


Fig. 2.—Margulies Spiral, Lippes loop and Coiled loop.

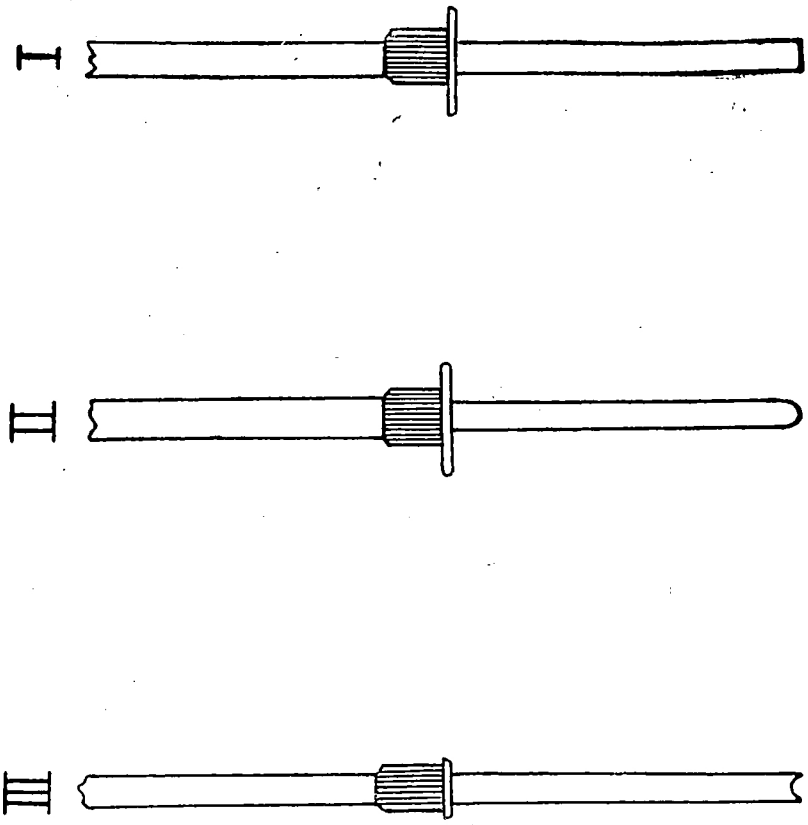
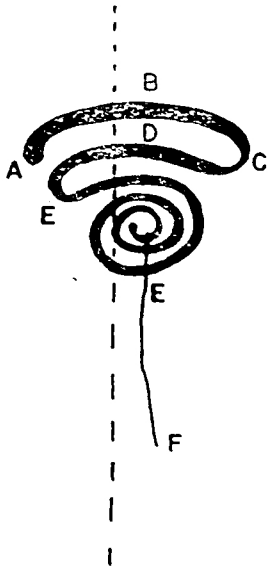


Fig. 3.—Diagram showing :
I.—Original cut circular end of Lippes Introducer.
II.—Antero-posterior view of the new blunt pointed inserter.
III.—Side view of the new inserter showing side opening.



A _ Rounded tip same diameter as B.

B _ Upper transverse line made in 2 lengths 27 5mm X 30mm.

C _ Flexible corners-diameter less than transverse lines.

D _ 2nd transverse line same thickness as B.

E _ The coil same thickness & softness as C made in 3 circuls.

F _ Nylone filament attached to the inner side. Not the terminal end of the coil.

Disturbance of the menestrual blood flow in the form of menorrhagia, metrorrhagia polymenorrhea and intermenestrual spotting of blood was encountered in 28% in group L and in 9.8% in group CL in the first three months of use.

29 women in group L asked for removal of the device because of excessive bleeding whereas in group CL only 2 women asked for removal for the same reason.

PAIN

A time of the insertion of the device (Lipes Loop) it was minimal except in 9 cases where suprapubic colic was experienced for a variable time ranging from few minutes to few hours. During insertion of the coiled loop pain was experienced by 33 cases and lasted a few minutes in 21 cases and in 12 cases it persisted up to one day. In all cases pain was immediately relieved by giving antispasmodics and analegiscs.

TABLE

Comparison of the side effects and complications between the two groups of women during the same months of exposure

Complaint	Lippes Loop		Coiled Loop	
Bleeding	109	28 %	41	9.8%
Pain and colic	9	1.9%	33	7.9%
Pregnancy*	5	1.2%	0	0
Pelvic Inflammatory disease	6	1.4%	7	1.7%
Expulsion	28	6.7%	7	1.7%
Re-expulsion **	10	35.7%	1	16.6%
Reemoval for :				
— Bleeding	29	7.0%	2	0.5%
— Discharge and Colic	2	0.5%	0	0
— Desire to get pregnancy	0	0	1	0.25%
Total	193	46.7%	91	21.9%

* Pregnancy was not included with total number of complications.

** Percentage of the re-expulsion is that related to the total number of first expulsion. The number was not included in the total number of complaint.

PELVIC INFLAMMATORY DISEASE

Pelvic infection as presented by tenderness over the uterus or adnexia was reported in 6 cases of the group L and the 7 cases of group CL. No inflammatory mass is palpable. Such complaint occured in the first 3 months following insertion of both devices and responded readily to antiinflammatory treatment.

PREGNANCY

Five failures or pregnancies have occured in group L of women (1.2%). Following «Pearls formula» the pregnancy rate was 1.6 per 100 woman years for the Lippes loop.

Not a single case of pregnancy was recorded among the women wearing the coiled loop, so far in the period of study.

EXPULSIONS

Expulsion has been a major problem with IUCD, (Fig. 5) shows Lippes Loop partially expelled through the cervical canal. 28 cases of those who were applying the Lippes Loop have expelled the device till now. In group CL only 7 expulsions have been reported, 6 cases accepted reinsertion and 5 of them has been successful in using this device till now. Only 1 expelled it again and refused a third insertion.

REMOVALS

Removals were done for relevant causes related to the device such as bleeding pain and discharge, or for irrelevant causes, suchas desire to get pregnancy, psychological upset or religious ideas. In group L the number of removals for relevant causes were 31 cases ; 29 cases of these were for bleeding and spotting and 2 cases for other reasons as colic and discharge. In group CL two women only have the device removed for bleeding, only one asked to discontinue the method because of her desire to get pregnancy.

DISCUSSION AND COMMENT

In an effort to determine the nature of the factors responsible for expulsion of various intrauterine devices several clinical data were collected regarding the size of the uterine cavity and condition of the cervical canal. From these studies it became apparent that the factors which underlie expulsion are either related to the uterine factors or to the type of the device used or both.

As regard the uterine factors we found that the dimensional disproportion between the device and the uterine capacity varies bet-

ween nulliparous women and parous women. The greater the parity the wider the uterine cavity and the more resilient is the isthmo cervical segment. Such phenomenon was observed in those who expell the device several times, the so called and habitual expellers, in whom the device was expellod without any discomfort and frequently undetected (Fig. 4).

We consider the device which can descend easily in the lower segment due to uterine contraction it will become wedged and the continuous pressure of the device on the wall of uterus will further increases the myometrial contractility. This mechanism is facilitated if there is weakness or incompetence of the isthmo uterine segment reducing the resistance to its descend.

The uterine cavity is normally a potential spaco which most readily accomodates the device if it lies in the frontal plane[6,7]. Should the device through faulty introduction come to lie in the sgittal plane, myometrical reactivity is greatly increased and result in spasmodic colic (Fig. 6).

In such cases the increased uterine activity will lead ultimately to the expulsion of the faulting placed device. As regards the factors

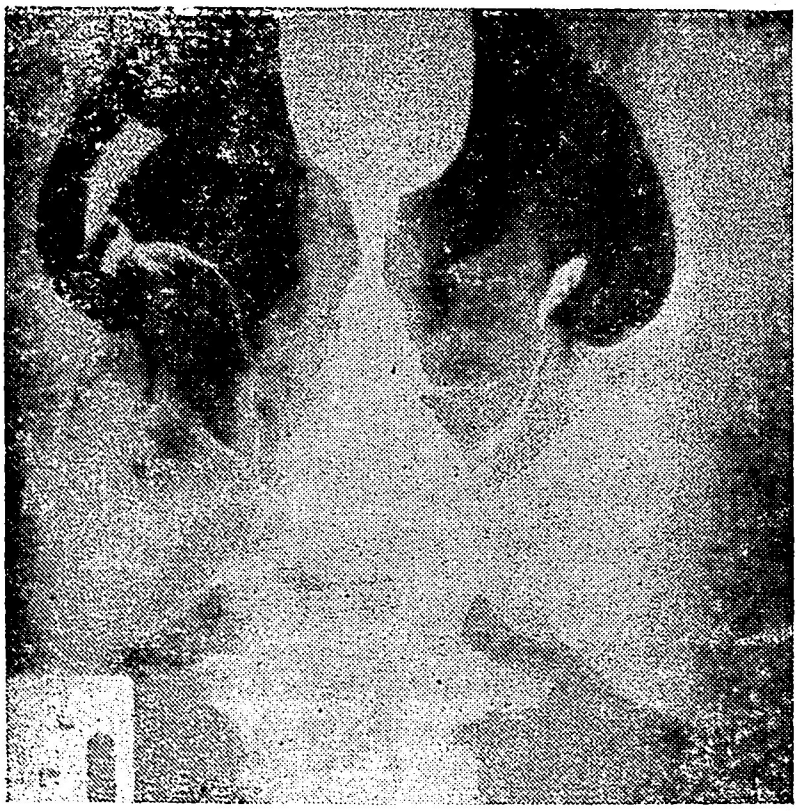


Fig.4.—Hysterosalpingography of a case of habitual expulsion of IUCD.

Fig. 5.—X-ray showing Lippes lopp during expulsion

related to the composition and configuration of the devices, the hand fashioned silk worm gut intrauterine rings, although, assume the intracavitary countrour of the pterus, yet they tend to evoke tissue reaction.

With the advent of the virtually inert and malleable plastic compounds, capable of architectural «recoil» several devices have been designed in the form of spirals, loops and rings.

Margulies claimed that his device for example (Fig. 2) has a very high expulsion rate at the beginning of his experimentation by increasing the size of the device the ejection rate was reduced, but this was on the expense of increasing the hazards due to uterine irritability. Mangulies expulsion rate now is 19.6 during the first year for the large spiral and 30.0% for small spiral . We consider that this high expulsion rate in fact is due to the tailed extension of the device being in the cervical canal and the uterine contractions would partially uncoil the

Fig. 6.—Coiled loop inserted in the sagittal plane-Expulsion was recorded one week after insertion.

device facilitating its expulsion. This fact has been obviated in our new device. Thus instead of the free end of the coil being direted to the cervical canal it is directed towards the uterine fundus. Thus uterine contractions will produce more coiling of the lower past of our device. This will result in drowing of the coil towards the fundus, rather than pushing it into the lower narrow ejectionive portion of the uterine cavity. The Lippes Loop has achieved its success in the positional stabilization in the higher and dimensionally greater area of the fundus through an «accordion» effect. However the lowest horizontal part of Lippes loop lying in the lower part of uterine cavity is week and liable to be streched under the effect of uterine contractions and may be pushed later into the carvical canal. This persumably is the mechanism of its expulsion see (Fig. 5). It may also explain the high rate of expulsion during the first year after insertion 8.5%. Also the tip of the lower end of Lippes Loop is always in direct contact with the endometrium of uterine wall which is activily contracting at different phases of the cycle. We consider that direct irritation of this tip may explain the high incidence of bleeding and spotting in the group of women using Lippes Loop. Frequently during removal of Lippes Loop

great force was needed and then their threads passing though the cervical canal were cut while pulling. Such cases needed dilatation of the cervical canal and we found that the cause of this difficulty is due to embeding of the tip in lower part of uterine wall (Fig. 7). So to overcome the problems of expulsion and bleeding we designed our new device which while fulfilling the desirable contraceptive effect at the same time it is almost devoid of the above mentioned hazards.

Our idia is to design a device that would fit in the uterine cavity and become stable at its upper part (fundus) so it will not drop in the lower part of uterus or rotate in its cavity. Also we avoided the formation of tipped tailed end that would be weak enough to streched or become easily wedges and into the relaxed ejective thinner cervical segment. The upper part of the device is fashioned in the form of an S to accomodate the trianguler or trapizoid shape of uterine cavity whereas the lower part is made in the form of a coil with its tip in the centre away from the uterine cavity (Fig. 8, 9, 10).

In order to achieve a painless insertion we used the small bore introduced used for Lippes 10 loop but we added a little modification to its tip. During the process of extrusion of the temporarily straigh-

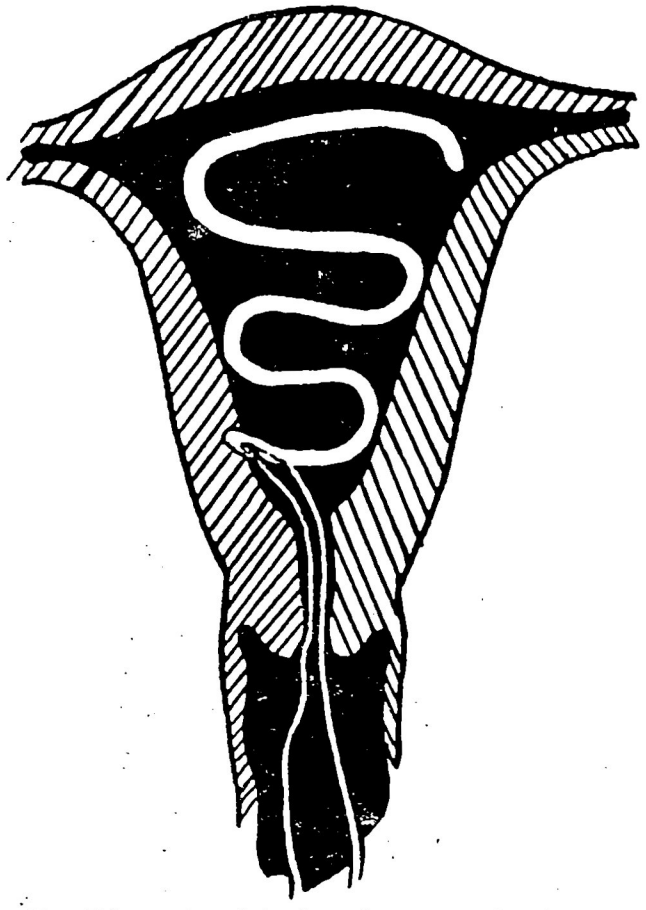


Fig. 7.—Diagram showing lower end of Lippes Loop embedded in the uterine wall.

Fig. 9.—X-ray showing the coiled loop in anteverted uterus, note loop in the frontal plane.

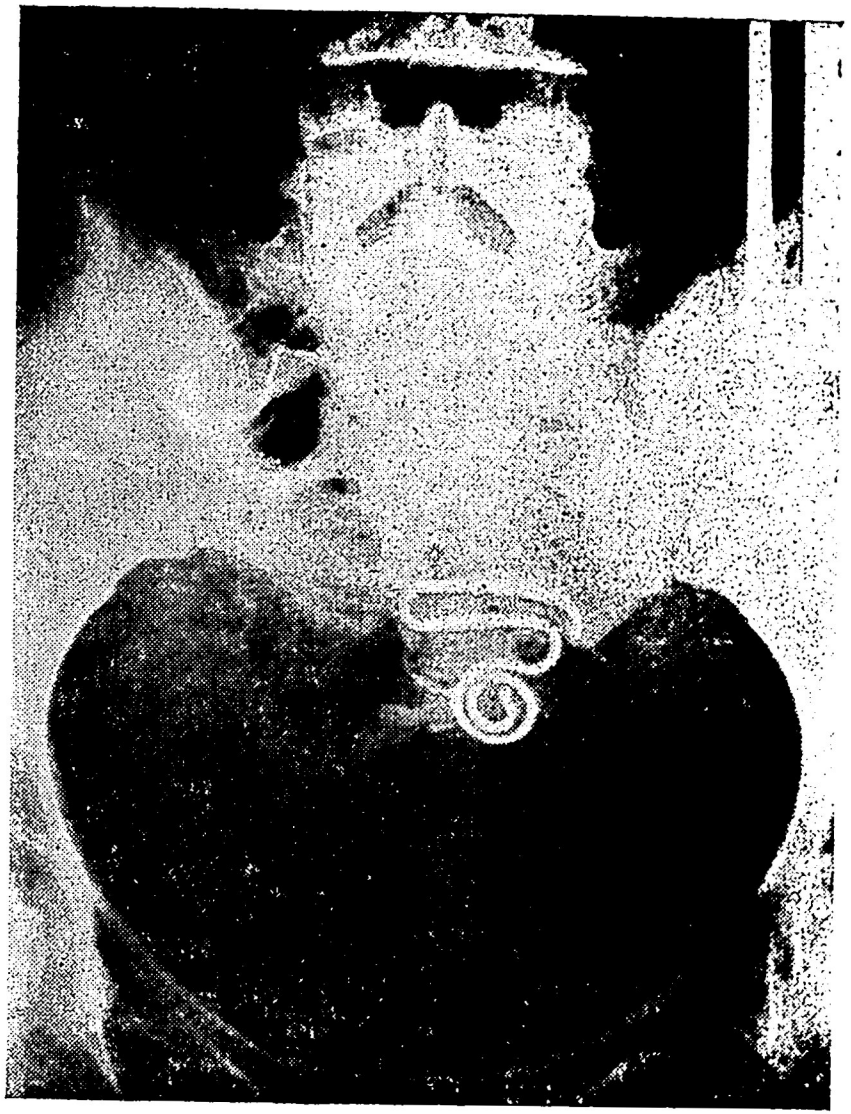


Fig. 8.—X-ray showing coiled loop in the uterine cavity.

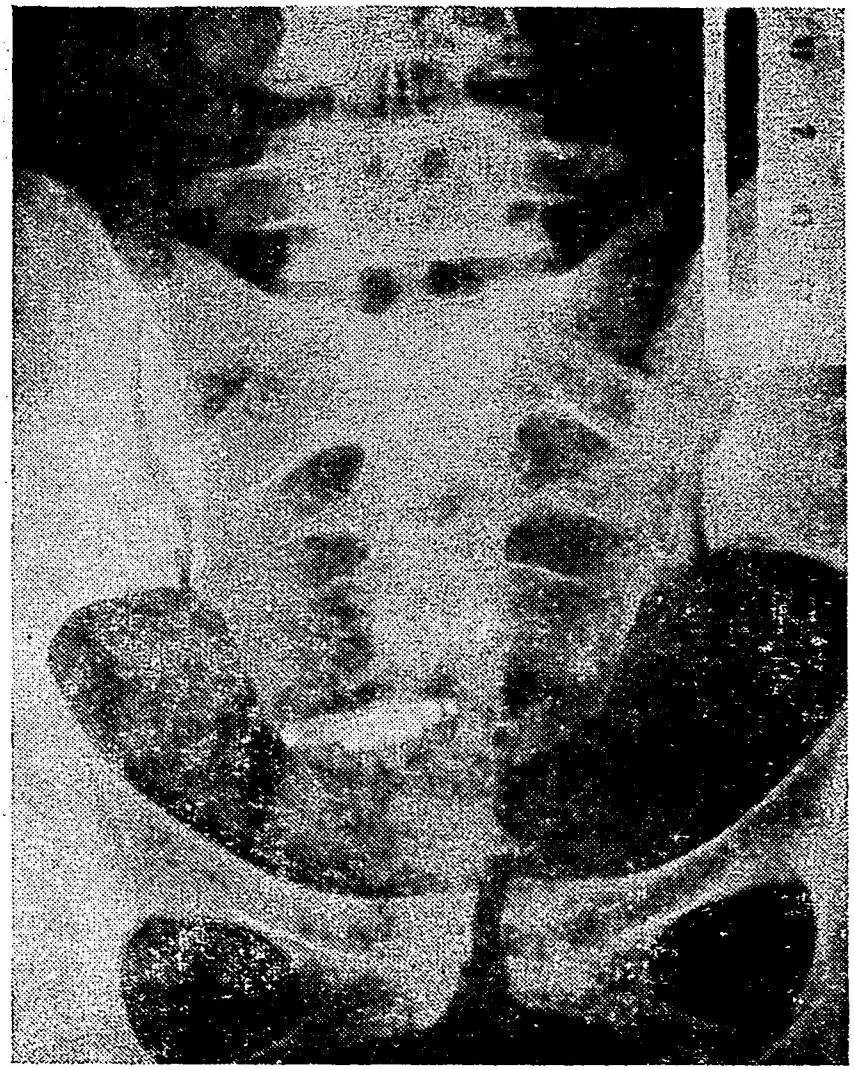


Fig. 10.—X-ray showing the coiled loop in Retroverted uterus, note loop in frontal plane.

tened device, we found that part of it goes to the right and another part to the left and so on till the coiled end is delivered through this narrow pore of the introducer. Sowe tought or cutting the tip of the introducer from both sides (Fig. 3) to allow the design to reform easily to its original shape by the so-called «memory capability». This new tip has also the advantage of being more easily pushed without need of dilating the cervix and also this blunt pointed end is less injurious to the cervical canal if compared to the circular sharp end of the Lippes introducer (Fig. 1 and 3).

CONCLUSION

Comparing the clinical results of the coiled loop as compared to the Lippes Loop (Table) we deduced the following data.

As regards its contraceptive efficiency not a single case of pregnancy is yet repoted although this is too premature to give final proof except after further follow up of more women monthes of use, which we are now doing, yet the preliminary report is most promising.

The total side effects with the coiled loop is 91 (21.9%) which is significantly lower as compared to those using Lippes Loop 193 (46.7%).

The expulsion rate is 1.7% as compared to lippes loop 6.7%.

The bleeding is 9.8% for the coiled loop which compared favourably with the 28% bleeding in the Lippes loop users.

SUMMARY

1. A new design for the intra uterine contraceptive devise is presented.

2. The shape of the coiled loop was so designed to fit in the uterus at the same time avoid the factors leading to its expulsion. The coiled loop was also designed to eliminate rotation and wedging in the uterine cavity so minimizing the two major side effect of the IUCD mainly expulsion and bleeding.

3. A clinical trial with the coiled loop is carried on a group of 417 women a total 2094 women months.

4. The results were analysed and so far are promising and indeed after further wider trial it would be an achievement towards an ideal contraceptive device.

ADDENDUM — MARCH 1968

Although this report is brief, it condences a fairly large amount of information obtained in the field survey of intrauterine contraceptive devices. A résumé of the major points might be of value.

1. The total number of women who applied the New Coiled Loop to date in these three family planning centres are 1028.

2. 80% of married women in this group do not want more children than they now have. They recognize that the fewer births are needed now in order to be able to give them full education and care.

3. The thable below shows the number of first insertions, aggregate women months of use, events i.e. pregnancies, expulsions, removal, cases of pelvic inflammatory disease and patient lest follow up .

4. Experience has shown that expulsion may be noticed or unnoticed by the wearers. In case of our new device the number of unnoticed is nearly the same as the noticed expulsion.

5. Removal for the reason of bleeding still encountered in very small number if compared for other reasons of removal as desire to get pregnancies or lack of confidence.

6. During the period of 11,417 months of use the device proved to be suitable to 90% of women. Comparing this with the results previously published by Makhlouf and Rifai which showed that the Lippes loop was suitable only to 80% of women.

Number of first insertions, women months of use and events.

Events	Number and percentage	
First insertions	1028	
Women months of use	11417	
Pregnancies	0	
Expulsions :	0	
Noticed by users	16	
Not noticed by users	15	
Total	31	(3%)
Removals :		
Bleeding	8	
Personal reasons	43	
Non relevant reasons	21	
Total	72	(7%)
Bleeding :		
Heavy	12	
Moderate	47	
Spotting	33	
Menstrual irregularities	23	
Total	115	(11.5%)
Pelvic Inflam. disease	12	
Lost follow up	24	

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