LIPPES LOOP — A CLINICAL EVALUATION

by

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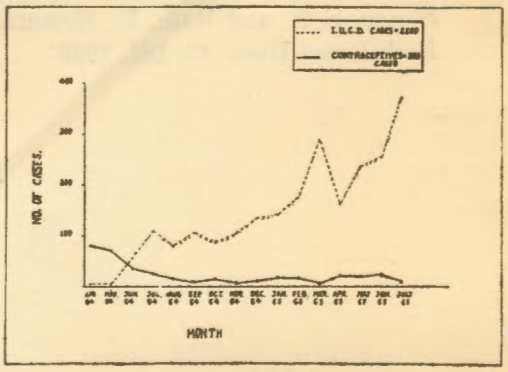
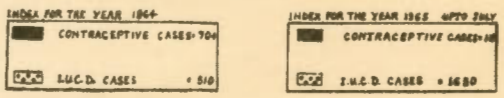
Grafenberg was the pioneer worker in the field of contraception by intra-uterine devices. His work, in 1920-1930, aroused a great deal of interest all over the world, but the high incidence of infection and other complications attendant upon the use of Grafenberg rings soon spelt their doom. Several modifications continued to be devised and formed the subject of small studies, till Oppenheimer published his remarkable results with the silk-worm gut ring, in 1959. This latter study caused their widespread use and renewed interest in intra-uterine devices, which at the present time have become one of the most widely accepted and popular methods of contraception.

Graph I shows the attendance month-wise of the patients seeking contraception by the traditional methods and the intra-uterine devices. The number of new patients seeking advice for the I.U.C.D. has been steadily increasing, but touched a peak in July 1965, i.e. 378. In spite of the unprecedented rush, the clinic has continued to give advice on the traditional contraceptives, besides encouraging female sterilization. Graph I also shows clearly that the demand for traditional contraceptives is steadily decreasing.



Graph 1.



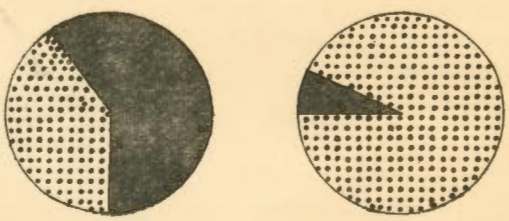


Fig. 1

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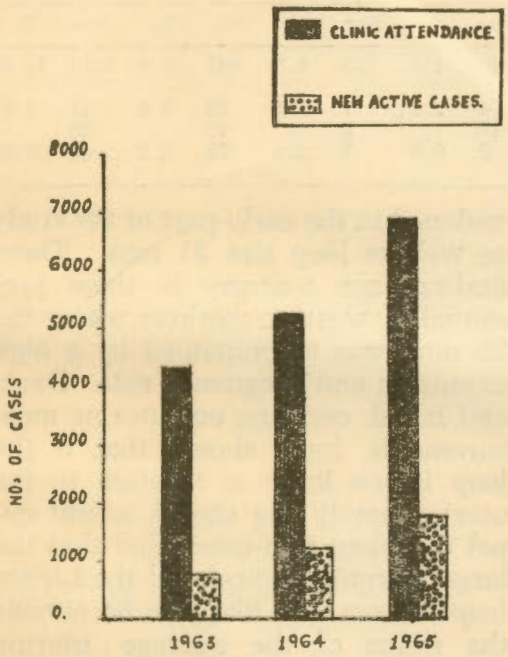
Figure I gives an idea of the patients with regard to the method of contraception during the year 1964 and the first seven months of 1965. The above figures are only for new patients who were actively using some method of contraception. The new cases for traditional contraceptives were 510 compared to 704 for I.U.C.D. in 1964 but in the first seven months it fell to 119 compared to 1950 for the I.U.C.D.



Graph 2.

In spite of the decrease in patients demanding traditional contraceptives, the work load of the clinic has continued to rise as seen from Graph 2. The total attendance at the clinic increased by nearly 20% in 1964 over that of 1963. In the first 7 months of 1963 the total attendance rose by 31.3% over that of 1964.

At the inception of the study both the Marguiles spiral and the Lippes loops were accepted for evaluation. In the early part of the study, it became obvious that Marguiles spiral gave rise to many more side-effects, expulsions and removals. As the patients had the least number of side-effects with the loop sizes, 27½ mm. and 25 mm., preference was given to these sizes.

The total number of insertions from April 1964 to the 1st of August 1965 was 2,411, the new cases being 2,350, giving 10,582 woman months of use. During this period a total of 5 pregnancies were observed. In 2 patients, the device was inserted on the 22nd and 24th day of the period and the pregnancy continued undisturbed. One delivered a full-term baby with the loop, size 27½ mm., in situ, and the other is continuing. One patient deliberately gave wrong dates and though the device was introduced, the pregnancy continued undisturbed and the device was removed easily 3 weeks later. Two patients reported unplanned pregnancies — one with device in utero and the other after an unnoticed expulsion 5 and 6 months respectively after insertion. The first patient started bleeding irregularly and expelled the loop 25 mm. with a 3½ months, foetus and the other patient is 28 weeks pregnant. This gives an extremely low rate of pregnancy i.e. 0.56% women years of use counting all the five pregnancies. This incidence is much lower than the 2.9, 6.3 and 5.3% reported by Jack Lippes, Satherthwaite and Lec *et al* respectively but is comparable to the Indian Council of Medical Research study of 0.62 (April 1965). Zipper using

nylon rings reported a figure of 3.7 while Tietze in a statistical analysis gave a figure of 4.6 in the group under medical supervision and 7.2 in the group without supervision. As our study has been carried out under close medical supervision, it may be responsible for the low pregnancy rate.

88%, though the number of cases is admittedly small. There is no significant difference in the expulsion and removal rates for the 27½ and 25 mm. size and the acceptability of the small size (25 mm.) is definitely higher. On account of the high failure rate and the complaints of the husbands, both the spirals were abandoned in the early part of the study as well as loop size 31 mm. These findings are contrary to those presented by western workers where the 25 mm. was accompanied by a high expulsion and pregnancy rate. Davis and Isreal, carrying out uterine measurements, have shown that if the loop is too large in relation to the uterine cavity the uterus would expel it. They also concluded that the large Marguiles spiral and the Lippes loop 31 mm. are likely to be outside the range of the average uterine cavity. This may also explain the high expulsion rates reported by western authors. Burnhill and Birnberg, using super imposition hysterography, concluded that the smaller devices (25 mm. Loop), by not providing adequate coverage of the fundus would be likely to result in a higher pregnancy rate. It may be further concluded that after a certain range, the smaller devices would show a higher expulsion rate.

TABLE I

Over all	No. of cases	Marguiles Spiral				Lippes Loop							
		Large		Small		31 mm.		30 mm.		27½ mm.		25 mm.	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
	1st Insertions 2,350.	35	1.5	57	2.4	45	1.9	113	4.9	887	37.8	1213	51.6
3.9	Expulsion 94	5	4.3	7	12.3	4	8.8	1	.88	25	2.8	51	4.2
3.5	Reinsertions 61	1	..	2	..	10	..	2	..	17	..	29	..
3.4	Removals 80	2	5.7	1	1.7	3	9.9	3	2.6	25	2.8	46	3.8

The above table gives the split up of the total number of devices according to size with the incidence of expulsions, re-insertions and removal size-wise. It is clear from this table that both the large and small spirals have a very high expulsion rate which is comparable with the large loop 31 mm. The removal rates for the large spiral and loop are also high i.e. 5.7 and 9.9 per cent respectively. The over-all expulsion rate is 3.9% which is much lower than the 13.8% reported by Satherthwaite but is close to the figure of 4.9% reported by the Indian Council of Medical Research. In Satherthwaites study the incidence of expulsion was higher with the smaller sizes of the loop, which is contrary to our findings. Tietze reported an expulsion rate of 8.2%. The incidence of bleeding and pain were also much higher with the large Lippes loop and both the Marguiles spirals. The expulsion rate for the 30 mm. size loop is the lowest

Keeney working in Taiwan on Chinese women has concluded that the loop size 27½ mm. gave the best results. Our findings would encourage us to think that perhaps the Indian uterus is smaller than its American counter-part. Thus the device characteristics must take into account the uterine morphology and should be so designed as to minimise side-effects and expulsions, besides achieving effective contraception; 50% of the expulsions were complete by the end of the first month and about 20% and 15% by the end of the second and the third month respectively. After the third month, the incidence fell rapidly. About 57% of the expulsions were accompanied by bleeding and cramps. In five of the seventeen cases where the device was expelled after 3 months, there was history of an excessive and profuse period.

Reinsertions

In several studies no reinsertions were carried out at all as it is usually argued that, if the indication is severe enough to warrant removal, reinsertion should be out of the question. In a total of 174 expulsions and removals there were 61 reinsertions, giving an incidence of 35%. In 51 of these cases, the device was retained giving a successful result in 84% of the cases. We do not agree with Tietze that reinsertion is of little or no value. In the Koyang project in South Korea no reinsertions were carried out in 60,000 insertions. Regarding reinsertions 10 cases could be classed as "habitutal expellers", the device being cast off soon after reinsertion. The size of the device in these cases did not appear to influence the expulsion and the last patient had every size and type of device without success. Reinsertion was carried out with a larger size when the small sizes were expelled and vice versa.

Removals

There were 80 removals in all in 2,411 insertions, giving an incidence of 3.4%. This is lower than the figure of 5% reported by Satherthwaite and the Indian Council of Medical Research. Our rates of removal are low and reinsertions high as the patients have no other suitable method of contra-ception to fall back upon. In some of the patients irregular bleeding and other symptoms persisted for 4 to 6 months before the patients consented to removal. The causes for removal are listed in Table II. The most frequent indication for

TABLE II

Causes for Removal

Relevant			Irrelevant		
Causes	No.	%	Causes	No.	%
Bleeding	27	33 8	Husband not agreeable	20	25.5
Pain in back	4	5.0	Patient nervous	7	8.7
Infection with bleeding	1	1.2	Not getting satisfaction	5	5.5
Rash with bleeding	1	1.25	Vasectomy	2	2.4
Pregnant when device inserted	2	2.4	Sterilization	1	1.25
			Wants children	9	11.25

removal was bleeding which was heavy, cyclic in 25% of the cases whereas it was spotting off and on in another 7 cases. The total number of removals for abnormal bleeding was 27 i.e. 33.8%. The bleeding was often accompanied by cramps and its aetiology remains obscure. In some cases where removal or expulsion occurred with abnormal bleeding, reinsertion was not accompanied by haemorrhage. Margolis *et al* working in San Francisco treated cases of abnormal bleeding with ascorbic acid or citrus bioflavinoids after I.U.C.D. insertion. They found no difference in the treated and the control groups. They, however, reported that the incidence of intermenstrual spotting was reduced in the treated cases, probably due to decreased capillary permeability. In 41.2% of the cases the removal was purely on psychological grounds. In 26.2% of the cases the husband insisted on removal for no apparent cause. One patient developed generalized rash and itching not responding to anti-allergic drugs necessitating removal. Frank evidence of infection with fever and bleeding was observed in only one case in the early part of the study. She had reinsertion 3 months later with no untoward results. In two cases removal was carried out as the patient was pregnant. Removals presented no difficulty and in no case was the device embedded in the uterus.

Follow-up

85.6% of 2,020 cases reported for follow-up after one month of the insertion of the device while 963 or 52.3% of the cases reported after 3 months; 753 or 32.3% of the patients reported after 6 months and 5% after one year. The latter figure is low because few devices were inserted in the early months. 361 or 15.4% of the cases have been excluded from the study as in 125 cases the device was expelled or removed and 136 cases have been completely lost to follow-up. 48.2% of the patients had no abnormal bleeding at all while in 51.8% there was some bleeding after insertion. In 45.5% the bleeding did not call for any special treatment while in 6.3% the bleeding was severe. Our figures are in agreement with those of Satherwaite i.e. 55% had abnormal bleeding while in 7% it required treatment. Baumgold on the other hand reported 95.4% abnormal bleeding in her series of cases with the Marguiles spiral. Marguiles observed 15% of his patients had bleeding severe enough to require treatment. This figure is more than double of ours. He observed good results with Vit. C 200 mgm. daily. 210 or 8.9% of our cases had side-effects necessitating repeated visits to the clinic. In the South Korean study 15% had mild, 3% moderate and .3% severe side-effects. Endometrial biopsies were carried out on 60 cases, 3 months after the insertion of the device, but the results are inconclusive. Bacteriological investigations are now in progress concurrently with endometrial biopsies, to see if any correlation can be obtained. Don Jessen and Jack Lippes found 9% and 9.5% incidence of inflammation in endometrial biopsies. Lippes was, however, unable to correlate his results with bacteriological findings and believed that the

endometrial findings only potrayed a sterile foreign-body reaction. Wilson, however, reported a considerable number of preinsertion positive cultures which fell after the insertion of the device. Other well controlled studies by Mishell *et al* and Vorys *et al* have indicated the definite presence of a subclinical infection in a certain percentage of cases. The effects and sequelae of this complication await further elucidation.

Summary

2,250 cases, fitted with the intrauterine devices, have been evaluated in relation to expulsion, removal and reinsertion.

2. Lippes loop, sizes 25 mm. and 27½ mm., have been extensively used forming 89.4% of the total insertions. The very high acceptability, low rates of expulsion and removal, make these devices a first choice. The results with 30 mm. loop are also encouraging but more work requires to be done as the number of cases is small.

3. Reinsertions in selected cases appeared to yield good results and 84.6% of the reinsertions were retained.

4. Though frank infection was not a big problem the question of subclinical infection requires further investigation.

5. Pregnancy rate was very low i.e. 0.56 per 100 women years of exposure.

6. The cause of abnormal bleeding remained obscure.

7. 80% of the expulsions were completed in the three months after insertion.

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