INTRA-UTERINE CONTRACEPTIVE DEVICES

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PROCEEDINGS OF THE CONFERENCE
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edited by

CHRISTOPHER TIETZE and SARAH LEWIT

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FOREWORD

The conference on intra-uterine contraceptive devices, initiated and sponsored by the Population Council, was held at the Carnegie Endowment International Center in New York City on April 30 and May 1, 1962.

Dr. ALAN F. GUTTMACHER, then Chief of the Department of Obstetrics and Gynecology at Mount Sinai Hospital and now President of the Planned Parenthood Federation of America–World Population Emergency Campaign, served as chairman of the conference. The steering committee consisted of Dr. GUTTMACHER, Dr. WARREN O. NELSON, Medical Director of the Population Council, and Dr. CHRISTOPHER TIETZE, Director of Research of the National Committee on Maternal Health. A preliminary report on the conference was issued by the Population Council in July, 1962.

The proceedings include the full text of all papers presented at the conference and a condensation of the discussion. All participants have had the opportunity to revise the transcript of their remarks, and most have done so. While the edited copy of all papers has been submitted to each author for his or her approval, the editors are responsible for condensation and rearrangement of the discussion.

The X-ray pictures accompanying Dr. MANN's paper were made by Mr. JOHN PEDERSEN; the other illustrations were drawn by Miss SHIRLEY BATY; both of Memorial Hospital, New York City.

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INTRODUCTION

by

WARREN O. NELSON, Ph.D. and ALAN F. GUTTMACHER, M.D.

DR. NELSON: Before turning the meeting over to your Chairman, I should like to welcome all the conferees in the name of the Population Council and of the Steering Committee. Some of you have come great distances and we appreciate your interest—as well as that of those who come from shorter distances—in joining us for what we hope will be a very pleasant and rewarding experience.

We are meeting today just two months after the decision was reached to have a conference on the subject of intra-uterine contraceptive devices. Obviously, the time was much too short to accomplish what we really would have liked and could have done had six months or more been available. We decided, however, that the subject was of sufficient importance to urge that a conference be held as soon as possible. I think we are very fortunate that almost everyone who was asked has accepted and is here. Many more people would have liked to have attended but the Steering Committee felt that the purpose of the conference, which is fact-finding—and let me emphasize that, purely fact-finding—would be defeated if the attendance were too large.

We hope that the experience of those who are assembled here will enable us to analyze the effectiveness, the safety, and the possibility of widespread use of intra-uterine contraceptives as a method of regulating fertility.

I shall now turn the meeting over to your Chairman, Dr. Alan Guttmacher. We hope that these two days will prove to be rewarding and valuable and we are confident that you will be happy that you have come.

Chairman GUTTMACHER: As Chairman, I trust you will hear little from me. My function is largely that of a traffic policeman—to keep things moving.

Thanks to the Population Council and the International Planned Parenthood Federation, I was able at first hand to see the population problem and what is being done about it in India and in much of Southeast Asia. I came back with the firm conviction that the reason the restraint of population growth in these areas is moving so slowly is the fact that the methods which we offer are Western methods, methods poorly suited to their culture and to the control of mass-population growth.

Our methods are largely birth control for the individual, not birth control for a nation. Therefore, I felt very strongly that new methods must be offered and, if the new methods are good and proper, results will be astounding.

Intra-uterine contraception, as Dr. Tietze will tell us, has an old history. Unfortunately, it has fallen into disrepute. Even if the newest modifications of the Gräfenberg ring prove to be safe and efficient, it is going to be extremely difficult to rehabilitate this method in the eyes of the medical profession throughout the world.

If these devices are really as valuable as they appear to be on superficial investigation, we will have the task of reinstating them into acceptable medical practice. The purpose

of this conference is to find out scientifically, honestly, and in depth the value of modern intra-uterine contraception. If it is efficient and safe, we must do everything we can to push it. If, on the other hand, you, who are assembled in this conference, feel that its use is hazardous or ineffective, then we must be equally frank in our appraisal.

This conference, in brief, is a fact-finding conference. Everyone must have the chance to state his experiences, his observations, and his opinions, because we are not trying to keep anything under the table. This is not a conference for the purpose of promulgating or even propagating intra-uterine contraception. This is a conference to attempt to determine what is known about it today. The group in attendance has been hand-picked, because it is felt that it can tell us most about the current situation all over the world.

INTRA-UTERINE CONTRACEPTIVE RINGS: HISTORY AND STATISTICAL APPRAISAL

by

CHRISTOPHER TIETZE, M.D.*

The history of intra-uterine contraceptive rings reaches back over four decades. Their forerunner was the stem pessary in its various forms, such as, the collar button, the wishbone, the Sterilett, and others. However, since stem pessaries are inserted into the cervix and do not lie wholly within the intra-uterine cavity, they are primarily intracervical rather than intra-uterine devices and, as such, do not belong in our discussion.

In the 1920's, German physicians began to use, for contraceptive purposes, silkworm gut, a suture material extracted in a single thread from a silkworm killed at the inception of its cocoon-spinning stage. Pust[62] described a pessary, consisting of several loops of silkworm gut attached to a glass button. The loops, placed in the uterine cavity, held the button over the external os. Another popular design consisted of two strands of silkworm gut, knotted at the ends to prevent injury, and united by a silver wire to be left in the cervical canal for easy removal.

Lehfeldt[46] has reported on the contraceptive effectiveness and side effects of these devices, based on 500 cases from his own practice and that of others over a period of two to three years. Known pregnancies numbered 24, or 4.8 per cent of the total. The method was found unsuitable for about one-third of the patients, of whom 5 per cent developed metrorrhagia; 10 per cent had a recrudescence of old inflammations in the adnexa and parametria; and 10 per cent, especially multiparous women, expelled the pessary. Cases of pelvic inflammatory disease and other side effects were reported by many authors of the period. [4, 5, 8, 19, 26, 36, 39, 41, 44, 57, 69]

Ernst Gräfenberg and his Time

Gräfenberg [22-24] of Berlin assumed that any device connecting the uterine cavity with the vagina provided an opportunity for an ascending infection. To avoid this risk, he placed the contraceptive entirely within the uterine cavity. His first intra-uterine pessaries were known as 'silk stars' and consisted of three short strands of silkworm gut, knotted at the ends, and tied in the center with fine silver wire to facilitate location either by sounding the uterine cavity or by roentgenography. Observing that the silk stars tended to be expelled by contractions of the womb, Gräfenberg abandoned them and replaced them with silkworm gut rolled into rings and bound with silver wire to hold them in shape. He used these rings for a number of years. By about 1928, Gräfenberg substituted for the silkworm gut pliable, spiral rings of coiled silver or gold wire, varying in size from 15 to 30 mm in diameter. A relatively small size (17.5 mm) was eventually found suitable for most of his patients. In later years, two or more strands of silkworm gut, or an additional

* National Committee on Maternal Health, Inc., New York, New York.

metal spiral, were introduced into the hollow of the coil to hold the ring together in case of a break at the point of junction. [29]

Gräfenberg was keenly aware of the existence of contraindications to the use of the intra-uterine ring. At each presentation of his method, he emphasized the necessity of carefully examining each patient to exclude all cases of pelvic inflammation, acute or chronic, and especially of gonorrhea. Submucous fibroids were another important contra-indication. To avoid inserting the ring when conception had already occurred, he advocated that the ring be placed immediately after menstruation.

Although inserting the ring was a relatively simple procedure, Gräfenberg stressed that 'a certain amount of gynecological experience is absolutely essential.' Strict aseptic precautions had to be observed; anesthesia was rarely needed. The anterior lip of the cervix was grasped with a tenaculum forceps and the cervical canal dilated to Hegar size 6. The ring could then be inserted easily by means of a specially designed instrument with a forked tip. (For a full description of the surgical technique in English, see Gräfenberg's report of 1930. [24]) Patients were instructed to take their temperatures for three days and were examined at the end of the first week and after the first menstrual flow.

In the beginning, Gräfenberg changed his rings at annual intervals, removing them before and replacing them after a menstruation. Later, he left the rings *in situ* for indefinite periods, but re-examined all patients wearing them each year to make sure that the ring had not been displaced and that no complications had arisen. For the removal of the ring, he designed an instrument ending in a slender hook.

Gräfenberg presented three reports on his intra-uterine contraceptive method—at a postgraduate seminar in Berlin in 1928, at the Third Congress of the World League for Sexual Reform in London in 1929, and finally at the Seventh International Birth Control Conference in Zurich in 1930. On this last occasion, he reported that of 600 patients fitted with silver rings, only 1.6 per cent had experienced failures of contraception.

The reception accorded to Gräfenberg by the medical profession ranged from enthusiasm to complete condemnation. His most important follower was Norman Haire [27-30] of London, who defended the method at the meeting of the German Gynecological Society in Frankfurt a.M. in 1931. In spite of a much higher percentage of failures among his patients than among Gräfenberg's, Haire continued to use the ring for a number of years, installing it in more than 1,000 cases. However, 'because of the possibility that it may be an unsuitable method, in a considerable proportion of women,' he did not recommend it in his last article, written shortly before his death in 1952.

Another early enthusiast was Leunbach [48-51] of Copenhagen, who learned about the ring at the Congress in London in 1929 and installed 175 rings during the next eight months. By June 1930, after observing a number of pregnancies and two cases of severe pelvic inflammation, Leunbach reversed his earlier judgment and rejected the ring as neither harmless nor sufficiently reliable.

The great majority of gynecologists did not wait until they had gained experience with the Gräfenberg ring but condemned the new method out of hand. This rejection was based partly on theoretical considerations, partly on a perhaps unavoidable confusion of the intra-uterine pessary with other, intracervical, devices, and partly on a series of unfavorable case reports involving the Gräfenberg ring itself. These reports will be discussed later. Suffice it to say that the opposition of the medical profession was so universal and so strong, especially in Germany [16, 17] and in the United States, [12] that with one single exception no reports on intra-uterine pessaries were published between 1934 [45] and 1959 in the medical journals of western countries by any physician who, himself, had used them. Textbooks of gynecology, if they discussed contraceptives at all, mentioned the intra-uterine ring 'only to condemn it.' Because of this attitude, Gräfenberg used his intra-

uterine rings rarely and with great reluctance after he came to the United States in about 1940; but it is not true, as claimed by Gesenius,[21] that he changed his favorable opinion about the method.[47]

The single exception referred to in the preceding paragraph is the report by Mary Halton *et al.*,[32] published in 1948. The present author was responsible for the statistical analysis in this report, and I frankly admit that I would not have dared to attach my name to so subversive a piece of medical literature had I not had the encouragement of the venerable Robert L. Dickinson, the other co-author. The device used was a single strand of the coarsest silkworm gut, about 30 cm long, rolled into a tight coil and sterilized by immersion in alcohol. The coil was then placed into a gelatin capsule and, after dilation of the cervix, introduced into the uterus by a probe. The capsule dissolved quickly, permitting the coil to expand and to fit itself into the contours of the uterine cavity. This procedure resulted in a diameter somewhat larger than that of the Gräfenberg ring, the average being 27.5 mm for 35 specimens examined.

To ensure continuous medical supervision, the coils were ordinarily removed every two months with a small blunt hook on the first or second day of a menstrual period and re-inserted as soon as the flow had stopped.

The Halton study was the first to compute a failure rate for an intra-uterine contraceptive method, according to the Pearl formula. The 266 patients included in the study experienced an aggregate of 468 years of exposure. During this period, four pregnancies occurred, corresponding to the exceedingly low failure rate of 0.9 per 100 years of exposure. Some uterine disturbance was, however, reported by almost two-fifths of the patients, resulting in the discontinuation of the method in one-fifth of the cases. Of the serious complications and sequelae, feared by so many in the medical profession, none were found.

A Second Look

By 1959 the time seemed ripe for a re-evalution of the Gräfenberg ring. Because no American physician could be found who had both personal experience with the method and was willing to report on it, the Editors of the *American Journal of Obstetrics and Gynecology* invited Oppenheimer [59] of Israel to contribute an article on the subject. Between 1930 and 1957, Oppenheimer equipped 329 women with a total of 866 rings. At first, he used silver spirals but later turned to rings of silkworm gut, which he improved by using four strands instead of three and by intertwining them three times instead of twice. The aggregate exposure of 793 woman-years with 20 pregnancies, for his cases, corresponded to a failure rate of 2.5 per 100 years of exposure. Oppenheimer considered the method to be absolutely harmless.

At about the same time, the *Yokohama Medical Bulletin* published an article by Atsumi Ishihama [37] on clinical experiences in the use of intra-uterine rings in Japan, based on 973 personal observations and a much larger but less intensively studied series of 18,594 cases in 149 hospitals. Japanese physicians had been interested in the subject since 1934 when Ota [60] described a modification of the Gräfenberg ring, consisting of an outer coil, 23 mm in diameter, in the center of which a small, hollow, lentil-shaped capsule about 8 mm wide and 4 mm thick, was suspended by three radial springs. Ota's ring was originally made of gold or gold-plated silver. It is still widely used in Japan, made either of metal or of plastics, such as, nylon or polyethylene. Some manufacturers have substituted a flat disk for the hollow capsule, and other modifications of the design have also been introduced. Although a considerable postwar literature exists on these rings, it is with few exceptions [13, 43] written in Japanese and thus not easily accessible to western scholars.

Ishihama's report was as favorable toward the intra-uterine ring as was Oppenheimer's. Among Ishihama's own patients, only eight (1.3 per cent) conceived with metallic rings and only six (1.7 per cent), with polyethylene rings. Although the percentage of pregnancies was slightly higher (2.3 per cent) in the large hospital series, the average period of observation was longer. Hence, any differences in failure rates between the three series, or between any of the Japanese series and Oppenheimer's patients, were probably quite small. Nor did Ishihama observe any serious side effects.

The two articles from Israel and Japan, especially Oppenheimer's, stimulated interest in intra-uterine contraceptive rings throughout the world. Physicians who had never previously seen a Gräfenberg ring began to use it. These experiments were not always successful, as shown by the case of a gynecologist in far-away New Zealand,[64] who inserted 140 rings. After a period of observation averaging less than ten months, nine women had become pregnant. His record also included two cases of severe hemorrhage, two severe inflammations, and two perforations of the uterus.

A far more encouraging conclusion to this brief historical survey is the article by Hall and Stone [31] of New York City, published in March, 1962. Hall had been a close associate of Gräfenberg, with experience extending over a period of 12 years. The rings were made of a coil spring of stainless steel, with a nylon thread within the hollow of the coil, and were about 22 mm in diameter. While the rings were left *in situ* for indefinite periods, patients were examined at intervals of six months.

The aggregate exposure of the 128 women included in this study amounted to 648 years with six pregnancies, corresponding to a failure rate of 0.9 per 100 years of exposure. Once more, there were no serious side effects of any kind.

Contraceptive Effectiveness

We are now ready to assess, in a systematic fashion, the accumulated experience with intra-uterine rings and related intra-uterine devices—not an easy task because of the rudimentary nature of some of the available statistics, especially those reported by early investigators. In some instances, it is not even clear whether the author's use of the term 'cases' refers to the number of patients or to the number of rings inserted.

Table 1 summarizes the information on pregnancies among ring wearers. The percentage of failures ranges from less than 1.0 to almost 10 per 100 patients. Owing to the fact that some series have had a much longer follow-up than others, the percentage of failures is not a suitable measure of contraceptive effectiveness. The low percentages of failures reported by Gräfenberg for rings, and by Manes,[53] Ota, and Ishihama reflect, at least in part, a relatively short observation, while the higher percentages of Torii and Maeda,[71] of Oppenheimer, and especially of Hall and Stone, are explained by the fact that their average periods of observation were two years, two and a half years, and five years, respectively. On the other hand, the series of Rutherford, Leunbach, and Haire, have high percentages of pregnancies in spite of a short average follow-up.

A more sophisticated measure of contraceptive effectiveness is the failure rate per 100 woman-years of exposure to the risk of pregnancy, which eliminates (or at least reduces) the effect of variations in the length of time patients are subject to observation. The requisite information on aggregate periods of exposure is available for the majority of the more recent studies, and can be estimated as rough approximations for the silver ring series of Gräfenberg and for those of Haire and of Leunbach. As shown in Table 1, the failure rate was less than 1.0 per 100 years of exposure, according to the observations of Halton and, more recently, of Hall and Stone. Rates between 2.4 and 2.9 were obtained by Gräfenberg, Oppenheimer, Torii and Maeda, and Ishihama, and even higher levels by

TABLE 1

Pregnancies with Intra-Uterine Rings and Related Devices

Author, Year, Material of Ring (Type of Device)	Number of Cases	Total Woman-years of Exposure	Number of Pregnancies	Pregnancies per 100 cases	Failure Rate per 100 Woman-years
Gräfenberg 1929					
silkworm gut (star)	451	NA	28	6.2	NA
silkworm gut	480	NA	2	0.4	NA
silver	150	NA	1	0.7	NA
Gräfenberg 1930					
silkworm gut (star)	400	NA	NA	3.1	NA
silkworm gut	1,100	NA	NA		NA
silver	600	*est* 400	NA	1.6	*est* 2.4
Manes 1930					
silver	100	NA	2	2.0	NA
Haire 1931					
silver	400	*est* 400	NA	8.5	*est* 8.5
Leunbach 1931					
silver	175	*est* 150	10	5.7	*est* 6.7
Ota 1934					
gold, silver	73	NA	1	1.4	NA
Halton *et al.* 1948					
silkworm gut (coil)	266	468	4	1.5	0.9
Doi 1953					
metal, nylon	100	NA	5	5.0	NA
Kondo 1953					
metal	188	NA	18	9.6	NA
nylon	91	NA	4	4.4	NA
Torii and Maeda 1956					
metal	258	550	16	6.2	2.9
Ishihama 1959					
metal	623	NA	8	1.3	NA
polyethylene	350	239	6	1.7	2.5
NA (hosp. series)	18,594	NA	425	2.3	NA
Oppenheimer 1959					
silver, silkworm gut	329	793	20	6.1*	2.5
Jackson 1961					
silver	98	NA	4	4.1	NA
Rutherford 1961					
silver, silkworm gut, nylon	140	111	9	6.4	8.1
Hall and Stone 1962					
stainless steel	128	648	6	4.7	0.9

* Computed per 100 insertions: 2.3 per cent.
NA: Not Available.

Haire, Leunbach, and Rutherford. These failure rates of the intra-uterine ring may be compared with the set of rates shown below, based on information obtained in 1957 from a sample of 1,165 metropolitan couples in the United States [74] and illustrating the use-effectiveness of the five most popular contraceptive methods.

Condom	13.8	Withdrawal	16.8
Diaphragm	14.4	Rhythm	38.5
	Douche	40.8	

One important reason for the high contraceptive effectiveness of the intra-uterine ring is, of course, the fact that once installed, it requires no further action by either partner, and thus does not permit 'taking a chance,' probably the most common cause of failure with other methods.

Contraceptive failure of the intra-uterine ring may result either from expulsion or displacement of the ring without the wearer's knowledge *(vide infra)* or from conception while the ring is in its proper place in the uterine cavity. Statistics on the relative frequency of the two categories of failures are fragmentary and contradictory.

The mode of action of the intra-uterine contraceptive ring has remained a mystery from the time of its introduction to the present day. Endometrial biopsies from Gräfenberg's patients, examined by the pathologist Robert Meyer, revealed an essentially normal picture: 'Highly functioning mucosa with viscous secretion in the glands and proliferation of the superficial epithelium. Localized edema of moderate degree. Stroma cells in the upper layers considerably enlarged. Distended vessels and occasional fresh blood extravasates throughout the mucosa.' Meyer did not find any changes of an inflammatory nature.[22] His observations were confirmed, with minor variations, by later investigators.[37, 59, 60] Some studies on animals (rabbits) suggest localized atrophy of the endometrium caused by pressure.[7]

There seems to be a consensus among those who have worked with the Gräfenberg ring that it does not interfere with the passage of sperm into the Fallopian tubes or with fertilization, but does prevent the implantation of the ovum in the uterine cavity. In support of this hypothesis, Gräfenberg [23] and others have cited the occurrence of tubal pregnancies, a number of which have been reported.[31, 35, 42, 52, 61, 63, 65] However, the argument is not conclusive since intra-uterine as well as extra-uterine pregnancies have occurred with the pessary *in situ*. Moreover, it can be shown that ectopic pregnancies occur far less frequently than would be expected if the contraceptive action consisted in preventing implantation, but not fertilization of the ovum.

While the incidence of tubal pregnancy varies considerably between populations, a ratio of 3 per 1,000 conceptions is probably a conservative estimate. If the frequency of conception is not reduced among wearers of intra-uterine rings, it must be assumed that it occurs at the same rate as conceptions during the first month of exposure among couples who have discontinued contraception with the intention of achieving pregnancy, *i.e.*, at a monthly rate between 200 and 300 per 1,000 couples. With 13 ovulations per year, the annual rate of conception would, therefore, be between 2,600 and 3,900 per 1,000 couples and the number of ectopic pregnancies, between 8 and 12.

We turn now to the seven studies of intra-uterine rings, which give sufficient information on aggregate exposure and pregnancies. Hall and Stone observed one tubal pregnancy; Oppenheimer states categorically that there were none; Leunbach discusses each

of his 10 pregnancies in detail and all are clearly intra-uterine. The other four studies (Halton *et al.*, Torii and Maeda, Ishihama, and Rutherford) are less explicit, but the presentation makes it extremely unlikely that any ectopic gestation occurred but was not mentioned. As shown in Table 1, the seven studies cover an aggregate exposure of about 2,960 woman-years during which one would expect between 24 and 36 tubal pregnancies, compared with the single one reported by Hall and Stone. 'Several' cases of ectopic pregnancy, reported by Gräfenberg, are not included here since it is not known among how many patients and during what period of exposure they were observed.

It would appear, therefore, that another mode of contraceptive action may be involved. The nature of the mechanism remains, however, unknown. Two early Russian authors, Stefko and Lourié,[67, 68] attributed the action of intra-uterine silkworm gut to a change in pH from a normal 7.5-8.0 to more than 9.0, but their findings have not been confirmed by later investigators.[7] Much work remains to be done in this area.

Effect on the Fetus and Future Fertility

The possibility of damage to the developing infant, conceived in spite of an intra-uterine contraceptive, has been a matter of concern. The usual evidence of severe fetal damage is, of course, the death and expulsion of the fetus. It is not known whether the incidence of spontaneous abortion is higher in the presence of a ring than under other conditions. The statistics are vague on this point, and one gets the impression that a sizeable proportion of unintended pregnancies has been artificially terminated, either on medical grounds or otherwise. Most of the few cases of apparently spontaneous abortion, reported in the literature,[9, 66, 72] present nothing unusual from the clinical point of view; one case [41] was followed by fever of 104° F, which raises some doubt about the diagnosis. More direct evidence of fetal damage was offered by Stefko and Lourié, who recovered five specimens by D & C in the third to sixth week of gestation. Prior to conception, intra-uterine pessaries of silkworm gut had been worn for periods of four to eight months. The embryo was missing in two cases, completely disintegrated in one case, and apparently undamaged in the remaining two. The authors also described changes in the chorionic villi, which they interpreted as indicating blastophthoric action.

Later investigators have discounted the validity of this interpretation and have pointed out that none of the infants carried to term by ring wearers, nor their respective placentae, have shown any deformity. The number of such cases, reported in the literature,[2, 18, 23, 40, 51, 54, 59, 65, 66, 70] is large enough to justify the conclusion that fetal damage, if it occurs at all, is not a common or frequent result of the use of intra-uterine pessaries.

Nor is there evidence that the ring causes permanent sterility. Gräfenberg [24] and Oppenheimer, both of whom had great experience extending over many years, state that 'numerous' patients conceived immediately or shortly after removal of the ring, and Oppenheimer adds that in no case was treatment for sterility required. Others give specific figures. Of the women studied by Halton *et al.*, 15 were 'known to have stopped or interrupted the use of the coil because they planned to have a baby. Of the 12 who could be followed, all but one conceived without undue delay. The one who did not was in her 44th year.' In the survey of Hall and Stone, 11 women had the ring 'removed 13 times because (they) contemplated pregnancy . . . After removal, conception followed readily in all cases. The longest interval from removal to conception was three months.' According to Torii and Maeda, conception occurred in 95 per cent of 151 women who had had the ring removed, including 74 per cent who conceived within six months.

An intra-uterine pessary may, of course, prevent a desired pregnancy if its presence is forgotten by the wearer or if she believes, erroneously, that the ring has escaped or been

removed. In recent years, seven such cases have been reported,[14, 63] who had worn Gräfenberg rings for periods of 4 to 11 years. Four of these patients are known to have conceived after the ring was taken out. In one case, sterility persisted and the uterine mucosa showed endometrial hyperplasia with chronic inflammation. For the remaining two cases, no information is available.

Side Effects and Complications

The insertion of a Gräfenberg ring is usually followed by a slight bleeding, until any superficial lesions of the uterine lining have healed, and by contractions of the uterus, which often cause pelvic pains. These symptoms ordinarily cease within a few days. However, more serious disturbances, which may force removal of the ring, have been noted by most investigators. These include menorrhagia beyond the first menstruation following insertion, metrorrhagia, persistent pain, discharge, and any kind of pelvic inflammation. The frequency with which these disturbances are reported varies greatly and probably reflects not only the shape, size, and material of the pessary and the surgical skill of the physician, but also his experience with the method and his confidence in it. Ishihama removed the ring in 3.2 per cent of his cases; Kondo in 3.6 per cent (both had a higher ratio with metallic than with plastic rings); Hall and Stone in 3.9 per cent; Haire in 5 per cent; and Torii and Maeda in 7 per cent. Halton *et al.* with 20 per cent, and Leunbach with about 30 per cent, reported much higher ratios.

The intra-uterine ring may be expelled by contraction of the uterus. Expulsion into the vagina may be complete or partial, resulting in a displacement of the pessary into the cervical canal, where it may be found protruding from the external os. Even complete expulsion may remain unnoticed by the wearer, in which case the usual result is an unintended conception. Expulsion appears to occur more often if the ring is too large.[24, 27, 59] On the other hand, too small a ring is said to permit conception with ring *in situ*.[24] Table 2 summarizes published data on expulsion. The overall average seems to be in the vicinity of 7 per cent, but the variation is great and does not follow a readily recognizable pattern. Repeated expulsions have been observed but seem to be the exception rather than the rule. 'False' expulsions may also occur, i.e., cases in which a pessary is actually in the uterus but is not found by the examining physician who tells the patient it had escaped.[58, 70, 73] If the search for the missing ring is conducted too energetically, the uterus may be perforated.[54] Such accidents, as well as perforations during the insertion of the ring,[64] may be responsible for most, if not all, of the cases involving alleged migration of the Gräfenberg ring into the parametria or other extra-uterine locations.[1, 14, 15, 55]

The most serious complications observed in connection with intra-uterine pessaries fall into the category of pelvic inflammatory disease, including endometritis, metritis, salpingo-oophoritis, pelveoperitonitis, and generalized sepsis. Gräfenberg in 1929 reported 13 cases of 'inflammation' following insertion of silk stars (2.9 per cent) and 4 cases with rings of silkworm gut (0.8 per cent), without specifying the nature and severity of the condition. No comparable accident occurred among 150 wearers of silver rings. Unfortunately, he gave no statistics for 1930, by which time the number of silver rings had quadrupled. Leunbach observed two cases of severe adnexitis among 175 women. He also removed the ring in three cases of acute gonorrhea. The hapless Rutherford had two cases of staphylococcus infection in his group of 140. Norman Haire, with 400 patients, also extracted two rings because of gonorrhea, but 'did not see anything of the other horrible consequences,' according to his statement at the meeting in Frankfurt in 1931.[28] No case of pelvic inflammatory disease was reported among the 2,604 patients observed by Manes, Ota, Halton, Doi, Torii and Maeda, Kondo, Ishihama, Oppenheimer, Jackson,[38] and

Hall and Stone. Seven instances of fever were, however, reported in Ishihama's hospital series of 18,594 cases.

TABLE 2

Expulsion of Intra-Uterine Rings and Related Devices

Author, Year, Material of Ring (Type of Device)	Number of Cases	Cases with Expulsion	
		Number	Per Cent
Gräfenberg 1929			
silkworm gut (star)	451	37	8.2
silkworm gut	480	6	1.2
silver	150	1	0.7
Haire 1931			
silver	400	NA	20.0
Leunbach 1931			
silver	175	34	19.4
Halton *et al.* 1948			
silkworm gut (coil)	266	21	7.9
Doi 1953			
metal, nylon	100	2	2.0
Kondo 1953			
metal	188	4	2.1
nylon	91	8	8.8
Torii and Maeda 1956			
metal	258	4	1.6
Oppenheimer 1959			
silver, silkworm gut	866*	NA	5.0
Rutherford 1961			
silver, silkworm gut, nylon	92	10	10.9
Hall and Stone 1962			
stainless steel	128	6	4.7

* Insertions of rings, not number of patients.
NA: Not Available.

A reasonably careful search of the medical literature in the English, German, and French languages revealed 18 additional cases of pelvic inflammatory disease involving intra-uterine rings, including one or two instances of inadequate descriptions of the foreign body. The majority of these reports is concerned with metal spirals. Most of them appeared in the 1930's, before sulfa drugs and antibiotics became available. The period during which the ring had been worn, when stated, ranged from a few months to several years.

In eight of the case reports,[3, 6, 20, 33, 66] the pelvic inflammatory disease was definitely severe, usually involving major surgery. One woman died eight months after insertion of a Gräfenberg ring. The post-mortem findings included chronic general infection, origi-

nating from an old encapsulated abscess of the left adnexa with perforation into the sigmoid and the soft tissues of the pelvis and thigh, etc., etc. Unfortunately, no clinical data are available for this patient.

In most of the other ten cases,[10, 11, 25, 34, 54, 56, 72] the complaints were of a comparatively minor nature and ceased promptly after removal of the pessary.

In spite of dire forebodings, no case of carcinoma seems to have been reported in the literature which could be traced to an intra-uterine ring. Gräfenberg, Halton *et al.*, Oppenheimer, and Hall and Stone, whose investigations extend over long periods, state categorically that no malignancies were observed. Ishihama reports one case of collum carcinoma, diagnosed one year after insertion of an Ota ring. The histological examination showed that 'the squamous cell carcinoma ... disappeared about 1.3 cm from the external os, and did not pass over the internal os. Therefore, there was no relation between the ring inserted in the uterine cavity and the ... carcinoma of the cervix.' A similar case was reported by Shimomura.[37]

In summary, then, the Gräfenberg ring and its modifications have proved themselves, in skilled hands, to be highly (but not 100 per cent) effective contraceptives. They do not cause permanent sterility nor are they known to have damaged any child accidentally conceived. While they are not tolerated by the uterus in a minority of cases, the risks to life and health, inherent in the use of intra-uterine pessaries, appear to have been greatly exaggerated. The risks are certainly much smaller now than they were in the years around 1930, when the rings were first used on a substantial scale. The current risks cannot be estimated in precise quantitative terms; they should be assessed against the background of the known risks of childbearing and of the frequently inconsistent and ineffectual practice of conventional contraceptive methods.

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MY VIEWPOINTS ON INTRA-UTERINE CONTRACEPTIVE DEVICES

by

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Numerous reports on experiments and research dealing with contraceptive rings, published in Japanese medical journals, testify to their usefulness, effectiveness, and almost complete harmlessness. I, myself, have conducted extensive research on the effects of the ring in about 20,000 cases and published a report setting forth the great effectiveness of the ring and the very limited number of cases in which some ill-effects were observed.

Notwithstanding this evidence, many physicians still hold the view that the ring is dangerous and harmful.

(1) Some are opposed on the basis that the ring is a foreign body.

(2) Others assert that chronic endometritis is caused by stimulation from a foreign substance within the body. The ring, being a foreign substance, is not a temporary contraceptive but a permanent one.

(3) Some believe that the ring is not a contraceptive but an abortive instrument. In other words, they state that the ring is used primarily to bring about abortion.

(4) Some further assert that the ring, as a foreign body, may cause a malignant neoplasm, particularly cancer of the uterus.

In addition to these four concepts, there are a number of absurd but popular ideas as to the possible effects of contraceptive rings.

Our experiments and research in the past ten years have made it clear that there is no basis for such fears. In other words, none of the four concepts outlined above has a basis in fact. I will discuss this briefly. For a more detailed discussion, the reader is referred to my earlier paper.[1]

The first concept is that the use of the ring should be opposed on the sole ground that it is a foreign substance within the living body. It is true that the ring is a foreign substance, and therefore, it is quite natural that the living body reacts to it in an effort to dispose of it. The important factor is the degree of the reaction. If the reaction is slight, the body becomes used to the foreign substance and, with time, manifests no conspicuous symptoms. Of course, we can all agree that the ideal is to avoid the use of any foreign matter in the body. But opposition merely on that account is superficial and inconsistent with the ready acceptance of the use of foreign bodies in modern plastic surgery, such as cosmetic and orthopedic operations, as well as for internal surgery. It may be an extreme position to take, but it is nevertheless correct to assert that suture threads customarily used in general operations, gold crowns on teeth, dental prostheses, artificial eyes, and contact lenses can be described as foreign bodies. We all know that a sponge, or tampon, left in the vagina for the purpose of obstetrical and gynecological treatment, is foreign matter and may cause

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vaginitis. Even the diaphragm, generally considered the safest contraceptive instrument, if left *in situ* for many years, is reported to have caused a disturbance. The theory that any foreign matter introduced into the body is dangerous goes back to the days when foreign substances were not used in surgical, orthopedic, ophthalmological, or otorhinolaryngological operations.

A second source of opposition to contraceptive rings arises from the assertion that chronic endometritis is caused by a foreign body. This assertion is made despite numerous clinical and histological reports to the contrary. In our experience, relatively few cases of adnexitis or increased vaginal discharge appeared to be caused by insertion of the ring, and even in these cases, careful observation revealed that either the patient already had chronic endometritis before the ring was placed, or that the ring had been inserted under conditions which failed to take account of the condition of the vagina.

The most undesirable situation for the use of the ring is its insertion immediately after curettage, that is, after artificial abortion. A study of the clinical records of 457 patients, who had experienced complications, such as endometritis, etc., revealed that among almost all of these patients the ring was placed immediately after curettage. It is generally understood that such routine tests as hysterosalpingography and tubal insufflation should not be performed during menstruation, immediately after artificial abortion, or when a normal vaginal flora cannot be ensured. This restriction is equally applicable to insertion of contraceptive rings. Therefore, the occurrence of endometritis or other disturbances when the ring is inserted at an improper time or under improper conditions should not be unexpected.

The theory, asserting that chronic endometritis and permanent sterility are caused by the ring, should be rejected in the light of the many reports in which conception occurred immediately after the removal of the ring. Any disturbance in the uterus due to the insertion of a ring is of a temporary nature, and the endometrium returns to its normal condition as soon as the ring is removed. We know that chronic endometritis is largely a disease belonging to the past—before the era of sulfa drugs and antibiotics. Acute inflammatory diseases, such as endometritis, adnexitis, and peritonitis were once serious diseases indeed, but their incidence today is very much reduced and their prognosis is no longer serious. The opposition to the use of the ring as foreign matter introduced into the body and causing inflammation belongs to an era prior to sulfa drugs and antibiotics.

A third source of opposition to the use of contraceptive rings is the assertion that it is not a contraceptive instrument but rather an abortive one. Different views depend on different definitions of what may be termed a pregnancy. According to many publications, abortion in the broadest sense refers to either spontaneous or induced delivery within the first 28 weeks of pregnancy, and abortion in the narrowest sense is induced delivery within the first 16 weeks of pregnancy, that is, before the formation of the placenta.

In our view, the union of sperm and ovum is fecundation, and the implantation of the spermatovum on the endometrium (more correctly, on the mucous membrane of the uterus) is defined as conception. We consider that pregnancy starts at conception, that is, at the time the spermatovum is implanted on the endometrium. In order to make the ring serve as an abortive instrument, the spermatovum must have been implanted on the endometrium and expelled thereafter from the uterus. Clinically speaking, the symptoms of pregnancy, such as, delay of menstruation, amenorrhea, or others, should have at least been apparent. The formation of decidua should always be noted on the endometrium. Our experiments and other reports on this point have revealed nothing of the sort, either clinically or histologically.

It is a fact that pregnancy may occur when the ring is improperly inserted. When such a pregnancy does occur and is undisturbed, the pregnancy usually ends in a normal delivery. This is evidence that even in the event of a contraceptive failure, abortion with the ring *in situ* does not occur before 16 weeks, or even before 28 weeks. Therefore, even in the case in which the ring is properly inserted, the spermatovum can be implanted on the endometrium, and the pregnancy may continue to develop without interruption.

It is emphasized repeatedly that clinical and histological symptoms of pregnancy should exist to justify the assertion that the ring is an abortive instrument and not a contraceptive one. However, neither we nor others have observed any symptoms suggesting pregnancy among our patients. If abortion is defined as including the expulsion of the spermatovum from the uterus without having been implanted on the endometrium, the ring may be called a kind of abortive instrument. However, on the basis of the definition of the onset of pregnancy, found in many well-known medical books, that pregnancy commences with the implantation of the spermatovum on the endometrium, the ring is not an abortive instrument but a contraceptive one.

A fourth reason for opposition to the ring is that its use irritates the tissues and causes a uterine cancer while it is *in situ*. My own experience, and that of others, have brought to light a total of three cases of uterine cancer. As a result of careful histological examination, all three cases were proved to have no relation to the ring. If cancer is generated by the stimulation of a foreign substance in the uterus, the location of the cancer should be related to that part of the endometrium with which the ring was in contact. In each instance, no such relationship existed. All three were cancers of the cervix, not of the corpus uteri.

As rings have been in constant use during the last 10 years in decidedly larger numbers than before, it is natural to assume that if their use and the incidence of cancer are related, cases of corpus carcinoma should have increased. But there is no such fact statistically.

In our experience, we may have inserted the ring without being aware of an already existing disposition for cancer. It is, however, difficult to draw the conclusion as to the etiological relationship between carcinogenesis in these patients and the insertion of the ring. At the present stage, therefore, it is unlikely that the insertion of the ring could induce carcinogenesis.

Conclusion

I have explained my views against the principal reasons for opposition to the use of the ring. A slight disturbance accompanying the insertion of the ring is similar to the side effects in certain treatments and drugs. Some reports described cases of serious complications of adnexitis and cancer, or one with extra-uterine pregnancy, of aberration into the myometrium, or emigration of the ring into the abdominal cavity. However, careful examination of these cases disclosed that they were not the result of the ring itself, but rather of improper and careless methods of fitting, such as, a wrong time of insertion, poor technique, inappropriate material of the ring, etc. Low quality of material and manufacture are also to blame. Even in artificial abortion, serious disturbances are often caused by the technique of a gynecologist.

The use of a ring is an authorized method of contraception, and it is proper and useful if used on the responsibility of a doctor. Further research is justified for the development of new materials and improved techniques.

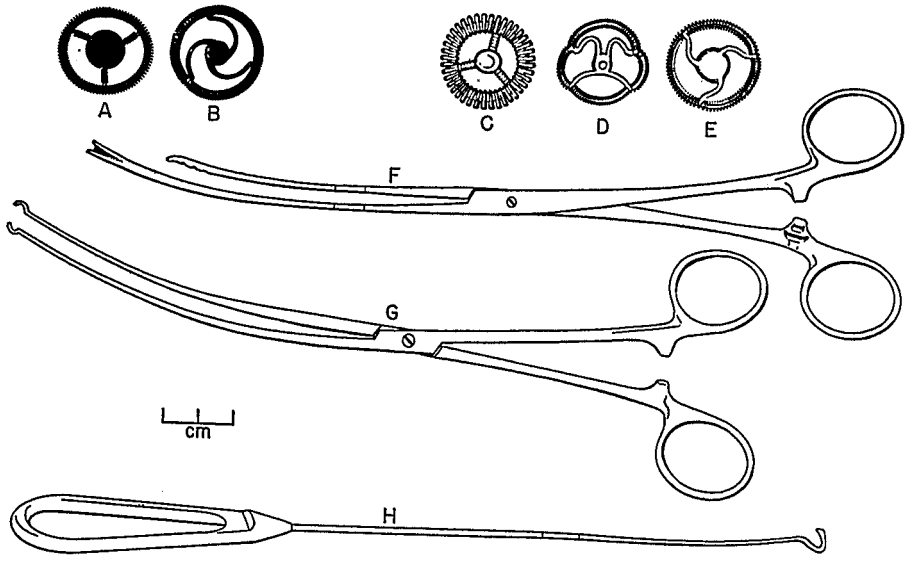

Fig. 1. Intra-uterine rings and instruments for their insertion and removal, used in Japan. A, B: metal rings; C, D, E: plastic rings; F, G: two types of insertion forceps; H: hook for removal.

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PREVENTION OF PREGNANCY BY INTRA-UTERINE SILKWORM GUT COIL

by

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In the early 1920's, while I was an assistant at University Hospital in Frankfurt-on-Main, Germany, my chief, Professor Ludwig Seitz, interested me in the work of Leo Loeb,[5, 6] who had experimented with animals, especially with rats, and produced a so-called deciduoma by introducing a foreign body into the uterine cavity. While I was repeating the experiment, Pust and Braun in Germany introduced an intra-uterine contraceptive device for human beings. It consisted of a silkworm gut ring with a silk thread hanging from it. At the end of the silk thread a round glass or hard rubber plate was attached, which, while it pressed against the external os, was supposed to keep spermatozoa from entering the uterus, and thus to prevent pregnancy.

Although the instrument was highly effective, it was soon abandoned by most doctors because of reported infections, such as endometritis, salpingitis, parametritis and septicemia and even cases of death. I myself used some of those instruments, however, with good results.

One day a patient asked to have a Pust pessary removed. On examination, I could not find the round plate, but while spreading the cervical lips, I found a foreign body which I removed. It turned out to be the silk ring of the pessary from which the plate had fallen off without the patient having observed it.

As this patient had not become pregnant, I assumed that the plate was not necessary, and that the intra-uterine part of the pessary alone was the deciding factor in preventing pregnancy. I therefore carried out a careful study of the Pust pessary, without the plate, in cases where the prevention of pregnancy was not vitally important, and had some very good results. I assumed that the deciduoma, which Loeb found in rats, was the cause of the sterility in these cases. Histological examinations of the curettage material taken from my patients did not show any deciduoma.

When in 1928 Gräfenberg first reported on his silkworm gut ring, I began to use his method. Gräfenberg discarded the vaginal plate and transcervical ring of the Pust pessary and placed his ring completely within the uterine cavity. Later, Gräfenberg changed to the silver ring, which actually gave better results than the silk ring. The Gräfenberg method has been condemned by most gynecologists. In recent years it has been taken up again, and, as far as I have read, with very good results.

After having used the silver ring effectively for more than two years, I gave it up because I observed a case which presented difficulties at removal. The ring had grown into the wall of the uterus. I took the patient to the hospital, where I removed the ring with great difficulties. Immediately, a heavy bleeding set in which could be stopped only by tamponade. After this experience, I abandoned the use of the silver ring and have ever since used the silkworm gut ring only.

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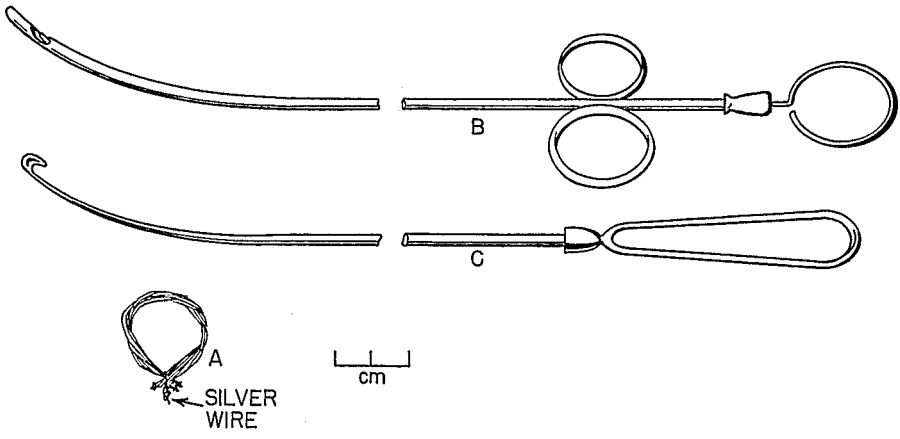

Fig. 1. Intra-uterine ring and instruments for insertion and removal. *A:* ring of silkworm gut with marker of silver wire (for X-ray); *B:* hollow uterine sound with notch and plunger used for insertion; *C:* hook for removal.

Since then, I have inserted about 1,500 rings, and I should like to mention again what I have said previously:[9] I have never seen any complications caused by the ring—no inflammation, no fever, no heavy bleeding, and no sterility when the patient wanted to become pregnant again. It is understood that much depends upon absolute asepsis when administering the method. Complications which had been reported were most probably relapses of old inflammations, which had existed before the ring was introduced, and had not been recognized in time. I have seen such cases in my practice. They should not have been selected for this method.

I always fasten a piece of silver wire to the ring, which shows in the X-ray. It often occurs that patients fear that they have lost the ring, and even miss a period for psychological reasons. Without intra-uterine manipulation, with a simple X-ray picture, we can prove that the ring is *in situ.*

Nowadays, cases of inflammation have become rare. At the time when I started to use intra-uterine contraception, many doctors believed that the ring, in itself, produced inflammation. After the publication of my paper, most doctors who have used the method, were able to draw the conclusion that these complications had nothing to do with the ring itself.

The method is a simple one if performed properly and in suitable cases. All women who are basically healthy, who do not suffer from inflammation of any kind, nor from genital tuberculosis, nor from abnormal bleeding caused by fibroids or polyps, nor from endometriosis or glandular hyperplasia, nor, naturally, from gonorrhea, are suitable subjects for the method.

Insertion and removal of the ring are practically painless procedures. I have never used any anesthetic, local or general, while introducing or removing the ring. There is no reason that the patient should have any pain after its insertion, and she can resume her normal activities after a few hours' rest. I believe most of the pain is psychologically induced, because people were warned against the method until about two years ago.

There is practically no experience in Israel with the method, because our doctors believed in the old stories which were told about the dangers of the method, and avoided

its use. Only recently some doctors came to me, discussed the method, and decided to use it.

I strongly advise a sounding of the uterus, before inserting the ring for the first time, and a notation in the case history concerning the size and position of the uterus. It might also be advisable to have the instrument with which we insert the ring marked like a uterine sound, and to record the length of the uterine cavity.

No dilatation is necessary, as the ring passes easily through the cervical canal and regains its round shape inside the uterus. I have made it a rule not to insert the ring post partum until after the patient has menstruated again, and never earlier than three months post partum. Furthermore, I do not remove and insert a new ring at the same time. I usually remove the ring a few days before menstruation and insert the new one a few days after menstruation. I never use the same ring again. The old ring must be discarded. Periodic examinations are advisable in every case, the first, one week after insertion.

A few years ago, I started to use the ring in nulliparae with good results. In these cases, the ring is, so to speak, 'made to measure', according to the size of the uterus. For nulliparous women, I manufactured the ring out of threads 12 cm long, instead of the usual 14 cm. Here also no dilatation was necessary.

In cases of retroflexion, it is of course necessary, as in the case of soundings, to introduce the instrument in conformity with the curvature of the uterus. I have never experienced difficulties in introducing a ring except in one case of stenosis of the external os, where I refrained from doing so. In such cases dilatation and incision of the cervical canal can be performed and the ring can be introduced.

In about 1,500 insertions, I have had about 2.4 per cent failures, which I think is a very good result. Ishihama,[4] who uses the Ota ring, metal or polyethylene, has recorded similar results.

Occasional failures are possible even in cases where the ring is in proper position. In all cases observed by me, pregnancy and delivery were normal. The babies were normally developed and healthy. In one case, X-ray showed the ring *in utero* six weeks after delivery, and I removed it easily shortly afterward. Haire, who had also had considerable experience with the intra-uterine method, made similar observations. However, in some of his cases of post-insertion pregnancy, he removed the ring immediately. A number of these cases miscarried while others went to term.

I should like to mention two interesting cases. One patient of mine, a mother of two children, has worn the ring for nearly 25 years, having it changed once a year. She has never, in all these years, become pregnant or had any complications. She is now approaching menopause but is still menstruating more or less regularly. This year she came to us because she felt the ring had slipped forward. At her age the uterus had shrunk and had probably pressed the ring partly outside the cervix because it was too big. I manufactured a smaller ring for her, as I do for my nulliparous cases. This ring has now been in position for many months.

The second case concerns a 27-year-old patient who had six children within six years. During this time, she had never experienced a menstruation because she always became pregnant immediately. The mouth of the uterus was torn open by her many confinements. Twice the ring slipped out within the first week after insertion. I inserted it a third time a month later and was successful. The patient now has worn the ring for one and a half years without further pregnancy, and it has remained in place. I could have repaired the cervix before inserting the ring, but this woman was very primitive and afraid, and I decided not to operate. It is interesting to note that, after insertion of the last ring, the woman started to menstruate, not very regularly, but every two to five months.

The effectiveness of the ring does not decrease by habitual wearing. I have had only one case of late failure after the patient had worn seven rings within ten years.

A careful study of the relevant literature in almost all cases of complications, fully described and attributed to the ring, reveals that between the ring-wearing period and the date of the complication, there occurred either a pregnancy with febrile abortion or another infection, or some other event which caused the complication, and that it had nothing to do with the ring. I might add that I, myself, have never seen any inflammation or infection as a result of wearing the ring, and never in all my cases have I had to apply any anti-inflammatory treatment whatsoever.

Removal of the ring because of stronger menstrual bleeding or profuse hemorrhage is rarely necessary. It is quite normal that some patients should have prolonged and increased menses in the beginning, which usually subside after the second or third menstruation. It is, in my opinion, very important to convince the patient that the method is harmless. With the amount of literature that has been written in the last 30 years condemning the method, most doctors have become biased without knowing it. They have frightened the patients to such an extent that even if the patient comes to have the ring inserted because one of her friends is very satisfied, she is subconsciously frightened, watches herself more than usual, and thus often produces bleedings, which subside immediately when she is reassured and loses her anxiety. In one case only I removed the ring when I realized that the patient could not overcome her worries.

In many cases the ring has even had the effect of shortening the menses. Severe and prolonged menstruations become shorter and, after some months, even completely normal. Patients who, by their prolonged bleedings, could not lead a normal sex life lose their fear of becoming pregnant after insertion of the ring and attain normal menstruation. In cases of chronic hypertrophy of the corpus uteri, which I consider largely psychological in origin, the ring has the effect of calming the patient. I have seen cases, where, after insertion of the ring, the uterus regains its normal size and function.

I have many patients who wear the ring on and off for years and plan their children according to their liking. Not one of them has had to be treated for sterility. All of them became pregnant within the first three months after removal of the ring.

Some patients wore the ring continuously without having it changed for many years. One of my patients, a former midwife, wore the ring for 12 years without changing it, against my advice, but became pregnant immediately when she decided to have a child.

I have never observed an extra-uterine pregnancy in ring wearers, except in two cases, where after the ring had been removed, a pregnancy occurred with an allegedly spontaneous abortion. A few months later an extra-uterine pregnancy was found, and it is quite obvious that there was no connection between the extra-uterine pregnancy and the ring.

I have not seen, among my ring-wearing patients, more fibroids than in other women. I should like to stress that I have not seen one case of carcinoma as a consequence of the ring amongst all my patients, some of whom I have observed for more than 30 years. I had one case of corpus carcinoma and this occurred 16 years after the last ring had been removed. There is no reason to assume that the ring can be responsible for a carcinoma, because the same percentage of carcinoma cases occurs in non-ring-wearing women. No endometriosis, externa or interna, was observed as a consequence of the ring.

In the late 1920's Stefko [10, 11] claimed that intra-uterine foreign bodies can cause malformation of the fetus. I have never seen any malformation of the fetus in any patients who had worn the ring, had become pregnant, and carried to term. It should be pointed out that Mall,[7, 8] as early as 1908 and again in 1910, when intra-uterine devices were as

yet unknown, found malformations in 70 per cent of the fetuses among women who had spontaneous miscarriages during the first month of pregnancy. In cases of miscarriage which occurred during the first two months, 50 per cent of the fetuses were malformed. Hertig and Rock [2, 3] had similar results with human ova, and Corner [1] with animal ova (pigs).

On examination of the placenta of one of my patients who had become pregnant while wearing the ring, I found the ring had attached to the chorion outside the amniotic sac. It could not have had any contact with the fetus. Neither the placenta, nor the amnion, nor the chorion showed any pathological findings. I therefore consider it most unlikely that the ring can cause any malformation of the fetus. A lot of research has been done to explain the function of the intra-uterine ring, but so far no reasonable explanation has been found. I have started hormonal studies but have as yet no final results. Test curettages have not so far revealed any pathological changes of the endometrium. Cytological examinations may bring some better understanding of the function of the ring.

In conclusion, let me state that the intra-uterine device, which I have just described, is at the moment, along with the oral pill with which we have as yet no long-range experience, our most effective and safest method for the prevention of pregnancy, provided it is administered by the skilled and experienced hands of a specialist and, like any intra-uterine manipulation, in an absolutely aseptic way.

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THE STAINLESS STEEL RING: AN EFFECTIVE AND SAFE INTRA-UTERINE CONTRACEPTIVE DEVICE

by

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Intra-uterine pessaries are not new. Their use has been advocated during the past 50 years for various indications. Their original application was in the treatment of uterine malposition and hypomenorrhea. The type of pessary employed was, in principle, a stem extending from the vaginal vault into the uterine cavity. A variety of materials was used, such as glass, silver, and steel covered with rubber. More or less elaborate additions to the stem were contrived to prevent the pessary from becoming dislodged and to aid in maintaining the corrected position of the uterus. It was hoped that correcting the malposition of the uterus and keeping the cervical canal open would help uterine drainage. This was in keeping with the views on uterine physiology in those days.

More recently the intra-uterine pessary has been used in the treatment of dysmenorrhea and infertility. The current interest is mainly in its use for contraceptive purposes. A variety of such pessaries have been devised. All have in common the rather undesirable feature of extending from the vagina into the uterine cavity. Ascending pelvic inflammatory disease would not infrequently occur during the use of these devices, most likely because the bridge between the vagina and the uterine cavity favored the migration of bacteria. The Gräfenberg ring presented a notable innovation inasmuch as the cervical portion was omitted. This pessary therefore lies entirely within the uterine cavity. Following Gräfenberg's recommendations, the ring was made of silkworm gut and later modified to consist of a silver spring. Thus, for the first time we had at our disposal a pessary which was acceptable both as to its safety and effectiveness.

It was nevertheless beset with certain failings. Silver, which is attacked by tissue fluids, tends to irritate the endometrium. For this reason the ring had to be removed and replaced by a new one at regular intervals. Failure to do so would lead to foreign-body granuloma formation and, in some instances, the ring would become embedded deeply within the uterine wall. Substituting surgical stainless steel for the silver has eliminated these shortcomings. This material is inert and does not cause tissue reaction. It is on this type of pessary that I wish to report.

The type of intra-uterine pessary employed in this series consists of a coil spring made of surgical stainless steel and shaped into a ring, 22 mm in diameter. Within the coils of the spring lies a nylon filament. The ring is introduced by means of an inserter with a forked tip. The resilience of the spring permits the ring to collapse, during its passage through the cervical canal, and allows its return to a circular shape beyond the internal os. Thus, the pessary lies within the uterine cavity, touching the fundus and lateral walls at three points only. To extract the ring, a similar instrument with a notched end is inserted into the uterine cavity. The notched end of the extractor is guided so that it catches the lower rim of the ring, and the pessary is easily pulled through the cervical canal. The

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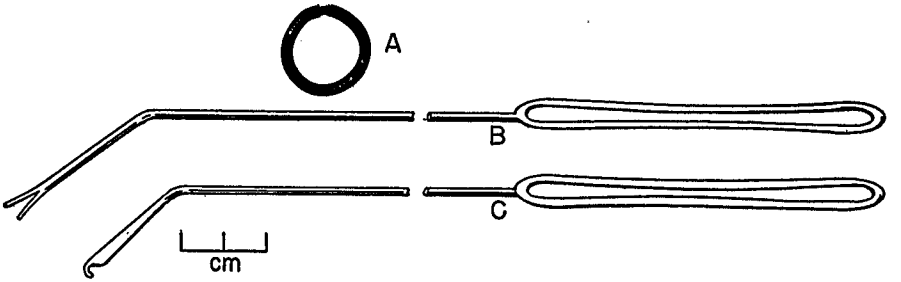

Fig. 1. Intra-uterine ring and instruments for insertion and removal. *A:* stainless steel ring; *B:* inserter with forked tip; *C:* hook for removal.

purpose of the nylon filament is to prevent over-extension, or springing, of the steel coils. The ring is introduced in the immediate post-menstrual period to avoid disruption of a possible early pregnancy, and also because at that time less resistance is encountered at the level of the internal os.

With the patient in lithotomy position, a bivalve speculum is used to expose the cervix. The vaginal vault and cervix are cleansed, and a cotton applicator soaked with a surface anesthetic is placed into the cervical canal. The rest of the cervix is also painted with the anesthetic agent. The uterine cavity is then sounded and note taken of the length and direction of the canal. The cervical canal is dilated to Hegar size 7 to 9. With the ring straddling the fork of the inserter, the cervix is grasped with a single-toothed tenaculum and, with gentle traction, the ring is passed into the uterine cavity. The inserter is withdrawn and the position of the ring is verified by passing the uterine sound into the uterine cavity. As the sound touches the metallic ring, a grating sensation can be felt by the examiner, and the position of the lower rim of the ring in relation to the internal os is noted. The sound is advanced to the fundus and the upper rim is felt. The patient is then instructed to return for examination after her next menstrual period.

As a rule, there will be some staining after insertion of the ring. This may last for several days and is probably due to abrasion of the cervical mucosa caused by the passage of the compressed ring through the cervical canal. Slight abdominal cramps may be felt by the patient for the next 48 hours. After the completion of the next menstrual period, the patient is re-examined and the position of the ring is verified by sounding the uterine cavity. If it is found to have remained within the uterine cavity, well above the internal os, it is assumed that the ring will continue to remain in this position. The patient is now told that she may rely on the contraceptive effectiveness of the pessary. She is instructed to return for re-examination at 6-month intervals. On these occasions the position of the ring is verified by sounding the uterine cavity. If there is no specific reason for removal of the ring, such as a desire for conception, the ring may be left *in situ* indefinitely.

This report covers a series of 128 patients observed during the period from 1949 to 1961. This is not the total number of patients on whom this method was used, but rather the number who could be followed up adequately. While this is not a very large series, the length of time for which the patients have been under observation permits one to evaluate possible effects after long-term use with a greater reliability. The fate of subsequent pregnancies and deliveries, the effect on fertility, and the incidence of neoplastic disease are important. Valid conclusions in this respect can be drawn only if the patients have remained under observation for a considerable time.

The specific indications, for the selection of the intra-uterine pessary as a contraceptive device, were medical and psychiatric conditions. It was also selected for anatomical reasons for women who could not be properly fitted with a diaphragm, and in those cases where precoital manipulation, required in the proper use of the diaphragm or chemical contraceptives, was unacceptable for personal reasons.

These 128 patients were under observation for a total of 648 exposure years. Six pregnancies occurred in this group. In 4 cases, the ring was found to have been expelled into the cervical canal. In 1 case, the ring was found within the uterine cavity and coexistent with a uterine pregnancy. There was 1 tubal pregnancy in this series. Of the 4 pregnant patients in whom the ring was found in the cervical canal, 3 had become pregnant within 3 months after insertion of the pessary. These failures might have been prevented by extending the trial period from 1 month to 2 months. Thus the failure rate during the 648 exposure years can be stated as 0.9 per 100 years of exposure. A total of 62 of the 128 patients were under observation for 5 years and more. Seventy-one of the patients ranged in parity from 1 to 4, and 57 had never been pregnant.

Among the 128 patients, the ring was removed 13 times because the patients contemplated pregnancy. In 2 of those cases, the ring was removed and replaced twice for this reason. After removal, conception followed readily in all cases. The longest interval from removal to conception was 3 months. No miscarriages and no obstetrical complication occurred. No fetal abnormalities were observed.

As a rule, the patients were completely unaware of the presence of the ring. Any increase or prolongation of the menstrual flow beyond the first menstrual period after insertion was considered an indication for removal of the ring. This occurred in five cases. Slight spotting, which preceded the actual onset of the flow by one or two days, was not considered abnormal and is probably due to premature shedding of the ischemic functional layer of the endometrium at the points of contact with the ring.

Expulsion of the ring, which was found with its greater segment wedged into the cervical canal, occurred in six cases. In one case, the ring was actually passed and was absent on re-examination. These expulsions may be due to abnormal irritability of the uterus followed by increased uterine contractions. However, I have gained the impression that the most important single factor responsible for this complication is distortion of the ring itself. If the ring is damaged in the process of introduction, it will not resume a perfectly circular shape within the uterine cavity. Consequently its smaller segment may impinge upon the internal os. Increased uterine activity may be triggered which will in turn push the pessary farther into the cervical canal. As a rule it will remain in this position, with only a small segment lying above the level of the internal os. This accident was much more frequently encountered in the use of the silver ring, which, being a softer material, is prone to damage in the process of insertion. Maintenance of the circular shape of the ring is most important in preventing these failures.

There was no evidence of either local infection, endometritis, or generalized pelvic inflammatory disease in any of these patients. Periodic pelvic examinations revealed no evidence of uterine, parametrial, or adnexal tenderness, thickening, or masses.

Uterine fibroids were present in two cases. In one case, fibroids developed while the ring had been *in situ* for six years. An abdominal hysterectomy was performed and pathological examination revealed no abnormality in the endometrium. The other case, in which the fibroids were present before the pessary had been inserted, was treated by myomectomy and the pessary replaced after the operation. She has remained asymptomatic for four years.

No cases of pelvic malignancy occurred in this series, nor have there been any cases of uterine malignancy in patients who at one time had been fitted with the pessary.

Excessive uterine bleeding beyond the menstrual period following insertion occurred in five cases. No satisfactory explanation can be given for this. While stainless steel may be considered biologically inert, it is conceivable that some individuals may react allergically to one of the components of this alloy.

No cases of dysmenorrhea were observed. In fact, the patients who were so afflicted prior to insertion of the ring, became remarkably free from menstrual pain.

Thus, the effectiveness of the intra-uterine pessary appears both impressive and puzzling. The mode of action is probably the most fascinating aspect of this method. How does this effect come about? Is it conceivable that the upward journey of the sperm is impeded by this rather flimsy structure? Does the presence of the pessary cause a change in the endometrium? Does it cause chronic infection and subsequent sterility? Could it in some way influence the endocrine function of the ovaries? All these possibilities and more have been considered at different times by different observers. The truth is that very little has been done in the way of earnest investigation in this respect. Animal experimentation pertaining to this problem is urgently needed.

Our experience has shown that the presence of a biologically inert object within the uterine cavity does not cause infection or tissue reaction. There is evidence in support of the contention that ovarian function is unaffected by the presence of the pessary, and that no histological changes in the endometrium occur. These observations were obtained in a number of cases in which the intra-uterine pessary was employed for the treatment of infertility. No change in the basal temperature pattern was found, and endometrial biopsies at the time of removal of the ring showed normal secretory endometrium.

It is my impression that a hitherto undefined principle of reproductive physiology is involved. Namely, that implantation of the ovum is prevented in the presence of an inert foreign body within the uterine cavity. Since no local effects of this intra-uterine foreign body could be observed, it is difficult to escape the conclusion that this rejection is due to a purely tactile effect upon the uterus. A parallel to such a tactile effect on uterine physiology exists in the phenomenon described by Reynolds and Kaminester. Their work showed that the presence of an inert material in the uterus brings about an effect on uterine development beyond that of hormonal stimulation.

While hypothetical at present, acceptance of the existence of such a phenomenon might be of considerable practical value in the search for improved materials and methods. We would thereby acknowledge that a substance free of any biological effect would make the most suitable material for the manufacture of the pessary. This material should also have physical properties which will permit insertion of the pessary with ease and yet be of sufficient strength to prevent distortion of its shape. Heat sterilization would also be a requirement.

We have found stainless steel to approach this goal in a high degree. This material has undergone prolonged trials in surgery and has been proven to cause a minimum of reactions. If the steel ring is manufactured with care, it will withstand compression of its shape during insertion and resume its original shape. As mentioned before, this feature is particularly important to prevent impingement upon the isthmic region of the uterus and subsequent drop-outs of the pessary.

We are now in the process of putting to trial a modification of the steel ring, which should reduce this tendency still further. We are also experimenting with a plastic device.

In summing up our experiences, I should like to say that the stainless steel ring has proved a very satisfactory method of temporary sterilization. Its effectiveness is superior to any other method of contraception. An uncorrected failure rate of 0.9 per 100 years of exposure compares favorably with such radical procedures as tubal ligation. The side effects are few and no serious complications were encountered. A contraceptive device

which does not require any manipulation on the part of the patient eliminates those failures which are due to improper and inconsistent use of such devices as diaphragms and contraceptive jellies. Because of this lack of esthetically objectionable manipulations, this method is accepted with a good deal of enthusiasm by the patient.

The technique of this intra-uterine pessary is simple and can be readily mastered by anyone trained in gynecology. It is self-evident that before inserting an intra-uterine device, pre-existing pathological conditions should be recognized. Failure to do so may have serious consequences. It lacks the simplicity of such methods as the diaphragm, etc. However, this should not in itself preclude its application on a large scale.

In addition to my own cases, there is now in existence a continuous series of more than 500 cases from the private practice of three of our former residents. Their results during the past two years are similar to the results reported here.

No mention of the intra-uterine pessary can be complete without paying tribute to the genius of Gräfenberg, who first devised the prototype of this pessary. He had shown that a pessary lying entirely within the uterine cavity could be employed effectively and with relative safety. We must note with regret that the present resurgent interest in his ideas has not found him among us.

THE GRÄFENBERG SILVER RING IN A SERIES OF PATIENTS WHO HAD FAILED WITH OTHER METHODS

by

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The group of 192 women about whom I am talking today, have all been fitted with a metal intra-uterine ring made of tightly coiled silver wire. Three sizes are kept in stock, 2 cm, 2.5 cm, and 3 cm. The 2.5 cm ring is used most frequently. These women are all highly fertile, with a range of 2 to 15 pregnancies and an average of 6. Many of them are problem patients and mothers of problem families. All of them had tried other methods of contraception and have failed at least once.

Indeed, it was the feeling of frustration produced by repeated failures with the usual methods of contraception (cap or sheath and chemical) that drove me to reconsider the Gräfenberg ring as a possible solution, although I had been taught as a student that fitting such things was devil's work. However, with the exception of sterilization, which is done very sparingly in England, it was the only method available where all responsibility could be removed from the shoulders of the couple.

From a consideration of the literature, it seemed clear that Gräfenberg's original results were good. There was little morbidity among his patients and the success rate was high. He selected his cases with care and kept them constantly under review. The method fell into disrepute when the need for these precautions was lost sight of.

An essentially normal pelvis is needed and, fortunately, high fertility tends to be associated with a healthy pelvis. As I have already said, the patients in whom I have fitted silver rings are all highly fertile. Some degree of subinvolution is not uncommon in such patients; the uterus is often hypermotile and may be retroverted or partially prolapsed, but inflammatory conditions, including venereal diseases, are not common; nor are such conditions as fibroids and endometriosis. Although hypermotility and subinvolution constitute a rather uncertain background for fitting a Gräfenberg ring, I felt it was better to fit these women than to abandon them as contraceptive dead losses.

Parous women are not difficult to fit. The cervix is usually easy to dilate without too much discomfort to the patient; if any anesthetic is needed, I have found an inhaled antispasmodic (e.g., amyl nitrite) just as effective as gas and air or Trylene, and more so than a local anesthetic injected into the cervix. I have tried dilating to various sizes of Hegar and have found that it is necessary to reach size 7 in order to make insertion possible without producing too much deformation of the ring.

The fitting and changing is best done in the first half of the cycle, although I have not been able always to stick to this. A patient, in whom a silver ring has been fitted, must not be lost sight of, and the ring should be taken out and renewed roughly once a year. I have tried longer intervals but find that after 15 or 16 months, the rings tend to become somewhat embedded and more difficult to find and remove. Moreover, in a restless uterus, they may become remarkably twisted and distorted.

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At the time of changing, the patient is carefully questioned and examined. Films from cervix and vagina are looked at microscopically and a fragment of endometrium is collected for biopsy. I have examined a large number of these endometrial sections and have never found any metaplastic changes. There is usually some round cell infiltration (but so there always is) and the endometrium tends to be well developed and hyperplastic, if anything, but I cannot say that I have found any noteworthy pathological changes. An interesting observation is that one often finds a toughening of the cervix in women who have had many ring insertions. This is partly because of the small traumata associated with repeated dilation and partly because child-bearing occurs less frequently. Also, of course, as they get older, their uteri tend to get firmer.

TABLE 1

*Number of Cases of Insertion of Gräfenberg (Silver) Ring by Outcome**

All cases			192
Fitted in error		2	
Rings *in situ*	120		
Moved away (ring probably in)	3	123	
Removed for:			
Menorrhagia (some with pain)	11		
Discharge and pain	3		
Irregular periods	5		
Disliked fitting	5	24	
Menopause	3		
Sterilized (wife)	5		
Left the county	2		
Wanted baby	4		
Husband died	1		
Husband objects	1		
Husband sterilized	2		
Separated	5	23	
Expulsion (noticed by patient)	7		
Minus reinsertions	–2	5	
Unwanted pregnancies			
Ring *in utero*	9		
Ring expelled (not noticed)	5		
Uncertain	4		
Minus reinsertions	–3	15	
		192	

* Exeter, Barnstaple, and Tothes Clinics.

Table 1 summarizes what has happened to the 192 women I have fitted with rings. Although there have been 18 unwanted pregnancies, and despite the fact that the ring was not well tolerated for one reason or another by 24 women and had to be removed, the

degree of protection offered by the Gräfenberg ring in this group of highly fertile women over a grand total of 10,711 cycles is quite high. Calculated in the usual way by the Pearl formula the pregnancy rate is:

$$\frac{18 \times 1{,}200}{10{,}711} = 2.0$$

This rate compares favorably with any other method.

A total of 120 women are currently under my observation. I have lost trace of 3 women, who have gone away from Devonshire. I no longer see them, but to the best of my knowledge and belief, they still have the ring in.

Forty-seven have had the rings taken out for various reasons; in 19 the amount of pelvic disturbance was more than the patient was prepared to put up with or the doctor to allow (*i.e.*, menorrhagia, uterine cramps, irregular losses, discharge, either alone or combined); 5 women so disliked the periodic removal and refitting that I felt it was kinder to offer some other method. Of these 24 women (for whom the method must really be regarded as having failed), 12 have been transferred to orals, 5 have been rendered sterile either by tying the tubes or by hysterectomy, and 7 chose to return to ordinary methods of birth control (at least 2 of these became pregnant within a few months). In 5 other cases, after considerable argument and delay, it was decided to sterilize the women, their rings having stood them in good stead during this period of procrastination. Three have reached the menopause and no longer need their rings; 2 left the area and I managed to remove their rings before they escaped. Four wanted a baby; or rather three wanted a baby and, in one case, the husband wanted a baby. There is a very subtle distinction here; anyway, the result is that three of the four are pregnant and one has not had time to get pregnant yet. Nine had their rings out for reasons connected with the husband.

Of the 14 pregnancies where I have been able to verify the facts, 9 occurred with the ring *in utero;* in 5 cases, the ring had definitely fallen out before conception occurred. In 4 cases, I could not get the answer. This is a point that I would like to make. I have extreme difficulty sometimes in getting precise information from the patients and the practitioners as to whether the ring was *in situ* at the time the woman conceived.

In the cases where the ring remained in place throughout pregnancy, they have all but one been outside the amniotic sac. One was reported to me by a most careful gynecologist as being inside the amniotic sac. I find that very difficult to explain.

In none of these pregnancies have the children been in any way disturbed or malformed. In two cases the woman was pregnant before I fitted the ring, and that was due to an early error in my technique, which I hope not to make again. In these two cases also the pregnancies went happily to term and the baby suffered no harm.

Seven rings were extruded, two of which have been reinserted. The reason for extrusion was not clear in all cases. Abnormal irritability of the uterine muscle may well be a factor, or an extremely lax internal os. The choice of a wrong size of ring is also important. A ring which is too large to be comfortably accommodated by the uterus may be pushed out, and one that is too small tends to find itself in the lower uterine segment, from where it may easily slip into the cervical canal if the internal os is at all incompetent.

Menorrhagia is, in my experience, the commonest and most troublesome side effect but, except in eleven cases, could be controlled by calcium, a short course of progestagens, or by temporary removal of the ring and D and C.

The mechanism whereby the Gräfenberg ring exerts its protective action against pregnancy, is not at all clear. I have found no evidence in the biopsies from these cases that the underlying factor is an endometritis induced by the presence of the ring. I thought at

one time I was finding a disturbance in timing, and that the endometrium was not passing through its proliferative and secretory phases at the correct rates, so that the ovum could not embed; but this has not been substantiated. Perhaps an increased irritability of the uterine muscle remains the most plausible explanation.

On the basis of my experience, I conclude that: (1) a woman's fertility is not disturbed by this method and (2) no pelvic inflammatory conditions have developed and no conditions necessitating an operation have arisen as a direct result of the presence of a silver ring in the uterine cavity.

THE GRÄFENBERG RING: A CLINICAL AND HISTOPATHOLOGIC STUDY

by

DON JESSEN, M.D.*

When Ernst Gräfenberg introduced a wholly intra-uterine contraceptive in the 1920's, he met with widespread criticism. Few people had had any personal experience in the use of the ring, which was considered as just another foreign body and equally as dangerous as another uterine device, the stem pessary; and many had seen or heard of serious complications with the use of the stem.

There are significant differences between the stem pessary and the wholly intra-uterine Gräfenberg ring. The stem pessary lies partially in the cervical canal with its mucous secreting glands, which offer an excellent site for a persistent infection. The stem offers a ladder for ascent of bacteria from the vagina with its rich flora to the uterine cavity. The Gräfenberg ring lies on a mucosa that renews its surface each month with menstruation. In Europe and in the United States, the ring has been little used.

My interest in this subject was aroused by an article by Oppenheimer,[3] of Jerusalem. He described 28 years' experience involving some 866 insertions in some 329 women. He reported failure in 2.4 per cent of the insertions, or 2.5 pregnancies per 100 woman-years of exposure. Even more interesting, he described the ring as almost completely innocuous. He reported no infections, no secondary sterility, no miscarriages while the ring was *in situ*, no effect on the fetus when pregnancy ensued, and only a rare effect on the menstrual period. Such results seemed very good, and we decided to study the histologic and clinical effects of the ring on a limited population.

A review of the literature in English reveals very few published experiences on the use of the ring. There is little doubt that it is an effective contraceptive agent. Halton,[1] who employed a coil of silkworm gut, reported an 18 per cent incidence of minor disturbances, such as, mild lower abdominal cramps, spotting, or heavier periods. Ishihama[2] reported 21 per cent such disturbances using the Ota ring and, in approximately 5 per cent of his cases, removal of the ring was required for relief of symptoms.

Material and Methods

In the present study, all patients were interviewed in an attempt to eliminate poorly motivated individuals and those with a history suggestive of genital disease. A pelvic examination and Papanicolaou smear were done next. Those with signs or symptoms suggestive of genital disease were eliminated. After insertion of the ring, the patients were requested to return monthly for three months for pelvic examinations. In addition, they were instructed to report each month the onset, duration, and character of their period. Those not responding (approximately 35 per cent) were contacted by phone or letter at the end of each calendar month. At the time of the ring's removal an endometrial biopsy

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was taken by suction curette. The tissue was preserved in Bouin's solution and examined in the Northwestern Obstetrical and Gynecological Pathology laboratory by Dr. Greene. All slides were then re-examined by me, without knowledge of the patient's identity. Those slides in which there was disagreement were reviewed jointly by Greene and myself. No biopsy was taken prior to the ring's insertion. Most of the rings were inserted six to eight weeks post partum.

The rings were made of four 15 cm strands of silkworm gut with a knot on each end and a small piece of stainless steel wire wrapped around the ring. The latter was used as a radio-opaque marker. The ring and instruments were autoclaved. Following the insertion of a sterile vaginal speculum, the cervix was wiped with cotton balls dipped in aqueous Zephiran. Next, the endocervical canal was wiped with cotton-tipped applicators, dipped in the same solution. The cervix was dilated to 0.5 cm and the ring inserted. The ring had been soaked in aqueous Zephiran several minutes prior to insertion. The dilator was re-inserted to be sure that the ring was not in the cervical canal. This procedure requires less than three minutes and is relatively painless. No anesthetic or sedation was used or needed. Following the same type of preparation and dilatation, the ring was removed with either a crochet hook or the biopsy curette. This proved to be very easy except in one or two instances.

A total of 121 patients was selected from an indigent population: 109 Negro, 1 Oriental, and 11 white. The oldest was 45, the youngest 17, and the average age, 29. All had had successful pregnancies. The largest number of pregnancies was 16 and the largest number of deliveries, 15. The average number of pregnancies was 6.4, the average number of deliveries, 5.5. Many patients had had failures with other methods of contraception.

All rings have been removed and all patients have been accounted for. Histologic specimens were obtained for 109 patients.

A total of 117 patients wore the ring for one month or longer. In addition, 4 patients were lost during the first month of the study for any one of the following reasons: (1) The ring fell out. (2) The ring was removed with retained secundines. (3) Severe cramps. (4) Patient's desire, but without medical indication.

Various complications, including change in menstrual periods; extrusion of the ring; pregnancy; symptoms, such as, cramps, bleeding, fever, discharge or histologic evidence of inflammation, were experienced by 45 out of 121 patients, or 37 per cent. Many complications were neither severe nor symptomatic. This can be seen when it is noted that only 11 rings were removed for medical indications; while 10 were extruded, 7 were removed without a medical indication, and the remainder were removed at the termination of the study.

Twenty-two patients reported some change in their periods. In 6 there was an increase in the length of flow, in 11 an increase in the amount, and in 5, an increase in both length and amount. In 2 cases, the change in the period caused the ring to be removed. Three patients of the 22 had symptoms or histologic evidence of infection.

Altogether, 122 rings were inserted into 121 patients. Ten rings were extruded. This constitutes 8.2 per cent of the insertions. One ring was lost in less than one month, 3 after two months, and one each after 4, 5, 8, 9, 10, and 11 months. In 3 cases, this was associated with pregnancy. In one, there was also an acute endometritis and in 6 cases, there were no associated symptoms.

Nineteen patients (16 per cent) complained of symptoms of pain, bleeding, discharge, or fever. I have arbitrarily classed them as minor or major, depending on their severity. Nine complained of minor complaints, 4 of which required some sort of symptomatic treatment. Ten had major complaints and in 8 of these, the ring had to be removed. In the 10 cases, where the diagnosis of infection was made, treatment was instituted, I regret to

say, without the benefit of smears for gram negative diplococci or cultures. Seven of these cases occurred after more than 3 months following insertion; 2, between 1 and 3 months; and 1 case, in less than 1 month.

Three, or 2.6 per cent of the 117 patients at risk, became pregnant. With a total exposure of 1,270 woman-months, the pregnancy rate amounted to 2.8 per 100 woman-years. All 3 had had the ring inserted 2 months post partum. All 3 expelled the ring: one at 2 months' gestation, one at 4 months, and 1 in less than 1 month. Two have had uneventful deliveries of normal children and one is now at term and apparently well. The rings were worn an average of 10.7 months per patient.

Follow-up since the ring's removal is incomplete and not too meaningful since many patients can no longer be traced. However, six of them have conceived, three delivered, and three others are carrying normally.

The condition of the ring at the time of removal was recorded in 80 instances. All were intact and none showed gross signs of fraying or change other than a slight yellow discoloration. In 44 cases, the ring was not coated with endometrium, in 27 it was slightly coated, and in 9, moderately to heavily coated.

In one patient I perforated the uterus in attempting to remove the ring. At surgery the ring was found protruding through the serosal surface of the uterus for approximately one-third of its diameter and attached to this was the right uterine tube and omentum. No evidence of infection was noted in the endometrial biopsy or the blocks of the removed uterus. The ring most likely had been forced through the myometrium at the time of its insertion 14 months earlier.

Another patient was hospitalized because of hepatitis, which became manifest approximately eight weeks after the ring's insertion. No other patient in this series developed hepatitis. Histologic studies were made of 109 of the 121 patients. Eleven patients had microscopic evidence of infection, and, in 3, there were associated symptoms suggestive of infection. In 2 cases, decidual changes suggestive of a pregnancy were found. One of these actually contained fetal cells. Six of the patients had hysterectomies. In 5, the indications were stress incontinence or a symptomatic cystourethrocele. In the other case, the indication was uterine perforation.

Of the 11 instances of infection, 2 were classed as acute, 3 as acute and chronic, 4 as subacute, and 2 as chronic.

In evaluating the above results, it must be realized that the population studied varies in many ways from that seen in a private practice. The incidence of poor hygiene and pelvic infections is no doubt higher among this study group. Just how much higher would be difficult to determine. Although infections occurring while the ring was being worn should be charged to the method, one wonders just what contributory role it played, since 70 per cent of the cases in which the clinical diagnosis was made occurred 3 or more months after the ring's insertion. In this study the method demonstrated its contraceptive efficacy since all patients have borne children and seemed to find little trouble in conceiving.

The ring was removed prior to the termination of the study in only 15 per cent of the cases. The large majority were very pleased with the ring and the freedom it offered them. Almost all patients, who had their rings removed, desired another ring.

Conclusion

(1) The Gräfenberg ring method of contraception is effective.
(2) Its mode of action is not apparent from these studies. Perhaps it works by disturbing implantation or by causing infection or both.

(3) It is a very convenient method for the patient, and the vast majority of the patients wanted another ring inserted.
(4) It is not innocuous and is associated with symptoms, menstrual disturbances, or histologic evidence of infection in a significant percentage of cases.
(5) In 8 per cent (9 out of 121) of the cases, the ring was extruded.
(6) I would not recommend this method for use in an indigent population.
(7) I would not recommend this method unless close medical supervision is possible, and 100 per cent follow-up is certain.
(8) In short, this method, as I used it, is unsuited for general use as a contraceptive.

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EXPERIENCE WITH INTRA-UTERINE DEVICES: 1928-1962

by

HANS LEHFELDT, M.D.*

My personal experience with intra-uterine devices consists of two parts: the period of insertion and the period of removal. The first period started in Germany in the 1920's and ended in 1935, when I left that country. The second period began in the United States in 1935 and extends to the present. It covers the years in which I no longer inserted such devices but had numerous opportunities to remove those inserted by other physicians.

A third period is about to start as we plan to use various types of intra-uterine devices on selected patients in Bellevue Hospital.

In December, 1928, during a postgraduate course for German physicians—which, incidentally, was inaugurated by Margaret Sanger—Gräfenberg presented his method to the public for the first time. During the same course, I reported on 500 cases of intra-uterine silk devices, observed over two to three years in my own practice and that of other physicians. Some of the patients in this series had been fitted with the Pust collar-button silk pessary, a very popular method at the time.

In the 1920's and early 1930's, the Gräfenberg ring was not the only uterine contraceptive device in use. In order to avoid confusion, I would like to suggest a division of these devices into three groups:

Group I, the *intra-cervical* devices, are dangerous appliances, made of metal and other materials, known as obturators, Steriletts, etc. Some lie wholly within the cervical canal; others reach beyond the internal os. The most dangerous forms extend into the uterine cavity, usually with two elastic prongs.

Group II, the *cervico-uterine* devices, are made of silkworm gut. They are inserted into the uterine cavity but connect with the cervical canal by a loop or strand of silk, mainly for the purpose of easy removal. The Pust pessary is one example of this type. Less dangerous than the first group, these appliances are nonetheless hazardous because of the connection between the uterine cavity and the vagina.

Group III consists of the strictly *intra-uterine* devices inaugurated by Gräfenberg. This group comprises the silk star, silk loop, silk ring, and, finally, the Gräfenberg metal ring.

The 500 patients in my study had all been fitted with group II, or cervico-uterine devices. For various reasons, 35 per cent of the women in this group were found unsuitable for insertion of intra-uterine devices. Among these, 5 per cent developed metrorrhagia following insertion and 10 per cent experienced exacerbation of pelvic inflammatory disease (PID). Another 10 per cent expelled the silk repeatedly. As this group was mainly composed of multiparous women, laceration of the cervix was probably the cause of expulsion. Another reason for unsuitability was interference with cohabitation, the male

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partner feeling the protruding part of the cervico-uterine device. There was one case of trauma to the penis.

The effectiveness of intra-uterine contraceptives seemed high; only 24 pregnancies, or 4.8 per cent of the total, were reported for this group of 500. However, since reporting was incomplete, the actual number of pregnancies was probably higher. Pust asserted that 150,000 of his collar-button silk pessaries were in use all over the world, with only 5 to 6 known pregnancies, which must be considered a highly exaggerated rate of effectiveness.

Gräfenberg's great contribution was that he recognized the superiority of strictly intra-uterine devices which prevent communication between the endometrium and the vagina via the cervical canal. It was he who introduced the metal ring, made of silver or gold, which can be detected by X-ray. Last but not least, credit is due to Gräfenberg for the courage he showed in publishing his findings at a time when most physicians who used his ring, or similar devices, chose to remain anonymous. There was strong opposition against all intra-uterine devices in pre-Hitler Germany, even though the use of other contraceptives was gradually becoming accepted. Thus, contraception was one of the topics at the German Congress for Gynecology in Frankfurt in 1931, where Gräfenberg read a paper on his method. Virtually every prominent gynecologist of that time opposed Gräfenberg. I particularly want to mention Ludwig Fraenkel, who, in his authoritative text-book on contraception, published in 1932, rejected all intra-uterine methods. Nevertheless, a test series with Gräfenberg rings was run at the Gynecologic Clinic of Berlin University, although the results were never published.

I should like to emphasize a few technical details of Gräfenberg's original method. The insertion instrument, which he used, was a hollow probe containing a metal rod for fixation of the ring, very similar to Oppenheimer's instrument. Gräfenberg originally recommended three sizes of rings, with a diameter ranging from 20 to 30 mm. Later he found the 17.5 mm diameter optimal, while Hall uses a ring of a uniform size of 22 mm. Gräfenberg's silkworm gut ring, as well as his silk star, had a fine silver wire attached to them to make X-ray visualization possible.

As a matter of curiosity I mention a modification of the Gräfenberg ring, presumably useful in a few special cases of intolerance of the uterus. It consists of two rings joined together and is, according to Norman Haire, known as the 'True Lover's Knot.'

I also want to draw your attention to the special type of tenaculum forceps, which Gräfenberg recommended. The prongs are exactly opposite each other, thereby making application less painful.

I now come to the second part of my report where my experience becomes limited to the removal of intra-uterine devices. My decision to stop using such devices after my arrival in this country was made after discussing the prevailing views on the method with Robert L. Dickinson and Alfred Hellman, past president of the New York County Medical Society. I became convinced that the insertion of intra-uterine devices would be considered malpractice. Gräfenberg, himself, while in the United States, had come to the same conclusion. This, however, must not be construed as a change of mind. Gräfenberg believed in his method all his life, and he passed it on to his friend and associate, Herbert H. Hall. I know he would have been gratified if he could have listened to this discussion.

I should now like to mention some of the intracervical and cervico-uterine contraceptives which I have in my collection. Let me assure you that not all of them were recovered in the pre-Gräfenberg era, nor are all of them of German origin. At least one is of American manufacture. It had to be removed, because of PID, from a California patient who was on her honeymoon trip to New York. Another device, removed only last year, also because of PID, had been inserted by a West German gynecologist.

I removed a strictly intra-uterine device, a silk strand, because of menometrorrhagia, from a patient who had fibroids. This woman was not sure whether she had lost her contraceptive. As it was of silk and had no wire attached, it could not be detected by X-ray but was found during curettage. One of the Gräfenberg rings I removed had been inserted by Norman Haire. This particular patient had a secondary sterility following removal. Of course, no conclusions can be drawn from a single observation of this type. Another ring, inserted many years before by Gräfenberg, had to be removed because of severe PID.

Two modern factors—antibiotics and the invention of inert plastic materials—are mainly responsible for the revival of interest in the Gräfenberg ring and its modifications. This method has many advantages. In the light of the histologic findings it may be assumed that the ring can be left *in situ* for several years without harm. With regard to prolonged protection, then, it is superior to all other reversible contraceptive methods. In distinction to other contraceptive methods, the factor of patient failure is completely eliminated for users of the ring and its modifications. A further advantage is that, in the multipara, the ring can be inserted within 10 minutes by a trained gynecologist, provided he has some assistance, not necessarily a trained nurse. Part of this time is needed for a thorough bimanual, speculum and probe examination of the pelvic organs to diagnose a possible malposition and to rule out contraindications, such as chronic PID and fibroids. Follow-up examinations during the first cycles would guarantee a higher rate of effectiveness, but could be dispensed with in areas where overpopulation constitutes an emergency. The low cost of this method is another great advantage as it facilitates mass application in underdeveloped areas.

One of the method's disadvantages is that it can be applied only by a properly trained physician, preferably a gynecologist. Otherwise there is danger of serious complications, such as perforation of the uterus and insertion in women with PID or fibroids. Menorrhagia, especially in the first months following insertion, which occurs in some patients, seems a side-effect of only minor importance of which the patient can be forewarned. Only in rare instances does this condition necessitate removal of the ring.

Conclusion

The time has come for a re-evaluation of the Gräfenberg intra-uterine ring and its various modifications.

In our antibiotic era, one of the main dangers of this method—pelvic infection—has become greatly reduced. While the method, even under ideal conditions, does not provide absolute safety from unwanted conception, an important cause of contraceptive failure, namely, patient failure, is completely eliminated. A high degree of protection may be achieved for several years by a single-time procedure, *i.e.*, insertion. This, and the low cost of the material, metal or plastic, makes the method highly economical.

As insertion of the ring is a comparatively simple and quick procedure, a trained gynecologist, with proper help, could fit 6 women per hour, 50 per day, or at least 15,000 per year. Theoretically, then, 100 trained physicians could provide protection extending over several years for 1.5 million women in 1 year.

Insertion of the ring should be performed only by an experienced physician, preferably a gynecologist.

Further experience will show which of the presently available modifications of the Gräfenberg ring has the greatest merits.

SOME OBSERVATIONS ON THE USE OF INTRA-UTERINE CONTRACEPTIVE RINGS IN TAIWAN (CHINA)

by

J. Y. PENG, M.D., D.P.H.*

Taiwan is an island province of the Republic of China and has an area of 140,000 square miles, two-thirds of which are mountainous. The climate is subtropical and tropical.

The population of Taiwan Province is close to 11 million, with a density of more than 750 persons per square mile. The birth rate in 1960 was 37.2 per 1,000 population, and the death rate, 6.8 per 1,000, corresponding to a rate of natural increase of about 30 per 1,000, or about 3 per cent. The fertility was highest among women between 25 and 30 years of age, with an annual rate of 330 births per 1,000 women; and women between 40 and 45 still had a rate as high as 78.

In Taiwan, a polyethylene Ota-type ring is the most widely used. It is manufactured locally and costs about NT$4.00 (equivalent to US$0.10). The charge for the insertion is between NT$80 and NT$150, usually NT$100 (equivalent to US$2.50).

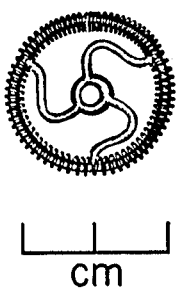

Fig. 1. Ota-type plastic ring made and used in Taiwan.

A survey conducted in a community in central Taiwan in July 1960 revealed that 27 per cent of the married women who reported use of contraception used an intra-uterine ring. The survey covered 2,175 women of whom 239, or 11 per cent, reported experience with contraception. Among these 239 women, the intra-uterine ring (27 per cent) and foam tablets (28 per cent) were the two most frequently reported methods; about 16 per cent used the condom; 11 per cent had had a tubal ligation; about the same number relied on the rhythm method; and the remainder, on other methods.

In January, 1962, visits to 268 families in urban, suburban, fishing, and rural mining communities in Taiwan showed that among contraceptive users in these areas, the intra-

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uterine ring was the most frequently reported method. Among the 33 women with a history of contraception, 20 used the intra-uterine ring; 4 used foam tablets; 3, the rhythm method; 1, the condom; and the remaining 5, other methods.

A survey of obstetricians in private practice, conducted in March, 1960, showed that at least 800 women each month are applying for the insertion of rings. The actual number is estimated at more than this figure; and in fact it is not uncommon for rural housewives in groups to visit obstetricians in town for this purpose.

The survey covered 240 obstetricians and gynecologists of whom 92 responded with 59 reporting use of intra-uterine rings in their clinics. The number of monthly insertions ranged from fewer than 10 in 38 clinics to almost 100 in 1 clinic. The estimated monthly total for all 59 clinics was 805.

Symptoms attributed to the intra-uterine ring were reported by 60 physicians. In 42 cases, menstrual disturbances were mentioned; in 10 cases, inflammation; in 6 cases, irritation; and in 2 cases, nervous symptoms.

Among the 92 physicians who responded to the questionnaire survey, 16 indicated that they advocated or approved of the use of intra-uterine rings, while an additional 58 stated that they should be used 'with some limitation according to the condition'. Eleven physicians disapproved, and 7 had no comment.

Under the auspices of the Taiwan Provincial Maternal and Child Health Institute, a survey was made of 11 obstetricians, who inserted intra-uterine rings, practicing in Taichung city and Nan-t'ou county: 4 in private gynecological clinics, 4 in health stations,

TABLE 1

Number of Women by Number of Pregnancies and Age

Age	Number of Pregnancies					
	2 & 3	4 & 5	6 & 7	8 & 9	10 and more	Total
Less than 25 years	8	3	—	—	—	11
25-29 years	35	54	12	—	—	101
30-34 years	6	80	78	13	1	178
35-39 years	2	14	78	38	10	142
40 years and more	0	2	24	29	34	89
Total	51	153	192	80	45	521

TABLE 2

Number of Women by Number of Induced Abortions and Age

Age	Number of Abortions					
	0	1	2	3	4 & 5	Total
Less than 25 years	6	4	1	—	—	11
25-29 years	53	41	6	1	—	101
30-34 years	76	83	11	7	1	178
35-39 years	48	74	14	5	1	142
40 years and more	23	48	11	2	5	89
Total	206	250	43	15	7	521

2 in government hospitals, and 1 in the Maternal and Child Health Institute. The survey covered 521 women wearing intra-uterine rings. Table 1 shows a distribution of these women by age and number of pregnancies prior to the insertion of the ring. A total of 315 women, or 60 per cent of the 521 cases, had induced abortions in the past. This is shown in Table 2.

By January 1962, one-fourth of the 521 women had worn the ring between 1 and 6 months; two-fifths between 6 months and 1 year; and the remainder, for one year and longer. The duration of use in shorter intervals was as follows:

Number of months	Number of women
1—3	78
4—6	57
7—9	113
10—12	99
13—24	163
25 and more	11
Total	521

Seventeen pregnancies occurred among the ring wearers, or 3.3 per cent of the total number of women. In an additional 36 cases, or 6.9 per cent of the total, the ring was removed because of side effects, and in 2 more cases, it fell out spontaneously. Pregnancies, reasons for removal and the duration of use are shown in Table 3. Thus, in 55 cases, or 10.5 per cent out of the total of 521, the method failed or was unsuitable. The remaining 466 women continued to use the ring successfully.

TABLE 3

Pregnancies and Removals of Rings by Duration of Use

Duration of Use (Months)	Pregnancies	Removals	Reasons for Removal		
			Disturbances of Menstruation*	Inflammation and Irritation	Nervous Symptoms
1—3	6	17	12	2	3
4—9	7	15	9	4	2
10 and more	4	4	3	1	—
Total	17	36	24	7	5

* Mainly irregular menstruation and/or hypermenorrhea.

Of the 466 women who continued to use the ring, 332 had no complaints and 134 had some complaints. There were 9 removals among those who later continued because they wanted to become pregnant.

Only one of the 17 pregnancies was carried to term. The rest were terminated by abortion.

Aggregate exposure with the intra-uterine ring was 5,507 months, of which 1,427 months were contributed by exposure during the first three months after insertion; 2,200 months by the fourth to ninth month; and 1,880 months by exposure during the tenth month and later. The pregnancy rate with the ring was 3.7 per 100 years of exposure,

compared with 71 prior to insertion. During successive periods after insertion, the pregnancy rate declined rapidly, as shown below:

Months after insertion	Pregnancy rate
1—3	5.0
6—9	3.8
10 or more	2.6

In summary, intra-uterine contraception is very widely used in Taiwan and has proved highly effective.

Our intention is to find a method which will be accepted by the people. Their attitude toward this method, which requires one simple action only, has been favorable. The economic and housing conditions in Taiwan, as in other developing countries, make this method practicable and reasonable.

Recently, a new device has been received from Dr. Margulies, which seems to be an improvement and will solve some of our problems. Our government officials are very much interested in this method, and we hope that this kind of new device will be used widely in our pre-pregnancy health services in Taiwan.

INTRA-UTERINE CONTRACEPTIVE DEVICES

by

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It would be worth while, before discussing our main subject, intra-uterine contraceptive devices, to give you a brief account of my very limited experience with intracervical pessaries, since these were my starting point 30 years ago. It may be interesting to note that intracervical pessaries were first used not to prevent conception, but to facilitate it. A hollow cylinder was devised to be placed into the cervical canal in cases with tight stenosis to keep it open and thus make impregnation easier. These cylinders were made in Frankfurt under the trade mark *Fructulet*. They were left in for only one month at a time. If left in place for a longer period, septic abortion usually occurred.

Some years later, intracervical pessaries in various forms were widely recommended for contraceptive purposes. Basically, all these pessaries consisted of a stem, which occupied the cervical canal, and a circular button-like plate at the vaginal end of the stem to cover the cervix. All sorts of materials were used—silver, gold, platinum, stainless steel, vulcanite, celluloid, glass, and various compositions. The best known, at the time, were the Sterilett and the gold pin. The latter consisted of a fenestrated circular plate, molded to form a shallow concavity, fitting over the lower end of the cervix. From the middle of the circular plate projected a hollow stem of closely wound wire, which fitted into the cervical canal. At the other end, this wire separated to form two diverging arms, which occupied the uterine cavity. Before introduction into the cervical canal, the diverging arms were pressed together and a gelatine capsule slipped over them to keep them together. After introduction, the gelatine capsule melted at body temperature, and the two diverging arms sprang apart to hold the apparatus in position. The constant pressure on the uterine walls, exerted by the two arms, led to atrophy with ulceration.

My own experience with intracervical pessaries was limited almost entirely to their removal, after they had been inserted by other doctors and had caused complications. I have never seen a case in which their presence has not been accompanied by a pathological condition, due to an ascending infection from the vagina to the cervix, uterus, and tubes. In order to avoid this ascending infection, and to overcome the objectionable feature of continual patency of the cervical canal, Gräfenberg of Berlin devised a completely intra-uterine pessary consisting of several strands of silkworm gut, knotted so as to form a small circular ring.

The ring was made in three sizes with diameters of 2 cm, 2.5 cm, and 3 cm, respectively. The cervical canal was dilated up to Hegar size 6 or 7. The correct size was determined by introducing a graduated uterine sound. The ring was then introduced through the cervical canal into the uterine cavity proper, where it resumed its circular shape and remained settled between the anterior and posterior walls of the uterus above the internal os. The cervical canal was thus permitted to close again. No channel remained open, which could

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facilitate any ascending infection from the vagina. The silkworm gut did not exert sufficient pressure to damage the uterine walls. Providing it was introduced with the proper surgical aseptic technique and only into a healthy genital tract, it never produced sepsis or inflammation.

The silkworm gut had, however, certain disadvantages. Owing to its high compressibility, it sometimes escaped from the uterus, either during the menstrual flow or at other times. Besides, its presence could not be checked by X-ray. Gräfenberg succeeded in overcoming this deficiency by winding a single strand of silver wire around the circumference of the silkworm gut ring. The silver wire could be detected by X-ray, and when the time came to remove the ring, contact of the silver wire with the metal produced a marked sensation, which enabled the surgeon to find and remove the ring more easily. Even with the strand of silver wire, the silkworm gut ring was still too compressible and sometimes escaped without the patient feeling it.

Gräfenberg, therefore, devised a silver intra-uterine ring, consisting entirely of a length of fine spiral silver wire, bent to form a circle, with the two ends fused and with two or more strands of silkworm gut running through the hollow of the coil to keep the circular form, if by accident or by lack of skill the surgeon broke the coil at the point of junction during introduction or removal. Experience has shown that these silver rings should be prepared in five different sizes: 1.5, 1.75, 2, 2.5, and 3 cm, respectively, and with varying degrees of resiliency. In some women, if the ring was too soft, it was easily pushed out; while in others, if it was too stiff, it caused uterine contractions, which expelled the ring. The choice of the right size and the right degree of springiness of the ring called for skill and experience.

Still another form of the ring has been prepared, consisting of two rings joined together near the middle of their circumference. This form was called the 'Lovers' Knot' by the late Norman Haire,[3] and is also known as the 'double ring.' It is more suitable in cases in which the uterus is intolerant of a single ring, since it is compressed only with considerable difficulty.

Later on, it was observed that silver rings became black when left *in utero* for a few years, and gold rings were substituted. Gold rings were also too soft and compressible and were in turn replaced by stainless steel, as Gräfenberg had advised. I have used rings of almost all forms, sizes, and resiliencies in about 500 cases during the past 30 years. Providing the patient's genital tract is healthy and a ring of the right size and consistency has been introduced properly with full aseptic surgical technique, it should cause no trouble whatsoever. I used to leave the ring in the uterus for as many years as the patient wanted. Some of my cases have worn it for over 30 years without any side effects or complications.

Nevertheless, some patients complain of symptoms, which are coincident with and not consequent to the presence of the ring. But if such a patient consults another doctor, who is not familiar with this method of contraception, then the presence of the ring is most likely to be blamed for anything from a sick headache to appendicitis. This is simply pure prejudice against a new technique with which some colleagues are not familiar. I remember one of my ring-wearing patients had once complained of an acute severe backache. On consulting her physician, she was referred to her gynecologist. Both physicians blamed the ring and insisted on its removal. I had to remove it as I could not convince her otherwise. But the backache did not subside. X-ray revealed a lumbo-sacral prolapsed disc. After she had been treated by her orthopedist, she came back to me and had another ring inserted.

It is sometimes suggested that the ring may cause permanent sterility. This likelihood is extremely remote since all my patients who had their rings removed in order to have

children quickly became pregnant, although some of them had worn them for over 10 years.

What exactly is the physiological action of the intra-uterine ring? It was once thought that the ring caused an early monthly abortion. This is incorrect, because the essential condition of an abortion is the previous nidation of the fertilized ovum. This is exactly what is prevented by the ring. Since the ovum does not become embedded at all in ring-wearing uteri, we can entirely disregard this theory.

It was also thought that the ring caused a low-grade chronic endometritis which prevented the embedding of the ovum, until Carleton and Phelps[1] made their studies. Their experimental observations were planned to answer three questions: To what extent does an intra-uterine ring protect the wearer from pregnancy? Do such foreign bodies in the uterus produce lesions? How do the rings act in inhibiting pregnancy?

The experiments were carried out on rabbits. Biopsies taken from the rabbits' endometria one year after being fitted with the ring, all showed the same tendency for the endometrial cells in contact with the ring to be flattened and the adjacent endometrial glands to be atrophied, but no inflammatory changes were noted. The changes were of the nature of a local pressure atrophy. A congested or hypertrophied endometrium was never noted in these experiments. Corresponding changes in the human female are temporary, since they occur in the epithelial layer, which is cast off monthly at menstruation and replaced by a new layer.

Nevertheless, one frequently hears the criticism, even from medical colleagues, that the presence of a foreign body in the uterus must be harmful and may even cause cancer! Why? We wear gold fillings in our teeth and dental plates in our mouths; metal bridge work is in constant contact with the mucous membrane of the gums, cheeks, and tongue, and metal plates with bones; and yet, normally, these do not cause inflammation or cancer. Why, then, should a foreign body in the uterus do so? This seems even less likely in the uterus, since here the mucous membrane, in which any changes might occur, is thrown off and renewed every month—a procedure which occurs nowhere else in the body.

Besides Gräfenberg, Drs. Eustace Chesser and Norman Haire, with whom I kept in constant contact, have stated on various occasions that they had never seen a case of cancer among the thousands of women they had fitted with rings, although many of them had reached the age at which cancer usually occurred. Scrapings were taken from the uteri of ring-wearing women, after removal of the ring, and submitted to skilled pathological examination. They all revealed the same picture previously described by Carleton and Phelps with the following conclusions: no evidence of malignancy or inflammation, no evidence of septic infiltration, and the general appearance of normal mucosa.

Similar reports of curetted endometria, taken in several cases where I removed the ring because the wearer desired pregnancy, showed the same normal picture, and all these women became pregnant after removal of the ring within a period ranging between two and six months.

I believe you all agree with me now that these results are rather convincing of the harmlessness and reliability of this method, if used in selected cases with healthy genital tracts and handled by efficient gynecologists.

So far as statistics are concerned, among 486 cases in which I have inserted a total of 1,258 rings during the period of the last 30 years, I had the following results:

In 5 per cent of the cases, the ring was almost expelled during a heavy menstrual flow, but was checked by the patient. In most of these cases I could control the menorrhagia by

either local or hormonal therapy and reinserted a new ring of a more suitable size and resiliency, which was retained.

In 1 per cent of the cases, the uterus rejected all sizes and resiliencies of single rings and had to be fitted with a double ring. In another 1 per cent of the cases, the ring escaped without the notice of the patient and was followed by unwanted pregnancy, or the ring was introduced unintentionally into a pregnant uterus, in which case pregnancy continued to full term without any harmful effects to either mother or child. They were all kept under my observation until I delivered them normally and safely, with the ring coming out entangled between the placenta and membranes.

In the remaining 93 per cent of the cases, the ring proved completely satisfactory and offered no trouble to either the patient or myself. I hope the success of this method will increase by replacing the metallic ring with the newly introduced polyethylene one described by Guttmacher.[2]

The medical committee of the Egyptian Association of Population Studies is responsible for carrying out scientific investigations on the various contraceptive methods, and will therefore try hard to find the means for obtaining a sufficiently large number of rings to enable it, through experimental use in its various clinics, to measure scientifically its effects, side effects, and after effects.

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CLINICAL EXPERIENCE WITH THE USE OF A FLEXIBLE NYLON RING (GRÄFENBERG RING) AS A CONTRACEPTIVE TECHNIQUE

by

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The urgency for the development of simple and effective contraceptive methods is an unquestionable necessity at present.

Ishihama[2] and Oppenheimer[3] presented evidence as to the effectiveness of the Gräfenberg technique. Their work suggested to us the possibility of employing a method which could offer ideal conditions, i.e., simplicity, effectiveness, and economy.

Subjects and Technique

Nylon thread, approximately 2 meters in length and 0.3 mm in diameter, was used instead of silkworm gut, as described by Oppenheimer. The ring was made of 20 to 25 interlaced turnings with a final diameter of 25 mm. It ended in a single thread about 20 cm in length. (See Figure.) The ring and the inserter were sterilized by immersion in an ethanol-iodine solution.

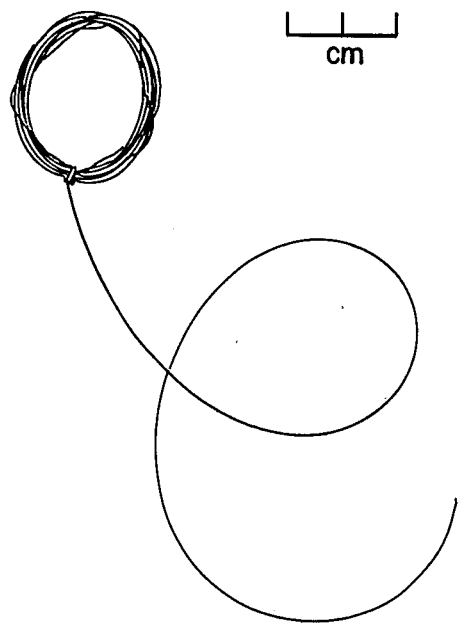

Fig. 1. Intra-uterine ring of nylon thread, with appendage.

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The ring was introduced into the uterine cavity without dilation of the cervical canal after iodization of the cervix, leaving the single thread in the vagina extending approximately 3 cm from the external os. The presence of this 'tail' made it possible to verify if the ring was in place either by the physician or by the patient and facilitated its extraction when necessary.

In the absence of this 'tail,' intra-uterine maneuvers, such as the use of an intra-uterine hook, were necessary to establish the location of the ring. In less than 5 per cent of the cases, the 'tail' remained within the uterine cavity instead of extending into the cervical canal.

A total of 1,252 patients volunteered for the study. They have been followed every 2 months at the Maternal Clinic of Barros Luco Hospital since October, 1959. In all, 994 patients were periodically controlled. Only extreme gynecological conditions were considered contraindications for its use. Even in the presence of cervical infection, the ring was placed in the uterine cavity. In 30 per cent of the cases, the ring was placed approximately 50 days after delivery. Women who were admitted to the clinic at least 6 months prior to the preparation of this report—a total of 628 subjects—were selected for study. This group was observed throughout 6,745 menstrual cycles. The ring was removed only when complications developed, or at the patient's request.

Results

Nine pregnancies were observed; no ectopic pregnancies were observed. Raymond Pearl's[4] formula was used to express the pregnancy rate per 100 years of exposure:

$$\frac{\text{Number of pregnancies observed} \times 1200}{\text{Number of cycles}}$$

Using this formula, 1.6 pregnancies per 100 years of exposure were recorded.

During the first 3 to 4 months after insertion of the ring, the following data were obtained: in 40 cases (6.4 per cent), the ring was spontaneously expelled; in 16 cases (2.5 per cent), menometrorrhagia occurred and the ring was removed; 5 patients (0.8 per cent) complained of pain; and 7 patients (1.1 per cent) asked to have the ring removed for fear that its presence in the uterine cavity would impair their health. In 2 patients, the ring was spontaneously expelled during the twelfth and fifteenth consecutive month of use. Clinical infections were not recorded in any of the cases.

Comments

Our data regarding pregnancy rates and complications compares favorably with that of Ishihama, who used rings made of polyethylene, nylon, and/or different metals; also with that of Hall and Stone;[1] and that of Oppenheimer, who used silkworm gut. It is noteworthy that in Oppenheimer's experience menometrorrhagia was not observed. This could be due to the type of material used, because in our experience the use of silkworm gut rings reduces the number of complications.

Tietze[5] compiled pregnancy rates per 100 years of exposure in patients using different contraceptive methods. The comparison of our data with that of Tietze indicates that the Gräfenberg ring is an excellent contraceptive technique.

Our findings may also be expressed in terms of the number of pregnancies prevented during a period of exposure as a percentage of the number expected without use of contra-

ceptive measures in the same group. The pregnancy rate without contraception was not determined for our subjects, but may be assumed to be in the order of 80 per 100 years of exposure. Computed on this basis, the effectiveness ratio was 98 per cent.

Summary

A flexible nylon ring was used as a contraceptive technique in 1,252 women. A total of 628 women was followed for more than 6 months during which 6,745 cycles were accumulated. All subjects belong in the low-income level category. The rate of pregnancy in this group was 1.6 per 100 years of exposure. The percentages of complications were: expulsion—6.4 per cent; menometrorrhagia—2.5 per cent; ring removed at patient's request—1.1 per cent; pain—0.8 per cent. The effectiveness ratio was 98 per cent. In our opinion the ring can remain in the uterine cavity for an indefinite period of time.

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PERMANENT REVERSIBLE CONTRACEPTION WITH AN INTRA-UTERINE PLASTIC SPIRAL (PERMA-SPIRAL)

by

LAZAR C. MARGULIES, M.D., F.A.C.S.*

My interest in contraceptives was aroused by Dr. John Rock of Boston who in November, 1958, delivered the Rubin Memorial Lecture at Mount Sinai Hospital. I was taken aback by the incongruity of this distinguished scientist's topic for the occasion. I expected to hear about new discoveries and progress in the treatment of sterility, which was Isidor Rubin's main aim in his life. To my surprise, Dr. Rock spoke for more than an hour about the dire consequences of overpopulation and the urgent necessity for large-scale conception control. The lecture gave me the incentive to search for a simple, inexpensive, and reliable permanent contraceptive that could be applied and removed easily. I knew of the Gräfenberg ring and that doctors did apply it here but did not feel that it lived up to all demands. In the literature I found only one recent publication in favor of intra-uterine contraceptives, while all others rejected and even condemned intra-uterine or intracervical devices.

The one recent paper in favor of intra-uterine devices was published in 1948 by Halton, Dickinson, and Tietze.[3] Halton wound several strands of coarse silkworm gut into rings just before insertion, compressed them into gelatin capsules, dilated the cervix to Hegar size 8, and pushed the capsules with the rings into the uterus. The capsules dissolved in the moisture, and the rings expanded filling the uterus. Halton reported a pregnancy rate of less than 1 in 100 years of exposure on her 266 private patients with an aggregate period of 486 years. This idea appealed to me but realizing that a device for mass consumption must be ready-made and mass produced, I prepared thin polyethylene tubes by injecting them with a radio-opaque fluid, sealed them, wound them into rings, and placed them in gelatin capsules. Dr. Alan Guttmacher, with the open mind of a genuine scientist, permitted me to use them in his clinic at Mount Sinai Hospital.

Between January and April, 1959, I inserted 2 of these capsules into the uteri of 26 women, who came to the post-partum clinic 6 weeks after tubal ligation. Disturbances and ejections occurred in the same high percentage as reported by Halton (40 per cent). I removed all rings in May and June, 1959, as had been intended. Ejections, spotting and/or bleeding, and the experience that the insertion in many patients was painful were sources of disappointment. Knowing that Dr. Guttmacher would let me start again if I devised something better, I kept on working for an entire year on a variety of ideas, forms, and materials, among others, 46 different plastics, before finding an approach which, I felt, could revolutionize the highly promising but stagnant field of intra-uterine contraception. I was encouraged by the papers of Oppenheimer[6] and Ishihama,[5] particularly by their observation that not one case of endometrial carcinoma was encountered in 20,000 patients, some carrying the device for twenty or more years.

In order to achieve a painless insertion, I had to design a form flexible enough to be

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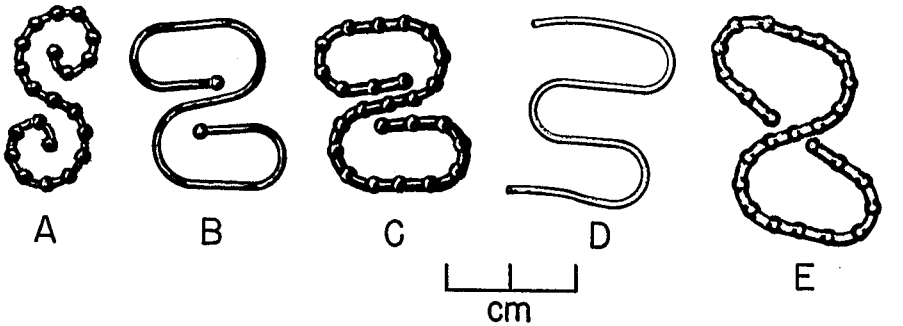

Fig. 1. Experimental intra-uterine devices: *A:* beaded S; *B:* double S, plain; *C:* double S, beaded; *D:* loop; *E:* pretzel.

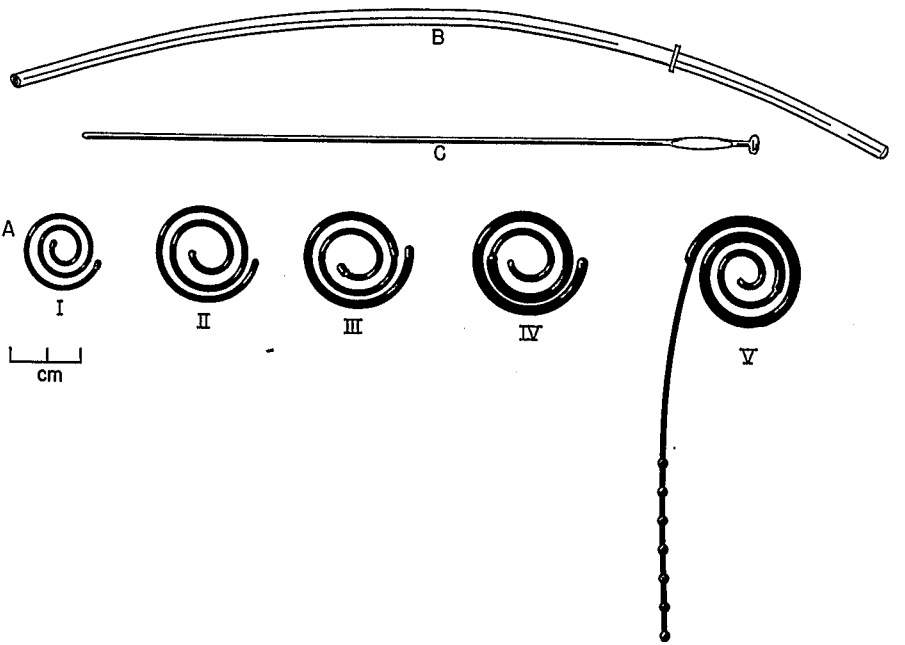

Fig. 2. Intra-uterine polyethylene spirals and instrument for their insertion. *A:* spirals, Nos. I-V; *B:* flexible plastic tube; *C:* metal plunger.

inserted and removed through the cervix without dilation, even in nulliparous women, and to resume its preshaped form within the uterus. To achieve this, I broke away from the established image of a ring as the only shape for a fully intra-uterine contraceptive device. I opened the ring into various forms and shapes, such as an S, double S, a pretzel, a loop, and finally a spiral.

The other breakthrough idea I developed simultaneously. This was to feed the device into a thin tube, insert the tube through the cervix into the uterus, and, by pushing the device with a plunger, have the molded plastic assume its original shape in the cavity of

the uterus. The tube, when manufactured for commercial distribution, will have two oval flanges. At this moment, for reasons of economy, I use a Teflon round tube with one oval marker. The marker, three inches from the end of the tube, marks the direction in which the device coils when prepared, so that after insertion into the ante- or retroverted uterus, we can actually see how to turn the tube by 90° in order that the device can recoil in the frontal plane of the uterus.

Figure 1 shows various shapes of molded devices, each of which I tried on a few patients but moved on to the next because they were not satisfactory: the beaded S; the double S, plain and beaded; the loop; and the pretzel. Figure 2 shows the various types of spirals, the insertion tube with its flange, and the metal plunger. The first spiral was inserted on

TABLE 1

Number of Patients by Size of Spiral

Size of Spiral	Total Wearing This Size	First Insertions*	Changed from Smaller Spiral	Now Wearing	Now Wearing Larger Spiral	Discontinued
I	49	49	—	3	35	11
II	58	47	11	18	31	9
I & II	35	9	26**	11	17	7
III	156	141	15	52	89	15
IV	109	94	15	92	14	3
V	279	160	119	276	—	3
Total	...	500	...	452	...	48

* Period of first insertion: Spiral
No. I Sept. 15, 1960, to Jan. 17, 1961;
No. II Jan. 18, 1961, to Mar. 20, 1961;
Nos. I & II Feb. 23, 1961, to Mar. 29, 1961;
No. III Mar. 21, 1961, to Aug. 16, 1961;
No. IV Aug. 20, 1961, to Dec. 31, 1961;
No. V Dec. 21, 1961, to Apr. 20, 1962.
** Addition of No. II to No. I.

TABLE 2

Ejections by Size of Spiral

Size of Spiral	First Ejections				Repeat Ejections	Total Ejections
	Number	Per cent*	Noticed by Patient	Not Noticed		
I	11	22.4	6	5	5	16
II	14	24.1	10	4	3	17
I & II	4	11.4	3	1	—	4
III	17	10.9	9	8	4	21
IV	6	5.5	4	2	2	8
V	5	1.8	5	—	—	5
Total	57	...	37	20	14	71

* Per 100 patients wearing this size.

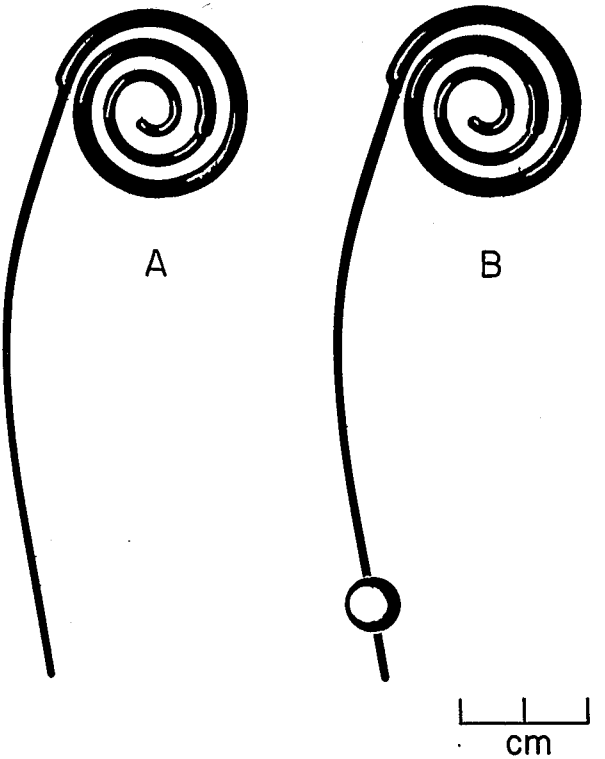

Fig. 3. A: Intra-uterine spiral with extension ('tail'); *B:* same with polyethylene bead threaded on tail.

September 15, 1960. Previous patients were then called in to exchange their devices for the spiral.

I started with a small spiral (size I), which was ejected in 11 out of 49 cases (22 per cent). By increasing the size, the percentage of primary ejections was reduced to 5.5 per cent in size IV and, so far, to less than 2 per cent in size V. The numbers of patients wearing each size of spiral are shown in Table 1 and the ejections in Table 2. Percentages are computed on the basis of first ejections in relation to the total number of patients wearing each size of spiral. For a short time in 1961, spirals Nos. I and II were inserted together or No. II added to No. I.

Most of the ejections occurred at the time of menses during the first to third month after insertion, with several after 14 months of use. Most, but not all, expulsions, were noticed by the patient. The patients who were not aware of the ejections caused embarrassment because they became pregnant immediately. Until recently, the only way we could ascertain reliably whether or not the spirals remained in the uterus was by X-ray. (The polyethylene has 20 per cent barium sulfate mixed in.) During the summer of 1961, I had long talks with Dr. Guttmacher about means of detecting the spiral which would be simpler, cheaper, and more readily available. We also discussed the pros and cons of Dr. Guttmacher's suggestion to devise a mechanical memento, which the patient herself is able to check and thus know whether the device is *in situ*, slipping, or has slipped out.

It took courage to revert from the concept of a pure intra-uterine device back to one which protrudes from the cervix into the vagina with its bacteria. Eventually, I had an extension made on the free end of spiral no. IV, thin enough not to keep the internal os of the cervix open and also not to disturb the male (Figure 3). It did not disturb the male, but it also blended so well into the vaginal folds that the women themselves could not feel it. So I had polyethylene beads drilled, and threaded one on the tail after the spiral had been inserted. This proved to be too time-consuming, taking 25 minutes in the first patient. Determined to stay within the bounds of the diameter of the tubing, I finally designed seven smaller beads on the distal end of the tail. After insertion, one or two beads are left sticking out from the cervix and the superfluous ones are cut off. The tail and beads are embedded in the cervical mucus and have not caused any irritation, discharge, or erosion.

The patients are taught to examine themselves with washed hands once a week in a squatting position to check whether and how many beads they feel. The plastic becomes so soft at body temperature that very few of the more than 250 husbands have complained yet of being disturbed. This extension has two additional advantages: (1) Removal of the spiral becomes simple, quick, and absolutely painless by simply pulling out the device in one second. Indeed, a few patients pulled out the spiral themselves, when they felt too many beads and were afraid that the device was on its way out. The previous spirals were removed by means of a blunt hook made by twisting the tip of a surgical probe, or by a biopsy curette. (2) The extension stem is flat and, by its position, we can see or feel outside the cervix in which plane the device is coiled in the cavity, eliminating the need for hysterography.

Over the past 19 months, spirals of different sizes have been supplied to 500 patients with about 3,600 months of exposure, almost equally divided between private and clinic patients. Pregnancy with the spiral *in situ* occurred in 4 patients: one had spiral II, the others, III. There were, in addition, 9 pregnancies in patients who passed the spirals without their knowledge and the frequency of this event shows well the importance of the increase in size. In patients with spirals No. I, No. II, and Nos. I and II, taken as a group, the pregnancy rate per 100 years of exposure was 7.7. With spiral No. III, the pregnancy rate was 5.8. None of the 388 consecutive patients who have had spirals IV and V, with a total of 1,250 months of exposure, has so far conceived. (See Table 3.) Only 5 of the 279 patients with spiral V expelled the whole device and all noted it.** Six patients pulled the spiral out themselves, 4 of them coming back for re-insertion.

TABLE 3

Months of Exposure, Pregnancies, and Pregnancy Rates by Size of Spiral

Size of Spiral	Months of Exposure	Number of Pregnancies			Pregnancy Rate*
		After Losing Spiral	With Spiral *in situ*	Total	
I	230	3	—	3	
II	550	3	1	4	7.7
I & II	308	—	—	—	
III	1,250	3	3	6	5.8
IV	600	—	—	—	—
V	650	—	—	—	—
Total	3,588	9	4	13	4.3

* Per 100 years of exposure.

** Four of these had a softer variety: plain polyethylene without barium, which I had inserted experimentally into 101 patients.

We have been calling in our patients to exchange the smaller spirals for size V. So far, I did not find it necessary to exchange the No. IV, nor to advise the nulliparous patients to have theirs exchanged, because only 2 of 56 expelled the larger spirals. Size I was too small even for them: 5 out of 10 expelled it. Only once in 20 nulliparas, I failed to insert size V. Four parous patients had too small uteri to contain it, although they had had their babies several years before. One of them came back before expected menses and the insertion at that time is easy. I had a spiral with a smaller tail made for these patients but received it only recently, and have had no time to try it out. This spiral will be known as No. V-J (for 'junior').

Only 2 of the 500 cases showed infection after insertion: one nulliparous patient reacted with an exacerbation of a tubo-ovarian abscess which had been aspirated during a laparotomy one year previously. One week on Mysteclin cleared it up and she did not have any further reaction. The second case was a patient in whom I exchanged spiral III for spiral V and, in the same session, cauterized a large cervical erosion. She ran a fever for 2 days with pain in the lower right quadrant of the abdomen, which was easily controlled with Panalba. I now cauterize erosions around the beads but not at the time of insertion.

A third case for which the spiral can by no means be blamed was a clinic patient, who had a spiral No. V inserted on January 30, 1962. She was found in perfect condition at a checkup on February 20, 1962, and came to the emergency clinic on March 15 with an acute pelvic peritonitis. When the spiral was pulled out, pus exuded from the uterus. Smears and cultures were negative, but gonorrhea was confirmed in her husband four days later. Dr. Bollinger, of Temple University, wrote to me about a similar experience with a patient only five days after the insertion. Of unusual cases, I have had two patients with double uteri, in whom I inserted one spiral into each uterus.

I had a few 'habitual ejecters,' as I call them. One of them submitted to hysterography, and the X-ray of the pelvis showed clearly the incompetent internal os with the fluid leaking down into the cervix while the spiral lay in the dilated isthmus in a transverse plane. This patient now has her seventh spiral and, astonishingly enough, has retained this one, a No. V, for the first time for a period lasting more than three months. She is a nulligravida and has been very happy to have a device inserted even every two months and not to have to worry about it in between. Two other habitual ejecters passed No. V also.

Of the 48 patients who discontinued the method permanently so far, 42 had spiral I, II, or III; 3 had spiral IV; and only 3 patients, spiral V. The most common reasons for discontinuation were bleeding, expulsion, and pregnancy. A few patients stopped at the insistence of their husbands or for other causes. (See Table 4.)

TABLE 4

Discontinuations, by Reason and Size of Spiral

Size of Spiral	Bleeding	Ejection	Pregnancy	Insistence of Husband	Psychological Factors	Cramps or Backache	Infection	Total
I	1	3	3	3	—	1	—	11
II	3	2	3	—	—	1	—	9
I & II	5	—	1	1	—	—	—	7
III	3	5	3	—	4	—	—	15
IV	1	1	—	—	1	—	—	3
V	1	—	—	1	—	—	1	3
Total	14	11	10	5	5	2	1	48

About 5 per cent of the patients complained of prolonged menses, or bleeding, or spotting in between. They are often the same women who come again and again. I have tried many medications, like Vitamin K or C alone and in combination, Adrestat and Adrenosem tablets and injections. Sometimes they help and sometimes not at all. Two patients were curetted and endometrial polyps found. One had a hysterectomy four months after insertion, revealing huge endometrial polyps of long standing.

I performed about 80 endometrial biopsies, especially after removal or during exchange of spirals. Only one showed an acute endometritis 9 months after insertion. All the others, examined by regular and electron microscopy, were normal specimens.

While no one has proved up to the present time what happens every month to the women with devices *in utero,* the broadest consensus is that the devices prevent the implantation of the fertilized egg because the foreign body causes a discoordination of the uterus musculature which is supposed to place the ovum in the center of the uterus between the seventieth and seventy-second hour after the ovum entered the uterine cavity. I can cite from my experience four cases, which will support my previous statement that insertion or removal of the device does not cause abortion, provided that the egg had implanted itself before the device was inserted. I put in spirals on days 23 and 28 of the cycle, respectively, and the women did not get their menses any more. I also inserted spirals in two pregnant patients, who had stated that they had had periods 2 weeks before. Their pregnancies continued; their last 'periods' had been shorter and scantier. Removal of devices with the hooklet in two cases did not disturb the pregnancies, and I certainly do not expect the pulling out of my newest spiral to cause any damage to an implanted egg.

My attention was drawn to complaints by some patients of spotting and/or bleeding and cramps, starting a few days after their menses had stopped and lasting a few days. Since they had never experienced this before, I at first attributed it to the presence of the spiral. Checking a number of forms, which we hand to every patient in order to find how much and when they bleed or spot, I found quite a number of patients who showed intermenstrual spotting. A few did not complain because they had had similar symptoms even before insertion. It was then possible to diagnose the syndrome as *mittelschmerz* and *mittelblutung.* The pain and cramps were always located laterally so that, in spite of some bleeding, I could not blame the uterus for moving the spiral around. I therefore assume that a foreign body in the uterus increases the normal peristalsis of the tubes after ovulation, similar to reports of some of my patients that a coitus at that time would bring on staining and bleeding. This *mittelblutung* is not an endometrial bleeding: the blood comes from a pool in the *cul-de-sac,* and is aspirated by the tube and transported through the uterus. Normally, the pace of a fertilized egg is slow. It takes 3 to 3.5 days to pass the tube. At this slow pace most of the blood is probably absorbed and does not appear macroscopically. However, several investigators [1, 2, 4] proved that 85 per cent of normal women showed occult blood at that time in secretions accumulated in cervical caps.

I suggest that in our patients the fertilized ovum is transported by spastic peristalsis of the tube so much more quickly than before that it may arrive in the uterus prematurely, after one or two days. In this shortened time the ovum has not yet divided into the normal amount of cells. Even after 'floating' in the cavity of the uterus for three days, as normal blastocysts do, the ovum would not have developed sufficient trophoblastic cells to be able to penetrate through the endometrium. It may be that the uterine musculature is also discoordinated, and that the rapid passage through the tube might explain the phenomenon that very few tubal pregnancies have been encountered in patients with intra-uterine devices, most of whom are highly fertile.

I sincerely hope that the study undertaken by Professor Willson and his staff at Temple University will accumulate, in 4-5 years, enough clinical material to observe whether the

ovum appears in the uterus on days 13 and 14 or on days 16 and 17, and that embryologists will be able to determine the stage of development of the retrieved blastocyst.

Even if the tailed spirals do not continue with the perfect score which we have had in the past four months, and even if we find a few patients not suited for intra-uterine contraception because of prolonged bleeding, or cramps, or for anatomical or psychological reasons, my new method provides for the painless insertion of a permanent, although reversible contraceptive through a thin, flexible tube, which will never perforate the uterus. It makes over 98 per cent of the women who have had it inserted happy, and it is well tolerated. And to quote Dr. Warren Nelson from his letter of February 28, 1962, convoking this conference: 'It has appeared to us that the widespread use of such (improved) devices might come closer to offering a method of acceptable fertility control than any other presently available procedure.'

In all modesty I feel proud to have initiated this improvement and want to thank especially Dr. Guttmacher for his advice and assistance, both moral and administrative.

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Addendum (November 20, 1962)

I want to report two important technical improvements:

(1) I now use a tapered uterine probe not only to feel the position of the uterus but also to measure its length. The probe is marked by a ring at 6 cm (2¼″). The larger spiral (No. V) is inserted if the probe goes in well past the marker and the smaller spiral (No. V-J) if the length is about or less than 6 cm.
This selective procedure reduced the number of ejections considerably. We find that among our patients about equal numbers need spirals No. V and V-J.

(2) I had the teeth of a 7″ Allis forceps ground down to provide a sharp-edged square jaw. It cuts off the stem from the beads much closer than the curved scissors did and will never leave a sharp edge on the 'tail'.

L. C. M.

A STUDY OF INTRA-UTERINE CONTRACEPTION: DEVELOPMENT OF A PLASTIC LOOP

by

JACK LIPPES, M.D.*

It is unfortunate that Gräfenberg never lived to see the acknowledgement of the value of his great idea. There is a saying in medicine that an idea is never accepted because it is good or logical but because the opposition dies off. This was certainly true of Gräfenberg. A study of the history of the ring reveals more than academic excellence, more than medical knowledge. It reveals another example of man's eternal struggle to enlighten himself.

Materials and Methods

My first work merely repeated that of Gräfenberg and Oppenheimer.[4] I made silk rings by hand and inserted them. When I learned of the availability of the Japanese Ota ring,[3] I tried inserting these. The disc of solid polyethylene in the center of the Ota ring made it necessary to dilate the cervix to Hegar size 12. This was difficult for both the doctor and the patient. My first modification was to cut out the disc. Although insertions were easier, I soon learned that removing rings was far more difficult than inserting them. With Gräfenberg's instrument, which resembles a crochet hook, one is guided entirely by a sense of touch in removing these devices. I have acquired this skill with time, patience, and practice. My nurses at the Planned Parenthood Center in Buffalo named me the 'Jimmy Valentine of the contraceptive world.'

If these devices are to become universal, inserted by general practitioners, perhaps by nurses and/or midwives, an easier means of removal and insertion is necessary. To accomplish this, I tied to the Ota ring a suture, which dangled through the cervix. This was, of course, contrary to the principles that Gräfenberg taught.[2] Friends and colleagues warned me not to do this—not to bridge the gap between the sterile uterine cavity and the infected vagina. However, I have now done so 271 times (171 rings and 100 loops, all

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I want to take this opportunity to express my gratitude to Dr. Clyde Randall, Chairman of the Medical Advisory Committee of the Planned Parenthood Center of Buffalo. Were it not for his courage in allowing me to carry on this project at our Planned Parenthood Center, my work on intra-uterine contraception would never have come to fruition.

I must acknowledge the help of the social workers, nurses, and volunteers of the Planned Parenthood Center of Buffalo. Their aid went above and beyond the call.

Acknowledgment with gratitude is made to Dr. Herbert Lansky, Director of Laboratories at the E. J. Meyer Memorial Hospital in Buffalo, for interpreting the endometrial biopsies and to Dr. Ernest Witebsky, Professor of Bacteriology and Immunology at the University of Buffalo, School of Medicine, for assistance in the bacteriological portion of this study.

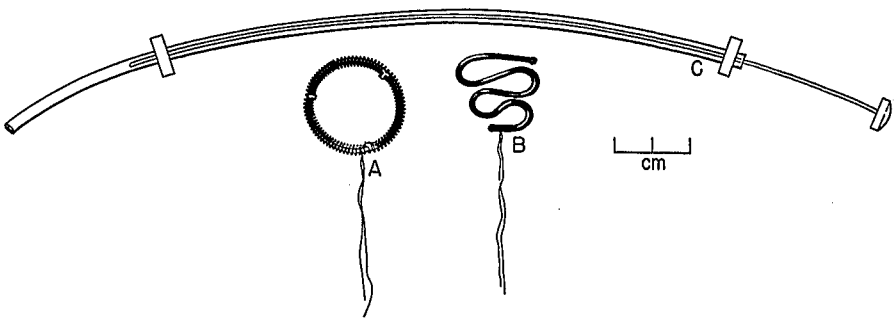

Fig. 1. Intra-uterine devices and instrument for insertion. *A:* plastic Ota ring with center removed; *B:* polyethylene loop, both with suture attached; *C:* flexible plastic inserter with plastic plunger.

with cervical appendages). All of these patients are clinically well. They are all multiparous, of proven fertility, and were between 18 and 38 years old. Of the total of 271 insertions, 160 were in clinic patients and 111 in private patients.

Bacteriological Study

Intra-uterine cultures from 20 clinic patients (10 from controls and 10 from patients wearing rings) were taken with an Ayre curette in order to avoid vaginal and cervical contamination of the cultures. The results of the culture examination were negative for five patients in each of the two groups. For the remaining five patients in each group, the results were quite similar.

Number of patients	*Cultures*
Ring-wearing:	
1	Streptococcus (nonhemolytic)
1	B. coli, B. aerogenes, and Streptococcus (nonhemolytic)
1	B. coli
1	B. coli and Streptococcus (nonhemolytic)
1	Bacteroides
Control:	
1	Streptococcus (nonhemolytic) and Diphtheroids
1	Staphylococcus albus (nonhemolytic) and Enterococci
1	Enterococci
1	Streptococcus viridans
1	Bacteroides

I have convinced myself that a suture dangling through the cervix provides an easy and harmless way to remove the ring or loop and to detect its presence. My belief that a cervical suture is harmless was confirmed by Zipper.[5] However, in 18 patients among the 171 in whom rings had been inserted, the suture was not visible at the cervix. These rings had to be removed by the original Gräfenberg technique. I believe that these 18 rings rotated when the uterine musculature contracted and, like the roller on the window shade, wound up the cervical suture.

I began thinking about a new design for an intra-uterine contraceptive device. I wanted a device that would fill the uterine cavity in a stable manner and that would not rotate.

At this time, Margulies demonstrated his spiral to me. He had originated a new and revolutionary principle, which I believe is a most important advance, by inserting the device through a narrow tube introduced into the cervix. I might have asked to use Margulies' device, but I wanted to get away from the circular shape because I believe it rotates.

As you know, the uterine cavity is triangular or trapezoid in shape. The uterine musculature runs in diagonal and transverse diameters[1] but not vertically. I wanted a device such that the muscular contractions of the uterus would not press on the entire piece of plastic but on one section at a time only. Since uterine contractions are rhythmic, this design and the nature of the plastic used would allow the device to assume its original shape. With this in mind, I designed a device which I call a 'loop.' The device corresponds to the shape of the uterine cavity. I insert the loop through a plastic tube, which is oval in cross section, so that I might know and control the plane in which my loop exits from the tube and enters the uterine cavity. The suture I am now using is a very fine monofilament of linear polyethylene, size 0000. My patients have been successful in learning to identify the presence of the loop by feeling the suture at the external os of the cervix.

Months of Exposure and Pregnancy Rate

A total of 171 modified plastic rings made of nylon and 100 polyethylene loops have been inserted, with a total observation of 1,660 months of exposure for the combined group. The following is a breakdown of months of exposure by type of patient and type of device:

Type of patient	*Months of exposure*		
	Ring	Loop	Total
Private	699	105	804
Clinic	697	159	856
Totals	1,396	264	1,660

Four failures or pregnancies have occurred, or 2.9 per 100 woman-years. Three pregnancies, or a pregnancy rate of 2.6 per 100 woman-years, have occurred during 1,396 months of exposure for the ring and 1 pregnancy, or a rate of 4.5 during 264 months, for the loop. Since we first began working with the loop in November, 1961, the number of months accumulated is necessarily small.

With regard to the one pregnancy among patients wearing the loop, it is possible that I inserted this loop into a uterus which was already pregnant. This woman had such irregular periods, I cannot be certain. I usually try to insert my loop at the end of a menstrual period because I believe it is easier at that time. The cervix is partially dilated and I am more certain of not interrupting a pregnancy. More patients and more months of exposure will be needed before I can speak with any authority on the loop's effectiveness.

Discontinuation

A total of 34 patients, or 12.5 per cent, discontinued the use of the intra-uterine device. Of these, 31 were ring patients and 3 were loop patients (see Table 1).

Expulsion has been a major problem. Since we began in October, 1959, 13 out of 171 ring wearers discontinued use because of spontaneous expulsion. The loop project is young but, as you can see, 2 loop wearers discontinued because of spontaneous expulsion. Four 'ring expellers' have been re-inserted with a loop and have been successful in using this second device over the past 6 months. Three of these 15 expulsions were responsible for 3 pregnancies because the device had been expelled without the patient's knowledge.

TABLE 1

Reason for Discontinuation of Intra-Uterine Device, by Type of Device

Reason	Total		Ring		Loop	
	Number	Per cent[1]	Number	Per cent[2]	Number	Per cent[3]
Expulsion	15	5.5	13	7.6	2	2.0
Bleeding	12	4.4	11	6.4	1	1.0
Pain	5	1.9	5	2.9	—	—
Leukorrhea	2	0.7	2	1.2	—	—
Total	34	12.5	31	18.1	3	3.0

[1] Refers to 271 insertions.
[2] Refers to 171 ring insertions.
[3] Refers to 100 loop insertions.

Most expulsions seem to occur within the first 4 months of use. Eleven of the 15 expulsion occurred during the first 4 months after insertion, and 4 occurred later (see Table 2).

The second major problem is bleeding. Eleven of 171 ring wearers insisted on having their devices removed because of persistent and annoying bleeding. This bleeding is usually not enough to alarm the physician. However, it does create fear and anxiety in the

TABLE 2

Duration of Use prior to Discontinuation of Intra-Uterine Device: by Reason and Type of Device

Type of device and duration of use (months)	Expulsion	Bleeding	Pain
Ring			
1	3	3	2
2	3	1	1
3	1	1	—
4	2[1]	1	1
5–8	1	5	1
9–12	3[2]	—	—
Total	13	11	5
Loop			
1	2	—	—
2	—	—	—
3	—	—	—
4	—	1	—
5–8	—	—	—
9–12	—	—	—
Total	2	1	—

[1] One pregnancy. [2] Two pregnancies.

patient. The bleeding usually stops after the second menstrual period after insertion. In the meantime, I have used Vitamin K, flavonoids, and mostly reassurance, to tide the patient over the first two months of use. Where the bleeding has persisted beyond the second month, I have been compelled to remove the ring or the loop. Only one loop has been removed for bleeding, perhaps because of the small number of loop insertions. However, I have the impression that the loop causes less bleeding than the ring. This may be due to the fact that the ring has a coil of nylon around it, while the loop is made entirely of polyethylene.

About one-half of the 12 removals for bleeding were done during the first 4 weeks and the rest later.

The third problem of ring wearers is pain. Five ring wearers have had their rings removed because of pain. This pain is described as backache or vague lower abdominal cramps. Usually, I attempt to treat pain with reassurance, aspirin, codeine, bed rest, and a hot water bottle. In the five patients who had their devices removed, the pain was persistent enough to necessitate removal. No loops have yet been removed because of pain. Again I have the impression that the loop gives less pain than the ring.

There were two ring patients who developed leukorrhea and insisted that their rings be removed. One of these had a monilia infection and the other, trichomonas. These two patients could not be convinced that the devices had nothing to do with their discharge. I was again compelled, at the patients' requests, to remove two more rings.

I believe the number of patients who have discontinued the loop, is low even for this early six-months period over which I have been working with the loop. I hope, of course, it continues to be low. However, time and further observation will be needed.

Nine patients have had their loops or rings removed because they were desirous of becoming pregnant. All are currently pregnant and none had more than 3 menstrual periods after removal. In fact, 2 patients missed the very next period. Both of these patients had their devices removed on day 17 of their cycle, 2 to 3 days after expected ovulation. Bleeding after removal prevented intercourse until day 22 of the cycle. This would suggest that intra-uterine contraception does prevent nidation, as Gräfenberg originally thought.

Among my patients, I have thus far taken 225 endometrial biopsies. A total of 146 biopsies were taken prior to insertion and used as controls and 79, during the use of intra-uterine contraception, 3 months to 1 year after insertion. As the following figures show, decidual reactions thus far have been the same in the control group as in the patients wearing rings or loops.

Type of reaction	*Before insertion*	*After insertion*
Decidual	2	2
Endometritis	2	7
Normal	142	70
Total	146	79

The one big difference that is readily noted is that 7 biopsies among ring wearers have shown endometritis, compared with 2 in the control group. I must point out, however, that all of these patients are clinically well. I believe that the inflammatory reaction in the endometrium, associated with intra-uterine contraception, is due to a foreign-body reaction and not infection. I will call it a 'sterile endometritis.' After all, these patients are well. Their bacterial flora has not changed.

No loop-wearing patients have shown endometritis. There has been no cancer, no hyperplasia, and no polyps found in any of my biopsies. This portion of my study is not yet complete. I shall continue to take endometrial biopsies on ring and loop wearers until their number reaches 146 also.

Engineering Principles

Recently, I have been taking readings to determine the amount of force which is needed to remove one of my loops. Thus far, the normal range runs from 70 to 80 grams. These readings have been taken with a spring scale which is attached by a thread to the loop's cervical appendage. I have taken one reading on a patient who has consistently expelled all loops. In this case, only 50 grams of pull was required to remove the loop. If this study continues to show that patients who expel loops and rings need less force to remove their devices, it may be possible in the future to predetermine the patients who are most likely to expel them. The physician in such a case could change the patient to another contraceptive technique. At the very least, the patient would be forewarned that she is liable to expel the device. Here, too, more work is needed. After all, these measurements must be an expression of the diameter of the cervical canal, or at least of the distensibility of the cervical canal, since the loop needs a constant amount of force to be deflected or straightened.

This technique opens up new avenues of research into uterine physiology, and perhaps the study of cervical incompetence.

Summary

A review of intra-uterine contraception through use of either the nylon ring or the polyethylene loop, both with cervical appendages, has been presented. With the evidence at hand, neither the ring nor the loop can be considered harmful. Furthermore, the presence of a cervical appendage, which bridges the uterine cavity and the vagina, is perfectly safe and without serious side effects. Both the ring and the loop provide an effective means of contraception for both private-type patients and clinic-type patients.

Inserting the contraceptive device through a tube has many advantages among which are:
(1) Elimination of the use of a tenaculum except for the occasional case.
(2) Elimination of cervical dilation except for the occasional case.
(3) The carrying of bacteria from the lower cervix into the uterine cavity must reasonably be reduced by the protective action of the tube through which the device is inserted.

About one patient out of eight discontinued intra-uterine contraception because of expulsion, bleeding, pain, and leukorrhea. All of these side effects were annoying enough to force discontinuation of this method. However, none of the side effects could be classified as a serious threat to health or life.

Conclusion

It would not be right to draw conclusions from a study that is as yet incomplete. Further work is obviously needed. Already mentioned are the additional biopsies that will be taken. The engineering principles are just beginning to be evaluated.

However, it is safe to say in this conclusion that intra-uterine contraception does provide a safe, effective, and acceptable means of birth control for both private and clinic patients.

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Addendum (November 20, 1962)

In an effort to improve results with the loop technic of intrauterine contraception, loop #2 has been designed and produced.

Loop #2 overall measurements:

The top bar measures 30 mm and the trapezoidal outline then narrows to 16.7 mm. The cross sectional diameter of loop #2 is 2 × 2.8 mm. The overall height is 27.5 mm.

Loop #2 was designed in an effort to reduce the number of expulsions and also to improve the effectiveness of this device.

At the present time all multiparous patients at the Planned Parenthood Center at Buffalo are having the #2 loop inserted exclusively. Only nulliparous patients are having loop #1 inserted.

Not enough months have lapsed to publish any of the results with loop #2.

J. L.

REPORT ON STUDY OF MARGULIES' CONTRACEPTIVE SPIRAL

by

DEBORAH BAUMGOLD, M.D.*

The use of the plastic intra-uterine spiral, devised by Margulies, was begun in January, 1962, at the Contraceptive Service of the Margaret Sanger Research Bureau. Each patient using the spiral is rechecked monthly for the first three cycles after insertion.

So far, 68 women have had spiral no. V inserted, and 10 have already had it permanently removed. This progress report is limited to the first 44 women, whose insertions were all made prior to March 16. Since our clinical experience with this intra-uterine device is so short, it is not possible to draw any conclusions from it as yet.

The mean age of these 44 patients is 31.8 years; 18 are under 30 years of age; and 26 are 30 years old or more.

Mean parity for the group is 2.5 with a range from zero in 4 cases to a maximum of 7 pregnancies for 1 woman. Of the 40 women who have had 1 or more pregnancies, 28 (70 per cent) reported at least 1 unplanned pregnancy, and 7 (18 per cent) reported induced abortions.

Among the 37 women over 24 years old, 11 reported 1 or more spontaneous abortions, and 3 have had more than 1 miscarriage.

All but 2 of the 44 women reported the use of some form of contraception before admission to this study. Since very few of our patients perceive any distinction between withdrawal and no method of contraception at all, we construe withdrawal as 'no method.' The methods reported are as follows:

13	Diaphragm
12	Combination of two or more methods
11	Condom
5	Cream or jelly alone
2	Withdrawal or 'no method'
1	Rhythm

At the first follow-up visit, which in some cases occurred only a day or a week after insertion, data were gathered on pain and bleeding following insertion:

Pain:

10	No pain (7 in the older group, 30 years old or more)
23	Mild pain
4	Moderate pain
7	Severe pain (5 in the older group)

* Margaret Sanger Research Bureau, New York, New York.

Bleeding:

2	No bleeding following insertion
26	Light bleeding or spotting
12	Moderate bleeding
4	Heavy bleeding (1 for as long as a week)

Therapy was used in five cases. Aspirin was usually advised for pain or cramps, or aspirin-phenacetin-codeine prescribed if the symptoms were intense. In some cases where bleeding was a problem, Hesper-C (2 capsules, t.i.d.) was advised, but results were not encouraging.

First menses following insertion can be reported for only 37 of these 44 patients, since 5 of them discontinued the spiral before menses began, and two moved out of town.

Time of menses:

22	began earlier than expected
10	began on expected date
5	began later than expected date

Duration of flow:

27	longer than usual
8	usual duration
2	shorter than usual

Amount of flow:

28	heavier than usual
8	same amount as usual
1	lighter than usual

Dysmenorrhea:

24	no dysmenorrhea
10	mild dysmenorrhea
3	moderate dysmenorrhea
8	increase in dysmenorrhea
5	decrease in dysmenorrhea

Papanicolaou tests were done both before insertion and during the first follow-up visit. So far, results are available in 20 cases. Although these show no change in 6 cases and improvement in 1 case, it is a matter of concern that in 13 cases, the Papanicolaou results were worse at the first follow-up. We feel that these tests are important and should be carefully watched.

Spontaneous ejection of the spiral has occurred in 3 cases—7 per cent of the 44 cases included in this report. Two spirals were removed by private physicians, and 2 were pulled out by the patients themselves. Partial displacement of the spiral was found and adjusted in 2 patients at the first follow-up visit.

Among the 10 women who discontinued use of the spiral, 5 did so because of pain, bleeding, or both; 2, because of fear of cancer; and 3, because of objections raised by private doctors. No pregnancies have occurred in our small series.

In an environment where traditional medical education has, without wide clinical experience, long held intra-uterine contraceptive devices in disrepute, it is somewhat astonishing to find that this spiral is so well accepted by our clientele, who is rather well informed. But the type of medical distrust which has already been responsible for removal of the spiral from three of our patients is a problem which we shall have to face more and more often as our clinical experience progresses.

EXPERIENCE WITH A POLYETHYLENE INTRA-UTERINE CONTRACEPTIVE DEVICE

by

WARNER NASH, M.D.*

The use of a polyethylene coil for contraceptive purposes was studied for the past year in a small series of patients from the Maternal Health Clinic at the Lenox Hill Hospital and from private practice. This study was based on a similar method reported by Oppenheimer,[2] and also on the technique of Margulies.[1] Dr. Mortimer W. Rodgers, Director of Obstetrics and Gynecology, Lenox Hill Hospital, stimulated efforts to devise a ring which might possibly have advantages over those used previously.

A polyethylene ring with two coiled ends was designed in an attempt to prevent the expulsion so frequently reported. This device is made of radio-opaque polyethylene with barium powder introduced during the molding process. It is thought to be biologically inert, and has a 3 mm diameter, the overall size being approximately 25 mm. This ring is very soft and pliable and has a knob at each end to facilitate its removal. It is made on large injection-molding presses by liquefying polyethylene powder and then injecting it into a steel die, adding the barium powder during this process. This procedure conveys to the device a plastic 'memory' which allows it to resume its circular shape in the uterine cavity after it has been straightened out for insertion.

The Figure shows the device (*A*) at the lower left, and a malleable metal cannula (*B*) with a plunger (*C*) used to introduce the ring. A fine hook (*D*) allows very easy removal of the ring if pregnancy is desired or for study purposes.

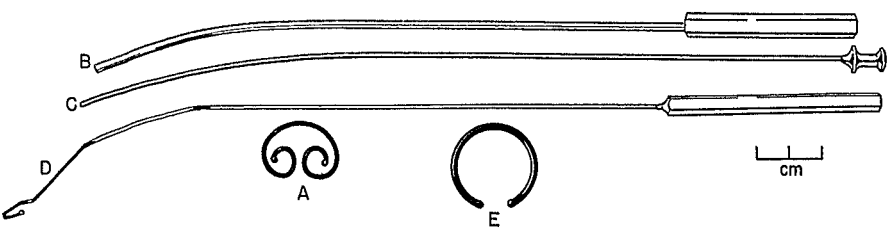

Fig. 1. Intra-uterine devices of polyethylene and instruments for their insertion and removal. *A:* double coil; *B:* metal cannula; *C:* plunger; *D:* removal hook; *E:* open-ended ring ('ear ring').

The insertion of this ring is a simple office procedure, which does not require dilatation of the cervix or anesthesia. The ring is kept in 1:1000 solution of Zephiran. After careful pelvic examination to avoid all contraindications and pathologic processes, the anterior lip of the cervix is held with a small single tooth tenaculum, the uterine cavity is sounded,

* Lenox Hill Hospital, New York, New York.

and the cannula with the ring in it is then introduced with aseptic technique. After reaching the fundus, it is withdrawn 1 cm and then turned 90 degrees in a lateral direction. Closing the plunger slowly allows the device to lie in the uterine cavity.

Patients are carefully instructed to record all bleeding and menses. They are also warned about the possible loss of the ring. No other form of contraception is required after a three-month trial period and, when another pregnancy is desired, no anesthesia is needed to remove the ring. Since possible legal complications might arise in the use of this not generally available method, private patients are asked to sign a consent form.

Fifty-eight patients with a total of 71 insertions have been studied during the year April, 1961, to March, 1962.

Months of use	*Patients*
1—3	20
4—7	19
8—11	19
Total	58

Twenty patients had the ring in place for less than 3 months, and 38 patients for more than 4 months. The aggregate number of woman-months of use is 327. Twenty-five primiparous and 20 multiparous patients are included. Thirteen women had no children; 25 had 1 child; 13 had 2 children each; 5 had three children each; and 2 women had more than 3 children apiece. Ages ranged from 19 to 38 years.

Contraindications to the use of the ring were: infections or inflammations of the cervix or of the tubes, severe dysmenorrhea, myomata or previous myomectomy, and a hypoplastic uterus. All patients who showed any reservation about this particular method of contraception on psychological grounds were likewise excluded. Re-examinations were performed every month after each period for the first three months. At this time a careful search for possible loss of the ring was undertaken. A few patients had lost the ring without being aware of it, and it was occasionally seen sitting on top of the cervix, or protruding from the cervical canal. No patient became pregnant, and re-insertion usually resulted in retention of the device. After monthly examinations during the first three months, patients were seen again after six months and one year following insertion, or more frequently if necessary, for any untoward symptoms.

Three rings were removed for the following reasons: 1 at the request of the patient who wanted to become pregnant; 1 because the patient had a very small hypoplastic uterus and should have been excluded in the first place; and 1 because of excessive bleeding which persisted for three months. In the last case, an endometrial biopsy showed a decidual-like pattern. There were no unintended pregnancies. The greatest difficulty lay with spontaneous extrusion which occurred in 13 cases, or 22.4 per cent, of this series.

If, on occasion, the patients were not sure whether they had lost the ring, an X-ray of the pelvis easily ascertained the presence or absence of the ring. Due to the high percentage of loss, another type of ring, more rigid and more in line with the original Gräfenberg ring, but still made of polyethylene, has been used recently. This type is shown under *E* in the Figure. No extrusions have been seen with this type of ring as yet, but the case number to date is too small for evaluation.

A total of 22 endometrial biopsies has been performed. These showed a normal endometrial appearance, such as proliferative endometrium or normal secretory changes. A

decidual-like formation was seen in a patient in my series, who required removal of the ring because of continuous spotting and bleeding. However, after removal she became entirely normal without any other form of therapy.

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INTRA-UTERINE CONTRACEPTION WITH PLASTIC DEVICES INSERTED WITHOUT CERVICAL DILATION

by

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and CLARENCE J. GAMBLE, M.D.*

In 1929, Gräfenberg reported on the use of a metal ring placed in the uterine cavity for contraception. In 1948, Halton, Dickinson, and Tietze [1] reported on the successful use of an intra-uterine coil of silkworm gut. More recently interest in this method was revived by Oppenheimer,[3] who published his 28 years of experience with the silkworm gut ring, and by Ishihama,[2] who reported on 19,567 cases in Japan. In the United States, Margulies in New York and Lippes in Buffalo have designed plastic devices which will occupy the frontal plane of the uterine cavity and which may, for convenience of insertion, be straightened and inserted through a plastic tube of small diameter. The plastic inserter eliminates the necessity of dilation of the cervical canal which usually involves pain. Once placed in the uterine cavity, it is believed that the device may be left indefinitely and will give continuous protection from pregnancy. Removal has been found to be followed promptly by pregnancy.

It seemed worth while, therefore, to make a test of these devices in a series of patients at the Ryder Memorial Hospital in Humacao, Puerto Rico. The method was offered to women in the childbearing ages with one or more children. Insertion was made eight weeks or more after delivery or abortion and preferably immediately following menstruation. Papanicolaou smears and endometrial biopsies were obtained at the time of insertion of the plastic device.

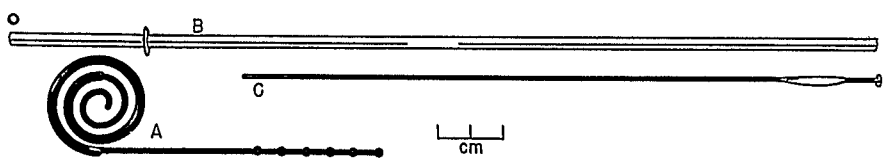

Fig. 1. The Margulies' spiral size V. *A:* intra-uterine spiral; *B:* flexible plastic inserter with flange; *C:* metal plunger.

Materials

Margulies' spiral is made of polyethylene to which a barium salt has been added to permit X-ray visualization if desired. Three sizes of spirals were provided, differing slightly in design. Each is flat, with the dimensions given in Table 1. Sizes III and IV are provided with an enlargement at the outer end which permits easier extraction from the uterus with

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a metallic hook or the endometrial biopsy curette. The outer end of size V bears a 90 mm tail on which there are seven evenly spaced beads.

TABLE 1

Dimensions of Intra-Uterine Devices and Inserters
(in millimeters)

	Size III	Size IV	Size V
1. Margulies' spiral[1]			
Flat spiral			
Diameter of spiral	26–29	27–31	29–33
Number of turns	2.5	2.5	2.75
Length when straightened	145	150	170
Diameters of cross-section of outer turn (360°)[2]	2.1 1.8	2.4 2.0	.. ..
Diameter of cross-section of outer 1.5 turns (540°)	..	..	2.6
Diameter of inner portion	1.7	2.0	1.8
Diameter of tail	..	..	1.5
Diameter of beads	..	..	2.5
Inserter			
Outside diameter	3.3	3.3	3.7
Length	200	200	280
2. Lippes' loop (with and without barium)			
S-shaped loop			
Number of horizontal portions		5	
Length when straightened		108	
Width at upper end		24	
Width at lower end		13	
Height		30	
Diameters[2]		1.4 2.2	
Inserter			
Outside diameters[2]		2.8 3.4	
Length		210	

[1] Patent applied for by Dr. Margulies. Sizes III and IV are no longer being used.
[2] The upper of each pair of diameters measures the upper section of the plane of the spiral or loop; the lower, that at right angles to the plane.
.. not applicable.

The inserters have an external flange, which indicates the direction of the plane of the spiral when this is placed in the inserter tube. The position of the flange can be adjusted to indicate the greatest depth to which it should be inserted into the uterus.

To push the spiral out of the tube a metal plunger, resembling a blunt knitting needle, has been made. For sizes III and IV, this is equal in length to that of the tube. For no. V it is 200 mm long, as it is not intended to extrude the tail from the tube. Since the plastic tube has a tendency to curl, the metal plunger is left inside it during storage and sterilization.

The Lippes' 'loop' is made of polyethylene. The later model contains barium salts. It is curved in a flat plane in the shape of a large 'S' continuing into a smaller 's'. The dimensions are given in Table 1. The smaller end has a perforation through which passes the mid-

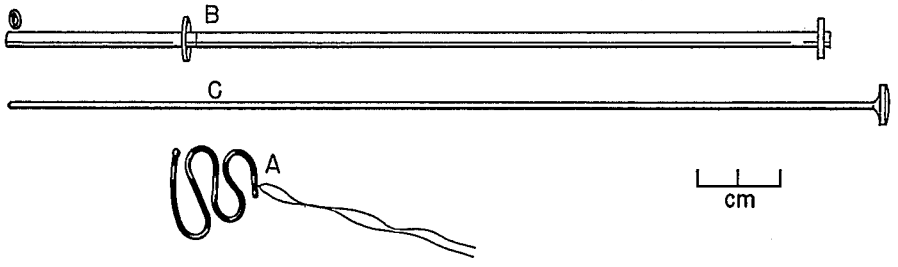

Fig. 2. The Lippes' loop. *A:* intra-uterine loop; *B:* flexible plastic inserter with flange; *C:* plastic plunger.

portion of a 150 mm long 00 nylon suture or 0000 monofilament polyethylene. 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 through the loop formed by the middle of the suture.

Lippes' teflon plastic inserter is oval in cross section. The plunger is of teflon and of the same length as the tube. A flange can be adjusted to indicate the portion which should remain outside the uterus, and the plane which the loop will assume when extruded into the uterine cavity.

Procedure

The spiral or loop is sterilized for 24 hours or more in 1:1000 aqueous solution of benzalkonium chloride (Zephiran). It is convenient to store them in this solution.

The teflon inserters may be similarly sterilized in aqueous Zephiran or by boiling. Sterile gloves and precautions are used to feed the spiral or loop into the appropriate inserter. The Margulies' spiral is pushed into the plastic inserter through the end which is to enter the uterus, with the tail or outer end first. The Lippes' loop is introduced in the reverse fashion, through the vaginal end of the tube, with the larger, unthreaded end of the loop first, until it reaches the uterine end of the inserter. The spiral or loop is inserted into the tube just before use, as prolonged storage in a straightened position will weaken the tendency to resume its original form.

A routine pelvic examination (including Papanicolaou smears if desired) should be performed to determine the axis and degree of flexion of the uterus and to assure that there is no pelvic disease. The cervix is exposed with a speculum and cleansed with the Zephiran solution. A uterine sound, Hegar dilator, or the endometrial biopsy curette may be used to sound the fundus carefully and to determine the direction and length of the uterine cavity. (When the endometrial biopsy curette was used, a specimen was obtained.)

The loaded inserter is then introduced into the uterine cavity until the fundus is reached. It is then slightly withdrawn and rotated as indicated by the flange so that the spiral or loop is delivered in the frontal plane, and the plunger is used to push the device into the uterus. The suture or beads outside the cervix are cut off, allowing about 15 mm of the suture or two beads to remain visible.

The patient is told that intermenstrual spotting may occur and that the first menses may be heavier than usual. She is given vitamin K 5 mg three times a day for five days to be used if there is prolonged or profuse bleeding. She is asked to return in a month, but told that she may come at any time before her appointment. Although protection from

pregnancy is believed to begin immediately, the patient is advised to continue another contraceptive method until examined after the next menstrual period. This will give protection in the event of expulsion of the device without her knowledge.

Results

Intra-uterine plastic devices (either Margulies' spiral or Lippes' loop) were inserted 132 times in 125 women between the ages of 16 and 48, with an average age of 27 years. These women had from 1 to 15 children, with an average of 4 children each. Eight patients discontinued the method and 117 remained under observation for periods up to 5 months, representing 207 months of observation for the continuing users and 15 months for those who had discontinued the method; a total of 222 woman-months.

Following insertion, spotting or mild vaginal bleeding during the first month and after the first menses was reported in 64 instances (48 per cent). There were 9 instances (7 per cent) of menorrhagia with the first or second menses post-insertion, but in no case was this sufficiently severe to necessitate removal. One patient is being studied for possible blood dyscrasia.

Pain at the time of insertion of the device was usually absent although it was reported in 8 insertions (6 per cent). Persistent cramp-like pain which required medication was observed in 11 cases (8 per cent). In only 1 case did the pain require removal. In this case, the size V spiral was replaced with a loop which did not give pain. However, it is suspected that this patient was scared and not that one method was in any way better than the other. The spiral was removed and shown to the patient, and the loop inserted immediately after that. The patient did not know that the loop had been inserted and did not complain of any pain. In 9 patients there was some difficulty in insertion of the device. Eight of those who complained of persistent pelvic discomfort had previously been treated for chronic pelvic inflammatory disease.

TABLE 2

Intra-uterine Plastic Devices, by Type. Insertions, Expulsions, and Removals; Pregnancies and Side Effects

	Spiral size III	Spiral size IV	Spiral size V	Loop without barium	Loop with barium	Totals
Primary insertions	9	27	30	54	5	125
Reinsertions	1	0	0	5	1	7
Total insertions	10	27	30	59	6	132
Expulsions	3	3[4]	0	3	2	11*
Removals	0	1	1	1	0	3
Continuing users	7	22	29	55	4	117
Discontinued	2[1,2]	4[3,4,9,10]	0	1[11]	1[6]	8
Pregnancies	1[1]	0	0	0	0	1
Spotting	6	21	4	30	3	64
Menorrhagia	0	5	0	4	0	9
Pain at insertion	0	4	3	1	0	8
Difficult insertion	0	0	7	1	1	9
Persistent pelvic pain	4	5	1	2	0	12

* 8 patients expelled 11 plastic devices; 3 patients had 2 expulsions each.
Note: Footnote numbers refer to the notes following Table 3.

TABLE 3

Months of Observation of Continuing and Discontinuing Users of Intra-uterine Plastic Devices

	Spiral size III	Spiral size IV	Spiral size V	Loop without barium	Loop with barium	Insertions	Patient-months
Months observed							
5	5	3	0	0	0	8	40
4	1	13	0	0	0	14	56
3	1	6	0	5	0	12	36
2	0	0	1	23	0	24	48
1	0	0	11	14	2	27	27
0	0	0	17	13	2	32	0
Total	7	22	29	55	4	117	207
Months observed before expulsion or removal							
2	1[12]	1[10]	0	0	0	2	4
1	2[1,3]	3[3,5,9]	0	4[2,7,6,11]	2[6,12]	11	11
0	0	1[4]	1[8]	0	0	2	0
Total	3	5	1	4	2	15	15
Grand total	10	27	30	59	6	132	222

Footnotes to Tables 2 and 3

1 Patient found spiral no. III expelled after first menses. Did not return until 8 weeks later and already pregnant.

2 Expulsion of spiral no. IV in second month felt by husband. Found protruding from cervix. Replaced by a plain loop which was expelled one month later.

3 Spiral no. IV found in vagina at examination after one month. Could not be reinserted, so size III was used and was found in vagina one month after reinsertion.

4 Insertion during bleeding at end of scanty (second post-partum) menses which occurred 32 days after the preceding menstruation. An abortion occurred two days later. This patient is not included in the spontaneous expulsions of spiral no. IV since this was related to an abortion.

5 Expulsion of spiral no. IV after one month. Replaced by a plain loop which has been retained 2 months so far.

6 Plain loop was expelled at one month. Replaced with barium loop which was also expelled one month later.

7 Plain loop, inserted during lactation amenorrhea, 60 days post partum, was expelled with the first postpartum menses which occurred 10 days post insertion. Plain loop reinserted and has now been retained for two months.

8 Spiral no. V removed after 1 week of persistent pain and replaced with plain loop. Pain was not reported after replacement.

9 Spiral no. V removed after 1 month because of fear of cancer.

10 Spiral no. IV expelled in second month with first postpartum menses. Not replaced. Separated from husband.

11 Plain loop removed after 1 month because of fear of cancer. Husband wanted another child.

12 Barium loop found protruding from the cervix after 1 month. Removed and replaced with plain loop.

There were no cases of acute pelvic infection related to the application of the method. One patient had an emergency appendectomy 10 days after insertion; a second had an acute pyelonephritis 15 days after insertion; and a third developed an acute cystitis during the second month. There were 29 patients with cervical erosion observed. Definitive treatment was carried out in the second month after insertion, with good results.

Eight patients expelled the device 11 times. The rate of expulsion was 6 per cent on the basis of patients (8 out of 125) and 8 per cent on the basis of insertions (11 out of 132). There may have been some anatomical reason for repeated expulsions. Expulsion usually occurs with the first menstrual period after insertion and in a somewhat higher proportion with the smaller devices. One patient found the spiral in the vagina after her husband detected its presence. When she returned to the clinic 8 weeks later she was already pregnant. No pregnancies have occurred to date with the device *in utero*.

The thread or tail protruding from the external cervical os makes it easy to detect the presence or absence of the device by vaginal examination. Leaving two beads on the tail of spiral no. V outside of the cervix allows for self-examination and reassurance that it is in correct position. Because such contact with the genitals is not customary in Puerto Rico, the beads have less advantage here.

The optimum time for insertion is on the fourth or fifth day of the menstrual cycle to avoid interference with possible pre-existing pregnancy. One patient, three months post partum, reported a slight bleeding at the end of the second but scantier menses, which had been delayed several days. The cervix was not dilated nor was the uterus notably enlarged, but two days following the insertion, she aborted and passed the spiral with decidual tissue and clots.

Of the eight patients who had discontinued the method, three had spontaneously expelled the device on two occasions. One wanted another child, and the other two decided to change to another contraceptive method. None of the three would accept X-ray studies to determine anatomical defects. All three had been using oral contraceptives for at least a year before the application of the plastic device and continued the use of the pills during the first month, at the end of which time the expulsion occurred. Another of the eight discontinuers was the patient who aborted and who wanted another method. Two others were patients who spontaneously expelled spiral size III; one returned pregnant and the other had separated from her husband. The remaining two, who had the devices removed at the insistence of their husbands because of fear of cancer, now say they want another child.

Conclusions

Although our test of contraception by means of placing a plastic device into the uterine cavity has been limited to only five months, it has shown no serious disadvantages. It was highly effective and free of infection and serious hemorrhage and in most cases of pain. It has the advantage that it does not require repeated action on the part of the user and cannot be forgotten at the critical moment. Furthermore, the user does not have to secure additional supplies, an important factor for families who live in isolated areas where roads may become impassable, or children become sick, or there is simply no money for transportation. While insertion of the device requires aseptic precautions and a trained person, hospitalization is not necessary and the method involves no subsequent expense. Others have found that pregnancy follows soon after removal. It may prove a highly satisfactory method for widespread population control in overpopulated countries, and would lend itself to a mobile-unit type of distribution.

Summary

For contraceptive purposes a Margulies' spiral or a Lippes' loop, each made of plastic material, was inserted into the uteri of 125 women of whom 117 were followed for periods up to 5 months with a total of 222 women-months of observation. Intermenstrual bleeding in the first month was noted by 48 per cent and menorrhagia, by 7 per cent. Moderate pain at insertion was reported by 6 per cent and later cramp-like pain by 8 per cent. No evidence of infection resulting from the insertion was observed. The device was expelled by 6 per cent of the patients. No pregnancies occurred during the use of this method.

Intra-uterine contraception provides an inexpensive and highly effective method which was found free of serious disadvantages at the time of insertion and in the limited number of months during which observation was possible.

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CINERADIOGRAPHIC OBSERVATIONS ON INTRA-UTERINE CONTRACEPTIVE DEVICES

by

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My interest in intra-uterine contraceptive devices dates back some ten months to a conversation over coffee with Dr. Guttmacher. He was intrigued with the variety of possible mechanisms by which an intra-uterine coil might effect contraception and interested in our experience, at the New York Hospital-Cornell Medical Center, with cineradiography as a methodologic approach to uterine research. He suggested that we apply this method to the problem in general and, as a starter, that I study the particular problem of uterine ejection.

Beginning with serial cineradiographic observations of one of Dr. Margulies' patients, who 'habitually' ejected even the largest of the untailed coils, and proceeding then to observation of other patients and other types of intra-uterine devices, we have, in recent months, become impressed not only with the segmental nature by which the uterus ejectively responds to the presence of an intra-uterine ring but also by the likelihood of analogous, non-ejective segmental responses which may effect contraception.

By way of a preface to more specific comments, it is perhaps worthwhile to review briefly the prior events and data from which this preliminary view has emerged. Following experimentation with and development of the two-stage intra-uterine balloon, over 2,000 hysterographic and balloon studies have been performed on over 1,000 menstrually and reproductively normal or abnormal women.[3, 4] The balloon, designed to sequentially expand within the corpus, isthmus, and cervix, is cineradiographically filmed during its downward expansion through the lower uterine sphincteric segment (Figure 1). Comprehensive hysterosalpingographic studies have added to the investigation, which has sought to define both normal and abnormal contractile, sphincteric, and peristaltic patterns occurring within the various uterine segments. These studies have increasingly revealed the fallopian tubes, the corpus, isthmus, and cervix to be remarkably dynamic uterine segments, which, in terms of tone and motility, have been found to function in direct or reciprocal relation to one another. Thus, to mention only the isthmic and fundal segments, the corpus, during the menstrual and early proliferative phases of the cycle, is physiologically hypertonic while the isthmus is hypotonic. Following ovulation, the corpus becomes increasingly hypotonic while the isthmus becomes increasingly hypertonic. In the immediate premenstrual period the isthmus normally loses tone, and with the onset of menstruation, the corpus again becomes hypertonic (Figure 2). This alternating, inverse relation between fundal and isthmic tone, consistently occurring as it does in fertile, ovulatory women, appears to be an affiliative pattern, which, in the presence of a fertilized ovum, provides a quiescent locale for nidation (fundal hypotonia) and sphincteric protection (isthmic hypertonia) from vaginal and cervical contaminants. In the absence of fertilization, reversal of fundal and isthmic tone ushers in menstruation.

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While, in the normal course of menstrual events, the isthmus and corpus function in reproductive concert, disaffiliative patterns have been observed in certain clinical syndromes and can be experimentally produced. In many instances of primary dysmenorrhea, for example, the isthmus remains constricted after the onset of fundal contractions resulting in an obstructive type of pain (Figure 3). Isthmic asynchrony of this order can be circumvented in succeeding cycles by the exogenous administration of a variety of hormones (Enovid, Norlutin, testosterone, and estrogen), each of which, in sufficient doses, inhibits ovulation. In the absence of ovulation isthmic hypertonicity does not develop; instead, the isthmic segment remains hypotonic throughout anovulatory cycles.

More immediate relaxation of the isthmus can be locally obtained by blocking the uterosacral ligaments (through which run autonomic fibers to the isthmic segment) with procaine or xylocaine or, more dramatically, by the introduction of small amounts of Bromelain (a proteolytic enzyme, the obscure action of which produces isthmic and cervical relaxation) into the intra-isthmic and intracervical canal. Even more dramatic is the effect of Bromelain (0.25 cc.), when introduced into the uterine cavity under such circumstances. In that event, the interstitial portion of the tubes, which normally is tightly spastic after the onset of menstruation, becomes dilated and the Bromelain, either reflexively or irritantly, is rapidly propelled by reverse tubal peristalsis into the abdominal cavity producing almost immediate peritoneal irritation.

In the light of the foregoing, it is apparent that elaborate sphincteric, tonal, and contractile systems are operative at segmental levels within the uterus. Physiologically, it would appear that these tubal, fundal, and isthmic-cervical systems function cyclically in a counterbalanced relationship which seems to facilitate fertilization, tubal transport, and nidation of the ovum, or failing fertilization to facilitate normal menstruation.

Failure of synchronization of one of the systems may evoke adaptive responses in other uterine systems which compound the initial maladaption. For example, persistent isthmic hypertonia, after the onset of menstruation, produces sphincteric obstruction to menstrual flow. The obstruction, in turn, produces compensatory overcontractility of the fundus which, in turn, through increased intra-uterine pressure may produce reflux of menstrual blood through the fallopian tubes. More obscure are 'feed back' responses which reflexively alter uterine physiology. The 'spreading' effect of such 'feed backs' is most dramatically illustrated in those patients with hematometra who adaptively develop loss of ovarian function. Lost menstrual and ovarian function (manifested by physical and hormonal changes characteristic of the menopause) returns to normal when the cervical obstruction is removed and the uterus is drained and decompressed.

While 'feed back' mechanisms of this extensive order are infrequently met with, lesser orders may well occur at clinically undetectable levels in response to a variety of dyskinetic stimuli. That dyskinetic stimuli of an extrinsic type can disrupt uterine physiology is quite clear. We have observed, for instance, that a balloon study performed with a balloon designed to develop high intra-uterine pressure will, if performed during the pre-ovulatory phase of a given cycle, usually result in an anovulatory cycle. Balloons with lower pressure gradients of expansion, however, do not inhibit ovulation. Since exogenous pressure stimuli can affect uterine physiology, it is not improbable that intrinsic (and perhaps quite minor) disorders of tone, contractility, or motility, occurring at the myometrial or tubal level, may produce less obvious but, in terms of fertility, equally telling effects.

Indeed, it is quite possible that the contraceptive mechanism, which results from the various intra-uterine devices, reflexively derives from the reaction of the myometrium to the centrifugally pressive force exerted by the device. Such an alteration in myometrial tone or contractility might unbalance the delicately integrated activity of the tubes and fundus and, in the disjunctive process, disrupt transport and union of sperm and ovum.

That tubal activity, like fundal and isthmic activity, varies according to phase of the cycle is apparent from our prior cinehysterographic observations; that alteration of this activity may occur has been suggested, if not proven, on two occasions by the qualitative disparity in tubal activity occurring in ipsi- and contralateral relation to a single, submucous, cornual myoma. With the advances in cineradiographic design, it should soon be possible to define, at the intrasegmental level, peristaltic and sphincteric activity as it cyclically occurs and varies within the tubes; to relate (at the intersegmental level) this activity with fundal, isthmic, and cervical patterns; and (at the interorgan level) to collectively correlate these activities with conceptive and contraceptive mechanisms.

Until then, the many gaps in our knowledge of intra-uterine devices can be at least partially bridged by observations of the more radiographically accessible fundal and isthmic-cervical segments and their responses to the presence of the varied intra-uterine devices.

Rejection and Ejection

The contraceptive effectiveness of the varied devices reported upon at this meeting clearly indicates that their overall efficacy derives more from their intra-uterine presence rather than from their design. In general, the extent to which configuration, size, and composition contribute to contraceptive effect is a function of the degree to which these variables contribute to endometrial irritation, myometrial irritability, and positional or dimensional displacement, which, separately or collectively, may produce reactive uterine discomfort leading to rejection of the device on the part of the user or myometrial over-contractility leading to uterine ejection. Since, in the great majority of instances, any given device is neither rejected by the user nor ejected by the uterus, there would appear to be other variables adding to the problem of rejection or ejection. In an effort to determine the nature of some of these variables, cineradiographic studies were performed on a variety of patients, using a variety of devices, under a variety of circumstances. From these studies it has become apparent that the causes which underlie rejection or ejection are usually discernible and usually the result of a combination of factors which derive from the host as well as from the device.

Uterine Factors

The intracavitary capacity of uteri varies tremendously. Intra-uterine balloon studies have revealed that the amount of radiopaque media required to produce myometrial resistance may vary from 2 cc. to over 30 cc. The capacity of the non-gravid uterus varies, physiologically, according to phase of the cycle; reproductively, according to both the pre-existence of and the temporal proximity to parity; and pathologically, according to the presence of uterine anomalies or tumors, hormonal insufficiency, etc. Thus, the nulliparous patient, having not only a smaller uterine capacity than the parous patient, but also a tighter, less resilient, isthmic-cervical segment as well (Figure 4), is comparatively far more subject to pain at the time a given device is inserted in her uterus, and more apt, as a result of dimensional disproportion between device and uterine capacity, to develop expulsive myometrial reactivity with resultant discomfort. If the disproportion is sufficiently great, the expulsive efforts of the uterus progressively increase and lead to ejection of the device. That the subjective discomfort experienced by the patient and the ejective predisposition of the uterus are a result of an oversized device is evidenced experimentally by the marked diminution of both when a smaller device is substituted.

Similarly, the introduction of the larger devices into the uteri of multiparous women during the immediate postmenstrual period, when the fundus is physiologically hypertonic,

is often followed by either uterine pain or ejection. In such instances, reintroduction of the device later in the proliferative phase of the cycle (when the fundus is less tonic and the isthmic-cervical segment not yet tightly constricted) often obviates these difficulties.

Conversely, introduction of a device in a subinvoluted postpartal or a myomatous uterus, both of which conditions are often associated with enlarged endometrial cavities and relaxed isthmic-cervical segments, leads to disproportion of a reverse order which, while unassociated with user discomfort, frequently results in 'silent', undetected ejection.

Complicating the problem of dimensional disproportion between device and uterine capacity is the matter of intra-uterine planes. The endometrial cavity is normally a potential space which, in terms of both contour and adaptability, most readily accommodates to the pressive presence of a device when the device lies in the frontal plane. Should the device, through faulty introduction or as a result of a septum or tumor, come to lie in the sagittal plane, myometrial reactivity is greatly increased (Figure 5).

Whether myometrial reactivity culminates in adjustment to or ejection of a device depends, in addition to the above, upon the positional relation of the device to the more narrow, lower reaches of the endometrial cavity and to the sphincteric resistance offered by the isthmic-cervical segment. In the face of uterine contractions, the smaller or the more rigid the device the greater the likelihood of descent and a concomitant wedging effect upon the decreasing intracavitary space. With descent and wedging the pressure on the walls of the uterus increases and with it there is an increase in myometrial counteractivity. Facilitating or impeding reactivity of the fundus and descent of the device are the cyclic changes in the fundal tone and in the sphincteric resistance offered by the isthmic segment. Since fundal tone and contractility are normally greatest and isthmic resistance least during the menstrual phase of the cycle, ejection is most likely to occur at this time. The time at which ejection is least likely to occur is following ovulation when the fundus is least tonic and reactive and the isthmus most tightly constricted.

In an occasional patient the sphincteric resistance of the isthmus is, either congenitally or through trauma, anovulation, etc., abnormally diminished. Such individuals, most of whom are habitual aborters during pregnancy, tend to eject recurrently all devices (Figure 6), which are not constructed with adaptive features which, in the face of uterine contractions, resist descent into the lower uterine segments.

Factors Relating to the Composition and Configuration of the Devices

This leads us to a consideration of the determining importance of structure and design in user rejection or uterine ejection. While many of the devices reported upon have unique advantages and disadvantages, comment here will be limited to those devices which, either through the addition of barium salts, or as a result of metallic composition, are radiopaque and which, in consequence, have lent themselves to a cineradiographic approach.

Intra-uterine Placement and Removal

Since the forceful dilatation of the isthmic-cervical segment entails pain and, reflexively through stretch receptors, uterine contractions, any intra-uterine device which requires mechanical dilatation prior to insertion or removal reduces acceptance on the part of the user, particularly if, as in the case of Halton's [2] silkworm gut coil, the device is periodically removed and reinserted.

While utilization of the menstrual relaxation of the isthmus and cervix diminishes the discomfort of the procedure, pain is circumvented only by those devices which do not require cervical dilatation for insertion or removal.

Such devices are made of the newer plastics, usually polyethylene. Molded in the form of spirals, coils, or loops, the malleability of the plastic material is such that the device, regardless of contour, can be threaded into a straight, small-bore introducer, which permits relatively painless introduction through the undilated isthmic-cervical segment.

After introduction in the frontal plane of the uterus, the introducer can then be rotated 90° and the device delivered, by means of a stylet or plunger, into the more capacious frontal plane of the uterus. During the process of extrusion, the temporarily straightened device reassumes its original shape (Figure 7). This 'memory' capability allows great latitude in configurational possibilities and in the future may prove very useful in the elucidation and clarification of the ideal design.

Accommodative Innovations arising Out of Configurational Experimentation

While hand-fashioned, silkworm gut, intra-uterine rings, after introduction, assume and maintain the intracavitary contour of the uterus into which they are placed (and in this adaptive respect, approach the ideal), they tend to evoke tissue reaction, which occasionally leads to granuloma formation, if the ring is not periodically removed.

With the advent of the virtually inert and malleable plastic compounds, capable of architectural 'recall', configurational experimentation, for the first time, has been both imaginative and extensive. This experimentation has led to the development of some devices which, more by accident than design, have increased our knowledge of operational principles which decrease the liability of ejection and which, more importantly, provide us with insights for future designs.

Margulies, for example, early in his experimentation with plastics, developed a plastic spiral which initially was very prone to uterine ejection. By increasing the size of the spiral, the ejection rate was reduced, but only at the expense of increasing uterine irritability and subjective discomfort on the part of the user. These spirals, while less unyielding than most of the metallic coil springs, continued to be ejected despite maximal increase in diameter. This tendency was quite fortuitously obviated when the spiral was modified to include a tailed appendage which traversed the isthmic and cervical segment and protruded through the cervical os, the intended purpose being to allow the user, through self-examination, to ascertain the continuing presence of the device. While this modification was clinically noted to reduce markedly the ejection rate without increasing infection, it was not until the device was cineradiographically investigated that the underlying principle which reduced the ejection rate became apparent. This principle which, in effect, suspends the device high in the fundus derives from the accidental provision of stabilization in the axis of the tailed extension along which the device, in the face of uterine contractions, partially uncoiled. The uncoiling of the spiral reduced descent into the lower, narrow, and more ejective portion of the endometrial cavity.

This same effect was independently achieved by Lippes, whose device achieves positional stabilization in the higher and dimensionally greater areas of the fundus through an 'accordion' effect rather than through an uncoiling effect (Figure 8).

Serendipity of this happy order, on the other hand, was conspicuously absent in the case of the device used by Nash. Conceptionalizing a 'pretzel' contour as a configurational device which would (1) apply pressure stimulation to both cornual regions, (2) incorporate each of the open ends into each of the connecting coils, thereby avoiding disruptive contact between the open end and the endometrium, and (3) circumvent downward displacement and consequent ejection through the twin-spring action of the connecting coils, the device, once within the uterus, was compressed into an overlapping, small, single coil, which was frequently ejected during menstruation (Figure 9).

Compositional Innovations

Just as the newer plastic compounds have been utilized in the ingenious design of a variety of spirals, loops, and coils, stainless steel has been utilized to excellent advantage by Hall and Stone [1] in their intra-uterine coil spring which resembles the original Gräfenberg ring save in the important respect that silver, which reacted with the endometrium, has been replaced by an entirely inert metal. This device, while smaller than most of the plastic coils, is, in terms of its contraceptive effectiveness, extremely successful. Its chief disadvantage resides in a tendency for the device to be ejected during menstruation. Interestingly, this device, perhaps more than any other, is ejected without the user being aware of its loss. Consequently, most of the unplanned pregnancies which were discovered following its placement actually occurred after ejection. One other disadvantage is the necessity for cervical and isthmic dilatation to effect introduction.

These disadvantages notwithstanding, the Hall-Stone device, with respect to cineradiographic observation and superimposed cinehysterographic investigation, exerts the greatest effect on the tubal and isthmic appendages among the devices thus far investigated. In our hands, as in the hands of Hall and Stone, it exerts a relaxing effect on the isthmic segment and has markedly diminished the symptoms of dysmenorrhea when these symptoms result from adaptive failure of the isthmus to relax at the time of menstruation. This device also is endowed with another almost paradoxical peculiarity in that it tends, regardless of the plane into which it is introduced, to become localized in the frontal plane at a relatively nonreactive level; at the same time, however, this ring, when the uterus is manipulated (Figure 10) into the position of anteflexion and retroflexion, produces marked uterine disturbances which are painful to the patient.

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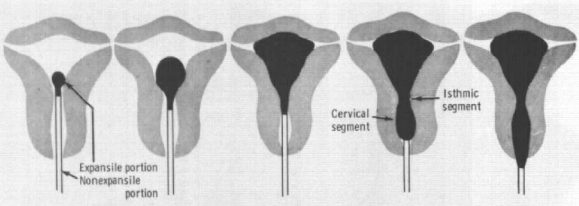

Fig. 1. The two-stage intra-uterine balloon is comprised of an expansile unit consisting of a latex head and latex neck to which is attached a non-expansile catheter. The balloon is introduced into the uterus by way of a stylet, following the removal of which an aqueous, radiopaque medium* is introduced through the open end of the catheter. The latex head, having a wider diameter than the latex neck and, in consequence, a lower threshold of expansion, expands first and continues to expand until it meets with myometrial resistance. With the introduction of additional fluid the pressure within the closed system rises. When the higher threshold for expansion of the latex neck is reached secondary expansion and sequential descent through the isthmic-cervical segment occurs.

* The radiopaque medium which we have found most satisfactory is Squibb's Sinografin.

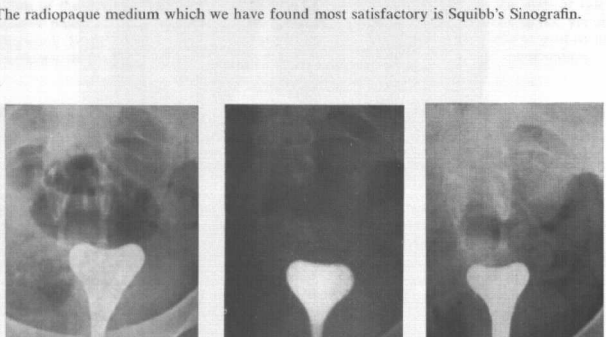

Fig. 2. Cyclic variations in isthmic tone in normal control. (*A*) Proliferative phase (day 7). The isthmus is patulous but fairly well defined. (*B*) Secretory phase (day 21). The isthmus, 14 days later, is constricted and very well defined. (*C*) Menstrual phase (day 1). The isthmus, 7 days later and 12 hours after the onset of menstrual flow, is physiologically incompetent.

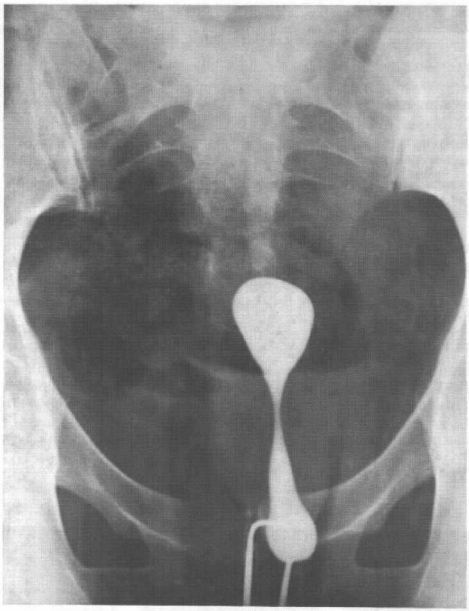

Fig. 3. Primary dysmenorrhea due to adaptive failure of the isthmus to relax. Fundal contractions during menstruation in the face of such powerful sphincteric resistance results in pain of an obstructive type. This isthmic mechanism usually disappears after parity.

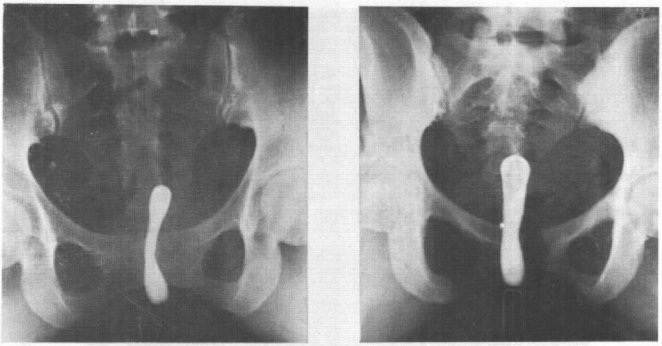

Fig. 4. Representative balloon studies which exemplify effect of parity on intra-uterine capacity (Left: Nulliparous patient; Right: Multiparous patient). Both balloon studies were performed during the latter part of menstruation and indicate why insertion of an intra-uterine device in the nulligravid uterus at this time might be either painful or impossible. In such cases introduction of the device should be deferred some six or seven days when, in the mid- or late proliferative phase of the cycle, the fundus is more capacious and the isthmus is not yet overly constricted. To delay introduction until after ovulation increases the pain due to post-ovulatory constriction of the isthmus and risks the possibility of prior conception and implantation.

EDWARD C. MANN

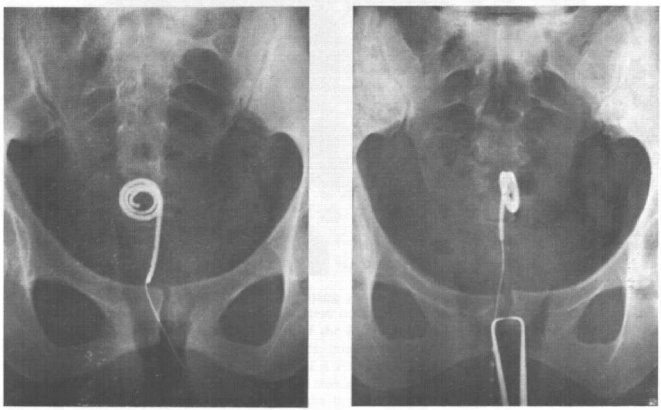

Fig. 5. Left: Film showing correct placement of Margulies' plastic spiral in the frontal plane of the fundus. *Right:* This film of a patient with a septate uterus illustrates the dimensional inability of the compromised cavity to accommodate the spiral in the frontal plane. As a result, the spiral produced painful uterine contractions which required its removal.

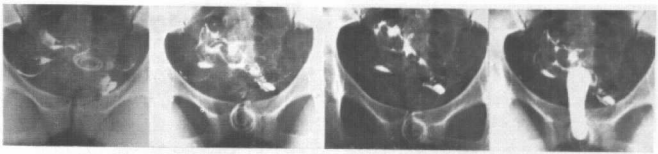

Fig. 6. Sequence showing ejection of spiral during menstruation and a balloon study (after the spiral was visible at the external os) showing marked cervical incompetence which graphically reveals loss of any semblance of sphincteric activity in the isthmic-cervical segment.

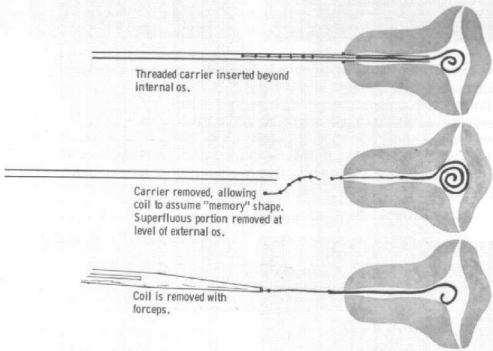

Fig. 7. Schematic representation of one of the plastic devices with configurational recall (Margulies' Perma-Spiral).

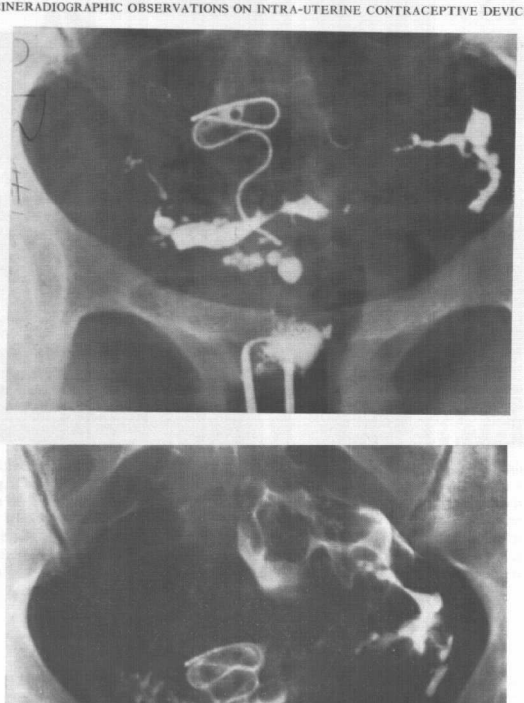

Fig. 8. Lippes' loop between (top) and during (bottom) a uterine contraction. The first film was taken immediately after relatively painless introduction of the device through a small bore introducer. Note that the widest diameter of the loop occupies the upper portion of the fundus. The second film was taken a few minutes later, immediately after introduction of a Kahn cannula. The cannula produced cervical dilation and a reflex uterine contraction. Note that during the contraction the widest diameter of the loop occupies the same fundal position. This 'accordion' effect decreases downward displacement into the lower uterine segments and the consequent tendency toward ejection.

The plastic portions of this device are intrafundal. However, attached to the lowermost portion of the plastic is a silk thread which traverses the isthmic-cervical segment. This silk thread protrudes through the external os and renders removal quite simple.

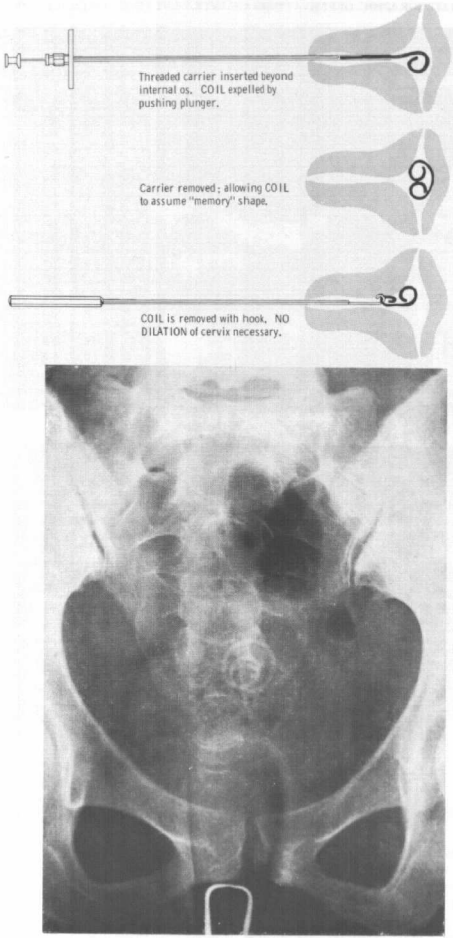

Fig. 9. The sketch is instructive in that it reveals the frequently observed disparity between theory which underlies design and its practical application, exemplified by the film. This coil, which was designed to maintain its 'pretzel' appearance after introduction in the uterus becomes, in effect, a single, small coil rather than connecting coils and, as such, is frequently ejected. (Nash's double coil.)

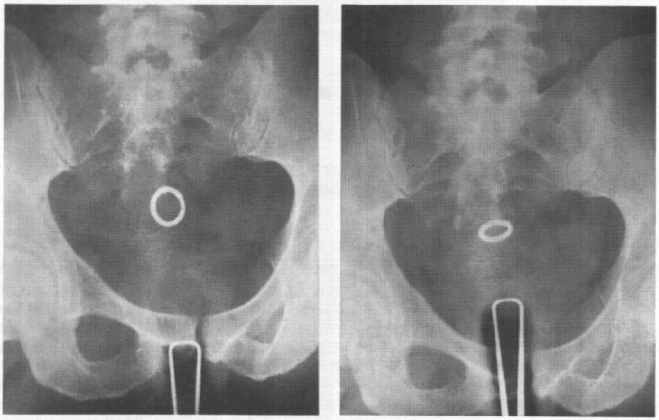

Fig. 10. Effect of anteflexion and retroflexion in the presence of the Hall-Stone stainless steel coil spring. The film on the left reveals the stainless steel coil spring to be placed in the frontal plane high in the fundus. The film at the right reveals what at first glance appears to be a placement in a transverse plane. Actually, as can be noted from the position of the tenaculum, the ring remains in the frontal plane of the fundus, which has been forced into acute anteflexion. Such a maneuver produces cramping pain which lasts for long periods and reflects the importance of using a tenaculum to reduce ante- or retroflexion during the course of introduction of the device.

BACTERIOLOGICAL STUDY OF THE INTRA-UTERINE PLASTIC SPIRAL

by

J. ROBERT WILLSON, M.D.,
and CHARLES C. BOLLINGER, M.D.*

A study of the Perma-Spiral has recently been initiated at Temple University Hospital in an attempt to determine: (1) what changes, if any, occur in the bacterial flora of the cervix and the endometrial cavity; (2) what changes, if any, occur in the histologic picture of the endometrium; and (3) the effect of the device on implantation of the fertilized ovum. To date the spiral has been introduced into only 37 patients, so our information obviously is limited. Of the 37 patients, 31 were Negroes and 6 were white. Seventeen had from 2 to 5 babies and 20, more than 5. The age range was from 19 to 39. The patients were all between 3 and 6 months post partum when the spiral was first introduced.

Study Plan

A significant number of ward obstetric patients are admitted to the gynecologic service for vaginal plastic operations and tubal ligation, or for vaginal hysterectomy, some time after delivery. The study patients are selected from this group. We attempt to use only cooperative and well-motivated women, but even with careful selection some of the patients return only when they please rather than when advised to do so.

Cervical and endometrial bacterial cultures are obtained at the time the device is introduced and repeated at each of three to four monthly follow-up visits. Material for cultures is obtained from the endometrial cavity with a special aspirator designed by one of us (C.C.B.). Each specimen is plated on four types of culture media: blood agar (anaerobic), blood agar (aerobic), eosin methylene blue (aerobic) and chocolate agar (CO_2).

Endometrial biopsies are performed when the spiral is introduced and are repeated after several months, unless a hysterectomy is planned. If hysterectomy is not done, the uterus will be curetted at the time of vaginal plastic repair.

Those scheduled for *hysterectomy* are instructed to have intercourse frequently during the anticipated fertile period. The uterus is removed about seven days after ovulation is presumed to have occurred. An attempt is made to recover the ovum either from the cavity of the uterus or from its implantation site.

The present report deals solely with the findings on bacterial cultures.

Results

A culture was diagnosed as positive whenever organisms grew on one or more of the culture media. A negative culture indicated no growth in 48 hours. The criteria for 'normal

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vaginal flora' are listed in Table 1. These organisms are of little significance when recovered from the cervix, but can be considered as abnormal in the endometrial cavity.

TABLE 1

Criteria for Normal Vaginal Flora

A. Any number of:
   1. Staphylococcus albus coagulase negative
   2. Diphtheroids

B. Equal numbers of:
   1. Nonhemolytic streptococcus
   2. Streptococcus viridans
   3. Minute type streptococcus

C. Few of:
   1. Bacteroides
   2. Anaerobic streptococcus
   3. Hemolytic streptococcus not Group A
   4. Escherichia coli or Aerobacter aerogenes

One of Group A appearing alone, overgrowth of any one of Group B, or more than a few of any of Group C in a culture from a cervical swab is considered abnormal and will be reported as a positive culture.

The results of the initial and subsequent cultures are listed below:

	Initial	*Subsequent*
Cervical swab		
Positive	21	12
Normal flora	16	31
Endometrial aspirate		
Positive	22	18
Negative	15	25

The majority of endometrial aspirates presented normal vaginal flora, but in some instances the following pathogenic bacteria were present in the cavity: Pseudomonas aeruginosa, Proteus, Staphylococcus aureus coagulase positive, Lactobacilli, Hemophilus, Clostridium welchii, and yeast.

We have attempted to correlate the endometrial cultures with the day of the menstrual cycle, as follows. The cultures are frequently positive during the menses.

Day of cycle	*Positive*	*Negative*
1–7	14	12
8–14	15	10
15–21	6	10
22+	6	7

Changes in the endometrial culture with the spiral in place occurred in 13 cases. Eight changed from positive to negative and 5, from negative to positive. Eight cultures were positive initially and remained positive, and 6 were negative initially and remained negative. Two of the patients, who changed from positive to negative, reverted to positive on the third culture, and again to negative on the fourth culture. The 5 patients, who

changed from negative to positive, have had only 2 cultures. The cases remaining either positive or negative have all had 2 or more cultures.

The interval between cultures varied from a week to as long as three months. The majority, however, were at four-week intervals. There was no correlation between the positive cultures and the length of time the spiral was in place.

Two patients developed pelvic inflammatory disease while using the spiral. The sequence of events is outlined below.

B. M. is a 30-year-old Negro gravida 6 para 6 with sickle cell anemia. She was treated intermittently in 1955-1957 with penicillin and diathermy for PID.
Last term pregnancy 11-10-61
Spiral inserted 1-22-62. Culture, cervix and endometrial: few aerogenes.
1st return visit 2-19-62. Culture, cervix and endometrial: negative.
Spiral removed 4-16-62 because of fever, purulent discharge, and adnexal tenderness. Culture: Streptococcus viridans and nonhemolytic streptococci.

C. C. is a 31-year-old Negro gravida 6 para 6 who had been treated in the past for PID.
Last term pregnancy 11-26-61.
LMP 2-16-62.
Spiral inserted 2-19-62. Culture, cervix: normal flora.
Endometrial culture: no growth.
Developed chills, fever, and urinary tract symptoms and was treated with Gantrisin on 2-25-62.
Spiral removed on 3-2-62 because of purulent endometrial discharge and 10 cm left adnexal tender mass. The endometrial culture showed no growth. Patient improved rapidly on antibiotic therapy. We feel that this patient may have had an acute gonococcal salpingitis that had responded to Gantrisin.

Conclusions

We can draw no clear-cut conclusions at this time. It is interesting, however, that positive cultures were obtained from the endometrial cavity in 41 of 80 specimens. Most of the positive endometrial cultures were obtained during the first half of the cycle.

Two out of 37 patients in whom the Perma-Spiral was introduced developed acute salpingitis. One had a positive initial endometrial culture and in the other, it was negative.

DISCUSSION *

Chairman GUTTMACHER: I have jotted down the various topics to which I think we should address ourselves, since I feel it is important to have our objectives clearly in mind. The first topic I should like to hear discussed concerns the mechanism by which intra-uterine contraceptives prevent pregnancy and the kinds of studies needed to learn more about this mechanism.

Second: I would like discussion on the acceptability of these devices, on objections by the patient or her husband, and on side effects, which may make the device unsuitable for some women.

Third: Do intra-uterine contraceptive devices cause infection, and how should infection be managed?

Fourth: What are the contraindications, if any, to intra-uterine contraception? This question has obvious implications for mass application, especially if insertion by paramedical personnel is contemplated. I am very much interested in this aspect.

Having traveled through India and Southeast Asia, I feel that if we are really going to serve the population in many areas, we have to make the whole technique so simple that it can be taught to paramedical personnel—perhaps well-trained midwives, or special technicians. From what I have observed, there is nothing desperately complicated about this technique. In a few years, after we learn about all the dangers ourselves, we can teach it to people who are not physicians. If we are going to restrict this technique to people who have M. D. degrees, we shall find that in much of the world it is going to make awfully slow progress.

We should discuss—and this is our fifth topic—the optimum timing for insertion, both within the menstrual cycle and as to the number of months or weeks one should wait after a delivery.

Sixth: How long may an intra-uterine contraceptive remain in the uterus, i.e., the maximum period of safe use? What is the significance, in this regard, of the material of which the device is made?

Seventh: The pros and cons of an appendage to the intra-uterine pessary, extending into the vagina, as advocated by several of the participants and firmly objected to by others.

Further topics for discussion will doubtless turn up as we go along.

Mechanism of Contraceptive Action

Chairman GUTTMACHER: I know there is a lot to say about each point, but I should like to turn our attention first to the mechanism by which intra-uterine contraceptives prevent pregnancy.

* Prior to the discussion, a motion picture film was shown, illustrating the techniques of inserting and removing intra-uterine contraceptive devices. Cf. Appendix IV.

Dr. CALDERONE: Shortly after the Conference on Physiological Mechanisms Concerned with Conception, held at West Point in 1959, I realized that an essential question would have to be answered in relation to certain drugs that were being tried which presumably affected the ovum after fertilization. 'When is an abortion? Is it something that happens to the fertilized ovum between fertilization and nidation, or is it something that happens after nidation?' I put this question to eight clinicians and physiologists all over the world. Two didn't answer; three clinicians agreed that abortion consists of anything that interferes with the fertilized ovum from the moment of fertilization; three physiologists, only after implantation.

I think that this is an extremely important question that must be settled, because if it turns out that these intra-uterine devices operate as abortifacients, not only the Catholic church will be against them, but the Protestant churches as well. It is a philosophical as well as a physiological question, and the answer will depend on finding out just when and how the fertilized ovum is affected by these devices.

Dr. LEHFELDT: Until recently, it has been assumed that the intra-uterine ring prevents nidation of the fertilized ovum, in accordance with Gräfenberg's explanation. This, however, is only a hypothesis for which we have no definite proof as yet.

In his historical review and analysis of the known facts, Dr. Tietze has shown that ectopic pregnancies actually do not occur among wearers of intra-uterine rings as frequently as might be expected statistically if nidation of the ovum were the preventive mechanism.

There are a number of possibilities of a different mode of action. One such possibility, which has been considered, is that the intra-uterine ring may prevent ovulation. But Lippes, after having studied the temperature charts of women wearing the ring, has come to the conclusion that ovulation does occur with the ring *in situ*.

There are, however, many other hypotheses that should be explored. I feel that we should not persevere in the preconceived idea that the Gräfenberg ring prevents nidation of the fertilized ovum. If this were so, it would have to be considered an early abortifacient. It is of great practical importance to investigate whether the Gräfenberg ring is, or is not, a true contraceptive preventing fertilization of the ovum.

Dr. HALL: I believe that the mode of action is prevention of nidation of the ovum. I don't think that we can properly rely on data on the incidence of ectopic pregnancies, because, actually, most of the studies on large numbers are not that complete, but Gräfenberg's own impression was that ectopic pregnancies did occur. I myself had one case with the ring *in situ* in the uterus.

I think that as far as clarifying this question is concerned, it shouldn't be too difficult if we could resort to animal experiments and, say, use rabbits or any animals with a double uterus, and insert the device into one horn and then see if they will become pregnant in the other one.

Dr. TIETZE: Carleton and Phelps did this in 1933, and the rabbits did become pregnant in the other horn.

Dr. MANN: In women with dysmenorrhea, with Dr. Margulies' spiral in place, the isthmus does not tighten up even though one finds a secretory endometrium. Moreover, the myometrial contraction patterns change, and there is a reciprocal relationship between tubal peristaltic motion and myometrial contractions; so I don't think that we can say at this juncture that there might not be some kind of contraceptive action involved in the spiral, at least in some patients.

I think this certainly bears looking into because it may be that the tubal physiology is altered to such an extent by the altered contractility that fertilization does not take place. There is no question that the position of the tubes changes—they are up and then down in relation to the day of the cycle. There are definite changes in the peristaltic pattern. We can document this.

Dr. JESSEN: Concerning the question of ectopic pregnancy, it may actually be that we are dealing with two different populations. A population that finds it very easy to conceive may also be a population that has less tubal disease, and certainly in some quarters salpingitis is considered to be one of the etiologies of tubal pregnancy. The people who need birth control the most are the people who perhaps are the healthiest and less likely to have an implantation in the tubes. Also, I would like to mention one hysterectomy specimen. The ring was lying free in the endometrial cavity in a pool of very clear mucous material. Histologically, this was a normal uterus. Perhaps the presence of mucus is something that might warrant investigation.

Dr. MARGULIES: In at least 40 per cent of the patients who wear the plastic spiral, spotting or staining appears in midcycle quite regularly, not every month, but many months in the year. This middle spotting, or *mittelblutung,* is mostly not bleeding from the endometrium. It is a bleeding from the pool in the cul-de-sac where blood from the ovary accumulates after the egg is ejected. Some patients told me that if they have relations at that time of the cycle, they will start bleeding a few hours afterwards.

As I have said in my paper, I believe that in patients who carry intra-uterine devices the peristalsis of the tubes is stimulated, cramp-like—and they do complain of cramps. It is stimulated to such an extent that the blood is passed through the tube and to the uterus quickly, instead of being absorbed in the tube during the three and a half days that the egg normally needs to pass the tube. Most probably the fertilized egg is also passed with the blood more quickly than normally.

Therefore, instead of appearing in the uterus after three and a half days, at which time the ovum would be divided into 80-100 cells, the egg may appear in the uterus after a day, a day and a half, or two days, divided into only 50-70 cells. The normal, mature egg stays in the uterus for another three days, and before it implants, it has divided normally into about 350 cells. Of these, at least 50-75 are trophoblast cells. They have the ability to dig themselves into the endometrium. However, the egg which is propelled quickly through the tube may possibly have only 150 or 200 cells after three days in the uterus and not enough trophoblast cells to dig itself into the endometrium.

Therefore, the ova would vanish because they entered the uterus in an immature condition and could not attach themselves. This could be studied in rabbits. It might be possible to check the uteri, into one of which a device had been inserted. The experiments might show whether there is only a one-sided stimulation of the tube and whether the tube passes the egg more quickly.

But there is another way to find out, which I suggested to Dr. Willson and Dr. Bollinger. They intend to run a series of tests on patients who need surgery. My device will be inserted several months before the operation. Between cycle day 16 and 20, these patients will undergo hysterectomy, and the uteri will be examined to determine where the egg is, whether it is fertilized, how many cells it has, whether it is damaged in any way.

I now suggest that the search for the eggs be started, not on cycle day 16, but as early as days 13 and 14, to determine whether there are any fertilized eggs in the uterus at that time, and to count the cells to see whether there are fewer cells in the eggs than when the eggs enter the uterus normally. If eggs were found *in utero* on the thirteenth or fourteenth day, I think that would prove my hypothesis.

I think the patients who do become pregnant with the device *in utero* probably lack the reflex from the tube, and the egg goes through in normal time and implants itself because it is mature when it comes into the uterus. Therefore babies carried to term are normal. Also, the hypothesis would explain why so few tubal pregnancies occur with the ring: probably the egg passes so much more quickly through the tube that it is still very small when it comes into the uterus and therefore does not get caught in the tube.

Dr. NELSON: I am of the opinion that the so-called middle-spotting is not from the ovary. This blood probably arises in the uterus since spotting occurs in patients with closed tubes. While middle-spotting has never been completely explained, it is noteworthy that castrated women or monkeys maintained on estrogen treatment can be made to bleed by dropping the level of estrogen. It is recognized that the secretion of estrogen normally decreases temporarily at the time of ovulation until the corpus luteum begins its production of estrogen. Thus, in some women, the drop in estrogen blood level probably is sufficient to cause partial collapse of the endometrium with resultant transient bleeding. Some people believe that at least occult bleeding occurs in all normally menstruating women.

Dr. LIPPES: Apropos this discussion, about a year ago I began an experiment to see if I could explain—not how it works— but at least where it works. Does the intra-uterine device prevent nidation or does it prevent fertilization?

I chose the rabbit. The first thing I wanted to do was to set up controls to see whether or not I could demonstrate the sperm migration time from the cervix to the outer one-third of the salpinx, where fertilization normally takes place. It took some time to coax these bucks into giving me semen. I finally learned to handle them with an artificial vagina. I have now been able to consistently secure semen from a male rabbit and inject it into the vagina of a female.

In the last two months, I have been able to demonstrate consistently the presence of sperm in tubal washings in rabbits after this type of artificial insemination.

The next step, of course, was to implant foreign material in the uteri of these rabbits, which I did about three weeks ago for the first time. I wanted to wait for the wound to heal from my surgery and inseminate these rabbits. Unfortunately, I didn't know the meticulous care needed to close a rabbit's wound. These rabbits reached into their wounds with their back heels and all died. I didn't have enough time before the meeting to get to the final stage of this experiment.

What I want to know is: Does an intra-uterine foreign body prevent any sperm at all from getting into the outer one-third of the tube? Does a foreign body merely delay sperm migration time? The normal time for a rabbit is three hours from cervix to tube. I am going to prepare these rabbits again and sacrifice them three hours, four hours, five hours, and six hours, after insemination.

I believe it is possible that such an experiment could be carried out on human subjects without endangering their lives, if they are to have a hysterectomy anyhow, or a tubal ligation. This should be considered in larger clinics than the one I am working in.

Dr. NELSON: The difficulty with working with rodents in an experiment like this would be the inevitable fact that their uteri undergo a curious response when foreign bodies are put in them. This is a decidual phenomenon that may become very marked. Furthermore, the presence of a foreign body exerts a sort of luteotrophic effect on the ovary so that the corpus luteum function is prolonged.

This uterine-ovarian relationship in the rodent is well-known since the time of Leo Loeb and is presently a phenomenon that has excited renewed research interest. However, rodent

experiments would not appear to be as applicable to the present problem as would be desired. Monkeys, on the other hand, I think would be excellent subjects, and we hope that studies can be made on them. I would not wish to discourage people from doing studies on rodents, but anyone who does must take into account the fact that the rodent presents problems in this experiment.

Dr. LIPPES: In a short experiment, the decidual reaction would not occur until after ovulation, and, since these rabbits will be sacrificed at the time of ovulation, or within three to four hours afterward, I don't think sperm migration time should be affected by production of a deciduoma.

Dr. NELSON: No, that part of your experiment is all right. I mean, in so far as studies on conception are concerned, the rodent is not a good choice.

Chairman GUTTMACHER: To apply to another species something which happens in an animal with an entirely different type of uterus is dangerous. We should find out what happens in rodents, but I doubt whether we can apply this with certainty to primates with their simple, rather than bicornuate, uteri. The whole reproductive tract is so different.

Dr. MANN: In addition to this, I would like to mention that in our work with double uteri we found that there are independent pacemakers in the two horns. You can stimulate one horn by inflating the balloon and get increased myometrial contractility, whereas you don't have any increase in the other horn. I don't think that the fact that you put a device in one horn and get a pregnancy in the other is altogether relevant.

Dr. NELSON: I think all of us recognize that we must learn as soon as possible how these devices work. At the moment we can do little more than speculate, since we have no evidence one way or the other, regarding the point in the reproductive mechanism that is affected when something is introduced into the uterus.

Obviously it is possible that there is an interference with the ascent of the sperm into the arena of fertilization. This might be at the level of the cervix, it might be somewhere in the uterus, or it might be somewhere in the fallopian tube. We know that sperm do not get through the tubes, where fertilization occurs, under their own power. The movements of the uterus have something to do with sperm ascent, probably more in some species than in others. Thus, it may be that the musculature of the uterus and its motility are altered in some way by the presence of a foreign body, with the result that ascent of sperm does not occur at all or occurs in a defective way only.

Obviously, studies on uterine motility are of great importance, and I think the kinds of studies that we have had outlined for us by Dr. Mann are very pertinent in this regard and should be encouraged. We know too little about the movements of the uterus following various forms of stimuli, including coitus, and we know virtually nothing as yet about uterine motility in the presence of intra-uterine devices. Perhaps it can be demonstrated that the mechanism of effectiveness relates to interference with fertilization through alteration of uterine motility.

Another mechanism that might be the focus of the effect would be interference with descent of the egg through the tube into the uterus. Dr. Margulies, I believe, favors this mechanism as an explanation. Thus the egg may be hastened in its passage, such passage through the fallopian tube occupying appreciably less than the 3 to 4 days that are required normally. This effect also would involve a change in the tubal musculature and is a consideration susceptible to investigation.

We know that a very nicely timed relationship exists between embryonic age and endometrial development, and that the two are normally timed in such a way that the egg is ready for implantation soon after it leaves the tube and enters the uterus. We know, too, that the endometrium, in the meantime, has completed its preparation for reception of the egg. If these two processes are thrown out of gear, so to speak, so that ovum development and endometrial preparation no longer show their nicely timed relationship, successful implantation is rendered less likely and, in some instances, does not occur at all. It would be possible to examine this possibility by searching for eggs in the uterus prior to their arrival time both in experimental animals and women, although there are obvious technical problems in the latter case.

An additional factor that might contribute to the present problem is the mechanics which relate to control of the utero-tubal junction. To the best of my knowledge nothing is known about the effect of an intra-uterine foreign body upon the so-called uterotubal sphincter. Perhaps this musculature is so affected that tubal patency is seriously impaired to the extent that sperm ascent or ovum descent does not occur, or occurs so abnormally that either fertilization does not take place, or the fertilized egg does not reach the uterus. In the latter case we might anticipate an increased incidence of tubal pregnancies. As Dr. Tietze has pointed out, such is not the case, but our knowledge of the mechanisms of tubal physiology is so incomplete that this contradictory evidence may not negate the role of the uterotubal junction. I would again urge that studies on tubal physiology be undertaken.

There is, of course, the possibility that the presence of a foreign body in the uterus interferes with implantation of the fertilized egg. Here we can do little more than speculate as to how this effect is produced. Perhaps surface phenomena that are important for attachment of the egg to the endometrium and its subsequent encapsulation are involved. It would seem that in this case studies on the enzyme chemistry and histochemistry of the endometrium may offer important avenues of study. The material that might be provided by planned use of elective hysterectomies, as Dr. Bollinger and Dr. Willson are doing, would offer valuable material for these studies.

The possibilities for investigations are almost limitless, and I hope many of you will give thought to experiments which you might undertake. You can be assured that the Population Council will be happy to entertain applications for support of research in this field of study. The Population Council would be interested also in your ideas for programs which you would like to undertake for the study of the effectiveness, safety, and acceptability of the various intra-uterine devices.

The conference was intended to be a fact-finding session, and I hope that it will have as one of its more important results the ultimate discovery of many facts about the subject of our attention. These facts are necessary for an objective evaluation of intra-uterine devices for contraceptive purposes.

Acceptance and Intolerance

Chairman GUTTMACHER: I should like to move on to the second topic: acceptability by the female and by the male of these various devices. Dr. Baumgold, yesterday you told us that three of your patients found the method unacceptable.

Dr. BAUMGOLD: They didn't find it unacceptable. When they came home, the husband called up the family doctor and the family doctor said the method should not be used.

Chairman GUTTMACHER: So they came right back and had the spirals removed?

Dr. BAUMGOLD: Another doctor removed them. Two other patients had fear of cancer. We assured them that there was no reason for such fear, but they wanted to have the spirals removed. Five more patients had cramps and bleeding. In these cases there were medical reasons for removing the device.

Chairman GUTTMACHER: Five patients then who could not tolerate the spiral because of cramps and bleeding, is that correct?

Dr. BAUMGOLD: Three with cramps and two with bleeding.

Chairman GUTTMACHER: Was this during the first cycle or later?

Dr. BAUMGOLD: One patient with cramps had the spiral removed 18 hours after it was inserted because she couldn't stand it. The two other women came a week later. They didn't have very strong cramps, but nevertheless found them annoying and didn't want the spiral any more.

In the two cases of bleeding, the spirals were removed during the first period. The bleeding was exceptionally heavy. The patients were afraid and didn't want to accept our advice to try to bear with it for another few days until the bleeding would subside.

Dr. HALL: There were five patients from whom I removed it because of prolonged menstrual bleeding that would not stop.

Chairman GUTTMACHER: After how many months of use was this?

Dr. HALL: The first month. The others, who had no intolerance to it, accepted it with enthusiasm and requested re-insertion after they had babies. The only time there was any problem was, just as Dr. Baumgold mentioned, if they would take their family doctor's advice or the advice of a gynecologist who wasn't familiar with this method.

In the early days, when the intra-uterine pessary was viewed with a good deal of prejudice by the medical profession, I had these patients carefully screened. One group were those with a strict medical or psychiatric contraindication to pregnancy. The others were doctors' wives or patients who were of sufficient intellectual integrity to understand the nature of the method and the situation in which I found myself.

If someone requested the ring, and I did not feel that they were emotionally suited to withstand the criticism of their doctors and friends, I refused to insert it.

Chairman GUTTMACHER: Dr. Bollinger, have you had any experience with patients rejecting the spiral?

Dr. BOLLINGER: We have had two cases where it was removed for bleeding. One was within three days after insertion. The patient had a heavy period. She was a rather nervous woman, and I removed the spiral and replaced it a week later, and she did all right with it after that. The other patient had bleeding. The spiral had dropped down into the isthmus of the cervix, and it was removed for this reason. This was just last week, and we expect to put it back later on. These are the only two cases.

Dr. JACKSON: If one could develop a method whereby the ring need not be changed very frequently and could be left *in situ* perhaps for several years without any fear of consequences, above all so that removal and fitting is virtually painless, that would go a long way toward removing objections from the patients. Five of my 192 patients objected so

strongly to the fitting that they refused to continue with the ring as a method. This is what we find they disliked most: coming back after a year to have their rings changed. In addition, 11 rings were removed because of menorrhagia and/or pain and 5 because of irregularities of the period. Another point is that occasionally one encounters this 'doctor objection,' which is a great nuisance but which is getting less and less frequent. But there is still a very real bar to this method in the medical mind.

Finally, as light relief, I would like to recount a very short story which may make people laugh. It concerns a husband's objection. He came into the clinic one day and virtually threatened the staff. Luckily, I have a very formidable secretary, who was able to quiet him, and finally I saw him. When he was a little calmer, I said, 'What is the trouble, Mr. N.?'

He said, 'Well, my wife can't get pregnant any more.'

I said, 'So what? I thought that is what you wanted.'

'Well,' he said, 'it is, in a way, but I don't like this way.'

So I said, 'What is the trouble? She had a cap before, and she was not very safe with that. She had three babies in spite of a cap. Now she has a ring, and she hasn't had a baby.'

He said, 'Yes, that is all very well, but in the old days I knew if she had a baby, it was my baby. And now sometimes she may go off and have a bit of fun and I don't know who it is with.'

I said, 'How did you know in the old days she didn't do the same thing?'
'Well,' he said, 'I kept her cap in my pocket.'

Chairman GUTTMACHER: Dr. Margulies, do you want to talk about the patients who have dropped out of your series?'

Dr. MARGULIES: There were 48 patients who stopped wearing the spiral permanently. Ten discontinued because of pregnancy. An additional 3 of the 13 who became pregnant came back for new spirals and are happy with them. Eleven patients discontinued because of ejection and 14, because of bleeding. One acquired gonorrhea and two had cramps and backache. Five more patients rejected the device for psychological reasons, as I mentioned yesterday—all between one day and two weeks. They all stated that they were not ready for it psychologically. There were five removals on the insistence of husbands.

Dr. JESSEN: Among 121 patients, only 11 rings were removed for medical indications, and 10 were extruded.

Chairman GUTTMACHER: So acceptability was very high in your series?

Dr. JESSEN: Very high.

Dr. TIETZE: In my historical survey, I also included these aspects and, as I said yesterday, the average incidence of expulsions was around 8 per cent, with considerable variation among investigators.

The proportion of rings that had to be removed for such reasons as hemorrhage, discharge, or bleeding was, in most series where information on this point was given, between 3 and 7 per cent. Only Halton and Leunbach had reported much higher percentages. I would say that it appears from the discussion that acceptability to the patient is far higher for intra-uterine devices than for any other contraceptive method.

Dr. PENG: The removal rate because of side effects in our country is around seven per cent.

Chairman GUTTMACHER: Notably pain and bleeding?

Dr. PENG: Yes, otherwise we don't have many reasons for removal. Women who wear the ring and are satisfied, talk about it. These favorable reports have had great influence in persuading other women to try the method.

Chairman GUTTMACHER: Before we consider the next topic, is it the consensus of this group that the acceptability of the method by both wife and husband is extraordinarily high? If there is no objection to such a statement we will move on.

Incidence and Management of Infection

Chairman GUTTMACHER: Now we are going on to the third topic: Is there any evidence that any of these rings cause infection?

Dr. JESSEN: I think that they do not, since 7 out of my 10 cases of clinical infection occurred more than three months after the insertion of the ring. To me this would seem to indicate that the rings do not, *per se,* cause infection. Whether they abet an infection that might come, that is another point.

Dr. OPPENHEIMER: I have never seen any infection after the ring was inserted, but I have seen many people who complained about infection after they had been seen by another doctor because of pains. And when they came to me and I assured them that there is nothing to fear, they became absolutely quiet and calm about it, and no signs of infection were found.

I think the most important factor in all of these questions is the psychological factor and, at least in our country, so many people were against it that I had to put up a hard fight. But in the course of time, I could convince all these people that they have nothing to fear. I have not found one woman in the last 25 years who refused to wear the ring.

Dr. HALL: I think that this question of infection is really very important and needs clarification on two points: firstly, what do we call infection, especially after we have heard that 50 per cent of all endometria are not sterile anyway?

If we speak of infection as cases that have fever, infiltration of the parametria, and who have to be given antibiotics, then I think this is valid. If we speak of a vaginal discharge or of some ill-defined symptom that may be reported by the patient, I don't think that we can draw any conclusions from that.

Secondly, and I think that this is very important to differentiate, the devices which were considered were obviously of several kinds. We are not speaking about uniform materials. There are the intra-uterine devices and the uterocervical or uterovaginal devices. Dr. Oppenheimer had no infections among his cases and I had no infections in mine, and by that I mean there were no cases that required hospitalization, or that had fever, or that had a palpable mass.

In the group on which Dr. Margulies reported, there were three cases of infection. I really believe that letting part of the pessary protrude into the vagina is taking a step backward rather than forward. I think that the great advance in intra-uterine pessaries took place when Gräfenberg discovered that the effectiveness of the pessary is due to its intra-uterine portion, and that the complications that resulted from the use of uterocervical pessaries were due to the cervical portion. Thus, by eliminating the objectionable cervical part, he first devised a usable intra-uterine pessary.

Chairman GUTTMACHER: We shall get to that a little later. First, I would like Dr. Margulies to go over his cases of infections.

Dr. MARGULIES: As I stated yesterday, I observed only three infections among 500 patients. One patient had an exacerbation of a tubo-ovarian abscess after insertion of spiral no. III (without a tail). The tubo-ovarian abscess was diagnosed one year before. It had quieted down completely. After insertion, she had some fever and pains, but after one week of antibiotics, these symptoms subsided completely.

Another patient had an infection after the cauterization of a very large erosion simultaneously with exchanging spiral III for V, which has a tail. That was really my fault. I shouldn't have done it at the same time. I could have waited one month and cauterized later.

The third case also concerned spiral no. V. This case was a gonorrhea which was acquired seven weeks after insertion of the spiral. She had been for a checkup before and was found perfectly all right.

Among the 276 patients with spiral V there are at least 150 clinic patients. I didn't have a single infection among these patients and I have been inserting this spiral for four months now. I am doing it without disinfection of the cervix and without any precautions. I don't even wipe off the mucus or the pus on the cervix. Many of them have erosions when the spiral is inserted, and we have not had a single infection.

Dr. ISHIHAMA: In my experience of 623 cases, only three cases of inflammation, such as adnexitis and endometritis, were observed. In one case, adnexitis was caused by insertion of a ring immediately after abortion.

Dr. JACKSON: Nobody has yet mentioned Trichomonas vaginalis. I found this parasite in many of the women who came for the fitting of a ring and who were otherwise strictly normal. The incidence of Trichomonas in this particular type of patient is quite high, but I have not yet found any evidence of Trichomonas being encouraged upward by the wearing of a ring, or insertion of a ring.

I have had, in the whole of my clinic series of more than 18,000 patients, two cases that had to have a hysterectomy because of uterine and tubal infestation with this parasite, but neither had ever been fitted with the ring. This was before the days of Flagyl.

Chairman GUTTMACHER: I would like to direct your attention to another aspect of infection. If infection occurs, is there any need to remove the ring? I feel that the infection could be treated with antibiotics with the ring *in situ*. Dr. Zipper, how do you feel about this?

Dr. ZIPPER: In our series, we had no infections, although our patients were an entirely unselected group. Many of them had very heavy leukorrhea, and some had severe cervical infections.

Chairman GUTTMACHER: Suppose you had an infection with the ring *in situ*, would you remove it?

Dr. ZIPPER: I think I would take out the ring, treat the patient, and put the ring back.

Dr. LEHFELDT: I think the ring should be taken out in case a secondary PID develops. This concurs with Gräfenberg's own opinion. He was particularly concerned when patients wearing his ring contracted a gonorrheal infection.

As we have heard here, it sometimes happens that an old chronic pelvic infection is overlooked, in spite of careful examination and history-taking. I think the ring should come out in every case of infection, old or new. The infection should be cleared up first, and if it was a gonoccoccus infection, then, after a while, we may give the ring another try.

Dr. SOUTHAM: There was one point I wanted to make about one of yesterday's papers on the bacteriology of the endometrial cavity. Regardless of the care with which transvaginal cultures of the cervix or endometrial cavity are taken, it is impossible to be sure that they are not contaminated by vaginal organisms. If cultures are taken at the time of laparotomy from the uterus or upper cervical canal, organisms are rarely found. I am not convinced that the organisms obtained by transvaginal culture reflect endometrial cavity contamination.

I think, though, in the case of active infection, I would be inclined to remove a ring and treat the infection on general principles.

Dr. BOLLINGER: In answer to your statement, in many of our cultures we got different bacteria from the cervix and from the uterine cavity. This was not always so. Frequently they were the same, and these may well be contaminants introduced from the cervix.

However, in many cases we recovered anaerobic bacteria from the uterine cavity which were not found in the cervical cultures. In our one case of inflammatory disease where we suspected gonorrhea, the patient had had the spiral in place for a week and was treated for a urinary tract infection elsewhere. When I saw her, I removed the spiral and she remained afebrile from that time on. In retrospect, I do not feel that it would have been necessary to remove the spiral. In the future, patients developing inflammatory disease will be treated with antibiotics with the spiral *in situ.*

Dr. MARGULIES: I have, fortunately, very little experience with infections. I removed the spiral in only one clinic case with gonorrhea.

In two other cases, one with an adnexal disease and one with parametritis after the cauterization of an erosion, they kept the spirals in and recovered immediately under treatment with Mysteclin or Panalba.

Dr. OPPENHEIMER: Do you sterilize the vagina with iodine before insertion?

Dr. MARGULIES: No, I haven't done it on my 250 clinic patients. I have never sterilized the vagina and have not wiped the cervix, even if there was a purulent discharge. It is not really necessary, although I recommend it in the instructions which I have prepared. The only absolutely sterile handling that is important is the feeding of the spiral into the tubing. For that reason I use sterile gloves. Afterwards, I can discard the gloves and take the instruments or the tubing into nonsterile hands, as long as the end of the tubing, which is to be inserted into the uterus, is reliably sterile.

Dr. SOBRERO: I believe that cleaning the cervix with Zephiran, or any other suitable antiseptic, takes very little time, and then, whatever complication might occur later on, you would at least be sure that you had taken every possible step to prevent infection.

Chairman GUTTMACHER: The question is: What do you accomplish by simply swabbing off the cervix? You are not going to rid the canal of bacteria.

I would like to move on to other topics, unless someone has something to contribute about the incidence of infection and whether or not the device should remain *in situ* in the presence of an infection.

The consensus appears to be that infection is very uncommon with intra-uterine contraceptive devices. It is generally thought that, when it occurs, it is a matter of coincidence more than a result of wearing the device.

Most clinicians feel that the ring should be removed when any pelvic infection occurs. A minority feels that the infection should be treated with the ring *in situ*. At the moment, this remains an open issue.

Contraindications

Chairman GUTTMACHER: Let us now consider the next topic: contraindications to the use of intra-uterine devices, if any. I have listed cervical tears, myomata, adnexal disease, and endocervicitis. Do any of these conditions actually act as a contraindication?

Dr. Zipper told us that in their study they have used totally unselected cases and taken each patient, irrespective of pathology. Apparently their non-selectivity has yielded no adverse effects. I should like to hear other opinions.

For example, is it possible that the ring or spiral or loop may have some effect on a myoma? Is a patient with cervical tears more likely to extrude the device? In other words, are there patients in our clinical experience to whom this method should not be recommended? According to Dr. Zipper, the answer is no. Is this correct?

Dr. ZIPPER: We excluded only very severe cases of gynecologic disease, for example, suspicion of cancer, ovarian tumors, parametrial complications, etc. But the mild cases, that means leukorrhea and cervical infections, were not excluded.

Dr. LIPPES: I did exclude women with gynecologic disease in general, such as fibroids, especially where I thought these were submucous and might distort the uterine cavity. I did eliminate patients who showed any evidence of pelvic inflammatory disease as adnexal masses.

I did not, however, exclude patients with severe cervical erosions. Those were all accepted. Patients with leukorrhea were also accepted. Essentially, I am in agreement with Dr. Zipper.

Dr. RAZZAK: I also excluded two cases with very heavy menstruation because these were always in trouble.

Chairman GUTTMACHER: So you feel a patient that gives you a history of hypermenorrhea should not have the ring. Is that correct?

Dr. RAZZAK: Yes, it either comes out with heavy clots, or causes a lot of trouble by extending the period more and more.

Dr. SATTERTHWAITE: Our cases are generally unselected. Anyone who accepts the method is taken. I could say that in my mind the only contraindication is pregnancy. But that is a reasonable contraindication.

Dr. HALL: I have excluded or rejected patients with evidence of chronic pelvic inflammatory disease and those with submucous fibroids. But I had two cases with intramural fibroids where there was no distortion of the uterine cavity. One ultimately had a hysterectomy, as I reported. The other had a myomectomy, after which the ring was reinserted. During the past four years, she has had no recurrence of her fibroids in the presence of

the ring. Those fibroids existed before the first insertion. I have not excluded patients with chronic cervicitis or erosions, but I have treated them before inserting the ring.

Dr. MARGULIES: In the instructions that I give out for my studies, I mention as a strong contraindication any acute or subacute adnexal disease. The flare-ups can be controlled by antibiotics. The second contraindication is pregnancy or suspected pregnancy. The third is large fibroids with distortion of the cavity, especially, submucous fibroids. However, one of my patients is a 30-year-old nullipara with fibroids the size of about 10 weeks' gestation. She tolerated her spiral very well and without complaints.

Menorrhagia, with suspicion of endometrial polyps, may also constitute a contra-indication, and so do acute and subacute cervicitis where there is any suspicion of an acute gonorrhea, carcinoma, or genital tuberculosis.

Chairman GUTTMACHER: I would like some of you to address yourselves to the question whether intra-uterine contraception should be instituted for a patient who gives a history of bleeding freely. Dr. Shirodkar, why do you think these people bleed with the ring in, perhaps for the first month or two?

Dr. SHIRODKAR: Well, I really do not know, because after all, with a submucous polyp, they don't seem to bleed so often. A polyp may be present without any intermenstrual bleeding. But with the ring in, the question is how well the ring fits, how much movement there is between the ring and the endometrium. That may be a factor. I think the work of Dr. Hurtig of Ottawa should be taken into account in these cases in order to study the number of cases where one has put in the ring and that show occult bleeding which can be discovered only by inserting Tampax daily throughout a cycle and doing chemical tests for blood.

Dr. JACKSON: I agree very much with what Dr. Shirodkar says. I would say that there is quite a lot of evidence that this is a mechanical business. One small piece of evidence I can advance is this: Three patients, who were extremely menorrhagic, had that tendency before insertion and it increased afterwards. I took the rings out and I found them grossly out of shape. In each case, the uterus had been at it, and turned the ring into a figure eight, which had twisted on itself.

Chairman GUTTMACHER: These were all metal rings?

Dr. JACKSON: Yes. It is in the hypermobile uterus that this sort of thing seems to occur.

Dr. OPPENHEIMER: May I say another word on the question of menorrhagia? I have seen a lot of bleeders, who became healthy after the introduction of the ring. I believe these are the cases where patients have some psychological disturbance, or want to reject the husband and produce bleeding in a psychological way. As soon as they are sure that the ring is in and they cannot become pregnant, they lose their fear of pregnancy and the bleeding becomes a normal one. That I have observed in many, many cases.

Dr. JACKSON: Most of the contraindications that have been mentioned are also factors which occur in subfertile people, and I would think that many of these women have no problems with regard to high fertility. Tuberculosis in the pelvis is a very considerable sterilizing factor. Quite a lot of other things mentioned, fibroids, etc., occur primarily in people who are subfertile.

Dr. SOUTHAM: The use of the intra-uterine contraceptive technique in highly fertile

women only, automatically rules out certain possible contraindications. Highly fertile women do not have salpingitis, pelvic tuberculosis, or major uterine abnormalities.

Dr. JACKSON: There is another point I would like clarified. Are we justified in fitting rings in women, regardless of whether they have gonorrhea? Should it be one of our provisos that a negative swab or a negative gonorrhea complement fixation test should be obtained first, at least in a population where one knows very well that the incidence of gonorrhea and other venereal diseases is extremely high?

Chairman GUTTMACHER: You have more faith in diagnosing gonorrhea by cultures and swabs than I have. In the clinically obvious cases one gets positive results. But there are many who seem to harbor the organism and give negative swabs and cultures, so that negative results are no guarantee. I think we would be very unwise to insert the device without first clearing up a true endocervicitis.

Dr. JESSEN: I think in the patient who is subjectively well, let us say one who doesn't have tenderness and no fever or malaise, that the ring can probably be very safely inserted. But I think if a woman is tender when you palpate the cervix, that you are ill advised to insert a ring.

Dr. OPPENHEIMER: In cases of cervical infection, I usually treat the patient until the symptoms have disappeared. If there are no clinical symptoms—I do not.

Chairman GUTTMACHER: You mean symptoms in the way of leukorrhea?

Dr. OPPENHEIMER: Yes, purulent leukorrhea. In cases where there are no symptoms, I am not afraid to introduce the ring because I think the body has enough immunity to deal with this.

I have not very much experience with gonorrhea, but I feel strongly that these cases should first be treated and that the husband also should be examined. Both partners should be cured before a ring is inserted. Otherwise, you can get very serious purulent adnexitis.

Dr. LEHFELDT: If we want better results, we should make every effort to obtain an accurate history. Patients with a history of PID should not be fitted with this method. If an incomplete history has failed to reveal previous pelvic infection, and the ring is inserted in such a patient, a recurrence of the old PID may be wrongly blamed on the method.

Chairman GUTTMACHER: My objection to making an elaborate history a prerequisite to insertion of an intra-uterine pessary is that it would make a more time-consuming job out of intra-uterine contraception. We dare not lose sight of our goal—to apply this method to large populations. I can assume Dr. Shirodkar can verify the statement that in villages of India one would have a hard time getting a meaningful history as to whether or not there had been infection. Am I correct, sir?

Dr. SHIRODKAR: Yes, you are right.

Chairman GUTTMACHER: It seems to me that programs in underdeveloped countries are more likely to be successful if there are fewer restrictions, particularly if paramedical personnel will be inserting intra-uterine contraceptive devices. Therefore, I think it would be valuable if further studies were made on unselected cases.

Dr. ROMNEY: It seems to me that when we discuss contraindications, we are basically

discussing good gynecology or even prophylactic gynecology, and we are not discussing the issue of contraception. If we are agreed that intra-uterine contraceptives do not produce infection and if we are supported by the statistical data, which suggest that the incidence of ectopic pregnancy is not increased, then I can't conceive of any contraindication to their use as a contraceptive device.

Dr. TIETZE: As a matter of research strategy, I would like to stress that the greatest obstacle to widespread adoption of intra-uterine contraceptive devices is the almost unanimous opposition of the medical profession. Therefore, our first objective must be to convince our colleagues outside of this room that intra-uterine contraception is a respectable medical procedure and not the devil's work. We have to demonstrate that the method, as such, is not only reliable, but also safe.

Our planning for the next few years should be oriented toward careful clinical testing and not use on a large scale, even if this is our ultimate goal. Only when we have won the support of a part of the medical profession should we turn to the question of how this method can be used in mass distribution.

Dr. WILLSON: I probably know less about intra-uterine contraceptive devices than anyone here. But I have an opinion on several aspects of the problem. Some of these opinions probably cannot be supported at the moment.

I was impressed by a number of things at this conference. First, the obvious importance of it, because, at short notice, it was possible to gather all these people from all over the world. It is ordinarily not possible with a group of medical people to do this in two months.

I was impressed also with the interest in these particular devices and their widespread use, of which I was not aware. I was also impressed with the paucity of information that is available about these devices. We have a number of large groups of patients, who have worn them apparently without any difficulty and with good effect as a contraceptive measure. However, I doubt very much that all the figures that were presented would stand up under careful statistical scrutiny.

I wish that this conference had ended last night because, at the end of the cocktail hour, I had my thoughts clearly arranged and knew exactly all there was to know about it and could have presented this much better. Today I am as confused as I usually am, so that I am not sure what is going to happen. Actually, some of the things that I am going to say here in the next minute or two I have never said out loud before, and I am not exactly sure how they are coming out.

I have a letter on my desk, which has been there for three months unanswered, because I didn't know how to answer it. I have been corresponding with an anthropologist who spoke at Temple University awhile back, and with whom I found some basic disagreements. His thesis was that having babies is such a simple, nontraumatic, nonlethal affair that it should be given back to the family. This is a family event, and one of the main problems in the world today is that so many women are having babies in hospitals, and that the rest of the family cannot participate. He said, 'I am willing to accept an increase in maternal mortality for the value of having the baby in the family group.' This is why I haven't answered the letter. I am not quite sure what I am going to say about this. However, I think that there is justice on his side. He is an anthropologist and is dealing with groups of people, races of people, and the world in general. The traditional medical training is toward a single individual. We are concerned with whether an individual develops infection, or whether she has her baby safely, as one person to another. We are less concerned, by training and tradition, about groups of people, and about the welfare of the world in

general. This is something that certainly has to be considered in any discussion of world-wide population control.

We have to stop functioning like doctors, thinking about the one patient with pelvic inflammatory disease; or the one patient, who might develop this, that, or the other complication from an intra-uterine device; and think of the need for this in general.

If someone had asked me in January, 1960, what I thought of intra-uterine contraceptive devices, I would have given them the information that I had acquired over the years: that they are horrible things, that they produce infections, that they have been outmoded, and that they aren't worth using. If someone had asked me in February, 1962, what the bacteriology of the nonpregnant uterus is, I would have said, with few exceptions, it is sterile. Yet our patients' uteri, and those of patients in Buffalo, are not sterile. It is interesting that the figures for positive intra-uterine cultures in Buffalo and in Philadelphia are exactly the same, approximately 50 per cent. Perhaps this doesn't mean anything and perhaps it does. Perhaps this is an accident of sampling. We intend to get many more uterine cultures, both on ward patients and on private patients, to see if there is a difference. I would suspect that there might very well be a difference. However, I don't think that is important.

We had two patients who developed pelvic inflammatory disease while the spiral was in. We are almost sure that one of them was infected with gonorrhea, and that the spiral had nothing to do with it. We might extend this even to say that, instead of getting pregnant and gonorrhea, all she got was gonorrhea, because she had the spiral in. The other patient was a patient with a chronic salpingo-oophoritis. She developed a mild intra-uterine infection, possibly due to the spiral, possibly due to something else.

On the other hand, is this actually very important? Nonpuerperal pelvic infections, for the most part, are self-limiting, nonlethal conditions. The patient who develops gonorrheal infection rarely dies, and it usually is a sterilizing adventure anyway. So that perhaps we don't have to be concerned about these patients at all. Suppose one does develop an intra-uterine infection and suppose she does end up with a hysterectomy and bilateral salpingo-oophorectomy. How serious is that for that particular patient and for the population of the world in general? Not very. Perhaps we have to stop thinking in terms of individual patients and change our direction a bit.

The studies that I think would be most necessary are those related to infection. It may well be that the incidence of infection is going to be pretty high in the patients who need the device most. However, I think we have to find that out.

As for preparations necessary before the spiral is inserted—I am sure that there is no need to wipe the cervix with Zephiran or to do anything of that sort. For many years I have used no preparation whatever for a hysterosalpingogram, sounding of the uterus, or endometrial aspiration. I simply wipe any visible mucus off the cervix and do what I am going to do, and I am not aware of any patients who have become infected because of this.

Who is going to insert intra-uterine contraceptive devices? There were several people who said this must be done by an experienced gynecologist. I am not at all sure that this is going to be practical. By 1973 there aren't going to be enough experienced obstetricians and gynecologists to deliver the babies in this country, much less take time out to do these other things. This I believe is a simple enough technique so that we could train people to do it.

Now, obviously, if we are going to use these devices, they are occasionally going to be put in the wrong patient. Again, if we look at this from an over-all, long-range view (these are the things that I have never said out loud before and I don't know how it is going to sound), perhaps the individual patient is expendable in the general scheme of things, particularly if the infection she acquires is sterilizing but not lethal.

So I would think that our project should be, first, to find out if this is a reasonable method of contraception, and second, to determine what complications occur when the device is inserted in large groups of women. There will be concern because those in whom the ring is installed may not return for follow-up examinations. I am not sure this should be a cause for concern. We have had reports of rings that have been in for 20 years; for example, Dr. Oppenheimer's midwife, who wouldn't let him take it out. Perhaps the thing to do is to follow as many as possible in family planning clinics, university clinics, etc., and see what we can learn. As for the patients who disappear, they have gone but presumably with the device still in place. They should not be getting pregnant regularly, which is what we are striving for anyway.

We need not be particularly concerned about the ejectors and the people who don't want to use it, because if 60 or 70 per cent of patients can tolerate the device and use it, and like it, and don't get pregnant, then we are that much ahead.

Dr. CALDERONE: It seems to me that we are in the position we were with the oral contraceptives about three years ago. Now, we are actually moving to the point where we are establishing minimal basic standards essential for mass distribution of oral contraceptives.

We are being queried by public health people about this. The Medical Committee of the Planned Parenthood Federation has agreed on minimal basic standards in terms of pelvic examination, etc., that would have been impossible three years ago, and we have arrived at this point only on the basis of very careful and well-controlled studies of the orals.

It thrilled me to hear a clinician, like Dr. Willson, talk in terms of public health application as I, a public health person, would not have dared talk, particularly in this assembly. For any contraceptive method at all, we must think in terms of mass distribution and in terms of not worrying too much about those women who cannot use intra-uterine devices, but just simply eliminating them and giving them other methods. These are the realities of mass application of any medical technique.

Timing of Insertion

Chairman GUTTMACHER: I would like to return to the agenda, and to turn your attention to the following question: At what time in the nonpregnant cycle is it wisest and best to introduce intra-uterine devices?

Dr. MANN: I think it would be in the immediate postmenstrual period. The only problem there is that the myometrium is hypertonic, so that the cavity is smaller in the immediate postmenstrual period than in the middle and in the late proliferative phase. I think that with multiparas, there is no problem at all. With the multiparous patient, I think perhaps the midproliferative or even the late proliferative phase might be the ideal time.

Chairman GUTTMACHER: Let us state it in terms of cycle days.

Dr. MANN: I would say day 7 would probably be the ideal time for a woman who has menses that last five to six days. Actually, there would be no problem inserting it during menstruation. We have not had any difficulty with infection, and we have done hundreds of insertions.

Chairman GUTTMACHER: So, any time from day 1 to day 7. Is that correct?

Dr. MANN: Yes, sir, that would give you really the conditions you would need. If you

try to pin it down to one day, it is difficult for both patient and doctor. I think it would be better to insert it after menstrual cramping has subsided. Therefore, the latter part of the menses would be better than the early part, because of the danger of expulsion.

Chairman GUTTMACHER: So then you would say day 3 to day 7?

Dr. MANN: Yes, that would be my feeling about it.

Chairman GUTTMACHER: Does anyone disagree with day 3 to day 7?

Dr. MARGULIES: The best time for insertion is around ovulation because at that time the cervical musculature is relaxed, and the mucus is clear and liquid. Entry into the uterus at that time is the easiest, especially in nulliparous patients.

Chairman GUTTMACHER: Then you disagree completely with what Dr. Mann has said?

Dr. MARGULIES: In my experience, except for days 1 and 2, where I wouldn't insert because of profuse bleeding and often dysmenorrhea in the nulliparous patients, there is not much difference on what day you insert it. However, in one case I couldn't insert the spiral when I tried it twice in mid-cycle. She had three children; the last one was two years old. I told her to come premenstrually, which she did, and then there was absolutely no difficulty whatsoever. Six beads were in; one was sticking out. Why she had a spasm the first time, I don't know.

Dr. SEGAL: Dr. Margulies said he believed the best time for insertion to be when the *spinnbarkeit* is most abundant. However, I believe menstrual blood may serve equally well as a lubricant and, therefore, the terminal phase of the menstrual flow may be the best time for insertion.

Dr. OPPENHEIMER: For more than 30 years I have always introduced the ring a few days after the menstruation had ended. I thought, first, that the mucosa should be entirely restored, and second, that we should do it before the next ovulation takes place. So I usually do the introduction of the ring between day 8 and day 12 after the beginning of the menstrual period, and I had the best experience with this.

Chairman GUTTMACHER: Have you ever tried it earlier, say, from the third to the seventh day?

Dr. OPPENHEIMER: I have sometimes done it.

Chairman GUTTMACHER: Is there any difference in the ease or difficulty in doing it earlier?

Dr. OPPENHEIMER: I don't think so.

Dr. LEHFELDT: I think we should stay away from ovulation time, because otherwise we will have more and more instances of inadvertent insertion of the ring into a pregnant uterus. Since we are mainly dealing with multiparous patients, I suggest that the ring be inserted not later than cycle day 3 to 6, particularly in women with short cycles of 20 or 21 days. Therefore, I feel we should act according to what Gräfenberg has always stated: the best time for inserting the ring is during the last few days of the menstrual period.

Chairman GUTTMACHER: How long is it necessary to wait post partum before inserting an intra-uterine contraceptive device? I want Dr. Satterthwaite to tell us about her experience in Puerto Rico.

Dr. SATTERTHWAITE: Dr. Margulies and Dr. Lippes recommended to us that we should wait at least three months post partum. Dr. Oppenheimer mentioned this also. However, we found that patients were pushing us to do it sooner, and so we have inserted at eight weeks post partum, without waiting for the first period, if they were having lactation amenorrhea. We have found that these patients had very little spotting after insertion. However, one of them had an unusually heavy first period within two months after insertion.

Chairman GUTTMACHER: Of course, you could have a heavy first postpartum period without an intra-uterine device.

Dr. SATTERTHWAITE: That is not unusual.

Chairman GUTTMACHER: So you think the ideal time is probably eight weeks post delivery, and that the presence of a lactation amenorrhea is no contraindication.

Dr. MARGULIES: Up to now, I did follow Dr. Oppenheimer's suggestion to postpone insertion until three months after delivery. However, lately, I've begun to insert earlier, going slowly down to two and a half months and two months, because I intend to try to have the gap closed between the postpartum visit and the insertion of the spiral, which I feel is of great importance. If we were able to insert the spiral during the first postpartum visit, at about the seventh or eighth week, it would be an enormous gain for the method.

Chairman GUTTMACHER: Has anybody tried to insert a ring within six weeks post partum?

Dr. OPPENHEIMER: I have usually waited until the first menstrual period was over and, after that, introduced the ring. But I had a lot of cases where patients had to go abroad and I had to do it earlier. And they tolerated it very well after six weeks. But if the patient can wait, I do it only after the first menstruation has come.

Dr. RAZZAK: I also introduced the ring on the fortieth day. There was no trouble at all.

Chairman GUTTMACHER: So now we have come down to 40 days. Would anyone want to do it earlier?

Dr. HALL: On the contrary, I think that that is the time when we are much more likely to run into perforation, because the puerperal uterus can be easily perforated. I usually wait until the patient has had her first period.

Dr. ISHIHAMA: I like to insert the ring after the patient has had her first menstruation post partum because at that time the uterus begins to function normally, and, if the patient does not have any menstruation after delivery, I think the uterus is not in normal condition.

Dr. JACKSON: I have done a fair number of biopsies post partum before putting in a ring, because I wanted to see what state the endometrium was in. And I would say that there are probably two types of patients here. One is where ovulation is still in abeyance, and the endometrium is still very thin and atrophic. I don't think they tolerate the ring very well. The other type is where the endometrium is already thickened, and it is possible that

they may have had a premenstrual ovulation, or, at any rate, are approaching it. I think that it is quite important to do a biopsy. I would not be very happy to put a Gräfenberg ring into a uterus with a completely atrophic endometrium.

Chairman GUTTMACHER: Dr. Satterthwaite's experience is contrary to yours. She says her patients tolerate insertion well during lactation amenorrhea.

Dr. JACKSON: I can't agree with that. In my experience they have bled quite a bit.

Dr. MILLIKEN: In this connection, I recall a vaginal hysterectomy about ten weeks post partum. At the time of sounding the uterus, the sound went through without any resistance whatsoever, perforating the uterus. This was a nonnursing, menstruating woman.

Dr. RICE-WRAY: Since some of you have inserted rings at 6 weeks and haven't had any trouble, I can't see any reason for waiting longer. If it is not inserted before the 40th day post partum, there will be a lot of pregnancies. In the Latin American culture, husbands are accustomed to waiting 40 days. It is very unlikely that any could be persuaded to wait longer.

Chairman GUTTMACHER: Undoubtedly many women do not menstruate between pregnancies, so I think if we can insert early, it has great advantage. These remarks do not concern the 'carriage trade'. I am talking primarily about clinic patients.

There is a subsidiary question which we may well discuss at this point: the period after insertion before coitus is allowed. Dr. Margulies, how long afterwards is coitus prohibited?

Dr. MARGULIES: One day.

Chairman GUTTMACHER: Why not 20 minutes?

Dr. MARGULIES: Because the uterus is open. I usually advise the patient not to have relations that night.

Chairman GUTTMACHER: We will note that point, but I see no rationale for it.

Dr. RAZZAK: After the insertion of the ring there is always a slight discharge and sometimes, bleeding. We tell the patient that this is like the menstrual flow. Immediately the discharge stops, you can have intercourse, and this is accepted by the patient.

We dilate the cervix for the insertion of the metal ring, and if we allow intercourse immediately after insertion of the ring, then there is a chance of ejection because the cervix is still dilated and there are some cramps with the orgasm, which might help to eject the ring.

Dr. LIPPES: All my patients ask about intercourse. I usually tell them that whenever the spirit moves them, they can have intercourse, even on the same day.

Dr. HALL: I have no restriction on the time when they have intercourse, but I ask the patients not to rely on it until after I have had an opportunity to check on the position of the pessary following their next menstrual period. I tell them to use either a diaphragm or a condom in the meantime, or whatever method they may have practiced before.

Dr. JACKSON: I have never given any restriction. They don't really ask. If they do, I shrug my shoulders. I don't answer.

Maximum Duration of Safe Use

Chairman GUTTMACHER: Now the text topic: How long may an intra-uterine device remain in the uterus, as a maximum period? Is there any advantage in removing the ring and changing it or leaving it out a certain number of days and then re-inserting it?

Dr. LIPPES: I think this needs a lot of work. We have heard what the side effects are for the first and second months, and even up to one year. We will have to wait and learn. I have about 15 patients now who have their rings in place for two years.

Chairman GUTTMACHER: You have not attempted to change them periodically?

Dr. LIPPES: I have not changed them in these 15 patients. The procedure we plan is that the devices which we have been inserting since January of this year will be left in the uterus for an indefinite period of time. I hope to be able to follow this series and learn: what is the pregnancy rate the second, third, fourth, and fifth year? And, what is the incidence of bleeding and of pelvic inflammatory disease in the years following insertion? I have no idea, and this is where more work is needed. I think that these devices can be left in place for years. I say this judging from the 15 rings that I now have in place for two years, and also judging from articles I have read, e.g., Dr. Samuel Rozin's article in *Fertility and Sterility*, reviewing seven women whose devices were left in place up to 14 years, and during this time the device remained effective. Upon removal, some of these patients became pregnant.

I have 18 charts from the records of the Buffalo General Hospital, where old Gräfenberg rings had been removed after periods varying from 4 to 18 years, and, during all this time, these people were infertile. Five of these 18 subsequently came into the hospital for pregnancy. I don't know what happened to the other 13. But the fact that these people could wear their rings for such a long period of time would lead me to believe that intra-uterine contraceptive devices can, in all probability, be left in for an indefinite period of time.

Chairman GUTTMACHER: What would happen to a plastic device if it were allowed to remain in the uterus?

Dr. MARGULIES: The plastic, it is proven, keeps its elasticity for eight years. So it would not deteriorate. I remember spirals, the tails of which kept the bend of the cervix. But otherwise, time and temperature do not affect the resiliency of the plastic.

Dr. SHIRODKAR: I want to address myself to Dr. Oppenheimer, because he has a great deal of experience with the Gräfenberg type of ring. Whenever I have had Gräfenberg rings remaining in the uterus, I have had more difficulty in taking them out. They have pushed themselves into the endometrium, and I had very often to curette the endometrium before I could feel the ring with the hook. I think anything up to two years is all right with the Gräfenberg type of ring, but not longer.

Dr. OPPENHEIMER: I usually keep the ring in for one year, but I have some patients with two years, three years, even six years, without any complications. I have seen only one ring, and that was a silver ring, which had grown into the uterine wall, and I had to take it out under quite strong pressure. I got it out and a heavy bleeding occurred. I had to get the patient to a hospital to remove the ring.

Chairman GUTTMACHER: Have you had any such experience in leaving in your silkworm

gut rings for several years? I mean evidence of their being implanted deep into the endometrium?

Dr. OPPENHEIMER: No, no.

Chairman GUTTMACHER: If I may summarize, we have evidence that the metal ring may become implanted into the uterus after long periods of residence, making its removal difficult. We have no evidence that a plastic ring becomes deeply implanted. Apparently, it can be removed after 10 years or longer without difficulty. Am I correct in these statements?

Dr. HALL: I think that we must not throw all metal rings into the same pot. There is a big difference between the silver ring and the stainless steel ring. I think that we know from our experience in surgery that stainless steel does not undergo the same changes that silver does. I have left a stainless steel ring *in situ* for as long as 12 years, and 50 per cent of my patients have had them in for more than six years. I have never had one that either produced foreign-body reaction, or that had become embedded, or where there was any difficulty in removing it.

But there were some complications with the silver ring, because silver is not a biologically inert material. It does react with the body and therefore creates complications.

Chairman GUTTMACHER: What about gold?

Dr. RAZZAK: I have had experience with gold rings. As I said in my paper, one of my patients has worn one for 30 years—since 1933. There was no need to take it out, because the patient is quite happy with it. I had many patients, of course, where I removed a gold ring after 15, 17, and 18 years, without any difficulty. But I have had difficulty with silver rings. That is why I changed to gold, and now, to stainless steel.

Dr. ZIPPER: I think that the quality of the material is one of the most complicated questions, because there is more than one kind of polyethylene, and to say 'plastic material' is not enough.

I have used some rings of polyethylene also, but that polyethylene, after three months in the uterine cavity, changed completely and acquired a rigidity like stainless steel. I have used threads of polyethylene thinner than those used by Dr. Lippes, and in one case they produced an acute hemorrhage in the penis of the husband.

That was the reason why I gave up polyethylene. But that is a different polyethylene than the polyethylene in Dr. Margulies' spirals.

Dr. MARGULIES: My material is called linear polyethylene. It is a completely different material from other polyethylenes.

Dr. TIETZE: Neither Dr. Margulies' spiral nor Dr. Lippes' loop has been in use for more than three years. We simply have to defer our judgment as to their long-term effects until more time has elapsed.*

* *Editor's Note:* Dr. Henry Dlugi of New York City has observed a case of angioneurotic edema (urticaria gigantea) developing within a few hours after insertion of an intra-uterine ring made of silkworm gut. It was ascertained that the patient had suffered from an allergy to silk for many years. (Personal communication.)

Pros and Cons of the 'Tail'

Chairman GUTTMACHER: Let us now turn our attention to the filament extending into the vagina from the Lippes loop and to the beaded 'tail' of Margulies' spiral no. V. What are the objections to these appendages? One obvious concern would be the creation of a potential ladder for infection to ascend into the uterus—a point brought up several times during this meeting. So far as I know, we have no evidence to support this concern. Yet we must be alert to the possibility that such a tail, descending from the uterus through the cervix into the vagina, may act as a ladder for bacteria.

Are there any other objections to the use of such a tail?

Dr. LIPPES: As you know, I have no reservations about ascending infection. This is not one of the things I worry about. However, there are other reasons for concern.

Every gynecologist who takes Pap smears has at times received a report from his pathologist stating that the cells in a smear are suspicious of carcinoma. The note would go on to say, 'Please clear up the trichomonas infection and repeat the smear.' Many times, after the infection is cleared up, the smear test reverts to normal. If it is possible for a mild vaginal infection to change the Pap smear, is it not reasonable to expect that an intra-uterine contraceptive device, which has a projection through the cervix—even rubbing against the squamocolumnar junction—will also produce positive smears?

To find an answer to this question, we, in the Buffalo Planned Parenthood Center, plan to take Pap smears on a control group and a group of loop patients. Should future studies show that a cervical projection does change the Pap smear, it may then be necessary for all of us to go back to the Gräfenberg principle of not bridging the gap between the uterus and the vagina. At any rate, it would take a great deal of moral courage at such a time to stand up and still say that intra-uterine contraception is good.

It is here that the value of magnetic localization and removal will come into play. If we are able to introduce a small amount of soft iron or magnetic material into a loop, then it may be possible for a magnet, fitted into the end of a uterine sound (either electromagnet or permanent magnet), to be introduced into the uterine cavity and to remove the device. It may be necessary to add an appendage to the intra-uterine device, which I would call the 'pilot cable.' This cable could be an extension of the loop, at the end of which there would be located a small bead of soft iron. When and if this bead of metal became attracted to a magnetic removing device, it would be easy to direct the pilot cable through the cervical canal into the vagina, where the cable could be grasped visually, and the loop, or some other device, manually removed.

My loop usually requires 70-80 grams of force to remove it from the uterus. To secure 70 or 80 grams of force from a magnetic connection would be difficult to accomplish. But a pilot cable can be deflected with as little as 5, 10, or 15 grams of force, depending on the thickness and flexibility of the material of the pilot cable. Five or ten grams of force is well within the realm of possibility for magnetic connections. This, also, needs more work.

Dr. MARGULIES: What would be the advantage of this pilot cable? Just removal of the loop?

Dr. LIPPES: Removing the loop would be one purpose. The pilot cable could also be used for diagnostic purposes. Very probably, a magnet in a loop could deflect a compass or a magnetometer external to the body, and one could thereby ascertain the presence of the loop without the use of X-ray.

Dr. HALL: I have, of course, stated before that I am against the tail, because I think that we are taking a step backward rather than forward. The great advantage of the completely intra-uterine device is that it does not have this connection with the vaginal canal.

I think this analogy of a bridge between the vagina and the uterus cannot be taken literally, because I don't believe that the bacteria require something to climb along. But the mechanical contact with the type of glands that we have in the cervical canal makes for a quantitative increase or a qualitative change in cervical secretion. This increased amount of cervical mucus, I believe, predisposes to flare-ups of vaginal infection, and thereby again will contribute to an increase in uterine and adnexal infections.

The reports on plastic devices, with extensions that reach through the cervix into the vaginal canal, seem to bear out the contention that pelvic inflammatory disease constitutes one of the complications encountered with these uterovaginal pessaries. Although the period of observation was less than one year, several cases of fulminating pelvic infections occurred, a complication that I have never seen with the intra-uterine stainless steel ring; nor did Dr. Oppenheimer report on such complications in his series.

In examining these facts, we should direct our attention to two factors. The one is the purely mechanical one concerning the shape of the pessary and its location, specifically, whether it is strictly intra-uterine or extending into the cervical and vaginal canal; the other aspect concerns the nature of the material employed.

Plastics, as such, are not necessarily biologically inert. We have seen that the surgeons who use plastic inserts for breast plastics have to remove them many times and with great difficulty, and that in the successful cases you find that the breasts get extremely hard, due to the fibrosis that is stimulated by this material.

We have, however, had no evidence that stainless steel has created any reaction, and, of all the tissues in the body that are most sensitive in that respect, the bones seem to tolerate such implants for prolonged periods of time. On the basis of my own personal experience, I would require a great deal of convincing before I would change over to another material than stainless steel. I would certainly try and experiment with all kinds of materials, but to come away with a feeling that this plastic, which we didn't even define on a chemical and biological basis, will be the only material that we should use, I think, would be premature at this point.

Dr. RICE-WRAY: I want to know whether any husbands have ever complained about the beads in the vagina.

Dr. MARGULIES: Only two husbands felt something. One of these patients had two beads, one of which I cut off, and afterward everything was all right. They were not hurt—they only felt something. Whether the patient told them before, I don't know. I advise my patients not to tell the husbands at all.

Dr. MILLIKEN: How many women are going to examine themselves intravaginally? There may be some in New York City or Buffalo, who may be taught to feel for these beads or threads. But how many women in Puerto Rico or in India are going to do that?

Dr. SATTERTHWAITE: Women in Puerto Rico will not self examine, generally speaking, so the appendage has no particular value for them. I think our Indian friend here is shaking her head also, indicating that it would not be of value in Asia any more than it is in Latin countries.

Dr. PANNU: I am sure that Dr. Shirodkar can tell you about city women, but in

rural areas I have found that women do not like to insert their hand into the vagina. Of course, there are certain women who do it. But in the majority of cases, I don't think they would be very willing to examine themselves.

Dr. TIETZE: Pregnancy rates with intra-uterine devices are very low, much lower than those obtainable with other contraceptive methods, excepting only the new oral tablets. These low rates are based on all pregnancies, including those following unnoticed expulsions. Can we reduce them still further by letting an appendage of some kind protrude into the vagina? I don't believe so, unless wearers can be taught to examine themselves after each menstrual period. Without self-examination, most unnoticed expulsions will be followed by pregnancy long before the next checkup.

To establish a permanent connection between the uterine cavity and vagina may increase the risks of infection or irritation, and it certainly will reduce the acceptance of the method by the medical profession. It may be wise to forego a further reduction of the pregnancy rate, which is already very low, in the interests of greater safety and more general use of intra-uterine contraception.

Chairman GUTTMACHER: While the arguments against the tail are mainly theoretical, they are still very pertinent. We have to keep on studying and comparing the safety, or lack of safety, of one intra-uterine device against another. I do not think we should discard the methods of Lippes and Margulies on purely theoretical objections. At the same time, I admit that the statement made, that most women in underdeveloped areas would be unwilling to examine themselves, is a strong argument against the addition of a tail.

Plans for Future Research

Chairman GUTTMACHER: Some of you, for example, Drs. Livingstone, Margolis, Segal, Milliken, and Dingle, have been invited by the Population Council because you direct large clinics suitable for the study of newer methods of birth control.

We must now consider how to set up well-planned studies on intra-uterine contraceptives in this country and in other parts of the world.

Dr. DINGLE: Use of Planned Parenthood Centers as a resource for clinical evaluation would seem logical. However, the medical policies of most such centers are determined by conservative medical advisory boards with the approval of lay boards of trustees. Intra-uterine contraceptive devices are still generally disapproved by the American medical profession. As a representative of the Planned Parenthood Center in Cleveland, I can anticipate questions which would be raised if such a clinical study were proposed. It is for this reason that I ask what is known about possible legal implications.

Dr. CALDERONE: I think this is a very serious question with many of our centers. They have been concerned about the possibility of legal action in relation to the use of oral contraceptives. The law is different in all states. If you had 50 lawyers in the 50 states, you would get 50 different opinions. But I think it is essential that something be arrived at that will give PPFA centers a sense of security if they want to undertake this kind of research.

This is a particularly difficult area, because the method has for so long been frowned on by the medical profession so completely. Therefore, it is not accepted medical practice. If a patient should get a coincidental PID, she could easily sue on the ground that this PID was caused by the ring, even though we were convinced that it was not, that it was coincidental.

I think this will have to be thought of carefully if you want Planned Parenthood Centers to participate in this research.

Chairman GUTTMACHER: The question Dr. Dingle raises is: are there medical or legal angles so far as potential suits are concerned for a patient's misadventure with one of the intra-uterine birth control devices? Dr. Lippes, how can you reassure Dr. Dingle?

Dr. LIPPES: I can offer her all the help that she would like, and I am sure any member of the Medical Advisory Committee or the Board of Trustees of the Planned Parenthood Center in Buffalo would be glad to cooperate.

I would personally be willing to come to Cleveland and talk to your group about it. I believe Dr. Clyde Randall, who is Chairman of our Medical Advisory Committee and who has had the courage to let me carry on my work, would also be willing to come.

Chairman GUTTMACHER: Do you have releases signed by patients?

Dr. LIPPES: In my private practice, I do not. In the clinic we do have a release of a type which says the method of intra-uterine contraception has been explained to me by Dr. So-and-So, and I have chosen this method of contraception. I further agree that I will notify the Planned Parenthood Center in Buffalo should I move out of town, and that is all. Then the patient signs it.

Dr. MARGOLIS: I don't think that a patient simply signing a paper would release us from any liability whatsoever.

Chairman GUTTMACHER: Are you concerned about starting a project in San Francisco?

Dr. MARGOLIS: No, not at all. My chief concern would be convincing members of our Medical Advisory Board of the suitability of this approach. But so far as patients are concerned, I think we would be able to run a group of patients, and we are fortunate in San Francisco in having relatively fewer transients than in other parts of the country.

Chairman GUTTMACHER: Dr. Jessen, do you feel there is any medical-legal problem involved in this? Did you have any releases signed?

Dr. JESSEN: No, I didn't, and I wished I had.

Chairman GUTTMACHER: Why? Is somebody suing you?

Dr. JESSEN: No, but I went to Wisconsin to get my last patient, brought her back to Chicago, took her ring out, and then took her back home.

Chairman GUTTMACHER: Why were you so frightened about this case?

Dr. JESSEN: Because there was no precedent that I knew of for the ring's use in this country. Most of the literature I have read condemned it. I just would not like to have this sort of thing go to a jury trial.

When I found my last patient had moved out of town to Wisconsin, where I am not licensed, I contacted my malpractice carrier. They asked me first if I had obtained releases when I inserted the rings. When I said: 'No,' they thought that was bad. But since that was the situation, they advised me to write a letter spelling out in detail all the things that could

happen with the ring in place, the chances of infection, of pregnancy, etc., and advising her to come back, stating my willingness to remove the ring. Then I was to get it notarized. Having done this, a separate agent was to take this letter that had been notarized to the post office and mail it registered for me. They thought that would constitute protection for me if the patient wouldn't come back. Fortunately, we avoided all this by convincing her she should come back to Chicago to have her ring removed.

Dr. HALL: When I first started using this device, I had a discussion with a representative of my malpractice insurance carrier. He said that I certainly was covered as far as any possible law suit.

Dr. MARGULIES: In New York State, any kind of a contraceptive is permitted as long as it is in common use. Intra-uterine contraception is not quite in common use, but if it is in use in Buffalo and in New York City, a case can be made that it is in common use.

Dr. JACKSON: May we ask our friends from foreign countries to express their opinions as to the legal situation in their countries.

As far as England is concerned, there is certainly no law forbidding the use of intra-uterine contraceptives. The Pharmacopeia does not list these things, nor does it list other contraceptives. I think we would be in trouble with malpractice just as much from doing a biopsy that went wrong as we should if the insertion of a Gräfenberg ring went wrong.

Chairman GUTTMACHER: Dr. Shirodkar is the President of the Asian Obstetrical and Gynecologic Society. Dr. Shirodkar, would you like to say what the legal aspects are in India?

Dr. SHIRODKAR: The legal aspects are very, very bad in any surgical procedure. I have now made up my mind to go to Delhi and ask Prime Minister Nehru a question: 'You are urging us to perform sterilizations. You are getting all of us doctors into trouble. What is it that prevents you from having at least an ordinance that for the next ten years those who do this sort of thing are, in the national interest, immune from any prosecution?'

Chairman GUTTMACHER: That sounds like a very straightforward way of handling the problem. I don't know whether we could go to President Kennedy and ask him that in this country. I doubt it.

Dr. RICE-WRAY: In Mexico the people are not so suit-prone as they are in this country, so I am sure we wouldn't have to worry about that. But we would have to worry if the insertion of an intra-uterine contraceptive device could be considered to constitute abortion.

One of the chief objectives of our program in Mexico is to prevent abortions. If we could be sure that the mode of action was not interference with nidation, we could easily use the method in Mexico. There would be no problem of patient acceptance. Once the patients have confidence in the doctor, they will accept almost anything. The clinic patients especially are so happy for the attention.

Dr. RAZZAK: In our clinics in Egypt, we require written consent from both the wife and the husband that they accept the method. I should advise my colleagues to do the same thing. As both wife and husband give a written consent, I think there will be no trouble later on.

Chairman GUTTMACHER: Well, there is some question how much protection that offers here in America.

Dr. NOTESTEIN: Experimentation with intra-uterine contraceptives could be done in the countries where the legal situation is less complicated than in the United States. However, it is completely clear that a method which is known but not used in the United States will meet very considerable resistance abroad.

It will be alleged again that we, in the United States, experiment with other peoples. This was said about oral contraceptives. It was never true, but the story has very wide currency indeed and has been an obstacle. We have to face the legal situation of experimentation in the United States.

Dr. DINGLE: Further research and evalution of this type of contraception in the United States would be aided by more general support of the medical profession. Very little information about the revival of interest in this country, the experience in other countries, and the current status of this method has been reported in the American medical literature to date. Therefore, one of the most important results of this conference would be the publication of the proceedings as soon as possible. This could then be shown to local medical groups to elicit their understanding and support. The fact that such a conference, international in character, was deemed important enough to be undertaken by the Population Council, in itself lends stature to the task ahead.

Chairman GUTTMACHER: It appears obvious that we should have well-controlled studies in this country and abroad. We ought to try to plan these studies so that we can have a comparative assessment of the various intra-uterine devices. In the main, three types of devices will have to be studied and compared: metal rings, silkworm gut, and plastic loops and spirals. It would be most valuable to have a clearing house for clinical studies. Perhaps you will allow the Steering Committee of this conference, Dr. Nelson, Dr. Tietze, and myself, to act as such a clearing house. Then if anyone wants to carry out a clinical study, he could contact us and inform us which methods he would like to study in his own group. Then, you could evaluate comparatively, in the same clinic sample, two of the three devices. Which two you choose is a matter of your selection. The Steering Com mittee would like to see all possible combinations explored.

At this point I would like to insert a word of my own. You have heard me say a great deal about Dr. Margulies' spiral. If it looks at times as though we are having a conference on the Margulies spiral, it is simply because we, who have planned this conference, are here in New York, and Dr. Margulies has done his work at a local institution, Mt. Sinai Hospital.

We have no evidence that the Margulies' spiral is better than the Lippes' loop, or Oppenheimer's silkworm gut, or Hall's stainless steel. No one should leave the conference with the idea that there is only one device that works well. It would be magnificent if people who are going to start studies would take all four devices and try each. Then perhaps they will come and say that in one type of patient, Hall's ring is best; in another, the Oppenheimer ring; in a third, the Lippes' loop; and for yet another, the Margulies' spiral.

If you are serious in your intent to carry out such studies, financial support could be furnished. I cannot speak for any organization, but I assume the Population Council would give you support. I am certain that the Planned Parenthood Federation would also attempt to raise funds for you, if this appears necessary.

Dr. TIETZE: It is important that the methodology of clinical studies be reasonably uniform. I have therefore prepared a document, entitled 'Proposed Minimum Standards

for Clinical Studies of Intra-Uterine Contraceptive Devices.' (See Appendix V.) In this document I have outlined what I consider the minimum information that should be supplied if the results of such studies are to be analyzed statistically.

Chairman GUTTMACHER: If we are able to collect all of our findings and satisfy ourselves within 30 months that *this* is the answer for India, or for Pakistan, or for other areas where population control is so vital, we will have accomplished a great deal. It is beyond my belief that we can do this in less than 30 months, because there are so many answers that must be supplied.

Dr. MANNAN: There is an item on the agenda for discussion—the use of paramedical personnel. We are almost at the close of the conference, and the item has not yet been discussed. I consider the item a very important one from the viewpoint of a family planning action program. Intra-uterine contraceptive devices, as they appear to me now, can be of real assistance if they can be used on a large scale. In most of the countries which need family planning badly, the number of medical personnel available for a family planning program is often inadequate. So, paramedical personnel will be required to work in any wide use of intra-uterine contraceptive devices in the family planning program. Under the circumstances, a variety of questions will arise which require consideration. One such question may be whether the idea of using paramedical personnel is at all desirable and advisable; if so, how they can best be selected and trained; and how they can be employed.

Chairman GUTTMACHER: This seems premature in view of the feeling of the group. The problem is not ready for that kind of investigation. We cannot do studies in large population samples without strict medical control for the time being.

Therefore, we have to wait for the next conference, which we hope will be two or three years from now, and then plan how we can employ paramedical personnel.

Dr. NELSON: Mr. Chairman, I am sure by your remarks you did not have any idea of excluding participation of paramedical personnel in well-controlled trials by our colleagues from other countries. I think we should like to encourage such trials.

Chairman GUTTMACHER: That's right, certainly. If a physician in Taiwan wants to use the ring and see whether he can teach the midwife to insert it, this would be a very vital, important contribution. This kind of information we need to know.

A summary at this point is hardly necessary, there is so much agreement among us. All have decided that this is an exciting potential method for limiting population growth in underdeveloped countries, and that much work must be done before a definitive answer can be made.

We have charted the areas of the greatest lack of knowledge. Number one, the way the devices function to prevent pregnancy. The potential dangers, particularly the matter of infection, have been emphasized.

We all agree that various types of intra-uterine devices must be compared, one to the other, to see whether or not there is actually any marked advantage for any one particular device. Thus far, we can say that we do not know whether any one method is better than another. We must study in greater detail those patients who eject the devices, because we may find that certain patients are not suited to this technique.

We agree that there is not sufficient knowledge today to tell us the best time in the cycle to insert a contraceptive device. The majority favors insertion early in the cycle, largely

in order not to interfere with a pregnancy already started. It is felt by most that it is wiser to insert the ring after the first postpartum menstrual period, though there are some who feel that it can be done as early as six weeks post partum. Perhaps, particularly in lactating women, this is preferable to waiting for the menses.

You have worked hard. If I have been unkind to any of you by cutting off your remarks, I apologize, and again I want to thank you all very much. Dr. Nelson will now take over.

Dr. NELSON: I would like to thank Dr. Guttmacher for being such a very effective Chairman. We knew he would be. We could think of no one else that we wished to have in the chair for this conference.

I would like to thank each and every one of you, who have come from near and far to participate in what I think was a very valuable, rewarding, and potentially, an important conference. I hope that we have good and sufficient reason to meet again in the course of a year and a half, or two years, at which time I hope, too, that we will have a great deal more information about all aspects of the problem, including something about how the devices work. As you are aware, we know very little on this score at the present time.

APPENDIX I

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APPENDIX II

INSTRUCTIONS FOR THE INSERTION OF THE PERMA-SPIRAL

by

LAZAR C. MARGULIES, M.D.

For sterilization the spirals must be kept in a 1:1000 aqueous ZEPHIRAN solution for at least 24 hours. They may stay in this solution indefinitely. **Do not boil or autoclave the spirals.**

Before insertion sterilize:
one or two insertion tubes with their plungers;
Hegar dilators up to 4½ mm or Hank dilators 13 - 14;
a tenaculum (may be needed for stretching the cervix);
a long plain forceps;
a vaginal speculum;
also have a curved scissors in reach.

Put patient on the edge of a gynecological table in position and examine in order to find out whether the uterus lies anteriorly or posteriorly, whether the adnexa are soft and not tender and to exclude other contraindications. Inspect cervix and take smears.

(1) Open jar with the sterile spirals.

(2) Put on sterile gloves; remove tray with instruments from the sterilizer and put it on a table. Remove plunger from the insertion tube; put both on the sterile tray.

(3) With sterile forceps pick out a spiral from the open jar. Feed the spiral the beaded end first—into that end of the insertion tube that is nearer to the oval marker until the central end of the spiral stays reliably in the tube. Put loaded tube on sterile tray.

(4) Insert sterile vaginal speculum, expose cervix, spray or swab cervix with a disinfectant. Do not push the speculum too deeply into vagina; try to keep cervix in mid-vagina. (If you have difficulty in exposing the cervix ask the patient to hold her knees on her abdomen until the whole procedure is finished. This helps especially in retroverted uteri.)

(5) Probe the cervical canal gently with the dilators while holding your other hand on the patient's abdomen above her pubis: that hand can bring the cervix close to the entrance, give the dilator better resistance and prevent a perforation. You have to make sure again whether the uterus is ante- or retroverted. (If you have the slightest difficulties in passing the dilators—or later the insertion tube—pinch the cervix with a tenaculum, stretch it and try again.)

(6) Insert the loaded tube gently into the uterus, the curve anteriorly or posteriorly depending on the position of the uterus, until the oval marker on the tubing comes close to the external os of the cervix. If you touch the fundus pull tube back by 1 cm.

(7) Turn tube left or right—whichever goes easier—by 90° to make sure that the spiral recoils in the frontal plane of the cavity when pushed in.

(8) Insert the plunger into the open end of the tube, push it slowly all the way in,

remove tube with plunger. This plunger is cut short purposely (it is just long enough to extrude the spiral into the cavity and to keep the beads out of it).

(9) If there were more than 2 beads protruding from the cervix, cut them off with a curved scissors very close to the bead you want to leave sticking out. Be sure not to leave a sharp end which might scratch the penis, although the plastic gets very soft in body temperature. For this manipulation you may hold the end of the 'tail' with the forceps from the tray.

(10) When the inserter is not in use, keep the pusher in the tubing inserted through the upper end. It protects the tubing from its natural tendency to roll in and the insertion of the loaded tube into a multiparous uterus is much easier with a straight inserter.

Absolutely sterile handling of the spiral, tubing, plunger, and instruments is imperative in order to avoid iatrogenic infections and complications.

Instruct the patients how to examine themselves in a squatting position *once every week* with washed hands so that they learn how to make sure by themselves that only one or two beads stick out from the cervix. Four or more beads indicate that the spiral is possibly slipping down; the patient will have to come for an adjustment immediately. Do not exchange the spiral unless the smooth part of the 'tail' is also visible. The uterus might have been enlarged pre-menstrually or by Enovid. Cut the superfluous beads off and check on the patient more frequently than the every three months you would check the average patient.

Warn the patients of cramps after insertion (especially the nulliparous may have violent cramps) and of spotting and bleeding for a few days or up to two weeks.

Warn them that the first and second period may come sooner, that it is mostly very heavy and/or prolonged and advise them to apply ice bags on the lowest part of the abdomen for half an hour repeatedly, if necessary. It is *the* best remedy.

Spirals may be inserted at any time of the cycle—even during menses.

Waiting time: 3 months after confinement (or two menses); 1 menses after abortion.

Once an ovum is implanted (after about 19th day of cycle) insertion of a spiral will not disturb the pregnancy (4 own cases observed).

To remove a Perma-Spiral simply pull on the end protruding from cervix.

Contraindications

Any acute or subacute adnexal disease. (Flare-ups can be controlled by antibiotics.)
Pregnancy.
Large fibroids with distortion of cavity especially submucous fibroids.
Menorrhagia with suspicion of endometrial polyps.
Acute or subacute cervicitis.
Suspicion of carcinoma.

See Addendum, p. 68.

APPENDIX III

INSTRUCTIONS FOR THE INSERTION OF AN INTRA-UTERINE LOOP

by

JACK LIPPES, M.D.

A pelvic examination (including Papanicolaou smears, if desired) is made to determine the direction of the uterus, to discover whether it is anteverted or retroverted, and to detect possible contraindications.

Contraindications:

(1) The presence of large fibroids

(2) Acute or subacute pelvic inflammatory disease

(3) Carcinoma

(4) Pregnancy

(5) A history of recent menorrhagia or metrorrhagia.

The time of insertion is preferably the last one or two days of a menstrual period. This prevents the disturbance of an early pregnancy. There is also less bleeding following insertion if it is done at this time. Insertion should not be sooner than 60 days after a delivery or an abortion. In lactating patients with amenorrhea insertion should be 60 days post partum. In non-lactating patients the end of the second postpartum menstruation is a convenient time.

Sterilization of the inserter and the loop can be done by ½ hour exposure to a 1 : 1000 aqueous solution of benzalkonium chloride (Zephiran) at room temperature. Somewhat preferable is prolonged storage of loops and inserter in the Zephiran solution. The loops should not be boiled or autoclaved.

The loop is placed in the inserter with well scrubbed hands, with or without gloves. The large end is inserted first into the proximal or vaginal end of the tube, with the suture dangling. The plunger is then pushed one or two inches into the tube.

The cervix is visualized with a sterile speculum and cleaned with a sterile cotton ball dipped in the aqueous Zephiran. It may be sprayed with Betadine.

A sound is inserted to learn the direction and depth of the uterine canal. Occasionally a tenaculum is required if the canal needs to be straightened, or a cicatrized cervix must be dilated. For dilation a Hank's dilator should be used, rather than a Hegar's.

The inserter is pushed into the uterus for 4.7 centimeters, a distance indicated by setting the position of the first fin. It is then rotated until the longer diameter is in the antero-posterior line of the patient (perpendicular to the horizon). In this position the loop, when extruded, will enter the uterine cavity in the correct frontal plane, that of the cornua. The plunger (which has previously been put one or two inches into the inserter tube) is now pushed in all the way, extruding the loop into the uterine cavity. The plunger is then with-

drawn completely, to prevent its binding or pulling on the suture, after which the inserting tube is pulled out of the uterus.

The suture is allowed to extend into the vagina, and is cut to allow about 1.5 cm to be visible. As the suture is soft in the moist vagina, husbands have not felt it. It has, however, been possible to teach patients to feel its presence for reassurance that the loop is still in position. Subsequent speculum examination also confirms loop position.

Instructions to the patient. The patient should be told that some *bleeding* is to be expected in the first month, and that the first or second menstruation may be larger than usual in amount. When this is large she should lie down for an hour a day with an ice bag on the abdomen. Vitamin K (Mephyton) 5 mg three times a day for five days may be helpful.

Warn the patient that there may be *cramps* after insertion, more frequent in the nulliparous. Localized heat, aspirin, and codeine in ½ grain doses are helpful.

The possibility of *expulsion* should be explained to the patient, together with the fact that it is more apt to occur at the time of menstruation, especially the first or second day. Menstrual pads should be examined. Many patients can learn to examine with a finger in the vagina for the suture to determine if it is present at the external os and of the original length. Since expulsion is more frequent in the first month, and may not be detected, greater protection can be assured if another method of contraception is used until a re-examination at the end of a month gives assurance that the loop is still in place.*

Follow Up. The patient should be examined after one or two months, and again after 12 months, and perhaps annually.

Equipment Needed:

Plastic loop stored in 1 : 1000 aqueous Zephiran solution
Inserter, sterilized in Zephiran
Sterile gloves
Sterile speculum
Sterile long forceps
Sounds
Tenaculum—single tooth
Hank's dilators
Curved scissors (Ferguson's scissors with serrated cutting edges are preferable)
Bowl of aqueous Zephiran or Betadine
Sterile cotton balls

* The suture is being redesigned with small beads about ¼ inch (6 mm) apart to allow the patient easier identification.

APPENDIX IV

MOTION PICTURE FILM ON INTRA-UTERINE CONTRACEPTIVE DEVICES

In preparation for the Conference, a motion picture film, entitled *New Intra-Uterine Plastic Contraceptive Devices,* was made under the auspices of the Population Council by Sturgis-Grant Productions, Inc., in New York. The major part of the film, prepared at Mount Sinai Hospital, New York, with the cooperation of Dr. Margulies, is devoted to the Perma-Spiral; however, the loop of Dr. Lippes and the silkworm gut ring used by Dr. Oppenheimer are also shown. Indications and contraindications are discussed, as are the procedures of insertion and removal. Opening and closing remarks are spoken by Dr. Guttmacher.

The film is in color, with a sound track in English. It is 16 mm wide and has a running time of 15 minutes. Information regarding the availability of copies may be obtained from the Population Council, The Rockefeller Institute, York Avenue at 66th Street, New York 21, New York.

The film was shown to the participants in the Conference at the beginning of the morning session on May 1, immediately preceding the general discussion.

APPENDIX V

MINIMUM STANDARDS FOR CLINICAL STUDIES OF INTRA-UTERINE CONTRACEPTIVE DEVICES

by

CHRISTOPHER TIETZE, M.D.

(1) Information should be furnished on construction and material of the contraceptive device and on the techniques of insertion and removal; on the distribution of patients by age and by parity; and on the physician's policies in regard to contraindications, instructions to patients, periodic re-examination, and routine changing of the device.

(2) The following statistics should be presented:

A. *Number of patients.*

B. *Number of insertions.*

C. *Aggregate number of woman-months of use.* Periods of use should extend from date of insertion to date of removal, expulsion, conception, or most recent examination. If patient is able to determine the presence of the device, date of last communication by letter or telephone may be substituted for date of examination.
If expulsion, unnoticed by the patient, was followed by conception, use date of conception; if not followed by conception, use date of last prior examination or communication.

D. *Number of patients* who experienced, on one or more occasions, side effects requiring temporary or permanent removal of the device or systemic treatment with antibiotics.

E. *Number of instances* of side effects requiring removal or systemic treatment, by type of side effect and time since last insertion.

F. *Number of patients* who discontinued permanently because of side effects.

G. *Number of patients* who experienced one or more complete or partial expulsions of the device without subsequent pregnancy.

H. *Number of expulsions* with distribution by type (noticed by patient, not noticed by patient), and number of months since last insertion.

I. *Number of patients* who discontinued permanently because of expulsion.

J. *Number of patients* who experienced one or more unintended pregnancies.

K. *Number of unintended pregnancies,* with distribution by type (after unnoticed expulsion, with device *in situ,* undetermined) and number of months since last insertion. Ectopic pregnancies should be shown separately and the absence of such pregnancies should also be reported.

L. *Number of patients* who discontinued permanently because of unintended pregnancy.

M. *Number of patients* who had the device removed, on one or more occasions in order to conceive.

N. *Number of instances* the device was removed in order to conceive, with distribution of *planned pregnancies* by number of months required for conception, and of *failures to conceive* by number of months of observation after removal.

(3) It is recommended that the number of patients should be at least 100; the aggregate period of use at least 2,400 woman-months; and the average duration of use per patient, at least one year.

APPENDIX VI

STATISTICAL COMPARISON OF INTRA-UTERINE CONTRACEPTIVE DEVICES

by

CHRISTOPHER TIETZE, M.D.

New clinical data on intra-uterine contraceptive devices, not previously published, presented at the Conference or communicated to the editors after the Conference, are summarized in this appendix.

Drs. Baumgold, Hall, Lippes, Margulies, and Satterthwaite submitted reports on their experience through August 31, 1962; the observations of Drs. Jackson, Jessen, Peng, and Zipper have been abstracted from their papers. In addition, data have been obtained from two physicians, who, as residents, had been instructed by Dr. Hall in the use of the stainless steel ring: Dr. Martin B. Stahl of Perth Amboy, New Jersey*, and Dr. Marvin B. Zuckerman of New York City. Devices for which less than 1,200 woman-months of observation are available are not included. Data on Dr. Margulies' polyethylene spiral are limited to spiral No. V with barium (including the slightly smaller V-J), the only model in continued use.

Tables 1 to 3 present, respectively, data on the number of patients, woman-months of use, unintended pregnancies, expulsions, and removals of the devices for medical and psychological reasons, with the appropriate rates and percentages. The reports are listed alphabetically by type of device, material, and author, with the exception that the basic report of Dr. Margulies precedes those of Drs. Baumgold and Satterthwaite.

Since the expulsion of an intra-uterine device, if not noticed by the wearer, is usually soon followed by conception, the chance of discovering the expulsion increases, *ceteris paribus*, with the frequency of medical supervision and the incidence of pregnancy after expulsion is reduced.

In order to eliminate, so far as possible, the effects of variations in the frequency of medical check ups between the several reports. Table 4 shows the estimated numbers of unintentional pregnancies and the corresponding failure rates, on the assumption of *no* routine medical examination after the insertion of the device. In the preparation of this table it was assumed that (1) all expulsions not noticed by the wearer would be promptly followed by pregnancy, and (2) that the proportion of unnoticed expulsions was the same among first expulsions as reported for all expulsions.

The requisite information is not available in the reports of Drs. Jessen and Zipper and their data are, therefore, omitted from Table 4. In the case of Dr. Peng's report from Taiwan, the number of expulsions not followed by conception was very small (2 cases); it was assumed that these had been noticed by the women concerned.

* Dr. Stahl's data include the experience of four associates: Dr. Henry A. Belafsky, Dr. Samuel Breslow, Dr. Jack E. Shangold, and Dr. Leonard M. Hirsch.

TABLE 1

Number of Patients, Woman-Months of Use, Unintended Pregnancies, and Failure Rate

Type of device, material, and author	No. of patients	Woman-months of use		Number of Unintended Pregnancies				Failure rate**
		Aggregate	Per patient	After unnoticed expulsion	With device in situ	Undetermined	Total	
Loop, Polyethylene								
Lippes	241	1,347	5.6	—	6	—	6	4.6
Satterthwaite	99	477	4.8	—	1	—	1	
Ring, Nylon								
Zipper	628	6,745	10.7	—	—	9	9	1.6
Ring, Polyethylene								
Lippes	204	2,222	10.9	3	—	—	3	3.1
Peng	521	5,507	10.6	—	—	17	17	
Ring, Silkworm gut								
Jessen	121	1,270	10.5	—	3	—	3	2.8
Ring, Silver								
Jackson	190	10,711	56.4	5	9	4	18	2.0
Ring, Stainless Steel								
Hall	184	8,134	44.2	4	2	—	6	0.9
Stahl	519	7,136	13.7	4	4	—	8	
Zuckerman	134	2,660	19.9	—	—	—	—	
Spiral, Polyethylene*								
Margulies	256	1,558	6.1	1	—	—	1	1.1
Baumgold	72	333	4.6	—	—	1	1	
Satterthwaite	56	205	3.7	—	—	—	—	

* Size V Spiral with barium.

** Unintended pregnancies per 100 woman-years of use.

TABLE 2

Expulsion of Intra-Uterine Devices without Subsequent Pregnancy

Type of device, material, and author	Number of expulsions without subsequent pregnancy				Patients who expelled the device	
	Noticed by patient*	Not noticed by patient	Not stated	Total	Number	Per cent
Loop, Polyethylene						
Lippes	12	2	—	14	14	8.2
Satterthwaite	14	2	—	16	14	
Ring, Nylon						
Zipper	—	—	40	40	40	6.4
Ring, Polyethylene						
Lippes	11	3	—	14	11	1.8
Peng	—	—	2	2	2	
Ring, Silkworm gut						
Jessen	—	—	10	10	10	8.3
Ring, Silver						
Jackson	7	—	—	7	7	3.7
Ring, Stainless Steel						
Hall	1	7	—	8	4	4.3
Stahl	32	6	—	38	31	
Zuckerman	1	—	—	1	1	
Spiral, Polyethylene						
Margulies	14	3	—	17	11	6.0
Baumgold	4	1	—	5	4	
Satterthwaite	8	3	—	11	8	

* Including expulsions followed by pregnancy (patient knew herself to be unprotected but did not care).

TABLE 3

Removals of Intra-Uterine Devices for Medical and Psychological Reasons

Type of device, material, and author	Number of removals, by reason							Removals per 100 patients
	Infection	Meno- and metro-rrhagia	Irregular menstruation	Pain	Psychological (fear, etc.)	Other	Total	
Loop, Polyethylene								
Lippes	1	3	—	2	2	—	8	5.0
Satterthwaite	2	7	—	—	—	—	9	
Ring, Nylon								
Zipper	—	16	—	5	7	—	28	4.5
Ring, Polyethylene								
Lippes	2	13	—	6	1	4	26	8.6
Peng	7*	24		—	5**	—	36	
Ring, Silkworm gut								
Jessen	8	2	—	1	—	—	11	9.1
Ring, Silver								
Jackson	—	11	5	3	5	—	24	12.6
Ring, Stainless Steel								
Hall	—	7	—	—	—	—	7	2.4
Stahl	1	6	—	3	—	—	10	
Zuckerman	—	2	—	1	—	—	3	
Spiral, Polyethylene								
Margulies	2	7	—	1	1	—	11	7.0
Baumgold	—	2	—	3	—	1	6	
Satterthwaite	2	3	—	3	—	2	10	

* "Inflammation and irritation."
** "Nervous symptoms."

TABLE 4

Estimated Pregnancies and Failure Rate without Medical Supervision

Type of device, material, and author	Woman-months of use	Actual pregnancies	First expulsions not noticed by patient*	Estimated pregnancies	Failure rate**
Loop, Polyethylene					
Lippes	1,347	6	2	8	7.2
Satterthwaite	477	1	2	3	
Ring, Polyethylene					
Lippes	2,222	3	2	5	3.4
Peng	5,507	17	—	17	
Ring, Silver					
Jackson	10,711	18	—	18	2.0
Ring, Stainless Steel					
Hall	8,134	6	3	9	1.5
Stahl	7,136	8	5	13	
Zuckerman	2,660	—	—	—	
Spiral, Polyethylene					
Margulies	1,588	1	2	3	4.0
Baumgold	333	1	1	2	
Satterthwaite	205	—	2	2	

* Estimate.
** Pregnancies per 100 woman-years of use.