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THE IUD

Intrauterine Devices For Contraception

THE IUD

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DEDICATED TO

REV. THOMAS MALTHUS, who discovered the problem before
the world understood the remedy

AND

DR. RICHARD RICHTER, who discovered the remedy before
the world understood the problem

FOREWORD

During the 1960's, contraceptive technology made enormous strides with the development of oral contraceptives and the rebirth of the IUD. The oral contraceptive rapidly developed enormous popularity and advocacy. The IUD, on the other hand, has lagged behind the Pill on both counts. Those who took time to evaluate the IUD properly have been mystified by the general tendency to categorize it as a "second class" method. There are many reasons for this state of affairs, the two most important being the lack of training programs for clinicians using the method and the relative lack of commercial promotion. Dr. Hugh Davis, of Johns Hopkins Medical School, Baltimore, Maryland, has had long experience in both the clinical and research aspects of IUD development, and the publication of this textbook should help redress the balance.

Dr. Davis has devoted the first two chapters to history and demographic considerations. The latter subject, i.e., the population explosion, deserves strong emphasis because it is a problem that must be solved, not by government decree or legislation, but by the application of efficient birth control technology and field programs. The history of the IUD as given is fundamental to gaining an understanding of present clinical use. Coupled with the Appendices on major and experimental IUD's, a total picture is provided of IUD design, performance and availability.

An important feature of this text is its stress on mechanism of action, clinical application and patient management. Certainly, those of us familiar with IUD programs have known that successes or failures depend in large part on whether or not the participating clinicians and staff had been well-trained in IUD insertion, removal and patient management. It is imperative that professionals and paraprofessional staff be thoroughly competent in these areas, for although the IUD is a relatively simple method, unskilled use can lead to less than favorable results. This book gives the detailed step-by-step consideration so necessary in learning IUD technology. I hope

for this reason it becomes required reading, particularly for doctors and nurses involved in family planning programs. The sections on clinic interviewing and patient management are particularly thoughtful and useful and should do much to stimulate better patient services.

Some clinicians and researchers will take exception to Dr. Davis' assessment of contraceptive effectiveness, particularly his stress of clinical or use-effectiveness. But there is ample evidence to lend major support to his thesis that we must pay much more attention to how well birth control methods actually perform, rather than consider theoretical effectiveness alone. Further, we must take into account the number and severity of side effects possible with long term use of contraceptives, because women today are using the more efficient methods of birth control for prolonged periods of time.

Although IUD research and development has been slighted over the past decade, the high promise of this important birth control method continues undiminished. We must recognize that contraceptive technology is in a state of dynamic evolution in the face of the manifest need for improved methods as well as better application of available methods. Modern intra-uterine devices deserve an important place in the contraceptive armamentarium, and this text will do much to assure that the IUD achieves wider and better utilization in the future.

GEORGE LANGMYHR, M.D.

Medical Director

Planned Parenthood—World Population
New York, New York

PREFACE

After seventy years of slow evolution, and a decade of increasing clinical use, the intrauterine device has achieved recognition as a superior birth control method because it uniquely combines medical safety, simplicity, long-term efficacy and reversibility. As this is written, over 12,000,000 women around the world have been fitted with IUD's, making insertion one of the most frequent minor technical procedures in medicine. Yet scientific information regarding the IUD remains scattered in over a thousand articles and is nowhere available for reference in a comprehensive fashion.

Our experience with intrauterine devices in private patients, in directing the family planning activities at the Johns Hopkins Hospital and as a consultant to the Maryland Planned Parenthood Clinic and the Maryland State Department of Health spans eight years. Over 10,000 women have been fitted in these programs, providing a substantial experience in patient management and an opportunity to evaluate a variety of IUD designs.

The initial use of IUD's at Johns Hopkins began with few insertions and a great many reservations. There was little confidence that the technic would prove as safe and effective as some pioneer enthusiasts claimed. Patients who could not use other methods were fitted with simple plastic rings similar to the silkworm gut devices used at the turn of the century. These initial patients were closely monitored for possible grim complications mentioned in the old literature. Fortunately, most of the alleged IUD hazards proved to be medical myths.

In the ensuing years, increasingly excellent results with the method have made us active advocates of intrauterine contraception. The second generation IUD's now available are extremely easy to insert, almost perfectly retained, well tolerated and virtually 100% effective. The outstanding performance of the best modern devices plus the unique advantages intrinsic in the method make the subject of considerable importance and presentation as a text timely.

Consideration of intrauterine devices in relation to other contraceptives

and the population problem as a whole may serve other purposes as well. The lag between the development and the application of medical advances remains a major barrier to delivering improved birth control services, as is true of other health services. The last to learn of significant progress are often those who administratively must provide funds and organization to implement action. Broader and more effective utilization of the IUD has undoubtedly been inhibited by a lack of adequate information as well as by lingering 19th century prejudices. As scientific faith springs from knowledge, misconceived prejudice should be dispelled by the available facts.

It is our hope that better understanding of intrauterine contraception will help others to avoid unnecessary complications, to select devices most suitable for individual patients and to observe the indications and contra-indications of the technic. It is also hoped that this writing will contribute to an improvement of birth control services as the intrauterine device takes a well-merited place in the front rank of medical methods of contraception.

H. J. D.

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One

HISTORICAL PERSPECTIVE

The September 1909 issue of the *Deutsche Medizinische Wochenschrift* contains a little-known article entitled "Ein Mittel zur Verhütung der Konzeption" ("A Means of Preventing Conception"). The author was Dr. Richard Richter, a practitioner in the village of Waldenberg near Breslau, in present-day Poland. The first practical intrauterine device was reported in this modest two-page communication.

The IUD devised by Richter was a flexible ring fashioned of silkworm gut (Fig. 1), a suture material obtained by drawing out in a single strand the fluid in a silkworm killed when it was just ready to spin its cocoon. Once in place, the ring functioned for months or years as an effective contraceptive. Prior to this extraordinary discovery, all known methods of conception control were coitally related, sexually frustrating and relatively unreliable.

Richter's ring made possible, for the first time in human history, a permanent, yet completely reversible, separation of sexual expression from involuntary reproduction. Intrauterine contraception requires only initial motivation and a few minutes of medical time to provide months or years of highly effective birth control. As Norman Haire so picturesquely pointed 40 years ago, the IUD "is free from the aesthetic disadvantages of all other methods of contraception, and does not interfere at all with the spontaneity of intercourse. It requires no preparation just before intercourse, which may take place equally well in the marital bed or on the sea-shore."

The development and testing of the first intrauterine device by Richter was accomplished despite strict laws prohibiting all birth control activities. Physicians had been tried, stripped of their licenses and jailed for providing contraceptive services. An innovation as radical as Richter's ring was almost certain to attract official censure if not actual prosecution.

What impelled this physician to risk disclosing his activities? Richter's historic article (17) provides insight into the humanitarian motives which caused him to publish: "One who knows life as it is, knows also that hun-

dreds of mothers sacrifice their health and happiness every year for the sake of childbearing. Anyone who does not reject the higher purposes of life finds intolerable the preponderance of suffering over happiness, causing distress and uneasiness and restricting the duration of life. It becomes a matter of obligation and conscience under these circumstances for the physician to restrain the excess of children.

"After many years of testing and improving I am able to offer to my colleagues a simple and safe contraceptive. This is a silkworm gut suture which is inserted into the uterus. Irritation of the endometrium by the thread is so slight that the majority of women do not feel it at all, yet it is sufficient to prevent pregnancy. The longest uninterrupted action of this device was in some of my cases almost four years. . . .

"In general, the thread is well tolerated . . . Slight bleeding ceases after a few days spontaneously . . . Removal is easy: the thread can be pulled out with a forceps. I have removed the thread when indications for temporary sterility disappeared. After removal, the fertility is restored and pregnancy has a normal course so far as baby and mother are concerned."

Abstracted from the original publication, the observations are as valid today as they were in 1909. Richter's historic device consisted of two strands of silkworm gut suture looped to form a ring some 27 mm. in diameter. The strands were bound together to form the ring by a spiral of aluminum-bronze wire. Richter had found that such a double ring was more effective as a contraceptive than an earlier version consisting of a single silkworm gut suture.

die Länge, Richtung und Weite festzustellen. Nunmehr werden zwei Fäden, zu einer einfachen Schlinge geschürzt, in das Auge der Hohlsonde gelegt, durch den Draht (Mandrin) festgeklemmt (vgl. die Abbildung) und langsam in den Uterus bis zum Fundus ge-

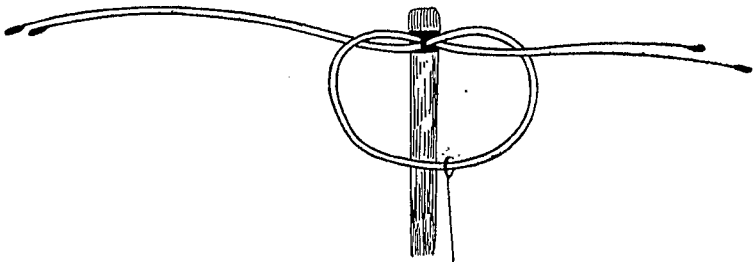


Abbildung in natürlicher Größe.
Die Fäden zu einer einfachen Schlinge geschürzt, in das Auge der Hohlsonde eingeklemmt und durch den Mandrin festgehalten.

FIG. 1. The first intrauterine contraceptive device—a ring formed of silkworm gut suture material—reproduced from Richter's 1909 article announcing the discovery of intrauterine contraception. The device was passed through the cervical canal into the uterine cavity by means of the notched sound, a technic employed for insertion of some types of IUD to the present day.

To have acquired the wealth of clinical information disclosed in his brief article, Richter must have fitted IUD's in quite a few women, commencing about 1900. He devised a special notched sound with a sliding lock mechanism to grip the ring during insertion and assure high fundal placement of the device. Following insertion, the terminal threads presenting through the cervix were trimmed just beyond the external os as a ready means of removal at a later date. Richter recommended insertions of the device 12 weeks post-partum, advised against insertion in cases of florid infection or if there was suspected pregnancy.

No concrete data on pregnancy rates or expulsion rates were given by Richter, nor did he reveal the number of women he had fitted with his IUD. Perhaps this was to avoid a firm basis for prosecution if the authorities took notice of his activities. Most of his observations have subsequently proven quite accurate, with the exception of the overly optimistic statement "The art of its (IUD) application under medico-technical precautions excludes any abuse." Richter erred sadly in expecting the skill and philosophic objectivity in others which he demanded of himself.

Had he lived to witness events over the ensuing years, a man of Richter's idealism would have suffered much disillusionment. Two World Wars and an incalculable amount of human misery were to ensue before the necessity of effective birth control was to be acknowledged. The right of a woman to determine the number of children she wants at a time when she wants them remained unrecognized, and even today, the exercise of this right is prohibited in many places.

SUPPRESSION OF THE METHOD

The practical development and use of intrauterine devices was effectively suppressed for the next 50 years, as much by ingrained medical prejudice as by official proscription. Until recently, "respectable" physicians simply did not actively involve themselves in fostering birth control. Richter himself published nothing further on the subject, and those who adopted the use of the ring did so in secret. The completely closed mind of most gynecologic authorities towards the IUD is well illustrated by the 1932 statement (2) of Prof. Ludwig Fraenkel, chairman of the Department of Obstetrics and Gynecology at Breslau, a few miles from where Richter had made his primary discovery: "All intrauterine devices have to be condemned because all of them are dangerous. The design and experimental application of newer devices is useless. Even if they could be made completely harmless, they would never achieve general acceptance because of the necessity of insertion and removal by specialists." In this completely negative atmosphere, IUD's continued in very limited use. We are aware of the existence of the devices only because of sporadic articles in the old gynecologic literature condemning contraception, including IUD's.

The suppression of discoveries is hardly new. Medical history is replete

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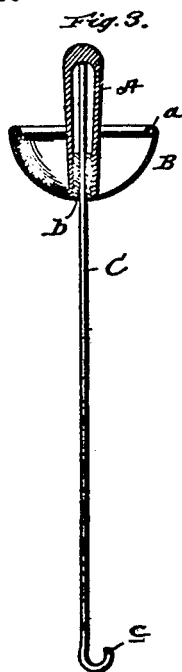
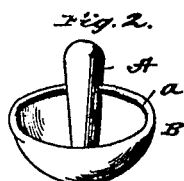
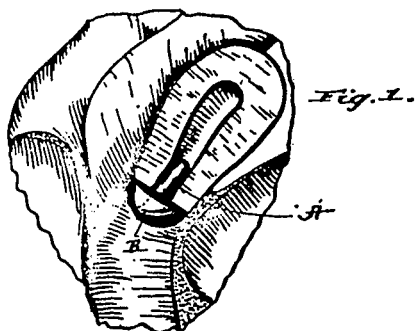
The suppression of discoveries is hardly new. Medical history is replete

(No Model.)

J. C. PETIT.
WOMB BATTERY.

No. 520,895.

Patented June 5, 1894.



Witnesses:
Chas. P. ...
S. C. ...

Inventor
J. C. Petit
By *James J. Shuby*
Attorney

FIG. 2. So-called "Womb Battery" patented by Petit in 1884. According to the galvanic theories of the inventor, this device would electrically stimulate the cervix and "promote the cure of the various diseases peculiar to the female sex." Though obviously designed to function as a cervical cap, no contraceptive action was claimed, probably to evade laws prohibiting the dissemination of birth control information.

several millenia ago to prevent pregnancies during caravan journeys (20). When attempts are made to verify this charming camel tale, however, the cited references vanish in the vast and uncharted sands of Araby.

Nevertheless, various intracervical or partially intrauterine pessaries have indeed been known to medicine for several centuries. An astonishing variety of such pessaries had become popular in Europe and America by the late 1880's. All manner of therapeutic triumphs were attributed to even the simplest of these gadgets. The claims made in U.S. Patent No. 520, 895 issued to one Julius C. Petit of Fort Worth Texas on June 5, 1884, are fairly representative. Petit termed his invention a "Womb Battery" (Fig. 2), and stated that "it has for its general object to provide an advantageous electrical or galvanic device adapted, when placed on the womb of a patient, where it will be subject to the chemical action of the mucous fluid, to develop a mild electric action and thereby stimulate the generative organs and promote the cure of the various diseases peculiar to the female sex." Whatever electrical stimulation Petit's pessary may have provided, it had the appearance of an effective cervical cap.

Cervico-Uterine Pessaries

Not to be outdone, other inventors in the Victorian era converted their fantasies to reality. The stems of the pessaries grew longer and longer, and many of them eventually became cervico-uterine with a terminal bulbosity, coil or fork entering the uterine cavity. Stem pessaries (Fig. 3) were fashioned of silver, copper, gold, ivory, horn, hard rubber and ebony. One popular version was the so-called wishbone pessary because of its shape. During insertion, the wings of the device were compressed to facilitate transit through the cervical canal.

It was claimed that such stem pessaries supported the uterus, prevented excessive bending of the organ, and cured dysmenorrhea. No doubt mindful of the fate of colleagues who had been openly active in birth control work, the inventors took elaborate care not to mention any contraceptive purpose for these cervico-uterine pessaries. The bravest inventors would sometimes suggest that the pessaries could be used to prevent irregular or *delayed* menses. Others claimed the pessaries to be helpful in the treatment of infertility (!) which was said to improve dramatically after removal of the apparatus. The pious fiction that these pessaries were not intended for contraception was generally maintained until 1902, when Dr. Carl Hollweg secured a patent on a wishbone pessary. In the official patent application, he made no contraceptive claims, but reported separately in a medical journal (8) on 700 women who had the pessary fitted for contraceptive purposes.

During the early 1900's serious gynecologic complications arose from

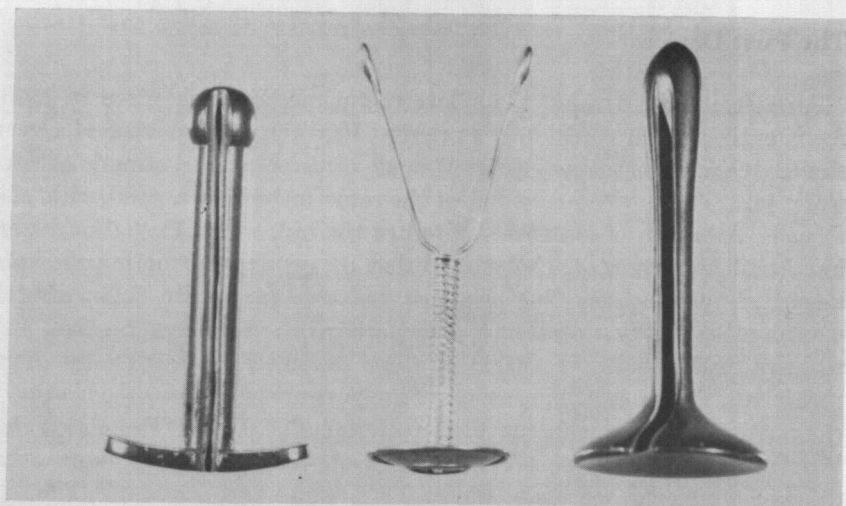


FIG. 3. Stem pessaries of hard rubber and metal made in the late 1880's. The flexible wings of the gold "wishbone" pessary could be compressed to facilitate insertion. These forerunners of the IUD were used to mechanically provoke abortions, in contrast with the contraceptive action of intrauterine devices. Complications resulting from the misuse of such stem pessaries made many physicians resistant to the concept of intrauterine contraception.

the widespread and indiscriminate use of cervico-uterine stem pessaries. Septic abortions were often provoked by the deliberate insertion of the pessary into pregnant women. One pessary advertised for this purpose became widely known as the "Sterilette" and was sold with instructions for self-insertion in order to "regulate the menses." These unsterile stem pessaries were indiscriminately used to provoke abortions by druggists, granny midwives, quacks and the women themselves.

Not that do-it-yourself intrauterine contraception died completely at the turn of the century. Freedman (3) reported the case of a woman who put her gold wedding ring to good use in 1950 by somehow inserting it into her uterus as a contraceptive device. The ring remained in place for two years and eight months, performing its job admirably and causing no problems. Then it was removed, cleaned and re-inserted, which proved her undoing, for she shortly thereafter became pregnant, carrying the infant to term.

The complications and deaths associated with the use of the abortifacient cervico-uterine pessaries caused a storm of protest. Resistance developed to carrying out any and all uterine manipulations. The gynecologic textbooks and journals were filled with condemnation of the pessaries, creating a completely negative attitude which greatly retarded the subsequent acceptance and development of true intrauterine devices.

The Pust Device

An attempted revival of the silkworm gut method took place in 1923. Apparently unaware of Richter's priority, Karl Pust (16) published a very similar technic using a ring (Fig. 4) made of three twisted strands of silkworm gut. The device had a tail of the same material wrapped with silk threads. A button of glass was affixed to the tail, which Pust thought an important improvement. He believed that the cervical button impeded the ascent of spermatozoa. Pust claimed to have personally followed 453 women after insertion without a single failure or serious complication, and to have distributed over 23,000 of these devices for insertion by other physicians. The most striking aspect of Pust's contribution was the blatantly clear title "Ein Brauchbarer Frauenschutz" ("A Useful Protection for Women"). The liberal post-World War I era was permitting more open discussion of contraceptive methods.

The claims of Pust regarding his device were undoubtedly overdrawn. The rather heavy silk-wrapped tail probably had some wicking action, providing a bridge to the vagina for ascending infections, as Gräfenberg and other opponents of the Pust device claimed. The pros and cons of intrauterine contraception were discussed in the 1920's in a slowly growing body of medical literature. But for the most part, gynecologists remained quite opposed to the technic (19).

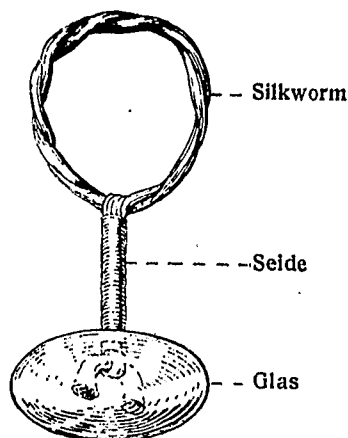


FIG. 4. The Pust device, a modification of Richter's ring used in the 1920's, with a trans-cervical tail of silk and a glass button to cover the external os of the cervix. The bulky silk-wrapped tail of this device was thought to predispose to ascending infection and its use was condemned by most medical authorities.

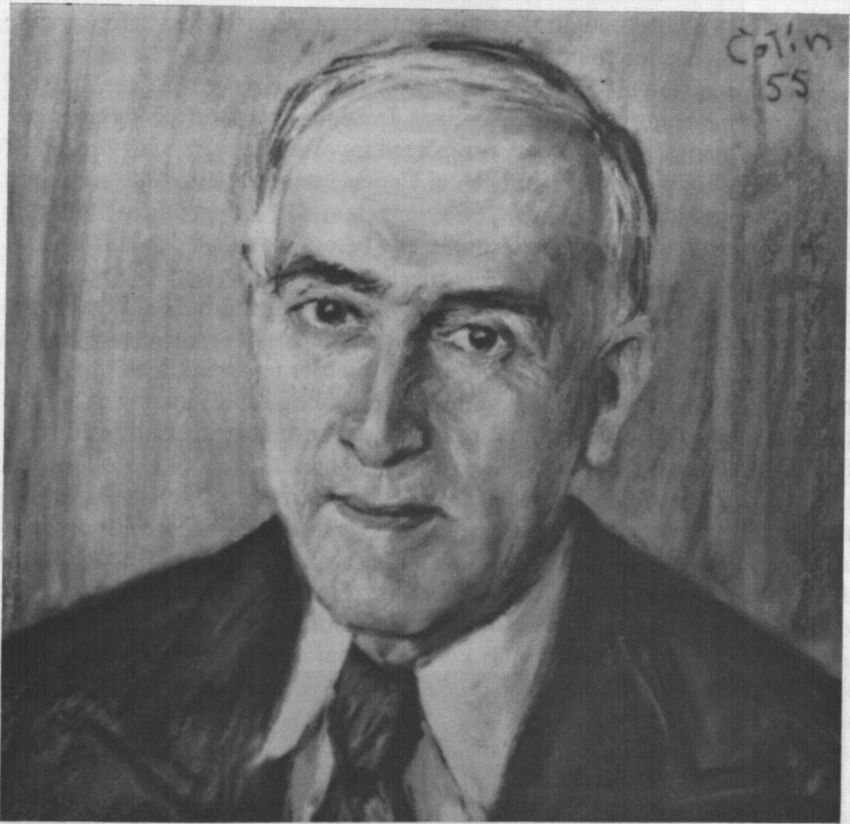


FIG. 5. Dr. Ernst Gräfenberg, 1881–1957, pioneer in the use of intrauterine contraceptive devices during the 1930's. His excellent results with silver rings showed the potential value of the method, setting the stage for the modern era of IUD development.

THE GRÄFENBERG RING ERA

For practical purposes, the professional use of intrauterine devices dates from the work of Ernst Gräfenberg (4) (Fig. 5) in the late 1920's. He wrote on the subject lucidly, and his results were outstandingly good. The timing of Gräfenberg's interest in IUD's coincided with the beginnings of the modern birth control movement so that he worked in less of a vacuum than did his predecessors. He was invited to speak at the Third Congress of the World League for Sexual Reform held in London in 1929, and at the Seventh International Birth Control Conference, held in Zurich in 1930. The proceedings of the 1930 conference were published in book form under the editorship of Margaret Sanger and Hannah Stone: *The Practice of Con-*

trapection (18). This brought the subject of intrauterine devices before a wide medical audience for the first time.

An entire section of the Zurich Birth Control Conference (18) was devoted to papers on intrauterine contraceptives. In addition to Gräfenberg's presentation, Norman Haire of London reported favorable results with the use of the rings in 270 patients. Leunbach of Copenhagen presented his results in 176 insertions (12% expulsions, 12% removals and 2% pregnancies). A lively discussion ensued, with vigorous opinions being expressed for and against the method.

Gräfenberg reported 3% failures in 1100 women fitted with silkworm gut intrauterine rings similar to Richter's pioneer device (Fig. 6), except for the absence of any trans-cervical marker tail. In order to permit localization by means of an x-ray, Gräfenberg later wound a fine spiral of silver wire around the silkworm gut ring. He found that this stiffened the ring and resulted in fewer expulsions.

Subsequently, Gräfenberg devised an intrauterine ring consisting of the coiled silver wire alone, the type of device which has borne his name. Among 600 women fitted with the silver ring, Gräfenberg reported only 1.6% pregnancies at the 1930 conference. Similar good results had been obtained by Dr. Manes, of Hamburg, who had used the silver ring in over

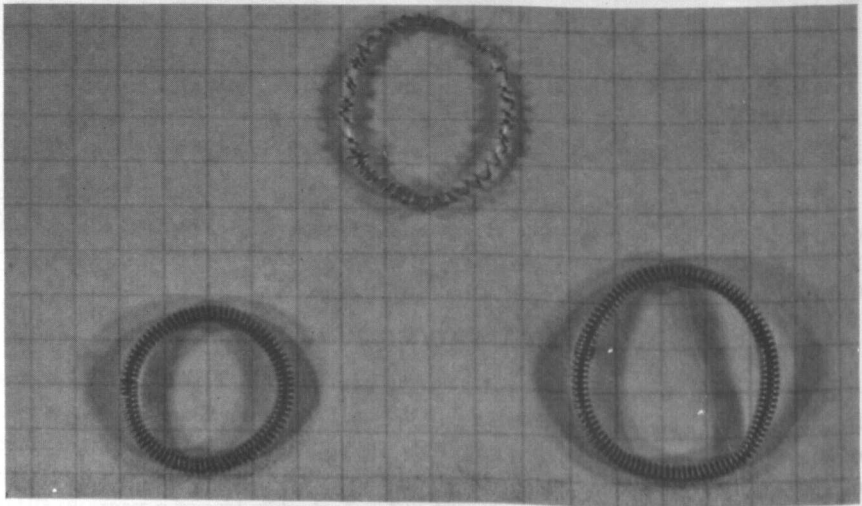


FIG. 6. Basic types of intrauterine rings developed by Gräfenberg. The uppermost is the modified Richter ring used in the late 1920's—a core of silkworm gut wound with silver wire. Later versions of the device (below) were of spirally coiled silver wire or of German silver (an alloy of copper, nickel and zinc) in two sizes. Gräfenberg rings are still manufactured in England, giving excellent results in the hands of gynecologists experienced in the insertion and removal of these tail-less devices.

100 women during the previous 2 years with only 2 failures. Manes reported expulsions in only 5% of patients.

The Zurich Birth Control Conference served to establish the primacy of the Gräfenberg type of device because of its combination of low expulsion rates and low pregnancy rates. In the pre-antibiotic era, the possibility of inducing an ascending endometritis with bulky trans-cervical appendages limited further use of the Pust pessary. Encouraged by the good results with the Gräfenberg ring, other workers began to cautiously use intrauterine rings. Ota (15) in Japan reported his initial results in 1934. Among Japanese physicians, the method began to achieve a moderate degree of acceptance.

PROFESSIONAL REJECTION OF IUD'S

Elsewhere, enthusiasm for the Gräfenberg ring, despite its evident safety and efficacy under strict medical precautions, was not generally shared by practicing gynecologists (19). As the technic slipped from the hands of the masters, difficulties with insertion and removal were experienced. Numerous serious infections were blamed on the method, many of which were probably coincidental cases of gonorrheal salpingitis. Nevertheless, in the pre-antibiotic era, pelvic infection was greatly feared. The lessons of Semmelweiss had been burned into the conscience of physicians so well that vaginal examinations in the last trimester of pregnancy with sterile gloves were considered hazardous. Only in recent years have obstetricians begun once again to timidly carry out such examinations under strict aseptic precautions. The very idea of inserting an intrauterine contraceptive ring has traditionally offended two powerful groups at once: (1) those who oppose contraception in the first place, and (2) those who regard the uterine cavity as an inviolable sanctuary. Little progress was achieved against these twin obstacles for many years.

In a survey of birth control habits of 10,000 women (10) carried out in New York in the 1930's, only 1.7% reported the use of intrauterine contraceptive devices. Even those few IUD insertions were carried out sub-rosa, at considerable expense to a sophisticated private patient clientele, ever mindful of the risk of malpractice suits if complications should develop. Without exception, the standard texts available through 1965 (if they mentioned intrauterine devices at all) confused the IUD with the long-since abandoned cervico-uterine pessaries and condemned the method.

Gräfenberg, Hans Lehfeldt, Herbert Hall and others who emigrated to the U.S. during the Hitler era brought with them expert knowledge of the intrauterine ring, but hesitated to use the method. Robert L. Dickinson—the major gynecologic authority on contraception in the U.S. at that time—had been interested in intrauterine devices for many years and understood their potential value; yet he cautioned Gräfenberg and Lehfeldt not to risk

using the technic. The gynecologic prejudice against IUD's was so ingrained that they risked censure by the medical community, despite their own long and favorable experience with the method. After his escape from Germany in 1941, Gräfenberg established a practice in New York and worked as an assistant in the Margaret Sanger Clinic—the first male gynecologist ever employed in the establishment—confining his contraceptive practice to fitting cervical caps and diaphragms until his death in 1957.

During the 1940's and early 1950's, the insertion of intrauterine contraceptives became virtually a lost art in the United States. The sole scientific publication which appeared on IUD's in the American literature was the brief paper by Halton *et al* in 1948 (6) reporting on results with a silkworm gut device. A few insertions of the Gräfenberg ring were carried out almost surreptitiously in a select private clientele, principally by Herbert Hall and Robert Freyman in New York. Hall reported his results with a stainless steel version (Fig. 7) of the ring in the American Journal of Obstetrics and Gynecology in 1962, after the subject of intrauterine contraception had become more respectable (5).

Meanwhile, no major medical institution in the U.S. countenanced the use of IUD's until after 1960. At that time, Dr. Lazar Margulies commenced testing the first of the linear devices in the form of a coil at the Mount Sinai Hospital in New York. He developed an interest in IUD's in 1958, after discussions with Freyman about the Gräfenberg ring. Margulies ordered some rings from a Canadian source but they never arrived, which impelled him to make one out of polyethylene tubing filled with barium sulfate powder to obtain radio-opacity. Prof. Alan Guttmacher granted permission to use the device in a few patients, provided the experiment was confined to women who had already had tubal ligations performed. Be-

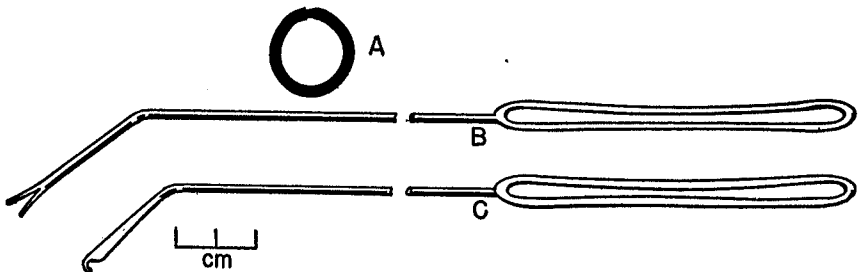


FIG. 7. Stainless steel version of the Gräfenberg ring developed in 1949 and used in New York by Dr. Herbert Hall. A. stainless steel ring; B. inserter with forked tip; C. removal hook. Hall was successfully inserting IUD's in his Park Avenue practice a full decade before other practitioners in the United States dared to use the method. The inserter and removal hook are identical to those used by Gräfenberg in the 1920's. (Intrauterine Contraceptive Devices, Proceedings of the Conference. Excerpta Medica Foundation, Amsterdam, 1962.)

cause of difficulties with insertion of this crude ring, Margulies conceived the coil design with the barium blended into the plastic (Fig. 8), carrying out the first insertion on his own wife in August, 1960. He demonstrated x-rays showing the coil in situ to Dr. Guttmacher one month later, who then authorized the first use of the coil for contraceptive purposes.

REHABILITATION OF THE METHOD

A revival of interest in IUD's had begun to develop in 1959 after favorable results were reported by Oppenheimer (14) from Israel. He had fitted silkworm gut rings in several hundred private patients since 1930 without major complications and with good efficacy. In the same year, Ishihama reported excellent results in nearly 20,000 Japanese women fitted with intrauterine rings (9). The Japanese workers, including Ota, had been the first to take advantage of the flexibility and memory of modern plastics for the elaboration of improved IUD's, a major factor in repopularization of the method. Prolonged use of these devices of silkworm gut, metal and plastic had not disclosed any evidence of carcinogenic effect on the cervix or endometrium, another question which had deterred many gynecologists from using IUD's up to that time.

In view of the discrepancies between the highly favorable reports of Oppenheimer and Ishihama, and the voluminous literature condemning the method, a need for objective appraisal was apparent. Under the joint chairmanship of Drs. Warren Nelson and Alan Guttmacher, a conference was convoked in 1962 in New York, supported by the Population Council. Workers actively interested in IUD's were brought together from Israel, Japan, Chile, England, Egypt, Puerto Rico, Taiwan and the United States. The modern era of IUD development dates from this meeting and the generally favorable results which were reported.

Several innovations were presented at this first international conference: Margulies (12) reported on the insertion technic he had developed for his device in the form of a spiral. The Margulies coil could be loaded into a straight piece of tubular plastic to simplify placing it in the uterine cavity. Mass manufacture and insertion of IUD's were made possible by this concept, which spawned a whole family of linear plastic devices.

Another important IUD development was first described at the 1962 meeting: Dr. Jack Lippes, who had used silkworm gut rings and Ota rings since 1959, reported on the first six month's experience in 264 patients fitted with his linear design, loop-shaped device (Fig. 9). He adopted the cannula principle developed by Margulies for insertion of the loop. Even more important, Lippes established that a filament of plastic could be attached as a tail on the device, without causing ascending endometritis or salpingitis. The marker tail made possible confirmation of the presence of the device and easy removal (11).

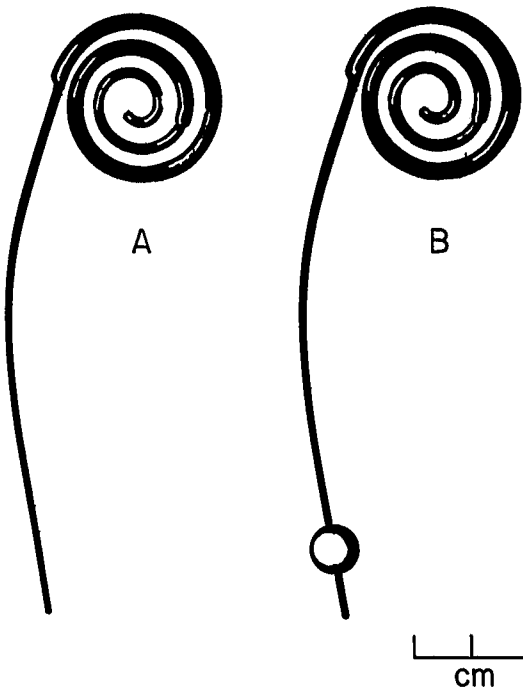


FIG. 8. Contraceptive coil developed by Dr. Lazar Margulies in 1960, the first of the linear plastic devices made of polyethylene containing barium sulfate for X-ray localization. The IUD could be stretched out inside of a cannula to facilitate transit through the cervical canal. Once inside the uterine cavity, the "memory" of the plastic material caused the coil to resume its original shape. Variations of this basic concept encouraged the mass use of IUD's by simplifying insertion. (Intrauterine Contraceptive Devices, Proceedings of the Conference. Excerpta Medica Foundation, Amsterdam, 1962.)

Other investigators, whose experience in the field of intrauterine contraception spanned 30 years or more, attended the 1962 conference and contributed their experiences attesting to the long-term safety of the method. The first modern studies on the mechanism of action of IUD's were presented, demonstrating that intrauterine devices did not function as mechanical abortifacients, as some earlier workers had suggested. These findings placed the IUD on the same plane of ethical acceptability as the oral or traditional contraceptives, paying the way for broad utilization.

The small 1962 conference made it apparent that intrauterine devices were highly effective and remarkably free of serious complications, although expulsions and menstrual disturbances were troublesome with the prototype linear devices. Over-all, the advantages of the IUD's appeared to outweigh the disadvantages, especially considering the relatively primitive state of the art. These generally favorable reports finally vindicated Rich-

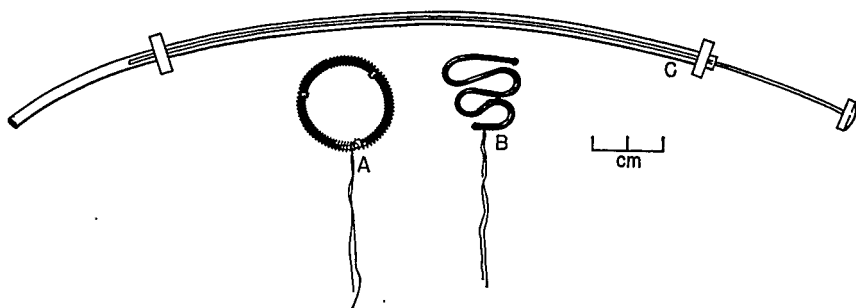


FIG. 9. Plastic ring and loop devices reported by Dr. Jack Lippes in 1962. Lippes showed that attachment of a filamentous plastic tail to the modified Ota ring (A) or the loop (B) did not result in ascending endometritis, while simplifying confirmation of the presence of the device or removal. The soda-straw type of inserter (C) devised by Margulies was adopted for insertion of the Loop. This small version of the Lippes Loop (Loop A) had a 24% expulsion rate and a 5% pregnancy rate, limiting its usefulness as a contraceptive. (Intrauterine Contraceptive Devices, Proceedings of the Conference. Excerpta Medica Foundation, Amsterdam, 1962.)

ter's hope that the intrauterine device, used with adequate precautions, would be accepted as a safe and effective birth control method.

INCREASING IUD ACCEPTANCE

In the wake of these reports, a larger number of investigators in the United States and abroad began using the devices, especially those of the linear spiral and loop types, because of their relative ease of insertion. Increasingly, scientific information about IUD's began to reach the practicing gynecologist. A second and much larger international conference was sponsored by the Population Council in 1964. The prejudice against intrauterine manipulations began to slowly dissipate. With the mounting concern over the population explosion, mass use of the linear devices was initiated in several countries. The importance of the topic may be judged by the volume of recent literature: in the decade from 1959 through 1969 more than 1000 separate scientific articles were published on intrauterine contraception.

Much of the credit for stimulating research and scientific evaluation of intrauterine devices must go to the Population Council, which has disbursed funds supplied by the Rockefeller Foundation, The Scaife Family, the Ford Foundation, other private sources, and federal agencies. The Council supported a Cooperative Statistical Program (CSP), originated under the National Committee on Maternal Health, which collected and analyzed data on the effectiveness and side-effects. By 1964 pooled information from 33 investigators was available on 10,324 women covering 89,305 months of use. By 1968 the data compiled by Christopher Tietze for the CSP covered 27,600 women with more than 477,000 women-months of experience.

Evidence attesting to the safety and efficacy of intrauterine devices became incontrovertible.

The CSP analysis provided detailed statistical data comparing the various linear loop and coil devices with the bows and stainless steel rings (Fig. 10). The large coil was shown to have the lowest pregnancy rate and the bow the lowest expulsion rate of the devices tested. The CSP study also confirmed that the plastic marker tail which Lippes had introduced did not usually result in a significant hazard of ascending infection, a source of great concern to Gräfenberg and the other pioneers in the field (21).

INCREASING IUD APPLICATION

Increasing application of IUD's commenced in the mid-1960's. Several Planned Parenthood Clinics in the United States began making the devices available in 1964 to women who requested the method. The mass use of intrauterine devices was undertaken in Taiwan, Korea, Pakistan and India as a major part of national family planning programs. By the end of the decade from 1960 through 1970, an estimated 12,000,000 women throughout the world had been fitted with intrauterine devices, including over 3,000,000 in the United States.

Another milestone in the official acceptance of intrauterine devices was passed in 1968 when the Advisory Committee on Obstetrics and Gynecology of the U.S. Food and Drug Administration issued a comprehensive report on IUD's. The 14 committee members included representatives from 9 academic institutions, the Population Council, and the National Institutes of Health. The available scientific data with regard to efficacy, side-effects, and complications was considered, as well as the results of a special survey of the 8,500 fellows of the American College of Obstetricians and Gynecologists who might have knowledge of adverse effects. After reviewing a veritable mountain of data on the subject, the FDA report concluded: "*The committee finds adequate scientific data attesting to the effectiveness and utility of intrauterine devices.*"

SUPPORT OF IUD RESEARCH

While progress in establishing and diffusing the use of the method has been rapidly accomplished and handsomely supported, progress in improving the performance of intrauterine devices has been slowed by a remarkable lack of serious research investment. During the early and mid-1960's, support of goal-oriented IUD research resulted in rehabilitation of this method of birth control, establishing the comparative advantages and disadvantages of the various loops, rings and coils available at that time. By 1968, however, the Cooperative Statistical Program (CSP) had been largely curtailed. As a result, comparable data on some of the modern devices are unavailable. The limitations of the linear polyethylene intra-

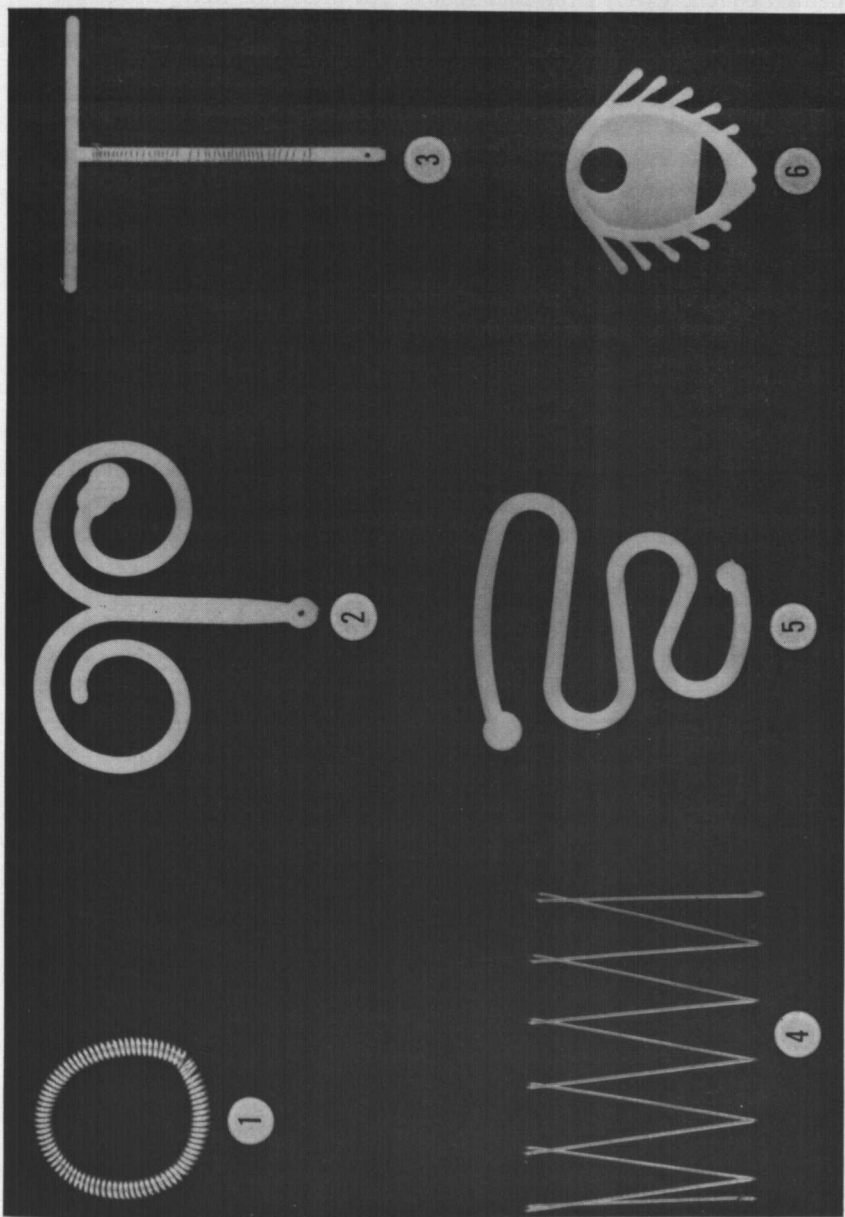


Fig. 10. Contemporary intrauterine devices photographed together with the Gräfenberg silver ring (1) used in the 1930's. The technic of injection molding with modern plastic materials has made possible a great variety of IUD design variations, simplifying insertion and improving performance. Double Coil (2); Tatum "T" (3); Majzlin Spring (4); Lippes Loop (5); Dalkon Shield (6).

uterine devices resulting from expulsions and bleeding complications were documented by the CSP in the mid-1960's, yet little was done to reduce the incidence of these complications.

During 1969, for example, the Population Council approved 354 grant requests, only 14 of which were directly or indirectly (such as collecting Papanicolaou smears from IUD users) concerned with intrauterine contraception. Out of total expenditures of over \$16 million through the Council in 1969, less than 1% was directed towards the development and testing of improved IUD's. Research support by the Federal Government has been negligible, even after large sums were earmarked by the Congress for improving contraceptive technology. According to its 1969 budget, the Center for Population Research of the National Institutes of Health disbursed over \$10 million in Congressional appropriations for contraceptive research, none of which was expended on projects to develop or improve intrauterine devices.

In fact, the first significant governmental support of research in the field of intrauterine contraception was a contract for \$500,000 awarded in 1970 to the Battelle Institute by the Agency for International Development. Meanwhile, disproportionately vast sums of money were expended on systemic approaches to contraception. According to Djerassi (1) the research investment of the pharmaceutical industry in hormonal contraceptives from 1965 through 1969 exceeded \$100 million. No significant investment was made by any drug firm in IUD research during the same 5 year period. The almost universal neglect of IUD research by foundations, the government and the drug industry has left the field largely in the hands of basement inventors and a hardy band of unfunded investigators, and it is a testimonial to their ingenuity that improved IUD's have nevertheless been contrived and tested.

CURRENT PROSPECTS

The second generation intrauterine devices now available demonstrate greatly improved retention, very low pregnancy rates and minimal side-effects, leading to increasingly wide appreciation and utilization of the method. The best IUD designs have practically eliminated difficulties with expulsion and bleeding complications associated with the prototype rings, coils and loops. The modern devices are retained without significant side-effects by 95% of women, and provide virtually 100% protection against pregnancy. Results with IUD's have also improved as an increasing number of physicians have gained experience in the insertion and removal of the devices, as well as confidence in the management of IUD patients.

The modern devices come very close to being perfect contraceptives. They are well retained, well tolerated and highly effective. Yet the IUD is not a universal panacea, and must be used with skill and discretion. Human

needs are so varied that it is unlikely any single method of contraception can or should ever replace all others. The pioneer Gräfenberg (18) maintained this balanced view, despite his enthusiastic advocacy of the IUD:

"The method is not suitable for every doctor, nor is it suitable for every patient. . . . We must differentiate very carefully between individual cases. . . . The important point is that it must not be regarded as the only method: *every physician must select the method that in his opinion is the right one for the individual patient.*"

Viewed in this perspective, the IUD can today stand on its own merits as a first class method of birth control. Because of its many unique advantages, intrauterine contraception is proving to be an ideal method for an increasing number of women, providing a practical means of fulfilling man's ancient dream of separating sexual expression from involuntary reproduction.

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Two

DEMOGRAPHIC CONSIDERATIONS

Although the scope of this text precludes a comprehensive consideration of population dynamics, contraceptive methodology is of relevance only in relation to the population crisis. If civilization as we know it is to survive, hardly any informed person fails to recognize the urgent need for man to control reproduction. From the beginnings of historic time until about 1850, the population of the world increased at a snail's pace to reach the first billion people. By 1930, the population had doubled to 2,000,000,000, largely due to lowered infant mortality. Another billion people were added to the world's population by 1960, and if the present rate of increase is sustained, by the year 2200 the incredible number of 500,000,000,000 will have been reached (see Fig. 11). To stem this tide of population may be the most difficult task man has ever undertaken.

The unprecedented upsurge in the population growth rate has come about because of a substantial drop in the death rate without a corresponding decrease in the birth rate. The present population problem can be contrasted with the balance between birth and deaths which existed in Medieval Europe. Plague, famine and war affected Western Europe often enough in this period so that there was no serious population pressure. The European population from the eleventh century to the end of the thirteenth century gradually rose. Then the Black Death in the Middle of the fourteenth century brought about a sharp decline. England's population, estimated at 3,700,000 in 1348, suffered a 40 % loss. During this time, the cities of Western Europe remained relatively small. *At the end of the fourteenth century, Florence, Rome, Brussels and London all had less than 50,000 inhabitants!*

Public health practices have dramatically altered the historic balance between births and deaths in modern times. In some areas, infant mortality has dropped as much as 90 % in 30 years. The population growth in the

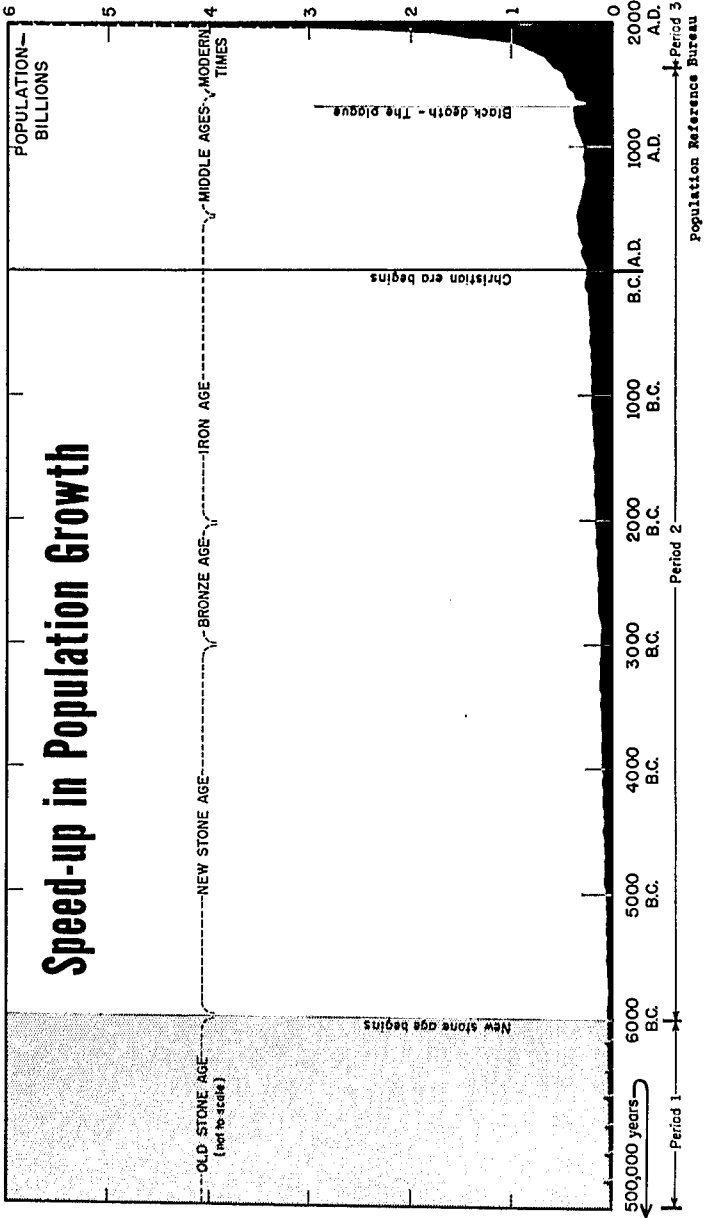


Fig. 11

nations of Asia, Africa and Latin America is far more terrifying than in the United States or Europe. Their 2.5 billion people are expanding 3 times as fast, with far less resources available to support an excess of births over deaths which results in roughly a doubling of their population with each new generation. Despite increasing efforts to balance death control with birth control, the world's population is continuing to increase faster than ever before.

At the present time the population of India is growing at over one million each month. *If this staggering rate of increase could be halved in the coming generation (and this is highly optimistic), the population of India would still be increasing at a rate of well over one million a month.* This is due to the maturation of massive numbers of young people *already born* who will be entering the fertile age group and spawning additional millions of progeny.

The numbers of people projected from current rates of population growth make effective family limitation essential to the survival of humanity. There is no conceivable means of increasing or distributing the limited resources of the world in order to provide even bare subsistence standards unless reproduction is curtailed. Yet the problem is far more complex than sheer numbers would indicate. If present trends continue, we shall be confronted long before the year 2,000 with a collapse of civilization produced by overcrowding, environmental pollution and destruction of the *quality* of human life.

CULTURAL IMPLICATIONS OF OVERPOPULATION

On the occasion of the International Conference on Family Planned Programs at Geneva, Switzerland in 1965, John D. Rockefeller III, who has been instrumental in supporting much of the modern research and field work in population dynamics, stressed the cultural implications of unrestrained reproduction:

"It is disturbing that so many people think of the population problem only as numbers of people versus available food. This seems to equate man with animal, food with fodder. The question, as I see it, has, in fact, three dimensions. It is number of people versus material resources—but also cultural resources. This third dimension of the population problem is society's ability to satisfy man's mental, emotional, and spiritual needs and aspirations, what every man needs in addition to bare necessities and creature comforts, to lead a life of satisfaction and purpose, to achieve a life more than mere existence.

"Those who are concerned with the *quality* of life have no choice but to be concerned as well with the quantity of life. Even if science by some magic could show the way to feed new billions of people, we still would not have solved the population problem. The moral, spiritual and intellectual aspects of life cannot be omitted from the solution. Indeed, there can be no true

solution until society can offer every individual an opportunity to live—in the fullest sense—as well as to survive.”

DEMOGRAPHICALLY EFFECTIVE METHODS

To be effective in the demographic sense, a birth control method must be suitable for *limiting family size* as well as useful in spacing the interval between pregnancies. The demographic importance of the intrauterine device stems from the unique combination of permanence and reversibility which the method offers. For child spacing purposes, the IUD, the oral contraceptives and various traditional methods are all satisfactory. But if limiting family size to an ideal not exceeding two children is a national objective, the use of intrauterine devices and surgical sterilization to provide prolonged protection becomes important.

Sterilization by tubal ligation or vasectomy is becoming increasingly well accepted, especially in Pakistan and India. In Pakistan, about 5,000 sterilizations were performed during 1964, the first year of serious effort. By 1970, over 1,000,000 had been performed. The Pakistan sterilization program is valuable, because neither sustained motivation nor medical surveillance is required for efficacy. However, the acceptors have averaged between four and five living children, so that a real impact on the Pakistani population problem will require recruitment of younger candidates of lower parity and the vigorous use of intrauterine devices among those not desiring permanent sterilization. From 1964 through 1970, over 2,000,000 intrauterine devices had been inserted in women in Pakistan, a beginning in coming to grips with a problem of massive proportions.

In India, the use of intrauterine devices, principally of the loop type, commenced in 1965 and by 1969 a total of 2,632,000 had been inserted. The IUD programs in Korea and Taiwan have been particularly effective in reaching a high proportion of women rapidly (see Table 1).

THE VAST UNMET NEED

While the millions of women being served seems impressive, it is well to recall that there are 90 million couples in the reproductive age in India alone, scattered in 560,000 villages and 3,000 towns and cities. India has 14% of the world population trying to exist on 2.4% of the world land area and 1.5% of the world income. The attempts to improve living conditions by increased agricultural and industrial production have been completely negated by unrestrained population growth. As yet, only a small fraction of the target population (about 8%) has been reached by effective family planning.

Despite the rather bleak world picture, some progress has been made in providing birth control services, considering that many of the national programs in developing nations are less than 5 years old. In countries for

TABLE 1
Cumulative acceptors of intrauterine devices in selected
countries with active programs
(In thousands)

	Chile	India	Korea	Pakistan	Taiwan	Turkey
1964	11	0	112	11	50	0
1965	31	318	345	49	149	5
1966	61	1250	737	532	260	32
1967	142	1970	1060	1207	381	74
1968	259	2632	1323	1071	462	136

which data is available, Nortman (5) has summarized the percent users of all types of birth control among married women aged 15-44 (Table 2).

The extent to which expanded services are needed is manifest. Except for specifically active local programs, such as Hong Kong and Singapore, only the national programs in Taiwan and Korea have succeeded in reaching a significant fraction of women in the fertile age group with family planning services.

SUCCESS WITH STERILIZATION AND ABORTION

Substantial progress has been made in increasing the acceptance of family planning services in recent years, especially with regard to sterilization and abortion. The expanding pressure of population growth in the face of limited resources has made traditional religious objections to contraception virtually a dead letter. A dramatic example of this fact is the popularity of sterilization among the Catholic women of Puerto Rico. A recent sample of mothers aged 20 to 49 indicates that 34% have undergone tubal ligation

TABLE 2
Percent of married women aged 15-44 using all methods of family planning
(January, 1969)

Country	Percent Users	Country	Percent Users
Hong Kong	42	Singapore	37
India	8	Taiwan	32
Iran	3	Thailand	7
Kenya	1	Tunisia	8
Korea	25	Turkey	3
Malaysia	6	United Arab Republic	10

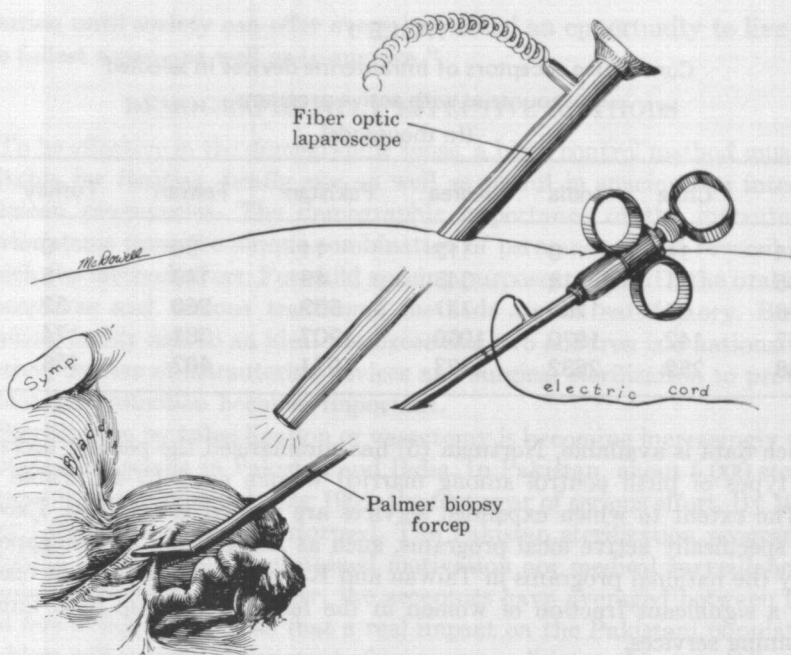


FIG. 12. Outpatient tubal sterilization by means of the laparoscope is a method assuming increasing popularity and importance. The Fallopian tubes are visualized through a 2 cm. subumbilical incision, cauterized and divided with the biopsy tong, the patient being discharged after 4 hours of post-operative observation. (Wheless, C. R.: Outpatient tubal sterilization, *Obst. Gynec.*, 31: 208-11, 1970.)

(8) (Fig. 12), a procedure so common on the island that it is referred to simply as "La Operacion".

Over half the Puerto Rican women sterilized had only 2 or 3 births, with a median age of 26 at the time of the operation. Thus, when surgical sterilization is made readily available as in Puerto Rico, acceptance has been excellent. Intrauterine devices and oral contraceptives have also been well accepted in Puerto Rico, as well as throughout most of Latin America.

Population growth in Japan has been brought to a stand-still by the liberalization of medical abortions (12). At the end of World War II, 85 million Japanese were living in an area about the size of Montana, only one sixth of that area suitable for cultivation, with negligible possibilities for emigration. Faced with a rapidly expanding population, medical abortion was legalized in 1949. Within 5 years, the number of medical abortions equalled the number of live births—about a million per annum. Government health centers and private associations were organized to provide counseling and train midwives and nurses in the methods of contraception. Availability of medical abortions, combined with the use of contraceptives,

made the Japanese birth rate the lowest in Asia, considerably below that in the United States.

The speed with which the Japanese halted their population growth is unparalleled in human history. The Eastern European countries, England and several states in the United States have made medical abortions available as a means of stemming population growth. To have real value in most of the developing nations, however, medical abortions must be linked with an effective contraceptive program. Otherwise, already inadequate health facilities can be overwhelmed by women returning for as many as three abortions in a single year.

EXPERIENCE WITH THE PILL

What other alternatives are available? The oral contraceptives have a level of *theoretical* efficacy approaching that of sterilization, but have proven of limited demographic value. The clinical efficacy of oral contraceptives among women of limited means or education has been particularly disappointing. Satterthwaite's data from the original group of women followed (10) on oral contraceptives at Humacao, Puerto Rico long since demonstrated this point. From 1957 through 1961, a total of 838 women were admitted to the study. Of these, 736 women or 88% had discontinued the use of norethynodrel by 1965, *by which time 449 pregnancies had been observed in the study group, largely due to motivational failure.*

A second study was initiated by Satterthwaite in 1961, using lower dose oral contraceptives (norethindrone 2 mg., norethynodrel 2.5 mg. and ethynodiol diacetate 1.0 mg., all in combination with mestranol 0.1 mg.). It was hoped that sustained use of these preparations might result because of a lower incidence of side effects. A total of 562 women started on the medication. *By June, 1965, twenty months after the last admission to the series, 77% had discontinued the oral contraceptives, leaving only 127 women in the program. A total of 228 pregnancies had been observed.* Among a second group of 608 women concurrently fitted with intrauterine devices of the loop type, 70% were still active at the end of 2 years of follow-up, with a far lower over-all incidence of pregnancies than among the women managed with the hormonal contraceptives.

The clinical efficacy of oral contraceptives in public health clinics in the United States has also been less than ideal. Andelman reported in 1968 on results with low-dosage oral contraceptives in the Chicago public health clinics, using norgestrel 0.5 mg. plus ethinyl estradiol 0.5 mg. (Ovral). The patients admitted to this program were screened for an expressed desire not to have any pregnancy for 12 months at least. Fully 57% of the women already had 3 or more children, and nearly 39% had 5 or more children. Despite the high degree of motivation which could be expected in such a selected population, 16% of the patients had discontinued the

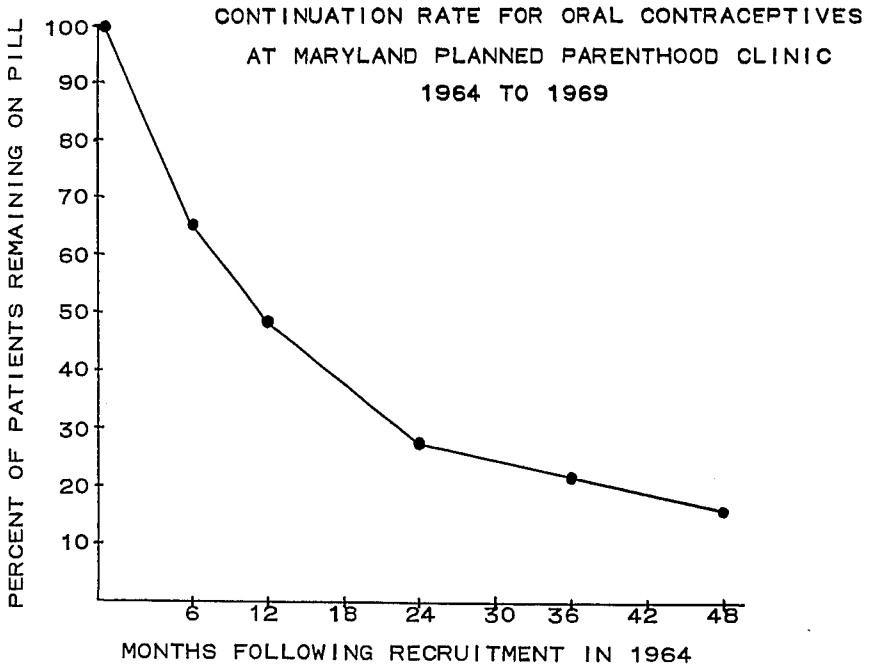


FIG. 13. Four year follow-up on patients commencing oral contraception in 1964 demonstrates high rates of discontinuation in an average clinic population. Ninety per cent of women of proven fertility who discontinue the pill become pregnant within 12 months unless other methods of contraception are instituted. The *clinical* efficacy of oral contraceptives in populations of average motivation is far below *theoretical* efficacy because of human failure to maintain rigid daily dosage schedules.

medication within 7 months. Among the 18,000 patients less rigorously selected in the Chicago Board of Health Family Planning Program, 40% of the patients abandoned the pill in less than one year.

Thus, the number of unwanted pregnancies which occur because of motivational failure with oral contraceptives far exceeds the failure rate of the method *per se*. This shortcoming of the oral method is very seldom reported, although its demographic impact is enormous. Unless other contraceptive methods are promptly substituted (which is frequently not the case in average populations), a high proportion of women starting oral contraceptives become pregnant within the year because of errors in taking the medication, side effects or failure to renew supplies on a rigid schedule.

A limited number of studies provide data showing continuation rates of oral contraceptives among women of average socio-economic status. Continuation rates are substantially lower than would be experienced in a well-motivated middleclass population in private practice. The percent of women active in four such programs at the end of 12 and 18 months are presented in Table 3.

TABLE 3
Continuation rates for oral contraceptives among women of
average socio-economic status

	Percent of Women Active in Program	
	12 Months	18 Months
Charlotte, N.C. (1)	68	62
Puerto Rico (10)	57	47
Singapore (3)	53	45
Baltimore, Md. (13)	46	35

Thus, among women of average means and average motivation, less than half continue the pill for as long as 18 months. Studies in Taiwan have also demonstrated that continuation rates with IUD's are substantially better than with the pill—69 % vs. 32 % at one year (7). From a demographic point of view, oral contraceptives have proven useful as a child spacing technic, but do not constitute a practical answer to population pressures. The continuous replenishment of supplies required by the use of oral contraceptive represents a very serious limitation. Supplying pills monthly to 560,000 separate Indian towns and villages, much less supervising adequately the taking of the medication, would be a problem of staggering proportions, not to mention the cost of such an undertaking. The nations in most desperate need (such as India and Pakistan) have among the lowest per capita incomes in the world—about \$8.00 a month. There is little room in such budget for the purchase of synthetic steroids for daily use.

RESULTS WITH INTRAUTERINE DEVICES

Failures due to discontinuation of use or expulsion of the loop and coil intrauterine devices are also troublesome, although less so than failures with either oral contraceptives or traditional barrier methods. Continuation rates for the loop device in several representative programs are reported by Mauldin et al (4) in Table 4.

In order to achieve a similar level of demographic impact, it can be estimated that two women must be started on barrier methods or oral contraceptives for every woman fitted with an intrauterine device. The demographic advantages of the IUD are becoming more marked as the continuation rates with modern devices improve. Fortunately, discontinuation of the IUD is largely the result of expulsions and medical removals due to correctable mechanical problems in the design. Continuation rates with modern IUD's exceed 90 % in the Maryland Planned Parenthood Clinic as compared with 46 % with oral contraceptives.

Even the least effective types of IUD or the oral contraceptives, however,

TABLE 4
Continuation rates for loop IUD according to life table method

	Percent of Women Active in Program	
	12 Months	18 Months
Taiwan	70	63
United States	79	72
Thailand	78	69
Pakistan	79	70

represent a tremendous advance as compared with traditional spacing methods. In Taiwan, free distribution of traditional methods have shown that only 36% of the acceptors actually used the methods when reached 8 to 11 months later, and the pregnancy rate among these was as high as 36 per 100 woman-years. In rural Korea, the pregnancy rate with traditional methods was 23 per 100 woman-years.

PROSPECTS WITH MODERN DEVICES

Improved types of IUD have not yet been extensively used in the developing nations. The excellent retention and minimal side effects associated with the newer devices should greatly increase their demographic efficacy. Because of these factors, the second generation devices can be expected to become an increasingly important element in national family planning programs. At the present time only surgical sterilization exceeds the IUD in terms of continuation rates, an essential requirement to halting population growth.

In the more active IUD programs, marked reductions in birth rates have been produced and documented, as compared with the actual or expected fertility in the women not participating in the program. In Taiwan (7) the birth rates per 1000 woman-years of exposure were reduced from an age-adjusted rate of 352 to 77, a dramatic drop in fertility of IUD acceptors relative to expected fertility.

A distinct advantage of a program weighted to encourage the insertion of IUD's is the speed and low cost of the procedure. Surgical sterilization requires at least two skilled individuals to perform the procedure and 30 minutes of time. A single operator moving among 3 examining tables can easily fit ten women with intrauterine devices in the same period of time. If health workers are trained to carry out the recruitment and follow-up examinations among candidates for intrauterine contraception, a massive number of insertions can be performed by a very small skilled cadre of

physicians or nurse-practitioners. The organization of such programs on a broad basis has barely commenced.

COST AND DISTRIBUTION PROBLEMS

The recurring cost of oral contraceptives remains a factor inhibiting use of this method in many areas of the world with rapidly expanding populations. To be sure, competition in the market has reduced the price of a cycle of pills in the commercial sector to levels which are bringing them within easy reach of many additional women. In Mexico, where complete manufacture of oral contraceptives from raw material to finished product is carried out and strong competition exists, prices of a years' supply of pills range from \$9.60 (U.S.) to \$20.00 depending on the product. According to estimates prepared by Sollins and Belsky (11) there were 9,600,000 women in Mexico aged 15 to 44, among whom distribution of oral contraceptives in 1968 would account for protection of 510,000 during the year. Distribution of oral contraceptives in the commercial sector accounted for 480,000 of the cycles, family planning agencies of a public character accounting for only 30,000. The most significant penetration of the potential market for oral contraceptives has been made in the nations with high living standards such as the United States, Western Europe and Australia, with half of the world's users of oral contraceptives concentrated in the United States alone.

The contrasting patterns of use of various types of contraceptives in the United States and throughout the world, excluding mainland China and Eastern Europe, but including the United States are shown in estimates in Table 5.

Users of diaphragms, aerosol foams and oral contraceptives are heavily concentrated in the United States, accounting for half of the world consumption of these three contraceptive products (10-13 million users in the United States as against 20-24 million in the entire world).

Because of its over-the-counter availability and wide distribution, the

TABLE 5
1968 estimate of contraceptive users in millions

Contraceptive	U.S. Users	World Users
Aerosol Foam	1-2	1-2
Condom	4-5	17-19
Diaphragm	2-3	2-3
Intrauterine Device	1-2	5-6
Oral Contraceptive	7-8	17-19
All Types	15-20	42-49

condom accounted for 13-14 million users outside the United States by 1968 as compared with 10-11 million users of oral contraceptives and 3-4 million users of intrauterine devices. A progressive increase in application of IUD's has occurred since that time, with estimates of world usage exceeding 12 million by 1970.

It is evident, however, from the distribution of contraceptive products in relation to the numbers of women in the reproductive ages that the surface has barely been scratched in provision of adequate birth control services. To cite another example, Indonesia can be considered. There are 25 million women aged 15-44 in that country. As of 1968, the monthly distribution of oral contraceptives was sufficient for the protection of only 55,000, while condoms were distributed in sufficient quantity to account for the protection of an additional 45,000. Yet Indonesia has a population density in some areas exceeding 1,500 inhabitants per square mile and one of the highest birth rates in the world. It is clear that in most of the developing countries, modern methods of contraception are neither practiced nor readily available.

CONCEPTS LIMITING ACTION

Attitudes towards population must be revised if the problem is to be dealt with effectively. The idea that "progress" can be equated with an ever-expanding economy fueled by population growth is entrenched in the minds of many business men and economists. Even in a technologically advanced society, each surplus baby is not only a potential consumer, but also a candidate for the ranks of the unemployed and disaffected. The chief accomplishment of the teeming millions of excess humanity now being spawned will be increased environmental pollution, if not revolution. Whether productively employed or not, the Rienows (9) estimate that each American baby born will directly or indirectly consume in a 70 year life span 26 million gallons of water, 21 thousand gallon of gasoline, 10 thousand pounds of meat, 28 thousand pounds of milk and cream, \$5,000 to \$8,000 worth of school building materials and \$6,300 worth of clothing. Certainly an impressive record of consumption, but to what purpose if man is born into a life of cultural and physical deprivation, undereducated, underemployed and unappreciated, a numbered ward of the state, destined in the words of Thomas Wolfe "to eat bad food, and having eaten, to grind out his life in distressful defecations."

Another fallacious concept is that the public is disinterested and incapable of utilizing birth control. Vis-a-vis the population problem, only a few U.S. Senators (such as Gruening, of Alaska, and Tydings, of Maryland) have exerted real leadership in the face of entrenched opposition to effective governmental support of expanded family planning. Yet the public is intensely interested in birth control services, and effectively makes use of

them when realistic opportunities are provided. As Notestein (6) has stated, "Any lack of interest on the part of the public is less serious than the apathy of the middle classes and the lesser officials who cannot bring themselves to believe that their illiterate peasants are sufficiently intelligent to understand their own problems. Both surveys and the public response to services clearly demonstrate that ordinary people have a much better understanding of their own problems than their lesser officials appreciate."

A lack of insight by officialdom into the desire of the disadvantaged to employ contraception—for so long the prerogative of the upper and middle classes—has caused some curious debacles. Subscribing to the philosophy that the poor are incorrigibly irresponsible, immature and animal-like, various coercive measures have been directed towards implementing family planning among recipients of public assistance. In Prince Georges County, Maryland, the authorities decided in 1967 to require a visit to a birth control clinic for all relief applicants; then discovered to their surprise that the clinic was inadequate to meet the existing demand for services, and could not book appointments for eight weeks or more!

INADEQUATE FEDERAL ACTION

Leadership by Federal officialdom in provision of adequate family planning services was virtually non-existent throughout the 1950's and 1960's, while the population crisis in the United States and abroad was becoming increasingly unmanageable. As late as 1970, only 48 people in the vast beurocracy of the U.S. Agency for International Development were working on population problems. *For 1968, the budget of the Department of Health, Education and Welfare exceeded 13 billion dollars, of which the fraction apportioned to population problems was less than one quarter of 1 %.*

The U.S. Congress has been preoccupied with the diseases of middle age, and the budgets of the National Institutes of Health have reflected this preoccupation: as of 1969, this agency expended 185 million dollars for cancer, 165 million for heart disease and only 10.8 million on research directly or indirectly related to reproductive biology. Even the budget for research in allergies exceeded by ten-fold the N.I.H. investment in birth control. Paul Ehrlich (2) succinctly described the scandalous state of affairs in 1968: "What is the government of the United States doing in the area of population control? It is bailing the sinking ship with a very small and leaky thimble."

SUMMARY

Up to the present time effective contraceptive services have been provided to the greatest extent where least needed. In most developing nations, birth control supplies reached less than 10 % of the adult female population by 1970. In consequence, we are losing the population war globally while

priding ourselves on winning a few local skirmishes. From a demographic point of view, the race between curbing births and starvation for millions of people is already virtually lost. *The developed nations must actively support at least a 20 fold increase in family planning services in the developing nations during the next decade, if global famine is to be averted. Failing to mount such a massive effort to curb population growth may be the greatest strategic blunder ever made, and future historians will derive wry humor from considering that the United States collected moon rocks while the population bomb exploded.*

The lack of adequate program organization, funding and shortages of trained personnel, all are the major barriers to rapid implementation of effective family planning programs. It was not until 1968 that the U.S. Agency for International Development (AID) began to play a significant role in providing technical assistance in family planning, delivering over 1 million IUD's by 1970 for use in developing nations. The Swedish International Development Authority (SIDA) expended more than 8 million dollars in 1968 in support of family planning activities, when the AID budget for such activities amounted to 35 million dollars. *If the United States is to merely equal the Swedish per capita contribution to solving the population problem, a six fold increase in expenditures will be required.* However commendable their pioneering efforts, the resources of private groups such as the Population Council, The International Planned Parenthood Federation, the Ford and the Rockefeller Foundations are inadequate in the face of world needs. Greatly increased governmental support of family planning activities is urgently needed throughout the world.

Pending the development of means of conception control which surpass the unique permanence, medical safety and high clinical efficacy of intrauterine devices, programs emphasizing the use of IUD's will undoubtedly achieve superior demographic success. If there is one lesson to be learned, however, from the past decade of attempts to stem population growth, it is that there are no monomethodic answers.

Failure to use intrauterine devices effectively will diminish the efficacy of national family planning programs. At the same time, crash programs which fail to make available a variety of technics for both spacing and terminating fertility will prove less effective than programs tailored to the varied needs of the target population.

Experience in the decade from 1960 to 1970 in dealing with population pressures indicates that the most successful programs have emphasized the use of intrauterine devices, medical abortions and sterilizations. The oral contraceptives and traditional technics have proven less than ideal in most programs because of the poor continuation rates. Nevertheless, no single contraceptive method can equal the results of a properly balanced program combining a broad range of effective technics. To implement such balanced national and international programs is the challenge of the next

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Three

MECHANISM OF ACTION

The anti-fertility effects of intrauterine devices have been recognized since the turn of the century, but the major hypotheses regarding mechanism of action have remained inadequately tested until comparatively recently. Speculations have included possible alterations in tubal transport, mechanical interference with implantation and local gametotoxic effects, among others. Clarification of the mechanisms responsible for IUD efficacy has proceeded slowly because of the many possible IUD effects requiring investigation, and the difficulties inherent in extrapolating experimental animal results to humans.

Animal investigations have shown a variety of effects depending on the experimental design and the particular species in question. Reviews of the myriad observations of the effects of intrauterine devices in animals and humans have been prepared by Corfman and Segal (7) and more recently by Eckstein (13). Certain exotic animal results in the literature are probably irrelevant in view of the rather specialized nature of the reproductive process in primates. Nevertheless, experimental observations deserve review since there is a common thread linking the human and animal observations in the form of a local endometrial response to the presence of the device.

EXPERIMENTAL ANIMAL OBSERVATIONS

Doyle and Margolis (11) showed in 1963 that in rats a length of silk suture lying in the lumen of one uterine horn effectively prevents pregnancy in that horn, without affecting the estrus cycle or fertility in the control horn. The antifertility effect of the IUD can be transferred by creating a fistula between the experimental and control uterine horns, producing a bilateral contraceptive action (1). Such a communication exists naturally in the mouse, and the effect of the IUD in this species is bilateral (12, 24). When the connection between the control and experimental horns is eliminated, the bilateral contraceptive action of the IUD is abolished.

The length of the intraluminal foreign body in contact with the endometrial surface has been shown to influence IUD efficacy in the rabbit. A long thread (which elicits an endometrial reaction throughout most of the experimental horn) exerts a more effective contraceptive action than shorter lengths of the same material (23).

An interesting finding is that the effects of polyethylene or nylon IUD's in rabbits are *downstream* from the position of the thread (Fig. 14). When such relatively inert plastic material is positioned near the cervix, implantations occur above this level, but are inhibited in the lower portions of the IUD-bearing horn. Specific and quite localized gametotoxic effects induced in the intraluminal milieu can be inferred from these results. The bilaterality of the contraceptive action of IUD's in mice (with naturally interconnected uterine horns) likewise indicates that the primary contraceptive action of intrauterine devices is accomplished via gametotoxic changes in the uterine fluid.

In a reflex ovulator such as the rabbit, distension of the uterus with an IUD can cause a curious neurogenic effect via the hypothalamus: there is a prolongation of several hours in the post-mating interval before ovulation, as compared with controls (20). Such an effect would not be apparent (and is probably irrelevant) in species such as man, which are not reflex ovulators. A similar animal observation has been the apparent inhibition of ovulation in response to uterine distension in the Indian water buffalo (4).

In sheep the IUD has been shown to exert spermatotoxic effects. Place-

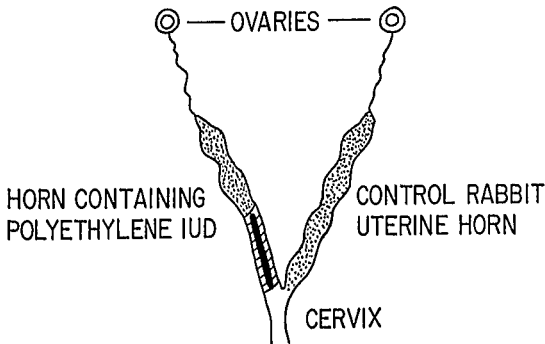


FIG. 14. A thread of polyethylene or nylon positioned in one uterine horn near the cervix exerts a strictly localized (barred zone) contraceptive action in the rabbit. No contraceptive effect (stippled zone) is exerted *upstream* from the position of such relatively inert materials. If, however, the thread is positioned at the distal end of the experimental horn, some contraceptive action will be exerted below this point, indicating that gametotoxic alterations in the uterine milieu are responsible for contraceptive efficacy. A chemotactically induced increase in the number of leukocytes occurs at the interface between the device and the endometrium, mobilizing natural body defenses which are gametotoxic. (After Parr *et al.*)

ment of the device in one uterine horn interferes with the transport of sperm into the opposite horn, and no sperm can be recovered from within the oviduct after natural mating. Ovulation and egg transport are unaffected (16).

In Rhesus monkeys ovulation is undisturbed by the presence of an IUD, but there was formerly some question about ovum transport. A widely cited experiment by Mastroianni showed that ovum transport was accelerated in monkeys wearing IUD's which had been ovulated artificially with gonadotrophins and artificially inseminated (25). The hypothesis was advanced on this basis in 1965 that rapid transport of ova might be responsible for IUD efficacy. The changes in gonadotrophin-treated monkeys, however, do not explain the anti-fertility effects of IUD's in normal monkeys. As a matter of fact, such changes are not demonstrable in control monkeys fitted with IUD's but not stimulated with gonadotrophins (21). The transport of ova in the rat and the rabbit oviduct has been found to be unaffected by the presence of an IUD in the form of a silk thread (18).

In reviewing the many observations on the anti-fertility effects of intra-uterine devices, Sahwi and Moyer (33) concluded that "The female reproductive tract reactions to the IUD appear to be dependent on the size, configuration and chemical composition of the foreign body, the animal species used experimentally and the variation in the experimental designs. . . . Some biological effects have been noted in one or more species, but usually not in all. However, one observation which appears to be universal to all species studied is the presence of increased numbers of inflammatory cells (principally polymorphonuclear leukocytes and, secondarily mononuclear cells) in the endometrium and/or uterine fluid. It is likely that that unifying principle of the anti-fertility effect of the IUD is directly related to the quality and quantity of the inflammatory cells and their degradation products as well as the associated biochemical changes occurring in the endometrium."

HUMAN OBSERVATIONS

The older literature contains speculations that intrauterine devices function as mechanical abortifacients. This view is untenable scientifically, since histologic investigations have produced no evidence to suggest that conception is established and subsequently dislodged. So long as the device is functioning as an effective contraceptive (27), the structural characteristics of the uterine mucosa typical of each day of the normal cycle are maintained in the presence of the device.

The suggestion was made by Rozin et al (31) that the contraceptive action of loops might be related to uterine distension, perhaps preventing blastocyst contact with the endometrium and resulting in destruction or rapid expulsion from the uterus. Indeed, Bengtsson and Moawad (2) have shown that distension of the uterus with a bulky device can cause severe

pre-labor like muscular activity which could conceivably interfere with the process of implantation. However, these speculations are unsupported by evidence that premature expulsion of the blastocyst does in fact occur, and fail to explain the excellent contraceptive action of small devices in the absence of gross uterine distention or contractions.

Investigations on women fitted with intrauterine devices have shown that some sperm ascent takes place, though the number of spermatozoa present in the upper generative tract is reduced in the presence of the device (28). Ova have been recovered from the Fallopian tubes of women (29) wearing intrauterine devices. Whether the few ova recovered were in fact biologically viable is unsettled since successful implantation is the sole definitive end-point of the process of conception. What is observed pragmatically is that pregnancy is prevented by the presence of the device, indicating that the mechanism of action is anticonceptive. Increasingly, both by demonstration of local effects, and by the exclusion of other hypotheses, the search for the mechanism of action of intrauterine devices in women has implicated a local interaction between the device and the endometrium as primarily responsible for contraceptive efficacy.

Histologic investigation of the endometrium in women however, has produced some conflicting results. Investigations (15) which failed to show significant alterations were generally carried out on randomly obtained endometrial biopsies, so that the tissue contiguous with the surface of the device may have escaped careful scrutiny. The endometrial response to the presence of the device is generally quite localized and quite superficial, and is easily overlooked if tissue samples are not obtained and prepared in a precise fashion.

Local Endometrial Response

Examination of coronal sections prepared from uteri removed at vaginal hysterectomy after several months of IUD use have demonstrated definite evidence of endometrial response to the presence of the device (19). The tissue alterations are apparent when comparison is made with controls matched for phase of the menstrual cycle. Histologically, the most prominent finding is a superficial leukocytosis, especially evident in the areas of endometrium in proximity to the surface of the device. Several independent investigations have shown such a specific leukocytic endometrial response to the IUD, so that a surface interaction between the material of the device and the endometrium is now well established (27, 39).

The local endometrial reaction to the presence of the IUD is inflammatory in the descriptive sense, but is not the result of chronic bacterial invasion of the uterine cavity. Endometrial cultures obtained from women fitted months previously with IUD's demonstrate bacteriologic sterility in the presence of the device (26). Thus, the microscopic evidence of local endometrial re-

sponse to the device is properly considered a chemotactic reaction to the IUD.

Chemotactic Effect of Intrauterine Devices

Can local endometrial response to a plastic or metallic foreign body be responsible for the anti-fertility effects of intrauterine devices? Observations in subhuman primates support this concept. A systematic investigation of the effects of IUD's in rhesus monkeys has been carried out by Kelly, Marston and Eckstein (22). After fitting with an IUD, the monkeys showed normal menstrual periodicity without any disturbance of the timing of the ovulation, ovum transport or corpus luteum development. Nevertheless, the rhesus monkeys fitted with intrauterine devices did not become pregnant after repeated matings, while over 60% of the control females without the devices did so. The endometrial response to the presence of the IUD was characterized by an increased number of leukocytes in the superficial layers of the endometrium in most intimate contact with the device. These findings in sub-human primates, which correspond to the human observations as well as to findings in numerous other mammalian species, have stimulated investigation of the anticonceptive effects of the subepithelial and intraluminal leukocytosis induced by the IUD.

The elegant experiments of Parr et al (30) in the rat, rabbit and mouse have shown a direct correlation between a leukocytic infiltrate induced by the device and efficacy in preventing pregnancy. *The local endometrial response was shown to be chemotactic in nature by reproducing it in animals maintained in a totally germ-free environment.* The intensity of the response varied with the chemical nature of the IUD, the slightly more reactive materials producing greater histologic response and superior efficacy in preventing pregnancy.

Parr further established that the endometrial response to the IUD in animals results in elevated lysozyme levels, a characteristic feature of reactions with persistent leukocytic infiltration. It was postulated that the prevention of pregnancy might be related not only to the increased number of leukocytes, but also the cytotoxic effects of this enzyme released intraluminally.

A chemotactically induced leukocytic response to the IUD could be expected to exert gametotoxic effects, precisely what is observed in both animals and humans. In women, Sagioglu has shown that macrophages are attracted to the surface of the IUD, creating a hostile environment in which spermatozoa are phagocytosed (32). (Fig. 15). Sedlis and Rejniak (36) have examined endometrial washings from patients wearing intrauterine devices, demonstrating an increase in the number of leukocytes in the uterine fluid. Experimentally, it has long been recognized that 99.998% of spermatozoa (3) are destroyed in attempting to transit the genital tract to

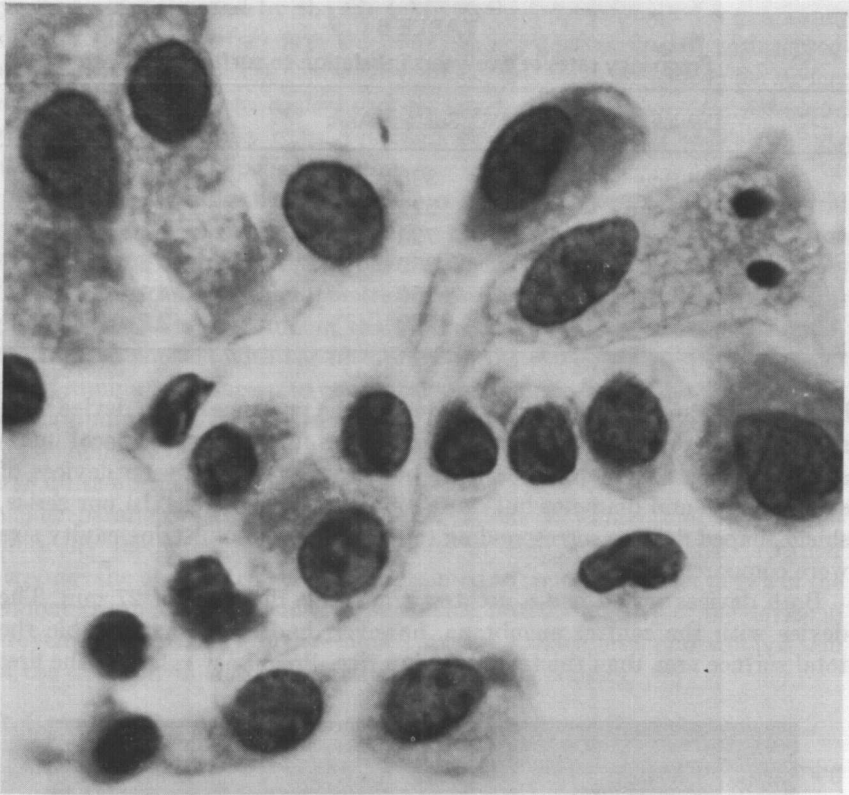


FIG. 15. Macrophages and leukocytes recovered from the surface of an intra-uterine device, demonstrating the chemotactic effect of the polyethylene-barium sulfate plastic material. Two sperm heads engulfed within a cell may be noted. (Courtesy of Dr. Nuri Sagiroglu: *Am. J. Obst. Gynec.* 106: 506-17, 1970.)

the Fallopian tubes, and that phagocytosis is an important natural mechanism for the elimination of excess sperm.

Relation of Surface Area to Efficacy

The surface interaction hypothesis is supported by clinical results with a variety of IUD's. Examination of pregnancy rates for the loops, coils and bows tested in the Cooperative Statistical Program (37) discloses an excellent correlation between the pregnancy rates and the total surface area of polyethylene-barium plastic potentially in contact with the endometrium (Table 6).

The polyethylene-barium devices with high surface area yield low pregnancy rates and vice versa. The close correlation between surface area of the plastic devices and pregnancy rates corresponds to the expected result

TABLE 6

Pregnancy rates at two years in relation to surface area

Device	MM ² Surface Area	Pregnancies
Small Bow	390	16.1
Small Loop	527	9.3
Large Bow	730	7.1
Small Coil	960	4.5
Large Loop	960	4.1
Large Coil	1200	2.2

if a locally induced chemotactic response to the presence of the device were an important determinant of IUD efficacy. To further test the local interaction hypothesis, comparisons have been carried out between devices of similar shape and diameter but quite different surface areas. In our series, shield-shaped devices corresponding to the mid-range of uterine cavity size were compared (Fig. 16).

Both devices tested had a greatest transverse diameter of 27 mm. The device with the central membrane, however, had more than double the total surface area than the fenestrated device. Pregnancy rates for the first

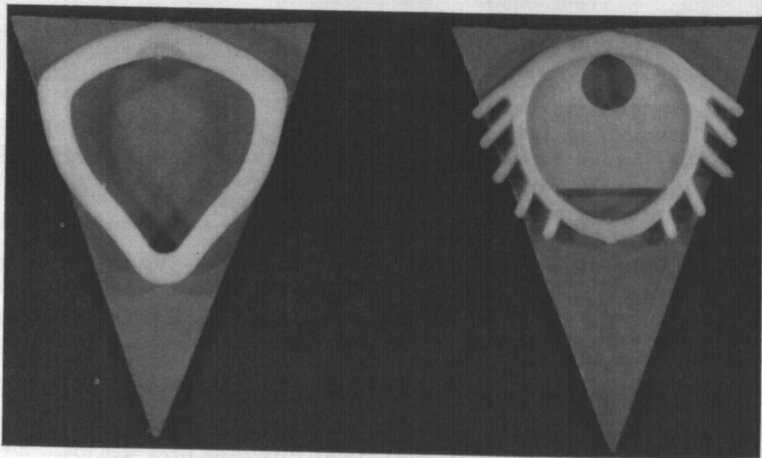


FIG. 16. Intrauterine devices of similar size but with markedly different surface areas in contact with the endometrium used to test the surface interaction hypothesis. Increasing the surface contact with the endometrium by means of the central membrane yielded a pregnancy rate of 1.1 per 100 woman-years, whereas the wholly fenestrated device had a pregnancy rate of three times greater. The devices are photographed against a schematic triangle representing average uterine cavity size. (Davis, H. J. and Lesinski, J.: *Obst. Gynec.*, 36: 350-58, 1970.)

year of use computed by the life table method demonstrated a pregnancy rate for the high surface area shield device of 1.1, as compared with a pregnancy rate of 3.4 for the fenestrated shield (9). *Thus, increasing the surface area of plastic in direct contact with the endometrium produced the postulated reduction in pregnancy rates, providing direct experimental support for the surface interaction hypothesis in women.*

Histologic investigation of the endometrium in contact with the central membrane of the shield device permits discrimination between effects due to surface interaction with the plastic of the device and mechanical effects due to pressure of the endometrial tissue by the rim of the device impinging on the lateral sulci of the uterus. In the central area of the endometrium in contact with the membrane of the shield device, the superficial gland lumina were shown to contain significant numbers of leukocytes (Fig. 17), a finding which is absent in control specimens. Except for this superficial chemotactic response to the presence of the device, the endometrium was quite normal in appearance.

The parallelism between these observations in women and the chemotactically mediated reactions described in animal experiments is rather striking: the endometrial response is related to zones of contact between the endometrium and the surface of the device, and the efficacy of the device in preventing pregnancy is determined by the surface area and composition of the device available for effective endometrial contact.

Relation of Composition to Efficacy

As might be anticipated from the surface interaction hypothesis, altering the chemistry of the interface between the device and endometrium can markedly influence pregnancy rates. The importance of the composition of the IUD is suggested by the results of Gräfenberg (14) in 1932. He noted 3.1% pregnancies in 1100 women fitted with silkworm gut rings, while the pregnancy rate among 600 women fitted with rings of spirally coiled silver wire was only 1.6%. Modern versions of the Gräfenberg ring (Hall-Stone Ring, Hall Band) made of less reactive stainless steel have consistently shown pregnancy rates of about 6% in the first year of use. Carleton and Phelps (6) described differences in the endometrial response to various materials in rabbits in 1933, comparing silver, gold, nickel, rubber, silk and celluloid.

The most significant modern work on the contraceptive efficacy of metallic ions has been carried out by Zipper, Medel and Prager at the University of Chile (40). They compared the effects of zinc, copper, tin, silver and magnesium in rabbits, noting that copper had outstanding anti-conceptive properties. The effects of the trace amounts of copper diffusing into the uterine milieu were localized to the uterine horn containing the experimental IUD, normal implantations occurring in the control horn of the

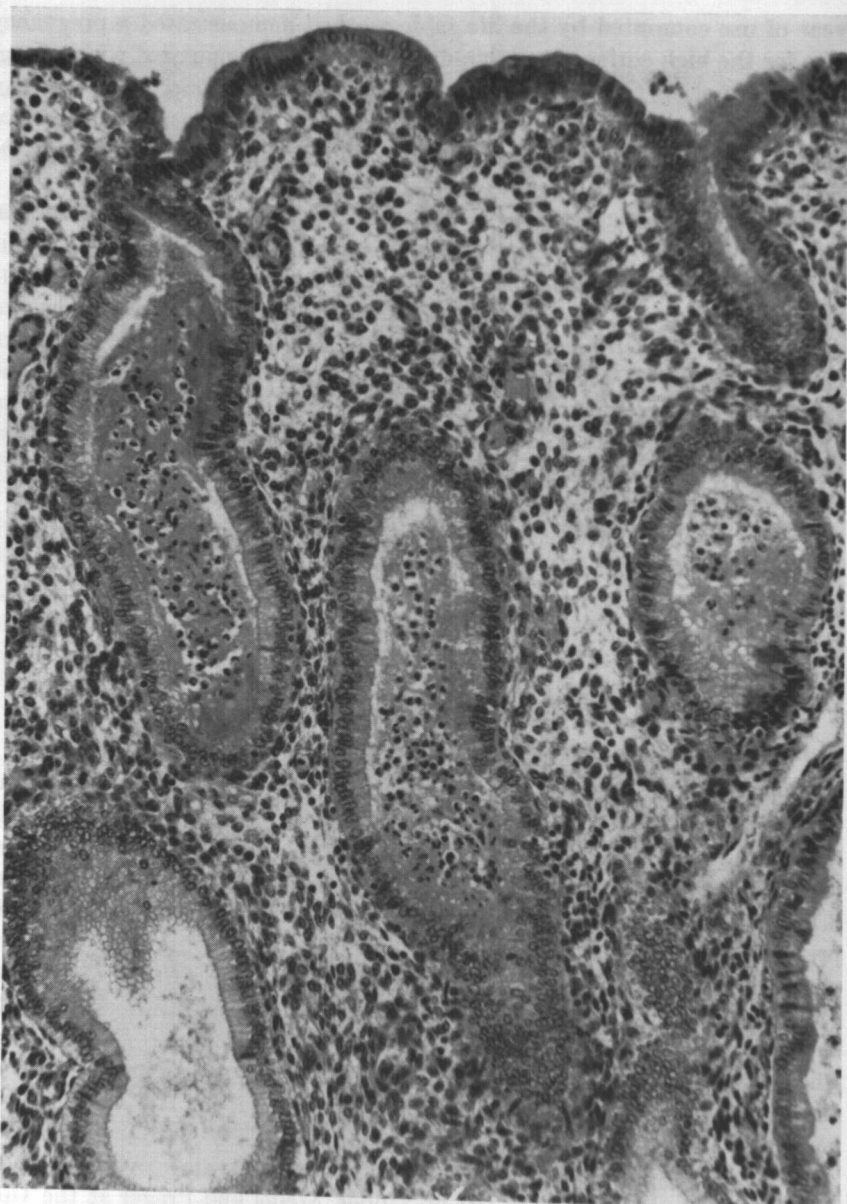


FIG. 17. The typical chemotactic response elicited at the interface between the membrane of the shield device and the endometrium. Leukocytes and plasma cells may be noted in the gland lumens near the surface. (Davis, H. J. and Lesinski, J.: *Obst. Gynec.* 36: 350-58, 1970.)

rabbit, and no systemic effects being observed. This work has now been extended to humans, comparing a T-shaped device of polyethylene plastic with and without a winding of copper wire. The experimental T device had a pregnancy rate of 18% in the first year of use, corresponding to its low surface area (315 sq. mm.) of polyethylene material. The attachment of a small copper wire to this otherwise ineffective device reduced the incidence of pregnancy three fold (41).

Effects of Copper

The effects of a length of copper wire placed in the uterine horn of the rabbit differ from the results if a corresponding length of material such as polyethylene or nylon are placed in a similar position. *In contrast with the plastic materials, the copper wire could be placed at the lower end of the experimental horn, where it nevertheless prevents pregnancy upstream from its position near the cervix.* Copper ions in very low concentration can have powerful effects as enzymatic inhibitors. The anti-conceptive effect of copper *upstream* at a considerable distance from the device indicates that the spermatozoa transiting the vicinity of the IUD are incapacitated. Saito et al (34) have shown that copper ions indeed exert a very toxic effect on rat and dog epididymal sperm.

Chang and Tatum (5) have shown that the contraceptive action of copper is indirectly mediated, rather than the result of direct contact between the copper device and blastocysts in the rat. A copper ring was introduced into the left uterine horn of 20 rats and removed 4 days later. The contralateral

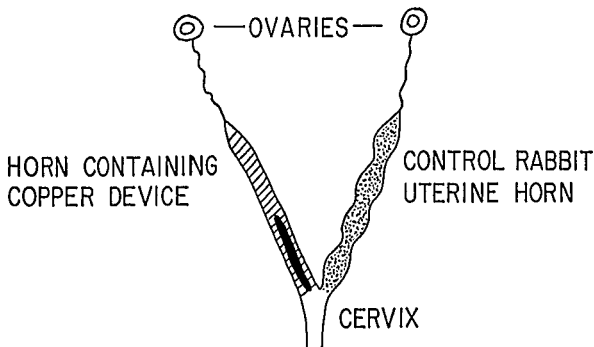


FIG. 18. The contraceptive action of a short length of copper wire placed in one uterine horn is manifest both locally and *upstream* (barred zone) from the position of the IUD near the rabbit cervix. This result indicates that spermatozoa are incapacitated as they transit the zone containing copper. The effects of copper ions diffusing from the device are localized to the experimental horn, normal implantations (stippled zone) occurring in the control uterine horn. Trace amounts of materials such as copper with specific contraceptive properties are greatly enhancing IUD efficacy both experimentally and clinically. (After Zipper *et al.*)

horns served as controls. Transfer of 108 blastocysts recovered from donor animals into the previously copper-influenced uterine horns resulted in no implantations, whereas 61 out of 81 donor blastocysts (76.5%) successfully implanted in the control horns not previously influenced by the presence of the copper device.

The importance of inorganic anti-conceptive materials such as copper has been belatedly recognized, although the use of such materials is venerable. The original 1909 device devised by Richter was bound into a ring shape with a *fine wire of copper alloy*. A copper wire intrauterine contraceptive loop was described by Schütze in 1913 (35). Hill (17) has reported the use of Gräfenberg rings containing copper alloyed with zinc and nickel (German silver) in over 1,000 private patients fitted between 1933 and 1969. Hill's pregnancy rates—less than 1 per 100 woman-years of exposure—are among the lowest ever reported. He followed a deliberate policy of replacing the rings at 2-year intervals. Endometrial biopsies obtained coincident with changing the copper alloy IUD disclosed no significant pathologic alterations among women wearing the device except for a leukocytic response in the superficial glands. Some of Hill's patients wore the copper alloy devices for 20 years, including removals for planned pregnancies and periodic replacement with a fresh device.

In a parallel line of inquiry, anti-conceptive materials have been blended into the plastic of experimental devices undergoing trials. This has the advantage of uniformity of distribution of the local reaction over a broad surface area, while controlling the gradual release of the material in ionic form. Direct contact between the effective additives and the endometrial surface is prevented by incorporating the material in the semipermeable plastic matrix. We have preferred using devices with the anti-conceptive materials blended into the plastic for these reasons, and also because eventual corrosion of a fine copper wire wound on the exterior of an IUD (as with the "T" device) can lead to fragmentation within the uterus.

Among patients fitted with devices containing anti-conceptive additives at Johns Hopkins, 3 pregnancies were observed after 4,200 woman-months of use. The copper shield has been tested simultaneously by Viel (38) in Santiago, Chile. Among 400 patients in the Chilean series, 2 pregnancies have been observed in over 2,000 woman-months of use. These preliminary results underscore the substantial progress made in improving performance by using current knowledge of the influence of surface area and surface chemistry on IUD efficacy.

SUMMARY

Relevant human and animal observations show a relationship between the induction of a local chemotactic response to the presence of the device

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SUMMARY

Relevant human and animal observations show a relationship between the induction of a local chemotactic response to the presence of the device

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Four

CHOICE OF METHOD

The selection of an appropriate contraceptive method must take into account a broad range of medical and personal factors for optimal results. Ideally, the choice of method should be made by the patient *and* the consultant. This requires an intelligent assessment of her needs plus accurate knowledge of the advantages and disadvantages of the principal methods of birth control.

The most successful and rational approach to contraceptive counseling is to consider the requirements of the patient carefully, rather than merely to prescribe on demand. The patient will often present herself stating, "I want X method," without in fact having much insight into her own requirements, much less the merits of alternative technics. A positive attitude towards a particular birth control method is often helpful, since it may lead to its more effective utilization. But this fact does not justify a permissive prescription policy. Professional counseling regarding an ideal contraceptive is a far more complex matter than offering so-called "cafeteria choice."

The efficacy of the intrauterine device in relation to traditional spermicidal or barrier methods is unchallenged in most applications. Only conscientiously used oral contraceptives offer levels of efficacy similar to those provided by intrauterine devices. While it is unquestionably true that a great variety of contraceptive technics (including rhythm and withdrawal) have proven useful in a sufficiently motivated clientele, for the majority of couples the options of interest involve the barrier methods, systemic contraceptives and intrauterine devices. Factors contributing to the relative safety and efficacy of the diaphragm, the pill and the IUD will be considered in this context.

MEDICAL SAFETY

In comparing the diaphragm, the pill and the IUD, the oral contraceptives have the greatest number of contraindications. Initially, the pill was thought to be perfectly safe for indefinite use by practically every woman.

An almost unrestrained enthusiasm for mass distribution of oral contraceptives developed shortly after their introduction in the United States, illustrated by the recommendations of the Planned Parenthood Federation of America. In the opinion of the Medical Committee in 1962, *the only contraindication to the prescription of oral contraceptives was pre-existing myomata uteri*. The committee specifically indicated that in the absence of symptoms or complaints, even pelvic examinations and Papanicolaou smears were optional. Substantial policy changes have since taken place.

Generally recognized contraindications to oral contraceptives include a history of thrombophlebitis, diabetes mellitus, thyroid disease, epilepsy, hypertension, psychic depression, migraine headaches, hepatic dysfunction, bronchial asthma or breast masses. Patients with a family history of diabetes or breast cancer and women with a history of toxemia or a tendency towards obesity are not ideal candidates for the Pill.

The Pill and Thromboembolism

Thromboembolic complications have resulted in hospitalization of approximately one woman per 2,000 users of oral contraceptives each year. The investigation of Inman and Vessey (7) established in 1968 the risk of thromboembolic morbidity and mortality inherent in the use of the pill. The risk of death and hospitalization due to oral contraceptives, according to their findings among British women is shown in Table 7.

An independent investigation completed in the United States by Sartwell *et al* (13) has confirmed the essential premise of the British study—that taking oral contraceptives entails a definite risk of thromboembolism. The 1969 Food and Drug Administration report on Oral Contraceptives calculates the age-specific risk of death among users of oral contraceptives to be increased by 3% during each year of use. *The risk of fatal thromboembolism is twice as great among women over the age of 30 as compared with younger women.*

A subsequent study by Inman *et al* (8) on the relationship between thromboembolic disease and the steroidal content of oral contraceptives prompted the Committee on Safety of Drugs to notify British physicians in December,

TABLE 7
Thromboembolic hazard per 1,000,000 pill users

Category	Deaths	Hospitalized
Controls	3.5	50
Pill Users	27.0	470
Risk Increase	8X	9X

1969, that the risk of thromboembolism is related to the estrogen content of oral contraceptives. It recommended that combination formulations not exceeding 50 micrograms of estrogen be prescribed for contraceptive purposes. Once the evidence was in hand, the British moved swiftly to switch their patients from high dose combinations and sequentials to the safer low dose combination type of oral contraceptive and abate the unnecessary hazards of pulmonary embolism, cerebral thrombosis and coronary thrombosis.

FDA Dosage Recommendations

The data analyzed by Sartwell for the FDA in the United States had shown essentially the same finding as the British study months previously. Yet nearly a full year elapsed before official action began in the United States to inform physicians and protect the public from the unnecessary hazards of high estrogen content oral contraceptives. Following the release by Searle of its low dose combination pill in April, 1970 (the only major drug firm in the U.S. lacking such a product), recommendations were issued to U.S. physicians in line with the British findings and the results of the Sartwell study.

The use of high estrogen content oral contraceptives of no greater efficacy is manifestly not rational therapeutics. A higher risk of thromboembolism combined with generally lower efficacy as a contraceptive makes the sequential pills (most of which contain excessive estrogen) particularly undesirable. *The importance of the British and United States findings linking the estrogen content of oral contraceptives with thromboembolism is that proper selection of patients and rational prescription practices can eliminate most of the thromboembolic hazards associated with this birth control method.*

Pill Hazards in Perspective

The hazards of using oral contraceptives must be viewed in relation to alternative procedures. Tietze (16) has estimated that the risk of thromboembolic death due to oral contraceptives is of the same order of magnitude as if an equal number of women had a medical abortion performed each year. From analysis of the various risks and alternatives he concluded: "In terms of risk to life, the most rational procedure for regulating fertility is the use of a perfectly safe, although not 100% effective method of contraception, and the termination of pregnancies associated with contraceptive failure under the best possible circumstances; i.e., the operating room of a hospital."

Metabolic alterations produced by oral contraceptives are another source of medical concern (19). Data with regard to carbohydrate metabolism suggests that prolonged use of the pill may be exerting a diabetogenic influence. Alterations in blood triglyceride levels have caused concern that chronic use of oral contraceptives might result in an increased incidence of atherosclero-

sis. At the present time the long range effects of the observed alterations in metabolism are unknown, but sufficiently well documented to justify a cautious attitude. Experience in the past decade indicates that the use of low dose combination type oral contraceptives in healthy young women under medical surveillance is an acceptable method for spacing pregnancies.

Experience with the Diaphragm

The medical safety of the diaphragm is well established. No serious effects have been noted since the invention of the modern rubber diaphragm by the German physician, Mesinga, in 1881. The diaphragm, like the IUD, is a locally placed appliance, with strictly local effects. Rare reactions to the rubber or the jelly used with the diaphragm are the only known side effects of this method.

Although failure rates with the diaphragm have been reported in the range of 10 to 20 pregnancies per 100 women in the first year of use (4), there is good evidence that these rates do not represent primary failures of the method. Westoff *et al* (18) have shown that *the efficacy of the diaphragm as a contraceptive rises to 97.4% among urban white couples in the United States who have already achieved desired family size*. Couples who were using the diaphragm for spacing purposes (whose motivation was therefore to postpone rather than to prevent pregnancy altogether) experienced five times as many failures. The critical nature of adequate motivation to secure a high level of clinical efficacy with diaphragm contraception is highlighted by these findings.

Major IUD Hazards

Certain hazards have been attributed to the use of intrauterine devices. They are chiefly related to the insertion procedure. Fittings in the early postpartum period or traumatic insertions are associated with an increased risk of perforation of the uterus. When appropriate technic is followed, and insertions carried out 10 weeks or more postpartum, this complication is exceedingly rare, occurring once in 5,000 insertions, and seldom leading to serious consequences.

A handful of fatal cases of sepsis have been associated with the insertion of intrauterine devices. A comprehensive survey conducted for the 1968 FDA report disclosed four such fatalities attributed to IUD insertion in the United States (14) out of an estimated 2 million devices in use. On this basis, one can calculate the risk of fatal sepsis following IUD insertion as two per million. At that time, standard practice was to "sterilize" IUD's by soaking them in inadequate solutions. Failure to observe sterile precautions, including the use of pre-packaged, adequately sterilized devices, were considered by the FDA Committee to be contributory factors to septic IUD complications.

It will be recalled that thromboembolic complications associated with the

use of oral contraceptives resulted in 30 deaths per million users *each year* according to the data of Inman and Vessey. The septic fatalities associated with the fitting of intrauterine devices (circa 2 per million insertions) therefore constitute a definite risk, but the incidence is far less than thromboembolic fatalities associated with the use of oral contraceptives. From a statistical point of view, the IUD is 15 times safer than the pill, though neither method is totally without risk. The risk of fatality associated with IUD insertion is of the same order of magnitude as the hazard of vaccination against smallpox, and is susceptible of reduction if appropriate precautions are observed.

EFFICACY

Oral contraceptives have had a higher theoretical efficacy than IUD's, though clinical results are often quite similar. A comparison of the Lippes Loop and the pill at the Buffalo Planned Parenthood Center demonstrated 1.5 pregnancies per 100 women on the orals and 3.3 pregnancies per 100 women with Loop D at the end of 3 years of use. Averaged on an annual basis there was 0.6 % greater protection against pregnancy achieved by the oral contraceptives during each year of use (10).

In terms of clinical efficacy, human error in taking daily medication leads to lower efficacy with the pill than is generally appreciated (Fig. 19). The omission of one or two tablets at critical times in the cycle can be exceedingly difficult to document retrospectively, making the comparative evaluation of oral contraceptives and IUD' is a complex undertaking. In the 1969 Report on Oral Contraceptives of the FDA Advisory Committee on Obstetrics and Gynecology, the use-effectiveness rates for several commercially available types of IUD's and oral contraceptives were estimated as follows:

<i>Contraceptive Method</i>	<i>Pregnancy Protection</i>
Combined Oral	99.3 %
Sequential Oral	98.6 %
Lippes Loop	97.3 %

The pregnancy protection of the loop approaches very closely the levels estimated for the oral contraceptives. Certainly the efficacy of both the oral and intrauterine methods far exceeds the protection afforded by traditional barrier techniques, which have failure rates substantially greater. Improved protection with IUD's has been realized with modern devices: a failure rate of only 1.1 % has been demonstrated with the shield IUD, a result superior to sequential oral contraceptives and equivalent to the efficacy of the combined type of pill. Second generation devices incorporating specific anti-conceptive agents are demonstrating even lower failure rates, so that the long sought after ideal of virtually 100 % efficacy with IUD's is at hand.

Also to be considered is the clinical efficacy of the pill, IUD and dia-

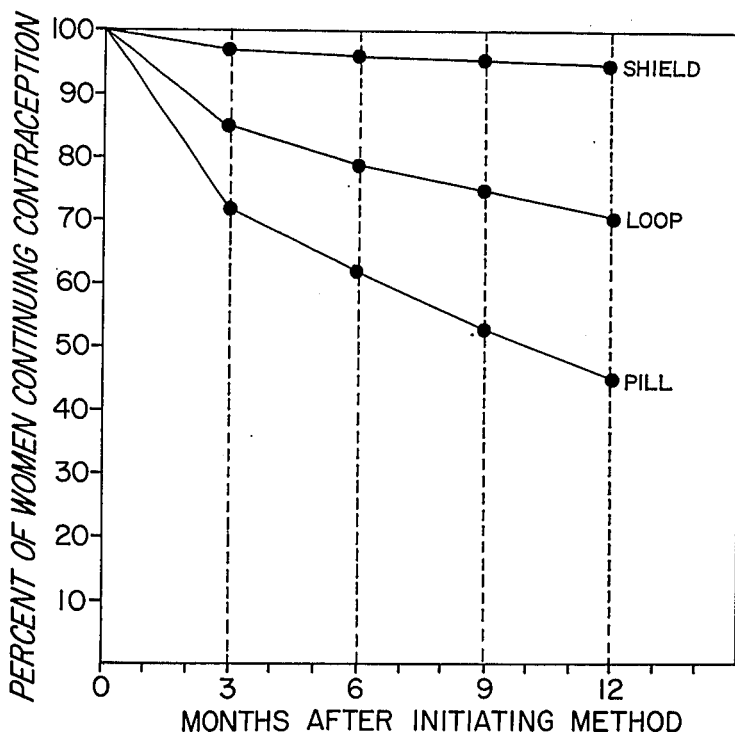


FIG. 19. Intrauterine devices demonstrate high clinical efficiency in average populations because continuation rates are independent of sustained daily motivation. The second generation shield device combines low pregnancy rates, low expulsion rates and low rates of medical removals, making over-all performance superior. (Maryland Planned Parenthood Ass'n.)

phragm. The usual published use-effectiveness rates for oral contraceptives do not include unplanned pregnancies after contraception has been stopped for reasons other than the wish to conceive. Abandonment of the pill because of real or imagined complications is a significant cause of failures. Both the oral and diaphragm methods, unlike the IUD, require sustained motivation. If one ranks first, second and third choices of the three methods—pill, IUD and diaphragm—according to medical safety and clinical efficacy, the following pattern emerges:

Medical Safety

1. Diaphragm
2. IUD
3. Pill

Clinical Efficacy

- IUD
- Pill
- Diaphragm

Because no method is superior to all others in every respect, the need for

sage counseling and careful patient selection is apparent. The medical safety of the diaphragm relative to the IUD and the pill is unchallenged. Because of the documented hazards of the pill, and the many contraindications to its use, both the diaphragm and IUD are medically safer. As between the pill and the IUD, the type of pill or IUD selected influences pregnancy rates. Beyond these facts, personal factors become increasingly important in choice of method.

SPACING VS TERMINATING

What is the degree of protection against pregnancy required? Although the IUD and the pill provide superior protection as compared with the diaphragm, the individual patients requirements must be taken into account. Whether a method is 98.8 % effective or 99.3 % effective may not be of paramount importance for the individual woman. This would be especially true for mothers of one or two children whose objective is child spacing.

The desire for spacing is not equivalent to a desire for absolute family size limitation. A difference in efficacy of 0.4 % means that one woman in 250 will have her second child sooner than planned. The woman who is spacing a pregnancy may be quite ambivalent about the timing of the arrival of a second child. In this situation the medical safety and convenience of a birth control method are far more important than an insignificant difference in efficacy. Even the least effective types of IUD are quite useful for child spacing purposes. For similar reasons the diaphragm serves for spacing pregnancies quite adequately, provided it is esthetically acceptable to the couple.

If, on the other hand, virtually absolute family size limitation is desired, the patient has four options: (1) Surgical sterilization; (2) use of a modern IUD with high performance qualities; (3) disciplined use of combined type oral contraceptives; and (4) moderately effective contraception combined with abortion for contraceptive failure.

The importance of discriminating between spacing and terminating in contraceptive counseling is emphasized by the calculations of Hulka (6), using a mathematical model to predict unplanned pregnancies. His estimates indicate that if 100 couples rely on a contraceptive which is 95 % effective (better than traditional methods) in order to limit family size to 3 children, over 80 of them will have more children during the remaining 12 to 15 years of fertile marriage. As many as 6 of these couples could end up with 7 children! Because of the cumulative effect of failure rates of even 99 % effective methods, patients who have achieved desired family size should be offered the options of sterilization and termination of pregnancy for contraceptive failure.

For certain patients the oral contraceptives are the method of choice.

Patients with a history of severe functional dysmenorrhea can be successfully treated with these agents, as can patients with menorrhagia. Oral contraceptives are useful in the management of patients with pelvic endometriosis and facial acne. The nulliparous patient has been generally managed by the oral method. The superiority of the pill over the older types of IUD's in nulligravidas was unchallenged until recently because of the poor tolerance of these devices. However, excellent results are being achieved with sophisticated modern devices in nulligravidas and this limitation on the use of IUD's is no longer valid.

CARCINOGENIC HAZARD OF STEROIDS

Another area of concern to patients in selecting a contraceptive method is the potential risk of cancer. It must be emphasized that no cause-and-effect relationship has been established between oral contraceptives, intrauterine devices or diaphragms and cancer in women. Numerous authorities have serious reservations, however, regarding the potential hazards of prolonged exposure to oral contraceptives, particularly in inappropriately high dosage forms.

The estrogenic component in oral contraceptives has well documented carcinogenic potentialities. An increased incidence of cancer at a specific site—the breast—has been shown in five separate mammalian species. In reviewing the problem, Hertz (5) has emphasized that all known carcinogens in man have been shown to be carcinogenic in animals. The converse may not be necessarily true, since there are undoubtedly many factors involved in carcinogenesis besides hormonal influences. Nevertheless, an agent which can be shown to increase the incidence of breast cancer in five mammalian species is exceedingly likely to produce similar effects if given in sufficient time to a sixth or seventh mammalian species, including humans. Two agents (Provest and C-Quens) have been withdrawn from the U.S. market because of the experimental evidence linking them to the production of breast tumors.

The available experimental evidence on the relationship between estrogenic substances and carcinoma of the breast indicates that chronic exposure is an important factor. Thus, the use of low dose oral contraceptives in young women for a few years may not be found to carry a significant risk. The degree of risk undertaken by women using the pill chronically as a form of chemical sterilization is impossible to calculate at this time. Many difficulties arise in the epidemiologic investigation of this suspected relation, including the need of a very large sample of chronic users of oral contraceptives who could be registered and followed for several decades. Such studies have not been carried out, and like the evidence on thromboembolism, may take many years to complete.

The carcinogenic hazard of oral contraceptives is also difficult to evaluate

because of the prolonged latent period between induction and clinical manifestation of many human neoplasms. The delay between the first cellular changes and the appearance of frank cancer may be as long as 20 years. Only a small number of women have taken oral contraceptives continuously for 5 years or more, though use of the method expanded so rapidly after 1965 that there were an estimated 8.5 million users in the United States by 1969.

An investigation by Melamed *et al* (11) has demonstrated a higher prevalence of carcinoma *in situ* of the cervix among women selecting oral contraception as compared with diaphragm users. The rate differences they observed were probably not due to the contraceptive method per se, but rather to other factors, since *the higher risk of oral contraceptive patients was not in fact a higher incidence after initiating the use of the pill*. A large scale study comparing women on oral contraceptives and women fitted with intrauterine devices is now being sponsored by the U.S. Food and Drug Administration and may provide better information with regard to the risks of cervical neoplasia.

CARCINOGENIC HAZARD OF IUD

There is neither human nor experimental animal evidence that intrauterine devices result in altered rates of carcinoma of the cervix, or adenocarcinoma of the endometrium. The series reported by Ishihama in 1959 covered an experience over 20 years with the Ota ring in Japan among nearly 20,000 women (9). Many of these patients had worn the devices for 5 years or longer. Only one case of cervical cancer was encountered, and it was not associated with significant endometrial pathology. A single case of endometrial carcinoma has been reported by Ober *et al* (12) in a 46 year old woman fitted 4 years previously with an intrauterine device. Otherwise, the experience with IUD's in millions of women during the decade from 1960 through 1970 has brought to light no reports of IUD-associated endometrial carcinoma. The paucity of reported cases may be related to the low natural incidence of endometrial carcinoma among the pre-menopausal women using IUD's. Another protective factor may be the cyclic menstrual shedding of the endometrial cells directly in contact with the device.

Experience with other locally implanted "foreign bodies" is reassuring. A great deal of experience has accumulated regarding plastic and metallic implants in man. There is no reported case of cancer in man attributable to medical use of plastics despite the fact that hundreds of thousands of patients have had plastic materials imbedded in their tissues (1). An even more extensive experience exists with respect to the chronic exposure of human tissues to surgical suture materials of silk, silver, copper, nylon, stainless steel, etc., without any evidence of such foreign bodies inducing neoplasia. Similarly, there is no reported case of carcinoma caused by

medically implanted steel, although fibrous tissue reactions have been noted around pieces of metal—such as grenade fragments—usually 25 to 50 years after embedment (15).

Corfman and Richart (2) attempted to induce endometrial carcinoma with IUD's in Wistar rats. They placed fragments of the Lippes loop device in the uterine horns of 102 animals. Three sarcomas were observed in the control animals of this susceptible rodent strain, while none appeared in the uteri of animals bearing the polyethylene IUD. Five of the animals with loop fragments in the uterine horns developed pyometra and histologic changes interpreted as epidermoid carcinoma, though only one animal had demonstrable metastases. Of probably greater significance is the fact that no adenocarcinomas were observed, except for one which appeared spontaneously in a control animal. The authors concluded "it is unlikely that the sequence of events which occurred in this study as a response to an intrauterine foreign body is important in predicting human disease."

The 9th report (1970) of the Cooperative Statistical Program (CSP) covers experience with 23,911 women, among whom 70 cases of carcinoma were reported in the first 6 years of use (17) (Table 8). Among these, 46 were carcinoma in situ, 5 were invasive carcinomas and 19 were carcinomas not otherwise defined. Thirty-eight of these cases were detected by cytologic or clinical examination at the time of insertion or within one month thereafter. The detection rate in the first month was 2.02 per 100 woman-years, accounting for cases already present at the time of insertion. Subsequent follow-up examinations covering 37,220 woman-years of experience shows detection rates of less than one case per 1000 women per year. This low incidence among IUD users is entirely comparable to detection rates in populations of women without IUD's who have been screened cytologically one or more times.

At the present time there is no direct evidence in women taking oral contraceptives to indicate an increased incidence of carcinoma. Experimental animal results suggest that *chronic use* of oral contraceptives may expose women to an increased hazard of breast carcinoma. There is neither

TABLE 8

Rates of cancer detection among women followed in CSP program, 1963-68

Months After Insertion	Number Detected	Woman-Years	Rate per 100 Woman-Years
1st	38	1,882	2.02
2-12	13	16,144	0.08
13-24	12	10,588	0.11
25-36	4	6,068	0.07
37-72	3	4,420	0.07

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and there are no alterations of carbohydrate or lipid metabolism, nor changes predisposing to thromboembolic complications.

(2) Secure Protection

Modern intrauterine devices represent one of the most secure birth control methods ever developed. Only the disciplined daily use of combined type oral contraceptives offer equivalent protection against pregnancy. In contrast with the old linear types of IUD, the second generation devices now available are retained almost perfectly. With the IUD, theoretical and clinical efficacy become virtually identical, because there is nothing extra the patient must take or remember to prevent conception.

(3) Convenient Protection

Intrauterine contraceptive devices are unquestionably the most convenient method of birth control ever developed. With the IUD, freedom from the necessity to take additional precautions before, during or after coitus make for uninhibited sexual expression. Because the IUD uniquely provides protection independent of sustained daily motivation, the method is equally effective in women of low, average or high socio-economic status.

(4) Safe Protection

Intrauterine devices have been fitted in over 12 million women throughout the world—over 3 million in the United States alone—demonstrating outstanding medical safety. In the tissues adjacent to the device, the major documented effect is a mild chemotactic reaction in the superficial layers of the endometrium. In response to the IUD, there is an increased number of leukocytes present, a change which carries no known neoplastic potentialities. The surface tissues in contact with the device are normally shed with each menstrual period, an inherent protective factor.

(5) Prolonged Protection

No other method of conception control offers the permanent—yet fully reversible—protection of the IUD. At the option of the patient and physician, the IUD provides months or years of virtually 100% efficacy. Yet following removal of the device, natural fertility is promptly restored. The majority of patients become pregnant within 3 to 6 months after IUD removal, 90% within 12 months.

For reasons of personal taste, for reasons of convenience, for reasons of degree of motivation, for reasons of medical safety, or to correct a pre-existing gynecological complaint, a particular method may be distinctly superior. Yet the choice of contraceptive remains a very personal decision, and cannot be made strictly on the basis of a statistical average of safety or acceptability. Individual counseling is the key to successful contraceptive practice. By any objective standard, however, the modern IUD is an outstandingly excellent method of birth control. Contraindications to the IUD are few, protection against pregnancy excellent, serious complications rare. In the practice of contraception, to neglect the use of intrauterine

devices is to deprive the patient of an important and effective option, and to offer her less than the professional counseling she has every right to expect.

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Five

INSERTION AND REMOVAL

Meticulous insertion technic is an important determinant of success with this form of contraception. Improper placement of the device can be responsible for unnecessary cramps, expulsions and pregnancies. As with any other minor surgical procedure, skill and experience in the use of IUD's will markedly diminish such complications.

The use of intrauterine contraceptive devices on a broad basis is a rather recent phenomenon and many physicians have received little training in the basic technical precautions which should be observed. Unfortunately, many medical centers still lack organized contraceptive services, and teaching of contraceptive technics of all kinds has been generally deficient. There is little doubt that many minor and most major complications associated with IUD's will diminish as professional training improves.

CONTRAINDICATIONS TO INSERTION

Absolute contraindications to the insertion of an intrauterine device are few. Distortion of the cervical canal or uterine cavity by myomata or a rare septate uterus represent situations in which difficulties with insertion and higher expulsion rates will be experienced. Sounding the uterine cavity can detect such irregularities or anomalies and should never be omitted. It is of course far better to avoid injudicious insertions than to experience unnecessary complications.

The generally recognized contraindications to the use of intrauterine contraceptive devices include the following:

- (1) Known or suspected uterine pregnancy.
- (2) Acute or subacute pelvic inflammatory disease.
- (3) History of incapacitating dysmenorrhea or menorrhagia.
- (4) Known or suspected cervical or uterine malignancy.
- (5) Hypoplasia, stenosis or distortion of the cavity.

Patients with such findings should use other contraceptive methods. An astonishing variety of "IUD complications" reported in the literature

have resulted from a disregard of these simple contraindications. Considering the ready availability of alternate contraceptives, the use of IUD's should be restricted to the 95 % of women who can be expected to become satisfied and happy users on the basis of their history and pelvic examination. Disappointing results with intrauterine devices will result from forcing the method on unsuitable candidates far more frequently than from the limitations of the method per se.

The equipment required for routine IUD insertions is:

- (1) Malleable uterine sound.
- (2) Bi-valve speculum.
- (3) Long sponge forceps.
- (4) Six cotton balls.
- (5) Antiseptic solution.
- (6) Curved Mayo scissors.
- (7) Disposable plastic gloves.
- (8) IUD and inserter.
- (9) Cervical tenaculum.

The sound, clamp, tenaculum, scissors and cotton balls may be conveniently placed on a towel backed by a metal tray and wrapped for autoclaving (Fig. 20). If several such IUD insertion kits are kept conveniently at hand, much time will be saved in searching and assembling the equipment for each patient. At the time of insertion, an assistant can open the kit, moisten the cotton balls with antiseptic solution and lay out the appropriate device and inserter while the physician carries out the bimanual examination. Organized in this manner, the insertion can be completed in less than three minutes.

IUD INSERTION PROCEDURE

(1) Bimanual examination to determine size, shape and position of the uterus, and to rule out adnexal masses.

(2) Exposure of cervix with the bivalve speculum and application of the tenaculum through the anterior lip of the cervix. *A secure grip with the tenaculum is obtained by placing one tooth within the cervical canal about 2 cm. from the external os* (Fig. 21A). A single tooth tenaculum which is deliberately blunted will minimize bleeding due to puncture of small vessels.

(3) Cleaning the cervix with a sterile dry cotton ball followed by a cotton ball moistened with antiseptic solution. The removal of infected material or cellular debris from the external os should be practiced routinely to prevent gross uterine contamination.

(4) While traction is maintained on the cervix with the tenaculum, the uterus is sounded to determine the axis of the canal, the contour of the cavity, the position of the internal os and to confirm the degree of anteversion or retroversion (Fig. 21B). Insertion should not be carried out if

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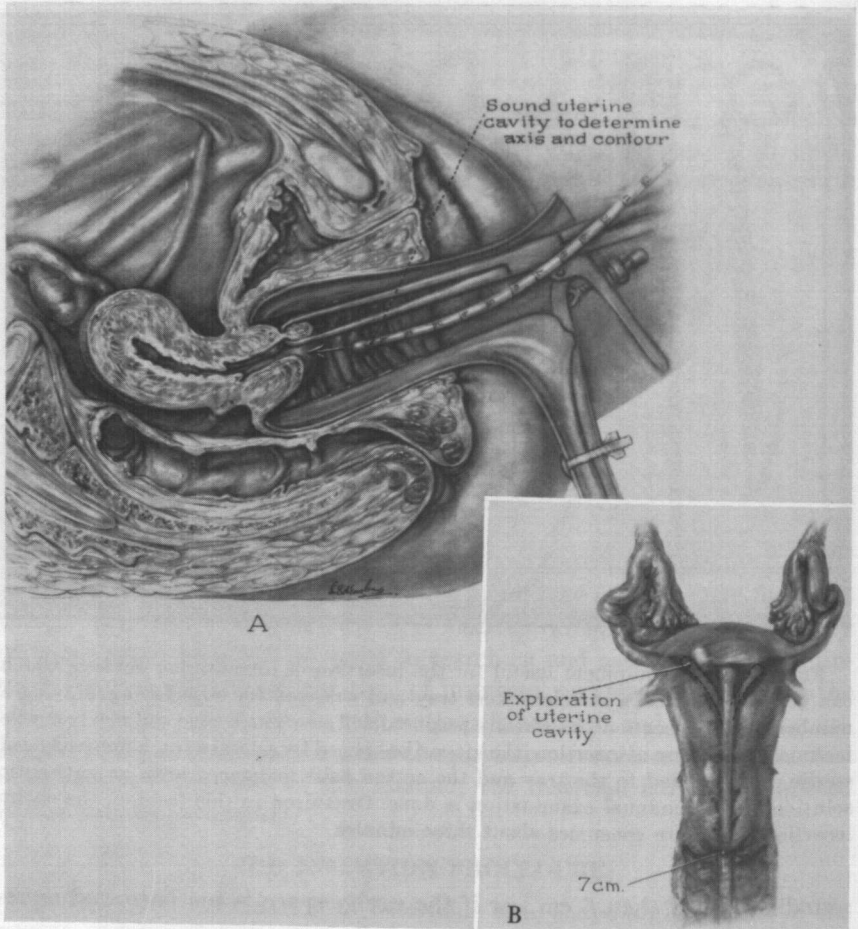


FIG. 21

(7) Confirmation of the positioning of the device within the uterine cavity (Fig. 23D). The shield IUD bears a knot on the tail at 7 cm. to permit visual confirmation of correct fundal placement in relation to the previous sounding. With the loop, sounding the cervical canal after insertion is advisable to insure that part of the device is not lying in the cervical canal (see Fig. 27B).

(8) Trimming the marker tail on the device, if necessary. It is desirable to have about 3 cm. of the marker thread protruding from the cervix to prevent its disappearance within the canal if the device later repositions itself at a higher level.

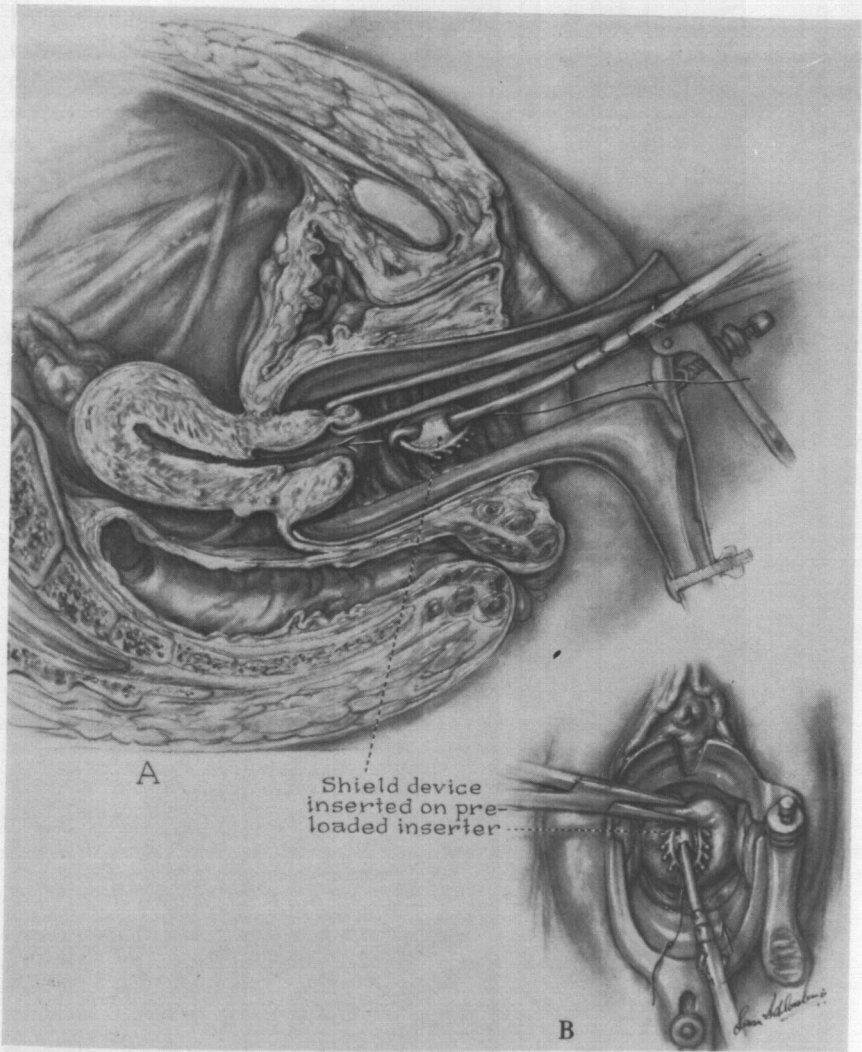


FIG. 22

TECHNICAL PRECAUTIONS

Observance of technical precautions will contribute to safe and correct placement of the device in the uterine cavity. It is well to recall that the uterine cavity seldom lies in a straight axis with the cervix. It is usually flexed at the level of the internal os, making the insertion potentially hazardous. This risk is minimized by exerting traction on the cervix with a

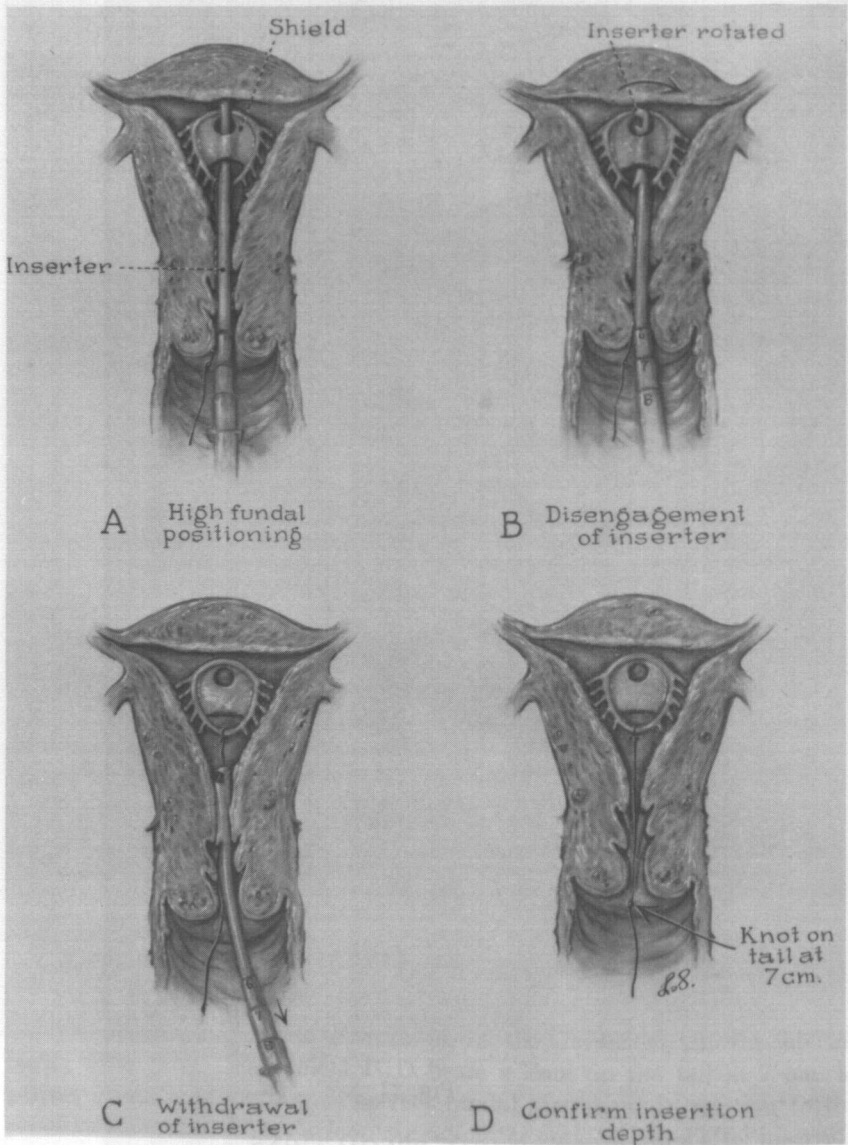


FIG. 23

tenaculum firmly placed *through* the anterior lip of the cervix. A much better grip, without risk of tearing the cervix while exerting traction, can be obtained by placing one tooth of the tenaculum *inside* the cervical canal.

Irrespective of the examiner's judgement as to the position of the uterus

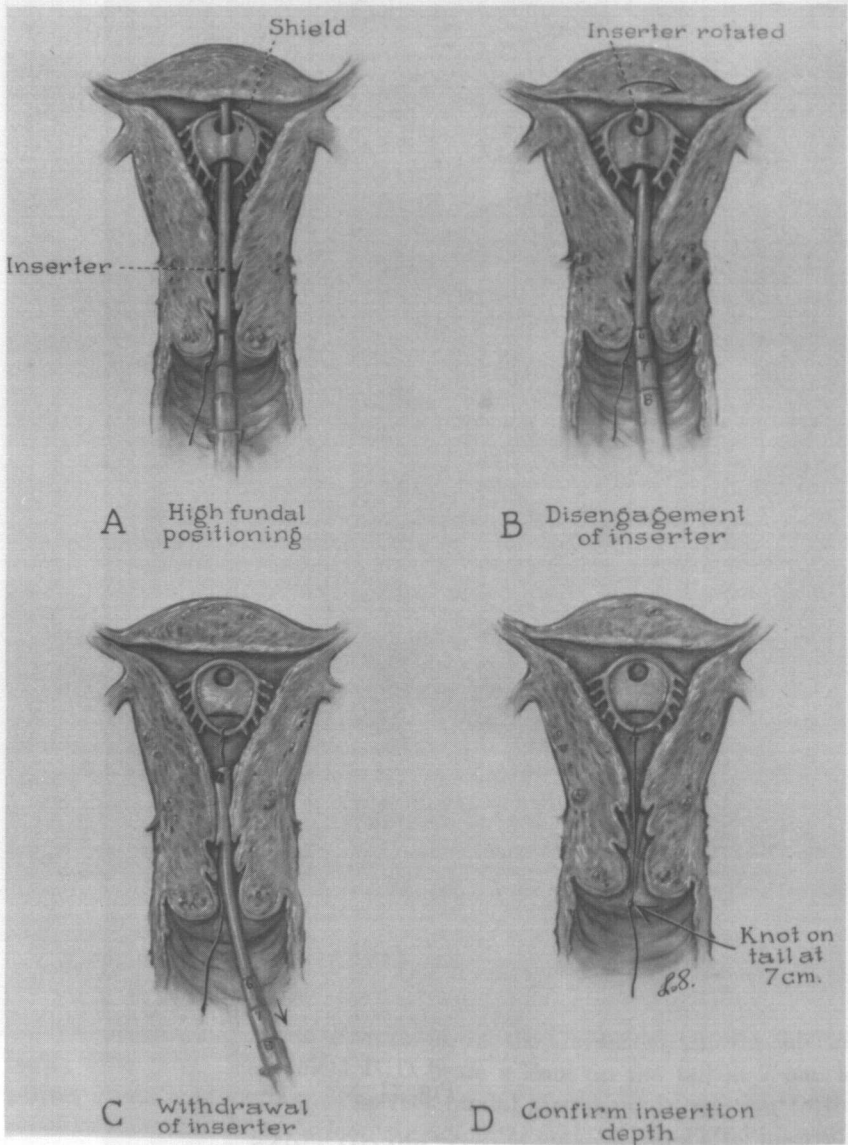


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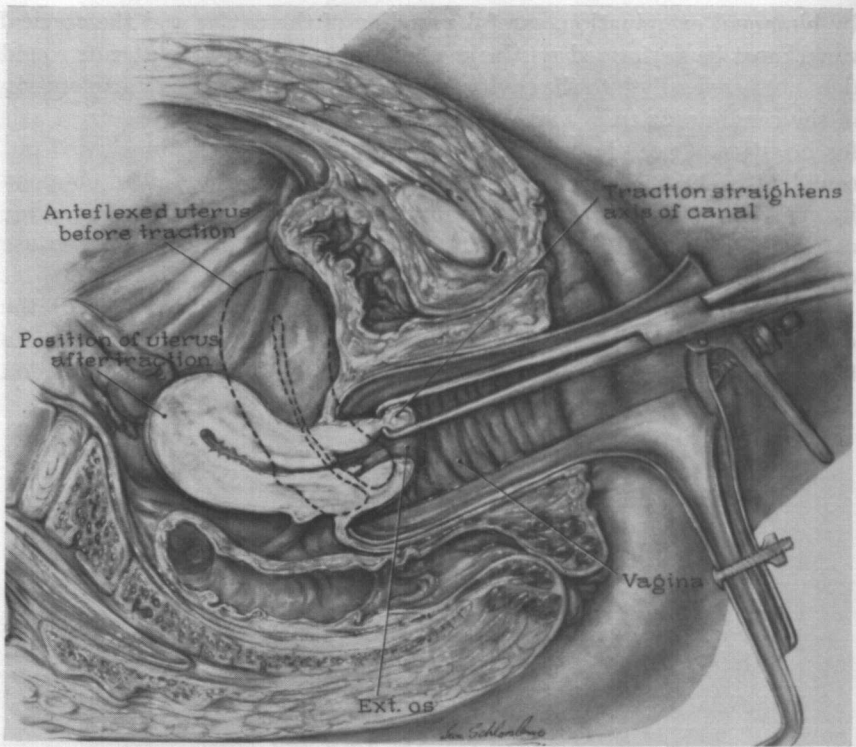


FIG. 25. Traction on the cervix with a tenaculum securely positioned with one tooth *within* the cervical canal straightens the axis of the canal, facilitating sounding and reducing the risk of uterine perforation.

on the cervix with the tenaculum straightens the axis of the canal, and exploration with the sound determines the direction to be followed and the resistance to be anticipated (Fig. 25). Neglect of precautions regarding the procedure of insertion, the optimal timing of insertion, and the requisite gentleness of insertion has undoubtedly contributed to many unnecessary perforations.

Little or no force should be required to place an IUD in the endometrial cavity. This is especially true of insertions carried out 10 to 12 weeks postpartum, when the cervical canal should readily admit the sound and the device. The easily inserted modern devices make dilatation of the cervix unnecessary. Should unusual difficulty be encountered when insertion is undertaken, the procedure should be halted, and the initial steps of sounding repeated to explore the canal and determine the correct axis of insertion. Inexperienced personnel should seek consultation rather than proceed with forceful insertions. The few additional insertions achieved by pro-

ceeding in the face of unusual resistance will be far outweighed by the negative effect on the entire program produced by avoidable accidents.

USE OF IUD'S IN NULLIGRAVIDAS

The insertion of intrauterine devices into nulliparous patients has been generally contraindicated until recently because of the high rates of cramping, bleeding complications and expulsions experienced with rather bulky types of IUD's. In a series of 27,000 IUD insertions reported by Tietze (7) from the Cooperative Statistical Program, only 390 were carried out in nulligravidae. High rates of removal because of severe pain in the first 24 hours after insertion were experienced. Later removals and expulsions were also troublesome, so that only 56 % of the patients completed the first year of use.

Success with IUD's in nulliparous patients is undoubtedly related to the types of IUD used. Excellent results can be secured in these patients provided small devices with good retention characteristics are used. In over 300 insertions carried out at Johns Hopkins Hospital with the shield device, only two expulsions occurred, and medical removals in the first year of use have been rare. Discomfort associated with insertions in nulligravidae can be minimized by administering 50 mg. of Demerol and 0.5 mg. of Atropine intramuscularly 20 minutes prior to the procedure. A paracervical block using 0.5 cc. of 2% Xylocaine at 3 points around the perimeter of the cervix provides excellent local anesthesia for insertion or removal of intrauterine devices (Fig. 26).

FACTORS INFLUENCING PERFORATIONS

The most distressing complication associated with the use of intrauterine contraceptives has been accidental perforation of the uterus. The frequency of this complication is related to the type of device and the experience of the operator. Under conditions of mass use, Tietze reported (6) nine perforations of the loop in 13,362 insertions. The bow type of IUD had a perforation rate of 1.3 % in the CSP series. Use of the bow has been largely abandoned for this reason and because of high pregnancy rates.

There is a clear relationship between the timing of insertion and risk of uterine perforation. Insertion in the first four weeks post partum is particularly hazardous, and should be carried out with caution. Tietze has calculated the perforation rate per 100 insertions with the bow (6) by interval since last confinement, indicating that many of the perforations attributed to the bow were due to injudicious insertions in the early postpartum period (Table 9).

It is apparent that *a ten-fold reduction in the risk of uterine perforation can be accomplished by timing insertions 10 to 12 weeks postpartum.* The risk of perforation with other types of device was 10 times lower than with the

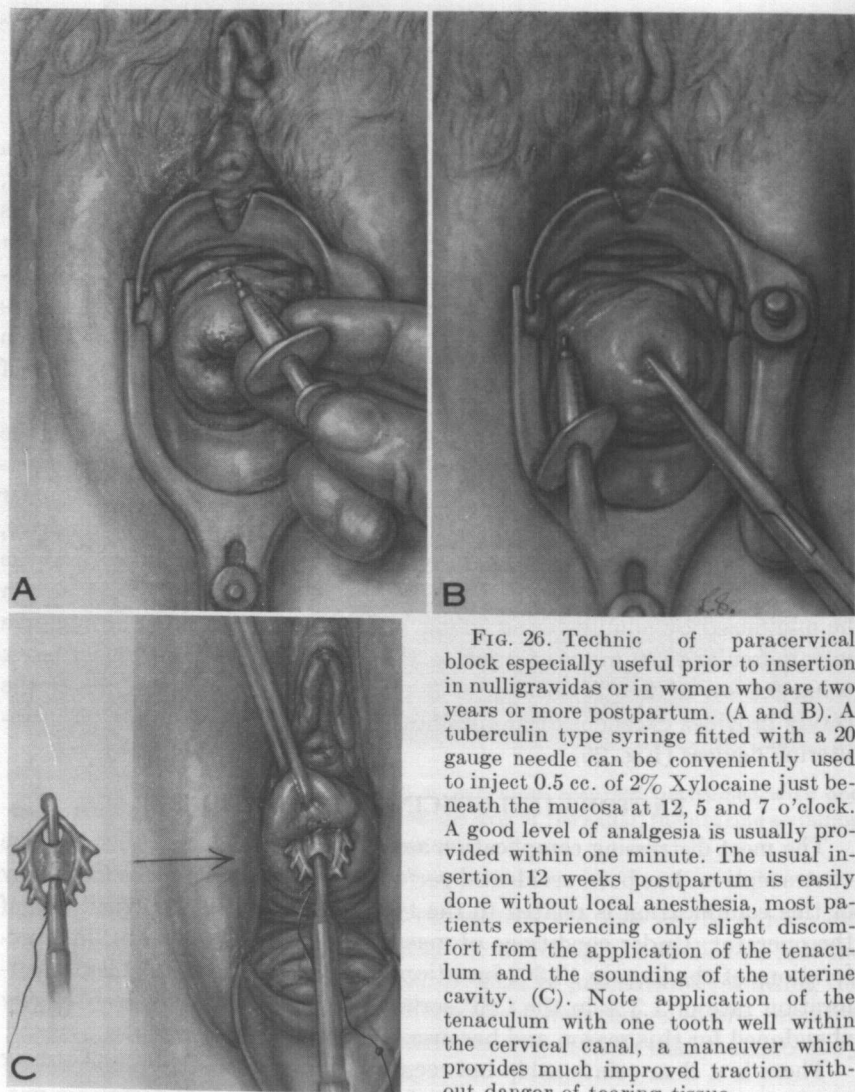


FIG. 26. Technic of paracervical block especially useful prior to insertion in nulligravidas or in women who are two years or more postpartum. (A and B). A tuberculin type syringe fitted with a 20 gauge needle can be conveniently used to inject 0.5 cc. of 2% Xylocaine just beneath the mucosa at 12, 5 and 7 o'clock. A good level of analgesia is usually provided within one minute. The usual insertion 12 weeks postpartum is easily done without local anesthesia, most patients experiencing only slight discomfort from the application of the tenaculum and the sounding of the uterine cavity. (C). Note application of the tenaculum with one tooth well within the cervical canal, a maneuver which provides much improved traction without danger of tearing tissue.

bow in the CSP series, indicating that the type of IUD used as well as the timing of the insertion is an important consideration. Although two-thirds of loop insertions were carried out 12 weeks or more postpartum, *two-thirds of the loop perforations occurred among women fitted earlier postpartum.* Selecting devices which carry a low risk of perforation and carrying out insertions 10 to 12 weeks postpartum will obviously make uterine perforation an exceedingly rare event.

In the patient material at Johns Hopkins Hospital, one uterine per-

TABLE 9
Influence of postpartum interval on perforations with Birnberg Bow

Time of Insertion	Percent Perforations
5 Weeks	3.4
6 Weeks	3.1
7 Weeks	1.4
8-12 Weeks	0.4
12 Weeks	0.2

foration has occurred among over 6,000 patients fitted with a great variety of intrauterine devices 10 to 12 weeks postpartum. The physician responsible for this accident was performing his first insertion. This low rate of accidental perforation was achieved despite the fact that the clinic operates as a training facility where many physicians have gained their first experience with the use of intrauterine contraception.

IUD DESIGN FACTORS

Inappropriate timing of insertions is the major cause of perforations. Nevertheless, the design of the device influences perforation risk. Linear devices which present a pointed leading tip can be forced through the uterine wall more readily than devices presenting a broad or relatively blunt leading edge. Similarly, devices made of stiff, relatively hard materials can be forced through a false passage more readily than those made of more pliable materials. The loop and coil devices have been recently improved by making the leading tip bulbous.

The construction of the inserter also influences perforation risk. The cannula principle employed to insert many of the commercially available IUD's can contribute to the danger of perforation of the uterus. Devices compressed for fitting inside of the tubular inserter can be inappropriately *injected* forcefully against the uterine wall, rather than being *inserted* into the uterine cavity. If, when the plunger on the cannula is advanced and the tip of the device happens to be positioned against the uterine wall, a forceful ejection of the loop or coil type of device can cause penetration of the uterine musculature (Fig. 27A).

Care should be taken in using the linear type devices not to draw the IUD into the insertion cannula until the procedure is well underway. The loop in particular tends to lose its memory rapidly and will assume bizarre and undesirable shapes within the uterine cavity if the device remains in the cannula for any appreciable length of time prior to insertion. The availability of devices which are supplied in sterile pre-loaded packages

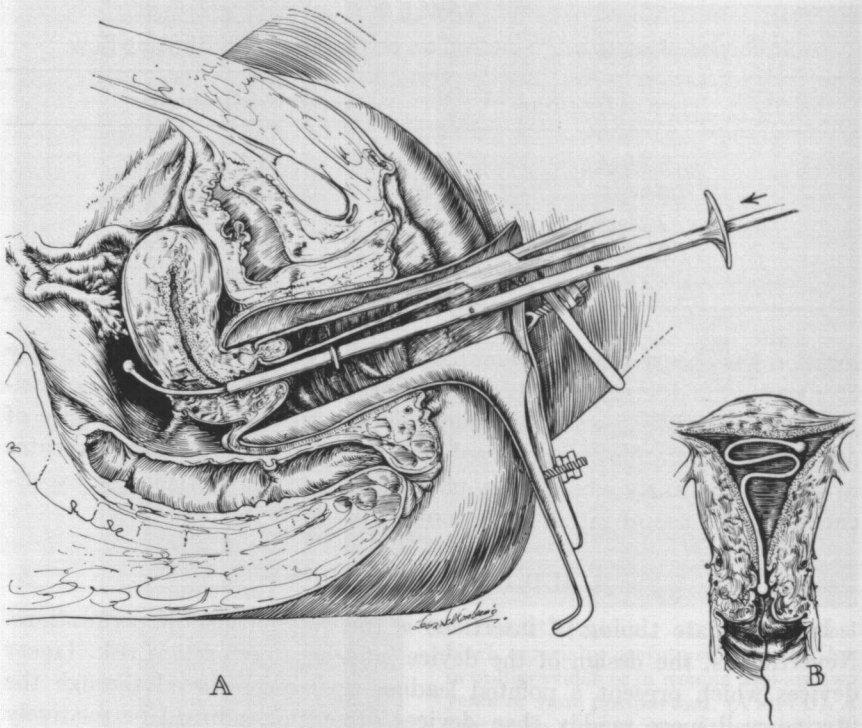


FIG. 27. Forceful *injection* of a linear loop or coil device can result in uterine perforation (A), especially if the axis of the canal has not been straightened by countertraction on the tenaculum. The bulbous tip on the newer versions of the loop has reduced this hazard. Failure to completely insert the loop (B), with the terminal portion of the device lying in the cervical canal, is a frequent cause of early expulsion.

with disposable inserters makes prolonged storage in the inserter unnecessary.

TECHNIC OF COIL INSERTION

Vaughn and Dominguez, who have had experience in the insertion and management of over 7,000 patients with the double-coil intrauterine device, have stressed the importance of careful technic in achieving high retention rates, low pregnancy rates and low complication rates (8). In two and a half years experience in this large patient material, only one uterine perforation occurred. Their technic is as follows:

"For each insertion, a sterile pack was prepared containing a speculum, sound, uterine forceps, tenaculum, scissors and sponges.

"The uterus was palpated to determine position, size and possible abnormalities. The vagina and cervix were prepared with Vagisec Liquid or Betadine Solution. The anterior lip of the cervix was grasped with a tena-

culum to maintain steady traction and to bring the uterus between the blades of the speculum, correcting as much as possible for malposition. The endocervical canal was probed to determine the patency of the internal os and the endometrial cavity sounded to confirm size and position.

"The double coil was then removed from its sterile pack and pulled into the inserter sheath in alignment with the wings of the stopper, which had been pulled back to the depth of the uterine cavity (previously measured with the sound). *The inserter was introduced slowly into the endocervical and endometrial cavity until the fundus was reached. Then the inserter was pulled outward about 1 or 2 cm. and held firmly in that position as the inserter sheath was retracted over it.* Thus, the device was deposited in the endometrial cavity without any pressure. If the position of the device was in doubt, it was removed immediately and reinserted using the same technic. Coil threads were observed for retraction for several minutes before cutting with scissors, leaving about 2 inches of thread exposed. Patients were then observed for a brief interval for signs of severe cramping, abnormal bleeding, or extrusion of the device."

These authors attributed their very low complication rate to the sterile prepackaging of the devices, the use of sterile instruments and routine cleansing of the cervix with antiseptic solution. Those precautions, together with timing of insertions preferentially during menstruation and the observance of other technical precautions, have made their IUD program in Dade County, Florida, one of the most effective in the United States.

IDEAL TIMING OF INSERTION

The combination of meticulous technic and careful time of insertions undoubtedly leads to very low complication rates. As a routine clinic policy, our postpartum insertions have been carried out 10 to 12 weeks after delivery. At this time the walls of the uterus are firm, and the size of the cavity has returned more nearly to a pre-pregnancy state. *Ideally, insertions can be carried out during menstruation, or during withdrawal bleeding induced by oral contraceptives.* The cervix at this time tends to be open, making the insertion generally easy and painless. This protocol also results in less inconvenience to the patient due to post-insertion bleeding, since she is already menstruating. Among women inserted early postpartum—day 1 to day 6—the probability of expulsion of a loop device is 2 to 3 times higher than among women inserted 8 to 12 weeks postpartum. The difference is related to high rates of expulsion (about 20%) in the first 3 months of use among women having loop insertions in the early postpartum period, the majority of these expulsions occurring in the first month. In the Singapore experience, there was an expulsion rate of 28% among women fitted with loops prior to 4 weeks postpartum, while later insertions carried an expulsion risk of about 12%. Thus, both the risk of perforation and the risk

of expulsion are substantially increased by carrying out insertions of loops prior to postpartum involution of the uterus.

UNRECOGNIZED PREGNANCIES

Still another distressing complication is avoided by scheduling insertions during menstruation: disturbance of unrecognized early pregnancy. Women who suspect that they may be pregnant have been known to supply a false menstrual history in the hope of being aborted by an IUD insertion. Complications in the form of excessive bleeding and possible sepsis can result from insertion in the face of unrecognized early pregnancy. Norman Haire (2) described such a case in 1931, recommending that insertions of the Gräfenberg ring be timed to coincide with menstruation:

"There is another possible complication. The patient may already be a few days or even a few weeks pregnant if the ring is put in at any other time than during the period. . . . The woman, who had already had 17 pregnancies, guessed that she was pregnant and got me to insert a ring 2 days before her next period was due, by assuring me that there had been no possibility of impregnation since her last period. As a matter of fact, having had so much experience, she felt that she was pregnant, and that is why she came for the ring. Later on, she admitted the truth—that she had come to us because she knew she was pregnant. Two days later the period did not arrive, though in between the insertion of the ring and the date of the expected period she had had no intercourse, owing to the bleeding which follows the insertion of the ring. She took quinine, hickory-pickory, ergot, apiol, gan-and-parsley, large doses of purgatives, she sat on chambers full of steaming hot coffee; she jumped off the table, fell downstains, lifted heavy furniture, and even took frequent hot baths (a habit quite foreign and antipathetic to her). But the pregnancy continued. In the fifth month she went to a quack, and had a septic miscarriage brought about by illegal operation, from which, as a matter of fact, she died."

In the management of private patients desiring IUD insertion, the secretaries can easily schedule appointments at the time of menstruation by having the patients telephone on the first day of the period. This is not to say that insertions of IUD's cannot be carried out at other times, or that insertion just after the completion of the menses are absolutely contra-indicated. Such is not the case. But as a matter of preference, for the reasons indicated, the fewest complications and the best results will be obtained from fittings 10 or more weeks postpartum during withdrawal bleeding induced by oral contraceptives or during menstruation. Approximately 80% of our insertions in both clinic and private patients have conformed to this basic protocol, and the results have been so excellent that the policy appears justified. In developing nations, where breast feeding is the rule, women can be fitted conveniently while they are protected from pregnancy by lactation amenorrhoea.

MANAGEMENT OF PERFORATIONS

Accurate localization of the perforated IUD is essential to management. An anterior-posterior and oblique X-ray view of the pelvis with a radio-opaque catheter in place can establish the position of the device and determine the most practical course of action to remove it. If the perforation is through the posterior aspect of the lower uterine segment, the device can usually be retrieved by colpotomy. Devices have been inadvertently inserted into the prevesical space and the broad ligament as well as into the cul-de-sac. Removal of the ectopic IUD is desirable to relieve the disquietude of a patient aware of a foreign object within the abdomen, and to prevent possible sequelae (4).

Rare cases of intestinal obstruction have occurred due to the entrapment of a segment of bowel in an open loop device which has only partially perforated a uterus. For these reasons we have advocated removal of the device as the wisest course of action. Under conditions of mass use in primitive circumstances, it can be argued that most uterine perforations do not result in significant morbidity, that the device is relatively inert, and that its presence in an extrauterine location may be ignored with relatively safety. Nevertheless, when circumstances permit, removal of the ectopic device is desirable.

THE SINGAPORE IUD EXPERIENCE

A well documented example of how a large scale program failure can be created is available from the experience in Singapore (3). Commencing in 1965, a hastily organized program of IUD insertions was initiated, using loops donated by the Population Council. Intensive recruitment was carried out among postpartum and postabortal women, and in a 12 month period 9,144 insertions were performed, *3,044 of these being almost immediately postpartum or postabortal*. Then a host of difficulties became apparent:

Among other complications, 93 known uterine perforations had occurred, a rate 15 times higher than that reported by Tietze (6) with the loop. Complaints of cramps, bleeding complications and expulsions were also extraordinarily common. All manner of grossly exaggerated and imaginative rumors were in circulation. Loops were said to have migrated into the lung; another loop was said to have been expelled by the mouth. As a result of these rumors and complications, the Singapore IUD project became a *crash* program in every sense of the word.

A comprehensive report on the Singapore experience with loop complications has been prepared by Wolfers, Ratnam and Tow (9). *Tow found that 86 of the 93 loop perforations observed occurred in patients fitted less than 8 weeks postpartum*. He was also able to determine the site of the perforation in 32 of these cases, and found that 30 of them occurred in the upper cervical

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presence of the device. If removal is indicated, grasping the tail and applying gentle traction will deliver the device easily in most instances.

There is a tendency for all intrauterine devices to accumulate small deposits of calcium on the surface of the plastic with prolonged use. Engineer *et al* (1) have studied the encrustations formed on the loop after 15 to 40 months of use, when the devices were removed because of menometrorrhagia. The strength of materials of the device and/or the tail of the device also tend to become compromised in time. The addition of a small amount of gum silicone to the loop device has been recently undertaken in an attempt to reduce this problem. The removal and insertion of the modern devices is such a simple matter that we have favored replacement with a fresh device after two years of use, thereby avoiding any such difficulties.

Problems with removal can arise because of partial embedment of the device or because of retraction or breakage of the marker tail. Embedment is most common with the bow type of device and the stainless steel spring wire devices. The rather stiff lower portions of the bow tend to work their way through the endometrium into the myometrium, thus accommodating the discrepancies between the shape of the device and the shape of the normal uterine cavity. Open ring, coil and open loop devices also can become partially embedded, causing difficulties in removal, but with lesser frequency. Because the central membrane of the shield device prevents the overgrowth of endometrial tissue, embedment is precluded. Usually, embedment of the loop or double coil devices can be overcome merely by applying somewhat greater traction on the tail.

Poor quality plastic IUD's represent a special problem in removal. Serious difficulties have arisen in some of the overseas programs from using intrauterine devices (principally of the loop type) made of inferior materials. The few pennies saved by this policy proved a poor economy when the inferior materials became brittle with prolonged use, tending to fragment when removal was undertaken. The use of such devices should be condemned, especially since the cost of even the finest intrauterine device is a negligible fraction of the cost of recruiting and managing patients in a family planning program. Hospitalization and currettement has been required for the removal of such fragmented loops.

Difficulties with removal of the Majzlin spring device (Fig. 28) can generally be overcome if suitable removal hooks are available. Majzlin (5) recommends: "In instances where removal was more obstinate, the string was grasped above the knot with an instrument called a 'retriever' and by continued twisting, the lower members of the IUD came close together until extraction became an easy matter. In about one third of the removals, the strings had become detached. In these instances, one of the members of the IUD was grasped, and by twisting once or twice, the device was freed and lifted from any depression into which it might have settled. Then, by firm, steady traction the device was delivered."

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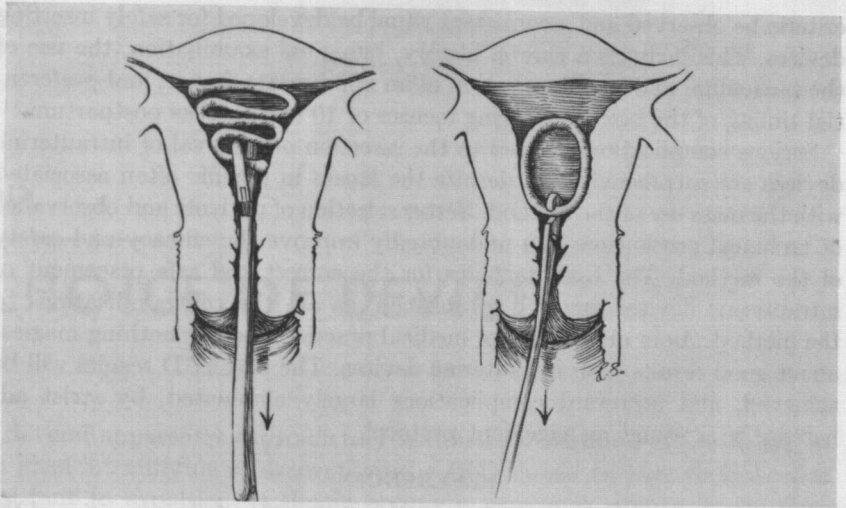


FIG. 29. Cystoscopic alligator forceps and IUD removal hook useful for the removal of devices when the trans-cervical marker tail is absent or retracted. In using these instruments, counter traction with a tenaculum applied to the cervix is important to straighten the axis of the cervical canal and minimize the risk of uterine perforation. A paracervical block is useful during difficult removals to minimize patient discomfort.

of the uterine cavity carried out to determine the axis of the cervical canal and the position of the device. The removal hook is then introduced and gently retracted until engagement with the device is felt. Firm, steady traction on the hook is then applied to deliver the device.

Rarely, the lower segment of the device may be broken, making engagement with the removal hook difficult. An alligator forceps, such as is commonly used to grasp and extract stones or foreign bodies from the bladder, is a useful instrument under these circumstances (Fig. 29). Major hospital or Planned Parenthood clinics should have available the necessary hooks and forceps to carry out removals. To prevent difficulties with removals, it is preferable to use intrauterine devices which do not readily embed. The plastic devices with a stout, high-quality tail will seldom occasion difficulties with removal. Simple traction on the tail will almost invariably deliver the device. Indeed, even if the tail of the device has retracted or broken, its removal by means of a hook is a simple procedure for anyone accustomed to taking endometrial biopsies.

SUMMARY

The cardinal principles to be followed in conducting a successful IUD program are careful observance of contraindications and meticulous adherence to technical precautions. It is of great importance that strict

criteria be observed and a consistent ritual be developed for safely inserting devices. This includes a careful history, bimanual examination, the use of the tenaculum and sound, selection of an appropriate device, and preferential timing of the insertion during menses or 10 to 12 weeks postpartum.

Serious complications related to the insertion or removal of intrauterine devices are surprisingly rare despite the lapses in technic often associated with the mass use of the method. Better selection of patients and observance of technical precautions can undoubtedly improve the efficacy and safety of the method. The basic technics for the correct and safe placement of intrauterine devices are well established, as are the contraindications to the method. As in other areas of medical practice, there is nothing magical about good results with intrauterine devices. The best IUD results will be achieved, and untoward complications largely eliminated, by strict adherence to a sound management protocol.

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Six

CHOICE OF DEVICE

Several apparently contradictory features are required in the design of an ideal intrauterine contraceptive: the IUD should be easy to insert but resistant to expulsion; it should occupy a variety of uterine cavity sizes adequately, but not distend the smaller uteri unduly; it should produce sufficient endometrial response to yield low pregnancy rates, but not produce high rates of medical removals. The challenge to bioengineers posed by these requirements is considerable, no doubt accounting for a plethora of designs.

In producing improved devices, progress has been hampered by a lack of accurate anatomic data. As long ago as 1931, Robert Dickinson reviewed the problems inherent in IUD design (5), and observed despairingly that "We have had singularly little detailed information on the conformation of the interior of the uterus." He contributed a number of measurements and drawings, well aware of the importance of accurate anatomic information as a basis for improved models. Unfortunately, most of the devices used since the revival of interest in IUD's in 1959 have been empirically designed because of the lack of precise anatomic information.

FACTORS INFLUENCING TOLERANCE

The problems created by insertion of large IUD's into small uteri have been evaluated by Tejuja and Malkani at the All-India Institute of Medical Sciences. (8). They found that 40 % of women had complaints of persisting heavy menstrual bleeding after insertion of a loop. This study provides data by hysterography and planimetry regarding the size variations of the normal Indian uterus *in vivo*. The frequency of complaints of menometrorrhagia correlated strongly with the disproportion between the size of the loop and the size of the average uterus.

The Indian investigators also found that pain, especially backache and dysmenorrhea, afflicted 30 % of their patients after loop insertion. Of these women with persistent complaints of pain, 60 % had uterine cavity areas

of 6 cm.² or less. Only 10 % of women with larger cavities had complaints of pain. On the basis of difficulties documented with bulky devices in clinical practice, one can conclude that incompatibilities between the size of devices and the potential uterine cavity space are responsible for most IUD symptoms.

The first contemporary studies of normal uterine cavity size were carried out by Israel (2) in 1964. Silicone rubber casts of the uterine cavity were prepared from a series of normal premenopausal uteri removed at vaginal hysterectomy six months or more postpartum. Several of these silicone rubber casts are reproduced in figure 30. Variations can be noted in the size and configuration of the normal cavity, although the basic pattern is that of an inverted isosceles triangle. If the specimens had included postpartum and nulliparous uteri, even greater variations in uterine cavity size would no doubt have been observed.

A useful index of the variance in uterine cavity size can be obtained by measuring the width of the cavity at two points—1 cm. from the top of the fundus (transverse superior) and 2 cm. from the top of the fundus (transverse inferior). Figure 31 shows the distribution of these values obtained by measurement of 50 normal interval uteri. A substantial variation can be seen, though in definite linear distribution, since the two values are interrelated. Twenty percent of the uterine cavities are 27 mm. or less in this dimension. Obviously, if a relatively stiff intrauterine device corresponding to the upper range of uterine cavity size is used, overdilatation of the smaller uteri will occur. Either the device must accommodate to the uterus or the uterus must accommodate to the device. When the latter occurs, uterine protest occurs in the form of cramps and bleeding, causing high rates of medical removals.

As a result of discrepancies between stiff linear devices and uterine anatomy, significant patient loss occurs because of expulsions and medical removals, principally for cramps or bleeding. These rates decline in the second and third year of use, as women with the most severe complaints abandon the method (Table 10).

According to the Cooperative Statistical Program (CSP) data, the usefulness of the D loop is compromised by expulsion or the need of medical removal during the first year of use in 25 % of patients. An additional 24 % of patients experience expulsion or removal during the next 24 months with the large loop, with medical removals unquestionably the most frequent cause of discontinuation. Data from the double coil type of IUD shows even more frequent medical removals, as might be expected, since the bulk of this device is even greater than that of the standard D loop. From a point of view of demographic effectiveness, discontinuation of the method because of expulsions and bleeding complications is 10 times as important as pregnancy rates with the device *in situ* in influencing the

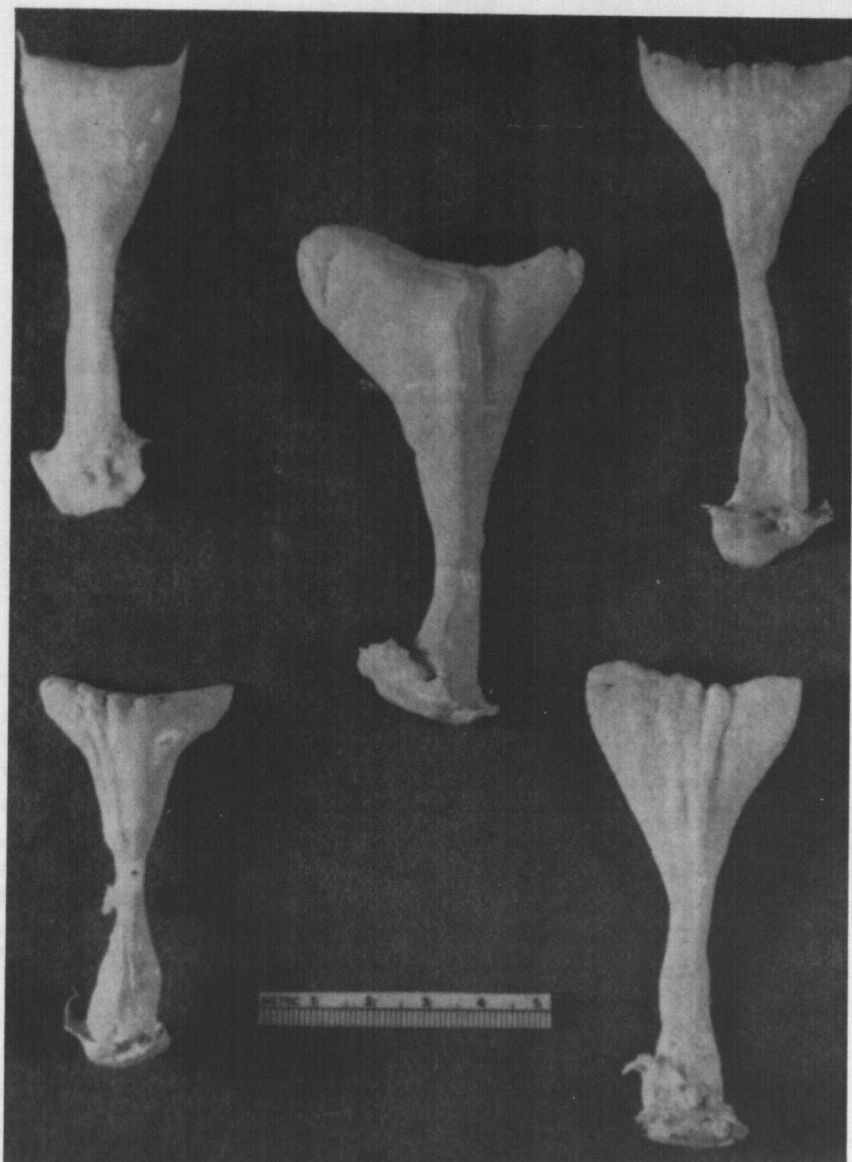


FIG. 30. Silicone rubber casts of normal, interval uterine cavities, prepared from fresh vaginal hysterectomy specimens. Data derived from such casts has proven useful in explaining complications, and in the development of more anatomically correct IUD designs. (Davis, H. J. and Israel, R.: Uterine cavity measurements in relation to design of intra-uterine contraceptive devices. *Proc. of the Second International Conference on Intrauterine Contraception*. Excerpta Medica Foundation, New York, 1964.)

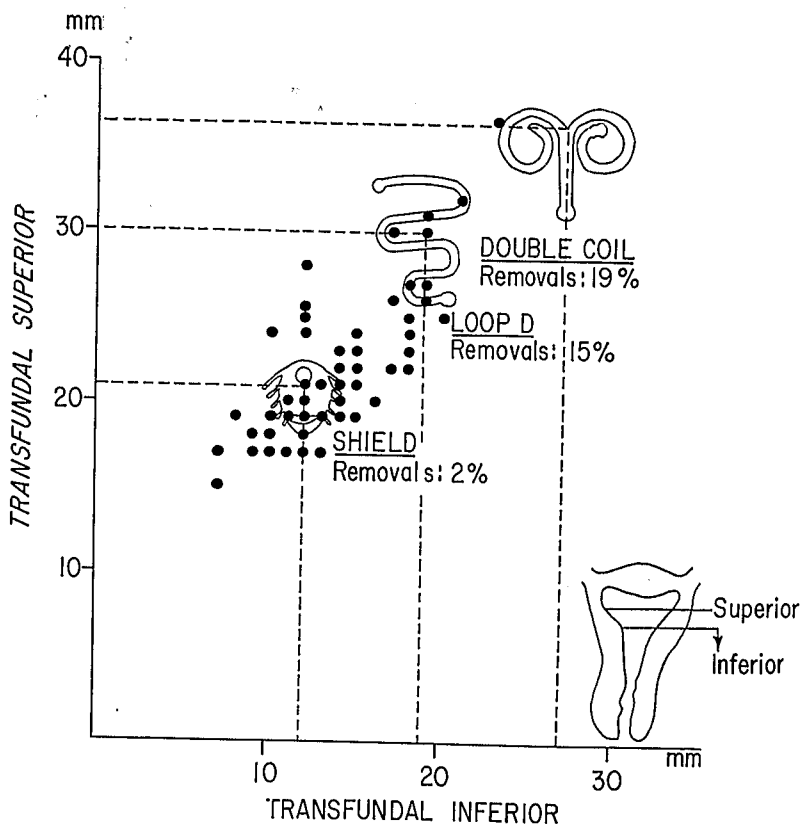


FIG. 31. Disproportion between standard size linear intrauterine coils and loop devices and uterine cavity size results in a significant incidence of removals, principally for cramping and bleeding complications. The use of small, flexible devices has greatly reduced the incidence of patient complaints and medical removals. (Davis, H. J. and Lesinski, J.: Design factors influencing IUD retention and tolerance (in press), 1971.)

TABLE 10

Net annual events per 100 women with loop D intrauterine device (10)

	1st Year	2nd Year	3rd Year	4th Year	5th Year	6th Year
Pregnancies	2.7	2.0	1.2	1.4	0.6	0.9
Expulsions	9.5	2.5	1.6	0.8	0.2	0.0
Medical Removals	15.2	10.6	9.5	7.2	5.8	2.8
Personal Removals	3.1	4.5	4.5	4.8	4.1	3.2

success of a national program. For this reason emphasis has shifted to the use of devices which are better retained and tolerated.

FACTORS INFLUENCING EXPULSION

The specific design of an IUD not only influences medical complications but expulsion rates as well. Obviously, if the device is to prove of value it must be well retained. As with pregnancy rates, the factors which lead to optimal IUD retention have not been generally appreciated.

If the expulsion problem is approached statistically rather than from a point of view of the anatomy and physiology of the uterus, misleading conclusions are reached. For example, the large loop has fewer expulsions than the small loop, and the same is true of the large coil as compared with the small coil. One can conclude, therefore, that the uterus has difficulty expelling the larger devices, simply because of their bulk. It also happens, however, that the larger versions of the loop and coil are not only larger, in terms of outside circumference, but also much less pliable. Uterine contractions can therefore more easily distort the small coils and loops into a linear form suitable for expulsion. The larger loop and coil devices being less flexible, distort less readily and expulse less frequently than the flimsier smaller versions.

Promoting the retention of IUD's by increasing the stiffness of the material has practical limits, however, and other mechanisms come into play when expulsions are reduced to 2% or less. If the pressure of uterine contractions is absorbed by the device and transformed into a distortion of the device which promotes retention, expulsions can be even more efficiently reduced.

To a unique degree among the modern intrauterine devices, the shield combines softness and flexibility with almost perfect retention. The specific design of this device makes it inherently fundus-seeking and resistant to expulsion. Lateral compressive forces applied to the shield cause the lower portions of the device to flex out of the plane of the uterine cavity, thereby increasing resistance to expulsion in proportion to the strength of the contraction. When a potentially expulsive contraction ceases, the pressure on the perimeter of the shield is relieved, and the device resumes its former position in the plane of the cavity. The orientation of the flexible lateral fins on the shield contributes to retention by making the device fundus-seeking.

Partial embedment can also result in efficient retention. The low expulsion rate of the bow device is undoubtedly due to this mechanism (Fig. 32). The wide lower prongs of the bow design impinge on the lower uterine segment, thereby fixing the upper portion of the device in position. It is an efficient, though not an ideal retention mechanism. According to the CSP data, patients fitted with the large bow had 2.1 expulsions per 100 users

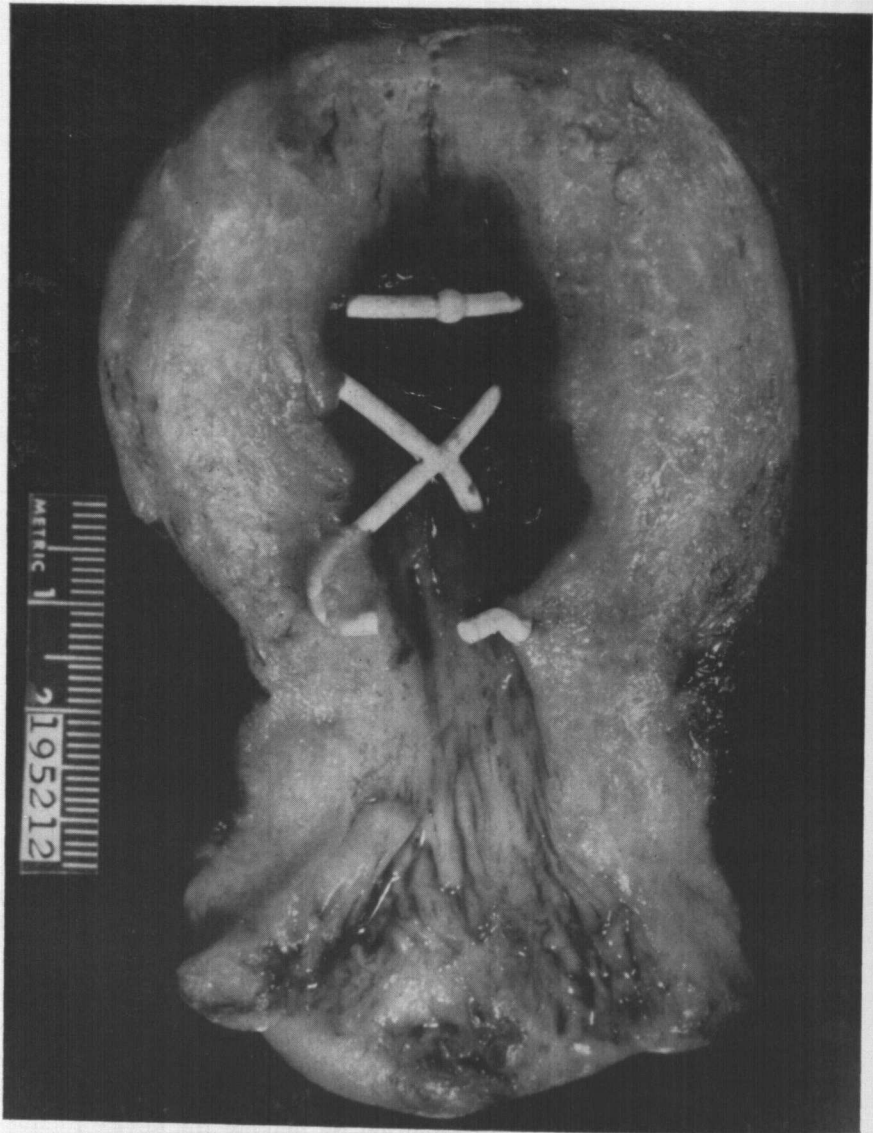


FIG. 32. Partial embedment of bow type of device resulting from disproportion between the stiff lower prongs and normal uterine cavity contour. Good retention is achieved, but poor endometrial surface contact results in unsatisfactorily high pregnancy rates.

in the first two years of use, as compared with 12.9 with the large loop and 26.9 with the large coil (10).

The Majzlin spring device is also retained because of embedment of the fine wires of the device in the uterus. The wires act like a cheese cutter,

driven by the restricted space within the cavity and uterine contractions. The tendency is for the device to form deep grooves, rather than to expulse under the influence of uterine contractions. The spring had only 2.1 % expulsions in the first year of use in an evaluation carried out at the Kings County Hospital in New York (7).

OTHER FACTORS INFLUENCING PERFORMANCE

The age of the patient markedly influences pregnancy and expulsion rates (Fig. 33) with the linear coils and loops. The age of the patient can therefore be used to anticipate the efficacy of a particular device, and should be taken into account in choosing such devices for contraception. The age-specific complication rates with the standard D loop demonstrate this relationship (Table 11).

Clinical disenchantment with the loop type of intrauterine device has occurred in view of the high incidence of complications. Pregnancies and expulsions are especially frequent causes of failure among women under the age of 30, having twice the incidence in these highly fertile young women as the usually published figures (averaging women of all ages) would indicate. Medical removals, principally for cramps and bleeding, became necessary in nearly one-third of the women under age 30 and in one-fourth of the older women in the CSP series (10) within 2 years after fitting with the commercially available D loop.

The complication rate with the loop is highest among women of low parity under the age of 25. Expulsions occurred in 20 % of these young women, removals were necessary in 29 % for medical reasons and 7.3 % became pregnant. Thus, the complication rate with the loop among women under age 25 is so high that over half the cases fitted experienced expulsion, medical removal or became pregnant. The performance of another popularly distributed linear type of IUD—the double coil—shows even higher rates of expulsion and medical removals than the loop and similarly high pregnancy rates. In fact, the linear coils and loops have little to recommend them in comparison with the 1930 Gräfenberg silver ring except for being easier to insert.

The cumulative effect of the major IUD complications categorized as pregnancies, expulsions and medical removals in the first year of use can be seen in figure 34. The major devices which have been used either clinically or experimentally from 1930 through 1970 have been ranked by Lardner et al (6) at the Massachusetts Institute of Technology on behalf of the Pathfinder Fund. Many of the devices listed are experimental designs which have been abandoned because of technical difficulties with insertion or removal. Others have achieved broad distribution without having outstanding qualities by virtue of promotion by commercial organizations or official agencies supporting mass programs. Those interested in the technical details and sources of specific devices can consult the appendix.

Among the commercially available devices, the shield has shown the best performance, with continuation rates of 95%. The distinctly superior retention qualities of the second generation IUD's in comparison with the old linear coils and loops is manifest.

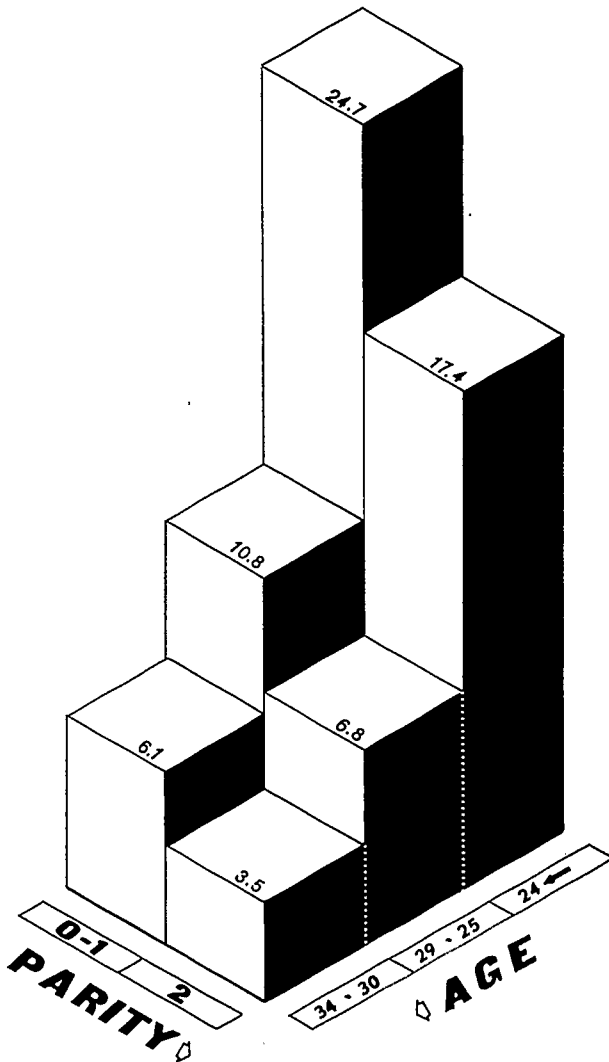


FIG. 33. High expulsion rates among young women of low parity compromise the effectiveness of the loop intrauterine device. Above the age of 30 at a parity of 2 or more, the retention of the loop is substantially better, making it a satisfactory contraceptive for spacing purposes among parous older women. (Courtesy of Dr. Roger Bernard.)

TABLE 11
Age-specific complication rates with loop D in 2 years

Age Group	Pregnancies	Expulsions	Removals
15-24	7.3	20.2	28.9
25-29	5.7	11.1	26.2
30-34	3.3	8.0	23.4
35-49	1.7	6.1	23.3

USE OF IUD'S IN NULLIGRAVIDAS

It has generally been held that women who have never been pregnant are unsuitable subjects for IUD insertion. Experience has shown that nulligravidas are quite likely to suffer severe cramps in the first 24 to 48 hours following insertion of a standard loop or coil intrauterine device, and that medical removals of such devices are nearly twice as frequent as in a parous population. The tolerance of an intrauterine device by nulligravid patients is therefore a good test of the uterine compatibility of various devices.

Among 27,000 insertions of intrauterine devices reported through the Cooperative Statistical Program (9), a total of 92 insertions of large loops, large spirals and large bows were carried out in nulligravidas. Nine of these devices had to be removed within 48 hours because of severe pain. Nearly half of the nulliparas, fitted with bulky coils and loops, terminated the use of IUD's within the first year because of symptoms or expulsions. Among 69 patients fitted with much smaller stainless steel rings, no removals for severe pain in the first 48 hours was reported.

During the past 3 years, a substantial number of nulligravidas have been fitted with small, flexible types of intrauterine devices at Johns Hopkins and at the Maryland Planned Parenthood Clinic. During the first part of this series, the stainless steel band device was used and found to be well retained and well tolerated, but with an unacceptably high pregnancy rate. Our more recent experience in nulliparas has been with the shield IUD. In 2 years, over 300 insertions were carried out. There have been only 5% removals for pain or bleeding, and only 2 expulsions of the small shield device in our series of nulligravidas. Thus, the nulligravid patient can be fitted with an IUD with every expectation of a satisfactory result, provided the device is compatible with the smaller size range of uterine cavities and has good retention qualities. (See Fig. 35.)

SUMMARY

The standard loop and coil types of intrauterine device popularized in the mid-1960's have been chiefly useful in mass programs where the problems of distribution, poor motivation and the relatively higher cost of oral

PERFORMANCE OF MAJOR IUD'S DEVELOPED SINCE 1930

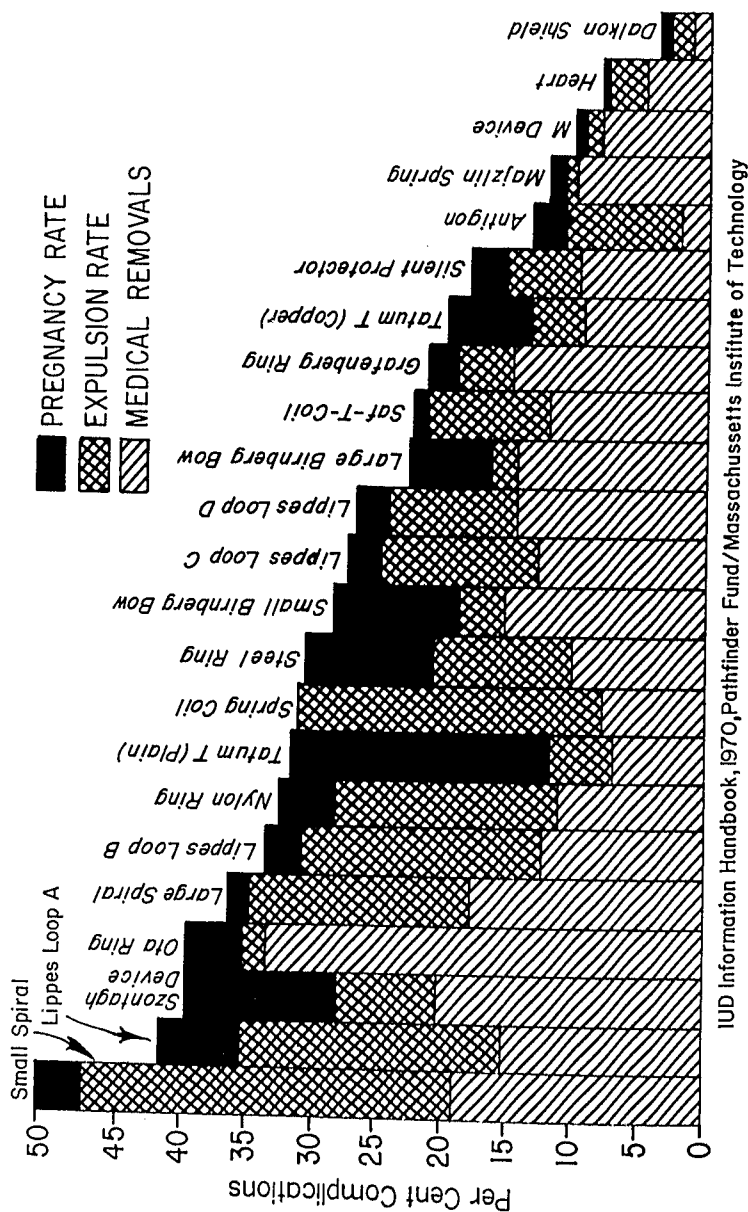


Fig 34. Comparison of the pregnancy rates, expulsion rates and removals necessary for cramping and/or bleeding complications shows differences as great as 10 fold in IUD performance. Particularly striking is the fact that results with the commercially distributed coil and loop devices are inferior to those obtained with the Grafenberg ring developed in 1930. (Courtesy of Prof. T. J. Lardner).

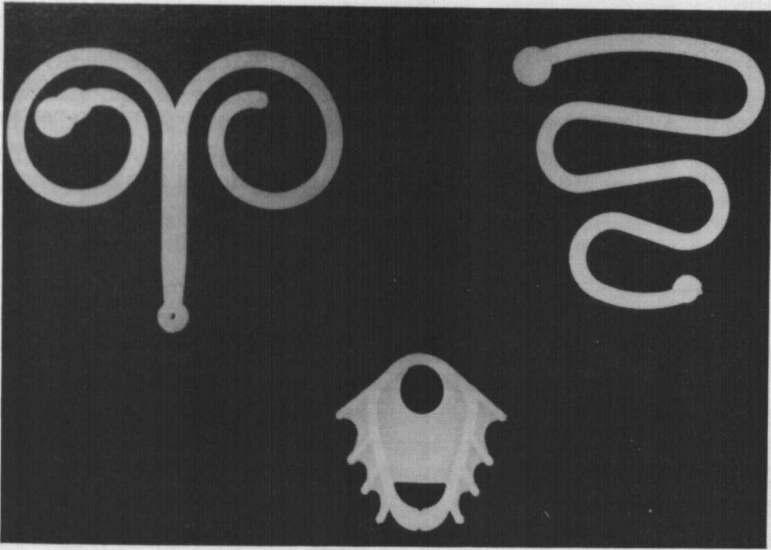


FIG. 35. Contrasting size of standard loop, double coil and shield intrauterine devices. The small shield measures 20 mm. transversely and 22 mm. in length. The small shield is well retained and well tolerated by nulliparas as well as by parous women with smaller than average uterine cavities. The relatively bulky standard size coil and loop devices are incompatible with nulliparous uteri, as well as with a significant proportion of multiparous uteri.

contraceptives make the IUD a superior contraceptive. The coils and loops have also achieved good acceptance as a means of spacing pregnancies in women who have borne one or more children, among whom the convenience and lack of systemic complications of the IUD method have made it popular.

Nevertheless, the cramping and bleeding complications, expulsions and relatively high pregnancy rates associated with the loops and coils have made these IUD's less effective and less popular than oral contraceptives in clinical practice. The pregnancy rates have been particularly high among women under the age of 30 with these linear devices, while their use among nulliparous women has been severely limited by high rates of complaints.

The performance of the second generation IUD's is distinctly superior to results with the old linear coils and loops. Expulsion of the modern devices is a rare event. Bleeding complications and pregnancy rates are also substantially lower with the modern IUD's than rates reported with the linear devices. Contraceptive programs which are effectively utilizing the modern IUD's are experiencing an increasing demand for this birth control method, as both patients and staff develop an appreciation of the advantages of intrauterine contraception.

As factors such as the surface area and chemical composition of the

device have been shown to influence pregnancy rates, advantage has been taken of these principles in the manufacture of IUD's. Virtually 100% efficacy is being obtained with the best modern intrauterine devices containing trace element additives with specific anti-conceptive properties.

Of the commercially available IUD's, the shield design has demonstrated the lowest rate of medical removals in clinical trials among both parous and nulliparous women (Fig. 36). Among the various devices, the shield also conforms most closely to the average uterine cavity size. The

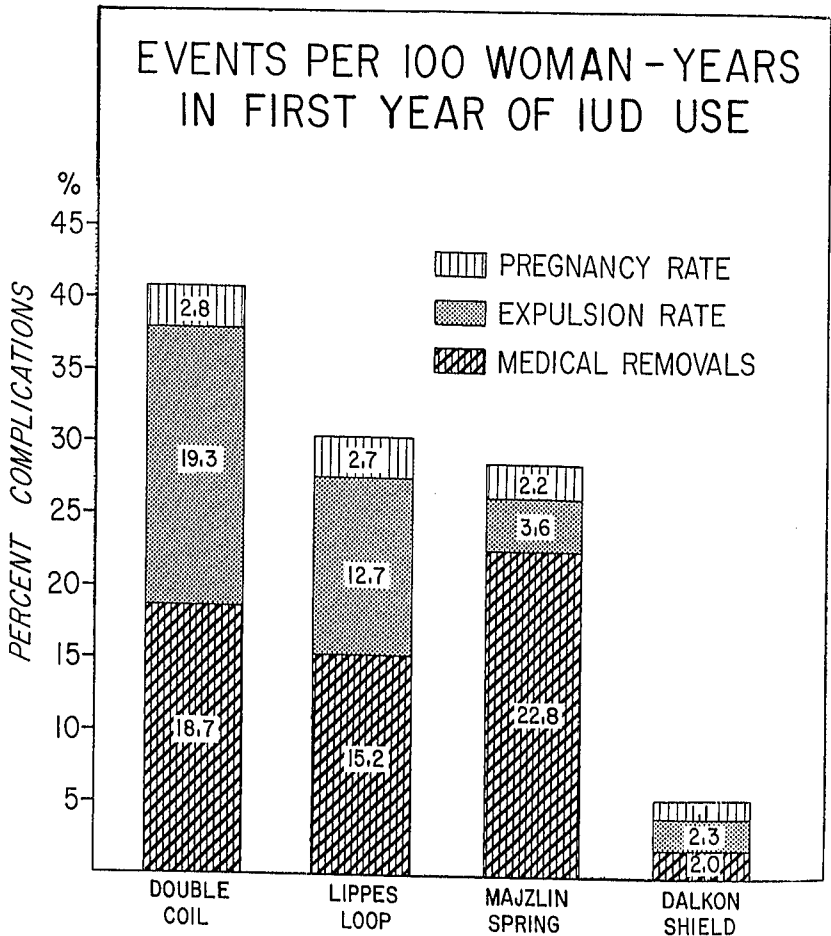


FIG. 36. Comparative performance of the major commercially available IUD's. Expulsion rates with the spring and shield devices are much lower than with the older coils and loops. Bleeding complications and pregnancy rates are lowest with the shield device. (Data from Tietze, C. and Lewit, S.: Evaluation of intrauterine devices: ninth progress report of the Cooperative Statistical Program. Studies in Family Planning, 55: 1-40, 1970. and Davis, H. J.: The shield intrauterine device—a superior modern contraceptive. Am. J. Obst. Gynec., 106: 455-56, 1970.)

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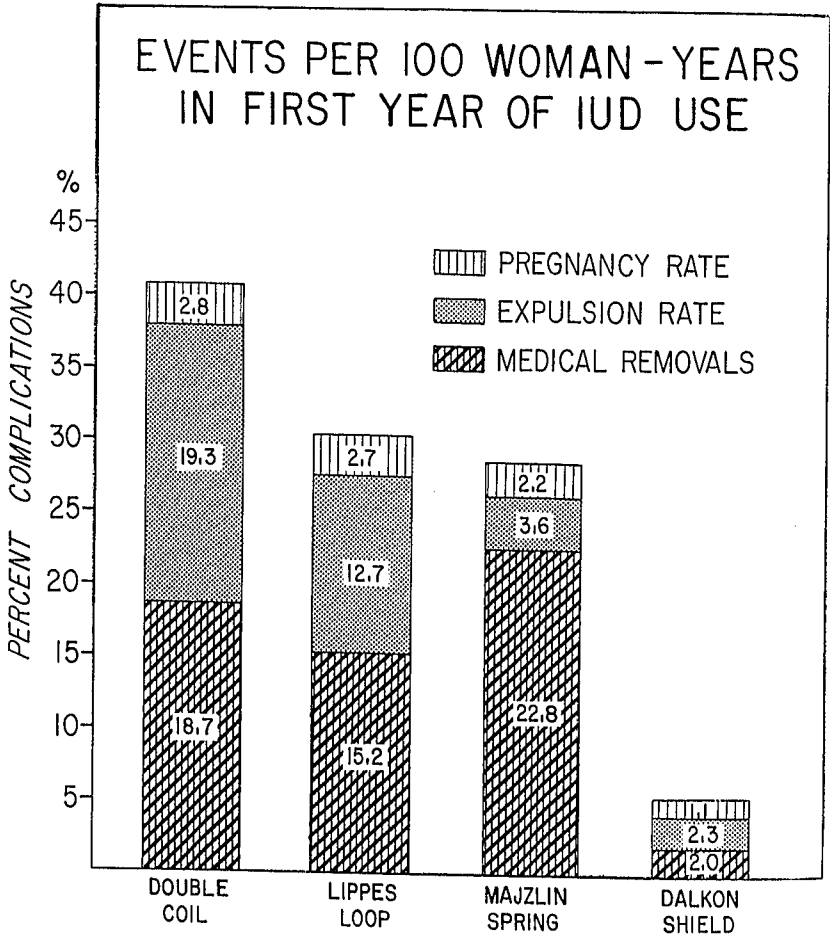


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such as her age, parity and the interval postpartum, have a profound influence on IUD performance. These factors particularly limit the usefulness of the linear coil and loop devices. The incidence of expulsions, bleeding complications, cramps and pregnancy rates are also influenced by the anatomy and physiology of the uterus. Taking these factors into account in the selection of devices most appropriate for a particular patient category can greatly enhance the quality of results achieved with intra-uterine contraception.

Years of empiricism in IUD design appear to be ending with the introduction of devices which are engineered for compatibility with normal uterine anatomy and physiology, and which take advantage of current knowledge of the mechanism of action of IUD's to achieve optimally low pregnancy rates.

Medical removals for cramping and bleeding complications can be largely eliminated by selecting the proper size of IUD and by the use of devices which are intrinsically flexible and therefore capable of adapting to physiologic uterine contractions. The sophisticated design of modern devices resists expulsion not by crude bulk or stiffness, but by utilizing the forces of uterine contraction to make the device fundus-seeking. Such second generation IUD's combine uterine compatibility, ease of insertion, excellent retention and virtually 100% protection against pregnancy. These outstanding features are destined to make the IUD increasingly useful in the clinical practice of contraception as well as in demographic applications.

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Seven

ETHICAL CONSIDERATIONS

The attitude of theologians and the body of law relative to contraceptive practices has undergone substantial modification in recent years. The position of the medical profession and the public attitudes towards fertility control have undergone no less significant change. Society increasingly recognizes that birth limitation is both a basic human right and a necessity for the preservation of civilized life. Today, no major body of religious opinion has failed to undertake review of its doctrines on birth control, and even the most conservative opinion no longer challenges the need for responsible parenthood.

Traditionally, there has been greater acceptance of contraception than of abortion or sterilization. Yet this view dates from the diffusion of contraceptive technics of reasonable efficacy, and has not always prevailed. Questions of what is right and what is wrong in the control of fertility have been considered by philosophers and theologians for millenia. Historically, regimes in need of soldiers have generally taken strong positions against birth limitation. A classic example of this policy is the code of the Assyrian Law relating to Women, circa 1500 B.C., which promulgated: "If a woman of her own accord causes to fall what her womb holds, she shall be tried, convicted, and impaled upon a stake and shall not be buried." In later and less barbaric era, most of the Greek philosophers recognized the problem inherent in unrestrained human breeding. Both Plato and Aristotle favored abortions to keep the population within the limits considered essential to a well ordered community.

CHRISTIAN ATTITUDES

Christian orthodoxy has generally opposed both contraception and medical abortion, though not without exceptions. Of interest in this regard was a letter of Innocent III to a Carthusian priory about a monk who had caused his mistress to abort. Asked for a ruling on whether the monk should be disciplined, the Pope held that he was not irregular (i.e., that his functions as a priest need not be suspended) because the fetus was not "vivified"

(4). In the fifteenth century Thomas Aquinas supported a similar point of view. He defined the soul as the first principle of life in those who lived, adding that life is shown principally by knowledge and movement. This concept became embedded in Common Law, dating from the time of Aquinas, associating ensoulment and therefore the commencement of human life with quickening. According to Blackstone, "Life begins in contemplation of law as soon as the infant is able to stir in the mother's womb."

The changing Christian attitudes towards family planning practices can be illustrated by events in Boston, spanning little more than a century. In that city, in 1832, Dr. Charles Knowlton published a pamphlet entitled, "Fruits of Philosophy or the Private Companion of Young Married People", describing post-coital douches as a contraceptive. He was denounced by the Boston Medical Journal on the grounds that the pamphlet—which sold nearly 250,000 copies—was "bad for public morals." Despite the distinction of being a fellow of the Massachusetts Medical Society, Knowlton was brought to trial and rewarded with three months at hard labor in the East Cambridge jail, which no doubt encouraged him to publish on less controversial subjects.

Such obstacles to providing contraceptive services persisted in Boston for over 100 years, but in the decade after 1960 tremendous changes in public attitudes and official policy took place even in that bastion of conservatism. One can contrast Knowlton's fate with the address delivered in April, 1970, by Harvard's Professor of Obstetrics, Dr. Duncan Reid, before the American Association of Planned Parenthood Physicians meeting in Boston. Prof. Reid strongly urged the necessity of contraception, sterilization and medical abortion. Needless to say, no arrests were made, although the standing ovation he was given must have been audible to the local gendarmerie.

The restrictions to contraceptive services in the United States have undergone significant change by court action as well as by the repeal of archaic legislation. In 1965 the U.S. Supreme Court rules unconstitutional the 1879 Connecticut law making illegal for anyone, married or otherwise, to use contraceptives, or for a physician to prescribe them. Until the early 1960's almost all efforts to change federal and state anti-birth control laws had failed. By 1966, however, most of the states having such repressive laws had either repealed them or modified them to permit expanded contraceptive programs. A similar fate appears likely for most of the laws prohibiting or unduly restricting the availability of medical abortion or sterilization.

ROMAN CATHOLIC ATTITUDES

Theological opinion on the subject of birth control within the Roman Catholic Church is currently in a state of flux, after centuries of silence.

It is only in the last 50 years that the Catholic Church has seriously re-evaluated its attitude towards sexuality and marriage or concerned itself with contraception aside from maintaining a traditional opposition to coitus interruptus. The deliberations of Vatican Council II and the issuance in July, 1968, of Pope Paul's encyclical *Humanae Vitae* focused attention on the ethics of current contraceptive methodology, and in the process, precipitated the greatest movement of dissent within the Roman Catholic Church since the Reformation.

The issuance of *Humanae Vitae* polarized Catholic opinion throughout the world by recognizing the seriousness of unrestrained population growth, while simultaneously inveighing against effective methods of dealing with the problem. This contradictory position has been rejected by many Catholic leaders, following the statement of the Dutch bishops one month after the encyclical:

"In the formation of conscience, an authoritative role should be given to the word of the magistry, even if in this case of *Humanae Vitae* we are not faced with an infallible teaching. The priests and the faithful have therefore to study the document carefully, giving however, the last word to conscience."

A similar pattern of reaction, giving emphasis to the role of individual conscience in determining methodology, rapidly developed in German, Belgian, Austrian, Canadian, Swiss, British, Irish, Indonesian, Australian, South African, Scandinavian and the United States Catholic Conferences. Meanwhile, the percentage of Catholic women conforming to the doctrinaire position of the Church opposing contraception has been steadily declining. *In 1960 the percentage of married white Catholic women in the United States conforming (using no contraception or rhythm only) was 62%. One year after the issuance of Humanae Vitae, a substantially lower proportion of Catholic women were conforming: only 36% accepted the restrictions on choice of birth control methods imposed by the encyclical (6).*

Interestingly, it was largely against a background of social pressures of a different sort—the threat of depopulation—that the opposition of the Christian Church to birth control evolved. Methods of inducing abortion, coitus interruptus and the woolen tampon technic were apparently well known and efficiently utilized among the upper social classes in Imperial Rome. In the last century B.C. and the first century A.D., the government became concerned with the decline of the Roman nobility when civil service posts had become difficult to fill from the citizenry, and the ranks of the army were being depleted (4).

Legislation introduced in the first century by Caesar Augustus reflected this concern with the falling birth rate in the upper class. The *Lex Julia de maritandis ordinibus*, of 18 B.C., and the *Lex Pappia Poppaea*, of A.D. 9, represented an effort to stimulate births among the governing group by a system of rewards and penalties. The childless were disqualified from hold-

ing high offices, such as praetorships or provincial governorships, and inheritance between surviving spouses restricted to one-tenth of the estate if the couple had remained childless. Tacitus, writing about A.D. 117, reported that the Augustan laws failed to increase marriages and the rearing of children. Serious plagues, such as that of 166-180, and a variety of wars further reduced the population of Roman citizens. It became necessary to recruit barbarians, commencing under Hadrian, to fill the ranks of the Army. The decline in population was further aggravated by the prevailing high rates of both infant and adult mortality.

THE MANICHEAN HERESY

The concern with a declining citizenry coincided with a threat to Roman Orthodox authority posed by a new religion—Manicheanism. The early Church doctrine crystallized into a rigid opposition to all forms of contraception when both the Church and the State felt threatened by this heresy which advocated celibacy and opposed procreation. The prophet Mani (216-177) founded a new religion in Babylon blending Christianity with Gnosticism and Iranian folk religion. Manicheanism spread before his death to Egypt, Palestine and Rome (5). Like Christianity, it was a missionary faith. By the middle of the fourth century many Christians had been converted, the most famous being St. Augustine, who was an active Manichean from the age of 18 to 29. The Manichean doctrine dissociated sexual activity from procreation, and praised virginity for the elect. Christians accused the Manicheans of practicing coitus in exotic positions and encouraging the use of withdrawal for contraception. A series of imperial enactments between 372 and 444 were designed to protect the Catholic Church and the Roman State from the challenge of this new religion.

After his conversion to Christianity, St. Augustine turned against his former Manichean colleagues, combating their contraceptive practices with an ethic making procreation the sole object and justification of intercourse. In his reaction to Manicheanism, Augustine condemned all forms of contraception (4), including the rhythm system, another Manichean practice:

“Is it not you who used to warn us to watch as much as we could the time after purification of the menses when a woman is likely to conceive, and at that time refrain from intercourse, lest a soul be implicated in the flesh? From this it follows that you consider marriage is not to procreate children, but to satiate lust. Marriage, as the marriage tablets themselves proclaim, joins male and female for the procreation of children. Whoever says that to procreate children is a worse sin than to copulate thereby prohibits marriage; and he makes the woman no more a wife but a harlot, who, when she has been given certain gifts, is joined to man to satisfy his lust. If there is a wife there is matrimony. But there is no matrimony where motherhood is prevented; for then there is no wife.”

Augustine's preoccupation with sexual questions, coupled with his zeal in stamping out Manicheanism, may have had its roots in his own experience. He had 11 years of active sexual life prior to re-embracing Christianity at the age of 29, when he abandoned his mistress and one son. In addition to his preoccupations about contraception, he was very concerned with "natural" coital positions, regarding any variation from the man-superior-woman-recumbent-on-the-back position as sinful. It is interesting that Augustine did not view abortion (not part of the Manichean doctrine) as the destruction of human life, considering the foetus not to be human until fully formed as a foetus and "ensouled". Over 70 generations of Christians were to share Augustine's reaction against Manichean sexual practices, once his views became embedded in the fabric of dogma.

Thus, the early Christian Church, acting under the threat of the Manicheans to its authority, and the urgent needs of Imperial Rome for Army recruits, adopted under Augustin a rigid posture making unrestricted procreation the sole object of marriage. Intercourse without procreative purpose and all forms of contraception (including rhythm) were considered sinful practices until modern times. In this curious manner, the "traditional" position of the Christian Church was formed in the fourth century.

Fifteen centuries later the stern language of Pius XI can be understood as an effort to restore the authority of the Augustinian view on sexuality. Certainly, the language of Casti Connubii in 1930 left little doubt as to Pius XI's support of unrestrained reproduction: "Any use whatever of marriage, in the exercise of which the act by human effort is deprived of its natural power of procreating life, violates the law of God and nature, and those who do such a thing are stained by a grave and mortal flaw."

Not long thereafter the prohibitions in Casti Connubii were being cautiously modified, as indicated in an address delivered by Pius XII before the Italian Catholic Society of Midwives. *For the first time, in 1951, the rhythm system of contraception was specifically approved by Papal authority.* Publication of this address in the Acta Apostolicae Sedis proclaimed the softening of the official Roman doctrine. Pius XII indicated that the use of contraception was not justified except for grave reasons, but given serious motives "It follows that observance of the sterile period would be licit."

ATTITUDES OF OTHER FAITHS

Other Christian churches were simultaneously modifying their position. Commencing with the Anglican decision in 1929, most Christian churches departed from the Augustinian restrictions and prohibitions on contraception. The bodies changing their stand were as follows: the Congregational Christian General Council (1931); the General Council of the United Church of Canada (1930); the Methodist Conference of Great Britain (1939); the British Council of Churches (1943); the Lutheran Church of Sweden (1951);

the Dutch Reformed Church (1952); the Methodist Church in the United States (1956); the United Lutheran Church in the United States (1956); the Lutheran Church of Finland (1956); the International Convention of the Disciples of Christ (1958); the World Council of Churches (1959).

Almost obscured in the conflict over the role of conscience in determining appropriate methods of contraception, and the obvious challenge which has developed to the Papal Authority, an even more significant change has taken place in the official position of the Roman Catholic Church: *Vatican Council II's official teaching indicated for the first time that parents and parents alone have the right to decide the number of children they will have.* This represents a major departure from the teaching of Pius XI in *Casti Connubii* in 1930, recognizing no such parental right to determine family size (1). Thus, in response to new developments and rapid social change, the Christian position on contraception has changed, as it has previously on such issues as slavery, religious freedom, usury and the discoveries of Galileo.

Faiths not restricted by the Augustinian tradition have adjusted to the demographic realities of the 20th century with greater ease, although some controversy has existed. Judaism shares with Christianity the Old Testament injunction "be fruitful and multiply." Adam (Gen. 1:28) repeated to Noah (Gen. 9:1, 7) and to Jacob (Gen. 35:11), which the Orthodox interpret as requiring unrestrained reproduction. The Reformed and Conservative congregations take a more liberal view, noting that the Talmud advises the use of a *mokh* (probably a spongy tampon of wool or cotton) to prevent pregnancy in minors and nursing mothers. To space pregnancies, the Talmud advises that the husband "must thresh inside and winnow outside," an obvious euphemism for coitus interruptus. Thus, there is ample basis in Jewish tradition for the use of contraception, and its practice is an accepted fact of modern Jewish life.

The classic Muslim tradition has attached high prestige to the parents of large families. The Koran echoes Genesis 1:28 in the injunction "marry and generate." Nevertheless, contraceptive methods were used and described by the great Islamic physician Al-Razi in the 9th century, as well as by Avicenna in the 11th century. This has been taken to imply a sanction of contraception in the tradition of Islam, since there is no specific prohibition of such practices in the Koran. Under the influence of explosive population pressures in Egypt, Indonesia and Pakistan, Islamic scholars have generally supported governmental efforts to promote family planning.

The attitude of Hinduism towards contraceptive practices is difficult to categorize because substantially different cults have emphasized divergent norms of conduct. There are strong pro-fertility elements in Hinduism, for example, sons being important to pray for their ancestors. On the other hand, the Hindu approach to such questions as contraception tends to emphasize spiritual attitudes rather than become embroiled in the ethics of par-

ticular methods, and there exists no doctrinal obstacle to curbs on parenthood. Similarly, the Buddhist approach to the use of contraceptives has been generally permissive, emphasizing the spiritual intent of family limitation rather than becoming preoccupied with the mechanics of methodology.

There is thus no major body of religious opinion in the world today that has failed to recognize the need of 20th century man to restrain his reproductive activities if the 21st century is to offer any meaningful promise to our children and grandchildren. Such minor differences which exist on questions of contraception concern the ethical acceptability of specific *methods* of limiting population growth, rather than acceptance of the concept that contraception is necessary if civilized life is to be preserved. In this context, the acceptability of modern contraceptive methods must be examined.

ACCEPTABILITY OF THE IUD

The use of intrauterine devices for contraception has necessarily raised moral questions as well as scientific questions. The ethical acceptability of the IUD must be viewed against the rapidly shifting background of theological, medical and legal attitudes towards all methods of family limitation. Is the IUD an abortifacient technic? Is it more or less licit than rhythm or withdrawal as a contraceptive? The pill? These and other questions are deserving of careful consideration.

One school of thought has maintained that intrauterine devices are nothing more than simple mechanical abortifacients despite the fact that there is no scientific evidence to support the concept. In part, such misconceptions arose because of the historic confusion between the contraceptive action of intrauterine devices and the obvious abortifacient action of pessaries deliberately inserted to disrupt an established pregnancy. This interpretation of the factors responsible for IUD efficacy as expressed by Strabel at the 1930 Birth Control Conference: "Most gynecologists assume, and it is my opinion too, that the Gräfenberg method does not constitute an intrauterine method for the prevention of conception, but a method for early abortion."

Indeed, intrauterine devices can function by provoking abortion if they are wittingly or unwittingly inserted into the pregnant uterus. The generally recommended insertion of IUD's during the menstrual flow is intended to avoid precisely such an event. Beyond this obvious misuse of the IUD, however, doubts have existed as to the ethical status of the method. Most of these doubts are inconsistent with contemporary theology as well as modern concepts of reproductive biology, but nevertheless deserve serious comment.

Theologians have extensively considered, but never completely agreed on, the distinction between potential life, biologic life, and *human* life. St.

Augustine and Thomas Aquinas considered the infusion of the soul, and therefore the commencement of human life, to occur at the time of quickening. More recent Christian theological opinion has favored earlier stages of the gestational process, yet the precise point at which the gametes or the products of their union are ensouled and therefore human remains difficult to determine. This philosophic interface between biology and dogma has been carefully evaluated by various religious groups, and *the prevailing view is that the implantation of the ovum is the critical event in the process of human reproduction from which the commencement of human life can be dated.* The British Council of Churches (2) pondered this question in 1962, concluding that "a distinction must be made between biological life and human life, and that in the absence of more precise knowledge, nidation may most conveniently be considered the point at which the former becomes the latter."

CONTRACEPTIVE VS ABORTIFACIENT ACTION

The ethical acceptability of contraceptives is related to the definition of human life, as distinct from potential human life or biologic life. The gametes can be said to represent potential human life, since human life can result from their successful conjunction. The logical dividing line between a contraceptive and an abortifacient technique, therefore, relates to the stage of the reproductive process which is interrupted. If the interference with reproduction occurs at a stage prior to the existence of an established conceptus, the method is generally considered a contraceptive. If pregnancy is interrupted after the establishment of a conceptus, most theologians will consider the method an abortifacient.

One can consider fertilization, for example, as part of the *process* of conception, as is the ascent of spermatozoa, the release of the ovum, and the extrusion of the polar bodies. The conceptus, however, is the end product of the process of conception, not any of the component stages in that process. According to medical terminology since time immemorial, the term conceptus has been considered synonymous with an immature foetus. Prior to successful implantation, there is no conceptus, because the process of conception is incomplete. It follows that a technic which prevents the completion of the process of conception is, by definition, a contraceptive.

The *potential* for human life, of course, exists at many stages of reproduction, both preceding and following the initiation of fertilization, which is itself a complex process completed in several stages. But for conception to be established and for an established conceptus to exist requires successful embedment. Prior to the critical threshold event of successful implantation, we can speak of gametes, we can speak of polar bodies, we can speak of cytokinesis and karyokinesis, we can speak of cell masses and blastocysts, but we cannot scientifically speak of an established conceptus. Whether the mechanism of action of a contraceptive is primarily due to a delay in ovum

release, an interference with ovum transport, a delay in the fertilization of the ovum, destruction of spermatozoa, or indeed, any other mechanism which interrupts the reproductive *process* at a stage preceding implantation, such a technic is without any doubt a contraceptive.

If one attempts to adopt other conclusions, even greater difficulties can arise. For example, according to the classic experiments of Marston and Chang (3), delayed fertilization results in failures of normal implantation, and therefore such delay has an effective contraceptive action by interfering with successful conception. The potential for conjunction between spermatozoa and ova which are 24 to 36 hours of age exists in the practice of periodic continence. If such a "stale" ovum is fertilized, is there pregnancy or is there not? We contend that if the products of such a union are incapable of *completing* the process of conception, and becoming a conceptus by successful implantation, a state of pregnancy does not exist. Those who would date conception from a point earlier than successful implantation are faced with a serious dilemma: If interrupting the biologic events preceding implantation are to be incorrectly considered abortifacient, the biologic basis for the rhythm system would have to be so classified.

A clear concept of the etymology of the term abortion, which was arrived at by common usage long before any of the present issues were raised, can provide a basis for discriminating between a contraceptive and an abortifacient. The derivation of the term abortion is from the Latin verb, *ab-oriri*; the prefix *ab* denoting motion away from a fixed point. Thus, we speak of persons being *ab-ducted*, when they are involuntarily removed from one place to another, and of criminals *ab-scending* with their loot. The physical act of separating, detaching or removing the conceptus from a fixed point of origin (*oriri*) is an essential requirement which distinguishes abortion from contraception. From a strict etymologic point of view, therefore, an abortifacient must produce the detachment of an established conceptus, an event which cannot take place prior to successful nidation of the fertilized ovum.

The popularization of oral contraceptives has also raised new problems for both scientists and theologians. Certain of the oral contraceptives appear to permit ovulation as well as some spermatozoal ascent, and yet successful implantation does not usually occur. Disturbed endometrial physiology produced by the steroid hormones has been shown capable of preventing pregnancy by interfering with nidation. Such a mechanism of action may be, from an ethical point of view, not dissimilar to that of the intrauterine devices, and can be the subject of extended theologic debate.

SUMMARY

It is logically inconsistent, if not impossible, to make a distinction between the ethical acceptability of methods which prevent conception by precluding successful conjunction of the sperm and egg and methods which

release, an interference with ovum transport, a delay in the fertilization of the ovum, destruction of spermatozoa, or indeed, any other mechanism which interrupts the reproductive *process* at a stage preceding implantation, such a technic is without any doubt a contraceptive.

If one attempts to adopt other conclusions, even greater difficulties can arise. For example, according to the classic experiments of Marston and Chang (3), delayed fertilization results in failures of normal implantation, and therefore such delay has an effective contraceptive action by interfering with successful conception. The potential for conjunction between spermatozoa and ova which are 24 to 36 hours of age exists in the practice of periodic continence. If such a "stale" ovum is fertilized, is there pregnancy or is there not? We contend that if the products of such a union are incapable of *completing* the process of conception, and becoming a conceptus by successful implantation, a state of pregnancy does not exist. Those who would date conception from a point earlier than successful implantation are faced with a serious dilemma: If interrupting the biologic events preceding implantation are to be incorrectly considered abortifacient, the biologic basis for the rhythm system would have to be so classified.

A clear concept of the etymology of the term abortion, which was arrived at by common usage long before any of the present issues were raised, can provide a basis for discriminating between a contraceptive and an abortifacient. The derivation of the term abortion is from the Latin verb, *ab-oriri*; the prefix *ab* denoting motion away from a fixed point. Thus, we speak of persons being *ab-ducted*, when they are involuntarily removed from one place to another, and of criminals *ab-scending* with their loot. The physical act of separating, detaching or removing the conceptus from a fixed point of origin (*oriri*) is an essential requirement which distinguishes abortion from contraception. From a strict etymologic point of view, therefore, an abortifacient must produce the detachment of an established conceptus, an event which cannot take place prior to successful nidation of the fertilized ovum.

The popularization of oral contraceptives has also raised new problems for both scientists and theologians. Certain of the oral contraceptives appear to permit ovulation as well as some spermatozoal ascent, and yet successful implantation does not usually occur. Disturbed endometrial physiology produced by the steroid hormones has been shown capable of preventing pregnancy by interfering with nidation. Such a mechanism of action may be, from an ethical point of view, not dissimilar to that of the intrauterine devices, and can be the subject of extended theologic debate.

SUMMARY

It is logically inconsistent, if not impossible, to make a distinction between the ethical acceptability of methods which prevent conception by precluding successful conjunction of the sperm and egg and methods which

EIGHT

SEPTIC COMPLICATIONS

The concept that placing a foreign body in the uterine cavity is a potential cause of endometritis and/or salpingitis has been generally accepted in the past, and is not wholly unfounded, especially when there is failure to observe appropriate precautions. It is probably impossible to cleanse the cervix so thoroughly that one can avoid introducing a few bacteria into the uterine cavity at the time of insertion. The situation may be considered analogous to catheterization of the bladder—a few contaminating organisms from the urethra are almost invariably introduced into the bladder by the procedure, despite the most elaborate clean-up. Nevertheless, gross uterine contamination at the time of insertion can be prevented by appropriate precautions. Inadequately sterilized devices and instruments undoubtedly contribute to the risk of septic complications associated with IUD insertion.

When clean insertion technic is followed, however, and contraindications to insertion observed, serious septic complications are exceptionally rare. Trivial vaginal, cervical and/or tubal infections are seen with much greater frequency. Most pelvic infections among patients wearing an IUD are cases of coincidental salpingitis. In any given year, about 2% of clinic patients will present with complaints diagnosed loosely as pelvic inflammatory disease (PID). *Unless a documented febrile illness follows immediately on the heels of the insertion procedure, a cause-and-effect relationship with the IUD is unlikely.* When facilities for culture are available, gonococci can often be identified from the cervical secretions of patients with PID in association with an intrauterine device. Treatment with antibiotics, without removal of the device, is usually successful. In a clientele with stable marital relationships, pelvic inflammatory disease is seldom encountered in the presence of the device.

The rarity of serious endometrial infection associated with the insertion of intrauterine devices indicates that the natural resistance of the normal

uterine cavity to contamination is considerable. Several factors probably contribute to this fortunate circumstance. Experimentally, the endometrium has been shown to respond to the presence of the IUD with a reaction which increases the number of histocytes and leukocytes in the uterine cavity. The levels of lysozyme present in the uterine fluid is also increased (7) in response to the IUD. The bacteriocidal properties of this enzyme, as well as the increased number of phagocytes present in the vicinity of the device, undoubtedly contribute to maintenance of the sterility of the uterine cavity.

UTERINE CONTAMINATION

The rates of pelvic inflammatory disease reported in the Cooperative Statistical Program (CSP) indicate that uterine contamination by unsterile devices or unsterile insertion practices, or both, was responsible for a few clinically significant pelvic infections. The devices supplied for this program were predominantly of the bulk-purchase, unsterile type, and cleansing accumulated debris from the face of the cervix was not part of the recommended protocol of the CSP. Indeed, sterile pre-packaged devices were unavailable in the early years of the program, and the prevailing practice was simply to pick up the device and load it bare-handed into a soda straw type of inserter.

Comparison of the rates of pelvic inflammatory disease in relation to the date of insertion in the CSP shows that the rate for the first month was substantially higher than in subsequent months of IUD use: the rate of pelvic inflammatory disease observed (7.7 per 100 woman-years) in the first 2 weeks after insertion was 3 times higher (2.2 per 100 woman-years) than the rate in the second year of IUD use (11). Although the rate of pelvic inflammation calculated per 100 woman-years is elevated, the actual number of cases reported is low, representing 75 instances of pelvic inflammatory disease associated with 23,911 insertions. In other words, the incidence of pelvic infection which occurred in the fortnight following insertion was 3 per 1000 women fitted.

Most of the cases of pelvic infection reported in the CSP series were of a trivial nature and responded promptly to antibiotic therapy. Except for the statistically increased PID attack rate related to the insertion procedure, the incidence of pelvic infection in subsequent months of use is not significantly different from attack rates in the absence of the IUD in comparable clinic populations. The circumstances surrounding the insertion procedure, rather than the IUD per se, are chiefly responsible for the increased incidence of pelvic inflammatory disease reported in such mass programs immediately post-insertion.

Even when unclean insertion technic results in gross contamination of the uterus, sterility is rapidly restored. Mishell and Moyer (6) obtained bacteriologic cultures through a transfundal incision from vaginal hysterec-

tomy specimens following loop insertion. The cervix was not cleansed prior to insertion and the devices used by these investigators were not of the pre-packaged sterile type available today. Among the patients with positive endometrial cultures within 24 hours after insertion, identical organisms were usually identified from the cervical mucous, indicating that contamination had occurred from this source. Despite the uterine contamination, however, 80% of the endometrial cultures became sterile within 48 hours. Thereafter, the positive endometrial cultures became increasingly rare. Endometrial cultures obtained more than one month post-insertion were uniformly sterile. Although it is evident that the body defenses rapidly eliminate the bacteria introduced into the uterine cavity by insertion, this study indicates the desirability of thoroughly cleansing the cervix and using sterile devices to minimize endometrial contamination.

COINCIDENTAL INFECTIONS

Quite unrelated conditions are often misdiagnosed as "IUD Complications." Lippes (5) investigated 23 patients with a tentative diagnosis of pelvic inflammatory disease among 1673 patients wearing loops. Of these 23, the diagnosis was unsupported by laboratory corroboration in 8; 3 were found in fact to have urinary tract infections; 1 had appendicitis; 1 had regional ileitis; and 1 has a postoperative wound infection. With appropriate antibiotic therapy, recovery was prompt in the remaining 9 cases of bona fide pelvic inflammatory disease. Considering the 1673 women at risk, this low incidence is essentially that which would have occurred without the loop. Similarly, among 2330 predominantly lower socio-economic group patients fitted at the Sloane Hospital for Women, Hall observed only 5 cases of severe pelvic inflammatory disease. Four of these cases occurred more than 7 months after insertion, making any relationship between the device and the pelvic infection highly speculative (3).

An indirect measure of whether the use of intrauterine devices causes pelvic inflammatory disease is the fertility among women who have their IUD removed in order to become pregnant. According to the data compiled for the Cooperative Statistical Program (10) about one woman in three conceived within one month after removal of the IUD; almost 3 out of 4 within six months; and almost nine out of ten, within one year (Table 12). These fertility rates are comparable to those observed after discontinuation of other birth control methods, and in no way suggest impairment of fertility, as might be expected if the devices were responsible for a significant incidence of pelvic infection.

THE SCOTT SURVEY

A few serious septic complications have definitely been attributed to the use of IUD's. A survey of the 8,500 Fellows of the American College of Obstetricians and Gynecologists with regard to critical illness associated

TABLE 12
Conceptions After Removal for Planned Pregnancy

Months After Removal	Percent Pregnant
3	59.4
6	75.1
9	84.5
12	88.2

with the use of intrauterine devices was conducted in 1967 by the late Dr. Roger Scott (9). The investigation was initiated on behalf of the Advisory Committee on Obstetrics and Gynecology of the Food and Drug Administration. A questionnaire was directed to these specialists in the United States, Canada, and Puerto Rico in the expectation that they would likely have knowledge of any critical illnesses, deaths or other major complications which had taken place in their communities. The Scott Survey deserves detailed consideration because it is the most complete evaluation available of the major risks associated with the use of intrauterine devices.

The questionnaire was completed by 76% of the Ob-Gyn specialists contacted. At the time of the survey, increasingly widespread use of plastic intrauterine devices of the loop, spiral and bow types had been underway for almost five years. An estimated 2 million IUD insertions had been carried out in the United States, based on the known distribution of 3 million IUD's from 1962 through 1967. Despite this substantial denominator, 88% or 5,698 of the gynecologists stated that they had neither seen nor had knowledge of even a single instance of critical illness associated with the use of intrauterine devices.

After corrections were made for multiple reports of a single episode (one case of intestinal obstruction following IUD insertion was reported by 21 physicians), there were 561 instances of complications associated with the use of intrauterine devices. These included such cases as infected abortions provoked by IUD insertions (wittingly or through medical error) in women who were pregnant. Also included in the cases reported were numerous instances of acute salpingitis arising months or years after an uneventful IUD insertion, making a relationship between the IUD insertion and subsequent pelvic inflammatory disease highly speculative.

After careful review of case summaries regarding fatalities associated with the use of IUD's, Scott concluded that four instances of fatal sepsis could be reasonably attributed to the insertion of intrauterine devices. In these four cases of fatal sepsis, the onset of the infection occurred within a few days following introduction of the device. Cultures were available from three of the cases and *Streptococcus viridans* was isolated from two,

β streptococcus "Group A" from the third. The two fatal cases due to infection with *Streptococcus viridans* experienced the onset of endometritis and died within six days of insertion. In one of the three cases, *Streptococcus viridans* was isolated from both the peritoneal cultures and direct cultures from the loop.

PREVENTION OF IUD COMPLICATIONS

It is of interest that the devices associated with the reported septic fatalities were supplied in an unsterile state by the manufacturer. The same inadequate packaging practices were being followed by most of the other IUD manufacturers. Under the circumstances, considering that insertions had been carried out on an estimated 2 million U.S. women by 1968, an incidence of two deaths per million insertions is a testimonial to the resistance of the human uterine cavity. Adequate cleansing of the cervix to prevent gross uterine contamination, the use of sterile instruments and devices packaged as sterile units with disposable inserters should be mandatory.

The amount of unnecessary sepsis induced by lapses in good surgical technic and still being induced by mass programs using bulk-manufactured unsterile devices may never be known. The devices used in many clinics and mass contraceptive programs have been of the bulk-purchased, unsterile type. This practice has continued despite the availability of sterile pre-packaged devices, and in the face of clear condemnation of the practice by the Advisory Committee of Obstetrics and Gynecology of the U.S. Food and Drug Administration.

It is remarkable that serious complications as a result of IUD insertions are relatively rare, since formal training in the technic is exceptional, and the procedures recommended in standard reference works on contraception are often grossly deficient: even the most recent edition of *The Manual of Family Planning and Contraceptive Practice* (1970) does not recommend sounding the uterine cavity or the use of the tenaculum to straighten the axis of the cervical canal during insertion. In the scant three paragraphs devoted to IUD insertion technic in this 475 page volume, no mention is made of sterile precautions or of cleansing the cervix, while loading unsterile devices into the inserter with bare hands is advised (1). Only bacteria should be pleased with such recommendations. Disregard of simple technical precautions to insure safe and clean insertion of an IUD ignores the advice of every competent authority in the field of intrauterine contraception since the time of Richter.

GRAFENBERG'S PROTOCOL

In this context the recommendations Ernst Gräfenberg made (2) in 1931 to prevent IUD complications are worth quoting:

"We must see that no harm comes to those who seek our advice. It must therefore not be forgotten that this method is not suitable for all women. *It cannot be used in cases of inflammation or infection of the pelvic organs. . . .* As long as the uterus is free from irritation and clean, there is no danger in using this method. If there is any trace of gonococci, however, these may spread upward through the manipulation and cause serious complications.

"Since I have at various times inserted a ring when the patient was already pregnant, either because she had not told me she had missed her period, or because menstruation was imminent and she was already pregnant, *I advise that the ring be inserted immediately after menstruation.*

"Naturally, as is the case in all intrauterine work, *the importance of asepsis cannot be too much emphasized. All instruments must be boiled, and the silver ring must be ready, attached to the instrument with which it is to be inserted.*

"The next size larger and the next size smaller rings must be prepared and sterilized so that it is possible to change the size at the last minute. . . . The cervix is exposed by means of a vaginal speculum. *The os is then washed with a piece of cotton-wool soaked in a disinfectant, and the outer lip held up with a hooked forceps. By means of a uterine sound, the position and size of the uterus, as well as the width and elasticity of the cervical canal is then ascertained.*

"It is best for the physician himself to hold the forceps, so that he may himself notice the details when inserting the sound. The sound is used particularly to determine the size of the uterus, because the ring must be placed in the cavity of the body. At the same time the sound indicates the length of the cervical canal, which is also most important in estimating the exact size of the uterine cavity. . . . It is most important that the introducer should be pushed upwards till it reaches the dome of the uterus. When it is withdrawn, the ring is pulled off the fork by contact with the walls of the uterus."

What are the results when the principles of patient selection, careful timing of insertions and technical precautions recommended by Gräfenberg are followed? In a word: outstanding. Skilled gynecologists, such as Arthur Hill, in Melbourne, Australia, have fitted large numbers of private patients without any serious complications whatsoever. Hill (4) reported in 1969 on the use of Gräfenberg rings made of German silver (an alloy of copper, nickel and zinc) in 1,070 women over a span of 33 years: he experienced a total of 32 primary expulsions, no uterine perforations, no septic complications and less than one failure per 100 woman-years of exposure. Those who have experienced disappointing failure and complication rates with IUD's should carefully reconsider the type of device and the technical routine they are using.

FDA COMMITTEE RECOMMENDATIONS

The 1968 Report of the FDA Advisory Committee on Obstetrics and Gynecology (8) made explicit suggestions on the avoidance of IUD complications, which suggestions echo Gräfenberg's recommendations:

(1) *Sterile prepackaging of all devices and inserters should be mandatory* (See Fig. 37.).

(2) *Sterile technique must be observed throughout the insertion* (See Fig. 38.).

(3) *Insertion is contraindicated in the presence of pregnancy or suspected pregnancy.*

(4) *The incidence of uterine perforation can be reduced by sounding the uterus before insertion and by aligning the corpus and cervix by traction on a tenaculum.*

(5) *Insertion is contraindicated in the presence of acute or subacute pelvic inflammatory disease.*

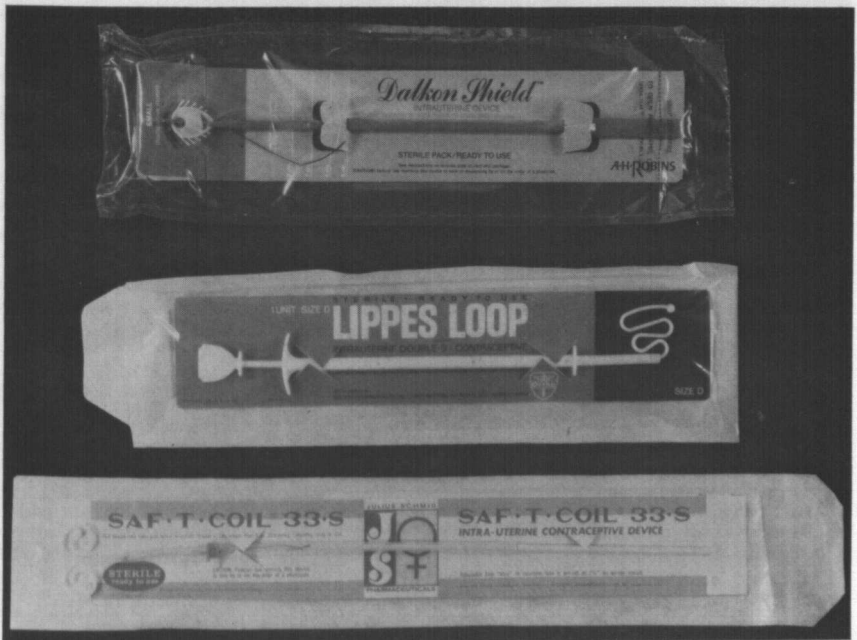


FIG. 37. Contemporary intrauterine devices supplied as pre-packaged, sterile units in accordance with FDA recommendations. The inserters for the loop, double coil and shield devices are disposable. Adequate sterile precautions cannot be observed with the bulk-purchased devices often supplied for mass use, a factor considered responsible for avoidable septic complications.

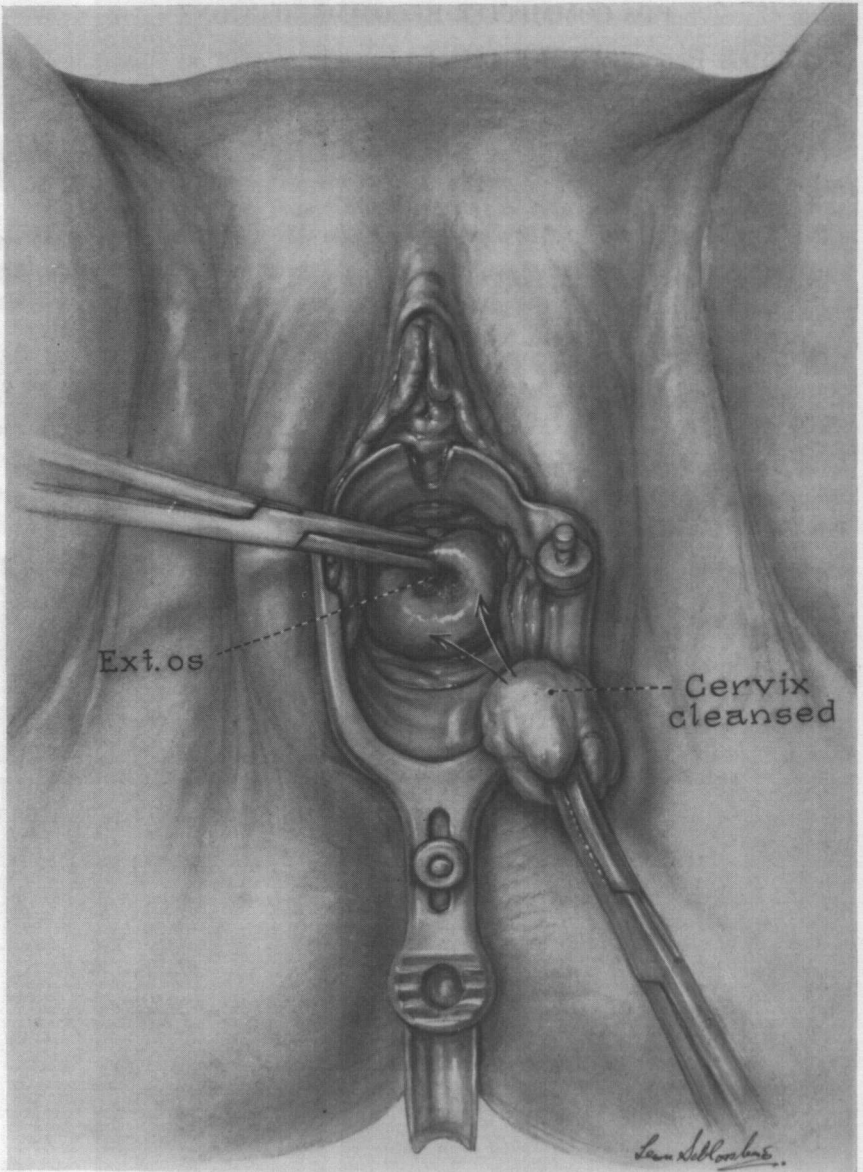


FIG. 38. Cleansing the cervix prior to IUD insertion can reduce gross uterine contamination. Iodine solutions such as Wescodyne and Betadine are particularly effective antiseptics for this purpose, as well as for cold sterilization of instruments when autoclaving is unavailable.

(6) *Insertion is contraindicated if there is a history of infected abortion or postpartum endometritis within the previous six weeks.*

(7) *Insertion is contraindicated if there is distortion of the uterine cavity, recent history of abnormal bleeding or suspicion of uterine malignancy.*

It will be noted that five of the seven FDA Committee recommendations dealt with the prevention of possible septic complications. Adherence to these simple precautions would undoubtedly reduce the hazard of even a transient bacterial endometritis being induced by the insertion of an intrauterine device. Thorough cleansing of the cervix prior to insertion is a frequently neglected step in the insertion procedure. The FDA Committee did not specifically recommend routine cleansing of the cervix, though this precaution is inherent in the recommendation that sterile technic be observed.

STERILIZATION OF INSTRUMENTS

When circumstances do not permit the preparation of steam autoclaved insertion kits, the instruments used for insertion can be sterilized most effectively by (a) thorough scrubbing with soap and water, and (b) immersion in a germicidal iodine solution such as Wescodyne or Betadine for 5 minutes. Solutions such as benzalkonium chloride have substantially inferior germicidal properties and should not be relied upon for this purpose.

The instruments for insertion can be laid out on a sterile disposable paper towel. Sterile gloves are not necessary if the device is of the pre-loaded sterile type which requires no handling. The instruments and the device are laid out with the handles oriented towards the operator, thus protecting that portion of the sterile field which will be in potential contact with the cervix and uterine cavity. Effective sterility can thus be maintained throughout the insertion procedure without using sterile gloves.

HAZARDS IN PERSPECTIVE

The statistically-minded can justify the risk of fatal sepsis related to IUD insertion of circa 2 per million as insignificant in relation to the maternal mortality if all one million women became pregnant instead. In the United States one million pregnancies would result in about 200 maternal deaths. Indeed, the fatalities attributed to the insertion of intrauterine devices are so rare that the procedure carries a risk equivalent to having a small-pox vaccination. It is also true that if the high dose oral contraceptives are prescribed for one million women, approximately 15 times as many would die from thromboembolic complications *during each year of use* and another 1,000 would be hospitalized annually for treatment of non-fatal strokes and embolic complications. From a statistical point of view, there is no doubt that using an intrauterine device is considerably safer than pregnancy. It is also true that both long and short range hazards

associated with the IUD are fewer than those arising from the use of oral contraceptives.

Nevertheless, the prevention of IUD complications, however rare, should be the first duty of the physician, rather than their statistical justification. *A disregard of sterile precautions in the manufacture, packaging, patient preparation and insertion of intrauterine devices has undoubtedly contributed to the inflammatory complications associated with the use of the technic. It is difficult to defend such policies, especially since simple precautions can prevent serious consequences.* The routine use of sterile, pre-packaged devices and aseptic insertion technic could unquestionably reduce the incidence of septic complications associated with IUD insertion. These precautions should be adhered to meticulously in clinics and in mass overseas programs as well as in using intrauterine devices among a private patient clientele.

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NINE

CLINIC INTERVIEWING

Various movies and brochures have been prepared to give instruction in family planning, yet the postpartum interview by a skilled family planning worker remains the most effective method of patient recruitment. On a face to face basis, supplying information is more personal, and even in a group situation, a sensitive interviewer can make sure that all the women have their individual problems considered. When women return for a postpartum check, motivation for family planning is high and interviews with small groups can be conducted efficiently.

The policy in our clinic has been to have postpartum returnees attend a discussion of family planning prior to seeing the physician. The interviews are conducted by the family planning nursing staff who will subsequently be responsible for maintaining follow-up on the patients, so a continuity of patient care is established. This approach saves the physician time in a clinic operation, and undoubtedly improves communication with the patients, who are generally more free in discussing their intimate concerns with the nurse than with a busy clinic doctor.

The materials necessary for patient instructions are quite simple—a packet of pills and an IUD, together with a chart showing a view of the female reproductive organs. One such convenient chart to explain the anatomy is an illustration by Dickinson available free of charge from the makers of Tampax showing a frontal view of the vagina, uterus, tubes and ovaries. Examples of other birth control methods should be available, such as foams, condoms and diaphragms, but with the advent of the modern pill and IUD, there is today little interest in these more cumbersome traditional methods. For this reason, unless a patient inquires about the traditional methods or the rhythm method, little time is devoted to these techniques, permitting a more complete presentation of the methods of greatest interest and highest efficacy.

In addition to presenting information about the IUD and the pill, a brief discussion of surgical sterilization is conducted. Many women are unaware of its availability and may be interested in terminating their reproductive careers rather than in using child spacing measures.

Our clinic interview has been developed by the family planning nurses at the Johns Hopkins Hospital under the direction of the program supervisor, Mrs. Jean Fowler. It is a general outline of a typical interviewing session from which departures are made according to the questions from the women and the needs of the group. The effectiveness of the presentation may be gauged from the fact that 95 % of all patients returning to our clinic for their postpartum check participate in the family planning program. A transcript of this presentation follows:

NURSE PRESENTATION

“Good morning. I’m Mrs. ——— and I’m here to talk to you about family planning. You’re all back here today for your check-up. Now, everyone who has a pregnancy and comes for her check, we do talk to about birth control, or family planning. I’m here to advise you and tell you what is available in the way of birth control, so that if you don’t want another pregnancy right away, you can get started on a good method of family planning now.

“The two best methods that are available today are birth control pills and intrauterine devices. And when I say the two *best* methods, what I mean is the two that are the most convenient and most effective. Quite honestly, nothing is 100 % perfect in the way of birth control. We wish it were, but it just isn’t so. But the pills, if they are used properly, and IUD’s are both over 99 % effective. So that with either of those methods you can get almost complete protection. The failures with the other methods of birth control such as the diaphragm, the rubber or foam are much more frequent than with these two modern methods. But if any of you are interested in knowing more about the older methods or the rhythm system, I’ll be glad to explain them to you.

“Now, when the pills came out about 10 years ago, there was only one kind. Today, there are about 20 different kinds of pills available and they vary in dosage—they vary in the ingredients that are in them. What we do is use the lowest dose pill which has been found effective. The lowest dose pills have been found to be the safest type of pill, because they disturb your own body system the least. It’s important that you take one pill each day. Not two today and none tomorrow. They just don’t work well that way, you must take them as they are prescribed. Now, when you get to the end of your package of pills, you will have your next period. Then, you start your pills all over again. You do this every month over and over as long as you don’t want to get pregnant.

PILL PROBLEMS

“You may have heard that the pill can be harmful to some women, and that is true. There are some women who cannot take birth control pills

at all for medical reasons. Some of the people who are advised not to take the pill are women who have had any kind of history of blood clotting in the past. That's because the pill has been shown to cause changes in the blood. Very often women who are diabetic or have trouble with asthma are advised not to take the pill. Women who have had any history of breast tumors are usually told not to take the pill. We'll check your history and the doctor will examine you before you start. So some women have to be ruled out right away as pill patients, they just aren't good candidates for birth control pills. Sometimes, though, a lady who seems perfectly healthy starts to take the pill and she'll develop what we call side effects. She may have some nausea or morning sickness. Or she may have some headaches. Or she may get pains in the legs or chest or have blurred eyesight. She may have just some vague feeling of uneasiness.

"Now I would suggest this to you: if you start on pills and you don't feel quite right—whether you've got headaches or you're nauseated or have pains in your legs—please report that to your doctor or to your clinic. Most often if you stay on the pills for a couple of months, minor complaints such as nausea will disappear and you can go on with your pills. But it is important to report symptoms to your doctor or your clinic because once in a while we'll find a woman with whom the pills don't agree and she may get into more serious difficulty if she tries to stay on the pill. So always take the pills under the care of a doctor or clinic.

HOW THE PILL WORKS

"Now, have you got any questions about pills, anything at all that I didn't cover that you might like to know about the pill? One question that most people ask about pills is what makes them work. I'll tell you briefly about this. You all know that you have a period every month. In between your periods, while you're not aware of it, there are other things that are happening. And one thing that happens, usually about mid-way between your menstrual periods, is that you ovulate. Now what this means is your ovary releases an egg. If you have relations at that time and the sperm meets with the egg, you can become pregnant. What the pill is all about is it prevents your ovary from releasing eggs. As long as you take the pill correctly, you stop producing eggs. Therefore, since there is no egg, pregnancy is prevented. That's why it's so important, if you take pills, to take one pill each day, because any day that you miss a pill, there is a chance you might ovulate.

Now, here's what to do if you miss a pill—say you're taking them at supper time each day and one day you're not home for supper and you don't have your pills with you. If that happens, take that pill as soon as you get home, or take it even the next morning if you forget it that night, but then get right back on your regular schedule. The problem with pills, as far as

women getting pregnant, is usually the woman's failure to take the pill correctly. If you have trouble remembering medicines, it might not be the best method for you. But if you can take the pills on schedule, it is one of the best birth control methods ever developed.

"The next method of birth control I'd like you to know about is the intrauterine device. Most IUD's are made of plastic, although some have been made of stainless steel. The IUD is different from the pill and most other birth control methods because it works without any extra effort on your part. IUD's are inserted by a doctor, usually while you are having a menstrual period or right after your period ends. For two reasons: first of all, if a lady comes to us with her period, we know she isn't pregnant and this is important; secondly, your cervix, which is the mouth or neck of your womb, opens up a little wider when you're having a menstrual period and that makes it easy to slip the device into the uterus.

"What the doctor does is use an inserter, which is a thin rod-like affair, to slip the device through the mouth of the womb, and right up into the hollow part of the uterus. Once the device is inside, he takes the inserter out and the IUD nestles inside of the uterus. A threadlike tail of soft plastic dangles through the cervix as a marker. It won't bother you or your partner. The tail is helpful when you come back for a follow-up visit, so we can look inside to see the string coming through, and know the device is OK.

IUD SIDE-EFFECTS

"There are some side effects from the IUD also. After insertion you may find that your periods for the first couple of months are a little longer than usual or your flow may be a bit heavier. Some women also spot or have some staining in between their periods in the first couple of months. Not everyone does this, but a lot of girls do and we find it's better to tell you you might bleed a little more or spot a bit than to have you get an IUD and go home and start bleeding and not know why and be worried about it. It usually will settle down, but it may take your uterus about two months to get accustomed to having the device inside. Now, even though you're having a period and probably won't have relations immediately when it's put in, your protection starts right away. With an IUD if you like to wear tampons, that's fine. It will not bother the device which is high up in the uterus. If you like to take douches, fine, that's not going to bother the device either.

"I mentioned bleeding or spotting as a side effect of the IUD. There's another problem—expulsion—which used to be common, but is rare today with modern devices. Each month when you're having a period, check your pad or tampon each time you change before you throw it away. Because if an IUD is going to come out, it probably is going to happen when you're having a period, when your cervix is open. The modern IUD is really very safe because it is retained perfectly by 99% of women and provides a

99% protection against pregnancy. The reason many women like the IUD is the protection is so natural. It works inside the uterus, so there is nothing for you to take or remember, nothing extra you must do before relations. Because it works inside the uterus, the IUD cannot change your natural hormone balance.

"The device can be left in for months or years, as long as you don't want any more children. A lot of women use this to space their pregnancies. You may have had a baby this year and maybe you don't want a baby for two more years. So you can have your IUD until you're ready to plan your next pregnancy and then when you want to get pregnant again, call us while you're having your period and let us take it out.

"I also would say that if you get an IUD—and this is a thing that you are choosing yourself, whether you choose pills or IUD or whatever kind of birth control you want—it's your privilege if you don't like the method for some reason, any reason at all, you can certainly switch to another type of birth control. Once you get an IUD doesn't mean you're stuck with it forever, and if you find the pills don't agree with you, you can change. We do find that most girls, once they get through the first two months, are very pleased with the safety and security of both methods.

"The first few weeks are important—you have to get used to taking the pill and you have to get used to wearing the IUD. After that, it's pretty smooth sailing for most women using either of these modern birth control methods.

STERILIZATION

"There is another type of birth control which some of you may want to think about, which is different from the other methods because it is really permanent. Yet it accomplishes the same thing—keeps you from getting pregnant—with even greater security than either the IUD or the Pill. That's permanent birth control by sterilization or having the tubes tied. If you are sure you already have all the children you want, and feel certain you'll never want to be pregnant again, then you should know about this method.

"Having the tubes tied keeps you from getting pregnant by keeping the egg from reaching the uterus. Your regular periods continue and the egg is released every month, but since the tube is blocked, the egg dissolves without reaching the uterus and pregnancy is prevented. Today having the tubes tied can be done very rapidly—it takes about 20 minutes and most women don't have to spend more than one day in the hospital. So if you feel your family is complete, and you are not interested in the other birth control methods, ask the doctor about having your tubes tied. Many women have had this done and find it more convenient than other birth control methods once their family is complete.

"You will be examined today by the doctor before starting birth control.

After that what we do in the way of follow-up with birth control is to bring you back in about eight weeks. What that does usually is let you have a period and by observing how much bleeding you had and how you are feeling, we can get a pretty good idea whether or not everything is settling down as it should. If everything is OK at that eight weeks check-up, then we ask you to come back again in six months. We'll be doing Pap smears on you and keeping track of you whether you're on the pill or IUD. Naturally, if you have any special problems, we can see you in between your check-ups.

"Now, unless you have further questions, you can each decide what type of birth control you want before the doctor examines you. I'll be seeing you again before you go to make sure you understand everything and have your appointments arranged. I'll have to get some information from you now. Mrs. _____, what sort of birth control are you interested in having?"

FREQUENT QUESTIONS AND ANSWERS REGARDING INTRAUTERINE DEVICES

How long can I wear the device?

Although women have worn the same IUD for five years or more, many doctors advise changing to a fresh device after two years. Removal and replacement is quite simple to do. For best protection, follow your doctor's advice and keep regular appointments for checkups.

May I take douches or use tampons if I am wearing an IUD?

Yes, you certainly may. This method of birth control in no way interferes with normal feminine hygiene practices. The device is higher up—inside the uterus—where it cannot be bothered by douches or tampons.

Does the IUD interfere with having relations?

No—the device nestles high inside the womb, and cannot be disturbed by sex relations. The IUD is not touched or felt during intercourse.

Can I use an IUD if I have never been pregnant?

Yes, you can. That is one of the advantages of the modern devices. There are special devices designed for women who have never been pregnant which give excellent results.

Can I use the IUD if I have bad veins?

Indeed you can. This type of birth control does not cause inflammation of the veins or blood clots. Using a locally effective birth control method, such as the IUD, would be safest for you.

Will wearing the IUD change my "nature" or sexual desires?

Most women find their sex drive improved by a good birth control method. The convenience of the IUD helps in this regard, because there is nothing extra you must do each day for protection, making sex more natural.

Will wearing an IUD change my periods?

Usually after insertion, some bleeding occurs. You may have a few cramps until the womb gets used to the device. If the device is inserted during the menstrual period, you probably won't notice any change other than the period lasting a little longer.

Is the IUD as effective as the Pill?

The pregnancy rates with the modern pills for birth control and the modern IUD are similar. A modern IUD prevents 99% of pregnancies, as do most oral contraceptives. Frankly, no birth control method is 100% perfect, but the modern pills and IUD come very close to this ideal.

Is the IUD more effective than a diaphragm?

Definitely. About 5 women out of every 100 using a diaphragm become pregnant in one year, which makes it 95% effective. A modern type of intrauterine device prevents 99% of pregnancies.

How does an intrauterine device prevent pregnancy?

The IUD prevents pregnancy by preventing conception. The device inside the womb arouses natural body defenses which cause the eggs and seed to dissolve and pass away as they do normally before the period comes.

I have heard of women having very heavy periods with an IUD. Is this to be expected?

They were probably fitted with one of the older types of IUD, which often cause bleeding. Some bleeding after insertion is normal. But after this adjustment, most women fitted with a modern IUD have essentially normal periods.

After I was fitted with an IUD, my Pap test for cancer was abnormal. Was this caused by the IUD?

The Pap test may be abnormal because of an infection, or because you have some other condition. Be glad your doctor checked you with the Pap test and found your trouble. There is no evidence that wearing an IUD increases your risk of cancer—that is one of the good things about this method of birth control.

After wearing an IUD for a year, I began to have cramps and spotting for the first time. Can this be corrected?

Fitting you with a smaller, more flexible type of IUD will probably correct your difficulty. Be sure to have your doctor check you, because there may be some entirely different reason for your complaints.

If I should become pregnant with an IUD, will the baby be harmed?

There is no increase in the number of abnormal children born under these circumstances. When pregnancy does occur, the bag of waters pushes the IUD to one side and the developing baby is not really touching the device at all.

A friend was using birth control—I don't know whether it was pills or an IUD—and she got pregnant. She went into the hospital and had an abortion. Is this legal?

That depends on the state you live in and the circumstances. In some states, abortion is legal when the health, including the mental health, of the mother will be endangered by the pregnancy. In other states, if the birth control method you are using fails, you can have an abortion performed if you and your husband wish to terminate the pregnancy. Your doctor will know what the laws are in your particular state.

POST-INSERTION REVIEW

"How are you feeling? If you are having any cramps caused by putting the device in, you can expect them to pass away in a few minutes. They are caused by the womb being stretched by the new device. If they are bothersome, you can take two aspirins every four hours until they are gone. We'll get you a prescription if you want something stronger.

"You have a tampon in the vagina to protect you from any spotting or bleeding caused by inserting the device. After you get home, pull on the string to take out the tampon, and use additional pads or tampons if you need them. Using pads or tampons or taking douches will not bother the device in any way because it is nestled higher up inside the uterus.

"Now here's what to expect from your new IUD: there are some side effects besides cramping. Some spotting or bleeding from the new device is natural, and your first one or two periods after insertion may be different—perhaps longer or with a heavier flow. Once the womb gets used to the new IUD, most women have pretty normal periods. We'd like you to keep a calendar record of your periods and bring it with you when you come back for your check up in eight weeks so we can see how you are adjusting to the new device.

"There is a threadlike tail on the device which hangs outside the mouth of the womb. It will not bother you or your husband, but is useful for us

to see when you come back to make sure the IUD is in correct position. Some women like to check themselves by feeling for this thread. You can do this by washing your hands, inserting a finger deep inside your vagina and feeling the thread against the cervix or mouth of the womb. Actually, the modern intrauterine devices very seldom slip out of place, so if you just want to relax and let us check on you, the chances are 99% you will be all right. Unless you have questions—anything you haven't understood—we'll line up your appointments for your first check-up in eight weeks."

TEN

PATIENT MANAGEMENT

A population of well-managed patients leads to greater acceptance and optimal continuation rates with intrauterine devices. An important factor in securing patient cooperation is competent counseling on the advantages and disadvantages of the IUD and the side effects which may be experienced. A thorough knowledge of the method is thus essential to good management.

Many of the complaints associated with the use of IUD's can be avoided by appropriate timing of insertion. Interval insertions are ideally scheduled during menstruation or withdrawal bleeding from oral contraceptives. Since the patient is already bleeding, the insertion procedure will cause little additional inconvenience. Menstrual insertions also completely avoid the risk of disturbing an unsuspected early pregnancy. Following menstrual insertion, the endometrium enters a regenerative phase and subsequent spotting is minimized.

Nevertheless, some patients will experience menstrual irregularities in the first days or weeks post-insertion, usually in the form of prolongation of the menstrual flow. The patient needs to be fully informed about the possibility of post-insertion spotting or bleeding, which can persist until she has completed her first or second menstrual cycle. Under such circumstances, the few patients who experience moderate bleeding will not be alarmed, and the majority who experience little or no inconvenience will be reassured. Having the patient keep a calendar record of cramps, spotting or bleeding permits objective assessment of the severity of any complaints. Our written instructions to patients fitted with intrauterine devices are the following:

"You have been fitted with an Intrauterine Device to protect you against pregnancy. The IUD is one of the most effective, convenient and safe birth control methods known to medical science, but it is not entirely trouble-free. After being fitted, some women have discomfort rather like menstrual cramps. If necessary, take two aspirin tablets every four hours

until you are comfortable. You might also have some spotting or bleeding for a few days after insertion of the device. Once the womb gets used to the device, most women feel comfortable and have normal, natural menstrual periods.

“A few women have developed infections while using an intrauterine device. This occurs no more often than with other birth control methods, or with no birth control at all. If you have trouble of this sort, it can usually be treated without removing the device, so you continue to have protection against pregnancy.

“The device works in a very simple and natural way, by preventing pregnancy inside the uterus. When you want another child, you should make an appointment to have your device removed. For best results, keep your appointments for regular check-ups, bringing with you a record of your periods on the calendar.” (See Fig. 39)

IUD SIDE EFFECTS

Minor discharge or spotting in the first few weeks following insertion can be alleviated by advising a cleansing douche with two tablespoons of vinegar in a quart of water. If spotting limits the possibility of sexual intercourse, the patient can cleanse herself by inserting a tampon, rotating it in the vagina and discarding it prior to coitus. The woman can be reassured that such spotting is not alarming, and that later cycles can be

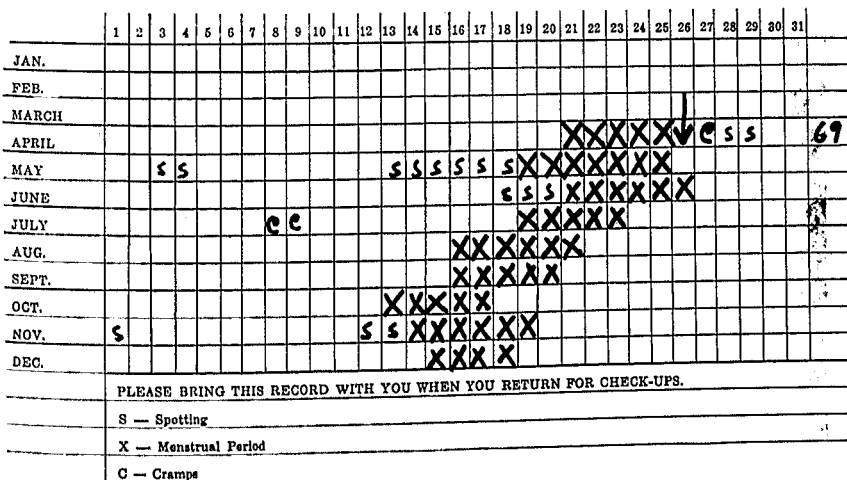


Fig. 39. Menstrual pattern of a patient fitted (arrow) with an intrauterine device. Slight spotting occurred for three days post-insertion and immediately preceding the next two menstrual periods, the periodicity of the cycle remaining undisturbed. Such a pattern indicates a normal adjustment to the device and good compatibility between the size of the IUD and the uterine cavity. Having the woman keep such a menstrual calendar is a useful adjunct in patient management.

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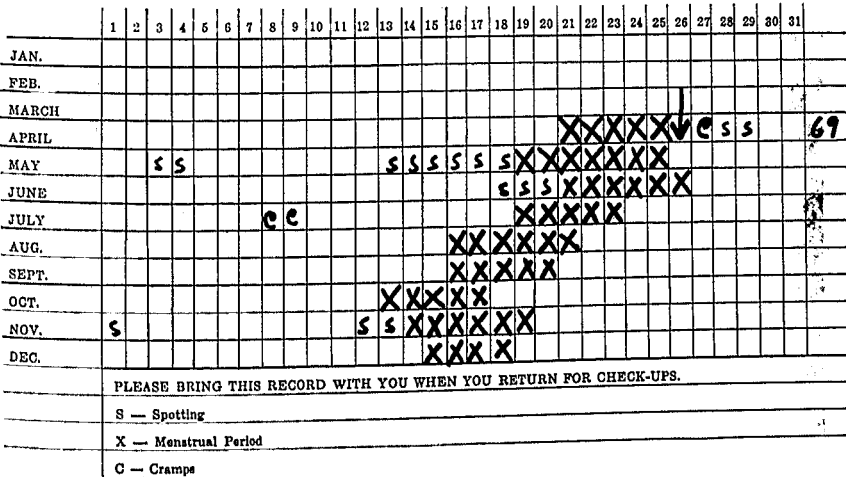


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expected to return to normal. The first return visit should be scheduled eight weeks post-insertion, when most trivial complaints related to insertion will have disappeared.

Discomfort following insertion varies greatly, depending on the type of device, the size of the uterus and the timing of insertion. Insertions carried out 10 to 12 weeks postpartum usually occasion little or no discomfort and seldom produce any bleeding complications except for temporary spotting. On the other hand, insertion of an intrauterine device through the nulliparous cervix, or in a woman who has not borne children for several years, can result in cramps which persist for one to two days. A "cervical shock" reaction is sometimes encountered during insertion into nulliparas. This reaction is characterized by nausea, hypotension and syncope. A paracervical block will prevent such reactions. An alternative technic is to give 50 mg. of Demerol and 0.5 mg. of Atropine intramuscularly 20 minutes prior to insertion. A routine analgesic such as codeine is helpful in the management of post-insertion cramps in nulliparas, or in women found by sounding to have a small, sensitive uterus.

A malinsertion or a fitting with too bulky a device should be suspected if severe cramps persist many hours after insertion (Fig. 40). The patient

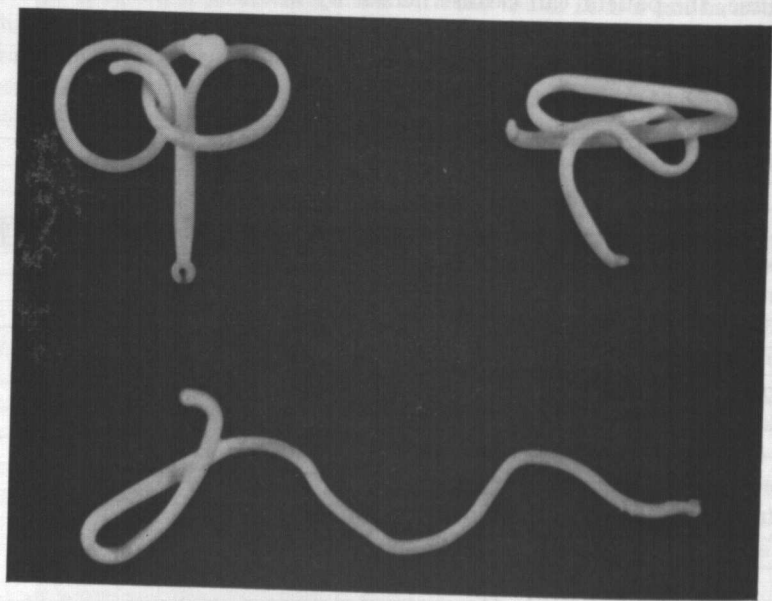


FIG. 40. Distorted IUD's expelled after many days of persistent cramping, resulting from malinsertion of bulky linear devices in small uterine cavities. The lowermost device had been churned into the Gregg shorthand symbol for "failure." Replacement with a device more compatible with uterine cavity size relieved the symptoms, and no further uterine messages were received.

sies or conization for diagnostic or therapeutic purposes) can be carried out without removal of the device.

SPONTANEOUS ABORTION

The incidence of spontaneous abortion is increased when pregnancy occurs in the presence of the device. The International Planned Parenthood Federation handbook on *Intrauterine Contraception* (1) estimates an abortion rate of 41 % with the device *in situ*. Ratmam (3) investigated the outcome of 200 pregnancies which occurred in Singapore following loop insertion. The incidence of abortion was higher when pregnancy occurred with the loop in place (50 %), than when pregnancy occurred after an unnoticed expulsion (14.5 %), or in the women who had the device removed early in pregnancy (24.8 %). A total of 163 pregnancies proceeded to term and delivered normal infants. There were two stillbirths not attributable to the loop and no foetal abnormalities observed. Nine of the infants delivered between the 36th and 38th week of gestation, all of whom were well at the time of discharge.

A report on pregnancy outcome with intrauterine devices has been prepared by Lewit (2), based on the Cooperative Statistical Program (CSP) material. A total of 456 pregnancies which were known to have occurred with the device *in situ* were investigated. Among 250 women who became pregnant with tailed devices (principally loops), the abortion rate was 54 %. Removal of the tailed device when visible at the cervix did not significantly increase the risk of abortion. In fact, the live birth rate was increased from 38.9 to 49.9 by the removal of the tailed devices.

If the removal of the IUD required considerable uterine manipulation (as with tail-less steel rings and bows), the abortion rate in the CSP series was 35 % among women from whom the tail-less device was extracted. The live birth rate was 62.9 % among 141 women with tail-less devices not manipulated and 17.6 % among the 25 women who had extraction of a tail-less device undertaken. Lewit concluded: (a) the IUD sometimes interferes with the course of the pregnancy, (b) removal of a tailed IUD (loop, coil) improves the chances of a live birth, and (c) removal of a tailless IUD (steel ring, bow) by manipulation in pregnancy increases the chances of abortion.

LENGTH OF MARKER TAIL

Most IUD's in current use have a marker tail consisting of one or more pliable threads for confirming their presence. Traction on the tail is also the easiest means of extracting the IUD, should removal be indicated. Following insertion, about an inch of tail should be left protruding from the external os of the cervix. It is best to leave it too long, rather than too short. The excess will curl up in the vaginal vault and will not interfere

with intercourse if it is pliable material. In the event the marker tail is trimmed too short, the device may reposition itself at a higher level in the fundus, causing the tail to disappear.

If linear types of IUD with high expulsion rates are used, it is desirable to instruct the patient to explore the upper vagina and check for the presence of the tail after each menstrual period. However, such self-examination engenders uncertainty which can be avoided by using devices with low expulsion rates. Most expulsions occur in the first days after insertion, or during the first few menstrual periods thereafter.

Among 1,000 patients fitted with shield devices at the Johns Hopkins Hospital, only 22 expulsions were observed in the first year, and all but 5 of these were recognized in the first 2 months of use. Thus, if a modern device with good uterine compatibility is used, the likelihood of retention after successful use for 2 months becomes 99.5%. The very rare later expulsions will usually occur during menses and can be identified by instructing the patient to inspect her perineal pads before discarding them.

ABSENT MARKER TAIL

At the time of the return visit, if the marker tail is not visible, several possibilities must be considered: (1) the tail may have been trimmed too short and has retracted into the cervical canal; (2) the patient may be pregnant, and the tail has retracted coincident with fundal enlargement; (3) the marker tail may have curled up in the cervical canal; (4) there may have been an unnoticed expulsion of the IUD; and (5) there may have been an unnoticed uterine perforation at the time of insertion.

If the menstrual history is normal and bimanual examination does not suggest enlargement or softening, pregnancy is unlikely. The possibility that the tail may have curled up in the cervical canal can be checked by gently exploring with the uterine forceps or a Kelly clamp. The tail which was trimmed too short and which disappeared when the device repositioned at a higher level can often be identified in a similar manner. When this maneuver is unproductive, unnoticed expulsion must be excluded by sounding the uterine cavity. If the device is present, the sound will be felt to strike a firmer object and to deviate slightly as it passes over the edge of the device. The uterine sound should be held lightly between the thumb and forefinger while gently exploring the cavity to give maximal tactile sensitivity when searching for the device. A malleable sound is desirable so that its curvature may be changed to facilitate exploration.

When the marker tail is absent and the sounding cannot establish the presence of the device in the uterus, unnoticed expulsion or possible perforation must be considered. Exploration of the uterus with a removal hook may engage a device which was missed by sounding, and if this proves to be the case, the device can be removed and replaced immediately with a new one bearing a marker tail of appropriate length.

RADIOLOGIC LOCALIZATION

Failure to locate the device by any of the foregoing methods is indication for an anterior-posterior and an oblique x-ray film of the abdomen (Fig. 41). If the film is taken with a radio-opaque catheter in place, determination of the IUD's exact position is simplified. If the x-ray does not demonstrate the device, unnoticed expulsion is the correct diagnosis by exclusion. A new intrauterine device, preferably one with a high retention rate, may be introduced immediately. Patients who have expelled one device should be checked more closely during the first six months after re-insertion, since their probability of having a second expulsion is increased. Re-insertion after one expulsion is justified, however, because most patients will not

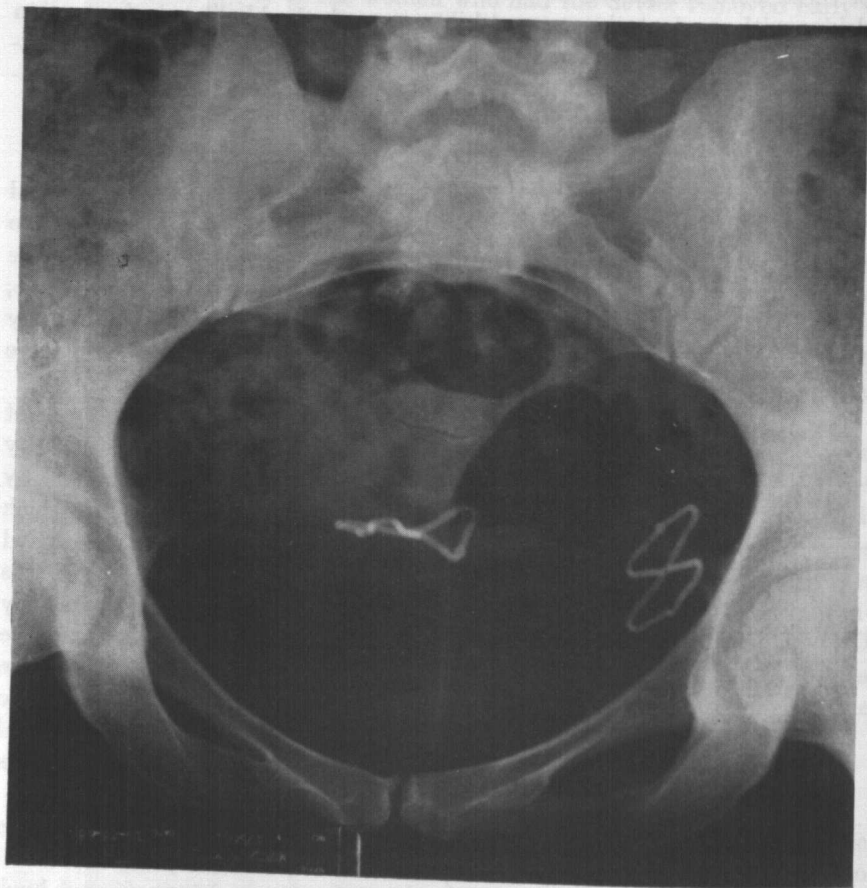


FIG. 41. Perforation with the Birnberg Bow device was not initially recognized because of failure to obtain x-ray. A second device was inserted and is lying transversely in the uterine cavity. The potential hazard of intestinal obstruction due to entrapment of a loop of bowel by this type of IUD makes surgical removal mandatory.

experience a second expulsion, especially if the replacement device has good retention qualities and good fundal positioning is achieved.

Perforation of the uterus is the most distressing complication encountered in the management of patients with intrauterine devices. When good technic of insertion is followed, *including the use of a tenaculum to straighten the axis of the canal and a sound to explore the cavity*, accidental perforation of the uterus is an exceedingly rare event. When perforation is recognized immediately during insertion, traction of the tail of the device should be undertaken to recover the device, and refitting of the patient deferred until the following menstrual period.

Individuals undertaking the management of patients with intrauterine devices can benefit from spending a day observing insertions in a major center experienced in these matters. As we have emphasized, when modern devices are used and meticulous technic is followed, major complications are exceedingly rare. Nevertheless, certain problems arise in the selection and management of IUD patients which can be dealt with more successfully if a minimum of training is secured. Most major hospital centers or Planned Parenthood facilities actively using IUD's will be pleased to make their facilities available for post-graduate orientation.

Because of the long-standing interest of our institution in the intrauterine device, experience has been gained in dealing with specific problems of patient management. Additional experience has been afforded by serving as a referral and training center for the program of the Maryland State Health Department and as consultants to the Maryland Planned Parenthood Clinic. Our clinic has had direct experience with the complications arising in a population of more than 10,000 women fitted with intrauterine devices. There have been no fatalities associated with the use of IUD's in this population, and even minor complications have become increasingly rare as devices of improved design and better tolerance have been introduced into the program.

MANAGEMENT PROBLEMS

To condense the total experience which one might gain by actively working in a family planning center for several months into a few general remarks is not wholly feasible. To amplify this section, some of the problems encountered in the selection and management of IUD patients are presented in the form of brief case histories. We have selected representative problems which will be encountered in managing a very large program, together with examples of patient management technics which have proven useful.

Case A—Pelvic Inflammatory Disease

The patient experienced some mild cramps and a prolonged menstrual period at the time of IUD insertion. Since then, she has had two normal

menstrual periods, but returns today with fever, bilateral lower abdominal pain. She noted some dysuria and increased vaginal discharge four days ago. On examination, the marker tail of the device is visible. There is tenderness present in both adnexa. Yellowish discharge is present over the cervix. There is moderate rebound tenderness in both lower quadrants. The temperature is 101.4.

Mrs. A has acute pelvic inflammatory disease. If the appropriate media are available, culture of the cervical discharge will often disclose gonococci. A stained preparation of the mucous may disclose Gram-negative intracellular diplococci. *Removal of the device is not indicated, since the device is unrelated to the disease process.* Treatment with antibiotics will resolve the pelvic inflammatory disease with the device *in situ*, with every expectation that she can continue using the IUD for birth control. Her husband should be examined and treated if the diagnosis is confirmed.

Case B—Mid-Cycle Spotting

The patient has done well since her IUD insertion three months ago, except for noting mild cramps and spotting for two days at mid-cycle, and a menstrual flow one day longer than usual. She is quite satisfied with the convenience and safety of the method, but is concerned about the intermenstrual spotting. Physical examination discloses the device to be in good position, with normal pelvic findings.

Mrs. B can be reassured that many women experience mild cramps and/or spotting coincident with ovulation. If the two days of mid-cycle spotting are interfering with her sexual activity, advise her to take a cleansing douche with two tablespoons of vinegar in a quart of water in the evening, before retiring. Repeat the Papanicolaou smear to check on a possible occult cervical lesion. Have her keep a menstrual calendar to document the pattern of the bleeding.

Case C—Prior IUD Failure

Mrs. C became pregnant one year after insertion of an intrauterine device. She carried the pregnancy uneventfully to term, delivering a normal infant. The device was delivered with the placenta. She now has four children, and does not desire further pregnancies. Prior to her pregnancy, she had taken oral contraceptives for three months, developing cramps in her legs. She discontinued the oral contraceptive because of these symptoms and promptly became pregnant. She is interested in being refitted with an IUD, but is concerned about the risk of becoming pregnant once again. Examination is entirely within normal limits.

Mrs. C can be advised that the pregnancy rate with a modern type of intrauterine device is lower than with some older devices. Nevertheless, the protection she will achieve with the best modern devices is not quite 100 %.

If complete protection is desired, advise her to apply a spermicidal foam prior to intercourse to add to the protection of the IUD. The possibility of tubal ligation or vasectomy should be offered as an option, provided that the patient and her husband concur in terminating their reproductive career.

Case D—**Spontaneous Abortion**

An intrauterine device was inserted five months ago. The device was in place at the last check-up six weeks after insertion. She has missed two menstrual periods, except for some vaginal spotting and brownish discharge for the past week. Today she began to have severe uterine cramps and started to bleed profusely. On examination, the uterus is somewhat enlarged, with bleeding from a soft, partially open cervix. The tail of the IUD is not visible. There is no fever and no evidence of peritoneal irritation.

Mrs. D is having a spontaneous abortion. The device may have been passed with a blood clot without being noted. Depending on the amount of bleeding, the hematocrit and the physical findings, the patient may be observed while she completes the spontaneous abortion, and curettment to complete the abortion may be undertaken. Treatment with iron tablets may be desirable if there is evidence of anemia after the episode is completed.

Case E—**Perimenopausal Bleeding**

Mrs. E is 46 years old. She was fitted with an intrauterine device 10 weeks after the delivery of her third child five years ago. Until two months ago, her menstrual periods were regular and normal. Recently she has noted a persistent brownish discharge and slight spotting intermenstrually. Her most recent Papanicolaou smear was reported as negative, but with a few clusters of glandular cells noted.

Mrs. E is entering an age bracket when endometrial or endocervical carcinoma will be coincidentally encountered with increasing frequency. A routine cervical scraping Papanicolaou smear is inaccurate in the early detection of adenomatous lesions. If there is cervical mucous present, this material should be aspirated and submitted for cytologic evaluation as a separate specimen, requesting special attention in view of the suspicious history. An endometrial biopsy is indicated. The old device can be removed at the time of curettage, and replaced with a new one.

Case F—**Pelvic Endometriosis**

Mrs. F is 23 years old. She had considerable pain with her menstrual periods until she got married and started using oral contraceptives two years ago. She has never been pregnant, but is concerned about having gained weight and wants to try an IUD instead of the oral contraceptive.

She also states that her sex drive has diminished gradually since starting the oral contraceptive. Physical findings are normal, except for a slight nodularity of the uterosacral ligament palpable on recto-vaginal examination.

Mrs. F should be advised to continue the oral contraceptive if she feels protection against pregnancy is important. Changing to a diaphragm or an IUD will probably result in the return of her severe dysmenorrhea. The physical findings and history are compatible with the diagnosis of pelvic endometriosis. The oral contraceptive is indicated to limit the symptoms and extension of the disease process. She should also be advised that she may be relatively infertile, and should consider attempting pregnancy.

Case G—Bleeding after Insertion

Mrs. G had an intrauterine device inserted two weeks ago. She returns because she has had spotting and mild cramps almost daily since insertion. She had been told that she might experience such spotting until after the completion of her first post-insertion menstrual period, but did not think it would happen to her. The husband is also upset and wants to have the device removed. Physical examination is normal, with the IUD in good fundal position.

Mrs. G may be frightened because she may think the spotting is a dangerous sign or disturbed because she is sexually frustrated. Find out the basis for her fear. Reassure her that the device can certainly be removed, but that it might be better for her to keep it, since she had already experienced most of her difficulties. Advise a cleansing douche. A tranquilizer may prove helpful in alleviating her complaints and anxiety for the next few days. Assure her that you will remove the device if symptoms persist at the time of her eight-week check.

Case H—Premedication for Insertion

Mrs. H is an anxious 24 year old woman who was divorced two years ago. While the divorce was pending, she had an abortion performed on psychiatric indication. She tried taking oral contraceptives for a few months, but developed frequent migraine headaches and discontinued them. Her sexual partner has been using condoms, but she is fearful of becoming pregnant. She has delivered no term infants and requests fitting with an IUD. Physical examination is unremarkable except for anasthenic build and a very rapid pulse. She has eaten no breakfast and drank several cups of coffee before coming to the office.

Mrs. H is likely to develop cervical shock if she is fitted with an IUD without premedication. She should be given 50 mgs. of Demerol and 0.5 mg. of Atropine intramuscularly 20 minutes before undertaking the IUD fitting. A type of device which has good compatibility with an essentially nullipa-

rous uterus is indicated. A paracervical block will minimize reaction to insertion. Advise her that she may have cramps after fitting for a day or two and provide her with a good analgesic.

Case I—Distorted Uterine Cavity

Mrs. I is a 34 year old para 3 whose youngest child is six years old. Her menstrual periods last seven to eight days and are often profuse with clots. She has been using a diaphragm for contraception, but desires to be fitted with an IUD because she finds the use of the diaphragm messy and inconvenient. On pelvic examination, the uterus is very irregular, enlarged to four times normal size with multiple myomata. The uterine cavity is distorted and sounds to a depth of 9 cm.

Mrs. I is a poor candidate for fitting with an intrauterine device because of the enlargement and distortion of the uterine cavity. She is having moderate menorrhagia now, and this will undoubtedly become worse as the myomata further enlarge. When the uterine cavity is significantly distorted, a good IUD fitting is unlikely. Advise her to continue the diaphragm contraception until hysterectomy for the menorrhagia and myomata uteri can be arranged.

Case J—Chronic Salpingitis

Mrs. J is 27 years old and has two children. She has been treated three times in the past year for pelvic inflammatory disease. For the past three years she has used no birth control. On examination, there is bilateral adnexal thickening, with slight tenderness on the left.

Mrs. J is a poor candidate for insertion of an IUD. Her fertility is obviously very much reduced by repeated bouts of pelvic inflammatory disease. If she is fitted, and continues her present pattern, she will be blaming future attacks on the IUD, and if she later decides to attempt pregnancy and fails, the device will be blamed for causing her sterility. A simple local contraceptive method such as cream or foam should answer her needs.

Case K—Dyspareunia

Mrs. K has worn an intrauterine device for two years without difficulty. She is 26 years old and has one child. Her husband is a graduate student and they are on a very restricted budget. She returns for a check-up complaining that she has pain during intercourse and low backache, which she never had earlier in her marriage, and which she now attributes to the intrauterine device. She states that her husband cannot afford any more children than the one they now have. Examination discloses the device *in situ* and entirely normal pelvic findings.

Mrs. K's underlying problem may be that she is desiring a second child, either consciously or subconsciously, and feels in conflict with her husband

over this issue. Complaints of everything from diminished libido to itching feet may be heard under such circumstances. You can offer to remove the device or to give her a tranquilizer, explaining to her that you doubt the device is related to her symptoms. In the last analysis, resolution of the sexual-reproductive conflict between the patient and her husband will probably be necessary before real improvement will take place.

Case L—Promiscuous Teen-Ager

Miss L is 16 years old, unmarried, but sexually active. Her mother is divorced and working to support the family, and brings the daughter for consideration of an IUD for birth control. The daughter took the pill for a while, but was not very consistent, and the mother fears that she may become illegitimately pregnant. Examination disclosed a marital outlet and a foamy discharge from trichomoniasis.

Miss L can be fitted with an intrauterine device. In some places, this must be carried out with the written consent of both the daughter and the mother, since the girl is a minor. Premedication should be given to prevent reaction to the fitting and an intrauterine device well tolerated by nulliparas selected. The girl should be informed about the risks of contracting venereal disease and condoms recommended as additional protection.

Case M—Possible Ectopic Pregnancy

Mrs. M is 23 years old, with one child aged four. She was treated with antibiotics for salpingitis at the age of 18. She was fitted with an intrauterine device two years ago. Since then, her periods have been normal in flow, at 28 to 30 day intervals, lasting four to five days. Two weeks ago, her expected period did not arrive and she felt some mild breast soreness. Yesterday some spotting was noted and discomfort in the right lower quadrant. On examination, there is some moderate tenderness in the right adnexa, but no palpable mass. The uterus is questionably enlarged. The temperature is 99.2 degrees. The intrauterine device is in place.

Mrs. M deserves close observation. She may have an early intrauterine pregnancy with the device *in situ*. However, the combination of menstrual irregularity, unilateral tenderness and lack of fever makes ectopic pregnancy a distinct possibility. Ectopic pregnancy can occur in patients wearing IUD's, a fact which should not be forgotten in judging whether to examine patients who call in with complaints of pain and menstrual irregularity.

Case N—Pregnancy with Device in Situ

Mrs. N was fitted with an intrauterine device seven months ago. She is 26 years old and has two children. At the time of expected menses seven weeks ago she had spotting for one day. She states that she feels pregnant

and comes in for examination, requesting that the device be removed. She has heard that if she is pregnant, the device may damage the foetus if left in place. On examination, the device is *in situ* and the uterus is enlarged and somewhat softened.

Mrs. N is probably pregnant. If the device is visible on inspection of the cervix, removal may provoke some bleeding, but does not usually cause abortion. There is no evidence of an increased incidence of foetal malformation in pregnancies which continue with the device left *in situ*. The device is pushed aside by the developing foetal membranes and is not in contact with the embryo. If the device is not visible, reassure her that leaving it in place will not increase the risk of foetal abnormality. She should also be informed that her chance of having a spontaneous abortion in the first trimester is about 50 % with the device *in situ*.

Case O—Dysfunctional Bleeding

Mrs. O is a 19 year old para 2. She has always had menses at intervals varying from 20 to 40 days, lasting four to five days. She was fitted with an intrauterine device six months ago, and continued having somewhat irregular menstrual intervals as before. The last two periods, however, have been profuse with large clots, lasting eight to nine days each. Examination discloses the device *in situ* and normal pelvic findings. Hematocrit is 28.

Mrs. O has dysfunctional bleeding probably quite unrelated to the IUD, unless it is a large bulky type of device. If such is the case, a trial of a better tolerated type of IUD should be made. Otherwise the patient can usually be treated successfully by administering two cycles of 1 mg. combination type oral contraceptive, together with supportive iron therapy. If the dysfunctional bleeding again recurs, a D & C is indicated.

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APPENDIX A

MAJOR INTRAUTERINE DEVICES: DESIGN, PERFORMANCE DATA AND AVAILABILITY

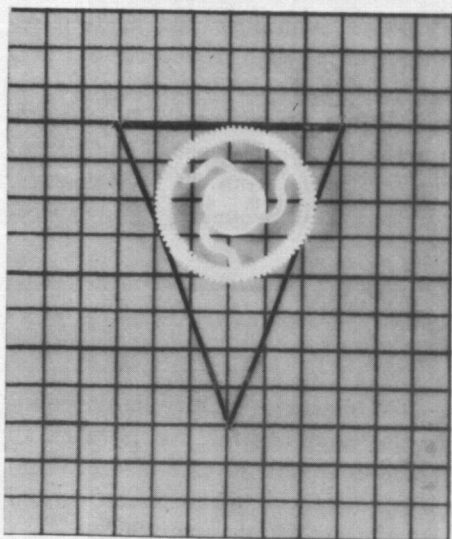
Literally hundreds of IUD design variations have been contrived since the revival of interest in this method of contraception in 1959. Reliable performance data is available, however, on only a few devices, which have distinctive characteristics and have therefore had extensive utilization. The major types of IUD which have achieved significant commercial distribution are presented in the order of their development, commencing with the Ota Ring. The devices have been photographed against a grid with lines at 5 mm. intervals and a triangle representing average uterine cavity size.

TABLE 13
Complications reported per 100 woman-years in first year
of use for 10 major IUD'S

	Pregnancy Rate	Expulsion Rate	Medical Removals	Total Percent Complications
Small Gynecoil	4.2	38.2	13.3	55.7
Large Gynecoil	1.3	25.8	22.1	49.2
Small Loop	5.3	23.9	12.2	41.4
Saf-T-Coil	2.8	19.3	18.7	40.8
Large Loop	2.7	12.7	15.2	30.6
Majzlin Spring	2.2	3.6	22.8	28.6
Small Bow	10.8	4.3	12.1	27.2
Large Bow	4.7	2.6	14.3	21.6
Ota Ring	5.2	4.3	7.3	16.9
Dalkon Shield	1.1	2.3	2.0	5.4

When possible, data on pregnancy rates, expulsions and medical removals is cited from independent sources such as the Cooperative Statistical Program (CSP) of the Population Council. Table 13 summarizes the performance of these selected devices. Rates are computed by the life table method per 100 woman-years for the first year of use. The CSP results represent pooled data compiled by Tietze from 29 investigators, covering experience with various IUD's in 31,767 women with an aggregate of 546,787 woman-months of use.

Age-specific differences exist with respect to pregnancy rates and expulsion rates (especially with the linear coils and loops), and should be borne in mind in comparing IUD performance among women under and over the age of 30. In general, the performance of the linear devices is better among parous women over age 30 than the cited averages. Because most expulsions and medical removals occur in the early months, results with all types of IUD improve in the second and subsequent years of use. Comments on the individual devices are based on the available literature and on our clinical experience in testing a variety of IUD's since 1962.



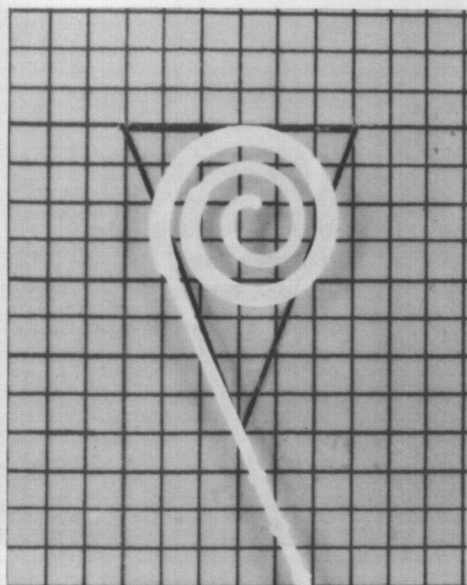
OTA RING (2)

Pregnancy Rate	5.2
Expulsion Rate	4.3
Medical Removals	7.4

Comment: A plastic modification of the Gräfenberg ring, the Ota ring has been widely used for many years in Japan. The first versions of this device were developed in 1934. Insertion and removal is somewhat more difficult than with linear type devices, often requiring cervical dilatation. Pregnancy protection is similar to that of the polyethylene loops and coils, making the Ota ring a satisfactory IUD primarily for child spacing purposes. Because of the lack of a transcervical marker tail, a removal hook is necessary to extract the ring. The Ota ring has not become popular outside of the Orient.

Inventor: Tenrei Ota

Availability: Ota Ring Kenkyusho, 2-1 Kanda Ogawa-Cho, Chyodaku, Tokyo, Japan

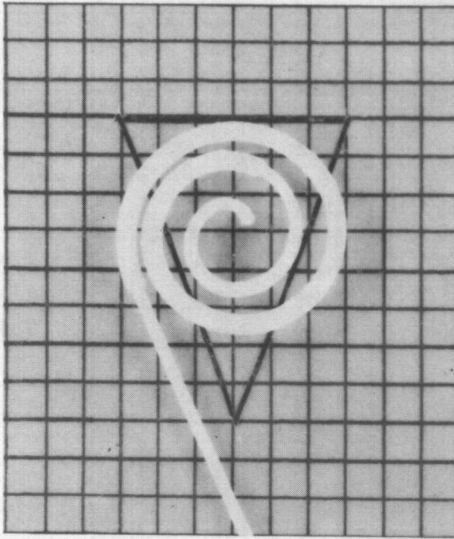


SMALL GYNEKOIL (4)	
Pregnancy Rate	4.2
Expulsion Rate	38.2
Medical Removals	13.3

Comment: The spiral was the first of the linear type IUD's to be developed. It is easy to insert and remove through a tubular inserter devised by Margulies, which has been subsequently adopted for several other types of IUD. Because of high expulsion rates, the beaded tail is left protruding through the cervix for the patient to check after each menstrual period. The rather stiff tail can cause complaints if struck by the penis. The small spiral is little used today because of very high rates of expulsion and high pregnancy rates without any distinct advantages in other areas of performance.

Inventor: Lazar Margulies

Availability: Ortho Pharmaceutical Co., Raritan, New Jersey

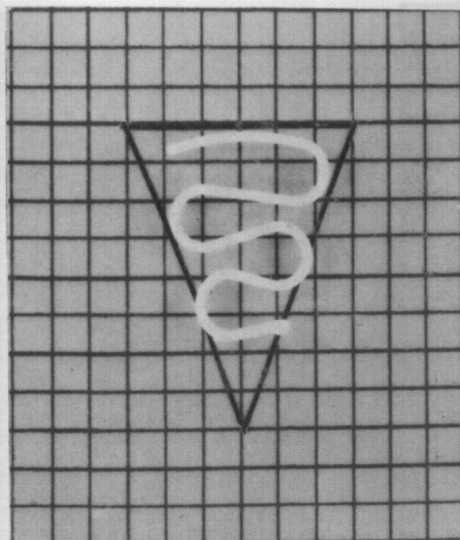

LARGE GYNEKOIL (4)

Pregnancy Rate	1.3
Expulsion Rate	25.8
Medical Removals	22.1

Comment: Among the linear type devices developed in the early 1960's, the large spiral had the best performance in terms of pregnancy rates. The coil is easy to insert and remove. However, the large coil is incompatible with the average uterine cavity, producing high rates of expulsion and frequent removals for cramping and bleeding complications. The stiff beaded tail protruding through the cervix can cause injury if struck by the penis during coitus. Because of these shortcomings, the large spiral has not maintained broad utilization.

Inventor: Lazar Margulies

Availability: Ortho Pharmaceutical Co., Raritan, New Jersey



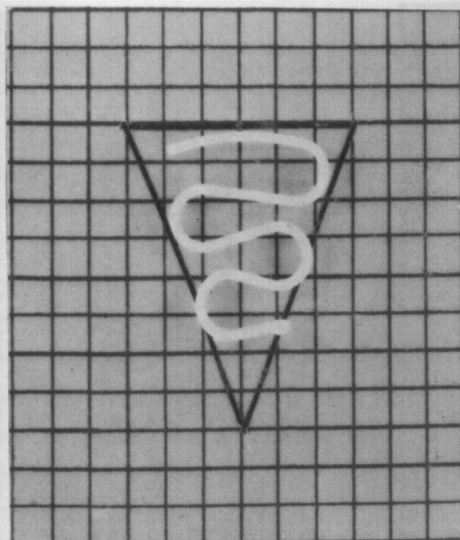
SMALL LIPPES LOOP

Pregnancy Rate	5.3
Expulsion Rate	23.9
Medical Removals	12.2

Comment: The small A loop was the first version of the loop developed by Lippes. It has the virtue of being extremely easy to insert and remove. Because of its relative flexibility, the A Loop is less likely to produce cramps and bleeding complications than the subsequent versions of this design. The A Loop is fairly compatible with the smaller size range of uterine cavities and can be worn by some nulligravidas successfully. Despite these advantages, the small loop has had unacceptably high pregnancy rates and expulsion rates in comparison with modern IUD's.

Inventor: Jack Lippes

Availability: Ortho Pharmaceutical Co., Raritan, New Jersey



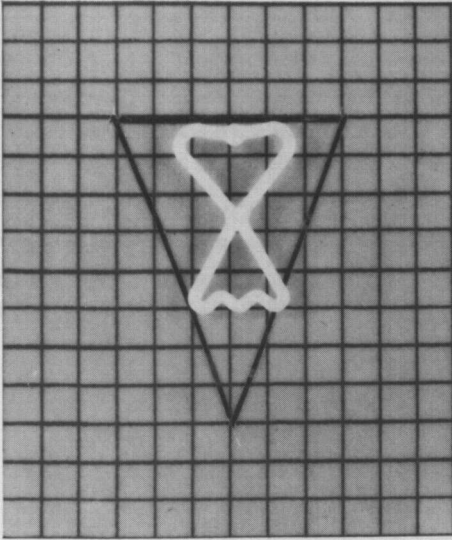
SMALL LIPPES LOOP

Pregnancy Rate	5.3
Expulsion Rate	23.9
Medical Removals	12.2

Comment: The small A loop was the first version of the loop developed by Lippes. It has the virtue of being extremely easy to insert and remove. Because of its relative flexibility, the A Loop is less likely to produce cramps and bleeding complications than the subsequent versions of this design. The A Loop is fairly compatible with the smaller size range of uterine cavities and can be worn by some nulligravidas successfully. Despite these advantages, the small loop has had unacceptably high pregnancy rates and expulsion rates in comparison with modern IUD's.

Inventor: Jack Lippes

Availability: Ortho Pharmaceutical Co., Raritan, New Jersey



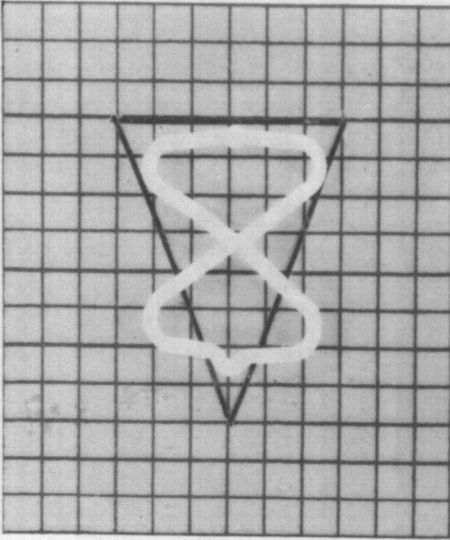
SMALL BOW (4)

Pregnancy Rate	10.8
Expulsion Rate	4.3
Medical Removals	12.1

Comment: The small bow is well retained by women with small uterine cavities, and has much better performance in this respect than the linear coils and loops. Women under the age of 30 (who are particularly prone to expulse linear devices) can be fitted with the bow with a lower risk of expulsion. Insertion and removal is slightly more difficult than with the linear devices. The high pregnancy rates with the small bow, however, make it an unsatisfactory device unless used with an adjunctive method such as a foam contraceptive pre-coitally. A variant of this device, called the Ancor, may overcome the difficulties with perforation followed by intestinal obstruction which diminished clinical enthusiasm for the original design.

Inventor: Charles Birnberg, John Marco

Availability: American Caduceus Industries, 110 Fifth Avenue, New York, New York



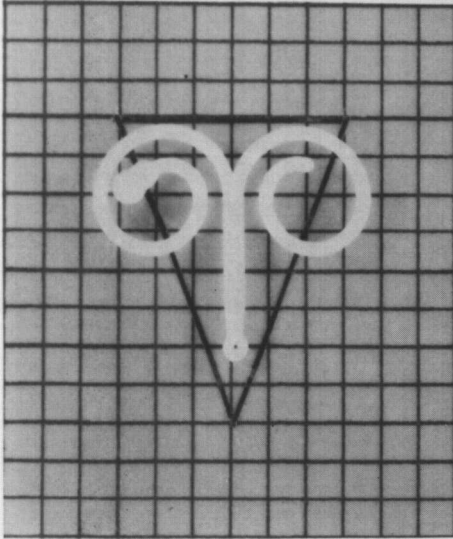
LARGE BOW (4)

Pregnancy Rate	4.7
Expulsion Rate	2.6
Medical Removals	14.3

Comment: The bow was the first of the plastic intrauterine devices to achieve almost perfect retention. The lower prongs of the bow tend to embed in the lower uterine segment, fixing the device in situ. The bow has a low surface area in relation to its bulk, however, and pregnancy rates have been unsatisfactorily high. The bow is somewhat more difficult to insert and remove than the loops and coils, and its use has resulted in high rates of uterine perforation in some studies. A partial perforation can result in entrapment of a loop of bowel within one limb of the bow, predisposing to intestinal obstruction. Despite the advantage of low expulsion rates, the difficulties with perforation and relatively high pregnancy rates have limited the popularity of this IUD design.

Inventor: Charles Birnberg, John Marco

Availability: American Caduceus Industries, 110 Fifth Avenue, New York, New York

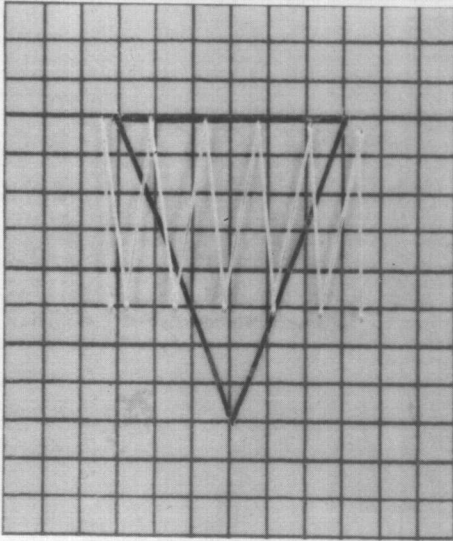


SAF-T-COIL (4)	
Pregnancy Rate	2.8
Expulsion Rate	19.3
Medical Removals	18.7

Comment: The performance of the double coil is similar to the loop in terms of pregnancy rates. Expulsion rates, however, are higher than with the loop. The design is rather bulky and incompatible with the smaller uterine cavities, resulting in frequent medical removals because of cramping and bleeding complications. The double coil was the first IUD made available as a sterile pre-packaged unit, the major factor which popularized it for clinical use. It is a satisfactory device for spacing purposes in parous women over the age of 30, among whom expulsions and medical removals occur less often. The double coil does not provide optimal protection or good retention for young women of high fertility, and is less popular now that most manufacturers supply better devices as sterile pre-packaged units.

Inventor: Frank Robinson

Availability: Julius Schmidt, Inc., 423 West 55th Street, New York, New York

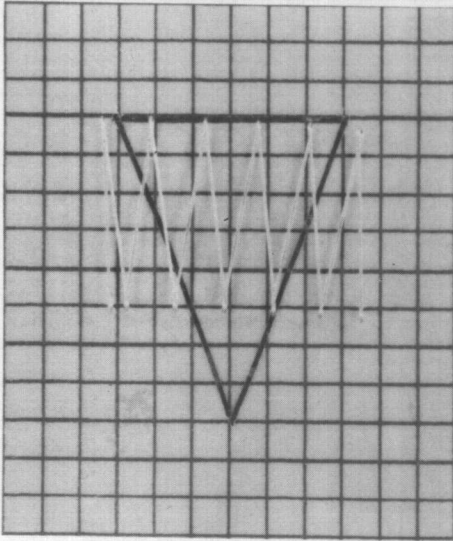
**MAJZLIN SPRING**

Pregnancy Rate	2.2
Expulsion Rate	3.6
Medical Removals	22.8

Comment: The Majzlin Spring device has outstandingly good retention, making it a more satisfactory device than the first generation linear IUD's, particularly for early postpartum applications. Small versions of this device are also well retained by nulligravidas. Insertion is quite easy, but removal of the spring can be difficult because of the tendency of the fine stainless steel wires to embed in the endometrium. The shearing action of the wires when subjected to lateral compression is probably responsible for the relatively high incidence of medical removals, principally for bleeding complications. If the problems of embedment and difficulties with removal are overcome, this type of device will achieve greater popularity because of its excellent retention.

Inventor: Gregory Majzlin

Availability: Anka Research Ltd., Jamaica, New York

**MAJZLIN SPRING**

Pregnancy Rate	2.2
Expulsion Rate	3.6
Medical Removals	22.8

Comment: The Majzlin Spring device has outstandingly good retention, making it a more satisfactory device than the first generation linear IUD's, particularly for early postpartum applications. Small versions of this device are also well retained by nulligravidas. Insertion is quite easy, but removal of the spring can be difficult because of the tendency of the fine stainless steel wires to embed in the endometrium. The shearing action of the wires when subjected to lateral compression is probably responsible for the relatively high incidence of medical removals, principally for bleeding complications. If the problems of embedment and difficulties with removal are overcome, this type of device will achieve greater popularity because of its excellent retention.

Inventor: Gregory Majzlin

Availability: Anka Research Ltd., Jamaica, New York

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2. Muramatsu, M.: *Japan's Experience with Family Planning*; Family Planning Federation of Japan, 1967.
3. Tietze, C.: Experience with new IUD's. *Contraception* 1: 73-80, 1970.
4. Tietze, C. and Lewit, S.: Evaluation of intrauterine devices: ninth progress report of the Cooperative Statistical Program. *Studies in Family Planning* 55: 1-40, 1970.

APPENDIX B

EXPERIMENTAL INTRAUTERINE DEVICES AND DEVICES OF LIMITED DISTRIBUTION

In the preparation of this section, the collection of IUD's maintained at the Population Council has been a useful reference source. Appreciation is expressed to Mr. Ray Belsky and Dr. Frank Shubeck for providing access to this material. The IUD Information Handbook prepared by T. J. Lardner, W. J. Shack and P. Y. Tam at the Massachusetts Institute of Technology on behalf of the Pathfinder Fund has been an invaluable source of performance data on some of the less well known devices.

Included in this section are intrauterine devices which have achieved some degree of recognition through publication, patent application or experimental use, as well as devices which have had limited commercial distribution. The 22 devices presented do not represent a complete index of the hundreds of variations of sizes, shapes and materials which have been contrived.

When possible, performance data has been cited from the most current sources independent of the inventor or developer of the device. References preferentially cited have been the computations of Tietze from the Cooperative Statistical Program, Bernard's Data from the International IUD Program of the Pathfinder Fund and the IUD Information Handbook. The performance data with regard to pregnancy rates, expulsion rates and medical removals are computed per 100 woman-years in the first year of use. The category of medical removals contains a major component of removals for pain and/or bleeding complications, and a minor component of removals for other reasons.

The various IUD's are presented alphabetically for ease of reference, most of them deriving their name from the inventor or through common usage. The standard size of each device has been used for illustrative purposes. Photographs were taken against a grid scored at 5 mm. intervals and are reproduced full scale. A schematic triangle representing the average

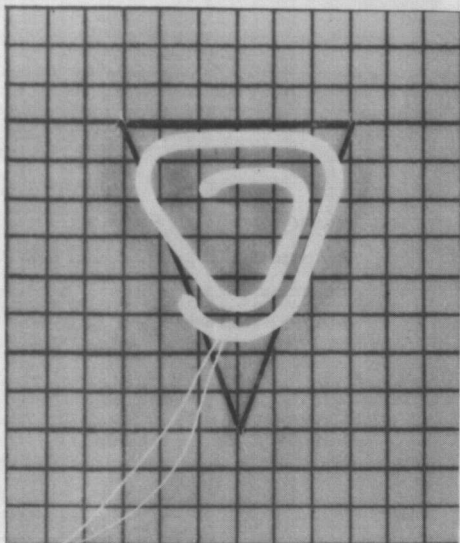
uterine cavity has been drawn on the grid for ready comparison of the individual devices and standard uterine cavity dimensions.

Available performance data is listed in Table 14. The information on some of these devices is quite limited in terms of the size of the series, the adequacy of follow-up and woman-months of exposure. The cited figures should be viewed accordingly. In instances when performance data is not available, it is so designated (N.A.). It will be noted that many of the devices presented in this section are variants of the basic types of IUD presented in Appendix A, with performance data similar to the parent device. Other designs are quite imaginative, but without particular merit, while still others are in advanced stages of development and may be destined to assume a more important role in the future.

TABLE 14

Complications reported per 100 woman-years in first year of use for minor devices

	Pregnancy Rate	Expulsion Rate	Medical Removals	Total Percent Complications
Szontagh Device	11.6	7.5	20.5	39.6
Zipper Ring	3.4	32.8	1.2	37.4
Steel Ring	6.7	18.0	9.7	34.4
Shamrock Device	4.0	13.0	17.0	34.0
"T" Device	18.3	5.9	3.2	17.4
Incon Device	3.4	16.0	5.0	24.4
Copper "T"	6.3	5.9	9.8	22.0
Silent Protector	3.0	5.5	10.0	18.5
"M" Device	1.7	2.7	13.5	17.9
Inhiband Device	4.7	3.5	9.2	17.4
Antigon Device	5.6	8.2	1.7	16.5
Heart Device	0.4	3.2	5.0	8.6

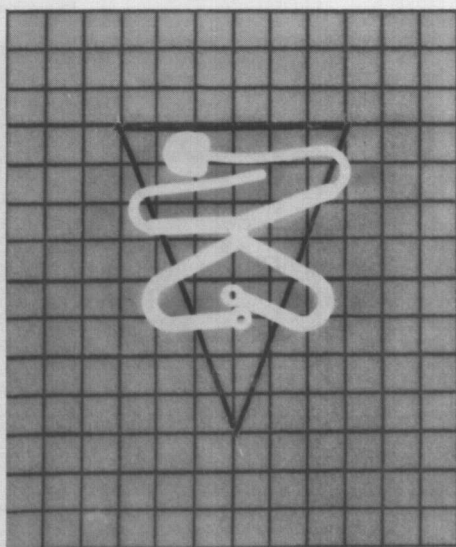


AHMED DEVICE	N.A.
Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.

Inventor: Mary Aftab Ahmed

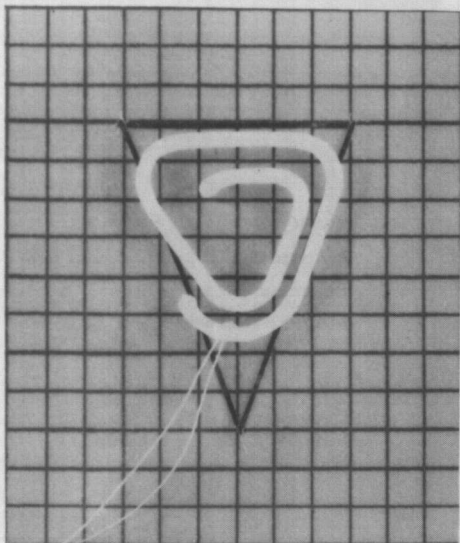
Availability: Schueler & Company, 110 Fifth Avenue, New York, New York

ANCOR DEVICE	
Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.



Inventor: Michael S. Burnhill

Availability: American Caduceus Industries, 110 Fifth Avenue, New York, New York

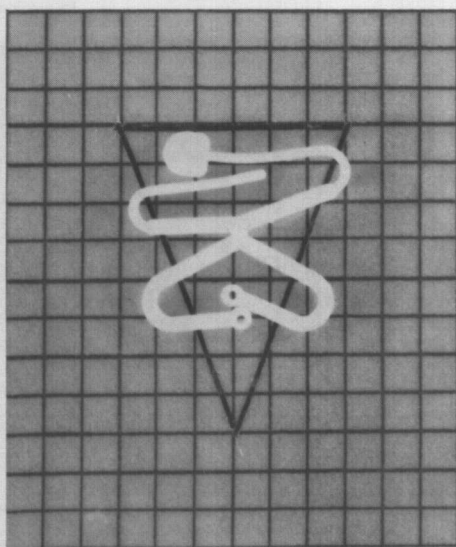


AHMED DEVICE	N.A.
Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.

Inventor: Mary Aftab Ahmed

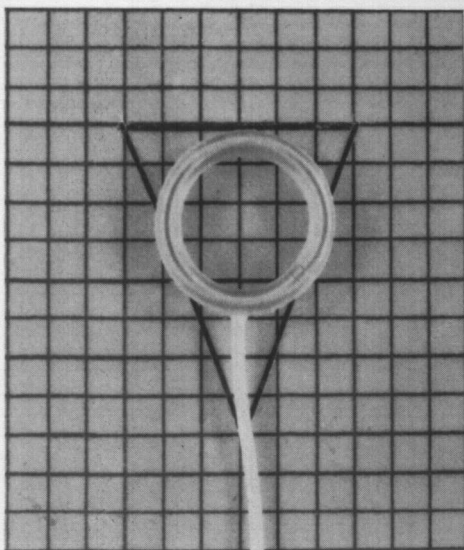
Availability: Schueler & Company, 110 Fifth Avenue, New York, New York

ANCOR DEVICE	
Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.



Inventor: Michael S. Burnhill

Availability: American Caduceus Industries, 110 Fifth Avenue, New York, New York



COMET DEVICE

Pregnancy Rate

N.A.

Expulsion Rate

N.A.

Medical Removals

N.A.

Inventor: Jerome Schwartz, Franklin C. Reyner

Availability: Skye-Ray Corp., 88-61 76th Avenue, Glendale, New York

COROLLE DEVICE

Pregnancy Rate

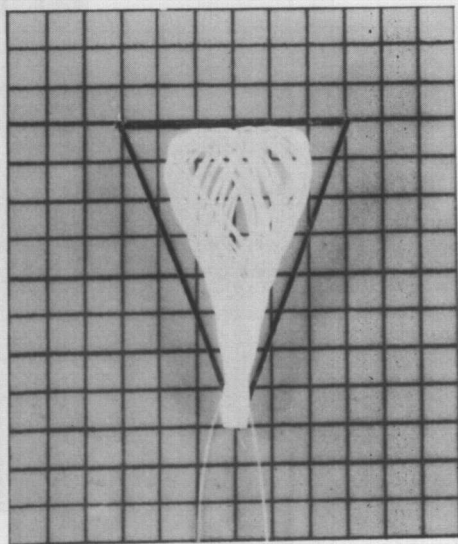
N.A.

Expulsion Rate

N.A.

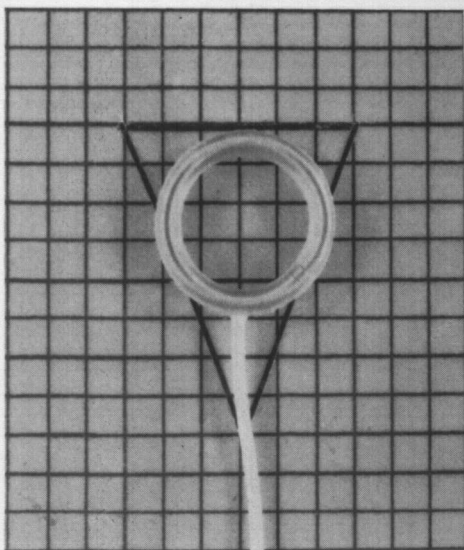
Medical Removals

N.A.



Inventor: Jean Cohen

Availability: A.T.N., 156 rue Oberkampf, Paris XI^e, France



COMET DEVICE

Pregnancy Rate

N.A.

Expulsion Rate

N.A.

Medical Removals

N.A.

Inventor: Jerome Schwartz, Franklin C. Reyner

Availability: Skye-Ray Corp., 88-61 76th Avenue, Glendale, New York

COROLLE DEVICE

Pregnancy Rate

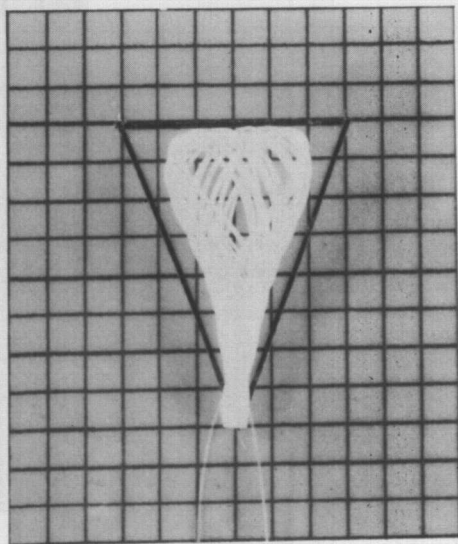
N.A.

Expulsion Rate

N.A.

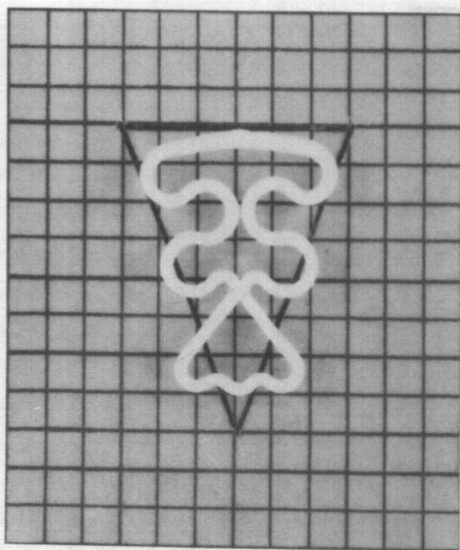
Medical Removals

N.A.



Inventor: Jean Cohen

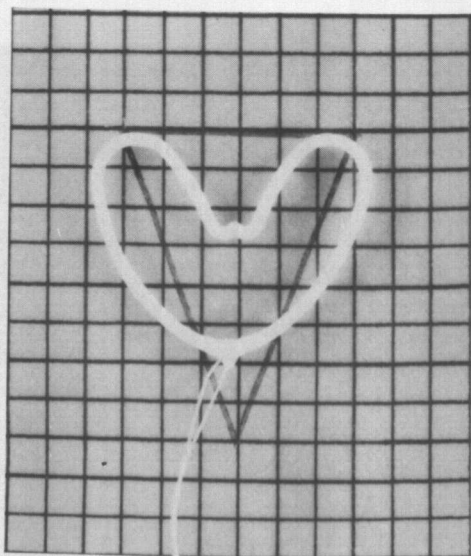
Availability: A.T.N., 156 rue Oberkampf, Paris XI^e, France



DANA DEVICE (4)	
Pregnancy Rate	3.9
Expulsion Rate	4.5
Medical Removals	3.1

Inventor: Unknown

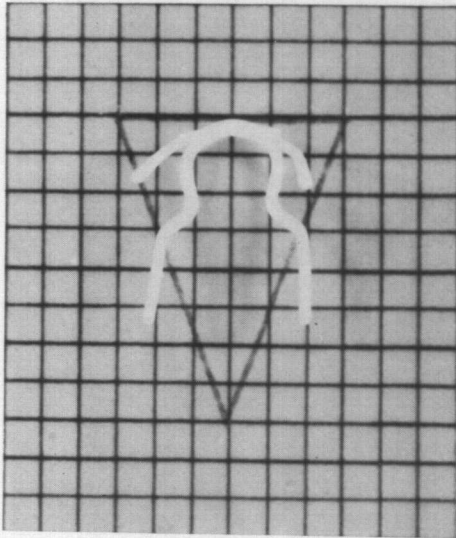
Availability: Textile Research Institute, Brno-Vaclavska 6, Czechoslovakia



HEART DEVICE (4)	
Pregnancy Rate	0.4
Expulsion Rate	3.2
Medical Removals	5.0

Inventor: Unknown

Availability: The Pathfinder Fund, 850 Boylston Street, Chestnut Hill, Massachusetts



LEM DEVICE

Pregnancy Rate

N.A.

Expulsion Rate

N.A.

Medical Removals

N.A.

Inventor: John L. Marco

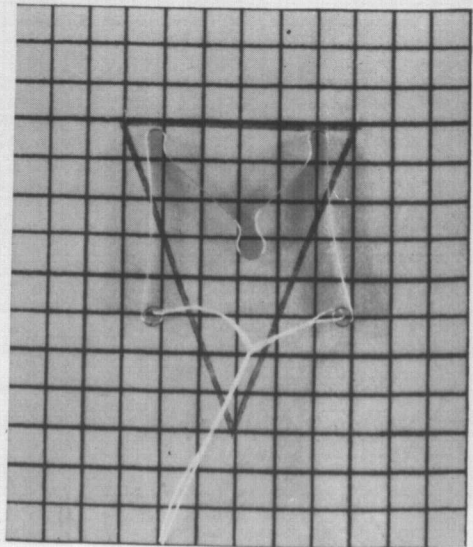
Availability: Marco & Sons Inc., 601 Dow Avenue, Oakhurst, New Jersey

"M" DEVICE (2)

Pregnancy Rate 1.7

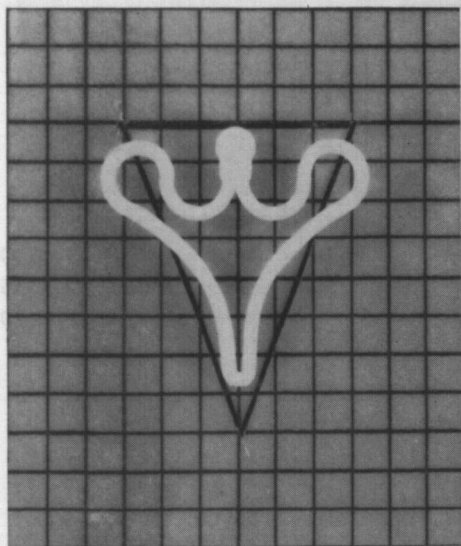
Expulsion Rate 2.7

Medical Removals 13.5



Inventor: Marc Chaft

Availability: Skyron Corp., 8 New York Avenue, Newark, New Jersey

**OMEGA DEVICE**

Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.

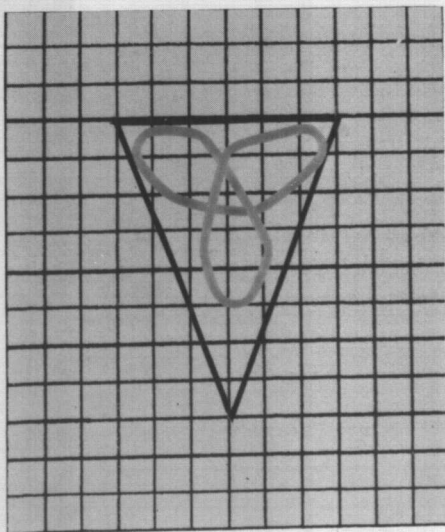
Inventor: R. Malgouat

Availability: Rene Cornut, 156 rue de Orangers, Cauderan, Gironde, France

by Ben, Sussex, England

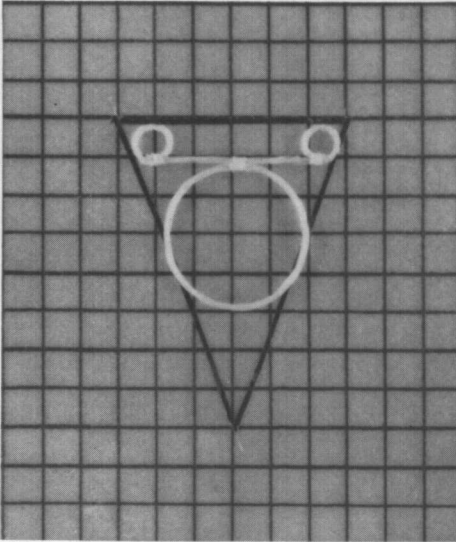
SHAMROCK DEVICE (1)

Pregnancy Rate	4.0
Expulsion Rate	13.0
Medical Removals	17.0



Inventor: C. Lalor Burdick

Availability: C. Lalor Burdick, 4400 Lancaster Pike, Wilmington, Delaware



SILENT PROTECTOR (4)

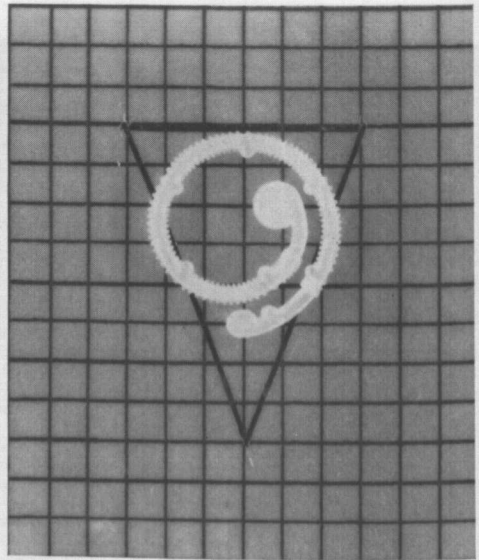
Pregnancy Rate	3.0
Expulsion Rate	5.5
Medical Removals	10.0

Inventor: M. H. Knoch

Availability: M. H. Knoch, 15 Djalan Rangka Malela, Bandung, Indonesia

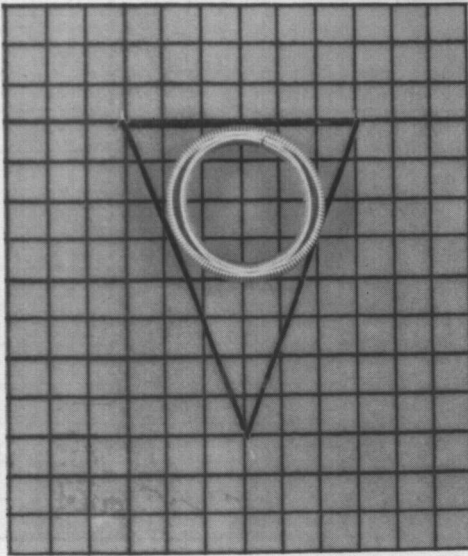
SPIRA-RING

Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.



Inventor: Tenrei T. Ota

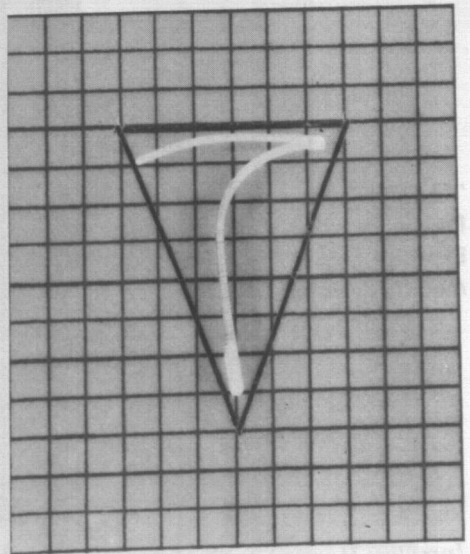
Availability: Ota Ring Kenkyusho, 2-1 Kanda Ogawa-Cho, Chyoda-Ku, Tokyo, Japan

**STEEL RING (6)**

Pregnancy Rate	6.7
Expulsion Rate	18.0
Medical Removals	9.7

Inventors: Herbert H. Hall, Martin L. Stone, Alexander Sedlis and Irwin Chabon

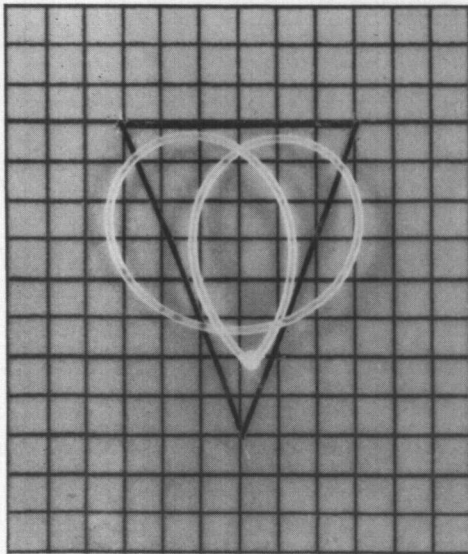
Availability: Eschman Bros. and Walsh Ltd., 24 Church Street, Shoreham-by-Sea, Sussex, England

**"SEVEN" DEVICE**

Pregnancy Rate	N.A.
Expulsion Rate	N.A.
Medical Removals	N.A.

Inventor: Harvey Abramson, Jaime Zipper

Availability: G. D. Searle Co., P. O. Box 5110, Chicago, Illinois

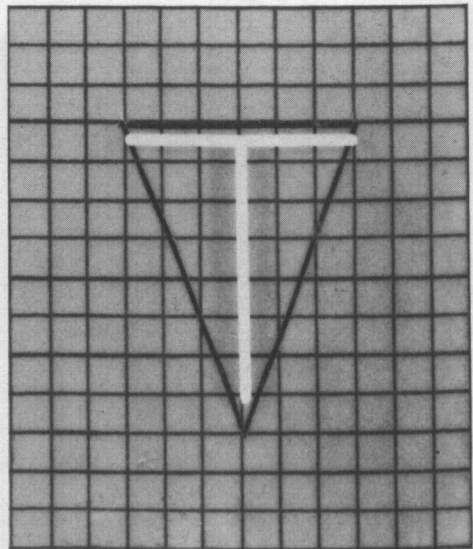


SZONTAGH DEVICE (4)

Pregnancy Rate	11.6
Expulsion Rate	7.5
Medical Removals	20.5

Inventor: F. E. Szontagh

Availability: Department of Obstetrics and Gynecology, Szeged Medical School, Szeged, Hungary

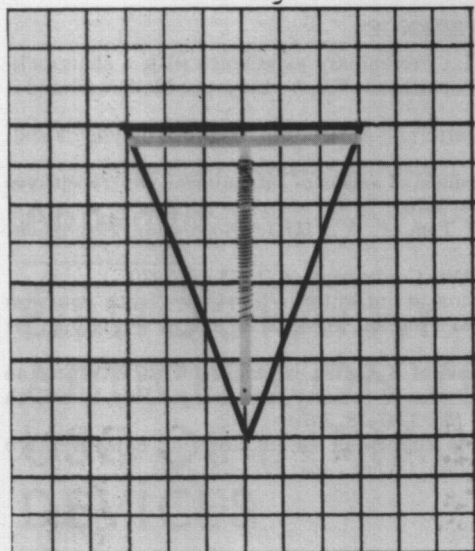


"T" DEVICE (8)

Pregnancy Rate	18.3
Expulsion Rate	5.9
Medical Removals	3.2

Inventor: Howard Tatum

Availability: The Population Council, 245 Park Avenue, New York, New York

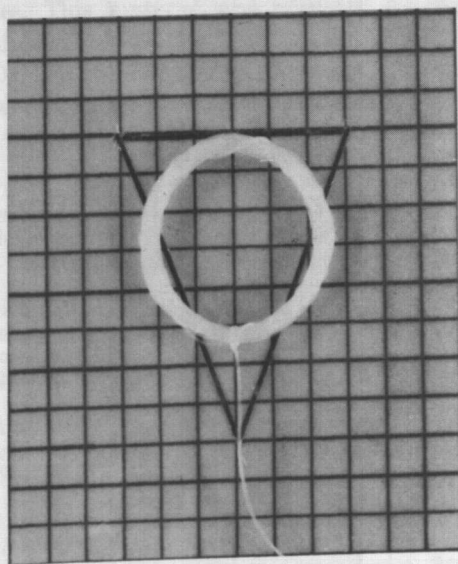


"T" DEVICE (COPPER) (8)

Pregnancy Rate	6.3
Expulsion Rate	5.9
Medical Removals	9.8

Inventors: Howard Tatum, Jaime Zipper

Availability: The Population Council, 245 Park Avenue, New York, New York



ZIPPER RING (7)

Pregnancy Rate	3.4
Expulsion Rate	32.8
Medical Removals	1.2

Inventor: Jaime Zipper

Availability: Shyf Plastic Chilena, Francisco Meneses 1980, Santiago, Chile

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