The making of the first loop

Jack Lippes

Editor's Note:
The American Journal of Obstetrics and Gynecology (AJOG) rarely prints previously published work. However, when provided with the opportunity to republish Dr Jack Lippes' original manuscript describing the evolution of the Lippes loop intrauterine device (IUD), we accepted. This manuscript forms the foundation for a subsequent large body of work related to the IUD over the intervening decades; indeed, since 1965, nearly 500 manuscripts on this topic have been published in AJOG, including a 1965 case series by Dr Lippes. We take advantage of this look into the past to pivot into the present. Dr Jeffrey Peipert, Deputy Editor for AJOG, discusses the evolution and current status of the IUD in women's health care in the accompanying editorial in this month's issue, "Lippes loop and the first IUDs: lessons from a bygone era." On our website (www.ajog.org), we have compiled all AJOG manuscripts published about the IUD in the past 5 years. Topics range from its role in preventing pregnancy to effectiveness in treating gynecologic conditions and beyond. This curated collection can be accessed at https://www.ajog.org/iud.

There is a plethora of nineteenth-century medical literature describing intracervical and intrauterine pessaries with a major impetus toward straightening a flexed or displaced uterus. The most significant outcome of these studies was the recognition that they might also be contraceptive. A variety of substances was used to make them, including natural products such as wood, wool and ivory, as well as metal such as silver, gold and platinum; some were adorned with diamonds. Then as now, controversy flared in Europe and in the United States over the safety and effectiveness of these devices. In the twentieth century, the medical profession continued to alternately praise and condemn intrauterine devices (IUDs).

Grafenberg presented data on silk and/or silver rings in 1928, 1929 and 1930, his last presentation being at the Seventh International Birth Control Conference in Zurich, 1930. He reported on 600 patients fitted with the silver ring and observed that only 1.6 percent had become pregnant. Only 5 years, later the Berlin Gynaecologic Society condemned intrauterine contraception as a careless procedure.

Grafenberg, who was Jewish, was incarcerated in a Berlin jail until Margaret Sanger raised a ransom to free him. He emigrated to the United States where he established a private practice in New York City. A library search revealed that doctors who protested intrauterine contraception were not the physicians with the greatest experience using IUDs but only those individuals who occasionally removed a device. Their opposition to IUDs was based on typical "I had a case" reasoning. For all practical purposes, intrauterine contraception stagnated in western society for the next 30 years. In spite of negative case reports, Japanese physicians continued to use a modification of the Grafenberg ring designed by Ota. Atsumi Ishihama of the Iwata Medical College in Morioka, Japan, inserted rings in his private practice and for years carefully followed the use of these devices throughout Japan. In 1959, more articles on intrauterine contraception were available in the Japanese medical literature than in the rest of the world. Western medicine did not renew interest in this subject until the same year, when the editors of the *American Journal of Obstetrics and Gynecology* invited W. Oppenheimer to write a review of his 28 years experience with IUDs. Oppenheimer and Ishihama claimed the method to be both safe and effective. Furthermore, using an IUD was inexpensive and required little motivation. The single act of having an IUD inserted provided years of protection. A new concept of sociological significance was introduced. By having an IUD inserted, the responsible act of parenthood became an act of deliberation. To become pregnant a woman had to make a decision to have the IUD removed and then see a physician to have this done. The reports by Ishihama and Oppenheimer aroused the curiosity of many gynaecologists.

In the twentieth century, as in the nineteenth century, inventors strove to meet the major IUD requirements: (1) design, (2) size, (3) material and (4) the inserter. My thoughts were then focused on clinical evaluation and the innovation of new designs for intrauterine contraceptive devices.

1. Design

In my private practice I began inserting handmade Oppenheimer rings. Ota rings imported from Japan were tried. It was found that the small lentil-shaped polyethylene (PE) disc in the centre of the Ota ring necessitated considerable dilatation of the cervix, which was painful for the patient and difficult for the operator. Excising the lentil-shaped disc from the centre of the ring made insertion easier, but expulsions occurred more frequently. Removal of the ring was accomplished with Grafenberg's instrument, which resembled a crochet hook. Success depended upon the operator's sense of touch. I soon learned that inserting IUDs was easier than removing them. Frequently, it was difficult to feel the device,

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much less remove it. Thus, the second modification was to tie a linear PE thread to the Ota ring, so that the device could be easily withdrawn when desired. (see Fig.1.)

Creating a cervical appendage was contrary to Grafenberg's tenet against connecting the uterine cavity with the vagina because that might increase infection. Grafenberg was correct, for in 1930, only a multifilamented thread was available, and from the Dalkon shield experience we know that a multifilament thread conveys bacteria from the vagina to the uterine cavity by capillary action. Fortunately, the single strand of PE does not do this. Patients became fond of the PE thread because it provided them with palpable reassurance that protection continued. With experience, more design changes evolved. It was noticed that round devices rotated, winding the thread into the cervix or uterine cavity in a manner similar to rolling up a window shade, and thereby eliminating the easy means of removal.

In the summer of 1960, a colleague questioned whether it was wise to do this type of clinical research in a private office. It was an intelligent question. A planned parenthood clinic was the right place to evaluate a new contraceptive. When approached, both the Medical Committee and the Governing Board of the Buffalo Planned Parenthood Clinic considered IUDs outside the realm of standard medical practice and were reluctant to grant permission for "such radical research;" after all, it was a time when gynaecological textbooks proclaimed that IUDs should be mentioned only in condemnation. I wrote a letter to Alan Guttmacher, then president of the Planned Parenthood Federation of America, asking for his advice and help. The letter was referred to Christopher Tietze, who encouraged me to continue IUD evaluation and offered his help. He came to Buffalo and persuaded the Buffalo Planned Parenthood Clinic to grant permission to investigate intrauterine contraception. Tietze provided credibility and encouragement for continuing these studies. The letter was also referred to Hans Lehfeldt, who had worked with Grafenberg in Berlin and who, in 1960, was chairman of the research subcommittee of the National Medical Advisory Committee for the Planned Parenthood Federation of America. Lehfeldt wrote to me explaining that the use of an IUD in the United States could be considered malpractice. This reply reflected the attitude of the medical profession of that day. Shortly thereafter, I visited Hans Lehfeldt and, while driving around New York City, he told me that IUDs were much better than most physicians believed and that my investigations with new designs should be vigorously pursued. "Forget about the letter I wrote on behalf of the Planned Parenthood Medical Advisory Committee." Later that afternoon, he took me to the office of Herbert Hall who had been an associate of Grafenberg in his Manhattan office. He dismissed his secretary for the day and the three of us retreated to his consultation room. When Herbert Hall carefully closed the door behind him, I felt as though I was entering some kind of subversive conspiracy. Furtively, Hall described how he and Grafenberg had inserted a stainless-steel modification of the Grafenberg ring into a number of celebrities from New York and Hollywood. Patients were sworn to secrecy and Hall was on call 24 hours a day. He was reluctant to publish his excellent results for fear that his colleagues might disgrace him for what they considered a repudiated medical practice. A few months later he did publish his long experience with the stainless ring, which was then named the "Hall-Stone ring." I returned to Buffalo, refreshed, encouraged and with a newly found enthusiasm for the task before me.

My attention was focused on how to prevent rotation of the IUD with disappearance of the useful removal thread. A departure from the geometry of the ring was essential. Perhaps, if the IUD closely fitted the contours of the uterine cavity, rotation might be prevented or at least minimized. Concurrently, other changes had to be incorporated in the design to reduce the incidence of expulsions.

If one assumes that the uterus expels an IUD in a manner similar to the way one expels a noodle or spaghetti from the mouth, then the IUD must similarly be deflected or straightened before the uterus expels it. However, this is not always the case. The uterus can and does expel an IUD *en masse*. Nevertheless, to inhibit expulsions, it seemed logical to maximize the work the uterus must do to expel an IUD. Because it requires more energy to straighten a "U" turn than anything smaller, a design that placed as many "U" turns as possible on the PE noodle (the IUD) could improve uterine retention. Obviously, the gist of this concept was further defined by uterine anatomy. The double "S" was designed to reduce expulsions and, simultaneously, to accommodate the IUD to the triangular, or some might say trapezoidal, shape of the uterine cavity. (See Fig. 2.)

2. Size

Measurements of the uterine cavity dictated the dimensions of the loop. Since the internal os of the cervix is 4 mm, the outside diameter (o.d.) of the inserter is also 4 mm. The inside diameter (i.d.) of the inserter barrel is 3.4 mm. For the loop to fit into the barrel of the inserter, its cross-sectional diameter had to be even smaller. In cross-section, loop D is 2.7 by 2.0 mm, while loop A is 2.4 by 2.0 mm. (See Fig. 3.)

According to Dickinson, the inside diameter of the uterine fundus varies between 25 and 35 mm while the inside diameter of the lower uterine segment is approximately 6 mm. A double S or loop shape had to be confined with this trapezoid. (See Fig. 4.)

The Population Council had awarded a grant to make steel moulds for the loop. Funds were sufficient to cut one or possibly two moulds. It seemed important to select the right size from the start. A loop which was 22.2 mm across the top bar appeared safer. The smaller device would fit within a uterine cavity with a fundus which measured either 25 or 35 mm. This 22.2 mm loop was at first called "loop I," and later was labelled "loop A." By 6 months it was observed that loop A had a cumulative expulsion rate of 14.6 per 100 women-years (hwy) and a pregnancy rate of 4.8/hwy. These rates were unacceptably high. Would a larger loop reduce the expulsion and pregnancy rates? Using the remaining funds in