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VOLUME 3

Intrauterine and Other Contraceptive Devices

宫内节育器及其它避孕器

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Selected Papers on Planned Parenthood

Vol. 3

Intrauterine & Other Contraceptive Devices

March 1975

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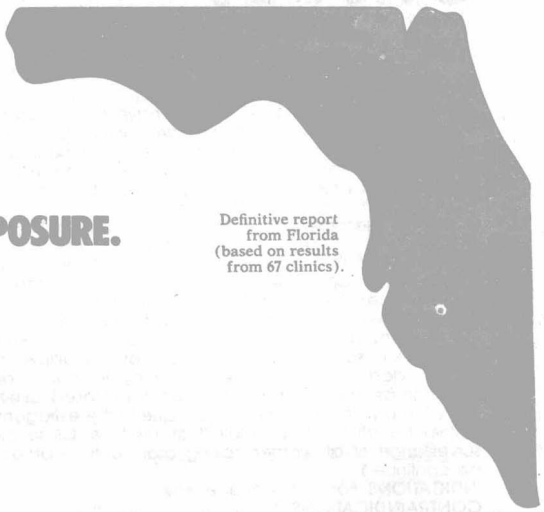

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1. Caraway, A. F. and Vaughn, B. J.: J. Reprod. Med. *10*: 171, April 1973.
2. Hayes, O. J.: South. Med. J. *66*: 254, Feb. 1973.

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Abstracts

摘　要

作者用人的各个发育时期作譬喻，较形象地综述了宫内节育器的发展过程。

（1）宫内节育器的“胚胎期”：早期记载骆驼过沙漠时，安置石头于子宫内以防止受胎。

（2）宫内节育器的“婴儿期”：1928 年开始临床初步试用的环型，因保守思想使宫内避孕技术的进展至少停滞 30 年。

（3）宫内节育器的“童年期”：1959 年公布临床经验，重新推广应用。

（4）宫内节育器的“青春期”：发展迅速。1962 年开展研究计划并对宫内节育器的各种形状、大小和材料进行评定。共同缺点是不能使宫腔适应节育器的形状。

（5）宫内节育器的“发身期”：1968—1969 年从改进宫内节育器的形状和大小着手，以减少宫腔的变形。

（6）宫内节育器的“成熟期”：宫内节育器含有缓释的有效抗生育制剂，例如金属铜和孕激素等。

介绍了未产妇和未孕妇宫腔内节育器的实际应用和流产后立即装置节育器的效应。

详细讨论了惰性和活性宫内节育器的作用机制。

由于应用已有的宫内节育器所发生的副作用，促使了“第二代”节育器的产生与发展。本研究的目的是从修改的原则和所引起的作用方面来评论这些新避孕器的发展。介绍了改变旧的“惰性”节育器的大小和形状以及新型“附着药品”的节育器。讨论了关于这些“第二代”节育器的作用效能和副作用。

本文综述了宫内节育器在各种哺乳动物中生物效应的实验结果。主要课题是讨论所观察到的关于宫内节育器作用机制的效果，着重对妇女和灵长动物的实验进行探讨。所讨论的作用机制分下列几方面：机械性的干扰；炎症的作用；子宫内膜组织学上的变化、成熟程度和对激素的敏感性；宫腔液体中的生物化学变化；对黄体的作用；对子宫活动的影响等。除了以上所提供的主要作用以外，还不能排除宫内节育器的其他辅助作用，总的抗生育作用是由多种因素的综合结果。似乎可以合理地认为宫内节育器的作用是发生在着床之前，因此节育器的抗生育作用不属于流产一类。

本文综述了铜与生育过程有关的生物学方面的资料。包括当宫腔装置有金属铜或把它取出后影响子宫内膜，宫内液体，宫颈粘液和血清内铜浓度的周期性变化，以及内膜里几种酶的变化。论述了含铜T形宫内节育器在体内铜的消失速度，这些资料是结合宫腔抗生育作用有效时间来考虑的；另外从理论上考虑到所用铜的剂量与全身铜代谢平衡的关系。特别提到威尔逊病。描述了在宫腔内铜丝表面可能发生的变化。介绍了从恒河猴实验中收集的资料，关于铜碎片可能引起的问题。介绍最近各国有关 T 铜 200 和 300 型的应用效能的临床资料，并初步报导了应用 9 个月后 T 铜 200 和 铜 7 型对照的结果。

T 铜 200 型宫内节育器，是一种非常适合于未产妇女避孕用的器具。作者对 471 例未产妇进行观察，发现可不使用麻醉进行放置，并于术后使用极少量止痛剂。在 26 个月期间，共积累了 6,044 妇女月的资料。作者对放置满一年的 4,430 妇女月的资料进行了第一阶段

可逆的。在雄鼠的输精管(Deferent Duct)中放置铜丝后，98.3% 精管中精子的成熟遭到抑制。有报导证明在子宫颈管内放入铜丝，也有杀精作用。

作者介绍了含铜 "7" 形宫内节育器的结构和放置方法，并将各种类型的铜丝节育器的疗效作了比较。54 例 316 妇女月的应用情况，说明其优点为放置时无痛苦，副反应、盆腔感染的发病率和带环妊娠的发生率均低，因此能被接受。

作者考虑到刮宫术后往往会产生子宫腔内粘连，引起术后月经少、闭经、自然流产与不孕症，所以设计了一种 Massouras 鸭爪 2 号宫内避孕器 (MDF No. 2 IUCD)，用于刮宫术后放置，可以避免上述症状的发生。MDF No. 2 IUCD 是一种软性聚乙烯或硅类器械，具一细的不锈钢丝埋存于其上支，以便于透视随访。所有的原材料均对人体无害。为了达到X线探测目的，可加入适量硫酸钡。节育器于宫颈扩张后放置。其两翼可产生适当重叠，以适应子宫腔的三角形，便于达到阻止宫腔内粘连或孕卵的着床。

本文介绍 Dalkon 盾作为宫内节育器共 291 例，累积 2143 妇女月的资料。本组妇女使用这种节育器，每 100 妇女年中的妊娠率为 10.1%，经过二年没有明显下降。说明这种装置还不如目前所采用的有效。由于受孕率高，故不宜继续使用。

249 名妇女为了避孕的目的，装置每天可释放 128 微克黄体的T形宫内节育器。6 个月换一次新节育器。当装有有效黄体释放器的时期中，没有发现妊娠。选择一些病例进行血浆激素测定和子宫颈粘液的观察，都属正常范围，提示了带黄体节育器的机制与抑制排卵和改变宫颈粘液性质无关。结论是：极少量的宫内黄体是一种有效的避孕剂，其作用机制可能是引起子宫内膜感受器的蜕膜改变，使之不宜于着床。

有证据说明在某些非灵长类哺乳动物中，宫内节育器促使子宫增加前列腺的释放。它的抗生育作用也许是通过前列腺素的溶解黄体作用。在灵长类动物，宫内节育器可能是由于子宫内膜前列腺素释放的增多，但显然没有对黄体直接抑制的作用。

作者报告了使用一种新式的充满液体的软性宫内节育器，由于放置与取除时，手术容易并且无痛，因此对未产妇也同样适用。由于其脱落率低，怀孕率等于零，副作用也极少，故为妇女所乐于接受的避孕措施。目前尚在进行扩大的临床使用中。

由于节育器在宫腔内所引起的炎性反应，可能为节育器产生避孕作用的某些机转。在比较使用聚乙烯宫内节育器组(Lippes 环)与对照组时，Holub 等氏(1971年)发现血清IgG与 IgM 均有相当增加。本文对妇女放置不锈钢宫内节育器，于放置前、后进行了 IgG，IgA 与 IgM 的测定。在同一人身上进行测定，可以排除产生免疫球旦白上升的其他非特异性的原因。IgA 常可作为粘膜面炎性反应的抗体，可惜在使用聚乙烯宫内节育器组中并未进行这一血清球旦白的测定。本文的测定结果证实了 IgG 与 IgM 的增加，但约于一年后开始有下降趋向。在同一测定期间，血清 IgA 的水平逐渐上升。

作者对放置 Lippes 氏环 D，标准大小的 Dalkon 盾与 T 铜 300 的妇女，进行了月经失

血量的测定。测定时间为放置后6、12与18个月。放置节育器后平均月经失血量的增加为41-112%。月经过多的发生率可达不放环对照组周期的9倍。在研究期间发现Lippes环与Dalkon盾两组的月经失血量不稳定，往往为不放节育器周期的一倍；而T铜300组的月经失血量在所有的观察期间相当稳定，且较其他两种避孕器的失血量为少。

本文作者引用了Nilsson和Rybo, Kagan等报导，由于子宫内膜胞浆素活性物质使局部纤维旦白溶酶增加是月经过多的主要原因，用抗纤维旦白溶酶制剂氨基己酸能有效的减少月经量。作者于1970年7月起临床观察了88例放置宫内节育器的妇女，对其中20例主诉月经增多的用氨基己酸3克，每天四次的治疗，能减少月经量，有一例因恶心而停药。临床分析了年龄、产次及末次分娩到放置节育器的间隔对以后是否需要治疗没有关系。月经过多史是预测放置节育器后可能月经增多的唯一因素。

本文介绍了在1971年装置宫内节育器的917例中，46例受孕的结果。研究对象是装节育器后随访达12个月，除了脱落，取出及失访者外共303例，怀孕率为15%。妊娠的发生是结合(1)宫内节育器的类型，(2)分娩与装置之间相隔的时间，(3)装置与受孕前的末次月经之间相隔的时间加以研究。妊娠的结果是从(1)自然中止妊娠时的妊娠月份，(2)产前后婴儿死亡率，(3)母体併发症方面进行分析。资料显示有不少妊娠是发生在产后装节育器后。妊娠发生的时间不限于装置的初几个月。带有节育器受孕者的流产，产后感染和死胎率增高。

本文介绍宫颈内放置含有氯地孕铜的硅橡胶装置，目的在于观察是否此种装置比口服孕激素的剂量小且效果好。

在兔的实验中此种宫颈装置能影响受孕、着床和精子的运送。当此装置的氯地孕铜的释放率在13.7～22.8 μg/公斤/天时，则100%能避孕；在2.4～7.0 μg/公斤/天时不影响受孕；在8.2～13.3 μg/公斤/天的剂量尚有47%的卵子受孕。应用不能防止受孕的剂量亦能抑制着床。兔子在两次交配后4小时，有宫颈装置的子宫角中的精子数比对侧子宫角明显减少。

文内还介绍了三种用医用硅橡胶制的宫颈图钉型装置，分别含15%醋酸氯地孕铜、20%醋酸氯地孕铜100 mg于Syloid中及作为对照的类固醇30 mg。在月经周期第二周放置，初步估计释放率在0.15 mg/天时，显示对宫颈粘液有反应，当释放率接近1.6～2.1 mg/天时可伴随全身的影响，例如基础体温升高、宫内膜孕激素样变化和子宫出血等。

阴道避孕剂在应用恰当时，是一种相当有效的避孕方法，这种避孕措施仍有潜力，但没有获得足够的重视。本文简单地评论关于目前使用的杀精子剂的某些方面，如性能、运载系统、剂型和效能等等以及将来有可能成为阴道避孕的有效制剂。强调了关于在人类中进行研究的资料。

24位妇女进行10个周期的研究以确定用浸透醋酸甲孕酮的塑胶阴道器的避孕效能、使用率和恢复率。治疗前她们都有2个推定证据的排卵周期作为对照。于月经第五天或第十天装置新的阴道器至第26天取出。治疗后随访2个周期。治疗期中，在黄体期血清孕酮没有上升，确定了排卵的抑制。用同样指标测定的排卵功能，一般在停治后第一周期恢复，很少有突破性出血。4例有阴道小溃疡，取出避孕药后即自然愈合。第一次由医生装置后，用者可以自己装取而没有困难。这些研究提示，这种持续性给于类固醇的技术，有希望成为避孕的一种方法。

Reviews

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CURRENT DEVELOPMENTS

Intrauterine contraception

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OVER THE past decade intrauterine devices have assumed an almost exponential increase in prominence as a method of providing safe and effective contraception. The intrauterine devices (IUD's) provide a method which has the attributes of combining a high degree of effectiveness and safety with simplicity and economy. It has the unique quality among reversible methods of contraception of providing long-term reduction in fertility by a single safe and relatively simple procedure. A chronologic history of the development and use of the IUD was presented by Southam[1] in 1964. I shall present here an outline of the evolutionary steps which depict the stages of transition of the IUD from its inception to the present, with some predictions as to its future role in human welfare.

The early history of IUD's is so poorly documented that the original concept has not been assigned to a person or in fact to a specific century. Early mention has been made of the use of stones placed within the endometrial cavity of camels to prevent pregnancy during long trips across deserts. Undoubtedly a similar method had been applied to women at or about the same time. These very early applications of the intrauterine foreign body as a means of regulating fertility may be considered as the *embryonal stage* of evolution of intrauterine contraception. This stage was relatively void of true scientific study and knowledge of the subject.

From the BioMedical Division, The Population Council, The Rockefeller University.

The *infancy stage* of IUD evolution began in the 1920's with the ingenious and daring studies of Gräfenberg,[2] as reported in 1928. His first device consisted of a six-pointed star made by tying three pieces of silkworm-gut together at the center (Fig. 1, *A*). Initially the central tie was of silkworm gut also. Gräfenberg soon found that he could not easily detect the presence of the star within the uterine cavity by means of a probe or sound. He attempted to correct this structural deficiency by substituting a center tie made of thin silver wire for one of gut (Fig. 1, *B*). The wire permitted detection with the uterine probe, and also rendered the star partially radiopaque. The star was so soft, however, that it was readily expelled from the uterus. Although the star has a relatively low retention rate, Gräfenberg thought that the silver-bound device was somewhat more effective as a contraceptive than the original silver-free star. In order to increase the retention rate, Gräfenberg conceived of and made the first intrauterine ring. This device consisted of several turns of silkworm-gut making a ring approximately 2 cm. in diameter having a cross section of about 2 mm. (Fig. 2, *A*). The rings were then made more rigid as well as radiopaque by binding them

with fine silver wire (Fig. 2, *B*). Although this silver bound gut ring was found by Gräfenberg to be highly effective, it was soon replaced by a ring made by joining the two ends of a tightly wound spiral of silver wire (Fig. 2, *C*). The spirally wound ring possessed moderate spring properties, and hence could be compressed into a smaller and oblong configuration for insertion through the cervical canal. Its inherent resiliency then caused it to return to the original circular ring shape when it was released within the more spacious endometrial cavity. This model of the Gräfenberg ring was inserted by him into several thousand women and was the first intrauterine device commercially manufactured. Gräfenberg first reported the results of his clinical experiences in 1928. His work attracted much interest from the medical profession and almost uniform condemnation by the obstetricians and gynecologists. The criticism primarily was based upon the occurrence (or recurrence) of endometritis and salpingitis subsequent to the introduction of the ring. Little consideration was taken of the high incidence of pelvic inflammatory disease which prevailed at the time. Thus, much of the criticism which was directed toward Gräfenberg and against the intrauterine ring was based more upon the conservative traditionalism of the gynecologist than upon scientifically valid reasons. It was indeed a tragedy that conservatism prevailed since the traditional taboo against inserting a foreign body into the uterine cavity thwarted the advance of contraceptive technology for at least 30 years.

During the same decade that Gräfenberg began his epoch-making studies, Ota[3] in Japan was working independently on intrauterine devices. Ota initially used silkworm-gut rings, and then developed small rings fabricated from flexible metals. Although the metal rings seemed to provide more effective contraception than did the gut rings, they were more difficult to insert. For this reason, Ota and his disciples in Japan directed their development toward rings fabricated from various synthetic plastics (Fig. 3).

The 30 year infancy stage of IUD's as

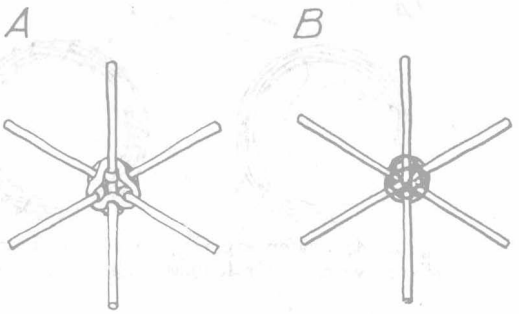

Fig. 1. *A*, Gräfenberg star, all silkworm-gut. *B*, Gräfenberg star, center tie of "silver" wire.

depicted by the works of Gräfenberg and Ota ended when the significance of their pioneering studies was finally realized. Appreciation of their contributions came in 1959 with the papers by Ishihama[4] in Japan and Oppenheimer[5] in Israel. A major step in opposition to the traditional objections against the use of intrauterine devices was taken by Dr. Howard C. Taylor who in 1959 was Editor of the AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY. Acting on behalf of the Editorial Board of the JOURNAL, Dr. Taylor invited Oppenheimer to submit for publication a review of his clinical experiences with the Gräfenberg ring. This paper was the first detailed clinical evaluation of intrauterine contraception ever published by an American scientific journal. Both Ishihama and Oppenheimer reported corroborating data on the long-term use of various intrauterine rings. With these independent and impressive demonstrations of effectiveness and safety of the intrauterine foreign body, the IUD entered its *childhood stage*. The *childhood stage* began between 1959 and 1964, when Margulies[6] (Fig. 4), Zipper and Sanhuerza[7] (Fig. 5), Lippes[8] (Fig. 6), Birnberg and Burnhill[9] (Fig. 7), Hall[10] (Fig. 8), among many others in the United States and abroad, designed and tested various forms of intrauterine contraceptive devices.

In 1962, The Population Council launched an intensive research program which included relevant basic laboratory studies and clinical and field trials with promising IUD's.[11] The data derived from these clinical studies

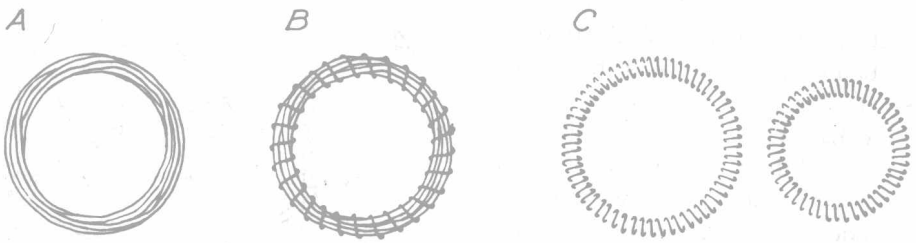

Fig. 2. *A*, Gräfenberg ring—all silkworm-gut. *B*, Gräfenberg ring—silkworm-gut wound with "silver" wire. *C*, Gräfenberg ring—tightly wound spiral of "silver" wire.

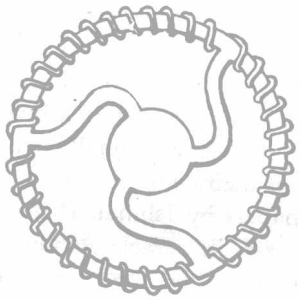

Fig. 3. Ota ring.

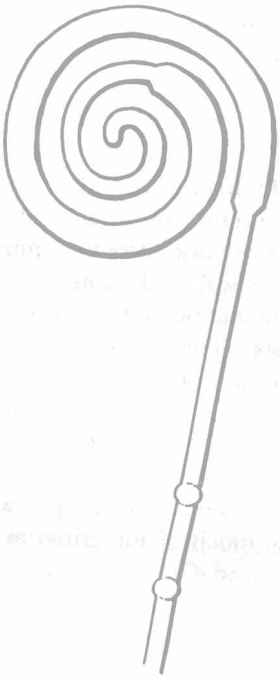

Fig. 4. Margulies spiral.

were evaluated by the Cooperative Statistical Program (C.S.P.) under the direction of Dr. Christopher Tietze. The most recent report on traditional IUD's by the C.S.P., as of 1968,[12] covers approximately 547,000 woman-months of use by almost 32,000 women. This extensive experience, particularly with the Lippes loop led the IUD into its *adolescence*. During the 6 years from 1962 to 1968, the loop was used more extensively than any other device. Because of the wide clinical experience with and the comprehensive evaluation of the loop, it became customary to use these data as points of reference in evaluating the clinical effectiveness (also referred to as use effectiveness) of newly conceived shapes and sizes of intrauterine devices.[13] The term clinical, or use effectiveness, is of fundamental importance and has been accurately defined by these authors as follows: "Use effectiveness, also known as clinical effectiveness, refers to the protection from unwanted pregnancy achieved by users under real life conditions, including the effects of carelessness, ambivalence, and other manifestations of human frailty."[14] According to the latest analysis of data derived predominantly from studies within the United States, the failure rate (pregnancy rate) per 100 users of Loop D for the first year is 1.9, decreasing to 1.6 at 2 years, and to 1.2 at the end of 4 years. On the other hand, the use effectiveness or continuation rate in the C.S.P. clientele ranged from 70 to 80 per cent of the users at the end of the first year and 60 to 70 per cent 2 years after the first insertion. Continuation rates derived from national family planning programs outside of the United States are on the order of 50 per cent after 2 years of use.[15] From these standards, we can assume that racial, environmental, and socioeconomic factors play an

Fig. 5. Zipper (Gräfenberg) ring.

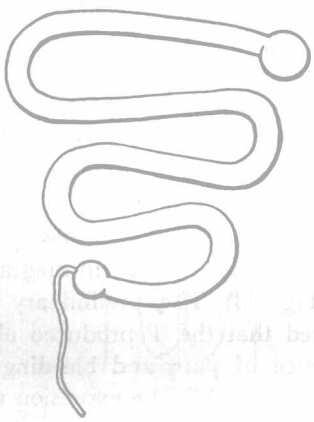

Fig. 6. Lippes loop.

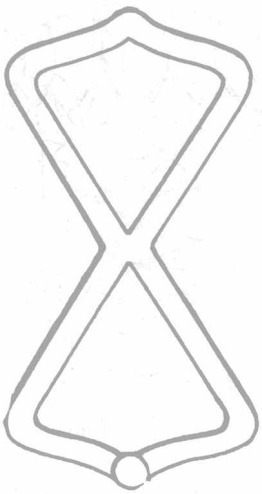

Fig. 7. Birnberg bow.

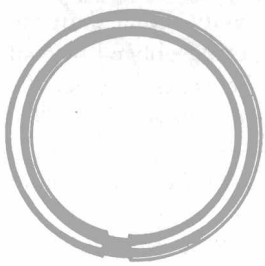

Fig. 8. Hall ring.

important although undefined role in determining the use effectiveness of an intrauterine device. Also the necessity of establishing statistically valid control population samples becomes self evident.

Although a wide variety of new devices were constructed from synthetic plastics, stainless steel, silicone rubber, and silkworm-gut, the associated side effects, such as bleeding, spotting, uterine cramps, lower abdominal pain, and noticed or unnoticed expulsion, resulted in growing dissatisfaction on the part of women and the medical profession. For the Lippes loop Size "D," these side effects may be translated to a discontinuation rate of 23 per cent at the end of the first year of use, and 35 per cent after 2 years of use. From a demographic viewpoint, this level of use effectiveness is discouraging, and pointed up the need to develop devices which could have more efficient performance. Thus the *adolescent stage* ended with a challenging mandate for improvement.

In 1966, the author concluded that most if not all of the IUD's then in use shared one common deficiency. Each device by virtue of its shape and over-all dimensions forced the endometrial cavity to *adjust to the configuration of the device.* As a result, the delicate endometrium is *compressed* and the myometrium is *distended.* This frequently results in bleeding from the endometrial surfaces as well as painful contractions as the myometrium reacts to oppose its distention and to expel the foreign body which has been placed within its cavity.

A logical sequence to this hypothetical consideration was to determine the shape and size of a foreign body which *would conform to the endometrial cavity and would thereby cause a minimum degree of distor-*

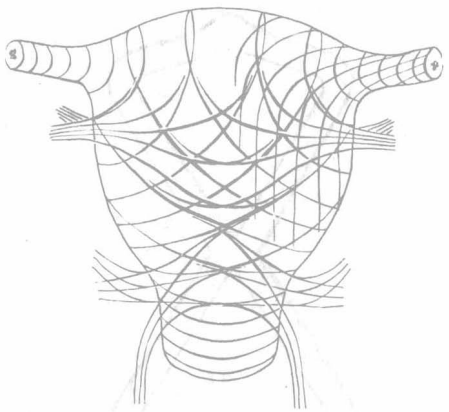

Fig. 9. Interlacing network of myometrial fibers.

tion, even at the height of a uterine contraction. The concept that an intrauterine contraceptive device should conform to the endometrial cavity *rather* than the *cavity* and myometrium being obliged to conform to the device, may be considered as the beginning of the *pubescent stage* of IUD development or evolution.

Consideration of certain anatomic factors and functional characteristics of the human uterus are essential requisites to progression from a philosophical concept to practical application. It seems appropriate at this point to discuss the more obvious of these factors. When the endometrial cavity is empty, the mucosal surfaces are separated only by a thin film of mucus and other secretions of the endometrial glands and tubal epithelium. The size and shape of the potential cavity depend upon the contractile state of the myometrium. Only when the walls of the uterus are distended is there an actual endometrial cavity with true spatial characteristics. Fig. 9 represents the directions and interlacing network of muscle fibers which control the size and shape of the uterus. The configuration and size of the endometrial cavity normally reflect the summation of myometrial forces. Fig. 10, *A* to *C* indicates progressive changes in the uterine wall and its cavity with increasing degrees of contraction. The walls thicken and shorten, and the cavity responds by becoming smaller in all dimensions. As the contraction increases, the lateral walls of the cavity approximate one another, and the cavity or potential space assumes the shape of a T. The assumption was made that this T-shaped configuration would persist even when the uterus contracted maximally. Based upon these theoretical considerations, it was logical to presume that an intrauterine foreign body in the shape of a T could be placed within the endometrial cavity and would conform *easily* to the normal shape and size of the cavity, and would cause a minimum degree of myometrial distension and endometrial compression. Fig. 11 illustrates this concept. Fig. 12 shows in diagrammatic form the sequential changes in the *uterine walls and its cavity* during several degrees of contraction, and indicates the relative conformity of the T-shaped device to the uterine cavity. This principle was tested in 1967 when the first T was molded from a mixture of polyethylene and barium sulfate and was tested clinically by Tatum and Zipper.[16] An example of the T is shown in Fig. 13. Its spatial relationship to the endometrial cavity is shown in diagrammatic form in Fig. 11. The preliminary clinical data showed that the T produced about ⅕ the incidence of pain and bleeding as did the Lippes loop "D." The expulsion rate was approximately half that of the loop.

The low incidence of expulsion is presumably due to two distinct features. The T conforms so well to the uterine cavity that the myometrium is subjected to only minimal distortion. Second, displacement and rotation of the T within the uterine cavity is resisted by the three points of contact between the device and the uterine walls which contain it. In effect, the T is suspended within the endometrial cavity by impingement of the tips of the two transverse arms against the superficial layers of the endometrium. The low incidence of pain, bleeding, and expulsion were in accordance with the theoretical considerations upon which the T was based. However, the low incidence of side effects was accompanied by a low level of contraceptive effectiveness. At the end of one year the pregnancy rate was approximately 18 per cent. Thus, although the

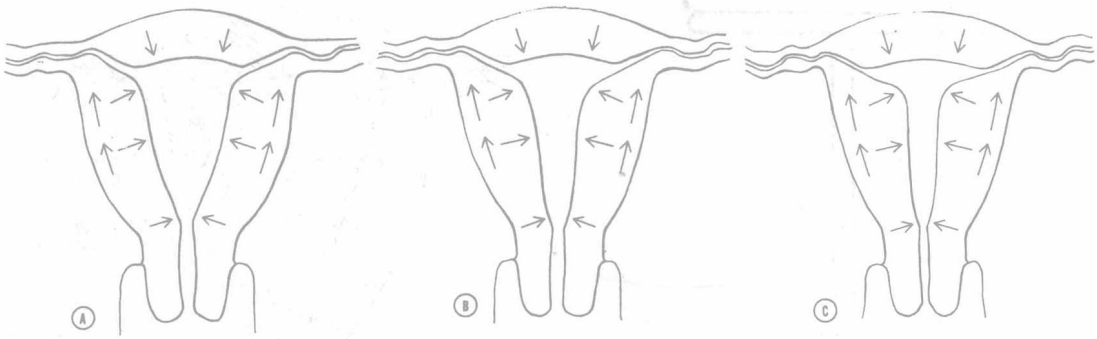

Fig. 10, *A* to *C*. Diagrammatic changes in endometrial cavity during sequential degrees of myometrial contraction.

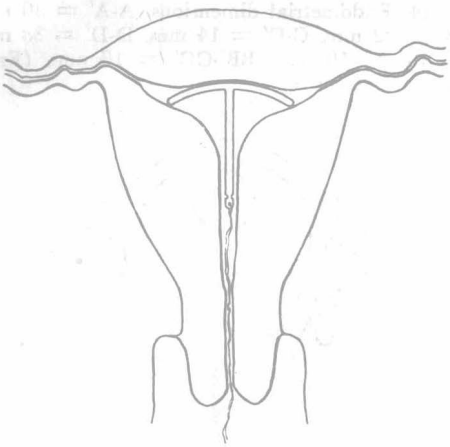

Fig. 11. Relationship between the T and endometrial cavity at the height of uterine contraction.

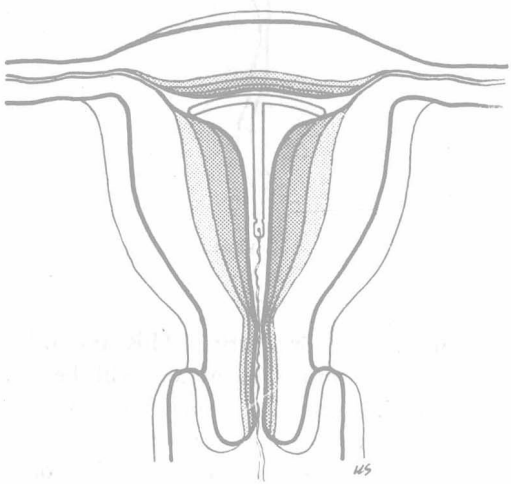

Fig. 12. Sequential changes in endometrial cavity during a uterine contraction.

T was tolerated well by the uterus, it was unacceptable as a contraceptive when used alone. It is likely that the small surface area of the T (approximately 315 mm.^{2}) explains its relatively low contraceptive effect.

In an independent study, Davis and Israel[17] computed the average dimensions of the endometrial cavity at several levels from the intercornual plane downward toward the internal cervical os. These dimensions are summarized schematically in Fig. 14. Based upon these measurements, and upon the premise postulated by Zipper and associates[18] that the antifertility effect of an "inert" IUD bears a direct relationship to the surface area of contact between the IUD and the endometrium, Davis[19] designed a device which he named the "Shield" (Fig. 15). This device is slightly pear-shaped, and its retention within the uterine cavity is enhanced by the presence of spicular projections along its lateral margins. Although the cephalocaudal and transverse dimensions of the shield are considerably smaller than those of Lippes loop "D," the total surface of the device is greater due to a thin membrane which partially covers the shield. Preliminary clinical data on the shield[19] suggest that its antifertility effect is considerably better than the 18 per cent pregnancy rate achieved by the plain T. It is logical to assume that the difference may be related to the disparity between surface areas of the two devices. It has been postulated that implantation may be jeopardized when normally opposing endometrial surfaces are separated by an

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