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Milestones in intrauterine device development

Several basic structural modifications and other major innovations have been made in intrauterine contraceptive devices (IUDs) during the past two decades.

In the early 1900s Richter¹ and Graefenberg² developed and used *small* gut and metal IUDs. Their intent was to introduce into the uterine cavity a foreign body which was so small as to minimize uterine distortion, yet at the same time would prevent conception. Thus, the gut stars and rings and finally the silver spring wire ring of Graefenberg (which was the first IUD to be manufactured and sold commercially) made medical history in the field of fertility control.

These small IUDs were replaced in the early 1960s by larger plastic devices such as the Lippes loop (Ortho Pharmaceutical Corporation, Raritan, NJ) the Birnberg bow, the Margules spiral, and many others. The increased dimensions were purported to be associated with lower pregnancy rates and reductions in rates of expulsion.

In spite of the doctrine vehemently espoused by Graefenberg that the IUD should *not* have an appendage (or tail) extending from the uterine cavity into the vagina because of its propensity to enhance microbial invasion, Lippes and others affixed monofilament tails to their IUDs. They considered the ease of detection and extraction of the IUD permitted by the transcervical tail to be of greater importance than the potential risk of an ascending infection. Their decisions seemed to be justified in most instances by the relatively small increased incidence of pelvic inflammatory disease (PID) observed to be associated during the first 3 to 4 months with the use of these tailed IUDs.

A very significant epoch in IUD development took place in the late 1960s and early 1970s when Davis developed the Dalkon Shield (A. H. Robins Company, Richmond, VA), and the Robins Company elected to use a sheathed multifilament tail on the Shield. During the next 4 years approximately 279 instances of spontaneous mid-trimester septic abortion were reported in women wearing IUDs. Of these, 242 were using Dalkon Shields. One hundred forty-nine were classified by Robins as being "positively" or "probably" associated with the Dalkon Shield. Ten of these terminated in maternal deaths.³ Cates et al.⁴ reported that the Dalkon Shield posed a three times greater risk of causing midtrimester septic abortion than did other types of IUDs. In addition to the septic abortions, there was an

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increased incidence of hospitalizations in the United States for salpingitis and severe PID among IUD wearers. The publicity in medical and in lay publications of this near epidemic occurrence of pelvic infection associated with IUD use caused major dissatisfaction with and apprehension about IUDs in general. The result was a significant reduction in IUD use throughout the United States and much of the rest of the world.

Although it appeared likely that there would be an increased rate of ascending infection in women wearing the *multifilament-tailed* IUDs (the Dalkon Shield and Majzlin Spring), the numbers were reported as being not statistically different than among wearers of IUDs bearing monofilament tails (Lippes loop, Saf-T-Coil [Schmid Products Company, Little Falls, NJ], Copper 7, and Copper T [G. D. Searle, Chicago, IL]). However, a recent reassessment of data from The Women's Health Study^{5, 6} has demonstrated conclusively for the first time that the incidence of hospital admissions for PID among IUD wearers was at least five times greater in women wearing Dalkon Shields than in those wearing monofilament-tailed IUDs. Of equal or even greater importance was the observation that when compared with noncontraceptors, the relative risk of PID was 15.6 for long-term users of Dalkon Shields (mean duration of use = 63.7 months) and only 1.5 for long-term users of other types of IUDs (mean duration of use = 74.5 months). These data indicated clearly that the risk of PID in a contraceptive wearing a Dalkon Shield increased with the duration of use, whereas there was no increased risk after the initial 4 months of use among women using other types of IUDs.

The implications of these data go far beyond the problem with the Dalkon Shield, since most of the adverse data relevant to PID and the IUD reflect, to a large extent, complications resulting from the use of the Dalkon Shield. Removal of the Dalkon Shield data leaves the remainder of IUDs with a very low rate of serious complications. Wider realization of this fact will inevitably result in an increased acceptance of the IUD as an important and relatively safe method of contraception, *provided* simple single- or double-monofilament tails are used.

The experiences with the Dalkon Shield and Majzlin Spring have stimulated efforts to resurrect the Graefenberg principle of the *tailless IUD*. The fundamental requisites for the successful use of a tailless IUD are: (1) a safe, reliable,

and inexpensive noninvasive method of ascertaining that the IUD is in its proper location within the uterine cavity, and (2) a simple and reliable extraction technique which can be employed with a minimum degree of intrauterine manipulation. Both of these requisites are currently being sought.

The philosophy behind the conception and development of the small T-shaped IUD was to use a device which was adapted to the size and shape of the uterine cavity rather than forcing the uterine cavity to adapt itself to the shape and size of the IUD. Although the plain T did not provide effective contraception,⁷ it did provide a good platform for a potent antifertility agent. Zipper and associates⁸ discovered the contraceptive effect of copper. Incorporation of this drug with the plain T provided the first of the medicated IUDs.⁹ Subsequently, the Copper 7, the Nova T (Leiras Pharmaceutical, Turku, Finland), and the Multiload (Organon Pharmaceutical Company, Amsterdam, The Netherlands), in that order, were added to the copper-bearing family of IUDs.

More recently, progestogens have been incorporated with the plain T, creating the second generic type of small medicated IUDs. The first of these, the Progestasert (Alza Corporation, Palo Alto, CA), contained progesterone, while the second was the Levonorgestrel T (Alza Corporation). Both of these IUDs effect a reduction in menstrual blood loss because of their suppressant action on the endometrium. There is also a possibility that their effects upon the endometrium and cervical mucus may provide a deterrent to ascending uterine and pelvic infections.

In this issue of *Fertility and Sterility*, the paper by Nilsson et al.¹⁰ presents clinical data from a 2-year comparison of levonorgestrel- and copper-releasing IUDs. This study illustrates a number of the generic modifications in IUDs which have been made over the past 20 years, and the authors discuss some of the advantages and disadvantages associated with them. It is apparent that while major advances have already been made in the field of intrauterine contraception, we can expect to see additional innovations and improvements in the future. It is quite possible that one of the next major modifications to be realized will be the development of a practical model of the tailless IUD.

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