THE ANTIGON-F, AN IMPROVED INTRAUTERINE CONTRACEPTIVE DEVICE

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ABSTRACT

The Danish intrauterine contraceptive device described by Lebech and Osler under the name Antigon was modified by covering the area enclosed by the polygon-shaped device with a membrane in order to eliminate the risk of intestinal obstruction if the device should get into the abdominal cavity. The modified device, called the Antigon-F, has been used at The New York Hospital and the Qualicap Clinic from June 1, 1969. The first 1480 insertions, observed until December 31, 1970, were computed and showed a pregnancy rate of 1.8/100 women-years. The expulsion rate is high, probably due to improper handling of the device before insertion. No perforations occurred.

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The Antigon® intrauterine contraceptive device was first described by Lebech and Osler in Denmark in 1967 under the name of polygon (1,2). It is a closed device of kite-shape, made of polyethylene, with a small magnet imbedded in one of the long sides (Fig. 1). It is easily compressed from side to side to accommodate it in the inserter, but it will tend to regain its shape as soon as released from the inserter. The inserter is about 10 mm wide with a collar at the proximal end (Fig. 2). This end is pressed firmly against the cervix at insertion, but it should not be introduced into the cervical canal. The protruding end of the device itself is inserted into the cervical canal and pushed through with the plunger. Insertion is done with great ease and this is one of the most advantageous features of the device. Because of the round corners it is very difficult to push it through the uterine wall and the risk of perforation to the peritoneal cavity is therefore minimal. So far there is only one perforation on record in many thousands of insertions (3).

In spite of the minimal risk of perforation, a modification of the Antigon became necessary when an advisory committee of the U.S. Food and Drug Administration issued a warning against "closed" or ring-shaped devices. An inquiry had revealed a substantial number of cases of intestinal obstruction after uterine perforation of various other closed devices (4). The Antigon was modified by adding a thin membrane covering the area enclosed by the polygon. Four small slits in the membrane permit compression of the device from side to side. The modified device is called the Antigon-F.

Apart from preventing intestinal obstruction in the unlikely instance of perforation, the membrane serves another purpose, namely increasing the area of endometrial surface covered by the device. To what extent the two opposing endometrial surfaces interact in the process of nidation in the human is not known. If the process is similar to that in the rodent, separation of the two surfaces

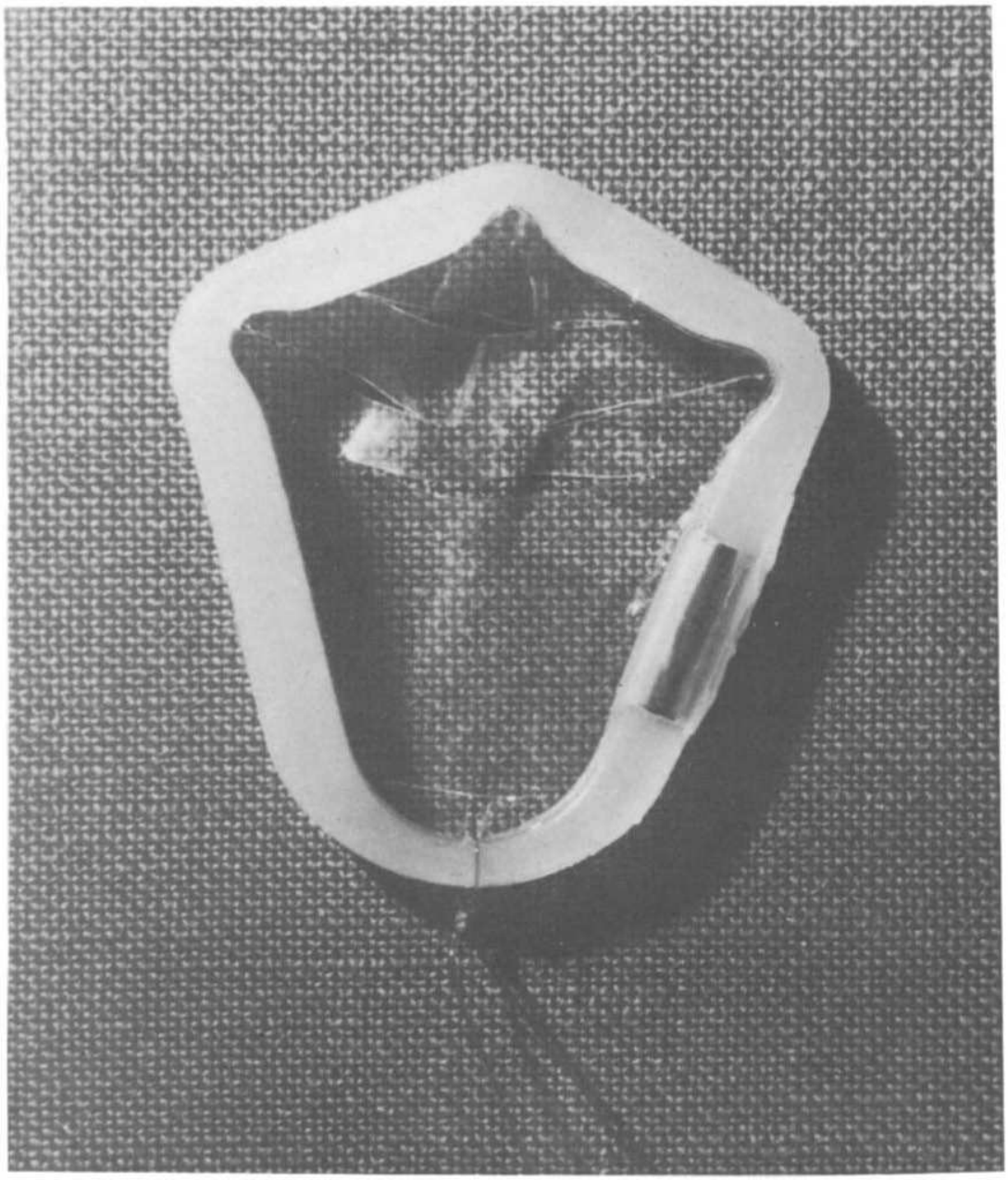

Fig. 1. The Antigon-F intra-uterine contraceptive device with tail.

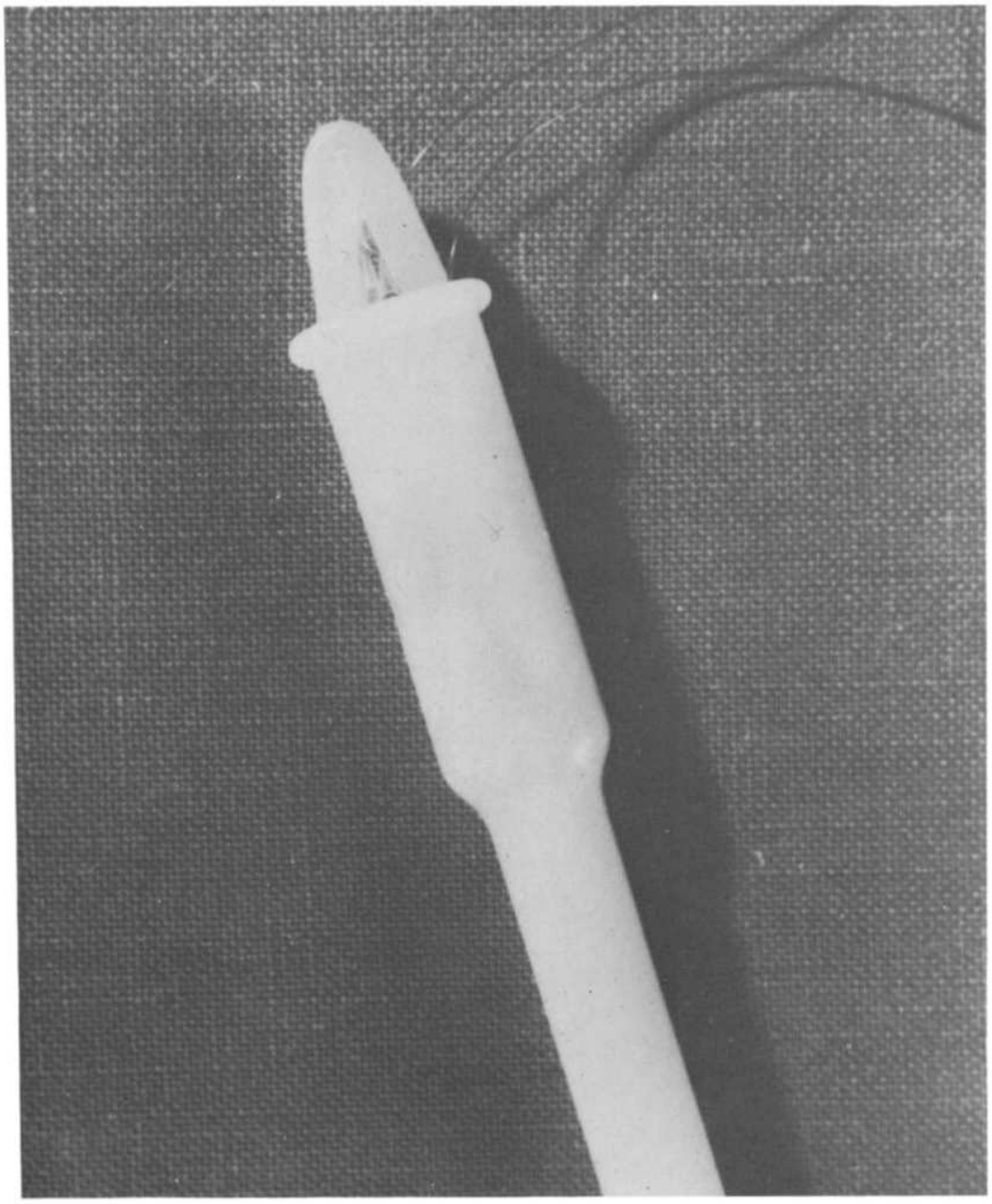

Fig. 2. The end of the inserter with the Antigen-F ready for insertion.

should reduce the chances of implantation of a fertilized ovum. The Antigon-F separates a higher percentage of the area of the two endometrial surfaces than any other device presently available. This is clearly demonstrated by Fig. 3 which shows a hysterogram with the Antigon-F in place. Another modification was the addition of a colored monofilament thread as a "tail" to ascertain the presence in the uterine cavity by palpation or inspection of the cervix and to facilitate removal of the device when necessary.

RESULTS

The Antigon-F has been subject to a trial at the Family Planning Clinic of The New York Hospital-Cornell Medical Center and at the Qualicap Health Center, a satellite clinic in Queens, New York, from June, 1969. The Antigon-F was inserted by members of the Attending Staff, Resident Staff, Nursing Staff, a midwife and a large number of medical students during their 3rd year course in Obstetrics and Gynecology. The case material was recorded and tabulated as prescribed by Tietze (5) to facilitate comparison with other contraceptive devices. The results in the first 1480 insertions, observed until December 31, 1970, and computed by courtesy of Tietze, are shown in Table I. The results in regard to pregnancy rate are better than those obtained with the previous generation of IUCD's and also better than with the original antigon (2,5). Less satisfactory is the expulsion rate, but the reason for this is undoubtedly an error committed by the Nursing Staff in handling the Antigon-F before insertion. The device is individually packed with the inserter in a plastic envelope. Before opening the envelope, the device is fitted into the inserter so that the sterile device does not have to be touched after removal from the envelope. To save time in the busy clinic,the nurses, unknown to the Medical Staff, inserted the device into the introducer in advance, often weeks or months before its use. This, of course, affects the "memory" of the device; it will not expand in the uterine cavity as readily as if it had been

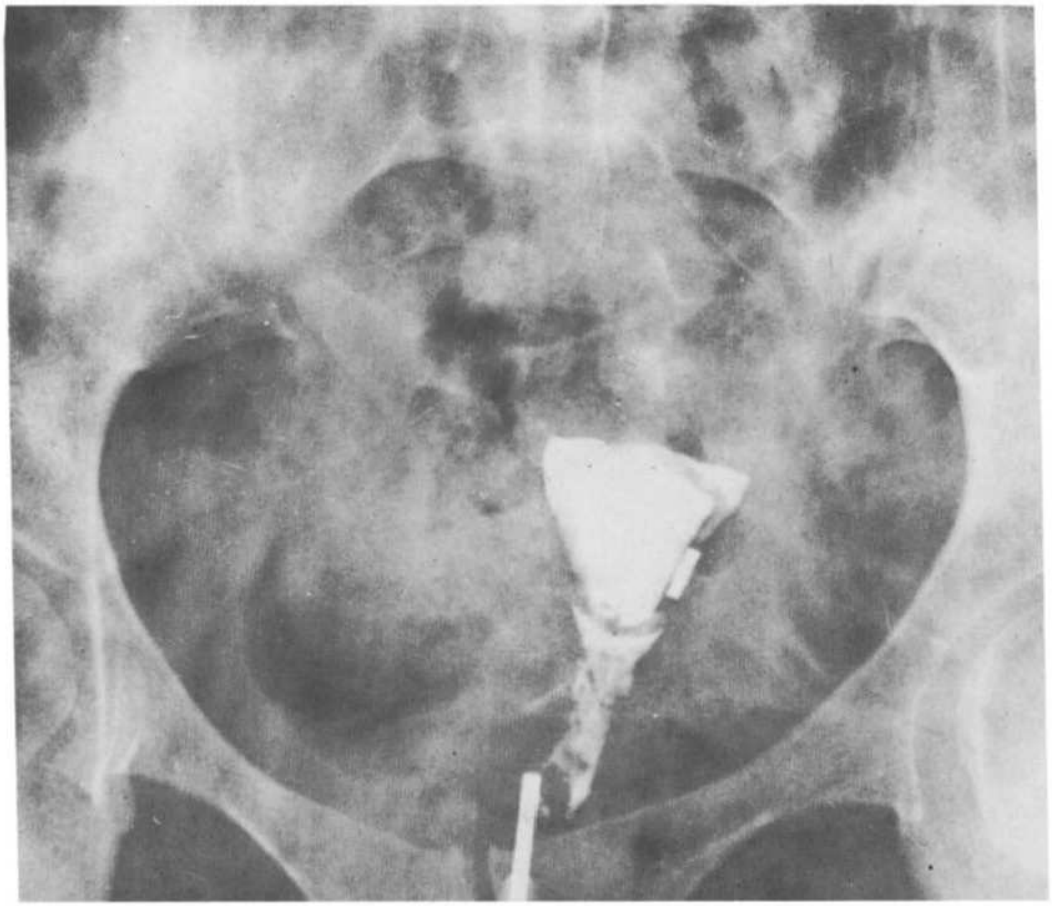

Fig. 3. Hysterogram from a 26-year-old multipara. An Antigon-F with tail had been inserted one year earlier. The tail could not be seen in the cerivcal os but the hysterogram confirmed that the device was still in place. Note how well the antigon fills the uterine cavity.

TABLE I

Net Cumulative Events and Closure Rates per 100 Users, by Type of Termination

EVENTS	12 months	15 months
Pregnancies	1.8	1.8
Expulsions		
First	16.9	17.7
Later	2.8	3.3
Removals		
Medical	10.1	10.1
Planning pregnancy	1.3	1.7
Other personal	8.2	8.8
CLOSURES		
Pregnancies	1.8	1.8
Expulsions	8.8	9.3
Removals		
Medical	9.6	9.6
Planning pregnancy	1.3	1.7
Other personal	6.7	6.7
Total closure rate	28.2	29.1
Continuation rate	71.8	70.9
First insertions	1,480	
Woman-months of use	8,093	8,567

compressed only for a couple of minutes during insertion. This illustrates how important it is to instruct the personnel in Family Planning Clinics about procedures which to the Medical Staff appear totally obvious.

The material includes a small number of nulliparous women. The Antigon-F is not ideal for the patient who has never been pregnant; the expulsion rate and the removal rate for this group (which has not been excluded from the tabulation) are higher than for the material as a whole. The material also includes insertions in the post-partum and post-abortum period, but these groups are not yet large enough for separate evaluation.

DISCUSSION

The intrauterine devices of inert plastic materials have amply proven their value as contraceptive methods. The pregnancy rate is low and the side effects are moderate. Ideally, however, there should be no pregnancies and a minimum of side effects. The Antigon-F has a pregnancy rate of less than 2 per 100 women years which is as low as other devices of its class. The most important complication, aside from pregnancy, is perforation of the uterus. Because of its shape, the risk of perforation with the Antigon is minimal, and none was found in our trial. The expulsion rate is too high, but in this regard our trial is not representative, as indicated. That this is not a conjecture is demonstrated by the expulsion rate found by Osler and Lebech (2) with the original Antigon (6.8 per 100 women-years) and by Margaret Jackson (7) in England with a modification called the "Winged Antigon" where flanges are projecting into the enclosed area (0.4 expulsions in 100 women-years in 248 patients studied over 19 months).

The side effects in form of increased menstrual bleeding and uterine cramps were within the range found with other devices. If nulliparas are excluded, the figures

are lower than those shown in Table I. Of interest is that Margaret Jackson found a lower incidence of such side effects, both with the original Antigon and with the Winged Antigon. We suspect that cramps sometimes may be due to the fact that the Antigon is not inserted into the uterine cavity but remains in the cervix; we have observed that inexperienced personnel occasionally fail to push the Antigon into the cavity, a nd although it tends to move upward once the widest part is inside the internal os, it will in some instances remain in the cervix.

The following intrauterine devices have been studied in our clinic since its inception in 1964: Birnberg's Bow, Lippes' Loop, and Saf-T-Coil and the modified Margulies' Spiral. A comparison of the results is in process, but there is general agreement among the staff that the Antigon-F is superior in performance to these devices.

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