

## COMPARISON OF THREE INTRAUTERINE CONTRACEPTIVE DEVICES: THE ANTIGON-F, THE YPSILON-Y, AND THE COPPER-T 200\*†

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The first generation of intrauterine contraceptive devices (IUDs), the Gräfenberg<sup>1</sup> and Ota<sup>2</sup> rings and their modifications, did not gain much recognition for contraception. The second generation IUDs, on the other hand, such as the Lippes loop, the Margulies Spiral, the Hall-Stone ring, and many others, achieved remarkable success within a short period of time. Several of these devices gave fairly satisfactory results with regard to pregnancy rates, expulsion rates, and continuation rates. A few of the second generation IUDs, such as the Majzlin Spring, the Birnberg Bow, and others, were associated with such undesirable side effects that their usage had to be discontinued. Thus, 16 perforations in 550 insertions of the Birnberg Bow were experienced in our institution.<sup>3,4</sup> Further exploration led to the development of a third generation of IUDs, including inert devices of improved design and various types of bioactive devices. This report deals with a comparative study of three new devices, the Copper-T 200 (TCu 200), the Antigon-F, and the Ypsilon-Y, carried out at The New York Hospital Family Planning Clinic.

The addition of metallic copper to an intrauterine device in order to enhance

its contraceptive effect was proposed by Zipper and associates.<sup>5</sup> The contraceptive failure rate with a plain polyethylene T-device was 18.3/100 woman-years,<sup>6</sup> but Zipper et al.<sup>7</sup> reported a reduction of the pregnancy rate to 0 when 200 sq mm of copper wire were added to the T-device. Later trials of the TCu 200, however, have shown pregnancy rates of the same magnitude as those which occurred with the best inert devices.<sup>8</sup>

The Antigon was first described by Lebech and Osler<sup>9,10</sup> in Denmark in 1967 under the name of Polygon. It is a closed device of kite shape, made of polyethylene, with a small magnet in one of the long sides. The purpose of the magnet was to permit detection of the device with a special detector and eliminate the need for a pelvic examination. The modification, called Antigon-F (Fig. 1), which has a slitted membrane within the area enclosed by the Polygon, was developed at our suggestion to satisfy a recommendation of the Food and Drug Administration Advisory Committee against closed, ring-shaped devices. The first results with the Antigon-F were reported by Fuchs and Risk.<sup>11</sup>

The Ypsilon-Y, designed by Soichet,<sup>12,13</sup> is a Y-shaped device consisting of a stainless steel spring covered by silicone rubber. The rubber extends from the stem of the Y as a continuation of the device, acting as a tail (Fig. 2). A thin web of silicone fills most of the area between the two arms of the Y. The inserter used in

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**CONTRACEPTIVE DEVICES:  
ANTIGON-F T 200\*†**

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First described by  
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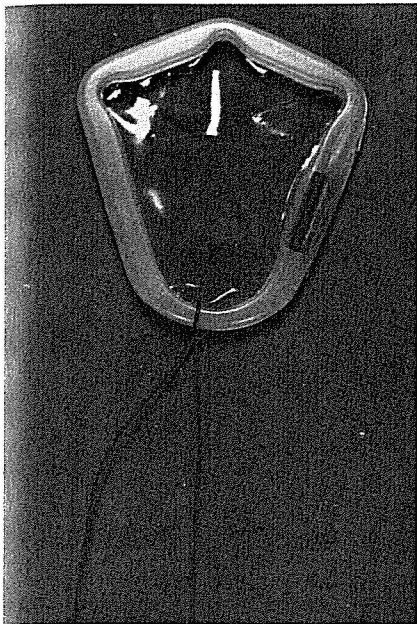


FIG. 1. The Antigon-F intrauterine contraceptive device.

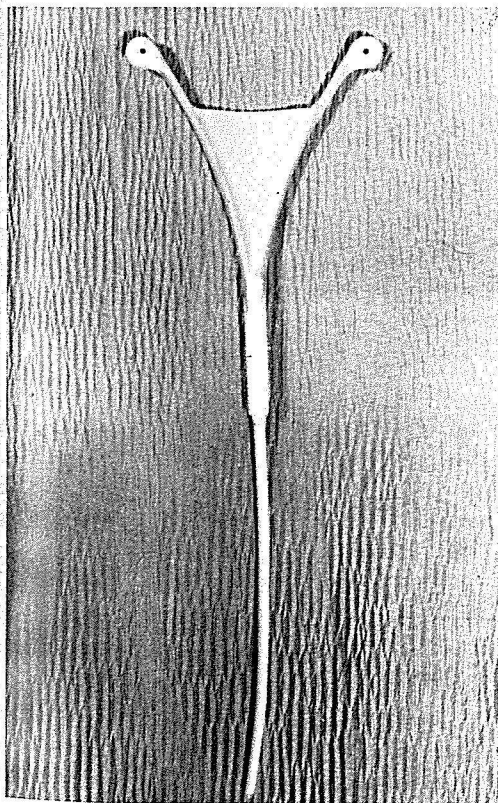


FIG. 2. The Ypsilon-Y intrauterine contraceptive device.

this study was made of stainless steel, with a collar constructed so that the tip of the inserter did not reach beyond the internal os. Because of the stainless steel frame, the Ypsilon-Y maintains its shape better than devices of plastic materials.

**MATERIALS AND METHODS**

The technique for inserting each of the three IUDs in this study was uniform. After a bimanual pelvic examination to determine the position of the uterus and to rule out pelvic abnormalities, a speculum was inserted into the vagina, and the cervix was inspected. The cervix and vagina were washed with iodine solution only if there was evidence of cervical irritation. The anterior or posterior lip was then grasped with a single tooth tenaculum and the uterine cavity was sounded in order to determine the depth of the uterus and the direction of the cervical canal. The insertion was usually carried out in the preovulatory phase of the menstrual cycle, but, if an insertion was difficult or impossible, the patient was asked to return during her menstrual period. The patients were seen 4 to 6 weeks following insertion. After this, they were seen every 6 months. Each time a patient was seen in the Family Planning Clinic, she was first interviewed by a nurse specifically about complications or side effects, and then examined by a physician who completed the record.

**Antigon-F.** The Antigon-F should be loaded into the inserter immediately prior to insertion, which can be done while the device and inserter are still within the sterile envelope, thus eliminating the use of sterile gloves. The Antigon-F is compressed from side to side to accommodate it into the inserter, but it reopens once it is released from the inserter. The introducer has a 10-mm wide collar at the proximal end (Fig. 3). For insertion, the loaded inserter is pressed firmly against

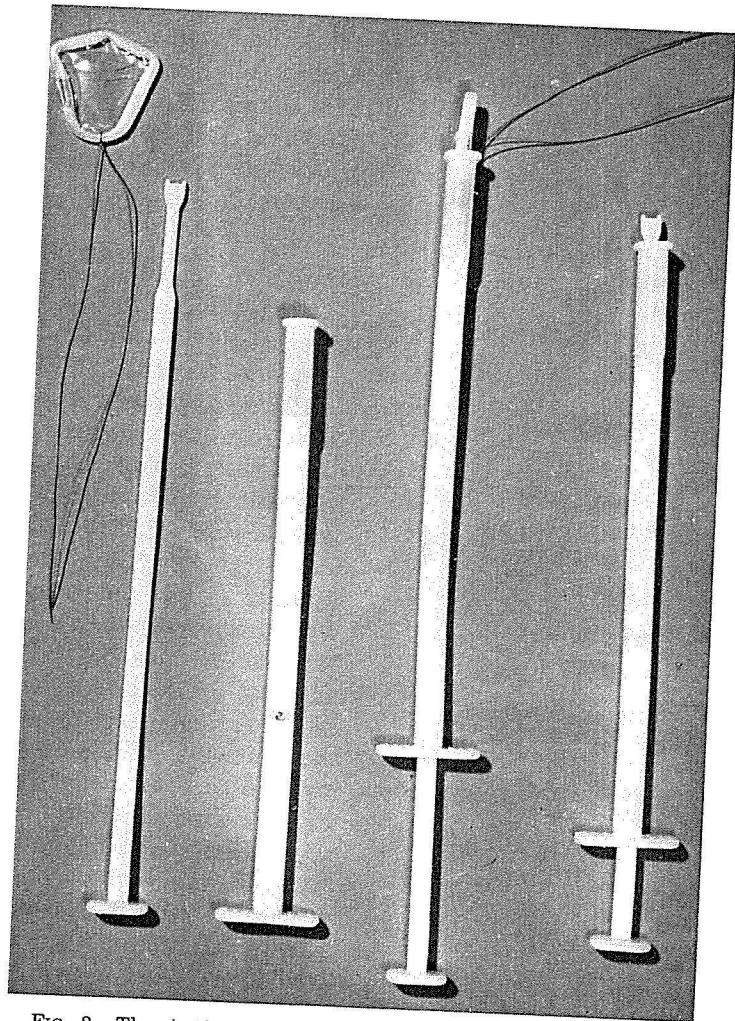


FIG. 3. The Antigon-F and its introducer: *left*, the plunger and inserter separated; *center*, the Antigon-F loaded into the inserter; *right*, the introducer after insertion.

the cervix, with the protruding tip of the device directed into the cervical canal. The Antigon-F is then pushed up into the uterus by the plunger, which does not reach beyond the level of the internal os. Once the Antigon-F is inserted, the tail is cut to a length of about 1 inch.

During an 18-month period from March 1, 1972, through August 31, 1973, 884 Antigon-F devices were inserted, 646 in multiparous women, 24 in nulliparous women, and 214 in connection with first trimester abortion.

*Ypsilon-Y*. Before insertion of the

*Ypsilon-Y*, the device is placed into the hollow plunger, which admits the tail. The device is then pushed into the introducer, except for the corner tips (Fig. 4). This makes insertion easy even in nulliparous patients, since cervical dilatation is unnecessary. A collar 3 cm from the tip prevents the introducer from being inserted beyond the internal os. The *Ypsilon-Y* is injected into the uterus by pushing on the plunger. Because of the stainless steel frame, the device will unfold inside the uterine cavity. One should make certain that the plane of the

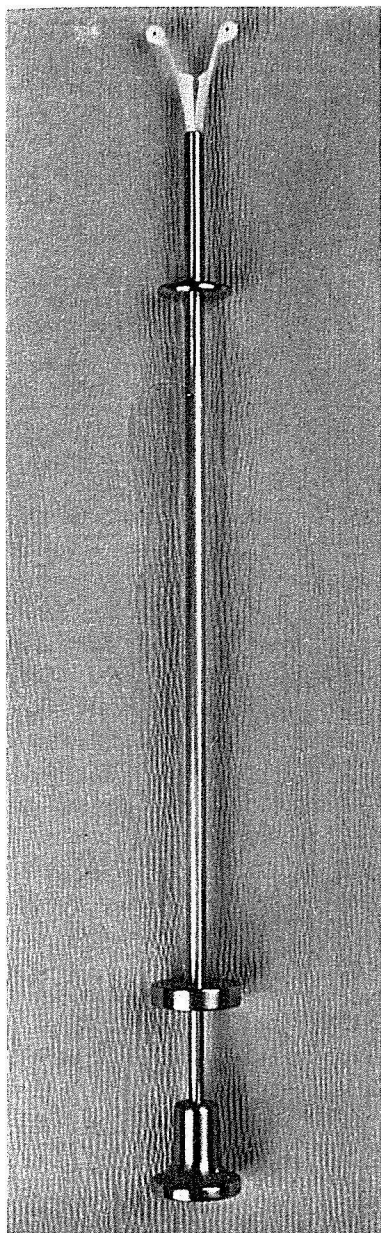


FIG. 4. The Ypsilon-Y partially loaded into its stainless steel introducer.

Ypsilon-Y is the same as that of the uterus.

During the period of study, 910 Ypsilon-Y devices were inserted, 492 in multiparous women, 224 in nulliparous women, and 194 in connection with first trimester

suction abortion. All patients in this series were given the same size Ypsilon-Y (3.4 cm between the tips of the device) (Fig. 2), which we now refer to as the small-size Ypsilon-Y.

*Copper-T 200.* For insertion of the Copper-T 200, sterile gloves are necessary. The TCu 200 should only be placed in the introducer within the envelope a few seconds prior to insertion, since this device tends to lose its "memory" rapidly. It is important to observe that when the Copper-T is loaded into the inserter the arms of the T must be pushed down alongside the stem of the device, so that after insertion the arms are in the correct position which diminishes expulsion. During insertion, the introducer is passed through the cervical canal and into the uterine cavity and carefully held against the fundus with the plunger while the tube is pulled back, releasing the device which retains its T-shape. Insertions in nulliparous patients can occasionally be difficult because the soft polyethylene does not negotiate the cervical canal, and cervical dilatation is frequently necessary.

During the period of study, 939 Copper-T 200 devices were inserted. Of these, 602 were inserted in multiparous and 197 in nulliparous women, while 140 patients had the device inserted in connection with first trimester abortion. The characteristics of the TCu 200 are well known from two reports by Tatum.<sup>8, 14</sup>

All three groups were followed until February 28, 1974. Thus, all patients were followed for a minimum of 6 months; the average observation time was 15 months.

#### RESULTS

*Antigon-F.* The 884 patients with Antigon-F devices were observed for a total of 14,436 woman-months. The overall pregnancy rate was 0.88, with an expulsion rate of 5.1 and a medical re-

TABLE 1. *Total Insertions*

Rate <sup>a</sup> per 100 woman-years	Antigon-F: 884 insertions, 14,436 woman-months	Ypsilon-Y: 910 insertions, 14,348 woman-months	Copper-T 200: 939 insertions, 15,558 woman-months
Pregnancies	0.88	1.8	0.85
Expulsions	5.1	1.9	1.8
Displaced and reinserted	1.9	0.92	1.4
Medical removals			
Bleeding/pain	7.9	2.9	3.8
Perforations	0	0	0.15
Other	1.2	0.83	0.62
Nonmedical removals			
Planning pregnancy	2.4	0.5	1.5
Other personal	0.64	2.2	1.5
Total event rate	20.2	11.1	11.6
Continuation rate	79.8	88.9	88.4

<sup>a</sup>Tabulated as Pearl's index. Period of study March 1, 1972, through August 31, 1973; follow-up through February 28, 1974.

removal rate of 9.1/100 woman-years. The continuation rate was 79.8 (Table 1). The pregnancy rate for the multiparous patients was 0.78, with an expulsion rate of 4.8/100 woman-years (Table 2). There were no pregnancies in the 24 nulliparous insertions of the Antigon-F, but the expulsion rate was 20.6 (Table 3). There were 214 postabortion insertions with the Antigon-F, with a total of 3,748 woman-months, and a pregnancy rate of 1.3 (Table 4).

*Ypsilon-Y.* The 910 patients with Ypsilon-Y devices were observed for a total of 14,348 woman-months. The pregnancy rate for the total group was 1.8, the expulsion rate was 1.9, and the medical removal rate was 3.7/100 woman-

years. The over-all continuation rate was 88.9 (Table 1). The pregnancy rate for the multiparous patients was somewhat higher, 2.4, than that for the total group, while the pregnancy rate for the nulliparous patients was only 0.78/100 woman-years. The expulsion rates for the multiparous and nulliparous patients were 1.7 and 2.4, respectively. The medical removal rates for the two groups were 3.7 and 4.7, respectively (Tables 2 and 3). The pregnancy rate for the postabortion insertions was 1.3, with a continuation rate of 90.3/100 woman-years (Table 4).

*Copper-T 200.* The 939 patients with Copper-T devices were observed for a total of 15,558 woman-months. The over-all pregnancy rate was 0.85, the expulsion

TABLE 2. *Multiparous Insertions*

Rate <sup>a</sup> per 100 woman-years	Antigon-F: 646 insertions, 10,283 woman-months	Ypsilon-Y: 492 insertions, 8,610 woman-months	Copper-T 200: 602 insertions, 10,399 woman-months
Pregnancies	0.78	2.4	1.04
Expulsions	4.8	1.7	1.7
Displaced and reinserted	2.2	0.56	1.5
Medical removals			
Bleeding/pain	9.1	3.1	3.6
Perforations	0	0	0.12
Other	1.2	0.55	0.35
Nonmedical removals			
Planning pregnancy	3.1	0.69	1.6
Other personal	0.44	2.6	1.7
Total event rate	21.6	11.5	11.6
Continuation rate	78.4	88.4	88.4

<sup>a</sup>Tabulated as Pearl's index. Period of study March 1, 1972, through August 31, 1973; follow-up through February 28, 1974.

TABLE 3. Nulliparous Insertions

Rate <sup>a</sup> per 100 woman-years	Antigon-F: 24 insertions, 405 woman-months	Ypsilon-Y: 224 insertions, 3046 woman-months	Copper-T 200: 197 insertions, 2943 woman-months
Pregnancies	0	0.78	0.82
Expulsions	20.6	2.4	2.5
Displaced and reinserted	2.9	1.2	2.0
Medical removals			
Bleeding/pain	5.9	3.5	4.5
Perforations	0	0	0.41
Other	2.9	1.2	0.82
Nonmedical removals			
Planning pregnancy	0	0	1.2
Other personal	0	2.0	0.41
Total event rate	32.3	11.1	12.7
Continuation rate	67.7	88.9	87.3

<sup>a</sup>Tabulated as Pearl's index. Period of study March 1, 1972, through August 31, 1973; follow-up through February 28, 1974.

rate was 1.8, and the medical removal rate was 4.6/100 woman-years. The pregnancy rate for the multiparous patients was 1.04 and for nulliparous patients the rate was 0.82. The expulsion rates for multiparous and nulliparous patients were 1.7 and 2.5/100 woman-years, respectively. The rates of medical removals, respectively, were 4.1 and 5.7 (Tables 2 and 3). The pregnancy rate in the post-abortion insertion group was 0 in 140 insertions, totaling 2,216 woman-months (Table 4).

DISCUSSION

The pregnancy rates for all three devices in this study compare favorably with

commercially available devices. All data in this study were calculated according to Pearl's index; calculation by Tietze's life-table index method would probably produce slightly higher figures. A pregnancy rate of 0.78/100 woman-years for the Antigon-F in multiparous patients is very satisfactory. Fuchs and Risk<sup>11</sup> reported in 1972 a pregnancy rate of 1.8/100 woman-years with the Antigon-F. The expulsion rate in their series, however, was 16.9, compared with 5.1 in the present series. The difference is undoubtedly related to the fact that the Antigon-F had been preloaded into the introducer many days prior to insertion in the first reported material, while in the present study the Antigon-F was not

TABLE 4. Postabortion Insertions

Rate <sup>a</sup> per 100 woman-years	Antigon-F: 214 insertions, 3748 woman-months	Ypsilon-Y: 194 insertions, 2692 woman-months	Copper-T 200: 140 insertions, 2216 woman-months
Pregnancies	1.3	1.3	0
Expulsions	4.5	2.2	1.1
Displaced and reinserted	0.96	1.8	0
Medical removals			
Bleeding/pain	4.8	1.8	3.8
Perforations	0	0	0
Other	0.96	1.3	1.6
Nonmedical removals			
Planning pregnancy	1.6	0.45	1.1
Other personal	1.3	0.89	1.6
Total event rate	15.5	9.7	9.2
Continuation rate	84.5	90.3	90.8

<sup>a</sup>Tabulated as Pearl's index. Period of study March 1, 1972, through August 31, 1973; follow-up through February 28, 1974.

Copper-T 200: 939 insertions, 15,558 woman-months
0.85
1.8
1.4
3.8
0.15
0.62
1.5
1.5
11.6
88.4

August 31, 1973; follow-up

continuation rate was 88.4%. The pregnancy rate for nulliparous patients was somewhat lower than for the total group, 0.82, and the rate for the multiparous patients was 1.04. The medical removal rates for the multiparous patients were 4.1 and 5.7, respectively. The medical removal rates for the two groups were 3.7 and 5.7 (Tables 2 and 3). The pregnancy rate for the post-abortion insertion group with a continuation rate of 88.4% (Table 4). The 939 patients with the Antigon-F were observed for a total of 15,558 woman-months. The over-all pregnancy rate was 0.85, the expulsion

Copper-T 200: 602 insertions, 10,399 woman-months
1.04
1.7
1.5
3.6
0.12
0.35
1.6
1.7
11.6
88.4

August 31, 1973; follow-up

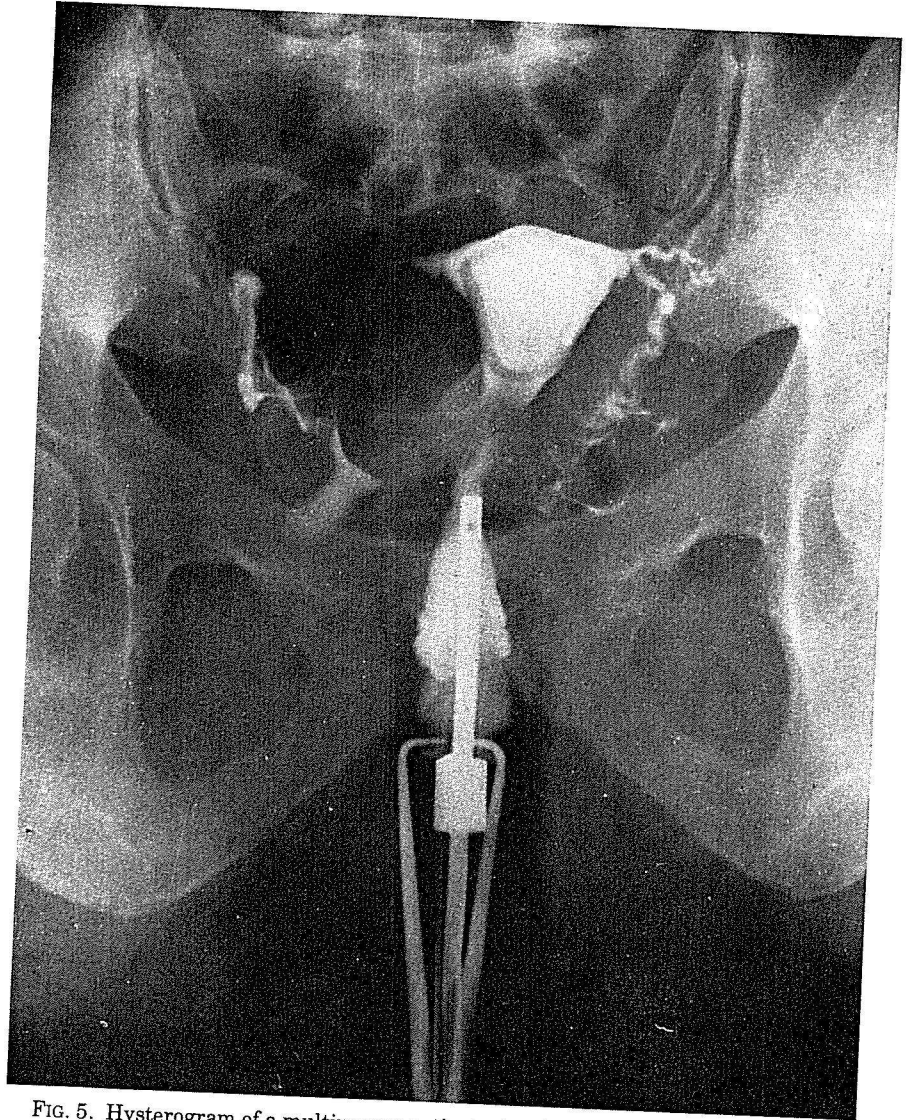


FIG. 5. Hystero-gram of a multiparous patient, showing the good fit of the Antigon-F to the uterine cavity.

loaded into the inserter until immediately prior to insertion in order to prevent loss of "memory." Only 24 nulliparous patients were fitted with the Antigon-F because insertion of this device in the nulliparous patient was difficult and painful; we elected early in the study to exclude nulliparous patients from the Antigon-F group.

The over-all pregnancy rate of 0.85 for the Copper-T 200 is the same as that for the Antigon-F in a comparable group of

patients. It compares favorably with that of 2.52/100 users of the Copper-T 200 in a total of 56,992 woman-months reported by Tatum.<sup>8</sup> The data were the result of work in several institutions. Our lower rates might be related to the fact that a uniform policy for insertion has been enforced under careful supervision.

The results of our study with the Ypsilon-Y indicate that this device seems to be favorable for nulliparous patients. The pregnancy rate of 0.78/100 woman-

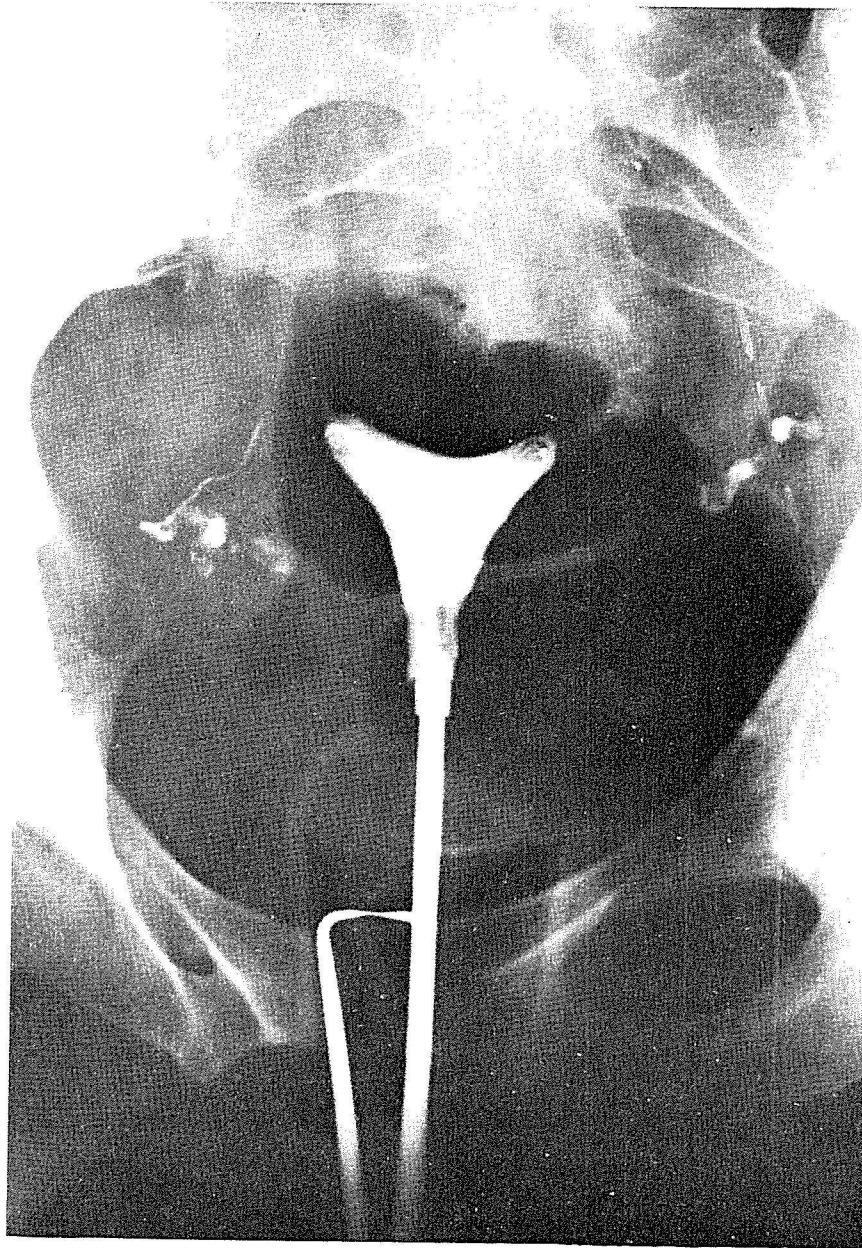


FIG. 6. Hystero-gram of a nulliparous patient, demonstrating good conformity of the Ypsilon-Y to the uterine cavity. Note that the ball-shaped tips of the Ypsilon-Y extend to the cornua of the uterus.

years is satisfactory, and, interestingly enough, is exactly the same as for multiparous patients with the Antigon-F. A pregnancy rate of 2.4 for the multiparous patients is higher than desirable, and we have therefore investigated the reasons

for the higher pregnancy rate in this group. Hystero-grams were carried out on several patients with the Antigon-F, the Ypsilon-Y, and the Copper-T 200. The Antigon-F is usually well conformed to the uterine cavity and reaches the fundus

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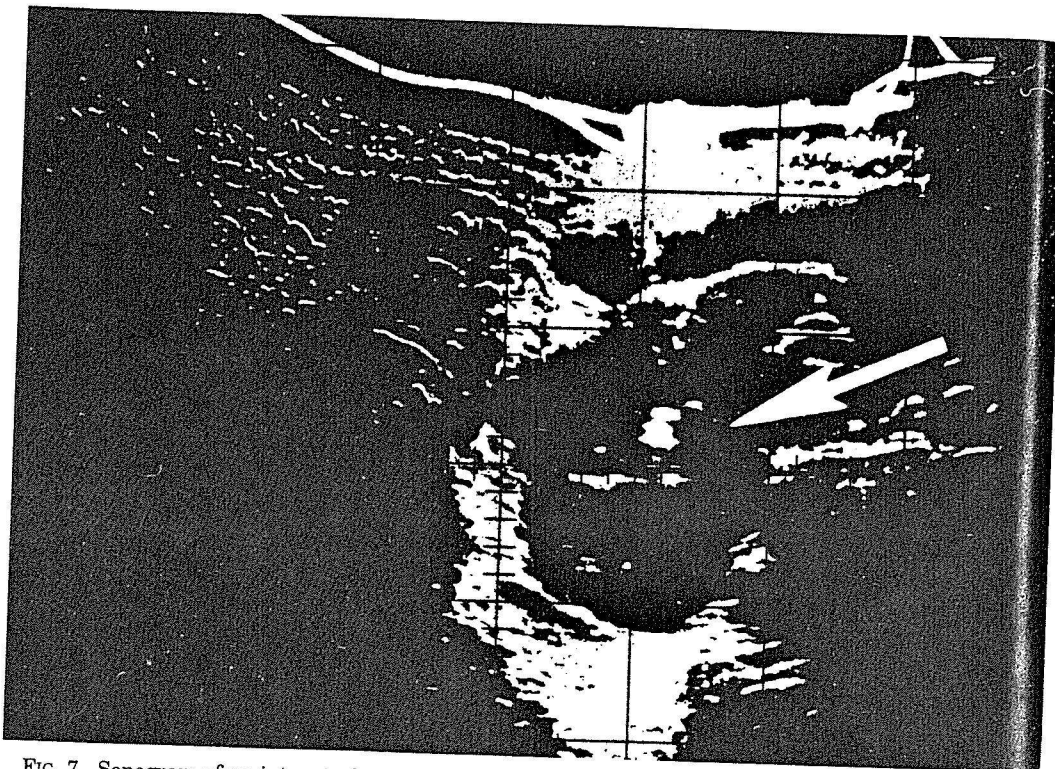


FIG. 7. Sonogram of an intrauterine pregnancy of 6 to 7 weeks' gestation, with the Ypsilon-Y in utero. The uterus is retroverted. The *arrow* indicates the echoes of the Ypsilon-Y; the cervix is located immediately above the *arrow*, and the gestational sac is located high in the uterine cavity, above the Ypsilon-Y.

even in multiparous patients (Fig. 5). Hysterograms with the Ypsilon-Y in the uterus (Fig. 6) indicate that this device also conforms well to the uterine cavity but that the device is too small to reach the fundus in some of the multiparous patients.

We have also studied several cases in which pregnancy occurred with the device in the uterus. In these cases we found on sonography that implantation had occurred in the fundal area when the Antigon-F or the Copper-T 200 were displaced to the endocervix. The implantation site and its correlation to the device in cases where pregnancy occurred with the Ypsilon-Y in situ have been studied both by sonography (Fig. 7) and by careful exploration at the time of abortion. In all pregnancies with the Ypsilon-Y in utero, the implantation site was found to be high in the uterine

cavity. This has also been confirmed in several cases by hysterogram (Fig. 8). We have interpreted these observations as support for the hypothesis that the contraceptive effect of an intrauterine device is related to the surface area covered, and we believe that the highest contraceptive effect is obtained when the largest possible percentage of the surface of the uterine walls is covered.<sup>15</sup> This is in accordance with the findings of Makino et al.<sup>16</sup>

As reported in detail elsewhere,<sup>17, 18</sup> we have now observed five perforations of the Copper-T 200 stem through the cervical tissue. In Thailand, five similar perforations were observed in 1220 insertions.<sup>19</sup> Similar perforations as well as penetrations of the arms into the uterine wall have been observed by other investigators.<sup>20</sup> This shortcoming of the design of the Copper-T, which is to some

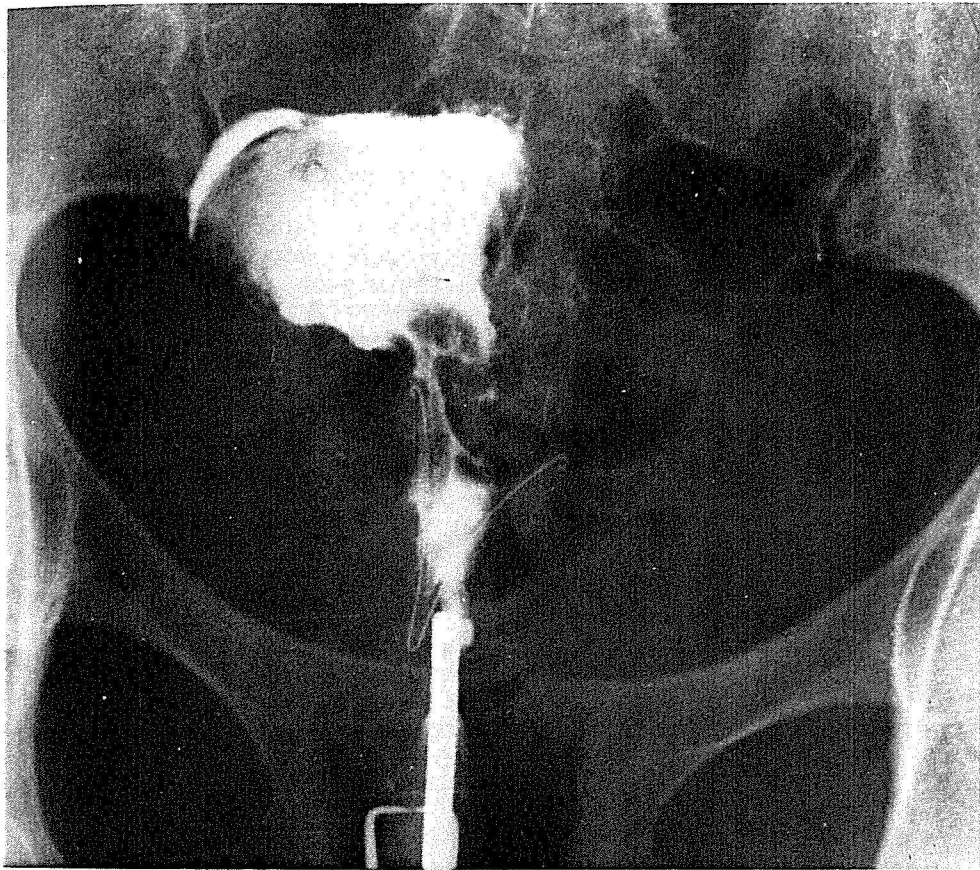


FIG. 8. Hystero-gram of a patient with an intrauterine pregnancy of 7 to 8 weeks' gestation, with the Ypsilon-Y in situ. The gestational sac is located high in the fundal area, while the Ypsilon-Y is seen low in the uterine cavity.

extent shared by the Copper-7, could easily be eliminated by modifications of the designs. We observed no perforations with the Antigon-F or the Ypsilon-Y, and the design of these two devices makes the risk of perforation minimal.

Although a life-table analysis by Tietze's method is likely to give slightly higher event rates, the results with all three devices are satisfactory. The Antigon-F seems to be the best in multiparous women, while the Ypsilon-Y in the size used is best in nulliparous women. The Copper-T is good both in multiparous and nulliparous women, but the insertion requires a little more experience, and the perforation rate is of some concern.

The contraceptive effect of the Antigon-

F may be augmented by copper sleeves placed on the frame of the device; both the Antigon-F and the Ypsilon-Y could conceivably be modified as progestin-releasing devices.

#### SUMMARY

A comparative study of three intrauterine contraceptive devices, the Antigon-F, the Copper-T, and the Ypsilon-Y, was carried out at The New York Hospital-Cornell Medical Center during an 18-month period from March 1, 1972, through August 31, 1973. At the cutoff date of February 28, 1974, all patients had been followed for at least 6 months.

During the period of study, 884 Antigon-F devices, representing 14,436 woman-

the Ypsilon-Y in utero. The cervix is located immediately above the Ypsilon-Y.

been confirmed in hystero-gram (Fig. 8). These observations support the hypothesis that the surface area of an intrauterine device that the highest obtained when the surface of the surface is covered.<sup>15</sup> This is in agreement with the findings of Makino

elsewhere,<sup>17, 18</sup> five perforations through the device, and, five similar perforations as well as arms into the uterine cavity observed by other investigators, which is to some

months of use, were inserted. The over-all pregnancy rate was 0.88, with an expulsion rate of 5.1 and a medical removal rate of 9.1/100 woman-years. This device was best tolerated by multiparous women.

There was a total of 910 insertions of the Ypsilon-Y, representing 14,348 woman-months of use. The over-all pregnancy rate was 1.8, with an expulsion rate of 1.9 and a medical removal rate of 3.7/100 woman-years. The pregnancy rate in nulliparous women was 0.78, with a continuation rate of 88.9. The pregnancy rate in multiparous women was higher, i.e., 2.4.

Nine hundred thirty-nine Copper-T 200 devices, representing 15,558 woman-months, were inserted. The over-all pregnancy rate was 0.85, with an expulsion rate of 1.8, a medical removal rate of 4.5, and a continuation rate of 88.4/100 woman-years. The pregnancy rate was 0.82 for nulliparous women and slightly higher, i.e., 1.04, for multiparous women.

Thus, all three devices had considerable merit. The Antigon-F and the Copper-T seemed the best in multiparous women; the Ypsilon-Y in the size used was best in nulliparous women. The only perforations occurred with the Copper-T.

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