A STUDY OF FOUR ANTIGON MODELS AND FACTORS IN THE USE-EFFECTIVENESS OF THE IUD

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ABSTRACT

Antigon models with surface areas 785-2740 mm^2 were studied in 914 patients followed through 24 months. Total observation months — 14,605. Follow-up % 94.5 after 12 and 91.4 after 24 months.

Surface area proved correlated with pregnancy rate. Antigon type I (smallest surface area) showed the highest pregnancy rate - 9.6 after 24 months. Antigon type III (bag model, largest surface area) showed significantly higher expulsion rate (24.8 after 12 months) than the other types. Type IV (wing model) and Antigon-F seem best suited, although removal due to bleeding/pain was 15.7 and 24.9, and 14.4 and 26.1 after 12 and 24 months, respecitvely. Continuation rates were thus only 66.0 and 47.6 for type IV and 68.3 and 42.5 for Antigon-F.

Age and parity affect the use-effectiveness of Antigon, total event rate decreasing with increasing age and parity. If the device is inserted 6-8 weeks postpartum, without intervening menstruation, pregnancy rate is significantly higher and expulsion rate significantly lower than if it is inserted after a menstrual period. Previous Caesarean section causes a significant increase in expulsion rate. Previous pelvic inflammations and bleeding disturbances do not affect Antigon use-effectiveness.

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The Antigon was first described by Osler and Lebech in 1968 (1). The pregnancy rate was 3.0 per 100 woman years. Subsequent investigations (2, 3), however, have shown higher pregnancy rates (4.5 and 10.0 in 100 women after 12 months). The pregnancy rate correlated with the surface area of polyethylene intrauterine devices (IUDs), falling with increasing surface area of the IUD (4, 5, 2). To increase the surface area and to satisfy the demand for a closed model, modifications of the original Antigon have been made. The present publication from the Contraception Clinic of Rigshospitalet, University of Copenhagen, presents the results of a comparative study of 4 different Antigon models and evaluates the influence of a number of factors (age, parity, time of insertion, previous pelvic diseases, and Caesarean sections) upon the event rates of the IUD.

MATERIALS AND METHODS

During the period 1967 - 1972 a total of 914 women had the Antigon inserted in the Contraception Clinic.

Four different types were used (Fig. 1). The original Antigon (type I) is kite-shaped, made of one piece of polyethylene measuring 30 x 23 mm and has a surface area of 785 mm^2. In the bag model (type III) the original Antigon is placed in a plastic bag. Its surface area is 2740 mm^2. The wing model (type IV) has on its inner surface plastic wings connected by a cross. Its surface area is 1057 mm^2. A previously designed model (type II) with wings, but without a cross, has not been studied in the Clinic. In Antigon-F, previously studied by Fuchs et al. (6), the frame is filled in with a thin plastic membrane having horizontal slits. Its surface area is 1725 mm^2. The technique of insertion is the same for all 4 types, as described by Osler and Lebech (1). It is important not to place the Antigon into the inserter until immediately before its insertion (6). 278 patients had the original Antigon (type I), 161 the bag model (type III), 227 the wing model (type IV), and 248 the Antigon-F inserted.

Tables I and II give the age distribution and parity. The more serious forms of pelvic inflammatory disease were considered to contra-indicate insertion of an IUD, but the material includes 191 patients with a history of minor pelvic infection or bleeding disturbances. Practically all the Antigons were inserted 6-8 weeks post-partum, in 466 cases after a menstrual period had occurred inbetween and 448 without a menstrual period. 121 of the patients had been delivered by Caesarean section.

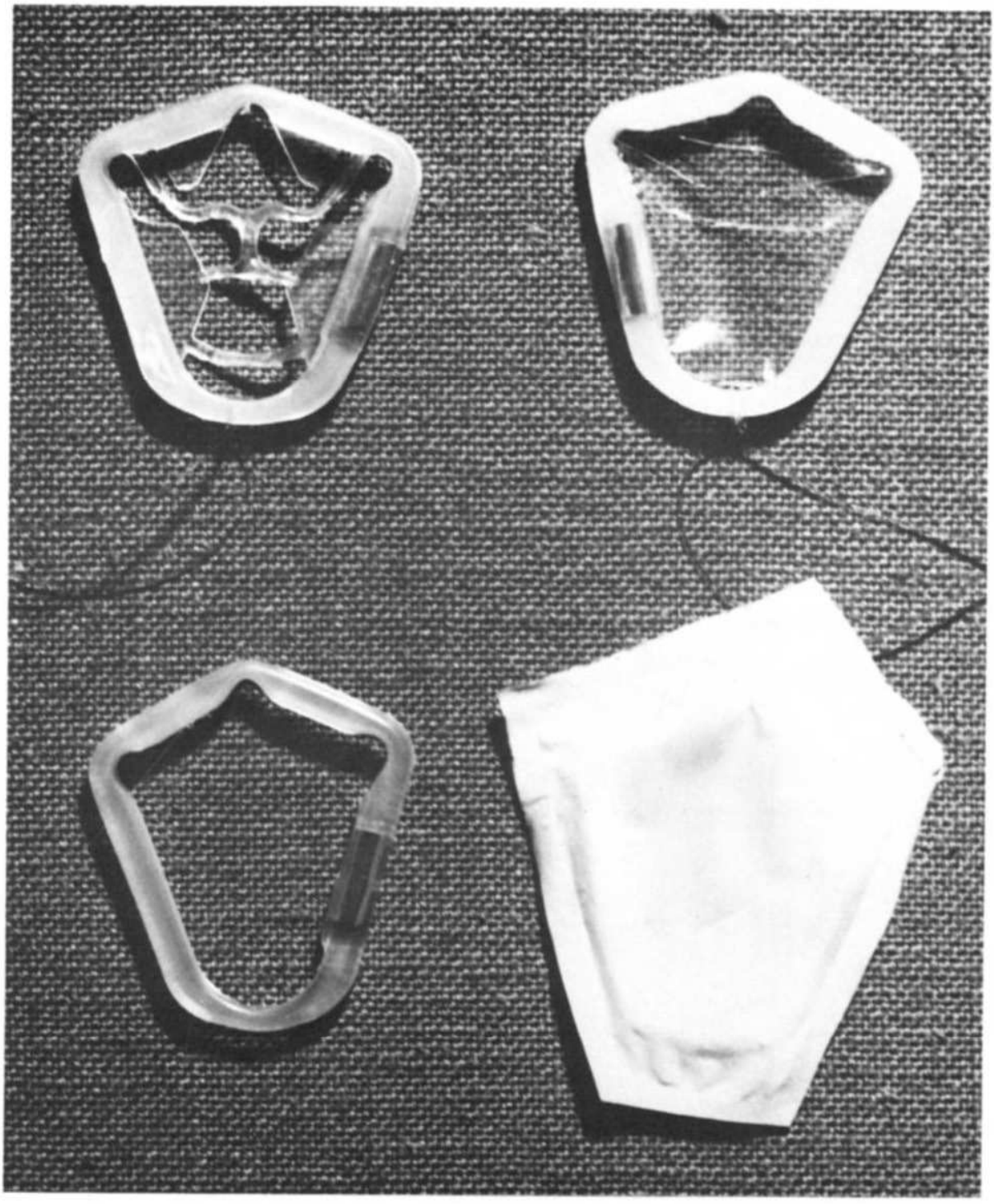

Figure 1: 4 types of Antigon

Table I: Age distribution for 4 types of Antigon

	Type I	Type III	Type IV	Antigon-F
< 18 years	9 (3.2%)	8 (5.0%)	0	2 (0.8%)
18 - 24 "	89 (32.0%)	57 (35.4%)	66 (29.1%)	72 (29.0%)
25 - 29 "	78 (28.1%)	48 (29.8%)	90 (39.7%)	104 (41.9%)
30 - 34 "	54 (19.4%)	32 (19.9%)	50 (22.0%)	44 (17.7%)
> 35 "	48 (17.3%)	16 (9.9%)	21 (9.3%)	26 (10.5%)
Total	278	161	227	248

Table II: Distribution by parity for 4 types of Antigon

	Type I	Type III	Type IV	Antigon-F
Parae 0	5 (1.8%)	5 (3.1%)	8 (3.5%)	3 (1.2%)
" I	83 (29.8%)	73 (45.3%)	94 (41.4%)	106 (42.7%)
" II	96 (34.5%)	48 (29.8%)	82 (36.1%)	85 (34.3%)
" III	94 (33.8%)	35 (21.7%)	43 (18.9%)	54 (21.8%)
Total	278	161	227	248

The patients were seen 3, 12, and 24 months after the insertion. The follow-up % is 94.5 after 12 months and 91.4 after 24 months. The insertion as well as the follow-up examinations were in the hands of changing members of the staff. No other form of contraception was practised. The data were analysed according to the so-called life-table method (7).

RESULTS

Table III sets out the cumulative event rates after 12 and 24 months for all 4 types of Antigon. The 914 patients were followed for a total of 14,605 months. Re-insertion of the Antigon was rarely done, as is apparent from the continuation rates in relation to total event rates.

Pregnancies: 27 patients conceived within the first year. Of them, 9 had type I, 3 had type III, 9 had type IV, 6 had Antigon-F. This gives pregnancy rates of 3.8, 2.5, 5.0, and 3.1. The differences are not significant. Eleven patients conceived during the second year, 10 of them with type I and one with type IV. The pregnancy rate during the second year is significantly higher ($P < 0.05$) for type I than for the other types. The cumulative pregnancy rates after 24 months are 9.6, 2.5, 5.7, and 3.1, respectively.

Expulsions: 98 Antigons were expelled during the first year: 25 of type I, 34 of type III, 21 of type IV, and 18 of Antigon-F. This gives expulsion rates of 10.3, 24.8, 11.3, and 8.9. The expulsion rate for type III is significantly higher ($P < 0.05$) than for the other types. Only 7 were expelled during the second year, 2 of type I, 3 of type III, and one each of types IV and Antigon-F. This gives a cumulative expulsion rate after 24 months of 11.4, 27.6, 11.9, and 9.6. The rate for type III is significantly higher ($P < 0.05$) than for the other types.

Removals: 94 Antigons were removed because of bleeding and/or pain during the first year, 20 of types I, 14 of type III, and 30 each of type IV and Antigon-F. This gives removal rates of 8.3, 11.1, 15.7, and 14.4. During the second year 49 Antigons were removed: 7 of type I, 8 of type III, 15 of type IV, and 19 Antigon-F. Thus, the cumulative removal rate after 24 months is 12.2, 19.8, 24.9, and 26.1. The removal rate for type I after 12 and 24 months is significantly lower ($P < 0.05$) than for type IV and Antigon-F, but not significantly lower than for type III.

Only a few removals were for "other medical" and "personal" reasons, and in these groups there is no difference between the rates.

Table III: Net cumulative event rates (± S.E.) per 100 women at 12 and 24 months for the 4 ypes of Antigon

Months of Use	Type I		Type III		Type IV		Antigon-F	
	12	24	12	24	12	24	12	24
Pregnancy	3.8±1.3	9.6±2.1	2.5±1.4	2.5±1.4	5.0±1.6	5.7±1.8	3.1±1.2	3.1±1.2
Expulsion	10.3±1.9	11.4±2.1	24.8±3.7	27.6±3.9	11.3±2.3	11.9±2.4	8.9±2.0	9.6±2.1
Removals: Bleeding/Pain	8.3±1.8	12.2±2.2	11.1±2.8	19.8±3.9	15.7±2.6	24.9±3.3	14.4±2.4	26.1±3.3
Other Medical	1.7±0.9	2.3±1.0	1.7±1.2	2.9±1.7	0.6±0.6	0.6±0.6	1.0±0.7	2.6±1.3
Planning Pregn.	3.0±1.1	7.7±1.9	4.9±2.0	17.5±3.9	0.6±0.6	7.9±2.3	3.6±1.3	12.2±2.7
Personal Reason	1.7±0.9	2.3±1.0	0.8±0.8	2.1±1.5	1.7±1.0	2.4±1.2	1.0±0.7	4.1±1.7
Total Event Rate	28.8	45.4	45.8	72.4	34.9	53.4	32.0	57.7
Continuation Rate	73.9	59.6	59.7	38.8	66.0	47.6	68.3	42.5
Woman Months of Use	2773	4712	1433	2359	2111	3669	2323	3865
Number of First Insertions	278		161		227		248	

As may be seen, planned pregnancy is a common reason for removing the IUD, especially during the second year, and most common for type III and Antigon-F.

Continuation rates after 12 and 24 months are 73.9 and 59.6 for type I, 59.7 and 38.8 for type III, 66.0 and 47.6 for type IV, and 68.3 and 42.5 for Antigon-F. When deducting removal because of planned pregnancy, the acceptability rate is 76.4 and 65.5, 63.7 and 52.4, 66.6 and 55.5, and 71.8 and 54.6, respectively.

Table IV presents the cumulative event rates afer 12 and 24 months for the total material in relation to parity. As only 21 patients were nulliparae, the event rates were not calculated for this group. After 12 months, but not after 24 months, the pregnancy and expulsion rates were significantly lower ($P < 0.05$) for parae III than for parae I. The removal rate because of bleeding/pain is higher for parae I than for parae II and III after 12 and 24 months, but the difference is significant ($P < 0.05$) only after 24 months. The total event rate after 12 and after 24 months is 42.9 and 75.4 for parae I and 25.5 and 28.7 for parae III. The difference is significant ($P < 0.05$) only after 24 months. The very marked differences in total event rates are largely due to a difference in removal because of planned pregnancy, which was after 24 months 20.4 for the parae I against 1.5 for the parae III.

Table V lists the cumulative event rates for the total material in relation to age. The pregnancy rate falls with increasing age, but the difference is significant ($P < 0.05$) after 12 months only between the groups 18-24 years and > 30 years. The expulsion rate after 12 and 24 months was significantly lower ($P < 0.05$) in the group 25-34 years than among younger women, while after the age of 35 the expulsion rate rises again. The total event rate declined evenly with increasing age. The age- and parity-related differences in the event rates are manifest also for each individual type of Antigon - and the differences between the individual types of Antigon remain even when age and parity are fixed.

Table VI gives the cumulative event rates after 12 months for the total material in relation to whether menstruation had occurred between delivery and the insertion of the Antigon. The 448 Antigons inserted without preceding menstruation are distributed by 126 on type I, 79 on type III, 115 on type IV, and 128 on Antigon-F. The pregnancy rate is significantly higher and the expulsion rate significantly lower ($P < 0.05$) if the Antigon is inserted without a preceding menstrual period. These differences are apparent for each individual type. There are no differences

Table IV: Net cumulative event rates (±S.E.) per 100 women at 12 and 12 months related to parity

Months of Use	Parae I		Parae II		Parae III	
	12	24	12	24	12	24
Pregnancy	4.0±1.2	5.2±1.4	4.0±1.2	6.6±1.7	2.2±1.1	5.1±1.8
Expulsion	14.9±2.1	16.9±2.3	11.8±2.0	11.8±2.0	9.0±2.1	11.0±2.3
Removals:						
Bleeding/Pain	15.5±2.1	27.4±2.9	9.6±1.8	18.5±2.6	11.5±2.3	14.7±2.6
Other Medical	1.9±0.8	3.4±1.0	1.2±0.7	2.3±1.0	0.6±0.6	1.3±0.9
Planning Pregn.	5.1±1.3	20.4±2.8	2.0±0.9	5.7±1.6	0.0	1.5±1.0
Personal Reason	1.5±0.7	2.1±0.9	0.8±0.6	1.9±0.9	2.2±1.1	5.1±1.8
Total event Rate	42.9	75.4	29.4	46.8	25.5	28.7
No Event	57.1	24.6	70.6	53.2	74.5	71.3
Woman Months of Use	3207	5181	2960	5160	2155	3776
Number of First Insertions	356		311		226	

Table V: Net cumulative event rates (± S.E.) per 100 women at 12 and 24 months related to age

Age	18 - 24		25 - 29		30 - 34		≥ 35	
Months of Use	12	24	12	24	12	24	12	24
Pregnancy	6.9±1.7	9.0±2.1	3.2±1.1	4.3±1.3	2.1±1.2	4.8±1.9	0.0	4.3±2.4
Expulsion	18.6±2.6	19.8±2.7	9.6±1.8	10.6±1.9	8.0±2.2	8.0±2.2	13.3±3.5	15.8±3.8
Removals:								
Bleeding/Pain	10.0±2.0	21.0±3.1	16.3±2.3	24.4±2.7	12.3±2.7	17.1±3.1	8.4±2.9	17.3±4.1
Other Medical	1.9±0.9	3.4±1.4	1.2±0.7	1.8±0.9	0.7±0.7	1.6±1.1	0.0	0.0
Planning Pregn.	5.1±1.5	14.1±2.7	2.0±0.9	13.1±2.4	2.7±1.4	7.2±2.3	1.1±1.1	2.5±1.8
Personal Reason	1.9±0.9	2.6±1.2	1.2±0.9	2.3±1.0	2.1±1.2	4.8±1.9	0.0	1.5±1.4
Total Event Rate	44.4	69.9	33.5	56.5	27.9	46.5	22.8	41.4
No Event	55.6	30.1	66.5	43.5	72.1	53.5	77.2	58.6
Woman Months of Use	2505	4077	2975	5075	1735	3020	1089	1910
Number of First Insertions	284		320		180		111	

Table VI: Net cumulative event rates (± S.E.) per 100 Women at 12 months related to menstruation since last pregnancy

	Menstruation	No Menstruation
Pregnancy	2.2±0.8	4.9±1.1
Expulsion	16.0±1.9	9.6±1.5
Removals:		
Bleeding/Pain	13.3±1.7	11.4±1.6
Other Medical	1.7±0.7	0.8±0.5
Planning Pregn.	2.8±0.9	2.8±0.9
Personal Reason	1.7±0.7	1.1±0.6
Total Event Rate	37.7	30.6
Continuation Rate	65.3	70.7
Woman Months of Use	4274	4266
Number of First Insertions	466	448

in the other rates. The continuation rate after 12 months was a little higher (70.7 as compared with 65.3), if the Antigon was inserted without a preceding menstruation. This difference is not significant. 121 Antigons (42 of type I, 17 of type III, 29 of type IV, and 33 Antigon-F) were inserted 6-8 weeks after Caesarean section. The expulsion rate after 12 months was significantly higher ($P < 0.05$) (28.3 as against 11.8) if the insertion was done after Caesarean section. The pregnancy rate was higher (7.3 against 3.4), but this difference is not significant. There are no differences in the other rates.

191 Antigons (71 of type I, 34 of type III, 45 of type IV, and 41 Antigon-F) were inserted in spite of a history of pelvic inflammatory disease or bleeding disturbances. Within this group the pregnancy rate was a little lower (2.1 against 4.0 after 12 months) and the removal rate because of bleeding/pain a little higher (17.2 against 11.3), but the differences are not significant. The expulsion rate was 13.1 in both groups, and there was no difference in the other rates.

Perforations or other serious complications did not occur.

DISCUSSION

There were no definite differences between the 4 types in the pregnancy rate during the first year. The Antigon was inserted 6-8 weeks post-partum, and as 3-6 months elapse before fertility is fully re-established after delivery (8), this can explain why differences in pregnancy rates do not manifest themselves during the first year. After 24 months the pregnancy rates for type I, type IV, Antigon-F, and type III were 9.6, 5.7, 3.1, and 2.5, respectively. The surface areas of the four types are 785, 1057, 1725, and 2740 mm^2, respectively. Thus, the type having the largest surface area also has the lowest pregnancy rate - in agreement with several previous studies (4, 5, 2). Davis et al. (5), for instance, found a pregnancy rate after 24 months of 9.3 for Lippes' loop A which has a surface area of 527 mm^2 against 4.1 for loop D, surface area 960 mm^2.

The expulsion rate (24.8 after 12 months and 27.6 after 24 months) of the bag model (type III) is significantly higher ($P < 0.05$) than that of the other types between which there were only small, and not significant differences,in expulsion rates. The removal rate for bleeding/pain was significantly lower ($P < 0.05$) for type I, having the smallest surface area, than for type IV and Antigon-F and lower than for type III. However, this difference is not significant. The reason that type III, which has the largest surface area, does not have a significantly higher removal

rate than type I may be the very high expulsion rate of type III, as part of the expelled IUDs would presumably later have been removed because of bleeding/pain. After 12 as well as after 24 months, the continuation rate is higher for Antigon type I than for the other types.

There have been only a few publications on the Antigon (1, 2, 3, 9). Previous studies (1, 3) on type I have shown higher continuation rates (87.5 and 82.4 against 73.9 after 12 months) than in our study because of very low removal rates for bleeding/pain (2.1 and 3.1). However, the pregnancy rate was 10.1 after 12 months (3). In a study of the wing model (type IV), Lebech et al. (2) found a pregnancy rate of 3.0, an expulsion rate of 6.8 and a removal rate of 10.1 after 12 months. This affords a continuation rate of 80.3 against our 66.0. Lauersen et al. (9) found a pregnancy rate for Antigon-F of 0.88 per 100 woman years, an expulsion rate of 7.0, and a removal rate due to bleeding/pain of 7.9, affording a continuation rate of 79.8 against our 68.3 after 12 months.

In other words, our results are poorer than those reported by others. However, the use-effectiveness of an IUD is influenced by so many factors that it is difficult to compare the results, and greater differences have been demonstrated in use-effectiveness between different clinics using the same IUD than between different IUDs in the same clinic (10). One of the factors influencing the contraceptive efficacy of an IUD is the patient's age and parity. Like previous studies (4, 11, 12), ours demonstrated that the total event rate falls with increasing parity and age. It has previously been recommended (13) to wait for 10-12 weeks after delivery before inserting an IUD, and Tatum (14) reported higher pregnancy and expulsion rates when T-Cu 200 had been inserted less than 8 weeks post-partum. Akinla et al. (15) found insertion immediately after a menstrual period to afford the best continuation rate.

We found a significantly lower pregnancy rate and a significantly higher ($P < 0.05$) expulson rate, if the Antigon was inserted after a menstrual period than in cases where no menstrual period had occurred after delivery.

A higher expulsion rate in these patients may be due to a higher estrogen level and thereby a greater contractility of the myometrium. This accords with Akinla (15) who found the highest expulsion rate when the IUD was inserted between the 8th and 14th day of the cycle, at the estrogen peak.

There is no immediate explanation of the difference in pregnancy rate. There is no difference in the other rates. The continuation rate is a little higher if the insertion has not been preceded by a menstruation (70.7

against 65.3 after 12 months). Caesarean section significantly increased the expulsion rate ($P < 0.05$). This does not seem to have been reported previously. The pregnancy rate was also a little, but not significantly higher (7.3 against 3.4). There was no difference in the other rates. As a rule, it is recommended not to insert an IUD if there is a history of pelvic inflammatory disease or bleeding disturbances. We did so in 191 cases and did not find event rates significantly different from a control group.

Antigon type I has a somewhat better continuation rate than Antigons having a larger surface area owing to the higher expulsion and removal rates of the latter, but the pregnancy rate with the type I Antigon is not satisfactory. The bag model (type III) cannot be recommended because of its high expulsion rate.

The wing model (type IV) and Antigon-F have acceptably low pregnancy and expulsion rates, but a significantly higher removal rate because of bleeding/pain than has type I. Insertion of type I took place during an earlier period than that of type IV and of Antigon-F, and it is possible that a change in patient as well as in doctor attitude can partly explain the marked differences in the removal rates. Differences in patient and doctor attitude as well as in type of clinic (10, 11, 16) may be the explanation why others have found far lower removal rates for the wing model and the Antigon-F (2, 9), but as demonstrated in the present study,differences in material and in time of insertion may also be important factors in the event rates of an IUD. It may be concluded that the wing model and Antigon-F are the best suited types of Antigon, as their relatively high removal rate is more acceptable than the high pregnancy rate with type I.

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