United States Patent

[72]	Inventor	Howard J. Tatum
		New York, New York
[21]	Appl. No.	760,609
[22]	Filed	Sept. 18, 1968
[45]	Patented	Oct. 13, 1970
[73]	Assignee	The Population Council
	-	New York, New York
		a corporation of New York

		128/267
[51]	Int. Cl	A61f 5/46

[11] 3,533,406

[50]	Field of Search	128, 129, 130, 13	128/127, 1,260,267		
[56] References Cited UNITED STATES PATENTS					
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Primary Examiner—Adele M. Eager Attorney—Brumbaugh, Graves, Donohue and Raymond					

ABSTRACT: An intrauterine contraceptive device is disclosed which has a characteristic "T" shape. The length of the crossbar of the "T" is approximately equal to the lateral dimension of the fundus of the uterus, and the length of the depending leg of the "T" is adapted to extend down toward the cervical os.





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INTRAUTERINE CONTRACEPTIVE DEVICE

This invention relates to an improved contraceptive device and method.

During recent past years due to world population pressures, a vast amount of research has been undertaken directed to developing improved contraceptive methods. One such method which has gained wide favor because of its high effectiveness is to employ certain hormones known to modify the body endocrinology and suppress ovulation. These hormones, popularly administered as birth control pills, if used regularly, prove to be highly effective and reliable for controlling conception. Nevertheless, they are not without difficulties when used in large-scale birth control programs in developed and developing countries, not only because they are relatively expensive, but also because considerable reliance has to be 15 placed upon the patient to take the pills in accordance with the prescribed regimen.

In view of these disadvantages of conventional birth control pills, the use of intrauterine contraceptive devices has achieved considerable popularity. Such devices may be in- 20 serted inexpensively in patients in large-scale programs, and, moreover, do not require reliance upon a patient's willingness or ability to follow a particular regimen of treatment. Despite these advantages of the intrauterine contraceptive devices which are already available and being manufactured commercially, it has been found that they are not as effective as the socalled conventional birth control pills, provided the latter are used within the prescribed regimen. Accordingly, considerable effort has been directed toward improving the efficacy of intrauterine contraceptive devices.

A recurrent problem in the use of most intrauterine contraceptive devices is that of involuntary expulsion. Because intrauterine devices are conventionally manufactured to "fill" the uterine cavity, these devices inherently apply some anterior-posterior and bilateral pressure to the muscle of the uterus. 35 As a consequence, there is an involuntary reaction of these muscles tending to expel the inserted device.

In accordance with the present invention, it has been discovered that effective contraception may be obtained using intrauterine devices notwithstanding that the device does not 40 "fill" the uterine cavity. There is provided by this invention a novel intrauterine contraceptive device having the shape of a "T". The top crossbar of the "T" is normally in the order of from 30 to 38 mm. in length, corresponding generally to the width of the fundal portion of the endometrial cavity. The 45 length of the depending leg of the "T" is from 35 to 40 mm., so that it is adapted to extend toward the cervical os when the the crossbar of the "T" lies at the fundus of the uterus. The diameter of the "T" and crossbar members is in the order of from 2 to 4 mm. The device may be prepared from any phar- 50 maceutically acceptable material, preferably inert plastic such as polyethylene or polypropylene, nylon, dacron, silastic, etc.

The present invention may be understood more fully by reference to the following figures in which:

FIG. 1 is a sketch of an intrauterine device in accordance 55 with the present invention;

FIGS. 2 and 3 are sectional views of the uterine cavity showing the disposition of the intrauterine device of the present invention therein; and

FIGS. 3 to 5 illustrate an inserter adapted for the implanta- 60 The results are set forth in the following table. tion of the intrauterine device of the present invention.

As already described, the intrauterine device of the present invention takes the form of a "T" as illustrated in FIG. 1. The top cross bar 11 is of a length in the order of 30 to 38 mm. and the depending leg 12 is in the order of 35 to 40 mm. The 65 diameter of the crossbar 11 and depending leg 12 is typically in the order of 1 to 4 mm. The lengths of the crossbar 11 and the leg 12 are selected so that the device will fit naturally within the uterine cavity as illustrated in FIG. 2 with the crossbar 11 extending across the fundus 15 of the uterus and the 70 depending leg 12 extending down toward the os 16.

While the present invention is not to be limited by any theory, on the basis of studies which have been performed, the intrauterine device of the present invention is believed to function in the following manner:

Typically, the device of the present invention is of such a size that the crossbar of the "T" may exert some lateral pressure on the endometrial wall of the uterus. X-ray studies indicate that the ends of the crossbar will become slightly imbedded in the endometrium at 17 this suggesting a gentle anchoring phenomenon. However, it is believed that by using materials of thin cross section, anterior-posterior and lateral pressure on the walls of the uterus are reduced.

As illustrated in FIG. 3, the uterine muscle 14 when in its normal relaxed condition causes an obliteration of the endometrial cavity. While commonly referred to as a "cavity", in the relaxed condition the uterus in fact contains little or no volume of fluids since the muscle walls are collapsed against each other. It is as a consequence of this normal relaxed condition that intrauterine devices adapted to fill the uterine cavity necessarily must apply some anterior-posterior and lateral pressures upon the uterine muscles in order to force apart the collapsed fold of the cavity. It is the pressure applied to the muscle in this fashion which is believed to lead to the involuntary expulsion reaction of these muscles and to the other common side effects of intrauterine devices such as bleeding and/or pain. As illustrated in FIGS. 2 and 3, the intrauterine device 10 of the present invention is adapted to lie essentially in the fold of the relaxed uterine muscle and to apply only 25 minimal anterior-posterior and lateral pressure upon those muscles and upon their mucosal lining.

As illustrated in FIGS. 4 to 6, the inserter for implanting the intrauterine device of the present invention comprises an elongated tube 20 adapted to be extended through the cervi-30 cal os and into the uterine cavity. The tubular element 20 is provided with a suitable indicator 22 to permit the physician to gauge the position of the inserter device in use and a suitable finger grip 24 for easy gripping and manipulation of the tubular element with the fingers.

When it is loaded for implantation, the intrauterine device of the present invention is placed into the distal end of the inserter tube 20 as shown in FIG. 4. The extended arms 11 of the "T" are pressed down along the outer walls of the tube 20 into a pair of grooves 26 formed in the sides thereof. The grooves 26, as shown most clearly in FIG. 6, are of a size and shape adapted to grip the folded arms 11 and to retain them while the inserter tube with the intrauterine device of the present invention is inserted through the cervical os into the uterine cavity. Upon locating the inserter tube in the desired position the patient, the intrauterine device is expelled therefrom by means of a plunger 28 which extends through the inserter 20 (this plunger 28 being shown separately in FIG. 5).

EXAMPLES

Clinical studies have been performed on expulsion rates of the intrauterine "T" of the present invention in comparison with a typical plastic loop intrauterine device such as has been recommended heretofore. The plastic loop used in these studies had a generally sinuous shape in which the height was in the order of 23 mm. and the maximum lateral dimension was in the order of 27 mm. The "T" used in these studies had a dimension of 32 mm. across the top of the "T" and a leg of 36 mm. and was formed of polyethylene 1½ mm. in diameter.

NET CUMULATIVE RATES OF TERMINATION PER 100 USERS SELECTED DEVICES—NINE MONTHS OF USE

65		Intrauterine "T"	Intrauterine Loop
	Termination:		
	Pregnancy	12, 4	2.0
	Expulsions:		
	First	5.2	8.8
70	Later	0, 3	2.4
70	Removals:		· · · · · ·
	Medical	1,9	12.8
	Planning pregnancy	1, 2	0,6
	Other personal	0.9	1.7
	Total Termination	19.4	18,6
	Continuation Rate	80.1	81.4
	Women-Months of Use	5, 989	55, 698
75	women-wonths of Ose	0, 505	

These data show that involuntary expulsions for patients wearing the device of the present invention are substantially lower than for patients wearing conventional loops. This was observed both for the first expulsion of an intrauterine device as well as for subsequent expulsion after re-insertion. Medical 5 removals because of contraindications or objectionable irritation was dramatically reduced. As a consequence, even through the unintentional pregnancy rate was higher, the percentage of patients who continued with the program was about the same in the group wearing the device of the present 10 bar and said leg being in the order of 1 to 4 mm., said "T" invention as compared with the control group.

It will be understood that the present invention may be combined with other methods of contraception to provide improved effectiveness. For example, it has been found that certain metals such as copper or zinc produced unexplained im- 15 provement in the contraceptive efficiency of intrauterine devices. These metals may be plated on to the device of the present invention, or a small sheath of foil or wire of such a

metal or an alloy thereof may be wrapped around a portion of the "T". In still another modification, the "T" of this in-vention may be prepared from a plastic into which a contraceptive drug has been incorporated.

I claim:

1. An intrauterine contraceptive device substantially in the shape of a "T" said "T" having a crossbar of between about 30 and 38 mm. in length and a depending leg of between about 35 and 40 mm., the cross-sectional dimensions of said crossbeing adapted to lie within the fold of the uterine cavity.

2. In the method of contraception wherein an intrauterine device is placed within the uterus, the improvement comprising employing as said intrauterine device a "T" having a crossbar of from 30 to 38 mm. in length and a depending leg of from 35 to 40 mm., the cross-sectional dimensions of said crossbar and said leg being from 1 to 4 mm., said "T" being adapted to lie within the fold of the uterine cavity.

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