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**O**UR OBSERVATIONS on a group of 397 women receiving a new vaginal contraceptive cream from April 1, 1954 to October 1, 1955 were presented in a preliminary report.<sup>1</sup> Since then constant follow-up has been done on this original group, as well as on an additional group of patients. Data concerning the spermicidal activity of the vaginal cream preparation were presented and will not be discussed in this report.

In that paper the following excerpt appeared.

In the period between April 1, 1954, and October 1, 1955, 397 patients were placed on the contraceptive cream. Of this group 170 failed to use the cream for intervals adequate for the purposes of the study. Some moved from the area or were lost for follow-up, or discontinued the use of the cream for various reasons such as husband in armed services overseas, husband objected to wife using contraception, pregnant before receiving the method, changed to another method which could be purchased in a nearby drugstore, and so forth. A total of 227 patients remained on the cream for a minimum of 3 months and up to one and one-half years.

Since such a large number of women (170) were not included in the previous report for

the reasons mentioned, and since follow-up data have become available on these women since October 1, 1955, an analysis of their case histories has been done. This group is being considered separately at this time in order to present in detail the findings (Table 1), although all these data will be included in the analyses to follow in this present paper.

On October 1, 1956, the case histories of 987 women, including the above 397 women, were analyzed; 875 received the above-mentioned vaginal contraceptive cream\* and 112 received a vaginal contraceptive gel\* from April 1, 1954 to July 1, 1956, a period of 27 months. The new vaginal contraceptive cream was being evaluated clinically during this period. The vaginal contraceptive gel had previously been the subject of several studies and so was prescribed only for those women who requested it or expressed a preference for it. The data obtained from analysis of the case history records will be presented.

## PURPOSE AND METHOD

A major purpose of our clinic is to instruct women in the use of a contraceptive method to help them plan their families and space their children in accordance with the health and well-being of the mother and family. Successful use of any method of contraception depends on thorough instruction of the

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## CREAM-ALONE AND GEL-ALONE CONTRACEPTION

TABLE 1. DATA FROM FOLLOW-UP OF 170  
WOMEN USING CREAM-ALONE METHOD

	<i>No.</i>
Using method regularly, not pregnant (934.5 total months) Includes all women receiving cream during August and September who had not returned for a visit prior to October 1, 1955.	100
Changed to another method after using 0 to 12 months	13
To diaphragm with jelly	6
To gel-alone method	6
To sponge and powder	1
Pregnant before receiving the method	10
Pregnancy after receiving the method	5
Ran out of supplies after using method 7 and 9 months	2
Used method incorrectly	1
After 3 months, no note about use	1
Planned	1
Moved, could never be located	14
Never returned	15
Never used method	8
Vasectomy (used method 0 and 6 months)	2
Hysterectomy (never used method)	1
Separated or divorced (never used method)	2
TOTAL	170

patient. A detailed lecture is given to all new patients attending the clinic; a model of the pelvis is shown to the group, and the anatomy is explained; and various methods of contraception are presented and an explanation given as to why different types may be prescribed. Questions are invited and, during free discussion, old wives' tales, superstitions, and so forth are brought out and an approach to correct thinking is presented.

During the lecture the subject of "contact," which we define as precoital play, is discussed. It is strongly stressed that the contraceptive agent always be placed in the vagina before retiring, love-making, or coitus. The importance of a pelvic examination by a physician is explained to the group, for it is part of our educational program to have the women come to the clinic every 6 months for such an examination. Following the lecture each woman is examined by the physician and taught how to use the method

prescribed. In order to prove that she understands thoroughly what has been taught she is required to demonstrate how she will use the method.

Our routine instructions to the women about the use of the cream-alone or gel-alone method is as follows: Every night upon retiring or at any other time marital contact might be made insert one-half applicatorful of the preparation (although the instructions accompanying the products state that a full applicator of the preparation be introduced) into the vagina to the depth of 2 inches, pointing the applicator down and back. Coitus may occur immediately or up to one hour without addition of more of the preparation. If coitus does not take place until after one hour, or if repeated later, another half applicatorful is to be introduced. Douching is not necessary, but, if desired, must not be done until 6 hours after coitus.

The patient is given the opportunity of expressing a method preference and will receive that method if the physician feels it is correct for her and if no contraindication is found. Many women come to the clinic conditioned to request the diaphragm-plus-jelly method because they have been told that "this is the safest method." However, following the lecture many women, when made aware of the reliability of the cream-alone and gel-alone methods, request such a method because of the simplicity of use. Some, who have been patients in our clinic for many years, have learned from their daughters and daughters-in-law of easier methods of contraception and have returned asking if they might use them because for many years their coital relationships have not been satisfactory due to the use of a more complicated method. In teaching a new method one problem that is difficult to overcome is the prejudice of the patient, stemming from the advice received previously from other sources. Not infrequently patients come to the clinic fearful of trying a method which does not require a diaphragm.

*Follow-up*

Constant, active follow-up is an indispensable part of any contraceptive program and must be conscientiously conducted. A detailed history must be taken at the time of the patient's first visit to the clinic, and on each subsequent visit thorough information must be recorded, including such facts as the date of the last menstrual period; date of last coitus and method of contraception or conception control used, if any, as well as facts about how the method was used. A code history sheet was kept for every patient.

Many methods of contraception may erroneously be considered to result in failure of the method due to the fact that there is inadequate or incomplete information about use and motivation. In the course of the initial lecture the women in our clinic are told how important it is to return for a check-up visit and are made to feel the responsibility of their cooperation. They are shown the type of postcard they will receive through the mail if they fail to return within 7 to 10 weeks after receiving a method. This is a double postcard, half of which the woman tears off and returns after filling in answers to the following: dates of the last two menstrual periods, statement about use of the method, and her comments. The clinic telephone number is printed on the card and the patient is requested to call for an appointment.

Every three months this postcard is sent. If the return card is not received a follow-up letter, written in a more personal vein, is mailed. If there is still no response within a few months a home visit is made. At the end of 12 months a yearly notice is also sent which urges the woman to come in for a pelvic examination and check-up. Some of the women who have moved elsewhere send in reports routinely.

**MATERIAL**

The average age in this series of married

women was 24.9 years, the youngest being 13 and the oldest 50 years. A number of women come for premarital advice and marriage counseling. In the total series this group represented 6.2 per cent of those receiving one of the previously mentioned methods. It was interesting to note that 35.2 per cent of the women in our series were married to their present husband 2 years or less, and that 34.9 per cent were married 6 years or longer to their present husband, the longest marriage being 30 years.

The reasons given for wanting advice about family planning were as follows: spacing, 69.1 per cent; have all the children desired, 23.9 per cent; and other, 7.0 per cent. The average number of pregnancies per woman before attending our clinic was 2.87 (the most pregnancies for any woman was 12—but only one woman). The total number of white and Negro women was approximately the same.

A vaginal examination is done by a physician at the time of the first visit and is repeated at least once every year. Such an examination, before the patient receives a method of contraception, reveals any pathology present and discloses the patients who are already pregnant. The pelvic findings of the entire series were as follows: negative, 15.8 per cent; pregnant at the time of the first visit, 2.4 per cent; vaginal pathology such as relaxed vaginal outlet, cervicitis, cervical laceration and/or erosion, 41.2 per cent; anteversion of the uterus, 15.5 per cent; retroversion, retrocession, retroflexion, prolapse or fibroid of the uterus, with or without vaginal pathology, 25.1 per cent.

Before coming to the clinic 30.5 per cent of the women had never used any method of contraception. The remainder used the following methods, either alone or combined, with varying degrees of success: diaphragm plus jelly, 28.7 per cent; condom, 37.9 per cent; douche, 14.5 per cent; suppository, 8.5 per cent; jelly alone, 5.2 per cent; withdrawal, 3.7 per cent; button (all who had

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employed this method were warned of the danger with its use), sponge and powder, or rhythm 1.5 per cent.

In talking with women regarding pregnancies that occurred while using the previous methods before coming to the clinic it was interesting to hear their comments. Some, for example, had been erroneously told that it was not possible to put the diaphragm in wrong, that it could not be dislodged, and that it was not necessary to check whether the cervix was covered, as long as the diaphragm was in place in back of the pubis. The most common statement, when patients were asked how they had been taught to use it, was that they had seen a ring by which the size of the diaphragm had been determined, that they obtained the supplies after leaving the office and so were not sure how it should have been used. With the cream-alone or gel-alone methods, due to simplicity of use, many patients had only been told about the preparation and given a prescription but had received no demonstration or instruction about use. Some patients with unplanned pregnancies said they had been told that the cream or gel could be inserted 8 hours ahead of time. In spite of the

instructions accompanying the preparation some introduced it after coitus or used it incorrectly in other ways.

### RESULTS

Of the 112 women using the gel-alone method, data about months of use were available on 100, giving a total of 1145 months. The use varied from 1 month to 30 months. A number of women moved away, but they had used the method from 1 to 18 months before the cases were placed in the inactive file; 1 woman died. Of the 12 women for whom there were no months of use, two did not use the method and changed to another method, and the others have not returned to the clinic as yet. Of the 100 patients, 15.0 per cent have used the method 3 months or less, 53.0 per cent used it 3½ to 12 months, and 32.0 per cent used it 12½ to 30 months.

Of the 875 women using the cream-alone method, data about months of use were available on 692, giving a total of 5232.5 months. The use varied from 1 month to 29 months. After varying periods of use some of these women moved away so additional follow-up was not possible. There were 183

TABLE 2. PREGNANCIES OTHER THAN PLANNED PREGNANCIES

<i>No. months of use before pregnancy</i>	<i>Comments</i>	<i>No. women</i>
<b>Cream-alone method</b>		
1½-10 (+?)	Ran out of supplies (did not care if pregnancy occurred; husband wanted a baby; wife wanted a baby; or contemplated a planned pregnancy)	14
0	Never used	8
	Used irregularly	4
	Used incorrectly	5
1-6	Stopped use	3
7	Then used irregularly 8 months	1
14	Failed to use on one occasion	1
15	Husband mentally ill, would not let wife use anything after 15 months.	1
3	No notes about use	1
4	Used regularly	1
<b>Gel-alone method</b>		
8-22	Ran out of supplies (did not care if pregnancy occurred; husband wanted a baby; wife wanted a baby; or contemplated a planned pregnancy)	3
5	Failed to use on one occasion	1

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TABLE 3. PLANNED PREGNANCIES

<i>Vaginal findings</i>	<i>No. months of use</i>	<i>Comments</i>
Cream-alone method		
Cervicitis	1	Changed her mind and decided to have a baby right away
Unknown	2½	
Anteflexion of uterus	3	
Negative	3	Conception occurred in one month
Retroversion, cervicitis	3	
Negative	3½	Last delivery nine months ago
Negative	4½	Conception occurred first exposure
Anteflexion of uterus	7	
Anteflexion of uterus	7	
Relaxed vaginal outlet, cervicitis	8	Conception occurred in two months
Cervicitis	10	
Relaxed vaginal outlet, lacerated cervix	14	
Cervicitis, lacerated cervix	16	
Lacerated cervix	19	
Gel-alone method		
Relaxed vaginal outlet	1	Changed her mind and decided to have a baby right away
Negative	4	
Negative	10	
Relaxed vaginal outlet, lacerated cervix	12	
Negative	12	
Negative	15	
Erosion of cervix	18	Conception occurred in one month

women for whom there were no months of use. These included (1) those women already pregnant when first seen (24 cases); (2) a group who never used the method because they wanted another baby right away, husband refused to let wife use anything, separated or divorced from husband, had vasectomy or hysterectomy, lacked confidence in method, religious reasons (31 cases); (3) those who could not be located (15 cases); (4) a premarital group coming for advice before leaving the city (13 cases); and (5) those who have not returned to the clinic as yet, joined husband in armed services, unable to return, no response to mail, or a group that need to come to the clinic just once a year for check-up and who are not due to return as yet (100 cases). Of the group for whom months of use were known 25.9 per cent used the method 3 months or less, 60.2 per cent used it 3½ to 12 months, and 13.9 per cent used it 12½ to 29 months.

There were 6 women in the group using the cream alone who suspected a pregnancy,

but the diagnosis of pregnancy was never definitely made nor confirmed. The months of use of the method in these cases were 3, 4, 4, 7, 8, and 12, respectively. Two of these women moved away, three had run out of supplies, and the woman who used the method 8 months stopped using it. No women using the gel-alone method had a suspected pregnancy.

In Table 2 are shown the pregnancies, other than planned pregnancies, and under the heading *Comments* notes have been entered about each one. A high degree of success obtained was with these 2 methods.

There have been 14 recorded planned pregnancies in the group of women using the cream-alone method, and 7 planned pregnancies among those using the gel-alone method. In Table 3 these are presented in detail.

## CONCLUSIONS

This study of 875 women for whom the cream-alone method was prescribed and 112

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who were advised to use the gel-alone method of contraception indicates that these simple methods are very acceptable and that, when a highly spermicidal cream or gel is used alone, successful contraception can be obtained without the use of a mechanical device. In obtaining effective contraceptive results with these methods adequate instruction and follow-up are extremely important and the value of these cannot be stressed too strongly. When pregnancies occur with the

use of any contraceptive method they cannot be casually referred to as "method failures"; more careful analysis of the circumstances must be made in order to determine whether the pregnancy resulted from inadequacy of the method, human failure, or whether the pregnancy was actually desired.

### REFERENCE

1. BEHNE, D., *et al.* Clinical effectiveness of a new vaginal contraceptive cream: A preliminary report. *West. J. Surg.* 64:152, 1956.