

# Acceptability of Spermicidal Film and Foaming Tablets Among Women in Three Countries

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*A convenience sample of 162 family planning clients in Kenya, the Dominican Republic and Mexico provided data for an evaluation of the acceptability of two woman-controlled contraceptive methods that may also provide disease protection. Women significantly preferred contraceptive film over foaming tablets at two sites: In Kenya, 86% of participants said they would rather use the film and 14%, the tablets; in Mexico, these proportions were 58% and 30%, respectively. Although a slight majority of women in the Dominican Republic preferred the film also, about one-half of participants there and in Mexico complained that the film sometimes stuck to their fingers during insertion.* (International Family Planning Perspectives, 21:104–107, 1995)

Laboratory studies indicate that nonoxynol-9, the most frequently used spermicidal agent, inactivates many sexually transmitted pathogens, including *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, herpes simplex virus, *Treponema pallidum*, *Candida albicans*, *Trichomonas vaginalis* and the human immunodeficiency virus (HIV).<sup>1</sup> In vivo data show that nonoxynol-9 protects against such common bacterial sexually transmitted diseases (STDs) as gonorrhea and chlamydia.<sup>2</sup>

However, the impact of nonoxynol-9 use on HIV transmission is controversial.<sup>3</sup> A study involving female sex workers in Kenya provided evidence that frequent use of a spermicidal sponge containing a high dose of nonoxynol-9 (1,000 mg) may have increased the women's risk of HIV seroconversion.<sup>4</sup> Furthermore, frequent use of nonoxynol-9 has been linked to genital irritation,<sup>5</sup> which may facilitate HIV transmission. On the other hand, two recent

studies of suppositories with a lower dose of nonoxynol-9 have found this method to have a protective effect against HIV infection among women.<sup>6</sup> Some researchers argue that the conflicting findings might be explained by the suppositories' lower dose of nonoxynol-9 and the suppository users' shorter duration of exposure.<sup>7</sup>

Some public health officials do not find current evidence sufficiently compelling to promote nonoxynol-9 for HIV protection,<sup>8</sup> while others recommend spermicides with nonoxynol-9 as a second choice when condom use is not possible.<sup>9</sup> Male condoms are recommended as a highly effective method of protection against HIV and other STDs, as long as they are used correctly and consistently.<sup>10</sup> A recent prospective study of 256 HIV-discordant couples found that after about 15,000 episodes of coitus, none of the seronegative partners who consistently used condoms had become HIV-infected.<sup>11</sup>

However, male condoms are not under women's control, and many men refuse to use them. The effectiveness of spermicides containing nonoxynol-9 against bacterial STDs such as gonorrhea and chlamydia (which are both risk factors for HIV<sup>12</sup>), plus the fact that they are female-controlled, has led many family planning programs to place an increased emphasis on their use.

Data on the contraceptive efficacy of spermicides are inadequate, unfortunately, as most clinical trials of these methods do not meet modern design standards.<sup>13</sup> More important, wide variations in counseling and acceptability lead to broad differences in user competence and preferences, and hence in use-effectiveness, with pregnancy rates ranging from 0% to more than 50% among typical users.<sup>14</sup>

More clinical research on spermicides is urgently needed, particularly research on acceptability, which may help to determine what spermicidal product is likely to be used most consistently. To date, clinical studies have too often been divorced from acceptability studies. Results from the two need to be considered jointly if the effectiveness of a method during typical use is to be determined. In this article, we present acceptability data on two forms of spermicide containing nonoxynol-9.

## Methodology

### Study Subjects

Informal data collected by Family Health International (FHI) staff in Kenya and Zambia had suggested that women would have a strong preference for contraceptive film over vaginal foaming tablets. To test this hypothesis, we recruited a convenience sample of 200 new or current female acceptors of vaginal foaming tablets during 1992 in Kenya (N=75), the Dominican Republic (N=65) and Mexico (N=60). In Kenya, participants came from four community-based distribution programs managed by the Family Planning Association of Kenya; in the Dominican Republic, the study was conducted at two Profamilia clinics in the capital, Santo Domingo; in Mexico, the participants were clients of a research and family planning clinic affiliated with the University of Juarez in Durango.

The study was judged to pose no serious risks to current users or new acceptors of spermicides. The selection criteria for the study consisted of the women's willingness to sign a form indicating informed consent, to maintain a coital log and to return for a follow-up visit and answer questions about the study products.

At study admission, each participant was administered a questionnaire that collected social and demographic information and assessed the participant's knowledge and preferences regarding available contraceptive methods. Each participant was given a supply of 15 foaming tablets, 15 pieces of contraceptive film and 15 condoms and was asked to use condoms along with one of the spermicides during each act of intercourse over a prescribed study period (14 days in Kenya and 21 days in Mexico and the Do-

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minican Republic).<sup>\*</sup> Participants were instructed about the use of the three methods during one-on-one sessions with the predominantly female study staff.

The women were requested to use at least two foaming tablets and two pieces of contraceptive film during the study period. If a participant or her partner refused to use condoms, clinic staff recommended that the woman use one of the spermicides alone. Participants were provided with a coital log to record when intercourse took place and the combination of contraceptive methods used. Upon returning for their follow-up clinic visit, women were administered a questionnaire assessing the acceptability and use of the spermicides.

Prior to their admission into the study, potential participants were informed of the study's purposes and procedures and were asked to acknowledge in writing their informed consent. (The study protocol and consent forms were approved by FHI's Protection of Human Subjects Committee.)

### Study Products

Three family planning methods were used in the acceptability study. The first method is a vaginal foaming tablet containing 100 mg of nonoxynol-9; the tablet is manufactured by Ortho Pharmaceuticals and is distributed in the developing world by the U.S. Agency for International Development (USAID) under the name Conceptrol<sup>®</sup>. The second product, a contraceptive film distributed in the United States by Apothecus, Inc., under the trade name VCF<sup>®</sup>, is a water-soluble, two-inch-square polyvinyl alcohol film containing approximately 70 mg of nonoxynol-9. The third is a standard (52 mm) lubricated latex condom manufactured by Ansell, Inc., and provided to family planning programs in developing countries by USAID.

### Statistical Tests

Study-size calculations were based on the assumption that participants would prefer the contraceptive film over the foaming tablets by a margin of at least 70% to 30% ( $\alpha=0.05$ , power=0.80). Because informal data from FHI staff in Kenya and Zambia indicated that women would prefer the film, tests of whether participants at each of the three sites significantly preferred contraceptive film over foaming tablets were calculated using one-tailed z-tests for paired data.<sup>15</sup> Differences in ratings of the two spermicides on a three-point scale (1=liked, 2=neutral and 3=disliked) were assessed with a one-tailed Wilcoxon matched-pairs signed-rank test. An alpha of 0.05 was used for the tests of statistical significance. No ad-

justments for multiple testing were made. All p-values are presented to three decimal places however, to allow readers to make their own adjustments for multiple testing.

## Results

### Characteristics

In Kenya, of 75 women who initially enrolled in the study, 51 provided usable data; another 14 never returned for their follow-up interviews, seven did not use at least two doses of each type of spermicide and three were dropped because of data irregularities. The women's median age was 26 (ranging from 15 to 35), and they had a median of 10 years of education (ranging from one year to 13 or more). A majority (80%) said they were in a stable relationship. The 24 who did not complete the study were slightly older (a median age of 27) and had less education (a median of eight years).

In the Dominican Republic, the analysis was based on data from 52 of the 65 women initially enrolled; three others never returned for follow-up interviews and 10 had not used two doses of each product. The Dominican participants' median age was 24 (ranging from 16 to 45), and their median education was 10 years (ranging from none to 13 or more). Ninety-four percent of the women said they were in a stable relationship. The 13 women who did not complete the study had the same median age (24) but were less educated (a median of seven years).

In Mexico, 59 of the 60 women who were administered the background questionnaire completed the study; one never returned for her follow-up interview. The 59 women had a median age of 27 (ranging from 16 to 40) and a median schooling of nine years (ranging from two years to 13 or more). All said that they were in a stable relationship.

### History of Contraceptive Use

Prior to their current use of foaming tablets, most of the women (82% in Kenya, 92% in the Dominican Republic and 97% in Mexico) had used at least one other method. In Kenya and the Dominican Republic, oral contraceptives were the most popular method, with two-thirds or more of the women having used the pill in the past (63% and 75%, respectively). In Mexico, the method most commonly used in

**Table 1. Percentage distribution of coital episodes, by type of contraceptive protection, according to country, 1992**

Protection status	Kenya* (N=592)	Dom. Rep.† (N=449)	Mexico (N=615)
<b>Protected</b>	<b>94</b>	<b>99</b>	<b>99</b>
Condom alone	4	4	0
Foaming tablet alone	10	42	12
Contraceptive film alone	39	49	12
Foaming tablet+condom	16	2	31
Contraceptive film+condom	30	3	45
<b>Unprotected</b>	<b>6</b>	<b>1</b>	<b>‡</b>
Total	100	100	100

\*Four coital logs were dropped because of data irregularities. †One coital log was dropped because of data irregularities. ‡Less than 1%. Note: In this and all subsequent tables, percentages may not add to 100% because of rounding.

the past was the IUD (by 71%).

At the time of the study, most of the Kenyan women (80%) said they had used foaming tablets for more than six months. Almost one-half of this group (49%) said they were using foaming tablets as their regular method, while 22% considered foaming tablets a temporary method—i.e., were relying on the spermicidal product for a short time until they were to begin using some other method. (Information was missing for most of the remaining 29%.)

In contrast, study participants in the other countries were mainly new users of foaming tablets (79% in the Dominican Republic and 97% in Mexico). The majority of users (63% in the Dominican Republic and 73% in Mexico) considered foaming tablets a temporary method.

### Experience with Study Products

Kenyan women recorded 592 acts of intercourse in their daily coital logs during the study period, while Dominican women registered 449 and Mexican women 615 (see Table 1). Participants were protected by at least one contraceptive method at virtually all coital acts. The proportion of protected acts of intercourse in which two methods were used was 76% in Mexico, 46% in Kenya and 5% in the Dominican Republic. In all three countries, the most frequently used methods were either film alone or film used in conjunction with condoms.

Contraceptive film was perceived more favorably than foaming tablets by women in all three countries (Table 2, page 106), and this preference was statistically significant

\*All study participants were encouraged to use condoms because we wanted to provide women the option of receiving the optimal degree of protection from infection with STDs and HIV; the condom has been shown to offer the best such protection. Condom use may have had a small impact on acceptability; however, since participants used condoms with both spermicidal methods, any biases most likely were in the same direction.

**Table 2. Percentage distribution of study participants, by their reaction and their partners' reaction to spermicidal methods, according to type of method and country**

Reaction	Kenya (N=51)		Dom. Rep. (N=52)		Mexico (N=59)	
	Tablet	Film	Tablet	Film	Tablet	Film
<b>How did you like the method?</b>						
Liked	35	86	46	60	73	97
Neutral	12	0	19	10	2	0
Disliked	53	12	35	31	25	3
Response missing	0	2	0	0	0	0
Total	100	100	100	100	100	100
Mean score*	2.2	1.2	1.9	1.7	1.5	1.1
<i>p</i> †		<.001		.265		<.001
<b>How did partner like method?</b>						
Liked	31	84	21	29	46	59
Neutral	6	4	12	8	37	27
Disliked	59	8	29	27	15	12
Don't know	4	4	38	36	2	2
Total	100	100	100	100	100	100
Mean score*	2.3	1.2	2.3	2.1	1.7	1.5
<i>p</i> †		<.001		.261		.046

\*Scale based on 1=liked, 2=neutral and 3=disliked. †Statistical significance of difference between mean scores. Note: "Response missing" and "Don't know" were excluded from mean score calculations. P values were calculated from one-tailed Wilcoxon matched-pairs signed-rank tests.

in Kenya ( $p<.001$ ) and Mexico ( $p<.001$ ). Kenyan women had the strongest preference for contraceptive film over foaming tablets: Eighty-six percent liked the film and only 12% disliked it; in contrast, 35% of Kenyan women liked the foaming tablets, while 53% disliked them. In addition, the Kenyan women reported that their partners' preferences for contraceptive film were similar to their own.

Between one-quarter and one-third of women in the study said they liked nothing about the foaming tablets (Table 3). In contrast, all women in Kenya mentioned some positive attribute of the contraceptive film, as did 69% in the Dominican Republic and 88% in Mexico. Common attributes that participants liked about either method included ease of use, general feel or comfort and lack of side effects.

The characteristic most frequently disliked about the foaming tablets was that they were messy or too wet (69% in Kenya, 40% in the Dominican Republic and 36% in Mexico). Women gave this response far less frequently for the contraceptive film (8% in Kenya, 13% in the Dominican Republic and 5% in Mexico).

One of the most frequent responses about contraceptive film was that the women disliked nothing about it. However, at least one-third of women in the Dominican Republic and Mexico said they disliked the fact that the film stuck to their finger during insertion (33% and 41%, respectively), although very few Kenyan women offered this response (6%). Similarly, when participants were asked if they had specific prob-

lems with inserting the contraceptive film, about one-half of the Dominican women (48%) and three in five Mexican participants (61%) mentioned that the film sometimes stuck to their fingers (Table 4), compared with very few participants in Kenya (4%).

Participants in Kenya reported that the film was significantly easier to insert than the tablet ( $p<.001$ ), but the opposite was true among Dominican and Mexican women: They believed that the foaming tablets were substantially easier to insert than the film. (The *p* values for the Dominican Republic and Mexico were not statistically significant, however, since the one-tailed *z*-test assessed if the contraceptive film was easier to insert.) Almost all participants in the three countries said they had no specific problems with inserting the foaming tablets (90% in Kenya, 94% in the Dominican Republic and 97% in Mexico).

In all three countries, women were significantly more likely to say that the contraceptive film was the less messy of the two methods than to report the opposite ( $p<.001$ ). A significant number of women at the three sites also reported preferring the contraceptive film's packaging ( $p<.001$ ). When asked what type of spermicide they would prefer to use in the future, a majority in all three countries chose the contraceptive film over the foaming tablets (86% vs. 14% in Kenya, 52% vs. 46% in the Dominican Republic and 58% vs. 30% in Mexico); however, the difference was statistically significant only in Kenya ( $p<.001$ ) and in Mexico ( $p=.021$ ). When participants who had problems with the film sticking to their fingers were excluded from the analysis,

a statistically significant majority preferred the film in all three comparisons.

Further analyses that took into account women's previous use of foaming tablets indicated that their experience with the method had no impact on the acceptability of either of the two products used in the study.

## Discussion

Vaginal spermicides are playing an increasingly important role in many family planning programs, since they provide both contraceptive protection and disease prevention. A contraceptive method's acceptability is likely to contribute to the consistency of its use; consistent use, in turn, is believed to be the most important factor in minimizing the contraceptive failure rates associated with spermicides.<sup>16</sup> Although our study group consisted of three small convenience samples of women who were continuing or new users of foaming tablets, their preference for the contraceptive film was strong. In Kenya, where few participants had problems with inserting the contraceptive film, 86% said they would prefer to use contraceptive film in the future; in the two other countries, contraceptive film was preferred, but by a smaller margin. (Anecdotal reports, especially from the Dominican Republic, showed that several of the women liked the contraceptive film because they could use it without their partner's knowledge.)

**Table 3. Percentage distribution of respondents, by most liked and most disliked attributes of spermicides, according to country and type of spermicide**

Attribute	Kenya (N=51)		Dom. Rep. (N=52)		Mexico (N=59)	
	Tablet	Film	Tablet	Film	Tablet	Film
<b>Liked most</b>						
Nothing	31	0	36	31	27	12
Easy to use	24	47	17	27	39	14
General feel/comfort	10	24	23	33	24	49
No side effects	16	4	4	2	5	14
Clears discharge	0	0	12	2	0	0
Additional lubrication	6	16	0	0	3	7
Only acceptable method	8	0	0	0	0	0
Effectiveness	2	2	2	0	2	3
Under my control	0	0	6	6	0	2
Prevents infection	4	2	0	0	0	0
Not messy	0	4	0	0	0	0
Dissolves fast	0	2	0	0	0	0
<b>Disliked most</b>						
Messy/too wet	69	8	40	13	36	5
Nothing	10	65	35	48	20	29
Burning sensation	14	4	6	2	32	5
Waiting before sex	4	4	6	0	3	3
Did not dissolve	0	0	8	0	2	3
Touching private parts	0	2	6	0	2	0
Offensive odor	0	6	0	0	3	0
Partner opposition	4	2	0	2	0	2
Do not trust method	0	0	0	2	2	7
Stuck to finger	0	6	0	33	0	41
Difficult to insert	0	2	0	0	0	3
Other	0	2	0	0	0	2
Total	100	100	100	100	100	100

**Table 4. Percentage of women responding to various questions on problems with spermicides, by country**

Problems	Kenya	Dom. Rep.	Mexico
<b>Which spermicide was easier to insert?</b>			
Foaming tablets	12	56	71
Contraceptive film	78	33	24
Both were easy	10	8	5
Both were difficult	0	2	0
Both were the same	0	2	0
<i>p</i>	<.001	.972	>.999
<b>Did you have specific problems inserting foaming tablets?*</b>			
No problem	90	94	97
Method dissolving	6	0	0
Touching myself	6	4	0
Finding the cervix	4	0	0
Hardness of tablets	0	2	0
Scratched during insertion	0	0	2
Came back out	0	0	2
<b>Did you have specific problems inserting contraceptive film?*</b>			
No problem	92	52	37
Hard to fold	8	0	2
Stuck to finger	4	48	61
Finding the cervix	2	0	0
Scratched during insertion	0	0	2
<b>What spermicide did you find less messy?</b>			
Foaming tablets	10	17	20
Contraceptive film	84	73	80
Disliked both	2	2	0
Liked both	4	8	0
<i>p</i>	<.001	<.001	<.001
<b>Which packaging did you like better?</b>			
Foaming tablets	20	17	14
Contraceptive film	78	81	61
Liked both	2	2	25
<i>p</i>	<.001	<.001	<.001

\*Percentages may add to more than 100% because of multiple responses.

The most frequent complaint about the contraceptive film—particularly among study participants in Mexico and the Dominican Republic—was that it stuck to their fingers during insertion. The importance of correctly inserting the contraceptive film may not have been stressed sufficiently at these sites. (Informal conversations with study participants revealed that some actually had added saliva to the contraceptive film before inserting it.) This study suggests that contraceptive film will be preferred over foaming tablets, if improved instructions can help women overcome problems with inserting the film.

Without sufficient efficacy data, however, product acceptability data are of limited use to service providers and their clients. The effectiveness of barrier methods is determined by how well a given method works when used correctly, combined with how consistently and correctly the method is

used. There is an urgent need to clinically evaluate the efficacy of nonoxynol-9 against pregnancy and STDs, including HIV. Only large-scale and expensive clinical trials can provide perfect-use efficacy data.

Equally important is an assessment of the extent to which the acceptability of a method translates into consistent and correct use among typical users. These types of studies may be conducted on a smaller scale and at a lesser cost. Only by evaluating clinical data, along with data on acceptability and on consistent and correct use, can the effectiveness of barrier methods for pregnancy and STD prevention be validly assessed.

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## Resumen

Una muestra no representativa de 162 clientes de planificación familiar en Kenya, República Dominicana y México, arrojó datos para evaluar unos agentes anticonceptivos controlados por la mujer que además pueden ofrecen protección contra enfermedades. En dos lugares, al comparar los niveles de aceptabilidad de las tabletas de espuma anticonceptiva y de la película anticonceptiva se notó que las mujeres prefieren significativamente más la película que la espuma: en Kenya, el 86% de las participantes indicaron que preferían la película en comparación con el 14% que preferían las tabletas; en México, estos índices fueron del 58% y 30%, respectivamente. Si bien una ligera mayoría de las mujeres dominicanas también prefieren la película anticonceptiva, aproximadamente la mitad de las participantes en ese país y en México se quejaban de que algunas veces la película se les pega a los dedos en el momento de insertarla.

## Résumé

Un échantillon de commodité de 162 clientes de planification familiale au Kenya, en République dominicaine et au Mexique a fourni des données pour une évaluation des agents contraceptifs contrôlés par les femmes qui peuvent également protéger contre les maladies transmissibles sexuellement. Une comparaison de l'acceptabilité des comprimés contraceptifs moussants et du film contraceptif a révélé que les femmes préféraient sensiblement le film aux comprimés moussants à deux sites: Au Kenya, 86% des participantes ont déclaré qu'elles préféraient utiliser le film et 14% les comprimés; au Mexique, ces proportions étaient respectivement de 58% et de 30%. Bien qu'une légère majorité de femmes en République dominicaine aient également préféré le film, environ la moitié des participantes dans ce pays et au Mexique se plaignaient que le film adhérait parfois à leurs doigts durant l'insertion.