

PN-ACA-616

**CONTRACEPTIVE FILM
ACCEPTABILITY STUDY**

MEXICO

MARCH 1993

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DURANGO, MEXICO**

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ACKNOWLEDGMENT

Support for this work was provided by Family Health International (FHI) with funds from the United States Agency for International Development (USAID). The views expressed in this document, however, do not necessarily reflect those of the funding agency. FHI is an international nonprofit organization that conducts research and provides technical assistance in health, family planning, STDs and AIDS. It is based in Research Triangle Park, North Carolina.

We would like to express our sincere thanks to Gloria Alvarado and her dedicated staff at the Instituto de Investigacion Cientifica (IIC) for making this research project possible. FHI staff members, Doug Nichols, Ron Roddy, Pat Stewart and Kathy Hinson all provided insightful reviews of the document. We are also grateful to Leda Hardesty for translating the report into Spanish.

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I. INTRODUCTION

Vaginal spermicides are playing an increasingly important part in the method mix of many family planning programs because they can serve the dual role of contraception and prevention of sexually transmitted diseases (STDs). An innovative spermicidal contraceptive method, commonly referred to as contraceptive film, has received clearance from the U.S. Food and Drug Administration (FDA) and was introduced into the U.S. market in 1987 under the trade name VCF^R. This spermicide is a water-soluble film containing nonoxynol-9, that works much like foaming tablets. The manufacturer claims that the advantages of contraceptive film over foaming tablets include: less burning; easier insertion; and a shorter wait before intercourse can be initiated. According to Contraceptive Technology Update/September 1992 "this highly effective barrier method just now is gaining wide acceptance in health departments and family planning clinics" in the United States (p. 146).

II. STUDY OBJECTIVES

The primary objective of this study was to assess whether the contraceptive film is preferred over foaming tablets among current acceptors of foaming tablets in Mexico. An additional objective was to see whether clients would use a spermicide in conjunction with condoms if they were provided with both methods. This study did not assess the clinical efficacy of the three methods.

III. STUDY SUBJECTS

The study was conducted with a convenience sample of 60 new or current acceptors of foaming tablets in Durango, Mexico, a city of approximately 500,000 inhabitants. All participants were clients of the Instituto de Investigacion Cientifica (IIC) family planning clinic. The IIC is a semi-autonomous research and family planning clinic affiliated with the University of Juarez in Durango. In general, these clients are from middle income, urban to semi-urban areas of Durango. According to IIC staff, contraceptive use among this convenience sample is thought to be higher than in the general population of Durango. ICC staff estimate that approximately 60 percent of their clients use an IUD, 35 percent receive oral contraceptives and about five percent use condoms.

IV. STUDY PRODUCTS

Three family planning methods were used in this acceptability study. The first method was the standard, lubricated (52mm) latex condom manufactured by Ansell Inc., and provided to developing country family planning programs by the U.S. Agency for

International Development (USAID). The second product was a foaming tablet containing nonoxynol-9 (100 mg) manufactured by Ortho Pharmaceutical and distributed in the developing world by USAID under the trade name Conceptrol^R. The third product was a contraceptive film distributed by Apothecus, Inc. under the trade name VCF^R. VCF^R is a water-soluble, polyvinyl alcohol film containing 5% glycerin and 28% nonoxynol-9 (72 mg).

V. STUDY DESIGN

Prior to admission into the study, potential participants were informed of the purposes and procedures of the study. If they chose to participate, they provided the Principal Investigator with written informed consent. The study protocol and informed consent forms were approved by FHI's Protection of Human Subjects Committee prior to initiation of the study.

At admission into the study, each participant was administered a questionnaire to collect sociodemographic information and to assess the participant's knowledge and preferences regarding available methods of contraception. Each participant was provided with a supply of 15 condoms, 15 foaming tablets and 15 contraceptive films and asked to use condoms along with one of the spermicides during each act of intercourse over the next three weeks. Participants were required to use at least two foaming tablets and two contraceptive films during the three-week study period. If the participant, or her partner, refused to use condoms, it was recommended that one of the spermicides be used alone. Participants were provided with a coital log to keep track of sexual episodes and the combination of contraceptive methods they used during the three-week study. Participants were administered a follow-up questionnaire after three weeks to assess the acceptability of the three methods.

VI. DATA ANALYSIS METHODS

The data set was analyzed by IIC staff with technical assistance provided by FHI. EPI-INFO version 5.01 was used to enter the data and to produce the frequencies and cross tabulations presented in this report. Statistical tests were calculated using SAS-PC version 6.04.

Informal data collected by FHI staff in Kenya and Zambia prior to this study suggested that participants would have a strong preference for the contraceptive film; thus one-tailed tests were employed to test for significance. A one-tailed z-test for paired data was calculated to assess whether there was a preference of contraceptive film over foaming tablets. 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. Compliance with the requested use of condoms along with a spermicide was described but not tested statistically. Alpha of .05 was used for the tests of statistical significance.

VII. RESULTS

A. Sociodemographic Characteristics

Of the initial 60 participants who were administered the background questionnaire and enrolled into the study, 59 participants completed the study. These 59 participants were all female with a median age of 27 (range 16-40) and a median education of 9 years (range 2-13+) (Table 1). All participants (100%) said they were in union and almost all (90%) were Catholic.

B. Contraceptive Use History

Prior to their current use of foaming tablets, most of the participants (97%) had used at least one method of contraception (Table 2). The most common methods used were IUDs (71%), followed by oral contraceptives (61%), condoms (42%) and injectables (19%).

When asked to cite the most important characteristic of a contraceptive method, almost all (95%) said "effectiveness" in preventing pregnancy (Table 2). Other responses included "partner approves" (3%) and "price" (2%).

At the time of the study, almost all the participants (97%) reported being new acceptors of foaming tablets (Table 3). Only two participants (3%) said they had been using foaming tablets two months or more. Almost three-fourths of the participants (73%) said they intended to use foaming tablets as a temporary method before switching to another method. About a fifth (17%) said they planned to use foaming tablets for sporadic sexual intercourse.

The most important reason cited for currently choosing foaming tablets was because they are considered a "good temporary method" (64%).

Only two participants (3%) said they had received foaming tablets in the past (Table 4). Neither of the two had ever received condoms along with their foaming tablets.

C. Experience with Study Products

All participants were asked to keep a coital log for 21 consecutive days. The 59 participants recorded a total of 615 coital episodes (Table 5). Daily coital frequency ranged from zero to two. Of the 615 coital episodes recorded in the study, 614 episodes (>99%) were reported to be protected by barrier contraception. Almost half (45%) of the protected episodes were reported to be protected by the contraceptive film and condoms, while about a third (31%) were protected by foaming tablets and condoms. The remaining protected episodes were evenly split between contraceptive film alone (12%) and foaming tablets alone (12%).

Table 6 presents the level of contraceptive protection that each participant recorded during the three-week study period. Virtually all participants (98%) said all their coital episodes were protected by a contraceptive method, while only one person said she was protected between 90 and 99 percent of the time. This participant said she did not use contraceptive protection when she had intercourse away from her home.

Over half the participants (58%) said they always used two methods during the three-week study. Only twelve percent of the participants said they used double protection less than 20 percent of the time.

The most frequently cited reason for not using two methods was because of "partner opposition" (84%) followed by "too much trouble" (12%) and "safe period" (4%).

D. Acceptability of Foaming Tablets and Contraceptive Film

According to the study participants, contraceptive film was perceived more favorably than foaming tablets (Table 7). About three-fourths of the participants (73%) said they like foaming tablets, while virtually all (97%) reported liking contraceptive film.

When the mean score was calculated where 1=liked, 2=neutral and 3=disliked, contraceptive film received a mean score of 1.1 versus 1.5 for the foaming tablets. The difference in preference scores was statistically significant ($p < 0.01$). According to the participants, their partners had a statistically significant difference in preference scores as well ($p = 0.05$)

When asked to state one characteristic they liked most about foaming tablets, 39 percent said the method was "easy to use", while a little over a quarter (27%) said they liked "nothing" (Table 8). An additional quarter (24%) reported they liked the "general feel/comfort" of foaming tablets. Half of the

participants (49%) said they like the "general feel/comfort" of the contraceptive film.

The reason most frequently stated for disliking foaming tablets was "burning sensation" (32%). A quarter (24%) found the method to be "messy", while one fifth (20%) said they found "nothing" they disliked about foaming tablets. Almost half the participants (41%) said they disliked most the fact that the contraceptive film "stuck to finger". Twenty-nine percent of the participants said they found "nothing" they disliked about the contraceptive film.

As shown in Table 9, foaming tablets were reported to be easier to insert than contraceptive film (71% vs. 24%). Since we predicted that the contraceptive film would be easier to insert, the null hypothesis was not rejected ($p > 0.99$). Two participants (3%) reported specific problems inserting foaming tablets. Well over half the participants (63%) said they had problems inserting the contraceptive film. Sixty-one percent of the participants complained that the contraceptive film "stuck to finger" during insertion.

When asked which method they found less messy, 80 percent of respondents chose contraceptive film ($p < 0.01$). Less than one fifth of the participants could either feel foaming tablets or contraceptive film during intercourse (15% and 10%, respectively).

Sixty-one percent preferred the packaging of the contraceptive film ($p < 0.01$), although almost all of the participants (90%) found both types of packaging easy to open.

When asked which type of spermicide they would use in the future, assuming both were available, 58 percent ($n=34$) said contraceptive film while 30 percent ($n=18$) said foaming tablets (Table 10) ($p = 0.01$). Of the 18 participants who preferred foaming tablets, all would be willing to pay at least 2,000 pesos (US\$ 0.65) for 12 units. Of the thirty-four participants who preferred contraceptive film, almost three-fourths (74%) would be willing to pay over 5,000 pesos (US\$ 1.65) for 12 units.

VIII. LITERATURE REVIEW

There are many vaginal spermicides on the market today in developed countries, including foams, creams, gels, spermicidal suppositories and contraceptive film. The spermicides have two main components: a spermicidal chemical which immobilizes the sperm by disrupting its membrane and an inert base, or carrier, which holds the spermicide and helps vaginal dispersion. The scientific literature presents a wide range of efficacy rates for the various types of vaginal spermicides. According to Contraceptive Technology 1990-1992, "our best guess is that the initial-year failure rate among perfect users of spermicides would be about 3%. The first-year

failure rate among typical users is about 21%. The most common patient error leading to an accidental pregnancy is failure to use the spermicide" (p. 183).

In the mid 1970's, two clinical trials were conducted on the contraceptive film manufactured by Potter and Clarke (United Kingdom) and marketed in Europe under the brand name C-FILM. The results of these clinical trials were hotly debated in a series of letter exchanges in the British Medical Journal. On November 2, 1974, the Family Planning Association U.K. presented the preliminary findings of their clinical trial. They included 45 subjects using C-FILM during a total of 185 months in their analysis. These participants recorded nine involuntary pregnancies for a pregnancy rate of 62 per 100 woman-years. The Family Planning Association terminated the clinical trial after this interim analysis due to the unacceptably high failure rate.

On November 1, 1975, N. Raabe and O. Frankman presented the findings from their clinical trial at three family planning clinics in Sweden. Two-hundred and thirty-seven women used C-FILM during 1866 months and reported a pregnancy rate of nine per 100 woman-years. Raabe and Frankman speculated that the high failure rate in the first clinical trial was due to inconsistent usage and improper instructions. In the final letter on December 20, 1975, the Family Planning Association asserted they did not believe the high pregnancy rate experienced in their clinical trial should be attributed to user failure.

A recent study presented in The Journal of the Society for the Study of Infertility of Japan 1980;25:2 found a surprisingly low pregnancy rate of 0.56 per 100 woman years for a sample of 168 women who had used the C-FILM during 2161 months.

Clearly, given this wide range of efficacy rates, there is a strong need to conduct more research to better document the efficacy rates of contraceptive film and other types of spermicides to help clients choose which method may be most appropriate for them.

IX. DISCUSSION

Based on the limited efficacy data available to date, the acceptability of the different vaginal spermicides may be the best predictor of the actual failure rate (method failure plus user failure) because of the clear link to non-use if a user finds a spermicide to be unacceptable. With the increased emphasis on vaginal spermicides for both family planning and disease prevention, research is being conducted to assess which delivery systems for spermicides are most acceptable.

The data presented in this report are from one of three sites in a multi-site acceptability study that compared foaming tablets with

contraceptive film. The two other study sites were the Dominican Republic and Kenya. Data from Kenya have been presented in the final report "Acceptability Film Study: Kenya - December 1992". Caution must be taken when interpreting the results from these three sites because they are based on small, convenience samples. However, the results do suggest varying degrees of acceptability of the two methods and potential problems with their use.

In Kenya, this multi-site study evaluated a convenience sample of 51 current foaming tablet acceptors. This study population expressed a strong preference for contraceptive film over foaming tablets. An overwhelming majority (86%) would prefer to use contraceptive film in the future if they had a choice of both methods ($p < 0.01$). Only two participants complained that the contraceptive film stuck to the finger during insertion and over three-fourths (78%) thought the contraceptive film was easier to insert than foaming tablets ($p < 0.01$).

In the Dominican Republic, the 52 participants who completed the study reported a much lower preference for contraceptive film over foaming tablets. Slightly over half (52%) said they would choose contraceptive film if both methods were available. More participants found foaming tablets easier to insert (56% vs. 33%) with almost half (48%) complaining that the contraceptive film stuck to their fingers during insertion. Informal interviews were conducted with 15 of the 25 participants who complained about the film sticking to their fingers during insertion in an attempt to understand why they were encountering this problem. All 15 participants said that study staff reviewed the written instructions with them and that they felt they understood how to use contraceptive film correctly. Nevertheless, five participants said they moistened the contraceptive film with saliva before insertion and eight participants said they failed to fold the contraceptive film in half before insertion.

In Mexico, the 59 participants who completed the study reported a statistically significant preference for contraceptive film over foaming tablets (58% vs. 30%, $p < 0.01$). Similarly to the Dominican Republican participants, 61 percent of the Mexican participants complained that the contraceptive film stuck to the fingers during insertion. Informal interviews were conducted with 23 of the 36 participants who said the contraceptive film stuck to their fingers during insertion.

All 23 participants with the exception of one said that study staff reviewed the instructions with them and they were provided written copies of the instructions. All 23 participants said they folded the film correctly and over half said they made sure they inserted the film quickly. Twenty of these participants said the contraceptive film stuck to their fingers immediately. When

probed, several participants said they were nervous when inserting the first contraceptive film and their hands may have been perspiring.

As mentioned before, the majority of the participants did not have previous experience inserting a spermicide. Seventeen of the 23 participants interviewed informally said that insertion became easier after the first attempt.

Data from the Dominican Republic and Mexico suggest that the current written instructions are not sufficiently clear to assure that contraceptive film is used properly. FHI has contacted Apothecus, Inc. and they are currently updating their written instructions. In addition, new acceptors of contraceptive film should be provided explicit instructions and encouraged to practice inserting the film prior to using the method with their partner.

Once inserted, participants in Mexico found the method to be less messy than foaming tablets (80% vs. 20%, $p < 0.01$). This study suggests that if problems with the contraceptive film sticking to the fingers can be overcome, this method may be an acceptable spermicide to be used by women in Mexico.

The secondary study objective was to assess whether clients would use a condom in conjunction with a spermicide if they were provided with both methods. During the three-week study period, over three-fourths (76%) of all coital episodes were protected by a condom and a spermicide. The results must be interpreted in the context of these users being enrolled in a well-controlled study lasting only three weeks. However the high use of two methods is encouraging and should be investigated in the general population to assess whether family planning programs should provide both methods together.

Currently, many family planning programs recommend that clients should be encouraged to use both condoms and spermicides at all times. However, Contraceptive Technology 1990-1992 asserts that "use of latex condoms along with spermicides....for one week each month, beginning five days before ovulation is expected" (p. 186) is also a reasonable alternative.

If future studies show that improved instructions can minimize problems with the film sticking to the fingers during insertion, we would recommend that additional research be conducted to better document the efficacy of contraceptive film. A clinical trial should be conducted in various study populations and have a strong acceptability component. If the clinical trial shows the method failure rate of contraceptive film to be comparable to foaming tablets, and continues to document high acceptability of the method, we would recommend that contraceptive film replace foaming tablets in commodity distribution programs.

Table 1
Sociodemographic Characteristics
N=59

	N	(%) *
Site		
Durango	59	(100)
Age (years)		
16-20	7	(12)
21-25	19	(32)
26-30	17	(29)
31-35	12	(20)
36-40	4	(7)
	(median: 27 years)	
Sex		
female	59	(100)
male	0	(0)
Education (years)		
0	0	(0)
1-5	2	(3)
6	10	(17)
7-9	23	(39)
10-12	18	(30)
13+	6	(10)
	(median: 9 years)	
Marital Status		
single	0	(0)
in union	59	(100)
Religion		
Catholic	53	(90)
Protestant	2	(3)
Mormon	2	(3)
other	2	(3)

*In this and all subsequent tables, percents may not equal 100 due to rounding.

Table 2
Use of Contraceptives
N=59

	N	(%)
Contraceptives Used in Past:*		
IUD	42	(71)
OCs	36	(61)
Condoms	25	(42)
Injectables	11	(19)
NFP	5	(8)
Vaginal Foaming Tablets	3	(5)
Suppository	2	(3)
Norplant	1	(2)
Female Condom	1	(2)
Coitus Interruptus	1	(2)
never used contraceptive in past	2	(3)
Most Important Characteristic of a Contraceptive:		
effectiveness	56	(95)
partner approves	2	(3)
price	1	(2)
Second Most Important Characteristic of a Contraceptive:		
partner approves method	18	(30)
do not know	15	(25)
prevention of STDs	6	(10)
ease of use/convenience	4	(7)
effectiveness	2	(3)
price	1	(2)
did not give a second response	13	(22)
*Multiple responses were allowed.		

Table 3
Current Foaming Tablet Use
N=59

	N	(%)
Length of Current Foaming Tablet Use:		
new acceptor	57	(97)
less than one month	0	(0)
two to six months	1	(2)
more than six months	1	(2)
Type of Current Foaming Tablet Use:		
for FP until a regular method can be adopted	43	(73)
regular FP method	3	(5)
for FP, sporadic use	10	(17)
missing	3	(5)
Most Important Reason for Choosing Foaming Tablets:		
good temporary method	38	(64)
rest from other method; rest from other method before desiring pregnancy	8	(14)
effectiveness in preventing pregnancy	6	(10)
partner approves method	4	(7)
no side effects	2	(3)
ease of use/convenience	1	(2)

Table 4
Past Foaming Tablet Use
N=59

	N	(%)
Have you ever received foaming tablets in the past?		
no (first time user)	57	(97)
yes	2	(3)
In the past, did you receive foaming tablets with condoms?		
always	-	
sometimes	-	
never	2	
Have you used foaming tablets in the past and stopped?		
no	1	
yes	1	
How long was your past use of foaming tablets?		
more than six months	1	
Why did you stop the past use of foaming tablets?		
desired pregnancy	1	

Table 5
Type of Contraceptive Protection of Total Coital Episodes
According to Coital Log
N= 615

	N	(%)
Total Coital Episodes	615	(100)
Unprotected Coital Episodes	1	(<1)
Protected Coital Episodes	614	(>99)
Type of Contraceptive Protection		
condom alone	-	-
foaming tablet alone	73	(12)
foaming tablet and condom	188	(31)
contraceptive film alone	77	(12)
contraceptive film and condom	276	(45)

Table 6
Level of Contraceptive Protection of Individual Clients
According to Coital Log
N=59

	N	(%)
Percentage of Coital Episodes Protected by Contraception:		
100%	58	(98)
90-99%	1	(2)
Reasons for having unprotected intercourse (n=1):		
had intercourse away from house	1	
Percentage of Coital Episodes Protected by Two Methods:		
100%	34	(58)
80-99%	4	(7)
60-79%	5	(8)
40-59%	4	(7)
20-39%	5	(8)
< 20%	7	(12)
Reason for not using two methods (n=25):		
partner opposition	21	(84)
too much trouble	3	(12)
safe period	1	(4)

Table 7
Acceptability of Foaming Tablets and Contraceptive Film
N=59

	TABLETS		FILM		p-value*
	N	(%)	N	(%)	
How did you like the method?					
liked	43	(73)	57	(97)	
neutral	1	(2)	0	(0)	
disliked	15	(25)	2	(3)	
mean score**	1.5		1.1		< 0.01
How did your partner like the method?					
liked	27	(46)	35	(59)	
neutral	22	(37)	16	(27)	
disliked	9	(15)	7	(12)	
don't know	1	(2)	1	(2)	
mean score***	1.7		1.5		0.05

*1-tailed Wilcoxon matched pairs signed rank test.

**Scale based on 1-liked, 2-neutral and 3-disliked.

***Scale based on 1-liked, 2-neutral and 3-disliked; participants who said "don't know" were excluded from the mean score calculations.

Table 8
Client Preferences for Foaming Tablets and Contraceptive Film
N=59

	TABLETS		FILM	
	N	(%)	N	(%)
What did you like most about the spermicide?				
easy to use	23	(39)	8	(14)
nothing	16	(27)	7	(12)
general feel/comfort	14	(24)	29	(49)
no side effects/contraindicated for other methods	3	(5)	8	(14)
additional lubrication	2	(3)	4	(7)
effectiveness	1	(2)	2	(3)
under my control	-	-	1	(2)
What did you dislike most about the spermicides				
burning sensation	19	(32)	3	(5)
messy	14	(24)	-	-
nothing	12	(20)	17	(29)
too wet	7	(12)	3	(5)
waiting before sex	2	(3)	2	(3)
offensive odor	2	(3)	-	-
touching private parts	1	(2)	-	-
did not trust method's efficacy	1	(2)	4	(7)
spermicide did not dissolve	1	(2)	2	(3)
spermicide stuck to finger	-	-	24	(41)
spermicide difficult to insert	-	-	2	(3)
partner opposition	-	-	1	(2)
spermicide came out	-	-	1	(2)

Table 9
Problems with Foaming Tablets and Contraceptive Film
N=59

	N	(%)	P-value**
Which spermicide was easier to insert?			
foaming tablets	42	(71)	
contraceptive film	14	(24)	
both were easy	3	(5)	> 0.99
Did you have specific problems inserting foaming tablets?*			
no	57	(97)	
yes, scratched during insertion	1	(2)	
yes, came back out	1	(2)	
Did you have specific problems inserting contraceptive film?*			
no	22	(37)	
yes, stuck to finger	36	(61)	
yes, scratched during insertion	1	(2)	
yes, difficult to fold	1	(2)	
What spermicide did you find less messy?			
foaming tablets	12	(20)	
contraceptive film	47	(80)	< 0.01
Could you feel the foaming tablets during intercourse?			
no	50	(85)	
yes, unpleasant lubrication	4	(7)	
yes, felt tablet dissolving	3	(5)	
yes, unpleasant burning	2	(3)	
Could you feel the contraceptive film during intercourse?			
no	53	(90)	
yes, pleasant burning sensation	2	(3)	
yes, other	4	(7)	
Did you have problems opening the package of either of the spermicides?			
foaming tablets	5	(8)	
contraceptive film	1	(2)	
both were easy to open	53	(90)	
Which packaging did you like better?			
foaming tablets	8	(14)	
contraceptive film	36	(61)	
liked both	15	(25)	< 0.01

*Multiple responses were allowed.

**1-tailed Z-test

Table 10
Future Preference of Foaming Tablets
and Contraceptive Film
N=59

	N	(%)	p-value*
What spermicide preferred in future:			
foaming tablets	18	(30)	
contraceptive film	34	(58)	
either, both are the same	1	(2)	
neither, will not choose spermicide in future	6	(10)	0.01
If foaming tablets preferred, how much willing to pay for 12 units? (n=18)			
not willing to pay	-	-	
pay less than 2,000 pesos (\$ 0.65)**	-	-	
pay 2,000-5,000 pesos (US\$ 0.65-1.65)	10	(56)	
pay more than 5,000 pesos (\$ 1.65)	8	(44)	
If contraceptive film preferred, how much willing to pay for 12 units? (n=34)			
not willing to pay	-	-	
pay less than 2,000 pesos (\$ 0.65)	-	-	
pay 2,000-5,000 pesos (US\$ 0.65-1.65)	8	(24)	
pay more than 5,000 pesos (\$ 1.65)	25	(74)	
missing	1	(3)	

*1-tailed Z-test

**Exchange rate at the time of the study.