



ORIGINAL CONTRIBUTIONS

Partner Characteristics, Intensity of the Intercourse, and Semen Exposure During Use of the Female Condom

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The objective of this study was to assess how characteristics of the intercourse and the couple relate to semen exposure during use of the female condom. From 1996 to 1998, 210 women in Birmingham, Alabama, were trained to use the female condom and follow study procedures during a group session and individually practiced inserting the device. The outcome was semen exposure as defined by comparing pre- and postcoital prostate-specific antigen levels in vaginal fluid. Women who had high income levels had lower rates of semen exposure (odds ratio (OR) = 0.3, 95% confidence interval (CI): 0.2, 0.7), while those in a relationship of less than 2 years were at greater risk (OR = 2.4, 95% CI: 1.3, 4.1). Couples with a large disparity in vaginal fundus size and penis size were at increased risk of semen exposure (OR = 2.7, 95% CI: 1.2, 6.0). Engaging in very active intercourse also increased the risk (OR = 1.7, 95% CI: 1.1, 2.6). Thus, the protective effect of the female condom appears to be a function of user- and intercourse-specific characteristics. Future studies of male condom efficacy should focus on collecting detailed data about the users and characteristics of intercourse to predict failure accurately.

biological markers; coitus; condoms, female; contraception behavior; prostate-specific antigen; semen; sex behavior; sexually transmitted diseases

Abbreviations: PSA, prostate-specific antigen; STD, sexually transmitted disease.

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The female condom is an intravaginal barrier device marketed to prevent pregnancy and sexually transmitted disease (STD). A key factor in determining the appropriateness of promoting the female condom to at-risk women is whether it is an effective barrier to STD and human immun-

odeficiency virus. In vitro studies suggest that the female condom can act as a barrier to viruses and small molecules (1). To our knowledge, in vivo evidence of contraceptive efficacy is limited to two studies, which show relatively low pregnancy rates (3–15 percent) during 6 months of typical use (2, 3). The only known published evidence of female condom effectiveness against STD/human immunodeficiency virus is from one small study of *Trichomonas* reinfection (4) (which showed no difference between randomized groups but no reinfections among women who used the

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condom perfectly) and from a study of Thai female prostitutes who were given both the male and female condoms (which showed a 34 percent reduction in STD when the female condom was offered as an option) (5).

Efficacy studies that evaluate clinical outcomes such as pregnancy and STD require large groups of subjects and long follow-up periods. Conventional breakage and slippage studies utilize user-reported problems as the primary outcome. We developed a protocol for short-term, phase II/III studies of condom efficacy that uses semen exposure as an intermediate outcome (i.e., a biologic marker of pregnancy and STD) to augment the conventional assessment of self-reported user problems (6). We applied this protocol in a study of the female condom (7). Breakage was rare (less than 1 percent of 2,300 uses). By contrast, slippage was more common (9 percent), and semen exposure was detected in 7–21 percent of uses (7).

In developing interventions to counsel and train prospective users, it is important to know not only how often the condom fails but also the specific circumstances associated with condom failure. Detailed information about each user and intercourse is necessary to adequately assess determinants of failure. This paper reports the measurement methods and results of a study of the characteristics of the users and of the intercourse associated with semen exposure during female condom use.

MATERIALS AND METHODS

The study design has been described in detail elsewhere (Macaluso et al., unpublished data). Briefly, this was a prospective study conducted from 1996 to 1998 in Birmingham, Alabama, with 210 couples recruited to use the female condom. Potential participants were screened for eligibility during a telephone interview. Eligibility criteria included current use of an effective nonbarrier method of birth control, being in a mutually monogamous relationship, a history of maintaining a minimum coital frequency of six times per month, experience with tampon use, being at low risk of STD, having an intact uterus, and being age 21–49 years. The female partner of an eligible couple participated in a training session, including a brief promotional intervention and instruction on the correct use of the female condom. The woman was also trained to 1) take pre- and postcoital vaginal samples by using swabs; 2) complete a form describing her experience using the condom during each act of intercourse; 3) package and return used condoms, swabs, and forms to the project staff; and 4) keep a coital log, which included information about the number of times the couple changed positions during intercourse, the positions used, activity level, and duration of the intercourse. At the end of the training visit, the participant practiced inserting the female condom and taking vaginal swabs under the supervision of a nurse practitioner. The nurse practitioner took a diaphragm measurement of the vaginal fundus of each participant by using an Ortho fitting diaphragm set with five ring sizes (65, 70, 75, 80, and 85 mm diameter (Ortho Pharmaceutical Corporation, Raritan, New Jersey)). Finally, the participant was shown five different-sized drawings of an

erect penis and was asked to indicate which was closest to her partner's penis size.

Each participant left the clinic with five female condoms to test with her partner. After testing the five condoms, she returned for a follow-up visit. At follow-up, the participant returned her coital log and was interviewed about her use of the female condom and any problems associated with it. The participant received 15 more condoms and was asked to return for the final visit after all of the condoms had been used. She was also given a penis-measuring kit (Los Angeles Regional Family Planning Council, Inc., Los Angeles, California) and was instructed on how to use the kit at home with her partner. The final visit was usually scheduled within 3 months of the training session and was similar to the follow-up visit.

Assessment of semen exposure

The laboratory procedures have been described elsewhere (7) and were based on detection of prostate-specific antigen (PSA) in vaginal specimens (6, 8, 9). Briefly, vaginal swabs collected by the participants were placed in plastic bags with desiccant and were returned to the study office. Swabs were eluted in saline and were frozen at -80°C . Thawed eluent samples from all postcoital swabs were tested for PSA by using the Abbott IMx immunoassay (Abbott Laboratories, Abbott Park, Illinois). If the postcoital sample had a PSA level of more than 1 ng/ml, the precoital sample was also tested for PSA.

We previously documented that PSA levels were below 1 ng/ml after 4 days of abstinence and that exposure to quantities of semen as small as 5 μl resulted in PSA levels of more than 1 ng/ml (6). In a second study, we demonstrated that 3 percent of women have PSA levels of more than 1 ng/ml 48 hours after exposure to 1 ml of semen (9). In addition, we measured the variability associated with repeated sampling and estimated an upper 95 percent confidence boundary of 22 ng/ml for the difference between two swabs both taken 48 hours after exposure to 1 ml of semen.

In assessing semen exposure, we assumed that 1) a postcoital PSA level of less than 1 ng/ml indicates no semen exposure during intercourse, and 2) a postcoital PSA level of at least 22 ng/ml following a precoital level of less than 1 ng/ml indicates exposure. Results that could not be classified in either category (e.g., when the precoital PSA level was above 1 ng/ml) were categorized as undetermined. To further minimize the likelihood of exposure misclassification due to residual semen from a prior act of intercourse, the analysis was restricted to those condom uses at least 24 hours after the previous act of intercourse.

These criteria for assessing semen exposure are appropriate for an analysis of potential determinants of semen exposure because they minimize the potential for false-positive results. Given the relatively low rate of semen exposure, a high false-positive rate in semen exposure assessment would bias any association with potential determinants toward the null (10). In addition, using a high threshold for semen exposure enhances the likelihood of discriminating associations that predict exposure to large quantities of semen, which are likely to carry a higher risk of adverse outcomes such as unintended pregnancy and STDs.

Estimates of penis volume

Participants measured the circumference of the penis at midshaft and at the base of the glans as well as the length of the penis from the base to the tip. The kit used for penis measurements included long strips of colored paper without any markings. Measurements were taken by wrapping the paper at the appropriate level to indicate the circumference or by laying it against the penis to indicate the length and then tearing off excess paper from each strip. Participants were trained to take the measurements in the clinic during the follow-up visit and were also given written instructions. Penis volume was estimated by assuming that the glans was a cone whose height was equal to the diameter of the base. The length of the shaft was calculated by subtracting the estimated height of the glans from the reported total penis length; the volume of the shaft was calculated from the estimated length and the reported shaft circumference. The estimated volumes of glans and shaft were added to obtain total penis volume.

Penis measurements were available for 73 of the 100 couples included in this analysis. Analysis of variance was used to determine whether the partner's penis measurements could be predicted by using the woman's estimate of her partner's penis size obtained during the training visit (both of these items were available for 65 couples). While all direct penis measurements (tip, length, and shaft) were significantly predicted by the woman's estimate, estimated penis volume had the strongest association and the clearest relation with the woman's initial estimate ($p < 0.001$). Model-predicted mean penis volume increased in a clear dose-response pattern with the woman's estimate of penis size. On the basis of this analysis, the penis volume of each of the 27 partners whose measurements were missing was estimated by using the model. To verify the validity of this method, we ran the final analysis models (see below) without including participants for whom we used estimated penis volumes; we found similar, although less precise, results.

Data analysis

The objective of this analysis was to assess the association between semen exposure and characteristics of the users and the intercourse. To assist in model selection, the potential risk factors were grouped into two broad domains: 1) sociodemographic and lifestyle characteristics of the users, and 2) physical characteristics of the couple and the sexual act.

Sociodemographic and lifestyle characteristics measured at the recruitment interview included age, race, education, employment status, relationship length, reported number of sex acts per month, marital status, student status, current tampon use, per capita income (i.e., household income divided by number of people in the household), and lifetime number of partners. The physical characteristics of the couple were determined from the diaphragm and the penis volume measurements discussed above. The characteristics of the sexual act were determined from the coital log and included length of intercourse, number of position changes, types of positions used, and activity level (low, usual, or high). Because the coital log was returned at follow-up visits, coital log information was available for only those

participants who were not lost to follow up, and this analysis was restricted to those acts of intercourse for which coital log information was available.

Logistic regression was used to estimate the odds ratio of semen exposure for each risk factor while adjusting for all other factors in the same domain. The risk factors that showed an adjusted odds ratio of more than 2 (or less than 0.5, regardless of significance) or were statistically significant at the 0.2 alpha level were included in the final logistic regression model. Age, race, diaphragm size, penis volume measurements, and the interaction between the latter two variables were forced into the final model because they were considered potential confounders a priori.

Because each participant used as many as 20 condoms, correlation of results within an individual was possible. All logistic models were fitted by using generalized estimating equations to take into account the correlation between repeated measurements in estimating predictors and standard errors (11). The order of condom use was included in all models to estimate the effect of experience on the risk of semen exposure. Goodness of fit was evaluated by examining the model deviance and plotting the deviance residuals against the predictor variables. Collinearity and other numeric problems were evaluated by examining the covariance matrix of the estimates and by tabulating the data as needed. No significant collinearity was observed (final model covariance matrix maximum value, 0.2).

Study population

A total of 210 women participated in the training session. Thirty-five (17 percent) never returned a female condom, and 175 returned at least one. Eighty-one women completed the study protocol of using 20 female condoms. The median age of the women who participated in the training session was 27 years, and their median household per capita income was about \$600 a month. They had been in their current relationships for a median of 4 years and reported a median of 12 sexual contacts per month. More than 70 percent of the women were White, over half were married, and more than half had completed college. This analysis of determinants of semen exposure included only condom uses 1) that occurred at least 24 hours after the previous act of intercourse, 2) for which coital log data were available, and 3) for which PSA measurements had been made. Of the 2,232 condoms returned during the study, 1,149 of the uses met this criteria. Thus, not all women who participated in the training session or returned a female condom contributed data to this analysis. The 100 women who contributed data had the same sociodemographic characteristics as the entire group at enrollment. None of the women had previous experience using the female condom, so use order during the study represented their total experience with the female condom.

RESULTS

Table 1 shows the distribution of condom uses and resultant semen exposure according to selected sociodemographic and lifestyle characteristics. The three variables from this domain associated with semen exposure and included in

TABLE 1. Semen exposure and selected sociodemographic and lifestyle characteristics of the participants, Birmingham, Alabama, 1996–1998

Characteristic	No. of women	Exposures*/ uses	% positive	Adjusted odds ratio†	<i>p</i> value‡
Age					
<24 years	23	15/262	6	0.74	0.49
≥24 years	77	71/887	8	1	Reference
Race					
White	77	52/897	6	0.70	0.30
Non-White	23	34/252	14	1	Reference
College graduate					
Yes	58	38/668	6	0.97	0.93
No	42	48/481	10	1	Reference
Current employment					
Yes	79	64/912	7	0.73	1.37
No	21	22/237	9	1	Reference
Married					
Yes	66	48/772	6	0.88	0.71
No	34	38/377	10	1	Reference
Current student					
Yes	46	33/500	7	0.66	0.23
No	54	53/649	8	1	Reference
Per capita income					
>\$900/month	33	14/365	4	0.36	0.04
≤\$900/month	67	72/784	9	1	Reference
Lifetime no. of partners§					
>3	59	63/635	10	2.2	0.07
≤3	40	231/496	5	1	Reference
Relationship length					
<2 years	16	25/219	11	2.0	0.07
≥2 years	84	61/930	7	1	Reference
Coital frequency					
<9/month	28	22/381	6	0.68	0.30
≥9/month	72	64/768	8	1	Reference
Tampon use					
Current	74	55/847	6	0.80	0.58
Past only	26	31/302	10	1	Reference
Total	100	86/1,149	7	Reference	Reference

* Exposure to semen after use of a condom.

† Adjusted in a repeated measures logistic regression model for all other variables shown, based on 1,118 uses with no missing data.

‡ *p* value for the null hypothesis of no association between semen exposure and levels of the characteristic.

§ One woman declined to answer this question.

the final model were relationship length, income, and number of lifetime partners. Participants who had been in their current relationship for less than 2 years were twice as likely to be exposed to semen with each use of the condom, as were women who had more than three sexual partners in their lifetimes. Women who lived in households in which the monthly income was over \$900 per household member were significantly less likely to be exposed to semen.

Semen exposure rates for the physical characteristics of the couples and the intercourse-specific variables are presented in table 2. Diaphragm size larger than 70 mm was strongly associated with semen exposure, but there was a strong negative interaction between penis and diaphragm size ($p = 0.01$): The odds of semen exposure were four times larger for couples in which the woman's diaphragm size was 75–85 mm and the man's penis size was below the median

TABLE 2. Physical characteristics of the couple, characteristics of the intercourse, and semen exposure, Birmingham, Alabama, 1996–1998

Characteristic	Exposures*/ uses	% positive	Adjusted odds ratio†	<i>p</i> value‡
Diaphragm size 75–80 mm				
Penis size above median	17/261	7	1.2	0.63
Penis size below median	28/160	18	3.7	0.01
Diaphragm size 65–70 mm				
Penis size above median	22/322	7	1.6	0.27
Penis size below median	19/406	5	1	Reference
Activity level of the intercourse				
High	28/223	13	3.2	0.004
Usual	49/706	7	1.6	0.17
Low	9/216	4	1	Reference
Intercourse duration				
Above median	50/605	8	1.3	0.30
Below median	36/544	7	1	Reference
Positions used				
Woman on top only	20/168	12	1.2	0.65
Other position only	1/32	3	0.53	0.45
Mixed positions	18/319	6	0.61	0.07
Man on top only	47/630	7	1	Reference
No. of position changes§				
At least one	26/370	7	0.88	0.57
None	60/777	8	1	Reference

* Exposure to semen after use of a condom.

† Adjusted in a repeated measures logistic regression model for time and all other variables shown, based on 1,144 uses with no missing data.

‡ *p* value for the null hypothesis of no association between semen exposure and levels of the characteristic.

§ Included in a separate model from Positions used.

compared with couples in whom the woman's diaphragm size was 70 mm or less and the partner's penis volume was below the median (odds ratio = 3.7). No significant increases in risk were observed for couples in which the woman's diaphragm size was 75–85 mm and the man's penis size was above the median or couples in which the woman's diaphragm size was 70 mm or less and the man's penis size was above the median. Activity level was the only other variable from this domain that was associated with semen exposure and was included in the final model. Women who reported that the intercourse was of a higher intensity than usual for the couple were more than three times more likely to be exposed to semen than were women who reported that the intensity was low.

Estimates from the final regression model are presented in table 3. The risk of semen exposure for women with a large diaphragm size was lower in the final model, indicating some of the effect observed in the domain-specific analysis may have been due to confounding by other variables. The negative interaction between diaphragm size and penis volume retained its strength and significance in this model. Here, activity level was modeled as a linear predictor, and the effect

measure of 1.7 indicates that a unit increase in activity category almost doubled the risk of semen exposure. The protective effect of high income remained strong in the final model; high-income women were three times less likely than lower-income women to be exposed to semen. Women who had been in their current relationship for less than 2 years were more than twice as likely to be exposed to semen when using the condom. In the final model, experience with the condom (condom use order) was not associated with semen exposure (odds ratio = 0.99). Restriction of the analysis to couples for whom we had a direct measurement of the partner's penis size led to the same conclusions as those presented here.

DISCUSSION

In this group of women, semen exposure occurred during at least 7 percent of the uses of the female condom. A high income level was strongly associated with protection from semen exposure. This association cannot be explained by student status, because the effect of income was similar for students, nonstudents, and the combined population. Because the study population was drawn largely from a

TABLE 3. Summary analysis of predictors of semen exposure, Birmingham, Alabama, 1996–1998

Predictor	Adjusted odds ratio*	95% confidence interval
Age <24 years	0.65	0.31, 1.4
White race	0.63	0.35, 1.1
Relationship length less than 2 years	2.4	1.3, 4.1
Per capita income >\$900/month	0.32	0.15, 0.68
More than three lifetime sexual partners	1.8	0.91, 3.7
Condom use order	0.99	0.95, 1.0
Diaphragm size 75–80 mm		
Penis size above median	1.1	0.51, 2.4
Penis size below median	2.7	1.2, 6.0
Diaphragm size 65–70 mm		
Penis size above median	1.2	0.48, 3.0
Penis size below median	1	Reference
Activity level of the intercourse	1.7	1.1, 2.6

* Obtained from a repeated measures logistic regression model adjusting for all variables in the table, based on 1,098 uses with no missing data.

university research environment, many of the higher paid employees were clinical or research professionals and had experience in clinical research as both participants and research staff. Thus, higher income may be an indicator of the ability to follow complex instructions and achieve correct condom use. This hypothesis was born out by the fact that only one user reported incorrect use during follow-up interviews about use habits (e.g., Did you always put the female condom in *before* your partner's penis entered your vagina?). Effective use of the female condom may be achieved more easily by rather sophisticated users.

The increased risk for women in shorter-term relationships is a concern if the target market for the female condom is women in newer relationships. It is possible that this effect is due to discomfort with the device or discomfort discussing proper use with a newer partner. This risk could be mitigated by increasing counseling and skills training for users in relatively new relationships.

Although the predictors described above may play an important role, the most compelling associations were observed with the physical characteristics of the partners and with the intensity of the intercourse. This study suggests that the combination of a large vaginal fundus and a small penis facilitates semen exposure, possibly because of a looser fit of the device. In fact, compared with women with a smaller diaphragm fit, women who had a diaphragm size of 75–80 mm were at significantly higher risk of experiencing a mechanical problem such as the penis entering to the side of the condom (odds ratio = 3.0, 95 percent confidence interval: 1.1, 7.9) or the outer ring being pushed into the vagina during intercourse (odds ratio = 3.5, 95 percent confidence interval: 1.7, 7.2). In this study, both mechanical problems were associated with high rates of semen exposure and with high postcoital PSA levels (7).

The association between activity level and semen exposure also was remarkable. In this study, activity level was assessed subjectively by the woman and was expressed as

departure from her usual experience with her current partner. Across-couples comparison may be problematic because one woman might rate as usual intensity what another woman would rate as high intensity. Despite these difficulties, the results clearly suggest that intense activity reduces the protective effect of the female condom.

Several weaknesses should be considered when interpreting the results of this study. First, loss to follow-up was high: fewer than half of the women who initially enrolled in the study completed the study protocol by using 20 condoms. The impact of this loss on the interpretation of our findings is probably small because the women who contributed data to this analysis were not substantially different from those who did not, with the exception that the women who did not complete follow-up were more likely to dislike the appearance of the female condom, to express an aversion to inserting it, and to experience problems during the study (Macaluso et al., unpublished data). Thus, the women who were included in this analysis were probably more similar than the group who started the protocol to women who would use the product over time.

In addition, 887 acts of intercourse were excluded from our analysis because of restrictions in the selection criteria for the analysis (i.e., availability of a matching coital log entry, no sex during the previous 24 hours). Matching coital logs were not available for the semen exposure data of 24 (40 percent) of the 60 women who withdrew from the study without completing the protocol. Slippage was reported more frequently among the female condom uses excluded from the analysis. It is possible that these exclusions reduced the precision of estimates of the association between semen exposure and potential determinants, but it is unlikely that they affected the validity of the estimates.

Within-couple clustering of effects may have biased the results and weakened the study. On the other hand, use of statistical methods for repeated measures enabled us to assess couple effects on semen exposure, which clarified that

the associations observed reflected average effects across the study group and were not highly dependent on the characteristics or behavior of a few couples (7).

Finally, this study was designed as a phase II trial. Thus, the population was at low risk of STD and was highly educated. The selection of participants limits the generalizability of the study findings. It is not clear whether the same associations would be found among high-risk users and whether the associations observed would have the same relative ranking. However, it seems likely that the risk of semen exposure would be higher among women with less training and a lower educational level.

These weaknesses are more than compensated for by the study's strengths. First, the outcome variable in this analysis was an objective marker of condom failure. To our knowledge, this is the first time an objective marker of failure has been used concurrently with conventional user-reported failure in a large-scale study. For example, in a recently published study of male condom failure, the outcome was retrospective self-report of failure after use of five condoms (12). This method is subject to recall bias and is very likely to underestimate the frequency of condom failure. User reports of female condom failure do not correlate well with rate of semen exposure (7). Thus, this study likely provides a more realistic appraisal of condom efficacy than conventional slippage and breakage studies (13). Second, data on intercourse-specific activity were collected prospectively in coital logs. Thus, recall bias was less likely, and the intercourse-specific data were more likely to be accurate. Although some recent studies have indicated that coital-log data may be inaccurate in assessing whether condoms have been used, our coital-log data concerned condom uses that were confirmed (by examination of the used condom). In addition, users were required to fill out forms immediately following the intercourse so they could return the condom the next business day. This requirement increased the likelihood that the coital-log data were filled in immediately following intercourse rather than retrospectively. Third, this analysis was based on a large number of condom uses and a sufficiently large number of couples so that relatively subtle effects could be measured and the effects of relatively rare predictors could be assessed. Finally, to our knowledge, this is the first study to assess the effect of the physical characteristics of the couple and of intercourse-specific characteristics on condom failure.

In conclusion, this study shows that the efficacy of the female condom in preventing semen exposure is a function of couple- and intercourse-specific variables. Reproductive health practitioners and educators should provide proper training to ensure that women have the knowledge and self-confidence necessary to use the female condom correctly. The female condom may not be the best option for couples with a large disparity between diaphragm and penis size. Couples who choose to use the female condom may also want to consider extra caution or another barrier method when engaging in very active intercourse. Unfortunately, little information is available to evaluate the performance of other methods according to the characteristics of the couple

or of the intercourse, and semen exposure data are available only for the female condom. The design used in this investigation should be applied to studies of the latex condom and of condoms made of new materials.

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