Efficacy of the Female Condom as a Barrier to Semen During Intercourse

Maurizio Macaluso¹, M. Louise Lawson¹, Glen Hortin², Ann Duerr³, Karen R. Hammond⁴, Richard Blackwell⁴, and Amy Bloom³

¹ Department of Epidemiology and International Health, School of Public Health, University of Alabama at Birmingham, Birmingham, AL.  
² Department of Pathology, School of Medicine, University of Alabama at Birmingham, Birmingham, AL.  
³ Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, GA.  
⁴ Department of Obstetrics and Gynecology, School of Medicine, University of Alabama at Birmingham, Birmingham, AL.

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In 1996–1998, the authors measured prostate-specific antigen (PSA) in vaginal fluid to assess the frequency of female condom failure and to evaluate the association of self-reported failure with semen exposure. Women at low risk of sexually transmitted diseases (n = 210) were recruited in Birmingham, Alabama. They were trained to use the female condom, sample vaginal fluid before and after condom use, and complete forms to report problems during each use. Semen exposure was assessed by comparing pre- and postcoital PSA levels in vaginal fluid. A total of 175 women used 2,232 condoms. The rate of semen exposure ranged from 7% to 21% of condom uses, depending on the exposure criterion. Exposure was more likely (21–34%) and more intense (mean postcoital PSA, 24.7 ng/ml) if participants reported a mechanical problem versus other problems or no problems (exposure rate, 5–20% in both instances; mean postcoital PSA, 9.6 and 7.8 ng/ml, respectively). In logistic regression analyses for repeated measurements, user-reported problems accounted for less than 59% of the instances of semen exposure. The female condom prevented semen exposure in 79–93% of condom uses. Exposure was associated with user-reported problems but also occurred in their absence. Reported problems and semen exposure decreased with user experience.

contraceptive devices, female; follow-up studies; safety; sexually transmitted diseases

Abbreviations: CFHC, California Family Health Council; PSA, prostate-specific antigen; STD, sexually transmitted disease.

Until recently, women who were unable or unwilling to convince their partners to use a latex condom had unsatisfactory options for protection against infection with human immunodeficiency virus or other sexually transmitted diseases (STDs). The Reality female condom (The Female Health Company, Chicago, Illinois) is a silicon-lubricated, intravaginal barrier consisting of a soft, loose-fitting polyurethane sheath with a flexible ring at each end. The device is inserted similar to a diaphragm; the inner ring is compressed and is pushed into the vagina until it rests above the pubic symphysis, anchoring the condom. The external ring and 1–2 inches (2.5–5 cm) of the sheath remain outside the vagina, partially covering the labia. Evidence in support of its effectiveness as a barrier to sperm and microorganisms is limited (1–4).

Measuring the frequency of mechanical failure of the female condom is necessary to assess acceptability and efficacy of the device. For mechanical failure to have biologic significance, however, it must lead to exposure to semen or to male urogenital secretions. Semen exposure is not a common endpoint in breakage and slippage studies. It is not known whether semen exposure actually occurs with user-reported failure or can occur in its absence. In principle, semen exposure is better than self-report as a marker of condom failure and could replace more serious events (unwanted pregnancy, STDs) as the endpoint of efficacy.

Correspondence to Dr. Maurizio Macaluso, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, Mail Stop K-34, Atlanta, GA 30341-3724 (e-mail: mmacaluso@cdc.gov).
studies. We used the presence of prostate-specific antigen (PSA) in vaginal fluid (5) as an objective marker of semen exposure and evaluated its association with self-reported problems.

MATERIALS AND METHODS

Study design and procedures

This study was conducted in 1996–1998. Women attending family planning clinics at the University of Alabama at Birmingham and Planned Parenthood of Alabama, Inc. or responding to advertisements in University publications were screened for eligibility by telephone interview. Eligible were current contraceptive users who were aged 21–49 years; were involved in a mutually monogamous relationship; maintained a coital rate of six times per month; and had an intact uterus, no STD during the past 6 months, and experience using tampons.

Eligible women who gave informed consent participated in a group session promoting the female condom and providing use instructions. Each participant practiced insertion with an anatomic model and on herself, and a nurse practitioner verified correct placement of the device. Each woman was trained to take pre- and postcoital vaginal samples by using a swab; to complete a form describing her experience using the condom; to package the form, swabs, and used condom in separate, sealed bags; and to return these items to the project staff. The form included questions about the time and duration of intercourse, problems experienced, partner ejaculation, and time elapsed since previous intercourse. Potential problems listed on the form included those associated with the swabs, condom breakage and slippage, penile misrouting, semen leakage, noise, and discomfort.

The participant also completed a questionnaire measuring attitudes and beliefs about condoms and was given five female condoms to try with her partner. After using five condoms (training phase), each participant returned to review data forms with project staff and to review use problems with the nurse. She then entered the proficiency phase, used as many as 15 condoms following the procedures described above, and returned for a final visit to report on her experience.

The following mechanical problems experienced during intercourse were considered a priori as potential causes of semen exposure and condom failure: 1) the condom broke; 2) the condom came out of the vagina; 3) the penis entered to the side of the condom; 4) the outer ring was pushed inside the vagina; 5) semen leaked on the woman’s body; 6) the condom clung to the penis, moving with it; or 7) the woman had a problem with the inner ring during intercourse.

The following acceptability problems were considered as potential determinants of use discontinuation but not of failure: 1) vaginal bleeding (nonmenstrual) occurred, 2) the male or 3) the female partner felt pain or discomfort, and 4) the condom made noise.

All returned condoms were first examined to confirm use and to detect tears. Condoms without evident tears were rinsed, suspended from a 2 inch × 2 inch (5 cm × 5 cm) polyvinyl chloride (PVC) reducer coupling, and filled with 300 ml of water containing methylene blue. The outer surface of the condom was dried and, 5 minutes later, was gently patted with a white tissue (Kimwipes, Kimberly-Clarke Corporation, Atlanta, Georgia); blue marks on the tissue indicated breakage. The process was repeated 5 minutes later to increase test sensitivity.

Participants collected vaginal samples using an 8 inch (20 cm) gynecologic swab with a 3/8 inch (9.5 mm)-diameter rayon tip (Hardwood Products Company, Guilford, Maine) inserted in a 3 inch × 1/2 inch (7.6 cm × 1.3 cm) cardboard tube (Custom Paper Tubes, Cleveland, Ohio), which was perforated at one end to allow the swab handle to slide through. With each condom, the participant received two plastic zipper bags (one labeled Before to collect the pre-coital sample of vaginal fluid and one labeled After to collect the postcoital sample), each containing one swab and two packets of desiccant (Desiccite 25, Tigerpak Inc., Clifton, New Jersey). A nurse practitioner observed each participant take a vaginal sample, retract and anchor the swab in the tube, and seal the swab in the bag without touching the swab tip.

Dried swabs were stored at room temperature for extraction. The swab was placed in 3 ml of saline for 15 minutes, resulting in 2 ml of eluent. The latter was stored at −80°C until thawed for testing with the PSA IMx immunooassay (Abbott Laboratories, Abbott Park, Illinois). In these conditions, postcoital PSA levels of >1 ng/ml indicate recent (<24 hours) semen exposure (6). Thus, one condom use was classified as negative for semen exposure if the PSA level of the postcoital sample was ≤1 ng/ml. If the postcoital PSA level was >1 ng/ml, the pre-coital specimen was also tested for PSA.

To contain costs, PSA testing was limited to 1) all post-coital proficiency-phase samples, 2) all training-phase post-coital samples from participants who completed the study, 3) a sample of training-phase post-coital swabs from participants who did not complete the study, and 4) all pre-coital samples corresponding to PSA-positive post-coital samples.

The study protocol was reviewed and approved by the Institutional Review Boards of the University of Alabama at Birmingham and the Centers for Disease Control and Prevention (Atlanta, Georgia).

Similar sampling procedures, coupled with a less-sensitive PSA immunooassay, were used in a small-scale study of male condoms (7).

Data analysis

The first analysis included data from all condoms used in the study to evaluate the rates of self-reported problems (per 100 uses). Crude and stratum-specific rates (by training/proficiency phase or by the order of condom use) were computed as 100 × condom uses with reported problems/condom uses.

The second analysis evaluated the rate of semen exposure by using PSA data from pre- and post-coital swabs. Two criteria specified a lower and an upper boundary of the numerator of the semen exposure rate: 1) criterion I—the lower boundary was defined by the number of condom uses in which a) post-coital PSA was >1 ng/ml and pre-coital PSA...
was ≤1 ng/ml and b) postcoital PSA was at least 22 ng/ml higher than precoital PSA; and 2) criterion II—the upper boundary was defined by the number of condom uses in which a) postcoital PSA was >1 ng/ml and precoital PSA was ≤1 ng/ml or b) postcoital PSA was at least 22 ng/ml higher than precoital PSA.

These two criteria consist of the intersection and the union of conditions a) and b), respectively. Condition a) is sensitive to small variations in PSA levels and is likely to detect exposure to small quantities of semen, but it is also prone to false-positive results (e.g., from random variation in vaginal fluid sampling or PSA measurement). Conversely, condition b) imposes a minimum difference between pre- and postcoital PSA levels unlikely to be due to random variation (in a previous study, 22 ng/ml was the 95th percentile of the difference between any two samples taken by the same woman 24 hours after exposure to 1 ml of semen (8)), but it may miss true exposure to small quantities of semen. PSA levels in vaginal fluid increase sharply after semen exposure, returning to <1 ng/ml 24–48 hours after exposure (8). To minimize exposure misclassification, estimation of semen exposure rates was restricted to condom uses that took place ≥24 hours after the previous act of intercourse.

The third analysis evaluated the association of semen exposure with self-reported problems. The odds ratio was the measure of association, and the significance of simple associations was evaluated by using a chi-square test. Adjusted odds ratios and their 95 percent confidence intervals were estimated by using logistic regression. The correlation of errors among condom uses pertaining to one person was modeled explicitly in generalized linear mixed models for binary outcomes (9). The order of condom use was forced in all models to adjust for experience with female condom use.

RESULTS

The median age of the women who attended the training session (n = 210) was 27 years, and their median monthly income was about $600 per person in the household. The median duration of their current relationship was 4 years, and their median coital rate was 12 times per month. More than 70 percent were White, over 50 percent were married, and more than 50 percent had completed college. Of these women, 35 (17 percent) never returned a female condom, 94 (45 percent) returned 1–19 condoms, and 81 (39 percent) completed the protocol by using 20 condoms. There were no differences in sociodemographic characteristics or semen exposure rates between the women who completed the protocol and those who did not.

Self-reported problems

A total of 2,232 female condoms were used by 175 women: 745 during the training phase and 1,487 during the proficiency phase (table 1). At least one mechanical problem was experienced in 17 percent of the uses. Only 15 condoms broke during use, or 0.7 per 100 uses. The most commonly reported mechanical problems (at rates of 3–7 per 100 uses) were that the condom rode on the penis, the condom came out of the vagina, and the outer ring was pushed inside the vagina. Additional mechanical problems (the penis entered outside the condom, semen leaked on the woman’s body, and inner ring problems occurred) were each

<table>
<thead>
<tr>
<th>TABLE 1. Frequency of problems reported with female condom use, by study phase, Birmingham, Alabama, 1996–1998</th>
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<tbody>
<tr>
<td>Reported problem</td>
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<tr>
<td></td>
</tr>
<tr>
<td>Mechanical problems</td>
</tr>
<tr>
<td>Condom broke</td>
</tr>
<tr>
<td>Condom rode on penis</td>
</tr>
<tr>
<td>Condom came out of vagina</td>
</tr>
<tr>
<td>Outer ring pushed into vagina</td>
</tr>
<tr>
<td>Semen leaked on woman's body</td>
</tr>
<tr>
<td>Penis entered outside condom</td>
</tr>
<tr>
<td>Inner ring problem</td>
</tr>
<tr>
<td>Acceptability problems</td>
</tr>
<tr>
<td>Woman felt pain or discomfort</td>
</tr>
<tr>
<td>Man felt pain or discomfort</td>
</tr>
<tr>
<td>Condom made noise</td>
</tr>
<tr>
<td>Bleeding (nonmenstrual)</td>
</tr>
<tr>
<td>Any problem</td>
</tr>
</tbody>
</table>

* p value for the test of the null hypothesis of no difference between the training and the proficiency phase.
At least one problem was reported with 324 (22 percent) of 1,485 uses included in the second analysis. When a problem was reported, the semen exposure rate was between 17 percent (criterion I) and 30 percent (criterion II). By contrast, the exposure rate was 5–19 percent when no problem was reported. Mean postcoital PSA levels were 19.3 ng/ml (median, 0.33 ng/ml) in the presence of any problem and 7.8 ng/ml (median, 0.24 ng/ml) in the absence of any reported problem ($p = 0.002$). Furthermore, semen exposure rates and mean postcoital PSA levels were higher after a mechanical problem (22–35 percent and 24.7 ng/ml, respectively) than after an acceptability problem (9–20 percent and 9.5 ng/ml, respectively). Semen exposure rates and postcoital PSA levels were highest with condom breakage and were higher than average for problems associated with complete displacement of the sheath (misrouting of the penis, pushing of the outer ring into the vaginal cavity) (figure 4). PSA levels were also high when semen spilled on the woman’s body. Pain or discomfort felt by the male partner was associated with a wide semen exposure range (11–32 percent) but with a modest elevation in mean postcoital PSA level (11.1 ng/ml) (figure 5). Other problems were associated with exposure rates and postcoital levels similar to those observed in the absence of any reported problems. The semen expo-

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**FIGURE 1.** Rates (per 100 uses) of problems reported during 2,232 female condom uses, by condom used and type of problem, Birmingham, Alabama, 1996–1998. Mechanical problems: the condom broke during intercourse; the condom came out of the vagina; the penis entered to the side of the condom; the outer ring was pushed inside the vagina; semen leaked on the woman’s body; the condom clung to the penis, moving with it; the subject had a problem with the inner ring during intercourse. Acceptability problems: the condom made noise; the female partner felt pain or discomfort; the male partner felt pain or discomfort; the female partner experienced nonmenstrual vaginal bleeding. Condom uses during which multiple problems of the same type were reported were counted only once in computing the relevant problem rate. Condom uses during which both mechanical and acceptability problems were reported were counted in both types but only once in computing the rate of “any problem.” The first five condom uses constitute the training phase; the following condom uses constitute the proficiency phase.

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reported in 1–2 percent of uses. Acceptability problems were reported during 12 percent of uses. Most prominently, the woman felt discomfort in 6 percent, and the man in 4 percent, of the uses (table 1).

Overall, one or more problems were reported in 25 percent of the uses. Problems were more frequent during the training phase than during the proficiency phase, the difference being statistically significant ($p < 0.05$) for six of 11 comparisons. However, problems continued to be reported throughout the proficiency phase (table 1).

The difference between the training and the proficiency phase reflects a steady decline in the problems reported with number of condoms used, observed with both mechanical and acceptability problems (figure 1). Although more than 40 percent of the women reported problems with the first female condom used, 12 percent reported problems at the 20th use. The rates of mechanical and acceptability problems were 33 percent and 25 percent at the first use and 6 percent and 9 percent at the 20th use, respectively. Because the trend could be an artifact due to early discontinuation by women who frequently experienced problems (and would have maintained high problem rates after many uses had they stayed in the study), problem rates were computed separately for women who discontinued after using fewer than 20 condoms and for those who completed the protocol. The women who discontinued use early had higher problem rates than those who completed the protocol, but the decline remained evident among women who completed the protocol (data not shown).

**Semen exposure**

PSA results were available for 1,485 condom uses that occurred ≥24 hours after the previous act of intercourse. The median postcoital PSA level was 0.25 ng/ml, the range including both 0 and 100 ng/ml, the maximum detectable level. Whereas 1,082 samples (73 percent) showed a PSA level of ≤1 ng/ml (figure 2, white bars), 403 (27 percent) had a PSA level of >1 ng/ml (figure 2, black bars). The precoital samples of these 403 cases were tested, and their median PSA was 0.23 ng/ml (figure 2, dotted bars). The median difference between the post- and precoital PSA values was 4.08 ng/ml, suggesting that many possible exposures are either measurement errors or due to small semen leaks. In 107 instances, however, the precoital PSA level was at least 22 ng/ml lower than the postcoital level. Thus, according to criterion I, semen exposure occurred in 7 percent of female condom uses, the lower boundary of the semen exposure rate. Because 315 precoital PSA levels were ≤1 ng/ml, according to criterion II, exposure occurred in 21 percent of the uses, the upper boundary of the semen exposure rate.

Semen exposure rates declined with the number of condoms used. However, the trend was statistically significant only for the upper boundary of the rate ($p = 0.001$) (figure 3).

**Association of semen exposure with self-reported problems**

At least one problem was reported with 324 (22 percent) of 1,485 uses included in the second analysis. When a problem was reported, the semen exposure rate was between 17 percent (criterion I) and 30 percent (criterion II). By contrast, the exposure rate was 5–19 percent when no problem was reported. Mean postcoital PSA levels were 19.3 ng/ml (median, 0.33 ng/ml) in the presence of any problem and 7.8 ng/ml (median, 0.24 ng/ml) in the absence of any reported problem ($p = 0.002$). Furthermore, semen exposure rates and mean postcoital PSA levels were higher after a mechanical problem (22–35 percent and 24.7 ng/ml, respectively) than after an acceptability problem (9–20 percent and 9.5 ng/ml, respectively). Semen exposure rates and postcoital PSA levels were highest with condom breakage and were higher than average for problems associated with complete displacement of the sheath (misrouting of the penis, pushing of the outer ring into the vaginal cavity) (figure 4). PSA levels were also high when semen spilled on the woman’s body. Pain or discomfort felt by the male partner was associated with a wide semen exposure range (11–32 percent) but with a modest elevation in mean postcoital PSA level (11.1 ng/ml) (figure 5). Other problems were associated with exposure rates and postcoital levels similar to those observed in the absence of any reported problems. The semen expo-
sure rate was lower (4–13 percent) when analysis was limited to condom uses in which acceptability, but not mechanical, problems were reported.

The exposure rate was lower in the absence of reported problems than when problems were reported. However, a large proportion of semen exposure occurred in the absence of reported problems: no problems were reported for 57 (53 percent) of 107 condom uses meeting criterion I or for 221 (70 percent) of 315 condom uses meeting criterion II.

Specific mechanical problems associated with semen exposure were evaluated in a multiple regression model that also included number of condoms used and explicit terms for the correlation among condoms used by the same woman. Within-subject correlation was modest, and similar results were obtained if condom uses were treated as independent observations. The number of uses was inversely associated with semen exposure. Even after we controlled for correlation of repeated measurements and number of uses, condom breakage, misrouting of the penis, pushing of the outer ring into the vaginal cavity, and leakage of semen on the woman’s body were strong predictors of semen exposure (table 2). These associations were statistically significant in models in which either criterion I or criterion II was used to define the dependent variable, but they were stronger when exposure was classified by using criterion I. This finding is compatible with reduced exposure misclassification associated with criterion I but also with the tendency of the four mechanical problems to correlate with high semen exposure levels.

**DISCUSSION**

To our knowledge, this is the first full-scale evaluation of a condom in which biologic markers of semen exposure were used to measure condom failure. A small-scale study comparing alternative markers (6) and one evaluating the performance of the PSA-based methods in detecting experimentally controlled semen exposure levels (8) showed that our methods are both highly sensitive and highly specific for recent (<24 hours) semen exposure. A pilot study carried out by the California Family Health Council (CFHC) also used PSA testing to detect condom failure among 15 couples who used 94 male condoms of five different brands (two latex, two polyurethane, and one natural membrane), half of which were punctured before use (7). PSA was detected by using rocket immunoelectrophoresis, which is less sensitive than the assay we used but possibly more specific for detecting high exposure levels. The CFHC study reported exposure in 24 of 24 unprotected acts, 13 of 34 acts protected with a punctured condom, and three of 47 acts protected with a nonpunctured condom. Of three exposures that occurred during use of a nonpunctured condom, two were associated with slippage and one with other self-reported problems. By contrast, seven of 13 exposures that occurred during use of a punctured condom were not associated with self-reported problems (7). The CFHC study size precludes drawing detailed conclusions, but its results lend support to the validity of PSA-based detection of semen exposure.

Despite uncertainties about which semen exposure level indicates condom failure, it is clear that the female condom

![Distribution of prostate-specific antigen (PSA) values (ng/ml) in postcoital samples from 1,485 female condom uses reported to have occurred ≥24 hours after the previous intercourse (white bars: 1,082 samples with levels ≤1 ng/ml, considered negative for semen exposure; black bars: 403 samples with levels >1 ng/ml, considered positive for semen exposure) and in the precoital samples corresponding to positive postcoital samples (dotted bars), Birmingham, Alabama, 1996–1998.](image_url)
is successful as a barrier to semen: complete protection occurred in 79–93 percent of the acts of intercourse in which the device was used. However, problems were common during female condom use (25 percent of more than 2,000 uses). Of the 175 women who returned one or more condoms, 83 percent reported problems (74 percent reported one or more mechanical problems, 61 percent reported one or more acceptability problems). Depending on the criterion used, 43–71 percent of the 141 women contributing data to the third analysis were exposed to semen at least once during the study. Such high rates were observed despite state-of-the-art training of the participants. The number of reported problems was a strong predictor of discontinuation, suggesting that acceptability of the device for long-term use may be limited (Lawson et al., unpublished results). We recently reported that, in a large group of women at high risk of STD, most tried the female condom but few chose the device as their primary method of STD protection (10, 11).

Problem and semen exposure rates declined with use, suggesting an effect of experience on modifiable determinants of condom failure. We made similar observations for the male latex condom among women whose STD risk was high (12). On the other hand, relatively high problem and semen exposure rates persisted even after 20 uses.

User-reported problems were associated with semen exposure. In particular, breakage and other mechanical problems were associated with high rates of semen exposure and high postcoital PSA levels. A large number of user-reported problems did not result in semen exposure, however. Conversely, user-reported problems explain only a portion of the instances of exposure. To the extent that semen exposure is a biologic marker of condom failure, users do not detect a substantial proportion of condom failures while they report problems that do not entail exposure.

The biologic significance of low semen exposure is uncertain. It is plausible that small quantities of semen, leading to low PSA levels, bear a lower risk of pregnancy or STD than do large quantities of semen. However, low-level exposures may be associated with a significant risk of STD with low infectious doses.

Certain limitations must be acknowledged in interpreting the results of this investigation. First, the study was carried out with a select group of couples at low risk of STD. Thus, the findings may not be generalizable. However, low-risk couples are the target of phase II studies of new condoms, and it was important that the present investigation follow the guidelines for conducting such studies. A group of 895 women attending STD clinics in Alabama, who were trained by using similar methods and used 7,895 female condoms, reported 443 slippages (rate, 5.6 percent) and nine breakages (rate, 0.1 percent) (Macaluso et al., unpublished data). Thus, women whose risk of STD is higher, who may be more moti-

![Figure 3](image-url)
vated to use the female condom correctly, may experience lower failure rates than those observed in this study.

Second, attrition was high; fewer than half of the participants completed the study. Women who contributed data to the analysis were not different from those who did not, with the exception that the women who did not complete follow-up more often disliked the appearance of the female condom and expressed aversion to inserting it (Lawson et al., unpublished data). In addition, because user problems are associated with increased risk of discontinuation and semen exposure, selective loss of couples who experienced problems and exposure led to underestimation of semen exposure. The cohort dynamics, though, are likely to reflect what would occur in the population, with many couples experimenting with the product and discontinuing use early, possibly because of high problem rates, and some couples continuing on and experiencing progressively lower rates of problems and exposure.

Finally, although the present study may represent an improvement over conventional designs based on only self-reported use and experiences, data collection was still dependent on subject participation. Accuracy of self-report may vary across subjects and should have led to our underestimating the frequency of problems and overestimating semen exposure in the absence of problems, which may in part explain semen exposure in the absence of reported problems. Furthermore, time since the previous act of intercourse may have been overestimated; this problem may explain why 25 percent of the precoital samples were positive for semen exposure even after the condom uses reported to have occurred less than 24 hours after the previous act of intercourse. Exposure assessment was based on the comparison between samples taken before and after use, however, and condom uses in which precoital PSA values were elevated were excluded from the analyses.

Specimen collection also was dependent on the participants, and the swabs may have been contaminated with semen if the instructions for collecting the postcoital samples were not followed. The sampling device and the procedures were carefully designed to minimize the potential for contamination and were tested for acceptability. In contrast to condom use problems, problems with the sampling procedures were rare. Contamination of the postcoital swabs most likely occurred by touching exposed skin surfaces and would
have often led to small increases in PSA levels in the sample. This mechanism may have led to overestimating the upper boundary of the semen exposure rate, but it is unlikely to have affected the lower boundary. The true rate of semen exposure during female condom use is likely to lie between 7 percent and 21 percent.

**TABLE 2.** Association between user-reported problems with female condom use and semen exposure, Birmingham, Alabama, 1996–1998*

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Lower boundary of exposure rate†</th>
<th>Upper boundary of exposure rate‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR§  95% CI§</td>
<td>OR§  95% CI§</td>
</tr>
<tr>
<td>Condom use number</td>
<td>0.96 0.94, 0.99</td>
<td>0.96 0.91, 1.00</td>
</tr>
<tr>
<td>Condom broke</td>
<td>13.3 3.1, 56</td>
<td>38 7.9, 180</td>
</tr>
<tr>
<td>Penis entered outside condom</td>
<td>2.9 1.2, 7.2</td>
<td>6.6 2.4, 18</td>
</tr>
<tr>
<td>Outer ring pushed into vagina</td>
<td>9.3 4.6, 19</td>
<td>13.6 6.4, 29</td>
</tr>
<tr>
<td>Semen leaked onto woman</td>
<td>4.3 2.1, 8.8</td>
<td>6.3 2.8, 14</td>
</tr>
</tbody>
</table>

*Restricted to 1,485 acts in which no sex was reported in the previous 24 hours.
†Semen exposure during condom use is defined as a postcoital prostate-specific antigen (PSA) level of >1 ng/ml following a precoital PSA level of ≤1 ng/ml and a postcoital PSA level at least 22 ng/ml higher than the precoital level.
‡Semen exposure during condom use is defined as a postcoital PSA level of >1 ng/ml and a precoital PSA level of ≤1 ng/ml or a postcoital PSA level at least 22 ng/ml higher than the precoital level.
§Semen exposure odds ratio (OR) and 95% confidence interval (CI) of the odds ratio, adjusted by all other variables shown in a generalized linear model with repeated effects. The dependent variable was semen exposure as defined by either the lower or the upper boundary of the exposure rate.
Despite these limitations, this study adds to our understanding of the efficacy of the female condom. First, it provides evidence that semen exposure is associated with user-reported problems, more often mechanical than acceptability related.

Second, the female condom provided complete protection in 79–93 percent of uses. Although these rates suggest that protection is not perfect, comparable evidence about the male condom is lacking. In the CFHC study (7), the semen exposure rate during use of nonpunctured male condoms was about 6 percent, similar to the lower boundary of the semen exposure rate of the female condom. Thus, it would be premature to conclude that the female condom offers less protection than the male latex condom.

Finally, this study breaks new ground by using an endpoint that is not a serious adverse outcome. Assessing semen exposure may be a valid alternative to assessing pregnancy rates when evaluating the contraceptive efficacy of new condoms. The design does not require using a condom as the only method of contraception, and participants may minimize their risk by using another contraceptive method during the study. Women were able to help us collect data without being overburdened by protocol requirements, and the laboratory procedures provided accurate PSA levels (8). Overall, 175 women returned 4,464 vaginal samples during the study, demonstrating that the sampling procedures can be implemented on a large scale.

In conclusion, we developed objective methods for assessing female condom failure and integrated them with conventional self-report in a study of couples at low risk of pregnancy and STD. We found a clear association between self-reported mechanical problems and semen exposure, but the association was not perfect, suggesting that objective methods are necessary for a valid assessment of condom safety and efficacy. The female condom was an effective barrier to semen in the vast majority of uses. Further research is needed to determine which semen exposure levels, as measured by PSA, predict the risk for pregnancy and STD and to compare the female condom with the male condom. This evidence is necessary to make informed decisions regarding the role of the female condom in large-scale programs to promote barrier contraception to prevent unintended pregnancy and STD.

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