Efficacy of the Male Latex Condom and of the Female Polyurethane Condom as Barriers to Semen during Intercourse: A Randomized Clinical Trial

Maurizio Macaluso¹, Richard Blackwell², Denise J. Jamieson¹, Andrzej Kulczycki³, Michael P. Chen¹, Rachel Akers⁴, Dhong-jin Kim⁴, and Ann Duerr⁵

¹ Division of Reproductive Health, Centers for Disease Control and Prevention, Atlanta, GA.
² Department of Obstetrics and Gynecology, School of Medicine, University of Alabama at Birmingham, Birmingham, AL.
³ Department of Maternal and Child Health, School of Public Health, University of Alabama at Birmingham, Birmingham, AL.
⁴ Department of Epidemiology, School of Public Health, University of Alabama at Birmingham, Birmingham, AL.
⁵ HIV Vaccine Trials Network, Seattle, WA.

Received for publication August 8, 2006; accepted for publication January 3, 2007.

In this 2000–2001 study, the authors compared the effectiveness of the male latex condom and the female polyurethane condom by assessing frequency and types of mechanical failure and by evaluating semen exposure during use. Eligible women from Birmingham, Alabama, were randomly assigned to begin the study with 10 male condoms and then switch to 10 female condoms (n = 55), or vice versa (n = 53), and were trained to use both types. Data collection included questionnaires for each condom use and measurement of prostate-specific antigen in specimens of vaginal fluid taken before and after intercourse. Participants returned 700 male condoms and 678 female condoms, and they reported mechanical problems for 9% and 34%, respectively. Moderate-high postcoital prostate-specific antigen levels (>22 ng/ml) were detected in 3.5% of male condom uses and 4.5% of female condom uses (difference = 1%, 95% confidence interval: 1.6, 3.7). Moderate-high prostate-specific antigen values (>22 ng/ml) were more frequent with mechanical problems (male condom, 9.6%; female condom, 9.4%) but less frequent with other problems (3.0% and 0.9%) or correct use with no problems (2.7% and 2.5%). This study indicates that although mechanical problems are more common with the female condom than with the male condom, these devices may involve a similar risk of semen exposure. Objectively assessed semen exposure is associated with self-reported mechanical problems.

clinical trials; condoms; condoms, female; contraception, barrier; prostate-specific antigen; treatment outcome

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

The male latex condom remains a key contraceptive method: 6.8 million (11 percent) US women of reproductive age (15–44 years) used male condoms as their primary method of birth control in 2002 (1). Many use condoms to prevent infection with the human immunodeficiency virus and other sexually transmitted diseases (STDs). Although male condoms are highly effective in preventing human immunodeficiency virus and unintended pregnancy when used consistently and correctly, there is less agreement on the size of the protective effect for STDs other than human immunodeficiency virus (2–5). Even less is known about the female polyurethane condom, although studies suggest an equivalent effect against STDs (6–9).

Evaluation of the effectiveness of condom use in preventing STDs faces serious challenges (2–4). Most studies rely on self-report of sexual activity and condom use, which is prone to bias (10). Semen exposure is a useful surrogate outcome in studies of the effectiveness of condoms in protecting women against the acquisition of STDs. We have developed an objective method to detect semen exposure,
which is based on testing pre- and postcoital samples of vaginal fluid for prostate-specific antigen (PSA) (11, 12). The concentration of PSA in vaginal fluid sharply increases after semen exposure, returning to values below 1 ng/ml 24–48 hours after exposure (12). Thus, PSA in vaginal fluid indicates recent semen exposure. Several investigations (13–16) have used PSA to assess condom effectiveness. This report presents the results of a randomized crossover trial comparing the frequency of mechanical failure and semen exposure during use of the male and female condoms.

MATERIALS AND METHODS
Design and eligibility criteria

The study group consisted of women attending an outpatient reproductive health clinic in Birmingham, Alabama, between January 2000 and July 2001. Women were eligible if they were aged ≥19 years, were in a mutually monogamous relationship and had no STDs during the past 6 months, and reported four or more acts of sexual intercourse in the past 30 days. We assessed eligibility by telephone and did not keep documentation on ineligible women. All eligible women who agreed to participate provided written informed consent. The institutional review boards of the University of Alabama at Birmingham and the Centers for Disease Control and Prevention reviewed and approved the study protocol.

Study procedures

As they provided informed consent, participants were given a sequential study number, which had been preassigned to a study arm by using an algorithm that ensured balanced random assignment within groups of four participants. The list of study numbers and assignments was generated by the study programmer and was updated by the study coordinator. Concealment of assignments and masking were not feasible because of obvious differences between condom types.

Participants were given a brief motivational intervention and instruction (with anatomic models) on correct use of the first set of 10 condoms (male or female, depending on the random assignment, each to be used once). They were trained to use a gynecologic swab protected by a cardboard tampon tube (11) to obtain samples of vaginal fluid. The training session emphasized avoiding contamination of the swab with semen present on the woman’s hands or external genitalia. They were instructed to take one vaginal sample immediately before and one after using a condom, place the swabs and the used condom in prelabeled bags with desiccant, fill out a brief questionnaire to report problems with the condom or with the self-sampling device, and return the packet (swabs, condom, and form) to the study clinic on the next business day. Participants practiced sample collection at the clinic under the direction of a nurse practitioner. After using the first 10 condoms, they returned for an interview, reviewed their experience with project staff, received instruction on using the other type of condom, and were given the second set of 10 condoms. After returning the second set of condoms, they participated in a posttrial interview.

Participants were expected to complete the study within 4 months. All were tested for gonorrhea and chlamydia infection at the enrollment and exit visits, and they were treated if positive. For their time and effort, women were reimbursed $25 at each visit and $15 for each packet (condom, samples, and form) returned.

PSA testing

Dried swabs were stored, eluted, and tested as previously described (11–13). The PSA assay used (IMx System; Abbott Laboratories, Abbott Park, Illinois) is highly sensitive (range of detection: 0.01–100 ng/ml), specific (the monoclonal anti-PSA antibodies have negligible cross-reaction with other proteins), and carries a small measurement error (coefficient of variation of 5 percent in repeated testing).

To determine semen exposure during a specific condom use, we first tested the postcoital sample. If the PSA value was ≤1 ng/ml, we concluded that there was no semen exposure and did not test the precoital sample. If the postcoital PSA value was >1 ng/ml, we tested the precoital sample to exclude previous exposure; if the precoital PSA value was ≥1 ng/ml, we classified the result as uninformative because exposure could have occurred before the present condom use (12, 13). We classified all informative postcoital PSA values into four categories: 1) nonexposed (≤1 ng/ml); 2) low (≥1–21 ng/ml) (16); 3) moderate (22–99 ng/ml); and 4) high (≥100 ng/ml). Under these self-sampling and assay conditions, PSA results of ≤1 ng/ml are incompatible with recent exposure (11, 12). Postcoital results of <22 ng/ml may be due to low semen exposure or may follow a false-negative precoital sample due to a self-sampling error (12). Postcoital PSA levels of ≥22 ng/ml following precoital values of <1 ng/ml are statistically incompatible with self-sampling variability (12).

Study size

We planned to enroll 160 women and obtain information on 1,000 uses of each condom type. If one condom type is associated with a breakage rate of 1 percent, this study size affords 80 percent power to declare significant a 1.5 percent excess in the rate for the other condom type (two-sided test of the difference between equal samples at the 95 percent confidence level), with ample power to detect differences in more common outcomes (e.g., slippage, PSA detection).

Data analysis

The objectives of the analysis were to describe the study groups at baseline and to compare the frequency of self-reported user problems and of semen exposure between the two types of condoms. For male condoms, self-reported mechanical problems included breakage, complete slippage, partial slippage (≥1 inch and <1 inch; 1 inch = 2.54 cm), and other mechanical problems (i.e., leakage of semen). For female condoms, the problems included breakage, misrouting (the penis entered to the side of the condom), invagination (the outer ring was pushed inside), slippage (the
condom came out), or other mechanical problems (e.g., leakage of semen).

The brief questionnaire completed after each condom use included several items to assess correct use. For the male condom, we specified two categories of incorrect use: 1) partial use (penile-vaginal contact before use or after removal of the condom) or incorrect donning of the condom (the tip of the penis touched the outer surface of the condom before it was donned); and 2) withdrawal without holding the rim of the condom or after losing erection. The first category should be associated with a higher probability of semen exposure, whereas the second may lead to exposure only if it causes slippage. We defined as incorrect use of the female condom any partial use (penile-vaginal contact before insertion of the condom or after removal) or insertion of the condom without its inner ring.

We used frequency distributions and simple univariate statistics to describe and compare the study groups. To test the null hypothesis of no difference between the two condoms or between study arms with respect to the proportion of uses in which a positive postcoital PSA test was observed or with respect to any problems reported, we used binomial regression with generalized estimating equations to adjust for correlation among observations pertaining to condoms used by the same woman. We used robust variance estimators from these models to compute the 95 percent confidence intervals for differences in proportions.

The order of condoms used (first, second, etc.) and the study arm (male condom first, female condom first) were included in regression models as predictors of log-transformed postcoital PSA values to account for a previously observed decline in postcoital PSA with the number of female condoms (table 13) and to evaluate order-of-use and crossover effects.

**RESULTS**

The target study size was not reached, and recruitment was closed after the enrollment of 108 participants. Of these, 55 were assigned to begin with male condoms and 53 with female condoms. The two study arms had similar baseline characteristics: 78 percent were less than 40 years of age, and a similar percentage were White (table 1). All had a main partner, and most were in a long-term relationship (58 percent for ≥5 years); 77 percent were married or living with their partner; and 87 percent were using modern methods of contraception. Fifteen (14 percent) reported having had one sexual partner, while 19 (17 percent) reported 10 or more. Most (n = 96) reported having used a condom with their main partner, 20 percent reported experiencing condom breakage with that partner, and 45 percent reported experiencing condom slippage. Only a few women reported prior experience with the female condom (table 1).

Of the 55 women who started with the male condom, 30 (55 percent) completed the study. Of the 53 women who started with the female condom, 33 (62 percent) completed the study (figure 1). Attrition was independent from study arm and from the type of condom used at the time of withdrawal from follow-up.

Participants returned 700 male condoms and 678 female condoms. They reported male condom breakage in nine uses (1.3 percent) and complete slippage in 15 uses (2.1 percent) (table 2). Women who started with the male condom reported mechanical problems with the male condom more frequently (12 percent) than women who started with the female condom (5 percent, p = 0.045). Participants reported partial use or incorrect donning in 131 uses of the male condom (19 percent) and incorrect withdrawal in 347 uses (50 percent) (table 2). Seventy-six percent (n = 263) of the instances of incorrect withdrawal were attributed to the man’s not holding the base of the condom. Although the rates of incorrect use were similar in the two study arms (data not shown), women who started with the male condom reported incorrect withdrawal less frequently (43 percent) than women who started with the female condom (57 percent, p = 0.047).

Participants reported female condom breakage in 0.3 percent of the uses (two uses), invagination and slippage in 14 percent, and misrouting of the penis in 6 percent (table 2). Overall, women reported mechanical problems in 34 percent of female condom uses, with little difference between study arms (table 2). The rate of incorrect use was 8 percent (52 uses): it was more frequent among women who started with the male condom (14 percent) than among those who began with the female condom (3 percent).

Postcoital PSA testing yielded results for 700 male and 677 of the 678 female condoms returned. We excluded results from 65 male condoms and 78 female condoms associated with postcoital PSA values of ≥1 ng/ml and precoital PSA values of ≥1 ng/ml. Thus, the analysis of semen exposure used results from 635 male condoms and 599 female condoms (table 3). Overall, 86/635 (14 percent) male condom uses and 100/599 (17 percent) female condom uses were positive for PSA. The 95 percent confidence interval for the difference of 3 percentage points was −3, 9. The proportion of condom uses with moderate-high postcoital PSA levels (≥22 ng/ml) was 3.5 percent for male condoms and 4.5 percent for female condoms (difference = 1 percentage point, 95 percent confidence interval: −1.6, 3.7). The rates of semen exposure during male condom use were higher among women who started with the male condom (15 percent) than among women who started with the female condom (12 percent). Similarly, the rates of semen exposure during use of the female condom were higher among women who started with the female condom (18 percent) than among those who started with the male condom (15 percent). This crossover effect was not statistically significant.

Postcoital PSA values were associated with self-reported problems (table 4). For the male condom, moderate-high PSA values (≥22 ng/ml) were more frequent with breakage (1/9, 11 percent), complete slippage (3/15, 20 percent), and partial use or incorrect donning (9/120, 7.5 percent) than with incorrect withdrawal (1.3 percent) or correct use without any problems (2.7 percent). Similarly, for the female condom, moderate-to-high PSA values were more frequent with breakage (1/1, 100 percent), misrouting (3/28, 11 percent), invagination and slippage (6/79, 8 percent), or other mechanical problems (9/94, 10 percent).
than with incorrect use (0/41) or no problems (7/283, 2.5 percent) (table 4).

Regression analysis of the log-transformed postcoital PSA values as a function of condom type and order (1st, 2nd ... 10th) showed that, whereas there was no significant change in PSA values with successive uses of the male condom ($p = 0.47$), there was a significant decrease in postcoital PSA values with successive uses of the female condom ($p = 0.001$) (figure 2). This “learning” effect with the female condom was present in both study arms, with no crossover effect ($p = 0.43$).

**DISCUSSION**

Consistent with previous research (16–30), this study found that although breakage was rare with the female condom, mechanical problems were reported almost four times as often with the female condom as with the male condom. Incorrect use was common with the male condom: participants reported incorrect donning/partial use in 19 percent of the uses. They reported that the man withdrew without holding the rim in 41 percent of the uses and after losing erection in an additional 9 percent. These observations are consistent with studies that have evaluated rates of incorrect use.
The use of the male condom among college students (30, 31) or the proportion of patients at STD clinics reporting incorrect use during a month (32). Investigations based on in-clinic demonstration of how to use the male condom showed poor performance among college students (33), adolescent African-American women (34), and female sex workers and their clients (35). The effect of specific forms of incorrect use on the risk of pregnancy or disease is unknown.

The nonsignificant 3 percent difference in PSA detection between male and female condom use suggests that the two devices are similarly effective in preventing semen exposure. Semen exposure should not be interpreted as protection failure, whether due to failure of the device or to incorrect use. Small increases in PSA values may reflect self-sampling error or low-level semen exposure that bears no risk of pregnancy or STDs (12, 13, 36–38). PSA in vaginal fluid was associated with gonorrhea and chlamydia in a recent cross-sectional study in West Africa (39). In the current study, we highlighted moderate-high PSA values as potentially more relevant to disease risk. The frequency of moderate-high postcoital PSA values was 3.5 percent for the male condom and 4.5 percent for the female condom, again suggesting comparable protection. The 95 percent confidence interval of the difference (−3, 9) is not narrow enough to exclude a moderate difference in performance in either direction, but it indicates that large differences are unlikely. In a similar trial in Brazil, PSA detection rates were higher with the female condom than with the male condom after use of two devices of each type (14). The report concluded that the female condom appeared to perform less well than the male condom, and it suggested that education and experience with use of the female condom might attenuate the difference (14). We note that if our analysis were restricted to the first two uses of each device, the PSA detection rates would also be higher with the female condom than with the male condom. Thus, the combined evidence from these studies suggests that although the female condom performs less well than the male condom during the first few uses, its effectiveness over repeated use is similar.

In our study, PSA detection rates decreased as the number of female condoms used by a woman increased, suggesting that women’s skills improved over time. PSA detection rates did not decline with male condom use, suggesting either that the participants were familiar with the device at entry into the study or that training and motivation of the woman without involvement of the male partner was insufficient to improve proficiency.

Consistent with previous research (13–16), we found that semen exposure was more frequent when participants

---

**FIGURE 1.** Participation in the study of the efficacy of the male condom (MC) and the female condom (FC), Birmingham, Alabama, 2000–2001. Value following the colon, number of female participants.

---

**Assessed for eligibility:** number unknown

**Eligible and agreeing to participate:** 108

**MC first:** 55

- Did not return any condoms: 10
  - Reasons:
    - Changed her mind (2)
    - Partner did not agree (1)
    - Protocol too demanding (1)
    - Did not like MC (2)
    - Health reasons (2)
    - Lost to follow-up (2)

  **Included in analysis:** 45 (used 370 MC and 309 FC)
  - Used only MC: 13
  - Used MC and FC: 32
  - Used 10 MC and 10 FC: 30

**FC first:** 53

- Did not return any condoms: 13
  - Reasons:
    - Changed her mind (7)
    - Moved out of area (1)
    - Did not like FC (2)
    - Health reasons (1)
    - Lost to follow-up (2)

  **Included in analysis:** 40 (used 330 MC and 369 FC)
  - Used only FC: 7
  - Used MC and FC: 33
  - Used 10 MC and 10 FC: 33

---

**Am J Epidemiol** 2007;166:88–96
reported mechanical problems such as breakage or slippage. In addition, we made new observations correlating semen exposure with incorrect use. Incorrect use of the female condom did not increase the rate of moderate-high PSA values, possibly because inserting the condom without the inner ring, a common instance of incorrect use, may not interfere with its ability to serve as a barrier to semen. In contrast, partial use or incorrect donning of the male condom led to moderate-high PSA values 8 percent of the time.

The findings of this study need to be interpreted in light of some limitations. First, the participants were women at low risk of STDs who shared certain background characteristics and a willingness to use both female and male condoms. Thus, they may not be representative of all women or of those who most likely will benefit from the female condom (e.g., at-risk women who cannot negotiate use of the male condom with a partner). The requirement that participants have a steady partner and test the condoms with that partner may hinder generalization to less stable partnerships, in which incorrect use and mechanical problems may be more frequent. On the other hand, the baseline characteristics of the participants are typical of those of reproductive health clinic patients. Second, participants often were experienced male condom users but were new users of the female condom. Thus, the rates of self-reported problems and PSA detection may reflect initial use of the female condom and proficient use of the male condom, possibly explaining why semen exposure decreased with female condom use but not with male condom use.

**TABLE 2.** Reported problems with condom use, by condom type and study arm, Birmingham, Alabama, 2000–2001

<table>
<thead>
<tr>
<th>Problem reported</th>
<th>Used male condom first</th>
<th>Used female condom first</th>
<th>Total</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td><strong>Male condom</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakage</td>
<td>8</td>
<td>2.2</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>Slippage, complete</td>
<td>13</td>
<td>3.5</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Slippage, partial (≥1 inch†)</td>
<td>10</td>
<td>2.7</td>
<td>8</td>
<td>2.4</td>
</tr>
<tr>
<td>Slippage, partial (&lt;1 inch)</td>
<td>10</td>
<td>2.7</td>
<td>2</td>
<td>0.6</td>
</tr>
<tr>
<td>Other mechanical problems</td>
<td>3</td>
<td>0.8</td>
<td>3</td>
<td>0.9</td>
</tr>
<tr>
<td>Partial use/incorrect donning</td>
<td>72</td>
<td>19.5</td>
<td>59</td>
<td>17.9</td>
</tr>
<tr>
<td>Incorrect withdrawal</td>
<td>159</td>
<td>43.0</td>
<td>188</td>
<td>57.0</td>
</tr>
<tr>
<td>Correct use, no problem</td>
<td>95</td>
<td>25.7</td>
<td>67</td>
<td>20.3</td>
</tr>
<tr>
<td>Total uses</td>
<td>370</td>
<td>100</td>
<td>330</td>
<td>100</td>
</tr>
<tr>
<td><strong>Female condom</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakage</td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>0.3</td>
</tr>
<tr>
<td>Penis misrouting</td>
<td>19</td>
<td>6.2</td>
<td>19</td>
<td>5.2</td>
</tr>
<tr>
<td>Invagination</td>
<td>12</td>
<td>3.9</td>
<td>8</td>
<td>2.2</td>
</tr>
<tr>
<td>Slippage</td>
<td>31</td>
<td>10.0</td>
<td>41</td>
<td>11.1</td>
</tr>
<tr>
<td>Other mechanical problems</td>
<td>36</td>
<td>11.7</td>
<td>65</td>
<td>17.6</td>
</tr>
<tr>
<td>Incorrect use</td>
<td>42</td>
<td>13.6</td>
<td>10</td>
<td>2.7</td>
</tr>
<tr>
<td>Other problems</td>
<td>37</td>
<td>12.0</td>
<td>46</td>
<td>12.5</td>
</tr>
<tr>
<td>Correct use, no problem</td>
<td>131</td>
<td>42.4</td>
<td>179</td>
<td>48.5</td>
</tr>
<tr>
<td>Total uses</td>
<td>309</td>
<td>100</td>
<td>369</td>
<td>100</td>
</tr>
</tbody>
</table>

* Test of the null hypothesis of no difference between arms.
† One inch = 2.54 cm.

**TABLE 3.** Postcoital PSA* concentration after precoital PSA concentration of <1 ng/ml, by condom type and study arm,† Birmingham, Alabama, 2000–2001

<table>
<thead>
<tr>
<th>PSA (ng/ml)</th>
<th>Used male condom first</th>
<th>Used female condom first</th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Male condom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1</td>
<td>290</td>
<td>85.3</td>
<td>259</td>
<td>87.8</td>
</tr>
<tr>
<td>&gt;1–21</td>
<td>37</td>
<td>10.9</td>
<td>27</td>
<td>9.2</td>
</tr>
<tr>
<td>22–99</td>
<td>5</td>
<td>1.5</td>
<td>2</td>
<td>0.7</td>
</tr>
<tr>
<td>≥100</td>
<td>8</td>
<td>2.4</td>
<td>7</td>
<td>2.4</td>
</tr>
<tr>
<td>Total</td>
<td>340</td>
<td>100</td>
<td>295</td>
<td>100</td>
</tr>
<tr>
<td>Female condom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤1</td>
<td>236</td>
<td>84.6</td>
<td>263</td>
<td>82.2</td>
</tr>
<tr>
<td>&gt;1–21</td>
<td>29</td>
<td>10.4</td>
<td>44</td>
<td>13.8</td>
</tr>
<tr>
<td>22–99</td>
<td>5</td>
<td>1.8</td>
<td>7</td>
<td>2.2</td>
</tr>
<tr>
<td>≥100</td>
<td>9</td>
<td>3.2</td>
<td>6</td>
<td>1.9</td>
</tr>
<tr>
<td>Total</td>
<td>279</td>
<td>100</td>
<td>320</td>
<td>100</td>
</tr>
</tbody>
</table>

* PSA; prostate-specific antigen.
† No significant differences by either condom type or study arm.
Third, attrition was considerable, and only 63 (58 percent) of the 108 participants completed the study. Attrition, however, was not associated with the type of condom used or the sequence of use. Additional analyses indicated that the rates of mechanical failure and moderate-high PSA values were higher among women who did not complete the study. Thus, had such women completed the study, the failure rates measured in this study could have been higher. On the other hand, the differences between women who did and did not complete the study were similar in both arms, and it is unlikely that the comparisons between arms or condom types were distorted by attrition. Finally, detection of PSA is an uncertain measure of condom failure and does not necessarily predict unintended pregnancy or STD, although absence of PSA in postcoital samples indicates absence of risk.

The limitations outlined above are offset by considerable strengths. First, this study used an objective measure of semen exposure to compare the effectiveness of male and female condom use. Using PSA in vaginal fluid as a marker of condom failure is gaining credibility (40) and has considerable advantages. Although this method depends on the participant’s willingness and ability to take samples at prescribed times, self-sampling is less prone to bias than self-reporting of condom use and problems. Self-report is especially prone to bias when participants must report socially desirable behavior, such as consistent condom use (10), and there is consensus that biologic markers of efficacy

### TABLE 4. Reported problems with condom use and postcoital PSA* concentration, by condom type, Birmingham, Alabama, 2000–2001

<table>
<thead>
<tr>
<th>Problem reported†</th>
<th>PSA (ng/ml)</th>
<th>Total (no.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>≤1</td>
<td>&gt;1–21</td>
</tr>
<tr>
<td></td>
<td>No. %</td>
<td>No. %</td>
</tr>
<tr>
<td>Male condom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakage</td>
<td>8 89</td>
<td>0 0</td>
</tr>
<tr>
<td>Slippage, complete</td>
<td>11 73</td>
<td>1 7</td>
</tr>
<tr>
<td>Slippage, partial (≥1 inch‡)</td>
<td>11 73</td>
<td>3 20</td>
</tr>
<tr>
<td>Slippage, partial (&lt;1 inch)</td>
<td>10 91</td>
<td>1 9</td>
</tr>
<tr>
<td>Other mechanical problems</td>
<td>2 100</td>
<td>0 0</td>
</tr>
<tr>
<td>Partial use/incorrect donning</td>
<td>90 75</td>
<td>21 18</td>
</tr>
<tr>
<td>Incorrect withdrawal</td>
<td>292 92</td>
<td>21 7</td>
</tr>
<tr>
<td>Correct use, no problem</td>
<td>125 86</td>
<td>17 12</td>
</tr>
<tr>
<td>Total uses§</td>
<td>549 86 64 10</td>
<td>7 1</td>
</tr>
<tr>
<td>Female condom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breakage</td>
<td>0 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Penis misrouting</td>
<td>22 79</td>
<td>3 11</td>
</tr>
<tr>
<td>Invagination</td>
<td>13 65</td>
<td>5 25</td>
</tr>
<tr>
<td>Slippage</td>
<td>48 81</td>
<td>7 12</td>
</tr>
<tr>
<td>Other mechanical problems</td>
<td>71 76</td>
<td>14 15</td>
</tr>
<tr>
<td>Incorrect use</td>
<td>31 76</td>
<td>10 24</td>
</tr>
<tr>
<td>Other problems</td>
<td>61 84</td>
<td>11 15</td>
</tr>
<tr>
<td>Correct use, no problem</td>
<td>253 89</td>
<td>23 8</td>
</tr>
<tr>
<td>Total uses§</td>
<td>499 83 73 12</td>
<td>12 2</td>
</tr>
</tbody>
</table>

* PSA, prostate-specific antigen; SD, standard deviation.
† Test of the null hypothesis of no heterogeneity in postcoital PSA among categories of self-reported problems: \( p < 0.0001 \) both within female condom use and within male condom use.
‡ One inch = 2.54 cm.
§ Test of the null hypothesis of no difference in postcoital PSA between condom types: \( p = 0.67 \).

---

**FIGURE 2.** Postcoital concentration of prostate-specific antigen (PSA) (mean log) by condom type and condom use order, Birmingham, Alabama, 2000–2001. Triangles, male condoms; squares, female condoms.
provide stronger evidence than self-reported behavior (41). An even more serious threat to validity arises when the partner’s infection status is unknown, as is often the case in studies of curable STDs. Because the risk of transmission occurs during sexual intercourse with an infected partner only, and the partner’s infection status may be associated with condom use, the effectiveness of condom use may be substantially underestimated in studies that fail to control for this source of confounding (42, 43). In contrast, PSA is present in very high concentrations in the semen of almost all men (0.5–2.0 mg/ml) (44), making it highly unlikely that condom users differ from nonusers with respect to the presence of PSA. Thus, PSA in postcoital vaginal fluids is, at the same time, a marker of behavior that is less prone to information bias than self-report and a marker of outcome for condom effectiveness that is less prone to confounding than conventional STD outcomes.

Another major strength of this study is the randomized crossover design, which provides a solid framework for inference because the same group of women provided information on exposure with both condoms. Comparisons between study arms and between condom types were balanced with respect to the characteristics of the participants and were likely to ensure internal validity. Finally, the design enabled us to study the association of semen exposure with self-reported mechanical problems and incorrect use. This investigation adds to the small number of studies (13–16) that have begun shedding new light on the risk of adverse outcomes determined by specific problems encountered by condom users. These studies provide the evidence base that should guide counseling for new and experienced condom users.

In conclusion, this study indicates that while the frequency of mechanical and other use problems is higher with the female condom, the risk of semen exposure is similar for the male and female condoms, suggesting that the devices are similar with respect to efficacy in preventing pregnancy and disease. This study also confirms that objectively assessed semen exposure is associated with self-reported mechanical problems and incorrect use.

ACKNOWLEDGMENTS

This study was supported by cooperative agreement S0747-18/19 between the Centers for Disease Control and Prevention and the Association of Schools of Public Health. The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

The authors gratefully acknowledge Dr. Lee Warner for his helpful comments.

Conflict of interest: none declared.

REFERENCES