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Effectiveness of female and male condoms in preventing exposure to semen during vaginal intercourse: a randomized trial

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Abstract

Objectives: Comparison of male condom (MC) vs. female condom (FC) with respect to self-reported mechanical and acceptability problems and semen exposure using prostate-specific antigen (PSA) as an objective biological marker and evaluation of the effect of an educational intervention on self-reported problems and semen exposure, by condom type.

Design: Randomized crossover trial.

Methods: Four hundred women attending a family planning clinic in Brazil were randomized and either received in-clinic instruction or were encouraged to read the condom package insert; all used two FCs and two MCs. We measured the rates of self-reported user problems with MC and FC use and the rates of semen exposure during use (assessed by testing vaginal fluid for PSA).

Results: The educational intervention group reported fewer problems with either condom as compared with the control group ($p=.0004$, stratified by condom type). In both groups, self-reported problems were more frequent with FC use than with MC use ($p<.0001$, stratified by intervention). The educational intervention did not significantly reduce semen exposure. Overall, semen exposure occurred more frequently with FC use (postcoital PSA, >1 ng/mL; 22%) than with MC use (15%); the difference, however, was small and nonsignificant for high PSA levels (≥150 ng/mL; 5.1% for FC vs. 3.6% for MC).

Conclusions: In this study, the FC was less effective than the MC in preventing semen exposure during use and led more frequently to self-reported user problems. Both devices were highly protective against "high-level" semen exposure, as measured by postcoital PSA levels in vaginal fluid. In-clinic education may reduce user problems and increase acceptability and use of both devices.

Keywords: Randomized trials; HIV; STD; Condoms; Educational intervention; Semen exposure; Women

1. Introduction

Barrier contraceptive methods such as the male condom (MC) and, more recently, the female condom (FC) offer protection against pregnancy as well as HIV and a number of other sexually transmitted infections (STIs). Regular condom use is associated with reduced incidence of HIV, gonorrhea, mycoplasma, chlamydia, trichomoniasis, hepatitis, cytomegalovirus and herpes [1–6]. The FC was approved by the U.S. Food and Drug Administration as a contraceptive method, which is also effective for STD

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prevention [7], and has been promoted as a woman-controlled method. The contraceptive efficacy of the FC has been adequately studied [8,9], and comparative analyses suggest that the contraceptive failure rate of the FC, if consistently and correctly used, is close to the lowest expected failure rates reported for MC [10]. However, the evaluation of the effectiveness of the FC in protecting users against STIs is more limited [11–14], and no direct comparison has been made between the efficacy of the FCs and that of the MCs.

Although previous studies have reported on both the mechanical and user problems encountered in using MCs and FCs, few studies have employed objective markers of semen exposure to measure condom effectiveness [15–18]. An objective measurement of condom failure should be based on laboratory tests that evaluate semen spillage during condom use. Suitable tests include the microscopic examination of vaginal fluid specimens to detect spermatozoa, biochemical assays to measure the enzymatic activity of acid phosphatase [19,20] and immunologic assays to detect semen components such as prostate-specific antigen (PSA, also known as P-30) [20,21] and the human seminal plasma antigen MHS-5 [22,23]. We developed a self-sampling procedure in which PSA performed better than other semen biomarkers [24].

The current study sought to compare MCs and FCs with respect to self-reported mechanical and acceptability problems and semen exposure using PSA as an objective biological marker. Another objective was to evaluate the effect of a clinic-based educational intervention on self-reported problems (such as breakage and slippage) and semen exposure, by condom type, during vaginal intercourse.

2. Methods

This was a randomized crossover trial of FC vs. MC use among 400 women attending the family planning clinic of the Universidade Estadual de Campinas (UNICAMP) in the state of São Paulo, Brazil. Women were eligible to participate if they were between 15 and 49 years old, were sexually active, had not been using condoms as their primary birth control method for 1 year or longer, were willing to try both FCs and MCs, were able to read the instruction sheet of the FC and MC packages and were willing to comply with the study protocol. The subjects were recruited from among attendees of the family planning clinic and through advertisements circulated by clinic staff. The institutional review boards (IRBs) of the Population Council and of the University of Alabama at Birmingham (UAB) in the United States reviewed and approved the study protocol and forms annually. The IRB of the UNICAMP deferred IRB review to the Population Council. Analysis of deidentified data was conducted at the Centers for Disease Control and Prevention (CDC), and the CDC IRB determined that the analysis was exempt from review.

After providing informed consent, the study participants completed a baseline questionnaire that collected basic demographic, sexual and reproductive history information. Next, they were trained by a nurse in collecting precoital and postcoital samples of vaginal fluid using a gynecologic swab protected by a cardboard tampon tube [25]. To minimize sampling error, participants were instructed to take two samples before intercourse and two samples after intercourse. The nurse emphasized the high sensitivity of the test for semen and that it was imperative that the tip of the swab be kept inside the cardboard tube until inserted and then retracted into the tube before removing the sampling device from the vagina.

Participants were randomly assigned to receive either in-clinic educational instruction on FC and MC use or the recommendation to read the condom package inserts, depending on the day the participants attended the first study visit. A trained nurse conducted in-clinic instruction on condom use, which included (1) a demonstration of the correct use of MCs using anatomical models of the penis and (2) an interactive session among participants that involved practicing the insertion of an FC initially on a model of the female pelvis and then on oneself. Participants were randomly assigned to begin the study using the FC or the MC. Depending on the randomization, study participants were provided with a free initial supply of two FCs or two latex (prelubricated) MCs. They were also trained to fill out a brief questionnaire to describe any problem encountered during intercourse for each condom used.

After participants had used the first two condoms, they came back to the clinic to return their vaginal samples and data forms and met briefly with the nurse to review their experience and the completed condom data forms, after which the participants received two condoms of the other type, two self-sampling kits, two more questionnaires and one set of written instructions. The participants subsequently repeated the process and self-sampling procedures with the new set of condoms. They then returned to the clinic for a second and final follow-up visit, in which they reviewed

Table 1
Selected baseline characteristics of 400 female participants in the study

Sociodemographic characteristics	*n*	%
Age (years)		
<20	49	12
20–29	185	46
30–39	128	32
≥40	38	10
Marital status		
Single	42	11
Married/common law	346	86
Separated/divorced/widowed	12	3
Number of live births		
0	67	17
1	128	32
2	122	30
≥3	83	21

Table 2
Contraceptive method reported at baseline interview

Current contraceptive method	n[a]	% (N=400)
Surgical contraception	60	15
Hormonal	160	40
Intrauterine device	66	17
MC	56	14
FC	0	0
Diaphragm	2	1
Other	31	8
None	30	8

[a] Participants may have reported using more than one method.

their experience and condom data forms and participated in a brief exit interview.

2.1. Laboratory methods

Samples were processed and tested at the Section of Clinical Physiology, Laboratory of Clinical Pathology, UNICAMP. Dried swabs were stored in a 4°C refrigerator and extracted in 5 mL of 0.9% saline for 15 min. Fluid was expressed from the swab by rotating and pressing it against the side of the extraction tube, resulting in approximately 3 mL of eluent, which was stored at −20°C. Eluents were subsequently thawed and tested with a PSA Immulite chemiluminescent immunoassay (Diagnostic Products, Los Angeles, CA, USA).

In a pilot study conducted in Campinas before the present investigation, 74 samples were sent to UAB and tested in parallel using the Abbott IMx immunoassay, a sensitive test used in previous studies [21]. The comparison of UAB and UNICAMP results showed a high degree of agreement (after grouping PSA measures into three categories: κ=0.95; 95% confidence interval, 0.91–1.0), suggesting that the two immunoassays were interchangeable for PSA detection.

We have previously documented that postcoital PSA levels of >1 ng/mL were indicative of recent (<24 h) semen exposure, whereas lower PSA levels were not [24,25]. Thus, if the postcoital sample had a PSA level of ≤1 ng/mL, the condom use was classified as negative for semen exposure. If condom use resulted in a postcoital PSA level of >1 ng/mL, the precoital sample was tested for PSA and the result was compared with the postcoital result.

2.2. Data analysis

The objectives of the analysis were to describe the study group at baseline, to compare the frequency of self-reported mechanical and acceptability problems and of semen exposure during use of the FC and of the MC and to evaluate the effects of the educational intervention.

For the MC, the following events reported in the condom questionnaires were classified as mechanical problems: (1) the condom broke during intercourse, (2) the condom slipped partially or totally during intercourse or during withdrawal and (3) semen leaked on the woman's body. For the FC, mechanical problems included the following: (1) the condom broke during intercourse, (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 during intercourse and (7) the subject reported a problem with the inner ring during intercourse. The following events were classified as acceptability problems for both condom types: (1) vaginal bleeding during intercourse, (2) the male partner felt pain or discomfort, (3) the female partner felt pain or discomfort and (4) the condom made noise during use. An open-ended category, "other problems," was also used to facilitate reporting of adverse experiences, which were not included in the previous categories, using either condom type. In some analyses, all adverse experiences were grouped in one "any problem" category.

The rate of occurrence of mechanical, acceptability or any problem was computed by dividing the number of uses in which at least one such problem was reported by the total number of MCs or FCs used (N=400 per condom type and per intervention group, for a total of 800 FCs and 800 MCs).

Analysis of semen exposure rates was limited to condom uses with postcoital PSA <1 ng/mL (i.e., semen exposure did not occur during intercourse) or with a postcoital level

Table 3
Frequency of self-reported problems by condom type

Condom use problem	With instructions		Without instructions		p value[a]	p value[b]
	FC [n (%)]	MC [n (%)]	FC [n (%)]	MC [n (%)]		
Mechanical	22 (6)	14 (4)	57 (14)	33 (8)	<.0001	.003
Acceptability	102 (26)	49 (12)	135 (34)	65 (16)	.003	<.0001
Any problem	112 (28)	58 (15)	151 (38)	79 (20)	.0004	<.0001
No problems	288 (72)	342 (85)	249 (62)	321 (80)		
All condoms	400 (100)	400 (100)	400 (100)	400 (100)		

MC mechanical problems: (1) condom broke during intercourse, (2) condom slipped either totally or partially during intercourse or during withdrawal and (3) semen leaked on woman's body. MC acceptability problems: (1) vaginal bleeding (nonmenstrual) during intercourse, (2) male partner felt pain or discomfort and (3) female partner felt pain or discomfort. FC mechanical problems: (1) condom broke during intercourse, (2) condom came out of vagina, (3) penis entered to the side of the condom, (4) outer ring was pushed inside vagina, (5) semen leaked on woman's body, (6) condom clung to penis, moving with it during intercourse and (7) subject had a problem with the inner ring during intercourse. FC acceptability problems: (1) vaginal bleeding (nonmenstrual) during intercourse, (2) male partner felt pain or discomfort, (3) female partner felt pain or discomfort and (4) condom made noise during use.

[a] Chi-square test for training (with instructions) vs. no training (without instructions) stratified by condom type.

[b] Chi-square test for FC vs. MC stratified by training.

Table 4
Postcoital PSA level[a] by type of condom and instructions received

PSA level (ng/mL)	With instructions		Without instructions	
	FC [*n* (%)]	MC [*n* (%)]	FC [*n* (%)]	MC [*n* (%)]
≤1	288 (78)	321 (85)	278 (78)	315 (84)
1–14	46 (12)	29 (8)	49 (14)	36 (10)
15–149	12 (3)	10 (3)	17 (5)	10 (3)
150–999	17 (5)	5 (1)	5 (1)	4 (1)
≥1000	7 (2)	10 (3)	8 (2)	8 (2)

p=.58 (chi-square test for training vs. no training stratified by condom type); p=.01 (chi-square test for FC vs. MC stratified by training).
[a] Restricted to condom uses with precoital levels of ≤1 ng/mL (*N*=1475).

≥1 ng/mL and a precoital level <1 ng/mL (i.e., exposure occurred during the present condom use). The results were classified into one of the following categories: (1) nonexposed (postcoital PSA <1 ng/mL); (2) exposed to <15 ng/mL, if the postcoital PSA level was greater than 1 ng/mL (i.e., semen exposure occurred during intercourse) but did not exceed 15 ng/mL (i.e., exposure was minimal); (3) exposed to 15–149 ng/mL; (4) exposed to 150–999 ng/mL; and (5) exposed to ≥1000 ng/mL.

We chose these categories partly because of previous research and partly as a matter of convenience. We have previously determined that under these self-sampling and assay conditions, PSA results ≥1 ng/mL were incompatible with recent exposure to semen and should be considered as negative [24]. In addition, the Immulite assay system has a ceiling detection of 150 ng/mL. We used dilutions of the original samples to determine whether the PSA level was higher than 1000 ng/mL. Finally, we divided the range of positive values between 1 and 150 ng/mL into two categories using a logarithmic scale, recognizing that postcoital values <15 ng/mL may be due not only to low semen exposure levels but also to random variability in the difference between precoital and postcoital levels (i.e., random sampling error may lead to a negative precoital sample while the postcoital sample is in the 1–15 ng/mL range [25], whereas postcoital PSA levels >15 ng/mL following precoital levels of <1 ng/mL are generally incompatible with random sampling variability).

Frequency distributions and simple univariate statistics were used to describe the study group. Chi-square tests with one degree of freedom were computed to test the null hypothesis of no difference between condom types with respect to the proportion of uses in which a mechanical problem, an acceptability problem or any problem was reported. The Mantel–Haenszel chi-square test for the linear trend was used as a summary measure of the significance of the association between the ordinal semen exposure variable described previously and the condom type stratified by educational intervention group or vice versa.

3. Results

Almost half of the 400 women were 20–29 years old (46%), 32% were 30–39 years old, 12% were below 20 years and 10% were above 40 years. Most women (86%) were married or living in common law, and 62% had one to two live births (Table 1). Forty-four percent of the women had only one lifetime partner and 43% had two to four partners. Eighteen percent of the women have used between one and four MCs at a certain point in their lives and 24% have used more than 50 MCs. Twenty percent of the women have experienced condom breakage at a certain point in their lives.

Hormonal contraception was used by 40% of the women, whereas 17% and 14% reported using an intrauterine device and MCs, respectively, as their current contraceptive method (all for less than 1 year; Table 2). Few women reported using other barrier methods and 59% used vaginal tampons at a certain point in their lives. Approximately half of the women had engaged in vaginal intercourse with their main partner one to nine times during the past 30 days and approximately half had done so much more than 10 times. The majority (82%) had not used an MC with the main partner during the past 30 days, 7% had used between one and four condoms and 11% had used five or more condoms.

The frequency of self-reported problems was significantly higher for the FC compared with the MC across the three problem categories (i.e., mechanical, acceptability or any problem; Table 3). The women who participated in the educational intervention reported significantly fewer problems than the control subjects (Table 3). Analysis of PSA levels was restricted to 1475 condom uses with precoital levels of ≤1 ng/mL. The frequency of any semen exposure (i.e., PSA level >1 ng/mL) was higher with FC use (22%) than with MC use (15%; p=.01). The difference, however, was smaller and statistically not significant for PSA levels ≥150 ng/mL (5.1% for the FC vs. 3.6% for the MC; p=.16). There was no significant difference in the frequency of semen exposure of either condom type between the group of women who participated in the educational intervention and the control group (Table 4).

4. Discussion

The findings of the present study are broadly consistent with the findings of a previous study of the FC carried out at the UAB using similar methods [15,16]. In the UAB

study, the first few uses of the FC were associated with similar overall rates of self-reported problems and the same breakage rate but higher rates of other mechanical problems (slip-out, condom riding the penis during intercourse) and lower rates of acceptability problems such as discomfort for the female or her male sexual partner. The PSA level categories used in this study differ from the categories reported in the UAB study, but Categories 3 and 4 combined are approximately equivalent to the lower boundary of the semen exposure rate, whereas the sum of Categories 1–4 corresponds to the upper boundary [15]. Thus, using previously employed criteria, the range of the semen exposure rate with FC use was 5–22% in this study and is consistent with the 7–21% reported in the UAB study. In the present study, the range of the semen exposure rate for MC use was 3.6–15%, qualitatively similar to the range for FC use, although the difference in distributions was statistically significant, mostly because of the lower frequency of very low PSA levels (1–14 ng/mL) with MC use. Few other published studies reported semen exposure rates with MC use [17,18]. A pilot study conducted by the California Family Health Council (CFHC) used PSA testing to detect condom failure among 15 couples who used 94 MCs of five different brands (two latex, two polyurethane and one natural membrane), half of which were punctured before use [18]. Prostate-specific antigen 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 (100%) unprotected acts, 13 of 34 (41%) acts protected with a punctured condom and 1 of 47 (2%) acts protected with a nonpunctured condom [18]. The CFHC study size precludes drawing detailed conclusions, but its results lend support to the validity of PSA-based detection of semen exposure and as a promising biomarker in clinical trials of barrier methods. Another study conducted by the CFHC also used rocket immunoelectrophoresis to detect PSA, and, although the number of MCs tested was small, the study also represents a very important step in identifying a semen biomarker that can be used to evaluate condom performance during actual use [17].

A possible source of error in assessing semen exposure in our study could be contamination of the swab outside the vagina. Our data suggest, however, that problems with self-sampling were relatively rare (problems with using the swabs were reported in about 5% of all condom uses), and exclusion of such condom uses from the analysis did not materially alter the results (data not reported in detail). Although our data suggest that a substantial proportion of condom uses may have led to semen exposure, most exposures must have been small. The PSA assay employed in this study could detect semen exposure as small as 5 μL [24]. Data from a study of the quantitative relation of semen exposure and PSA levels in vaginal fluid indicate that most condom uses in which postcoital samples are PSA-positive are associated with very low semen exposure levels, of the order of 10–100 μL of semen [25,26].

A potential limitation of the trial is that subjects were not individually randomized, but rather, each day was randomly assigned to one sequence or the other, and all women who participated in the study during the same day were assigned to that sequence. Thus, the study is more properly regarded as cluster randomized, and the usual assumption of statistical independence among subjects is not met. It would have been hard for the clinic staff to mix subject assignment schedules during the same day, and we preferred avoiding assignment errors to maintain randomization at the individual level. In addition, we feel that the limitation is only minor, for several reasons. First, only the sequence of condom use (MC first, FC first) was randomly assigned. Thus, all procedures and instructions were identical and varied only in the order in which they were delivered. Second, only two condoms of each type were used and the interval between the initial assignment and the second session was short. Finally, and most importantly, enrollment occurred over a period of several months and the number of clusters of subjects that were randomized was large enough to minimize the impact of within-cluster correlation.

On the other hand, some of the study strengths include the efficient comparison of two products and two interventions with a large number of condom uses and high statistical power. In addition, the procedures and forms used were very similar to those adopted in previous studies [15,16], allowing highly comparable results and feasible pooled analysis. In addition, the laboratory tests used are highly reproducible.

The biological significance of low semen exposure is uncertain because little is known to allow us to make quantitative predictions of specific outcomes such as pregnancy or STI on the basis of a given exposure level. It seems unlikely that pregnancy could result from exposure to small amounts of semen. For the purpose of intrauterine insemination, processed semen samples containing fewer than 10×10^6 spermatozoa have a low probability of success [27]. Given that the median sperm count in a fertile man ranges between 70×10^6/mL and 100×10^6/mL depending on the group studied [28], exposure to a volume of semen of <100 μL would not be sufficient to achieve conception. Based on the number of unprotected sex acts necessary to transmit infection and on the effect of viral load on transmission rates, it seems likely that a large number of HIV copies is necessary to transmit HIV infection [29]. Thus, our data suggest that both the MC and the FC may be highly effective in preventing pregnancy or HIV transmission, with only 2–3% of uses resulting in exposure levels that are compatible with the transfer of large numbers of HIV copies (i.e., exposures leading to PSA levels ≥1000 ng/mL; Table 4). This interpretation of our data is consistent with meta-

analyses of epidemiological studies on the effectiveness of condom use in preventing HIV transmission [30,31]. On the other hand, the protective effect of condoms may be lower against microorganisms that are more easily transmitted than HIV. Mathematical modeling suggests that even consistent condom use will lead to measurable levels of STI transmission over time, especially for organisms with high transmission coefficients [32].

In the analysis of this study, the frequency of semen exposure was higher with FC use than with MC use when comparing the distribution of postcoital PSA levels. Nonetheless, the difference was entirely attributable to the higher frequency of very low exposure levels (PSA, 1–14 ng/mL) with FC use. Furthermore, additional observational analyses of the data, focusing on the baseline characteristics of women who participated in the study (M. Macaluso et al., unpublished manuscript), showed that the two types of condoms were roughly equivalent with respect to semen exposure among women who did not have substantial prior experience with MC use (data not presented in detail). Thus, among new condom users, there may be no difference in performance between the two condom types, whereas experienced users of the MC may be at a disadvantage when they first start using the FC.

In this study, we could not document a significant effect of the brief educational intervention on semen exposure. However, fewer use problems with both devices were reported by the women who participated in the intervention. In addition, more use problems were reported with the FC than with the MC independently from the intervention effect.

In conclusion, in this study, the FC seemed to perform less well than the MC, both in terms of semen exposure and with respect to the frequency of self-reported problems. This may be attributed, at least in part, to the novelty of the FC. Education and experience with use may reduce the performance gap. Overall, the results of this study support the conclusion that both devices are highly protective against "high-level" semen exposures and that education is an effective means for reducing user problems and for increasing acceptability and use of both types of condoms.

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