

the past 30 days. In all, 108 women enrolled and were randomly assigned to receive either 10 male or 10 female condoms. All participants received instruction on correct use of the assigned method and were taught to collect samples of vaginal fluid. The women were then asked to collect one sample before and one after using each condom, to place the samples and the used condom in a prelabeled bag, and to return the bag to the clinic the next business day, along with a form on which they reported problems with the condom or with the device for collecting the samples. After using the first 10 condoms, women repeated the process with the second type of condom.

To determine semen exposure, the researchers first assessed the PSA level (measured in nanograms per milliliter) of the postcoital sample of vaginal fluid. If PSA was detected (i.e., if the level was more than 1 ng/ml), they assessed the precoital sample, to rule out previous exposure.

Study participants were predominantly white (78%) and married (77%); six in 10 had been in their current relationship for at least five years. Eighty-nine percent had ever used a male condom with a main partner; 19% of these had experienced condom breakage, and 43% condom slippage. Only 6% had ever used a female condom with their current partner. Most (69%) had not used condoms in the past 30 days. Background characteristics did not differ between women assigned to use male condoms first and those assigned to use female condoms first.

Participants returned 700 male and 678 female condoms to the clinic. Nine percent of male condoms were accompanied by reports of mechanical problems (primarily breakage or slippage), and 68% by reports of partial or incorrect use. Thirty-four percent of forms returned with female condoms noted mechanical problems (mainly that the condom broke or slipped, the penis entered to the side of the device or the condom's outer ring was pushed into the vagina), and 8% recorded instances of incorrect use.

PSA assessments of the vaginal fluid samples indicated that women had been exposed to semen 14% of the time they used male condoms and 17% of the time they used female condoms; the difference was not statistically significant. Moderate or high levels of PSA (22 ng/ml or more), which indicate sufficient semen exposure to pose a risk of STD transmission, were detected in 4% of samples accompanying male condoms

Female and Male Condoms Offer Similar Protection Against Exposure to Semen

Breakage, slippage and other mechanical problems occur more frequently with female than with male condoms, but the two devices are about equally effective barriers to semen exposure, according to findings from a randomized crossover trial conducted among women attending an Alabama reproductive health clinic in 2000–2001.¹ Prostate-specific antigen (PSA), an indicator of exposure to semen, was detected in similar proportions of vaginal fluid samples collected after use of male and female condoms during the study—14% and 17%, respectively. PSA was present in high enough levels to potentially affect STD risk in 4–5% of samples associated with each type of device. Exposure to semen was more common if women reported mechanical problems with condoms than if they reported incorrect use.

Women were eligible to participate in the study if they were at least 19 years old, were in a mutually monogamous relationship, had not had an STD in the past six months and had had intercourse at least four times in

and 5% of those submitted with female condoms; the confidence interval around this one-point difference (-1.6 to 3.7) was not narrow enough to establish that the difference was statistically significant. PSA levels did not change with successive uses of male condoms but declined significantly with each use of female condoms.

The frequency with which moderate or high PSA levels were detected was related to the types of problems women reported with use of each method. For male condoms, such levels were more common if the device had slipped (20%), broken (11%) or been put on incorrectly (8%) than if the man had withdrawn without holding its base (1%) or if the couple had had no problems using it (3%). For female condoms, moderate or high exposure was fairly frequent if the penis had entered to the side of the device (11%), if the device's outer ring had been pushed into the vagina or had slipped (8%), or if other mechanical problems were reported (10%); the only report of breakage was accompanied by a vaginal fluid sample with a moderate or high PSA level. By contrast, no reports of incorrect use were accompanied by such levels, and exposure was moderate or high in only 3% of instances in which no problems were reported.

According to the researchers, their findings on moderate and high PSA levels do not "exclude a moderate difference in performance" between the two types of condoms, but the results indicate that "large differences are unlikely." Thus, the investigators comment that in conjunction with findings from other studies, their results suggest "that although the female condom performs less well than the male condom in the first few uses, its effectiveness over repeated use is similar." While acknowledging a number of limitations of their study (for example, participants were at low risk of STDs and had greater experience with male than with female condoms), the researchers conclude that it adds to the growing literature "shedding...new light on the risk of adverse outcomes determined by specific problems encountered by condom users."—D. Hollander

REFERENCE

1. Macaluso M et al., Efficacy of the male latex condom and of the female polyurethane condom as barriers to semen during intercourse: a randomized clinical trial, *American Journal of Epidemiology*, 2007, 166(1):88–96.