Safety and acceptability of the Reality™ condom for anal sex among men who have sex with men

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Objectives: To assess safety and acceptability of Reality™ condoms for anal sex among men who have sex with men.

Methods: Crossover study among HIV-seroconcordant (33 HIV-negative and 5 HIV-positive) monogamous male couples, randomized to latex male and Reality condom use with anal sex.

Results: Slippage with removal was reported more frequently with Reality than male latex condoms [odds ratio (OR), 2.7; 95% confidence interval (CI), 1.2–5.8 for receptive partners and OR, 34.1; 95% CI, 13.8–84.1 for insertive partners]. Receptive partners more frequently reported pain or discomfort (OR, 5.0; 95% CI, 2.6–9.4) and rectal bleeding (OR, 1.9; 95% CI, 0.9–4.1) with Reality condoms than male condoms. Over 20% reported willingness to use the Reality condom in the future with a partner of unknown HIV status; willingness was associated with past problems with male condoms and no problems with Reality condoms among receptive partners, and with past use of Reality condoms and HIV seropositivity among insertive partners.

Conclusions: Men reported more frequent problems with Reality condoms than male latex condoms used for anal intercourse, particularly slippage, discomfort, and rectal bleeding. Design modifications, training, and research on the clinical significance of safety outcomes are needed for use of Reality condoms with anal sex.

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Introduction

Unprotected anal intercourse is the major mode of sexual transmission of HIV and other sexually transmitted infections between men and has been associated with increased heterosexual transmission risk [1,2]. Latex male condoms are the main barrier method promoted for HIV and sexually transmitted disease prevention but are associated with usage problems including breakage, slippage, latex allergies, and lack of control by receptive partners [3].

The Reality™ 'female condom' (Wisconsin Pharmaceutical Co., Chicago, Illinois, USA) was approved in the United States in 1992 for vaginal contraceptive use [4–6] and has since been reported to reduce reinfection with trichomonas [7]. The Reality condom has two flexible polyurethane rings and a thin, loose-fitting

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polyurethane sheath, demonstrated in laboratory studies to be impermeable to viruses and less likely to rupture than latex condoms [8]. The removable inner ring is used for insertion and to anchor the condom to the cervix; the non-removable ring at the open end of the sheath is designed to cover the external genitalia.

Previous studies of the Reality condom used for anal sex are limited. Among 10 monogamous, HIV-negative male couples who used an average of three Reality condoms, complaints were primarily seam abrasiveness and discomfort from the inner ring [9]. Approximately 20% of 100 men who have sex with men (MSM) who used one or two Reality condoms for anal sex reported problems with the Reality condom, 86% would use Reality condoms again, and 54% preferred them to male condoms [10]; higher acceptability of Reality condoms was reported by men who were HIV infected, in non-monogamous or HIV-serodiscordant partnerships. In a cohort of 2277 HIV-negative MSM, 13% of the 1084 men who had heard of the Reality condom for anal sex reported use in the prior 6 months and were at higher risk than men who had not used the Reality condom [11].

Given the need to identify safe and acceptable alternatives to the male condom and the limited safety data available for Reality condoms for anal sex, the present study compares Reality and male latex condoms for anal sex with respect to safety (breakage, slippage, rectal disruption, inflammation and bleeding) and acceptability in future partnerships.

Methods

Study population

The study enrolled 56 monogamous HIV-seroconcordant MSM couples who had not regularly used condoms in the past 3 months for a crossover study of male and Reality condoms. Participants were recruited from HIV clinics, advertisements, and outreach in Seattle, Washington, during 2001. Eligibility criteria were age $\geqslant 18$ years, relationship duration of $\geqslant 3$ months, and willingness to use each condom during anal sex up to 10 times (minimum of three uses for each type). Each couple designated one partner as receptive and the other as insertive for anal sex. Receptive partners were ineligible based on inflammatory bowel disease, rectal bleeding, or rectal surgery. The protocol was reviewed and approved by the University of Washington Institutional Review Board. All study participants provided written informed consent.

Study procedures

Baseline information was obtained at screening with HIV counseling and testing. At enrollment, couples were randomly assigned to an initial condom type, 10 Reality or lubricated male latex condoms without nonoxynol-9, to use with anal sex during the subsequent 6 weeks. In the second 6 weeks, couples crossed over to the other condom type. Couples were instructed to remove the inner ring of the Reality condom to reduce potential rectal trauma and bleeding, based on previous reports of discomfort and rectal bleeding from the inner ring [9–11].

Safety outcomes

Safety outcomes included self-reported condom breakage, condom slippage, semen spillage, rectal bleeding, and pain or discomfort during condom use. Participants were instructed to examine used condoms for breakage and bleeding. Condom slippage was defined as the condom slipping off the penis either into or out of the rectum during use or withdrawal. Anal Papanicolaou (Pap) smears for rectal inflammation were obtained from receptive partners at baseline and at the end of each condom phase; these were graded on a three-point scale, described previously [12]. Rectal epithelial disruption was assessed among receptive partners who consented to rectal biopsies at baseline and after each condom use phase. Biopsies were obtained with 2 mm forceps through an anoscope, 4 cm above the dentate line. Participants were instructed to refrain from anal sex for 1 week to allow for healing. Pathologists blindly evaluated epithelial disruption (loss of colonocytes), basement membrane disruption, ulceration, and degree of inflammation.

Acceptability outcomes

After each condom use, participants separately completed a structured diary sheet on safety outcomes. At the end of each period of 6 weeks, acceptability was assessed by willingness to use Reality or male condoms for anal sex in future partnerships of varying degrees of HIV risk, using a 5-point Likert scale (strongly preferring male condoms to strongly preferring Reality condoms). The primary acceptability outcome measure was strongly or somewhat preferring the Reality or male condom for anal sex with a new partner of unknown HIV status.

Statistical analysis

Data from receptive and insertive partners were analyzed separately. To compare the proportion of episodes of Reality and male condom use in which insertive and receptive partners reported specific problems, a per-use analysis was performed in which the denominator was the total number of condoms used by all men who completed the study. Odds ratios (OR), 95% confidence intervals (CI) and P values were calculated to compare risk of each of the safety outcomes for each type of condom. Generalized estimating equation logistic regression with robust standard errors

was used to take into account multiple non-independent observations for each individual [13]. Proportions of receptive and insertive individuals who reported specific problems with the Reality and male condoms were compared in a per-person analysis with calculation of McNemar's exact *P* values. The frequency of specific problems reported repeatedly by individual participants was also analyzed.

Results

Characteristics of the study sample

Of the 200 men who were pre-screened, 45 were not eligible, mainly because of non-monogamy or HIV discordant partnership, and 43 refused to participate because of time or partner's unwillingness. Of 112 men enrolled, 76 completed the study; their characteristics are summarized in Table 1. The only significant difference between men who did and did not complete the study was the proportion with current relationship of $\geqslant 2$ years (68% and 47%, respectively; $P = 0.03$). The most common reason for not completing the study was change in relationship (22%). HIV-positive couples used a total of 59 male and 50 Reality condoms and HIV-negative couples used 352 male and 349 Reality condoms.

Table 1. Demographic and behavioral characteristics of the 76 study participants.[a]

	No. (%)
HIV status	
Negative	66 (86.8)
Positive	10 (13.2)
Age (years)	
< 30	21 (27.6)
30–39	31 (40.8)
$\geqslant 40$	24 (31.6)
Education	
High school or less	31 (40.8)
College or higher	45 (59.2)
Race	
Caucasian	60 (79.0)
Others	16 (21.1)
Duration of relationship with partner	
< 2 years	24 (31.6)
$\geqslant 2$ years	52 (68.4)
Frequency of anal sex last month	
0–4	29 (38.2)
5–9	23 (30.3)
$\geqslant 10$	23 (30.3)
Male condom use last month	
Never	57 (75.0)
Once or more	18 (23.7)
Used Reality™ condom prior to study	
Never	59 (77.6)
Once or more	16 (21.1)
Past problems with male condoms	
Never	60 (79.0)
Once or more	16 (21.1)
Baseline opinion about male condoms	
Like	15 (19.7)
Neutral	34 (44.7)
Dislike	26 (34.2)

[a]Data presented only for participants who used a minimum of three Reality™ and three male condoms after enrollment (i.e., the couples who completed the study). Totals may vary for some variables because of missing responses.

User problems analyzed on per-use basis

Receptive partners were more likely to report pain or discomfort with use of Reality than with male condoms (Table 2), described as mild and often attributed to the Reality condom outer seam, a burning sensation, or excessive bunching of the Reality condom. Both partners were significantly more likely to report Reality condom slippage during use or withdrawal. Differences in reported rectal bleeding did not reach statistical significance (OR, 1.9; 95% CI, 0.9–4.1 for Reality versus male condoms). Rates of condom breakage were similar for Reality and male condoms.

User problems analyzed on per-person basis

Reality condom slippage was reported at least once by 76% of receptive partners and 90% of insertive partners, compared with 50% ($P = 0.04$) and 21% ($P < 0.001$), respectively, with male condoms. Slippage of the Reality condom was reported five or more times by 29% of receptive and 57% of insertive partners. Differences in pain or discomfort with Reality (55%) compared with male condoms (37%) ($P = 0.12$) and rectal bleeding after intercourse with Reality (32%) versus male condoms (16%) ($P = 0.15$) did not reach significance. Receptive partners reported multiple (two or more) occurrences of condom breakage infrequently (5% and 8% for male and Reality condoms, respectively).

Anal inflammation and rectal mucosal epithelial disruption

Among 34 receptive partners with complete anal Pap data, mild (grade 1+) inflammation was observed in seven (21%) of baseline anal Pap smears. Among men without baseline inflammation, the same proportion of receptive partners (11%) had inflammation on anal Pap smears at the end of the Reality and male condom phases. Five (19%) receptive partners had epithelial disruption observed at baseline, limited to loss of surface colonocytes without basement membrane disruption. There was no difference in epithelial disruption after Reality condom and male condom use (36% and 29%, respectively; McNemar's exact $P = 0.69$). Concordance of epithelial disruption on rectal biopsies and semiquantitative measures of anal inflammation on Pap smears for a given sampling time was modest ($k = 0.27$).

Willingness to use Reality condoms with future partners

Willingness to use Reality condoms in the future with

Table 2. Proportion of Reality™ and male condom uses with self-reported safety or usage problems.

	Condom use receptive partners (%)				Condom use insertive partners (%)			
	Reality	Male	OR (95% CI)[a]	*P* value	Reality	Male	OR (95% CI)[a]	*P* value
N[b]	406	411			400	414		
Condom breakage	3.7	2.4	1.5 (0.6–4.2)	0.4	ND	2.2		
Condom slippage	33.5	15.8	2.7 (1.2–5.8)	0.01	52.5	3.1	34.1 (13.8–84.1)	< 0.001
Pain or discomfort	23.7	5.8	5.0 (2.6–9.4)	< 0.001	9.8	10.4	0.9 (0.4–2.4)	0.9
Rectal bleeding	6.7	3.7	1.9 (0.9–4.1)	0.1	ND			

ND, data not collected from insertive partners.
[a]Odds ratio (OR) comparing Reality condoms versus male condoms with confidence intervals (CI) using generalized estimating equation logistic regression robust standard errors.
[b]Total number of condoms used by all individuals who completed the study.

partner(s) of unknown HIV status was reported by 21% of receptive and 26% of insertive partners, compared with 61% for latex male condoms by both receptive and insertive partners. With a future HIV-positive insertive partner, 24% of HIV-negative receptive men would be willing to use Reality condoms; with a future HIV-negative receptive partner, 60% of HIV-positive insertive men would be willing to use Reality condoms. Among receptive partners, willingness to use Reality condoms was associated with recent male condom use, past problems with male condoms, and lack of problems with Reality condoms during the study (Pearson's chi-square test $P < 0.05$). Among insertive partners, willingness to use Reality condoms was associated with past Reality condom use, being HIV positive, and age ≥ 40 years (data not shown). The main reasons reported by participants for preferring the Reality condom with future partners of unknown HIV status were that the Reality condom was more comfortable, easier to use, and perceived to be stronger and safer. Among participants preferring the latex male condoms, the main reasons were ease of use, greater comfort, and lack of slippage.

Discussion

This crossover trial among HIV-seroconcordant MSM couples is the first prospective study comparing safety and acceptability of male latex and Reality condoms for anal sex with both objective (anal Pap, rectal biopsy) and subjective safety assessments. When compared with the male condom, men more frequently reported slippage of the Reality condom during use or withdrawal, caused in part by the loose fit of the Reality condom and the removal of the inner ring. Receptive partners reported significantly higher rates of mild pain or discomfort with the Reality condom than the male condom in the per-use, but not the per-person analysis, and a trend towards more frequent rectal bleeding after intercourse. A non-significant trend toward more frequent breakage with Reality condoms may result from low frequency and limited power of the study (80% to detect an OR of 2.4). Reported male condom breakage rates in this study are similar to previously reported rates during anal sex [3,10].

Problems associated with Reality condom use for anal sex in this study are similar to previous reports [10]. Frequent slippage of the Reality condom was not associated with semen spillage and, therefore, was unlikely to be a safety risk; nor did it adversely affect willingness to use Reality condoms. Slippage of Reality condoms did not diminish with increasing usage, suggesting it was not solely a consequence of participants' lack of experience with Reality condoms. Approximately 20% reported a willingness to use the Reality condom with future partners of unknown HIV serostatus, lower than reported previously (54%), possibly biased by the low response rate (14%) in the previous study [10]. Acceptability of Reality condoms may have been overestimated because participants may represent more motivated men.

Similar proportions of men had rectal epithelial disruption after each condom phase, and at a somewhat higher rate (although non-significant) than baseline, perhaps indicating rectal disruption from anal sex and not specific condom type. Although rectal epithelial disruption could indicate increased susceptibility to HIV or sexually transmitted diseases during subsequent exposure, this is uncertain since disruption was limited to surface colonocytes. Research on clinical correlations of surface rectal epithelial disruption and mild anal inflammation is needed for future studies of barrier protection methods and microbicides.

A design enrolling HIV-seroconcordant MSM couples in mutually monogamous relationships was selected as appropriate to test condom safety and acceptability, but it did involve substantial participant burden; almost one-third of eligible participants dropped out because of time constraints or relationship difficulties. Safety and usage problems may have been reported more

commonly after Reality condom use since it was a new barrier method for most participants. The non-significant trend towards higher rates of rectal bleeding with Reality condom use is surprising, given the substantial lubrication and loose fit; this may be associated with the lateral seam; further investigation with inversion of the Reality condom is warranted.

The objective of this study was to determine whether the Reality condom was a safe and acceptable form of barrier prevention among MSM who were not regular condom users. For the 20% in this study who reported a preference for Reality condoms, the potential utility and equivalent breakage and inflammation rates are balanced by a need for further evaluation of rectal bleeding and the significance and sources of discomfort. Training is needed related to slippage and methods for avoiding semen spillage that might expose anal mucosa. Given recent increasing rates of HIV and sexually transmitted diseases among MSM, effective and acceptable barrier protection methods for anal sex for MSM and heterosexuals who engage in anal sex must be identified. Further work is warranted on design modifications, safety and acceptability of the Reality condom in HIV-negative MSM, as well as accelerated efforts to develop non-barrier methods such as rectal microbicides.

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