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Breakage and Acceptability of a Polyurethane Condom: A Randomized, Controlled Study

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Context: *Although the first commercial polyurethane condom was approved for use several years ago, no U.S. clinical trial has compared its performance to that of the latex condom.*

Methods: *In a masked crossover study, 360 couples were randomized to use three polyurethane condoms and three latex condoms. After each use, couples recorded condom breaks, condom slips and other aspects of performance. At completion of the study, couples compared the sensitivity, ease of use, fit and lubrication of the two types of condoms.*

Results: *The clinical breakage rate of the polyurethane condom was 7.2%, compared with 1.1% for the latex condom (relative risk of 6.6, 95% confidence interval of 3.5-12.3). The complete slippage rate (combining incidents during intercourse and withdrawal) of the polyurethane condom was 3.6%, compared with 0.6% for the latex condom (relative risk of 6.0, 95% confidence interval of 2.6-14.2). Most male users preferred the sensitivity provided by the polyurethane condom to that of the latex condom.*

Conclusions: *The clinical breakage rate of the polyurethane condom is significantly higher than that of the latex condom. However, nearly half of the users preferred the polyurethane condom, which provides an option for couples who have rejected conventional condoms or who cannot use latex products.*

The condom is the only nonsurgical method of male contraception marketed throughout the world, and it is recognized as highly effective against the sexual transmission of HIV. Nevertheless, condoms are underutilized compared with other methods and, for many consumers, are an unacceptable option.

Until recently, male condoms were available only in latex or in natural materials. However, it has long been recognized that polyurethane has many properties suited to condom production.¹ It is inherently stronger, though less elastic, than latex, and resists both oil-based lubricants and the harmful effects of ozone. In addition, polyurethane is usually odorless and transparent; given that these are attributes that some condom consumers prefer, use of polyurethane might produce condoms that people would use more consistently.

In 1994, the London International Group introduced the first male polyurethane condom in the United States, after having received premarket approval by the Food

and Drug Administration (FDA) in 1989. Prior to the commercial debut of this polyurethane condom, its manufacturer had commissioned a series of slippage and breakage studies; these indicated consistently low clinical breakage rates of 0.3-2.1%.²

A series of small-scale studies that compared this polyurethane condom and a latex control condom in 1991-1993, undertaken by the California Family Health Council (formerly known as the Los Angeles Regional Family Planning Council) in preparation for a contraceptive efficacy study, obtained breakage rates of 4-15% for the polyurethane condom and 1-2% for the latex condom, respectively.³ These small studies, however, lacked sufficient power to produce statistically significant results. In the following article, we report on a recent study specifically designed to overcome this limitation, one with sufficient power to detect an absolute difference of 2% or more between the clinical breakage rates of the two types of condoms.

METHODOLOGY

Study Population and Design

Study enrollment began in October 1995 and ended in February 1996; data collection was completed in April 1996. Participants were recruited through announcements placed in a local newspaper in the Los Angeles area. Of the 798 couples who responded, 360 (45%) eventually enrolled in the study, 96 (12%) were deemed ineligible and 342 (43%) declined to participate.

The study protocol conformed to the guidelines issued by the FDA in 1995, outlining current requirements for premarket approval of a condom made of new material.⁴ All participants were aged 18-45, were in a monogamous heterosexual relationship and were not at known risk of sexually transmitted diseases (STDs). While half of the 360 enrolled couples were using an effective nonbarrier back-up method at the beginning of the study and continued to do so throughout, the other half relied on the study condoms alone for pregnancy prevention.

The single-masked, crossover clinical study compared a polyurethane condom (marketed as AvantiTM) with a latex condom (Ramses SensitolTM). Couples were required to use three condoms of one type, followed by three of the other type. Informed consent was obtained from each partner before enrollment. All data were collected on self-administered, standardized questionnaires.

Both partners completed three visits as part of the study. At the enrollment visit, they were asked to provide data on their social and demographic characteristics, contraceptive use history, and current knowledge and attitudes about condom brands, including the study condoms. The 180 couples initially randomized to polyurethane and the 180 randomized to latex received the following supplies at their first visit—three condoms of the assigned type, a tube of water-based lubricant, a set of instructions for home reference, a penis measurement kit, and three use reports to record each condom's use and performance (breakage and slippage). In addition, at this first visit, a trained member of the research staff instructed participants on how to complete all forms and used a male anatomical model to demonstrate how to use condoms correctly and how to use the kit to measure penis length and circumference.

At the follow-up visit approximately two weeks later, the remaining couples—175 in

the original polyurethane group and 173 in the original latex group^{*}—returned the completed condom use reports and measurement records. In addition, each partner independently completed a questionnaire summarizing what they had liked and disliked about the first set of condoms. These participants then "crossed over" to the type of condom that they had not yet used, and received three of those condoms and three use reports to complete at home.

At the exit visit, which took place approximately two weeks later, the remaining couples from the second visit—168 of the 175 who crossed over from polyurethane to latex and 171 of the 173 who crossed over from latex to polyurethane[†]—returned the second set of reports, and each partner again independently completed a questionnaire on his or her experience with the second set of condoms. Each partner independently compared the two study condoms, by rating various measures of acceptability of the condom and its lubricant. Thus, data were available for analysis on 1,036 individual polyurethane condoms (96% of the 1,080 available for distribution) and 1,023 latex condoms (95% of the available 1,080).

The Study Condoms

Both types of condoms used in the study were made and packaged by the same manufacturer (London International Group).[‡] Both the polyurethane and latex condoms are nipple-tipped and packaged with a silicone-based lubricant. They are identical in length (180 mm) and in open-end diameter (33 mm). The wall of the polyurethane condom is thinner than that of the latex condom (0.035-0.040 mm vs. 0.070-0.080 mm),[§] and when laid flat, the polyurethane condom is wider than the latex condom (64 mm vs. 52 mm).

Assignment and Masking

We purchased equal numbers of polyurethane and latex condoms at 16 retail stores throughout the greater Los Angeles area. The polyurethane condoms represented 27 lots, the oldest manufactured in February 1994, while the latex condoms represented 15 lots, with the oldest dating from March 1993. No single lot or store contributed more than 10% of the condoms to either condom group.

The sample of polyurethane condoms was evenly split between condoms packaged as Avanti and as Avanti Super Thin. We divided the condoms into sets containing either three latex or three polyurethane condoms from different lots and dates of manufacture. We numbered each condom package within a set to specify its order of use and placed all three condoms in a sealed envelope labeled by couple identification number.

We used a computer-generated sequence of binary numbers to randomly assign couples to begin with either condom. Neither the research staff nor the participants knew which condom type was distributed at the enrollment visit. However, since we used commercially packaged condoms, participants discovered the identity of the condoms after opening the envelope. Since the data collection forms had no identifying information, though, the investigators and research staff did not know which condoms had been used until the data collection and processing were complete.

OUTCOME MEASURES AND ANALYSES

Table 1 illustrates the definitions of the various condom failure rates that are the outcome measures of the analysis; these definitions are consistent with those outlined previously.⁵ We were especially interested in total failures (which combine clinical and nonclinical failures), total clinical failures (which include all breaks and slip-offs among condoms used for intercourse) and clinical breakage (all breaks among condoms used for intercourse). Secondary outcome measures include the rates of total breakage (breaks among both condoms used for intercourse and those opened but not ultimately used) and complete slippage (both during intercourse and during withdrawal), as well as several measures of condom acceptability.

Measure	Numerator	Denominator
Nonclinical failure	No. of condoms that could not be used because of breaks, donning problems or defect	No. of condoms opened for use
Total clinical failure	No. of condoms that broke during intercourse or withdrawal, plus the no. that slipped off penis during intercourse or withdrawal	No. of condoms used for intercourse
Clinical breakage	No. of condoms that broke during intercourse or withdrawal	same
Complete slippage	No. of condoms that slipped off penis during intercourse or withdrawal	same
During intercourse	No. of condoms that slipped off penis during intercourse	same
During withdrawal	No. of condoms that slipped off penis during withdrawal	same
Total failure	No. of condoms that broke during package opening, donning, intercourse or withdrawal, plus no. that slipped off penis during intercourse or withdrawal, plus no. that could not be used (donning problems or defect)	No. of condoms opened for use
Total breakage	No. of condoms that broke during package opening, donning, intercourse or withdrawal	same
Total slippage	No. of condoms that slipped off penis during intercourse or withdrawal	same
Other failure	No. of condoms that could not be used for reasons other than breakage (donning problems or defect)	same

We based the study's sample size on the assumption that the latex condom would have a clinical breakage rate of 2%. The study was designed to detect in the experimental condom a doubling of this clinical breakage rate of the control condom ($\alpha < .05$; $\beta < .2$). To minimize the possibility that couples prone to condom failure might contribute a disproportionate number of outcomes (breaks and slip-offs), we limited couples to three uses of each study condom. Thus, to ensure data from at least 1,000 uses of each condom type, we estimated that we had to enroll at least 360 couples (to contribute data on up to 1,080 uses of each type).

We used chi-square tests of homogeneity or Fisher's exact test (where the expected cell sizes were small) to compare breakage, slippage and failure rates for the polyurethane

and latex condoms. All p-values presented in this article are two-tailed. We used EpiInfo Version 6-Statcalc to compute risk ratios and 95% confidence intervals for the failure rates of the two condom types, using individual uses as the unit of analysis.

The same tests were used to assess the statistical significance of risk factors associated with clinical breakage of the polyurethane condom. We entered risk factors with p values less than .15 into a forward stepwise logistic regression analysis, using the SAS Logistic package, to determine the major predictors of condom breakage. Since we included both couple and condom use factors, condom use became the unit of analysis. The stepwise regression program was instructed to enter sequentially all variables with p-values below .15, and to remove variables that entered the model if their p-value subsequently exceeded .10.⁶ (Significance levels should be viewed with caution, since we relied on a stepwise procedure for variable selection. Also, the assumption of independence may have been violated because each couple contributed up to three observations.)

We used the LogXact software package to perform logistic regression analysis, which included condom type and was stratified by couple. We relied on a two-sided, exact conditional scores test to compare total clinical failure rates and their two components—rates of breakage and of slip-offs among condoms used for intercourse—for both study condoms.

RESULTS

Participant Characteristics

A majority of participants were younger than age 30 and were non-Hispanic white (Table 2). Sixty-three percent of men and 57% of women were employed, either full-time or part-time. Approximately 45% of men and 30% of women reported having had more than 10 sexual partners during their lifetime. Slightly less than half (47%) of participants had ever been pregnant or been responsible for a pregnancy, and roughly one-third (30-33%) reported that they or their partner had had an abortion. Nearly three-quarters (74%) of the men were circumcised.

Table 2. Percentage distribution of participants in condom trial, by characteristics at enrollment, according to sex, Los Angeles, 1995-1996

Characteristic	Male (n=360)	Female (n=360)
Age		
18-20	8	14
21-25	32	38
26-30	31	29
31-45	29	19
Race/ethnicity		
Non-Hispanic white	67	59
Hispanic	11	13
Black	12	9
Asian	5	12
Other	5	7
Education		
<high school	4	3

High school graduate/some college	53	53
College graduate	43	44
Employed		
Yes	63	57
No	37	43
Currently smokes		
Yes	26	24
No	74	76
Alcohol consumption		
Weekly/daily	45	33
Other	55	67
No. of lifetime sexual partners		
≤10	55	70
>10	45	30
Ever pregnant/caused pregnancy		
Yes	47	47
No	53	53
History of induced abortion		
Yes	30	33
No	70	67
Circumcised		
Yes	74	na
No	26	na
Penis length		
<180 mm	80	na
≥180 mm	20	na
Penis circumference		
≤140 mm	79	na
≥140 mm	21	na
No. of times used condom		
≤10	18	14
>10	82	86
No. of condom breaks with previous partners		
≤5	92	97
>5	8	3
Total	100	100
<i>Note: na=not applicable.</i>		

Sixty-seven percent of the couples participating in the study were married or living together, while 20% had been in their current relationship for fewer than six months (not shown). Sixty percent of couples reported an annual household income of more than \$20,000. At enrollment, couples reported high coital frequency (59% said they had intercourse at least three times a week), and 28% of couples used a lubricant during intercourse. Among the 178 couples who were using some other, nonbarrier contraceptive method beside the condom, 82% were relying on the pill, and the remaining 12% were using other hormonal methods, the IUD or sterilization.

Most individuals, including both those who were using condoms only and those relying

on condoms plus their regular nonbarrier method, had extensive experience using condoms—82% of the men and 86% of women had used condoms more than 10 times over their lifetime, and 65% had used a condom at least 10 times with their study partner (not shown).

Few participants had experienced frequent condom breakage: Only 8% of men and 3% of women reported more than five instances of condoms breaking with previous partners. Only 3% of couples reported at least five instances of a condom breaking with their study partner before their participation in the study (not shown).

Less than half of participants (324 of 718) had heard in the media about the latex condom, while only 20% (143 of 718) had heard about the polyurethane condom; relatively few had already used either that specific latex brand (29%—210 of 716) or the polyurethane condom (7%—52 of 716). Among these users, 9% (18 of 210) who had tried the latex condom said the experience had been unfavorable, compared with 15% (eight of 52) of those who had tried the polyurethane condom.

CONDOM PERFORMANCE

• *General experience.* Table 3 describes the outcomes of the study condoms for which use was attempted and reported. Nearly 99% of the polyurethane condoms (N=1,036) and 98% of the latex condoms (N=1,023) were successfully donned. Unrolling difficulties accounted for most of the failures to don the polyurethane condom (eight of 11), while fit problems caused more than half of the donning failures with the latex condom (12 of 22). One polyurethane condom (0.1%) and three latex condoms (0.3%) broke during donning, while one latex condom was discarded because of a noticeable rip in the package (0.1%).

Table 3. Number of condom-use experiences reported, by type of condom

Experience	Polyurethan-	Latex
Total uses attempted	1,036	1,023
Not used for intercourse	11	22
Defective	0	1
Could not put on/unroll	8	6
Did not fit	2	12
Broke while putting on	1	3
Used for intercourse	1,025	1,001
Did not complete intercourse	88	15
Broke	74	11
Slipped off	14	4
Completed intercourse	937	986
Slipped off during withdrawal	23	2
Successfully used	914	984

Note: Table is based only on the number of condoms for which

Of the condoms that were successfully donned, 12% of the polyurethane condoms (124 of 1,033) and 7% of the latex condoms (75 of 1,021) were difficult to unroll (not shown). In addition, men reported problems with the fit of 3% of the polyurethane condoms (35 of 1,033) and with 11% of the latex condoms (117 of 1,021).

•**Breakage.** Approximately 17% of couples experienced one or more breaks when using a polyurethane condom (58 of 348), compared with 3% (10 of 348) when using a latex condom (not shown). Among the 58 couples who broke at least one polyurethane condom, 78% broke only one, 17% broke two and 5% broke all three polyurethane condoms. In contrast, nine couples broke one latex condom and only one couple broke two.

Table 4 shows that the clinical breakage rate for the polyurethane condom (based on the 1,025 polyurethane condoms used for intercourse) was 7.2%. This rate includes 72 condoms that broke during intercourse and two that broke during withdrawal. In comparison, 11 latex condoms broke during intercourse and none did so during withdrawal, yielding a clinical breakage rate of 1.1% (based on the 1,001 latex condoms used for intercourse). Thus, users of polyurethane condoms were 6.6 times as likely as latex condom users to experience a break.

Table 4. Number and percentage of selected types of condom failures, by type of condom used, and risk ratio (95% confidence interval)

Type of failure	Polyurethane		Latex		Risk ratio
	N	%	N	%	
Clinical					
Breakage	74	7.2	11	1.1	6.6 (3.5-12.3)
Complete slippage	37	3.6	6	0.6	6.0 (2.6-14.2)
During intercourse	14	1.4	4	0.4	3.4 (1.1-10.4)
During withdrawal	23	2.2	2	0.2	11.2 (2.7-47.5)
Total clinical failure	111	10.8	17	1.7	6.4 (3.9-10.5)
Total					
Breakage	75	7.2	14	1.4	5.3 (3.0-9.3)
Slippage	37	3.6	6	0.6	6.1 (2.6-14.4)
Other failure	10	1.0	19	1.9	0.5 (0.2-4.4)
Total failure	122	11.8	39	3.8	3.1 (2.2-4.4)
Notes: The Ns for clinical failures are 1,025 polyurethane condoms used for intercourse and 1,001 latex condoms; the Ns for total failures are 1,036 polyurethane condoms opened for use and 1,023 latex condoms.					

Although there were more clinical breaks with Avanti Super Thin (44) than with the Avanti (30), the clinical breakage rates for each style of polyurethane condom (8.6% and 5.8%, respectively) were significantly higher than that of the latex condom (p<.0001), even when analyzed separately.

The total breakage rate, based on the total number of condoms opened for use (1,036 polyurethane and 1,023 latex), was also 7.2% for the polyurethane condom, although it includes one additional break that occurred during donning. The comparable rate for the latex condom, on the other hand, includes three that broke during donning, yielding a total of 1.4%. Thus, when nonclinical condom breaks are considered, the

polyurethane condom was 5.3 times more likely to break than the latex condom.

- *Slippage.* Both types of study condom slipped completely off the penis during intercourse less often than they broke. The polyurethane condom's slippage rate during intercourse (1.4%) plus that during withdrawal (2.2%) produced a complete slippage rate of 3.6%. The comparable rate for slippage during intercourse for the latex condom was 0.4%, while the rate for slippage during withdrawal was 0.2%, yielding a complete slippage rate of 0.6%. Thus, total slippage rates were far higher for the polyurethane condom than for the latex condom (risk ratio of 6.0). (Slip-offs during withdrawal with either condom are considered preventable, since the instructions specified the need to hold on to the condom while withdrawing the penis.)

- *All failures.* The total clinical failure rate, which combines all incidents of breakage and slippage, was 10.8% for the polyurethane condom and 1.7% for the latex condom, which yields a risk ratio of 6.4. None of the clinical failures resulted in a pregnancy. The overall total failure rate, which covers both clinical and nonclinical failures, was 11.8% (122 of 1,036) for the polyurethane condom and 3.8% for the latex condom (39 of 1,023).

The differences in rates by condom type were confirmed by exact logistic regression analyses, stratified by couple and controlled for the sequence of use of each condom type. Two-sided exact conditional score tests produced highly significant differences by condom type in clinical rates of breakage, slippage and failure ($p < .0001$). The sequence of use was not significant in any of these models.

Data were also collected on other aspects of condom performance, including stretching, bunching and sliding along the shaft of the penis, as well as participants' reactions to specific attributes. Roughly 22% of the polyurethane condoms used by participants bunched and stretched, compared with 15% of the latex condoms. Moreover, 11% of the polyurethane condoms slid along the shaft of the penis, while 7% of the latex condom did so.

VARIABLES ASSOCIATED WITH BREAKAGE

A univariate analysis identified a number of characteristics at enrollment and condom preference and use variables that appeared significantly associated with clinical breakage of the polyurethane condom; these included the male partner being 25 or younger or a current smoker, a history of condom breakage with the study partner, a penis circumference of greater than 140 mm, condom slippage during intercourse, penile constriction caused by condom bunching and use of the rear-entry position for intercourse.

Some other variables that were less strongly related to the risk of a polyurethane condom breakage ($p < .15$) were the female partner being age 25 or having a high school education or less, having an annual household income of less than \$20,000, having been in the current relationship for less than six months, having ever been pregnant or responsible for a pregnancy, having a history of abortion, having intercourse at least three times weekly, having a penis length of more than 180 mm and reporting insufficient lubrication during intercourse.

Couples who were using a backup method along with the polyurethane condom did not

have significantly higher breakage rates than those relying on a condom alone ($p=.21$). Although such a significance level did not meet the criterion for inclusion in the multivariate model, we forced the entry of this variable into the analysis because study enrollment was stratified along these lines. The only variable that reduced the risk of breakage was the condom stretching during intercourse ($p=.09$).

We used stepwise logistic regression to assess the relative importance of these risk factors in clinical breakage of the polyurethane condom (Table 5). (We could not carry out a comparable stepwise logistic regression for the latex condom because there were too few clinical breaks.) The participant characteristics that significantly increased the likelihood of breakage, in order of declining significance, were history of condom breakage with study partner (odds ratio of 3.8), having been with the study partner for less than six months (odds ratio of 2.4), having ever been pregnant or caused a pregnancy (odds ratio of 1.9), having a penis longer than 180 mm (odds ratio of 1.9) and having an annual household income of less than \$20,000 (odds ratio of 1.8).

Table 5. Odds ratios from stepwise logistic regression on the likelihood of breakage of the polyurethane condom

Variable	Odds ratio	p value
Use of a backup method	1.6	0.08
History of condom breakage with study partner	3.8	0.0001
Use of rear entry position	2.7	0.0004
Relationship <6 months	2.4	0.01
Penile constriction with condom bunching	3.1	0.01
History of pregnancy	1.9	0.03
Condom stretching	0.4	0.03
Penis length >180 mm	1.9	0.04
Annual income <\$20,000	1.8	0.06
Condom sliding along shaft of penis	1.9	0.07

Note: Data refer to 63 breaks among 949 uses. All cases with missing values are excluded.

Those condom use variables that independently increased the likelihood of condom breakage included using the rear-entry position for intercourse (odds ratio of 2.7), the occurrence of penile constriction with condom bunching (odds ratio of 3.1) and having the condom slide along the shaft of the penis (odds ratio of 1.9). The sole variable that reduced the likelihood of polyurethane breakage was experiencing stretching of the condom (odds ratio of 0.4).

COMPLAINTS AND PREFERENCES

In their responses to a list of potential problems, male partners cited discomfort significantly less often with the polyurethane condom than with the latex condom (15% of uses vs. 23%, $p <.0001$). The greater likelihood of discomfort with the latex condom was largely because men complained more often that it constricted the penis; such a complaint was made in 17% of uses of the latex condoms, compared with just 7% of uses of the polyurethane condoms.

The female participants reported discomfort slightly more often than did the men—in

18% of instances in which the polyurethane condom was used and in 23% of uses of the latex condom. Women most commonly specified irritation (8% of polyurethane condoms and 10% of latex condoms) and burning (8% with each type of condom).

After completing use of a set of condoms, study participants were asked whether they had experienced any problems, and were requested to rate the severity of these problems. Moderate or severe problems that men encountered more often with the polyurethane condom than with the latex condom included loose fit (21% vs. 1%), slippage (19% vs. 11%), breakage (15% vs. 3%), stretching out of shape (14% vs. 8%) and having to avoid vigorous intercourse to prevent the condom from breaking or slipping (13% vs. 4%).

On the other hand, study participants reported several problems more frequently with the latex condoms than with the polyurethane condoms, such as lessened stimulation (41% vs. 26%), constriction of the penis (15% vs. 6%) and too tight of a fit (31% vs. 12%). The women's responses on these items were similar to those given by the men. Women also noted insufficient lubrication more often with latex condoms than with polyurethane condoms (27% vs. 21%), although men noted lubrication problems with nearly the same frequency for the two types of condoms (23% vs. 20%).

After using both types of condoms, participants were provided with a list of condom and lubricant attributes and were asked to specify whether they preferred one condom over the other in that specific attribute, or whether they had no preference.

Participants, both men and women, were as likely to express an overall preference for one condom as for the other—47% of men and women said they preferred the polyurethane condom overall, while 44-45% preferred the latex condom overall (Table 6).

Table 6. Percentage distribution of condom users, by condom preference, according to condom and lubricant characteristics

Characteristic	Male			Female			Total
	Polyurethane	Latex	No preference	Polyurethane	Latex	No preference	
Condom							
Attractiveness	26	26	48	27	23	50	100.0
Fit	33	43	23	na	na	na	100.0
Ease of unrolling	31	34	35	27	35	38	100.0
Sensitivity	51	28	21	47	25	28	100.0
Overall preference	47	44	9	47	45	7	100.0
Lubricant							
Amount	29	28	43	34	31	35	100.0
Persistence	27	27	46	33	29	39	100.0
Odor	24	14	63	19	14	67	100.0
Slipperiness	31	32	37	37	34	29	100.0
Less messiness	23	14	63	23	17	60	100.0
Overall preference	40	34	26	42	37	21	100.0

Note: na=not applicable.

However, the polyurethane condom was preferred over the latex condom in several

categories. For example, 51% of men preferred the sensitivity of the polyurethane condom over that of the latex condom, whereas 28% of men preferred the latex condom's sensitivity; comparable proportions among women were 47% and 25%, respectively. While the majority expressed no preference for the lubricant's odor (62%), the remaining men who had a preference favored the odor of the polyurethane condom's lubricant over that of the latex condom (24% vs. 14%, respectively); women also indicated a slight preference for the odor of lubricant in the polyurethane condom over the odor of that used in the latex condom (19% and 14%, respectively).

Similarly, the majority of respondents (60-63%) expressed no preference for either condom's lubricant in terms of messiness, but 23% of both men and women thought the polyurethane condom's lubricant was less messy, compared with 14-17% who perceived the latex condom's lubricant to be less so. Men specified a preference for the latex condom's fit over that of the polyurethane condom (43% vs. 33%).

DISCUSSION

This case-control study had many strengths, including high rates of compliance and continuation and the enrollment of couples, instead of individuals (which allowed for collection of more complete data on condom performance and acceptability than would have been possible otherwise). In addition, we employed a community-based recruitment strategy rather than a conventional clinic-based one to obtain an ethnically and economically diverse population that was representative of typical U.S. condom users.

Moreover, the study was unique, in that half of the participating couples were currently using the condom as their sole means of protection from pregnancy, while the other half were relying on a nonbarrier method, and were asked to continue their method use while participating in the study. Typically, studies of condom breakage and slippage limit enrollment to monogamous couples not at risk of pregnancy, who may not use condoms with the same degree of care as couples who need contraceptive protection. To minimize a potential "learning effect" should the risk of condom breakage decline with increasing use, we randomized the order in which couples used each type of condom. Finally, we limited couples to three uses of each condom, even though this increased the required number of participating couples. The low number of condoms used by each couple lessened the impact of couples predisposed to breakage.

Nonetheless, our study has several weaknesses that are inherent in most condom research. First, all of the study outcomes were self-reported. To improve the quality of the data collected, we used questionnaires pretested in our previous condom studies, and we required participants to complete separate reports immediately following each condom use.

Second, while our study population represented a large segment of the condom market, exclusion criteria as well as self-selection factors certainly prevented or discouraged certain users from participating. Among those subgroups that were not represented because of exclusion criteria were nonmonogamous couples, persons younger than age 18 or older than 45, and those at known risk of STDs. Moreover, the likelihood of self-selection meant that, to a large extent, persons of limited education and inexperienced condom users were not represented.

Third, because of the widespread availability of latex condoms, most participants (86%) had had considerable experience using them. Relatively short-term condom studies such as ours (i.e., a two-week duration in which a total of three polyurethane condoms are used) may not allow sufficient time for participants to become proficient in donning, fitting or using condoms made of a new material that may perform differently from latex. However, clinical breakage rates for the polyurethane condom were significantly higher even among those male participants who had had limited experience with latex. (Among those who had used only 10 or fewer condoms in their lifetime, clinical breakage rates were 8.6% for the polyurethane condom and 2.0% for the latex condom, $p=.004$.)

Fourth, our multivariate results identified several baseline characteristics of our study population that increased the risk of condom breakage. These included a history of condom breakage with the study partner and having been involved with that partner for a relatively short period (fewer than six months). Although clinical breakage rates were significantly higher for the polyurethane condom in all subgroups in our study, future trials might fail to detect a clinically important difference if the population were primarily composed of couples who were at low risk for condom breakage.

Fifth, couples used more than one condom of each type, so couples who are more likely to experience a condom break might have contributed a disproportionate number of condom breaks. The distribution of polyurethane condom breakage suggests some clustering of breaks: Although only 4% of couples broke more than one polyurethane condom, these couples contributed 39% of the total number of clinical breaks with the polyurethane condom. However, even when we excluded data from couples breaking more than one polyurethane condom, polyurethane clinical breaks still were five times more numerous than latex condom breaks (45 vs. nine, respectively).

Sixth, since this was an "open-label" study, participants might have been influenced by media exposure to or personal experience with one or the other brand of condoms studied. This potential for bias was limited, however, because participants' prior exposure to either study condom was minimal, and because among those who had used them, the proportions who had a negative experience were also quite low (9% for the polyurethane condom and 15% for the latex condom).

As one of the first large, randomized clinical trials to compare breakage and slippage of polyurethane and latex condoms, this study both provides data on a condom made from a new material and furthers what is known about latex condoms. The first commercial polyurethane condom broke significantly more often than the latex control; this held true among both those relying solely on condoms as their contraceptive method as well as among participants who continued to use their nonbarrier methods as a backup.

The factors identified in the multivariate analysis that increased the risk of breakage of the polyurethane condom involved either increased stress on the condom (rear-entry position and penis length) or greater movement of the condom during intercourse (bunching that resulted in penile constriction and sliding along the shaft).

Paradoxically, polyurethane condoms that stretched during intercourse broke less often than polyurethane condoms that did not stretch. Moreover, the polyurethane

condom appears to be more vulnerable to slipping off the penis during withdrawal when it is not firmly held as instructed.

Despite the higher failure rate for the polyurethane condom, nearly half of participants expressed a preference for it, which suggests that polyurethane may offer a viable alternative to consumers who have rejected latex condoms or who are unable to use latex products.

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*Five couples from the original polyurethane group and seven couples from the original latex group dropped out of the study at this stage. Reasons included disqualification for not using any of the study condoms, not complying with the study protocol and being lost to follow-up.

†Couples who stopped participating in the study at this point included six couples who broke up (all from the original polyurethane group), one couple who experienced discomfort using condoms (from the original polyurethane group) and two couples who found the study too time-consuming (from the original latex group).

‡The polyurethane condom was marketed in two nearly identical styles—either Avanti™ or Avanti Super Thin™ (which, while the same thickness, is coated with slightly more lubricant)—and both styles were treated as the same product by the FDA.

§According to the condom's manufacturer, the thickness of the polyurethane condoms used in our study was increased in April 1996, about the time our study was completed (personal communication with W.D. Potter, director, Group Scientific Affairs, London International Group, London, May 1997).

