Can Condom Users Likely to Experience Condom Failure Be Identified?

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A study based on a convenience sample of 177 couples who each used 11 condoms found that 103 condoms (5.3%) broke before or during intercourse and 67 condoms (3.5%) slipped off during sex. Couples who had not used a condom in the past year were almost twice as likely to experience condom failure as were couples who had used at least one during that period (p<.001). Of the couples who had used a condom in the previous year, the failure rate among those who reported at least one condom break during that period was more than twice the failure rate among those who reported no breaks (p<.001). Among couples who had used condoms in the past year without breaking any, those who did not live with their partner and those who had a high school education or less were at increased risk of condom failure (adjusted odds ratios of 3.2 and 2.7, respectively). (Family Planning Perspectives, **25**:220–223 & 226, 1993)

The rapid spread of the human immunodeficiency virus (HIV) and other sexually transmissible diseases (STDs) during the last decade has led to increased research on the male condom. Because condom breakage during intercourse or withdrawal seriously undermines this protection, numerous studies have examined the frequency of this problem.[1] Data from these studies suggest that breakage rates range from less than 1% to 12% of condoms used.[2]

Does this wide range in condom breakage rates result from chance, from differences in the material integrity of condoms or from variations among individual users in their likelihood of breaking condoms? Anecdotal evidence suggests that a relatively small proportion of condom users are responsible for a disproportionate number of breaks. If this is the case, the proportion of these "condom breakers" in a study could affect the study's overall breakage rate. Because so little is known about the characteristics of such individuals, we cannot predict accurate condom breakage rates for a given user. If simple methods of identifying condom breakers existed, service providers could maximize the impact of their educational interventions by targeting the cohort of users who experience the majority of breaks.

The analysis presented in this article examines possible explanations for the wide range of breakage rates presented in the literature and attempts to provide a basis for identifying condom users who are at increased risk of breaking condoms. This analysis uses a subset of data from a study conducted by Family Health International (FHI) to assess the value of laboratory tests in predicting condom breakage.[3]

In the original study, breakage and slippage data were collected for 20 different lots of condoms. Four lots were new condoms from four U.S. manufacturers; the remaining 16 were recovered from warehouses in Tanzania, the Dominican Republic, Egypt, Mexico, Kenya, Jamaica and Barbados. All recovered condoms were made by a single U.S. manufacturer and were distributed by the Commodities Procurement and Support Division of the U.S. Agency for International Development.

Three hundred couples were recruited for the study from professional organizations and institutions in the Research Triangle Park area of North Carolina (Raleigh, Durham and Chapel Hill) via fliers and word of mouth. Couples who expressed interest in participating were sent a fact-sheet outlining the purpose of the study and a list of criteria for participation. The study protocol required participants and their partners to be in a monogamous heterosexual relationship, at least 18 years old, protected against pregnancy, not practicing behaviors that would put them at risk of STDs (including HIV), and free from known sensitivities to latex. Further, each participating couple agreed to use 20 condoms during the four-month study period and to complete a self-administered questionnaire. FHI's Protection of Human Subjects Committee approved the study protocol and informed consent forms.

The 20 study condoms—one from each lot—were equally divided into four packets, which were mailed to participating couples along with the study questionnaire, a one-page form on which respondents answered a series of questions on slippage and breakage for each condom and filled in an identifying code from the condom packaging. The participants were asked to use the five condoms in each packet in random order. This scheme was devised to reduce potential bias from the order in which the condoms were used. When the investigators received the completed questionnaires, they paid the participating couples for each condom used.

One of the main conclusions of the original study of condom breakage was that condoms less than two years old are of essentially the same quality as new condoms, provided they have not been exposed to extremely harsh conditions during storage. Because some of the 16 condom lots recovered from overseas warehouses had been manufactured more than two years earlier and some might have been stored under adverse conditions, we considered both condom age and laboratory results when deciding whether to use data for a given condom lot in the current analysis. Seven of those lots and all four lots of new condoms passed the bursting and pressure standards set by the International Organization for Standardization (ISO)[4] and were less than two years old. Data on condoms from the remaining nine lots were not used in this analysis because the condoms failed the ISO standards and were not considered of acceptable quality for distribution.

Although most research has addressed only condom breakage, we also calculate rates of condom slippage and overall failure (slippage and breakage combined). Overall failure should not be confused with contraceptive failure, which by definition is the occurrence of a pregnancy.

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Data and Methods

Sample Characteristics

Of the 262 couples who completed the original study, 260 used at least one of the 11 condoms that met ISO standards and were less than two years old. This analysis is based on 177 couples who used all 11 of those condoms. This assures that rates will not be influenced by the use of different combinations of condom lots by the participants. However, to make sure that we did not introduce a selection bias by eliminating the experience of 83 couples who used some but not all of the 11 condoms, we also report selected rates based on the larger group of 260 couples.

The first packet of condoms sent to the participants included a questionnaire that asked for social and demographic data and information on previous experience with condoms. Female and male participants in our sample were similar in age, education and ethnic background. The median age of the participants was about 30, and the median education was approximately 15 years. Caucasians made up the great majority of the sample (84%), followed by blacks (10%), Asians (2%), Hispanics (2%) and those of other ethnic backgrounds (2%). Most of the couples (84%) were either married or living together.

About three-fourths of participants reported having used 10 or more condoms during their lifetime (women, 75%; men, 83%) and a similar proportion had used at least one condom during the year before the study (women, 80%; men, 80%). Thirty-nine percent of the women and 41% of the men reported using 10 or more condoms during that period. Among the participants with condom experience in the previous year, 75% of the women and 74% of the men reported no condom breakage during that time. Three percent of men and women (four couples) reported five or more breaks in the previous year.

Definition of Slippage and Breakage

The self-administered questionnaire included a series of specific questions about each condom used. The couples were asked: 1) if the condom slipped off during sex; 2) if the condom broke; and 3) if the condom did break, whether the break occurred while the package was being opened, while the condom was being unrolled onto the penis, during sex, during withdrawal, while the condom was being taken off, or at an unknown time.

To avoid double counting and to calculate accurate rates for breakage, slippage and overall failure, we used a hierarchical convention similar to one developed by James Trussell and colleagues.[5] Unlike Trussell, however, we included in the breakage rate calculations condoms that broke while the user was opening the package or putting on the condom. As in the Trussell convention, those condoms were subtracted from the denominator used to calculate the slippage rate; thus, that rate is based only on condoms that were used during intercourse. Because the question on slippage asked if a condom had "slipped off during sex," some respondents may have reported condoms that slipped down (but not off) the penis or those that slipped off during withdrawal. Therefore, the condom slippage rate presented in this paper may overstate the proportion of condoms that slipped off during intercourse.

We counted condoms that both broke and slipped off as breaks only (not as slips), because we believe that in most of these cases, the condom slipped off because it had broken. We calculated overall failure by adding the number of condoms that broke to the number of condoms that slipped off during intercourse and dividing the sum by the total number of condoms used by the participants.

We divided condom breaks into two categories, based on whether they had clinical implications. We classified breaks that occurred before intercourse as nonclinical because they would not expose the couple to the risks of pregnancy and STD transmission. We classified all other breaks as clinical. We included breaks noticed during withdrawal in this category, because many of these might have occurred during intercourse.

When calculating condom breakage rates, some researchers exclude nonclinical breaks because such breaks do not put the couple at risk. Although we provide rates for clinical breakage, we based our analyses on all breakage because we believe that both types of breakage are important. Nonclinical breakage, whether caused by misuse or by defects in the condoms themselves, could lead users to distrust condoms. This in turn could lead to increased user failure through nonuse or inconsistent use. User failure is as important as, if not more important than, method failure in its impact on rates of pregnancy and STD infection among condom users. Moreover, if a couple has access to only one condom and that condom breaks before intercourse, the couple may engage in unprotected intercourse.

Data Analysis

First, we calculated rates of breakage, slippage and overall failure among the couples in our sample. Next, we compared the expected binomial distribution and the observed distribution of condom failures in the entire sample to determine whether instances of repeated condom failure in this study population were independent events. (Similarity in the two distributions would suggest that condom failure is the result of chance and not of user behaviors or characteristics.) We used a chi-square goodness-of-fit test to assess whether differences in the expected and observed frequencies were statistically significant.

We then compared rates of breakage, slippage and overall failure among couples who had used condoms in the previous year with rates among those who had not. We also compared those rates among couples who had experienced condom breakage in the year before the study with rates among couples who had not experienced breakage during that period. These variables were based on the male partner's responses on the background questionnaire. We used a two-tailed Fisher's exact test for both comparisons.

Finally, we used logistic regression to identify social and demographic risk factors for condom failure. The regression was modeled only on couples who had used condoms during the previous year and had not reported any breakage, because those who had previously experienced condom failure were already identified as being at increased risk. The logistic regression model assessed the usefulness of four sociodemographic characteristics of the man—age, race, education and whether he lived with his partner*—in predicting condom failure. In two instances, race was missing from the man's questionnaire, so we used the woman's response. Collinearity and interaction of variables were also evaluated.

Results

Overall Failure Rates

The 177 couples included in our analysis used 1,947 condoms. Of these condoms, 5.3% broke (1.6% nonclinical; 3.7% clinical) and 3.5% slipped off during sex, resulting in a clinical failure rate of 7.2% and an overall failure rate of 8.7%.

The larger sample of 260 couples who had used at least one of the 11 condoms that met our criteria used a total of 2,519 condoms. Of these condoms, 6.2% broke (2.1% nonclinical; 4.2% clinical) and 4.1% slipped off during sex, for a clinical fail-

*The four variables were dichotomized for this analysis: cohabitation status, living with partner vs. not living with partner; education, ≤12 years vs. >12 years; age, <30 years vs. ≥30 years; race, Caucasian vs. non-Caucasian.

Table 1. Binomial probability of failure, and expected and observed number of couples experiencing condom failure, by number of failures per couple

Failures per couple	Binomial probability†	No. of couples	
		Expected	Observed
0–11	**1.0000**	**177**	**177**
0	.3660	65	110
1	.3852	68	26
2	.1843	33	17
3	.0529	9	8
4	.0101	2	6
5	.0014	0	4
6	.0001	0	4
7	.0000	0	0
8	.0000	0	0
9	.0000	0	2
10	.0000	0	0
11	.0000	0	0
χ^2=162.96 df=4 p<.001			

†The expected probability of one couple experiencing the given number of failed condoms out of 11 condoms used. *Note:* Cells 4–11 were combined to eliminate any frequency of zero before conducting the goodness-of-fit χ^2 test.

ure rate of 8.3% and an overall failure rate of 10.2%.

We also compared the failure rate of the four new condom lots with the failure rate of the seven condom lots that had been stored overseas. The 177 couples in our study reported breaking 3.4% of the new condoms (1.1% nonclinical; 2.3% clinical) and 6.4% of the condoms that had been stored overseas (1.9% nonclinical; 4.5% clinical); the difference in overall breakage was significant (p=.004). They said that 4.7% of the new condoms had slipped off during sex, compared with 2.8% of the condoms that had been stored overseas (p=.038). Thus, the overall failure rate was 8.1% for the new condoms and 9.1% for those that had been stored overseas; these rates were not significantly different.

The data for the 260 couples in the larger sample were similar. These couples reported breaking 4.4% of the new condoms (1.6% nonclinical; 2.8% clinical), compared with 7.3% of the condoms that had been stored overseas (2.2% nonclinical; 5.1% clinical). They said that 5.2% of the new condoms had slipped off during sex, compared with 3.4% of the condoms stored overseas. Thus, the overall failure rate was 9.5% for the new condoms and 10.6% for the condoms stored overseas.

Distribution of Failure

If condom failure is truly independent of the user, the outcome of each subject's first condom use is independent of the subject's subsequent condom use. The pattern of failures among subjects would follow a binomial distribution. This distribution models the number of failures per subject where the outcome is binary (i.e., failure vs. nonfailure). We assumed that the true condom failure rate was the observed rate of 8.7%.

Using the binomial probability function, we calculated the numbers of subjects who would be expected to experience each possible number of condom failures (0–11) and used a goodness-of-fit chi-square statistic to compare the expected number with the actual number of subjects who experienced each of the possible numbers of condom failures (Table 1). The expected and observed distribution of condom failures differed significantly (p<.001); thus, we concluded that the condom failures occurring in this study population were not random events. In our sample, more couples experienced no condom failures, fewer couples experienced one, two or three failures and more couples experienced four or more failures than would be expected if condom failure were randomly distributed.

Overall, 170 condoms failed, and the small proportion of couples who experienced multiple condom failure accounted for a larger proportion of condom failures than expected. According to the binomial probability function, two couples (1%) would be expected to experience four or more condom failures each and to be responsible for 5% of all condom failures. However, in this study population, 16 couples (9%) experienced four or more condom failures each (for a total of 86 failures) and were responsible for 50% of all condom failures.

Failure by Condom Use History

When we divided the couples in our sample into two groups according to whether they reported using condoms in the year before the study, the condom breakage, slippage and overall failure rates were significantly higher for the group with no condom experience in the previous year (Table 2). The overall failure rate for the group that had not used condoms during the previous year was nearly twice that of the group that had (13.9% vs. 7.5%, p<.001).

We further divided the group reporting condom use in the previous year by whether they reported breaking one or more condoms during that year. The group with reported condom breakage in the previous year had breakage and slippage rates more than twice as high as the group with no reported condom breakage during that period (overall failure rate, 13.1% vs. 5.6%, p<.001). These two simple screening questions (whether a couple had used condoms in the previous year and, if so, whether they had experienced a condom break during that period) identified 70 couples (40% of the sample) who were at increased risk of condom failure.

Logistic Regression Analysis

We then compared the observed and expected condom failures using data from the 107 couples who reported having used condoms in the previous year without breaking any. Once again, the goodness-of-fit chi-square was significant (χ^2=35.81, p<.0001), strongly suggesting that condom failures were not independent events among these couples. We conducted further analyses to identify factors that differentiate risks of failure.

Table 3 shows the condom failure rates for this subgroup within categories of age, education, race and cohabitation status. These results must be interpreted cautiously because of the small sample size in some of the cells. The lowest failure rates were experienced by couples aged 30 or older who had more than 12 years of education (2.5%), couples with more than 12

Table 2. Calculation of condom failure rates, by type of failure, according to condom use experience in the year before the study.

Type of failure	Total	Used condom in previous year		Broke condom in previous year	
		Yes (n=143)	No (n=34)	Yes (n=36)	No (n=107)
Total failure					
No. used*	1,947	1,573	374	396	1,177
No. failed	170	118	52	52	66
Rate	8.7	7.5	13.9	13.1	5.6
95% C.I.	7.5–10.1	6.3–8.9	10.6–17.9	10.0–16.9	4.4–7.1
P-value		.0002		.0001	
Breakage					
No. used*	1,947	1,573	374	396	1,177
No. broken†	103	71	32	31	40
Rate	5.3	4.5	8.6	7.8	3.4
95% C.I.	4.4–6.4	3.6–5.7	6.0–12.0	5.4–11.0	2.5–4.6
P-value		.0029		.0006	
Slippage					
No. used‡	1,915	1,553	362	387	1,166
No. slipped§	67	47	20	21	26
Rate	3.5	3.0	5.5	5.4	2.2
95% C.I.	2.7–4.4	2.2–4.0	3.5–8.5	3.4–8.3	1.5–3.3
P-value		.0256		.0030	

*All condoms used, including those that broke before intercourse. †All condoms that broke, before, during or after intercourse. ‡All condoms that did not break before they were put on. §All unbroken condoms that slipped. *Notes:* Man's response was used to categorize couple's condom use experience. P-value determined by two-tailed Fisher's exact test.

Table 3. Rates of condom failure among 107 couples who had not broken a condom in the year before the study, by selected characteristics of male partner

Characteristic	No. of couples	Failure rate*	P-value†
AGE-GROUP			
19–29			
10–12 yrs. of education	6	7.6	1.000
13–17 yrs. of education	42	6.9	.091
Not living with partner	14	11.7	.169
Living with partner	34	5.1	.002
30–65			
10–12 yrs. of education	22	7.9	.702
13–17 yrs. of education	37	2.5	<.001
Not living with partner	1	9.1	1.000
Living with partner	58	4.4	<.001
EDUCATION			
10–12 yrs.			
Not living with partner	0	na	na
Living with partner	28	7.8	.558
Non-Caucasian	3	15.2	.202
Caucasian	25	6.9	.272
13–17 yrs.			
Not living with partner	15	11.5	.181
Living with partner	64	3.3	<.001
Non-Caucasian	10	4.6	.112
Caucasian	69	4.9	<.001
RACE			
Non-Caucasian			
Aged 19–29 yrs.	9	4.0	.094
Aged 30–65 yrs.	4	13.6	.269
Not living with partner	2	9.1	1.000
Living with partner	11	6.6	.496
Caucasian			
Aged 19–29 yrs.	39	7.7	.391
Aged 30–65 yrs.	55	3.8	<.001
Not living with partner	13	11.9	.157
Living with partner	81	4.4	<.001

*Each couple used 11 condoms. †Two-tailed Fisher's exact test used to determine whether failure rate of subgroup differs significantly from that of rest of population. *Note:* na=not applicable.

years of education who were living together (3.3%) and Caucasian couples aged 30 or older (3.8%). Couples with 12 years or less of education who were non-Caucasian had the highest failure rate (15.2%), but this rate is based on only three couples.

Because of this wide range of failure rates within subgroups of our sample, we performed further analyses of the data. We used logistic regression to assess the joint contribution of age, education, race and cohabitation status to condom failure. We considered all two-way interaction terms of the four predictors. One term (cohabitation status by education) had no subjects in a cell and was not included in the model. Another term (cohabitation status by age) was removed to control collinearity.

Because so few couples (0 to 4) were represented in many of the strata defined by cross-classification of predictors, estimates of interaction effects could be extremely variable. This instability was confirmed through use of regression diagnostic procedures. Consequently, we fitted a model without interaction terms. The rates in Table 3 suggest that the difference in risk of condom failure attributable to age may not be the same for both categories of race and that a model with an interaction term may provide a better fit.

Of the four factors, cohabitation status and education were the most helpful in identifying couples at risk of condom failure (Table 4). Not living with one's partner had an adjusted odds ratio of 3.2, while having 12 years of education or less had an adjusted odds ratio of 2.7. In this population, race and age were not significant predictors of condom failure.

Discussion

Because it is unlikely that a vaccine against HIV will be available soon,[6] the public health community must rely heavily on the condom to slow the spread of HIV among sexually active individuals. However, recent prospective condom studies have found breakage rates varying from less than 1% to about 12%.[7]

Our data are from a study population that was protected from pregnancy by a method other than the condom. Because the couples in our sample were not regular condom users, their behaviors and characteristics might differ from those of typical users. They probably had less experience using condoms and might not have been as careful in their use of condoms during the study period because they were already using another form of contraception. However, we believe that some of the results presented in this article may apply to typical users as well.

Our data support the theory that a small group of condom users is responsible for a disproportionate number of condom failures. Couples with no condom experience in the year before the study and couples who had experienced condom breakage during that period had relatively high rates of condom failure. This suggests that such couples have characteristics or behave in ways that increase their risk of failure. How useful this information would be in screening typical condom users is unknown.

Couples who had used condoms in the year before the study without experiencing condom breakage had a failure rate of 5.6%. In light of the AIDS epidemic and the increasing prevalence of STDs, this failure rate is still unacceptably high. Cohabitation status and education were helpful in identifying couples in this subgroup who were at increased risk of condom failure. Couples who were not living together had significantly higher failure rates than their cohabiting counterparts. If the male partner had a high school education or less, the couples experienced significantly higher failure rates than if he had more education.

Little quantitative research has been conducted on the behaviors that adversely affect condom failure rates. Qualitative data collected in the past few years point to four main categories of behavior that may contribute to condom failure: incorrect methods of putting on condoms, use of oil-based lubricants, reuse of condoms, and duration and intensity of coitus.[8]

The higher condom failure rates among couples in less stable relationships and among less educated couples may be caused by some of these behaviors. Cou-

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Table 4. Adjusted odds ratios (and 95% confidence intervals) among 107 couples who had not broken a condom in the year before the study, by selected characteristics of the male partner

Characteristic	No. of condoms		Adjusted failure rate†	Adjusted odds ratio‡
	Used	Failed		
Cohabitation				
Not living with partner	165	19	8.3	3.2 (1.6–6.5)
Living with partner	1,012	47	2.6	
Education				
≤12 years	308	24	7.0	2.7 (1.5–5.0)
>12 years	869	42	2.6	
Race				
Non-Caucasian	528	37	3.3	1.2 (0.6–2.5)
Caucasian	649	29	2.6	
Age				
<30	143	4	3.8	1.4 (0.8–2.6)
≥30	1,034	56	2.6	

†The failure rate of the characteristic of interest when the other three variables in the model are held at "not-at-risk" level. ‡The odds ratio of the variable of interest when the other three variables are included in the model.

traception for women in general.

Second, the pattern of implant adoption suggests that this method is being chosen more often by women who are spacing their children or discontinuing childbearing than by women who are postponing childbearing. This finding is supported by the regression model, in which having two or more children increased the odds of adopting the implant and younger age was not associated with choosing the implant. If women were using the implant to postpone childbearing, we would expect having children to decrease the odds of choosing the implant.

An important question raised here is why, when the effect of cost is removed, the implant is not being adopted more frequently by adolescents to postpone childbearing. (In the clinic in this study, providers view the implant as an appropriate, but not necessarily preferred, method for adolescents; adolescents are generally not dissuaded from choosing it.) While the availability of long-acting methods might be expected to reduce the rate of adolescent pregnancies, such an outcome will depend on adolescents' early access to long-term methods and a willingness to adopt them. A study of adolescents' perceptions of the implant's attributes, of their understanding of the five-year time frame involved, and of the desirability of early childbearing is needed for this issue to be examined.

Third, having had an abortion was not associated with choosing the implant in the multivariate analysis, suggesting that the desire to avoid additional unwanted pregnancies is not a major factor motivating the choice of the implant over the pill in this clinic sample. Further analysis will be needed to assess whether a reduction in the rate of pregnancy terminations occurs as a result of the availability of long-term hormonal contraception.

Future research should also follow women who have adopted the implant, compared with women using other hormonal methods, to ascertain whether some of the variables identified here, including method of payment, affect how women cope with method side effects and make decisions to continue or discontinue use. In this group of early implant users, nine women (or 7% of those receiving the implant) had already had their implants removed within 9–14 months of insertion. The average duration of use among these women who discontinued was 38 weeks. The reasons given for removal varied widely, although bleeding problems were mentioned most frequently.

All of the removals were among Medicaid patients, for whom the cost of removal was fully covered. This situation raises the question of whether Medicaid reimbursement might encourage early removals or, conversely, whether having to pay for removal out-of-pocket might be a disincentive to early removal. Future research should examine how women perceive their options to continue or discontinue use under different payment mechanisms. An important social policy question is whether Medicaid reimbursement for the implant would increase woman-years of protection from unintended pregnancy, compared with other effective contraceptive methods.

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ples who live together may engage in less vigorous or lengthy intercourse and thus have lower failure rates. Couples likely to engage in vigorous or lengthy intercourse could be supplied with extra-strong condoms and additional lubricant. Less educated couples may have difficulty understanding instructions on how to put on condoms and understanding the importance of not using oil-based lubricants. Instructions should be written at a reading level comprehensible to condom users of all educational levels.

Although this study found relatively high slippage, breakage and overall failure rates, our analysis of the distribution of failures indicates that condoms are an appropriate method for the prevention of pregnancy and STDs (including AIDS) for the majority of users. This article presents preliminary methods by which users at high risk of failure can be identified. Further research is needed to determine the behaviors that place these individuals at increased risk. If these adverse behaviors can be identified, it may be possible to develop instructional materials that alter these behaviors and thus increase the degree of protection condoms offer all users against pregnancy and STDs.

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