Identifying Condom Users at Risk for Breakage and Slippage: Findings from Three International Sites

Alan Spruyt, Markus J. Steiner, MSPH, Carol Joanis, Lucinda H. Glover, MPH, Carla Piedrahita, Gloria Alvarado, MD, MPH, Rebecca Ramos, MD, Cesar Maglaya, MD, and Milton Cordero, MD

ABSTRACT

Objectives. This study examined whether past condom failure (breakage, slippage, or both) can predict future failure and evaluated other predictors of condom failure.

Methods. At each of 3 international sites, approximately 130 male condom users were enrolled and given 5 condoms to use for vaginal intercourse over a 3-week period.

Results. Men at increased risk (history of 1 or more condoms that broke or slipped off) reported approximately twice as many condom failures as those not in this group. Condom failure increased with the number of adverse condom use behaviors reported per participant. Opening condom packages with sharp objects and unrolling condoms before donning were associated with breakage. Unrolling condoms before donning and lengthy or intense intercourse were associated with slippage. Of background characteristics evaluated, having less education was associated with condom failure.

Conclusions. These data suggest that a history of condom failure predicts future failure, a finding that may be useful for targeted intervention. Moreover, these data provide further evidence that certain behaviors and lower educational attainment are associated with condom failure. (*Am J Public Health.* 1998; 88:239–244)

Introduction

When used correctly and consistently, the male latex condom is an effective contraceptive; the estimated perfect-use pregnancy rate is 3%.[1] The male condom is also highly effective against sexually transmitted diseases.[2,3] However, condom breakage and slippage vary widely during typical use. International prospective studies have reported breakage rates from less than 1% to as high as 13%, while several prospective studies based in the United States have reported breakage rates from less than 1% to about 7%.[4–6] Slippage occurs with comparable frequency.[5,6] Because condom breakage and slippage can diminish efficacy and may be used as a rationale for nonuse, it is important to better understand condom breakage and slippage.

For most condom users, the risk of a condom's breaking or slipping completely off the penis (hereafter referred to as condom failure) is rare; a minority of users seem to experience disproportionate failure.[6–9] Research suggests that condom failure may be associated with personal characteristics such as history of condom breakage or slippage, less experience with condom use, young age, less education, low income, and large penis size.[6,7,9–17] Behaviors that may be associated with condom failure include rough handling of condoms, improper donning techniques, use of oil-based lubricants, reducing natural vaginal lubrication, lengthy or vigorous sex, anal sex, intercourse in certain positions, delayed withdrawal after intercourse, withdrawal without holding onto the condom rim, and reuse of condoms.[6,9,11–15,17–25]

Information on the distribution of failure among users and on user characteristics and behaviors is necessary for interpreting condom failure data and may also prove useful for identifying and counseling condom users at increased risk of condom failure.[7,26] In this study we assessed whether past condom failure can predict condom failure, and we evaluated specific behaviors and user characteristics as they relate to condom failure.

Methods

The study was conducted in 1994 in collaboration with the Instituto de Investigación Científica in Durango, Mexico; the Comprehensive Family Planning Center at the Jose Fabella Memorial Hospital in Manila, Philippines; and the Asociación Dominicana Pro Bienestar de la Familia (PROFAMILIA) in Santo Domingo, Dominican Republic. Prior to initiation, the study was approved by the Protection of Human Subjects Committee of Family Health International.

Alan Spruyt, Markus J. Steiner, Carol Joanis, Lucinda H. Glover, and Carla Piedrahita are with Family Health International, Research Triangle Park, NC. Gloria Alvarado is with the Instutito de Investigación Científica, University of Juarez, Durango, Mexico. At the time of the study, Rebecca Ramos was with the Comprehensive Family Planning Center, Jose Fabella Memorial Hospital, Manila, Philippines; she is now with Reproductive Health Philippines, Inc, Manila. Cesar Maglaya is with the Comprehensive Family Planning Center. Milton Cordero is with the Asociación Dominicana Pro Bienestar de la Familia (PROFAMILIA), Santo Domingo, Dominican Republic.

Requests for reprints should be sent to Alan Spruyt, Family Health International, P.O. Box 13950, Research Triangle Park, NC 27709.

This paper was accepted March 14, 1997.

Note. Family Health International in an international nonprofit organization that conducts research and provides technical assistance in the areas of family planning, sexually transmitted diseases, and AIDS. The views expressed in this paper do not necessarily reflect the views of the funding agency.

Subjects

At each of the three sites, consecutive male family planning clients were recruited until approximately 130 men were enrolled. To participate, men must have used at least one condom during the 12 months prior to the study, been at least 18 years old, agreed to answer in-depth questions regarding use of the study condoms, and signed an informed consent form.

On the basis of past condom experience, men were assigned to one of two groups: (1) increased risk—men who had experienced condom failure (at least one condom that had broken or slipped off completely during vaginal intercourse) during a specified reference period prior to the study; (2) low risk—men who had not experienced condom failure during the specified reference period prior to the study.

At each site, once the low-risk group was filled ($n = 65 \pm 2$), no more men eligible for this category were enrolled. Approximately equal numbers of men were enrolled in each of the two risk categories. In the Dominican Republic men were assigned to a risk group on the basis of condom failure during the 12 months prior to the study. Inconsistent with the protocol, the other two sites based risk-group assignment on lifetime condom failure.

Procedures

Background information was collected and participants were given five condoms and instructed to use them for vaginal intercourse over the 3-week study period. Prior to the study, when receiving condoms for the first time at all three sites, all clients were given instructions on proper condom use, including opening the condom package carefully, putting the condom on after becoming erect, avoiding oil-based lubricants, and removing and disposing of the condom carefully. At enrollment, no additional instructions were given. After using the study condoms, the men returned to the clinics to complete an interviewer-assisted questionnaire on specific behaviors associated with condom use.

The participants were given standard (52-mm) silicone-lubricated latex condoms manufactured by Ansell Inc and distributed by the US Agency for International Development. All condoms came from the same lot and were used within 13 months of manufacture (February 1992). Prior to use, samples from the condom lot were tested by the Family Health International condom laboratory to ensure that they met guidelines set by the International Organization for Standards. The condoms were transported to the study sites and stored in a manner consistent with the manufacturer's specifications.

Definitions

Total breakage is defined as the number of condoms that reportedly broke at any time from opening the package to removing the condom from the penis, divided by the total number of condoms opened. Clinical breakage excludes (from numerator and denominator) condoms that broke before intercourse. Clinical slippage is defined as the condom's slipping all the way off the penis during intercourse or withdrawal and is calculated as the number of condoms that completely slipped off divided by the number of condoms that were used for intercourse. When the same condom both broke and slipped off, only breakage is counted, on the assumption that breakage, in most instances, leads to slippage. Total failure is the sum of condoms that broke, slipped off, or both at any time divided by the number of condoms that were opened. Clinical failure is the sum of clinical breakage and clinical slippage.

These definitions are consistent with recently proposed standardized definitions,[26] with the following exception: condoms that reportedly broke while being removed from the penis were included in clinical breakage (and therefore total breakage, clinical failure, and total failure) because participants were not told to inspect the condoms immediately after withdrawal (thus breakage may have occurred before removal in some instances).

Data Analysis

The Wilcoxon Rank Sum Test[27] (1-tailed exact), stratified by country and number of study condoms tested, was used to evaluate the primary hypothesis that past condom failure predicts failure. The Binomial Trend Test,[28] stratified by country, was used to evaluate the relationship between the number of behaviors reported and condom failure. For bivariate analysis of background characteristics and condom failure and specific behaviors and condom failure, country-level results were tested for significance with 1-tailed Fisher's Exact Tests and the combined results were tested with 1-tailed Cochran-Mantel-Haenszel analysis, stratified by country. Exact tests were chosen to provide the most conservative estimate of significance. All analyses were performed with SAS (SAS Institute Inc, Cary, NC), StatXact (Cytel Software Corp, Cambridge, Mass), and Epi Info (Centers for Disease Control and Prevention, Atlanta, Ga) software.

Multivariable regression models were used to evaluate simultaneously multiple behaviors and their association with breakage and slippage. Condom-specific data were collected only for condoms that failed. For other condoms, participants reported the proportion of condoms used while engaging in different behaviors, but not specifically which condom was used during a particular behavior. Thus, multivariate analyses are based on the user, not the condom, as the unit of analysis. For all tests, results were considered significant at $\alpha = .05$. No adjustments were made for multiple testing. Exact *P* values are reported.

Results

Between July 1992 and March 1993, 130 men in Mexico, 130 in the Philippines, and 126 in the Dominican Republic completed the study (Table 1). The median age of the men was lowest in the Dominican Republic (25 years) and highest in the Philippines (33 years). Median years of education completed ranged from 11 years in the Dominican Republic to 13 years in Mexico. The proportion of men in nonstable relationships was highest in the Dominican Republic (48%) and lowest in the Philippines (15%).

At enrollment, most Filipino men (60%) reported condom use for family planning only (Table 1). Conversely, in the Dominican Republic most men (64%) reported condom use for protection against sexually transmitted diseases. The Filipino men reported less condom use and less breakage prior to the study than did the other men. The Dominican Republic had the highest proportion of men (27%) who had used more than 100 condoms and the highest proportion (25%) for whom more than six condoms had failed prior to the study.

All enrolled participants completed the admission and follow-up interviews. In Mexico, the Philippines, and the Dominican Republic, 88%, 98%, and 58% of the men, respectively, used all 5 study condoms. Total breakage rates ranged from 0.8% in the Philippines to 4.7% in the Dominican Republic (Table 2) . Clinical slippage rates ranged from 0.8% in the Dominican Republic to 1.9% in Mexico. Total failure rates ranged from 2.0% in the Philippines to 5.5% in the Dominican Republic.

At all 3 sites, the men who had experienced condom failure during the 12-month period before the study reported failure about twice as often as those men who had not experienced condom failure during the 12 months prior to the study (Table 3). This

TABLE 1—Characteristics of Male Condom Users Recruited at Family Planning Clinics in Durango, Mexico; Manila, Philippines; and Santo Domingo, Dominican Republic, 1994

	Mexico (n = 130)	Philippines (n = 130)	Dominican Republic (n = 126)
Median age, y (range)	29 (18–53)	33 (18–64)	25 (18–58)
Median education, y (range)	13 (3–13+)	12 (2–13+)	11 (0–13+)
Relationship status, %			
Nonstable	25	15	48
Stable	75	85	52
Purpose of Condom Use, %[a]			
Family planning only	48	60	19[a]
Protection from disease only	8	10	64
Family planning and disease protection	43	29	15
No. condoms used (lifetime)			
1–25	32	49	31
26–100	46	33	42
>100	22	18	27
No. condoms that broke or slipped off (lifetime)[b]			
None	50	52	42
1–3	23	34	23
4–6	12	9	10
>6	15	5	25

Note. Percentage may not add to 100 owing to rounding.
[a]Two responses missing in the Dominican Republic.
[b]Condoms that reportedly broke and slipped off were counted only as breakage.

TABLE 2—Condom Failure among Study Participants in Mexico, the Philippines, and the Dominican Republic

	Mexico	Philippines	Dominican Republic
Total no. condoms supplied	650	650	630
Total no. condoms opened	630	648	532
Total failure, %[a]	4.0	2.0	5.5
Clinical failure, %[b]	3.0	2.0	2.3
Total breakage, %[c]	2.1	0.8	4.7
Clinical breakage, %[d]	1.1	0.8	1.6
Clinical slippage, %[e]	1.9	1.2	0.8

[a]Total failure is the sum of total breakage and clinical slippage.
[b]Clinical failure is the sum of clinical breakage and clinical slippage.
[c]Total breakage is defined as the number of condoms that reportedly broke at any time between opening the package and removing the condom from the penis, divided by the total number of condoms that were opened.
[d]Clinical breakage excludes (from numerator and denominator) condoms that broke before intercourse.
[e]Clinical slippage is defined as the condom's slipping all the way off the penis during intercourse or withdrawal, and is the number of condoms that completely slipped off divided by the number of condoms that were used for intercourse. Condoms that reportedly broke and slipped off do not count toward slippage.

pattern is consistent for the alternative reference periods based on lifetime and 6-month condom failure.

Participants reported many potentially adverse behaviors during condom use (Table 4). Varying by country, 10% to 39% of the condom packages were opened with teeth, scissors, knives, or pencils. In the Philippines, 20% of the condoms were reportedly unrolled before being donned and 7% were filled with air or water before use. In the Dominican Republic, 4% of the condoms were initially donned inside out. Use of additional lubrication or removal of lubrication (e.g., for "dry sex") was reported infrequently. Because of the infrequent use of additional lubrication, no meaningful subanalysis could be performed on the basis of use of oil-based vs non–oil-based lubricants. In the Dominican Republic, 8% of the condoms were used during intercourse that reportedly lasted for at least 20 minutes, 41% of the condoms were used during particularly intense intercourse, and with 56% of the condoms withdrawal took place after loss of erection. In the Philippines, 44% of the condoms were reportedly not held during withdrawal. Fewer than 1% of the condoms were reused for more than 1 act of coitus.

Analysis of condom failure by the number of adverse behaviors reported per participant is based on 10 selected behaviors: opening condom packages with methods other than fingers; unrolling condoms before donning; filling condoms with air or water; donning condoms inside out; using additional lubrication; removing lubrication before or during use; using condoms during particularly intense or lengthy coitus; losing erection before withdrawal; not holding on to the base of the condom during withdrawal; and reusing condoms (Table 5). The proportion of condoms that failed increases significantly with the number of these behaviors reported (exact $P < .01$, Binomial Trend Test stratified by country). For example, the condom failure rate was less than 3% among the group of men who reported none of these behaviors, while it was almost 10% among the group that reported from 4 to 7 behaviors.

Bivariate analysis of the combined sample (with the condom as the unit of observation) suggests that some behaviors are related to breakage or slippage (1-tailed Cochran-Mantel-Haenszel analysis stratified by country, data not shown). Both using methods other than fingers to open the condom packages and unrolling the condoms before putting them on were associated with breakage ($P = .02$ and $P = .01$, respectively). Unrolling condoms before putting them on, having intercourse for more than 20 minutes, and having especially intense intercourse were all associated with slippage ($P = .03$, $P = .01$, and $P = .01$, respectively). In the Philippines, loss of erection before withdrawal was associated with slippage ($P < .01$), while in Mexico and the Dominican Republic the association was not significant ($P = .81$ and $P = .78$, respectively).

Potential correlates of condom breakage and slippage were also examined through multivariable regression analysis (with the individual as the unit of observation), controlling for past failure (to see whether specific behaviors contributed to the predictive strength of the model beyond knowledge of past failure). When variables

TABLE 3—Total Condom Failure during Study by Past Condom Failure among Study Participants in Mexico, the Philippines, and the Dominican Republic

	Condom Failure during Study						
	Mexico (n = 130)[a]		Philippines (n = 130)[a]		Dominican Republic (n = 126)[b]		
Past Condom Failure	No. Used	% Failed	No. Used	% Failed	No. Used	% Failed	P^c
Ever							
Yes	318	5.0	314	2.2	316	7.6	
No	312	2.9	334	1.8	216	2.3	.03
In past 12 mo							
Yes	156	7.1	190	3.7	281	7.1	
No	474	3.0	458	1.3	251	3.6	.01
In past 6 mo[d]							
Yes	88	9.1	40	2.5	194	9.3	
No	451	2.7	513	2.1	298	3.0	.02

[a]Condom failure during the participant's lifetime was used for the purpose of recruitment.
[b]Condom failure during the past 12 months was used for the purpose of recruitment.
[c]Wilcoxon Rank Sum Test, 1-tailed exact, stratified by country and number of condoms used.
[d]Men who did not use any condoms during the 6 months prior to the study are excluded from this analysis.

TABLE 4—Prevalence of Behaviors That May Increase the Risk of Condom Failure among Study Participants in Mexico, the Philippines, and the Dominican Republic

	Mexico	Philippines	Dominican Republic
No. condoms opened	630	648	532
	% Reporting Behavior Per Condom		
Putting condom on			
Not opening with fingers	11	10	39
Unrolling before donning[a]	7	20	12
Filling condom with air or water[a]	2	7	2
Donning inside out[a]	2	1	4
Lubrication[a]			
Adding lubrication	3	1	1
Removing lubrication	<1	. . .	3
Intercourse[b]			
Lasting more than 20 min	2	4	8
Especially intense	12	11	41
Withdrawal[b]			
Losing erection before	33	15	56
Not holding condom during	42	44	38
Reuse[c]	—	<1	<1

[a]Excluding condoms that broke when package was being opened.
[b]Excluding condoms that broke when package was being opened or while being put on.
[c]Excluding condoms that broke.

that were significant during bivariate analysis were evaluated simultaneously, combinations of these behaviors did not add to the ability to predict breakage or slippage, nor did the past-failure variable lose its significance.

Analysis of participant characteristics relative to condom failure included the number of condoms used during the participant's lifetime, age, education, and relationship status. Lower education level was found to be associated with prospective condom failure ($P < .01$, linear regression model, controlling for country). Lower education was also associated with condom failure during the year prior to the study in Mexico ($P < .01$, 1-tailed Fisher's Exact Test) and in combined data ($P < .01$, Cochran-Mantel-Haenszel statistic controlling for country).

Discussion

Factors Associated with Condom Failure

This study suggests that basic information concerning past condom failure can accurately identify condom users at increased risk of future condom failure. Those groups of men identified as being at increased risk of failure reported failure approximately twice as frequently during the study as the corresponding low-risk groups.

The data also suggest a strong link between reported behaviors and condom failure. Trend analysis shows that condom failure increased significantly with the number of adverse condom behaviors reported per participant. Bivariate analysis of these same associations should be interpreted with caution. The potential for recall bias is significant, particularly for measures such as intensity or length of intercourse. Moreover, bivariate analysis ignores possible confounding and interaction between the different behaviors.

Multivariable analysis did not identify specific behaviors associated with condom failure, perhaps owing to two limitations in particular. First, the outcomes of interest were rare; fewer than 4% of the condoms tested failed. Second, condom-specific data were collected only for condoms that failed. Inferences on how condoms were used were drawn from responses concerning all condoms each participant used. From the information provided when condoms broke

TABLE 5—Condom Failure by Number of Behaviors That May Increase the Risk of Failure Reported by Study Participants in Mexico, the Philippines and the Dominican Republic

	No. Risk Behaviors Reported					
	0	1	2	3	4–7	Total
% Failed	2.7	1.7	4.0	4.0	9.8	3.7
(95% CI)	(1.4, 4.9)	(0.7, 3.2)	(2.4, 6.1)	(1.9, 7.2)	(6.0, 14.9)	(2.9, 4.7)
No. condoms used	401	482	481	252	194	1810

Note. CI = confidence interval. Binomial Trend Test, exact $P < .01$, stratified by country, includes only men who tested 5 condoms (n = 1580 condoms used by 316 men).

and from the information on the number of times specific risk behaviors occurred, the number of times that each risk behavior occurred when condoms did not break can be deduced; however, the joint distribution cannot. Thus, bivariate but not multivariate analyses can be based on condoms as the unit of analysis. Future research should collect detailed data on each condom used, regardless of whether failure occurred.

Future research would also benefit from increasing the probability of cases of condom failure, for example by oversampling (to a greater extent than in this study) condom users who have experienced condom failure in the past. In the present study, owing to inconsistent recruitment procedures, the Dominican Republic had the largest proportion of men who had experienced condom failure prior to the study. Where appropriate, analyses were stratified by country; thus this inconsistency was controlled. Nevertheless, it is interesting to note that prospective condom failure and adverse behaviors were generally most prevalent among the men from the Dominican Republic.

In addition to potential causes of condom failure evaluated in this study, some researchers have analyzed penis size, sexual positions, dry sex, anal intercourse, and other variables that may contribute to condom failure.[9–15,19,29] Nevertheless, few behaviors or user characteristics consistently cause condom failure, and they can be difficult to measure accurately. Data from this study suggest that engaging in multiple adverse behaviors is more strongly associated with failure than is any one adverse behavior in particular. Moreover, engaging in multiple adverse behaviors may be associated with unexamined factors that may contribute to condom failure (for example, handling or storage of condoms prior to use).

Because condom failure was rare, the number of terms in the multivariate analysis was limited. Thus, we did not evaluate the combined effect of behaviors and characteristics. Nevertheless, condom failure was clearly higher among condom users with less education, a finding similar to the findings of other research.[7,12] This association suggests a need to simplify condom instructions or to take other steps to ensure that condom users understand how to use condoms correctly.

Prevalence of Behaviors

If future research does provide sufficient reason to try to rank causes of condom failure, two factors should be kept in mind: how strongly a specific behavior seems to be related to breakage and slippage, and the prevalence of the behavior. If a given behavior is likely to result in condom failure but almost never occurs, it should have a minor impact on failure rates. Conversely, if a behavior is only mildly associated with failure but commonly occurs, efforts to curb the behavior may have a significant impact on overall condom failure.

In the present study, many men reported opening condom packages with teeth, knives, scissors, and pencils, practices associated with breakage. If breakage that occurs during opening of the package is not discovered prior to intercourse, or if another condom is not available, protection against pregnancy and disease will be compromised. Consistent with recent findings,[30] many men also reported losing their erection before withdrawal or not holding the base of the condom during withdrawal, both of which contribute to slippage.

In contrast, few men indicated that they used additional lubrication and even fewer reported reusing condoms. Some research suggests that use of additional lubricants (oil-based and non–oil-based) may lead to increased slippage and that use of oil-based lubricants may be associated with breakage.[23,24,31] Nevertheless, use of additional lubricants is uncommon in some populations. Condom reuse was infrequent, perhaps owing to a short study period and easy access to additional condoms.

More generally, caution should be used when interpreting the findings of this study, because men who experienced condom failure prior to the study were oversampled to test the primary study hypothesis. Thus, recruitment was not designed to provide a representative sample of condom users for the other analyses.

Conclusions

As is true of other methods that depend heavily on user compliance, the effectiveness of condoms decreases significantly as imperfect use increases. Moreover, condom breakage and slippage may fuel inconsistent or discontinued use. Given the central role that condoms must play in protecting against pregnancy and sexually transmitted diseases, family planning providers should help clients maximize condom effectiveness. The results of this study suggest that baseline information collected on history of condom failure is a good predictor of future failure. They also suggest that engaging in multiple adverse behaviors during condom use is linked with failure. Keys to reducing failure may include identifying condom recipients at increased risk of condom failure and discouraging behaviors associated with condom failure. Further research is needed to determine whether condom failure can be reduced through targeted interventions among condom acceptors at increased risk of failure. □

Acknowledgments

Support for this work was provided by Family Health International with funds from the US Agency for International Development (contract AID/DPE-3041-A-00-0043-00).

We thank the dedicated staff of the Instituto de Investigación Científica, the Comprehensive Family Planning Center, and the Asociación Dominicana Pro Bienestar de la Familia (PROFAMILIA). We are also grateful to Ward Cates, Paul Feldblum, Ron Frezieres, Caroline Hurst, Barbara Janowitz, Doug Nichols, Ron Roddy, David Sokal, Barbara Taylor, Dorace Trottier, and James Trussell for their insightful reviews of the manuscript. We also thank Pat Stewart for data management.

References

1. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 16th rev ed. New York, NY: Irvington Publishers; 1994.
2. Cates W, Stone K. Family planning, sexually transmitted diseases and contraceptive choice: a literature update—part I. *Fam Plann Perspect*. 1992;24:75–84.
3. DeVincenzi I. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *N Engl J Med*. 1994;331: 341–346.
4. Liskin L, Wharton C, Blackburn R, Kestelman P. *Condoms—Now More Than Ever: Promoting Condoms*. Baltimore, Md: Johns Hopkins School of Public Health, Population Information Program; September 1990. *Popul Rep H*, No. 8.
5. Steiner M, Piedrahita C, Joanis C, et al. Condom breakage and slippage rates among study participants in eight countries. *Int Fam Plann Perspect*. 1994;20:55–58.
6. Albert AE, Warner DL, Hatcher RA, et al. Condom use among female commercial sex workers in Nevada's legal brothels. *Am J Public Health*. 1995;85:1514–1520.
7. Steiner M, Piedrahita C, Glover L, et al. Can condom users likely to experience condom failure be identified? *Fam Plann Perspect*. 1993;25:220–226.
8. Richters J, Donovan B, Gerofi J. How often do condoms break or slip off in use? *Int J STD AIDS*. 1993;4:90–94.
9. Sparrow MJ, Lavill K. Breakage and slippage of condoms in family planning clients. *Contraception*. 1994;50:117–129.
10. Nelson A, Bernstein GS, Frezieres R, et al. *Study of the Efficacy, Acceptability and Safety of a Non-Latex (Polyurethane) Male Condom (Final Report)*. Bethesda, Md: National Institutes of Health; September 15, 1997. NIH Contract NO1-HD-1-3109.
11. Nelson A, Frezieres R, Walsh T, et al. *Controlled, Randomized Evaluation of a Commercially Available Polyurethane and Latex Condom (Avanti vs Ramses Sensitol) (Final Report)*. Bethesda, Md: National Institutes of Health; November 6, 1996. NIH Contract NO1-HD-1-3109.
12. Linberg LD, Sonenstein FL, Ku L, et al. Young men's experience with condom breakage. *Fam Plann Perspect*. 1997;29:128–131,140.
13. Richters, Gerofi J, Donovan B. Why do condoms break or slip off in use?: an exploratory study. *Int J STD AIDS*. 1995;6:11–18.
14. Grady WR, Tanfer K. Condom breakage and slippage among men in the United States. *Fam Plann Perspect*. 1994;26:107–112.
15. Chan-Chee C, De Vincenzi I, Sole-Pla M, et al. Use and misuse of condoms. *Genitourin Med*. 1991;67:173.
16. Hatcher RA, Hughes MS. The truth about condoms. In: *SIECUS Report*. New York, NY: Sex Information and Education Council; 1988;17:1–8.
17. Rugpao S, Beyrer C, Toanabutra S, et al. Multiple condom use and decreased condom breakage and slippage in Thailand. *J Acquired Immune Def Syndr Hum Retroviol*. 1997; 14:169–173.
18. Gabbay M, Gibbs A. Does additional lubrication reduce condom failure? *Contraception*. 1996;53:155–158.
19. Van de Wijgert JH. *The Effect of Douching, Wiping and Inserting Herbs inside the Vagina on the Vaginal and Cervial Mucosa, on the Vaginal Flora, and on the Transmission of Human Immunodeficiency Virus and Other Sexually Transmitted Diseases in Women in Zimbabwe*. Berkeley, Calif: University of California; 1997. Dissertation.
20. Finger W, Steiner M, Manuel J, et al. How human use affects condom breakage. *Network*. 1991;12:10–13.
21. Piedrahita C, Steiner M. Why condoms break. *IPPF People*. 1992;19:44.
22. Albert AE, Hatcher RA, Graves W. Condom use and breakage among women in a municipal hospital family planning clinic. *Contraception*. 1991;43:167–176.
23. Steiner M, Piedrahita C, Glover L, et al. The impact of lubricants on latex condoms during vaginal intercourse. *Int J STD AIDS*. 1994;5: 29–36.
24. Trussell J, Warner DL, Hatcher RA. Condom slippage and breakage rates. *Fam Plann Perspect*. 1992;24:20–23.
25. Folmar S, Alam S, Sharif A. *Condom Use in Bangladesh. FHI Final Report*. Durham, NC: Family Health International; September 1992.
26. Steiner M, Trussell J, Glover L, et al. Standardized protocols for condom breakage and slippage trials: a proposal. *Am J Public Health*. 1994;84:1897–1900.
27. Lehmann EL. Cited by: Mehta C, Patel N. *StatXact User Manual, Version 2*. Cambridge, Mass: Cytel Software Corp; 1991: section 4.2.
28. Mantel N. Cited by: Mehta C, Patel N. *StatXact User Manual, Version 2*. Cambridge, Mass: Cytel Software Corp; 1991: section 4.2.
29. Bernstein GS, Frezieres R, Walsh T, Coulson AH, Clark V. Stretching the barriers: the changing methodology for non-latex condom research. Presented at the 121st Annual Meeting of the American Public Health Association; October 24–28, 1993; San Francisco, Calif.
30. Oakley D, Bogue E. Quality of condom use as reported by female clients of a family planning clinic. *Am J Public Health*. 1995;85: 1526–1530.
31. Voller B, Coulson AH, Bernstein GS, et al. Mineral oil lubricants cause rapid deterioration of latex condoms. *Contraception*. 1989;39:95–102.