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Condom Breakage and Slippage Rates Among Study Participants in Eight Countries

By Markus Steiner, Carla Piedrahita, Carol Joanis, Lucinda Glover and Alan Spruyt

Condom research conducted in the Dominican Republic, Ghana, Kenya, Mali, Mexico, Nepal, Sri Lanka and the United States shows that condom breakage rates during vaginal intercourse using lubricated latex condoms range from 0.6% of all condoms used in Sri Lanka to 13.3% in Ghana. Most research sites reported breakage rates below 5%. The rate at which the condom slipped off completely is as high as 9.3% in Kenya, with most of the remaining sites reporting rates below 4%. When breakage and slippage are combined, total condom failure rates range from 3.8% to 13.3%. Although such high condom failure rates may cause alarm, there is evidence that for a majority of users, condoms provide an effective method of preventing pregnancy and sexually transmitted disease infection if they are used correctly. The high overall breakage and slippage rates may be caused by incorrect behavior or by certain characteristics of a few participants.

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The history of the condom dates to 1350 B. C., when Egyptian men wore sheaths over their penis for decorative purposes.¹ Since then, condoms have been used for protection against sexually transmitted diseases (STDs) and pregnancy, and even to enhance penile or vaginal stimulation.² Early condoms were made of linen or sheep cecum and were not widely used, in part because of their

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high cost. With the introduction of vulcanization in the mid-19th century, latex condoms could be mass-produced at an affordable price. By the 1930s, the U. S. market for condoms was more than 300 million units annually.³

In the 1960s, the introduction of the pill and other highly effective contraceptive methods resulted in a sharp decline in the demand for condoms. The appearance of the human immunodeficiency virus (HIV) more than a decade ago and the rapid spread of other STDs in recent years, however, has caused a renewed interest in condoms, and worldwide demand has increased accordingly.⁴ Currently, it is estimated that about six billion condoms are used worldwide per year.⁵

Although condoms have been used for centuries, surprisingly little is known about how well this method protects against pregnancy and STDs, including HIV infection. Laboratory tests have shown that intact condoms offer an impermeable barrier to semen and to all STD organisms except hepatitis-B fragments.⁶ A recent laboratory study that attempted to simulate conditions during coitus detected leakage of particles the size of HIV in 33% of condoms tested,⁷ but the number of particles that leaked was extremely small, leading the authors to conclude that "worst-case condom barrier effectiveness (fluid transfer prevention)... is shown to be at least 10,000 times better than not using a condom at all."

According to a review of clinical studies that assessed the efficacy of condoms

in protecting against pregnancy,⁸ first-year contraceptive failure rates among typical users averaged about 12%, while comparable method failure rates among perfect users were estimated at about 3%. No randomized controlled studies have evaluated the extent of protection offered by condoms against STDs.⁹ Observational studies have found widely divergent levels of disease transmission among condom users, much higher than would be expected on the basis of laboratory data.¹⁰ Misuse and nonuse have been offered as explanations for why condoms provide less protection in vivo than in the laboratory.¹¹

In trying to understand how well condoms protect against pregnancy and STDs, one could start by evaluating how often the condom's latex barrier remains intact during coitus. As recently as 1990, the scientific literature and the popular press asserted that condoms break less than 1% of the time.¹² In 1990, the authors of a report on condoms quoted a condom breakage rate range of "less than one percent to 12 percent."¹³

Reports in the literature seldom mention slippage rates, and thus may understate how often a condom offers reduced protection against pregnancy and STDs. Two recent articles that mentioned slippage rates for latex condoms (i.e., the proportion of condoms that slipped off the penis completely) presented rates ranging from 0.8% to 6.4%.¹⁴

Since 1989, Family Health International (FHI) has conducted condom functionality and acceptability studies in several countries. These studies, which compare breakage rates during vaginal intercourse for two or more types of condoms differing in size, age, strength, lubricant or material, have involved more than 11,000 condoms. This article provides slippage, breakage and total failure rates for 52-mm lubricated latex condoms used during vaginal intercourse in the Dominican Republic, Ghana, Kenya, Mali, Mexico, Nepal, Sri Lanka and the United States.

Methodology

Study Products

The condoms used in the FHI studies came from a single U. S. manufacturer. All

Table 1. Selected social and demographic characteristics of participants in six condom studies, by study site

Study site	N	Age (in years)		Education (in years)		% in union
		Median	Range	Median	Range	
International Study I						
Dominican Republic	100	25	17–49	≥12	2–≥12	39
Kenya	187	30	18–63	9	0–≥12	75
Mali	100	29	16–57	11	0–≥12	46
Mexico	99	30	18–52	≥12	3–≥12	80
Sri Lanka	98	39	24–29	10	3–≥12	100
International Study II*						
Ghana	98	27	19–51	u	u	u
Kenya	75	30	21–51	u	u	u
Mali	99	27	20–55	u	u	u
International Study III						
Nepal	150	27	18–59	7	0–≥12	99
Sri Lanka	121	38	25–54	9	2–≥12	96
U.S. Study I	227	30	19–65	≥12	10–≥12	83
U.S. Study II†	113	33	18–58	≥12	10–≥12	u
U.S. Study III	291	32	19–70	≥12	6–≥12	88

*Participants were not asked about their education or marital status. †Participants were not asked about their marital status.

were manufactured to the same specifications as those distributed as part of the Family Planning Commodities Program of the U.S. Agency for International Development (U.S. AID). The condoms are contoured in shape, lubricated with silicone (an average of 450 mg per condom), and have a nominal length of 180 mm, a nominal width of 52 mm and a nominal thickness of 0.07 mm. They are packaged in square cellophane pouches.

There are believed to be no relevant differences in size, lubricant or packaging between these condoms and other condoms manufactured in the United States, at least as they relate to breakage. Differences in the latex formulations used by condom manufacturers may have a significant impact on the likelihood of breakage, but more research will be needed before any definitive conclusions can be drawn.

The condoms in these studies came from six different manufacturing lots. Shortly before the studies, all lots passed both the tensile test of the American Society for Testing and Materials (ASTM) and the airburst test of the International Standards Organization (ISO). Previous research has addressed the relationship between these tests and condom breakage during human use.¹⁵

Study Populations

•*International.* Sexually active males who were current or past condom users and

*The inclusion criteria were stricter because participants were part of a larger study in which older (and potentially compromised) condoms were compared with new condoms. The data reported here are all from couples who used new condoms.

were willing to use the study products and answer questions about them were recruited for the studies from a variety of settings, including clinics, factories, pharmacies and universities. Potential participants were read a factsheet outlining the purpose of the study and a list of selection criteria for participation in the study. If they met all of the selection criteria, they were asked to sign an acknowledgment of informed consent. FHI’s Protection of Human Subjects Committee approved the study protocols and consent forms prior to study initiation.

Participants were provided with written or verbal instructions on correct condom use and were asked to use a specified

number of condoms (2–10, depending on the study objective) during a defined study period (two weeks to two months). They were requested to use each condom during one act of vaginal intercourse. After the study period, each participant was asked a series of questions on the acceptability of the study condoms and on how well the condoms performed in actual use.

•*United States.* Participating couples were recruited from professional organizations and institutions in the Research Triangle Park area of North Carolina (the area between Raleigh, Durham and Chapel Hill) via fliers and word of mouth. Interested couples were sent a factsheet outlining the purpose of the study and a list of selection criteria for participation in the study.

Inclusion criteria in U.S. studies were slightly stricter than were those for the international studies: Participants and their heterosexual partners had to be at least 18 years old; in mutually exclusive sexual partnerships during the course of the study; protected against pregnancy by recognized, reliable methods of contraception; and not at risk of STDs (including HIV).* If they met all of these criteria, they were asked to sign and return the acknowledgment of informed consent, which, along with the study protocols, had been approved by FHI’s Protection of Human Subjects Committee.

Participating couples were provided with written instructions on correct condom use and were asked to use 2–20 condoms (depending on the study objective) during a defined study period (two weeks to three months). Couples were instructed to complete sections of a self-administered

Table 2. Proportion (and 95% confidence interval) of study participants reporting condom slippage or breakage, and total condom failure rates, by study site

Study site	No. of subjects	No. of condoms	% breakage	% slippage	Total condom failure rate
International Study I*					
Dominican Republic	100	498	3.8 (2.3–5.9)	u	u
Kenya	187	898	2.4 (1.5–3.7)	u	u
Mali	100	482	6.2 (4.2–8.8)	u	u
Mexico	99	495	4.6 (3.0–6.9)	u	u
Sri Lanka	98	488	0.6 (0.1–1.8)	u	u
International Study II†					
Ghana	98	98	13.3 (7.2–21.6)	0.0 (0.0–3.0)	13.3 (7.2–21.6)
Kenya	75	75	4.0 (0.8–11.2)	9.3 (3.8–18.3)	13.3 (6.6–23.2)
Mali	99	99	4.0 (1.1–10.0)	7.1 (2.9–14.0)	11.1 (5.7–19.0)
International Study III					
Nepal	150	750	4.0 (2.7–5.7)	3.5 (2.3–5.1)	7.5 (5.7–9.6)
Sri Lanka	121	597	2.7 (1.5–4.3)	1.2 (0.5–2.4)	3.8 (2.5–5.7)
U.S. Study I	227	227	4.0 (1.8–7.4)	2.7 (1.0–5.8)	6.6 (3.7–10.7)
U.S. Study II	113	422	0.9 (0.3–2.4)	2.8 (1.5–4.9)	3.8 (2.2–6.1)
U.S. Study III	291	582	3.4 (2.1–5.3)	3.9 (2.4–5.8)	7.2 (5.2–9.6)

*Participants were not asked to report on condom slippage. †Participants were not asked to report on the timing of any condom breaks. Thus, it was not possible to exclude condoms that broke prior to intercourse when slippage rates were calculated.

questionnaire immediately after each condom was used during vaginal intercourse.

Definitions

International participants were asked the number of study condoms that broke, as well as the timing and location of each break. Information on condom slippage was also collected at five of the 10 international sites. U.S. couples answered a series of questions on a self-administered questionnaire following each condom use; data on both slippage and breakage were collected at all three sites.

At sites where both types of information were collected, we used a hierarchical convention similar to one developed by other researchers to avoid double-counting and to calculate accurate rates for breakage, slippage and total condom failure.¹⁶ If a participant broke a condom while opening the package or putting the condom on, that was counted as a condom break and was subtracted from the denominator used to calculate the slippage rate. Hence, the slippage rate was calculated only for condoms used during intercourse. Slippage was defined as a situation in which a condom was reported to have slipped off completely.

We counted condoms that both broke and slipped off as breakage only (not as slippage) because we believe that in most of these cases, the condom slipped off because it had broken. We calculated total condom failures by adding the number of condoms that broke to the number of condoms that slipped off during intercourse, and then dividing that sum by the total number of condoms used. (The term "total condom failure" used in this article should not be confused with contraceptive failure or pregnancy rates, since by itself condom failure may not necessarily result in a pregnancy.) In certain instances, some data necessary for making calculations according to the above definitions were missing; in such cases, we have noted in the table where we have had to modify definitions.

When calculating condom breakage rates, some researchers have included only a subset of all breaks—those occurring during intercourse or withdrawal (clinical breaks).¹⁷ They argue that condom breaks occurring before intercourse (non-clinical breaks) do not put a couple at risk of pregnancy and STD transmission. We present data on all breaks because we believe that both clinical and nonclinical breaks are important. From a behavioral perspective, nonclinical breaks, whether caused by misuse or by defects, could lead users to distrust condoms. This could lead

Table 3. Percentage distribution of study participants reporting a condom break, by timing and by location of break, according to study site

Study site	No. of broken condoms	Timing of break				Location of break			Total
		While putting on	During coitus*	During removal	Data missing	Near opening	Along shaft	At tip	
International Study I									
Dom. Rep.	19	32	68	0	0	11	21	68	100
Kenya	22	41	50	0	9	50	18	32	100
Mali	30	40	53	7	0	43	40	17	100
Mexico	23	26	65	9	0	39	17	43	100
Sri Lanka	3	67	33	0	0	33	33	33	100
International Study III									
Nepal	30	7	93	0	0	10	7	83	100
Sri Lanka	16	31	62	6	0	6	56	38	100
U.S. Study I	9	33	44	22	0	u	u	u	100
U.S. Study II†	4	0	50	u	50	0	50	50	100
U.S. Study III	20	25	35	40	0	u	u	u	100

*Includes condoms that broke during withdrawal. †Participants were not asked if the condom broke during removal. Note: Participants in International Study II were not asked to report on the timing of any condom breaks.

to increased user failure, either through nonuse or through inconsistent use. User failure is as important as, if not more important than, method failure in rates of pregnancy and STD infection among condom users. In addition, a condom user may, on occasion, have access to only one condom. If that condom were to break before the couple has sex, they might then engage in unprotected intercourse.

Data and Analyses

Differences in study design, time frame and sample population make comparisons among studies and sites imprecise; thus, we have not conducted statistical tests of the differences among rates. For each site's breakage, slippage and total condom failure rates, however, we did calculate the exact 95% confidence interval, using StatXact, version 2.11.

Results

Characteristics

Table 1 presents social and demographic characteristics for the study subjects from the 13 sites. There were three international multisite studies and three U.S. single-site studies. The participants ranged in age from 16 years to 70 years (with study medians ranging from 25 to 39). The median age at most sites was about 30; the two sites in Sri Lanka had the oldest participants (medians of 38 and 39), while the site in the Dominican Republic had the youngest (a median of 25).

Although participants' schooling ranged from none to more than 12 years at the 10 sites for which data on educational level were available, most subjects were well educated, with the median education in the

different studies ranging between seven years and 12 or more. The level of education among participants in these studies may have been high because recruitment for most studies took place in urban centers. The lowest reported median level of education was at the site in Nepal (seven years).

At most of the nine sites where data on marital status were collected, the overwhelming majority of study subjects were married or living in union with their partner. The proportion of married subjects was lowest in the Dominican Republic (39%), which is consistent with its being the site that had the youngest population.

Breakage, Slippage and Condom Failure

At the 13 sites, 1,758 couples used a total of 5,711 condoms during acts of vaginal intercourse (Table 2). Condom breaks ranged from a low of 0.6% in one study in Sri Lanka to 13.3% in the study in Ghana. Slippage rates ranged from 0.0% in Ghana to 9.3% in one of the studies in Kenya. (In one study with five sites, participants were not asked questions related to slippage.) At the eight sites where information on both breakage and slippage was gathered, total condom failure rates ranged from 3.8% (in Sri Lanka and the United States) to 13.3% (in Ghana and Kenya).

Table 3 presents information on the timing and location of condom breaks. There is a surprising consistency across most sites, with approximately one-third of breaks occurring as the condom is put on and the remaining two-thirds during coitus or when the condom is removed. Participants at two of the U.S. sites reported that a sizable proportion of the breaks occurred during removal, although some of them may have

occurred during intercourse and have simply not been discovered until removal. (Improved study designs may in the future provide more accurate data and enable researchers to define clinical and nonclinical breakage more precisely.¹⁸)

When participants were asked to report where precisely the condom had broken, they gave varying responses. Overall, nearly half (47%) of the 147 condoms that broke and for which we have location data were reported to have broken at the tip or the closed end; slightly more than one-quarter broke along the shaft (26%) or near the open end (27%).

Discussion

Since 1989, condom breakage rates in a series of condom studies conducted in eight countries by FHI have ranged from 0.6% to 13.3%. At only two study sites were breakage rates of greater than 6% reported, while at the remaining 11 sites breakage rates were all less than 5%. Since the methodology, data collection instruments and condoms used in these studies were very similar, differences in the characteristics or behavior of the participants may have played an important role in determining breakage rates.

Qualitative data collected as part of this research and presented in earlier articles identified four types of user behavior that may cause condoms to break—an incorrect method of putting on a condom, the use of oil-based lubricants, the reuse of condoms and the duration or intensity of coitus.¹⁹ Quantitative research is needed, however, both to validate these findings and to identify further behavior that may cause condoms to break or slip off.

Secondary analysis of one of the U.S. studies supports the theory that a small group of condom users is responsible for a disproportionate number of condom failures.²⁰ In this analysis, four factors predicted if couples were at increased risk of experiencing condom breakage: no condom experience in the past year; condom breakage in the past year; not living with one's partner; and having had 12 or fewer years of schooling. The proportion of condom "breakers" in a given study has an important impact on breakage, slippage and total failure rates, and may explain the wide range of rates seen in the literature. At the sites where data on condom slippage were collected, reported rates were as high as 9.3% and total failure rates (which include both breakage and slippage) ranged from 3.8% to 13.3%, with at least one-third of the sites having a rate of more than 10%. Such apparently high fail-

ure rates may cause alarm, but the FHI research presented here and elsewhere provides evidence that for a majority of users, if the condom is used correctly and consistently, it is an effective method for preventing pregnancy and STDs, including HIV infection. The high rates may be caused by incorrect behavior or by certain characteristics of a few participants. More research is urgently needed to help identify condom users at increased risk of experiencing condom failure and to learn how family planning providers can help them reduce that risk. The ultimate goal is to provide all condom users with reliable barrier protection against pregnancy and STDs.

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Resumen

Una investigación sobre el uso del condón, realizada en Ghana, Kenya, Malí, México, Nepal, la República Dominicana, Sri Lanka y los Estados Unidos, indica que las tasas de casos de ruptura de condones durante la copulación vaginal, cuando se utilizan condones de látex lubricados, varía entre el 0,6% en Sri Lanka y el 13,3% en Ghana. La mayoría de los lugares estudiados revelaron tasas menores al 5%. Los casos en que el condón se corre y sale del lugar llegan a una elevada tasa del 9,3% en Kenya, y el resto de los lugares estudiados presentan una tasa de menos del 4%. Cuando se combinan los dos casos anteriormente mencionados, la tasa total de falla varía entre el 3,8% y el 13,3%. Si bien estas elevadas tasas pueden causar alarma, se ha comprobado que para la mayoría de los usuarios, si es utilizado en forma correcta, el condón resulta un método anticonceptivo eficaz para evitar los embarazos y prevenir las enfermedades transmitidas sexualmente. Las tasas globales de ruptura o que se sale pueden ser causadas debido al uso incorrecto o por las características de algunos de los participantes.

Résumé

Les recherches effectuées sur les préservatifs en République dominicaine, au Ghana, au Kenya, au Mali, au Mexique, au Népal, en Sri Lanka et aux Etats-Unis révèlent que les taux de rupture des préservatifs latex lubrifiés durant les rapports sexuels vaginaux varient entre 0.6% sur tous les préservatifs utilisés en Sri Lanka et 13.3% au Ghana. La plupart des centres de recherche ont signalé des taux de rupture inférieurs à 5%. Le taux de glissement complet du préservatif s'élève à 9.3% au Kenya, tandis que la plupart des autres centres ont signalés des taux inférieurs à 4%. Lorsqu'on réunit la rupture et le glissement, le taux global de défaillance des préservatifs varie entre 3.8% et 13.3%. Bien que ces taux élevés de défaillance des préservatifs puissent inquiéter, les données indiquent que, pour la plupart des utilisateurs, les préservatifs constituent une méthode efficace pour prévenir les grossesses et les maladies transmissibles sexuellement s'ils sont utilisés correctement. Les taux élevés de rupture et de glissement peuvent être causés par un comportement erroné ou par certaines caractéristiques de quelques participants.