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Standardized Protocols for Condom Breakage and Slippage Trials: A Proposal

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Introduction

The male condom continues to be the principal method by which sexually active people protect themselves from sexually transmitted diseases, including the human immunodeficiency virus (HIV). First-year contraceptive failure rates are estimated to be about 12% during typical use and about 3% during perfect use.¹ In the absence of well-controlled studies that provide accurate data on the clinical effectiveness of condoms against pregnancy and sexually transmitted diseases, breakage and slippage data may provide the best indication of the protection offered by condom use.

As recently as 1990, the scientific literature and the popular press were asserting that less than 1% of condoms break.^{2,3} In 1990, however, one comprehensive review concluded that condom breakage rates range from “less than one percent to 12 percent.”⁴ Since then, a series of studies has provided additional information.^{5–15} Unfortunately, results from these studies cannot be readily compared because of wide variation in trial design, execution, and analysis. In this paper, we propose a standardized protocol for future condom breakage and slippage studies.

Methodological Issues

Anal intercourse may lead to more condom breakage than vaginal intercourse because of increased friction.^{11,16} Commercial sex workers may experience lower than average condom breakage because they typically engage in vaginal intercourse of shorter duration and have more experience using condoms.¹⁷ Therefore, when evaluating condom breakage and slippage data, investigators must distinguish vaginal from anal intercourse and the general population from sex workers.

The notion that condoms break less than 1% of the time arose chiefly from large-scale retrospective studies. In one such study, 282 people reported breaking 244 of 39 383 condoms used during their

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ABSTRACT

In the absence of well-controlled studies on the clinical effectiveness of condoms against pregnancy and sexually transmitted diseases, breakage and slippage data may provide the best indication of the protection offered by condom use. According to the recent literature, condom breakage rates range from 0% to 12%, with many US studies falling in the 2% to 5% range. Few studies have collected slippage data. In addition to discussing methodological issues associated with these studies, we propose a standardized protocol for future condom breakage and slippage trials and discuss how results may be used to estimate perfect-use and typical-use pregnancy rates. (*Am J Public Health.* 1994;84:1897–1900)

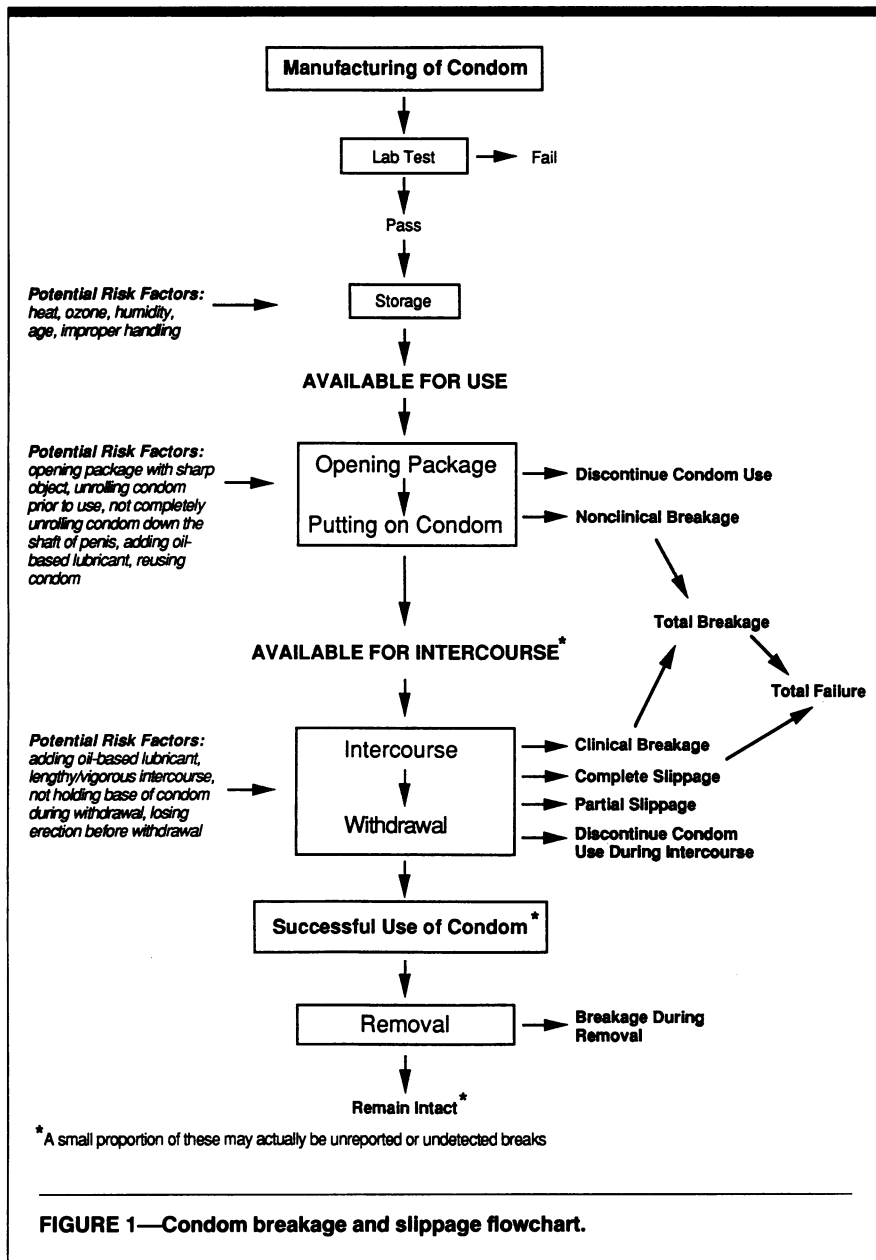


FIGURE 1—Condom breakage and slippage flowchart.

lifetime.² This numerator may be fairly accurate because condom breakage is a memorable, even traumatic event. However, recalling the number of condoms used in a lifetime is likely to be impossible. Thus, we caution against relying on retrospective data, even if recall is confined to the past year or past month.

In most recent studies,^{6-9,12-14} participants were required, for ethical reasons, to use a nonbarrier contraceptive and not be at risk of sexually transmitted diseases. Therefore, the participants may not have used the condoms with the same care as would a typical user. Furthermore, many were inexperienced users. Lack of experience has been shown to be a strong predictor of condom breakage,¹² so the rates

found in the literature may be higher than those among experienced condom users.

Condom quality may have an important impact on condom breakage.³ Laboratory testing shows considerable variation among condom brands. However, results from a recent study assessing 16 aged condom lots and 1 new lot from the same manufacturer suggest that many laboratory tests are not as reliable in predicting condom breakage as has been previously thought.⁷ Condom age was a better predictor of breakage than any laboratory test or combination of tests. We suggest that studies on condom breakage and slippage present summary data on the age of the condoms along with relevant laboratory data.

Preliminary results from ongoing condom trials conducted by the Los Angeles Regional Family Planning Council suggest a strong relationship between penis circumference and condom slippage, stretching, and tip displacement.¹⁸ Erect penis size was measured by the female partner, who used a special kit containing instructions and two unmarked color-coded strips of paper, one for length and the other for circumference.

Standardization of Definitions

Early studies often simply asked respondents whether the condom broke.^{2,3,19} More recent studies have collected data on timing of breaks and on slippage. With this additional information, more precise definitions have been formulated.^{9,12} In order for condom breakage and slippage data to be comparable across studies, researchers must use the same definitions. Figure 1 illustrates the complexity of this task. We propose that the following definitions of breakage and slippage rates be used in future studies.

- **Nonclinical breakage:** Number of condoms reported to have broken while the package was being opened or the condom was being put on divided by the number attempted to be used. This proportion may be slightly understated because some participants may not report or detect all nonclinical breaks. It may be further understated because a few participants may simply stop trying to use the condom during this phase but still complete study questionnaires as if they had used the condom during the entire act. Special instructions on the data collection forms and precise wording of questions should minimize these types of biases.

- **Clinical breakage:** Number of condoms reported to have broken during intercourse or withdrawal divided by the number of condoms used during intercourse. This proportion may be understated because some condom breaks discovered during removal may have actually occurred during the clinical phase. Study participants must be instructed to examine the condom carefully before it is removed from the penis and to report when they think the break occurred and not when it was discovered. In addition, some participants may not report or detect all of the clinical breaks, or they may remove the condom before termination of intercourse but still report having used the condom during the entire act.

- **Total breakage:** Number of condoms reported to have broken (both nonclinical and clinical breakage) divided

by the number of condoms attempted to be used.

- *Complete slippage:* Number of condoms reported to have completely slipped off the penis during intercourse or withdrawal divided by the number of condoms used during intercourse. If participants report a clinical break and a complete slip, only the clinical break is counted.

- *Total clinical failure:* Number of condoms reported to have broken during intercourse/withdrawal or slipped off completely divided by the number used during intercourse. (Total clinical failure is not included in Figure 1.)

- *Total failure:* Number of condoms that have broken (both nonclinical and clinical breakage) or slipped off completely divided by the number attempted to be used.

Data on breakage during removal of the condom from the penis should be collected and reported separately. Likewise, partial slippage data should be reported as well. Finally, location of the breaks should be reported since this is an important issue for quality control.

Two recent studies have shown that a small group of condom users is responsible for a disproportionate number of breaks.^{11,12} Thus, using the condom as the unit of analysis may be misleading. For example, one study reported a total failure rate of 8.7% (using the original investigators' definition).¹² If failures were independent events, each study participant could expect to have almost 1 of 10 condoms fail. However, more than half of the couples did not experience any condom failures involving the 11 condoms they used ($P < .001$). Presenting the condom failure distribution among study participants illustrates that breakage and slippage are relatively rare events for most condom users.

Discussion

Four pieces of information about contraceptive effectiveness would help couples to make an informed decision when choosing a contraceptive method.

1. Pregnancy rates during typical use show how effective the different methods are during actual use (including inconsistent or incorrect use).

2. Pregnancy rates during perfect use show how effective methods can be (perfect use defined as following the directions for use); true method failures are still possible even if the method is used correctly during every act of intercourse.

3. Pregnancy rates during imperfect use show how effective methods will be if they are used incorrectly or inconsistently.

4. The percentage of users who are perfect users or the percentage of months during which a method is used perfectly reveals how hard it is to use a method correctly and consistently.

The difference between pregnancy rates during imperfect use and pregnancy rates during perfect use reveals the extent to which a method is forgiving of imperfect use. The difference between pregnancy rates during typical use and pregnancy rates during perfect use reveals the consequences of imperfect use. This difference depends both on the extent to which a method is unforgiving of imperfect use and on how difficult it is to use that method perfectly. The same typology can be used for transmission of sexually transmitted diseases, with *infection* replacing *pregnancy* as the event of interest.

Among the barrier methods, contraceptive clinical trials that are well designed, well executed, and well analyzed exist only for the sponge, cervical cap, diaphragm, and female condom. Spermicides and the male condom simply have never been subjected to the same level of scrutiny.²⁰ The very large gap in our knowledge about the contraceptive efficacy of the male condom has been partially closed by recent prospective studies of breakage and slippage. However, these studies have reported considerable variation in rates of breakage and slippage, in part because these events have been defined differently and the instruments used to collect data vary widely across studies. In this paper, we have proposed that a standard set of definitions of breakage and slippage and a standard set of detailed questions about these events (Table 1) be used in future studies.

These studies may yield valuable information about pregnancy rates during perfect use if detailed information on incorrect use is collected. If the number of condoms that are used incorrectly is subtracted, clinical breakage and slippage rates during perfect use can be assessed. The use of oil-based lubricants has been clearly linked to condom failure.^{14,21} Other types of incorrect use include improper methods of opening packages or putting on condoms, reuse of condoms, and failure to hold the rim of the condom against the base of the penis during withdrawal. More research is needed to compile a comprehensive list of incorrect types of condom use.

TABLE 1—Information to Be Collected in Trials of Condom Breakage and Slippage

Breakage—when condom broke
While removing from package
While putting on condom
During intercourse or withdrawal
While removing from penis (examine carefully before removing)
Breakage—where condom broke (provide diagram)
Rim
Shaft
Tip
Slippage
Slipped down but not completely off the penis (how far down?)
During intercourse
During withdrawal
Was condom rim held against base of penis?
Slipped completely off the penis
During intercourse
During withdrawal
Was condom rim held against base of penis?
Partner type
Monogamous (exclusive) relationship
Primary partner
Secondary partner
Casual partner
Sex worker
Lubricant
Type used
Type of intercourse
Vaginal
Anal
Oral
Penis size
Length
Circumference

Perfect-use pregnancy rates can then be estimated from the clinical breakage and slippage rates with some additional assumptions.²² To estimate typical-use pregnancy rates, data on the extent of inconsistent use among typical users must be combined with clinical breakage and slippage rates during typical use. Thus, it may be possible to estimate perfect-use and typical-use pregnancy rates without conducting contraceptive efficacy studies, which are both costly and time consuming. □

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