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# THE IMPACT OF LUBRICANTS ON LATEX CONDOMS DURING VAGINAL INTERCOURSE

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## SUMMARY

The objective was to evaluate the impact of additional lubricant on condom breakage and slippage. Two hundred and sixty-eight couples used six new and six aged condoms during vaginal intercourse and were instructed to use two of each type with either water-based lubricant, oil-based lubricant or no additional lubricant.

The use of either oil-based or water-based lubricant increased slippage rates of new and aged condoms, although only one pairwise comparison (oil-based lubricant vs. no additional lubricant) was statistically significant (8.5% vs. 3.8%, p = .004). The use of oil-based lubricant increased clinical breakage, although not statistically significantly, in both new and aged condoms. Water-based lubricant did not impact the clinical breakage rate of the new condoms and decreased the breakage rate of the aged condoms (no additional lubricant 4.5% vs. water-based lubricant 2.1%, p = .029).

From a functional perspective, this study suggests that condom users should be told not to use oil-based lubricants. The negative impact of water-based lubricant on slippage may be outweighed by the protective influence on clinical breakage, especially for aged condoms.

Over three-fourth of the couples (76%) had at least some incorrect knowledge, according to current condom instructions, of the type of lubricant that should be used with condoms.


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## INTRODUCTION

More than ten years after the first case of acquired immunodeficiency syndrome (AIDS) was diagnosed in the United States, current research is addressing condom breakage in greater detail and results suggest that breakage may be a more serious problem than had previously been thought. As recently as 1990, the scientific literature and the popular press were asserting that condoms break less than one percent of the time.[1,2] At that time, the main emphasis of the public health community was to provide sexually active people access to condoms. Instructions on proper condom use to lower the risk of breakage were often neglected.

More recent data suggest that the range of condom breakage during vaginal intercourse is between less than one percent to 12 percent,[3-14] with many US-based studies falling in the three to five percent range. With these new findings, there is growing interest in better understanding what causes condom breakage and adopting strategies to reduce such breakage.

In the December 1991 issue of Network, factors that may cause condoms to break were grouped into three general categories; quality at manufacture, storage conditions and user behavior. Recent studies suggest that of these three categories, user behavior has the largest impact on determining condom breakage rates.[11,12,15,16] Preliminary qualitative research has identified four

types of user behavior that may cause condoms to break; incorrect methods of putting on condoms, use of oil-based lubricants, reuse of condoms, and duration or intensity of coitus[17,18]

Laboratory studies have shown that oil-based lubricants are detrimental to latex condoms.[19-21] Voeller et al. assert that 60 seconds of exposure to mineral oil caused approximately 90 percent decrease in strength as measured by the International Standards Organization (ISO) air burst test.[19]

To our knowledge, no study to date has been specifically designed to assess the impact of lubricant on condom breakage and slippage during intercourse. Three recent studies explored the impact of lubricants on condom breakage during vaginal intercourse during secondary analysis.[13,14,16] None of these studies found statistically significant differences in condom breakage due to lubricant use. However, this may have been due to the lack of statistical power because of the small number of lubricant users in these three studies.

Although there is a lack of data linking the use of oil-based lubricants with condom breakage during intercourse, results from laboratory studies have been so convincing that most condom instructions caution against their use. The problem with these condom instructions are two-fold. First, many condom users cannot distinguish between oil-based and water-based lubricants.[22] Second,

even if condom users can successfully avoid oil-based lubricants, they may not have access to water-based lubricants, especially in the developing world.

To complicate matters further, there is a debate on the effect of water-based lubricants on condom slippage and breakage. Some researchers speculate that condom breakage may be reduced if water-based lubricants are used because mechanical friction between the condom and the vaginal lining may be lessened.[23] To date, no study provides data to support this assertion. Interestingly, Trussell et al. found slippage to be significantly related to the use of any type of lubricant.[14]

Considering the problems associated with correctly identifying the different types of lubricants, it is of paramount importance that there actually is an appropriate lubricant to be used with condoms before we spend resources on education. The purpose of the present study was to quantify breakage and slippage rates of condoms during vaginal intercourse when used with an oil-based lubricant, a water-based lubricant or no additional lubricant.

## METHODS

### Study Subjects

Three hundred couples were recruited 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. Interested couples were sent a fact sheet outlining the purpose of the study and a list of selection criteria for participation in the study.

Participants were at least 18 years of age; in exclusive, heterosexual relationships during the course of the study; protected against pregnancy by recognized, reliable non-barrier methods of contraception; not at risk of sexually transmitted diseases, including HIV; and had no known sensitivities to latex, baby oil or water-based lubricants. If they qualified for the study, they were requested to return the signed informed consent form. Family Health International's (FHI) Protection of Human Subjects Committee approved the study protocol and informed consent form prior to study initiation.

Study Products

Two lots of 52mm latex condoms obtained from the Commodities Procurement and Support Division of the U.S. Agency for International Development were studied. Both lots of condoms were prelubricated with silicone. One lot of condoms consisted of recently manufactured (new) condoms that passed both the American Society for Testing Materials (ASTM) and the International Standards Organization (ISO) standards.

Since the breakage rate for the new condoms was expected to be low, we were concerned that it would be difficult to statistically detect a clinically significant effect of the different types of lubricants on these new condoms without evaluating a very large number of condoms. Therefore, one lot of older condoms was also evaluated in the hopes of amplifying the impact of the different lubricants. This second lot of (aged) condoms consisted of condoms retrieved from Jamaica after one year of storage in a hot and humid climate. The aged condoms passed the ASTM standards, but failed the ISO standard for airburst volume.

Two types of lubricants were used in this study. The first is an oil-based lubricant marketed under the brandname Johnson's Baby Oil by Johnson & Johnson, Skillman, NJ. It contains mineral oil and fragrance. The second lubricant used in the study is a water-based lubricant marketed by Astro-Lube Inc., North Hollywood, CA under the brandname Astroglide$^{R}$. This lubricant contains purified water, glycerin, propylene glycol, polyquaterium #5, methyl paraben and propylparaban.

General Procedures

Enrolled couples were mailed the study condoms along with corresponding sections of a self-administered questionnaire and asked to use the study condoms during vaginal intercourse. The 12 study condoms were divided into three study packets with two new and two aged condoms per packet. Two of the three study packets

also included additional lubricant (Johnson's Baby Oil or Astroglide[R]). If the study packet contained a lubricant, the participants were instructed to don the condoms and then lubricate them well with the lubricant found in that packet before using the condoms during vaginal intercourse.

Participants were sent the three study packets and were asked to choose the order in which they used the study packets and the condoms within each study packet. Upon receipt of the completed questionnaires, couples were remunerated for each condom used.

Definition of Breakage, Slippage and Total Failure

The self-administered questionnaire asked couples a series of specific questions about each condom used (Table 1). To avoid double counting and to calculate accurate rates for breakage, slippage and total failure, a hierarchical convention similar to one developed by Trussell et al.[14] was used in the analysis. If a condom broke while opening the package or putting on the condom, the condom was counted as a break and was subtracted from the denominator used to calculate the slippage, clinical breakage and clinical failure rates. Hence, only condoms which were used during intercourse were used to calculate these three rates. Condom slippage was defined as condoms that were reported to have slipped off completely.

Condoms that both broke and slipped off were counted only as breaks. This convention is based on the assumption that in most of these cases, condom breakage led to condom slippage. Total failure is calculated by adding all the broken condoms to the number of condoms that slipped off during intercourse and dividing by the total number of condoms used by the participants.

When calculating condom breakage rates, some researchers only employ a subset of the total breaks (clinical breaks). They argue that condom breaks occurring before intercourse (non-clinical breaks) do not put the couple at risk of pregnancy and STD transmission. Although we believe in the importance of both clinical and non-clinical breaks[12], in this paper our statistical analysis is based only on clinical failure (clinical breaks and slippage). The rationale for this decision is that the exposure of latex to lubricant prior to intercourse is minimal and would not impact non-clinical breakage rates.

Statistical Tests

The test of marginal homogeneity for ordered data (an extension of McNemar's test) was used to test pairwise comparisons of clinical breakage, slippage and clinical failure rates of the three lubricant groups (oil-based, water-based and no additional lubricant)[24]. Differences in preference ratings of the three lubricant groups on a five-point scale (1=liked very much to

5-strongly disliked) were assessed with a two-tailed Wilcoxon matched pairs signed rank test.

Alpha of 0.05 was used for the tests of statistical significance. To adjust for any potential effect of multiple testing on the p-values, alpha was set at $\leq$ .05 for a family of three paired comparisons of functionality. Each paired comparison (water vs. oil, water vs. none and oil vs.none) within a family of tests (clinical breakage, slippage and clinical failure) was assessed at .017. For the tests of differences in preference ratings, alpha was also set at $\leq$ .05 for the family of three paired comparisons. Each paired comparison was assessed at .017.

Approximate 95 percent confidence intervals for condom failure rates were calculated using the normal approximation to the binomial distribution (with an added continuity correction factor).

## RESULTS

### Background Characteristics

Of the original 300 couples recruited, 293 couples used at least one study condom and completed the data collection forms. However, this analysis is based on the 268 couples who used all 12 of their study condoms (Table 2). Participants reported a median age

slightly over 30 years (females-31 years, males-32 years) with a high level of formal education (median: females-14.5 years, males-15 years). Eighty-eight percent of the participants reported living together and they were predominately Caucasian (female-85%, males-84%).

Past Condom Use

Most of the study participants had experience using condoms, with well over half reporting having used more than 25 condoms during their lifetime (females-66%, males-74%) (Table 3). Of the participants with condom experience in the past year, about 40 percent of both females and males reported using lubricants at least some of the time (Table 4). However, less than five percent said they always used lubricants with their condoms in the past year. Almost one third of both female and male participants reported using oil-based lubricants in the past year (females-30%, males-29%).

Knowledge About Lubricant Type

When couples were asked what type of lubricant should not be used with condoms, 76 percent gave at least one incorrect answer according to information in current condom instructions (Table 5). Over half the couples (63%) believed it was correct to use baby oil (massage oil 40% and vaseline 35%).

Condom Breakage, Slippage and Total Failure Rates

The 268 couples used two condoms from each of the six groups presented in Table 6. To help decide whether to pool the data from both types of lots (new and aged), clinical breakage, slippage and clinical failure rates were calculated separately for each type. The ratio of slippage rates of condoms lubricated with water-based and oil-based lubricant compared with slippage rates of condoms with no additional lubricant were similar in both new and aged lots. However, the ratio of breakage rates, when compared in the same manner, were not similar. This interaction was contrary to what was expected. Thus we chose to perform the analyses separately by new and aged condom lots.

Total breakage rates for the new condoms ranged from 3.2 percent for the condoms used with the water-based lubricant to 4.5 percent for the condoms used with the oil-based lubricant. For the aged condoms, total breakage rates ranged from 3.5 percent for the condoms used with water-based lubricant to 6.0 percent for the condoms used with oil-based lubricant.

The slippage rates ranged from 3.8 percent for the new condoms used with no additional lubricant to 8.5 percent for the new condoms used with the oil-based lubricant. For the aged condoms, slippage rates ranged from 5.6 percent for the ones used with no additional lubricant to 9.4 percent for the aged condoms used with oil-based lubricant.

Table 7 presents the p-values for the pairwise comparisons of clinical breakage, slippage and clinical failure rates of the three lubricant groups (oil-based, water-based and no additional lubricant). For the new condoms, the oil-based lubricant had a small, though non-significant, negative impact on the clinical breakage rate when compared to new condoms used with no additional lubricant (3.6% vs.2.4%, p = .379). Water-based lubricant had no impact on the clinical breakage rate when compared to the clinical breakage rate of the new condoms used with no additional lubricant (both 2.4%). For the new condoms, slippage rates increased with both lubricants (oil-based 8.5%, water-based 7.0%) when compared to no additional lubricant (3.8%). The pairwise comparison of the slippage rate of new condoms used with no additional lubricant vs. new condoms used with oil-based lubricant was significant (p = .004) and the pairwise comparison of no additional lubricant vs. water-based lubricant approached significance (p = .026) at the study's alpha level, which was set at .017 to control for multiple testing.

The pairwise comparison of clinical failure rates was statistically significant for new condoms used with no additional lubricant vs. new condoms used with the oil-based lubricant (6.2% vs. 12.1%, p = .001). New condoms used with water-based lubricant had a higher clinical failure rate than their counterparts used with no additional lubricant (9.4 vs. 6.2%); however this difference was not statistically significant (p = .067).

For aged condoms, the oil-based lubricant had a small, though non-significant, negative impact on the clinical breakage rate when compared to the clinical breakage rate of the aged condoms used with no additional lubricant (5.1% vs. 4.5%, p = .789). Interestingly, the water-based lubricant reduced the clinical breakage rate of aged condoms when compared to the clinical breakage rate of aged condoms used with no additional lubricant (2.1 vs. 4.5%); however this difference was not statistically significant (p = .029) at the study's alpha level of .017. The pairwise comparison of the clinical breakage rate of aged condoms used with the water-based lubricant vs. the clinical breakage rate of age condoms used with the oil-based lubricant approached significance (2.1% vs. 5.1%, p = .018).

The slippage rates of aged condoms used with either lubricant (oil-based 9.4% and water-based 6.4%), was higher than the slippage rate of the aged condoms used with no additional lubricant (5.6%), though neither of the pairwise comparisons was statistically significant.

Adding clinical breakage and slippage, the clinical failure rate of the aged condoms used with the oil-based lubricant was higher than the clinical failure rate of aged condoms used with no additional lubricant (14.5% vs. 10.2%, p = .056). The water-based lubricant's negative effect on the slippage rate is outweighed by the water-based lubricant's positive effect on clinical breakage of aged

condoms. As a result, the clinical failure rate of the aged condoms used with water-based lubricant is lower than the clinical failure rate of the aged condoms used with no additional lubricant (8.5% vs. 10.2%, p = .376). Finally, the pairwise comparison of the clinical failure rate of aged condoms used with oil-based lubricant (14.5%) vs. the clinical failure rate of aged condoms used with water-based lubricant (8.5%) was statistically significant (p = .001).

Preference for Lubricants

Couples were asked to rate how well they liked the condom lubricant when oil-based, water-based or no additional lubricant were added to the condoms. (Table 8). When no additional lubricant was compared to the oil-based lubricant, couples preferred no additional lubricant ($p < 0.001$). When the comparison was between no additional lubricant and the water-based lubricant, they preferred the water-based lubricant ($p < 0.001$). As expected, couples preferred the water-based lubricant over the oil-based lubricant ($p < 0.001$).

## DISCUSSION

Laboratory studies clearly show that even short exposure of latex condoms to oil-based lubricants adversely affects the results of various laboratory tests used by the International Standard

Organization (ISO) and the American Society for Testing Materials (ASTM).[19-21] How well these laboratory tests predict condom performance in human use is still not well understood. In a recent study correlating nine laboratory tests with condom breakage during vaginal intercourse, the age of the condom was the best predictor of breakage.[25] The objective of the present study was to assess whether an oil-based lubricant impacts condom integrity during vaginal intercourse as adversely as suggested by laboratory tests.

For new condoms that passed both the ISO and ASTM standards, the use of either an oil-based, a water-based or no additional lubricant did not significantly impact clinical breakage rates. However, the clinical breakage rate for the new condoms used with oil-based lubricant was higher (3.6%) than the clinical breakage rate for the new condoms used with either no additional lubricant or water-based lubricant (both 2.4%).

For the aged condoms, the use of oil-based lubricant again led to a small increase in clinical breakage when compared to the aged condoms used with no additional lubricant. Interestingly, for the aged condoms, our data supports the theory that a water-based lubricant reduces clinical breakage. The clinical breakage rate was reduced from 4.5 percent (no additional lubricant) to 2.1 percent (water-based lubricant), although this difference was not statistically significant (alpha = .017). These findings suggest that the protective influence of water-based lubricants may become

more pronounced as the material integrity of the latex deteriorates over time.

Although many researchers have focused solely on condom breakage, condoms that slip off completely during intercourse also contribute to a decrease in barrier protection. In this study, the use of either lubricant increased the slippage rates for both new and aged condoms, although only the pairwise comparison of the slippage rate of new condoms used with the oil-based lubricant vs. new condoms used with no additional lubricant was statistically significant (alpha = .017). How much this increase in slippage is due in part to the excessive use of lubricants by some study participants is not known.

For the new condoms, the clinical failure rate (clinical breakage and slippage) was highest for the condoms used with the oil-based lubricant (12.1%) and lowest for the condoms used with no additional lubricant (6.2%). For the aged condoms, again the condoms used with the oil-based lubricant had the highest clinical failure rate (14.5%). However, the water-based lubricant's protective influence on clinical breakage outweighed its negative impact on slippage. As a result, the aged condoms used with the water-based lubricant had the lowest clinical failure rate (8.5%).

From a functional perspective, this study suggests that condom users should be told not to use oil-based lubricants. The impact of using a water-based lubricant is less clear. The negative impact of water-based lubricant on slippage may be outweighed by the protective influence on clinical breakage, especially for aged condoms.

Study participants showed a statistically significant preference for the use of an additional water-based lubricant. Couples were asked on a five point scale how they liked the water-based, the oil-based and no additional lubricant. They reported the highest preference for the water-based lubricant and the lowest preference for the oil-based lubricant.

Condom users are often instructed to use additional water-based lubricant for increased sensitivity.[26] Caution should be used when providing these types of instructions because many condom users cannot distinguish water-based from oil-based lubricants.[22] In our study, 76 percent of the couples had at least some incorrect knowledge, according to current condom instructions, of the type of lubricant that should be used. Condom instructions need to make certain that users can correctly identify water-based lubricants. In developed countries where there is ready access to lubricants that contain spermicidal agents such as nonoxynol-9 (N-9), we would advise condom users who desire additional lubricant to choose

lubricants containing N-9 for the additional protection against pregnancy and STDs the spermicide may offer.[27]

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**Table 1: Wording of Breakage and Slippage Questions**

| |
|---|
| Did the condom slip off completely?<br>0-no<br>1-yes<br>-->if yes, when did the condom slip off?<br>1-during sex<br>2-during withdrawal<br>3-don't know |
| Did the condom break?<br>0-no--->end of section<br>1-yes |
| When did condom break?<br>1-opening package<br>2-unrolling onto penis<br>3-during sex<br>4-withdrawing penis<br>5-taking condom off<br>6-do not know |

Table 2: Socio-demographic Characteristics

(N = 268 couples)

| | Female | | Male | |
|---|---|---|---|---|
| | n | (%)[1] | n | (%)[1] |
| **Age (in years)** | | | | |
| 18 to 25 | 58 | (22) | 38 | (14) |
| 26 to 30 | 70 | (26) | 75 | (28) |
| 31 to 35 | 60 | (22) | 50 | (19) |
| 36 to 40 | 43 | (16) | 54 | (20) |
| 41 to 45 | 36 | (13) | 50 | (19) |
| not specified | 1 | (<1) | 1 | (<1) |
| **median** | **31** | | **32** | |
| **Education** | | | | |
| less than 12 years | 5 | ( 2) | 10 | ( 4) |
| 12 years | 57 | (21) | 66 | (25) |
| 13 to 16 years | 161 | (60) | 132 | (49) |
| more than 16 years | 43 | (16) | 59 | (22) |
| not specified | 2 | ( 1) | 1 | (<1) |
| **median** | **14.5** | | **15** | |
| **Ethnic Background** | | | | |
| Asian | 3 | ( 1) | 3 | ( 1) |
| Black | 34 | (13) | 33 | (12) |
| Caucasian | 228 | (85) | 224 | (84) |
| Hispanic | 1 | (<1) | 1 | (<1) |
| other | 1 | (<1) | 1 | (<1) |
| not specified | 1 | (<1) | 6 | ( 2) |
| **Marital Status** | | | | |
| living with partner | 236 | | (88) | |
| not living with partner | 30 | | (11) | |
| not specified | 2 | | ( 1) | |

[1] On this and all subsequent tables, percents may not add to 100 due to rounding.

**Table 3: Condom Experience in Past**

**(N=268 couples)**

| Number of Condoms | Female | | Male | |
|---|---|---|---|---|
| | n | (%) | n | (%) |
| **Used During Lifetime** | | | | |
| none | 9 | ( 3) | 1 | (<1) |
| 1 to 9 | 18 | ( 7) | 13 | ( 5) |
| 10 to 25 | 63 | (24) | 51 | (19) |
| 26 to 100 | 131 | (49) | 143 | (53) |
| more than 100 | 45 | (17) | 55 | (20) |
| not specified | 2 | ( 1) | 5 | ( 2) |
| **Used in Past Year** | | | | |
| none | 21 | ( 8) | 18 | ( 7) |
| 1 to 9 | 40 | (15) | 42 | (16) |
| 10 to 25 | 131 | (49) | 129 | (48) |
| 26 to 100 | 66 | (25) | 69 | (26) |
| more than 100 | 7 | ( 3) | 7 | ( 3) |
| not specified | 3 | ( 1) | 3 | ( 1) |

**Table 4: Past Experience with Lubricants**

**(N=268 couples)**

| | Female | | Male | |
|---|---|---|---|---|
| | n | (%) | n | (%) |
| **Did you use condoms in the past year?** | | | | |
| no | 23 | ( 8) | 20 | ( 7) |
| yes | 245 | (91) | 248 | (92) |
| **If yes, how often did you use additional lubricant with the condoms?** | | | | |
| never | 147 | (60) | 151 | (61) |
| less than half the time | 65 | (26) | 65 | (26) |
| more than half the time | 25 | (10) | 23 | ( 9) |
| always | 7 | ( 3) | 6 | ( 2) |
| not specified | 1 | (<1) | 3 | ( 1) |
| **Type of Lubricant Used Most Often in Past Year[1]** | | | | |
| oil-based | 29 | (30) | 27 | (29) |
| water-based | 57 | (59) | 57 | (61) |
| combination of the two | 3 | ( 3) | 2 | ( 2) |
| not specified | 8 | ( 8) | 8 | ( 9) |

[1] Excludes subjects who did not report using a lubricant during the past year.

Table 5: Incorrect Knowledge of Lubricant Use

(N = 268 couples)

| | Couples who said they agreed with statement | |
|---|---|---|
| | n | (%) |
| **Oil-based Lubricants can be used**[1] | | |
| Baby oil | 169 | (63) |
| Massage oil | 107 | (40) |
| Vaseline | 94 | (35) |
| **Subtotal with at least one incorrect response** | **196** | **(73)** |
| **Water-based Lubricants cannot be used**[1] | | |
| Astroglide | 10 | ( 4) |
| KY Jelly | 11 | ( 4) |
| Contraceptive Foam | 34 | (13) |
| **Subtotal with at least one incorrect response** | **51** | **(19)** |
| **Total with at least one incorrect response** | **203** | **(76)** |

[1] Multiple responses allowed.

Table 6: Condom Failure Rates (Breakage and Slippage) by Age of Condom Lot and Type of Lubricant Used

(N = 268 couples)

| | New Condoms | | | Aged Condoms | | |
|---|---|---|---|---|---|---|
| | No Additional Lubricant | Oil-Based Lubricant | Water-Based Lubricant | No Additional Lubricant | Oil-Based Lubricant | Water-Based Lubricant |
| **Breakage** | | | | | | |
| number of condoms used | 536 | 536 | 536 | 536 | 536 | 536 |
| non-clinical breakage rate[1] | 0.9% | 0.9% | 0.7% | 0.9% | 0.9% | 1.5% |
| (confidence interval 95%) | (0.3,2.3) | (0.3,2.3) | (0.2,2.0) | (0.3,2.3) | (0.3,2.3) | (0.7,3.0) |
| clinical breakage rate[2] | 2.4% | 3.6% | 2.4% | 4.5% | 5.1% | 2.1% |
| (confidence interval 95%) | (1.4,4.3) | (2.2,5.6) | (1.4,4.3) | (3.0,6.7) | (3.4,7.4) | (1.1,3.8) |
| total breakage rate[1] | 3.4% | 4.5% | 3.2% | 5.4% | 6.0% | 3.5% |
| (confidence interval 95%) | (2.1,5.4) | (3.0,6.7) | (1.9,5.1) | (3.7,7.8) | (4.2,8.4) | (2.2,5.6) |
| **Slippage** | | | | | | |
| slippage rate[2] | 3.8% | 8.5% | 7.0% | 5.6% | 9.4% | 6.4% |
| (confidence interval 95%) | (2.4,5.9) | (6.3,11.3) | (5.0,9.5) | (3.9,8.1) | (7.1,12.3) | (4.6,9.0) |
| **Total Failure** | | | | | | |
| clinical failure rate[2] | 6.2% | 12.1% | 9.4% | 10.2% | 14.5% | 8.5% |
| (confidence interval 95%) | (4.4,8.7) | (9.5,15.2) | (7.1,12.3) | (7.8,13.1) | (11.7,17.9) | (6.3,11.3) |
| total failure rate[1] | 7.1% | 12.9% | 10.1% | 11.0% | 15.3% | 9.9% |
| (confidence interval 95%) | (5.1,9.7) | (10.2,16.1) | (7.7,13.0) | (8.5,14.0) | (12.4,18.7) | (7.6,12.8) |

[1] Includes all condoms used.
[2] Includes all condoms not broken before donning.

**Table 7: P-values for Pairwise Comparisons[1] of Condom Failure Rates by Age of Condom Lot and Type of Lubricant Used**

**(N = 268 couples)**

| Rates Compared | New Condoms | | Aged Condoms | |
|---|---|---|---|---|
| | Rates | p-value | Rates | p-value |
| **Clinical Breakage** | | | | |
| None Added vs Oil-Based | 2.4 vs 3.6 | .379 | 4.5 vs 5.1 | .789 |
| None Added vs Water-Based | 2.4 vs 2.4 | 1.000 | 4.5 vs 2.1 | .029 |
| Oil-Based vs Water-Based | 3.6 vs 2.4 | .379 | 5.1 vs 2.1 | .018 |
| **Slippage** | | | | |
| None Added vs Oil-Based | 3.8 vs 8.5 | .004 | 5.6 vs 9.4 | .037 |
| None Added vs Water-Based | 3.8 vs 7.0 | .026 | 5.6 vs 6.4 | .701 |
| Oil-Based vs Water-Based | 8.5 vs 7.0 | .442 | 9.4 vs 6.4 | .056 |
| **Clinical Failure** | | | | |
| None Added vs Oil-Based | 6.2 vs 12.1 | .001 | 10.2 vs 14.5 | .056 |
| None Added vs Water-Based | 6.2 vs 9.4 | .067 | 10.2 vs 8.5 | .376 |
| Oil-Based vs Water-Based | 12.1 vs 9.4 | .198 | 14.5 vs 8.5 | .001 |

[1] Test of marginal homogeneity for ordered data with exact p-values for two-tailed test.

**Table 8: Lubricant Preference**

**(N=268 couples)**

| | No Additional Lubricant | | Oil-Based Lubricant | | Water-Based Lubricant | |
|---|---|---|---|---|---|---|
| | n | (%) | n | (%) | n | (%) |
| **Lubricant Preference** | | | | | | |
| liked very much | 27 | ( 10) | 23 | ( 9) | 98 | ( 37) |
| liked fairly well | 68 | ( 25) | 55 | ( 20) | 65 | ( 24) |
| neutral | 83 | ( 31) | 42 | ( 16) | 30 | ( 11) |
| somewhat disliked | 35 | ( 13) | 72 | ( 27) | 30 | ( 11) |
| strongly disliked | 16 | ( 6) | 51 | ( 19) | 14 | ( 5) |
| not specified | 39 | ( 15) | 25 | ( 9) | 31 | ( 12) |
| total | 268 | (100) | 268 | (100) | 268 | (100) |
| **Mean Score[1]** | 2.8 | | 3.3 | | 2.1 | |
| Two-tailed Wilcoxon matched pairs signed rank test | No additional lubricant vs. oil-based lubricant | | | | $p < .001$ | |
| | No additional lubricant vs. water-based lubricant | | | | $p < .001$ | |
| | Oil-based lubricant vs. water-based lubricant | | | | $p < .001$ | |

[1] On a scale from 1 to 5, where 1 = liked very much and 5 = strongly disliked