An evaluation of a thicker versus a standard condom with gay men

Susan Golombok, Richard Harding and Jonathan Sheldon

Objectives: Although thicker (stronger) condoms are advocated in western Europe for anal intercourse between men, empirical evidence supporting their greater efficacy is lacking. The present study aimed to determine whether a thicker condom is less likely to fail (break or slip off) than a standard (regular thickness) condom, and to establish factors associated with condom failure among gay men.

Design: A total of 283 homosexual couples participated in a double-blind, randomized, controlled trial of a standard and a thicker condom.

Methods: Each couple was allocated nine of either condom type. Data were collected on user characteristics, and a questionnaire completed immediately after the use of each condom. The thicker and the standard condoms were used by 142 and 141 couples, respectively.

Results: No significant differences were found between the two condom types with respect to either clinical or non-clinical definitions of failure (breakage and slippage). With instances of inappropriate use removed, failure rates for the standard and the thicker condom were low at 2.5 and 2.3%, respectively. User characteristics associated with breakage were lower educational achievement, lack of confidence in condom use, and a history of condom breakage. Behaviours associated with breakage were unrolling the condom before fitting to the penis, longer penis length, absence of additional lubricant, the use of inappropriate lubricant, and longer duration of intercourse.

Conclusion: Breakage and slippage rates were low for both condom types. There is no evidence from the present investigation to support the use of stronger (thicker) condoms over standard strength condoms among gay men. The appropriate use of additional lubricant should be encouraged.

Introduction

The use of condoms is recommended to gay men as the most effective way of reducing the risk of HIV transmission during anal intercourse. However, there is no clear evidence as to the most appropriate type of condom. Some European countries (including the UK, the Netherlands, Germany and Switzerland) recommend the use of ‘strong’ (i.e. thicker) condoms for anal intercourse, whereas in the United States and Australia prevention information does not generally advocate a particular strength of condom. The European position appears to stem from the assumption that anogenital intercourse requires the use of stronger condoms because of the ‘greater friction’ involved [1,2]. To date, no rigorous evaluation of the comparative effectiveness of different types of condoms has taken place, partly because of the ethical problems associated with such trials [3].

The majority of existing studies have lacked operational definitions of failure and, crucially, have not separated participants according to sexual orientation and sexual behaviour. In addition, the reported methods used to
measure condom reliability for gay men have been weak, depending almost entirely on retrospective self-report surveys of failure. A further shortcoming is that the strength of condom used has rarely been reported. Although some studies have published comparative condom reliability data using laboratory tests, and a high correlation has been shown between failure rates for heterosexual use and laboratory testing, this has not been replicated for anal intercourse between gay men [4,5]. The literature thus does not provide reliable values for failure rates of condoms during anogenital intercourse between men [6].

Previous studies have consistently reported that some men report frequent incidents of condom failure whereas others report never having experienced failure at all. Although there is a larger body of evidence on heterosexual than on homosexual condom failure, investigations in both populations have demonstrated a range of predictors of failure. User characteristics associated with instances of condom failure include longer penile length [7] and larger circumference [8], having low income/low employment status [9], lack of personal efficacy and knowledge of correct condom use [10], low educational attainment [11], being circumcised [12] and identifying as Afro-Caribbean [13]. Behaviours associated with condom failure include a history of failure [14], the infrequent use of condoms [15], engaging in anal rather than vaginal intercourse [9], not using additional lubricant consistently [10], the use of inappropriate (i.e. not water-based) additional lubricant [16], and the absence of additional lubricant during anogenital intercourse [17]. In addition to these user characteristics and behaviours, condom failure has been associated with the age of the condom used [18], and a small investigation found a relationship between condom failure and condom strength, reporting that Australian and ISO standard condoms were five times more likely to break during anal intercourse than the (stronger) Swiss standard condom [19].

By conducting a prospective, randomized, double-blind, controlled trial of a thicker and a standard (regular thickness) condom with a large sample of gay men, the present investigation aimed to determine whether thicker condoms are less likely to fail during anal intercourse than are standard condoms. A further aim was to establish factors associated with condom failure among gay men.

Methods

Recruitment
Gay couples were recruited through a range of gay press editorials and news features, flyers in commercial venues, genitourinary clinics, community-based organisations (using publications and both postal and e-mail mailing lists) and snowballing (i.e. recruiting participants through existing participants). Only couples who were currently not using condoms in their relationship, or currently not using strong condoms in their relationship, were recruited into the study. Therefore, those respondents not using condoms when they entered the study were at reduced risk of HIV transmission (within the relationship relative to their usual behaviour) for the duration of the trial, and those using standard condoms were at no greater risk than had they not participated in the trial. The trial was approved by the City University Ethics Committee. Participants entered the study as a ‘couple’ (i.e. two men in a sexual relationship), were at least 18 years old, and gave written informed consent.

Procedure

Each couple was randomly allocated either nine standard (regular thickness) or nine strong condoms using a set of random numbers (allocation was blind to both participants and research staff). Condoms were sampled from standard production batches, packed and hermetically sealed in unmarked square aluminium laminate foil packaging, and lubricated with 0.4 g silicone lubricant. Before commencing the study, both sets of condoms were tested to confirm compliance with the requirements of EN600: 1996. The thicker condom met the higher tensile requirements defined in clause 7 for extra strong condoms. Retained samples of condoms were also tested on completion of the trial to confirm that there had been no change in properties. Each couple also received nine sachets of a water-based additional lubricant widely used by gay men in the UK.

On entering the trial, baseline data were collected by postal questionnaire independently from each participant on user characteristics previously shown to be predictive of failure: (i) education and employment; (ii) history of both condom breakage and slippage rated on a 5-point scale from ‘1, very often’ to ‘5, never’; (iii) number of condoms used both in the past year and ever; (iv) confidence in using condoms rated on a 5-point scale from ‘1, strongly agree’ to ‘5, strongly disagree’; and (v) whether the participant had been circumcised.

In addition, each respondent was asked to measure his partner’s penile dimensions, specifically the length and girth, using a validated procedure [20]. Each couple was sent two sets of colour-coded cardboard strips. One strip measured 26 × 4.5 cm, and was printed with instructions to measure erect penis length along the top of the penis from base to tip. The second strip measured 21 × 4 cm and was printed with instructions to measure the girth of the erect penis on the shaft just below the glans. Respondents were not asked to
provide the information in scale measurements (i.e. centimetres or inches) in order to encourage honest reporting. Measurements were marked on the strips and the strips were returned at the beginning of the study.

Immediately after the use of each of the nine condoms, a questionnaire was completed recording the nature of each episode of anal intercourse including: (i) which partner was insertive; (ii) when the condom was unrolled, i.e. before or after fitting to the penis; (iii) the type of additional lubricant used, i.e. name of additional lubricant if the water-based additional lubricant supplied was not used; (iv) sites of additional lubricant application, including sites on the penis both under and on the condom, and in and around the anus; (v) duration of intercourse; (vi) whether the condom tore and when, i.e. before or during intercourse; (vii) whether the condom slipped off completely, and whether this was during intercourse or withdrawal. Expenses of £1 per questionnaire were paid to each couple on completion of the trial.

The number of condom uses was calculated to be capable of detecting a difference in breakage rates from 4 to 2%, with 95% confidence at a power of 80%. Data were analysed using chi-squares, t-tests, and where appropriate, Fisher’s exact 2 × 2 tests.

Results

Sample characteristics
A total of 356 couples completed informed consent forms during 1998–1999, 296 entered the trial, and 283 couples completed (i.e. 268 couples who used nine condoms and 15 couples who used eight condoms). The criterion for completion was that at least eight of the nine condoms had been used. A total of 1269 standard and 1278 thicker condoms were used in the trial, the former by 141 couples and the latter by 142 couples. Slight variations occurred in the total number of condoms used to calculate the different types of failure because of missing data and the removal of instances of slippage and non-clinical breakage when calculating clinical breakage. Additional water-based lubricant was used in 95% (n = 1185) of usages of the standard condom and 96% (n = 1202) of usages of the thicker condom. The key physical properties of the condoms tested are shown in Table 1.

Approximately 50% of participants were resident in London, the remainder residing around the UK. The mean age of participants was 33 years, and participants were predominantly white (92.7%). Six per cent had no educational qualifications, 25% had ‘O’ levels/GCSEs, 17% had ‘A’ levels, 17% had a diploma, and 35% were educated to university degree level. These characteristics of the sample are very similar to those of large-scale annual sociosexual surveys of gay men across the UK [21–23]. Professional/managerial positions were held by 25% of participants, 30% were in skilled non-manual occupations, 20% were in manual employment and 22% were unemployed.

Condom failure rates
Definitions of failure have been inconsistent in the literature. In the present study we used the comprehensive set of clinical and non-clinical definitions advocated by Steiner et al. [6], which distinguish between non-clinical and clinical incidents of both breakage and slippage. Non-clinical breakage is defined as condom breakage before intercourse, and clinical breakage is defined as breakage during intercourse or withdrawal. Non-clinical plus clinical breakage together give the total breakage rate. Slippage is defined as condoms that slip completely off the penis during intercourse or withdrawal, having removed from the sample those condoms that tore. Total clinical failure rate is the clinical breakage rate plus slippage rate, and the total failure rate is the sum of the clinical breakage rate, the non-clinical breakage rate and the slippage rate. There was no significant difference between the thicker and the standard condom with respect to non-clinical breakage, clinical breakage, total breakage, slippage, total clinical failure or total failure. Failure rates are summarized in Table 2.

Three criteria were selected to denote inappropriate

<table>
<thead>
<tr>
<th>Table 1. Physical properties of the standard and the thicker condom.</th>
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<td>Standard</td>
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<td>Single wall thickness (mm)</td>
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<tr>
<td>Force at break (median) Newtons</td>
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<td>Burst pressure (kPa)</td>
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<td>Burst volume (litres)</td>
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<td>Length (mm)</td>
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<td>Lay flat width (mm)</td>
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<th>Table 2. Comparative breakage and slippage rates for the standard and the thicker condom.</th>
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<td>Standard</td>
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<td>%</td>
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<td>Non-clinical breakage:</td>
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<td>Removing from packaging</td>
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<td>Fitting condom to the penis</td>
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<td>Clinical breakage</td>
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<td>Total non-clinical breakage</td>
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<td>Total breakage</td>
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<td>Slippage</td>
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<td>Total clinical failure</td>
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condom use. These were: (i) inappropriate lubrication (including no additional lubricant used, saliva used or an oil-based additional lubricant used, or the use of additional lubricant on the inside of the condom); (ii) condom unrolled before fitting to the penis; and (iii) the use of penile jewellery. With inappropriate use removed from the sample, there were no significant differences between condom types for clinical breakage, slippage or total clinical failure. Failure rates with inappropriate use removed are summarized in Table 3.

**Factors associated with breakage**

Breakage was significantly associated with the duration of intercourse ($t = 3.50$, $P < 0.001$). The mean duration of intercourse when the condom broke was 28.76 min ($N = 79$) compared with 15.45 min when the condom did not break ($N = 2372$). An examination of the distributions of the duration of intercourse for cases of breakage versus cases of non-breakage suggested a strong association between breakage and lengthy intercourse, particularly when in excess of 45 min. The clinical breakage rate was 2.2% when intercourse lasted 45 min or less, compared with 15.2% for cases when intercourse lasted for more than 45 min. No significant relationship was found between condom type and the length of intercourse. The time at which the condom was unrolled significantly affected breakage (Fisher’s exact test, $P = 0.04$), with 6.4% of those who unrolled the condom before fitting it experiencing failure compared with 3.1% who unrolled the condom when it was on the penis end (before instances of inappropriate use were removed).

The type of additional lubricant used was found to be associated with condom breakage ($\chi^2 = 44.34$, $P < 0.0001$). When the supplied additional lubricant was used, 3% of condoms broke, 7.7% of condoms broke when an oil-based lubricant was used, 10.8% of condoms broke when saliva was used, and 21.4% of condoms broke when no additional lubricant was used. The site of application of the additional lubricant was also related to condom breakage. Breakage tended to be less likely if the additional lubricant was applied: in the anus (Fisher’s exact test, $P = 0.06$; 3.7% broke with no additional lubricant in the anus and 2.5% broke with additional lubricant in the anus), around the anus (Fisher’s exact test, $P = 0.07$; 4.0% broke with no additional lubricant around the anus and 2.5% broke with additional lubricant around the anus) or all over the condom (Fisher’s exact test, $P = 0.04$; 4.0% broke when additional lubricant was not applied at all over the condom and 2.4% broke when additional lubricant was applied all over the condom). Whether or not additional lubricant was placed on the tip of the penis under the condom, all over the penis under the condom or on the condom at the tip made no difference to condom breakage. Although a relationship was identified between the site of additional lubricant application and breakage, this was independent of condom type.

In addition to factors associated with condom usage, breakage was associated with the characteristics of the sample. Penis length was found to be associated with condom breakage ($t = 3.25$, $P < 0.001$). Mean penis length was 16.39 cm for men who reported condom breakage, and 15.24 cm for men who did not report condom breakage. With respect to penis girth, no significant difference was found between men who reported breakage and those who did not. Neither was there a significant difference in breakage rate between men who had been circumcised and those who had not. No significant relationship was found between condom type and penile dimensions.

Condom breakage was less likely to occur among men of higher social class ($\chi^2 = 13.15$, $P < 0.05$), and although there was no overall difference in condom breakage with respect to educational level, some group differences were identified. For example, the number of men with no educational qualifications reporting breakage was 16.1% (five out of 26) in comparison with 8.3% (14 out of 155) for men with a university degree.

Condom breakage was not associated with previous frequency of condom use or the type of condom generally used. There was no difference in the number of condoms used in the previous year, or in the number of condoms ever used, between men who reported condom breakage during the clinical trial and those who did not. Confidence in using condoms was related to condom breakage during the trial ($t = 2.08$, $P < 0.05$), with 20.0% of those who disagreed/strongly disagreed with the statement ‘I am confident using condoms’ experiencing breakage during the trial compared with 11.35% of those who agreed/strongly agreed with this statement. Those who had experienced condom breakage in the past were more likely to report condom breakage in the trial ($t = 22.8$, $P < 0.01$). Among those who reported breakage in the trial, 9.2% had never experienced breakage, 14.3% had occasionally/sometimes experienced breakage, and 42% had often/very often experienced breakage. Breakage was significantly more frequent among younger men ($t = 2.06$, $P < 0.05$).

### Table 3. Comparative breakage and slippage rates for the thicker and the standard condom with inappropriate use removed.

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<tr>
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<th>Standard</th>
<th>Thicker</th>
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<tr>
<td></td>
<td>%</td>
<td>N</td>
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<tr>
<td>Clinical breakage</td>
<td>2.2</td>
<td>27</td>
</tr>
<tr>
<td>Slippage</td>
<td>2.4</td>
<td>30</td>
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<tr>
<td>Total clinical failure</td>
<td>4.6</td>
<td>57</td>
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A ‘couple effect’ was identified among those couples who experienced breakage (Fisher’s exact test, \( P = 0.009 \)). For those couples, if partner A had no break then the probability of partner B experiencing a break was 8.4%. If partner A experienced a break, then the probability of partner B experiencing a break was 25.8%. It should be noted that the insertive and receptive roles during sex are not evenly distributed between the partners. As found among heterosexual couples, breakage and slippage tend to occur in a cluster of couples. Regarding the number of breakages experienced by ‘breaker couples’, 55 couples reported one breakage, 11 couples reported two breakages, three couples reported three breakages and one couple reported four breakages. There was no significant difference with respect to condom type between these condom-breaking couples, i.e. a similar proportion of breaker couples had been allocated each condom type.

The use of additional lubricant was not evenly distributed between the conditions. Those using the standard condom were more likely to use an additional lubricant (\( \chi^2 = 11.50, P < 0.05 \)). Of those who used no additional lubricant at all (i.e. no saliva or other additional lubricant) 75% (\( n = 24 \)) were using the thicker condom and 25% (\( n = 8 \)) were using the standard condom. Breakage rates were not significantly different for the two condoms when no additional lubricant was used. All other categories of additional lubricant use showed no difference between condom types.

Factors associated with slippage

Neither the duration of intercourse, nor penis length or girth, were associated with condoms slipping off. Although the slippage rate was higher when saliva (5.1%), oil-based lubricant (8.3%) or no additional lubricant (7.7%) was used than when the supplied additional lubricant was used (3.2%), it is important to note that the number of occasions of slippage on which inappropriate lubrication was used was small (less than 5%), which makes these figures difficult to interpret.

The site of application of the additional lubricant was found to be related to slippage. Condoms were more likely to slip off when additional lubricant was applied on the tip of the penis under the condom (Fisher’s exact test, \( P = 0.02 \)) and when additional lubricant was applied all over the penis under the condom (Fisher’s exact test, \( P = 0.06 \)). When additional lubricant was applied on the tip of the penis under the condom the slippage rate was 5.3% in comparison with 2.8% when no additional lubricant was applied to this area. Similarly, the slippage rate was 5.4% when additional lubricant was applied all over the penis under the condom, but only 3.0% when this was not the case. However, when additional lubricant was applied all over the outside of the condom the significant difference in slippage rate (Fisher’s exact test, \( P = 0.003 \)) reflected less slippage (2.6%) than when additional lubricant was not applied all over the outside of the condom (5.1%). It seems, therefore, that there is a greater risk of slippage when additional lubricant is applied under the condom, and a lower risk of slippage when additional lubricant is applied all over the outside of the condom. Whether or not additional lubricant was applied over the tip of the condom and in, or around, the anus was not associated with condom slippage. No difference in slippage was identified according to whether or not the man had been circumcised.

Higher social class (\( F = 23.97, P < 0.001 \)) and greater experience of previous condom use (\( \chi^2 = 4.03, P < 0.05 \)) were associated with a lower slippage rate. Men with greater experience of condoms in the past year (\( \chi^2 = 4.03, P < 0.05 \)), and men with greater experience of condoms ever (\( \chi^2 = 17.18, P < 0.001 \)) were also less likely to report instances of condoms slipping off. Interestingly, previous experience of condoms slipping off was not associated with slippage during the course of the trial, but previous experience of condoms tearing was associated with slippage during the trial (\( \chi^2 = 10.41, P < 0.001 \)). Neither the type of condom generally used nor the level of confidence in using condoms was related to the slippage rate.

Discussion

The overall rates of breakage and slippage for the two types of condom studied were low, and were in line with reported rates for heterosexual use, ranging from 1.3 to 3.7% [24–26]. Our findings show that there were no significant differences in failure rate between the two strengths of condom tested, and this was true for all definitions of failure. It can therefore be concluded that standard condoms do not have a lower failure rate than thicker condoms.

Although there were no differences between the two types of condom with respect to failure, a number of user characteristics and behavioural factors associated with breakage and slippage were identified. User characteristics associated with breakage were longer penis length, lower social class and lower educational qualifications, younger age, lack of confidence in using condoms and previous experience of breakage. Behavioural factors significantly associated with breakage were longer duration of intercourse, lack of additional lubricant, the use of an oil-based lubricant or saliva, and unrolling the condom before fitting it to the penis. Breakage was less likely to occur if additional lubricant was applied in the anus, around the anus or all over the outside of the condom. Breakage was more likely if the participant’s partner also experienced breakage. Beha-
vioural factors associated with slippage were the application of additional lubricant under the condom, and having less previous experience of using condoms. The application of additional lubricant all over the outside of the condom was associated with less slippage. Men of lower social class were more likely to experience failure (both breakage and slippage), and those with greater previous experience of using condoms were less likely to experience slippage during the trial. Those with previous experience of condoms tearing were also more likely to experience slippage.

Conclusion
The main finding of this study, that there were no significant differences in the categories of failure between the two types of condom tested, have implications for global HIV prevention for gay men. For many European countries, the evidence from the trial contradicts the fundamental HIV prevention message that has been given since the beginning of the epidemic, i.e. that gay men should use stronger condoms for anal intercourse. For North America and Australia, it is the first piece of evidence confirming the validity of their chosen prevention message. The findings that failure rates were higher in the absence of additional lubricant (particularly on the outside of the condom) highlight the importance of the use of additional lubrication and good quality condoms during anal sex, irrespective of the thickness of condom used. Our findings suggest that gay men no longer need to be encouraged to buy, or to be provided with, extra strong condoms as failure rates did not differ between the two condom types. The study also provides key information for health education aimed at increasing gay men's self-efficacy in condom use. The data concerning the predictors of failure should be used in health promotion to reduce the incidence of condom failure among gay men.

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