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Evaluation of the Efficacy of a Polyurethane Condom: Results from a Randomized, Controlled Clinical Trial

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Context: Condoms made of latex are not comfortable or appropriate for all consumers. Polyurethane condoms may provide a needed alternative.

Methods: In a double-masked study, 805 monogamous couples were randomized to use either the polyurethane condom or the latex condom for six months. Couples recorded the frequency of intercourse, of condom use and of breakage and slippage throughout the trial in coital diaries and in detailed reports on the first five uses. Breakage and slippage rates were determined, and typical-use and consistent-use pregnancy rates were calculated using life-table analysis, adjusted for use of emergency contraception.

Results: The six-month pregnancy rate during typical use (adjusted for use of emergency contraception) was 4.8% for the polyurethane condom and 6.3% for the latex condom. Similarly adjusted pregnancy rates during consistent use over six completed menstrual cycles—2.4% for the polyurethane condom and 1.1% for the latex condom—did not differ significantly. Clinical failure rates (including breakage and slippage occurring during either intercourse or withdrawal) were 8.5% for the polyurethane condom and 1.6% for the latex condom. In general, male participants were more satisfied with the latex condom, and users of latex were significantly less likely to drop out of the study for condom-related reasons than were users of polyurethane.

Conclusions: Although polyurethane and latex condoms provide equivalent levels of contraceptive protection, the polyurethane condom's higher frequency of breakage and slippage suggests that this condom may confer less protection from sexually transmitted infections than does the latex condom.

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The latex male condom is unacceptable to many consumers despite its safety, low cost and high degree of effectiveness in preventing pregnancy and the transmission of HIV and other sexually transmitted diseases (STDs). Thus, consumers have sought an alternative type of condom that is more comfortable and attractive than the latex condom. Polyurethane has much promise as an alternative to latex.[1] It is inherently stronger, it resists oil-based lubricants and ozone deterioration, and in vitro testing has shown it to be effective against STD transmission.[2] Furthermore, polyurethane is transparent and odorless, and may fit less restrictively than latex, which could lead to

improved acceptance and wider use of a condom made of this material.

In this article, we present results from the first randomized, controlled, double-masked clinical trial to compare the contraceptive efficacy, acceptability and safety of a polyurethane condom with a commercial latex product. We also incorporated a nested breakage, slippage and acceptability study into the clinical trial, which provides a unique opportunity to evaluate the impact of condom breakage and slippage on contraceptive efficacy.

METHODOLOGY

Study Population and Design

Study enrollment began in October 1993, and data collection ended in July 1996. The trial conformed to all U.S. Food and Drug Administration requirements for clinical studies of condoms made of new material.[3] Multimedia advertising (i.e., in newspapers and on radio) was used to recruit a study population from the Los Angeles metropolitan area that was ethnically and economically diverse and representative of couples who choose the condom as their contraceptive method.

Of the 2,647 couples who responded to the advertisements, 401 (15%) were ineligible and 1,441 (54%) declined to participate, yielding an enrollment of 805 couples (30% of responding couples). These were randomly assigned to use either polyurethane (401 couples) or latex (404 couples) condoms as their only contraceptive method for at least six months.

All participants were in a monogamous heterosexual relationship, were aged 18-45 and had no known risk of infertility or infection with an STD. Both partners attended the enrollment visit, where they were screened for eligibility and gave their informed consent. During the enrollment interview, research staff collected detailed social and demographic information, a reproductive history and a contraceptive history.

The 805 study couples received an initial three-month supply of the assigned condom; a penis measurement kit; five condom use forms with which to report detailed information on breakage, slippage and adverse events with the first five condoms used; a tube of water-based lubricant; an information sheet on emergency contraception; and a set of instructions on proper use of the condom (for reference). Research staff instructed participants in how to complete the forms and used a male anatomical model to demonstrate correct condom use. Participants were instructed to notify study personnel if they suspected a pregnancy, wanted to use emergency contraception or experienced any persistent or severe adverse events.

Throughout their participation, couples also maintained a diary recording coital acts, uses of the condom and days of menstruation, as well as any problems encountered with condom use, including breakage, slippage and discomfort.

At three months and six months after the initial visit, we interviewed each partner separately by telephone to elicit further information on problems with condom use in the previous three-month period (e.g., tears, breaks or physical reactions such as irritation or rashes). An exit visit occurred either after the conclusion of the female partner's first menstruation following six months of participating in the study or after a couple had participated in the study for seven full menstrual cycles, whichever

occurred later. We asked each partner to summarize their condom's advantages, disadvantages and problems, and to describe any physical reactions related to use.

Both the polyurethane condom (which had specifications equivalent to those of the commercially available Avanti™ polyurethane condom produced after April 1996[4]) and the latex condom (marketed as Ramses Sensitol™) are manufactured and packaged by London International Group. Both study condoms are nipple-tipped and packaged with a silicone-based lubricant, and have the same length (180 mm) and open-end diameter (33 mm). However, when laid flat, the polyurethane condom is wider than the latex condom (64 mm vs. 52 mm), and its single wall is also thinner than that of the latex condom (0.045-0.050 mm vs. 0.07-0.08 mm).

ASSIGNMENT AND MASKING

The manufacturer supplied equal numbers of both study condoms, packaged in identical sealed opaque foil wrappers. To further conceal the identity of the condoms from both study participants and research staff, the condoms were distributed in sealed, opaque containers that were pre-labeled with participants' identification numbers.

We randomly assigned couples to either condom, according to a computer-generated sequence of binary numbers. The sequence was not accessible to study personnel directly, and neither staff nor participants knew which condom type was distributed at enrollment. (Couples also were not shown samples of the condoms at enrollment.) Furthermore, the data collection forms contained no information on condom type, so research staff were unable to determine who was assigned to which condom until data collection and processing were completed.

OUTCOME MEASURES AND ANALYSES

Table 1 defines the various condom failure rates that are the outcome measures of the analysis. Primary outcomes were total failure rates (which combine failures among all condoms opened for use, whether they were eventually used for intercourse or not), as well as total clinical failure rates (failures among condoms used for intercourse), which include clinical breakage (breaks among condoms used for intercourse). The outcome measure definitions are consistent with those outlined elsewhere.[5]

Table 1. Definitions of various condom failure rates

Measure	Numerator	Denominator
Nonclinical failure	No. of condoms that could not be used because of breaks, donning problems or defect	No. of condoms opened for use
Total clinical failure	No. of condoms that broke during intercourse or withdrawal, plus the no. that slipped off penis during intercourse or withdrawal	No. of condoms used for intercourse
Clinical breakage	No. of condoms that broke during intercourse or withdrawal	same as above
Total slippage	No. of condoms that slipped off penis during intercourse or withdrawal	same as above
During intercourse	No. of condoms that slipped off penis during intercourse	same as above
During withdrawal	No. of condoms that slipped off penis during withdrawal	same as above

Total failure	No. of condoms that broke during package opening, donning, intercourse or withdrawal, plus no. that slipped off penis during intercourse or withdrawal, plus no. that could not be used (donning problems or defect)	No. of condoms opened for use
Total breakage	No. of condoms that broke during package opening, donning, intercourse or withdrawal	same as above
Total slippage	No. of condoms that slipped off penis during intercourse or withdrawal	same as above
Other failure	No. of condoms that could not be used for reasons other than breakage (donning problems or defect)	same as above

The proportion of condoms that either broke or slipped off the penis during intercourse was based on approximately 2,000 uses of each condom type—the number of condoms used in the first five acts of vaginal intercourse by all 805 couples who were enrolled in the study. This number of uses should be sufficiently large to reveal a statistically significant difference (alpha<.05; beta<.2) if the clinical breakage rate of the latex control condom is as low as 1.1% (derived from an earlier randomized controlled clinical trial[6]), and if the comparable minimum breakage rate for polyurethane is thus 2.3%.

We used chi-square tests of homogeneity or (where expected cell sizes were small) Fisher's exact test to compare breakage, slippage and failure rates for both study condoms. All p-values presented are two-sided. We used StatXact 3 to compute risk ratios and 95% exact confidence intervals for the failure rates, with individual uses as the unit of analysis. However, we did not correct these data to reflect the multiple tests of significance that were performed or adjust them for couples who contributed multiple failures.

We calculated typical-use cumulative life-table pregnancy rates based on six calendar months of data, and also calculated typical-use and consistent-use cumulative rates based on the first six complete menstrual cycles following enrollment. To ensure that at least 240 couples would contribute to the analysis of the proportion pregnant at the end of six months (either contributing six full months of follow-up or the outcome event-in this case, a pregnancy), we needed to enroll approximately 400 couples in each condom group.[*]

We performed life-table analyses (BMDP Program 1L) to compare the pregnancy rate associated with typical use of the polyurethane condom with that of the latex condom. In the calendar life table, a couple was entered on the date of enrollment and was removed upon completion of six calendar months of participation (or on the date of last condom use, if the couple withdrew from the study). For the unadjusted pregnancy rates, we censored all data (including pregnancies) following the day emergency contraception was used in the calendar life tables or the cycle of emergency contraceptive use in the cycle life tables. We used the estimated date of conception for the removal date for couples who discontinued the study because of a pregnancy.

The cumulative life-table rates presented in this article were obtained by subtracting the estimated cumulative proportion surviving the sixth month (or the sixth cycle) from 1.0 and then multiplying by 100. The resulting rate allows the reader to evaluate

the estimated probability of an event (pregnancy or discontinuation) per 100 participants over the period of follow-up (either six months or six cycles).

Pregnancies were confirmed using a commercial urine pregnancy test, which was administered if menses were delayed. To avoid missing a pregnancy that had not yet been detected at the time of discontinuation, we continued to follow women until the onset of the first menses following study discontinuation. Couples who were lost to follow-up were removed from the life table on the date they were last observed (either the date of last interview or the date of last diary entry). We used the generalized Wilcoxon test statistic to evaluate the equality of survival curves.

To obtain a life-table pregnancy rate based on consistent condom use, we identified all pregnancies that occurred when the study condom was consistently used at each act of intercourse between the previous menses and the next expected menstrual period. Thus, pregnancies that did not fit this definition were excluded from the consistent-use analysis—those that occurred in cycles with unprotected intercourse, with donning the condom after initiating intercourse, with removing the condom before completing intercourse or with using a method other than the study condom—withdrawal, spermicides, diaphragm or a nonstudy condom.

We developed a life-table program so consistent-use cycles could be entered selectively within the appropriate interval. Even though just 8% of all acts of intercourse were unprotected and 2% involved use of a nonstudy method, only 68% (1,042 of 1,529) of cycles contributed by polyurethane users qualified as consistent-use cycles, as did 65% (1,150 of 1,776) of cycles contributed by latex users. Study couples often contributed a mix of consistent- and inconsistent-use cycles, but the life-table program allowed us to include all consistent-use cycles, even those preceded by cycles of inconsistent use. We used Greenwood's formula to obtain approximate 95% confidence intervals for cumulative pregnancy rates obtained from the cycle life tables.

We also developed a life-table program that allowed us to adjust the data for the use of emergency contraception. We assigned a mean probability of 0.076 to represent the likelihood that pregnancy would result from the exposure to the risk of pregnancy (condom failure or unprotected sex) that led to emergency contraceptive use. We based this estimate on the mean probability of pregnancy derived from the timing of exposure relative to ovulation (from a high of a 0.33 probability on the day of ovulation to a low of 0.0 on certain cycle days), reduced by 24% to allow for possible early pregnancy loss.[7]

Since none of the couples who had used emergency contraception experienced a delay in the onset of menses, we allowed them to remain in the study. We used Greenwood's formula to obtain approximate 95% confidence intervals for the typical-use pregnancy rates, adjusted for emergency contraceptive use.

In addition, we developed a model to predict consistent-use pregnancy rates using slippage and breakage data collected from the first five condom uses. The model included the mean frequency of intercourse (as estimated from our study data), as well as fecundity factors derived from an earlier study (i.e., the proportion of fertile days within the menstrual cycle, the probability of conception, and the proportion of

conceptions that result in clinically identified pregnancies[8]). Our model assumes that intercourse occurs randomly throughout the menstrual cycle, that the fertility of couples in our efficacy study is comparable to that of the study population used to derive conception and pregnancy probabilities,[9] that condom failure remains constant over the course of study participation and that every condom failure results in an exposure equivalent to unprotected intercourse. We then compared the rates derived from this model with estimates from a conventional Pearl index calculation, to see how well the two approaches compare and to determine whether the model could be used to predict long-term pregnancy rates based on short-term breakage and slippage data.

RESULTS

Characteristics of Participants

At the start of the study, there were no statistically significant differences between the groups assigned to each condom in their social and demographic characteristics, reproductive history or previous condom experience (Table 2). The average age of participants was 27 years, more than two-thirds were married to or living with their partner (68%) and two-thirds were non-Hispanic whites (66%). (Among the remainder of the sample, 16% were Hispanic, 6% were black, 6% were Asian and 6% were of some other race or ethnicity.) Participants averaged 15 years of education (with more than three-quarters having completed at least some college). Most participants were employed either full-time or part-time (68%) and had an annual household income of more than $20,000 (75%). While just 21% identified themselves as current smokers, 36% drank alcohol either weekly or daily.

Table 2. Characteristics of individuals participating in condom trials, by type of condom assigned, Los Angeles, 1993-1996

Characteristic	All (N=1,610)	Polyurethane (N=802)	Latex (N=808)
Social/demographic/physical characteristics			
Mean age	27	27	27
% non-Hispanic white	66	66	66
% married to/living with partner	68	68	69
Mean yrs. of education	15	15	15
% employed	68	65	71
% with annual household income >$20,000	75	73	77
% who currently smoke	21	21	21
% consuming alcohol daily or weekly	36	35	37
% circumcised (males)	74	73	75
Sexual activity			
Mean lifetime no. of sexual partners	13	13	13
% ever pregnant/caused pregnancy	53	52	54
% ever had/partner had an abortion	33	33	34
% usually having intercourse >4 times weekly	26	24	28
% using lubrication at least	35	32	39

occasionally			
% who had unprotected intercourse >5 times in past 3 mos.	26	24	27
Condom use factors			
% currently using condom as contraceptive method	89	89	88
% who ever used a condom <=10 times	6	6	5
% who ever used a condom <=10 times with current partner	10	10	10
% who had >5 condom breaks with previous partners	4	4	4
% who had >5 condom breaks with current partner	3	3	3
Mean penis circumference (mm)	131	132	131
Mean penis length (mm)	159	159	159
Note: Ns refer to total numbers of individuals, male and female.			

Participants reported having had an average of 13 lifetime sexual partners. While 53% either had been pregnant or been responsible for a pregnancy, 33% had either had an abortion or been responsible for a pregnancy that resulted in an abortion. Nearly three-quarters of the male participants had been circumcised. Twenty-six percent of couples said they usually had intercourse more than four times a week, and 35% said they used lubrication at least occasionally. Approximately one-quarter of couples had had unprotected intercourse more than five times during the three months preceding the study.

Most couples had had experience using condoms; in fact, 89% were using them as their contraceptive method at the start of the study. Fewer than 5% of participants had experienced more than five condom breaks with either their current or previous partners. According to participants' measurements, the erect penis averaged 131 mm in midshaft circumference and 159 mm in length.

CONDOM PERFORMANCE: FIRST FIVE USES

•*General experience.* Approximately 95% of the couples contributed data for more than 90% of the condoms distributed for the first five acts of intercourse (1,823 of the 2,023 polyurethane condoms distributed and 1,894 of the 2,031 latex condoms distributed, Table 3). Nearly all of the condoms (99%) for which use was attempted and recorded were successfully donned and used for five initial acts of intercourse (1,804 of 1,823 polyurethane condoms and 1,882 of 1,894 latex condoms). Of the 19 polyurethane condoms that were not used (nonclinical failures), 16 did not unroll properly, two were not sufficiently lubricated and one did not fit. Of 12 unused latex condoms, five did not unroll properly, four broke while being donned, onedid not fit, one was not sufficiently lubricated and one was defective.

Table 3. Number of condom-use experiences recorded in the first five uses per couple, by type of condom

Experience	Polyurethane	Latex
Total uses attempted	**1,823**	**1,894**
Nonclinical failures	19	12

Could not put on/unroll	16	5
Broke while putting on	0	4
Did not fit	1	1
Insufficient lubrication	2	1
Defective	0	1
Used for intercourse	**1,804**	**1,882**
Clinical failures	154	31
Broke during intercourse	66	7
Broke on withdrawal	6	1
Slipped off during intercourse	22	3
Slipped off on withdrawal	60	20
Completed intercourse	**1,650**	**1,851**
Broke during removal	6	0
Successfully used	**1,644**	**1,851**

•*Breakage and slippage.* As Table 4 shows, the clinical breakage rate, which includes only condom breaks that occurred during intercourse or withdrawal, was significantly higher for the polyurethane condom than for the latex condom (4.0% vs. 0.4%), for a risk ratio of 9.4 ($p<.0001$). In terms of couples, 14% of those using the polyurethane condom experienced one or more breaks during intercourse or withdrawal, compared with 2% of couples using the latex condom, a highly significant difference (not shown, $p<.0001$).

Table 4. Percentage of selected types of condom failures, and risk ratios (and 95% confidence intervals) for the polyurethane and latex condoms, by duration of use reported

Type of failure and duration of use	% polyurethane	% latex	Risk ratio
FIRST FIVE USES			
Clinical	**8.5**	**1.6**	**5.2 (3.4-8.3)**
Breakage	4.0	0.4	9.4 (4.3-28.7)
Combined slippage	4.5	1.2	3.7 (2.2-6.7)
Slippage during intercourse	1.2	0.2	7.7 (2.0-102.8)
Slippage during withdrawal	3.3	1.1	3.1 (1.8-6.1)
Total*	**9.8**	**2.3**	**4.3 (3.0-6.4)**
Breakage	4.3	0.6	6.8 (3.5-15.9)
Slippage	4.5	1.2	3.7 (2.2-6.7)
Other failure†	1.0	0.4	2.5 (0.9-9.2)
SIX MONTHS			
Clinical	**3.6**	**0.9**	**4.3 (3.6-5.1)**
Breakage	2.0	0.3	5.8 (4.5-7.5)
Slippage	1.7	0.5	3.3 (2.6-4.1)

*Clinical failures plus nonclinical failures. †Condoms not used for intercourse because they could not be unrolled or donned, did not fit, were insufficiently lubricated or were defective. *Notes:* The overall Ns for the six-month diary data were 17,799 uses of polyurethane condoms and 20,325 uses of latex condoms. The individual Ns from the diaries for the polyurethane condom

were 352 breaks and 297 slip-offs, and for the latex condom, 69 breaks and 104 slip-offs. The 95% confidence intervals calculated from the first five use reports are exact confidence intervals, while those calculated from the six-month diaries are asymptotic.

Although both condoms were less likely to slip completely off the penis during intercourse than they were to break, the polyurethane condom slipped completely off more often than did the latex condom (1.2% vs. 0.2%, a risk ratio of 7.7). Rates of complete slippage during withdrawal were also higher for polyurethane than for latex (3.3% vs. 1.1%, a risk ratio of 3.1). Consequently, the combined slippage rate (slippage during intercourse plus slippage during withdrawal) was significantly higher for the polyurethane condom than for the latex condom (4.5% vs. 1.2%), for a risk ratio of 3.7 ($p<.001$).

Adding together the above clinical rates of breakage and slippage yields the total clinical failure rates, based only on condoms actually used for intercourse. These were 8.5% for the polyurethane condom and 1.6% for the latex condom, for a risk ratio of 5.2 ($p<.0001$).

•*Clinical plus nonclinical failure rates.* The total breakage rate, which reflects all breaks, including those that occurred during donning, was significantly higher for the polyurethane condom than for the latex condom (4.3% vs. 0.6%), for a risk ratio of 6.8 ($p<.0001$). The overall total failure rate, which combines clinical and nonclinical failures (i.e., all condoms that broke or slipped, as well as those that could not be donned), was 9.8% for the polyurethane condom and 2.3% for the latex condom (a risk ratio of 4.3). These differences in total failure rates were statistically significant ($p<.0001$).

SIX-MONTH DIARY DATA

The clinical failure rates calculated from the participants' diaries were 3.6% for the polyurethane condom and 0.9% for the latex condom, for a risk ratio of 4.3 ($p<.0001$). Although these six-month rates were lower than those calculated from the first five uses only, the difference by condom type was still statistically significant. Clinical breakage rates for the polyurethane and latex condoms based on the diaries (2.0% vs. 0.3%), for a risk ratio of 5.8 ($p<.0001$), were correspondingly lower than those calculated from the first five uses, as were the slippage rates during intercourse or withdrawal (1.7% vs. 0.5%), for a risk ratio of 3.3 ($p<.0001$). For the polyurethane condom, there was an especially large difference in total slippage rates according to whether they were calculated from the six-month diary data or from the reports on the condoms' first five uses.

PREGNANCIES AND EMERGENCY CONTRACEPTION

For the efficacy study, all but 4% of couples assigned to the polyurethane group (18 out of 401) and all but 5% in the latex group (20 out of 404) contributed data.† However, the number who successfully completed the efficacy study was 233 of 383 polyurethane couples and 272 of 384 latex couples.‡ There were 17 pregnancies among users of the polyurethane condom, compared with 23 among users of the latex condom, and most of these conceptions occurred during cycles of inconsistent use (11 and 20, respectively). In accounting for pregnancies that occurred despite consistent condom use, four couples using the polyurethane condom reported condom failure

(breaking or slipping off), one reported a leak during intercourse and one occurred even though the couple noted no method failure. All three of the pregnancies occurring within consistent-use cycles among users of the latex condom were attributed to condom failure.

Nineteen couples relying on polyurethane condoms resorted to emergency contraception 24 times, and eight couples using latex condoms did so nine times. Overall, only three uses of emergency contraception were precipitated by unprotected intercourse; all other instances (30) followed condom failures. Emergency contraceptive use, however, failed to prevent pregnancy in one woman relying on the polyurethane condom who became pregnant in a consistent-use cycle.

PREGNANCY AND CONTINUATION RATES

According to the life-table analysis of calendar-months of condom use, the six-month typical-use pregnancy rates (4.1% for polyurethane and 6.2% for latex) did not differ significantly (p=.44) between the two condom types (Table 5). Adjusting the data for emergency contraceptive use increased the typical-use pregnancy rates slightly for both condoms, to 4.8% for polyurethane and to 6.3% for latex. The life-table rates changed little when menstrual cycles rather than calendar months served as the measure—adjusted rates of 5.1% for the polyurethane condom and to 7.0% for the latex condom.

Table 5. Life-table pregnancy rates (and 95% confidence intervals) before and after adjustment for emergency contraceptive use, by use measure and type of condom

Measure of use and type of condom	Unadjusted			Adjusted		
	No. of months/ cycles	No. of pregnancies	Pregnancy rate	No. of months/ cycles	No. of uses of emergency contraception	Pregnancy rate
CALENDAR MONTHS*						
Typical use						
Polyurethane	1,802	13	4.1 (1.9-6.3)	1,839	22	4.8 (2.4-7.2)
Latex	1,952	20	6.2 (3.6-8.8)	1,971	9	6.3 (3.7-8.9)
MENSTRUAL CYCLES†						
Typical use						
Polyurethane	1,476	12	4.5 (2.0-7.0)	1,529	16	5.1 (2.5-7.7)
Latex	1,720	20	7.0 (4.0-10.0)	1,776	8	7.0 (4.1-9.9)
Consistent use						
Polyurethane	1,013	4	2.1 (0.1-4.1)	1,042	10	2.4 (0.2-4.6)
Latex	1,117	2	1.0 (0.0-2.4)	1,150	3	1.1 (0.0-2.7)

*Based on the first six months of follow-up. †Based on the first six complete menstrual cycles of follow-up.

The six-cycle consistent-use pregnancy rate for the polyurethane condom was 2.1%, while that for the latex condom was 1.0%. Once the data were adjusted for emergency contraceptive use, the consistent-use pregnancy rate among polyurethane users rose

slightly to (2.4%), while that among latex users rose only to 1.1%. The differences in these rates by type of condom were not statistically significant.

In the model that we developed to predict consistent-use pregnancy rates using slippage and breakage data from the first five condom uses (Table 6), we assumed certain probabilities that the day in the cycle would be a fertile day (0.195),§ that conception would occur (0.218) and that a conception would become established as a pregnancy (0.759).[10] The model indicated that there would be 34.5 pregnancies per 100 woman-years of use for the polyurethane condom and 6.5 per 100 for the latex condom. These estimates were both substantially higher than the observed Pearl index failure rates for either the polyurethane condom (5.9 per 100) or the latex condom (2.5 per 100).

Table 6. Selected data testing model for predicting consistent-use pregnancy rate (Pearl index) from condom slippage and breakage data, and observed pregnancy rate, all by type of condom

Measure	Polyurethane	Latex
Model		
A. Number of failures per year*	10.7	2.0
B. Probability of fertile day†	0.195	0.195
C. Probability of conception†	0.218	0.218
D. Probability of clinical pregnancy†	0.759	0.759
E. Predicted number of pregnancies per 100 woman-years§	34.5	6.5
Observed		
Actual number of pregnancies per 100 woman-years**	5.9	2.5

*Obtained by multiplying the number of condoms used in one year (assumed based on data from the six-month efficacy data to be 10.5 per month, or 126 per year) by the clinical failure rate (estimated from the breakage and slippage data from the first five uses to be 0.085 for the polyurethane condom and 0.016 for the latex condom). †Calculated by dividing six assumed fertile days (source: reference 7) by an average cycle length of 30.83 days (estimated from six-month efficacy data). †Based on reference 7. §A x B x C x D x 100. **Calculated from a cycle of consistent use, adjusted for use of emergency contraception.

Overall, users of polyurethane condoms were less likely than users of latex condoms to have completed six full months of the study (62% vs. 73%). Users of polyurethane condoms were more likely to drop out of the study for condom-related reasons, such as breakage, slippage, poor fit and discomfort (12%) than were couples using latex condoms (5%). There were no significant differences by condom type, however, either in the proportions discontinuing for reasons not related to the type of condom, such as having medical problems, moving away, ceasing sexual activity, planning a pregnancy or other reasons (17% polyurethane vs. 15% latex) or in the proportions lost to follow-up (5% polyurethane vs. 4% latex).

As Table 7 shows, the six-month life-table continuation rate was significantly lower (p=.002) among users of polyurethane condoms than among users of latex condoms (62% vs. 72%). The six-month life-table discontinuation rates for condom-related reasons were significantly higher (p=.01) among those using the polyurethane condom than among those relying on the latex condom (18% vs. 11%), while life-table discontinuation rates for reasons not related to the condom were not significantly

higher for the polyurethane condom (21% vs. 16%).

Table 7. Life-table rates of continuation, discontinuation and loss to follow-up (and 95% confidence intervals), by type of condom

Type of rate and condom	No. of discon-tinuations	Rate
Continuation rate		
Polyurethane	144	62.4 (57.6-67.3)
Latex	106	72.4 (67.9-76.9)
Discontinuation rate		
For reasons related to study condom*		
Polyurethane	62	17.5 (13.5-21.5)
Latex	39	11.0 (7.8-14.3)
For reasons unrelated to study condom†		
Polyurethane	68	20.6 (16.2-25.0)
Latex	56	15.9 (12.1-19.7)
Loss to follow-up		
Polyurethane	14	4.7 (2.3-7.2)
Latex	11	3.2 (1.4-5.1)

*Includes discomfort, diminished sensitivity, dislike of fit, lubrication complaint, breakage, slippage, preference for nonstudy condom, difficulty in donning and pregnancy. †Includes medical problems unrelated to condom, inconvenience of participation in study, moving away, no longer sexually active, no longer with study partner, planning a pregnancy and other personal reasons. *Note:* Life-table rates are based on 1,839 months of use of the polyurethane condom and 1,971 months of use of the latex condom.

ACCEPTABILITY AND PREFERENCES

Although neither condom was associated with any persistent or serious adverse event, use of the polyurethane condom was significantly ($p<.0001$) less likely than use of the latex condom to cause transitory discomfort to the male partner, such as irritation, itching or constriction—5.1% of 17,831 uses vs. 8.0% of 19,912 uses. Penile constriction was the most commonly reported discomfort, and occurred more frequently ($p<.0001$) with the latex condom (6.0% of uses) than with the polyurethane condom (2.2% of uses).

When male participants were asked how highly they would recommend their study condom, those who used the latex condom were more likely than users of the polyurethane condom to say they would highly or somewhat highly recommend their condom to others (83% vs. 62%, Table 8). Although the proportion who would not recommend their condom was low among users of either condom, those who used the polyurethane condom were significantly more likely ($p<.0001$) than those who used the latex condom to say that they would not recommend their condom to others (15% vs. 7%).

Table 8. Number and percentage distribution of male study participants, by measures of condom acceptability, according to

type of condom used				
Measure	Polyurethane (N=360)		Latex (N=363)	
	N	%	N	%
Recommendation on study condom				
Strongly recommend	114	32	152	42
Recommend	108	30	150	41
Recommend with reservations	82	23	36	10
Not recommend	55	15	25	7
Adequacy of lubrication				
Just right	188	53	206	57
Too much	10	3	8	2
Not enough	159	45	148	41
Attractiveness of study condom*				
More attractive	60	17	66	18
Less attractive	103	29	35	10
No difference	194	54	259	72
Ease of donning study condom*				
Easier	91	25	86	24
Harder	105	29	25	7
No difference	161	45	248	69
Sensitivity of study condom*				
Better	151	42	132	37
Worse	56	16	53	15
No difference	150	42	174	48
Odor of study condom*				
More pleasant/scentless	251	72	218	61
Less pleasant	13	4	11	3
No difference	85	24	126	35
Total	360	100	363	100

*Compared with latex condoms used previously. *Note:* Ns do not always add to totals because data are missing for some measures.

When asked to compare their current study condom with latex condoms they had used in the past, male participants assigned to the polyurethane condom were significantly more likely ($p<.0001$) than those assigned to latex to say that their current condom was less attractive (29% vs. 10%). Moreover, a significantly larger percentage ($p<.0001$) of those using the polyurethane condom than of those using the latex condom said that their assigned condom was more difficult to don than condoms they had used in the past (29% vs. 7%). A higher proportion of users of polyurethane condoms preferred the odor (or the lack of one) of their study condom to the odor of condoms they had used in the past (72% vs. 61%, $p=.006$). In addition, polyurethane condoms were more likely than latex condoms to be described as providing more sensitivity than latex condoms used in the past (42% vs. 37%), although this difference was not statistically significant ($p=.21$).

DISCUSSION

This randomized, controlled efficacy study had several strengths. Using the media to

recruit participants produced an ethnically and economically diverse study population that was broadly representative of couples who use condoms for contraception. Moreover, enrolling both partners in the study instead of just one enhanced compliance and provided an opportunity to collect information from both men and women. A low proportion—fewer than 5%—of couples in each group was lost to follow-up.

The collection of breakage and slippage data for the first five uses of the study condoms allowed us to compare results from a model predicting efficacy from condom performance with actual life-table rates obtained from longitudinal data from our study. Finally, organizing the data collection by menstrual cycles allowed us to calculate precise estimates of the consistent-use and typical-use pregnancy rates for the two study condoms.

These strengths are partially offset, however, by the difficulties inherent in evaluating condom efficacy. For example, the ability of users to detect failures may have led to differing patterns of early discontinuation, which would remove couples at greatest risk before a pregnancy could result, and thus a true difference between pregnancy rates with the two study condoms could have been obscured; 20 of the 61 couples in the polyurethane group who discontinued before completing two months of the study reported condom breakage, compared with only one of the 36 couples using latex condoms who discontinued within this time span.

Another difficulty in evaluating efficacy is that reliance on the condom, as on other coitus-dependent methods, frequently results in nonuse. Approximately 50% of couples in both groups reported one or more acts of unprotected intercourse. Such nonuse greatly decreases the number of menstrual cycles that can be used to estimate consistent-use pregnancy rates, and thus reduces the power of the study to identify true differences between the study condoms. This problem was compounded by the fact that 15% of the study participants failed to contribute six cycles of condom use for reasons unrelated to the study condom, such as breaking up with their partner or moving away from the study area.

Ours is the first contraceptive efficacy study to adjust the data for the use of emergency contraception. In doing so, we recorded patterns of emergency contraceptive use that had not been previously observed. Despite 2,755 acts of unprotected intercourse and 599 condom failures, emergency contraception was used only 24 times by those using the polyurethane condom and nine times by those using the latex condom. If we assume that any single exposure necessitating emergency contraception would have had only a 7.6% chance of resulting in a conception, and if we subtract the one pregnancy that occurred despite emergency contraceptive use (in a user of the polyurethane condom), then emergency contraception prevented only 1.5 pregnancies with the polyurethane condom and 0.7 with the latex condom.

Breakage and slippage data from the first five uses of the study condom showed that the polyurethane condom failed significantly more often during intercourse or withdrawal than did the latex condom. Condom breaks were not distributed evenly throughout the study population, but more couples using the polyurethane condom (14%) experienced breakage the first five times than did couples using the latex condom (2%).

For both study condoms, rates of clinical failure obtained from six months of diary data (clinical breakage plus combined slippage) were approximately one-half as high as those obtained from reports of the first five uses. The lower, diary-based estimates could have resulted from early discontinuation among users who experienced a failure, from deliberate changes in use to avoid another failure or from underreporting over the lengthy follow-up period. However, by either data source, the relative difference between each study condom's failure rate was identical—the polyurethane condom was uniformly about four times as likely to fail as the latex condom.

The typical-use pregnancy rates derived from our study suggest that the male condom is more effective than female barrier methods. For example, doubling the six-month cumulative life-table rates, adjusted for emergency contraception, yields 12-month typical-use estimates of 12.6% for the latex condom and 9.6% for the polyurethane condom—lower than the comparable rates for female barrier methods of 20-26%.[11]

Moreover, our consistent-use data suggest that male condoms, when used consistently, provide at least as effective protection from pregnancy as do female barrier methods. Annualized consistent-use pregnancy rates (over 13 cycles) were 4.8% and 2.2% for the polyurethane and latex condom, respectively, a nonsignificant difference. Both of these rates are lower than the 12-month "perfect-use" cumulative life-table estimates reported in the literature for female barrier methods (ranging from 5% to 26%).[12] We chose to make this comparison using consistent-use rates—based on respondents' affirmation that the study condom was used, but not necessarily as directed, for every act of intercourse during the cycle—instead of using "perfect-use" rates, because it is unreasonable to expect participants to accurately report whether all instructions were followed for each condom used.

The breakage and slippage data collected from the first five uses of the study condoms provided an opportunity to test our model; if it proved reliable, it could be used to predict contraceptive failure rates from short-term data. However, the model yielded far higher pregnancy rates than were observed, with the predicted rate for the polyurethane condom being especially high relative to the observed rate.

One source of error in the model may have been the assumption that short-term breakage and slippage rates would reflect the risk associated with long-term use. However, this was not the case in our study, since the risk of polyurethane condom failure declined over time, partially because couples who had had a condom failure exited the study early: The failure rate among the 133 couples assigned to the polyurethane condom who discontinued use was 7.0%, compared with 1.8% among the 233 couples who completed the study.

Because we lacked more precise information on the risk of pregnancy associated with condom failure relative to that from unprotected intercourse, we assumed that these two rates would be equivalent; however, many condom failures, such as breaks that occurred before ejaculation and slip-offs during withdrawal, are probably less likely to result in conception than is unprotected intercourse. Additional data are needed before any model can be expected to accurately predict consistent-use pregnancy rates from breakage and slippage data.

Regarding acceptability, users of the latex condom expressed greater satisfaction with

their method (i.e., were more likely to recommend it to others) than did those using the polyurethane condom. The latex condom was also significantly less likely to be discontinued because of dissatisfaction: A total of 47 couples using the polyurethane condom cited a condom-related reason for dropping out, compared with 19 of those using the latex condom. Nonetheless, male partners rated the polyurethane condom more highly than the latex condom on several subjective characteristics, including sensitivity and odor. Furthermore, male users of the polyurethane condom were less likely to complain of discomfort (particularly constriction) than were males using the latex condom.

CONCLUSIONS

Our analysis addresses a number of concerns held by public health professionals and consumers about the condom's effectiveness in preventing both conception and the transmission of STDs. The low pregnancy rates for the two condom types associated with both typical use and consistent use confirm that they can provide effective long-term contraception. Moreover, with the exception of one pregnancy with the polyurethane condom, all study pregnancies were attributable to either a reported failure of the condom or to nonuse. Thus, concerns that condoms failures might occur unseen (such as "seepage" or "wicking" of sperm over the opening) appear unwarranted. However, this does not guarantee protection against infective agents, which might behave differently from sperm.

While the polyurethane condom offers acceptable long-term contraceptive protection to experienced couples, the high incidence of breaks and slip-offs, particularly among new users, showed that this particular polyurethane condom did not perform as well as the latex condom. Since the consequences of condom failure can be extreme, such as the transmission of HIV, the latex condom would be a more prudent choice. However, when latex cannot be used because of allergies or personal objections, the polyurethane condom appears to be an acceptable choice, since it provides effective protection in nine of 10 uses, a risk far lower than that associated with unprotected intercourse.

References

1. Contraceptive and Reproductive Health Branch, Development Branch, National Institute of Child Health and Development (NICHD), *Anonymous Minutes of a Roundtable Meeting on New Condom Design*, Bethesda, MD: NICHD, 1988.

2. Voeller B et al., Gas, dye and viral transport through polyurethane condoms, *Journal of the American Medical Association*, 1991, 266(21):2986-2987.

3. Center for Devices and Radiological Health, Office of Device Evaluation, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices, Obstetrics-Gynecology Devices Branch, Food and Drug Administration (FDA), *Testing Guidance for Male Condoms Made from New Material*, Washington, DC: FDA, 1995.

4. Potter WD, director, Group Scientific Affairs, London International Group, personal communication, May, 1997.

5. Steiner M et al., Standardized protocols for condom breakage and slippage trials: a proposal, *American Journal of Pubic Health*, 1994, 84(12):1897-1900.

6. Frezieres RG et al., Breakage and acceptability of a polyurethane condom: a randomized, controlled study, *Family Planning Perspectives,* 1998, 30(2):73-78.

7. Wilcox AJ et al., Timing of sexual intercourse in relation to ovulation: effects on the probability of conception,

survival of the pregnancy, and sex of the baby, *New England Journal of Medicine*, 1995, 333(23):1517-1521.

8. Ibid.

9. Ibid.

10. Ibid.

11. Hatcher RA et al., *Contraceptive Technology*, 17th Revised Edition, New York: Ardent Media, 1998, p. 216.

12. Ibid., p. 800.

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*We based this sample size on the assumption that the control group (users of latex condoms) would experience an annualized typical-use pregnancy rate of 10%. If at least 18% of the polyurethane group experienced a pregnancy, the two groups would not be significantly equivalent in a one-sided test of the null hypothesis of equal proportions (alpha=.05; beta=.8).

†Couples that were disqualified included those who never used the study condom (seven couples assigned to polyurethane and five to latex), those who were pregnant at entry into the study (five couples using polyurethane condoms, one couple using latex condoms), those who were never at risk of pregnancy (three couples in the polyurethane group, four in the latex group), those who did not meet study inclusion criteria (two assigned to polyurethane, seven assigned to latex) and those who had no contact with the research staff after their enrollment (one couple using polyurethane condoms and three using latex condoms).

‡Among the 150 couples using polyurethane condoms who either discontinued the contraceptive efficacy study or were lost to follow-up, 64 withdrew because of problems with the condom (14 couples disliked it, 22 had had a break or slip, 11 had experienced discomfort and 17 had a pregnancy), 71 withdrew for personal reasons (39 because of a breakup, 10 because they moved away and 22 for other reasons) and 15 were lost to follow-up. Among 112 couples assigned to the latex condom who discontinued, 42 did so because of a condom-related reason (13 disliked their condom, one experienced a break or slip, five felt discomfort and 23 became pregnant), 59 withdrew for personal reasons (31 couples broke up, four moved away and 24 withdrew for another reason) and 11 were lost to follow-up.

§Estimated as six fertile days (source: reference 7) per average cycle of 30.8 days (taken from the six-month diaries).