

## CHAPTER 6: MODELS OF SEX IN CONDOM TESTING

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MODELS

Condoms are made to withstand the rigors of sex. But the models used by governments to test condom durability have nothing to do with sex.

# Goals in 2 layers: personal and manufacturing goals

Condoms (the male variety) are possibly the oldest form of contraception used today. They are popular, with something like a billion sales in the U.S. every 2 years. Contraception is not the only appeal; they are also used to prevent the spread of sexually transmitted diseases (STDs). Contraception and STD avoidance are thus two important 'personal' goals in condom use -- the ultimate goal that people have in using condoms. However, they are not the only important personal goals. A third is to minimize the loss of sensation, and the loss of sensation is perhaps the main reason some people avoid condom use.

For the most part, condoms are manufactured. To satisfy consumer personal goals, the manufacturing process is guided by a secondary set of goals, the manufacturing goals, which are aligned with but not the same as the personal goals. Thus, for manufacturing purposes, a condom needs to provide an impenetrable barrier to microbes, and it must not break during sex. And to satisfy the personal goal of maintaining sensation, the condom must be made thin and flexible. The latter goal is in conflict with the first two goals: the thinner and more flexible the condom, the more likely it is to break or pass microbes. This conflict underlies a great deal of the oversight on condom quality.

The material used in condoms is latex (rubber). Advantages of latex are that it can be produced in thin sheets, and it can stretch greatly without breaking. But latex is a biological material, and it is profoundly sensitive to various environmental conditions. Even temperatures as high as body temperature degrade it, albeit slowly, and oils (as in vegetable oil and baby oil) degrade it rapidly. So even if condoms meet reasonable standards in the factory, they may fail under a wide array of conditions experienced in "the field."

To make sure that condoms function properly for disease prevention and contraception, governments of Western countries test condoms to ensure they meet minimum quality standards. These tests are ultimately intended to evaluate how well a condom will perform during sex, so that it won't break, leak, or pass infectious microbes. For practical reasons, the immediate goals that motivate the condom tests are more closely tied to manufacturing goals than to personal goals. The personal goals underlying condom use are only secondarily connected to the tests.

# No humans are used in testing the manufacturing goals of condom quality

Condoms need to be tested to ensure that they meet certain quality standards. Each batch manufactured may be different from previous batches, and it is important to keep bad batches from reaching market. Batches are made from the same pool of latex, and impurities might affect every condom made at that time. There are many models of condom quality used in these tests, and it is reasonable to ask why a single test is not used. The reason is that none of the individual tests is useful for all of the many manufacturing goals – each has major limitations. Different tests/models are used to overcome the perceived shortcomings of the other tests, so collectively they should have few limitations.

It is obvious that the most accurate model for testing condom performance is sex itself – involving humans. It is otherwise difficult to know how much sensation is being lost, or what the real breakage or transmission rate of disease is. Using humans to test condom manufacturing quality has several drawbacks, however. Foremost, people are not convenient. Governments are not about to hire people to have sex as condom testers, which would mean they were paid to have frequent sex with different partners, some with sexually-transmitted diseases. We let people make their own choices about who to sleep with and whether they are willing to risk HIV, hepatitis, gonorrhea, etc., but we cannot ethically assign them to such risks. Any pregnancies arising from such experiments would raise problems as well.

A possible alternative to trained human “sex technicians” is human volunteers. Volunteers avoid the ethical/convenience complication, but it introduces a new one: lack of uniformity. Untrained people are notoriously inconsistent in how they use condoms, the condoms may be mistreated (e.g., they degrade rapidly when exposed to any kind of oils or Vaseline). Another drawback of human volunteers to test condoms is time. If a batch of condoms was being tested for disease transmission or blocking pregnancy, it would take weeks to months after sex to determine whether the condom had done its job. So volunteers have problems. They are used for some studies, however, as we will come back to below, but those studies are not for testing manufacturing quality.

Add up all these problems with humans, and we can begin to understand why condom testing to meet manufacturing goals is done with non-human (non-animal) physical models.

# Mechanical models of durability are used for testing condom quality

**“Empty-condom” tests:** There are lots of ways to test condom quality that avoid ethical issues while adhering to high standards of condom integrity and uniformity . These kinds of tests are what all governments use or mandate to industry. Some tests measure the durability of the entire condom, some measure only part of the condom, and some test for holes. Some of the more common tests involve testing empty condoms (or putting water in them):

- **Electrical conductance test:** This is a non-destructive test applied to all condoms. Each condom is tested to see if it blocks electricity. An intact condom should not allow electricity to pass through it.

The next tests are all destructive – a tested condom cannot be sold.

- **Water leak test:** Used by the Food and Drug Administration, this test involves filling a condom with 10 ounces of water and looking for leaks.
- **Tensile test (stretch test):** This method involves slicing a band from the shaft of a condom and testing its stretchability.
- **Airburst test:** A method used by many European countries, Canada, and now the U.S., inflates the condom with air until it bursts; the maximum volume of air tolerated is used as the measure of strength.

Other tests are of the packaging (package integrity test, lubricant test) and a simulated aging test by warming the wrapped condom in an oven at 70° C.

All these mechanical models may be regarded as models of sex because they are used to evaluate condom quality for sex. However, all these models score impossibly low on accuracy. They compensate with strengths in convenience and uniformity.

Regardless of which specific test is used, condom testing involves taking a sample of several condoms from a batch and calculating the fraction that pass the test. The condoms tested are thus a sample (model) of the others in the batch. In the US, a batch of condoms cannot be sold if 5 or more condoms per 1000 fail the test. (For non-destructive tests, such as the electrical conductance test, all condoms are tested before being sold.)

So you can be relatively confident that any condom sold in the U.S. and maintained under proper conditions will survive the water test and airburst test. Should we be comforted with that knowledge? Only to the extent that condom survival in these tests reflects condom performance during sex. That is, only to the extent that a water test or airburst test is a good model of the rigors of sex. Furthermore, the fact that different batches of condoms pass the FDA test does not mean that all of them are equivalent. Consumer Reports has evaluated several brands of condoms using the airburst test and has ranked them accordingly. Perhaps surprisingly, a few brands had failure rates of 10% or more.

There are several levels at which models apply in condom testing, beginning with the lowly one in which a few condoms in a batch are treated as a model of the entire batch (otherwise, we would have to test every condom in the batch). At a higher level, we may regard one condom brand as a model of other brands (hence the advice from healthcare workers to "use a condom," which makes no statement about a brand). Then we have the government models of sex that are applied to batches to evaluate condom survival, such as the airburst test, the water test, and the stretch tests; whether the batch can be sold depends on how many condoms failed.

Validation of the "empty-condom" mechanical tests. It takes little imagination to understand how these models are limited and may be seriously in error. However, although the airburst test is not anyone's idea of sex, when properly calibrated, it might give us a good idea of whether a condom will hold up during sex. Not surprisingly, people have been interested in this question. The organization Family Health International was involved in several studies and has also evaluated other studies to determine just how accurately the empty-condom tests predict condom failures in humans. These tests involve (i) evaluating some of the condoms with the airburst test (most commonly), and (ii) using other condoms from the same batch to obtain breakage rates from volunteers. These tests have been the most illuminating when done with aged condoms, because breakage rates are higher with aged condoms. In general, the physical, **empty-condom tests are only mildly good at predicting condom failure rate** experienced by human volunteers.

## More Accurate Physical Models: Fake Penises

The foregoing physical models can be objected to on the grounds that they don't mimic realistic forces during sex. Decades ago, a few studies tested condoms by simulating sex with various types of dildos. None of those studies have inspired widespread acceptance. The most elaborate system was developed a decade ago by the "Mariposa" Foundation of Topanga California (now defunct ) consisted of a rubber "vagina" through which water (at body temperature) is circulated and into which a dildo (model of a penis) is thrust with a piston device. The condoms were inserted over the dildo and subjected to several "cycles" of piston thrusting. An ejaculation was also simulated. The various parameters used in this simulation had been established by a number of methods. From their experience, few seem interested in a more realistic mechanical model for condom testing that could be used as an industry standard.

## Back to personal goals: models of actual STD transmission

Even if the mechanical models used to test condoms are reasonable indicators of whether a condom will break during sex, and thus whether they will prevent sperm from reaching the woman's reproductive system, they may be poor indicators of whether a microscopic pathogen can pass from one partner to the other. The tests (models) are motivated by manufacturing goals and only indirectly tied to the personal goals in condom use. For example, the water leak test can detect holes only as small as 5 mm, but this sized hole is many times the size of sexually-transmitted viruses and even of the bacterium *Chlamydia*. Similarly, the airburst test is insensitive to small holes. So here we find limitations of existing methods of testing condoms for the personal goals of condom use. That is, the mechanical models have serious limitations when considering condoms as barriers to infectious disease transmission.

Other mechanical models have been tried. Several involve filling a condom with a pathogen (in water, for example) and determining whether the pathogen escapes to the outside - a passive transmission test. Some passive transmission tests use the sexually-transmitted pathogen itself, which is the best model of a pathogen. But those tests are expensive because they require special facilities for working with pathogens. So other, simpler tests use the harmless bacterial virus phi-X174, which is somewhat smaller than the smallest sexually-transmitted pathogen (Hepatitis B Virus) and is easily assayed on bacterial plates. These mechanical tests can also be made more realistic by subjecting the condom to various forces, such as might be encountered during sex.

Volunteers. When we want definitive data on how condom use influences disease transmission rates, there is no substitute for accuracy – using sexually active humans known to be exposed to STDs, thus volunteers. There were several studies of this sort in the 1990s, mostly with HIV. These studies used “discordant” couples, in which one partner was not infected and the other was infected, and they were followed for many months. Couples were rated (after the fact) as to whether they used condoms consistently or inconsistently (the latter category including those who didn't use them at all). Overall the studies suggest that condom use greatly decreases the risk of HIV transmission, as in the following table:

NUMBER OF COUPLES IN WHICH THE HIV- PARTNER BECAME HIV+ DURING THE STUDY	
CONSISTENT USERS	INCONSISTENT USERS
0/123	12/122 (10%)
3/171 (2%)	8/55(12%)
<2%	12% (300 total couples)
0%	10% (250 total couples)

Despite the desirability of the accuracy afforded by volunteers, the `uniformity' limitation becomes apparent: individuals were not always behaving in exactly the same way across the study period. Thus, couples could be assigned only to the approximate categories of `consistent' or `inconsistent' condom use, not to absolute categories of `always' or `never.'

This chapter ends with some tables summarizing the nature of models in condom testing. These tables have overlapping information and reveal the different goals and the many ways that the information can be classified.

# Summary of Models used in Condom Testing

For the manufacturing goals of ensuring the quality of a batch of condoms:

MODEL	KIND	USE	LIMITATIONS	STRENGTHS
Volunteers	physical	not used for this goal	poor uniformity: possible lack of compliance by untrained people; long time to complete studies; other risk factors	accuracy
Airburst test	physical	condom integrity and breakage during sex	lacks the complexities of sex; does not test porosity	convenient and uniform; provides an overall measure of condom integrity
electrical conductivity	physical	condom integrity and breakage during sex	lacks the complexities of sex; does not test durability of the condom	convenient, uniform, non-destructive. detects holes
Stretch test	physical	condom integrity and breakage during sex	tests only part of a condom and lacks the complexities of sex; does not test porosity	convenient and uniform; provides a measure of flexibility
A few condoms in a batch	physical	model of entire batch	not all condoms in one batch have the same properties	mostly that there is no alternative

All these models are considered models of sex for this goal.

For the personal goals of preventing STD transmission and pregnancy:

<b>MODEL</b>	<b>KIND</b>	<b>USE</b>	<b>LIMITATIONS</b>	<b>STRENGTHS</b>
Volunteers	physical	to test condom efficacy	poor uniformity and poor convenience	accuracy, measures actual STD transmission
mechanical tests	physical	to test condom efficacy; not very useful for this goal	too inaccurate to know if condoms actually work at preventing pregnancy or STD transmission	convenient and uniform; but limitations outweigh these strengths

These models are also considered models of sex.

# External Links

[See how LifeStyles Condoms Are Made and Tested](#)

[National Geographic on Condom Testing](#)

[Condom Testing from Consumer Reports](#)