

Full Length Research Paper

Permeability and breakage status of male condoms artificially and naturally aged in humid tropical climate, the case of Jimma town, South-western Ethiopia

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Condoms are made up of polymers of rubber latex which undergoes gradual deterioration upon exposure to environmental conditions like high heat, ultraviolet light and humidity. This natural aging can also be simulated in laboratory and comparable results observed within short time. Deteriorated condoms show poor tensile strength and higher breakage rates. The breakage rate and permeability of condoms can be tested in laboratory. This study aimed to determine the effects of high heat, humidity, sunlight and visible light on integrity and breakage of condom latex. Sample condoms were exposed to different environmental conditions and their permeability and brakeage rates were tested in laboratories of drug administration and control authority of Ethiopia. The air burst test results showed some differences in bursting pressures and bursting volumes for the aged and control groups of the different branded condoms and even much higher difference between the breakage rates of the same during vaginal sex. On the other hand, there were observed closely comparable permeability status results. There was no significant effect of artificial and natural aging on permeability status of condoms. On the other hand, there was observed significant association between the artificial aging factors and condoms breakage rates in laboratory. Drug administration and control authority and other responsible bodies should promote good handling of condoms by keeping away from high heat, UV- light and humidity.

Key words: Condoms, artificial aging, natural aging, permeability, breakage

INTRODUCTION

Condom distribution networks would benefit from increased knowledge of recent research findings about how to handle and store condoms to maximize their reliability. Therefore, systems to track condoms failure in field conditions and correlate these with laboratory

measures of quality should be developed (Youssef, 1993).

During the first recommendation of condoms by National government of U.S, governmental officials and scientists went into libraries and laboratories to see what

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data supported such recommendations. Government regulating agencies still have another emphasis to ensure that various laws and regulations are being met and that condom is safe. Regulators, therefore, monitor the accuracy of claims made by manufactures on its reliability. This is an extremely serious issue as it may come up with unintended pregnancy or sexually transmitted infection including Human immunodeficiency virus/ acquired immune deficiency syndrome (HIV/AIDS). In 1980s, researchers began to test condoms stored in warehouses to assess the importance of condom deterioration. Manufactures at the time knew that latex deteriorated or aged gradually overtime and that certain conditions such as intense heat humidity or moisture could accelerate the aging process (Holmes, 2004).

One way to slow the aging process of condoms and to ensure product stability is to increase attention to packaging, accordingly, major buyers including World Health Organization (WHO) and United States Agency for International Development (USAID) added package integrity test to their specifications. This test is done by subjecting the package seal to stress under a vacuum seal. This is regarded by American Society for Testing and Materials (ASTM) but not by International Organization for Standardization (ISO) and European Committee for Standardization (CEN). The other radical change on related researches is due to the use of artificial aging recently instead of the use of natural aging in the former researches. Recent research recommended that in accelerated aging measurements, the mean burst volume should not be less than 30 L. The limit might be slightly higher for condoms intended for use in hot climates and for smaller condoms. Although the intuition suggests the higher the minimum volume of burst, the better the product; there is no significant clinical data to justify raising the limit at this point (Holmes, 2004).

Sadly, the great improvements in condom design and reliability of the tests are not well known. Consumers and service providers alike continue to lack confidence in condom's ability to prevent pregnancy and disease. Despite all these, provided that the social, cultural, economic or individuals related causes for nonuse or incorrectly using of condoms is circumvented, currently available condoms, if peaked and stored correctly will maintain their quality for five years or more (Allen, 2006). The published studies do not reach the same conclusion. There is no single indicator of potential failure in human use. Moreover, because of variations in human behavior and practices and differing designs of latex condoms, there is high methodological challenge to definitive answers for reliability of condoms (Free et al., 1980; Free et al., 1986; Steiner et al., 1992).

Condoms strength testing results can be correlated with condom breakage during human use to some extent and therefore is of very great importance in determining the strength and cure of condoms artificially aged according to the literatures as concluded by a research conducted in 2009 by 'Family health international' on

topic; 'Assessment of correlation between condoms laboratory strength test results and breakage rates in human uses' (Russell-Brown et al., 1994; Speneer, 1996). A study published in 1991 used unusual design to see the results of tensile test correlated with human use during anal intercourse. Although the condoms were new and stored at optimal conditions, cool, dry and dark place, 40% of the condoms used by the participants were broken and 60% were unbroken (Gerofi et al., 1991; FHI, 1994). There are no similar studies so far in Ethiopia. This study aimed to assess the effect of artificial and natural aging of condoms on their permeability tests and their breakage in laboratory.

MATERIALS AND METHODS

Study design

Controlled experimental study design was employed. Two different branded condoms namely 'Sensation' and 'Hiwot Trust' condoms were collected from their usual supply drug stores, in Jimma town south west Ethiopia, Oromia regional state. The previous storage conditions of these condoms were investigated before collecting to minimize the bias on the study variables. Then some of the condoms were exposed to exaggerated conditions to facilitate accelerated aging called artificial aging. According to WHO criteria, the condoms were exposed to 70°C temperature constantly for 7 days and were then exposed to UV-light for 11 h (UNAIDS, WHO and UNFPA, 2009; National Institute of Allergy and Infectious Diseases, Department of Health and Human Services, 2001). Then these condoms along with their control group condoms which were not accelerated aged were tested for permeability test electronically and for breakage status by air burst test. The study was conducted from January to March, 2010.

Sampling control group condoms

To sample among either of the branded condoms: 'Sensation' or 'Hiwot trust', as control group, non-random sampling method was used. Accordingly, the visually so inspected most intact boxes and sackets of a randomly selected batch of condoms were selected as sample in order to minimize the bias of natural aging on artificial aging process.

Sampling experimental group condoms

These, on the contrary, were sampled by random systematic sampling because the amount of environmental conditions influence compared to the artificial aging conditions is very much less significant and the bias is just a little.

Variables and measurement of variables

Variables are conditions to which the experimental group condoms are exposed differently while the control groups are not. The variables were then measured by appropriate instrumentation.

1. Heat: According to WHO criteria for condoms, accelerated aging condoms should be exposed to heat oven temperature of 70°C for seven days.
2. UV-light: Wherever there is assumption that the condoms might

Table 1. Frequency and percentage of permeability rate of sample condoms of 'Hiwot Trust' and 'Sensation' condoms before and after aging, Jimma town, Ethiopia, 2011.

Brand	Group	No	%	Yes	%	Total	%	P value and Crude odd ratio
'Hiwot Trust'	Control	313	99.36	2	0.64	315	100	P=0.563; COR=0.4984
	Aged	314	99.68	1	0.32	315	100	
'Sensation'	Control	310	98.41	5	1.59	315	100	P = 0.737; COR=0.7974
	Aged	311	98.73	4	1.27	315	100	

be exposed to sunlight during its transportation, storage and in the hands of the users, the WHO standards of condoms artificial accelerated aging also adds UV-light as a variable. Because there is less attention of preventing condoms from sunlight degradation, especially by the sellers and users in Ethiopia, UV-light should also be better included in the simulation of the artificial aging process. Sunlight exposure of the period of 11 h is selected because it is supposed to bear optimum and tangible correlation between sunlight and condoms breakage rate in laboratories as recognized from the literatures (Weller and Davis-Beaty, 2007; WHO, 2010).

3. Humidity: Because there is high chance for condoms to be exposed to humid conditions in Ethiopia, a certain amount of moisture condition exposure of the experimental condoms increases comparability of the result of the research with the actual environmental conditions. During the seven days of oven drying, moisture was also applied as water vapor in and around the oven. The moisture should not be excessive but just to imitate environmental humid conditions especially during rainy season (CDC, 2008).

Artificial aging

The storage condition of 70°C for seven days is an accelerated aging test derived from latex condoms standard ASTM D 329489. This condition was designed to challenge the product. When there is expectation of exposure, the condoms artificial aging also considers the exposure to humid and UV-light environmental conditions (Sexuality Information and Education Council of the United States (SIECUS), 2002).

Electronic testing of condoms

1. First the condoms were placed over a 'mandrel' which is a fancy way of saying grant metal dildo.
2. Then the condoms were passed through an electric field.
3. Normally, condoms do not conduct electricity.
3. The condom therefore fails if the mandrel registers any electric current even when the condom seems intact, unbroken.

Condoms strength testing

These tests were done to measure condoms strength and effectiveness. Aging of the condoms in oven at 70°C for seven days is a criteria for both tensile test and airburst test. WHO requires 27 L minimum mean burst volume for a batch of condoms after seven days of oven conditioning of 70°C with 1 Kpa pressure of tensile test. The equipment required for airburst test is an apparatus capable of inflating 150 mm of the condom from the closed end while for tensile test is a standard tensile tester equipped with ring test fixture.

Data analysis and interpretation

The data was analyzed manually using tallying methods and presented as tables showing frequency and percentages. Odd ratios were calculated manually and p-values were calculated using online chi-square calculators for permeability status of the condoms. The bursting pressures and volumes were automatically grouped and output by the computerized testing machines.

Ethical consideration

Before the tests were done at the drug administration and quality control authority of Ethiopia where the necessary instrumentation was available, a formal letter from Jimma University was provided to the administration office of the authority. The study was conducted by approval and support of the technical staff of the National Drug Administration and Control Authority.

RESULTS AND DISCUSSION

The permeability of condoms solely depends on the presence of pores on condoms during their manufacturing or due to condoms damage during transportation, storage or handling (Morrow et al., 1980). Out of the total condoms electronically tested in this study, very few condoms were observed to be permeable. According to the criteria of approval of condoms impermeability of DACA, in this study 315 condoms of each of the control group and experimental group of brands 'Hiwot Trust' and 'Sensation' condoms were electronically tested in the national laboratory of DACA, Addis Ababa. In this test, 2 control and 1 aged condoms of 'Hiwot Trust' brand, 5 control and 4 aged condoms of 'Sensation' brand condoms were observed to be permeable and the corresponding distances of the holes were measured to be between 2 and 16.5 cm from the base (Table 1). From these results, the permeability rate of the control group of 'Sensation' condoms was observed to be slightly above the allowance rate of DACA's condoms approval criteria (≤ 2 of 315) (DACA, 2010); 'Hiwot Trust' control group condoms being in the range of allowance of DACA. This slightly higher permeability rate of the 'Sensation' condoms than recommendations is most probably due to exposure of the condoms to unfavorable environmental conditions and thus promoting appropriate handling of condoms should be implemented in all suppliers, during

Table 2. Bursting volumes of artificially aged and normally stored condoms of 'Hiwot Trust' and 'Sensation' brand condoms collected from Jimma town, Ethiopia, 2011.

Brand	Group	Bursting volumes							
		<27 L		27-36 L		36 L and above		Total	
		Frequency	%	Frequency	%	Frequency	%	Frequency	%
'Hiwot Trust'	Control	10	20	30	60	10	20	50	100
	Aged	15	30	30	60	5	10	50	100
'Sensation'	Control	0	0	5	10	45	90	50	100
	Aged	0	0	40	80	10	20	50	100
	Aged	23	7.3	203	64.4	89	28.3	315	100

transportation or storage to minimize these problems. The authority should also search for possible marketing of unapproved or disapproved batches of condoms routinely. On the other hand, there was observed no significant association between condoms permeability status and aging ($P = 0.563$, $P = 0.563$) in both 'Hiwot Trust' and 'Sensation' condoms.

The bursting volumes of the aged condoms were found to be less than that of their control counterparts. Accordingly, 10 (20%) and 0 (0%) of the control group condoms and 15 (30%), 0 (0%) of the experimental group condoms showed bursting volumes less than 27 L for 'Hiwot Trust' and 'Sensation' condoms, respectively. On the other hand, 10 (20%) and 45 (90%) of the control group condoms and 5 (10%) and 10 (20%) of the aged condoms of 'Hiwot Trust' and 'Sensation' condoms, respectively showed bursting volumes more than 36 L (Table 2). WHO recommended that in accelerated aging measurements, the mean bursting volume should not be less than 27 L and the bursting pressure not less than 1 kpa. The limit might be slightly higher for condoms intended for use in hot climates and for smaller condoms. The intuition suggests the higher the minimum volume of burst, the better the product (Youssef, 1993).

In this study, the bursting volumes of both brands were slightly lowered after aging. Accordingly, the bursting volumes of the aged condoms were found to be less than that of their control counterparts. Accordingly, 10 (20%) and 0 (0%) of the control group condoms and 15 (30%) and 0 (0%) of the experimental group condoms showed bursting volumes less than 27 L for 'Hiwot Trust' and 'Sensation' condoms, respectively. However, no single control or aged condom showed bursting volume below Ethiopian DACA's standard for approval which is 18 L. Some gap is observed between WHO recommendation and Ethiopian DACA's approval and this gap should be lowered because the intuition suggests the higher the minimum volume of burst, the better the product. Ethiopian DACA should also consider the fact that Ethiopia is a tropical country where higher minimum bursting volume is required.

On the other hand, 10 (20%) and 45 (90%) of the

control group condoms and 5 (10%) and 10 (20%) of the aged condoms of 'Hiwot Trust' and 'Sensation' condoms, respectively could show bursting volumes more than 36 L. Generally, control 'Sensation' condoms showed higher bursting volumes than 'Hiwot Trust' control condoms as 45 (90%) of the control group condoms could show bursting volumes more than 36 L compared to only 10 (20%) for 'Hiwot Trust' condoms. 'Sensation' condoms, therefore, are supposed to have slightly better elasticity than the 'Hiwot Trust' as condoms evidenced from. On the contrary, 'Sensation' condoms were more significantly affected by aging although both brands aged by the same parameters; their bursting volume above 36 L reduced from 90 to 20% after aging compared to from 20 to 10% for condoms. This is probably due to slightly more vulnerability of 'Sensation' condoms to artificial aging parameters and thus for adverse environmental factors. Generally, however, the bursting volume decreased after aging for both brands and good handling of condoms is an indispensable idea. Accordingly, there was no single condom observed to show bursting pressure below WHO criteria of 1 kpa which contrasts their respective bursting volumes where some condoms failed to meet the criteria of WHO. The aged 'Sensation' condoms and their control counterparts showed the highest percentage of rate of aged condoms bursting pressure and the lowest percentage of rate of control condoms bursting pressures of between 1 to 2 kpa; being 0 and 70%, respectively. 'Hiwot Trust' condoms showed bursting pressures in range of 1 to 2 kpa and 2 to 2.6 kpa with percentage rates of 20 and 80%, respectively (Table 3).

Although bursting pressure cannot alone define the reliability of condoms, it is generally indicative for the strength of condoms (Steiner et al., 1992). In this study there was no single condom observed to show bursting pressure below WHO criteria of 1 kpa which contrasts their respective bursting volumes where some condoms failed to meet the criteria of WHO. The aged 'Sensation' condoms and their control counterparts showed the highest and the lowest bursting pressures; 0 and 70% of which have between 1 to 2 kpa, respectively. There was higher rate of decrease in bursting pressure after aging

Table 3. The bursting pressure distribution among artificially aged and normally stored condoms of 'Hiwot Trust' and 'Sensation' brand condoms collected from Jimma town, Ethiopia, 2011.

Brand	Group	Bursting pressures					
		1-2 kpa		2-2.6 kpa		Total	
		Frequency	%	Frequency	%	Frequency	%
'Hiwot Trust'	control	10	20	40	80	50	100
	Aged	15	30	35	70	50	100
'Sensation'	Control	0	0	50	100	50	100
	Aged	35	70	15	30	50	100

for 'Sensation' condoms than 'Hiwot Trust' condoms; from 0 to 50% versus 20 to 30%. Control group 'Hiwot Trust' condoms showed bursting pressures in range of 1 to 2 kpa and 2 to 2.6 kpa with percentage rates of 20 and 80%.

Generally, the bursting pressures are also decreased after aging. In case of control condoms, 'Sensation' condoms showed higher average bursting pressures than the 'Hiwot Trust' condoms. Generally, the permeability and strength of the randomly collected condoms met the standards of approval of condoms by DACA and WHO except slight deviations which might be due to the possible poor care of condom sellers and users on the appropriate handling of condoms, keeping them away from heat, sunlight and humidity. On the other hand, the recent tireless endeavors being undertaken by DACA in Ethiopia to ensure the safety and effectiveness of condoms is an extremely encouraging commitment.

CONCLUSIONS AND RECOMMENDATIONS

From this study was identified that generally speaking, condoms in market were observed to possess acceptable impermeability, bursting pressure and bursting volume measures in Ethiopia. However, there was observed slight insufficiency of confirmation criteria of bursting volume of 18 L vs. 27 L and insufficiency in consistency of laboratory test for impermeability on some batch of condoms in market. There were also observed bursting volumes of less than 27 L of WHO standard criteria although none was shown below 18 L, which is a DACA criterion. On the other hand, aging the condoms by exposing to heat, UV light and humidity moderately reduced the bursting pressures and volumes of the same in contrast to permeability for which no association was observed with aging. This indicates the significance of optimal handling of condoms for its effectiveness and cure. The exposure of condoms to heat, UV light and humidity are environmental factors that significantly decreased the strength and elasticity of condoms which can also increase the breakage rate of condoms during human uses. The condom producers, distributors, sellers and users should handle it appropriately and protect it

from sunlight, heat and humidity during storage or distribution.

ABBREVIATIONS

HIV, Human immunodeficiency virus; **AIDS**, acquired immune deficiency syndrome; **STD**, sexually transmitted diseases; **FDA**, Food and Drug Administration; **ISO**, International Organization for Standardization; **WHO**, World Health Organization; **USAID**, United States Agency for International Development; **ASTM**, American Society for Testing and Materials; **CEN**, Comité Europeas de Normalización; **UV**, ultraviolet light; **PATH**, program for appropriate technology in health; **USA**, United States of America; **C.QI**, condom quality index; **FHI**, Family Health International; **DACA**, Drug Administration and Control Authority of Ethiopia

Conflict of interest

The author declared he has no conflict of interest.

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