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**FUNCTION TEST OF PROTOTYPE CONDOMS  
AN EVALUATION OF LEFFLER 1, 2 AND 3**

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## Introduction

The spread of sexually transmitted diseases (STDs) and Acquired Immune Deficiency Syndrome (AIDS) has generated renewed interest in condoms in recent years. Concurrently, condom breakage has become a much more important issue for condom users, family planning program administrators and health policymakers on local and national levels. The development of stronger materials that resist breakage and do not deteriorate when stored under adverse conditions should increase condom efficacy, whether used for birth control or disease prevention. Improvements in materials that permit heat transfer through the condom and a change in device functioning which permits the penis to move freely inside the condom may further assist in increasing user acceptability of this method of contraception and disease prevention.

## Study Objectives

FHI's Prototype condom development program is an iterative process requiring information from actual use experiences to guide the various stages of product design. This study was the first test evaluating the functional and aesthetic aspects of a series of Prototypes designed by John Leffler. The safety and/or effectiveness of these Prototypes in preventing pregnancy and disease transmission was not tested in this study.

## Study Products

The study tested three Prototype condoms (Leffler 1, 2 and 3) differing only in the diameter of the aperture (retention mechanism). Leffler 1 has an aperture diameter of 16mm, Leffler 2 a 19mm diameter and Leffler 3's diameter measures 22mm. The condom itself is made of a soft Elastollan (polyurethane) film, 25 microns in thickness. The film is folded and heat sealed into an oblong shape. The condom is packaged in a plastic and paper sleeve. The unique design of this packaging permits the user to don the condom without actually touching it. The condoms are lubricated with Astroglide<sup>R</sup>, a water-based lubricant which has been classified as a cosmetic by the FDA. In addition, Vaseline Petroleum Jelly and Johnson and Johnson Baby Powder are used in the sealing and packaging procedures.

## Methodology

Ten couples from the staffs of Family Health International (FHI) and Clinical Research International (CRI) were recruited for this study. Participating couples were required to meet the following criteria:

1. protected against pregnancy by oral contraceptives, an IUD or sterilization; and not pregnant or nursing an infant at the time of the study;
2. not at risk for sexually transmitted diseases, including AIDS, and not aware of having sexually transmitted diseases, including seropositive results for HIV;

3. willing to use the study products within a three-week testing period;
4. willing to record their candid opinions about the study product using self-administered questionnaires;
5. willing to give written informed consent and sign a Confidential Disclosure Agreement.

The participants were asked to use one each of the three different Prototype condoms and to complete a self-administered questionnaire. Couples only tested one condom of each Prototype because these designs are in an initial stage of development. Larger scale studies are anticipated when the designs are further along in the development process.

### Results

In total, eight couples returned completed questionnaires. The general reactions to the three Prototypes were fairly negative (Table 1). At least one fourth of the participants said they "strongly disliked" the three designs. The general reaction to Leffler 2 was the most favorable, with almost half the respondents (4 females, 3 males) commenting favorably on the device.

Not surprisingly, when subjects were asked which Prototype they preferred with respect to certain characteristics, Leffler 2 was once again perceived the most favorable (Table 2). It must be noted that a large portion of the participants said they had no preference.

Almost all the male participants noted problems with donning Leffler 1 and 3 (7 males for both devices), while half (4 males) gave this response to Leffler 2 (Table 3). Participants most often reported that the collar was "too small, hard/painful to put on". Two couples were unable to use Leffler 1 because the opening was too small. One couple could not use Leffler 2 for the same reason.

Almost all the male participants (6 males for Leffler 1, 2 and 3) said that the three condoms felt tight around the collars. A few said the collars became looser during intercourse (2 males for Leffler 1, and 1 each for Leffler 2 and 3). Condom slippage was only a problem for Leffler 1 and Leffler 3, with two incidents of slippage reported per device.

Participants reported that Leffler 1 and Leffler 3 broke on 2 occasions each, while Leffler 2 broke on 1 occasion. One male said his condom broke along the seam, while the remaining male participants reported that the material of the condoms failed. One participant said his condom broke during intercourse, while the remaining study subjects who experienced condom breakage were not sure what caused their condoms to break. One female participant said that she had two condoms "pop like balloons".

Table 4 presents the characteristics the participants liked best about the general condom design. Three females and two males liked the sensation or the relative freedom of movement these devices provided. Several participants (1 female, 3 males) liked the novel idea of the applicator. In all, four participants said they liked nothing about the general design.

The characteristic liked least (3 females, 2 males) about the general design was that the condoms were "hard and/or painful to put on" (Table 5). Another frequently mentioned complaint was that the cardboard was too stiff (2 females, 2 males).

When the male participants were asked if the condom design permitted the penis to move within the condom, almost all (6 males) responded favorably (Table 6).

### Discussion

Because of the small and non-representative sample of users involved in the testing of Leffler 1, 2 and 3, no firm conclusions can be made about the acceptability of these condoms in the general population. However, the study participants' overall negative responses to the condom design, combined with the fact that 5 out of 24 condoms broke suggests that this device will only be acceptable to the general population with major modifications.

John Leffler was most interested in receiving feedback about the potential relative movement of the penis inside the condom that this design is to provide. Six of the eight males affirmed that the condom did permit this relative movement. Unfortunately, many participants encountered severe problems with donning the condoms. The feedback of the actual experience of intercourse with the condoms was severely tainted by the negative experience of donning the devices.

### Recommendations

The results of this study suggest the following recommendations:

- The cardboard applicator needs to be improved before the next round of tests are initiated. Participants' perception of the condoms during intercourse are biased negatively if they encounter problems donning the condoms.
- Instructions on the donning of the condoms need to be improved to include a statement of the necessity to squeeze the packaging to expose the aperture.
- Laboratory testing of the device needs to be carried out in order to determine if breakage rates are related to design or material.

**TABLE 1: GENERAL REACTION**

**N = 16**

General Reaction:	Leffler 1 16mm aperture		Leffler 2 19mm aperture		Leffler 3 22mm aperture	
	<u>females</u>	<u>males</u>	<u>females</u>	<u>males</u>	<u>females</u>	<u>males</u>
liked it very much	0	0	1	1	0	0
liked it fairly well	2	0	3	2	2	2
neutral	2	2	1	1	2	0
somewhat disliked it	0	2	1	2	1	3
strongly disliked it	3	2	2	2	3	3

**TABLE 2: PREFERENCE OF CHARACTERISTICS**

**N = 16**

Characteristics:	Leffler 1 16mm aperture		Leffler 2 19mm aperture		Leffler 3 22mm aperture		No Preference	
	<u>females</u>	<u>males</u>	<u>females</u>	<u>males</u>	<u>females</u>	<u>males</u>	<u>females</u>	<u>males</u>
ease of donning	1	0	2	4	0	2	3	2
retention	2	0	2	3	0	0	2	5
sensitivity	1	0	1	1	0	0	4	7

5

**TABLE 3: MALE QUESTIONS**

**N = 8**

	<b>Leffler 1</b> 16mm aperture	<b>Leffler 2</b> 19mm aperture	<b>Leffler 3</b> 22mm aperture
<b>QUESTIONS:</b>	<b>males</b>	<b>males</b>	<b>males</b>
<b>Did you have problems donning the device?</b>			
yes	7	4	7
no	1	4	1
<b>If yes, what were the problems?</b>			
too small/hard/painful to put on	4	2	4
too small, could not use	2	1	0
problems with cardboard falling apart	1	1	2
<b>Did condom feel tight around collar?</b>			
yes	6	6	6
no	1	2	2
<b>If yes, did it become looser with use?</b>			
yes	2	1	1
no	1	4	4
<b>Did condom slip off?</b>			
yes	2	0	2
no	5	7	6
<b>If yes, when did it slip off?</b>			
at start of intercourse	0	0	0
during intercourse	1	0	1
during withdrawal	1	0	1
<b>Did condom break?</b>			
yes	2	1	2
no	4	6	6
<b>If yes, where did it break?</b>			
seam	0	1	0
material itself	2	0	2
packaging	0	0	0
collar	0	0	0

**TABLE 4: CHARACTERISTICS LIKED MOST ABOUT GENERAL DESIGN**

N = 16

Characteristic:	Leffler 1, 2 and 3	
	<u>females</u>	<u>males</u>
freedom of movement	3	2
clever idea	1	3
easy to put on	2	0
lubrication	0	1
nothing	2	2

**TABLE 5: CHARACTERISTICS LIKED LEAST ABOUT GENERAL DESIGN**

N = 16

Characteristic:	Leffler 1, 2 and 3	
	<u>females</u>	<u>males</u>
hard or painful to put on	3	2
breakage	1	3
cardboard too stiff	2	2
slippage	2	0
sizing	0	1

**TABLE: 6 RELATIVE MOVEMENT OF THE PENIS**

N = 8

Question:	Leffler 1,2 and 3	
	<u>males</u>	
Did condom design enable the penis to slide within condom?		
yes	6	
no	0	
not sure	1	

APPENDIX 1

**ASSORTED COMMENTS:**

1. Sample condom also broke/real problem with the question of are these things sterile.
2. Maybe the cardboard could be rounded and not so sharp.
3. Liked lubrication but there was too much lubrication.
4. Cardboard detached too easily. Then trying to pull condom down with fingers was difficult because of lubrication.
5. Back to the drawing board folks. These were much worse than the early ones I tried.
6. You will never get anyone in the 1st, 2nd or 3rd world to use these.
7. I liked the method of application but the edge of the package should be rolled to make a less sharp applicator.
8. Being loose fitting; movement within the condom provided excess room, therefore increased movement and stress on the seam caused the break.
9. I thought the condom felt good, but the air trapped inside bothered me.
10. Very difficult to figure out applicator; need arrow or some sort of directions on the cardboard applicator.
11. Was horribly scratchy (Leffler 3), removed during use for this reason. Scratchy as hell (Leffler 2). Hard to explain, but felt like air was going in with the condom. Genuine concern for causing pneumoperitoneum.

APPENDIX 2

FAMILY HEALTH INTERNATIONAL  
FUNCTION TEST OF PROTOTYPE CONDOMS  
PROTOTYPE LEFFLER 1, 2 AND 3  
SITE: FHI/CRI  
PROJECT NUMBER: 0510

**INSTRUCTIONS:**

Complete the general information part of the interview. Then randomly choose one of the test condoms and note the colored dot. Use the condom according to the enclosed diagram. After intercourse, fill out the questionnaire page with the corresponding colored dot. Repeat this process for all three condoms and complete the final page before returning the questionnaire to Kathy Hinson.

**GENERAL INFORMATION:**

1. Patient Order Number: \_ \_
  
2. Your sex: (circle one)  
1. = female  
2. = male ----> are you circumcised?  
0. = no  
1. = yes
  
3. How often do you use latex condoms?  
0. = never used before  
1. = used in past, but not now  
2. = use condoms less than half the time  
3. = use condoms more than half the time  
4. = always use condoms
  
4. Did you participate in a previous test condom study?  
0. = no  
1. = yes

END OF GENERAL INFORMATION SECTION

**PROTOTYPE CONDOM**

5. What is today's date? \_\_/\_\_/90

6. What was your general reaction to the condom?

- 1. = liked it very much
- 2. = liked it fairly well
- 3. = neutral
- 4. = somewhat disliked it
- 5. = strongly disliked it

7. Did you have any problems donning the device?

- 0. = no
- 1. = yes
- 8. = not applicable

if yes, describe problems \_\_\_\_\_  
\_\_\_\_\_

8. Did the condom feel tight around the collar?

- 0. = no
- 1. = yes
- 8. = not applicable

if yes, did collar become looser during intercourse?

- 0. = no
- 1. = yes

9. Did the test device ever slip off?

- 0. = no
- 1. = yes

if yes, when did it slip off?

- 1. = at the very start of intercourse
- 2. = during intercourse
- 3. = during withdrawal

10. Did the test device break or tear?

- 0. = no -----> end of this section
- 1. = yes

if yes, where did it break?

- 1. = seam
- 2. = condom material itself
- 3. = packaging
- 4. = collar

11. What caused the break or tear?

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**END OF THIS SECTION**

**PROTOTYPE CONDOM**

12. What is today's date? \_\_/\_\_/90

13. What was your general reaction to the condom?

- 1. = liked it very much
- 2. = liked it fairly well
- 3. = neutral
- 4. = somewhat disliked it
- 5. = strongly disliked it

14. Did you have any problems donning the device?

- 0. = no
- 1. = yes
- 8. = not applicable

if yes, describe problems \_\_\_\_\_  
\_\_\_\_\_

15. Did the condom feel tight around the collar?

- 0. = no
- 1. = yes
- 8. = not applicable

if yes, did collar become looser during intercourse?

- 0. = no
- 1. = yes

16. Did the test device ever slip off?

- 0. = no
- 1. = yes

if yes, when did it slip off?

- 1. = at the very start of intercourse
- 2. = during intercourse
- 3. = during withdrawal

17. Did the test device break or tear?

- 0. = no -----> end of this section
- 1. = yes

if yes, where did it break?

- 1. = seam
- 2. = condom material itself
- 3. = packaging
- 4. = collar

18. What caused the break or tear?

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**END OF THIS SECTION**

B

**PROTOTYPE CONDOM**

19. What is today's date? \_\_/\_\_/90

20. What was your general reaction to the condom?  
1. = liked it very much  
2. = liked it fairly well  
3. = neutral  
4. = somewhat disliked it  
5. = strongly disliked it

21. Did you have any problems donning the device?  
0. = no  
1. = yes  
8. = not applicable

if yes, describe problems \_\_\_\_\_  
\_\_\_\_\_

22. Did the condom feel tight around the collar?  
0. = no  
1. = yes  
8. = not applicable

if yes, did collar become looser during intercourse?  
0. = no  
1. = yes

23. Did the test device ever slip off?  
0. = no  
1. = yes

if yes, when did it slip off?  
1. = at the very start of intercourse  
2. = during intercourse  
3. = during withdrawal

24. Did the test device break or tear?  
0. = no -----> skip to question #26  
1. = yes

if yes, where did it break?  
1. = seam  
2. = condom material itself  
3. = packaging  
4. = collar

25. What caused the break or tear?

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**END OF THIS SECTION**

14

GENERAL REACTION TO CONDOM DESIGN:

26. What did you like best about the condom's general design?

\_\_\_\_\_

27. What did you like least about the condom's general design?

\_\_\_\_\_

28. Did you have problems with donning the devices?

- 0. = no
- 1. = yes

if yes, did it get easier with practice?

- 0 = no
- 1 = yes

29. Did you like the package design?

- 0. = no
- 1. = yes

if no, what did you not like (any recommendations)?

\_\_\_\_\_

30. Could you tell a difference between the three condoms?

- 0. = no
- 1. = yes

if yes, specify differences noted.

\_\_\_\_\_

31. According to the following criteria, which design did you prefer?

	<u>blue dot</u>	<u>red dot</u>	<u>green dot</u>	<u>no preference</u>
1. ease of donning	—	—	—	—
2. retention	—	—	—	—
3. sensitivity	—	—	—	—

32. Did this condom design enable the penis to slide within the condom? (or did the condom stick to the penis)

- 0. = no
- 1. = yes
- 3. = not sure

33. Any additional comments? (about the condoms, questions or study)

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34. Would you like to be in future condom studies?  
0. = no  
1. = yes

END OF QUESTIONNAIRE

THANK YOU FOR YOUR PARTICIPATION IN THIS FUNCTION TEST OF  
PROTOTYPE CONDOMS.