FUNCTION TEST OF PROTOTYPE CONDOMS
AN EVALUATION OF 5E AND 10A

Round vs. Square Flange

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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 designed primarily to evaluate consumer's preferences of flange shape (square vs. round). 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 two Prototype condoms (5E and 10A). Both condoms are made of a soft Elastollan 1185A (polyurethane) film, 25 microns in thickness. The film is folded and heat sealed into an oblong shape and packaged in gold foil. The condoms are lubricated with 0.6 ml. Astroglide, a water-based lubricant which has been classified as a cosmetic by the FDA. The two devices varied only in the shape of the flange. Prototype 5E has a square flange, while Prototype 10A has a rounded, embossed flange.

Methodology

Twelve 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 two 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 and no preference in flange shape was anticipated. Larger scale studies will be conducted when the designs are further along in the development process.

Results

In total, eleven couples returned questionnaires. Of the eleven couples, one couple did not use the second device and was therefore unable to complete the questionnaire. The general reactions to the two Prototypes were fairly negative (Table 1). Half of the participants responded that they either somewhat disliked or strongly disliked each of the two Prototypes. Five participants neither liked nor disliked each of the two Prototypes, while about one quarter of the participants stated that they liked the Prototypes fairly well or very much (6 for the square flange and 3 for the round flange).

When subjects were asked which Prototype they preferred with respect to specific characteristics, the majority of the participants responded that they had no preference between the two devices (Table 2). When asked whether the participants could tell a difference between the two condoms, 8 said that they could (5 females and 3 males). However, the differences noted by the respondents did not, for the most part, pertain to the flanges but rather the ease of donning, opening size, noise, retention, size of condom and burning. All of these parameters should have been identical since the devices only differed in flange shape. Only three participants noted that the flanges were different.

Especially interesting was the fact that when asked specifically whether respondents could tell that the two condoms had different shaped flanges, 15 could not. Of the five participants who could tell the difference between the flanges when asked, one female (and no males) preferred the square flange, two males (and no females) preferred the round flange and 1 female and 1 male had no preference. Of the three respondents who preferred one flange over another, the reason given was that it was easier to grip and put on. Ironically, this reason was given for both the round and square flanges.

All except one of the participants involved in the donning process noted problems with donning both of these Prototypes (Table 3). Some of the donning problems specified by participants were that the opening was too small, the devices were hard to unroll or pull onto the penis and that the lubricant made handling difficult.

A majority of the male participants (7 males for Prototype 5E and 8 males for Prototype 10A) said that the condoms felt tight around the collars (Table 4). About half of the males who thought the collar was

tight said the collars became looser with use (3 males for Prototype 5E and 5 males for Prototype 10A). Only two incidents of condom slippage were reported for Prototype 5E, while 4 were reported for Prototype 10A.

Participants reported that Prototype 5E broke on 3 out of 11 occasions while Prototype 10A broke on 1 out of 9 occasions (Table 4). For Prototype 5E, one male said his condom broke along the seam, one said the material itself broke, while the remaining male reported that the condom did not tear, but that it stretched at the opening. The only male who reported breakage for Prototype 10A said it broke along the seam.

Half of the participants (5 females and 6 males for each of the two devices) reported that the condoms caused some type of irritation or discomfort (Table 5). The main discomfort reported for both devices was that the condom bunched up (3 females and 1 male for Prototype 5E, and 5 females and 4 males for Prototype 10A). Two males and two females for each device complained that there was too little lubrication. As shown in Table 5 other irritations or discomforts, reported by more than one participant each, were that the texture was unpleasant, the condom pinched the skin, and that the noise was unpleasant.

When asked specifically about whether they liked the package design (Table 6), thirteen (6 female and 7 male) participants stated that they liked the design (while only 5 did not).

Table 7 presents the characteristics the participants liked best about the general condom design. Twelve of the participants liked the feel of the devices, stating that they were thin, natural or comfortable. Nine participants liked the lubrication and 5 liked the packaging. A few participants liked the devices because of their retention (3), they were durable (3), they did not have an unpleasant odor (2), and two respondents specifically stated that they liked the flanges (in general). It is important to note that 1 female and 3 males were unable to say anything good about the condoms at all.

The overwhelming characteristic that respondents liked least (12) about the general design was that the condoms were hard to don (Table 8). Other frequently mentioned complaints were that the devices were baggy or bunched up (5), that they broke or slipped, were too small, and were hard to unroll (4 respondents each). Other complaints, mentioned by 3 participants each, were that there was too much lubrication, the opening was too small, the condom was not sensitive, and that the material was not elastic. (See table 8 for other minor complaints).

Discussion

Because of the small and non-representative sample of users involved in the testing of Prototypes 5E and 10A, no firm conclusions can be made about the acceptability of these condoms in the general population. This particular study was to assess consumer's flange shape preferences. Most participants could not tell that the two condoms had different flange shapes and those that could showed no particular

preference for one shape over the other. Thus, according to this small sample of participants, square vs. round flanges make no difference in the acceptability of these Prototype devices.

However, the study participants' somewhat negative responses to different aspects of the general design of these devices, combined with the fact that 4 out of 21 condoms broke suggests that this device will only be acceptable to the general population with major modifications.

Most of the complaints about these Prototype condoms centered around problems with donning the devices; including difficulty unrolling the condom, the opening being too small or hard to find, and the lubricant causing difficulty in handling the condoms. In addition, these Prototypes caused some type of irritation or discomfort in half of the participants.

Encouraging however, is that once these Prototypes had been donned, in general participants liked the way they felt, stating that they were thin, natural or comfortable. Respondents were also positive about the lubrication (when it did not interfere with handling) and packaging of these Prototypes.

Recommendations

The results of this study suggest the following recommendations:

- Since consumers showed no preference for square or round flanges, we recommend using a square flange because of the cost savings involved.

- New, innovative ideas must by tried in order to overcome the donning problem. Until this problem is solved, consumers are unlikely to have overall positive responses to these Prototype condoms.

- Further research must be done to design a condom which does not break during use. This may include testing of different materials, lubrication types and levels, as well as different retention mechanisms.

- Generally favorable responses to the condom packaging suggests that future packaging should continue to incorporate gold foil.

TABLE 1: GENERAL REACTION

N = 22

General Reaction:	Prototype 5E Square Flange		Prototype 10A Round Flange	
	females	males	females	males
liked it very much	1	1	0	1
liked it fairly well	1	3	0	2
neither liked nor disliked	3	2	3	2
somewhat disliked it	2	2	4	3
strongly disliked it	4	3	2	2

TABLE 2: PREFERENCE OF CHARACTERISTICS

N = 22

Characteristics:	Prototype 5E Square Flange		Prototype 10A Round Flange		No Preference	
	females	males	females	males	females	males
flange shape	1	0	0	2	1	1
putting on	2	3	2	2	5	5
staying on	3	1	1	2	5	7
appearance	1	0	0	0	8	10
sensitivity	2	1	1	1	7	8
comfort	2	1	0	0	8	9

TABLE 3: DONNING

N = 22

	Prototype 5E Square Flange	Prototype 10A Round Flange
Did you have problems putting on the device?		
yes	13	10
no	0	1
not applicable	9	9

TABLE 4: MALE QUESTIONS

N = 11

	Prototype 5E Square Flange	Prototype 10A Round Flange
Did condom feel tight around collar?	males	males
yes	7	8
no	4	2
If yes, did it become looser with use?		
yes	3	5
no	2	2
not sure	1	0
Did condom slip off?		
yes	2	4
no	8	5
Did condom break?		
yes	3	1
no	8	8
If yes, where did it break?		
seam	1	1
material itself	1	0
collar	0	0
other	1	0

TABLE 5 : IRRITATIONS AND DISCOMFORTS

N = 22

	Prototype 5E Square Flange		Prototype 10E Round Flange	
Did the condom cause any irritation or discomfort?	females	males	females	males
yes	5	6	5	6
no	5	5	4	4
What irritation or discomfort?				
condom bunched up	3	1	5	4
too little lubrication	2	2	2	2
texture unpleasant	1	1	1	2
condom pinched skin	1	1	1	1
noise unpleasant	1	1	1	1
too much lubrication	0	1	0	2
application painful	0	1	0	1
too much friction	0	0	1	0
condom caught hair	1	0	0	0
odor unpleasant	0	0	0	0
taste unpleasant	0	0	0	0
seam was irritating	0	0	0	0

TABLE 6: PACKAGE DESIGN

N = 22

	females	males
Did you like the package design?		
yes	6	7
no	2	3

TABLE 7: CHARACTERISTICS MOST LIKED

RANKED IN ORDER OF IMPORTANCE

N = 22

CHARACTERISTICS:	Ranked First		Ranked Second		Ranked Third		**Total**
	females	males	females	males	females	males	
thin/natural	2	3	1	3	2	1	**12**
lubrication	4	1	2	0	0	2	**9**
packaging	2	0	0	1	0	2	**5**
retention	0	2	0	0	1	0	**3**
durable	1	0	1	1	0	0	**3**
no (unpleasant) odor	0	0	2	0	0	0	**2**
flanges	0	1	0	0	1	0	**2**
easy to remove	0	0	0	1	0	0	**1**
texture	0	0	1	0	0	0	**1**

TABLE 8: CHARACTERISTICS LEAST LIKED

RANKED IN ORDER OF IMPORTANCE

N = 22

CHARACTERISTICS:	Ranked First		Ranked Second		Ranked Third		**Total**
	females	males	females	males	females	males	
hard to don	2	3	4	3	0	0	**12**
bunched up/baggy	2	1	2	0	0	0	**5**
hard to unroll	0	0	0	0	0	4	**4**
too small/tight	2	1	0	1	0	0	**4**
broke/slipped	1	0	0	1	1	1	**4**
too much lubrication	0	1	1	0	1	0	**3**
opening too small	1	0	0	1	0	1	**3**
not sensitive	0	0	0	1	1	1	**3**
not elastic	0	1	0	2	0	0	**3**
noisy	2	0	0	0	0	0	**2**
appearance	0	1	0	0	1	0	**2**
too long	0	0	0	0	1	0	**1**
like a sandwich bag	0	0	1	0	0	0	**1**
no receptacle tip	0	0	0	0	1	0	**1**
finding opening	0	1	0	0	0	0	**1**
painful	0	0	0	0	1	0	**1**

APPENDIX 1

FAMILY HEALTH INTERNATIONAL
FUNCTION TEST OF PROTOTYPE CONDOMS
PROTOTYPE 5E AND 10A
SITE: FHI/CRI
PROJECT NUMBER: 3386-6

INSTRUCTIONS:

1. Complete the general information part of the interview.
2. Randomly choose one of the test condoms and note the colored dot. After intercourse, fill out the questionnaire page with the corresponding colored dot.
3. Repeat this process for the second condom.
4. Complete the final section 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 condoms in past, but have not used them in last year
   2 = used condoms less than half the time in last year
   3 = used condoms more than half the time in last year
   4 = always used condoms in last year

4. Did you participate in a previous round of condom tests?
   0 = no
   1 = yes

END OF GENERAL INFORMATION SECTION

PROTOTYPE CONDOM

5. In this round of condom testing, this is the
   1 = first condom tested
   2 = second condom tested

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 putting on the device?
   8 = not applicable, partner put on device
   0 = no
   1 = yes--->if yes, describe problems:_____

   _____

FEMALES SKIP TO QUESTION 12

8. Did the condom feel tight around the collar (opening)?
   0 = no
   1 = yes-->if yes, did collar become looser during intercourse?
   0 = no
   1 = yes
   2 = not sure

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----->skip to question 12
    1 = yes

    if yes, where did it break?
    1 = seam
    2 = condom material itself
    3 = collar (opening)
    4 = other,_____

11. What caused the break or tear?

    _____

    _____

12. Did the condom cause you any irritation or discomfort?
0 = no
1 = yes-------->circle all that apply
01 = applicator painful
02 = condom bunched up
03 = condom pinched skin
04 = condom caught hair
05 = texture of material unpleasant
06 = odor unpleasant
07 = taste unpleasant
08 = seam was irritating
09 = too much lubrication
10 = too little lubrication
11 = noise unpleasant
12 = too much friction
88 = other,_____

_____

_____

13. Any additional comments about the use or design of this condom?

_____

_____

_____

_____

END OF THIS SECTION

B

PROTOTYPE CONDOM

14. In this round of condom testing, this is the
    1 = first condom tested
    2 = second condom tested

15. 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

16. Did you have any problems putting on the device?
    8 = not applicable, partner put on device
    0 = no
    1 = yes--->if yes, describe problems:_____

    _____

FEMALES SKIP TO QUESTION 21

17. Did the condom feel tight around the collar (opening)?
    0 = no
    1 = yes-->if yes, did collar become looser during intercourse?
    0 = no
    1 = yes
    2 = not sure

18. 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

19. Did the test device break or tear?
    0 = no----->skip to question 21
    1 = yes

    if yes, where did it break?
    1 = seam
    2 = condom material itself
    3 = collar (opening)
    4 = other,_____

20. What caused the break or tear?

    _____

    _____

21. Did the condom cause you any irritation or discomfort?
0 = no
1 = yes-------->circle all that apply
01 = applicator painful
02 = condom bunched up
03 = condom pinched skin
04 = condom caught hair
05 = texture of material unpleasant
06 = odor unpleasant
07 = taste unpleasant
08 = seam was irritating
09 = too much lubrication
10 = too little lubrication
11 = noise unpleasant
12 = too much friction
88 = other,_____

_____

_____

22. Any additional comments about the use or design of this condom?

_____

_____

_____

_____

END OF THIS SECTION

GENERAL REACTION TO CONDOM DESIGN:

23. You have just tested two slight variations of a new condom design. In order of importance, what **three** things did you like **best** about the two condoms' general design?

1. _____

2. _____

3. _____

24. In order of importance, what **three** things did you like **least** about the two condoms' general design?

1. _____

2. _____

3. _____

25. Did you have problems with donning the devices?
8 = not applicable, partner put on devices
0 = no
1 = yes--->if yes, did it get easier with the second device?
0 = no
1 = yes

26. Did you like the package design?
0 = no
1 = yes

if no, what did you not like about the package design?

_____

_____

27. Could you tell a difference between the two condoms?
0 = no
1 = yes--->if yes, specify differences noted;

_____

_____

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

	blue dot	red dot	no preference
1. putting on	___	___	___
2. staying on	___	___	___
3. appearance	___	___	___
4. sensitivity	___	___	___
5. comfort	___	___	___

29. One of the main objectives of this study is to assess the acceptability of a square vs. a round flange. Could you tell that the two condoms had different shaped flanges?
0 = no----->skip to question 31
1 = yes

30. Which shaped flange did you prefer and why?
0 = square flange, _____

_____

1 = round flange, _____

_____

2 = no preference

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

_____

_____

_____

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

END OF INTERVIEW, THANK YOU FOR YOUR PARTICIPATION