

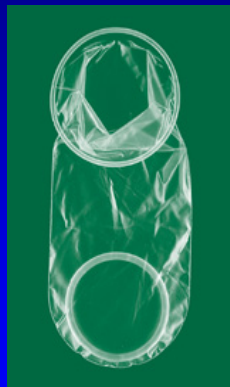
# GLOBAL CONSULTATION ON THE FEMALE CONDOM

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## FEMALE CONDOMS

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C O N R A D

## REDDY FEMALE CONDOM

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- ◆ Evaluation of two shaft lengths
- ◆ Objectives:
  - ▶ Functional performance & fit
  - ▶ Acceptability
  - ▶ Safety

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## Evaluation of two shaft lengths

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- ◆ Study Design: single site (CFHC); crossover study; randomized to first device use
- ◆ Population: 25 low risk couples
- ◆ Condom Use: 3 uses of each condom type

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## Evaluation of two shaft lengths

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- ◆ Description of condoms:
  - ▶ 150 mm shaft length
  - ▶ 90 mm shaft length
  - ▶ Sponge:
    - 60 mm X 10 mm
    - Covered by polyurethane film
  - ▶ Frame: equilateral triangle with ridges on inside of frame

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## Evaluation of two shaft lengths

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- ◆ Selected Demographics:
  - ▶ Age:
    - Females: 28 +/- 8 years
    - Males: 30 +/- 9 years
  - ▶ Race:
    - White, not Hispanic: 32% (F) – 40% (M)
    - Black, not Hispanic: 20% (F) – 24% (M)
    - Hispanic: 16% (F) – 28% (M)
    - Asian: 16% (F) – 8% (M)

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## Evaluation of two shaft lengths

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- ◆ Demographics (continued):
  - ▶ Relationship with partner:
    - Living together: 72%
    - Not living together: 28%
  - ▶ Length of current relationship:
    - Median: 2 years
  - ▶ Education (> 12 years):
    - Females: 84%
    - Males: 76%

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## Evaluation of two shaft lengths

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- ◆ Demographics (continued):
  - ▶ Contraceptive Use (in study):
    - Hormonal: 84%
    - Sterilization: 16%
  - ▶ History of condom use:
    - Male condom: 96-100%
    - Female condom: 0%

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## Evaluation of two shaft lengths

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- ◆ Primary Endpoint:
  - ▶ Condom performance measure of “outer frame displacement” for each given condom type

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## Evaluation of two shaft lengths

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- ◆ Outer Frame Displacement:
  - ▶ 90 mm Shaft:
    - 26.5% (15.9-37.0) 18/69  
uses
  - ▶ 150 mm Shaft:
    - 17.4% (8.4-26.3) 12/71  
uses

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## Evaluation of two shaft lengths: Selected Acceptability Data

	Version 6 (150)		Version 6 (90)	
	Females	Males	Females	Males
Compared to male condoms used previously (scale 1-7, better-worse)	5.0	4.9	4.9	5.0

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## Evaluation of two shaft lengths

	Version 6 (150)		Version 6 (90)	
	Females mean	Males Mean	Females mean	Males mean
Length of condom outside the vagina (1 = too long; 7 = too short)	3.0*	3.5	4.2*	4.0
Length of condom within the vagina (1 = too long; 7 = too short)	3.6*	3.6*	4.4*	4.7*

\* Statistically significant difference between the scores for the two condom types (t-test)

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## Condom Preference Data

Which condom did you like the best?	Females		Males	
	n	%	n	%
Version 6 (150)	9	39	9	39
Version 6 (90)	9	21	9	21
No preference	5	7	5	7

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## Condom Functionality Data

	Version 6 (150)		Version 6 (90)	
	n	%	n	%
Number of condoms opened	71		69	
Broken while opening	1	1	1	1
Used during vaginal intercourse	69	97	67	97
Clinical breakage	0	0.0	0	0.0
Incorrect penetration	0	0.0	0	0.0
Outer frame displacement	12	17	18	26
Pullout	9	13	8	12
Complete slippage	0	0.0	0	0.0
Partial slippage	25	36	8	12
Complete turning inside out	0	0.0	0	0.0
Partial turning inside out	2	3	3	4
Total clinical failure	14	20	21	31
Total failure	38	54	33	48

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## Comparison of Performance Measures: FC1 & Reddy

	FC1 Study #5	Reddy 5 Study #5	Reddy 6 (150)	Reddy 6 (90)
Condoms used	42	44	69	67
Clinical breakage	2.2	2.3	0.0	0.0
Outer frame displacement	2.3	9.3	17.4	26.5
Partial turning inside out	2.3	2.3	2.9	4.4
Total clinical failure	9.3	13.6	20.3	30.9

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## PATH Woman's Condom



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## PATH's WC AND FC1

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- ◆ Study Design: Comparative, open-label, crossover at 3 sites with 1 site colposcopy assessment
- ◆ Population: 75 low risk couples
- ◆ Condom Use: 4 uses of each type

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## PATH's WC AND FC1

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- ◆ Sites:
  - ▶ U. of Pittsburgh/Magee Womens Research Institute
  - ▶ Advances in Health, Houston, TX
  - ▶ U. of Pennsylvania Medical Center (Colposcopy site)

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## PATH's WC AND FC1

- ◆ Selected Demographic Info.
  - ▶ Contraceptive Use:
    - In study: Hormonal 80%; Tubal ligation/vasectomy 12%; other 8%
    - History of condom use: Male condom, 97%; Female condom, 0%
  - ▶ Age:
    - Females: 29 +/- 8 years
    - Males: 31 +/- 8 years

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## PATH's WC AND FC1

- ◆ Demographics (continued)
  - ▶ Ethnicity
    - Hispanic: 16%
    - Not Hispanic: 84%
  - ▶ Race:
    - White: 73% (F) 74% (M)
    - Black/African American: 20% (F) 20% (M)
    - Asian: 4% (F) 1% (M)
    - Other/Mixed: 3% (F) 3% (M)

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## PATH's WC AND FC1

- ◆ Demographics (continued)
  - Education: 15 +/- 2 years
  - Relationship with male partner:
    - Living together: 54%
    - Not living together: 46%
  - Length of time with male partner:
    - Median: 3 years

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## Preliminary Functionality Data

N= Number of condoms used	WC N=274		FC1 N=272	
	n	%	n	%
Clinical breakage	2	0.7	0	0.0
Incorrect penetration	6	2.2	7	2.6
Complete turning inside out	2	0.7	1	0.4
Partial turning inside out	12	4.4	25	9.2
Complete slippage	4	1.5	10	3.7
Outer ring displacement	27	9.8	27	9.9
<b>Total clinical failure</b>	<b>46</b>	<b>16.8</b>	<b>64</b>	<b>23.5</b>

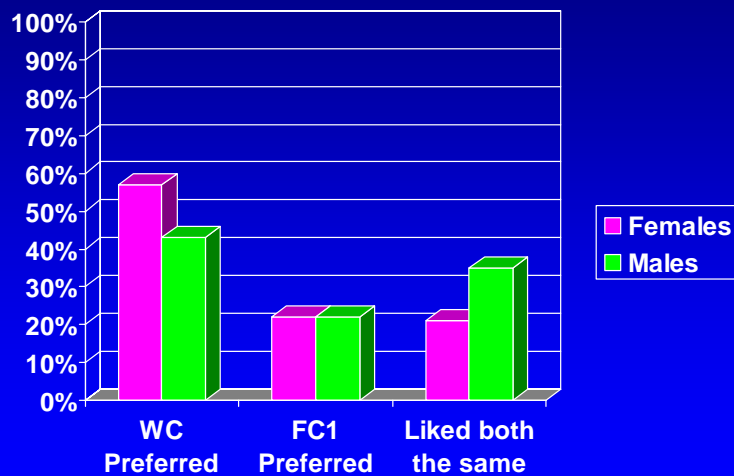
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## PATH's WC AND FC1: Selected Acceptability Data

	WC		FC1	
	Females	Males	Females	Males
Compared to male condoms used previously (Scale 1-7, better-worse)	3.9	3.9	4.7	4.4
In sexual satisfaction... (Scale 1-7, better-worse)	3.8	3.9	4.6	4.3

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## PATH's WC AND FC1: Condom Preference



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# FEMALE CONDOMS

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- ◆ Where do we go from here?
  - ▶ Clinical Plans
    - Reddy Female Condom
    - PATH Woman's Condom
    - FC2

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