



Three Female Condoms: Which one do South African women prefer?

Carol Joanis, Mags Beksinska, Jenni Smit, Catherine Hart

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Reproductive Health and HIV Research Unit (RHRU)

Witwatersrand University, Durban, SA

Commercial City Clinic, Durban, SA

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Study Products

PATH Woman's Condom (PATH)



- Polyurethane
- Circular outer ring
- Insertion capsule
- Foam retention pads
- Requires self-lubrication
- Investigational device
 - *Chinese approval 2010*
 - *EU approval 2011-2012*

FC2 (Female Health Company)



- Synthetic latex (nitrile)
- Circular outer ring
- Inner ring
- Pre-lubricated
- EU and US FDA approved
- WHO list

V-Amour or VA w.o.w. (Medtech, Ltd.)



- Latex
- V-shaped outer frame
- Sponge insertion device
- Pre-lubricated
- EU approved



Study Design

Study Design

Part 1: Randomized, prospective cross-over trial

- 170 women (160 completed – used all three devices)
- 5 uses of each type of device
- Coital diary completed after each device use
- Follow-up visit/survey after use of each device type
- Option of continuing into **Part 2** of study

Part 2: Simulated market

- 148 women (132 completed)
- Free choice of device[s] over 3-month period
- 3 re-supply visits
- 10 FCs given per visit

Part 3: Qualitative (In-depth Interviews)

Study Objectives

Primary:

- To determine participant **preference** for 1 of the 3 FCs

Secondary:

- To determine **safety** of each device
- To determine **acceptability** of each device
- To determine **functional performance** of each device

Study Population

- 18+ years old
- Literate
- Sexually active (2 acts/week)
- Monogamous during study period
- With current partner for at least 6 months
- Not a sex worker
- Not pregnant or breastfeeding
- No evidence of STI (vaginal exam + syndromic diagnosis)
- Using non-barrier contraceptive method (e.g. injectable)
- Not allergic to latex, polyurethane or the lubricants used on condoms



Study Results

Participant Demographics

N=170

- **Age:** 18-48 years (mean = 28)
- **Race/Ethnicity:** 168 African
- **Education:** 1-12 years (mean = 11.2)
- **Occupation:** 45% unemployed; 20% students
- **Living Children:** 1-6 (mean = 1.4)
- **Marital Status:** 15 married; 40 reside w/partner
- **Contraception:** 72% injectable; 21% pills; 7% surgical sterilization
- **FC Experience:** 146 (85%) never used

Which condom did SA women prefer?

Part 1: Randomized trial (n=160)

	(n)	(%)
PATH WC	76	47.5
FC2	57	35.6
V-Amour	26	16.3
Same	1	0.6

Significant difference between condom types ($p < .0001$). PATH WC vs. FC2 = .0995; PATH WC vs. V-Amour = $< .0001$ and FC2 vs. V-Amour = .0007. PATH WC and FC2 preferred over V-Amour. PATH WC preferred over FC2.

Part 2: Market (n=148)

	(n)	(%)
PATH WC	57	39.0
FC2	51	34.0
V-Amour	30	20.0
Same	10	7.0

Significant difference between condom types ($p < .0001$). PATH WC vs. FC2 = .2398; V-Amour vs. FC2 = .0013. No significant difference in preference between PATH WC and FC2.

Adverse Events Related to Use of Study Products (179 Events, 55 women)

Safety Event	PATH WC (n=165)	FC2 (n=164)	V-Amour (n=164)
No Problems	161	162	155
Itching	10	9	14
Pain	10	10	29
Rash	2	3	1
Other Problems	4	2	3

Part 1: Acceptability

Participants Who Somewhat/Very Much Liked Devices

Acceptability Measure	PATH WC (n=165)	FC2 (n=164)	V-Amour (n=164)	p-value
Feel/ Sensation	135	124	112	0.0140
Lubrication Amount	102	127	132	<.0001
Appearance	133	119	109	0.0144
Ease of Use	152	141	113	<.0001
Overall Fit	145	139	118	0.0082

Part 1: Function (Total Clinical Failure)

n= number of failure events

Condom Type (# used)	(n)	(%)	95% CI
<i>PATH WC (n=798)</i>	29	3.63	(2.45-5.18)
<i>FC2 (n=794)</i>	31	3.90	(2.67-5.50)
<i>V-Amour (n=784)</i>	26	3.32	(2.18-4.82)

Note: Of the main function outcome (total clinical failure), there is no statistical difference between condom type and the odds of a failure event (p-value = .8751).

Overall Conclusions

- Participants generally preferred the PATH WC and FC2 condoms over V-Amour.
- PATH WC preferred over FC2 though difference was not significant.
- All 3 condoms were well accepted, frequently used and caused few adverse events.
- While a RCT may be the gold standard for clinical trials of efficacy and function, it may not be the best method for evaluating preference or acceptability.