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

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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)

<table>
<thead>
<tr>
<th></th>
<th>(n)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATH WC</td>
<td>76</td>
<td>47.5</td>
</tr>
<tr>
<td>FC2</td>
<td>57</td>
<td>35.6</td>
</tr>
<tr>
<td>V-Amour</td>
<td>26</td>
<td>16.3</td>
</tr>
<tr>
<td>Same</td>
<td>1</td>
<td>0.6</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th></th>
<th>(n)</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PATH WC</td>
<td>57</td>
<td>39.0</td>
</tr>
<tr>
<td>FC2</td>
<td>51</td>
<td>34.0</td>
</tr>
<tr>
<td>V-Amour</td>
<td>30</td>
<td>20.0</td>
</tr>
<tr>
<td>Same</td>
<td>10</td>
<td>7.0</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Safety Event</th>
<th>PATH WC (n=165)</th>
<th>FC2 (n=164)</th>
<th>V-Amour (n=164)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Problems</td>
<td>161</td>
<td>162</td>
<td>155</td>
</tr>
<tr>
<td>Itching</td>
<td>10</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Pain</td>
<td>10</td>
<td>10</td>
<td>29</td>
</tr>
<tr>
<td>Rash</td>
<td>2</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Other Problems</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
## Part 1: Acceptability

### # Participants Who Somewhat/Very Much Liked Devices

<table>
<thead>
<tr>
<th>Acceptability Measure</th>
<th>PATH WC (n=165)</th>
<th>FC2 (n=164)</th>
<th>V-Amour (n=164)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feel/Sensation</td>
<td>135</td>
<td>124</td>
<td>112</td>
<td>0.0140</td>
</tr>
<tr>
<td>Lubrication Amount</td>
<td>102</td>
<td>127</td>
<td>132</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Appearance</td>
<td>133</td>
<td>119</td>
<td>109</td>
<td>0.0144</td>
</tr>
<tr>
<td>Ease of Use</td>
<td>152</td>
<td>141</td>
<td>113</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Overall Fit</td>
<td>145</td>
<td>139</td>
<td>118</td>
<td>0.0082</td>
</tr>
</tbody>
</table>
### Part 1: Function (Total Clinical Failure)

n = number of failure events

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

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.