Couples’ use of Woman’s Condom in China: results from a performance, safety, and acceptability study

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PATH
A catalyst for global health
Woman’s Condom – designed and validated through user-centered development process

Performance objectives:
• Easy to handle and insert
• Easy to use (especially for new users)
• Stable during use
• Comfortable for both partners
• Easy to remove
Woman’s Condom – unique features allow ease of use and good sensation
Woman’s Condom acceptability and performance confirmed in multiple studies

Three-country design verification study\(^1\)
- Majority of users found the device comfortable, easy to insert, and stable during use.

US Phase I comparative performance, failure mode, and safety study\(^2\)
- Woman’s Condom had fewer failures and less slippage, and it was preferred by men and women when compared with FC1.

South Africa comparative performance and acceptability study\(^3\)
- Woman’s Condom performed well and was preferred over two other female condom designs.

Formative research: 18 FGDs with potential user groups in preparation for Phase I study

- University students (F/M)
- College-educated professionals (F/M)
- Married couples (F/M)
- Migrant workers (F/M)
- Women in the entertainment industry

- Conducted in collaboration with Shanghai Institute of Planned Parenthood Research

Photo credit: iMorpheus flickr
FGD Participant Characteristics (n=130)

• 100% Han ethnicity; most were highly educated.
• About 50% used contraception (rates varied by group).
  • Highest rates: migrant women, married women, women in the entertainment industry.
  • Female students had much lower rates of contraceptive use.
• Low awareness of female condoms.
• Male condom used for contraception, not for STI prevention.
• Very low perception of risk of STIs.
FGD Key Findings

- Men expressed more willingness to use a female condom than women.
- Men expressed positive images about the Woman’s Condom: “fresh, mystical, brilliant, exquisite.”
- Women’s lack of interest possibly related to satisfaction with existing contraceptive method and perceived lack of risk for STIs.
- Women’s concerns: unsure about insertion, partner’s satisfaction, use of lubricant.
- Migrant women and women in the entertainment industry were most motivated to use Woman’s Condom.

“Women can use it by ourselves; that’s reassuring.”
Performance and failure mode study summary

- **Study design**: single-arm, multisite, non-blinded study implemented among 60 couples in Shanghai.

- **Research sites**: Shanghai Institute of Planned Parenthood Research and Fudan University OB/GYN Hospital.

- **Primary endpoints**: clinical and nonclinical failures, safety, and acceptability.

- **Data collection methods**: surveys completed after each product use; SMS text message after each product use; debrief interview after four product uses.
Performance and failure mode study: participant characteristics

- **Age**: (F) 25-55 years; (M) 27-57 years
- **Duration of current partnership**: average of 13 years
- **Education**: Over 70% completed junior high school; almost 50% of women attended university; about 30% of men attended university
- **Employment**: 70-80% of M/F were company or factory workers
- **Current contraceptive method use**: IUD, Oral Contraceptives
- **Previous female condom use**: None
Key Failure Modes for Female Condoms

• **Clinical Breakage** is defined as a female condom that breaks during intercourse or removal of the condom from the vagina.

• **Misdirection** is defined as vaginal penetration whereby the penis is inserted between the female condom and the vaginal wall.

• **Invagination** is defined as part or all of the external components of the female condom being pushed into the vagina during intercourse.

• **Slippage** is defined as a female condom that slips completely out of the vagina during intercourse.
# Clinical performance of Woman’s Condom

<table>
<thead>
<tr>
<th>Failure modes</th>
<th>Condoms</th>
<th>Events n (%)</th>
<th>Couples</th>
<th>Events n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total breakage</td>
<td>236</td>
<td>2 (1)</td>
<td>59</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Nonclinical breakage</td>
<td>236</td>
<td>2 (1)</td>
<td>59</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Clinical breakage</td>
<td>234*</td>
<td>0 (0)</td>
<td>59</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Misdirection</td>
<td>234</td>
<td>5** (2)</td>
<td>59</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Invagination</td>
<td>234</td>
<td>2† (1)</td>
<td>59</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Slippage</td>
<td>234</td>
<td>3 (1)</td>
<td>59</td>
<td>3 (5)</td>
</tr>
</tbody>
</table>
## Adverse events by condom, female and male users

<table>
<thead>
<tr>
<th>Type of event</th>
<th>Condoms used (n=234)</th>
<th>Women (n=59)</th>
<th>Men (n=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>With event, n (%)</td>
<td>With event, n (%)</td>
<td>With event, n (%)</td>
</tr>
<tr>
<td>Genital pain/discomfort</td>
<td>3 (1)</td>
<td>2 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Burning, stinging, or pressure while urinating</td>
<td>4 (2)</td>
<td>2 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Genital itching</td>
<td>7 (3)</td>
<td>2 (3)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Genital irritation/rash</td>
<td>1 (0.4)</td>
<td>0 (0)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>
Trends in acceptability for female and male users

- Women first use
- Women fourth use
- Men first use
- Men fourth use
Effect of lubricant on sexual experience by percent of female users

First use (n=51)
- Enhanced: 22
- No effect: 69
- Detracted/DK: 10

Fourth Use (n=53)
- Enhanced: 42
- No effect: 53
- Detracted/DK: 6
Regulatory strategy

Complete

- CE technical dossier on production and QA/QC
  *Submitted by Dahua*

- Shanghai FDA application
  *Submitted by Dahua*

- WHO Female Condom Technical Review Committee or WHO/UNFPA recommendation

In process

- Premarket approval (PMA) application and Dahua factory audit

In future

- CE Mark (2010)

- Chinese regulatory approval (2011)

- Clearance for public-sector procurement (2012)

- USFDA application (2013-2014)
Key lessons learned

• Formative research helped prepare the researchers for the couples’ use study.
  • Explored product perceptions; pretested the user instructions, developed language to describe the product.
• Important to liaise with regulatory authority regarding size/type of study necessary for market approval.
• Woman’s Condom performed comparable to other female condom designs.
Thanks to our funders and researchers who made Woman’s Condom possible

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