So the female condom is an effective contraceptive and disease prophylactic. But will women use it?
Aims

- What do we know about short-term acceptability of the female condom?
- What are the patterns of use, especially over the longer-term?
- What are some challenges to acceptability?
  - Individual, partner, and environmental influences

Short-Term Acceptability Studies

- Tried it, liked it, willing to use in the future
- Western and developing nations
- Higher risk -- female sex workers, STI clinics &
  Lower risk -- family planning, general population
- Range of acceptability rates (37% to 96%)
- Qualitative data - positives and negatives

WHO, 1997, Cecil et al., 1998
Short-Term Acceptability Findings – FC Positives

- Female initiated
  - Enhances women’s ability to negotiate and ensure safer sex (Ankrah & Attika, 1997; Niang, 1996; Hernández et al., 1996; Rivers, et al., 1998; Pool et al., 2000b; Gollub, 2000).

- Method features
  - Polyurethane is less allergenic, stronger

- Sexual pleasure
  - Less restrictive for men
  - Conducts heat
  - Can be inserted before sex

Short-Term Acceptability Findings – FC Negatives

- Aesthetic responses – It looks “weird”.
- Insertion and use challenges
- May reduce sexual pleasure - discomfort
- Male partner responses range from enthusiastic to rejecting
Short-Term Acceptability Studies – Developing Nations

- Female sex workers in China
  94% willing to use (N=165)

- Female sex workers in Thailand
  68% satisfied (N=88)

- Rural women in Zimbabwe
  93% liked it (N=700)


What Do We Mean By Acceptability?

Voluntary sustained use of a method in the context of alternatives (Severy & Newcomer, 2005).
Does adding the female condom to the method mix increase the percent of protected sex acts?

If yes, how do couples achieve this?

<table>
<thead>
<tr>
<th>Studies of Longer-Term FC Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What Is Known</strong></td>
</tr>
<tr>
<td>EFFECTIVE INTERVENTIONS</td>
</tr>
<tr>
<td>- <strong>Can</strong> increase % of women who use the FC</td>
</tr>
<tr>
<td>- <strong>Can</strong> increase the % of protected sex acts</td>
</tr>
<tr>
<td>- FC does not replace MC</td>
</tr>
<tr>
<td>- Couples with 100% protected occasions tend to mix FC and MC use</td>
</tr>
</tbody>
</table>
Studies of Longer-Term FC Use

- 3 to 18 months follow-up

- Outcomes vary
  - Use of male and female condoms
  - Occasions - % protected (or unprotected) – MC or FC
  - Women - % with consistent MC or FC use or any unprotected occasions

- Randomized & observational

Studies of Longer-Term FC Use

- Intervention Targets
  - Female sex workers
  - STI clinic attendees
  - Women in high-prevalence areas
  - Family planning clinic attendees

- Intervention Types
  - Individual and couple counseling
  - Group-based
  - Structural
Studies of Longer-Term FC Use

Of 14 studies, 11 show some evidence of a positive effect of adding the female condom.

▲▲ = strong positive effect
▲ = some positive effect
○ = no effect

---

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thai female sex workers – R</td>
<td>▲</td>
</tr>
<tr>
<td>Welsh, Feldblum et al., 2001</td>
<td></td>
</tr>
<tr>
<td>Kenyan plantation residents – R</td>
<td>▲</td>
</tr>
<tr>
<td>Latka, et al., 2000, Gollub et al., 2001</td>
<td></td>
</tr>
<tr>
<td>Phila. STI clinic attendees – O</td>
<td>▲</td>
</tr>
<tr>
<td>Hatzell et al. unpub.</td>
<td></td>
</tr>
<tr>
<td>Madagascar FSWs – O</td>
<td>▲▲</td>
</tr>
<tr>
<td>Fontanet et al.1998</td>
<td></td>
</tr>
<tr>
<td>Alabama STI clinic attendees – O</td>
<td>▲▲</td>
</tr>
<tr>
<td>Artz et al., 2000, Macaluso et al. 2000</td>
<td></td>
</tr>
<tr>
<td>R = Randomized O = Observational</td>
<td></td>
</tr>
<tr>
<td>▲ = positive effect</td>
<td></td>
</tr>
<tr>
<td>○ = no effect</td>
<td></td>
</tr>
</tbody>
</table>
### Studies of Longer-Term FC Use

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zambian STI clinic attendees (couples) – O</td>
<td>↑</td>
</tr>
<tr>
<td>Musaba et al., 1998</td>
<td></td>
</tr>
<tr>
<td>US STI clinic attendees – R</td>
<td>↑</td>
</tr>
<tr>
<td>Kalichman, et al., 1999</td>
<td></td>
</tr>
<tr>
<td>Zimbabwean FSWs – R</td>
<td>○</td>
</tr>
<tr>
<td>Ray et al., 2001</td>
<td></td>
</tr>
<tr>
<td>Brazilian FSWs – O</td>
<td>○</td>
</tr>
<tr>
<td>Galvao, et al., 2002</td>
<td></td>
</tr>
<tr>
<td>US family planning clinic attendees – O</td>
<td>↑↑</td>
</tr>
<tr>
<td>Choi et al., 2003</td>
<td></td>
</tr>
<tr>
<td>R = Randomized O = Observational</td>
<td></td>
</tr>
<tr>
<td>↑ = positive effect ○ = no effect</td>
<td></td>
</tr>
</tbody>
</table>

### Studies of Longer-Term FC Use

<table>
<thead>
<tr>
<th>Study</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>US family planning clinic attendees – R</td>
<td>○</td>
</tr>
<tr>
<td>Hoffman et al., 2003</td>
<td></td>
</tr>
<tr>
<td>Brazilian family planning clinic attendees – O</td>
<td>↑↑</td>
</tr>
<tr>
<td>Barbosa et al., unpub.</td>
<td></td>
</tr>
<tr>
<td>Kenyan FSWs – O</td>
<td>↑</td>
</tr>
<tr>
<td>Thomsen et al., unpub.</td>
<td></td>
</tr>
<tr>
<td>Phila. drug users (BestBet) – R</td>
<td>↑</td>
</tr>
<tr>
<td>Gollub et al., unpub.</td>
<td></td>
</tr>
<tr>
<td>R = Randomized O = Observational</td>
<td></td>
</tr>
<tr>
<td>↑ = positive effect ○ = no effect</td>
<td></td>
</tr>
</tbody>
</table>
Alabama (USA) STI Clinic

**Intervention**
- Nurse-delivered, single counseling session
- Goal – 100% barrier protection, FC use
- Content – Insertion skills training, negotiation, partner materials

**Method**
- Observational – no control group
- 1159 women recruited from 2 STI clinics
- Monthly follow-up for 6 months

Artz et al., 2000, Macaluso et al, 2000

---

**Results**

- Female condom use
  ~ 25% of occasions throughout FU

- Women with consistent condom use
  **Baseline**: 28%  **6-months**: 56%
  ~36% after estimating for dropouts

- Percent of protected sex occasions
  **Baseline**: 40%  **6-months**: 67%
  ~50% after estimating for dropouts

Artz et al., 2000, Macaluso et al, 2000
Results

FC Use - Proportion FC-Protected Acts

Artz et al., 2000

Results

Proportion Male or Female Condom Protected Acts

Artz et al., 2000
How Do Couples Increase Protection?

- In the Alabama STI clinic study
  - 35% of women maintained consistent condom use
  - Of these, 75% achieved this by using a mix of male and female condoms

- Studies in STI clinics in Zambia and Philadelphia report similar findings


Does the FC Replace the MC?

**RANDOMIZED**

- Thai sex establishments
  - Some replacement, but overall ↑

- Kenyan communities
  - No replacement, overall ↑

**OBSERVATIONAL**

- Kenyan FSWs
  - Some replacement, no overall ↑

- Madagascar FSWs
  - Some replacement, but overall ↑
Mean proportion of protected sex acts with clients (last 30 days)

Studies of Longer-Term FC Use

What Is Known

EFFECTIVE INTERVENTIONS

- Can increase % of women who use the FC
- Can increase the % of protected sex acts
- FC does not replace MC
- Couples with 100% protected occasions tend to mix FC and MC use
Studies of Longer-Term FC Use

Unanswered Questions

- How can we increase the size of the increment in protected sex occasions?
- What are the most effective promotional methods for each population?
- How can we help to sustain FC use?

What Influences Acceptability? A Broader Perspective

- Acceptability is not a static quality of the method - FC, MC, microbicide
- Acceptability is influenced by
  - Individual factors - insertion skills and practice
  - Male partner and relationship type
  - Social and political environment - provider training, marketing, access, and cost
**Individual Factor - Insertion Difficulties**

- Insertion difficulties for some users
  - *Cecil et al., 1998*
- However….Insertion can be learned!
  - With insertion skills training and opportunity to practice insertion, difficulties decreased from 25% to 3%
  - *Artz et al., 2002*
- Insertion and use challenges decline with practice
  - *Yimin et al., 2002, Galvao, 2002*

---

**Male Partners and Relationship Type**

- In which type of partnerships is FC most likely to be used?
- Male partner challenges
In What Types of Partnerships is FC Most Likely to be Used?

- In US studies, FC use is greater with regular partners (spouse or boyfriend) than with casual partners. Macaluso et al., 2000a, Sly et al., Hoffman et al., 2004, Choi et al., 2003.
- MC use is greater with casual and new partners.
- For women in established partnerships, the female condom may help them achieve 100% protected sex. Macaluso et al., 2000b

Partner Type and FC Use

<table>
<thead>
<tr>
<th>Partner Type</th>
<th>Any Use - % of Women</th>
<th>% of Occasions Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse or boyfriend</td>
<td>77</td>
<td>18</td>
</tr>
<tr>
<td>Lover</td>
<td>75</td>
<td>16</td>
</tr>
<tr>
<td>Friend</td>
<td>42</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td>All Partners</td>
<td>67</td>
<td>17</td>
</tr>
</tbody>
</table>

Choi et al., 2003
Post Marketing Studies

- FC use is greater with regular, non-marital partners than with marital partners
- Women: Single ↑ than married
- Men: Single = married


<table>
<thead>
<tr>
<th>Partner Type</th>
<th>Women %</th>
<th>Men %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spouse</td>
<td>7.4%</td>
<td>12.8%</td>
</tr>
<tr>
<td>Regular partner</td>
<td>11.7</td>
<td>12.1</td>
</tr>
<tr>
<td>Casual partner</td>
<td>24.1</td>
<td>9.5</td>
</tr>
</tbody>
</table>

Agha, 2001
Partner Type and FC Use –
Female Sex Workers

In both US and developing world studies among FSWs, FC use is greater with paying than with non-paying partners

Thomson 2005, Witte et al., 1999

Challenges: Male Partners

- Qualitative studies worldwide show FC can increase women’s sense of empowerment
- Covert use is generally not possible
- In US studies, positive attitude of male partner \( \Rightarrow \) increased FC use
  
  Choi et al., 2003 Hoffman et al., 2004
- Worldwide, male partner objection is a reason for FC non-use or discontinuation
  
  Ford & Mathie, 1993; Farr et al., 1994; Welsh et al., 2001; Beksinska et al., 2001.
Strategies: Male Partners

Qualitative Findings - US STI Clinic
Consistent FC users used multiple strategies to present the FC to partners
- Persuasion
  - Dual protection
  - Sexual pleasure – natural feeling
  - Help with insertion
- Direct materials for men – pamphlets, testimonial video

Penman-Aguilar et al., 2002

Strategies: Male Partners

Qualitative findings – Kenya & Brazil
- Successful FC users used a range of strategies to introduce FC to partners
  - Non-confrontational persuasion
  - Focus on pregnancy prevention
  - Left FC on bed to stimulate discussion
  - Inserted before sex
- Men - concerns about sexual pleasure
- Some men wanted to introduce FC

Ankrah & Attika, 1997
Male Partners: Future Directions

- Interventions need to compare different approaches to reaching men
- Prevailing gender norms will influence successful partner introduction strategies

Susser & Stein, 2000, Mantell et al., unpub.

Social Environment Challenge: Cost and Re-Use

- High cost relative to the male condom remains a challenge for sustaining use
- Reuse may reduce cost
- Studies demonstrate FC-1 can be safely washed and re-used
  - Structural integrity maintained up to 7 washes
  - No microbial retention

Joanis, et al., 2000; Beksinska, et al., 2001; Potter et al., 2002
Re-Use Practices

Three small studies

- Women who re-use the FC on their own employ a variety of re-use and cleaning practices
- Women who have not re-used the FC are willing to re-use it
- In a trial setting, women find a standardized re-use protocol acceptable
- Remaining question: Can women follow the WHO protocol?

Smith et al., 2001, Pettifor et al., 2001

Future Directions: Getting the Answers

- Short-term acceptability no longer needed with FC-1
- Identify population-specific interventions that will enhance FC use over the longer term
- Focus on approaches to gaining male partner acceptance of FC use
- Use the strongest research designs possible
- For program evaluations - Seek creative approaches to answer key questions
Acknowledgments

Jessica Adams-Skinner, M.P.H.
Mags Beksinska, M.Sc.
Patricia Coffey, Ph.D.
Bidia Deperthes, Ph.D.
Theresa Exner, Ph.D.
Erica Gollub, Dr.P.H.
Theresa Hatzell-Hoke, Ph.D.
Maggie Kilbourne-Brook, B.S.
Joanne Mantell, Ph.D.
Jennifer Smit, Ph.D.
Jason Smith, Ph.D.
Zena Stein, M.B., B.Ch.