SILCS Diaphragm for delivery of microbicide gel: an exploratory study of user acceptability

Presented at M2012

Kathleen M. Morrow, The Miriam Hospital/Alpert Medical School of Brown University
Patricia S. Coffey, PATH
Maggie Kilbourne-Brook, PATH
SILCS: background and rationale

• Single-size diaphragm designed to expand options for non-hormonal contraception.
• Validated in clinical studies. Provides similar protection to traditional multi-sized diaphragm.
• SILCS could provide a low-cost, reusable option for microbicide gel delivery and provide contraceptive protection at the same time.
• Potential advantages:
  • Contains gel high in the vagina near cervix.
  • Reduces gel leakage.
  • May reduce stigma associated with HIV.
Study design

- Exploratory, randomized, cross-over study at the University of Pennsylvania Medical Center, Philadelphia, PA.

- 6 women assessed **feasibility and acceptability** of the SILCS Diaphragm as a microbicide gel delivery system, as an alternative to single-use vaginal applicators.

- Ethics approval by: UPenn, PATH, and Miriam Hospital.
**Gel loading scenarios: single-sided, double-sided compared to vaginal applicator**

<table>
<thead>
<tr>
<th>Single-sided:</th>
<th>Double-sided:</th>
<th>Vaginal applicator:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ml into cervical cup</td>
<td>2.5 ml cervical cup and 2.5 ml vaginal side</td>
<td>No diaphragm—5 ml with applicator</td>
</tr>
</tbody>
</table>

A

B

C
Methodology

MRI scans at three time points:

1. after insertion;
2. after simulated intercourse; and
3. 6 hours after simulated intercourse.

Visualized gel distribution over time.

[These data not presented here.]
Methodology (cont.)

- Women completed a computer-assisted self interview (CASI) questionnaire for each gel scenario after each of the three time points.
- Women participated in in-depth interviews at study end to capture overall preferences.
- Data categorized across 11 themes.
Study group characteristics

- 22-32 years; unmarried; nulligravida.
- 1-2 sex partners within last 12 months.
- Caucasian, Black, Latina, Asian, and other (mixed race).
- Most were college graduates; low to medium income.
- All were using contraception (a study eligibility requirement). All had used OC pills, and 2 were current users.
- 3 used male condoms regularly.
- 1 used withdrawal and fertility awareness methods.
  - Only 1 woman had any previous diaphragm experience.
• All three delivery systems were “relatively easy” to prepare for insertion, with applicator rated as easiest.
• Applicator was easiest because it was “familiar.” If applicator was not available, either SILCS scenario would be “okay.”
• Loading gel onto the diaphragm “did not take long.” Getting gel out of the sachets made the process seem long and difficult.
• Several women liked the idea of inserting SILCS ahead of time, like the night before, then adding gel before “morning sex.”
Insertion

• Insertion with all three systems described as “easy.” Applicator was the quickest and easiest.
• Insertion time ranged from 1-2 minutes for applicator to 1-5 minutes for the SILCS scenarios.
• SILCS insertion got easier with practice.
• Women able to confidently insert/check position with both single-sided and double-sided SILCS gel delivery.
• Checking SILCS placement was “somewhat messy” (especially double-sided), but the level of messiness was acceptable.
5 of the 6 participants reported some leakage with each scenario.

- Women reported most sensation of leakage with vaginal applicator, followed by SILCS single-sided.
- Leakage with the vaginal applicator continued even at the 6-hour time point.
Sensation and comfort

- After simulated intercourse, no participants thought that the SILCS would be felt by them or would cause discomfort during actual intercourse.
- All 6 participants reported not feeling the diaphragm when properly placed and were comfortable wearing the SILCS for 6 hours.
- As 004 reported, it was “amazing that I didn’t feel it at all! If I started wearing it all the time, I would be completely comfortable.”
- Discomfort (when reported) was due to characteristics of the gel itself (e.g., being aware of intravaginal wetness, leaking, or dislike of gel characteristics).
## “Hassle factor”

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Range</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep SILCS in for 6 hours</td>
<td>0-4</td>
<td>1.33</td>
</tr>
<tr>
<td>Use gel with diaphragm and insert before sex</td>
<td>0-2.5</td>
<td>0.75</td>
</tr>
<tr>
<td>Insert new gel if longer than 2 hours since last application</td>
<td>0-3</td>
<td>1.0</td>
</tr>
</tbody>
</table>

0-4 scale, with 0 being no hassle and 4 being huge hassle
Mixed methods research: compared imaging data and qualitative interviews

- CASI data and in-depth interviews revealed women experienced most leakage with the vaginal applicator—the delivery mode with most coverage on MRI.
  - Need to balance optimizing drug delivery while minimizing negative user experience.
- CASI revealed difficulty squeezing gel from the sachets. This was critical for interpreting the SILCS MRI scans where less gel volume was seen than expected.
  - Gel packaging matters (a lot)—must be easy to open and dispense the total volume.
Conclusions

• SILCS single-sided and double-sided gel delivery is feasible. Acceptability differed by gel loading scenario.

• Gel volume and gel packaging affect ease of use and acceptability.

• Despite preference for the ease of the applicator, some participants saw value for a reusable delivery system and also liked the potential for contraceptive protection when using SILCS.

• Need to balance gel characteristics with the delivery system. SILCS holds the gel high in the vagina near the cervix and reduces leakage—appropriate for gels where total vaginal coverage is not required.
Research utilization

- Evaluate SILCS for microbicide drug delivery: CONRAD initiating studies to assess the safety and efficacy of SILCS as a delivery system for Tenofovir 1% gel.
- Investigate provider and user attitudes toward SILCS as a reusable delivery system for microbicide gel.
- Assess potential target market segments and identify opportunities/challenges for future introduction of SILCS + microbicide gel for dual protection.
- Future studies should include women who are interested in and willing to use a diaphragm. Perspectives of women using hormonal methods may differ from those who are willing to use a barrier method.
Acknowledgments

- Participants in this study
- University of Pennsylvania Medical Center
- ReProtect, Inc. for use of BufferGel®
- USAID
- CONRAD
- Research partners and couples who participated in development and evaluation of the single-size diaphragm
Thank you!

Maggie Kilbourne-Brook
PATH
mkilbou@path.org