Over-The-Counter Provision of the SILCS Diaphragm

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PATH/SILCS Diaphragm

- Finger-tip removal dome
- Grip dimples
- Firm insertion edge
- Cervical cup membrane
- Relief arch

Dimensions:
- POSTERIOR: 67 mm
- ANTERIOR: 75 mm
Provision of SILCS
Over-The-Counter

SILCS single size:

- Removes obstacle of physical exam and fit assessment to both provider and client
- Simplifies logistics of supply and provision
- Would be accessible 24/7 in some locations
USFDA OTC Regulatory Requirements

- Benefits outweigh risks
- Potential for misuse and abuse is low (not addictive)
- Can be adequately labeled
- Consumer can self-diagnose (assess) for use
- Health practitioners are not needed for the safe and effective use of the product
Contraceptive Effectiveness and Safety Study of the SILCS Diaphragm: The Pivotal Study

**Design:** Multi-center contraceptive trial in 450 U.S. couples using the SILCS diaphragm

**Randomized study arms:**
- BufferGel (n=300)
- Nonoxynol-9 (n=150)

**Primary objectives:**
- Six month pregnancy probability during typical use
- Safety of the SILCS diaphragm

Recruitment Began: Q1 2008

Clinical Study Complete: Q4 2009
Pivotal Study--Secondary Objective
Feasibility of Over-the-Counter Provision

◆ Assess whether women can correctly:
  ▶ insert, position, and remove the SILCS diaphragm
  ▶ determine if it is inserted/positioned correctly
  
  *After reading written instructions only and after one attempt*

◆ Assess the proportion of women who could not be fit

◆ Explore characteristics predicting inability to fit, particularly standard diaphragm size
SILCS Fit Assessment by Study Participant

- Woman given SILCS device plus contraceptive gel and written instructions at clinic. Attempts to insert on her own (up to 15 minutes)
- “Attempt” defined as inserting/positioning device until participant believes that:
  - Device is correctly positioned
  - Device is incorrectly positioned & given up trying, or
  - Unable to insert device & given up trying
- After first attempt, if participant unable to insert/position, clinician attempts insertion. If clinician able to insert:
  - Participant was given 2 more attempts, with additional instructions (as needed)
SILCS Fitting Assessment

- Each participant was asked to assess correct positioning based on instructions.
- Definition of SILCS correct positioning:
  - Clinician assessed by 4 criteria & overall impression:
    - Cervix covered
    - Device behind pubic bone
    - Device does not protrude
    - Device is comfortable to participant
- Participants also sized for the Ortho Diaphragm to determine baseline “size”
Clinicians’ Assessment of Positioning at First Attempt (N=418)

<table>
<thead>
<tr>
<th>Participant’s First Attempt</th>
<th>Clinician Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CORRECTLY POSITIONED</td>
<td>358/418 (86%)</td>
</tr>
<tr>
<td>INCORRECTLY POSITIONED</td>
<td>60/418 (14%)</td>
</tr>
<tr>
<td>Not Behind Pubic Bone</td>
<td>31</td>
</tr>
<tr>
<td>Not Covering Cervix</td>
<td>20</td>
</tr>
<tr>
<td>Protruding</td>
<td>9</td>
</tr>
<tr>
<td><strong>TOTAL INSERTED</strong></td>
<td><strong>418</strong></td>
</tr>
</tbody>
</table>
## Participants’ Assessment of Positioning at First Attempt (N=418)

<table>
<thead>
<tr>
<th>Clinician Assessment</th>
<th>Correctly Positioned</th>
<th>Incorrectly Positioned</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correctly positioned</td>
<td>353</td>
<td>5</td>
<td>358</td>
</tr>
<tr>
<td>Incorrectly positioned</td>
<td>54</td>
<td>6</td>
<td>60</td>
</tr>
</tbody>
</table>
Who might be at risk if SILCS was purchased OTC?

- 54 of 450 (12%) might be able to insert the device but not recognize that it was incorrectly positioned (not covering cervix, not behind the pubic bone or protruding)

- Additional instructions on correct positioning might optimize OTC success
## Clinician Fit Assessment (N=450)

<table>
<thead>
<tr>
<th>PARTICIPANT ASSESSMENT</th>
<th>CLINICIAN ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to insert</td>
<td>32 (7%)</td>
</tr>
<tr>
<td>Incorrectly positioned</td>
<td>60 (14%)</td>
</tr>
<tr>
<td>Correctly positioned</td>
<td>358 (80%)</td>
</tr>
<tr>
<td>Total (able to correctly position)</td>
<td>358/450 (80%)</td>
</tr>
</tbody>
</table>

Good fit was achieved with 98% of devices compared to 80% of participants who achieved good fit on first try.
## Sociodemographic Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Could not be fit (N=11)</th>
<th>Could be fit (N=439)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean years)</strong></td>
<td>28</td>
<td>29</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>7 (64%)</td>
<td>208 (47%)</td>
</tr>
<tr>
<td>Black</td>
<td>2 (18%)</td>
<td>156 (36%)</td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0%)</td>
<td>11 (3%)</td>
</tr>
<tr>
<td>More than one race</td>
<td>1 (9%)</td>
<td>30 (7%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (9%)</td>
<td>33 (8%)</td>
</tr>
<tr>
<td><strong>Education (Mean years (SD))</strong></td>
<td>14.8 (2.7)</td>
<td>14.1 (2.7)</td>
</tr>
<tr>
<td><strong>Living with Partner</strong></td>
<td>9 (82%)</td>
<td>331 (75%)</td>
</tr>
<tr>
<td><strong>Relationship Length (&gt;6 months)</strong></td>
<td>11 (100%)</td>
<td>414 (94%)</td>
</tr>
<tr>
<td><strong>Ever Pregnant</strong></td>
<td>7 (64%)</td>
<td>307 (70%)</td>
</tr>
</tbody>
</table>
## Prior Experience with Barrier Methods

<table>
<thead>
<tr>
<th></th>
<th>Could not be fit (N=11)</th>
<th>Could be fit (N=439)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Condom</td>
<td>11 (100%)</td>
<td>417 (95%)</td>
</tr>
<tr>
<td>Female Condom</td>
<td>1 (9%)</td>
<td>32 (7%)</td>
</tr>
<tr>
<td>Contraceptive Sponge</td>
<td>0</td>
<td>26 (6%)</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>1 (9%)</td>
<td>35 (8%)</td>
</tr>
</tbody>
</table>
## Physical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Could not be fit (N=11)</th>
<th>Could be fit (N=439)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>30.9 (14)</td>
<td>29.1 (8.3)</td>
</tr>
<tr>
<td>Median (Range)</td>
<td>25.5 (17-56)</td>
<td>26.6 (16-64)</td>
</tr>
<tr>
<td><strong>Ortho Sizing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No size fits</td>
<td>3 (27%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>60-65</td>
<td>5 (45%)</td>
<td>58 (13%)</td>
</tr>
<tr>
<td>70-75</td>
<td>3 (27%)</td>
<td>300 (69%)</td>
</tr>
<tr>
<td>80-85</td>
<td>0 (0%)</td>
<td>78 (18%)</td>
</tr>
</tbody>
</table>
Summary

- The device fit 98% of participants based on established fit criteria
- 86% of women who were able to insert the diaphragm were able to correctly position it
- 12% of women would be at risk of using an incorrectly positioned device if purchased over the counter and might be at greater risk for pregnancy
- Participants who could not be fit were
  - More likely not to fit any Ortho diaphragm
  - More likely to wear a smaller sized device
  - No demographic factors
Conclusions

- OTC provision of the SILCS diaphragm is feasible

- Written instructions on correct positioning might be augmented with pharmacy or telephone assistance, or web-based information so that health practitioners do not need to be present at the time of dispensing
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**SILCS STUDY COUPLES**