

SILCS diaphragm: a reusable system for microbicide gel delivery

SILCS DIAPHRAGM

The SILCS diaphragm is a new single-size cervical barrier designed to expand women's options for nonhormonal barrier protection, especially in low-resource settings. For women with an unmet need for family planning, access to a user-initiated, nonhormonal barrier method could improve their options. The single-size diaphragm simplifies supply and provision, which should reduce barriers that have limited use of traditional diaphragms. PATH incorporated user feedback from health care providers, women, and their partners to design special features that allow the device to be easy to use—even for new users.

SILCS AS A MULTIPURPOSE PREVENTION TECHNOLOGY

Since diaphragms are commonly used with contraceptive gel, there is interest in SILCS as a microbicide gel delivery system. Initial feasibility and acceptability studies, clinical research, and other introduction work are discussed below.

Using SILCS could offer several advantages:

- *Reduced messiness and leakage:* SILCS diaphragm holds gel high in the vagina near the cervix, possibly leading to greater acceptability and less gel usage.
- *More consistent product use:* Women who use the SILCS diaphragm for pregnancy prevention may use the microbicide gel products more consistently.
- *Less stigma:* SILCS diaphragm is designed as a family-planning method, so there may be less stigma associated with use.
- *Lower cost:* As a reusable gel delivery system, the SILCS diaphragm could be less expensive to use than vaginal applicators and have less environmental impact than disposable gel delivery systems.

INITIAL FEASIBILITY AND ACCEPTABILITY

Two exploratory studies in the United States have shown the feasibility and acceptability of using SILCS as a gel delivery system. The first study in 2007 evaluated the feasibility and ease of use of four gel delivery scenarios



SILCS—a single-size diaphragm that may also serve as a microbicide delivery system.
Photo: PATH

using two different gel volumes (3.5 and 5 ml per side) and application scenarios (sachet vs. sachet and applicator) on both the cervical and vaginal sides of the cup.

Nineteen women participated in this study, and all were able to successfully prepare, insert, and wear the device. Acceptability varied by scenario—with the least amount of gel most preferred (7 ml total). Recommendations from this study included using the least volume of gel required, and loading on the cervical side only, if possible.

The second study in 2009 assessed gel distribution and retention in the vagina comparing gel delivered by the SILCS diaphragm to a vaginal applicator. Women used three gel application scenarios—SILCS cervical side only (5 ml), SILCS cervical and vaginal sides (2.5 ml/each), and vaginal applicator only (5 ml). Magnetic resonance imaging (MRI) scans assessed gel distribution at three time points (immediately after insertion, after simulated coitus, and six hours after simulated coitus). Qualitative data were collected on women's experiences and preferences with these scenarios. MRI scans showed no significant difference in gel coverage between methods. Although all gel delivery scenarios were found to be feasible, acceptability differed by scenario. All three delivery systems were rated “relatively easy” to prepare and “easy” to insert; the

applicator was rated as “*easiest*” potentially because it was more “*familiar*.¹

ACCEPTABILITY—UNITED STATES AND SOUTH AFRICA

Following these studies, a pilot study was conducted in 2009 among 36 couples in the United States to evaluate acceptability of SILCS single- and double-sided gel delivery compared to a vaginal applicator. Couples used each delivery scenario during two acts of intercourse for a total of six sex acts. Acceptability data were collected from both women and their partners. All three gel delivery scenarios were found to be acceptable, although the vaginal applicator was rated more favorably for most attributes. This study clearly showed that in a population where women use non-barrier contraceptives and are at low risk of STIs, the vaginal applicator is more acceptable for gel delivery. However, further research of SILCS for microbicide delivery was recommended among populations that more closely reflect diverse potential user groups, such as women from high-HIV-prevalence settings and women who may be more likely to use a diaphragm for contraception.²

A couples’ acceptability study in South Africa is underway 2014–2015 to evaluate single-sided gel delivery using SILCS compared to a vaginal applicator. More than 100 women will evaluate both delivery scenarios during five acts of sex. Acceptability data will be collected from male partners. Study results will be available in late 2015.

EVALUATING DRUG DELIVERY AND BARRIER EFFECTIVENESS OF SILCS PLUS MICROBICIDE GEL

Several microbicide gel products are being developed and evaluated for HIV/STI protection. PATH is in discussion with product sponsors and donors seeking opportunities to evaluate SILCS as a reusable delivery system for microbicide gel.

INTRODUCTION RESEARCH

The SILCS diaphragm was launched in Europe in 2013 and is now marketed in 26 countries as the Caya® contoured

diaphragm. PATH and partners are currently working to build awareness for SILCS in low-resource settings. Market research in South Africa found strong support for SILCS as a microbicide delivery system. Women are attracted to a product that could provide protection against unintended pregnancy, sexually transmitted infections, and HIV.

ACKNOWLEDGMENTS

PATH developed the SILCS diaphragm with partners including CONRAD and researchers in multiple countries. In 2010, the technology was licensed to Kessel medintim GmbH of Germany for commercialization.

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