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FEATURED RESEARCH

Below, we highlight recently completed research related to cervical barriers and female condoms. Peer-reviewed publications from these studies are also included in our [online bibliographies](#).

CERVICAL BARRIERS

A randomized crossover study evaluating the use and acceptability of SILCS Diaphragm compared to vaginal applicators for placebo gel delivery

Randomized crossover study

Location: Durban, South Africa



This study evaluated the use and acceptability of the SILCS Diaphragm compared to standard vaginal applicators for delivery of a placebo vaginal gel. This is a foundational step before evaluating additional questions such as feasibility and acceptability of service delivery scenarios for the SILCS Diaphragm as either a microbicide delivery system or a contraceptive diaphragm.

In this crossover study, 115 female participants were randomized to use the SILCS Diaphragm with placebo gel (delivered by applicator into SILCS cervical cup) for five sexual acts followed by use of vaginal applicators for five sexual acts to deliver placebo gel directly into the vagina, or vice-versa. The vaginal applicators in both study arms were of the same design. The use and acceptability of both methods of gel delivery were assessed at four follow-up visits in total (two visits per method, after first use and fifth use). Women completed a coital log at home that gathered data on experience after use of each method. A sub-sample of male partners (n=20) were interviewed to gather issues of partner acceptability of each method. These interviews were conducted after completion of their partner's last visit. A sub-sample of male and female participants were also asked to participate in focus group discussions on completion of the crossover study. Participants were recruited from the Commercial City Reproductive Health/Primary Health Care (PHC) Clinic in Durban, South Africa.

This study was launched in September 2014, and the clinical portion of the study was completed in January 2015. Results were shared at international conferences in 2016, and a manuscript has been submitted to share the study results more broadly.

This study was funded by USAID via the Program for Appropriate Technology in Health (PATH), and was implemented by MRU (MatCH Research Unit).

Related presentations:

Beksinska M, Smit J, Maphumulo B, et al. SILCS Diaphragm as an MPT: new data from South Africa. 14th European Society for Contraception (ESC) Congress, May 2016. Basel, Switzerland.

Beksinska M, Smit J, Maphumulo B, et al. SILCS Diaphragm as a multipurpose prevention technology: An Acceptability study comparing SILCS Diaphragm and standard applicators to deliver vaginal gel in Durban, South Africa. 21st International AIDS Conference, July 18-22, 2016. Durban South Africa.

Postcoital barrier effectiveness study of the SILCS Diaphragm with Contragel

Phase I PCT study, multi-center, randomized crossover, nonsignificant risk

Location: United States and Dominican Republic

Clinical guidelines recommend that diaphragms be used with a contraceptive gel to increase effectiveness. Most commercially available contraceptive gel products contain nonoxonyl-9 (N-9), and are only available in developed countries. Products with N-9 are no longer recommended for use in countries where women are at risk of HIV (see the [WHO guidance](#) or [RHTP fact sheet](#) on N-9). Alternative contraceptive gel products that do not contain N-9 are needed for use with diaphragms, especially for women in countries where N-9 products are no longer available, or for women who cannot or do not want to use N-9 gel.



Contragel is a lactic acid based contraceptive gel product approved in Europe for use with cervical barrier products such as diaphragms and cervical caps. It has CE Mark certification and has been marketed for nearly 20 years primarily in Europe, where it has a good safety and acceptability profile. Since 2013, Contragel also has been marketed as Caya Gel for use with the Caya (SILCS) diaphragm in more than 25 countries. Contragel has not been submitted to the US FDA for market approval.

In 2012, CONRAD evaluated Contragel safety in animal studies. No safety concerns were found. This laid the groundwork for a clinical study in humans. CONRAD then evaluated SILCS used with Contragel in a postcoital study of barrier effectiveness. This study compared effectiveness in preventing sperm from penetrating midcycle cervical mucus of each of the following scenarios: SILCS Diaphragm used with 3% N-9 gel; SILCS Diaphragm used with Contragel; and SILCS Diaphragm used with no gel.

The study was launched in late 2014 and completed in August 2016. Twenty-seven women were enrolled into the study and nine women completed all test cycles. Results suggest that SILCS with Contragel appeared to function as well as SILCS with the marketed product N-9 in preventing progressively motile sperm from reaching mid-cycle mucus.

A manuscript was submitted to a peer-reviewed journal in early 2017.

The study was implemented by CONRAD at Eastern Virginia Medical School and by Profamilia in the Dominican Republic. The study was funded by USAID.

Health systems and market opportunities for SILCS as a barrier contraceptive in India

Health systems assessment

Location: Delhi, Mysore (Karnataka), and Rajasthan, India

This assessment explored opportunities and challenges for future introduction of the SILCS Diaphragm in India. The study team interviewed 22 national stakeholders in Delhi and seven state-level stakeholders in the state of Karnataka, including family planning/sexual and reproductive health providers and members of NGOs. They also conducted focus group discussions (FGDs) with potential SILCS users. Additionally, this assessment explored perceptions among potential end users. A total of nine FGDs were conducted in Karnataka and Rajasthan. FGD participants included urban and rural women who were either married or in a relationship; female sex workers; and male partners and clients. Using a systems perspective, this assessment characterized issues and attitudes that will need to be considered when planning for future introduction of this non-hormonal barrier contraceptive in this context. This assessment outlined the regulatory pathway, potential service delivery scenarios, target audiences, and communications and training materials needed to support future introduction in India. Market research has been implemented in India separately to supplement findings from this health systems assessment about potential target markets and to inform potential introduction strategies.

The health systems assessment was conducted in November 2012-March 2013. Results from this health systems assessment were presented at the European Society for Contraception meeting in Lisbon in May 2014. In 2016, PATH created a Project Brief summarizing key findings.

This assessment was conducted by Ashodaya Samithi of Mysore in Karnataka state, India, and Katharine Shapiro, a reproductive health consultant, in collaboration with PATH. This assessment was funded by USAID.

Related publications:

Shapiro K , Roy A , Reza-Paul S , Gupta N, Kilbourne-Brook M , Coffey PS. Is SILCS Diaphragm an appropriate method for women in India? The European Journal of Contraception and Reproductive Health Care. 2014;19(1):S117-S118. Available at:

<http://informahealthcare.com/doi/pdf/10.3109/13625187.2014.894779.11>

Poster: http://sites.path.org/rhtech/files/2014/06/FINAL_SILCS-poster_ESC_23April2014.pdf

PATH. Feasibility of SILCS introduction in India (Project Brief) September 2016:

<http://www.path.org/publications/detail.php?i=2648>

MRU. Expanding Contraceptive Options for Women:the SILCS Diaphragm. Policy Brief. June 2016.

Health systems assessment of SILCS diaphragm in South Africa as a multipurpose prevention technology

Health systems assessment

Location: South Africa

This assessment explored opportunities and challenges and country readiness for future introduction of the SILCS Diaphragm in South Africa, both as a barrier contraceptive and as a multipurpose prevention technology when used in combination with a microbicide gel. The assessment, implemented by MatCH Research Unit (MRU) of Durban, South Africa, began with a

desk review of policies that would need to be considered for SILCS introduction. The policy assessment determined that the current policy environment is enabling for SILCS introduction, the newly revised contraception policy and guidelines promote choice, and dual protection is encouraged in several policies.

The health systems assessment was comprised of stakeholder interviews, facility assessments, and focus group discussions (FGDs) with potential users. MRU conducted 31 interviews with stakeholders such as policymakers, program managers, regulatory authorities, service providers, pharmacists, training managers, health center staff, NGO staff, and advocacy groups. They conducted seven facility assessments across public sector clinics, NGO service delivery sites, and tertiary education health center to explore feasibility of integrating SILCS distribution into current programs. MRU then conducted 24 focus FGDs (17 with women and seven with men). Using a systems perspective, this assessment characterized issues and attitudes that will need to be considered when planning for future introduction of the SILCS Diaphragm in South Africa. MRU presented findings from this health systems assessment at a meeting with key stakeholders in the HIV and sexual and reproductive health fields in November 2013 and developed recommendations for next steps. Market research also was implemented to supplement findings from this health systems assessment about potential target markets and to inform potential introduction strategies.

The policy landscape review was finalized and distributed in March 2014. MRU presented preliminary results from the assessment regarding SILCS as a multipurpose prevention technology at the International Family Planning Conference in Ethiopia in November 2013. Results from the FGDs also were presented at the R4P (Research for Prevention) in October 2014. The report from this assessment was finalized in 2016, and a project brief is available online. This assessment was funded by USAID.

Related presentations and publications:

SILCS in South Africa: Opportunities for introduction as a barrier contraceptive and as an MPT. International Conference on Family Planning, Addis Ababa, Ethiopia, November 12-15, 2013.

Introduction of the SILCS Diaphragm as a multipurpose technology in South Africa: Potential users, perceived benefits, and barriers to use. R4P Conference, October 2014.

Desktop review of the policy, research, and regulatory environment in South Africa relating to future introduction of the SILCS Diaphragm as a nonhormonal barrier contraceptive and reusable delivery system for microbicide gel for HIV prevention. PATH Report. March 2014. http://sites.path.org/rhtech/files/2014/06/FINAL_SILCS-desk-review_24March2014.pdf
 MatCH Research Unit. Assessment of opportunities and challenges for potential introduction of the SILCS Diaphragm in South Africa. October 2016 (Full report and abridged report versions available). <http://www.path.org/publications/detail.php?i=2660>
 PATH. Feasibility of SILCS introduction in South Africa (Project Brief). September 2016. http://www.path.org/publications/files/DT_silcs_hsa_sa_br.pdf



FEMALE CONDOMS

Potential distribution channels for the Woman's Condom in China

Market assessments

Location: Multiple sites across nine provinces in China

As part of the Protection Options for Women (POW) Product Development Partnership (PDP), PATH and partners in China implemented market tests to explore uptake and acceptability

of the O'Lavie Condom (Woman's Condom) across various market segments from 2012-2014.

Female condoms are a new product in China. They are not currently included in the national family planning program or HIV prevention programs, and few women or men have seen or heard of female condoms. Female condoms have been evaluated primarily in studies focused on sex workers. To explore public and commercial sector opportunities for the Woman's Condom in China, research partners have implemented five market tests to assess uptake and acceptability of the Woman's Condom across different market segments in nine provinces in China. These included: 1) unmarried youth/factory workers at Marie Stopes International (MSI) clinics in three cities, with MSI; 2) married couples/general population at family planning centers in Beijing (urban) and ten villages in Guangdong (rural), with the China Population and Development Research Center and China Contraceptive Supplies Administration; 3) married couples/general population at family planning centers in three cities, with the Shanghai Institute of Planned Parenthood Research; 4) female sex workers in three cities, with the Beijing Union Medical College; and 5) HIV discordant couples in Sichuan and Hunan provinces, with the National AIDS Control Center (NCAIDS).

The methodology for each market assessment was developed by the local research partner in consultation with PATH. In all studies participants were asked to report on use over several months.

The Woman's Condom was well accepted by women/couples across all target groups, with 58%-89% of the participants across the market tests expressing willingness to continue use, and 10% reporting liking it very much. The MSI market study generated particular interest by the

family planning stakeholders, since the MSI clinic reaches target groups not well covered by government clinics. The NCAIDS study showed that including the Woman's Condom into outreach services for sero-discordant couples helped increase levels of protected sex and reduced the reported levels of forced sex. Health providers and family planning managerial staff at various levels were positive about introducing this new contraceptive method. Results from the market tests were shared with family planning and HIV stakeholders and provincial and district levels decision makers at two stakeholder meetings in late 2014.

The POW PDP was created to promote sexual and reproductive health, including the prevention of HIV/AIDS, by expanding access to the Woman's Condom. The POW PDP was supported by funding from the Netherlands Ministry of Foreign Affairs from 2011 to 2015.

Related publications and presentations:

Kilbourne-Brook M, Coffey P, Nundy N, Zhang L. Woman's Condom-Testing Market Strategies in China. Panel: "From innovation to impact: The road map for new contraceptive introduction." International Conference on Family Planning, Addis Ababa, Ethiopia, November 12-15, 2013.

PATH. Introducing O'Lavie Woman's Condom to China: expanding dual protection options. (Final report from POW PDP Market tests in China)

<https://issuu.com/powpdp/docs/wcchina-english-12.31.15>

Potential distribution channels for the Woman's Condom in South Africa

Market assessments

Location: Multiple sites across two provinces in South Africa

As part of the Protection Options for Women (POW) Product Development Partnership (PDP), PATH and partners in South Africa implemented market tests to explore uptake and acceptability of the V Condom (Woman's Condom) across various potential market segments.

MatCH Research Unit implemented four market tests between August 2014 and July 2015. Data were collected from 119 women and 78 men who were potential and actual V Condom users (male and female students, male factory workers, and female and male sex workers) to assess uptake and acceptability across multiple distribution channels (a tertiary health service center a factory, and two nongovernmental organizations). This prospective evaluation included initial awareness-raising and distribution of currently available and V condoms to those interested. Baseline data collection included a quantitative survey and two focus group discussions. After one-month follow-up, V Condom use data were collected through self-completed condom logs and SMS text messages, four focus group discussions, and three inventories and in-depth interviews with three site coordinators.

Results:

The quantitative results indicated high V Condom usage during the study period. Most sex acts were protected, with participants using more V Condoms than male condoms or other female condoms. Many participants reported preferring the V Condom over male and other female condoms. Ideal distribution channels included tertiary institutions, factories, government facilities, pharmacies, shops/supermarkets, schools, entertainment places, and tuck shops. Factors influencing preferred distribution channels were ease of access, convenience, operating hours, users' previous experiences, and peer influences. Most participants were willing to pay for the V Condom due to the perception that paying ensured a quality product and that free products are not as trustworthy.

Conclusions:

There is a non-public-sector market for V Condoms in Durban, and some women and men are willing to pay for the V Condom at a price approaching the estimated market price. This novel mixed-methods approach to understanding consumer interest in a new female condom provided data relevant for both programmatic planning and future market introduction.

During the same time, WISH Associates of Cape Town, South Africa implemented a six-month, multi-phased market test among female and male students at two tertiary institutions: University of Cape Town and False Bay College. This assessment included awareness raising and educational activities with various university partners, and free distribution of V Condom and other female and male condom products on campus. Feedback about product positioning, key messages, ease of use, and uptake relative to other condom products was collected via focus group discussions and SMS messaging.

The POW PDP was created to promote sexual and reproductive health, including the prevention of HIV/AIDS, by expanding access to the Woman's Condom. POW PDP was supported by funding from the Netherlands Ministry of Foreign Affairs from 2011 to 2015.

Publications:

Smit J, Mosery N, Pillay L, Beksinska M, et al, A Mixed-Methods Evaluation of Potential Distribution Channels for the V Condom in South Africa. *International Journal of Women's Health and Wellness*. 2015, 1:2; pp1-8,

<https://clinmedjournals.org/articles/ijwhw/international-journal-of-womens-health-and-wellness-ijwhw-1-007.pdf>

PATH. Introducing V Condom to South Africa: Expanding the female condom market. (Final report from POW PDP Market tests in South Africa)

<https://issuu.com/powpdp/docs/wcsouthafrica-12.31.15>

RESOURCES

Updated bibliographies

Bibliographies of published peer-reviewed research on female condoms, diaphragms, and cervical caps are available at the links below. We have included research published before April 1, 2017 in this update. If there are relevant publications that should be added to these lists, please let us know.

[Cervical barriers bibliography](#)

[Female condom bibliography](#)

Additional Resources

FC2 has created another useful online repository of published research on female condoms. Check out their [research database](#) where you can search for articles by topic, author, or publication date!

In November 2016, UNFPA, WHO, USAID, and IPPF convened a three-day meeting, The Global Consultation on Personal Lubricants. Attended by more than 80 participants from research, manufacturing, and advocacy sectors, the meeting provided an opportunity for multi-sector engagement around producing safe, effective, and affordable personal lubricants. A summary of the meeting outcomes, including three action plans developed to guide future work by researchers, manufacturers, and civil society members can be found [here](#).

ABOUT US

Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information

For more information, contact Laura Fix, CBAS Executive Director, at info@cervicalbarriers.org.

CBAS is coordinated by Ibis Reproductive Health.



www.ibisreproductivehealth.org

Note: We are always updating our research listings on the CBAS website. Please contact us at info@cervicalbarriers.org with study updates or information on new research related to cervical barriers or female condoms.

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