SILCS Diaphragm

Health need

Access to family planning has helped millions of women plan and space births and subsequently has improved health outcomes. Despite these successes, a recent analysis of unmet needs for family planning estimates that 222 million women worldwide who want to avoid pregnancy are not using modern contraceptives. Many of these women are not using existing methods because of concern about side effects and health consequences, for other women it is because they have infrequent sex or are postpartum and breastfeeding. Existing contraceptive methods do not meet the needs of all women. This results in approximately 86 million unintended pregnancies globally and an estimated 385,000 women who die every year from complications associated with pregnancy and childbirth and with unsafe abortion. Women want and need more female-initiated methods that can protect against pregnancy and also sexually transmitted infections (STIs). Diaphragms could help meet this need, but some characteristics of traditional diaphragms limit their use and acceptability.

Technology solution

PATH developed the SILCS Diaphragm, a simple-to-use, single-size, reusable device with a contoured rim that fits most women. Design and development of the SILCS Diaphragm began in 1994, and user-centered evaluations of over 200 prototype designs were tested at various stages. We used stakeholder assessments to ensure that comfort, ease of handling, and acceptability were built into the product. As a result, the SILCS Diaphragm directly addresses user and programmatic needs. We conducted acceptability studies among naïve users in South Africa and Thailand and found that women easily learned to use the device and that it was acceptable during use for both women and men. In a comparative crossover study of the SILCS Diaphragm with a traditional diaphragm in the Dominican Republic, 19 of 20 women preferred the SILCS Diaphragm after short-term use. Fit data from clinical studies confirm the single-size device fits most women. Where regulatory authority and clinical practice allow, the single-size device could be provided over the counter or outside the clinic-based system.

Current status and results

The SILCS Diaphragm design was patented in 1998; a second patent on spring modifications was filed and granted in several countries. In 2010, we licensed the technology to Kessel Marketing & Vertriebs GmbH (Kessel) of Germany for commercialization. In 2011, CONRAD, our research partner and regulatory sponsor, completed clinical validation of contraceptive effectiveness. CE marking was achieved in March 2013, allowing for sales in Europe, and regulatory applications for the US Food and Drug Administration are under way. While Kessel introduces the product through existing distribution channels in developed and middle-income countries, we are undertaking health systems assessments in India, South Africa, and Uganda to develop strategies for its introduction in developing-country markets. In addition, at the clinical feasibility stage, we are evaluating the device as a delivery system for microbicide gel. Once a microbicide gel is approved, the SILCS Diaphragm could offer protection from both unintended pregnancy and STIs.

PATH/Mike Wang

The SILCS Diaphragm, an intravaginal barrier contraceptive.

"A significant advantage [of the SILCS Diaphragm] for resource-poor settings is that it is a reusable method that women can control with little dependence on the health care system."

W. Holmes editorial in Sexual Health, May 2010.

Availability

For more information regarding this project, contact Maggie Kilbourne-Brook at mkilbou@path.org.

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