Woman's Condom

Summary of clinical evaluation

The Woman's Condom is a new option for barrier contraceptive protection. Developed by PATH, an international global health nonprofit organization, the Woman's Condom is designed to offer women and their partners safe and effective protection from pregnancy and sexually transmitted infections (STIs). The Woman's Condom is manufactured by the Dahua Medical Apparatus Company (Dahua) of Shanghai, China.

USERS AS DESIGNERS

With input from women and couples in several countries, PATH and its research partners designed the Woman's Condom to be acceptable to use for both partners. Its unique design features enable easy insertion, secure fit during use, good sensation, and easy removal.

CLINICALLY PROVEN

Years of clinical work with the first-generation female condom product show that the device is safe, effective, and well accepted by women in many countries. A comprehensive Cochrane review of clinical studies comparing the female condom to the male condom found that female condoms offer effective protection from unwanted pregnancy and STIs and are as effective as male condoms.[1] Researchers estimate through mathematical modeling that consistent female condom use could reduce the risk of HIV infection by up to 90 percent compared to unprotected sex.[2]

PATH/Glenn Austin

Since 2004, the Woman's Condom has been evaluated for acceptability, performance, and safety in clinical studies across five countries. These studies have found that the Woman's Condom is safe, acceptable, and easy to use and that it performs well when compared to other female condom products. Three additional clinical studies are underway that will further support this evidence. These include: a contraceptive effectiveness study, funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); a slippage and breakage study comparing the Woman's Condom and FC2 using prostate-specific antigen (PSA) as a biomarker of semen exposure; and a multisite study comparing performance, safety, and acceptability of four female condom products.

COMPLETED CLINICAL STUDIES

Design verification study of the Woman's Condom: Mexico, South Africa, and Thailand (2006)[3]

Principal investigator	Description	Sample	Product uses	Endpoint	Key findings
P. Coffey, PATH	Nonrandomized, multisite posttest evaluation to determine user acceptability of the PATH-fabricated Woman's Condom.	60 couples, consisting of new and experienced users. Most women from Mexico and Thailand were married.	180	Safety, function, and acceptability	Female and male participants reported: • High levels of condom stability during sex. • Acceptable condom comfort during insertion and use. • Positive sensation when using the condom during sex. • Relative ease of use.

Phase 1 comparative performance, failure mode, and safety study: United States (2008)[4]

Principal investigator	Description	Sample	Product uses	Endpoint	Key findings
J. Schwartz, CONRAD	Open-label, multi center, randomized crossover study to compare the functional performance, safety, and acceptability of the PATH-fabricated Woman's Condom and the FC1 female condom.	75 couples, the majority of whom lived together. Women and men both had a mean age of about 30.	274	Functional performance, safety, and acceptability	• Both female condoms were safe and acceptable in short-term use, but the Woman's Condom led to less failure, was associated with fewer adverse events, and was more acceptable than the FC1 female condom. • Woman's Condom was preferred by 57% of women and 43% of men while the FC1 was preferred by 22% of both women and men.

Woman's Condom performance, failure mode, and acceptability study: China (2010)

Principal investigator	Description	Sample	Product uses	Endpoint	Key findings
H. Zirong, Fudan University W. Junqing, SIPPR P. Coffey, PATH	Performance and failure mode study to ascertain functionality, acceptability, and safety of the Dahua-fabricated Woman's Condom.	59 couples, almost all of Han ethnicity and married. Mean age of women just under 40.	234	Functional performance, safety, and acceptability	• Woman's Condom performed well in terms of clinical failure with a total clinical failure (types of failures that could result in pregnancy or STIs) rate of 4.3%. • Fifteen mild and no serious adverse events were reported. • Further analysis on acceptability is underway.

Comparative performance and acceptability study: South Africa (2011)[5]

Principal investigator	Description	Sample	Product uses	Endpoint	Key findings
C. Joanis, Family Health International	Acceptability, function, and product preference three-part study of three female condom types: Woman's Condom (PATH-fabricated), FC2, and Reddy 6. Part 1: Random sequence crossover study Part 2: Simulated market with choice among 3 types Part 3: Qualitative study of product preference	Part 1: 165 women, majority of whom were African and unmarried. Ages ranged from 18–48 years old (mean=28.0). Part 2: 148 women (subset of Part 1)	Part 1: 798 Part 2: 1,898	Part 1: Functional performance, safety, and acceptability Part 2: Preference and acceptability	• Total clinical failures were low (<4%) regardless of condom type. • In Part 1, participants preferred the Woman's Condom and FC2 over the Reddy 6 (p= < .0001) and the Woman's Condom over FC2 (p= .0007). • In Part 2, women took home more Woman's Condoms than FC2 or Reddy 6, though this preference was not significant.

CLINICAL STUDIES IN PROCESS

Study type, timeline, and sponsor	Description	Sample *	Product uses*	Endpoint
Study of vaginal semen exposure and clinical failure in the Woman's Condom and FC2; 2010-2011; (CONRAD).	The Woman's Condom will be compared with the FC2 by reported clinical failure and presence of PSA in the vagina. This is a comparative, open-label, two-period crossover study taking place in the United States.	330 couples	1,650	Functional performance, safety, and acceptability of Woman's Condom compared to FC2 using PSA as a marker of semen exposure.
Evaluation of the Woman's Condom, FC2, Reddy 6, and Cupid; 2011; (UAFC).	This is a randomized, comparative crossover trial to evaluate device function, safety, and acceptability of four condom designs taking place in South Africa and China.	500 women	2,500	Failure and performance, safety, and acceptability.
Woman's Condom safety and contraceptive efficacy study; 2011-2012; (NICHD).	This is a multicenter, open-label, non-comparative study testing the safety and efficacy of the Woman's Condom taking place in the United States. A subset of women will assess detection of vaginal PSA by self-collected swabs before and after intercourse.	500 women	Use Woman's Condom for 6 months as primary contraceptive.	Contraceptive effectiveness, safety, and acceptability.

*Sample sizes and product uses are estimates because these studies are not complete.

OUR SUPPORTERS

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2 Trussell J, Sturgen K, Strickler J, Dominik K. Comparative contraceptive efficacy of the female condom and other barrier methods. *Family Planning Perspectives*. 1994;26(2):66–72.

3 Coffey PS, Kilbourne-Brook M, Austin G, Seamans Y, Cohen, J. Short-term acceptability of the PATH Woman's Condom at three sites. *Contraception*. 2006;73(6):588–593.

4 Schwartz JL, Barnhart K, Creinin MD, et al. Comparative crossover study of the PATH Woman's Condom and the FC Female Condom®. *Contraception*. 2008; 78(6):465–473.

5 Joanis C, Beksinska M, Hart C, et al. Three new female condoms: Which do South-African women prefer? *Contraception*. 2011; 83(3):248–254.

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