

Effectiveness of female condoms in the prevention of pregnancy and sexually transmitted infections

Bidia Deperthes

Technical Advisor Condom Programming
United Nations Population Fund

Theresa Hatzell Hoke

Senior Research Associate
Family Health International



Presentation Overview

Effectiveness of female condom in preventing pregnancy

- evidence from literature
- recent findings from WHO multi-site trial

Effectiveness of female condom in preventing STI transmission

- evidence from literature
- recent findings from trial conducted in Madagascar

Female condom effectiveness in preventing pregnancy



Measuring female condom contraceptive effectiveness

Definitions

- Perfect use: Effectiveness among women who use the device every time they have sexual intercourse, in accordance with instructions every time
- Typical use: Effectiveness among women who report occasional incorrect or inconsistent use of the device

Bounds et al., 1992

106 women recruited in Great Britain

- STI free
- Mean age: 32 years
- 11 sex acts/month
- Prior experience with male condoms: 98%



Results

- 7 accidental pregnancies, 4 of which among women reporting inconsistent female condom use
- Discontinuation rate: 56% at 12 months
- **Typical use** 15% (rate at 12 months)

Farr et al., 1994

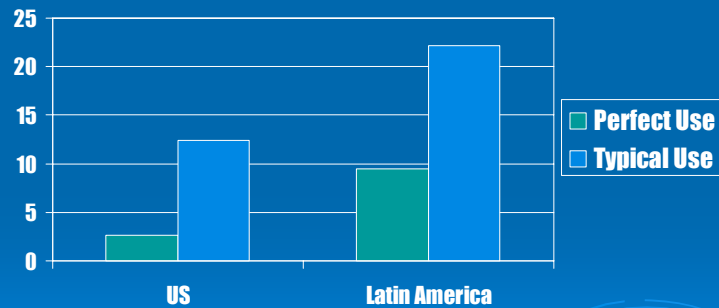
Studied the contraceptive efficacy of the female condom in a multi-center study with STI free US and Latin American women



	US	Lat Am.
• Mean age	29	26
• Sex acts/month	12	12.5
• MC prior experience	97%	69%
• Discont. Rate	33%	55%

Effectiveness of the Female Condom in Preventing Pregnancy

6 - Month Pregnancy Rate



Sources: Farr et al, *Am J Public Health* 1994

Trussell, 1998

Conducted in 10 family planning centers in Japan; 195 participants used female condom as their only contraceptive method for 6 months.

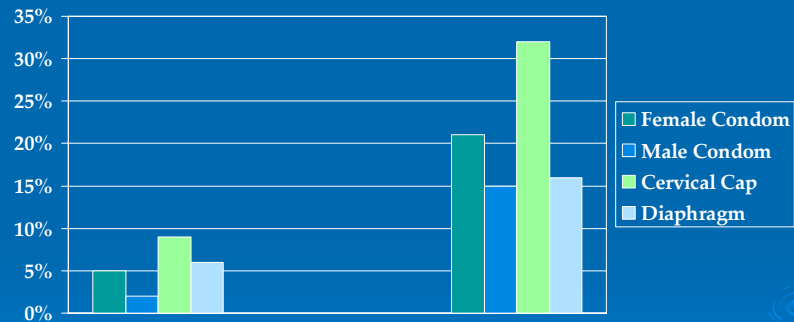
- Mean age: 32 years
- 5 sex acts/month
- Prior experience with male condoms: 96%



Results

- **Perfect use** 1%
- **Typical use** 3%

12-month Pregnancy Rates of Various Barrier Methods



Source: *Contraceptive Technology* 2004.

WHO multicentric study – preliminary results

Key question

- Is FC equivalent to MC in the prevention of pregnancy in women attending FP clinics?

Study sites

- 4 WHO collaborative centres: China, Panama, Nigeria, South Africa

WHO Study- the design

- Prospective non- randomized trial
 - Typical FP patients (students in SA) choosing either MC or FC as their main method of contraception
 - 1 week to try out (training phase)
 - Scheduled monthly follow-up visits (≤ 6 mo)
 - Once every 2 months (> 6 months)
- Data collection
 - Coital diary card for condom use, frequency of sex acts, etc
 - Emergency contraception request
 - Use of other contraceptive methods
- Study endpoints
 - pregnancy or EC request

China (Chengdu)

- 316 women (112 MC, 158 FC, 36 MX)

	MC	FC
• Mean age	32	32
• MC prior experience	100%	98%
• MC as main meth.	96%	94%

- Results

• Sex acts/month	7	6.5
• 6-mo preg. Rates %	8.4(8.5)	4.3(4.4)
• Discont. Rate %	0.8%	15.4% *

Panama

- 235 women (108 MC, 100 FC, 27 MX)

	MC	FC
• Mean age	27	26
• MC prior experience	58%	55%
• MC as main method	25%	29%

- Results

• Sex acts/month	6→5	5→4
• 6-mo preg. rates	6.2(6.7)	2.4(3.0)
• Discont. rates	12%	25%

Nigeria (Sagamu)

- 260 women (62 MC, 157 FC, 41 MX)

	MC	FC
• Mean age	26	28
• MC prior experience	77%	73%
• MC as main method	63%	53%

- Results

• Sex acts/month	12→11	11→9
• 6-mo preg. rates	3.6(3.9)	5.9 (5.9)
• Discont. rates	25%	22%

South Africa (Durban)

➤ 260 women (62 MC, 157 FC, 41 MX)

	MC	FC
• Mean age	21	22
• MC prior experience	96%	94%
• MC as main method	98%	92%

➤ Results

• Sex acts/month	13→7	12→10
• 6-mo preg. rates	0(0.7)	0(0.1)
• Discont. rates	71%	36% *

WHO FC study- conclusions

- First contraceptive trial comparing MC to FC
- Few pregnancies leading to low pregnancy rates
- High level of condom use (>95%)
- No statistical difference was observed between the pregnancy rates at 6 months.
- In that respect the **two devices are substantially identical** in preventing unwanted pregnancy.

Female Condom Effectiveness in Preventing Sexually Transmitted Infection



Indirect Evidence of STI Protection Offered by the Female Condom

Physical properties:

- polyurethane impermeable to virus particles smaller than HIV, hepatitis B, and herpes virus
- less prone to breakage
- more genital coverage

Mathematical models:

- use pregnancy data to project that female condom use reduces HIV transmission

Female Condom's Protection against Trichomoniasis, Soper et al., 1993

Assessed whether appropriate use of the female condom decreased the rate of recurrent trichomoniasis.

Methods

- Enrolled 104 US women with recurrent TV
- Assigned to either a group using the female condom or a control group of non-FC users

Results

Re-infection with trichomoniasis occurred in

- 14% of controls
- 14.7% of non-perfect users
- none of the perfect users

Female condom's protection against STIs, Fontanet et al., 1998

Assessed whether use of protection was greater and STI prevalence was lower among sex workers having access to female condom.

Methods

Brothels (N=71) in four cities randomized into two groups:

- 249 sex workers had access to both FC and MC
- 255 sex workers had access only to MC

Participants returned every 2 weeks for interview, coital log review, and testing for GC, CT, TV, GUD

Female condom's protection against STIs, Fontanet et al., 1998

Results (over 24 weeks)

Trial completion rates

- 27% in FC + MC group
- 24% in MC group

Unprotected sex acts

- 5.9% for FC + MC group
- 7.1% for MC only group

STI incidence per 100 women per week

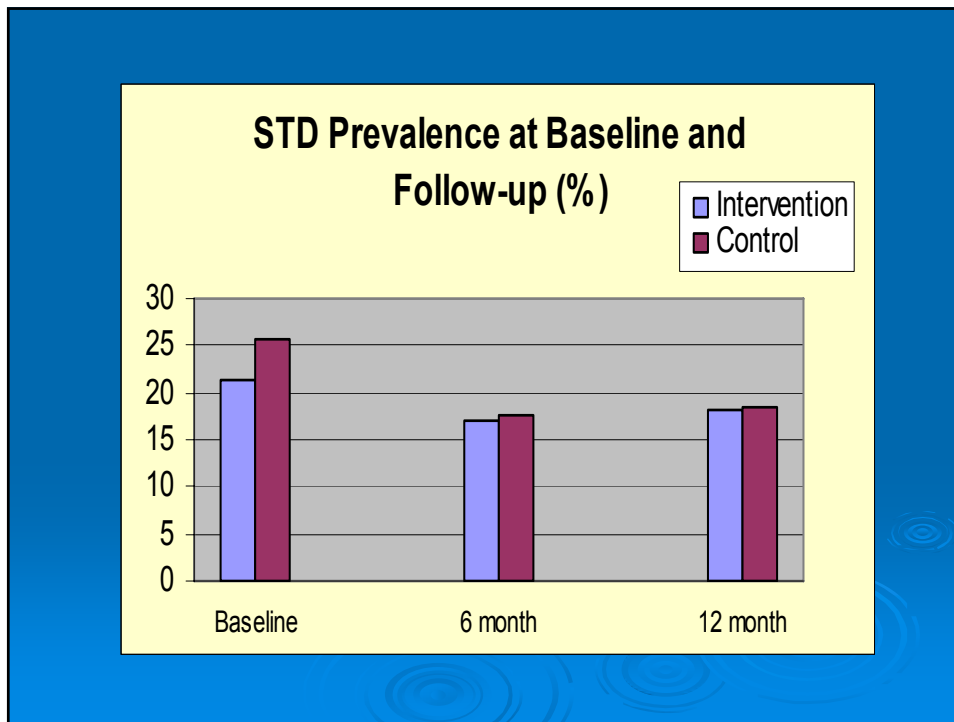
- 2.8 for FC + MC group
- 3.7 for MC only group

Female condom's protection against STIs, Feldblum et al., 2000

Measured impact of female condom introduction and education on STI prevalence among female agricultural workers in Kenya.

Methods

- 6 matched pairs of plantations; in each pair, one site randomized to MC only; the other site to MC + FC
- Total of 160 female employees enrolled per site
- Clinic- and community based condom distribution and risk-reduction education
- Participants interviewed, tested for STI at baseline, 6 months, 12 months



Kenya community intervention trial: process evaluation findings

- Novelty of male condom promotion
- Weak encouragement of condom use by clinic-based providers
- Inconsistent female condom distribution in intervention sites
- Social opposition to female condom distribution

Female condom's protection against STIs, French et al., 2003

Compared STI rates between women given small-group education on, and free samples of, either male or female condoms.

Methods

- 1,442 female STI clinic patients randomized to receive either the male or female condom.
- Assessed new cases of gonorrhea, chlamydia, trichomoniasis, and primary syphilis by mean of medical records.

Results

- STI incidence per 100 women per month
 - 8.5 for MC group
 - 6.8 for FC group

Female condom's protection against STIs, University of Alabama at Birmingham, 1997

Compared STI rates and time to first infection among male and female condom users

Methods

- Enrolled 1,159 STI clients
- Exposed participants to a comprehensive male and female condom promotion intervention
- Assessed gonorrhea and chlamydia incidence and condom use in 6 monthly follow-up visits

Results

- Consistent and correct use of either device reduced STI risk by 70%
- STI incidence was lower among consistent users who mixed methods, compared to exclusive male condom users

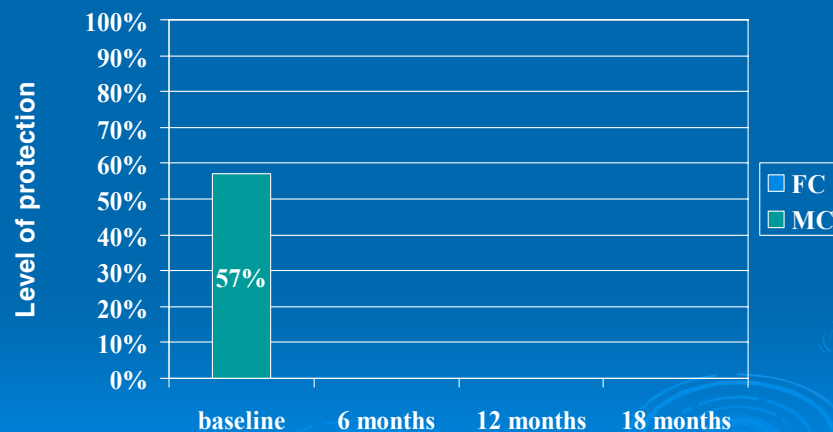
Measuring the Impact of Male and Female Condom Promotion among Sex Workers in Madagascar, 2005

Examined effect of adding the female condom to a male condom distribution system targeting sex workers.

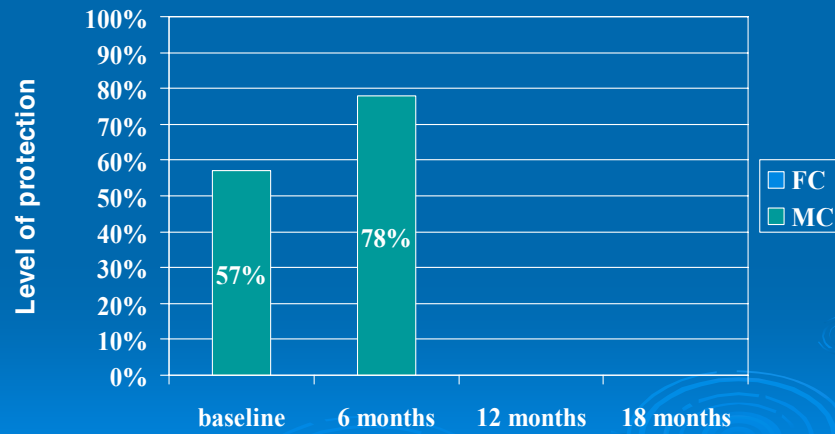
Methods

- Enrolled 1000 sex workers
- Months 1-6: male condom promotion
Months 7-18: male + female condom promotion
- Measured levels of protection and STI prevalence at baseline, 6, 12, and 18 months

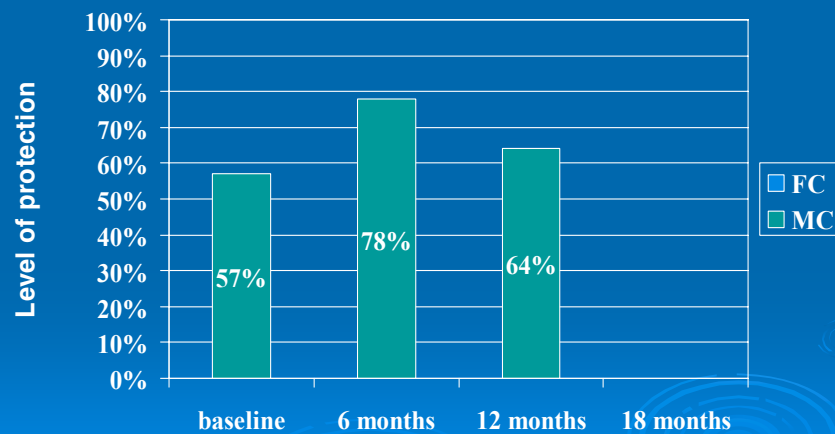
Mean proportion of protected sex acts with clients (last 30 days)



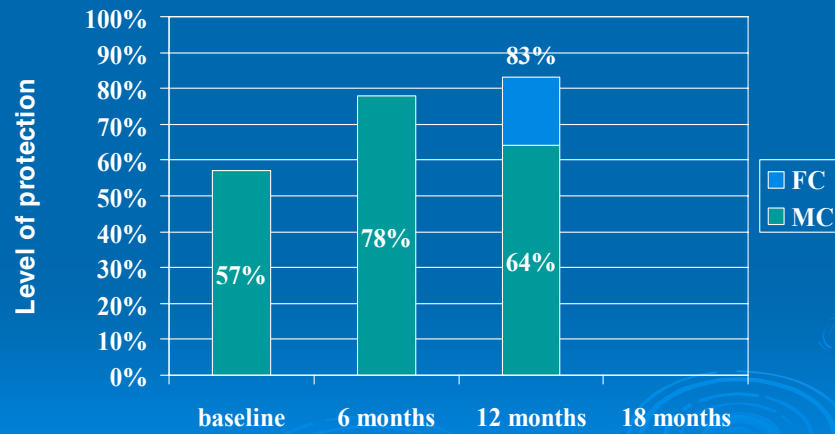
Mean proportion of protected sex acts with clients (last 30 days)



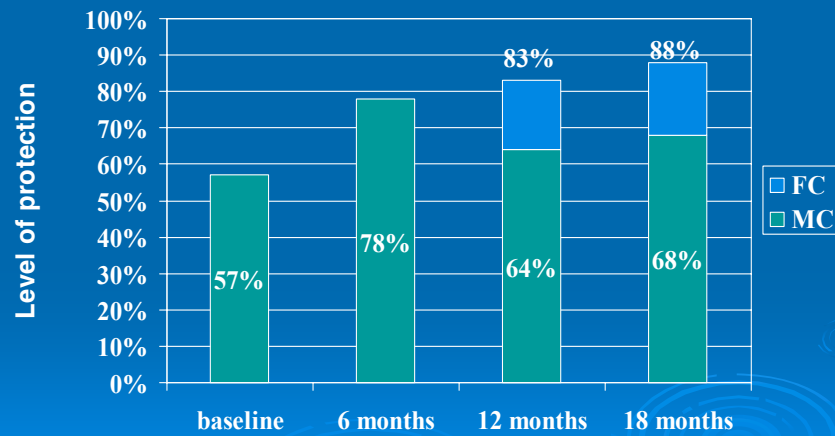
Mean proportion of protected sex acts with clients (last 30 days)



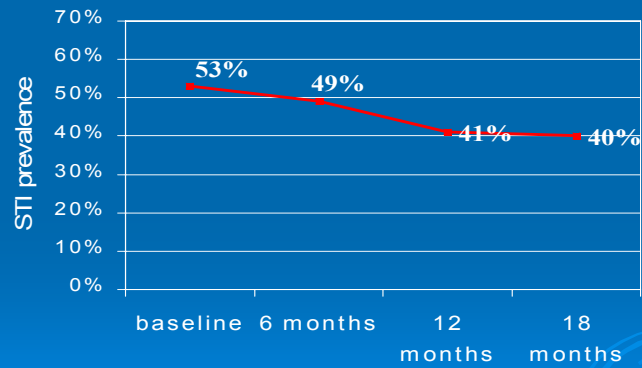
Mean proportion of protected sex acts with clients (last 30 days)



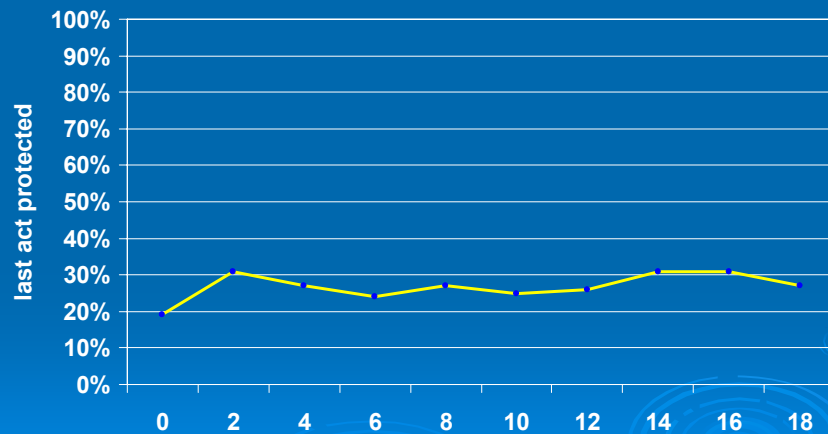
Mean proportion of protected sex acts with clients (last 30 days)



Proportion of participants with any STI (n=818)



Proportion of participants reporting use of protection in last sex act with non-paying partner



Conclusions on female condom effectiveness

1. Female condom is an effective contraceptive
2. Female condom is an effective method for preventing STI transmission
3. Slender evidence that the addition of the female condom to a male condom distribution system targeting high-risk women decreases STI prevalence

Priority issues for future research on female condom effectiveness

- Effectiveness of promoting female condom as a dual protection method
- Effect of female condom availability on STI prevalence in other populations
- Effectiveness of female condom in preventing genital ulcerative disease
- ★ Impact of female condom introduction on HIV transmission