

Diaphragms—an underused method in India

Evidence and best practices on new & underutilized contraceptives

Sita Shankar Wunnava
Director-MCHN
PATH India
September 6, 2012



What is a diaphragm?

- Soft latex or silicone cup that covers the cervix.
- Flexible rim keeps diaphragm in place.
- Used with spermicide to improve effectiveness.
- Comes in different sizes and requires fitting by a trained provider.
 - A one-size-fits-most device may be available soon that would not require fitting- SILCS
- Prevents Pregnancy by blocking sperm from entering cervix.
- Protects cervix from infection

Advantages of diaphragms

- Non-hormonal, no systemic side effects.
- User-initiated. Use only when needed.
- Appropriate for almost all women.
- Reusable.
- Discreet—more so than male or female condom.
- Protects from pregnancy and possibly some STIs that infect the cervix.

Diaphragm - evidence for disease protection

<u>Design</u>	<u>Sample</u>	<u>STI</u>	<u>Odds ratio</u>	<u>95% C.I.</u>	<u>Author</u>
Case control	STI clinic	GC	.45	.15-1.3	Austin et al
Cross sectional	STI clinic	GC	.8		Madger et al
Cross sectional	STI clinic	GC, CT, TV	.32*	.16-.45	Rosenberg et al
			.24*	.05-1.36	
			.25	.12-.48	
Case control	STI clinic	CIN 1,2	.3*	.1-.8	Becker et al
Case control	STI clinic	PID	.3	.09-.75	Wolner-Hanssen et al
Case control	Hospital	PID	.4	.2-.7	Kelaghan et al

Contraceptive failure rates of barrier methods

	Typical use	Perfect use	Continue at 1 yr
Diaphragm with spermicide	16	6	57%
Condom			
<i>Female</i>	21	5	49%
<i>Male</i>	15	2	53%
Spermicide	29	18	42%

Challenges with traditional diaphragms

- Service delivery:
 - Provider bias
 - Multiple-sized device: requires fitting exam from trained provider; complicates supply.
 - Providers don't feel confident assessing size; requires additional time for counseling in method use.
 - Need appropriate contraceptive gel (alternative to N-9)
 - Assumption that women will be hesitant to insert
 - Hygiene issues
- User perspective: Can be difficult to learn to insert/remove.

SILCS has been developed to address these challenges

Diaphragm research in 12 countries

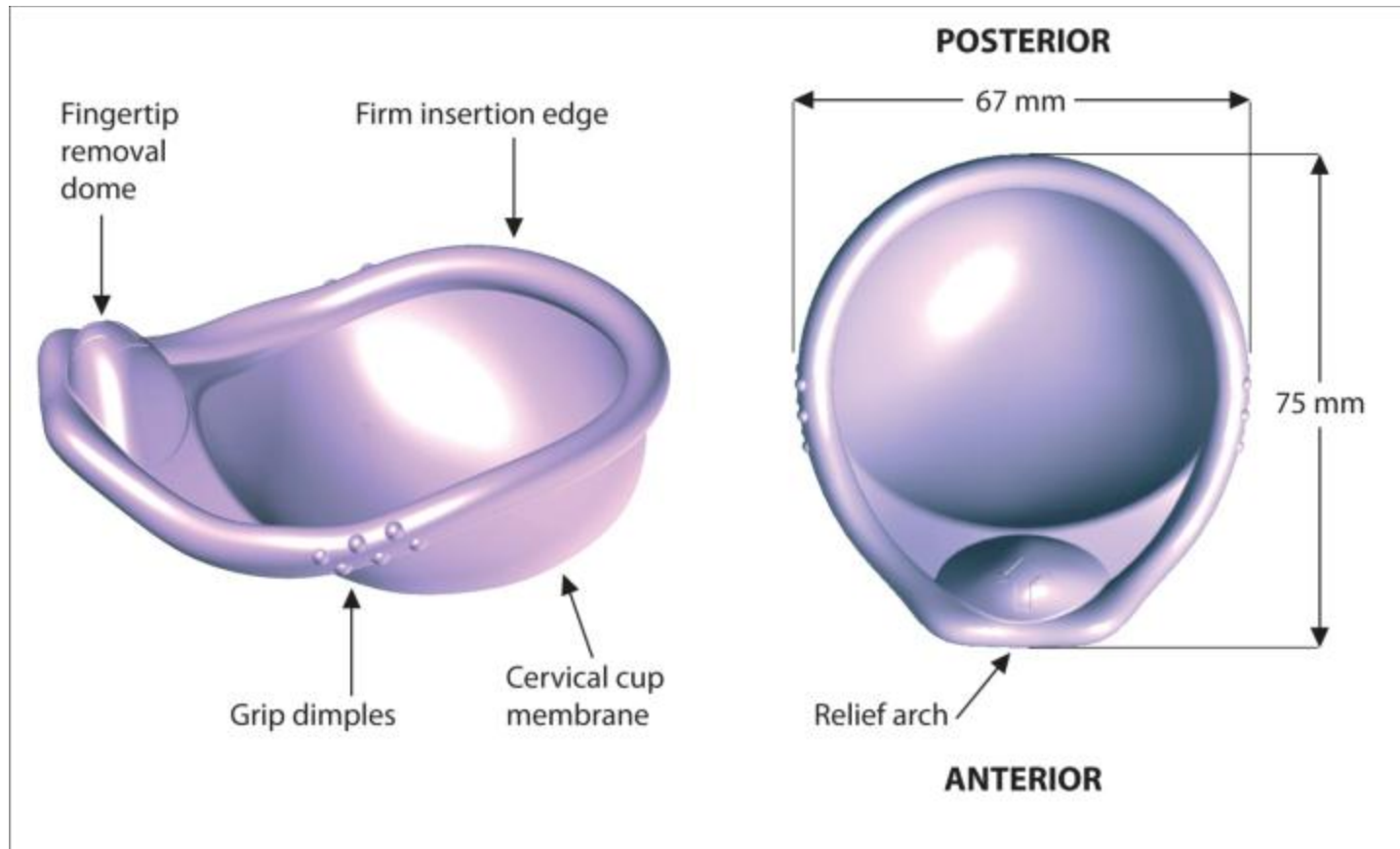


Diaphragm acceptability among low-income Women, Madras, India*

- Study group: 97 currently married women (15–49 years), from urban, low income settlements, recruited at 3 family planning clinics in Madras.
- Collected user perspectives after 6–7 months use on:
 - User experience;
 - Consistency of use and sexual life;
 - Support from partners;
 - Positive factors; and
 - Service delivery.
- Follow-up after 18 months of diaphragm use, found almost 70% of women contacted were still using diaphragm.

*Ravindran and Rao. In *Beyond Acceptability*

SILCS Diaphragm: one-size-fits-most



SILCS Diaphragm: status

- Evaluated in 7 studies in 5 countries for safety, acceptability, fit, and ease of use.
- Contraceptive effectiveness study in United States completed in 2010. Effectiveness similar to traditional diaphragm.
- In 2010, PATH licensed SILCS to Kessel Marketing , Germany, for commercialization.
- Regulatory applications underway in Europe and United States.
- PATH working to raise awareness and explore feasibility for low resource countries.
- PATH and CONRAD evaluating alternative contraceptive gel product for use with SILCS. Contragel is a lactic-acid based contraceptive gel with CE Mark approval, available in European countries.

SILCS Diaphragm: cost

- SILCS is reusable for 2 years. Initial product cost spread over the use life results in a low-cost contraceptive method.
- Manufacturing cost for public sector in developing countries not yet determined.
- Kessel Marketing committed to providing product at affordable price for low resource countries.
- What is a reasonable cost for a reusable contraceptive that lasts 2+ years?
- Diaphragms recommended for use with a contraceptive gel. The gel is a recurring cost.



Could diaphragms improve reproductive health options in India?

- Family planning (FP) in India has a high reliance on sterilization and low availability of birth spacing methods.
- Lack of female initiated methods
- Lack of methods without systemic side effects
- Will introducing a single-size diaphragm improve women's RH options in India?
- Who are the groups of women who would benefit from access to a non-hormonal barrier method for birth spacing?

Health Systems Assessment for SILCS - India

Ashodaya, a local NGO, is implementing a health systems assessment in 2012 to identify opportunities and challenges for future introduction of SILCS in India

Key areas being explored:

- Facility based opportunities
- Procurement logistics
- Community level opportunities
- Communication channels with key target audience
- Training needs for SILCS introduction
- Stakeholder assessment & mapping

Urgent need to expand basket of contraceptive choices in
India

Time to Act!

Thank you!