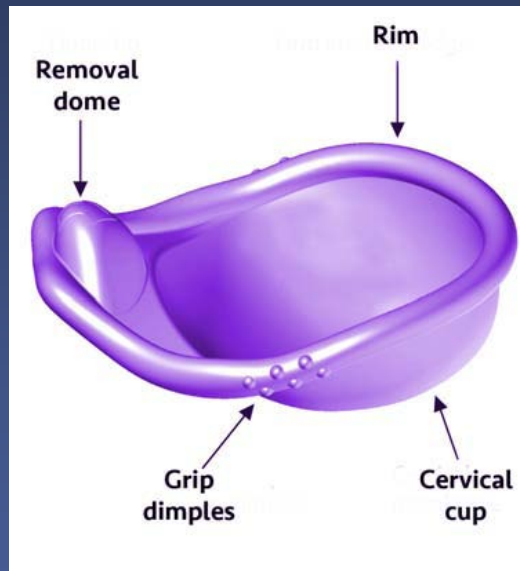


SILCS Pivotal Data: Implications for MPTs

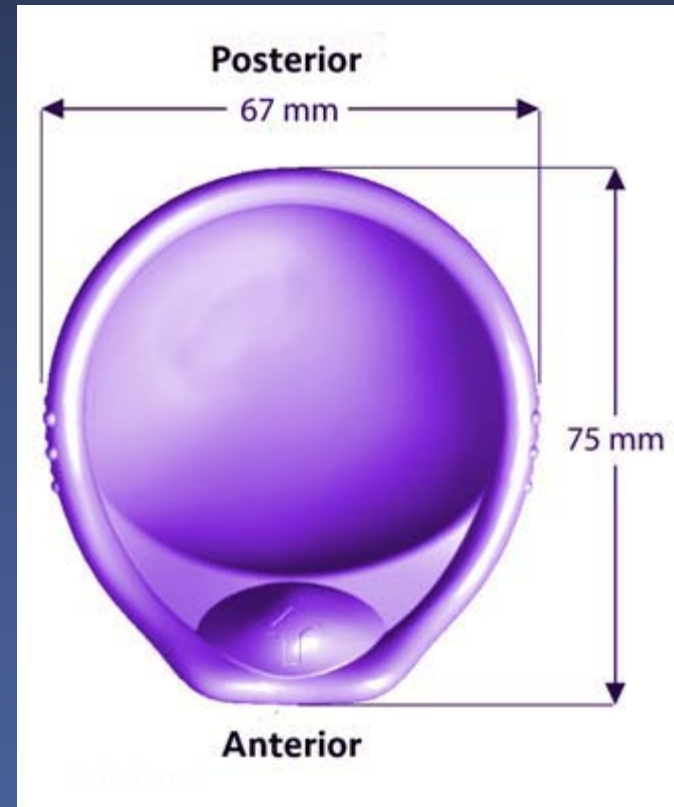
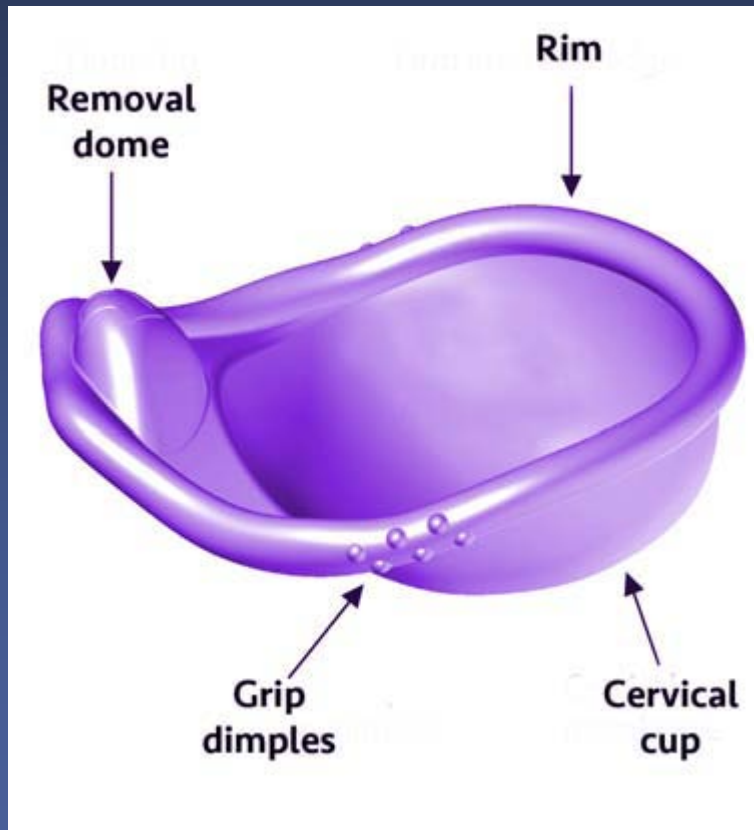
Reproductive Health 2011
Las Vegas, Nevada, 9/17/11
Jill Schwartz, MD



This is NOT your Mother's Diaphragm



SILCS Diaphragm



SILCS -Advantages

- ◆ Single size removes obstacle to both provider and client of pelvic exam and fit assessment
- ◆ Simplifies logistics of supply and provision
- ◆ Potential as a dual protection method is promising to address multiple reproductive health risks and needs

Contraceptive Effectiveness and Safety Study of the SILCS Diaphragm: The Pivotal Study

Study Design:

- ◆ Multi-center trial in 450 US couples using SILCS with gel for 6 months
- ◆ Study visits at baseline, after 1 cycle, 3 cycles & 6 cycles (190 days)
- ◆ Similar design to NICHD study using fitted diaphragm

Randomized study arms:

- ◆ BufferGel (n=300)
- ◆ Nonoxynol-9 (n=150)

Study Objectives:

- ◆ Six month typical use pregnancy probability
- ◆ Safety of the SILCS including colposcopy and microflora subset
- ◆ Feasibility of over-the-counter use and fit

Sex Acts and Product Use

	BufferGel (N=283)	Gynol II (N=138)	Total (N=421)
Mean # (SD) of coital acts per month	14 (14.1)	11.8 (6.6)	13.3 (12.2)
Mean % (SD) of coital acts with SILCS and gel	83.4 (20.6)	87.7 (14.9)	84.8 (19)

Safety Subendpoints Female Participants

	BufferGel (N=283)	Gynol II (N=138)	Total N=421
Urogenital AE	137 (49.3)	75 (54.7)	212 (51.1)
Abnormal bleeding	38 (13.7)	21 (15.3)	59 (14.2)
Symptomatic vaginal infection	37 (13.3)	16 (11.7)	53 (12.8)
Symptomatic UTI	7 (2.5)	7 (5.1)	14 (3.4)
Deleterious Pap Smear change	8 (2.9)	5 (3.6)	13 (3.1)
Symptomatic cervical infection	1 (0.4)	4 (2.9)	5 (1.2)

Serious and/or Product-Related

	BufferGel (N=278)	Gynol II (N=137)	Total (N=415)
Serious AEs	3 (1.1)	1 (0.7)	4 (1.0)
Product Related	106 (38.1)	50 (36.5)	156 (37.6)
Serious and product-related	0	0	0

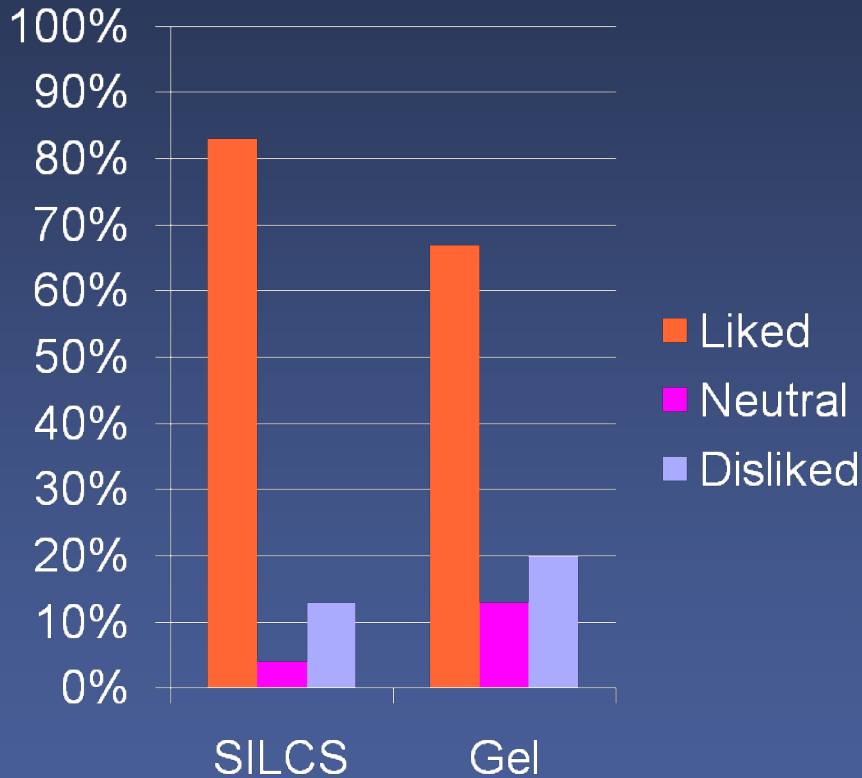
Colposcopy Subset Findings

N=70

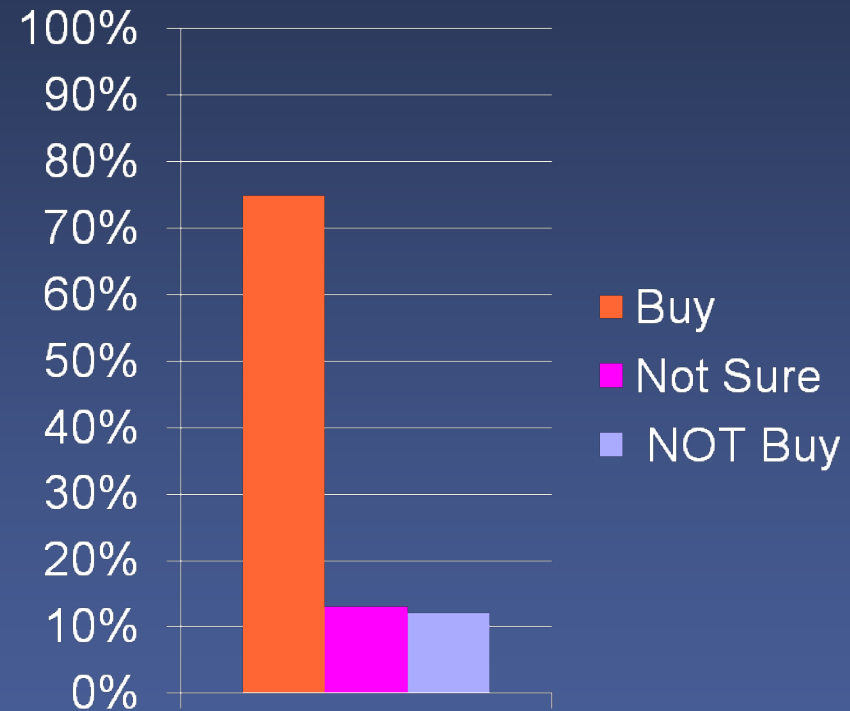
	Baseline	FU Visit 1	FU Visit 2	Final Visit
Erythema	3	1	5	0
Edema	0	0	0	1
Grossly White	1	1	0	1
Petechiae	3	5	1	2
Ecchymosis	0	0	1	0
Peeling	1	5	4	1
Other	2	0	0	0
TOTAL	10	11	9	5

Acceptability (N=342)

Liked/Disliked SILCS or Gel



If SILCS was available in drugstore...



SILCS Typical Use Pregnancy Rates

	N	6 –month (95% CI)	12-month (95% CI)*
Buffer Gel (BG)	184	9.6 (5.5-13.6)	16.5 (9.6-22.9)
Gynol II (N-9)	73	12.5 (5.4-19.5)	21.2 (9.5-32.0)
Total (BG & N-9)	257	10.4 (6.9, 14.0)	17.8 (12.0-23.6)

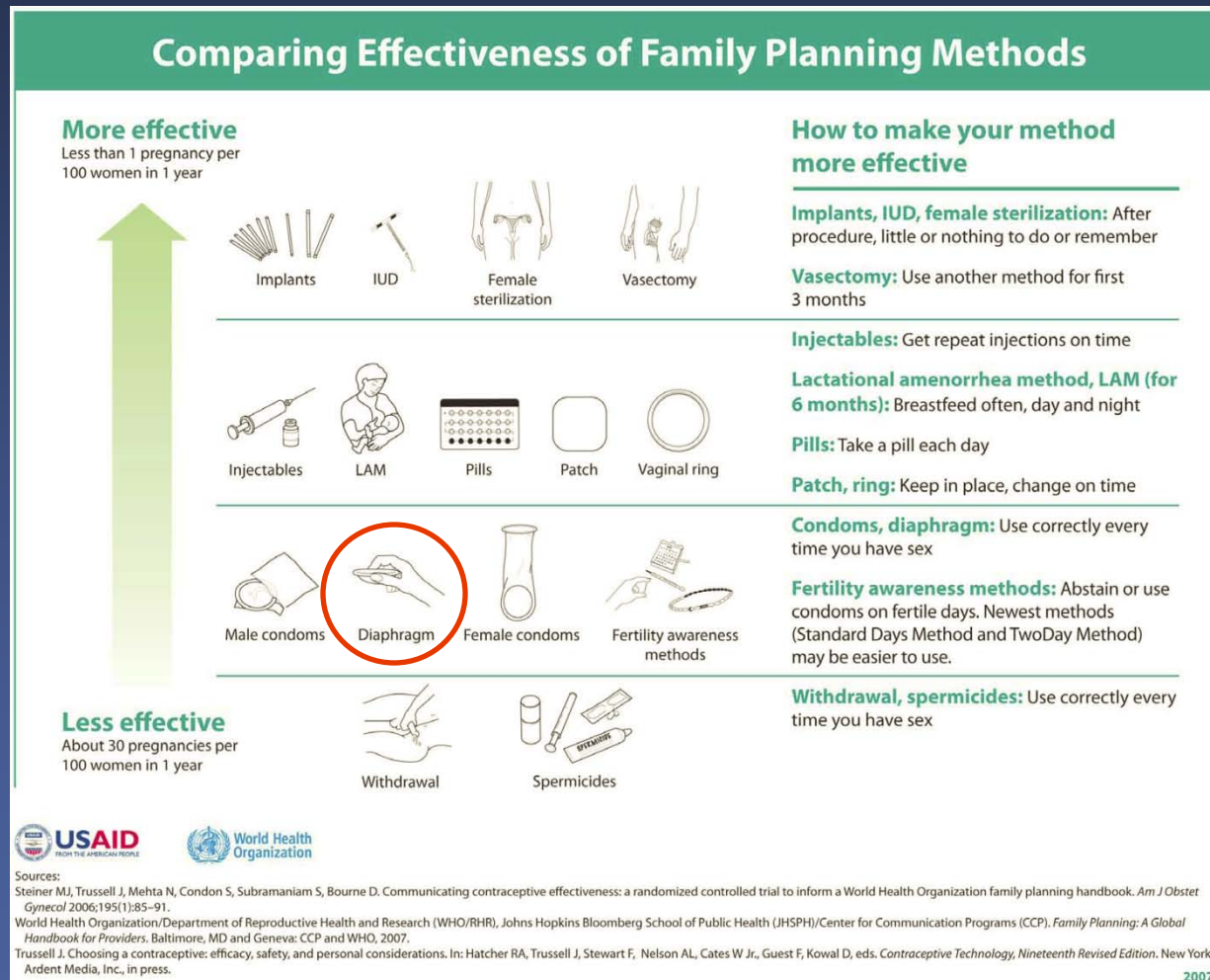
*12-month rate extrapolated from 6 month rate

SILCS Versus Ortho All-Flex 6-month Typical Use Pregnancy Rates

	SILCS 6 -month (95% CI)	Ortho AF 6-month (95% CI)*
Buffer Gel (BG)	9.6 (5.5-13.6)	10.1 (7.1-13.1)
Gynol II (N-9)	12.5 (5.4-19.5)	12.3 (7.7-16.9)
Total (BG & N-9)	10.4 (6.9, 14.0)	--

*Barnhart et al. **Contraceptive efficacy of a novel spermicidal microbicide used with a diaphragm: a randomized controlled trial.** *Obstet Gynecol* 2007 Sep;110(3):577-86.

Effectiveness of Contraceptive Methods



Fit Assessment (N=450)

Assessment After First Try		Assessment After Coaching	
Unable to insert	32 (7%)	Able to Fit	29/32
Incorrectly positioned	60 (14%)	Able to Fit	52/60
Correctly positioned	358 (80%)	Good Fit	358
Total (able to correctly position)	358/450 (80%)	Total (Good fit)	439/450 (98%)

80% correctly positioned the device on the first try
98% were good fit after more than one try

Next Steps for SILCS

- ◆ Data from this study will support regulatory application to the United States FDA
- ◆ PATH licensed the SILCS design to Kessel of Frankfurt, Germany, in late 2010, and the device will be manufactured and distributed in select markets
- ◆ Kessel is preparing regulatory applications for Europe and US
- ◆ Through a phased approach, the SILCS will be introduced in both developed and developing countries to provide a new affordable family planning option to women globally

MPT: Device and Drug Combination

- ◆ Simultaneously address multiple RH risks and needs –Pregnancy and STIs
- ◆ SILCS can be used as a delivery system for effective Microbicides
- ◆ The SILCS Diaphragm used with Tenofovir gel could potentially prevent pregnancy, HIV and HSV-2

SILCS Study Team

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