

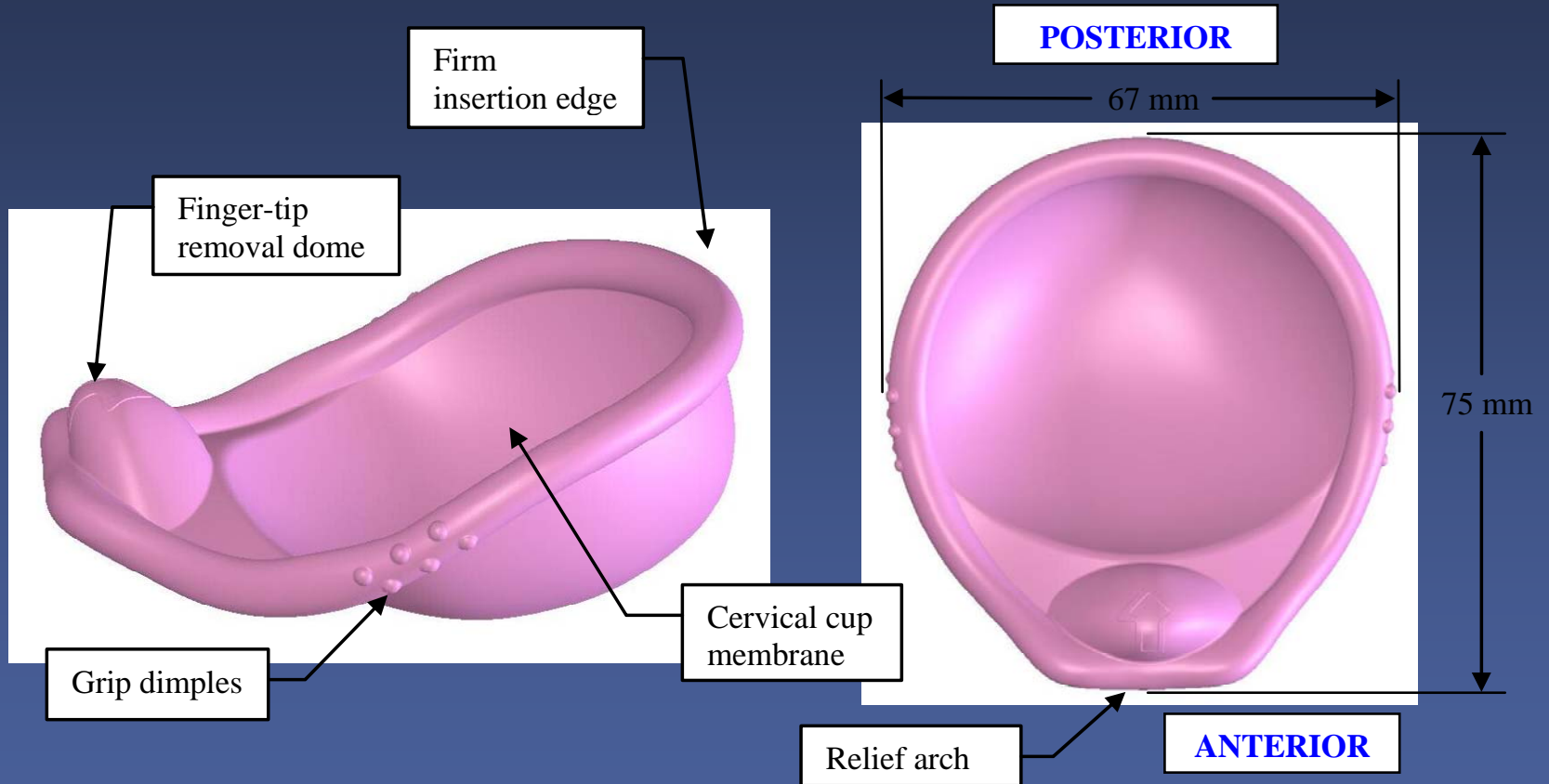
Over-The-Counter Provision of the SILCS Diaphragm

Jill L Schwartz, MD

Maggie Kilbourne-Brook, Ron Frezieres, Mitchell Creinin, David Archer, Lynn Bradley,
Kurt Barnhart, Alfred Poindexter, Christine Mauck, Jaim-Jou Lai,
Debra Weiner, Marianne Callahan



PATH/SILCS Diaphragm



Provision of SILCS Over-The-Counter

SILCS single size:

- ◆ Removes obstacle of physical exam and fit assessment to both provider and client
- ◆ Simplifies logistics of supply and provision
- ◆ Would be accessible 24/7 in some locations

USFDA OTC Regulatory Requirements

- ◆ Benefits outweigh risks
- ◆ Potential for misuse and abuse is low (not addictive)
- ◆ Can be adequately labeled
- ◆ Consumer can self-diagnose (assess) for use
- ◆ Health practitioners are not needed for the safe and effective use of the product

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

Design: Multi-center contraceptive trial in 450 U.S. couples using the SILCS diaphragm

Randomized study arms:

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

Primary objectives:

- ◆ Six month pregnancy probability during typical use
- ◆ Safety of the SILCS diaphragm

Recruitment Began: Q1 2008

Clinical Study Complete: Q4 2009

Pivotal Study--Secondary Objective Feasibility of Over-the-Counter Provision

- ◆ Assess whether women can correctly:
 - ▶ insert, position, and remove the SILCS diaphragm
 - ▶ determine if it is inserted/positioned correctly

After reading written instructions only and after one attempt
- ◆ Assess the proportion of women who could not be fit
- ◆ Explore characteristics predicting inability to fit, particularly standard diaphragm size

SILCS Fit Assessment by Study Participant

- ◆ Woman given SILCS device plus contraceptive gel and written instructions at clinic. Attempts to insert on her own (up to 15 minutes)
- ◆ “Attempt” defined as inserting/positioning device until participant believes that:
 - ▶ Device is correctly positioned
 - ▶ Device is incorrectly positioned & given up trying, or
 - ▶ Unable to insert device & given up trying
- ◆ After first attempt, if participant unable to insert/position, clinician attempts insertion. If clinician able to insert:
 - ▶ Participant was given 2 more attempts, with additional instructions (as needed)

SILCS Fitting Assessment

- ◆ Each participant was asked to assess correct positioning based on instructions
- ◆ Definition of SILCS correct positioning:
 - ▶ Clinician assessed by 4 criteria & overall impression:
 - Cervix covered
 - Device behind pubic bone
 - Device does not protrude
 - Device is comfortable to participant
- ◆ Participants also sized for the Ortho Diaphragm to determine baseline “size”

Clinicians' Assessment of Positioning at First Attempt (N=418)

Participant's First Attempt	Clinician Assessment
CORRECTLY POSITIONED	358/418 (86%)
INCORRECTLY POSITIONED	60/418 (14%)
Not Behind Pubic Bone	31
Not Covering Cervix	20
Protruding	9
TOTAL INSERTED	418

Participants' Assessment of Positioning at First Attempt (N=418)

	Participants' Assessment		
Clinician Assessment	Correctly Positioned	Incorrectly Positioned	TOTAL
Correctly positioned	353	5	358
Incorrectly positioned	54	6	60

Who might be at risk if SILCS was purchased OTC?

- ◆ 54 of 450 (12%) might be able to insert the device but not recognize that it was incorrectly positioned (not covering cervix, not behind the pubic bone or protruding)
- ◆ Additional instructions on correct positioning might optimize OTC success

Clinician Fit Assessment (N=450)

PARTICIPANT ASSESSMENT		CLINICIAN ASSESSMENT	
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%)

Good fit was achieved with 98% of devices
 Compared to 80% of participants who achieved
 good fit on first try

Sociodemographic Characteristics

	Could not be fit (N=11)	Could be fit (N=439)
Age (mean years)	28	29
Race		
White	7 (64%)	208 (47%)
Black	2 (18%)	156 (36%)
Asian	0 (0%)	11 (3%)
More than one race	1 (9%)	30 (7%)
Other	1 (9%)	33 (8%)
Education (Mean years (SD))	14.8 (2.7)	14.1 (2.7)
Living with Partner	9 (82%)	331 (75%)
Relationship Length (>6 months)	11 (100%)	414 (94%)
Ever Pregnant	7 (64%)	307 (70%)

Prior Experience with Barrier Methods

	Could not be fit (N=11)	Could be fit (N=439)
Male Condom	11 (100%)	417 (95%)
Female Condom	1 (9%)	32 (7%)
Contraceptive Sponge	0	26 (6%)
Diaphragm	1 (9%)	35 (8%)

Physical Characteristics

	Could not be fit (N=11)	Could be fit (N=439)
BMI		
Mean (SD)	30.9 (14)	29.1 (8.3)
Median (Range)	25.5 (17-56)	26.6 (16-64)
Ortho Sizing		
No size fits	3 (27%)	0 (0%)
60-65	5 (45%)	58 (13%)
70-75	3 (27%)	300 (69%)
80-85	0 (0%)	78 (18%)

Summary

- ◆ The device fit 98% of participants based on established fit criteria
- ◆ 86% of women who were able to insert the diaphragm were able to correctly position it
- ◆ 12% of women would be at risk of using an incorrectly positioned device if purchased over the counter and might be at greater risk for pregnancy
- ◆ Participants who could not be fit were
 - ▶ More likely not to fit any Ortho diaphragm
 - ▶ More likely to wear a smaller sized device
 - ▶ No demographic factors

Conclusions

- ◆ OTC provision of the SILCS diaphragm is feasible
- ◆ Written instructions on correct positioning might be augmented with pharmacy or telephone assistance, or web-based information so that health practitioners do not need to be present at the time of dispensing

Acknowledgements

Advances in Health, Inc.

Alfred Poindexter, Principal Investigator
Melissa Poindexter, President AHI Inc.
Diane Lemus, Study Coordinator

California Family Health Council

Ron Frezieres, Principal Investigator
Karen Peacock, Study Coordinator
Terri Walsh, Sub-Investigator

Eastern Virginia Medical School

David Archer, Principal Investigator
Thomas Kimble, Sub-Investigator
Bela Oza, Study Coordinator

Johns Hopkins Community Physicians

Lynn Bradley, Principal Investigator
Kathy Brugh, Study Coordinator

University of Pittsburgh Medical Center

Mitchell Creinin, Principal Investigator
Carol Priest, Study Coordinator

University of Pennsylvania Medical Center

Kurt Barnhart, Principal Investigator
Courtney Schreiber, Sub-investigator
Beth Steider, Study Coordinator

PATH

Maggie Kilbourne-Brook
Patricia Coffey

USAID

Judy Manning
Jeff Spieler

Family Health International (FHI)

Debra Weiner
Jaim-Jou Lai
Belinda Irsula
Nicole Roberge

CONRAD

Henry Gabelnick
Marianne Callahan
Chalyce Grace
Christine Mauck
Janet Schafer
Debra Laukhuff
Lamia Khiali

SILCS STUDY COUPLES