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FemCap™ with removal strap: ease of removal, safety and acceptability

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Abstract

Objectives—FemCap™ is a silicone–rubber barrier contraceptive approved for marketing in the United States. To address reported problems with removal and dislodgment, the device’s developer added a strap to the device and increased the height of the brim. This trial assessed whether the new design reduced removal difficulties and had any effects on dislodgment, genital pain/discomfort, safety, and acceptability.

Methods—Women used the strapped device for 8 weeks with follow-up visits at 2 and 8 weeks. Outcome measures were obtained through diary cards, questionnaires, and naked eye examination. Data from these 120 women were compared with data from 419 women who used the unstrapped FemCap in a previous contraceptive effectiveness study.

Results—The strapped device was not significantly easier for users to remove than the unstrapped device. Similar odds of dislodgment and cervical/vaginal irritation were seen with the two devices. Both female and male participants were significantly more likely to report pain/discomfort with use of the strapped device. Female users of the strapped device were significantly more likely to say they disliked their device. In six weeks, two pregnancies were observed, but pregnancy was not an endpoint in the study and no conclusions should be drawn regarding pregnancy rates.

Conclusions—The modifications to the FemCap did not significantly improve the ease of device removal and appears to have resulted in significantly more female and male partner pain/discomfort and decreased acceptability, compared with the unstrapped device.

Keywords

FemCap; Diaphragm; Contraception; Vagina; Device; Barrier

1. Introduction

FemCap (FemCap™, Del Mar, CA) is a silicone–rubber barrier contraceptive intended to be used with spermicide (Fig. 1). It has a dome that covers the cervix, a rim that fits into the vaginal fornices and a brim that conforms to the vaginal walls around the cervix. It can be worn up to

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48 h. Users may engage in as many acts of intercourse as desired for the first 42 h, but must wait at least 6 h before removing the device. At the time of this study, the device was considered an investigational product, but the modified design tested in this study has since been approved for marketing in the United States and is available in several European countries.

A Phase II/III contraceptive effectiveness trial comparing FemCap with the All-Flex[®] diaphragm (Ortho-McNeil Pharmaceutical, Raritan, NJ) showed that, according to the criterion set by the study, the FemCap was inferior to the diaphragm in contraceptive efficacy, although both had associated pregnancy rates that were within the expected range for barrier methods [1]. However, significantly, more FemCap users than diaphragm users reported difficulty with removal and occurrences of dislodgment (meaning the device partially or completely coming out on its own).

The developer attempted to address problems with removal by adding a strap to the device. The strapped device was evaluated in an ad hoc study of 47 women who had reported trouble with removal of the original unstrapped device while in the contraceptive effectiveness trial (unpublished data, CONRAD, 1997). Seventy-two percent of these women still had trouble removing the unstrapped FemCap compared to only 21% for the strapped device. Eighty-one percent reported that the strap made removal easier.

The developer has subsequently also increased the height of the brim in the medium- and large-sized strapped devices to reduce dislodgment. It was anticipated that the larger brim would increase contact between the brim and vagina, enhancing stability and reducing dislodgment of the device during use by women with less vaginal muscle tone.

The current study was designed to test these device modifications in women naive to the device. Data from this study were compared with data from the FemCap arm of the contraceptive effectiveness study of the original device design [1]. The primary objective was to determine whether the new design reduced removal difficulties observed with the unstrapped device. The secondary objectives were to determine whether the changes in the device had any effects on dislodgment, participant genital pain/discomfort, partner genital pain/discomfort and safety, as evidenced by cervical/vaginal irritation, and to assess acceptability.

2. Materials and methods

This was an open-label, nonrandomized study employing a historical control analysis. Women were enrolled at the General Clinical Research Center at Magee-Women's Hospital in Pittsburgh, PA, and CONRAD's Clinical Research Center at the Eastern Virginia Medical School in Norfolk, VA. Both sites were among the 10 centers that had participated in the Phase II/III contraceptive effectiveness study [1]. The current study was approved by the institutional review board for each site. Data management, data entry and statistical analysis were performed by Family Health International, Research Triangle Park, NC.

Women were eligible if they were between 18 and 40 years of age, sexually active in a stable, mutually monogamous relationship, not pregnant or nursing, willing to avoid using tampons or any intravaginal products and not actively desiring pregnancy but willing to accept an unknown risk of pregnancy. Couples were excluded if either the female or male partner had a history of sensitivity to silicone or spermicide, fertility problems or any known risk for sexually transmitted infections or HIV. After obtaining informed consent from both partners, the female participant provided her medical history and had a pelvic exam, Pap smear, wet mount, tests for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, urine pregnancy test and cervical/vaginal colposcopy as per the CONRAD/WHO guidelines [2].

The female participant was then fitted for an Ortho All-Flex diaphragm followed by fitting of the FemCap device. Initial FemCap sizing was based on obstetrical history: small for women who had never been pregnant, medium for women who had been pregnant but had not delivered vaginally, and large for women with a prior vaginal delivery. If the initial size fit poorly, other sizes were tried as deemed appropriate by the clinician. The participant was instructed on how to insert and remove the device and left to insert the device on her own. After she inserted the device, the clinician checked for proper placement. The participant then removed the device unassisted. If the participant had difficulty inserting or removing the device properly, the clinician provided further instructions until the participant could perform these procedures easily on her own. Women who were unable to use the device or had a poor fit were discontinued.

Each participant received two individually packaged Fem-Cap with removal strap devices and a commercially available spermicide gel containing 2% nonoxynol-9 (Gynol II[®], Ortho-McNeil Pharmaceutical). Diary cards were distributed for women to record each act of intercourse, use of the device and any medications. Dates of menses and any problems experienced by the participant or her partner while using the device were also captured on the diary. Although comparison of contraceptive effectiveness was not an objective of the study, participants were asked to consider the strapped device their primary means of contraception.

Participants were seen two and eight weeks after enrollment. Before each follow-up visit, the participants were instructed to time intercourse so that the device could be removed at least 24 h before the appointment. At the 2-week visit, the participant demonstrated that she could correctly insert and remove the device on her own. If fit or placement was incorrect, the participant was discontinued. At both follow-up visits, the female participant had a urine pregnancy test and a pelvic exam with colposcopy. She completed an acceptability questionnaire and was given two questionnaires for her partner to complete and return by mail. If the participant was experiencing vaginal itching or unusual discharge, a wet mount and any other clinically indicated tests were performed.

Couples in which the female partner became pregnant, who developed a significant medical/safety concern including a sexually transmitted infection or who requested to be withdrawn were discontinued from the study.

2.1. Analysis

The objectives were tested by comparing the data from couples using the strapped device to data from the first 8 weeks of follow-up among couples using the unstrapped device in the contraceptive effectiveness study [1]. In the current study, female participants had follow-up visits 2 and 8 weeks after enrollment, whereas for the contraceptive effectiveness study [1], female participants were seen 2, 6, 12 and 28 weeks after enrollment. Identical data were collected in the current study as in the initial study with an additional male questionnaire. All enrolled women were used in the analysis of the primary objective (removal endpoint). Only those providing follow-up data were included in the analysis of the secondary and tertiary objectives. Only data sources available from both studies were used to determine endpoints.

To test the primary objective, women were classified into one of four device-removal categories: severe problem (discontinued for inability to remove device), moderate problem (removal considered the aspect least liked about device or device removal problems reported during at least 20% of coital acts), slight problem (removal problems reported during less than 20% of coital acts) or no problem. We tested whether the strapped device would make removal easier (i.e., a one-tailed test).

Secondary endpoints were dislodgment, participant genital pain/discomfort, partner genital pain/discomfort and cervical/vaginal irritation. Reports of device dislodgment and pain/discomfort were taken from the diaries and the 2-week questionnaire. Women were categorized as either having or not having reported device dislodgment. The two pain/discomfort endpoints were each classified at three levels: pain/discomfort, awareness of the device but no pain/discomfort or neither pain/discomfort nor awareness of the device. Because only 21 women in the contraceptive effectiveness study [1] underwent colposcopy, cervical/vaginal irritation was defined as the presence of epithelial changes observable with the naked eye alone. We tested whether the strapped device was worse than the unstrapped device with respect to these problems (i.e., a one-tailed test).

Acceptability was determined by the responses of both partners on the 2-week questionnaire: general opinion of the device, whether she/he would recommend it to a friend, and (for those with diaphragm experience) her/his preference for FemCap over the diaphragm. Tests for these endpoints were two tailed.

To control for potential confounding from baseline differences between groups, we used the method of propensity score [3]. In the present case, a propensity score was a given woman's probability of being in the strapped group, based on her baseline characteristics. This probability was obtained from a logistic regression model with device group as the outcome and baseline variables imbalanced between groups or prespecified as key covariates requiring control as the predictors. By including this propensity score in the analysis of study objectives, we simultaneously controlled for all baseline variables from which the propensity score was derived. All tests of primary and secondary objectives controlled for baseline variables in this manner.

Endpoints with two levels (e.g., either having or not having reported device dislodgment) were compared between groups using logistic regression. Endpoints with more than two levels (e.g., four levels of severity for device removal) were tested by proportional odds regression, an extension of logistic regression that estimates a single measure of effect (odds ratio) for being in the adjacent worse category (e.g., moderate vs. slight problem and severe vs. moderate problem). If a single estimate could not be computed (i.e., the proportional odds assumption was violated), the endpoint was evaluated using generalized logits regression, which produces separate odds ratios for each level as compared to the lowest category (i.e., severe removal problem vs. none; moderate removal problem vs. none). Level-specific results are reported only when statistically required because of violation of the proportional odds assumption. Where possible, an overall p value is reported to reflect all levels of generalized logits regression.

A cumulative 6-week probability of pregnancy and its 95% confidence interval were estimated for women in the two device groups using the Kaplan-Meier method. The standard error used to compute the confidence interval was calculated using the method of Peto et al. [4]. Although the study was not designed to have sufficient power to test for differences between devices in contraceptive effectiveness, survival curves were compared using the log-rank test.

The study had 80% power to detect a 21% relative reduction in the proportion reporting removal problems, a 52% relative increase in the proportion reporting dislodgment, an 83% increase in the proportion reporting participant pain/discomfort and a 200% increase in the proportion reporting partner pain/discomfort. These calculations were based on binary endpoints and did not attempt to control for baseline covariates.

3. Results

There were 120 couples enrolled in this study, 74 in Pittsburgh and 46 in Norfolk. These 120 women were compared on baseline characteristics and the primary endpoint (removal problems) with 419 women receiving the unstrapped device in the contraceptive effectiveness study. Characteristics of women at baseline are presented in Table 1. Eighteen percent of the 120 women in the strapped device study received a small device, 25% received a medium size and 58% received a large size. There was a good agreement between the size expected based on obstetrical history and size received ($\kappa = 0.83$, 95% CI=0.74–0.92, controlling for center), similar to what was observed in the contraceptive effectiveness study.

Ease of removal was not significantly better for users of the strapped device compared with the unstrapped device (Table 2). Although proportionately fewer women using the strapped device had moderate removal problems compared with women in the unstrapped group (24% vs. 35%, respectively), they did not experience fewer severe (12% vs. 8%, respectively) or slight (18% vs. 17%, respectively) removal problems, and the overall test comparing groups on this endpoint was not statistically significant ($p = .1422$, one tailed).

Twenty-three women in the strapped group and 61 in the unstrapped group provided no follow-up data and were therefore not included in analyses of the secondary and tertiary objectives. Of the 97 strapped-group couples with follow-up data, 85 (88%) completed 8 weeks of follow-up; three were discontinued for medical/safety reasons, four for nonsafety, device-related reasons, two because the woman became pregnant, two because the woman was unable to insert the device at the 2-week visit and one woman was lost to follow-up. Compared to the historical control group, proportionately, more women in the strapped device group were discontinued due to their inability to insert or remove the device (18.3% in the strapped group vs. 10.7% in the control group). Percentages for other reasons for discontinuation were similar between groups.

Among couples who provided follow-up data, the strapped device was used in an average of 87% of all coital acts and the unstrapped device in 89% of acts. The average number of coital acts per week was similar in both groups: 2.4 (SD 1.32) for the strapped-device users and 2.2 (SD 1.50) for the unstrapped-device users.

Comparison of the strapped FemCap group vs. the historical control group on secondary objectives is summarized in Table 3. The proportions of women experiencing dislodgment and having evidence of cervical/vaginal irritation on naked eye exam were similar in the two device groups. Pain/discomfort was significantly worse for both female and male participants using the strapped device, being reported in 27% of women in the strapped group vs. 12% in the unstrapped group (pain/discomfort vs. none: OR=2.81; 95% CI=1.36–5.83; $p = .0027$, one tailed) and in 14% vs. 4%, respectively, of men (OR= 2.08; 95% CI = 1.25–3.44; $p = .0023$, one tailed). However, there was no significant difference in the odds of females reporting awareness of the device. Neither of the two men whose female partners discontinued the study due to male penile discomfort reported having sustained a visible penile injury.

Responses to the selected acceptability items on the 2-week questionnaire are shown in Table 4. Whereas women in the unstrapped group liked their device significantly more than women in the strapped group, males did not significantly differ in their general opinion of the device or whether they would recommend it to a friend. However, among persons with diaphragm experience, both women and men in the strapped group had significantly higher odds than those in the unstrapped group of having less preference for the FemCap (i.e., preferring the diaphragm or having no preference) (OR=2.75; 95% CI=1.11–6.81; $p = .0286$, two tailed). Some users expressed the opinion that the strap should have been placed in a transverse rather than anterior–posterior orientation over the dome.

Of the 449 women (95 strapped group, 354 unstrapped group) in the pregnancy analysis, 2 (2.1%) in the strapped group and 11 (3.1%) in the unstrapped group had a study pregnancy. The cumulative 6-week probability for women in the strapped group was 2.15 per 100 women (95% CI=0.00–5.24). This was not significantly different from that of the unstrapped group (3.37 per 100 women, 95% CI=1.34–5.39, log-rank $p=.5933$). Pregnancy was not an endpoint in the study, and it was not expected that there would be sufficient power to make a meaningful comparison of pregnancy rates.

4. Discussion

The developer of FemCap modified the unstrapped device principally to address device removal difficulties identified in the contraceptive effectiveness trial [1]. Results of the current study indicate that the modifications to FemCap did not significantly improve ease of device removal. A possible explanation is that there may not have been sufficient room between the newly added strap and the dome to allow gripping of the strap by the fingertip. Also, the higher brim of the medium- and large-size devices, a modification intended to increase the internal stability of the device, may have made it necessary to exert more force to remove the cap. Placing the strap transversely, as suggested by some users, may have made removal easier.

The modifications apparently had the undesired effect of increasing reports of pain by both partners. The presence of the strap in the path of the penis may have contributed to reports of partner discomfort, and the increased bulk of the device may have been responsible for discomfort of both the female participants and their partners.

Compared with users of the unstrapped device, women using the strapped device were significantly more likely to say they disliked their device. Among men and women with diaphragm experience, persons using the strapped device were more likely to prefer the diaphragm or to have no preference than those using the unstrapped device. It is possible that although similar data sources were used to determine the partner pain endpoint, the added emphasis in the strapped study on the males' experience (i.e., the supplementary questionnaire) may have caused a selection bias due to differences in willingness of men to be enrolled in the two studies, or may have heightened the men's awareness of, memory of or willingness to report device problems. This explanation does not apply to the differences observed in the women's opinions.

For the three objectives in which a significant difference between groups was not found (removal problem, dislodgment, cervical/vaginal irritation), the study had less statistical power than expected (e.g., 64% power to detect the odds ratio associated with the hypothesized 21% reduction in removal problems). The fact that the observed relative effect sizes were in all cases less than the hypothesized effect sizes (12% vs. 21% reduction in removal problems, 21% vs. 52% increase in dislodgment, 24% vs. 112% increase in irritation) suggests that insufficient statistical power is not the sole reason the hypotheses were not confirmed. Observed relative proportions were a 3% increase in slight removal problems, a 32% decrease in moderate removal problems and a 44% increase in severe removal problems.

Pregnancy was not an endpoint of the study, and it was not expected that there would be sufficient power to make a meaningful comparison of pregnancy rates; therefore, no conclusion should be drawn from the two pregnancies observed.

Although the use of historical controls is never as rigorous an evaluation of a product as a head-to-head prospective, randomized, controlled trial, the use of virtually identical data collection methods, the careful attention paid to covariate analysis in this study and the fact that two of the sites were common to both studies give us confidence that the comparison between the modified device and the historical controls was valid.

Because the strapped device differed from the original design in more than one aspect, it cannot be determined if only one or both modifications may have led to the problems reported by users and their male partners. The U.S. Food and Drug Administration approved the strapped FemCap for use as a barrier contraceptive in March 2003. The device will suit the needs of some users and expand the range of contraceptive options available to women. What is of interest to practicing clinicians is not the comparison between two devices, one of which was not submitted for approval, but rather the advice that the clinician may give patients as to the likelihood of removal problems as well as other side effects that may be experienced by users of this device.

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References

1. Mauck C, Callahan M, Weiner DH, Dominik R. the FemCap Investigators' Group. A comparative study of the safety and efficacy of FemCap, a new vaginal barrier contraceptive, and the Ortho All-Flex diaphragm. *Contraception* 1999;60:71–80. [PubMed: 10592853]
2. Manual for the standardization of colposcopy for the evaluation of vaginally administered products, update 2000. CONRAD and the World Health Organization; 2000.
3. Rosenbaum PR, Rubin DR. Reducing bias in observational studies using subclassification on the propensity score. *J Am Stat Assoc* 1984;79:516–24.
4. Peto R, Pike MC, Armitage P, et al. Design and analysis of randomized clinical trials requiring prolonged observation of each patient. II. Analysis and examples. *Br J Cancer* 1977;35:1–39. [PubMed: 831755]

Fig. 1.
FemCap with removal strap.

Table 1

Selected baseline characteristics, enrolled population

	Strapped FemCap, <i>n</i> =120	Unstrapped FemCap, <i>n</i> = 419
Age (years, mean±SD)	29.7±5.9	29.1±5.7
Race (number, %)		
Caucasian	100 (83.3%)	298 (71.1%)
African American	15 (12.5%)	89 (21.2%)
Hispanic	1 (0.8%)	20 (4.8%)
Other	4 (3.3%)	12 (2.9%)
Education (years in school, mean±SD)	14.8±2.6	14.8±2.4
Marital status (number, %)		
Living with partner	99 (82.5%)	266 (63.5%)
Lifetime obstetrical history (number, %)		
Ever pregnant	90 (75.0%)	317 (75.7%)
Vaginal delivery	66 (55.0%)	210 (50.1%)
History of use of (number, %)		
Any female barrier method ^a	53 (44.2%)	261 (62.3%)
Diaphragm	35 (29.2%)	161 (38.4%)
Cervical cap	2 (1.7%)	16 (3.8%)
Contraceptive sponge	26 (21.7%)	165 (39.4%)
Female condom	9 (7.5%)	12 (2.9%)
Spermicide alone	50 (42.0%)	111 (26.5%)
Vaginal film	10 (8.3%)	33 (7.9%)
Height (in., mean±SD)	64.4±3.3	65.0±2.7
Weight (lb, mean±SD)	167.0±42.3	153.0±37.5
Position of uterus (number, %)		
Anteverted	76 (63.9%)	280 (67.1%)
Midline	25 (21.0%)	79 (18.9%)
Retroverted	18 (15.1%)	58 (13.9%)
Diaphragm measurement (mm, median)	75.0	70.0
Colposcopy findings ^b	23 (23.7%)	4 (20.0%)

^aDefined as ever use of diaphragm, cervical cap, Lea's Shield®, FemCap, sponge or female condom. Prior experience with the FemCap was an exclusion criterion for the strapped study. It was not an exclusion criterion for the FemCap/diaphragm study; however, none of the women in the unstrapped FemCap group had prior experience with the device.

^bFigures apply only to participants who provided follow-up data and, for the unstrapped group, who participated in the colposcopy substudy (denominator is 97 for the strapped group and 20 for the unstrapped group).

Table 2

Comparison of device groups on ease of removal (primary objective)

Removal problem ^a	Strapped FemCap (n = 120)		Unstrapped FemCap (n =419)	
	n	%	n	%
Severe	14	12	34	8
Moderate	29	24	148	35
Slight	21	18	71	17
None	56	47	166	40

^a Odds ratio is controlled for baseline characteristics. Proportional odds assumption violated. Generalized logits model testing strapped vs. unstrapped groups on odds of removal problem, controlling for propensity score. Severe vs. none: OR=0.67 (95% CI=0.27–1.68), p= .1975, one-tailed; moderate vs. none: OR=0.56 (95% CI= 0.30–1.05), p=.0343, one tailed; slight vs. none: OR= 0.96 (95% CI =0.47–1.95), p= .4526, one tailed. It may seem counterintuitive that the odds ratio for strapped vs. unstrapped device for the severe-removal category is less than 1.0 (indicating that the strapped device is better), whereas the relative percentages gives the opposite impression. This is due to the effect of controlling for propensity score. In a generalized logits model not controlling for propensity score, the odds ratio for the strapped group was 1.22 (data not shown).

Table 3Comparison of device groups on secondary objectives^a

	Strapped FemCap (n =97)^a		Unstrapped FemCap (n = 348)	
	<i>n</i>	%	<i>n</i>	%
<i>Dislodgement^b</i>				
Yes	30	30.9	89	25.6
No	67	69.1	259	74.4
<i>Participant pain/discomfort^c</i>				
Pain/discomfort	26	26.8	42	12.1
Awareness only	16	16.5	63	18.1
None	55	56.7	243	69.8
<i>Partner pain/discomfort^{d,e}</i>				
Pain/discomfort	13	13.7	13	3.9
Awareness only	40	42.1	128	38.1
None	42	44.2	195	58.0
<i>Cervical/vaginal irritation^{f,g}</i>				
Yes	7	7.22	20	5.81
No	90	92.8	324	94.2

^aIncludes only couples providing follow-up data and who used the device at least once.^bLogistic regression testing strapped vs. unstrapped device, controlling for propensity score: OR= 1.28; 95% CI= 0.69–2.38, p = .2184, one tailed.^cProportional odds assumption violated. Generalized logits model testing strapped vs. unstrapped groups, controlling for propensity score: pain vs. none, OR= 2.81, 95% CI=1.36–5.83, p =.0027, one tailed; aware vs. none, OR=1.40 (95% CI= 0.65–3.01), p = .1956, one tailed.^dFrom 95 partners in the strapped group and 336 partners in the unstrapped group providing data.^eProportional odds regression testing strapped vs. unstrapped device, controlling for propensity score: OR= 2.08, 95% CI= 1.25–3.44, p = .0023, one tailed.^fFrom 97 women in strapped group and 344 women in unstrapped group with exam data.^gResults of logistic regression analysis controlling for propensity score: OR= 0.71, 95% CI= 0.23–2.17, p =.7253, one tailed.

Table 4

Comparison of device groups on tertiary acceptability endpoints^a

	Strapped FemCap				Unstrapped FemCap			
	Participants		Partners		Participants		Partners	
	n	%	n	%	n	%	n	%
<i>General opinion^{b,c}</i>								
Liked a lot	26	28.0	15	18.1	98	29.8	58	22.1
Liked somewhat	35	37.6	23	27.7	154	46.8	72	27.4
Neutral	12	12.9	29	34.9	42	12.8	96	36.5
Disliked somewhat	15	16.1	11	13.3	30	9.1	25	9.5
Disliked a lot	5	5.4	5	6.0	5	1.5	12	4.6
Total	93		83		329		263	
<i>Recommend to friend^{d,e}</i>								
No	15	16.5	29	35.8	41	12.7	67	27.3
Yes	76	83.5	52	64.2	282	87.3	178	72.7
Total	91		81		323		245	
<i>Preference among FemCap users with diaphragm experience^{f,g}</i>								
Prefer FemCap	11	44.0	9	31.0	94	72.3	46	51.1
Prefer diaphragm	11	44.0	11	37.9	28	21.5	14	15.6
No opinion	3	12.0	9	31.0	8	6.2	30	33.3
Total	25		29		130		90	

^aFrom the 2-week questionnaire. Excludes respondents who did not use device or who completed questionnaire after knowing they had a positive pregnancy test. Some categories were collapsed for analysis.

^bParticipants: proportional odds assumption violated. Generalized logits model comparing strapped vs. unstrapped groups, controlling for propensity score: dislike vs. like a lot, OR=2.88, 95% CI =1.19–6.99, p =.0193, two tailed; neutral vs. like a lot, OR=1.14, 95% CI =0.44–2.98, p =.7825, two tailed; like somewhat vs. like a lot, OR=0.95, 95% CI=0.47–1.91, p =.8787, two tailed.

^cPartners: proportional odds regression comparing strapped vs. unstrapped groups on odds of having a worse opinion of the device, controlling for propensity score, OR= 1.29, 95% CI=0.78–2.15, p =.3252, two tailed.

^dParticipants: logistic regression comparing strapped vs. unstrapped groups on odds of not recommending device to a friend, controlling for propensity score, OR= 1.49, 95% CI= 0.67–3.34, p =.3309, two tailed.

^ePartners: logistic regression comparing strapped vs. unstrapped groups on odds of not recommending to a friend, controlling for propensity score, OR= 1.45, 95% CI =0.79–2.67, p =.2317, two tailed.

^fParticipants: proportional odds assumption violated. Generalized logits model comparing strapped vs. unstrapped groups, controlling for propensity score; prefers diaphragm vs. prefers FemCap, OR=3.88, 95% CI=1.16–12.97, $p = .0275$, two tailed; no preference vs. prefers FemCap, OR= 10.04, 95% CI = 1.50–67.15, $p = .0173$, two tailed.

^gPartners: proportional odds regression comparing strapped vs. unstrapped groups on odds of not preferring the FemCap, controlling for propensity score, OR= 2.75, 95% CI= 1.11–6.81, $p = .0286$, two tailed.