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Retrospective vs. Prospective Coital Frequency and Menstrual Cycle Length in a Contraceptive Effectiveness Trial

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PURPOSE: To determine how well information at enrollment would predict coital frequency and menstrual segment length during a prospective contraceptive effectiveness trial.
METHODS: We compared retrospective reports of monthly coital frequency and menstrual segment (cycle) length with prospective information for women participating in a contraceptive trial of the Reality® female condom.
RESULTS: Participants reported slightly higher mean monthly coital frequency and slightly longer menstrual segments prior to the study than during the study (12.6 acts vs. 12.0 acts per month and 30.8 days vs. 28.4 days). We examined the actual distribution of differences between the retrospective and prospective measures and found considerable variability. Among the 195 participants studied, parous women were less likely to predict accurately menstrual segment length (OR 0.4; 95% CI 0.3–0.9), while older women were more likely to predict accurately coital frequency (OR 1.9; 95% CI 0.9–3.3).
CONCLUSIONS: Coital frequency and menstrual segment length vary considerably over time. Hence, prospective data collection is essential to accurately characterize these variations and to properly interpret results from contraceptive trials and other studies concerned with fecundability and hazards of reproduction.
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KEY WORDS: Female Condoms, Menstrual Cycle, Coitus, Family Planning, Contraception Behavior.

INTRODUCTION

Coital frequency and menstrual segment length may have a substantial influence on the risk of pregnancy (1–5). In contraceptive trials, the primary outcome of interest is the risk of pregnancy during a prescribed period of time using an assigned contraceptive method. Accurately characterizing coital frequency and menstrual segment length is important for interpreting the results of contraceptive trials since the risk of pregnancy is not solely influenced by efficacy of the method.

Currently, much debate centers around different methodologic approaches of collecting sexual behavior data to increase validity (6–13). Some investigators have demonstrated that coital frequency reported retrospectively is higher than coital frequency reported prospectively on daily diaries and argue that the prospective data are more valid (14, 15). Others believe this perceived increase in data quality is not worth the logistical demands of daily data collection. For example, some current randomized controlled trials of vaginal products under the auspices of Family Health International (FHI) have eliminated daily diaries entirely, while other FHI studies continue the task of collecting this detailed information.

Contraceptive trials often employ strict selection criteria to enroll participants with a specified level of coital frequency (e.g., two or more acts per week) and menstrual segments within a certain range (e.g., 21–35 days). A question of interest for researchers of contraceptive methods, as well as those concerned with fecundability and hazards to reproduction, is how well information provided during enrollment will predict coital frequency and menstrual segment length during a prospective study. In other words, is it possible to select participants who will have a certain coital frequency and segment length profile during a prospective study based on information reported during the enrollment interview? This selection will not be possible if these two factors vary greatly from cycle to cycle. If substantial variability of coital frequency and segment length occurs over time, then more frequent data collection will be required to accurately characterize this variability.

Information about length and variability of menstrual cycles comes mainly from four menstrual diaries studies (16–19) recently reviewed by Harlow and Ephross (20). How well findings from these large-scale prospective studies apply to

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Selected Abbreviations and Acronyms

FHI = Family Health International

women who participate in contraceptive trials is not known. One relevant finding is that women 20 to 40 years in age reported the least amount of variability in cycle length. This is the general age range typically recruited into contraceptive trials. To our knowledge, no published data are available on the intra-individual variability of coital frequency.

The goal of this analysis is to provide a detailed description of prospectively collected coital frequency and menstrual segment length data and to compare these data with retrospective information collected during an enrollment interview. The findings are aimed to guide the design of future contraceptive trials and observational studies with respect to frequency of data collection of important covariates influencing the risk of pregnancy.

METHODS

In previous work, data from 221 participants at six U.S. study sites were used to calculate the gross cumulative 6-month life-table probabilities of pregnancy among users of the Reality® female condom. A detailed description of the methods and the primary results are available elsewhere (21). Briefly, participants were eligible if they were between 18 and 40 years of age, were in an ongoing mutually monogamous heterosexual relationship, reported an average coital frequency of two or more acts per week, were willing to use the female condom as their only means of contraception for 6 months, and reported an average menstrual segment length between 21 and 35 days. The women were followed up at 1, 3, and 6 months after admission. Women recorded on daily diaries their menstrual bleeding, acts of intercourse and whether they used the female condom. In this article, we limit our analysis to the subset of 195 women with complete daily diary information during the course of the study.

This analysis has four components. First, we provide a detailed description of the retrospectively and prospectively collected data on coital frequency and menstrual segment length. The retrospective data come from the enrollment interview where participants were asked to report their average monthly coital frequency and average menstrual segment length. Each prospectively collected menstrual segment is counted from the first day of bleeding of one bleeding episode up to and including the day before the next bleeding episode (22). Second, we determine how well the retrospective information on average monthly coital frequency during the enrollment interview predicted the monthly coital frequency gleaned from the prospective daily diaries. Third, we determine how well average menstrual segment length reported during the enrollment interview predicted segment length calculated from the daily diaries. Fourth, we examine factors that were associated with the ability to predict accurately coital frequency and segment length.

Monthly coital frequency was coded as accurately predicted if it was within six acts of the monthly frequency reported during the enrollment interview, six acts being one standard deviation of the prospectively reported coital frequency. Segment length was coded as accurately predicted if it was within 1 week of the length the women reported during the enrollment interview. One week is close to one standard deviation of the segment length (8 days) and is a commonly used unit. Thus, for each of these two variables, coital frequency and segment length, we created a binary variable for how accurately the retrospective report predicted prospective information (1 = accurate and 0 = not accurate). An earlier article provides a detailed description of the decision rules we used to calculate monthly coital frequency and menstrual segment length (5).

We fit logistic regression models using generalized estimating equations (GEE) to adjust standard errors for correlation due to repeated outcome measures in SAS 6.12. Independent variables in the models included age (<30/>30 years), education (<14/>14 years), parity status (nulliparous/parous) and whether the woman reported exactly 28-day segments in the background interview (yes/no). This latter variable was included to evaluate the possibility that some of the large proportion of women who had reported 28-day segments (52%) did so because they did not actually know their own cycle length but believed that 28 days is typical.

RESULTS

The 195 participants with diary information had a mean age of 29 years (range 18–40) and had completed on average 14 years of education (range 1–21). A previous paper showed that the 195 women with diary information are similar to the total sample (N = 221) with respect to these background characteristics (5). Of the 195 women with complete daily diaries, 106 completed the 6-month study (188 women completed the first month; month 2 = 174; month 3 = 159; month 4 = 149 and month 5 = 143). The 195 women reported a mean monthly coital frequency of 12.6 acts/month and a mean segment length of 28.4 days during the enrollment interview (Table 1). During the trial, these participants were enrolled for a total of 968 person-months (30.5 days = 1 month) and recorded on their daily diaries a per-woman mean monthly coital frequency of 12.0. The participants recorded a total of 965 complete segments with a per-woman mean segment length of 30.8 days.

When we subtracted the woman's average monthly coital frequency reported on the background questionnaire

2

AEP Vol. 11, No. 6
August 2001: 428–433

TABLE 1. Participant characteristics

	N	Mean	Min	5%	10%	50%	90%	95%	Max
Coital frequency (acts per month)									
Mean acts (retrospective)	195	12.6	8	8	8	11	18	24	60
Mean of all acts across all months (prospective)	968	11.3	0	6	7	11	17	21	62
Mean of women's means (prospective)	195	12.0	4	7	8	11	17	20	54
Menstrual Segment Length (days)									
Mean segment (retrospective)	195	28.4	21	25	27	28	30	31	35
Mean of all segments across all months (prospective)	965	29.6	3	20	24	29	36	42	95
Mean of the women's means (prospective)	195	30.3	13	25	26	30	37	41	62

from her prospectively reported monthly coital frequencies, the result is a negatively skewed, peaked distribution with a mode of 0 (mean = −0.7; median = 0) (Figure 1). Thus women frequently had fewer acts of intercourse recorded in the prospective data than the retrospective data. The differences between the woman's prospectively reported segment lengths and average segment length reported on the background questionnaire produce a positively skewed, peaked distribution with a mode of 0 (mean = 1.4; median = 0) (Figure 2). Thus women's segments were frequently longer, often quite a bit longer, in the prospective data.

Figures 3 and 4 illustrate the proportion of women who were able to predict their prospectively recorded coital frequency and segment length based on the information provided during enrollment. For over two-thirds of the women (70%), all their prospective monthly coital frequencies were within six acts of what they reported on their background questionnaire. For about half (53%) of the women, all the prospective segments fell within 1 week of what they retrospectively reported their average menstrual segment to be at enrollment.

Older age was related to the woman's ability to accurately predict coital frequency (OR 1.7; 95% CI 0.9–3.2) (Table 2). This association persisted when adjusted for education and parity. Parous women were less likely to predict their menstrual segments accurately than were nulliparous women (crude OR 0.4; 95% CI 0.2–0.8) (Table 3). Again, this association remained when adjusted for age, education and cycle length. Because participants were enrolled for varying amounts of time, these last two results could be biased (e.g., parous women might remain in the study longer, thereby increasing their chance of experiencing an inaccurate menstrual segment). To control for this potential bias, we repeated the analysis for the subset of women who contributed at least 3 months of data. Once again, the results remained virtually unchanged.

DISCUSSION

Information about average coital frequency and average menstrual segment length collected during the enrollment

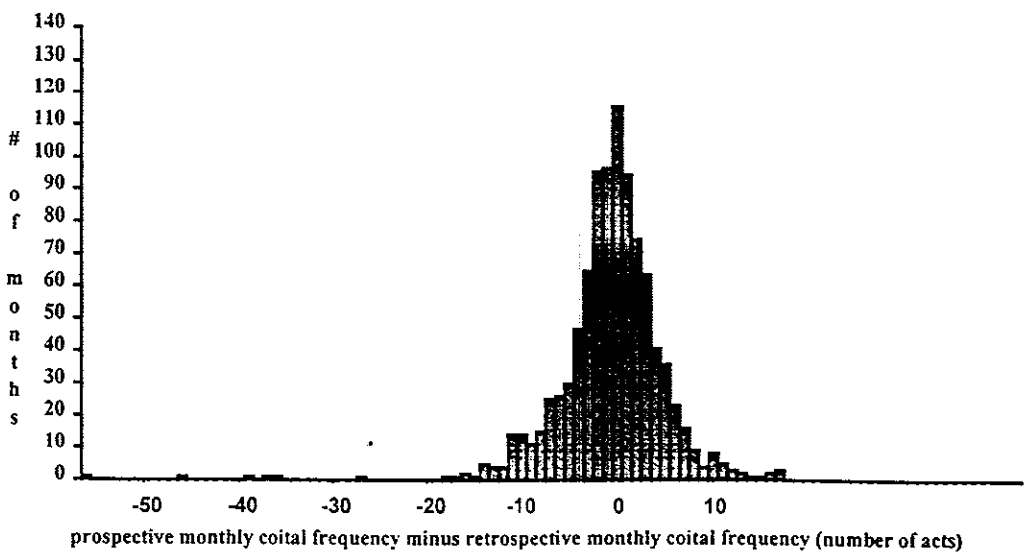

FIGURE 1. Prospectively minus retrospectively reported coital frequency (N = 968).

3

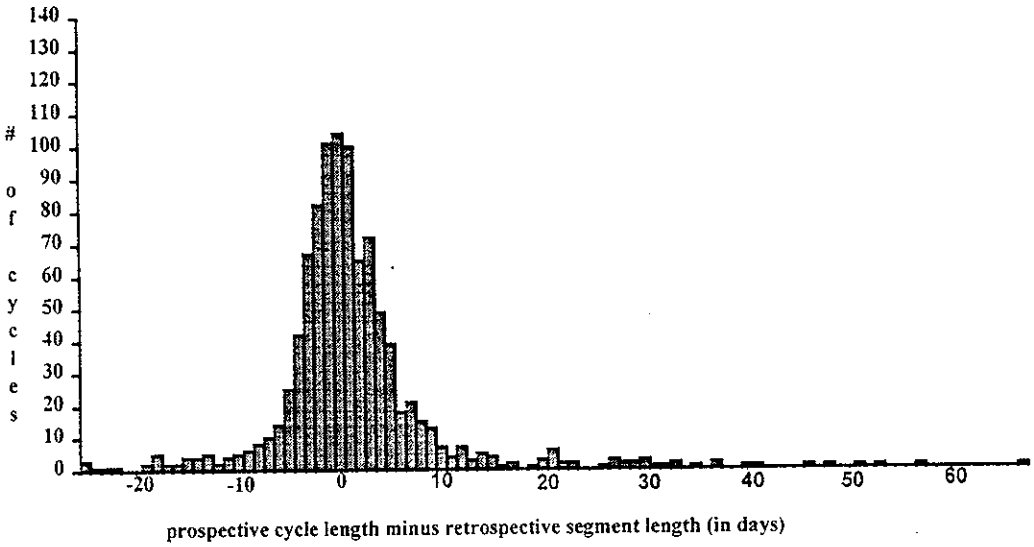

FIGURE 2. Prospectively minus retrospectively reported segment length (N = 965).

interview of the Reality® female condom trial failed to predict accurately these two factors during the 6-month prospective study. Similar to past studies (14, 15), we found that women may exaggerate coital frequency during an enrollment interview. However, contrary to expectations, the difference was not as dramatic here (difference per month = 0.6; 12.6 vs. 12.0 acts per month) as in previous studies [difference per month = 3.2 acts (14) and 1.6 acts (15)]. In the current study, participants were followed for up to 6 months, whereas in the two previous studies, participants were followed for 1 to 3 months.

To be enrolled into the study, participants had to report average menstrual segment lengths between 21 and 35 days. Over 15% of all prospectively reported segment lengths were outside this range, with some substantially shorter or longer (minimum 3 days, maximum 95 days). Because we did not collect daily urine to help determine segment length, but rather relied solely on self-reported information, we have no way to determine which segments are true menstrual cycles. Instead of making an arbitrary decision on what constitutes a true cycle (e.g., delete segments less than 15 days) we decided to present the complete data. We certainly suspect that some of the very long segments may have been caused by participants simply not completing the daily diaries properly. When compared to a recent study characterizing menstrual segment lengths of healthy premeno-

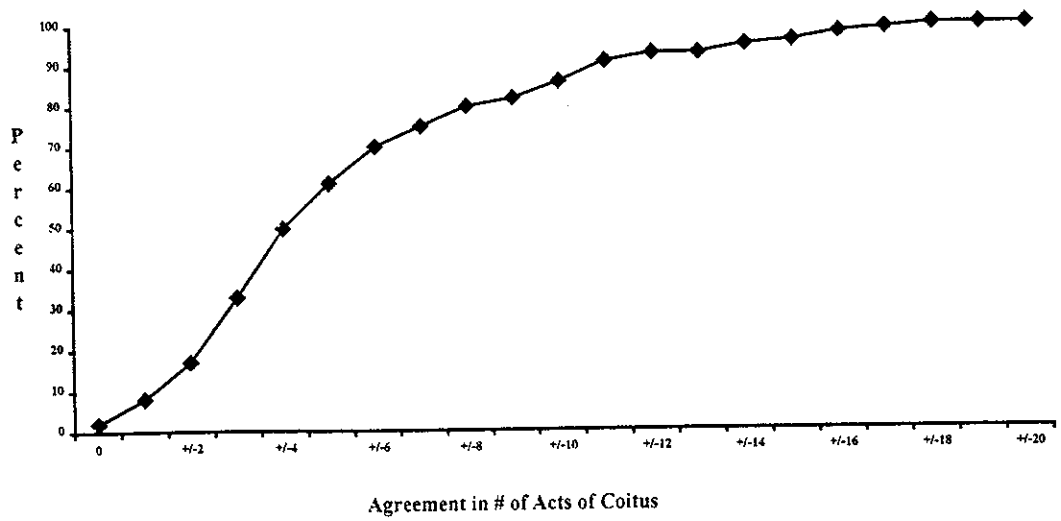

FIGURE 3. Agreement between prospective and retrospective coital frequency. Percent of women with all prospective monthly coital frequency within given range (N = 195).

4

AEP Vol. 11, No. 6
August 2001: 428–433

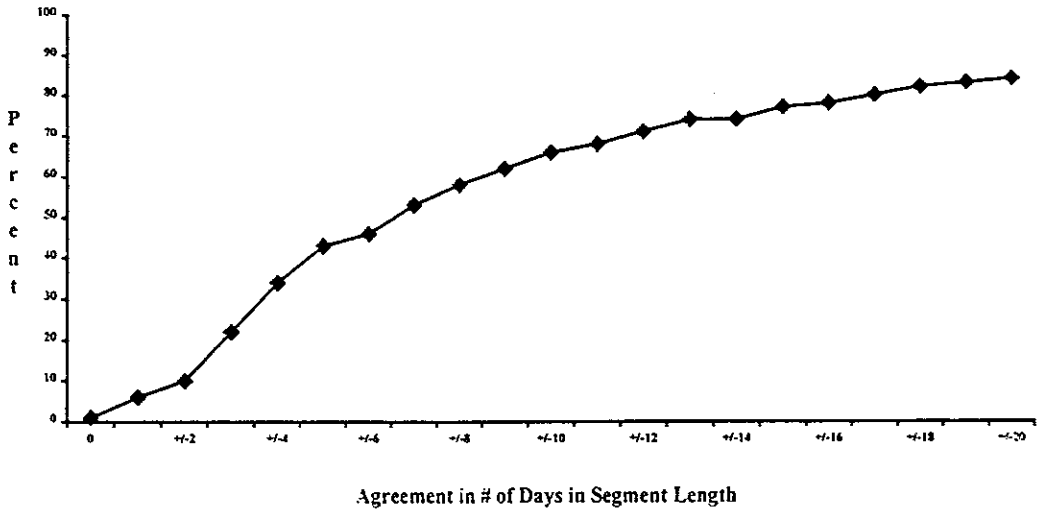

FIGURE 4. Agreement between prospective and retrospective segment length. Percent of women with all prospective cycles within given range ($N = 195$).

pausal women using daily urine biomarkers (23), the distribution of segments in our study was wider with a higher mean and median (29.6 vs. 28.8 days, 29 vs. 28 days, respectively). How much of this difference is due to reporting error in our cohort cannot be determined and reflects the most serious limitation of studies that rely exclusively on self-reported information regarding menstrual segment length.

The implications of our analysis are two-fold. First, the selection criteria used to recruit participants were not sufficient to ensure that participants would have a certain profile of coital frequency and segment length during the study. Second, even with more strict selection criteria to exclude women with substantial variation in coital frequency and menstrual segment length, these factors are likely to continue to vary considerably over time. If we are to accurately characterize these variations, prospective data collection remains essential.

Fortunately, two technological advances show promise in reducing the burden of frequent data collection during a prospective contraceptive trial. First, advances in telecommunication permit the programming of short surveys that can be accessed by dialing a toll-free telephone number and answered by participants using a telephone keypad. An FHI pilot study of this approach showed participants in contraceptive trials may be willing and able to call daily to report their sexual behavior and contraceptive use (24). An advantage of this technology is that we can document when a participant is providing information for a certain day. Using daily diaries in the past, we had no means of preventing participants from completing all the daily diaries immediately before the follow-up visit and thus reducing the validity of the data. A further advantage is that we can analyze the incoming data on a daily basis and contact participants as soon as they become non-compliant with the study protocol.

The second technological advance that shows promise for contraceptive research is a simple device to assay hor-

TABLE 2. Characteristics associated with being able to predict coital frequency (within plus or minus six acts, $N = 195$)

	Accurate	Not accurate	Crude OR (95% CI)	Adjusted OR[a] (95% CI)
Age				
≥30 years	74	24	1.7	1.9
<30 years	62	35	(0.9–3.2)	(1.0–3.8)
Education				
≥14 years	87	39	0.9	0.8
<14 years	49	20	(0.5–1.7)	(0.5–1.8)
Parity				
≥1	88	33	1.4	1.4
0	48	26	(0.8–2.7)	(0.7–2.7)

[a]Using GEE and all months ($N = 968$).

TABLE 3. Characteristics associated with being able to predict segment length (within plus or minus one week, $N = 195$)

	Accurate	Not Accurate	Crude OR (95% CI)	Adjusted OR[a] (95% CI)
Age				
≥30 years	56	42	1.4	1.3
<30 years	48	49	(0.8–2.4)	(0.8–2.1)
Education				
≥14 years	70	56	1.3	1.1
<14 years	34	35	(0.7–2.3)	(0.7–1.8)
Parity				
≥1	55	66	0.4	0.5
0	49	25	(0.2–0.8)	(0.3–0.9)
Reported 28-day cycles				
Yes	54	43	1.2	1.0
No	50	48	(0.7–2.1)	(0.7–1.7)

[a]Using GEE and all cycles ($N = 965$).

5

mones at home (25). This computerized device measures urinary luteinizing hormone (LH) and estrone-3-glucuronide (E3G) throughout the cycle and uses an algorithm to divide the menstrual segments into low fertility, high fertility and peak fertility around ovulation. The device can also record days on which a participant engaged in intercourse by inserting an event card into the device. These data should help us understand the relative effectiveness of different contraceptive methods by accurately characterizing the exposure to the risk of pregnancy.

We hope these two technologies will be embraced by researchers to help improve the quality of the detailed information regarding sexual behavior necessary for the evaluation of contraceptive effectiveness. In the meantime, the type of analysis presented in this article confirms the need for prospective data on coital frequency and segment length.

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6