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A Comparison of the Fertile Phase As Determined by the Clearplan Easy Fertility Monitor™ and Self-Assessment of Cervical Mucus

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A comparison of the fertile phase as determined by the Clearplan Easy Fertility Monitor™ and self-assessment of cervical mucus

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Abstract: *The purpose of this study was to compare the fertile phase of the menstrual cycle as determined by the Clearplan Easy Fertility Monitor (CPEFM) with self-monitoring of cervical mucus. One-hundred women (mean age = 29.4 years) observed their cervical mucus and monitored their urine for estrogen and luteinizing hormone metabolites with the CPEFM on a daily basis for 2–6 cycles and generated 378 cycles of data; of these, 347 (92%) had a CPEFM peak. The beginning of the fertile window was, on average, day 11.8 (SD = 3.4) by the monitor and day 9.9 (SD = 3.0) by cervical mucus ($r = 0.43$, $p < 0.001$). The average first day of peak fertility by the monitor was 16.5 (SD = 3.6) and by cervical mucus 16.3 (SD = 3.7) ($r = 0.85$, $p < 0.001$). The mean length of the fertile phase by the monitor was 7.7 days (SD = 3.1) and by cervical mucus 10.9 days (SD = 3.7) ($t = 12.7$, $p < 0.001$). The peak in fertility as determined by the monitor and by self-assessment of cervical mucus is similar but the monitor tends to underestimate and self-assessment of cervical mucus tends to overestimate the actual fertile phase*.

1. Introduction

Researchers have demonstrated that there is a potential 6-day window of fertility in a woman's menstrual cycle and that peak fertility occurs on the 2 days preceding ovulation [1, 2]. The fertile window includes the 5 days before ovulation and the day of ovulation. The accurate determination of those 6 days of fertility (i.e., the fertile phase) and the peak of fertility is critical for women and couples who wish to use natural biological markers to achieve or avoid pregnancy.

Self-monitoring of cervical-vaginal mucus is one of the most common biological markers used in the self-assessment of the fertile window. The estrogen rise from a ripening follicle in each menstrual cycle stimulates cervical mucus production and indicates the beginning of fertility. The cervical mucus progresses from a tacky cloudy appearance to a clear, slippery, watery consistency at the peak of fertility. The peak in cervical mucus correlates closely with the day of ovulation and indicates the beginning of the end of the fertile window [3, 4]. However, cervical mucus can at times be a confusing and subjective biological marker [4–7].

The Clearplan Easy Fertility Monitor (CPEFM; Unipath Diagnostics Company, Princeton, NJ, USA) is a new electronic device that has been developed to help women to determine their fertile window [8]. The CPEFM measures urinary metabolites of estrogen and luteinizing hormone

(LH) and provides the user with a daily indication of “low,” “high” and “peak” fertility. The monitor is currently sold and marketed in the United States only as a device to aid in achieving pregnancy. Evidence from the manufacturer shows that, on average, the monitor will provide the user with 3–5 days of high to peak fertility [8]. Research also shows a strong correlation of the CPEFM “peak” with the actual day of ovulation as determined by serial transvaginal ultrasound and serum measures of LH [9]. Used alone, the CP monitor does not always provide a long enough warning before fertility to be used as a device to prevent pregnancy. A pregnancy could occur because sperm can live from 3–5 days in cervical mucus before the actual day of ovulation. If the CPEFM is used in conjunction with the information provided by other natural markers of fertility (i.e., cervical mucus), the information and feedback provided by each marker might facilitate a more accurate determination of the fertile window. The specific objective of this study was to compare the beginning, peak, and length of fertility in a woman’s menstrual cycle as determined by the CPEFM with the beginning, peak and length of the fertile period as determined by self-monitoring of cervical mucus. The comparison was made with a 6-day fertile phase as the standard for comparison (i.e., the day of ovulation and the 5 days preceding ovulation). The estimated day of ovulation was defined as the day after the LH surge or, i.e., the second “peak” day on the CPEFM.

2. Materials and methods

Potential women participants were recruited from a university clinic and a private medical practice. The first 100 healthy women who were seeking to learn how to monitor their fertility for the purpose of avoiding pregnancy were taught how to observe their cervical mucus and were invited to monitor their urine for estrogen and LH metabolites with the CPEFM on a daily basis for two to six cycles. Criteria for participation were that the participant be between the ages of 18 and 42 years; have a menstrual cycle range of 21–42 days; had not used depot medroxyprogesterone acetate over the past 12 months; had no history of oral or subdermal contraceptives for the past 3 months; if post-breastfeeding, to have experienced at least three cycles past weaning and have no known fertility problems. All 100 participants signed a research consent form approved by a university office of research compliance before beginning the study. The same office approved the research protocol as meeting Federal regulations for human subject protection.

2.1. Measurement of fertility by the CPEFM

The CPEFM is a handheld electronic device that provides the users with a daily reading of “low,”“high” or “peak” fertility. The high reading of the monitor indicates the rising level of urinary estrone-3-gluconuride (E3G) and the peak reading indicates the surge in urinary LH. The monitor will automatically provide 2 days of “peak” readings followed by 1 day of “high.” For this study, the

fertile period for the CPEFM was defined from the first day of a “high” reading until 1 full day past the last “peak” day, i.e., all “high” and “peak” readings on the monitor.

The CPEFM is based on urinary hormonal immunoassay techniques. Product testing has shown the CPEFM to be 98.8% accurate in detecting the LH surge [8]. The CPEFM detected the LH surge in 169 of 171 cycles from 88 women, in agreement with a quantitative radioimmunoassay for LH. Detection of urinary metabolites of urinary estradiol (E3G) has been recognized by the World Health Organization (WHO) as a reliable marker for the beginning of the fertile phase of the menstrual cycle [10]. In a study with 90 women who used the CPEFM for 1–4 cycles, in 352 cycles with an LH surge, the first day of high fertility (i.e., the day of the threshold rise in E3G) was 3.01 ± 2.33 days before the LH surge [8].

The CPEFM is initiated when the user pushes a button on the monitor labeled “M” on the first day of her menses. The monitor then indicates which day of the cycle the user is on. The monitor requests either 10 or 20 daily urine tests per cycle. When the monitor requests a test, the user places the test strip under her urine stream for 3 s only. The test strip is then placed in the monitor and read. The participants in this study recorded on a specially designed fertility chart their fertility status (low, high or peak) and any intercourse that occurred on a daily basis.

2.2. Measurement of the fertile period by monitoring cervical mucus

The beginning of the fertile period was defined as the first day that cervical mucus is observed or felt. The peak day of cervical mucus is the last day of clear, stretchy and/or slippery mucus. The end of the fertile period is the third day past the peak day. These are standard criteria for the fertile period as defined by the ovulation method (OM) and are the criteria that were used in the WHO (1983) multicountry study of the OM [11]. The women participants were asked to observe their cervical mucus on a daily basis (i.e., at each void) and to make mental notes of the sensations and observed characteristics. The mucus was rated on a 1–8 scale (with 1 = “dry sensation, no mucus” to 7 = “stretchy, slippery and clear” or 8 = “slippery sensation, variable amount”). The “peak” day of cervical mucus observations was defined as the last day of the 7 or 8 rating—which in effect was the last day of “clear, stretchy, or slippery mucus.” The mucus ratings were modified from a scale used by Flynn and Lynch in a study that correlated self-assessed mucus with plasma levels of LH [12]. The cervical mucus observations and ratings were recorded daily on a fertility chart. Two certified professional nurse natural family planning (NFP) teachers verified the beginning and peak of the fertile period on each NFP chart. A 100% inter-rater agreement was obtained on a random selection of 30 charts for the (CPEFM and cervical mucus) beginning and peak day.

2.3. Data analysis

Information from the fertility charts were entered into a computer data set and analyzed with the 10.1 version of the Statistical Package for the Social Sciences (SPSS). To compare the fertile phase of the CPEFM with the fertile phase of cervical mucus monitoring, a mean, range, and standard deviation of the day of the beginning, peak, and length of each fertile period were determined. A Pearson's correlation was calculated between each of the variables of the CPEFM fertile phase with the cervical mucus fertile phase. A paired t test was calculated to determine if there were any significant differences between the mean day of the beginning, peak and length of the fertile phase between the two methods of fertility monitoring.

3. Results

3.1. Demographics

The 100 women participants had a mean age of 29.5 years (SD = 5.8; range, 20–42), 0–8 children (mean = 1.4, SD = 1.7) and at least a high school education. They generated 378 cycles of data, of which 346 (or 92.0%) had a CPEFM peak, 336 (or 89.4%) had a cervical mucus peak and 315 had both a CPEFM and cervical mucus (CM) peak. The length (of the 346 CPEFM cycles) was from 22 to 42 days with a mean of 29.1days (SD =3.2). The following results are from the 346 charts/cycles that had a CPEFM peak.

3.2. Beginning and peak of the fertile phase

The beginning of the fertile window was, on average, day 11.8 (SD = 3.4) as determined by the CPEFM monitor and on day 9.9 (SD = 3.0) by cervical mucus ($t = -9.16$, $p < 0.001$). The correlation between the two parameters ($n = 331$) was $r = 0.43$, $p < 0.001$. The average first day of peak fertility determined by the monitor was 16.5 (SD = 3.6; range, 8 –27) and by cervical mucus 16.3 (SD = 3.7; range, 6–39) ($t = -1.91$, $p < 0.06$). The correlation between the mucus "peak" and CPEFM "peak" ($n = 315$) was $r = 0.85$, $p < 0.001$.

3.3. Length of the fertile phase

The mean length of the fertile phase as determined by the first day of cervical mucus through 3 full days past the peak day of cervical mucus was 10.9 days (SD = 3.7). The mean length of the fertile phase as determined by the CPEFM was 6.7 days (SD = 3.1). There was a statistical difference between the mean length of fertility as determined by the two methods ($t = 18.80$, $p < 0.001$; $r = 0.27$, $p < 0.001$). Fig. 1 shows a visual comparison of the beginning, peak and length of the fertile phase as determined by the CPEFM and cervical mucus assessment.

3.4. Other statistical parameters

The average number of “high” day readings before the 2 “peak” days on the monitor was 4.0 (SD = 2.72) and the average total days of “peak type” mucus before the mucus “peak” was 3.7 (SD = 2.7) ($r = 0.201$, $p < 0.01$). Two-hundred and eight (61.0%) of the 341 CPEFM cycles (with “high” and “peak days”) had 5 days or more of “high” or “peak” fertility readings on the CPEFM before the estimated day of ovulation. There was a range of 1–16 days of “high” days before the first CPEFM “peak.” There were 246 (or 73.5%) of the cycles that had 5 days or more of mucus days before the estimated day of ovulation. The beginning of mucus ranged from 18 days before to 5 days after the estimated day of ovulation.

3.5. Mucus ratings

The average mucus ratings ranged from a low of 3.4 (SD =1.92) 6 days before the estimated day of ovulation to 6.6 (SD =1.76) the day before the estimated day of ovulation. The highest mucus ratings occurred on the 2 days before the estimated day of ovulation; see Fig. 2 for a graph of the mucus ratings. The mucus ratings dip to an average of 4.2 (SD = 2.2) the day after the estimated day of ovulation. Assuming that the higher ratings of mucus (i.e., the 7–8 ratings) coincide with higher levels of urinary E3G as indicated by a “high” reading on the monitor, Fig. 3 shows the frequency of the “7–8” mucus ratings in comparison with the frequency of “high” readings on the monitor the 6 days before the first “peak” monitor reading. The differences in frequency between the 7–8 mucus ratings and the “high” readings range from a low of “5” six days before the monitor “peak” to “52” two days before the monitor “peak.”

4. Discussion

The beginning of the fertile phase as determined by the CPEFM is, on average, almost 2 days later than the beginning of fertile phase as determined by the self-observation of cervical mucus. These results make sense in that the monitor is based on an elevated threshold level of urinary estrogen and is designed to target the high and peak days of fertility, i.e., narrow the fertile window. The first externally observed signs of cervical mucus probably reflect a lower level of circulating estrogen. A previous study demonstrated a fairly strong correlation between the first day of observed mucus and the first significant rise of urinary estrogen [12]. The average number of “high” day readings before the peak day of the monitor and the number of “peak type mucus” days before the peak day of cervical mucus were similar (4.0 vs. 3.7). This also makes physiological sense because higher estrogen levels probably stimulate the higher quality of cervical mucus. However, the correlation between the two parameters was fairly low ($r = 0.16$, $p < 0.1$).

The average day for the peak of fertility by the CPEFM and the self-observation of cervical mucus were very similar (i.e., day 16). The correlation of 0.85 (although high) is somewhat lower than found in previous studies (i.e., around 0.98) that correlated serum or urinary LH with the cervical mucus peak [4]. A recent study of 15 women in Turkey who generated 30 cycles of data with cervical mucus observations and urinary LH also showed that the average day of the LH surge and the peak mucus day was similar (i.e., day 13) [13]. The average length of the fertile phase by self-observation of cervical mucus in the Turkey study was 10 days.

The graph in Fig. 2 of the mean pattern of self-rated mucus before and after the estimated day of ovulation found in the current study was similar to the mucus patterns in two previous studies and also similar to the fecundity curve found in probability research [2, 4, 14]. The 2 “peak” days of self-rated cervical mucus equate with the 2 days of the highest fecundity in the menstrual cycle. This makes sense physiologically because sperm need good quality cervical mucus to survive, filter out poor quality sperm, to be capacitated and to seek out a viable egg (ovum). It also makes sense physiologically that the higher-rated mucus would coincide with the higher threshold of urinary E3G that the monitor detects. This is demonstrated by the close frequency of the “7–8” rated mucus with the frequency of the “high” readings on the monitor the 6 days before the urinary LH surge as seen in Fig. 3.

The fact that the average length of the fertile phase as determined by cervical mucus was statistically longer by almost 4 days as compared to the CPEFM fertile phase is not surprising. The fertility monitor was designed to narrow the fertile window and past studies that have shown that cervical mucus observations overestimate the fertile window by almost 200%, i.e., on average, about 4 days more than necessary. Most cervical mucus only methods include the menses as days of potential fertility and, therefore, add another 3–5 days to the time of abstinence. Cervical mucus monitoring also underestimated the beginning of the estimated 6-day fertile phase in about 26% of the cycles in this study. However, as expected, the CPEFM misses the beginning of the fertile window about 40% of the time.

The monitor tends to be more accurate in estimating the day of ovulation and the end of fertility. In a recent study on the CPEFM, ovulation as detected by ultrasound occurred 91.1% of the time during the 2 peak days on the monitor and 97.0% during the 2 peak days plus 1 (i.e., the high day after the peak) in 135 of 149 ovulatory cycles [9]. Ovulation never occurred before the first peak day. Studies on the peak of cervical mucus as a predictor of ovulation showed that the peak day can be off as much as 3 days or more and demonstrated that urinary LH is a more accurate predictor of ovulation [3, 4, 15]. However, in about 1 out of 10 cycles, the monitor will not

provide or detect a LH surge and record a “peak” day. In about 1 in 20 cycles there will be no peak in cervical mucus. A recent study detected a peak day of cervical mucus in only 75% (n = 215) of the 283 ultrasound confirmed ovulatory cycles [15]. The “peak” mucus absent cycles might reflect an anovulatory cycle. Proponents of mucus only methods suggest that if there is no mucus, then the woman is not fertile. However, research indicates that there is a probability of pregnancy even on dry mucus days in the actual 6-day fertile phase [16].

The implication these results have for women trying to achieve a pregnancy is that the use of the “high” and “peak” days on the fertility monitor and the peak days of cervical mucus are the best days to have intercourse to achieve pregnancy [17]. Focused intercourse on the high-quality days of cervical mucus have shown that they result in achieving pregnancy at a greater rate than random acts of intercourse throughout the menstrual cycle [18]. There might be some benefit to combining the two methods of estimating the fertile phase for women trying to achieve a pregnancy. One reason is that the peak in cervical mucus can be off by as much as 3 days and sometimes more. The monitor might help to pinpoint the high fertile days more accurately. Cervical mucus is also more subjective and when there is continuous mucus due to infections or irritations, the mucus sign can be confusing. However, without good cervical mucus present, the likelihood of pregnancy is diminished.

Use of the CPEFM and cervical mucus monitoring together as a means to avoid pregnancy might be beneficial. Having two markers to estimate the beginning, peak and end of the fertile time could be thought of as a double check. A recent European study that compared a double-check method (cervical mucus and a calendar count) with a single-check method found that the double-check method was somewhat more effective in helping couples to avoid pregnancy [19]. However, a downside is that this results in the risk of uncorrelated signs of fertility, e.g., the peak in mucus and the peak in LH are off. Users of this method would also have to realize that in approximately 8 –10% of their cycles, there would be no “peak” indication provided by the monitor. Furthermore, the monitor was designed only for women who have cycles between 21 and 42 days. Teaching couples and women how to monitor the two signs of fertility and to interpret them makes the process much more complex. The complexity of using both markers might also decrease the compliance with instructions and continuation of use. Users of the CPEFM and a similar fertility monitor (the Persona) have found the ease of use as a single measure of fertility to be high [20].

Use of the monitor as a sole source of avoiding pregnancy would be easier and more accurate if the monitor provided a longer preovulatory warning of fertility, i.e., detected a lower

threshold of estrogen. On average, the monitor provides a long-enough warning time in about 60% of the cycles. Therefore, to use the monitor as a method to avoid pregnancy would require the use of another marker, unless the woman user is comfortable with a 60% accuracy for the beginning of the fertile phase or uses the monitor as a postovulatory device only. One of the easiest markers would be to use a simple formula as a double-check for the beginning of the fertile time. For example, the earliest first peak day of the last 6 –12 cycles indicated by the monitor minus 5 days. The end of fertility would be the last day of "peak" on the monitor plus a count of 2 or 3 days, depending on how conservative you would want to be. Studies are underway to determine the effectiveness of these two approaches in using the CPEFM monitor as an aid to estimating the fertile window.

Problems that can occur when two biological signs are used to determine the fertile phase is that one of the two fertile signs is not observed or present or that the fertile signs do not correlate. When using the monitor, the "peak" of the monitor (i.e., the LH surge) should override the "peak" in cervical mucus. This is recommended because the monitor is actually measuring the hormone rather than a reaction to it. Furthermore, as previously stated, recent research has indicated that the LH surge is more accurate than the peak in cervical mucus [3, 15]. When the peak on the monitor is not present, it is the most problematic. This can be solved by utilizing another LH test in the evening to increase the likelihood of picking up the LH surge. Or you could use temperature recordings to verify the postovulatory phase or a calendar formula for the end of the fertile phase. A calendar formula is built into the electronic algorithm of the Persona monitor to determine the end of the fertile phase when the LH surge is not detected. Because the Persona utilizes the same technology as the CPEFM, most likely, about 1 in 10 of the cycles monitored will not have a detected LH surge [21].

The implications for health professionals are that both the CPEFM and the tracking of cervical mucus could be recommended for those women/couples trying to achieve pregnancy [17]. However, the use of cervical mucus will necessitate training and guidance. The use of the monitor for avoiding pregnancy with other markers of fertility has promise. However, the monitor is not recommended for use in avoiding pregnancy at this time. Protocols for such use are currently in review and research.

References

[1] Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation: effects of the probability of conception, survival of the pregnancy, and sex of the baby. N Engl

J Med 1995; 333:1517–21.
[2] Dunson DB, Baird DD, Wilson AJ, Weinberg C. Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation. Hum Reprod 1999; 14:1835–9.
[3] Guida M, Tommaselli GA, Palomba S, et al. Efficacy of methods for determining ovulation in a natural family planning program. Fertil Steril 1999; 72:900–4.
[4] Fehring R. Accuracy of the peak day of cervical mucus as a biological marker of fertility. Contraception 2002; 66:231–5.
[5] Moghissi KS. Prediction and detection of ovulation. Fertil Steril 1980; 34:89–98.
[6] Moghissi KS. Cervical mucus changes and ovulation prediction and detection. J Reprod Med 1986; 31(Suppl):748 –53.
[7] Batzer F. Test kits for ovulation and pregnancy. Technol 1987: Contemp Ob/Gyn 1986; 28:7–16.
[8] May K. Home monitoring with the ClearPlan Easy Fertility Monitor for fertility awareness. J Int Med Res 2001; 29(Suppl 1):14A–20A.
[9] Behre HM, Kuhlage J, Gassner C, et al. Prediction of ovulation by urinary hormone measurements with the home use Clearplan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. Hum Reprod 2000; 15:2478–82.
[10] World Health Organization. A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase. Fertil Steril 1983; 40: 773–8.
[11] Flynn AM, Lynch SS. Cervical mucus and identification of the fertile phase of the menstrual cycle. Br J Obstet Gynecol 1976; 83:656–9.
[12] Cortisi S, Rigon G, Zen F, Sposetti R. Correlation of plasma gonadotropin and ovarian steroids pattern with symptomatic changes in cervical mucus during the menstrual cycle in normal cycling women. Contraception 1981; 23:629–41.
[13] Attar E, Gokdemirel S, Serdaroglu H, Coskin A. Natural contraception using the Billings ovulation method. Eur J Contracept Reprod Health Care 2002; 7:96–9.
[14] Leader A, Wiseman D, Taylor PJ. The prediction of ovulation: a comparison of the basal body temperature graph, cervical mucus score, and real-time pelvic ultrasonography. Fertil Steril 1985; 43: 385–8.
[15] Ecochard R, Boehringer H, Rabilloud M, et al. Chronological aspects of ultrasonic, hormonal, and other indirect indices of ovulation. Br J Obstet Gynecol 2001; 108:822–9.
[16] Dunson DB, Sinai I, Colombo B. The relationship between cervical secretions and the daily

probabilities of pregnancy: effectiveness of the TwoDay Algorithm. Hum Reprod 2001; 16:2278–82.

[17] Stanford JB, White GL, Hatasaka H. Timing of intercourse to achieve pregnancy: current evidence. Obstet Gynecol 2002; 100:1333–41.

[18] Hilgers TW, Daly KD, Prebil A. Cumulative pregnancy rates in patients with apparently normal fertility and fertility-focused intercourse. J Reprod Med 1992; 37:864–6.

[19] The European Natural Family Planning Study Groups. European multi-center study of natural family planning (1989 –1995): efficacy and drop-out. Adv Contracept 1999; 15:69–83.

[20] Severy LJ. Acceptability of home monitoring as an aid to conception. J Int Med Res 2001; 29(Suppl):28A–34A.

[21] Bonnar J, Flynn A, Freundl G, et al. Personal hormone monitoring for contraception. Br J Fam Plan 1999; 24:128–34.

Notes

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Appendix
Figure 1
Comparison of the mean beginning, peak and length of the fertile phase between the Clearplan Easy Fertility Monitor and self-assessed cervical mucus.

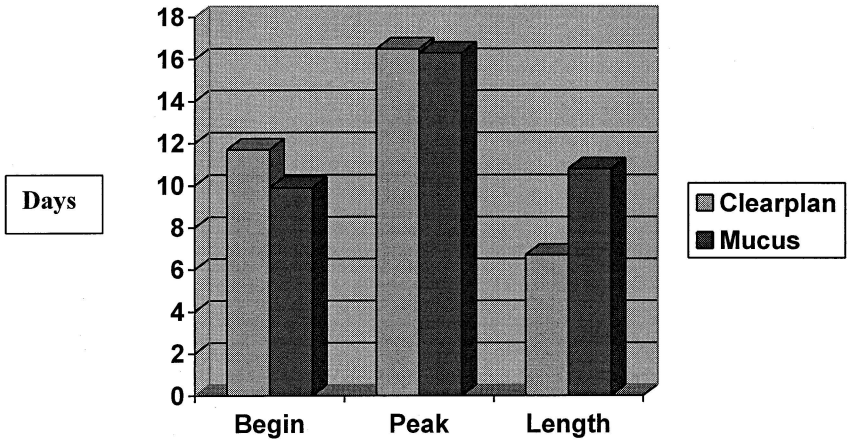

Figure 2
Average self-observed cervical mucus ratings based on 1–8 scale (1 = no mucus to 8 = peak).

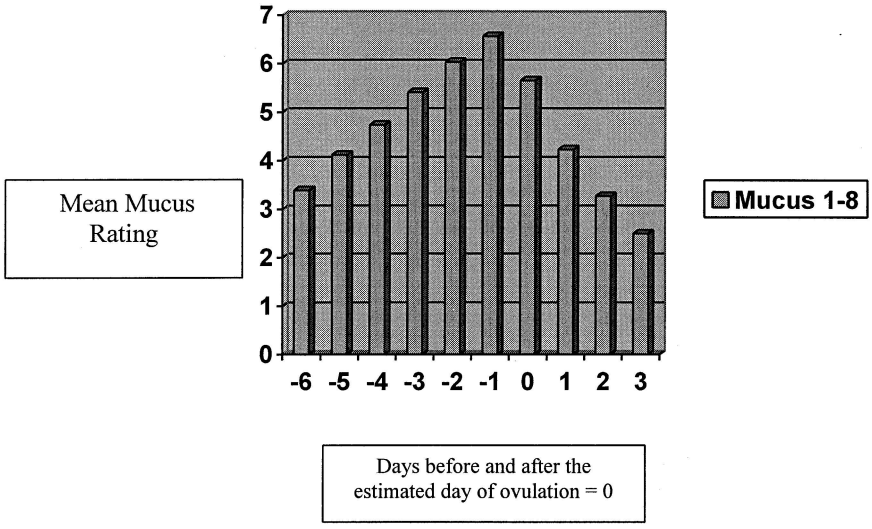

Figure 3
Bar graph comparing the frequency of "high" readings on the Clearplan monitor 6 days before the first Clearplan "peak" with the frequency of 7–8 mucus ratings 6 days before the Clearplan "peak."