Internet Appendix 2

Scientific Foundations of the Creighton Model System

Dr. John Billings, in 1953, began a search for a biological marker of fertility that women could themselves easily recognize. To his surprise—not being a gynecologist—he found several accounts of a stringy, lubricative mucus produced at about the time of ovulation by the cells lining the cervix.[1-4] Indeed, as early as 1855, Smith[5] observed that conception was most likely to occur when the mucus was "in its most fluid condition." In 1868, the famous gynecologist J. Marion Sims[6] also pointed out the importance of cervical mucus to human fertility.

Although this mucus had been observed by doctors for many years, gynecologists never questioned women about their awareness of it. *Dr. John Billings*, a neurologist, began questioning a small number of women with regard to the possible significance of the cervical mucus as a marker of ovulation. It became evident that the occurrence of a mucus discharge during the menstrual cycle was a familiar observation. From 1953 to 1971, these patterns were refined, the application of instructions was designed, hormonal correlations were accomplished and the *Ovulation Method* came into existence. *Dr. Lyn Billings* joined the effort in 1966.[7]

The cervical mucus and other biological markers have now become the single most studied observations in natural fertility regulation.

In 1976, a team of investigators at St. Louis University School of Medicine began a critical independent investigation of the Billings Ovulation Method. Out of that work, the legitimate, standardized off-

spring of the Billings Method, the **CREIGHTON MODEL FertilityCare™ System** (CrMS), was developed.

Background of the System

The fundamental principles of the CrMS have been known to physicians for many years and well documented although, as Cohen, et al[4] observed, "They have been almost disregarded by gynecologists." In 1952, this group published a schemata of the events that occur relative to the changes in the cervical mucus as ovulation approaches. In retrospect, this schemata also defined the basic principles of the not yet described Ovulation Method (Figure 1).

It was noted that as ovulation approached, the stretchability and clarity of the mucus increased along with its quantity of production. At the same time, the viscosity and its content of leukocytes decreased. The most pertinent observation, however, was the indication that the survival of the spermatozoa was directly related to the presence or the absence of an ovulatory or periovulatory type of mucus produced form the cervix.

In the CrMS, *external vulvar observations of the discharge of the cervical mucus, the presence of bleeding, and the days when no discharge is present* (dry days) are all used to obtain pertinent information on the phases of fertility and infertility, and the state of the woman's procreative and gynecologic health the information is obtained prospectively.

While the following paragraphs and figures were previously presented in Chapter 4, they are worth reviewing at this time.

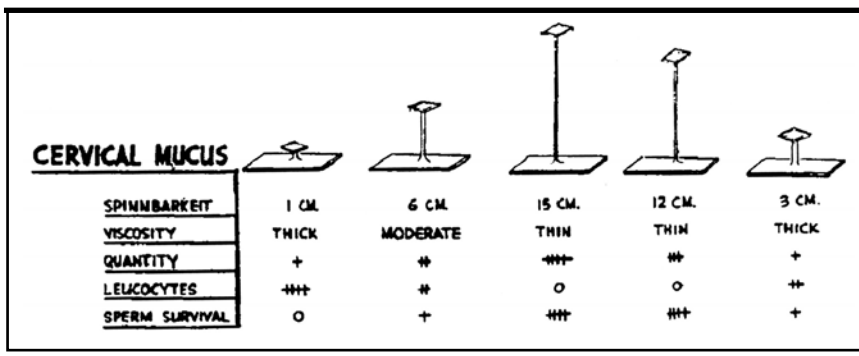

Figure 1: Cohen's original schemata for the events that occur in the cervical mucus around the time of ovulation Of special note is the depiction of the sperm survival and the, de facto, recognition of the role of the cervicl mucus as a biological valve (From: Cohen MR, Stein IF, Kaye BM: Spinnbarkeit: A Characteristic of Cervical Mucus. Fertil Steril, 3: 201, 1952).

In the woman with ***regular cycles***, the cycle begins with the onset of menstruation (see the first cycle of Figure 2). As menstruation tapers there is generally no discharge and the woman observes this as dry. As ovulation approaches, there becomes apparent a cervical mucus discharge which often begins as sticky, cloudy or tacky, cloudy discharge and eventually becomes clear, stretchy, or lubricative. The *last day* of the mucus discharge that is clear, stretchy or lubricative is identified as the *Peak Day*.

The presence of the cervical mucus discharge correlates well with the rising levels of estrogen (Figure 3) and the occurrence of the Peak Day is correlated well with the timing of ovulation.

Because the *production of the periovulatory cervical mucus is an estrogen dependent effect* and is produced at the time of follicular development, when estrogen is increasing and ovulation approaching, the cervical mucus is produced and will be discharged before and during the time of ovulation. In ***long cycles*** (Figure 4) there may be occasional "patches" of mucus prior to the onset of the mucus associated with ovulation. What is prolonged in these cycles is the pre-Peak (or preovulatory) phase of the cycle and what remains relatively consistent is the post-Peak (post-ovulatory) phase of the cycle.

The same principles apply in anovulatory conditions such as ***breast feeding*** (Figure 5). In this circumstance, infant suckling may suppress ovulation and fertility for a number of months. The presence or absence of the characteristic cervical mucus discharge associated with ovulation is then delayed until fertility returns and predicts the onset of the first

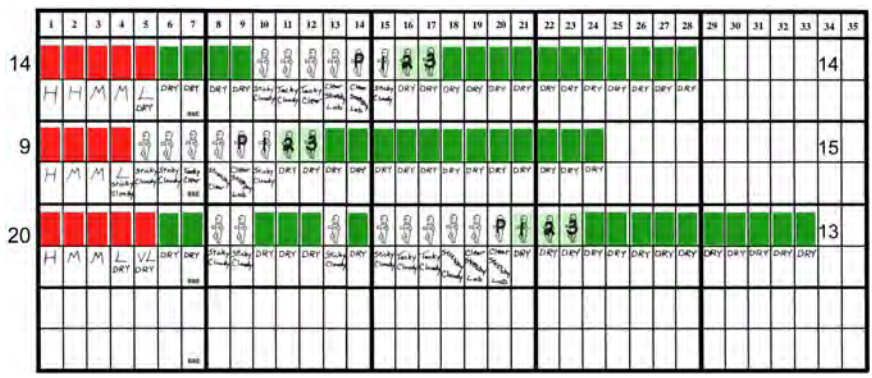

Figure 2: Three cycles charted for the CrMS showing the occurrence of menstruation, the pre-Peak dry days, the mucus cycle, the Peak Day (P), and the post-Peak dry days. The pre-Peak phases are variable in length (14, 9, and 20 days) but the post-Peak phases are consistent (14,15, and 13 days).[60]

menstrual period.

The *versatility* of the system, clearly *one of its strongest features*, is found in its fundamental biology. Because it *relies on events leading up to ovulation*, it defines the times of fertility and infertility in a *definitive, day-by-day, prospective fashion*. Previously difficult cases, such as long and irregular cycles, breast feeding, coming off of contraceptive pills, anovulatory states and the premenopause, all can now be dealt with in a positive fashion without delay.

Even in the case of a woman with a ***continuous mucus discharge*** (Figures 6 and 7), the days of fertility can be properly identified with

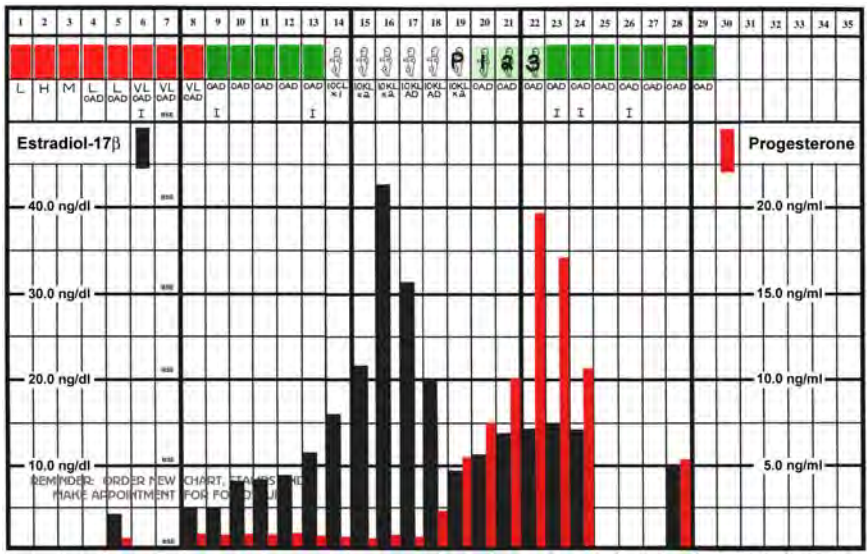

Figure 3: The relationship of serum levels of estradiol-17β and progesterone during the course of the menstrual cycle and the occurrence of the mucus sign and the Peak Day (P) in one cycle of a woman with normal fertility.[60]

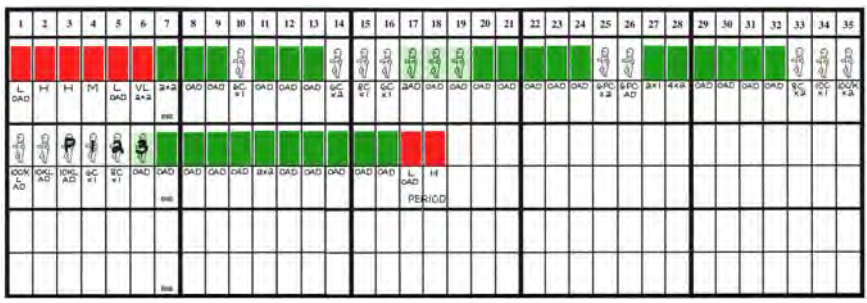

Figure 4: The application of the **CrMS** in long cycles. In this 51-day cycle, the Peak Day (P) occurred on day 38. The post-Peak phase was 13 days in duration. During the pre-Peak phase, "patches" of mucus are apparent.[60]

the use of a ***base infertile pattern*** (BIP) which is identified with the presence of an unchanging discharge. When fertility begins, *there will be a change in the pattern*, which is easily identified by the woman who has been properly instructed, and with this change the beginning of fertility is identified.

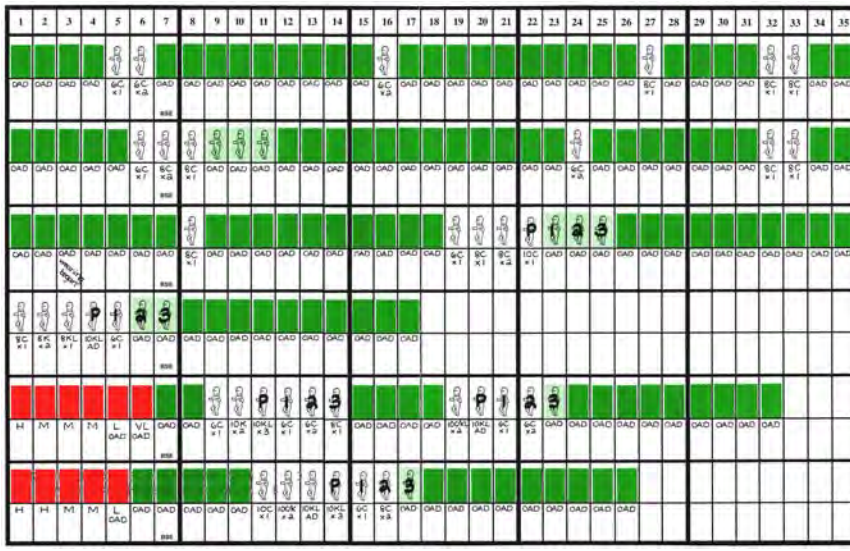

Figure 5: The application of the **CrMS** in breast feeding. "Patches" of mucus occur sporadically, dry days ususally predominate, and as fertility returns, the mucus pattern and fertility return.[60]

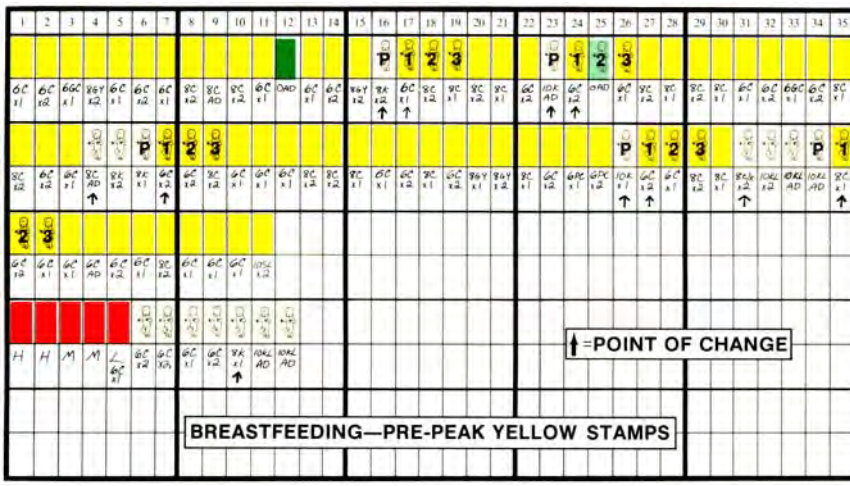

Figure 6: The example shows the use of the **CrMS** in a breast-feeding woman with a continuous mucus discharge. The plain yellow stamps indicate a discharge pattern which is the same from one day to the next. The arrows indicate the points of change and the baby stamps indicate days of fertility.[60]

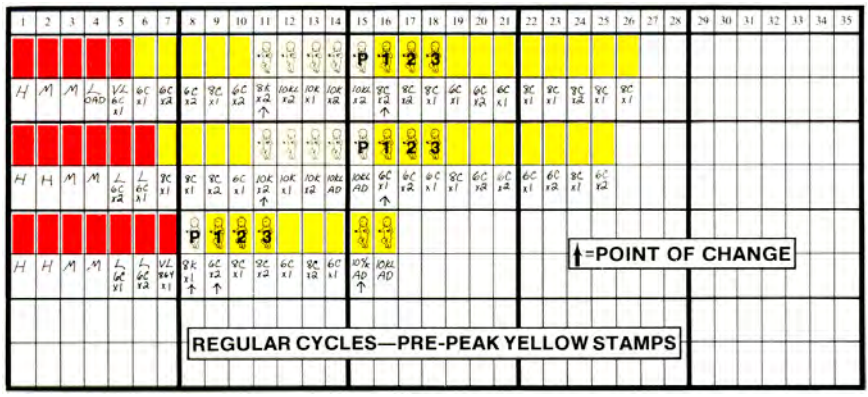

Figure 7: In a woman with regular menstrual cycles and continuous mucus discharge, the base infertile pattern is shown up to the point of the change. The Peak Day is identified and the pre- and post-ovulatory days of infertility are shown with plain yellow stamps.[60]

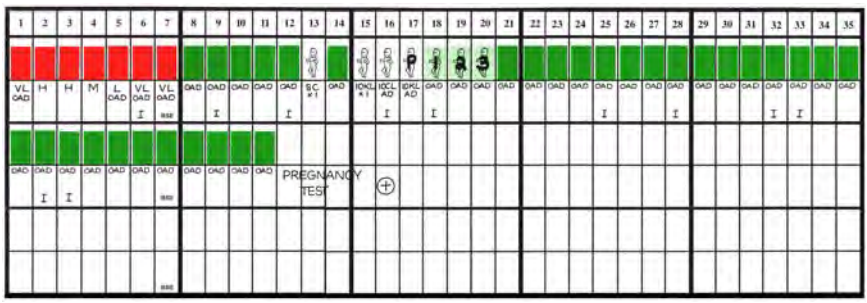

Figure 8: In this case, a woman of normal fertility, the system is used to achieve pregnancy. The acts of intercourse in the midst of the mucus cycle (days 16 and 18) should be expected to result in pregnancy as they did in this example.

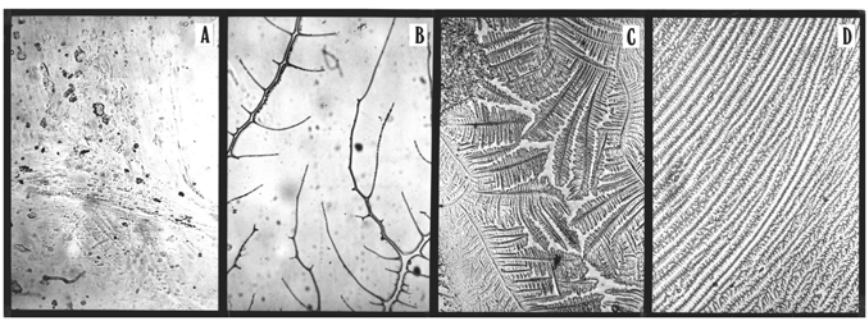

Figure 9: Examples of a negative fern (A), channel formation when the fern is negative (B), a good positive fern (C), and channel formation when the fern is positive (D) (100x) (From: Hilgers TW, Prebil AM: The Ovulation Method – Vulvar Observations as an Index of Fertility/ Infertility. Obstet Gynec, 53: 12-22m 1979).[13]

The system is *not* a contraceptive one. It is a system of *true family planning* (see Figure 8). Thus, the information obtained from monitoring the phases of fertility and infertility can be used to either *achieve or avoid pregnancy*. Users of the CrMS know their fertility status on any particular day and are given the freedom to utilize that information as they so choose. In addition, the CrMS has now expanded its use as a *reproductive and gynecologic health maintenance system and is the "hub" of the new women's health science of* **NaProTECHNOLOGY**.

The Cervical Mucus as a Biologic Valve

The biophysical characteristics of the cervical mucus, as they change throughout the menstrual cycle, have received considerable attention over the years.[8-11] In 1972, a World Health Organization colloquium on the topic of "Cervical Mucus and Human Reproduction" likened the uterine cervix to that of a "biological valve" which, "at certain periods during the reproductive cycle allows the entry of sperm into the uterus, and at other times bars their admission."[12] The CrMS basically provides the couple with the information on when that valve is ***open*** (*a time of fertility*) and when it is ***closed*** (*a time of infertility*).

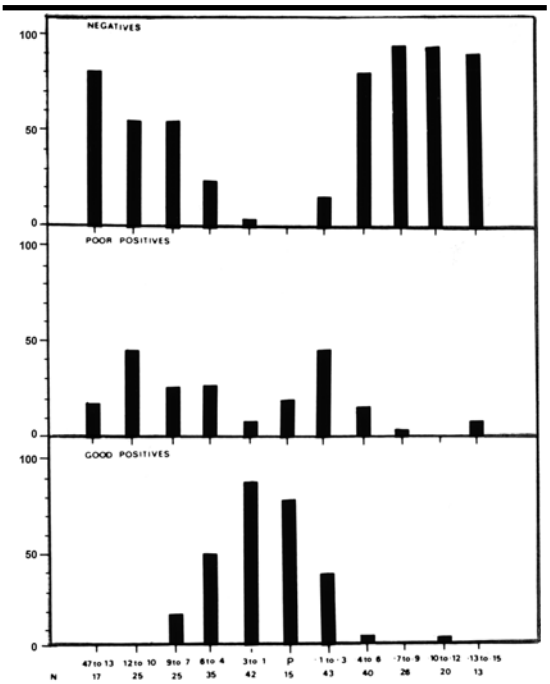

Figure 10: The distribution of negative, poor positive, and good positive ferns (n=301) ± Peak Day (P) at three-day intervals.[13] Negative and poor positive ferns are impenetrable to sperm. Only good positive ferns are associated with sperm penetration (From: Hilgers TW, Prebil AM: The Ovulation Method –Vulvar Observations as an Index of Fertility/Infertility. Obstet Gynec 53: 12-22, 1979).

An evaluation of fern and channel patterns of the cervical mucus in women using the CrMS has also been undertaken.[13] Cervical mucus was obtained from the endocervical

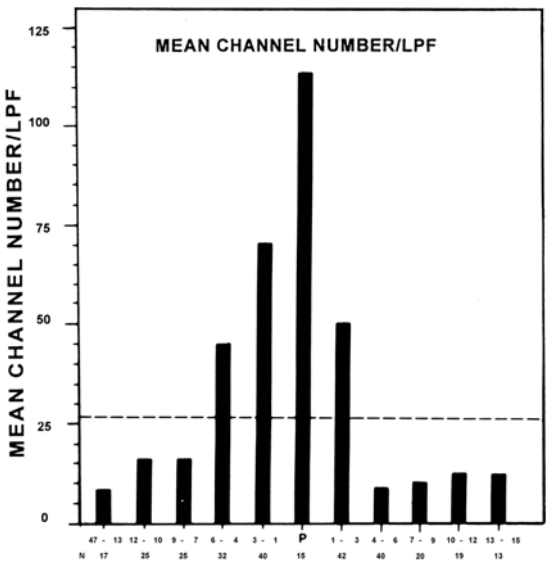

Figure 11: The mean number of channels/LPF ± Peak Day (P) at three-day intervals (n=294).[13] No sperm penetration occurs (theoretically) when the channel number is below the hash marked line (From: Hilgers TW, Prebil AM: The Ovulation Method –Vulvar Observations as an Index of Fertility/Infertility. Obstet Gynec 53: 12-22, 1979).

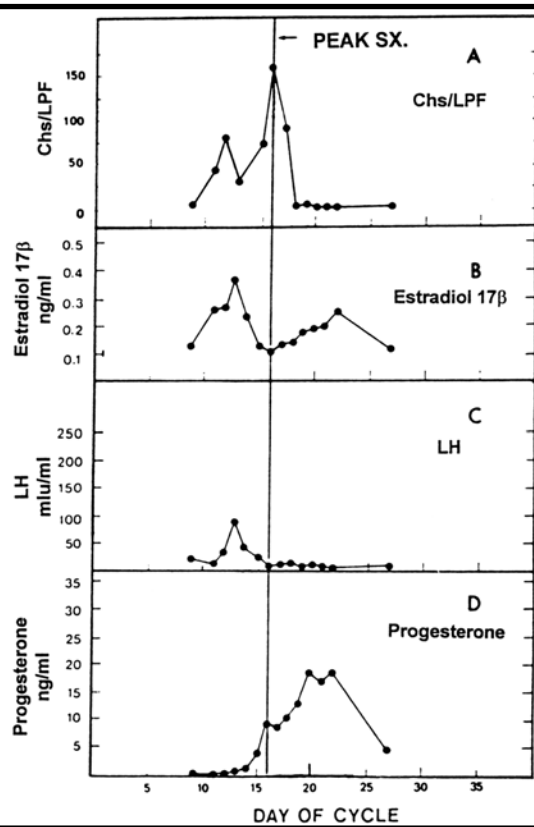

Figure 12: Individual cycle with (A) channel number per LPF, (B) estradiol-17β, (C) LH, and (D) progesterone.[13] The largest number of channels is consistently observed on the same day as the woman's observation of her Peak Day (Peak Sx) (From: Hilgers TW, Prebil AM: The Ovulation Method –Vulvar Observations as an Index of Fertility/Infertility. Obstet Gynec 53: 12-22, 1979).

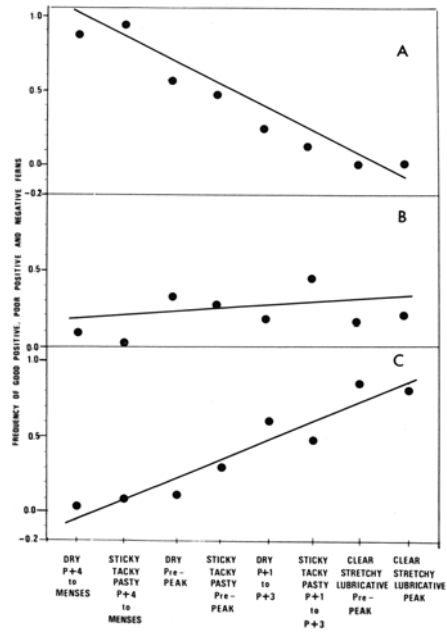

Figure 13: Frequency of (A) negative (b=0.14, $p \leq .0001$), (B) poor positive (b=0.02, $p \leq .333$), and (C) good positive ferns (b=0.13, $p \leq .0002$) by woman's vulvar observations (From: Hilgers TW, Prebil AM: The Ovulation Method–Vulvar Observations as an Index of Fertility/ Infertility. Obstet Gynec 53: 12-22, 1979).

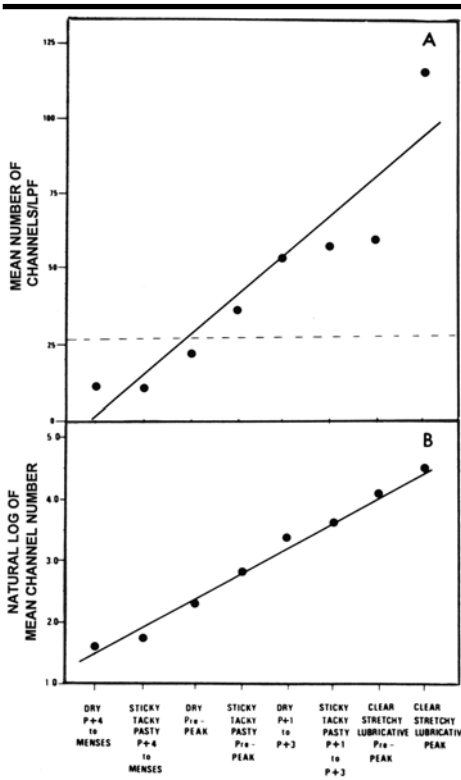

Figure 14: (A) Mean number of channels/LPF (b=12.95, $p \leq .0008$) (no sperm penetration occurs when the channel number is below the hash marked line) and (B) natrual log of mean channel number by woman's vuvlar observation by stage of **CrMS** cycle (b=0.42, $p \leq .0001$) (From: Hilgers TW, Prebil AM: The Ovulation Method –Vulvar Observations as an Index of Fertility/Infertility. Obstet Gynec 53: 12-22, 1979).

canal and assessed for the presence or absence of crystallization (ferning) and dendritic channel formation in dried cervical mucus. These physical characteristics of the cervical mucus were then *correlated with the vulvar observations* of the mucus discharge as *observed by the women* using the system (Figures 9 to 14).

As the Peak Day approaches, the appearance of positive ferning becomes predominant and the negative ferns disappear (Figure 10). The number of dendritic channels present (per low power field of the microscope) increases dramatically beginning six days prior to the Peak Day. The largest number of channels was observed on the Peak Day itself (Figure 11). The daily increase in the number of channels/LPF as the Peak Day and ovulation approach along with the hormonal correlates are shown for one cycle in Figure 12. Because the mucus cycle is an estrogen dependent and ovulation-related event, the data on these two estrogen-related events, that is the development of positive ferning and an increasing number of dendritic channels, correlate themselves impressively around the woman's observation of her Peak Day. These data show the existence of a true biologic valve and correlates with the observations of Odeblad in his recent description of P type mucus.

Similar data on the presence or absence of ferning and the number of channels in the cervical mucus were also evaluated and correlated with the woman's vulvar mucus observations made throughout the course of the menstrual cycle.[13] The frequency of negative, poor positive and good positive ferns was plotted according to the observed spectrum of fertility (Figure 13), through eight practical stages of the CrMS cycle. Regression lines were then generated for these three groups and significance testing performed. The linear regression coefficient for the negative fern group was –0.14 and the observed data fit this line at a high degree of significance ($p \leq .0001$). The regression coefficient for the good positive ferns was 0.13 and this again indicated a correlation that was statistically highly significant ($p \leq .0002$).

The mean channel number for the same eight stages of vulvar mucus observations was also plotted in a similar fashion (Figure 14). The regression line had a regression coefficient of 12.95 and is highly significant ($p \leq .0008$) (Figure 14A). In order to test the precision of this significance testing, a natural log transformation of the mean channel number was done. In Figure 14B, the natural log of the mean channel number of these same eight stages is plotted. The regression coefficient for this line

was 0.42 and the fit of the observed data was statistically highly significant ($p \leq .0001$). These data have lent enormous support to the idea that *the woman's vulvar mucus observations are an extraordinary reflection of the biophysical events the mucus is undergoing at the level of the endocervix*. In addition, with the definition of these stages of the CrMS cycle, the system has become an excellent tool for the modeling and further study of human fertility.

In looking at the fertility cycle based upon the observation of these biological markers, the study of an *anticipated spectrum of fertility* (Figure 16) could be compared to an *observed specturm of fertility* (Figure 17). In

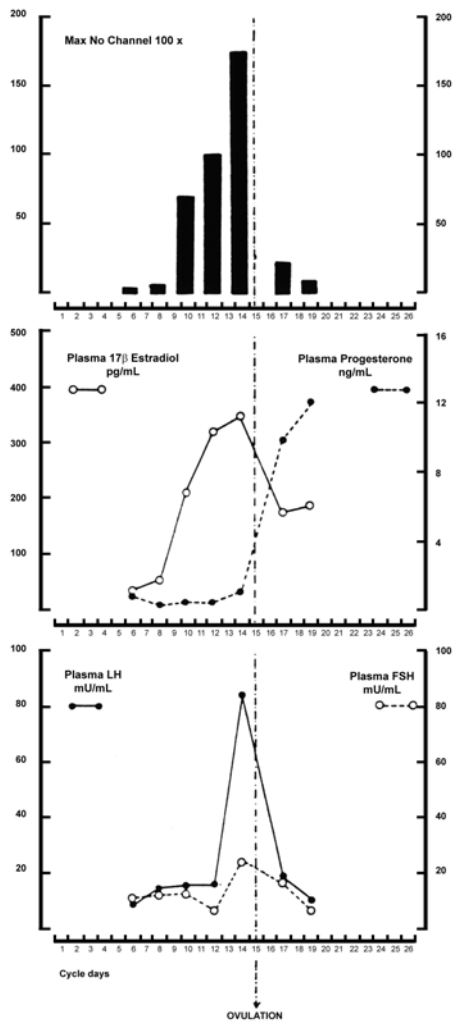

Figure 15: Plasma levels of FSH, LH estradiol -17β, and progesterone, maximum number of channels in the highest canalized mucus area during a 26-day menstrual cycle (From: Faccioli G, Cortesi S, Calderoni P: Structure of Human Cervical Mucus Correlation with Plasma Ovarian Hormone Levels. Acta Europaea Fertilitatis. 14: 41-50, 1983).

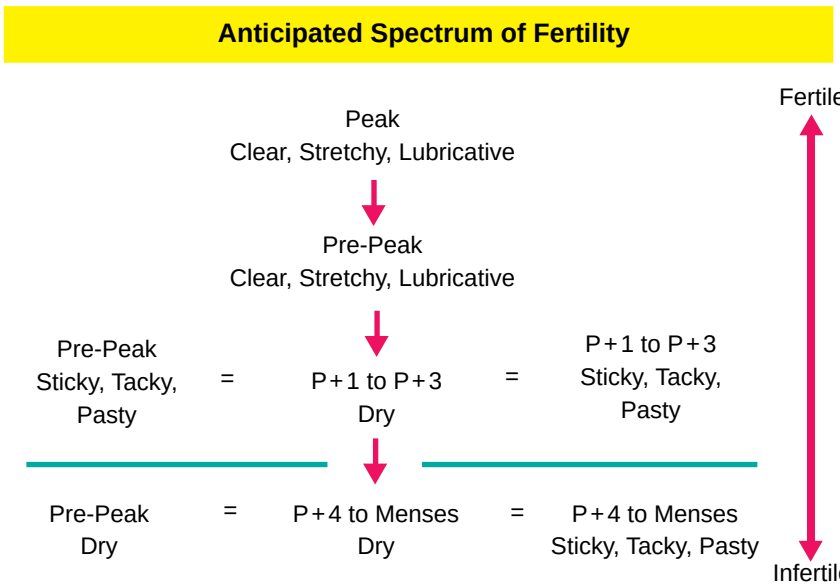

Figure 16: The anticipated spectrum of fertiilty based upon the **CREIGHTON MODEL System**.

the anticipated spectrum of fertility, eight stages of fertility/infertility could be expected based on these observations. These same eight stages of the presence or absence of ferning and the number of channels that were observed in the different stages, could be objectively ordered in a sequence from fertility to infertility. This could be subsequently subdivided into two separate stages based uon what was now known from sperm penetration studies. Those stages of fertility above the hashed marked line in Figure 17 are objectively shown to be fertile and those beneath the line objectively shown to be infertile.

This modelling of human fertility, as observed in the CrMS, was thus shown to have an objective, scientific foundation and since the observations could be easily made and collected from cycle to cycle and woman to woman, a new way of looking at human fertility emerged. This approach has allowed a whole new and dynamic way of looking at human fertility/infertility to come into existence lending itself to widespread study and evaluation.

Using identical techniques for assessing the channel formation of cervical mucus, Faccioli, et al[14] and Garcia, et al[15] made similar observations

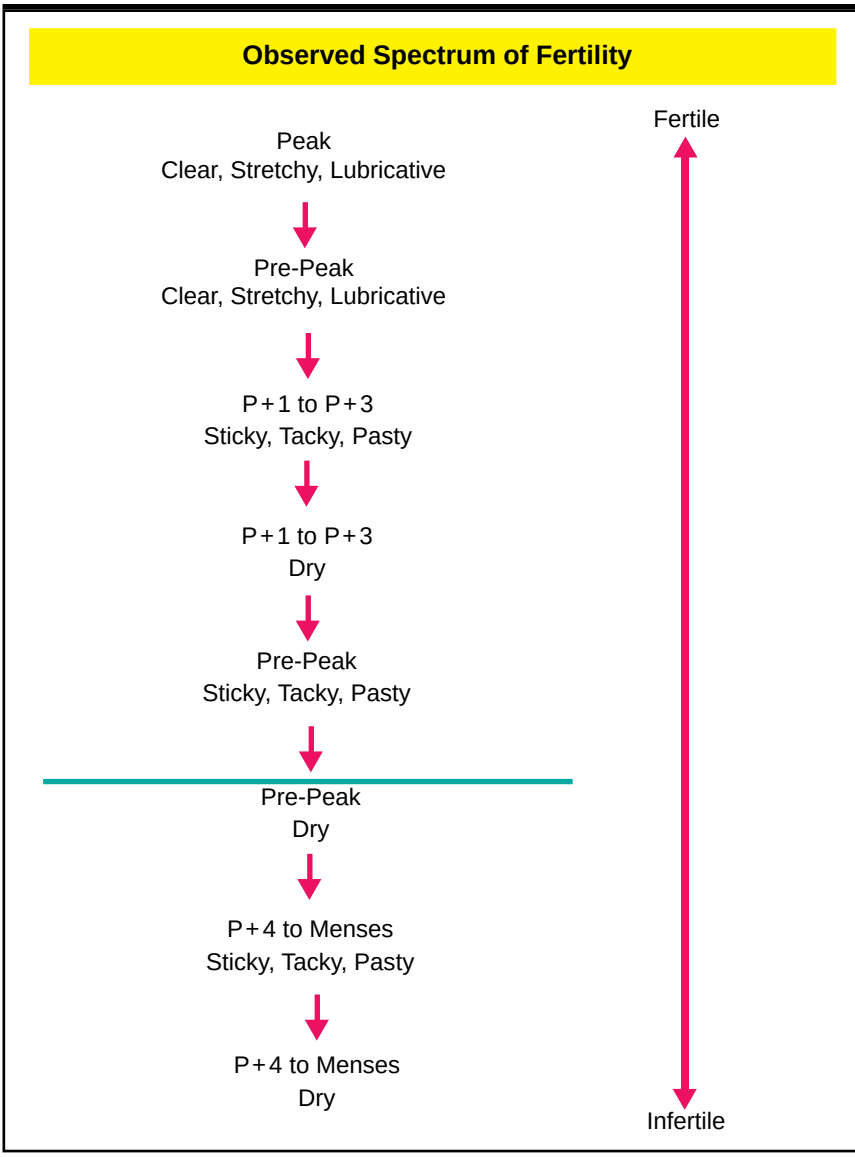

Figure 17: The observed spectrum of fertility using fern and channel studies arranged according to the various stages of the **CrMS** cycle (see Figures 15-13 and 15-14). Those observations above the line are assoicated with sperm penetration and those below the line are assoicated with no sperm penetration. This reveals two basic phases of the cycle: fertile and infertile (see text).

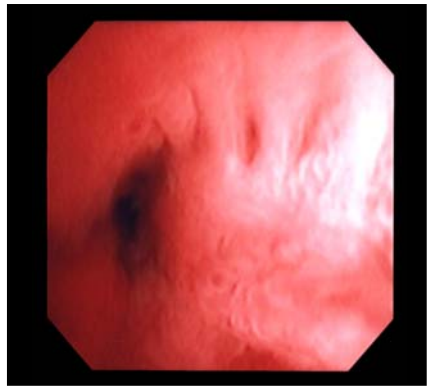

Figure 18: This photograph of the endocervical canal shows the canal (left) and four separate openings of the endocervical crypts into the endocervical canal. In doing his studies, Odeblad microsampled these individual crypts (From: Pope Paul VI Institute research, 2004).

(Figure 15) and advanced our knowledge. It was clearly demonstrated[15] that as ovulation approached the level of estradiol-17β increased, and there was a coincidental increase in the number of channels formed in the cervical mucus. Thus, the establishment of channel formation as an event dependent upon estrogen stimulation of the endocervix was further substantiated (Figure 19).

As an aside, it was also shown that the number of channels continued to increase while the good positive ferning stabilized, indicating the channel formation was *a more sensitive indicator* of endocervical function and estrogen stimulation. In addition, pregnancy, in gonadotropin-stimulated cycles, was observed to occur more frequently in patients who had ever-increasing dendritic channel formation (Figures 20 and 21).

The Work of Professor Erik Odeblad

The lifetime work of Professor Erik Odeblad is a classic and unique research effort in natural fertility regulation and the biophysical characteristics of the cervical mucus.[16-20] This work, meticulously evaluating the anatomy and physiology of the endocervical canal, the biophysical characteristics of its cervical mucus throughout the various phases of the menstrual cycle and the mapping of the endocervix are significant contributions and deserve special attention and description. A chronology of Odeblad's work is outlined in Table 1.

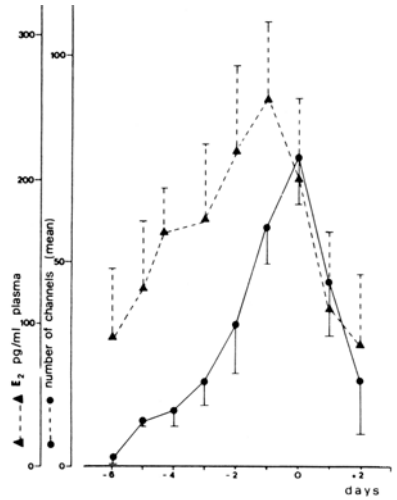

Figure 19: The relationship of rising levels of estradiol-17β (E_2) and the number of channels observed in dry cervical mucus.[15] The shape of the two curves is nearly identical although the peak in channel formation precedes the peak in E_2 by about 24 hours (From: Garcia N, Giacchi E, Campo S, et al. Canalization of Human Cervical Mucus. Obsert Gynec, 64: 164-169, 1984).

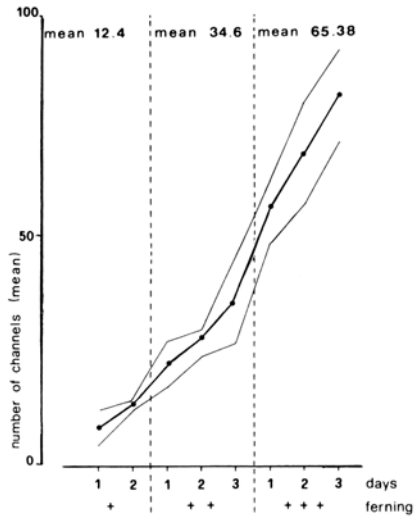

Figure 20: The mean number of channels according to the grade of the fern an the number of days that grade was observed.[15] The grade of ferning is divided into three (+, ++, +++) over a period of eight days. While ferning grade remains the same, the number of channels continues to increase. This confirms that the number of dendritic channels observed in dried cervical mucus is a more sensitive indicator of endocervical function and estrogen stimluation (From: Garcia N, Giacchi E, Campo S, et al. Canalization of Human Cervical Mucus. Obsert Gynec, 64: 164-169, 1984).

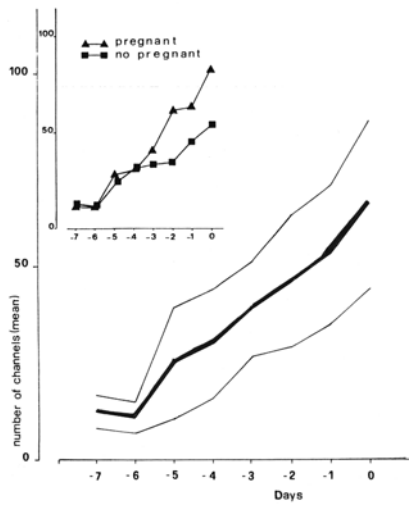

Figure 21: The mean number of channels in gonadotropin stimulated menstrual cycles as ovulation approaches. Those women who became pregnant versus those who did not acheive pregnancy are separated in the inset graph (From: Garcia N, Giacchi E, Campo S, et al. Canalization of Human Cervical Mucus. Obsert Gynec, 64: 164-169, 1984).

Odeblad has shown that there are three groups of cells in the mucus membrane of the cervix.

1. Cylindrical (columnar) **secretory** cells (the majority);
2. Cylindrical (columnar) **ciliated** cells; and
3. "**Reserve**" cells.

The origin of the secretory cells is known but the mode of development of the other two groups of cells has not yet been defined. The cells of the mucus membrane are slowly detached and are displaced with the mucus. New cells are formed to replace them.

The *molecular weight of the mucus is about 70,000 Daltons* and it is believed to be several million Daltons for gels. According to Odeblad, the mucus is not a normal but an abnormal fluid and its viscosity cannot be measured using liquid-flow techniques. It is, therefore, necessary to use other methods preferably nuclear magnetic resonance (NMR) techniques, which do not involve flow but rather the use of the thermal movements of molecules in the fluid.

Odeblad gathered mucus samples by using two different approaches:

1. Investigations of intracanalicular mucus using *macrosamples* of mucus.
2. Investigations of mucus obtained from individual crypts using *microsampling* techniques (a meticulous gathering of mucus and mapping of the endocervix using micropipettes) (see Figure 18).

Table 1: Chronology of Odeblad's Work Mapping the Endocervical Canal

Year	Event
1959	First reported that different types of cervical mucus were produced by different crypts (NMR)
1966-1968	Two mucus types described: Type G and Type E
1977	First published G, L, S model
1983	Began working with Drs. Billings and Brown
1990	P-type mucus was characterized
1993	F-type mucus was characterized

In 1959, he reported the results of microscopic examinations which showed that the cervical mucus was composed of different types which were produced by different cervical crypts. In 1966, the existence of crypts which responded differently to the same hormonal stimulation was shown. Rudolfsson,[21] a collaborator of Odeblad's, showed in 1971 the existence of crypts which could contain two types of mucus. These crypts are thought to have two branches with a common opening with the branches having different secretory functions.

By 1968, two types of cervical mucus had been identified and characterized. One of these types had a high viscosity (G) and the other had a low viscosity (E). The **Type E** mucus was stimulated by estrogens and the **Type G** mucus by progesterone. The G type mucus was produced in **G crypts** and the E type mucus in **E crypts**.

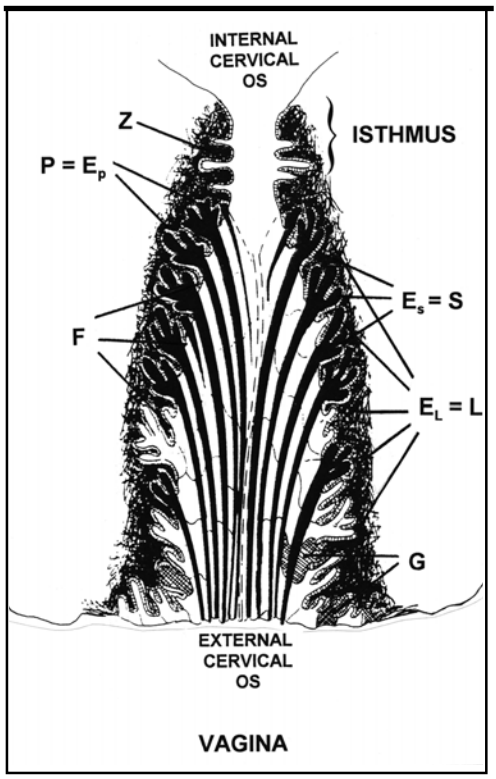

Figure 22: A schematic drawing of the endocervical canal indicating the distribution in the cervix of the four types of mucus: E_S, E_L, E_P,and G. The location of the production of the F mucus is identified (F) and the originating location of the Z granules (Z) (This schematic is adapted from Odeblad, 1977 and 1994).[19]

Research during the years 1970 to 1975 indicated that the progression of spermatozoa in the Type E mucus was complicated and this mucus was composed of two different types of mucus named **Type S** (S = sperm transmission mucus, E_S) and **Type L** (L = locking-in mucus because of the capacity of that mucus to attract and enclose malformed sperm, E_L). This allowed for the development of the **G, L, S model** of cervical mucus production, and it explained the major factors associated with the upward movement of sperm in the cervical canal. The *mapping of the endocervical canal*, worked out by Odeblad, is shown in Figure 22.

Over the years it has been shown that the **S-type mucus** is *very fluid* (Figure

23) and that the sperm cells move along the canal very rapidly reaching the S crypts in *3-10 minutes*. The **L-type mucus** has a *medium viscosity*. Unit structures of L type mucus *attract malformed sperm cells* or those which move slowly in an efficacious *"filtration" of sperm cells*. The **G-type mucus** has *high viscosity* and forms an *impenetrable plug*.

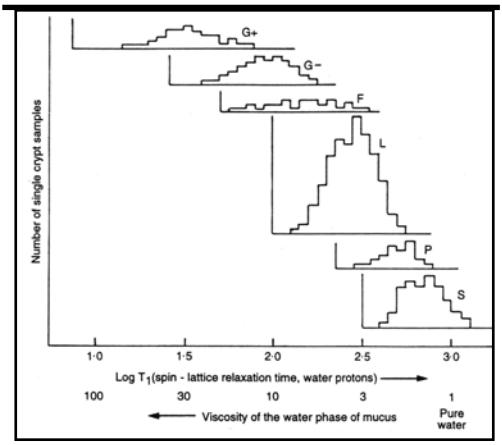

Figure 23: Viscosities of microsamples of the different types of mucus (from Odeblad, 1994).[19]

In 1983, Odeblad began working with the Drs. Billings and Professor James Brown in Melbourne, Australia.[19] The hormonal response of the G, L, and S mucus was studied. It was found that the L-type mucus was stimulated by *medium and increasing levels of estrogen* while the S-type mucus was stimulated by *high levels of estrogen*. Later, it was also shown that S-type mucus was stimulated by *noradrenalin*. The G-type mucus was stimulated by *progesterone* In the first infertile phase of the menstrual cycle the progesterone level, which is low at that time, is, according to Odeblad, sufficient to feebly stimulate the G crypts (*G – mucus*). After ovulation, when the progesterone levels are increasing and elevated, the G crypts are strongly stimulated. This G mucus is very dense (*G + mucus*).

When comparing these types of mucus to the woman's observations, no vulvar mucus is usually associated with the G-type mucus and the days are *dry* during the infertile phases. When estrogen levels increase, the L-type mucus begins to be produced. Later, when estrogen levels are high, the S-type mucus is also produced and there develops a *lubricative sensation* and this generally remains until the Peak Day. On that day, estrogen levels are already decreasing but the noradrenalin-like activity of the sympathetic nervous system additionally stimulates the S-type mucus. After the Peak Day, G-type mucus is accompanied by a *dry sensation* due to the abundant secretion of progesterone by the corpus luteum. The temporal relationships of the different secretions around the timing of ovulation are shown in Figure 24.

The characteristics of the cervical mucus have also been studied

rather extensively by other investigators using scanning electron microscopy techniques (SEM)[22-24] (Figures 25 to 27).

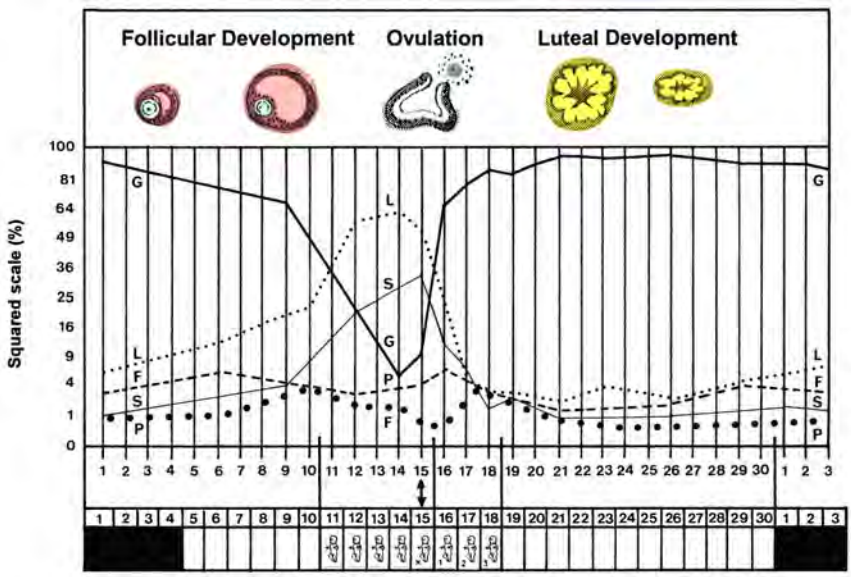

Figure 24: The cycle of a high school student, a virgin of 15 years of age. She has been charting for several years. Analyses of types of mucus (S, L, G, P, F) on a microscopic slide are given. Day of ovulation was determined by repeated palpatation (from Odeblad, 1994).[19] The Ovulation Method chart (BOM) is correlated with the graph and the Peak Day is marked (X) (adapted from Odeblad),

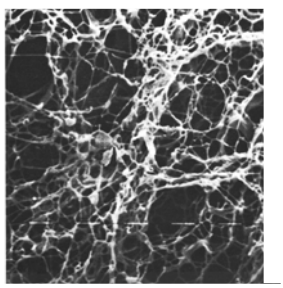

Figure 25: Scanning electron microscopic photograph of filamentous mucus of the middle preovulatory phase.[22,23] Sperm do not penetrate this type of mucus.

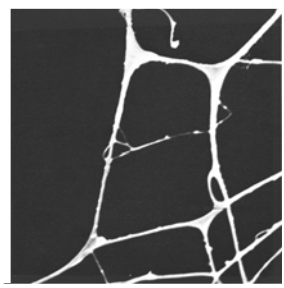

Figure 26: Scanning electronic features of filamentous mucus of the ovulatory phase.[22,23] There is an opening of the spaces in the mucus allowing for sperm penetration.

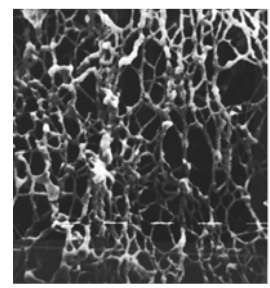

Figure 27: Scanning electronic aspect of filamentous mucus of post-ovulatory phase.[22,23] Sperm do not penetrate this type of mucus.

(From: Faccioi G: Preliminary Results on the Scanning Electron Microscopic Sructure of the Infertile Human Cervical Mucus. Acta Europaea Fertilitatis, 15: 381-382, 1984)

Sperm Penetration

One of the biological principles of the CrMS is the concept that the survival and penetration of the spermatozoa are directly related to the presence of a good quality, estrogen stimulated cervical mucus. And this, too, may be related to the quantity of that mucus production. The presumption exists that the penetration of sperm through the endocervical canal is anticipated when an estrogen-stimulated cervical mucus is present at the vulva. It also presumes that when there is no discharge of cervical mucus or during the base infertile pattern or during the post-Peak phase of the menstrual cycle, there is a natural impenetrability of the sperm. At one point in the cycle, the biological valve is open while at other points the biological valve is closed. These presumptions are built on the extensive basic science evaluation of the cervical mucus that has been just presented.

Good studies on sperm penetration are difficult to find. One of the few pregnancies in which the timing of sexual intercourse and the timing of ovulation (by indirect hormonal parameters) is known was published by Ferin, et al[25] (Figure 28). While this appears to be a 5-day sperm survival, the rise in progesterone suggests that the sperm survival may have been only 4 days and certainly no greater than 5 days.

Moghissi, et al,[26] evaluated sperm penetration *in vitro* in a group of patients whose cervical mucus was also being evaluated for a variety of other parameters. Significant penetration of the cervical mucus by spermatozoa did not occur until the third day prior to the LH surge (or an estimated 4 days prior to ovulation). Prior to that time and on the third day following the LH surge (or 2 days past the estimated time of ovulation), there was again no significant sperm penetration identified (see Sperm Penetration F2 in Figure 29-B). This study, perhaps more than any other, shows the impact of the cervical mucus acting physiologically as a biological valve with regard to sperm penetration. These observations have qualitatively been made by others.

An *in vivo* model was studied by Insler.[27] By pretreating the uterus and cervix with various estrogenic and progestagenic hormones followed by insemination and subsequent hysterectomy, the were able to conclude that the amount, physical qualities and chemical composition of the cervical mucus determine both the extent of cervical invasion by sperm cells and the storage capacity of the crypts. Furthermore, they

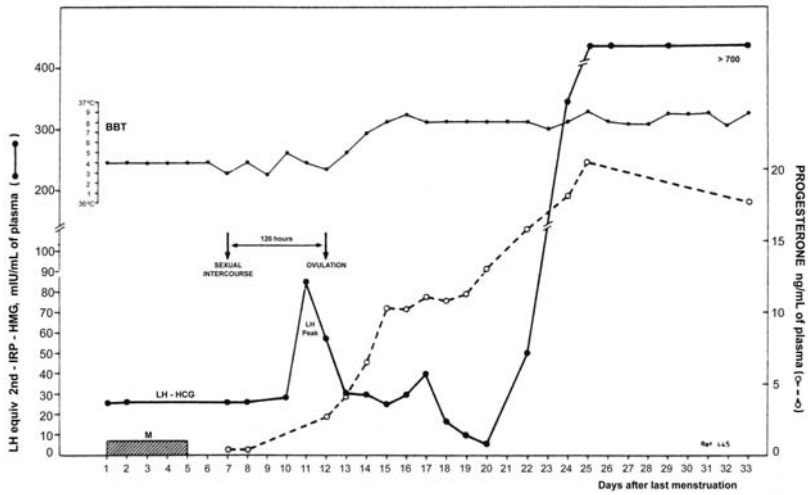

Figure 28: Time relationship between plasma LH-HCG levels, plasma progesterone levels, basal body temperature (BBT), sexual intercourse, and beginning pregnancy. Note time elapsed between intercourse and estimated date of ovulation[25] (From: Ferin J, Thomas and Johansson EDB: Ovulation Detection. In Human Reproduction: Conception and Contraception (Hafez ESE and Evans TN, Eds.) Harper and Row, Hagerstown, MD, 1973).

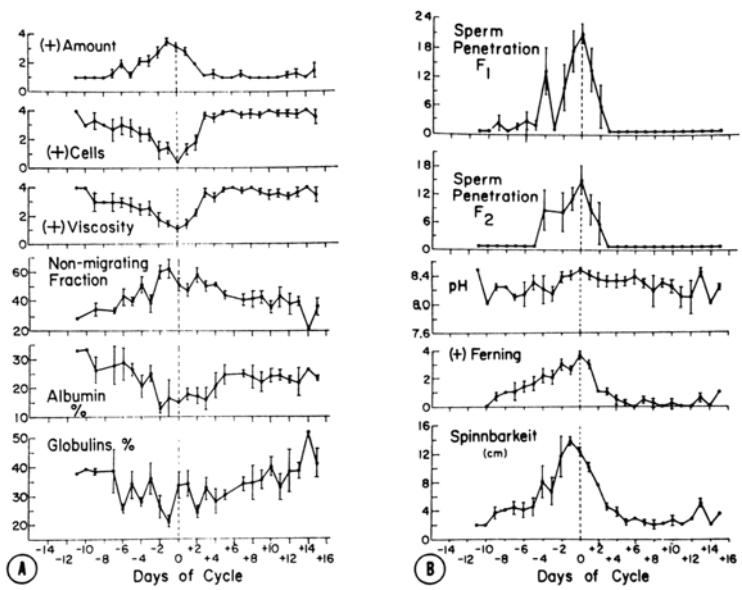

Figure 29 A&B: Changes in various properties of cervical mucus throughout the menstrual cycle. Day 0 = day of LH peak (dotted line), F_1 and F_2 indicate the number of spermatozoa in first and second microscopic fields (x200), from interface in *in vitro* sperm-cervical mucus penetration test. Vertical bars represent one standard error of the mean[26] (From: Moghissi KS, Syner FN, Evans TN: A Composite Picture of the Menstrual Cycle. Amer J Obstet Gynec. 114: 405-416, 1972).

observed that *estrogen enhances* and *progesterone and related compounds significantly hinder the sperm's ability to penetrate the uterine cervix*. Other studies of penetration of the cervical mucus by the sperm suggest that the ability of the sperm to survive and penetrate the cervix may last only between 24 and 48 hours. Indeed, practical experience with the use of the CrMS over the past several years continues to support the principle that sperm survival and penetration is directly related to the production of an adequate quality and quantity of good cervical mucus.

Hormone Assessment and Correlation

A number of investigators have evaluated the relationship of the time of ovulation to the woman's observation of the Peak Day.[28-33] The results of these observations appear in Table 2. Taking into account some variations in the structure of each of these studies, there is a striking relationship between the woman's observation of the Peak Day and the occurrence of ovulation as determined by indirect hormonal parameters. Morishita, et al,[34] have described similar hormonal correlates to increasing quantities of clear endocervical mucus.

The relationship of the reproductive hormones to the woman's observation of the Peak Day and the estimated time of ovulation are shown in Figure 30.[32] Hilgers, et al[32] published a number of menstrual cycles showing, in addition, the relationship of the preovulatory rise in estradiol-17β

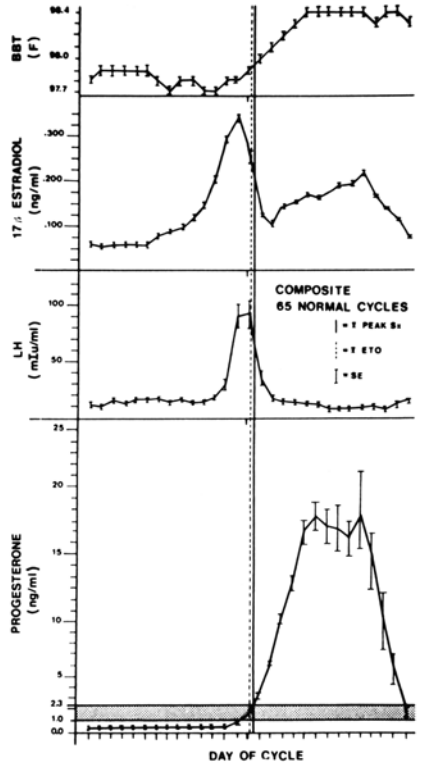

Figure 30: The mean serum progesterone, LH, estradiol-17β, and BBT values for 65 hormonally normal cycles iwth the day of the estimated time of ovulation (ETO) used as the center point. The Peak symptom and standard error are identified[25] (From: Hilgers TW, Abraham GE, Cavanagh D: Natural Family Planning - I. The Peak Symptom and Estimated Time of Ovulation. Obstet Gynec 52:575-582, 1978).

Table 2: Relationship to the Estimated Time of Ovulation Measured by Various Hormonal Methods and the Woman's Observation of the Peak Day, Published Evaluations

Estimated Time of Ovulation to Peak Day	Investigator and Year of Study									
	BILLINGS[a] Australia[29] 1972		FLYNN[b] England[30] 1976		CASEY[c] Australia[31] 1978		HILGERS[d] USA[32] 1978		CORTESI[e] Italy[33] 1981	
	n	%	n	%	n	%	n	%	n	%
P-3	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0
P-2	1	4.5	0	0.0	0	0.0	12	18.5	1	3.1
P-1	1	4.5	3	10.3	0	0.0	13	20.0	4	12.5
PEAK DAY	5	22.7	10	34.5	3	30.0	24	36.9	21	65.6
P+1	9	40.9	13	44.8	7	70.0	9	13.8	6	18.8
P+2	4	18.2	3	10.3	0	0.0	4	6.2	0	0.0
P+3	2	9.1	0	0.0	0	0.0	1	1.5	0	0.0
NO PEAK	–	–	–	–	–	–	1	1.5	–	–
TOTAL	22	99.9	29	99.9	10	100.0	65	99.9	32	100.0

a. Used day after LH surge as estimated day of ovulation: P-2 to P+2=90.8 percent.

b. Used maximal mucus grading (MMG) which was defined as the maximum amount of clear mucus. Where equal scores occurred on two days, the second of these was taken as the maximum. Data has been recognized from the original to correlate MMG with the estimated time of ovulation as calculated as the day after the LH surge: P-1 to P+2=99.9.

c. Used time between LH surge and rise in progesterone to estimate time of ovulation: Peak to P+1=100.0 percent.

d. Used midpoint in progesterone rise from 1.0-2.3 ng/ml to estimated time of ovulation: P-2 to P+2=95.4 percent.

e. Used day after LH Peak as estimated time of ovulation. P-2 to P+1=100.0 percent.

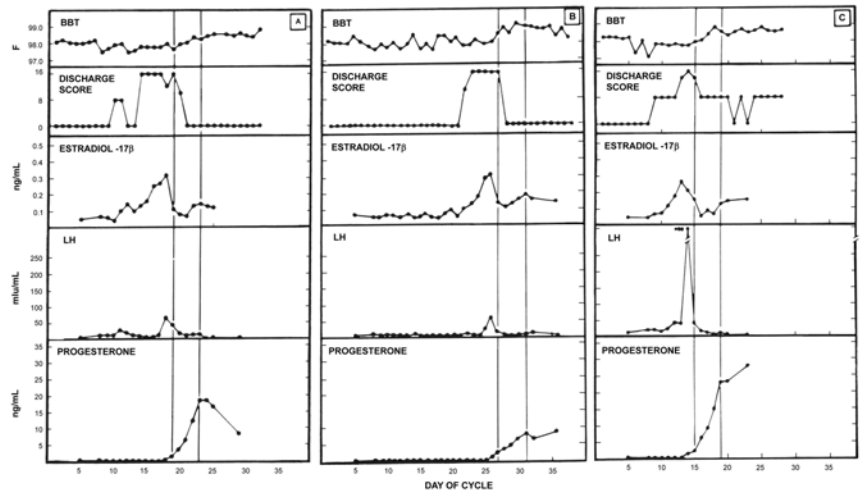

Figure 31: Serum progesterone, LH, estradiol-17β, discharge scores, and BBT values for a normal 32-day cycle (A), a long 38-day cycle (B), and a cycle with continuous discharge (C). The first vertical line indicates the Peak Day and the second vertical line indicates the fourth day after the Peak or the beginning of post-Peak infertility[32] (From: Hilgers TW, Abraham GE, Cavanagh D: Natural Family Planning - I. The Peak Symptom and Estimated Time of Ovulation. Obstet Gynec 52:575-582, 1978).

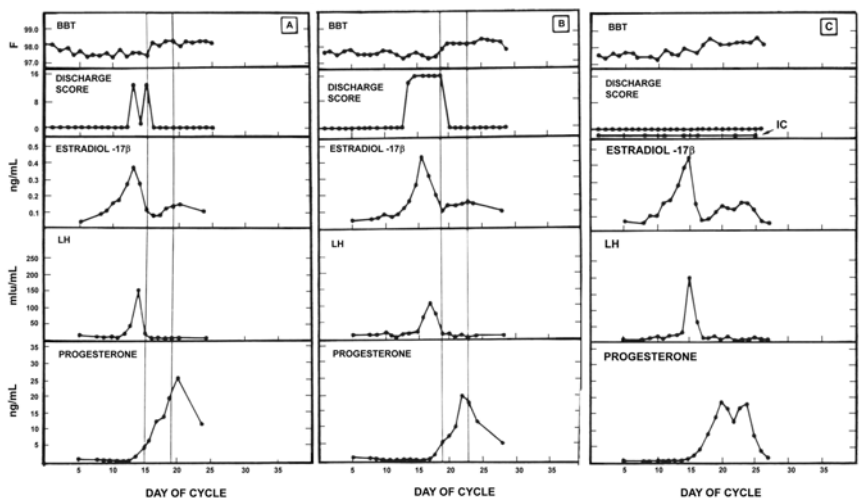

Figure 32: Serum progesterone, LH, estradiol-17β, discharge scores, and BBT values in three consecutive cycles from the same patient. The third cycle was "dry" with no Peak. Acts of intercourse are indcated (IC) and the estimated time of ovulation was day 15 (cycle C)[32] (From: Hilgers TW, Abraham GE, Cavanagh D: Natural Family Planning - I. The Peak Symptom and Estimated Time of Ovulation. Obstet Gynec 52:575-582, 1978).

and the occurrence of ovulation (using indirect hormonal parameters) with the presence or absence of the mucus cycle. These are shown in Figures 31 and 32. In Figure 31A, a normal 32-day menstrual cycle is shown. The mucus cycle begins at the start of the preovulatory rise in estradiol and ovulation occurred by Peak + 1. In Figure 31B, a *longer menstrual cycle* is shown, 38 days in duration. While the preovulatory rise in estradiol and ovulation are both delayed in this cycle, a concomitant delay in the appearance of the mucus sign and occurrence of the Peak Day are also observed. There is an additional coinciding of the Peak Day with the time of ovulation. Finally, in Figure 31C, the discharge score reflects a *continuous mucus discharge*. Even in the presence of such a discharge, the woman was able to identify the preovulatory change in the mucus pattern and the Peak Day all correlating very well with the various hormonal parameters.

In Figure 32, the hormone levels and discharge scores in three consecutive cycles from the same patient are shown. There are a couple of important features in this pattern. The first cycle shows a short 3-day mucus cycle. Intercourse in this normally fertile couple occurred *the day before the beginning of the Peak type mucus*. *No pregnancy occurred* and the correlation of the mucus sign and the Peak Day correlated well with the hormonal events. Figure 32B shows a normal mucus cycle in

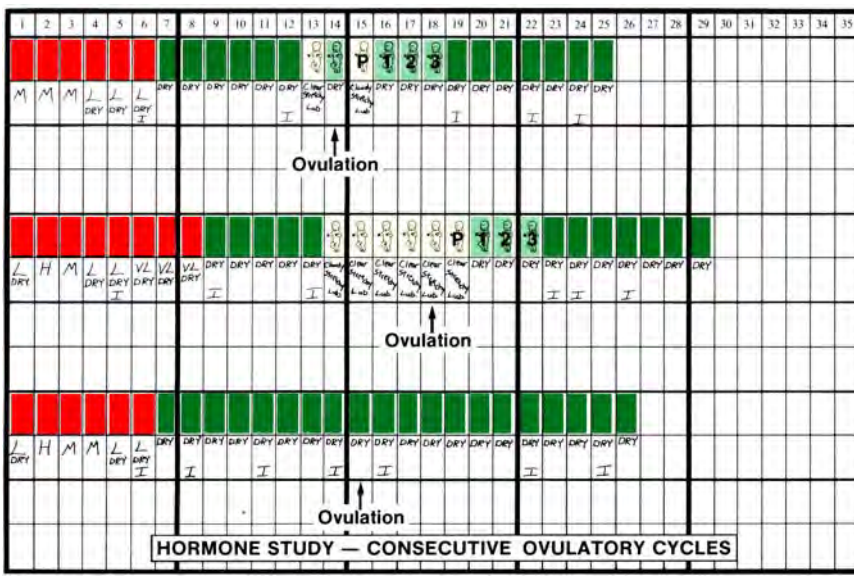

Figure 33: The **CrMS** chart, three consecutive cycles, of the woman shown in Figure 32 A, B, and C.

the same patient with similar correlation. In Figure 32C, no mucus was observed in spite of the presence of a perfectly normal hormonal pattern of ovulation. An exact explanation for this dry cycle has not yet been forthcoming but a target (end) organ failure of the cervix could explain this particular set of circumstances. Intercourse that occurred both before and after the estimated time of ovulation did not result in pregnancy. Two cycles after the conclusion of this study, the patient had the resumption of a cervical mucus pattern similar to that found in Figure 32B and pregnancy occurred and proceeded without difficulty. Her actual CrMS chart is shown in Figure 33.

Extensive hormone evaluation of the mucus sign in hundreds of menstrual cycles has been done both in *Melbourne* and in *Omaha*. *These profiles continue to show these exacting relationships*.[35]

Correlation with Ultrasound

Serial ultrasound examination of the ovarian follicle is the newest technology to be used to assess the correlation between the changes in the biophysical properties of the cervical mucus and the events occurring at the time of ovulation. Leader, et al,[36] showed the relationship between the increasing diameter of the dominant preovulatory follicle and its subsequent rupture with the increasing Insler cervical mucus score (Figure 34). Similar observations were made by Daily, et al,[37] and Nulsen, et al.[38]

In looking at the relationship of the Peak Day to the occurrence of ovulation by ultrasound, Depares, et al[39] published the data found in Table 3.

Ultrasound assesses the anat-

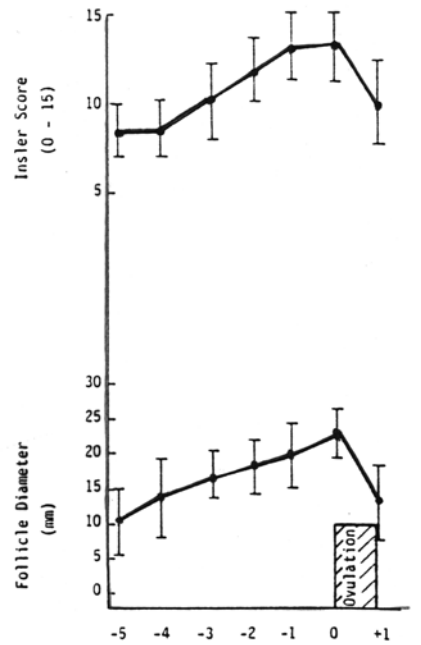

Figure 34: The Modified Insler Score as ovulation approaches corelated with the increasing size and subsequent rupture of the ovarian follicle as detected by ultrasound (From: Leader A, Wiseman D, Tayler PJ: The Prediction of Ovulation: A Comparison of the Basal Body Temperature Graph, Cervical Mucus Score and Real Time Pelvic Ultrasonograph. Fertil Steril, 43: 385-388, 1985).

omy of follicular development and subsequent rupture of the follicle (presumptive ovulation). This study revealed the continuing, remarkably close association of the timing of ovulation to the occurrence of the Peak Day. Hilgers has correlated the rupture of the ovarian follicle relative to the woman's observation of her Peak Day in women with infertility. The results of this study are shown in Table 4. The rupture of the follicle in this study (n=33) revealed a close association, once again, with the observance of the Peak day and a range consistent with previous hormonal evaluation (P-2 to P+3). This study has now been expanded to 432 cycles with the same results (see Chapter 61).

Also, Hilgers has followed 47 infertile patients, by serial ultrasound, ***in cycles in which the woman actually became pregnant***. In these pregnancy cycles, the rupture of the ovarian follicle was also associated with the occurrence of the Peak day in a similar fashion. The pregnancies occurred from Peak -2 through Peak +3 (Table 5). This is the first study of its kind associating ultrasound with the occurrence of ovulation and pregnancy while at the same time correlating the woman's observation of the Peak day. In the study of *over 2,000 menstrual cycles* by serial ultrasound evaluation of ovulation, no pregnancies have ever been observed before P-2 or after P+3 (experience at Pope Paul VI Institute, Omaha, Nebraska, USA).

Table 3: Mucus Signs Related to Ovulation and Determined by Ultrasound (N = 9 and 12)

	Day	n	%
Most abundant fertile-type mucus	-1	1	11.1
	0	7	77.8
	+1	1	11.1
Last day of fertile-type mucus	-1	0	0.0
	0	4	33.3
	+1	7	58.3
	+2	1	8.3

1. Depares J, Ryder REJ, Walker SM and Scanlon MF: Ovarian ultrasonography highlights precision of symptoms of ovulation as markers of ovulation. British Medical Journal. 292:1562, 1986.

Table 4: The Creighton Model System: Correlating the Peak Day with Ultrasound Parameters of Ovulation (N=33), Patients with Infertility

Follicular Rupture Relative to the Peak Day[1]	n	%
P-2	2	6.1
P-1	5	15.2
Peak	11	33.3
P+1	9	27.3
P+2	3	9.1
P+3	3	9.1
Totals	**33**	**100.1**

1. X ETO = Peak + 0.45 days; ETO ± days of Peak = 91.0%
Data from: Hilgers, Pope Paul VI Institute

Table 5: Follicular Rupture vs. Peak Day in Pregnancy, Same Cycle Ultrasound, Women with Infertility (N=47)

Follicular Rupture Relative to the Peak Day[1]	n	%
P-2	2	4.2
P-1	7	14.9
Peak	17	36.2
P+1	11	23.4
P+2	6	12.7
P+3	4	8.5
Totals	**47**	**99.9**

1. Pope Paul VI Institute Division of Reproductive Ultrasound.
2. No pregnancies have been observed before P-2 or after P+3 in eighteen years of study with ultrasound.

The Karyopyknotic Index Correlation

Taylor, et al,[40] reported on the relationship of the ***Karyopyknotic Index*** (KPI) and the woman's observation of her Peak day. The KPI is the ratio of cells with mature pyknotic nuclei (superficial cells) to cells with immature vesicular nuclei (intermediate cells). The cells were obtained from the vagina. Vaginal cells mature from basal to intermediate to superficial with estrogen stimulation. These vaginal cytology smears, taken serially throughout the menstrual cycle, provide a relatively simple and reliable procedure for the evaluation of ovarian function, especially the estrogen status during the preovulatory phase of the cycle. The striking relationship between the KPI and the Peak mucus day is shown in Figure 35 (78 menstrual cycles, 67 women). The Peak PI occurred on Peak ±3 days in 98.7 percent of the cycles.

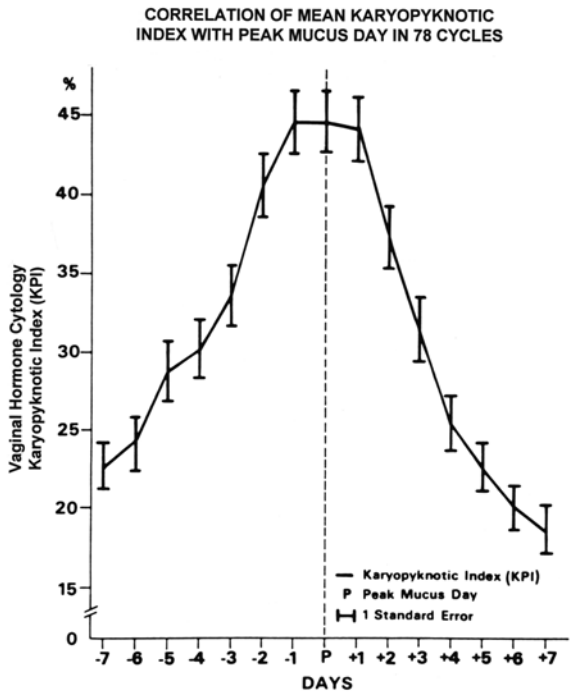

Figure 35: The correlation of the mean Karyopyknotic Index (KPI) with mean mucus days ± 7 days in 78 cycles (From: Taylor, R.S., Woods, J.B. and Guapo, M.: Correlation of Vaginal Hormonal Cytograms with Cervical Mucus Symptoms. The Journal of Reproductive Medicine. 31, 1986).

Breast Feeding

Women who are breast feeding or postpartum, not breast feeding, have also been studied extensively with hormonal correlation. Brown, et al,[28] using weekly urinary estrogen and pregnanediol assays in 24-hour urine collections and daily mucus scores, found that the endocrine relationships to the woman's observation of mucus and the Peak Day were related and the indirect estimation of ovulation was well correlated. Examples of these studies are included in Figures 36, 37, and 38. This study included 42 women for periods of up to a year or more, all with similar results.

Mucus Observation Study

One of the techniques used to assist us in the development of the standardized system for observing the mucus was an anonymous survey with questions directed at the woman's mucus observation routine. This survey was answered by 130 women (70.2 percent response) using the system of observation described for use with the CrMS.[41] From this evaluation, a number of important facts came forward (Tables 6 through 9).

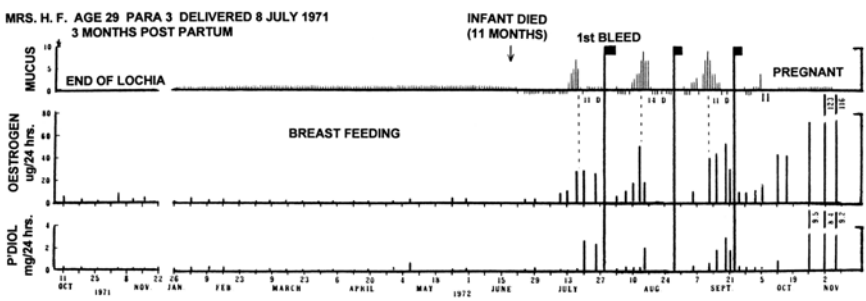

Figure 36: Weekly urinary estrogen and pregnanediol values and daily mucus scores during latation amenorrhea, first ovulation and pregnancy. In this study, the dotted vertical lines represent the best estimate of the days of ovulation and the solid vertical lines mark the first day of menstruation. The calculated lengths of the luteal phases are shown. I = intercourse (From: Brown JB, Harisson P, Smith MA, et al.: Correlations between the Mucus Symptoms and the Hormonal Markers of Fertility throughout Reproductive Life. Ovulation Method Research and Reference Centre of Australia, Melbourne, Victoria, Australia, 1981).

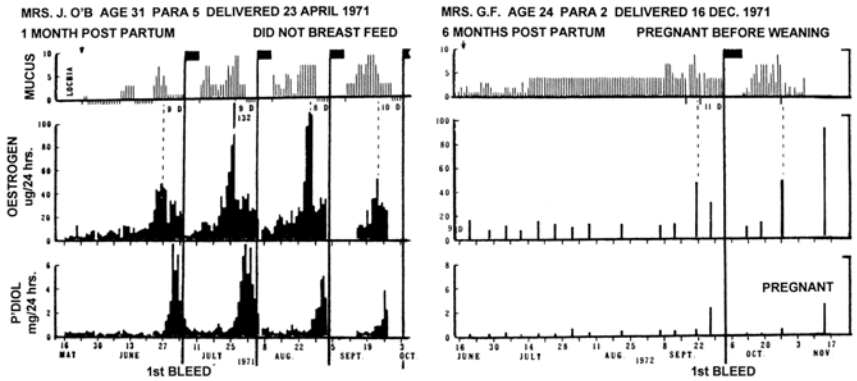

Figure 37: Urinary estrogen and pregnanediol values and daily mucus scores postpatum in a subject who did not breast feed (Mrs. J. O'B.) and another subject who conceived during breast feeding (Mrs. G.F.) (From: Brown JB, Harisson P, Smith MA, et al.: Correlations between the Mucus Symptoms and the Hormonal Markers of Fertility throughout Reproductive Life. Ovulation Method Research and Reference Centre of Australia, Melbourne, Victoria, Australia, 1981).

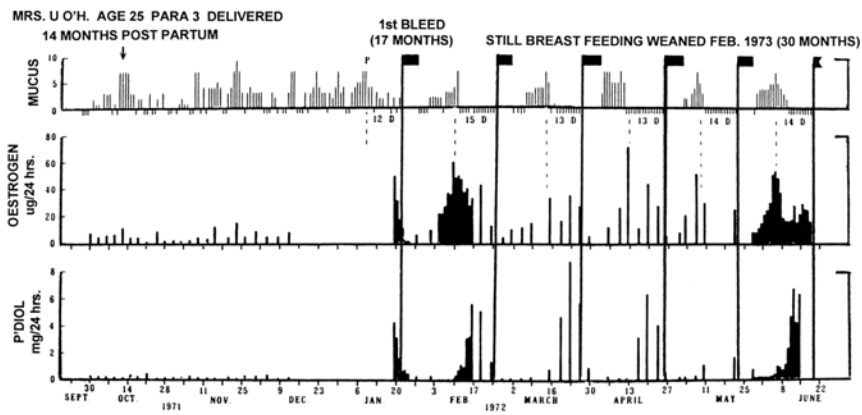

Figure 38: Urinary estrogen and prenanediol values and daily mucus scores in a subject who breastfed for 30 months. First ovulation postpartum occurred 17 months after delivery (From: Brown JB, Harisson P, Smith MA, et al.: Correlations between the Mucus Symptoms and the Hormonal Markers of Fertility throughout Reproductive Life. Ovulation Method Research and Reference Centre of Australia, Melbourne, Victoria, Australia, 1981).

Table 6: Mucus Observation Study (N=130)

Item	Percent
Checked every time	90.0
Observed with folded tissue	96.0
Did not do internal exams	99.0
Most difficult time to observe: early morning	57.7
Observing the mucus was easy or very easy	93.0
Observing the mucus after a bowel movement was easy or very easy	82.0
Seminal fluid instruction: easy or very easy	85.4
Seminal fluid instruction is helpful or very helpful	84.6
Bearing down at end of the day: helpful or very helpful	86.9
Kegel's exercise: helpful or very helpful	79.2

Table 7: Mucus Observation Study cont'd (N=130)

Item	Percent
Mucus was most obvious:	
Before urination	57.7
After urination	45.4
Before bowel movement	20.0
After bowel movement	79.2
Ever observed the mucus:	
Before urination, not after	73.1
After urination, not before	61.5
Before a bowel movement, not after	33.8
After a bowel movement, not before	73.8

Table 8: Mucus Observation Study cont'd (N=130)

Item	Percent
Ever obvserved the mucus once during the day and this was:	
After urination	58.5
After bowel movement	57.7

1. Of the population of women studied, 90.0 percent indicated that they checked for the mucus *every time* they went to the bathroom. This percentage was lower for those women who indicated that they were using the system to achieve a pregnancy and higher for those who indicated they were using it to avoid pregnancy.

2. Over 96.0 percent of women observed the mucus with folded tissue and less than one percent did internal examinations.

3. When asked to pick one time of the day in which the mucus was thought to be the most obvious, *no clear pattern* developed. The mucus was seen in this population of women throughout the course of the day, and there was no time during the day where it was consistently more obvious.

4. The most difficult time during the day to observe the mucus discharge was in the early morning. Over 57.7 percent of the women marked that choice out of a list of six. This undoubtedly is related to the hectic events of this time of day. If the teacher is aware of this, he or she can provide helpful assistance to the client where this is a problem.

5. When asked whether the mucus was most obvious before or after urination and before or after a bowel movement, 57.7 percent indicated before urination, 45.4 after urination, 20.0 before a bowel

Table 9: Mucus Observation Study cont'd (N=130)

Item	Percent
How long does it take to make the observation	
0–10 seconds	44.0
10–20 seconds	39.0
20–30 seconds	11.5
30–40 seconds	3.1
>40 seconds	2.4
30 seconds or less	94.5
Time of day mucus was most obvious	No time more obvious than others

movement, and 79.2 after a bowel movement. There was room for multiple answers to these questions, thus the totals do not add to 100.0. Nonetheless, it indicates that the mucus was sometimes more obvious at any one of those observations. Of course, it cannot be predicted at any one observation when the mucus might be observed.

6. When asked if the mucus had *ever* been observed *before* urination but not after, 73.1 indicated it had. When asked if the mucus had *ever* been observed *after* urination but not before, 61.5 percent indicated it had. When asked if the mucus had *ever* been observed *before* a bowel movement but not after 33.8 percent indicated it had. When asked if the mucus had *ever* been observed *after* a bowel movement but not before, 73.8 percent indicated that it had.

7. The women were also asked if they had *ever* observed the mucus just *once* during the day and at that time it was observed only *after urination*. For the 130 responders, 58.5 percent indicated this circumstance had occurred to them. The same question was asked relative to the observation of the mucus *only after* a bowel movement and 57.7 percent indicated this had occurred to them. The data presented in items 5, 6 and 7 lend support to the importance of the 100-percent observational routine.

8. The women were asked, "When in the bathroom, about how much time does it take you to check for the mucus?" About 44 percent indicated 0 to 10 seconds, 39 percent 10 to 20 seconds, 11.5 percent 20 to 30 second, and 3.1 percent 30 to 40 seconds. Only 2.4 percent indicated that it took longer than 40 seconds.

9. Over 93 percent of women studied indicated that observing the mucus was either *easy* or *very easy* to do.

10. Over 82 percent of the women indicated that observing the mucus after a bowel movement was either *easy* or *very easy*.

11. Of the 130 women, 122 were in a position to answer the question, "*Prior* to coming to the **Fertility*Care*™ Center**, did you empty your bladder *after* having intercourse?" A large majority (76.2 percent)

answered yes to this question. Thus, we learned from our patients that the practice of emptying the bladder following intercourse was a customary event.

12. For those women who had used the seminal fluid instruction, 84.6 percent found emptying the bladder either *helpful* or *definitely helpful*. In 86.9 percent, bearing down was found to be either *helpful* or *definitely helpful* and 79.2 percent found Kegel's exercise *helpful* or *definitely helpful*. Overall, 85.4 percent of the women indicated that the seminal fluid instruction was either *easy* or *very easy* to do.

Statistical Parameters of the Mucus Cycle

A preliminary study of 600 menstrual cycles form 100 women was undertaken to examine the statistical parameters of the mucus cycle. This study involved women with regular cycles, those coming off birth control pills, those approaching menopause, those who are breast feeding, and those with long and irregular cycles.[42] A number of interesting findings were revealed. These data can be helpful in teaching, in reviewing charts and interpreting their meaning (Table 10).

1. In 94.0 percent of cycles, a Peak Day was observed. However, the absence of a Peak Day was observed in only 2.5 percent of women with

Table 10: Statistical Parameters of the Mucus Cycle (N=600)

Item	Answer
Peak Day observed[1]	94.0
Average length of the mucus cycle	5.6 days
Average length of the post-Peak phase	12.3 days
1–7 days	7.7%
8–16 days	89.9%
>16 days	2.4%
Incidence of premenstrual mucus	12.3%
Incidence of "double" Peak	7.8%

1. Only 2.5 percent in women with regular cycles.

regular cycles while the incidence was higher in women approaching menopause. This could be anticipated since ovarian function tends to decline with advancing age.

2. The average length of the mucus cycle was 5.6 days in women with regular cycles. There was a tendency for the mucus cycle to be somewhat longer in women coming off birth control pills but shorter in breast feeding women and those approaching menopause.

3. The average length of the post-Peak phase in women with regular cycles was 12.3 days. This was slightly shorter in women coming off birth control pills, breast-feeding women, women with long cycles, and women approaching menopause. In women with regular cycles, the post-Peak phase was 1-7 days in duration in 7.7 percent and greater than 16 days in 2.4 percent. The short post-Peak phase was found to be higher in women coming off birth control pills, breast-feeding women, and those women approaching menopause. The post-Peak phase was found to be longer more frequently in women coming off of birth control pills and women who were breast feeding.

4. The overall incidence of premenstrual mucus was found to be 12.3 percent in women with regular cycles but less than that in women coming off of birth control pills and those approaching menopause.

5. The overall incidence of "double" Peak was 7.8 percent.

Evaluation of the Education System

Clients' evaluations of this educational system have been tabulated for a large national experience. With the use of the Introductory Session, teacher, and follow-up evaluation forms, a large volume of client response has been collected. In Tables 11 through 17, the Introductory Session evaluation is presented for 4,136 observers. In Tables 18 through 22, evaluations of the follow-up sessions from 936 respondents are presented. In Table 23 and 24, the results of 925 teacher evaluations are presented.

A total of 97.3 percent of the clients felt that the *amount of material*

Table 11: Introductory Session Evaluation: "The amount of material was..." (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Too much	36	1.4	29	1.9	65	1.6
Appropriate	2,529	97.7	1,497	96.7	4,026	97.3
Too little	23	0.9	22	1.4	45	1.1
Totals	2,588	100.0	1,548	100.0	4,136	100.0

Table 12: Introductory Session Evaluation: "The quality of material was..." (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Too advanced	18	0.7	9	0.6	27	0.6
Appropriate	2,505	96.8	1,482	95.7	3,987	96.4
Too simple	65	2.5	57	3.7	122	2.9
Totals	2,588	100.0	1,548	100.0	4,136	99.9

Table 13: Introductory Session Evaluation: "The teacher's presentation was..." (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Exciting	365	14.1	153	9.9	518	12.5
Interesting	2,089	80.7	1,250	80.7	3,339	80.7
Average	129	5.0	142	9.2	271	6.6
Dull	5	0.2	3	0.2	8	0.2
Totals	2,588	100.0	1,548	100.0	4,136	100.0

Table 14: Introductory Session Evaluation: "Explanations were..." (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Always clear	1,527	59.0	923	59.6	2,450	59.2
Usually clear	1,053	40.7	625	40.4	1,678	40.6
Seldom clear	8	0.3	0	0.0	8	0.2
Dull	0	0.0	0	0.0	0	0.0
Totals	2,588	100.0	1,548	100.0	4,136	100.0

Table 15: Introductory Session Evaluation: "Opportunity questions for was..." (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Excellent	1,798	69.5	1,050	67.8	2,848	68.8
Good	748	28.9	474	30.6	1,222	29.5
Fair	39	1.5	22	1.4	61	1.5
Poor	3	0.1	2	0.1	5	0.1
Totals	2,588	100.0	1,548	99.9	4,136	99.9

Table 16: Introductory Session Evaluation: "Overall, how would you rate the Introductory Session?" (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Excellent	1,507	58.2	833	53.8	2,340	56.6
Good	1,053	40.7	690	44.6	1,743	42.1
Fair	28	1.1	25	1.6	53	1.3
Poor	0	0.0	0	0.0	0	0.2
Totals	2,588	100.0	1,548	99.9	4,136	100.0

Table 17: Introductory Session Evaluation: "Check any words that describe the Introductory Session" (N=4,136)

	Female		Male		Totals	
	n	%	n	%	n	%
Worthwhile	2,458	95.0	1,378	89.0	3,836	92.7
Threatening	16	0.6	8	0.5	24	0.6
Open to comment	1,343	51.9	613	39.6	1,956	47.3
Frustrating	54	2.1	14	0.9	68	1.6
Comprehensive	1,255	48.5	672	43.4	1,927	46.6
Dull	13	0.5	22	1.4	35	8.5
Enthusiastic	1,090	42.1	477	30.8	1,567	37.9
Closed to comment	5	0.2	2	0.1	7	1.7
Enlightening	1,918	74.1	1,119	72.3	3,037	73.4
Discouraging	34	1.3	15	1.0	49	1.2
Totals	2,588	—	1,548	—	4,136	—

Table 18: Follow-up Evaluation: Teacher's Presentation, Explanation, and Opportunity for Questions (N=936)

Teacher's Presentation	n	%	Explanations	n	%	Opportunity for Questions	n	%
Exciting	119	12.7	Always clear	511	54.6	Excellent	779	83.2
Interesting	745	79.6	Usually clear	423	45.2	Good	153	16.3
Average	72	7.7	Seldom clear	2	0.2	Fair	4	0.4
Dull	0	0.0	Clear	0	0.0	Poor	0	0.0
Totals	936	100.0		936	100.0		936	99.9

Table 19: Follow-up Evaluation: Amount and Quality of Material (N=936)

Amount of Material	n	%	Quality of Material	n	%
Too much	119	12.7	Too advanced	511	54.6
Appropriate	745	79.6	Appropriate	423	45.2
Too little	72	7.7	Too simple	2	0.2
Totals	936	100.0		936	100.0

Table 20: Follow-up Evaluation: Use of Teaching Aids (N=936)

	Introductory Booklet		Picture Dictionary		Sample Chart	
	n	%	n	%	n	%
Very useful	511	54.6	655	70.0	608	65.0
Useful	393	42.0	229	24.5	265	28.3
Somewhat useful	31	3.3	52	5.6	61	6.5
Not useful	1	0.1	0	0.0	2	0.2
Totals	936	100.0	936	100.1	936	100.0

Table 21: Follow-up Evaluation: "Check any words that apply to teaching/follow-up sessions" (N=936)

	n	%		n	%
Worthwhile	853	91.1	Enthusiastic	422	45.1
Threatening	3	0.3	Anxiety-provoking	48	5.1
Supportive	755	80.7	Encouraging	726	77.6
Frustrating	64	6.8	Closed to comment	4	0.4
Dull	7	0.7	Discouraging	15	1.6
Open to comment	653	69.8	Essential to learning	808	86.3
Hostile	1	0.1	Condescending	9	1.0
Enlightening	579	61.8	Comprehensive	484	51.7

Table 22: Follow-up Evaluation: "Overall, how would you rate the teaching/follow-up session?" (N=936)

Rating	n	%
Excellent	670	71.6
Good	259	27.7
Fair	7	0.7
Poor	0	0.0
Totals	936	100.0

Table 23: Teacher Evaluation (N=925)

Rating Score	General Presentation n	%	Using Teaching Aids n	%	Opportunity for Question n	%	Personal Approach n	%	Confidence Development n	%	Overall Evaluation n	%
	Poorly Organized		*Not useful*		*Poor*		*Unsupportive*		*Not Important*		*Poor*	
0	0	0.0	0	0.0	0	0.0	1	0.1	3	0.3	0	0.0
2	0	0.0	0	0.0	0	0.0	0	0.0	7	0.8	1	0.1
3	6	0.6	8	0.9	1	0.1	5	0.5	9	1.0	1	0.1
	Organized		*Useful*		*Good*		*Supportive*		*Important*		*Good*	
4	65	7.0	90	9.7	32	3.4	38	4.1	69	7.4	30	3.2
5	108	11.7	121	13.1	39	4.2	59	6.4	77	8.3	44	4.8
6	275	29.7	244	26.4	126	13.6	145	15.7	241	26.0	259	28.0
	Very Organized		*Very Useful*		*Excellent*		*Very Supportive*		*Very Important*		*Excellent*	
7	471	50.9	462	49.9	727	78.6	677	73.2	519	56.1	590	63.8
	925	99.9	925	100.0	925	99.9	925	100.0	925	99.9	925	100.0

Table 24: Teacher Evaluation:
"Check any words that apply to your teacher"
(N=925)

	n	%		n	%
Disorganized	4	0.4	Supportive	779	84.2
Sensitive	640	69.2	Thorough	752	81.3
Discouraging	4	0.4	Hostile	1	0.1
Threatening	3	0.3	Organized	724	78.3
Interested	840	90.8	Dominating	9	1.0
Frustrating	11	1.2	Enthusiastic	700	75.7
Open to comment	729	78.8	Closed to comment	3	0.3
Unclear	14	1.5			

* Of 925 clients, this data reflects the number and percent of those who checked each word. Many clients checked more than one word.

in the *Introductory Session* was ***appropriate*** and 96.4 percent found that the ***quality of material*** was *appropriate*. Very few felt that the amount of material was either *too much* or *too little* or that the quality of material was *too advanced* or *too simple*. The ***teacher's presentation*** was judged to be *interesting* by 80.7 percent of the clients and *exciting* by 12.5 percent. ***Explanations*** during the Introductory Session were found to be *usually* or *always clear* by 99.8 percent. The ***opportunity for questions*** was judged to be *good or excellent* by 98.3 percent.

When asked to check words that describe the ***Introductory Session***, clients rated it (in descending order) *worthwhile*, *enlightening*, *open to comment*, *comprehensive*, and *enthusiastic*. Less than 10 percent found it to be (in descending order) *dull*, *closed to comment*, *frustrating*, *discouraging*, or *threatening*. The session ***overall*** was rated *excellent* by 56.6 percent and *good* by 42.1 percent of the clients. There was very little difference between male and female responders.

The ***teacher*** is evaluated for six different items (including an overall evaluation) on rating score of 1 through 7 with 7 being the best score. The *overall evaluation of the teachers* was either a score of 6 or 7 for 91.8 percent of the clients. The teacher's *general presentation* was judged a 5, 6, or 7 by 92.3 percent. The teacher's *use of teaching aids* was judged a 5, 6, or 7 by 89.4 percent. *Opportunity for questions* was score a 6 or 7 by 92.2 percent. The teacher's *personal approach with regard to support* of

the client was judged a 6 or 7 by 88.9 percent. Finally, the importance of the teacher in the development of the client's confidence was judged a 5, 6 or 7 by 90.4 percent.

When asked to check words that would apply to the ***teacher***, the clients recorded the following words most frequently (in descending order): *interested*, *supportive*, *thorough*, *open to comment*, *organized*, *enthusiastic* and *sensitive*. Less than 2 percent of the clients judged their teachers to be (in descending order): *unclear*, *frustrating*, *dominating*, *disorganized*, *discouraging*, *threatening*, *closed to comment*, *hostile*.

With regard to the ***follow-ups***, 92.3 percent of the clients judged their teacher's presentation as either *interesting* or *exciting*. *Explanations* were judged to be *usually* or *always clear* by 99.8 percent. *Opportunity for questions* was judged to be *good* or *excellent* by 99.5 percent. The *amount of material* presented at the time of the follow-up was judged to be *appropriate* by 94.5 percent and the *quality of the material* was judged to be *appropriate* by 97.9 percent. Very few clients judged the amount of material to be either too much or too little or the quality of the material to be too advanced or too simple.

The use of the ***introductory booklet*** was found to be either *useful* or *very useful* by 96.6 percent of the clients. *The Picture Dictionary* was judged to be *useful* or *very useful* by 94.5 percent. The *Sample Teaching Charts* were found *useful* or *very useful* by 93.3 percent.

When asked to check the words that described the ***teaching/follow-up sessions***, the following words were given the most frequently (in descending order): *worthwhile*, *essential to learning*, *encouraging*, *supportive*, *open to comment*, *enlightening*, *comprehensive* and *enthusiastic*. Less than 7.0 percent of the clients viewed the teaching/follow-up sessions as (in descending order): *frustrating*, *anxiety-provoking*, *discouraging*, *condescending*, *dull*, *closed to comment*, *threatening* or *hostile*.

Finally, when asked to provided an ***overall rating of the teaching/follow-up session***, 71.6 percent of the clients judged them to be *excellent* while 27.7 percent indicated *good*. Only 0.7 percent said they were fair, and none of them indicated they were poor.

Spousal Communication with the CrMS

A pilot survey of 48 couples were interviewed regarding the communication patterns that they observed or developed with the use of

the CrMS.[43] This survey, which is preliminary in its findings, provides some initial insight into what can be expected of couples that use the CrMS.

When the couples were asked whether they had discussed their decision to either achieve or avoid pregnancy while following the CrMS, 100 percent indicated they had. When asked whether the couple verbally discussed when they would and would not have genital intercourse, 89.6 percent indicated they had. When asked whether the CrMS encouraged or discouraged *verbal* communication in the decision to have genital intercourse, 92.8 percent indicated that it encouraged communication. When asked whether *verbal* communication in deciding to have intercourse had increased, remained the same or decreased since changing from their previous method of contraception to the CrMS, 72.9 percent indicated it had increased, 18.8 percent indicated it had remained the same, and no one indicated it had decreased (Table 25).

Table 25: Communication in Creighton Model Users: Pilot Survey Results (N=48 couples)

Couples discussed pregnancy intentions	100.0%
System encouraged verbal communication re: intercourse	92.8%
Couples verbally discussed having intercourse	89.6%
Verbal communication re: intercourse increased after using the system (from their previous method)	72.9%

Table 26: Communication in Creighton Model Users: Pilot Survey Results (N=48 couples)

Husbands liked system	95.0%
Husbands showed interest in charting or observations	81.0%
Husbands indicated support in use of the system	95.0%
Avoiding genital contact was reasonably easy or very easy	70.8%

These patterns of communication were thought to be revealing. Most teachers of the CrMS have felt that such patterns existed and these data support that contention.

Over 81 percent of women indicated that their ***husbands showed interest in their charting*** or observations and over 95 percent of the husbands indicated that they like of the CrMS (as opposed to disliking) (Table 26). When the wives were asked if their husbands had given them support in the use of the CrMS, 75 percent said that their husbands were very supportive and another 20.8 percent indicated they were somewhat supportive. Data such as this, if collected on a much larger scale, could dispel the old myth that natural methods of fertility regulation are disliked by men.

Finally, the couples were asked whether they found that ***avoiding genital contact*** was *very easy*, *reasonably easy*, *reasonably difficult* or *very difficult*. For 70.8 percent of couples, avoiding genital contact was thought to be either reasonably easy or very easy. However 21.2 percent indicated that it was either *reasonably difficult* or *very difficulty*. That group was also asked if they found that it does or does not interfere with the development of their overall relationship. The overwhelming majority, 85.7 percent, indicated it did not interfere with the development of their overall relationship.

These data suggest that avoiding genital contact is, in general, not particularly difficult when using the CrMS. At the same time, it does not rule out the possibility that some couples will have some degree of difficulty with this. However, for those couples, one can gain confidence in the fact that avoiding genital contact is not deleterious to their overall relationship.

Fehring[44-46], in a comparison of users in the CrMS with couples using oral contraceptives, administered psychometric assessments to both sets of users. In this assessment, statistically significantly improved scores were found in the CrMS for *spiritual well-being*, *religious well-being*, *existential well-being*, *self-esteem*, *intellectual intimacy*, *sexual intimacy*, and *recreational intimacy*. For emotional intimacy and social intimacy, there was no statistically significant difference between the two groups (see Table 27).

Table 27: A Comparison of Psychological/Spiritual Variables Between the Creighton Model FertilityCare™ System (N=88) and Couples Using Oral Contraceptives (Fehring)[46]

Psychometric Assessment	Creighton Model FertilityCare™ System		Oral Contraceptives			
	X	SD	X	SD	*t*-test	*p*-values
Spiritual well-being	108.70	10.27	96.43	14.98	6.36	.001
Religious well-being	55.33	6.36	46.74	10.40	6.98	.001
Existential well-being	53.37	5.31	49.67	7.70	3.73	.01
Self-esteem	84.16	11.99	78.13	17.26	2.70	.01
Intellectual intimacy	77.72	14.22	71.67	16.92	2.57	.01
Sexual intimacy	78.23	13.42	72.82	16.00	2.43	.01
Recreational intimacy	72.80	13.51	68.29	14.99	2.09	.05
Emotional intimacy	72.32	17.51	70.35	19.79	0.70	NS
Social intimacy	73.44	15.11	73.51	16.84	0.03	NS

Effectiveness of the System

The *effectiveness* of the **CREIGHTON MODEL System**, *because it is not a contraceptive*, must take into account its ability to be used both *as a system to achieve pregnancy as well as avoid pregnancy*.[47] The normal use of a system such as this, during the reproductive years in couples desiring a family, is to use it for a while to avoid pregnancy and then use it to achieve pregnancy (or vice versa). This cycle is then repeated on a *freely chosen* basis according to a married couple's ability to have and raise children. *This is the only family planning method* (including other natural methods) that can be used consciously and conscientiously in both ways (with the exception of the Billings Ovulation Method).

In considering these concepts of use, the *method and use effectiveness as a means of avoiding pregnancy* and *the method and use effectiveness as a means of achieving pregnancy* can both be measured. The method and use effectiveness as a means of avoiding pregnancy can then be compared to comparable data for artificial methods of contraception. The method and use effectiveness to achieve a pregnancy gives on the one hand, cycle-by-cycle success rates in the use of fertility focused intercourse for the achievement of pregnancy (*method effectiveness to achieve pregnancy*) and, on the other hand, data on the *use-dynamics* of the system in a population of couples (*use-effectiveness to achieve pregnancy*). The total

pregnancy rate is a combination of its use-effectiveness to avoid pregnancy and its use-effectiveness to achieve pregnancy and is expressed as a rate. The sum of these two rates (subtracted from 100) gives an estimate of its **demographic effectiveness** (or, as some have called it, the **extended use-effectiveness**). The development of data such as this gives insight into the use of the system, as compared to contraceptive methods.Additionally, measurements of effectiveness will reflect the ability of the system to be taught properly.

The CrMS has been extensively studied and a **meta-analysis** of the system has incorporated the data from five studies into a composite including **1,876 couples over 17,130 couple months of use**.[49-53] These studies, all utilizing life-table analysis and *an objective assessment of pregnancies*, reported the range of the *method effectiveness to avoid pregnancy* at the 12th ordinal month to be 98.7 to 99.8 (with the 5-study composite **99.5**). The *use effectiveness to avoid pregnancy* for the same time period ranged from 94.6 to 97.9 and was shown to continually improve over the 14 years of the studies (the 5-study composite was **96.8**) (Table 28).

The use effectiveness of the CrMS to achieve a pregnancy showed expectedly wide fluctuations. At the 12th ordinal month, the achieving-related pregnancy rate ranged from 14.2 to 28.0 (the 5-study composite was 21.0). The use-effectiveness to achieve pregnancy is a demographic statistic which *applies to a population of users and not individuals*. It is the mathematical opposite of the demographic effectiveness to avoid pregnancy (Table 29).

***Discontinuation rates** were the highest (9.4) in the first six months of use*. The discontinuation rate after the first six months of use was only 2.9. The study did not involve any *learning phases* as other studies have promoted. At the 12th ordinal month the discontinuation rate was 11.3 and at the 18th ordinal month 12.1 (Table 30). It is notable that the *discontinuation rate* for the stated reason of "*difficulty avoiding genital contact*" was less than one percent .

The estimated ***demographic effectiveness*** (extended use-effectiveness) for the *oral contraceptive* and *intrauterine device* is shown in Table 31 at the 6th, 12th, and 18th ordinal month. Only a few studies of the *extended use effectiveness* (*demographic effectiveness*) *of these or any other artificial method have been done*. It is not well known that these percentages are *significantly lower* than the effectiveness normally quoted. That is, or course, as it should be since these include pregnancies after the

Table 28: Creighton Model Method and Use Effectiveness to Avoid Pregnancy by Center, 5-Study Composite and Ordinal Month of Use

	Creighton University Omaha	St. John's Mercy Hospital St. Louis	St. Francis Hospital Witchita	St. Joseph Hospital Houston	Marquette Nursing Center Milwaukee	5-Study Composite
Year of Study	1980	1980	1985	1989	1994	1995
Number of Couples	286	273	378	697	242	1,876
Number of Couple-Months	2,224.0[1]	1,980.0[1]	2,471.0[1]	7,084.5[1]	1,819.5[1]	17,130.0[1]
Method Effectiveness[3]						
Ordinal Month						
1	100.0	100.0	100.0	100.0	100.0	100.0
6	99.6	99.6	99.4	100.0	99.6	99.8
12	99.6	99.6	99.1	99.8	98.7	99.5
18	n/a	n/a	n/a	99.8	n/a	99.5
Use Effectiveness[3]						
Ordinal Month						
1	100.0	99.6	99.7	100.0	100.0	99.9
6	95.8	96.4	97.3	98.4	98.7	97.9
12	94.6	95.1	96.2	97.2	97.9	96.8
18	n/a	n/a	n/a	97.1	n/a	96.4

1. Through 12 ordinal months
2. Through 18 ordinal months
3. To avoid pregnancy
n/a = Not applicable

Table 29: Creighton Model Method- and Use-Effectiveness to Achieve Pregnancy by Center, 5-Study Composite and Ordinal Month of Use

Ordinal Month	Creighton University Omaha	St. John's Mercy Hospital St. Louis	St. Francis Hospital Witchita	St. Joseph Hospital Houston	Marquette Nursing Center Milwaukee	5-Study Composite
1	2.1	1.8	5.3	0.7	1.2	2.1
6	10.5	13.6	19.9	7.9	14.0	12.8
12	19.1	23.7	28.0	14.2	24.8	21.0
18	n/a	n/a	n/a	17.9	n/a	25.6

n/a = Not applicable

Table 30: Creighton Model Cumulative Discontinuation Rates by Reason and Ordinal Month of Use, 5-Study Composite

Reason for discontinuation	1	3	6	12	18
To use another natural method	0.0	0.3	0.3	0.7	0.7
To use an artificial method	0.2	2.5	3.9	4.5	4.9
Lack of confidence	0.2	0.6	0.6	0.7	0.8
Difficulty with avoiding genital contact	0.5	0.5	0.6	0.7	0.7
Personal reasons	0.8	2.6	3.8	4.4	4.6
Medically induced infertility	0.0	0.2	0.2	0.3	0.4
Totals	1.4	6.7[1]	9.4[2]	11.3	12.1

1. 55.4 percent of all discontinuations occurred in the first three months
2. 77.7 percent of all discontinuations occurred during the first six months
The discontinuation rate after six months was 2.9.

individuals discontinue the method as a means of avoiding pregnancy. It is the demographic effectiveness of these methods, however, that is the correct effectiveness rate to be compared to the total pregnancy rates of methodologies which are natural fertility regulators.

The extended use effectiveness of an artificial method includes a *significantly increased number of pregnancies* because the artificial method may not be tolerated for a variety of different reasons over the time period of the study. While some pregnancies in the categories would be of a similar nature in the use of a natural method of fertility regulation, most pregnancies occurring from a natural method will be in those who *knowingly use it to achieve pregnancy*.

Total pregnancy rates, in users of natural methods, are often quoted with regard to the *long-term "failure rate" of these methods*. However, to do so takes a group of people who have been *successful users* of the method (to achieve pregnancy) and classifies them inappropriately as failures of the method. More appropriately, *these pregnancies belong in the above category of extended use-effectiveness*, a concept developed by *Tietze and Lewit* and referred to originally as *demographic effectiveness*. [48,54-56] The term *demographic effectiveness* is probably more pertinent to the concept of total pregnancy rates because these data reflect the use of a method in a population of people over a period of time.

What may appear to be different between the natural and artificial

Table 31: Estimate Demographic Effectiveness (Extended Use-Effectiveness) for BCP and IUD, 6th, 12th and 18th Ordinal Month

Ordinal Month	Method and Range of Estimated Demographic Effectiveness		
	BCP[1]	BCP[2,3]	IUD[2,3]
6	—	89.9 – 97.0	94.4 – 97.5
12	62.0	75.7 – 91.6	89.9 – 95.2
18	—	65.9 – 85.4	82.8 – 95.8

1. Polaneczky M, Slap G, Forke C, et al.: The Use of Levonorgesterol Implants (Norplant) for Contraception in Adolescent Mothers. NEJM. 331: 1201, 1994.
2. Tietze C and Liewit S.: The IUD and the Pill: Extended Use-Effectiveness. Family Planning Perspectives 3: 53-55, 1971
3. Tietze C and Lewit S.: Use Effectiveness of Oral and Intrauterine Contraception. Fertil Steril. 22: 508-513, 1971.

methods is in the answer to the question: "*are the extended use pregnancies the result of successful use or failure of the methods*?" It can be properly assumed that for the artificial methods these would be considered failures. Table 32 lists the rates of wanted and unwanted pregnancy in those couples who became pregnant in the five CrMS studies. Out of 428 total pregnancies, only 4.5 couples identified their pregnancies as unwanted at the time of the pregnancy evaluation which was usually conducted, in person, within the first three months of the pregnancy. Thus, the *wanted pregnancy rate was 98.5 percent*. This has important behavioral implications which will require further study.

In other studies it has been shown that as the age of the woman increases, the pregnancy rate decreases in users of natural methods.[57] With the Ovulation Method, Billings[7] studied 98 women who were judged to be *approaching menopause*. The women ranged in age from 38 to 54 years and each was followed for an average of 4 years. One pregnancy occurred in this group in a woman who used the days of fertility for intercourse. *The method-related pregnancy rate was zero*. In a similar study of 137 women, 40 years of age or older, Klaus[58] revealed a total pregnancy rate of 0.98 (with the Billings Ovulation Method).

The *method effectiveness to achieve a pregnancy* is a pregnancy rate based on *fertility-focused intercourse* compiled in a cumulative fashion from one cycle to the next. In one such study,[59] in which 50 consecu-

Table 32: Rate of Wanted and Unwanted Pregnancy – Creighton Model Users who Became Pregnant[1] (N=428)

	Wanted		Unwanted	
Center	n	%	n	%
Creighton	91	98.9	1	1.1
St. John's Mercy[2]	66.5	99.2	0.5*	0.7
St. Francis[3]	109	97.3	3	2.7
St. Joseph	88	97.8	2	2.2
Marquette	67	100.0	0	0.0
Totals	421.5	98.5	6.5	1.5

1. Pope Paul VI Institute research, 2004.
2. There were three in which no reply was recorded.
3. There were eight in which no reply was recorded.

* 0.5 is shown because for one spouse the pregnancy was unwanted while for the other spouse the pregnancy was wanted.

tive patients were followed as they began using the method to achieve pregnancy, 76.0 percent became pregnant in the first cycle of use. By three cycles of use, 90.0 percent were pregnant and by the sixth cycle, 98.0 percent (Figure 39).

These data suggest that the *efficiency of the human reproductive system is actually greater than previously thought*. In addition, by understanding normal fertility, it gives us a better opportunity to understand conditions of abnormal fertility.

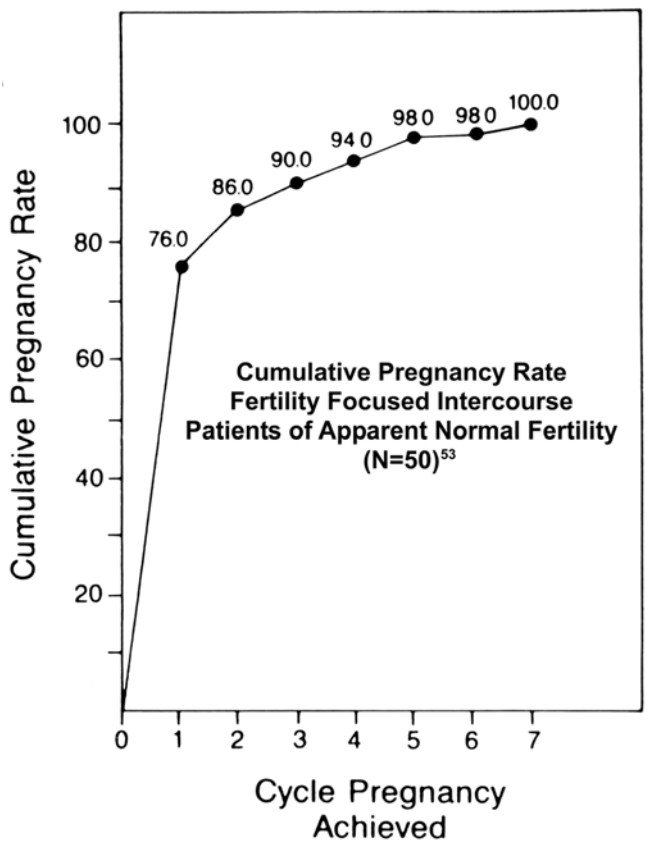

Figure 39: Cumulative pregnancy rate, fertility focused intercourse, patients of apparent normal fertility (N=50) (From: Hilgers TW, Daly KD, Prebil AM: Cumulative Pregnancy Rates in Patients with Apparently Normal Fertility and Fertility Focused Intercourse. J Repro Med, 10: 864-866, 1992).

NaProEDUCATION Technology

CREIGHTON MODEL NaProEDUCATION Technology has been extensively evaluated over the last 25 years. It is an approach to natural procreative education which allows for the transfer of information to be conducted in a way which is standardized and the actual use of the system can be measure in an objective fashion. It is the *only medical model* of natural fertility regulation currently in existence and it is a model that specifically provides instructions both for the achievement of pregnancy (in couples of normal fertility) and the avoidance of pregnancy and allows, by its very design, the ability to measure its effectiveness in a prospective fashion using life-table analysis.

In addition, because of its standardized and objective format, it has been instrumental in the development of a *new reproductive science* of **NaProTECHNOLOGY**.

End Note

The **CREIGHTON MODEL FertilityCare™ System**, an authentic offspring of the Billings Ovulation Method, is, like its parent system, *unique* among natural methods. Because it attends to the details of the cervical mucus sign, *it allows fertility to be prospectively identified* and the naturally occurring phases of fertility and infertility to be identified on a day-by-day basis. It is simple to use and easy to keep records. Its *versatility* is unmatched.

An *extensive amount of research* has been conducted over the last 27 years. The cervical mucus plays an essential role in human fertility and the ability of the cervix to act as a *biological valve* has now been *well established*. In the CrMS, a woman is simply being taught when that valve is open. (which allows for sperm penetration and survival) and when it is closed (when the cervix acts as a barrier to sperm penetration and survival). Studies on the role of the cervical mucus have been done from the points of view of *nuclear magnetic resonance*, *ferning* and *channeling* studies and *scanning electron microscopy*. They have been done *by multiple investigators* and *the same principles continue to be verified*.

The system has been extensively evaluated *hormonally*. The mucus cycle has been shown to be associated with the preovulatory rise in estradiol-17β. The Peak Day is associated with the timing of ovulation

and these studies show *reproducible results* between *different investigators* in various places in the world. New technologies such as *ultrasound* observation and timing of ovulation are adding to this already existent body of knowledge continually lending support to the basic principles of the system. Even *vaginal cytology* has been used to confirm these findings.

There is now no question that the method effectiveness of the **CREIGHTON MODEL** *to avoid pregnancy is comparable to any drug or device on the market*. Its method and use effectiveness to avoid pregnancy are comparable with artificial methods and its demographic effectiveness, because it is safe and has a high continuity of use, actually *holds greater promise than current artificial forms of contraception* when applied to a population of users.

NaProTECHNOLOGY has expanded the uses of the system into the treatment of a variety of different gynecology conditions and these uses will continue to expand with further research (Table 33).

There continues to be a need for research in the **psychosexual aspects** of the use of natural methods. It is in this component of its use that we anticipate its most critical successes. While periodic abstinence has always been considered to be a negative relative to natural methods, in fact, if properly and maturely approached, it is believe that it can become one of the strongest building blocks for a strong marriage relationship. Strong, bonded and loving marriage relationships also have a very positive impact on the children in the family. Thus, the CrMS's versatility and its potential to further allow the discovery of these psychosexual components—and our ability to understand and communicate these to new users—will allow this work to be expanded indefinitely into the future.

Table 33: Applications of NaProTechnology

- Family planning
- Chronic discharges
- Targeted hormone evaluation
- Targeted hormone replacement
- Identify ovarian cysts
- The effects of stress
- Infertility
- Miscarriages
- Premenstrual syndrome
- Chronic infections
- Other reproductive disorders
- Prematurity prevention
- Abnormal bleeding
- Dating pregnancy
- Psychosexual understanding

References

1. Pommerenke WT: American Journal of Obstet Gynecol 52: 1023, 1946.
2. Rydberg E: Acta. Obstet Gynec Scand 29 (fac.1):127, 1948.
3. Breckenridge MA and Pommerenke WT: Analysis of Carbohydrates in Human Cervical Mucus, Fertil Steril 2: 29, 1952.
4. Cohen MR, Stein IF and Kaye BM: Spinnbarkeit: A Characteristic of Cervical Mucus. Fertil Steril 3: 201, 1952.
5. Smith WT: The Pathology and Treatment of Leucorrhea, Churchill, London, 1855.
6. Sims JM: British Medical Journal, 2: 465-492, 1868.
7. Billings EL and Westmore A: The Billings Method: controlling Fertility Without Drugs or Devices. Random House, New York, New York, 1980.
8. Roland M: A Simple Test for the Determination of Ovulation, Estrogen Activity and Early Pregnancy Using the Cervical Mucus Secretion. Am J Obstet Gynecol 63: 81-89, 1952.
9. Zondek B and Rosen S: Cervical Mucus Arborization: Its Use in the Determination of Corpus Luteum Function. Obstet Gynecol 3: 463-470, 1954.
10. Insler V, Melmed H, Eichenbrenner I., et al: The Cervical Score: A Simple Semiquantative Method for Monitoring of the Menstrual Cycle. Int J Gynec Obstet 10: 223-228, 1972.
11. Clift AF: Early Studies on the Rheology of Cervical Mucus. Am J Obstet Gynecol 134: 829-832, 1979.
12. Cervical Mucus: Present State of Knowledge, In: Cervical Mucus in Human Reproduction. World Health Organization—Colloquium, Published Proceedings, Geneva, Switzerland, 1972.
13. Hilgers TW and Prebil AM: The Ovulation Method—Vulvar Observations as an Index of Fertility/Infertility. Obstet Gynecol 53: 12-22, 1979.
14. Faccioli G, Cortesi S, and Calderoni P: Structure of Human Cervical Mucus Correlation with Plasma Ovarian Hormone Levels. Acta Europaea Fertilitatis. 14:41-50, 1983.
15. Garcia N, Giacchi E, Campo S, et al: Canalization of Human Cervical Mucus. Obstet Gynecol 64: 164-169, 1984.
16. Odeblad E: Cervical Factors. Int Rev Nat Fam Plan 5: 153-162, 1981.

18. Odeblad E: The Biophysical Properties of the Cervical-Vaginal Secretions. Int Rev Nat Fam Plan 7: 1-56, 1983.

19. Odeblad E.: The Discovery of Different Types of Cervical Mucus and the Billings Ovulation Method. Bulletin of the Natural Family Planning Council of Victoria. 21: 3-34, Sept. 1994.

20. Odeblad E. Molecular Biology of the Cyclic Changes of Cervical Mucus. Paper presented at the meeting "Scientific Bases and Problems of Natural Fertility Regulation," sponsored by the Pontifical Academy of Sciences, Vatican City, Italy, Nov. 16, Italy, Nov. 16, 1994.

21. Rudolfsson C: Nuclear Magnetic Resonance and Cytometric Studies on Mucus from Single Cervical Glands. Int J Fert 16: 147-150, 1971.

22. Faccioli G. Hormonal Bases of the Correspondence Between Microscopic and Ultra Microscopic Features of Human Cervical Mucus. Acta Europaea Fertilitatis, 15: 131-136, 1984.

23. Faccioli G: Preliminary Results on the Scanning Electron Microscopic Structure of Infertile Human Cervical Mucus. Acta Europaea Fertilitatis, 15: 381-385, 1984.

24. Takano N, Maekawa I, Takamizawa H: Ultrastructure of Human Cervical Mucus Observed by Cryo-scanning Electron Microscopy. Fertil Steril 32: 604-607, 1979.

25. Ferin J, Thomas, and Johansson EDB: Ovulation Detection. In: Human Reproduction: Conception and Contraception, (Hafez, E.S.E, and Evans, T.N., Eds.) Harper and Row, Hagerstown, Maryland, 1973.

26. Moghissi KS, Syner FN, and Evans TN: A Composite Picture of the Menstrual Cycle. Am J Obstet Gynecol 114: 405-416, 1972.

27. Insler V, Glezerman M, Zeidel L, et al: Fertil Steril 33: 288-293, 1980.

28. Brown JB, Harisson P, Smith MA, et al: Correlations Between the Mucus Symptoms and the Hormonal Markers of Fertility Throughout Reproductive Life. Ovulation Method Research and Reference Centre of Australia, Melbourne, Victoria, Australia, 1981

29. Billings EL, Billings JJ, Brown JB, et al: Symptoms and Hormonal Changes Accompanying Ovulation. The Lancet, February 5, pp. 282-284, 1972.

30. Flynn AM, and Lynch SS: Cervical Mucus Identification of the Fertile Phase of the Menstrual Cycle. Brit J Obstet Gynaecol 83:545, 1976.

31. Casey JH: The Correlation Between Midcycle Hormonal Profiles, Cervical Mucus and Ovulation in Normal Women. In: Human Love and Human Life. Santamaria, J.N. and Billings, J.J., Eds. The Polding Press, Melbourne Australia, p68, 1979.

32. Hilgers TW, Abraham GE, and Cavanagh D: Natural Family Planning-I. The Peak Symptom and Estimated Time of Ovulation. Obstet Gynecol 52: 575-582, 1978.

33. Cortesi S, Rigoni G, Zen F, et al: Correlation of Plasma Gonadatropins and Ovarian Steroid Pattern with Symptomatic Changes in Cervical Mucus During the Menstrual Cycle in Normal Cycling Women. Contraception. 23: 635-641, 1981.

34. Morishita H, Hashimoto T, Mitani H, et al: Cervical Mucus and Prediction of the Time of Ovulation. Gyn Obstet Invest 10: 157-162, 1979.

35. Hilgers TW: Hormonal Profiles in Users of the Ovulation Method. In: Human Love and Human Life. Santamaria, J.N. and Billings, J.J., Eds. The Polding Press, Melbourne, Australia, p59, 1979.

36. Leader A, Wiseman D, Taylor PJ: The Prediction of Ovulation: A Comparison of the Basal Body Temperature Graph, Cervical Mucus Score and Realtime Pelvic Ultrasonography. Fertil Steril 43: 385-388, 1985.

37. Daily DC, Reuter K, Cohen S, et al: Follicle Size by Ultrasound versus Cervical Mucus Quality: Normal and Abnormal Patterns in Spontaneous Cycles. Fertil Steril 51: 598-603, 1989.

38. Nulsen J, Wheeler C, Ausmanas M, et al: Cervical Mucus Changes in Relationship to Urinary Luteinizing Hormone. Fertil Steril 48: 783-786, 1987.

39. Depares J, Ryder, REJ, Walker SM, et al: Ovarian Ultrasonography Highlights Precision of Symptoms of Ovulation as Markers of Ovulation. Brit Med J 292: 1562, 1986.

40. Taylor RS, Woods JB and Guapo M.: Correlation of Vaginal Hormonal Cytograms with Cervical Mucus Symptoms. J Reprod Med 31, 1986.

41. Hilgers, TW, Prebil AM, Daly KD, Hilgers SK: Observation of Mucus Survey. St. Louis University Natural Family Planning Center, 1977.

42. Hilgers TW, Prebil AM: The Statistical Parameters of the Mucus Cycle: A Study of 600 Cycles. St. Louis Univeristy Natural Family Planning Center, 1977.

43. Hilgers TW: Psychodynamics of the Use of the Ovulation Method. Unpublished manuscript. Creighton University Natural Family Planning Education and Research Center. Omaha, Nebraska, 1978.

44. Fehring RJ, Lawrence DM, Sauvage CM: Self-esteem, Spiritual Well-being and Intimacy: A Comparison Among Couples Using NFP and Oral Contraceptives. Int Rev Nat Fam Plan 13 (3/4): 227-236, 1989.

45. Fehring RJ and Lawrence DM: Spiritual Well-being, Self-esteem and Intimacy Among Couples Using Natural Family Planning. Linacre Quarterly. pp. 18-29, August 1994.

46. Fehring R: Personal communication, July 1999.

47. Hilgers TW: The Statistical Evaluation of Natural Methods of Family Planning. Int Rev Nat Fam Plan 8: 226-264, 1984.

48. Tietz C and Lewit S: Statistical Evaluation of Contraceptive Methods: Use-Effectiveness and Extended Use-Effectiveness. Demography 5: 931, 1968.

49. Hilgers TW and Stanford JB: The Use-Effectiveness to Avoid Pregnancy of the CREIGHTON MODEL NaProEDUCATION Technology: A Meta-Analysis of Prospective Trials. J Repro Med 43:495-502, June1998.

50. Hilgers TW, Prebil AM, and Daly KD: The Effectiveness of the Ovulation Method as a Means of Achieving and Avoiding Pregnancy. Paper presented at the Education Phase III Continuing Education Conference for Natural Family Planning Practitioners, Mercy Fontenelle Center, Omaha, Nebraska, July 1980.

51. Doud J: Use Effectiveness of the Creighton Model of NFP. Int Rev Nat Fam Plan 9:54-72, 1985.

52. Howard MP: Use Effectiveness of the Ovulation Method (CREIGHTON MODEL) of Natural Family Planning. Paper presented at the Ninth Annual Meeting of the American Academy of Natural Family Planning, Milwaukee, Wisconsin, July 1990.

53. Fehring RJ, Lawrence D, and Philpot C: Use Effectiveness of the Creighton Model Ovulation Method of Natural Family Planning. J Obstet Gynecol, and Neonat Nurs 23: 303-309, 1994.

54. Tietze C: The Clinical Effectiveness of Contraceptive Methods. Am J Obstet Gynecol 78: 650-656, 1959.

55. Tietze C and Lewit S: The IUD and the Pill: Extended Use-Effectiveness. Fam Plan Perspec 3: 53-55, 1971.

56. Tietze C and Lewit S: Use Effectiveness of Oral and Intrauterine Contraception. Fertil Steril 22:508-513, 1971.

57. Marshall J: A Field Trial of the Basal Body Temperature Method of Regulation of Births. The Lancet, pp8-10, July 6,1968.

58. Klaus H: Natural Family Planning: A Review. Obstet Gynecol Surv 37: 128-150, 1982.

59. Hilgers TW, Daly KD, Prebil AM, et al: Cumulative Pregnancy Rates in Patients with Apparently Normal Fertility and Fertility-Focused Intercourse. J Reprod Med10: 864-866, 1992.

60. Hilgers TW, Prebil AM, Daly KD, and Hilgers SK: The Picture Dictionary of the CREIGHTON MODEL FertilityCare™ System. Pope Paul VI Institute Press, Omaha, Nebraska, 1999.

Excerpted from Hilgers, TW, ***The Medical & Surgical Practice of NaProTECHNOLOGY***, Pope Paul VI Institute Press, Omaha, Nebraska, 2004.
Chapter 4: Introduction to the Creighton Model System