Natural birth control: A brief review and some bioelectronic solutions

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Abstract. In this paper, the authors review the different measurable physiological parameters that can provide an indication of the time of ovulation and hence could be a potential aid to natural birth control (NBC) practitioners. They then proceed to select and evaluate a few physiological parameters that can easily be electronically detected, processed and measured, resulting in technically feasible methods for ovulation detection. Their suggestions include basal body temperature (BBT) measurement with adaptive signal processing for improving reliability; a new differential skin temperature (DST) measurement; and improved viscosity sensors for cervical mucus evaluation. They also comment on the possible future use of chemically sensitive electronic devices (CSED) and improved biopotential measurement techniques for ovulation detection. Preliminary experimental results on the DST method are presented, raising the hope that this technique may lead to precise and reliable electronic ovulation detection and may therefore be useful for NBC.

Keywords. Natural birth control; electronic aids; contraception; basal body temperature; differential skin temperature

1. Introduction

Control of population is of crucial socio-economic importance for the whole world and particularly for developing nations. Many techniques have been adopted to control the birth rate. They broadly include the following categories: pharmaceutical, mechanical, surgical, abstinence from natural intercourse during the fertile interval of a woman's menstrual cycle (known as the natural birth control (NBC) method) and at the worst abortion of the foetus after conception. Except for the NBC method, all other methods involve external interference with natural body functions and therefore result in side-effects. Further, NBC is not only the safest method but also the only method acceptable from all religious and philosophical viewpoints. However, the problem with NBC so far has been that of its unreliability as a contraceptive technique. Therefore, there is urgent need for further research for estimating the time of ovulation in advance, in order to determine exactly both the onset and the end of the fertile interval of a woman's menstrual cycle by a simple and reliable technique.

The purpose of this article is threefold: (i) to summarize briefly the most common methods of contraception, indicating their advantages, shortcomings and side-effects and thereby substantiating the motivation for further research in NBC; (ii) to discuss the measurable physiological parameters that vary over the menstrual cycle and to enumerate those that can be used in a practical bio-electronic technique to determine the ovulation time; and (iii) to indicate various electronic instruments that could be made available for NBC practitioners.

2. Conventional methods

As mentioned above, we can classify all the contraceptive methods available today into 5 broad categories: (i) pharmaceutical, (ii) mechanical, (iii) surgical, (iv) abortion and (v) NBC. Tables 1 and 2 provide a brief summary of these conventional methods.

3. Measurable physiological parameters for ovulation detection

To improve the reliability of NBC to minimize the period of abstinence the fertile interval of the menstrual cycle has to be determined in advance. The three major factors interfering with the exact estimation of the fertile interval are (Moghissi 1980) (i) differing menstrual cycle length (varying between 22 and 45 days); (ii) the life span of spermatozoa in the vagina (normally 2 to 3 days); and (iii) the life span of the ovum (known to be around 24 hours). Assuming a maximum of 3 days' life span for spermatozoa in the vagina, the minimum fertile interval can be reduced to 4 days, if the ovulation time is detected in advance. Determination of the fertile interval is of interest, not only to achieve contraception by abstinence, but also to achieve conception with higher probability among couples desiring children by proper timing of natural intercourse or through artificial insemination. It has been reported that the relation between ovulation time and the time of natural intercourse also plays a certain part in determining the child's sex on conception (Seguy 1980).

Various physiological factors changing during the menstrual cycle are shown in figure 1 (Moghissi 1980). Different methods have been developed to estimate the fertile/infertile interval of the woman's menstrual cycle, and are briefly discussed here:

3.1 *The Ogino-Knaus method* (Engel 1978)

This method, also known as "calendar method", is the simplest form of NBC: here the woman calculates her fertility interval depending on the minimum and maximum length of her menstrual cycles during the past 12 months.

First day of fertile interval = [length of shortest cycle - 18]; last day of fertile interval = [length of longest cycle - 11]. Based on this principle, M/s Kowa Ltd of Japan have brought out an electronic gadget to indicate the abstinence period [International Assistance Foundation of Family Planning, Japan].

3.2 *Basal body temperature (BBT) method*

A woman's menstrual cycle has a cyclic hormonal activity. It has three phases, namely: (Marshall 1976; Marshall *et al* 1978) (i) follicular phase (beginning with menstruation until a rise in estradiol level—infertile interval); (ii) ovulatory phase (rise of estradiol until rise in progesterone concentration—fertile interval) and (iii) luteal phase (rise in progesterone until next menstruation—infertile interval). Progesterone being thermogenic in nature, body temperature rises in the luteal phase by 0.2°C to 0.4°C over the normal temperature. Hence body temperature can confirm the occurrence of ovulation and the beginning of the postovulatory infertile interval. Steady morning temperature called basal body temperature has thus come to be used among NBC practitioners. However, the reliability of this method suffers due to disturbing physiological factors, mental stress and any long journey involved, which tend to change the body

Table 1 Brief summary of the conventional contraceptive methods.

2.1 Pharmaceutical contraceptives*	2.2 Mechanical contraceptives**
<p>Contraception is achieved by controlling the estrogen and progesterone levels in the woman's body through oral pills, implant capsules, long-durable injections, etc.: all these suppress the LH surge and thus avoid ovulation, making the whole menstrual cycle infertile. General problems: by disturbing the natural hormonal functions of the body, pharmaceutical contraceptives increase the body's weakness to thromboembolism, stroke, myocardial infection, hepatic adenoma, gallbladder disease, hypertension, etc. Not very economical for the Third World.</p> <p><i>Oral pills</i></p> <p>Problems: Besides the regular need of intake and rather high economical load on an individual user, supply and proper choice of oral pills to suit an individual are not guaranteed in third world countries.</p> <p><i>Implant capsules</i></p> <p>Release slow and steady level of progesterone, providing the protection against conception over a year. Could perhaps be good in third world countries, among the illiterate section of the population.</p> <p>Problem: Involves a doctor for implantation. Long-term results on side-effects are not yet known.</p> <p><i>Estrogen-Progesterone injection</i></p> <p>An injection once a month provides a complete protection over one cycle. Higher dosage of hormones injected into the body may have serious side-effects in the long run, which are not yet fully known.</p> <p>Problem: Involves medical personnel.</p>	<p>Contraception is achieved by blocking the cervical path for the spermatozoa in the case of diaphragm, cervical cap, vaginal ring and condom, or by changing the enzyme function in the uterus with the presence of intra-uterine device, thus avoiding the implantation of the fertilized ovum. General problems: Psychologically not acceptable among many sections of the population.</p> <p>General advantages: Easily available, economical and sufficiently reliable. Relatively simple to use.</p> <p><i>Intra-uterine device (IUD)</i></p> <p>Problems: Many women experience increased bleeding during menstruation. Therefore not recommended for anaemic or malnourished women. Pelvic inflammations are observed with women having venereal disease. Expulsion rate is high with young women. Because of bleeding, expulsion risk, etc. a follow up phase by a doctor is necessary which is unfortunately not guaranteed in rural areas of third world countries.</p> <p>Progestin-coated IUDs have shown improved performance compared to ordinary CU-7 or Lippes-loop type of IUD. Failure rate varies between 3% and 10% depending on type of IUD and individual attention.</p> <p><i>Diaphragm</i></p> <p>Made of rubber/plastic material. When properly placed in the vagina, it protects the cervix from spermatozoa.</p> <p>Problems: It has to be inserted properly in the vagina before each act of intercourse. Requires prior training. Failure rate is as high as 15% among untrained users.</p>

continued

Table 1 continued

2.1 Pharmaceutical contraceptives*	2.2 Mechanical contraceptives**
<p><i>Monthly pills for men</i></p> <p>Recent reports claim a successful development of pills for men, to limit the production of spermatozoa without affecting the natural sex drive. Side-effects and problems associated with this new development remain to be seen.</p> <p>General advantage of the above methods remains to be seen.</p> <p><i>Vaginal spermicides</i></p> <p>Often used as a contraceptive. They cover the cervix and kill the spermatozoa deposited in the vagina.</p> <p>Problem: They should be applied at least 10 minutes before the act of intercourse for good protection.</p> <p>Problem: Reliability is poor. Failure rate is around 4%.</p>	<p><i>Vaginal ring</i></p> <p>Similar to diaphragm but contains progesterone coating. Has the advantage of remaining in the vagina for one complete cycle.</p> <p><i>Cervical cap</i></p> <p>Made of lucine/rubber material. It is held in position by suction and has an adjustable property of adopting itself for little changes of cervix in size. Failure rate is around 3%. It can remain in position for longer periods; to be cleaned at convenience and reintroduced.</p> <p><i>Condom</i></p> <p>Made of thin strong latex rubber to fit the erect penis to block the path of spermatozoa.</p> <p>Problems: Aesthetically not attractive. Some men complain of loss in natural sensation due to lack of direct contact between penis and vagina. Not too economical for the poorer class of third world countries. Failure rate is around 2.5%.</p>

* Brochure (1980); Engel (1978); Seaman (1979); ** Engel (1978); Seaman (1979)

Table 2. Brief summary of conventional contraceptive methods.

2.3 Surgical methods*	2.4 Abortion**	2.5 Natural birth control***
<p>Permanent barrier to conception is achieved by a simple operation either on man or on woman. Surgical method of contraception is well suited for those couples who are sure of their present family size and could decide once for all against having further children.</p> <p>General problems: Permanent contraceptive method. The couple opting for this method cannot easily have children later on, though some doctors claim the possibility of this by a second operation. Some people have a general aversion to surgery.</p> <p>Advantages: High reliability. Failure rate is below 0.01 %. No economical problems are involved. After the operation free sexual activity is possible.</p> <p><i>Vasectomy</i></p> <p>A simple operation on a man wherein the "vas deferens" canal carrying the spermatozoa is surgically interrupted.</p> <p>Problems: Some men complain about change in coital performance after the operation due to psychological factors.</p> <p><i>Tubectomy</i></p> <p>This is a simple operation, in which the fallopian tubes are raised to a knuckle and the tube included within is cut-off, blocking the path of the ovum. This operation is recommended just after a vaginal delivery.</p> <p>Problems: More of a psychological nature and basically the same as for vasectomy.</p>	<p>Interruption of pregnancy before the foetus is sufficiently matured. Abortion's surgical implications extend from that of a simple operation at an early stage of pregnancy to a complicated surgery like hysterectomy at the later stage of pregnancy. Abortion certainly does not constitute a rational method for birth control.</p> <p>Problems: Basically immoral as it involves killing of the foetus and is therefore banned by almost all religions of the world. Needs hospitalization and safety depends on the stage of pregnancy. In many third world countries illegal abortions in unhygienic conditions are common due to fear of society. Mortality is as high as 4.2 % in case of hysterectomy. Further it is not at all economical.</p> <p>Advantages: When the mother's health is in danger due to pregnancy, abortion may be resorted to rather than risk her life.</p>	<p>Contraception is achieved by periodic abstinence from sexual intercourse.</p> <p>Advantages: Safest method of contraception. As there is no interference with the physiology, there is no possibility of any side-effect. Natural birth control (NBC) has been accepted by all religions as a method of contraception. Natural sexual activity may bring more harmony and understanding to the couple. Also a woman can have a personal knowledge of her cycle status with proper motivation.</p> <p>Problems: Precise and reliable estimation of the fertile interval for abstinence remain a fundamental problem. Reliability of the method suffers when this fertility interval is minimised or wrongly estimated. NBC demands good motivation from both partners. Failure rates between 4 % and 20 % are quoted for methods presently used.</p> <p>The measurable parameters for estimation of the fertile interval of a woman's menstrual cycle and presently known methods are briefly discussed in § 3.</p>

* Seaman (1979)

** Brochure (1980); Engel (1978)

*** Dolack (1978); Hilgers *et al* (1980)

Figure 1. Measurable parameters for ovulation detection during the menstrual cycle.

temperature and mislead the NBC practitioners. Improved BBT thermometers like "Bioself" [Desjacques, Rue de Genève 91, Geneva, Switzerland], "Ovudate" [ARES N.V., Geneva, Switzerland] and "Ovutest" [Medical Electronics Trading, Hamburg, West Germany] have been reported. Statistical results on the use of electronic BBT thermometers are not yet available.

3.3 Billings' method

Cervical mucus viscosity has been observed to be a function of menstrual cycle status. Dr Billings has divided the menstrual cycle into 5 phases with respect to cervical mucus viscosity and the fertility interval: Phase 1: period of menstruation flow; Phase 2: feeling of dryness in the vagina; Phase 3: flow of mucus with whitish cloudy colour, pasty and sticky in nature, providing a favourable condition for the spermatozoa in the vagina; Phase 4: increase of cervical discharge, very clear and less viscous mucus, lubricative and stretchy in nature, corresponding to peak fertility interval; Phase 5: mucus loses its stretchy nature and becomes more watery—infertile interval.

The use of Billings' method (1972) needs prior training (to decide the nature of mucus) and therefore this method suffers from unreliability among untrained and non-motivated people (Dolack 1978). Dr Kosasky of the United States has reported the design of a simple ovumeter to measure precisely the mucus viscosity condition (Bantam 1979).

3.4 Sympto-thermic method

This is a combination of BBT and Billings' method and is practiced by well-trained NBC practitioners (Moghissi 1980). Failure rate as low as 4% has been reported (Dolack 1978).

3.5 Mucus spinnability

The measurement of spinnability or "Spinnbarkeit" of mucus is an extension of Billings' method. The day on which mucus can be drawn into the largest thread is estimated to be the day of ovulation (Chretien *et al* 1977).

3.6 Fern test

Chloride content in the mucus has been observed to be maximum during the ovulation time (Misweeney *et al* 1965). There are reports of chloride test papers which change colour depending on the degree of chloride content to determine the ovulation time (Moghissi 1980).

All tests on cervical mucus parameters need a prior training to interpret the status. Individual motivation is also important for proper determination of the fertility interval.

3.7 Vaginal blood flow

Increased vaginal blood flow has been correlated with ovulation time (Abrams *et al* 1978). Vaginal blood is measured indirectly by measuring thermal conductance in the vagina (Borth *et al* 1980).

3.8 Follicle explosion

Some women feel and experience within themselves the follicle explosion and a kind of tickling sensation associated with it (Janata, Personal Communication).

3.9 Bio-potential measurement

Some scientists have claimed skin surface potential to have significant changes prior to ovulation (Burr and Musselman 1936; Burr *et al* 1938). Ovutron Company has brought out a finger potential measuring gadget to correlate with ovulation time (Ravitz 1977). However, Utah University studies have shown no such correlation (Poulson *et al* 1978). Further, any external or internal injury is expected to cause significant skin surface potential change outdoing those due to ovulation (Spieler, Personal Communication).

3.10 Vaginal wall optical back scattering

Optical back scattering of infrared radiation from the vaginal walls are claimed to indicate the ovulation time in advance (Borth *et al* 1980).

3.11 Hormonal measurement

So far, only hormonal measurements are accepted for precise determination of ovulation time. Measuring LH, FSH and estradiol hormones by standard radioimmunoassay in the laboratory is well known in clinical analysis, but is very expensive,

time-consuming and laborious. Therefore, hormonal analysis is not useful as a contraception method unless a simple electronic measuring device can be realized.

3.12 Protein/enzyme analysis

Analysis of proteins like albumin, globulin and enzymes (Davis *et al* 1973) like N-acetyl-B-D Glucosaminidase concentration in mucus/saliva can provide advance information of ovulation timing (Misweeney *et al* 1965; Blain *et al* 1975; Diamant *et al* 1979; Moghissi 1980). However, so far these analysis are meant only for clinical purposes in the laboratory and not as general methods for contraception.

3.13 Cycle-regulation

A regular menstrual cycle would evidently be a great asset to NBC practitioners. Further research work on the physiological, psychological and other factors influencing the cycle's course and length is certainly needed. An interesting but speculative idea is proposed by Lacey (1976) under the name of "Lunaception": She suggests exploring the possibility of synchronizing/regulating the cycle by sleeping under a variable light source (similar to the moon's light).

4. Some proposals for bio-electronic solutions

4.1 Introduction

In §3 we briefly explained the various measurable parameters which permit the detection of ovulation time. The most reliable and precise method, *viz* the hormonal analysis of plasma for determining the LH surge by radioimmunoassay is invasive and not available for home use. Simple non-invasive methods like BBT and cervical mucus viscosity measurements, remain unreliable so far due to the influence of various physiological variations on the measured parameters and also due to the high degree of motivation required by such methods. Therefore, there is urgent need for simple and reliable bio-electronic solutions in the field of NBC. Such bio-electronic solutions may have mainly 3 objectives: (i) to simplify the use of existing methods of ovulation detection; (ii) to introduce new methods with improved sensors, to measure the parameters mentioned in §4, with greater accuracy and precision; (iii) to improve the reliability of existing methods by applying electronic signal processing techniques.

In this section we will describe various electronic solutions for estimating the ovulation time, which appear to be promising.

4.2 Temperature measurement

4.2a Basal body temperature (BBT) At present, the BBT method is widely used by NBC practitioners. BBT has the inherent disadvantage of detecting only the postovulation phase. Furthermore, it involves the ordeal of daily temperature recording. The use of a clinical mercury thermometer with a high time constant (> 5 minutes) to reach a stable temperature, brings additional unreliability to the method. For reliable detection of the BBT rise, WHO (1976) has recommended as "thumb rule" a minimum of 0.2°C rise for 3 continuous days over the previous 6 consecutive days. However, even this rule can fail, if a woman has a slight fever for 3 days. To overcome these limitations, the authors

suggest the use of an adaptive algorithm, incorporated in an electronic BBT thermometer (Rao *et al* 1982). Thereby, we define pre- and post-ovulation temperature thresholds and probable fertility interval depending on the adaptively updated data of, say, the previous 3 menstrual cycles as shown in figure 2. T_l and T_h are, respectively, the pre- and post-ovulation phase average temperature records of the past 3 menstrual cycles.

The temperature margin of ΔT , around T_l and T_h , sets the limit of temperature-levels acceptable as normal. Similarly, a temperature-level transition time interval Δt around the mid-cycle can be defined. In figure 2, t_1 and t_2 are, respectively, the earliest expected day of the temperature-level transition (Ogino-Knaus definition as explained in §3.1). If the measured temperatures are within these defined thresholds, the cycle is considered to be normal and the ovulation detection is reliable, otherwise the user is warned of the unreliability of the instrument in that particular cycle.

With commercially available microprocessors, all these functions as well as adaptive signal processing can be incorporated in a small electronic BBT thermometer, to detect the post-ovulation phase much more reliably than the existing method.

4.2b Differential skin temperature (DST) A further improvement on temperature measurement can possibly be obtained by measuring skin temperature distribution over a few hormonally sensitive/insensitive areas of the body. Such interesting spots can be localized by contactless thermometry or more precisely by means of infrared thermography (IRT). One can expect some parts of the breasts, vagina, etc. to reach higher temperatures than other areas because of hormonal, chemical and vascular activity during ovulation (Verzini *et al* 1977). Absolute skin temperature being a function of ambient temperature, it cannot be of any significant importance. To overcome this problem, the authors have introduced the principle of differential skin temperature (DST) measurement, involving *e.g.* the measurement of temperature difference between two points, one corresponding to a vascularity sensitive area (dynamic part) and the other to a vascularity insensitive area, on the body skin surface. This differential skin temperature (DST) should be independent of ambient temperature (if the biological tissues of the area hereby studied have the same thermal characteristics over the ambient temperature range) and hence the measurement of DST may have a significant importance. If the DST hypothesis is true, it may lead to detection of ovulation time in advance.

Figure 2. Adaptive BBT measurement algorithm.

Once the hormonally sensitive areas are localized by IRT, DST can be measured by a simple electronic thermometer with precise temperature sensors.

Test of DST hypothesis: The authors, in co-operation with the Cadolles Hospital of Neuchâtel, conducted a study on 5 young, healthy and regularly menstruating women, none of them using pharmaceutical contraceptives, over one menstrual cycle. The method used and the details of this study are brought out in a separate publication (Rao *et al* 1982). The results of this preliminary study are shown in figures 3 and 4. From these figures, one can observe that DST reaches a peak ahead of ovulation and is also independent of physiological disturbances like fever (figure 4), as observed in one case. At present, the authors are continuing the study with a larger number of volunteers to test for a possible generalization of the hypothesis, *viz* that DST can detect the ovulation time in advance independent of physiological disturbances. If the experiments are successful, a simple electronic thermometer measuring the DST and BBT can be made available, useful both for NBC practitioners and women with infertility problems.

Figure 3. Mean variables during the middle part of menstrual cycle.

Figure 4. BBT and DST changes with fever in a particular case.

4.3 Cervical mucus viscosity measurement

Motivated women can predict the ovulation time sufficiently in advance by observing their cervical mucus viscosity. However, due to variations in the degree of change in mucus viscosity from cycle to cycle, the intuitive estimation of ovulation time, based on mucus observation, so far remains unreliable.

Measurement of mucus viscosity is difficult with the available commercial viscometers, due to the small volume of mucus. A recent development of an electro-mechanical tuning fork viscometers (Berger *et al* 1978) could be extended to measure mucus viscosity. The authors are presently developing a miniature viscometer using a piezoelectric quartz tuning fork or a ceramic tuning fork instead of a mechanical tuning fork. Normally, a torsionally vibrating quartz crystal in the form of a tuning fork (similar to the ones used in wrist-watch crystal oscillators) would be an excellent choice. The torsionally vibrating crystal has resistive and reactive components in its equivalent electronic circuit. When the crystal is immersed in the test fluid the static interelectrode capacitance dominates the reactive component. So the measurement of reactive impedance can be correlated with the characteristics of the liquid (Beukema *et al* 1981). But a miniature quartz tuning fork cannot oscillate in the liquid at low frequency due to its physical structure and size. It also acquires a high series impedance suppressing the oscillations. Quartz crystals thus appear to set difficult problems for miniature viscometer development (the problems could partly be overcome by the use of tunnel diodes or other negative-impedance devices in parallel with the quartz). The authors have overcome this problem by using ceramic tuning forks with a resonant frequency of 3 kHz. The principle of the operation is to measure the damping factor of the oscillation in correlation with the viscosity of the fluid. The damping factor is defined as the time required for the signal to reach $(1/e)$ th of its original amplitude. The block diagram of the system is as shown in figure 5a.

The piezoelectric crystal is excited with a sharp high energy impulse, to bring the crystal into its fundamental oscillating mode. Due to the high mechanical stress of the fluid media, the oscillation is dampened exponentially with a time constant T , inversely proportional to the viscosity of the fluid. At the receiver, an amplifier and a precision rectifier convert these signals into high level unipolar signals. The envelope detector and the control circuit determines the time constant T of the signal and display the

Figure 5. (a) Viscosity measurement using ceramic tuning forks. (b) Viscosity measurement using pressure transducers.

measured viscosity directly. The ceramic sensor and the associated electronic circuits could be miniaturized so as to be incorporated within a mucus extractor (Jondet *et al* 1980) to measure the viscosity of the mucus directly at the vaginal opening, to avoid any temperature effects on the measurements.

Another alternative solution for the measurement of mucus viscosity has been suggested by Stauffer (Personal Communication) using two pressure transducers and a capillary. The principle of this method is to correlate the pressure applied on the liquid to obtain a known force on the hitting target with the viscosity of the liquid. The system to be used in such a measurement is shown in figure 5b.

4.4 Bio-potential measurements

So far, the research in ovulation detection has been restricted to the direct observation of the potential difference between two points (say *A* and *B*) and to correlate $V_{AB}(t) = V_A(t) - V_B(t)$, with the ovulation time (Ravitz 1977). The main difficulties found in this method are (i) the points of observation have not yet been found optimally (no comparative data are available), (ii) body injuries and other physiological interferences will influence the potential measurement giving rise to false alarms. So, bio-potential measurement at its present state of development is not suitable for birth control purposes. The authors, however, wish to propose that there may certainly be scope for further research in observing bio-potential changes with respect to ovulation timing, through the understanding of the detailed potential distributions on the surface of the body over the whole menstrual cycle of a woman. Once such data are available, adaptive signal processing together with localized multiple-point potential measurement would perhaps be used to analyse and estimate ovulation time. (This extension is similar to the preceding proposal of using differential skin temperature measurement). Such potential profile imaging can be referred to as "potentiography" as it involves potential distribution (similar to "thermography" for thermal profile). But until today, there is no technique available to display potential images directly, as in the case of temperature.

However, with the physical-contact switched electrodes in contact with the skin one can possibly obtain such images. The switched electrodes would be in the form of matrix semiconductor sensor arrays with a multiplexed accessing in two ordinates. The block schematic of such a system and of a hypothetical image are shown in figure 6.

4.5 Follicle explosion detection

Reliable follicle explosion detection gives the precise time of ovulation. One can detect the follicle explosion by an acoustical or ultrasonic method.

4.5a Passive acoustical Two very sensitive miniature microphones mounted on the two ovaries pre-localized by uterosonography may be able to detect the acoustical signal of follicle explosion. To avoid interference with other ventricular noises, the signal can be processed further to select a predefined spectrum only and to perform a geometrically-selective correlation. The size of the microphones and their sensitivity will be a limiting factor in the system's size and its performance.

4.5b Ultrasonic system The limitation of the passive acoustical system could be overcome using an ultrasonic system. The principle of the Doppler technique, as used in the foetus heart rate monitor and blood flow detector can be extended for follicle explosion detection using two transducers, one on each ovary.

The follicle explosion method could be an excellent solution only for infertility problems, in timing the artificial insemination.

4.6 Chemical and hormonal measurement

4.6a Test papers Chemically-treated test papers, which change colour as a result of chemical concentration, have of late been introduced to measure the chemical activity in mucus and saliva (Misweeney *et al* 1965). But the absolute level of chemical concentration varies from one woman to another and also from one cycle to another for the same person. In fact, only relative changes are supposed to indicate the menstrual cycle status. Therefore, chemically treated test papers are not generally applicable in estimating the menstrual cycle status, unless a way is found to combine them with an electronic instrument to determine the degree of change in chemical activity.

Figure 6. Hypothetical system and image of bio-potential measurement.

4.6b Chemically sensitive electronic devices (CSED) Recently, a new type of semiconductor devices called chemically sensitive electronic devices (CSED) has been developed (Bergeveld *et al* 1980; Haemmerli *et al* 1980). These devices provide an electric signal proportional to the chemical activity on the device interface. Such electric signals could be processed electronically as desired, making CSEDs more interesting for biological studies. CSEDs in the form of CHEMFETs with a suitable chemically selective membrane as their gates are generally being developed to analyse chemical concentrations in a solution.

The principle of construction and operation of a CHEMFET is shown in figure 7 (Janata *et al* 1979).

The solution to be analysed is placed in contact with the chemically selective-membrane of the FET. The solution-membrane interface acts as an electrical resistance and the potential developed across the interface is related to the ionic activity on the interface. Because of the field effect, the drain current is varied proportional to the gate potential. Now, the electrical signal proportional to the chemical activity can be further processed in a conventional manner.

Thus, CHEMFETs can be used to measure pH values and possibly with further improvement in the technology, they could be used to measure hormone, protein and enzyme concentrations.

4.6c pH measurement Though there is no significant change in pH, either in plasma or in urine over a menstrual cycle (figure 1) some gynaecologists expect the uterine fluid to have a significant pH change during the ovulatory period. This could be easily seen with a miniature CHEMFET or a simple gate-controlled diode (GCD), placed in the uterus. The pH characteristics of these CSEDs have already been proved for precision and repeatability. However, such pH sensors in the uterus could be expelled as in the case of IUDs, making pH measurement in the uterus a speculative method only.

4.6d Hormone concentration The LH surge is a well-established reference for ovulation detection and is used in all the performance measurements of other methods of ovulation detection. Therefore, the development of a simple means to measure LH concentration will constitute a breakthrough in the field of ovulation detection.

The actual knowledge of CSEDs extended in the future to immunoreactive measurements (similar to those applied to RIA analysis) can perhaps give a simple solution for

Figure 7. Device structure of CHEMFET.

measurement of the LH concentration. If the chemically-sensitive membrane is replaced by a specific anti-body membrane, the interfacial immuno-reaction of the antigen hormone (like LH, FSH) with the antibodies in the FET membrane will result in the drain potential varying according to the degree of antigen-antibody activity. But for the time being, it is not known how to re-activate the antibody layer so as to make a FET re-usable after a test. If CHEMFETS with a re-activatable antibody interface layer for immuno-reaction are developed, an excellent device could be found in such an "IMMUNOFET" for measuring any antigenic hormone concentration.

In theory, the antibody could be either natural or synthetic, depending on the type of antigen hormone to be analysed.

4.6e *Enzyme/protein analysis* CSEDs can also be used to analyse enzymes, proteins, etc with a suitable membrane to have an ionic activity, which gives rise to corresponding drain current variation. At the Twente University in Holland, tests are made to measure the albumin concentration in a compound. The threshold sensitivity achieved so far is in the order of 6 mg per litre of solution (Bergeveld *et al* 1981).

The albumin concentration in the mucus is about 10 μ g per litre, which corresponds to a factor a thousand times less than the sensitivity achieved so far.

5. Conclusions

In conclusion, the authors wish to look in a more general and speculative way at the whole problem of contraception and its future. This may perhaps help to view NBC and electronic aids for NBC in their proper perspective. One can possibly divide all *present and future* methods into four categories:

The *first category* (pharmaceutical contraceptives) involves changes in the body functions that always have some side-effects, though, in the future, one can expect further improvements which minimize them (further research on alternative herbal drugs could be envisaged here).

The *second category* (spermatozoa barriers) will remain an unsatisfactory method at least from an aesthetic and psychological point of view.

The *third category* (operative measures) may result in an effective and reversible fertility control in future but will always remain as invasive.

The *fourth category* (NBC, achieved through abstinence from sexual activity) could become an acceptable and very satisfactory form of birth control. It means to decide whether or not to engage in natural sexual activity, by observing the natural symptoms of the body, without the risk of unwanted conception. In the past, natural birth control has not been accepted fully due to its high failure rate, long abstinence required, etc. There is clearly a real need for improved methods of ovulation detection today, in connection with natural birth control. For example, with the methods mentioned in §4, electronic aids could possibly achieve a breakthrough, resulting in making natural birth control widely acceptable. This depends on obtaining high reliability through a profound understanding of body physiology.

According to our present understanding of body physiology and based on the electronic methods proposed in §4 of this paper, the following comments on electronic aids for NBC can be made.

There is a possibility of improving the reliability of the existing basal body temperature (BBT) method by adaptive electronic signal processing. The differential

skin temperature (DST) method of ovulation detection suggested by the authors may also lead to further improvements. It also gives an earlier signal about the occurrence of ovulation and this could be useful, at least for conception. (So far, BBT only gives post-ovulation detection and has to be combined either with a long period of sexual abstinence or with mechanical contraceptives). DST may not give a signal early enough as to detect the onset of the fertile interval. It should, however, help to improve the reliability of detection.

Electronic viscometers may become a more reliable method of measuring mucus viscosity. But measurement of mucus viscosity being more cumbersome and messy than that of temperature, this method may not be well accepted in the Third World countries.

Follicle explosion detection, by passive or ultrasonic means, may only be of clinical use, and not suited for actual birth control. The future of the bio-potential measurements for ovulation detection remains speculative, until more research work is done in this field, involving correlative studies of potential distributions.

Though the development of IMMUNOFETS for electronic hormone or enzyme measurements is still far away, from the practical point of view, the whole field of chemically-sensitive electronic devices (CSED) has to be watched carefully, for possible application for ovulation detection.

Whichever type of electronic aid is introduced to promote NBC it has to be so designed that it should involve the woman user herself in observation and decision making (and not just be a green-red light gadget). One should not forget that personal motivation and involvement will always remain the key factors in NBC.

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