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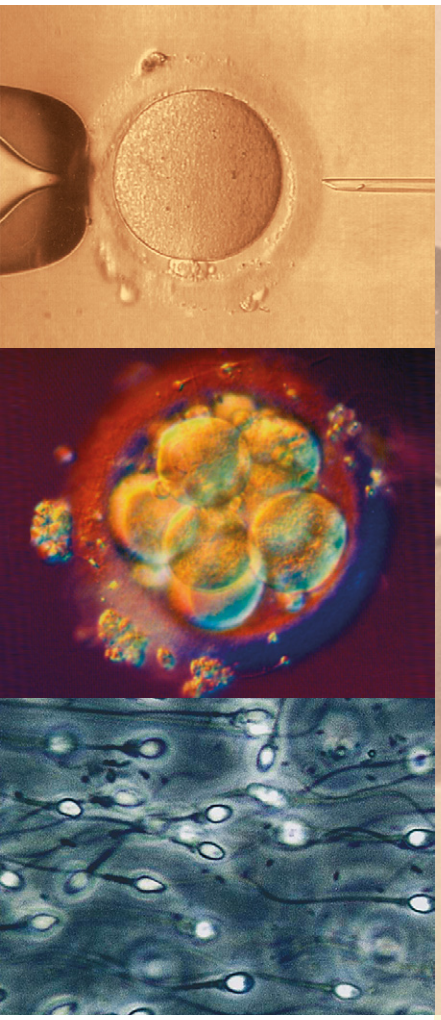

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# Cycle Monitors and Devices in Natural Family Planning

G. Freundl[1], P. Frank-Herrmann[2], Ch. Gnoth[3]

For fertility awareness based methods- (FAB-) users charting and checking of menstrual cycle symptoms may be supported by different instruments and devices. These cycle monitors promise to detect the fertile and infertile days by using direct and indirect markers of fertility in a woman´s menstrual cycle. In this article we use data of our own studies, data out of the literature research in Medline and PubMed and from our own German NFP (natural family planning) database. We tried to rate the efficacy of the tested monitors. We figured out that only for one hormone- and for one temperature-computer reasonable prospective studies exist. To get more comparable results we have performed in 2000 a small pilot study on 6 devices and the symptothermal method of NFP (NFP-DAG) together with "Stiftung Warentest". The efficacy of the various devices differed significantly. We therefore urgently need more clinical studies on menstrual cycle monitors for reliable information of users. **J Reproduktionsmed Endokrinol 2010; 7 (Special Issue 1): 90–6.**

**Key words:** contraception, fertility, menstrual cycle, cycle monitor, cycle devices, natural family planning, NFP, fertility awareness based methods, symptothermal method, STM

## Introduction

Every menstrual cycle has a fertile window of several days in which a woman may become pregnant from unprotected intercourse with varying degrees of likelihood [1–3]. This fertile window lasts from approximately five days prior to ovulation until the day after ovulation, with the probability of pregnancy increasing from approximately 10 % from unprotected intercourse five days before ovulation to about 33 % on the day of ovulation, decreasing rapidly to virtually zero within 24 hours after ovulation has occurred. The length of the fertile window is physiologically based on the in vivo lifetime of the gametes and determined by the conception probabilities from intercourse on the different cycle days.

Today, women are able to reliably observe the fertile window as well as peak fertility in the cycle without much effort. They develop a high level of reproductive competence which can be used in various situations. Menstrual cycle depending changes in the levels of estrogen and progesterone, produce observable signs of fertility. The German NFP method combines the observation of the periovulatory temperature rise and cervical mucus changes and determines the onset as well as the end of the fertile phase according to the double-check principle (Symptothermal Method) [4]. Actual data found a method-effectiveness of 0.4 pregnancies per 100 women years, provided the appropriate guidelines are consistently adhered to [5]. Therefore this method is one of the most effective methods of family planning and may also be an option for patients at risk.

Cervical mucus methods are single indicator methods (e. g. the Billings-Ovulation Method or new simplified mucus methods like the TDM) which are suitable for developing countries due to only a medium efficacy; same with the Standard Days Method which is a simple calendar rule for developing countries [6].

NFP may be integrated also into the management of subfertility and it makes an interesting contribution to gynaecological endocrinology: long-term cycle monitoring may support medical diagnosis and therapy. For all applications, it has turned out that effective use depends on good instruction of the women [4]. Medical doctors may be supported by qualified local NFP teachers.

### Why Cycle Monitors and Gadgets?

For developers of technical tools it is interesting, that for some women monitoring their fertility signs in the conventional way may be difficult and inconvenient. Additionally, some women lack confidence in their subjective observations and interpretations of their fertility signs. Others, particularly those who are attempting to avoid pregnancy by abstaining from unprotected intercourse on those days they identify as fertile, are bothered by the fact that their observations require them to abstain from unprotected intercourse for more days than may really be necessary.

### Different Devices and Evaluation Methods

Table 1 summarizes the indicators used in different devices developed for cycle monitoring. There are indirect markers like basal body temperature (BBT), electrical resistance of the cervical mucus, crystallisation phenomenon of cervical mucus, electrostatic charge, enzymes, ions, sugars and proteins of the cervical mucus and the vaginal fluid and there are direct markers of ovulation like ovarian sonomorphology and ovarian hormons. Also the trade names of the currently available products are shown.

There are devices which were developed, tested and have been shown to be of limited usefulness or to be really beneficial. Relatively few of them have been subjected to rigorous testing, and several have being actively marketed without sufficient evidence of their ability to accurately identify the fertile days of the menstrual cycle. Indeed, there are no clear guidelines for testing these devices.

According to a suggestion made by Martinez et al., 1995 [7] we shortly want

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to review what has been done so far and comment on published results in the order of indirect markers and direct markers of fertility.

Generally, so called new technologies (NT) for identifying the fertile days of the menstrual cycle should be assessed in two ways: Efficacy-Finding Studies (EFS), and Effectiveness Studies (ES).

An EFS precedes an ES and it is essential to conduct both types of studies in order to evaluate the appropriateness of a technology or device for use by women who wish to avoid a pregnancy in a first line. An EFS compares the fertile phase of the menstrual cycle detected by the device to the fertile phase detected by another established and reliable reference method. This is sufficient to assume that the device helps to identify the fertile phase (method performance), but it is not sufficient to confirm that the device is proven useful to prevent pregnancy (user performance).

An EFS is clearly the first step in assessing the potential appropriateness of a device for a woman who wants to avoid pregnancy. There are two ways to approach an EFS.

1. In an "indirect" EFS, the information produced by the device may be compared to the information produced by the use of an established reference method of Natural Family Planning (NFP), such as the Sympto-Thermal Method (STM). In this instance, charts from women who have recorded their observations of their fertility signs and identified the fertile phase of their menstrual cycles can be used as the basis of comparison. The information that theoretically would have been provided by the device can be compared to the NFP charts. If we find, for example, that the STM identified days 8–16 of a particular cycle as fertile, and the device would have identified only days 10–16 as fertile, this would suggest that the device is not sufficiently accurate in determining the beginning of the fertile time.
2. Alternatively, in a "direct" EFS, the information provided by the device can be compared to direct observations of the woman's fertility status: Ultrasound for evaluating follicular development combined with serum hormone assays (estradiol, LH, and progesterone). If the device identifies a fertile window that is consistent with the results of these tests, we can rely that it is likely to provide appropriate information to a users who want to avoid a pregnancy. For example, if the device identifies the onset of the fertile phase approximately five days prior to ovulation, as determined by vaginal ultrasound and hormone assays, and identifies when ovulation has occurred, it is highly likely to give useful and sufficient information.

**Table 1:** Indicators used in devices developed for cycle monitoring

| Indicator used | Devices |
|---|---|
| BBT | Babycomp/ Ladycomp, Bioself, Cyclotest |
| Cervical mucus: electrical resistance | CUE-Fertility Monitor; Dist4 |
| Cervical mucus: crystallisation | PC 2000; PG 53; Maybe Baby |
| $PCO_2$ | Capnodig |
| Electrostatic charge | Ovulation controller |
| Pregnandiol-G and E1-3G, | Brown's Ovarian Monitor |
| LH/E3G | Persona |
| Basal body temperature/LH or cervical mucus | Cyclotest 2 plus |
| Progesteron | Safeplan |
| Lipid-profile | Skin-check |

An ES determines the effectiveness of the device in preventing a pregnancy (user performance), which is the property of the device to provide accurate and timely information that allows users to avoid pregnancy by abstaining from intercourse or using a barrier method of contraception during the identified fertile time. An ES also provides final information about the results of perfect and imperfect use of the device (i.e., the likelihood of pregnancy if the woman uses the information provided by the device correctly and consistently during each cycle of use) and the results of typical use of the device (i. e., the likelihood of pregnancy experienced by women who do not always use the information provided by the device correctly and consistently during each cycle of use).

## Evaluation of Published Data

### Systems Using Indirect Markers

There are five devices reported in the literature which measure indirect markers of the fertility status. The data are of variable quality, and only one, the Bioself has recently undergone a prospective efficacy study.

Temperature Computers

*1. Ladycomp®/Babycomp*

Effectiveness finding studies (EFS)

a) Indirect EFS: Freundl et al. [8] have compared in 168 cycles the fertile time detected using the STM of NFP with the FT detected by the device. Only in one cycle the device failed completely. In 3 cycles the beginning of the fertile time was located at day –4, in 1 cycle at day –2. The end of fertile time was shown at day 0 in 1 case and at day +1 in 2 cycles. The duration of fertility according to this device was 16.88 ± 5.63days.
b) Direct EFS: To have a more accurate comparison the same authors looked into the fertile time detected by LH and ultrasound monitoring of the growing follicle in 20 cycles. In no case the recognition of the defined fertile phase was missed by the device [8]. In 1992 the same group has performed such a study with Ladycomp only [9].

Efficacy studies (ES)

With BC/LC there is one retrospective efficacy study (rES) available. The data were collected in the following way: after tracing the addresses of purchasers of BC/LC over the past 3 years, questionnaires were sent to 800 German purchasers. 182 letters came back unopened as the addressees had changed their homes and the new addresses were not known. 16 customers had bought devices but had not used them. Consequently, 602 were able to answer the questionnaire. Of these, 538 returned the questionnaires, resulting in an answering rate of 89.7 %. In the same way, 110 questionnaires

were collected from Switzerland. Thus, for the statistical analysis a total of 538 + 110 = 648 questionnaires were included in the study [10].

The most important question referred to the occurrence of pregnancy while using the device. When we heard about a pregnancy we examined the type of pregnancy according to the opinion of the user: Did it occur during the use of the device? Did the BC/LC show a green, red or yellow light? When had the intercourse taken place?

With the rES in 597 women with 10275 cycles 33 pregnancies occurred, which gives a Pearl-Index of 3.8. With the data reported it is not possible to determine failure rates with perfect and typical use. The cycle length (mean, SD) was 29.2 ± 5.4 days, the length of the fertile phase was 16.3 ± 4.6 days.

*2. Cyclotest*

With the Cyclotest-system until now only EFS are published. The design of the studies is the same as reported for the BC/L: the number of cycles in the indirect EFS was 16, the number in the direct test was 5 [11].

With the Cyclotest 2 plus device an indirect EFS was performed using cycles estimated according to STM-rules as comparison [12]. Always the 13$^{th}$ cycle of 207 women which contributed 4430 cycles alltogether were used for evaluation. It was found that the algorithm led to dangerous reduction of the fertile time (FT) in only 2 out of 207 women cycles (0.96 %). At the end of fertile time the device requested more abstinence than was necessary in about 12 % of the cycles.

With the Cyclotest 2 plus system there is a possibility to enter the symptom of mucus of highest quality or the peak day of LH measured by an urine strip. So this computer uses a double check observation to calculate the fertile time. It seems that with the addition of another parameter it is possible to shorten the length of the abstinence (from 15.8 per cycle down to 15.14 ± 5.63 days of abstinence per cycle).

*3. Bioself*

With Bioself 110® a number of studies have been performed [13–16]. Unfortunately this device has been removed from the market about 2 years ago.

Ismail et al. [15] have performed a EFS with 33 women contributing altogether 88 cycles. 24 women used the device to help them to achieve a pregnancy, while 9 were using it as a contraceptive aid. 8 of the first group conceived during the study. Interestingly in 7 of the 9 couples preventing a pregnancy the partners used also condoms and 5 of the volunteers also used natural methods! However, one of the nine women had an unplanned pregnancy during the study. But her contraceptive intention was not clear.

The effectiveness of the Bioself 110 was evaluated by comparing the information it provides with four "objective" indicators such as ultrasound, luteinizing hormone (LH), basal body temperature and cervical mucus characteristics.

From 88 cycles available for analysis 11 (12.5 %) were excluded for different reasons. From the remaining 88 cycles there were 75 with LH data, 68 with ultrasound and 66 with both. Finally for analysis of the fertile period data were available for 65 cycles using US and Bioself and 72 cycles using LH and Bioself. For analysis of the postovulatory infertile period, data were available for 63 cycles using US and Bioself and 71 cycles using LH and Bioself. Out of 77 cycles in 4 cycles the green signal appeared during the postovulatory fertile time, in 7 cycles in the possibly fertile time.

Labrecque et al. [16] also performed an EFS comparing the results of the Bioself 110 with a reference method, the Ovustick LH-surge detection kit, which detects the LH-peak on average 24–30 hours before ovulation.

For the purpose of this study the fertile period was assumed to be 6 days, starting 3 days before the LH-peak and ending on the second day after the LH-peak.

60 women (age 21–40 years) were recruited into the study with regular menstrual cycles (23–33 days). Interestingly in this study the Bioself 110 was modified so that the light signal would not appear. The women were asked to use the device for 3 cycles. The information of the device's memory was printed out monthly. These 60 women contributed 252 cycles. Of these in 24 cycles there was no LH-peak, in 20 cycles were < 23 or > 35 days, in 3 cycles there was malfunction of the Bioself, 5 women did not take temperature properly.

For the final analysis 200 cycles remained to answer the question on the correlation between the reference fertile time and first and last fertile day detected by the device.

It was found that in 4 cycles (2 %) out of 200 the red light started one day in the fertile time, in 5 (2.5 %) cycles 2 days in the FT and in 1 (0.5 %) on the third day prior to the expected ovulation: 10 cycles in risk prior to ovulation!

The green light after ovulation started in 2 cases at –1, in 2 cases at +1 and in 7 cases at +2.

Altogether the risk of pregnancy was given in 11 (6.2 %) out of 178 cycles.

Summarized the green signal appeared in 11 (6.2 %) out of 178 cycles during the postovulatory fertile time, the red light appeared to late in the preovulatory fertile time in 10 (5.6 %) out of 178 cycles. So the total failure rate was 11.8 %.

Drouin et al. [17] reports on a prospective three-center-study evaluating the Bioself as a contraceptive aid. 83 women accumulated 745 cycles. The study design fitted into our rES-concept. 6 unplanned pregnancies occurred from unprotected intercourse during the fertile phase of the cycle, as indicated by the Bioself device. The pregnancy rate was 9.02 per 100 women-years.

In our study in 3 of 42 cycles the beginning of the postovulatory infertile phase fell into the time of ovulation [14].

Flynn has reported on a well done Bioself 110 study which was performed as a pES [13]. 150 sexually active women (age 18–40) were recruited for participation in a 24-months study. After discontinuation for various reasons a total of 131 women entered the study and contributed 1238 cycles. 80 women stayed in the study until its termination. 41 women completed 12 cycles or more.

A total of 30 pregnancies resulted from all cases. 2 pregnancies resulted from an apparent failure of the Bioself 110. According to analysis of the manufacturer nine (5.1 %) of the 175 devices in the study were actually defective. In a maximum of 116 cycles the algorithm of Bioself 110 was unable to identify a temperature shift.

It has to be mentioned that this prospective study gives also the figures for perfect and imperfect use of the device.

Summarized the method failure rate (according to Pearl) was 1.9 in this study.

Self Tests for Body Fluids

*PC 2000, PG 53*

With other devices the ferning phenomenon is used occurring when cervical mucus or saliva are drying on a fat-free slide in open air. Unfortunately only very few studies in EFS-design are performed until now: Jordan et al., 1992 found with 300 cycles of use a total failure rate of 18.4 % [18].

Barbato et al., 1993, using the PG53 reported in a similar setting with 32 cycles a failure rate of 12.5 % [19]: of the 32 women participating in this research, 28 women had a good salivary test with positive ferning by the microscope in the same period as other markers of fertility. In 4 cycles the ferning was uninterpretable as there was no correspondence with the cycle phase. Ferning began 1–2 days before cervical mucus appearance, and lasted a mean of 6.2 days. Ferning occurred, on average, 7.2 days before the first day of temperature shift. The authors concluded that there is a direct correlation between salivary ferning and fertile period. Salivary ferning may be used as a new parameter to aid women to detect the fertile period in combination with other symptothermal methods of ovulation detection. Further research in order to improve the use-effectiveness of salivary ferning is needed.

Electrical Resistance Gauges

*Cue Fertility Monitor*

Attempts were made to measure the electrical resistance of saliva or vaginal fluid [20], which have been found to fluctuate during the cycle. Table 2 shows some studies and the results performed with the Cue Fertility Monitor®.

**Table 2:** Reports on the Cue Fertility Monitor

| Cycles | Mean fertile time | Failure-Rate (n/%) | Study Design | Ref. |
|---|---|---|---|---|
| 29 | 9,6 | | EFS | [22,51] |
| 30 | | 4/13,8 % | EFS | [23] |
| 18 | 8,5 | 7/38,9 % | EFS | [52] |
| 65 | 9,8 | 35/53,8 % | EFS | [21] |

Our studies have shown [21] that there are many cycles where the Cue signals can be found. However, in about one-third of the cycles the signal (Cue peak) could not be found. The beginning of the fertile time was captured easily in almost all cycles (control-cycles: 14 out of 14 [100 %], NFP-cycles 41 out of 49 [83.7 %]). However, the end of fertile time was detected to early in 13 out of 14 and 41 out of 49 (83.7 %).

Moreno reports on 29 cycles from 11 women [22]. In contrast to our findings all but one of the 29 cycles were associated with an oral peak and a vaginal nadir. A nadir in vaginal readings occurred on or before the expected ovulation day (EOD) in all but one of the cycles (3.5 %). 93 % of the salivary electrical resistance (SER) nadirs occurred within two days prior to EOD.

Loewit reported a failure rate of 4 out of 30 (13.8 %) [23].

As there are characteristic cyclic changes of salivary electrical resistance, it may be possible that the device can increase its safety for the users by improving the algorithm for evaluation.

Roumen and Dieben [24] reported of 27 cycles in 18 volunteers and the relationship between the SER and the time of ovulation. They found that the changes in SER values, arranged to the LH-peak were not statistically significant. The days of SER peak in relation to the day of LH peak were not reproducible in individual women. They concluded that measuring the SER is of no use in predicting the day of ovulation. As the used methodology corresponds to the EFS it is expected that further testing for efficacy is not necessary.

Endexspiratory $CO_2$-Pressure Change during Cycle

Döring [25, 26] observed that the $pCO_2$ values were significantly higher during the follicular phase than during the luteal phase of the cycle. In the way of an EFS the time course of the endexspiratory pressure of $CO_2$ was determined daily during the menstrual cycle of 15 women using the Capnodig $CO_2$, Monitor of Dräger AG, Lübeck, Germany. This was correlated to the changes of LH, E2 and Progesterone in serum and the basal body temperature [27]. There is a significant reduction of the $pCO_2$ in the exspiratory flow already 1–2 days prior to LH-peak. With 6 volunteers this reduction happened at day –1, with 4 women with day –2, with 3 women with day –3 and with 1 woman with day –4. The preliminary results show that the method may be useful for ovulation detection, but will not be expected to give sufficient warning for abstaining intercourse to prevent pregnancy. Recently there are more studies available showing that the $CO_2$ pressure is more convenient to predict ovulation in dealing with fertility problems [28–30].

## Other Developments

There are technical developments which are not generally recognised as they are using rather unknown indicators of the woman's cycle fertility:

Stoller et al., 1986 report on a device, which measures changes of the electrical potency of the fingertip [31]. Treves et al. has reported on changes in enzyme levels in human cervical mucus during the menstrual cycle [32]. Calamera reports on changes in sialic acid concentration in human saliva during the menstrual cycle [33]. Mancuso reports 1992 on a device showing the proportion of palmitin acid and cholesterol in the skin of the face [34, 35]. Others report on a brassiere measuring the temperature and the circulation of the breast tissue caused by estrogens.

Last but not least a wrist-watch has been developed by Weiland, which measures the surface temperature at the wrist . In 1983 this watch was honored by the Phillip-Morris-research price. All these

**Table 3:** Devices compared in a small pilotstudy in respect of their contraceptive efficacy. Only the Brown's Ovarian Monitor was not tested in this context. The devices were compared with our STM (NFP-DAG) [4, 53]

| Product | Price (approx., €) | Method | www | Manufacturer |
|---|---|---|---|---|
| Babycomp/Ladycomp | 750 | Temperature computer, BBT and calculation rules | www.babycomp-ladycomp.com | Valley electronics GmbH Wengwiese 3, D-82438 Eschenlohe, Germany |
| Cyclotest 2 Plus | 150 | Temperature computer, BBT and calculation rules | www.cyclotest.de | UEBE GmbH Zum Ottersberg 9, D-97877 Wertheim, Germany |
| Brown's Ovarian Monitor | 100 + 0.5/assay tube | Hormone computer: Pregnandiol-G and E1-3G | | St. Michael NFP Services |
| Persona | 150 + 12 €/month for testsicks | Hormone computer: LH & E3G, calculation rules | www.persona.org.uk | Unipath GmbH An Lyskirchen 14, D-50676 Köln, Germany |
| PC 2000 | 60 | Mini-microscope, fernig pattern of saliva | www.thedonna.com | IMPCON |
| PG 53 | 39 | Mini-microscope, fernig pattern of saliva or cervical mucus | www.intercom.es/pg53 | Aplicationes Opticas PG/53 Paseo de Gracia 53, ES-08008 Barcelona, Spain |
| MayBe Baby | 80 | Mini-microscope, fernig pattern of saliva | www.maybe-baby.com | OPTIX Wiesenstraße 58, D-63071 Offenbach, Germany |

developments are interesting, but none of them have been tested in carefully designed studies.

### Systems Using Direct Markers

Hormonal Computers

*1. Brown's Ovulation Monitor*

The Monitor assists the woman to avoid a pregnancy by periodic abstinence [36] or to achieve a pregnancy by timing intercourse to the most fertile days of the cycle. Ovarian and pituitary hormone production show characteristic patterns during the cycle. Urinary estrone and pregnanediol glucuronide measurements yield reliable information concerning the beginning, peak, and end of the fertile period. Enzyme immunoassays for urinary estrone and pregnanediol glucuronides were developed so that they can be performed at home. The tests gave 4 days or more warning of ovulation in 99 % of cycles and allowed intercourse to be resumed 1 to 3 days after ovulation in 88 %, giving a mean period of abstinence of 7 days. No woman had difficulties with the daily urine testing, and their results consistently identified the distinctive hormone pattern of the ovulatory cycle for each individual including the day of ovulation and correlated closely with the mucus symptoms. No pregnancy occurred from intercourse during the late safe days defined by the Monitor, but some early-day pregnancies occurred through long sperm survivals of 6 to 8 days, mostly during the return of fertility after breastfeeding [37–44].

*2. Persona*

Another approach to identify the fertile phase of the menstrual cycle is the device Persona that allows a woman to measure cyclical changes of estrogens and LH in urine. A hand-held monitor and disposable test sticks measures changes in the urinary levels of E3G and LH and a program calculated the stage of the cycle. Estrone-glucuronide should be able to mark the beginning of the fertile phase, while LH is used to detect the end of the fertile phase. Until now, it has been difficult to identify a precise measurable hormonal marker for the beginning of the fertile phase.

The results of a prospective efficacy study (pES) on Persona® have been reported in 1999 (see also [1, 45, 46]): 710 women have contributed 6833 cycles. The trial was designed to determine the method effectiveness of personal hormone monitoring in preventing pregnancy when used with abstinence from sexual intercourse during the identified fertile days of the cycle. The use of the system resulted in 33 method related pregnancies giving a method pregnancy rate of 12 % during perfect use. This should be ameliorated to an estimated pregnancy rate of 6 % after some changes of the algorithm.

## Comparative Trial

As no comparable results concerning the different devices were available so far we have performed a small clinical observational pilot study [47] with the following design:

- Objectives: The effectiveness of cycle monitors like temperature computers (Babycomp/Ladcomp, Cyclotest 2 Plus, Bioself 2000), a hormonal computer (Persona), mini-microscopes (PC 2000, PG 53, MayBe Baby) and the Symptothermal Method (STM) of Natural Family Planning (NFP) in detecting the fertile window in a woman's cycle was evaluated. Table 3 shows the details of the devices and computers tested.
- Materials and Methods: A total of 65 women have tested two of the above devices in variable combinations after a learning phase. 122 test cycles and 558 learning cycles were available for evaluation. In the test cycle the fertile window was detected using the usual tools (LH-Peak testing and sonography of the growing follicle).
- Results: The number of women and cycles in whom/in which the various devices indicated false negative (not

**Table 4:** Detection of cycle days as fertile or infertile in relation to the clinical status as revealed by ultrasound and daily urinary LH (false negative: defines a day predicted as infertile by the monitor was clinically fertile, false positive: a day predicted as fertile by the monitor was clinically infertile) [44]

| Device/Method | Women $n_1$ | Cycle days $n_2$ | Absolute numbers and rates (%t) | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | false neg.[1] | | false pos.[2] | | correct[3] | |
| PG 53 | 16 | 460 | 94 | 73.4 | 22 | 6.6 | 344 | 74.8 |
| PC 2000 | 14 | 387 | 65 | 58.0 | 31 | 11.3 | 291 | 75.2 |
| MayBe Baby | 16 | 441 | 66 | 51.6 | 71 | 22.7 | 304 | 68.9 |
| Persona | 15 | 416 | 25 | 20.8 | 68 | 23.0 | 323 | 77.6 |
| Babycomp/LC | 16 | 442 | 6 | 4.7 | 92 | 29.3 | 344 | 77.8 |
| Bioself 2000 | 15 | 454 | 9 | 7.5 | 180 | 53.9 | 265 | 58.4 |
| Cyclotest 2 Plus | 15 | 392 | 2 | 1.7 | 108 | 39.7 | 282 | 71.9 |
| NFP | 15 | 416 | 0 | 0.0 | 75 | 25.3 | 341 | 82.0 |

[1] related to total number of fertile cycle days ($n_1 \times 8$)
[2] related to total number of infertile days ($n_2 - n_1 \times 8$)
[3] related to all cycle days ($n_2$)

fertile in the true fertile phase) or false positive (fertile in the true non-fertile phase) differed significantly. The temperature computers indicated false negative days in 1.7 % to 7.5 %, the hormonal computer in 20.8 %, the mini-microscopes between 51.8 % and 73.4 % and NFP in 0 %. Comparing the length of the preovulatory infertile time the PC 2000, Bioself 2000 and NFP differed significantly from Cyclotest 2 Plus and MayBe Baby; in the postovulatory infertile time only NFP and PC 2000 differed significantly from Cyclotest 2 Plus and MayBe Baby; in the length of the fertile time only Bioself and PC 2000 differed significantly.

- Conclusions: For contraception purposes the devices and methods tested vary: the best results were obtained with the symptothermal method of Natural Family Planning followed by the temperature computers and Persona. The mini-microscopes are not recommendable. For achieving a pregnancy the devices show more positive results.
- General outlook: To generate a simple but effective way to predetermine the practical value of a new device we estimated for every device the maximum failure rates using the daily conception probability rates taken from the European Fecundability Study. Intercourse was assumed to occur on each of falsely predicted days of infertility [48]. The maximum unintended pregnancy rates per cycle for temperature computers were estimated to be 0.0134–0.0336, for the hormonal computer 0.1155 and for mini-microscopes 0.2313–0.2369. For the STM of NFP, there were no false infertile days. Thus the estimated pregnancy rate per cycle turned out to be 0.
- Summary: The symptothermal method of NFP is the most effective contraceptive method as it has the lowest false negative (not fertile in the true fertile phase) rate among all the methods tested. But the period of abstinence required is somewhat longer compared to other monitors. The estimated efficacy of the Fertility monitors range from the temperature computers (upper level) to the hormonal computer (medium level) and the mini-microscopes with very low estimated contraceptive efficacy. The false negative results deserve our special interest, as they are connected with the efficacy of the systems used (Tab. 4).

## Conclusions

Until now there has been no device tested which has a method effectiveness comparable to the German symptothermal method which is in the high efficacy range [49, 50]. Only Persona® and Bioself® have been tested in prospective effectiveness studies (pES). We therefore still need well designed prospective effectiveness studies (pES) on all the devices which are sold over-the-counter.

Other devices have still been rejected to be tested carefully in any kind of studies. They are sold without having any sound scientifical basis. Therefore, we as the advocates of the users can not recommend them.

## Relevancy to Practice

More and more instruments and devices are sold to help women detecting their fertility status. However, only very few of these devices are tested sufficiently in respect of their efficacy to support or avoid a pregnancy. In counselling this fact must come across.

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