

**Commentary on the content and background of the independent clinical study:  
“Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: results of a retrospective efficacy study of Daysy and DaysyView app”**

by Dr. Niels van de Roemer (Medical Director and author of the manuscript)

For more than 30 years, Valley Electronics has been engaged in various areas of research with the focus on "Fertility Awareness Methods." This led to 8 published clinical tests (see literature) and many other published reports and oral talks. The founder of Valley Electronics, Dr. Hubertus Rechberg, is one of the pioneers in the field of natural family planning. In this tradition, it was a matter of great concern to us, to be a part of a clinical aim again in 2018.

**Background:**

The aim of the study was to determine whether the additional use of an app (DaysyView) and the associated digitalization of the data would change the way the fertility tracker, Daysy, is used.

**Conflict of interest:**

What was Valley Electronics' contribution? Data protection has the highest priority! Since very few people have access to the digitized data after the user's consent, it was Valley Electronics' task to obtain this consent and make the data available for the duration of the study.

Quote from the study:

“...NvdR is an internal scientist and employee of the company. NvdR analyzed the stored data. There are no other relationships or activities that could appear to have influenced the submitted work.....”

**The retrospective design of the study**

There are several reasons why the scientists now, and in the past, chose a retrospective study:

- Retrospective design gives scientists the opportunity not to limit the study by region. Since there are many cultural differences, it is important to get an international cross-section of the population. For example: Women from the USA, Switzerland, Germany, South Africa, Israel, Thailand, Australia, India, and many more participated in the study (36 different countries in total).
- It was designed so that it was not possible, for example, to exclude certain ethnic groups or social strata. Similarly, the design insured that it would not be possible to exclude participants due to illness or their educational background.
- The retrospective design of the study has another very practical background. The study commented upon here is only a portion of other research projects. The same survey also asked questions about pain, irregular cycles, endometriosis, and the use of medication. The first results of further studies (not published) have already been orally presented at international congresses.

Of course, we also know about the disadvantages of a retrospective study. These disadvantages were named transparently.

Quote from the study:

...”The retrospective design is a very time efficient and elegant way of answering new questions with existing data. The primary disadvantage of the retrospective study design is the limited control the researchers have over the data collection. The information provided by the participants may be inaccurate or biased by the fact that participants already know the device. To counter incorrect information, the data provided by the participants were double checked for their correctness from comparison with the internal database. With this measure, it could be further ensured that no doubts had taken part in the survey”....

**Methods:**

In order to obtain comparability with previous studies and current studies in the field of fertility awareness methods, the researchers decided to make use of the Pearl-Index (PI), among others.

In principle, the PI is clearly defined and allows comparability with other methods: 100 women use a contraception method for one year (or 13 cycles). At the end of the year, it is counted how many of them have become unintentionally pregnant.

- A PI of 1 says: One in 100 women got pregnant unintentionally.
- A PI of 0.5 means that only one in 200 women has become unintentionally pregnant.

The drawback of the Pearl index is that it assumes a constant failure rate over time. This assumption is incorrect: It does not include women who use the method for less than 1 year (or 13 cycles). This group in particular is susceptible to unwanted pregnancies, as the method is still new for them.

The authors have decided to use another method for calculating contraceptive safety: **The Life-Table Analysis**. In this type of analysis, there is no single endpoint that is the major focus of the study (like it is by the PI). Life table-analysis calculates cumulative failure rates over a specified timeframe (1 year). The weaknesses of the PI were addressed transparently.

Quote from the study:

“...One major problem of the PI is that it does not account for duration of exposure; the PI is reasonably reflective of contraception failure if duration of use is short (i.e. 6 to 12 months) and most users use the method for about the period of time [18]. In a life-table analysis, or (in this case equivalently) the Kaplan-Meier approach, a separate failure rate is calculated for each month of use such that varying durations of use are not problematic. The result at observation cycle 13 can roughly be compared to the PI. The Kaplan-Meier approach was used to calculate the overall effectiveness rates. Pregnancy due to both typical-usage safety as well as the method failure were included in the calculation....”

### **1 year Discontinuation Rate**

How good or bad a method of family planning is can also be seen from how continuously and over what period of time this method is used. To verify this, the authors checked the accounts of all participants one year after the start of the clinical trial:

Quote from the study:

“...One year after the survey started, 98% of the participants’ accounts were still active. If only the accounts that continue to be synchronized with the fertility monitor after 1st June 2017 are considered, it is still 79%....”

### **Daysy is not a contraception**

Explicitly the authors attach importance to the fact that Daysy is not a contraceptive in the real sense. Daysy is a fertility tracker that uses the fertility awareness method (FAM) by tracking and analyzing the individual menstrual cycle.

Quote from the study:

“...Daysy is a tool of the so-called fertility awareness-based method. These types of tools do not control contraception, but rather use quantitative data and statistical models based on this data to advise the users to be aware of the fertile days. During these days, one must use an alternative form of contraceptive such as a barrier method (condom, diaphragm, etc.) to avoid pregnancy or abstain from sexual intercourse, as practiced by the NFP method, to avoid pregnancy....”

There is criticism that FAM does not include the risk of additional contraceptives. The authors are aware of this risk and address it transparently.

Quote from the study:

“.....Through the digital analysis of temperature data, fertility monitors can reduce the risk of inaccurate or misinterpretation (as it is done by a computer) of fertility indicators and they can remind the user that a pregnancy risk exists on fertile (red) days but they cannot reduce the risk of the additional contraceptive methods or unprotected intercourse. It must be noted, that unwanted pregnancy is not a harm arising from the application of the device. It is a risk of FAM per se. Using fertility awareness-based methods means accepting this risk...”

### **Literature**

- BabyComp as an aid for adolescent contraception. [Freundl 1988]
- LadyComp as an aid in natural family planning. [Freundl 1992]
- Monitoring of ovulation by sophisticated digital electronic BBT recording “Babycomp“ in patients with unexplained infertility. [Dessole 1997]
- The retrospective study of the reliability, acceptance and safety. [Bachhofer 1997]
- Retrospective clinical trial of contraceptive effectiveness of the electronic fertility indicator LadyComp/BabyComp. [Freundl 1998]
- Review: Calculation of the Pearl Index of Lady-Comp, Baby-Comp and Pearly cycle computers used as a contraceptive method [Binkiewicz 2010]
- Published Survey: Evaluation of the effectiveness of selected natural fertility symptoms used for contraception: estimation of the Pearl index of Lady-Comp, Pearly and Daysy cycle computers based on 10 years of observation in the Polish market. [Demianczyk 2016]
- Improving usability and pregnancy rates of a fertility monitor by an additional mobile application: results of a retrospective efficacy study of Daysy and DaysyView app. [Koch 2018]

**The Valley Electronics team prides itself on professionalism, transparency, and integrity and will continue to support scientific projects in the fields of endometriosis, conception, and the general health of women.**