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IDENTIFICATION AND PREDICTION OF THE FERTILE WINDOW WITH A NEW WEB BASED MEDICAL DEVICE USING A VAGINAL BIOSENSOR FOR MEASURING THE CIRCADIAN AND CIRCAMENSUAL CORE BODY TEMPERATURE

Regidor P (DE) [1], Kaczmarczyk M (DE) [2], Schiwek E (DE) [3], Goeckenjan-Festag M (DE) [4], Alexander H (DE) [5]

Context
Fertility awareness based (FAB) methods represent a term that includes all family planning methods that are based on the identification of the fertile window. They are based on the woman's observation of physiological signs of the fertile and infertile phases of the menstrual cycle.
The first approach consists basically in symptothermal methods accompanied by cervical mucus measurements and clinical menstrual cycling data recording. The second most often used methods are the urinary measurement of E3G and LH with a personalized computer system. Hence these systems lack the efficacy of the continuous circadian and circamensual measurement of the core body temperature. Only this approach enables the accurate detection of the ovulation during the fertile window.
Objective
A new medical device called OvulaRing has been developed to fill this gap. In the present study, the system and its first clinical results are presented.
Methods
OvulaRing is a medical device used just like a tampon. The device is a vaginal ring of evatane that contains an integrated biosensor. This sensor measures continuously every 5 minutes the core body temperature throughout the entire cycle. This device allows a circadian and circamensual intravaginal exact measurement. With this system 288 measurements are created per day. The system can detect retrospectively and predict prospectively the fertile window of the users.
Patients
158 women aged between 18 and 45 years used this medical device in an open non-randomized clinical study for 15 months. A total of 470 cycles could be recorded and were able for analysis. By the same time in a subgroup of patients, hormonal assessments of LH, FSH, estradiol and progesterone as well as vaginal ultrasound were performed in parallel between the 9th and the 36th day of the cycle.

Results
The validation error due to software errors was 0,89 % for the retrospective analysis; that means that the

[1] Exeltis Germany, [2] University Dresden, Reproductive Medicine, Dep. of Gynecol and Obstetrics, [3] University Dresden, Reproductive Medicine, Department of Gynecol & Obstetrics, [4] University Dresden, Reproductive Medicine, Dep. Gynecol and Obstetrics, [5] Centre of reproductive medicine City Leipzig

accuracy for the detection of the ovulation was 99,11 %. Accuracy of 88,8 % for a window of 3 days before ovulation, the day of ovulation and the three days after ovulation was achieved for the prospective analysis. In the subgroup of woman with recorded pregnancies it could be shown that after 3,79 months of use (median) pregnancies were observed. In 67,72 % in up to 3 months, in 16,36 % between 3 and 6 months of use, in 7,27 % between 7 and 9 months, in 5,45 % between 10 and 12 months and in 1,82 % between 13 and 15 months of use of the system.

Conclusions

With this new web based system, a precise determination of the fertile window even in women with ultralong cycles (> 35 days) could be detected independently of their personal live circumstances. Exact determination of the fertile window is herewith possible so that OvulaRing represents an evolution in the FAB method for the cycle diagnosis of women with regular, irregular or anovulatory menstrual cycles.