

The new women's health science of NaProTECHNOLOGY

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Abstract

The paper presents the main concepts of NaProTECHNOLOGY. Such problems as family planning effectiveness, targeted hormonal assessment of the menstrual cycle, ovarian hormone and target organ dysfunction, disorders of human ovulation, cooperative progesterone replacement therapy, premenstrual syndrome, postpartum depression, unusual bleeding, infertility and antiadhesion therapy are discussed.

Key words: family planning, contraception, NaProTECHNOLOGY

Introduction

In 1960, the oral contraceptive became available for use as a contraceptive agent. However, it wasn't long thereafter that there were a whole host of gynecologic conditions that were symptomatically treated with the oral contraceptive. This has become so prominent, in fact, that much of the emphasis on the use of "the pill" today is for its "health benefits"[1].

Over this period of time, there has not been a significant amount of research oriented toward identifying the underlying causes of the various symptoms that were being treated by the oral contraceptive agent. In fact, recently, it has been stated fairly emphatically that "normal ovarian function rather than reproductive endocrine imbalance is associated with menstrual-cycle-related disorders" [2]. One particular item has been missing from the medical literature. That item is the assessment of vulvar changes during the course of the menstrual and fertility cycles. These changes have been almost completely ignored by specialists in gynecology and reproductive medicine.

It is the purpose of this paper to present an overview of the new women's health science of NaProTECHNOLOGY [3] (*Natural Procreative Technology*) and, with that, a discussion of its foundational family planning system, the Creighton Model FertilityCare™ System [4].

The Creighton Model FertilityCare™ System is the first and only family planning system that is completely integrated with a woman's health. It is based upon objective and standardized vulvar observations of biological markers and it is the foundational system to the new women's health science of NaProTECHNOLOGY. The Creighton Model System (CrMS) evaluates a set of phy-

siologic processes of vulvar discharge that are easily observed in an objective, reproducible and prospective manner in a way that is easy to do. This new women's health science has been described in detail in the 1244-page medical textbook entitled, *The Medical & Surgical Practice of NaProTECHNOLOGY*[3].

Methods

The research investigation into the vulvar changes in discharge patterns which eventually led to NaProTECHNOLOGY was begun in 1976 at the St. Louis University Natural Family Planning Center. Out of this research, a standardization of the observational routine for the discharge patterns and the terminology used to describe these patterns was developed. A Picture Dictionary of these observations was developed and is used routinely in the teaching of this system to couples [5].

In Figure 1, a Creighton Model chart is shown with its correlating pre- and postovulatory estrogen and progesterone profiles. There is an excellent correlation between the rising levels of estrogen and the external presence of cervical mucus and the Peak Day which is the last day of the mucus the woman interprets as being either clear, stretchy or lubricative. Ovulation occurs on ± 3 days of the Peak Day in 100% of cycles [6]. It is now the single most studied observation in the natural regulation of human fertility [7-11].

A chart such as the one shown in Figure 1 reveals a variety of different biological markers (biomarkers). These include such things as the overall length of the cycle, the length of the pre- and post-Peak phases of the cycle, the length of the mucus cycle itself (and its in-

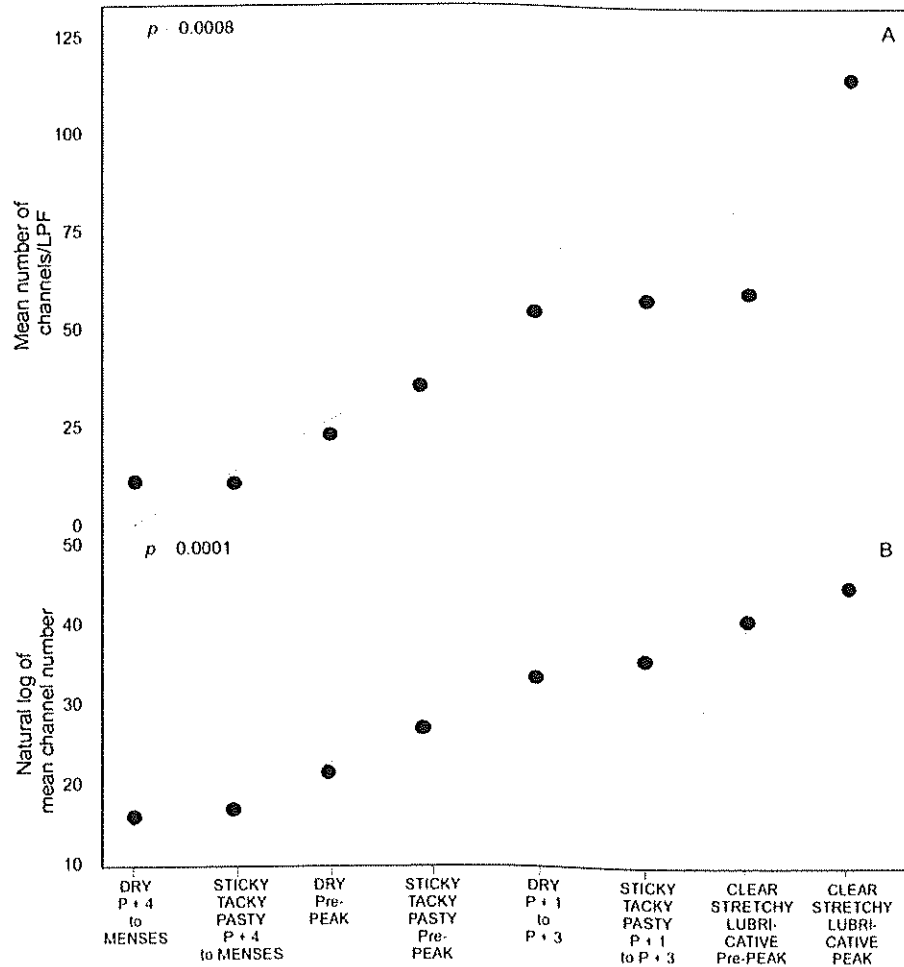


Fig. 3. (A) The mean number of channels/LPF ($p \leq 0.0008$) and (B) the natural log of the mean channel number by the woman's vulvar observation over eight stages of fertility/infertility ($p < 0.0001$) [13]

Results

A brief review of the type of results that have been obtained and published with regard to this system is presented in this section.

Family Planning Effectiveness (CrMS)

A meta-analysis of five different studies of the use effectiveness of the Creighton Model System was published in 1998 [14]. There were 1830 couples with over 17 000 couple-months of use in this study. The method effectiveness to avoid a pregnancy (perfect use) was 99.5%. The use effectiveness to avoid a pregnancy (typical use) was 96.8%.

Targeted Hormonal Assessment of the Menstrual Cycle

The physician's ability to adequately evaluate the hormonal status of the menstrual cycle is woefully lack-

ing. However, with the advent of the Creighton Model System we can now target the assessment of the menstrual and fertility cycle in ways that we have not been able to in the past. In many cases, the doctor will order a day 22 progesterone level, for example, even if that is not related to her postovulatory phase of the cycle. In Figure 4, the Creighton Model Fertility Care™ System is shown with its ability to target both periovulatory and postovulatory hormone profiles. This is an incredibly good system and it allows for diagnosing very specifically and reproducibly poor follicular function and inadequate luteal function.

Ovarian hormone and target organ dysfunction

By being able to assess the vulvar discharge patterns, it can be noted that there are significant changes that occur in certain types of conditions. For example, it has been shown that types I, II and III luteal phase

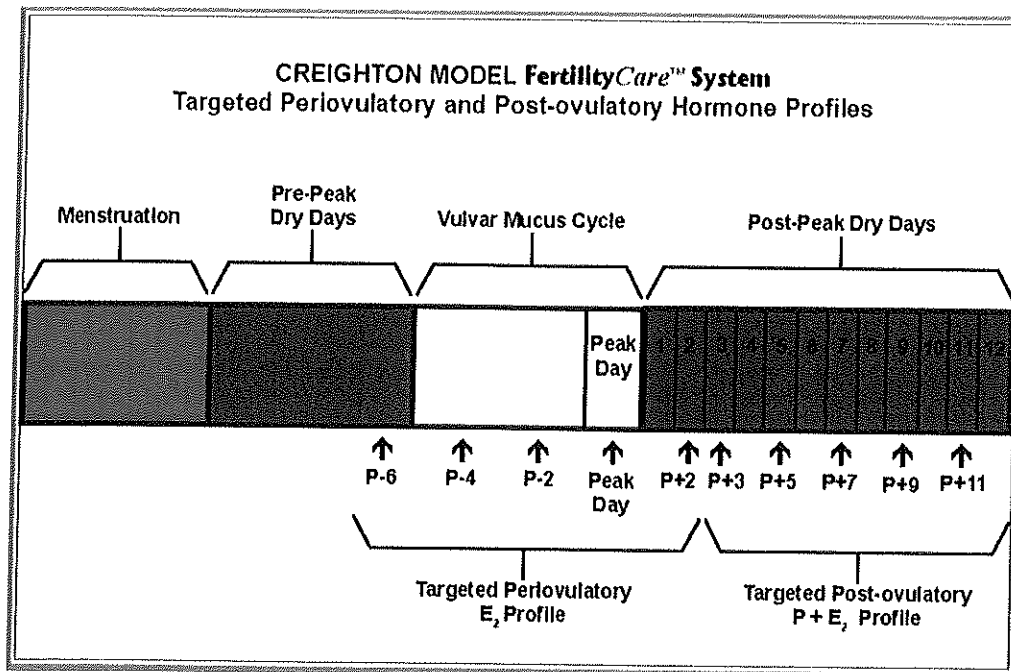


Fig. 4. A schematic of the CrMS and its ability to target the cycle for perioviulatory and postovulatory assessment

deficiencies, women with endometriosis, polycystic ovaries, and all infertility patients with regular cycles have a significant decrease in the mucus cycle score as calculated from the Creighton Model chart [15]. It has also been shown with extensive endocrine correlation studies, that the reduction of the mucus is, at least in part, due to decreased production of estradiol from the ovarian follicle; but it also may be due to a decrease in the presence of estradiol receptors in the endocervical canal [16].

Disorders of human ovulation

At the Pope Paul VI Institute, 3000 cycles of spontaneous ovulation have been evaluated by both transabdominal and transvaginal ultrasound. This has been reported on extensively [17]. In Table 1, the ovulation disorder identified by serial ultrasound examination and its association with reproductive anomalies are listed. Some of the conditions such as the luteinized unruptured follicle syndrome and afollicularism are associated with absolute infertility. Others such as immature follicles, partial rupture of the follicle and the empty follicle syndrome are associated with relative degrees of infertility.

When the mucus cycle score is calculated in patients of normal fertility and compared to those with documented disorders of human ovulation by ultrasound, the mucus cycle scores are significantly decreased (p va-

lues all < 0.03). These ovulation disorders, it has been shown, are associated with abnormal hormone production from both the follicle and the corpus luteum and that is the suspected etiology for the reduction in mucus or the development of a limited mucus cycle which is easily identified from the Creighton Model charts.

Table 1. Summary of reproductive anomalies clinically associated with the disorders of ovulation

Ovulation disorder	Reproductive anomalies
Luteinized unruptured follicle (LUF: \pm)	Absolute infertility
Afollicularism (AF)	Absolute infertility
Immature follicles (IFS: \pm Re)	Relative infertility and abnormal pregnancies
Partial rupture (PRS: \pm Re)	Relative infertility and abnormal pregnancies
Empty follicle syndrome	Relative infertility
Delayed rupture (DRS: \pm Re)	Needs further study

Cooperative progesterone replacement therapy

When a woman is charting her cycles, one can evaluate the function of the corpus luteum with ease. If the corpus luteum is not functioning normally, as noted by a decrease in progesterone production, for example, one

can replace the progesterone by prospectively timing it to the post-Peak phase of the cycle. If the cycles are long or short, it does not make any difference because the progesterone will be given at the right time of the cycle in the overwhelming majority of cases. The Creighton Model System allows for a prospective identification of the postovulatory phase of the cycle where progesterone will be therapeutic. In this regard, only isomolecular progesterone is used (bioidentical).

Premenstrual Syndrome (PMS)

In Figure 5, one can see the decrease in progesterone produced starting on P+7 and continuing on P+9 and P+11 in a group of women who have premenstrual syndrome compared with a group of women who do not have premenstrual syndrome. This is a statistically significant decrease in production of progesterone. Many studies have suggested that progesterone is not a factor in the premenstrual syndrome, however, data achieved by using a prospective charting system with the ability to target the cycle has led to the conclusion that progesterone actually is a significant factor. The success of progesterone support, either by giving progesterone or using human chorionic gonadotropin (hCG) during the post-Peak phase of the cycle has been shown to be significantly higher than it is either with placebo or fluoxetine (the latter is often thought to be the treatment of choice) [18].

Postpartum Depression (PPD)

With the interest in the use of progesterone in women with premenstrual syndrome, we have applied it also to those women who suffer from postpartum depression. When progesterone is given to a woman who has postpartum depression, there is a statistically significant decrease in the presence of the symptoms and the patient feels much better as a result of it. In 30 patients who were studied with postpartum depression, they had an average number of symptoms of 7.57 before progesterone was used and after progesterone, it was down to 2.1 (p value < 0.001).

Unusual bleeding

There are a variety of types of unusual bleeding that will show up on the chart of the Creighton Model System. Keep in mind that this is a prospective data collection system and that is one of its strong points. Abnormal bleeding, such as brown bleeding at the end of menstruation, the presence of premenstrual bleeding, the presence of intermenstrual bleeding, or heavy men-

strual periods or continuous bleeding all are conditions that can be nicely documented with the use of the Creighton Model System. Then, various types of conditions can be further evaluated.

For example, in women who have tail-end brown bleeding, we are in the process of evaluating a large number of patients and have found that chronic endometritis appears to be one of the main causes. This is identified by the presence of micropolyps and endometrial stippling in the endometrial cavity discovered at the time of hysteroscopy. In many cases, the use of antibiotics can be helpful in eliminating this discharge pattern. The premenstrual bleeding is often due to low progesterone and the supplementation with progesterone can often eliminate it. If progesterone supplementation does not eliminate the bleeding, then it can be a sign of chronic endometritis.

Infertility

When we began our work in April 1976, the Drs. John and Lyn Billings had published a series of cycles in a woman who experienced infertility and in this woman, there was no cervical mucus discharge pattern. That is all that we knew when we got involved in this further with regard to infertility.

Since that time, and published extensively in the textbook on NaProTECHNOLOGY, we have identified a variety of different conditions that are associated with infertility and cannot be evaluated in any other way. In Figure 6, a dry cycle is shown and in that dry cycle there is a very poorly functioning follicle and, following that, a poorly functioning corpus luteum (compare to Fig. 1). This type of ovarian dysfunction has target organ effects and this was new to us as we began to look at these conditions. As we looked further, it became obvious that a variety of conditions could be further evaluated by the use of hormone assessment of the menstrual and fertility cycle, ovarian ultrasound series to determine if there is an ovulation-related disorder or a diagnostic laparoscopy and hysteroscopy which will give an idea about organic and/or anatomic elements. In our laparoscopies which are done routinely on all infertility patients, 95% of the time, an organic lesion of some sort will be identified (most often endometriosis).

The CrMS also becomes a form of treatment. In Figure 7, you will see that the days that are considered to be fertile (the baby stamp days) can be used to time intercourse. This is referred to as fertility-focused intercourse and is shown in Figure 7.

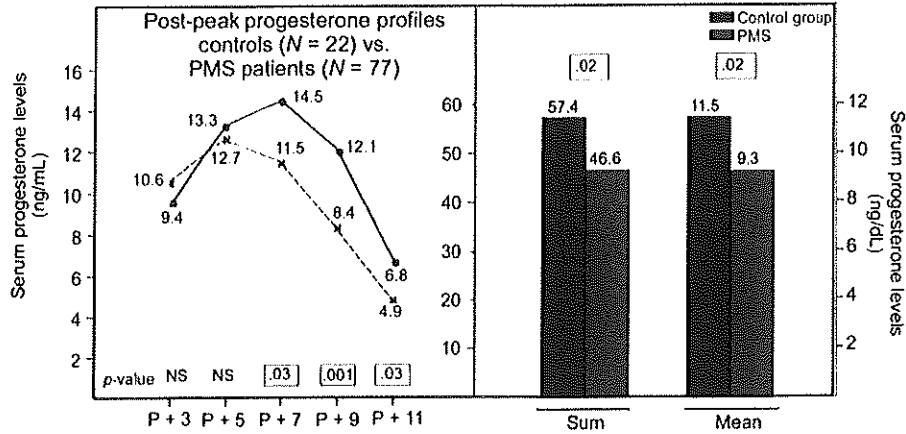


Fig. 5. Post-Peak progesterone levels in a group of women with premenstrual symptoms. The levels on P+7, 9 and 11 are significantly lower

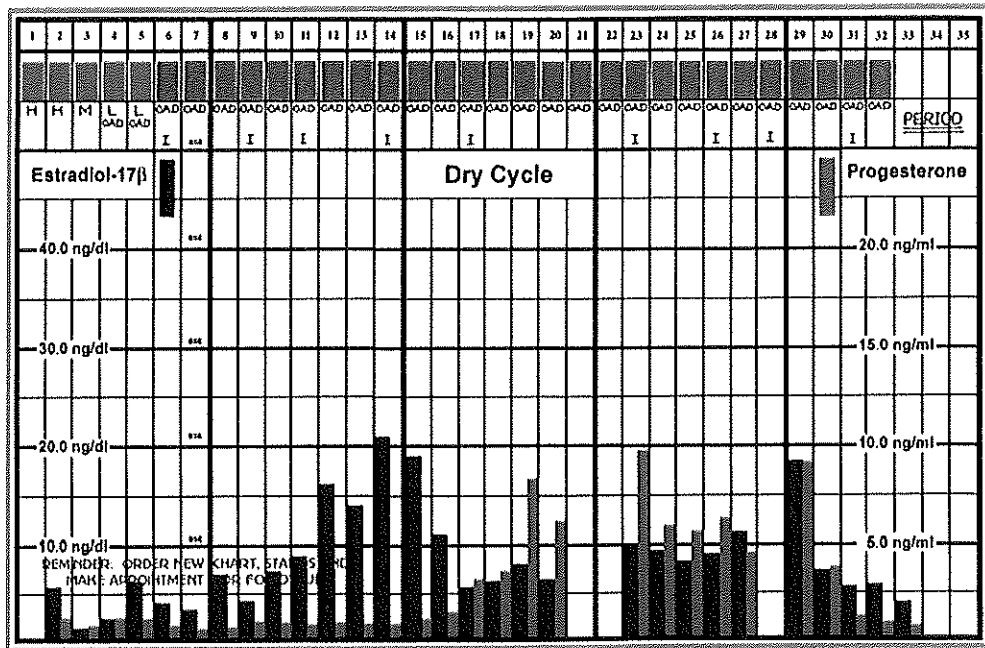


Fig. 6. A dry cycle in an infertile woman who is also evaluating her estradiol and progesterone levels. The association with abnormal folliculogenesis with subsequent abnormal luteogenesis can be seen with the very poor hormone production

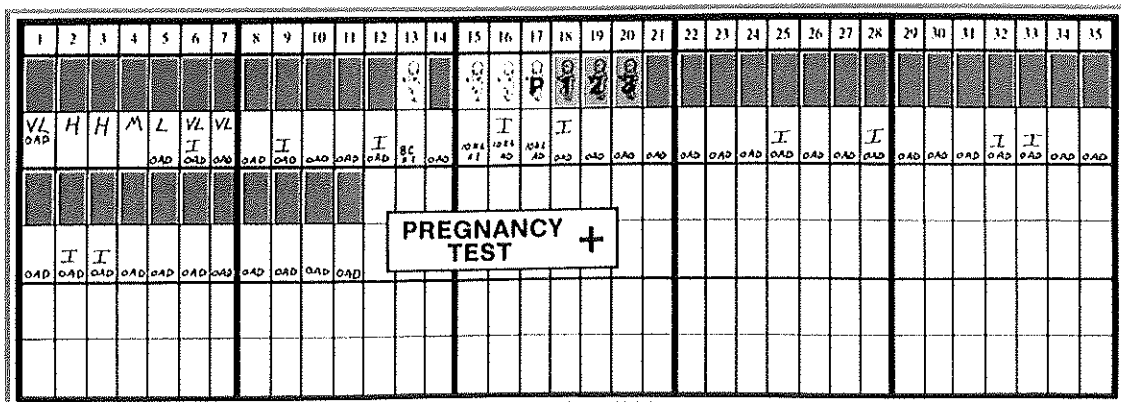


Fig. 7. Intercourse (I) during the time of fertility as identified by the CrMS. This is referred to as Fertility-Focused Intercourse (FFI)

Antiadhesion surgery

If one is going to treat patients for infertility in such a fashion as to eradicate the underlying diseases, one needs to know how to surgically reconstruct the pelvis in such a way that will not create more scar tissue and adhesions. This is particularly true for patients who have endometriosis, polycystic ovaries (who have a wedge resection) or women who have extensive pelvic adhesive disease from previous pelvic infection. In a paper published a little over one year ago, we showed the 23-year progress in the development of near adhesion-free reconstructive pelvic surgery. A highly significant reduction in the adhesion scores postoperatively have been identified at followup laparoscopy [20]. This is a very significant contribution because now it allows us to treat surgical conditions in a way which are better than anything that we have had in the past.

Success

NaProTECHNOLOGY has exceeded the pregnancy rates for patients with endometriosis and for polycystic ovaries as compared to studies that were considered "gold standards" in the past [21, 22]. In Figure 8, we show a comparison of odds ratios of "per-woman" pregnancy and family building rates showing NaProTECHNOLOGY versus *in vitro* fertilization. In all cases, the success rates with NaProTECHNOLOGY exceed that of IVF and, in addition, the endocrine and organic diseases are all being evaluated and subsequently treated.

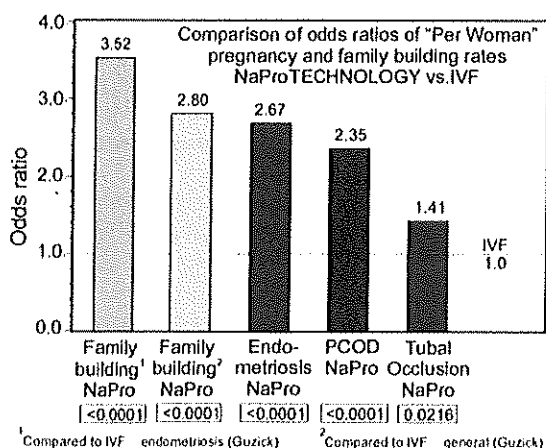


Fig. 8. A comparison of odds ratios of *per woman* pregnancy rates and family building rates (includes adoption) for NaProTECHNOLOGY and IVF (1.0)

Discussion

In the current status of gynecology and reproductive medicine, the approach to treatment is either oral con-

traceptives or *in vitro* fertilization. With IVF, the approach to infertility is to "skip over" the underlying or root causes. As a result, we have lost over 30 years of good research opportunities; and when women go to the IVF clinics with underlying disease, they walk away from these clinics with the same disease.

In the most recent 2008 data on the IVF programs in the United States, published in 2010, we find that the incidence of endometriosis in those populations is reported to be 4.6% and ovarian dysfunction 6.7% [23]. However, in a NaProTECHNOLOGY-driven program, endometriosis is identified in 77.4%, target organ dysfunction in 68.2%, anatomic ovulation disorders in 56.5% and luteal phase deficiencies in 53.7%. The difference between the two approaches is because in the IVF program they are not looking for the underlying causes and in the NaProTECHNOLOGY program they are.

In Table 2, we have put the comparison of NaProTECHNOLOGY versus IVF side by side.

Table 2. Side-by-side comparison NaProTECHNOLOGY (NPT) vs. ART (IVF)

	NPT	ART
Diseases are identified	Yes	No
Diseases are treated	Yes	No
Foundation is laid for future success	Yes	No
More total pregnancies are achieved	Yes	No
Multiple pregnancy rate is low	Yes	No
Prematurity rate is low	Yes	No
No frozen embryos	Yes	No
Fertility-focused intercourse	Yes	No
Speed to pregnancy is greater*	-	Yes
Cycle-by-cycle pregnancy rate is greater*	-	Yes
Per woman pregnancy rate is higher	Yes	No
Built on foundation of destroying life	No	Yes
Most cost effective	Yes	No

*When successful, but overall much lower *per woman* success

With NaProTECHNOLOGY, diseases are identified and treated, the foundation is laid for future success, more total pregnancies are achieved, the multiple pregnancy rate is much lower (3.2% versus 31.9%), the prematurity rate is also lower and there are no frozen embryos. In addition, fertility-focused intercourse is a part of NaProTECHNOLOGY but is not seen with IVF and the *per-woman* pregnancy rate is higher. There are three things that IVF is associated with, and these include the speed to pregnancy itself is greater and the cycle-by-cycle pregnancy rate is greater. However, the overall *per-woman* pregnancy rate is higher with NaProTECHNOLOGY. In

addition, IVF is built on a foundation of destroying life whereas NaProTECHNOLOGY is built on a foundation of nurturing life. NPT is also more cost effective because it is looking for the underlying causes and the root causes of the infertility problem.

In conclusion, this has been a review of a new women's health science called NaProTECHNOLOGY which holds a lot of hope for approaching the conditions that women suffer from in the reproductive age group in a way which identifies the underlying causes, tackles an approach for treatment and generally exceeds success being seen with the current approaches. This is seen to be highly beneficial for women who select this approach to evaluation and treatment.

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