Preface to the Krantz Analysis of the Vipon Tampon

The following Clinical Safety and Efficacy Report on the Vipon was written in 2002 by Dr. Kermit E. Krantz. The report is well-written and cited, offering the first professional insights on the Vipon and its core technology; we have incorporated this technology into subsequent devices. Dr. Krantz neither published nor signed this report. Furthermore, he misstated or was given incorrect electrical data. This data has been corrected by Charles Tepper, who was an engineer on the Vipon project. The text has been notated as required with the explanations below. Dr. Krantz dedicated 31 years to the University of Kansas as Chairman of Obstetrics and Gynecology. A respected leader in the field, he passed away in 2007.

https://en.wikipedia.org/wiki/Kermit_E._Krantz

David Conroy
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N1 The number of women was omitted but cross-referenced in the High Jinks article.

N2 The work 'Ultrasonic' was removed as the frequency was not in the ultrasonic range.

N3 The frequency was misstated to be 1800 Hz.

N4 The battery voltage was misstated to be 2-volts

Investigation *in vivo* of the effect and safety of VIPON tampons.

Dr. Kermit E. Krantz

ABSTRACT:

Dysmenorrhea is the medical term for pain during menstruation. Menstrual cramps are thought to be the result of muscle spasm within the uterus. A woman's experience of dysmenorrhea is subjective---what might be mildly irritating for one woman, might be excruciating for another. However, based upon the reality of women's experience, the pain is real. A group of 8 [n1] women who experience severe dysmenorrhea were tested with VIPON TAMPONS to ascertain the safety and effectiveness of the device. Patients who employed the device found that it relieved all the pain associated with menses. The tampon unit was placed in the posterior fornix to achieve the greatest effect. The pain was relieved through the mechanism of disturbing or stimulating (to the point of anesthetizing) the conductivity of the afferent pain fibers primarily in the utero-sacral ligaments and the Frankenhaüser plexus. The [n2]effect of the VIPON unit is similar to that of TENS Units, uterosacral blocks which use lidocaine and other local anesthetics that have been employed to control labor pain and menstrual cramping.

INTRODUCTION:

Dysmenorrhea is a Greek term that means painful menstrual flow. Approximately 50% of all menstruating women experience appreciable pain at some time during their menstruation.[1] It is expensive too--- an estimated 600 million work hours are lost annually to this affliction[2] with an average loss of time of two or more work days per female employee.[3] Painful periods may be caused by a number of reasons, often a combination of factors.

Causes of pain during menstruation and ovulation include the following:

- **Tipped or retroverted uterus**. There are no actual collected statistics for the distribution condition, but it is often associated with Endometriosis.
- **Endometriosis** – The tissue lining the uterus – the endometrium – may grow outside the uterus causing pain during periods.[4] [5] [6]
- **Hormonal changes and imbalances** – for example a hormone produced by cells in the uterine lining called prostaglandin causes uterine contractions. Women with severe Dysmenorrhea have higher prostaglandin levels in their menstrual fluid than other women. [7]
- **Adenomyosis** – In this condition uterine tissue grows into the uterine wall – also associated with Endometriosis
- **Fibroids** – Non-malignant growths in the uterus can cause pain during periods. [8]

- **Polycystic Ovary Syndrome** – in this condition many cysts are formed in the ovaries which are triggered by abnormally high levels of androgens and insulin resistance---leading to diabetes and heart problems. While these women do not menstruate regularly, when they do menstruate, their cycles are usually quite painful. [9]
- **Pelvic inflammatory disease**. Because this disease is associated with a bacterial infection, all medical authorities would strongly recommend that tampons NEVER be used.

Menstrual cramps have been classified in the following way:

1. **Primary Spasmodic Dysmenorrhea –** with severe viselike pain, backache, tightening and pain sensations in the inner thighs, nausea, vomiting, diarrhea, constipation, faintness, dizziness, fatigue, headaches.
2. **Primary Congestive Dysmenorrhea –** with dull aching in low back and pelvis, bloating, weight gain, breast tenderness, headaches, irritability.
3. **Secondary Dysmenorrhea –** with pelvic and back pain, spotting, pain during or after sexual intercourse, fever, chills, pus-like vaginal discharge, urinary frequency, bowel changes.

Currently, the usual treatment for dysmenorrhea consists of medication. These medications range from over-the-counter (OTC) analgesics to strong prescription drugs. Some of these are aspirin, acetaminophen, ibuprofen, and naproxen sodium. Women also self-medicate with natural herbs, heating pads, and alcohol. Before 1960, when drugs failed, the surgical approach was used---the severing of the inferior hypogastric nerve plexus (presacral neurectomy).[10]

Currently, a more popular surgery (LUNA) for dysmenorrhea is employed which involves the interruption of the uterorsacral nerves. First described in 1899, Doyle studied the effects of a group of women who had this surgery in 1955 and reported that over 70% of patients had relief from pain.[11]

MATERIALS

The VIPON is a tampon with a motor unit within its confines, which vibrates at a nominal frequency of 125Hz. [n3] The battery unit (1.5 volt) [n4] is attached and lies exterior to the body. The tampon material is 100% organic cotton. The battery unit and wires are totally encased in CYCOLAC HP30 (manufactured by General Electric).

One hundred percent cotton in the tampons has been tested for TSST-1 production by Dr. Philip Tierno et al and shown not to amplify the production of TSST-1 as compared to tampons that are made of rayon of rayon/cotton blends.[12]

All lots of CYCOLAC resin have been subjected to the battery of biological tests specified by the United States Pharmacopoeia (USP) to judge the suitability of plastic material intended for use as containers or accessories for parenteral (within the human body) preparations. These resins have passed tests under FDA Tripartite Guidelines and ISO-10993-1 modified matrix for medical devices that include such biological tests as :
1.

Acute Systemic Toxicity test, 2. Intracutaneous Toxicity test, 3. Implantation test, 4. Cytotoxicity test, 5. Hemolysis test, 6. Ames Mutagenicity test, 7. Pyrogenicity test, 8. Sensitization test, and 9. Sub-chronic Toxicity test (14-day implantation test with Histopathology test). The vibration unit and wires will be covered by 100% organic cotton so the plastic will not make any direct contact with vaginal mucosa.

SUBJECTS

A relatively homogeneous group of women with severe and incapacitating dysmenorrhea were selected on the basis of the following criteria: documented absences from work or school; no improvement with at least two NSAIDS (Motrin, Anaprox, Ponstal or Naprosyn); reporting of dysmenorrhea for more than 5 years.

METHOD

The 8 [n1] women in the study came to the participating doctors' offices upon onset of menstruation and/or onset of dysmenorrhea. The tampon unit was placed in the posterior fornix so as to be located nearest the utero-sacral ligaments and the Frankenhaüser plexus. [13] [14] The VIPON was then activated. The women reported their sensations and reactions every 5 minutes for the next hour. They then left the doctor's office but continued to keep track of their symptoms and feelings for the next 10 hours. They were also asked to report on any outstanding symptoms or experiences relating to the use of the VIPON for that cycle.

RESULTS

All subjects reported a slight tingling sensation and then reported that their dysmenorrhea complaints of pain were eliminated within seconds of insertion. Any problems that they were experiencing at the time such as headaches, backaches, nausea were not affecting them significantly. Nor did they have these symptoms return for 6 to 10 hours after that initial treatment. None of them reported any unusual discomfort or irritation during the 10-hour period or afterwards. Since the initial study all have requested VIPON.

DISCUSSION

Research done in the 1930's involving anatomic dissection resulted in the knowledge of the pathways of the sympathetic and parasympathetic fibers to the cervix and uterus. Counseller[15] in his study made mention of the fact that the sympathetic fibers from T10 to L1 were contained within the inferior hypogastric nerve coursing along the vena cava and sacrum to enter the uterus through the uterosacral ligaments. It was also noted that the parasympathetic fibers from S1 to S4 traveled within the nerve erigentes, emerging in the lateral pelvis and forming ganglia lateral to the cervix (Frankenhaüser's ganglion).[16]

And Meigs noted in his study that an epidural anesthetic at T10-11 prevented the pain from endometrial curettage but not that from cervical dilatation.[17]

Further research revealed four studies undertaken with TENS units for the treatment of dysmenorrhea which bears a similarity to the VIPON due to the application of a device that uses some electrical mechanism to disrupt the parasympathetic fibers to the uterus and cervix.[18] [19] [20] [21] The following results were found: 42 to 60% of patients had at least moderate relief; less NSAID was needed in one study; TENS worked faster than naproxen in one study.

A 1996 Case Report[22] of a woman suffering from severe dysmenorrhea describes treatment with microwave diathermy (utilizing high-frequency electromagnetic waves to heat deep tissues) with frequencies used 2,450 MHz. This process was successful. The exposure of 2,450 MHz is safe. According to the authors, it raises tissue temperature, increases extensibility of deep collagen tissue, relieves deep pain and muscle spasm, increases blood flow and assists in the resolution of inflammation. This frequency is also too fast to depolarize nerve of muscle membranes preventing muscle contraction. The authors speculate that the absence of muscle contraction is beneficial because it stops the severe cramping. The treatment of this particular patient resulted in permanent changes and alleviation of the dysmenorrhea. Since the study showed this microwave diathermy at 2450 MHz to be safe, obviously, the VIPON, at a much lower frequency (125 Hz) [n3] would be safe.

Other studies have shown the effectiveness and safety of vibratory stimulation.

1. The human threshold of sensation is at 50Hz with an absolute threshold of sensation at 1.5 volt. This is due to electrostatic forces in the skin caused by the electric field in a poorly conducting stratum corneum.[23] VIPON is inserted into an area where there is no sensing mechanism.
2. A 1992 study demonstrated that vibration reduced pain by stimulating the large myelinated fibres.[24]
3. By applying vibratory stimulation to patients suffering from pain, it is possible to set up an inhibitory control on the pain pathways, which is based on the activation of large-sized afferent fibres. The exact mechanisms responsible for these analgesic effects still remain to be determined, however. An investigation was done to see whether or not the analgesic effects were accompanied by a decrease in the CSF substance P-like immunoreactivity levels (SPLI) in the test subjects. The results showed that the SPLI levels decreased, as a result of the vibration, but the decrease seemed to be too slight to account for the pain relief obtained.[25]
4. A study of the value of vaginal electrostimulation for genuine stress incontinence was evaluated over a period of 15 months. There was a subjective improvement. There were no side effects observed with electrostimulator use. The conclusion was that vaginal electrostimulation seems to be a simple and well-tolerated means of managing genuine stress incontinence in a selected group of women.[26]

SAFETY

Steven Kilgore approached me in 1998 about using the VIPON on women. Mr. Kilgore advised me of the experience of women who had used it. I received several VIPON tampons from him.

I held the VIPON in my hand to study it. The VIPON (with the micro-unit inside) weighed about 2 grams. The micro-unit was completely encased in cotton. The VIPON was the length and width of any other tampon (between a regular size and the super-size). I activated the power source and held the VIPON in my hand. It produced a low frequency. The VIPON did not move my hand. I could feel the low frequency being emitted. The vagina itself is a negative space. It contains the VIPON and does not allow for gross movement.

I studied the matter before using it on subjects. Prior studies using frequencies showed that there is no danger. The study by Vance applied microwaves at over 2,450 MHz to the vagina to alleviate dysmenorrhea. The study concluded that there was no harm in using 2,450 MHz in and around the vagina. By comparison, the VIPON elaborates 125 [n3] hertz, which is a fraction of the frequency involved in the Vance study.

Prior studies using TENS devices for dysmenorrhea showed that there was no harm. These studies used electrodes to send an electrical charge into the vagina. TENS was effective in alleviating the pain of dysmenorrhea, and was found to be safe.

Prior studies on other parts of the body had shown that frequencies much higher than that produced by the VIPON are safe.

Medesign, a German company sells a product known as Voltrain that uses electrodes inserted in the vagina to send an electrical charge through the vagina for therapeutic purposes. This product apparently is safe, as we have heard no reports of problems and, from prior studies and experience, we know that electrical stimulation in the vagina is not dangerous at frequencies of 2,450 MHz and below.

In addition to the studies, we know that TENS devices are used by doctors in the United States to alleviate the pain of dysmenorrhea, and that these devises are safe and effective.

Genital vibrators that are commonly used by women are many times greater in mass. Because there mass is much greater, and they use much electrical power, they have a much more intense vibration. There is no reason to believe these are unsafe. They are approved for use by the FDA and can be sold over the counter.

The FDA approves therapeutic vibrators, genital vibrators and diathermy devises that use more voltage and produce higher frequencies than the Vipon. It stands to reason, that if devices that can be used inside the vagina that produce a higher frequency and

more voltage are already approved by the FDA as safe, the Vipon should also be considered safe. These other devices are safe.

TENS devices are also approved by the FDA. TENS devices send an electric current through the body. A person attaches the unit to the body such that the electric charge can flow through the body, back to the TENS unit. These are safe. By comparison, the VIPON emits low level frequencies that are just significant enough to affect the long fibers of the nervous system on a temporary basis, which causes the nerve receptors to not send the pain stimuli to the brain (in other words, under the gate way theory, the gate closes). The VIPON is as safe or safer than a TENS unit.

The VIPON is powered by a 1.5 volt battery. A 1.5 volt battery will not harm anyone. The human body itself has a charge that may be greater than 1.5 volts. You can take the human body, unadorned, and through the use of a spectrum analyzer, get a reading of over 1.5 volts. You can put a 1.5 volt battery on your tongue and not feel a charge. Static electricity that is produced by shuffling your feet on a carpet is around 10 to 15 volts. Obviously, there is no danger at all that the VIPON will cause harm through the use of electricity.

The VIPON uses tripartite plastic for the micro-unit and related parts. As far as TSST-1 is concerned, tripartite plastic is inert. It does nothing to increase TSST-1. The plastic is similar to elastomeric polymer, which has been tested and reported to not promote production of TSST-1. General Electric reports that the tripartite plastic that Another Way Products is committed to use is tested and is approved by the FDA to be used in the human body.

The subjects were familiar with tampons and needed no particular advise on using the product. They inserted the VIPON as any other tampon. They had no problem, as the VIPON is the same size as any other tampon that is on the market. The subjects reported no problems: that is, no increase in pain, no increase in bloating feeling, no increase in discomfort, no increase in back pain, no increase in headaches, no increase in other symptoms. None of the subjects had any symptoms of Toxic Shock at any time after insertion or after removal.

In fact, the subjects reported decrease and absence of pain and other dysmenorrhea complaints.

The subjects removed the VIPON after a few hours. The VIPONs are not to be re-used. (Another Way Products advises that the VIPON in normal use is to be discarded like any other tampon.) I talked to the subjects and determined from our discussions and my observations that none of them had any symptoms of Toxic Shock or of any other health problem. I determined also from our discussions and my observations that there was no irritation of any kind.

From my own experience of over 55 years in gynecology, from studies I reviewed or of which I was aware, from my study of the VIPON and from my observations of the patients, I conclude that there is no danger in women using the VIPON.

CONCLUSIONS

In observations with VIPON, vibrating at the frequency of 125 Hz [n3] does not stop muscle contraction, but does affect the afferent sympathetic and parasympathetic fibers to the cervix and uterus. The rate of vibration is a fraction of most electronic devices cited in the studies. It's effect is measured in hours, not days, months or permanence. In terms of difficulty of use it is totally safe for OTC (over-the-counter) use and does not require professional supervision. And, unlike drugs or high-powered equipment, there is no concern about over-use or over-exposure.

For reasons that are not clear, a percentage of women with primary dysmenorrhea do not respond to treatment with NSAIDs or oral contraceptives. In addition, some women have contraindications to these medications. Consequently, researchers have investigated some of the alternative treatments described above. Trials of these methods have been footnoted. Women should be encouraged to try any safe option and to feel comfortable discussing these options with their physicians. Americans are increasingly using natural therapies and not discussing them with their primary care physicians as shown by this 1993 survey.[27]

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[4] According to a handbook from the International Pelvic Pain Society http://www.pelvicpain.org written by Dr. Michael Wenof and Dr. C Paul Perry. This disease affects 15% of women.

[5] According to Department of Health & Human Services, Public Health Service, Centers for Disease Control, National Center for Health Statistics, Series 13, No. 92, 1987, 10% of women were affected at that time.

[6] According to a report circulated to the members of EDANA (the European Hygiene Absorbent Products Industry Association) in 1998, an estimate of the frequency of Endometriosis would be closer to 25%.

[7] There are no official statistics on the frequency of this condition, but this disease is associated with Endometriosis, Adenomyosis, Fibroids, and Polycystic Ovary Syndrome.

[8] According to **The Center for Uterine Fibroids, Brigham and Women's Hospital in Boston, Massachusetts,** http://www.fibroids.net/html/diagnosis.htm, between 20% and 80% of women have fibroid-related symptoms which include abnormal uterine bleeding and pelvic pressure (or cramps).

[9] According to **Health News** from the publishers of the **New England Journal of Medicine,** http://onhealth.com/ch1/in-depth/item/item.4717_1_1.asp. Polycystic Ovary Syndrome affects 6% of all women.

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