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REVIEW
OF THE REPORT

Survey to Determine the Effect of the Static Magnetic Device, *LadyCare*, on Menopause Symptoms

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1. OVERVIEW

1.1 *Menopause as a medical problem*

Menopause can be an extremely challenging time for all female individuals. At a given point of her life, any woman reaches the physiological state that arises from the cessation of ovarian function and ends her reproductive capacity. It is know to occur between the ages of 47 and 55. The price paid for this transition can be high with a variety of symptoms, very well explained in the report. The menopause is can be associated with personal discomfort and decreased quality of life.

1.2 *Hormonal problem?*

It is the prevalent opinion that menopause is linked to a dramatic change in the level of female hormones. Contemporary medicine prescribes women in the menopause "hormone replacement therapy". However, there is no knowledge what the oestrogen level before the menopause. It is something of guessing game as to the level of hormone that needs to be replaced. My own opinion is that at the age of 45-50 each female individual should be asked to get screening of her hormone levels. This would provide a baseline for further hormonal therapy.

1.3 *Medical help*

It should be recognized that the current state of western medicine's help for menopause "victims" is insufficient and basically loads the body of women with drugs in an attempt to reduce the manifestation of the symptoms, but without helping the subtle physiology of the woman. The adverse effects can be significant, but in most cases are neglected because of the intention to treat the manifestation of the menopause.

1.4 *Could magnetotherapy be an alternative?*

During the last two decades western medicine has slowly begun to acknowledge and accept some alternative and complimentary methods for treatment of a variety of problems. In the USA the National Institute of Health has created a National Center of Alternative and Complimentary Medicine. One of the aims of this Center is to promote, fund and supervise research in Bioelectromagnetics. Today, magnetic fields are

recognized as a plausible gentle, non-invasive, safe and inexpensive method for treatment of various medical problems. It should be noted that in most cases people turn to magnetic fields after conventional pharmaceutics-based medicine had failed.

Even scientists and medical practitioners who are in favour of magnetotherapy affirm that this modality should be considered as a complimentary approach. We should not forget that the main goal of medicine is to maintain the proper physiological status of the organism and to help the human body to recover when the balance is violated.

In 2004 I co-edited (together with Dr. Paul Rosch, President of the American Institute of Stress) the book BIOELECTROMAGNETIC MEDICINE. In this 50 chapter, 850-page book, with 86 authors from Europe, North America and Asia the application of various magnetic and electromagnetic fields for treatment of different diseases and injuries is discussed. Starting from bone non-union and wound healing, through pain relief and cancer treatment, to Parkinson's and Alzheimer's disease, the biophysical and physiological background and clinical utilisation of magnetic fields have been discussed. Unfortunately, we failed to look at the possibility of using magnetic fields for treatment of menopause symptoms.

Dr. Nyjon Eccles has undertaken to be a pioneer in this area. In recent years he has been using permanent magnets for treatment of several medical problems, including menopause symptoms. He has combined basic science and clinical application and already has a paper published on using permanent magnets to reduce dysmenorrhoea in women. The present report summarizes several years of experience and more specifically, a large randomised survey using a magnetic field to relieve symptoms of menopause.

2. THE REPORT

2.1 The background

This 88-page report consists of a 35-page summary of the study, 3 pages of references and 50 pages of raw data, located as Appendices.

The main objective of the study is to assess the effectiveness of the LadyCare device (that generates magnetic field) in relief of the menopause symptoms. As shown on Table 1, p.3, the study analyses 23 menopause symptoms, which showed that Dr. Eccles looked at the complex manifestation and treatment of menopause symptoms.

Following this definition, the author explains very well the physics of LadyCare device and the way of positioning of the device inside the patient's underwear. The main component of the LadyCare device is a neodymium-boron magnet, originally designed as a magnet within an application frame. The author correctly defined the surface magnetic field induction as strong as 2700 Gauss. It should be understand that this field strength is transferred to the patient's skin, but the field strength diminishes within the body according to the distance from the magnet surface. Dr. Eccles chose to characterise the magnet in LadyCare device by the surface field strength.

The statistical analysis of the data includes well-accepted Biostatistical methods, such as ANOVA, Friedman analysis of variance, Mann-Whitney two-sample test, and Wilcoxon match-pair signed rank test.

2.2 Results

2.2.1 Description of the sample

The histogram on p. 5 demonstrates the age of the cohort of patients with normal curve superimposed. The normal distribution justifies the author's use of the above-mentioned statistical methods. The duration of the menopause is obviously not normally distributed and exponentially decreases within 10 years. One typographical mistake is seen here in that at the top of p.6 the author speaks about duration in months, but the figure shows duration in years. I am inclined to consider the statement in the text as simple error.

2.2.2 Benefit of use of LadyCare device

On p.7 data are presented for the benefit of the use of LadyCare in several ways. The chart indicates that the hot flashes decreased from 3.10±0.07 to 2.3±0.07 (after 1 month of use), to 2.0±0.07 (after 2 months of use), to 1.8±0.06 (after 3 months of use). At the same time it is shown that while after 1 month of use 43% of woman did not see result, this percentage decreases to 24% after 2 months of use.

Two conclusions could be drawn here:

- To observe the effect one needs to wear the LadyCare device for longer period of time
- The effect is long lasting.

Similar patterns are seen with irritability (p.9). From 3.2±0.06 the irritability decreases to 2.4±0.06 (after 1 month of use), to 2.0±0.06ter 2 months) and to 1.8±0.05 (after 3 months of use). The percentage of reporting "no effect" falls from 39% (after 1 month of use) to 23% (after 3 months of use)

For mood swings (p.10) the improvement from 3.0±0.06 is shown to 2.2±0.06 (after 1 month), to 1.9±0.06 (after 2 months), to 1.6±0.6 (after 3 months). Again from 41% non-seeing effect after 1 month, this number is down to 23% (after 3 months)

Anxiety level (p.12) went down from 2.9±0.07 to 2.2±0.06 (after 1 month), to 1.9±0.06 (after 2 months) and to 1.7±0.06 (after 3 months). "No effect" falls down from 48% after 1 month of use to 26% after 3 month of use

For fatigue (p.13) the improvement from 3.5±0.06 to 2.8±0.06 (after 1 month of use), to 2.5±0.06 (after 2 months), and to 2.2±0.06 (after 3 months of use). "No response" went down from 46% (after 1 month) and to 25% (after 3 months).

Vaginal dryness (p.15) went down from 2.0±0.07 to 1.7±0.07 (after 1 month), to 1.5±0.06 (after 2 months) to 1.3±0.06 (after 3 months) with a significantly small reduction of "no effect" from 67% to 54% after 3 months of use.

Serious effects were observed in sleeping troubles: from 3.7±0.06 these troubles decreased to 2.8±0.07 (after 1 month), to 2.4±0.07 (after 2 months) to 2.2±0.07 (after 3 months). "No effect" falls from 37% after 1 month to 19% after 3 months (p.17).

"Itchy, crawly skin" complaints fall from 1.7±0.07 to 1.2±0.06 (after 1 month), to 1.0±0.06 (after 3 months), to 0.8±0.05 (after 3 months) while "no response" changes were from 58% to 44%. (p.19)

"Sudden weight gain" decreases from 2.4±0.08 to 2.1±0.08 (after 1 month), to 1.8±0.07 (after 2 months) and to 1.6±0.07 (after 3 months) with " no response" decreasing from 70% (after 1 month) to 43% (after 3 months) (p.20)

Very significant improvement was registered for indigestion/gas: from 2.6±0.07 to 2.1±0.07 (after 1 month) and to 0.9±0.05 (both after 2 and 3 months of use). "No

response" also significantly dropped - from 54% after 1 month of use to 21% after 3 months in use. (p.22)

Muscle' pain and soreness decreases from 2.9±0.07 to 2.5±0.07 (after 1 month), to 2.1±0.07 (after 2 months) and to 1.9±0.07 (after 3 months) with "no response" down from 61% to 38% from 1 to 3 months of use of LadyCare. (p.23)

Breast soreness/tenderness improves from 2.0±0.07 to half of this value: 1.0±0.05 after 3 months of use while "no response" diminished from 53% to 38%. (p.24).

The same patterns could be seen also for other measured parameters – bladder infection, urinary incontinence, inability to concentrate, feelings of doom/dread, lapses of memory, increased muscle tension, irregular vaginal bleeding, and loss of libido.

Probably the smallest changes were recorded for painful intercourse and hair loss. The small improvement reported by patients was also accompanied with a small change in "no response" from 1 to 3 months use of LadyCare.

It is important that all reported values are very coherent. The largest SEM (standard error of means) is 0.08 which in most cases is in the range of 4-5% of the mean values.

2.2.3 Summary of findings

Women reported that the following symptoms were reduced by 50 to 67% across the group: Anxiety, Feelings of Doom, Sudden weight gain, Increased Muscle tension, Mood swings, Marked Fatigue, Vaginal Dryness, Trouble Sleeping, Urinary Incontinence, Breast tenderness/soreness.

Women reported that the following symptoms were reduced by 33% across the group:

Hot flashes, Irritability, Loss of Libido/Sex drive, Inability to concentrate, Painful sore muscles, Disturbing lapses of memory.

3. My comments on findings

This is remarkably large both in terms of number of investigated subjects (508) and by the investigated parameters (23). I would like to highlight the achievement of this study:

- Large number of patients
- Comprehensive analysis of the menopause symptoms
- Application of physical modality (permanent magnets)
- Systematic follow-up with collection of data after 1, 2, and 3 months of wearing the LadyCare devices
- Comprehensive statistical analysis

It is also remarkable that except several symptoms (in which less than 20 patients were lost), all 508 patients were kept into the study. Only those who conducted large clinical study might evaluate the importance of the work reported by Dr. Eccles. I personally have not seen so large study with so small a number of drops-out. The six-point scale, implemented in this study, as in any survey study, might be questioned, but the large number of participants allows for objectivity and statistical significance of data.

I disagree with the author's statement that stomach problems (bloating and gas) were reduced 100% - at least the data shown does not support such statement.

However, for 10 of the symptoms the improvement was in the range of 50-67%, with improvement with more than 33% for another 6 symptoms. These results show that

LadyCare seems to have been remarkably helpful in treatment of this difficult symptomatic problem. We frequently underestimate the statistical data, not seeing the real people with real problems behind the numbers. Ask the person who has pain or discomfort if reduction with 1/3 is of importance for him/her. Even the NIH recognises a study to be effective if the improvement is not less than 20%. In the case of LadyCare nearly all studied symptoms satisfy this criteria.

Let me focus now on the magnetic field issue. This large, comprehensive study definitely demonstrates the health benefit of using permanent magnets for relief of menopause symptoms. Dr. Eccles deserves compliments for selecting an appropriate magnetic field delivering device and for consistent evaluation of the efficacy of the use of LadyCare device. One thing that is missing in the report is the information for how many hours a day the device was applied. I guess that total use was around 23 hours/day.

It is surprising to me that the effect within the first month was smaller than within months 2 and 3. On the other hand, the findings suggest that the LadyCare device has long-lasting effect. I am sure that Dr. Eccles does not need to be prompted on the suggestion to have a follow-up for a small cohort of patients who wear (or not) the LadyCare device after 6 or/and 12 months. This would confirm or reject my statement for long-lasting effect of the magnetic stimulation.

I took the liberty to re-evaluate the mean values for the 23 symptoms as well as for “no effect statement”. My computation is shown below

Group	Mean value	Improvement [%]
Starting scores	2.45	---
After 1 month	1.94	27%
After 2 months	1.61	34%
After 3 months	1.43	42%

Group	No response [%]	Improvement
1 month	58%	
3 months	38%	34%

This summary computation confirms that the overall improvement for the whole cohort enrolled in the study: one month wearing of LadyCare leads to 27% relief, followed by 34% improvement after 2 months and 42% after 3 months. At the same time, the average “no response” after 1 month wearing of LadyCare was 58% which is reduced to 38% after 3 months – this is 34% better response to the applied magnetic field.

It is difficult to convince a patient to wear a device which did not show efficacy for 1 or 2 months. The advantage here is that LadyCare is lightweight, easy to apply to the underwear, non-invasive and an inexpensive device. Unlike medication, magnets do

not seem to cause any adverse effects. Therefore patients should be encouraged to apply the device for a longer period of time, even the effect is not immediately seen.

4. **Some general considerations about analgesic effects of magnetic fields**

Reports for relief of various types of pain can be found in the bioelectromagnetic publications in the last decades. Furthermore, evidence for the use of magnets for pain relief may be found in sources from Ancient Greece, China and India. The famous nature philosopher William Gilbert, the personal physician to the Queen of England, in 1600 published a book in which he described the healing power of permanent magnets.

The following is a summary of the most recent publications on the therapeutic use of permanent magnets. Despite the resistance of the mainstream medicine and the resistance of pharmaceutically based medicine to accept magnetotherapy, millions of people around the world benefit from the revival of this invention of the Ancient civilizations. During the last decade, there has been an explosion of interest of the general public for the use of permanent magnets for pain and discomfort relief. This has turned into a multimillion business. As always, when business steps in, the science is often ignored. Hundreds of small companies offer magnets for pain relief, even without any background of the biological and clinical effects of magnetic fields. For this reason in many cases the effect is absent or far from that promised by the manufacturer.

Obviously, this is not the case with LadyCare. The utilisation of this convenient to wear, lightweight, inexpensive device demonstrates the potential benefit for women who are suffering menopause symptoms. I believe that the complexity of the study, the analysis of data provide Science and Medicine with a significant advance in understanding the potential of this device manufactured and distributed by Magnopulse Ltd.

It should be emphasized that in principle magnets do not and can not heal, but there is much published evidence that they can relief pain and discomfort. **Magnets are only a tool that delivers to the human body magnetic fields.** It is not the purpose of this review to discuss the mechanisms of interactions of magnetic fields with living tissues.

As it was pointed, “not all magnets are equal”. The magnetic field delivered by a given magnet is a complicated function of magnetization, volume and shape of the permanent magnet. In addition, the depth of penetration of the magnetic field strongly depends not only on the distance from the surface of the magnet, but also on the type of magnet in use. **It should be remembered that the most important factor is the magnetic field strength at the target tissue.** (Markov, 2004, 2006)

Papers discussing the benefit of the use of magnetic fields may be found elsewhere. I strongly recommend two papers that appeared in the 2004 book BIOELECTROMAGNETIC MEDICINE. One, written by myself, is on pain relief; the other, written by Agatha Colbert summarizes the benefit shown in 22 papers that reported (by the summer of 2002) the use of permanent magnets for therapy. (Markov, 2004; Colbert, 2004)

In a separate publication a team that includes, among others Colbert and myself, reported an overall 33% improvement in 7 of 8 studied parameters of patients suffering from fibromyalgia. (Colbert et al., 1999).

Later on, the application of permanent magnets for pain relief in plastics and cosmetic surgery was reported by Man et al.,1999.

Dr. Eccles himself has several publications that demonstrate significant benefit that occurs in pain relief and wound healing, some of them cited in the report under review. I should specifically emphasize his critical review of randomized controlled trials of static magnetic field for pain relief (Eccles, 2005).

Recent advances in the therapy that utilizes permanent magnets are summarized in the plenary lecture given at the Fourth International Workshop "Biological Effects of EMF" in Crete, October 2006 (Markov, 2006) and in the review paper that just has been published (Markov, 2007).

Very plausible information can be found in the review paper published recently by McKay et al, 2007. A team has written this paper from the laboratory of Frank Prato (London, Canada) – a laboratory that has made significant contributions in studying the mechanisms of analgesic effects of magnetic fields.

Finally, I recommend the paper which is to appear shortly in Evidence Based Complimentary and Alternative Medicine. The paper provides a critical review of reported treatment parameters in 56 studies that utilized permanent magnets. (Colbert et al., 2007)

In conclusion:

The report of Dr. Eccles is not simply a survey of the effects of the static magnetic field delivered by the LadyCare device on menopause symptoms. It makes a fundamental contribution to knowledge and is a well designed and executed study of the effects of a magnetic field on 23 menopause symptoms. As stated above, there has not been another study reporting this finding in the available literature. Also worth mentioning is the fact that Dr. Eccles did not do a snapshot of the effects, but assessed the effects over 3-months treatment and follow-up, reporting every detail in the collection and analysis of the data.

I strongly recommend that Dr. Eccles make this report public knowledge by publishing it in an appropriate journal. This is really a pioneering study and not a pilot study. The information included in the report has extremely important scientific and clinical value.

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