PAIN EASE MICROCURRENT THERAPY TREATMENT IN SUBJECTS WITH PERIOD PAIN (DYSMENORRHOEA)

A PILOT STUDY

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Objective: To determine if the pain, mood alteration, sleep disturbance, energy and ability to perform every day tasks associated with the onset of period pain can improved with the use of Pain Ease microcurrent patches.

Setting: Patients' homes.

Patients: 57 female subjects diagnosed with period pain.

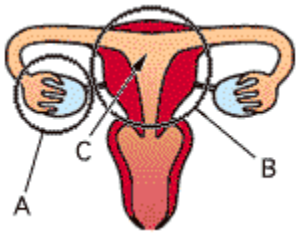
Outcome Measures Visual Analog Scales (VAS) for period pain, mood, sleep, ability to perform every day tasks, and energy levels.

Pain Ease Patches: Supplied by Lifes2Good

INTRODUCTION

Painful period or dysmennorrhoea taken from the Greek word 'difficult monthly flow' is one of the most common gynaecological complaints affects up to 80% of UK women at some point in their life, of which 20% experience pain severe enough to disrupt their lives. (Harris Research September 1995 – August 1996). In 40% of women, period pain is accompanied by premenstrual symptoms, such as bloating, tender breasts, a bloated stomach, lack of concentration, mood swings and tiredness.

The pain is associated with uterine contractions and ischaemia resulting from the production of inflammatory prostaglandins and the reduction in blood flow during uterine contractions. These uterine contractions are more frequent and stronger in sufferers of painful periods than in women who do not report period pain.



A – Ovary and fallopian tube

B – Uterus

C – Prostaglandins release by the uterine muscle

Elevated levels of leukterienes (substances that are similar to prostaglandins) and vasopressin have also been found in the endometrium of women with painful periods, however the primary stimulus for excessive production remains unknown. This new information has led to a more scientific approach to management so that pharmaceutical agents such as non-steroidal anti-inflammatories (NSAIDS) such as ibuprofen, diclofenac, naproxen and mefenamic acid are now the mainstay of treatment. Recommended complementary therapy treatments include

- First and foremost, stopping or cutting down smoking. Smoking is thought to increase the incidence of period pain by reducing the supply of oxygen to the pelvic area.
- Reducing alcohol consumption
- Eating high fibre foods, and plenty of salads and vegetables
- Eat chicken and fish instead of red meat
- Cutting down on sugary foods, chocolate, cakes and biscuits
- Reducing salt intake
- Choosing pure fruit juices or mineral water rather than sugary drinks
- Taking a supplement containing gamma linolenic acid (GLA) such as evening primrose oil or starflower oil, or vitamin B6 to maintain hormonal balance

Microcurrent Therapy

Microcurrent therapy (MCT) represents the latest, state-of-art medical advancement in non-invasive pain management. Developed as a superior, safer alternative to the TEN's machines it embraces over 50 years of clinical research which reveals that the process of tissue regeneration is orchestrated by the flow of minute intercellular electrical currents and that low ampere currents (used in MCT) not high ampere currents (used in TEN's) can mimic

and augment this process.

TEN'S VS MCT

Since their introduction in the 1970's TEN's technology has helped millions of people worldwide to manage their pain better, but as most TEN's users have discovered it rarely, if ever fully eliminates pain. Microcurrent technology the successor to TEN's was developed over 10 years ago in direct response to this problem. The following table highlights the key differences between TEN's and MCT.

	TEN's	**MCT**
Strength of Current	Uses milliamps	Uses microamps (1000 times weaker than TEN's)
Pain Relief	Blocks transmission of pain carrying C nerve fibres	Stimulates the regeneration of damaged tissue
Effectiveness	Effective in about 40 to 50% of cases	Preliminary observational data reveals it be effective in about 85 % of cases
Ease of Application	Requires co-ordination and dexterity to adjust dials.	Involves placing patches either side of treatment area
Side Effects	Some evidence that the relatively high output may cause cell electrolysis	Might cause a little redness where electrode patches were placed, disappears after 10 minutes
	Causes discomfort in about one third of users	No discomfort
Sensation	Causes mild tingling to throbbing	Below sensory threshold
Post Treatment	Once switched off, there are no residual benefits	Bioelectrical changes continue even after the MCT treatment stopped

BIOELECTRICITY – THE BODY'S HEALING CURRENTS

Studies dating back to the 1960's have shown that the process of healing, growth, and regeneration in all living organisms is mediated by the flow of endogenous electrical current and that this "current of injury" occurs in the pico (trillionths) and nano (billionths) of an ampere range (1). Becker (1985) has shown that trauma affects the electrical potential of cells in damaged tissues and in doing so creates an area of much higher resistance than that of the surrounding tissue. Basic physic laws dictate that electricity tends to flow towards the path of least resistance. Therefore endogenous bioelectricity avoids areas of high resistance and takes the easiest path, generally around the

injury. The decreased electrical flow through the injured area decreases the cellular capacitance, resulting in a reduction in blood flow and an impairment of the healing process. (Windsor, 1993)

BIOELECTRICAL EFFECTS OF MCT

Microcurrent devices deliver exogenous negative microcurrents (millionths of an amp) to the injured site to augment the flow of endogenous current. In doing so it rapidly restores the natural electrical balance of every injured cell, re-charging them, just as a weak battery is re-charged. The resistance of the injured tissue is then reduced allowing bioelectricity to enter the area, thereby triggering the body's own natural biochemical healing processes resulting in the restoration of intracellular fluid levels, replenishment of electrolyte levels, the removal of toxins and re-establishment of homeostasis.

PHYSIOLOGICAL EFFECTS OF MCT

Studies have shown that microcurrent stimulation increases adenosine triphosphate (ATP) generation by almost 500%. This is crucial to the restoration of cellular function. Increasing the level of current to milliampere levels (as used by TENs) actually decreases ATP concentrations. Microcurrent therapy has also been shown to enhance amino acid transport and protein synthesis in the treated area to between 30 and 40% above controls and increase capillary perfusion and capillary proliferation by as much as 300%.

Although, to date, the clinical literature on therapy using microcurrent therapy is sparse, there is compelling evidence that microcurrent therapy has physiologically relevant biological effects on the human organism

In light of this background information on microcurrent therapy, and the fact that pharmaceutical management strategies for treating patients with period pain have limited success and some associated adverse effects, this study was designed to investigate the potential benefits of a microcurrent patches for reducing pain and improving wellbeing in this patient population.

Inclusion/exclusion criteria

Subjects were enrolled in the study if they had period pain for more than 6 months and had no contraindications to the use of microcurrent therapy – this includes having a pacemaker, pregnancy or the use of nicotine patches.

Subjects must agree to start no new pain medications, or additional pain management modalities during the 4-week trial period.

Study participants are allowed to continue taking current medications or maintain therapies such as physical therapy, acupuncture, chiropractic or magnet therapy, if they had been taking the medications or engaged in the specific therapeutic modality for a minimum of four previous weeks.

Research design

At baseline all subjects were required to fill in a one page questionnaire that assessed their suitability to enter the pilot study, capture basic information about alcohol and caffeine consumption, smoking habits and current prescribed and non-prescribed medication and record a baseline score for impact of period pain on lifestyle and well-being.

Eligible subjects were asked to then fill in second questionnaire, four weeks after starting Pain Ease, recording on a visual analog scales their improvement for period pain, mood, sleep, ability to perform every day tasks and energy levels.

Therapeutic Intervention

Subjects were asked to place both patches just above the pelvis, starting one day prior to the usual onset of period pain. These were then left in place for a maximum of 4 days total.

Outcome measures.

The primary outcome measure was related to the improvement in period pain. The secondary outcome variables were mood improvement, sleep improvement, improvement in every day tasks and improvements in energy.

Visual Analog Scales (VAS)

Subjects are requested to complete five VAS for improvement in period pain, mood improvement, sleep improvement, improvement in every day tasks and improvements in energy, placing a circle around the score that best represents their improvement. An example is provided below

0__1__2__3__4__5__6__7__8__9__10

No improvement Dramatic improvement

Additional Comments

In addition to completing VAS after 4 weeks, subjects were asked whether they would continue using pain ease patches, whether they would like to see pain ease available on the NHS and for any other comments.

RESULTS

Of the 100 subjects that agreed to take part in the study, the following results relate to the first 58 responses received. Reponses were recorded as an improvement if scored 2 or more and a dramatic improvement if scored 8 or above.

IMPROVEMENT IN PERIOD PAIN

76 % of subjects said that their period pain had improved
22 % of subjects said that their period pain had improved dramatically

IMPROVEMENT IN MOOD

72 % of subjects said that there mood had improved
19 % of subjects said that there mood had improved dramatically

IMPROVEMENT IN SLEEP

72 % of subjects said that their mood had improved
31 % of subjects said that their mood had improved dramatically

IMPROVEMENT IN ABILITY TO CARRY OUT EVERYDAY TASKS

78 % of subjects said that their ability to carry out every day tasks had improved
22 % of subjects said that their ability to carry out every day tasks had improved dramatically

IMPROVEMENT IN ENERGY

78 % of subjects said that their energy had improved
31 % of subjects said that their energy had improved dramatically

INTENTION TO CONTINUE USING PAIN EASE

81 % of subjects said they would continue to use pain ease

REQUEST FOR PAIN EASE TO BE AVAILABLE ON THE NHS

81 % of subjects said they would like pain ease to be available on the NHS

CONCLUSION

Pain Ease is a powerful and effective treatment for period pain sufferers. Over 76% of users benefited from not only improved pain control, but between 72 and 78% reported an improvement in sleep, energy, ability to carry our every day tasks and mood. The design of the trial unfortunately was unable to convey the true impact that pain ease had on a number of the trial participants. Numerous and authentic personal testimonials have described in detail the effect it has on their lives, are available to anyone who so wishes to see them. For those who did not respond to Pain Ease, subsequent phone calls and follow up revealed that many had incorrectly placed the patches, it is reasonable to expect that with proper placement a higher success rate would be indicated.

In view of the extremely positive preliminary data, I recommend a much larger randomized double blind controlled trial in conjunction with a university to capture statistically significant data on Pain Ease's effectiveness on the management of period pain.