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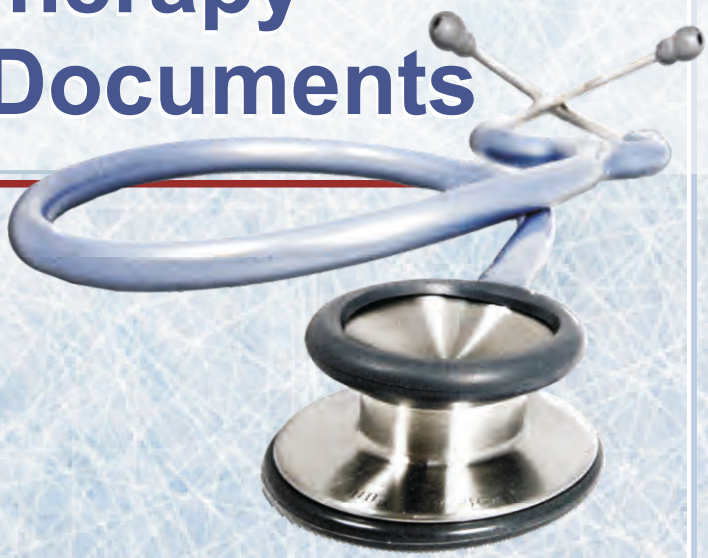

A·P·S Therapy

APS Therapy
Research Documents

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A·P·S Therapy

Clinical Evaluation
of the
APS Device

Conducted by:

Dr. Piet Botes
(M.B.,Ch.B.,F.R.N.Z.C.G.P.)
New Lynn
Auckland
New Zealand

May - August 1998

THE DOCTORS

Clinical Evaluation Report

Date Started: 20 May 1998
Date Ended: 20 August 1998
Name of Clinic: The Doctors (New Lynn)

My colleagues and I have used the APS device in our clinic for over four months. During the last three months we undertook a clinical evaluation on behalf of APS Technologies Ltd. 38 patients were treated for a range of musculosketal pain conditions, particularly those affecting the lower back. Three of the participants presented with slow-healing wounds.

The APS device was the sole form of treatment, although some participants were previously prescribed NSAIDs. Pads were placed over the affected anatomical areas in accordance with the manufacturers guidelines and the current increased to the maximum tolerable by the patient (whilst remaining comfortable).

The efficacy was generally good, especially for conditions relating to the lumbar/sacroiliac region. Not all participants responded immediately to treatment but the success rate was relatively high. Patients generally found the treatment beneficial although some complained of minor skin irritations when the current was maintained at excessive levels. Overall patient opinion was very positive.

In addition to pain relief, the device appeared to have a noticeable effect on mobility. Nearly all the patients with limited ranges of motion reported an increased ability to perform daily tasks after treatment. Those who presented with slow-healing wounds experienced dramatically accelerated rates of healing.

I found the device easy to use and a useful addendum to my range of treatment options. It integrated into the practice with no problems and was well accepted by most of the staff at the clinic.

Patient contact increased by providing in-house treatment, which facilitated compliance and monitoring. There was also a reduced need for pharmaceutical prescription. The device has been a useful addition to our practice and we will continue to use it on a regular basis.

Sincerely,

Dr. Piet Botes

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Study Overview

Purpose
To evaluate the efficacy of the APS device in providing pain relief for a wide range of musculoskeletal pain conditions. Also, to determine the impact of the APS device on wound healing and mobility.

Time frame
The evaluation commenced on 20 May 1998 and ended on 20 August 1998.

Method
An observational study based on 38 participants. 15 received one treatment, 19 received two treatments and four received between four and five treatments.

Each patient reported, amongst other things, their pain level before and after each treatment using Visual Analogue Pain Scales (VAPS). These were used to determine:
(a) the average change in VAPS after each treatment, and,
(b) the proportion of participants who reported a decrease in VAPS after treatment.

Clinicians also reported qualitative changes in mobility, range of motion, oedema, muscle strength, imbalance and ability to perform daily activities.

Standard inferential tests were used to evaluate the significance of the results.

Results
After the first treatments, the average VAPS score fell 40% (from 6.84 to 4.08). After the second treatments, the average VAPS score fell 38% (from 4.52 to 2.83). Both changes in VAPS score were highly significant with $p<0.0001$ for the corresponding t-tests.

28 participants (74%)reported a positive response to their first treatment. Of the 23 participants who received a follow-up treatment, 19 (83%) reported a positive response. In most cases, mobility and range of motion also improved.

3 participants presented with slow-healing wounds, all of whom reported accelerated rates of healing (in addition to reduced discomfort).

Conclusion
Dr. Botes: "The efficacy was generally good, especially for conditions relating to the lumbar/sacroiliac region. In addition to pain relief, the device appeared to have a noticeable affect on mobility. Those who presented with slow-healing wounds experienced dramatically accelerated rates of healing. Patient contact increased by providing in-house treatment, which facilitated compliance and monitoring. There was also a reduced need for pharmaceutical prescription."

Study Design

Dr. Botes practices general medicine in Auckland. He treats musculoskeletal pain in the standard fashion, with either a prescription and/or referral for acupuncture physiotherapy or similar. In this study, patients were offered another option - treatment with the APS device.

Patients were diagnosed in the normal way and then treated with the APS device. Each was asked to record their pain levels before and after treatment using Visual Analogue Pain Scales (VAPS). In addition, Dr. Botes monitored changes in range of motion, mobility, stiffness, gate deviations, oedema and muscle strength - see protocols at the end of this report.

These evaluations were used to determine:
(a) the average change in VAPS after each treatment, and,
(b) the proportion of participants who reported a decrease in VAPS after treatment

Standard inferential procedures were used to test the statistical significance of results.

The study was not placebo-controlled, randomised or double-blinded. Consequently, a degree of "placebo effect" is latent in the data. However, the results (and Dr. Botes' comments) indicate far greater efficacy than can reasonably be attributed to the "placebo effect" alone. Moreover, placebo-controlled studies are extremely difficult to administer with electrotherapeutic modalities and thus are not commonly used.

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Study on 99 patients with osteoarthritis (OA) of the knee to investigate the effectiveness of low frequency electrical currents on mobility and pain:

Action Potential Simulation therapy (APS) current compared with transcutaneous electrical nerve stimulation (TENS) and placebo

P Berger. L Matzner

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Research Article

Study on 99 patients with osteoarthritis (OA) of the knee to investigate the effectiveness of low frequency electrical currents on mobility and pain: action potential simulation therapy (APS) current compared with Transcutaneous electrical nerve stimulation (TENS) and placebo.

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Keywords:
Action potential simulation therapy; Transcutaneous electrical nerve stimulation; Osteoarthritis of the knee, Mobility; Pain control.

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Summary
This randomised, single blind study, compares the effectiveness of APS Therapy (a recently developed low frequency current) to TENS and placebo, on 99 patients with osteoarthritis of the knee. The study also explores the most effective duration and intensity of this current in these patients. Patients had to correspond with the criteria recommended by the American College of Rheumatology to be accepted for the study and these patients were randomly allocated to six groups. The groups were Placebo for 16 minutes, APS high intensity 16 minutes, TENS for 20 minutes, APS high intensity 16 minutes, TENS for 20 minutes, APS high intensity 8 minutes, APS low intensity 8 minutes. All patients received six treatments on alternate days. The therapeutic effects were evaluated by measuring :- (i) existing pain, pain experienced over 24 hours and walking ability on the visual analogue scale; (ii) knee flexion by goniometer; (iii) circumference of the knee measured both below the patella and 10 centimeters above the patella by tape measure; (iv) night pain; (v) use of analgesics; and (vi) subjective evaluation of overall benefit from treatment. These variables were measured before each treatment and at a 1 monthly and 3 monthly follow-up.

It was statistically proven that APS therapy is effective in the treatment of patients with osteoarthritus of the knee. Within groups (APS and TENS) improvements were shown over time. The study indicates that electrical therapy (APS and TENS) is beneficial in the relief of pain, stiffness and night pain in osteoarthritis of the knee. Although the repeated measures analysis of variance did not show differences between treatment groups, the Mc Nemar tests highlight the strong points of the various APS groups, especially at an APS high intensity of 8 minutes. The flexibility of the knee was, highly significantly, improved by APS high intensity of 8 minutes and this improvement continued ro increase 1 month after the last treatment.

Introduction
Electrical currents can be used to reduce pain by exploiting the body's neurobiological control mechanisms such as selective stimulation of particular subtypes of primary afferent nerve fibres. Afferent fibres can be activated by transcutaneous electrical nerve stimulation (TENS)[1] and other currents, including a new low frequency current recently developed in South Africa, the so-called action potential simulation (APS) therapy.[2]

The (APS) therapy produces a current that is claimed to simulate an action potential in the neurone. This current is supposed to mimic the body's natural electrical impulse, which then causes synchronous depolarisation. Thus, it is claimed that electrolysis may occur within the cell. This current is supposedly four times stronger than the naturally occuring action potential (Lubbe GA, 1992).

In the area of pain or inflammation, there be a blockage somewhere along the path of the nerve impulse. A weakened current or even no current at all may then be

produced depressing the response in muscles, glands or any other organ.

Stimulation by the APS current, is said to create a normal action potential which is then said to restore the inherent biochemical processes in the region. This current stimulates the production of neurotransmitters in the brain and spinal cord, such as melatonin and leuenkephalin. [2]

The understanding of the mechanism of pain control was enhanced by Melzack and Wall in the 1960's, when the explanation of a "gate control" theory was proposed. [1] The theory proposes that the type of afferent input from the periphery affects secondary neurones in the spinal cord, which will then close the gate to the incoming messages at this level and thus prevents onward transmission to supraspinal levels. TENS when passed through the skin, will inhabit the transmission of pain from small diameter niciceptive afferents on the periphery of the nervous system to the second order neurones in the spinal cord. by activating the large diameter afferent fibres.

Depending on the frequency of the current, different mechanisms and areas of the central nervous system will be activated. In the spinal cord, non-endorphinergic substances such as dynorphin and enkephalin are released. In the brain endorphin and serotonin, among other neuro chemicals, are released. This is the body's natural mechanism to combat pain, inflamation and anxiety. Physiotherapists have the ability to enhance or stimulate these homeostatic processes with many electrical currents, and particularly with low frequency electrical currents. These currents are non-invasive and have no deleterious side effects on the system.

Osteoarthritis (OA) is the commonest of all the rheumatic diseases, and causes symptoms and disability in a large proportion of elderly people. It presents a special challenge to clinicians as it is a common cause of severe, chronic, disabling and intractable pain.

Osteoarthritis is characterised by focal destruction of cartilage and remodelling of subchondral bone with the joint capsule, synovial membrane as well as the ligaments, tendons and muscles surrounding the diseased joint susceptible to varying degrees of degenerative change. Alone, or in combination the profound anatomical and physiological alterations may produce signs of inflammation, swelling, spasm, instability, limited motion, deformity, proprioceptive abnormality, decreased strength, endurance and aerobic power [5.6], and pain which is the most concern to patients. The knee is the most commonly involved major joint affected and is associated mostly with symptoms of pain, stiffness, inflammation, instability, decreased range of motion, angular deformity and muscle weakness.[7]

Due to infection, instability, nerve palsy, vascular damage, non-union, recurrence of deformity and loosening of prosthetic components, joint replacement or joint surgery may not always be the most suitable method of treating OA of the knee. [8] Unfortunately, of the various treatments available for the condition, pharmacological approaches have not always proved efficacious. The excess mortality among persons with OA is due to their aspirin usage which caused gastrointestinal disease. Compared to placebo injections, injections of local anaesthetic or of corticosteroids given to reduce synovial inflammation, have not always provided adequate long term pain relief and have been found to accelerate disease progression. 10

Clinically, the APS therapy may demonstrate rapid relief of pain, improvement in mobility and ambulation, in patients with OA knees. These symptom changes may begin to occur even after the second treatment and often these improvements persist for a month or more after treatment has ceased.

In the light of the above observations, it was decided to study the effects of the APS treatment in a single blind randomised protocol on 99 patients with osteoarthritis of the knee. If it is statistically substantiated that APS therapy assists in the management of the pain and disability of osteoarthritis of the knee and if, in addition, there is the unexpected advantage of the reduction of medication usage, then these patients will indeed have benefitted from this new low frequency treatment.

Literature Review

The review of literature will encompass the non-surgical physical management of OA and any particular reference to treatment with low frequency currents. The main goal of treatment being to relieve pain, improve mobility and function.

The most recent report of management of OA knees is an out-patient programme of physiotherapy which includes:- an exercise programme of quadriceps; isometrics; active range of motion stretching; ultrasound; short-wave diathermy; interferential current; ice; frictions; laser; education; and gait training. It was concluded that a high proportion of patients with moderate top severe knee joint disease may experience continued functional benefits from a relatively brief out-patient physiotherapy programme (with a mean number of 15.8 treatments[7]).

A controlled trial using TENS to treat the pain of osteoarthritis of the knee, was reported by Taylor, indicating that initially there was a 50% reduction in pain, falling to only 20% at one year.[12] There are also a number of reports of cl9inical success with TENS in arthritic or specific joint pain.[13,14]

Several authors who made log-term studies on the use of TENS in chronic pain conditions, indicate that TENS produces a 60 - 80% relief, a proportion of this success being ascribed to the placebo phenomenon. This latter effect falls off very rapidly, while the therapeutic efficacy of TENS tends to decrease more slowly until a stable long-term success rate of 20 - 30% is achieved.[15]

Rubrefascients, such as capsaicin cream can be helpful in relieving the pain of OA joints. Capsaicin depletes substance P from C-fibres and any action on OA is presumably due to an effect on peri-articular nerves, includ-

ing those emerging from the joint and subchondral bone.[16] From the above, if rubrefascients with effects on afferent nerve fibres can relieve pain in OA knee, then it may be beneficial to intensively review the old transcutaneous electrical treatments and consider newly developed, low frequency currents, to add to the armamentarium of treatment in this condition.

As was noted in the 1994 edition of the "Textbook of Pain", pain remains the main consequence of OA and the causes of pain and adequate ways of controlling it, have yet to be discovered![15]

There are a few treatments and limited studies of physical applications (low frequency currents), that were found to be effective in the treatment of OA of the knee. It is therefore necessary to investigate any current that has the clinical potential to improve this condition.

At the present time there is an obvious scarcity of published literature on APS therapy. The device was invented and designed by GA Lubbe in 1991 in South Africa and marketed in 1994 even without published studies in peer-reviewed journals.

Aim of the present study

The purpose of the present study was to determine:

1) The effectiveness of APS therapy in patients suffering from osteoarthritis of the knee, compared with TENS or placebo
2) To find the optimum duration and intensity of APS therapy in the treatment of osteoarthritis of the knee.

Planning

It was decided to examine a sample size of 20 patients per group. At the time of the study, 120 plus patients applied to join the protocol and these were randomly allocated into six groups and then assessed before treatment.

Population

A single blind study was conducted on 99 patients with osteoarthritis of the knee, under the supervision of a physiotherapist, associated with the Pain Relief and Research Unit, Department of Anaesthesiology, Chris Hani Baragwanath Hospital of the University of the Witwatersrand. The protocol was accepted b the Ethics Committee of the South African Medical Research Council.

These patients were only permitted to present themselves for the research after they had consulted their medical practitioner or orthopedic surgeon, and the diagnoses of osteoarthritis had been confirmed.

All patients presenting for the study were assessed by one physiotherapist and after fulfilling the criteria for inclusion in the study were those as identified by the American College of Rheumatology.[17]

Patients had to have both:-

Knee pain and radiological evidence of osteophytic change.

Furthermore patients were required to have at least one of the following three items:-

(i) Crepitation in motion; (ii) morning stiffness of the knee lasting for at least 30 minutes, or (iii) aged fifty years or older.

Patients were required to sign consent forms before commencing treatment. The patients were randomly allocated to six groups. If patients had symptoms in both knees, then only one knee was randomly selected for the study.

Methodology

Patients were assessed before entering the study to ensure that they met the criteria required and that they were also screened to eliminate patients who had pacemakers, epilepsy, cancer, thrombosis and those patients on ant-coagulant medication. Any electrical current may effect demand type pacemakers or patients with epilepsy.[18,19]

The six groups of patients were to receive the following treatment:-

Group 1: received placebo for 16 minutes from a placebo APS unit.
Group 2: received the 0.70 mA (or as near as possible) of APS therapy for 16 minutes.
Group 3: received the highest comfortable dosage of APS therapy for 16 minutes.
Group 4: received TENS therapy for 20 minutes
Group 5: received the highest comfortable dosage of APS therapy for 8 minutes.
Group 6: received 0.70 mA (or as near as possible) for 8 minutes.

Before the first treatment, patients were assesed by the one physiotherapist to determine of the patient had the criteria necessary to participate in the programme. Once this was established, questions concerning their daily intake of non-steroidal anti-inflamatory drugs and analgesics were asked. Other questions included, "the presence of night pain" and "whether they rubbed or did not rub their knee for pain relief", in order to evaluate changes in the above. It was decided that patients should continue taking medication as usual.. This was Card number 1. There were 9 Cards that had to be completed by the one therapist for evaluation by the biostatistician.

Cards 2 to 7 measured the variables.

The variables measured were:-

1. Self reported pain measured on a visual analogue scale (VAS) of pain at the present time.[20] A card was presented to the patient which demonstrated a line drawn of 10 centimeters, where zero was marked at the beginning of the line. The zero indicated "no pain" and 10 indicated the "most severe pain". This was carefully and clearly explained to the patient and the patient was then advised to put an X on the line which indicated their feeling of pain at the present time.

2. VAS over the past 24 hours. The same procedure was followed, as above.
3. VAS which indicated self reported walking ability at the present time. The same procedure was followed as above, except that the zero indicated that the patient could "walk easily" and the 10 indicated that the patient could "not walk at all".
4. The circumference of the knee as measured by the same tape measure, 10 centimeters above the upper border of the patella. This would indicate the change in swelling at this level.
6 Flexion of the knee as measured by a goniometer, with the patient in the supine position.

Data was collected before each treatment by the same physiotherapist.

The patients then received their treatment, (by another physiotherapist), according to the group to which they were randomly allocated. All treatments were applied in the same manner by the same physiotherapist. Four gel electrodes were placed on the knee in the same configuration. Two negative electrodes were placed, one on the anterior and one on the medial knee joint line and the two positive electrodes were placed with one on the lateral joint line and one posteriorly, on the popliteal fossa.

These electrodes were marked positive and negative and were attached to the corresponding positive or negative leads. The same application and type of electrode was used in the placebo and the TENS treatments only. All patients were advised that they may or may not feel any current during the treatment.

In Group 1. the placebo treatment was administered through a modified APS unit for 16 minutes. Although there was no current passing through the circuit to the patient. The patient was advised that the treatment may or may not feel any current during the treatment.

In Groups 2 and 3, the APS treatment was given for 16 minutes. Although there was no current level visible to the patient. The patient was advised that the treatment may or may not be subliminal.

In Groups 2 and 3, the APS treatment was given for 16 minutes. Group 2 was given treatment at a dosage of 0.70 mA or as close as possible. This dose is the lowest effective treatment that can be given with APS therapy, according to the machine. Group 3 had the highest comfortable dosage tolerable without discomfort. This is an individual patient preference.

Group 4 received TENS for 20 minutes. These patients were also informed that the treatment was subliminal but most patients were able to tolerate the intensity comfortably, at 4 mA. This is the level of TENS current that most patients comfortably tolerate, in clinical practice, for any condition.

Groups 5 and 6 received 8 minutes of treatment with APS therapy. Group 5 received the highest possible comfortable dosage tolerable and Group 6 received 0.70 mA, or as close as possible.

All patients received six treatments on alternate days, over a two week period. This was followed by assess-ents, one month and then three months, after the sixth treatment. All these measurements were performed by the same physiotherapist throughout the study.

At the one and three months assessment (Cards 8 and 9), "night pain" and the "use of analgesics and anti-inflammatories" were also assessed.

To evaluate overall subjective assessment of benefit an extra question was asked:

"Do you feel that overall, you have benefited from this treatment?" Scores:-

Yes = 1 ; Stayed the same = 2 ; No = 3

Patients then had to indicate their preference.

All the results were processed by L Matzner, an independent biostatistician at Medunsa, Gauteng, Republic of South Africa.

Material used

The equipment used to perform the study were three APS units, and one placebo unit modified to exclude the APS current. Sufficient electrodes were made available to be changed weekly. One TENS unit was used with specific electrodes changed weekly. Strapping was used to apply the electrodes firmly and uniformly to the skin. A standardised goniometer and a tape measure, in centimeters were used. Cards numbered 1-9 were used for assessment.

The study

The actual number of patients participating in the study is shown in Table 1.

A) Respondents were randomly allocated to each group.

TABLE 1

Group	Treatment (1-6) Total no. 99 No. by group	1 Month Total no: 80 No. by group	3 Months Total no: 50 No. by group
1 - Placebo	n = 17	:n = 14	:n = 14
2 - APS low 16 min:	n = 14	:n = 11	:n = 11
3 - APS high 16 min:	n = 17	:n = 13	:n = 13
4 - TENS:	n = 17	:n = 15	:n = 15
5 - APS high 8 min:	n = 17	:n = 15	:n = 15
6 - APS low 8 min:	n = 17	:n = 12	:n = 12

As would be expected, a gradual drop-out of patients took place over time. Due to the nature of the study, very strict adherence to the protocol concerning consecutive treat-ments could not be guaranteed. Patients deviating from the set scheduled dates were excluded from the study. Those patients who missed more than one treatment in the order of the protocol of the study, were removed from the study.

B There was a total of 34.3% males to 65.7% females with no significant association between gender and group ($p = 0.5650$).

C) Information provided by Table II on age, indicated no statistically significant difference found between the age groups ($p>0.05$).

TABLE II

Group	Mean age	Std Dev	Range
Placebo	71	11.0	50 - 85
APS low 16 min:	72	9.8	56 - 85
APS high 16 min:	68	14.5	41 - 90
TENS:	69	12.6	49 - 85
APS high 8 min:	64	9.3	50 - 81
APS low 8 min:	64	9.0	49 - 80

There was also no statistically significant association found between the number of patients taking non-steroidal anti-inflammatories (NSAIDs) and/or analgesics and treatment group ($p>0.05$). The amount of daily medication did not differ between treatment groups ($p>0.05$).

D) Baseline values taken before the onset of the first treatment did not differ statistically for present pain, pain experienced over the past 24 hours, walking ability and knee flexion ($p>0.05$).

However, a statistically significant difference ($p<0.05$) was found between the treatment groups for mean baseline circumference values below and above the patella. No explanatory reason for this could be found. It was corrected by statistics in the final analysis.

The above statistical findings demonstrate the principles of random sampling. Further differences to be found between treatment groups can, with reasonable confidence, be attributed to treatment effect and not to confounding design factors.

Results

Extensive descriptive statistics were evaluated for every continuous variable by the different treatment groups. The data was normally distributed.

An analysis of variance (ANOVA) was performed to determine if differences occurred between the six treatment groups at the consecutive six treatments and at the two follow-up assessments. No statistically significant differences were thus found for present pain, pain experienced over the last 24 hours, walking ability and knee flexion ($p>0.05$).

In the below and above the patella circumference measurements, it was found that there were differences already occurring between the treatment groups at consecutive treatments, for below and above the patella circumference measurements ($p<0.05$). As this particular statistical technique cannot distinguish between differences due to treatment effect, and differences due to a possible carry-over effect, the repeated measures analysis of valiance was used to deal with this problem.

The information relating to the rubbers and non-rubbers will not be covered in this analysis of the results.

Dunnet's one-tailed t-test was applied to test for differences between the placebo group and the five experimental groups. A statistically significant difference was found between TENS and placebo ($p<0.05$) groups, and APS low 8 minutes and placebo ($p<0.05$) groups, at thethree monthly follow-up for the pain experienced over the last 24 hours. These two groups thus experienced less pain than the placebo group.

Differences were detected between various consecutive treatments within each group. The paired t-test was applied for continuous variables.

In the present pain analysis, a significant decrease in present pain between the 3 monthly and 1st treatments was found within the TENS group ($p=0.0411$).

Within the APS high 8 minutes group a significant decrease was found between 2nd and 3rd treatments ($p=0.0442$), between 4th and 5th treatments ($p=0.0305$), between 5th and 6th treatments ($p=0.0095$), and between 1st and 6th treatments ($p=0.0330$).

In the pain experienced over the last 24 hours, a significant decrease was found in the placebo group between the 1st and 2nd treatments, 1st and 6th treatments and the 1st treatment and 1 monthly follow-up ($p<0.05$). However, a significant increase took place between the 1 monthly and 3 monthly follow-ups ($p=0.0426$).

Within the APS low 16 minutes group, a significant decrease was found between the 1st and 2nd treatments ($p=0.0275$).

Within the APS high 16 minutes group, significant decreases were experienced between the following treatments:- 1st and 2nd treatments, 1st and 6th treatments, 1st treatment and 1 monthly follow-up and between the 1st treatment and 1 monthly follow-up ($p<0.05$).

Within the TENS group significant decreases were found between exactly the same treatments as the APS high 16 minutes.

Within the APS high 8 minutes group, significant decreases were found between the 1st and 6th treatments, and the 1 treatment and 1 monthly follow-up ($p<0.05$).

Within the APS low 8 minutes group, significant decreases were found between; 1st and 2nd treatments, 1st and 6th treatments, 1st treatment and 1 monthly follow-up and 1st treatment and 3 monthly follow-up ($p<0.05$).

With walking ability within the TENS group, significant decreases were found between the following treatments:- 1st and 2nd treatments, 1st and 6th treatments, 1st treatment and 1 monthly follow-up treatments and 3 monthly follow-up treatments ($p<0.05$).

Within the APS high 8 minutes group, significant decreases were noticed between the 5th and 6th treatments ($p<0.05$).

APS low 8 minutes yielded significant decreases between the 5th and 6th treatments, and the 1st and 6th treatments ($p<0.05$).

In below patella knee circumference, measured in centimeters, a significant increase was detected in the placebo group between 3rd and 4th treatments ($p<0.05$).

Within the APS high 16 minutes group a significant

decrease in swelling was found between the 1st treatment and 1 monthly follow-up (p=0.0384).

In knee flexion within the APS low 16 minutes group, significance was found between 1st and 6th treatment (p=0.384).

Within the APS high 16 minutes group, significance was found between 6ht treatment and 1 monthly follow-up (p=0.0350).

Within the TENS group, a significant increase occured between the 1st treatment and the 1 monthly follow-up (p=0.0118)

A highly significant increase in flexion was found in the APS high 8 minutes group between the 1st and 6th treatment (p=0.0006). This increase was maintained until the 1 monthly follow-up (p=0.0159).

No significance was found within the APS low 8 minutes group with regard to knee flexion..

In the paired T-tests for the combined APS low intensity groups, in both the 16 minutes and the 8 minutes groups for pain experienced over the last 24 hours, significance was found between the 1st and 2nd treatments, 1st and 6th treatments and 1st treatment and 3 monthly follow-up. (p<0.05).

Walking ability showed significance between the 1st treatment and 1 monthly follow-up (p=0.0170).

Knee flexion showed significance between the 1st treatment and 1 monthly follow-up. (p=0.0405).

In the paired t-test results for the combined APS high intensity groups, (16 minutes and 8 minutes), with no regard to present pain, significance was noted between the following treatments: 2nd and 3rd treatments, 4th and 5th treatments and 1st treatment and 3 monthly follow-up. (p<0.05).

For pain experienced over the last 24 hours, significance between the following treatments was noted: 1st and 2nd, 4th and 5th treatments, 1st and 6th treatments, 1st and 1 monthly follow-up treatments, as well as 1st and 3 monthly follow-up (p<0.05).

For walking ability, significance was found between the 1st and 6th treatment (p=0.0099).

The swelling measured below the patella yielded a significant difference between the 5th and 6th treatments (p=0.0489).

A significant increase in knee flexion was experienced between 1st and 6th treatment (p=0.0068) as well as between the 1st treatment and 1 monthly follow-up (p=0.0047).

In the combined APS treatments with a duration of 8 minutes with both high and low intensity for present pain, significance was noted between the following treatments: 2nd and 3rd treatments, 4th and 5th treatments, 5th and 6th treatments, 6th and 1 monthly follow-up, 1st and 6th treatments, as well as 1st treatment and 3 monthly follow-up (p<0.05).

For pain experienced over the last 24 hours, significance occurred between :- 1st and 2nd treatments, 5th and 6th treatments, 1st and 6th treatments, 1st treatment and 1 monthly follow-up as well as between 1st treatment and 3 monthly follow-u (p<0.05).

Walking ability showed significant improvement between the 5th and 6th treatments, 1st and 6th treatments, 1st treatment and 1 monthly follow-up as well as between 1st treatment and 3 monthly follow-up (p<0.05).

Knee flexion showed significant improvement between the 1st treatment and the 1 monthly follow-up (p<0.0061).

In the combined APS treatments with a duration of 16 minutes for both high and low intensity pain experienced over the last 24 hours, yielded significance between the 1st and 2nd treatments, 1st and 6th treatments, 1st and 1 monthly follow-up as well as between the 1st and 3 monthly follow-up (p<0.05).

A significant decrease in swelling was found between the 5th and 6th treatments (p=0.0442) as well as between the 1st treatment and the 1 monthly follow-up (p=0.0244).

Knee flexion showed a significant increase between the 1st treatment and 1 monthly follow-up (p=0.0244).

Repeated measures analysis of variance was carried out for continuous variables from the 1st treatment to 1 monthly follow-up. Due to patients lost-to-follow-up, small sample sizes were experienced at the 3 monthly follow-up.Inclusion of this last treatment in the repeat-ed measures analysis of variance could lead to unreliable results. Therefore it was decided that the cut off date was to be at the 1 monthly follow-up.

Thus in the total samples for each treatment group the results were as follows:-

Present Pain

No statistically significant difference was found between the treatment groups _p=0.2111). However, significant differences were detected over time within the respective treatment groups (p=0.0001). No significant interaction was found between treatment groups and between consecutive treatments over time (p=0.4650).

Pain experienced over 24 hours

No statistically significant difference was found between the treatment groups (p=0.5711). However, significant differences were detected over time within the respective treatment groups (p=0.0001). Significant interaction was found between treatment groups and consecutive groups over time (p=0344). Differences were calculated between consecutive treatments. These calculations were found to be of significance between 1st and 2nd, 2nd and 3rd, and 4th and 5th treatments (p=0.0001, p=0.0001, p=0.0060 respectively). A significant difference for these calculations with regard to treatment groups was found between the 1st and 2nd treatment (p-0.0111).

Walking ability

No statistically significant difference was found between the treatment groups (p=0.7316). However, significant

differences were detected over time within the respective treatment groups (p=0.0001).No significant interaction was found between treatment groups and consecutive treatments over time (p=0.2266). Differences were calculated between consecutive treatments. These calculations were found to be of significance between the 1st and 2nd, and the 2nd and 3rd treatments. (p=0.0023, p=0.0004 respectively).

Below patella

A statistically significant difference was found between the treatment groups at baseline (p=0.0249). No significant differences were detected over time within the respective treatment groups (p=0.1991). No significant interaction was found between treatment groups and consecutive treatments over time (p=0.2609). A significant difference between treatment groups was found for the difference between 2nd and 3rd treatments (p=0.0175.

Above patella

No significance was found.)

Knee flexion

No statistically significant difference was found between the treatment groups (p=0.5714). However, significant differences were detected over time within the respective treatment groups (p=0.1991). No significant interaction was found between treatment groups and consecutive treatments over time (p=0.2313). Differences were calculated between consecutive treatments. These calculations were found to be of significance between the 1st and 2nd treatments (p=0.0001).

In the Mc Nemar test for each treatment group, significant deviation from symmetry was found in the APS high 8 minutes group, between night pain at onset and night pain at the 1 monthly follow-up (p=0.003) and between night pain at onset and the 3 monthly follow-up (p=0.008).

In the same test the placebo group also had a significant deviation from symmetry between night pain at onset and night pain at the 1 monthly follow-up (p=0.003) and between night pain at onset and the 3 monthly follow-up (p=0.046).

In the combined APS groups, the MC Nemar test indicated significant deviation from symmetry, between night pain at onset and night pain at the 1 monthly follow-up (p=0.001), and between night pain at onset, and the 3 monthly follow-up (p=0.001).

In the TENS group, the MC Nemar test indicated significant deviation from symmetry between night pain at onset, and night pain at the 1 monthly follow-up (p=0.005), and between night pain at onset, and the 3 monthly follow-up (p=0.008).

In the combined APS groups, the Mc Nemar test also indicated significant deviation from symmetry between the use of analgesics at onset, to the use of analgesics at the 1 monthly follow-up (p=0.001).However this was not sustained at the 3 month follow-up.

The Chi square test was applied to establish statisti-cal association between two variables, in this case association of benefit, same, or no association of benefit..

The association between Groups at the 1 monthly follow-up is demonstrated in table III.

TABLE III Association between group and 1 monthly overall benefit

GROUP Frequency Percent Row %	OVERALL BENEFIT YES	SAME	NO	TOTAL
Placebo	7 8.75 50.00 13.21	0.00 00.00 0.00	7 8.75 50.00 63.64	14 17.50
APS low 16 min	6 7.50 54.55 11.32	5 6.25 45.45 31.25	0 0.00 0.00 0.00	11 13.75
APS high 16 min	10 12.50 76.92 18.87	0 00.00 0.00 0.00	3 3.75 23.08 27.27	13 16.25
TENS	10 12.50 66.67 18.87	5 6.25 33.33 31.25	0 0.00 0.00 0.00	15 18.75
APS high 8 min	12 15.00 80.00	2 2,50 13.33	1 1.25 6.67	15 18.75
APS low 8 min	8 10.00 66.67 15.09	4 5.00 33.33 25.00	0 0.00 0.00 0.00	12 15.00
TOTAL	53 66.25	16 20.00	11 13.75	80 100.00

APS high 8 minutes had the highest row percentage of the overall subjective benefit for OA of the knees (p=0.0001).

In the assessment of association between placebo and the experimental groups, respectively with regard to outcome of overall treatment benefit at the 1 monthly follow-up, using the Fisher's exact test, the following was found:-

Between placebo and APS high 8 minutes, the placebo group benefited by 36.84% as opposed to the APS high 8 minutes group, that benefited by 63.16% (p=0.001).

Yet 87.50% of placebo verses 12.50% of the APS high 8 minutes did not benefit from the treatment.

Between TENS and placebo, the placebo group benefited by 61.11% (p=0.00552).

But 100% of placebo verses 0% of the TENS group did not benefit from treatment.

Between the combined APS groups and placebo, the placebo group benefited by 50% as opposed to the com-

bined APS groups, that benefitted by 70.59% (p=0.00085).

Therefore 50% of placebo verses 7.84% of the combined APS groups did not benefit from the treatment.

Descriptive statistics on knee flexion were performed of less or equal to 122 degrees and above 122 degrees. The median value of knee flexion at onset for the total sample (n=99) was found to be 122 degrees. The first quartile of the total sample for knee flexion at onset was found to be 114 degrees. Again descriptive statistics are provided for each treatment group. The purpose of this was to determine if differences occurred between patients with very limited knee flexion, and those with not so limited knee flexion.

The paired t-test was applied to the data for knee flexion within each treatment group and these results indicated the following:-

In knee flexion of equal or less than 122 degrees versus above 122 degrees, the placebo group demonstrated significance in knee flexion equal or less that 122 degrees, between the 1st treatment and the 1 month follow-up (p=0.0018).

In knee flexion of equal or less than 122 degrees, the APS low 16 minutes demonstrated significance between the 1st treatment and the 1 month follow-up (p=0.0018).

In knee flexion equal or less that 122 degrees, the APS high 16 minutes demonstrated significance between the 1st treatment and the 1 month follow-up (p=0.0313).

In the APS high 8 minutes significance was demonstrated in knee flexion of equal or less than 122 degrees between the 1st treatment and the 1 month follow-up (p=0.0234) and between the 1st and 6th treatments (p=0.0050.) Significance was also demonstrated in the knee flexion of greater than 122 degrees between the 1st and 6th treatments (p=0.0307).

Discussion

There were over 120 patients that initially joined the study with confirmed osteoarthritis of the knee. As expected, a gradual drop-out of patients occurred over time, thus producing a total number of 99 patients for the final statistical evaluation. In the patients that participated in the study, only two patients left the study due to pain and swelling after the first treatment (2.02%). One of these patients was from the TENS group. Their pain was increased due to irritation by the current, because of the presence of a metal screw from a previous osteotomy (this irritation has often been noted to occur in such patients receiving TENS treatments). The other patient was in the APS low 16 minutes group, and swelling and pain increased markedly. This patient was also allergic to certain medications.

It has also been noted clinically, that patients sensitive to medications, or experiencing allergic reactions have been found to develop increased swelling and pain, especially in a joint after APS therapy. In this situation, shorter treatment duration (4 minutes) and a lower intensity current (<1 mA) can still be applied, without exacerbation, in order to give the patient the benefit of this treatment. It is advisable to give a lower current intensity (<1.5mA) for the fist two treatments to an acutely swollen or painful joint, in order to prevent excess pain and swelling. It is postulated that the increase of inflammatory exudate released into the local blood circulation may create a temporary situation of local joint congestion, only to be greatly lessened over the following 24 hours.

The age and sex of the patients participating in the study agreed with population-based epidemiology, that OA is relatively uncommon until middle age but is found equally in men and women. However, after the age of 50 years, there is a steep increase in the prevalence of the disease in women.8 This study found a higher prevalence in females (65.7%), in comparison to males, (34.3%) when suffering from OA of the knee.

The ANOVA did not detect differences between the six groups, either at the six consecutive treatments or at the two follow-up assessments. The trend indicated by the APS high 8 minutes group (figures 1,2 and 3) shows the most consistent decrease in the present pain, walking ability and, in the pain experienced over 24 hours. The flexion graph also demonstrated consistent improvement of range of movement (figure 4), in the APS high 8 minutes group.

There were marked differences in the scores of the present pain and pain experienced over 24 hours. This may indicate a difference in the types of pain experienced by these patients, in that the degree of pain experienced in the present pain is of a lower intensity than the pain experienced over 24 hours. The former has a low grade quality, with possible associated depression, due to its chronicity, whereas the latter may reflect an acute episode during the period of the last 24 hours. It may be necessary to address these different types of pains in the treatment of the osteoarthritis patient.

The Dunnet's one-tailed t-test found differences between placebo and TENS and APS low 8 minutes for pain experienced over the last 24 hours. This was found 3 months after the last treatment, which may infer that electrical currents are more effective than placebo, even 3 months after the last treatment.

One other difference detected between groups, was in the repeated measures analysis of variance carried out in the continuous variables from the 1st treatment to the one monthly follow-up. These differences were detected between treatment groups and consecutive treatments (p=0.0344) over time, only for the present pain (p=0.0001), pain experienced over the last 24 hours (p=0.0001), walking ability (p=0.0001) and for knee flexion (p=0.0001).

The placebo group, as mentioned, did not differ markedly in the ANOVA from the treatment groups, yet the validity of the role of placebo in treatment in these patients would not substantiate it as a stand-alone treatment for this condition. In the paired t-test in pain experienced over the last 24 hours, a significant decrease of pain occurred between the 1st and 2nd treatments, 1st and 6th treatment and 1st treatment and 1 monthly fol-low-up. However the fact that there was a significant increase in pain, as compared to the other treatments at the 3 monthly follow-up, signifies that placebo alone, may

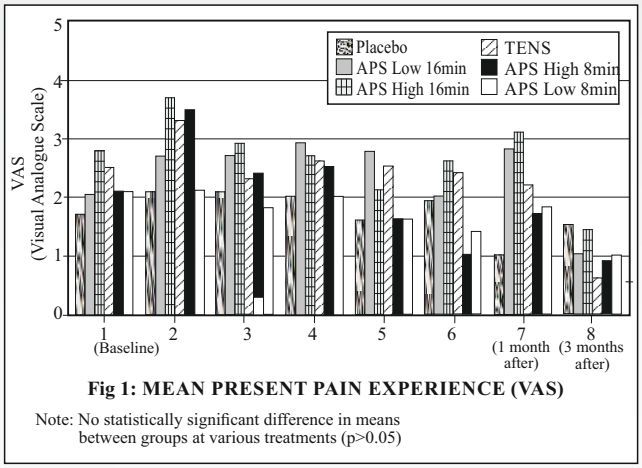

Fig 1: MEAN PRESENT PAIN EXPERIENCE (VAS)

Note: No statistically significant difference in means between groups at various treatments (p>0.05)

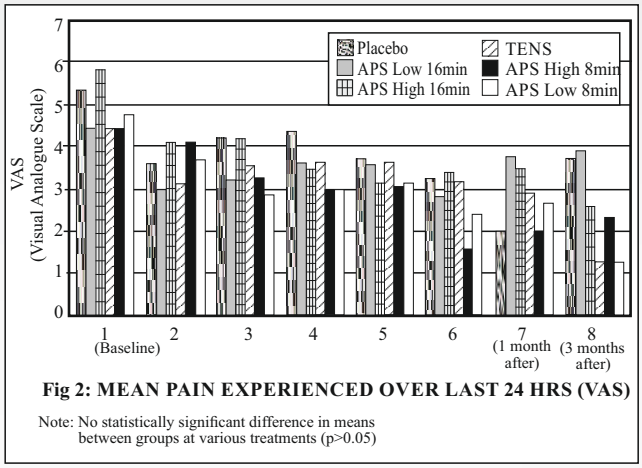

Fig 2: MEAN PAIN EXPERIENCED OVER LAST 24 HRS (VAS)

Note: No statistically significant difference in means between groups at various treatments (p>0.05)

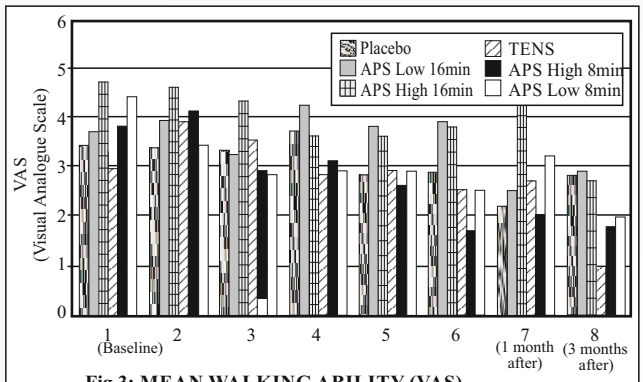

Fig 3: MEAN WALKING ABILITY (VAS)

Note: No statistically significant difference in means between groups at various treatments (p>0.05)

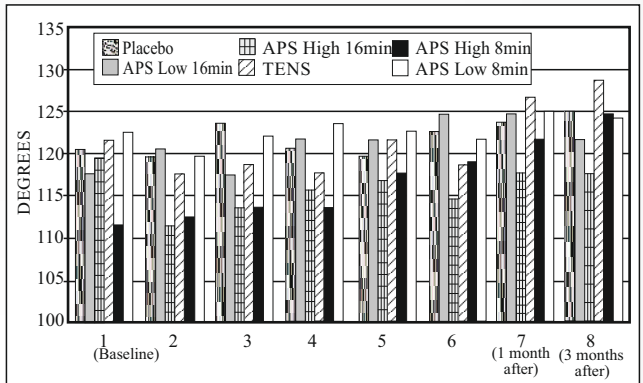

Fig 4: MEAN KNEE FLEXION (DEGREES)

Note: No statistically significant difference in means between groups at various treatments (p>0.05)

give a false evaluation of improvement. Also in this group, in the evaluation of circumference of below patella measurement, a significant increase in swelling occured between the 3rd and 4th treatments. This increase was not found between the other treatments.

Using the Chi square test, the placebo group had a 50% benefit and a 50% non-association of benefit for these patients.

This level of subjective assessment of benefit perceived by the patient is high and although other improvements are not achieved, it reveals the importance of placebo in treatment. Placebo in this study implied the physiotherapists interest in the patient's condition, interactive questioning, follow-up and interest in progress, inter-patient communication with patient's suffering from the same condition, pleasant music, professional surroundings and application of electrodes with pressure (applied by strapping) in the painful area.

Although significant deviation was found in the Mc Nemar test for symmetry in the placebo group for night pain at onset and for night pain at the 1 and 3 monthly follow-up intervals, this does not influence swelling or the other variables evaluating mobility.

In the Fisher's exact test between placebo and the experimental groups, it was found that :- both the APS high 8 minutes and TENS had greater association of benefit than placebo (63.16%, and 61.11% respectively);more patients did not benefit from placebo than the APS high 8 minutes (87.50% and 12.50% respectively) and between placebo and TENS (100% and 0% respectively). Between the combined APS groups versus placebo, the combined groups indicated benefit by 70.59% as compared to placebo, which benefitted by 50%. However, the placebo indicated a much higher non-association of benefit than the combined APS groups (50% versus 7.84% respectively).

It is obvious from the above, that placebo plays a role in pain relief and well being. But on its own, it is not sustainable as treatment for walking ability, flexion and for swelling.

The TENS group indicated that this electrical therapy also benefits osteoarthritis of the knee.

In the paired t-test for present pain, significance was found between the 3 monthly follow-up and the 1st treatment. In the same test in the pain experienced over the last 24 hours, significance was found between the 1st and 2nd treatments, the 1st and 6th treatments, 1st treatment and 1 monthly follow-up and the 1st treatment and 3 monthly follow-up. The same significance was found in walking ability between the same treatments stated above. Significance was also found in the paired t-test for knee flexion, between 1st treatment and 1 monthly follow-up.

In the Mc Nemar test for symmetry between night pain

at onset and night pain at the 1 monthly and the 3 monthly follow-up, there was significant deviation from symmetment once monthly with the APS therapy and that their swelling, circulation and mobility may continue to improve, and even maintain itself.

The other groups of APS therapy did not yield all the positive effects of the APS high 8 minutes group.

It was also decided to evaluate the groups of the low and high intensities, and of short and long duration of treatment, in order to assess the most effective of these treatments for osteoarthritis of the knee.

The high intensity groups of APS therapy, (both the 8 and 16 minute groups), demonstrated significance in the present pain between treatments: (2nd and 3rd treatments, 4th and 5th treatments,1st treatment and 3 monthly follow-up: significance in the pain experienced over the last 24 hours between treatments: (1st and 2nd treatments, 4th and 5th treatments, 1st and 6th treatments, 1st treatment and extending into the 1 monthly and 3 monthly follow-ups); significance in the walking ability between the 1st and 6th treatments; slight significance in the swelling between the 5th and 6th treatments ($p=0.0489$) and a definite significance in knee flexion between the 1st and 6th treatment ($p=0.0068$), that persisted to the 1 monthly follow-up ($p=0.0047$).

The short duration treatment groups of APS therapy, 8 minutes (both low and high intensity), demonstrated significance in the present pain between treatments: 2nd and 3rd treatments, 4ht and 5th treatments, 5th and 6th treatments, 6th and the 1 monthly and 3 monthly follow-up. Significance in the pain experienced over the last 24 hours was found between treatments: 1st and 2nd treatments, 5th and 6th treatments, 1st treatment and 1 monthly and 3 monthly follow-ups. Significance in the walking ability was found between treatments 5th and 6th treatments, 1st and 6th treatments, 1st treatment and 1 monthly and 3 monthly follow-ups. Significance with knee flexion occurred between 1st treatment and the 1 monthly follow-up.

The above indicates that the best APS therapy will be obtained by a high current intensity and a short duration (8 minutes) for osteoarthritis of the knee. The longer duration (16 minutes) of treatment may have a greater influence on swelling than the shorter duration. If the short duration high intensity current is less effective in some patients, the longer duration high intensity current can then be applied.

Conclusion

It is statistically proven that APS therapy treatment is effective in the treatment of patients with osteoarthritis of the knee. Within treatment groups (APS and TENS), improvements were shown over time and persisted even 1 month after the treatment had ceased. Therefore electrical therapy should be considered an important adjunct for the osteoarthritis sufferer, both in the short-term treatment for improvement of mobility and in pain relief (APS) and in long term use as in pain control (TENS). A multimodel electro-therapeutical approach utilising the best aspects of individual current therapies should become part of the medical management of pain and dysfunction in osteoarthritis of the knee. These techniques should become an integral part of the non-pharmacalogical treat-

ment of osteoarthritis of the knee. This could include acupuncture, laser, mobilisation, massage and exercise.

Although the repeated measures analysis of variance did not show many differences between treatment groups, the Mc Nemar tests highlight the strong points of the various treatment groups. This has particular significance in night pain, decreased analgesic use and subjective assessment of overall benefit, (especially in the APS high 8 minute group).

The importance of the above is the long lasting value of electrotherapy treatment, as all these results were obtained one month after treatment had ceased.

The APS high 16 minute group indicated a greater decrease in swelling than in the other groups. This treatment can be selected when the patient has symptoms of swelling. as the swelling in osteoarthritis is often insidious, indurated and may be of long- standing, it may be necessary to treat these patients over a longer period in order to produce effective and persistent change. This would impact on the patient's early morning stiffness and mobility. This indicates that chronic disease often requires protracted treatment management.

The increased improvement in flexion in the APS high 8 minutes group is remarkable considering that the treatment had ceased, yet, ongoing changes were occurring. It is postulated that the electrical, and therefore, the biochemical status of the diseased joint was stimulated to produce natural regenerative improvement.

The increased flexibility of the patients in the APS high 8 minutes group enables the patient to participate more easily in an exercise regimen, improves swelling due to increased mobility and assists with the improvement of the quality of life of the osteoarthritis patient.

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APS Therapy
A new way of treating chronic backache
A Pilot Study

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APS Therapy - A new way of treating chronic backache - a pilot study

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Background: Transcutaneous electrical nerve stimulation (TENS) has been extensively used to control acute and chronic pain, but its effects are controversial. The development of Action Potential Simulation (APS) therapy may have introduced a different mode in the treatment of pain with electrical apparatus.

Methods: Patients with chronic backache due to osteoporosis were included in this randomized, "patient blinded", placebo-controlled study to evaluate the clinical efficacy of the APS therapy apparatus. Seventy six patients took part in the study (43 in the APS group, 33 in the placebo group). Each patient received treatment every second day for 16 minutes with a total of 16 treatments. Visual Analogue Pain Scales (VAPS) evaluations were performed directly before each treatment which reflected the pain situation of the previous 48 hours.

Results: A statistically, highly significant result was obtained from the APS group. The improvement was reflected in the mean pre-treatment baseline VAPS value of 57,79 in the APS group that diminished to a post- treatment value after the sixth treatment of 9,7 ($p = 0,0001$). A specific difference between the two groups could not be demonstrated because the trial population in the groups was too small.

Conclusion: APS treatment may be an effective treatment for chronic backache in the osteoporotic patient.

Key words:
Electrical Therapy: Backache from Osteoporosis.

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Introduction

Scribonius Largus, a Roman in ancient times, used a decapitated torpedo fish pressed against the patient's head or any other painful pa rt to induce numbness and pain relief.[1] A wide variety of medical stimulating devices in the 1800's were advocated for the treatment of many kinds of diseases and also for the relief of pain. Since the 1900's few attempts have been made to separate bona fide uses of electrical stimulation for the treatment of pain from other useless means of therapy. The application of electrical stimulation for any purpose in the medical field virtually disappeared due to this reason.

The "gate-theory" of Wall and Melzack frist described in 1965 provided the first potential explanation for the control of pain by the effects of electrical stimulation[2]. Since then a new interest arose in this field. The "gate theory" has always been controversial, as there are certain conditions such as hyperalgesia, which it does not fully explain. It may be that the relief of pain by electrical stimulation of a peripheral nerve, or even of the spinal cord, is due to a frequency-related conduction block which is acting on primary afferent branch points where dorsal column fibres and dorsal horn collaterals diverge. It also appears from clinical reports (using spinal cord stimulation) that patients show a significant preferance for a minimum pulse repetition rate of 25 pulses per second[3]

The potential advantage of electrical stimulation as an adjunct to other pain therapies is that these treatment modalities are non-invasive and are relatively safe. Few side-effects or complications have been associated with its use.[4] However, it has been found to be of little or no value in the treatment of post-operative pain (eg. post thoracotomy pain[5]).

Transcutaneous electrical nerve stimulation (TENS) was, since its discovery in the 1070's, the most commonly used electrical stimulation apparatus available. The mechanism of action of TENS is not completely understood. It is thought by some that analgesia may be produced by the modulation of nociceptive input in the dorsal horn of the spinal cord by peripheral electrical stimulation of the large sensory afferent nerves, which would comply with the "gate-theroy" (as mentioned above[6]). Alternatively, electrical stimulation of certain receptor sites in the dorsal horn is thought to produce and release endogenous opoids."

The development of APS therapy in 1992 in South Africa brought another perspective of electrical treatment to the fore. *

It is claimed to have a different pulse wave when compared to TENS. The device uses an electrical current that supposedly mimics the normal physiological action potential of nerve conduction. This may be a unique concept to electro -physics. In comparison with TENS, it needs only a treatment time of 16 minutes maximum per day (suggested by the manu-

facturer), whereas TENS needs continuous treatment sessions, from 1 hour up to 18 hours per day.

The APS Therapy device has been developed primarily for use in chromic pain management situations, although it may reduce swelling due to injury and may also restore mobility to stiff joints and muscles.

Technical Specifications of the APS Therapy Device

Wave Form:	Simulated Action Potential
Wave Type:	Monophasic Square Pulse with Exponential Decay
Amplitude:	Adjustable, 0 - 24.4 mA peak into 500 ohm load
Pulse Rate:	150 Hz
Pulse Width:	800 μ sec- 6.6 msec
Modulation:	Variable pulse width; automatic adjustment depending on distance between electrodes
Burst:	Continuous
Voltage:	0 - 46 Volts (open Circuit.)

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Presented here is a study on the use of APS Therapy on patients suffering from chronic osteoporosis associated with backache. This trial was developed purely to evaluate the clinical efficacy of the apparatus.

Material and Method

Approval for the study was obtained from Combined Ethics Committee of the University of the Orange Free State and Provincial Health Authorities. A randomized, "patient-blinded", placebo-controlled study was done on 76 patients suffering from backache with osteoporosis. The electrodes were connected to their backs and they could see the LCD display reading on the APS Therapy device. No current was delivered to the placebo group, although the LCD displayed a reading and the patients could turn the knob on the APS Therapy device to keep the reading between 1,0mA and 1,7mA. No indication was given to any patient as to what they could or might feel or experience during the treatment.

Due to the fact that osteoporosis is a disease of the elderly no limitations were put on age. The majority of these patients came from old-age homes which might have had an influence on the results. (see later.)

All patients had X-rays taken of their backs and had full blood counts and chemical analysis done. X-rays confirmed osteoporosis and degenerative changes in the vertebral column, but none of the blood results were out of range (eg. full blood count, electrolyte profile, kidney and liver functions).

The protocol was designed for six visits. At visit 1, after a thorough physical examination, every patient gave a VAPS value for their backache. This value represented a combined impression of their back pain for the previous three months and was the baseline on which the whole trial was built.

The initial application was 16 minutes between 1.0mA and 1.7 mA; after which they waited for 3 minutes and received another 16 minute treatment. A VAPS was given directly after the second session and a further evaluation 30 minutes later.

The second and consecutive treatments were applied every second day with a VAPS given before and after each treatment. The "before" reading reflected the pain scale of the previous 48 hours (after the previous APS Therapy). These were the figures that were taken into account for statistical analysis.

Follow-up phone calls to some of the patients were done by three and six months after the initial treatment. Mobility was also taken into account by asking them simple questions like: "Do you feel better than before? Do you more

TABLE 1 Demographic data

Gender:	Female:	51	67.1%
	Male:	25	32.9%
Distribution	APS Therapy:	43	56.58%
	Placebo:	33	43.42%

TABLE III VAPS Baseline values

Mean Values	Baseline Values	Std. Deviations
APS Group	57.79	20.54
Placebo	63.33	23.61

General Trend VAPS

Mean Values	Before second Visit	Std Dev.	After last Visit	Std. Dev.
APS Group	48.67	25.05	9.67	14.46
Placebo	54.35	25.57	28.37	23.79

TABLE II Statistical Analysis

MEAN VALUES	Age	Std Dev.	Mass	Std Dev.	Systolic BP	Std Dev.	Diastolic BP	Std Dev.
APS Group	62.84	14.19	76.72	18.24	140.67	16.33	82.79	9.55
Placebo Group	66.15	14.60	77.67	15.70	142.55	25.52	87.15	14.65

TABLE IV Paired T-test to examine the difference in pre- and post -treatment

APS Group

Variable	Mean	Std.Dev	T	P-value	95%C1
Visit 1	6.52	15.89	1.880	0.0746	(-0.72 : 13.8)
Visit 2	27.05	18.26	6.623	0.0001	(18.5 : 35.6)
Visit 3	26.10	20.43	5.712	0.0001	(16.5 : 35.7)
Visit 4	22.95	26.87	3.822	0.0011	(10.4 : 35.5)
Visit 5	20.10	20.13	4.465	0.0003	(10.7 : 29.5)
Visit 6	9.67	17.77	3.358	0.0001	(5.03 : 21.7)

Placebo Group

Variable	Mean	Std.Dev	T	P-value	95%C1
Visit 1	5.75	19.55	1.018	0.3304	(-6.68: 18.2)
Visit 2	10.81	13.67	2.624	0.0254	(1.64 : 20.0)
Visit 3	17.45	12.20	4.744	0.0008	(9.25 : 25.6)
Visit 4	12.18	23.76	1.700	0.1199	(-3.76 : 28.2)
Visit 5	13.90	14.63	3.152	0.0103	(4.08 : 23.7)
Visit 6	28.37	22.86	1.688	0.1223	(-3.72 : 27.0)

mobile or loose?". Two patients were totally pain- free after three months and one after six months.

Statistical methods

Per treatment group changes from baseline to each time point, were calculated. These changes are summarized by means, and the two groups are compared by 95% confidence intervals (CI) for the mean difference in change APS group -placebo. A positive mean difference APS - placebo indicates that the improvement in the APS group was higher than in the placebo group. For each group, 95% confidence intervals were also calculated for the mean change to determine whether there was significant change in the group.

Results and Discussion

From the results it can be seen that fro both groups, APS and placebo, there were statistically significant improvements from baseline to all subsequent time points, except for APS- group, visit 1 (p = 0.0746) and in placebo-group visits 1, 4 and 6 (p -values of 0.3304, 0.1199 and 0.1223, respectively).

The 95% confidence intervals indicate that there were clinically significant improvements on many of the time points in APS -group (cases where lower limit of 95% CI is 10 or higher), but also in the placebo-group, but less often.

The 95% CI comparing the changes between the two groups indicates that there is a tendency for APS to improve more than placebo (the confidence interval goes from a slightly negative value to a large positive value) especially following the first visit and after the third visit. Only one negative value was found in the APS-group but three were found in the placebo-group.

Conclusion

1. The "mean " values obviously show that in the APS Therapy group there was a marked difference between values at Baseline 57.79; Visit 2 (Before) and Visit 6 (After) (e.g. mean of 48.69 down to a mean of 9.7). With the placebo group the difference from baseline 63.33; visit 2 (Before) 57.52 down to Visit 6 (After) 28.37.
2. The paired T-test to examine the difference between "Before" and "After" treatment showed a marked positive result in the APS Therapy group. Except for the value "baseline to before 2nd treatment" with a p-value of 0.4139, all the others were statistically significant - (p-value 0,0001 nine times; one 0,0055 and one 0.0043).
   Of the six visits in the placebo group, four out of the six were statistically not significant. The p-value of the others also displayed higher overall values.
3. The reason why so many of the placebo group had good relief on placebo treatment cannot be explained, but was probably due to the fact that the majority of these patients came from old-age homes. When admitted to the Pain Control Unit they received more attention than they were used to and this factor may have played a major role in the results obtained from the placebo group.
4. Clinically the effect of treatment was very successful. Out of 43 APS Therapy group patients, 7 ended with an "0" VAPS score and 16 with a score of 5 and less (i.e. 23 out of 43 with a score of 5 or less). All the others decreased their VAPS score by more than 40. All were extremely happy with the treatment and six months later 6 patients still had good relief (the one with no pain at all is included in this group).
5. The trial population was too small to come to a definite conclusion of the "between groups" situation.

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** Because no literature exists on medical trials done with APS before, references will be taken from the booklet issued by the manufacturer, Tech Pulse (Pty.) Ltd.*

Neurosurgical Pain Conditions

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NEUROSURGICAL PAIN CONDITIONS

INTRODUCTION

From a clinical point of view, two major categories of chronic pain have been recognized. One often referred to as "somatic pain", is hypothesized to be due to prolonged activation of nociceptors responsible for acute pain. Guilband has suggested that prolonged activation of nociceptors which are sensitized by the pathological process might produce changes in the central nervous system.

The other category of pain, often referred to as "central", "deafferentation" or dysesthetic pain, results from injury to the nervous system. This pain does not depend on activation of peripheral nociceptors, but must be the result of changes in the signal elaborating machinery.

The most popular designation for this group appears to be "deafferentation" pain.

Tusker classified "all painful states associated with neurological injury except the pain associated with neurological injury except the pain associated with neurological compression and including specifically:

- the chronic pain of peripheral nerve injury;
- certain types of peripheral neuritis;
- arachnoiditis;
- avulsion of the brachial plexus;
- trauma to spinal chord or cauda equina;
- postcardotomy dysesthesia;
- postherpetic neuralgia;
- thalmic pain;
- post amputation pain; and
- destruction of neurological tissue by cancer.

Do all pains caused by neural injury have a central abnormal component and hence, are they appropriately classed as central pain?

Probably yes, but for the present we shall designate as "neurogenic", the pains associated with primary injury of neural tissues - peripheral or central - reserving the term "central pains" for those in which the primary lesion is in the brain or spinal chord and for neural peripheral pains. Thereto, the designation : peripheral neurogenic will be used Dysesthesia not synonomous with either of the abovementioned we will use in terms of "an unpleasant abnormal sensation".

We as therapists of pain confront a trichotomy of modes of management:

1. The time- honoured method relies largely on drugs.

   The conscientious psycho- or neuropharmacologist, like the neurosurgeon, has an understandable tendency to cling tenaciously to his patients and explore regimes in his field with which he is familiar, even when the likelihood of success is small or the degree of relief inadequate. Opoids have, for many physicians, become the mainstay of therapy for patients with pain due to cancer. In a Mayo Clinic study of 59 patients with nonmalignant pain, followed on narcotics for an average of 36 months, they excluded, after careful selection, all patients with a history of significant abuse or addiction.

   27% developed serious abuse and 24% became addicted in the sense of drug seeking behaviour. Tolerance developed in another 22%. On the cheerful side of the ledger were the 34% who had satisfactory relief. The successes were largely confined to the 74% that had somatic pain. The results were poor in the 26% with primarily central pain.

2. The group had cognitive-behavioural multi-disciplinary treatment programmes where the primary objective is treatment for excess disability instead of treatment for pain. This concept highlights the major problem of people with chronic pain, namely that they are more functionally disabled than necessary.

3. With respect to the third and invasive components of the trichotomy, anaesthesiology and neurosurgery - this role is being aggressively downplayed by the non surgeons, both because of better non-surgical therapies, as well as unwarranted operations, especially in the spinal canal by neuro- and orthopedic surgeons. They have produced such hordes of failures in the United States that patients in this category outnumbered all others with chronic pain of a non- lethal cause, leading some distinguished physicians to regard one of their main roles to be the protection of the patient from the surgeon. We fear that some physicians have lost sight of the fact that a fully successful neurosurgical destructive procedure enables the patients to forget about their pain and that electrical stimualtion for suppression of pain has no systemic side effects.

ELECTRICITY AND PAIN

The Roman Scribonius Largus pressed a decapitated black Torpedo fish against his patient's head or other painful area to induce torpor (numbing) and pain relief (electrical current). In the late 1800's there were a wide variety of medical stimulating devices that were advocated for the treatment of many kinds of diseases and the relief of pain. The claims are a curious admixture of truth and fiction with the truth relating mostly to the therapy of pain.

The rapid growth of scientific medicine in the 1900's eliminated much of the quackery associated with electrical stimulation. Since there had been few attempts to separate bona fide uses from useless therapy, the application of electrical stimulation for any purpose virtually disappeared. In 1965, the Melzach-Wall hypothesis provided the first potential explanation for the pain relieving effect of general stimulation and kindled a new interest in the field.

Long and Hagfors produced the first carefully engineered device with controllable parameters and began a systematic survey of the effect of cutaneously applied electrical stimulation on many pain states.

The first phase studies were performed utilizing the routine application of electrical stimulation in chronic pain states without regard for underlying diagnosis or related factors. The results showed uniformly that approximately one-third of the patients found electrical stimulation to be satisfactory therapy. Patients with central pain states and pain that appeared to be purely a matter of disordered thinking, virtually never benefit from electrical stimulation, while pain that related to peripheral nerve injury was improved regularly. Subsequently, a series of controlled studies proved that transcutaneous electrical nerve stimulation had a greater than placebo effect on chronic somatic pain of virtually every kind.

The greatest deterrent to the effective use of electrical stimulation in pain control has been the lack of any organized method of patient education, trial of stimulation or acquisition of the devices.

The most important thing in the successful use of trancutaneous electrical nerve stimulation is the identification of a pain problem that can reasonably be expected to be improved by stimulation.

As Danlin Long stated in relation to trancutaneous electrical nerve stimulation, it is very successful in the treatment of incisional pain, acute and chronic musculo skeletal myofascial disorders, localized arthritis and pain of peripheral nerve injury origin. Phantom limb and stump pains are treated very effectively, as is post herpetic neuralgia.

Patients presenting with a metabolic polyneurophathy, pain of central nervous system origin, generalized arthritic pain, or one of those states in which phsycosocial factors are more important than a physical cause of pain, will usually fail to benefit.

The publication of the "gate theory" of pain transmission in the dorsal horn in the spinal cord in 1965 provided a rationale for using electrical stimulation in the treatment of pain.

The "gate theory"proposed that the activity of cells in the dorsal horn in the spinal cord, which signaled the neural transmission of pain, is governed by the balance of small and large fibre afferent activity in the peripheral nervous system. The "gate" would open in response to an excess of small fibre activity and would close in response to a predominantly large fibre activity. It happens that large fibres have a lower threshold for depolarization by an electrical field applied to a mixed peripheral nerve. Therefore, they can be recruited selectively. The motor threshold in a mixed peripheral nerve, however, may not be very close to the sensory threshold and so amplitude adjustment may be critical. Furthermore, most pain problems encountered clinically involve the distribution of more than one peripheral nerve.

The "gate theory" has always been controversial and there are certain pathalogical, painful conditions that it does not explain. For example, hyperalgesia can be signalled by large fibres. In this circumstance, it may be that relief of pain by electrical stimulation of peripheral nerve or spinal cord is due to a frequency related conduction block - acting at primary afferent branch points where dorsal column fibres and dorsal horn collaterals converge. It also looks clinically that spinal cord stimulation patients show a significant preference for a minimum stimulation pulse repetition rate of 25 pulses per second.

Of course, alternative mechanisms involving interneurons in the dorsal horn, or involving descending fibres or sympathetic mechanisms, may be frequency dependant.

Analysis of cerebrospinal fluid in patients undergoing spinal cord stimulation has shown some changes in neurotransmitter and neurotransmitter metabolite concentrations. The administration of the narcotic antagonists' naloxone had no effect on the relief of pain by spinal cord stimulation or by any other form of transcutaneous or peripheral nerve stimulation.

Campbell has evidence that the effect of peripheral stimulation may be a blockage of peripheral function. He has suggested that one aspect of its effectiveness may be in retarding the propagation of the nerve signal.

It is also possible that there is an effect upon a peripheral neural transmitter. The available data leave no doubt that it is possible to provide a total blockage of nerve transmission by

electrical stimulation of nerve trunks, but whether this is the mechanism of the efficacy of transcutaneous stimulation remains in doubt.

Another possibility is that a pain suppressing mechanism is activated by orthodromic stimulation in non-pain carrying fibres, as suggested by the "original" gate control theory. Whether this inhibition of the transmission of painful stimuli occurs at the dorsal horn level or via a long routed system of descending inhibition located in the brain stem or thalmus is unknown and has not been investigated in any substantial way.

PERSONAL EXPERIENCE WITH APS THERAPY

Most of the patients discussed below were seen only in the past three months. For the past few years APS Therapy has been used with success as an adjunctive to neurosurgery in different patients presenting both acute and chronic pain states.

I Lower Back Pain (13 Patients)

Donlin Long stated that most of the original data concerning transcutaneous stimulation was accumulated in the treatment of patients with syndromes of chronic low back pain. Approximately one third of these patients found the stimulation to be of benefit and in order to achieve even that success rate, it was necessary to be highly selective.

The author used APS Therapy on eight patients with low back pain, and with predominant leg pain, i.e. ischias pain.

Patient no. 1

This patient was waiting to be operated on for a disc herniation. It was a female patient, age 33. She had excellent results after two treatments of 16 minutes. She was treated for one week preoperatively and was kept almost pain- free.

Patient no. 2

This patient was also awaiting surgery. She was a female patient, age 43. She also had excellent results after two treatments of 16 minutes. She was treated for one week preoperatively and was kept almost pain- free.

Patient no. 3

This patient was similar to patients no 1 and 2 and did not respond to the treatment.

Patient no. 4

This 80 year old lady had a big lumbar L_3 dumbbell tumour (neurofibroma) with weakness as well as pain in the L_3 distribution. Due to systemic problems, surgery had to be postponed for two months. During that time she was kept pain free by a once daily treatment of 16 minutes.

Patient no. 5

This patient was a 70 year old male who had a bad spinal stenoses with ischias, neurogenic claudication and morning stiffness. After only 3three treatments he was ambulating directly after waking up.

Patient no. 6

a 60 year old patient who had been operated on one year earlier for a spinal stenoses with a 30% slip of the vertebral bodies, presented with a L_4 root distribution pain in one leg and a L_5 dermatome distribution in the other. After three treatments his ischias pains virtually disappeared. He was left with lower back pain which responded moderately after a daily treatment of APS Therapy.

Patient no. 7

A 23 year old patient with an ischias suggestive of a L_3 for lateral disc herniation who did not want to take leave for surgery, had good relief of pain by using APS Therapy treatment twice daily.

Patient no. 8

A 60 year old woman with listeses on several levels presented with bad muscle spasmat the lower back as well as multiple nerve root pains in the legs. She did not respond after three treatments and refused further treatment.

Patient no. 9

This patient, 23 years old, who had a fusion and instrumentation a few years earlier, had predominantly low back pain, experienced good relief from a once daily treatment.

Patient no. 10

A 35 year old man who had a discectomy L_{34} level approximately four months earlier was readmitted with acute discitis. No organism was cultured, but he was still treated with antibiotics for three months. He experienced moderate relief of pain for approximately two hours after each treatment.

Patient no. 11

A 55 year old kidney transplant patient who had a big central disc herniation. He was operated on via a transdural route. the cause of the arachnoiditis was probably because of spillage of blood in the thecal sac. He did well on APS and subsequently bought an APS Therapy device.

Patient no. 12

This was a patient who underwent multiple operations. as a result of wound sepsis with a subsequent arachnoiditis. Initially he experienced pain relief for one hour bu improved drastically with subsequent treatments.

Patient no. 16

A This last patient had a failed back surgery syndrome with arachnoiditis as well as rheumatoid arthritis. Treatments did not improve his pain.

As a group 9/13 patients responded favourably to APS Therapy. Out of the 4 patients that did not respond well, 1 experienced a slight improvement.

II Intercostal Neuralgia (4 Patients)

Patient no. 1

This patient was a 40 year old male who had intercostal neuralgia a few months after a thoracic epidural meningioma was removed. After three treatments the pain disappeared completely.

Patient no. 2

This patient was a 45 year old woman sent from a private neurosurgeon. He suspected a thoracic disc herniation, but this condition was ruled out after an MR-scan. She responded with a few hours of improvement initially. After one week's treatments, the time of improvement gradually increased. She bought an APS Therapy device and the last news from her was that she was still using the device once a day for almost 24 hours of pain relief.

Patient no. 3

This patient was a young woman in her late 20'swith an idiopathic intercostal neuralgia. Unfortunately she also had marital and psychological problems. She did not respond to APS Therapy.

Patient no. 4

The last patient had a past thoracotomy intercostal neuralgia who had a slight improvement of short duration after each treatment with APS Therapy.

The excellent results of 50% good pain relief for this difficult condition looks very promising if compared to the surgical results after DREZ lesions and even epidural stimulation.

III Cervical Syndromes (5 patients)

Patients with a cervical radiculopathy without myelopathy, either with osteophytes or "soft disc" herniations too often lands up with surgery. With a thorough trail of conservative treatment the majority may be spared unnecessary cervical discectomy and/or fusion. Within three months most of these patients will spontaneously go into lasting remission. Four out of five patients with cervical radiculopathy responded favourably with APS. 2/5 of these patients had residual radiculopathic pain after their operations and only one failure was out of this group.

IV Central Pain (5 patients)

Most of the central pain syndromes, i.e. because of damage to either spinal cord or brain tissue, respond poorly to any kind of ablation or stimulation therapy. Destructive procedures like myelotomy, often give promising initial results , but after a few months show a completely different picture.

Even though were anecdotal very rewarding results were obtained in the first case.

Patient no.1

A young boy was paraparetic pre-op and an ependymoma was diagnosed and subsequently removed. Post operatively he had bad spinal cord swelling which not only left him totally paraplegic, but also with bad post paraplegia pains in the back as well as both legs. Various medications including morphine were used to little effect.

Not only did the pains disappear after APS Therapy - he also started walking. This might have been as a result of relieving the incapacitating pain or because of another unknown effect.

Patient no. 2

This patient had bad cervical myelopathy (28 years old), for which an anterior cervical discectomy and fusion were done in order to remove a spondylitic bar .He was extremely spastic and had a deep central type of pain in both legs. APS Therapy improved the pain for between 2 - 6 hours after each session. He also reported a slight improvement in the spacticity.

Patient no. 3

A 60 year old man with bad post paraplegia pains in his legs did not respond to the therapy.

Patient no. 4

A 38 year old man who had upper extremity pain after brachial plexus avulsion from the cord, had an unsuccessful DREZ lesion. We obtained small amounts of lasting improvement for this type of phantom limb pain after each session of APS Therapy.

V Carpal Tunnel Syndromes (2 patients)

Patient no.1

A 50 year old woman who had an operation for bilateral carpal tunnel syndromes had residual pains in both hands with retrograde spreading pains to the arms and shoulders. She responded favourably to APS Therapy and experienced a total relief of pain after a once daily session.

Patient no.2

The second patient responded similarly to the first.

VI Miscellaneous (2 patients)

Patient no.1

A 47 year old man with a post polio syndrome with pain in the arms and legs responded well. He, however experienced autonomic disturbances after treatment, namely flushing, palpations and sweating.

Patient no.2

A 16 year old boy was diagnosed with primary cerebellar atrophy and reported an improvement in stiffness and better coordination after treatment with APS Therapy. (Subjective)

VII Peripheral Nerves

Numerous patients were treated with acute peripheral nerve and other peripheral injuries such as muscle injuries and musculoskeletal as well as joint injuries with good results . . .as were expected. Also arthritis, especially the single arthritic joints were treated with good results.

VIII Muscle Spasm Headache

Unexpected rebound headaches were found in a few of the abovementioned patients. After adjustment to a lower reading these problems were eliminated.

CONCLUSION

Usually the patient that seeks help from a neurosurgeon for chronic pain conditions had already tried various other modalities. Also the neurosurgeon knows that he represents the last resort.

There is a lot of stimulative and ablative procedures in his armamentarium which he can offer to the patient for various pain conditions.

Unfortunately he can never guarantee success.

If we look for instance at the failed back surgery syndrome, we see that a follow up operation is not always the answer.

> At John Hopkins Hospital, North and Zeldman found that only 34% of re-operated patients had > 50% relief of pain.
>
> Danlin Long used dorsal column stimulation in the arachnoiditis group with a 60 -70% success rate.
>
> Lumbar facet denervation procedures yielded a success of just over 50%.
>
> DREZ lesions after traumatic avulsion of nerve roots has about a 50% good result outcome.
>
> Post herpetic neuralgia - DREZ lesions - 25% long term good results.
>
> Spinal and medullary tractomies are used only for malignant pains where the life expectancy is not more than one year because of the high reoccurrence rate of pain.
>
> Deep brain stimulation, according to Robert Levy (Neurosurgery 87) had only a 25% lasting relief for intercostal neuralia patients.
>
> Tusker (Journal of Neurosurgery 92) in cases of intractable pain of spinal cord origin had an improvement.
>
> Destructive surgery (Cordotomy DREZ) - 26% improvement
> Deep brain stimulation - 36% improvement

The number of patients with whom we used APS Therapy were much too low to reach a statistical conclusion, but the trend we saw was very promising and definitely warrants a more extensive study.

If one takes into account that there were no complaints or side effects reported and the low cost involved, we propose that all patients waiting for destructive surgery should first be put on a thorough trial of APS Therapy.

APS Therapy Validation

Conducted by:

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June 1998 – August 1998

APS VALIDATION

Dr Cilliers Marais

Yorkton, Saskatchewan, Canada

An APS validation study was conducted over a 3 month period (June 1998 – August 1998). This was done in a GP practice setup which is different from a physiotherapy or chiropractic validation. In most patients no electrotherapy devices have been tried before. The outcome and results therefore are typical what one will expect from a similar GP practice setup. From the results you will notice that the study was mainly a comparison between APS therapy vs Drug therapy.

A total of 174 patients were treated. All the patients were carefully evaluated for any possible contra-indications before therapy was started.Apart from 2 superficial burns in 2 different patients, no other complications were encountered. The majority of patients were very happy with the results. Out of the 174 patients 157 had follow up treatments. Because 17 patients only had one treatment and did not return for follow up treatments, it was decided to exclude them from the study.

Out of 157 patients treated, the following observations were made:

72% improved or felt that APS therapy was better than other treatment modalities

28% did not improve or felt that APS therapy was equal to other treatment modalities

50% had immediate relief of pain

20% had immediate improvement of swelling

54% had immediate improvement of stiffness

50% had immediate improvement of mobility

23% had gradual improvement of pain

8% had gradual improvement of swelling

15% had gradual improvement of stiffness

14% had gradual improvement of mobility

Most of the patients were treated every 2nd day and the average amount of treatments were 3-5.
Most of the patients had 8 minute treatments

The following conditions were treated successfully:

Acute and chronic backache
OA of the back
Sciatica
Plantar fasciitis
Tarsal tunnel syndrome
TM joint dysfunction
Bell's Palsy
Post Herpetic neuralgia
Sartorius muscle strain
Rectus Abdominis strain
Post-operative pain
Piriformis muscle syndrome
Reflex Sympathetic Dystrophy
Hip and Shoulder Capsulitis
Supraspinatus
Archilles Tendonitis
Pain from spinal compression fractures
Osteoporosis of the spine
Fibromyalgia
Spinal nerve root irritation and Radiculophathy
OA of the shoulders and knees
Painful knee and hip prosthesis
Subacromial bursitis
Rotator cuff syndromes and shoulder impingement
Rotator cuff tears
Latissimus Dorsi Strain
Gluteus medius muscle strain
OA of the neck and cervical spondylosis
SI joint dysfunction
Swelling and pain secondary to a humerus fracture
Headaches secondary to Cervical Spondylosis
Carpal Tunnel syndrome
Tennis Elbow
Backache secondary to Spinal Stenosis
Backache from lumbar scoliosis
Backache from congenital malformations in L3 L4 L5 area
Collateral ligament injury of the knees
Iliotibial Band Syndrome
Post viral Arthopathy
Coccydynia
Prepatellar Bursitis
Pain from cervical disc protrusion
Pain from lumber disc protrusion
Intercostal muscle strain
Mechanical Backache secondary to obesity
Post-operation swelling and stiffness of the shoulder
Restless leg syndrome
Cervical, thoracic and lumbar muscle spasms
Patella femoral syndrome
Backache from degenerative disc disease and fascet joint arthritis
Backache from Scleroderma
Psoriatic Arthritis of feet and back
Post-operative stiffness of the wrist
Thoracic muscle spasm secondary to multiple sclerosis

APS VALIDATION

PATIENT #1 : 60 year old Male

Presenting Problem: Chronic lower backache and stiffness, unable to sleep as night for past few years, minimal relief with physiotherapy and massage therapy, also minimal relief with NSAIDS. Previous surgery L-5 S-1 laminectomy, as well as lumber spinal fusion. Myelogram in 1994 showed minimal spinal stenosis at L-3 L-4 level. MRI in 1994 showed minimal disc bulge at the L-3 L-4 level.

Diagnosis: Chronic lower backache following previous lower back surgery.

Treatment: patient received a total of six treatments with the APS devise. He had immediate relief after his first treatment. He also had immediate improvement in his range of motion in the lower back. After the third treatment the patient was able so sleep through the night. The patient was followed up for two weeks after his sixth treatment. He was still pain free and was still able to sleep throughout the night. The patient is a truck driver by occupation.

PATIENT #2 : 57 year old Male

Presenting Complaint: Painful left hip with radiculopathy into the left knee following three days of prolonged sitting due to book work. On examination, decreased internal and external rotation, as well as flexion of the hip. Pain with internal and external rotation.

Diagnosis: Left hip capsulitis.

Treatment: Muscle relaxants and anti-inflammatory drugs with no relief. Received one treatment of APS to the left hip with complete alleviation of his pain and symptoms.

PATIENT #3 : 33 year old Female

Presenting Complaint: Severe lower backache due to ovulation. Usually the backache. Lasts two to three days.

Diagnosis: Backache due to ovulation.

Treatment: Advil and Ponstan with not much relief. One treatment of APS resulted in Complete relief of patients symptoms within twelve hours. Electrode placement L-5 S-1 and suprapubic region, as well as both lateral hips.

PATIENT #4 : 9 year old Boy

Initial Complaint: Injured right hip and right leg in baseball match.

Diagnosis: Right sartorius muscle strain.

Treatment: Ice. Two treatments with APS over the entire muscle led so complete alleviation of his symptoms.

PATIENT #5 : 90 year old Female

Presenting Problem: Severe lower backache.

Diagnosis: Acute L-2 compression fracture and osteoporosis.

Treatment: Electrode placement T-1 to L-5, as well as L-2 to the suprapubic region.

Conclusion: Acute relief of pain in the lower lumber area, also increased range of motion. She was prescribed a lumber brace and she informed me that she was well enough to do a thousand kilometre trip the next day.

Total Treatment: One.

PATIENT #6 : 65 year old Male

Presenting Complaint: Severe pain and discomfort in both shoulders as well as the cervical region. Also chronic headaches and history of depression.

Diagnosis: Fibromyalgia and depression. Cervical spondylosis as well as antero Listhesis C-3 and C-4.

Medication and Treatment: Trimipramine 125 mg Hs, massage therapy, physiotherapy. These treatments are of limited value. Patient had been unable to sleep throughout the night for the past few years. Patient was started on APS. His neck, shoulders and back were treated. He had immediate relief of his headaches and he had been able to sleep throughout the night since treatment was initiated. He is usually pain free for two to three days as a time. He responds very well to a treatment to the neck and upper thoracic spine every three to four days. He has received a total of six treatments to date.

PATIENT #7 : 67 year old Male

Presenting Problem: Neck pain with radiation into the left shoulder. Severe cervical Spondylosis as well as intra vertebral disc space narrowing, especially at the level of C-4, C-3.

Diagnosis: C-4 nerve root irritation with radiculopathy into the left shoulder.

Treatment and Medications: Advil. Patient received three treatments of APS. He had Immediate relief of his neck pain and the referred pain into his left shoulder improved with each treatment. He was discharged after three treatments. I've noticed that this man's symptoms have been present for four months. Pads were placed on both sides of the neck at the C-3 C-4 level. The C-3 dermatrodes were also treated with the pad placement on the tip of the left shoulder.

PATIENT #8 : 76 year old Male
Presenting Problem: Severe arthralgia in both knees.

Diagnosis: Severe osteoarthritis in both knees, as well as chondrocalcinosis. Patient on waiting list for bilateral knee replacement.

Treatment: Treatments consisted of nonsteroidal anti-inflammatory drugs. Patient is not getting any relief from this and is not sleeping at night. Patient had immediate pain relief after initial treatment with APS. APS pads were placed on the sides of the knees on the joint lines. The patient is able to sleep throughout the night. He usually gets relief from 48 hours. Patient received a total of four treatments and was advised to return as needed for treatment.

PATIENT #9 : 43 year old Male

Presenting Problem: Long-standing history of severe recurrent lumbar back spasms. Nonsteroidal anti-inflammatory drugs not helping. He usually gets some relief from acupuncture.

Provisional Diagnosis: Lumbar back spasm and mechanical back discomfort secondary to degeneration of lower lumbar spine. X-rays confirm progressive narrowing of L-3 L-4 and L-5 disc spaces.

Treatment: Patient received a total of five treatments with APS. He had absolutely no relief from APS treatment.

PATIENT #10: 51 year old Male

Presenting Problem: Chronic headaches, chronic neck pain with radiation into the right arm. Patient was involved in an MVA in 1995. He sustained a whiplash injury.

Diagnosis: Chronic C-5 radiculopathy which is post traumatic. Also, post traumatic migraine and analgesic induced headaches. Emotional overlay with depression. Cervical CT Myelogram revealed minor extradural indentation as the C-5 C-6 level. No significant nerve root compression is identified to justify surgery.

Current treatment: Anti-depressants and Naproxyn. The effects are of limited value. Treatment also consisted of extensive physiotherapy, massages therapy, and chiropractic treatment, also of limited value. The patient received a total of six APS treatments but there had been very little relief in his radiculopathy symptoms. He does, however, state that he has had fewer headaches. Electrode pad placements were on the sides of the neck at the C-5 level as well as from C-5 to the right upper arm.

PATIENT #11 : 67 year old Male

Presenting Problem: Painful right shoulder after fall on shoulder two months ago.

Diagnosis: Subacromial bursitis and possible small rotator cuff tear.

Treatment: NSAIDS, with not any relief. Patient received four APS treatments without any relief of his shoulder pain. Patient will be referred to an orthopaedic surgeon to assess him for possible rotator cuff tear. If an arthogram fails to show a rotator cuff tear this patient might respond on a Cortisone injection into the subacromial bursa.

PATIENT #12 : 40 year old Male

Presenting Problem: Slipped on ice in January of 1998, and since that time pain in the left lower lumbar region and left buttock area. Examination failed to show any evidence of neurological deficit or nerve root entrapment.

Diagnosis: Chronic latissimus dorsi and gluteus medius muscle strain.

Treatment: Nonsteroidal anti-inflammatory drugs with limited relief. Patient received six APS treatments. He had gradual improvement of his symptoms to the point where he could sleep throughout the night. Best results were achieved with electrode pad placement over the L-5 area through to the umbilicus area.

PATIENT #13 : 71 year old Female

Presenting Problem: Chronic pain in the cervical region as well as right trapezius area. X-rays revealed cervical spine spondylosis with moderate prominent syndesmophytes suggesting diffused idiopathic skeletal hyperostosis .

Diagnosis: Cervical spondylosis with C-3 nerve root irritation and radiculopathy into the right shoulder area.

Treatment Modalities: Acupuncture, NSAIDS, no relief. Patient was started on APS. Patient received a total of four treatments. The patient had gradual relief of pain and improvement after the fourth treatment. Electrode pad placements were from C-3 into the right C-3 dermatome.

PATIENT #14 : 44 year old Female

Presenting Problem: Chronic left lower backache since March after lifting a heavy roast out of the oven. She works as a cook.

Diagnosis: Left SI joint dysfunction.

Treatment: Patient was treated with analgesics, NSAIDS, chiropractic treatment, as well as extensive physiotherapy. She made a very slow recovery with minimal improvement. She was started on APS treatment. She had immediate relief after the first treatment. She received a total of three treatments. Electrode placements were over the left SI joint to the left inguinal region.

PATIENT #15 : 79 year old Female

Presenting Complaint: Painful right knee of a few weeks duration. No apparent injury. On examination tender over the medial joint line, as well as the pes anserinus bursa. X-rays only showed minimal size of osteoarthrosis.

Diagnosis: Pes anserinus bursitis versus a medial meniscus lesion.

Treatment: NSAIDS, not much relief. APS: No relief with the first two treatments. She had good relief with the third treatment. Patient was pain free for three days with relapse of symptoms after three days. The fourth and fifth treatment did not give the same relief.

Conclusion: She might have a bursitis that's not responding on APS treatment. She will be referred to an orthopedic surgeon to exclude a medial meniscus lesion.

PATIENT #16 : 65 year old Female

Presenting Problem: Chronic headaches, chronic painful neck, and chronic upper thoracic backache following a whiplash injury sustained in a motor vehicle accident in 1994. X-rays of the cervical spine are normal apart from an area of calcification posterior to the C-7 spinuos process which could be indicative of previous ligamentous injury. Patient had extensive physiotherapy, massage therapy. She was seen by an orthopaedic surgeon and she had extensive rehabilitation at a tertiary centre.

Diagnosis: Chronic headaches, chronic painful neck with decreased range of motion, as well as chronic thoracic backache.

Treatment: The patient received a total of seven APS treatments. She had some improvement in the range of motion after the third treatment, but she had a relapse shortly after this. After seven treatments I came to the conclusion that she had some improvement in the range motion of her neck but no real relief in her headaches and cervical thoracic pain. Of note that this lady had been tried on various non-steroidal anti inflammatory drugs as well as anti-depressants. None of these treatments modalities worked for her. There is, however, a big component of emotional overlay.

PATIENT #17 : 65 year old Male

Presenting Problem: Bilateral carpal tunnel syndrome symptoms confirmed with conduction studies. The patient is currently waiting for surgery.

Diagnosis: Bilateral carpal tunnel syndrome.

Treatment: Patient received a total of three treatments with the APS device. He had immediate improvement in his symptoms after the first treatment. There was a remarkable reduction in the swelling of his hands and wrists. Patient will be followed up as needed for pain relief and symptomatic relief.

PATIENT #18 : 44 year old Male

Presenting Problem: Sustained acute lower lumber back injury after heavy lifting in May, 1998. Patient had previous laminectomies at L-4 and L-5.

Diagnosis: Acute lumber back injury as L-3 L-4 level with nerve root irritation into the left leg. Previous lumbar back surgery.

Treatment; Patient was started on physiotherapy. After two weeks of physiotherapy he still had severe spasm and tenderness in the L-3 L-4 area. He had some improvement in his nerve root irritation symptoms. The patient also had treatment with analgesics and nonsteroidal anti- inflammatory drugs, as well as muscle relaxants. APS treatment was initiated three weeks after his injury. The patient had no relief after two treatments. Treatments were mainly aimed the lower back. The third treatment was with one pad placement over the L-3 area and another pad placement over the L-3 dermatome, as well as the left groin area. Patient had remarkable improvement after the third treatment session and he was discharged to come back as needed after the fourth treatment.

PATIENT #19 : 42 year old Female

Presenting Problem: Right rectus abdominis muscle injury following a hysterectomy in February 1998. She also has associated right lower quadrant pain with radiation into the right thigh. She also has significant dyspareunia on the right side. She had severe tenderness over the right lower quadrant with palpation.

Diagnosis: Chronic right abdominal pain following hysterectomy, most likely secondary to superficial nerve entrapment or chronic abdominal muscle injury.

Treatment: Patient had received a total of eight treatments so far. Electrode placements were over the whole length of the rectus abdominis muscle as well as the T-12 dermatrode. Her recovery with APS treatment had been very slow, but subjectively she feels that there is progressive improvement with each treatment. There was a marginal decrease in the swelling on the right side.

PATIENT #20 : 63 year old Female

Presenting Problem: Chronic lower backache, unable to sleep as night, very poor response to appropriate analgesics and muscle relaxants. The patient cannot tolerate nonsteroidal anti-inflammatory drugs. X-rays of the lumbar sacral spine shows evidence of early spinal stenosis. The patient has symptoms of pain radiating into both legs, as well as associated paresthesia.

Diagnosis: chronic low backache with radiation into both legs, secondary to early spinal stenosis. Patient is waiting to see a neurosurgeon for possible back surgery.

Treatment: Patient was initiated on APS treatment concentrating on pad placements on the spine as well as L-3 or 4 dermatomes. So far patient has had six treatments. She has had progressive improvement in her symptoms and is able to sleep throughout the night. She will continue to come for treatment every three to four days.

PATIENT #21 : 38 year old Male

Presenting Problem: Eight month history of lower backache with paresthesia into both legs. X-rays showed multi level spondylosis with degenerative disc narrowing at L-4 L-5 and L-5 L-6. Neurological examination is essentially normal.

Treatment: Patient received a total of two APS treatments. He had immediate relief in his lower backache. He was discharged after the second treatment and will come back as needed. Patient tried NSAIDS before without any significant success.

PATIENT #22 : 77 year old Female

Presenting Problem: chronic right shoulder pain. X-rays confirmed advanced osteoarthritis of the right shoulder. Patient was advised to have a total shoulder replacement.

Diagnosis: Advanced osteoarthritis of the right shoulder.

Treatment: Patient received two shots of Cortisone, as well as physiotherapy. None of this caused any significant relief in her symptoms. Patient received a total of two APS treatments. She had immediate relief of pain after each treatment, as well as increased range of motion of the right shoulder. She will be followed up as needed for symptomatic relief.

PATIENT #23 : 35 year old Female

Presenting Problem: Chronic left knee and weakness in the quadriceps tendon after left knee quadriceps tendon reconstruction. Evidence of severe quadriceps atrophy due to lack of usage of the quadriceps muscle. She had evidence of quadriceps tendonitis as well as prepatellar bursitis. This lady had been followed up for orthopaedic surgeon extensively. She had received extensive physiotherapy and she is currently using a knee brace to stabilize her leg.

Diagnosis: Prepatellar bursitis, quadriceps tendinitis with secondary quadriceps atrophy.

Treatment: This lady has received a total of eight APS treatments so far. There has been minimal relief in her pain symptoms but there has been remarkable improvement every second day. She was encouraged to start with quadriceps strengthening exercises.

PATIENT #24 : 62 year old Female

Presenting Problem: chronic lower backache.

Diagnosis: Chronic lower backache from of lumbar scoliosis, congenital malformations in the L-3, L-4 and L-5 area and osteoporosis.

Treatment: Narcotic analgesics and Fosamax. APS treatment was mainly aimed at treating the spine. She had immediate relief from pain. She usually gets three to four days of good pain relief and improved range of motion from one treatment.

PATIENT #25 : 41 year old Male

Presenting Problem: This patient fell of roof in February, 1998 injuring his neck and lower back. He sustained compression fractures to C-7, as well as transverse process fractures on the right side of L-3 L-4 and L-5. He's in chronic pain and was getting very little relief from nonsteroidal anti-inflammatory drugs, analgesics and physiotherapy. He currently still complains of severe pain in back with pain radiating into the right gluteal area. He has specific tenderness in the right gluteal area.

Diagnosis: Lower back injury with radiculopathy into the right leg.

Treatment: He received a total of six APS treatments mainly concentrating on the lower back and the right sciatic. He had good relief of pain after his third treatment. His pain returns after two to three days. He is scheduled to have a CT scan and myelogram to exclude any disc herniation. He will also have an EMG study so exclude peripheral compression on the sciatic nerve through the area of transverse process fractures.

Conclusion: This gentleman is getting relief from APS therapy but he has ongoing discomfort in his right lumbar and gluteal area. Diagnosis not established yet.

PATIENT #26 : 41 year old Male

Presenting Problem: Rotational valgus type injury to the left knee two months ago. No relief with nonsteroidal anti-inflammatories and pain killers.

Diagnosis: Medial collateral ligament injury as well as suspected medial meniscus injury of the left knee.

Treatment: Patient had immediate relief after one treatment with APS. The pads were placed over the joint lines on both sides. He was discharged to come back as needed after his second treatment. He will probably require as athroscopy of he has any recurrent medial meniscus symptoms.

Neurohormonal Consequences of APS Therapy

Study carried out by : Prof. Dr. J.M.C. Oosthuizen MBCHB; DMEDSCI
(Head of the Dept. of Physiology; University of the Free State)

Prof. Dr. E.H. de Wet MBCHB; MMED; MD
(Dept. of Physiology; University of the Free State)

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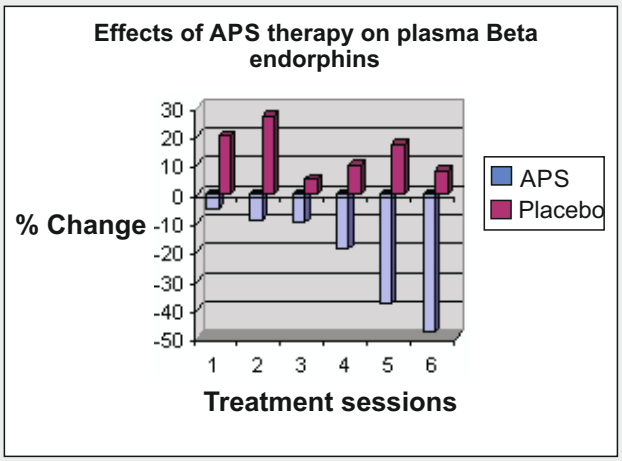
Beta-endorphin



Beta-endorphin, the bodies endogenous analgesic, is a peptide consisting of 31 amino acids with properties similar to morphine.

Disadvantages of abnormally high concentrations of plasma beta-endorphin.

- **Decreases/volume of the heart.**
  (Leads to deterioration in patients with heart failure)
- **Decreases coronary blood flow.**
  (Compromises patients with ischaemic heart disease and angina Pectoris)
- **Suppresses breathing/decreases tidal volume and respiratory rate.**
  (Leads to deterioration in patients with chronic obstuctive pulmonary disease, emphysema and/or diffusion disturbances).
- **Increases appetite for food and alcohol.**
  (Causes deterioration of overweight in patients with chronic pain due to large joint disease).
- **Inhibits the corticoliberin-corticotropin-cortisol axis.**
  (Leads to a negative pain experience).
- **Enhances emotional stress.**
  (Leads to a negative pain experience).

Advantages of a decrease in plasma beta-endorphin concentrations.

With the use of APS therapy, plasma beta-endorphin concentrations decrease.
This positive results leads to:

- The availability opioid receptors for binding with other potent endogenous opioids the (leukine enkephalin) or analgesics.
- APS therapy is safe in patients with:
  - Heart failure.

- Ischaemic heart disease, angina pectoris.
- Chronic obstructive pulmonary diseases.
- Emphysema.
- Respiratory diffusion disorders.

- APS therapy may assist in regulating alcohol intake.
- APS therapy releases the inhibition of beta-endorphin on cortisol production. Cortisol has potent anti-inflammatory effects.
- APS therapy will result in the more realistic self-assessment of pain.

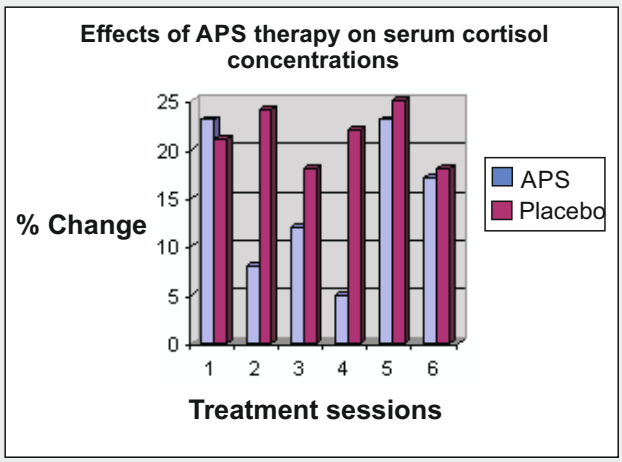
Conclusions

1. Findings in the treatment group were attributed solely to APS therapy. (Due to effective removal of pain.)
2. On average, a minimum of 5 treatments were required for the desired effect.
3. Findings in the treatment group were consistent with the effect of epidural block for chronic pain.

Cortisol

Cortisol is essential for life because of its major role in maintaining harmonised bodily functions, such as normal psyche, normal glucose metabolism and normal endogenous anti-inflammatory mechanisms.

The findings on cortisol



Non significant changes in both the treatment group as well as the placebo group.

Advantages of normal serum cortisol concentrations:

With the use of APS therapy, serum cortisol concentrations remain within the normal range.
This positive result leads to:

- Maintenance of the normal psyche.
- Maintenance of normal glucose metabolism.

- Maintenance of normal endogenous anti-inflammatory mechanisms.

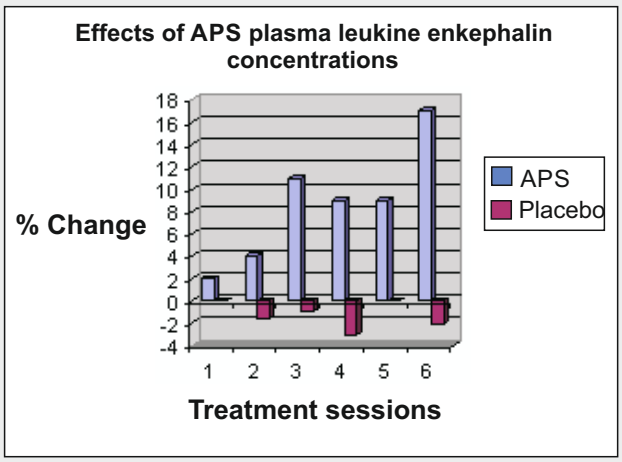
Conclusions

1. Findings in both groups were attributed to the normal circadian fluctuations in cortisol secretion
2. Essentially serum cortisol concentrations remain within the normal range.

Leukine enkephalin

Leukine enkephalin, the human bodies endogenous analgesic is a pentapeptide consisting of five amino acids with analgesic properties. The findings on leukine enkephalin.

The findings on leukine enkephalin.



Progressive increase with physiological and clinical relevance in the treatment group, with non significant changes in the placebo group.

Advantages of an increase in plasma leukine enkephalin concentrations.

With the use of APS therapy, plasma leukine enkephalin concentrations increase. This positive results leads to:

- More effective analgesic due to interaction with opioid receptors as well as inhibition of substance P (the neurotransmitter responsible for pain transmission).
- Limitations of tissue damage at sites of inflammation and/or hypoxia.
- Increase in pulse rate and systemic blood pressure, associated with peripheral vasodilation which results in better perfusion at the affected areas.
- APS therapy is safe in patients with ischaemic heart disease and/or angina pectoris.

Conclusions

1. Findings in the treatment group were attributed to APS therapy.
2. On average, a minimum of 4 treatments was required for the desired effect.

3. Findings in the treatment group were contrary to the effect on an epidural block for chronic pain.

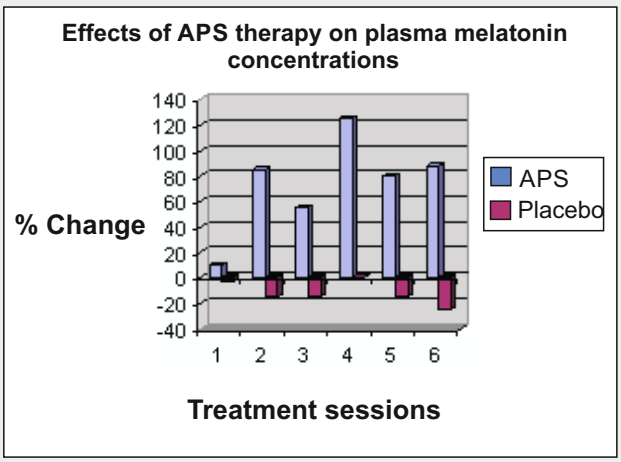
Melatonin

Melatonin, the human bodies endogenous anti anxiety agent, is a derivative from the nutritionally essential amino acids tryptophane, with sedative and anxiolytic properties.

The most notable physiological effects of melatonin include:

- Sedation
- Relief of anxiety
- Analgesia
- Activation of anti-inflammatory mechanisms

The findings on melatonin



Progressive increase with physiological and clinical relevance in the treatment group, with non significant changes in the placebo group.

Advantages of an increase in plasma melatonin concentrations:

With the use of APS therapy plasma melatonin concentrations increase.
This positive result leads to:

- More effective analgesic.
- Sedation and reduction of anxiety.
- Enhancement of renal function with more effective removal of waste products.
- Patients with renal pathology can safely apply this device.
- Local vasodilation and anticoagulation, with limitation of tissue damage at sites of inflammation due to the effects on prostaglandins and free oxygen radicals. (Apply APS therapy with caution in patients using anticoagulation therapy warfarin, heparin).
- APS therapy is safe for patients suffering from ischaemic heart disease and/or angina pectoris.
- APS therapy may be effective in the prevention of seasonal affective disorders and normalisation of sleep patterns.

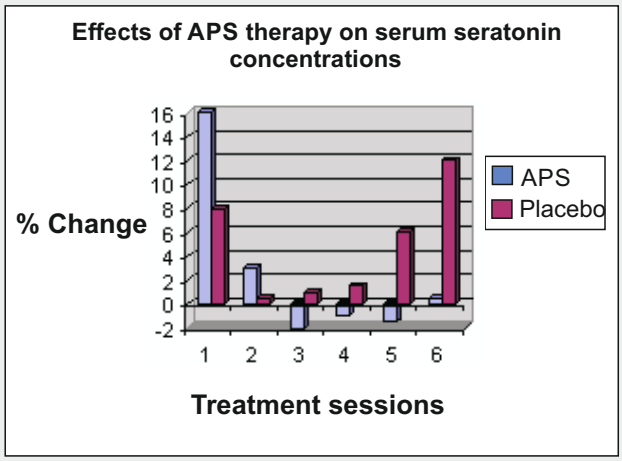
Conclusions

1. Findings in the treatment group were attributed to APS therapy.
2. On average, a minimum of two treatments were required for the desired effect.

Seratonin

Seratonin is the endogenous derivative from the nutritionally essential amino acid tryptophane with antidepressant and anorectic properties. There is outcry about the safety of elevated seratonin levels.

The findings on seratonin:



Non significant changes in both the treatment group as well as the placebo group.

Advantages of normal serum seratonin concentrations:

With the use of APS therapy, serum seratonin concentrations remain within the normal range.
This positive result leads to:

- A low risk of anxiety disorders and depression.
- No risk of seratonin syndrome which is associated with heart valve lesions.
- A low risk of the derangement of the secretion of other life sustaining hormones, e.g. beta-endorphin, melatonin and grow hormones.
- Adequate amounts of seratonin available for the biosynthesis of melatonin.

Conclusions

1. Findings during the first treatment session in the treatment group were attributed to two treatments of 16 minutes. 2. Essentially serum seratonin concentrations remain within the normal range.

Summary

Indications for the use of the APS Therapy device (scientifically proven).

- **Acute and chronic pain conditions**
- **Sports injuries**

APS Therapy has the following effects on pain management:

1. Analgesia, owing to more effective utilisation of endogenous opoids and the inhibition of pain transmission.
2. Reduction of pain and more realistic self-assessment of pain.
3. Anti-inflammatory effects, owing to beneficial influences of the prostaglandin mechanisms involved in inflammation.
4. Local vasodilation and better perfusion of affected areas with limitation of tissue damage at sites of inflammation/hypoxia.

Please take note:

The APS Therapy device can be safely used on patients suffering from:

- Heart failure.
- Ischemic heart disease and engina pectoris.
- Vascular insufficiency.
- Chronic obstructive pulmonary disease, emphysema and/or respiratory diffusion disorders.
- Renal pathology.
- Thrombosis.
- Pain associated with cancer.A

Please take note:

- The APS Therapy device was not tested on pregnant women or children under the age of 12 years.
- The APS Therapy device should be used with caution on patients on anti-clotting therapy, as well as underweight persons. (BMI ‹19kg/m2) Medical supervision is advised.
- The efficiacy of the APS Therapy device may be compromised by the concurrent intake of alchohol, ß-blockers (sympatholytics), and non-steroidal anti-inflammatory analgesics.

Recommendations

- A minimum of five treatment sessions of APS Therapy is indicated. Is a patient does not respond after six treatment sessions, treatment should be discontinued temporarily for at least on week. In cases where there is no pain relief after six treatment sessions, the patient should be referred to a physician.

- A balanced diet providing essential nutrients, is recommended. For a beneficial effect, additional supplementation with amino acids and calcium is strongly recommended.

Areas indicated for further research:

- Regulation of food and alchohol intake.
- Prevention of seasonal affectice isorders, depression and jet lag.
- Normalisation of sleep patterns.
- Improvement of blood circulation in patients with cardiovascular disorders, vascular insufficiency and renal pathology.
- Possibility of substitution of anti-inflammatory drugs/antidepressants/sedatives and sleeping tablets.

The Use of APS Therapy in Leg Ulcer Treatment

A case study of a patient with a chronic wound

Published Reserach in Health & Hygiene January 2000
Dr. Kahl (Van der Bijlpark SA)

The Use of APS
therapy in leg ulcer treatment

Dr P. Kahl
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On the previous page attention was given to the approach to follow when treating a patient with chronic wounds. In this case study you should be able to identify the approach that was suggested. You should also try to identify the aspects that are assessed regarding wounds. List them as you read along. In the next issue of Health 8- Hygiene, you can evaluate yourself when the assessment of wounds is discussed.

Case History
Fourteen months ago the 74-year-old wife of a retired farmer drove 500km to consult me about two venous leg ulcers of 15 years' duration- one lateral and one medial on the lower third part of the left leg. She was obese, hypertensive and had had a deep vein thrombosis 15 years previously in the left leg. She was on treatment for the two last-mentioned conditions.

According to her history she was allergic to most antibiotics and traditionally used wound care products like Eusol and Betadine. She twice had skin grafts done which were both unsuccessful. She spent several weeks at a time in hospital - without success. She consulted different medical doctors, but no healing took place.

The first time she visited me her wounds were dressed with hydrophilic polyurethane dressing (once or twice a day!) and a retention bandage to keep the dressing in situ. The bandage was wet with exudate. The wound care products had been prescribed to her at the provincial hospital. She could not stand or sit for long periods of time and the ulcers were very painful. Pain, however, diminished when the leg was evaluated.

She had smoked previously, but not any longer, and did not take alcohol. She lived with her husband and could stay with their children in Potchefstroom while on treatment.

Although the Continuity of daily treatment upset her, she was very positive the treatment which she had heard about from a pharmacist who referred her to me.

Physical examination and wound assessment
Proximally and distally l0 the bandage the leg had pitting oedema. Due to the oedema the Ankle Pressure Index could not be measured. The capillary refill in her toes was good. Her blood pressure was 160/85mm Hg.

She had extensive lipodermatosclerosis. Wound exudate was superfluous without being malodorous and the skin surrounding the wounds was macerated. They were full-thickness wounds and their bases red with granulation tissue.

The size of the wounds was: Medially; Superior-Inferior = 60mm; Posterior- Anterior: 67mm; Laterally: Superior-Inferior = 106mm; Posterior-Anterior = 73mm. The two ulcers were 10mm apart posteriorly over the Achilles Tendon. A tracing of the wounds was made and photos were taken.

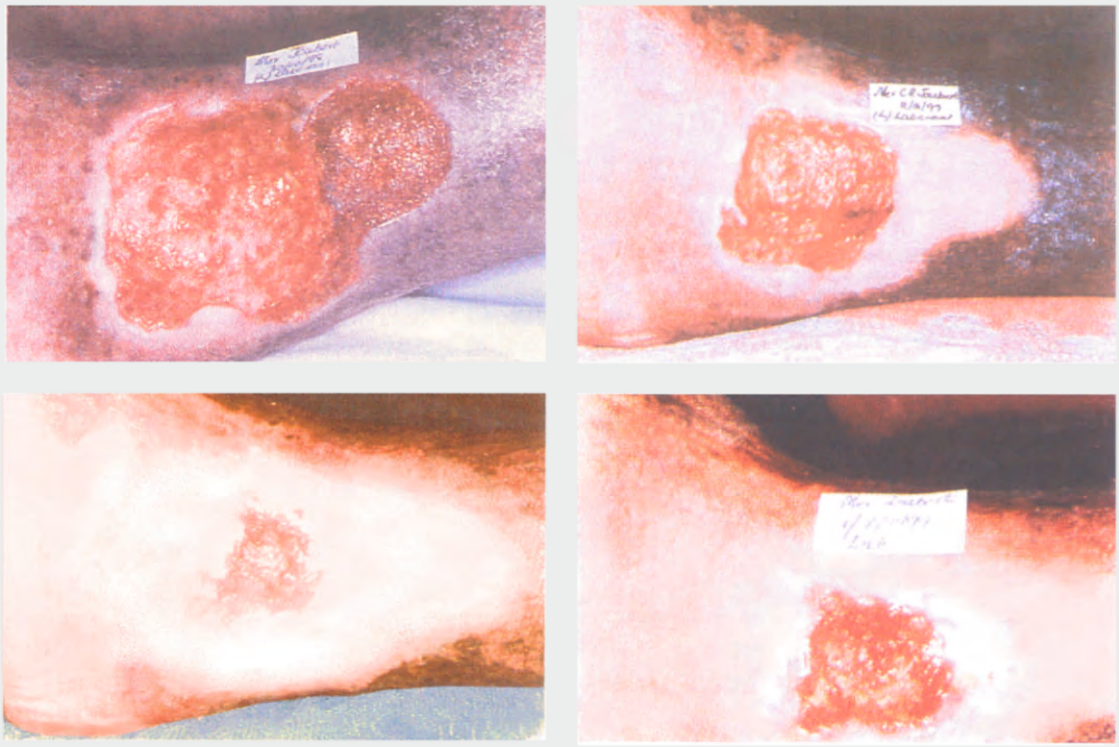
Discussion
The main reason for the wounds and pain, namely venous hypertension causing oedema, was not treated and therefore the wounds could not heal and pain could not be relieved.

Although she had very effective products to dress the wounds, they were not cost effective seeing that the wounds had to be dressed twice daily at a cost of R175 for dressings alone!

The skin maceration around the wounds would only deteriorate, causing enlargement of the ulcer due to no protection of the skin against the superfluous exudate. She did not take Vitamin C, the only essential vitamin to be added when a patient's wounds are treated.

Treatment
The suggested treatment and its aims were:

- to motivate the patient to accept the suggestions for treatment by informing her about the causes of the wounds and the treatment, based on scientific findings;
- to improve blood supply to the leg by using the Bio-Beam 660nm for eight minutes at a time;



Clockwise: These photographs show the positive progression of the lateral wound over time.

- to protect the surrounding skin with zinc oxide paste/barrier cream;
- to prevent scabbing and itching under bandages by applying a mixture of Vaseline and Liquid Paraffin and an anti-pruritic ointment and tablets;
- to absorb the exudate effectively by using an alginate dressing and hydrophilic polyurethane dressing, as well as the orthopaedic wool, as part of the four-layer compression bandaging;
- to promote back flow of venous blood to the heart by the four-layer compression bandaging technique;
- to monitor the progress of the wounds scientifically by taking tracings and photographs monthly;
- to repeat treatment according to the amount of exudate and/or discomfort of the patient; and
- to promote wound healing by keeping her healthy in body, mind and spirit.

The treatment was accepted and started on the first visit. The wounds were heavily exuding and sometimes treated up to three times a week and later twice a week. The wounds progressed well for two months. Thereafter granulation was stunted.

The patient's emotional health was also an attributory factor to the slow progress, as during that' time her daughter-in-law was terminally ill and subsequently died, She was very upset and developed pruritis under the bandages; which was treated systemically. A natural antidepressant was also prescribed. The wounds were heavily to moderately exuding and at times greenish in appearance and slightly offensive. She developed flu with a secondary bronchitis and was very ill for one week. At that time she was on systemic antibiotics for the flu and topical antibiotics for the wound. The wound care was then applied every second day.

In April last year, six months after treatment was commenced, I bought an Action Potential Simulation (APS} apparatus. According to scientific findings the APS therapy, by means of neurostimulation, improves microcirculation and evokes an anti-inflammatory response - thus helping against the superfluous exudate and pain.

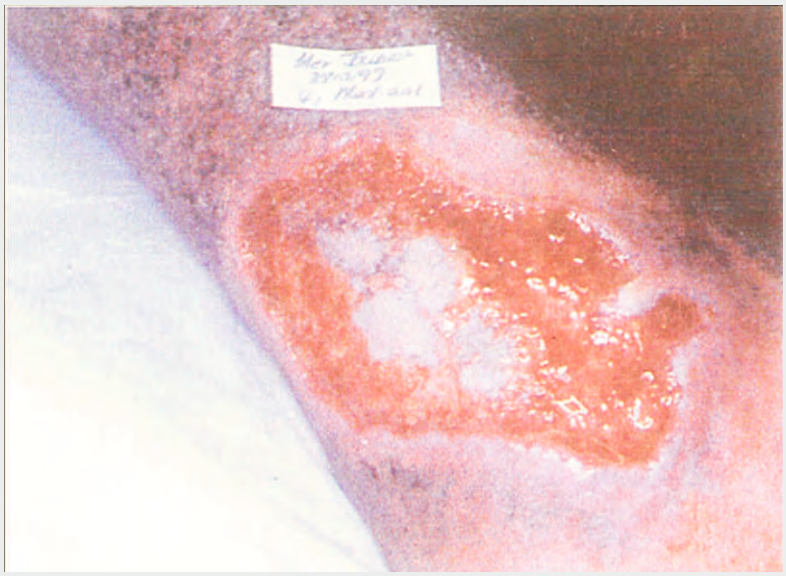
The APS treatment, in coordination with the four-layer compression bandaging, commenced on '26 April 1999 (instead of using the Bio~Beam treatment). Four dermatodes were placed around the wound and stimulation was applied for eight minutes. Thereafter the dermatodes were placed bilaterally to the spinal column: superior, two were placed distal to the neck; and inferior, two were placed proximal to the sacral area. Neurostimulation was then applied for I6 minutes - a total of 24 minutes per day as indicated by the manufacturers.

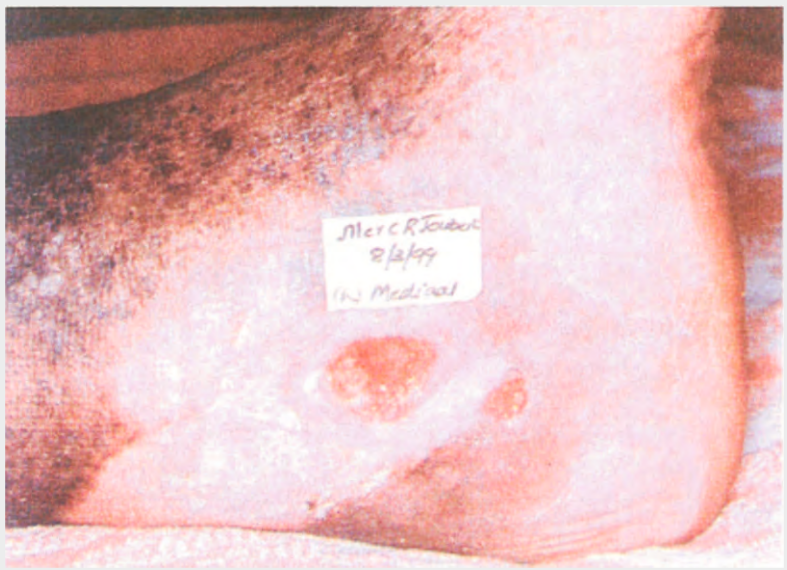
Two treatments after the commencement of this regimen, the wounds started to granulate better and exudate was less; the wounds started to epitheliase. Now we could start dressing them twice a week. The improvement in the wounds was astonishing.

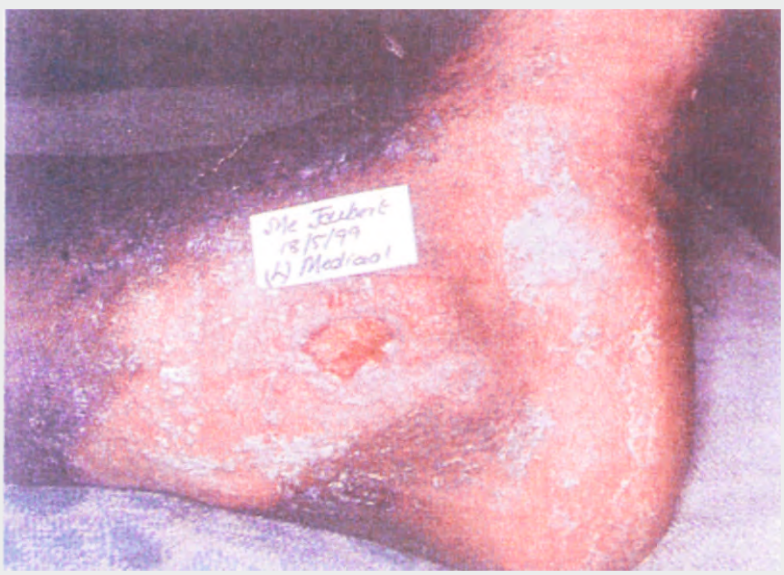
From 14 July 1999 to the present, the wounds were dressed only once a week. The medial wound was completely covered with epithelium on 27 July 1999.

The size of the lateral wound is now 25mm in circumference. The patient does not complain about pain, except for arthritic pains now and then. She is very happy because, just perhaps her legs will be free of ulcers this year -for the first time in 16 years!

What a woman she is! I never had to encourage her to continue with the treatment- she was always very positive about it.







These photographs show the positive progression of the medial wound over time.

APS Therapy Altering ATP Levels

Head of Project JC Seegers,
(Faculty of Science Department of Physics Senior Lecturer)
M-L Lottering, AM Joubert, F Joubert,
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Abstract
Recently it was shown that extracellular ATP, acting through purinergic receptors, has many physiological functions, including opening of Ca2+-ion channels, activation and mediation of signal tranduction mechanisms as well as activation of the pain sensation. Since electrical stimulation is also known to affect many signal transduction processes as well as the alleviation of pain, we hypothesized that electric stimulation may affect the extracellular release of ATP. We investigated the effects of a small DC electric field (101–102 V m−1 range and with frequencies below 150 Hz) on the release of ATP in vitro (HeLa cells), and on the levels of ATP in vivo (the plasma of healthy volunteers). In HeLa cells ATP release was increased 50 fold, while the total amount of ATP in the cells was increased by 163%. In the plasma a significant decrease ($P<0.05$) in ATP concentration was seen after electrical stimulation, in all the volunteers. The small DC electric field also affected the cAMP signal transduction system in vitro (HeLa cells and human lymphocytes) and in vivo (human plasma). Decreased levels of cAMP ($P<0.05$) were seen in HeLa cells and increased levels of cAMP ($P<0.05$) in isolated human lymphocytes. The cAMP levels in the plasma of the electrically treated volunteers were lower than control values. These results show that the frequency, waveform and signal strength of the applied electric field are suitable for effecting measurable changes on signal transduction in vitro and in vivo.

Study
The aim of the study was to investigate the effects of the application of a small amplitude, direct current (DC), (APS Therapy) pulsed electrical field on extracellular and intracellular ATP levels and total (intracellular and secreted) cAMP levels in in vitro and in vivo systems. Method Two APS devices were used, delivering a periodic, direct current, pulsed electrical field. The pulsed frequency used was 150Hz and the duration of treatment was 8 minutes for all studies. ATP was determined with an ATP Bioluminescence assay kit. cAMP was determined with a cAMP Enzyme-immunoassay system.

Results
In all nine Results ATP levels in vitro showed that the total concentration of ATP (intracellular and extracellular) was, however significantly, higher in the electrically treated cells. The total cAMP levels were decreased in cultured HeLa cells with electrical treatment. Further results showed the total cAMP levels were significantly increased in isolated lymphocytes with electrical treatment.

Conclusion
The clear effects on ATP and cAMP levels seen in these experiments indicate that the frequency, waveform and signal strength of the applied electrical field, is suitable for affecting measurable changes in the body.

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APS Therapy Assessment by 285 Patients with Chronic Pain

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APS Therapy Assessment by 285 Patients with Chronic Pain

Project:Van Papendorp DH, Kruger MC, Maritz C, Dippenaar NG.
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Nociception is defined as the neural response to noxious stimulation, pain as the conscious perception of nociception, and pain expression as the verbal coupled to behavioural signals that allow the clinician to assess the severity of the nociceptive stimulus. The outward expression of pain is influenced by a variety of biopsychosocial factors including culture, mood and psychological state, and physical function. In addition, as the brain is actively involved in modulating and processing nociceptive stimuli, cognitive function is also likely to influence pain expression.

Excitable tissues, muscles and nerves, can be stimulated by suitable currents. This may lead to many effects such as muscle contraction and modification of pain perception through the stimulation of the motor or sensory nerves. All sensations recognised at a conscious level, can be altered by the central nervous system. Chronic pain, which is recognised as slow pain, as opposed to acute pain (carried by small myelinated A-delta fibres and recognised as fast pain), is equated with tissue damage and is carried by small unmyelinated C-fibres[5].

The gate control theory suggested by Melzack and Wall in 1965, proposed that pain perception is regulated by a physiological "gate" which may be opened or closed, thus increasing or decreasing the pain perceived, by means of other inputs from peripheral nerves or from the central nervous system[6]. The A-beta fibres, low threshold mechanoreceptors from the skin, travel without synapsing, up the posterior columns of the spinal cord. These fibres give off collaterals, which impinge on the nociceptor cells of the A-delta and C-pain fibres in different laminae of the substantia gelatinosa of the spinal cord. It is believed that input from these mechanoreceptors effectively reduces the excitability of the nociceptor cells to pain-generated stimuli[7].

Thus electrical impulses, which stimulate these A-beta mechanoreceptor fibres, are effective in reducing pain perception. “From the spinal region, transmission proceeds onward to supra-spinal levels, where pain perception is altered through the release of endogenous opioids.” These and other substances are released at many other key regions in the brain and spinal cord, and through efferent discharge in local regions too.

Evidence has also shown that various forms of electrotherapy are capable of restoring normal cell membrane potential, thus affecting tissue growth and repair[8].

Opiates exert their action in the central nervous system by binding to specific receptors, and it has been discovered that there is an increased density of receptors in regions where electrical stimulation has an antinociceptive effect. An intense search for the natural ligand to these receptors led to the isolation of a number of endogenous opioid peptides, e.g., the enkephalins and the endorphins. It has also been discovered that they exert an inhibitory modulation on the transmission of pain impulses. Furthermore, the electrical stimulation which leads to pain control and relief, sometimes correlated with the release of endogenous opioids.[9.10.11]

Electrotherapy is the use of electricity to cause a specific physiological response, and is a well known and accepted treatment modality used by physiotherapists. There are many different electrotherapy modalities available, each defined by different parameters such as frequency and intensity. Electrotherapy is considered to be an effective way of treating clinical conditions such as pain and swelling, by causing peripheral vasodilatation, which results in better perfusion of the affected areas.

The potential advantage of electrical stimulation, as an adjunct to other pain therapies, is that this treatment modality is non-invasive and relatively safe. Such treatments have minimal side effects, assist in the reduction of medication and may improve the quality of life of the patient, permitting return to normal working and social activities[12].

In 1992, a new electrotherapy modality was designed and brought onto the South African market - known as Action Potential Simulation (APS) Therapy. It was developed specifically for use in pain relief and pain control and for the improvement of mobility of stiff joints and muscles.[13] The device uses an electrical

current that supposedly mimics the normal physiological action potential of nerve conduction. This may be a unique concept to electro-physics. The device is said to produce action potentials that are four times stronger than those naturally occurring in the neuron.[8] When swelling, inflammation, poor circulation and pain occur due to mechanical, chemical or electrical disturbances, by stimulating the body's natural regenerative processes (as in depolarisation), these conditions are encouraged to resolve.

Various instruments have been designed for the actual measurement of the degree of pain; for example, the verbal rating scale; McGill pain questionnaire, pain drawings and descriptor pain perception profile, to name a few.[14,15] Each measuring instrument has its own degree of reliability and validity.[14] The word pain tends to be confusing. For some it is merely a pinprick, while for others it is an unbearable sensation. This makes it difficult to compare individuals' experiences of pain.[15,16] Thus the clinician, in order to evaluate the efficacy of pain intervention, due to lack of more substantive methods, must surely rely on self assessment of pain relief and control by patients. Use can be made of a pain intensity scale where each patient acts as its own control.

The aim of this study then was to allow self assessment, before and after APS therapy of,

1. Pain relief
2. Improvement in mobility by patients with chronic pain and stiffness.

Subjects and Methods

Approval for the study was obtained from the combined Ethics Committee of the University of Pretoria and the Gauteng Provincial Health Authorities.

Patients, who routinely attended two pain clinics for therapy, were used in this study. The total number of patients were 285. The clinical diagnosis varied considerably and was anatomically 'classified' as back, neck, knees, hands, hips, etc.

After a thorough physical examination, all patients were asked to fill in a visual analog pain scale (VAPS) and mobility index (MI). Every patient gave a VAPS value for their specific pain condition. This value represented a combined impression of their pain for the previous week and was the baseline on which the whole study was built.

The VAPS consists of a 10cm horizontal line bounded by "no pain" on the left and "worst pain imaginable" on the right end. Patients indicate their pain intensity on a 1-10 scale. The MI is a self-report and instrument to assess the degree to which chronic pain interferes with daily activities.[17+18] It has test-retest reliability and validity. As MI seems to be associated with levels of pain expression shown by patients,[17] VAPS and MI's were re-assessed in patients after five days of APS therapy. The average duration of treatment was 12 minutes with an intensity of between 1,1 and 1,3 mA.

Technical specifications of the APS Therapy Device

Wave form: Simulated Action Potential

Wave Type: Monophasic Square Pulse with Exponential Decay

Amplitude: Adjustable, 0-24.4 mA peak into 500 ohm load

Pulse rate: 150 Hz

Modulation:Variable pulse width; automatic adjustment depending on distance between electrodes

Burst: Continuous

Voltage: 0-46 Volts (open circuit)

Table I: The demographics of the study population.

Total number of patients	285	Percentage
Male	161	56
Female	124	44
Mean age	50	
Male	42	
Female	60	
Oldest Patient	94	
Youngest Patient	9	
Medication		
Anti-inflammatory	48	17
Analgesics	4	1
No medication	233	82

The VAPS and MI before day 1 and after day 5 for all the patients as a whole are shown in table II. The mean VAPS and MI improved dramatically from 6,6 and 6,5 to 2,7 and 3,3 respectively.

Table II: The visual analog pain scale and mobility index before and after treatment

	Before treatment		After 5 treatments	
	Mean	STDev	Mean	STDev
VAPS (total)	6.6	1.4	2.7*	2
VAPS (male)	6.4	1.5	2.3*	2.1
VAPS (female)	6.8	1.1	3.3*	1.7
Mobility (total)	6.5	1.4	3.3*	1.8
Mobility (male)	6.4	1.5	3.2*	1.9
Mobility (female)	6.8	1.1	3.5*	1.7

These changes are also depicted in fig I and II. *P<0.001.

The 'anatomical' classification of different injuries and conditions were as follows: The largest 2 groups (97 + 45) were classified as back and neck patients. These patients suffered mostly from back and neck pain due to spondilosis, disc degeneration with narrowing of the intervertebral disc spaces, paravertebral osteoarthritis, previous back surgery, spandilolisthesis, spandilolysis and N.ischiaclicus root irritation, postural and mechanical (functional) back and neck ache. Clinical diagnosis in the other groups included osteoarthritis, rheumatoid arthritis, gouty arthritis, menisci lesions, ligamentous injuries, malalignment, flat feet, planter fasciitis, rotation cuff syndrome, bad circulation, varicose veins, migraine, carpal tunnel syndrome, osteoarthritis jaw, tennis elbow, muscle spasms, etc. The effect before and after treatment on the VAPS and MI are depicted in Fig 1 and 2. In all groups, except for that with arms and jaw pain, the changes in VAPS were statistically significant (P < 0.001). The small number of subjects (3) in the arms and jaw group may explain their non-significant results.

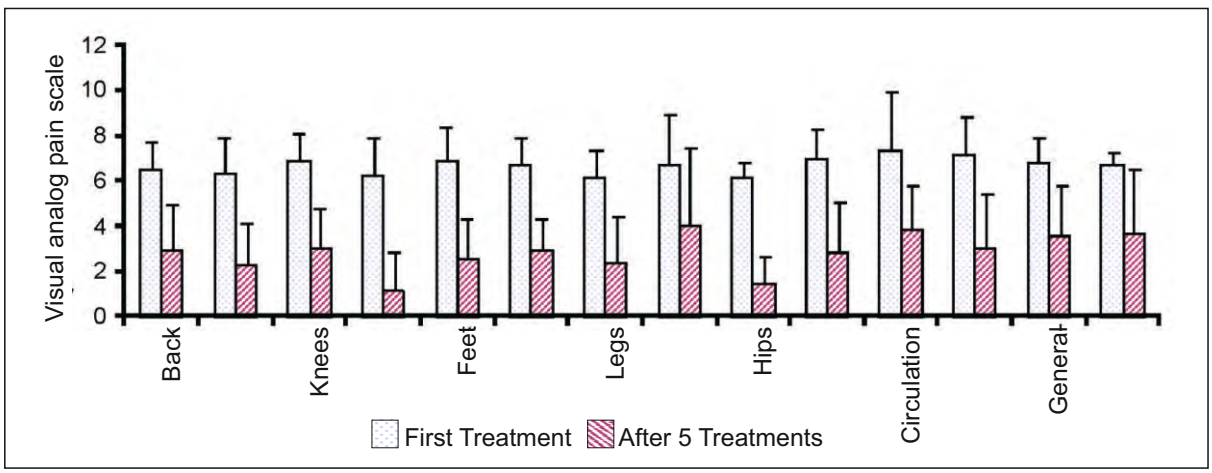

Figure 1. The effect of APS treatment on VAPS.

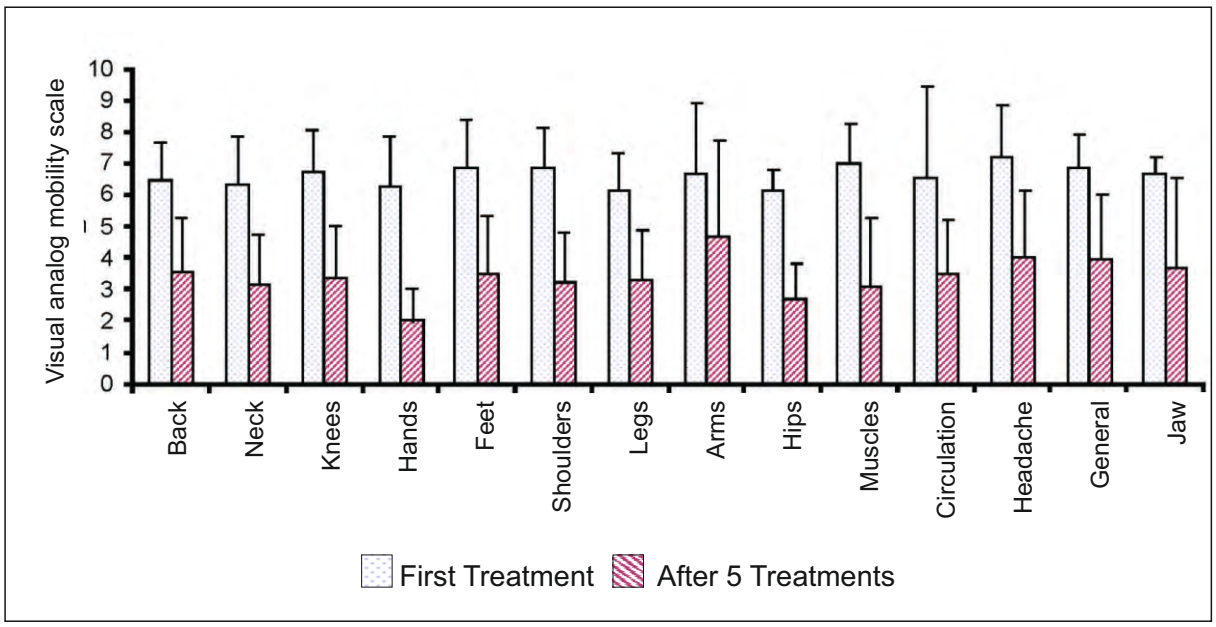

Figure 2. The effect of APS treatment on mobility index (MI).

The patients were also divided in an above 50 years of age group and a below 50 years of age group, for both the VAPS and MI. The average value as a whole for the VAPS for >50 years was 6,8 before treatment and 3,3 after treatment. In the <50 years age group, it was 6,3 and 2,2 respectively. Although both age groups improved dramatically there was a 15 % overall better response in the older age group.

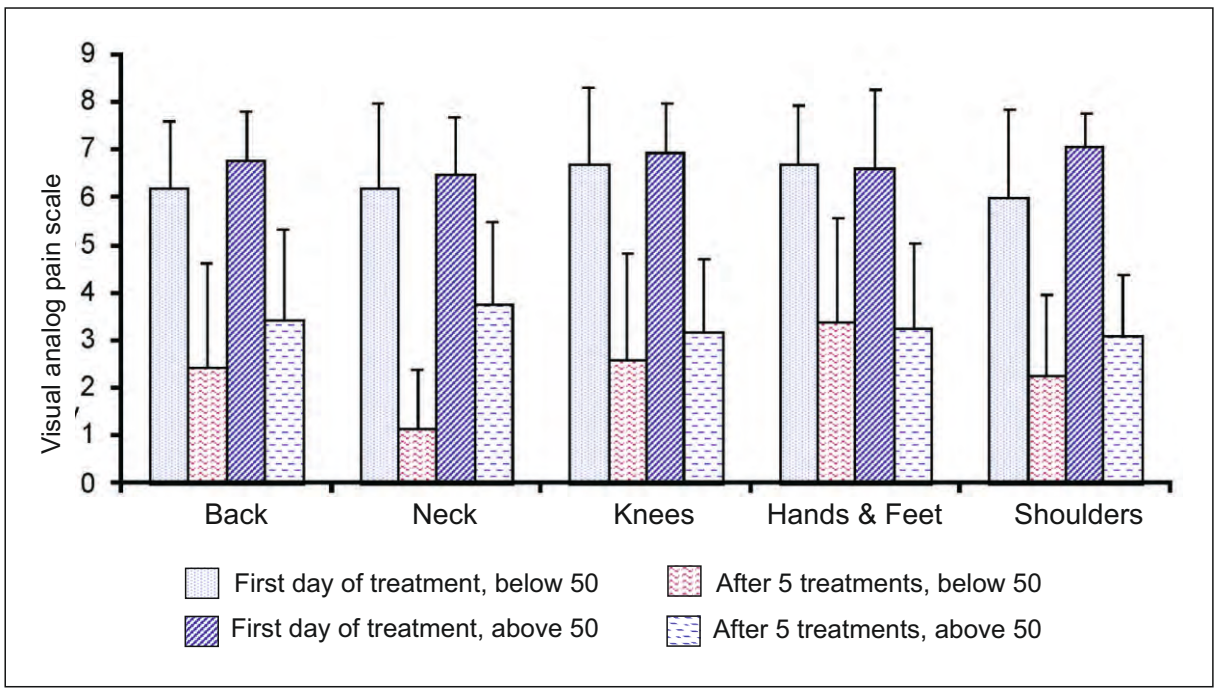

Figure 3: The effect of APS treatment on VAPS in patients above and below 50 years of age.

The average value as a whole for the MI for >50 years was 6,7 before treatment and 3,4 after treatment. In the <50 years age groups it was 6,4 and 3,2 respectively. Both groups responded equally to treatment.

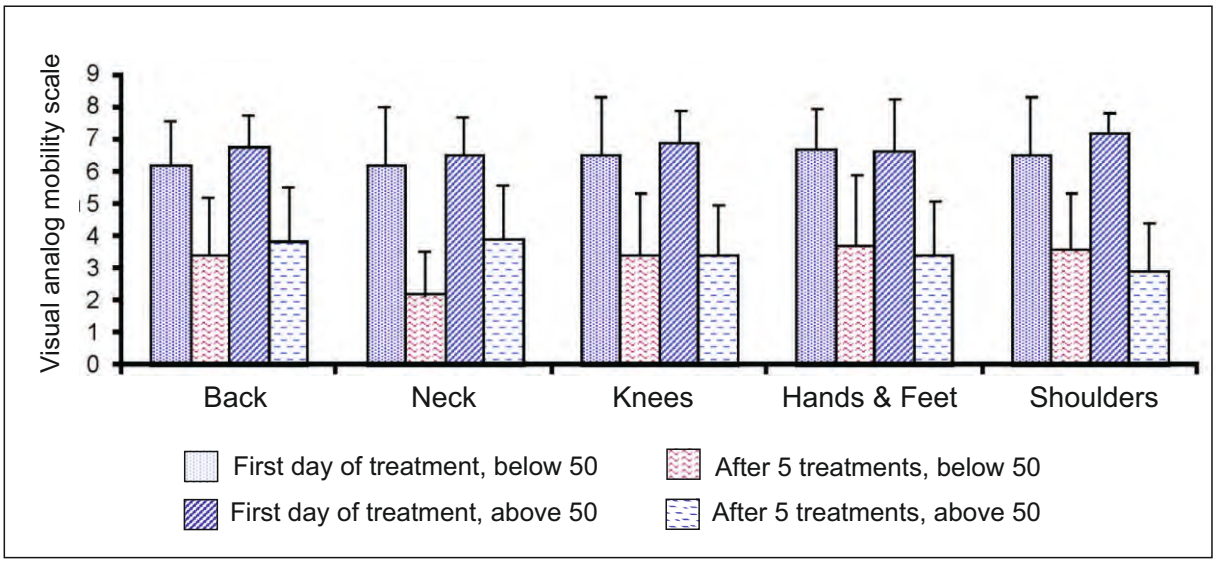

Figure 4: The effect of APS treatment on mobility index in patients above and below 50 years of age.

The best results were obtained in the elderly patients with neck problems. There was a 39 % and 25 % improvement in both their pain perception and mobility index.

Both clinically and on a subjective level, APS therapy appeared very successful. Out of the 285 patients, 44 (15%) ended with a '0' VAPS and 199 (69%) with a score of 5 or less. It is just as effective in younger as in older patients. All were extremely happy with the treatment and experienced both pain relief and pain control, with improved mobility in daily life. This study has also demonstrated significant clinical efficacy of the APS device. It was observed clinically that patients with severe osteoarthritic conditions and those that needed a total hip or knee replacement, responded less favorably when compared to people with less joint restriction and with only soft tissue injury. It is possible to speculate as to the physiological mechanisms involved. Measurement of endogenous opioid peptides, the enkephalins and the endorphins, will hopefully be a more substantial future tool in the complex evaluation of pain.

APS utilises peripheral nerve stimulation to relieve pain by the myelinated afferent nerve fibres, which activate local inhibitory circuits within the dorsal horn of the spinal cord. These fibres (A beta) mediate inhibition largely segmentally[14]. These large, myelinated A beta fibres are sensory afferents, which are low-threshold mechanoreceptors for light pressure, rubbing and vibration and are classified as the class II, secondary sensory fibres of muscle spindles. These fibres are faster conducting than the slow nonmyelinated, polymodal, C fibres (nociceptors)[15]. Stimulation of these fibres therefore intercepts the stimulation from the C fibres and, according to the gate mechanisms, blocks pain perception. Among the opioid peptides, one of the most potent for analgesia is beta endorphin. Three classes of opioids are currently known: the enkephalins, dynorphin and beta endorphin. [16+21] The discovery of endogenous opioid peptides was one of the most important keys to the understanding of central nervous system pain-modulating circuits[14]. The opiate binding sites relevant to analgesia are found throughout the primary afferents and the neuraxis and are stereospecific and of high affinity[14]. These opioid receptor sites may be stimulated by input from the A beta fibres[21].

There is a marked increase in mobility with the APS current treatment. It possibly has an action on inflammation, which profoundly assists in improving mobility. A study on osteoarthritis of the knee revealed that APS highly significantly improved mobility in knee flexion in the short duration (8 minutes) and high intensity treatment, and this effect was even further improved one month after the study had been completed[19].

It has also been noted that there are changes that occur spontaneously in the intensity display during treatment with APS therapy. There may be an immediate interaction in the tissue with the current. It also appears that the greater the resistance in the tissues owing to disease, inflammation or swelling, the lower the intensity will register during treatment. As the resistance decreases, the intensity increases, indicating changes in the condition towards normalising the tissue. One can speculate that normal tissue provides less resistance to an electrical current and that diseased or damaged tissue produces a greater resistance to

an electrical current. It may therefore be more beneficial, in some patients, to encourage a higher intensity of current in order to affect disease processes.

Injury or disease causes oedema, inflammation, neuronal dysfunction, circulatory disturbance and lack of oxygen supply to the tissues or organ systems. If there is poor transmission or even cessation of activity along the neuron, as a result of injury or disease processes that may affect the Schwann sheath, the system cannot conduct its action potentials, and the homeostatic and regenerative mechanisms are disturbed. Inflammation in tissue promotes the build-up of chemicals, known as the "inflammatory soup" which may also interfere with neural transmission (increases the resistance). This may be caused by mechanical, chemical or electrical disturbance to the neuronal complex[20].

It is postulated that this therapy produces electrolytic effects in such disturbed areas, and that the current there may result in metabolic catabolism of various inflammatory substances. These products are then transported via the bloodstream to the kidneys, for elimination from the body. Circulation improves (thermograpy) with the use of APS therapy, and thus antibodies, enzymes, neurotransmitters and hormones are conveyed at an increased rate to the treated area. An increase in the rate of removal of metabolic wastes can also be expected from the above regions. Inflammatory metabolites may be a major cause of pain and thus by removing the cause, pain often diminishes quite rapidly. [20] The improved circulation also produces a reduction in swelling in joints and limbs, and this may also positively affect the lymphatic drainage of that area.

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Analgesic Efficacy of APS (Action Potential Simulation). Pilot Study of the patients with chronic pain due to muscoloskeletal disorders

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Analgesic efficacy of APS (Action Potential Simulation). Pilot study of the patients with chronic pain due to musculoskeletal disorders

Abstract

Background and aims. Pain in musculoskeletal disorders is common medical problem, however frequently difficult to treat. That is why different methods of physical therapies have been tried with the controversial results. APS-therapy (Action Potential Simulation) falls under the broad definition of MET (Microcurrent Electrical Stimulation). MET may be a useful treatment for many pain-related disorders, providing fast relief of symptoms. The aim of this pilot clinical study was to investigate the analgesic efficacy of APS--therapy in chronic pain due to musculoskeletal disorders.

Methods. The study involved 12 patients with musculoskeletal disorders who suffered from chronic pain. Each patient received treatment for 3 weeks time. APS-therapy was administered for a period of 16 minutes, 5 times a week. Treatment was given by portable unit, that generated an APS waveform (monophasic, pulse width 800 ms, frequency 150 Hz and intensity 0.5 1.5 mA). NRS (Numerical Rating Scale) evaluation was performed for 3 days of pre-treatment period, before each treatment which reflected the pain situation of the previous 24 h, and once daily for 2 weeks after treatment.

Results. The initial mean NRS in pre-treatment period was 5.53 (SD = 1.94), decreased after APS-therapy to 3.45 (SD = 1.4) ($p = 0.002$) and even more to 2.56 (SD = 1.23) in the post-treatment period ($p = 0.0003$). Mean pain intensity decreased significantly after 11 sessions and remained on the same level up to 2 weeks of post-treatment observation.

Conclusion. APS-therapy may be an effective method of nonpharmacological treatment of chronic pain in muscoskeletal disorders.

Key words: APS-therapy, musculoskeletal disorder, chronic pain

Introduction

Electrotherapy is useful for treating a variety of clinical conditions. Indeed, it may be the main or complementary method for treating many pain related disorders, providing fast relief of symptoms. APS-therapy (Action Potential Simulation) falls under the broad definition of MET (Microcurrent Electrical Stimulation). This type of electrical modality uses an electrical current of less than 1 mA, which is measured in the microamperage range. The APS--therapy produces current that is claimed to stimu-

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late an action potential in the neuron. According to the Arndt-Schultz Law weak stimuli increase physiological activity [1]. Investigation into the physiological mechanisms involved has shown that these subthreshold currents cause the following effects: changes in cell wall permeability, increase of the intracellular concentrations of Ca^{2+} and adenosine triphosphate (ATP) production, stimulation of protein synthesis and increase of fibroblast activity [2]. The APS device was invented and designed by G.A. Lubbe in 1991 in South Africa, and marketed in 1994 even without published studies in peer-reviewed journals [2]. Nowadays there is scarcity of published literature of APS therapy. A controlled trial using APS-therapy and TENS (Transcutaneous Electrical Nerve Stimulation) to treat the pain of osteoarthritis of the knee was reported by Berger [3]. In this study electrotherapy (APS and TENS) proved to be beneficial in the relief of stiffness and pain, especially occurring at night [3]. Other authors who studied the usage of APS therapy in chronic and acute post-traumatic pain conditions (low back pain, tennis elbow, sports injuries, shoulder pain, arthritis) indicate that APS therapy produces 40––80% pain relief after 5–15 treatment sessions [4–7].

The aim of this pilot study was to investigate the analgesic efficacy of APS-therapy in chronic pain due to musculoskeletal disorders.

Methods

The study protocol was accepted by the Ethics Committee of the Nicolaus Copernicus University, Collegium Medicum Bydgoszcz in Poland. Before the trial each patient was examined by the physician and signed an informed consent. The inclusion and exclusion criteria are presented in the Table 1. The study involved 12 patients with musculoskeletal disorders who suffered from chronic pain. The demographic and clinical data of investigated subjects are presented in the Table 2. Each patient received three weeks treatment. The APS-therapy was administered for a period of 16 minutes, 5 times a week. The treatment was given by portable unit, that generated APS waveform. Technical specifications of the APS therapy device and information about stimulation parameters and electrodes placements are presented in the Table 3. NRS (Numerical Rating Scale) evaluation was performed for 3 days of pre-treatment period, before each treatment which reflected the pain situation of the previous 24 h and once daily for 2 weeks after treatment.

On 24th day of treatment the patients were asked to estimate the level of satisfaction in seven degrees scale (from 3 to 3) Satisfaction Scores.

Statistical analysis was made using a licensed version of statistical software STATISTICA PL 5.0 for Windows. Distribution of variables by Kolomogorow-Smirnow test was abnormal, therefore non-parametric statistical tests were chosen. The results were calculated as median NRS score value for respective day of the investigation and presented in Figure 1. Moreover, for every study phase for each subject the mean of NRS score value was calculated. The statistical significance of difference between values calculated for each day of the study (Fig. 1), as well as for every study phase (Table 4) was estimated using one way ANOVA method with 38 repetitions and Scheffe post hoc test. The final results were presented as the median and 95% CI (confidence interval).

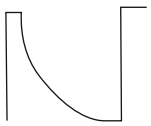
Table 2. Patients characteristics

Total number of patients	12
Gender	
Male	3
Female	9
Age (median – 95% CI)	26 – 21.9 40.3
Clinical diagnosis	
Degenerative Joint Disease	9
Painful Shoulder Syndrome	1
Rheumatoid Arthritis	2
Medication	
Anti-inflammatory	1
Analgesics	2
No medication	9

Table 1. Patients inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Patients with chronic pain due to musculoskeletal disorders	Cardiac pacemaker
Average pain intensity not less than 3 measured in NRS	Epilepsy
Patients able to estimate pain intensity	Inflamed or infected skin in planned electrodes placement
Patients, which signed an informed consent	Thrombosis in anticoagulants treatment period
Patients over 18	Pregnancy

Table 3. Procedure parameters

Stimulation parameters	Wave form APS	Electrodes placements
Frequency = 150 Hz Pulse width = 800 ms Intensity = 0.5 1.5 mA Treatment duration = 16 min		Two channels, electrodes were placed to surround the target area

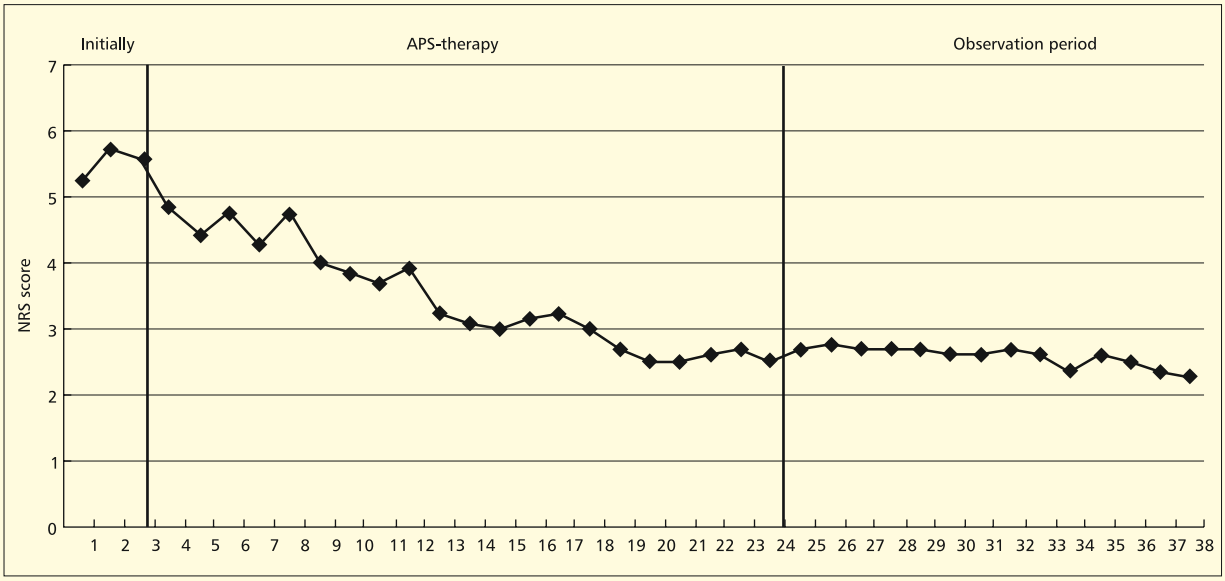


Figure 1. The intensity of pain in NRS score in following days and phases of the investigation, ANOVA; F (37.407) = = 14.12; p < 0.001

Table 4. The medians and 95% CI of mean NRS score values observed in individuals within respective study phases as well as the levels of improvement of NRS score values in respective phases of investigation (n = 12)

Parameter	Pre-treatment period (1)	APS-therapy period (2)	Post-treatment period (3)
Median of mean NRS values	5.5 – 4.3 to 6.8	3.45 – 2.56 to 4.34∗	2,36 – 1.77 to 3.35∗ #
Delta1 2 (median – 95%CI)		2.07 – 3.19 to 0.95	
Delta1 3 (median – 95%CI)			2.97 – 4.21 to 1.73
Delta 2 3 (median – 95%CI)			0.90 – 1.27 to 0.52

Statistical significance in Scheffe post hoc, in ANOVA analysis F (2.22) = 22.17, p < 0.001); ∗p < 0.01 in comparison between i nitial values and treatment or observation period, #p < 0.001 in comparison between APS treatment period and post-treatment observational period

Results

The median values of NRS score within respective days of the study were presented in Figure 1. The effect of applied therapy was significant in estimation by one-way ANOVA method [F (22.22) = = 22.17; p < 0.001]. In comparison to NRS score values obtained within three days of the pre-treatment period, after 11 days of APS therapy pain intensity significantly decreased (Table 4). The effect of therapy was maintained for the subsequent ten days of the APS therapy, as well as within 14 days of post-treatment observation period (Fig. 1).

The median of the means NRS score values obtained within the pre-treatment period, within 14 (21)-days long APS therapy and during 14-days long observation period are presented in table 4. In comparison to the initial value, the NRS score after APS therapy and after observation period were significantly lower, in average by 36% and 51%, respectively. Pain intensity was also significantly lower during post-treatment observation period in compari-

son to APS-treatment period (in average by 27%) (Table 4).

The median of Satisfaction Score after 21-days long APS therapy in seven degrees scale (from –3 to 3) was 2 (95% CI 1.2–2.2). 11 patients found the treatment satisfactory (Satisfaction Scores between 1 and 3), one patient didn't notice any changes (Satisfaction Score = 0). During the treatment no side effects were observed.

Discussion

Many patients suffering from pain due to musculoskeletal disorders are treated with pharmacotherapy only. However, physical methods like electrotherapy should be considered more frequently as a therapeutic option. Our study suggests that APS-therapy can be used as an alternative to drugs or complementary methods for chronic pain management . We showed that APS-therapy significantly decreased pain due to different musculoskeletal disorders. Furthermore, this kind of treatment is cheap and causes no side effects. Another advantage of this method is the fact that the treatment session takes a very short time (approximately 16 minutes once a day for 3 weeks) and in many cases can be applied by the patient himself at home. To compare, the TENS (transcutaneous electrical nerve stimulation) takes a few hours a day [8]. Besides it is worth mentioning that on the contrary to TENS, APS is a causal treatment of pain. Increase of ATP generation after microcurrent stimulation in rat skin models was reported by Cheng [9]. ATP plays an essential role in the inter-body communication (generation of nerve impulses for communication and control purposes), muscle contraction (e.g. during walking, breathing etc.), nerve conduction, transport, growth, etc. That is the reason that APS therapy can be used in pain relief, breakdown of inflammation and wound healing.

Moreover the patients were satisfied with the effects of the treatment what can be noticed in the Satisfaction Scores.

Our study gives the rational reason for further randomized controlled trials with placebo group which should more accurately assess analgesic efficacy of APS-therapy.

Conclusion

APS-therapy may be an effective method of non-pharmacological treatment of chronic pain in musculoskeletal disorders.

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Management of ischemic pain with Action Potential Simulation - a case report

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Management of ischemic pain with action potential simulation — a case report

Abstract

Ischaemic pain belongs amongst the most difficult to treat pains in palliative care. The pain is frequently severe and resistant to available analgesics. Treatment of this condition is difficult especially when the condition is inoperable. We describe a patient with severe ischaemic pain in the lower leg due to previous vascular problems and superimposed deep venous thrombosis who responded well to action potential simulation (APS), atherapy using microcurrents which resemble the body's own biocurrents. This technology is frequently used by complementary therapists but is still barely known to evidence-based medicine.

Key words: limb ischaemia, iscaemic pain, arterial emboli, opioids, micro electro therapy, action potential simulation

Adv. Pall. Med. 2009; 8, 1: 23–26

Introduction

Ischemic pain belongs to the most recalcitrant symptoms in Palliative Care. Fortunately, this type of pain is rare among patients suffering of cancer, but its prevalence is dramatically higher in patients suffering of diabetes and vascular diseases [1, 2]. As a rule ischemic limb pain is severe, highly variable during the day and is accompanied by paleness and a cold feeling in the distal part of extremity. Treatment of this condition is primarily by surgical procedure: a bypass or arterial prosthesis/stent [3, 4]. When this is impossible or contraindicated some improvement can be expected from sympathectomy [5, 6], nerve section [7] or epidural morphine [8] but the evidence for this is weak. Ischemic pain responds poorly to analgesics and this is the reason why different techniques are often tried [9, 1]. In this article we describe a patient with severe ischemic pain in lower leg who responded well to action potential simulation (APS), therapy with micro-currents that resembles body own biocurrents. This technology is frequently used by complementary therapists, but still hardly known to the evidence based medicine [11, 12].

Case report

Mr. K (65) was urgently referred to the pain clinic because of the severe pain in his left lower leg. He had a history of arterial insufficiency and prosthesis in the left popliteal artery and in the past he was using warfarin. However, when he developed oesophageal cancer and became anaemic warfarin was discontinued. Two months later he developed left sided deep vein thrombosis. This

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was accompanied by a severe pain in the left leg. Doppler ultrasound investigation confirmed thrombosis in the femoral vein, but also showed no blood circulation beyond the popliteal artery. Fraxiparin was commenced but discontinued because of small brain bleeding confirmed by the brain CT scan. The pain was present during and after therapy with Fraxiparine. At assessment the pain was much worse on movement and the action radius was not more than several meters. He slept poorly, usually sitting in the chair. He used oral morphine (morphine sulphate tablets with controlled release, 100 mg a day and oral morphine sulphate of immediate release several times a day, 15 mg per dose). Unfortunately this medication was not able to influence his pain. He and his surrounding noticed his mental deterioration, depression, sometimes agitation. On examination: multiple venectasies. The left lower leg was swollen and cold around the knee. Palpation was not painful. There were no arterial pulsations palpable starting from the iliac artery in the groin. No bruits. Pulsations on the right leg were normal. On the shin, on the heel and on the second toe of the left leg small areas of necrosis were observed.

The patient was treated using APS technology. An MK2 US two channel machine produced by Tech Pulse Manufacturing Pty Ltd. South Africa was used. Four gel electrodes PALS Platinum Blue 901220, 5 ¥ 5 cm, were placed on both sides of the left upper leg and under his feet. The current intensity was slowly increased with potentiometer until the patient could feel it under the electrodes. The current intensity was then decreased to just below the threshold and the therapy was continued for 8 minutes in one session.

He was swapped to oxycodone controlled release 30 mg bd and oxycodone immediate release 15 mg, paracetamol 1 g and ketamine 30 mg per dose. After the first treatment the patient suffered severe muscle shakes but was not breathless, agitated or had hyperthermia. The therapy was administered usually in the morning and this resulted in 6–7 hours of analgesia. At the later stage the treatment intensity was increased to 8 minutes therapy twice daily. This resulted in much better analgesia, especially at night. He used his breakthrough medication once or twice a day. He felt so much better that he volunteered to undergo radiotherapy again.

Ischemic pain can originate from vascular intraluminal obstruction, usually by thrombo-embolus, external compression by the tumour and dissecting aneurysm. Deep venous thrombosis, like in our case can cause ischemic pain in the situation where the arterial circulation is already compromised. Increased pressure in the limb, due to congestion may especially impair circulation in new collaterals.

Pharmacological treatment of this kind of pain is very difficult. Fraxionated heparine (Fraxiparin) is the treatment of choice as it has a potential of decreasing congestion in the limb and decreasing the pressure [13]. However, in our case this treatment was not effective and needed to be discontinued because of serious haemorrhage.

Another possibility in this treatment is the use of ketamine in combination of morphine. This treatment is sometimes effective at the higher doses and it is frequent that the cognitive functions of the patients are severely compromised. In our case the original treatment with morphine alone was not effective and needed to be changed. We have chosen for oxycodone as this drug has less potential to compromise cognitive functioning [14]. Ketamine and paracetamol were added to the “acute” break through doses and appeared to be adequate.

Important in the treatment is positioning of the patients. Some patients prefer to sit in the chair with their leg supported. A good explanation for this was found by Ubbink et al [15]. Under physiological conditions arterioles respond with vasoconstriction when changing position from supine to sitting. This is probably due to increased sympathetic tonus. However, this mechanism is probably disturbed in patients experiencing ischemic pain and the perfusion of the limb is higher in sitting than in supine position.

The main treatment was by applying a new technology of APS. Action potential simulation simulates the bio-currents. The sub-threshold electric current has as an effect on the synthesis of the ATP by the cells. In that way the cells can be “vitalised” and damages can be repaired. This is very much different to the use of TENS principle, where the electric shocks stimulate nociceptors and close the “gate” in the spinal cord hampering the conveyance of ascending pain impulses. However, comparison of the two methods reveals short term similar results [11]. In our patient APS was effective within several minutes after the first treatment. Apparently the patient experienced during the first night severe shaking without increased body temperature or breathlessness. This reaction, seen very often by the APS therapist, suggest that some toxins are freed from the ischemic area and are absorbed to the circulation.

Discussion

Treatment with APS not only improved pain but also, visibly, improved skin circulation as within several days the necrotic discolorations of the skin disappeared. Potentially the therapy may improve collateral circulation to such an extent that the patient may discontinue it one time.

In the Netherlands and in Poland, APS therapy is known by the physiotherapists. However, in the UK, there is much less interest in development of these kind of methods. Before the method can be used in routine treatments, it should be first validated in different clinical settings, the staff should be trained to use it and cheap devices can be developed and used by the patients themselves. Our case suggest that the method may be useful in some otherwise intractable pain conditions.

However, before we shall conduct clinical trials, we should better understand how the technology is working and what kind of physiological effects are involved. Without this, clinical trials lacking this internal validity may render negative results [16] and the technology will be discarded before it is understood.

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Action Potential Simulation Therapy (APS Therapy) for pain in people with MS; Report on a One Year Pilot Study

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April 11th, 2014

Action Potential Simulation Therapy (APS Therapy) for pain in people with MS; Report on a One Year Pilot Study.

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Abstract

People with MS commonly suffer from both nociceptive and neuropathic pain, and the latter is often resistant to treatment, or hard to resolve due to the unwanted side-effects of most of the appropriate drugs.
We carried out a one year pilot using the electrotherapy device APS Therapy to treat pain in people with MS, at the voluntary sector multi-disciplinary MS Therapy Centre, in Bedford, UK. An 8 week course of the therapy 3 times a week was offered initially, and 38 people used APS Therapy to treat 61 different pains.
Within 8 week periods, 28 people (76%) got beneficial reduction in pain. Of the 58 pains, 50 (86%) had a reduction of at least one point on the Visual analogue Scale (VAS) for pain. Of the pains that improved, 17 (30%) were reduced to pain free. The average reduction in points on the VAS was 4.7 points. 12 people reduced or discontinued medications as a direct result of the effects of APS Therapy; with more structured review and supervision, we feel that this number could be higher, and have adjusted our practice accordingly.

Many participants reported improved sleep and enhanced energy, and the improved quality of life that this afforded.

Many of the participants who benefitted, especially those with chronic neuropathic pain, felt that they needed long term treatment, but were able to maintain the benefits sustained at a reduced frequency of treatment (once a week or even fortnightly), and elected to carry on. We were able to offer this as an ongoing service.

Robust research on APS Therapy is scant, but based on the outstanding results of this pilot is a very promising area for further research and clinical treatment.

Introduction

The problem of pain in the UK

Pain is defined as ‘An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage’ (1)

Chronic pain is defined as continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery.(2)

Almost eight million people in the UK have chronic pain, or an estimated one in 5 Europeans. (3) As well as the human suffering, it also represents a significant burden to wider society and economies. Chronic pain accounts for 4.6 million GP appointments every year at a cost of £69 million. Expenditure is on referrals, appointments, prescribing, consequences of ineffective home prescribing and adverse events. (4)

Current medical treatment centres around medication, but drug treatments often cause unwanted side effects or other medical problems, and the costs of drugs for managing pain alone in England in 2009 amounted to £449 million. (5)

Access to pain management services in the UK is inconsistent and available health services for pain differ markedly in the type of care they offer.(6)

Although in some chronic pain clinics, TENs, acupuncture, physical, psychological techniques, invasive treatments, and complementary therapies are offered, availability varies widely, rates of successful pain resolution are low, and 38% of people with chronic pain report inadequate pain management.(7,8, 9)

The problem of pain in MS

Estimates vary as to the proportion of people with MS who suffer from pain, with some reports suggesting that up to 80% of people with MS may suffer from pain at some stage. (10,11,12)

People with MS commonly suffer from both types of pain; both nociceptive ('normal' type, after injury or with inflammation) and neuropathic. Neuropathic pain is defined as 'pain caused by a lesion or disease of the somatosensory nervous system' (13) is often characterized as burning, severe shooting pains, and/or painful numbness or tingling. It is commonly a long term or chronic pain, and effective treatment is difficult as the classes of drugs to which it responds best are associated with various adverse effects. (sedation and weight gain most commonly) (14)

The aim of treatment is to minimise the level of pain and to develop coping strategies so that the individual can carry out normal day-to-day living. Treatment options include drugs and non-drug treatments such as physiotherapy, electrotherapy or a combination.

Electrical therapies

There are many modalities of electrical therapies currently in use within physical therapy for pain relief and injury repair, which have been categorised into 3 broad areas(15)

Electrical stimulation agents, including Transcutaneous Electrical Nerve stimulation (TENS), Action Potential Simulation Therapy (APS Therapy), Interferential Therapy (IFT), Functional Electrical Stimulation (FES), and Microcurrent therapy (MCT),

Thermal modalities, including Infra red Irradiation (IFR), Therapeutic Ultrasound and Laser Therapy, and

Non Thermal Modalities including Pulsed Ultrasound, Pulsed Electromagnetic Fields (PEMFs) and Microcurrent Therapy (MCT)

The most commonly used form of electrotherapy in healthcare is TENS. This uses an alternating current to affect pain gate mechanisms. A Cochrane review concludes that 'despite the widespread use of TENS machines, the analgesic effectiveness of TENS still remains uncertain'(16)
There are many studies demonstrating its' usefulness, however, in my experience with MS it has only occasionally been effective for mild or moderate pain, but has been limited to the duration of treatment with the electrodes, or a one or two hour carryover at best.

We heard about some exceptional case studies carried out in Hull using the electro-therapy Action Potential Stimulation (APS)Therapy showing effectiveness in reducing both pain and fatigue; drastically reducing the medication used, and increasing mobility, independence and quality of life in people with MS(17) and decided to investigate.

APS Therapy

APS Therapy (Action potential simulation therapy) is a type of micro-current therapy.
These therapies involves application of electric currents of similar form and magnitude to those produced naturally by the body and there is evidence that this can promote healing in a variety of damaged tissues. (18)
The APS Therapy device uses an electrical current that supposedly mimics the normal physiological action potential of nerve conduction. The device is said to produce action potentials that are four times stronger than those naturally occurring in the neuron. When swelling, inflammation, poor circulation and pain occur due to mechanical, chemical or electrical disturbances, by stimulating the body's natural regenerative processes (as in depolarisation), it is postulated that these conditions are encouraged to resolve. (19) See discussion.

Literature review for micro-current and APS Therapy

A literature review on over 70 papers on micro-current therapy in 2009 concluded that there was evidence for its use with non-uniting fractures, spinal fusions and a skin ulcers, particularly where other forms of treatment had not been successful; that In vitro studies also suggest that there is unexplored potential for its use in musculoskeletal disorders. However, higher quality and more comprehensive research is needed. (20)

An assessment of APS Therapy on 285 Patients with Chronic Pain in 2002 reported a mean average VAPS was 6.8 before treatment and 3.3 after treatment in the over 50s, and 6.3 and 2.2 respectively in the under 50s. Out of the 285 patients,44 (15%) ended with a '0' VAPS and 199 (69%) with a score of 5 or less. (21)

A trial of APS Therapy in patients awaiting or having neurosurgery for intractable spinal pain concluded that the number of patients treated was too low to reach a statistical conclusion, but that the trend was very promising and they recommended that patients waiting for destructive surgery should first be put on a thorough trial of APS Therapy.(22)

In a 1999 randomized, patient blinded, placebo-controlled study, on 76 patients with chronic osteoporotic back pain, reported pretreatment baseline VAPS value average of of 57.79, and post- treatment value after the sixth treatment of 9.7 (p= 0,0001); 6 patients maintained benefits 6 months post treatment.(23)
A study in 1999 on APS Therapy compared with TENS in 99 patients with osteoarthritis of the knee did not find a significant difference between the two treatment groups given just 6 treatments over a 2 week period. The authors did note, however, that the APS group showed a significant improvement in measures of knee flexion and swelling, which persisted even 1 month after the last treatment. (24)

Methods

Sample

People with MS who presented with pain in the MS Nurse's clinic were screened for suitability and contra-indications, and offered the chance to trial the therapy. Pain due to spasticity/muscle spasm , or pain whose origin was uncertain, where more investigations were needed, were excluded.

Contra-indications include having a Pacemaker, epilepsy, pregnancy, or cancer, or in the past 3 months, stroke, heart attack, deep vein thrombosis or pulmonary embolus. One participant had a baclofen pump; after discussion with the manufacturers of both devices, this was allowed in this case. We also checked that participants felt able to drink the recommended litre and a half of water daily during therapy.

All the participants gave their informed consent to take part in the study; it was made clear that this was optional. 39 had MS, 3 did not. (2 were members of staff, and one a volunteer)

An 8 week course of APS Therapy, with 3 x sessions a week, comprising of 4, back to back 8 minute electrode placements, was offered, in a clinic room at the multi-disciplinary, voluntary sector MS Therapy Centre in Bedford, UK. We had first one, and then 2 APS Therapy clinic machines. People who could apply the electrodes themselves had one teaching session and then self-treated, with floating supervision from staff.

During the 8 week course, 6 people dropped out. One had vomiting and headache after 1st treatment, decided not to proceed. Detoxification reactions (usually headache) are possible, although not common if drinking the recommended amount of water, and are self-limiting. One experienced flickering in her vision and decided not to proceed. Although there is no documented precendent for this, and the cause was uncertain, electrotherapies can trigger migraine in susceptible people. Three people became unwell, two with existing other conditions

and one with an MS relapse since starting treatment and either unable or decided not to proceed. One struggled to travel for treatment and felt discouraged after no benefit felt at 2& ½ weeks.

36 people in this study went on to use APS Therapy to treat 58 different pains.

25 of the pains were neuropathic, including 2 sciatic type pains, and 34 were nociceptive, including headaches, fibromyalgia type tender spots, backache, joint pain and arthritic type pain.

32 were women and 4 were men. The average age was 52 for women and 51 for men. 11 people had relapsing remitting MS, 22 had primary or secondary progressive, and 3 did not have MS.

We measured pain using the visual analogue pain scale (VAS), asking each participant to score for the average, or constant level of pain, and the worst level of pain, and how much of the time the pain was average, how much of the time worse. Medication use was recorded.

Results:

In 8 week periods;

Of the 36 people, 28 (78%) had reduction in pain.

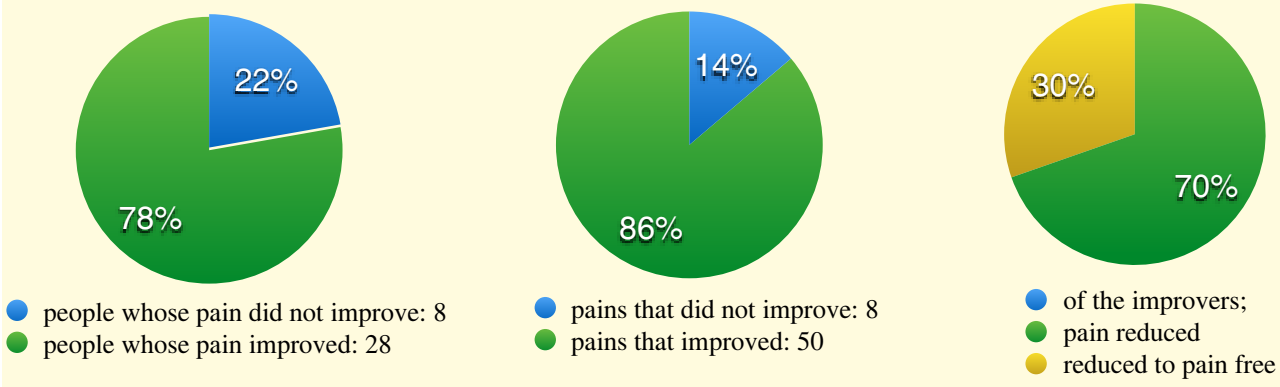
Of the 58 pains, 50 (86%) had reduction.

Of the pains that improved, 17 pains (30%) went down to 0/10, or pain free.

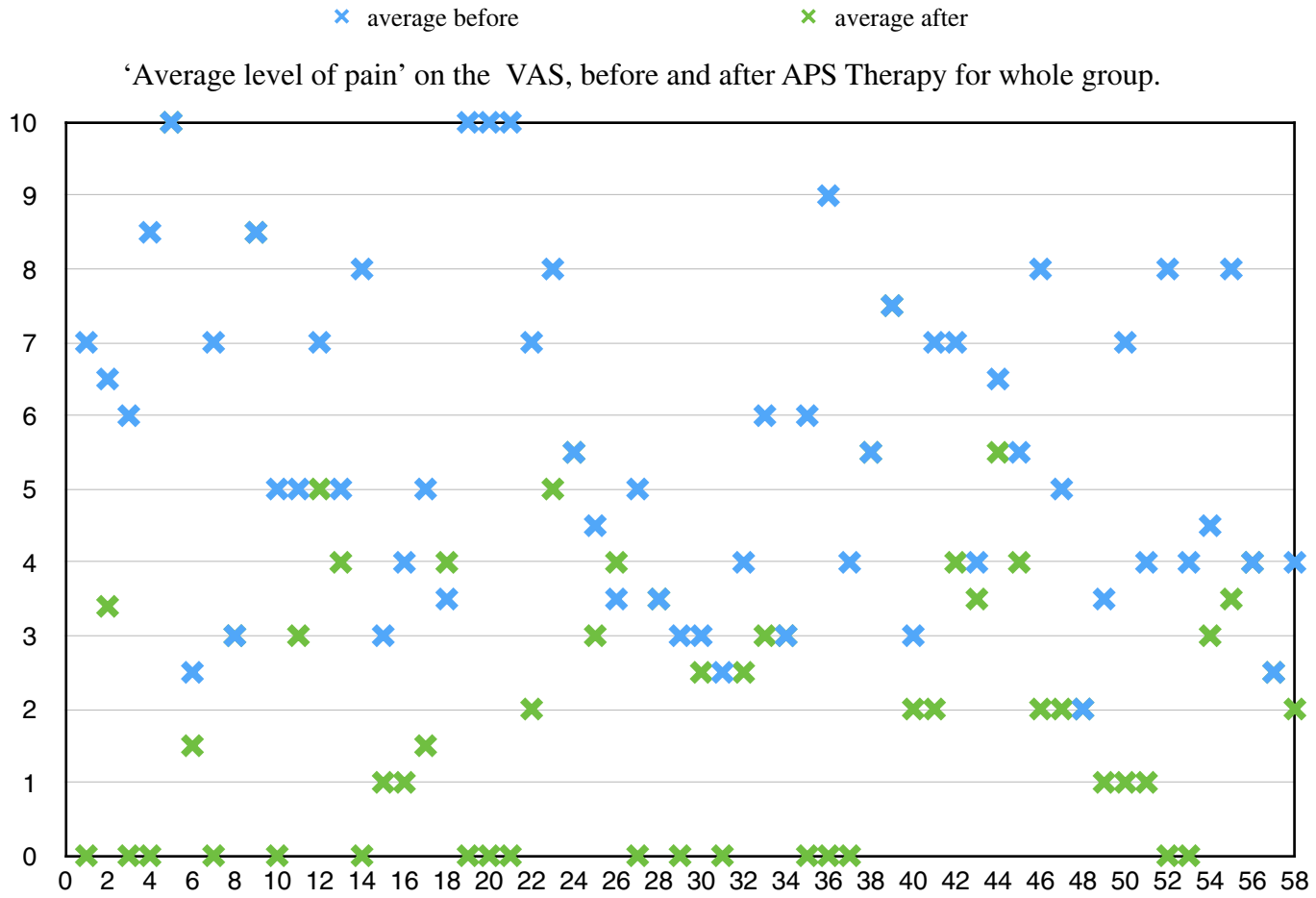
'Reduction' was quantified as 1 or more whole points on the VAS for pain.

Neuropathic pains appeared to respond almost as well as nociceptive pains to the treatment

12 people reduced or discontinued medication as a direct result of the results of the APS Therapy, on reflection, with more supervision, we feel that this could have been more.



The mean pre-treatment score on the VAS for 'Average level of pain' overall was 5.56. Mean reduction in pain was 4.7 points, to a mean post-treatment VAS of 2.3.

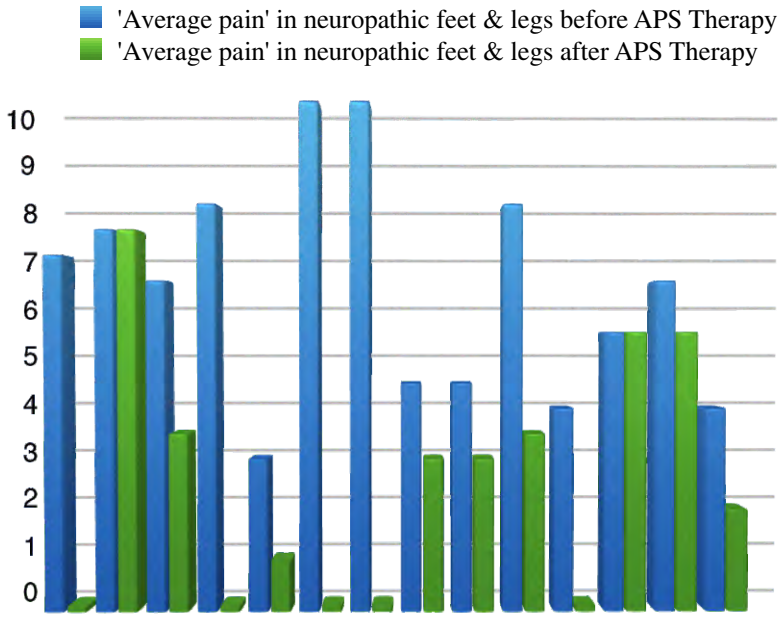


‘Average level of pain’ on the VAS, before and after APS Therapy for whole group.

Average reduction for ‘worst pain’ scores was 4.1 points on the VAS scale.

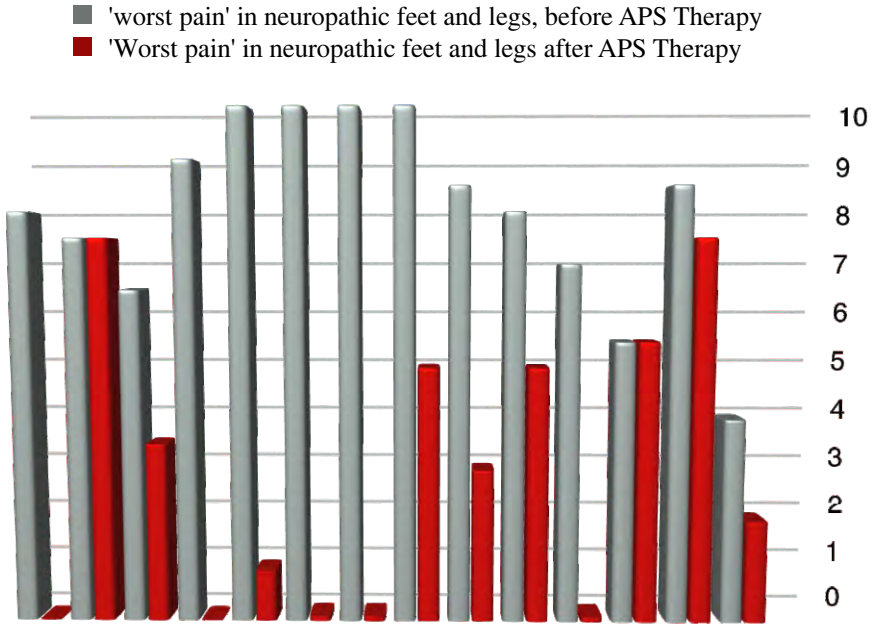
Neuropathic & nerve pain.

nb. in the charts below, a score of 0 or pain free, has been represented by a score of 0.01, in order to show up as a colour.



‘Average pain’ in the 14 cases of neuropathic feet and legs had a mean pre-treatment score of 6.3, which reduced by 3.8 points on the VAS on average to 2.5.

2 individual’s pain did not respond at all, 12 people experienced a benefit, and of these, 5 people went to pain free.

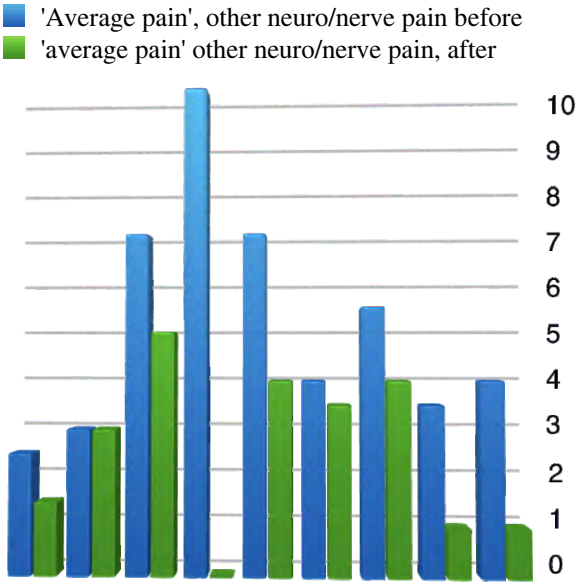


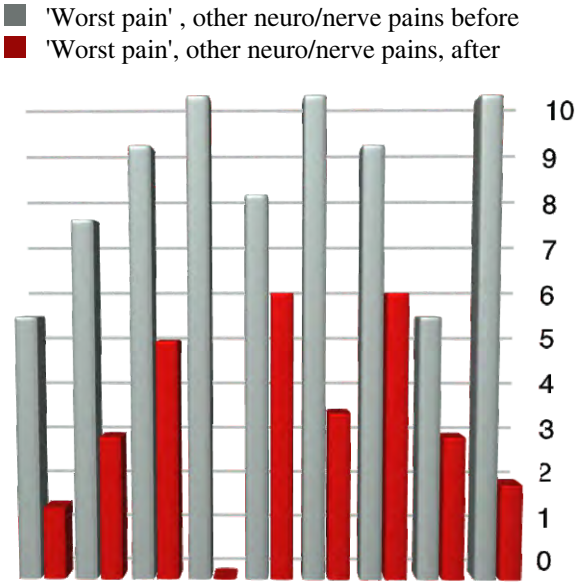
'Worst pain' for neuropathic feet and legs was a pre treatment mean of 8.03, and reduced by 5.17 on the VAS on average, to a post treatment mean of 2.46, with 5 people at pain-free.

Combined 'average' and 'worst' pain scores gave a mean reduction of 4.5 points on the VAS.

Other neuropathic or nerve pain:

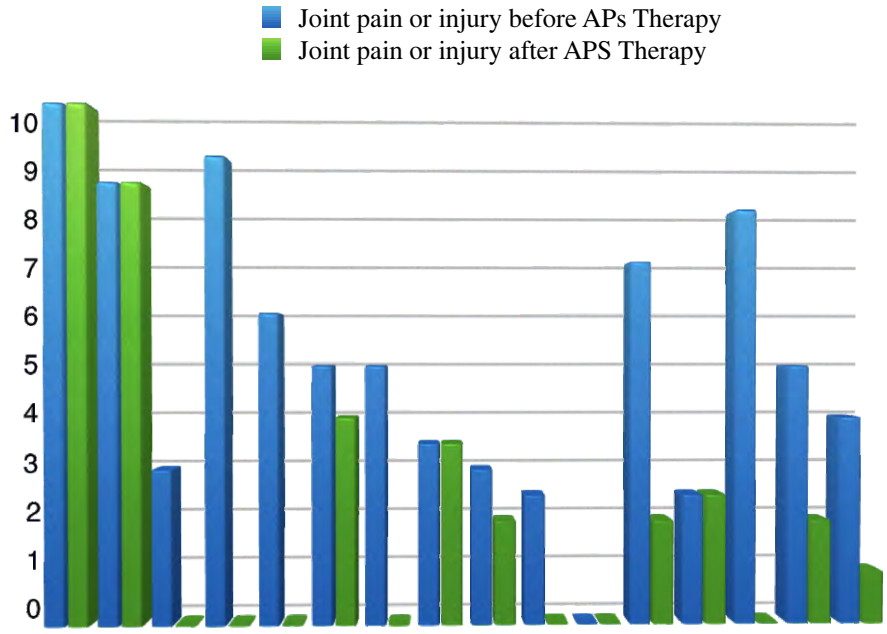
In neuropathic pain of the trunk, arms, hands and face, reduction in 'average pain' was a mean of less, at 2.5, but still had a reduction in 'worst pain' of 4.9 points on the VAS.



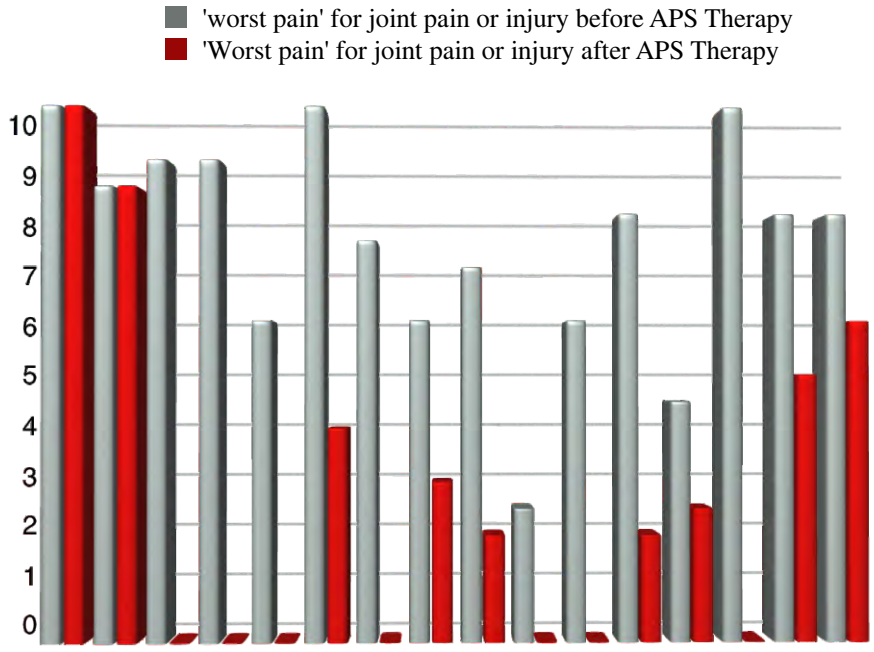


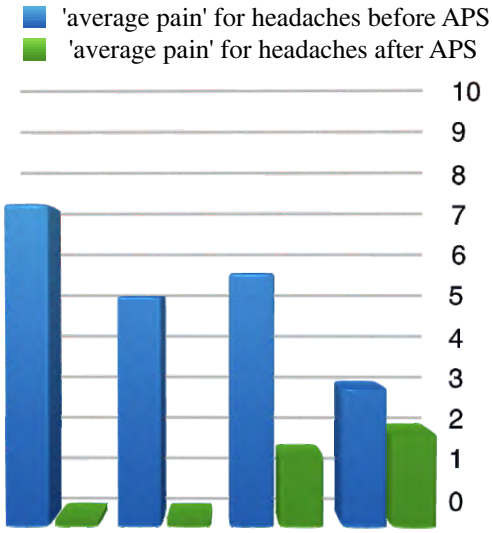
Joint pain or injury

'Average pain' scores for joint pain or injury had a pre treatment mean of 5.1 and fell 2.9 points on the VAS to a mean of 2.2 . Actual results were quite polarised, with 4 people having no response, and 7 going to pain free.

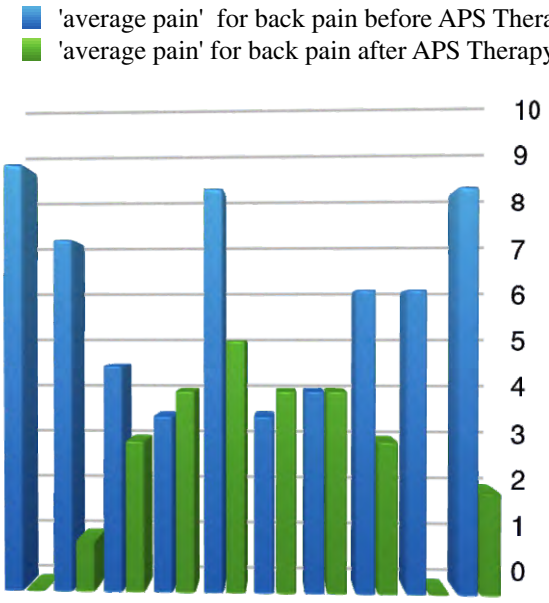


'Worst pain' for the 16 joint type pains had a pre treatment mean of 7.5 points on the VAS, and fell by an average 4.9 points on the VAS to a mean of 2.6. 2 people's worst pain did not respond, and 7 pains went to pain free.

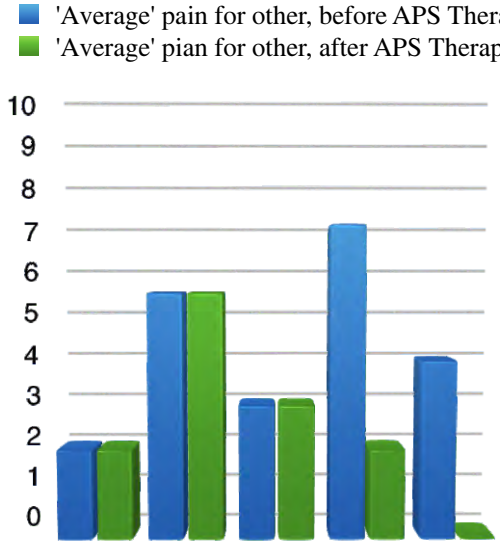




People with headaches responded particularly well to APS Therapy; the reduction in 'average pain' as scored by the VAS was 4.7, but our data does not catch the reduced incidence in those still experiencing headaches.



'Average pain' for back pain had a response of 3.3 points reduction on the VAS on average; 2 people's pain got worse, one was unchanged, 7 benefitted, and of these, 2 went to pain free.



The remaining pains were 2 cases of muscle fatigue type pain and one pain from metalwork post pin and plate, which did not respond, and 1 psoriasis pain and 1 varicose vein pain, both of which did benefit.

‘Other benefits’

For this report, we have not managed to keep accurate data about other benefits reported during APS Therapy treatment. These have been: 4 cases of significant improvement in energy/ reduction in MS fatigue, 2 cases of significant reduction swollen legs and ankles, 1 report of improvement in skin discolouration due to poor circulation, reduction in size of ‘fatty lump’ on hip, swollen gland in neck, and fluid under the skin on the scalp, 2 cases of alleviation of life-long insomnia, and many reports of improvement in sleep quality. 2 people reported no further urinary tract infections, which had been recurrent, and which they attributed to the APS Therapy, and 1; reduction in dizziness and improvement in cognitive function, which again they attributed to the therapy, and reported as a post-treatment effect.

We have identified reliable and valid outcome measures that we will be using for future clinical governance to measure sleep quality and energy levels, and the effect of pain on everyday life and mood.

Discussion

One of our concerns when starting this project was that people might benefit, but need long term therapy, which we would not be able to offer long term. We hoped to be able to use the NHS one-off personal budgets to allow people to purchase their own machine if necessary, but the scheme was only available for people on continuing health funding in our area. In actual fact, we found that although we did have a group of people who needed to maintain therapy to maintain the benefit; but they were able to reduce the frequency of their treatment to once a week, or in one case once fortnightly, and still retain the effect, and a such we have been able to continue to provide a service for these people.

We did not have research funding for this study, there was no control group, and many variables. Our sample, as typical in MS, often had to cancel appointments due to health problems, transport or general difficulties, but still achieved a remarkable result.

It was interesting to note that effectiveness was similar between the neuropathic and nociceptive type pains when using APS Therapy.

The mode of action is not fully understood, but injury or disease can cause oedema, inflammation, neuronal dysfunction, circulatory disturbance and lack of oxygen supply to the tissues or organ systems. Inflammation in tissue also promotes the build-up of chemicals, known as the “inflammatory soup” which may interfere with neural transmission.
If there is poor transmission or even cessation of activity along the neurone, as a result of injury, inflammation, or disease process, the system cannot conduct its action potentials, and the homeostatic and regenerative mechanisms are disturbed.
It has been postulated by Papendorp (25) that introducing external action potentials through the use of APS Therapy may result in the metabolic catabolism and subsequent excretion from the

body of inflammatory substances. As inflammatory metabolites may be a major cause of pain, removing the cause allows for pain reduction. Circulation is also improved and thus antibodies, enzymes, neurotransmitters and hormones are conveyed at an increased rate to the treated area, stimulating the body's own healing mechanisms.

Conclusion

APS Therapy seemed to be a safe and effective therapy to try in cases of both neuropathic and nociceptive pain. Participants in this study, most of whom had MS, achieved positive results using APS Therapy in 78% of cases. The therapy was safe, and in the main, people were extremely happy with mode of treatment, preferring it to drug therapy, and in some cases reducing and discontinuing analgesic drugs as a result.

We hope that by presenting our pilot study of an APS Therapy service in the context of available research on the subject, we can stimulate further clinical use and research.

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