Report not published because the responsible person for the study left the hospital before submission

REPORT

Report on the clinical evaluation of the Curatron 2000 system (Curatronic Ltd. Israel), during the period of July 2004 – December 2004 at the Chaim Sheba Medical Center, affiliated to the Tel Aviv University, Sackler School of Medicine, Israel.

Summary

Purpose of the evaluation was to establish the efficacy and ease of use of applied therapy with the Curatron 2000 pulsating electromagnetic field therapy system for treatment of patients of the orthopedic and neurological departments of hospitals and clinics.
The authors give an account of their experiences over this evaluation period for 220 orthopedic and 86 neurological patients.
The results, conclusions and recommendations of the findings will be presented.

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Introduction.

Pulsating electromagnetic fields have been widely used in the field of ***traumatology and orthopedics*** to treat non-union fractures with related problems, osteoarthritis, pain reduction, recovery of joint mobility, rheumatoid arthritis, sports traumata, vertebral spondylosis and osteoporosis, and in the field of ***neurology*** for alleviating spasticity and fatigue and improving bladder control for multiple sclerosis patients, treatment of migraine and tension headache, cerebrovascular insufficiency, nerve regeneration and reduction of ischemic neuronal damage.

High success rates have been reported in multiple centers in many countries. In addition, this technology looks promising for a wide verity of additional diseases.

The therapeutic effect of the application of pulsating electromagnetic field therapy has at last received worldwide recognition. Research has now shown that it has the potential to improve a wide range of conditions and extensive research has been carried out to determine the mechanism by which this occurs. For the therapist presented with a wide range of clinical problems, pulsating electromagnetic field therapy is an invaluable aid to the clinic.

Over the past few years, research has shown that its effectiveness is not through heat production - as is the case with some modern treatments - but is at the cellular level. As early as 1940 it was suggested that magnetic fields might influence membrane permeability. It has since been established that magnetic fields can influence ATP (Adenosine Tri-Phosphate) production; increase the supply of oxygen and nutrients via the vascular system; improve the removal of waste via the lymphatic system; and help to re-balance the distribution of ions across the cell membrane.
Healthy cells in tissue have a membrane potential difference between the inner and outer membrane. This causes a steady flow of ions through its pores. In a damaged cell the potential is raised and increased and improvement in sodium inflow occurs. As a result, interstitial fluid is attracted to the area, resulting in swelling and oedema.
The application of pulsating electromagnetic field therapy to damaged cells accelerates the re-establishment of normal potentials.

Acceptance of pulsating electromagnetic fields in medicine came about firstly in the field of orthopedics. Low frequency fields have been used extensively for the treatment of non-union fractures. This method was approved in the USA and Europe as a safe and effective treatment for non-union fractures, for failed arthrosis and for congenital pseudo-arthrosis.
No patient suffered complications and biological side-effects included improved healing and increased neural function.
In-depth research carried out to investigate this, shows that pulsating electromagnetic fields influence the process of bone formation in the

intercellular medium. Bone healing is promoted by means of the influence of the pulsating electromagnetic field on the crystal formation of calcium salts.

Bone is essentially calcium structure, which contains trace elements. When this material is compressed, it develops a voltage across its two compressive faces, a phenomenon known as the piezoelectric effect.
In bone, areas of stress generate small electric charges which are greater than those of less stressed areas, so that polarized bone-laying cells (osteoblasts) are attracted to these areas and begin to build up extra bone material to counter the stress.

With bone injuries, bleeding occurs to form a haematoma in which capillaries quickly form, transporting enriched blood to the injury site. Pulsating electromagnetic field therapy causes vasodilatation and capillary dilatation, so helping to speed up the process of callus formation. Within the bone itself, pulsating electromagnetism causes the induction of small eddy currents in the trace elements, which in turn purify and strengthen the crystal structures. These have the same effect as the stress-induced voltages and as such, attract bone cells to the area under treatment. This can, therefore, accelerate the bone healing process to allow earlier mobilization and eventual full union. Ligaments and tendons are affected in similar ways to solid bone by pulsating electromagnetic therapy, since they are un-calcified bone structures in themselves.

Pulsating electromagnetic field therapy has been shown to bring reduction of pain, which again is due to action at the cellular level. Pain is transmitted as an electric signal, which encounters gaps at intervals along its path. The signal is transferred in the form of a chemical signal across the synaptic gap and this is detected by receptors on the post-synaptic membrane. A charge of about -70mV exists across the inner and outer membranes, but when a pain signal arrives, it raises this to +30mV. This action causes channels to open in the membrane, triggering the release of a chemical transmitter and allowing ions to flow into the synaptic gap. The cell then re-polarizes to its previous resting level. Pulsating electromagnetic field therapy affects the quiescent potential of the membrane and lowering it to a level of -90mV. Transmission is effectively blocked since the pain signal is unable to raise the potential to the level required to trigger the release of the chemical transmitter.

The value of pulsating electromagnetic field therapy has been shown to cover a wide range of conditions. Due to vasodilatation and improved oxygen perfusion and improved partial oxygen pressure, local tissue perfusion and capillary blood flow are drastically increased.

There are no side effects and 20% of the patients experienced a feeling of “well-being” during the treatment due to a very slight sedative, warm feeling of the body.

Materials and methods

Patients:

Of the 306 patients treated, 146 were male and 160 were female, with ages varying from 28 to 79 years. Patients carrying pacemakers, suffering from cancer or pregnancy were excluded. The patients were divided into 2 groups: othopedic and neurologic. All participating patients in this study had to undertake to complete the therapy sessions, 3 times a week for a period of 8 weeks. All patients filled out a comprehensive questionnaire before therapy commenced and again 3 weeks after the last therapy session.
12 Patients did not complete the therapy due to various reasons and they were excluded from the evaluation.

Instrumentation:

At the functional therapy center of the hospital there are in use 3 Curatron 2000 systems, being used for treatment of the patients.
The Curatron 2000 computer system is able to generate pulsating electromagnetic fields with frequencies between 1 and 50 Hz and with field strengths between 60 to 400 Gauss (6 milliTesla to 40 milliTesla) for the 50 x 70 cm therapy pad and between 140 to 700 Gauss (14 milliTesla to 70 milliTesla) for the 20 cm diameter coil electrode.
The treatment time, used frequencies and intensities are pre-programmed in the computer system of the Curatron 2000 system, which offers a wide choice of programs. The applied parameters are combinations of the generated parameters and each treatment program contains a series of different treatment parameters in order to avoid adaptation of the body of the patient to the applied frequencies and thus guaranteeing optimal therapy results.
This method of therapy application makes the Curatron 2000 system unique and offers the most advanced therapy system of this kind in the world.

Evaluation results

The 2 groups op patients were again divided into 3 groups: general orthopedics (table 1) osteoporosis (table 2) and neurological (table 3).
Each group was again sub-divided into different types of pathology.
Patients suffering from osteoporosis first had to undergo a whole body DXA bone scan to obtain their bone BMC, BMD, T and Z -scores and to enable further sub-division according to their T -scores.

The patients were asked to interrupt all other kinds of treatment they were using to date, whether they were drugs, physiotherapy or other forms of therapy, except for the patients with rheumatoid arthritis undergoing therapy with gold salts or cortisones. In these cases the patients were invited to progressively reduce the dose until full suspension, before they underwent treatment.

Patients suffering from osteoporosis were advised to increase their calcium intake to above 1500 mg / day to make sure that sufficient free calcium was available in their bloodstream to enable increased calcium deposit into their bones under influence of the pulsating electromagnetic field therapy.

Table 1A **Overview**

PATHOLOGY	**TOTAL PATIENTS 160**	**MALE (M) FEMALE (F) M**	**F**	**AGE DISTRIBUTION**
Fractures	24	6	18	32 - 74
Non-union fractures	10	4	6	43 - 78
Osteoarthritis	18	11	7	48 - 75
Pain reduction	35	20	15	28 - 72
Recovery of joint mobility	10	8	2	31 - 64
Rheumatoid arthritis	25	15	10	52 - 74
Sports traumata	20	14	6	28 - 42
Vertebral spondylosis	12	4	8	34 - 68
Rotator cuff tendinitis	6	4	2	32 - 57

Very large fractures of more than 1.5 cm were bridged within a 2 weeks period, which was clearly proved by X-ray pictures. For fractures exceeding an opening of 0.6 cm. the 20 cm coil electrode was used and for all other treatments the therapy pad.

Table 1B **Results**

PATHOLOGY	**IMPROVEMENT**				
	None	**Slight**	**Good**	**Excellent**	**Total**
Fractures	1	1	9	13	24
Non-union fractures		1	5	4	10
Osteoarthritis	1	2	10	5	18
Pain reduction	2	1	9	23	35
Recovery of joint mobility		1	4	5	10
Rheumatoid arthritis	1	2	13	9	25
Sports traumata		2	6	12	20
Vertebral spondylosis		2	5	5	12
Rotator cuff tendinitis	1		3	2	6

Overall results (good & excellent) 142 / 160 x 100% = 89 % success rate.

Table 2A **Overview**

OSTEOPOROSIS	**TOTAL PATIENTS 68**	**MALE (M) FEMALE (F) M**	**F**	**AGE DISTRIBUTION**
Normal	6	5	1	42 - 62
Osteopenia	19	11	8	45 - 68
Osteoporosis	31	8	23	48 - 72
Severe Osteoporosis	12	2	10	52 - 74

Patients have been divided according to the criteria of the World Health Organization as follows:

Normal:	T score better than	– 1
Osteopenia:	T score between	– 1 and – 2.5
Osteoporosis:	T score between	– 2.5 and – 3.5
Severe osteoporosis:	T score less than	– 3.5

Table 2B **Results**

OSTEOPOROSIS	**IMPROVEMENT**				
	None	**Slight**	**Good**	**Excellent**	**Total**
Severe back pain syndrome		2	10	22	34
Moderate back pain syndrome	1	1	8	8	18
Slight back pain syndrome		1	6	5	12
Absence of pain	1	1	2		4

Overall results (good & excellent) 61 / 68 x 100% = 90 % success rate.

Table 3A **Overview**

PATHOLOGY	**TOTAL PATIENTS 78**	**MALE (M) FEMALE (F) M**	**F**	**AGE DISTRIBUTION**
Multiple Sclerosis	30	10	20	28 - 52
Migraine	21	6	15	32 - 61
Tension Headache	14	10	4	27 -58
Cerebrovascular insufficiency	4	2	2	49 - 79
Nerve regeneration	3	1	2	31 - 63
CVA / TIA	6	5	1	62 - 78

The patients suffering from Multiple Sclerosis were sub-divided into 3 groups according to spasticity, fatigue and bladder control. In those cases where the same patient suffered from more than one of these symptoms the calculation was corrected accordingly to avoid double counting of the same patients for the total column. Noticed was that in order to obtain persistent good results for MS patients daily treatment sessions are recommended over prolonged time periods.

In cases of Central Venous Attacks and Transient Ischemic Attacks, it turned out to be very important that therapy should be started as soon as possible after the event, in order to obtain the best possible results.

Table 3B **Results**

PATHOLOGY	**IMPROVEMENT**				
	None	**Slight**	**Good**	**Excellent**	**Total**
Multiple Sclerosis: Spasticity	1		9	18	^ 28
Multiple Sclerosis: Fatigue		2	10	15	^ 27
Multiple Sclerosis: Bladder Control		1	7	3	^ 11
Migraine			9	12	21
Tension Headache		1	5	8	14
Cerebrovascular insufficiency	1		2	1	4
Nerve regeneration		1	2		3
CVA / TIA	2	1	3		6

For Multiple Sclerosis patients (good & excellent):
(27 / 28 + 25 / 27 + 10 / 11) : 3 x 100% = 93 % success rate.

For other neurological patients (good & excellent):
42 / 48 x 100% = 87.5 % success rate.

Conclusions

Due to the very high overall success rates by the use of the Curatron 2000 Pulsating Electromagnetic Therapy systems for orthopedic and neurological patients, there are currently evaluations underway also for other uses of these systems e.g. in the field of proctology and wound healing.
So far some patients with rectal fissures have been treated, who were already scheduled to undergo operations, which were avoided after spontaneous healing of their fissures by applying very high intensity fields.
Also the first results for treatment of wound healing look very promising and do show fast results in a very short time period.

This state-of-the-art therapy system has proved to be very important for treatment of many different diseases in a simple way, without the need for any contact with the body of the patients. The therapy applicator is placed above or under the body part of the patient to be treated and the flexibility of the therapy method without any contra indication is extremely easy accepted by the patient. The short overall treatment time guarantees a high patient throughput, which make the Curatron 2000 devices also very attractive for smaller hospitals and private clinics.

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