

Scientific Evaluation of the Effectiveness of whole-body MBST[®]-NuclearMagneticResonanceTherapy for treatment of Osteoporosis

Introduction:

The rising number of Osteoporosis within the population poses a challenge for the treating personnel to develop adequate therapeutic methods. These therapies should reduce the pain of the patients and stop or even increase again the permanent reduction of the bone density. Besides of the medicinal treatment methods with their sometimes serious side-effects, research is made on supplementary therapeutical methods. The positive effects of external electromagnetic fields for treatment of bone fractures are already known. With the help of a completely novel technology named „OsteoDolorMed“, a product of the MBST[®]-Nuclear ResonanceTherapy Procedure, which is producing nuclear resonance fields within one complete treatment zone, an objective and subjective evaluation of the effectiveness of the whole-body Osteoporosis treatment can be realized.

For many years already MBST[®]-Nuclear Magnetic Resonance Therapy was high-effectively applied for treatment of degenerations, eg. degeneration of intervertebral discs, arthrosis, arthrosis of temporomandibular joint, local osteoporosis, necrosis as well as injuries caused by sport activities or in an accident.

Contrary to the common technology of pulsed electromagnetic fields (PEMF) the new MBST[®]-Nuclear Magnetic Resonance Therapy System is producing a three-dimensional treatment field, which is forming one homogeneous treatment zone. The system consists of over 12 separately controlled and independent coil systems (partly orthogonally arranged).

Several larger multi-central evaluations of some thousand treated patients evidenced continuous and highly significant improvements of the basic symptoms in the course of 6 months after treatment with MBST[®]-NuclearMagneticResonanceTherapy.

In a prospective examination in the year 2002, 33 patients with arthroscopically (Outerbridge 1989) and 27 patients with roentgenologically (Kellgren et al 1957) diagnosed cartilage damages of the knee joint (out of a total number of 60 patients) were treated with MBST[®]-Nuclear MagneticResonanceTherapy in the Forest Clinic Bad Döben under the leadership of Prof. Dr. Med. Melzer from February to November 2002. The therapy consisted of 5 sessions of 1 hour each on consecutive days. The knee joint was centered within the highly complex air-core coil, which was provided with a static permanent magnetic field. The course of treatment was controlled by the programmable computerchip cards, which were individually adapted to the patients requirements. In a prior examination contraindications, such as tumors, infections, pregnancy, pacemakers, defibrillators could be excluded.

There was a modification of points in the single scores between 32% and 40% in the course of 6 months after the therapy. Thus a statistically significant modification of the point values could be evidenced for all evaluation criteria. Taking every score into consideration this meant a clear improvement of the evaluation results.

The influence on the pain (WOMAC part A: ↓40%, VAS pain while resting: ↓39%, VAS pain in motion: ↓35%, joint stiffness (WOMAC part B: ↓40%) and the joint function (LEQUESNE-Index: ↓37%, LYSHOLM-Score: ↑33%, WOMAC part C: ↓38%) was nearly homogeneous and balanced.

Electromagnetical fields are able to promote the cartilage growth in animal experiments and experiments with cultures (Lipiello at al 1996). Within a time period of 8 weeks after termination of treatment and the results achieved 6 months later, a significant improvement of the point values in the single scores by 11-20 % was found again. MBST[®]-Nuclear Magnetic ResonanceTherapy is a completely new treatment method, the operating principle of which is a direct outgrowth of magnetic resonance tomography (MRT), it may thus not be compared or confused with the common PEMF method.

Froböse conducted a scientific study (in 1999) with clinically diagnosed gonathrosis patients (with stages II and III). This study allowed a world-wide unique (in vivo) three dimensional reconstruction and quantitation of the cartilagenous structure by means of magnetic resonance imaging. Cartilage thickness, cartilage volume and cartilage surface were evaluated by means of MRT-images, which were provided and quantified before of the therapy and 10 weeks later. Froböse ascribed the positive modifications of the cartilage structure to the activation of intact cartilagenous cells and the stimulation of the synthetic collagen activity and supposed that the process of regeneration was not terminated after 10 weeks.

Question:

How effective is MBST[®]-NuclearMagneticResonanceTherapy for treatment of whole-body Osteoporosis ?

Material and method:

The medical application of strong electromagnetic fields (from its diagnostic application) is known as highly resolving, imaging procedure (MRT = Magnetic Resonance Tomography, NMR= Nuclear Magnetic Resonance). Electromagnetic fields and frequencies from Magnetic Resonance Imaging are aligned to processes in the tissues. Radiological observations revealed, that patients, after final diagnosis of a long-term examination by magnetic resonance imaging, reported on inexplicable improvements of their arthrotic complaints. Basing on the new MBS-therapy principle the MedTec Medizintechnik GmbH in D -35578 Wetzlar has developed new appliances, whereby nuclear resonance protons of the hydrogen nuclei (amount of liquid in vivo) are brought into resonance, resp. energy, which is released in the relevant region of the body to be treated. The MBST[®]-Nuclear Magnetic Resonance Therapy is provided by a couch system, which has three treatment zones on a 180 cm long and 60 cm wide surface, consisting of 3 nuclear resonance fields. Separately controlled and completely independently driven high-complex coil systems, ranging to almost the entire couch length, are creating a homogeneous treatment field within a height of 15 cm. The MBST[®] treatment software with its therapy parameters is precisely adjusted to the individual patient and directed to the different regions of the body in accordance with the patient's requirements. This is done via a computerchip card, which is inserted into the appliance before treatment. On this card the number of sessions and specific parameters for the individual patient are precisely determined. So it is possible to create a pre-defined nuclear resonance field in the part of the body to be treated. Due to the easy handling of the therapy appliances and the fact that the operating software can be optimized at any time on the computerchip card, the treatment can be done very easily and without any setting errors. Due to the cards there is no need to update the appliances directly.

Active principle:

According to the active principle of MBST[®]-NuclearMagneticResonance Therapy electrical charges are balanced in line with the decreasing cell potential (core and membrane), e.g. by a permanent magnetic field and a dynamic field and linkage of radio frequencies with modulated treatment sequences. Due to the special static multi-coil system the hydrogen protons align their poles (spin axis) in the magnetic field in accordance with the lines of force. Defined frequency changes of the electromagnetic fields via linked radio frequencies with modulated treatment sequences are influencing the energy level of the hydrogen cores. The achieved nuclear resonance of the hydrogen protons is setting energy free by inverting its spin direction. The proton spin decays back to its original direction and by doing so transfers the energy in a highly effective manner and in resonance to the surrounding tissue. Assumption is made that repair processes are induced by these impulses, which are having

a direct impact on the bone structure and pain situation. A stimulation of the synthetic activity of the Chondrocytes by the nuclear magnetic resonance effect and in vitro a reduction of the Proteoglykandegradation could already be evidenced in studies (Liu et al. 1996).

Selection and procedure

To guarantee independent evaluations of the effectiveness of MBST[®]-NuclearMagnetic ResonanceTherapy for the whole-body treatment of Osteoporosis, 3 specialist practices and one „Behandlungszentrum“ (treatment centre) were selected for the scientific research work.

- Facharztpraxis (Specialist practice) 1
Practice of Dr. med. Joachim Overbeck, Deggendorf - Germany
- Facharztpraxis (Specialist practice) 2
Practice of Dr. med. Urban, Worms - Germany
- Facharztpraxis (Specialist practice) 3
Practice of Dr. Günther Gerhard, Wendelsheim - Germany
- ReAktiv-Behandlungszentrum, Wetzlar - Germany

In every specialist practice as well as in the „Behandlungszentrum“ (treatment center) one treatment couch was installed for whole-body Osteoporosis treatment. 27 patients whose degenerations (caused by Osteoporosis) were diagnosed after a bone density measurement (Osteo-CT and DEXA-measuring method) were treated in the practices by MBST[®]-Nuclear-MagneticResonanceTherapy from May 2002 to October 2003. The therapy was conducted within 2 weeks in 10 one hour treatment sessions on consecutive days. The patients were positioned onto the 3-field-nuclear resonance applicators (located inside of the treatment couch). The defined treatment procedure was controlled by the programmable computerchip cards, which were individually adapted to the patients' need and which were inserted into the appliance. In a prior examination contraindications, such as tumors, infections, pregnancy, pacemakers, defibrillators could be excluded. During the evaluation period the patients did not receive any medicine for osteoporosis treatment (such as Bisphosphates, Calcitonin, Fluoride, SERM-products or similar medicine) and no accompanying physical treatment. To ensure an optimum therapeutical success the patients had to drink sufficient liquid (2-3 liter per day) one week before of the therapy as well as during the therapy. They also received a Calcium product as well as Vitamin D3 during the therapy. The data were collected and evaluated within a time period of 6 months.

The following blood values were measured and evaluated in the laboratories during the 10-days therapy:

- Calcitonin
- Phosphate
- Calcium
- Creatinine
- Parathormon
- Desoxipyridivolin in the second morning urine

During the MBST-Therapy a daily evaluation protocol of the pain situation was written by a visual analog-scale (ranging from 0 to 10 points).

- Pain while resting
- Pain in motion
- Maximum pain

4 measurements of the bone density were performed within a time period of 6 months.

1. Measurement before of the therapy

2. Measurement about 6 weeks after the therapy
3. Measurement about 3 months after the therapy
4. Measurement about 6 months after the therapy

Results:

The data of 21 patients (out of 27 patients, who were treated by this new method and who were diagnosed osteoporosis patients) could be determined within a time period of 6 months by means of four bone density measurements. The average age of the patients was 65,07 years (35 years minimum and 90 years maximum). 21 women and 6 men received a whole-body treatment. The mean weight was 75,9 kg.

All patients reported that they did not realize any side-effects or pain and were convinced of the gentle treatment. Nobody interrupted the therapy in advance.

1. Daily determined laboratory values of blood and urine:

The daily laboratory values of all patients such as Calcitonin, Phosphate, Calcium, Creatinine and Parathormon of the blood as well as Desoxypyridivolin in the second morning urine, did not show any modifications with regard to the basic values.

2. Pain situation of the patients during and after MBS-Therapy

2.1 Maximum pain, pain in motion and pain while resting

(analog-scale 0 = no pain up to 10 = unbearable pain situation)

After the third and fifth therapy session already, highly significant improvements by at least 3 – 5 evaluation points could be noted.

The subjective pain situation directly after therapy as well as 3 and 6 months later, which was indicated by the patients, even revealed that the highly significant effects were still continuing after the 6 months evaluation period.

2.2 Pain incidence of maximum pain, pain in motion and pain while resting

(analog-scale 0 = no pain up to 10 = permanent pain)

Over 80 % of the treated patients realized a diminished pain incidence after 3 – 5 therapy sessions, which means an evident reduction in pain incidence by at least 3 – 6 evaluation points. Within the evaluation period of 6 months even highly significant improvements of up to 8 points could be noted. Acc. to the analog scale system, which measures the phases of permanent pain right from the beginning, the incidence of pain could be reduced to 1 or 2 times per day. The most important modification of high significance could be achieved for pain in motion.

Determination of bone density.

To determine the bone density two internationally approved methods were applied:

- Osteo-CT-measurement
- DEXA-Osteodensitometry measurement

3. Measuring results in specialist practice 1

Measurement of bone density of 11 patients via Osteo-CT-procedure.

Evaluation period June 2002 to Oct. 2003

pat. no.	age years	m / f	Osteo-CT before MBST®	Osteo-CT after MBST®	Osteo-CT 3 Mon. after MBST®	Osteo-CT 6 Mon. after MBST®	Increase of bone density Mineral saltgeh. 6 Monate after MBST® modification %
			Contents of mineral salt value	Contents of mineral salt value	Contents of mineral salt value	Contents of mineral salt value	
01	52	f	43,10 mg	59,20 mg	61,90 mg	66,70 mg	35,40%
02	75	f	54,00 mg	52,30 mg	51,90 mg	57,70 mg	6,42%
03	66	f	48,17 mg	44,60 mg	51,53 mg	56,34 mg	14,50%
04	61	f	51,42 mg	51,69 mg	45,80 mg	54,17 mg	5,08%
05	67	f	56,73 mg	55,02 mg	53,80 mg	57,30 mg	1,00%
06	68	f	11,79 mg	-1,23 mg	2,50 mg	13,12 mg	10,14%
07	90	f	52,20 mg	52,24 mg	56,70 mg	59,48 mg	12,24%
08	69	M	no measurement	56,06 mg	46,58 mg	51,90 mg	-8,02%
09	77	M	30,04 mg	31,48 mg	30,00 mg	35,80 mg	16,09%
10	81	f	52,56 mg	65,55 mg	54,70 mg	55,85 mg	5,90%
11	72	f	17,80 mg	12,22 mg	no measurement	no measurement	not analyzable

table. 3.1 measurement of CT-mineral salt-Äquivalentkonzentration

In case of patient no. 06 a calculation error with negative bone density values occurred. This result was received during the second measurement. The reason was overweight of the central yellow bone marrow.

In case of patient no. 11 only the values before and after the therapy could be applied, as the patient was suffering from a disease during the therapy.

4. Measuring results in specialist practice 2

Measurement of bone density of 8 patients with the DEXA-measuring procedure.

Evaluation period Sept. 2002 to Oct. 2003

pat. no.	age years	m / f	DEXA-value before MBST®		DEXA-value after MBST®		DEXA-value 3 Monats after MBST®		DEXA-value 6 Monats after MBST®		increase of bone density 6 Monats after MBST®	
			value L1-L4	Z-value	T-value	Z-value	T-value	Z-value	T-value	Z-value	T-value	Z-value
01	35	m	-2,98	-2,98	-3,26	-3,26	-3,31	-3,31	-2,71	-2,70	9,96%	10,37%
02	56	f	-3,20	-4,32	-3,16	-4,28	-3,20	-4,34	o. M.	o. M.	0,00%	-0,46%
03	53	m	-2,32	-2,76	-2,38	-2,80	-2,42	-2,85	-2,24	-2,65	3,57%	4,15%
04	73	f	-1,02	-3,30	-1,06	-3,34	-0,82	-3,11	-0,84	-3,16	21,42%	4,43%
05	61	f	-1,13	-2,58	-1,30	-2,77	-1,07	-2,56	-1,08	-2,59	4,62%	-0,39%
06	62	f	o M	o. M.	-2,75	-4,28	-2,49	-4,04	-2,36	-3,93	16,52%	8,91%
07	52	f	-2,48	-3,32	-2,29	-3,14	-2,05	-2,90	-1,83	-2,71	35,51%	22,50%
08	48	m	o. M	o. M.	-2,77	-3,06	-2,75	-3,04	-2,46	-2,77	12,60%	10,47%

table 4.1 measurement of Z- und T-Werte

pat. no.	age years	m / f	DEXA-value before MBST®	DEXA-value after MBST®	DEXA-value 3 Monats after MBST®	DEXA-value 6 Monats after MBST®	increase des BMD-value 6 Monats after MBST® value % L1-L4
			value L1-L4	value L1-L4	value L1-L4	value L1-L4	
			BMD (gms/cm2)	BMD (gms/cm2)	BMD (gms/cm2)	BMD (gms/cm2)	BMD (gms/cm2)
01	35	m	0,763	0,733	0,727	0,793	4,79%
02	56	f	0,572	0,576	0,570	o. M.	-0,35%
03	53	m	0,787	0,783	0,777	0,799	1,51%
04	73	f	0,684	0,679	0,705	0,700	2,29%
05	61	w	0,763	0,743	0,766	0,763	0,00%
06	62	w	o. M.	0,576	0,603	0,614	6,19%
07	52	w	0,681	0,702	0,728	0,749	9,08%
08	48	m	o. M.	0,755	0,757	0,787	4,07%

table 4.2 determination of BMD-value

4 Measuring results in specialist practice 3

Measurement of bone density of 6 patients via Osteo-CT-measuring procedure

Evaluation period May to Oct. 2002

pat. no.	age years	Diff. days zwischen der 1. und 2. Osteo-CT value	1. Osteo-CT value before MBST®		2. Osteo-CT value after MBST®		increase of bone density 6 Monts after MBST®	
			value L1-L4	Z-value	T-value	value L1-L4	Z-value	T-value
01	67	29 days	-1,80	-4,90	-0,70	-3,70	60,98%	24,51%
02	77	65 days	-1,80	-5,20	-0,50	-3,90	72,46%	25,00%
03	52	49 days	-0,63	-1,68	-0,26	-1,11	58,82%	33,90%
04	78	28 days	-1,60	-5,30	-1,40	-4,05	12,50%	4,72
05	73	35 days	-1,25	-4,50	-1,10	-4,30	12,00	4,44
06	62	54 days	-0,68	-1,55	-0,26	-1,32	62,11	14,84

table 5.1 measurement of Z- und T-value

5 Measuring results in the „Behandlungszentrum“ (treatment center)

Measurement of bone density of 2 patients via DEXA-measuring method.

Evaluation period Oct. 2002 to March 2003

pat. no.	age years	m / f	DEXA-value vor MBST®		DEXA-value nach MBST®		DEXA-value 3 Monts nach MBST®		DEXA-value 6 Monts nach MBST®		Increase of bone density 6 Monts nach MBST®	
			value L1-L4	Z-value	T-value	value L1-L4	Z-value	T-value	value L1-L4	Z-value	T-value	value % L1-L4
01	64	m	-2,18	-3,82	-2,23	-3,91	-2,10	-3,73	-1,85	-3,35	17,84%	14,03%
02	73	f	-1,40	-2,90	-1,42	-2,94	-1,30	-2,80	-1,18	-2,36	18,64%	22,88%

table 6.1 measurement of Z- und T-value

pat. no.	age years	m / f	DEXA-value before MBST®	DEXA-value after MBST®	DEXA-value 3 Monts after MBST®	DEXA-value 6 Monts after MBST®	Increase of BMD-value 6 Monts after MBST®
			value L1-L4	value L1-L4	value L1-L4	value L1-L4	value % L1-L4
			BMD (gms/cm2)	BMD (gms cm2)	BMD (gms/cm2)	BMD (gms/cm2)	BMD (gms/cm2)
01	64	m	0,573	0,559	0,575	0,629	8,01%
02	73	f	0,851	0,842	0,862	0,919	8,40%

table 6.2 determination of BMD-value

In case of 24 patients significant and highly significant modifications of the bone density could be evidenced (e.g. Z-; T-; content of mineral salt and BMD-values).

As we can note from the measuring tables the time of success is differing for each patient.

Starting from the basic values before of the therapy the measuring values of some patients directly after the MBS-NuclearMagneticResonanceTherapy, resp. after a time period of three months, first showed a decrease in bone density, but in the course of time e.g. 6 months later, most of the values showed a highly significant increase in bone density.

In case of 3 patients the bone density values (which were received during the evaluation time) were negative compared with the basic values attained before start of the therapy. This may be subject to the missing measuring values or subject to a diminished or delayed therapeutical effect.

If we compare the basic values of 24 patients, measured before start of the therapy, with the measuring results achieved 6 months after the MBST[®]-NuclearMagneticResonanceTherapy (for whole-body treatment of Osteoporosis), we can realize a clearly positive modification of the bone density.

Positive modification of the bone density values evidenced within a time period of 6 months.

• Increase of T-values	4,15 %	up to	33,90 %
• Increase of Z-values	3,57 %	up to	72,46 %
• Increase of mineral salt value	1,00 %	up to	35,40 %
• Increase of BMD-value	1,51 %	up to	9,08 %

Discussion:

Due to the definite results achieved during the internationally approved measuring procedures, which clearly evidenced a substantial increase in bone density, it was not necessary to establish a control group as placebo-group. Placebo-effects did not occur during bone density measurements.

The very fast and positive modifications already reached within the 2-weeks treatment, as well as the continuous improvement of the subjective pain symptoms after the time period of 6 months (pain situation and mobility of the patients), can not be referred to placebo-effects, as no continuous improvement can be attained by a placebo-effect within a time period of 6 months.

The high effectiveness of MBST[®]-NuclearMagneticResonanceTherapy is very impressive and without any side-effects. According to our results no other therapeutical method is able to improve the bone density and thus the bone stability in the same way as the MBST[®]-NuclearMagneticResonanceTherapy.

We understand our scientific research work as observation of the application. As far as we know there are no comparable appliances for whole-body treatment of Osteoporosis available until now. This means that no comparisons can be drawn in this field.

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