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The effect of MBST®-NuclearResonanceTherapy with a complex 3-dimensional electromagnetic nuclear resonance field on patients with Low Back Pain

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Abstract. A new treatment system using nuclear resonance as its active principle was applied, as an adjunct to a normal standardized physiotherapy programme. This novel NuclearResonanceTherapy (MBST® or MBS-Therapy) was applied for one hour on five successive days. The study was performed double blind, placebo-controlled and randomised on 62 rehabilitation patients suffering from chronic Low Back Pain at baseline, after one week and after 3 months. The pain measurements using the Visual Analogue Scale (VAS) showed a distinct reduction of pain after active MBST® and placebo. The Roland & Morris Disability Index (RM) total score also improved significantly in both groups, but the improvement was more distinct in MBST® patients compared to placebo. After three months, the positive effect of MBST® on the RM total score was still significant ($p < 0.00001$) whereas this was not the case for the placebo-treatment.

The significant improvement in the MBST®-group was primarily evident in the RM-questions regarding incapacities caused by Low Back Pain, particularly sleeping problems, fatigue, bending ability, and the time required to get dressed.

NuclearResonanceTherapy as a complementary treatment can improve the outcome obtained by inpatient rehabilitation programmes after 3 months.

Keywords: NuclearResonanceTherapy, MBST®, chronic low back pain, rehabilitation, roland & morris disability index

1. Introduction

Chronic Low Back Pain is a disorder with important socio-medical consequences. First of all, current and previous treatment methods are costly. Secondly, Low Back Pain causes considerable disability losses to the economy. Often patients are in such pain that they no longer believe in their ability to cope with the problems of everyday life, and especially with the daily stress of their occupations. Since such psychological stress is an important component of the factors which cause Low Back Pain to become chronic, a cure that reduces sick time and injury losses must interrupt this stress cycle with the help of appropriate therapeutic measures. Novel rehabilitation concepts are now being tested in order to develop new interdisciplinary approaches to reducing pain-induced disabilities. These concepts sug-

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gest that the treatment of Low Back Pain should comprise several modalities, best achieved during a period of inpatient rehabilitation.

It is by no means easy to render an objective evaluation of chronic Low Back Pain. This problem is mainly caused by the fact that "pain" cannot be quantified. However, it is this objectively non-quantifiable symptom that controls patients' limitations and functional capacity, or in other words, their incapacity for, and reduction of, their everyday activities.

To document therapeutic results it is best to use specially developed and validated questionnaires for the evaluation of non-specific Low Back Pain, which are also available in a German version (Roland & Morris, Oswestry). These questionnaires record all aspects involved, such as damage, activity, participation, and contextual matters. They are the most frequently used questionnaires in the pertinent literature [16]. Such documented therapeutic results form an important foundation for the evaluation of rehabilitative improvements.

Magnetic field effects on the human body have been studied in many papers, however, technical as well as physical details of magnetic field applications (amplitudes, frequency, application times, etc.) vary widely limiting the validity of the data.

A special form of nuclear magnetic resonance technique (NMR), a therapeutic procedure based on nuclear resonance, and known as MBST® – NuclearResonanceTherapy [10], has been developed recently. The active principle is based on the same principles as nuclear magnetic resonance diagnostic systems (MRI). NMR became popular in medicine as NMR imaging technology providing excellent images of the body. But little is known about NMR effects on cells.

Resonance is a vibration phenomenon that occurs whenever vibration of a certain frequency is transmitted to a receiver with the same basic frequency, which is thus stimulated to more intense vibrations of its own. The frequency and intensity of the electromagnetic field is adjusted appropriately to induce resonant vibration of molecular structures within cartilage or bone tissue, thereby stimulating proliferation of chondroblasts and osteoblasts.

Using NMR as a tool for stimulating cells recently it could be demonstrated in a controlled double- blind study that NMR in vitro causes enhanced cell proliferation of chondrocytes and osteoblasts [21].

It has been established [9] that NuclearResonanceTherapy regenerates cartilage tissue. Using nuclear resonance tomography, that study clearly showed that MBS-Therapy caused an increase in both volume and thickness of cartilage in patients suffering from gonarthrosis.

On the other hand, treatment of chronic Low Back Pain with static magnetic fields formed by permanent magnets must now be considered ineffective [1], as no scientific proof for any positive effect has been presented [8].

On the basis of potential NMR effects like 1.) positive findings of NMR effects in a recent in vitro study on human cell lines of chondrocytes and osteoblasts of Temiz-Artmann et al. [21], which could demonstrate that NMR treatment causes enhanced proliferation rates, and 2.) furthermore possible effects on signal transduction cascades and ion channel transport [2, 4]. The objective of our study was to investigate in vivo the therapeutic effects of nuclear magnetic resonance on clinical symptoms and outcome variables in patients with painful chronic Low Back Pain.

2. Methods

2.1. Study patients

The study included 62 patients (36 males and 26 females). The youngest patient was 18 years old; the eldest was 71. Their mean age was 48.1 years. All patients suffered from Low Back Pain and had been admitted for a three-week inpatient rehabilitation therapy at the Rehabilitation Centre (specialised hospital, Saalfelden for disorders of the musculoskeletal system), part of the Pension Insurance Authority, Austria. The disorders diagnosed were: chronic Low Back Pain (chronic lumbar syndrome) $n = 52$, protruding intervertebral disk $n = 7$, post-laminectomy syndrome after intervertebral diskectomy $n = 6$, cervical syndrome $n = 10$. Sometimes, patients suffered from a combination of these disorders.

All patients were given a detailed briefing about all aspects of the study as well as a printed information brochure about the therapy applied in the study. At the beginning of the study all patients signed a document stating that he/she agreed to be part of the study.

2.2. Inclusion criteria

Painful chronic Low back Pain, spinal diagnosis using the methods of computer tomography (CT), radiological or magnetic resonance imaging (MRI); minimum at baseline in the 10 point VAS (Visual Analogue Scale) pain rating scale ≥ 4.0.

2.3. Exclusion criteria

The following exclusion criteria were defined: Malignant diseases, bacterial infections, rheumatoid arthritis, HIV-positive patients, disorders of the cardiovascular system, arrhythmia, patients with a pacemaker, inplanted cardioverter, insulin pumps, or total endoprothesis of the hip, alcohol abuse, pregnancy and lactation.

2.4. Study design and treatment

The study was designed as a placebo controlled, double blind, randomised mono-centric multiple data study with a duration of three months. In the context of a multi-disciplinary rehabilitation concept for spinal syndromes, all patients participated in a standardized, inpatient physiotherapy programme. This programme comprised gymnastics in and out of the water, mechanotherapy, massages, parafango applications, and medicinal baths. The therapeutic schedule excluded electrotherapeutic applications on the spine as well as hydroelectric baths.

All patients were subjected to a special therapy sequence on the damaged spinal regions. The NuclearResonanceTherapy sequence consisted of five treatments of one hour each, on five consecutive days. The total therapy duration with the MBST was thus five [5] hours [7].

2.5. NuclearResonanceTherapy system

The appliance used for the treatments was a magnetic nuclear resonance air-cored coil therapy system (MBST = NuclearResonanceTherapy), version KSRT-Key K1B, type MBST 600 KSRT, serial number 12100015, produced and supplied by MedTec Medizintechnik GmbH., Wetzlar, Germany. The appliance uses a novel MBS-therapeutic principle based on controlled nuclear resonance of protons of hydrogen atoms.

A special permanent magnetic field causes the protons of hydrogen atoms (hydrogen nuclei) to align their resonant axes along the field lines. A radio frequency (RF) field at the nuclear resonant frequency transfers energy to the protons, and this extra energy is transferred highly effectively into the surrounding tissue. This added energy is therapeutic.

In contrast to the PEMF methods currently in use, MBST® constructs complex 3-dimensional therapy fields with the help of twelve independent, and independently controlled, coil systems that are, in part, spaced in an orthogonal pattern, at angles of 90° to each other. Together with the permanent magnetic field, these 3-dimensional therapy fields form a nuclear resonance field in the centre of the coil system [7].

The desired dose of MBS-Therapy into the target regions of the patient's body is achieved with the help of MBST®-Treatment software. This software is controlled by a computer chip card at the beginning of therapy, to allow fine adjustment of therapy parameters [10].

Patients rested comfortably on a couch, with the appropriate body part, the painful section of the spine, positioned into the coil of the MBST-appliance as described above.

2.6. Randomization

The double-blind randomising was carried out by means of the coded chip cards. Thus, for half of the patients, the control unit activated the construction of the complex therapy fields (= Patients *subjected* to MBS-Therapy) whereas such therapy fields were not activated for the remaining patients (again 50%), (= Patients *not subjected* to MBST® = Nuclear Resonance Placebo Treatment).

2.7. Clinical evaluation

An extensive clinical examination of each patient was carried out at the time of admittance to the rehabilitation clinic. Following that, important clinical factors were evaluated at the beginning of the MBST-Study (Day 0), at one week after the five treatments, and at 3 months after the termination of therapy.

2.8. Outcome variables

The factors evaluated at all three points in time were: a) the peak level of pain, b) the mean level of pain when moving, and c) the level of pain at rest. For the evaluation of the level of incapacity caused by chronic Low Back Pain the Roland & Morris questionnaire for Low Back Pain [14,15] was used at the three evaluation times defined above. The Roland & Morris Disability Questionnaire (RMDQ) is a short and simple method of a self rated assessment of physical function in patients with back pain [16]. This clinical questionnaire comprises 24 subjective detailed questions by which the functional disability caused by Low Back Pain can be evaluated. Each item is supplemented with the phrase

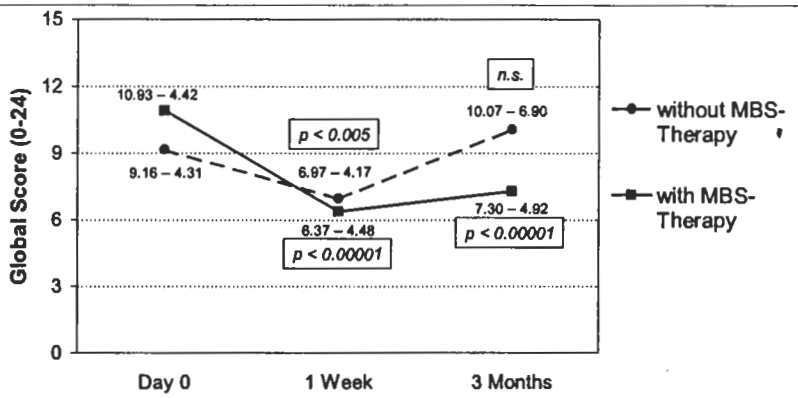

Fig. 1. Changes in the Roland & Morris total scores from 24 questions in patients suffering from Low Back Pain with and without MBST®-NuclearResonanceTherapy.

"because of my back pain" to distinguish back pain disability from disability due to other causes – a distinction that patients are in general able to make without difficulty [16].

2.9. *Statistical methods*

The statistical evaluation was carried out with the help of SYSTAT version 9.0 Statistics for Windows (SPSS Inc., USA) and MedCalc Statistics for Biomedical Research version 5.0 (MedCalc Software, Belgium). The procedures used mainly descriptive statistics, the Wilcoxon test, and the Student-t test.

3. Results

The standardized multidisciplinary rehabilitation procedure improved the Roland & Morris total score for Low Back Pain for all patients during the inpatient rehabilitation period. The improvement was significant at the $p < 0.00001$ level for rehabilitation patients that obtained additional MBS-Therapy treatment and at the $p < 0.005$ level for those patients that did not get MBS-Therapy. In both groups, the improvements were significant at the end of the three week inpatient treatment, (Fig. 1).

It is noteworthy that those patients that had higher Roland & Morris scores at the beginning of the study and that received MBS-Therapy showed a much greater improvement (from 10.93 ± 4.42 to 6.37 ± 4.48) than those belonging to the comparison group. In respect to their mean values, both study groups were just about identical after one week rehabilitation.

After three months, however, the Roland & Morris score of the patients belonging to group without MBST® had increased again, until the score value of this group (10.07) was not significantly less than the starting value. On the other hand, those patients who during the inpatient rehabilitation had been subjected to 5 hours of MBST®-NuclearResonanceTherapy showed a Roland & Morris score that was still, at the end of three months, significantly better (7.30; $p < 0.00001$) than the initial value.

The improvement within the MBST-Group was especially marked for question 18, which relates to sleeping problems. In this case, a significant improvement of sleep quality ($p < 0.02$) had already occurred after therapy, and this improved sleep quality remained stable to three months, (Table 1).

Another improvement was observed in relation to question 6: "Because of my back, I lie down to rest more often." In this case, the percentage of patients that answered with "yes" was reduced by half, (Fig. 2).

Furthermore, disability because of Low Back Pain when bending at the waist or kneel down was reduced significantly ($p < 0.05$) after MBS-Therapy and this improvement was observed in an even larger group after three months ($p < 0.01$). This disability remained practically unchanged in the placebo group, (Table 2).

Another improvement observed with the patients of the MBST®-Group: They needed less time to dress (Roland & Morris questionnaire item 9).

Neither group showed significant score improvement for several of the Roland & Morris questions, although there was a tendency for distinctly better results in the MBST-group. For example, a high percentage of patients in both groups indicated improvement for ques-

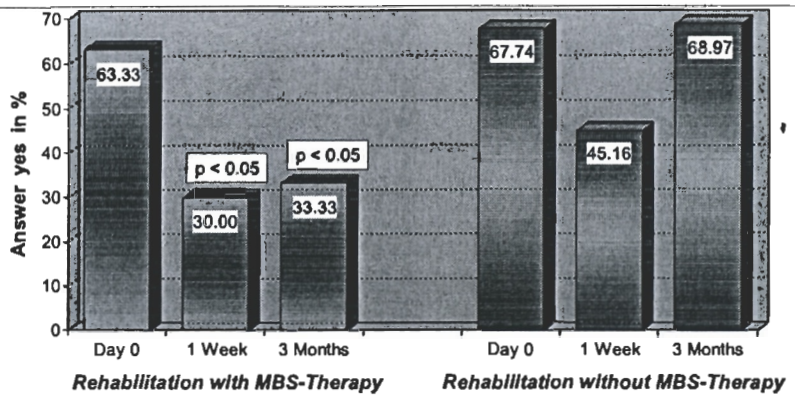

Fig. 2. MBST®-NuclearResonanceTherapy in the case of Low Back Pain – Roland & Morris Question *6: "Because of my back, I lie down to rest more often".* Frequency distribution of the "yes" answers.

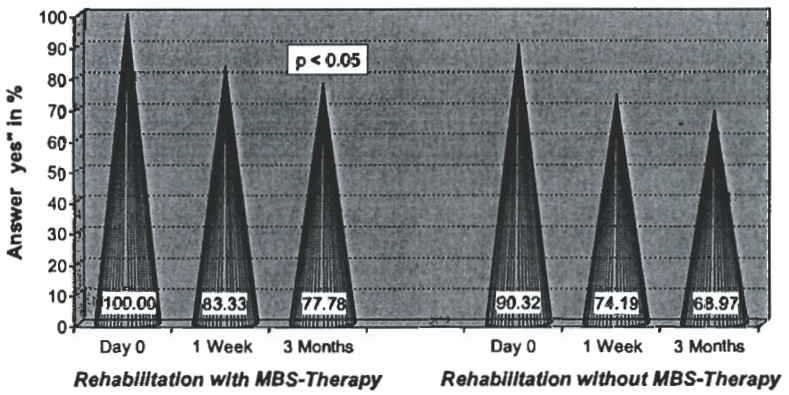

Fig. 3. Roland & Morris-Score Question 2: "I change position frequently to try and get *my back comfortable".* Percental changes of the impairment caused by Low Back Pain with and without MBST®-NuclearResonanceTherapy.

tion 2: "I change position frequently to try and get my back comfortable," (Fig. 3).

The results for question 13: "My back is painful almost all the time" correlate with the pain measurements as recorded with the help of the Visual Analogue Scale. Twenty percent of the MBS-Therapy group showed slightly better results on Roland & Morris item 13, which is related to the decrease of pain.

The *measurements of pain* with the help of the *ten-part Visual Analogue Scale* showed that there was distinct relief during the three-week inpatient rehabilitation period, independently of whether or not the patients had been subjected to MBST®-NuclearResonanceTherapy, (Fig. 4).

This decrease of pain could still be observed three months later. The observation by the Low back pain patients of the peak pain level by use of the VAS-Score-Improvements was 5.3, respectively 5.1 and therefore distinctly lower than the peak pain level before the 5-day therapy series (VAS 7.9, respectively 8.1). The VAS values for pain on weight bearing were still considerably lowered in patients that had been submitted to the MBS-Therapy, whereby this was not so in patients submitted to the Placebo procedure.

The frequency distribution of the VAS-Score-Improvements for pain under stress after exercise, although showing a slight advantage after therapy for the patients in the MBS-Therapy-Group (40% pain reduction as compared to 24.1% pain reduction for the patients that did not get the MBS-Treatment) and a somewhat longer lasting pain reduction during resting periods (−27.0% as compared to −19% reduction achieved using purely physical standard therapy methods), shows that there was no statistically significant difference in peak pain level and pain level on weight bearing between the groups three months after the completion of the inpatient rehabilitation period, (Table 3).

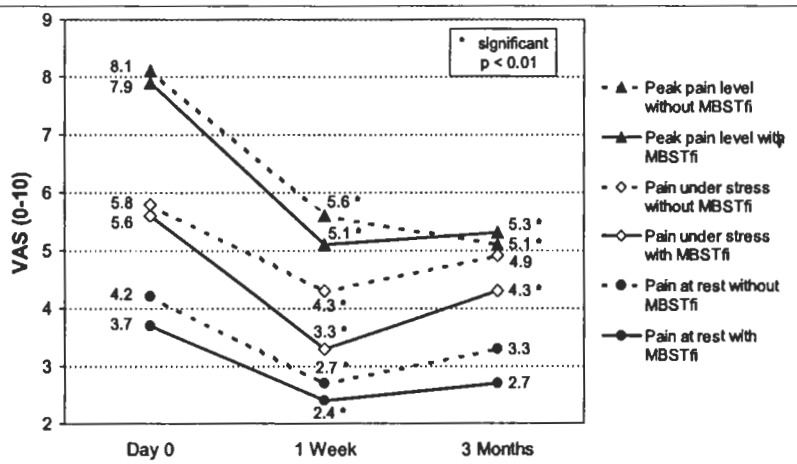

Fig. 4. Visual Analogue Scale (VAS) – Changes in pain intensity in Rehabilitation patients suffering from Low Back Pain with or without additional MBS-Therapy.

It is, however, interesting to note, that the patients of the MBST®-Group still reported a statistically significant (23.2%) reduction of pain as late as three months after termination of the therapy. The pain reduction at that time in patients belonging to the Placebo-Group, however was only 13.8%, and therefore no longer to be regarded as a statistically significant improvement. In general, the patients belonging to the active MBST®-Group reported that the treatment was agreeable, did not cause any pain, and that they did not experience any negative side effects.

4. Discussion

The prevalence of Low Back Pain, or in other words, the fraction of the population with pain caused by disorders of the spine some time in their lives, is estimated to be 50 to 80% [19,22]. This enormous prevalence of Low Back Pain causes considerable costs to the health care system and is, therefore an important factor in the general socio-medical context of our life [20]. Today, therapy results are generally evaluated in the context of back-specific function, pain, general health status, work capacity, and general happiness of the patients [6].

The Roland & Morris Incapacity Questionnaire [3] is the most often used questionnaire to evaluate the physical functioning of Low Back Pain patients [24]; it takes into consideration the complex activities of daily life. The Questionnaire is also available in German, and in that form has been accepted as a validated instrument for the recording of the functional status of Low Back Pain patients. The Roland & Morris questionnaire and the ten-part Visual Analogue Scale (VAS) for pain are useful for evaluating the results of Low Back Pain therapy for pain, incapacity and physical improvement [13].

The fact that classical physical therapy for chronic Low Back Pain [19] results in improvement at the symptomatic level (pain) and in everyday function in only about one third of rehabilitation patients clearly demonstrates the need for novel measures in this field.

Electromagnetic fields can stimulate cells as a reaction to changes in mechanical stress [12]. In the case of cartilage tissue and connective tissue structures, the electrical activities are somewhat more complex than in bone tissue, but the principle discussed above still obtains. Changes of tension within collagen structures caused by differences in mechanical stress induce the transport of electrical signals to and from the tissue structures and thus have a positive effect on the metabolism [17]. It has been shown that pulsating electromagnetic fields (PEMF) induces positive biological reactions such as cell proliferation, matrix construction, etc. [18].

MBST®-NuclearResonanceTherapy is a very interesting and very effective new approach to electrotherapy for regenerating cartilage or cartilage-like structures [9]. According to Rothschild [17] the application of traditional pulsating electromagnetic fields (PEMF) enhances DNA synthesis and collagen products, especially in the marginal zones. The special nuclear resonance field of MBST®, however, may be assumed to reactivate all chondrocytes or may possi-

Table 1
Question 1 *8: "I sleep less well because of my back"* of the Roland & Morris Questionnaire in rehabilitation patients after a MBST®-NuclearResonanceTherapy serie as compared to a standard rehabilitation programme without MBST®

	Day 0		1 Week		3 Months	
	yes	no	yes	no	yes	no
With MBS-Therapy	73.33%	26.67%	36.67%**	63.33%**	37.04%**	62.96%**
Without MBS-Therapy	64.52%	35.48%	45.16%	54.84%	55.17%	44.83%

**$p < 0.02$.

Table 2
Roland & Morris *Question 11: "Because of my back, I try not to bend or to kneel down" in the case of* Low Back Pain rehabilitation patients with and without MBST®-NuclearResonanceTherapy respectively (Significance p in comparison to the value at the beginning of the study

	Day 0		1 Week		3 Months	
	yes	no	yes	no	yes	no
With MBS-Therapy	86.67%	13.33%	66.67%*	33.33%*	55.56%***	44.44%***
Without MBS-Therapy	70.97%	29.03%	70.97%	29.03%	65.52%	34.48%

*$p < 0.05$; ***$p < 0.01$.

Table 3
Evaluation of pain using the Visual Analogue Scale (VAS) for the evaluation of peak pain level, average pain level under stress and average pain level at rest. Indication of the VAS changes in percentage related to the values at the beginning of the therapy of rehabilitation patients suffering from Low Back Pain. Results of the rehabilitation with or without MBST®-NuclearResonanceTherapy

	Inpatient Rehabilitation without MBS-Therapy		Inpatient Rehabilitation with MBS-Therapy	
	after 1 week	after 3 months	after 1 week	after 3 months
Peak pain level	−28.40%*	−37.04%*	−35.44%*	−32.91%*
Pain on weight bearing	−24.14%*	−13.80%	−41.07%*	−23.21%*
Pain at rest	−38.10%*	−19.05%	−35.14%*	−27.03%

*Indicates significance $p < 0.01$.

bly even regenerate cells that have already been damaged. Indeed, this has already been shown in animal experiments [11] using the PEMF method. According to Valberg [23] the PEMF method can be used for the treatment of degenerated cartilage structures, but one must pay attention to the quality and quantity of the complex electromagnetic field.

MBST®-NuclearResonanceTherapy is a novel, highly technical therapy procedure for which the effective mechanism has been derived directly from nuclear resonance tomography und therefore cannot and should not be compared or confused with PEMF or complex PEMF.

The MBST® appliances generate a static magnetic field and a 3-dimensional radio frequency field, leading to the build-up of a nuclear resonance field at the site of the tissue that is to be treated. The nuclear resonance field has a pre-defined cell biorhythm frequency which is basically amplitude modulated with a modulation frequency similar to the nuclear resonance frequency. The purpose is to obtain the highest possible actively directed resonant energy transfer using the smallest possible field strength. When cells are placed in a high frequency NMR field energy is deposited and the cellular metabolism might be affected leading to stimulated protein expression [5], activated signal transduction cascades [2] and affected ion channel transport [4].

The results of our study of therapy methods for patients with chronic Low Back Pain show that significant improvements in functionality can be achieved with standard rehabilitation methods during inpatient rehabilitation, as measured with the help of the Roland & Morris questionnaire for Low Back Pain. When patients were subjected to MBST®-Therapy as part of the treatment, the improvement in Roland & Morris global score was distinctly retained at the end of a three-month evaluation period, but the score for patients that did not receive the additional MBST® treatment had reverted to values similar to those measured at the beginning of the treatment.

For some of the Roland & Morris questions, the patients subjected to MBST® showed improvement over those in a control group that had only been subjected to the standard rehabilitation programme and a placebo "treatment" in the MBST® appliance. For example, at the end of the three-month evaluation period patients that had received the MBST® had much less difficulty getting dressed than those of the placebo group.

It is also very interesting to note that a distinct amelioration of sleeping problems caused by Low Back Pain was observed within 5 days after completing MBST®, and that the improvement lasted throughout the entire three-month evaluation period. Further, patients that were subjected to MBS-Therapy reported that they required less pain-induced rest periods (Roland & Morris, question 6).

The VAS measurement of Low Back Pain showed that a comparable lasting positive enhancement in pain tolerance could be achieved in both patient groups (Fig. 4).

This fact documents the success of the standardized rehabilitation treatment.

However, in respect of the improvement of pain under stress a very distinct advantage was to be observed in those patients that had been part of the active MBST® group. This distinct advantage was to be observed during the entire observation period. This does, of course, point towards an effect through the modification of structures. Such a modification of structures would be quite possible after a period of three months. The distinct improvement in respect to pain on weight bearing, observed as early as one week after therapy, however, indicates that quite possibly other, more rapidly pain relieving effects may also be induced.

In further studies, it would be interesting to show whether the positive impact of MBST®-NuclearResonanceTherapy remains after a period longer than the 12 weeks that were studied by us. Further, it would be interesting to study whether, in addition to the positive effects on symptoms (pain) and function, it is possible to obtain structural improvement of the spine similar to the improvement of knee joint cartilage shown by a German research team [9].

As a general conclusion, we can state that we consider MBST®-NuclearResonanceTherapy to be an additional, complementary, therapeutic method that is easy to apply and that requires only very short therapeutic procedures. MBST® can positively enhance therapeutic success in the rehabilitation of patients suffering from Low Back Pain, without side effects. For the patient the main effect is the improvement of activities of daily living.

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