Evaluation of the effectiveness of MBST®-NuclearMagnetic Resonance Therapy

Introduction:

The rising number of gonarthrosis within the population requires sufficient therapeutic methods (Günther et al. 1998, Sun et al. 1997) to be worked out by the treating personel, to ensure pain reduction, improved joint function, as well as a declining arthrosis process. Beside of the modifying operative (Grifka 1993, Rudert et al. 1998) and partly medicamental treatment methods (Frizziero et al. 1998, Listrat et al. 1997, Reginster et al. 2001) additional therapy concepts are being looked for with great interest. Electromagnetical fields are able to stimulate the cartilage growth in animal experiments and cultures (Lipiello at al 1990). The verification of the clinic effects is thus very important (lw 2002, Gierse 2003, Kladny 2001, Rothschild 1996).

Question:

How effective is MBST®-NuclearMagneticResonanceTherapy for treatment of disorders caused by arthrosis of the knee joint ?

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, Germany has developed new appliances, whereby nuclear resonance protons of the hydrogen nuclei (amount of liquid in vivo) are transferred into resonance, resp. energy, which is released in the relevant region of the body to be treated. Contrary to the common technology of pulsed electromagnetic fields (PEMF) with the new MBST®-NuclearMagnetic ResonanceTherapy System over 12 separately controlled and independent coil systems (partly orthogonally arranged) are producing a three-dimensional treatment field, which is forming one homogeneous treatment zone. The MBST® treatment software with its therapy parameters is precisely adjusted to the individual patient and directed to the different regions of the body according to 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 area of the knee joint. Due to the easy handling of the therapy appliances and the fact that the operating software can be optimised 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®-NuclearMagneticResonanceTherapy 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. The special permanent magnetic field induces the hydrogen protons to 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. A stimulation of the synthetic activity of the Chondocytes by the Nuclear Resonance Effect and in vitro a reduction of the Proteoglykandegradation was already proved by studies (Liu et al. 1996).

From 60 patients 33 patients with arthroscopically (Outerbridge 1989) and 27 patients with roentgenologically (Kellgren et al 1957) diagnosed cartilage damages of the knee joint were treated with MBST®-NuclearMagneticResonanceTherapy in the Forest Clinic Bad Düben from February to November 2002. The therapy was done in 5 sessions of 1 hour each on consecutive days. The knee joint was centered within the highly complex air-core coil provided with a static permanent magnetic field, which is necessary for the therapy. The course of treatment was controlled by the programmed computerchip cards, which were individually adapted to the patient's requirements. In a prior examination contraindications, such as tumors, infections, pregnancy, pacemakers, defibrillators of the patients could be excluded.

With the help of the LESQUESNE-Index (Lesquesne 1987), visual analogue scale for pain in resting condition and for pain in motion (VAS) (Huskisson 1974, Flandry et al. 1991), Lysholm-Score (Lysholm 1982, Bengtsson et al. 1996) as well as Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) (Bellamy et al. 1988, 1991, 1995, 1997, Stucki et al. 1996) the effectiveness of the therapy was studied within a period of 6 months. In this study information on influences on joint pain (VAS pain in resting condition and in motion, WOMAC part A), joint function (LESQUESNE-Index, LYSHOLM-Score, WOMAC part C) and the joint stiffness (WOMAC part C) were provided.

The data of 59 patients before and after the MBS-therapy, as well as 8 weeks and 6 months later were collected and statistically evaluated by means of the WILCOXON-test (Trampisch et al. 1997, Windeler et al. 1992).

Results:

From the 60 patients (treated by this method) with discomfort of the knee joint due to arthrosis, the data of 59 patients could be determined within 6 months. One patient was moved – address unknown. One 75-year old patient with roentgeneologically proved pongonarthrosis III got an implantation before expiration of the 6 months.

The average age of the patients was 48,57 years (aged between13 to 75 years). 31 women, 29 men, 36 times the right and 24 times the left knee joint were treated. The average weight was 81,6 kg thus an average overweight of 14,5 % in comparision with the normal weight according to Broca.

33 patients were undergoing an arthroscopy of the relevant knee in our hospital, before. According to Outerbridge (1989) the following distribution of the degree of cartilage damages was found out: 1 x I.°, 7 x II.°, 19 x III.° and 6 x IV.°. In the roentgenological evaluation of the degree of gonarthrosis according to Kellgren and Lawrence (1957) the distribution for 27 patients was as follows: 7 x II.°, 12 x III.°, 8 x IV.°.

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

To avoid an influence of the arthroskopy on the evaluation of the initial value of the patient, we were comparing the values of the patients with arthroskopy with those of the patients, which were subject to a radiological diagnosis before. The comparison was done by means of a WILLCOXON-test. The p-value was between 0,38 and 0,94 so that statistically significant differences could be excluded and the initial values were considered as homogeneous and balanced.

Results of the single scores and indices in the course of time:

LESQUESNE-Index (0-24 points/maximum point number 0):
Median point value before start of therapy: 10,74 (2 min., 21 max.), 9,79 (1 min., 20 max) after completion of therapy (5 days later) 8,05 (0 min, 19 max.) after 8 weeks and 6,84 (0 min, 20 max) after 6 months. This meant an 8,84 % improvement of the point value of the index after 5 days, 25,04 % after 8 weeks and 36,31 % after 6 months.

VAS pain in motion (0-100mm pain scale/maximum point number 0):
Before therapy the median basic value was 54,79 (0 min., 85 max.), after therapy 50,56 (0 min., 85 max.) 44,5 (0 min., 85 max.) after 8 weeks and 35,7 (0 min., 90 max.) after 6 months. This meant a 7,72 % reduction of the pain in motion after therapy, 18,78% after 8 weeks and 34,8% after 6 months.

VAS pain in resting condition (0-100mm pain scale/maximum point number 0):
The median basic value was 33,74 (0 min., 85 max.), after therapy 30,98 (0 min., 85 max.) 26,55 (0 min., 85 max.) after 8 weeks and 20,48 (0 min, 85 max.) after 6 months. This meant a 8,18% reduction of the pain in resting condition after 5 days, 21,31 % after 8 weeks and 39,30 % after 6 months.

LYSHOLM-Score (0-100 points/maximum point number 100):
The median point value before start of therapy was 49,86 (7 min., 90 max.), 52,89 (7 min., 95 max.) after therapy, 59,13 (min. 7, max. 100) after 8 weeks and 66,21 (7 min., 100 max.) after 6 months. Thus an increase of the values by 6,07% could be noted after the therapy, 18,59 % after 8 weeks and 32,79 % after 6 months.

WOMAC part A (pain: 0-20 points/maximum point number 0):
The initial value was 7,62 (2 min., 15 max.), after therapy 6,51(0 min., 16 max.), 5,55 (0 min., 16 max.) after 8 weeks and 4,52 (0 min., 15 max.) after 6 months. The improvement of point values after completion of therapy was 14,56 %, 27,16 % after 8 weeks and 40,68% after 6 months.

WOMAC part B (joint stiffness: 0-8 points/maximum point number 0):
Before therapy the initial median value was 2,93 points (0 min., 8 max.),
2,5 points (0 min., 8 max.) after the therapy, 2,34 (0 min., 8 max.) after 8 weeks and 1,74 points (0 min., 8 max.) after 6 months. The reduction of point numbers was thus in the course of time: 14,67 % after 5 days, 20,13 % after 8 weeks and 40,61 % after 6 months.

WOMAC part C (joint function: 0-68 points/maximum point number 0):
The median point number before start of therapy was 26,32 (0 min., 59 max.), 23.01 (0 min., 57 max.) after therapy, 20,39 (0 min., 52 max.) after 8 weeks and 16,36 (0 min., 62 max.) after 6 months. This meant a reduction of the point value by 12,5 % after the therapy, 22,53 % after 8 weeks and 37,84 % after 6 months.

In the following table die p-values of the statistic assessment for all scores, indices resp. scales used are indicated. Especially the values (after therapy, after 8 weeks and 6 months) in addition to the basic values before start of therapy were investigated by means of the WILCOXON-tests. A conventional α-error-level of 5 % (possibility of error: p</= 0,05) was evaluated as statistically significant.

p-value (WILCOXON-Test)			
Method of investigation	after therapy	after 8 weeks	after 6 months
LEQUESNE-Index	0,001	0,001	0,001
LYSHOLM-Score	0,009	0,001	0,001
VAS pain in motion	0,006	0,001	0,001
VAS pain in rest	0,015	0,001	0,001
WOMAC part A	0,001	0,001	0,001
WOMAC part B	0,006	0,002	0,001
WOMAC part C	0,01	0,004	0,001

Table 1: p-value (WILCOXON-Test)

The change of point values in the single scores was between 32 % and 40 % in the course of 6 months after therapy. Thus for all criteria a statistically significant change in point values could be demonstrated. Taking every score into consideration this means a clear improvement of the results. The influence on the pain (WOMAC part A: ↓40%, VAS pain in rest: ↓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.

As very impressively shown by the results a very high effectiveness of the tested MBST®-Nuclear Magnetic Resonance Therapy for patients with advanced athrosis disorder can be achieved. Thes patients are thus very appropriate for an objective evaluation of the applied tests. For evaluation of former arthrosis stages, it is necessary to adapt, resp. change the evaluation questionaires of the score-forms.

Discussion:

In the Cochrane Review 2002, containing 102 studies, entitled: „Electro-magnetic fields during treatment of osteoarthrosis“ only 3 double-blind, placebo-controlled studies meet the test requirements (Hulme et al. 2002). In the studies of Trock 1993 and 1994 as well as Zizic 1995 statistically significant improvements of clinic parameters of gonarthrosis of 13 – 23 % could be noted. The follow up was within 4-6 weeks. Our results 8 weeks after therapy are matching the values indicated in literature.

In the time period 8 weeks after final treatment and 6 months later the results showed again a significant improvement of the point values in the single scores by 11-20 %. This is due to the fact that MBST®-Nuclear Magnetic Resonance Therapy is a new treatment method, the active principle of which is directly deviated from magnetic resonance imaging and can not be compared or confused with PEMF.

A negative aspect is a missing a control group for our investigations. We, however, understand our clinic trial as prospective method to study the application. Placeboeffects are not able to show a continuous improvement within a time period of 6 months.

Froböse accomplished a scientific study (1999) with gonathrosis patients (clinically diagnosed) (wirth stages II and III). This study allowed a world-wide unique (invivo) three dimensional reconstruction and quantification of the cartilagenous structure by means of magnetic resonance imaging. Cartilage thickness, cartilage volume and cartilage surface were tested by means of MRT-images, which were made and quantified before of the therapy and 10 weeks later. Froböse ascribed the positive modifications of the cartilagenous 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. This clearly coincided with our test results.

In order to verify the positive effects of electromagnetic fields on the synthesis of the chondozytes (Liu 1996) and on the stimulation of the cell proliferation (Pezzetti 1999, Indouraine 2001) and stimulation of regulatory cytokines (Aaron 1999) on the one side research (quality and quantity) of highly complex electromagnetic fields (nuclear resonance field of MBST) must be intensified and on the other side the representation of the cartilage characteristics (Lösch 1997) must be optimised. We were just able to prove the good therapy effect. We can only assume that a structure modification of the degenerized cartilage is the reason for the good effect.

Summary:

In summary we can say that we consider MBST®-NuclearMagneticResonanceTherapy as a very sensible supplementary therapeutic procedure, providing short therapy times besides it is suitable to reach significant modifications of arthrosis disorders of the knee-joints. After 6 months a considerable pain reduction, improvement of the joint function as well as reduction of joint stiffness in case of gonarthrosis could be noted. Due to its easy handling, significant therapeutic success and no side-effects it is a convincing method and a real alternative to invasive procedures, such as operation and injection. A permanent improvement could be noted without follow-up treatment, until receipt of the last data-acquisition 6 months after the MBST®-NuclearMagneticResonance Therapy. Another study would be necessary to find out to which extent there is a structure modification beside of the symptom modified effect.

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