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One-year-survey with multicenter data of more than 4,500 patients with degenerative rheumatic diseases treated with therapeutic nuclear magnetic resonance

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Abstract.
BACKGROUND AND OBJECTIVES: Nuclear magnetic resonance (NMR) has been shown to stimulate repair processes and cartilage and to influence pain signalling. It represents an alternative therapy for patients suffering from osteoarthritis (OA). To prove the clinical success of this new therapeutical method, validated measuring parameters are important that are convincing for pain and function in a one-year-follow-up.
METHODS: During the course of its application over the last 10 years, over 4,500 protocols of a one-year-follow-up have been collected to record the outcome of NMR therapy. This report reflects the outcome of NMR therapy on patients with the following degenerative rheumatic diseases: OA of the knee ($n = 2.770$), OA of the hip ($n = 673$), OA of the ankle joint ($n = 420$) and chronic low back pain ($n = 655$). Data were collected at baseline, 6–8 weeks and 6 and 12 months following NMR treatment.
RESULTS: Pain was reduced significantly 6 weeks after NMR treatment in the cases of all four examined indications and stayed measurably reduced up to 6 and 12 months. The improvements in all three forms of pain (pain on load, pain on motion, pain at rest) following NMR treatment were around 21–50% on average.
CONCLUSIONS: Following therapy with NMR, patients with OA of all four types experienced a distinct improvement in their ability in functional parameters. Overall, the 10 years of a one-year-survey with multicenter data gathered on the effect of NMR therapy on patients verifiably proved its efficacy amongst patients with degenerative rheumatic diseases.

Keywords: Nuclear magnetic resonance, osteoarthritis, outcome measurement

1. Introduction

Nuclear magnetic resonance (NMR) as a therapeutic form of treatment had already been developed more than 10 years ago and is applied in degenerative rheumatic diseases. Therapeutic nuclear magnetic resonance in medicine characterizes a technology that makes use of NMR to activate metabolic processes and to indicate regenerative processes in specifically selectable cellular tissue. Until now, its development has been extremely successful, considering that this kind of therapy is often incorrectly – as there are clear physical differences – perceived in connection with diverse magnetic field applications which have as yet not resulted in verified effects. The technology of these ther-

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apeutic nuclear magnetic devices differs to those using only static or pulsed magnetic fields.

The easy-to-use therapeutic method for regenerative stimulation of disturbed and irreparable cell processes is directly based on the technology behind NMR imaging (= MRI).

The biological effect of this technology rests on the knowledge that cell functions are only possible if energy supply is assured. Deficient energy flow in endogenous regeneration processes unavoidably leads to cell death. To prevent such conditions, the incurred energy deficit has to be compensated by suitably measures (e.g. nuclear magnetic resonance).

Effectiveness and tolerance of nuclear magnetic resonant fields were proven in therapy of various forms of osteoarthritis (OA) in numerous *in vitro* and *in vivo* studies [2,3,7,8,18,19,21]. The application of 1 hour a day on 5–10 consecutive days has been found to be efficient.

OA, a degenerative disease of large and small joints and of the spine, is one of the most frequent problems in treatment, especially due to the progressive aging of the population. Today's aims in the treatment of osteoarthritis are pain relief and the prevention of functional loss.

Osteoarthritis pain, especially pain on load in the knee or hip joints, causes reduced activity and limited mobility. The resulting pain-induced inactivity is an additional health risk associated with muscular atrophy, overweight, and cardiovascular diseases. Osteoarthritis of the knee is a very frequent disability of more than a third of the population over 65 years in the USA [16].

The predominant symptom of osteoarthritis is pain which at first appears only on load but also at rest in the advanced disease. After periods of rest, start-up pain – typical for osteoarthritis – and stiffness can be observed.

Conventional therapy is administered with training, physiotherapy, loss of weight, acupuncture, rehabilitation, etc. Medical therapy with intra-articular corticoids or oral non-steroidal anti-inflammatory drugs (NSAID), topic NSAIDs or capsaicin only reduce the symptoms but usually do not prevent progression and is accompanied by distinct risks in long-term application. Failure of conventional therapy often results in joint replacement [16]. There is need of new treatment principles with long-lasting effects. Therefore, examinations about the efficiency of nuclear magnetic resonance therapy (NMR) in osteoarthritis as a new additive treatment appear to be of interest.

As well as osteoarthritis of the knee and the hip, osteoarthritis of the ankle joint is also a relatively frequent condition. Twists, sprains or strains of the ankle, lesions of the ligaments or the cartilage and its displacement often induce osteoarthritic alterations of the ankle joint, which is also exposed to high loads. In the early stage of osteoarthritis – the best time for NMR intervention – conservative treatment often can result in a clear reduction of complaints.

Chronic pain caused by osteoarthritis is greatly induced by various psychosocial factors and can ultimately affect activity and participation. Chronic low back pain (LBP) occurs extremely frequently and causes considerably high psychosocial and healthcare costs. Low back pain is often accompanied by functional deficits/disabilities [22]. LBP is steadily on the increase in all industrial countries and, besides patient's impairment in work and everyday activities, it entails therapy costs and job loss accompanied with high socioeconomic expenses for the general public [1,14,23]. In degenerative osteoarthritic alterations the vertebral joints can provoke affecting pain (osteoarthritis of the facet joint).

The aim of this study is to gain the verified and testable evidence that nuclear magnetic resonance can positively and sustainably influence various degenerative rheumatic diseases.

Evaluation of data collected over 10 years of a large multicenter collective of OA patients treated with NMR therapy, combined with several follow-ups during the 12 months after therapy, can reveal interesting answers with regard to efficacy and sustainability.

2. Methods

2.1. Therapeutic nuclear magnetic resonance

The construction of the device is very complex: static electromagnetic fields align the nuclear spins, and an alternating field, exactly adjusted to the resonance frequency of the respective tissue type, makes the nuclei of the target tissue accumulate energy, leading to their saturation. During the following relaxation, this energy is transferred to the surrounding tissue which induces resonance.

All nuclear magnetic applications in the presented study were made with devices belonging to the MedTec Company, Wetzlar, Germany. The nuclear field consists of three matched fields: (a) main magnetic field, (b) variable, modulating sweep-field, (c) alternating magnetic field at the Larmor frequency vertically to (a) and (b). It is generated in a Helmholtz coil with a permanent basic field up to 40 mT and a dynamic field strength of radiofrequency up to 2.3 mT. The nuclear magnetic resonance frequency is about 17–85 kHz. The applicators of the therapy systems respond to a central control unit according to a chipcard which is programmed for the special parameters adapted for tissue and indication.

The duration of the treatment totalled up to 9 therapy units for 1 hour each on consecutive days.

2.2. Study parameters

Evaluation criteria for the therapeutic effect of NMR were pain at rest, pain on load, and peak pain, measured with a visual analogue scale (VAS). Further evaluation of clinical success was carried out using validated function indices, which work well for the long-term documentation of osteoarthritis, covering disability, function deficit and restrictions of everyday functions.

The indices used for evaluation of symptoms and physical function deficits in osteoarthritis of the knee as well as the hip were designed by Lequesne [9–11] and are often recommended as endpoints in testing symptom-oriented therapies [20]. The Lequesne index is an internationally-established self-assessment instrument. It is low time-consuming, change sensitivity is excellent. The score by Mazur et al. [13] was used for the assessment of osteoarthritis of the ankle, the Oswestry low back disability questionnaire by Fairbank et al. [4] was used for assessing the disability level of back pain.

2.3. Period of assessment

To document the sustainability of the therapeutic administration of NMR, the measuring parameters were ascertained at baseline, immediately following treatment, 6–8 weeks, 6 months, and 1 year after treatment. The period of data collection was 01/2000 to 12/2010.

2.4. Patients' recruitment and indications

Data of NMR-treated patients were collected with regard to the following indications: Osteoarthritis of the knee, osteoarthritis of the hip, osteoarthritis of the ankle, painful affections of the spine (low back pain). Patients were recruited in 61 therapy centres and medical offices in Germany and Austria (see acknowledgements). The protocols with descriptive patients' data and the afore-mentioned measurement parameters at the appointed times were completed with the patients in the respective centres, or mailed there from the patients at the follow-up dates.

The diagnoses osteoarthritis of the knee [6], osteoarthritis of the hip, osteoarthritis of the ankle, and low back pain were verified by radiological diagnostics.

Only patients were included who had given their informed consent for data collection and who had been treated with NMR in accordance with the indications mentioned above.

2.5. Statistics

The collected protocol data were entered centrally (IEB – Institute for Development of New Therapy Methods, Wetzlar, Germany). The statistical evaluation was done in the IEB-Institute as well as in the Ludwig Boltzmann Institute in Saalfelden, Austria. The following statistical tests were used: descriptive statistics, Student's t-test for normally distributed samples, Mann–Whitney U test (Wilcoxon rank-sum test), Spearman's rank-order correlation for nonparametric correlation coefficients.

3. Results

One-year-follow-up protocols of 4518 patients were analysed: $N = 2770$ osteoarthritis of the knee, mean age 62.4 $\pm$ 12.9 years; $N = 673$ osteoarthritis of the hip, mean age 64.6 $\pm$ 10.7 years; $N = 420$ osteoarthritis of the ankle joint, mean age 58.6 $\pm$ 15.3 years; $N = 655$ low back pain, mean age 62.8 $\pm$ 14.1 years.

3.1. Osteoarthritis of the knee

This group with the highest evaluated amount of cases included 41.9% male and 58.1% female patients. It also shows the highest percentage of overweight (45.8%) and obese (22.2%) persons, only 32% had a normal body weight and a BMI below 25. With regard to BMI, there was no gender difference (mean: men 22.1, women 27.5), the mean BMI of obese patients was 33.9 $\pm$ 4.0.

During the 1-year follow-up peak pain, pain on load, and pain at rest decreased steadily (Fig. 1). Immediately after the 9 NMR treatment sessions, patients showed reduced pain scores using the VAS scale, with further gains in improvement after 3, 6, and 12 months. At no time did they return to initial levels. All three types of pain were shown to have reduced significantly ($P < 0.00001$) at all follow-up dates. Likewise, the frequen-

Table 1
Osteoarthritis of the knee: Lequesne-Index (Globalscore with 3 components); all results are significant ($^{***}p < 0.000001$)

Lequesne osteoarthrtis index		Baseline	After NMR	3 months	6 months	12 months
Global score	*Mean ± SD*	7.77 ± 4.33	6.62 ± 3.92	5.70 ± 3.87	4.97 ± 3.86	4.69 ± 3.94
	Median	7.50	6.50	5.50	4.50	4.00
Pain/complaints (1st component)	*Mean ± SD*	3.05 ± 1.86	2.52 ± 1.75	2.03 ± 1.62	1.74 ± 1.63	1.58 ± 1.64
	Median	3.00	2.00	2.00	1.00	1.00
Walking distance (2nd component)	*Mean ± SD*	1.80 ± 1.66	1.63 ± 1.50	1.49 ± 1.47	1.29 ± 1.34	1.21 ± 1.24
	Median	1.00	1.00	1.00	1.00	1.00
Function (3rd component)	*Mean ± SD*	2.92 ± 1.82	2.47 ± 1.64	2.18 ± 1.63	1.94 ± 1.63	1.89 ± 1.74
	Median	3.00	2.00	2.00	2.00	2.00

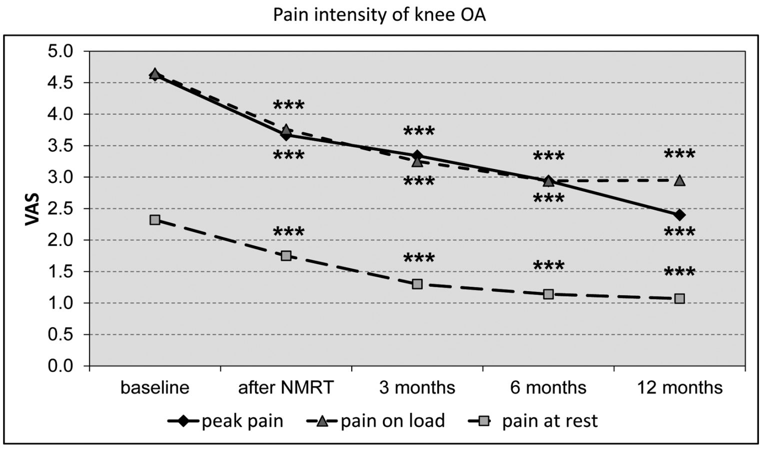

Fig. 1. Osteoarthritis of the knee: Course of pain within one year after NMRT. Significances to baseline $^{***}p < 0.000001$.

cy decreased clearly with all three types of pain, especially 6 and 12 months after NMR therapy. Pain on load diminished on a ten-part scale from 6 (daily) to 4 (once a week), the frequency of peak pain reduced to "very little/only twice a month" (= 3), and pain at rest decreased to "rare" to "very rare".

In parallel with the reduction of pain, there was an improvement in functional disturbance measured with the aid of the Lequesne index. The details are shown in Table 1.

The Lequesne osteoarthritis index comprises three segments, 10 questions in total. In addition to the global score, all questions concerning complaints, walking, and functions were statistically evaluated. The three components improved as well as the overall score, highlighting the significant ($P < 0.000001$) decrease in complaints/pain and the significant reduction in functional restriction. The number of patients with osteoarthritis of the knee who had no complaints during the night increased from 39% at baseline to 72% 12 months following NMR therapy.

Also with regard to walking, the pain-free group increased from 23.5% to 48.2%. 6–12 months after NMR therapy remarkable improvements with high percentages were recorded with regard to climbing stairs, walking on uneven ground, kneeling down and walking distances. One year after treatment, 31.9% of patients with osteoarthritis of the knee could kneel down or crouch down without any difficulty, at baseline this was possible for only 14.9% of the 2,770 patients.

Statistical analysis showed significant correlations between pain and functional restrictions for the period of 1 year following application of NMR therapy (Table 2). For example, the decreased pain on load correlated with the walking complaints (Lequesne index; $r = 0.42$, $P < 0.000001$). Other examples are the relation between decline in intensity of peak pain and easier "to crouch down" ($r = 0.38$, $P < 0.000001$) or going downstairs ($r = 0.40$, $P < 0.000001$) during the 12 months. More relations are shown in Table 2.

As early as three months after NMR therapy, significant improvements in the active range of motion were recorded, with a further enhancement of flexion and extension after 6 and 12 months (Fig. 2). The gender-based analysis resulted in no statistically significant differences between men and women for the majority

Table 2
Spearman's rank order correlation of changes (differences) of study parameters one year after NMRT

Correlations		Corr. coefficient	Significance
of	to	(r_s)	(p) <
Osteoarthritis of the knee			
Pain on load – intensity	Lequesne – walking complaints	0.42	0.0000001
Lequesne – pain early after starting	Lequesne – walking complaints	0.39	0.000001
Pain on load – intensity	Lequesne – climbing stairs	0.35	0.0000001
Peak pain – intensity	Lequesne – crouch/kneel down	0.38	0.0000001
Peak pain – intensity	Lequesne – downstairs	0.40	0.0000001
Lequesne – walking on uneven ground	Pain on load – intensity	0.38	0.0000001
Lequesne – walking on uneven ground	Lequesne – downstairs	0.41	0.000001
Extent of movement – extension	Lequesne – climbing stairs	0.30	0.002
Osteoarthritis of the hip			
Peak pain – intensity	Lequesne – pain	0.32	0.01
Peak pain – intensity	Lequesne – global	0.33	0.01
Pain on load – intensity	Lequesne – pain	0.45	0.0001
Pain on load – intensity	Lequesne – function	0.34	0.01
Pain on load – intensity	Lequesne – global	0.47	0.0001
Low back pain			
Peak pain – intensity	Oswestry – personal care	0.46	0.001
Peak pain – intensity	Oswestry – lifting	0.54	0.0001
Peak pain – intensity	Oswestry – total	0.56	0.00001
Pain on load – intensity	Oswestry – lifting	0.53	0.0001
Pain on load – intensity	Oswestry – total	0.48	0.001
Oswestry – pain	Oswestry – sleeping	0.43	0.001
Osteoarthritis of the ankle			
Peak pain – intensity	Mazur – walking distance	−0.40	0.01
Peak pain – intensity	Mazur – climbing stairs	−0.39	0.02
Peak pain – intensity	Mazur – downstairs	−0.47	0.002
Peak pain – intensity	Mazur – function (total)	−0.46	0.003
Mazur – walking aid	Mazur – walking distance	0.53	0.0002
Mazur – walking distance	Mazur – downhill	0.60	0.00001
Mazur – walking distance	Mazur – uphill	0.68	0.000001

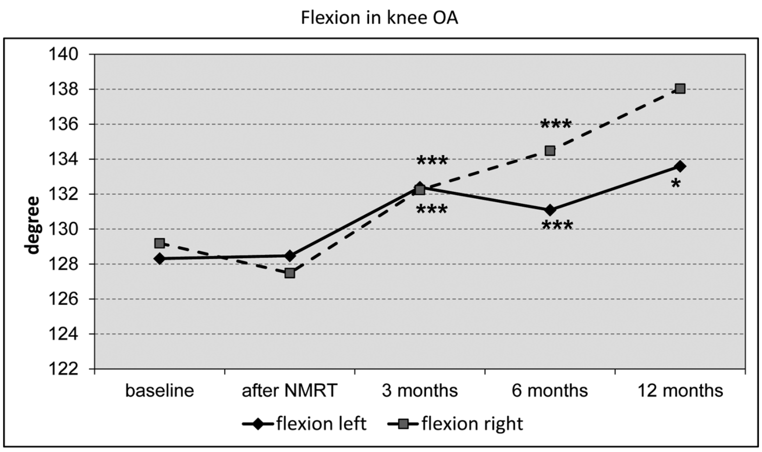

Fig. 2. Extent of movement – flexion in patients with osteoarthritis of the knee within one year after NMRT. Significances to baseline $^{*}p < 0.01$, $^{***}p < 0.000001$.

of evaluated parameters. After one year, however, the improvement of the active range of motion was found more distinctly for flexion in women and for extension in men. The significantly higher intensity and frequency of pain (peak pain, pain on load, pain on motion) in females at baseline showed no difference of improvement to men 12 months after NMR.

Data analysis regarding Body Mass Index (BMI) is interesting too. Obese patients with BMI $\geqslant 30$ at all dates of data collection showed a significantly higher

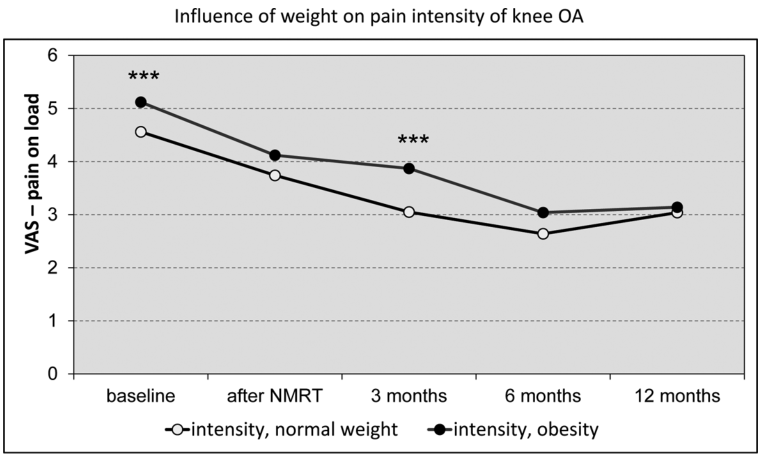

Fig. 3. Osteoarthritis of the knee: pain on load (VAS) in normal weight and obese patients. All follow-up time points of assessment were significant to baseline $p < 0.000001$. Additionally, the significant differences between normal weight and obese patients are indicated by $^{***}p < 0.000001$.

Lequesne global index, the same applies to the components pain/complaints, walking distance, and functional restriction too. The significantly more intense and more frequent pain of obese patients at baseline (Fig. 3) did not differ from that of normal-weight osteoarthritis patients with BMI < 25 one year after NMR therapy.

3.2. *Osteoarthritis of the hip*

The gender distribution of patients with osteoarthritis of the hip was relatively balanced with 51% females and 49% males. The share of obese patients with BMI $\geqslant 30$ (14.1%) was clearly lower than that in the group with osteoarthritis of the knee; also the proportion of normal weight patients with osteoarthritis of the hip was distinctly higher at almost 40%.

The application of a series of NMR treatments on patients with osteoarthritis of the hip resulted in clear improvements with regard to pain and function that could be ascertained even up to 1 year after treatment (Table 3, Fig. 4). The mean VAS score for pain on load diminished from 4.6 ± 2.4, which means distinct pain, to 3.3 ± 2.1. Also the intensity of peak pain reduced significantly ($P < 0.000001$) from 5.2 ± 2.7 to 3.1 ± 2.9 after 1 year (Fig. 4). The frequency of peak pain showed in paired statistic testing that the percentage of patients with reduced pain increased from 18.9% after 3 months, to 27.7% after 6 months, and up to 34.5% after 12 months.

The reduction in pain is also true for pain at rest ($P < 0.000001$) which, astonishingly enough, showed a clear difference between baseline (VAS 1.4 ± 1.7) and one year after NMR therapy (2.8 ± 2.5). Every single patient showed improvements in pain at rest, in terms of both intensity (42.8%) and frequency (36.3%). Along with the decrease in pain intensity within a year, we found a significant reduction in the ten-part ranking of pain frequency for peak pain, pain on load, and pain at rest. Peak pain and pain on load correlated significantly with the total Lequesne index ($r = 0.33$ / $r = 0.34$; $P < 0.01$) and with restriction of functions ($r = 0.34$, $P < 0.01$; Table 2).

These changes explain the improvement in sleep quality as shown by the Lequesne index. Overall, the total score of the Lequesne index, used for the evaluation of symptoms and the physical restriction of daily functions, reduced significantly ($P < 0.000001$) from 7.14 to 4.58 (mean) for osteoarthritis of the hip during the one-year follow-up period, confirmed by the distribution-independent median value that decreased from 7.0 to 4.0 (Table 3). Supplementary to the global score, which consists of three components of 10 questions each, the components regarding complaints/pain, walking, and function were evaluated separately for osteoarthritis of the hip. Complaints particularly fell ($P < 0.000001$), while functional restriction was also clearly less evident 3 to 12 months after NMR treatment when compared to the baseline.

Remarkably, the percentage distribution of the items showed that almost half of all patients (47.5%) reported to have no complaints when walking one year after treatment (baseline: about 20%). While 21.9% reported having to make serious efforts to put on socks before treatment, only 12.1% reported this after 12 months; 13 patients were unable at all to put on socks before NMRT because they could not bend the leg at the hip

Table 3
Osteoarthritis of the hip: Lequesne-Index (Globalscore with 3 components)

Lequesne osteoarthrtis index		Baseline	After NMR	3 months	6 months	12 months
Global score	*Mean* ± *SD*	7.14 ± 3.67	6.18 ± 3.60***	5.58 ± 3.50***	5.28 ± 3.51***	4.58 ± 3.51**
	Median	7.00	5.50	5.00	5.00	4.00
Pain/complaints (1st component)	*Mean* ± *SD*	3.28 ± 1.72	2.69 ± 1.65***	2.38 ± 1.73***	2.24 ± 1.76***	2.00 ± 1.83***
	Median	3.00	3.00	2.00	2.00	2.00
Walking distance (2nd component)	*Mean* ± *SD*	1.90 ± 1.47	1.81 ± 1.50	1.70 ± 1.36	1.52 ± 1.18*	1.42 ± 1.05
	Median	1.00	1.00	1.00	1.00	1.00
Function (3rd component)	*Mean* ± *SD*	1.96 ± 1.46	1.67 ± 1.39***	1.49 ± 1.26***	1.52 ± 1.31***	1.16 ± 1.24***
	Median	2.00	1.50	1.50	1.50	1.00

Significances to baseline $^{*}p < 0.01$, $^{**}p < 0.001$, $^{***}p < 0.000001$.

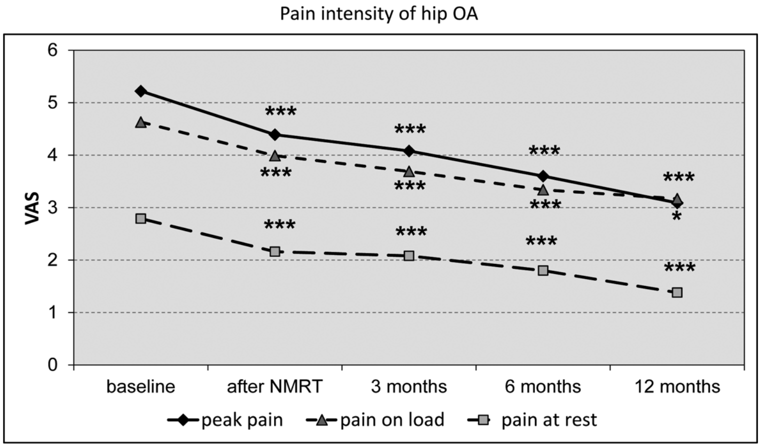

Fig. 4. Pain intensity within one year after NMRT in patients with osteoarthritis of the hip. Significant differences of all time points of assessment to baseline $^{*}p < 0.01$, $^{***}p < 0.000001$.

and raise their foot high enough. One year later, there was not a single patient still suffering from this functional disorder. Moreover, more than half of the patients with osteoarthritis of the hip (53.5%) were able to put on their socks without difficulty.

Similarly, all patients could get in and out of a car without difficulty, no one had great problems doing so, and only 4% had to struggle after one year. In parallel to the declined functional restriction and the decreased pain, the percentage of patients climbing up and down the stairs without complaint was doubled after 12 months (59.6%).

The Spearman's Rank-Order Correlation, which allows an exact analysis also in non normally distributed measurements, resulted in clear and significant correlations between pain intensity in osteoarthritis of the hip and the functional oriented Lesquesne-Index between baseline and 12 months after NMRT ($P < 0.01$–$P < 0.001$; Table 2).

In contrast to the patients with osteoarthritis of the knee 85.9% of the patients in this group had normal weight or overweight, and 14.1% were obese with 2% moderate (BMI 35–< 40) resp. 0.6% ($N = 3$) morbid obesity (BMI ⩾ 40).

Although tendencies indicate a slightly faster pain relief in normal weight persons, statistics of obese patients, however, show that the data have to be considered as equal. The gender-specific data analysis proves that men compared to women show a higher experience of pain resp. a worse function expressed in higher global score values of the Lequesne index at the beginning. After 6–12 months this difference did not persist any longer. In this follow-up-period both genders did not differ in terms of the quality of their response to NMRT.

3.3. Low back pain

655 patients (247 men – 37.7%; 408 women – 62.3%) with chronic low back pain were included.

The nuclear magnetic resonance therapy also had a clear influence on low back pain which was markedly reduced during daytime peaks as well as pain on

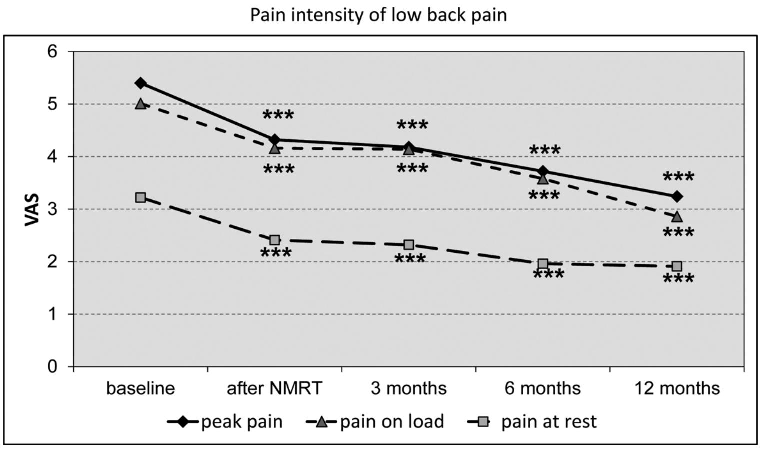

Fig. 5. Pain intensity in low back pain (VAS). Significance to baseline $^{***}p < 0.000001$.

load and at rest during the one-year monitoring period (Fig. 5).

The intensity of pain on load was reduced remarkably one year after NMRT, it decreased from an average of 5.01 to 2.86. Parallel to its intensity, the median of the peak-pain decreased from 6.0 of the baseline to 2.5 after 12 months. Also the intensity of pain at rest was reduced clearly and significantly ($P < 0.000001$) with a mean of 1.96 (median 1.0) at 6 months and 1.91 (median 1.0) at 12 months contrary to the baseline mean of 3.2 (median 3.0). Also the frequency of peak-pain, pain on load, and pain at rest reduced clearly and significantly during the process of the 12-months follow-up ($P < 0.000001$). Taking a look at the percentage improvement of the pain-intensity of each single patient, the greatest reduction is observed 6 months after NMRT (peak pain – 37.7%; pain on load – 32.4%; pain at rest – 35.9%). After 12 months these parameters were negligibly lower (– 35.5%; – 32.0%; – 33.1%). These results prove the ongoing, positive effect of nuclear magnetic resonance therapy in the field of chronic low back pain.

Particularly six months or one year after treatment, patients with affections of the spinal column enjoyed not only lower pain-exposure, but they could also carry out daily routine activities such as lifting, walking, sitting, standing and travelling much more easily. Their quality of sleep improved continuously and personal care also became less hindered. These functional improvements are comprised in the Oswestry Disability Index. The global score of the Oswestry disability questionnaire showed a clearly decreasing tendency of the mean as well as of the median (Fig. 6). The change of 23.9 (median 22.5) points of the baseline to 12.4 (median 7.5) points in the Oswestry Disability Index after 12 months meant a distinct improvement which is usually given for 10 points or more. The data-handling yielded a significant decline of the Oswestry Disability score ($P < 0.000001$). As a consequence, the decrease in disability with regard to the subjectively experienced impairment, positive psychosocial effects on the chronification of low back pain were also experienced.

The correlation analysis of the changes within a year proved the formal coherence between the reduced types of pain and the improvement of back-specific limitation of function when lifting, walking, sitting, standing, and in personal care (Table 2). Gender-specific differences for all 3 determined types of pain recording to intensity and frequency of pain couldn't be proved. In the 12 month period after NMRT, no variation between men and women could be detected in terms of the Oswestry Disability Index.

Comparing the sustainability of the effect of NMRT in obese and normal weight patients, the impact differs: In obesity the effects are weaker and after 12 months the patients suffer a distinct aggravation of all types of pain concerning intensity and frequency. The VAS-results show significant differences between normal weight and obese patients. After one year, normal weight patients specified least pain scores. This fact is confirmed by the Oswestry Disability Index registering significantly ($P < 0.000001$) improved back function of normal weight patients (BMI < 25) in contrast to obese patients (BMI $\geqslant 30$) (Fig. 6) 12 months after NMRT.

3.4. *Osteoarthritis of the ankle joint*

For patients suffering from painful osteoarthritis of the ankle, significant reductions in pain intensity un-

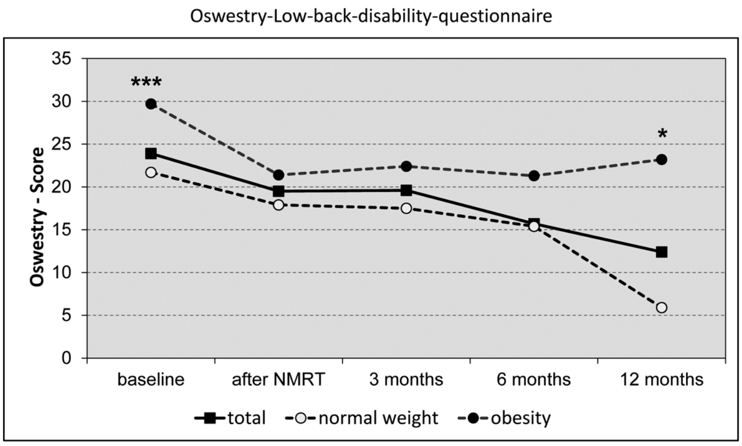

Fig. 6. Low back pain: Oswestry – Scores of the total patients collective. All follow-up time points of assessment were significant to baseline $p < 0.000001$. Additionally, the significant differences between normal weight and obese patients are indicated by $^{*}p < 0.01$, $^{***}p < 0.000001$.

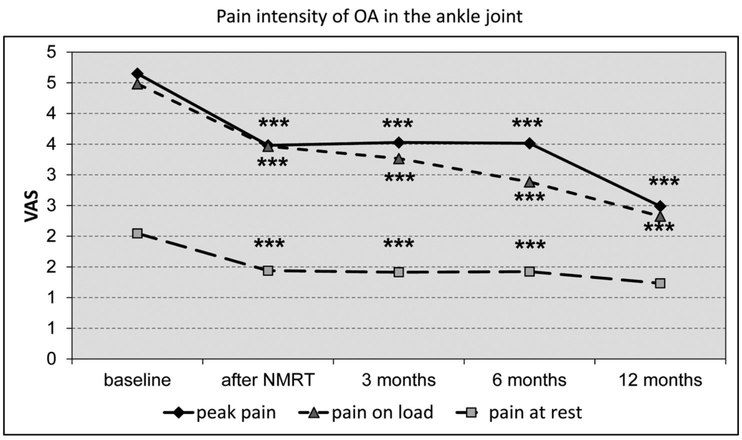

Fig. 7. Osteoarthritis of the ankle joint: pain intensity (VAS) within the 12 months follow-up after NMRT. Significances to baseline $^{***}p < 0.000001$.

der load as well as peak pain and pain at rest were attained as soon as the NMR therapy series was completed (Fig. 7). One year after NMRT the mean reduction of peak pain was 46.7%, pain on load 47.0%, and pain at rest 40.4%. 37–40% relief of pain was already observed 3 to 6 months after NMRT. Also the frequency of pain showed a declining and significant ($P < 0.000001$) trend beginning with a score of 6 (often/daily) down to 4 (once a week) and to 2 (rare/once per month).

The Mazur-Score (Fig. 8) resulted in 51.8 points in the mean (median 53.0) with pain as the major complaint. The 12 month follow-up showed a continuous increase to 69.3 (median 75.0) points, intermediately 63.5 (median 70.0) points 3 months after NMRT. Complaints in the upper ankle joint caused distinct limitations in the form of limping, especially when walking distances and climbing stairs. These parameters were significantly improved after 12 months (stair climbing: $P < 0.01$; walking distance: $P < 0.000001$) (Fig. 8). These observations demonstrate clear functional improvements in the upper ankle joint following NMR therapy. Even after 6–8 weeks, the walking distance, which is a good indicator of improvement in the ankle joint, clearly increased and continued to do so over the total monitoring period. In parallel, other parameters such as climbing stairs, going uphill, standing on tiptoes and the use of walking aids also decreased distinctly.

The statistical analysis of the results yield correlations especially between the intensity of peak pain and the total Mazur score ($r = 0.46$; $P < 0.003$), climbing stairs ($P < 0.02$–$P < 0.002$), and walking distance ($r = 0.40$; $P < 0.01$). Certainly, there was a significant formal correlation found between an increase

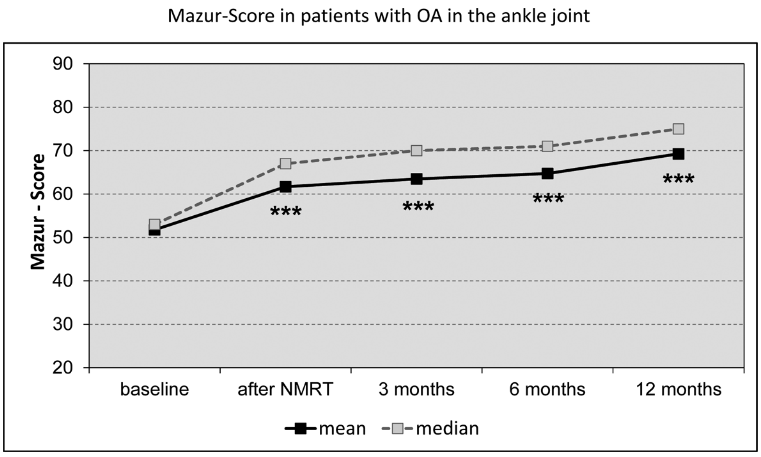

Fig. 8. Osteoarthritis of the ankle: functional improvement (Mazur ankle score) within one year after NMRT. Significance to baseline $^{***}p < 0.000001$.

of the walking distance and going uphill or downhill ($r = 0.68$ resp. $r = 0.60$; $P < 0.00001$ resp. $P < 0.000001$) (Table 2).

Gender-specific differences in pain assessment could not be found within the one year follow-up. Interestingly, however, there was a significantly higher increase (better function) of the Mazur ankle score for women with 70.1 than for men with 62.7 points in the total score one year after NMRT. The single items did not show this gender-specific difference.

Although normal weight patients with osteoarthritis of the ankle reported lower mean VAS values in intensity of pain on load and at rest after NMR therapy than obese patients (BMI $\geqslant 30$), there was no significance found because of the deviations. Also, there was no significant correlation between normal weight and obese patients with osteoarthritis of the ankle regarding the function of the foot [13].

4. Discussion

Treatment of osteoarthritis without drugs often focuses on decompression of the joint in order to reduce the symptoms. A sufficient treatment (e.g. NMR) can help to avoid the degradation of cartilage caused by inactivity and enables painless movement [15]. Over a 10 year period, the presented study analysed multicentrically collected data of patients with various types of osteoarthritis treated with a series of therapeutic NMR with follow-ups at day 10 as well as 3, 6, and 12 months.

With regard to its therapeutic success, of course, there are also, from the patient's view, the important metrics relating to pain relief and an improvement in restricted functions. Considering the social-economic costs, a return to employment and the prevention of absenteeism are both of particular interest.

The good results of this study concerning pain and disability of patients suffering from osteoarthritis of the knee, of the hip, of the ankle joint, and from chronic low back pain 6 and 12 months after nuclear magnetic resonance therapy document its long-term success. Effects on capacity for work cannot be concluded from this because it is also influenced by mental and somatic factors at the place of employment, as well as by the aggregate economic position.

Chronic pain is accompanied by hyperaesthesia and retention of aversive sensations in the pain matrix [24]. Seen from this perspective, the yielded pain reductions in all inquired indications within one year after NMR treatment must be assessed as eminently beneficial.

Osteoarthritis of the knee, as is generally known, is found more frequently in females at the ratio of approx 3:1. In fact, the presented collective included 58.1% females and 41.9% males but not with the above mentioned distribution pattern. Most of them – not gender specific – gained a long-lasting benefit following NMRT. Recent investigations from the University Aachen/Germany could demonstrate long time effects for NMR in the treatment of knee OA [12]. Own determinations with a small group of 32 patients illustrated clearly the pain-reducing effects of NMRT, even after application of only 5 units; however, there was a declining trend after 6 months [3]. Empirically, and after analysing this study's data with 9 therapy units, the NMR treatment indicates long term effects on pain and disability.

Matching reductions of restricted functions of daily life along with the reported pain intensity by use of the visual analogue scale, as shown with some thousands of patients with NMR therapy, permit good aggregate assessment of long-term disease processes.

In many cases osteoarthritis of the hip occurs unilaterally and the origin is secondary. Along with the advancing disease, the walking distance shortens more and more accompanied by characteristic limping. Our study results show that patients with OA of the hip benefit from nuclear magnetic resonance therapy with a distinct improvement of the restricted walking distance along with declining walking complaints.

The presented improvements of pain and function in osteoarthritis of the knee and the hip after NMRT have also positive effects on the fatigue which occurs in about 50% of the patients. This connection of pain and function has been described in a Dutch study with 231 patients with osteoarthritis of the knee and the hip [17].

The osteoarthritis of the upper ankle joint with depletion of cartilage is like other joints linked to abrasion and joint space narrowing. In consequence of the OA with functional disorders the life quality of the patients continues to decline. These adverse processes can be delayed by NMRT. The results show sustainable pain reductions and improvements of functions (Mazur ankle score) after therapy of the ankle joint using NMR.

There is no clear indication of surgical interventions for patients suffering from chronic unspecific low back pain, therefore usually drugs and/or physiological therapy are applied dependent on the perception of pain. These non-surgical therapies try to prolong the progress of the disease.

The chronic low back pain comprises individual, psychosocial, and acquired risk factors, such as, for instance, modification of pain threshold (pain memory), depression, and obesity. Every long-term pain reducing therapy, such as NMRT, is important to interrupt the chronification of pain with negative effects on the pain memory. A double-blind, randomized, placebo-controlled study (assessed with the Roland and Morris Questionnaire) shows that NMRT can achieve significant improvements regarding disability due to pain and low back pain 3 months after treatment [7]. The current elicitation confirms this finding. The evaluation of the Oswestry disability questionnaire exhibits clearly the improvement of function in everyday activities such as walking, sitting, lifting and travelling inclusive personal care and sleep quality.

A Finnish study reports an adverse effect of high BMI on the therapy success with low back pain [5]. Our observations confirm this. Following application of NMRT, the effects on pain of patients with a high BMI ($\geqslant 30$) are worse than those of normal weight (BMI < 25) patients, especially after 12 months. Also the spine function was significantly better in normal weight than in obese patients after one year.

In contrast to this finding, the effects of NMRT did not differ on normal weight or obese patients suffering from osteoarthritis of the ankle joint, of the knee, and of the hip.

The one-year-follow-up data within an observation period of 10 years show clearly that NMRT achieves an ongoing improvement in pain experience and in disability as a result of function deficit of everyday routine. The fact that the study shows positive results on more than 4,500 patients, over a follow-up period of several months up to one year after NMRT, confirms the results of numerous *in vivo*- and *in vitro*-studies as well as observations which have already demonstrated the effect of NMRT on cells and diseases.

Considering the cost-benefit ratio involved, the performed statistical analysis shows that the application of NMRT in degenerative rheumatic diseases, especially in osteoarthritis, depicts an economically beneficial therapy and a viable alternative in treatment because of its long-term effects. In this form, NMRT could make a positive contribution to healthcare costs. The data encourage further investigation into the costs of medication and treatment.

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References

[1] Deyo RA, Cherkin D, Conrad D, Volinn E. Cost, controversy, crisis: low back pain and the health of the public. Annu Rev Public Health 1991; 12: 141-156.

[2] Digel I, Kurulgan E, Linder P, Kayser P, Porst D, Braem GJ, Zerlin K, Artmann GM, Artmann AT. Decrease in extracellular collagen crosslinking after NMR magnetic field application in skin fibroblasts. Med Biol Eng Comput 2007; 45(1): 91-7.

[3] Fagerer N, Kullich W. Anwendung der Kernspinresonanz als neue Therapiemöglichkeit bei Gonarthrose. Arzt & Praxis 2007; 61(927): 180-182.

[4] Fairbank JCT, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain questionnaire. Physiotherapy 1980; 66: 271-273.

[5] Karjalainen K, Malmivaara A, Mutanen P, et al. Outcome determinants of subacute low back pain. Spine 2003; 28(23): 2634-2640.

[6] Kellgren JH, Lawrence JS. Radiological assessment of osteoarthrosis. Ann Rheum Dis 1957; 16: 494.

[7] Kullich W, Schwann H, Walcher J, Machreich K. The effect of MBST®-NuclearResonance Therapy with a complex 3-dimensional electromagnetic nuclear resonance field on patients with Low back pain. J Back Musculoskelet Rehabil 2006; 19: 79-87.

[8] Kullich W, Außerwinkler M. Funktionsverbesserung bei Fingergelenkarthrosen durch therapeutischen Einsatz der Kernspin (Functional improvement in finger joint osteoarthritis with therapeutic use of nuclear magnetic resonance). Orthopädische Praxis 2008; 44(6): 287-290.

[9] Lequesne M, Méry C, Samson M, Gérard P. Indexes of severity for osteoarthritis of the hip and knee. Scand J Rheumatol 1987; 65(Suppl): 85-89.

[10] Lequesne M, Samson M, Gérard P, Méry C. Indices algofonctionnels pour le suivi des arthroses de la hanche et du genou. Rev Rhumatisme 1990; 57: 32-36.

[11] Lequesne M. Indices of severity and disease activity for osteoarthritis. Semin Arthritis Rheum 1991; 20 (Suppl 2): 48-54.

[12] Levers A, Staat M, van Laack W. Analyse der Langzeitwirkung der MBST® Kernspinresonanz Therapie bei Gonarthrose. Orthopädische Praxis 2011; 47(11), Sonderdruck

[13] Mazur JM, Schwartz E, Simon SR. Ankle arthrodesis. Long-term follow-up with gait analysis. J Bone Jt Surg 1979; 61-A: 964-975.

[14] Murtezani A, Hundozi H, Orovcanec N, Sllamniku S, Osmani T. A comparison of high intensity aerobic exercise and passive modalities for the treatment of workers with chronic low back pain: a randomized, controlled trial. Eur J Phys Rehabil Med 2011; 47: 1-2.

[15] Rannou F, Poiraudeau S. Non-pharmacological approaches for the treatment of osteoarthritis. Best Pract Res Clin Rheumatol 2010; 24(1): 93-106.

[16] Ringdahl E, Pandit S. Treatment of knee osteoarthritis. Am Fam Physician 2011; 83(11): 1287-1292.

[17] Snijders GF, van den Ende CH, Fransen J, van Riel PL, Stukstette MJ, Defoort KC, Arts-Sanders MA, van den Hoogen FH, den Broeder AA. Fatigue in knee and hip osteoarthritis: the role of pain and physical function. Rheumatology. First published online: July 12, 2011; doi: 10.1093/rheumatology/ker201.

[18] Steinecker-Frohnwieser B, Weigl L, Höller C, Sipos E, Kullich W, Kress HG. Influence of NMR therapy on metabolism of osteosarcoma- and chondrosarcoma cell lines. Bone 2009; 44(2): 295.

[19] Steinecker-Frohnwieser B, Weigl L, Fagerer N, Kullich W, Kress HG. Modulation of VEGF and Cytokines by Therapeutic Nuclear Magnetic Resonance. J Mineralstoffwechsel 2010; 17(4):146-159.

[20] Stucki G, Meier D, Stucki S, Michel BA, Tyndall AG, Elke R, Theiler R. Evaluation einer deutschen Fragebogenversion der Lequesne Cox- und Gonarthrose- Indizes. Z Rheumatol 1996; 55: 50-57.

[21] Temiz-Artmann A, Linder P, Kayser P, Digel I, Artmann GM, Lücker P. NMR *in vitro* effects on proliferation, apoptosis, and viability of human chondrocytes and osteoblasts. Methods Find Exp Clin Pharmacol 2005; 27(6): 391-4.

[22] Urwin M, Symmmons D,Allison T, Brammah T, Busby H, Roxby M, et al. Estimating the burden of musculoskeletal disorders in the community: the comparative prevalence of symptoms at different anatomical sites, and the relation to social deprivation. Ann Rheum Dis 1998; 57: 649-655.

[23] Waddell G. Low back pain: a twentieth century health care enigma. Spine 1996; 21: 2820-2825.

[24] Weh L, Marnitz U. Orthopädische Aspekte in der multimodalen Therapie chronischer Rückenschmerzen. Schmerz 2011; 25(3): 266-271.