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The effects of the “physical BEMER® vascular therapy”, a method for the physical stimulation of the vasomotion of precapillary microvessels in case of impaired microcirculation, on sleep, pain and quality of life of patients with different clinical pictures on the basis of three scientifically validated scales

Abstract: As part of the statutory market monitoring of certified medical devices, 658 valid patient questionnaires were evaluated between April 2011 and March 2013. The questions consisted mainly of three scientifically recognized scales for assessing the changes of sleep, pain and quality of life in patients who had used the “physical BEMER® vascular therapy” for different diseases over 6 weeks. The result clearly shows that there are significant improvements in all areas surveyed through the application of this complementary treatment option, regardless of the underlying disease.

Keywords: physical BEMER® vascular therapy; vasomotion; vasomotion stimulation; microcirculation; sleep disorders; Jenkins sleep scale; chronic pain; NRS(VAS) according to Borg; quality of life; SF12 questionnaire.

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Introduction

All regulatory processes in the body are dependent on the performance of the cells that carry them out. The regulatory process that affects the blood distribution in the microcirculation is one of the most important. The “physical BEMER® vascular therapy” stimulates in a targeted manner limited or impaired reactions of the small-caliber vessels involved in this regulation (local spontaneous vasomotion), as well as, via the improved BEMER technology, also larger-caliber arteriole and venules subject to central control (humorally or neurally controlled vasomotion), and thus expands the regulatory range of tissue and organ blood flow to bring it in line with the respective metabolic requirements [1].

While looking for an effective complement or alternative to limited drug-based therapy for limited or pathologically impaired microcirculation, the Institute for Microcirculation in Berlin, under the direction of R. Klopp, developed, after many years and costly research efforts, a specific complex signal configuration with which a very effective stimulation of impaired microcirculatory regulation processes can be achieved. This research started from the treatment devices used in earlier years (BEMER 3000 systems). They used specific low-intensity, alternating electromagnetic fields to transfer energy, and their then-proven effects made a further and targeted development appear promising [1]. After several years of intensive research, new basic scientific insights opened up new approaches to optimize the initially non-specific electromagnetic field therapy.
Electromagnetic field therapy

For decades, systems with weak, pulsed electromagnetic fields have been used for prevention purposes and in support of healing processes in connection with a variety of conditions. The systems differ from each other essentially with respect to the type and form of the signals used to generate an electromagnetic field, the flux densities chosen, and the repetition rates of the signals (signal frequencies). A general insight in the application of these systems had been for years that a more or less relevant influencing of the blood flow occurred, because pathological changes that were known to have a temporary or causal progression or origin in an impaired blood-flow regulation responded particularly well to treatment with electromagnetic fields [4–43]. But it was only in recent years that the direct connections could be clarified scientifically. Much of it has been contributed by the fact that especially processes in microcirculation had caught the eye of researchers, which led to the discovery of causal relationships [1].

Microcirculation

Microcirculation ensures the transports, necessary for the metabolism, in both directions between the cells and the microvessel. Oxygen and nutrients must be transported to the cells. The cells must, among other things, transport back to the blood the proteins formed and the metabolic end products created during the “work” of the cells, e.g., carbon dioxide that was formed during the energy production, in order to remove them ultimately from the organism. If these transports function, the cell functions, as does everything else that depends on its performance, that is, life and health. If these transports do not function, the cells will fail one by one, and the function of the organ formed by these cells diminishes – this, in so many words, is the onset of a disease or condition. Thus, the functional state of an organ is essentially determined by the functional state of its microcirculation. Microcirculation does not only affect the reactions of small and very small blood vessels in their branched networks (flow conditions), but also the interactions of the cellular and plasmatic components of the flowing blood and their flow properties, as well as the initial lymph flow in connection with transcapillary fluid exchange. Not to be overlooked are the microhemodynamic circumstances for cellular and humoral immune responses [1, 2, 44, 45].

Distribution problems in microcirculation (impaired diffusion) and, in particular, the lack of oxygen associated with it will lead to a rapid decline in oxidative phosphorylation and, subsequently, a deficiency in ATP (adenosine triphosphate), which is universal biological energy. This deficiency affects primarily the two cellular processes that depend on this energy the most, that is, the maintenance of the cell membrane potential and the transcription of the genetic code as the central process of protein synthesis [44].

Limitations or even impairments of locally and neurally and/or humorally controlled regulatory mechanisms of the arteriolar microvessel cause problems in the distribution of the plasma-blood-cell mix in the downstream capillary networks and thus impair the entire organism’s self-regulation, which can function only with sufficient cell membrane potential and optimal protein biosynthesis. As such, this is the indirect cause of the decline in performance and the onset of a variety of conditions. Proper blood distribution in line with the requirements, particularly in microcirculation, ensures the formation of a sufficient amount of biological energy in the form of ATP, improved cell, tissue and organ supply and disposal, and thus the optimal functioning of the self-regulatory mechanisms. This, in short, is how every biological system, or its health, is adjusted and optimized [2, 3].

It is generally recognized by the scientific community that limitations on physical and mental performance and a large number of conditions are, if not caused, then at least accompanied by limitations or disturbances in the microcirculatory blood-flow regulation. Manifest disturbances in microcirculation (e.g., as a consequence of chronic stress), in the sense of a vicious circle, tend to reinforce themselves and substantially affect the progression of illnesses caused by them – regardless of the clinical picture, they may actually come to define their further progress through a dynamic of their own.

Vasomotion

Based on current knowledge, the most important regulatory mechanism of local tissue and/or organ blood flow is arteriolar vasomotion with its biorhythmically and differently determined vessel wall movements in the areas of large-caliber and small-caliber arteriolar sections. A drug-based influencing of vasomotion (e.g., β-receptor blocker) is only possible in the large-caliber part of the arteriole, which has receptors. As a result, some considerable side effects will have to be expected and accepted. The small-caliber arteriolar section, given its lack of receptors, cannot be stimulated in a targeted manner by transferring chemical energy (drugs), but can only be
influenced by transferring physical energy. The lack of the drug-based therapy option for the small-caliber part of the arteriole is one of the reasons behind inadequate therapeutic interventions, or even resistance to treatment, as may occur in connection with chronic conditions or multiple organ failure in intensive care patients following shock or sepsis.

The key characteristic for the blood perfusion of tissue is the diameter of the microvessels (this concerns microvessels whose vascular walls have smooth muscle cells: minuscule arteries, arterioles, venules and minuscule veins). Changes in the vascular diameter requires vessel wall movements, which are realized by a different activity state (contraction) of the smooth muscle cells. The smooth muscle cells in the vessel walls of the large-caliber arterioles and downstream small-caliber arterioles behave differently. The muscle cells in the large-caliber parts of the arteriole act on neural and humoral commands. In the small-caliber arterioles, the movements of the smooth muscle cells are autorhythmic.

The autorhythm of the smooth muscle cells in the vessel walls of the small-caliber arterioles has a phylogenetic origin. Smooth muscle cells are among the phylogenetically oldest cells in our organism, and retain the ability to contract in response to mechanical stimuli. Depending on the activity state of an organ, the metabolic requirements change, and thus its blood-flow condition. The regulation of vascular diameters necessary for this is the result of a changing balance between many metabolic and hormonal vasoconstrictor factors (EDCFs) and a vessel-relaxing factor (EDRF, identical to nitrogen monoxide). The vasorelaxant factor EDRF (nitrogen monoxide, NO) is formed and released in the endothelium, and initiated by the respective shear force of the flowing blood (shear-force-dependent tone regulation facilitated by the endothelium, via an enzymatic cascade and signal transduction cascade in the endothelial cell). In the smooth muscle cells, NO causes a relaxation of the contractile elements, thereby expanding the lumen of the vessels [1–3].

The overarching regulation (CNS, hormones) of the lumens of larger microvessels is slower compared to local regulation (vasomotion in larger microvessels). The most important local regulatory mechanism of microcirculation is spontaneous autorhythmic vasomotion in small-lumen arterioles. Higher-level and local regulations are synchronous in the physiological area, with the local regulation mostly predominating on site. In case of illness, however, particularly in connection with chronic stress, it is not uncommon for this synchronization to be disrupted, which causes additional disturbance phenomena for organ blood flow.

In a microvascular network, not all existing capillaries of a network are always perfused with blood equally (resting phase, working phase). Some capillaries transport many blood cells in the plasma, while others transport mainly plasma and no, or only few, blood cells. This creates a microcirculatory reserve that can be used if necessary. The ability to switch capillaries on or off essentially determines the regulatory range and thus the range of adjustment in an organ to changing metabolic requirements (microcirculatory regulatory range).

In a way, spontaneous autorhythmic vasomotion represents the pulsatile component of microcirculation, and as the most important local regulatory mechanism, it is mainly responsible for the distribution of the plasma-blood-cell mix in the networks (via the small-caliber arterioles to the branchings of the capillary network and, downstream, via the vessels of the venous system). The fluid-mechanical conditions of the venous downstream must be taken into consideration in this context. For physical reasons, the drainage from the capillary networks via the venules is of great significance. Microcirculatory problems very often start in the venules [1–3].

**Objective of the study**

When a newly developed generation of devices was introduced to the market, there were sufficient scientific findings on the study of the working mechanism and the influencing of relevant parameters of microcirculation [1, 46]. But there were only few data on therapeutic evidence, which is why it was decided to introduce customer questionnaires in connection with the use of systems applying the “physical BEMER® vascular therapy” over a period of at least 6 weeks. The questionnaires were to yield sufficient evidence-based facts on the effects in therapeutic use within a short amount of time. In order to ensure that the results would be of a scientifically required and acceptable level, three internationally validated scales on sleep, pain and quality of life were incorporated into these customer questionnaires.

Since the second quarter of 2011, all treatment systems delivered have been accompanied by two customer questionnaires. The first one is to be completed and returned immediately, that is, before beginning the treatment. Thus, this questionnaire essentially represents a current snapshot of the patient’s health prior to using the treatment equipment. The second questionnaire is to be completed and returned by the patient after 6 weeks. In the second questionnaire, questions, identical to the ones in the first questionnaire, are asked about sleep, pain as well
as the physical and mental well-being over the previous 6 weeks. The present analysis also includes new data to the end of March 2013. Compared to the evaluations done in October 2011, March 2012 and October 2012, everything was essentially kept the same in order to render the results comparable. The following numbers represent the complete data record, that is, also including those cases that were part of the initial analyses.

**Materials and methods**

The first and second questionnaires were returned by 770 patients. Of these, 112 did not state their sex, age or both. The remaining 658 patients form the basis for descriptive statistics and further selections for other metrics. The following scales were used:

1. Jenkins sleep scale: The Jenkins score is calculated from the mean value of four questions on sleep disorders or difficulties sleeping. All these questions are graduated using six characteristics [1, 3–6, 47]. A mean value above 3 allows for the conclusion of a sleep disorder.

2. NRS(VAS) according to Borg: The Numeric Rating Scale (NRS) according to Borg determines the intensity of pain on a scale of 1–10, with 1 meaning no pain and 10 excruciating pain.

3. Health-related quality of life based on SF12 (short form of SF 36): The SF 12 questionnaire contains six questions each on the physical and mental well-being. To assess physical and mental well-being, one value is determined for each questionnaire. The values for the so-called SF12 indicator are computed on the basis of complex formulas, and compared before and after the 6-week treatment.

Numbers and proportions (n, %) were documented for categorical variables. Continuous variables were described using the mean value, standard deviation and standard error (SEM: Standard Error of the Mean). In addition, key values are represented by means of box-and-whisker diagrams, and tested for statistical significance using the non-parametric Wilcoxon signed rank test (matched pairs). The statistical analysis was performed using SPSS Version 20 [47].

All patients used treatment devices of the latest generation from the company BEMER Int. AG, and applied the given basis plan according to the user instructions contained in the user manuals. The treatment consists of an 8-min application in the morning and evening using the B. Body (whole-body applicator), while the intensity is increased weekly, starting at 3.5 µT (microtesla) with level 1, and up to 21 µT with level 6.

**Descriptive statistics**

Around 60% of the responses came from female patients. Around 40% were male patients. Compared to previous analyses, patients were marginally younger. The number of 50-year-old or younger persons increased (new 25.5%), while the number of 70-year-old or older persons decreased (new 22%). As before, the share of persons between ages 50 and 70, making up more than half, is the largest (52.4%) (Table 1).

The duration of symptoms is also part of demographic statistics. Since the distribution does not match the selections in the questionnaire, this variable was recoded to other categories without regard for the selection “3 months”. Around 70% of the patients have experienced symptoms for over a year, which is a small decline over the initial analyses. The number of persons with a duration of symptoms of more than 10 years, too, fell by approx. 3% to 18% (Table 1).

At the beginning of the second questionnaire, the patient is asked whether the BEMER therapy has improved the symptoms. This was answered in the affirmative by 48%. About a fifth each answered “Partially” (19.9%) and “No” (18.6%). (Table 1)

In addition, the symptoms reported were listed as major categories. It should be noted that multiple responses were possible. The symptoms most often mentioned are diseases of the musculoskeletal system (72%), followed by quality of life (20.6%), diseases of the nervous system (13.5%), cardiovascular diseases (13.5%) and vascular diseases (13.2%). Here, too, hardly any changes have been observed from the previous analyses. Overview tables of the symptoms mentioned are listed in Table 2.

**Results**

**Jenkins scale (sleep disorder)**

The overall evaluation showed that significant improvements in sleep values on the Jenkins scale can be achieved through the use of physical vascular therapy (Figure 1).
**VAS(NRS) according to Borg (sensation of pain)**

The total analysis shows a significant reduction in pain in patients with painful diseases of various origins due to the treatment (Figure 2).

**SF 12 – Physical health status (quality of life)**

The overall analysis showed an improvement in physical health through treatment, including in cases where the treatment was used for prophylaxis only (Figure 3).

**SF 12 – Mental health status (quality of life)**

Regarding this subscore of the SF 12 questionnaire, the overall analysis shows very significant improvements in the quality of life of patients in terms of mental health (Figure 4).

**Discussion**

The “physical BEMER® vascular therapy” is a physical treatment method to stimulate the body’s own regulatory mechanisms for organ blood flow in the case of limited regulatory ranges and/or dysfunctional perfusion in microcirculation by stimulating deficient mechanisms of the higher-level regulated and spontaneous (local) arteriolar vasomotion by means of a biorhythmically defined physical energy transfer in terms of a physiological stimulus. The influencing achieved in this of the periodic contraction behavior of the smooth muscle cells in the arteriolar vessel walls in the area of metabolically inadequate vasomotion movements toward largely metabolically adequate periodicities (physiological biorhythm) can be seen as being analog to the frequency-defined energy transfer of a stimulus signal to an excitable resonator.

The consequences of effective stimulation of deficient arteriolar vasomotions are: needs-adequate distribution of the plasma-blood-cell mix in the capillary networks, expansion of regulatory ranges, and thus of the microcirculatory reserve, facilitation of a transport of substances in line with metabolic requirements between the blood and tissue cells to increase the functionality of the organ to be supplied, as well as facilitation of an unlimited transport of cellular and plasmatic factors of the immune system as a prerequisite for the unimpeded working of immunological reactions.

The statistical analysis of the valid customer questionnaires 1 and 2 returned shows, for a broad spectrum of diseases (see Table 2), therapeutic evidence for the “physical BEMER® vascular therapy” with respect to the parameters sleep, pain and quality of life.

The positioning of this therapy as a complementary basic therapy should be strengthened by the results of this analysis. Especially with diseases that have been resistant to other therapeutic interventions for a long time (chronic conditions), this type of therapy seems to be a meaningful and important additional option in the physician’s therapeutic arsenal. Since the therapy does not rely on the distribution of an active ingredient applied through the blood stream, but instead achieves its effect “physically” through specific electromagnetic fields and reaches the site of action directly, its effectiveness is not limited, unlike other treatments, by existing disorders or disturbances in microcirculation. On the contrary, the improvement in impaired

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**Table 1** Demographic data.

<table>
<thead>
<tr>
<th>Age</th>
<th>≤ 50 years: 21.8%</th>
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<tbody>
<tr>
<td></td>
<td>51–70 years: 52.5%</td>
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<tr>
<td></td>
<td>70 years: 25.7%</td>
</tr>
<tr>
<td>Completion date FB2*</td>
<td>before April 2011: 19.9%</td>
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<tr>
<td></td>
<td>April–June 2011: 21.0%</td>
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<tr>
<td></td>
<td>July–September 2011: 19.9%</td>
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<tr>
<td></td>
<td>October–December 2011: 12.3%</td>
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<td></td>
<td>January–March 2012: 26.8%</td>
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<tr>
<td>Sex</td>
<td>Male: 38.1%</td>
</tr>
<tr>
<td></td>
<td>Female: 61.9%</td>
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<tr>
<td>Duration of symptoms</td>
<td>≤ 1 year: 14.7%</td>
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<tr>
<td></td>
<td>2–5 years: 31.5%</td>
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<td></td>
<td>6–10 years: 20.2%</td>
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<tr>
<td></td>
<td>&gt; 10 years: 17.8%</td>
</tr>
<tr>
<td></td>
<td>Unknown: 15.7%</td>
</tr>
<tr>
<td>Improvement of symptoms</td>
<td>Yes: 48.3%</td>
</tr>
<tr>
<td></td>
<td>Partially: 19.9%</td>
</tr>
<tr>
<td></td>
<td>No: 18.6%</td>
</tr>
<tr>
<td></td>
<td>Unknown: 13.1%</td>
</tr>
</tbody>
</table>

*If available. Otherwise, the date of receipt FB2 is used.

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**Table 2** Most frequently mentioned symptoms.

<table>
<thead>
<tr>
<th>Most frequently mentioned symptoms*</th>
<th>n=273/72.0%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Disease of the musculoskeletal system:</td>
<td>n=273/72.0%</td>
</tr>
<tr>
<td>2. Quality of life:</td>
<td>n=78/20.6%</td>
</tr>
<tr>
<td>3. Cardiovascular disease:</td>
<td>n=51/13.5%</td>
</tr>
<tr>
<td>4. Nervous system disorders:</td>
<td>n=51/13.5%</td>
</tr>
<tr>
<td>5. Vascular disease:</td>
<td>n=50/13.2%</td>
</tr>
</tbody>
</table>

*Multiple answers possible.
1.2 Jenkins-Mean values after completion date FB2

Figure 1 1.2 Jenkins-Mean values after completion date FB2.

604 patients
Scale of 1–6, values from 3 (and higher) imply a sleep disorder
Total mean values
Before treatment: 3.3
Week 6: 2.7
Wilcoxon test (p<0.001) 370 improvements

1.3 NRS (Borg) Mean values after completion date FB2

Figure 2 1.3 NRS (Borg) Mean values after completion date FB2.

628 patients
Scale of 1–10, 1=none, 10=raging pain
Total mean values
Before treatment: 4.6
Week 6: 3.7
Wilcoxon test (p<0.001) 324 improvements

1.4 SF12 Physical scale values after Completion date FB2

Figure 3 1.4 SF12 Physical Scale values after completion date FB2.

530 patients
Percentage-expressed scale of 1–100, 1=poor, 100=good health
Total mean values
Before treatment: 44.4
Week 6: 46.7
Wilcoxon test (p<0.001) 314 improvements

1.5 SF12 Mental scale values after Completion date FB2

Figure 4 1.5 SF12 Mental Scale values after completion date FB2.

530 patients
Percentage-expressed scale of 1–100, 1=poor, 100=good health
Total mean values
Before treatment: 45.5
Week 6: 51.0
Wilcoxon test (p<0.001) 341 improvements
microcirculation achieved “physically” by its effect can help other treatments become more effective. Assuming a favorable constellation, it may open up the possibility of reduced doses of other active ingredients with the same therapeutic effect. This is an advantage that is not to be underestimated, particularly for older, multimorbid patients who, due to multiple conditions in some cases, need to take a variety of drugs (with effects and adverse effects). This complementary therapy option could also be of vital help to patients whose life-threatening condition is mainly based on the fact that their microcirculation has failed (multiple organ failure). Another focus of the complementary use of the BEMER system is on prevention: through distribution of the blood-cell-plasma mix in a manner that meets the requirements as much as is possible at any time, preventing deficient supply to organ tissues and thus the development of diseases.

Conflict of interest statement

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