

Prospective, Controlled / Randomised (Single Blind) Study of Efficacy Differences between Different Jet Control Techniques for Dry Water Jet Massage Using the Medyjet System

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Introduction

Curative rehabilitation or physical therapy measures focus on improvement of physical performance and work capacity. Restoration of muscle function in general and improvement of psychological and physical tolerance to "objective stress" in particular play an important and active role in recovery.

In active, intensity-controlled therapeutic exercise, physical work and performance are objective parameters of exercise stress that describe the ratio of muscular exertion to stress load and the efficacy of muscular reconditioning. When performing such exercise, the load intensity in high-intensity exercise phases must be high enough to induce hypertrophic and acidotic responses which, in turn, trigger positive adaptation processes in pathologically degenerated muscle structures (type II muscle fibres) [Bandy, 1990] [Meyer, 1985].

The elimination of catabolites such as lactic acid takes place via venous return in cardiovascular structures. Other debris related to physical exertion (cell material, etc.) is transported out of the muscles via the passive lymphatic system, a process normally enhanced by muscle activity.

Compared to healthy, untrained individuals without back problems, patients with chronic back pain have a distinct form of combined functional-structural atrophy of the muscles that stabilise the spinal column (complex deconditioning syndrome) [Denner, 2005]. This results in:

- Inadequacy of effector organ function and
- Destabilisation of degenerated joint structures,

resulting in an increased risk of co-morbidities.

In addition, the number of complaints related to muscle pain and hyperacidity of bradytrophic structures in the spinal region increase over the course of chronification due, especially, to metabolic deficiencies.

In causal exercise therapy, the involved muscle groups are subjected to high-intensity stress (e.g. acidosis). Lactic acid catabolites produced during exercise result in a sensation of muscle tension and must be broken down as quickly as possible within a given super-compensatory phase between training sessions. The intensity of exercise determines the effectiveness of therapy but is limited by exertion-related termination criteria (muscular and/or mental fatigue → radiation, pain). The ratio of objective stress to mental resistance to fatigue, as determined by

- Physiological metabolic capacity of the effector organ, i.e. the muscle, and
- Stress perception by the individual patient,

determines an individual's level of exercise readiness.

The perception of physical stress is persistently impaired in patients with chronic back pain (leading to fear and avoidance behaviour). The muscles that stabilise the patient's spinal column under everyday stress conditions are no longer supplied with the normal, physiological, strength-preserving stimuli as those of healthy individuals without back problems or strength training [Harter, 2005].

Efficacy of the system and shortening of the super-compensatory phase (5-6 days after high-intensity exercise) are relevant for methodological as well as economical reasons (shortening of stay in rehabilitation or treatment centres or spas).

The objective of various physical therapy techniques in general and of massage in particular is to medially displace tissue fluids in order to achieve systematic toxin elimination through mechanical manipulation of the tissues.

Hypothesis

This prospective, controlled/randomised (single-blind) study was designed to test for differences in the efficacies of different techniques of dry water jet massage, a technology solution amenable to standardisation.

In this technique of dry water jet massage, the patients lie on their back on a massage table filled with warm water and covered with a plastic sheet. According to the hydrostatic principle, the patient's weight is evenly distributed across the sheet. Individually controlled (pre-programmed, automated control) water jets inside the system's water tank exert controlled massage pressure on the patient's body (Fig. 1).

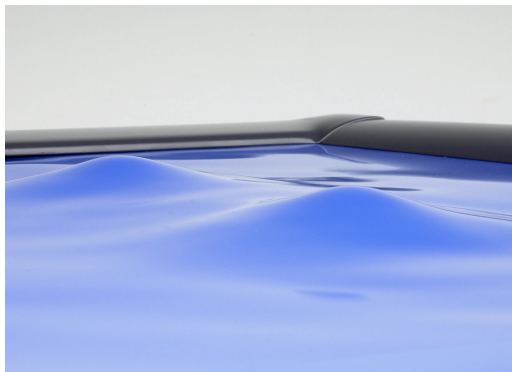


Fig. 1: Pressure exerted by the water jets

The following control techniques were used for cervical/neck muscle massage:

1. Synchronous jet control: general, non-directional jet guidance (synchronous, alternating lateral-medial and medial-lateral movements) with uniform jet control and jet pressure;
2. Asynchronous jet control: specific jet guidance (asynchronous jet control with lateral to medial movements only) with non-uniform jet control (no pressure when returning from medial to lateral).

Stroking and kneading movements towards the centre of the body are preferentially used for this purpose in classical massage techniques [Muschinsky, 1995].

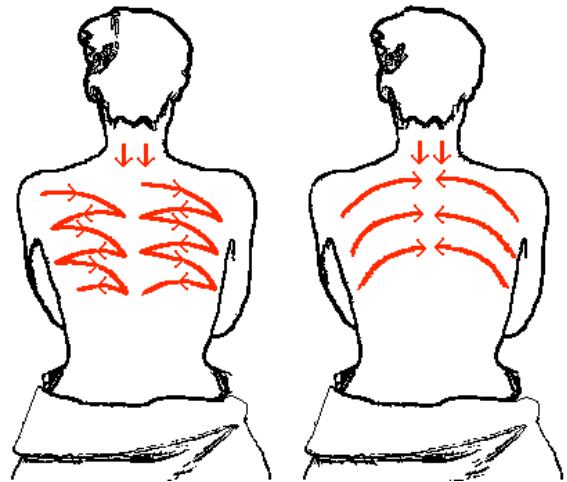


Fig. 2: Study design 1 and study design 2

In agreement with the general objectivity and efficacy criteria for physical therapy measures, jet guidance should achieve the following results:

1. Relaxation and general improvement of arterial circulation
2. Additional systematic elimination of venous and lymphatic toxins, especially of the lactate that is produced

[Muschinsky, 1995]. In periods of high-intensity lactic acid stress during a series of six cervical spine extensor exercise therapy sessions, these results should be reflected as

- Physiological development of maximum isometric strength
- Low level of exercise-related complaints (pain intensity, exertion).

In addition, training of the cervical extensor muscles is greatly dependent on auto-stabilisation in the exercise system, which occurs in the neck muscles.

However, the exercise tolerance level is dependent on the individual patient's prior experiences, especially

- History of pain and pain experiences and
- Fear-related cognition of pain.

Materials and Methods

At the following two study centres,

- Alfeld/Leinebergkliniken Municipal Hospital (N=29)
- Saline Relax / Halle Rehabilitation Centre (N=37),

patients with subacute or chronic back pain were recruited into the study and randomised. Each patient underwent a series of six high-intensity (lactic acid) cervical extensor muscle exercise therapy sessions conducted in accordance with the FPZ Method of Integrated Functional Back Pain Therapy [Denner, 1998] (Fig. 3).

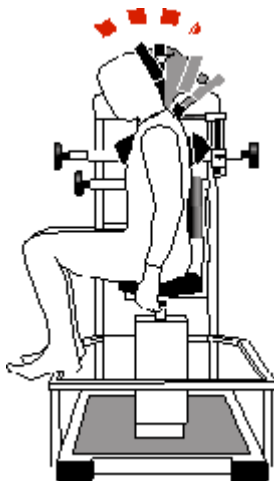


Fig. 3: Cervical extensor muscle exercise.

After each exercise therapy session, the patients received one of the following variants of dry water jet massage, which were standardised in terms of therapeutic and physical criteria and administered via the Medyjet system:

- Control group → Jet control variant 1 (synchronous) (N=35, 43% women),
- Experimental group → Jet control variant 2 (N=31, 57 % women)
- Duration of treatment: 20 minutes.

These factors determine the perception of exercise stress and/or physical exertion; hence, they determine the time of discontinuation of exercise and, thus, the intensity and efficacy of treatment [Harter, 2005].

Precise, standardised reproduction of each dry water jet massage variant was achieved by using chip cards to control the Medyjet system (Fig. 4). The patients were not told which massage variant they received (single-blind). The only identifying marks on the pre-programmed chip cards for standardized massage delivery were the letters "A" or "B".

The following variables were assessed:

- Maximum isometric torque
- Total duration of stress/exercise
- Repetition frequency per session
- Total load moved (work) and load moved per unit time (performance) per session
- Patient well-being:
 - Borg scale (rating of perceived exertion—RPE)
 - Pain intensity (visual analogue scale)



Fig. 4: Precise reproduction of the study design was achieved using pre-programmed chip cards.

Control variables for exercise therapy, which were established in accordance with the FPZ method [Denner, 1998], were exactly identical in both groups.

Variance and regression analyses of group variables were performed to test the hypothesis with respect to these variables.

Results

Randomisation was tested based on the parameters pain intensity, pain duration, relative maximum isometric strength, age (42.2 [\pm 6.5] years) and sex across the groups. No significant differences at baseline were detected ($p>0.102$).

Likewise, the two groups did not differ significantly with respect to the duration of treatment (mean duration: 19.2 [\pm 4.97] days; $p=0.795$, two-tailed)

The test of pain intensity prior to exercise did not reveal any significant differences in Sessions 1-4. In Session 5 ($p=0.050$) and even more so in Session 6, pain intensity in the experimental group (0.71 [1.49]) was significantly lower than in the control group (1.73 [2.09]; $p=0.013$). Because a directional hypothesis was used, the p values reflect the one-sided significance levels.

This trend manifested itself early on. In regard to the pain intensity after exercise, the significance level was not comparable ($p>0.082$), although the trend itself was.

In the case of the control group, the difference between the mean change in pain intensity before and after exercise was significant ($p=0.017$, two-tailed). However, since the scores for this group increased consistently, the corresponding decreases produced considerably greater variance. The comparison of variance analyses confirmed this with a high level of significance ($p=0.008$) (Table 6).

Perceived exertion experienced by the individual patient was measured using the Borg Scale [Borg, 2004]. The Borg Scale is an internationally established tool for rating of perceived exertion (RPE). Alongside physiological and metabolism-related fatigue and co-ordination, perceived exertion determines when an individual will terminate physical exercise or work when subjected to exercise stress. Hence, it is a treatment control variable.

Initially, the experimental group and control group did not differ significantly with respect to perceived exertion (14.52 [1.83] and 14.5 [1.42], respectively; $p=0.968$) (Table 8).

Considerable correlation between Borg Scale values and load parameters was observed in the two study groups (Tables 12 and 13).

The duration of exercise and thus the exercise repetition frequency per session, which remained constant for each session (n repetitions per session), allow the therapist to document the exercise intensity and degree of muscle fatigue and, thus, to control the workload [Denner, 1998]. This also allows the therapist to determine the individual exercise workload. This information makes it possible to systematically activate the training stimulus in a standardised manner.

Direct comparison did not reveal any significant differences between the groups with respect to the corresponding parameters. The variables derived from them, i.e. work performed (load moved) and performance (load moved per unit time), also did not display any significant differences (Tables 9, 10, and 11).

The most significant statistical differences were detected in the correlation analyses (Tables 12 and 13).

The number of repetitions, duration of exercise, load moved (total load moved per exercise) and load moved per unit time correlated regressively and significantly with the rating of perceived exertion (Borg Scale value). This basically confirmed our assumption that perceived exertion, an individually variable factor, is a co-determinant of load. However, when comparing the study groups, this high level of correlation was only maintained in the control group:

- The number of repetitions per session correlated in both study groups ($p<0.02$)
- The duration of training correlated in the first session only in the experimental group, ($p=0.024$), but correlated in the first four sessions in the control group ($p<0.014$).

The load moved—a measure of work—is calculated from the product of load and exercise repetitions in a treatment session. The correlation of load moved with the mean Borg Scale value, i.e. perceived exertion, was increasingly significant from the third session on (Session 3: $p=0.044$; Session 4: $p=0.024$; Session 5: $p=0.013$; Session 6: $p=0.013$), but only in the control group. Consequently, this was also the case for the load moved per unit time—a measure of performance—in the control group (Session 1: $p=0.017$; Session 2: $p=0.020$; Session 3: $p=0.012$; Session 4: $p=0.010$; Session 5: $p=0.009$; Session 6: $p=0.012$).

In the case of the experimental group, these parameters were not significant in any of the sessions (load moved $p>0.068$; load moved per unit time $p>0.163$).

Regression analyses confirmed these results. Starting with the third or fourth session, respectively, the number of repetitions showed a significantly regressive correlation with the Borg Scale value (experimental group: $p<0.02$; control group: $p<0.009$).

The total exercise duration correlated significantly with perceived exertion in both groups in Session 1 (experimental: $p=0.24$; control: $p=0.001$), but later became systematically independent of perceived exertion in the experimental group ($p>0.241$). In the control group, the regressive correlation was maintained until Session 4 ($p<0.014$).

This type of systematic regressive correlation to perceived exertion persisted throughout the entire study period, but only in the control group, for the following variables:

- Work (load moved per session) and

- Experimental group results by session number:

#1: $p=0.488$; #2: $p=0.439$; #3: $p=0.260$;
#4: $p=0.100$; #5: $p=0.068$; #6: $p=0.109$;

- Control group results by session number:

#1: $p=0.054$; #2: $p=0.066$; #3: $p=0.044$;
#4: $p=0.024$; #5: $p=0.013$; #6: $p=0.013$

- Performance (load per unit time)

- Experimental group results by session number:

#1: $p=0.315$; #2: $p=0.408$; #3: $p=0.218$;
#4: $p=0.170$; #5: $p=0.127$; #6: $p=0.163$;

- Control group results by session number:

#1: $p=0.017$; #2: $p=0.020$; #3: $p=0.012$;
#4: $p=0.010$; #5: $p=0.009$; #6: $p=0.012$

In the experimental group, the correlation between load moved and load moved per unit time proved to be completely nonlinear.

Mittlere Anstrengungsempfinden zur Last/Zeit T 6; $R_{sq}=0,163$
Experimentalgruppe

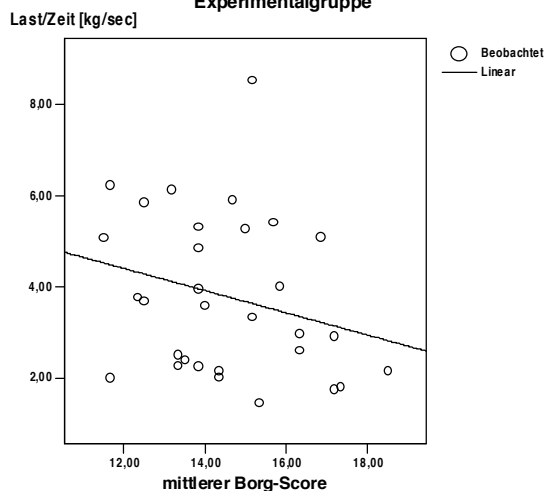


Fig. 5: Illustration of the lack of correlation between perceived exertion (Borg Score) and load moved per unit time (performance) in the experimental group during the six training sessions.

Mittlere Anstrengungsempfinden zur Last/Zeit T6; $R_{sq}=0,012$
Kontrollgruppe

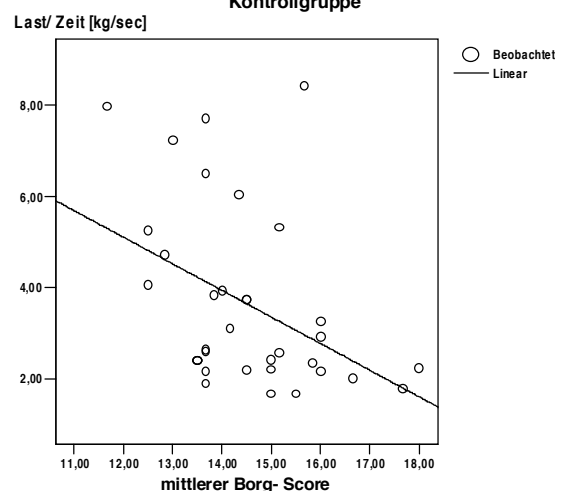


Fig. 6: Illustration of the correlation between perceived exertion (Borg Score) and load moved per unit time (performance) in the control group during the six training sessions.

Interpretation and Perspectives

A systematic exercise therapy programme—the FPZ Method of Integrated Functional Back Pain Therapy [Denner, 1998] [Harter et al., 2005]—was used to systematically treat the patients with individual supervision. The load control

guidelines were set by specially trained independent (external) therapists.

Therefore, it was not surprising that physiological core parameters of treatment, e.g. maximal isometric torque as

well as the intensity variables load and intensity (criterion: duration of exercise) did not display any significant inter-group differences upon direct comparison.

The high-intensity exercise phase, which is characterised by lactic acid stress, was deliberately chosen because the individual tolerability and tolerance to physical exertion plays a central role in it, especially in patients with chronic back pain. However, in this treatment phase, adaptation by means of hypertrophy, especially in rapidly contracting type II muscle fibres, generally does not lead to any significant improvement of maximum isometric strength [Denner, 1998].

Stress tolerance, defined as perceived exertion measured on the Borg/RPE scale, proved to be the decisive criterion for differentiation between the two study groups.

The experimental group initially exhibited weak correlations that were increasingly lost over the course of the study. However, these correlations were systematically maintained in the control group. This can be interpreted as a sign that perceived exertion exerted a controlling effect on load tolerance in this patient group. The change in load tolerance plays a critical role in the change in pain behaviour, especially with respect to cognition of pain by the patient [Hildebrandt et al., 1995].

The non-linearity of the physical parameters of work and performance, "load moved" and "load per unit time", in the experimental group indicates their high level of significance for rehabilitation and physical therapy measures. Patients who systematically received tissue-detoxifying treatment measures (asynchronous, medially directed dry water jet massage) after strenuous physical exercise experienced physical work differently than the patients who received uncontrolled detoxification measures (control group).

The systematic study findings obtained with this standardised dry water jet massage technique are in agreement with the conventional school of thought regarding classical massage techniques [Muschinsky, 1992] [Földi & Stößenreuther, 1995]

The method of eliminating toxins from affected tissues by systematically displacing the toxins towards the centre of the body is one of the main lymph drainage strategies. The positive effect of massage after physical exertion has always been postulated. It should be possible to achieve even better effects by combining the different strategies.

However, selective treatment of specific regions of oedema, painful areas of muscle hardening, and strained tendinous or fascial structures should be left to experienced therapists. This may also explain the scattering effects observed with this study design.

Future studies are required to determine the extent to which the effects on perceived exertion can be described in terms of work performed and performance, also with respect to the physiological conditions in tissue and the breakdown of lactate. Investigations with different test subjects (patients, healthy controls, and athletes) can also be expected to reveal interesting new findings.

With modern dry water jet massage technology systems, it is possible to administer individually pre-programmed massage treatments with individual jet control in a standardised manner, as was the case in the present study. This type of technology makes it possible to validate the physical and mechanical effects of massage in a standardised manner and, most importantly, in the context of evidence-based medicine, and to systematically implement these research findings in rehabilitation and physical therapy.

Tables to be attached as in Appendix by Medyjet or the author

Figure texts (up-down, left-right)

Fig. 5

Mean perceived exertion for load/time – 6 sessions, $R^2 = 0.163$

Experimental group

Load/time [kg/sec]

O Observed

– Linear

Mean Borg Score

Fig. 6

Ditto except "Kontrolgruppe" -> "Control group"

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