Treadmill Ambulation With Partial Body Weight Support for the Treatment of Low Back and Leg Pain

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Study Design: A single-subject experimental design using an A-B-A treatment protocol.
Objective: To determine whether walking on a treadmill with partial body weight support (PBWS) would be an effective adjunct treatment method to standard care for decreasing pain and increasing function in patients suffering from low back and leg pain.
Background: Mechanical low back pain (LBP) is commonly aggravated by activities that increase axial loading in the spine, such as sitting, standing, and walking. Patients with mechanical LBP usually describe relief with positions that unload the spine. One traction technique now being used in clinics to unload the spine is the PBWS system. The use of endurance exercise has also been found to be a consistent predictor of better outcomes in patients with LBP. Thus treatment that combines spinal unloading using PBWS and endurance exercise may be an effective intervention for patients with low back and leg pain.
Methods and Measures: Eleven subjects participated in this study using an A-B-A design. Phase A was defined as the baseline condition and phase B was intervention with PBWS provided by a mechanical unloading system. The Roland-Morris Questionnaire (RMQ) and Visual Analog Scale (VAS) were utilized to collect data on functional status and perceived pain, respectively. Visual Analysis and 2 standard deviation band method (2SDBM) were used to analyze the data.
Results: Pain scores between baseline and PBWS treatment phases were significantly improved for 3 out of the 6 subjects who completed the study. RMQ baseline and treatment scores revealed that 5 out of 6 subjects had significant functional improvements in the PBWS treatment phase.
Conclusion: The results suggest that ambulation with PBWS combined with the standard level of care for this population holds sufficient promise for pain relief and functional improvement to justify testing its efficacy in larger groups of subjects with these complaints. *J Orthop Sports Phys Ther 2002;32:202–215.*

Key Words: *back pain, endurance exercise, spinal unloading*

Low back pain (LBP) is a major socioeconomic problem in the industrial world. In the United States it is the second leading cause of worker absenteeism, and the most expensive in terms of lost productivity.[36] Nearly 80% of all adults experience LBP at sometime in their lives.[3] Many people experience their first episode of LBP in their early twenties, and it becomes more common as people approach their early forties.[18] Despite a reasonably favorable prognosis, back pain in general and herniated discs in particular have an enormous effect on health care utilization and costs. Three months after the onset of symptoms, only 5% of patients have persistent symptoms. However, these patients account for 85% of the LBP costs associated with compensation and time lost from work.[13] Back pain is the second leading cause of office visits to primary care physicians.[7]

It is estimated that 5% to 10% of patients with persistent sciatica will require surgery.[13] In a randomized trial that compared surgery with conservative treatment for herniated lumbar discs, results revealed improved pain relief for the surgical group at 1-year follow-

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up. However no significant differences between groups were found at 4- and 10-year follow-ups.[44] This important outcome demonstrates the need to find and implement effective alternative nonsurgical procedures for these patients, which could reduce the number of patients seeking surgery for pain relief. The long-term results of such procedures could be at least equivalent to those of patients who underwent surgery.

Mechanical LBP is commonly aggravated by activities that increase axial loading on the spine, such as sitting, standing, and walking. Patients with radiating lower-extremity pain often present with difficulty ambulating functional distances, as ambulation involves both extension and compressive loading of the spine. These patients usually describe some relief with rest, more particularly with lying down, which unloads the spine and reduces the intradiscal pressure.[27]

Lumbar traction is a therapeutic modality frequently used in the treatment of LBP. It is considered to bring about (1) flattening of the lumbar lordosis (if done in flexion or neutral spine) with distraction of the vertebral bodies and an increase in disc height;[37] (2) stretching of spinal ligaments and muscles;[25] (3) a widening of intervertebral foramina;[35] (4) decreased venous congestion and increased axoplasmic flow to the region; and (5) separation of the facets of the apophyseal joints.[14]

There is still, however, some disagreement among authors as to whether the joints can actually be distracted. Caillet[6] stated that sustained lumbar traction does not physically distract the vertebrae but suggested that its principal effect is to decrease lordosis. Cyriax[8] stated unequivocally that not only are the vertebrae distracted, but that a negative pressure develops within the disc that ''sucks'' back any protrusion. Wyke[45] suggested that the stretch imposed by traction influences the mechanoreceptors of the disc, ligaments, and facet joints. The mechanical effects of lumbar traction have been widely described in the literature; however, the results of studies examining clinical effectiveness are conflicting.

The number of satisfactory studies is limited despite thousands of patient-hours spent annually by therapists administering traction on patients with spinal impairments.[24,43] Many of the available studies performed on the efficacy of traction for back and neck pain do not allow clear conclusions because of methodological flaws in the design and conduct.[43] Further, well designed clinical studies are needed for conclusions to be drawn about the efficacy of specific traction techniques.

One traction technique now being used in clinics is the partial body weight support (PBWS) system. Unloading with partial body weight support involves the use of a traction harness and the application of a vertical traction force while the patient ambulates on a treadmill. The traction force is intended to reduce the gravitational compressive forces on the spine during ambulation and to decrease the patient's pain symptoms. PBWS during locomotion has been used primarily in the treatment of patients with neurological deficits following strokes and spinal cord injuries (partial and complete)[9,11,29] as well as in other clinical conditions such as lower-extremity fractures,[19] osteoarthritis in the knee,[23] lower-extremity amputations,[15] ankle sprains and strains,[19] and spinal stenosis.[12] Theoretically, we may expect a decrease in the symptoms of patients with LBP if we are able to decrease the compressive forces on the lumbar spine with the use of a PBWS system. However, the use of this system for these patients has yet to be evaluated.

Jette and Jette[16] found that the use of endurance exercise was the most consistent predictor of better outcomes in patients with spinal impairments in both the emotional and physical health dimensions. They reported that endurance exercises may help to reduce sensitivity to pain, increase blood flow to painful muscles, and increase endorphin levels. These results are supported by the findings of Lindstrom et al,[22] which show that workers with LBP who participated in an individualized exercise program that included some form of endurance exercise returned to work quicker than a control group that did not receive exercise instruction. These findings are also supported by the acute low back pain guidelines published by the Agency of Health Care Policy and Research (AHCPR),[4] which recommends endurance and low-stress aerobic programs such as walking, biking, or swimming.

A treatment plan that combines spinal unloading using PBWS and endurance exercise may be an effective intervention to decrease pain and increase function in patients with low back and leg pain. The purpose of this study was to determine whether walking on a treadmill with the use of PBWS would be an effective adjunct treatment method to the standard care for decreasing pain and increasing functional ability in patients with low back and leg pain.

METHODS AND MEASURES

A single-case experimental design[1,28] using an A-B-A treatment strategy was used to test whether ambulation on a treadmill using PBWS would result in a decrease in patient-reported pain levels and an increase in functional status. This study was reviewed and approved by the Lahey Clinic Institutional Review Board.

Patient Selection

Eleven patients referred to the Lahey Clinic Outpatient Physical Therapy Department with the diagnosis of low back and leg pain were recruited for this study. Specific inclusion criteria consisted of patients between the ages of 18 and 65 years who had been referred to physical therapy with the diagnosis of low back and leg pain. Duration of pain complaints was no longer than 6 months and no less than 1 month.

Each subject underwent a standardized lumbar spine examination as performed at the Lahey Clinic. This included an assessment of the subject's subjective complaints and relevant medical history, active range of motion in the lumbar spine, lower-extremity flexibility testing, myotomal strength and neurological testing, observation of gait abnormalities, and soft tissue and spinal joint palpation.

Patients were excluded if they presented with LBP secondary to neoplastic or metabolic causes, had lumbar spine or lower-extremity surgery within the last year, or were candidates for urgent low back or lower-extremity surgery. Patients presenting with a history of neurological or cardiovascular disease, or both, were also excluded.

Following the initial examination, eligible subjects were invited to participate in the study. The nature of the study was explained and an informed consent form was presented to those who volunteered to participate.

Rater

The investigator was an outpatient physical therapist with seven years experience. He was trained in the testing protocol and the use of all relevant documentation. The investigator administered all tests and measurements and completed all necessary documentation.

Instrumentation and Measurements

The equipment included a treadmill, a pneumatic unloading station (Vigor Equipment, Inc., Stevensville, MI), gravity lumbar vests (large, medium, and small), and a scale and compressor (Figure 1).

The tools used to obtain data were the Visual Analog Scale (VAS) and the Roland-Morris Questionnaire (RMQ). These measures have been shown to be reliable and sensitive to change in patients with LBP.[20,21,32,41] The VAS was used to assess perceived changes in pain levels (0 = no pain, 10 = worst pain imaginable). Patients rated their pain levels before and after every treatment.

The RMQ was used to assess changes in the patient's functional status. The RMQ is a self-administered questionnaire that assesses pain-related disability in patients with LBP. Each of the 24 items is scored as 1 if endorsed and 0 if not endorsed. The scores can vary from 0 (no disability) to 24 (severe disability). During the study, subjects completed the questionnaire prior to the start of phase A, at every second treatment session, at the end of baseline and treatment phases, and at discharge. Completion of

FIGURE 1. Treadmill with partial body weight support.

these questionnaires required on average 6 to 8 minutes.

Procedure

Subjects were given logbooks that they kept on a daily basis. They were instructed to answer 3 specific questions that may have had an impact on pain or function. The questions were related to (1) whether the subject had performed daily exercises; (2) if the pain level had changed in any noticeable manner; and (3) if the performance of any activities that day may have been related to the change. This study was divided into 3 separate phases: A1, B, and A2.

Phase A1

This phase began with an exercise regimen that included lumbar stabilization exercises and specific flexibility exercises for the lower extremities. Soft-tissue mobilization to the thoraco-lumbar spine was administered if indicated, and instructions were given in the use of correct body mechanics and posture. Patients were also instructed in techniques for self-unloading the spine. For example, the patients were instructed to sit on the edge of a firm chair with their hands holding onto both sides of the seat. They were then instructed to slide their buttocks off the edge of the chair, relaxing their body, while supporting themselves with their arms. This constituted the standard care for this population. Each subject was instructed by the investigator to perform these exercises twice a day. Stretching exercises were performed 3 times for 30 seconds each. Strengthening exercises were usually prescribed as 3 sets of 10 repetitions.

Phase A1 continued until a stable level in the subject's symptoms was reached or until 3 weeks had passed. The frequency of treatment in the clinic was no less than 2 but no more than 3 times per week, with each treatment session lasting 45 to 60 minutes. The subjects marked their perceived pain level on the VAS before and after every treatment. When the subjects reached a stable level in their symptoms, or when 3 weeks passed, they completed the RMQ and phase B began.

Phase B

Subjects were weighed at the beginning of phase B to determine the recommended ranges for unloading. Instructions were given to the subjects regarding ambulating on a treadmill with PBWS. The approximate amount of unloading used initially was determined according to the subject's pain presentation at the initial examination. For subjects whose pain symptoms increased with sitting and standing activities, the recommended amount of initial unloading was 85% to 95% of trunk weight (TW). TW is calculated as follows: TW = [(0.6 × body weight) + 3.08 kg].

For subjects with increased pain symptoms with walking and quick relief of symptoms with sitting, the recommended amount of initial unloading was 20% to 40% of TW. The initial speeds recommended for ambulation ranged from 0.40 to 0.89 m/s for the subjects who completed the study. These recommended amounts of unloading and initial walking speeds were communicated by the manufacturer of the unloading device. However, in selected cases, the amount of unloading administered was increased until relief in pain symptoms was obtained and patients were instructed to walk at a comfortable pace. These speeds ranged from 0.36 to 0.8 m/s at the initial visit. The amount of weight needed to achieve the initial unloading effect was noted and did not exceed 70% of body weight.[10]

Each subject performed a 5- to 10-minute trial session of ambulation on the treadmill with PBWS (Figure 1). The purpose of this session was to familiarize the subject with the treadmill and the PBWS system, and to optimize the amount of unloading to be used to relieve the subject's symptoms.

The subjects ambulated on a treadmill up to 45 minutes using the unloading device in addition to the program initiated in phase A1. The total distance covered, amount of unloading performed, speed at which the subject was able to ambulate, and the total amount of time each subject ambulated were noted at every treatment session. The amount of unloading applied was the least amount of unloading needed to relieve the patient of low back and leg symptoms during ambulation. The patients were instructed to ambulate at a pace comfortable to them without holding onto the rails of the treadmill. The intention was that as subjects progressed, they would be able to tolerate decreased amounts of unloading and would be able to ambulate at a faster speed. On average, all subjects ambulated 30 to 40 minutes on the treadmill during the intervention phase.

During this phase the subjects marked their perceived pain level on the VAS before and after each treatment. The subjects were instructed to continue at home with the same exercise regimen received during phase A1, and continued to fill out the logbook. Treatments were no less than 2 but no more than 3 times per week, and lasted up to 60 minutes unless terminated due to patient fatigue or increase in pain symptoms.

Phase B continued no longer than 3 weeks. At completion of phase B, the subjects completed the RMQ, and the treadmill unloading was withdrawn.

Phase A2

Phase A2 continued until the patients were discharged from care. This phase consisted of the same type of exercise regimen as prescribed in the initial phase A1, and new exercises were instituted according to the subjects' level of improvement.

Data Analysis

Visual Analysis and the 2 standard deviation band method (2SDBM) were used to analyze and compare data for the VAS and RMQ scores.[30] The 2SDBM involves calculation of the means and standard deviation of the data points within the baseline phase. Lines are drawn 2 standard deviations above and below the mean level of performance for the baseline phase. If at least 2 successive data points in the intervention phase fall outside the 2 standard deviation band of the baseline phase, the changes from the baseline to the intervention phase are considered significant.

RESULTS

Demographic Data

Six out of the 11 initial subjects completed the study. The mean age was 42 years within a range of 25 to 56 years of age. Patient data are summarized in the Table. Mean duration of symptoms was 10.1 weeks with a range of 1 to 5 months. Five of the 6 subjects who completed the study reported limitations in their gait capabilities on the initial RMQ. They reported walking less, walking slower, or both

TABLE. Subject demographic information.

Patient	Medical Hx	Functional Limitations at Initial Evaluation	Straight Leg Raise	Diagnostic Imaging	Initial RMQ*	Discharge RMQ
Subject 1: 50-year-old woman, secretary, 83 kg	• Borderline hypertension • Migraines • Breast reduction (1996)	• Pain with walking and transfers • Avoided bending activities Duration since onset: 1 mo	Left (+) Right (+)	Radiographs 9/99: • Disc space narrowing L2–3, L4–5, L5–S1 • Osteophytes on anterior vertebral bodies at L2–4	16	1
Subject 2: 52-year-old man, project manager, 109 kg	• Diabetes • Hypertension (since pain onset)	• Difficulty walking more than 20 m • Difficulty sleeping, no comfortable position • Arrived at initial evaluation in wheelchair Duration since onset: 3 mo	Left (−) Right (+)	MRI† 11/99: • Disc space narrowing L1–2, L3–4, L4–5 • L3–4 DDD‡ with mild concentric bulge • L4–5 shallow, broad right posterior lateral protrusion identifying the right thecal sac and impinging upon the L4 nerve root • L5–S1 left posterior lateral shallow protrusion, not compromising the exiting nerve root	17	0
Subject 3: 25-year-old woman, teacher, 54.4 kg	• Right elbow tendon repair (1992) • Right wrist arthroscopic surgery (1996)	• Difficulty driving and bending down to tie shoes Duration since onset: 5 mo	Left (−) Right (+)	MRI 11/99: • Disc space narrowing L4–5 • L4–5 shallow central disc protrusion that minimally indents ventral aspect of thecal sac • Facet and ligamentum flavum hypertrophy causing minimal central stenosis at this level • Neural canals open bilaterally	4	3
Subject 4: 30-year-old man, software engineer, 68 kg	Noncontributing	• Difficulty sitting • Avoided bending and cautious with transfers Duration since onset: 5 wk	Left (−) Right (+)	MRI 3/00: • Mild Schmorl nodes at several disc levels • Central disc extrusion at the L4–5 level • Possible disc fragment extending into the right ventral epidural space which may be impinging on the right L5 nerve root	8	0
Subject 5: 39-year-old woman, housewife, 75 kg	• Irritable bowel syndrome • Reflux	• Difficulty sitting and bending Duration since onset: 4 mo	Left (+) Right (−)	Radiographs: • Minimal levoscoliosis MRI: • L4–5 posterior-lateral disc protrusion on right impinging on neural canal but not compressing L4 nerve root	11	5
Subject 6: 56-year-old woman, teacher, 104 kg	• Obesity • Hypertension • Uterine fibroids • Type II diabetes mellitus • Hypothyroidism • Depression • Migraines	• Difficulty walking and standing more than 15 min • Avoided bending and lifting Duration since onset: 1 mo	Left (−) Right (−)	MRI 8/99: • DDD at L4–5 • L4–5 disc space narrowing • Spondylotic stenosis L4–5	17	3

* Roland-Morris Questionnaire
† Magnetic resonance imaging
‡ Degenerative disc disease

because of their back and leg pain. One subject used a wheelchair to get to the clinic, as he could not ambulate more than 15 yards without stopping to rest. The remaining subjects ambulated without assistive devices. All the subjects had initial complaints of pain that brought them to seek help. Initial mean VAS score was 5 within a range of 1.8 to 7.6. Five out of 6 subjects had herniated discs that were clinically diagnosed by magnetic resonance imaging (MRI).

Five of the 11 subjects did not complete the study. One recovered fully in phase A1. The investigator excluded a second subject in phase A1 as a result of poor compliance with treatment attendance. A third subject was disqualified following complications from psychiatric medications in addition to an inability to attend therapy sessions consistently for a portion of the study as a result of a family emergency. A fourth subject had surgery in phase B, and the fifth stopped therapy in phase A2 after consulting with a neurosurgeon and was referred to a pain clinic for pain management.

Effects of Treadmill PBWS on Pain Levels

The results of the VAS are presented in Figures 2A to 7A. Analysis of the VAS data comparing initial pretreatment pain measurements to discharge pretreatment measurements demonstrates significant improvement in 5 of the 6 subjects. Change-of-pain scores between baseline and the PBWS treatment phase using the 2SDBM were significant for 3 of the 6 subjects, indicating the positive effect of the intervention phase on pain symptoms (Figures 2A, 4A, 5A). Throughout all treatment sessions, all subjects demonstrated lower posttreatment VAS scores throughout the 3 phases (unless they had already reached the no-pain level at the beginning of the treatment session).

In all subjects who demonstrated overall improvements in pain levels, none had an increase in pain following the withdrawal of the PBWS intervention phase.

Effects of Treadmill Unloading on Function

When comparing pretreatment RMQ scores from the initial evaluation and discharge, all 6 subjects demonstrated improvements in their scores (Figures 2B–7B). Using the 2SDBM, 5 out of these 6 subjects had significant improvements in function that were related to the PBWS intervention phase (Figures 2B, 3B, 5B–7B).

Following the withdrawal of the treadmill unloading, all of the subjects either maintained their RMQ scores or had a small decrease in their scores. No significant change in function was observed between the PBWS intervention and second baseline phase A2 (using the 2SDBM), except for subject 2, who continued to improve significantly.

PBWS Treatment Parameters

Figures 8 through 13 present the walking speed and amount of unloading used for each patient at each treatment session of the PBWS phase.

DISCUSSION

Visual Analysis is the most commonly used method to evaluate data from single case experimental designs. It does not require mathematical operations and, with basic information, researchers can accurately describe outcomes using this method. The current study used both visual inspection and statistical analysis to interpret data. Visual inspection has been compared with statistical analysis of single-subject data and has been shown to have high agreement.[5]

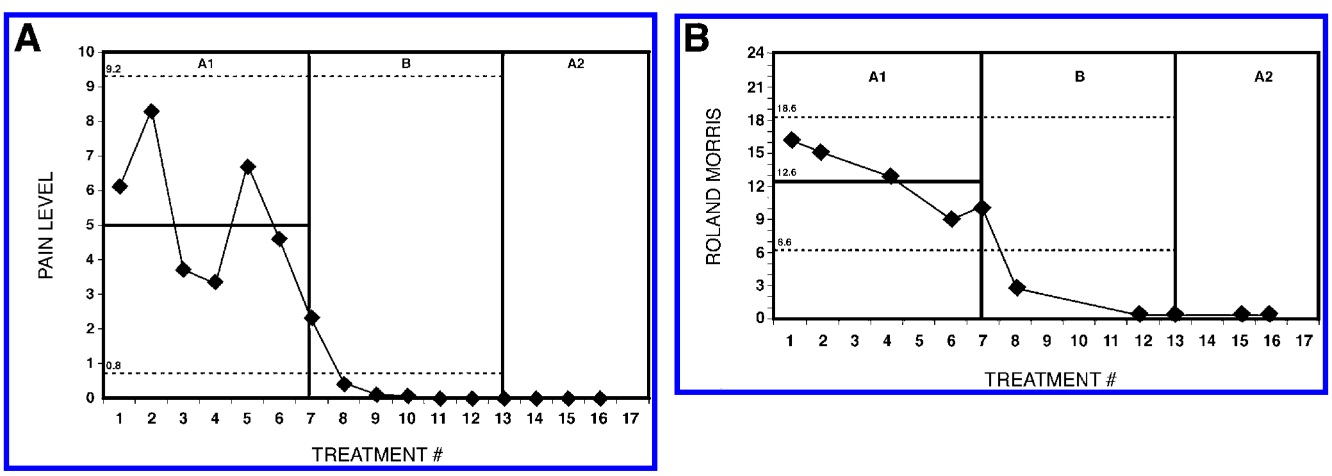

FIGURE 2. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 1. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

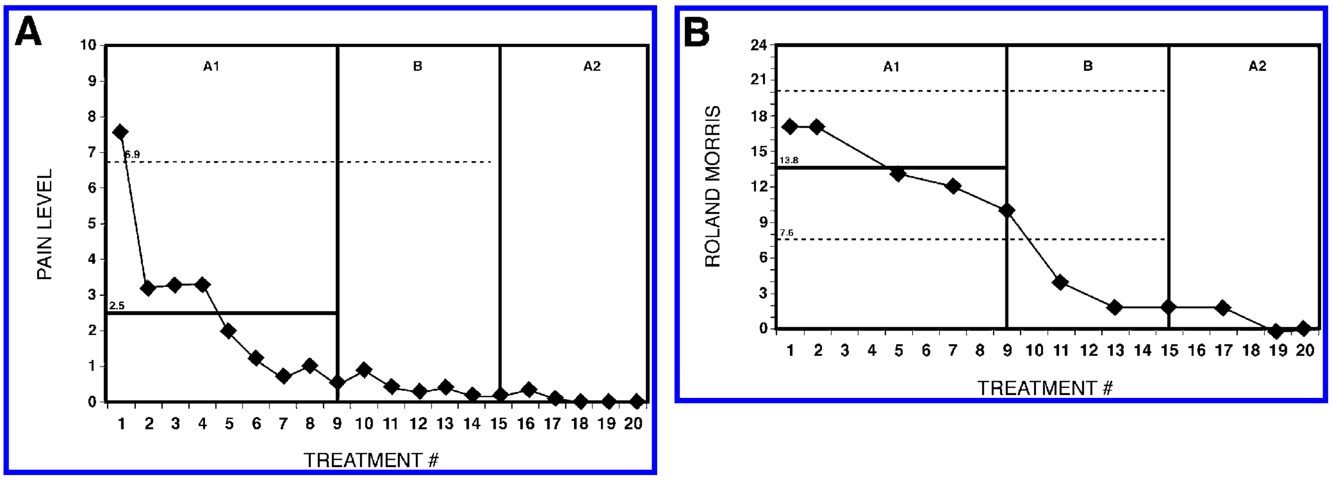

FIGURE 3. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 2. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

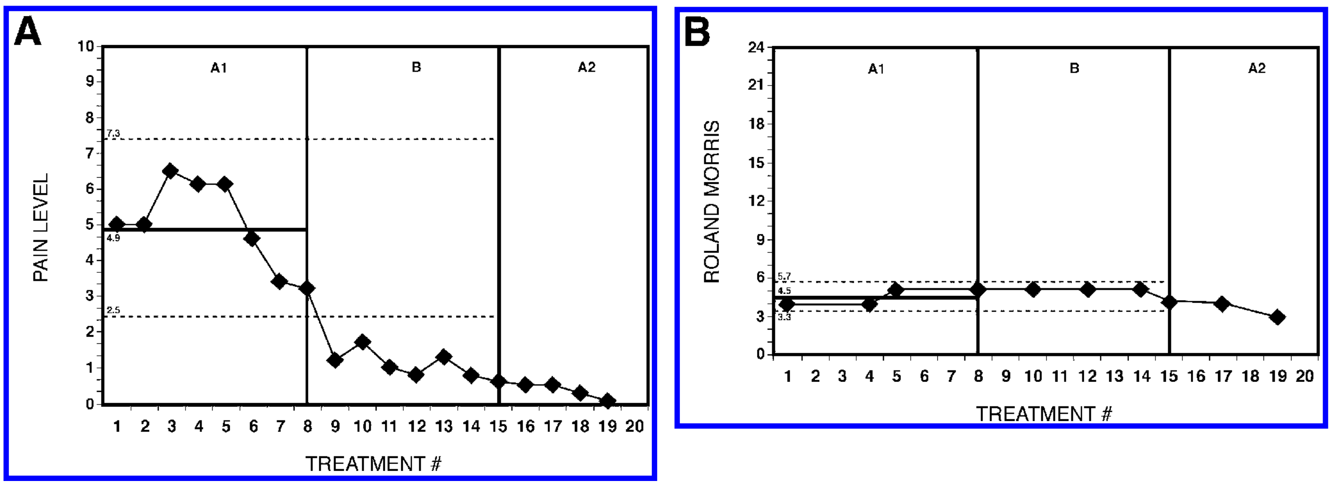

FIGURE 4. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 3. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

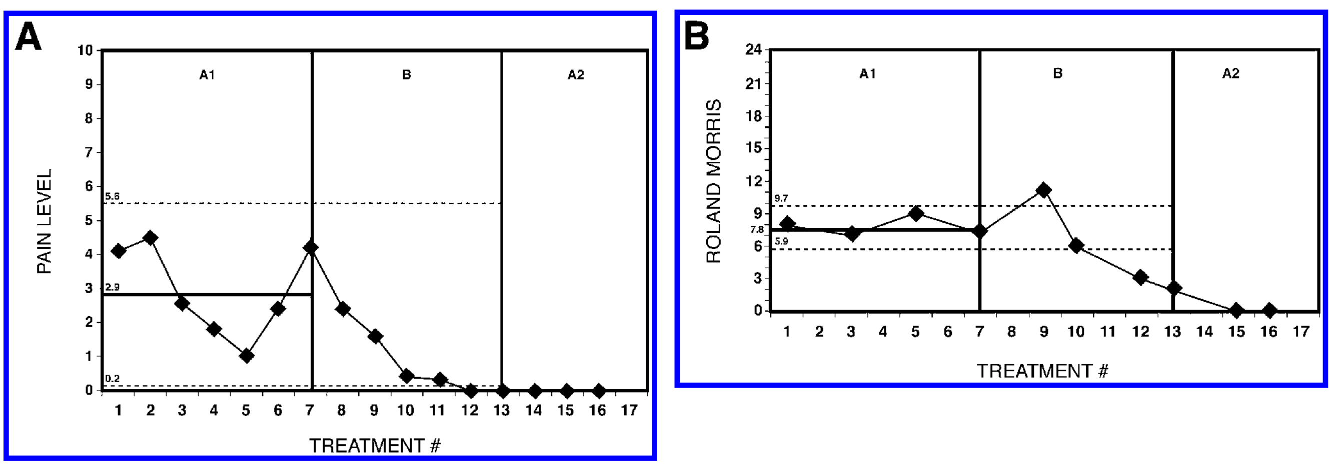

FIGURE 5. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 4. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

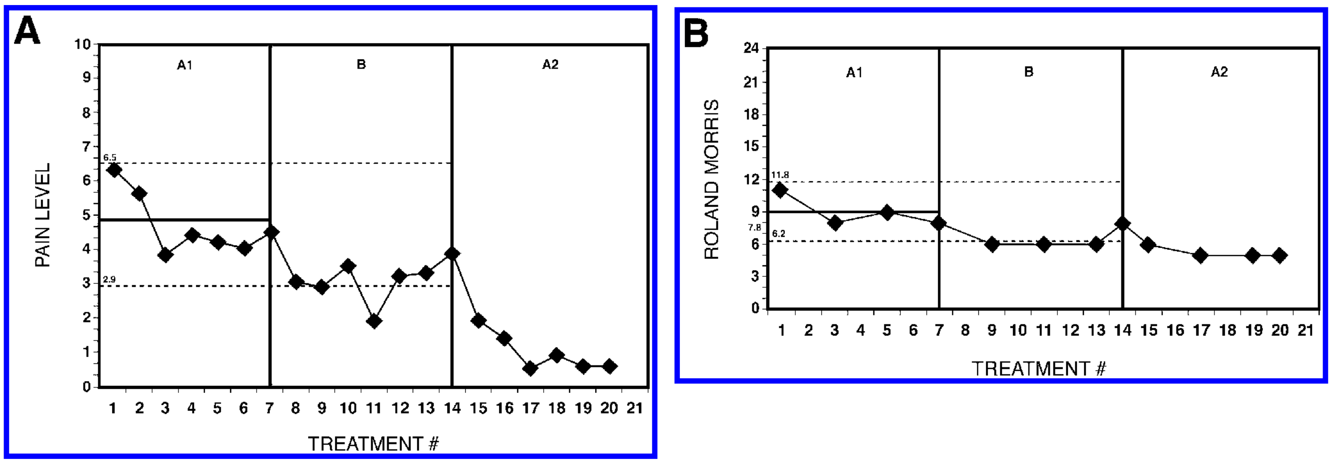

FIGURE 6. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 5. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

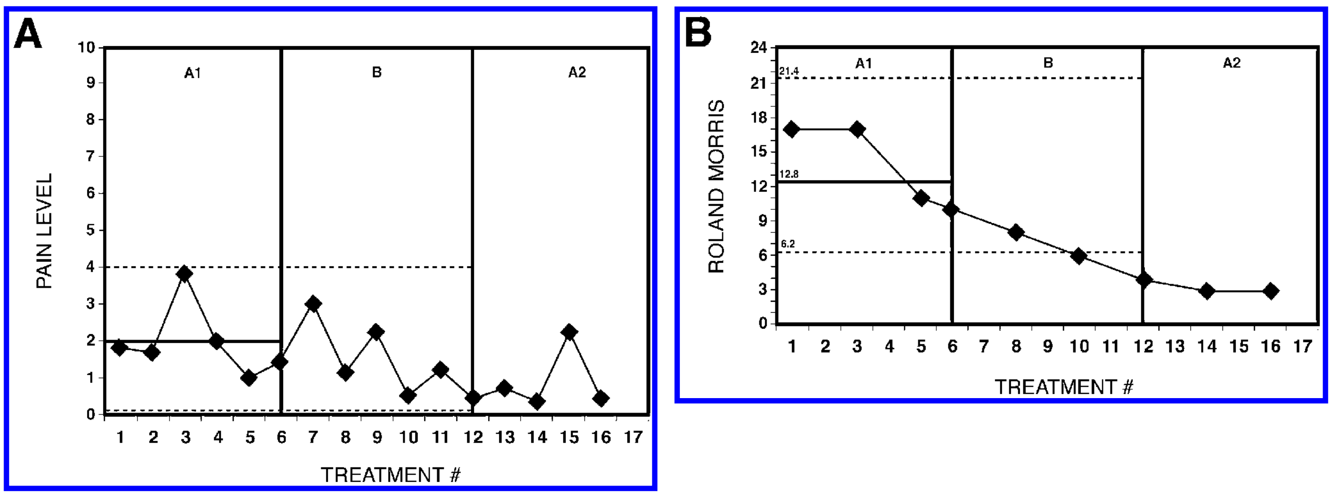

FIGURE 7. Two standard deviation band method of analysis for Visual Analog Scale (A) and the Roland-Morris Questionnaire (B) during phase A1 (baseline) and phase B (PBWS intervention) for subject 6. The solid line in phase A1 represents the average score across the treatment sessions. The dashed lines are the mean ± 2 standard deviations.

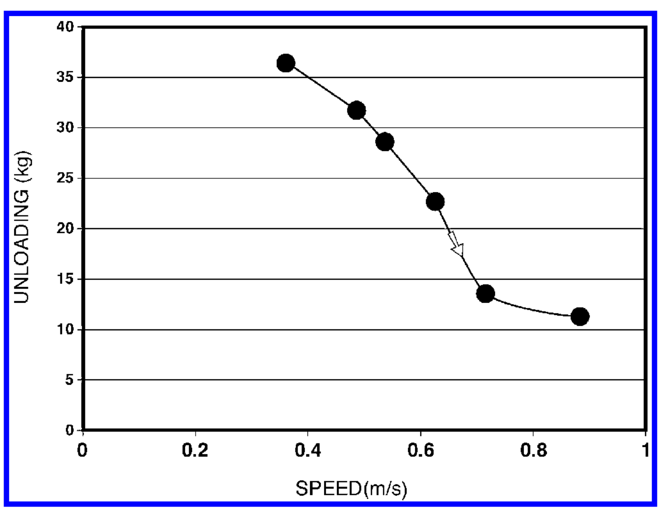

FIGURE 8. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 1.

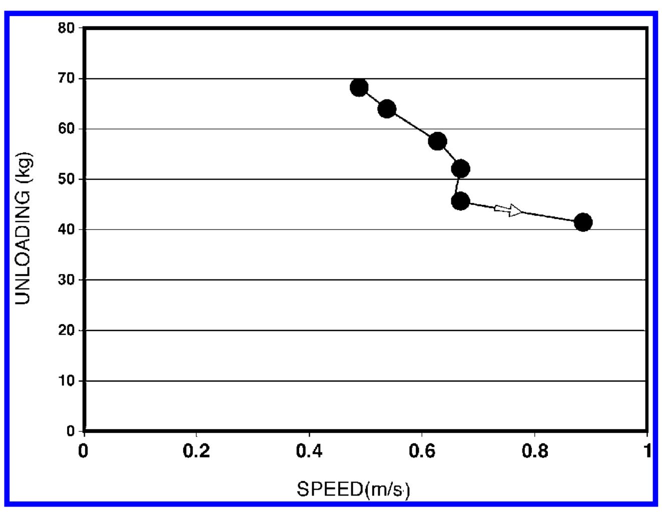

FIGURE 9. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 2.

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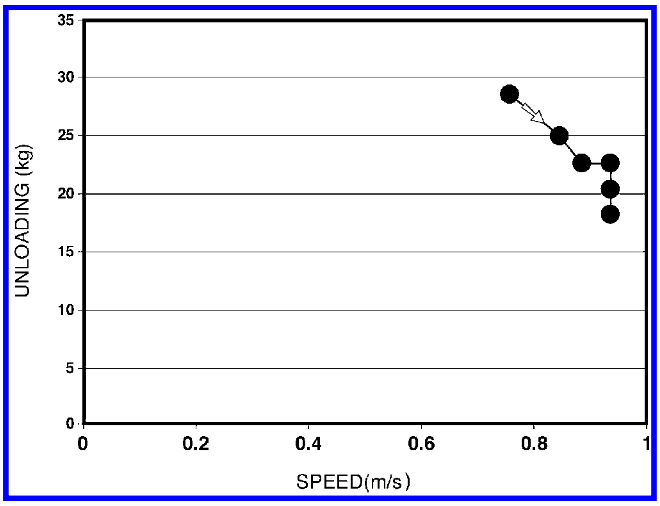

FIGURE 10. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 3.

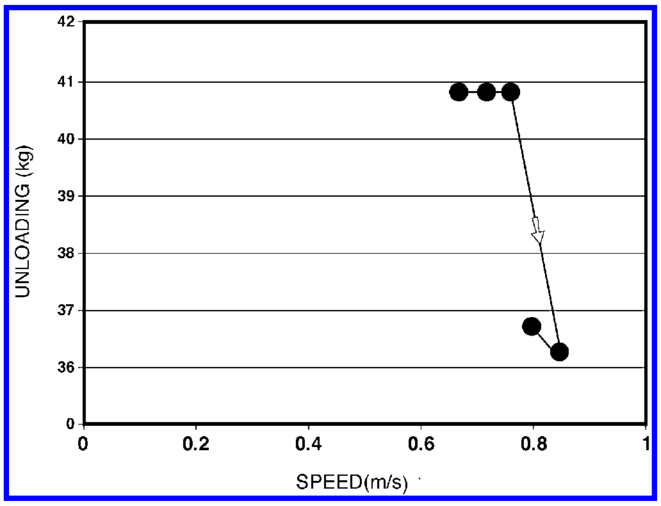

FIGURE 13. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 6.

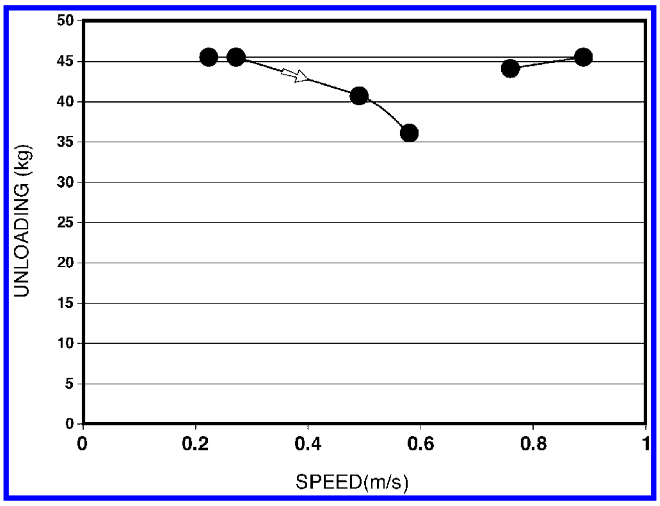

FIGURE 11. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 4.

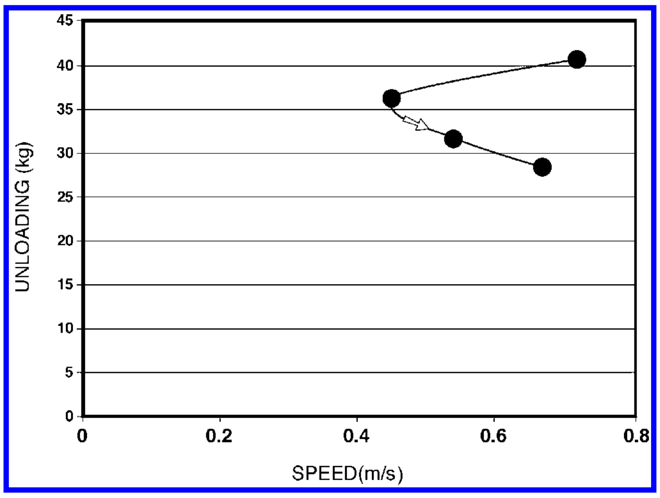

FIGURE 12. Unloading amount (kg) and treadmill speed (m/s) during each PBWS treatment session for subject 5.

Effects of Treadmill PBWS on Pain Levels

Visual Analysis of the pain VAS in this study showed that all 6 subjects improved in phase B (Figures 2A–7A). These results agree with the study performed by Fritz et al,[12] which evaluated the effect of PBWS on a treadmill on 2 patients diagnosed with spinal stenosis. Both subjects demonstrated improvements in their functional status questionnaires as well as their VAS scores. Carryover of pain relief and function was still good at 6 weeks following discharge. The only other study using PBWS to assess pain and functional changes was conducted by Mangione et al,[23] who found that patients with knee osteoarthritis were able to ambulate on a treadmill with PBWS for longer periods of time than they would have without PBWS. However, there was no carryover of pain relief once the unloading was withdrawn. The limited number of controlled studies on the clinical effects of mechanical traction have either shown poor results of treatments or positive effects that were of limited or marginal significance.[24,43]

Carryover of Pain Improvements

Session-to-session changes in the pretreatment pain scores were evident in phases A1 and B for subjects 1, 2, 3, and 5. Subject 6 also demonstrated an overall downward trend in pain scores but had some increase in pain on days that she bent over young children's school desks. Based on Visual Analysis, these pain reports showed a downward trend during phases A1 and B, suggesting carryover of improvements from session to session. Variables related to fluctuations in the subjects' pain levels were lifting and bending activities as well as lying still in an MRI machine.

During phase A2, subjects 3 and 5 continued to demonstrate session-to-session improvements, although these were minor in the case of subject 3. Subjects 1, 2, and 4 had already reached the no-pain level in phase B, and did not demonstrate an increase in pain levels following withdrawal of the intervention. In all subjects who demonstrated overall improvements in pain levels, none had increases in their pain levels following the withdrawal of the intervention phase. This is consistent with a study done by Fritz et al[12] that evaluated the effects of PBWS on a treadmill on 2 patients diagnosed with spinal stenosis.

Effects of Treadmill Unloading on Functional Status and the Influence of Possible Confounding Factors

Self-reported functional status measures represent one method of assessing functional change in patients with LBP. The principal dilemma is the difficulty in determining the change in scores that corresponds to a clinically important change. Despite the fact that no standard interpretation exists, the literature suggests several ways to look at change using the RMQ. The first method suggests that important change is equal to 5 RMQ points.[2,35] However, all of the studies used to arrive at that measure were restricted to estimates of important improvement and no information is available concerning deterioration of function.[2,35] In our study, 5 out of 6 subjects had improvements of greater than 5 points when comparing initial and final RMQ scores, and 4 out of 6 subjects had improvements of 5 points or more during the course of the PBWS intervention phase. Even though these results may reflect a clinically important change, we need to question whether a 5-point change at the upper or lower end of the scale is equivalent to the clinical change in the functional status of a patient who improved 5 points in the center of the scale. Stratford et al[35,40] reported an average discharge score of 4 on the RMQ for those patients receiving physical therapy who experienced an important change over the course of treatment compared with patients who did not experience an important change during treatment. In the present study, 5 out of 6 subjects had discharge RMQ scores of less than 4. Riddle et al[34] reported that patients receiving physical therapy and meeting their treatment goals had an average RMQ discharge score of 1.7 compared with an average score of 6.8 RMQ score for patients who did not meet their treatment goals. These results were consistent with the results of our study, in which the average discharge RMQ score was 2.0 for patients who improved, based on both VAS and RMQ scores.

An alternative method for using the RMQ to describe functional change is described by Stratford and Binkley.[40] They estimated a 90% confidence level for detecting minimal functional change using this questionnaire. Applying this method in our study, 4 out of the 6 subjects who improved would have shown significant improvement during the PBWS intervention phase compared with 5 out of 6 subjects using the 2SDBM. Functional improvement of 1 subject (subject 3) would not be considered significant. This subject had an initial score of 4 (considered to be a low score). The subject was totally functional with all activities of daily living, but had been limiting herself from high level activities (skiing, running, and aerobics).

Clinical Relevance

The medium of water (aquatic therapy) is frequently used for treating spinal impairments.[26,39] McNamara[26] reported that unloading of spinal structures secondary to buoyancy seemed to minimize postexercise soreness and allowed patients to do more exercise earlier in the rehabilitative process. However, the question of whether aquatic therapy can enhance the rehabilitative process more than the standard care has yet to be answered. Sjorgen et al[38] performed a 2-group pretest-posttest study in which 56 subjects with chronic LBP completed group physical therapy exercises either in water or on land. The conclusions of the study were that both groups significantly improved in variables of pain and functional ability and there was no significant long-term difference between the effect of aquatic and land therapy.

The treatment technique of PBWS on a treadmill allows patients with weight bearing limitations to exercise pain-free in a partially unweighted environment on land. There is no need for the patient to have access to a pool, as the treadmill can be easily located in a clinic. The harness and supporting device enables the therapist to accurately quantify and monitor the amounts of unloading needed to relieve pain symptoms in patients suffering from LBP (with or without leg pain). This can also be a good alternative for patients who may have benefited from aquatic therapy but either do not have access to a pool or do not want to exercise in water.

Limitations of the Study

The current study examined each subject as a single case; therefore, our ability to generalize is limited. Other limiting factors in this study included heavy reliance on a stable baseline in order to progress to the next phase, the questionable sensitivity of the VAS to detect small but possibly significant changes, and the frequent use of pain and functional status questionnaires.

One of the limitations of Visual Analysis is its heavy reliance on the presence of a stable baseline as a standard of comparison of subsequent data. A trend in baseline data does not present a serious problem when it reflects changes in a direction opposite than expected during intervention. One would then anticipate a distinct change in direction once treatment is initiated. However, it is a problem when the baseline trend follows the direction of expected change. If the improving trend follows the direction of change expected during treatment and continues into the intervention phase, it becomes difficult to assess treatment effects, as the target behavior is already improving without treatment intervention (Figure 3A). In this study, Visual Analysis of the pain VAS showed that all 6 subjects were already improving during phase A1 and continued to improve in phase B (Figures 2A–7A). It is important to consider what other factors may be contributing to this improvement. Perhaps changes during the PBWS phase only reflected maturation or the continued positive effect of the phase A1 treatments. Instituting PBWS treatment under these conditions makes it difficult to draw definitive conclusions. A control group receiving the same course of treatment with the exception of PBWS could have helped establishing this answer. Therefore, the lack of a control group was a limitation of this study.

Another limitation of Visual Analysis is its potential inability to detect small but possibly significant changes in pain levels. For example, subject 6's initial pain reading (Figure 7A) was below 2 out of 10 at the first treatment session. Using the 2SDBM to assess statistical significance would prove almost impossible in the PBWS intervention phase, because even a pain report of 0 would fall on or above the 2 standard deviations line (floor effect).

The fact that some of the subjects' initial pain scores were in the lower half of the scale (Figure 7A) may have affected the results in that there was less room for improvement under these conditions. Demonstrating statistical significance becomes more difficult as the sensitivity of the VAS has been affected.

To obtain sufficient data points, subjects were required to frequently complete pain and functional status questionnaires. Possible learning effects may have had an impact on the RMQ and VAS scores. Clinicians considering what functional status questionnaire to choose should take into account that leg pain may be a separate contributing factor to the patients' functional status.[31] Not all low back functional status questionnaires take this into account when assessing patients with low back and leg pain.

Should another investigator want to replicate this study, it would be advisable to design a randomized controlled trial study that could incorporate various patient populations as well as both aquatic and PBWS therapy.

CONCLUSION

This study provides initial indications that ambulation with PBWS on a treadmill, combined with the standard care for patients suffering from low back and leg pain, may lead to pain relief and functional improvement; however, the lack of a control group precludes definitive conclusions. Nevertheless, observations presented in this study should provide stimulus to further investigation into the use of a combination of ambulation and partial unweighting of body weight as a viable treatment method for specific groups of patients with low back and leg pain.

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Invited Commentary

Partial body weight reduction (PBWR) during treadmill ambulation is a treatment technique that has rather recently been described as a useful intervention for patients with a variety of diagnoses. There are descriptions in the literature of the use of PBWR for patients with stroke,[9,11] spinal cord injuries,[13] knee osteoarthritis,[10] lower-extremity amputation,[1,8] and fracture.[2] The use of PBWR has also been recommended for patients with low back pain in previous case reports.[6,11] When new interventions are developed, thoughtful practitioners will begin to look for evidence to support their effectiveness. One of the first steps in developing an evidence base for a new intervention is the publication of case reports or case series describing the implementation of the new intervention. These publications often serve as the impetus for subsequent experimental investigations. The importance of well conducted case studies is frequently underappreciated, and Joffe and colleagues are to be commended for contributing to the literature in this way.

One valuable aspect of case series for new intervention techniques is the description of the technique itself. With respect to PBWR, the questions that exist typically involve how much weight reduction should be used, and the pace and duration of ambulation. Although Joffe et al recommend beginning with 85% to 95% reduction in trunk weight, it appears the authors actually do what most therapists do when using PBWR—use adequate weight reduction to produce the desired decrease in symptoms, then reduce the weight gradually over subsequent treatments until the patient can ambulate symptom-free without PBWR. It has been our experience that most patients treated with PBWR for low back pain require between 20% and 40% reduction in body weight initially to achieve adequate symptom relief, and when PBWR exceeds about 60%, ambulation can become difficult because of the excessive reduction in weight bearing. From the figures in this article, the 6 patients had initial body weight reductions ranging between 39% and 67%. Flynn et al,[5] in a study of healthy men, reported that a 20% reduction in body weight provided an average reduction in peak vertical ground reaction forces of about 23%. It is currently unknown how much reduction in ground reaction force is helpful for patients with low back pain, and the amount certainly will vary among individual patients. The best method for determining the initial amount of weight reduction may require further investigation.

Overall, the results for the 6 patients described by Joffe et al are generally positive. The charts provide an excellent visual representation of the progress of the individual patients with respect to pain and disability (Roland-Morris) scores. These are two very relevant outcome measures. As pointed out by the authors, the charts tend to indicate improvements during the PBWR phase that exceed those achieved during the initial exercise phase; however, no distinction can be made between the natural history of low back pain recovery and an actual treatment effect from the PBWR given the study's design. Future research will need to use control groups who do not receive PBWR to determine the true usefulness of this treatment beyond standard exercise therapy. In addition, future studies will need to compare patients with low back pain who receive treadmill training without PBWR to those receiving PBWR. It is possible that the benefit of PBWR observed by the authors is strictly due to the ambulation itself, irrespective of any body weight reduction. Though current clinical practice guidelines[3] advocate the use of low-stress aerobic activity such as treadmill walking, the question remains whether or not PBWR offers an improvement beyond simple treadmill walking.

One temptation that exists when a new intervention technique is described is to adopt it as a panacea for all patients of a particular type. This may be particularly enticing in the treatment of patients with low back pain since few interventions have been shown to work consistently, and methods for subgrouping patients are not well defined. No reflective practitioner, and certainly not the authors of this article, would advocate the use of PBWR for all patients with low back pain. When considering a new intervention such as PBWR, we must ask the question that underlies the concept of clinical classification: ''What characterizes the patients who really stand to benefit from this particular intervention?''

Joffe et al begin to implicitly answer this question through the establishment of their inclusion criteria for this study. The authors included patients between the ages of 18 and 65 years with symptoms of low back and leg pain. The duration of symptoms had to be between 1 and 6 months. Although the authors do not offer a specific rationale for these criteria, it appears that they believe PBWR to be most beneficial when lower-extremity symptoms are present. The authors did not require patients to have self-reported difficulties with walking in order to participate in the study. According to the data in the table, the 3 patients who did have problems with ambulation (patients 1, 2, and 6) experienced the largest decreases in disability scores (15, 17, and 14 points, respectively). These 3 patients also happened to be the oldest patients in the study. In our previous work, we have described PWBR as an intervention particularly useful for patients fitting into a flexion classification.[6] Patients placed into a flexion classification are characterized by a preference for flexed postures (eg, sitting) versus extended postures (eg, standing or walking).[4] These patients are typically older, usually report limitations in walking tolerance and often have degenerative, stenotic findings on imaging studies.[7] The results reported by Joffe et al appear to support the hypothesis that the patients most likely to benefit from PBWR are older individuals with self-reported limitations in walking and a preference for sitting. Further work is required to determine with certainty which patients will receive the greatest benefit from PBWR. The results reported by Joffe et al indicate that this is a line of research that is worth pursuing.

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