EVIDENCE-BASED REVIEW OF THE EFFICACY OF FUNCTIONAL
RESTORATION FOR THE MANAGEMENT OF CHRONIC LOW BACK PAIN

Robert J. Gatchel, Ph.D., ABPP and Tom G. Mayer, M.D.

The writing of this manuscript was supported in part by grant numbers 1K05 MH071892 and 3R01 MH 045462 from the National Institutes of Health, and DAMD 17-03-1-0055 from the Department of Defense
ABSTRACT

Background Context. There are now almost 20 years of evidence-based clinical outcome data, from the United States as well as from other countries around the world, demonstrating the therapeutic effectiveness of functional restoration, a specific form of interdisciplinary rehabilitation, in successfully managing chronic low back pain (CLBP) and disability.

Purpose. This article comprehensively reviews all the available evidence evaluating the therapeutic effectiveness of functional restoration for CLBP.

Study Design. Searches of the CLBP and functional restoration literature during the past 20 years were conducted, using MEDLINE, PSYCHLIT and the Cochrane Database of Systematic Reviews.

Patient Sample. All studies evaluating CLBP patients who were administered functional restoration were included in this review.

Outcome Measures. Studies reporting treatment-outcome data for variables such as self-reported pain and disability, functional measures such as strength and range-of-motion, medication use, and socioeconomic outcomes such as work return/retention, health care utilization, insurance claim resolution, and recurrent injuries were used in this review.

Results. The scientific literature is quite clear in demonstrating the therapeutic effectiveness of functional restoration for the management of CLBP, not only for traditional measures of self-reported pain and disability, but also for important socioeconomic-outcome variables.

Conclusions. The significant advantage of functional restoration relative to traditional unimodal methods of treating CLBP is that it simultaneously addresses, and has a positive impact on, multiple outcome measures: traditional self-report indices of pain and disability; more objective
physical functional measures; and important socioeconomic outcomes that often “drive up” the societal economic costs of this prevalent chronic pain disorder.

**KEY WORDS:** Functional restoration, chronic pain, disability, workers’ compensation, chronic low back pain, chronic spinal disorders, return to work, health utilization, recurrent injury, biopsychosocial approach, chronic pain/disability management
At the outset, it should be noted that functional restoration first developed by Mayer and Gatchel, refers not only to a treatment methodology for chronic low back pain (CLBP), but also to a wider conceptualization of the entire problem, its diagnoses, and its management. Rather than accepting traditional limitations of history-taking based solely through patients’ self-report of pain, and of diagnosis through musculoskeletal imaging technology, this approach involves even more objective information. Structured interviews and quantified self-report measures provide information for patient management issues. Most importantly, though, objective assessment of physical capacity and effort, with comparison to a normative data base, adds a new dimension to diagnosis. In keeping with a sports medicine approach, this allows the development of treatment programs of varied intensity and duration, individually tailored for each patient, aimed primarily at restoring physical functional capacity and psychosocial performance. Objectives are more ambitious than merely attempting to alter pain complaints and to decrease medications. The main focus is on restoring function and activities of daily living, as well as return-to-work, decreasing health utilization, and resolving financial disputes.

The major treatment components of functional restoration are listed below:

- Formal, repeated quantification of physical deficits to guide, individualize, and monitor physical training progress.
- Psychosocial and socioeconomic assessment to guide, individualize, and monitor pain, disability, behavioral responses and outcomes.
- A multimodal disability management model using cognitive-behavioral therapy approaches.
- Psychopharmacological interventions for any required narcotic and psychotropic management.
• Formal outcome assessment using standardized outcome criteria.

• Interdisciplinary, medically directed team approach with formal staffings and frequent conferences.

In terms of the interdisciplinary-team approach required for functional restoration, it is based on the biopsychosocial approach which views pain and disability as a complex and dynamic interaction among physiologic, psychologic and social factors that perpetuate, and may even worsen, the clinical presentation (e.g.\(^2,3\)). This explains the frequent differences among CLBP patients in terms of symptomatology and response to treatment. The major health care providers required for an effective functional restoration program are listed below. These have been presented in a number of previous publications (e.g., \(^1,4-8\)).

• A physician serves as the medical director or supervising doctor of the treatment program. The physician must have a complete understanding of the biopsychosocial philosophy of multidisciplinary care, and a firm background in providing medical rehabilitation for the various types of pain disorders frequently encountered in such treatment facilities. Most comprehensive multidisciplinary pain management programs provide interventional services, involving injections, stimulators and other medical procedures.

• A nurse is often required to assist the physician, follow-up the procedures, and serve as a physician-extender and impact to address patient needs. Another role is as the medical representative to the treatment team on a daily basis.

• The psychologist plays the leading role in the day-to-day maintenance of the psychosocial aspects and status of patient care. It is well known that significant psychosocial barriers to successful recovery may develop as a patient progress from acute to more chronic
stages of a pain syndrome. Therefore, comprehensive psychological evaluations are required to identify potential barriers to recovery, as well as a patient’s psychosocial strengths and weaknesses. A cognitive–behavioral treatment (CBT) approach can then be used to address important issues, such as pain-related depression, anxiety, substance dependence and other forms of psychopathology. A CBT approach has been found to be the most appropriate and effective modality to use in multidisciplinary programs.\textsuperscript{9,10}

- A physical therapist is required to interact with patients on a daily basis regarding any issues related to physical deconditioning, and the reconditioning progression toward recovery. This therapist and the exercise physiologists and technicians working alongside, plays an important role in educating the patient about the physiological bases of pain, and teaching methods of reducing the severity of pain episodes through the use of appropriate body mechanics and exercise pacing. Effective communication with other team members is crucial so that patients’ fear avoidance of exercise will not interfere with their physical reconditioning. Periodic Functional Capacity Evaluations (FCEs) monitor progress and guide training.

- An occupational therapist is involved in both the physical and vocational aspects of the patient’s rehabilitation. Most patients participating in a multidisciplinary pain treatment program are most likely not to be working at all, or be limited in their work capacity, because of their pain. Frequently, they have become pessimistic about the prospect of returning to work or other activities of daily living. The occupational therapist addresses such vocational concerns, as well as serving as an advocate for the patient with insurance issues, employer contact and, if needed, vocational retraining.
A case manager, usually a licensed professional counselor (LPC) is another important team member. While the occupational therapists, in their attention to improving whole-person functional capacity, pay close attention to the relationship between physical performance and work physical demand levels (PDLs), the case managers are involved in the psychosocial aspects of work reintegration. Essentially, the case managers team up with the psychologists to deal with the psychosocial barriers to recovery, while the physical and occupational therapists team up to deal with the physical barriers.

Specifically, the case managers deal with special rules of the work comp jurisdiction (or other type of compensation injury) issues that affect both financial and medical benefits. They may also interact with attorneys, insurance nurse case managers, adjusters, administrators from the work comp jurisdiction, or the relevant vocational rehabilitation agency to help achieve the specific socioeconomic outcomes goals set through discussion between the patient and case manager.

For a functional restoration program to be maximally effective, all of the above treatment component team members need to be working collaboratively on a daily basis. As will be discussed next, removing one component from the program will seriously jeopardize successful treatment outcomes.

**EVIDENCE OF TREATMENT EFFECTIVENESS**

As recently reviewed by Gatchel and Okifuji, initial clinical research conducted by Mayer, Gatchel and colleagues clearly demonstrated that functional restoration, when fully implemented, is associated with substantive improvement in various important socioeconomic outcome measures (e.g., return to work and resolution of outstanding legal and medical issues) in chronically disabled patients with spinal disorders in both 1-year follow-up studies, as well
as a 2-year follow-up study.\textsuperscript{14} For example, in the 2-year follow-up study by Mayer et al.,\textsuperscript{14} 87% of the functional-restoration-treatment group was actively working at 2 years, compared to only 41% of a nontreatment comparison group. Although a randomized control trial (RCT) would have been more desirable, a replication RCT funded by a large insurance carrier was prevented by \textit{denial of care} legal issues of concern at the time. Nonetheless, because the comparison group was based on standard behaviors of certain insurance carriers denying chronic pain/disability treatment for patients, neither the health providers nor the patients controlled the allocation into the treatment or comparison groups. Since the insurance carrier was blinded to the study, the relatively low potential bias made this a high-quality chronological series of prospective cohort studies.\textsuperscript{13-15} Results also clearly revealed that approximately twice as many of the comparison group of participants had both additional spine surgery and unsettled workers' compensation litigation relative to the treatment group. The comparison group continued with approximately a five-times-higher rate of patient visits to healthcare professionals and had higher rates of recurrence or re-injury. Thus, the results demonstrate the striking effect of a functional restoration program on these important outcome measures in a chronic group consisting primarily of workers' compensation cases (traditionally the most difficult cases to treat successfully).

The effectiveness of this original functional restoration program has been independently replicated by Hazard et al.\textsuperscript{11} and Patrick, Ahmaier, and Found\textsuperscript{16} in the United States. Randomized controlled trials demonstrating positive outcomes include: Bendix et al.\textsuperscript{17} and Bendix and Bendix\textsuperscript{18} in Denmark; Hildebrandt, Pfingsten, Saur, and Jansen\textsuperscript{19} in Germany; Corey, Koepfler, Etlin, and Day\textsuperscript{20} in Canada; Jousset et al.\textsuperscript{21} in France; and Shirado, Ito, Kikumoto et al.\textsuperscript{22} in Japan. Other interdisciplinary programs comparable to functional
restoration have also shown positive outcomes (e.g.,23,24). The fact that different clinical treatment teams, functioning in different states and different countries, with markedly different economic and social conditions and workers' compensation systems, produced comparable positive outcome results speaks highly for the robustness of the research findings and utility, as well as the fidelity, of this approach to pain management in occupational settings. This functional restoration approach has also been found to be effective with chronic upper extremity disorders.25 In addition, this type of approach has been shown to be an effective early intervention treatment for preventing chronic disability. For example, in a randomized controlled study, acute low-back-pain patients who were identified as “high risk” for developing chronic back pain disability were randomly assigned to an early functional restoration group or a treatment-as-usual group.26 The functional restoration group displayed significantly fewer indexes of chronic pain disability at one-year follow-up on a wide range of work, healthcare utilization, medication use, and self-reported pain variables. The functional restoration group was less likely to be taking narcotic analgesics (odds ratio = 0.44), and also less likely to be taking psychotropic medications (odds ratio = 0.24). Moreover, the treatment-as-usual group was less likely to have returned to work (odds ratio = 0.55). The cost-comparison savings data from this study were also quite impressive: The treatment-as-usual group cost twice as much as the functional restoration group over a 1-year period. The concept of early intervention was further supported in a prospective cohort study comparing early to late intervention, with allocation based on treatment decisions made prior to referral to the providers in the functional restoration program.27 Patients who demonstrated at least 4 months of chronic pain/disability, but no more than 8 months, had significantly improved socioeconomic outcomes of those disabled 18 months
or longer. Yet, even after 5 years of disability, acceptable objective outcomes were demonstrated in this study.

As further support, in a systematic review of such programs for CLBP, Guzman and colleagues \(^{28}\) found strong evidence that intensive multidisciplinary rehabilitation with functional restoration reduces pain and improves function in CLBP patients significantly more than less intensive programs or usual care. In addition, van Tulder, Koes and Bombardier \(^{29}\) found “strong evidence” for such functional restoration programs, using the Cochrane Collaboration’s high methodology and analysis standards. Long-term effectiveness (up to five years) of such multidisciplinary back programs has also been documented in a systematic review. \(^{30}\) Finally, in a relatively recent review in *The New England Journal of Medicine*, Carragee \(^{31}\) concluded that such an approach that focuses on functional outcomes produces the best outcomes for persistent low back pain.

**CLINICAL TREATMENT ISSUES**

**Costs**

Although multidisciplinary pain management programs, such as functional restoration, have been shown both to be more therapeutically and cost-effective treatment approaches to chronic pain management than traditional unimodal methods, there has been some resistance by third party payors to authorize such programs, usually because of the stated reason that they are “too costly” \(^{5,9}\). However, in many cases, the payors are actually responding to concerns about the outcomes produced by programs attempting to replicate outcomes in the scientific literature. While the principle of functional restoration may be accepted by many payors, the quality of the implementation is at least as much of a factor in resistance as is the cost. Because such programs involve multiple professionals in a time-intensive manner, the initial cost for such an approach
may be higher than that for the conventional medical management approach. Recent evidence has shown cost-effectiveness for chronic pain management programs in comparison to other invasive or medication interventions.\textsuperscript{32} Despite this medical evidence, some resistance among payors persists.

Instead of authorizing full multidisciplinary pain management programs such as functional restoration, some managed care organizations (MCOs) have been “carving out” portions of comprehensive, integrated programs (i.e., sending patients to different providers for their various needs outside of the comprehensive pain management programs), thus diluting the proven successful outcomes of such integrated programs in an effort to cut costs \textsuperscript{9,33-36}. The MCOs may lose sight of the fact that, in the long run, multidisciplinary programs that help chronic pain patients to resume productive lives produce much greater long-term cost-effectiveness in terms of future healthcare, tax, legal, and general economic factors. Gatchel and colleagues have conducted a number of empirical studies that clearly demonstrated how treatment component “carve-outs” significantly compromised the effectiveness of interdisciplinary pain management programs \textsuperscript{33,36}. For example, the study by Robbins et al \textsuperscript{36} revealed that “carving out” physical therapy services had a negative impact on both the short-term and one-year follow-up outcome measures in a heterogeneous sample of chronic pain patients undergoing a multidisciplinary pain management program. This was true for measures of both physical and psychosocial functioning: the SF-36, the Oswestry Pain Disability Questionnaire, and the Beck Depression Inventory. Significant differences in vocational status were also found between the two groups. The full interdisciplinary treatment group showed the anticipated decrease in the percentage of patients who were not working because of their original injury, and these gains were maintained at one-year follow-up. In striking contrast, the “carve...
out” group did not show significant changes at either immediate post-treatment or one-year follow-up. Thus, taken as a whole, these data clearly demonstrate that the “carve out” patients did not achieve the same level of therapeutic benefits, relative to the multidisciplinary pain management patients who received all of their treatment in the same clinic. With the growing number of insurance carriers considering treatment “carve outs,” these data again are especially important to consider because of their significant compromising of patients’ long-term improvement and vocational status.

Indications

Functional restoration is an appropriate tertiary care option for those CLBP patients who:

- have failed to respond to secondary care programs such as reactivation and work-hardening;
- have not improved after surgical or other interventional methods;
- have no acute, objective pathophysiology requiring immediate stabilization.

Complications

There are no undue complications, such as re-injury, because functional restoration is carefully monitored, quantitatively-directed through repeated physical measures, and directed by a physician and a multidisciplinary team of health care professionals who meet on a regular basis to discuss patient issues/problems. Often, there are certain barriers to recovery, such as secondary gain associated with perceived financial incentives for remaining disability, medication dependency, or work adjustment issues. However, even these secondary gain issues can be successfully dealt with in a comprehensive functional restoration program.37.

Contraindications
The only potential major contraindication to consider is a language barrier arising from the requisite ability to read and comprehend the important educational material presented to patients. Many functional restoration programs, though, such as that of the Productive Rehabilitation Institute of Dallas for Ergonomics (PRIDE), have a number of bilingual therapists who make it possible to treat both English- and Spanish-speaking patients. Translation for other ethnic groups may be available through the state vocational rehabilitation agency, or through community resources.

It should also be noted that chronic pain syndromes, such as CLBP, often are associated with significant comorbid psychiatric disorders. However, it has been empirically demonstrated that such concomitant psychopathology can be effectively be managed within the context of a functional restoration program (e.g. 38-41).

The Ideal Patient

The ideal patient for functional restoration, similar to that for any other comprehensive pain management program, is one who is motivated to learn to manage pain more effectively and who is compliant with the rehabilitation regimen.

**Level of Evidence:** Level I

**SUMMARY AND CONCLUSIONS**

The scientific literature clearly demonstrates the therapeutic effectiveness of functional restoration, an interdisciplinary, medically-supervised rehabilitation approach for CLBP patients. The fact that it has been successfully implemented in different states of the U.S., as well as different countries around the world, with different workers’ compensation and socioeconomic systems, speaks highly for its generalizability and robustness. A significant advantage of functional restoration, relative to traditional unimodal medical intervention methods, is that it
simultaneously addresses and has a positive impact on multiple outcome measures: traditional self-report indices of pain and disability; more objective physical functional measures; and important socioeconomic outcomes such as return-to-work. The major deterrent to the wider use of this effective evidence-based approach is the reluctance of third-party payers to authorize its use because of perceived high cost factors, as well as inconsistency of program outcomes for those providing such treatment. In the absence of mandated quality outcome monitoring, the unfortunate economic fact is that low-quality programs producing poor outcomes may earn higher profits because of the coding used to pay for the treatment, and the limited staff, equipment and other resources such programs commit to their patients. Ultimately, the only solution to this enigma will be the standardization of such programs, mandated outcome monitoring, and a regulator oversight mechanism. In the meantime, individual programs that have demonstrated treatment efficacy, are likely to be favored for referral and reimbursement over those that have not. At the time of this writing, workers' compensation systems are being reformed through implementation of healthcare networks and treatment guidelines. These techniques allow payors and administrators to select (rather than deselecting) quality providers, and apply evidence-based medicine (EBM) principles to many types of surgical and rehabilitation treatments for chronic spinal disorders. It remains to be seen whether the implementation of these symptoms will be exploited for short-term cost-cutting purposes, or whether long-term outcome quality will be the standard for treatment approval.
REFERENCES


