Pilot Study of Patient Response to Multiple Impulse Therapy for Musculoskeletal Complaints

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ABSTRACT

Objective: To investigate patient response to multiple impulse therapy provided by the PulStarFRAS (Sense Technology, Inc, Murrysville, Pa) for a variety of musculoskeletal symptoms encountered in clinical practice.

Methods: A retrospective analysis of patient files was used to determine symptomatic improvement over the course of treatment. The multiple impulse therapy was supplemented, at the discretion of the practitioner, with manual adjustments. The manual adjustments consisted of high-velocity low-amplitude and drop table, and represented fewer than 5% of the adjustments. Therapy was provided by a single practitioner in a private clinic setting.

Results: Patients expressed improvement in symptoms after the first visit (average improvement in subjective pain rating scale of 41%). Patient symptoms improved between the first and second visits for 70% of patients (average improvement in subjective pain scale for all patients was 58%). The majority of patients achieved complete resolution of symptoms between the third and fourth visits. Maximum benefit for patients across all symptoms required an average of 4.2 visits. The half-life for response to multiple impulse therapy for all symptoms was 17 to 26 days. The half-life for response to multiple impulse therapy using the PulStarFRAS for low back pain was 9 to 16 days.

Conclusion: The results of this study suggest the further study of multiple impulse therapy provided by the PulStarFRAS as a means of resolving musculoskeletal complaints. (J Manipulative Physiol Ther 2006;29:51.e1-51.e7)

Key Indexing Terms: Manipulation; Chiropractic; Treatment Outcome; Kaplan-Meier Analysis; Physical Therapy

There are many techniques of musculoskeletal therapy. Thirty techniques are currently taught in chiropractic colleges alone. More than 100 chiropractic techniques are used in the profession. However, little published data are available that document the effectiveness of a specific technique. There is some question that musculoskeletal therapeutic techniques are any more effective than exercise, educational programs, or simply the passage of time. There are some studies of the effectiveness of manual techniques for specific musculoskeletal symptoms such as low back pain, cervicogenic headache, and migraine. Despite these recent efforts, many questions remain unanswered. These include the following: (1) Are certain manual techniques more effective than others? (2) Are certain manual techniques more effective than others for specific categories of musculoskeletal complaints? (3) Given a specific musculoskeletal symptom, when in the course of treatment should the clinician and patient reasonably expect to achieve improvement?

The literature relating to these questions is sparse and complicated by the fact that chiropractors, physical therapists, and osteopaths use multiple techniques. These techniques are often lumped under one general category as if all techniques within a discipline were equivalent and that any combination of techniques were equivalent to any other combination of techniques selected by the practitioners involved in any particular study. This study also suffers in some respects from this same phenomenon. The clinician occasionally complemented, with purely manual adjustments, the multiple impulse therapy that is the subject of this study.

The primary purpose of this study was to analyze the effectiveness for the continuing development and improvement of the analysis and treatment protocols used with a particular instrument, the PulStarFRAS (Sense Technology, Inc, Murrysville, Pa).

The PulstarFRAS provides the clinician with an analysis of the stiffness of the patient’s musculoskeletal system and multiple impulse output of variable frequency that can be used to provide percussive therapy. The basic design of the
instrument and methodology for its use was first described by one of the authors (JME). The analysis function has been adapted to various chiropractic techniques including Upper Cervical, Diversified, Pierce, Pettibon, Gonsted, Logan, and Activator, among others. The technique used in this study consisted of a full spine analysis following a protocol developed by the second author (DLC), which is a refinement of the original protocol developed by the late Vernon Pierce, DC, who was instrumental in the development of the first generation of the PulStarFRAS.

**History of Multiple Impulse Therapy**

Instrumentation has been used to provide mechanical percussive therapy to the spine since the beginning of chiropractic. Early percussive techniques included single impulses delivered with a stick and mallet and cam or pneumatically operated single and multiple percussive devices.

Our experience with multiple impulse therapy began when JME invented an adjusting head designed to deliver a single mechanical impulse to the musculoskeletal system at the point and line of drive chosen by the clinician. A unique feature of this instrument was the incorporation of a preload control to initiate the impulse. In the late 1980s, Dr Vernon Pierce observed under an x-ray intensifier that the initial tissue compression resulting from the preload increased if a second impulse was delivered at the same location immediately after the first impulse. Tissue compression increased further but seemed to stabilize after the third impulse. This led to the 1991 development of a multiple impulse adjustor (Kinetic Technology Model SHCLP-4; Kinetic Technology, Inc, Murrysville, Pa) that provided 3 consecutive impulses when applied to the patient. Soon thereafter, Dr Pierce requested that the number of impulses be increased so that a continuous train of impulses could be applied to the patient. This feature was incorporated in the next model of the instrument. Clinicians observed that the sound of the impulses being applied with these instruments changed, often at the same time that the patient expressed relief. This suggested that the mechanical response of the musculoskeletal system was changing measurably during therapy.

Instrumentation to monitor the mechanical response of the point of contact during the application of multiple impulse therapy as a means of providing feedback to the clinician was added by incorporating a force transducer and computer display in 1994 in the force recording and analysis system and subsequent generations of the instrument known as the PulStarFRAS.

Users of these instruments anecdotally reported that they could more effectively provide relief to patients suffering from musculoskeletal complaints. However, until this study, no attempt has been made to document the results that are obtained with multiple impulse therapy or to compare these results with other means of treatment.

**Instrumentation**

The PulStarFRAS consists of 3 components that provide an analysis of musculoskeletal stiffness at each vertebral level and a multiple impulse treatment. For analysis of the patient, a handheld impulse head is pressed against the patient and provides a single low-energy impulse to the vertebral level of interest. A force sensor in the impulse head measures the resistance to the impulse, which is related to the compliance of the vertebra tested.

The second component, the impulse head control system, monitors the impulse head and provides the electrical impulses to the head to create the impulse, interpret the output of the head, and communicate the results of the analysis to the third component, a digital computer. The computer displays the compliance readings in a series of bar graphs.

During the treatment phase, these components supply multiple impulses to the areas selected by the clinician while measuring the musculoskeletal stiffness at each impulse. The changes in musculoskeletal stiffness that occur during treatment are displayed for the clinician and used to monitor the treatment.

This retrospective file review sets out to answer the following questions: (1) What is the patient response to multiple impulse therapy provided with the PulStarFRAS? (2) How does patient response to multiple impulse therapy provided with the PulStarFRAS compare to patient response when other methods or techniques of therapy are employed?

**Methods**

The files of patients who entered the clinic after May 2001 and had not previously been treated at the clinic were the data for the study. Clinic personnel, beginning with the file of the first patient admitted after the start date, flipped a coin to determine whether the file was to be included in the study. This randomization of selected files continued until 50 patient files were selected. Random patient file selection was used to ensure that selection did not depend on patient outcome, minimizing the chance that only “easy” cases were included in the study.

The output measure used in this study was the subjective rating of patients’ current level of pain compared to their pain on their first visit. On the first visit, the clinician informed each patient that his/her current level of pain should be considered to be a 10 on an 11-point scale from 10 to 0, 10 being their current level and 0 being a pain-free condition.

The pain relief scale used for this study has the advantage that 10 equal segments are used, allowing a change of as little as 10% to be recorded and that all patients start at the same level (1 end is normalized to the patient’s current pain level) and have the same perceptual distance to travel to a “pain-free” state. Patients were asked to rate their
current pain level compared to their initial pain level at the beginning of each subsequent visit. These subjective ratings were combined with the current visit number or the days from the initial visit to the current visit to generate a measure of rate of recovery for each patient. That is, a patient who rated pain at the beginning of the second visit as a 9 showed a 10% reduction in pain from the first visit. A patient who rated pain at the beginning of the second visit as a 1 showed a 90% reduction in pain from the first visit, and a patient who was pain free, a rating of 0, showed a 100% reduction in pain. Patient progress was followed only until (1) patient symptoms were resolved, (2) the patient was referred out, (3) or the patient voluntarily quit the program. Many patients (78%) continued treatment after their symptoms were resolved. This study, however, does not address the ongoing preventive stage of patient care.

The pain ratings obtained at each patient visit were used in 2 ways. First, the gradations in response, that is, the visit-to-visit ratings that could register changes in perceived pain of as little as 10%, were averaged at each visit. This was done to get a sense of the visit-to-visit response to the therapy. Second, the visit-to-visit changes were ignored and only the rating on the final visit was used. That is, only whether the patients were pain-free or still in pain on their final visit was noted. The final visit rating was used as input to a Kaplan-Meier survival analysis10,11 to determine the probability of pain during the course of therapy. The Kaplan-Meier survival analysis is designed to account for the ongoing preventive stage of patient care.

Before the treatment, the patients were asked to rate current pain on the same scale used at the first visit before any analysis or treatment by the clinician (often in concert with the patient) to confirm that the desired results have been achieved.

Each step in this process is conducted according to a basic clinical protocol developed by Collins.7 This protocol was supplemented with manual high-velocity low-amplitude and drop table adjustments at the discretion of Collins. It is estimated by Collins that these adjustments represented no more than 5% of the total adjustments.

**RESULTS**

**Summary Statistics**

Fifty patient files were included in the study. Of these patients, 23 were male ranging in age from 17 to 79 (mean, 44.6); 27 were female ranging in age from 12 to 78 (mean, 44.5); 26 complained of low back pain; 11 complained of neck pain; 6 complained of shoulder pain; 3 complained of headache; 2 complained of rib pain; 2 complained of leg pain below the knee; 8 patients identified the date of onset of symptoms as being less than 1 month before their first visit; these patients were considered to suffer from acute conditions. Fifteen patients identified the date of onset of symptoms as being greater than 1 month and less than 3 months; these patients were classified as subacute. Twenty-seven patients identified the date of onset of symptoms as being equal to or greater than 3 months; these patients were classified as chronic.

Before the treatment, the patients were told that their current state of pain should be considered a 10. Immediately after the first treatment with multiple impulse therapy, each patient was asked to rate pain on a scale of 0 to 10. All patients in the study reported a decrease in pain. The minimum decrease after 1 treatment was 20%, the maximum was 100%, and the average was 41%.

On the second and each succeeding visit, the patient was asked to rate current pain on the same scale used at the first visit before any analysis or treatment by the clinician. This reading, taken at the beginning of the patient visit, represents the cumulative effect of all prior patient visits and the process of self-healing over time. In particular, the pain scale reading taken at the beginning of the second visit represents the effect of the treatment provided by the patient on the first visit and the effects of the patient accommodating to the treatment over the time between the first and second visit. The minimum decrease was again 20% and the maximum decrease was 100%. The average decrease in the pain scale was 59% if 2 patients who rated their improvement as 100% after the first visit but did not show up for the second visit are included. Excluding those patients, the average decrease in the patients’ pain rating was 58% between the first and second visits.

Of the 50 patients included in the study, 78% stayed the course of therapy until they reached a pain-free state. The
The average number of visits for these patients before attaining that pain-free state was 3.0. Twenty-two percent of the patients elected to exit the treatment program before attaining a pain-free state. The average number of visits for this group before leaving the program was 4.1. The average pain reduction attained by this second group was 65% (minimum 40%, maximum 90%).

Analysis of the Influence of Patient and Symptom Characteristics on Rates of Recovery

Analysis of variance was used to examine possible interactions between patient characteristics such as age, sex, height, weight, ratio of height to weight, and the interaction between patient symptomatology (symptom, time between onset and patient visit, and classification of chronic, subacute, and acute). With the exception of age, no statistically significant results were found. There was a very small influence due to age (younger patients responded slightly more quickly to treatment than older patients), but this relationship was judged to have little clinical importance. There was also a suggestion that neck pain required a longer treatment period than low back pain, but the difference was not statistically significant.

Kaplan-Meier Analysis of Response Rates

Following the methodology of van den Hoogen et al, the results were plotted using a Kaplan-Meier procedure (Fig 1). Two estimates of response rate were used since the pain ratings were obtained before each visit. Each patient’s pain rating was reached sometime immediately after the last visit and before the current visit. Therefore, 1 Kaplan-Meier curve was generated using the last visit and a second Kaplan-Meier curve was generated using the next to last visit. These 2 estimates of the rate of patient response form an upper and lower bound on the response rates. The Kaplan-Meier method was then extended in the following manner. The results of the Kaplan-Meier plot were fitted to a logarithmic function using nonlinear regression. The Kaplan-Meier results and the fitted curves for all symptoms are shown in Fig 1. The Kaplan-Meier results and the fitted curves for low back pain are shown in Fig 2. The fitted curves are of the form:

\[ P = Ce^{-kt} + b \]

where \( P \) equals the probability of pain; \( C \) is a constant (in our case, \( C=1 \) as the value of the function \( P \) equals 1 at time 0); \( e \) equals the base of natural logarithms (approximately 2.71828); \( k \) is a constant (\( 1/k \) is referred to as the time constant); \( t \) is time (in our case expressed as days); and \( b \) is a constant (in our case, \( b=0 \) as the exponential function is asymptotic to the x axis).

Knowledge of the constants \( C \) and \( k \) allows the time to 50% response (or half-life) to be calculated. Half of the patients will be symptom free in this amount of time.

The half-life for the lower bound of multiple impulse therapy for all symptoms is 17 days. The half-life for the upper bound for all symptoms is 26 days. This means that half the patients have had their symptoms completely resolved somewhere between day 17 and day 26. For low back pain, the half-life is between 9 and 16 days. This extension of the Kaplan-Meier methodology enables a comparison of the results using only 1 figure of merit, the half-life of the patient response to therapy. The spread between the upper and lower bounds of the half-life is a function of the distribution of intervals between successive visits, which was not controlled.
DISCUSSION

The results of this study suggest that multiple impulse therapy delivered with the PulStarFRAS provided effective treatment for the 2 major conditions observed in this specific patient population: low back pain and neck pain. Follow-up of the patients who “dropped out” of the treatment program revealed that 4 of the dropouts did so because their pain level approached 0 after their last visit. Of the remainder, 3 stopped coming because they felt that the treatment did not help, 3 moved and could not be contacted, and 1 was referred out.

The patients in the study reported perceiving an immediate positive benefit after the first visit across all symptoms and that benefit increased (on average) between the first and second visit without additional treatment. A small number of visits were required to achieve maximum benefit across all symptoms. The average number of visits required to achieve 100% relief for those patients who continued therapy until they achieved a pain-free state was 3. When all patients in this group are included in the calculation, the average number of visits required to reach “maximum benefit” increased to 4.2. Maximum benefit was defined as the subjective ranking of pain made by each patient on his or her last visit. These results compare favorably with Cox flexion distraction (19 visits and 43 days to maximum benefit) and diversified (50% of patients reported that they had “improved” at the fourth visit and within 2 weeks).4,13

Figs 3 and 4 compare the rate of patient response to physical therapy, osteopathic manipulation, and multiple impulse therapy performed with the PulStarFRAS. Physical therapy is defined in van den Hoogen et al as heat, cold, and massage, and advice on daily behavior.” As can be seen, the Kaplan-Meier analyses of the results obtained with the PulStarFRAS compare favorably to osteopathic manipulation and physical therapy for the patient complaint of low back pain.10,14 It should be noted that the Kaplan-Meier results of van den Hoogen et al12 were based on data obtained through the use of patient questionnaires and not through a face to face encounter. It is hypothesized that the responses might reflect a better outcome if the data were obtained directly by the clinician as the patient might wish to please the clinician (van den Hoogen, personal communication).

Comparison of these results to recent studies where the results are presented as a graph of 3 points is problematic. However, such a comparison using the simple exponential model as an approximation has been attempted by Evans.15

As this was a pragmatic retrospective study, the number of days between treatments was not controlled as part of the research design. Because the time between visits was not controlled, these results are likely to mirror common clinical practice more closely than results obtained in studies that control visit frequency. In this study, the clinician determined the time between patient visits on the basis of the apparent severity of the patient’s complaint and on the capacity of the clinic. Following common practice, the patient is referred to the appointment desk for assignment to an open treatment slot as close as possible to the time for the return visit specified by the clinician. It is possible, indeed likely, that the number of days between treatments affects the rate of response to the treatment. No investigation of the treatment of musculoskeletal complaints has identified an optimal treatment frequency or
suggested a procedure for developing a means of scheduling patients that will result in a maximum response to the treatment.

Rates of recovery were not found to be dependent on the length of time between the onset of the complaint and the first patient visit. Some studies find that chronic conditions respond more slowly to therapy than acute conditions. However, this finding is not universal. Again, the study of van den Hoogen et al may be helpful. Fig 5 is a plot of the results of that study showing the response rates of untreated patients with acute, subacute, and chronic low back pain. For comparison, the responses of patients treated with multiple impulse therapy are also shown. Examination of this graph reveals that the response rate of patients treated with multiple impulse therapy is greater than the response rates of patients in the van den Hoogen study. That is, even patients with acute symptoms respond more slowly than patients treated with multiple impulse therapy. One interpretation of this observation is that multiple impulse therapy provided with the PulStarFRAS overpowers the effects of condition (acute, subacute, chronic) because the response of patients is much faster than the “untreated” response.

These observations lead to the hypothesis that methods of musculoskeletal therapy that exceed the rate of the natural healing response of the musculoskeletal system will not show differences in patient response related to the duration of symptoms before treatment. Or the corollary hypothesis that methods of therapy that are associated with differences in the response rate due to the duration of symptoms before treatment are unlikely to have exceeded the natural response rate of the musculoskeletal system.

Limitations of the study include the following: the clinician supplemented the multiple impulse therapy with manual adjustments; the number of patients (50) included in the study was small; the study was conducted at a single clinic; only 1 clinician provided the treatment; and the study used a retrospective, nonexperimental design. Before these results may be extended to the general patient population, additional studies are required that include larger patient samples, multiple clinicians, and clinics, and improved research designs to include randomized controlled trials.

**CONCLUSION**

The results of this study support continued study of multiple impulse therapy provided by the PulStarFRAS as a means of treating musculoskeletal symptoms.

**REFERENCES**