

# **The Effects of a Tempur-Pedic Mattress on Reducing Insomnia in Patients with Fibromyalgia: An Exploratory Study**

## **Introduction**

Fibromyalgia is a chronic disorder syndrome characterized by musculoskeletal pain, fatigue, and multiple tender points (tenderness that occurs in precise, localized areas, particularly in the neck, spine, shoulders, and hips). People with fibromyalgia frequently experience anxiety, irritable bowel syndrome, sleep disturbances awakening with stiffness, and other symptoms.

Fibromyalgia affects 3 to 6 million Americans (American College of Rheumatology). It is most often observed in women of childbearing age, however men, children, and the elderly are not immune.

The management of fibromyalgia requires physicians, physical therapists, and the patient each to take an active role in treatment. A comprehensive holistic treatment regime which includes a combination of exercise, medication, and physical therapy has been shown the most effective approach. Aerobic exercise, such as swimming and walking, has been shown to improve muscle conditioning while reducing pain and tenderness. Antidepressant medications may be useful in elevating mood, helping relax muscles, and improving sleep quality. Heat and massage are also useful in obtaining short-term relief.

Insomnia is a frequent complaint of individuals with the syndrome. They report difficulty in falling asleep and when they do, sleep is often disturbed because of chronic pain. It is theorized that if this pain could be reduced, without the side-effects of heavy medication, these individuals could see improvement in sleep quality that might improve daily functioning. To this end, it was determined to evaluate a mattress shown to be effective in reducing the pain and discomfort associated with cancer and its treatment.

The Tempur-Pedic mattress was selected for review. The material this mattress is made of conforms to the body secondary to the forces of time, gravitational mass, and body temperature. Within a reasonably short time, the conformation results in an infinitely variable "body mold" that distributes pressure over a substantially greater surface area than would a traditional mattress, effectively reducing the pressure at any single point. Reported impact of using the Tempur-Pedic mattress includes: reducing or alleviating shoulder tension; arm pain; swollen feet and calves; circulatory problems resulting in pressure ulcers; back pain; aching knees; sciatica; and other maladies related to sleeping. Because of successes in treating an array of medical conditions, in addition to restoring and improving the overall quality of sleep, the Tempur-Pedic mattress may also be beneficial to patients with fibromyalgia.

## **Study Design**

Five subjects, each having been diagnosed with fibromyalgia, were provided a standard twin size Tempur-Pedic mattresses for a two-week evaluation period. Along with the mattress, a data collection instrument (Sleep Diary) was provided to collect demographic information and allow the communication of objective and subjective data on a daily basis. The objective questions

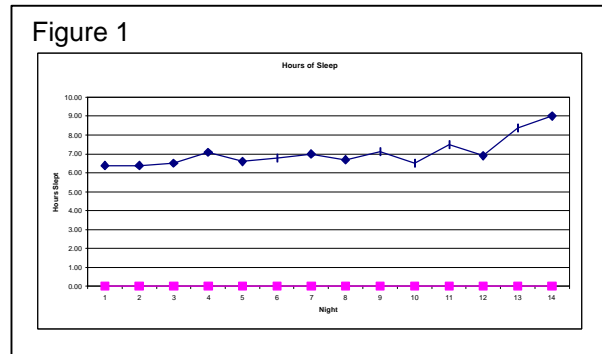
were intended to support a quantitative assessment of the number of hours slept, the incidents of sleep interruptions, whether or not pain was experienced while sleeping, and whether or not the subject awakened refreshed after an evening's sleep.

In addition to the quantitative data, each subject was provided space to record subjective information which was intended to support qualitative analysis.

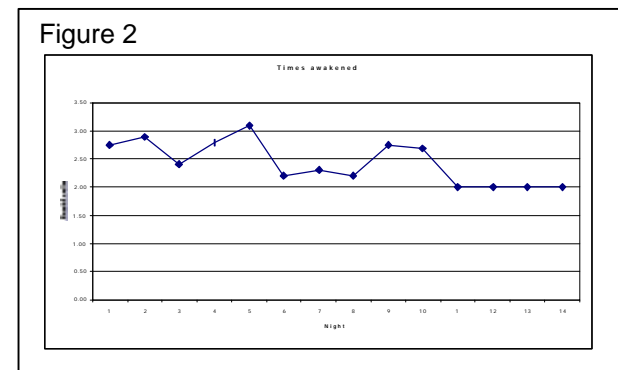
**Quantitative Analysis**

As this is a pilot study, a baseline on which comparison could be based was not available. Accordingly, any benefit observed in the initial nights' use is likely not reported. In determining a trend, the first nights' report was used as the baseline and the final nights' report was used in determining change, over time, secondary to the mattress variable.

The initial question sought to determine if using the Tempur-Pedic mattress had an impact on quantity of sleep as expressed in hours of sleep time per night. When comparing the differences over time, a 29% increase in the average sleep period was observed after using the Tempur-Med mattress for a 14 day period. The trend is illustrated in Figure 1

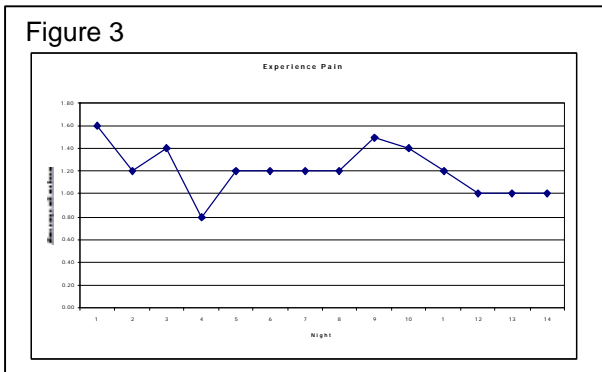


The second question sought to determine sleep quality based on how many times, on average, the subjects awakened at night for any reason. Again, if the initial night was considered as the baseline and the final night as the outcome value, a 38% decrease in the incidents of awakening was observed. Figure 2 shows the trend line.



This decrease may have been more pronounced. One of the subjects specifically mentioned that the awakening was because of the need to toilet. If the remarks about toileting were considered, and the incidence of awakening was not the result of pain or discomfort, the improvement would have been at a greater rate.

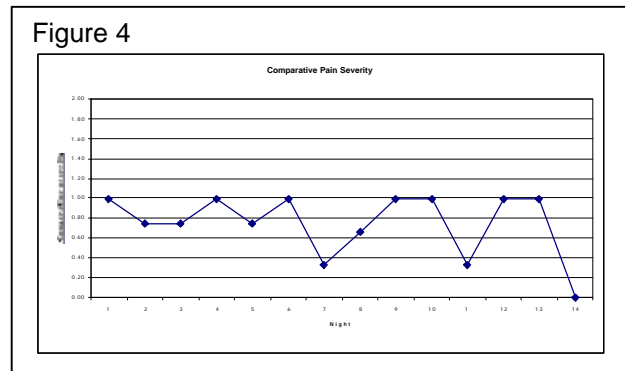
The third question sought to qualify the amount of pain experienced during sleep. As before, the first measurements and the final measurements are compared and shown in Figure 3. In this case, three variables were possible, No pain ("0"), Slight pain ("1"), Pain ("2"). Although pain is very subjective and thresholds may vary from day to day, based on these values, a 60% reduction in pain was reported by the subjects.



The subjects specifically reported day time activities, physical therapy, and stress as impacting their pain levels. It is likely that influences not mentioned by the subjects may also impact the presence and degree of pain experienced.

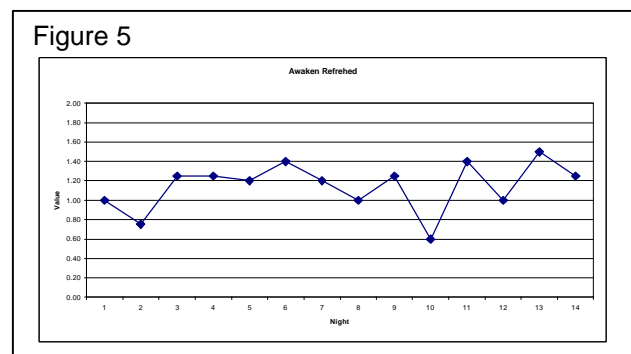
The trend line presents averages for all subjects evaluated. The trend was impacted as a result of one of the subjects not reporting pain information during the final two days of the evaluation. Pain reported by this subject was declining in the days preceding the omitted period. If the subject did not report pain because he felt it unnecessary to make a remark, and if this data were included in the average, the pain reduction reported for the final two reporting periods would have been greater.

The fourth question examined pain severity. Values of “0” for Less pain, “1” for Same / Similar pain, and “2” for More pain were assigned. On the initial night, three of the five subjects reported similar pain and one reported more pain resulting in a value of “5”. On the final night, each of the subjects reported less pain, or a value of “0”, representing a five-fold reduction in severity. The trend is shown in Figure 4.



In interpreting the trend, a value of “1” on the chart indicates comparable pain with the previous night. A score greater than “1” would indicate an increase in pain and any score less than “1” is indicative of reduction in pain over the previous night. While the trend indicates a general reduction of pain experienced, it is uncertain if the subjects actually made a comparison to the previous night, which would have a compounding effect, or simply used their recall of a “normal” night sleep in comparing historical pain, which would demonstrate a reduction in pain from the baseline. This finding has no corollary with any other objective finding, however the trend supports a belief that the subjects experienced less pain over the course of an evening sleep as result of mattress use.

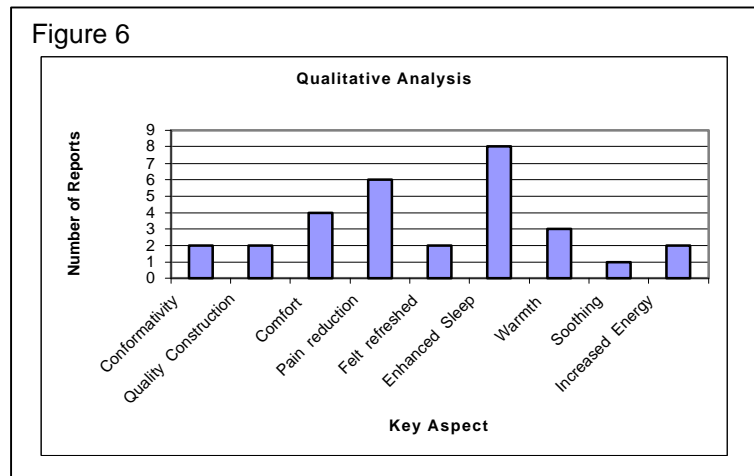
The fifth question attempted to determine the quality of sleep by asking if the subject felt “refreshed” upon awakening. A value of “0” indicated that the subject was not refreshed. “1” indicated the subject was somewhat refreshed, and a value of “2” was assigned if the subject stated they were refreshed. These values were tallied and an increase in sleep quality of 20% was observed between the initial night and the final night. Comments offered by many subjects suggested that variables not quantified impacted this question. For example, some subjects offered reasons for fatigue that could not be related to the mattress (eg. they got to bed late or had cause to arise earlier than normal). If these data were considered, the trend line might have been more informative.



## Qualitative analysis

The sixth question was purely subjective in asking the subject for observations. In presenting qualitative analysis of the data a subjective review of written comments was made. Key phrases and concepts were identified and a count of the number of times the comment was made was tallied. Each of the subjects had fifteen (15) potential opportunities to offer an opinion, once each evening and at the conclusion of the investigation period.

The comments offered were overwhelmingly positive. Only one subject offered what might be perceived as adverse input, which were multiple comments that his “arm went to sleep”. It is difficult to assess the significance of this observation, especially since the same individual offered a concluding statement, “While using the mattress, I found no negative areas.” From the data available, it is impossible to determine if the complaint was associated with or predated the use of the evaluated mattress.



Many comments were offered regarding increased comfort and improved quality of life. Each of the five subjects appeared to have a positive experience. Two of the subjects remarked about a feeling of “warmth” while laying on the mattress. It is unknown if this had any impact on overall satisfaction and/or comfort. As a measure of satisfaction, three of the five subjects asked questions (eg. price, materials, construction methods, etc.) that could reasonably be perceived as special interest in the mattress. This may be considered indicative of a significant degree of satisfaction.

## Conclusion

This pilot study cannot support claims of efficacy for any purpose. However, clear trends can be observed in both the quantitative and qualitative analyses. The averages indicate improvements in sleep quality, hours of sleep, and reduction in pain levels experienced while sleeping. The preponderance of comments offered by the subjects were indicative of enhanced quality of life.

Based on the findings, a recommendation can be offered in support of the need to conduct a comprehensive study investigating the issues associated with the impact of the Tempur-Pedic mattress on insomnia and quality of life in patients with Fibromyalgia.