0008-3194/97/16–26/$2.00/©JCCA 1997

Before-after study to determine the effectiveness of an adjustable wood frame-foam and wool mattress bed-system (The Natura Mattress System) in reducing chronic back pain in adults

Carol Hagino, BSc, MBA
Parham Erfanian, DC

Objective and Design: *The purpose of this 6-week Before-After trial was to investigate the effectiveness of the Natura Mattress System in reducing back pain by ≥ 1 unit on the 11-Point Pain Severity Scale ($p \leq 0.05$), in chronic low back pain sufferers.*

Subject Profile: *The subjects were adults recruited from within and outside the Canadian Memorial Chiropractic College (CMCC) Outpatient Clinic, with chronic low back pain (LBP) of ≥ 2 months duration at the time of entering the study.*

Sample Size: *15 subjects were targeted to complete the study.*

Outcome Measures: *The primary outcome measure consisted of: morning severity of pain as measured by an 11-point ordinal pain scale (Numeric Rating Scale or NRS). Secondary outcome measures consisted of: (1) daily quality of sleep as measured by a 4-point ordinal scale; (2) effect on daily activity as measured by a 4-point ordinal scale; and (3) daily quantity of analgesics. These outcomes were collected via a daily diary-type of questionnaire.*

Statistical Analysis: *Baseline to 4-week post treatment-commencement differences were analyzed for statistical significance using Repeated Measures ANOVA, at the 0.05 level of significance. In addition, all outcome measures were graphed and examined descriptively for any clinically important changes across the 6 week time-frame of the study.*

Methods Protocol: *Eligible subjects who read and signed the written informed consent form, were given a package containing a copy of the written informed consent form, and upon completing the 2 week baseline*

Objectifs et méthodologies : *le but de cet étude avant-après d'une durée de 6 semaines était de vérifier l'efficacité du système de matelas Natura dans la réduction des maux de dos atteignant 1 point ou plus sur l'échelle de 11 points de gravité de la douleur ($p \leq 0,05$), chez les personnes souffrant de lombalgie chronique.*

Profil des sujets : *les sujets étaient des adultes recrutés à l'intérieur et à l'extérieur de la clinique de consultation externe du Canadian Memorial Chiropractic College (CMCC), souffrant de lombalgie chronique depuis 2 mois ou plus au moment de leur inscription à l'étude.*

Mesures des résultats : *la mesure principale du résultat était la suivante : la gravité de la douleur matinale mesurée par une échelle ordinale de douleur de 11 points (échelle d'évaluation numérique). Les mesures secondaires des résultats comprenaient : (1) la qualité quotidienne du sommeil mesurée par une échelle ordinale de 4 points ; (2) l'effet sur l'activité quotidienne mesuré par une échelle ordinale de 4 points ; et la quantité quotidienne d'analgésiques. Ces résultats ont été recueillis tous les jours sur un agenda-questionnaire.*

Analyse statistique : *les différences entre les données d'origine et les données obtenues 4 semaines après le début du traitement, ont été analysées afin de déterminer une signification statistique grâce à l'analyse de la variance par mesures répétées, à un niveau de signification de 0,05. En outre, toutes les mesures des résultats ont été transposées sur des graphiques et examinées de façon descriptive pour déceler tout changement clinique important sur les six semaines de l'étude.*

Contact: Carol Hagino, BSc, MBA, Canadian Memorial Chiropractic College, Division of Research, 1900 Bayview Avenue, Toronto, Ontario, Canada M4G 3E5. (416) 482-2340 ext 178.

daily diary questionnaires, were contacted by the bed manufacturer, who arranged with the subject a date and time of mutual convenience to deliver the bed (twin or queen size). The subject was then required to complete 4 more weeks of diary questionnaires. Thank-you cards were sent to each subject who completed the study.

Results: *The sample consisted of 6 caucasian females and 7 caucasian males, between the ages of 22 and 75 years, with an average(sd) age of 37.0 (18.44) years. Five subjects were adult students, 5 had sedentary occupations, while 3 had relatively physical occupations. Baseline low back pain (LBP) severities of the sample ranged from 2 to 8 on the 11 point pain scale (NRS), with an average(sd) level of 3.0 (1.75). Average duration of the subjects' chronic LBP state was 5.6 years, ranging from 3 months to 30 years. Only 2 subjects were taking LBP medications at the start of the study.*

Conclusion: *For a generally well educated, young (20–40 years of age), caucasian population with mild-moderate chronic LBP, use of the Natura Bed can be expected to result in a clinically important reduction in pain severity upon both waking and at the end of the day, of at least 1 point (on the NRS) over a 4 week period ($p \leq 0.05$).*

Further research is recommended which utilizes the Randomized Clinical Trial (RCT) design to investigate the performance of the Natura Bed compared to other beds on the market, and assesses patient characteristics predicting suitability for the Natura Bed.
(JCCA 1997; 41(1):16–26)

KEY WORDS: sleep, bed, foam mattress, back pain, clinical trial.

Protocole des méthodes : *les sujets admissibles qui ont lu et signé la formule de consentement éclairée, ont reçu un paquet contenant une copie de la formule de consentement éclairé. Après avoir complété les questionnaires pendant les deux premières semaines, ils ont été contacté par le fabricant de lit qui a fixé avec eux une date et une heure de livraison (lit à une place ou grand lit à deux places). Le sujet a ensuite continué à remplir les questionnaires quotidiens pendant quatre semaines supplémentaires. Des cartes de remerciements ont été envoyées à toutes les personnes qui ont pris parf à l'étude.*

Résultats : *l'échantillon était composé de 6 femmes et 7 hommes de race blanche, âgés de 22 à 75 ans, avec un âge moyen de 37 (18,44) ans.*

Cinq sujets étaient des étudiants adultes, 5 avaient des occupations sédentaires, tandis que 3 avaient relativement peu d'activités physiques.

Les données de départ sur la gravité de la lombalgie variaient de 2 à 8 sur une échelle de douleur de 11 points avec un niveau moyen de 3 (1,75). La durée moyenne de la lombalgie chronique était de 5,6 ans, allant de 3 mois à 30 ans. Deux sujets uniquement prenaient des médicaments contre la lombalgie chronique au début de l'étude.

Conclusion : *pour une population jeune (20 à 40 ans), de race blanche, globalement bien instruite, souffrant de lombalgie chronique légère à modérée, l'utilisation du lit Natura se traduit par une réduction importante, sur la plan clinique, de la gravité de la douleur, au réveil et à la fin de la journée, d'au moins 1 point (sur l'échelle d'évaluation numérique), sur une période de 4 semaines ($p \leq 0,05$).*

On recommande d'approfondir les recherches utilisant le modèle d'essai clinique aléatoire pour comparer la performance du lit Natura à celle des autres marques disponibles sur le marché. On conseille également d'évaluer les caractéristiques du patient qui permettent de prédire que ce dernier bénéficiera de l'utilisation d'un lit Natura.
(JCCA 1997; 41(1):16–26)

MOTS CLÉS : sommeil, lit, matelas en mousse, maux de dos, essai clinique.

Introduction

The potentially therapeutic role of "the bed" in the management of back pain is generally acknowledged by most health care practitioners; in fact, bed rest still is a central component of conservative management of back pain in mainstream medicine.[1] It is well known too, that sleep deprivation, whether due to pain and discomfort while lying in bed, or other reasons, results in a lack of productivity and other disorders.[6–11] It is important, therefore, that back pain management strategies give due consideration to the patient's bed design.

Since sleep is such an integral part of overall well-being, it may not be surprising that several mattress and bed designs are available on the market; therefore it is perhaps surprising, that there is very little good quality, English-language, published evidence available supporting these products.

One study, wherein a "Canadian chiropractic research team" examined comfort levels for five kinds of mattresses (foam, futon, spring, water, air), on different body sizes, received a cursory description in a 1989 issue of the Oklahoma Chiropractic Journal.[2] While the foam and air mattresses were judged by the investigators to be superior to the other 3 mattresses tested, the descriptions and terms used in the article were too vague to enable drawing any conclusions about the quality of the study. The full paper in the English-language was not revealed in our searches of the literature on the Medline, Index to Chiropractic Literature, or Chirolars databases.

From a 1987 survey[3] based on the responses of 50 of the author's own patients who were documented waterbed users in 1984, the author concluded that "A majority of patients derive benefit from their waterbeds for upper and middle back pain stiffness. Fifty percent derive benefit for low back pain." The paper, however, is fraught with reporting and methodological problems, and is essentially not much more useful than anecdotal evidence. Specifically, since respondents were self-assigned to waterbed use, the results are biased towards people who are attitudinally predisposed towards waterbeds. The paper neither discloses what proportion of the clinic's waterbed users the 50 respondents are, nor what proportion of all those waterbed users who were solicited to complete the survey, the 50 respondents are, so that it is impossible to assess either the sample compliance rate, and ultimately, the sample profile representativeness. While the paper provided percentages for positive and negative responses for effects on leg cramps, cold feet, back stiffness and back pain, it was not disclosed how many subjects comprised each of these complaint categories; so, for example, if there were only 2 subjects in the leg-cramp category, and the paper stated that 100% of leg-cramp sufferers experienced relief, then it would be evident that this complaint category is very poorly represented, and the results generated from it have extremely limited usefulness.

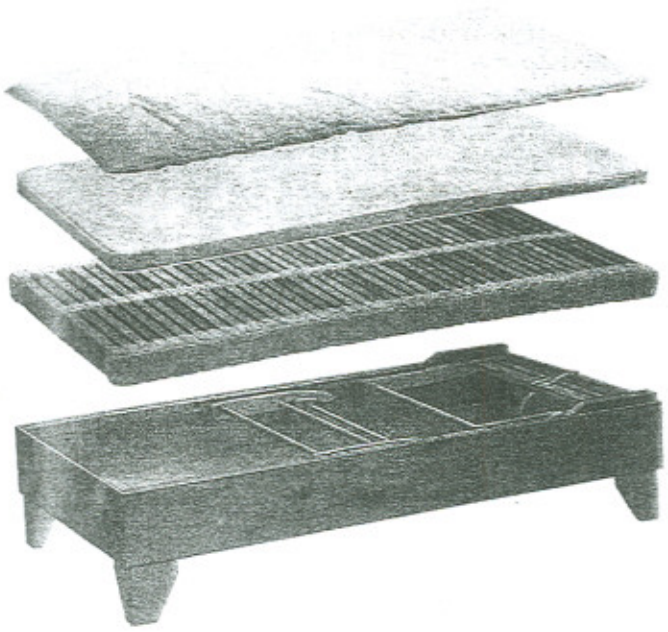
Our literature search revealed only one relevant Randomized Clinical Trial (RCT). In this study, Scriver et al.[5] found that a combined customized exercise and alternating-air-mattress regimen was more effective in reducing back pain than either the exercise regimen or the alternating-air-mattress alone, in patients having recently undergone percutaneous transluminal coronary angioplasty (PTCA).

While the study appears to have merit for the PTCA backpain population, it is not clear that these results are generalizable to any other low back pain population; in addition, it is not possible to determine from this study how the alternating-air-mattress compares against any other type of mattress or bed-system, in reducing back pain.

Somewhat more relevant, is the Before-After-Cross-over study by Garfin and Pye.[1] The authors concluded from the results of 15 chronic low back pain subjects, that "hard beds" are more effective in reducing back pain and improving straight leg-raising than "soft beds." The softer beds even appeared to exacerbate most subjects' back pain. Unfortunately, the study did not provide any data quantifying the extent of these pain reductions/increases, so that it is difficult to judge whether these changes are clinically significant; in addition, it appears that statistical significance was not achieved, so that this study's findings, while somewhat useful in the absence of any stronger evidence, should be regarded with caution.

One type of bed system which is relatively inexpensive and simple to assemble and disassemble, is that manufactured by *Natura World Incorporated*. This bed system features an all-wood frame, a flexible wood slat mattress supporting a foam mattress, which in turn, is covered by a sheep-wool mattress pad; other characteristics of the bed are: a sheep-wool duvet and pillow with added neck support, a neck contour rise and lumbar support lever incor-

Figure 1



The Natura Bed System

From bottom to top: Adjustable all-wood frame, flexible wood slat mattress, foam mattress, sheep wool mattress pad.

porated into the frame, and adjustable elevations of the head/back-rest portion of the frame.

It should be noted that while there is at least some weak support in the literature favouring elevated bed-backrests for recovering coronary angiography patients,[4] our search of the literature did not reveal even one study which tested the therapeutic effectiveness of this type of bed for LBP. It is therefore the purpose of this 6-week Before-After trial to investigate the effectiveness of the Natura Bed System in reducing back pain by ≥ 1 unit on the NRS ($p \leq 0.05$), in adult chronic low back pain sufferers. Chronic back pain sufferers were targeted for this study because: (a) they lend themselves more appropriately to the Before-After study design, and (b) this sector of back pain sufferers is the most likely to be interested in investigating in a therapeutic mattress or bed system.

Methods

Study Design: The design was that of a Before-After Study.

Subject Profile: The subjects were adults recruited from within and outside the Canadian Memorial Chiropractic College (CMCC) Outpatient Clinic, with chronic low back pain (LBP) of ≥ 2 months duration at the time of entering the study.

Sample Size: 15 subjects were required to achieve statistical power of 80% at the 5% level of significance for a clinically important improvement in LBP severity of 1 unit on the NRS (11 point pain scale).

Intervention: This bed system features an all-wood frame, a flexible wood slat mattress, support foam mattress, which in turn, is covered by a sheep-wool mattress pad; other characteristics of the system are: a sheep-wool duvet and pillow with added neck support, a neck contour rise and lumbar support lever incorporated into the frame, and adjustable elevations of the head/back-rest portion of the frame.

The subject was required to use the bed every day for 4 weeks, fill in the diary questionnaire (postcard format) on a daily basis, and upon completion of each 1-week pre-stamped and addressed diary postcard, drop the postcard into the mail. During the baseline and experimental periods, an assistant followed up each subject on a weekly basis by telephone, to ensure that each subject was progressing in a satisfactory manner.

After the 4 week experimental period, the Company picked the bed up at a date and time prearranged with the subject. Thank-you cards were subsequently sent to each subject.

In the event that the subject was not compliant, in that she/he stopped submitting the diary postcards in a timely fashion, stopped using the bed, or asked to be excused from the study, and no reconciliation could be arranged with the subject, the investigator notified the Company, which in turn was responsible for retrieving the bed.

Ethics: The protocol was approved by the CMCC Institutional Review Board (IRB), and each subject was required to sign an informed written consent form.

Outcome Measures: The primary outcome measures consisted of morning, noon, and evening severity of pain as measured by the NRS (an 11-point ordinal pain scale).

Figure 2

Subject # _____

NATURA BED STUDY DIARY

_____

Month Day Year

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1a) Did you wake up with a backache today? Answer Yes or No							
b) If YES, how long did it last? (in hours)							
c) How severe was it? (0-10) 0 2 4 6 8 10 None mild moderate severe very severe horrible							
2a) Did you go to bed with a backache today? Answer Yes or No							
b) How severe was it? (0–10) 0 2 4 6 8 10 None mild moderate severe very severe horrible							
3) Rate your quality of sleep: 0 = Couldn't sleep at all because of backpain/discomfort. 1 = Was awake quite a bit because of pain/discomfort. 2 = Only lost a little sleep due to pain/discomfort. 3 = Had a good night's sleep without interruptions due to pain/discomfort.							
4) Rate your overall activity today: Normal ..... 0 Minimal Effect on Activity ..... 1 Interference with work/leisure ..... 2 Absent from work/school 3							
5) Have you done any abnormally strenuous activity today? What?							
6) (Back) pain killers taken today: For each (back) pain killer, how often did you take it today? How much each time?							

WHEN THIS IS FILLED IN, PLEASE DROP IN MAIL.

Secondary outcome measures consisted of: (1) daily quality of sleep as measured by a 4-point ordinal scale; (2) effect on daily activity as measured by a 4-point ordinal scale; and (3) daily quantity of analgesics. These outcomes were collected via a daily diary-type of questionnaire (Figure 2). The NRS has shown to be valid and reliable[12,13] and the other measures were judged by the principal investigator to have adequate face-validity.

Statistical Analysis: Baseline to 4-week post-baseline differences were analyzed for statistical significance using Repeated Measures ANOVA, at the 0.05 level of significance. In addition, all outcome measures were examined descriptively for any clinically important changes across the 6 week time-frame of the study.

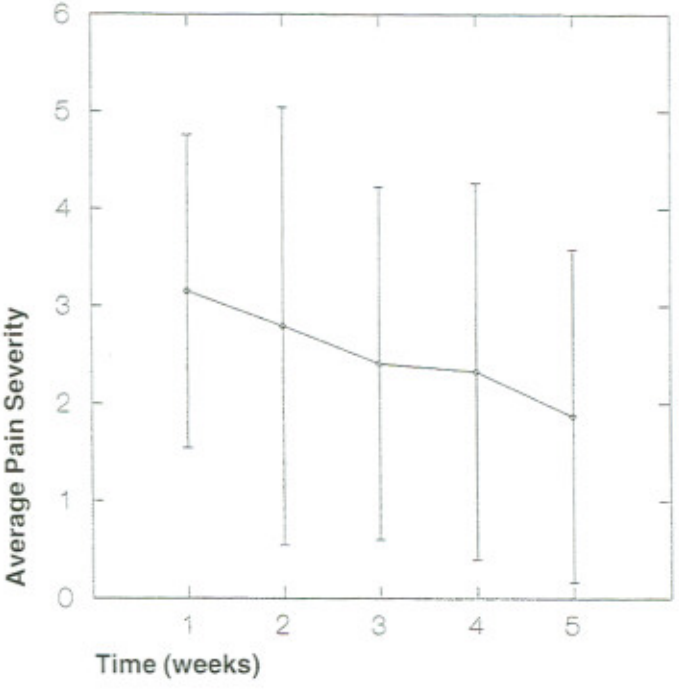
Methods Protocol: The student assistants consulted the CMCC New Patient Book on a daily basis for new LBP patient bookings. Permission was sought by the student assistants (SA) from the treating interns, in order to approach these new patients during the history-taking session or subsequent treatment sessions. Where permission was granted, the SA dropped by at the pre-arranged time during the history-taking or treatment session and presented a 2 minute briefing of the study objectives and desired contribution from the patient. If the patient expressed interest, the SA determined eligibility per the General Information Sheet (Appendix 1).

If the subject was eligible, she/he was given the Written Informed Consent form (Appendix 2), and the SA spent about 2 more minutes explaining the study protocol. If the subject read and signed the consent form, she/he was subsequently given a package containing a copy of the Written Informed Consent form (for reference about the study protocol); a study contact person's name and telephone number; pictorial information about the Natura Bed; and two 1-week daily diary type questionnaires which were pre-stamped and pre-addressed to the CMCC Research Division in postcard format.

This 2-week baseline period was also helpful in enabling the investigators to determine if a subject was going to be adequately compliant in completing the rest of the study. Subjects who successfully finished the 2-week baseline data-gathering period by mailing in 2 properly completed diary postcards, were contacted by the manufacturer (Company) within 1 week after the CMCC Research Division forwarded the subject's name, address, telephone number(s), and other demographic profile data (per the General Information Sheet) to the Company. The Company arranged with the subject a date and time of mutual convenience to deliver the bed ensemble (twin or queen size, whichever the subject preferred) to the subject's home.

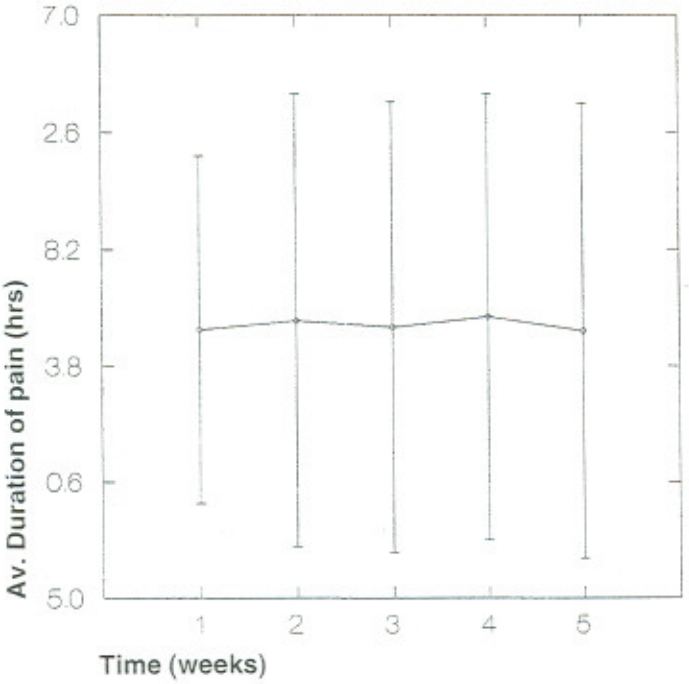
Fifteen 4-week diary packages were sent to the Company ahead of time. The Company delivered a 4-week post baseline daily diary package to each subject at the time that the bed delivery was made. The Company also set up the bed upon delivery.

Figure 3
Average Severity of Back Pain Upon Waking



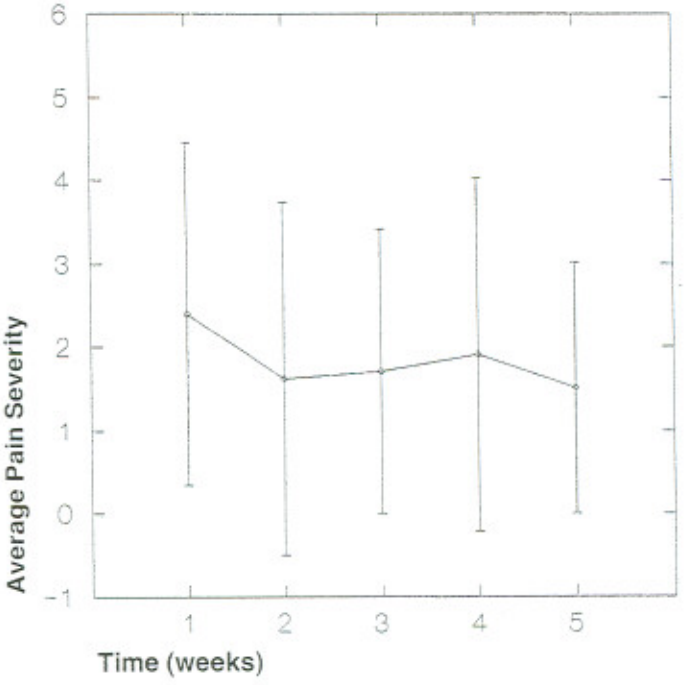
Baseline: Time = 1
There was a clinically (> 1 point) and statistically significant reduction in pain severity ($F = 4.45$, $p = 0.004$) experienced upon waking, between the baseline period and 4th week of bed use. 3.2 → 1.8
3 subjects achieved a symptomless waking pain severity state. One subject experienced an overall deleterious effect, with a baseline to week 4 (of treatment) increase in pain severity of 1.2 points on the NRS.

Figure 4
Average Duration of Back Pain Experienced Upon Waking



Baseline: Time = 1
The duration of pain episodes experienced upon waking remained unchanged during the entire course of the trial ($p > 0.05$).

Figure 5
Average Severity of Back Pain Before Bedtime



Baseline: Time = 1
There was a clinically (> 1 point) and statistically significant ($F = 3.04$, $p = 0.03$) reduction in pain severity experienced at the end of the day, between the Baseline period and 4th week of bed use.

Results

Of the 15 subjects who consented to participate only 2 failed to complete the study: one due to a wool allergy (which the subject initially thought would not be a problem), and the other due to severe injuries sustained midway during the study in a motorcycle accident.

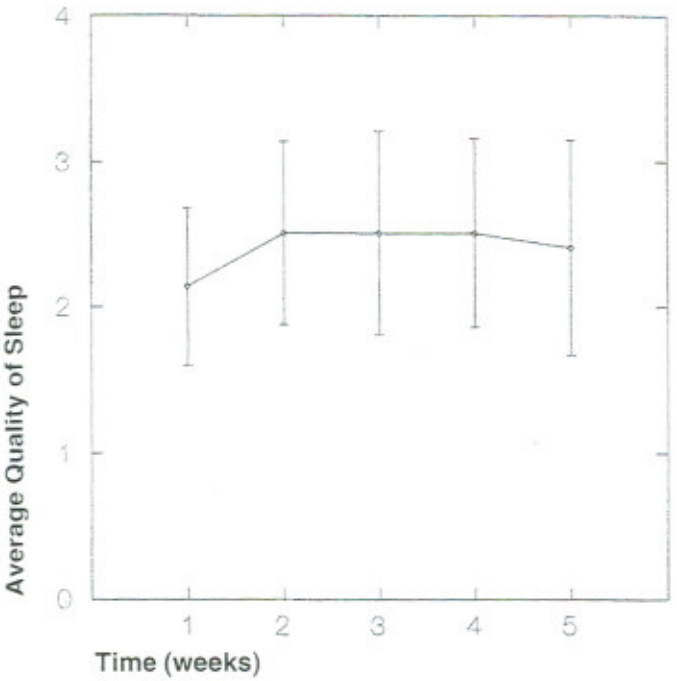
The sample consisted of 6 caucasian females and 7 caucasian males, between the ages of 22 and 75 years, with an average(sd) age of 37 (18.44) years. Five subjects were adult students, 5 had sedentary occupations, while the other 3 had relatively physical occupations. During the 6 week study period, none of these subjects underwent any unusually pain-aggravating activities which would have disqualified them from the study. Baseline LBP severities of the sample ranged from 2 to 8 units on the NRS, with an average(sd) value of 3 (1.75). Average duration of the subjects' chronic LBP state was 5.6 years, ranging from 3 months to 30 years. Only 2 subjects were taking LBP medications at the start of the study thereby eliminating "medication use" as a secondary outcome measure. Only one subject was not under chiropractic care during the 6 week study period.

Primary and Secondary Outcome Measure Results are summarized in Figures 3–7.

Discussion

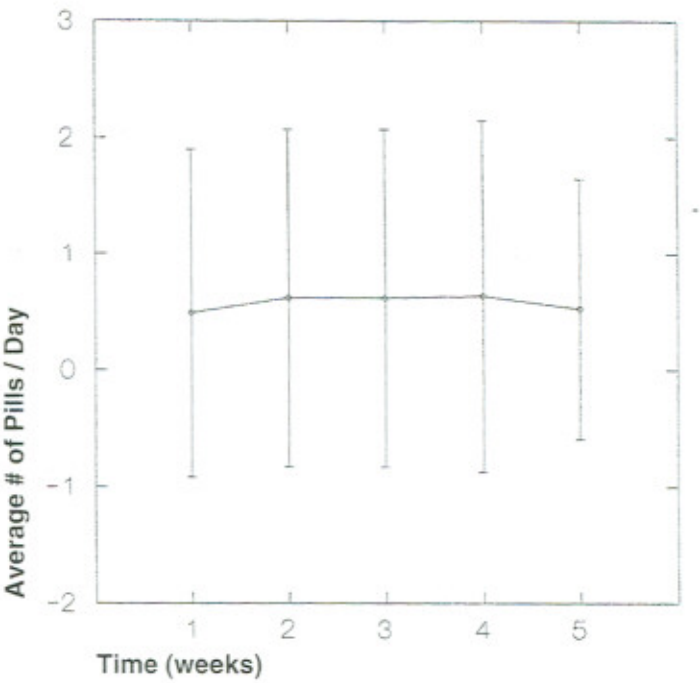
It was noted that the waking-pain was still on a negative slope (decreasing) at the end of the 4 week experimental period, suggesting that the subjects' waking-pain was, on average, still on a declining trend. This is a clinically very important trend in chronic LBP sufferers since these subjects were not expected to improve over the 6 week study

Figure 6
Quality of Sleep



Baseline: Time = 1
Subjects' perceptions of their quality of sleep improved marginally (descriptively only), but this change was not statistically significant ($F = 1.28$, $p = 0.29$).

Figure 7
Amount of LBP Medication Taken During Study Period



Baseline: Time = 1
The data apply to only 2 subjects whose medication consumption was very low, and are therefore of limited usefulness. For these 2 subjects, there was essentially no change in LBP medication consumption.

period due to the chronic nature of their LBP. These subjects had fairly consistent pain levels throughout the 2 week baseline period, even though all subjects (except one) were receiving concurrent chiropractic treatment, suggesting that the clinically important and statistically significant reductions in back pain severity upon waking and at bedtime in this sample of chronic LBP subjects was due to the Natura Bed; this in turn suggests that the Natura Bed is an effective therapy for a target population having a similar profile as our sample. Since only 2 subjects were taking medications for LBP, medication use cannot be regarded as a useful outcome measure for this sample.

Interestingly, average pain severity was consistently slightly higher (by approximately 0.5 points) upon waking, than at the end of the day before bedtime. It appears that the subjects were experiencing an average 0.2 units pain severity reduction as the day progressed; this difference, however, was not clinically or statistically significant ($p > 0.05$). It is also not known whether subjects recorded their waking-pain levels while in bed, or after getting out of bed. It would be interesting to know the pain severity levels both immediately before and after getting out of bed. This would indicate whether or not discomfort levels were minimized while actually reclining on the bed and exacerbated by the act of getting up.

Possible problems with this study design are:

1 There was possibly a lack of subject blinding about the merits of the intervention; however, since care was taken not to lead the subjects into believing that a positive outcome was hoped for by the investigators, we do not believe this was a serious problem.
2 Because no other bed design was tested, we are not able

to comment on how well the Natura Bed compares to other beds on the market.

3 Because subjects were required to have enough space at home to accommodate an additional (experimental) bed, recruitment for this study was very difficult.

4 Of the 15 subjects who consented to participate, 2 had to drop out (1 due to an allergy to wool, and one because of sustaining motorcycle accident injuries midway through the study); otherwise however, compliance with the bed use and record keeping was very good.

5 The wording of the pain diary should have been more specific about the level of LBP "upon waking" in that subjects should have been requested to indicate their pain levels while both lying in the bed just before getting up and while standing immediately after getting out of the bed.

The fact that these subjects did not experience any reductions in duration of their LBP episodes after waking in the morning, is not unexpected, since this cohort consisted of individuals with chronic LBP.

While several subjects found the bed initially uncomfortable and/or difficult to get used to, most experienced clinically important reductions in LBP severity when they persevered and/or made adjustments to the bed. The Natura Bed may not be suitable for every chronic back pain sufferer and determining those patient characteristics most suitable for this bed design is also recommended for future studies.

Conclusion

For a generally well educated, young (20–40 years of age*), caucasian population with mild-moderate chronic LBP, use of the Natura Bed system can be expected to result in a clinically and statistically significant ($p \leq 0.05$) reduction in pain severity upon both waking and before retiring, of at least 1 point (on the NRS) over a 4 week experimental period.

Further research investigating (a) the performance of the Natura Bed compared to other popular beds on the market, and (b) patient characteristics predicting maximum benefit from the Natura Bed System is recommended.

* Only one subject was over 40 years of age, and this individual did not experience any improvements for any of the outcome measures.

References

1 Garfin SR, Pye SA. Bed design and its effect on chronic low back pain – a limited controlled trial. Pain 1981; 10:87–91.

2 Mattress research could save marriages. Oklahoma Chiro J 1989; 1(1):7.

3 Stierwalt DD. Five-year follow-up study on waterbed effect on backaches and stiffness. The Digest of Chiropractic Economics. September/October 1987.

4 Coyne C, Baier W, Perra B, Sherer BK. Controlled trial of backrest elevation after coronary angiography. Am J Critical Care 1994; 3(4):282–288.

5 Scriver V, Crowe J, Wilkinson A, Meadowcroft C. A randomized controlled trial of the effectiveness of exercise and/or alternating air mattress in the control of back pain after percutaneous transliminal coronary angioplasty. Heart & Lung 1994; 23(4):308–316.

6 Grandjean E. Fatigue in industry. British J Industrial Medicine 1979; 36:175–186.

7 Linde L, Bergstrom M. The effect of one night without sleep on problem-solving and immediate recall. Psychological Research 1992; 54(2):127–136.

8 Wu JC, Gillin JC, Buchsbaum MS, Hershey T, Hazlett E, Sicotte N, Bunney WE Jr. The effect of sleep deprivation on cerebral glucose metabolic rate in normal humans assessed with positron emission tomography. Sleep 1991; 14(2):155–162.

9 Steyvers FJ, Gaillard AW. The effects of sleep deprivation and incentives on human performance. Psychological Research 1993; 55(1):64–70.

10 Smith A, Maben A. Effects of sleep deprivation, lunch, and personality on performance, mood, and cardiovascular function. Physiology & Behavior November 1993; 54(5):967–972.

11 Kamphuisen HA, Kemp B, Kramer CG, Duijvestijn J, Ras L, Steens J. Long-term sleep deprivation as a game. The wear and tear of wakefulness. Clinical Neurology & Neurosurgery 1992; 94 Suppl: S96–99.

12 Jensen MP, Karoly P, Brauer S, The Measurement of Clinical Pain Intensity: A Comparison of Six Methods. Pain 1986; 27:117–126.

13 Fish RG, Bolton JE, Responsiveness of the revised Oswestry Disability Questionnaire (RODG) as a measure of outcome in back pain research. Proceedings of the 1996 International Conference on Spinal Manipulation. Virginia: Foundation for Chiropractic Education & Research, 1996: 53–54.

APPENDIX 1

General Information Sheet

Name: _____ Date: _____

Address: _____ Tel: _____

_____

_____

Age: _____ Sex: Male _____ Female _____

Present and/or previous occupations: _____

_____

_____

Do you currently have Low Back Pain (LBP)? Yes _____ No _____

If yes, how long have you had Low Back Pain? Days _____ Months _____ Years _____
(please indicate number)

Is your LBP there continuously? _____ Or does if come and go? _____

If yes, do you get pain at least once a week? Yes _____ No_____

Could you rate the intensity of the pain on a scale of 1–10 (10 being the worst pain ever experienced)? _____

Does the severity of your Low Back Pain fluctuate throughout the month?

_____

What size of bed do you use? Twin _____ Queen _____

Do you have enough floor space? _____

APPENDIX 2

INFORMED CONSENT FORM
NATURA BED STUDY

INVESTIGATORS: C. Hagino

We are requesting your participation in this study investigating the NATURA BED when used by patients with chronic low back pain.

Participants will follow the proceeding study design:

Suitable consenting individuals like yourself with chronic low back pain are asked to complete a two week baseline period which involves filling a short diary type questionnaire. During the third week of study and by prior appointment at a time convenient for you, a NATURA BED will be delivered to your home and installed. Then you are required to sleep on the NATURA BED for a period of 4 weeks during which time you will continue filling out the diary questionnaire. The questionnaire must be mailed back to us every week in the pre-stamped self-addressed envelopes provided. At the end of this study period the NATURA BED will be picked up from your residence. The NATURA BED will be delivered and installed in your residence and also picked up at the end of study by investigators at no cost to you. The manufacturers may also want to administer an opinion survey to you after the study. Your participation in this investigation is completely voluntary.

The risk and pain involved:

The risks involved in this study are minimal; however, there is a very slight possibility that you may experience some discomfort with the NATURA BED.

This is to certify that I, _____, hereby agree to participate as a volunteer in a scientific study which is authorized as part of the research program at the Canadian Memorial Chiropractic College. The investigation, my part in it and any risks have been described to me in detail and I understand the explanation. I have been given the opportunity to ask whatever questions I may have had and all such questions and inquiries have been answered to my satisfaction. I understand that I am free to deny any interviews or questionnaires, but that this will disqualify me from the study. I understand that any data or answers to questions will remain confidential with regard to my identity. I further understand that I am free to withdraw my consent to participate in this study, meaning that I may terminate my participation at any time without penalty.

Date _____ Signature of subject _____

I, the undersigned, have fully explained the study to the above subject.

Date _____ Signature of Study Assistant _____