A preliminary study assessing adverse effects of a semi-customized cervical pillow on asymptomatic adults

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Objective: To determine if asymptomatic adults will experience the adverse effects of headache and neck pain following one week of test-pillow usage.

Design: The study design is that of a Before-After trial.

Subjects: The subjects were 23 healthy adults with asymptomatic cervical spines, with a mean (sd) age of 26.4(4.4) years, without any known organic pathology within or referring from the cervical spine.

Outcome Measures and Statistical Analysis: The outcome measures of pain severity, sleep quality and pillow comfort were used via a daily diary-type of questionnaire. The diary-questionnaire was judged to demonstrate acceptable sensibility. Pre- and post-trial pain states, as well as ratings of comfort were analyzed using the paired t-test at the (Bonferroni-corrected) 0.025 level of significance.

Results: Because none of the 4 paired t-tests yielded clinically important or statistically significant differences between pre vs. post measures, this trial suggests that the majority (91%) of asymptomatic subjects did not become symptomatic after one week of using this pillow.

Conclusions: This study suggests that asymptomatic young adults will not experience the adverse effects of headache and neck pain following one week of using this newly designed semi-customized cervical pillow. It is therefore concluded that this pillow is ethically safe to further test on a demographically similar symptomatic population.

Perhaps the most important message to be taken away from this paper is that all care givers should actively look for adverse effects information on all forms

Objectif : Déterminer si l'utilisation d'un oreiller d'essai pendant une semaine entraîne des réactions indésirables, telles que des céphalées ou des douleurs cervicales, chez des adultes asymptomatiques.

Type d'étude : Observations antérieures et postérieures à un essai.

Sujets : 23 adultes sains dont la moyenne d'âge (ÉT) était de 26,4 ans (4,4), présentant une colonne cervicale asymptomatique et ne souffrant d'aucune maladie organique connue reliée à celle-ci.

Mesures effectuées et analyse statistique : Un questionnaire se présentant sous forme de journal quotidien a servi à mesurer la sévérité de la douleur, la qualité du sommeil et le confort de l'oreiller. Il a été établi que le journal quotidien pouvait démontrer une sensibilité acceptable. Les différents types de douleurs antérieurs et postérieurs à l'essai, ainsi que les degrés de confort, ont été analysés en utilisant le test de t pour séries appariées à un niveau de signification de 0,025 (Bonferroni-corrigé).

Résultats : Étant donné qu'aucun des quatre tests de t pour séries appariées n'a démontré de différences significatives d'un point de vue clinique et statistique entre les mesures antérieures et postérieures à l'essai, il semble donc, d'après les résultats obtenus, que la majorité (91 %) des sujets asymptomatiques n'étaient pas incommodés par des symptômes après une semaine d'utilisation de l'oreiller d'essai.

Conclusion : Cette étude semble indiquer que de jeunes adultes asymptomatiques ne subiront pas de réactions indésirables, telles que des céphalées et des douleurs cervicales, après avoir utilisé pendant une semaine ce nouvel oreiller cervical semi-personnalisé.

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of treatment relevant to their practice. It is not enough to know that one intervention is better than another by an average of "x" units (of some outcome measure); the astute consumer of the research literature will also look for:

a) the proportion of subjects reaching some clinically important positive endpoint:

b) the proportion of subjects reaching some clinically important negative (adverse) endpoint; and

c) the proportion of subjects experiencing NO clinically important endpoint.

(JCCA 1998; 42(3):156–162)

Par conséquent, cet essai nous amène à conclure que cet oreiller est sûr d'un point de vue éthique et peut être utilisé lors d'essais subséquents chez des personnes éprouvant des symptômes et présentant les mêmes caractéristiques démographiques.

Le message le plus important à retirer de cet article est que tous les dispensateurs de soins de santé devraient se renseigner activement sur les réactions indésirables que peuvent entraîner tous les types de traitements relevant de leur pratique. Il n'est pas suffisant de savoir que telle intervention est meilleure que telle autre par une moyenne de « x » unités (de certaines mesures effectuées); le fin lecteur d'informations sur les travaux de recherche devra se pencher sur :

a) la proportion de sujets qui atteignent un point d'aboutissement positif important d'un point de vue clinique;

b) la proportion de sujets qui atteignent un point d'aboutissement négatif (indésirable) important d'un point de vue clinique; et

c) la proportion de sujets qui ne connaissent AUCUN point d'aboutissement important d'un point de vue clinique

(JACC 1998; 42(3):156–162)

KEY WORDS: pillow, cervical, thickness, predictor.

MOTS CLÉS : oreiller, cervical, épaisseur, élément prédictif.

Introduction

This is the second in a series of pilot studies involving the pre-testing of an experimental prototype cervical pillow. The first appeared in a recent issue of JCCA.[14] The literature is discussed in greater detail in that paper.

The chiropractic and medical literature anecdotally discuss various aspects of postural supports including cervical pillows.[1–6] In 1990 there were at least 12 different patented cervical pillow designs on the North American market.[7]

It is estimated that one-third of the average person's life is spent sleeping in bed.[3] The development of the lordotic cervical curve has long been recognized as a necessity for the maintenance of the human bipedal posture.[8] Gray's Anatomy[9] states that the cervical curve is a secondary curve which first appears in intrauterine life and "is further accentuated when the child is able to hold up its head (at three to four months), and to sit upright (about nine months)".

Leach[10] radiographically evaluated cervical curve depths (CCD) of 35 patients who presented with cervical hypolordosis or kyphosis (CH/K). Of these, one group of 20 patients who received only chiropractic manipulative therapy (CMT) gained a mean improvement of 4.55 degrees ($p < 0.01$) while the second group of 9 patients who received both CMT and orthopaedic cervical pillow therapy improved 2.22 degrees. The control group of 6 patients had a mean improvement of 0.83 degrees. The significance of this finding is clouded by the fact that the author had no way of knowing if the patients given the

cervical pillow used it properly. Proper use of the "right" kind of pillow during sleep may be important in improving the posture of the whole body.[2]

A case series by Smythe[11] involving 91 prior fibromyalgia patients and 60 non-prior fibromyalgia patients, all with neck pain, found that after 18 months of using a cervical pillow, 63% and 84% of the respective groups achieved clinically significant relief.

Jackson,[12] in a study using lateral radiographs of the cervical spine with and without exposure to regular and roll-shaped pillows, concluded that the roll-shaped pillow restores the cervical lordosis and decreases neck pain and discomfort while sleeping.

Lavin et al.,[13] in a study using 41 subjects in a randomized cross over trial compared three pillows with regard to pain intensity, pain relief, quality of sleep, disability, and overall satisfaction in subjects with benign cervical pain, concluded that proper selection of a pillow can significantly reduce pain and improve quality of sleep but does not significantly affect disability outcomes measured by the Sickness Impact Profile (SIP).

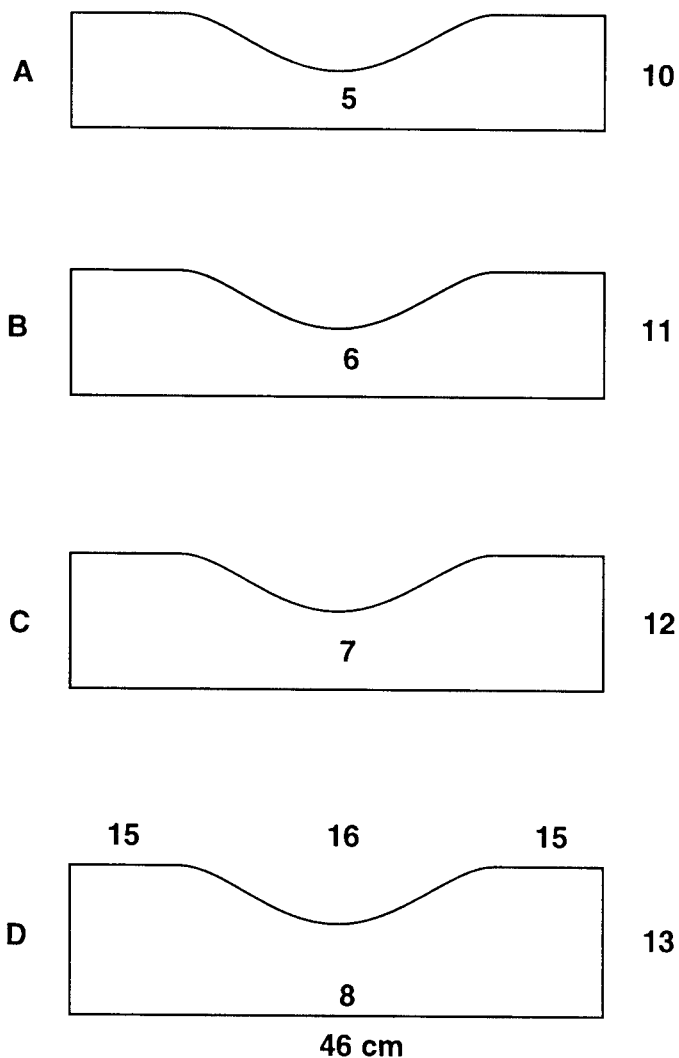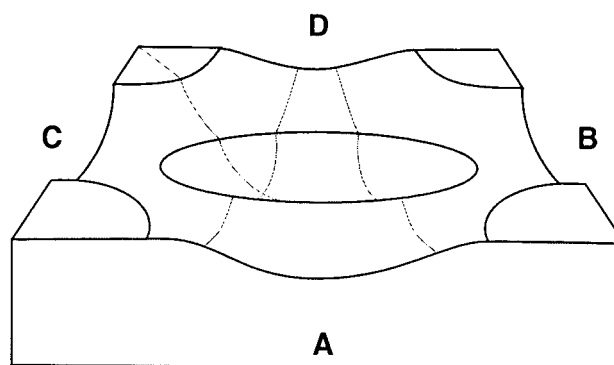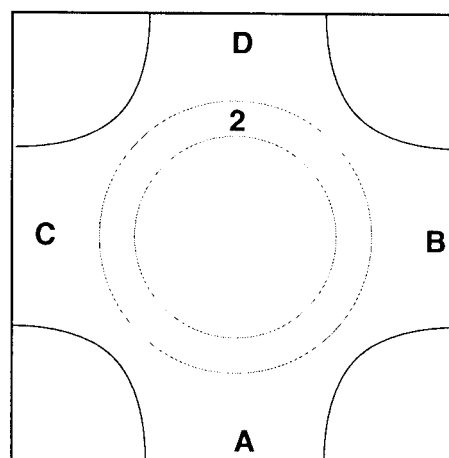Erfanian et al.[14] assessed whether external measure-

Figure 1 The test (semi-customized) pillow Universal Pillow.

Universal Pillow

ments of the subject's neck are predictive of the preferred thickness of cervical pillow, given a choice of four different contour thicknesses. A total of 105 subjects were assessed using measurements of the cervical spine from (1) the external occipital protuberance (EOP) to the seventh cervical spinous process posteriorly, (2) from the mastoid to the acromioclavicular joint laterally, and (3) the neck girth measured at the fourth cervical vertebra. After being given about 10 minutes to try the pillow out, subjects were asked to choose the most comfortable of the four thicknesses. This study found no statistically or clinically significant correlation between neck dimensions and pillow size preference. The authors suggested that pending further investigation, it may be prudent to continue recommending double-contoured or other variably-sized pillows.

Before examining any pillow's therapeutic benefits, it is wise to investigate its possible side effects or even harmful effects. None of the papers reviewed addressed adverse effects; therefore, the authors of this paper decided to investigate the possible adverse effects of a semi-customized cervical pillow (Figure 1) on a convenience sample of asymptomatic subjects before examining its benefits and adverse effects on symptomatic subjects.

The objective of this study is to determine if asymptomatic adults will experience the adverse effects of neck and headache symptoms, following one week of test-pillow usage.

Methods and materials

Design architecture
The study design is that of Before-After trial.

Sample profile
The sample was recruited from faculty, staff, students and CMCC outpatient patients, and consisted of adults eighteen years of age or older, without any known organic pathology within or referring from the cervical spine. The mean (sd) age was 26.4 (4.4) years; all the participants were asymptomatic for headaches neck pain for the past 12 months; 15 subjects were male while 8 were female.

Sample size
A convenience sample of twenty-three adults was recruited for this trial.

Outcome measures
Subjective findings were assessed using a pre and post pillow-use self-report diary-type of questionnaire. Subjects were asked to report on their pain level at night and in the morning, their sleep quality, and the comfort level of the pillow. Pain severity rating was based on a four-point scale where 0 = no pain, and 4 = excruciating pain.

Sleep quality was assessed using a four-point scale where 0 = not being able to sleep at all because of neck pain/discomfort, and 3 = being able to have a good night's sleep without interruptions from neck pain/discomfort. Subjects were requested to assess the comfort level offered by the pillow over time. A four-point scale was used for this question where 1 = uncomfortable, and 4 = very comfortable. The diary-questionnaire demonstrated acceptable initial sensibility[15] (i.e. face validity, comprehensibility, simplicity, ease of completion, acceptable compliance) and this is discussed in greater detail in the discussion section.

Protocol
Eligible subjects who filled out an informed consent form were loaned a semi-customized cervical pillow, each having four built-in sizes from which to choose. They were then given the pillow to take home for the one week trial. They were instructed to consistently sleep on the size that they had originally chosen. During the week they were expected to fill out the daily diary-type questionnaire which documented their pain and comfort status over the one week period. Baseline data commenced the evening before "Day 1" of the diary-questionnaire.

The intervention (pillow)
The prototype (semi-customized) pillow in this paper was a square cervical pillow consisting of four sides of increasing height. Although this pillow is not totally customized for each person, it allows the individual to choose one of the four possible heights (see Figure 1).

Most pillows offer only one height throughout the entire pillow which could alter the ideal position of the head and neck and cause discomfort when the user changes sleep posture from a supine to lateral recumbent position or vice versa. Due to differences in neck thickness and shoulder width, a different height of pillow may be required when the person is on his/her back or side. This potential problem is addressed with the semi-customized pillow by pro-

viding a shorter height throughout the middle curved area for supine sleeping and a higher height on the either side of the curved area for lateral recumbent sleep posture.

Statistical analysis

Results of this study were analyzed using the 2-tailed paired t-test, as calculated by Systat statistical software, at the .10 level of significance (Bonferroni corrected to .1/4 ~ .025). Norman and Streiner[16] state that "from the pragmatic viewpoint, it appears that under most circumstances, unless the distribution of scores is severely skewed, one can analyze the data from rating scales as if they were interval data without introducing severe bias. The .1 level of significance was judged to be adequate in light of the preliminary nature of this study, and the fact that the consequences of a Type 1 error for this study are not at all severe. A clinically important change on 'neck-pain and headache-severity' upon wake-up time as well as for 'quality of sleep' was judged to be 1 unit on each of the scales.

Results

Of the 23 subjects who began the study, 2 subjects dropped out on day 4 due to dissatisfaction with the pillow's shape and size; specifically, because the pillow was square and large, it caused their feet to hang off of the edges of their beds! The data from these subjects were not included in the analysis. Of the remaining 23 subjects, 8 were female, 15 were male, and the mean (sd) age was 26.4 (4.4) years.

Primary outcomes

Although none of the 4 paired t-tests (Table 1) yielded statistical significance, the descriptive data suggest that the majority (91%) of subjects did not experience adverse effects after one week of using this pillow (95% CI = 91 ± 12.4%).

Secondary outcomes

With regard to "restful and stress free sleep" on the first day after test-pillow use, 14 of the 23 (61%) subjects responded positively, while by the seventh day this number increased to 83% (95% CI = 61 ± 19.6%; 83 ± 16.4% respectively).

With regard to the size of the pillow, 21 (91%) subjects found their initially chosen size of pillow to be of the right size, and 1 subject ultimately found it too small, while 1 subject found it too large.

Analysis of the sleep posture data, revealed that ten subjects slept on their backs, 5 on their sides, and 8 on the backs and sides, while using the test pillow.

Discussion

This preliminary trial was designed to determine whether 1 week of use of this semi-customized pillow will result in adverse effects in symptomatic volunteers. The results of this study were not statistically significant due to the low effects sizes. Since the objective of this study was to show a clinically *un*important adverse effect, achieving statistical significance is not feasible here. These results suggest that one week of the test-pillow usage did not result in

Table 1
2-tailed Paired-Samples T-test (α = .05/4 = .025).

	Baseline Mean	After 1 Wk	Mean Difference (sd)	t value	probability
Bed time pain severity of day 1 vs. day 7	0.11	0.09	0.20 (0.20)	1.00	0.328
Wake up pain severity of day 1 vs. day 7	0.38	0.17	0.21 (0.58)	0.55	0.589
Sleep quality of day 1 vs. day 7	2.60	2.85	−0.25 (0.55)	−1.14	0.266
Comfort level at day 1 vs. day 7	2.69	3.04	−0.35 (0.82)	−1.78	0.090

painful adverse effects in the majority of subjects.

The descriptive results suggest that in the short term (3–4 days), there was an "adaptation" phase during which there was a slight mean increase in subjective discomfort; but in the longer term (end of one week), mean subjective discomfort actually decreased from the Day 1 measurement.

Twenty one of the 23 subjects (91%) found their chosen pillow quadrant to be of the right size and shape for their necks and heads. This supports the hypothesis that when given a number of choices with respect to size and shape of the pillow, most users are quickly able to find one which is consistently comfortable for them.

With regard to sleep posture, after one week, subjects still varied considerably between supine, prone and side posture preferences; it does not appear that one week of usage is enough time to train users to adopt the recommended supine posture.

Sources of error in this study include

1 No record of the subjects' history of neck pain was collected; this may be problematic in that at baseline, some subjects may have been in remission from neck pain;
2 The inclusion of prone sleepers may pose a problem in that they will be highly unlikely to find the pillow comfortable.
3 There is the possibility that the size/side of pillow preference may change with bed characteristics (soft/hard bed).
4 There is also the possibility that subjects may have required more time than 1 week to accommodate to a new pillow.
5 According to Norman and Streiner, the minimum number of categories in a scale should be 5–7, with a maximum of 15.[17] Our scale may have sacrificed some sensitivity with only 4 categories.

It is recommended that

1 A longer baseline period be incorporated into the protocol. This would effectively "weed out" non-compliers so that expensive effort and test-product are not wasted on these individuals.
2 A longer period of time be allowed for accommodation to the pillow.
3 Follow up should be longer to assess longer-term ef-

fects.
4 Because sleeping position is likely to classify people into distinct risk categories, further studies should also stratify the analysis by prone, supine and side-posture (semi-prone) sleepers; they should also determine whether this pillow encourages what is believed to be a more biomechanically correct sleeping posture (i.e. supine or semi-prone).
5 A randomized clinical trial (RCT) using symptomatic subjects and comparing the cervical pillow used in this study against other cervical pillows currently on the market should be conducted.

Perhaps the most important message to be taken away from this paper is that all care givers should actively look for adverse effects information on all forms of treatment relevant to their practice. It is not enough to know that one intervention is better than another by an average of "x" units (of some outcome measure); the astute consumer of the research literature will also look for:

a) the proportion of subjects reaching some clinically important positive endpoint;
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Conclusion

This study suggests that most asymptomatic young adults will not experience the adverse effects of headache and neck pain following one week of this newly designed semi-customized cervical pillow usage. It is therefore concluded that this pillow is ethically safe to further test on a demographically similar symptomatic population.

Acknowledgements

Preliminary study

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