Volume 21 • Number 2 • February, 1998
0161-4754/98/2102–0089 $4.00/0 © 1998 JMPT

# Before/After Study to Determine the Effectiveness of the Align-Right Cylindrical Cervical Pillow in Reducing Chronic Neck Pain Severity

*Carol Hagino,[1] Julie Boscariol, D.C.,[2] Lori Dover, D.C.,[2] Rene Letendre, D.C.[2] and Melissa Wicks, D.C.[2]*

## ABSTRACT

**Objective:** To determine the effectiveness (at the 0.1 level of statistical significance) of the Align-Right (roll-shaped) cervical pillow (ARCP) on neck pain severity and headache/neck pain medication use in chronic neck pain subjects.

**Design:** The design was a "before/after" (i.e., a "pre/post" trial).

**Subjects:** Twenty-eight subjects, 25–45 yr of age with cervical spine pain of biomechanical origin of > 2 on an 11-point ordinal pain scale.

**Outcome Measures:** The primary outcome measure was severity of morning and evening neck pain. The secondary outcome measure was daily quantity of analgesics ingested. The data were analyzed descriptively and inferentially for clinically and statistically significant pre/post intervention differences.

**Methods:** Eligible subjects who successfully finished a 2-wk baseline data-gathering period by mailing in two properly completed diaries each received a pillow and four more diaries (to be filled in over the subsequent 4 wk). Three repeated-measures analyses of variance were performed using the Bonferroni-corrected level of statistical significance of 0.03. Ninety-five percent confidence intervals (for paired-samples mean differences) were also calculated for those pre/post differences that seemed descriptively clinically important.

**Results:** The clinically and statistically significant reductions in neck/shoulder pain severity in this sample of chronic neck pain subjects suggest that the ARCP is an effective therapy for target populations with the same profile as this sample. Patient characteristics predicting suitability were not studied in this project.

**Conclusion:** The results suggest that the ARCP has clinically important beneficial effects on the neck pain severity of most chronic neck-pain sufferers. Further randomized clinical trial research comparing the ARCP with other commonly used cervical pillows is recommended. (J Manipulative Physiol Ther 1998; 21:89–93).

**Key Indexing Terms:** Neck; Pain; Cervical Vertebrae

## INTRODUCTION

Cervical pillows are commonly prescribed by health-care providers to patients suffering from neck pain. Their manufacture involves a sizable industry; in 1990, there were at least 12 different patented designs on the North American market, with at least one company listed on the American Stock exchange (1).

Cervical pillows come in a a vast array of different shapes and sizes, but most of them share the goal of attempting to restore cervical lordosis (2, 3). Several support the head around the occiput to achieve slight cervical flexion, and many also cradle the head on each side to prevent lateral flexion and rotation. There is still considerable controversy over certain design aspects, with little published evidence supporting any of the viewpoints; for example, some authors advocate maintaining slight cervical flexion (3) and others do not (2).

With regard to the effectiveness of cervical pillows in reducing neck pain, our search of the published literature revealed only one company that claimed to have conducted extensive research on its product (1), but this research was not revealed in our literature search; in addition, it is not clear whether this research included efficacy testing. Essentially, most of the evidence supporting the effectiveness of cervical pillows in reducing neck pain is anecdotal.

Our search of the literature also failed to reveal any robust randomized clinical trials (RCTs) investigating the effectiveness of cervical pillows. Lavin et al. conducted a cross-over RCT investigating the relative effectiveness of roll-shaped, regular, and water-based pillows (3a). The article does not reveal, however what the water-based vs. roll-shaped pillows' baseline data (regular pillow) were, so it cannot be determined if randomization was successful in yielding acceptably equivalent baseline measures. There does not seem to have been a 'washout period' between pillow administrations (bringing the subjects back to their baseline levels); without this, it is unclear

[1] Research Faculty, Division of Graduate Studies and Research, Canadian Memorial Chiropractic College, Toronto, Ontario, Canada.

[2] Private practice of chiropractic.

Submit reprint requests to: Carol Hagino, B.Sc., M.B.A., Division of Research, Canadian Memorial Chiropractic College, 1900 Bayview Avenue, Toronto, Ontario M4G 3E6, Canada.

Paper submitted March 4, 1997; in revised form May 27, 1997, and July 21, 1997.

This work was completed while J.B., L.D., R.L. and M.W. were students at CMCC.

whether there were interaction effects between the pillows. Furthermore, the analysis seems to have used the averages of each treatment period, rather than pre/post-treatment period changes, so it is possible that the cross-over data may be largely the post-treatment data of the previous pillow. A case series by Smythe involving 91 prior fibromyalgia patients and 60 new fibromyalgia patients, all with chronic neck pain, found that after 18 months of using a cervical pillow, 63% and 84% of the groups, respectively, achieved clinically important relief (4). Because this uncontrolled (for any comparison intervention or nonintervention) design is considerably inferior to the RCT, it should be regarded with some degree of caution.

Although Smythe provided somewhat persuasive evidence supporting the further study of cervical pillows for chronic neck pain, it is not evident to which kind of cervical pillow(s) the subjects were exposed (4). This is a rather critical omission, because there are so many different types of cervical pillows available.

By studying lateral radiographs of the cervical spine with and without regular and roll-shaped pillows, Jackson concluded that the roll-shaped pillow restores the cervical lordosis and decreases neck pain and discomfort while sleeping (5). Details about the author's research methods and data were not provided, however, making it difficult to appraise the quality of the findings.

In light of the dearth of published research in the area of cervical pillow effectiveness for neck pain, our study utilized the before/after (pre/post) design to determine the potential effectiveness (at the 0.10 level of statistical significance) of the Align-Right (roll-shaped) cervical pillow (ARCP) on neck pain severity in chronic neck pain subjects. An improvement $\geq 1$ on the Numeric Rating Scale (NRS) pain scale was judged to be sufficiently clinically significant to warrant recommending further confirmatory study with an RCT.

## METHODS

### Intervention

The ARCP used in this study was a cylindrical pillow filled with a trade-marked polyester fiber that, at the time of the study, was electronically weighed and hand-rolled (Figure 1). It was designed to support the forward curve of the neck for supine sleep, and the neck and head for side-posture sleep.

### Study Design

The design was a "before-after" (i.e., "pre/post") trial. Subjects were also categorized into two prognostic groups, namely gender and age [$\leq$ 35 yr of age (yoa) and $>$ 35 yoa].

### Subject Profile

The subject profile was designed to resemble the manufacturer's main target market. Subjects had to be adults between 25 and 45 yoa with neck pain of biomechanical origin of $> 2$ on the 11-point pain NRS. At baseline, subjects had to have had neck pain for $\geq 2$ months. The chronic nature of the subjects' neck pain minimized the effect of natural history, which can be a serious bias in the before/after trial design.

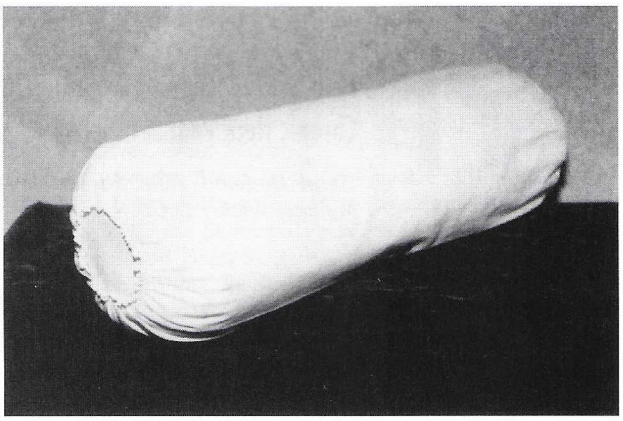

**Fig. 1** *The ARCP.*

Subjects were recruited from the Canadian Memorial Chiropractic College (CMCC) Outpatient Clinic, the CMCC student body, and staff of the Ryerson Polytechnical University (RPU).

### Sample Size

Using Systat Design Software, a sample size estimate revealed that at alpha = 0.03, power = 80% and an average (standard deviation) change on the NRS of 1.0 (1.5), a minimum of 30 subjects would be required.

### Outcome Measures

The primary outcome measure consisted of daily morning and evening neck pain severity, with and without the test-product, as measured by an 11-point (0–10) pain NRS. This outcome measure has been shown to be reliable and valid, perhaps even more so than the 100-mm pain visual analog scale (6). The secondary outcome measure consisted of a simple count of analgesic tablets consumed by the subject on each day of the study. These outcomes were collected via a daily diary-like questionnaire.

### Statistical Analysis

The data were analyzed descriptively and inferentially for clinically and statistically ($p \leq .03$) significant pre/post intervention differences using the Repeated Measures ANOVA (RM ANOVA). Because three RM ANOVAs were performed for each of the three outcome measures, the Bonferroni-corrected level of significance of $[0.10]/3 = 0.03$ was used. Where the RM ANOVA revealed statistical significance, it was assumed that without proceeding into pair-wise post hoc tests that the largest pair-wise difference could be counted on to be statistically significant. Because the baseline-to-week-5 difference was of primary interest, further pair-wise post hoc tests were not performed when this was the largest difference. Ninety-five percent confidence intervals (CI) for paired samples mean differences were also calculated for those pre/post differences that seemed descriptively clinically important.

### Protocol

The manufacturer delivered 30 pillows to the CMCC Research Division for distribution to eligible subjects. CMCC

Outpatient Clinic neck pain patients underwent the following protocol:

An investigator introduced herself to the patient and presented a 2-min briefing of the study objectives and invited the subject to participate in the study. RPU subjects were recruited differently. Permission was secured from the RPU Ethics Review Board to access the faculty and staff internal mailing list and send each of these individuals, via the RPU internal mail system, a recruitment letter and sign-up form.

The recipients who met the inclusion criteria stated on this form were invited to provide their names, telephone numbers and preferred contact times, and were requested to drop the form into the RPU internal mail system where it was forwarded to a RPU faculty person who also had a cross-appointment with CMCC. This individual then forwarded these forms to the principal investigator (PI). Interested respondents were followed-up by telephone to confirm eligibility.

If the eligible subject read and signed the consent form at the subsequent prearranged time, he/she was given a package containing a study contact-person's name and telephone number, and two 1-wk daily-diary questionnaires to record the baseline data. The two diary-like questionnaires were to be returned to the PI at the CMCC Research Division via the prestamped, CMCC-addressed envelope provided.

This 2-wk baseline phase was also an effective strategy for screening out noncompliant subjects, which in turn avoided the problem of wasting the test product on noncompliant individuals. Subjects who successfully finished the 2-wk baseline data-gathering period by mailing in two properly completed diaries were contacted by another investigator to arrange for the delivery of a test-pillow and four more 1-wk diaries. Subjects were required to return each diary questionnaire in the mail upon completion, using one of the four prestamped CMCC-addressed envelopes provided.

During the baseline and treatment periods, the four coinvestigators conducted follow-up telephone calls with any subjects who delayed in submitting their diary questionnaires. Compliant subjects were permitted to keep their test pillows if they wished to do so. Where possible, subjects who completed the study were sent "thank you" notes for their participation.

Figure 2 demonstrates the study protocol.

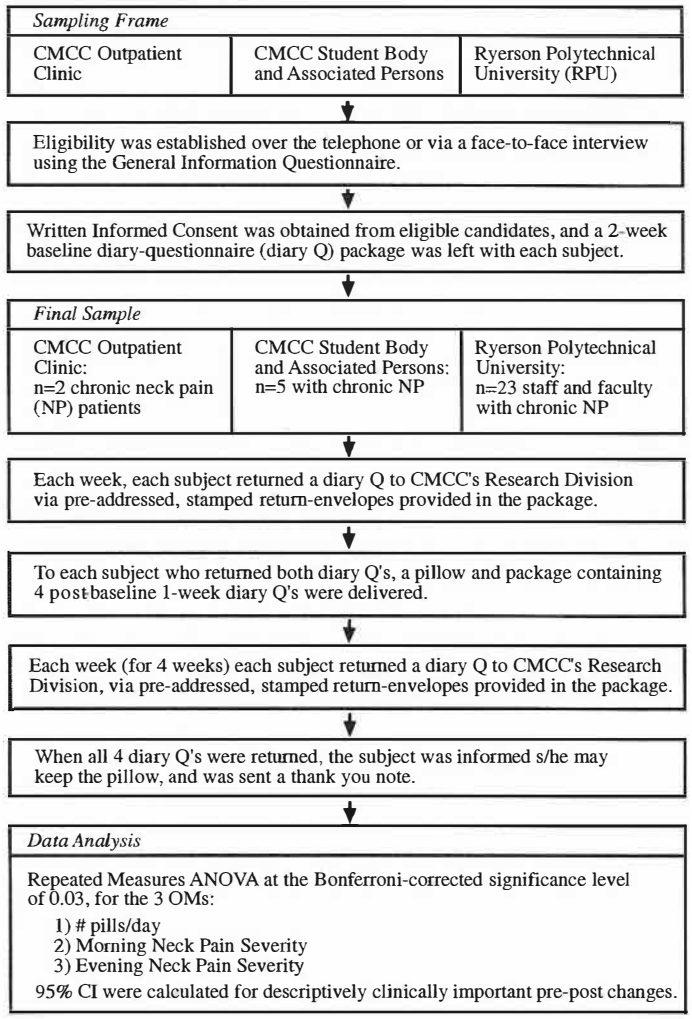


**Fig. 2** *Methods flowchart.*

## RESULTS

### Baseline Characteristics of the Sample

In the initial sample size of 30, 12 (40%) were men and 18 (60%) were women. Two subjects (both female) dropped out, unable to tolerate the discomfort experienced when using the pillow. Forty-seven percent of the subjects were > 35 yoa, and 53% were ≤ 35 yoa. The average age (SD) of the sample was 39 (9.4) yr. The sample's average (SD) initial neck pain severity was 2.5 (1.5) on the NRS, and the average (SD) duration of the sample's neck pain was 6.7 (6) yr. Two thirds of the subjects had mostly sedentary occupations. Thirteen subjects (43%) were initially taking pain medications for neck, neck and headache and neck and shoulder pain; average (SD) pain medication consumption at baseline was four (seven) pills/day (range, 1–28). 97% of subjects initially used either down or foam pillows. None of the subjects used a roll-shaped cervical pillow before the study; most (77%) used regular-sized pillows and 20% initially used queen-sized pillows.

### Pillow-Use Compliance

The duration of pillow-use per night during the treatment period was fairly consistent and acceptable at an average (SD) of 7 (2) hours. This consistency is a desirable finding from a "quality control" standpoint.

### Changes in Average Number of Pills/Day for Headache and Neck Pain

Most respondents who took analgesics on any given day indicated taking them for neck pain and headache. There was a potentially clinically significant reduction of 75% (from an average of four to one pills/day) in analgesic use between the baseline and week 5 of the study. This reduction however, was not statistically significant ($F = 1.88$, $p = .13$; 95% CI = 3 ± 2 pills) (Figure 3).

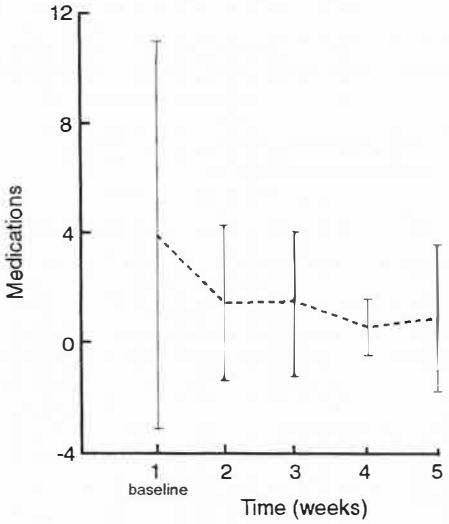


**Fig. 3** *Changes in average number of pills per day for headache and neck pain.*

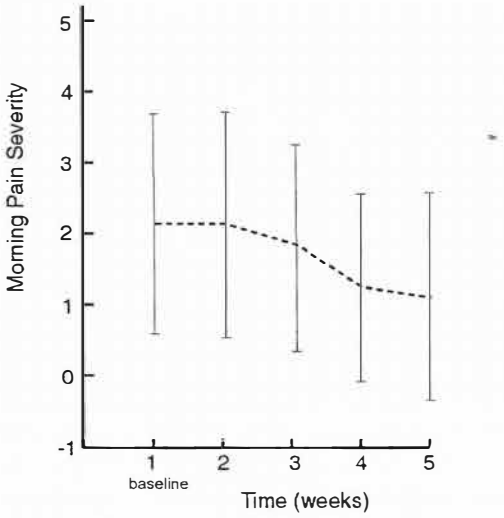


**Fig. 4** *Changes in morning neck pain severity.*

### Changes in Morning Neck Pain Severity

There was a clinically significant average reduction of 1 point (SD 1.5) in morning pain severity between the baseline and week 5 of the study (Figure 4).

This difference was statistically significant ($F = 4.9$, p = .002; 95% CI = 1.5 ± 0.5). Three subjects (two women and one man, between 30 and 38 yoa) experienced slightly deleterious changes of 0.4–0.9 points on the NRS during the treatment period, and four subjects actually improved to an asymptomatic state.

### Changes in Evening Pain Severity

There was a clinically significant average reduction (≥ 1 point) in evening pain severity between the baseline and week 5 of the study. This difference was statistically significant ($F = 3.1$, $p = .02$; 95% CI = 1.0 ± 0.5) (Figure 5).

### Average Morning Pain Levels over the Duration of the Study

At baseline, the female and >35-yoa subgroups seemed to describe slightly more severe symptoms that the male or ≤35-yoa subgroups. These differences were clinically trivial, however. The older subgroup also demonstrated the largest descriptive baseline-to-week-5 pain-severity reduction. This reduction, although 'potentially' clinically important, was not statistically significant ($p > .03$) (Table 1). (We say "potentially" because, strictly speaking, any change that is not statistically significant is not truly clinically significant beyond the confines of the study sample.)

## DISCUSSION

The clinically and statistically significant reductions in neck pain severity upon waking and at bedtime in this sample of chronic neck pain subjects suggest that the ARCP was an effective therapy for a target population resembling our sample of 25–45-yr-old subjects. Some subjects found the pillow very uncomfortable at the start but experienced positive results when they persevered. Two subjects could not persevere and subsequently dropped out, and three subjects experienced mildly adverse effects of slightly increased neck pain severity, which indicates that this pillow is potentially suitable for most but not all chronic neck-pain sufferers. We did not assess patient characteristics that predict suitability for this pillow, but this may be a worthwhile endeavor in future studies.

### Problems with This Study That Should Be Addressed by Further Research

A possible lack of subject blinding about the relative value of the intervention (with vs. without the pillow) is a potential bias; however, because care was taken not to lead the subjects into believing that we hoped for a positive outcome, we do not believe that this was a serious problem.

Because no other cervical pillow was tested, we are neither able to factor out placebo effects nor comment on how well the ARCP compares with other cervical pillows on the market. We do feel, however, that we have been able to comment how the

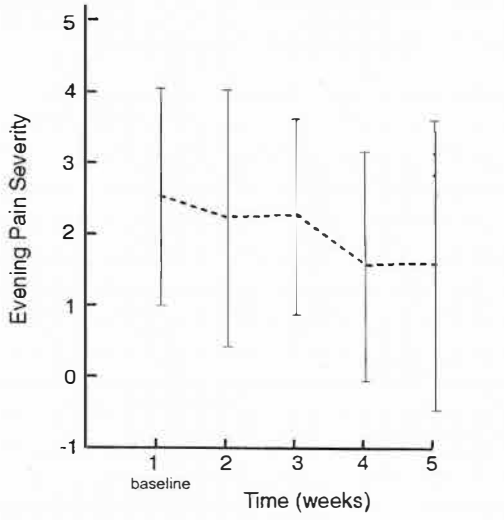


**Fig. 5** *Changes in evening neck pain severity.*

**Table 1.** *Average morning pain levels over the duration of the study*

| | Baseline | | Week 1 | | Week 2 | | Week 3 | | Week 4 | | Baseline-Week 5 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Subjects | Avg. | (SD) | Avg. | (SD) | Avg. | (SD) | Avg. | (SD) | Avg. | (SD) | Average pain reduction |
| All | 2.18 | (1.55) | 2.14 | (1.57) | 1.86 | (1.48) | 1.31 | (1.34) | 1.17 | (1.45) | 1.01 |
| Men | 1.93 | (1.62) | 1.89 | (1.87) | 1.68 | (1.57) | 1.61 | (1.66) | 0.93 | (1.35) | 1.00 |
| Women | 2.33 | (1.53) | 2.31 | (1.37) | 1.99 | (1.46) | 1.08 | (1.03) | 1.34 | (1.56) | 0.99 |
| ≤35 yr | 2.10 | (1.80) | 1.89 | (1.63) | 1.46 | (1.57) | 1.33 | (1.59) | 1.19 | (1.28) | 0.91 |
| >35 yr | 2.28 | (1.23) | 2.34 | (1.54) | 2.26 | (1.33) | 1.30 | (1.13) | 1.15 | (1.70) | 1.13 |

ARCP compares with "no treatment, " because the nature of the complaint studied was chronic and its status was therefore not expected to change over 4 wk without treatment from baseline levels.

The study did not always clearly differentiate between 'neck' and 'neck and shoulder pain' and 'neck and headache.' Future studies should examine each type of pain separately, because the pillow may be more effective for one type of pain than for another; in addition, we recommend that future studies also investigative the effect of the pillow on cervicogenic headache.

Our definitions of "clinical significance" were based on the PI's best subjective judgment on the matter (face validity) but cannot be strongly defended at present. With regard to the statistical analyses, it may be argued that three Bonferroni-corrected paired *t* tests would have sufficed, because we essentially used RM ANOVAs to compare only pre- and post-treatment mean differences. It was our initial intention, however, to perform pair-wise post hoc analyses wherever the "omnibus" RM ANOVA revealed statistical significance. After inspection of the descriptive data, we subsequently determined that the pretreatment-to-week-5 post-treatment data yielded the largest pre/post treatment differences and were, therefore, the only results worth subjecting to inferential analyses. The fact that paired *t* tests were not performed instead of the RM ANOVA is irrelevant, because both tests will yield essentially the same results under these circumstances.

## CONCLUSION

The morning (waking) and evening (bedtime) pain improvements between baseline and the week 5 of the study were statistically significant ($p \leq .03$) and seem to be sufficiently clinically important to warrant further study using the RCT design comparing the ARCP to a no-treatment control group as well as other popular pillows on the market.

With regard to future study, it was determined that for a three-group RCT with alpha = 5%, power = 80% and a minimum between-group average (SD) difference of ≥ 1.0 (1.5), the minimum number of subjects needed per group should be 36 for a total sample size of 108. We also recommend that future studies investigate patient profile characteristics that are good predictors of cervical pillow suitability.

## ACKNOWLEDGMENTS

We are particularly grateful to two of our reviewers, who provided us with very detailed and helpful critiques.

## REFERENCES

1. Busch RE. Chiropractix: a new orthopaedic pillow offers unprecedented adjustability. Am Chiropr 1990; 12(8):45–6.
2. Summer J. Pillows and posture. Dig Chiropr Econ 1990; 32(5): 70–3.
3. Cailliet R. Neck and arm pain. 2nd ed. Philadelphia: FA Davis; 1982. p. 118–36.

3a. Lavin RA, Pappagallo M, Kuhlemeier KV. Cervical pain: a comparison of three pillows. Arch Phys Med Rehabil 1997;78: 193–8.

4. Smythe HA. The C6–7 syndrome: clinical features and treatment response. J Rheumatol 1994; 21:8.
5. Jackson R. The cervical syndrome. 4th ed. Springfield (IL): Charles C Thomas; 1987.
6. Fish RG, Bolton JE. Responsiveness of the Revised Oswestry Disability Questionnaire (RODQ) as a measure of outcome in back pain research. Proceedings of the International Conference of Spinal Manipulation; 1996 Oct 17–19; Bournemouth, UK. Arlington (VA): Foundation for Chiropractic Education and Research; 1996. p. 53.