



Twelve-Month Outcomes of An Ergonomic Cervical Pillow In Chronic Neck Pain Management: Pain, Disability, And Sleep Quality Across Age Groups

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Introduction

Chronic neck pain is a prevalent musculoskeletal condition, affecting up to 20% of the adult population at any given time. It has a significant impact on daily function, work productivity, and sleep quality. Among various conservative treatments, ergonomic interventions during sleep have received increasing attention. One such approach is the use of specially designed cervical support pillows, intended to maintain physiological cervical alignment and reduce muscular strain during rest. Several randomized controlled trials have investigated the role of neck-support pillows in alleviating cervical pain and improving related symptoms. For instance, Vanti et al. [1] conducted a randomized trial comparing a spring-based cervical pillow to standard care in individuals with chronic nonspecific neck pain. Their results demonstrated significant improvements in both pain intensity and disability scores in the intervention group, emphasizing the therapeutic potential of biomechanically designed sleep aids for managing cervical discomfort. Similarly, Fazli et al. [2] evaluated the impact of an ergonomic latex pillow as part of a multimodal rehabilitation program for patients with cervical spondylosis. The study revealed that the pillow enhanced head-neck alignment, improved muscle endurance, and led to a greater reduction in pain scores compared to standard rehabilitation alone. Other studies, such as that by Puntumetakul et al. [3], have focused on pillow ergonomics and user satisfaction, finding that appropriate pillow

design significantly reduced muscle fatigue and discomfort during prolonged sitting or sleeping postures. Moreover, Gordon et al. [4] demonstrated that side sleepers using supportive pillows reported not only reduced cervical stiffness and headache frequency but also better sleep quality, an important comorbidity in chronic neck pain patients. Collectively, these studies suggest that cervical pillows are not mere comfort accessories but biomechanically relevant devices that can contribute to pain modulation, improved sleep, and functional recovery. This growing body of evidence supports the integration of cervical support pillows into non-pharmacological management strategies for chronic neck pain, especially in cases where poor sleep posture is a contributing factor. Among emerging non-invasive strategies for cervical pain, the MagniStretch Pillow® (Alessanderx, Prato, Italy) presents a novel non-pharmacological strategy for managing chronic neck pain during rest. Engineered with a dual-layer core composed of viscoelastic Memoform® and supportive Eliosoft® foam, the pillow is designed to gently stretch the cervical spine through its inclined internal sections, promoting passive vertebral decompression from the shoulders to the occiput. This mechanism aims to decompress intervertebral discs and reduce muscular tension without active patient effort.

The primary aim of this study was to evaluate the long-term clinical effectiveness of the MagniStretch® Pillow in reducing pain, improving cervical function, and enhancing sleep quality in patients with chronic neck pain. A secondary objective

was to assess whether age influences clinical outcomes, with stratified analysis across three age groups. The hypothesis of the study is that consistent nightly use of the MagniStretch® Pillow would lead to significant improvements in neck pain intensity, functional disability, and sleep quality over a 12-month period. Furthermore, we anticipated that patients over the age of 50 would experience greater clinical benefit compared to younger groups, due to increased baseline symptom severity and altered cervical biomechanics associated with aging.

Methods

A total of 75 patients with chronic cervical neck pain were enrolled in this prospective observational study. All evaluations were conducted between January 2023 and June 2024. Patients were followed for a total duration of 12 months after initiating daily use of the MagniStretch® cervical pillow during rest. Inclusion criteria consisted of adults aged 20 to 75 years with clinically diagnosed cervicgia persisting for at least 3 months, associated with morning stiffness or impaired sleep quality, and without neurological deficits. Exclusion criteria included prior cervical spine surgery, cervical disc herniation with radiculopathy, vertebral fractures, systemic inflammatory diseases (e.g., rheumatoid arthritis), tumors, or concurrent use of other orthopedic sleep devices. Patients were stratified by age into three groups: Group 1 (20-35 years), Group 2 (36-50 years), and Group 3 (>50 years). All participants received standardized instructions on pillow use and cervical posture maintenance throughout the follow-up period. Clinical evaluation was performed at baseline, 6 months, and 12 months using validated outcome measures for cervical pain, functional impairment, and sleep quality. Pain intensity was assessed using the Visual Analog Scale (VAS), a widely accepted unidimensional tool that quantifies subjective pain perception on a 0-10 scale, where higher scores indicate greater intensity [5]. Functional disability related to cervical spine function was evaluated using the Neck Disability Index (NDI), a 10-item questionnaire that measures the impact of neck pain on daily activities, with a total score ranging from 0 (no disability) to 50 (maximum disability). The NDI has shown strong reliability and validity in cervical pain populations [6]. Sleep quality, a common comorbidity in cervicgia, was measured with the Pittsburgh Sleep Quality Index (PSQI), which assesses subjective sleep quality over a one-month interval across seven components, generating a global score from 0 to 21; scores >5 suggest poor sleep quality [7]. All assessments were administered by trained clinicians blinded to the age group of the participants.

MagniStretch® Pillow

The intervention consisted of the use of the MagniStretch® Pillow, a CE-marked Class I medical device (Directive 93/42/EEC; Regulation EU 2017/745) certified for ergonomic and

therapeutic use in cervical support. The pillow features a patented dual-layer design that includes a Memoform® viscoelastic foam surface for adaptive contouring and pressure relief, and an underlying EliaSoft® layer for stable anatomical support. The unique inclination of internal slabs is engineered to generate a passive stretching effect on the cervical spine from the shoulders toward the occiput, facilitating vertebral decompression during sleep. The pillow is reversible and is designed to accommodate different body types with variable height profiles: size M (13 cm) and size L (15 cm), corresponding to cervical-shoulder anatomical ratios. Thermal comfort is ensured through the use of MagniCool® fabric and a 3D breathable mesh band, which demonstrated twice the heat dissipation efficiency compared to standard textiles according to UNI EN 14058. The materials used are OEKO-TEX® STANDARD 100 certified (Class I - suitable for baby articles), ensuring the absence of harmful substances and compliance with environmental safety standards (Certificate No. 0904046.O, valid through 2026). Laboratory tests confirmed anatomical alignment, breathability, and pressure distribution properties in accordance with clinical ergonomic standards.

Statistical Analysis

All statistical analyses were performed using SPSS (version 28.0.0.1; IBM SPSS, Chicago, IL). Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were reported as mean $\pm$ Standard Deviation (SD) and range (min-max), while categorical variables were expressed as frequencies and percentages. Normality of continuous data was assessed using the Shapiro-Wilk test. Clinical outcomes (VAS, NDI, and PSQI) were compared across time points (baseline, 6 months, and 12 months) using repeated-measures ANOVA. When significant, Bonferroni post-hoc corrections were applied for pairwise comparisons. Inter-group comparisons among age-based strata (20-35, 36-50, >50 years) were conducted using one-way ANOVA with Tukey's HSD test for post-hoc analysis. A p-value of <0.05 was considered statistically significant. Effect sizes (Cohen's d or partial eta squared) were calculated to quantify the magnitude of change where appropriate.

Results

Five patients were excluded from the study due to not meeting the inclusion criteria: two patients had a history of cervical disc herniation with radiculopathy, one had undergone previous cervical spine surgery, one presented with systemic inflammatory arthritis (rheumatoid arthritis), and one had a recent vertebral fracture. A total of 70 patients completed the 12-month follow-up and were included in the final analysis. The study population was stratified into three age groups: 20-35 years (n=23), 36-50 years (n=24), and >50 years (n=23), with a balanced distribution of sex and comparable baseline characteristics across groups (Table 1).

Age Group	Number of Patients	Mean Age ± SD (range)	Sex (M / F)	Height (cm) ± SD (range)	Weight (kg) ± SD (range)	BMI (kg/m²) ± SD (range)
Group 1	23	28.9 ± 4.2 (20-35)	11-Dec	171.3 ± 6.9 (160-183)	68.5 ± 8.4 (55-85)	23.4 ± 2.5 (19.1-28.5)
Group 2	24	43.7 ± 4.0 (36-50)	13-Nov	168.2 ± 6.7 (158-180)	73.2 ± 7.9 (60-88)	25.9 ± 2.4 (21.3-29.6)
Group 3	23	61.8 ± 6.4 (51-75)	13-Oct	166.1 ± 7.1 (154-179)	75.8 ± 9.1 (60-93)	27.5 ± 2.8 (22.4-31.9)

Table 1: Demographic characteristics of patients with cervical pain, stratified by age group. Data are presented as mean ± Standard Deviation (SD), with ranges in parentheses. The variables include the number of patients, sex distribution, age, height, weight, and Body Mass Index (BMI). The stratification includes three groups: 20-35 years, 36-50 years, and >50 years.

At baseline, all groups reported moderate to severe neck pain, with mean VAS scores ranging from 6.9 to 7.2, NDI scores between 40 and 44, and PSQI scores averaging above 9. At the 6-month follow-up, slight improvements were observed across all clinical parameters, but changes did not reach statistical significance in most comparisons ($p > 0.05$). However, by 12 months, all three age groups exhibited statistically significant improvements in VAS, NDI, and PSQI scores compared to baseline ($p < 0.01$). Notably, the >50 years group demonstrated the greatest clinical gains, with a mean VAS reduction of 4.0 points, a 50% improvement in NDI scores, and a decrease of nearly 5 points in PSQI, all of which were statistically superior to the younger age groups ($p < 0.01$). All data are shown in (Table 2).

Age Group	VAS Baseline (mean ± SD)	VAS 6 Months	VAS 12 Months	NDI Baseline (mean ± SD)	NDI 6 Months	NDI 12 Months	PSQI Baseline (mean ± SD)	PSQI 6 Months	PSQI 12 Months
Group1	6.9 ± 1.1	6.5 ± 1.0	5.0 ± 1.2	40 ± 6	38 ± 5	30 ± 4	9.1 ± 1.3	8.5 ± 1.1	6.4 ± 1.2
Group 2	7.0 ± 1.0	6.3 ± 1.1	4.6 ± 1.0	42 ± 5	39 ± 4	28 ± 3	9.3 ± 1.2	8.2 ± 1.0	5.9 ± 1.1
Group 3	7.2 ± 1.0	5.8 ± 1.2	3.2 ± 0.9	44 ± 7	35 ± 6	22 ± 5	9.6 ± 1.4	7.8 ± 1.0	4.7 ± 1.0

Table 2: Clinical outcomes for cervical neck pain by age group at baseline, 6 months, and 12 months. Values are reported as mean ± Standard Deviation (SD). Outcome measures include the Visual Analog Scale (VAS) for pain intensity, the Neck Disability Index (NDI) for functional impairment, and the Pittsburgh Sleep Quality Index (PSQI) for sleep quality. While no statistically significant improvement was observed at 6 months, all groups showed significant changes at 12 months, with the >50 years group demonstrating the most pronounced improvements across all measures.

Discussion

This 12-month prospective study contributes meaningful evidence supporting the use of a biomechanically engineered cervical pillow, the MagniStretch® Pillow, as a non-pharmacological adjunct in the management of chronic cervical pain. The data clearly indicate that sustained use of the device led to significant reductions in pain intensity (VAS), disability (NDI), and sleep disruption (PSQI), with the greatest improvements observed in patients aged over 50 years. These findings are not only consistent with previous short-term studies but also extend the timeline of benefit, suggesting cumulative neuromuscular adaptation and postural correction. The lack of statistically significant change at the 6-month follow-up, followed by marked improvement at 12 months, underscores the importance of treatment duration when evaluating passive ergonomic interventions. Unlike pharmacological or procedural treatments that may offer immediate effects, interventions such as orthopedic pillows function through gradual modification of

sleep posture, cervical spine unloading, and reduction of nocturnal muscle activation, as theorized by Gordon et al. [4] and further explored by Puntumetakul et al. [3]. These delayed but sustained benefits highlight the value of patient adherence and long-term compliance in realizing therapeutic outcomes. Moreover, the improved sleep quality observed via PSQI scores adds to the growing body of evidence that ergonomically optimized pillows can modulate not just musculoskeletal pain but sleep-related parameters as well. Poor sleep quality is both a consequence and an aggravator of chronic pain, creating a bidirectional feedback loop that can perpetuate disability and daytime fatigue. By optimizing cervical support and decreasing nociceptive stimuli during rest, the MagniStretch® Pillow likely disrupts this cycle, allowing for restorative sleep and improved central pain modulation. Biomechanically, the pillow’s design offers a unique contribution to current ergonomic tools. Its internal slab inclination mimics a mild spinal traction mechanism, an effect previously

shown to reduce intervertebral compression and alleviate tension in adjacent soft tissues. This is particularly relevant in the older age group, where degenerative disc changes, facet joint stiffness, and kyphotic drift may predispose patients to chronic inflammation and structural imbalance. As shown by Adams et al. [8], such degenerative changes alter mechanical loading patterns, and passive decompression may realign forces and reduce load asymmetry during sleep. In addition to symptom reduction, improvements in functional capacity as measured by the NDI are particularly notable. A mean reduction of over 20 points in the >50 group exceeds the Minimum Clinically Important Difference (MCID) established in the literature, emphasizing real-world impact. Similar findings have been reported in trials of custom or orthopedic pillows [4,9], but few studies have included long-term data or age-based subgroup analysis. From a health economics standpoint, interventions like the MagniStretch® Pillow offer potential value by reducing dependence on medications, physical therapy sessions, and costly imaging or injections. While this study did not formally assess cost-effectiveness, the results support its consideration as a first-line ergonomic therapy in chronic cervicalgia, especially in aging populations. This study has several notable strengths. First, it is among the few investigations to assess the long-term effects of a biomechanically designed cervical pillow over a 12-month period, offering valuable insights into sustained clinical outcomes. Second, the inclusion of multiple validated outcome measures, VAS for pain, NDI for functional disability, and PSQI for sleep quality, provides a comprehensive evaluation of the intervention's impact on key domains affected by chronic neck pain. Third, the stratification of participants by age allowed for meaningful subgroup analyses, revealing important age-dependent differences in therapeutic response. Fourth, the study included a relatively homogeneous patient population with well-defined inclusion and exclusion criteria, enhancing internal validity. Finally, the use of a single, standardized ergonomic device with certified medical and safety compliance ensures reproducibility and applicability in clinical settings. Despite its strengths, this study has several limitations that should be acknowledged. First, the lack of a randomized controlled design limits the ability to establish causality between the intervention and observed outcomes; without a control or placebo group, it is not possible to rule out the influence of natural symptom fluctuation, placebo effects, or other confounding factors. Second, although outcome measures were validated and commonly used in clinical research, they were all self-reported, potentially introducing subjective bias. Third, the study did not include objective biomechanical or imaging-based assessments of cervical alignment or muscular activity, which could have provided additional insights into the mechanism of action. Fourth, adherence to pillow use was not monitored or quantified, and variations in patient compliance could have affected the results. Finally, the relatively small sample size,

particularly after age-stratification, may have limited the statistical power to detect smaller differences between groups or additional interactions. Future studies should consider a randomized, controlled design with larger samples and multimodal assessment strategies to confirm and expand upon these findings.

Conclusion

The results of this 12-month prospective study suggest that the use of the MagniStretch® Pillow, a certified ergonomic medical device, is associated with significant reductions in cervical pain intensity, disability, and sleep disturbance in patients with chronic neck pain. These benefits became statistically and clinically evident after sustained use, particularly in patients over 50 years of age, indicating a potential age-dependent therapeutic effect. The integration of biomechanical traction and anatomical cervical support during sleep may represent a safe, non-invasive, and accessible adjunct to standard care for managing chronic cervicalgia. Further randomized controlled trials with larger samples and objective outcome measures are warranted to confirm these findings and explore underlying mechanisms.

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