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Original Article

Changes in neck pain and somatic symptoms before and after the adjustment of the pillow height

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Abstract. [Purpose] The purpose of this study was to determine whether strict adjustment of the pillow height using the Set-up for Spinal Sleep method improves clinical outcomes like neck pain and somatic symptoms. [Participants and Methods] A total of 84 participants with chief complaints of stiff shoulders and neck pain were evaluated using the numerical rating scale and the Somatic Symptom Scale-8. Questionnaires were used to collect data at the baseline, after two weeks, and after three months of adjusting the pillow height. [Results] Forty-two participants (50%) achieved the minimal clinically important difference for neck pain with a decrease of three points or higher in the numerical rating scale. The baseline neck pain scores were significantly higher in the group that achieved the minimal clinically important difference. The three-month change in neck pain and the Somatic Symptom Scale-8 was significantly greater in participants who were satisfied with treatment. There was a significant positive association between improvement in the numerical rating scale score and improvement in the Somatic Symptom Scale-8 at three months. [Conclusion] Strict adjustment of the pillow height using the Set-up for the Spinal Sleep method significantly improved both physical neck pain and somatic symptoms related to psychological and social problems.
Key words: Pillow, Neck pain, Somatic symptoms

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INTRODUCTION

Neck pain causes significant adverse physical and psychological effects and has a high prevalence worldwide; thus, social measures against this disease remain needed[1, 2)]. Cervical spine alignment is strongly associated with neck pain and it has been suggested that inadequate pillow support of the neck and shoulders during sleep can induce neck pain by altering cervical spine alignment, resulting in poor sleep quality[3–6)].

The term "Cervical Pillow" was first coined by the orthopedic surgeon Ruth Jackson in 1949, who designed the cervical contour pillow and studied its use in the improvement of neck pain[7)]. Since 1990, the term "Cervical Pillow" has been widely used[8, 9)]. However, while there are multiple reports on contour pillows, whether they reduce neck pain, sleep quality, and other clinical outcomes better than ordinary pillows is controversial, and the evidence to date remains insufficient[10–13)].

In 2021, Radwan et al. conducted a systematic review to determine the level of evidence of different pillow parameters (material, height, shape, and thermal properties) for sleep quality, spinal alignment, and waking symptoms[14)]. The review

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found that a latex pillow material, a contoured pillow design, a 7–11 cm pillow height, and a cooling surface had moderate evidence for improving sleep quality and spinal alignment, and decreasing sleep-related pain[14]. In the same year, Chun-Yiu et al. published a systematic review and meta-analysis on the effects of different pillow types on neck pain, waking symptoms, neck disability, sleep quality, and spinal alignment[15]. They assessed parameters related to the design of the pillow, i.e., shape, height, and material, and reported that spring and rubber pillows are effective in reducing neck pain, waking symptoms, and disability and in enhancing pillow satisfaction in patients with chronic neck pain. In addition, they reported that cervical alignment is not changed by pillow material, but rather by pillow shape and height[15].

On the other hand, we believe that the most important parameter is pillow height, which should be adjusted to the physique of each patient using our previously developed Set-up for Spinal Sleep (SSS) method[16–18], and that other parameters can be subsequently determined once pillow height is set (i.e., firmness and material to maintain the adjusted pillow height). In our opinion, the surface of the pillow should be flat to allow patients to turn over smoothly, and therefore, contour or curvature is unnecessary. According to our previous data, the physique (height and weight) of adult patients had a high positive correlation with adjusted pillow height using the SSS method, with a multiple correlation coefficient of 0.79.

A retrospective study of 410 patients with cervical spine diseases who underwent pillow adjustment using this method revealed a significant improvement in subjective symptoms such as neck pain[18].

It has been suggested that sleep disturbance mediated by neck pain not only causes fatigue but also leads to psychiatric disorders, such as somatization. The Somatic Symptom Scale-8 (SSS-8) is a relatively short questionnaire that has been used in various clinical studies to assess common somatic symptoms and has well-established psychometric properties[19].

The purpose of this study was to longitudinally analyze whether strict pillow height adjustment using the SSS method improves clinical outcomes such as neck pain and somatic symptoms assessed by the SSS-8. In addition, we aimed to identify and further analyze any factors related to neck pain improvement and treatment satisfaction. Ultimately, we aimed to verify the usefulness of the SSS method with these analyses.

PARTICIPANTS AND METHODS

Patients who came to the hospital between April 1, 2016, and July 31, 2016, with a chief complaint of stiff shoulders and neck pain were evaluated using the SSS-8. The eligibility criteria were as follows: 1) patients who visited the hospital complaining of neck pain or stiff shoulders with or without radiating upper extremity pain, with a score of 8 or higher on the SSS-8; 2) patients who provided written consent; and 3) patients who understood how to adjust the pillow and were able to use it as instructed. The third inclusion criterion was determined by interviewing patients before they started using the pillow. If the patient consistently awoke with their head on the pillow, it was judged that they understood how to properly adjust and use the pillow.

The exclusion criteria were as follows: 1) patients who wished to receive medication, rehabilitation, or physical therapy at the time of participation in this study; 2) patients who had obvious findings of cervical myelopathy and indication for surgical treatment, and 3) patients judged by the physician in charge to be inappropriate for participation in this study.

Participants were instructed to not receive any additional medication, rehabilitation, physical therapy, or orthotic therapy during their participation in the study. If the participant was already receiving medication from a previous physician, administration of the medication was continued at a fixed dosage. Participants were not instructed on how to adjust their posture during the day, except when asked. Participation in the study was stopped if the participant did not wish to continue the study or if the participant or the research physician judged that concomitant therapy, such as medication, was necessary due to severe symptoms such as pain.

Pillows adjusted by the SSS method were prescribed to participants who met the eligibility criteria described above. Information including the numerical rating scale (NRS) and SSS-8 for neck pain was collected by questionnaires at baseline and after 2 weeks and 3 months of pillow use. Ethical approval was obtained from the institutional review board of Kurashiki Medical Center (approval number 219) and written informed consent was obtained from each patient before participation in the study.

The SSS method (Fig. 1) was developed at 16 Gou Orthopedic Clinic and involved three steps. First, the pillow height was adjusted so that the participant's head and trunk were aligned parallel to the surface of the bed in the lateral position. Second, the cervical spine was held at an anterior tilt angle of approximately 15° from the bed surface in the supine position. Third, we checked how smoothly the participant was able to turn over at different pillow heights, by adjusting the pillow height in 5-mm increments and decrements. The pillow height that enabled the participant to turn over most smoothly was considered optimal[18]. The smoothness of turning over was determined by two factors. The first factor was the subjective judgment of the patient. The patient was instructed to cross both arms in front of the chest, flex both knees about 60 degrees, and rotate twice to the left and right without recoil. The patient then subjectively judged whether they were able to rotate without effort. The second factor was the objective judgment of the evaluator. The evaluator visually judged whether the patient's left or right shoulder and pelvis were moving in synchrony[18]. The relationship between features associated with the motion of turning over and smoothness of turning over at different pillow heights has been previously studied using a 3D optical motion capture system. As a result of this analysis, differences in the numerical values for some features, such as the ratio of high frequency

components, were identified according to the smoothness of turning over[17]. Based on this result, we visually evaluated the smoothness of turning over.

The same material was used for all handmade pillows, and the adjusted pillow heights were measured and determined using the SSS method (Fig. 2). The materials used were Japanese entrance mats (CAINZ Co., Saitama, Japan), composed of 100% polyester on the front, polyester and cotton on the back, and non-slip vinyl chloride resin, with a length, width, and height of 90 cm, 60 cm, and 1 cm, respectively, and 100% cotton towelket (sold by the Japan Towel Wholesalers Association, size: 140 cm ×190 cm). The Japanese entrance mats were folded in thirds to create the base of a pillow 30-cm long, 60-cm wide, and 3-cm high. The towelket was folded in and set on the mat bellows, and the surface was flattened. The height was adjusted by increasing and decreasing the surface layers one by one. As the average head weighs 4 kg, the pillow was then compressed by hand (simulating a 4-kg weight) to achieve a firmness that would prevent the pillow from sinking by more than 5 mm under the weight. Compression was measured using an automatic food scale and sinkage in pillow height was measured with a ruler in 1 mm increments.

Somatization was assessed using the Japanese version of the SSS-8, a self-administered questionnaire. The SSS-8 was developed as an abbreviated 8-item version of the Patient Health Questionnaire-15 to assess the presence and severity of common somatic symptoms[19]. The SSS-8 assesses how much the respondent has been bothered by the following somatic symptoms during the past 7 days: 1) stomach or bowel problems, 2) back pain, 3) pain in the arms, legs, or joints, 4) headaches, 5) chest pain or shortness of breath, 6) dizziness, 7) feeling tired or having low energy, and 8) having trouble sleeping. Each item is scored from 0 (not at all) to 4 (very much)[20]. One of the authors translated the English version of the SSS-8 into Japanese[21]. The Japanese version of the SSS-8 has been linguistically and psychometrically validated[22]. The total SSS-8 score (0–32) was categorized, as in Gierk et al.[20], into the following five groups: no to minimal (0–3); low (4–7); medium (8–11); high (12–15); and very high (16–32).

Changes over time in neck pain, measured by NRS, and SSS-8 scores were analyzed using the Jonckheere–Terpstra test to determine whether pillow treatment relieved clinical symptoms.

The clinical outcome of this study was the achievement of the minimal clinically important difference (MCID) in neck pain NRS and patient satisfaction at the end of 3-month treatment period. The MCID for neck pain NRS was defined as 3 points or more, based on previous reports. At the end of treatment, patients rated their satisfaction on a 4-point scale (1=satisfied, 4=unsatisfied); patients who answered 1=satisfied were defined as the satisfied group.

To extract factors associated with MCID achievement, baseline characteristics were compared. To examine whether the achievement of MCID could be predicted at baseline, only baseline data were used in this analysis. Comparisons between the two groups were analyzed using the t-test for continuous data and the χ^2 test for categorical data. In addition, a logistic regression analysis was performed with MCID achievement as the dependent variable.

We hypothesized that the effect of treatment during the 3-month period would be reflected in the level of patient satisfaction; therefore, the change in NRS and SSS-8 during the 3-month period was also included in the analysis, and logistic regression analysis was performed with patient satisfaction as the dependent variable.

JMP® Pro 16.0.0 (SAS Institute Japan Ltd., Tokyo, Japan) and IBM SPSS Statistics 26 (IBM Japan, Ltd., Tokyo, Japan) were used for statistical analysis. Two-tailed tests were performed at a significance level of 0.05.

RESULTS

The baseline characteristics of the 84 patients who participated in this study are shown in Table 1. The mean values of neck pain NRS at baseline, 2 weeks, and 3 months were 6.8, 5.1, and 4.1, respectively, while the corresponding SSS-8 scores were 13.2, 9.9, and 8.2, respectively (Jonckheere–Terpstra test; $p<0.001$ for both).

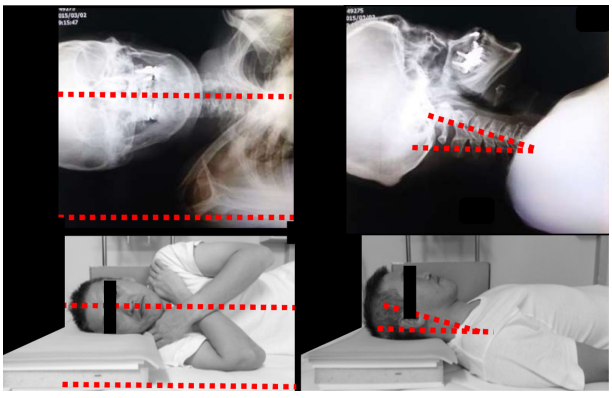

Fig. 1. Set-up for Spinal Sleep method (SSS method).

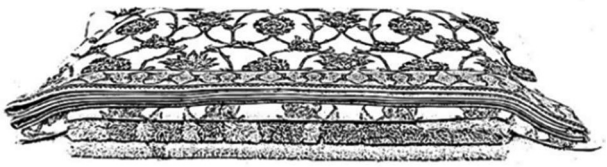

Fig. 2. Handmade pillow. The pillow heights were measured and determined using the Set-up for Spinal Sleep method (SSS method) for each patient.

A total of 42 patients (50%) achieved the MCID for neck pain NRS, with a decrease of 3 points or more. Table 2 shows the results of the comparison of the baseline data according to whether MCID was achieved. Baseline neck pain NRS scores were significantly higher in the group that achieved MCID.

Age- and gender-adjusted logistic regression analysis showed a significant positive association between MCID achievement and baseline neck pain NRS, with an odds ratio of 2.02 and a 95% confidence interval (CI) of 1.42–2.88.

Table 3 shows the results of the comparison of baseline data and changes in neck pain NRS and SSS-8 over 3 months according to patient satisfaction. The 3-month change in neck pain NRS and SSS 8 was significantly greater in the satisfied group.

Table 1. Baseline characteristics of study participants

	n=84
Age, years	50.1 ± 14.0
Gender, female, n (%)	60 (71.4)
BMI, kg/m^2	21.7 ± 3.2
Neck pain, NRS	6.8 ± 1.9
SSS-8	13.2 ± 4.8
Disease period, months	103.8 ± 124.8
Smoking, n (%)	5 (5.9)

Values are presented as mean ± standard deviation unless otherwise specified.
BMI: body mass index; NRS: numerical rating scale; SSS-8: Somatic Symptom Scale-8.

Table 2. Comparison of baseline data according to achievement of MCID

	MCID (+)	MCID (−)	
Participants, n	42	42	
Age, years	49.8 ± 13.8	50.5 ± 14.4	
Gender, female, n (%)	30 (71.4)	29 (69.1)	
BMI, kg/m^2	21.8 ± 3.4	21.5 ± 3.0	
Neck pain, NRS	7.8 ± 1.4	5.9 ± 2.2	***
SSS-8	13.6 ± 4.9	12.9 ± 4.9	
Disease period, months	94.2 ± 123.6	113.5 ± 126.8	
Smoking, n (%)	3 (7.1)	2 (4.7)	

Values are presented as mean ± standard deviation unless otherwise specified.
MCID: minimal clinically important difference; BMI: body mass index; NRS: numerical rating scale; SSS-8: Somatic Symptom Scale-8.
***p<0.001.

Table 3. Comparison of baseline data and changes in neck pain NRS and SSS-8 over 3 months, grouped by the presence or absence of satisfaction

	Satisfaction (+)	Satisfaction (−)	
Participants, n	31	53	
Age, years	53.0 ± 12.6	48.5 ± 14.7	
Gender, female, n (%)	23 (74.2)	36 (67.9)	
BMI, kg/m^2	21.9 ± 4.0	21.5 ± 2.7	
Neck pain, NRS; baseline	7.1 ± 2.2	6.7 ± 1.8	
Change in neck pain, NRS; baseline–3 months	4.2 ± 2.7	1.8 ± 2.3	***
SSS-8; baseline	13.2 ± 5.6	13.3 ± 4.5	
Change in SSS-8; baseline–3 months	7.6 ± 4.8	3.5 ± 3.9	***
Disease period, months	110.4 ± 133.1	100.0 ± 120.8	
Smoking, n (%)	2 (6.5)	3 (5.7)	

Values are presented as mean ± standard deviation unless otherwise specified.
BMI: body mass index; NRS: numerical rating scale; SSS-8: Somatic Symptom Scale-8.
***p<0.0001.

In the age- and gender-adjusted logistic multivariate regression analysis with patient satisfaction as the dependent variable, there was a significant positive association between improvement in neck pain NRS score and improvement in SSS-8 at 3 months. The odds ratio for neck pain NRS was 1.36, with a 95% CI of 1.09–1.73, and the odds ratio for SSS-8 was 1.25, with a 95% CI of 1.08–1.48.

DISCUSSION

This was an observational study in which all patients used pillows personalized through our SSS method, and neck pain and somatic symptoms were evaluated longitudinally. Pillow treatment significantly improved neck pain and somatic symptoms.

Since Ruth Jackson first coined the term cervical pillow in 1949[7], there has been much discussion about the effects of pillows of various materials, shapes, heights, and hardness on the cervical spine. There had been no clear evidence for these effects for some time[13], but new information was provided in 2021. In their systematic review and meta-analysis, Chun-Yiu et al. analyzed the relationship between pillow design and selection in terms of the following five common concerns: 1) neck pain and waking symptoms, 2) neck disability, 3) pillow satisfaction, 4) sleep quality, and 5) spinal alignment[15]. Among these concerns, neck pain and pillow satisfaction were the most relevant to this study.

In the present study, there was a significant positive association between neck pain NRS at baseline and achieving MCID in neck pain NRS. This result suggests that pillow treatment may have a strong effect on pain relief in patients with severe neck pain at baseline.

In the meta-analysis by Chun-Yiu et al., nine high-quality studies were analyzed, of which three investigated the relationship between neck pain and various pillows[15]: Helewa et al. used a foam pillow and reported a standardized mean difference (SMD) of −0.121 (95% CI [−0.608,0.366], p<0.625)[23]; Fazli et al. used a latex pillow and reported a SMD of 0.744 (95% CI [0.121,1.367], p=0.019)[24]; and Vanti et al. used a spring pillow and reported a SMD of −0.577 (95% CI [−0.964, −0.189], p<0.004)[25]. SMD is the difference between two estimated means divided by the estimated standard deviation and is used to integrate the results of studies that measure the same continuous variable on different scales across studies, such as pain. Based on Cohen's interpretation, a SMD of 0.2 represents a small effect, SMD of 0.5 represents a moderate effect, and SMD of 0.8 represents a large effect[26]. Thus, the results of Fazli et al. and Vanti et al. can be interpreted as statistically significant improvements in neck pain, with large and moderate effects, respectively[24, 25].

However, the authors believe that the pillows used in these studies have some inherent problems. Fazli et al. claimed that the ergonomic latex pillow used in their study had material properties that supported the neck and restored cervical kyphosis, and that it ergonomically supported both supine and side-lying positions[24]. However, the paper did not specifically indicate how the supine and lateral positions were supported when the one-size pillow was used by participants with different physiques. The pillow used by Vanti et al. was deemed appropriate for the majority of the population, referring to the anthropometric parameter average width of one shoulder[25]. However, an average size that fits the majority of the population does not necessarily mean that it fits every individual's body physique optimally. In our study, we assumed that the appropriate pillow height would be different for each individual; thus, we measured and tailored the pillow height to each individual.

Regarding factors related to patients' treatment satisfaction, there were no significant differences in baseline characteristics, and there was a significant positive association between improvement in neck pain NRS score and improvement in SSS-8 at 3 months. The results showed that both the reduction in neck pain and improvement in somatic symptoms were related to the subjective satisfaction of the patients.

The meta-analysis conducted by Chun-Yiu et al. also found that spring and rubber pillows are effective in increasing pillow satisfaction in patients with chronic neck pain[15]. Three studies investigated satisfaction with pillow use in this meta-analysis: Gordon et al. reported a SMD of 2.804 (95% CI [1.876,3.732], p<0.001) for latex pillows and a SMD of 2.600 (95% CI [1.886, 3.314], p<0.001) for polyester pillows[27]; Lee et al. reported a SMD of 1.024 (95% CI [0.469,1.579], p=0.000) for polyester pillows[28]; and Vanti et al. reported a SMD of −1.012 (95% CI [0.565, 1.458], p<0.001) for latex pillows[25]. Thus, a statistically significant improvement in satisfaction was observed in all studies.

However, Gordon et al. described their pillows as "Dunlopillo high-profile latex pillows" (Hanes Australasia, Pacific Brands Ltd., Hartwell, Australia) and "Tontine Easy Care" polyester pillows (Tontine Bedding Australia), but did not provide detailed information on their shape, height, or firmness[27]. Since the pillows used in their study were made of soft materials, the authors predict that the shape and height of the pillows would change easily during sleep. Therefore, it is unclear what pillow parameter improved the satisfaction level.

The polyester pillow used by Lee et al. was referred to as a functional cervical pillow, compartmentalized into a head base support structure, two cores, a cervical support structure, and two side flaps[28]. This design concept supports the cervical curve in both the supine and prone positions. In addition, the authors claimed that the bilateral side flaps were intended to protect the shoulders from pressure while sleeping in the supine position, and to support the curve of the neck to prevent an abnormal neck alignment in the prone position[28]. We consider that humans do not sleep only in the supine and lateral positions, but also alternate between the two positions. Therefore, we believe that a flat structure is the most suitable for allowing people to smoothly turn over, and that compartmentalized pillows such as the functional cervical pillow have not been proven to allow for smooth turning.

The external structure of the spring pillow by Vanti et al. was made of viscoelastic polyurethane, and the interior contained 60 independent springs[25]. Spring pillows utilize the well-known properties of viscoelastic materials and can be successfully adapted to the shape of an individual; the spring pillow used in their study was 410 mm wide, 700 mm long, and 120 mm thick. In the present study, the heights of individual pillows measured by the SSS method ranged from 55 to 85 mm. Assuming that the participants had an average body shape, we consider a pillow height of 120 mm to be abnormally high. In addition, we think that if the viscoelastic polyurethane of the external structure collapsed and lowered the entire pillow, the height change may pose a risk of destabilizing the cervical spine.

Ruth Jackson and other orthopedic surgeons in general consider poor cervical spine alignment to be one of the main causes of neck pain[7]. Chun-Yiu et al. also addressed neck pain and spinal alignment in their systematic review[15].

Although cervical spine alignment was not directly analyzed in this study, since our SSS method includes the concept of cervical spine alignment adjustment, it is also discussed below. The aforementioned meta-analysis also showed that the use of rubber or feather pillows may not change cervical alignment in the side-lying position; rather, the shape and height of the pillow may significantly change cervical alignment. Ultimately, they concluded that "the effects of different shapes and heights of pillows on the outcomes and alignment of the cervical spine remain unclear, although the stability of the cervical segment in the side-lying position appears to be satisfactory. The pillow design that provides the best cervical angle in the supine position is still unknown". Jia-Xing Lei et al. investigated limitations of the current pillow height evaluation studies and summarized the research progress in this field and proposed several quantitative and objective indicators for pillow height evaluation, including cervical spine alignment, body dimension, contact pressure, and muscle activity[29]. This was an important study in terms of highlighting the importance of pillow height adjustment. In this study the authors stated that "Dynamic adaptation to the pillow height refers to a staged fine-tuning of the pillow height, which can correct the cervical spine step-by-step, based on a small adjustment in the pillow height instead of a large change"[29]. However, we believe that pillow height can be tailored optimally for every individual according to their physique and that this can be used to maintain a certain cervical alignment. Therefore, cervical spine alignment can be corrected directly without undergoing step-by-step adaptation using small adjustments.

In our history of pillow development leading up to this study, we have empirically studied the design of pillows for outpatients to improve cervical symptoms since 1971. After measuring supine X-ray images taken with a pillow in patients whose symptoms had improved, the cervical tilt angle in the supine position was found to be approximately 15°; based on this fact, we developed a pillow height adjustment method (the SSS method) in our previous study[18]. In this study, this SSS method was used to confirm cervical alignment and a cervical tilt angle of 15° in the supine position was used as an index.

The results of this study showed that the SSS method was useful, since we found a significant positive association between improvement in clinical symptoms and pillow satisfaction. The results also indirectly showed the usefulness of our index of 15° for adjusting the cervical tilt angle in the supine position. Most researchers select pillows for their studies from commercially available products or semi-customized pillows with theoretically ideal concepts; however, these pillows are limited to a certain form, height and materials. In other words, one pillow contains multiple parameters. Therefore, when a pillow is unsuitable for a participant, it is difficult to determine whether the cause is a matter of material, form, or height. The SSS method gives the highest priority parameter to height adjustment, and uses a material with a shape that allows for height adjustment in mm and a firmness that maintains the determined height (limiting sinkage to within 5 mm), thus solving the adjustment problem described above.

The following two points are the limitations of this study. The first and major limitation was the study design. This study was a one-arm, before-and-after comparison study, and the lack of a control/comparison group limited the interpretation of the effects. As such, we did not compare pillows with the same height but different shapes, or pillows with different heights or cervical tilt angles. Furthermore, the single approach was based on our own evidence for the SSS method. Therefore, further studies comparing this method against other parameters/approaches are required to provide more robust results. Second, posture during sleep has not been objectively evaluated because it is only subjectively assessed by the patient. Since it has been suggested that the smoothness of turning and posture during sleep are related to pain relief and satisfaction, we plan to conduct an objective evaluation in the future with a view to monitoring pillow use (video, sensors, etc.).

In conclusion, pillow height adjustment using the SSS method significantly improved not only physical neck pain but also somatic symptoms related to psychological and social issues. Moreover, a cervical tilt angle in the supine position of approximately 15° may be ideal. We believe this simple, non-invasive, permanent, and low-cost method of pillow height adjustment may prove useful in the treatment of cervical spine symptoms; however, further studies with a more robust study design are required to validate these findings.

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Conflict of interest

SY is a shareholder and a chief executive officer of YAMADA SHUORI Pillow Research Institute Co., Ltd. HO received grants from Teijin Pharma Limited, Pfizer Inc., and Fujifilm Medical Co., Ltd. and grants and personal fees from Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Chugai Pharmaceutical Co., Ltd., AYUMI Pharmaceutical

Corporation, Sompo Holdings, Inc., MS&AD InterRisk Research & Consulting, Inc., Inotech Co., Ltd., NUVASIVE Japan, Medical Data Scientist, and Medical AI Device Development Organization, The Association for Preventive Medicine of Japan, MTG Co., Ltd., and Shionogi & Co., Ltd. that were unrelated to the submitted work. KM is a shareholder and an adviser of Trunk Solution CO., Ltd. He submitted work and received a research grant from the Ministry of Health, Labour and Welfare, grant support from Sumitomo Dainippon Pharma Co., Ltd. and Okamura Corporation, and grant support, including personal fees, from Nippon Zoki Pharmaceutical Co., Ltd., Ono Pharmaceutical Co., Ltd., Chugai Pharmaceutical Co., Ltd., AYUMI Pharmaceutical Corporation, Sompo Holdings, Inc., MS&AD InterRisk Research & Consulting, Inc., Inotech Co., Ltd., NUVASIVE Japan, Medical Data Scientist and Medical AI Device Development Organization, The Association for Preventive Medicine of Japan, MTG Co., Ltd., and Shionogi & Co., Ltd. He also received lecture fees from Eli Lilly Japan K.K., Astellas Pharma Inc., TOTO Ltd., Eisai Co., Ltd., Pfizer Japan Inc., Hisamitsu Pharmaceutical Co., Inc., Janssen Pharmaceutical K.K., Kaken Pharmaceutical Co., Ltd., and Teijin Pharma Limited. Furthermore, he received lecture and advisory fees from Murata Manufacturing Co., Ltd. that were unrelated to the submitted work. The other authors have no conflicts of interest directly relevant to the content of this article.

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