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Assessment of the Sheffield Support Snood, an innovative cervical orthosis designed for people affected by neck muscle weakness

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Sheffield Support Snood, an innovative cervical orthosis designed for people affected by neck muscle weakness. The orthosis is designed to be adaptable to individual users. The main requirements of an orthosis to be used for neck muscle weakness, which is adaptable to different anatomical planes.

Abstract

Background: This study aimed at quantifying the biomechanical features of the Sheffield Support Snood, a cervical orthosis specifically designed for patients with neck muscle weakness. The orthosis is designed to be adaptable to a patient’s level of functional limitation using adjustable removable supports, which contribute support and restrict movement only in desired anatomical planes.

Methods: The snood was evaluated along with two commercially available orthoses, the Vista and Headmaster, in a series of flexion, extension, axial-rotation and lateral flexion movements. Characterization was performed with twelve healthy participants with and without the orthoses. Two inertial-magneto sensors, placed on the forehead and sternum, were used to quantify the neck’s range of motion.

Findings: In its less supportive configuration, the snood was effective in limiting movements to the desired planes, preserving free movement in other planes. The Headmaster was only effective in limiting flexion. The range of motion achieved with the snood in its rigid configuration was equivalent (P > 0.05, effect size < 0.4) to that achieved with the Vista, both in trials performed reaching the maximum amplitude (range of motion reduction: 25%–34% vs 24%–47%) and at maximum speed (range of motion reduction: 24%–29% vs 25%–43%).

Interpretation: The Sheffield Support Snood is effectively adaptable to different tasks and, in its most supportive configuration, offers a support comparable to the Vista, but providing a less bulky structure. The chosen method is suitable for the assessment of range of motions while wearing neck orthoses and is easily translatable in a clinical context.

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2. Methods

2.1. Participants and protocol

Twelve healthy participants (5 females, 7 males, ages $26 \pm 2$ years, body mass index $23 \pm 3 \text{ kg/m}^2$) without any history of neck disorder or pain were involved in the study, which was approved by the Ethical Committee of the University of Sheffield (Sheffield, UK). Participants were informed about the protocol and signed a consent form prior to the acquisition sessions. The number of participants was chosen on the basis of a power analysis (probability 0.05, power level 95%) conducted using the values of ROM measured in a pilot study in which the same protocol was performed with and without orthoses by 6 healthy participants.

The experimental protocol included a series of active head movements (AHM): flexion (F), extension (E), right and left axial rotation (AR) and right and left lateral flexion (LF). The participants were requested to sit on a chair with a backrest that provided support for their thoracic spine and to maintain a trunk upright posture throughout the procedure. They were then asked to perform the head movement in one direction, come back to the reference position and maintain it for about three seconds before performing the movement in the opposite direction. Each movement was repeated six times: three asking the participants to reach the maximum amplitude and three to reach the maximum speed. Only the trial in which the highest value of amplitude/speed was achieved, among the three repetitions, was retained for further analysis.

The entire protocol was repeated by each participant while wearing each of the three investigated orthoses (SSS, HR and VA) and without wearing any orthosis to have a reference measure. The SSS can have several different configurations, according to the number of supports used. We chose to test it in the two configurations, according to the number of supports used. We chose to test it in the two configurations: (1) without supports (Fig. 1B) and (2) with supports (Fig. 1C).

Fig. 1. (A) Sheffield Support Snood; (B) Sheffield Support Snood with supports (from left to right: straight support, lateral support, jaw support and A-shaped support); (C) Headmaster cervical orthosis; (D) Vista cervical orthosis.
and both orthoses and movement orders were randomized to minimize fatigue or learning-related effects.

Two IMUs (OPAL, APDM, Inc., Portland, Oregon, USA) were located on the forehead and sternum of the participants using straps/dermatological patches (see Supplementary Fig. 1 in Appendix A). Each IMU included a tri-axial accelerometer, that was able to measure the three-dimensional components of the IMU linear acceleration, a tri-axial gyroscope to measure the three-dimensional components of the IMU angular velocity and a tri-axial magnetometer to provide an estimate of the sensor orientation. The signals were recorded at a sampling frequency of 128 samples/s.

2.2. Data processing

The acquired acceleration and angular velocity signals were low pass filtered using a 4th order zero-lag Butterworth filter with a cutoff frequency of 5 Hz (Luine & Veltink, 2005). Data processing was performed using custom procedures written in MATLAB R2013a (MATLAB, Mathworks Inc., Natick, MA, USA). The sensor orientation was then computed using a functional calibration approach (Duc et al., 2013b) and a quaternion-based algorithm that integrates the angular velocity (Favre et al., 2006). Details about the relevant experimental and data processing procedures are provided in Appendix A, together with their validation, which was performed using a stereophotogrammetric system as the gold standard. This validation showed the suitability of the methods chosen to estimate the IMU’s orientations for the purposes of this study and an excellent concordance between the angle curves measured by the two systems (see Supplementary Fig. 2 in Appendix A).

The differences between AHM performed with and without ROM were quantified for each orthosis and each movement using the ROM calculated from the sensor rotation angles, as estimated using the above-mentioned techniques. In addition, its percentage variation from the values obtained without orthosis was calculated as

\[
\% ROM_{NC} = \frac{ROM_{NC} - ROM_{C}}{ROM_{NC}} \times 100
\]

(1)

where \( ROM_{C} \) and \( ROM_{NC} \) are the difference between the maximum and minimum angle obtained by the participant while moving along a given direction in a given task, with and without cervical orthosis, respectively.

2.3. Statistical analysis

An initial analysis was carried out in order to check the repeatability of the movements performed by the participants and to verify whether the ROM is a reliable parameter to describe the neck movements (Anderst, 2015). A reliability analysis was performed using the intraclass correlation coefficient (ICC) (Shrout & Fleiss, 1979) to estimate, for each movement, the level of agreement between the repeated tests. The significance of ICC was interpreted as good, ICC > 0.75; moderate, 0.40 < ICC < 0.75; poor, ICC < 0.40 (Fleiss, 1981).

To identify any differences among ROMs reached with and without orthoses, a statistical analysis was carried out using a one-way repeated measure ANOVA with a post hoc Tukey analysis. Statistical significance was set at an alpha level of 0.05. A second level of analysis involved those orthoses and movements for which significant variations were observed from the reference condition. In order to investigate the inter-orthosis differences, a one-way repeated measure ANOVA with a post hoc Tukey analysis was performed between the values measured with those orthoses and expressed as a percentage of the values obtained without any orthosis. Also, in this second analysis, the alpha level was set at 0.05.

Finally, Cohen’s d was chosen as an indicator of the effect size. According to Cohen’s definition, an effect size of 0.2 was considered as small, an effect size of 0.5 was considered as medium and an effect size of 0.8 or greater was considered large (Cohen, 1969).

3. Results

3.1. Reliability of the assessment protocol

Table 1 shows the ICC values obtained for the AHM. As we can see from the table, in trials at maximum amplitude, the ICC was above 0.8 in all tasks except in the axial rotation performed without orthosis where the ICC was 0.65. Similar results were obtained in trials where movements were performed at self-selected maximum speed.

3.2. Comparison between the orthoses

Table 2 shows the ROMs obtained for the different orthoses. In the trials performed at maximum amplitude, the ROM measured with the HR orthosis was significantly reduced (52(9)° vs 36(13)°, \( P < 0.001 \), \( d = 0.7 \)) with respect to the trials without orthosis, but only in the flexion movement. A significant reduction in both flexion (52(9)° vs 36(13)°, \( P < 0.05 \), \( d = 0.6 \)) and axial rotation (145(12)° vs 101(30)°, \( P < 0.05 \), \( d = 0.7 \)) was observed for the SSS with the A support. Finally, significant reductions of the angles were observed for all the movements when performed with the VA (see values in Table 2; \( P < 0.05 \) and \( d > 0.5 \)) and the SSS with six supports (see values in Table 2; \( P < 0.05 \) and \( d > 0.5 \)). These results were confirmed in the trials at maximum speed, except for the flexion movement, where no significant differences were found between the values measured with the SSS with the A support and without orthosis.

The second level of analysis focused only on the data obtained for those orthoses and movements for which significant variations were observed from the reference condition, in order to allow for an inter-orthosis comparison. The results of this analysis are shown in Figs. 2 and 3, where the \( %ROM_{NC} \) are plotted for the maximum amplitude and maximum speed trials, respectively.

In both trials at maximum amplitude (Fig. 2) and at maximum speed (Fig. 3) the \( %ROM_{NC} \) measured with the HR was significantly different from the reference condition only in the flexion movement where a \( %ROM_{NC} \) of 47% and 43% was observed, respectively. However, the values measured with the HR were not significantly different from the
values measured with the other orthoses ($P < 0.05$, $d < 0.4$). In the trials at maximum amplitude, the $\% \text{ROM}_{\text{NC}}$ measured with SSS with six supports was not significantly different ($P > 0.05$, $d < 0.4$) from the one measured with VA in any of the movements performed. The use of SSS with six supports and VA led to a respective $\% \text{ROM}_{\text{NC}}$ of between 25% and 34% and between 24% and 47%. These results were confirmed in trials at maximum speed where the use of SSS with six supports and VA led to a $\% \text{ROM}_{\text{NC}}$ between 24% and 29% and between 25% and 43%, respectively. No statistically significant difference ($P > 0.05$, $d < 0.1$) was observed between the SSS with the A support and the SSS with six supports in the values measured for the axial rotation movement: both orthoses led to a $\% \text{ROM}_{\text{NC}}$ around 30% in trials performed reaching the maximum amplitude and around 25% in trials performed at maximum speed.

4. Discussion

The aim of this study was to test a cervical orthosis specifically designed for people affected by neck muscle weakness, the Sheffield Support Snood, and to compare it to two other orthoses, the Headmaster and the Vista, by assessing their performances in providing support and limit the neck of motions in desired movement directions. A protocol based on the use of wearable sensors has been proposed to this purpose, which is easily translatable to a clinical context. Significant differences in the participant neck motion were detected when performed with and without orthoses and the experimental results were highly informative in the characterization of different orthoses’ performance.

Although for each participant, the highest value among the three tests was considered in our analysis, the level of agreement between the three repetitions was checked for each movement using the intraclass correlation coefficient (ICC) in order to verify if, when the movements were performed repeatedly under the same conditions, it was possible to record the same values. In addition, it was hypothesised that the limitations imposed by the orthoses could increase the repeatability of the task. The ICC obtained was high overall, indicating good reproducibility. The worst results corresponded to the movements performed without orthosis, likely due to the absence of the constraint offered by the device, which reduces an individual’s capability to perform the movement. It is important to note, however, that the repeatability obtained in those trials was still satisfactory, being good in the flexion-extension and lateral flexion and moderate in the axial rotation. The reliability value found for the axial rotation, lower than that reported by other authors (Duc et al., 2013b; Jordan et al., 2000), might be due to the fact that this movement does not involve actions against gravity. Further studies are needed to test this hypothesis.

The results reported in this study demonstrated that the ROM measured with the Headmaster was significantly reduced compared to the trials without orthosis only in the flexion movement. Furthermore, the reduction in movement offered by the Headmaster was not significantly different from the reduction in movement observed with the other orthoses.

The ROMs measured with the SSS in its stiffer configuration and the Vista were significantly lower than those observed in the trials performed without orthosis in all the tasks and no significant differences were observed between them showing that the SSS with six supports is comparable to the Vista in terms of support provided, even though its structure is much less bulky than that of the latter. The same results were obtained in the trials at maximum speed, confirming the capability of the new orthosis to effectively reduce the movement in the desired direction, even in the presence of a movement causing higher mechanical stimuli. These results, despite having been obtained from a limited sample of healthy participants, are extremely encouraging in relation to the use and utility of the SSS in patients with neck muscle weakness.

| Max ROM (deg) | Trials without orthoses | HR | SSS A support | SSS 6 supports | VA |
|---------------|-------------------------|----|---------------|---------------|----|
| E             | Max amplitude           | 54 (13) | 50 (12) | 43 (7) | 35 (10)** | 35 (7)** |
| F             | Max amplitude           | 52 (9) | 47 (10) | 46 (9) | 39 (13)** | 35 (9)** |
| AR            | Max amplitude           | 145 (12) | 116 (21) | 101 (30)** | 96 (33)** | 77 (30)** |
| LF            | Max amplitude           | 80 (12) | 70 (13) | 67 (11) | 60 (18)** | 61 (15)** |
| Max speed     |                         | 82 (14) | 72 (13) | 71 (15) | 63 (18)** | 62 (16)** |

**Table 2** Mean (SD) values for the ROM reached performing extension (E), flexion (F), axial rotation (AR) and lateral flexion (LF) with orthoses (HR, Headmaster; SSS-A support, SSS with the A support; SSS-6 supports, SSS with six supports; VA, Vista) and without orthoses. (*) Level of significance for the difference with “trials without orthosis” is $P < 0.05$. (**) Level of significance for the difference with “trials without orthosis” is $P < 0.01$. ...

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One of the main innovative features in the design of the SSS is that the device is intended to facilitate the movements about selected anatomical axes by providing a more robust support and limiting the excessive range of motion that could be generated by weakness of specific neck muscles, but without limiting the movements in the other planes. This is achieved by changing the number and location of the additional supports (Fig. 1B). Despite the limitation that the collar was only tested in two of its possible configurations, the reported results seem to confirm the achievement of this design goal. The ROM measured with the SSS with the A support was significantly reduced compared to the trials without orthoses only in the flexion and the axial rotation movements. This indicates that the SSS provides support under the chin without affecting the capability to perform extension and lateral flexion. In addition, no significant differences in the axial rotation values were observed between the SSS using solely the A support, aiming at limiting only flexion, and the SSS using all six supports (two frontal, two lateral and two posterior), aiming at limiting all movements apart from axial rotation. Further studies, possibly carried out by instrumenting the SSS device directly, are certainly needed to confirm these encouraging results. One other aspect to consider in future studies is that the healthy participants were applying loadings actively against the orthosis during short time spans (either at preferred velocity or maximal achievable velocity). With regard to the capabilities of each orthosis to support and control the head of an individual with neck muscle weakness, the loading generated is more typically due to passive gravitational loading resulting from the failure of the muscle or muscles to generate or maintain sufficient activation to support the head.

5. Conclusions

We have demonstrated that the SSS is effectively adaptable to different tasks, offering the possibility to reduce neck movement in a selected direction without affecting the ability to move in other directions. The SSS offered a support comparable to the Headmaster in flexion movements both performed at maximum amplitude and maximum speed in its more supportive configuration and in movements performed at maximum amplitude even in its less supportive configuration. Furthermore, the SSS in its stiffer configuration offered a support comparable to the Vista in all the tasks performed, both at maximum amplitude and maximum speed, although its structure is much less bulky and cumbersome compared to that of the Vista. These results and the definition of a reliable clinically translatable protocol pave the way for further testing in patients with neck muscle weakness.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.clinbiomech.2015.11.010.

Conflict of interest

Heath Reed, Andrew Stanton, Dr. Joe Langley, Dr. Chris McDermott and the NIHR Devices for Dignity Healthcare Technology Co-operative (D4D HTC), of which Professor Wendy Tindale, the Clinical Director, Dr. Nicola Heron and Dr. Avril McCarthy are among the inventors of the Sheffield Support Snood.

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Appendix A1. Sensor orientation estimate

Sensors were placed on the forehead and sternum of each participant as shown in Supplementary Fig. 1.

Theoretically, the output of the magnetometer could be used together with those of the accelerometer and of the gyroscope to estimate a sensor’s orientation. However, since the magnetometer can be strongly affected by the vicinity of ferromagnetic metals and by electronic equipment generating magnetic fields, the sensor orientation was computed using a quaternion-based algorithm that integrates the angular velocity (Favre et al., 2006). This algorithm provides an estimate of the sensor rotations from the fusion of the 3D gyroscope and the 3D accelerometer data. The drift error caused by the DC offset, inevitable when evaluating orientation by integrating the gyroscope data (Favre et al., 2006), was corrected using a quaternion-based algorithm (Sabatini, 2004). This algorithm imposes equal conditions at the beginning and at the end of the acquisition and applies a spherical linear interpolation (SLERP) procedure to the estimated quaternions (Sabatini, 2004). Temporal intervals in which the IMUs were stationary were introduced between the active head movements in order to further reduce the drift error (Bergamini et al., 2014).

The IMUs acquire data according to their own reference frame. In order to remove orientation errors due to their placement, the two sensor frames need to be aligned to the segment anatomical frame. This was attained using a functional calibration approach, following the procedure and methodology described by Duc et al. (2013b). The anatomical reference frames were then built for both the sternum and forehead according to the ISB definition (Wu et al., 2002), i.e. with X pointing anteriorly, Y pointing upward and Z pointing to the right. Once the two sensor reference frames were aligned to the anatomical reference frame, their orientation was computed and used to measure the neck angle.

1.2. Procedures for the validation of the sensor orientation estimate

The above described approach to estimate the sensor orientation and hence the neck ROM has been previously validated using a stereophotogrammetric system as reference (Duc et al., 2013b). Eventual errors induced by the alternative method implemented to correct the drift and by the use of a different system of IMUs than the one adopted by Duc et al. (2013b) were verified on ad hoc trials. Three additional participants (1 female, 2 males, age 26 ± 2 years, body mass index 26 ± 4 kg/m²) were asked to perform the entire set of movements. Three reflective markers were attached to each of the IMUs using double-sided tape and a 10-camera stereophotogrammetric system (Vicon T160 Camera, Oxford Metrics Ltd., Oxford, UK) was used to measure their trajectories. From these, a reference frame was defined and used to describe a set of three orientations equivalent to those obtained from the IMUs after the realignment of the two reference systems (Duc et al., 2013b). The matrix that rotates the camera’s technical frame to the segment anatomical frame was defined through a functional calibration analogous to the one used to align the IMU’s frames. Stereophotogrammetric and IMU’s data were compared in terms of ROM, correlation and root mean square error (RMSE).

1.3. Results of the validation of the sensor orientation estimate

The comparison with the data obtained from the camera’s system showed the suitability of the methods chosen to estimate the IMU’s orientations for the purposes of this study. In Supplementary Fig. 2, a comparison between the angle curves measured by the IMUs and the cameras systems for the same movement is shown while Table A1 shows the results obtained for the comparison between the angles.
measured by the IMUs and the cameras system reported in terms of correlation, ROM absolute difference and RMSE. As can be seen from the table, the correlation was higher than 0.9 in all the movements, both in trials performed at maximum amplitude and at maximum speed. In the trials at maximum amplitude, the difference between the measured ROMs was less than 5° for the extension/flexion movement (corresponding to 4.5% of the maximum ROM), less than 3° for the axial rotation movement (corresponding to 2.5% of the maximum ROM) and less than 4° for the lateral flexion (corresponding to 4.5% of the maximum ROM), respectively. These values were equivalent to those found in the trials performed at maximum speed (Table A1), except for the lateral flexion movement, where the measured difference was less than 5°, which approximately corresponded to 5.5% of the maximum measured ROM. The RMSE associated with the movements performed at maximum amplitude was less than 4° for the flexion/extension and the lateral flexion and less than 3° for the axial rotation. Equivalent values were measured in the trials performed at maximum speed (Table A1).

1.4. Discussion

The method proposed here to estimate the angles using the inertial sensors, where the drift is corrected assuming no difference in the position of the participant’s head at the beginning and at the end of each movement, is certainly limited by the fact that it cannot be excluded that these positions might be slightly different. For this reason, the accuracy of the angles estimated was tested against a stereophotogrammetric reference system during a series of active head movements. The angles obtained from the two systems were compared in terms of correlation, ROM and RMSE. An excellent concordance between the angle curves measured by the two systems was observed. This concordance between the two motion patterns was confirmed with the overall correlation between the two curves, both in trials at maximum amplitude and maximum speed. The values measured were consistent with those reported in the literature (Duc et al., 2013b) and the differences in ROM were much lower than the observed experimental differences (see values in Table 2). Also, values measured for the RMSE confirmed the close correspondence between the two measurement systems (see Table A1). For these reasons, the error introduced by the use of the drift correction method was deemed to be not significant for our investigation.

Table A1: Comparison between angles estimated with the IMUs and the camera’s system in terms of correlation, mean (SD), difference in ROM measured, mean (SD) and RMSE, mean (SD) for each movement: flexion/extension (F/E), axial rotation (AR) and lateral flexion (LF).

| F/E | Max amplitude | 0.98 (0.02) | 4.4 (3.2) | 3.2 (1.8) |
|-----|---------------|-------------|-----------|-----------|
| Max speed | 0.98 (0.02) | 4.6 (1.7) | 3.3 (1.1) |
| AR | Max amplitude | 1.00 (0.00) | 2.9 (2.6) | 2.1 (0.9) |
| Max speed | 0.99 (0.00) | 2.4 (1.5) | 2.4 (0.7) |
| LF | Max amplitude | 0.96 (0.01) | 3.1 (1.7) | 3.4 (1.0) |
| Max speed | 0.99 (0.01) | 4.2 (1.1) | 2.5 (0.6) |

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