

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

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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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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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1. Introduction

Neck orthoses are used in three settings: to stabilize/immobilize the neck following trauma or surgery, to provide support for individuals with chronic neck pain and to provide support to patients with neck muscle weakness. There are several studies in the literature that explore the ability of these orthoses to restrict motion (McCabe & Nolan, 1986).

The Sheffield Support Snood, SSS, is a Class 1 medical device (C.E. Self Certified to 93/42/EEC as amended by 2007/47/EC by Sheffield Teaching

Hospitals NHS Foundation Trust, the registered manufacturer). The SSS (Fig. 1A) is a new orthosis specifically designed for people affected by progressive neck muscle weakness caused by neurological diseases such as motor neuron disease or muscular dystrophy. A key feature of its design is that of being customisable to increase or decrease head support as required and configure the support provided appropriately for individual users. The main requirements of an orthosis to be used for such individuals are linked to the need of keeping the head in an upright position without further degrading the muscle tone from restricted movement. The main limitation of many commercially available orthoses is that they are designed for trauma use and completely immobilize the neck, resulting in them being uncomfortable to wear and overly restrictive in planes where muscle strength remains strong. The SSS was designed with the goal of overcoming these limitations. The orthosis is characterized by a minimally bulky structure, which is adaptable

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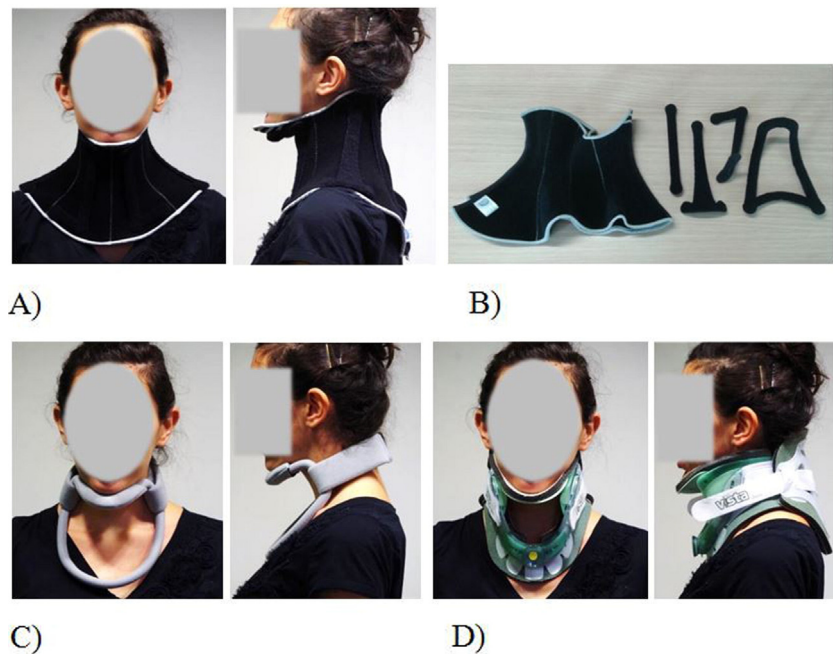


Fig. 1. (A) Sheffield Support Snood; (B) Sheffield Support Snood with supports (from left to right: straight support, lateral support, jaw support and A-shaped support); (C) Headmaster cervical orthosis; (D) Vista cervical orthosis.

due to the incorporation of adjustable supports (Fig. 1B), according to the task performed and to the participant's level of functional limitation. However, these biomechanical features of the SSS have not been previously objectively quantified either in healthy or pathological users. The aim of this study was to characterize and quantify the biomechanical features of the SSS and compare them to those of two other commercial neck orthoses, widely used by people affected by neck muscle weakness: the Headmaster (HR, Symmetric Designs Ltd., Salt Spring Island, Canada; Fig. 1C) and the Vista (VA, Aspen Medical Products, Inc., Irvine, CA; Fig. 1D).

The assessment of neck orthoses is typically based on the assessment of the full, active head or intervertebral range of motions (ROMs) that are allowed by the orthoses during the execution of movements along the three principal anatomical axes (anterior-posterior, medio-lateral and vertical) (Rosen et al., 1992). Furthermore, there are studies in which, together with the full active ROMs, the functional ROMs, allowed by the cervical orthoses in some selected activities of daily living are also investigated (Miller et al., 2010a,2010b). Head and/or intervertebral residual range of motion have been classically investigated through different techniques: radiographic measurements (McCabe & Nolan, 1986), motion capture systems (Evans et al., 2013; Gavin et al., 2003; Schneider et al., 2007; Zhang et al., 2005), goniometric techniques (Aker et al., 1991; Rosen et al., 1992; Whitcroft et al., 2011) and measurement systems based on ultrasound pulses (Quinlan et al., 2006). Although motion capture is the gold standard in movement analysis, it cannot be performed outside a laboratory and requires very cumbersome procedures, which make it unsuitable for a protocol translatable to a clinical context. Recently, inertial magneto units (IMUs) have been recognized as a valid instrument to assess the range of movements of the neck in healthy participants (Theobald et al., 2012) and in post-surgery evaluations (Duc et al., 2013a,2013b). These sensors are relatively easy to use and allow the measurement to be performed in real-life settings (either in the clinic or at home), which makes them suitable for future application in participants in the clinical setting. Within this study, the aimed characterization of the SSS and the comparison of the chosen orthoses will hence be performed using a protocol based on the measurement of kinematics data using a system of IMUs.

2. Methods

2.1. Participants and protocol

Twelve healthy participants (5 females, 7 males, ages 26 ± 2 years, body mass index 23 ± 3 kg/m²) 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 that more closely resembled the Vista (which offers frontal, lateral and posterior supports) and the Headmaster (which offers only frontal support), respectively. The SSS was hence tested both in its most supportive (with six supports: two frontal, two lateral and two posterior) and less supportive configuration (with one A-shaped frontal support; Fig. 1B). Participants were allowed to rest whenever needed

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 (Luinge & 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 orthoses 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

$$\%ROM_{NC} = \frac{ROM_{NC} - ROM_C}{ROM_C} * 100 \quad (1)$$

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 ($52(9)^\circ$ vs $28(13)^\circ$, $P < 0.001$, $d = 0.7$) with respect to the trials without orthosis, but only in the flexion movement. A significant reduction in both flexion ($52(9)^\circ$ vs $36(13)^\circ$, $P < 0.05$, $d = 0.6$) and axial rotation ($145(12)^\circ$ vs $101(30)^\circ$, $P < 0.05$, $d = 0.7$) 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

Table 1

ICC values calculated for each movement: 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.

ICC		Trials without orthoses	HR	SSS A support	SSS 6 supports	VA
E	Max amplitude	0.88	0.86	0.88	0.89	0.82
	Max speed	0.84	0.92	0.86	0.97	0.94
F	Max amplitude	0.92	0.90	0.96	0.85	0.93
	Max speed	0.87	0.93	0.94	0.97	0.94
AR	Max amplitude	0.65	0.94	0.98	0.95	0.94
	Max speed	0.59	0.92	0.95	0.96	0.87
LF	Max amplitude	0.91	0.85	0.96	0.94	0.92
	Max speed	0.92	0.92	0.94	0.97	0.98

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 $P < 0.01$.

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)**
	Max speed	51 (9)	47 (10)	46 (9)	39 (13)*	35 (9)**
F	Max amplitude	52 (9)	28 (13)**	36 (13)*	36 (12)*	27 (10)**
	Amplitude	52 (11)	30 (14)**	40 (13)	37 (12)*	32 (11)**
AR	Max amplitude	145 (12)	116 (21)	101 (30)**	96 (33)**	77 (30)**
	Max speed	143 (15)	117 (23)	105 (35)*	105 (32)*	81 (29)**
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)*

values measured with the other orthoses ($P > 0.05$, $d < 0.4$). In the trials at maximum amplitude, the %ROM_{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 %ROM_{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 %ROM_{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 %ROM_{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.

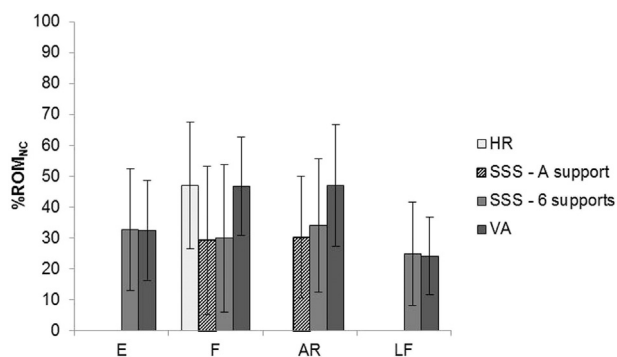


Fig. 2. Trials performed reaching the maximum amplitude. Mean (SD) values for the percentage of ROM reached performing extension (E), flexion (F), axial rotation (AR) and lateral flexion (LF) with orthoses (HR, Headmaster; SSS-A support, SSS with the A support; SSS-6 supports, SSS with six supports; VA, Vista) with respect to trials performed without any orthoses. (*) $P < 0.05$. Values are reported only when significantly different from those measured in the trials performed without orthosis (as per Table 2).

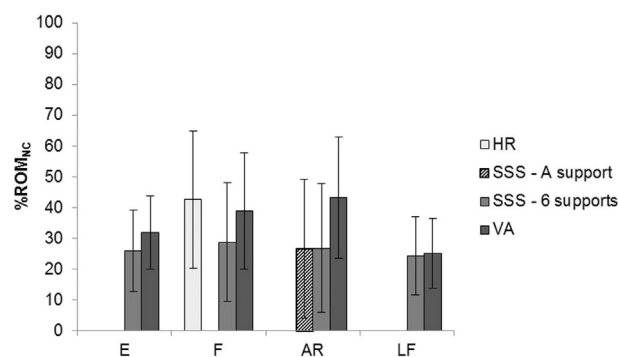


Fig. 3. Trials performed reaching the maximum speed. Mean (SD) values for the percentage of ROM reached performing extension (E), flexion (F), axial rotation (AR) and lateral flexion (LF) with orthoses (HR, Headmaster; SSS-A support, SSS with the A support; SSS-6 supports, SSS with six supports; VA, Vista) with respect to trials performed without any orthoses. (*) $P < 0.05$. Values are reported only when significantly different from those measured in the trials performed without orthosis (as per Table 2).

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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received funding from the EPSRC Frontier Engineering Awards, Grant Reference No. EP/K03877X/1.

Appendix A1.1. 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 systems 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).

		Correlation	Difference in ROM (deg)	RMSE (deg)
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 (0.03)	3.1 (1.7)	3.4 (1.0)
	Max speed	0.99 (0.01)	4.2 (1.1)	2.5 (0.6)

References

- Aker, P.D., et al., 1991. Restriction of neck flexion using soft cervical collars: a preliminary study. *J. Can. Chiropr. Assoc.* 35 (3), 139–145.
- Anderst, W.J., 2015. Bootstrap prediction bands for cervical spine intervertebral kinematics during in vivo three-dimensional head movements. *J. Biomech.* 48 (7), 1270–1276. <http://dx.doi.org/10.1016/j.jbiomech.2015.02.054>.
- Bergamini, E., Ligorio, G., Summa, A., Vannozzi, G., Cappozzo, A., Sabatini, A.M., 2014. Estimating orientation using magnetic and inertial sensors and different sensor fusion approaches: accuracy assessment in manual and locomotion tasks. *Sensors* 14 (10), 18625–18649. <http://dx.doi.org/10.3390/s140x000x>.
- Cohen, J., 1969. *Statistical Power Analysis for the Behavioral Sciences*. Academic Press, NY.
- Duc, C., Salvia, P., Lubansu, a, Feipel, V., Aminian, K., 2013a. Objective evaluation of cervical spine mobility after surgery during free-living activity. *Clin. Biomech.* 28 (4), 364–369. <http://dx.doi.org/10.1016/j.clinbiomech.2013.03.006>.
- Duc, C., Salvia, P., Lubansu, a, Feipel, V., Aminian, K., 2013b. A wearable inertial system to assess the cervical spine mobility: comparison with an optoelectronic-based motion capture evaluation. *Med. Eng. Phys.* 36 (1), 49–56. <http://dx.doi.org/10.1016/j.medengphys.2013.09.002>.
- Evans, N.R., Hooper, G., Edwards, R., et al., 2013. A 3D motion analysis study comparing the effectiveness of cervical spine orthoses at restricting spinal motion through physiological ranges. *Eur. Spine J.* 22 (S1), 10–15. <http://dx.doi.org/10.1007/s00586-012-2641-0>.
- Favre, J., Jolles, B.M., Siegrist, O., Aminian, K., 2006. Quaternion-based fusion of gyroscopes and accelerometers to improve 3D angle measurement. *Electron. Lett.* 42 (11), 612–614. <http://dx.doi.org/10.1049/el>.
- Fleiss, J.L., 1981. *Statistical Methods for Rates and Proportions*. John Wiley and Sons, Inc., New York, NY, p. 218.
- Gavin, T.M., et al., 2003. Biomechanical analysis of cervical orthoses in flexion and extension: a comparison of cervical collars and cervical thoracic orthoses. *J Rehabil Res Dev* 40 (6), 527–538.
- Jordan, K., Dziedzic, K., Jones, P.W., Ong, B.N., Dawes, P.T., 2000. The reliability of the three-dimensional FASTRAK measurement system in measuring cervical spine and shoulder range of motion in healthy subjects. *Rheumatology (Oxford)* 39 (4), 382–388. <http://dx.doi.org/10.1093/rheumatology/39.4.382>.
- Luinge, H.J., Veltink, P.H., 2005. Measuring orientation of human body segments using miniature gyroscopes and accelerometers. *Med. Biol. Eng. Comput.* 43 (2), 273–282. <http://dx.doi.org/10.1007/BF02345966>.
- McCabe, J.B., Nolan, D.J., 1986. Comparison of the effectiveness of different cervical immobilization collars. *Ann. Emerg. Med.* 1 (15), 50–53.
- Miller, C.P., Bible, J.E., Jegede, K. a, Whang, P.G., Grauer, J.N., 2010a. The effect of rigid cervical collar height on full, active, and functional range of motion during fifteen activities of daily living. *Spine (Phila Pa 1976)* 35 (26), E1546–E1552. <http://dx.doi.org/10.1097/BRS.0b013e3181cf6f73>.
- Miller, C.P., Bible, J.E., Jegede, K. a, Whang, P.G., Grauer, J.N., 2010b. Soft and rigid collars provide similar restriction in cervical range of motion during fifteen activities of daily living. *Spine (Phila Pa 1976)* 35 (13), 1271–1278. <http://dx.doi.org/10.1097/BRS.0b013e3181c0ddad>.
- Quinlan, J.F., Mullett, H., Stapleton, R., FitzPatrick, D., McCormack, D., 2006. The use of the Zebris motion analysis system for measuring cervical spine movements in vivo. *Proc. Inst. Mech. Eng. H J. Eng. Med.* 220 (8), 889–896. <http://dx.doi.org/10.1243/09544119JEM53>.
- Rosen, P.B., et al., 1992. Comparison of two new immobilization collars. *Ann. Emerg. Med.* 21 (10), 1189–1195.
- Sabatini, A.M., 2004. Quaternion based attitude estimation algorithm applied to signals from body-mounted gyroscopes. *Electron. Lett.* 40 (10), 584–586. <http://dx.doi.org/10.1049/el:20040401>.
- Schneider, A.M., Hipp, J. a, Nguyen, L., Reitman, C.a., 2007. Reduction in head and intervertebral motion provided by 7 contemporary cervical orthoses in 45 individuals. *Spine (Phila Pa 1976)* 32 (1), E1–E6. <http://dx.doi.org/10.1097/01.brs.0000251019.24917.44>.
- Shrout, P.E., Fleiss, J.L., 1979. Intraclass correlations: uses in assessing rater reliability. *Psychol. Bull.* 86 (2), 420–428. <http://dx.doi.org/10.1037//0033-2909.86.2.420>.
- Theobald, P.S., Jones, M.D., Williams, J.M., 2012. Do inertial sensors represent a viable method to reliably measure cervical spine range of motion? *Man. Ther.* 17 (1), 92–96. <http://dx.doi.org/10.1016/j.math.2011.06.007>.
- Whitcroft, K.L., Massouh, L., Amirfeyz, R., Bannister, G.C., 2011. A comparison of neck movement in the soft cervical collar and rigid cervical brace in healthy subjects. *J. Manip. Physiol. Ther.* 34 (2), 119–122. <http://dx.doi.org/10.1016/j.jmpt.2010.12.007>.
- Wu, G., Siegler, S., Allard, P., Kirtley, C., Leardini, A., Rosenbaum, D., Whittle, M., D'Lima, D.D., Cristofolini, L., Witte, H., Schmid, O., Stokes, I., Standardization and Terminology Committee of the International Society of Biomechanics, 2002. *ISB recommendation on definitions of joint coordinate system of various joints for the reporting of human joint motion—part I: ankle, hip, and spine*. International Society of Biomechanics. *J. Biomech.* 35 (4), 543–548.
- Zhang, S., Wortley, M., Clowers, K., Krusenklau, J., 2005. Evaluation of efficacy and 3D kinematic characteristics of cervical orthoses. *Clin. Biomech.* 20 (3), 264–269. <http://dx.doi.org/10.1016/j.clinbiomech.2004.09.015>.