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A comfort assessment of existing cervical orthoses

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Abstract

Purpose: identify location and intensity of discomfort experienced by healthy participants wearing cervical orthoses.

Method: convenience sample of 34 healthy participants wore *Stro II*, *Philadelphia*, *Headmaster*, and *AspenVista*[®] cervical orthoses for four-hour periods. Participants reported discomfort level (scale 0-6) and location.

Results: participants reported mean discomfort for all orthoses over the four-hour test between 'a little discomfort' and 'very uncomfortable' (mean discomfort score=1.64, SD=1.50). Seven participants prematurely stopped tests due to pain and six reported maximum discomfort scores. Significant linear increase in discomfort with duration of wear was found for all orthoses. Significantly less discomfort was reported with Stro II than Headmaster and Philadelphia. Age correlated with greater perceived discomfort. Orthoses differed in the location discomfort was experienced.

Conclusion: existing cervical orthoses cause discomfort influenced by design and duration of wear with orthoses' design the more significant factor. This work informed the design of a new orthosis and future orthoses developments.

Keywords: comfort assessment; neck collar; neck support; Motor Neurone Disease; amyotrophic lateral sclerosis; neck weakness; assistive technology; Head-up; Headup

Practitioner Summary

The purpose of this study was to gain knowledge about discomfort caused by wearing existing neck orthoses in order to inform the design and development of a new neck orthosis. This study gathers empirical data from a surrogate population and concludes that orthosis design is more influential than the duration of wear.

Introduction

Motor Neurone Disease (MND) is a rapid and progressive neurodegenerative disease with a complex profile of associated disabilities, ultimately leading to death (McDermott and Shaw 2008). MND predominantly affects the motor neurones, the cells controlling muscle activity. This causes problems with speaking, walking, breathing, swallowing, general body movement and, frequently, neck weakness. In the absence of a cure, efforts to support patients are heavily focused on relieving symptoms, preserving independence and maximising quality of life (QoL). For those patients who develop neck weakness, cervical orthoses are usually prescribed. However, available orthoses are often rejected by people living with MND due to factors including discomfort, poor aesthetics, associated stigma and inappropriate levels of support (too much or too little) (Shaw and Wood-Allum 2010; Lee 2012).

Typical wear of such orthoses is highly varied although appears to be summarised by the quote reported to authors of “*as little as I can get away with*”. Typically, as the disease progresses, the duration of wearing increases and the more supportive or immobilising the orthosis becomes. As the onset and progression of MND is highly varied, there is no consistent pattern to when individuals require neck support nor in the way in which this support evolves as the disease progresses (Shaw and Wood-Allum 2010; Lee 2012). Individuals with MND have reported durations of wear ranging from 20-30 minutes up to 8 hours or more; often with an underlying message of reluctance.

Several studies have assessed adult human head mass, (Yoganandan et al. 2009) with a reported average head mass of 4.06 kg and greatest head mass of 4.72 kg. This mass is predominately supported by the cervical spine; effectively a large ball balanced on a small surface. Keeping the head balanced and under control are a complex system of relatively small muscles. Simplistically, muscle fibres tie into the back of the skull and pull down the back, sides and around the front of the neck, extending the neck and pulling the head up. This system of muscles adjusts (flexion, extension and rotation) to cater to voluntary movements of the head and/or body. The muscles must also adjust and react quickly involuntarily by reflexes to movements of the body’s centre of mass or ‘base’ in order to safely balance the weight of the head on top of the spinal column and maintain postural control of the head.

For many people with MND, as these muscles begin to weaken the head droops or flops forward. This head-drop exacerbates problems with swallowing, breathing, eating, communication and drinking.

Ideally cervical orthoses should alleviate these problems by providing a load bearing substitute to the weakened neck muscles and supporting the weight of the head, keeping it in an upright position. A review of existing neck supports concluded that current provision of cervical orthoses falls into two categories: weak and strong support orthoses. Weak orthoses may allow movement but provide insufficient support. This lack of support can result in health professionals prescribing strong orthoses: these orthoses are developed for trauma scenarios and almost completely restrict head movement, pushing the jaw upwards. Strong orthoses have been reported to be extremely uncomfortable and have a negative effect on quality of life (Whitcroft et al. 2011).

Assessments of existing cervical orthoses reported in the literature, undertaken with healthy participants focused on restricting range of motion (Askins and Eismont 1997; Bell et al. 2009; Gavin 2003). This reflects the primary purpose of these orthoses of neck immobilisation in trauma cases or following head and neck surgery.

Comfort assessment is also crucial when evaluating a device which is designed to substitute or support a body component and is meant to be worn for an extended period. Comfort assessments for a range of prostheses have been carried out and demonstrate the need for this type of assessment (Murray and Fox 2002; Pezzin 2004).

Only two studies on the assessment of cervical orthoses included, as a secondary outcome, a subjective overall rating of comfort (Karason 2014; Schneider 2007) and no studies were found exploring areas of discomfort. Karson et al used 10 participants and a scale of 1-5 for subjective assessment of overall comfort (5 being most comfortable) of four different devices, two of which were included in this study; the Philadelphia and the Aspen Vista. Karson found that the Philadelphia was the least comfortable (with a mean score of 2.2) and the Vista was the most (with a mean score of 4.2). For three of the orthoses tested by Karson (including the Vista) there appeared to be a non-statistically significant correlation between the degree of immobilisation and comfort – those orthoses that immobilised more were ranked as less comfortable. The exception was the Philadelphia, which was ranked least comfortable yet was also ranked the second least immobilising i.e. allowed more movement than two other devices). The Vista was ranked as the most comfortable and allowing the most movement.

Head-Up was a co-design project between clinicians, engineers, designers, patients and carers (Caplan 1990; Schuler and Namioka 1993; François 2016). The use of co-design methods for orthoses to address both functional and aesthetic aspects is supported by other research and has been demonstrated to have an impact on user acceptance and compliance (Law et al. 2016). The goal of the Head-Up project was to develop an orthosis specifically designed for individuals living with MND with neck muscle weakness to provide tailored support to the head whilst still permitting normal movement where possible. Since the purpose of the new orthosis was to overcome the main limitations of existing orthoses, an evaluation of the devices currently available was essential. The aim of this paper is to present a comfort assessment of existing cervical orthoses, which was then used to inform the design process of a new orthosis.

Methods

Study design

The primary outcome of this study was discomfort level associated with orthotic wear. Secondary outcomes were locations of discomfort and perceptions about each orthosis. The study involved healthy participants and was divided in two parts. The first part was a pilot study which aimed to define the experimental method. The second part used the developed method to compare the different orthoses. Ethical approval was granted by Sheffield Hallam University Research Ethics Committee in May 2012.

Identification of test orthoses

An expert panel of four patient participants with MND, five carers, five MND healthcare professionals, two designers and one engineer identified five devices commonly used by people living with MND and representative of meaningful differences in design:

- (1) Stro II (Trulife, Dublin, Ireland) – a soft foam collar that wraps around the neck and fastens at the rear with hook and loop.
- (2) Philadelphia (Philadelphia Cervical Collar Co., Thorofare, NJ) – a two-part rigid immobilisation collar made from a closed cell foam, that encases the neck from

a high jawline, just below the ear lobe, down to shoulders and onto the chest, fastening at both sides.

- (3) Headmaster (Symmetric Designs Ltd., Salt Spring Island, Canada) – a ‘minimalist’ support developed specifically for patients with MND, this device consists of a curved metal bar that follows the jaw line, curves down the neck and onto the chest. It is held and fastened at the back of the neck by a velour fabric covered hook and loop fastener. The chin rests on a velour fabric stretched between the metal bar under the jaw.
- (4) Aspen Vista[®] (Aspen Medical Products, Inc. Irvine, CA) – a two-part rigid immobilisation collar made from a rigid polymer scaffold and lined with a layered foam, fabric and gauze material.
- (5) Nexus (Nexus Europe Ltd, UK) – an inflatable collar made from a polymer like swimming flotation aid with a velour fabric surface in areas of skin contact. The devices are inflated by a hand pump.

Data collection tool

A data collection tool (DCT) was designed (shown in Supplementary Material) enabling participants to report location, perceived scale of discomfort and perceptions about wearing the orthoses such as how they felt it looked, ease of application, difficulties eating, perceptions of how supportive it felt and how visually attractive they perceived it to be.

- Section A of the tool measured locations of discomfort and was based on the head and shoulders section of the McGill Pain Map tool (Escalante 1996) combined with a seven-point Likert scale (Aitken 1969). This allowed ratings from ‘no discomfort’ to ‘severe pain’ and is described as the discomfort scale. A seven-point scale created multiple points of discrimination and better data distribution for a small sample (n<100). The location map covered the domains identified by the expert panel and tested in a pilot study.
- Section B presented 10 statements based upon experiences of people living with MND when wearing orthoses. All statements were positively phrased e.g. ‘this device caused *no restriction* to my breathing’. Perceptions of agreement with each statement were presented to be rated on a seven-point Likert scale from ‘Strongly Agree’ to ‘Strongly Disagree’. This is described as the perception scale.
- Finally, an open-ended question enabled general comments.

An expert panel reviewed the tool and it was evaluated in a pilot to identify possible improvements.

Pilot study

A pilot study was conducted using the five orthoses in Figure 1. The aim was to test the experimental design, especially in terms of orthoses selected and duration of the test.



Figure 1: Stro II, Philadelphia, Headmaster, Aspen and Nexus orthoses being worn and tested for contact and pressure comfort by the design team. Participants written consent for publication has been obtained.

Four healthy participants, without any history of neck pain, wore each device for eight-hours, recording data hourly using the DCT. Eight hours was chosen to capture data regarding the effects of wearing the orthoses during a broad range of activities.

The first four hours of test data for the pilot participants produced mean discomfort scores of 3.50 (standard deviation 1.96) across all orthoses, with specific mean values and standard deviations of Aspen = 3.56 (1.41), Philadelphia = 4.00 (1.78), Headmaster = 4.75 (2.05) and Stro II = 1.69 (1.14). All four participants had ceased wearing the Headmaster and Philadelphia orthoses by hours five or six. The scores for both Stro II and Aspen orthoses for all four participants continued to increase for hours four to eight following a broadly linear trend.

Following the pilot study, three changes were made to the protocol, none to the DCT:

- (1) Specification of a minimum of seven-days' 'rest' between subsequent device tests, eliminating legacy effects.
- (2) Nexus orthosis was excluded due to difficulties in standardising its use. An inflatable orthosis, it self-deflated twice during the pilot.
- (3) The test duration was reduced to four hours to be more representative of patient use based on feedback from patients in our expert panel and the experience of the participants in the pilot.

Main study

A convenience sample of roughly 300 healthy participants, defined as individuals without any medical problems, chronic diseases, or acute infections, were invited to take part in the study via staff email lists within the authors' respective organisations. A convenience sample was used for time and resource expediency. Age parameters of 18-60 years were applied, and those with a history of neck or back related problems were excluded. Participants for whom there were no suitably sized orthoses were also not recruited.

Procedure

The study was explained to participants and consent recorded. Participants were issued with an orthosis (of appropriate size and fit) and trained in its use. The DCT was

demonstrated to participants. Participants were instructed to use the orthosis for four hours, reporting on the DCT, and then rest for seven days before exchanging for a subsequent device. Orthoses were issued to each participant in a convenience sequence depending on availability of untested orthoses and appropriate size and fit according to the manufacturers' instructions for use.

During each four-hour test, participants were instructed to keep hourly records of discomfort score and locations using DCT Section A, and perceptions of wearing the orthosis after the test, using DCT Section B.

Analysis

SASTM v9.4 and Microsoft ExcelTM 2010 were used for analysis of the quantitative data. Mean scores and standard deviations were calculated for discomfort and perception.

Locations of discomfort for each orthosis were summarised with frequencies and percentages and compared using Fisher's Exact test. General linear models were fitted to the perception scores and discomfort scores.

General linear repeated-measures mixed models were fitted to the discomfort scores. This allowed exploration of differences in discomfort levels between orthoses and across duration of wearing while accounting simultaneously for covariates. Unlike traditional analysis of covariance models, mixed models allow all recorded data to be considered, even for those individuals for whom some data are missing. A p-value <0.05 was taken to indicate statistical significance. The open-ended question field was analysed to identify recurring positive and negative comments.

Results

Fifty-one participants registered for the study. Eight were excluded based on prior history of neck and back pain, nine due to a lack of suitably fitting devices from available samples: the Stro II collar was too small for four of the participants and the Philadelphia was too large for five of the participants (due to the height of the orthosis cutting into the ears).

Thirty-four participants wore one or more orthoses for one hour or more, including four project team members. Participants' ages ranged between 22 and 60, with a mean of 38.2 (SD 10.9) years. 19 (55.9%) were male and 15 (44.1%) were female. Twenty-one participants completed the full study, wearing all four orthoses for four hours.

Seven participants were unable to continue wearing one or more of the orthoses for four hours due to severity of discomfort experienced: these were given a discomfort rating of 'Severe Pain' for each subsequent duration time point. Three of these unfinished tests were for the Headmaster orthosis and four for the Philadelphia. Six participants were unable to wear some of the orthoses for reasons unrelated to the study; in these cases, the data for the orthoses these participants did test are included in the analysis.

Discomfort scores

Discomfort scores were 0 (No discomfort), 1 (A Little Discomfort), 2 (Very

Uncomfortable), 3 (Extremely Uncomfortable, 4 (A Little Painful), 5 (Very Painful) to 6 (Severe Pain). The mean reported discomfort score for all orthoses over the four-hour test was 1.64 (SD 1.50), equating to a rating between a ‘little discomfort’ and ‘very uncomfortable’. Mean discomfort scores for each orthosis (regardless of location of discomfort) and for each hour of wear are shown in table 1 and a distribution of all responses for each device is shown in figure 2. This shows a concentration around scale point 2 (Very uncomfortable) and a distribution either side of this using the full extent of the scale.

Table 1: Mean discomfort scores & standard deviations

Duration	Orthosis			
	Stro II(n=30)	Philadelphia(n=30)	Headmaster(n=32)	Aspen(n=33)
1 hr	0.63 (SD 0.76)	1.60 (SD 1.33)	1.52 (SD 1.67)	1.15 (SD 1.06)
2 hr	1.00 (SD 0.83)	1.97 (SD 1.61)	1.81 (SD 1.84)	1.27 (SD 0.94)
3 hr	1.23 (SD 0.77)	2.43 (SD 1.81)	2.09 (SD 1.96)	1.55 (SD 1.12)
4 hr	1.30 (SD 0.84)	2.70 (SD 1.80)	2.41 (SD 2.05)	1.61 (SD 1.12)

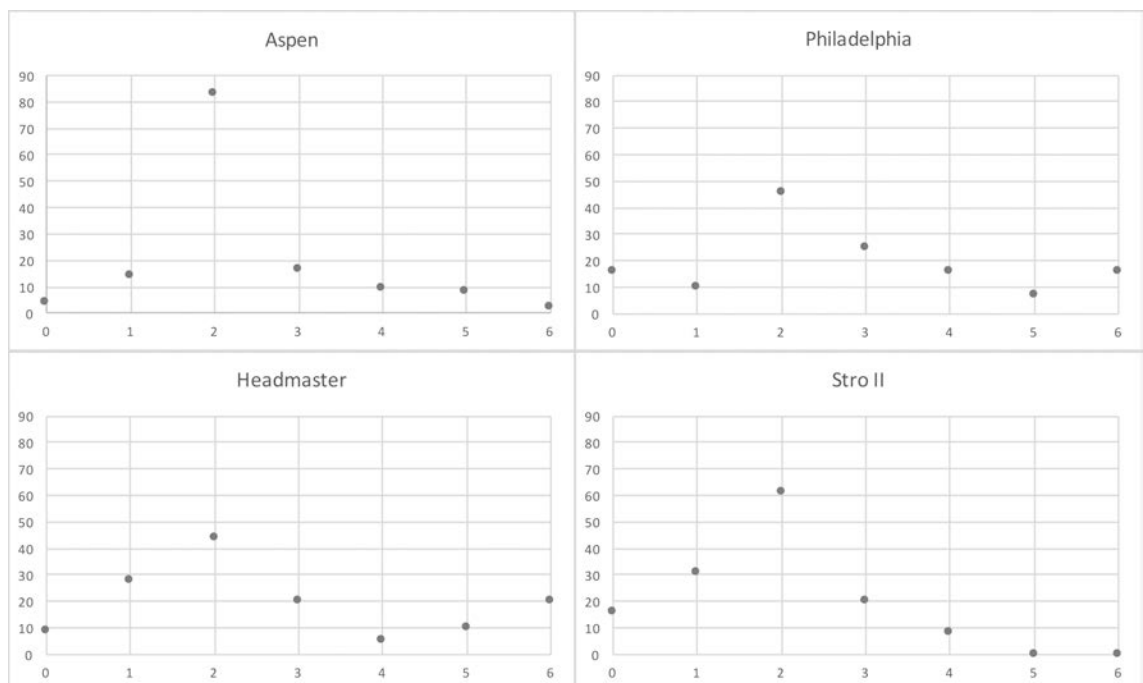


Figure 2: Scatter plots showing the distribution of all responses for each device

At all time points, the Stro II was associated with the least discomfort, the Philadelphia with the most. Discomfort increased over duration of wear for all orthoses. The least variation in scores was associated with the Stro II and the most with the Headmaster.

There was no difference between genders in the mean discomfort score recorded (males 1.49 SD 0.95, females: 1.76 SD 0.74).

Linear regression of mean discomfort score against age (unadjusted for other factors) showed a significant increase ($p=0.018$) in discomfort of 0.03 ± 0.01 scale points per additional year, amounting to an average increase in discomfort score of nearly 0.5

points from the youngest to the oldest in the study. There was one outlier, a male aged 35, with a mean discomfort score overall of 4.44 - data retained in all analyses.

Repeated measures mixed models were fitted to the data, treating individuals as random effects and orthosis, duration and age as fixed. A homogeneous unstructured covariance pattern model was found to be the most appropriate fit to the data. Orthoses were found to differ significantly overall in their comfort. Disregarding location, significantly greater discomfort of 1.1 ± 0.3 points was reported with the Philadelphia ($p < 0.001$) orthosis than the Stro II. Similarly significantly greater discomfort of 0.9 ± 0.3 points was reported with the Headmaster than the Stro II orthosis ($p = 0.003$).

Linear and non-linear effects of duration of wearing were considered; discomfort was found to increase linearly with duration by an average of 0.24 ± 0.03 scale points per hour ($p < 0.001$), but there was no further significant non-linear effect. There was no significant interaction of orthosis with duration, suggesting that discomfort increased at a similar rate with all four orthoses. The repeated measures mixed models analysis also indicated a significant increase in reported discomfort with age of 0.03 ± 0.01 ($p = 0.004$). Model parameters for the final model are shown in table 2.

Table 2: Model estimates for the discomfort model

Effect	Estimate†	Std Error	p-value
Intercept	0.250	0.442	0.572
Age	0.029	0.010	0.004 **
Orthosis			0.003 **
Stro II (reference)			
Philadelphia	1.080	0.310	<0.001 ***
Headmaster	0.942	0.305	0.003 **
Aspen	0.492	0.303	0.107
Duration	0.241	0.031	<0.001 ***

† Estimates adjusted for all other effects in the model

** Significant at 1% level; *** Significant at 0.1% level

Twenty-one participants recorded the location of discomfort for each orthosis over the four hours. Those who did report location data did so for all devices for full duration. The reported locations were reviewed by observation by three members of the team. Digital images with transparent backgrounds were created for each of the raw data maps. The transparent maps were overlaid on each other to give one map showing all location data for all orthoses and for each orthosis separately. The combined location map data formed 12 specific location clusters around the neck, shoulders, jaw and base of skull. An additional location was added in analysis (site 13), creating a zero-reference point of no discomfort. The 13 locations are: 1. Posterior midline – occiput; 2. Post auricular; 3. Posterior Lateral neck; 4. Lateral neck; 5. Angle of the jaw; 6. Chin; 7. Anterior Midline – larynx; 8. Posterior lateral – scapulae; 9. Lateral clavicle; 10. Medial clavicle, 11; Anterior Midline – Sternum; 12 Posterior midline - lower cervical and 13 – no discomfort location. Posterior midline - upper thoracic. They are shown in figure 3.

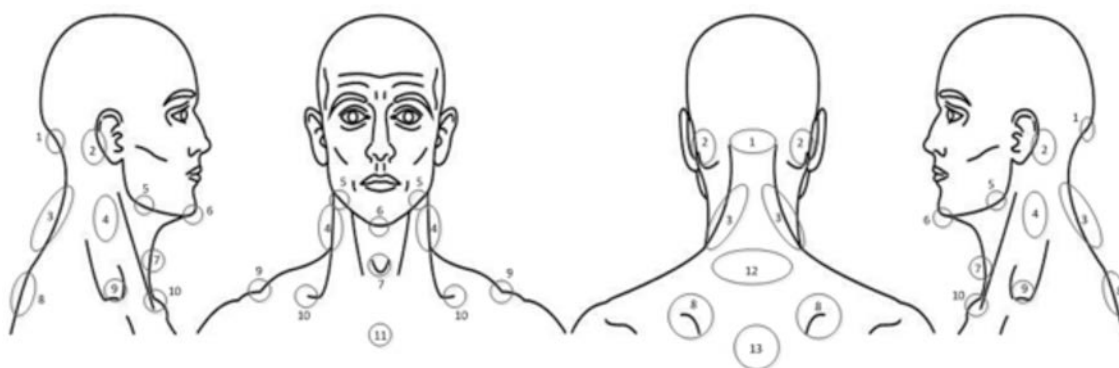


Figure 3: 13 locations of discomfort identified by participants through the data collection instrument

Table 3: Frequency of reporting of discomfort at selected sites by orthosis

Site*	1		3		5		6		7		10	
	Posterior midline - occiput		Posterior Lateral neck		Angle of the jaw		Chin		Anterior Midline - larynx		Medial clavicle	
	n	%	n	%	n	%	n	%	n	%	n	%
(n=21)												
Aspen	8	29.6	6	22.2	8	29.6	12	44.4	0	0.0	2	7.4
Philadelphia	4	14.3	7	25.0	12	42.9	12	42.9	3	10.0	3	10.7
Headmaster	0	0.00	2	7.4	3	11.1	15	55.6	1	3.7	10	37.0
Stro II	3	11.1	5	18.5	3	11.1	8	29.6	8	29.6	2	7.4
p-value	0.011		0.338		0.014		0.298		0.002		0.012	

* Sites not included here received fewer than 15 reports of discomfort over 84 tests

Table 3 gives frequencies of reporting of discomfort by orthosis at those sites where the most reports were made based on 84 tests (21 individuals x 4 orthoses each). Across all orthoses, discomfort was most frequently reported at site 6. For individual orthoses, the most frequent locations for reported discomfort were site 6 for the Aspen and Headmaster, sites 5 and 6 for the Philadelphia and sites 6 and 7 for the Stro II. For each location, the orthosis with the most reports of discomfort varied. These variations were tested individually using Fisher's Exact test. It suggests each orthosis has its own problem point (indicated by significant differences at sites 1, 5, 7 and 10), where the Aspen, Philadelphia, Stro II and Headmaster orthoses respectively gave rise to the most reports of discomfort.

Reported locations and intensity of discomfort combined are illustrated in figure 4 for the four different orthoses in mannequin visuals showing variation over duration.

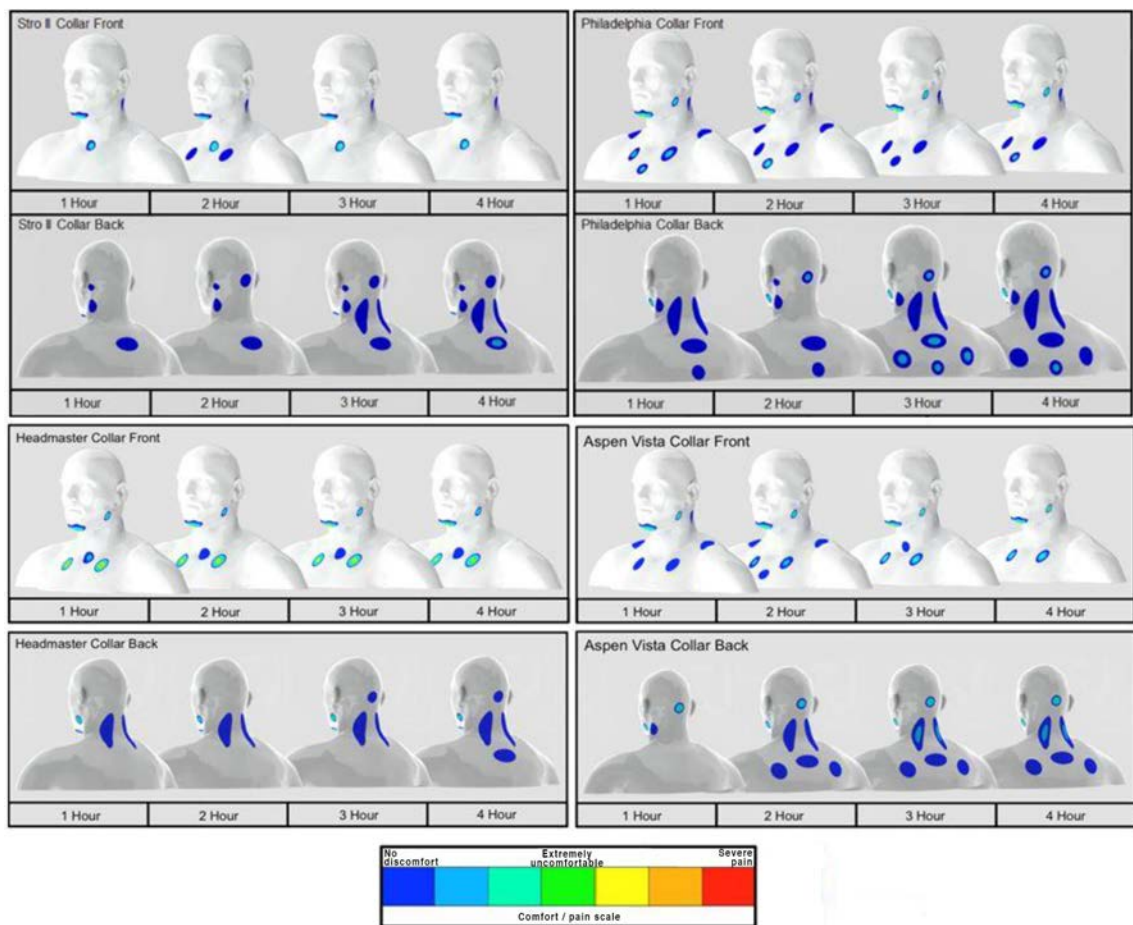


Figure 4: Location and intensity data against duration for all the orthoses and for all participants.

Practical Issues and Aesthetic Considerations

31 participants rated their perceptions of various practical experiences and aesthetic impressions for each orthosis. Responses were coded from 3 (strongly agree) to -3 (strongly disagree) so that positive scores reflected agreement with the statements.

Table 4 shows levels of agreement or disagreement. The mean scores reported in this table provide a profile of the features of each orthosis. For example, the Stro II has positive scores for each statement except 'offering support' and being 'visually attractive'. The Stro II was the only orthosis to have a negative mean score for 'offered support' ($p < 0.001$). All orthoses except the Stro II had negative mean reported scores for '... free movement' and '... no frustration'.

No orthosis had a positive mean score for 'visually attractive' and all orthoses had a positive mean score for 'no restriction to breathing' and 'no restriction to swallowing'.

Table 4: Mean levels of agreement or disagreement with given statements about perceptions relating to practical experiences and aesthetic impressions (Section B of data collection tool)

Statement: "This device ..."		Orthosis				p-value
		Stro II (n=30)	Philadelphia (n=30)	Headmaster (n=32)	Aspen (n=33)	
"...caused restriction to breathing"	no to my	1.87 (SD 1.25)	1.33 (SD 1.71)	0.97 (SD 1.99)	1.94 (SD 1.54)	0.085
"...caused difficulties eating"	no when	0.83 (SD 1.70)	-0.70 (SD 1.60)	-0.41 (SD 1.76)	0.03 (SD 1.88)	0.003**
"...caused problems drinking"	no when	1.20 (SD 1.67)	-0.50 (SD 1.68)	-0.19 (SD 1.80)	0.61 (SD 1.71)	0.001**
"...caused restriction swallowing"	no to	1.33 (SD 1.47)	0.57 (SD 1.96)	0.53 (SD 2.02)	1.06 (SD 1.64)	0.244
"...offered support"		-0.23 (SD 1.83)	1.30 (SD 1.49)	0.88 (SD 1.24)	1.67 (SD 0.82)	<0.001***
"...caused no perspiration"		0.20 (SD 1.88)	-0.63 (SD 1.71)	1.31 (SD 1.79)	0.70 (SD 2.05)	0.003**
"...is attractive"	visually	-1.30 (SD 1.44)	-1.63 (SD 1.43)	-1.03 (SD 1.66)	-0.39 (SD 2.03)	0.094
"...gave completely free movement"	me free	0.03 (SD 1.47)	-2.00 (SD 1.11)	-0.72 (SD 1.44)	-1.48 (SD 1.72)	<0.001***
"...was easy to fit"		1.57 (SD 1.19)	-0.67 (SD 1.49)	0.72 (SD 1.59)	0.21 (SD 1.93)	<0.001***
"...caused frustration"	no	0.13 (SD 1.76)	-1.67 (SD 1.42)	-0.94 (SD 1.72)	-0.97 (SD 1.74)	<0.001***

p-values relate to differences between orthoses based on general linear models.

** Significant at 1% level; *** Significant at 0.1% level

General linear models were fitted to the perception scores, individually for each question, to account for orthosis, age and gender. Significant differences between orthoses were reported for several statements: restrictions to eating and drinking, support, perspiration, freedom of motion, ease of fitting and frustration. For each of these statements, except perspiration, the Stro II rated significantly better than the Philadelphia. For many aspects the Stro II was also rated slightly better than at least one other orthosis. A significant effect of gender was noted for restriction to eating and ease of fitting, with females reporting more difficulty. Age had a significant effect on reported discomfort, with older people reporting higher levels of discomfort.

Free text responses

The number of participants utilising the free text field for each orthosis was 17/30 (Stro II), 12/30 (Philadelphia), 18/32 (Headmaster) and 15/33 (Aspen). Ten participants did

not complete the field for any orthosis.

The free text data indicated areas of frequent negative experiences. The most common issues described were difficulty looking downwards (and associated difficulty using a urinal, walking, ascending/descending stairs, navigating kerbs), difficulty with line of sight (need to rotate whole upper body for group communicate or to look in both directions to cross a road), difficulty using a mobile phone and yawning.

Other issues raised felt worthy of mention include a reference to being ‘looked at with pity and curiosity’ and four comments about ‘hair’; facial hair as an irritant and long hair having to be ‘kept up’ to avoid interference during application of the orthosis.

Discussion

In terms of overall comfort and lack of restriction, the Stro II produced the most favourable results followed by the Aspen and the Headmaster, with the Philadelphia being least favourable. However, the Stro II offered the least support. When comparing perceived degree of immobilisation for each orthosis (see Table 4 results for agreement with “gave me completely free movement”) to perceived level of discomfort (see Table 1), there was a non-statistically significant correlation between immobilisation and discomfort with the Stro II giving the most freedom to move and being the most comfortable, and the Philadelphia giving the least freedom to move and being the least comfortable. The largest average differences between any two orthoses were of the order of 1 point for discomfort and 1-2 points for restriction. All other factors being equal, such a difference, corresponding to a difference between two scale points (for example, "a little uncomfortable" and "very uncomfortable"), could have real clinical significance in terms of the willingness of a patient to wear an orthosis for an extended period. Our findings are similar to previous observations that the Aspen Vista is more comfortable and less restricting than the Philadelphia (Karson 2014). Further comparison is limited given the different collars assessed and a lack of detailed outcome measures in previous work.

Discomfort reported for all orthoses increased with duration, but less than the maximum mean differences between orthoses. The apparently significant effect of age was unexpected and should be explored further – it may indicate that older people are more sensitive to discomfort, or more inclined to report perceived discomfort, or simply inherent effects of ageing such as arthritic conditions, reduced range of motion or muscle condition. The literature on this topic is inconsistent, with some studies finding an increased pain perception and willingness to report pain with increasing age (Lautenbacher *et al.* 2005; Wander *et al.* 2012) while others suggest a decrease in sensitivity with age (Ritter *et al.* 2011). This literature gives us little insight into why we have seen this age effect in our study, but supports the case for further investigation into this. Since differences between orthoses were assessed within subjects, the differences in reporting by age do not affect the main results. The single male outlier aged 35 referred to in the results section above did not show any specific factors that might have related to higher discomfort scores. No significant physical features had been noted during the fitting process for any of the orthoses and no explanation could be gleaned from the free text comments by this participant.

As regards location of discomfort, each orthosis has its own problem point and these might be attributed to specific design differences between orthoses. Small numbers of incidences of reported discomfort at each location for each orthosis have precluded an examination of the possible effects of age and gender here. The mixed model analysis suggests that there is a ‘built-in’ discomfort factor in the wearing of

these cervical orthoses, an orthosis specific discomfort factor, a duration of wearing dependent discomfort factor and an age-related discomfort factor.

The comfort assessment across all four orthoses indicates that these participants would be uncomfortable with having to wear these orthoses. Nearly all participants indicated that they would avoid having to wear any orthosis at all despite all perceived potential needs. The primary causes of discomfort in this study were pressure and unnatural posture. Other causes included heat and wear duration. There were no references to sensitivity reactions to materials.

The perception data (table 4) indicates that none of the orthoses tested were visually appealing to participants. Individually, the Stro II was not supportive at all, the Philadelphia had the greatest number of negative scores for the specific questions asked (7/10), the Headmaster presented difficulties eating, drinking, moving and overall frustration whilst the Aspen restricted movement and caused frustration.

This work has informed the design of a new cervical orthosis aiming to overcome the problems identified in this study. The design of the Head-Up orthosis is discussed in detail in Reed *et al* (2015). The work outlined here plus other investigative work in the design process informed the development of an adaptable orthosis (support can be added and taken away) addressing restriction of movement associated with increasing support. Specifically, this work led to the development of support elements that distributed the load of the head particularly around the chin and jaw line. The new device will be similarly tested with populations of both healthy participants and people living with MND as a way of comparing the new design to existing products and as a mechanism for comparing differences between healthy and MND populations.

The total of these design features gives aggregated benefits that reduce ‘initial design’ and ‘duration dependent’ discomfort factors.

Limitations

The rating scale used to assess discomfort and difficulty level was not validated and may suffer from known limitations of such scales – primarily that it is uncertain how individuals use the scale - and inter and intra-rater reliability of the scale and tool may be poor. Some ‘unexpected’ locations of discomfort were reported where there was no contact with the orthosis, which may be a consequence of using healthy participants. When contact pressure became too uncomfortable, healthy participants may have unconsciously lifted their heads to relieve pressure, using unfamiliar muscles with resulting discomfort. Despite careful instruction when fitting orthoses, we cannot say for sure that the orthoses were being worn correctly.

A further limitation of the study could be the 4-hour exposure in the duration of wearing each orthosis. There are mixed views in the literature on this with some suggestion of improving tolerance with long term usage for ‘worn items’ but largely a lack of tolerance for longer term usage for ‘orthotics and braces’ (Andringa, van de Port and Meijer 2013). Dialogue with our patient participants in our co-design team indicated that the neck orthosis given to MND patients were worn as little as possible, with 20-30 minute periods being cited by some although greater time frames being cited by others. This view from MND patients was formally captured in a later evaluation (Baxter *et al.* 2016) with a wider, external group of MND patients.

A final limitation of the study is the difference between mean values reported from the pilot study compared to the main study. The main study reported a concentration of data points within a smaller spectrum of the scale. Further work to

explore the use of the scale, particularly the terminology descriptors related to each point on the scale needs to be considered.

Conclusions

This study has identified key levels and locations of discomfort for commonly used cervical orthoses. The study suggests that there is a design related discomfort factor and a duration of wearing discomfort factor. In addition, the study suggests that age and gender also influence the level of reported discomfort. These factors were unexpected and deserve to be explored further.

From the perception data gathered, none of the orthoses tested were found to be visually attractive; the soft foam orthoses (e.g. Stro II) were considered to not be supportive, whilst the more rigid and immobilising orthoses (e.g. Philadelphia, Aspen and Headmaster) were felt to restrict movement.

The protocol developed here can be utilised by those designing cervical orthoses in the development stages to assess the level of comfort of their proposed design, and to evaluate how it compares to four existing orthoses designs for healthy participants.

Declaration of Interests:

The work associated with this research may lead to the development of products which may be licensed to a commercial third party with appropriate manufacturing capability. None of the authors or host organisations have financial interests in any of these third-party businesses but authors host institutions are likely to benefit via the licensing agreement. These interests have been fully disclosed to the publisher. The views expressed are those of the author(s) and not necessarily those of the UK NHS, the NIHR or the Department of Health.

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Suppliers:

All devices used in this study are prescribed for a range of purposes by the UKs National Health Service (NHS). The provision of devices for test purposes was approved by the NHS and therefore no direct contact with commercial suppliers was necessary.