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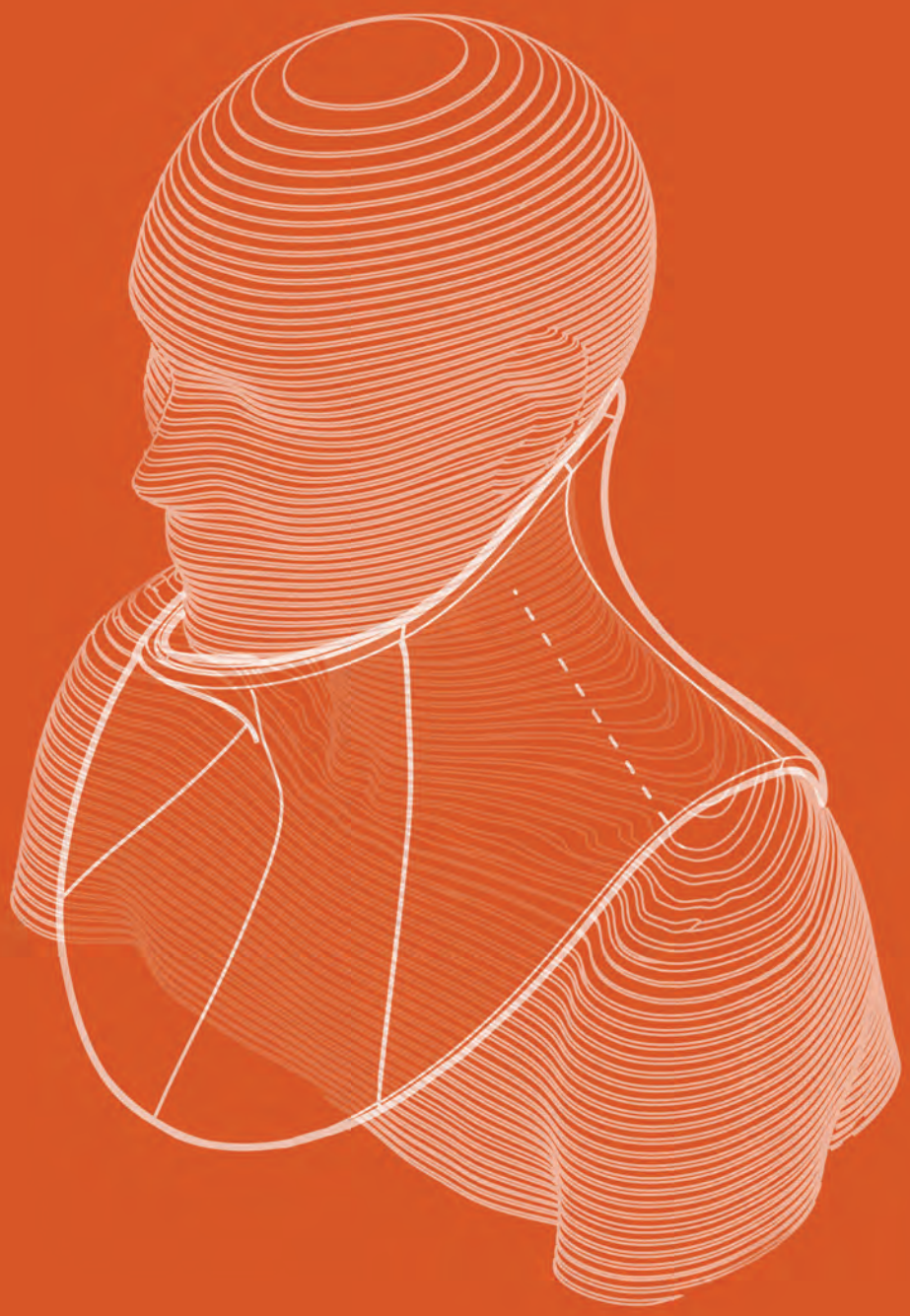
HeadUp Collar

Revolutionary new evidence based collar for neck weakness.



NHS National Institute for Health Research

NHS Sheffield Teaching Hospitals NHS Foundation Trust

D4D Devices for Dignity Ltd

Sheffield Hallam University

LAB 4 LIVING

The University Of Sheffield.

SITraN

NHS Barnsley Hospital NHS Foundation Trust

mnda motor neurone disease association

HeadUp Collar

The HeadUp Collar is a revolutionary new cervical orthosis device to replace conventional neck support collars currently used for conditions resulting in head drop. Originally developed for Motor Neurone Disease patients the collar can offer a functional alternative for many conditions that require support for the head and neck.

The award-winning ‘HeadUp’ project was originally a collaboration between Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield and Sheffield Hallam University. The team was brought together by the NIHR Devices for Dignity Healthcare Technology Co-operative. Talarmade were selected as the distributor of choice for the HeadUp Collar due to their forward thinking and evidence based approach to healthcare interventions.

The cervical orthosis collar came from a complete rethinking of existing collars making it much easier for patients to carry out everyday tasks such as eating, driving and communicating. The involvement of patients in the research and design has been strongly promoted and patients have played an extensive part in the design workshops for the new cervical orthosis collar.

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Backed Up By Research

Research Paper:

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

Pancani S, Rowson J, Tindale W, Heron N, Langley J, McCarthy AD, Quinn A, Reed H, Stanton A, Shaw PJ, McDermott CJ, Mazzà C.

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.

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.

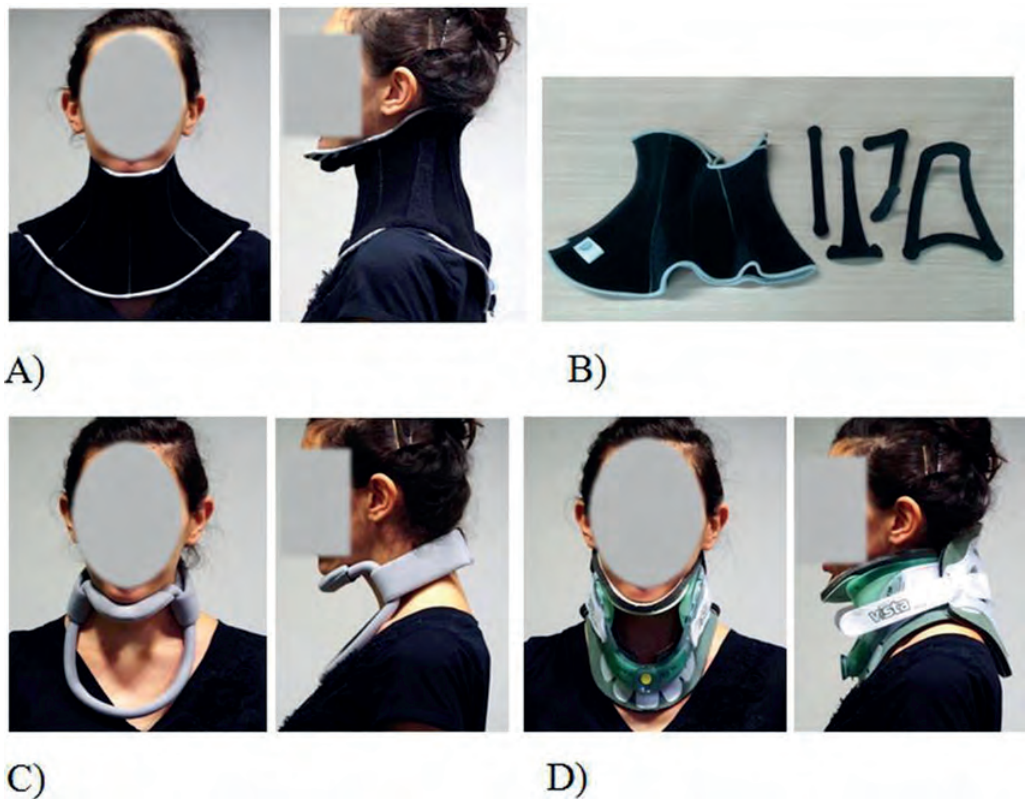


Fig. 2. Trials performed reaching the maximum amplitude. Mean (SD) values for the percentage of ROM reached performing extension (E), flexion (F), axial rotation (AR) and lateral flexion (LF) with orthoses (HR Headmaster; SSS-A support, SSS with the A support ; SSS-6 supports, SSS with six supports;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

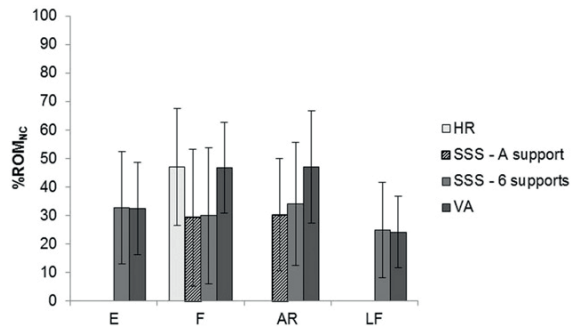
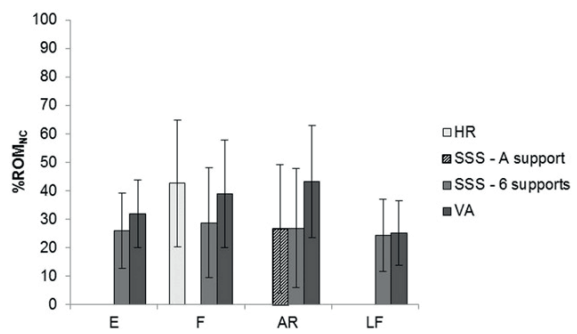


Fig. 3. Trials performed reaching the maximum speed. Mean (SD) values for the percentage of ROM reached performing extension (E), flexion (F), axial rotation (AR) and lateral flexion (LF) with orthoses (HR Headmaster; SSS-A support, SSS with the A support;



Backed Up By Research

Research Paper:

HeadUp; An interdisciplinary, participatory and co-design process informing the development of a novel head & neck support for people living with progressive neck muscle weakness.

Reed H, Langley J, Stanton A, Heron N, Clarke Z, Judge S, McCarthy A, Squire G, Quinn A, Wells O, Tindale W, Baxter S, Shaw PJ, McDermott CJ.

ABSTRACT:
This paper presents the HeadUp project; an innovation project developing a novel head and neck support for people with neck weakness due to neuromuscular diseases, and more specifically the needs of patients living with motor neurone disease (MND). This summary presents a successful case study and blue print for a collaborative, interdisciplinary research and design practice, under pinned by user-centred and participatory processes, supported by an NIHR Healthcare Technology Co-operative (HTC) model of collaboration. The paper will give a broad overview of the deployed process, along with a reflective summary of the key considerations to success.

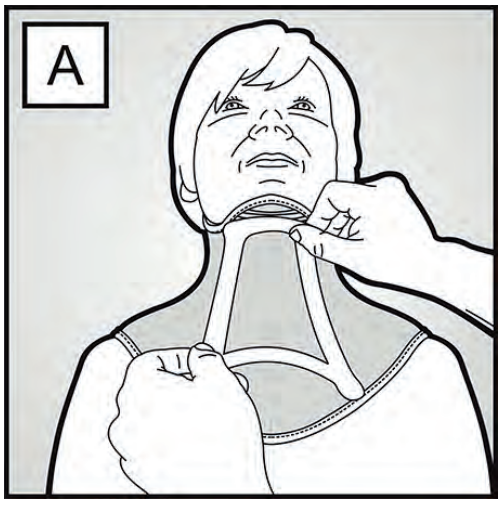
BACKGROUND:
Motor Neurone Disease (MND) is a rapidly progressive neurodegenerative disease with a relentless progression, a profile of complex disabilities and fatal consequences, to which there is currently no cure [1]. MND predominantly affects the motor neurones, the cells that control muscle activity including speaking, walking, breathing, swallowing and general movement of the body. As the disease is incurable, the efforts to support patients are heavily focused on sustaining a maximum quality of life (QoL) [1].

The adult human head weighs approximately 5kg and is supported by a complex system of relatively small muscle groups that co-ordinate to support and control head movements. In very simplistic terms, the weight of the head is supported by muscles fibres that tie into the back of the base of the skull at one end and attach to the back and sides of the lower neck. Contraction of these muscles lift the head backwards and allow more complex side to side movements. For people with MND, as these muscles begin to weaken, the head drops or flops, usually forwards and/or sideways.

Head drop exacerbates problems with swallowing, breathing, eating, communication and drinking. Ideally a neck collar should help alleviate these problems. However, during workshops conducted with MND patients and carers in the pre-proposal stages of this project, participants confirmed that currently available collars are of limited use for people with MND and are often rejected. Previously reported assessments of existing neck support collars have been undertaken in healthy volunteers and focused on the effect of the collars on restricting range of motion [2,3,4]. Although comfort assessments have been developed for a range of other limb prostheses [5], there appears to be little literature evaluating fitness for purpose of current neck support collars in this application area. A review of existing neck supports by the project partners concluded that broadly speaking, current provision of neck collars falls into two categories: low level support and high level support. Lower level, 'unstable' support, such as soft foam collars, provide some support whilst allowing movement. High level, 'stable' support collars are often used to immobilise trauma or post-surgical patients.

Pre-study workshop participants reported that the 'unstable' variety of collars do not provide sufficient support hence allow the head to drop leading to the problems listed above. This often leaves health professionals prescribing increasingly stiffer, 'stable' type immobilisation collars. These work by supporting the jaw from below and almost completely restrict head movement. This is an unnatural way of supporting the head, can be extremely uncomfortable, and the resulting restricted movement was reported to negatively impact daily activities such as communication, eating, mobility and result in general user discomfort. The participants in early workshops clearly expressed the unmet need as: “a neck and head support system for MND patients, and potentially those with other neck weakness conditions that provides sufficient support whilst allowing freedom for head movements, is comfortable to wear and is non-stigmatising in its cosmetic appearance”.

CONCLUSION:
The process can be described as an exemplar of a user involved design and innovation process with genuine user participation in the design. This has helped ensure that the novel head and neck support meets the needs of many of the target user group as well as the functional requirements identified at project outset and those that emerged during the course of the enquiry. In the context of medical device development, there were direct benefits to participation, in particular, in regard to developing deep, qualitative understandings of the context of use.. Although the neck support has only been evaluated by a relatively small sample, the results indicate a very positive response that validates the innovation model applied in this project, the user and clinician involvement and the design output.



Backed Up By Research

Research Paper:

Evaluating a novel cervical orthosis, the Sheffield Support Snood, in patients with amyotrophic lateral sclerosis/motor neuron disease with neck weakness.

Baxter S, Reed H, Clarke Z, Judge S, Heron N, Mccarthy A, Langley J, Stanton A, Wells O, Squire G, Quinn A, Strong M, Shaw PJ, Mcdermott CJ.

ABSTRACT:
Current practice and guidelines recommend the use of neck orthoses for people with amyotrophic lateral sclerosis (ALS) to compensate for neck weakness and to provide surrogate neck control. However, available options are frequently described by patients as restrictive and unsuitable and there was a need for a new device that addressed the needs of people with ALS. This project utilized a co-design process to develop a new neck orthosis that was more flexible yet supportive. Following development of a prototype device, a mixed methods cohort study was undertaken with patients and carers, in order to evaluate the new orthosis. Twenty-six patients were recruited to the study, with 20 of these completing all phases of data collection. Participants described the impact of neck weakness on their life and limitations of existing supports. Evaluation of the new orthosis identified key beneficial features: notably, increased support while providing a greater range of movement, flexibility of use, and improved appearance and comfort. In conclusion, the results of this evaluation highlight the value of this alternative option for people with ALS, and potentially other patient groups who require a neck orthosis.

RESULTS:
Twenty six patients were recruited to the study, with 20 of these completing all phases of data collection. Three potential participants could not be successfully fitted with the SSS, and therefore were unable to complete the study. In addition, three participants died in the interval between fitting and follow up. The final sample comprised 12 females and 14 males, with nine rating their neck weakness as severe and 17 rating their neck weakness as mild- moderate at the time of initial fitting. The data provide insights regarding the impact of neck weakness on patient quality of life and limitations of existing neck supports, and provide an evaluation of the new orthosis.

i) Impact of neck weakness
Participants described a number of ways in which neck weakness adversely impacted on their lives. These included: problems with eating and saliva for example, “I’m having to try and get him a bit upright by sort of gently pushing on his head, that causes a problem with meal times” Participant (P) 3; the effect on social interaction due to a low eye level, “If anybody talks or wants to talk to her she can’t see who it is” P7, the challenge in getting around, “she won’t go out a lot because she can’t support her head” P7; and discomfort and neck pain, “it’s looking down that brings on my neck pain” P2.

ii) Limitations of existing neck supports
Patients had tried or were using a range of existing devices including; a foam collar (seven individuals; the Head Master (four patients), Beanie collar (two participants) and a single individual reported using either the Hereford, Oxford, Vista Aspen, Miami, Stro II, or Traction Fixer. Two patients used travel neck cushions. Daily usage of supports varied from none (six patients) to 1-4 hours, and one person who used a Beanie collar for much longer (10 hours).

During the interviews participants described their views of collars that they were using or had tried in the past. Their comments were grouped into five main themes: difficulty in fitting, for example, “they’re not easy to fit on your own” P5; lack of physical support, “I didn’t find that it’’ P6;‘’The neck collar gave me any support” P4; being overly restrictive, “it really was like body armour from medieval times” P1; feeling uncomfortable, “that put too much pressure on her collar bone and her chin was slipping off the chin guard” P18; or being unsuitable, “It is as if I have to explain I haven’t just suffered a car crash” P11.

iii) Evaluation of the orthosis
We obtained evaluations of a previously worn collar from 24 participants, and an evaluation of the SSS from 20 participants. Nineteen participants evaluated both a previously worn collar and the SSS. There is some missing data for questions that related to eating and drinking (questions 2, 3, 4) since some participants had either not tried their collar during eating and drinking, or had a gastrostomy and were not fed orally.

CONCLUSION:
The results of this evaluation highlight the significant impact of neck weakness on the everyday lives of people with ALS, and the value of an orthosis which better addresses the requirements of this group of patients. The client-focused development process that was used during the design of the SSS, provided valuable insights and feedback to underpin the production of an orthosis that was suitable for patient needs. While developed specifically for people with ALS, there is potential for the SSS to be suitable for a wider range of patients requiring cervical orthosis.

Supported By Patients

Case Study 1:

Moya Briggs, 67, who was diagnosed with MND four years ago and chose to take part in a unique patient-led project, called ‘HeadUp’ to create a more suitable cervical orthosis collar for patients with MND.

Moya said, "I hate the current collar I have to wear, absolutely hate it. When I’m wearing it I feel like an Egyptian mummy, all choked around my neck. For it to give me enough support I’ve got to have it really tight and when it’s tight I feel like I’m choking in it. It makes me feel as if I’m only partly communicating with the world. I hate the look of my current collar too and I cover it with a scarf. The fact that this new collar is inconspicuous and comfortable will make all the difference.”

Clinical Impact:

Whilst the cervical orthosis developed as a result of this project uses MND as a case condition, it will also benefit individuals with weakness of the neck muscles due to other diseases, such as stroke, myopathy, dystonia and multiple sclerosis. In addition to the 5000 people in the UK living with MND / ALS, there is also an estimated 100,000 people living with multiple sclerosis and 250,000 people living with the effects of stroke. (Source: NIHR Devices for Dignity 2016).

Having spoken with a number of healthcare professionals, it is clear that there is a need in the cervical orthoses market for a collar that provides support, without restricting movement, which is exactly what this neck support offers. Having completed a successful pilot study on 20 patients, the team have gone on to conduct a full Clinical Evaluation in 150 patients with MND and other conditions whereby patients suffer neck muscle weakness. Early feedback that we have received from patients and carers has been extremely positive and encouraging:

“No comparison to other cervical orthosis collars – it works”

“This cervical orthosis collar gives support but also freedom of movement – I can wear it to drive.”

“My head is better positioned therefore do not feel as tired as before having the head resting on my chest.”

“[This cervical orthosis collar] has helped me to enjoy shopping again because my head is up.”

Why TalarMade?

Leading and educating the healthcare profession around the world...

Our vision is to design, develop and source quality products that have a positive impact for all our stakeholders including patients. Our mission is to support our valued customers through delivering cost efficiencies, innovation and best in class education.

Quality Focus

TalarMade is owned and managed by professionals from the fields of orthotics, podiatry, rehabilitation and physical therapy. With over 30 years market experience and using their extensive professional knowledge the team have worked diligently to create this leading product portfolio.

TalarMade are committed to research and development. TalarMade also focus heavily on our educational programme.

Whilst actively encouraging the further research efforts of our clinical business partners. In turn we will continue to invest in continued product development as we strive in collaboration together for excellence.

By engaging our valued customers for constructive developmental feedback our interactive approach in designing products allows us to meet clinical needs whilst meeting other key market factors such as cost, time and patient compliance.

Our respected customer service and logistics teams strive to ensure deliveries are received on time and in full, maintaining our reputation for reliability and consistent customer satisfaction.

For more information on the HeadUp collar:

Please feel free to contact TalarMade regarding the revolutionary new evidence based cervical orthosis collar device for neck weakness.

For a clinical presentation to your team contact us on:

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