Aergo PS: a responsive postural support device for paediatric neuromuscular conditions: post-market surveillance case studies

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Summary
Aergo PS is a novel, patent-filed and CE-marked, innovative postural support device designed to assist paediatric neuromuscular diseases (NMDs). A post-market surveillance study demonstrated Aergo PS was safe for use at home, and that children with NMDs had positive experiences of comfort, posture, independence from carer support, and usability.

Aims and objectives
Aim:
To determine whether Aergo PS is a safe device for use within the home-based setting, and collect user feedback regarding the comfort, independence from carer support, and usability of Aergo PS for children living with NMDs and their parents.

Objectives:
1. Assess safety of Aergo PS in the home-based setting
2. Collect user feedback about independence from carer support, comfort, usability and posture of Aergo PS's automated postural management feature during prolonged sitting
3. Collect user feedback from children with NMDs regarding their ability to control Aergo PS device for optimal postural support with the remote control

Background
Congenital NMDs require specialist seating to prevent spinal deformities and organ compression (Muscular Dystrophy Campaign, 2011). Existing solutions maintain optimal postural alignment; however, as children move throughout the day, the prescribed position can often be lost, and requires carer and clinician resource to conduct frequent adjustments. To address this, we developed a CE-marked class 1 medical device called Aergo PS, which is a responsive postural support seating system. Aergo PS uses a network of pressure sensitive air cells to monitor the user's sitting position, and automatically adjusts support levels accordingly to maintain an optimal sitting position. A remote control also allows users to self-initiate minor adjustments for improved comfort. We present initial findings of our post market surveillance (PMS) study.

Technique
An eight-week, home-based postmarket surveillance (PMS) case study was carried out with seven children with NMDs. Aergo PS was fitted to the children's wheelchairs and they were asked to use it during their waking hours. Safety was monitored throughout, including adverse events (AE) and serious adverse events (SAE). A Likert scale, validated for use with children (the Five Degrees of Happiness; Hall et al. 2016) was administered to children after one week. Children rated their enjoyment, independence from carer, comfort, and postural support, and were given an additional opportunity for open feedback. Barriers to adherence were assessed with the Problematic Experiences of Therapy Scale (PETS; Kirby et al. 2014), and parent feedback was collected through usability and safety feedback diaries at bi-weekly intervals.

Standards
MHRA Medical Device Guidelines for safety reporting of medical devices.

Clinical Detail

Users were required to have a clinical diagnosis of a NMD, be aged 5-16 yrs, able to give informed consent, and cognitively able to use Aergo PS. Users were also required to be medically stable and have a parent/carer willing and able to assist with using Aergo PS. Contraindications were uncontrolled epilepsy/seizures, active pressure ulcer/open wound, severe loss of sensation or loss of bowel and/or bladder control. Here, users were aged 9-16 years old and had been diagnosed with the following paediatric NMDs: Lamin A/C gene mutation (n=1), Duchenne Muscular Dystrophy (DMD) [n=3], Cerebal Palsy (CP) [n=2], and undiagnosed NMD [n=1].

Results and Testing

Four children and six parents reported on their experiences using Aergo PS. Descriptive mean reported values by children for enjoyment (5/5), independence (4/5), comfort (4.25/5), and postural management (4.25/5). Comfort was the most frequently reported benefit [n=3] followed by adaptability of posture [n=1]. Users reported that the Aergo PS remote control improved their independence. Parents reported improvements in their child's independence [n=4], postural management [n=4], comfort [n=5], and usability [n=3]. The greatest benefits of Aergo PS were comfort [n=3], postural management [n=2], and adaptability [n=1]. One parent reported no benefit due to their child having too high functional ability. Reported challenges were size of components [n=3], none [n=1], transfers [n=1] and sensory feedback [n=1]. No users reported any AEs or SAEs during the PMS case study. The PETS (Kirby et al. 2014) demonstrated minimal barriers to adherence of using Aergo PS in the home-based setting.

Discussion

This PMS case study has provided self-reported feedback that Aergo PS led to improved independence, comfort and posture for children with NMDs. We have confirmed Aergo PS is safe for use in the home-based environment, and users did not report any safety concerns. Children reported benefits that focused on improved postural management, comfort, and independence when compared to using standard seating systems. At present, users with complex needs for postural control may have limited benefit; for example, the level of sensory feedback needs to be assessed for potential users.

Results from the PMS study also suggest benefits of including digital tools to postural management practices. For example, young wheelchair users reported that the responsive features of the Aergo PS air cells have enhanced comfort during prolonged sitting, while the remote control also increased their independence from carer support. This feedback opens up future potential for Aergo to introduce additional digital features to enhance postural care provision. Further development will explore a digital postural management platform for clinicians to access Aergo PS remotely for prescription and adjustment of postural support settings. In future clinical studies will be conducted to evaluate the long-term health impacts of Aergo PS on children with NMDs.

References

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