Paul Sprague, NeuroMuscular Orthotics / **Hugo Marchant**, Ability Made / **Jackie O'Connor**

Using digital manufacture to achieve client goals

Methodical refinement of orthosis designs via digital manufacture has the potential to enhance the abilities of existing technology to meet a broader range of client goals with safety and efficiency.

The challenge

When lower limb orthosis-users are trying to participate in specific physical activities, we need to be able to tune their orthosis using sophisticated methods so their range of needs can be met. Often methods such as adjustments to talo-crural joint angles and dynamic stiffness in both the plantarflexion and dorsiflexion directions, requires the use of components such as the Posterior Dynamic Element (PDE) spring, NexGear Tango and NeuroSwing ankle joints. These joints are often incorporated into rigid, composite devices with full-length footplates to achieve maximum energy return (Faustini et al., 2006, Houdijk et al., 2021) for achieving goals related to optimising speed and efficiency in walking, especially on flat ground. However, in the case described below, the subject had additional goals of traversing undulating terrain to access paddocks on a property and to use the orthosis during gym workouts. Rigid footplate design can inhibit natural movement such as MTPJ extension, and past attempts to incorporate semi-rigid composite or thermoplastic materials into the footplate had failed either due to poor durability or dynamics. A solution that enabled all tuning methods, satisfactory energy return and enabled flexible design of the custom aspects of the orthosis that would be compliant with the Therapeutic Goods Administration (TGA) requirements was ideally required.

Designing and testing an innovative solution

Literature showed an orthosis 3D printed from Nylon 11 material would likely meet this client's needs if a PDE strut could be incorporated (Faustini et al., 2006, Harper et al., 2014a, Harper et al., 2014b, Ranz et al., 2016). Collaboration between NeuroMuscular Orthotics Orthotists and AbilityMade Design Engineers provided the opportunity to design an orthosis with variable stiffness custom shells, a toe plate with graduated flexibility, and an ankle section with targeted reinforcing to facilitate force transfer from the ground to the carbon fibre strut.

However, literature only reported on short term use, meaning durability and client safety was of concern. Computational simulation was used to ensure known stress points remained within the yield strength of the material, frog-mouthing was minimised to less than 5mm at 10 degrees of bending, and ultimately to design an AFO that would meet the client's functional and durability requirements in a minimalistic manner. The design was then laboratory tested with results suggesting the 3D printed Nylon 11 AFO incorporating a carbon fibre PDE spring and alloy anchors could be used safely for over 5 months assuming an average daily step count of 3000 steps per day. All parties agreed this was a suitable safety level for beginning a community trial.

Outcomes

During this client's trial of the design it was demonstrated she was able to achieve all her activity related goals, however, the calf cuff designed became too flexible after 4 weeks. The flexibility caused an associated fitting challenge as the flexibility enabled rotation of the orthosis to occur. The rotation needed to be resolved for the AFO to be suitable for long term use. Once this limitation was identified, the AbilityMade Design Engineers were able to adjust this aspect of the orthosis. This method ensured three key aspects important to the Orthotist/Prosthetist:

1. Minimal time was required by the Orthotist and no in-house manufacturing time was utilised to achieve a repeat fabrication
2. Only the intended changes occurred to the design given the precise nature of the manufacturing method
3. The design was known to be TGA compliant.

The second iteration of this design is now being utilised by the client to test in all her chosen environments.

The future

Collaborative, methodical, evidence-based use of digital manufacturing is allowing the possibility of accurately tuning custom orthoses to enable currently available technology to achieve a broader range of client goals in a safe and repeatable manner

A full list of references is available by contacting the author.