Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint

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Abstract: Neuromuscular disorders and injuries such as cerebral palsy and stroke often result in foot-drop which can result in a person having great difficulty walking. Ankle foot orthoses (AFOs) or splints have been prescribed for many years now to limit the range of motion of the ankle, provide the patients with support and assist with rehabilitation. However the majority of AFOs require a long, labour-intensive manufacturing process which results in unacceptable waiting times for children that are rapidly growing and patients with varying conditions. This research proposes a new approach to AFO manufacturing that utilizes digital and additive manufacturing technologies to customise the fit and form to an individual. By implementing an interchangeable carbon fibre spring at the ankle joint the design will result in a stronger, more comfortable, more flexible AFO that can adaptively constrain ankle movement for various different activities. Three iterations of AFO design have been developed and tested to validate their efficacy. A custom machine has been designed and constructed in order to empirically test stiffness values for the AFO and allow for optimal AFO geometry based on input parameters. This machine has proven the structural integrity of the final AFO design. Progress has been made in automating parts of the design process which will significantly reduce labour requirements and hence manufacturing delay times.

ABOUT THE AUTHORS

This research into 3D printed ankle-foot orthoses forms part of an overall research programme led by Dr Andrew McDaid at The University of Auckland in New Zealand. The team’s major focus is on developing innovative devices for people suffering from physical and neurological injuries and diseases. To achieve this the main technologies being investigated are robotics, digital and additive manufacturing, soft robotics and electroactive polymers. Advanced robust and adaptive control systems are also being developed to ensure optimal device performance. This technology is being applied to various applications such as rehabilitation robotics, prosthetics and other medical devices.

PUBLIC INTEREST STATEMENT

Neuromuscular disorders and injuries such as cerebral palsy and stroke often cause foot-drop, a condition that results in the forefoot dragging or catching during the swing phase of walking. Ankle foot orthoses (AFOs) or splints have been prescribed for many years now to restrict the range of motion of the ankle, and hence prevent foot-drop and assist rehabilitation. However the majority of AFOs require a long, labour-intensive manufacturing process which results in unacceptable waiting times.

This research proposes a new approach to AFO manufacturing that utilizes digital and additive manufacturing technologies (3D printing and scanning) to rapidly customise the fit and function to an individual’s requirements. The design also uniquely includes an interchangeable carbon fibre spring that results in a stronger, more comfortable, more flexible AFO that can adaptively constrain ankle movement for various different activities. Three iterations of AFO design have been developed and tested to validate their efficacy.
1. Introduction

Musculoskeletal and neuromuscular diseases and injuries, such as cerebral palsy (CP), amyotrophic lateral sclerosis (ALS) and stroke, reduce patients’ control over their limbs and result in abnormal alignment of wrists and ankles. In the case of the ankle, this can cause great difficulty walking (Dunning, O’Dell, Kluding, et al., 2015; Tugui & Antonescu, 2013) with symptoms including foot drop which is a gait abnormality causing involuntary plantarflexion and trouble raising the front of the foot, due to weakness or nerve damage (Reynolds, 2001; Winters, Gage, & Hicks, 1987; Yücesoy, Acar, & koyuncuoğlu, 2001). Foot-drop is a common symptom among sufferers of CP, ALS and stroke as well as muscular dystrophy diseases and cancer patients receiving chemotherapy.

Devices such as an ankle foot orthotic (AFO) can provide support for the ankle during daily activities and can assist with stretching during rehabilitation (Karas, 2002). There are two broad types of commercial AFO currently being used: standard off-the-shelf models with no patient customisation (e.g. available from AliMed–AFO, 2016) and custom-moulded models created through a time consuming, expensive, labour intensive process (e.g. Orthomerica–Custom Fabricated Orthoses, 2016; Phat Braces–Custom Braces, 2016). A recently introduced third method of orthosis production involves digital surface capture and additive manufacturing (AM) techniques (Jin, Plott, Chen, et al., 2015). This method shows great promise by greatly simplifying production of the AFOs, and allows for mass customisation, although little in-depth research has been done on the efficacy of such braces.

Mass customisation using AM technology is becoming increasingly popular in a variety of applications such as consumer goods. AM, including 3D printing, offers almost complete freedom of complexity, mass customisation, lower material usage and shorter processing times when compared to traditional subtractive manufacturing techniques. In the context of rehabilitative medical devices AM offers the benefits of bespoke fit with improved aesthetics (Paterson & Campbell, 2012), for example commercial solutions available for orthotics (3D orthotics, 2016).

Recent developments in digital scanning and AM technology have opened up new possibilities for creating cheap and highly customisable AFOs (Chen, Chen, Tai, et al., 2014; Meisel, 2014; Pallari, Dalgarno, Munguia, et al., 2010). Alam, Choudhury, Mamat, and Hussain (2015) developed a method to successfully scan a human adult leg and create an AFO from this. Using rapid prototyping methods they then constructed an AFO consisting of a foot plate, side bar and calf band. This AFO had excellent ventilation and reasonable strength but minimal contouring to the patients leg. A process planning method for printing AFOs has been described in Kunieda, Okada, Furutani, et al. (2016) and gait analysis has shown 3D printed AFOs can have similar performance with thermoplastic AFOs of a similar design (Creylman, Muraru, Pallari, et al., 2013). This research proposes a novel 3D printed design with a standardised and easily interchangeable carbon fibre reinforced polymer (CRFP) composite spring strengthening element. This element allows variation of stiffness without the complex modification of the custom parts.

The primary contribution of this research is a new method for 3D printing AFOs that both customises the fit and form while allowing for variable stiffness of the ankle joint due to a CRFP spring. This results in more efficient 3D printed AFO production process while also increasing AFO strength and flexibility to provide increased patient functionality through accurate control of ankle movement during walking. This hugely significant as it allows a single customised device to be interchanged for night and day use for a child for example. The methodology and results are presented in the subsequent chapters (preliminarily presented at the 2016 ICIDM conference Walbran & McDaid, 2016) followed by a discussion of this research.
2. Methodology

2.1. Novel segmented AFO design
A novel three segment design (consisting of a calf section, foot section and a central beam spring) for an AFO is proposed (Figure 1), where the calf and foot section are 3D printed and the CRFP spring provides strength and variable stiffness as required. The spring element can be easily interchanged for different uses or activities providing flexibility for everyday use. This overcomes a number of practical clinical issues as well as manufacturing complications where due to the complex 3D shape of a leg, a single piece AFO cannot be orientated for printing in such a way where the strength is maximised for all directions. This segmentation allowed for the optimal orientation (for material use, print time and strength) during manufacture of the additive manufactured components, while ensuring that the anisotropic properties of additive manufacture method used did not affect the strength greatly. The use of a connecting spring enabled the control of the rotational stiffness of the AFO in the three principle ankle rotation axes. The stiffness is focussed upon the plantar-dorsi flexion rotation due to the majority of the applied moments go through this axis during a full gait cycle.

2.2. Carbon fibre spring design
The carbon fibre springs are designed to be an off-the-shelf standardised part which can be interchanged as the patient’s requirements change and are recyclable between AFOs as a patient grows, this helps to lower reoccurring costs for the patient/health system. The spring was made from carbon fibre due to high strength-to-weight ratio. Although on its own carbon fibre has limited elasticity, the addition of a polymer based matrix such as epoxy resin has the effect of increasing the strength and rigidity while permitting more strain at yield.

The spring provides the majority of the displacement desired for the AFO used, thus allowing a more natural walking gait. This means that the additive manufactured components can be very stiff as they are not required to provide any displacement. The spring was attached between the two AFO halves with four button head bolts. They provided a good mechanical constraint while being low profile enough to not make unwanted rubbing contact with the patient wearing the AFO. The design of the spring was based around the use of unidirectional CFRP due to its high modulus of elasticity in the fibre direction. This allowed for the fibres to be orientated at differing angles, which in turn varied the spring’s stiffness for different loading directions. To calculate the spring design required Euler-Bernoulli beam theory for cantilevered beams was used in conjunction with a Classical Laminate Theory calculator, allowing the number of CFRP layers required to be found.

The CFRP that was used was a pre-impregnated unidirectional CFRP supplied by Gurit called SE 84LV. This allows for ease of manufacture as the carbon fibre is pre-impregnated with an epoxy
matrix which is in its b phase of curing, this enables clean and simple production of the spring as the epoxy matrix is already partially cured. The effective modulus of elasticity in the fibre direction for this CFRP is 144 GPA while each layer is 0.3 mm thick. The springs width and length was designed as 20 and 60 mm, respectively. From this data the layer requirement for production of the upper and lower limit of possible AFO stiffness's were found.

The springs, as described in Table 1, will be referred to as Springs 1–5 from this point onwards for simplicity.

### 2.3. Surface modelling and automation

A method for extracting the three segment AFO is described here where it has been designed to enable easy automation of the AFO manufacturing process in the future. For an adult subject it was fairly easy to ensure the ankle was held stationary during scanning. However, with a child there can be significant issues with them maintaining a stationary pose. Even with an adult subject it was difficult to ensure a perfect 90° angle of the ankle without inversion, eversion, pronation or supination. To solve these problems a fixture was designed to hold the subject’s leg in a fixed position during the scan. Figure 2 shows the scanning fixture being used to hold a subject’s leg at approximately 90° during scanning. The scan data of the patient’s leg was imported into MeshLab (2016), voids were filled and a Laplacian smoothing filter was applied. The result of these two steps is seen in Figure 3.

The scan data was then exported from MeshLab and imported into CREO Parametric CAD software. Three key reference points along the sagittal plane were located and used to define a central plane as seen in Figure 1 and 2. The scan data was then oriented so that cross sections could be taken following the legs curvature in that central plane. A spline was fitted to each cross section to produce a mathematical model of the legs surface. The number of cross sections taken affected the detail of the model created. It was found that a total of 25 evenly spaced cross sections produced a sufficiently detailed model for this application. The definition of the central plane and creation of the cross sections can be seen in Figure 4.

| Table 1. CFRP spring designs |
|-----------------------------|
| **Spring name** | **Description (angles in reference to length of spring)** |
| Spring 1 | Single 12 layer composite w/fibres at 0° |
| Spring 2 | Three 4 layer composites w/fibres at 0° |
| Spring 3 | Two 4 layer composites w/fibres at 0°, one 4 layer composite w/fibres at +45° |
| Spring 4 | Two 4 layer composites w/fibres at 0° |
| Spring 5 | Single 6 layer composite w/fibres at 0° |

Figure 2. Scanning fixture holding a subject’s ankle at approximately 90° with marker points (a) during scanning and (b) 3D scan.
Once the leg surfaces were imported into CREO Parametric, the upper and lower halves of the AFO were created. This was done by intersecting the leg surfaces with a second surface defining the bounds of the AFO and removing any overlapping material as seen in Figure 5. The AFO surface can then be solidified to the desired thickness based upon the strength and fit required. Hardware mounts can be extruded from the model to enable strap mounting and the carbon fibre spring installation. The result of these two steps can be seen in Figure 6.

2.4. AM methods

Three AM methods are being considered, selected due to their availability and desirable material properties; (1) Selective laser sintering (SLS) with nylon, (2) Fused deposition modeling (FDM) with Polylactic acid (PLA) and (3) FDM high-modulus carbon fibre filled polyethylene terephthalate (PETG).

The relative advantages and disadvantages of each AM method are compared in Table 2. The SLS Nylon material had been used by Meisel (2014), and had significant structural issues. However it is
believed that these structural issues can be mitigated. As such, the SLS Nylon was tested with four separate samples with printer parameters varied as in Table 3.

The tests were set to record stress and strain as the material is stretched out over time. The tests were set to run until either the material fractured, or 5% strain was reached, whichever came first. The results of the testing can be seen in Figures 7 and 8 as a plot of flexural stress vs. flexural strain.

As seen in these results, none of the SLS Nylon samples ever reached fracture point as it is a highly elastic material. This would be very desirable in a single piece AFO as it allows the bending of the

| Method               | Advantages         | Disadvantages     |
|----------------------|--------------------|-------------------|
| SLS with Nylon       | Isotropic          | Low strength      |
|                      | High elasticity    | Expensive         |
| FDM with PLA         | High strength      | Anisotropic       |
|                      | Cheap              | Low elasticity    |
| FDM with CF PETG     | Some elasticity    | Anisotropic       |
|                      | Highest strength   | Fairly expensive  |
plastic. However, due to the addition of the carbon fibre spring, very limited elasticity is required in the plastic material of this AFO design. The strongest SLS Nylon sample was SLS #2 with a fracture stress of only 28 MPa. Due to this low fracture strength and the high cost of SLS printing, this method of manufacture was discounted.

The carbon filled PETG provided the highest yield stress, with a value of 97 MPa. This was closely followed by the PLA sample with a yield stress of 88 MPa. The PLA sample provided a significantly higher yield and fracture strain than the carbon filled PETG. Due to its higher yield/fracture strain than the PETG, very similar yield stresses and significantly lower printing cost, the PLA plastic was selected as the AM technology of choice for the all full-size prints.

3. Results

3.1. Print and assembly
The final prototype was constructed from ABS plastic using an FDM 3D printer. This prototype was modelled with a 4 mm plastic thickness, selected fairly arbitrarily, although partially based on the thickness of previous design attempts. The selection of 4 mm thickness and a reduced toe section compared to previous prints allowed the AFO to fit inside a shoe for increased comfort. The rear and side views of the fit of the AFO prototype being worn on the subject both with and without a shoe can be seen in Figure 9.

| Sample name | Contouring power (%) | Hatching power (%) |
|-------------|----------------------|--------------------|
| SLS #1      | 27                   | 65                 |
| SLS #2      | 21                   | 65                 |
| SLS #3      | 25                   | 55                 |
| SLS #4      | 19                   | 50                 |
3.2. Stiffness testing

A custom machine (Figure 10) was developed to allow for the measurement of force under set displacements and calculation of sagittal plane stiffness parameters based on the results. The machine works by displacing the upper edge of the calf section of the AFO while holding foot section fixed in place. The bottom plate of the machine was constructed out of ultra-high density fibrewood and the back plate was made from aluminium sheet. A 10 mm leadscrew and nut were used to displace the top of the AFO such that when the leadscrew is rotated, the nut displaces the AFO.

The AFO was fixed in place on the machine through tightening of a clamp on the toe and securing of a strap around the heel. Displacement of the upper calf section was adjusted through rotation of a knob at the rear of the lead screw. The stiffness testing machine, fully manufactured and being used to displace the AFO, can be seen in Figure 10.

10 trials were performed with each of the 5 springs and AFO iteration 2 using the stiffness testing machine described above. The displacement was gradually increased up to 100 mm and the force values measured. The results were averaged, converted to angular values and plotted for each spring in Figure 11.

Figure 9. AFO being worn by the subject—Left: without shoe, Right: with shoe.

Figure 10. AFO under 100 mm displacement in the stiffness testing machine.
During the testing of Spring 1 it was noticed that the plastic was bending more than the carbon fibre spring. As such the stiffness results from this spring are not reliable and it is feasible for use on an AFO as ankle movement cannot be accurately controlled by the spring alone.

Of the remaining 4 springs, Spring 2 proved to be the stiffest, followed by Springs 3–5. The moment vs. rotation relationships appeared to be somewhat non-linear (with a slight logarithmic trend). However, for the purposes of ankle control, the relationship could be approximated as linear. Approximate linear stiffness coefficients for the 4 feasible springs were calculated and are presented in Table 4.

### Table 4. Approximate linear stiffness coefficients

| Spring   | Linear stiffness coefficient (Nm/°) |
|----------|------------------------------------|
| Spring 1 | 0.53                               |
| Spring 2 | 0.40                               |
| Spring 3 | 0.26                               |
| Spring 4 | 0.16                               |
| Spring 5 | 0.12                               |

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### 4. Discussion

From the linear stiffness coefficients calculated (see Table 4), two observations can be made about the effect of spring layup parameters (see Table 1) (i) increasing the number of total layers tends to increase spring stiffness and (ii) varying the fibre angle of the layers tends to decrease spring stiffness in the sagittal plane.

The results obtained from the stiffness testing machine were useful and allowed approximate determine of carbon fibre spring stiffness coefficients. However, it relied on the assumption of zero deformation of the plastic components. This assumption was made based on the appearance of little movement in the components. However, no measurements were made and this assumption may not be valid.

Biomechanical analysis is currently being performed using the Vicon motion capture system. The movement of the subject’s limbs in 3D space will be captured throughout a gait cycle via 16 markers placed on their lower body and 8 cameras spaced evenly around the room. The angles of the foot/tibia (ankle joint), tibia/femur (knee joint) and femur/pelvis (hip joint) flexion can be calculated for both legs. A comparison for each of the 6 angles between a control trial and trails with different AFOs and carbon springs can then be made to identify the effect of the AFO.

Further clinical trials of the AFO are taking place. Based on feedback from the patients, further adjustments will then be made to the automation process. As mentioned in the discussion,
psychosocial aspects of the AFO, such as physical appearance have a major bearing on patient comfort. Because of this, further research needs to be done into patient perception of the aesthetics of the AFO.

Further development could be undertaken in order to custom-mould foam materials to the inner surface of the AFO. There is also a possibility with the foam material for the addition of an anti-bacterial component for the purposes of smell and sanitation. This anti-bacterial component could either come from an external spray applied to standard foam, or from specially designed foams.

It is proposed that various sensors could be placed around the AFO in order to continuously record patient information. Readings from temperature and humidity sensors placed on the inner surface of the AFO could be taken to evaluate patient comfort and see where improvements need to be made. Readings from an accelerometer could tell the clinician the movement patterns of the patient, such as whether they are walking, running or remaining still while wearing the AFO. Pressure sensors could also be used to measure how many hours per day the patient is wearing the AFO and thus determine patient compliance.

A graphical user interface should be developed so that the clinician can easily specify AFO parameters, such as thickness, strength and elasticity. The AFO thickness and positioning of any add-ons could then be set based on these inputs from the clinician.

Two main steps have been identified in further automating the CAD AFO development process. Firstly the point cloud created from the STL file must be imported into mathematical software, such as MATLAB, and 3D curves fitted to it. It is proposed that this be achieved using the least-squares minimization method applied to a 3D domain.

A method would then need to be developed in order to create equations representing the surface of the AFO based on the equations representing the outline of the leg. The inner and outer surfaces of the AFO should be relatively simple to model, both based on the equations of the leg’s outer surface, with a linear offset added. These two surfaces would then need to be smoothly connected in order to create the sides of the AFO. Finally, additional components such as the connection points of the composite beam and any straps would need to be added.

The current results from empirical stiffness testing along with further trials could be compared in order to calculate the relationship between AFO shape and effective stiffness. This relationship can be used during the CAD automation process to determine the thickness and width of the AFO and carbon spring based on stiffness parameters given.

5. Conclusions
A novel segmented 3D printed and CFRP AFO design has been proposed. The manufacturing methods have been developed such that automation of the 3D printed segments can be achieved and will significantly reduce the labour costs of AFO production. An apparatus has been developed to hold the ankle in a fixed position during scanning. This allows consistent and repeatable models of the leg and foot to be obtained relatively independent of the skill of the operator and restraint of the subject. There is a lot of potential for further automation of the AFO design process.

A stiffness testing machine has been designed and developed which allows repeatable empirical testing of sagittal plane stiffness using a computer interface. This machine can be used to verify the stiffness results once the carbon spring has been manufactured.

Three iterations of AFO design have been developed, each improving upon areas deemed lacking in the previous design. Results from the stiffness testing machine have proven good structural integrity of the final AFO design.
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