

# ONE CLINIC'S EXPERIENCE WITH CARBON FIBER ORTHOSES IN NEUROMUSCULAR DISEASE

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**ABSTRACT:** *Introduction:* The purpose of this study was to summarize our experience with off-the-shelf anterior shell carbon fiber ankle-foot orthoses (CFAFOs) prescribed to adult neuromuscular patients in an outpatient clinic. *Methods:* We studied ambulatory patients who were seen in Muscular Dystrophy Association or amyotrophic lateral sclerosis clinics between 2011 and 2014 and prescribed anterior shell CFAFOs. Charts were reviewed with attention to diagnosis, satisfaction with use, and reasons for acceptance or rejection. We included individuals who were currently using AFOs and those being prescribed AFOs for the first time. We were especially interested in reasons for acceptance or rejection of the orthosis. *Results:* Two hundred eighty-three charts were reviewed. Of these, 109 of 123 (89%) patients were satisfied or extremely satisfied with the anterior shell CFAFOs, including 38 who had previously used other styles. *Conclusion:* Anterior shell CFAFOs should be considered for most neuromuscular patients with distal leg weakness.

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Ankle-foot orthoses (AFOs) to support weak dorsiflexors are commonly prescribed in patients with peripheral neuropathy, motor neuron disease, and muscle disease with concurrent distal lower extremity weakness.<sup>1–4</sup> In these settings, AFOs can partially reduce the functional limitations of distal-predominant weakness by assisting toe clearance during swing stage, decreasing fatigue, and decreasing energy consumption.<sup>5–7</sup> Unfortunately, treatment failure or non-compliance with AFOs is common. This is often related to the fact that this intervention draws attention to a patient's disability, restricts movement, and reduces the choice of footwear. In addition, AFOs are often uncomfortable due to rubbing or pressure.<sup>8,9</sup>

Although a patient may initially accept the intervention of an AFO, finding the most appropriate orthosis may be costly and time-consuming. Providers typically have prescribed custom-made posterior plastic AFOs for those who required dorsiflexion assist.<sup>10,11</sup> In recent years, however, anterior shell CFAFOs have been developed that provide

many advantages over custom-fit plastic AFOs. Functionally, the carbon fiber material allows the orthosis to “store energy” and release on push off and therefore benefit patients with coincident plantarflexion weakness.<sup>12,13</sup> In addition, anterior shell CFAFOs are thinner and lighter than plastic models, and the anterior tibial shell can act as a floor reaction AFO to provide quadriceps assist. Practically, because the anterior shell CFAFOs are not custom-fit (although they do come in several prefabricated sizes), they can be tried on in the clinic or orthotist's office to assess patient satisfaction and tolerability before expensive permanent orthoses are prescribed. When anterior shell CFAFOs gained approval by third-party payers as an alternative to custom-fit bracing, and recognizing the theoretical advantages of this device, we at the Ohio State Wexner Medical Center (OSUWMC) began routinely offering them to patients. There is a paucity of knowledge regarding the acceptance or rejection of anterior shell CFAFOs in the neuromuscular disease (NMD) population. In this report we summarize our initial experience with this orthotic device.

## METHODS

Patients were seen in the neuromuscular clinics at OSUWMC between 2011 and 2014. Under an approved institutional review board protocol, we collected demographic information and functional status on all ambulatory patients diagnosed with peripheral neuropathy (PN), motor neuron disease (MND), and muscle disease who exhibited distal lower extremity weakness. Of these 283 patients, 143 (51%) were ambulatory but did not have significant distal weakness and therefore did not meet the inclusion criteria. Patients initially recommended for AFOs were prescribed off-the-shelf anterior shell ToeOFF or BlueRocker CFAFOs (Allard, Heisingborg, Sweden) (Fig. 1) unless there were contraindications, such as significant plantarflexion contractures, severe spasticity, or substantial joint deformities. Individuals currently wearing posterior plastic AFOs were offered the ToeOFF or BlueRocker for their next AFO. When patients returned to the clinic (generally in 3 or 6 months), they were asked to grade their satisfaction with the ToeOFF or BlueRocker on a scale of 0–5 (5 being the best) and, if not satisfied, asked to indicate

**Abbreviations:** AFO, ankle-foot orthoses; ALS, amyotrophic lateral sclerosis; CFAFO, carbon fiber ankle-foot orthoses; CMT, Charcot-Marie-Tooth; DM1, myotonic dystrophy type 1; MD, muscle disease; MDA, muscular dystrophy association; MND, motor neuron disease; NMD, neuromuscular disease; OSUWMC, Ohio State University Wexner Medical Center; PN, peripheral neuropathy

**Key words:** amyotrophic lateral sclerosis; anterior shell carbon fiber orthosis; carbon fiber ankle-foot orthosis; Charcot-Marie-Tooth; muscular dystrophy

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**FIGURE 1.** Bilateral off-the-shelf anterior shell CFAFOs (carbon fiber ankle-foot orthosis, ToeOFF style) on a patient with ALS.

why. Whether the patient received a ToeOFF or BlueRocker was generally left up to the orthotist and patient, although heavier or taller individuals almost always required the stiffer BlueRocker. We did not separate these 2 varieties in our findings, as some patients tried a ToeOFF initially and then switched to the BlueRocker.

## RESULTS

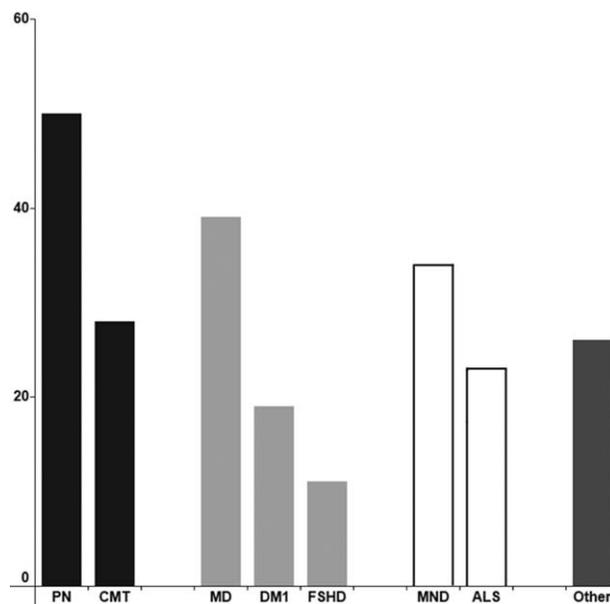
A total of 138 individuals were prescribed ToeOFF or BlueRocker CFAFOs. Two individuals initially tried ToeOFFs but received the Allard Ypsilon style (an anterior shell CFAFO that offers

	Motor neuron disease	Muscle disease	Neuropathy
Number (N)	34	39	50
Gender (M/W)	17/17	19/20	32/18
Age (years)*	56.9 (14.3)	51.2 (13.2)	56.8 (16.4)
Age range (years)	20–78	17–78	14–87
Weight (kg)*	80.1 (16.2)	75.5 (20.9)	82.7 (21.9)
Weight range (kg)	44–111	46–132	47–146
Height (cm)*	170 (9.9)	170 (11.5)	172.7 (12.3)
Height range (cm)	153–196	152–191	150–203
Satisfaction score	4.6	4.1	3.9

\*Values expressed as mean (standard deviation) as indicated.

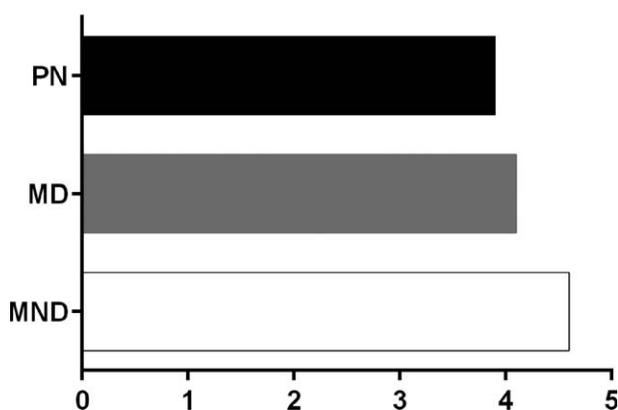
less restriction) because of their distinctly petite body type and were also added to the cohort. Of the 140 patients, we included 123 in our final analysis. The remaining 17 patients were excluded for the following reasons: 3 had inclusion-body myositis, and the ToeOFF was prescribed exclusively for quadriceps weakness; 1 had another neuromuscular disease; 2 were too weak proximally and required stance control knee ankle-foot orthoses; and 11 were lost to follow-up. The population demographics and neuromuscular type are shown in Table 1. A further breakdown of the specific diagnoses included is shown in Figure 2. Within the MND group, 5 individuals were thought to have amyotrophic lateral sclerosis (ALS) but did not meet El Escorial criteria, 3 had distal spinal muscular atrophy, and 3 had spinobulbar muscular atrophy (Kennedy disease). Overall, 89% (109 of 123) of the patients were satisfied (satisfaction grade 4) or extremely satisfied (grade 5). This included 38 individuals who previously had been prescribed custom-made, solid ankle posterior AFOs (Fig. 3). The range of responses on the satisfaction scale for each group was: MD range 1–5; MND range 3–5; and PN range 1–5. The most common reasons given by satisfied individuals were

## NMD Database and Largest Subgroups



**FIGURE 2.** The 3NM disease groups, peripheral neuropathy (PN), motor neuron disease (MND), and muscle disease (MD), included in the database and their largest subgroups: Charcot-Marie-Tooth (CMT); myotonic dystrophy type 1 (DM1); facioscapulohumeral dystrophy (FSHD); and amyotrophic lateral sclerosis (ALS). In addition, 5 subjects had chronic inflammatory demyelinating polyneuropathy, 5 had distal limb-girdle muscular dystrophy, 3 had inclusion-body myositis, 3 had distal spinal muscular atrophy, and 26 others had 17 additional neuromuscular diagnoses.

### Satisfaction (0-5)



**FIGURE 3.** Average satisfaction scores by neuromuscular disease category: muscle disease (MD); peripheral neuropathy (PN); and motor neuron disease (MND).

that the braces were lighter in weight, cooler to wear, assisted at push-off during ambulation, and allowed them to wear a normal-sized shoe.

Fourteen individuals (11%) discontinued their anterior shell CFAFOs. Some chose to return to posterior AFOs ( $N=7$ ), whereas the rest discontinued using any AFO. Reasons given for dissatisfaction were that the orthoses did not provide enough support ( $N=2$ ) or were not comfortable ( $N=3$ ). Two patients did not provide a reason. One individual with inclusion-body myositis liked the ToeOFF very much for walking, but could not as easily transition from sitting to standing.

#### DISCUSSION

Neuromuscular clinicians routinely see patients with mobility limitations. For ambulatory individuals with distal leg weakness, orthotics can provide a genuine improvement in overall quality of life.<sup>7,14</sup> Technology has offered more choices to patients; it is imperative that providers recognize the potential advantages and disadvantages of each option. Overall, our experience with anterior shell CFAFOs has been very positive in that most patients were satisfied with their fit, comfort, and performance. What was especially gratifying was the number of patients who preferred the anterior shell CFAFO orthotic to their standard custom-made solid ankle plastic AFOs. In addition to less weight and a thinner material, patients could try these orthoses in the clinic or in the orthotist's office and provide immediate feedback, both positive and negative. The clinic orthotist almost always was able to accommodate discomfort issues, and individuals with some degree of foot deformity, sensory abnormality, or joint contracture could be made comfortable by additional padding or a heel lift. There were no instances of skin breakdown. This was

likely due to the fact that the anterior shell CFAFOs have less total skin contact than the custom-made AFOs. The most frequent complaint related to the anterior shell CFAFO was inadequate support. Four severely weak patients, 3 diagnosed with Charcot-Marie-Tooth (CMT) hereditary neuropathy, appreciated the advantages but needed more medial or lateral stability. Those patients returned to custom-made orthoses.

In an attempt to analyze why some individuals were dissatisfied, we charted the manual muscle testing grades of hip flexion, knee extension, ankle dorsiflexion, and ankle plantarflexion of all 3 groups (MND, PN, and MD), and compared the numbers across the groups. We also charted the average scores of the major subgroup within these 3 groups and compared them with the averages of their larger group [ALS average vs. MND average, CMT average vs. PN average, myotonic dystrophy type 1 (DM1) average vs. MD average].

We found that the only significant difference in the NMD population was ankle dorsiflexion and plantarflexion. Those with CMT had significantly weaker dorsiflexion and plantarflexion than the rest of the PN population. Those individuals with DM1 had stronger dorsiflexion and weaker plantarflexion than the general MD population. Ultimately, however, these deviations did not have a significant impact on patient satisfaction.

Two individuals (facioscapulohumeral MD DM1) who were prescribed a ToeOFF or Blue-Rocker AFO as their initial orthosis, discontinued them, but could not provide a reason.

Cost was generally not a factor, as the CFAFOs were only modestly more expensive (by 15%, which currently equals \$90USD) than the posterior plastic type. Since this review began, we have also prescribed the Matrix brand (ProLAB Orthotics, Napa, California) off-the-shelf anterior shell CFAFO because of third-party payer requirements.

A limitation of this review is that our patient satisfaction scale was simple and had not been validated. However, the scale did correlate with the patients' continued use of the anterior shell CFAFO, and this is the only real satisfaction point that is important. This was not a longitudinal study, so we did not formally track repeated satisfaction scores over time. Some individuals we have seen over numerous regular clinic visits remained satisfied (shown by a 4 or a 5) throughout their follow-up visits. If patients were not satisfied at their first encounter with the anterior shell CFAFOs, their satisfaction was not tracked, as they did not receive the orthoses. The overwhelming majority of ambulatory neuromuscular patients with distal leg weakness will benefit from off-the-shelf ToeOFF or BlueRocker CFAFOs. Almost all

individuals achieved comfort with custom inserts, padding, or a heel lift. A brief AFO trial during a clinic visit, without a separate trip to the orthotist, is appreciated by patients for economic and practical reasons. In the future, we hope to stock more styles and sizes.<sup>15</sup> A minority of patients with more significant foot deformities, ankle contractures, or abnormal sensation will continue to require a custom-made orthosis.<sup>16</sup>

In conclusion, our patient cohort with mixed neuromuscular diagnoses, who have ankle dorsiflexion and or plantarflexion weakness, are good candidates for anterior shell CFAFOS and reported positively on their experience.

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