Molded Ankle Foot Orthoses of variable stiffness offload Achilles Tendon during ambulation.

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INTRODUCTION: Achilles tendinopathy is a painful and debilitating condition that affects 2.35 per 1,000 adult individuals [1]. Mechanical overload is thought to be a primary driver of pathology. Management of severe tendinopathy usually requires immobilization to offload the Achilles tendon to relieve symptoms and promote tissue healing. However, patients do not tolerate immobilization via controlled ankle motion (CAM) boots for prolonged periods and often undergo surgical debridement if symptoms do not remit after immobilization. The senior author and many of her partners employ a molded ankle foot orthosis (MAFO), which is a custom non-articulating brace. Anecdotally, we find that patients with MAFOs are willing to wear the MAFO for prolonged periods of time and experience better outcomes with lower rates of surgical intervention. The relative benefits of MAFO vs CAM include ability to wear a regular shoe, elimination of limb length discrepancy and resultant increased hip and lumbar spine pain. However, the basic mechanical mechanisms that facilitate these good outcomes and symptom resolution are unknown. For this reason, we developed techniques to quantify the biomechanical loading environment during ambulation as we prepare to longitudinally study a cohort of patients at Penn Medicine. We hypothesized that 1) MAFOs reduce Achilles tendon loading compared to shod ambulation and 2) stiffer MAFOs offload the Achilles tendon more than compliant MAFOs during ambulation.

METHODS: We tested three custom fit MAFOs of a '*stiff*', '*intermediate*', and '*compliant'* on a single healthy control subject (Male, Age: 22 y/o, BMI: 26) in this IRB approved study. These MAFOs are representative of the prescribed range of MAFO designs. We instrumented the three MAFOs with a strain gauge on the back of the MAFO near the Achilles **(Figure 1**) to quantify loads carried by the brace. We determined the relative stiffness of each of these MAFOs by fixing them to a table and pulling on the shin strap with a tensile loadcell until the MAFO buckled. The test subject walked at slow, medium, and fast speeds in a motion capture laboratory in the three MAFOs and regular shoes. We synchronously captured 1) total ankle loading using inverse dynamics using the external motions of the lower extremity captured using a 12-camera motion capture system and force plates, 2) Achilles tendon loading using our validated instrumented insole (Loadsol, Novel) paradigm that was placed under the foot to measure the loads produced by the calf muscle and experienced by the Achilles Tendon [2], and 3) MAFO loading using the calibrated strain gauge secured to the back of each MAFO. The data from these insoles were streamed to a wireless device (Ipod Touch, Apple) running a manufacturer provided app (Loadsol App, Novel). We analyzed 5 gait cycles for each of the 12 conditions (4 MAFO/shoe x 3 speed). We compared the peak Achilles tendon loads – normalized by the participant's bodyweight – across each test condition. We performed this initial proof of concept study to determine best laboratory practices to quantify Achilles tendon loading in patients wearing their custom fit MAFO in our follow-up clinical study.

RESULTS SECTION: Achilles Tendon load was 27% greater in the shod condition than all the MAFO conditions. We found that the '*stiff*' MAFO was 2.3 times stiffer than the '*intermediate'* MAFO and the '*compliant*' MAFO was 2.1 times more compliant than the *'intermediate'* MAFO. Despite these large differences in compliances, we did not detect large differences in Achilles tendon loading across these three MAFOs. The greatest difference in Achilles Tendon load was 6% between MAFOs.

DISCUSSION: Our study confirmed our primary hypothesis that a custom-fit MAFO brace offloads the Achilles Tendon during ambulation compared to shod walking. However, we also expected that stiffer MAFOs would further decrease the loading. This was not the case, as all three MAFOs resulted in nearly identical walking forces. This proof-of-concept study focused on technology development and an experimental protocol to rigorously characterize biomechanical loading in a single, healthy experimenter. Our ongoing work is applying this wearable sensor paradigm in a cohort of patients with mid-substance tendinopathy to identify the link between MAFO-mediated Achilles tendon loading with patient outcomes. We expect that our novel instrumented MAFO paradigm will provide new opportunities to determine the mechanical mechanism that explain symptom relief in patients receiving conservative treatment for mid-substance Achilles tendinopathy.

SIGNIFICANCE/CLINICAL RELEVANCE: This experiment is a necessary step towards developing precision rehabilitative care for patients with tendinopathy. We expect that by linking patient biomechanics with tendon healing and symptoms, we will establish evidence-based tendon loading profiles that improve patient outcomes and decrease the need for surgical treatment. Minimizing surgical treatment is critical to improve outcomes for many patients who are bad candidates for surgery because of comorbidities like smoking and diabetes.

REFERENCES: [1] de Jonge, S., et al., Br J Sports Med, 2011, [2] Hullfish, TJ et al. J. Biomech., 2020.

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IMAGES AND TABLES:

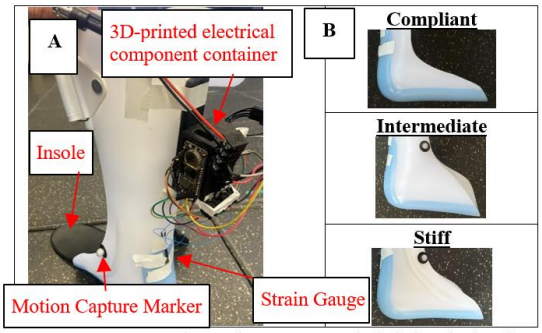

Figure 1: MAFO Experimental Setup. **(A)** Labeled electrical and mechanical instrumentation of MAFO. **(B)** Representative images of ankle region of MAFO, demonstrating varying levels of supporting material

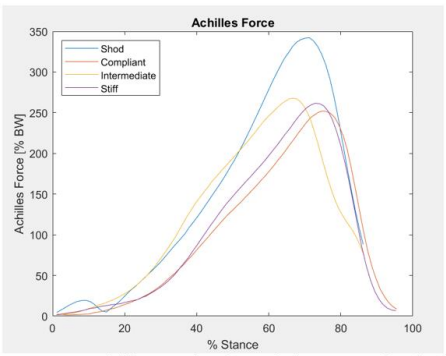

Figure 2: Achilles Tendon force during stance for shod, compliant MAFO, intermediate MAFO, and stiff MAFO