Title: Reliability of Force Measurement within the Carbon Fiber Orthosis Proximal Cuff

NCT Number: Not Yet Assigned

Date: October 17, 2023

Study Protocol

Purpose and Procedures

The primary purpose of this research study is to determine if forces within carbon fiber custom dynamic orthoses (CDOs) can be reliability assessed using Loadpad and Loadsol force measuring sensors (Novel GMBH, St. Paul, MN). An improved understanding of the forces acting within orthoses may help to guide future orthosis related research studies, provision methods, and patient education.

Study participants will consist of healthy, able-bodied adult participants using generic sized CDOs, which consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that runs the length of the leg and bends to store and return energy, and a semi-rigid footplate that acts as a lever arm to bend the posterior strut. Participants will be asked to fasten the proximal cuff to a self-selected cuff tightness 'SSCT', as well as three different predefined force levels; 'Loose' where the proximal cuff is loosely fastened around the participants leg, 'Moderate' where the proximal cuff is fastened with moderate tightness, and 'Tight' where the proximal cuff is tightly fastened around the participants leg. Forces acting on the leg, within the proximal cuff, will be measured using wireless Loadpad sensors and forces acting on the foot will be measured using wireless Loadsol insoles. Testing will include collection of force data as participants sit quietly, stand quietly, and walk and completion of questionnaires. Testing in the predetermined force levels (Loose, Moderate, Tight) will occur in a randomized order.

Objectives and Specific Aims

Specific Aim 1: Determine the within-session reliability of a novel method for measuring forces within the proximal cuff.

Specific Aim 2: Determine the effect of altering forces acting within the proximal cuff on foot loading during gait.

Specific Aim 3: Determine the effect of short bouts of walking on forces acting within the proximal cuff.

Specific Aim 4: Determine the range of forces applied within the proximal cuff.

Background and Significance

Ankle foot orthoses (AFOs) are medical devices often used to support the foot and ankle during daily activities. Carbon fiber custom dynamic orthoses (CDOs), one subset of AFOs, that consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that runs the length of the leg and bends to store and return energy during gait, a semi-rigid carbon fiber footplate that acts as a lever arm to bend the posterior strut, and in some cases a foam heel wedge placed between the footplate and the shoe. Different CDO design characteristics, such as posterior strut stiffness, device alignment, and heel cushion height and stiffness have been studied in the past.1, 3, 8-11 While different design characteristics have been studied previously, there is little information available concerning the proximal cuff and how it impacts patient outcomes. Different types of AFOs and CDOs have been used in an effort to offload the limb for years.5, 12, 13 Both CDOs and patellar tendon bearing (PTB) style AFOs have been shown to reduce forces acting on the plantar surface of the foot.5, 12, 13 While multiple studies have indicated the importance of fastening the proximal cuff, few have actually investigated the forces acting within the proximal cuff.6, 13-15 A loose proximal cuff has been associated with pistoning of the limb, where the limb translates down within the proximal cuff during loading, potentially increasing forces acting on the foot and reducing the offloading effects of the orthosis.6, 15 Only one study investigated the effects of altering forces within the proximal cuff by adding more padding to the proximal cuff, which was shown to improve limb offloading.13

A better understanding of the forces acting within the proximal cuff, and how these effect patient outcomes would help to guide future AFO related research studies, provision, and patient education. At this point in time there is little guidance available to inform patients how tightly they need to secure the proximal cuff when wearing an AFO, many clinicians recommend tightening it so that it's secure, but not uncomfortable. The ability to measure forces within the proximal cuff and an idea of the range of forces seen in a clinical setting will act as a first step to better understanding how forces acting within the proximal cuff impact patient outcomes.

Inclusion Exclusion Criteria

Inclusion Criteria

- Between the ages of 18 and 65
- Healthy without current complaint of lower extremity pain, spine pain, open wounds or active infections, or medical or neuromusculoskeletal disorders that have limited their participation in work or exercise in the last 6 months
- Able to hop without pain
- Able to perform a full squat without pain
- Ability to read and write in English and provide written informed consent

Exclusion Criteria

- Diagnosed with a moderate or severe brain injury
- Lower extremity injury resulting in surgery or limiting function for greater than 6 weeks
- Injuries that would limit performance in this study
- Diagnosed with a physical or psychological condition that would preclude functional testing (e.g. cardiac condition, clotting disorder, pulmonary condition)
- Visual or hearing impairments that limit walking ability or limit the ability to comply with instructions given during testing
- Require use of an assistive device
- Unhealed wounds (cuts/abrasions) that would prevent AFO use
- BMI > 35
- Pregnancy

Design and Methods

We anticipate the study will be completed in one visit. The approximate time to complete study activities is 1-2 hours. Although we will attempt to collect all data in the specific order listed, the number of study activities completed, and the specific order of completion will be dependent on participant, staff, and study equipment availability. There is a chance that additional visits may be required to complete all study activities. The order of events is listed below.

Timepoint 0

- don the CDO
- place, calibrate, and zero sensors

Timepoint 1 (repeat for SSCT, Loose, Moderate, and Tight conditions)

- fasten proximal cuff, mark straps
- collect sitting trial(s)
- collect standing trial(s)
- unfasten proximal cuff

Timepoint 2

- remove and replace CDO

Timepoint 3 (repeat for SSCT, Loose, Moderate, and Tight conditions)

- re-fasten proximal cuff to mark on straps
- collect sitting trial(s)

- collect standing trial(s)

- unfasten proximal cuff

Timepoint 4

- remove and replace CDO

Timepoint 5 (repeat for NoCDO, Loose, Moderate, and Tight conditions)

- place, calibrate, and zero sensors

- don CDO (Loose, Moderate, and Tight)

- fasten proximal cuff (Loose, Moderate, and Tight)

- collect sitting pre trial(s)

- collect standing pre trial(s)

- 5 minute accommodation period

- collect walking trial(s)

- collect standing post trial(s)

- collect sitting post trial(s)

- complete questionnaires

- unfasten proximal cuff

Potential participants will answer pre-screening questions prior to their visit. If they meet all inclusion and none of the exclusion criteria they will be consented to participate in the study. Following informed consent, participants will be screened using the post-screening checklist. If participants fail to meet the inclusion or exclusion criteria, their participation will end at that point.

Personal/demographic and anthropometric information will be used to fully characterize participants. Demographic factors include characteristics that are independent of the health condition but can potentially influence physical performance and an individual's course of recovery. We will collect multiple variables that have been previously associated with outcomes as listed: race, ethnicity, education level, age, biological sex, height, weight, leg length, shoe type, shoe length and width.

Patient-reported outcomes questionnaires will be used to evaluate participant pain and comfort and smoothness. These patient-centric assessments will provide insight that can be used to interpret other study findings. We have used the selected measures in the target population and expect that they will effectively capture device-related outcomes. Participants will complete comfort and smoothness and pain questionnaires after walking in each of the predetermined cuff tightness study conditions (Loose, Moderate, Tight).

Comfort and smoothness will be assessed using a modified version of the Socket Comfort Score, a reliable, valid, and sensitive measure of device fit and comfort.16 These measures have been shown to effectively capture patient perception, are responsive to simple modifications to CDO device function, and will be applied in a manner consistent with a prior publication by the research team.17 Comfort scores range from 0 = most uncomfortable to 10 = most comfortable, and smoothness scores range from 0 = least smooth to 10 = most smooth.16

Pain will be assessed using a standard 11-point numerical pain rating scale, in which 0 = no pain and 10 = worst pain imaginable, in a manner consistent with multiple other protocols.18, 19 Using this highly reliable approach, participants will be asked to rate their pain at the start of each session and at different points during each testing condition.

Force measurement sensors will be used to measure forces acting within the orthosis. Loadpad sensors (Novel GMBH, St. Paul, MN) will be placed in the proximal cuff to measure forces acting on the leg. Loadsol insoles will be placed in the shoe and in the orthosis footplate to measure forces acting on the foot. The Loadsol system has been found to be accurate, precise, and repeatable in measuring plantar pressures during normal gait.20, 21 Data will be collected as participants sit and stand quietly after initially fastening the proximal cuff to each cuff tightness. A mark will then be made on the strap of the proximal cuff to indicate the position of the strap at each cuff tightness (timepoint 1). Participants will then be asked to take off the CDO and put it back on (timepoint 2). The proximal cuff will then be fastened again to each tightness based on the mark made on the strap and data will be collected as participants sit and stand quietly (timepoint 3). Participants

will then be asked to take off the CDO and put it back on again (timepoint 4). Data will then be collected as participants sit and stand quietly, as they walk after a minimum of 5 minutes accommodation period and then as they stand and sit quietly without the CDO and with the proximal cuff fastened to each tightness. Participants will also be asked to complete questionnaires after each bout of testing in the CDO (timepoint 5).

Video recordings and pictures of the participants leg will be collected throughout testing, and participants will be informed as videos or pictures are being recorded. Video recordings will be taken as participants are walking. The camera will be positioned to the best of the research staff's ability so the top of the field of view will be at the participant's shoulders to minimize the likelihood of capturing the participant's face. Collection of video recordings is required during testing for quality control purposes. Pictures of the participants leg and orthosis will be taken during sitting and standing trials for quality control purposes. Files will be stored securely as described in section X.4 and will only be available to members of the research team. Video recordings and pictures will be removed from the camera after being transferred to the secure network drive server and will be retained to facilitate future analysis consistent with "Data Storage for Future Use" section in the informed consent document.

Statistical Analysis Plan

Analysis Methods

Aim 1: Intraclass correlation coefficients (ICCs) and minimal detectable change values will be calculated for the average force measured within the proximal cuff when it is initially fastened (Timepoint 1), removed and replaced (Timepoint 2), and then refastened (Timepoint 3).

Aim 2: A one-way repeated measures ANOVA will be used to evaluate the effect of proximal cuff tightness on foot loading as participants walk in the pre-determined cuff tightness conditions (Timepoint 5).

Aim 3: Paired sample t-tests with Bonferroni-Holm corrections will be used to determine the change in force within the proximal cuff that may occur before and after short bouts of walking (Timepoint 5).

Aim 4: Descriptive statistics will be used to describe the range of SSCT forces measured within the proximal cuff (Timepoint 1/3).

Power Analysis

The number of participants proposed for this study are consistent with those from prior investigations by Dr. Wilken related to orthosis design. Thirteen participants were sufficient to detect differences associated with orthosis stiffness in a recent study by Dr. Wilken (PMID: 25193884). A total of 20 participants were included in to adequately evaluate reliability of the novel method for measuring forces within the proximal cuff.

Literature Cited

1. Brown SE, Russell Esposito E and Wilken JM. The effect of ankle foot orthosis alignment on walking in individuals treated for traumatic lower extremity injuries. J Biomech 2017; 61: 51-57. 2017/07/25. DOI: 10.1016/j.jbiomech.2017.06.037.

2. Haight DJ, Russell Esposito E and Wilken JM. Biomechanics of uphill walking using custom ankle-foot orthoses of three different stiffnesses. Gait Posture 2015; 41: 750-756. DOI: 10.1016/j.gaitpost.2015.01.001.

3. Harper NG, Esposito ER, Wilken JM, et al. The influence of ankle-foot orthosis stiffness on walking performance in individuals with lower-limb impairments. Clin Biomech (Bristol, Avon) 2014; 29: 877-884. 20140808. DOI: 10.1016/j.clinbiomech.2014.07.005.

4. Kearney RS, Lamb SE, Achten J, et al. In-shoe plantar pressures within ankle-foot orthoses: implications for the management of achilles tendon ruptures. Am J Sports Med 2011; 39: 2679-2685. 20110909. DOI: 10.1177/0363546511420809.

5. Stewart J, Djafar T, Miltenberger R, et al. Plantar Pressure Changes with Use of an Intrepid Dynamic Exoskeletal Orthosis. JPO: Journal of Prosthetics and Orthotics 2020; 32.

6. Trepman E and Donnelly P. Patellar Tendon-Bearing, Patten-Bottom Caliper Suspension Orthosis in Active Charcot Arthropathy: Crutch-Free Ambulation with No Weight Bearing in the Foot. Foot & Ankle International 2002; 23: 335-339. DOI: 10.1177/107110070202300408.

7. Kay H. Clinical Applications of the Veterans Administration Prosthetics Center PatellarTendon-Bearing Brace Artificial Limbs 1971; 15: 46-67.

8. Ikeda AJ, Fergason JR and Wilken JM. Effects of altering heel wedge properties on gait with the Intrepid Dynamic Exoskeletal Orthosis. Prosthet Orthot Int 2018; 42: 265-274. 20170904. DOI: 10.1177/0309364617728116.

9. Russell Esposito E, Choi HS, Owens JG, et al. Biomechanical response to ankle-foot orthosis stiffness during running. Clin Biomech (Bristol, Avon) 2015; 30: 1125-1132. 2015/09/16. DOI: 10.1016/j.clinbiomech.2015.08.014.

10. Russell Esposito E, Ranz EC, Schmidtbauer KA, et al. Ankle-foot orthosis bending axis influences running mechanics. Gait Posture 2017; 56: 147-152. DOI: 10.1016/j.gaitpost.2017.04.023.

11. Schmidtbauer KA, Russell Esposito E and Wilken JM. Ankle-foot orthosis alignment affects running mechanics in individuals with lower limb injuries. Prosthet Orthot Int 2019; 43: 316-324. 2019/02/15. DOI: 10.1177/0309364619826386.

12. Alimerzaloo F, Kashani RV, Saeedi H, et al. Patellar tendon bearing brace: Combined effect of heel clearance and ankle status on foot plantar pressure. Prosthetics and Orthotics International 2013; 38: 34-38. DOI: 10.1177/0309364613486916.

13. Saltzman CL, Johnson KA, Goldstein RH, et al. The Patellar Tendon-Bearing Brace as Treatment for Neurotrophic Arthropathy: A Dynamic Force Monitoring Study. Foot & Ankle 1992; 13: 14-21. DOI: 10.1177/107110079201300103.

14. Guse ST and Alvine FG. Treatment of Diabetic Foot Ulcers and Charcot Neuroarthropathy Using the Patellar Tendon-Bearing Brace. Foot & Ankle International 1997; 18: 675-677. DOI: 10.1177/107110079701801015.

15. Davis FJ, Fry LR, Lippert FG, et al. THE PATELLAR TENDON-BEARING BRACE: REPORT OF 16 PATIENTS. Journal of Trauma and Acute Care Surgery 1974; 14.

16. Hanspal RS, Fisher K and Nieveen R. Prosthetic socket fit comfort score. Disabil Rehabil 2003; 25: 1278-1280. DOI: 10.1080/09638280310001603983.

17. Ikeda AJ, Fergason JR and Wilken JM. Effects of altering heel wedge properties on gait with the Intrepid Dynamic Exoskeletal Orthosis. Prosthet Orthot Int 2017: 309364617728116. 2017/09/06. DOI: 10.1177/0309364617728116.

18. Williamson A and Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs 2005; 14: 798-804. DOI: 10.1111/j.1365-2702.2005.01121.x.

19. Hjermstad MJ, Fayers PM, Haugen DF, et al. Studies comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for assessment of pain intensity in adults: a systematic literature review. J Pain Symptom Manage 2011; 41: 1073-1093. DOI: 10.1016/j.jpainsymman.2010.08.016.

20. Hsiao H, Guan J and Weatherly M. Accuracy and precision of two in-shoe pressure measurement systems. Ergonomics 2002; 45: 537-555. DOI: 10.1080/00140130210136963.

21. Ramanathan AK, Kiran P, Arnold GP, et al. Repeatability of the Pedar-X in-shoe pressure measuring system. Foot Ankle Surg 2010; 16: 70-73. 20090709. DOI: 10.1016/j.fas.2009.05.006.