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Material properties and application of biomechanical principles provide significant motion control performance in experimental ankle foot orthosis-footwear combination

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ABSTRACT

Background: This study, the first of its kind, originated with the need for a brace (an ankle foot orthosis), to constrain ankle plantarflexion and dorsiflexion within a motion threshold of $<5^\circ$. A conventional thermoplastic, solid brace failed during a quasi-static loading study, informing the investigation and development of an experimental carbon composite brace, maximizing stiffness and proximity of shank and foot cylindrical shells to provide the required degree of control.

Methods: Two experiments were conducted: a quasi-static loading study, using cadaveric limbs ($n = 2$), and a gait study with healthy subjects ($n = 14$). Conditions tested were STOP, FREE, and CONTROL. Data for all studies were collected using six motion-capture cameras (Vicon, Oxford, UK; 120 Hz) tracking bone-anchored markers (cadaveric limbs) and skin-anchored markers (subjects). In the quasi-static loading study, loading conditions were congruent with the gait study. Study 1 involved a quasi-static loading analysis using cadaveric limbs, compared motion data from a conventional thermoplastic solid brace and the experimental brace. Study 2 involved quantifying ankle plantarflexion and dorsiflexion in subjects during treadmill walking, in brace STOP, FREE, and CONTROL conditions.

Findings: The experimental brace in STOP condition consistently constrained ankle plantarflexion and dorsiflexion below the motion threshold of $<5^\circ$, across all studies.

Interpretation: Collectively, these findings demonstrate (1) that a conventional thermoplastic, solid brace was ineffective for clinical applications that required significant motion control, and (2) that ankle motion control is most effective when considered as a relationship between the brace, the ankle-foot complex, and the external forces that affect them both.

1. Introduction

This study of motion control in an experimental ankle foot orthosis-footwear combination (exAFO-FC) using healthy human subjects originated with the collapse of a conventional thermoplastic solid AFO (SOLID AFO) during a quasi-static loading study, that was tested in previous experiments requiring use of an orthotically constrained ankle during walking. Our subsequent investigation revealed few studies providing a quantitative baseline for AFO motion control performance (Kobayashi et al., 2011; Sumiya et al. 1996; Totah et al., 2009), despite the AFO's ranking as the most prescribed lower limb orthosis (Practice Analysis, 2019). We found a similar paucity of publications on the role of integral footwear in minimizing gait compensation in an AFO-restrained ankle (Hutchins et al. 2009).

Absent this evidence, we reasoned that the beginnings of a normative baseline, derived from tightly controlled investigations, could provide clinicians with evidence, never before reported, of an AFO's ability to constrain ankle motion. Producing this baseline would require a systematic, quantifiable approach to AFO design. This approach, detailed below, combined a reconsideration of materials with the application of biomechanical principles that improve stiffness and leverage. This was subsequently followed by systematic testing to quantify the AFO's

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ability to constrain ankle motion.

The fact that we used fundamental principles in biomechanics and common knowledge of material properties to guide our design should not be remarkable, nor should it be a surprise that significant performance benefits accrued from this approach. What is remarkable, however, is that systematic, scientific evidence of AFO performance is largely absent from, thus unavailable for, clinical consideration. This study, is our contribution to literature aimed at better informing clinical expectations regarding device efficacy, improving decisions and providing clinicians a fresh perspective on patient response to AFO treatment.

Our investigations required an AFO capable of delivering near-total ankle constraint, i.e., $<5^{\circ}$ combined ankle plantarflexion (PF) and dorsiflexion (DF) during gait. When our first motion control device, a SOLID AFO, collapsed into dorsiflexion during a quasi-static loading study, we saw an opportunity to design an AFO for strictly experimental purposes, without regard for commercial concerns, such as cost, size, and fault-tolerant custom fitting, all of which support the prevalence of thermoplastic AFOs in clinical practice.

The exAFO-FC we described had three characteristics: 1) sufficient stiffness to minimize anatomical ankle motion within a stipulated motion threshold ($<5^{\circ}$ combined PF and DF); 2) articulated ankle joint and linear bearing, to maintain ankle motion control in two experimental conditions, STOP (maximum restriction of motion) and FREE (minimum restriction of motion); and 3) custom footwear, to minimize gait compensation and preserve rollover dynamics.

Focusing on these characteristics, we built an exAFO-FC, testing its effectiveness in two performance studies: (1) a quasi-static loading study using cadaveric limbs, to quantify the motion control capability of the experimental AFO without footwear (exAFO); and, (2) a gait study, involving human subjects, to quantify the combined effectiveness of the exAFO-FC for motion control and preservation of rollover.

Section 2 of this article describes the exAFO-FC design processes. *Section 3* presents the methods, results, and discussions of the two performance studies. *Section 4* provides our conclusions, regarding clinical relevance, the significance of our findings and how our approach may benefit the rehabilitation community.

2. AFO-FC design process

2.1. Material properties and biomechanical principles used to design exAFO

The ankle functions biomechanically as a modified hinge joint to allow motion of the shank and foot segments. An AFO that effectively restricts ankle motion should be made from materials with sufficient stiffness to withstand motion in the shank and foot segments of the limb, as well as motion of the ankle joint itself. To improve the stiffness of the exAFO, we employed three common tropes from structural and mechanical engineering: *modulus of elasticity*, *geometry of shape*, and a *three-force system*.

2.1.1. Modulus of elasticity (Young's modulus)

Modulus of elasticity or Young's modulus, a numerical representation of the ratio of *stress* (force) to *strain* (deformation), describes the relative stiffness of a material. Very low-modulus materials (e.g., thermoplastics) exhibit lower resistance to force and deformation than, for example, titanium, which has a very high modulus. Given the likely deformation of the thermoplastic AFO, a material with a significantly higher modulus of elasticity was required. We selected carbon composite laminate, a combination of materials that is familiar to clinical orthotists for its superior strength, its ability to be molded, and its high strength-to-weight ratio, all of which are important advantages for patients whose clinical conditions require maximum restriction of ankle motion during walking. The typical modulus of elasticity for polypropylene used in thermoplastic AFOs is 0.23 (x 10^6 psi). By comparison, carbon composite's modulus of 18.5 (x 10^6 psi) is over 80 times greater than that of polypropylene (Weber and Murphey, 2019).

2.1.2. Geometry of shape

Our observed assessment of the failed SOLID AFO also called into question its half cylindrical shell geometry. Even using a stiffer material such as carbon composite, we were doubtful a half cylindrical shell would be able to reliably stop ankle PF and DF motion during gait, as required for our experimental studies. Tubes are stiffer than solid rods of the same weight; they are more resistant to torsion and their wider radius of curvature (compared to a rod of the same weight) has a greater resistance to bending (Calladine, 2007). With this in mind, our carbon composite design consisted of two cylindrical shells, encapsulating the shank and the foot (Fig. 1).

2.1.3. Three-force system

Both the material stiffness of carbon composite and the structural stiffness provided by the two cylindrical shells were required in order to effectively use a three-force system to minimize plantarflexion (PF) and dorsiflexion (DF). The three-force system as described here is an adaptation of the well-known Euler–Bernoulli theory of beam bending, which uses three points of contact to transmit bending forces (Timoshenko, 1953).

In our adaptation, the three forces were applied to *counter* or *limit* bending (of the ankle) (Fig. 2), using the orthosis as the medium that transmits the (counter-bending) forces and strategically transfers those forces to skeletal structures (Bowker et al., 1993; Von Baeyer, 1935; Jordan, 1939; Thomas, 1952; Lehmann and Warren, 1976; Condie and Meadows, 1977; Condie and Meadows, 1993; Smith and Juvinall, 1980; Rose, 1986; Redford, 1987; Weber and Agro, 1993). In order to maximize the moment arm length of reactive forces during standing and walking, these transfer points were located as far as possible from the ankle joint axis on the proximal shank and at the distal foot of the exAFO (Fig. 3, parts a and b). A linear slide bearing anchored the contact points near the endpoints of the shank and foot cylindrical shells. We attached a tibial plate to the interior of the proximal shank cylindrical shell, using a ball and socket joint. This allowed for transmission of forces to the tibia in the sagittal plane based on transtibial prosthetic limb force transmission principles (Klopsteg and Wilson, 1968; Davenport et al. 2017), while mitigating rotational forces in the transverse and frontal planes (Fig. 3, part c and d).

Because these transfer points were located where the orthosis contacts the limb, the exAFO design also required an understanding of pressure tolerance of the anatomical structures, so that the orthosis could be worn comfortably by human subjects. We addressed this issue in our design by installing closed-cell foam padding to the tibial plate and to the foot cylindrical shell to enhance subjects' tolerance to force transmission at contact points.

2.2. Material properties and biomechanical principles used to design footwear

A gait study involving subjects using the exAFO-FC during acutely restricted ankle joint motion required subjects to walk at their preferred speed with minimal movement compensation. We needed to minimize the interruption during rollover which is known to accompany restricted joint motion in the ankle-foot complex and which increases movement compensation, energy expenditure, muscle fatigue, and reduces gait efficiency (Ackermann and Schiehlen, 2006; Nepomuceno et al., 2017; Wutzkea et al., 2012; Vanderpool et al. 2008; Adamczyk et al. 2006; Waters et al. 1988; Ralston 1965; Waters et al., 1982; Fowler et al. 1993; Waters and Mulroy, 1999).

A growing body of evidence spanning several disciplines, including biomechanics and engineering, suggests that a well-designed external sole component includeing the heel, midfoot, and forefoot can contribute to restoring rollover (Adamczyk et al. 2006; Branthwaite and

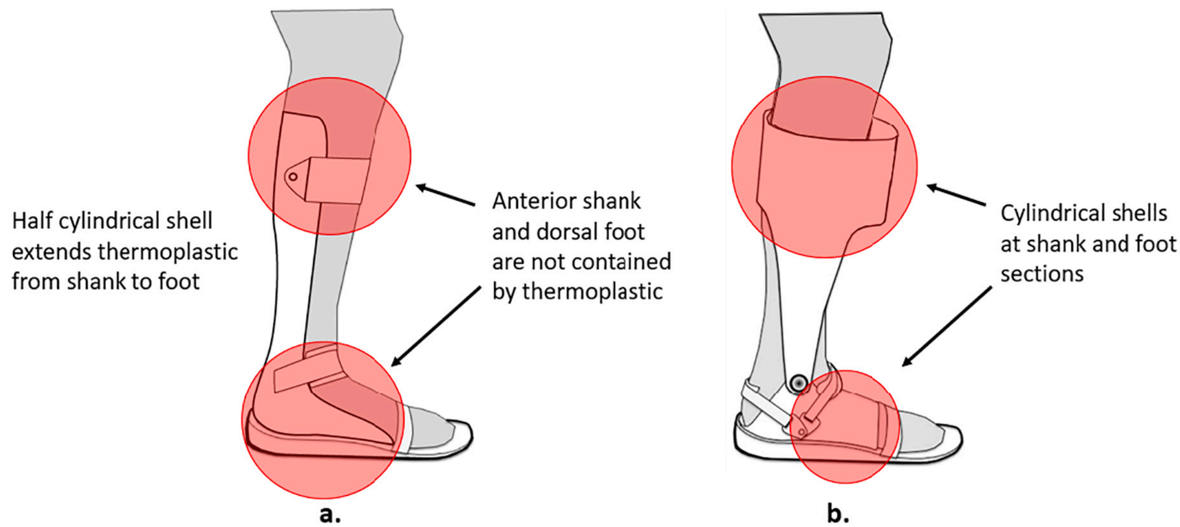


Fig. 1. Illustration of shell design in two ankle foot orthoses. (a) conventional thermoplastic solid ankle foot orthosis (SOLID AFO) consists of a half cylindrical shell component extending from the shank to the foot section and forefoot with metatarsophalangeal joints (MTPJs) free. (b) Experimental AFO (exAFO) consists of two cylindrical shell components, one at the shank and one at the foot to provide increased stiffness. Foot section extends from heel to forefoot with MTPJs free.

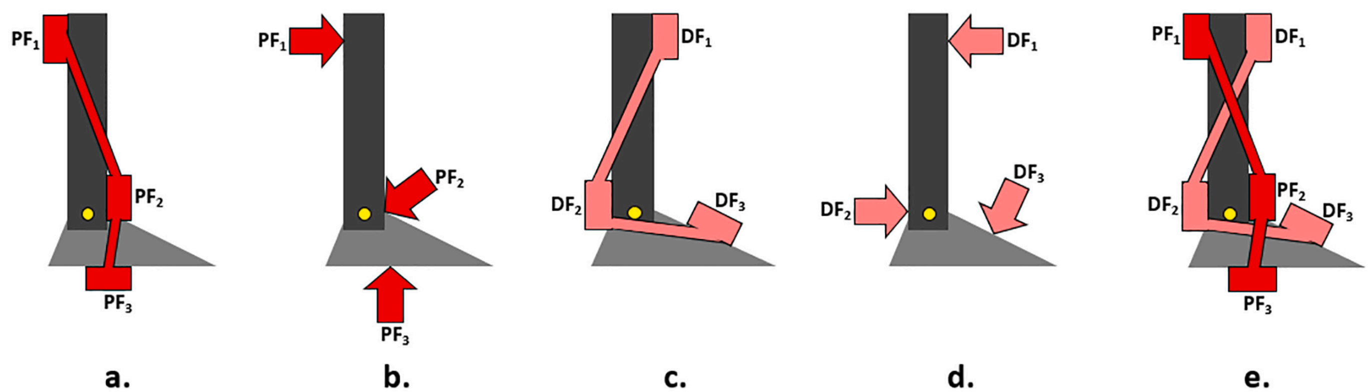


Fig. 2. Illustration of three-force system using anchors to control ankle motion in an orthosis. (a) Orthosis itself provides anchors at each point of force transmission to minimize ankle plantarflexion (PF_1, PF_2, PF_3); (b) Corresponding three-force system on lower limb; (c) Orthosis with anchors at each point of force transmission minimizes ankle dorsiflexion (DF_1, DF_2, DF_3); (d) Corresponding three-force system on lower limb; (e) Combining both anchored force systems in an orthosis minimizes ankle plantarflexion and dorsiflexion.

Chockalingam, 2009; Hutchins et al. 2009; Wang and Hansen, 2010; Vanderpool et al. 2008; Nepomuceno et al., 2017). Informed by this evidence, we developed footwear to minimize the interruption during rollover and other movement compensations due to the constraint provided by the exAFO.

Commercially available footwear could not be adequately integrated into the exAFO-FC; in response, we designed footwear to be worn in conjunction with the exAFO in all experimental conditions (STOP, FREE, and CONTROL). Subjects used the footwear on both limbs to minimize disruption of rollover, aid in forward progression of gait and minimize the potential for gait asymmetries that might occur due to orthotic constraint of ankle-foot motion.

Our footwear design was based on current biomechanical understanding of the four rockers of the healthy ankle-foot complex and how they contribute to rollover (Owen 2010; Perry and Burnfield, 2010) in order to produce an effective roll over shape (Hansen et al. 2004; Hansen and Wang, 2010). The result was a footwear sole that incorporated a curved profile shape and material flexibility in four regions: heel, midfoot, forefoot, and toe.

As illustrated in Fig. 4, the *heel rocker zone*, which acts as a surrogate heel rocker during early stance, consisted of flexible vulcanized rubber. The *ankle rocker zone*, which acts as a surrogate ankle rocker when the ankle is constrained by the exAFO, consisted of rigid thermocork in the shape of a wedge, to facilitate transmission of ground reaction force from heel rocker to the forefoot rocker during midstance. The *forefoot rocker zone*, which facilitates natural metatarsophalangeal joint (MTPJ) rocker, consisted of rigid thermocork in the shape of a half cylinder located proximal to the MTPJ and a flexible forefoot hinge at MTPJ to enhance heel rise and transfer of ground reaction force from ankle to forefoot. The *toe rocker zone*, which facilitates natural toe rocker, consisted of a curved profile ramp, made from flexible materials to allow natural interphalangeal joint motion during pre-swing.

3. Performance studies

In this section, we describe the experiments used to validate our exAFO-FC design for controlling ankle motion and maintaining rollover dynamics during gait. First, a quasi-static loading study, used a cadaveric lower limb, to quantify the motion control performance of the exAFO and a replica of the SOLID AFO by emulating peak forces during the stance phase of gait. Second, we describe a gait study of healthy subjects using the exAFO-FC to quantify motion control performance of the exAFO and rollover dynamics of the footwear, in three conditions: maximum ankle constraint (STOP), minimum ankle constraint (FREE)

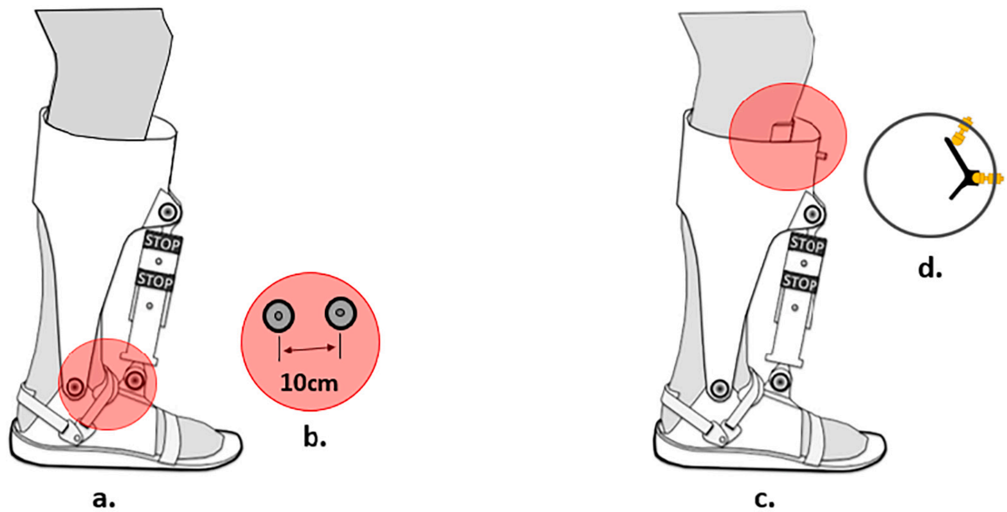


Fig. 3. (a) Experimental ankle foot orthosis (exAFO) provides increased leverage (b) by maximizing moment arm length (10 cm) from ankle joint to the end point of linear bearing anchored to a cylindrical shell at foot. (c) Tibial plate at anterior proximal shank of the exAFO, and (d) cross-section of tibial plate (black) on ball joints (gold) attached to cylindrical shell at shank allows transmission of forces between tibia and orthosis while allowing tibial transverse plane rotation. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

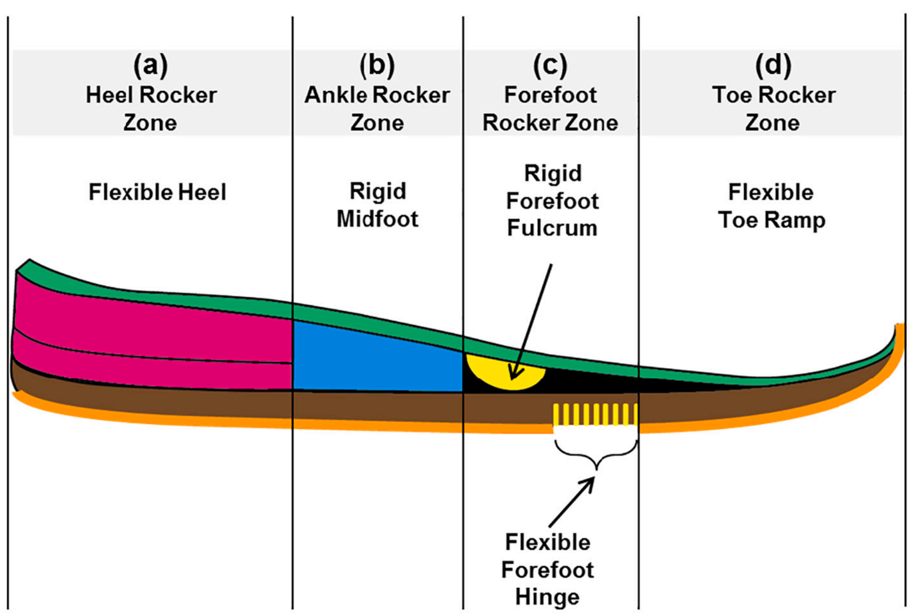


Fig. 4. Curved-flexible footwear sole consists of a rounded exterior profile shape with materials of varying stiffness contained within four rocker zones to allow compression, pivoting, and rolling and lower limb rollover motion during gait.

and no orthotic ankle constraint (CONTROL).

3.1. Quasi-static loading study: cadaveric limb (no footwear) in exAFO and SOLID AFO.

3.1.1. Methods

We set out to quantify motion control of the exAFO, and predicted that the exAFO in the ankle STOP condition would decrease motion when compared to the SOLID AFO condition during a quasi-static loading study.

Two right cadaveric adult lower limbs were utilized. The study involved a 3-D gait lab using six high-speed infrared cameras (Vicon, Oxford, UK; 120 Hz); four retroreflective markers attached to metal intramedullary screws in the tibia and calcaneus were used to collect ankle motion during peak quasi-static loading to simulate conditions during the stance phase of gait.

All limbs were fitted with the two AFOs, each with the footwear removed, and all AFOs aligned to a shank to vertical angle (SVA) of 10° degrees incline (i.e., modest ankle dorsiflexion angle) as per the findings of Owen (2010). All limbs were tested in two conditions: STOP (exAFO, linear bearing locked) and SOLID AFO. For each AFO condition, each limb underwent five static loading trials in randomized order, to measure maximally loaded DF and PF. Each trial was initiated in unloaded SAV inclined 10°. Moment values were determined in a prior gait study of healthy adult subjects. Using a custom cable-driven loading apparatus, a controlled force was applied to cadaveric limbs to produce an external dorsiflexor moment of 140 Nm and to produce an external plantarflexor moment of 29 Nm. The magnitude of the observed moments was equivalent to maximum moments during stance phase of gait.

All motion data were collected for 15 continuous seconds using the Vicon workstation and imported to MATLAB Version 7.11.0 (The Mathworks Inc., Natick, MA, USA) for post-processing. Motion data were filtered using 4th order Butterworth low pass filter with 10 Hz cutoff frequency, then analyzed to quantify motion of the ankle during unloaded and loaded DF and PF trials. Ankle PF and DF angles (°) mean (standard deviation) were calculated for limbs in each AFO condition for all trials.

3.1.2. Results

During loaded DF, the SOLID AFO failed to cease bending, which required the test be halted. The external moment applied to the ankle (to produce a peak dorsiflexor moment) was then reduced by 50%, to 70 Nm, and was applied to a duplicate of the SOLID AFO condition for all remaining tests. The exAFO limb maintained its original load of 140 Nm (to produce a peak dorsiflexor moment) throughout the testing (Fig. 5).

Ankle total range of motion mean (standard deviation) was 2.1 (0.2)° in exAFO in STOP condition, compared to 14.0 (0.1)° in SOLID AFO condition. Ankle PF motion was 0.7 (0.1)° in exAFO in STOP condition, compared to 3.5 (0.1)° in SOLID AFO condition. Ankle DF motion was 1.5 (0.2)° in exAFO in STOP condition compared to 10.5 (0.2)° in SOLID AFO condition (Fig. 6).

3.1.3. Discussion

The effective constraint of ankle motion by the exAFO in STOP condition supported our contention that applying relevant principles in material science and biomechanics to our design would improve motion control. Consideration of this information is requisite to successfully achieving the desired motion control performance of an AFO. This message has not been previously conveyed in the literature. Across all trials, the exAFO provided constraint of total ankle motion that was well below our pre-determined threshold of $<5°$. During quasi-static loading, the exAFO in STOP condition exhibited greater restraint of ankle DF, PF and total ankle motion than did the SOLID AFO.

In the exAFO, stiffness was increased by employing carbon composite, a material with greater modulus of elasticity than thermoplastic, and by employing a cylindrical shell design, the geometry of which provided greater resistance to bending. Our successful modification of the three-force system was due to the increase of moment arm length, and the addition of a linear bearing and tibial plate. A comparison of the force systems employed in the two AFOs is informative for clinicians and designers of lower limb orthoses because it illustrates the shortcomings of a representative conventional thermoplastic solid AFO design and provides solutions to improve ankle motion control performance as exemplified in the exAFO.

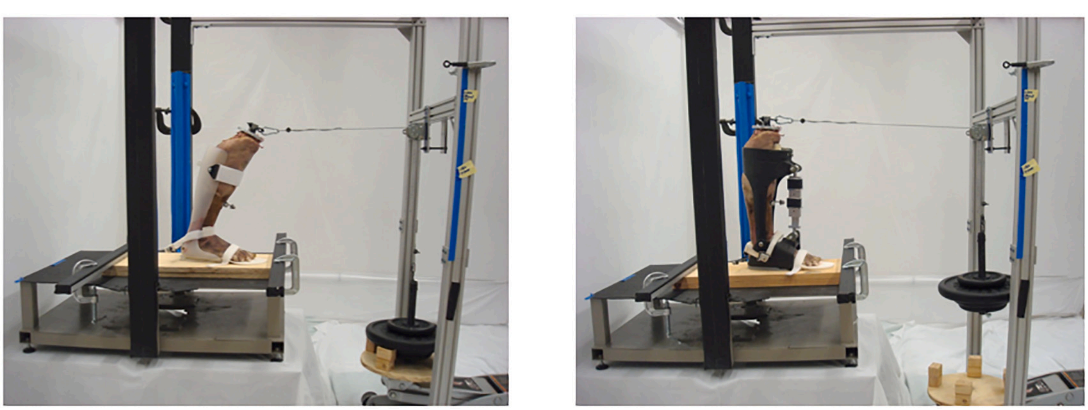
In the SOLID AFO we studied (Fig. 7), material weakness (low elastic modulus) was exacerbated by the geometry of the half cylindrical shell itself. In addition to its inherent weakness compared to a cylindrical shell, the lack of anterior coverage provided a shorter, thus less effective moment arm from the ankle, due to the location of the plastic trim line with respect to the ankle (Sumiya et al. 1996) and the flexibility of the fabric straps. The notable decrease in PF, compared to DF, may be due to the limited coverage provided by the half cylindrical shell itself, which ended at the ankle joint while extending up the calf, far proximal and distal to the ankle joint. While this may have provided sufficient leverage and stiffness at force transmission points PF_1 and PF_3 to restrain ankle PF, the counterbalancing force at transmission point PF_2 was compromised due to flexibility of the strap which reduced the stiffness needed as the counterbalancing force to effectively restrain ankle PF motion.

In the exAFO, we amplified the previously described motion control benefits of carbon composite and a cylindrical shell design with the addition of a tibial plate and a rigid linear bearing, to address leverage and force transmission in plantarflexion and dorsiflexion. For DF, the increased height of the tibial plate (DF_1) allowed greater leverage, and its rotating element uniquely allowed force transmission in more than one cardinal plane; the linear bearing anchored shank and foot shells anteriorly (F_4), preventing DF motion in concert with a counterbalancing force at the heel (DF_2) (Fig. 8). Plantarflexion was restricted by placement of the linear bearing far from the ankle joint (F_4) to counterbalancing moment arm length, in concert with the ankle control strap (PF_2) (Fig. 8).

3.2. Gait study: Healthy subjects in experimental AFO-footwear combination

To test the ankle motion control performance of the experimental AFO-FC during gait, we expected that subjects wearing the exAFO-FC in STOP condition would demonstrate decreased ankle motion when compared to wearing the exAFO-FC in FREE and CONTROL (no exAFO, footwear only) during walking, and that the footwear would minimize any movement compensations due to orthotic constraint of ankle motion.

Fourteen healthy human subjects [eight females, six males, ages 21.04 (0.89) yrs., height 171.19 (4.11) cm, mass 65.74 (4.72) kg] gave written informed consent to participate in a protocol approved by the



a. b.

Fig. 5. Photographs during quasi static loading tests in the two ankle foot orthoses (AFOs). (a) SOLID AFO condition exhibited continuous bending and failed to completely stop ankle dorsiflexion during loading to produce a 140 Nm peak dorsiflexor moment. (b) Experimental AFO in STOP condition exhibited restricted ankle dorsiflexion during loading to produce a 140 Nm peak dorsiflexor moment.

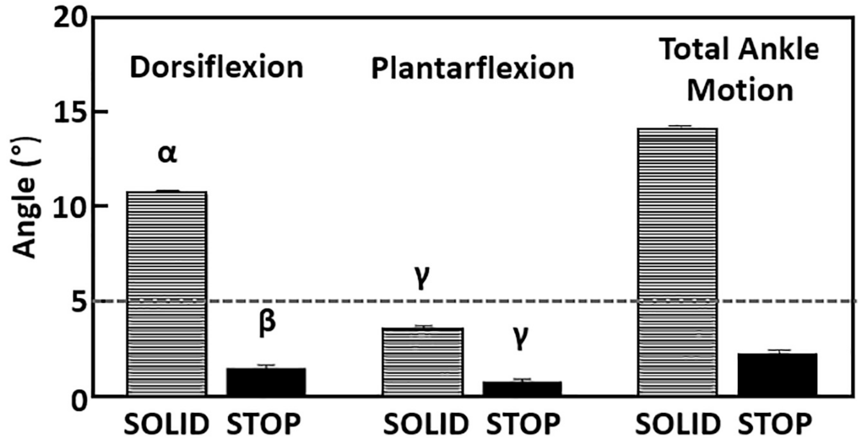


Fig. 6. Cadaveric limb segment dorsiflexion and plantarflexion mean (standard deviation) during quasi static loading in cadaveric limbs wearing SOLID AFO condition and experimental AFO in STOP condition. All values are expressed in degrees of limb segment motion. (α) loading to produce 70 Nm dorsiflexor moment, (β) loading to produce 140 Nm dorsiflexor moment, (γ) loading to produce 29 Nm plantarflexor moment. Dashed line is threshold for total ankle motion.

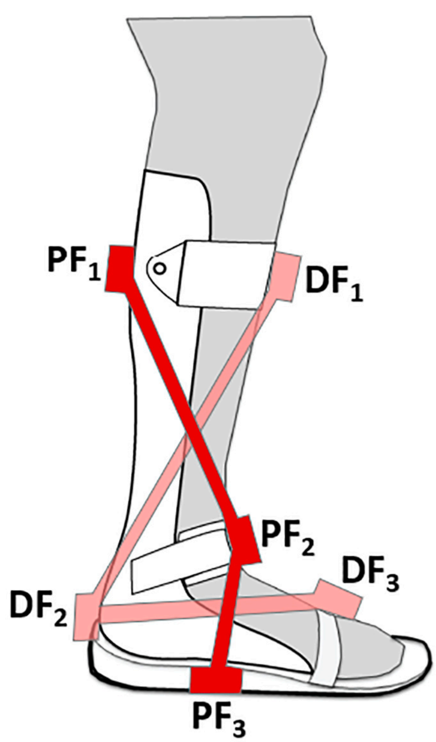


Fig. 7. Illustration of an interpretation of three-force system approach using anchors to control ankle motion in the SOLID AFO condition. Forces at three transmission points (PF_1, PF_2 and PF_3) control ankle plantarflexion motion. Forces at three transmission points (DF_1, DF_2, DF_3) control ankle dorsiflexion motion.

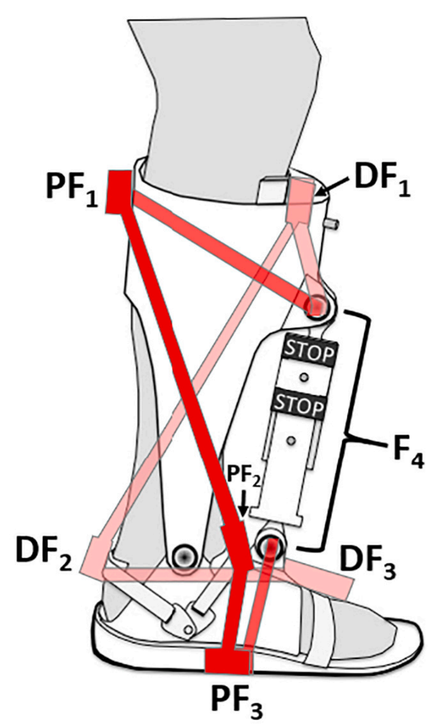


Fig. 8. Illustration of an interpretation of three force system approach using anchors to control ankle motion in the experimental AFO condition. Forces at multiple transmission points (PF_1, PF_2 and PF_3) in concert with linear bearing (PF_1, F_4 and PF_3) control ankle plantarflexion motion. Forces at multiple transmission points (DF_1, DF_2, DF_3) in concert with linear bearing (DF_1, F_4 and DF_3) control ankle dorsiflexion motion.

Georgia Tech Institutional Review Board. The study involved a 3-D gait lab using six high speed cameras (Vicon, Oxford, UK; 120 Hz), 16 retroreflective markers taped to the pelvis and lower limbs of subjects using a method modified by Kadaba (Kadaba et al. 1990) to record joint motion. A custom dual belt treadmill with imbedded force plates, one under each belt (AMTI, Watertown, MA, USA; 1080 Hz) was used to collect ground reaction forces, joint moments and temporal-spatial parameters (i.e. stance duration, swing duration and cadence) respectively.

3.2.1. *Methods*

In order to ensure proper fit of the single exAFO-FC and congruency between the anatomical and orthotic ankle joints, subject inclusion criteria specified a range for individual foot length, ankle height, and calf girth. Alignment of the ex-AFO-FC in STOP condition, for all 14 legs, was set at SVA 10° incline (i.e., modest ankle dorsiflexion angle) as per the findings of Owen, (2010). Subjects were tested walking at their preferred speed [1.34 (0.09) $m \cdot s^{-1}$], wearing the exAFO-FC in three conditions: CONTROL (bilateral footwear, no exAFO), FREE (contralateral footwear, ipsilateral exAFO-FC, no joint constraint) and STOP (contralateral footwear with ipsilateral exAFO-FC in maximal constraint) (Supplementary Fig. S1). Preferred walking speed was determined by administering three trials of the 10-m walk test for over ground walking (Peters et al. 2013). The mean over ground walking speed was then matched to individuals' treadmill speeds by adapting a method described by Amorim et al., (2009).

All data were collected in the Vicon workstation and motion data were processed using the Plug-in-Gait model to identify and label markers. All data were imported to MATLAB version 7.11.0 (The Mathworks Inc., Natick, MA, USA) for additional processing. Raw force signals were filtered (4th order Butterworth low pass filter with cutoff frequency of 20 Hz) and analyzed to determine ground reaction force components and joint moments during stance and to identify the duration of stance and swing phases. Motion data were filtered (4th order Butterworth low pass filter with 10 Hz cutoff frequency) and analyzed to determine angular motion of the ankle joint. All motion and force data were synchronized, and time normalized to 100% of the gait cycle and analyzed using standard inverse dynamics calculations and estimated inertial characteristics based on subject specific anthropometrics and consideration of the inertial properties of the orthosis (Winter 2009).

Because the dominant motions of the ankle joint complex occur through the talocrural articulation as plantarflexion and dorsiflexion during gait, analysis of ankle motion was limited to the sagittal plane (Perry and Burnfield, 2010; Zatsiorsky 1998; Farris and Sawicki, 2012). Mean ankle joint angle and moments in each condition were analyzed using 95% confidence interval and a repeated-measures ANOVA with Bonferroni post hoc comparison.

To examine potential movement compensation, we analyzed temporal-spatial outputs (stance duration, swing duration, and cadence). We computed the mean and standard deviation and performed comparisons of means (one-way ANOVA) and Bonferroni post hoc analysis to determine differences in outputs between each condition.

3.2.2. Results

All data were analyzed during minute 4 of treadmill walking when subjects had achieved the onset of steady state gait with minimal movement compensation. Subjects exhibited decreased ipsilateral ankle range of motion to within 3.7 (2.1)° in STOP condition, compared to 27.7 (4.2)° in CONTROL condition ($P = 0.000$) and 24.2 (3.6)° in FREE condition ($P = 0.091$) and no difference in ankle moments ($P > 0.05$) (Fig. 9). Cadence was similar in CONTROL, STOP and FREE conditions ($P > 0.05$). There was no difference ($P > 0.05$) in mean stance phase and mean swing phase duration in CONTROL condition. There was a modest (<2.5%) but statistically significant difference ($P < 0.05$) between legs in mean stance phase duration during STOP and FREE conditions, and a modest (<2.5%) but statistically significant ($P < 0.05$) difference between legs in mean swing phase duration during STOP and FREE conditions (Table 1).

The exAFO-FC in STOP condition substantially limited motion during stance phase, when the ankle experiences the greatest joint moments and, typically, where one might observe lack of motion control.

Table 1
Cadence, stance and swing duration, mean (standard deviation) of CONTROL, FREE and STOP conditions of all subjects ($n = 14$) during minute 4 (onset of steady state gait). Percent gait cycle (% GC).

	Ipsilateral	Contralateral	*P*-Value (between legs)
Cadence (steps·min^{-1})			
CONTROL	54.3 (3.1)	54.4 (3.3)	0.752
FREE	53.3 (2.4)	53.1 (2.4)	0.752
STOP	52.6 (1.5)	52.4 (1.6)	0.721
Stance duration (% GC)			
CONTROL	62.6 (0.7)	62.9 (0.6)	0.116
FREE	62.9 (0.5)	64.4 (0.4)	0.001
STOP	62.3 (0.7)	64.9 (0.9)	0.002
Swing duration (% GC)			
CONTROL	39.4 (0.4)	39.2 (0.1)	0.137
FREE	40.4 (0.3)	39.1 (0.5)	0.002
STOP	42.0 (0.8)	39.3 (0.6)	0.001

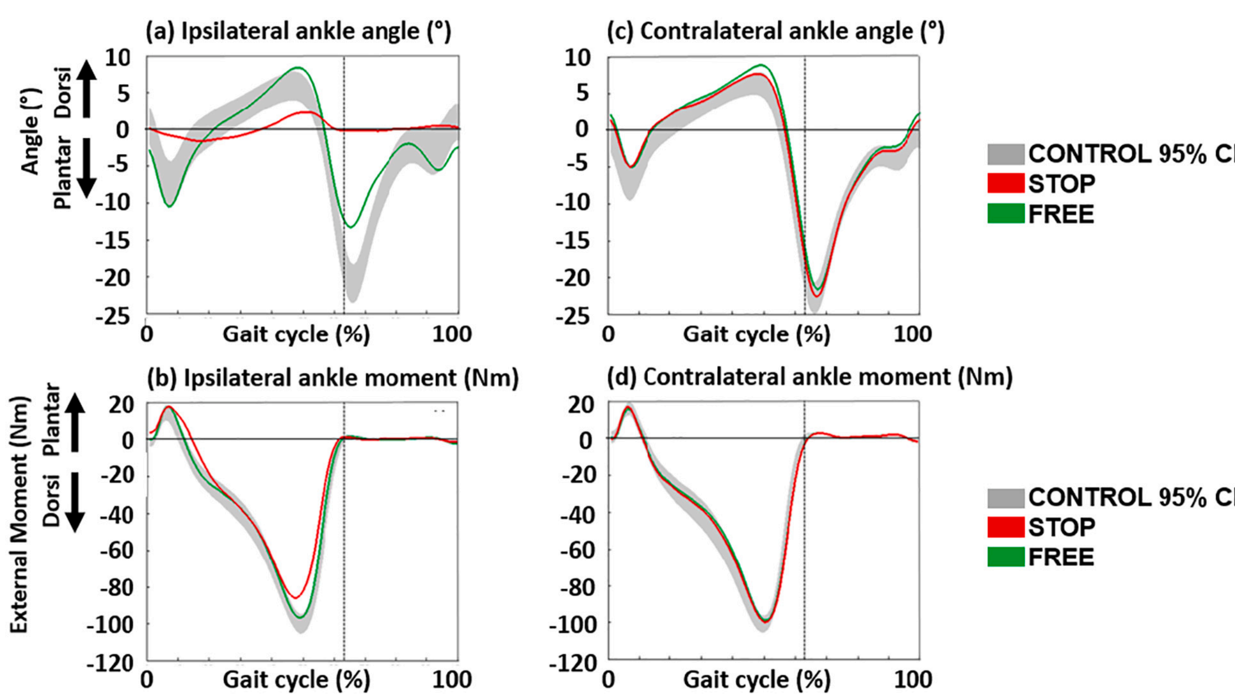


Fig. 9. (a) Ipsilateral ankle angle (°) and (b) ipsilateral ankle moment (Nm), (c) contralateral ankle angle (°) and (d) contralateral ankle moment (Nm). Data normalized to gait cycle (%) in CONTROL, FREE and STOP conditions during minute 4. A 95% confidence interval (CI) of CONTROL (gray), mean of FREE (green) and mean of STOP (red) for all 14 subjects. Toe off in CONTROL (vertical line). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

3.2.3. Discussion

Overall, results of our performance study showed that the exAFO-FC in STOP condition was effective in restricting total ankle motion within the desired threshold (<5°), both resisting deformation and maintaining the ankle near neutral alignment. During terminal stance (30–50% of gait cycle [GC]) (Perry and Burnfield, 2010), when the ankle experiences its greatest moments, and when one would expect greater ankle motion, the exAFO-FC restricted DF motion to within <2°. During loading response (0–10% GC) and midstance (10–30% GC), (Perry and Burnfield, 2010) when the ankle experiences substantially lower moments, the exAFO-FC similarly restricted motion to <2°.

Furthermore, evidence showing no difference in ankle motion and moments on the contralateral leg in the conditions (CONTROL, FREE and STOP) suggests that the integral footwear included in the exAFO design achieved our goal: to minimize interruption in rollover. Despite considerable restriction of ipsilateral ankle motion in STOP condition, the footwear may have minimized subjects' movement compensation on the contralateral leg. This is supported by no difference ($P < 0.05$) observed in mean cadence between any of the conditions (STOP, FREE, CONTROL) and only a modest (<2.5%) difference observed in mean stance duration and mean swing duration between each of the conditions (STOP, FREE and CONTROL) when movement of both legs is reciprocal. This evidence supports the likelihood that the footwear design contributed to maintaining rollover and minimized interruption of forward progression, despite the maximal restriction of ankle motion provided by the exAFO-FC.

We also found that subjects using the exAFO-FC in STOP condition exhibited the same amount of ankle motion — approximately 2 degrees PF in early stance and approximately 2 degrees DF in late stance — while the mean external ankle moment of 19 Nm in early stance was four times lower than the mean external ankle moment in late stance (81 Nm). We believe these similarities in motion, despite substantial differences in force, are due to differences in anatomical tissue stiffness at force transmission points of the orthosis. Specifically, lower-stiffness calf tissue at the posterior proximal force transmission point (PF_1) produces greater deformation to a lower force, compared to the higher-stiffness tibia at the anterior proximal shank force transmission point (DF_1) (Fig. 8).

3.3. Limitations

Our analysis revealed a limitation in the exAFO-FC design: the available length of travel in linear bearing was insufficient for some subjects, whereby the FREE condition (compared to CONTROL) restricted ankle PF during terminal stance and pre-swing phase of gait. Future researchers implementing our design should make the requisite adjustments in the linear bearing to avoid this limitation.

4. Conclusion

Today's near-total emphasis on specific patient populations, with few details about devices used in studies (Eddison et al., 2017), fails to acknowledge the importance of device development and performance baselines. Our study addresses these shortcomings - demonstrating that an experimental AFO, incorporating three common tropes from structural and mechanical engineering: use of high modulus materials, full shell geometry of shape, and a three- force system maximizing leverage, produced superior resistance to deforming moments in stance. Since many countries in the world use thermoplastics in AFOs for clinical applications that require significant constraint of motion, designers may consider replacing the half cylinder shell to full cylinder shells at shank and foot; stiffening the ankle region by extending deep ankle trimlines or adding ankle corrugation reinforcements (Fatone et al., 2020, Sumiya et al. 1996); and using footwear that laces tight over the dorsum of the foot to enhance leverage. These alterations may improve stiffness and resistance to deforming moments in stance, as many of these features were used in the experimental AFO. Future researchers are encouraged to conduct experimentally rigorous, device-specific studies on patient populations and healthy subjects (e.g., to provide values for normal limits of device function and human response) that include intended function (e.g., ankle motion control), material and mechanical properties (Kobayashi et al., 2011), alignment (Eddison et al., 2017, Owen 2010) and impact on human performance and quality of life.

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Declaration of Competing Interest

None.

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References

Practice Analysis of Certified Practitioners in the Disciplines of Orthotics and Prosthetics, 2019. American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc, Alexandria, VA.
Ackermann, M., Schiehlen, W., 2006. Dynamic analysis of human gait disorder and metabolical cost estimation. Arch. Appl. Mech. 75, 569–594. https://doi.org/10.1007/S00419-006-0027-7.
Adamczyk, P.G., Collins, S.H., Kuo, A.D., 2006. The advantages of a rolling foot in human walking. J. Exp. Biol. 209 (Pt 20), 3953–3963. https://doi.org/10.1242/JEB.02455.
Amorim, P.R.S., Hills, A., Byrne, N., 2009. Treadmill adaptation and verification of self-selected walking speed: a protocol for children. Res Quar Exer Sport. 80 (2), 380–385. https://doi.org/10.1080/02701367.2009.10599574.
Bowker, P., Condie, D.N., Dl, Bader, Pratt, D.J., 1993. Biomechanical Basis of Orthotic Management. Butterworth Heinemann, Oxford U.K, pp. 100–108.
Branthwaite, H., Chockalingam, N., 2009. The role of footwear in rehabilitation: a review. Int. J. Ther. Rehabil. 1 (1), 1–15.
Calladine, C.R. (Ed.), 2007. Theory of Shell Structures. Cambridge University Press, Cambridge, UK.
Condie, D.N., Meadows, C.B., 1977. Some biomechanical considerations in the design of ankle foot orthoses. Orthot Prosthet. 31 (3), 45–52.
Condie, D.N., Meadows, C.B., 1993. Ankle-foot orthoses. In: Condie, D.N., Bowker, P., Bader, D.L., Pratt, D.J. (Eds.), Biomechanical Basis of Orthotic Management. Butterworth-Heinemann, Oxford, UK, pp. 99–123.
Davenport, P., Snroozi, S., Sewell, P., Zahedi, S., 2017. Systematic review of studies examining transtibial prosthetic socket pressures with changes in device alignment. J. Med. Biol. Eng. 37, 1–17. https://doi.org/10.1007/s40846-017-0217-5.
Eddison, N., Mulholland, M., Chockalingam, N., 2017. Do research papers provide enough information on design and material used in ankle foot orthoses for children with cerebral palsy? A systematic review. J. Child. Orthop. 11, 263–271. https://doi.org/10.1302/1863-2548.11.160256.
Farris, D.J., Sawicki, D.S., 2012. The mechanics and energetics of human walking and running: a joint level perspective. J. R. Soc. Interface 9, 110–118. https://doi.org/10.1098/rsif.2011.0182.

Fatone, S., Owen, E., Gao, F., Shippen, G., Orendurff, M., Bjornson, K., 2020. Stiffness of solid ankle-foot orthoses. J. Prosthet. Orthot. 32 (2), 26. Suppl 1.
Fowler, P.T., Botte, M.J., Mathewson, J.W., Speth, S.R., Byrne, T.P., Sutherland, D.H., 1993. Energy cost of ambulation with different methods of foot and ankle immobilization. J. Orthop. Res. 11 (3), 416–421. https://doi.org/10.1002/jor.1100110314.
Hansen, A.H., Wang, C.C., 2010. Effective rocker shapes used by able-bodied persons for walking and fore-aft swaying: implications for design of ankle foot prostheses. Gait Posture 32, 181–184. https://doi.org/10.1016/j.gaitpost.2010.04.014.
Hansen, A.H., Childress, D.S., Knox, E.H., 2004. Roll over shapes of human locomotor systems: effects of walking speed. Clin. Biomech. 19 (4), 407–414. https://doi.org/10.1016/j.clinbiomech.2003.12.001.
Hutchins, S., Bowker, P., Geary, N., Richards, J., 2009. The biomechanics and clinical efficacy of footwear adapted with rocker profiles - evidence in the literature. Foot 19, 165–170. https://doi.org/10.1016/j.foot.2009.01.001.
Jordan, H.H., 1939. Orthopedic appliances. In: The Principles and Practice of Brace Construction for the Use of Orthopedic Surgeons and Brace Makers. Oxford University Press, New York, p. 70–100, 258–259, 274–278, 348–350.
Kadaba, M.P., Ramakrishnan, H.K., Wootten, M.E., 1990. Measurement of lower extremity kinematics during level walking. J. Orthop. Res. 8 (3), 383–392. https://doi.org/10.1002/jor.1100080310.
Klopsteg, P.E., Wilson, P.D., 1968. The Fitting of Below-Knee Prostheses. In: Human Limbs and their Substitutes. Hafner Publishing Co, New York.
Kobayashi, T., Leung, A.K.L., Hutchins, S.W., 2011. Techniques to measure rigidity of ankle foot orthosis: a review. J. Rehabil. Res. Dev. 48 (5), 656–576. doi.10.1682%2FJRRD.2010.10.0193.
Lehmann, J.F., Warren, C.G., 1976. Restraining forces in various designs of knee ankle orthoses: their placement and effect on the anatomical knee joint. Arch. Phys. Med. Rehabil. 57, 430–437.
Nepomuceno, A., Major, M.J., Stine, R., Gard, S., 2017. Effect of foot and ankle immobilization on able-bodied gait as a model to increase understanding about bilateral transtibial amputee gait. Prosthetics Orthot. Int. 41 (6), 556–563 doi.10.1177%2F0309364617698521.
Owen, E., 2010. The importance of being earnest about shank and thigh kinematics especially when using ankle-foot orthoses. Prosthetics Orthot. Int. 34 (3), 254–269. https://doi.org/10.3109/03093646.2010.485597.
Perry, J., Burnfield, J.M. (Eds.), 2010. Gait Analysis Normal and Pathological Motion, 2nd ed. Slack Inc, Thorofare, NJ.
Peters, D.M., Fritz, S.L., Krotish, D.E., 2013. Assessing the reliability and validity of a shorter walk test compared with the 10-meter walk test for measurements of gait speed in healthy, older adults. J. Geriatr. Phys. Ther. 36, 24–30. https://doi.org/10.1519/JPT.0b013e318248e20d.
Ralston, H., 1965. Effects of immobilization of various body segments on the energy cost of human locomotion. Ergon Suppl. 53, 39–46.
Redford, J.B., 1987. Orthotics: general principles. In: Physical Medicine and Rehabilitation State of the Art Reviews: Orthotics. Hanley & Belfus, Inc, Philadelphia, PA, pp. 1–5.
Rose, G.K., 1986. A functional biomechanical classification. In: Orthotics Principles and Practice. William Heinemann Medical Books, London, UK, pp. 41–52.
Smith, E.M., Juvinall, R.C., 1980. Mechanics of orthotics. In: Licht SH, Redford J.B. (Ed.), Orthotics Etcetera, 3d. ed. Williams & Wilkins Co., Baltimore, MD, pp. 28–33.
Sumiya, T., Suzuki, Y., Kashahara, T., 1996. Stiffness control in posterior type plastic ankle foot orthoses: effect of ankle trimline part 2: orthosis characteristics and orthosis/patient matching. Prosthetics Orthot. Int. 20, 132–137.
Thomas, A., 1952. Appliances for the spine and trunk. In: Edwards, J.W. (Ed.), Orthopaedic Appliances Atlas. Volume 1. Braces, Splints, Shoe Alterations: A Consideration of Aids Employed In: The Practice of Orthopaedic Surgery. American Academy of Orthopaedic Surgeons, Ann Arbor, MI, pp. 202–203.
Timoshenko, S. (Ed.), 1953. History of the Strength of Materials. McGraw-Hill New, New York, NY.
Totah, D., Menon, M., Jones-Hershinow, C., Barton, K., Gates, D.H., 2009. The impact of ankle foot orthosis stiffness on gait: a systematic literature review. Gait Posture 69, 101–111. https://doi.org/10.1016/j.gaitpost.2019.01.020.
Vanderpool, M.T., Collins, S.H., Kuo, A.D., 2008. Ankle fixation need not increase the energetic cost of human walking. Gait Posture 28, 427–433. https://doi.org/10.1016/J.Gaitpost.2008.01.016.
Von Baeyer, H., 1935. Grundlagen Der Orthopadischen Mechanik. Verlag Von Julius Springer, Berlin, p. 4–5, 30, 37–38.
Wang, C.C., Hansen, A.H., 2010. Response of able bodied persons to changes in shoe rocker radius during walking: changes in ankle kinematics to maintain a consistent roll-over shape. J. Biomech. 43, 2288–2293. https://doi.org/10.1016/J.Jbiomech.2010.04.036.
Waters, R.L., Mulroy, S., 1999. The energy expenditure of normal and pathological gait. Gait Posture 9 (3), 207–231. https://doi.org/10.1016/S0966-6362(99)00009-0.
Waters, R.L., Barnes, G., Husseri, T., Silver, L., Liss, R., 1988. Comparable energy expenditure after arthrodesis of the hip and ankle. J. Bone Joint Surg. Am. 70 (7), 1032–1037.
Waters, R.L., Campbell, J., Thomas, L., Hugos, L., Davis, P., 1982. Energy costs of walking in lower extremity plaster casts. J. Bone Joint Surg. Am. 2 (64), 6:896–899.
Weber, D., Agro, M. (Eds.), 1993. Clinical Aspects of Lower Extremity Orthotics, 2nd ed. Elgan Enterprises and Canadian Association of Prosthetists and Orthotists, Oakville, Ontario, pp. 65–75.
Weber, J.B., Murphey, D.P., 2019. Ch. 2 Material science. In: Atlas of Orthoses and Assistive Devices, 5th ed. Elsevier, Philadelphia, PA, p. 12.
Winter, D.A. (Ed.), 2009. Biomechanics and Motor Control of Human Movement, 4th ed. John Wiley & Sons, Inc., Hoboken, NJ, pp. 45–138.
Wutzkea, C.J., Sawicki, G.S., Lewek, M.D., 2012. The influence of a unilateral fixed ankle on metabolic and mechanical demands during walking in unimpaired young adults. J. Biomech. 45 (14) https://doi.org/10.1016/j.jbiomech.2012.06.035, 2405–2010.
Zatsiorsky, V. (Ed.), 1998. Kinematics of Human Motion. Human Kinetics, Champaign, IL, pp. 296–298.