EVALUATION OF THE ANKLE ROLL GUARD'S EFFECTIVENESS TO IMPROVE ITS CLINICAL BENEFIT

PROGRESS REPORT

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Research Methodology

Subjects:

To date, fourteen recreationally active participants have been enrolled to participate. Potential participants were required to be 6 or higher on the Tegner Scale. Any potential participant that reported current pain or recent injury to the back or lower extremity (previous six months), history of back or lower extremity injury or surgery, and/or any known neurological disorder was excluded. Prior to testing, research approval was obtained from the local institutional review board and all participants provided written informed consent.

Of the enrolled participants, ten have completed testing and are included in the analysis herein. Subject demographics for the ten (7 male and 3 female) participants are included in Table 1.

Table 1: Subject Demographics (n = 10).

Age	20.2 ± 1.8 years
Height (m)	1.7 ± 0.8 m
Weight (kg)	76.0 ± 12.4 kg

Each participant completed two separate test sessions. During each test session, participants completed the study tasks with two different conditions. The conditions included four different ankle prophylactic devices: Ankle Roll Guard (ARG), Medspec ASO Ankle Stabilizer (Brace), Closed Basket Weave Athletic Tape (Tape), and no prophylactic device (Control). The sequence of testing each condition was randomly assigned to each participant prior to beginning the study from a 4 x 4 Latin square.

With each condition, participants completed a sudden inversion event and a battery of functional tasks. The functional tasks included: over-ground running, single-leg cutting, vertical jump, drop landing, and single-leg balance. The order the tasks will be executed during each biomechanical testing session was randomized using a 5 x 5 Latin square prior to beginning the study. For this report, only the vertical jump has been analyzed.

Study Tasks:

The sudden inversion event required participants stand on a wooden platform, similar to Hopkins et al., 2007, with feet shoulder width apart, arms to the side, and looking straight ahead (Figure 1). The wooden platform contains side-by-side trap doors that rotate inward to 30 degrees when released, allowing the ankle to invert from a neutral standing position (Hopkins et al., 2007 & 2009). Randomly, a research assistant removed the mechanical support of one trap door, allowing the door to fall producing a sudden ankle inversion. Adhesive, non-slip strips on each trap door marked appropriate foot placement and prevented the foot from slipping when the trap door falls. Each participant performed five successful trials of the sudden inversion event with each leg, but only dominant limb has been included in this analysis.

Each participant also performed three maximal countermovement jumps. Each jump required the participant start in athletic position, with feet shoulder width apart on side-by-side force platforms, and bend down into a squatting position before performing a maximal effort vertical jump. Vertical jump height was determined by the time in air, which was defined as period between take-off and landing of the vertical jump:

Height (m) = ⅛g(t/2)^2; where g = 9.81 m/s^2, t = time in air (s)

A.  B. 

Figure 1: For the sudden inversion event, participants stood with feet shoulder width apart on a wooden platform that contained trap doors under each foot (A). Then, a researcher randomly dropped one of the trap doors, causing the ankle to invert 30° (B).

Biomechanical Analysis:

During each sudden inversion trial, participants had dominant limb lower limb 3D biomechanical data recorded. To record biomechanical data, a force platform (OR-6, AMTI, Watertown, MA, USA) quantified ground reaction force (GRF) data at 2400 Hz, while eight high-speed (240 fps) optical cameras (Vicon, Oxford, UK) captured 3D marker trajectories.

Dominant limb ankle kinematics were quantified from the 3D trajectories of 32 retro-reflective skin markers. After securing each marker, participants stood in anatomical position to create a kinematic model with Visual 3D v5.00 (C-Motion, Rockville, MD). The kinematic model had 24 degrees of freedom (Dof) and included seven skeletal segments (bilateral foot, shank and thigh, and pelvis segments). The pelvis had six (three translational and three rotational) DoF and was defined with respect to the global coordinate system. For the hip, a functional joint center was calculated (Schwartz and Rozumalski, 2005) and assigned a local coordinate system. The knee and ankle had three DoF with joint centers and local coordinate systems defined according to Grood and Suntay (1983) and Wu (2002).

During each trial, the marker trajectories recorded were low pass filtered with a fourth-order Butterworth filter at a cut-off frequency of 12 Hz. The filtered 3D marker trajectories were then processed to solve joint rotations at each time frame in Visual 3D. Each joint rotation was expressed relative to each participant's anatomical position. The ankle kinematics were time-normalized to 100% of the sudden inversion event and re-sampled at 1% increments (N = 101).

Statistical Analysis:

Ankle kinematics related to the excessive inversion implicated in injury of the ankle were selected for statistical comparison. For analysis, peak ankle inversion angle, range of ankle inversion, and time to peak ankle inversion were calculated during the sudden inversion event (0% - 100%). Jump height was also calculated for statistical comparison. For each participant, the dependent variables were averaged across all successful trials to create a subject-based mean. The subject-based means was then submitted to separate one-way repeated measures ANOVA to test the effect of each ankle prophylactic (ARG, Brace, Control and Tape). In instances where statistically significant differences between ankle prophylactics were observed, Tukey's HSD procedure was used. Alpha level was set *a priori* at 0.05.

Results

The ankle inversion angle quantified during the sudden inversion event for each ankle prophylactic is present in Figure 2.

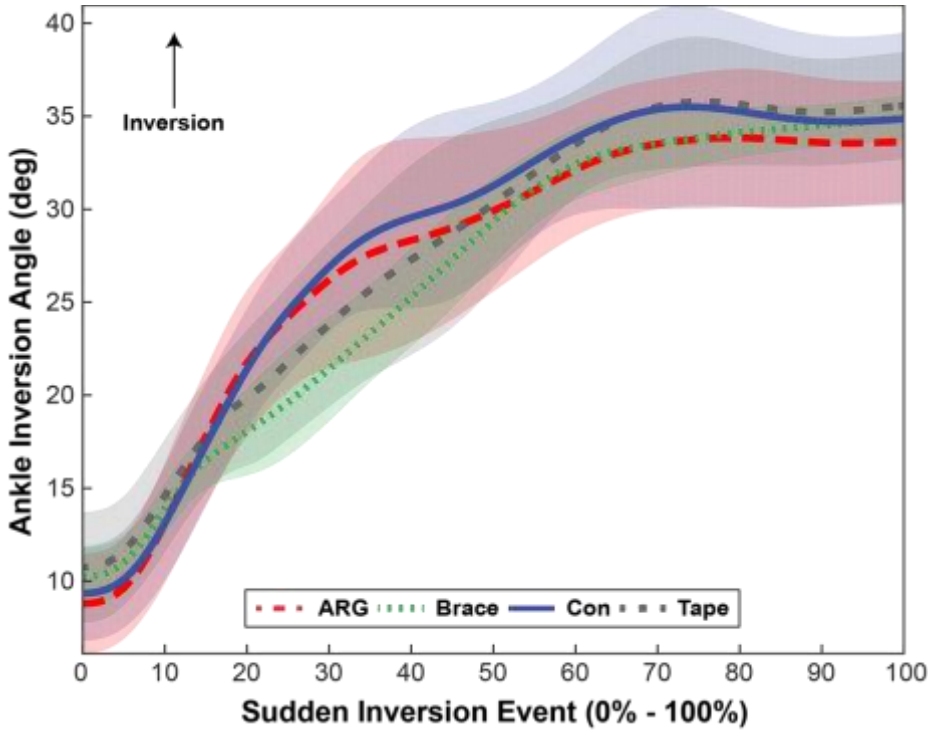

Figure 2: A plot depicting the mean (SD) of ankle inversion angle recorded during the sudden inversion event (0% - 100%) for each ankle prophylactic device (ARG, Brace, Control and Tape) tested.

The peak ankle inversion angle exhibited during the sudden inversion event was 33.8 ± 3.3 ° with the ARG, 34.2 ± 1.7 ° with the Brace, 35.3 ± 6.0 ° with the Control, and 35.4 ± 3.7 ° with the Tape (Figure 3). The ANOVA revealed no significant effect of ankle prophylactic on the peak ankle inversion angle ($p = 0.489$) exhibited during the sudden inversion event.

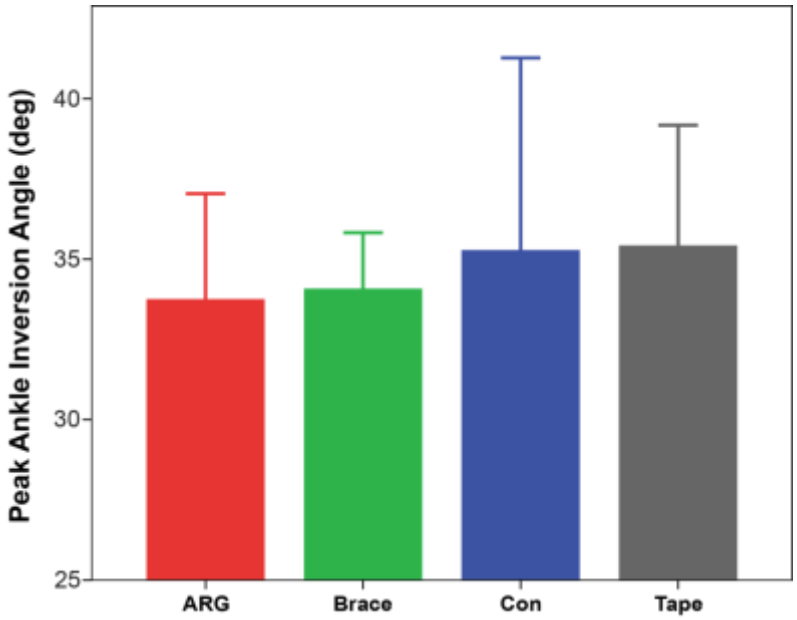

Figure 3: The mean (SD) of peak ankle inversion angle exhibited during sudden inversion event (0% - 100%) for each ankle prophylactic device (ARG, Brace, Control and Tape).

The range of ankle inversion exhibited during the sudden inversion event was 25.0 ± 2.6 ° with the ARG, 23.8 ± 2.0 ° with the Brace, 25.93 ± 4.9 ° with the Control, and 24.7 ± 3.2 ° with the Tape (Figure 4). The ANOVA revealed no significant effect of ankle prophylactic on range of ankle inversion ($p = 0.276$) exhibited during the sudden inversion event.

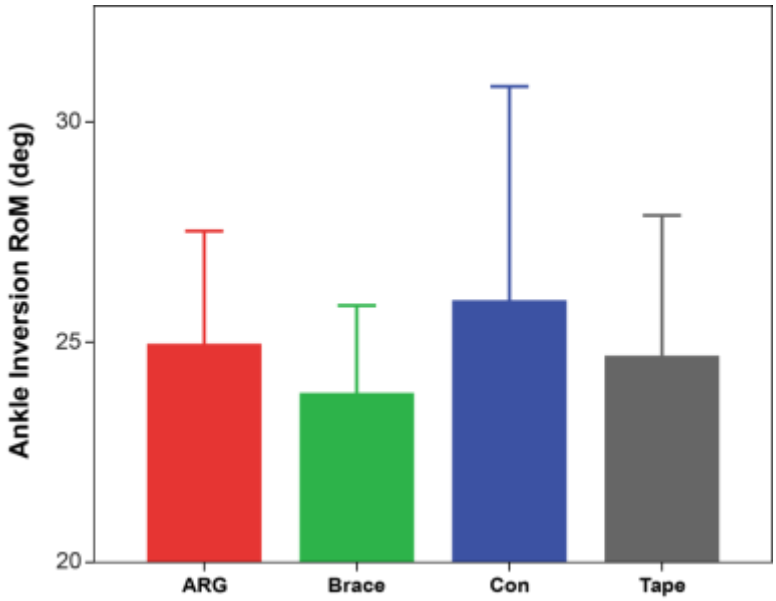

Figure 4: The mean (SD) of the range of ankle inversion exhibited during sudden inversion event (0% - 100%) for each ankle prophylactic device (ARG, Brace, Control and Tape).

The time to peak ankle inversion angle during the sudden inversion event was 0.20 ± 0.04 seconds with the ARG, 0.24 ± 0.05 seconds with the Brace, 0.20 ± 0.05 seconds with the Control, and 0.23 ± 0.05 seconds with the Tape (Figure 5). The ankle prophylactic device had a significant effect on time to peak ankle inversion ($p = 0.038$). Further analysis revealed the it took significantly longer to reach peak ankle inversion angle with the Brace compared to ARG ($p = 0.007$), but a significant difference in time to peak ankle inversion was not evident ($p > 0.05$) between any other ankle prophylactic device.

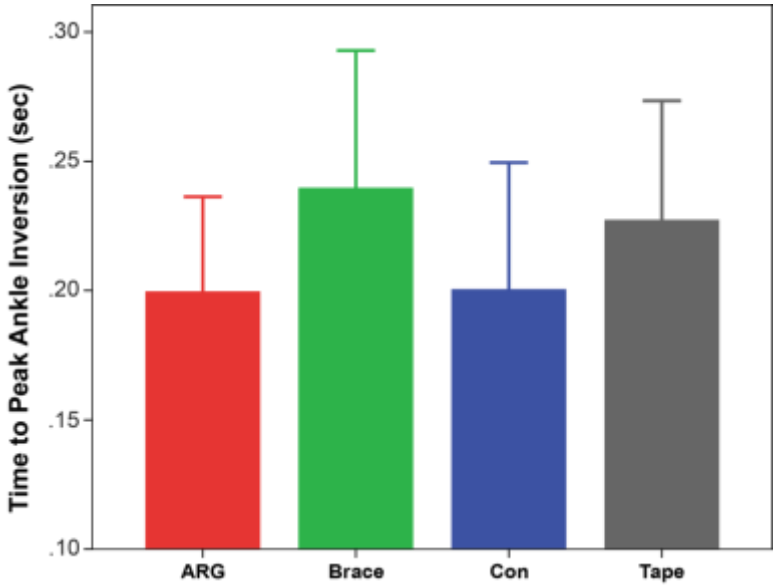

Figure 5: The mean (SD) of the time to peak ankle inversion angle exhibited during sudden inversion event (0% - 100%) for each ankle prophylactic device (ARG, Brace, Control and Tape).

Vertical jump height was 0.35 ± 0.08 m with the ARG, 0.34 ± 0.07 m with the Brace, 0.34 ± 0.08 m with the Control, and 0.33 ± 0.08 m with the Tape (Figure 6). The ankle prophylactic device had a significant effect on vertical jump height ($p = 0.036$). When wearing the Tape, participants vertical jump height was significantly lower than when wearing the ARG ($p = 0.021$), Brace ($p = 0.045$) and Control ($p = 0.048$) devices, respectively.

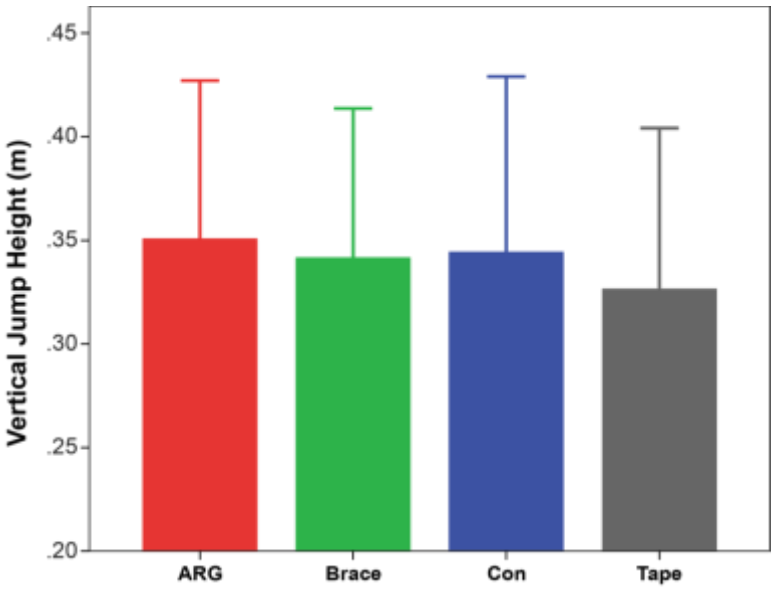

Figure 6: The mean (SD) of the maximal vertical jump recorded with each ankle prophylactic device (ARG, Brace, Control and Tape).

Results Summary:

To date, none of the chosen ankle prophylactic devices exhibited a significant effect on the peak ankle inversion angle or range of ankle inversion exhibited during the sudden inversion event. Considering that the ARG and Brace limited participants' peak ankle inversion angle to approximately 34 °, we anticipate with more participants that a significant difference in peak ankle inversion angle will be evident between those prophylactic products and the Control condition. In fact, it is anticipated with the addition of participants, all prophylactic products (ARG, Brace and Tape) will produce a significant reduction in range of ankle inversion compared to the Control condition. We do not, however, anticipate a significant difference in either peak ankle inversion angle or range of ankle inversion will be evident between the "braced" conditions – i.e., ARG, Brace or Tape – with the addition of participants. During the sudden inversion event, the current participants took significantly longer to reach peak ankle inversion angle with the Brace compared to ARG, but similar difference in time to peak ankle inversion angle was not evident between any other condition. Considering, participants reached their peak ankle inversion angle approximately 0.2 seconds after the initiation of the sudden inversion event with the both the ARG and Control conditions, we anticipate that those "braced" conditions will exhibit a significant reduction in time to peak inversion compared to the Brace and Tape conditions with the addition of participants to the analyses. Further work is needed to determine whether this anticipated difference is a function of the increased mechanical restriction provided by the Brace and Tape to the ankle that leads to a reduction in injury risk, or conversely has deleterious effect on the wearer's physical performance. Currently,

the participants only exhibited a significant reduction in physical performance, as measure by maximal vertical jump height, when using the Tape as an ankle prophylactic device. Donning either the ARG or Brace did not have a significant effect on vertical jump height compared to the Control condition. However, with the addition of participants, we anticipate that participants will exhibit a reduction in physical performance with the Brace and Tape compared to ARG and Control conditions, but do not anticipate this difference to reach statistical significance.