INTRODUCTION

Ankle sprains are well known to be among the most common sports-related injuries.\(^1\)\(^,\)\(^2\) Lateral sprains account for nearly half of all ankle sprains\(^3\)\(^,\)\(^4\) and have a reported recurrence rate of more than 70%.\(^5\) Ankle sprains induce overloading of the anterior talofibular ligament (ATFL) and calcaneofibular ligament (CFL) and their successive rupture.

Ankle orthoses are used for functional treatment after a sprain by protecting the ligaments from excessive stresses and reinjury, as a previous history of an ankle sprain is one of the most important risk factors.\(^6\)\(^,\)\(^7\) Their main function is the mechanical stabilization against moments in inversion, plantar flexion, and internal rotation.\(^8\)\(^,\)\(^9\) Despite some positive clinical results, an extensive literature review\(^10\) concluded that there was still a lack of well-controlled studies which addressed orthotic
ankle support and no clear recommendation could be given as to whether particular device was useful as a preventive strategy. Biomechanical evidence on the effectiveness of various orthoses is limited to the description of altered range of motion in either solely healthy or solely injured ankles. These data also reveal large differences between the evaluated devices in their ability to limit passive movements. At the same time, ankle orthoses alter knee and hip kinematics indicating higher risk of injury and should therefore only be worn if necessary. In most cases, ankle sprains result from trauma, where the patient lands either on the inverted foot in plantar flexion, inversion, and internal rotation or on an obstacle with the momentum of the body amplifying the extent of these rotations. The result is a moment about the ankle, overloading of the ATFL and CFL, and their successive rupture. While most studies have evaluated orthotic stabilization in terms of ankle's reduced range of motion, ligament ruptures are caused by increased stresses (acting moments and loads) in excessive motion. In other words, an orthosis should primarily limit joint stresses, rather than motion. Therefore, the aim, in this biomechanical study, was to quantify the isolated mechanical ability of commonly prescribed semi-rigid orthoses to stabilize the ankle in a simulated recurrent ankle sprain.

2 | MATERIALS AND METHODS

2.1 | Specimen preparation

A total of 12 unpaired human lower leg specimens, which were obtained from donors to the Centre for Anatomy and Cell Biology, Medical University of Vienna, were used. The donors had given written consent for their bodies to be used for research and education. The study was approved by the Ethics Committee of the Medical University of Vienna (1614/2013). The criteria for exclusion of specimens were donor age lower than 20 and higher than 100 years, history of injury, disease or prosthetic restoration of the hindfoot, evidence of degeneration or injury of ankle or lateral ligaments. One specimen showed a pre-existing rupture of the ATFL and was excluded from further testing. The mean donor age of included specimens (n = 11) was 81.0 ± 11.6 years (mean ± SD) (range: 61-95 years; 8 male, 3 female). In order to prevent dehydration and change in mechanical properties of the soft tissue, all specimens were fresh frozen at −80°C and exposed to room temperature 48 hours prior to preparation and testing.

Prior to testing, a J-shaped incision was performed anterior from the distal tip of the fibula along its anterior margin proximally to the level of the ankle mortise allowing easy exposure of the ATFL and the CFL. The syndesmosis tibiobibifibularis remained intact. The joint capsule was incised and the ligaments inspected for prior injury. After the initial biomechanical test on the intact ankle joint, the ATFL was meticulously divided into mid-substance with a scalpel, creating an anterior instability of mid-substance with a scalpel, creating an anterior instability of the ankle, which was confirmed with the anterior drawer test.

2.2 | BMD assessment

Prior to preparation, dual-energy X-ray absorptiometry (DEXA) scans were performed in the calcaneus to determine the areal bone mineral density (BMD) for each specimen using Lunar Prodigy series X-ray, (GE Lunar Prodigy; GE Healthcare). BMD was assessed to reveal possible correlation between bone quality and joint stability.

2.3 | Ankle orthoses

The orthoses were selected based on authors’ clinical experience and their common application in clinical routine for protection of lateral ligaments. Following orthoses were tested:

- AirGo Ankle Brace (DJO, LLC; Vista, CA, USA),
- Air Stirrup Ankle Brace (DJO, LLC; Vista, CA, USA),
- Dyna Ankle 50S1 (Otto Bock HealthCare GmbH; Duderstadt, Germany),
- MalleoLoc (Bauerfeind AG; Zeulenroda-Triebes, Germany), and
- Push Aequi (Push; Maastricht-Airport, Netherlands).

Further information on each device, provided by the manufacturer, was summarized in the Appendix S1.

FIGURE 1 Biomechanical tests were carried out in a hydraulic load frame (1). Using custom-made steel cups (2) and Wood’s metal specimens (3) were fixed proximally. The correct alignment was controlled with a laser beam. A Steinmann pin (4) was drilled through the calcaneus and allowed locking in the guide block (5) of the mounting platform (6).
2.4 | Mechanical testing

All experiments were carried out using the servo-hydraulic load frame, 858 Mini Bionix (MTS Systems Corporation, Eden Prairie, MN, USA) and a specially designed mounting platform (Figure 1). Each lower leg was potted with its tibia into a steel cup and mounted superiorly into the load frame. All specimens were positioned with their mechanical tibial axis coinciding with the axis of rotation of the load frame using a fixed laser beam. Furthermore, the specimens were placed in 20° of plantar flexion and 15° of hindfoot inversion to simulate the kinematics during an ankle sprain.1,8,15 The specially designed mounting platform enables fixation of the calcaneus with a 4.5 mm Steinmann pin. The pin is drilled through the calcaneus, posterior to the longitudinal axis of the tibia. The Steinmann pin is then locked in a guide block attached to the platform. The guide block of the platform enables anterior-to-posterior motion of the hindfoot during internal rotation, allowing anterior translation of the talus.16-19 Torsion was applied by internal rotation of the tibia against the fixed calcaneus from 0° to 40° in order to simulate stresses in lateral ligaments during a vivo ankle sprain. The angle of 40° was chosen upon the experience of the authors and aimed to induce maximum moment without causing a lesion of the stabilizing structures. The procedure was carried out quasi-statically (0.5°/s), stopped at 40°, and relaxed to the initial unloaded state of 0°. Subsequently, the test was repeated in a rapid dynamic mode at 50°/s. The first test series was carried out on the intact specimens with intact ATFL, followed by visual inspection of lateral ligaments for their intactness. The second test series was conducted on specimens with transected ATFL and finally on transected ATFL and stabilized by each of the five described orthoses in a randomized order. The orthoses were used in the appropriate foot size, fastened tightly avoiding any interaction between the Steinmann pin and the stabilizing elements of the orthoses, and checked for relative motion to the lower leg. The test cycle with transected ATFL (control state) was performed first and repeated again after testing all orthoses. Comparison of measurements in the initial and final control state, as well as in the quasi-static and dynamic test modes, revealed no significant differences and provided direct confirmation of the preservation of initial joint stability and of strong hold of the Steinmann pin throughout the tests.

The moment (Nm) required to resist the internal rotation, as well as the corresponding rotary displacement (°) of the load frame, were digitized at a sampling frequency of 200 Hz. The uncertainty in measurement for torque and angular displacement of the system was 1%.

2.5 | Statistical analysis

In order to evaluate the stabilizing effect of the orthoses in relation to the unprotected intact ankle, the percent change in the internal rotation moment relative to the intact condition was calculated as:

\[
\frac{T_{\text{support condition}} - T_{\text{intact}}}{T_{\text{intact}}} \times 100\%
\]

where \(T\) was the maximum value of the internal rotation moment obtained for 40° of rotation in line with the anatomic axis of the tibia against the calcaneus. All data were tested for normal distribution using Shapiro-Wilk test.20 One-tailed \(t\) test was performed to analyze for statistically significant differences between the internal rotation moment in the unprotected ankle after transection of the ATFL and intact ankle joint or stabilized with one of the orthosis after the simulated ATFL rupture. The one-tailed testing was used, because the stabilization with an orthosis or an intact ATFL was not expected to further reduce the resisting moment after ATFL transection.21 Pearson product-moment correlation coefficient was computed to investigate linear correlations between (a) areal BMD and resisting internal rotation moment in intact and unprotected ankle, (b) age and internal rotation moment in intact and unprotected ankle, (c) internal rotation moment in intact ankle and ankle with ruptured ATFL, and (d) internal rotation moment measured in quasi-static and dynamic test mode in intact ankle and ankle with ruptured ATFL. Statistical significance was set at the 95% confidence level (95% CI).

3 | RESULTS

Due to corrupt data recording, one test cycle for the Air Stirrup could not be included in the data analysis. All other test series were successfully completed, without interlocking of the test setup or tissue failure. The results for the maximum moment measured at 40° internal rotation for different support conditions are presented in Table 1.

A statistical significant difference was found between internal rotation moment before and after ATFL transection \((P < 0.05)\). The internal rotation moment was statistically greater from the unprotected ankle with ruptured ATFL for the AirGo Ankle Brace in quasi-static and for Air Stirrup Ankle Brace in quasi-static and dynamic test mode. For better visualization, the data in Figures 2 and 3 are presented as ratios obtained by dividing the difference in internal rotation moment between the stabilized and intact ankle and the moment in the intact ankle. The baseline in both figures represents the intact and unprotected state. Hence, the negative values indicate a lower primary stability of the ankle in internal rotation from the intact physiological state.

A strong correlation was found for the internal rotation moment between the intact ankle and the unprotected ankle with ruptured ATFL for both the quasi-static
and dynamic test mode \( R^2 = 0.921 \) (\( P < 0.00001, 95\% \) CI: 0.845-0.996) and \( R^2 = 0.916 \) (\( P < 0.00001, 95\% \) CI: 0.835-0.995), respectively (Figure 4). Also, a strong correlation was found for the internal rotation moment between quasi-static and dynamic test mode for both the intact ankle and the unprotected ankle with ruptured ATFL \( R^2 = 0.974 \) (\( P < 0.00001, 95\% \) CI: 0.974-0.999) and \( R^2 = 0.941 \) (\( P < 0.00001, 95\% \) CI: 0.883-0.997), respectively (Figure 5). A moderate correlation was found between the BMD and moments in intact ankle and unprotected ankle with ruptured ATFL for both the quasi-static and dynamic test mode \( R^2 = 0.741 \) (\( P < 0.001, 95\% \) CI: 0.519-0.962) and \( R^2 = 0.738 \) (\( P < 0.001, 95\% \) CI: 0.513-0.961), respectively. No correlation was found for the age of the donors and measured internal rotation moments.

### DISCUSSION

The present study delivered quantifiable data on mechanical effectiveness of various semi-rigid orthoses in ankle stabilization in a recurrent sprain simulation in comparison to the uninjured and injured unprotected ankle. Based on biomechanical evidence, only two out of five tested orthoses showed a significant protective ability in recurrent ankle sprains, indicating the need for objective evaluation of all ankle support devices, prior their clinical application.

Ankle sprains predominantly occur at high loading rates, and while there are no data on these rates, it is assumed they are subjected to great variations. For this reason, the authors chose to conduct a rapid dynamic and alternatively, a better controllable and easy repeatable quasi-static test series to possibly produce better comparable results. The data of the
quasi-static and dynamic series showed a very strong 1:1 relation. In consideration of the high test-retest reliability, the presented setup provided reliable results.

A simulated rupture of the ATFL led to a significant reduction in resisting moment in inversion and dorsiflexion during ankle internal rotation, which was in accordance with previously published data. The mean moment at 40° internal rotation was reduced by 14%, after the ATFL was transected. Subsequently, only the AirGo and Air Stirrup showed a positive reinforcement of the ankle joint, compared to its injured state in both, the quasi-static (both $P < 0.05$) and dynamic loading ($P = 0.13$ and $P < 0.05$, respectively). Their similar design is likely responsible for the highest measured mechanical effectiveness. The Air Stirrup incorporates two large, a medial, and a lateral plastic shell element with approximately 26 cm in height, 9 cm in width, and with a wall thickness of 2.5 mm in its large size. Additionally, the preinflated and cushioned aircells allow sufficient adhesion on the skin. The cushioning is reinforced in the area of both the inferior tibiofibular and subtalar joint, allowing a higher compression of the joints. The overall good stabilizing ability of the Air Stirrup was also confirmed in another biomechanical study. The AirGo includes two similar, but smaller stabilizing elements with 20 cm in lengths and 5-7 cm in width (medium/ large size) and is cushioned with preinflated aircells. They are also lower in thickness and without additional cushioning around the joints compared to the AirGo. The support with the Aequi showed internal rotation moment in the magnitude of an intact ankle joint. In contrast to the quasi-static test mode, the Aequi reinforced the stability in the dynamic loading compared to the intact state, however, statistically not significant. This orthosis has a single stabilizing element on the lateral side with the height of approximately 20 cm, a varying width between 3.5 and 7 cm, and a wall thickness of 1.5 cm. The authors assume that the lack of a medial stabilizer makes the ankle brace prone to higher internal rotation. Both the Dyna ankle orthosis and the MalleoLoc provided hardly any additional stability in a recurrent sprain ($<2.5\%$ of internal rotation moment ratios).

Several authors investigated the protective ability of ankle orthoses in biomechanical experiments. In subjects with chronic ankle instability, 10 different orthoses reduced the passive range of motion and induced inversion with large differences in the magnitude of the reductions between devices. In a different study, ankle braces successfully restricted the range of motion in passive inversion and plantar flexion. Shapiro et al. compared the stabilizing moment in inversion of eight different braces with taped ankle and with different types of worn footwear in a carefully conducted in vitro study. A comparable or superior effect for most braces, independent of the shoe type, was observed compared to intact and unprotected ankle joint. Using lower leg anatomic specimens as well, Omori et al. described an increase of internal and inversion rotation following the transection of the lateral ligaments, while the application of one specific orthosis showed no alteration of internal rotation. Previous clinical research on the stabilizing effect of ankle orthoses focused simply on the effect of the functional performance and delivered conflicting results. Prospective studies with soccer players demonstrated orthoses to significantly reduce the incidence of recurrent ankle sprains. On the other hand, a laboratory study on volunteers with previously sprained ankle showed no restriction of inversion by semi-rigid and soft orthoses compared to the unprotected condition. Scheuffele et al. investigated orthotic devices under functional conditions,
by simulating an inversion trauma in running movements. Different orthoses showed statistically significant lower angular displacement of the foot following the inversion stimuli of 20 or 30° with significant intragroup differences and lower surface electromyograms (EMG) signal from the ankle stabilizing muscles in most cases. In running, none of the different braces and stabilizing shoes could fully prevent eversion and inversion. In summary, subjects in most of these studies were samples from specific athletic populations, with no inclusion criteria relative to previous ankle sprain injury or presence of ankle instability. Also, none of these studies includes quantitative data on the stabilizing ability of the orthosis in injured ankles, compared to the intact state. Consequently, these results may not be applicable to patients, who have incurred a recent ankle sprain and who may wear one of these orthoses for protection against reinjury.

An additional finding of the present study was the moderate correlation between the BMD in the calcaneus and the internal rotation moment. A possible explanation would be a higher degree of physical activity in patients with higher BMD and a more stable joint due to stronger ligament structures. While this finding resulted primarily from curiosity of the authors and might be also a chance event due to a low number of specimens, the correlation between BMD and ligament mechanical properties or the strength of a surgical reconstruction has been previously reported and could have an important implication for injury prediction.

Several limitations of this study remain to be mentioned. First, the testing methodology included a loading scenario that represents sprain trauma in inversion and plantar flexion and a situation of maximum load under unprotected conditions. In most lateral ankle sprains, the soft tissue is subjected to excessive stresses caused by momentum of the body on the inverted foot, which amplifies the degree of internal rotation, inversion, and plantar flexion. The presented setup and applied internal rotation moment mimic both, the momentum of the body (bodyweight in motion) and excessive rotations during a sprain inducing maximum stress to the lateral ankle. Second, the physiological ankle is stabilized passively by anatomic structures and shoes but also actively by ankle stabilizing muscles (m. peroneus longus, m. tibialis anterior, and m. gastrocnemius). In this in vitro study, active stabilization was not included, which might have influenced the overall resisting moment. All specimens were also tested without footwear. This represents on one hand the worst case scenario and, on the other hand, excludes the variability of data caused by (interaction with) different types of footwear. It was shown previously that different ankle support devices, in combination with shoes, significantly increase the passive stabilization, which was, however, independent of the footwear type. Furthermore according to the product information, only the Aequi is advised to be worn with closed shoes.

In conclusion, tested orthoses vary significantly in their ability to resist a recurrent ankle sprain. Failing of particular orthoses to sufficiently stabilize the ankle joint indicates a necessity for a critical review of all ankle stabilizing devices and their designs.

5 PERSPECTIVE

Ankle orthoses are widely used in prevention of recurrent ankle sprain. At the same time, there is very little evidence on the ability of single orthoses to sufficiently stabilize the ankle joint during a sprain. Biomechanical evaluation showed that orthoses vary significantly in their ability to resist a recurrent ankle sprain. Three out of five biomechanically tested orthoses failed to sufficiently stabilize the ankle joint during a recurrent ankle sprain. The results of the study should assist clinicians in selecting the most effective orthosis, for use in protection against recurrent ankle sprain.

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CONFLICT OF INTERESTS

Tested orthoses were donated by ORMED GmbH (Freiburg, Germany). Other than that, the authors declare that they have no conflict of interest.

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