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Effects of patella tendon and hydrostatic ankle foot orthoses on foot plantar pressure and pain: Pilot study in healthy subjects

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ABSTRACT

This study compared the efficacy of three ankle-foot orthosis (AFO) designs: patellar tendon bearing AFO (PTB-AFO), hydrostatic AFO (H-AFO), and hydrostatic AFO with a four-ply sock (H4-AFO). The research explored pressure distribution on the leg and foot, potential correlations with gender, body mass index (BMI), body fat percentage, and pain scores between PTB-AFO and H4-AFO. Six healthy participants were included, and the study revealed that PTB-AFO effectively reduced plantar pressure, while H-AFO displayed lower average leg pressure than H4-AFO. A significant negative correlation was identified between BMI and average leg pressure in PTB-AFO. However, PTB-AFO was associated with higher discomfort, likely due to its structural design. These findings highlight the need for further investigations involving larger sample sizes and dynamic gait analyses to better understand the impact of orthosis design on pressure distribution and user comfort. This study suggests potential improvements in AFO design that could enhance patient experience and orthotic effectiveness in clinical applications.

Keywords: patellar tendon bearing; hydrostatic; ankle foot orthosis; functional brace

1. INTRODUCTION

Patellar tendon bearing ankle foot orthoses (PTB-AFO) are designed to reduce weight transmission through the middle or distal tibia, ankle, or foot. This is achieved by redistributing pressure to a proximal part of the limb, thereby off-loading the foot (Karimi & Kamali, 2021; Sarmiento, 2004; Thornell, 1973). These orthoses are commonly prescribed in cases where weight-bearing on the affected limb must be minimized or eliminated, such as with distal tibial fractures, painful post-operative ankle fusions, or Charcot's joint (Thornell, 1973).

There are two primary concepts for reducing loading in an orthosis. The first is the patellar tendon bearing principle, which redistributes the load to pressure-tolerant areas by applying compression to the patellar tendon bar and through firm molding over the tibia's medial flare, and femoral condyles. However, during gait, soft tissue displacement can generate shear forces that can cause pain, tissue damage, and skin problems, particularly when pressure is concentrated over bony anatomy or sensitive areas. Moreover, the trimlines encompassing the knee joint can cause discomfort (Moo et al., 2009; Safari et al., 2015). Therefore, the comfort and effectiveness of this load transfer method remain areas for improvement. The second concept is the hydrostatic loading principle, which involves containing soft tissue within the same volume as the device, thereby minimizing shear forces and tissue displacement. Based on previous studies, the hydrostatic principle is considered a more effective loading approach (Goh et al., 2004; Moo et al., 2009).

Transtibial prostheses and PTB-AFOs share a common weight-bearing concept, with both utilizing the patellar tendon-bearing principle in the socket. Nevertheless, patients have reported discomfort when using these devices. Previous studies comparing pressure distribution in PTB and hydrostatic principles have shown that hydrostatic sockets offer superior pressure distribution and increased comfort compared to PTB sockets. Despite these findings, no comparative studies have been conducted to evaluate pressure distribution in orthotic devices, specifically PTB-AFOs. This raises the possibility that AFO designs relying solely on the hydrostatic principle may offer more comfort. Additionally, several factors influence soft tissue pressure distribution, including gender, body mass index (BMI), and muscle contraction. For the reasons mentioned above, we aim to assess the effectiveness of foot off-loading across three PTB-AFO designs, using plantar pressure measure-ments as an outcome metric (Alimerzaloo et al., 2014; Karimi & Kamali, 2021; Tanaka et al., 2000).

The lack of comparative studies examining the pros and cons of incorporating the weight-bearing concept at the PTB into AFO designs is a significant gap in current research. Moreover, the effects of factors such as BMI, body fat percentage, and gender on pressure distribution have not been adequately investigated in orthotic research. Understanding these variables is vital in clinical practice, as better pressure distribution and increased comfort can significantly improve patient outcomes by reducing pain, enhancing mobility, and promoting adherence to orthotic use. Therefore, evaluating weight-bearing AFO designs, both PTB-AFO and those without PTB trimlines, particularly those that use hydrostatic principles, is crucial for optimizing future treatment approaches.

This study aimed to evaluate the pressure distribution and comfort provided by three distinct AFO designs: the traditional PTB-AFO; the hydrostatic AFO (H-AFO) with removable PTB trimlines incorporating the hydrostatic concept; and the hydrostatic AFO worn with a four-ply sock (H4-AFO). While current AFO designs primarily focus on structural stability and functional support, they often overlook essential factors like comfort and weight distribution, both of which are essential for extended wear and patient compliance. Traditional designs tend to concentrate pressure in certain areas of the limb, which can result in discomfort, localized pain, and restricted blood flow, ultimately discouraging consistent use and reducing treatment effectiveness. In contrast, the hydrostatic principle presents a promising alternative by distributing pressure across the limb. This approach has the potential to increase comfort by minimizing high-pressure points and improving weight distribution.

The three main objectives of this study were to compare pressure distribution on the plantar surface and lower leg across the three designs; to assess the correlation between pressure distribution and individual factors such as gender, BMI, and body fat percentage; and to compare pain scores between the PTB-AFO and H4-AFO designs. Additionally, the study explored the application of hydrostatic principles in AFO design, a topic that has received limited attention in orthotics research.

2. MATERIALS AND METHODS

2.1 Study period and design

A quasi-experimental study design was conducted from December 2017 to December 2018.

2.1.1 Participants

Six healthy volunteers were recruited from the Sirindhorn School of Prosthetics and Orthotics Clinic. The Siriraj Ethical Review Board approved the study (study number 613/2560(EC4)), and all participants provided informed consent prior to data collection. Inclusion criteria required participants to be between 18 and 30, have a BMI within the normal range, and be in good health with no underlying disease or lower leg deformities. Exclusion criteria included a history of lower leg fractures, cognitive problems, wounds or scars on both lower limbs, and significant deformities below the knee.

2.1.2 Intervention design

Three AFO designs were evaluated in this study: (A) the PTB-AFO; (B) the H-AFO; and (C) the H4-AFO (Figure 1). In the PTB-AFO, weight is distributed over the medial flare of the tibia, tibial condyles, patellar tendon, and through the hydrostatic concept. In the H-AFO, based on the hydrostatic concept, it had the PTB trimline removed. The H4-AFO incorporates additional compression above the ankle joint using four-ply socks to enhance the hydrostatic effect. To minimize experimental bias, strap tightness was standardized across all orthoses by marking the devices.

2.1.3 Manufacturing procedure of interventions

Casting and modification. The orthotist cast the PTB-AFO for each participant using the procedures outline by the International Committee of the Red Cross (ICRC) (International Committee of the Red Cross, 2006), with the ankle positioned in a neutral alignment. All three AFO designs for each participant were fabricated from a single casting.

Fitting. Device fitting was performed by the orthotist following ICRC fitting procedures. This process included verifying trimlines of the device following each intervention, ensuring proper contouring to the lower leg, checking the placement of suspension straps, and assessing sitting comfort.

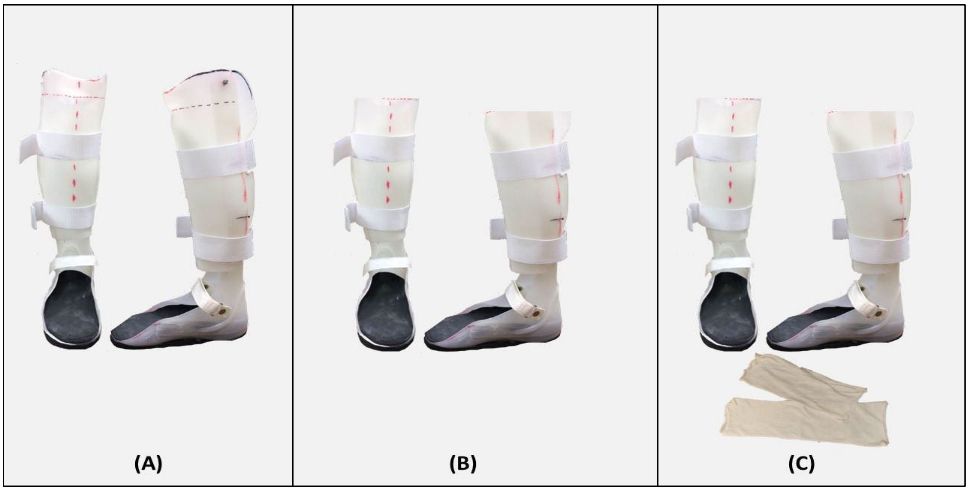

Figure 1. Three designs of the patellar tendon bearing ankle-foot orthosis (PTB-AFO)
Note: Patellar tendon bearing ankle foot orthosis (PTB-AFO) (A); hydrostatic ankle foot orthosis (H-AFO) (B); hydrostatic ankle foot orthosis with four-ply socks (H4-AFO) (C).

2.1.4 Intervention A

This design is PTB-AFO. It combines both hydrostatic and weight-bearing principles to offload the foot. Its two main bracing mechanisms are the PTB brace, which uses the patellar tendon for weight support, and hydrostatic support, achieved through compression of the plastic exterior around the shank area (See Figure 2).

2.1.5 Intervention B

This design is the H-AFO, which incorporates hydrostatic principles. It consists of an anterior and a posterior shell. The primary unloading mechanism is the hydrostatic concept, where the compression of the plastic shell around the user's leg helps distribute the weight and reduce load on the foot.

2.1.6 Intervention C

This design is the H4-AFO, which incorporates hydrostatic principles, like the H-AFO. To enhance static pressure on the leg, this design utilizes a four-ply sock, similar to walking boots with air pumps, to fill the space between the leg and the device.

2.2 Data collection

Participant demographic information, including gender, age, body weight, and height, was recorded. BMI and body fat percentage were calculated using measurements obtained with a skinfold caliper. A methodological flowchart illustrating the study's experimental design is shown in Figure 2.

2.3 Average pressure on the leg and plantar surface

In this study, average pressure refers to the mean pressure exerted across the surface of the leg and plantar region by each orthosis design. Additionally, this measurement can also be used to determine the percentage of load borne by the device through the leg and foot. Static pressure data on various areas of the calf and plantar surface were collected and analyzed using the Force Sensitivity Application (FSA) system (Vista Medical Ltd., Winnipeg, MB, Canada). Pressure sensors were placed between the participant's leg and the device. The FSA software recorded data and helped identify any misalignment. To eliminate bias in weight-bearing, alignment was verified and adjusted using the L.A.S.A.R posture alignment apparatus (Laser-Assisted Static Alignment Reference Posture, Otto Bock, Duderstadt, Germany).

2.4 Visual analog scale (VAS)

The (VAS) was used to measure participants' pain scores (Lazaridou et al., 2018). Pain scores reflect the level of discomfort associated with wearing each orthosis, as reported by participants, and serve as a direct indicator of device comfort, which is an essential factor for assessing user adherence and the practicality of each orthosis in daily life. Participants were asked to walk on a treadmill at a comfortable speed for five minutes while wearing the device. Immediately afterward, they rated pain levels using the VAS, with 0 indicating no pain and 100 indicating the worst imaginable pain. This study specifically aimed to compare VAS scores between PTB-AFO and H4-AFO. The H4-AFO, which relies on hydrostatic pressure for weight-bearing, is hypothesized to be more preferable. When comparing only the hydrostatic designs, the H4-AFO provides a level of offloading similar to the H-AFO.

2.4.1 Statistical analysis

2.4.1.1 Power analysis

A power analysis was conducted to determine the appropriate sample size required to detect statistically significant differences between the hydrostatic AFO (H4-AFO) and PTB-AFO in terms of pressure distribution, comfort, and pain scores. Based on an estimated effect size of 0.5 (medium effect), an alpha level of 0.05, and a desired power of 0.80, the power analysis suggested a minimum sample size of 30 participants per group would be required to achieve sufficient statistical power to detect meaningful differences in the primary outcomes. However, due to budgetary and resource limitations, a smaller sample size was used in this study, which may limit its statistical power and the ability to detect significant differences. Future studies should aim for larger sample sizes to validate these findings and improve generalizability.

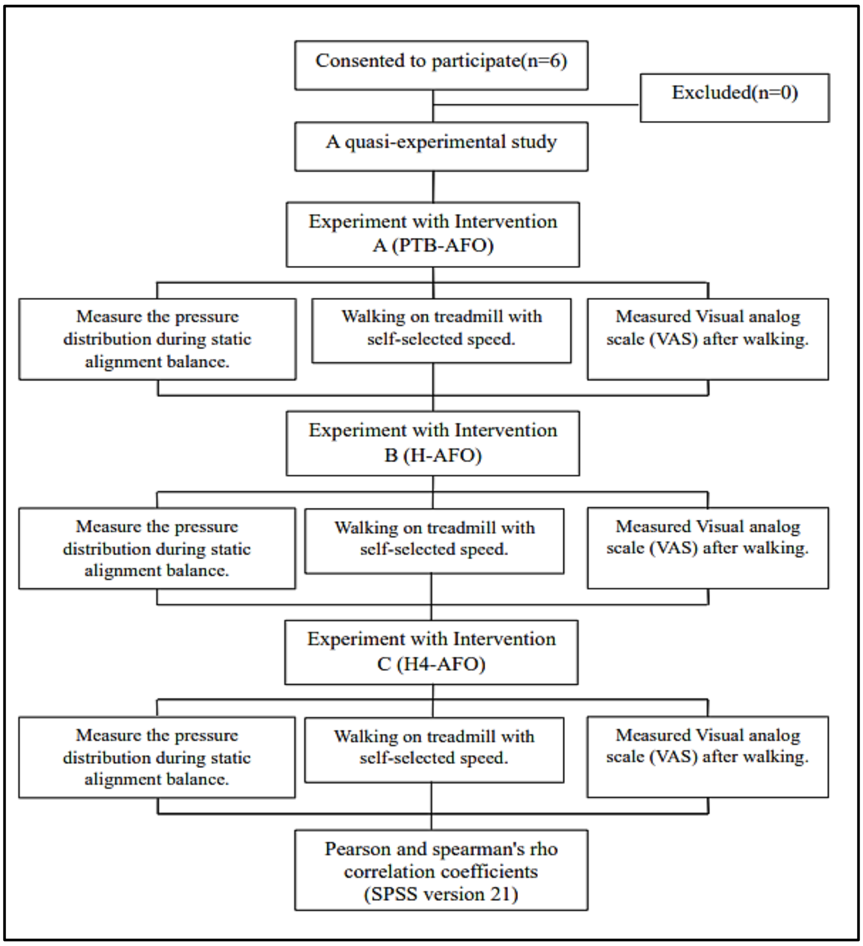

Figure 2. Methodological flowchart

2.4.1.2 Data analysis

Statistical analyses were conducted using SPSS software (Version 21, SPSS Inc., Chicago, IL, USA). Descriptive statistics were used to describe the data. Normality was tested using both the Kolmogorov-Smirnov and Shapiro-Wilk tests. For pressure comparisons, Friedman's test was used for related samples to analyze average leg and plantar foot pressure across different interventions. Additionally, a repeated-measures ANOVA was applied to assess changes in pressure measurements across the three interventions. Pain scores measured by the VAS were analyzed using the related-samples Wilcoxon signed rank test. Correlations between participant characteristics and average pressure were analyzed using Pearson's and Spearman's rho correlation coefficients, interpreted according to the guidelines outlined by Akoglu (2018). Statistical significance was set at a p value <0.05.

3. RESULTS

A total of six healthy participants, three females and three males, were recruited for this study. The average age was 21.2 years (range: 20–22 years). Participants had a mean BMI of 22.0 kg/m^2 (range: 20.37–23.72 kg/m^2), an average weight of 64.6 kg (range: 53–76 kg), and an average height of 1.71 m (range: 1.58–1.80 m). The average body fat percentage was 25.78% (range: 15.34%–36.5%).

Among the three orthotic designs, the PTB-AFO demonstrated the highest level of plantar off-loading, with an average of 0.32 Psi. In contrast, the H-AFO design showed lower compression and pressure distribution over the leg, with an average of 0.21 Psi (Figure 3).

Correlational analysis revealed relationships between gender, BMI, body fat percentage, and average pressure. The strength of correlations was interpreted using the following thresholds: r = 0.8–0.9, very strong; r = 0.6–0.7, moderate correlation, r = 0.3–0.5, fair correlation; and r = 0.1–0.2, poor correlation (Akoglu, 2018). A statistically significant strong negative correlation was found between BMI and leg average pressure in the PTB-AFO design (p < 0.05) (Figure 4).

The interpretation of VAS results for the PTB-AFO design indicated significantly higher pain levels (p = 0.028), with an average score of 65.33 (range = 54–82), which is classified as moderate to severe pain. This finding is significantly higher when compared to other designs after a short period of use, with an average pain score of 23.66 (range = 13–40), characterizing mild pain (Figure 5). The comparison of VAS scores between the PTB-AFO and H4-AFO also suggests a walking comfort similar to that of walking in boots. This similarity is likely due to both devices supporting weight-bearing through the patellar tendon while utilizing hydrostatic features.

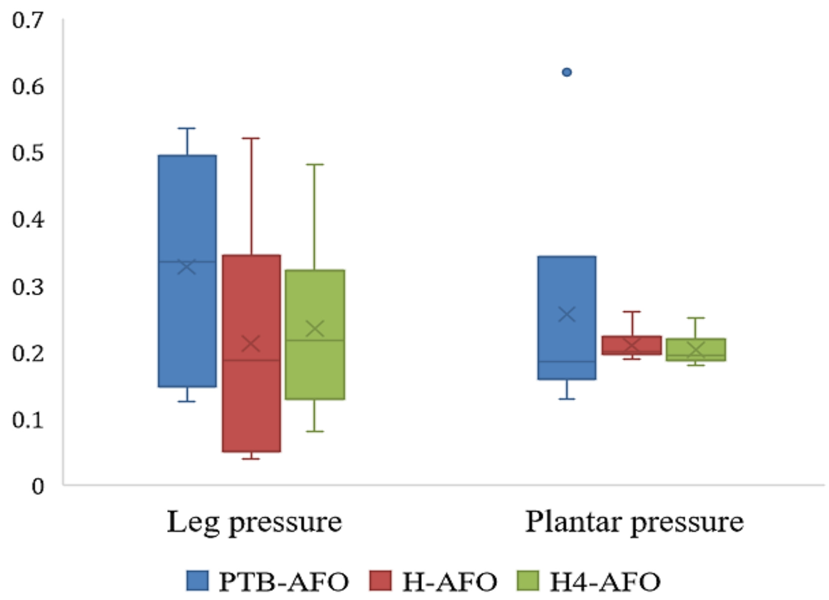

Figure 3. Comparison of average leg pressure and plantar pressure across the three interventions
Note: PTB: patella tendon bearing, H: hydrostatic, H4: hydrostatic with add-on four plies' sock.
AFO: ankle foot orthosis. Psi: pounds per square inch.

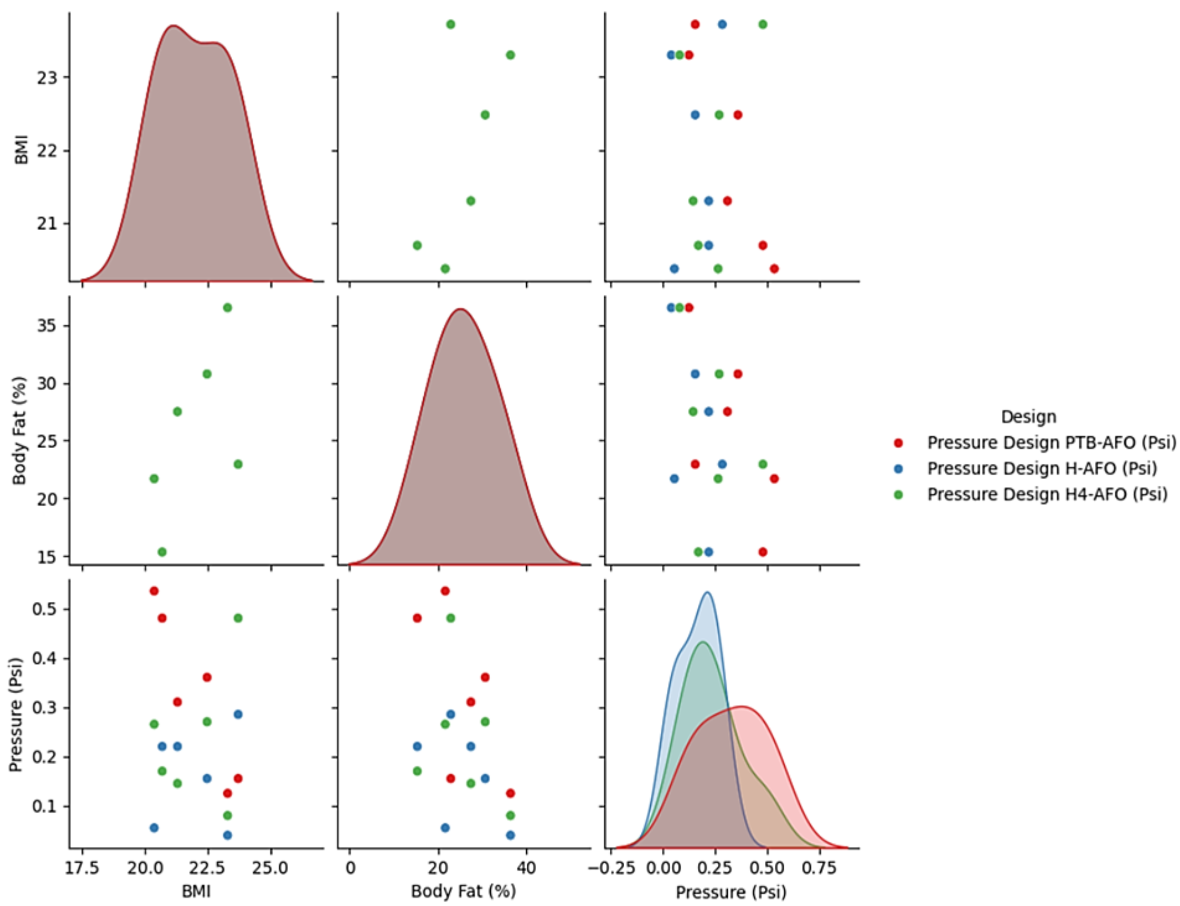

Figure 4. Correlations between participant characteristics and average pressure across the three designs

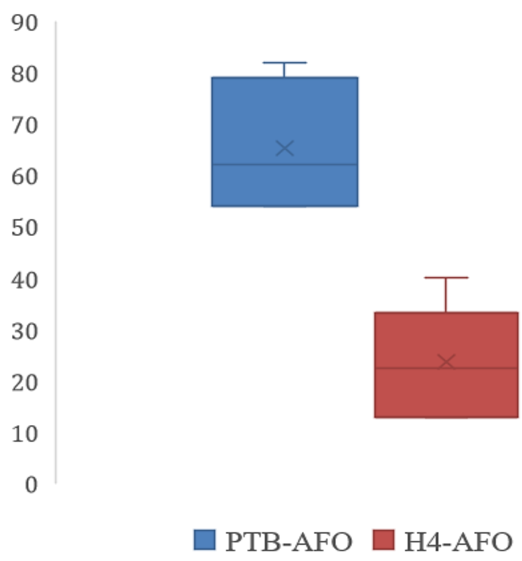

Figure 5. Comparison of average VAS pain scores between the PTB-AFO and H4-AFO design
Note: VAS: visual analog scale, PTB: patella tendon bearing, H4: hydrostatic with add-on four plies' socks, AFO: ankle foot orthosis

4. DISCUSSION

This study compared three orthosis designs (PTB-AFO, H-AFO, H4-AFO) to evaluate average pressure distribution over the leg and plantar surface. It assessed user comfort via VAS pain scores, and explored correlations between pressure distribution, and participants factors such as gender, BMI, and body fat percentage. Our results demonstrate that the PTB-AFO design is the most effective at off-loading plantar pressure. In contrast, the H-AFO design exhibited the lowest average pressure distribution over the leg. Notably, applying the off-loading concept over the patellar tendon and proximal condyle in the PTB-AFO can reduce plantar pressure by approximately 18% after trimline modification, suggesting a direct relationship between leg pressure and decreased plantar pressure.

The results also found that pressure distribution was influenced by BMI, with a lower BMI resulting in more concentrated loading over bony areas than seen in participants with higher BMI (Pretty et al., 2017). Furthermore, correlational analysis revealed a significant negative relationship between body mass index and leg average pressure in the PTB-AFO condition ($p<0.05$). Furthermore, VAS pain scores indicated that the PTB-AFO design was associated with significantly greater discomfort, likely due to device's weight-bearing focus on the tendon and condyles.

Despite the study's limitations, it suggests that the effectiveness of plantar off-loading is not solely dependent on the proximal trimline but rather on the holistic design of the orthosis. Previous studies have shown that off-loading depends on ankle motion and the depth between the foot and the device (Alimerzaloo et al., 2014; Tanaka et al., 2000). However, the application of hydrostatic pressure offers a promising strategy to stabilize soft tissue and improve pressure distribution. Increasing pressure through the use of additional sock layers is a viable method to enhance unloading near the PTB region. In the H4-AFO design, the application of four-ply socks plays a key role in improving pressure distribution and comfort compared to traditional AFO designs, such as the PTB-AFO and H-AFO. The rationale behind using four-ply socks lies in their capacity to generate more uniform pressure across the leg surface, thereby minimizing the risk of localized high-pressure points that may cause discomfort and compromise circulation. When combined with design features such as an ankle lock in neutral alignment and appropriate insole depth, the H4-AFO has the potential to enhance treatment effectiveness and improve comfort.

While this study provides important insights, it has several limitations. First, the sample size limits the statistical power and generalizability of the findings. Although the results highlight important differences between hydrostatic AFO designs and PTB-AFO, a larger sample is necessary to validate the observed trends and achieve statistical significance. Additionally, individual variability, such as body type, activity level, and other personal characteristics, may have contributed to variations in the results. Future studies should include more diverse and larger populations to validate these results. Furthermore, this study focused on static and dynamic pressure measurements, however, it did not assess other factors, such as long-term comfort, and device durability. Longitudinal studies examining the long-term effects of hydrostatic AFOs on skin integrity and tissue health are warranted. This study also did not examine the effects of different activity levels or gait patterns on pressure distribution. Future research could explore how hydrostatic AFO designs perform in more varied functional settings, such as during different physical activities or among patients with varying levels of mobility.

To address these limitations, the researcher strongly recommends that future studies investigate dynamic gait patterns and compare the forces generated by PTB-AFO and hydrostatic AFO designs. Such an approach would enhance the effectiveness of evaluating the study's first objective, particularly if supported by a larger sample size enabled by increased funding, extended timelines, and appropriate medical interventions. Another critical limitation is the study's short-term scope, which does not account for long-term use effects. While the hydrostatic AFO appears to reduce pressure points and potentially improve short-term comfort, there is limited evidence regarding how these benefits persist over time. Long-term use may introduce new challenges, such as material degradation changes in fit due to limb volume fluctuations and cumulative impacts on skin health, all of which could influence the long-term viability of hydrostatic AFOs.

In orthosis manufacturing, our findings suggest incorporating hydrostatic principles into designs to improve comfort and reduce the risk of pressure-related injuries. The even pressure distribution observed in hydrostatic AFOs presents a promising alternative to traditional designs, particularly for patients with sensitive or bony areas susceptible to irritation. Development efforts should also consider modular AFO systems that enable customization based on individual body composition, such as BMI and body fat percentage. Additionally, integrating components like compression socks, as demonstrated in the H4-AFO, may further optimize pressure distribution and user comfort.

While this study offers valuable insights into the comparative effectiveness of different AFO designs, it is important to acknowledge the individual differences observed in pressure distribution and pain perception. Differences in body composition, such as BMI, muscle mass, and fat distribution, can significantly influence how an orthosis interacts with the limb. These factors may influence pressure points and discomfort levels ultimately impacting the overall comfort and effectiveness of the orthosis. For example, individuals with higher body fat percentages may experience increased localized pressure, while those with greater muscle mass might experience more direct pressure on bony structures. The hydrostatic AFO design, which aims to achieve more even pressure distribution, may provide a more adaptable solution for a range of body types. However, the lack of diversity in this study, relating to participant characteristics, highlights the need for future research with a larger and more varied sample to better understand how body composition and other individual factors influence orthosis performance, and to confirm these findings across different populations.

The integration of hydrostatic AFO designs into standard clinical practice has the potential to significantly enhance patient outcomes by addressing essential factors, such as pressure distribution, comfort, and patient adherence. A key advantage of this design is its ability to reduce the risk of skin breakdown. Traditional PTB-AFO designs often concentrate pressure in specific areas, which can lead to localized irritation, ulcers, and other skin issues (Moo et al., 2009). In contrast, the hydrostatic principles promote more even pressure distribution across the limb, thereby lowering the risk of pressure sores and promoting overall skin health. This feature is especially beneficial for patients requiring long-term orthotic use, as sustained pressure on certain regions can worsen skin conditions. Moreover, hydrostatic AFOs may enhance patient compliance. Comfort is a crucial factor in ensuring consistent orthosis use, and discomfort remains a leading cause of non-compliance. By increasing comfort through even pressure distribution, hydrostatic designs may increase comfort and encourage patients to wear their orthoses for longer periods. Consequently, improved adherence can lead to more effective treatment and better long-term outcomes.

5. CONCLUSIONS

This study evaluated three orthosis designs in terms of pressure distribution and comfort, while also examining the potential influence of gender, BMI, and body fat percentage. The results revealed that although the PTB-AFO design was the most effective in reducing plantar pressure, the H-AFO design provided better overall pressure distribution across the leg. A negative correlation was found between BMI and leg pressure in the PTB-AFO group; however, this design was also associated with increased discomfort, likely due to its structure. The study's small sample size was a limitation, and future research should focus on dynamic gait analysis and compare force generation of the different orthosis designs.

As this was a short-term study, it also leaves open important questions regarding the long-term impact of hydrostatic AFOs on patient comfort, skin integrity, and overall adherence. To validate the preliminary findings presented here, future research should incorporate longer follow-up periods to assess the impact of prolonged wear and a broader set of clinical outcomes, including quality of life and functional mobility assessments. Despite these limitations, the hydrostatic AFO shows promising potential in improving comfort and reducing the risk of skin breakdown, marking an important advancement in orthotic design.

Future studies should explore ways to combine the off-loading benefits of the PTB-AFO with an ankle lock in neutral alignment and a well-designed insole. Such a combination could enhance treatment outcomes and increase patient comfort. Additionally, expanding the sample size and incorporating long-term wear studies could further validate these findings and refine AFO designs for diverse patient needs.

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