A NOVEL SITE-SPECIFIC SOMATOSENSORY STIMULATION FOOT ORTHOSIS TO IMPROVE BALANCE AND STABILITY IN OLDER ADULTS

ABU JOR

PhD

The Hong Kong Polytechnic University

2026

The Hong Kong Polytechnic University

Department of Biomedical Engineering

A Novel Site-Specific Somatosensory Stimulation Foot Orthosis to Improve Balance and Stability in Older Adults

Abu Jor

A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy

June 2025

CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

_____ (Signed)

____ABU JOR_________ (Name of student)

ABSTRACT

Older population is rapidly increasing globally; 1 in 6 people will be 65 or older by 2030, doubling by 2050. Despite improvements in life expectancy, the disability burden remains high because of declines in function and sensory deficits. Age-related diseases contribute over half of the global health burden among adults. The changes in the musculoskeletal and nervous systems because of age can decrease sensory inputs and motor control, increase postural sway and ultimately impair postural balance. This highlights an urgent need for effective interventions to address balance and stability issues in older adults, which are crucial for reducing fall risk and related injuries.

The human foot, as the primary interface between the body and the ground, plays a critical role in providing stability, balance, and propulsion during locomotion. Its tactile perception is essential for maintaining balance and coordination, yet it is often overlooked. The non-hairy glabrous skin of the foot contains numerous sensory mechanoreceptors that detect inputs through mechanical changes such as pressure, touch, stretch, and vibration. They provide crucial somatosensory feedback necessary for postural adjustments. Stimulating these mechanoreceptors with orthotic interventions can offer faster transmission of information about the body position to the central nervous system, facilitating necessary adjustments and enhancing postural control in older adults.

Foot orthoses, including insoles and shoe inserts, are often recommended as orthotic interventions to improve balance, stability, and gait. However, traditional foot orthoses design primarily focus on structural support, with limited research on their impact on balance through sensory feedback and proprioception. Somatosensory stimulation foot orthoses, designed with surface protrusions or textures, have gained attention for their potential to enhance tactile sensitivity and proprioceptive feedback. Despite promising results in improving balance and stability, there remains a research gap in utilizing foot orthoses design features, such as the shape, height, and placement of protrusions, and structure, to maximize their efficacy. Addressing these gaps could offer more targeted orthotic interventions, significantly enhancing balance and stability in older adults, thereby improving overall life quality.

The study aims to design a novel foot orthosis that enhances balance and stability in older adults through site-specific somatosensory stimulation. It outlines five key objectives to achieve this goal.

Objective 1: Review existing evidence on the impact of somatosensory foot orthoses on postural balance and stability, focusing on specific design features such as structure, shape, height, hardness, and positioning of protrusions. In this phase, a systematic review, meta-analysis, and meta-regression were conducted to evaluate the effects of somatosensory foot orthoses on balance and stability in older adults. A comprehensive literature search was conducted across electronic databases to identify studies examining the effects of somatosensory foot orthoses on static and dynamic balance. Eighteen studies with 27 somatosensory foot orthoses conditions were included in the meta-analysis, with balance parameters related to center of pressure (CoP) trajectory reported in at least ten conditions selected for meta-regression analysis. The existing evidence from the systematic review and meta-analysis underscore the importance of specific design features of stimulating protrusion. Our findings showed that somatosensory foot orthoses significantly reduced CoP displacements during standing, particularly for arch-support structures, medium to large size rounded knobs, and site-specific placements. Timed Up and Go test outcomes also improved while other gait measures did not show significant changes although investigated in a fewer number of studies.

Objective 2: Assess whether prefabricated somatosensory foot orthoses with entire surface protruding knobs and arch-support improve postural balance. In this experimental phase, a prefabricated somatosensory foot orthoses and flat foot orthoses were provided to 23 healthy older participants. The postural control measures such as CoP trajectory, spatiotemporal gait, and plantar forces/pressures were assessed while standing with eyes open and closed conditions as well as walking on level, upward, and downward terrains. The participants with these foot orthoses also underwent computerized dynamic posturography assessments. The reductions in CoP displacements were observed with prefabricated somatosensory foot orthoses across certain movement terrains. The improvement in composite equilibrium scores and weight symmetry were also observed.

Objective 3: Identify potential foot sites for tactile stimulation by mapping tactile sensitivity thresholds on the foot. In this cross-sectional study, tactile sensitivity thresholds mapping across 30 distinct foot locations, including plantar, medial, lateral, and dorsal areas were conducted in 46 healthy older adults using Semmes Weinstein monofilaments. Tactile sensitivity thresholds varied by foot locations, with heel, lateral midfoot, and metatarsal heads exhibiting higher sensitivity thresholds. In contrast, medial midfoot, intermedius midfoot, medial and lateral metatarsal bases, and base of navicular exhibited lower thresholds.

Objective 4: Explore dose-response effects of varying protruding knob heights on postural balance, targeting areas of higher tactile sensitivity and lower plantar pressure. This aims to identify optimal protrusion heights that maximize sensory feedback while minimizing discomfort. In this randomized cross-over study, four different foot orthoses including three 3D-printed site-specific somatosensory foot orthoses with short, medium-height, and tall protruding knobs, and one conventional flat foot orthoses were randomly delivered across ten healthy older participants. Postural balance and control were assessed using standardized tests, including CoP trajectory, computerized dynamic posturography, and subjective feedback to explore the effects of varying protrusion heights. Site-specific somatosensory foot orthoses with tall protruding knobs reduced CoP displacements during standing while increased maximum velocity during walking on slopes. However, uniform distribution of tall protruding knobs might produce discomfort at certain areas.

Objective 5: Evaluate the effectiveness of novel site-specific somatosensory foot orthoses with adjusted knob heights compared to conventional flat and placebo foot orthoses without stimulating knobs, utilizing static and dynamic balance and stability measures on varied terrains as well as computerized dynamic posturography in response to perturbations. This phase involved two stage investigations. In the first stage, a randomized crossover trial with 23 healthy older participants. Three distinct foot orthoses including novel site-specific somatosensory foot orthoses, placebo foot orthoses without stimulating knobs and conventional flat foot orthoses were randomly delivered to the participants. The postural control and stability were assessed through standardized tests, including CoP trajectory, spatiotemporal gait, plantar forces/pressures, and subjective feedback regarding tactile perception and satisfaction. The results demonstrated that the novel somatosensory foot orthoses significantly reduced anteroposterior CoP displacements during standing, as well as mediolateral stability at heel strike during walking on upward terrain, compared to both placebo and conventional flat foot orthoses. The somatosensory foot orthoses also led to significant plantar pressure redistribution with reductions in maximum plantar forces at key foot regions during walking on varied terrains. The level of tactile subjective perception was higher at higher tactile sensitivity areas, particularly under the foot arches. The subjective ratings regarding effectiveness to balance control were also higher for the somatosensory foot orthoses.

In the second stage, a randomized controlled trial with 46 older adult participants compared both novel site-specific somatosensory foot orthoses and placebo to flat foot orthoses. Site-specific somatosensory foot orthoses and placebo were assigned to experimental group while flat foot orthoses only assigned to control group. The postural control and stability were assessed through computerized dynamic posturography. The postural equilibrium, weight symmetry, and sway energy to maintain balance in postural adjustments were improved with the novel somatosensory foot orthoses, while increasing latency compared to placebo and flat foot orthoses.

This study advances our understanding of somatosensory stimulation by identifying key design features of protruding knobs that enhance postural balance and stability in older adults. The findings underscore the importance of considering height, shape, and positioning of protrusions, foot orthoses structure, as well as variations in tactile sensitivity across foot regions, when designing orthoses. Notably, a positive dose-response effect was observed with taller knobs at areas of greater tactile sensitivity, suggesting improved postural control, though addressing discomfort through design modifications remains essential. Incorporating site-specific, height-adjusted stimulating knobs may optimize mechanoreceptor activation and postural coordination, broadening clinical applications for individuals with balance impairments. Further longitudinal studies are recommended to refine these designs and ensure their efficacy and comfort in real-world settings.

PUBLICATIONS ARISING FROM THE THESIS

Jor A, Winser SJ, Gao F, Zhang M, Kobayashi T. 3D Printed Somatosensory Stimulation Foot Orthoses with Customized Knobs: A Computerized Dynamic Posturography Assessment in Older Adults.

(Under review) [Chapter 7].

Jor A, Winser SJ, Gao F, Zhang M, Kobayashi T. Effects of 3D Printed Somatosensory Stimulation Foot Orthoses with Customized Knob Heights on Postural Balance and Gait in Older Adults. Journal of Biomechanics.

(Under review: 1st Revision) [Chapter 6]

Jor A, Kobayashi T, Lai CH, Khan MJ, Lam W, Gao F, Winser SJ, Zhang M. Effects of protruding knob heights in site-specific somatosensory foot orthoses on postural balance in older adults: A dose-response study. Clinical Biomechanics, Elsevier, 128, 106624, August 2025. http://dx.doi.org/10.1016/j.clinbiomech.2025.106624.

[Chapter 5]

Jor A, Winser SJ, Gao F, Zhang M, Kobayashi T. Foot Tactile Sensitivity Thresholds Across Various Skin Locations in Older Adults. Clinical Biomechanics.

(Under review) [Chapter 4]

Jor A, Kobayashi T, Lai CH, He Y, Opu SH, Lam WK, Winser S, Gao F, and Zhang M. Enhancing Postural Stability and Gait in Older Adults: The Role of Somatosensory Foot Orthoses on Varied Inclined Terrains. Assistive Technology. In press. http://dx.doi.org/10.1080/10400435.2025.2582062.

[Chapter 3]

Jor A, Lai CH, Khan MJ, He Y, Lam WK, Winser SJ, Gao F, Zhang M, and Kobayashi T. Effects of somatosensory-stimulating foot orthoses on postural balance in older adults: A computerized dynamic posturography analysis," Gait & Posture, Elsevier, Volume 119, Pages 189-196, 2025. https://doi.org/10.1016/j.gaitpost.2025.03.016.

[Chapter 3]

Jor, A, Kobayashi, T, Khan, MJ, Opu, SH, Lam, W, Winser, SJ, Gao, F, Zhang, M. Effects of somatosensory stimulation foot orthoses on balance and stability in the older adults: A systematic review and meta-analysis with meta-regression. Gait & Posture, Elsevier, Volume 123, 109974, 2026. http://dx.doi.org/10.1016/j.gaitpost.2025.109974.

[Chapter 2]

Pollen TN, **Jor A,** Yufan H, Daryabor A, Lam WK, Gao F, Kobayashi T. Effects of 3D-printed ankle-foot orthoses on gait: a systematic review. Assistive Technology, Volume 37, Issue 4, 2025. https://doi.org/10.1080/10400435.2024.2411563.

Jor A, Lau WK, He Y, Daryabor A, Lam W, Hobara H, Gao F, Kobayashi T. Effects of foot orthoses on lower extremity joint kinematics and kinetics in runners with asymptomatic flatfeet: a systematic review and meta-analysis, Gait & Posture, Elsevier, Volume 121, Pages 281-294, 2025. http://dx.doi.org/10.1016/j.gaitpost.2025.06.003.

Jor A, Lau WK, Daryabor A, and Kobayashi T. Effects of ankle-foot orthoses on step activities in the community: a systematic review. Disability and Rehabilitation, Volume 46, Issue 2, 2024. https://doi.org/10.1080/09638288.2023.2169774.

Jor A, Lau NWK, Daryabor A, Koh MWP, Lam WK, Hobara H, Kobayashi T. Effects of foot orthoses on running kinetics and kinematics: A systematic review and meta-analysis. Gait & Posture, Volume 109, Pages 240-258, 2024. https://doi.org/10.1016/j.gaitpost.2024.02.003.

[1]Munim F, **[1]Jor A**, 1Munim F, 1Jor A, Pollen TN, Opu SH, Lam W, Gao F, Kobayashi T. Effects of rocker bottom shoes on the gait biomechanics of running and walking: A systematic review, Gait & Posture, Elsevier, Volume 121, Pages 44-63, 2025. https://doi.org/10.1016/j.gaitpost.2025.04.019.

[1]Co-first author

Jor A, Hu M, Koh MWP, Lau NWK, Daryabor A, Lam WK, Kobayashi T. Biomechanical effects of foot orthoses on jump landing performance: A systematic review. Prosthetics and Orthotics International, Volume 49, issue 1, pages 92-104, 2024. https://doi.org/10.1097/PXR.0000000000000335.

CONFERENCE PROCEEDINGS

Jor A, Lai CH, Khan MJ, He Y, Lam W, Winser SJ, Gao F, and Kobayashi T. Dynamic Balance Responses to Somatosensory Foot Orthoses in Older Adults: A Posturographic

Assessment, Proceedings of the 51st Annual Meeting and Scientific Symposium, American Academy of Orthotists and Prosthetists, Atlanta, USA, 2025.

Jor A, Lau, WK, He Y, Daryabor A, Lam W, Hobara H, Gao F, and Kobayashi T. Systematic Review and Meta-Analysis of Foot Orthosis Biomechanics in Runners with Asymptomatic Flatfeet, Proceedings of the 51st Annual Meeting and Scientific Symposium, American Academy of Orthotists and Prosthetists, Atlanta, USA, 2025.

OTHER PUBLICATIONS

Kobayashi T, **Jor A**, He Y, Hu M, Koh MWP, Hisano G, Hobara H. Transfemoral Prosthetic Simulators versus Amputees: Ground Reaction Forces and Spatiotemporal Parameters in Gait. Royal Society Open Science, Volume 11, Issue 3, 2024.
http://dx.doi.org/10.1098/rsos.231854

Yufan H, Hu M, **Jor A**, Hobara H, Gao F, Kobayashi T. Dynamics of Center of Pressure Trajectory in Gait: Unilateral Transfemoral Amputees versus Non-disabled Individuals. IEEE Transactions on Neural Systems & Rehabilitation Engineering, Volume 32, 2024.
http://dx.doi.org/10.1109/TNSRE.2024.3381046

Kobayashi T, Koh MWP, **Jor A**, Hisano G, Murata H, Ichimura D and Hobara H. Ground reaction forces during double limb stances while walking in individuals with unilateral transfemoral amputation. Frontiers in Bioengineering and Biotechnology, Volume 10, January 12, 2023. https://doi.org/10.3389/fbioe.2022.1041060

ACKNOWLEDGEMENTS

First and foremost, I wish to express my deepest gratitude to my Almighty Creator Allah for granting me the strength and perseverance necessary to complete this PhD research thesis.

With great pleasure, I would like to first express my sincere gratitude to my chief supervisor, Professor Ming Zhang, for his all the necessary support, guidance, constructive advice, and encouragement. His readiness to support with both research and administrative matters has been instrumental to my academic progress.

A special mention must be made of Dr. Toshiki Kobayashi, a chief supervisor, who played a pivotal role at the outset of my academic journey. When I was exploring opportunities for higher education at world reputed university, Dr. Toshiki offered invaluable advice and recommended that I apply to PolyU. His ongoing guidance, support, encouragement, and motivation have been crucial in bringing dynamism and qualitative improvements to my research work.

I must extend my gratitude to my co-supervisor, Dr. Duo Wai-chi WONG, whose invaluable suggestions on the methodological aspects as well as his constructive comments and recommendations has been a significant support to my research efforts.

I would like to express my sincere gratitude to the Board of Examination Chair Prof. M. S. WONG, External Examiners Prof. Ho Man CHAN and Prof. Vincent Chi Kwan CHEUNG for their constructive advice, suggestions, and encouragements.

I wish to express my sincere thanks to the collaborative professors and researchers (Dr. Stanley J. Winser, Dr. Fan Gao, Dr. Wing Kai Lam, Dr. Hiroaki Hobara, and Dr. Aliyeh Daryabor). Their collaboration and fellowship have greatly enriched my research experience.

I wish to express my appreciation to my colleagues and research fellows in the Orthotics and Prosthetics Lab (Lai Chun Hei Alpha, Pak Nin Fok, Mark W. P. Koh, Dr Babak Hassan Beygi), Research Institute for Sports Science and Technology (Dr. Jason Cheung), Biomechanics and 3D Printing Lab (Dr. Tommy Hong, Linjuan Wei), U3DP IC (Tab Cheng), Human Locomotion Laboratory (Yufan He, Dr. Mingyu Hu), and Bertec Laboratory (Mohammad Jobair Khan,) at PolyU, as well as to Shakawath Hosen Opu.

I wish to express my heartfelt thanks to my beloved family for their unwavering support, prayers, and love throughout this journey. I am also deeply thankful to all my friends and well-wishers for their encouragement and companionship.

This journey has been enriched by the support and guidance of many individuals to whom I am profoundly grateful. I am truly thankful for the opportunity to work alongside some of the finest educators and researchers in my field at this esteemed institution. The modern, well-equipped laboratory facilities provided here have been instrumental in advancing my research, and I extend my sincere appreciation to all those involved.

Finally, I gratefully acknowledge the research support received from the Hong Kong Polytechnic University Research Postgraduate Scholarship (PRPgS); Hong Kong Research Grants Council and the University Grants Committee (No. PolyU15211322); and the older adult participants for their persistent adherence to the study until completion. My heartfelt thanks go to the Department of Biomedical Engineering, whose people have been unwavering in their support throughout my study and research endeavours. To all those who have contributed to this journey, I offer my sincerest thanks. Your support has been invaluable in the completion of this thesis.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

CNS	Central Nervus System
CoP	Center of Pressure
AP	Anteroposterior
ML	Mediolateral
CoM	Center of Mass
CoG	Center of Gravity
GRF	Ground Reaction Force
BoS	Base of Support
MoS	Margin of Stability
RMS	root mean square
BBS	Berg Balance Scale
TUG	Timed Up and Go
CDP	Computerized Dynamic Posturography
SOT	Sensory Organization Test
MCT	Motor Control Test
ADT	Adaptation Test
SWM	Semmes-Weinstein Monofilament
CAD	Computer-Aided Design
CAM	Computer-Aided Manufacturing
3D	Three-Dimensional
FDM	Fused Deposition Model
TPU	Thermoplastic Polyurethane
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analysis
PROSPERO	International Prospective Register of Systematic Reviews
PICO	Population, Intervention, Comparison and Outcome
MD	Mean Differences
RCT	Randomized Controlled Trial
SPM	Statistical Parametric Mapping
BMI	Body Mass Index
ANOVA	Analysis of Variance
ICC	Intraclass Correlation Coefficient
VAS	Visual Analog Scale

QUEST	Quebec User Evaluation of Satisfaction with Assistive Technology
FFO	Flat Foot Orthoses
PFO	Placebo Foot Orthoses
SSFO	Somatosensory Stimulation Foot Orthoses

CHAPTER 1
GENERAL INTRODUCTION

1.1 Background and Context

The global demographic of older adults is expanding rapidly, with projections indicating that by 2030, approximately one in six individuals will be aged 60 or older. The number is expected to double by 2050 [1, 2]. While life expectancy continues to rise, the burden of disability remains significant, primarily due to functional deterioration and sensory impairments [3]. Aging is one of the most critical risk factors of impaired balance and stability, falls, and associated injuries. Approximately one-third of older adults living in the community experience balance problems and subsequent falls [4, 5]. Impaired balance and related falls seriously affect independence and quality of life and have become a global public health concern [6, 7]. The human balance system involves several key components including sensory systems, motor responses through the musculoskeletal system, and cognitive functions. The brain integrates these components to track the position, posture, and movement of the body and make any necessary adjustments to maintain stability and orientation [8, 9]. The feet play a crucial role in providing proprioception essential for balance and locomotion through somatosensory feedback. Consequently, numerous studies on footwear interventions have sought to investigate how footwear and foot orthoses, including shoe inserts, or insoles affect postural stability via artificially enhancing somatosensory stimulation [10-13]. Existing somatosensory foot orthoses typically uses uniform height protrusions across the entire foot surface. This can elevate frictional forces particularly in areas experiencing higher plantar pressure, which may result in potential skin complications [14-16]. While most research with somatosensory foot orthoses has focused on the efficacy of uniform shape, height, and distribution of protrusions, less attention has been paid to site-specific positioning based on the tactile sensitivity of the foot skin and adjusted heights. This underscores the need for more tailored approaches that consider variations in site- specific tactile sensitivity and pressure distribution across the foot skin locations.

1.2 Balance Impairments in Older Adults

1.2.1 Prevalence and impacts of balance impairments

Impaired balance and stability pose a significant concern for older adults, often stemming from sensory and motor control deficits. Nearly one-third of this population experiences falls each year, primarily due to age related functional declines in neuromuscular and sensory systems [17-19]. These declines impair postural control and coordination, resulting in diminished physical and mental performance and making daily activities increasingly challenging. Older adults with impaired balance often face limitations in daily living activities, leading to fear of falling, social isolation, emotional distress, and depression [20-22]. According to a recent study, balance and stability problems are associated with a more than 60% decrease in quality-adjusted life years [23]. This demonstrated a substantial burden of impaired balance among the older adults. The economic burden associated with injuries related to impaired balance and subsequent falls is also considerably high. The associated costs of medical care are straining healthcare systems and families [24]. Long-term consequences including medical attention, rehabilitation, and potential long-term care, may impose significant financial burden on individuals and service providers [25].

1.2.2 Factors associated with balance impairments

The human balance system involves several key components including sensory responses from the proprioceptive, visual, and vestibular systems, motor responses through the musculoskeletal system, and cognitive functions. Age-related changes in balance system including proprioceptive responses, soft tissue structures, and musculoskeletal systems are heavily responsible for balance deficits and are considered critical risk factors for falling [26-30]. Proprioception represents the ability to perceive the movement and position of the body parts. During standing and walking, the foot's plantar surface is the only interface in direct contact with the supporting surface, providing important proprioceptive information to maintain dynamic balance and stability and prevent falling [31]. The non-hairy, or glabrous foot skin function as a key source of tactile mechanoreceptors and provides proprioceptive feedback [32]. The brain integrates sensory information through the central nervus system (CNS) pathways to track the movement and position of the body. After that it sends commands to the musculoskeletal system through motor neurons to make necessary adjustments. This feedback is essential for coordinating movements and ensuring functional mobility, balance, and stability.

Aging brings about various physiological changes in sensory systems, including declines in vision, proprioception, and vestibular function, which affect the crucial sensory feedback system necessary for maintaining equilibrium [5]. As people age, their proprioceptive sense can decline with the natural degeneration of sensory systems, joint tissues, ligaments, and muscular systems [26-30]. The declined function of sensory receptors may affect the brain's ability to accurately interpret body position and movement. Motor control, which relies on sensory feedback and central nervous system coordination, also deteriorates with age. The reduced joint flexibility and muscle weakness along with altered muscle mass and strength further exacerbate balance issues in older adults [33]. The biomechanical functions of the foot and ankle joint complex, such as dorsiflexion-plantarflexion, inversion-eversion, and abduction-adduction motions, reduce with age [34, 35]. Besides, the loss of strength and physical degeneration of joint tissues, ligaments, and the muscular system have a potential impact on the ability to track changes in body position and movement [36]. This renders postural adjustments less effective, resulting in slower reactions and heightened instability during movement [37]. Thus, age related changes can substantially affect postural control, balance, and functional mobility of the lower limb and is a crucial factor in overall performance decline and falling [38, 39]. Furthermore, deterioration of the fat pad and plantar fascia tissues could disrupt the shock absorption capability of foot arches during standing, walking, and other weight-bearing activities [27]. The change in tissue structures and integrity, including subcutaneous tissues could result in adverse consequences. In some instances, frictional forces or rubbing on the plantar side of the foot, particularly over the higher plantar pressure regions from the supporting surfaces can lead to discomfort, keratotic lesions, or callous and subsequent ulcer formation [14-16, 40, 41].

1.3 Interventions for Enhancing Balance Function in Older Adults

1.3.1 Foot orthoses

Foot orthoses, such as shoe inserts or insoles, are interventions aimed at redistributing plantar pressure and forces, correcting abnormal lower extremity biomechanics, and providing sensory feedback [42-44]. These orthoses are often recommended to enhance postural balance and stability, particularly in older adults [45].Foot orthoses attributed with varying design features, particularly with prefabricated or customized shapes, arch-supports, heel cups, metatarsal pads, and textured or protruding surfaces, were reported their potential in enhancing postural control in older adults [46]. Previous studies reported that the incorporation of an arch-support, heel cup, and/or metatarsal pad into the foot orthoses potentially improved static and dynamic balance in older adults [47-49].Foot orthoses with combined features of medial arch-support with metatarsal pad and heel cup [47], medial arch-support with heel cup [49, 50], and customized medial arch-support with metatarsal pad and heel cup [48], significantly improved postural control in elderly. Among those combinations, arch-support and heel cup could provide a greater contact area and redistribute plantar pressure.

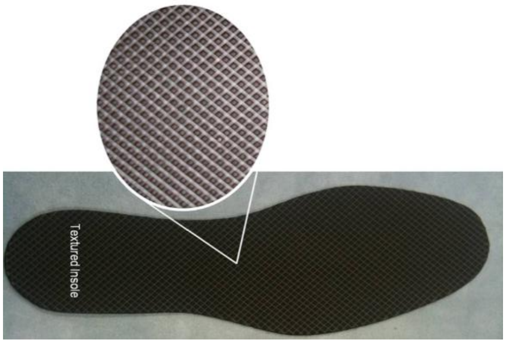
The increased contact surfaces with the contoured bottom and raised heel cup structures may support improving sensory input. Placing a raised edge around the perimeter of the foot orthoses can exert counteracting forces against ankle sprain and would contribute to moving the body's Center of Mass (CoM) to its stable position [51]. In addition to prevent injuries like sprains and strains, the raised surface at the heel cup provides an additional area to enhance somatosensory feedback through tactile mechanoreceptors around the heel and improve static balance in the anteroposterior direction [49]. However, studies investigating single components, such as either arch support or heel cup, reported non-significant changes [52, 53]. A single design component with increased contact areas may not offer enough sensory input to effectively enhance balance outcomes.

1.3.2 Somatosensory feedback and foot orthoses

Somatosensory stimulation through the lower extremity is an emerging therapeutic modality to artificially stimulate tactile receptors in the glabrous foot skin. This can serve as a potential strategy to enhance balance and gait performance, considering the significant biomechanical role of the plantar-ground interface [44]. This aimed at improving balance and posture, and reducing the fall risk, specifically among the older adults. Various forms of artificial stimulation, such as electrical noise, mechanical noise, vibrotactile, and stimulating protrusions, have been explored to enhance sensory feedback and proprioception. Electrical stimulation, often delivered in the form of transcutaneous electrical nerve stimulation, has been shown to improve balance by activating cutaneous receptors and muscle afferents in the lower extremities. This form of stimulation can be particularly beneficial for those with peripheral neuropathy, where the loss of protective sensation is a significant risk factor for falls [54-56].

Mechanical noise or vibrotactile stimulation, a concept derived from the principle of stochastic resonance, involves the application of subthreshold mechanical noise to enhance the detection of weak sensory signals. This form of stimulation can improve balance by increasing the sensitivity of the somatosensory system to proprioceptive inputs. Previous studies showed that low-amplitude tactile vibrations applied to the feet can significantly reduce postural sway in elderly population [57-61]. The vibrations are thought to act on mechanoreceptors in the skin, providing additional sensory cues that the central nervous system can use to maintain equilibrium. However, a continuous supply of suprathreshold vibrations may negatively influence balance by affecting a person's ability to detect mechanical input from stepping on the floor. Additionally, this may cause discomfort and increase cognitive load by disrupting the natural balance control process [62, 63]. Another study on healthy older adults reported non-significant effects and suggested that subthreshold vibrations might be associated with severe balance impairments [64]. The cost-effectiveness and complexity of vibrating foot orthoses made large-scale popularization even more difficult [65].

Somatosensory stimulation foot orthoses featured with protrusions including raised elements, or textures, have been often recommended and employed to enhance tactile stimulation and proprioception in older adults [66, 67]. These strategies aim to improve sensory feedback and balance by stimulating mechanoreceptors through touch, pressure, and skin stretch by altering the mechanical properties of the foot-ground interface. The somatosensory foot orthoses can offer enhanced perception about the foot position and movement through improved afferent firing and sensory feedback from the sole of the foot [68-72]. Previous studies used medium-hard to rigid surface texture and on-surface protrusions in the somatosensory foot orthoses and reported reduction in postural sway and improvement of balance in older adults [73-75]. Examples of such somatosensory foot orthoses consisted of surface edge elevations [51], rounded knobs [76], and pyramidal spikes [11] (Figure 1-1). However, these interventions are typically developed and implemented without considering individual variations in tactile sensitivity across different locations on the foot's plantar surface.

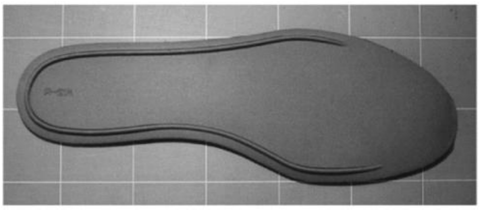


- ✓ Distribution: uniform, entire bottom surface
- ✓ Shape: pyramidal spikes
- ✓ Protrusion height/size: small
- ✓ FO structure: flat

(Hatton et al. 2012)

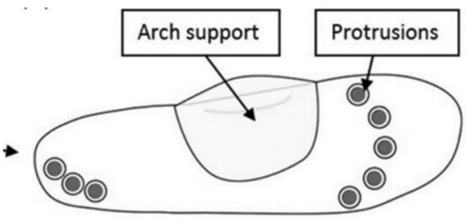
- ✓ Distribution: uniform, entire bottom surface
- ✓ Shape: rounded knob
- ✓ Protrusion height/size: medium
- ✓ FO structure: flat

(Qiu et al. 2013)



- ✓ Distribution: around the perimeter
- ✓ Shape: rib or raised edge
- ✓ Protrusion height/size: large
- ✓ FO structure: flat

(Perry et al. 2008)

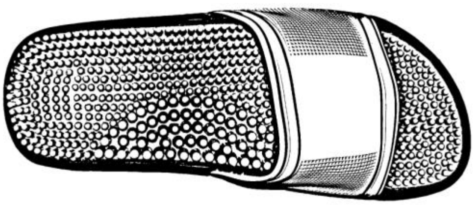


- ✓ Distribution: at the metatarsal heads and heel
- ✓ Shape: rounded knob
- ✓ Protrusion height: medium
- ✓ FO structure: arch-support

(Li et al. 2019)

- ✓ Distribution: at the toes, metatarsal heads and heel
- ✓ Shape: rounded knob
- ✓ Protrusion height/size: medium
- ✓ FO structure: flat

(Lirani-Silva et al. 2017)



- ✓ Distribution: non-uniform, entire bottom surface
- ✓ Shape: pyramidal spikes
- ✓ Protrusion height/size: medium to large
- ✓ FO structure: flat

(Palluel et al. 2008)

Figure 1-1. Somatosensory foot orthoses (FO) featuring stimulating protrusions.

For instance, most studies with somatosensory foot orthoses employed evenly distributed protrusions across the entire upper surface and did not consider site-specific variations of plantar tactile sensitivity [12, 71, 73, 75, 77]. This may limit the potential of tactile mechanoreceptor stimulation for improved sensory feedback, particularly in older people with reduced mechanoreceptor activity. Tactile sensitivity mapping offers a promising solution, which gives an in-depth understanding of the distribution of sensitivity perception across the foot. By considering variable tactile sensitivity level as well as plantar pressure distribution, orthotic interventions can be personalized with the protrusions of variable shapes, heights, hardness, and site-specific positioning, to have better sensory inputs and balance outcomes.

1.3.3 Mechanoreceptor stimulation and feedback mechanism

Sensory input relies on somatosensory (proprioception and cutaneous sensitivity), vestibular, and visual cues, and weighted to task nature. Although proprioceptive and vestibular inputs have traditionally been emphasized as primary contributors to postural balance, reflected in clinical assessments such as the Romberg test [78], recent emerging research has emphasized the critical role of cutaneous sensation from the foot mechanoreceptors in maintaining stability, particularly among older adults. Under static posture in an optimal condition, healthy individuals rely predominantly on somatosensory input (approximately 70%), with vestibular (20%) and visual (10%) cues, play supporting roles in postural orientation [79]. Within the somatosensory domain, mechanoreceptors in the plantar surface of the foot provide essential tactile feedback regarding pressure distribution, stretching, and contact with the support surface, enabling the CNS to finely tune motor activity and adapt to changing environments [80]. This tactile information is especially important for detecting subtle changes in surface texture/characteristics and for setting appropriate motor activity, which is crucial for maintaining upright stance.

Previous studies have demonstrated that reduced plantar tactile sensitivity, whether due to aging, neuropathy, or anaesthesia, leads to increased postural sway and impaired static balance, particularly under challenging conditions such as eyes-closed stance or single-leg support [81-83]. In older adults, the decline in proprioceptive senses often leads to a compensatory shift in sensory weighting, with an increased reliance on tactile input from the feet to maintain stability [84, 85]. Moreover, the significant correlation between plantar cutaneous sensitivity and ankle proprioceptive performance suggests that tactile sensation may be an integral component of overall somatosensory function [84, 86].

Interventions that enhance cutaneous feedback, such as textured/somatosensory insoles, stochastic resonance stimulation, or orthotic designs targeting mechanoreceptor stimulation, have demonstrated moderate to high efficacy in improving postural control in older populations [87, 88]. These approaches directly augment the tactile input available to the central nervous system, facilitating better balance control and potentially reducing the risk of falls. These suggest that optimizing tactile/cutaneous sensation should be considered as a vital component in the multifactorial approach to postural stability in aging populations, complementing the traditional focus on proprioceptive and vestibular systems and offering a promising avenue for targeted intervention through orthotic design.

Mechanoreceptor stimulation and somatosensory feedback is a complex network system essential for human sensory interaction and motor control. It encompasses a network of receptors, neural pathways, and cortical regions that work together to process and respond to tactile information from the body, including the plantar surface of the foot. Tactile sensitivity in humans is mediated by a sophisticated network of mechanoreceptors that relay information about various forms of touch, pressure, skin stretch, or vibration to CNS. There are four major types of mechanoreceptors in the glabrous foot skin, each specialized to provide different aspects of tactile sensitivity [89, 90]. Meissner's corpuscles and Pacinian corpuscles, predominantly located in the glabrous (non-hairy) skin. Meissner's corpuscles are responsible for detecting light touch and surface texture, while Pacinian corpuscles can detect deep pressure and/or vibrations. These receptors are characterized by their fast adaptation and higher threshold values, enable it to respond quickly to changes in stimulus, but require a greater force to be activated. Furthermore, Merkel's disks and Ruffini's corpuscles are distributed throughout all types of skin, including areas with hair follicles. They provide information regarding the touch, pressure, and the stretching of skin to the CNS. These mechanoreceptors adapt more

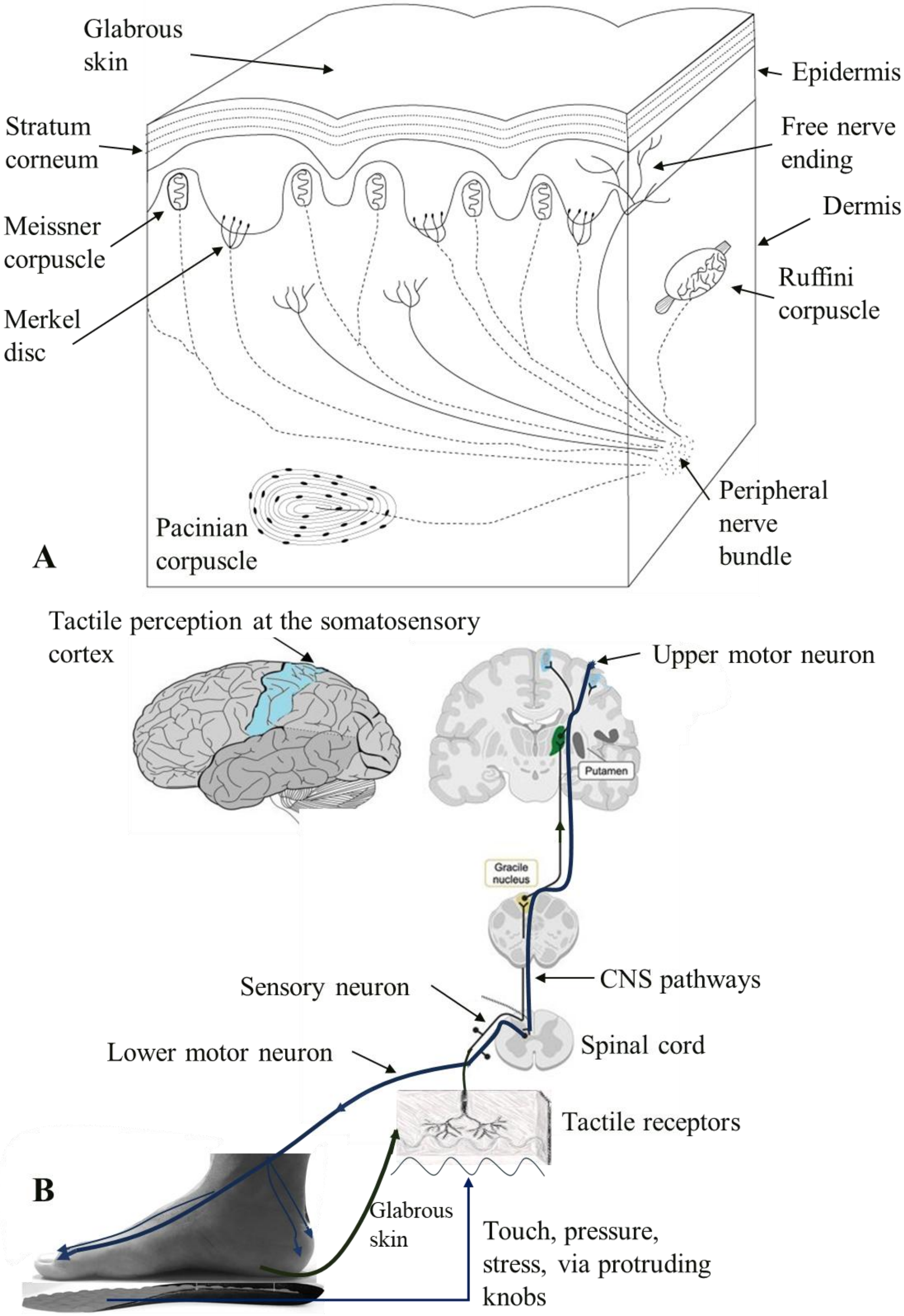


Figure 1-2. Schematic illustration of A. cross section of glabrous foot skin demonstrating different layers, mechanoreceptors, and nerve endings; B. complex sensory network system including tactile receptors, neural pathways, central nervous system, and motor neurons.

slowly to stimuli and have lower threshold values, allowing them to respond to more subtle tactile inputs [89, 90].

Rapidly adapting receptors such as Meissner's corpuscles and Pacinian corpuscles respond intensely but briefly to stimuli, quickly decreasing their firing rate if the stimulus is sustained. These receptors are particularly sensitive to dynamic changes. In contrast, slowly adapting receptors, including Merkel's disks and Ruffini's endings, maintain their response as long as the stimulus persists, providing consistent feedback about sustained pressure and skin stretch. The complementary dynamic and static responses of these mechanoreceptors are crucial for discriminating among various tactile stimuli such as texture, pressure, stretch, and motion. This nuanced sensory input enables CNS to monitor limb position and movement, supporting postural stability and coordinated motor control. By integrating afferent cues from this diverse network of cutaneous mechanoreceptors, the CNS acquires detailed somatosensory information necessary for effective interaction with the environment. Targeted stimulation of these receptors, such as through strategically placed protrusions in foot orthoses, can enhance somatosensory feedback, particularly in older adults, in whom mechanoreceptor function often declines.

The plantar surface, or the sole of the foot, is a crucial interface between the body and the environment, providing sensory inputs to the CNS vital for balance, posture, and gait [91] (Figure 1-2). When the foot contacts a surface, these mechanoreceptors activate and send nerve impulses through the peripheral nerves to the dorsal root ganglia, where these impulses enter the spinal cord. Some of these impulses in the spinal cord cause immediate reflex responses, such as the withdrawal reflex, to protect the body from potential injury [92]. The reflex arc involves sensory neurons, interneurons in the spinal cord, and motor neurons that activate the muscles that help the foot to be withdrawn. There are also impulses that ascend through the dorsal columns to the brainstem and to the thalamus, which acts as a relay station, sending the information to the somatosensory cortex in the parietal lobe of the brain [93]. The somatosensory cortex is organized in a somatotopic way, indicating that specific regions correspond to specific parts of the body and the medial aspect of the cortex is dedicated to processing sensory information from the foot plantar surface [89]. This precise mapping enables discriminate between different types of stimuli, and integrate this information with input from other sensory systems, such as vision and the vestibular system, to maintain balance and posture [93]. The CNS uses the feedback from the foot to adjust the muscle activation patterns and gait accordingly, optimizing stability and efficiency [89]. The information these impulses convey includes the surface texture of the ground, weight distribution across the foot plantar, changes in terrain (level, up or down), and any potential risk to balance and stability, such as slipping or stepping on uneven surfaces.

1.3.4 Mechanoreceptors stimulation potential

The neurons of the non-hairy glabrous foot skin mainly consist of elongated axons and large populations of mechanoreceptors, which can detect a range of stimuli, including site, velocity, vibration, acceleration, pressure, and temperature [94, 95]. The quantity and size, along with the myelin sheath that encases the axons, undergoes serious deterioration [96]. Furthermore, a study indicated that up to 90% of the activity of tactile receptors on the plantar foot surface lost with age [26, 97]. This leads to a decrease in the velocity of nerve conduction, resulting in significant reductions in spatial acuity, touch and pressure sensitivity, as well as vibration perception [98-100]. The selection of the glabrous region of the foot for stimuli could be the key for a successful balance-improving foot orthoses design. The plantar heel, metatarsal heads, and lateral midfoot areas feature thicker and harder skin due to their role as higher plantar pressure or weight-bearing regions. In contrast, the medial midfoot, medial arch cavity, and perimeter areas, starts from the outer line of the flat weight-bearing part, are covered by thinner and softer skin, characteristic of non-hairy with lower plantar pressure regions [101-103]. The lower plantar pressure regions including the thinner and softer glabrous foot skin were reported to have higher tactile sensitivity than the higher plantar pressure region [104-106]. Strategically placing stimulation protrusions over higher tactile sensitivity regions could maximize somatosensory input, while minimizing frictional forces or abnormal rubbing at the higher plantar pressure regions.

1.3.5 Tactile sensitivity threshold

The assessment of tactile sensitivity is important particularly for the older adults, as age-related changes in skin and nerve function can lead to decreased protective sensation, increasing the risk of foot complications. Early detection and management of sensory deficits can aid in preventing foot-related complications, maintaining balance, stability, and life quality among the older people. This is important to explore individuals with loss of protective tactile sensitivity as well as plantar tactile sensitivity across foot skin locations. Thus, tactile sensitivity mapping can support healthcare providers and orthotists to apply preventative strategies, such as foot care education, training, use of protective footwear, and foot orthoses for somatosensory stimulation. The Semmes-Weinstein monofilament (SWM) test is a widely recognized non-invasive technique for assessing plantar tactile sensitivity. The SWM test lies in its ability to detect sensory nerve dysfunction against a calibrated amount of pressure applied to the skin until the monofilament bends, providing a quantitative measure of pressure perception [107]. The SWM test kit includes a set of 20-piece monofilaments, each with a different thickness that corresponds to a specific force ranging from 0.008g to 300g when applied to the skin [104, 106, 108]. The inability to perceive the monofilament at a certain force of 10g threshold indicates reduced tactile sensitivity, which is a sign of protective sensory loss.

1.4 Design and Fabrication of Foot Orthoses

The design and fabrication of foot orthoses are critical components of advanced orthotic care. The foot orthoses are used as conservative treatment options aimed at addressing various issues, related to foot, ankle, and lower extremities [109]. The design and fabrication process of these foot orthoses devices involves a series of steps, including assessment of the patient's foot structure, gait pattern, and specific needs through clinical examination, foot imaging, material selection, design modification, fabrication, and fitting and adjustment [110-112]. There are variety of fabrication technologies including labor intensive manual plaster casting, foam impressions, to advanced three-dimensional (3D) printing technologies [112, 113]. Each fabrication process has its advantages and disadvantages, and the selection of which to use depends on the specific needs of the user.

In traditional approach, fabrication of foot orthoses involves capturing its exact negative impression covering shape and contours, by pressing the foot plantar surface into a foam box or forming a plaster mold from the participant's foot. The mold with the negative foot impression is then used to fabricate a custom foot orthosis. This process typically used thermoplastic materials that can be molded to provide the necessary support [113]. However, this method is labour-intensive, can be time-consuming, requiring multiple visits to the clinic, and uncomfortable for patients, particularly during the casting phase [114].

Advancements in technology have led to the adoption of computer-aided design (CAD) and computer-aided manufacturing (CAM) including milling or laser cutting in the fabrication of foot orthoses. CAD allows to create precise 3D computer models of the foot and the foot orthoses [112]. Additive manufacturing or 3D printing technology has emerged as a revolutionary fabrication method for foot orthoses, offering a wide array of benefits over traditional techniques [115-119]. The theoretical basis for custom 3D printed foot orthoses lies in their ability to provide targeted support, redistribute plantar pressures, and correct abnormal foot alignments and biomechanics. The 3D printing process begins with creating a 3D model of the foot orthoses using CAD software. This model is then sent to a 3D printer, which constructs the physical object layer by layer using compatible materials, such as thermoplastics and flexible polymers. This rapid prototyping technique allows quicker iteration of foot orthoses with custom designs based on user feedback. The 3D-printing technology enables the creation of complex geometries including intricate shapes and design elements, lattice structures, modification of densities and stiffness that would be challenging or impossible to achieve with conventional fabrication methods [120-122]. Hence, 3D printing by fused deposition model (FDM) can be suitable for the fabrication of the novel somatosensory foot orthoses with protruding knobs of rounded shapes, varying heights, and positioning. Compatible materials with adjustable flexibility and rigidity, such as thermoplastic polyurethane (TPU, shore 70A) or LuxCreo 3Li+ (thermoplastic polyurethane) [123] reported suitable for using in the fabrication process.

1.5 Methodologies in Evaluating Balance and Stability

A variety of methodologies have been developed to assess varying aspects of balance and stability. The center of pressure (CoP) trajectory and computerized dynamic posturography (CDP) assessments are particularly crucial for analyzing balance and stability in older adults [124-128] (Table 1.3.1). The CoP trajectory indicates body's CoP movement during both static and dynamic conditions. Another sophisticated system for assessing balance and stability is CDP, which is particularly effective in analyzing balance responses to different perturbations and visual and/or platform conditions.

1.5.1 Center of pressure trajectory

The analysis of CoP trajectory provides critical insights into postural control and stability.

Tracking CoP sway variability helps identify patterns that indicate whether balance is deteriorating or improving over time or different intervention conditions. This assessment typically involves the measurement of CoP displacements at the anteroposterior and mediolateral directions, CoP gait line velocity, lateral symmetry, and anterior/posterior positions. The displacements of CoP at anteroposterior and mediolateral directions are the movements of CoP along the sagittal and frontal planes, respectively, and they provide valuable information about the directional control of balance [129, 130]. The CoP path length refers to the overall distance covered by the CoP, while the CoP velocities reflect the rates at which the CoP moves. These quantitatively describe the extent and speed of postural sway. Higher CoP velocity and displacements, particularly during static stance, may indicate a less stable system that demands more corrective actions to maintain balance. Conversely, increased CoP maximum velocity and anteroposterior displacement within certain limits might suggest a more stable system during walking.

1.5.2 Computerized dynamic posturography

Computerized dynamic posturography (CDP), often comprising the sensory organization test (SOT), motor control test (MCT), and adaptation test (ADT), serves as a valuable tool for identifying specific deficits in the sensory and motor systems [131]. The strength of CDP lies in its ability to systematically manipulate somatosensory, visual, and vestibular inputs. This is achieved by altering the surrounding visual and platform conditions while measuring the body's motor responses. These responses are captured through force platforms that detect shifts in the center of gravity (COG) [132, 133]. CDP assesses how well individuals react to different challenges under different sensory conditions, such as altering visual sway or platform sway reference, and can maintain balance. This system plays a crucial role in rehabilitating impaired balance by enabling targeted rehabilitation strategies. This can be utilized to assess and differentiate between the sensory and motor aspects of balance, particularly when interventions are applied. In a controlled setting, various balance challenges are simulated to provide an objective measure of postural control. A participant's ability to use proprioceptive, visual, and vestibular cues in maintaining postural balance can be assessed through SOT. By altering the availability of these sensory inputs, the SOT identifies which sensory systems the participant relies on more or less. The MCT evaluates automatic motor responses to unexpected external disturbances. This is done by translating the platform backward and forward, offering insights into the reflexive mechanisms of postural balance. Lastly, the ADT assesses the participant's ability to adjust to changes in support surface conditions, such as moving the toes up and down. This demonstrates the plasticity of the motor control system.

1.5.3 Plantar forces and pressure

Assessing plantar forces and pressure is a crucial element in evaluating foot health and stability, particularly among the elderly [134, 135]. This involves measuring how different locations on the foot plantar surface exert forces on the ground when standing, walking, or running. The theoretical basis for measuring plantar forces and pressure lies in understanding how the foot interacts with the ground and how this interaction influences gait, posture, and overall stability. As population ages, changes in the lower extremity structure along with modifications in gait patterns can result in abnormal plantar forces and pressure distribution. These alterations increase the likelihood of experiencing foot pain, developing ulcers, and suffering falls [136, 137]. The assessment of plantar forces and pressures for the older adults is important for several reasons. In the elderly, high plantar pressure can lead to ulceration, and measurement of plantar pressure can help early detection and treatment of peripheral neuropathy, a condition that diminishes tactile sensitivity. Furthermore, this can help design off-loading custom foot orthoses or therapeutic footwear to redistribute peak plantar pressure from the high risk to low-risk areas and prevent foot complications. Research indicates that the general patterns of low-plantar-pressure and high-tactile-sensitivity regions on the foot are relatively consistent across people. Separate studies on tactile sensitivity across foot anatomy and plantar pressure mapping have shown that certain areas, such as the medial arch (inner and medial midfoot), the margins of the medial and lateral midfoot, and the margins of the rearfoot, typically experience lower plantar pressures and higher tactile sensitivity. In contrast, areas such as the toes, forefoot (particularly metatarsal heads 1-4), and the heel are more commonly associated with higher maximum plantar pressure [41, 138-140]. These consistent patterns provide a strong foundation for designing orthoses that target these regions to maximize somatosensory stimulation and enhance postural balance for a broad population. Understanding plantar pressure dynamics can also help balance and fall prevention programs by highlighting the need for orthotic interventions that enhance foot strength, flexibility, and proprioception [141].

1.5.4 Spatiotemporal gait parameters

The investigation of spatiotemporal parameters is a fundamental aspect of evaluating gait function, as it provides critical insights into an individual's mobility, safety, and stability. Spatiotemporal parameters include measures such as stride length, stride time, step width, cadence (steps/min), and stance time. These parameters are indicative of the rhythmic and coordinated movement patterns that are necessary for efficient and stable walking [142, 143]. In the context of dynamic gait control, walking is a critical motor task that require central processing of sensory inputs and motor execution. Alteration of postural control with changes in muscle strength, joint flexibility, and sensory perception, can affect spatiotemporal gait parameters. Shorter stride lengths, longer stance, and slower gait speeds all are associated with higher fall risks [144]. By identifying these alterations, clinicians and orthotists can tailor interventions to address specific gait complications. Advancements in technology, including instrumented walkways, force plate-integrated treadmills, and 3D motion capture systems, enable the precise measurement of spatiotemporal gait parameters.

1.6 Knowledge Gap and Study Rationale

The prevalence of impaired balance and subsequent falls among older adults is a significant public health concern, often leading to severe injuries and a decline in quality of life. Despite advancements in somatosensory orthotic design, there remains a critical knowledge gap in maximizing foot orthoses benefits. Particularly to enhance balance and stability through targeted somatosensory stimulation. Research has demonstrated that somatosensory stimulation via foot orthoses can improve postural stability and gait, highlighting its potential as an effective intervention modality. However, most studies have concentrated on general design elements, such as adding stimulating protrusions to flat foot orthoses, and seldom to arch support foot orthoses, often overlooked the strategic application of somatosensory stimulation across distinct foot regions. The current research aims to address this gap by designing a novel somatosensory foot orthosis that strategically places stimulating protrusions with adjusted heights at higher tactile sensitive and lower plantar pressure areas of the foot. Thus, enhance postural control by maximizing somatosensory stimulation while minimizing unnecessary frictional forces or rubbing.

The rationale for this study stems from the understanding that placing stimulating protrusions at the higher tactile sensitive and lower plantar pressure regions can maximize tactile stimulation. Previous designs have often placed stimulating protrusions of uniform height at the entire top surface [74]. Except in a few studies where protrusions were sparsely distributed across the foot orthoses surface. However, such application of protrusions including rounded knobs, or pyramidal spikes, especially at the areas of higher plantar pressure, can reduce surface contact with the foot while abnormally increasing frictional forces. Therapeutic foot orthoses studies typically attempted to redistribute plantar pressure away from areas of higher plantar pressure and commonly painful sites, such as the heel and metatarsal heads [145]. However, stimulation protrusions may inadvertently elevate frictional forces in these regions. Thus, somatosensory stimulation via the entire areas of foot sole could be a potential risk factor for discomfort and foot complications [14-16, 40, 41, 146]. This study proposes a shift in design philosophy by focusing on lower plantar pressure and higher tactile sensitive regions, which are more receptive to mechanoreceptor stimulation and less prone to pressure-induced discomfort. Additionally, expanding the contact area between the plantar foot surface and the foot orthoses by extending the outer line of the flat weight-bearing part can enhance the area of somatosensory input. For instance, covering areas of highly tactile-sensitive glabrous skin, such as from the elevated back heel to the medial and lateral heads of the metatarsals, can increase this input. This design allows the somatosensory foot orthoses to provide additional stimulation to mechanoreceptors. Such stimulation might be beneficial, particularly when the CoM approaches the limits of the plantar flat surface [51].

In summary, older adults with impaired balance need a somatosensory foot orthosis that could support maximum stimulation of tactile receptors with minimal peak plantar pressure and frictional forces. Positioning stimulation protrusions in areas of higher tactile sensitivity and lower plantar pressure, along with elevated surface to cover the more sensitive glabrous skin, could offer some benefits. This arrangement can help to redistribute and reduce the peak plantar and forces from the higher plantar pressure regions. The contact surface area may increase when providing somatosensory stimulation. Finally, placing stimulating protrusions at lower plantar pressure and higher tactile sensitive regions could result in two distinct solutions. This might ensure maximum tactile stimulation of mechanoreceptors to enhance somatosensory input and improve balance. The arrangement of protrusions at the lower plantar pressure regions may support minimizing abnormal frictional forces or peak pressure at the higher plantar pressure regions of the foot.

This novel somatosensory foot orthosis can maximally stimulate the mechanoreceptors while minimizing the possibility of inducing foot complications. Furthermore, using 3D scanning and printing technology can confirm maximum contact with the foot orthoses through customization of the contoured surface along with site-specific positioning of stimulation protrusions. This design addresses the limitations of previous studies that applied somatosensory stimulation across the entire top surface or particularly at higher plantar pressure regions, which often led to discomfort and altered gait patterns. Thus, this study aims to address the existing knowledge gap by designing a site-specific somatosensory foot orthosis with adjusted protrusion heights that maximizes tactile stimulation of mechanoreceptors. The innovative design features, including a customized bottom contour, elevated surface, and site-specific stimulation protrusions, have potential to provide a more effective solution for postural balance and stability, addressing the shortcomings of previous orthotic designs.

1.7 Objectives and Hypotheses

1.7.1 Overall objectives

The main objective is to design a novel somatosensory foot orthosis that provides site-specific somatosensory stimulation to enhance balance and stability in older adults. This involves reviewing existing evidence on orthotic design features, assessing the impact of stimulating protrusions on static and dynamic balance control, identifying optimal foot sites for tactile stimulation, and exploring the effects of different protrusion heights across site-specific areas. The study aims to compare the novel somatosensory foot orthoses as well as placebo foot orthoses without stimulating protrusions with conventional flat foot orthoses, hypothesizing significant improvements in both static and dynamic balance and stability. This study outlines five key objectives to achieve this goal and presented as chapters.

1.7.2 Objectives and hypotheses for individual chapters of the thesis.

Objective 1: To review existing evidence on the impact of somatosensory foot orthoses on postural balance and stability in older adults, with a focus on the effects of specific protrusion design features.

This systematic review aims to address the following research questions: 1) How do somatosensory foot orthoses affect static and dynamic balance, as well as stability, in older adults? 2) In what ways do various design features of somatosensory foot orthoses—such as structure, shape, height, hardness, and the arrangement of stimulating protrusions—affect overall efficacy? 3) What mechanisms underlie the enhancement of balance and stability in older adults through mechanoreceptor stimulation? By integrating and analyzing current evidence, this review seeks to elucidate both the benefits and limitations of somatosensory foot orthoses, while also highlighting the design elements that most significantly contribute to their effectiveness. (Chapter 2)

Objective 2: To assess whether prefabricated somatosensory foot orthoses with stimulating knobs across the entire surface and arch-support can enhance postural balance in the elderly. To evaluate the effects of these somatosensory foot orthoses on postural stability and gait across different terrain conditions. Additionally, to evaluate the effects on computerized dynamic posturography scores related to sensory organization, motor control, and adaptation in response to various static and dynamic perturbations.

We hypothesized that somatosensory foot orthoses with entire surface stimulating knobs and arch-support would enhance postural balance and stability in the elderly under varying static as well as dynamic movement conditions. (Chapter 3)

Objective 3: To identify specific foot sites for tactile stimulation by exploring the tactile sensitivity over the glabrous areas of the foot. This involves mapping tactile sensitivity thresholds at 30 distinct skin locations on the foot of older adults.

We hypothesized that foot skin areas experienced lower plantar pressure may exhibit different tactile sensitivity thresholds than areas experienced higher plantar pressure. Additionally, older adults exhibit declined overall tactile sensitivity level than younger adults. (Chapter 4)

Objective 4: To explore the dose-response effects of site-specific somatosensory foot orthoses with varying protruding knob heights on postural balance and stability in older adults. This study will specifically investigate the dose-response effects of different knob heights placed in areas of higher tactile sensitivity.

We hypothesized that site-specific positioning of protruding knobs would provide more effective somatosensory stimulation of mechanoreceptors, leading to improved postural balance and stability compared to flat foot orthoses. Furthermore, it was hypothesized that an optimal knob height at specific regions would maximize sensory feedback while minimizing discomfort or adverse effects. (Chapter 5)

Objective 5: To evaluate the effectiveness of a novel site-specific somatosensory foot orthoses with adjusted knob heights in improving postural balance and stability in older adults. This evaluation was conducted through a two-stage investigation. In the first stage, we compared the effects of the novel somatosensory foot orthoses and placebo without stimulating knobs to conventional flat foot orthoses using a randomized crossover study design. We assessed the effects on postural balance, stability, and gait on varied terrains by analyzing CoP trajectory, maximum plantar forces and pressures, and spatiotemporal parameters. Additionally, we gathered subjective feedback on the perception of tactile stimulation and user satisfaction after approximately 20 minutes of walking with each type of foot orthosis. (Chapter 6)

In the second stage, we compared the effects of the novel somatosensory foot orthoses as well as placebo in target group of participants with the conventional flat foot orthoses in the control group using a randomized controlled trial approach. We assessed the impacts on postural control using computerized dynamic posturography analysis. The postural control was measured through the outcomes related to sensory organization, motor control, and adaptation in response to varying perturbations.

We hypothesized that the novel somatosensory foot orthoses, with strategically placed protrusions and adjusted heights based on tactile sensitivity, would significantly improve balance and stability while minimizing discomfort in older adults. (Chapter 7)

1.8 Outline of the Thesis

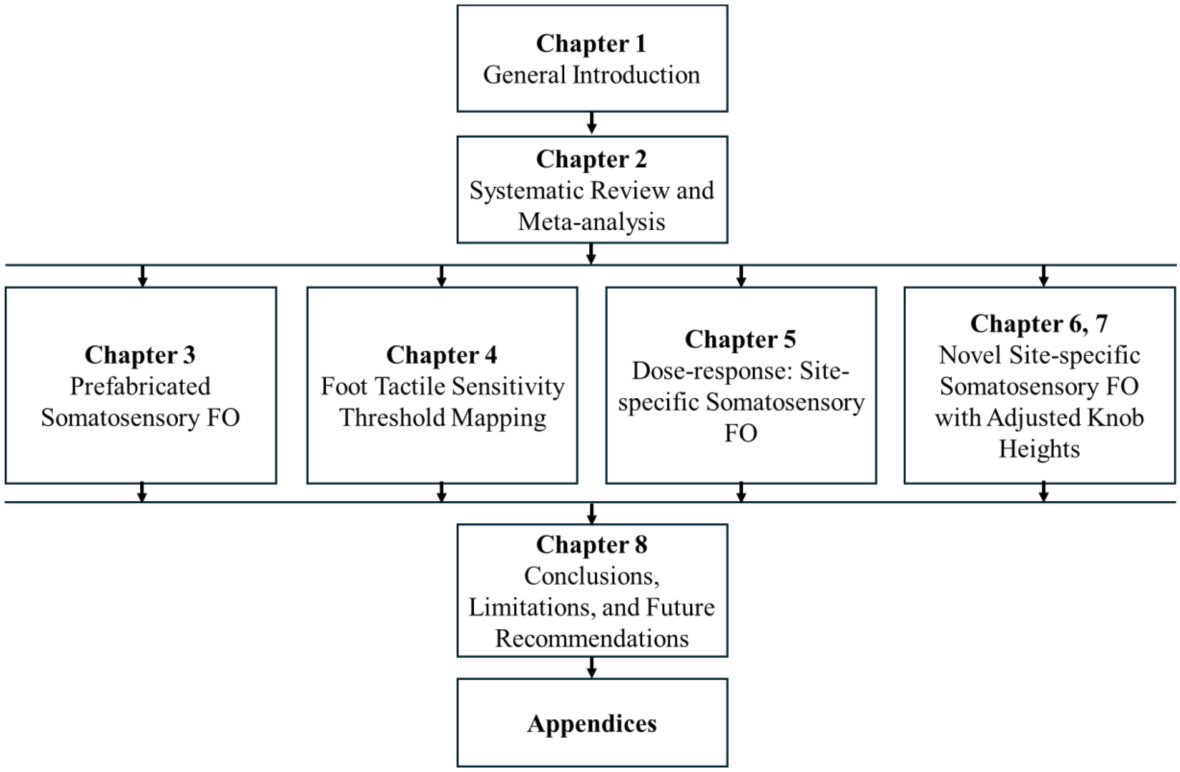


Figure 1-3. The schematic representation of the thesis structure. FO stands for foot orthoses.

1.9 Ethical Considerations

This study protocol has been registered and approved by the Human Subjects Ethics sub-committee at the Hong Kong Polytechnic University (or its Delegate) (Reference Number: HSEARS20231115003). All procedures have been conducted following the guidelines outlined by the Declaration of Helsinki (1983). The content of the study has been made clear to the participants and asked to sign an informed consent form. (APPENDIX A-C)

References

[1] G. Collaborators, Global, regional, and national burden of diseases and injuries for adults 70 years and older: systematic analysis for the Global Burden of Disease 2019 Study, BMJ 376 (2022) e068208. https://doi.org/10.1136/bmj-2021-068208

[2] S. Naja, M.M.E. Din Makhlouf, M.A.H. Chehab, An ageing world of the 21st century: a literature review, International Journal Of Community Medicine And Public Health 4(12) (2017) 4363-4369. https://doi.org/10.18203/2394-6040.ijcmph20175306

[3] A.Y. Chang, V.F. Skirbekk, S. Tyrovolas, N.J. Kassebaum, J.L. Dieleman, Measuring population ageing: an analysis of the Global Burden of Disease Study 2017, Lancet Public Health 4(3) (2019) e159-e167. https://doi.org/10.1016/s2468-2667(19)30019-2

[4] M.M. Kwan, J.C. Close, A.K. Wong, S.R. Lord, Falls incidence, risk factors, and consequences in Chinese older people: a systematic review, J Am Geriatr Soc 59(3) (2011) 536-43. https://doi.org/10.1111/j.1532-5415.2010.03286.x

[5] J. Wang, Y. Li, G.Y. Yang, K. Jin, Age-Related Dysfunction in Balance: A Comprehensive Review of Causes, Consequences, and Interventions, Aging Dis 16(2) (2024) 714-737. https://doi.org/10.14336/ad.2024.0124-1

[6] J.A. Haagsma, N. Graetz, I. Bolliger, M. Naghavi, H. Higashi, E.C. Mullany, et al., The global burden of injury: incidence, mortality, disability-adjusted life years and time trends from the Global Burden of Disease study 2013, Inj Prev 22(1) (2016) 3-18. https://doi.org/10.1136/injuryprev-2015-041616

[7] H.B. Menz, S.R. Lord, The contribution of foot problems to mobility impairment and falls in community-dwelling older people, J Am Geriatr Soc 49(12) (2001) 1651-6.

[8] B.L. Riemann, S.M. Lephart, The sensorimotor system, part I: the physiologic basis of functional joint stability, J Athl Train 37(1) (2002) 71-9.

[9] R.J. Peterka, Sensory integration for human balance control, Handb Clin Neurol 159 (2018) 27-42. https://doi.org/10.1016/b978-0-444-63916-5.00002-1

[10] E. Palluel, V. Nougier, I. Olivier, Do spike insoles enhance postural stability and plantar-surface cutaneous sensitivity in the elderly?, Age (Dordr) 30(1) (2008) 53-61. https://doi.org/10.1007/s11357-008-9047-2

[11] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[12] F. Palazzo, A. Nardi, N. Lamouchideli, A. Caronti, A. Alashram, E. Padua, et al., The effect of age, sex and a firm-textured surface on postural control, Exp Brain Res 239(7) (2021) 2181-2191. https://doi.org/10.1007/s00221-021-06063-2

[13] G. Annino, F. Palazzo, M.S. Alwardat, V. Manzi, P. Lebone, V. Tancredi, et al., Effects of long-term stimulation of textured insoles on postural control in health elderly, J Sports Med Phys Fitness 58(4) (2018) 377-384. https://doi.org/10.23736/s0022-4707.16.06705-0

[14] A. Gefen, Why is the heel particularly vulnerable to pressure ulcers?, Br J Nurs 26(Sup20) (2017) S62-s74. https://doi.org/10.12968/bjon.2017.26.Sup20.S62

[15] H.B. Menz, G.V. Zammit, S.E. Munteanu, Plantar pressures are higher under callused regions of the foot in older people, Clin Exp Dermatol 32(4) (2007) 375-80. https://doi.org/10.1111/j.1365-2230.2007.02421.x

[16] V.V. Broderick, L.J. Cowan, Pressure injury related to friction and shearing forces in older adults, Journal of Dermatology and Skin Science 3(2) (2021). https://doi.org/10.29245/2767-5092/2021/2.1136.

[17] N.I.o. Aging, Falls and fractures in older adults: Causes and prevention, National Institute on Aging, 2022.

[18] K.N.K. Fong, A.M.H. Siu, K.A. Yeung, S.W.S. Cheung, C.C.H. Chan, Falls Among the Community-living Elderly People in Hong Kong: A Retrospective Study, Hong Kong Journal of Occupational Therapy 21(1) (2011) 33-40. https://doi.org/10.1016/j.hkjot.2011.05.005

[19] Q. Su, M. Song, Y. Mao, H. Ku, Y. Gao, H. Pi, An analysis of the associated factors for falls, recurrent falls, and fall-related injuries among the older adults in senior Chinese apartments: A cross-sectional study, Geriatr Nurs 52 (2023) 127-132. https://doi.org/10.1016/j.gerinurse.2023.05.016

[20] E. Angın, F. Can, G. İyigün, B. Kırmızıgil, M. Malkoç, Ü. Değer, Does balance influence daily living activities and quality of life in community-dwelling older people?, Physiotherapy 102 (2016) e227-e228. https://doi.org/10.1016/j.physio.2016.10.281.

[21] A. Iaboni, A.J. Flint, The complex interplay of depression and falls in older adults: a clinical review, Am J Geriatr Psychiatry 21(5) (2013) 484-92. https://doi.org/10.1016/j.jagp.2013.01.008

[22] A.C. Scheffer, M.J. Schuurmans, N. van Dijk, T. van der Hooft, S.E. de Rooij, Fear of falling: measurement strategy, prevalence, risk factors and consequences among older persons, Age Ageing 37(1) (2008) 19-24. https://doi.org/10.1093/ageing/afm169

[23] H. Jia, E.I. Lubetkin, K. DeMichele, D.S. Stark, M.M. Zack, W.W. Thompson, Prevalence, risk factors, and burden of disease for falls and balance or walking problems among older adults in the U.S, Prev Med 126 (2019) 105737. https://doi.org/10.1016/j.ypmed.2019.05.025

[24] G.J. Hoffman, R.D. Hays, M.F. Shapiro, S.P. Wallace, S.L. Ettner, The Costs of Fall-Related Injuries among Older Adults: Annual Per-Faller, Service Component, and Patient Out-of-Pocket Costs, Health Serv Res 52(5) (2017) 1794-1816. https://doi.org/10.1111/1475-6773.12554

[25] N.V. Carroll, J.C. Delafuente, F.M. Cox, S. Narayanan, Fall-related hospitalization and facility costs among residents of institutions providing long-term care, Gerontologist 48(2) (2008) 213-22. https://doi.org/10.1093/geront/48.2.213

[26] S. McIntyre, S.S. Nagi, F. McGlone, H. Olausson, The Effects of Ageing on Tactile Function in Humans, Neuroscience 464 (2021) 53-58. https://doi.org/10.1016/j.neuroscience.2021.02.015

[27] G.S. Sorock, D.M. Labiner, Peripheral neuromuscular dysfunction and falls in an elderly cohort, Am J Epidemiol 136(5) (1992) 584-91. https://doi.org/10.1093/oxfordjournals.aje.a116536

[28] J.R. Wingert, C. Welder, P. Foo, Age-related hip proprioception declines: effects on postural sway and dynamic balance, Arch Phys Med Rehabil 95(2) (2014) 253-61. https://doi.org/10.1016/j.apmr.2013.08.012

[29] A. Dhital, T. Pey, M.R. Stanford, Visual loss and falls: a review, Eye (Lond) 24(9) (2010) 1437-46. https://doi.org/10.1038/eye.2010.60

[30] G.F. Marchetti, S.L. Whitney, M.S. Redfern, J.M. Furman, Factors associated with balance confidence in older adults with health conditions affecting the balance and vestibular system, Arch Phys Med Rehabil 92(11) (2011) 1884-91. https://doi.org/10.1016/j.apmr.2011.06.015

[31] A. Kavounoudias, R. Roll, J.P. Roll, The plantar sole is a 'dynamometric map' for human balance control, Neuroreport 9(14) (1998) 3247-52. https://doi.org/10.1097/00001756-199810050-00021

[32] D. Purves, G.J. AUGUSTINE, D. FITZPATRICK, W.C. HALL, A. LAMANTIA, J.O. MCNAMARA, et al., Neuroscience, Sinauer Associates, Inc., Sunderland, MA 01375 U.S.A., 2004.

[33] R. Gouveia É, A. Ihle, B.R. Gouveia, M. Kliegel, A. Marques, D.L. Freitas, Muscle Mass and Muscle Strength Relationships to Balance: The Role of Age and Physical Activity, J Aging Phys Act 28(2) (2020) 262-268. https://doi.org/10.1123/japa.2018-0113

[34] B.M. Nigg, V. Fisher, T.L. Allinger, J.R. Ronsky, J.R. Engsberg, Range of motion of the foot as a function of age, Foot Ankle 13(6) (1992) 336-43. https://doi.org/10.1177/107110079201300608

[35] J.C. Nitz, N.L. Choy, The relationship between ankle dorsiflexion range, falls and activity level in women aged 40 to 80 years, N Z J Physiother 32 (2004) 121+.

[36] H.B. Menz, M.E. Morris, S.R. Lord, Foot and ankle risk factors for falls in older people: a prospective study, J Gerontol A Biol Sci Med Sci 61(8) (2006) 866-70. https://doi.org/10.1093/gerona/61.8.866

[37] B.E. Maki, W.E. McIlroy, Control of rapid limb movements for balance recovery: age-related changes and implications for fall prevention, Age Ageing 35 Suppl 2 (2006) ii12-ii18. https://doi.org/10.1093/ageing/afl078

[38] A. Tiedemann, C. Sherrington, S.R. Lord, Physiological and psychological predictors of walking speed in older community-dwelling people, Gerontology 51(6) (2005) 390-5. https://doi.org/10.1159/000088703

[39] J.M. Guralnik, L. Ferrucci, E.M. Simonsick, M.E. Salive, R.B. Wallace, Lower-extremity function in persons over the age of 70 years as a predictor of subsequent disability, N Engl J Med 332(9) (1995) 556-61. https://doi.org/10.1056/nejm199503023320902

[40] J.W. Albright, J.F. Albright, Ageing alters the competence of the immune system to control parasitic infection, Immunol Lett 40(3) (1994) 279-85. https://doi.org/10.1016/0165-2478(94)00066-2

[41] H. Che, B.M. Nigg, J. de Koning, Relationship between plantar pressure distribution under the foot and insole comfort, Clin Biomech (Bristol) 9(6) (1994) 335-41. https://doi.org/10.1016/0268-0033(94)90062-0

[42] A. Jor, M. Hu, M.W.P. Koh, N.W.K. Lau, A. Daryabor, W.K. Lam, et al., Biomechanical effects of foot orthoses on jump landing performance: A systematic review, Prosthet Orthot Int (2024). https://doi.org/10.1097/pxr.0000000000000335

[43] A. Jor, N.W.K. Lau, A. Daryabor, M.W.P. Koh, W.K. Lam, H. Hobara, et al., Effects of foot orthoses on running kinetics and kinematics: A systematic review and meta-analysis, Gait Posture 109 (2024) 240-258. https://doi.org/10.1016/j.gaitpost.2024.02.003

[44] H. Nagano, R.K. Begg, Shoe-Insole Technology for Injury Prevention in Walking, Sensors (Basel) 18(5) (2018). https://doi.org/10.3390/s18051468

[45] A. Aboutorabi, M. Bahramizadeh, M. Arazpour, R. Fadayevatan, F. Farahmand, S. Curran, et al., A systematic review of the effect of foot orthoses and shoe characteristics on balance in healthy older subjects, Prosthet Orthot Int 40(2) (2016) 170-81. https://doi.org/10.1177/0309364615588342

[46] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act (2020) 1-16. https://doi.org/10.1123/japa.2019-0293

[47] C.Z. Ma, D.W. Wong, A.H. Wan, W.C. Lee, Effects of orthopedic insoles on static balance of older adults wearing thick socks, Prosthet Orthot Int 42(3) (2018) 357-362. https://doi.org/10.1177/0309364617752982

[48] M.T. Gross, V.S. Mercer, F.C. Lin, Effects of foot orthoses on balance in older adults, J Orthop Sports Phys Ther 42(7) (2012) 649-57. https://doi.org/10.2519/jospt.2012.3944

[49] X. Qu, Impacts of different types of insoles on postural stability in older adults, Applied Ergonomics 46 (2015) 38-43. https://doi.org/10.1016/j.apergo.2014.06.005

[50] T.H. Chen, L.W. Chou, M.W. Tsai, M.J. Lo, M.J. Kao, Effectiveness of a heel cup with an arch support insole on the standing balance of the elderly, Clin Interv Aging 9 (2014) 351-6. https://doi.org/10.2147/cia.S56268

[51] S.D. Perry, A. Radtke, W.E. McIlroy, G.R. Fernie, B.E. Maki, Efficacy and effectiveness of a balance-enhancing insole, J Gerontol A Biol Sci Med Sci 63(6) (2008) 595-602. https://doi.org/10.1093/gerona/63.6.595

[52] K.-H. Bae, J.-H. Shin, J.-S. Lee, J.-O. Yang, B.-J. Lee, S. Park, Analyses of Plantar Foot Pressure and Static Balance According to the Type of Insole in the Elderly, Korean Journal of Sport Biomechanics 26 (2016) 115-126. https://doi.org/10.5103/KJSB.2016.26.1.115

[53] H. Samimi, M. Anbarian, U.G. Kersting, A. Sarshin, The effect of an arch supporting insole on postural sway and lower limb muscle activity, 2014.

[54] P.P. Breen, J.M. Serrador, C. O'Tuathail, L.R. Quinlan, C. McIntosh, G. ÓLaighin, Peripheral tactile sensory perception of older adults improved using subsensory electrical noise stimulation, Med Eng Phys 38(8) (2016) 822-5. https://doi.org/10.1016/j.medengphy.2016.05.015

[55] Z. Bassiri, C. Austin, C. Cousin, D. Martelli, Subsensory electrical noise stimulation applied to the lower trunk improves postural control during visual perturbations, Gait Posture 96 (2022) 22-28. https://doi.org/10.1016/j.gaitpost.2022.05.010

[56] M.S. Alenazy, R. Al-Jaafari, S. Daneshgar, A. Folkesson-Dey, R.M. Enoka, Influence of transcutaneous electrical nerve stimulation on the distance walked by older adults during the 6-min test of walking endurance, J Electromyogr Kinesiol 73 (2023) 102827. https://doi.org/10.1016/j.jelekin.2023.102827

[57] G. Ballardini, V. Florio, A. Canessa, G. Carlini, P. Morasso, M. Casadio, Vibrotactile Feedback for Improving Standing Balance, Front Bioeng Biotechnol 8 (2020) 94. https://doi.org/10.3389/fbioe.2020.00094

[58] V.B. Carrasco, J.M. Vidal, C. Caparrós-Manosalva, Vibration motor stimulation device in smart leggings that promotes motor performance in older people, Med Biol Eng Comput 61(3) (2023) 635-649. https://doi.org/10.1007/s11517-022-02733-7

[59] E.D. Gerber, C. Giraldo, B. Whorley, P. Nichols, S. Ring, C.W. Luchies, Subthreshold white noise vibration alters trembling sway in older adults, Hum Mov Sci 90 (2023) 103119. https://doi.org/10.1016/j.humov.2023.103119

[60] T. Ito, Y. Sakai, K. Yamazaki, Y. Ito, K. Kawai, Y. Kato, et al., Postural Sway in Older Patients with Sagittal Imbalance and Young Adults during Local Vibratory Proprioceptive Stimulation, Healthcare (Basel) 9(2) (2021). https://doi.org/10.3390/healthcare9020210

[61] I. Bourdel-Marchasson, S.C. Regueme, M. Kelson, J. Poustis, P. Barralon, O. Laosa, et al., A Therapeutic Vibrating Insole Device for Postural Instability in Older People with Type 2 Diabetes: A Randomized Control Study, Diabetes Ther 13(5) (2022) 995-1006. https://doi.org/10.1007/s13300-022-01246-8

[62] G. Wulf, N. McNevin, C.H. Shea, The automaticity of complex motor skill learning as a function of attentional focus, Q J Exp Psychol A 54(4) (2001) 1143-54. https://doi.org/10.1080/713756012

[63] E.A. Keshner, J.C. Slaboda, L.L. Day, K. Darvish, Visual conflict and cognitive load modify postural responses to vibrotactile noise, J Neuroeng Rehabil 11 (2014) 6. https://doi.org/10.1186/1743-0003-11-6

[64] M. Dettmer, A. Pourmoghaddam, B.C. Lee, C.S. Layne, Associations between Tactile Sensory Threshold and Postural Performance and Effects of Healthy Aging and Subthreshold

Vibrotactile Stimulation on Postural Outcomes in a Simple Dual Task, Curr Gerontol Geriatr Res 2016 (2016) 9797369. https://doi.org/10.1155/2016/9797369
[65] A.L. Hatton, K. Rome, J. Dixon, D.J. Martin, P.O. McKeon, Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults, J Am Podiatr Med Assoc 103(6) (2013) 516-33. https://doi.org/10.7547/1030516
[66] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can insoles be used to improve static and dynamic balance of community-dwelling older adults? a systematic review on recent advances and future perspectives., J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293
[67] F. Cerritelli, M. Chiera, M. Abbro, V. Megale, J. Esteves, A. Gallace, et al., The challenges and perspectives of the integration between virtual and augmented reality and manual therapies, Front Neurol 12 (2021) 700211. https://doi.org/10.3389/fneur.2021.700211
[68] F.S. Alshammari, J.S. Petrofsky, N. Daher, E.S. Alzoghbieh, S.O. Dehom, M.S. Laymon, Tactile intervention as a novel technique in improving body stability in healthy elderly and elderly with diabetes, Diabetes Technol Ther 16(12) (2014) 822-7. https://doi.org/10.1089/dia.2014.0183
[69] L. Bernard-Demanze, N. Vuillerme, M. Ferry, L. Berger, Can tactile plantar stimulation improve postural control of persons with superficial plantar sensory deficit?, Aging Clin Exp Res 21(1) (2009) 62-8. https://doi.org/10.1007/bf03324900
[70] D.J. Goble, J.P. Coxon, A. Van Impe, M. Geurts, M. Doumas, N. Wenderoth, et al., Brain activity during ankle proprioceptive stimulation predicts balance performance in young and older adults, J Neurosci 31(45) (2011) 16344-52. https://doi.org/10.1523/jneurosci.4159-11.2011

[71] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11

[72] D.P. Kiel, M.T. Hannan, B.A. Barton, M.L. Bouxsein, T.F. Lang, K.M. Brown, et al., Insights from the conduct of a device trial in older persons: low magnitude mechanical stimulation for musculoskeletal health, Clin Trials 7(4) (2010) 354-67. https://doi.org/10.1177/1740774510371014

[73] C. de Morais Barbosa, M.B. Bértolo, J.Z. Gaino, M. Davitt, Z. Sachetto, E. de Paiva Magalhães, The effect of flat and textured insoles on the balance of primary care elderly people: a randomized controlled clinical trial, Clin Interv Aging 13 (2018) 277-284. https://doi.org/10.2147/cia.S149038

[74] P.L. Li, K.L. Yick, S.P. Ng, J. Yip, Influence of Textured Indoor Footwear on Posture Stability of Older Women Based on Center-of-Pressure Measurements, Hum Factors 61(8) (2019) 1247-1260. https://doi.org/10.1177/0018720819837414

[75] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Effects of textured insoles on balance in people with Parkinson's disease, PLoS One 8(12) (2013) e83309. https://doi.org/10.1371/journal.pone.0083309

[76] D.M. Corbin, J.M. Hart, P.O. McKeon, C.D. Ingersoll, J. Hertel, The effect of textured insoles on postural control in double and single limb stance, J Sport Rehabil 16(4) (2007) 363-72. https://doi.org/10.1123/jsr.16.4.363

[77] N. Asgari, G. Yeowell, E. Sadeghi-Demneh, A comparison of the efficacy of textured insoles on balance performance in older people with versus without plantar callosities, Gait Posture 94 (2022) 217-221. https://doi.org/10.1016/j.gaitpost.2022.03.022

[78] A. Shumway-Cook, M.H. Woollacott, Motor control : translating research into clinical practice, Fifth edition. ed., Wolters Kluwer, Philadelphia, 2017.

[79] F.B. Horak, Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls?, Age Ageing 35 Suppl 2 (2006) ii7-ii11. https://doi.org/10.1093/ageing/afl077

[80] W.G. Wright, Y.P. Ivanenko, V.S. Gurfinkel, Foot anatomy specialization for postural sensation and control, J Neurophysiol 107(5) (2012) 1513-21. https://doi.org/10.1152/jn.00256.2011

[81] P.F. Meyer, L.I. Oddsson, C.J. De Luca, The role of plantar cutaneous sensation in unperturbed stance, Exp Brain Res 156(4) (2004) 505-12. https://doi.org/10.1007/s00221-003-1804-y

[82] H.J. Kars, J.M. Hijmans, J.H. Geertzen, W. Zijlstra, The effect of reduced somatosensation on standing balance: a systematic review, J Diabetes Sci Technol 3(4) (2009) 931-43. https://doi.org/10.1177/193229680900300441

[83] K. Song, T.K. Kang, E.A. Wikstrom, H.P. Jun, S.Y. Lee, Effects of reduced plantar cutaneous sensation on static postural control in individuals with and without chronic ankle instability, J Sci Med Sport 20(10) (2017) 910-914. https://doi.org/10.1016/j.jsams.2016.04.011

[84] N. Yang, R. Adams, G. Waddington, J. Han, Ankle complex proprioception and plantar cutaneous sensation in older women with different physical activity levels, Exp Brain Res 240(3) (2022) 981-989. https://doi.org/10.1007/s00221-021-06273-8

[85] Z. Liu, Q. Wang, W. Sun, Q. Song, Balancing sensory inputs: somatosensory reweighting from proprioception to tactile sensation in maintaining postural stability among older adults with sensory deficits, Front Public Health 11 (2023) 1165010. https://doi.org/10.3389/fpubh.2023.1165010

[86] Y. Liu, Q. Song, Z. Liu, S. Dong, C. Hiller, D.T.P. Fong, et al., Correlations of Postural Stability to Proprioception, Tactile Sensation, and Strength Among People With Chronic Ankle Instability, Motor Control 28(4) (2024) 464-479. https://doi.org/10.1123/mc.2023-0084

[87] S. Machado Á, C.B. da Silva, E.S. da Rocha, F.P. Carpes, Effects of plantar foot sensitivity manipulation on postural control of young adult and elderly, Rev Bras Reumatol Engl Ed 57(1) (2017) 30-36. https://doi.org/10.1016/j.rbre.2016.03.007

[88] M.T. Woo, K. Davids, J. Liukkonen, D. Orth, J.Y. Chow, T. Jaakkola, Effects of different lower-limb sensory stimulation strategies on postural regulation-A systematic review and meta-analysis, PLoS One 12(3) (2017) e0174522. https://doi.org/10.1371/journal.pone.0174522

[89] D. Purves, G.J. Augustine, D. Fitzpatrick, W.C. Hall, A. LaMantia, R.D. Mooney, et al., Neuroscience, 6th ed., Sinauer Associates Inc2017.

[90] R.S. Johansson, A.B. Vallbo, Tactile sensibility in the human hand: relative and absolute densities of four types of mechanoreceptive units in glabrous skin, J Physiol 286 (1979) 283-300. https://doi.org/10.1113/jphysiol.1979.sp012619

[91] P.M. Kennedy, J.T. Inglis, Distribution and behaviour of glabrous cutaneous receptors in the human foot sole, J Physiol 538(Pt 3) (2002) 995-1002. https://doi.org/10.1113/jphysiol.2001.013087

[92] M.F. Bear, B.W. Connors, M.A. Paradiso, Neuroscience: Exploring the Brain, Wolters Kluwer2016.

[93] E.R. Kandel, S.J. H., J.T. M., S.A. Siegelbaum, A.J. Hudspeth, S. Mack, Principles of Neural Science, Principles of Neural Science, Fifth Edition, McGraw-Hill Education, New York, NY, 2014.

[94] R.S. Johansson, A.B. Vallbo, Spatial properties of the population of mechanoreceptive units in the glabrous skin of the human hand, Brain Res 184(2) (1980) 353-66. https://doi.org/10.1016/0006-8993(80)90804-5

[95] J.P. Vedel, J.P. Roll, Response to pressure and vibration of slowly adapting cutaneous mechanoreceptors in the human foot, Neurosci Lett 34(3) (1982) 289-94. https://doi.org/10.1016/0304-3940(82)90190-2

[96] E. Verdú, D. Ceballos, J.J. Vilches, X. Navarro, Influence of aging on peripheral nerve function and regeneration, J Peripher Nerv Syst 5(4) (2000) 191-208. https://doi.org/10.1046/j.1529-8027.2000.00026.x

[97] D.R. Kenshalo, Sr., Somesthetic sensitivity in young and elderly humans, J Gerontol 41(6) (1986) 732-42. https://doi.org/10.1093/geronj/41.6.732

[98] J.C. Stevens, L.A. Cruz, Spatial acuity of touch: ubiquitous decline with aging revealed by repeated threshold testing, Somatosens Mot Res 13(1) (1996) 1-10. https://doi.org/10.3109/08990229609028907

[99] G. Rosenberg, A. Adams, EFFECT OF AGE ON PERIPHERAL VIBRATORY PERCEPTION, Journal of the American Geriatrics Society 6(6) (1958) 471-481. https://doi.org/10.1111/j.1532-5415.1958.tb00742.x.

[100] S.D. Perry, Evaluation of age-related plantar-surface insensitivity and onset age of advanced insensitivity in older adults using vibratory and touch sensation tests, Neurosci Lett 392(1-2) (2006) 62-7. https://doi.org/10.1016/j.neulet.2005.08.060

[101] M.J. Hessert, M. Vyas, J. Leach, K. Hu, L.A. Lipsitz, V. Novak, Foot pressure distribution during walking in young and old adults, BMC Geriatrics 5(1) (2005) 8. https://doi.org/10.1186/1471-2318-5-8.

[102] P.R. Cavanagh, M. Rodgers, Pressure distribution underneath the human foot, Biomechanics: current interdisciplinary research, Springer1985, pp. 85-95.

[103] C.J. Bennetts, T.M. Owings, A. Erdemir, G. Botek, P.R. Cavanagh, Clustering and classification of regional peak plantar pressures of diabetic feet, J Biomech 46(1) (2013) 19-25. https://doi.org/10.1016/j.jbiomech.2012.09.007

[104] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[105] S. Smith, M.K. Yokich, S.M. Beaudette, S.H.M. Brown, L.R. Bent, Cutaneous Sensitivity Across Regions of the Foot Sole and Dorsum are Influenced by Foot Posture, Front Bioeng Biotechnol 9 (2021) 744307. https://doi.org/10.3389/fbioe.2021.744307

[106] N.D. Strzalkowski, J.J. Triano, C.K. Lam, C.A. Templeton, L.R. Bent, Thresholds of skin sensitivity are partially influenced by mechanical properties of the skin on the foot sole, Physiol Rep 3(6) (2015). https://doi.org/10.14814/phy2.12425

[107] B.A. Perkins, D. Olaleye, B. Zinman, V. Bril, Simple screening tests for peripheral neuropathy in the diabetes clinic, Diabetes Care 24(2) (2001) 250-6. https://doi.org/10.2337/diacare.24.2.250

[108] N.D. Strzalkowski, R.L. Mildren, L.R. Bent, Thresholds of cutaneous afferents related to perceptual threshold across the human foot sole, J Neurophysiol 114(4) (2015) 2144-51. https://doi.org/10.1152/jn.00524.2015

[109] K.A. Kirby, S.K. Spooner, P.R. Scherer, J.M. Schuberth, Foot orthoses, Foot Ankle Spec 5(5) (2012) 334-43. https://doi.org/10.1177/1938640012458900

[110] L. Hale, E. Linley, D.M. Kalaskar, A digital workflow for design and fabrication of bespoke orthoses using 3D scanning and 3D printing, a patient-based case study, Sci Rep 10(1) (2020) 7028. https://doi.org/10.1038/s41598-020-63937-1

[111] M. Fantini, F. De Crescenzio, L. Brognara, N. Baldini, Design and Rapid Manufacturing of a customized foot orthosis: a first methodological study, in: B. Eynard, V. Nigrelli, S.M. Oliveri, G. Peris-Fajarnes, S. Rizzuti (Eds.), Advances on Mechanics, Design

Engineering and Manufacturing : Proceedings of the International Joint Conference on Mechanics, Design Engineering & Advanced Manufacturing (JCM 2016), 14-16 September, 2016, Catania, Italy, Springer International Publishing, Cham, 2017, pp. 457-467.

[112] J. Barrios-Muriel, F. Romero-Sánchez, F.J. Alonso-Sánchez, D. Rodríguez Salgado, Advances in Orthotic and Prosthetic Manufacturing: A Technology Review, Materials (Basel) 13(2) (2020). https://doi.org/10.3390/ma13020295

[113] M. Farhan, J.Z. Wang, P. Bray, J. Burns, T.L. Cheng, Comparison of 3D scanning versus traditional methods of capturing foot and ankle morphology for the fabrication of orthoses: a systematic review, J Foot Ankle Res 14(1) (2021) 2. https://doi.org/10.1186/s13047-020-00442-8

[114] R.K. Chen, Y.-a. Jin, J. Wensman, A. Shih, Additive manufacturing of custom orthoses and prostheses—A review, Additive Manufacturing 12 (2016) 77-89. https://doi.org/10.1016/j.addma.2016.04.002

[115] S. Telfer, K.S. Gibson, K. Hennessy, M.P. Steultjens, J. Woodburn, Computer-aided design of customized foot orthoses: reproducibility and effect of method used to obtain foot shape, Arch Phys Med Rehabil 93(5) (2012) 863-70. https://doi.org/10.1016/j.apmr.2011.12.019

[116] A. Daryabor, T. Kobayashi, H. Saeedi, S.M. Lyons, N. Maeda, S.S. Naimi, Effect of 3D printed insoles for people with flatfeet: A systematic review, Assist Technol 35(2) (2023) 169-179. https://doi.org/10.1080/10400435.2022.2105438

[117] S. Vennam, V. Kn, F. Pati, 3D printed personalized assistive devices: A material, technique, and medical condition perspective, Applied Materials Today 40 (2024) 102403. https://doi.org/10.1016/j.apmt.2024.102403

[118] T.N. Pollen, A. Jor, F. Munim, Y. He, A. Daryabor, F. Gao, et al., Effects of 3D-printed ankle-foot orthoses on gait: a systematic review, Assist Technol (2024) 1-17. https://doi.org/10.1080/10400435.2024.2411563

[119] S. Telfer, J. Woodburn, The use of 3D surface scanning for the measurement and assessment of the human foot, J Foot Ankle Res 3 (2010) 19. https://doi.org/10.1186/1757-1146-3-19

[120] N. Thirunavukkarasu, J. Gao, S. Peng, A. Laroui, L. Wu, Z. Weng, Mechanically robust 3D printed elastomeric lattices inspired by strong and tough hierarchical structures, Additive Manufacturing 66 (2023) 103451. https://doi.org/10.1016/j.addma.2023.103451

[121] E. Wojciechowski, A.Y. Chang, D. Balassone, J. Ford, T.L. Cheng, D. Little, et al., Feasibility of designing, manufacturing and delivering 3D printed ankle-foot orthoses: a systematic review, Journal of Foot and Ankle Research 12(1) (2019) 11. https://doi.org/10.1186/s13047-019-0321-6.

[122] Z. Lu, L. Xin, S. Dong, S. Yang, F. Gusztáv, K. András, et al., Will this be the next step? A systematic review of 3D printing in footwear biomechanics, Footwear Science 1-16. https://doi.org/10.1080/19424280.2025.2472251.

[123] M. Ntagios, R. Dahiya, 3D Printed Soft and Flexible Insole with Intrinsic Pressure Sensing Capability, IEEE Sensors Journal (2022) 1-1. https://doi.org/10.1109/JSEN.2022.3179233

[124] Z. Li, Y.Y. Liang, L. Wang, J. Sheng, S.J. Ma, Reliability and validity of center of pressure measures for balance assessment in older adults, J Phys Ther Sci 28(4) (2016) 1364-7. https://doi.org/10.1589/jpts.28.1364

[125] R. Khanmohammadi, S. Talebian, M.R. Hadian, G. Olyaei, H. Bagheri, The relative and absolute reliability of center of pressure trajectory during gait initiation in older adults, Gait Posture 52 (2017) 194-201. https://doi.org/10.1016/j.gaitpost.2016.11.042

[126] P.Y. Lo, B.L. Su, Y.L. You, C.W. Yen, S.T. Wang, L.Y. Guo, Measuring the Reliability of Postural Sway Measurements for a Static Standing Task: The Effect of Age, Front Physiol 13 (2022) 850707. https://doi.org/10.3389/fphys.2022.850707

[127] C.C. Harro, C. Garascia, Reliability and Validity of Computerized Force Platform Measures of Balance Function in Healthy Older Adults, J Geriatr Phys Ther 42(3) (2019) E57-e66. https://doi.org/10.1519/jpt.0000000000000175

[128] C.D. Ford-Smith, J.F. Wyman, R.K. Elswick, Jr., T. Fernandez, R.A. Newton, Test-retest reliability of the sensory organization test in noninstitutionalized older adults, Arch Phys Med Rehabil 76(1) (1995) 77-81. https://doi.org/10.1016/s0003-9993(95)80047-6

[129] D.A. Winter, Human balance and posture control during standing and walking, Gait & Posture 3(4) (1995) 193-214. https://doi.org/10.1016/0966-6362(96)82849-9

[130] M. Moghadam, H. Ashayeri, M. Salavati, J. Sarafzadeh, K.D. Taghipoor, A. Saeedi, et al., Reliability of center of pressure measures of postural stability in healthy older adults: effects of postural task difficulty and cognitive load, Gait Posture 33(4) (2011) 651-5. https://doi.org/10.1016/j.gaitpost.2011.02.016

[131] N.D. Eriksen, D.D. Hougaard, Age- and gender-specific normative data on computerized dynamic posturography in a cohort of Danish adults, Eur Arch Otorhinolaryngol 280(5) (2023) 2191-2200. https://doi.org/10.1007/s00405-022-07706-y

[132] M. Alfuth, M. Ebert, J. Klemp, A. Knicker, Biomechanical analysis of single-leg stance using a textured balance board compared to a smooth balance board and the floor: A cross-sectional study, Gait Posture 84 (2021) 215-220. https://doi.org/10.1016/j.gaitpost.2020.12.014

[133] S.J. Winser, M.C. Schubert, A.Y.Y. Chan, P. Kannan, S.L. Whitney, Can pre-screening vestibulocerebellar involvement followed by targeted training improve the outcomes of

balance in cerebellar ataxia?, Med Hypotheses 117 (2018) 37-41. https://doi.org/10.1016/j.mehy.2018.06.001

[134] A. Mohd Said, M. Justine, H. Manaf, Plantar Pressure Distribution among Older Persons with Different Types of Foot and Its Correlation with Functional Reach Distance, Scientifica (Cairo) 2016 (2016) 8564020. https://doi.org/10.1155/2016/8564020

[135] B. Zhang, Q. Lu, A Current Review of Foot Disorder and Plantar Pressure Alternation in the Elderly, Physical Activity and Health (2020). https://doi.org/10.5334/paah.57

[136] L. Xu, H. Zeng, J. Zhao, J. Zhao, J. Yin, H. Chen, et al., Index of Plantar Pressure Alters with Prolonged Diabetes Duration, Diabetes Ther 10(6) (2019) 2139-2152. https://doi.org/10.1007/s13300-019-00697-w

[137] V. Bullo, E. Roma, S. Gobbo, F. Duregon, M. Bergamo, G. Bianchini, et al., Lower Limb Strength Profile in Elderly with Different Pathologies: Comparisons with Healthy Subjects, Geriatrics (Basel) 5(4) (2020). https://doi.org/10.3390/geriatrics5040083

[138] Q.Q. Shi, P.L. Li, K.L. Yick, N.W. Li, J. Jiao, Effects of contoured insoles with different materials on plantar pressure offloading in diabetic elderly during gait, Sci Rep 12(1) (2022) 15395. https://doi.org/10.1038/s41598-022-19814-0

[139] B.Y. Tsung, M. Zhang, A.F. Mak, M.W. Wong, Effectiveness of insoles on plantar pressure redistribution, J Rehabil Res Dev 41(6a) (2004) 767-74. https://doi.org/10.1682/jrrd.2003.09.0139

[140] N. Guldemond, Plantar pressure measurement, Plantar pressure, diabetes and amputation: studies on etiological, diagnostic and therapeutical aspects, Maastricht2007, pp. 27-68.

[141] G. Aminian, Z. Safaeepour, M. Farhoodi, A.F. Pezeshk, H. Saeedi, B. Majddoleslam, The effect of prefabricated and proprioceptive foot orthoses on plantar pressure distribution

in patients with flexible flatfoot during walking, Prosthet Orthot Int 37(3) (2013) 227-32. https://doi.org/10.1177/0309364612461167

[142] T. Kobayashi, A. Jor, Y. He, M. Hu, M.W.P. Koh, G. Hisano, et al., Transfemoral prosthetic simulators versus amputees: ground reaction forces and spatio-temporal parameters in gait, Royal Society Open Science 11(3) (2024) 231854. https://doi.org/10.1098/rsos.231854.

[143] J.H. Hollman, E.M. McDade, R.C. Petersen, Normative spatiotemporal gait parameters in older adults, Gait Posture 34(1) (2011) 111-8. https://doi.org/10.1016/j.gaitpost.2011.03.024

[144] M. Montero-Odasso, J. Verghese, O. Beauchet, J.M. Hausdorff, Gait and cognition: a complementary approach to understanding brain function and the risk of falling, J Am Geriatr Soc 60(11) (2012) 2127-36. https://doi.org/10.1111/j.1532-5415.2012.04209.x

[145] S.A. Bus, J.S. Ulbrecht, P.R. Cavanagh, Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity, Clin Biomech (Bristol, Avon) 19(6) (2004) 629-38. https://doi.org/10.1016/j.clinbiomech.2004.02.010

[146] A. Yoshii, T. Ono, K. Kayashima, M. Kitoh, An unusual mechanical hyperkeratosis of the soles--health sandals keratosis, J Dermatol 18(5) (1991) 291-4. https://doi.org/10.1111/j.1346-8138.1991.tb03085.x

CHAPTER 2

EFFECTS OF SOMATOSENSORY STIMULATION FOOT ORTHOSES ON POSTURAL BALANCE AND STABILITY IN OLDER ADULTS: A SYSTEMATIC REVIEW, META-ANALYSIS, AND META-REGRESSION

2.1 Introduction

Older population is rapidly increasing globally; 1 in 6 people will be 65 or older by 2030, doubling by 2050 [1, 2]. Although people are living longer than ever before, the prevalence of disability remains high, primarily because of declines in function and sensory deficits. The Global Burden of Diseases Study 2017 reported that age-related conditions contributed to more than half of the worldwide health burden in adults [3]. Consequently, there is growing attention on addressing health issues on aging population, particularly those related to balance and stability. This trend highlights the urgent demand for effective and widely accessible interventions.

Previous studies have investigated the effectiveness of several interventions to improve balance in older adults. These includes medical treatments, exercise programs, and assistive technologies [4, 5]. The use of somatosensory foot orthoses is one of promising foot orthoses interventions to improve balance and stability. The mechanical features, such as textured surfaces or protrusions in somatosensory orthoses are designed to enhance proprioceptive feedback and improve postural control. Somatosensory foot orthoses have attracted growing attention as a non-invasive and easily accessible intervention. By delivering tactile input to the soles of the feet, somatosensory foot orthoses may influence both static and dynamic balance, as indicated via changes to center of pressure (CoP) displacements. These orthoses have also been associated with improved outcomes on functional tests such as the Timed Up and Go (TUG) and the Berg Balance Scale (BBS) [6-11]. However, findings across studies are inconsistent and their overall effectiveness and the underlying mechanisms are not yet fully understood. Some studies report significant improvements, while others show little-to-minimal effect. The differences in the design features of the somatosensory foot orthoses, such as the texture, shape, height, hardness, density, and positioning of the stimulating protrusions may results this variability. However, these design features have not been systematically analyzed and recommended in relation to their impact on balance outcomes.

Understanding how specific design features of somatosensory foot orthoses can influence their effectiveness is crucial for optimizing their use in older adults. This meta-analysis aimed to assess the overall effects of somatosensory foot orthoses on static and dynamic balance and stability in older adults, with a focus on the role of protrusion designs. While existing studies have investigated somatosensory foot orthoses with various protrusion designs, we will conduct a meta-regression analysis to examine how these differences influence the results across. This systematic review aims to address the following research questions: 1) How do somatosensory foot orthoses affect static and dynamic balance, as well as stability, in older adults? 2) In what ways do various design features of somatosensory foot orthoses—such as structure, shape, height, hardness, and the arrangement of stimulating protrusions—affect overall efficacy? 3) What mechanisms underlie the enhancement of balance and stability in older adults through mechanoreceptor stimulation? By integrating and analyzing current evidence, this review seeks to elucidate both the benefits and limitations of somatosensory foot orthoses, while also highlighting the design elements that most significantly contribute to their effectiveness. These insights regarding key design features can inform clinical practice and guide the development of more effective balance enhancing orthotic interventions.

2.2 Methods

2.2.1 Study protocol

The protocol for this review with meta-analysis was registered in the International Prospective Register of Systematic Reviews (PROSPERO, ID: CRD42024592630). The guidelines of Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA 2020) was employed to ensure transparency and comprehensive reporting.

2.2.2 Literature search

A systematic and comprehensive searching across five electronic databases, including PubMed, Scopus, Web of Science, Cochrane Library, and CINHL via EBSCOhost, were conducted to identify relevant articles published in English from database inception to December 2024 (APPENDIX D). Three categories of keywords and their synonyms were combined using Boolean operators (OR, AND, NOR). The terms under population category includes older adults, aging population, and elderly. The terms under intervention category includes stimulating or textured foot orthoses, insoles, shoe inserts, as well as terms related to somatosensory, tactile, massage, and mechanoreceptor stimulation. The terms under outcome category includes postural balance, stability, sway, equilibrium, control, and also center of pressure, center of mass, center of gravity, and displacements.

2.2.3 Study selection

The lead author conducted the initial search of the databases and removed any duplicate records. Relevant articles were short listed first by screening titles and abstracts, after which the full texts were assessed by both the lead author and a co-author. The eligibility criteria were set following the PICO (Population, Intervention, Comparison, and Outcome) framework. Specifically, the population included studies with older adults; the intervention involved the use of somatosensory foot orthoses designed to stimulate mechanoreceptors; the comparison required a control or baseline condition without tactile stimulation; and the outcomes focused on measures of static and dynamic balance as well as functional mobility. Only peer-reviewed, single group quasi-experimental and randomized controlled trials with full-text were included for subsequent analysis. Studies involving participants with severe conditions including neurological, orthopaedic, or cardiovascular disorders. The non-mechanical forms of foot stimulation were also excluded. Discrepancies between the evaluators were resolved through consensus.

2.2.4 Methodological rigor and risk of bias assessment

The methodological quality was assessed using a modified version of the Downs and Black Index, adapted to 21 items that were most applicable to the included study designs (single-group crossover and randomized controlled trials). Each item on the index was scored '0' for 'no' or 'unable to determine' and '1' for 'yes,' with a maximum possible score of 21. Two authors independently conducted the quality assessment of each study to ensure objectivity and reliability. In cases of disagreement between the evaluations, a third author facilitated consensus discussions. Studies were classified into three tiers of quality: good, fair, and poor. Those scoring 60% or below were considered as poor quality, while scores ranging from 61% to 74% as fair quality. A score of 75% or above were reported as good quality [12-14].

2.2.5 Data extraction

Data extraction was comprehensively conducted to ensure thorough coverage of pertinent study characteristics and outcomes. The lead author extracted the data, and then a co-author verified them to ensure accuracy and reliability. Key information extracted from each study included study design, demographics such as sample size, age, and gender. Additionally, to confirm adequate baseline sensory capabilities of the foot skin, the tactile sensitivity status was documented. The somatosensory foot orthoses conditions delivered in each included study was extracted, along with comparisons made with barefoot or in-shoe flat foot orthoses, to evaluate the effectiveness of different interventions. Detailed features including shape, height, material, hardness, and distribution of the stimulating protrusions as well as foot orthoses construction were extracted, to understand the specific design elements and their potential effect on balance outcomes. Information regarding familiarization periods and follow-up durations was also recorded to evaluate both adaptation and long-term effects.

2.2.6 Outcome measures

The systematic review extracted several key outcome metrics related to balance control and postural stability. The anteroposterior (AP) and mediolateral (ML) CoP ranges, as well as average CoP velocities were included, which indicate postural stability by the extent of sway during standing with eyes open or closed conditions. The margin of stability (MoS) between the center of mass (CoM) and base of support (BoS) data during walking was extracted, indicating the body's ability to maintain equilibrium by calculating the distance between the CoM and the stability boundary. Among the other parameters, step length and cadence were included to assess gait characteristics including stride efficiency and rhythm. The TUG test measures basic functional mobility by timing how long it takes a person to stand up from a chair, walk a short distance, and return to sit down. The BBS evaluates both static and dynamic balance. This is achieved through a series of specific balance tasks. The mini-BESTest assesses balance in different contexts, including anticipatory and reactive postural control. The Star Excursion Balance focuses on dynamic balance by having participants reach as far as possible in multiple directions while standing on one leg.

2.2.7 Data processing and synthesis

The data from each study including mean, standard deviations, and sample size for both treatment and control conditions were systematically input into Excel tables. For studies that did not provide raw data on mean and standard deviation, a plot digitizer was utilized to extract numerical data from the graphs or figures [15]. The random-effects model was applied in the meta-analysis as it produces better results for studies with small sample sizes and heterogeneity across studies [16]. Subgroup analyses were conducted based on several study level criteria. First, sample size was evaluated. Studies with smaller samples (20 or fewer participants) were compared to those with larger samples (more than 20 participants), since smaller groups may reduce statistical power [17]. Second, the average age of participants was considered. Subgroup distinguished older adults aged 70 or younger and those over 70 years [18, 19]. Third, features of the stimulating protrusions were examined, including shape, height, distribution, and hardness. The construction of the foot orthoses (flat or arch-support) was also assessed. Fourth, follow-up duration (immediate and follow-up) and methodological quality were evaluated, with studies classified as good, fair, or poor using the Downs and Black Index.

Meta-regression analysis was performed for outcome measures with data from at least 10 somatosensory foot orthoses conditions [20]. The regression coefficient was used to assess the relationship between intervention effects and potential effect modifiers, such as study design, participant demographics, and protrusion characteristics [21]. Particularly, this was performed to evaluate the level of associations between the effect sizes and the study-level demographics corresponding to study design (sample size, follow-up Downs and Black score), sample features (average age), features of stimulating knobs (shape, dimension, distribution, and hardness). The regression coefficient in the meta-regression analysis demonstrates how the intervention effect changes with the potential effect modifier(s). The potential bias in publication was assessed visually using funnel plots when the number of trials exceeded 10 or Egger's regression test when less than 10 trials [22, 23]. All outcomes were measured as continuous variables and reported as mean differences (MD) with 95% confidence intervals. Statistical significance was defined as $p<0.05$. Regression coefficients between 0 and 1 were considered significant. Heterogeneity was considered high and unacceptable when I^2 statistic exceeded 50% in meta-analyses and regressions. All statistical analyses were performed using Stata version 17 (Stata Corp LLC, College Station, TX, USA).

2.3 Results

2.3.1 Study selection

A total of 1,383 records were initially identified through database searches, with 1,019 records screened after removing duplicates (Figure 2-1). Of these, 52 full-text articles were assessed for eligibility. Additionally, 3 more records were identified from other sources. We assessed all of them for eligibility and reported the excluded articles along with their reasons in the Appendix E. Finally, 18 studies that met the eligibility criteria were included in the quantitative synthesis and meta-regression analysis.

2.3.2 Methodological quality

Among the 18 included studies, three [17, 24, 25] studies were rated as having good methodological quality (Downs and Black index scores: 77-95%), twelve [26-37] were rated as fair (scores: 62-72%), and three [38-40] were rated as poor (scores: 52-58%). Frequent methodological flaws were identified, such as insufficient blinding—only 16% of studies reported blinding participants, and none reported blinding outcome assessors. Allocation concealment was also lacking, with just 16% of studies addressing this domain. Additionally, only 5% of studies adequately controlled for confounding variables. Furthermore, a priori power analysis for estimating sample size was reported in 11% of the studies (Table 2-1).

2.3.3 Study characteristics

This systematic review and meta-analysis included 18 [17, 24-40] studies, comprising 12 single group quasi-experimental designs [24, 28-37, 39] and 6 randomized controlled trials (RCTs) [17, 25-27, 38, 40] (Table 2-2).

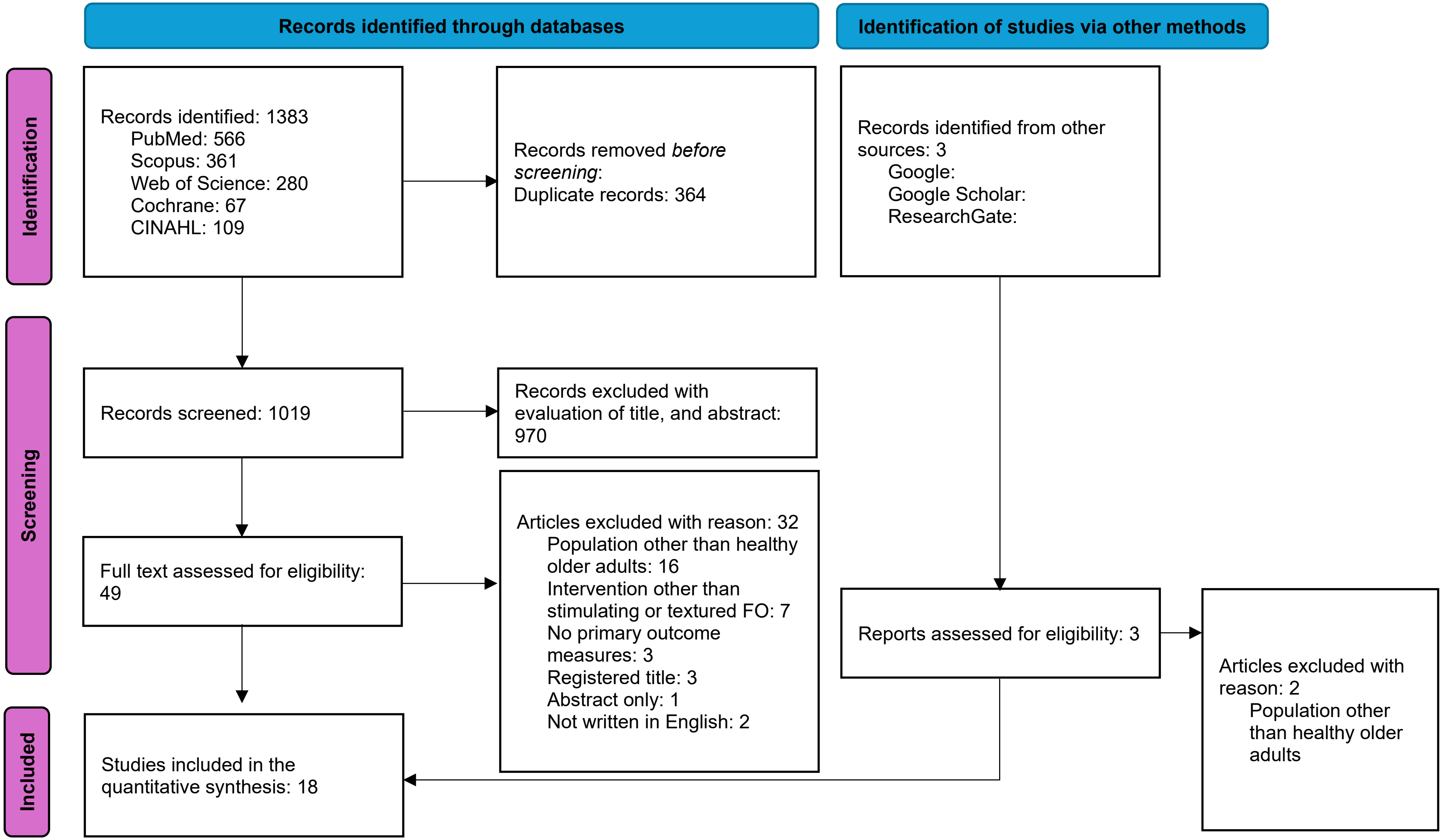


Figure 2-1. Flowchart of study selection through the PRISMA guidelines.

Table 2-1. Modified downs and black checklist for methodological quality assessment

Studies	Reporting								External validity		Internal validity - Bias					Internal validity - confounding/ selection bias					Power	Total score	Quality score
Items	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**10**	**11**	**12**	**14**	**15**	**16**	**18**	**20**	**21**	**22**	**23**	**24**	**25**	**27**	**Out of 21**	
Annino et al 2018 [26]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Asgari et al. 2022 [24]	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	1	1	1	1	0	0	17	81%
de Morais Barbosa et al. 2018 [17]	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	20	95%
Hartmann et al 2009 [27]	1	1	1	0	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	0	0	15	72%
Hatton et al. 2011 [28]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Hatton et al. 2012 [29]	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	1	1	1	0	0	0	15	72%
Huang et al. 2020 [30]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Kiaghadi et al. 2020 [39]	1	1	1	1	1	1	1	1	0	0	0	0	1	0	1	0	1	1	0	0	0	12	58%
Li et al. 2019 [31]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Palazzo et al. 2020 [32]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Palluel et al. 2008 [33]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Palluel et al. 2009 [34]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Perry et al. 2008 [40]	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	0	1	1	0	0	0	12	58%
Pinvanichkul et al. 2022 [25]	1	1	1	1	1	1	1	1	0	0	1	0	1	1	1	0	1	1	1	0	1	16	77%
Qiu et al. 2012 [35]	1	1	1	1	1	1	1	0	1	1	0	0	1	1	1	1	1	1	0	0	0	15	72%
Qiu et al. 2013 [36]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Qu et al. 2015 [37]	1	1	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	0	13	62%
Sharma R et al. 2024 [38]	1	1	1	1	1	0	1	1	0	0	0	0	1	1	0	0	1	1	0	0	0	11	52%

"1: yes; 0: no and unable to determine or not applicable. 01. Hypothesis/aim/objective clearly described; 02. Main outcomes in Introduction or Methods; 03. Participants characteristics are clearly described; 04. Interventions of interest clearly described; 05. Principal confounders clearly described; 06. Main findings clearly described; 07. Estimates of random variability provided for main outcomes; 10. Probability values reported for main outcomes; 11. Subjects asked to participate were representative of the source population; 12. Subjects prepared to participate were representative of the source population; 14. Study participants blinded to treatment.; 15. Blinded outcome assessment; 16. Any data dredging clearly described; 18. Appropriate statistical tests performed; 20. Outcome measures were reliable and valid; 21. All participants in different intervention groups were recruited from the same source population; 22. All participants in different intervention groups were recruited over the same time period; 23. Participants randomized to treatment(s); 24. Allocation of treatment concealed from investigators and participants; 25. Adequate adjustment for confounding in the analyses; 27. Statistical power estimation was used for sample size calculation."

Table 2-2. Study characteristics

Author and Year	Study design	Participants (Sample size; Gender M/F; Mean Age; Age range); plantar tactile sensitivity	Testing conditions (Static/ Dynamic)	Exp condition: Foot orthoses (FO) delivered	Comparison	Features of stimulating protrusion	Familiarization time	Follow up time	Outcome measures
Annino et al 2018	RCT	Control group: 12; 8/4; 66.0±8.02, Exp group: 12: 8/4; 69.5±4.06; Not specified	Static: standing EO & EC	a. SSFO_immediate b. SSFO_4 weeks	a. SSFO_immediate vs FFO b. SSFO_4 weeks vs FFO	Shape: Variable pebble Height/dimension: small; not specified Positioning: Uniform across the whole upper surface Material: rigid pebble covered with soft Alcantara Densities: Not specified Hardness: Rigid FO construction: Flat	Not specified	4 weeks (30 days)	AP CoP range ML CoP range Avg CoP velocity
Asgari et al. 2022	SGQE	15;9/6; 65.7±5.1; 10g SWM test	Static: standing EO Dynamic: functional mobility	a. SSFO	a. SSFO vs FFO	Shape: Rounded knobs Height/dimension: small; 2mm height, 5mm diameter, 10mm center-to-center distance Positioning: Uniform across the whole upper surface Material: PVC Densities: Not specified Hardness: Semi-rigid FO construction: Flat	One practice trial	Immediate	AP CoP range ML CoP range Avg CoP_ velocity TUG
de Morais Barbosa et al. 2018	RCT	Control group: 27; 12/15; 69.4±4.1, Exp group: 33: 14/19; 70.1±4.5; 10g SWM test	Dynamic: functional mobility	a. SSFO_immediate b. SSFO_4 weeks	a. SSFO_immediate vs FFO b. SSFO_4 weeks vs FFO	Shape: Pyramidal spikes Height/dimension: small; ~1mm height*, ~2mm diameter*, 2mm center-to-center distance Positioning: Uniform across the whole upper surface Material: EVA Densities: Not specified Hardness: Semi-rigid (Shore A40) FO construction: Flat	Not specified	4 weeks	BBS TUG
Hartmann et al 2009	RCT	Control group: 14; 10/4; 76.0±6.0, Exp group: 14: 10/4; 76.4±5.9; Not specified	Dynamic: level walking Dynamic: functional mobility	a. SSFO_immediate b. SSFO_12 weeks	a. SSFO_immediate vs FFO b. SSFO_12 weeks vs FFO	Shape: Widened raised projections Height/dimension: not specified Positioning: Site-specific raised projections Material: MedReflex1 Densities: Not specified Hardness: Not specified FO construction: Flat	Not specified	12 weeks	Step length Cadence Falls Efficacy Scale International FES-I score
Hatton et al. 2011	SGQE	50; 21/29; 75.1+5.0; 10g SWM test	Static: standing EO & EC	a. SSFO (pyramid granulations) b. SSFO (rounded knobs)	a. SSFO (pyramid granulations) vs Barefoot b. SSFO (rounded knobs) vs Barefoot	Shape: Pyramidal spikes & rounded knobs Height/dimension: small (spikes); 1mm height*, ~1.75mm diameter*, 2.5mm center-to-center distance, small (rounded knobs); ~3mm diameter*, 2mm height*, 5mm center-to-center distance Positioning: Uniform across the whole upper surface Material: EVA Densities: Not specified Hardness: Semi-rigid (Shore A50)	One practice trial	Immediate	AP CoP range ML CoP range Avg COP velocity

						FO construction: Flat			
Hatton et al. 2012	SGQE	30; 9/21; 79.0±7.1; 10g SWM test	Static: standing EO & EC Dynamic: level walking	a. SSFO	a. SSFO vs FFO	Shape: Pyramidal spikes Height/dimension: small; 1mm height, 1.75mm diameter, 2.5mm center to center distance Positioning: Uniform across the whole upper surface Material: EVA Densities: Not specified Hardness: Semi-rigid (Shore A50) FO construction: Flat	One practice trial	Immed iate	**Static:** AP CoP range ML CoP range Avg CoP_ velocity **Dynamic:** Step length, Cadence
Huang et al. 2020	SGQE	23; 23/0; 65.1±3.3; 10g SWM test	Static: standing EO	a. SSFO	a. SSFO vs FFO b. SSFO vs Barefoot	Shape: Rounded knobs Height/dimension: large; 5mm and 3mm heights, 15mm diameter Positioning: 5 at metatarsal heads and 3 at lateral heel areas Material: Silicon Densities: 1.12 g/cm3 Hardness: Soft (Shore A8) FO construction: Arch-support	One practice trial	Immed iate	AP CoP range ML CoP range Avg CoP_ velocity
Kiaghadi et al. 2020	SGQE	30; 13/17; 68.9±3.7; Not specified	Dynamic: functional mobility	a. SSFO	a. SSFO vs arch-support FO with medical shoe b. SSFO vs arch-support FO with sports shoe	Shape: Rounded knobs Height/dimension: small; 3mm height, ~2.5mm diameter, 2.5mm center-to-center distance Positioning: Uniform across the whole upper surface Material: EVA Densities: Not specified Hardness: Semi-rigid (Shore A53) FO construction: Arch-support with a raised heel cup	Six practice trials	Immed iate	Star Excursion Balance Test (SEBT): SEBT_Anteromedial SEBT_Medial SEBT_Posteromedial
Li et al. 2019	SGQE	24; 24/0; 65±3.6; Not specified	Static: standing EO Dynamic: level walking	a. SSFO	a. SSFO vs FFO	Shape: Rounded knobs Height/dimension: large; 5mm & 3mm heights, 15mm Positioning: 5 at metatarsal heads and 3 at lateral heel areas Material: Silicon Densities: 1.12 g/cm3 Hardness: Soft (Shore A8) FO construction: Arch-support	Two practice trials	Immed iate	**Static:** AP CoP range ML CoP range Avg CoP velocity **Dynamic:** AP CoP range ML CoP range Avg CoP velocity
Palazzo et al. 2020	SGQE	20; 10/10; 68.60±4.74, 68.00±5.17; Not specified	Static: standing EO & EC	a. SSFO	a. SSFO vs Barefoot	Shape: Rounded knobs Height/dimension: medium; 3.5mm height, 2mm diameter, 17mm center-to-center distance Positioning: Uniform across the whole upper surface Material: Not specified Densities: Not specified Hardness: Rigid FO construction: Convex	Not specified	Immed iate	AP CoP range ML CoP range Avg CoP velocity
Palluel et al. 2008	SGQE	19; 8/11; 69.0 (62-80); SWM test	Static: standing EO	a. SSFO	a. SSFO vs FFO	Shape: Pyramidal spikes Height/dimension: large; 5mm height (distributed in all areas except the medial arch-support), 3mm diameter, 10mm height (distributed at the medial arch-support), 5mm diameter	Not specified	Immed iate	Static: RMS of AP CoP displacement, RMS of ML CoP_displaceme

						Positioning: Site-specific placement, 4 spikes/cm2 Material: PVC Densities: Not specified Hardness: Semi-rigid FO construction: Arch-support			nt, Avg CoP velocity
Palluel et al. 2009	SGQE	19; 8/11; 68.8 (61-80); SWM test	Static: standing EO Dynamic: level walking	a. SSFO_5 minutes	a. SSFO vs FFO	Shape: Pyramidal spikes Height/dimension: large; 5mm height (distributed in all areas except medial arch-support), 3mm diameter, 10mm height (distributed at medial arch-support), 5mm diameter Positioning: Site-specific placeemnt, 4 spikes/cm2 Material: PVC Densities: Not specified Hardness: Semi-rigid FO construction: Arch-support	Not specified	Immediate	Static: RMS of AP CoP_displacement, RMS of ML CoP displacement, Avg CoP velocity
Perry et al. 2008	RCT	Control group: 20; 10/10; 69±3.1, Exp group: 20: 11/9; 69.6±3.6; Vibration-sensation test	Dynamic: level walking	a. SSFO	a. SSFO_up slope vs FFO b. SSFO_down slope vs FFO c. SSFO_lateral slope vs FFO d. SSFO_medial slope vs FFO	Shape: Perimeter tube/widened raised projections Height/dimension: large; 3mm height, 3mm diameter, 10mm from edge Positioning: perimeter 10mm from the edge Material: elastomeric Densities: Not specified Hardness: Soft flexible FO construction: Flat	Unspecified practice trials	Immediate	COM-BOS_ML-MOS
Pinvanichkul et al. 2022	RCT	Control group: 15; 2/13; 64 (62-71), Exp group: 15: 2/13; 67 (62-73); 10g SWM test	Dynamic: level walking Dynamic: functional mobility	a. SSFO_immediate b. SSFO_4 weeks	a. SSFO_immediate vs FFO b. SSFO_4 weeks vs FFO	Shape: Rounded knobs Height/dimension: large; 2mm height & 2mm diameter (smaller), 5mm height & 5mm diameter (larger) Positioning: larger knobs at metatarsal heads & arch, smaller knobs across rest areas, ring shaped pattern at heel Material: Not specified Densities: Not specified Hardness: Not specified FO construction: Flat	1-3 practice trials	4 weeks	Step length Cadence mini-BESTest
Qiu et al. 2012	SGQE	7; 4/3; 72±4; Not specified	Static: standing EO & EC	a. SSFO_Soft b. SSFO_Hard	a. SSFO_Soft vs Barefoot b. SSFO_Hard vs Barefoot	Shape: Rounded knobs Height/dimension: medium; 3.1mm height, 5mm diameter Positioning: Uniform across whole upper surface Material: EVA Densities: 270 (a), 320 (b) Hardness: Soft (a), Rigid (b) FO construction: Flat	Not specified	Immediate	AP CoP range, ML CoP range
Qiu et al. 2013	SGQE	20; 13/7; 68.9±4.8; Not specified	Static: standing EO & EC	a. SSFO	a. SSFO vs FFO	Shape: Rounded knobs Height/dimension: medium; 3.1mm height, 5mm diameter Positioning: Uniform across whole upper surface Material: EVA Densities: 270 Hardness: Soft FO construction: Flat	Not specified	Immediate	AP CoP range ML CoP range

Qu et al. 2015	SGQE	13 5/8; 69.2±7.2; Not specified	Static: standing EO Dynamic: level walking	a. SSFO	a. SSFO vs FFO	Shape: Rounded knobs Height/dimension: small; 2mm height*, 7-8mm diameter, 10mm center to center distance Positioning: Uniform across whole upper surface Material: EVA Densities: Not specified Hardness: Not specified FO construction: Flat	10 min	Immed iate	Static: AP CoP range ML CoP range Dynamic: COM-BOS_ML-MOS
Sharma R et al. 2024	RCT	Control group: 10; 7/3; 75.5±13.51, Exp group: 10: 7/3; 71.2±9.74; Finger touch test	Dynamic: functional mobility	a. SSFO_immediate b. SSFO_4 weeks	a. SSFO_immediate vs FFO b. SSFO_4 weeks vs FFO	Shape: Pyramidal spikes Height/dimension: small; ~2mm diameter, 2mm center-to-center distance Positioning: Uniform across whole upper surface Material: EVA Densities: Not specified Hardness: Not specified FO construction: Arch-support FO	Not specified	4 weeks	TUG BBS

EO: Eyes open; EC: Eyes closed; SGQE: single group quasi-experimental; RCT: randomized controlled trial; SSFO: somatosensory foot orthoses; FFO: flat Foot orthoses; CoP: center of pressure; CoM: center of mass; MoS: margin of stability; BoS: base of support; BBS: Berg Balance Scale; TUG: Timed Up to Go

The 12 single group quasi-experimental studies included 270 participants, while 6 RCTs recruited 98 individuals in control groups and 104 in experimental groups. Plantar tactile sensitivity status was assessed using Semmes Weinstein Monofilament (SWM) tests in 8 studies [17, 24, 25, 28-30, 33, 34], a vibration sensation test in one study [40], and a finger touch test in another study [38], while 8 studies [26, 27, 31, 32, 35-37, 39] did not report this assessment. A total of 12 studies [24, 26, 28-37] investigated static balance, examining participants under both eyes open and eyes closed conditions. Dynamic balance during walking on level surfaces was assessed in 7 studies [25, 27, 29, 31, 34, 37, 40]. Additionally, 6 studies [17, 24, 25, 27, 38, 39] focused on evaluating functional mobility.

Across the 18 studies, a total of 27 different orthotic conditions were tested: 17 flat foot orthoses [17, 24-29, 35-37, 40] and 10 arch-supported somatosensory foot orthoses [30-34, 38, 39]. Nineteen orthotic conditions were compared with flat foot orthoses in shoes [17, 24-27, 29-31, 33, 34, 36-40], and six were compared with barefoot conditions [28, 30, 32, 35]. Regarding the design features of somatosensory foot orthoses, the protrusion shapes on somatosensory foot orthoses varied, with ten using pyramidal spikes [17, 26, 28, 29, 33, 34, 38], fourteen using rounded knobs [24, 25, 28, 30-32, 35-37, 39], and three using widened raised projections [27, 40]. Seventeen of the somatosensory foot orthoses conditions featured uniform placement of protrusions across the whole upper surface [17, 24, 26, 28, 29, 32-39], while eight had site-specific placement [25, 27, 30, 31, 40]. Regarding protrusion height, thirteen somatosensory foot orthoses utilized small protrusions [17, 24, 26, 28, 29, 37-39], four employed medium-sized protrusions [32, 35, 36], and eight incorporated large protrusions [25, 30, 31, 33, 34, 40].

As for material hardness, six somatosensory foot orthoses used soft materials [30, 31, 35, 36, 40], ten used semi-rigid [17, 24, 28, 29, 33, 34, 39], four used rigid [26, 32, 35], seven did not report hardness [25, 27, 37, 38]. Most studies (twenty-two somatosensory foot orthoses conditions) focused on immediate effects [17, 24-40], while five studies examined follow-up effects over 4 to 12 weeks [17, 25-27, 38]. Key outcome measures included AP and ML CoP ranges, average CoP velocity for static balance, MoS to CoM, cadence, and step length for walking movement, as well as functional mobility assessments (TUG, BBS, and Mini-BESTest).

Table 2-3. Results of the main group and subgroup/sensitivity analysis for the effects of somatosensory stimulation foot orthoses (SSFO) on postural balance while standing with eyes open.

Static Balance During Standing with Eyes Open				
Variables	**Category**	**AP CoP Range**	**ML CoP Range**	**Avg CoP velocity**
All comparisons		MD=-0.18, 95%CI (-0.27, -0.09), **p<0.001,** I^2=0%, NFOC=15, PN=324	MD=-0.26, 95%CI (-0.84, 0.31), p=0.37, I^2=96.46%, NFOC=17, PN=364	MD=-0.10, 95%CI (-0.39, 0.19), p=0.50, I^2=0%, NFOC=12, PN=297
Sample size	n ≤20	MD=-0.34, 95%CI (-0.53, -0.15), **p<0.001**, I^2=33.78%, NFOC=09, PN=124	MD=-0.29, 95%CI (-1.31, 0.73), p=0.57, I^2=98.79%, NFOC=11, PN=164	MD=-0.11, 95%CI (-0.42, 0.19), p=0.47, I^2=0%, NFOC=06, PN=97
	n >20	MD=-0.00, 95%CI (-1.29, 1.29), p=1.00, I^2=0%, NFOC=06, PN=200	MD=-0.07, 95%CI (-0.33, 0.19), p=0.62, I^2=0%, NFOC=06, PN=200	MD=0.04, 95%CI (-0.99, 1.08), p=0.94, I^2=0%, NFOC=06, PN=200
Average age	<70	MD=-0.17, 95%CI (-0.27, -0.08), **p<0.001**, I^2=0%, NFOC=10, PN=180	MD=0.16, 95%CI (-0.25, 0.57), p=0.44, I^2=93.27%, NFOC=12, PN=220	MD=-0.09, 95%CI (-0.39, 0.21), p=0.56, I^2=0%, NFOC=09, PN=167
	≥70	MD=-0.53, 95%CI (-2.10, 1.05), p=0.51, I^2=63.26%, NFOC=05, PN=144	MD=-2.11, 95%CI (-3.56, -0.66), **p<0.001**, I^2=69.73%, NFOC=05, PN=144	MD=-0.23, 95%CI (-1.36, 0.91), p=0.69, I^2=0%, NFOC=03, PN=130
Follow-up time	Immediate	MD=-0.39, 95%CI (-0.60, -0.19), **p<0.001,** I^2=0%, NFOC=13, PN=293	MD=-0.29, 95%CI (-0.96, 0.37), p=0.30, I^2=93.64%, NFOC=15, PN=333	MD=-0.18, 95%CI (-0.52, 0.17), p=0.31, I^2=0%, NFOC=11, PN=285
	Long-term	MD=-0.47, 95%CI (-1.27, 0.33), p=0.25, I^2=88.44%, NFOC=02, PN=31	MD=-0.14, 95%CI (-0.40, 0.13), p=0.31, I^2=0%, NFOC=02, PN=31	MD=0.10, 95%CI (-0.45, 0.65), p=0.72, I^2=0%, NFOC=01, PN=12
Shod/Unshod conditions	Barefoot	MD=-0.23, 95%CI(-0.61, 0.15), p=0.23, I^2=0%, NFOC=06, PN=157	MD=-1.03, 95%CI (-2.36, 0.31), p=0.13, I^2=94.97%, NFOC=07, PN=177	MD=0.12, 95%CI (-1.18, 1.43), p=0.85, I^2=64.58%, NFOC=04, PN=143
	Shoe	MD=-0.35, 95%CI(-0.82, 0.11), p=0.14, I^2=81.46%, NFOC=09, PN=167	MD=-0.14, 95%CI (-0.23, -0.05), **p<0.001,** I^2=0%, NFOC=10, PN=187	MD=0.07, 95%CI (-0.36, 0.50), p=0.75, I^2=0%, NFOC=08, PN=154
SSFO structure	Flat	MD=-0.48, 95%CI (-1.25, 0.29), p=0.22, I^2=81.50%, NFOC=09, PN=196	MD=-0.36, 95%CI (-1.30, 0.58), p=0.45, I^2=93.70%, NFOC=11, PN=236	MD=0.05, 95%CI (-0.37, 0.46), p=0.82, I^2=0%, NFOC=06, PN=169
	Arch-support	MD=-0.12, 95%CI (-0.22, -0.02), **p=0.02**, I^2=0%, NFOC=06, PN=138	MD=-0.21, 95%CI (-0.30, -0.11), **p<0.001,** I^2=0%, NFOC=06, PN=128	MD=-0.25, 95%CI (-0.67, 0.17), p=0.24, I^2=0%, NFOC=06, PN=128
Material hardness	Soft	MD=-0.51, 95%CI (-1.40, 0.38), p=0.26, I^2=0%, NFOC=07, PN=207	MD=-0.04, 95%CI (-0.79, 0.72), p=0.93, I^2=85.32%, NFOC=09, PN=247	MD=0.04, 95%CI (-0.99, 1.08), p=0.59, I^2=0%, NFOC=06, PN=200
	Semi-rigid	MD=-0.12, 95%CI (-0.22, -0.02), **p=0.02,** I^2=0%, NFOC=03, PN=53	MD=-0.25, 95%CI (-0.36, -0.14), **p<0.001,** I^2=0%, NFOC=03, PN=53	MD=0.04, 95%CI (-1.43, 1.52), p=0.95, I^2=0%, NFOC=03, PN=53
	Rigid	MD=-0.39, 95%CI (-0.90, 0.12), p=0.14, I^2=59.63%, NFOC=04, PN=51	MD=-0.86, 95%CI (-2.73, 1.01), p=0.37, I^2=99.10%, NFOC=04, PN=51	MD=-0.120, 95%CI (-0.43, 0.19), p=0.45, I^2=0%, NFOC=03, PN=44
Protrusion shape	Pyramidal/ Spikes	MD=-0.29, 95%CI (-1.42, 0.83), p=0.61, I^2=95.48%, NFOC=06, PN=142	MD=-0.19, 95%CI (-0.28, -0.09), **p<0.001,** I^2=0%, NFOC=06, PN=142	MD=-0.02, 95%CI (-0.44, 0.41), p=0.94, I^2=0%, NFOC=06, PN=142
	Rounded knobs	MD=-0.41, 95%CI (-0.66, -0.16), **p<0.001,** I^2=0%, NFOC=09, PN=182	MD=-0.35, 95%CI (-1.37, 0.67), p=0.50, I^2=0%, NFOC=11, PN=222	MD=-0.18, 95%CI (-0.58, 0.23), p=0.39, I^2=0%, NFOC=06, PN=155

	Widened raised projections	---	---	---
Protrusion height	Small	MD=-0.31, 95%CI (-1.22, 0.59), p=0.50, I^2=84.41%, NFOC=07, PN=182	MD=-0.02, 95%CI (-0.21, 0.17), p=0.85, I^2=0%, NFOC=07, PN=182	MD=0.05, 95%CI (-0.37, 0.46), p=0.82, I^2=0%, NFOC=06, PN=169
	Medium	MD=-0.23, 95%CI (-0.62, 0.16), p=0.26, I^2=0%, NFOC=03, PN=34	MD=-0.64, 95%CI (-2.97, 1.70), p=0.59, I^2=97.56%, NFOC=05, PN=74	MD=-0.29, 95%CI (-0.72, 0.14), p=0.18, I^2=0%, NFOC=01, PN=20
	Large	MD=-0.12, 95%CI (-0.22, -0.02), **p=0.020,** I^2=0%, NFOC=05, PN=108	MD=-0.22, 95%CI (-0.32, -0.12), **p<0.001,** I^2=0%, NFOC=05, PN=108	MD=0.47, 95%CI (-1.36, 2.30), p=0.62, I^2=0%, NFOC=05, PN=108
Protrusion positioning	Uniform across whole surface	MD=-0.42, 95%CI (-1.10, 0.25), p=0.21, I^2=83.55%, NFOC=10, PN=216	MD=-0.34, 95%CI (-1.19, 0.51), p=0.43, I^2=95.58%, NFOC=12, PN=256	MD=-0.12, 95%CI (-0.41, 0.18), p=0.45, I^2=0%, NFOC=07, PN=189
	Site-specific	MD=-0.12, 95%CI (-0.22, -0.02), **p=0.02,** I^2=0%, NFOC=05, PN=108	MD=-0.22, 95%CI (-0.32, -0.12), **p<0.001,** I^2=0%, NFOC=05, PN=108	MD=0.47, 95%CI (-1.36, 2.30), p=0.62, I^2=0%, NFOC=05, PN=108
D&B Index score	Good	MD=0.03, 95%CI (-1.27, 1.33), p=0.96, I^2=0%, NFOC=01, PN=15	MD=0.58, 95%CI (-1.72, 2.88), p=0.62, I^2=0%, NFOC=01, PN=15	MD=0.31, 95%CI (-1.48, 2.10), p=0.73, I^2=0%, NFOC=01, PN=15
	Fair	MD=-0.18, 95%CI (-0.28, -0.09), **p<0.001,** I^2=0%, NFOC=14, PN=309	MD=-0.30, 95%CI (-0.91, 0.32), p=0.34, I^2=96.98%, NFOC=16, PN=349	MD=-0.11, 95%CI (-0.41, 0.19), p=0.46, I^2=0%, NFOC=11, PN=292
	Poor	---	---	---
Static Balance During Standing with Eyes Closed				
Variables		**AP CoP Range**	**ML CoP Range**	**Avg CoP velocity**
All comparisons		MD=-0.10, 95%CI (-0.25, 0.45), p=0.57, I^2=0%, NFOC=08, PN=188	MD=-1.69, 95%CI (-3.15, -0.23), **p=0.02,** I^2=96.28%, NFOC=10, PN=228	MD=-0.08, 95%CI (-0.48, 0.32), p=0.70, I^2=0%, NFOC=06, PN=174
Sample size	n ≤20	MD=0.13, 95%CI (-0.22, 0.49), p=0.47, I^2=0%, NFOC=05, PN=58	MD=-1.83, 95%CI (-4.25, 0.60), p=, I^2=98.84%, NFOC=07, PN=98	MD=-0.09, 95%CI (-0.54, 0.37), p=0.70, I^2=14.48%, NFOC=03, PN=44
	n >20	MD=-1.19, 95%CI (-3.49, 1.11), p=0.31, I^2=0%, NFOC=03, PN=130	MD=-1.49, 95%CI (-3.20, 0.22), **p=0.09,** I^2=0%, NFOC=03, PN=130	MD=0.52, 95%CI (-1.37, 2.42), p=0.59, I^2=0%, NFOC=03, PN=130
Average age	<70	MD=0.07, 95%CI (-0.32, 0.46), p=0.74, I^2=9.10%, NFOC=03, PN=44	MD=-0.05, 95%CI (-0.65, 0.55), p=0.87, I^2=79.63%, NFOC=05, PN=84	MD=-0.09, 95%CI (-0.54, 0.37), p=0.70, I^2=14.48%, NFOC=03, PN=44
	≥70	MD=0.61, 95%CI (-0.61, 1.83), p=0.33, I^2=0%, NFOC=05, PN=144	MD=-4.13, 95%CI (-6.06, -2.20), **p<0.001,** I^2=66.86%, NFOC=05, PN=144	MD=0.52, 95%CI (-1.37, 2.42), p=0.59, I^2=0%, NFOC=03, PN=130
Follow-up time	Immediate	MD=0.09, 95%CI (-0.30, 0.48), p=0.65, I^2=0%, NFOC=07, PN=176	MD=-1.93, 95%CI (-3.51, -0.35), **p=0.02,** I^2=94.64%, NFOC=09, PN=216	MD=-0.09, 95%CI (-0.57, 0.39), p=0.72, I^2=0%, NFOC=05, PN=162
	Long-term	MD=0.14, 95%CI (-0.64, 0.92), p=0.72, I^2=0%, NFOC=01, PN=12	MD=0.02, 95%CI (-0.42, 0.46), p=0.93, I^2=0%, NFOC=01, PN=12	MD=-0.06, 95%CI (-0.81, 0.69), p=0.87, I^2=0%, NFOC=01, PN=12
Shod/Unshod conditions	Barefoot	MD=-0.08, 95%CI (-0.54, 0.39), p=0.74, I^2=0%, NFOC=05, PN=134	MD=-2.84, 95%CI (-5.21, -0.48), **p=0.02,** I^2=95.25%, NFOC=06, PN=154	MD=-0.28, 95%CI (-0.83, 0.27), p=0.32, I^2=0%, NFOC=03, PN=120
	Shoe	MD=0.34, 95%CI (-0.20, 0.87), p=0.21, I^2=0%, NFOC=03, PN=54	MD=0.15, 95%CI (-0.20, 0.50), p=0.40, I^2=0%, NFOC=04, PN=74	MD=0.16, 95%CI (-0.44, 0.75), p=0.61, I^2=0%, NFOC=03, PN=54

SSFO structure	Flat	MD=0.39, 95%CI (-0.10, 0.88), p=0.12, I^2=0%, NFOC=07, PN=168	MD=-1.90, 95%CI (-3.5-, -0.31), **p=0.02,** I^2=94.07%, NFOC=09, PN=208	MD=0.18, 95%CI (-0.39, 0.75), p=0.54, I^2=0%, NFOC=05, PN=154
	Arch-support	MD=-0.20, 95%CI (-0.70, 0.30), p=0.43, I^2=0%, NFOC=01, PN=20	MD=-0.19, 95%CI (-0.52, 0.14), p=0.25, I^2=0%, NFOC=01, PN=20	MD=-0.34, 95%CI (-0.91, 0.23), p=0.24, I^2=0%, NFOC=01, PN=20
Material hardness	Soft	MD=0.33, 95%CI (-1.16, 1.83), p=0.66, I^2=0%, NFOC=04, PN=137	MD=-0.83, 95%CI (-1.44, -0.21), **p=0.01,** I^2=0%, NFOC=06, PN=177	MD=0.52, 95%CI (-1.37, 2.42), p=0.59, I^2=0%, NFOC=03, PN=130
	Semi-rigid	---	---	---
	Rigid	MD=0.09, 95%CI (-0.27, 0.45), p=0.64, I^2=0%, NFOC=04, PN=51	MD=-1.89, 95%CI (-5.70, 1.91), p=0.33, I^2=96.28%, NFOC=04, PN=51	MD=-0.09, 95%CI (-0.54, 0.37), p=0.70, I^2=14.48%, NFOC=03, PN=44
Protrusion shape	Pyramidal/ Spikes	MD=0.29, 95%CI (-0.24, 0.82), p=0.28, I^2=0%, NFOC=04, PN=104	MD=0.00, 95%CI (-0.37, 0.37), p=0.99, I^2=0%, NFOC=04, PN=104	MD=0.13, 95%CI (-0.45, 0.71), p=0.67, I^2=0%, NFOC=04, PN=104
	Rounded knobs	MD=-0.05, 95%CI (-0.52, 0.42), p=0.83, I^2=0%, NFOC=04, PN=84	MD=-2.38, 95%CI (-5.04, 0.28), **p=0.08,** I^2=97.43%, NFOC=06, PN=124	MD=0.03, 95%CI (-1.46, 1.52), p=0.97, I^2=33.67%, NFOC=02, PN=70
	Widened raised projections	---	---	---
Protrusion height	Small	MD=0.27, 95%CI (-0.26, 0.79), p=0.32, I^2=0%, NFOC=05, PN=154	MD=-0.02, 95%CI (-0.39, 0.34), p=0.91, I^2=0%, NFOC=05, PN=154	MD=0.18, 95%CI (-0.39, 0.0.75), p=0.54, I^2=0%, NFOC=05, PN=154
	Medium	MD=0.03, 95%CI (-0.54, 0.60), p=0.91, I^2=5.57%, NFOC=03, PN=34	MD=-2.62, 95%CI (-5.82, 0.57), p=0.11, I^2=98.23%, NFOC=05, PN=74	MD=-0.34, 95%CI (-0.91, 0.23), p=0.24, I^2=0%, NFOC=01, PN=20
	Large	---	---	---
Protrusion positioning	Uniform across whole surface	MD=-0.10, 95%CI (-0.25, 0.45), p=0.57, I^2=0%, NFOC=08, PN=188	MD=-1.69, 95%CI (-3.15, -0.23), **p=0.02,** I^2=96.28%, NFOC=10, PN=228	MD=-0.08, 95%CI (-0.48, 0.32), p=0.70, I^2=0%, NFOC=06, PN=174
	Site-specific	---	---	---
D&B Index score	Good	---	---	---
	Fair	MD=-0.10, 95%CI (-0.25, 0.45), p=0.57, I^2=0%, NFOC=08, PN=188	MD=-1.69, 95%CI (-3.15, -0.23), **p=0.02,** I^2=96.28%, NFOC=10, PN=228	MD=-0.08, 95%CI (-0.48, 0.32), p=0.70, I^2=0%, NFOC=06, PN=174
	Poor	---	---	---
Dynamic Stability Through Walking				
Variables		**COM-MOS**	**Step length**	**Cadence**
All comparisons		MD=0.25, 95%CI (-0.24, 0.75), p=0.31, I^2=0%, NFOC=05, PN=117	MD=-0.07, 95%CI (-5.60, 5.46), p=0.98, I^2=73.59%, NFOC=05, PN=88	MD=1.22, 95%CI (-2.27, 4.71), p=0.49, I^2=0%, NFOC=05, PN=88
Sample size	n ≤20	MD=0.31, 95%CI (-0.60, 1.23), p=0.50, I^2=0%, NFOC=05, PN=93	MD=0.23, 95%CI (-6.88, 7.33), p=0.95, I^2=79.53%, NFOC=04, PN=58	MD=1.93, 95%CI (-1.86, 5.72), p=0.32, I^2=0%, NFOC=04, PN=58
	n >20	MD=0.23, 95%CI (-0.35, 0.81), p=0.44, I^2=0%, NFOC=01, PN=24	MD=-1.50, 95%CI (-7.61, 4.61), p=0.63, I^2=0%, NFOC=01, PN=30	MD=-2.70, 95%CI (-11.61, 6.21), p=0.55, I^2=0%, NFOC=01, PN=30

Average age	<70	MD=0.25, 95%CI (-0.24, 0.75), p=0.31, I^2=0%, NFOC=05, PN=117	MD=-5.00, 95%CI (-14.80, 4.80), p=0.32, I^2=73.33%, NFOC=02, PN=30	MD=3.75, 95%CI (-6.50, 14.00), p=0.47, I^2=25.94%, NFOC=02, PN=30
	≥70	---	MD=2.94, 95%CI (-1.87, 7.75), p=0.23, I^2=0%, NFOC=03, PN=58	MD=0.79, 95%CI (-3.01, 4.60), p=0.68, I^2=0%, NFOC=03, PN=58
Follow-up time	Immediate	MD=0.25, 95%CI (-0.24, 0.75), p=0.31, I^2=0%, NFOC=05, PN=117	MD=-2.62, 95%CI (-10.08, 4.85), p=0.49, I^2=75.65%, NFOC=03, PN=59	MD=0.94, 95%CI (-6.17, 8.05), p=0.79, I^2=39.77%, NFOC=03, PN=59
	Long-term	---	MD=3.86, 95%CI (-2.97, 10.68), p=0.27, I^2=55.73%, NFOC=02, PN=29	MD=1.86, 95%CI (-2.82, 6.53), p=0.44, I^2=0%, NFOC=02, PN=29
Shod/Unshod conditions	Barefoot	---	---	---
	Shoe	MD=0.25, 95%CI (-0.24, 0.75), p=0.31, I^2=0%, NFOC=05, PN=117	MD=-0.07, 95%CI (-5.60, 5.46), p=0.98, I^2=73.59%, NFOC=05, PN=88	MD=1.22, 95%CI (-2.27, 4.71), p=0.49, I^2=0%, NFOC=05, PN=88
SSFO structure	Flat	MD=0.31, 95%CI (-0.60, 1.23), p=0.50, I^2=0%, NFOC=05, PN=93	MD=-0.07, 95%CI (-5.60, 5.46), p=0.98, I^2=73.59%, NFOC=05, PN=88	MD=1.22, 95%CI (-2.27, 4.71), p=0.49, I^2=0%, NFOC=05, PN=88
	Arch-support	MD=0.23, 95%CI (-0.35, 0.81), p=0.44, I^2=0%, NFOC=01, PN=24	--	---
Protrusion shape	Pyramidal/ Spikes	---	MD=-1.50, 95%CI (-7.61, 4.61), p=0.63, I^2=0%, NFOC=01, PN=30	MD=-2.70, 95%CI (-11.61, 6.21), p=0.55, I^2=0%, NFOC=01, PN=30
	Rounded knobs	MD=0.24, 95%CI (-0.34, 0.81), p=0.42, I^2=0%, NFOC=02, PN=37	MD=-5.00, 95%CI (-14.80, 4.80), p=0.32, I^2=73.33%, NFOC=02, PN=30	MD=3.75, 95%CI (-6.50, 14.00), p=0.47, I^2=25.94%, NFOC=02, PN=30
	Widened raised projections	MD=0.31, 95%CI (-0.66, 1.27), p=0.53, I^2=0%, NFOC=04, PN=80	MD=5.09, 95%CI (0.99, 9.19), **p=0.01,** I^2=0%, NFOC=02, PN=28	MD=1.58, 95%CI (-2.64, 5.79), p=0.46, I^2=0%, NFOC=02, PN=28
Protrusion height	Small	MD=0.36, 95%CI (-2.40, 3.12), p=0.80, I^2=0%, NFOC=01, PN=13	MD=-1.50, 95%CI (-7.61, 4.61), p=0.63, I^2=0%, NFOC=01, PN=30	MD=-2.70, 95%CI (-11.61, 6.21), p=0.55, I^2=0%, NFOC=01, PN=30
	Medium	MD=0.31, 95%CI (-0.66, 1.27), p=0.53, I^2=0%, NFOC=04, PN=80	---	---
	Large	MD=0.23, 95%CI (-0.35, 0.81), p=0.44, I^2=0%, NFOC=01, PN=24	MD=-5.00, 95%CI (-14.80, 4.80), p=0.32, I^2=0%, NFOC=02, PN=30	MD=3.75, 95%CI (-6.50, 14.00), p=0.47, I^2=0%, NFOC=02, PN=30
Protrusion positioning	Uniform across whole surface	MD=0.36, 95%CI (-2.40, 3.12), p=0.80, I^2=0%, NFOC=01, PN=13	MD=2.94, 95%CI (-1.87, 7.75), p=0.23, I^2=0%, NFOC=03, PN=58	MD=0.79, 95%CI (-3.01, 4.60), p=0.68, I^2=0%, NFOC=03, PN=58
	Site-specific	MD=0.25, 95%CI (-0.25, 0.75), p=0.33, I^2=0%, NFOC=05, PN=104	MD=-5.00, 95%CI (-14.80, 4.80), p=0.32, I^2=73.33%, NFOC=02, PN=30	MD=3.75, 95%CI (-6.50, 14.00), p=0.47, I^2=25.94%, NFOC=02, PN=30
D&B Index score	Good	---	MD=-5.00, 95%CI (-14.80, 4.80), p=0.32, I^2=73.33%, NFOC=02, PN=30	MD=3.75, 95%CI (-6.50, 14.00), p=0.47, I^2=25.94%, NFOC=02, PN=30
	Fair	MD=0.24, 95%CI (-0.34, 0.81), p=0.42, I^2=0%, NFOC=02, PN=37	MD=2.94, 95%CI (-1.87, 7.75), p=0.23, I^2=0%, NFOC=03, PN=58	MD=0.79, 95%CI (-3.01, 4.60), p=0.68, I^2=0%, NFOC=03, PN=58
	Poor	MD=0.31, 95%CI (-0.66, 1.27), p=0.53, I^2=0%, NFOC=04, PN=80	---	---

Dynamic Stability Through Functional Mobility Assessment				
Variables		**TUG**	**BBS**	**Mini-BESTest**
All comparisons		MD=-1.15, 95%CI (-1.82, -0.47), **p<0.001,** I^2=0%, NFOC=05, PN=101	MD=-0.36, 95%CI (-1.45, 0.73), p=0.51, I2=0%, NFOC=04, PN=86	MD=-0.03, 95%CI (-1.38, 1.33), p=0.97, I^2=0%, NFOC=02, PN=30
Sample size	n ≤20	MD=-1.19, 95%CI (-2.38, 0.00), **p=0.05,** I^2=0%, NFOC=03, PN=35	MD=-0.51, 95%CI (-1.69, 0.67), p=0.40, I^2=6.88%, NFOC=02, PN=66	---
	n >20	MD=-1.12, 95%CI (-1.94, -0.31), **p=0.01,** I^2=0%, NFOC=02, PN=66	MD=1.42, 95%CI (-2.81, 5.65), p=0.51, I^2=0%, NFOC=02, PN=20	---
Average age	<70	MD=-1.10, 95%CI (-1.79, -0.40), **p<0.001,** I^2=0%, NFOC=03, PN=81	MD=-0.51, 95%CI (-1.69, 0.67), p=0.40, I^2=6.88%, NFOC=02, PN=66	---
	≥70	MD=-1.95, 95%CI (-4.81, 0.91), p=0.18, I^2=0%, NFOC=02, PN=20	MD=1.42, 95%CI (-2.81, 5.65), p=0.51, I^2=0%, NFOC=02, PN=20	---
Follow-up time	Immediate	MD=-1.23, 95%CI (-2.19, -0.28), **p=0.01,** I^2=0%, NFOC=03, PN=58	MD=-1.00, 95%CI (-3.15, 1.16), p=0.36, I^2=4.65%, NFOC=02, PN=43	MD=0.60, 95%CI (-2.30, 3.50), p=0.69, I^2=0%, NFOC=01, PN=15
	Long-term	MD=-1.06, 95%CI (-2.01, -0.10), **p=0.03,** I^2=0%, NFOC=02, PN=43	MD=-0.10, 95%CI (-1.36, 1.26), p=0.94, I^2=0%, NFOC=02, PN=43	MD=-0.20, 95%CI (-1.73, 1.33), p=0.80, I^2=0%, NFOC=01, PN=15
Shod/Unshod conditions	Barefoot	---	---	---
	Shoe	MD=-1.15, 95%CI (-1.82, -0.47), **p<0.001**, I^2=0%, NFOC=05, PN=101	MD=-0.36, 95%CI (-1.45, 0.73), p=0.51, I2=0%, NFOC=04, PN=86	---
SSFO structure	Flat	MD=-1.10, 95%CI (-1.79, -0.40), **p<0.001,** I^2=0%, NFOC=03, PN=81	MD=-0.51, 95%CI (-1.69, 0.67), p=0.40, I^2=6.88%, NFOC=02, PN=66	---
	Arch-support	MD=-1.95, 95%CI (-4.81, 0.91), p=0.18, I^2=0%, NFOC=02, PN=20	MD=1.42, 95%CI (-2.81, 5.65), p=0.51, I^2=0%, NFOC=02, PN=20	---
Material hardness	Soft	MD=-1.19, 95%CI (-1.97, -0.40), **p<001,** I^2=0%, NFOC=04, PN=86	MD=-0.36, 95%CI (-1.45, 0.73), p=0.51, I2=0%, NFOC=04, PN=86	---
	Semi-rigid	MD=-1.03, 95%CI (-2.34, 0.28), p=0.12, I^2=0%, NFOC=01, PN=15	---	---
	Rigid	---	---	---
D&B Index score	Good	MD=-1.10, 95%CI (-1.79, -0.40), **p<0.001,** I^2=0%, NFOC=03, PN=81	MD=-0.51, 95%CI (-1.69, 0.67), p=0.40, I^2=6.88%, NFOC=02, PN=66	---
	Fair	---	---	---
	Poor	MD=-1.95, 95%CI (-4.81, 0.91), p=0.18, I^2=0%, NFOC=02, PN=20	MD=1.42, 95%CI (-2.81, 5.65), p=0.51, I^2=0%, NFOC=02, PN=20	---
SSFO: somatosensory stimulation foot orthoses; AP: anteroposterior; ML: mediolateral; Avg: average; CoP: center of pressure; COM-MOS: center of mass to margin of stability; TUG: Timed Up and Go; BBS: Berg Balance Scale; MD: mean difference; CI: confidence interval; NFOC: number of foot orthoses conditions;				

Table 2-4. Results of meta-regression exploring the influences of study-level characteristics.

Variables	Category	EyesOpen_AP CoP Range	EyesOpen_ML CoP Range	EyesOpen_Average CoP Velocity	EC_ML CoP Range
		Coefficient (95% CI), P-value, % heterogeneity explained	**Coefficient (95% CI), P-value, % heterogeneity explained**	**Coefficient (95% CI), P-value, % heterogeneity explained**	**Coefficient (95% CI), P-value, % heterogeneity explained**
Sample size		0.02 (-0.0114337 0.0661494), 0.167, 37%	0.020 (-0.037 to 0.079), 0.485, 88%	-0.00 (-0.041 to 0.023), 0.581, 0%	0.05 (-0.071 to 0.172), 0.420, 97%
Average age		-0.10 (-0.248 to 0.042), 0.166, 43%	-0.15 (-0.33 to 0.037), 0.116, 86%	-0.06 (-0.185 to 0.055), 0.288, 0%	-0.34 (-0.818 to 0.131), 0.167, 96%
Follow-up time	Immediate	**0.26** (0.031 to 0.497), **0.026,** 0%	-0.31 (-1.067 to 0.441), 0.416, 89%	-0.17 (-0.523 to 0.167), 0.312, 0%	-1.96 (-3.940 to 0.003), 0.050, 96%
	Long-term	-0.39 (-0.604 to -0.185), <0.001, 0%	-0.11 (-2.120 to 1.882), 0.907, 89%	0.1 (-0.453 to 0.653), 0.723, 0%	0.02 (-5.454 to 5.494), 0.994, 96%
Shod/Unshod conditions	Barefoot	-0.23 (-0.609 to 0.146), 0.230, 0%	-0.97 (-1.937 to -0.012), 0.047, 86%	-0.24 (-0.646 to 0.152), 0.226, 0%	-0.66, (-1.01 to -0.31), 0.002, 0%
	Shoe	0.052 (-0.336 to 0.442), 0.790, 0%	0.25 (-0.605 to 1.122), 0.558, 86%	0.07 (-0.360 to 0.500), 0.750, 0%	0.149, (-0.26 to 0.55), 0.425, 0%
SSFO structure	Flat	-0.57 (-0.816 to -0.324), 0.000, 0%	-0.36 (-1.196 to 0.473), 0.396, 88%	0.04 (-0.365 to 0.459), 0.823, 0%	-0.44 (-0.813 to -0.072), 0.025, 0%
	Arch-support	**0.45** (0.1868 to 0.718), **0.001,** 0%	-0.14 (-1.123 to 0.837), 0.775, 88%	-0.25 (-.667 to 0.165), 0.238, 0%	-0.19 (-0.572 to 0.192), 0.286, 0%
Material hardness	Soft	-0.45 (-1.411 to 0.504), 0.353, 0%	-0.07 (-1.102 to 0.950), 0.885, 89%	0.04 (-0.994 to 1.080), 0.936, 0%	-1.66 (-4.221383 .8935903), 0.202, 97%
	Semi-rigid	-0.26 (-0.753 to 0.223), 0.288	-0.03 (-1.825 to 1.745), 0.965, 89%	0.04 (-1.432 to 1.518), 0.954, 0%	---
	Rigid	-0.38 (-0.849 to 0.088), 0.111, 0%	-0.89 (-2.380 to 0.583), 0.235, 89%	-0.11 (-0.431 to 0.192), 0.452, 0%	-1.84 (-4.683 to 0.998) 0.204, 97%
Protrusion shape	Pyramidal/ Spikes	-0.35 (-0.722 to 0.010), 0.057, 43%	-0.12 (-1.373 to 1.113), 0.838, 89%	-0.01 (-0.441 to 0.408), 0.940, 0%	-0.61 (-3.622869 2.4023), 0.691, 96%
	Rounded knobs	-0.045 (-0.598 to 0.507), 0.871, 43%	-0.36 (-1.220 to 0.492), 0.405, 89%	-0.17 (-.5802518 .2280687), 0.393, 0%	-2.35 (-4.597 to -0.117), **0.039,** 96%
Protrusion height	Small	-0.453, (-0.879 to -0.026), 0.037, 38%	-0.12 (-1.339 to 1.080), 0.834, 88%	0.04 (-.3651727 .4591899), 0.823, 0%	-0.71 (-3.369 to 1.947), 0.600, 96%
	Medium	-0.39 (1.003 to 0.216), 0.207, 38%	-0.61 (-1.912 to 0.680), 0.352, 88%	-0.29 (-0.717 to 0.137), 0.184, 0%	-2.57 (-4.977 to -0.1655), 0.036, 96%

	Large	-0.27 (-0.754 to 0.205), 0.263, 38%	-0.14 (-1.420 to 1.130), 0.824, 88%	0.46 (-1.360 to 2.299), 0.615, 0%	---
Protrusion positioning	Uniform across whole surface	-0.44 (-.657 to -0.230), <0.001, 0%	-0.35 (-1.216 to 0.500), 0.413, 88%	-0.11 (-0.412 to 0.181), 0.447, 0%	-0.73 (-3.521 to 0.053), 0.057, 97%
	Site-specific	**0.32** (0.085 to 0.559), **0.008,** 0%	-0.14 (-1.379 to 1.089), 0.818, 88%	0.46 (-1.360 to 2.299), 0.615, 0%	---
SSFO: somatosensory stimulation foot orthoses; AP: anteroposterior; ML: mediolateral; Avg: average; CoP: center of pressure; MD: mean difference; CI: confidence interval;					

2.3.4 Meta-analysis and meta-regression

In the main analysis, the somatosensory foot orthoses significantly reduced AP CoP range [MD = -0.18; 95% CI (-0.27 to -0.09); p<0.001)] during standing with eyes open (Figure 2-2A). Subgroup analyses revealed that this effect was more pronounced in studies that examined immediate effects [MD = -0.39; 95% CI (-0.60 to -0.19); p<0.001], included 20 or fewer participants [MD = -0.34; 95% CI (-0.53 to -0.15); p<0.001], or focused on older adults under 70 years old [MD = -0.17; 95% CI (-0.27 to -0.08); p<0.001]. Greater effects were also observed for somatosensory foot orthoses with arch-support structures [MD = -0.12; 95% CI (-0.22 to -0.02); p=0.02], protrusions of semi-rigid hardness [MD = -0.12; 95% CI (-0.22 to -0.02); p=0.02], rounded knobs [MD = -0.41; 95% CI (-0.66 to -0.16); p<0.001], larger protrusion heights [MD = -0.12; 95% CI (-0.22 to -0.02); p=0.020], and site-specific placement [MD = -0.12; 95% CI (-0.22 to -0.02); p=0.02] (Table 2-3). The meta-regressions analysis confirmed significant positive correlations between effect sizes and immediate intervention [0.26 (0.031 to 0.497), p=0.026], somatosensory foot orthoses with arch-support structure [0.45 (0.1868 to 0.718), p=0.001], and site-specific placement of stimulating protrusions [0.32 (0.085 to 0.559), p=0.008] (Table 2-4). Under the same visual static conditions, no significant effects on ML CoP ranges were observed in the main group [MD = -0.26; 95% CI (-0.84 to 0.31); p=0.37] (Figure 2-2B). However, subgroup analyses revealed significant reductions in ML CoP range among: participants aged 70 or older [MD = -2.11; 95% CI (-3.56 to -0.66); p<0.001], somatosensory foot orthoses used with shoes [MD = -0.14; 95% CI (-0.23 to -0.05); p<0.001], somatosensory foot orthoses with arch-support structures [MD = -0.21; 95% CI (-0.30 to -0.11); p<0.001], protrusion of semi-rigid hardness [MD = -0.25; 95% CI (-0.36 to -0.14); p<0.001], pyramidal spikes [MD = -0.19; 95%CI (-0.28 to -0.09); p<0.001], larger heights [MD = -0.22; 95% CI (-0.32 to -0.12); p<0.001], and site-specific placement [MD = -0.22; 95% CI

(-0.32 to -0.12); p<0.001]. No significant association between these subgroup characteristics and effect sizes were observed in the meta-regression.

The main group analysis showed a reduction in ML CoP range [MD = -1.69; 95% CI (-3.15 to -0.23); p=0.02] during standing with eyes closed, while no significant effects were found for AP CoP range in either the main or subgroup analyses (Figure 2-3A-B). Notably, reductions in ML CoP range were observed in the following subgroups: studies with more than 20 participants [MD = -1.49; 95% CI (-3.20 to 0.22); p=0.09], participants aged 70 or older [MD = -4.13, 95% CI (-6.06 to -2.20); p<0.001], immediate investigations [MD = -1.93; 95% CI (-3.51 to -0.35); p=0.02], somatosensory foot orthoses used with barefoot [MD = -2.84; 95% CI (-5.21 to -0.48); p=0.02], somatosensory foot orthoses with flat structures [MD = -1.90; 95% CI (-3.5- to -0.31); p=0.02], protrusions of softer hardness [MD = -0.83; 95% CI (-1.44 to -0.21); p=0.01], rounded knobs [MD = -2.38; 95% CI (-5.04 to 0.28); p=0.08] and uniform placement [MD = -1.69; 95% CI (-3.15 to -0.23); p=0.02]. However, no significant correlations to effect sizes were identified in the regression analysis.

During level-ground walking, both main and subgroup analyses revealed no significant effects on: mediolateral MoS between the CoM and BoS [MD = 0.25; 95% CI (-0.24 to 0.75); p=0.31], step length [MD = -0.07; 95% CI (-5.60 to 5.46); p=0.98], and cadence [MD = -0.07; 95% CI (-5.60 to 5.46); p=0.98] (Figure 2-4A). However, the main group analysis demonstrated a significant reduction in the TUG score [MD = -1.15; 95% CI (-1.82 to -0.47); p<0.001] during functional mobility assessment (Figure 2-4B). This improvement was consistent across subgroups regardless of sample size, age (70 or older), timing of assessment, and somatosensory foot orthoses characteristics (use with shoes, flat structures, and softer protrusion materials). For both main and subgroup analyses, no significant effects were observed on other balance assessments including BBS [MD = -0.36; 95% CI (-1.45 to 0.73); p=0.51] and Mini-BESTest [MD = -0.03; 95% CI (-1.38 to 1.33); p=0.97] (Figure 2-4C).

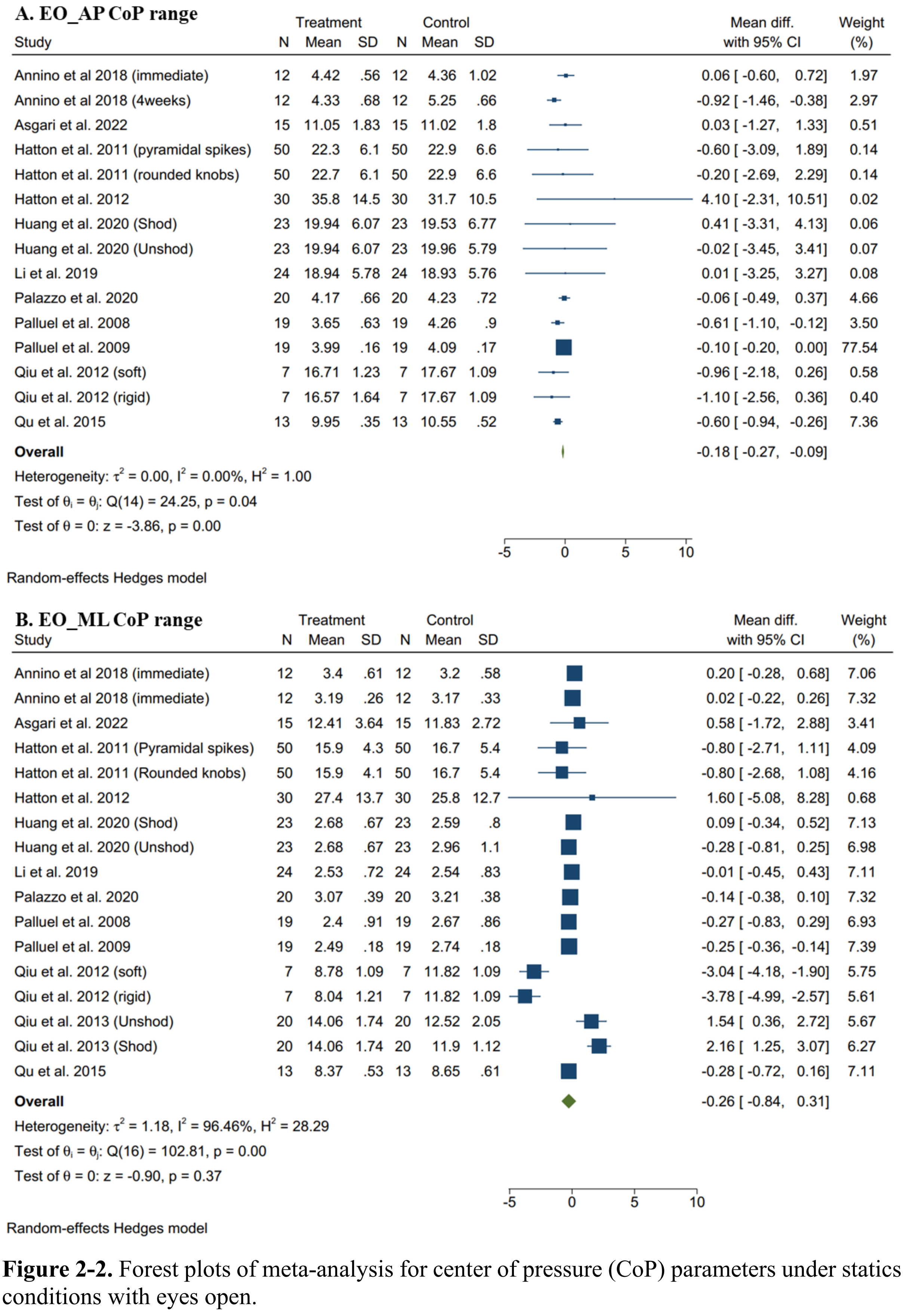


Figure 2-2. Forest plots of meta-analysis for center of pressure (CoP) parameters under statics conditions with eyes open.

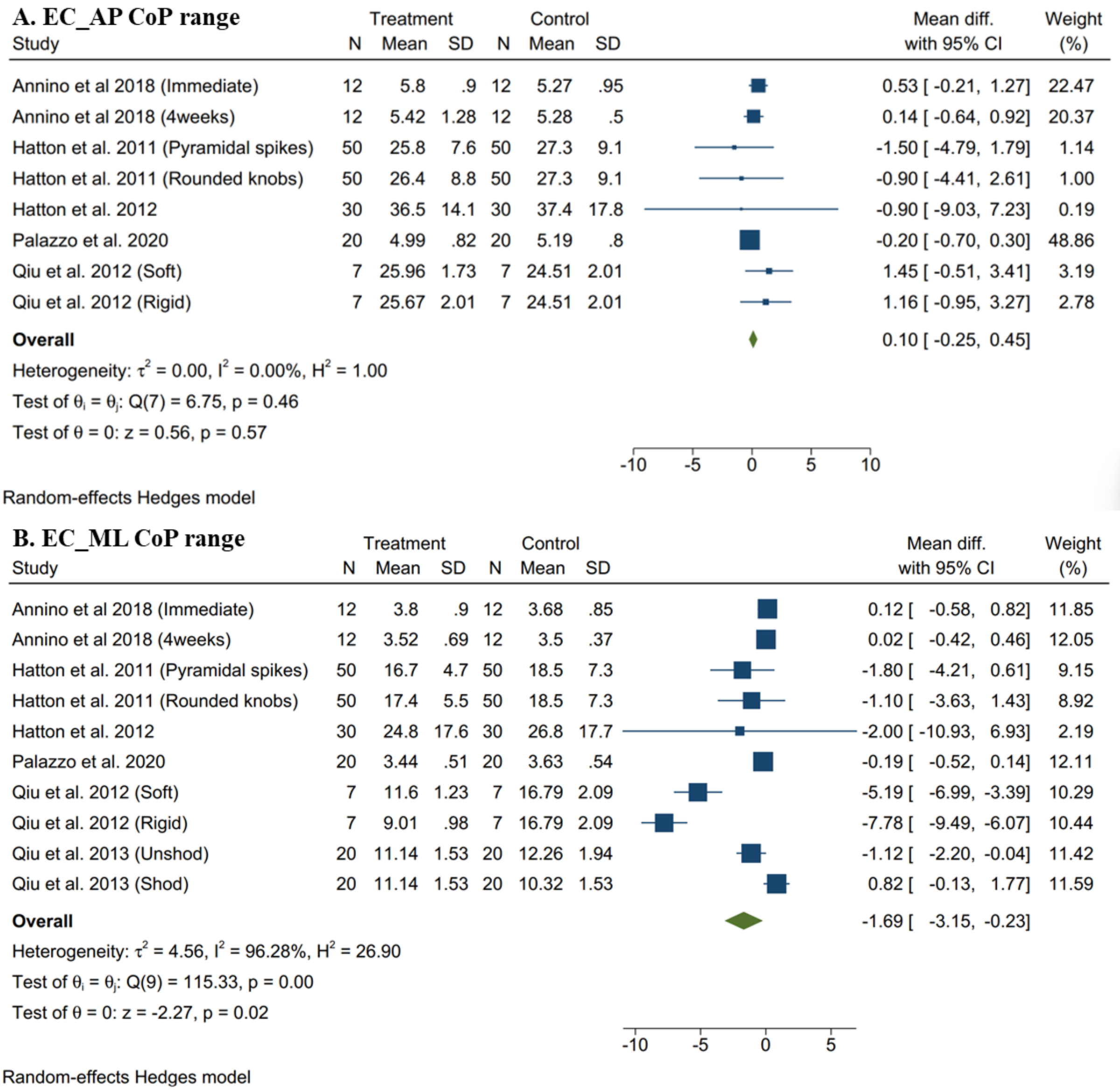


Figure 2-3. Forest plots of meta-analysis for center of pressure (CoP) parameters under statics conditions with eyes closed.

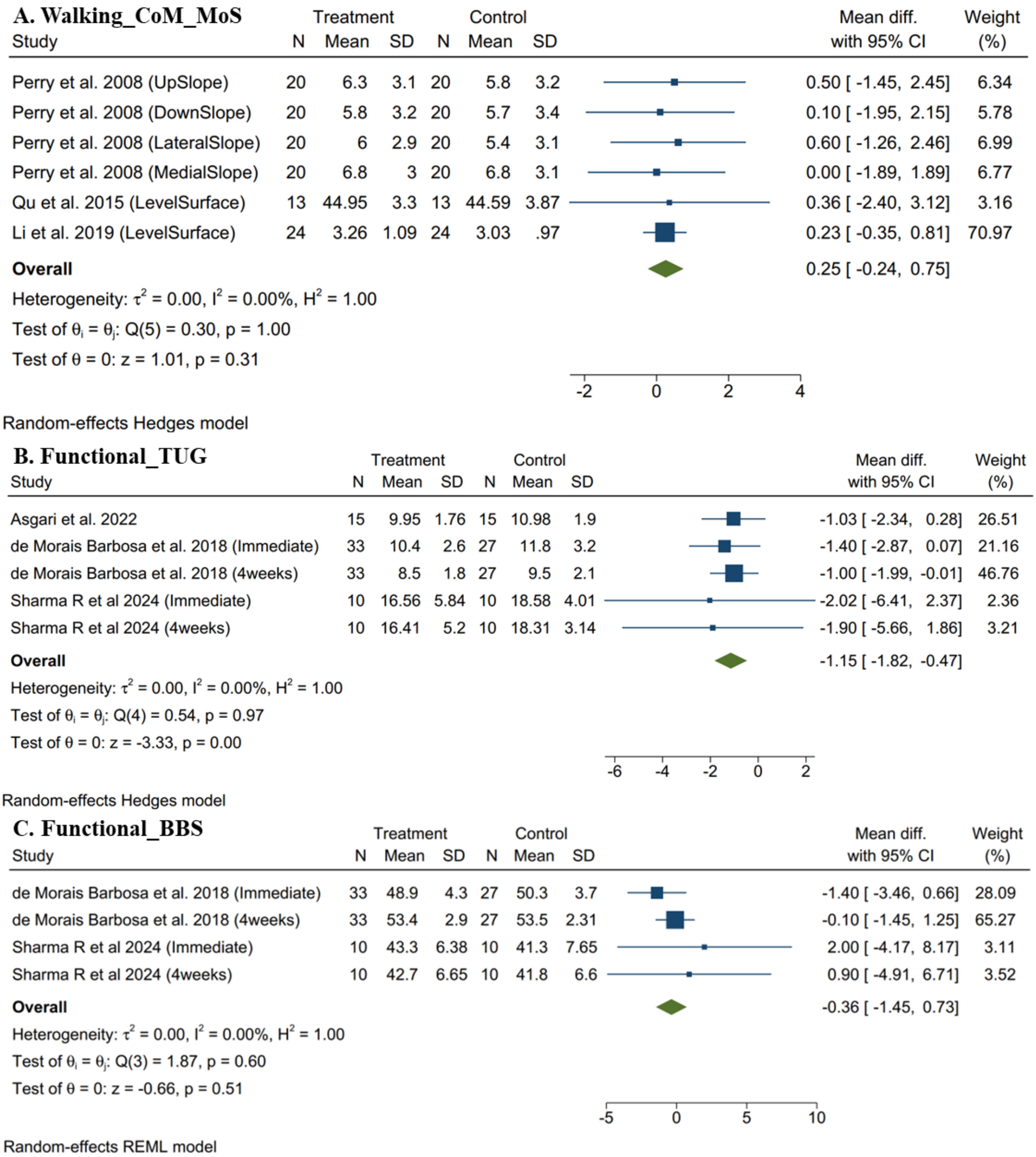


Figure 2-4. Forest plots of meta-analysis for functional/dynamic conditions.

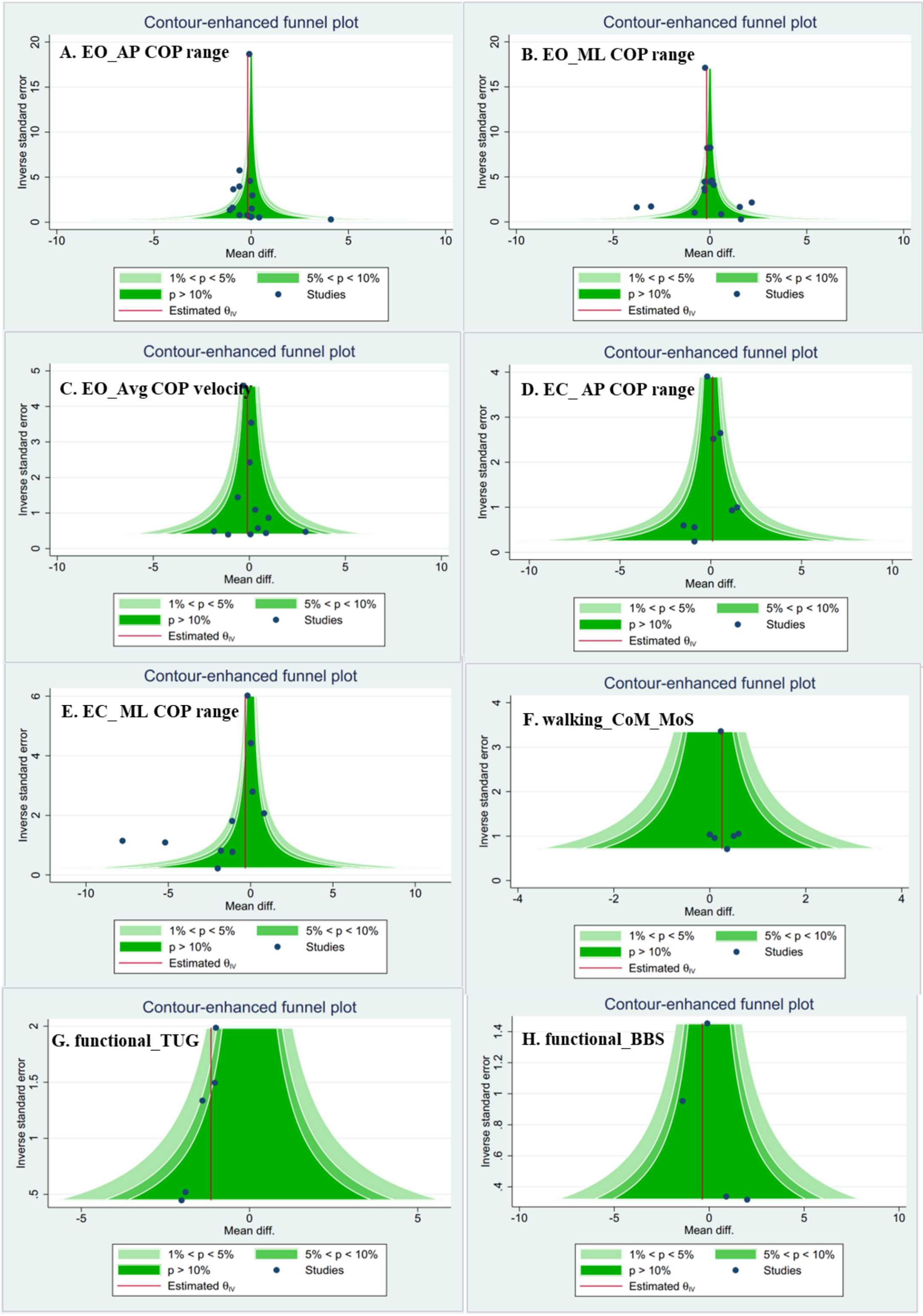


Figure 2-5. Visual illustration of funnel plots for publication bias.

2.3.5 Reporting publication biases

Visual inspection of funnel plots for the included somatosensory foot orthoses trials (Figure 2-5) revealed no evidence of publication bias. Furthermore, Egger's regression test indicated the absence of small study effects across all outcome measures, as all p-values > 0.05.

2.4 Discussion

This meta-analysis along with meta-regression provides a comprehensive understanding of how somatosensory foot orthoses affect postural stability and balance under static and dynamic conditions, particularly in older adults. Our findings indicate that somatosensory foot orthoses significantly reduce AP and/or ML range of CoP displacements, particularly when using somatosensory foot orthoses with specific features such as foot orthoses structures, shapes, heights, positioning, and hardness of protrusions. Additionally, the use of somatosensory foot orthoses consistently led to reductions in the TUG score (i.e., better performance), highlighting their potential to enhance functional mobility in this population.

The observed reduction in range of CoP displacements suggest improved postural stability and decreased sway variability during standing [41]. These findings align with previous studies that emphasizes the role of mechanoreceptor stimulation and enhanced sensory feedback in supporting balance and stability [42, 43]. Specifically, sensory input generated by in-shoe somatosensory foot orthoses with carefully designed features of protrusion such as shape, height, hardness, and positioning, appears critical for optimizing postural control. In the AP direction, reduced CoP range indicates enhanced ability to maintains its center of gravity over the BoS [44, 45]. Similarly, in the ML direction, reduced CoP range indicates better lateral stability. This is achieved through coordinated muscle activation, alongside proprioceptive feedback that facilitates real-time adjustments [46].

Interestingly, earlier studies reported limited or no effects of arch-support foot orthoses on ML CoP displacement [47]. Conversely, our meta-analysis found that incorporating stimulating protrusions into arch-support structures improve static balance, as indicated by reduced CoP ranges at both AP and ML directions. This suggests that integrating stimulating protrusions may enhance mechanoreceptor activation by increasing contact areas and tactile sensitivity between the foot orthoses and the mechanoreceptor of a foot [48]. Research has shown that AP and ML measures of CoP movement during static standing, such as amplitude, root-mean-square displacements, and mean speed, are significantly associated with future fall risk [49, 50]. This suggests that improvements in static balance can contribute to fall prevention and reduced associated injury risks in older adults. However, the design of these stimulating protrusions needs careful consideration. For example, although larger protrusions may improve somatosensory input, they can also increase frictional forces in high plantar loading areas, potentially causing discomfort or callus formation [51-53].

The findings underscore the importance of site-specific placement of stimulating protrusions to balance effective sensory stimulation with user comfort. Although some studies reported improved CoP displacement through strategic positioning, most of these studies did not account for tactile sensitivity mapping in their designs. Placing protrusions under high plantar loading areas, such as metatarsal heads and heel areas [30, 31], may increase contact forces and lead to discomfort or even contribute to ulcer formation [51, 52]. Additionally, protruding tubes at the foot perimeter limit the applicability across the plantar surface [40].

Variations in tactile sensitivity thresholds [54-56] and plantar pressure patterns [57, 58] are observed across different regions of the foot. These differences highlight the need for individualized somatosensory foot orthoses with strategic protrusions. The heel, metatarsal heads, lateral midfoot, and big toe typically experience higher plantar loads during standing and walking. In contrast, the medial arch, midfoot, and raised surfaces are exposed to lower load. These low plantar loading areas tend to have greater tactile sensitivity. Protrusion height, diameter, and density can be adjusted in these sensitive areas to optimize mechanoreceptor stimulation. Meanwhile, minimizing excessive vertical and frictional forces in high-load zones is necessary to avoid discomfort or injury.

Although, correlation between design parameters and effect sizes were not statistically significant, somatosensory foot orthoses with flat structures and pyramidal spikes were associated with improved mediolateral stability. A small number of studies also reported enhancements in functional mobility, as evidenced by reduced Timed Up and Go (TUG) scores on efficient transition from sitting to standing and walking [59]. However, findings varied and some somatosensory foot orthoses with softer protrusions and flat structure showed limited benefits, suggesting a complex interplay between design parameters. Moreover, no significant improvements were observed in broader functional assessments such as the MoS during walking, BBS and mini-BESTest of functional mobility assessments [60]. One possible explanation is that somatosensory foot orthoses would deliver varying degrees of mechanoreceptor stimulation in response to different postural conditions or activities. Notably, studies reporting positive effects often involved immediate post-intervention testing and small sample sizes.

Emerging evidence from populations with neurological conditions, such as Parkinson's disease [61], diabetic peripheral neuropathy [62-64], and multiple sclerosis [65], further supports the potential of somatosensory foot orthoses to enhance plantar sensory feedback and improve static balance, stride length, and plantar sensation. In these groups, some participants report increased mobility confidence and foot awareness [61, 62, 65], while others experience minimal effects [63, 64], underscoring the individualized nature of these interventions.

Overall, these findings suggest that somatosensory foot orthoses may serve as a promising adjunct for improving balance and mobility across both healthy older adults and those with neurological conditions. However, the effectiveness of these devices is influenced by both design features and individual characteristics, highlighting the need for further research into long-term adaptations, refined orthosis designs, and larger, more diverse study populations to optimize outcomes and clinical applicability [66].

Despite the valuable insights gained, several limitations should be acknowledged. First, variability in study designs and foot orthoses specifications, including structure, shape, height, materials, and positioning of stimulating protrusions, may affect the consistency and generalizability of the results. The use of machine learning and deep learning approach, the AI would help to understand how these specifications interact each other and optimize them into a somatosensory foot orthoses design. Further understanding how these design features interact with participant demographics (tactile sensitivity threshold, age, and gender) could aid foot orthoses designs for diverse populations with balance impairments. Secondly, most of included studies focused on immediate effects, which limits understanding of long-term outcomes. To address this, future investigations should implement standardized protocols and utilize uniform somatosensory foot orthoses designs. Emphasis should be placed on conducting longitudinal studies with larger and diverse individuals with sensory deficits or neurological conditions. Additionally, customizing orthoses according to individual plantar tactile sensitivity maps could enhance effectiveness. Third, only a limited number of studies investigated postural stability during dynamic movements. Future studies should explore somatosensory foot orthoses effects on postural stability across a broader range of conditions, including static standing, walking on varying terrains, as well as reactive postural responses to various perturbations.

2.5 Conclusion

This systematic review and meta-regression analysis highlight the potential of somatosensory foot orthoses in improving postural control and functional mobility in older adults. Key design features, included the protrusion shape, height, hardness, and positioning of stimulating protrusions, are crucial for maximizing somatosensory foot orthoses's effectiveness. Personalized orthotic interventions, guided by user-specific characteristics, may offer the most promising outcomes. To improve generalizability, further studies should include a broader range of participants, investigate the underlying mechanisms, and evaluate long-term impacts. Additionally, developing standardized protocols and design guidelines is crucial for validating and expanding the clinical and everyday benefits of somatosensory foot orthoses.

References

[1] G. Collaborators, Global, regional, and national burden of diseases and injuries for adults 70 years and older: systematic analysis for the Global Burden of Disease 2019 Study, BMJ 376 (2022) e068208. https://doi.org/10.1136/bmj-2021-068208

[2] S. Naja, M.M.E. Din Makhlouf, M.A.H. Chehab, An ageing world of the 21st century: a literature review, International Journal Of Community Medicine And Public Health 4(12) (2017) 4363-4369. https://doi.org/10.18203/2394-6040.ijcmph20175306

[3] A.Y. Chang, V.F. Skirbekk, S. Tyrovolas, N.J. Kassebaum, J.L. Dieleman, Measuring population ageing: an analysis of the Global Burden of Disease Study 2017, Lancet Public Health 4(3) (2019) e159-e167. https://doi.org/10.1016/s2468-2667(19)30019-2

[4] D. Rand, W.C. Miller, J. Yiu, J.J. Eng, Interventions for addressing low balance confidence in older adults: a systematic review and meta-analysis, Age Ageing 40(3) (2011) 297-306. https://doi.org/10.1093/ageing/afr037

[5] K. Khanuja, J. Joki, G. Bachmann, S. Cuccurullo, Gait and balance in the aging population: Fall prevention using innovation and technology, Maturitas 110 (2018) 51-56. https://doi.org/10.1016/j.maturitas.2018.01.021

[6] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293

[7] A.L. Hatton, K. Rome, J. Dixon, D.J. Martin, P.O. McKeon, Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults, J Am Podiatr Med Assoc 103(6) (2013) 516-33. https://doi.org/10.7547/1030516

[8] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology 70(8) (2024) 801-811. https://doi.org/10.1159/000539591

[9] D. Orth, K. Davids, J. Wheat, L. Seifert, J. Liukkonen, T. Jaakkola, et al., The role of textured material in supporting perceptual-motor functions, PLoS One 8(4) (2013) e60349. https://doi.org/10.1371/journal.pone.0060349

[10] A. Aboutorabi, M. Bahramizadeh, M. Arazpour, R. Fadayevatan, F. Farahmand, S. Curran, et al., A systematic review of the effect of foot orthoses and shoe characteristics on balance in healthy older subjects, Prosthet Orthot Int 40(2) (2016) 170-81. https://doi.org/10.1177/0309364615588342

[11] R.P.W. Kenny, G. Atkinson, D.L. Eaves, D. Martin, N. Burn, J. Dixon, The effects of textured materials on static balance in healthy young and older adults: A systematic review with meta-analysis, Gait Posture 71 (2019) 79-86. https://doi.org/10.1016/j.gaitpost.2019.04.017

[12] C.B. Terwee, L.B. Mokkink, D.L. Knol, R.W. Ostelo, L.M. Bouter, H.C. de Vet, Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist, Qual Life Res 21(4) (2012) 651-7. https://doi.org/10.1007/s11136-011-9960-1.

[13] G. Desmyttere, M. Hajizadeh, J. Bleau, M. Begon, Effect of foot orthosis design on lower limb joint kinematics and kinetics during walking in flexible pes planovalgus: A systematic review and meta-analysis, Clin Biomech (Bristol) 59 (2018) 117-129. https://doi.org/10.1016/j.clinbiomech.2018.09.018.

[14] M. Hajizadeh, A. Hashemi Oskouei, F. Ghalichi, G. Sole, Knee Kinematics and Joint Moments During Stair Negotiation in Participants With Anterior Cruciate Ligament

Deficiency and Reconstruction: A Systematic Review and Meta-Analysis, Pm r 8(6) (2016) 563-579.e1. https://doi.org/10.1016/j.pmrj.2016.01.014.

[15] G. Tsafnat, P. Glasziou, M.K. Choong, A. Dunn, F. Galgani, E. Coiera, Systematic review automation technologies, Syst Rev 3 (2014) 74. https://doi.org/10.1186/2046-4053-3-74

[16] J.R. Dettori, D.C. Norvell, J.R. Chapman, Fixed-Effect vs Random-Effects Models for Meta-Analysis: 3 Points to Consider, Global Spine J 12(7) (2022) 1624-1626. https://doi.org/10.1177/21925682221110527

[17] C. de Morais Barbosa, M.B. Bértolo, J.Z. Gaino, M. Davitt, Z. Sachetto, E. de Paiva Magalhães, The effect of flat and textured insoles on the balance of primary care elderly people: a randomized controlled clinical trial, Clin Interv Aging 13 (2018) 277-284. https://doi.org/10.2147/cia.S149038

[18] L.C. Lam, C.W. Tam, V.W. Lui, W.C. Chan, S.S. Chan, S. Wong, et al., Prevalence of very mild and mild dementia in community-dwelling older Chinese people in Hong Kong, Int Psychogeriatr 20(1) (2008) 135-48. https://doi.org/10.1017/s1041610207006199

[19] H. Lohne-Seiler, B.H. Hansen, E. Kolle, S.A. Anderssen, Accelerometer-determined physical activity and self-reported health in a population of older adults (65-85 years): a cross-sectional study, BMC Public Health 14 (2014) 284. https://doi.org/10.1186/1471-2458-14-284

[20] J.J. Deeks, J.P.T. Higgins, D.G. Altman, Analysing data and undertaking meta-analyses, Cochrane Handbook for Systematic Reviews of Interventions2019, pp. 241-284.

[21] P.T.J. Higgins, S. Green, 7.7.3.2 Obtaining standard deviations from standard errors and confidence intervals for group means, in: P. Higgins, Green, S (Ed.), Cochrane Handbook for Systematic Reviews of Interventions, The Cochrane Collaboration2011.

[22] J.A. Sterne, M. Egger, Funnel plots for detecting bias in meta-analysis: guidelines on choice of axis, J Clin Epidemiol 54(10) (2001) 1046-55. https://doi.org/10.1016/s0895-4356(01)00377-8.

[23] M. Egger, G. Davey Smith, M. Schneider, C. Minder, Bias in meta-analysis detected by a simple, graphical test, Bmj 315(7109) (1997) 629-34. https://doi.org/10.1136/bmj.315.7109.629.

[24] N. Asgari, G. Yeowell, E. Sadeghi-Demneh, A comparison of the efficacy of textured insoles on balance performance in older people with versus without plantar callosities, Gait Posture 94 (2022) 217-221. https://doi.org/10.1016/j.gaitpost.2022.03.022

[25] C. Pinvanichkul, A. Siriphorn, Effect of Walking Training with Textured Insole Socks in Older Adults, Physical & Occupational Therapy In Geriatrics 40(2) (2022) 135-149. https://doi.org/10.1080/02703181.2021.1994097.

[26] G. Annino, F. Palazzo, M.S. Alwardat, V. Manzi, P. Lebone, V. Tancredi, et al., Effects of long-term stimulation of textured insoles on postural control in health elderly, J Sports Med Phys Fitness 58(4) (2018) 377-384. https://doi.org/10.23736/s0022-4707.16.06705-0

[27] A. Hartmann, K. Murer, R.A. de Bie, E.D. de Bruin, The effect of a training program combined with augmented afferent feedback from the feet using shoe insoles on gait performance and muscle power in older adults: a randomised controlled trial, Disabil Rehabil 32(9) (2010) 755-64. https://doi.org/10.3109/09638280903295441

[28] A.L. Hatton, J. Dixon, K. Rome, D. Martin, Standing on textured surfaces: effects on standing balance in healthy older adults, Age Ageing 40(3) (2011) 363-8. https://doi.org/10.1093/ageing/afr026

[29] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11

[30] M. Huang, K.L. Yick, S.P. Ng, J. Yip, R.T. Cheung, The effect of support surface and footwear condition on postural sway and lower limb muscle action of the older women, PLoS One 15(6) (2020) e0234140. https://doi.org/10.1371/journal.pone.0234140

[31] P.L. Li, K.L. Yick, S.P. Ng, J. Yip, Influence of Textured Indoor Footwear on Posture Stability of Older Women Based on Center-of-Pressure Measurements, Hum Factors 61(8) (2019) 1247-1260. https://doi.org/10.1177/0018720819837414

[32] F. Palazzo, A. Nardi, N. Lamouchideli, A. Caronti, A. Alashram, E. Padua, et al., The effect of age, sex and a firm-textured surface on postural control, Exp Brain Res 239(7) (2021) 2181-2191. https://doi.org/10.1007/s00221-021-06063-2

[33] E. Palluel, V. Nougier, I. Olivier, Do spike insoles enhance postural stability and plantar-surface cutaneous sensitivity in the elderly?, Age (Dordr) 30(1) (2008) 53-61. https://doi.org/10.1007/s11357-008-9047-2

[34] E. Palluel, I. Olivier, V. Nougier, The lasting effects of spike insoles on postural control in the elderly, Behav Neurosci 123(5) (2009) 1141-7. https://doi.org/10.1037/a0017115

[35] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[36] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Effects of textured insoles on balance in people with Parkinson's disease, PLoS One 8(12) (2013) e83309. https://doi.org/10.1371/journal.pone.0083309

[37] X. Qu, Impacts of different types of insoles on postural stability in older adults, Appl Ergon 46 Pt A (2015) 38-43. https://doi.org/10.1016/j.apergo.2014.06.005

[38] L. Sarma R, Minakshi, S. Raju, Effect of Customized Foot Insoles and Textured Insoles on the Balance and Postural Control in Elderly with Pes Planus: A Randomized Controlled

Trial, RGUHS Journal of Allied Health Sciences 4(1) (2024).
https://doi.org/10.26463/rjahs.4_1_5

[39] A. Kiaghadi, M. Bahramizadeh, M. Hadadi, Effect of Textured and Prefabricated Insole Use With Medical or Sports Shoes on Dynamic Postural Control in Elderly People, Topics in Geriatric Rehabilitation 36(1) (2020). https://doi.org/10.1097/TGR.0000000000000255

[40] S.D. Perry, A. Radtke, W.E. McIlroy, G.R. Fernie, B.E. Maki, Efficacy and effectiveness of a balance-enhancing insole, J Gerontol A Biol Sci Med Sci 63(6) (2008) 595-602. https://doi.org/10.1093/gerona/63.6.595

[41] D.A. Winter, F. Prince, J.S. Frank, C. Powell, K.F. Zabjek, Unified theory regarding A/P and M/L balance in quiet stance, J Neurophysiol 75(6) (1996) 2334-43. https://doi.org/10.1152/jn.1996.75.6.2334

[42] R.J. Peterka, Sensory integration for human balance control, Handb Clin Neurol 159 (2018) 27-42. https://doi.org/10.1016/b978-0-444-63916-5.00002-1

[43] F.B. Horak, Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls?, Age Ageing 35 Suppl 2 (2006) ii7-ii11. https://doi.org/10.1093/ageing/afl077

[44] S.S. Hasan, D.W. Robin, D.C. Szurkus, D.H. Ashmead, S.W. Peterson, R.G. Shiavi, Simultaneous measurement of body center of pressure and center of gravity during upright stance. Part II: Amplitude and frequency data, Gait & Posture 4(1) (1996) 11-20. https://doi.org/10.1016/0966-6362(95)01031-9

[45] D.A. Winter, Human balance and posture control during standing and walking, Gait & Posture 3(4) (1995) 193-214. https://doi.org/10.1016/0966-6362(96)82849-9

[46] J. Wang, Y. Li, G.Y. Yang, K. Jin, Age-Related Dysfunction in Balance: A Comprehensive Review of Causes, Consequences, and Interventions, Aging Dis 16(2) (2024) 714-737. https://doi.org/10.14336/ad.2024.0124-1

[47] A. Aboutorabi, M. Arazpour, S.W. Hutchins, S. Curran, M. Maleki, The efficacy of foot orthoses on alteration to center of pressure displacement in subjects with flat and normal feet: a literature review, Disabil Rehabil Assist Technol 10(6) (2015) 439-444. https://doi.org/10.3109/17483107.2014.913716

[48] M. Nouman, W. Leelasamran, S. Chatpun, Effectiveness of Total Contact Orthosis for Plantar Pressure Redistribution in Neuropathic Diabetic Patients During Different Walking Activities, Foot Ankle Int 38(8) (2017) 901-908. https://doi.org/10.1177/1071100717704427

[49] P. Poncumhak, A. Srithawong, W. Duangsanjun, P. Amput, Comparison of the Ability of Static and Dynamic Balance Tests to Determine the Risk of Falls among Older Community-Dwelling Individuals, J Funct Morphol Kinesiol 8(2) (2023). https://doi.org/10.3390/jfmk8020043

[50] M. Piirtola, P. Era, Force platform measurements as predictors of falls among older people - a review, Gerontology 52(1) (2006) 1-16. https://doi.org/10.1159/000089820

[51] A. Gefen, Why is the heel particularly vulnerable to pressure ulcers?, Br J Nurs 26(Sup20) (2017) S62-s74. https://doi.org/10.12968/bjon.2017.26.Sup20.S62

[52] H.B. Menz, G.V. Zammit, S.E. Munteanu, Plantar pressures are higher under callused regions of the foot in older people, Clin Exp Dermatol 32(4) (2007) 375-80. https://doi.org/10.1111/j.1365-2230.2007.02421.x

[53] V.V. Broderick, L.J. Cowan, Pressure injury related to friction and shearing forces in older adults, Journal of Dermatology and Skin Science 3(2) (2021). https://doi.org/10.29245/2767-5092/2021/2.1136.

[54] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[55] N.D. Strzalkowski, R.L. Mildren, L.R. Bent, Thresholds of cutaneous afferents related to perceptual threshold across the human foot sole, J Neurophysiol 114(4) (2015) 2144-51. https://doi.org/10.1152/jn.00524.2015

[56] N.D. Strzalkowski, J.J. Triano, C.K. Lam, C.A. Templeton, L.R. Bent, Thresholds of skin sensitivity are partially influenced by mechanical properties of the skin on the foot sole, Physiol Rep 3(6) (2015). https://doi.org/10.14814/phy2.12425

[57] P.R. Cavanagh, M.M. Rodgers, A. Iiboshi, Pressure distribution under symptom-free feet during barefoot standing, Foot Ankle 7(5) (1987) 262-76. https://doi.org/10.1177/107110078700700502

[58] M.J. Hessert, M. Vyas, J. Leach, K. Hu, L.A. Lipsitz, V. Novak, Foot pressure distribution during walking in young and old adults, BMC Geriatr 5 (2005) 8. https://doi.org/10.1186/1471-2318-5-8

[59] D. Podsiadlo, S. Richardson, The timed "Up & Go": a test of basic functional mobility for frail elderly persons, J Am Geriatr Soc 39(2) (1991) 142-8. https://doi.org/10.1111/j.1532-5415.1991.tb01616.x

[60] G. Moisan, K. Robb, C. Mainville, V. Blanchette, Effects of foot orthoses on the biomechanics of the lower extremities in adults with and without musculoskeletal disorders during functional tasks: A systematic review, Clin Biomech (Bristol) 95 (2022) 105641. https://doi.org/10.1016/j.clinbiomech.2022.105641

[61] E. Lirani-Silva, R. Vitório, F.A. Barbieri, D. Orcioli-Silva, L. Simieli, L.T.B. Gobbi, Continuous use of textured insole improve plantar sensation and stride length of people with Parkinson's disease: A pilot study, Gait Posture 58 (2017) 495-497. https://doi.org/10.1016/j.gaitpost.2017.09.017

[62] A.L. Hatton, M.D. Chatfield, E.M. Gane, J.N. Maharaj, T. Cattagni, J. Burns, et al., The effects of wearing textured versus smooth shoe insoles for 4-weeks in people with diabetic

peripheral neuropathy: a randomised controlled trial, Disabil Rehabil 47(3) (2025) 751-761. https://doi.org/10.1080/09638288.2024.2360658

[63] J. Paton, S. Glasser, R. Collings, J. Marsden, Getting the right balance: insole design alters the static balance of people with diabetes and neuropathy, J Foot Ankle Res 9 (2016) 40. https://doi.org/10.1186/s13047-016-0172-3

[64] J. Son, J.A. Ashton-Miller, J.K. Richardson, Do ankle orthoses improve ankle proprioceptive thresholds or unipedal balance in older persons with peripheral neuropathy?, Am J Phys Med Rehabil 89(5) (2010) 369-75. https://doi.org/10.1097/PHM.0b013e3181d89861

[65] Y. Baron, A.L. Hatton, P.O. McKeon, K. Rome, D. Martin, J. Dixon, Experiences of people with Multiple Sclerosis using textured insoles: an interpretive phenomenological exploration, Research Square (2019). https://doi.org/10.21203/rs.2.10505/v1

[66] K. Mills, P. Blanch, A.R. Chapman, T.G. McPoil, B. Vicenzino, Foot orthoses and gait: a systematic review and meta-analysis of literature pertaining to potential mechanisms, Br J Sports Med 44(14) (2010) 1035-46. https://doi.org/10.1136/bjsm.2009.066977

CHAPTER 3

EFFECTS OF PREFABRICATED SOMATOSENSORY FOOT ORTHOSES ON POSTURAL BALANCE, STABILITY, AND GAIT IN OLDER ADULTS

3.1 Introduction

Postural balance and stability are crucial for promoting healthy aging and reducing fall risks in older adults. The critical components of postural stability and gait relying on a complex balance system that integrates sensory inputs from the visual, vestibular, and somatosensory systems [1]. These inputs are processed by the central nervous system to generate appropriate motor responses through the body's musculoskeletal system, helping to maintain equilibrium. Age-related declines in sensory function, muscle strength, and cognitive processing can compromise these systems, leading to impaired balance in older adults [2, 3]. The prevalence of balance deficits is associated with an increased risk of instability, resulting in higher fall risk, severe injuries, and even mortality [3, 4]. Therefore, developing strategies to enhance postural stability and gait in older adults is of paramount importance.

A variety of conservative treatment modalities or interventions including physical therapy, balance exercises, and assistive devices have been developed to address balance and stability issues in older adults [5-7]. While these interventions can be effective, they often require significant time, effort, cost and adherence from individuals. Foot orthoses, including insoles, shoe inserts, and specialized footwear are another strategy recommended to enhance postural stability and gait [8]. These orthoses are often designed to provide structural and geometrical support to the foot, redistribute plantar pressure and force, and improve alignment. For instance, traditional foot orthoses, such as flat and contoured foot orthoses with arch-supports, raised heel cups, and/or mediolateral wedges have been shown to offer some benefits in terms of support, stability, and comfort [9, 10]. Though traditional foot orthoses have shown benefits in correcting specific biomechanical misalignments of the foot and ankle, they have not adequately ameliorated the tactile sensory deficits that contribute to balance impairments in older adults [10, 11]. More recently, foot orthoses featuring textured surfaces or protrusions designed to stimulate mechanoreceptors on the glabrous skin of the foot have been proposed to boost somatosensory feedback. This enhanced tactile input may contribute to improvements in postural balance and stability [10, 11]. However, their impact on sensory feedback and proprioception is not fully understood. Somatosensory foot orthoses in these studies often incorporated protrusions into flat structure lacking contact surfaces for stimulation. A recent systematic review with meta-regression on somatosensory foot orthoses revealed positive correlation to improved postural sway with arch-support structure (see Chapter 2). Additionally, these studies have been conducted during static standing or in a fewer cases during walking on level terrains, which are less challenging and do not fully represent the varied and dynamic environments encountered in daily life [12-18]. Real-world environments often involve varied inclined terrains, such as walking on level, upward, or downward terrains, which pose additional challenges to balance and stability.

Previous research has often utilized force plates and motion capture systems to collect center of pressure (CoP) data for analyzing sway variability. Functional clinical tools have also been employed to evaluate balance and stability [10]. Computerized dynamic posturography (CDP) provides a quantitative method for assessing balance performance under various sensory conditions, including visual, vestibular, and somatosensory inputs with varying perturbations [19-21]. This technique offers a comprehensive evaluation of how the balance system integrates sensory and motor components. CDP allows for tracking the center of gravity (CoG) within the limits of stability to measure postural sway. Postural sway analysis can reveal the use of ankle or hip strategies during static and dynamic perturbations, assess weight-bearing symmetry between limbs, and identify motor adaptations in response to perturbations [22-24]. A comprehensive understanding of whether foot orthoses with tactile stimulating protrusions can provide benefits in postural stability and gait on varied static and dynamic terrains as well as perturbation conditions in older adults, through enhanced somatosensory feedback, is still needed.

Thus, this study aimed to evaluate the effects of prefabricated somatosensory foot orthoses with entire bottom stimulating knobs and arch support on postural balance while standing with eyes open and closed as well as while walking across varied inclined terrains in older adults. Additionally, this study aimed to investigate the immediate effects of somatosensory foot orthoses on postural stability using the CDP method. We hypothesized that foot orthoses with entire top stimulating knobs and arch-support would enhance postural balance in the elderly by reducing postural sway under varied terrain conditions and improving scores related to equilibrium in postural strategies, sensory inputs, and gait symmetry under various perturbation conditions.

3.2 Methods

3.2.1 Participants

Healthy older adults were recruited from local elderly centres using convenience sampling. To be eligible, participants needed to be at least 65 years old. They also had to be capable of walking continuously for 30 minutes without breaks or external assistance. Additionally, participants were required to engage in at least 150 minutes of walking per week. Participants were excluded if they had a BMI greater than 40, high arches (pes cavus), or flat feet (pes planus). Additional criteria included neuromuscular or central nervous system, or vestibular conditions, and severe foot deformities such as peripheral neuropathy, ulcers, or pain. To confirm adequate protective tactile sensitivity, a Semmes Weinstein Monofilament (SWM) test using a 10g load was applied at 10 plantar sites, outlined in a previous study [25]. Individuals who were unable to detect the monofilament at four or more sites were excluded. All participants provided informed consent after being informed on the study details.

3.2.2 Foot orthoses

The participants' postural control was examined with two different foot orthoses conditions: (i) conventional flat foot orthoses and (ii) prefabricated somatosensory foot orthoses with integrated arch-support. The flat top of the somatosensory foot orthoses (Copper Fit Zen Step Comfort, China) was entirely covered with a uniformly distributed array of rounded shaped protruding knobs (larger knobs: length–15mm, width–10mm, height–3mm; smaller knobs: length–12mm, width–8mm, height–2mm; hardness: Shore A 30. A raised heel-cup with arch-supports (hardness: Shore A 40) was integrated into the full-length foot orthoses (Figure 3-1A-B). Both the arch-support structure and the rounded protrusions have been shown to be positively correlated with balance outcomes, as reported in a recent systematic review (see Chapter 2). During the balance trials, foot orthoses were inserted into the standardized elderly shoe (Shiying 520A, Shiying Trading Co. Ltd., China). Standardized socks made of 75% cotton and with a thickness of 1 mm (Zhuji Dongling Needle Textile Co., Ltd., China) were provided to all participants to minimize the confounding effects of material and thickness during the trials.

3.2.3 Data collection and processing

There are two parts of assessments: Postural control via Force plate integrated treadmill (for assessing postural sway, spatiotemporal gait, and plantar forces/pressures on varied inclined terrains) and postural stability via Bertec Balance Advantage System (sensory organization, motor control, and adaptation in response to various perturbation conditions). The first part comprised of five conditions: two static (standing with eyes open and eyes closed) and three dynamic (walking on level terrain: 0-degree inclination, upward terrain: +5 degrees inclination, and downward terrain: -5 degrees inclination), with participants wearing either flat foot orthoses or somatosensory foot orthoses (Figure 3-1C). Three successful trials were collected to ensure data reliability.

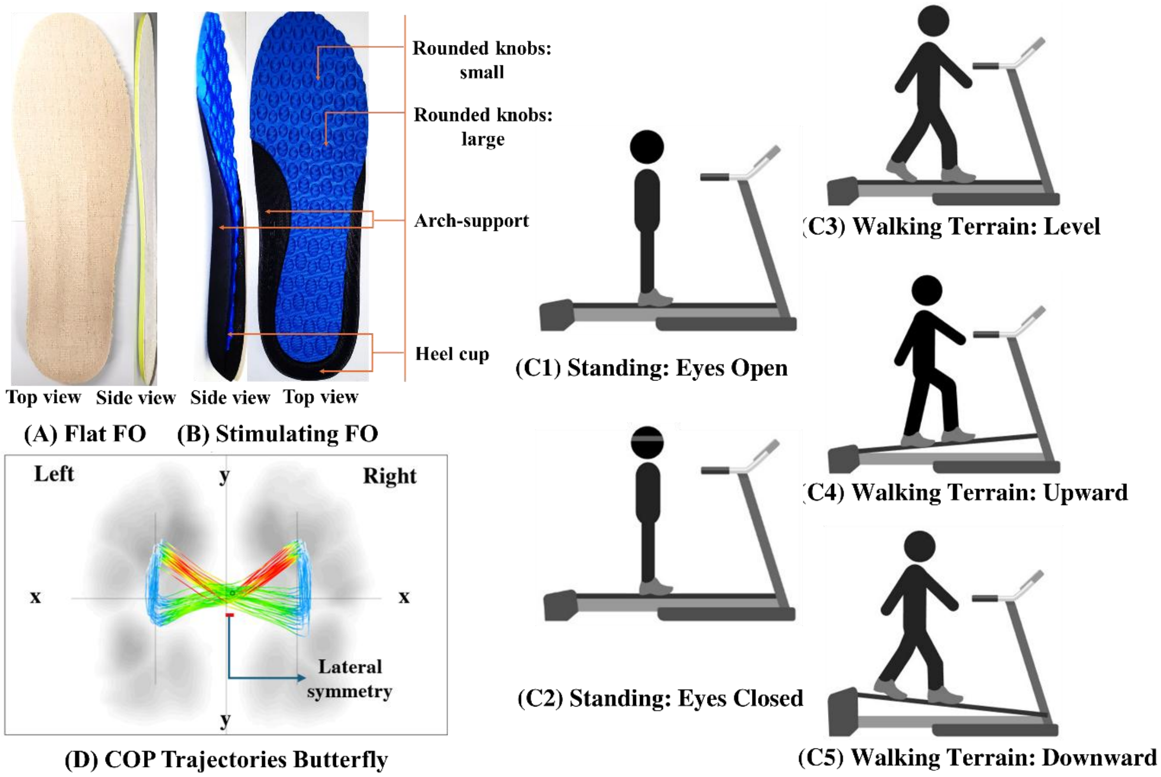


Figure 3-1. Illustration of the experimental setup for CoP trajectory assessments: (A) Flat foot orthoses (FO); (B) FO with stimulating konbs; (C) Balance assessment on the treadmill: (C1) standing_eyes open, (C2) standing_eyes closed, (C3) walking terrain_level, (C4): walking terrain_upward, (C5) walking terrain_downward; (D) Butterfly diagram with center of pressure (COP) trajectory.

The parameters related to postural control and gait, including CoP trajectory, spatiotemporal parameters, and plantar forces/pressures, were evaluated under both static and dynamic conditions. These measurements were conducted using the instrumented treadmill Zebris FDM-T with a capacitance-based force platform (Zebris Medical GmbH, Germany). The force plate operated at a sampling frequency of 120 Hz. Before commencing the gait analysis, participants were given adaptation period of five minutes to familiarize themselves with the instrumented treadmill while wearing the tested foot orthoses, ensuring their comfort and confidence to reduce potential learning effects during actual data collection. A comfortable walking speed was set for each participant on each terrain condition and maintained consistently throughout all foot orthoses investigations to ensure data comparability. To ensure the safety of the older adults, a safety harness was used and adjusted to provide sufficient slack during the dynamic gait assessments on various treadmill inclines.

The instrumented Zebris FDM-T treadmill, integrated with a capacitance-based force platform and Zebris FDM software (Zebris Medical GmbH, Germany), was used to collect and process the data [26]. The treadmill system had a built-in algorithm to acquire and analyze the CoP trajectory, spatiotemporal parameters, and plantar forces and pressure distributions for each participant. For static conditions, outcome measures included CoP parameters such as mediolateral and anteroposterior displacements, and CoP velocity. In dynamic gait conditions, measures included CoP trajectory parameters such as range of displacements, maximum COP velocity, lateral symmetry, and anterior/posterior position. The Zebris instrumented treadmill demonstrated good reliability for maximum plantar forces and pressure (ICC $\geq$ 0.8), and good (ICC $\geq$ 0.8) to excellent (ICC $\geq$ 0.9) for spatiotemporal parameters [26, 27].

The CoP was computed for each limb throughout the stance phase using measured ground reaction forces and moments. Specifically, the CoP was transformed into the foot-based coordinate system, with x (mediolateral) and y (anteroposterior) directions normalized by foot width and length. This built-in normalization process accurately determined the CoP trajectory throughout the stance phase [26, 28]. For comparison left-sided CoP trajectories were mirrored to the right. The CoP trajectory coordinates along the mediolateral and anteroposterior directions were transformed into relative coordinates, where positive values indicated lateral (x direction) and anterior (y direction) displacements respectively, while negative values represented medial (x direction) and posterior (y direction) displacements (Figure 3-1D). The range of mediolateral and anteroposterior displacements was calculated as the difference between the maximum and minimum values in each direction. Lateral symmetry was defined by the left/right shift of the butterfly intersection point, with zero indicating perfect symmetry. The anterior/posterior position of CoP was defined as the distance between the butterfly intersection point and the initial contact position, normalized by foot length.

A threshold of 20 N was used to identify the stance phase from heel strike to toe-off based on vertical ground reaction force components. Plantar forces data were collected for seven distinct foot regions: toes, medial forefoot, inner forefoot, lateral forefoot, midfoot, medial rearfoot, and lateral rearfoot and normalized to participants' body weight. Maximum plantar pressure data were also collected for the same seven distinct foot regions. For curve analysis, CoP gait line data for both mediolateral and anteroposterior displacements, as well as vertical ground reaction force across the stance phase of gait, were normalized to 101 data points (0 to 100% stance). Given the minimal differences between the sides in healthy older participants, the average values of the left and right feet were used.

For the second part of the assessments, the Bertec Balance Advantage System (Bertec Corporation, Columbus, OH, USA) was used to collect comprehensive CDP data [19, 29, 30]. This advanced system is equipped with dynamic force plates that record changes in the participant's weight distribution on their feet in response to body movement. The system also includes built-in software that displays a visual background showing anterior/posterior displacement to alter visual information. This feature is designed to alter visual input for the participant (Figure 3-2A). Prior to beginning data recording, each participant was given a thorough demonstration of all experimental procedures. To ensure participants safety and comfort, a harness was used throughout the trials. This precaution was taken to prevent falls and alleviate any fears related to balance testing. The order in which foot orthosis conditions were tested was randomized for each participant. This helped minimize confounding effects, and a rest period of 5 to 7 minutes was provided between conditions to reduce fatigue [31-33].

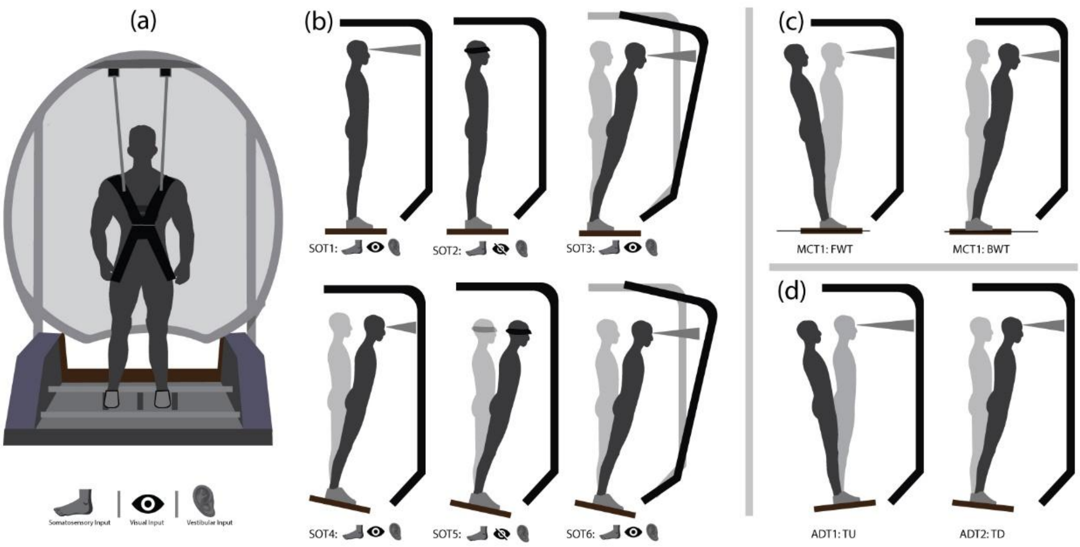


Figure 3-2. Experimental setup for CDP assessments: (A) Bertec Balance Advantage System featuring integrated force plates; (B) Six Sensory Organization Test (SOT) conditions, including SOT1-SOT3 with a stationary platform and SOT4-SOT6 with a sway-referenced platform, each tested under three visual scenarios; (C) Motor Control Test (MCT) involving forward and backward platform translations; (D) Adaptation Test (ADT) with platform movements for toes up (ADT1) and toes down (ADT2).

The CDP measurement included three main tests: the Sensory Organization Test (SOT), Motor Control Test (MCT), and Adaptation Test (ADT). The SOT was designed with six distinct experimental conditions. Each condition was performed in three separate trials, and each trial lasted 20 seconds (Figure 3-2B). In the first three SOT conditions, participants stood on a stationary platform while the visual environment was altered. Specifically, SOT1 involved eyes open with a fixed support, SOT2 required eyes closed with a fixed support, and SOT3 used sway-referenced vision with a fixed support. The remaining three conditions introduced a dynamic, sway-referenced platform. These conditions mirrored the visual settings of the first three: SOT4 was eyes open with sway-referenced support, SOT5 was eyes closed with sway-referenced support, and SOT6 combined both sway-referenced vision and support. For the SOT, a composite equilibrium score was calculated as a weighted average across all six conditions.

This score, along with sensory scores for somatosensory, visual, vestibular, and vision preference, quantified the CoG sway or postural stability in the anteroposterior direction.

The MCT included two conditions, each involving three backward and three forward translations of the support surface (Figure 3-2C). For every condition, participants completed three trials. Each trial lasted less than one second, and a random delay of 1.5 to 2.5 seconds between trials [23]. The MCT was designed to assess several parameters. Latency score measured the time in milliseconds from the initiation of platform movement to the participant's active force response. Amplitude scaling evaluated the rate of recovery per second from support surface disturbances, indicating whether force exertion was inappropriate or asymmetrical. Additionally, the weight symmetry score assessed the distribution of weight between the left and right limbs, ranging from 0 (complete asymmetry) to 100 (perfect symmetry with equal weight on both limbs).

The ADT featured two distinct conditions: platform rotations with toes up and toes down, with movement centered at the ankles (Figure 3-2D). Each condition included five trials, during which participants experienced rotational perturbations. The intervals between these trials were randomized to prevent participants from assuming the timing of the next rotation. Following each platform movement, the sway energy required for the participant to restore balance was assessed. The reliability of the SOT and MCT scores was also evaluated and demonstrated excellent test-retest reliability for balance assessment in older adults, with intraclass correlation coefficients (ICC) of 0.90 for SOT and 0.85 for MCT [34].

3.2.4 Statistical analysis

The Shapiro-Wilk test was employed to assess the normality of all stability and gait parameters. Regarding the first part of assessments, a two-way repeated measures ANOVA with Bonferroni post hoc comparison was conducted to compare two different foot orthoses conditions across three walking terrains (2 foot orthoses x 3 Terrain) and two standing (2 foot orthoses x 2 Visual) conditions, for normally distributed data. For non-normally distributed data, the Friedman test followed by the Wilcoxon signed-rank test or Mann–Whitney U test was used. Additionally, statistical parametric mapping (SPM) analysis was used to examine curves for anteroposterior and mediolateral CoP displacements, as well as vertical ground reaction forces across the stance phase of the gait cycle. The post-hoc paired sample *t*-tests were employed to compare foot orthoses conditions across three inclined terrains. For the second part of the assessment, paired samples t-tests were conducted on each outcome variable to determine whether significant differences existed between the two foot orthoses conditions. To explore whether gender influenced the effects of the foot orthoses, independent t-tests and one-way ANOVA, followed by Bonferroni post-hoc corrections, were employed. All statistical analyses were performed using IBM SPSS software (version 22, SPSS Inc., Chicago, IL). The open source spm1d code (Version 0.4, available at https://spm1d.org/) in Python (Version 3.11) was employed for SPM analysis. In all cases, statistical significance was set at $p<0.05$.

3.3 Results

3.3.1 Participant characteristics

A total of twenty-three older adults who met the eligibility criteria participated in the balance assessment. The sample consisted of 16 females (mean age: 72±3 years; height: 154±6 cm; BMI: 22.5±3.4; foot length: 236±9 mm; US shoe size: 5.5–8.5; SWM: 9.9±0.2) and 7 males (mean age: 72±4 years; height: 165±7 cm; BMI: 22.8±2.0; foot length: 251±7 mm; US shoe size: 5.5–7.5; SWM: 9.5±0.9). A priori power analysis was conducted using G-power software (version 3.1.9.7). Based on CoP mediolateral displacement data from Huang et al. [12] (a within-subject repeated measures ANOVA, $\alpha=0.05$, $\beta=0.20$, power=80%, number of groups=2, number of measurements=6, and correlation among repeated measures=0.30), a sample of size of 23 participants was obtained. In addition, a recent study on the effects of foot orthoses with tactile stimulating protrusions in older adults also supports this sample size, demonstrating 80% power at a 95% confidence level with 20 participants [18].

Table 3-1. Mean and standard deviation of CoP parameters during static standing with eyes open and eyes closed conditions as well as walking on varying inclined terrains.

Parameters (Standing)	**Testing conditions**	**Norm**	**FFO**		**SSFO**		**P value**	**FO*Visual**
			Mean	SD	Mean	SD		
Mediolateral CoP Range, mm	Eyes open	No	3.43	1.57	3.78	1.92	0.693	0.548
	Eyes closed	Yes	3.21	0.99	3.50	1.23	0.302	
Anteroposterior CoP Range, mm	Eyes open	Yes	19.69	7.68	19.73	5.49	0.978	0.483
	Eyes closed	Yes	20.52	4.62	22.71	6.35	0.102	
CoP average CoP velocity, mm/sec	Eyes open	Yes	13.53	7.34	13.06	4.59	0.751	0.347
	Eyes closed	No	17.24	8.20	18.63	7.35	0.693	
Parameters (Walking)	**Testing conditions**	**Norm**	**FFO**		**SSFO**		**P value**	**FO*Terrain**
			Mean	SD	Mean	SD		
Mediolateral CoP Range, mm	Walking Level	Yes	28.15	14.86	30.56	14.35	**0.052**	0.266
	Walking Up	Yes	29.13	12.57	32.41	14.40	0.069	
	Walking Down	Yes	33.15	13.09	33.95	14.25	0.476	
Anteroposterior CoP Range, mm	Walking Level	Yes	200.33	37.67	199.02	40.50	0.766	0.613
	Walking Up	Yes	189.69	39.96	188.37	41.64	0.697	
	Walking Down	Yes	192.77	42.68	195.99	40.71	0.547	
CoP max velocity, cm/sec	Walking Level	Yes	657.36	326.08	635.29	370.00	0.586	0.600
	Walking Up	Yes	672.29	271.48	680.64	301.02	0.751	
	Walking Down	Yes	682.06	313.68	715.93	334.65	0.384	
Anterior/posterior position	Walking Level	No	0.40	0.35	0.42	0.38	0.201	0.380
	Walking Up	Yes	0.35	0.40	0.30	0.40	0.200	
	Walking Down	No	0.68	0.53	0.62	0.52	0.412	
Lateral symmetry, mm	Walking Level	No	10.10	10.03	10.03	10.33	0.795	
	Walking Up	No	13.09	11.98	13.45	11.53	0.503	
	Walking Down	No	10.90	8.96	10.72	10.01	0.715	
FO: foot orthoses; FFO: flat foot FO; SSFO: somatosensory stimulation FO; CoP: center of pressure, ML: mediolateral displacement, AP: anteroposterior displacement.								

Table 3-2. Mean and standard deviation of spatiotemporal parameters during walking at varying inclined terrains.

Parameters (Walking)	**Testing conditions**	**Norm**	**FFO**		**SSFO**		**P value**	**FO*Terrain**
			Mean	SD	Mean	SD		
Stride length, cm	Walking Level	Yes	64.55	17.76	62.93	19.45	0.346	0.293
	Walking Up	Yes	63.50	17.92	61.53	19.09	0.073	
	Walking Down	Yes	57.43	17.47	57.36	17.18	0.447	
Stride time, sec	Walking Level	Yes	1.22	0.21	1.16	0.18	0.218	0.355
	Walking Up	Yes	1.25	0.22	1.19	0.20	0.054	
	Walking Down	Yes	1.13	0.19	1.11	0.16	0.201	
Step width, cm	Walking Level	Yes	13.54	3.13	13.04	3.02	0.136	0.263
	Walking Up	Yes	13.35	2.95	13.32	3.04	0.926	
	Walking Down	Yes	13.85	3.42	13.89	3.48	0.865	
Stance, %	Walking Level	Yes	68.68	1.97	68.65	2.17	0.869	0.224
	Walking Up	Yes	68.92	2.05	68.17	5.34	0.346	
	Walking Down	Yes	68.01	2.88	68.00	2.64	0.945	

Cadence, steps/min	Walking Level	Yes	101.20	18.27	105.49	17.88	0.212	0.350
	Walking Up	Yes	98.59	17.23	99.77	18.04	0.153	
	Walking Down	Yes	109.57	18.22	110.50	15.76	0.274	
FO: foot orthoses; FFO: flat foot FO; SSFO: somatosensory stimulation FO								

Table 3-3. Mean and standard deviation of maximum plantar forces and pressure distribution during walking at varying inclined terrains

Parameters (Maximum plantar forces)	**Testing conditions**	**Norm**	**FFO**		**SSFO**		**P value**	**FO*Terrain**
			Mean	SD	Mean	SD		
Toes, N/kg	Walking Level	Yes	1.62	0.51	1.72	0.67	0.288	
	Walking Up	Yes	1.46	0.47	1.43	0.51	0.587	
	Walking Down	Yes	1.84	0.71	1.78	0.76	0.586	
Forefoot medial, N/kg	Walking Level	Yes	1.87	0.36	1.88	0.36	0.814	
	Walking Up	Yes	1.77	0.36	1.65	0.34	**0.015**	
	Walking Down	Yes	1.82	0.25	1.76	0.28	**0.051**	
Forefoot inner, N/kg	Walking Level	Yes	2.71	0.40	2.72	0.48	0.908	
	Walking Up	Yes	2.63	0.46	2.46	0.52	**0.051**	
	Walking Down	Yes	2.54	0.39	2.45	0.44	0.068	
Forefoot lateral, N/kg	Walking Level	Yes	1.43	0.21	1.49	0.23	**0.044**	
	Walking Up	Yes	1.36	0.24	1.36	0.26	0.977	
	Walking Down	Yes	1.44	0.23	1.46	0.29	0.611	
Midfoot, N/kg	Walking Level	Yes	3.08	0.75	3.02	0.74	0.625	
	Walking Up	Yes	3.07	0.49	2.98	0.66	0.434	
	Walking Down	Yes	3.06	0.97	3.24	1.11	0.112	
Rearfoot medial, N/kg	Walking Level	Yes	2.16	0.41	2.11	0.40	0.461	
	Walking Up	Yes	2.19	0.50	2.11	0.51	0.057	
	Walking Down	Yes	2.06	0.30	2.02	0.33	0.430	
Rearfoot lateral, N/kg	Walking Level	Yes	2.19	0.45	2.21	0.40	0.796	
	Walking Up	Yes	2.32	0.53	2.30	0.49	0.792	
	Walking Down	Yes	1.93	0.38	1.98	0.40	0.349	
Parameters (Maximum plantar pressure)	**Testing conditions**	**Norm**	**FFO**		**SSFO**		**P value**	**FO*Terrain**
			Mean	SD	Mean	SD		
Toes, N/cm2	Walking Level	No	11.93	1.91	11.92	2.50	0.260	
	Walking Up	No	10.83	2.31	10.22	2.50	**0.003**	
	Walking Down	No	12.00	2.16	11.53	1.93	**0.019**	
Forefoot medial, N/cm2	Walking Level	Yes	14.00	2.44	13.85	2.35	0.107	
	Walking Up	No	13.78	2.81	12.72	2.96	**0.000**	
	Walking Down	No	13.09	1.90	12.54	2.05	**0.013**	
Forefoot inner, N/cm2	Walking Level	No	14.72	2.46	14.59	2.85	**0.007**	
	Walking Up	No	14.66	3.06	13.51	3.30	**0.001**	
	Walking Down	No	13.65	2.41	13.11	2.33	**0.000**	
Forefoot lateral, N/cm2	Walking Level	No	12.15	2.35	11.95	2.22	0.107	
	Walking Up	No	12.33	3.81	11.56	2.71	0.128	
	Walking Down	No	11.25	2.23	11.21	2.37	0.627	
Midfoot, N/cm2	Walking Level	No	12.02	2.33	11.88	2.28	0.370	
	Walking Up	No	11.85	1.62	11.94	2.22	0.761	
	Walking Down	No	11.02	1.73	11.33	2.08	0.494	
Rearfoot medial, N/cm2	Walking Level	No	10.78	1.88	10.76	2.94	**0.029**	
	Walking Up	No	10.81	2.18	10.83	3.45	0.153	
	Walking Down	No	10.39	1.67	10.24	2.34	**0.018**	
Rearfoot lateral, N/cm2	Walking Level	No	11.41	1.66	11.46	2.69	0.274	
	Walking Up	No	11.33	2.00	11.69	3.13	0.784	
	Walking Down	No	10.36	1.59	10.63	2.13	1.000	

FO: foot orthoses; FFO: flat foot FO; SSFO: somatosensory stimulation FO

Table 3-4. Mean and standard deviation data for computerized dynamic posturography assessments

Parameters	**Testing conditions**	**FFO**		**SSFO**		**SSFO vs FFO**	FO*Gender interaction
Equilibrium, score	C-1	89.20	3.7	88.91	3.53	0.474	No
	C-2	88.14	4.74	88.94	3.78	0.661	No
	C-3	87.83	3.94	88.54	4.59	0.485	No
	C-4	59.84	10.82	61.28	13.27	0.251	No
	C-5	57.58	12.16	59.00	12.61	0.346	No
	C-6	53.18	12.32	55.65	12.39	0.086	No
	Composite	68.17	3.54	69.61	7.84	**0.037**	No
Latency, mm	LAT-BT-Avg.	137.26	8.22	136.39	7.34	0.558	No
	LAT-FT-Avg.	137.13	9.92	135.17	10.84	0.173	No
Weight symmetry, %	WS-BT-Avg.	90.60	7.33	92.35	6.03	**0.024**	No
	WS-FT-Avg.	91.35	6.28	91.85	5.98	0.323	No
Amplitude scaling	AS-BT_S	2.91	1.24	2.93	1.28	0.901	No
	AS-BT_M	4.21	1.56	4.28	1.58	0.678	No
	AS-BT_L	4.60	1.6	4.70	1.74	0.628	No
	AS-BT-Avg.	3.91	1.38	3.97	1.38	0.614	No
	AS-FT_S	3.50	1.5	3.83	1.3	0.189	No
	AS-FT_M	4.43	1.32	4.93	1.94	0.065	No
	AS-FT_L	4.95	1.76	5.26	1.92	0.157	No
	AS-FT-Avg.	4.30	1.44	4.67	1.46	0.057	No
Sway energy, score	Toes Up-T1	97.74	20.22	99.04	31.72	0.788	No
	Toes Up-T2	98.96	33.74	102.22	32.02	0.657	No
	Toes Up-T3	100.57	27.94	102.00	26.54	0.813	No
	Toes Up-T4	94.74	25.8	91.78	25.38	0.641	No
	Toes Up-T5	92.83	32.44	92.74	24.7	0.991	No
	Toes Up Avg.	96.97	21.98	97.56	22.22	0.889	No
	Toes Down-T1	92.87	26.1	101.30	31.82	0.061	No
	Toes Down-T2	94.83	30.1	95.17	29.78	0.940	No
	Toes Down-T3	83.04	27.22	86.91	32.18	0.475	No
	Toes Down-T4	83.22	30.78	80.83	34.66	0.677	No
	Toes Down-T5	81.00	29.56	80.00	32.2	0.853	No
	Toes Down Avg.	86.99	25.22	88.84	26.42	0.414	No

"FO: foot orthoses; FFO: flat foot FO; SSFO: somatosensory FO; C-1: eyes open, C-2: eyes closed, C-3: eyes open with surrounding visual sway-referenced, C-4: eyes open with support surface sway-referenced, C-5: eyes closed with support surface sway-referenced, and C-6: eyes open with both surrounding visual and support surface sway-referenced. LAT-BT-M: latency during backward translation with medium speed; LAT-BT-L: latency during backward translation with large speed; LAT-BT-Avg.: average latency during backward translation; LAT-FT-M: latency during forward translation with medium speed; LAT-FT-L: latency during forward translation with large speed; LAT-FT-Avg.: average latency during forward translation; WS-BT-S: weight symmetry during backward translation with slow speed; WS-BT-M: with medium speed; WS-BT-L: with large speed; WS-BT-Avg.: average weight symmetry during backward translation; WS-FT-S: weight symmetry during forward translation with slow speed; WS-FT-M: weight symmetry during forward translation with medium speed; WS-FT-L: weight symmetry during forward translation with large speed; WS-FT: average weight symmetry during forward translation; AS-BT-S: amplitude scaling during backward translation with slow speed; AS-BT-M: amplitude scaling during backward translation with medium speed; AS-BT-L: amplitude scaling during backward translation with large speed; AS-BT-Avg.: average amplitude scaling during backward translation; AS-FT-S: amplitude scaling during forward translation with slow speed; AS-FT-M: amplitude scaling during forward translation with medium speed; AS-FT-L: amplitude scaling during forward translation with large speed; AS-FT-Avg.: average amplitude scaling during forward translation;"

3.3.2 Center of pressure trajectory and gait

No significant interactions of visual, terrain and gender to foot orthoses effects were found, indicating that vision, terrain and gender did not influence the outcome variables (Table 3-1 to 3-3). COP trajectory analysis revealed no significant differences between flat foot orthoses and somatosensory foot orthoses while standing with eyes open or closed (Table 3-1).

There was a significant main effect of foot orthoses on CoP mediolateral displacements during walking ($F(1)=4.374$, $p=0.048$, $\eta 2=0.166$). However, no significant differences were observed on pairwise post-hoc comparisons (Table 3-1). Statistical parametric mapping (SPM) analysis revealed decreased mediolateral displacements at 15-65% of the stance phase on downward terrain ($p<0.001$) (Figure 3-2). Spatiotemporal parameters showed non- significant differences between flat foot orthoses and somatosensory foot orthoses across different terrains (Table 3-2). However, SPM analysis revealed increased vertical ground reaction forces at 35-45% of stance on level terrain ($p=0.001$) and decreased at 5-10% and 55-60% of stance on upward terrain ($p=0.020$ and $p=0.025$) with somatosensory foot orthoses (Figure 3-3).

There were significant differences in plantar pressure distribution across different foot regions between flat foot orthoses and somatosensory foot orthoses while walking on various terrains (Table 3-3). On both upward and downward terrains, maximum plantar pressure at toes (Up: MD=0.66, $p=0.003$; Down: MD=0.47, $p=0.019$) and medial forefoot (Up: MD=1.06, $p<0.001$; Down: MD=0.55, $p=0.013$) was decreased with somatosensory foot orthoses. Across all terrains, maximum plantar pressure was lower at inner forefoot (Level: MD=0.13, $p=0.007$; Up: MD=1.15, $p=0.001$; Down: MD=0.54, $p<0.001$) with somatosensory foot orthoses.

Maximum plantar pressure at medial rearfoot decreased while walking with somatosensory foot orthoses on downward terrain (Down: MD=0.15, p=0.018).

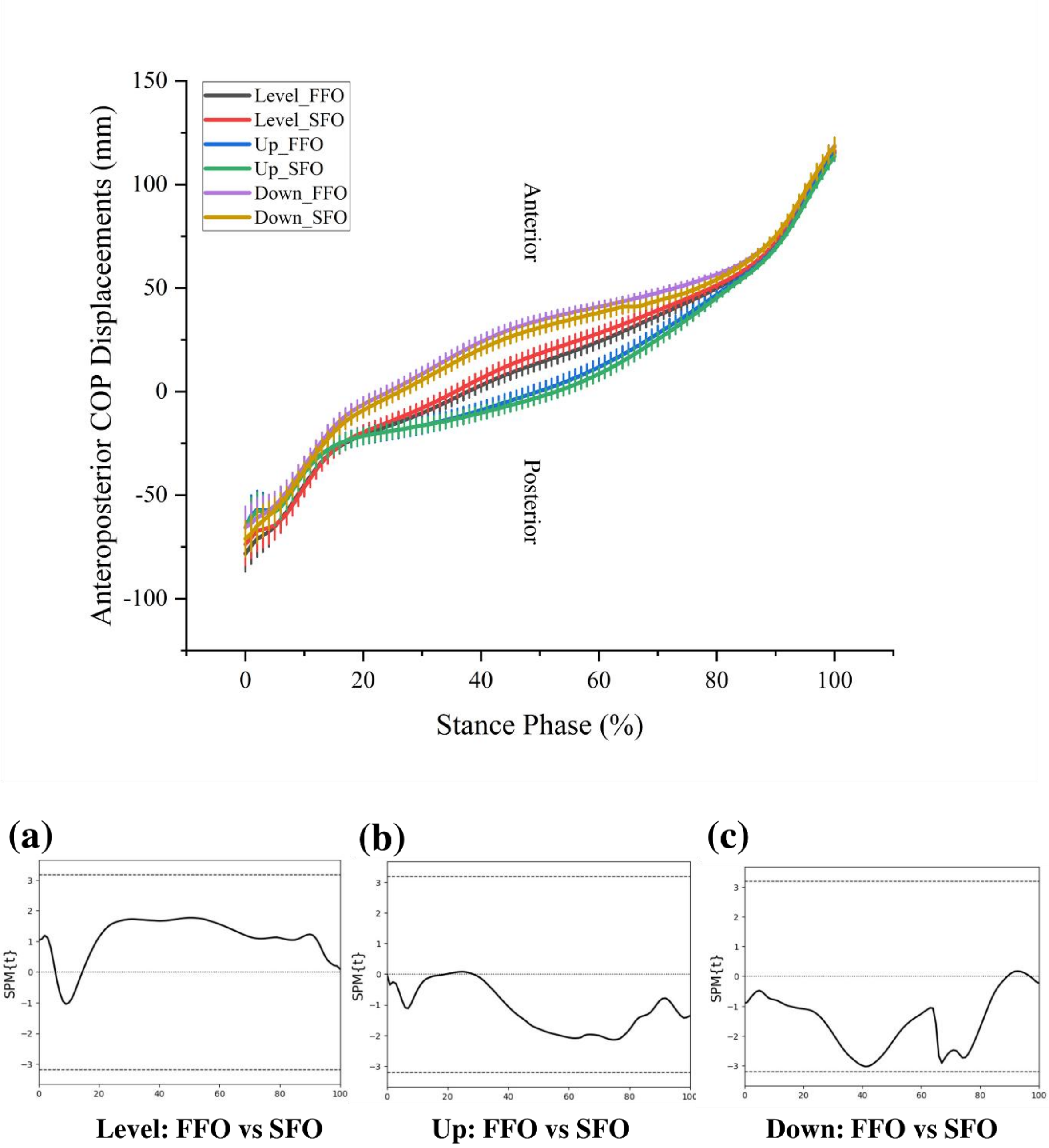
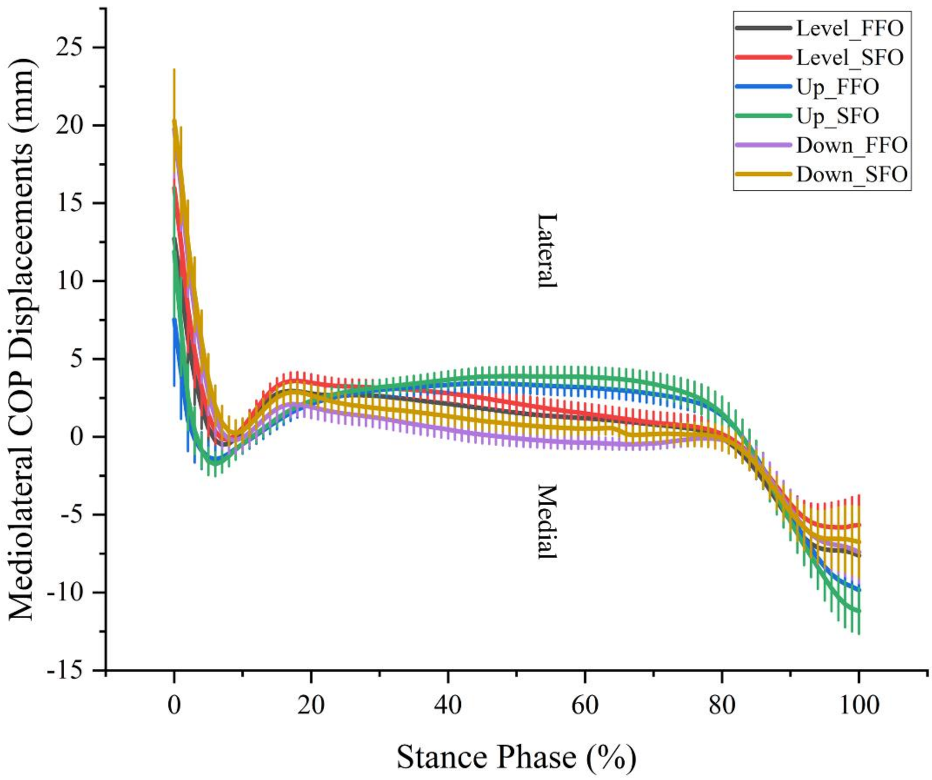


Figure 3-3. Anteroposterior displacement of the center of pressure (CoP) with standard deviations across 0 to 100% stance where black (Level-FFO) and red (Level-SFO) represent flat and stimulating foot orthoses (FO) on level terrain, blue (Up-FFO) and green (Up-SFO) represent flat and stimulating FO on upward terrain, and purple (Down-FFO) and brown (Down-SFO) represent flat and stimulating FO on downward terrain. In the results of statistical parametric mapping (SPM) analysis, no significant differences across (a) level terrain (Level:

FFO vs SFO), (b) upward terrain (Up: FFO vs SFO), and (c) downward terrain (Down: FFO vs SFO).



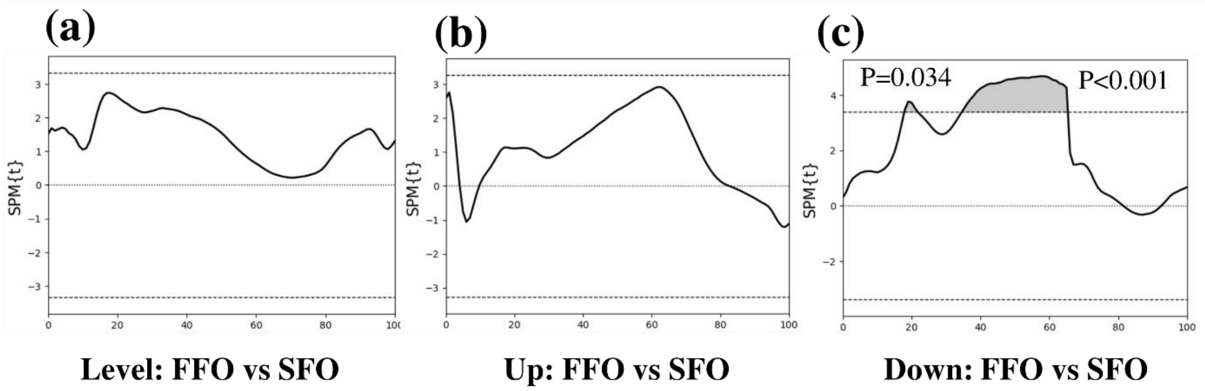


Figure 3-4. Mediolateral displacement of the center of pressure (CoP) with standard deviations across 0 to 100% stance where black (Level-FFO) and red (Level-SFO) represent flat and stimulating foot orthoses (FO) on level terrain, blue (Up-FFO) and green (Up-SFO) represent flat and stimulating FO on upward terrain, and purple (Down-FFO) and brown (Down-SFO) represent flat and stimulating FO on downward terrain. In the results of statistical parametric mapping (SPM) analysis, (a) shows no significant differences on level terrain (Level: FFO vs SFO), (b) shows no significant differences on upward terrain (Up: FFO vs SFO), and (c) shows significant reductions in COP lateral displacement with stimulating FO on downward terrain (Down: FFO vs SFO).

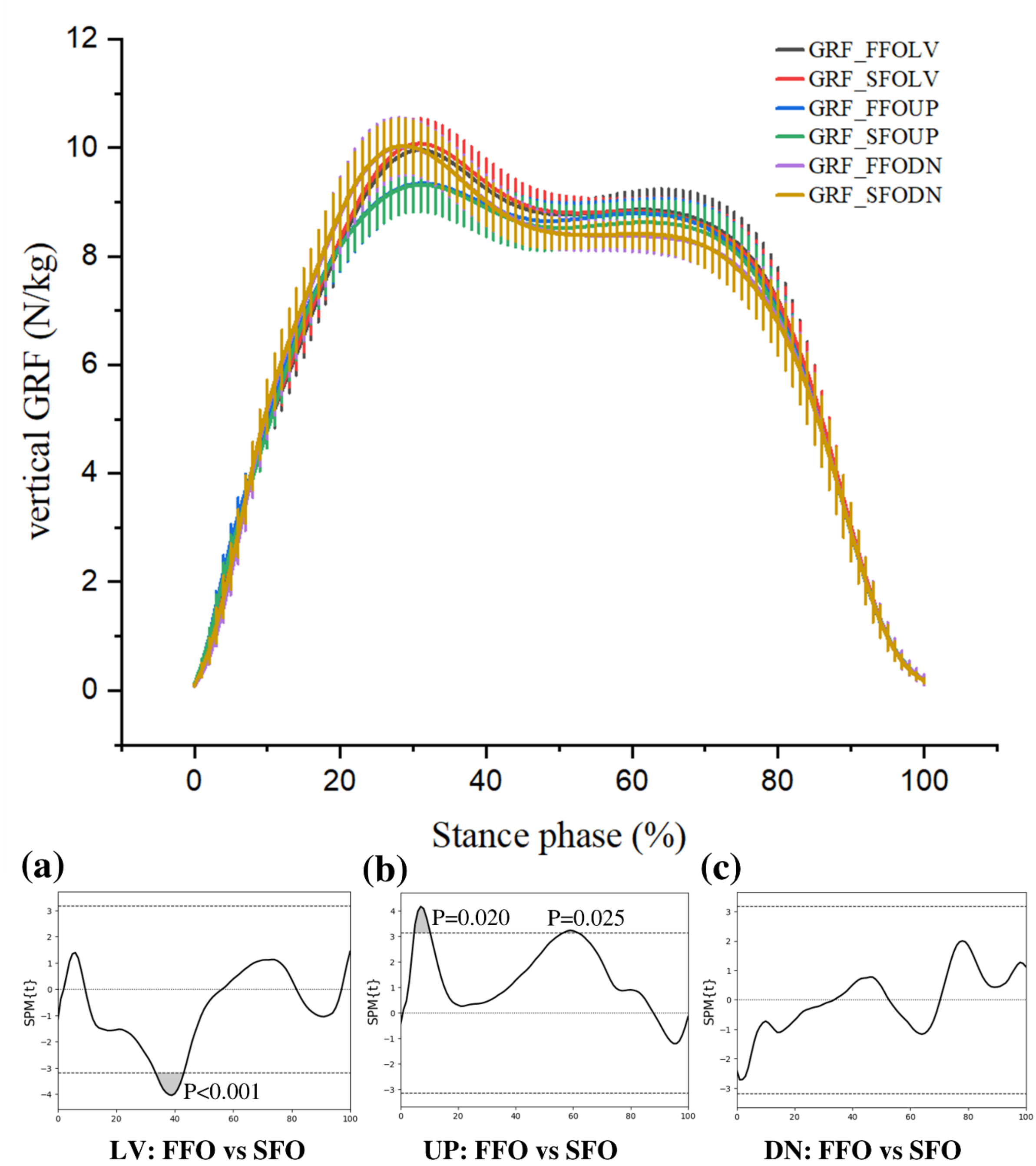


Figure 3-5. Vertical ground reaction force (GRF) with standard deviations across 0 to 100% stance where black (Level-FFO) and red (Level-SFO) represent flat and stimulating foot orthoses (FO) on level terrain, blue (Up-FFO) and green (Up-SFO) represent flat and stimulating FO on upward terrain, and purple (Down-FFO) and brown (Down-SFO) represent flat and stimulating FO on downward terrain. In the results of statistical parametric mapping (SPM) analysis, (a) shows significant increase in vertical GRF with stimulating FO on level terrain (Level: FFO vs SFO), (b) shows significant decrease in vertical GRF with stimulating FO on upward terrain (Up: FFO vs SFO), and (c) shows non-significant differences on downward terrain (Down: FFO vs SFO).

3.3.3 Computerized dynamic posturography assessments

No significant interaction was identified for gender and age variations to foot orthoses effects on balance performance during the CDP assessment (Table 3-4). However, a significant main effect of gender was detected. Female participants showed lower amplitude scaling than males during forward translation with both flat and stimulating foot orthoses. Specifically, for flat orthoses, the differences were medium (MD = -1.83, p = 0.001) and large (MD = -2.62, p < 0.001). For stimulating orthoses, the differences were also medium (MD = -2.55, p = 0.002) and large (MD = -2.70, p = 0.001). Furthermore, with stimulating foot orthoses, females exhibited lower latency and amplitude scaling during backward translation, as well as reduced sway energy during motor adaptation to downward perturbations, compared to males (Latency: MD = -6.62, p = 0.044; Amplitude scaling: MD = -1.75, p = 0.011; Sway Energy: MD = -40.08, p = 0.007).

Descriptive data from the CDP assessments, which includes SOT, MCT, and ADT, are shown in Table 3-4. The analysis indicated a statistically significant improvement in the composite equilibrium score when participants wore stimulating foot orthoses (MD = 1.44, p = 0.048) (Figure 3-6). In addition, weight symmetry during backward translation was significantly higher with the stimulating foot orthoses (MD = -1.85, p = 0.024) (Figure 3-7). There were also observable trends toward reduced postural latencies and increased amplitude scaling during both backward and forward translations for the stimulating foot orthoses (Figure 3-7). However, no statistically significant differences were found in sway energy for motor adaptation in response to perturbations. The results were consistent regardless of whether the rotations were toes-up or toes-down, when comparing somatosensory foot orthoses to flat foot orthoses (Figure 3-8).

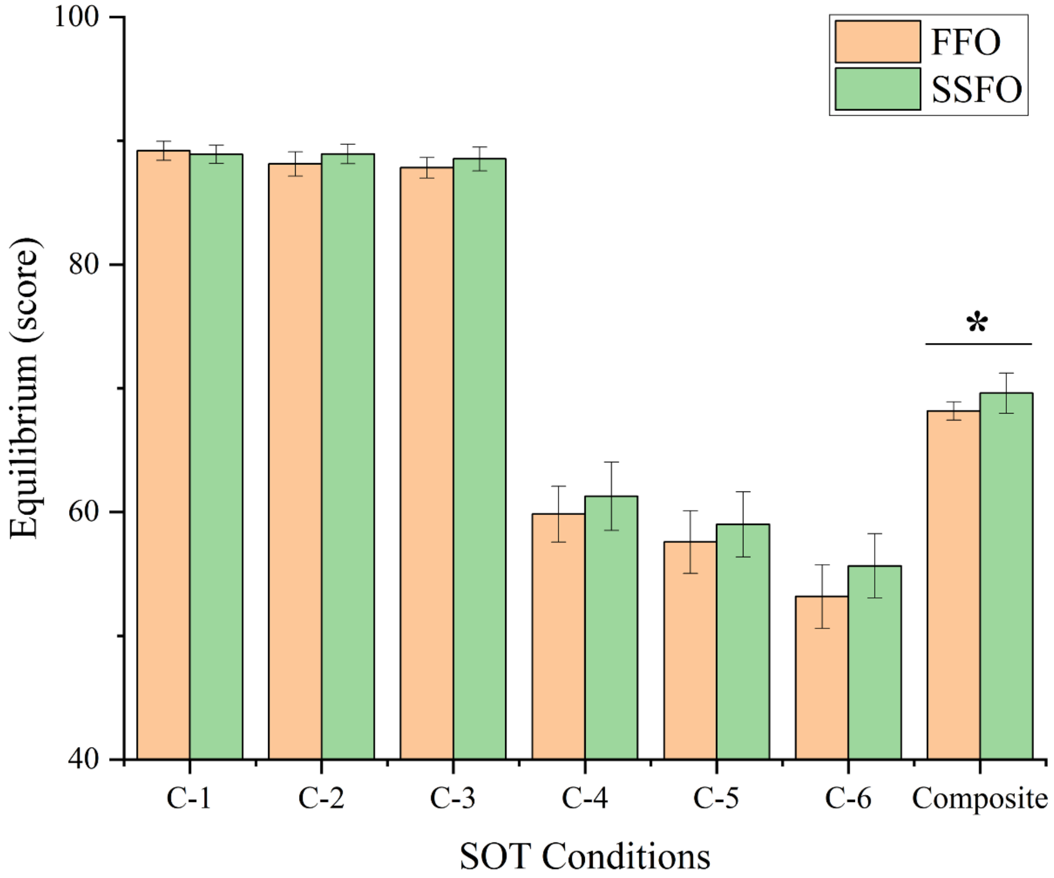


Figure 3-6. Mean ± standard error for sensory organization results (SOT) results for six sensory conditions and three types of foot orthoses (FO, FFO, SSFO); an asterisk indicates statistically significant differences ($p < 0.05$).

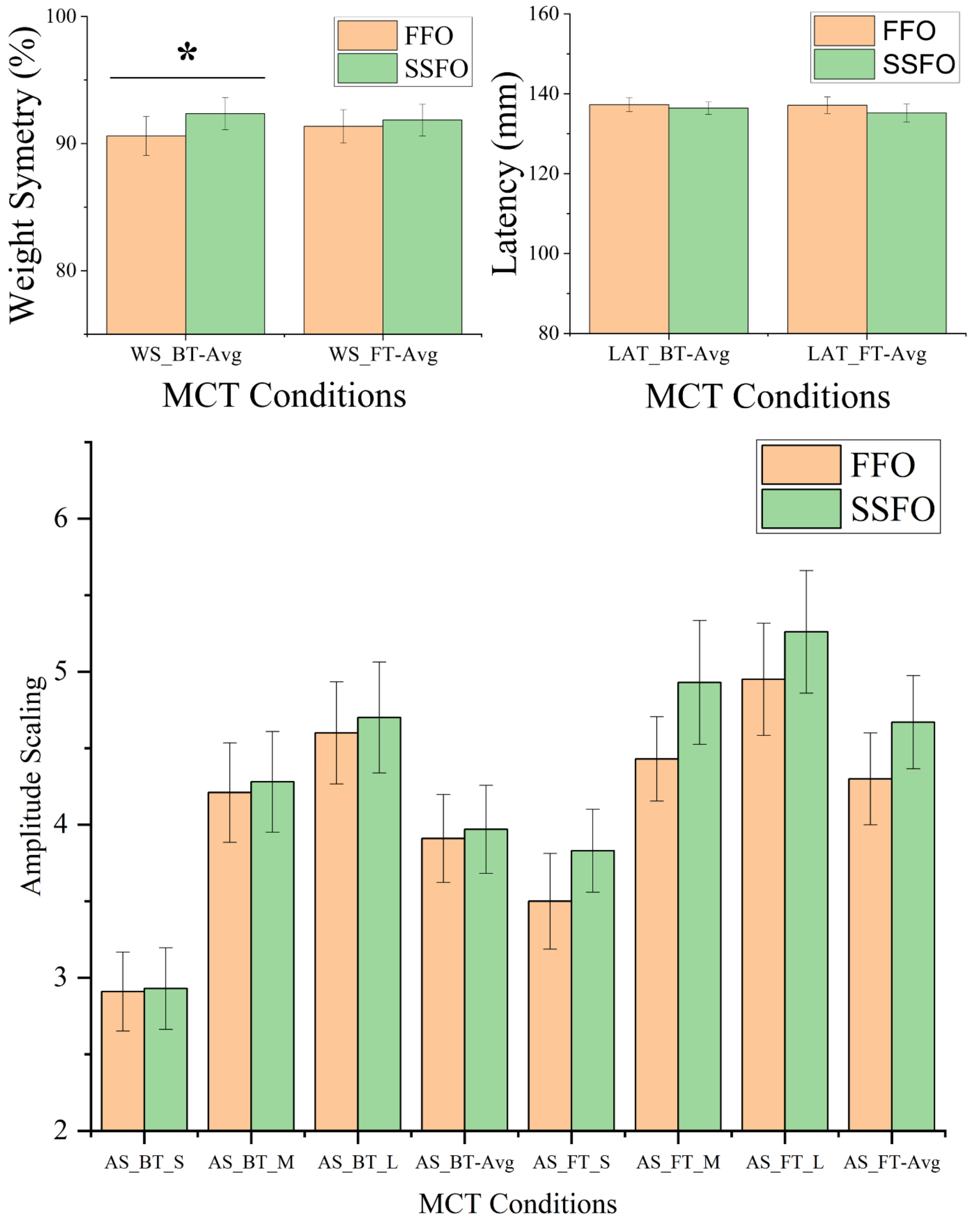


Figure 3-7. Mean ± standard error for Motor Control Test (MCT): LAT-BT-M: latency during backward translation with medium speed; LAT-BT-L: with large speed; LAT-BT-Avg.: average latency for backward translation; LAT-FT-M: latency during forward translation with medium speed; LAT-FT-L: with large speed; LAT-FT-Avg.: average latency for forward translation; WS-BT-S: weight symmetry during backward translation with slow speed; WS-BT-M: with medium speed; WS-BT-L: with large speed; WS-BT-Avg.: average weight symmetry for backward translation; WS-FT-S: weight symmetry during forward translation with slow speed; WS-FT-M: with medium speed; WS-FT-L: with large speed; WS-FT: average weight symmetry

for forward translation; AS-BT-S: amplitude scaling during backward translation with slow speed; AS-BT-M: with medium speed; AS-BT-L: with large speed; AS-BT-Avg.: average amplitude scaling for backward translation; AS-FT-S: amplitude scaling during forward translation with slow speed; AS-FT-M: with medium speed; AS-FT-L: with large speed; AS-FT-Avg.: average amplitude scaling for forward translation; FO: foot orthoses; FFO: flat foot FO; SSFO: somatosensory FO. The asterisk (*) refers to a significant difference at $p < 0.05$.

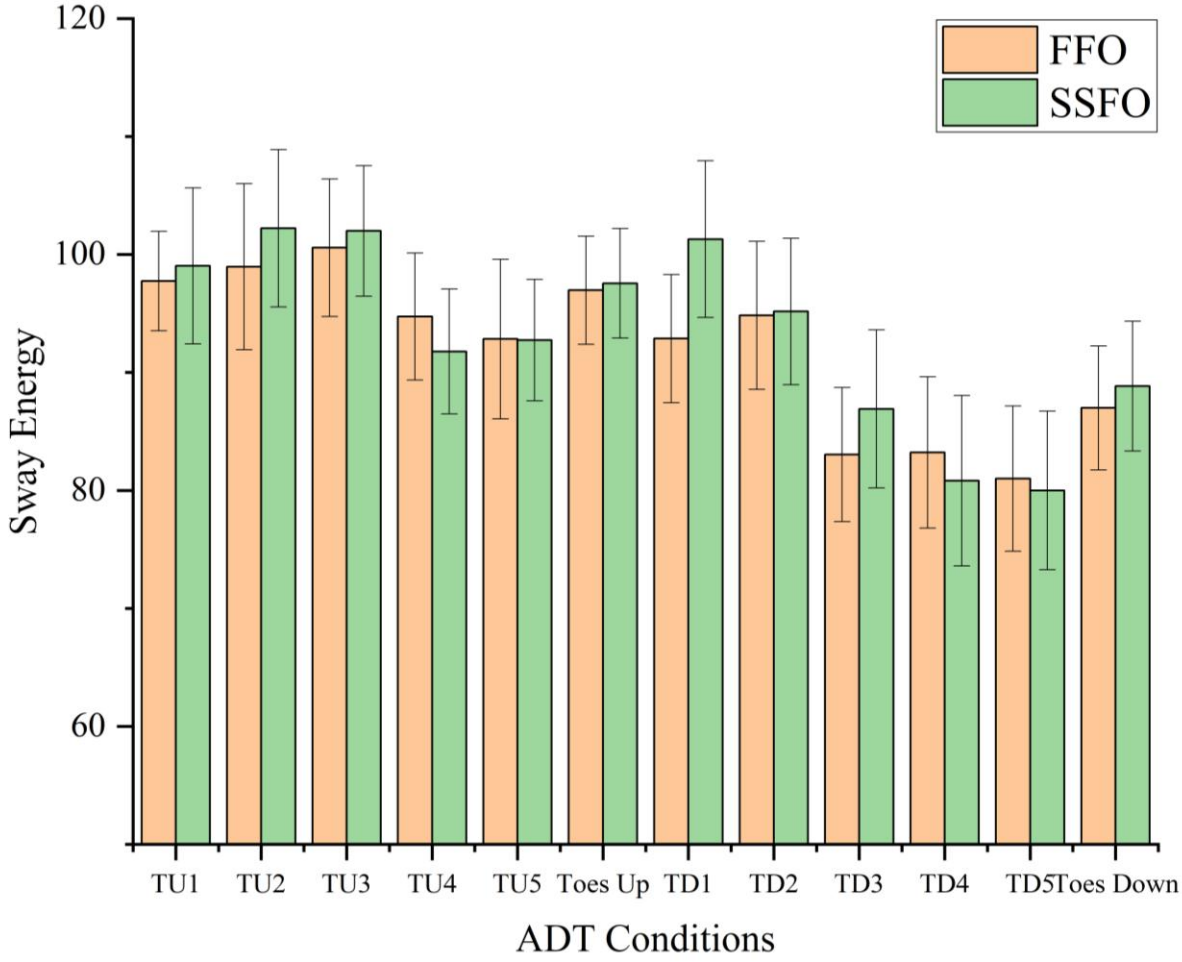


Figure 3-8. Mean ± standard error for Adaptation Test (ADT): TU1: toes up trial 1; TU2: toes up trial 2; TU3: toes up trial 3; TU4: toes up trial 4; TU5: toes up trial 5; TD1: toes down trial 1; TD2: toes down trial 2; TD3: toes down trial 3; TD4: toes down trial 4; TD5: toes down trial 5. The asterisk (*) refers to a significant difference at $p < 0.05$.

3.4 Discussion

This study investigated the effects of foot orthoses with stimulating knobs on postural balance and gait parameters across different terrains as well as postural stability in response to varied perturbation conditions. The study revealed several key findings that contribute to our understanding of how foot orthoses with tactile stimulating knobs influence postural balance, stability, and gait. Postural control, assessed through CoP displacement and velocity, is crucial for postural balance and stability [35, 36]. By employing the CDP, this study is the first to explore the comprehensive effect of plantar tactile stimulation on postural control and balance in older adults.

Older adults may experience reduced control over CoP movement or sway because of declined muscle strength and sensory feedback, both of which are critical for maintaining balance and preventing falls [2]. Increased CoP displacement or postural sway reflects greater challenge in maintaining balance due to increased stabilization effort. The non-significant differences in CoP parameters during standing were found between somatosensory and flat foot orthoses, consistent with a previous investigation with somatosensory foot orthoses featured protruding knobs [17]. Similarly, foot orthoses with only medial arch supports, or heel cups did not effectively improve static balance in healthy older adults [37]. In contrast, other studies reported significant improvement in CoP parameters while wearing foot orthoses with protruding surfaces (Chapter 2) [13, 31, 38]. For instance, an somatosensory foot orthoses covered with protruding spikes improved postural stability [31]. Another study with strategically placed stimulating knobs at the metatarsal heads and heel reported improved static stability [13]. These findings suggest that optimizing the design and positioning of stimulating knobs might be crucial for enhancing postural stability and gait performance.

The lack of significant changes in the average CoP trajectories during walking between somatosensory and flat foot orthoses aligns with previous studies showing minimal or no effects of tactile stimulating knobs on CoP parameters [15, 17, 31]. However, the reduced CoP lateral displacements in curve analysis observed with somatosensory foot orthoses, may indicate improved control over CoP movements in older adults, particularly during the pre-swing phase of the contralateral side on the downward terrain. A possible explanation is that the protruding knobs in the somatosensory foot orthoses might induce stimulation forces to the mechanoreceptors, especially during midstance when the foot has maximum plantar contact with the somatosensory foot orthoses. The skin stretching induced by these protrusions may enhance mechanoreceptor activation, improving somatosensory feedback [39]. This enhanced feedback could lead to a more stable and controlled gait pattern, potentially reducing the risk of falls in challenging conditions [38, 40]. The decreased range of anteroposterior CoP displacement on upward terrain, observed with both somatosensory and flat foot orthoses, could be attributed to the cautious, shorter steps to enhance stability and reduce fall risks on inclined terrains. This aligns with previous study which reported modified movement strategy to prepare and adapt the limb for elevated heel strike on inclined terrain [41].

Similar to the CoP parameters, the non-significant changes in spatiotemporal gait parameters were in line with previous research indicating that foot orthoses with stimulating knobs often do not significantly alter spatiotemporal parameters [42, 43]. However, a previous study reported a negative impact of somatosensory foot orthoses on stride length and gait velocity [17]. The flat configuration of foot orthoses, without arch support or a raised heel cup, might limit the effectiveness of somatosensory stimulation by reducing contact surface areas (see Chapter 2). The maximum plantar forces and pressures were reduced, particularly in higher plantar pressure regions such as the medial and inner forefoot, while an increase was observed at the lateral forefoot. This redistribution could be attributed to the increased contact surfaces due to elevated heel cup with medial and lateral arch supports and/or the massaging effect of the soft cushion protruding knobs. This can alleviate stress on high-pressure areas and potentially reduce the risk of pressure-related injuries and falls [13, 44, 45]. Additionally, the contoured arch-support structure of the somatosensory foot orthoses, may enhance this effect by improving contact and support for tactile stimulation, promoting a more even pressure distribution and postural stability [46]. These findings suggest that while the arch-support structure in somatosensory foot orthoses facilitates pressure redistribution in certain higher plantar pressure regions, the addition of protruding knobs may increase plantar forces in other areas, such as the lateral forefoot.

Our findings support the hypothesis that somatosensory foot orthoses enhance overall equilibrium and weight symmetry, during postural tasks, as compared to the flat foot orthoses. The observed enhanced composite equilibrium score signifying reduced anteroposterior sway of the CoG. This reduction in sway suggests that motor strategies and postural responses to perturbations become more effective. Keeping the CoG within the normal maximum limit is essential for maintaining balance [23]. When the composite equilibrium score approaches 100, it indicates optimal stability, typically achieved through the ankle strategy. Conversely, a score nearing 0 points to a loss of balance, which is usually compensated for by employing the hip strategy [23]. The somatosensory foot orthoses may facilitate more efficient integration of sensory information from somatosensory, visual, and vestibular cues. Additionally, the tactile input they provide could accelerate information transfer to the cognitive system, allowing the musculoskeletal system to implement the ankle strategy more efficiently for better balance control [47].

The observed symmetrical weight distribution between the two limbs with the somatosensory foot orthoses further support the improvement in balance outcomes. Enhancing balance posture through symmetrical weight distribution indicate the use of ankle strategy and could be supportive as this is a more energy-efficient way to counteract mild perturbation for maintaining balance than other strategies [48]. This could help maintain uniform weight distribution between the two limbs before and after the translations, particularly in the backward direction. When backward translation of the platform takes place, the entire body weight shifts onto the plantar surface of the feet. To maintain balance in this situation, individuals exert plantar force against the base of support [49]. This redistribution of weight enables the body to utilize sensory feedback from the support surface. Somatosensory foot orthoses with protruding knobs are particularly helpful in this regard. The knobs can provide increased stimulation to the mechanoreceptors located in the glabrous skin of the foot. Consequently, this enhanced sensory input is quickly transmitted to the brain, which then coordinates muscle contractions around the ankle to counteract disturbances and restore stable posture.

The improvements in balance performance with the somatosensory foot orthoses in response to perturbations align with findings from previous investigations during static and dynamic gait analyses [10, 11]. Previous studies have primarily explored the effects of somatosensory foot orthoses on postural balance through CoP displacements or postural sway [16, 50] and clinical functional outcomes [18]. These studies employed somatosensory foot orthoses with protruding knobs of various sizes and shapes to improve static and dynamic balance. Notably, studies employing somatosensory foot orthoses with flat structure and smaller granulations have reported non-significant changes in static balance [15-17]. One possible reason is that the mechanoreceptors located in the glabrous skin on the sole of the foot may not be adequately stimulated. Effective tactile input to these receptors plays an important role in keeping the CoG within its normal range of sway in the anteroposterior direction [51, 52]. When the contact area between the foot plantar surface and a flat orthosis is limited, the amount of tactile stimulation is reduced. Thus, there may be insufficient activation of the mechanoreceptors. In contrast, the somatosensory foot orthoses with a 3mm ridge around the perimeter effectively engages the lateral perimeter areas of the foot, counteracting sway movements and enhancing lateral stability during walking [53]. Additionally, incorporating arch-support into somatosensory foot orthoses has been shown to improve dynamic stability [13]. Configurations featuring larger knobs placed in regions of higher plantar pressure, such as the heel and metatarsal heads, may provide enhanced tactile stimulation, thereby improving dynamic stability. Mechanistically, protruding knobs may offer sufficient tactile input to activate cutaneous mechanoreceptors on the plantar surface, which send afferent signals through peripheral nerves to the dorsal root ganglia and into the spinal cord [54]. These signals can elicit immediate reflex responses at the spinal level and promote via the dorsal columns to the brainstem, thalamus, and somatosensory cortex, where sensory information from the foot is precisely mapped and integrated [55-57]. Recent evidence indicates that cutaneous receptors contribute directly to proprioception by enhancing perceptual information about joint position and movement, which is combined with input from muscle spindles [58, 59]. Enhanced cutaneous stimulation from the orthosis may therefore increase the sensitivity and integration of proprioceptive information reaching balance control centers, ultimately contributing to improved posture, joint positioning, and balance performance.

In this study, the somatosensory foot orthoses incorporated protruding knobs across the entire top surface, along with arch support and a heel cup. This combination offers a promising strategy for maximizing tactile stimulation of the glabrous skin on the foot. The increased tactile input is meant to enhance sensory feedback to the nervous system. Consequently, these orthoses may help improve balance and promote more effective weight distribution. However, significant improvements were only found in a few variables, which appear to be particularly sensitive to tactile stimulation. However, placing protruding knobs in regions of higher plantar pressure may generate abnormal frictional forces, potentially leading to foot complications. Future research should explore the site-specific potential of foot skin for mechanoreceptor stimulation, examining optimal locations and knob sizes to maximize mechanoreceptor activation while minimizing discomfort and the risk of foot complications.

Amplitude scaling results suggest that females have superior musculoskeletal control compared to males. Their ability to recover more rapidly from unexpected external disturbances during medium and large translations supports this notation. In the present study, females also showed shorter latency and reduced sway energy with somatosensory foot orthoses relative to males. These outcomes are consistent with previous research. Studies have proposed that physiological and morphological factors may allow females to use their motor systems more efficiently [60-62]. This finding is also in line with earlier studies that females respond better to sensory perturbations than males [19, 60]. Nevertheless, the protruding stimulation did not significantly change sway energy. The lack of significant effect could be attributed to the small sample size or variations in body mass index and weight, which may impact sway energy [63]. Further investigation is needed to explore site-specific and long-term effects. Longitudinal studies focusing on afferent axon recruitment and muscle activation are recommended to better understand the underlying mechanisms.

Overall, these findings highlight the potential of somatosensory foot orthoses with tactile stimulating knobs to enhance postural stability. These findings have significant implications for clinical applications, particularly for older adults, who often face challenges in maintaining balance due to age-related declines in muscle strength and sensory feedback [2]. By enhancing mechanoreceptor stimulation through design modifications and somatosensory feedback, somatosensory foot orthoses could serve as valuable tools in rehabilitation programs and improve overall mobility and confidence in these individuals. Future studies should explore the effects of varied material hardness, design specifications (shape, height) and knob placements to maximize their benefits and broaden applications for populations with balance impairments or risk of falls.

The current study has several limitations. First, only healthy individuals were recruited, leaving the impact on populations with peripheral sensory deficits, neurological conditions, or increased fall risk unexamined. While healthy community-dwelling older adults were recruited, we did not include baseline assessments or comparisons to younger adults to stratify sensorimotor or balance abilities. This may have introduced variability in participant function, potentially influencing the observed effects of the orthoses, as differences in benefit may only be evident in higher or lower functioning subgroups. The somatosensory foot orthoses featured protruding knobs and arch-support, but the effects of these components were not analyzed separately, making it difficult to isolate the contribution of the stimulating knobs. Additionally, a single type of protruding knob across the entire surface of the somatosensory foot orthoses was considered in this study. A variety of stimulating knob features, including different shapes, heights, and positioning effects should investigate and explore in the future studies, to optimize specific knob arrangements with adjusted heights for enhancing postural stability.

Participants wore the foot orthoses only during the assessment sessions and the long-term impact on both performance and physiological adaptations remains unknown. Further research is warranted to explore if use of somatosensory foot orthoses for longer duration influences somatosensory feedback. Additionally, the assessor was not blinded to both the intervention and the outcome measures, which may introduce bias. Methodological shortcomings, such as the absence of controlled study designs, underscore the necessity for more robust randomized controlled trials (RCTs). Upcoming controlled approach should aim to isolate the effects of specific design elements, like the stimulating knobs, and recruit larger, more diverse individuals with sensory deficits to improve the applicability of the findings.

3.5 Conclusion

The somatosensory foot orthoses with protruding knobs may enhance postural balance through equilibrium, symmetric weight distribution, redistributing plantar forces/pressure in response to both static and dynamic perturbations and gait in healthy older adults, although improvements were significant in only a few variables. Incorporating protruding knobs into somatosensory foot orthoses has the potential to stimulate mechanoreceptors on the foot's plantar surface. These findings contribute to the growing body of literature on the role of somatosensory foot orthoses with protruding knobs/textures for tactile stimulation in improving gait mechanics and building a foundation for future investigations. Future studies should consider careful interpretation the results. Also, should explore design optimization, incorporate larger sample sizes including diverse individuals with varying sensory or neurological conditions to confirm and maximize the effects of passive stimulation of plantar tactile mechanoreceptors.

References

[1] R.J. Peterka, Sensory integration for human balance control, Handb Clin Neurol 159 (2018) 27-42. https://doi.org/10.1016/b978-0-444-63916-5.00002-1

[2] M.Y. Osoba, A.K. Rao, S.K. Agrawal, A.K. Lalwani, Balance and gait in the elderly: A contemporary review, Laryngoscope Investig Otolaryngol 4(1) (2019) 143-153. https://doi.org/10.1002/lio2.252

[3] J. Wang, Y. Li, G.Y. Yang, K. Jin, Age-Related Dysfunction in Balance: A Comprehensive Review of Causes, Consequences, and Interventions, Aging Dis (2024). https://doi.org/10.14336/ad.2024.0124-1

[4] Y. Lajoie, S.P. Gallagher, Predicting falls within the elderly community: comparison of postural sway, reaction time, the Berg balance scale and the Activities-specific Balance Confidence (ABC) scale for comparing fallers and non-fallers, Arch Gerontol Geriatr 38(1) (2004) 11-26. https://doi.org/10.1016/s0167-4943(03)00082-7

[5] N. Labata-Lezaun, S. Rodríguez-Rodríguez, C. López-de-Celis, J. Rodríguez-Sanz, M. Canet-Vintró, R.O. G, et al., Effectiveness of Different Training Modalities on Static Balance in Older Adults: A Systematic Review and Meta-Analysis, Life (Basel) 13(5) (2023). https://doi.org/10.3390/life13051193

[6] A. Halvarsson, I.M. Dohrn, A. Ståhle, Taking balance training for older adults one step further: the rationale for and a description of a proven balance training programme, Clin Rehabil 29(5) (2015) 417-25. https://doi.org/10.1177/0269215514546770

[7] B.A. West, G. Bhat, J. Stevens, G. Bergen, Assistive device use and mobility-related factors among adults aged≥65years, J Safety Res 55 (2015) 147-50. https://doi.org/10.1016/j.jsr.2015.08.010

[8] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology 70(8) (2024) 801-811. https://doi.org/10.1159/000539591

[9] A. Aboutorabi, M. Bahramizadeh, M. Arazpour, R. Fadayevatan, F. Farahmand, S. Curran, et al., A systematic review of the effect of foot orthoses and shoe characteristics on balance in healthy older subjects, Prosthet Orthot Int 40(2) (2016) 170-81. https://doi.org/10.1177/0309364615588342

[10] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293

[11] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology (2024) 1-11. https://doi.org/10.1159/000539591.

[12] M. Huang, K.L. Yick, S.P. Ng, J. Yip, R.T. Cheung, The effect of support surface and footwear condition on postural sway and lower limb muscle action of the older women, PLoS One 15(6) (2020) e0234140. https://doi.org/10.1371/journal.pone.0234140

[13] P.L. Li, K.L. Yick, S.P. Ng, J. Yip, Influence of Textured Indoor Footwear on Posture Stability of Older Women Based on Center-of-Pressure Measurements, Hum Factors 61(8) (2019) 1247-1260. https://doi.org/10.1177/0018720819837414

[14] A. Kiaghadi, M. Bahramizadeh, M. Hadadi, Effect of Textured and Prefabricated Insole Use With Medical or Sports Shoes on Dynamic Postural Control in Elderly People, Topics in Geriatric Rehabilitation 36(1) (2020).

[15] N. Asgari, G. Yeowell, E. Sadeghi-Demneh, A comparison of the efficacy of textured insoles on balance performance in older people with versus without plantar callosities, Gait Posture 94 (2022) 217-221. https://doi.org/10.1016/j.gaitpost.2022.03.022

[16] X. Qu, Impacts of different types of insoles on postural stability in older adults, Appl Ergon 46 Pt A (2015) 38-43. https://doi.org/10.1016/j.apergo.2014.06.005

[17] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11

[18] C. de Morais Barbosa, M.B. Bértolo, J.Z. Gaino, M. Davitt, Z. Sachetto, E. de Paiva Magalhães, The effect of flat and textured insoles on the balance of primary care elderly people: a randomized controlled clinical trial, Clin Interv Aging 13 (2018) 277-284. https://doi.org/10.2147/cia.S149038

[19] N.D. Eriksen, D.D. Hougaard, Age- and gender-specific normative data on computerized dynamic posturography in a cohort of Danish adults, Eur Arch Otorhinolaryngol 280(5) (2023) 2191-2200. https://doi.org/10.1007/s00405-022-07706-y

[20] Z. Lai, R. Wang, B. Zhou, J. Chen, L. Wang, Difference in the recruitment of intrinsic foot muscles in the elderly under static and dynamic postural conditions, PeerJ 11 (2023) e15719. https://doi.org/10.7717/peerj.15719.

[21] E. Valverde-Guijarro, I.M. Alguacil-Diego, L. Vela-Desojo, R. Cano-de-la-Cuerda, Effects of contemporary dance and physiotherapy intervention on balance and postural control in Parkinson's disease, Disabil Rehabil 44(12) (2022) 2632-2639. https://doi.org/10.1080/09638288.2020.1839973.

[22] L.M. Nashner, C.L. Shupert, F.B. Horak, F.O. Black, Organization of posture controls: an analysis of sensory and mechanical constraints, Prog Brain Res 80 (1989) 411-8; discussion 395-7. https://doi.org/10.1016/s0079-6123(08)62237-2.

[23] N. Vanicek, S.A. King, R. Gohil, I.C. Chetter, P.A. Coughlin, Computerized dynamic posturography for postural control assessment in patients with intermittent claudication, J Vis Exp (82) (2013) e51077. https://doi.org/10.3791/51077.

[24] D.T.M. Oda, C.F. Ganança, Computerized dynamic posturography in the assessment of body balance in individuals with vestibular dysfunction, Audiol Commun Res 20(2) (2015) 89-95. https://doi.org/10.1590/S2317-64312015000200001469.

[25] M.J. Mueller, Identifying patients with diabetes mellitus who are at risk for lower-extremity complications: use of Semmes-Weinstein monofilaments, Phys Ther 76(1) (1996) 68-71. https://doi.org/10.1093/ptj/76.1.68.

[26] K. Van Alsenoy, A. Thomson, A. Burnett, Reliability and validity of the Zebris FDM-THQ instrumented treadmill during running trials, Sports Biomech 18(5) (2019) 501-514. https://doi.org/10.1080/14763141.2018.1452966

[27] C. Nüesch, J.-A. Overberg, H. Schwameder, G. Pagenstert, A. Mündermann, Repeatability of spatiotemporal, plantar pressure and force parameters during treadmill walking and running, Gait & Posture 62 (2018) 117-123. https://doi.org/10.1016/j.gaitpost.2018.03.017

[28] V. Lugade, K. Kaufman, Center of pressure trajectory during gait: a comparison of four foot positions, Gait Posture 40(4) (2014) 719-22. https://doi.org/10.1016/j.gaitpost.2014.07.001

[29] P.R. Trueblood, M. Rivera, C. Lopez, C. Bentley, N. Wubenhorst, Age-based normative data for a computerized dynamic posturography system that uses a virtual visual surround environment, Acta Otolaryngol 138(7) (2018) 597-602. https://doi.org/10.1080/00016489.2018.1429653.

[30] A.A. Alharbi, E.G. Johnson, A.A. Albalwi, N.S. Daher, T.K. Cordett, O.I. Ambode, et al., Effect of visual input on postural stability in young adults with chronic motion sensitivity: A

controlled cross-sectional study, J Vestib Res 27(4) (2017) 225-231. https://doi.org/10.3233/ves-170534.

[31] E. Palluel, V. Nougier, I. Olivier, Do spike insoles enhance postural stability and plantar-surface cutaneous sensitivity in the elderly?, Age (Dordr) 30(1) (2008) 53-61. https://doi.org/10.1007/s11357-008-9047-2

[32] A. Kiaghadi, M. Bahramizadeh, M. Hadadi, Effect of Textured and Prefabricated Insole Use With Medical or Sports Shoes on Dynamic Postural Control in Elderly People, Top Geriatr Rehabil 36(1) (2020). https://doi.org/10.1097/TGR.0000000000000255.

[33] D. Malatesta, M. Canepa, A. Menendez Fernandez, The effect of treadmill and overground walking on preferred walking speed and gait kinematics in healthy, physically active older adults, Eur J Appl Physiol 117(9) (2017) 1833-1843. https://doi.org/10.1007/s00421-017-3672-3

[34] C.C. Harro, C. Garascia, Reliability and Validity of Computerized Force Platform Measures of Balance Function in Healthy Older Adults, J Geriatr Phys Ther 42(3) (2019) E57-e66. https://doi.org/10.1519/jpt.0000000000000175

[35] B. Chen, P. Liu, F. Xiao, Z. Liu, Y. Wang, Review of the Upright Balance Assessment Based on the Force Plate, Int J Environ Res Public Health 18(5) (2021). https://doi.org/10.3390/ijerph18052696

[36] A. Rizzato, A. Paoli, M. Andretta, F. Vidorin, G. Marcolin, Are Static and Dynamic Postural Balance Assessments Two Sides of the Same Coin? A Cross-Sectional Study in the Older Adults, Front Physiol 12 (2021) 681370. https://doi.org/10.3389/fphys.2021.681370

[37] K.-H. Bae, J.-H. Shin, J.-S. Lee, J.-O. Yang, B.-J. Lee, S. Park, Analyses of Plantar Foot Pressure and Static Balance According to the Type of Insole in the Elderly, Korean Journal of Sport Biomechanics 26 (2016) 115-126. https://doi.org/10.5103/KJSB.2016.26.1.115

[38] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[39] J.M. Hijmans, J.H. Geertzen, P.U. Dijkstra, K. Postema, A systematic review of the effects of shoes and other ankle or foot appliances on balance in older people and people with peripheral nervous system disorders, Gait Posture 25(2) (2007) 316-23. https://doi.org/10.1016/j.gaitpost.2006.03.010

[40] D.M. Corbin, J.M. Hart, P.O. McKeon, C.D. Ingersoll, J. Hertel, The effect of textured insoles on postural control in double and single limb stance, J Sport Rehabil 16(4) (2007) 363-72. https://doi.org/10.1123/jsr.16.4.363

[41] A.N. Lay, C.J. Hass, R.J. Gregor, The effects of sloped surfaces on locomotion: a kinematic and kinetic analysis, J Biomech 39(9) (2006) 1621-8. https://doi.org/10.1016/j.jbiomech.2005.05.005

[42] A. Valizadeh orang, A. Mokhtari Malekabadi, A. Jafarnezhadgero, The acute effect of using of texture foot orthoses on ground reaction forces in older adults during walking, Med J Tabriz Uni Med Sciences Health Services 42(6) (2021) 756-763. https://mj.tbzmed.ac.ir/Article/27095.

[43] A. Hartmann, K. Murer, R.A. de Bie, E.D. de Bruin, The effect of a training program combined with augmented afferent feedback from the feet using shoe insoles on gait performance and muscle power in older adults: a randomised controlled trial, Disabil Rehabil 32(9) (2010) 755-64. https://doi.org/10.3109/09638280903295441

[44] K.J. Mickle, B.J. Munro, S.R. Lord, H.B. Menz, J.R. Steele, Foot pain, plantar pressures, and falls in older people: a prospective study, J Am Geriatr Soc 58(10) (2010) 1936-40. https://doi.org/10.1111/j.1532-5415.2010.03061.x

[45] F. Pol, S. Forghany, S.M. Hosseini, A. Taheri, H.B. Menz, Structural and functional foot and ankle characteristics associated with falls in older people, Gait Posture 88 (2021) 78-83. https://doi.org/10.1016/j.gaitpost.2021.05.012

[46] D.R. Bonanno, K.B. Landorf, H.B. Menz, Pressure-relieving properties of various shoe inserts in older people with plantar heel pain, Gait Posture 33(3) (2011) 385-9. https://doi.org/10.1016/j.gaitpost.2010.12.009

[47] V.E. Abraira, D.D. Ginty, The sensory neurons of touch, Neuron 79(4) (2013) 618-39. https://doi.org/10.1016/j.neuron.2013.07.051.

[48] P. Morasso, Integrating ankle and hip strategies for the stabilization of upright standing: An intermittent control model, Front Comput Neurosci 16 (2022) 956932. https://doi.org/10.3389/fncom.2022.956932.

[49] M. Fujimoto, W.L. Hsu, M.H. Woollacott, L.S. Chou, Ankle dorsiflexor strength relates to the ability to restore balance during a backward support surface translation, Gait Posture 38(4) (2013) 812-7. https://doi.org/10.1016/j.gaitpost.2013.03.026.

[50] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Effects of textured insoles on balance in people with Parkinson's disease, PLoS One 8(12) (2013) e83309. https://doi.org/10.1371/journal.pone.0083309

[51] S.D. Perry, W.E. McIlroy, B.E. Maki, The role of plantar cutaneous mechanoreceptors in the control of compensatory stepping reactions evoked by unpredictable, multi-directional perturbation, Brain Res 877(2) (2000) 401-6. https://doi.org/10.1016/s0006-8993(00)02712-8.

[52] B.E. Maki, S.D. Perry, R.G. Norrie, W.E. McIlroy, Effect of facilitation of sensation from plantar foot-surface boundaries on postural stabilization in young and older adults, J Gerontol A Biol Sci Med Sci 54(6) (1999) M281-7. https://doi.org/10.1093/gerona/54.6.m281.

[53] S.D. Perry, A. Radtke, W.E. McIlroy, G.R. Fernie, B.E. Maki, Efficacy and effectiveness of a balance-enhancing insole, J Gerontol A Biol Sci Med Sci 63(6) (2008) 595-602. https://doi.org/10.1093/gerona/63.6.595

[54] A.L. Hatton, J. Dixon, K. Rome, D. Martin, Standing on textured surfaces: effects on standing balance in healthy older adults, Age Ageing 40(3) (2011) 363-8. https://doi.org/10.1093/ageing/afr026.

[55] P.M. Kennedy, J.T. Inglis, Distribution and behaviour of glabrous cutaneous receptors in the human foot sole, J Physiol 538(Pt 3) (2002) 995-1002. https://doi.org/10.1113/jphysiol.2001.013087

[56] M.F. Bear, B.W. Connors, M.A. Paradiso, Neuroscience: Exploring the Brain, Wolters Kluwer2016.

[57] E.R. Kandel, S.J. H., J.T. M., S.A. Siegelbaum, A.J. Hudspeth, S. Mack, Principles of Neural Science, Principles of Neural Science, Fifth Edition, McGraw-Hill Education, New York, NY, 2014.

[58] D.F. Collins, K.M. Refshauge, G. Todd, S.C. Gandevia, Cutaneous receptors contribute to kinesthesia at the index finger, elbow, and knee, J Neurophysiol 94(3) (2005) 1699-706. https://doi.org/10.1152/jn.00191.2005

[59] Q. Song, X. Zhang, M. Mao, W. Sun, C. Zhang, Y. Chen, et al., Relationship of proprioception, cutaneous sensitivity, and muscle strength with the balance control among older adults, J Sport Health Sci 10(5) (2021) 585-593. https://doi.org/10.1016/j.jshs.2021.07.005

[60] A. Julienne, E. Verbecque, S. Besnard, Normative data for instrumented posturography: a systematic review and meta-analysis, Front Hum Neurosci 18 (2024) 1498107. https://doi.org/10.3389/fnhum.2024.1498107.

[61] I. Farenc, P. Rougier, L. Berger, The influence of gender and body characteristics on upright stance, Ann Hum Biol 30(3) (2003) 279-94. https://doi.org/10.1080/0301446031000068842.

[62] H. Kollegger, C. Baumgartner, C. Wöber, W. Oder, L. Deecke, Spontaneous body sway as a function of sex, age, and vision: posturographic study in 30 healthy adults, Eur Neurol 32(5) (1992) 253-9. https://doi.org/10.1159/000116836.

[63] G. Olchowik, M. Tomaszewski, P. Olejarz, J. Warchoł, M. Różańska-Boczula, The effect of height and BMI on computer dynamic posturography parameters in women, Acta Bioeng Biomech 16(4) (2014) 53-8. https://pubmed.ncbi.nlm.nih.gov/25598290/.

CHAPTER 4

FOOT TACTILE SENSITIVITY THRESHOLDS ACROSS VARIOUS SKIN LOCATIONS IN OLDER ADULTS

4.1 Introduction

The human foot plays a vital role in providing stability, balance, and propulsion during locomotion, such as standing, walking and running. As the primary interface between the body and the ground, the foot supports these stability, balance and propulsion through complex interactions between its anatomical structures and sensory systems. Among these, tactile sensitivity of the foot—though critical for posture control and movement—is often unclear [1]. Tactile sensitivity is the ability to perceive and respond to mechanical stimuli such as pressure, texture, and vibration. The glabrous skin of the foot contains numerous mechanoreceptors that contribute to this sensory input. These include Merkel cells, Meissner's corpuscles, Pacinian corpuscles, and Ruffini endings—each tuned to specific types of tactile information [1-5]. Merkel cells detect sustained pressure and texture, Meissner's corpuscles respond to light touch and low-frequency vibration, Pacinian corpuscles are sensitive to high-frequency vibration, and Ruffini endings detect skin stretch and contribute to joint position sense. These mechanoreceptors work in coordination with the visual and vestibular systems to send sensory inputs to the central nervous system. This enables the musculoskeletal system to make appropriate adjustments in foot placement, posture, and load attenuation based on information about the supporting surface, as well as the position and acceleration of the body. This proprioceptive feedback (i.e. the ability to perceive the movement, pressure, and position of the body parts) is essential for coordinating movements and ensuring functional mobility, balance, and stability [2, 3].

The foot's plantar surface serves as the only interface with the supporting surface, making it as one of the key sources of proprioceptive feedback for dynamic balance and stability during standing and walking [6, 7]. However, our sensory and motor systems naturally decline across aging. Structural and functional changes such as a reduction in mechanoreceptor density, altered skin properties, and diminished neural activity can impair tactile perception [8, 9]. These sensory deficits may reduce the efficiency of central nervous system to accurately interpret body position and movement based on the displacement, velocity and acceleration information of the skin surface. Along with age-related musculoskeletal degeneration, these can compromise balance and increase fall risk [10, 11].

Previous studies have mostly investigated foot tactile sensitivity in younger populations [12-14], which demonstrate that tactile sensitivity varies across foot regions, with higher sensitivity (i.e. lower sensitivity threshold) reported at the toes, medial longitudinal arches, medial and lateral calcaneus below malleolus, and medial and lateral bases of metatarsus, and lower sensitivity at the heel, lateral midfoot, and metatarsal heads [12-14]. However, these findings may not apply to older adults due to age-related changes in sensory function. Research has shown that older adults experience significant declines in plantar tactile receptor activity, contributing to decreased posture control and increased fall risk [8]. Therefore, mapping the distribution of tactile sensitivity across the foot in older adults is essential for informing interventions aimed at enhancing sensory feedback, balance, and stability. It is also questionable how the age-related degeneration may affect the foot tactile sensitivity across different regions. Additionally, studies involving older populations often focus on a limited number of foot locations [15, 16] or incorporated investigations for intervention effects [17], limiting their generalizability. Studying comprehensive data on foot tactile sensitivity thresholds in healthy older adults could provide insights of foot orthoses design that provide targeted somatosensory stimulation. Such designs can optimize mechanical stimulation to enhance sensory input, thereby improving balance and reducing the risk of falls among older adults.

Hence, this study aimed to identify tactile sensitivity thresholds across 30 different foot skin locations among ambulant healthy older adults. We hypothesize that tactile sensitivity would vary significantly across foot regions, with certain areas exhibiting higher sensitivity than others. Additionally, we further subdivided into three age groups (65-69, 70-74 versus 75-80 years) and BMI groups (18.5-24.9, 25.0-29.9 versus 30-40) for additional analyses in accordance with previous studies [18, 19]. Based on the previous studies on aging and BMI, we hypothesize that lower tactile sensitivity may be found in older adults and the adults with higher BMI.

4.2 Methods

4.2.1 Participants

Healthy older adults aged 65 years and above, residing in Hong Kong, were recruited for the study. Participants were capable of walking for at least 30 minutes without the use of assistive walking devices or rest. Individuals were excluded if they had neuromuscular or central nervous system disorders, such as stroke, dementia, Parkinson's disease, or vestibular disorders. Additional exclusion criteria included major foot pathologies, such as severe foot pain, peripheral neuropathy, ulcers, a history of foot surgery, or lower limb amputations. A total of eligible 46 participants were recruited: 30 women (age: 71.26±2.87 yrs; weight: 54.61±10.00 kg; height: 151.60±6.71cm; BMI: 24.27±4.72) and 16 men (age: 72.43±3.68 yrs; weight: 66.03±10.01kg; height: 165.84±6.50 cm; BMI: 25.53±3.02). Participants were categorized into three age groups: Group I (65-69 years: n = 13), Group II (70-74 years: n = 24), and Group III (75-80 years: n = 9) [18, 19] and they were also categorized by BMI: Group I (18.5-24.9: n =

34), Group II (25-29.9: n = 10), and Group III (30-40: n = 2) [20] for additional sub-group analyses.

4.2.2 Data Collection and Processing

All participants were blindfolded and comfortably seated on the examination table with their legs extended and feet in a neutral position, toes pointing straight up. Assessments were conducted in a quiet, climate-controlled room to ensure optimal testing conditions. The thresholds of tactile sensitivity mapping were assessed using Semmes-Weinstein Monofilament kits demonstrated excellent reliability on the foot (ICC=0.9) (20-piece stick set, North Coast Medical Supply, Morgan Hill, CA) [21, 22]. These kits feature non-linear bending force ranging from 0.08mN (monofilament stick 1) to 3000mN (monofilament stick 20). Tactile sensitivity thresholds are inversely related to tactile sensitivity: higher thresholds indicate lower sensitivity, as more force is required for the stimulus to be detected. The sensitivity thresholds were measured exclusively on the right foot to minimize variability and ensure consistent testing conditions [13-16]. These measurements were taken at 30 standardized foot skin locations, covering the plantar (P), medial (M), lateral (L), and dorsal (D) regions [13]. The locations and definitions were provided in Table 4-1 as well as illustrated in Figure 4-1. To minimize potential order effects, the sequence of site testing was randomized across participants. Each monofilament was applied four to five times perpendicularly to the skin surface at each location. A threshold was considered detected if the participant correctly responded in 75-80% of the trials [23]. All threshold measurements were conducted by the same trained investigator (AJ) to ensure consistency and reliability of the measurements [24].

4.2.3 Statistical Analysis

A repeated measures ANOVA was conducted to investigate the differences in tactile sensitivity threshold across the 30 foot skin locations. While significant effects were found, post-hoc pairwise comparisons with Bonferroni adjustments were applied to identify specific site differences. To assess the effects of demographic variables, one-way ANOVA and independent sample t-test were utilized to compare tactile sensitivity thresholds at each foot skin location by age group, BMI category, and gender. Additionally, Hierarchical Cluster Analysis was performed to identify groups of skin locations with similar sensitivity threshold profiles. Euclidean distance was used as the measure of similarity, and Ward's method was applied for clustering. Correlation coefficients within the cluster were analyzed using the Spearman correlation test. Statistical significance was set at $p < 0.05$. All statistical analyses were conducted using IBM SPSS Statistical software (Version 22, SPSS Inc., Chicago, IL).

Table 4-1. 30 different foot skin locations, their definitions, and tactile sensitivity thresholds (mean and standard deviations)

Foot Skin Locations	Definitions	All (mean, SD)	Male (mean, SD)	Female (mean, SD)	P value
P1	Heel	26.14 (22.27)	31.02 (23.65)	23.54 (21.45)	0.283
P2	Midfoot medial	2.59 (2.98)	3.77 (4.18)	1.95 (1.88)	0.114
P3	Midfoot intermedius	2.90 (2.96)	4.16 (4.13)	2.22 (1.86)	0.091
P4	Midfoot lateral	8.70 (6.46)	12.38 (8.35)	6.73 (4.14)	**0.003**
P5	Metatarsal head I	9.14 (10.02)	12.36 (13.32)	7.42 (7.44)	0.113
P6	Metatarsal head III	9.81 (8.96)	11.03 (9.00)	9.16 (9.02)	0.506
P7	Metatarsal head V	10.89 (9.99)	13.95 (11.10)	9.26 (9.12)	0.130
P8	Plantar distal hallux	7.94 (12.72)	11.88 (15.61)	5.83 (10.58)	0.126
P9	Plantar distal phalanx III	6.31 (9.59)	7.69 (9.83)	5.58 (9.54)	0.484
P10	Plantar distal phalanx V	8.90 (12.09)	11.66 (11.78)	7.42 (12.18)	0.262
M1	Medial malleolus	5.22 (6.42)	7.67 (9.11)	3.91 (3.99)	0.058
M2	Medial calcaneus below malleolus	3.94 (3.71)	5.95 (4.07)	2.86 (3.06)	**0.006**
M3	Base of navicular	3.17 (2.98)	4.85 (3.94)	2.28 (1.84)	**0.023**
M4	Medial base of metatarsus I	2.26 (2.81)	3.41 (3.71)	1.65 (1.99)	0.094
M5	Medial head of metatarsus I	3.88 (6.33)	4.42 (4.41)	3.59 (7.20)	0.677
L1	Lateral malleolus	4.86 (3.44)	7.15 (3.90)	3.64 (2.47)	**0.004**
L2	Lateral calcaneus below malleolus	4.78 (3.92)	7.25 (4.76)	3.47 (2.65)	**0.008**
L3	Lateral base of metatarsus V	3.04 (2.48)	4.35 (2.47)	2.33 (2.23)	**0.007**
L4	Lateral head of metatarsus V	3.68 (3.58)	5.83 (4.57)	2.54 (2.28)	**0.014**
AT	Achilles tendon	4.06 (2.91)	4.29 (2.36)	3.94 (3.20)	0.703

D1	Articulation talocruralis	5.65 (8.09)	7.81 (9.64)	4.50 (7.03)	0.189
D2	Dorsal metatarsal base I	2.95 (3.68)	4.79 (4.56)	1.96 (2.73)	**0.012**
D3	Dorsal metatarsal base III	2.83 (3.65)	4.26 (4.65)	2.06 (2.78)	0.051
D4	Dorsal metatarsal base V	2.12 (1.95)	2.72 (1.76)	1.80 (2.00)	0.130
D5	Dorsal metatarsal head I	2.86 (2.70)	4.01 (3.23)	2.24 (2.18)	**0.032**
D6	Dorsal metatarsal head III	2.42 (2.14)	2.87 (2.00)	2.17 (2.21)	0.298
D7	Dorsal metatarsal head V	2.10 (2.16)	3.20 (2.04)	1.52 (2.01)	**0.010**
D8	Dorsal distal phalanx I	2.88 (3.60)	4.04 (4.64)	2.27 (2.80)	0.113
D9	Dorsal distal phalanx III	2.78 (2.87)	3.98 (2.94)	2.14 (2.66)	**0.037**
D10	Dorsal distal phalanx V	3.74 (4.78)	6.46 (6.45)	2.30 (2.79)	**0.024**
P: plantar foot site, M: medial foot site, L: lateral foot site, D: dorsal foot site					

4.3 Results

Descriptive statistics of tactile sensitivity thresholds across 30 foot skin locations are provided in Table 4-1. Significant gender differences were observed at several sites, with male exhibiting higher tactile sensitivity thresholds (i.e. lower sensitivity) compared to females (Table 4-1). The gender differences were found at lateral midfoot (P4) (p=0.003), medial calcaneus (M2) (p=0.006), base of navicular (M3) (p=0.023), lateral malleolus (L1) (p=0.004), lateral calcaneus (L2) (p=0.008), lateral base of metatarsal V (L3) (p=0.007), lateral head of metatarsal V (L4) (p=0.014), dorsal base of metatarsal I (D2) (p=0.012), dorsal head of metatarsal I (D5) (p=0.032), dorsal head of metatarsal V (D7) (p=0.010), dorsal medial phalanges III (D9) (p=0.037), and dorsal medial phalanges V (D10) (p=0.024). In contrast, no significant differences in tactile sensitivity thresholds were found across older adult age groups nor BMI groups.

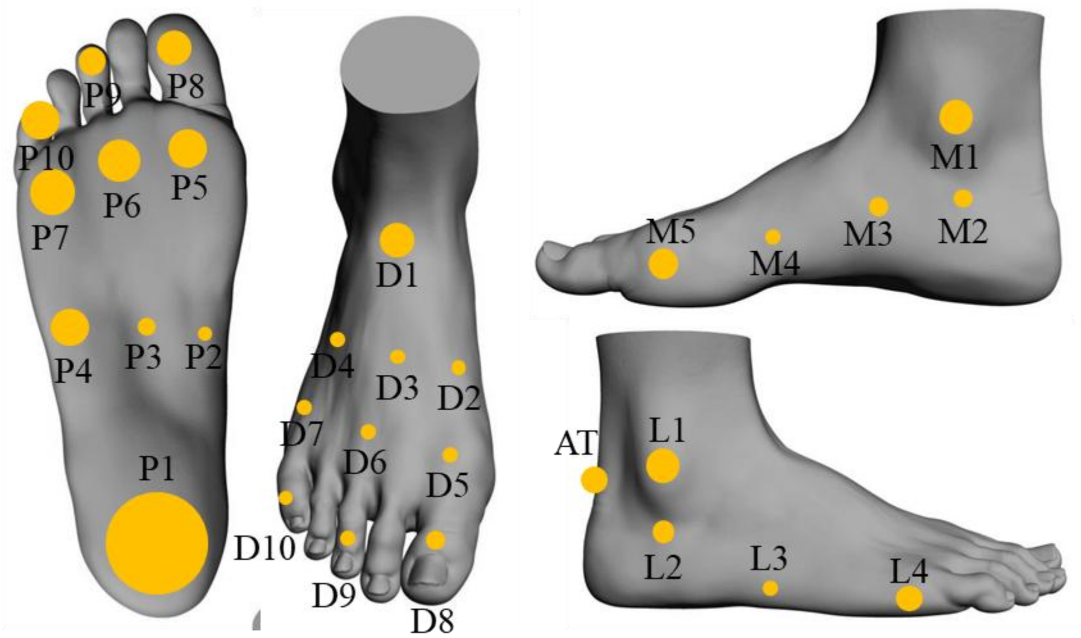


Figure 4-1. 30 foot skin locations including plantar, medial, lateral, and dorsal areas with their tactile sensitivity thresholds (Larger circles indicating higher thresholds). P1: Heel; P2: Midfoot medial; P3: Midfoot intermedius; P4: Midfoot lateral; Metatarsal head I; P6: Metatarsal head III; P7: Metatarsal head V; P8: Plantar distal hallux; P9: Plantar distal phalanx III; P10: Plantar distal phalanx V; M1: Medial malleolus; M2: Medial calcaneus; M3: Base of navicular; M4: Medial base of metatarsal I; M5: Medial head of metatarsal I; L1: Lateral malleolus; L2: Lateral calcaneus; L3: Lateral base of metatarsal V; L4: Lateral head of metatarsal V; AT: Achilles tendon; D1: Articulation talocruralis; D2: Dorsal metatarsal base I; D3: Dorsal metatarsal base III; D4: Dorsal metatarsal base V; D5: Dorsal metatarsal head I; D6: Dorsal metatarsal head III; D7: Dorsal metatarsal head V; D8: Dorsal distal phalanx I; D9: Dorsal distal phalanx III; D10: Dorsal distal phalanx V. Larger circles represent higher thresholds, while smaller circles indicate lower thresholds.

The heel exhibited the highest tactile sensitivity threshold of all foot locations ($p<0.05$ and $p<0.001$), indicating it was the least sensitive area (Figure 4-2). Among the plantar, medial, and lateral foot skin regions, significantly lower tactile sensitivity thresholds were observed ($p<0.05$ and $p<0.001$) at the medial midfoot (P2), intermedius midfoot (P3), medial calcaneus (M2), navicular base (M3), medial base of metatarsal I (M4), and lateral base of metatarsal V (L3) than heel (P1), lateral midfoot (P4), metatarsal head I (P5), metatarsal head III (P6), and metatarsal head V (P7). However, dorsal regions exhibited significantly lower tactile sensitivity thresholds ($p<0.05$ and $p<0.001$) than plantar (P1, P4, P5, P6, P7) and lateral regions (L1, L2).

P1	**P1**																													
P2	.000	**P2**																												
P3	.000	1.000	**P3**																											
P4	.000	.000	.000	**P4**																										
P5	.000	.010	.009	1.000	**P5**																									
P6	.001	.000	.000	1.000	1.000	P6																								
P7	.004	.000	.000	1.000	1.000	1.000	**P7**																							
P8	.003	1.000	1.000	1.000	1.000	1.000	1.000	**P8**																						
P9	.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**P9**																					
P10	.002	.238	.226	1.000	1.000	1.000	1.000	1.000	1.000	**P10**																				
M1	.000	1.000	1.000	1.000	1.000	1.000	.568	1.000	1.000	1.000	**M1**																			
M2	.000	1.000	1.000	.001	.340	.020	.003	1.000	1.000	.839	1.000	**M2**																		
M3	.000	1.000	1.000	.000	.015	.001	.000	1.000	1.000	.487	1.000	1.000	**M3**																	
M4	.000	1.000	1.000	.000	.002	.000	.000	1.000	1.000	.067	.687	.457	.899	**M4**																
M5	.000	1.000	1.000	.020	.912	.082	.016	1.000	1.000	.320	1.000	1.000	1.000	1.000	**M5**															
L1	.000	.030	.230	.015	1.000	.199	.041	1.000	1.000	1.000	1.000	1.000	.606	.000	1.000	**L1**														
L2	.000	.001	.699	.001	1.000	.135	.039	1.000	1.000	1.000	1.000	1.000	.307	.000	1.000	1.000	**L2**													
L3	.000	1.000	1.000	.000	.048	.002	.001	1.000	1.000	.373	1.000	1.000	1.000	1.000	1.000	.106	.578	**L3**												
L4	.000	1.000	1.000	.000	.105	.004	.001	1.000	1.000	1.000	1.000	1.000	1.000	.083	1.000	1.000	1.000	1.000	**L4**											
AT	.000	1.000	1.000	.003	.491	.018	.006	1.000	1.000	1.000	1.000	1.000	1.000	.129	1.000	1.000	1.000	1.000	1.000	**AT**										
D1	.000	1.000	1.000	1.000	1.000	1.000	.320	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**D1**									
D2	.000	1.000	1.000	.000	.051	.001	.001	1.000	1.000	.048	1.000	1.000	1.000	1.000	1.000	.486	1.000	1.000	1.000	1.000	1.000	**D2**								
D3	.000	1.000	1.000	.000	.001	.000	.000	1.000	1.000	.205	1.000	1.000	1.000	1.000	1.000	.421	.389	1.000	1.000	1.000	1.000	1.000	**D3**							
D4	.000	1.000	1.000	.000	.003	.000	.000	1.000	1.000	.074	.299	.333	1.000	1.000	1.000	.000	.001	1.000	.297	.011	.841	1.000	1.000	**D4**						
D5	.000	1.000	1.000	.000	.012	.000	.000	1.000	1.000	.130	1.000	1.000	1.000	1.000	1.000	.122	.253	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**D5**					
D6	.000	1.000	1.000	.000	.004	.000	.000	1.000	1.000	.106	.726	1.000	1.000	1.000	1.000	.002	.009	1.000	1.000	.202	1.000	1.000	1.000	1.000	1.000	**D6**				
D7	.000	1.000	1.000	.000	.002	.000	.000	1.000	.951	.057	.414	.246	1.000	1.000	1.000	.000	.001	1.000	.034	.018	.765	1.000	1.000	1.000	1.000	1.000	**D7**			
D8	.000	1.000	1.000	.000	.023	.001	.000	1.000	1.000	.292	1.000	1.000	1.000	1.000	1.000	.096	.075	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**D8**		
D9	.000	1.000	1.000	.000	.013	.000	.000	1.000	1.000	.095	1.000	1.000	1.000	1.000	1.000	.010	.015	1.000	1.000	.952	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**D9**	
D10	.000	1.000	1.000	.000	.276	.018	.007	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	**D10**

P<0.001
P<0.010
P<0.050
P>0.050
P=1.000

Figure 4-2. Pairwise post hoc comparisons were performed across various foot skin locations, including heel (P1), midfoot (P2–P4), metatarsal heads (P5–P7), plantar distal phalanges (P8–P10), medial (M1–M5) and lateral (L1–L4) regions, Achilles tendon (AT), and multiple dorsal sites (D1–D10).

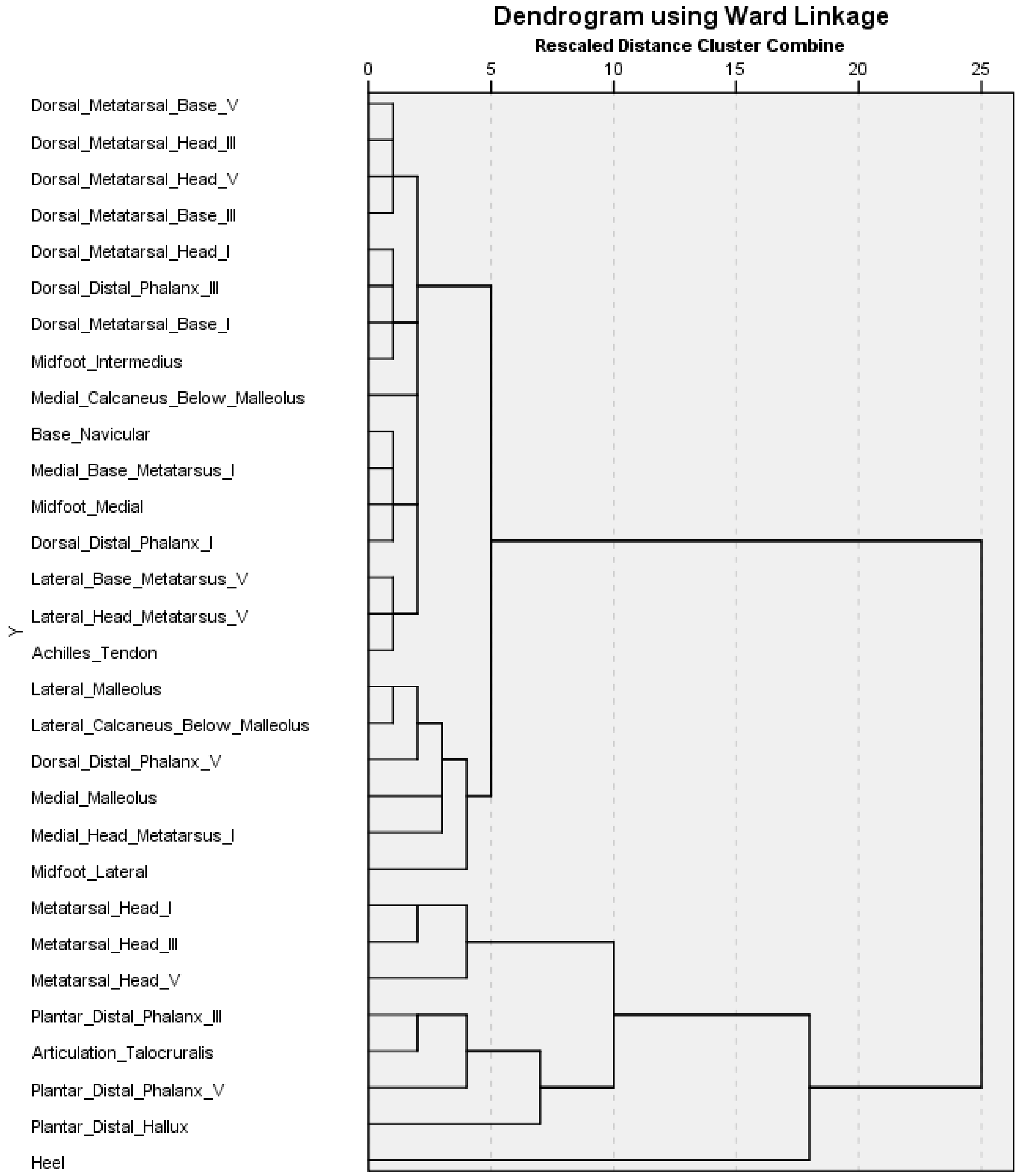


Figure 4-3. The dendrogram visually represents the clusters, revealing which skin locations exhibited closely related sensitivity threshold levels.

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	M1	M2	M3	M4	M5	L1	L2	L3	L4	AT	D1	D2	D3	D4	D5	D6	D7	D8	D9	D10
P1	1.00	0.43	0.29	0.37	0.55	0.58	0.46	0.36	0.48	0.48	0.55	0.42	0.39	0.58	0.57	0.28	0.38	0.43	0.45	0.34	0.36	0.42	0.38	0.41	0.33	0.39	0.50	0.57	0.56	0.40
P2	0.43	1.00	0.72	0.42	0.42	0.43	0.38	0.52	0.31	0.38	0.39	0.52	0.53	0.67	0.56	0.46	0.59	0.60	0.53	0.41	0.37	0.44	0.48	0.41	0.40	0.43	0.49	0.57	0.67	0.53
P3	0.29	0.72	1.00	0.59	0.46	0.48	0.46	0.48	0.45	0.42	0.35	0.57	0.53	0.64	0.53	0.33	0.33	0.49	0.51	0.30	0.49	0.39	0.42	0.48	0.52	0.36	0.46	0.42	0.59	0.43
P4	0.37	0.42	0.59	1.00	0.68	0.61	0.58	0.49	0.45	0.53	0.43	0.42	0.42	0.41	0.46	0.36	0.38	0.52	0.47	0.37	0.45	0.40	0.40	0.52	0.47	0.37	0.38	0.40	0.45	0.33
P5	0.55	0.42	0.46	0.68	1.00	0.84	0.81	0.69	0.48	0.63	0.44	0.35	0.50	0.38	0.51	0.37	0.45	0.32	0.30	0.22	0.57	0.49	0.48	0.53	0.54	0.49	0.49	0.45	0.53	0.43
P6	0.58	0.43	0.48	0.61	0.84	1.00	0.75	0.59	0.53	0.56	0.39	0.31	0.44	0.45	0.48	0.42	0.41	0.43	0.41	0.37	0.52	0.47	0.50	0.55	0.50	0.45	0.43	0.53	0.58	0.54
P7	0.46	0.38	0.46	0.58	0.81	0.75	1.00	0.68	0.51	0.71	0.44	0.37	0.45	0.49	0.52	0.38	0.45	0.39	0.44	0.35	0.41	0.48	0.46	0.50	0.51	0.39	0.41	0.43	0.57	0.49
P8	0.36	0.52	0.48	0.49	0.69	0.59	0.68	1.00	0.50	0.61	0.42	0.43	0.44	0.38	0.39	0.47	0.50	0.29	0.28	0.16	0.55	0.51	0.44	0.48	0.41	0.34	0.44	0.44	0.59	0.55
P9	0.48	0.31	0.45	0.45	0.48	0.53	0.51	0.50	1.00	0.74	0.50	0.50	0.38	0.44	0.46	0.28	0.44	0.33	0.39	0.36	0.52	0.52	0.48	0.48	0.39	0.44	0.44	0.43	0.58	0.49
P10	0.48	0.38	0.42	0.53	0.63	0.56	0.71	0.61	0.74	1.00	0.57	0.62	0.52	0.56	0.54	0.42	0.54	0.39	0.45	0.43	0.55	0.70	0.62	0.54	0.54	0.53	0.60	0.46	0.65	0.56
M1	0.55	0.39	0.35	0.43	0.44	0.39	0.44	0.42	0.50	0.57	1.00	0.71	0.37	0.60	0.53	0.44	0.54	0.46	0.49	0.43	0.57	0.66	0.63	0.70	0.57	0.62	0.65	0.74	0.72	0.70
M2	0.42	0.52	0.57	0.42	0.35	0.31	0.37	0.43	0.50	0.62	0.71	1.00	0.59	0.72	0.44	0.57	0.62	0.55	0.58	0.45	0.63	0.66	0.65	0.54	0.53	0.47	0.63	0.56	0.73	0.66
M3	0.39	0.53	0.53	0.42	0.50	0.44	0.45	0.44	0.38	0.52	0.37	0.59	1.00	0.72	0.56	0.43	0.44	0.57	0.58	0.41	0.44	0.51	0.47	0.51	0.61	0.46	0.53	0.51	0.61	0.48
M4	0.58	0.67	0.64	0.41	0.38	0.45	0.49	0.38	0.44	0.56	0.60	0.72	0.72	1.00	0.73	0.62	0.57	0.71	0.77	0.48	0.41	0.61	0.59	0.56	0.62	0.53	0.63	0.67	0.75	0.65
M5	0.57	0.56	0.53	0.46	0.51	0.48	0.52	0.39	0.46	0.54	0.53	0.44	0.56	0.73	1.00	0.52	0.52	0.68	0.67	0.41	0.35	0.53	0.40	0.52	0.47	0.57	0.51	0.57	0.62	0.46
L1	0.28	0.46	0.33	0.36	0.37	0.42	0.38	0.47	0.28	0.42	0.44	0.57	0.43	0.62	0.52	1.00	0.79	0.65	0.61	0.28	0.47	0.65	0.60	0.54	0.42	0.44	0.43	0.52	0.61	0.57
L2	0.38	0.59	0.33	0.38	0.45	0.41	0.45	0.50	0.44	0.54	0.54	0.62	0.44	0.57	0.52	0.79	1.00	0.56	0.49	0.36	0.57	0.56	0.59	0.49	0.47	0.51	0.53	0.46	0.64	0.63
L3	0.43	0.60	0.49	0.52	0.32	0.43	0.39	0.29	0.33	0.39	0.46	0.55	0.57	0.71	0.68	0.65	0.56	1.00	0.86	0.63	0.28	0.51	0.49	0.47	0.39	0.40	0.44	0.57	0.59	0.48
L4	0.45	0.53	0.51	0.47	0.30	0.41	0.44	0.28	0.39	0.45	0.49	0.58	0.58	0.77	0.67	0.61	0.49	0.86	1.00	0.61	0.31	0.55	0.55	0.57	0.53	0.53	0.59	0.66	0.66	0.54
AT	0.34	0.41	0.30	0.37	0.22	0.37	0.35	0.16	0.36	0.43	0.43	0.45	0.41	0.48	0.41	0.28	0.36	0.63	0.61	1.00	0.22	0.33	0.43	0.38	0.37	0.32	0.35	0.50	0.56	0.53
D1	0.36	0.37	0.49	0.45	0.57	0.52	0.41	0.55	0.52	0.55	0.57	0.63	0.44	0.41	0.35	0.47	0.57	0.28	0.31	0.22	1.00	0.64	0.62	0.62	0.69	0.57	0.66	0.44	0.61	0.48
D2	0.42	0.44	0.39	0.40	0.49	0.47	0.48	0.51	0.52	0.70	0.66	0.66	0.51	0.61	0.53	0.65	0.56	0.51	0.55	0.33	0.64	1.00	0.80	0.71	0.63	0.60	0.70	0.59	0.70	0.63
D3	0.38	0.48	0.42	0.40	0.48	0.50	0.46	0.44	0.48	0.62	0.63	0.65	0.47	0.59	0.40	0.60	0.59	0.49	0.55	0.43	0.62	0.80	1.00	0.83	0.71	0.76	0.75	0.58	0.71	0.64
D4	0.41	0.41	0.48	0.52	0.53	0.55	0.50	0.48	0.48	0.54	0.70	0.54	0.51	0.56	0.52	0.54	0.49	0.47	0.57	0.38	0.62	0.71	0.83	1.00	0.75	0.78	0.70	0.59	0.66	0.63
D5	0.33	0.40	0.52	0.47	0.54	0.50	0.51	0.41	0.39	0.54	0.57	0.53	0.61	0.62	0.47	0.42	0.47	0.39	0.53	0.37	0.69	0.63	0.71	0.75	1.00	0.73	0.79	0.50	0.69	0.62
D6	0.39	0.43	0.36	0.37	0.49	0.45	0.39	0.34	0.44	0.53	0.62	0.47	0.46	0.53	0.57	0.44	0.51	0.40	0.53	0.32	0.57	0.60	0.76	0.78	0.73	1.00	0.78	0.56	0.64	0.53
D7	0.50	0.49	0.46	0.38	0.49	0.43	0.41	0.44	0.44	0.60	0.65	0.63	0.53	0.63	0.51	0.43	0.53	0.44	0.59	0.35	0.66	0.70	0.75	0.70	0.79	0.78	1.00	0.61	0.72	0.65
D8	0.57	0.57	0.42	0.40	0.45	0.53	0.43	0.44	0.43	0.46	0.74	0.56	0.51	0.67	0.57	0.52	0.46	0.57	0.66	0.50	0.44	0.59	0.58	0.59	0.50	0.56	0.61	1.00	0.86	0.69
D9	0.56	0.67	0.59	0.45	0.53	0.58	0.57	0.59	0.58	0.65	0.72	0.73	0.61	0.75	0.62	0.61	0.64	0.59	0.66	0.56	0.61	0.70	0.71	0.66	0.69	0.64	0.72	0.86	1.00	0.81
D10	0.40	0.53	0.43	0.33	0.43	0.54	0.49	0.55	0.49	0.56	0.70	0.66	0.48	0.65	0.46	0.57	0.63	0.48	0.54	0.53	0.48	0.63	0.64	0.63	0.62	0.53	0.65	0.69	0.81	1.00

Figure 4-4. Correlation coefficients are plotted across 30 foot skin locations, including the heel (P1), midfoot (P2–P4), metatarsal heads (P5–P7), plantar distal phalanges (P8–P10), medial (M1–M5) and lateral (L1–L4) regions, Achilles tendon (AT), and various dorsal sites (D1–D10).

The dendrogram reveals distinct groupings of skin locations based on their tactile sensitivity thresholds (Figure 4-3). Locations with lower tactile sensitivity thresholds, such as the midfoot medial, midfoot intermedius, and both the base and head of the medial and lateral metatarsus, are grouped closely together. Additionally, the medial calcaneus, the base of navicular, and the lateral calcaneus also grouped within this lower-threshold cluster. Conversely, sites with higher tactile sensitivity thresholds, including the heel, midfoot lateral, and metatarsal heads, form a separate cluster. Within both low- and high-threshold clusters, moderate to strong correlations were observed ($r>0.42$; $p<0.001$), while correlations between clusters were weak ($r<0.42$) (Figure 4-4). Similarly, dorsal foot locations exhibited moderate to strong internal correlations ($r>0.410$; $p<0.001$) but were weakly associated with high-threshold plantar and lateral sites ($r<0.42$).

4.4 Discussion

This study aimed to investigate regional variations in tactile sensitivity thresholds across different foot skin locations in older adults. Our key results revealed that the heel exhibited the highest sensitivity thresholds (i.e., lowest tactile sensitivity), followed by the lateral midfoot, metatarsal heads, and articulation talocruralis. In contrast, lower sensitivity thresholds (i.e., higher tactile sensitivity) were observed in the medial and intermedius midfoot, base and head of the medial and lateral metatarsals, medial and lateral calcaneus, and foot dorsum. These differences in tactile sensitivity thresholds underscore the importance of underlying biomechanical and physiological properties of the skin in shaping regional sensitivity patterns.

Our results align with findings from older adults [16], and reported higher sensitivity thresholds than young, particularly at the heel (SMD [standard difference in means] = 0.60, 95% CI [0.21, 1.00], $p = 0.003$), lateral midfoot (SMD = 0.45, 95% CI [0.06, 0.84], $p = 0.03$), and metatarsal heads [13, 14], regions subject to greater mechanical loading during gait and standing [25, 26], although non-significant changes were at the medial midfoot (SMD = -0.30, 95% CI [-0.99, -

0.20], p = 0.15) and great toe (SMD = -0.29, 95% CI [-0.69, 0.08], p = 0.13) [14]. Reduced sensitivity in heel may result from adaptations in skin and calcaneal fat pad properties, such as increased thickness, elasticity and stiffness, to protect lower limb against repetitive stress [14, 27]. In contrast, regions with lower mechanical loading, such as the midfoot medial and intermedius, may better preserve their original skin properties, supporting higher tactile sensitivity [14, 25, 26].

The transmission of force necessary to stimulate mechanoreceptors and generate afferent responses may be affected by the changes in physiological properties of the skin [14, 27]. Mechanoreceptor distribution also contributes to regional variation. Regions with higher sensitivity likely have a greater density of Meissner's corpuscles and Merkel's discs, which respond to light touch and pressure. In contrast, deeper receptors such as Pacinian corpuscles (responsive to high-frequency vibrations and deep pressure) and Ruffini corpuscles (responsive to skin stretch) may be more prevalent in less sensitive regions such as the heel and metatarsal regions [5, 28, 29]. Moreover, skin thickness can affect mechanoreceptor responsiveness. For instance, Meissner's and Pacinian corpuscles are typically located in the papillary ridges of the epidermal layer, and a thicker epidermis that is common in the low-sensitivity regions, may attenuate mechanical stimulus transmission [30].

Age-related deterioration in plantar soft tissue further contributes to sensory decline [8, 9, 27, 31]. Our mapping results reveal lower sensitivity in all foot regions in older adults compared to younger adults [13]. The decline in tactile sensitivity levels might be related to the degeneration of fast-adapting mechanoreceptors such as Meissner's corpuscles, Merkel cell, and Pacinian corpuscles, which may decrease up to 90% against the applied force with age [32, 33]. These changes underline the vulnerability of sensory function in the aging foot. By further examining subgroups of older adults, our data did not reveal further changes in tactile sensitivity between the ages of 65 and 80. This may suggest that tactile sensitivity declines sharply from middle age to old age [8, 34], but then stabilizes or plateaus at a minimal level in later years [15], potentially to support the locomotion.

The weak correlations between regions with high and low tactile sensitivity thresholds further supports the notion that tactile perception is regional specific, governed by localized skin-tissue structure and loading conditions. Conversely, moderate to strong correlations within locations with similar tactile sensitivity thresholds indicate that these regions may share common skin properties that influence their sensitivity levels. The foot dorsum, typically exposed to minimal pressure, may retain higher tactile sensitivity due to preserved skin properties. Our study also found significant gender effects on tactile sensitivity thresholds, with females exhibiting lower tactile thresholds in several skin locations, consistent with previous findings [35]. Females are believed to have lower calcaneal pad stiffness [36] and higher density of mechanoreceptor distribution and faster tactile signal transmission than the males [37, 38]. However, they did not find gender effects either to the more spatially demanding nature of the two-point discrimination task or variations in body fat. These differences may be explained by response bias, as females might be more willing to report the presence of a stimulus [39]. These findings have important practical implications for foot orthoses and footwear designs for older male and female adults [40]. Footwear and orthotics comfort may be enhanced from extra padding and finer material at higher sensitive locations of the foot. Tactile feedback from the plantar surface is vital for maintaining balance and posture and controlling the body's center of mass [15, 41]. Recognizing regions of high tactile sensitivity enables strategic placement of mechanical stimulating elements, such as textured protrusions, in foot orthoses to enhance somatosensory input and improve postural control.

Approximately 70% of the mechanoreceptors in glabrous foot skin are fast-adapting afferents [42], and their function declines substantially with age [32]. Tactile sensitivity thresholds related to skin properties are primarily influenced by mechanical stimulation via touch, pressure, skin stretch, and vibration [14]. Hence, the activation of these mechanoreceptors may be enhanced through artificial modalities of mechanical stimulation such as foot orthoses and footwear with textured or contoured protrusions. These features, particularly in regions of higher tactile sensitivity can promote skin stretch or deep pressure in response to applied forces, thereby stimulating afferent mechanoreceptor firing of a certain muscle. Confining these protrusions to higher tactile sensitive regions can help minimize abnormal frictional and shear forces at higher plantar pressure regions, such as the heel, midfoot lateral, and metatarsal heads, thereby reducing the risk of skin damage and complications [43-45]. Targeting regions of preserved tactile function offers a promising strategy for improving postural control in older adults whilst avoiding excessive mechanical loading. This approach leverages the critical role of mechanoreceptors in providing sensory feedback for maintaining balance and reducing fall risk.

This study has several limitations when interpreting our results. First, we did not assess two-point discrimination or vibration thresholds, which could offer a more comprehensive evaluation of tactile function. Second, mechanical properties of the skin, such as hardness, thickness, elasticity and stiffness, were not directly measured, limiting our ability to link skin biomechanics with sensory thresholds. Third, the influence of participants' shoe-wearing habits, such as duration/ day or shoe types, on the tactile sensitivity thresholds was not considered. Future research should consider shoe-wearing behaviors as a potential confounding factor. Finally, the sample size was relatively small, which may affect the generalizability of our findings. Future studies should incorporate larger samples with a broader range of sensitivity assessments and consider the mechanical properties of the skin in the older adults to enhance the robustness and applicability of the results.

4.5 Conclusion

Large regional variations in tactile sensitivity thresholds were found across foot skin locations in older adults, with heel showing the highest tactile thresholds, followed by the lateral midfoot and metatarsal heads. Males exhibited higher tactile sensitivity thresholds at several locations compared with females. Our findings highlight the potential to develop orthotic interventions that enhance somatosensory input and balance control, potentially reducing fall risk by optimizing stiffness and design at targeting regions with higher tactile sensitivity. Future research should explore the relationship between tactile sensitivity and skin properties in various foot regions with larger samples to inform evidence-based design of orthoses and footwear for aging population.

References

[1] F.J.F. Viseux, The sensory role of the sole of the foot: Review and update on clinical perspectives, Neurophysiol Clin 50(1) (2020) 55-68. https://doi.org/10.1016/j.neucli.2019.12.003

[2] J. Ficke, D.W. Byerly, Anatomy, bony pelvis and lower limb: Foot, StatPearls, StatPearls Publishing, Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL), 2024.

[3] D. Purves, G.J. Augustine, D. Fitzpatrick, L.C. Katz, A. LaMantia, J.O. McNamara, et al., Neuroscience, Sunderland (MA): Sinauer Associates2001.

[4] V.E. Abraira, D.D. Ginty, The sensory neurons of touch, Neuron 79(4) (2013) 618-39. https://doi.org/10.1016/j.neuron.2013.07.051

[5] F. Iheanacho, A.R. Vellipuram, Physiology, mechanoreceptors, StatPearls, StatPearls Publishing, Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL), 2024.

[6] A. Kavounoudias, R. Roll, J.P. Roll, The plantar sole is a 'dynamometric map' for human balance control, Neuroreport 9(14) (1998) 3247-52. https://doi.org/10.1097/00001756-199810050-00021

[7] A. Jor, C.H. Lai, M.J. Khan, Y. He, W.K. Lam, S.J. Winser, et al., Effects of somatosensory-stimulating foot orthoses on postural balance in older adults: A computerized dynamic posturography analysis, Gait Posture 119 (2025) 189-196. https://doi.org/10.1016/j.gaitpost.2025.03.016

[8] S. McIntyre, S.S. Nagi, F. McGlone, H. Olausson, The effects of ageing on tactile function in humans, Neuroscience 464 (2021) 53-58. https://doi.org/10.1016/j.neuroscience.2021.02.015

[9] D. Deflorio, M. Di Luca, A.M. Wing, Skin properties and afferent density in the deterioration of tactile spatial acuity with age, J Physiol 601(3) (2023) 517-533. https://doi.org/10.1113/jp283174

[10] L.I. Wolfson, R. Whipple, P. Amerman, J. Kaplan, A. Kleinberg, Gait and balance in the elderly. Two functional capacities that link sensory and motor ability to falls, Clin Geriatr Med 1(3) (1985) 649-59.

[11] A.C. Grundstrom, C.E. Guse, P.M. Layde, Risk factors for falls and fall-related injuries in adults 85 years of age and older, Arch Gerontol Geriatr 54(3) (2012) 421-8. https://doi.org/10.1016/j.archger.2011.06.008

[12] N.D. Strzalkowski, R.L. Mildren, L.R. Bent, Thresholds of cutaneous afferents related to perceptual threshold across the human foot sole, J Neurophysiol 114(4) (2015) 2144-51. https://doi.org/10.1152/jn.00524.2015

[13] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[14] N.D. Strzalkowski, J.J. Triano, C.K. Lam, C.A. Templeton, L.R. Bent, Thresholds of skin sensitivity are partially influenced by mechanical properties of the skin on the foot sole, Physiol Rep 3(6) (2015). https://doi.org/10.14814/phy2.12425

[15] S.D. Perry, Evaluation of age-related plantar-surface insensitivity and onset age of advanced insensitivity in older adults using vibratory and touch sensation tests, Neurosci Lett 392(1-2) (2006) 62-7. https://doi.org/10.1016/j.neulet.2005.08.060

[16] F. Yang, Identification of optimal foot tactile sensation threshold for detecting fall risk among community-dwelling older adults, Phys Ther 101(8) (2021). https://doi.org/10.1093/ptj/pzab119

[17] C.H.M. Mascarenhas, J.A.O. Carneiro, T.T.X. Nobre, L. Schettino, C.M. de Araujo, L.A. Dos Reis, et al., Analysis of plantar tactile sensitivity in older women after conventional proprioceptive training and exergame, Int J Environ Res Public Health 20(6) (2023). https://doi.org/10.3390/ijerph20065033

[18] L. Perucca, A. Robecchi Majnardi, S. Frau, S. Scarano, Normative Data for the NeuroCom(®) Sensory Organization Test in Subjects Aged 80-89 Years, Front Hum Neurosci 15 (2021) 761262. https://doi.org/10.3389/fnhum.2021.761262

[19] I.N. Miller, J.J. Himali, A.S. Beiser, J.M. Murabito, S. Seshadri, P.A. Wolf, et al., Normative Data for the Cognitively Intact Oldest-Old: The Framingham Heart Study, Exp Aging Res 41(4) (2015) 386-409. https://doi.org/10.1080/0361073x.2015.1053755

[20] C.B. Weir, A. Jan, BMI classification percentile and cut off points, StatPearls, StatPearls Publishing Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL), 2024.

[21] E.H. Tracey, A.J. Greene, R.L. Doty, Optimizing reliability and sensitivity of Semmes-Weinstein monofilaments for establishing point tactile thresholds, Physiol Behav 105(4) (2012) 982-6. https://doi.org/10.1016/j.physbeh.2011.11.002

[22] E. Mamino, S. Lithfous, T. Pebayle, A. Dufour, O. Després, Test-retest and inter-rater reliability of two devices measuring tactile mechanical detection thresholds in healthy adults: Semmes-Weinstein monofilaments and the cutaneous mechanical stimulator, Muscle Nerve 70(6) (2024) 1163-1171. https://doi.org/10.1002/mus.28258

[23] M.J. Mueller, Identifying patients with diabetes mellitus who are at risk for lower-extremity complications: use of Semmes-Weinstein monofilaments, Phys Ther 76(1) (1996) 68-71. https://doi.org/10.1093/ptj/76.1.68

[24] E.W. Peters, H.M. Bienfait, M. de Visser, R.J. de Haan, The reliability of assessment of vibration sense, Acta Neurol Scand 107(4) (2003) 293-8. https://doi.org/10.1034/j.1600-0404.2003.01333.x

[25] P.R. Cavanagh, M.M. Rodgers, A. Iiboshi, Pressure distribution under symptom-free feet during barefoot standing, Foot Ankle 7(5) (1987) 262-76. https://doi.org/10.1177/107110078700700502

[26] M.J. Hessert, M. Vyas, J. Leach, K. Hu, L.A. Lipsitz, V. Novak, Foot pressure distribution during walking in young and old adults, BMC Geriatrics 5(1) (2005) 8. https://doi.org/10.1186/1471-2318-5-8.

[27] M. Helili, X. Geng, X. Ma, W. Chen, C. Zhang, J. Huang, et al., An investigation of regional plantar soft tissue hardness and its potential correlation with plantar pressure distribution in healthy adults, Appl Bionics Biomech 2021 (2021) 5566036. https://doi.org/10.1155/2021/5566036

[28] D. Purves, G.J. Augustine, D. Fitzpatrick, W.C. Hall, A. LaMantia, R.D. Mooney, et al., Neuroscience, 6th ed., Sinauer Associates Inc2017.

[29] J. Turecek, D.D. Ginty, Coding of self and environment by Pacinian neurons in freely moving animals, bioRxiv (2023). https://doi.org/10.1101/2023.09.11.557225

[30] C.Y. Chao, Y.P. Zheng, G.L. Cheing, Epidermal thickness and biomechanical properties of plantar tissues in diabetic foot, Ultrasound Med Biol 37(7) (2011) 1029-38. https://doi.org/10.1016/j.ultrasmedbio.2011.04.004

[31] C.C. Hsu, W.C. Tsai, C.P. Chen, Y.W. Shau, C.L. Wang, M.J. Chen, et al., Effects of aging on the plantar soft tissue properties under the metatarsal heads at different impact

velocities, Ultrasound Med Biol 31(10) (2005) 1423-9. https://doi.org/10.1016/j.ultrasmedbio.2005.05.009

[32] D.R. Kenshalo, Sr., Somesthetic sensitivity in young and elderly humans, J Gerontol 41(6) (1986) 732-42. https://doi.org/10.1093/geronj/41.6.732

[33] J. García-Piqueras, Y. García-Mesa, L. Cárcaba, J. Feito, I. Torres-Parejo, B. Martín-Biedma, et al., Ageing of the somatosensory system at the periphery: age-related changes in cutaneous mechanoreceptors, J Anat 234(6) (2019) 839-852. https://doi.org/10.1111/joa.12983

[34] S.W. Shaffer, A.L. Harrison, Aging of the somatosensory system: a translational perspective, Phys Ther 87(2) (2007) 193-207. https://doi.org/10.2522/ptj.20060083

[35] D.B. Boles, S.M. Givens, Laterality and sex differences in tactile detection and two-point thresholds modified by body surface area and body fat ratio, Somatosens Mot Res 28(3-4) (2011) 102-9. https://doi.org/10.3109/08990220.2011.627068

[36] U.C. Ugbolue, E.L. Yates, S.C. Wearing, Y. Gu, W.K. Lam, S. Valentin, et al., Sex differences in heel pad stiffness during in vivo loading and unloading, J Anat 237(3) (2020) 520-528. https://doi.org/10.1111/joa.13207

[37] P. Gazerani, X. Dong, M. Wang, U. Kumar, B.E. Cairns, Sensitization of rat facial cutaneous mechanoreceptors by activation of peripheral N-methyl-d-aspartate receptors, Brain Res 1319 (2010) 70-82. https://doi.org/10.1016/j.brainres.2010.01.018

[38] V. Wai, L. Roberts, J. Michaud, L.R. Bent, A.L. Clark, The Anatomical Distribution of Mechanoreceptors in Mouse Hind Paw Skin and the Influence of Integrin α1β1 on Meissner-Like Corpuscle Density in the Footpads, Front Neuroanat 15 (2021) 628711. https://doi.org/10.3389/fnana.2021.628711

[39] J.C. Craig, K.O. Johnson, The Two-Point Threshold: Not a Measure of Tactile Spatial Resolution, Current Directions in Psychological Science 9(1) (2000) 29-32. https://doi.org/10.1111/1467-8721.00054.

[40] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology 70(8) (2024) 801-811. https://doi.org/10.1159/000539591

[41] B.E. Maki, S.D. Perry, R.G. Norrie, W.E. McIlroy, Effect of facilitation of sensation from plantar foot-surface boundaries on postural stabilization in young and older adults, J Gerontol A Biol Sci Med Sci 54(6) (1999) M281-7. https://doi.org/10.1093/gerona/54.6.m281

[42] P.M. Kennedy, J.T. Inglis, Distribution and behaviour of glabrous cutaneous receptors in the human foot sole, J Physiol 538(Pt 3) (2002) 995-1002. https://doi.org/10.1113/jphysiol.2001.013087

[43] V. Broderick, L.J. Cowan, Pressure injury related to friction and shearing forces in older adults, Journal of Dermatology and Skin Science (2021). https://doi.org/10.29245/2767-5092/2021/2.1136

[44] A. Gefen, Why is the heel particularly vulnerable to pressure ulcers?, Br J Nurs 26(Sup20) (2017) S62-s74. https://doi.org/10.12968/bjon.2017.26.Sup20.S62

[45] N. Mondragon, P.M. Zito, Pressure injury, StatPearls, StatPearls Publishing Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL), 2024.

CHAPTER 5

DOSE-RESPONSE OF SITE-SPECIFIC SOMATOSENSORY FOOT ORTHOSIS VARYING PROTRUDING KNOB HEIGHTS ON POSTURAL BALANCE AND STABILITY IN OLDER ADULTS

5.1 Introduction

The aging process involves many physiological changes, including decline in neuromuscular control, biomechanical functions of the musculoskeletal system, proprioception, and sensory feedback. These changes can significantly affect postural balance, stability, and gait [1, 2], which are associated with increased risk of falls, subsequent injuries, and diminished quality of life in older adults. Postural balance and stability depend on intricate coordination between sensory and motor systems. Mechanoreceptors in the plantar surface of the foot are essential for providing somatosensory input necessary for postural adjustments [3, 4]. Consequently, interventions aimed at enhancing foot somatosensory feedback have gained attention to improve balance and stability in older adults [5, 6].

Foot orthoses, including insoles or shoe inserts, have been widely recommended to improve balance by providing mechanical support and enhancing somatosensory feedback [7]. Among these, somatosensory foot orthoses, designed with surface textures such as rounded protruding knobs, nodules or pyramidal spikes have been increasingly employed to stimulate the mechanoreceptors in the plantar glabrous skin and enhance somatosensory feedback [7-10]. The mechanoreceptors are responsible for detecting tactile stimulation through changes in touch, pressure, and cutaneous tension, and providing feedback to the central nervous system [11]. Somatosensory foot orthoses with varying protruding nodules or knobs are specifically designed to enhance mechanoreceptor stimulation and somatosensory input, potentially leading to improvements in balance and stability. Several studies have investigated the efficacy of somatosensory foot orthoses and reported improvement in balance and stability in older adults [8, 9, 12, 13].

However, existing studies have primarily focused on the overall effects of stimulating protrusions across the entire plantar foot surface (see Chapter 2 and Chapter 3). Previous investigations often overlooked the varying tactile sensitivity level across different regions of the foot skin. A recent systematic review on somatosensory foot orthoses emphasized that strategic positioning of protruding knobs into contoured foot orthosis's structure might facilitate maximize mechanoreceptor stimulation (see Chapter 2). Since different areas of the foot plantar skin have varying densities of mechanoreceptors (see Chapter 4) [14], a uniform distribution of protruding knobs may not adequately stimulate them, and maximize postural control and stability. There is a lack of research on the site-specific placement of stimulating knobs based on the tactile sensitivity thresholds. It is questionable how strategically placing these knobs in areas with higher tactile sensitivity can optimize somatosensory input and enhance postural stability. Additionally, the size and shape of the protruding knobs have not been systematically investigated to determine the most effective configuration for improving balance and stability. Site-specific positioning of stimulating protrusions, combined with optimized knob height, has the potential to maximize the effectiveness of somatosensory foot orthoses.

This study aimed to investigate the dosing effects of site-specific somatosensory foot orthoses varying heights of protruding knobs on postural balance and stability in older adults. Specifically, this study examined the acute-response effects of different heights of protruding knobs placed in regions of higher tactile sensitivity with lower plantar pressure. It was hypothesized that site-specific placement of protruding knobs would provide more effective somatosensory stimulation of mechanoreceptors, leading to improved postural balance and stability compared to conventional flat foot orthoses with no protruding knobs. Furthermore, it was hypothesized that an optimal knob height at specific regions would maximize sensory feedback while minimizing discomfort or adverse effects.

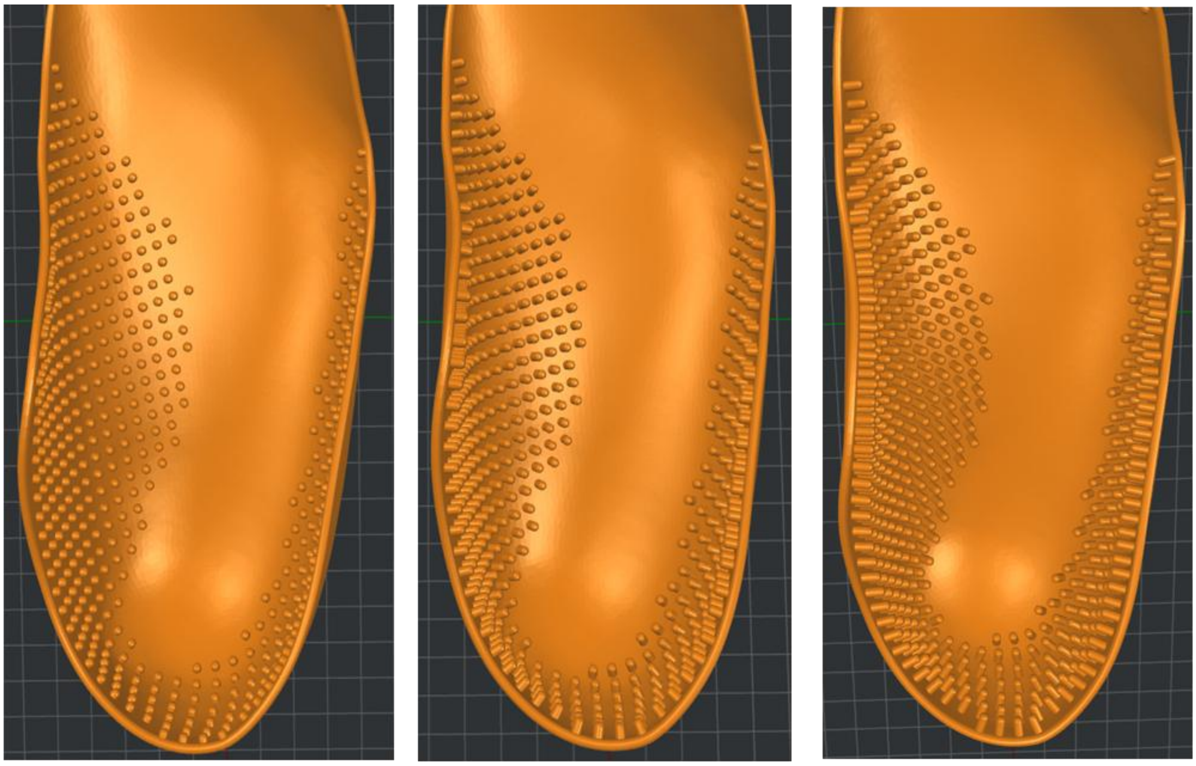
5.2 Methods

5.2.1 Participants

Ten healthy community-dwelling older adults participated in the study. The group included five males and five females aged 65 years or older. Recruitment was conducted through convenience sampling at local elderly centers in Hong Kong. Each individual could walk independently and continuously for at least 30 minutes. Exclusion criteria included foot deformities such as pes cavus or pes planus. Other exclusions were severe foot pain, peripheral neuropathy, neuromuscular or central nervous system disorders, vestibular disorders, or a BMI over 40. Participants also had to pass the 10g Semmes-Weinstein monofilament (SWM) test for foot tactile sensation. Participants unable to detect sensation in at least 4 out of 10 tested foot sites was excluded to ensure adequate sensory function for safe ambulation [15].

5.2.2 Foot orthoses

The study examined and compared balance outcomes in older adults under four distinct foot orthosis conditions with varying knob heights. These included a flat orthosis without stimulating knobs, as well as three customized site-specific somatosensory orthoses featuring short, medium, and tall protruding knobs, as depicted in Figure 5-1. All somatosensory foot orthoses used in the study were three-quarter length, extended to cover the metatarsal heads. Each orthosis was precisely crafted using 3D printing technology. This approach ensured a personalized fit for individual participant. The process began by scanning each participant's feet with a handheld 3D scanner (EinScan, SHINNING 3D®, China). Detailed 3D foot models were generated from these scans. The digital models were then refined using Canfit Design software (CanfitTM Orthotics and Prosthetics CAD, Vorum Research Corp., USA) to create custom foot orthoses with a uniform thickness of 3mm. To accommodate the protruding knobs, a raised surface was incorporated, covering the glabrous skin of the rearfoot and both the medial and lateral midfoot.



(A) SSFO-S (B) SSFO-M (C) SSFO-T

Figure 5-1. Site-specific somatosensory stimulation foot orthoses (SSFO) with protruding knobs: (A) 2 mm height (SSFO-S), (B) 3.5 mm height (SSFO-M), and (C) 5 mm height (SSFO-T).

Materialize 3-matic (Materialise, Belgium) was used to design and position the knobs on the foot orthoses. The protruding knobs were strategically positioned at areas of contact with the glabrous skin of the foot, focusing on regions characterized by lower plantar loading and heightened tactile sensitivity. These areas included the raised surfaces of the rearfoot, the medial arch-support areas covering the intermedius midfoot, and both the medial and lateral raised surfaces of the midfoot. The protruding knobs varied in height: short knobs were 2mm in height and diameter, medium-height knobs were 3.5mm in height with a 2mm diameter, and tall knobs were 5mm in height with a 2mm diameter. The center-to-center distance between knobs was consistently maintained at 5mm. The somatosensory foot orthoses were fabricated using a FDM type printer (Raise3D E2, USA), guided by 3D slicing software (ideaMaker, version 4.2.3, USA). Thermoplastic polyurethane (TPU) with a Shore A hardness of 70 was used as the 3D printing material [16, 17]. To maintain consistency across all trials, each participant wore standard elderly shoes (Shiying 520A, Shiying Trading Co. Ltd., China) during the experiments. They also wore socks made of 75% cotton with a thickness of 1mm (Zhuji Dongling Needle Textile Co., Ltd., China).

5.2.3 Data collection and processing

Balance and stability among older adults were evaluated across different postural and gait conditions: (1) static standing trials conducted with both eyes open and eyes closed, and (2) dynamic walking trials performed on level as well as on uphill and downhill slopes. In addition, computerized dynamic posturography (CDP) assessments were carried out using sessions with a perturbed platform. We utilized a Zebris FDM-T instrumented treadmill and Zebris FDM software (Zebris Medical GmbH, Germany) for both static standing and dynamic gait analyses. During the static analysis, participants were asked to stand as still as possible on the treadmill under both eyes-open and eyes-closed conditions. Each condition was performed three times, with every trial lasting 10 seconds. For the dynamic walking analysis, participants were allotted about five minutes to become accustomed to the treadmill. Then determined a comfortable, self-selected walking speed ranging from 0.67 to 1.34 m/sec and maintained across foot orthoses conditions. Walking trials were conducted on level, uphill, and downhill inclines. Each of these conditions was also repeated three times, with each trial lasting 30 seconds. Data collected were then reduced into center of pressure (CoP) parameters, such as anteroposterior and mediolateral CoP displacement ranges, as well as CoP average velocity.

CDP data were collected using the Bertec Balance Advantage system (Bertec Corporation, Columbus, OH, USA) for three main assessments: the sensory organization test (SOT), motor control test (MCT), and adaptation test (ADT) [18]. The SOT and MCT scores demonstrated high test-retest reliability (ICC=0.90 and 0.85, respectively) for assessing balance in older individuals [19]. In the SOT, participants were required to stand still while undergoing six different testing conditions. The conditions tested included various combinations of eyes open or closed, and sway-referencing of the visual field and/or support surface. These six conditions were designed to assess different aspects of postural control. Equilibrium scores were recorded separately for each condition. Composite equilibrium scores calculated as a weighted average of the six conditions were also collected. These composite scores were used for comparative purposes. The equilibrium score served as a measure of anteroposterior postural stability or center of gravity sway. A score of 100 represented no sway, indicating a full ankle strategy and perfect balance, while a score of 0 indicated maximal sway or a fall, reflecting a full hip strategy with maximal shear stress.

During MCT, participants remained stationary while the platform underwent translations—three backward and three forward. Each translation was performed three times, using small, medium, and large magnitudes. Latency was defined as the time in milliseconds between the onset of platform movement and the participant's active force response. The weight symmetry index was also measured, reflecting the distribution of weight between the left and right limbs. For ADT, participants stood still as the support surface under the toes was move up and down five times. Sway energy was measured during these movements. Participants were given five to seven minutes of rest between testing conditions to minimize fatigue and confounding effects. The foot orthoses conditions were tested in a randomized sequence to control for potential order effects. A safety harness was used to ensure participant safety throughout the experiments.

After walking for 18 to 20 minutes under each foot orthoses condition across varying surface inclinations, participants provided their feedback on pain and satisfaction using the 'Visual Analog Scale (VAS)' and the 'Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)' index, respectively. The VAS allowed participants to rate their pain experience from 0 (no pain) to 10 (worst pain imaginable) across four different plantar foot locations: raised areas of the rearfoot, medial midfoot, lateral midfoot, and medial arch. The QUEST 2.0 index allowed participants to rate their satisfaction regarding perceived adjustments, safety, and comfort when using the foot orthoses. Additionally, it assessed the effectiveness of the orthoses in supporting postural balance. Scores on the QUEST 2.0 ranged from 1 (not satisfied) to 5 (very satisfied), providing valuable information about user satisfaction across different foot orthoses conditions with varying protruding knob heights.

5.2.4 Statistical analysis

The Shapiro-Wilk test was employed to check the data normality distribution for CoP trajectories and CDP assessment parameters across the four different foot orthoses conditions. For the data that were normally distributed, repeated measures ANOVA was conducted to compare the effects across different foot orthoses conditions with Bonferroni adjustment as post-hoc analysis. For data that did not follow a normal distribution, the Friedman test was used to assess significant effects across conditions. Post-hoc comparisons were then performed using Wilcoxon signed-rank tests. Similarly, Friedman test and Wilcoxon signed-rank tests were employed to analyze subjective feedback on the QUEST 2.0 index. Mean and standard deviations were calculated for all CoP and CDP parameters while median and minimum to maximum values were reported for subjective feedback under each foot orthoses condition (Table 5-1). All statistical analyses were conducted using IBM SPSS (IBM SPSS Statistics, Version 22.0, IBM Corp., Armonk, NY). A significance level of $p < 0.05$ was set for all test outcomes.

Table 5-1. Mean and standard deviations of center of pressure (CoP) and computerized dynamic posturography (CDP) parameters across various foot orthosis conditions.

Parameters	Testing conditions	Normality	FFO	SSFO-S	SSFO-M	SSFO-T	P value					
			Mean SD	Mean SD	Mean SD	Mean SD	SSFO-S vs FFO	SSFO-M vs FFO	SSFO-L vs FFO	SSFO-M vs SSFO-S	SSFO-L vs SSFO-S	SSFO-L vs SSFO-M
Anteroposterior COP Range, mm	Standing Eyes open	No	23.46 11.85	23.65 7.99	28.64 9.25	18.22 6.37	0.878	0.203	0.059	**0.047**	0.059	**0.007**
	Standing Eyes closed	Yes	26.42 9.11	26.35 10.71	27.75 11.20	28.63 9.83	1.000	1.000	1.000	1.000	0.443	1.000
	Walking Level	Yes	158.79 57.20	156.41 62.42	157.68 65.28	154.06 66.26	1.000	1.000	1.000	1.000	1.000	1.000
	Walking Up	No	143.57 52.85	140.14 54.48	139.63 60.10	136.89 56.64	0.285	0.508	0.059	0.721	0.646	0.386
	Walking Down	Yes	284.75 118.57	288.59 135.04	306.12 132.10	261.64 121.30	1.000	1.000	1.000	1.000	1.000	1.000
Mediolateral COP Range, mm	Standing Eyes open	No	4.93 2.47	5.05 1.84	7.33 4.47	3.84 1.30	0.646	**0.047**	**0.037**	**0.017**	**0.028**	**0.009**
	Standing Eyes closed	No	4.96 1.81	5.42 3.41	5.93 2.65	5.80 3.43	0.799	0.333	0.169	0.508	0.575	0.799
	Walking Level	No	33.72 10.83	32.03 12.74	34.56 11.98	32.84 11.15	0.445	0.508	0.646	0.169	0.959	0.445
	Walking Up	No	35.95 10.14	38.38 16.15	39.65 13.95	38.96 16.24	0.508	0.059	0.285	0.721	0.799	0.721
	Walking Down	No	28.95 5.59	28.87 7.00	28.91 6.31	27.97 6.30	0.721	0.959	0.508	0.878	0.575	0.646
COP average velocity, mm/sec	Standing Eyes open	Yes	13.83 6.23	12.80 4.67	19.10 9.68	11.08 3.77	1.000	0.836	0.167	0.604	1.000	0.223
	Standing Eyes closed	No	16.97 7.06	14.92 7.73	18.37 7.96	17.41 6.61	0.333	0.721	0.575	0.093	0.059	0.878
	Walking Level	Yes	1139.10 535.87	1423.52 608.25	1284.47 643.81	1812.21 758.60	0.504	1.000	0.158	1.000	0.574	0.101
	Walking Up	No	1375.46 590.31	1500.85 717.70	1705.18 891.04	1821.80 726.15	0.508	0.285	**0.007**	0.878	0.169	0.333
	Walking Down	No	1506.21 1268.12	1649.58 761.46	1943.01 1011.29	2215.04 1449.55	0.114	0.059	**0.007**	0.445	**0.005**	0.241
Equilibrium, score	C-1	Yes	86.43 4.05	85.96 4.80	85.06 3.56	88.00 3.67	1.000	1.000	1.000	1.000	1.000	0.258
	C-2	Yes	86.83	87.63	86.40	87.66	1.000	1.000	1.000	0.966	1.000	1.000

			4.37	3.40	3.16	5.04						
	C-3	Yes	85.33 6.85	83.36 11.35	81.80 10.66	84.43 9.42	0.441	**0.007**	0.610	0.139	0.635	0.109
	C-4	Yes	51.20 11.72	57.73 8.73	59.73 11.73	58.76 13.93	0.292	0.110	0.650	1.000	1.000	1.000
	C-5	No	48.53 12.28	53.93 15.34	55.66 11.19	57.86 11.34	0.208	**0.017**	**0.017**	0.575	0.203	0.575
	C-6	Yes	49.50 13.20	52.46 11.74	54.76 10.55	52.06 15.50	1.000	1.000	1.000	1.000	1.000	1.000
	Composite	No	62.70 8.20	65.70 8.40	66.40 8.18	66.80 8.81	0.168	**0.015**	**0.025**	0.540	0.474	0.831
Latency, mm	Backward translation	Yes	138.10 6.41	142.00 8.31	141.10 8.04	142.70 8.45	0.487	1.000	1.000	1.000	1.000	1.000
	Forward translation	Yes	146.30 10.69	141.60 11.74	146.20 10.03	146.70 8.00	**0.032**	1.000	1.000	0.099	0.242	1.000
Weight symmetry, %	Backward translation	No	91.64 5.57	88.92 6.39	88.72 6.57	91.23 6.39	0.203	**0.022**	0.953	0.721	0.285	0.285
	Forward translation	Yes	91.67 4.28	88.87 6.33	90.39 5.69	91.47 5.28	0.988	1.000	1.000	1.000	1.000	1.000
Sway energy, score	Toes up	No	92.02 31.68	86.28 35.93	86.62 20.00	87.94 28.25	0.721	0.508	0.333	0.445	0.799	0.721
	Toes down	No	72.00 16.25	74.54 30.64	74.98 16.63	81.08 32.14	0.386	0.575	0.333	0.646	0.799	0.721
Subjective feedback, score	Adjustments	-	4.00 2-5	3.00 1-5	3.00 1-5	3.50 1-5	0.109	0.279	0.279	0.705	0.680	1.000
	Safety	-	4.00 3-5	4.00 2-5	3.50 3-5	4.00 3-5	0.317	0.480	1.000	0.705	0.705	0.157
	Comfort	-	4.00 2-5	3.50 1-5	3.00 1-5	2.50 1-5	0.257	0.161	0.143	0.206	0.219	0.564
	Effectiveness	-	4.00 2-5	3.00 2-5	3.00 1-5	3.50 1-5	0.063	0.238	0.577	1.000	0.285	0.180

FO: foot orthoses, FFO: flat foot orthoses, SSFO-S: site-specific stimulating FO with short protruding knobs, SSFO-M: site-specific stimulating FO with medium-height protruding knobs, SSFO-T: site-specific stimulating FO with tall protruding knobs; CoP: center of pressure, C-1: eyes open, C-2: eyes closed, C-3: eyes open with surrounding visual sway-referenced, C-4: eyes open with support surface sway-referenced, C-5: eyes closed with support surface sway-referenced, and C-6: eyes open with both surrounding visual and support surface sway-referenced. Significance, $p<0.05$

5.3 Results

5.3.1 Participants characteristics

A total of ten participants including five males had a mean age of 74.8 ± 4.8 years, weight of 73.34 ± 8.10 kg, height of 168 ± 7 cm, and BMI of 26.06 ± 3.28 kg/m², and five females had a mean age of 71.2 ± 3.11 years, weight of 61.24 ± 16.49 kg, height of 150.4 ± 6.7 cm, and BMI of 27.1 ± 7.5 kg/m². Both groups had a mean SWM score of 10 ± 0.

5.3.2 Center of pressure trajectories

During standing with eyes open, the range of CoP anteroposterior displacements increased with medium-height protruding knobs [MD=4.98, p=0.047] compared with short protruding knobs but decreased with tall protruding knobs [MD=-10.41, p=0.007] compared to medium-height protruding knobs (Figure 5-2A). Similarly, mediolateral displacements increased with medium-height protruding knobs [MD=2.39, p=0.047] and decreased with tall protruding knobs [MD=-1.08, p=0.037] compared to flat foot orthosis (Figure 5-2B). Additionally, tall protruding knobs reduced mediolateral displacements compared to both short [MD=-1.20, p=0.028] and medium-height protruding knobs [MD=-3.48, p=0.009]. In walking conditions, no significant differences in CoP displacements were observed across the foot orthoses conditions on level, upward, and downward slopes (Figure 5-2C-D). However, a trend of reduced anteroposterior displacements was observed with short protruding knobs during walking on slopes. Surprisingly, CoP maximum velocity during walking on upward and downward slopes increased significantly with tall protruding knobs compared to both flat foot orthoses [upward: MD=446.34, =0.007; and downward: MD=708.83, p=0.007;] and short protruding knobs [downward: MD=565.45, p=0.005] (Figure 5-2F).

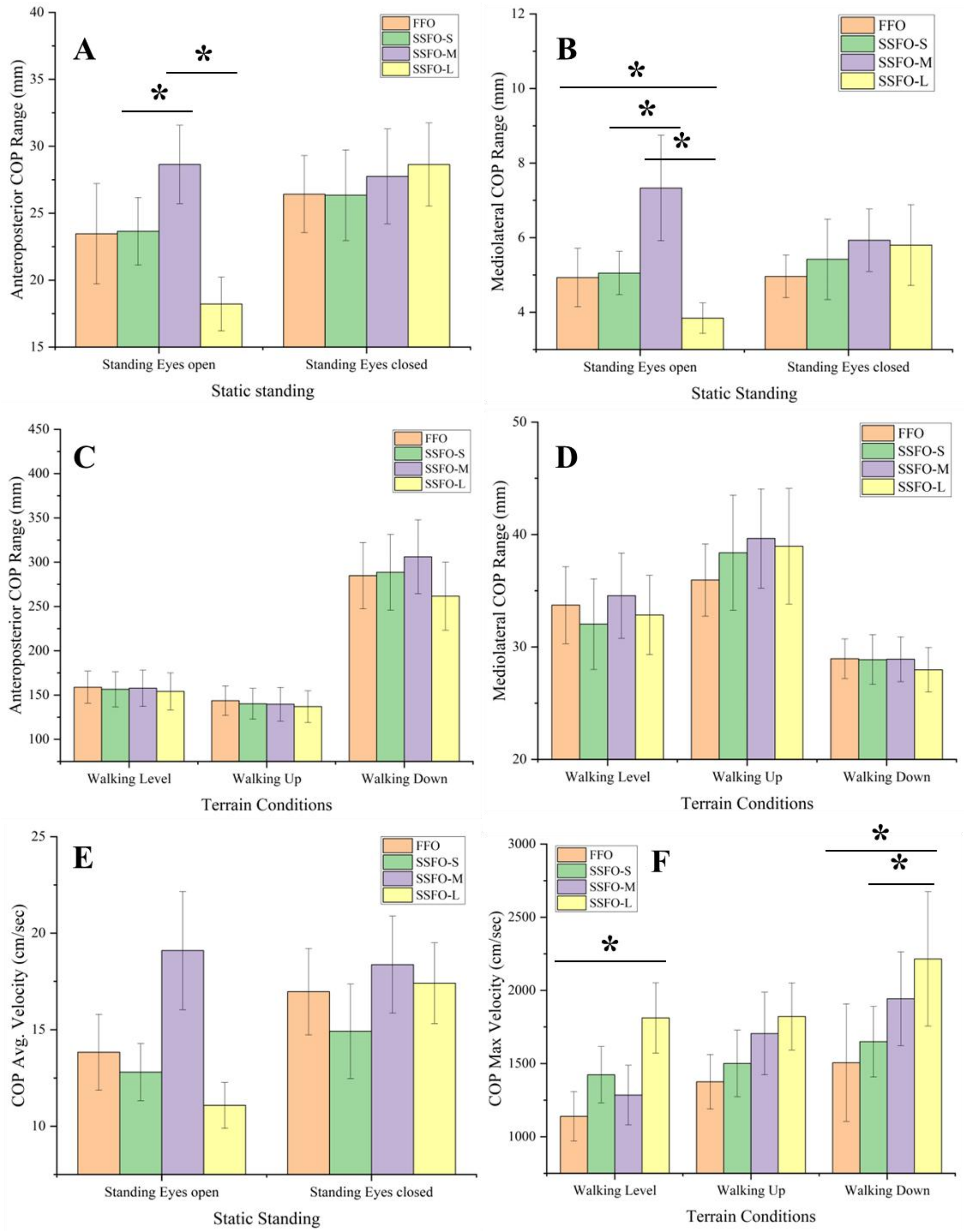


Figure 5-2. Center of pressure (CoP) trajectories are shown for four foot orthosis conditions (FFO, SSFO-S, SSFO-M, SSFO-L), illustrating anteroposterior and mediolateral displacement ranges during standing (eyes open/closed) and walking, as well as average and maximum CoP velocities.

5.3.3 Computerized dynamic posturography

In computerized dynamic posturography (CDP) assessments, both medium-height [MD=3.70, p=0.015] and tall protruding knobs [MD=4.10, p=0.025] showed higher composite equilibrium scores, compared to flat foot orthoses (Figure 5-3A). Specifically, both medium-height [MD=7.13, p=0.017] and tall protruding knobs [MD=9.33, p=0.017] improved equilibrium scores during the eyes closed with support surface sway-referenced condition. However, medium-height protruding knobs showed lower equilibrium scores in the eyes open with surrounding visual sway-referenced condition [MD=-3.53, p=0.007]. Weight asymmetry during backward platform translations increased with medium-height protruding knobs [MD=2.92, p=0.022] compared to flat foot orthoses, while a trend of decreased weight asymmetry was observed with tall protruding knobs [MD=-2.51, p=0.285] (Figure 5-3C).

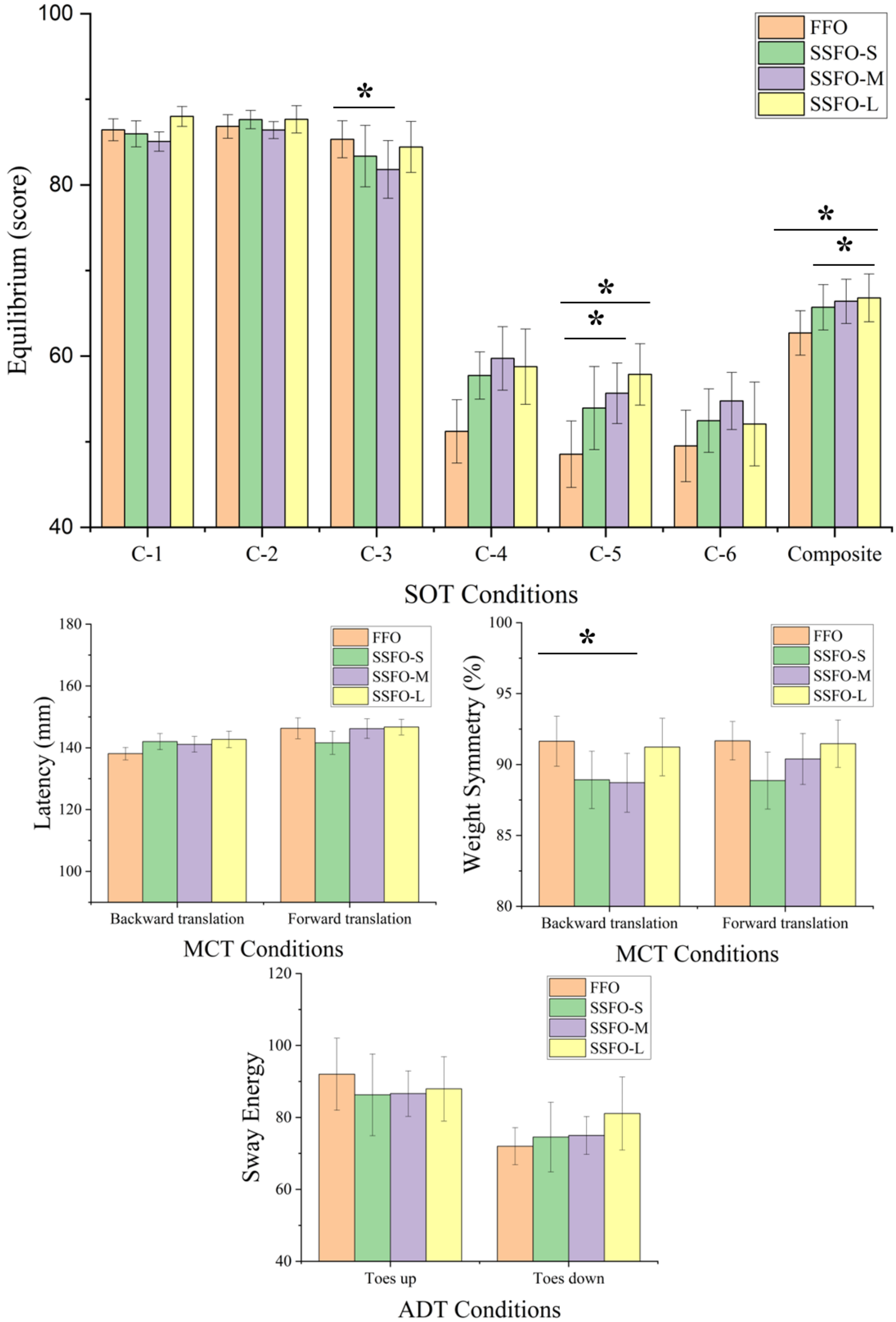


Figure 5-3. Computerized dynamic posturography (CDP) results are presented for four foot orthosis conditions (FFO, SSFO-S, SSFO-M, SSFO-L) across six perturbed platform scenarios (C-1 to C-6), varying visual and support surface references.

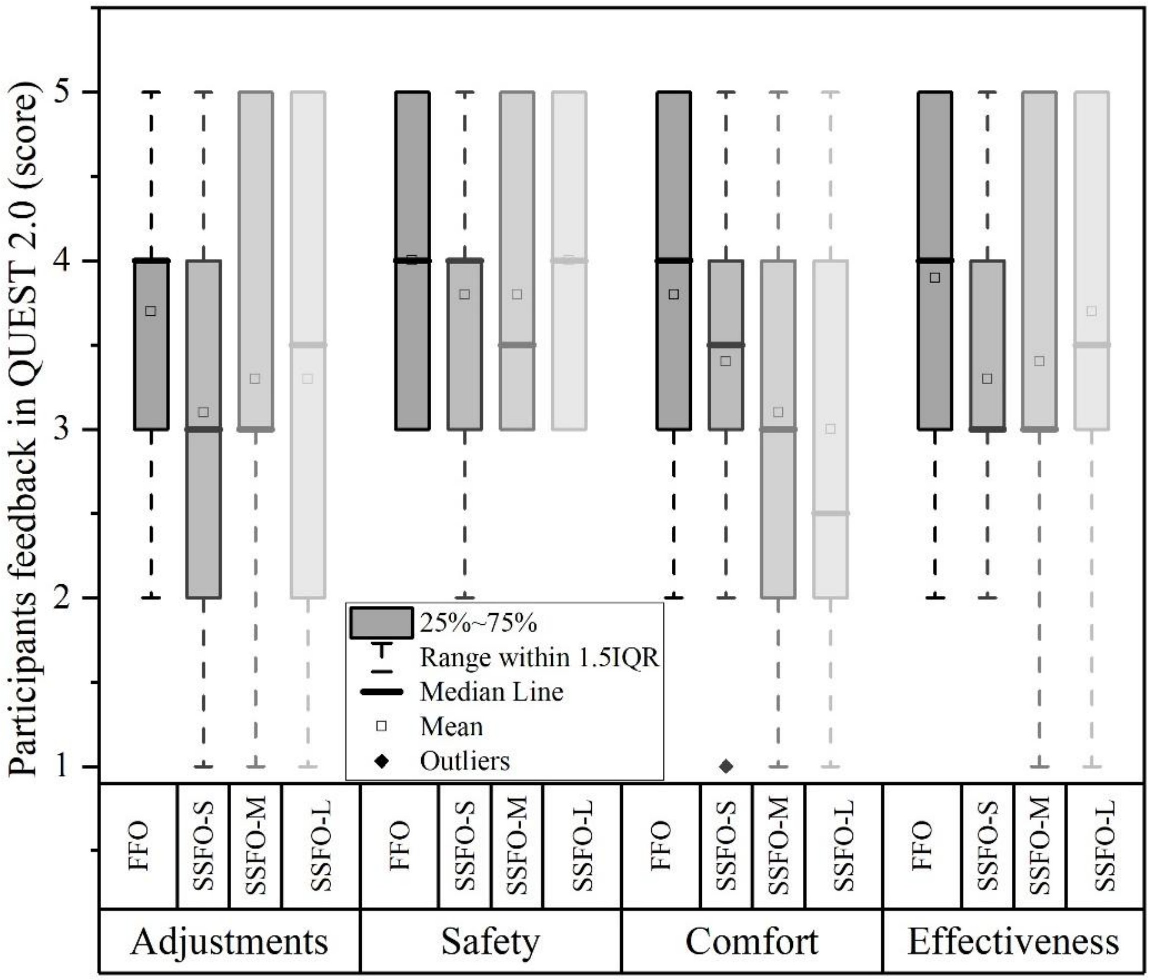


Figure 5-4. Participant feedback on the QUEST 2.0 index is shown for four foot orthosis conditions: FFO, SSFO-S, SSFO-M, and SSFO-L.

5.3.4 Subjective feedback

There were no significant differences in subjective satisfaction on QUEST 2.0 scale across foot orthoses conditions. However, a trend of decreasing user comfort [flat foot orthoses: MD=-1.5, p=0.143; short: MD=-1.0, p=0.219; medium-height: MD=-0.5, p=0.564] was noted with increasing effectiveness to postural control [flat foot orthoses: MD=-0.5, p=0.577; short: MD=0.5, p=0.285; medium-height: MD=0.5, p=0.180] when comparing tall protruding knobs to flat foot orthoses, short protruding knobs, and medium-height protruding knobs (Figure 5-4).

Table 5-2. Assessment of Subjective Feedback on Various Foot Orthosis Conditions Using the Visual Analogue Scale

Participant	FFO	SSFO-S	SSFO-M	SSFO-T
1	No pain	No pain	Mild: Experiencing discomfort due to compressing pressure in the raised regions of rearfoot. Mild: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.	Mild: Experiencing discomfort due to compressing pressure in the raised regions of rearfoot. Moderate: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.
2	No pain	No pain	No pain	No pain: Experiencing discomfort due to heavy touch at raised medial and lateral regions of rearfoot
3	No pain	No pain	No pain	No pain
4	No pain	No pain	No pain	No pain
5	No pain	No pain	No pain: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.	No pain: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.
6	No pain	No pain	Mild: Experiencing discomfort due to compressing pressure in the regions of rearfoot. Mild: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.	Mild: Experiencing discomfort due to compressing pressure in the regions of rearfoot. Mild: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.
7	No pain	No pain	No pain	No pain
8	No pain	No pain	No pain: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.	No pain: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.
9	No pain	No pain	Mild: Experiencing discomfort due to compressing pressure in the regions of rearfoot. Mild: Experiencing discomfort due to heavy touch at the regions of lateral midfoot.	Mild: Experiencing discomfort due to compressing pressure in the regions of rearfoot. Mild: Experiencing discomfort due to heavy touch at the raised lateral regions of midfoot.
10	No pain	Mild: Experiencing discomfort due to Metatarsophalangeal regions of forefoot.	Mild: Experiencing discomfort due to compressing pressure in the raised regions of rearfoot. Mild: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.	Mild: Experiencing discomfort due to compressing pressure in the raised regions of rearfoot and lateral midfoot. Moderate: Experiencing discomfort due to trimline at the MTP joint regions of forefoot.
FFO: flat foot orthoses, SSFO-S: site-specific stimulating FO with short protruding knobs, SSFO-M: site-specific stimulating FO with medium-height protruding knobs, SSFO-L: site-specific stimulating FO with tall protruding knobs, MTP: metatarsophalangeal				

Regarding the perceived comfort, there were no pain with flat foot orthoses and short protruding knobs, except for one participant who reported mild pain at the metatarsophalangeal (MTP) joint region with the trimline of short protruding knobs while walking on slope conditions (Table 5-2.). When using medium-height protruding knobs, four participants reported experiencing mild pain. This pain was mainly located at the rearfoot due to mediolateral compressive pressure, and at MTP joint because of the distal trimline. With tall protruding knobs, four participants noted mild to moderate pain in both the rearfoot and ball of foot areas. This discomfort was linked to compressive pressure and issues with the trimline. Additionally, three participants described mild pain and discomfort resulting from pronounced contact at the elevated lateral midfoot regions. Additionally, even in the absence of pain, two participants with medium-height knobs and three with tall knobs reported discomfort at the ball of foot. This discomfort was attributed to the trimline near the MTP joint region.

5.4 Discussion

This study investigated the effects of foot orthoses with varying heights of stimulating protrusions on CoP trajectories, posturography assessment, and subjective feedback. Our findings supported that all protruding knob conditions can improve both static and dynamic postural balance control compared with no-protruding knob condition. Although participants wearing somatosensory foot orthoses with tall protruding knobs exhibited better static and dynamic postural balance and posturography score than the short/no protruding knobs, but it can induce the perceived pain. Our findings also supported that somatosensory foot orthoses could enhance balance control regardless of terrain, indicating the potentiality of somatosensory foot orthoses use in daily life. These results offer valuable insight into how increased protruding knob heights may affect postural control and equilibrium. This is particularly relevant during standing under different visual and environmental conditions, as well as walking on slopes. The findings underscore the critical interplay between tactile stimulation, balance, and user satisfaction and suggests potential pathways for refining somatosensory foot orthoses design. Improved designs could enhance postural stability, particularly for older adults.

Although the foot orthoses conditions were non-significant, the observed trend of reduced CoP anteroposterior displacements with tall protruding knobs during slope walking is in line with earlier research that involved site-specific protrusions. For example, Perry et al. (2008) [12] found that a 3mm protruding ridge positioned along the perimeter of the foot led to improved postural balance control. Similarly, Pinvanichkul and Siriphorn (2022) [20] observed enhanced postural adjustments and control in functional mobility assessments. This was achieved when 5mm protruding knobs were placed at the metatarsal heads and arch, with 2mm knobs used on the remaining plantar areas. These results indicate that 5mm-high protruding knobs, when strategically employed, can enhance tactile stimulation and support maintain stability on sloped surfaces. Together with our findings, it appears that a 5mm protruding knob height represents upper threshold for effectively stimulating somatosensory input in older adults.

A decrease in CoP displacements was observed with tall protruding knobs during standing with eyes open, while medium-height protruding knobs results increased displacements. This pattern indicates that tall protruding knobs may contribute to improved anteroposterior and mediolateral stability. In contrast to the entire surface stimulating protrusions (see Chapter 3), strategic positioning of protruding knobs may support better postural control. This may be attributed to enhanced activation of mechanoreceptors located in key areas of the midfoot (i.e. arch-support and raised medial midfoot regions). Our findings align with previous studies on the role of tactile stimulation [8]. Notably, the current study found improvements in postural control under eyes open conditions. Earlier research has documented similar enhancements during eyes closed scenarios [8, 13, 21, 22]. It is important to consider that those previous studies utilized somatosensory foot orthoses with flat designs. In addition, they used small or uniformly sized protruding knobs. Such differences in findings may arise from variations in the design of the protrusions in the somatosensory foot orthoses. Factors include the shape, size, stiffness, and placement of the protruding knobs. The interaction between the foot and the orthosis may also play a role. These design elements can affect mechanoreceptor activation and reflex responses. This may help explain the divergent outcomes reported across studies [23, 24]. Another possible explanation is the interplay between visual and tactile inputs. Research has shown that tactile responses are quicker when visual input is present [25, 26]. Visual cues may offer an additional spatial reference for the body. This may enhance integration of tactile input with proprioceptive feedback and make tactile stimulation more effective in modulating balance. Further investigation is warranted to better understand these interactions and the mechanisms involved.

While foot orthoses with medium-height protrusions may enhance sensory input, they may not provide sufficient stability, possibly due to inadequate tactile stimulation in critical regions during static standing. This finding is further supported by our CDP assessments, which also showed lower equilibrium scores during eyes open with visual surrounding sway-referenced conditions, coupled with increased weight asymmetry during backward translation in the medium height protruding knobs. Conversely, the tall protruding knobs condition showed increased equilibrium scores, particularly during eyes closed with support surface sway-referenced conditions, as well as composite scores, along with decreased weight asymmetry during backward translation. Previous studies highlighted the importance of even weight distribution in maintaining balance [27]. The increased equilibrium and decreased weight asymmetry in tall protruding knobs suggest that taller protrusions may promote more controlled postural strategies and better weight distribution in response to both static and dynamic perturbations [28]. This enhancement may be associated with increased somatosensory feedback from mechanoreceptors located in the midfoot area during perturbations. Specifically, positioning taller protruding knobs at the arch-support and elevated midfoot regions may promote improved postural control by expanding contact areas as the center of pressure shifts from the rearfoot to the forefoot during backward translation [18]. These findings underscore the potential of site-specific placement of stimulating knobs to enhance sensory integration and postural control.

However, using protruding knobs of the same height throughout the entire foot plantar region can decrease the shoe's internal volume and place undue pressure on certain areas, like the rearfoot and lateral midfoot. This may result in poor fit, discomfort, and even pain. The higher CoP maximum velocity on slopes with tall protruding knobs may be attributed to an adaptive response to such localized pressure [29]. These results underscore the need to redesign the protruding knobs with varying heights tailored to specific regions to improve postural control and balance while minimized discomfort. Further study should also consider determining the height of the protruding knobs on arch-support and flat foot orthoses.

The subjective feedback on QUEST 2.0 index underscores the important interplay between foot orthoses design and user performance. This highlights the necessity of redesigning somatosensory foot orthoses to enhance comfort and postural strategies. VAS assessments offered additional information about discomfort and pain associated with various orthoses conditions. Medium-height and tall protruding knobs, in particular, were frequently associated with increased experience of mild-to-moderate pain and discomfort. This was particularly evident when the mediolateral side walls narrowed the heel area. Such narrowing may cause compression and unpleasant sensations at the rearfoot and lateral midfoot. These findings are consistent with previous research. Earlier studies found mild discomfort when a protruding ridge of constant diameter was used around the foot perimeter, even though postural balance improved [12]. The present study indicates that shorter protruding knobs in the rearfoot and lateral midfoot regions may help reduce discomfort and mild pain, as participants report no pain or discomfort with shorter protrusions in these areas. However, it is possible that the discomfort caused by taller knobs may itself lead to improved postural stability. This could occur by encouraging a more mindful and cautious gait. Future research should explore whether this discomfort decreases over time. These suggestions are in line with existing literature emphasizes the importance of prioritizing user comfort alongside functional benefits [30]. Additionally, using an elastic shoe upper could be a practical solution. This would provide more internal space and reduce impingement when somatosensory foot orthoses are prescribed.

The results from the current study have important implications for somatosensory foot orthoses design for older adults in the future. Although taller protrusions may improve sensory integration and postural control, users reported increased discomfort. This finding highlights the importance of prioritizing comfort in orthotic design as it is essential to promote consistent use in daily life. In this study, only rounded protruding knobs with a uniform level of hardness were examined. Future investigations should explore different heights, shapes, hardness levels, and distributions of protrusions in maximizing tactile stimulation and postural control while reducing discomfort. While this research focused on healthy older adults, those with reduced tactile sensitivity or balance impairments may benefit even more from the additional stimulation of protruding knobs. Individual differences, such as foot morphology and tactile sensitivity thresholds, could be investigated to help customize foot orthoses designs. Additionally, examining the long-term impact of different somatosensory foot orthoses designs on balance and control mechanism in older adults could offer valuable insights into their practical applications.

Several limitations should be considered when interpreting our results. Firstly, the modest sample size increases the risk of a type II error. Thus, these outcomes should be interpreted with caution and may not be broadly applicable to larger populations. Second, the height of the selected stimulating knobs on each specific foot orthoses condition was the same across foot regions, which may have influenced the outcomes and does not fully capture the potential benefits of site-specific variations in foot orthoses design. Although standardized shoes were used in the study, the orthoses featured raised surfaces at the medial, lateral, and heel regions to fit the protruding knobs. This extra thickness can decrease the shoe's internal space, potentially requiring specially fitted footwear for better outcomes. The use of standardized shoes without such adjustments might have influenced the effectiveness of the somatosensory foot orthoses, potentially limiting the applicability of the results. Future research with larger samples should address these factors and explore the optimal effects of site-specific somatosensory foot orthoses with appropriately fitted footwear to enhance both validity and applicability of the findings.

5.5 Conclusion

This study underscores the critical interplay among heights of protruding knobs, site-specific tactile stimulation, balance, and comfort across different foot orthoses conditions. Although taller protrusions in the somatosensory orthoses appear to offer greater benefits for postural control, the associated discomfort should be addressed for their practical application. Optimizing protruding knob design and configurations of somatosensory foot orthoses should be customized to individual needs to improve balance while minimizing associated discomfort. Further research should recruit larger sample sizes including diverse populations with sensory deficits or neurological conditions and conduct longitudinal evaluation before making a viable conclusion.

References

[1] A. Ferlinc, E. Fabiani, T. Velnar, L. Gradisnik, The Importance and Role of Proprioception in the Elderly: a Short Review, Mater Sociomed 31(3) (2019) 219-221. https://doi.org/10.5455/msm.2019.31.219-221.

[2] J. Wang, Y. Li, G.Y. Yang, K. Jin, Age-Related Dysfunction in Balance: A Comprehensive Review of Causes, Consequences, and Interventions, Aging Dis (2024). https://doi.org/10.14336/ad.2024.0124-1.

[3] A. Shumway-Cook, M.H. Woollacott, Motor control: theory and practical applications, Williams & Wilkins, the University of Michigan, 1995.

[4] A. Nedelkou, V. Hatzitaki, K. Chatzinikolaou, G. Grouios, Does somatosensory feedback from the plantar foot sole contribute to verticality perception?, Somatosens Mot Res 38(3) (2021) 214-222. https://doi.org/10.1080/08990220.2021.1949977.

[5] A.L. Hatton, K. Rome, J. Dixon, D.J. Martin, P.O. McKeon, Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults, J Am Podiatr Med Assoc 103(6) (2013) 516-33. https://doi.org/10.7547/1030516

[6] M.T. Woo, K. Davids, J. Liukkonen, D. Orth, J.Y. Chow, T. Jaakkola, Effects of different lower-limb sensory stimulation strategies on postural regulation-A systematic review and meta-analysis, PLoS One 12(3) (2017) e0174522. https://doi.org/10.1371/journal.pone.0174522

[7] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293.

[8] E. Palluel, V. Nougier, I. Olivier, Do spike insoles enhance postural stability and plantar-surface cutaneous sensitivity in the elderly?, Age (Dordr) 30(1) (2008) 53-61. https://doi.org/10.1007/s11357-008-9047-2

[9] N. Asgari, G. Yeowell, E. Sadeghi-Demneh, A comparison of the efficacy of textured insoles on balance performance in older people with versus without plantar callosities, Gait Posture 94 (2022) 217-221. https://doi.org/10.1016/j.gaitpost.2022.03.022

[10] X. Qu, Impacts of different types of insoles on postural stability in older adults, Appl Ergon 46 Pt A (2015) 38-43. https://doi.org/10.1016/j.apergo.2014.06.005.

[11] D. Purves, G.J. Augustine, D. Fitzpatrick, Mechanoreceptors Specialized to Receive Tactile Information, Sunderland (MA)2001.

[12] S.D. Perry, A. Radtke, W.E. McIlroy, G.R. Fernie, B.E. Maki, Efficacy and effectiveness of a balance-enhancing insole, J Gerontol A Biol Sci Med Sci 63(6) (2008) 595-602. https://doi.org/10.1093/gerona/63.6.595

[13] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11

[14] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[15] C. de Morais Barbosa, M.B. Bértolo, J.Z. Gaino, M. Davitt, Z. Sachetto, E. de Paiva Magalhães, The effect of flat and textured insoles on the balance of primary care elderly people: a randomized controlled clinical trial, Clin Interv Aging 13 (2018) 277-284. https://doi.org/10.2147/cia.S149038

[16] J. Zuñiga, M. Moscoso, P.G. Padilla-Huamantinco, M. Lazo-Porras, J. Tenorio-Mucha, W. Padilla-Huamantinco, et al., Development of 3D-Printed Orthopedic Insoles for Patients with Diabetes and Evaluation with Electronic Pressure Sensors, Designs 6(5) (2022). https://doi.org/10.3390/designs6050095.

[17] M.C. Iacob, D. Popescu, D. Petcu, R. Marinescu, Assessment of the Flexural Fatigue Performance of 3D-Printed Foot Orthoses Made from Different Thermoplastic Polyurethanes, Applied Sciences 13(22) (2023). https://doi.org/10.3390/app132212149.

[18] A. Jor, C.H. Lai, M.J. Khan, Y. He, W.K. Lam, S.J. Winser, et al., Effects of somatosensory-stimulating foot orthoses on postural balance in older adults: A computerized

dynamic posturography analysis, Gait Posture 119 (2025) 189-196.
https://doi.org/10.1016/j.gaitpost.2025.03.016

[19] C.C. Harro, C. Garascia, Reliability and Validity of Computerized Force Platform Measures of Balance Function in Healthy Older Adults, J Geriatr Phys Ther 42(3) (2019) E57-e66. https://doi.org/10.1519/jpt.0000000000000175

[20] C. Pinvanichkul, A. Siriphorn, Effect of Walking Training with Textured Insole Socks in Older Adults, Physical & Occupational Therapy In Geriatrics 40(2) (2022) 135-149. https://doi.org/10.1080/02703181.2021.1994097.

[21] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[22] M. Huang, K.L. Yick, S.P. Ng, J. Yip, R.T. Cheung, The effect of support surface and footwear condition on postural sway and lower limb muscle action of the older women, PLoS One 15(6) (2020) e0234140. https://doi.org/10.1371/journal.pone.0234140.

[23] R.J. Peterka, Sensorimotor integration in human postural control, J Neurophysiol 88(3) (2002) 1097-118. https://doi.org/10.1152/jn.2002.88.3.1097.

[24] A.L. Hatton, J. Dixon, K. Rome, D. Martin, Standing on textured surfaces: effects on standing balance in healthy older adults, Age Ageing 40(3) (2011) 363-8. https://doi.org/10.1093/ageing/afr026.

[25] L. Tamè, E. Azañón, M.R. Longo, A Conceptual Model of Tactile Processing across Body Features of Size, Shape, Side, and Spatial Location, Front Psychol 10 (2019) 291. https://doi.org/10.3389/fpsyg.2019.00291.

[26] S. Reschechtko, J.A. Pruszynski, Voluntary modification of rapid tactile-motor responses during reaching differs from its visuomotor counterpart, J Neurophysiol 124(1) (2020) 284-294. https://doi.org/10.1152/jn.00232.2020.

[27] D.A. Winter, Human balance and posture control during standing and walking, Gait & Posture 3(4) (1995) 193-214. https://doi.org/10.1016/0966-6362(96)82849-9

[28] N. Vanicek, S.A. King, R. Gohil, I.C. Chetter, P.A. Coughlin, Computerized dynamic posturography for postural control assessment in patients with intermittent claudication, J Vis Exp (82) (2013) e51077. https://doi.org/10.3791/51077.

[29] S.D. Perry, W.E. McIlroy, B.E. Maki, The role of plantar cutaneous mechanoreceptors in the control of compensatory stepping reactions evoked by unpredictable, multi-directional perturbation, Brain Res 877(2) (2000) 401-6. https://doi.org/10.1016/s0006-8993(00)02712-8.

[30] A.C. Redmond, K.B. Landorf, A.M. Keenan, Contoured, prefabricated foot orthoses demonstrate comparable mechanical properties to contoured, customised foot orthoses: a plantar pressure study, J Foot Ankle Res 2 (2009) 20. https://doi.org/10.1186/1757-1146-2-20.

CHAPTER 6

EFFECTS OF 3D PRINTED SITE-SPECIFIC SOMATOSENSORY FOOT ORTHOSES WITH ADJUSTED KNOB HEIGHTS ON POSTURAL BALANCE, STABILITY, AND GAIT IN OLDER ADULTS

6.1 Introduction

The progressive loss in sensory perception along with muscle strength and joint flexibility with aging process can lead to impaired balance and stability, represent a growing public health concern [1, 2]. Enhancing balance and stability is crucial for smart ageing such as maintaining quality of life and preventing falls and related injuries in older adults. Foot orthoses often have suggested as a promising intervention to address balance issues in older adults [3, 4]. However, conventional foot orthoses often lack the ability to stimulate mechanoreceptors and enhance sensory feedback.

Recent advancements have introduced textured or somatosensory foot orthoses, designed to enhance sensory stimulation on the sole of the foot. These orthoses aim to improve balance by stimulating mechanoreceptors, thereby enhancing proprioceptive feedback [5-7]. Despite their potential benefits, current somatosensory foot orthoses design often incorporate protruding knobs with uniform heights and shapes, distributed evenly across the entire sole, typically following a flat structural approach. Such structures lack the ability to maximize contact with the plantar foot surface, which is crucial for effective stimulation. Conversely, protruding knobs under the higher plantar pressure zones might increase abnormal frictional forces, potentially leading to foot complications [8-10]. A recent systematic review with meta-regression highlighted positive correlations between balance outcomes and somatosensory foot orthoses that incorporate rounded knobs, site-specific distribution, and taller heights, and arch-support structure (see Chapter 2). Consistent with the findings of this review, a recent study on prefabricated somatosensory foot orthoses with arch-support structure demonstrated enhanced balance outcomes (see Chapter 3) [11]. While this design approach increases the contact surface between the foot orthoses and the foot, the distribution of protruding knobs was limited to the concept of even distribution across the entire bottom surface.

Although some previous studies have used protruding knobs in site-specific areas, most of them targeted regions of higher plantar pressure, such as the heel and metatarsal heads [12-14]. Interestingly, research have demonstrated significant variations in tactile sensitivity across different foot locations, with higher plantar pressure areas exhibiting lower tactile sensitivity and vice versa (see Chapter 4) [15, 16]. The current approach to designing somatosensory foot orthoses may not effectively stimulate mechanoreceptors as it overlooks differences in tactile sensitivity and plantar pressure distribution patterns across the foot [16]. Designing somatosensory foot orthoses with strategically placed protruding knobs in regions of higher tactile sensitivity, while avoiding areas of higher plantar pressure with lower sensitivity, could provide adequate mechanoreceptor stimulation and maximize somatosensory feedback in older adults. A recent study on dose-response effects utilizing site-specific somatosensory foot orthoses with varying knob heights in higher tactile sensitivity regions showed reduced postural sway and improved balance outcomes with increased knob heights (see Chapter 5). However, applying protruding knobs of uniform height across all the selected areas may cause discomfort in certain regions (see Chapter 5). This suggests that site-specific somatosensory foot orthoses with adjusted knob heights at key foot locations can enhance somatosensory feedback without causing discomfort or pain [8-10]. Consequently, there is a need for innovative designs that incorporate protruding knobs at specific locations of the foot plantar surface with adjusted heights into somatosensory foot orthoses, considering the tactile sensitivity threshold and plantar pressure distribution. Furthermore, earlier research on somatosensory foot orthoses primarily concentrated on static balance and stability [6, 17], even though daily activities are predominantly dynamic in nature.

Thus, this study aims to investigate the effects of site-specific somatosensory foot orthoses with adjusted knob heights on balance, stability, and gait on varied terrains in older adults. This involves placing protruding knobs of varying heights in areas that are more sensitive to touch and experience less plantar pressure. This approach may enhance balance outcomes by improving sensory feedback while minimizing discomfort in regions that experience greater plantar pressure. Specifically, the research seeks to examine the effects on parameters such as center of pressure (CoP) trajectory, butterfly force and gait line curves, maximum plantar forces/pressures, and spatiotemporal measures. Additionally, subjective feedback including tactile stimulation perception at the selected areas on a 7-point Likert scale as well as level of satisfaction with the orthosis on QUEST 2.0 index, will be assessed to provide a comprehensive understanding of the tactile perception and orthoses' effectiveness.

6.2 Methods

6.2.1 Participants

Healthy older adults aged 65 and older, capable of walking continuously for 30 minutes without external assistance, and engage in at least 150 minutes of walking per week were recruited. Participants were excluded if they had a body mass index (BMI) exceeding 40, or conditions such as vestibular disorders, central nervous system disorders (including Parkinson’s disease, dementia, or stroke), foot disorders such as pes planus or pes cavus, foot pain, or peripheral neuropathy/ulcers. To ensure intact protective tactile sensation, a Semmes-Weinstein Monofilament (SWM) test was performed at ten different plantar locations on the foot.

6.2.2 Foot orthoses

This study delivered three distinct types of foot orthoses in older adults: conventional flat foot orthoses, placebo foot orthoses lacking stimulating protrusions and flat foot orthoses, and somatosensory foot orthoses equipped with site-specific protruding knobs with adjusted heights and flat foot orthoses. The somatosensory foot orthoses and placebo foot orthoses were fabricated using 3D printing technology to ensure a personalized fit for each participant's feet. The process started by capturing detailed 3D models of each participant's feet using a handheld 3D scanner (EinScan, SHINNING 3D®, China) (Figure 6-1A). These digital models were then refined with Canfit Design software (Canfit^{TM} Orthotics and Prosthetics CAD, Vorum Research Corp., USA) to create custom placebo foot orthoses with a uniform thickness of 2.5 mm (Figure 6-1B-C). The placebo foot orthoses included extended raised surfaces designed to accommodate the protruding knobs in the somatosensory foot orthoses, specifically targeting the rearfoot and both the medial and lateral midfoot (Figure 6-1D-E).

The design and strategic positioning of protruding knobs in the site-specific somatosensory foot orthoses were accomplished using Materialize 3-matic (Materialise, Belgium). This design focused on regions with low plantar pressure and high tactile sensitivity. The regions cover medial and intermedius midfoot including arch cavities and raised glabrous skin at the perimeter including medial and lateral metatarsal. The protruding knobs varied in size, with short knobs measuring 2 mm in both height and diameter, medium-height knobs 3.5 mm in height with a 2 mm diameter, and tall knobs 5 mm in height with a 2 mm diameter. The knobs maintained a consistent center-to-center distance of 5 mm (Figure 6-2). The positioning of knobs with adjusted heights was guided by previous research recommendations (see Chapter 5). Short knobs were placed at the elevated rearfoot and lateral midfoot regions, medium-height knobs on the intermedius midfoot and transition areas between short to tall knobs, and tall knobs at the medial midfoot covering arch cavities.

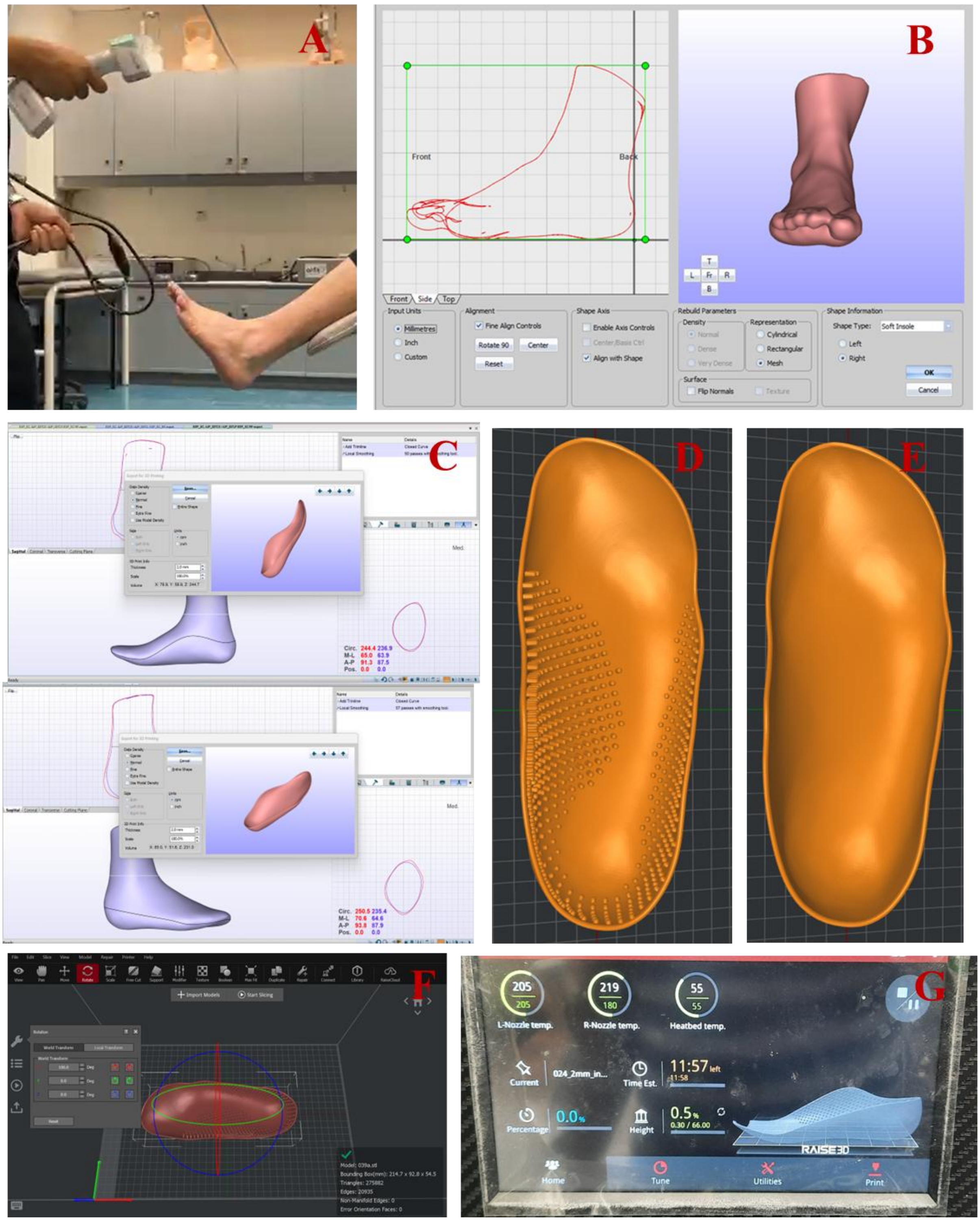


Figure 6-1. Foot orthoses design and fabrication process: (A) 3D scanning of the participant's foot; (B) post-processing of the 3D foot model; (C) design of 3D foot-contoured orthoses; (D) novel foot orthoses with strategically positioned protruding knobs; (E) placebo foot orthoses without protruding knobs; (F) 3D printing pre-processing; and (G) 3D printing using the Raise3D printer.

The site-specific somatosensory foot orthoses were fabricated using a FDM type printer (Raise3D E2, USA) and 3D slicing software (ideaMaker, version 4.2.3, USA) (Figure 6-1F-G). Thermoplastic polyurethane (TPU) with a Shore A hardness of 70 was utilized in their fabrication [18, 19]. To ensure minimize confounding shoe effects, all participants wore standard elderly shoes (Shiying 520A, Shiying Trading Co. Ltd., China) and 1 mm thick socks composed of 75% cotton (Zhuji Dongling Needle Textile Co., Ltd., China) during the trials.

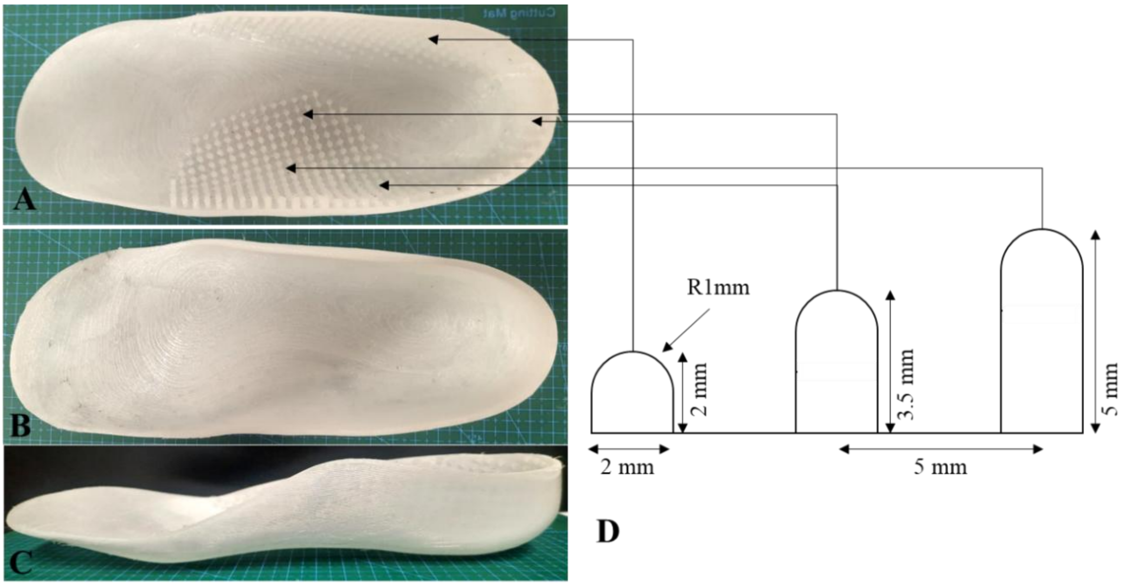


Figure 6-2. 3D Printed Foot Orthoses: (A) Site-specific somatosensory foot orthoses featuring adjusted heights of protruding knobs; (B) Placebo foot orthoses without protruding knobs; (C) Side view of the orthoses; (D) Showing protruding knobs of varying sizes, including their dimensions and positions.

6.2.3 Data collection and processing

The study assessed balance, stability, and gait in older adults through a series of sessions, which included static balance during standing with eyes open and closed, and dynamic balance during walking on level, upward, and downward terrains. A Zebris FDM-T instrumented treadmill, along with Zebris FDM software (Zebris Medical GmbH, Germany), was employed for both static and dynamic analyses. Participants stood quietly on the treadmill during static sessions, and they were given approximately five minutes to acclimate to the treadmill and select a comfortable walking speed across different inclines during dynamic sessions. The treadmill's integrated system captured and analyzed center of pressure (CoP) trajectory, spatiotemporal parameters, and maximum plantar forces/pressures distributions. The Zebris treadmill demonstrated high reliability for measuring maximum forces and plantar pressure (ICC $\geq$ 0.8), and spatiotemporal parameters (ICC $\geq$ 0.8 to 0.9) (Nüesch et al., 2018; Van Alsenoy et al., 2019). This study employed a randomized within-subjects crossover design in which all participants completed all three foot orthoses (SSFO, PFO [Sham control], and FFO [Baseline control]) conditions in a randomized order generated online (https://www.random.org/). Participants rested for five to seven minutes between conditions to minimize fatigue. A safety harness was worn throughout testing to ensure participant's safety (Figure 6-3).

CoP was calculated for each limb during the stance phase using ground reaction forces and moments and was transformed into a foot-based coordinate system. The x (mediolateral) and y (anteroposterior) directions were normalized by foot width and length, respectively, to accurately determine CoP trajectory (Lugade & Kaufman, 2014; Van Alsenoy et al., 2019). Positive values indicated lateral and anterior displacements, while negative values indicated medial and posterior displacements. For comparison, left-sided CoP trajectories were mirrored to the right. The CoP anteroposterior and mediolateral displacement ranges were calculated as the difference (maximum to minimum values) in each direction. The root mean square (RMS) of the CoP displacements was calculated for each participant to quantify balance variability and stability, using the formula (1). Lateral symmetry was assessed by the left/right shift of the butterfly intersection point, with zero indicating perfect symmetry. The anterior/posterior CoP position was defined as the distance between the butterfly intersection point and the initial contact position, normalized by foot length.

$$RMS = \sqrt{\frac{1}{N}\sum_n X^2}, \text{ n=0, 1, 2, …., 100} \quad (1)$$

where X represents individual COP displacement measurements and N is the sample size.

A threshold of 20 N identified the stance phase from heel strike to toe-off based on vertical GRF components. Maximum plantar pressure and force data were collected for seven foot regions: toes, medial forefoot, inner forefoot, lateral forefoot, midfoot, medial rearfoot, and lateral rearfoot. CoP mediolateral and anteroposterior displacements, along with butterfly GRF curves, were normalized to 101 data points (0 to 100% stance) for curve analysis. Given minimal differences between sides in healthy older participants, average values of the left and right feet were used. Participants rested for five to seven minutes between testing conditions to minimize fatigue and confounding effects. The foot orthoses (FO) conditions were provided in a randomized order to control for potential sequence effects. A safety harness ensured participant safety throughout the experiments (Figure 6-3).

After walking for 18 to 20 minutes under each foot orthoses condition across varying inclines, participants provided feedback on tactile perception and satisfaction using a 7-point Likert scale, and the 'Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)' index, respectively. The Likert scale rated tactile perception from 1 (minimal or no perception) to 7 (maximum tactile perception) [20]. The QUEST 2.0 index assessed satisfaction with adjustments, perceived safety, physical comfort, and effectiveness in supporting postural balance, with scores ranging from 1 (not satisfied) to 5 (very satisfied).

Figure 6-3. Participants walking on a treadmill while wearing the experimental foot orthoses during gait analysis.

6.2.4 Statistical analysis

The normality in the collected data was tested using the Shapiro-Wilk test method. To evaluate significant changes across foot orthoses conditions, a repeated measures ANOVA was conducted, followed by post-hoc pairwise comparisons using Bonferroni adjustments. Additionally, a mixed factorial ANOVA was utilized to examine the interaction effects of gender, terrain, and age variations on foot orthoses conditions. For data that did not follow a normal distribution, the Wilcoxon signed rank test was applied, with the Friedman test serving as a post-hoc correction. All statistical analyses were carried out utilizing IBM SPSS software, version 22, developed by SPSS Inc., Chicago, IL. In all analyses, statistical significance was determined at a threshold of $p<0.05$. Furthermore, statistical parametric mapping (SPM) was utilized to assess the curves for anteroposterior and mediolateral COP displacements, along with vertical ground reaction forces (GRF) throughout the stance phase of the gait cycle. To compare foot orthoses conditions across three inclined terrains, post-hoc paired sample t-tests were conducted. The SPM analysis was performed using the open-sourced spm1d code (Version 0.4, available at https://spm1d.org/) in Python (Version 3.11).

6.3 Results

6.3.1 Participant characteristics

A total of 23 older adult participants were recruited for the study, comprising 16 females and 7 males. The female participants had an average age of 71.63 ± 2.60 years, with a mean weight of 55.03 ± 11.73 kg, height of 150.38 ± 8.02 cm, and a BMI of 24.29 ± 4.71. The male participants had an average age of 72.29 ± 4.07 years, a mean weight of 73.07 ± 8.40 kg, height of 168.50 ± 5.42 cm, and a BMI of 25.91 ± 3.06. No interactions between gender, terrain, and age affecting the foot orthoses effects were observed (Tables 6-1 to 6-5).

Table 6-1. Mean and standard deviation of COP parameters during static standing with eyes open and eyes closed conditions as well as walking on varying inclined terrains.

Parameters	Testing conditions	Normality	FFO		PFO		SSFO		PFO vs FFO	SSFO vs FFO	SSFO vs PFO	FO*Gender	FO*Terrain
Static Balance During Standing Eyes Open/Closed Conditions													
			Mean	SD	Mean	SD	Mean	SD					
Mediolateral CoP RMS, mm	Eyes open	Yes	122.40	26.32	116.93	21.69	120.22	19.57	0.730	1.000	0.960	0.805	
	Eyes closed	Yes	122.36	25.76	117.21	21.75	120.25	19.61	0.641	1.000	1.000	0.918	
Anteroposterior CoP RMS, mm	Eyes open	No	12.97	7.06	14.26	6.13	11.96	6.81	0.212	0.503	**0.014**	0.673	
	Eyes closed	No	13.36	5.98	15.21	6.62	12.62	4.19	0.095	0.855	**0.023**	0.978	
Mediolateral CoP Range, mm	Eyes open	NO	25.32	11.34	21.33	6.46	19.49	3.72	0.282	0.113	0.085	0.672	0.115
	Eyes closed	NO	23.82	7.44	24.82	6.07	24.64	5.48	1.000	1.000	0.938	0.814	
Anteroposterior CoP Range, mm	Eyes open	Yes	6.49	5.51	4.59	2.31	4.05	1.40	0.409	**0.045**	0.372	0.636	0.107
	Eyes closed	Yes	4.53	2.17	4.78	2.23	4.47	2.35	1.000	1.000	1.000	0.919	
COP average velocity, mm/sec	Eyes open	Yes	16.58	8.90	12.39	4.74	12.82	3.99	0.088	0.083	1.000	0.787	0.261
	Eyes closed	Yes	16.90	5.66	15.51	4.34	16.81	4.27	0.916	1.000	0.400	0.619	
Dynamic Balance During Walking on Level, Up, and Down Terrains													
			Mean	SD	Mean	SD	Mean	SD					
Mediolateral CoP RMS, mm	Walking Level	Yes	6.34	1.76	6.36	1.66	6.20	1.28	1.000	1.000	1.000	0.645	
	Walking Up	Yes	6.61	1.71	6.80	1.81	6.59	1.54	1.000	1.000	0.685	0.764	
	Walking Down	Yes	6.33	1.78	6.55	1.50	6.44	1.53	1.000	1.000	1.000	0.380	
Anteroposterior CoP RMS, mm	Walking Level	Yes	51.71	7.77	51.97	8.19	51.26	8.73	1.000	1.000	0.764	0.992	
	Walking Up	Yes	49.29	7.71	49.45	8.38	49.16	8.13	1.000	1.000	1.000	0.922	
	Walking Down	Yes	55.21	8.70	55.34	8.90	54.19	8.36	1.000	1.000	0.224	0.988	
Mediolateral CoP Range, mm	Walking Level	Yes	31.82	12.13	32.40	11.88	30.32	9.91	1.000	1.000	0.687	0.986	0.999
	Walking Up	Yes	31.26	12.38	32.47	12.48	29.86	10.87	0.780	0.777	0.270	0.854	
	Walking Down	Yes	35.17	10.91	36.94	9.66	34.52	10.73	0.859	1.000	0.342	0.936	
Anteroposterior CoP Range, mm	Walking Level	Yes	215.89	40.60	219.36	41.43	220.45	42.14	1.000	0.634	1.000	0.956	1.000

	Walking Up	Yes	203.51	40.21	208.82	41.95	209.10	39.61	0.681	1.000	0.428	0.903	
	Walking Down	Yes	215.17	36.99	218.12	37.26	218.08	38.73	1.000	0.970	1.000	0.826	
CoP max velocity, cm/sec	Walking Level	Yes	711.65	318.35	723.24	317.11	691.78	325.21	1.000	1.000	1.000	0.776	0.932
	Walking Up	Yes	794.70	273.56	737.43	307.45	799.62	296.63	0.322	1.000	0.089	0.988	
	Walking Down	Yes	766.59	318.94	799.33	306.07	808.00	336.91	1.000	1.000	1.000	0.919	
Anterior/posterior position	Walking Level	Yes	10.74	8.39	10.91	9.34	10.32	8.55	1.000	1.000	1.000	0.618	1.000
	Walking Up	Yes	10.31	7.32	10.09	7.86	9.27	8.32	1.000	1.000	1.000	0.786	
	Walking Down	Yes	17.31	9.06	17.22	9.71	16.41	8.40	1.000	0.732	0.847	0.988	
Lateral symmetry, mm	Walking Level	Yes	2.61	8.71	2.51	10.19	2.65	9.63	1.000	1.000	1.000	0.593	1.000
	Walking Up	Yes	2.90	11.23	2.51	12.50	3.03	14.75	1.000	1.000	1.000	0.821	
	Walking Down	Yes	6.99	9.63	7.17	9.82	7.91	10.64	1.000	1.000	1.000	0.820	
FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: somatosensory stimulation FO; CoP: center of pressure. Significance, p<0.05													

Table 6-2. Mean and standard deviation of spatiotemporal parameters during walking on varying inclined terrains.

Parameters	**Testing conditions**	**Normality**	**FFO**		**PFO**		**SSFO**		**PFO vs FFO**	**SSFO vs FFO**	**SSFO vs PFO**	**FO*Gender**	**FO*Terrain**
Dynamic balance during walking on level, up, and down surfaces													
			Mean	SD	Mean	SD	Mean	SD					
Stride length, cm	Walking Level	Yes	61.16	14.69	61.19	15.31	62.55	16.43	1.000	0.908	0.840	0.673	0.893
	Walking Up	Yes	63.13	14.89	63.23	14.96	64.35	16.41	1.000	0.874	1.000	0.983	
	Walking Down	Yes	58.80	13.83	58.93	13.54	59.13	14.14	1.000	1.000	1.000	0.996	
Stride time, sec	Walking Level	Yes	1.20	0.19	1.19	0.17	1.22	0.20	1.000	1.000	1.000	0.979	0.256
	Walking Up	Yes	1.24	0.18	1.24	0.16	1.26	0.20	0.602	0.789	1.000	0.994	
	Walking Down	Yes	1.15	0.15	1.15	0.14	1.16	0.15	1.000	1.000	1.000	0.662	
Step width, cm	Walking Level	Yes	14.19	3.48	14.50	3.58	14.25	3.71	0.785	1.000	1.000	0.968	0.999
	Walking Up	Yes	13.90	3.62	14.29	3.71	14.27	3.78	0.653	0.432	1.000	0.993	
	Walking Down	Yes	14.00	2.84	14.19	3.13	13.75	2.99	1.000	1.000	0.100	0.998	
Stance, %	Walking Level	Yes	70.10	0.02	69.97	0.30	70.08	0.19	1.000	1.000	1.000	0.994	0.294

	Walking Up	Yes	69.96	0.02	70.17	0.00	70.29	0.23	1.000	1.000	1.000	0.275	
	Walking Down	Yes	68.79	0.28	68.83	0.39	68.84	0.07	1.000	1.000	1.000	0.992	
Cadence, steps/min	Walking Level	Yes	102.84	15.96	102.65	15.33	101.32	16.10	1.000	1.000	1.000	0.992	0.335
	Walking Up	Yes	98.74	14.40	98.58	12.97	97.64	15.19	0.102	0.107	1.000	0.832	
	Walking Down	Yes	106.00	13.92	105.90	13.99	105.53	14.45	1.000	1.000	1.000	0.985	
FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: somatosensory stimulation FO; Significance, p<0.05													

Table 6-3. Mean and standard deviation of maximum plantar forces as well as pressure distribution during walking on varying inclined terrains.

Parameters	**Testing conditions**	**Normality**	**FFO**		**PFO**		**SSFO**		**PFO vs FFO**	**SSFO vs FFO**	**SSFO vs PFO**	**FO*Gender**	**FO*Terrain**
Dynamic balance during walking on level, up, and down surfaces													
Maximum Plantar forces			**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**					
Toes, N/kg	Walking Level	Yes	1.49	0.51	1.45	0.58	1.44	0.57	1.000	1.000	1.000	0.811	0.959
	Walking Up	Yes	1.37	0.43	1.31	0.49	1.36	0.51	0.759	1.000	0.692	0.955	
	Walking Down	Yes	1.67	0.62	1.59	0.68	1.50	0.64	0.055	0.062	**0.042**	0.829	
Forefoot medial, N/kg	Walking Level	Yes	1.67	0.31	1.71	0.33	1.63	0.31	0.904	1.000	**0.005**	0.889	0.990
	Walking Up	Yes	1.66	0.32	1.63	0.31	1.59	0.29	0.827	0.168	0.957	0.988	
	Walking Down	Yes	1.68	0.30	1.69	0.32	1.62	0.29	1.000	**0.033**	**0.035**	0.988	
Forefoot inner, N/kg	Walking Level	Yes	2.69	0.53	2.80	0.52	2.70	0.53	0.221	1.000	**0.027**	0.940	0.997
	Walking Up	Yes	2.69	0.50	2.72	0.49	2.65	0.50	1.000	1.000	0.438	0.903	
	Walking Down	Yes	2.61	0.42	2.66	0.36	2.58	0.41	0.665	1.000	**0.041**	0.919	
Forefoot lateral, N/kg	Walking Level	Yes	1.32	0.22	1.33	0.29	1.35	0.27	1.000	0.778	0.547	0.901	0.999
	Walking Up	Yes	1.26	0.21	1.26	0.29	1.27	0.26	1.000	1.000	1.000	0.913	
	Walking Down	Yes	1.38	0.26	1.38	0.30	1.40	0.31	1.000	1.000	0.569	0.917	
Midfoot, N/kg	Walking Level	Yes	3.39	0.87	3.40	0.89	3.86	0.88	1.000	**<0.001**	**<0.001**	0.861	1.000
	Walking Up	Yes	3.36	0.83	3.43	0.84	3.86	0.92	1.000	**<0.001**	**<0.001**	0.914	
	Walking Down	Yes	3.39	1.18	3.46	1.25	3.89	1.19	0.877	**<0.001**	**<0.001**	0.949	
Rearfoot medial, N/kg	Walking Level	Yes	2.12	0.49	2.16	0.50	2.13	0.50	0.719	1.000	1.000	0.877	1.000
	Walking Up	Yes	2.06	0.50	2.09	0.50	2.08	0.48	1.000	1.000	1.000	0.899	
	Walking Down	Yes	2.02	0.40	2.07	0.41	2.03	0.40	0.506	1.000	0.776	0.999	
Rearfoot lateral, N/kg	Walking Level	Yes	2.18	0.54	2.20	0.56	2.08	0.52	1.000	0.450	**0.043**	0.850	1.000
	Walking Up	Yes	2.26	0.52	2.26	0.51	2.15	0.49	1,000	0.320	0.091	0.853	
	Walking Down	Yes	1.93	0.44	1.93	0.49	1.82	0.46	1.000	**0.006**	**0.034**	0.914	

Maximum Plantar pressures			Mean	SD	Mean	SD	Mean	SD					
Toes, N/cm2	Walking Level	Yes	12.06	2.50	12.00	2.75	11.79	2.78	1.000	1.000	1.000	0.779	0.994
	Walking Up	Yes	11.28	2.47	11.25	2.68	11.03	2.74	1.000	1.000	1.000	0.968	
	Walking Down	Yes	12.30	2.69	12.46	2.42	11.86	2.45	1.000	0.449	**0.026**	0.799	
Forefoot medial, N/cm2	Walking Level	Yes	13.09	2.10	13.04	2.10	12.62	2.12	1.000	0.106	**0.016**	0.865	0.969
	Walking Up	Yes	13.25	2.24	12.95	2.04	12.47	2.27	0.265	**0.018**	0.245	0.832	
	Walking Down	Yes	12.54	2.06	12.71	1.89	12.20	1.89	1.000	0.475	**0.014**	0.799	
Forefoot inner, N/cm2	Walking Level	Yes	14.64	2.39	14.77	2.31	14.21	2.27	1.000	0.235	**0.007**	0.982	0.998
	Walking Up	Yes	14.71	2.43	14.66	2.30	14.11	2.49	1.000	0.097	**0.020**	0.921	
	Walking Down	Yes	13.96	2.46	14.07	2.09	13.64	2.23	1.000	0.647	**0.014**	0.999	
Forefoot lateral, N/cm2	Walking Level	Yes	11.82	2.20	11.72	2.00	11.58	1.92	1.000	0.912	0.932	0.874	0.999
	Walking Up	Yes	11.71	2.02	11.58	1.85	11.41	1.84	1.000	0.353	0.383	0.919	
	Walking Down	Yes	11.54	2.16	11.40	1.69	11.40	1.83	1.000	1.000	1.000	0.977	
Midfoot, N/cm2	Walking Level	Yes	11.73	2.48	11.44	1.86	11.45	1.70	0.734	0.865	1.000	0.753	0.973
	Walking Up	Yes	12.15	2.43	11.70	1.79	11.55	1.87	0.250	0.122	1.000	0.955	
	Walking Down	Yes	11.26	2.02	11.15	1.65	11.20	1.59	1.000	1.000	1.000	0.835	
Rearfoot medial, N/cm2	Walking Level	Yes	10.53	2.18	10.33	2.10	10.18	2.10	0.134	0.220	1.000	0.891	0.996
	Walking Up	Yes	10.47	2.17	10.23	2.00	10.15	1.90	0.826	**0.028**	0.139	0.989	
	Walking Down	Yes	10.36	1.89	10.17	1.92	9.96	1.89	1.000	0.468	1.000	0.709	
Rearfoot lateral, N/cm2	Walking Level	Yes	10.96	1.72	10.73	1.82	10.62	1.83	0.830	0.642	1.000	0.875	0.957
	Walking Up	Yes	11.33	2.40	11.05	1.95	10.74	1.87	0.198	**0.008**	0.086	0.867	
	Walking Down	Yes	11.16	2.20	10.72	1.87	10.31	1.85	0.808	**0.022**	0.133	0.907	
FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: somatosensory stimulation FO; Significance, p<0.05													

Table 6-4. Median and range of Tactile perception level on 7-point Likert scale

Parameters	Testing conditions	FFO		PFO		SSFO		PFO vs FFO	SSFO vs FFO	SSFO vs PFO
		Median	Range	Median	Range	Median	Range			
Tactile stimulation perception	Raised-rearfoot	1	1-4	1	1-5	5	1-6	0.167	<0.001	<0.001
	At arches	1	1-3	1	1-4	5	1-7	0.985	<0.001	<0.001
	Raised-medial-midfoot	1	1-4	1	1-3	5	1-7	1.000	<0.001	<0.001
	Raised-lateral-midfoot	1	1-4	1	1-4	5	1-6	1.000	<0.001	<0.001
FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: somatosensory stimulation FO; Significance, p<0.05										

Table 6-5. Median and range of Subjective satisfaction on using foot orthoses on Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0)

Parameters	**Testing conditions**	**FFO**		**PFO**		**SSFO**		**PFO vs FFO**	**SSFO vs FFO**	**SSFO vs PFO**
		Median	Range	Median	Range	Median	Range			
Subjective feedback, score	Adjustments	3	1-5	3	2-5	3	2-5	1.000	0.624	0.585
	Safety	3	2-5	4	2-5	4	2-5	1.000	**0.024**	0.108
	Comfort	3	2-5	4	2-5	4	1-5	0.471	0.414	0.093
	Effectiveness	3	2-5	3	2-5	4	2-5	**0.012**	**0.003**	**0.024**

FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: somatosensory stimulation FO; Significance, $p<0.05$

6.3.2 Center of pressure trajectories and gait

The root mean square (RMS) of anteroposterior CoP displacements was significantly reduced with somatosensory foot orthoses compared to placebo foot orthoses during standing with both eyes open (MD=-2.30; p=0.014) and closed (MD=-2.59; p=0.023) conditions (Table 6-1, Figure 6-4). Additionally, anteroposterior CoP ranges were also significantly decreased with somatosensory foot orthoses compared to placebo foot orthoses during standing with eyes open (MD=-2.44; p=0.045). There were no significant differences in CoP trajectory measures, including displacements in mediolateral and anteroposterior directions, CoP maximum velocities, and anterior/posterior positions, while participants walked on varied inclined terrains (Table 6-1, Figure 6-5). In the analysis of statistical parametric mapping (SPM) curves, the somatosensory foot orthoses showed significantly lower mediolateral CoP displacement when compared to the placebo foot orthoses at 0-10% of the stance phase during walking on upward terrain (p=0.048) (Figure 6-7). Additionally, somatosensory foot orthoses showed higher ground reaction forces compared to the flat foot orthoses at 35-45% of the stance phase during walking on upward terrain (p<0.001) (Figure 6-8). However, there were no significant differences observed in the CoP gait line curves during walking across level and downward terrains. Similarly, spatiotemporal gait measures such as stride length, time, step width, stance, and cadence showed no significant differences across terrains (Table 6-2, Figure 6-9).

6.3.3 Plantar forces and pressure distribution

Regarding maximum plantar forces, significant decreases were observed with somatosensory foot orthoses compared to placebo foot orthoses at the toes during walking on downward terrain (MD=-0.09; p=0.042), and at the medial forefoot during walking on level terrain (MD=-0.08; p=0.005) (Table 6-3, Figure 6-10). Somatosensory foot orthoses also led to decreased maximum plantar forces at the medial forefoot compared to both placebo foot orthoses (MD=-

0.07; p=0.035) and flat foot orthoses (MD=-0.06; p=0.033) during downward terrain walking. At the inner forefoot, maximum plantar forces were reduced with somatosensory foot orthoses compared to placebo foot orthoses during both level (MD=-.10; p=0.027) and downward (MD=-0.08; p=0.041) terrains. Conversely, maximum plantar forces at the midfoot increased significantly with somatosensory foot orthoses compared to both placebo foot orthoses and flat foot orthoses across all terrains (level: MD=0.46; p<0.001, MD=0.47; p<0.001, upward: MD=0.43; p<0.001, MD=0.50; p<0.001, downward: MD=0.46; p<0.001, MD=0.50; p<0.001). Maximum plantar forces at the lateral rearfoot decreased with somatosensory foot orthoses compared to placebo foot orthoses during level terrain walking (MD=-0.12; p=0.043) and compared to both placebo foot orthoses (MD=-0.11; p=0.034) and flat foot orthoses (MD=-0.11; p=0.006) during downward terrain walking.

Regarding plantar pressures, somatosensory foot orthoses significantly decreased at the toes compared to placebo foot orthoses during walking on downward terrain (MD=-0.60; p=0.026) (Table 6-3, Figure 6-11). At the medial forefoot, maximum plantar pressures were reduced with somatosensory foot orthoses compared to placebo foot orthoses during level terrain (MD=-0.42; p=0.016), compared to flat foot orthoses during upward terrain (MD=-0.78; p=0.018), and compared to placebo foot orthoses during downward terrain (MD=-0.51; p=0.014). Additionally, somatosensory foot orthoses consistently decreased maximum plantar pressures at the inner forefoot compared to placebo foot orthoses across all terrains (level: MD=-0.56; p=0.007, upward: MD=-0.55; p=0.020, downward: MD=-0.43; p<0.014,).

6.3.4 Subjective feedback

On a 7-point Likert scale, the subjective rating of tactile perception of stimulating knobs was marginal (1.36 to 1.45) with placebo foot orthoses and flat foot orthoses (Table 6-4, Figure 6-12A). In contrast, somatosensory foot orthoses received significantly higher ratings, ranging from 3.61 to 4.95, with the lowest perception at the lateral raised midfoot areas and the highest under the foot arches.

Using the QUEST 2.0 index, participants rated their level of satisfaction with the orthoses. The effectiveness in controlling postural balance was significantly higher with somatosensory foot orthoses compared to both placebo foot orthoses ($p=0.024$) and flat foot orthoses ($p=0.003$), as well as rating was higher with placebo foot orthoses compared to flat foot orthoses ($p=0.012$) (Table 6-5, Figure 6-12B). A significant increase in safety scores was observed with somatosensory foot orthoses compared to flat foot orthoses ($p = 0.024$). While the difference was statistically significant, there was a trend toward greater comfort with somatosensory foot orthoses relative to placebo foot orthoses.

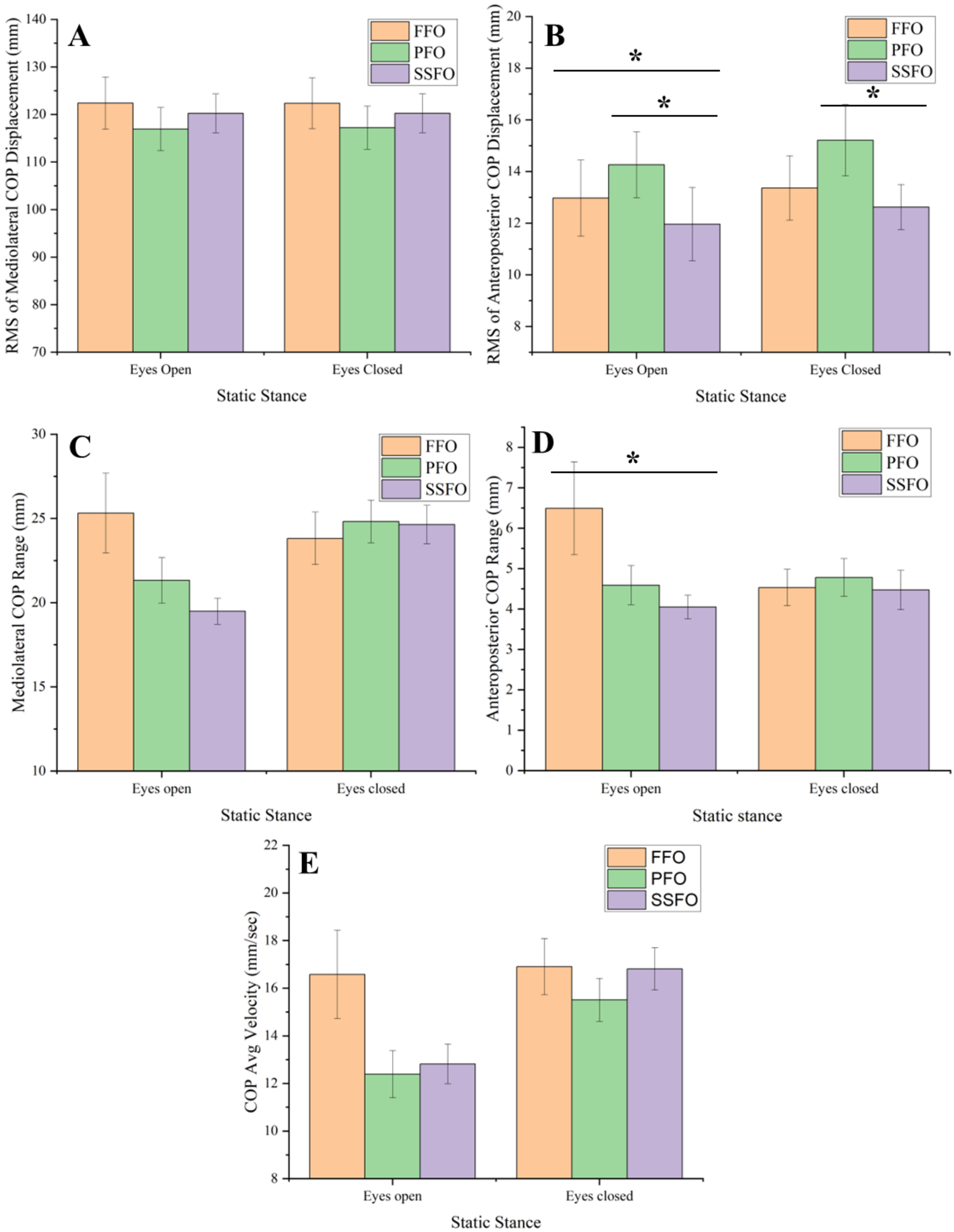


Figure 6-4. Center of Pressure (CoP) trajectory during static standing under different visual input conditions. Root Mean Square (RMS) of CoP displacements: (A) Mediolateral direction and (B) Anteroposterior direction. COP displacement ranges: (C) Mediolateral direction and (D) Anteroposterior direction; (E) CoP velocity. Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO). The asterisk (*) refers to a significant difference at $p < 0.05$.

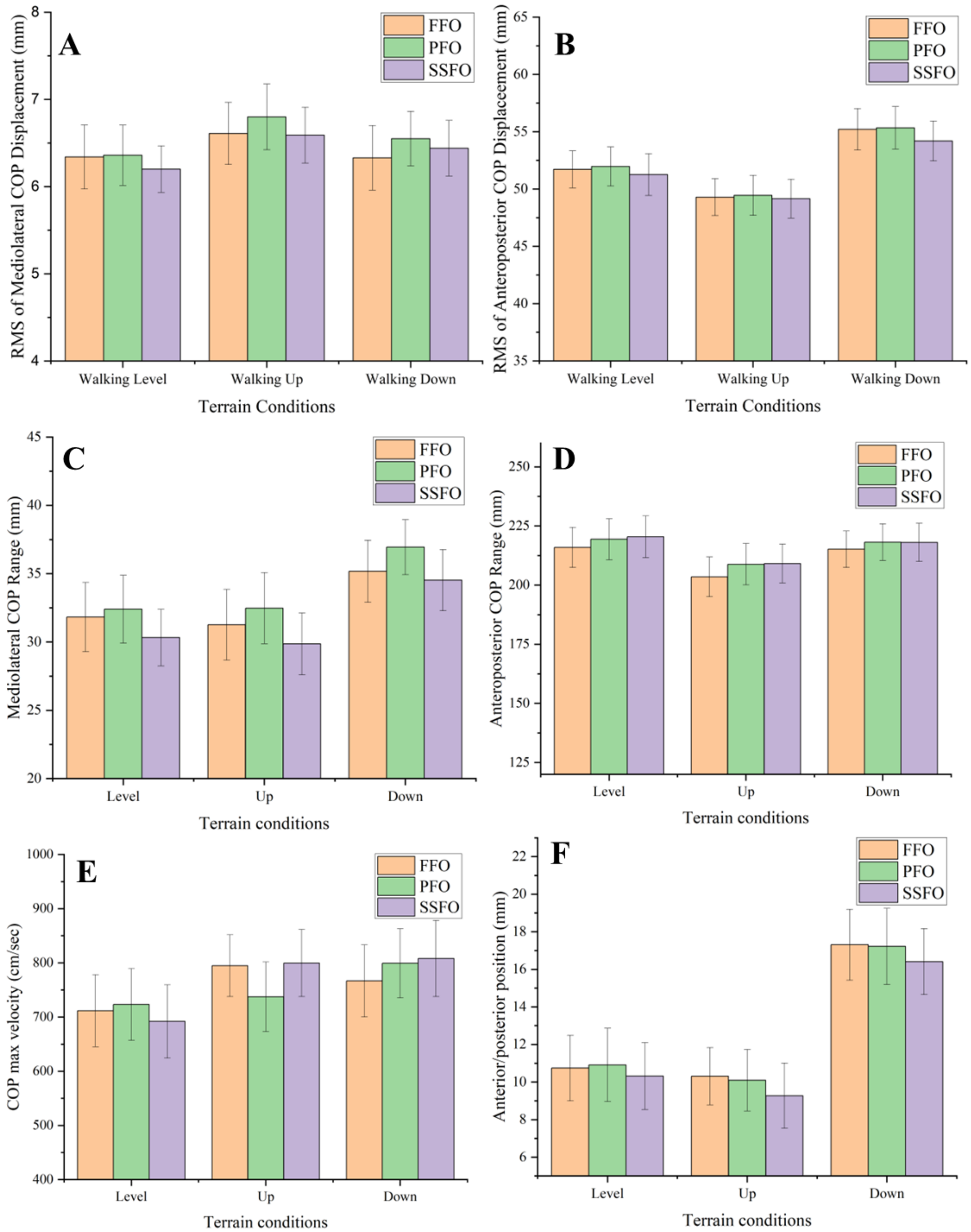


Figure 6-5. Center of Pressure (CoP) trajectory during walking on varied inclined terrains. Root Mean Square (RMS) of CoP displacements: (A) Mediolateral direction and (B) Anteroposterior direction; CoP displacement ranges: (C) Mediolateral direction and (D) Anteroposterior direction; (E) CoP maximum velocity, and (F) Anterior/Posterior position. Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO).

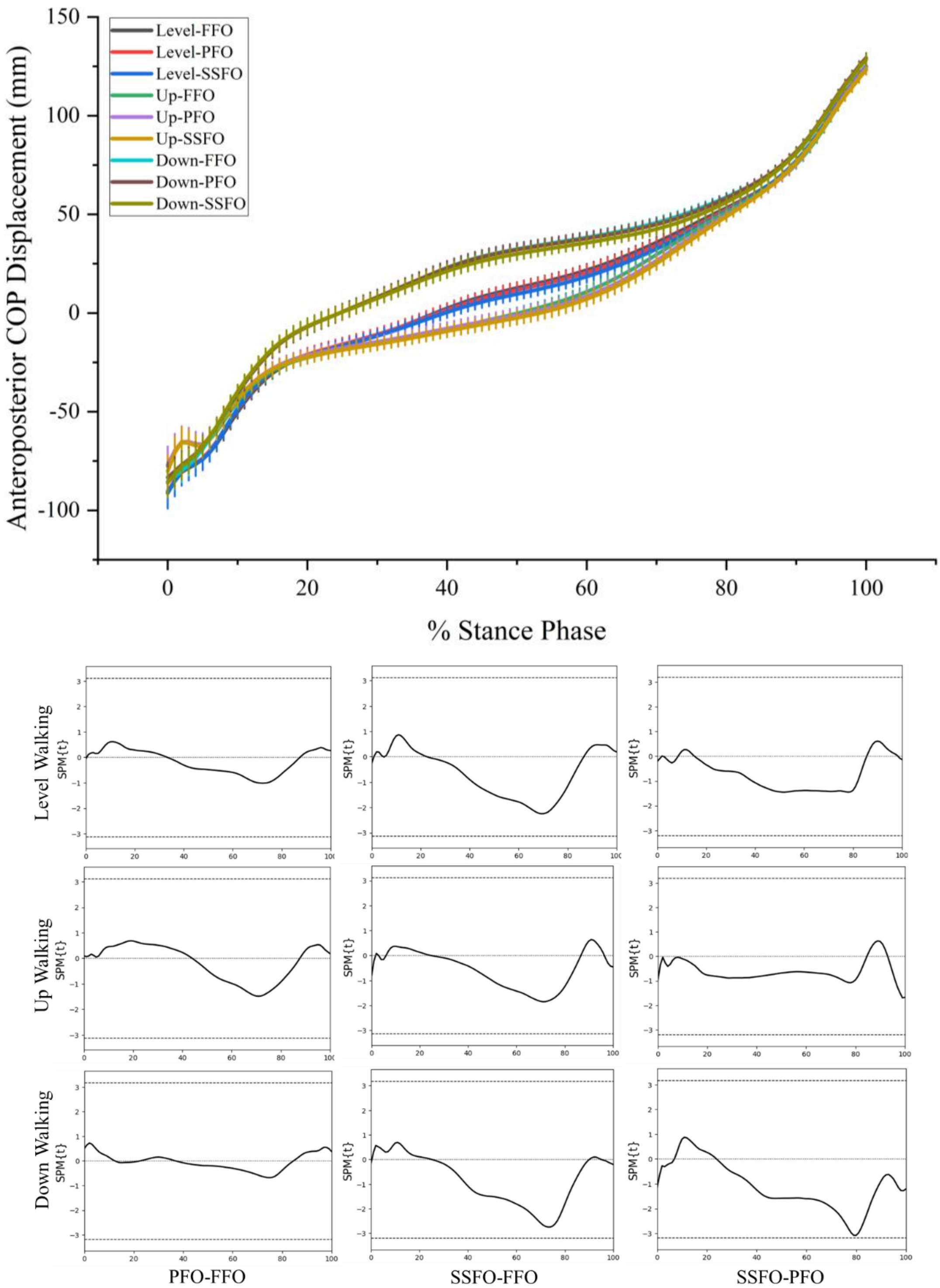


Figure 6-6. Anteroposterior displacement of the center of pressure (CoP) with standard deviations across 0 to 100% stance where black (Level-FFO), red (Level-PFO), and blue (Level-SSFO) represent flat, placebo, and somatosensory foot orthoses (FO) on level terrain, green (Up-FFO), purple (Up-PFO), and gold (Up-SSFO) represent flat, placebo, and somatosensory FO on upward terrain, and cyan (Down-FFO), brown (Down-PFO), and olive (Down-SSFO) represent flat, placebo, and somatosensory FO on downward terrain, respectively. In the results of statistical parametric mapping (SPM) analysis, no significant differences across foot orthoses conditions on either (a) level walking, (b) upward walking, or and (c) downward ward walking.

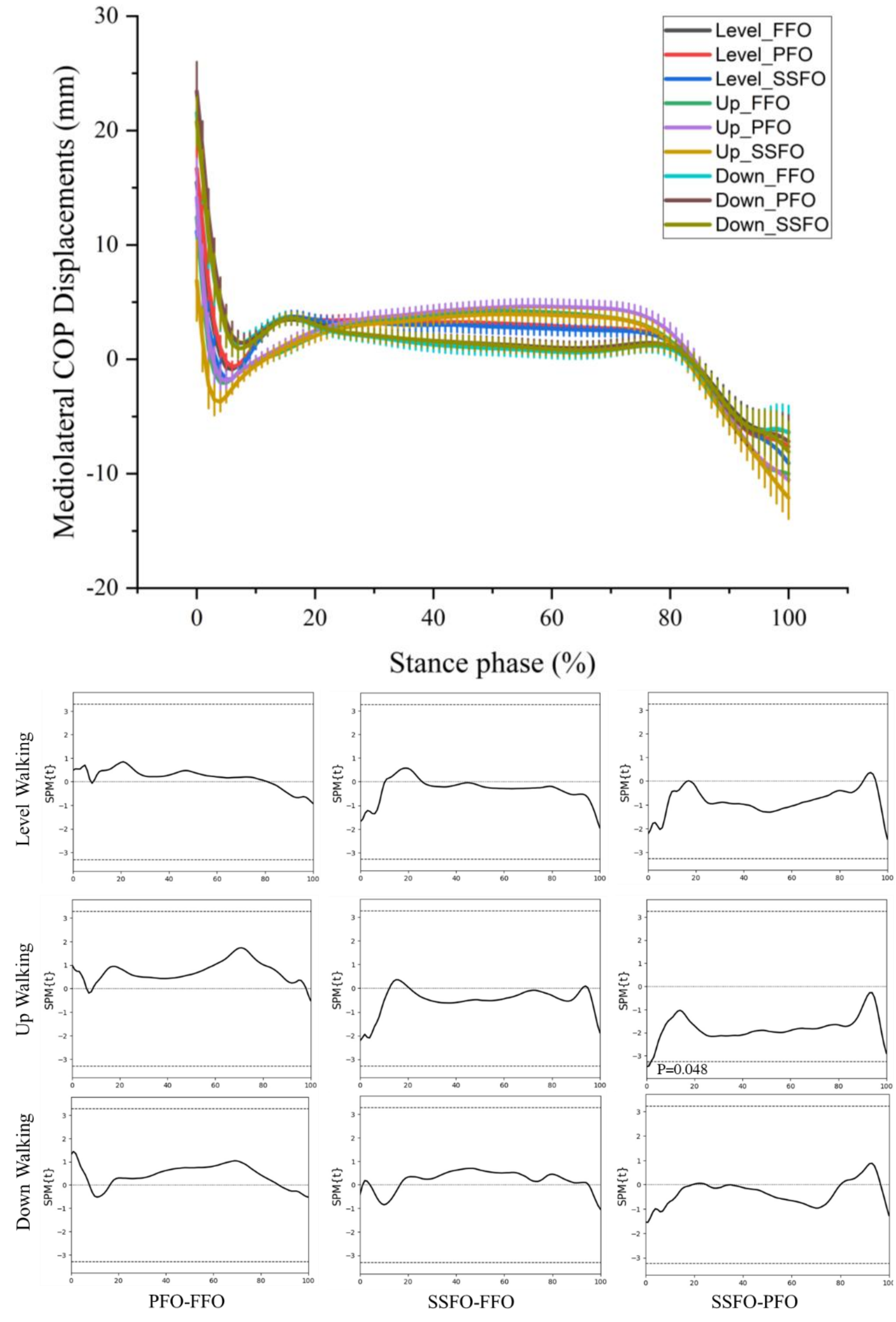


Figure 6-7. Mediolateral displacement of the center of pressure (CoP) with standard deviations across 0 to 100% stance where black (Level-FFO), red (Level-PFO), and blue (Level-SSFO) represent flat, placebo, and somatosensory foot orthoses (FO) on level terrain, green (Up-FFO), purple (Up-PFO), and gold (Up-SSFO) represent flat, placebo, and somatosensory FO on upward terrain, and cyan (Down-FFO), brown (Down-PFO), and olive (Down-SSFO) represent flat, placebo, and somatosensory FO on downward terrain, respectively. In the results of statistical parametric mapping (SPM) analysis, no significant differences across foot orthoses conditions on either (a) level walking, (b) upward walking, or and (c) downward ward walking, except between somatosensory foot orthoses and placebo (SSFO-PFO) on upward terrain (p=0.048).

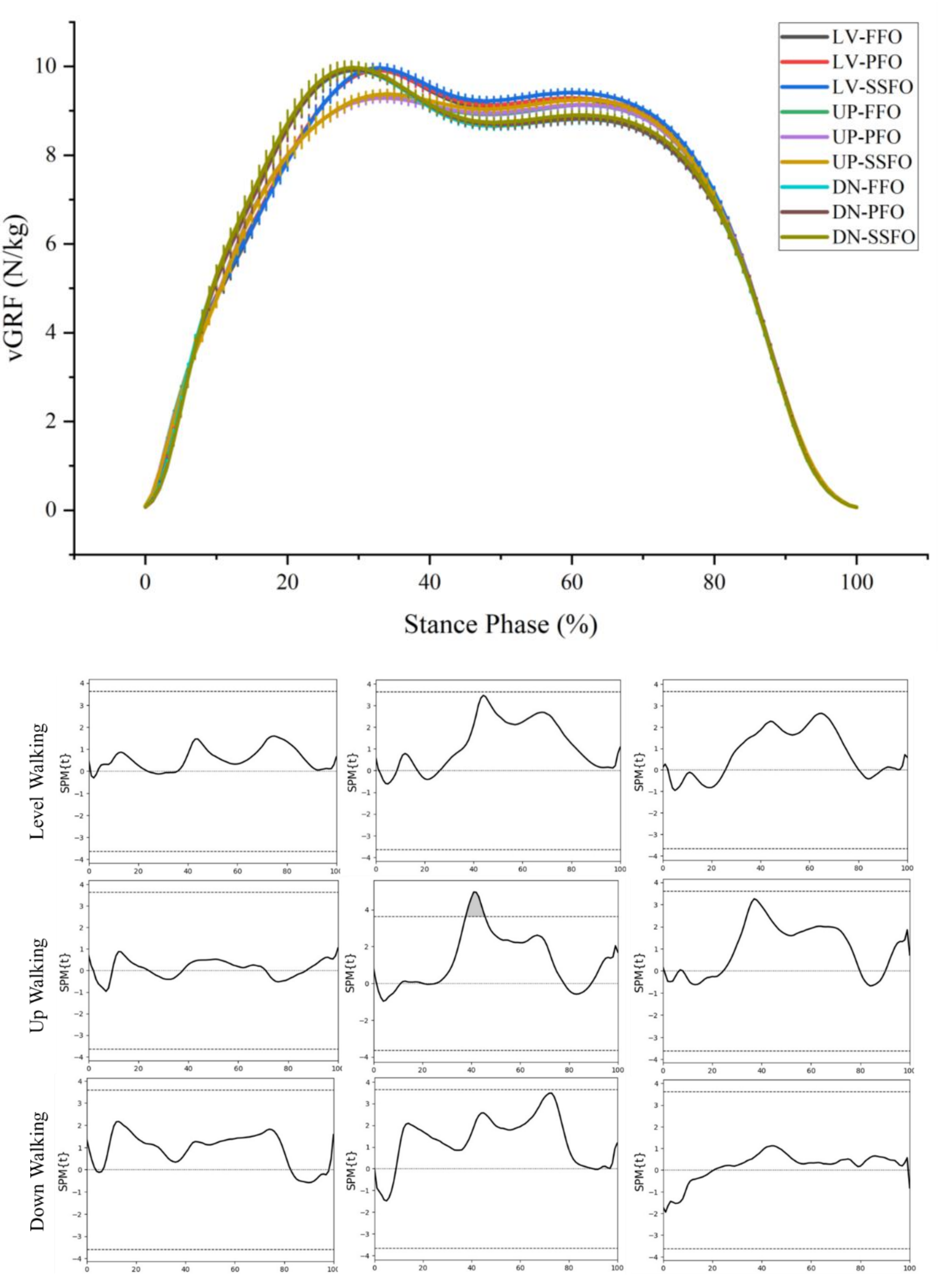


Figure 6-8. Vertical ground reaction force (GRF) with standard deviations across 0 to 100% stance where black (Level-FFO), red (Level-PFO), and blue (Level-SSFO) represent flat, placebo, and somatosensory foot orthoses (FO) on level terrain, green (Up-FFO), purple (Up-PFO), and gold (Up-SSFO) represent flat, placebo, and somatosensory FO on upward terrain, and cyan (Down-FFO), brown (Down-PFO), and olive (Down-SSFO) represent flat, placebo, and somatosensory FO on downward terrain, respectively. In the results of statistical parametric mapping (SPM) analysis, no significant differences across foot orthoses conditions on either (a) level walking, (b) upward walking, or and (c) downward ward walking, except between somatosensory foot orthoses and placebo (SSFO-FFO) on upward terrain ($p<0.001$).

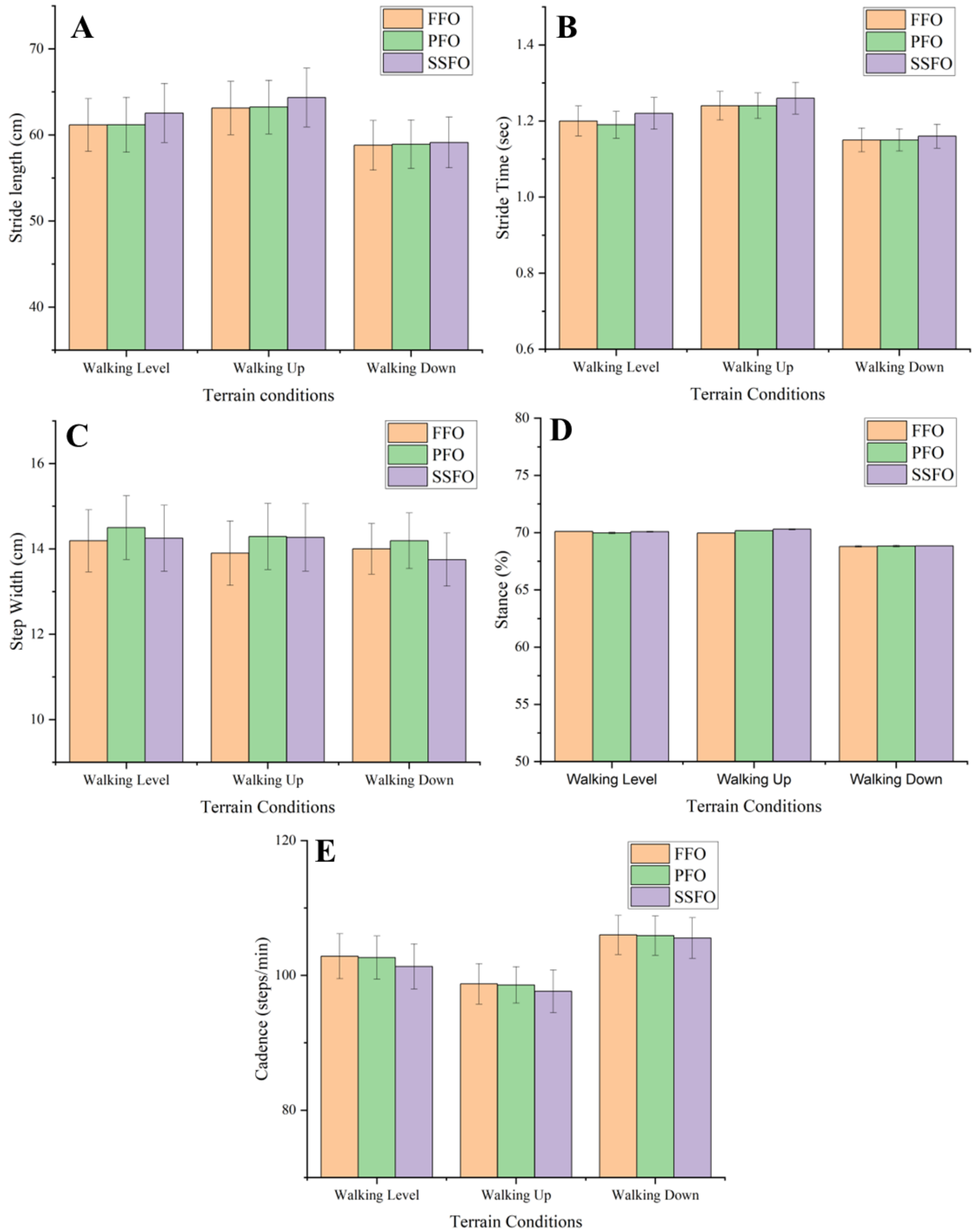


Figure 6-9. Spatiotemporal gait during walking on varied inclined terrains. (A) Stride length, (B) Stride time, (C) Step width, (D) Stance, and (E) Cadence. Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO).

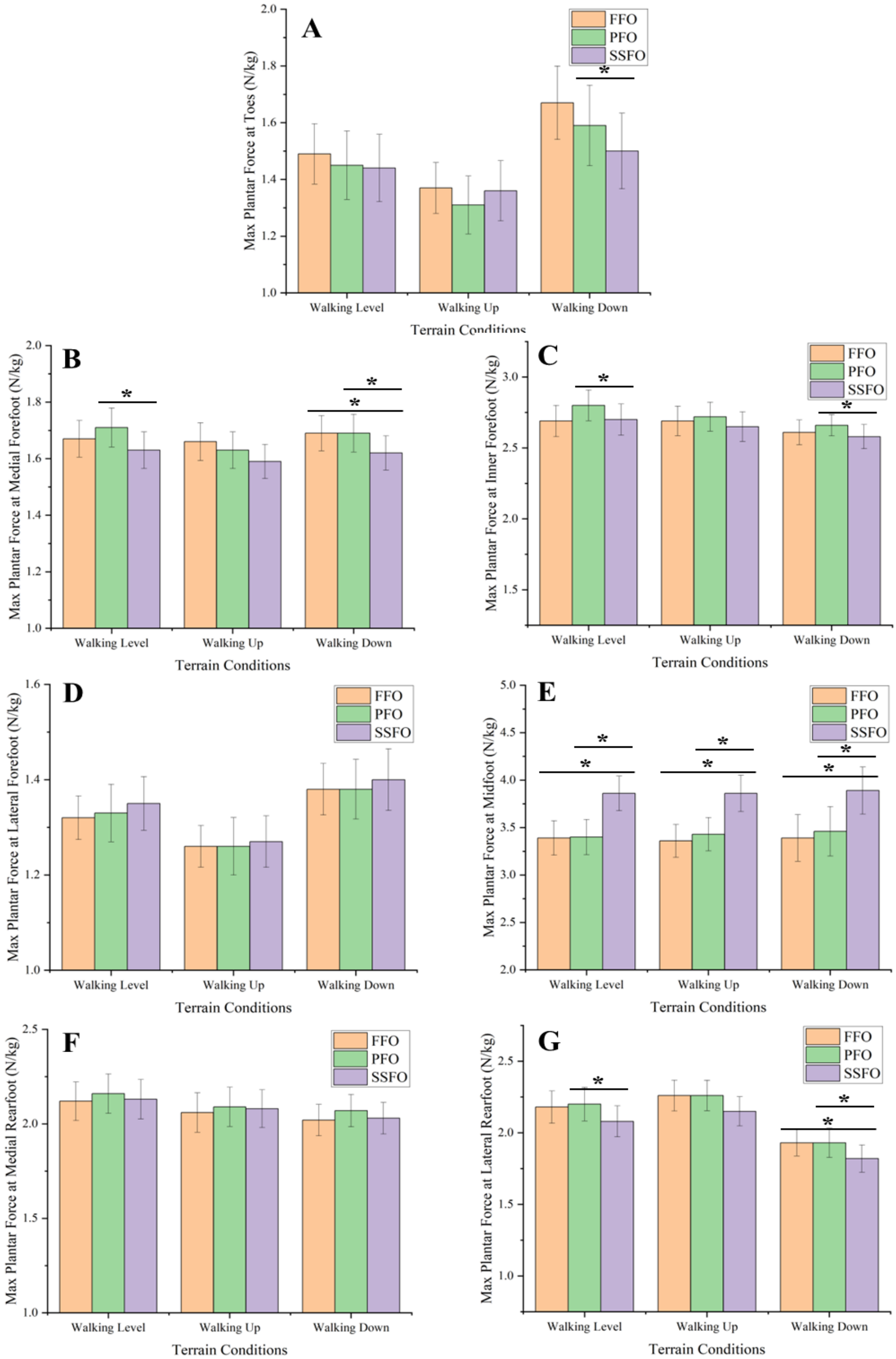


Figure 6-10. Maximum plantar forces across seven regions of the foot during walking on varied inclined terrains. (A) Toes, (B) Medial forefoot, (C) Inner forefoot, (D) Lateral forefoot, (E) Midfoot, (F) Medial rearfoot, and (G) Lateral rearfoot. Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO). The asterisk (*) refers to a significant difference at $p < 0.05$.

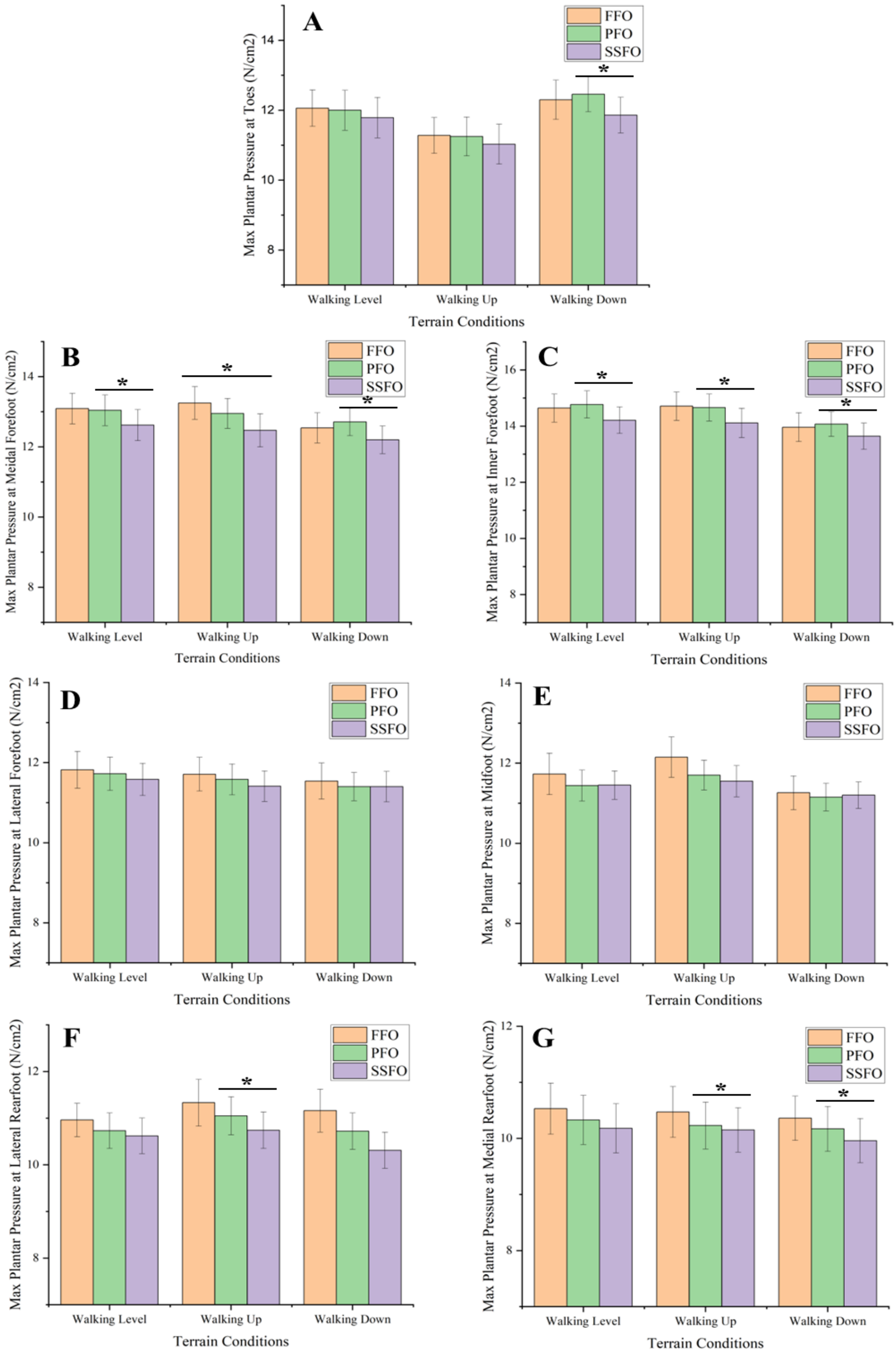


Figure 6-11. Maximum plantar pressure distribution across seven regions of the foot during walking on varied inclined terrains. (A) Toes, (B) Medial forefoot, (C) Inner forefoot, (D) Lateral forefoot, (E) Midfoot, (F) Medial rearfoot, and (G) Lateral rearfoot. Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO). The asterisk (*) refers to a significant difference at $p < 0.05$.

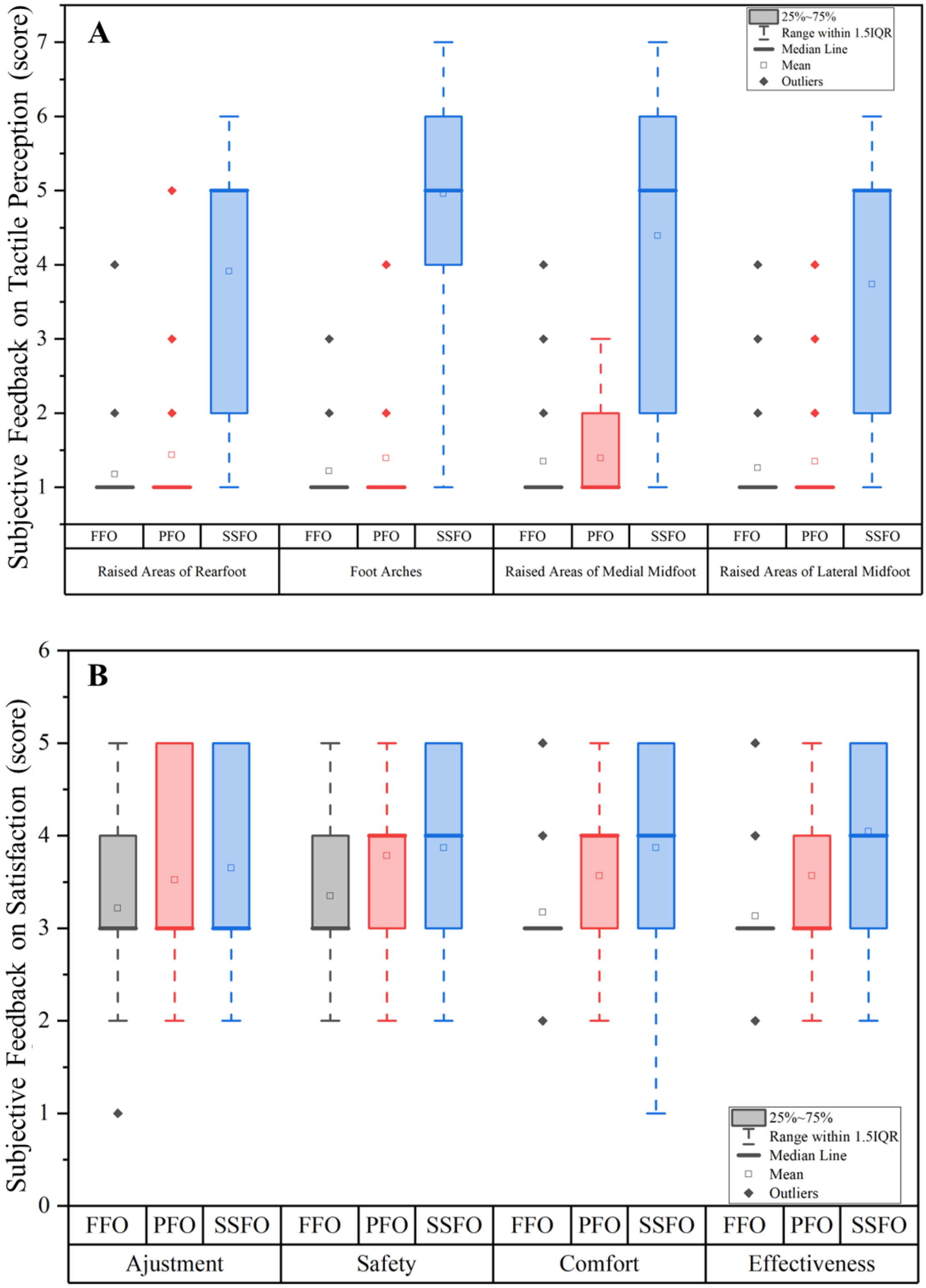


Figure 6-12. Subjective feedback. (A) Tactile perception level on 7-point Likert scale; (B) Subjective satisfaction on using foot orthoses on Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0). Comparisons are made across Flat Foot Orthoses (FFO), Placebo Foot Orthoses (PFO), and Somatosensory Stimulation Foot Orthoses (SSFO).

6.4 Discussion

In this study, we sought to examine whether strategically positioning protruding knobs with adjusted heights could serve as an effective approach to enhancing postural control and balance. Site-specific somatosensory foot orthoses as well as placebo foot orthoses without stimulation protrusions were examined and compared to conventional flat foot orthoses in terms of effects on postural balance and stability. Unlike conventional flat and placebo foot orthoses, site-specific somatosensory foot orthoses incorporated with protruding knobs of rounded shape and adjusted heights positioned at higher tactile sensitive regions of the foot.

The results during static standing showed that site-specific somatosensory foot orthoses influenced postural control in a way that decreased postural sway. This finding is consistent with previous research reporting enhanced postural stability by somatosensory foot orthoses (see Chapter 2) [6]. Different from other two foot orthoses, the strategical positioning of protruding knobs in site-specific somatosensory foot orthoses might be the cause of greater postural control, since the positioning of stimulating knobs at higher tactile sensitive regions is able to stimulate mechanoreceptors and enhance somatosensory feedback [14, 21]. The effectiveness of strategically positioned protruding knobs is further supported by comparisons with somatosensory foot orthoses that have protrusions covering the entire surface, where no significant changes in postural control were observed (see Chapter 3). This may be because the protruding knobs placed around the extended surface of rearfoot to medial and lateral midfoot primarily provide feedback about body posture [21]. Furthermore, the reduced postural sway and improved lateral stability at heel strike during walking on upward terrain can support this notion. The protruding knobs at the higher tactile sensitive regions could provide external stimulation forces/pressure to the foot skin. This aligns with the understanding that mechanoreceptors such as Pacinian corpuscle, Merkel discs and Ruffini endings play a crucial role in detecting light to deep pressure and skin stretch, which are essential for maintaining balance [22, 23]. These stimulation forces to the mechanoreceptors could enhance somatosensory feedback and contribute moving center of mass to its stable position, particularly when it approached the limits of base of support [21]. Additionally, higher ground reaction forces at the 35-45% of stance phase may be due to the better support and load distribution allowing for greater force generation through the limbs. Again, walking upward generally requires more muscle activation and force [24]. Higher GRF could reflect the body's adaptation to the increased demands of the slope.

In contrast, site-specific somatosensory foot orthoses appeared not to significantly influence spatiotemporal gait parameters or dynamic postural sway under various terrain conditions. This finding aligns with previous research on dynamic movement and gait parameters (see Chapters 2 and 3) [12, 25]. The lack of significant differences in gait-related dynamic stability and performance may be attributed to treadmill walking at fixed speeds, where participants tend to adopt similar gait patterns in this controlled setting [26-28]. Research has shown that individuals walking on a treadmill at a comfortable and consistent speed exhibit lower vertical foot acceleration with improved postural control [29]. Notably, a previous study using somatosensory foot orthoses reported improved postural sway during walking on a surface walkway [13]. However, this effect might be attributed to the footwear condition used in the study, as the results were compared to barefoot conditions. Assessing gait and stability under diverse, real-world conditions could provide greater insight into the functional benefits of this novel somatosensory foot orthosis, as daily activities often involve unpredictable environments and dynamic movements that are not fully replicated in a controlled treadmill environment.

The redistribution of plantar forces and pressures observed with somatosensory foot orthoses lends further support to the hypothesis that strategically placed protruding knobs increase the contact area between the foot and the orthosis [13]. This enhanced contact is thought to improve somatosensory feedback while redirecting plantar forces from regions of higher plantar pressure to areas of lower pressure. This redistributing forces/pressures further could be attributed to the stimulation of mechanoreceptors that are sensitive to touch, changes in texture, dynamic pressure and/or stretch through the stimulating knobs. By redistributing plantar forces and enhancing the sensory input from these regions, somatosensory foot orthoses may facilitate more effective postural adjustments and stability [30, 31].

The subjective feedback from participants added additional insights regarding stimulation potential of site-specific somatosensory foot orthoses. The higher ratings for tactile perception as well as satisfaction indicate that the participants perceived the immediate benefits of the somatosensory foot orthoses, particularly in terms of effectiveness to postural balance, device safety, and comfort. Furthermore, the strategic positioning of protruding knobs with adjusted heights helped minimize discomfort and mild pain that were previously associated with uniform-height designs, as reported in earlier studies (see Chapter 5).

There are several limitations to this study that need to be acknowledged. This study only focused on immediate effects of site-specific somatosensory foot orthoses. As people tend to adapt to foot orthoses over time, a longitudinal study is warranted to examine how prolonged use may influence postural balance. The effects on balance and stability were evaluated exclusively within a laboratory setting at a fixed walking speed. However, postural control mechanisms may differ when navigating across surface walkways or real-life environments. Future research should therefore investigate the somatosensory foot orthoses effects on dynamic stability during overground walking conditions. Additionally, to validate these results, future studies should involve larger and more diverse populations.

6.5 Conclusion

This study sought to explore the potential of site-specific somatosensory foot orthoses in enhancing balance among older adults. Through a comprehensive evaluation of balance-related parameters and subjective feedback, this research revealed critical insights regarding the effectiveness of site-specific somatosensory foot orthoses in enhancing stability in the elderly population. This approach offers a promising direction for designing and developing orthotic interventions that enhance balance in older adults by enhancing somatosensory feedback. However, additional research is necessary to investigate the long-term effects of using somatosensory foot orthoses. Future studies should include larger sample sizes and examine different combinations of protrusion distribution. This could explore robust insights regarding the mechanisms through which the approach of artificial mechanoreceptors stimulation enhances somatosensory feedback and improve postural control.

References

[1] J. Wang, Y. Li, G.Y. Yang, K. Jin, Age-Related Dysfunction in Balance: A Comprehensive Review of Causes, Consequences, and Interventions, Aging Dis 16(2) (2024) 714-737. https://doi.org/10.14336/ad.2024.0124-1

[2] D.L. Sturnieks, R. St George, S.R. Lord, Balance disorders in the elderly, Neurophysiol Clin 38(6) (2008) 467-78. https://doi.org/10.1016/j.neucli.2008.09.001

[3] A.L. Hatton, K. Rome, J. Dixon, D.J. Martin, P.O. McKeon, Footwear interventions: a review of their sensorimotor and mechanical effects on balance performance and gait in older adults, J Am Podiatr Med Assoc 103(6) (2013) 516-33. https://doi.org/10.7547/1030516

[4] A. Aboutorabi, M. Bahramizadeh, M. Arazpour, R. Fadayevatan, F. Farahmand, S. Curran, et al., A systematic review of the effect of foot orthoses and shoe characteristics on balance in healthy older subjects, Prosthet Orthot Int 40(2) (2016) 170-81. https://doi.org/10.1177/0309364615588342

[5] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology 70(8) (2024) 801-811. https://doi.org/10.1159/000539591

[6] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293

[7] J.H. Park, H.S. Jeon, J.H. Kim, H.B. Yoon, O.B. Lim, M. Jeon, Immediate effect of insoles on balance in older adults, Foot (Edinb) 47 (2021) 101768. https://doi.org/10.1016/j.foot.2020.101768

[8] A. Gefen, Why is the heel particularly vulnerable to pressure ulcers?, Br J Nurs 26(Sup20) (2017) S62-s74. https://doi.org/10.12968/bjon.2017.26.Sup20.S62

[9] H.B. Menz, G.V. Zammit, S.E. Munteanu, Plantar pressures are higher under callused regions of the foot in older people, Clin Exp Dermatol 32(4) (2007) 375-80. https://doi.org/10.1111/j.1365-2230.2007.02421.x

[10] V.V. Broderick, L.J. Cowan, Pressure injury related to friction and shearing forces in older adults, Journal of Dermatology and Skin Science 3(2) (2021). https://doi.org/10.29245/2767-5092/2021/2.1136.

[11] A. Jor, C.H. Lai, M.J. Khan, Y. He, W.K. Lam, S.J. Winser, et al., Effects of somatosensory-stimulating foot orthoses on postural balance in older adults: A computerized dynamic posturography analysis, Gait Posture 119 (2025) 189-196. https://doi.org/10.1016/j.gaitpost.2025.03.016

[12] C. Pinvanichkul, A. and Siriphorn, Effect of Walking Training with Textured Insole Socks in Older Adults, Physical & Occupational Therapy In Geriatrics 40(2) (2022) 135-149. https://doi.org/10.1080/02703181.2021.1994097.

[13] P.L. Li, K.L. Yick, S.P. Ng, J. Yip, Influence of Textured Indoor Footwear on Posture Stability of Older Women Based on Center-of-Pressure Measurements, Hum Factors 61(8) (2019) 1247-1260. https://doi.org/10.1177/0018720819837414

[14] S.D. Perry, A. Radtke, W.E. McIlroy, G.R. Fernie, B.E. Maki, Efficacy and effectiveness of a balance-enhancing insole, J Gerontol A Biol Sci Med Sci 63(6) (2008) 595-602. https://doi.org/10.1093/gerona/63.6.595

[15] N.D. Strzalkowski, R.L. Mildren, L.R. Bent, Thresholds of cutaneous afferents related to perceptual threshold across the human foot sole, J Neurophysiol 114(4) (2015) 2144-51. https://doi.org/10.1152/jn.00524.2015

[16] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[17] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[18] J. Zuñiga, M. Moscoso, P.G. Padilla-Huamantinco, M. Lazo-Porras, J. Tenorio-Mucha, W. Padilla-Huamantinco, et al., Development of 3D-Printed Orthopedic Insoles for Patients with Diabetes and Evaluation with Electronic Pressure Sensors, Designs 6(5) (2022). https://doi.org/10.3390/designs6050095.

[19] M.C. Iacob, D. Popescu, D. Petcu, R. Marinescu, Assessment of the Flexural Fatigue Performance of 3D-Printed Foot Orthoses Made from Different Thermoplastic Polyurethanes, Applied Sciences 13(22) (2023). https://doi.org/10.3390/app132212149. https://doi.org/10.3390/app132212149

[20] O.D. A, S.M. Cooney, F.N. Newell, Self-reported vividness of tactile imagery for object properties and body regions: An exploratory study, Conscious Cogn 103 (2022) 103376. https://doi.org/10.1016/j.concog.2022.103376

[21] X. Qu, Impacts of different types of insoles on postural stability in older adults, Appl Ergon 46 Pt A (2015) 38-43. https://doi.org/10.1016/j.apergo.2014.06.005
[22] D. Purves, G.J. Augustine, D. Fitzpatrick, W.C. Hall, A. LaMantia, R.D. Mooney, et al., Neuroscience, 6th ed., Sinauer Associates Inc2017.
[23] R.S. Johansson, A.B. Vallbo, Tactile sensibility in the human hand: relative and absolute densities of four types of mechanoreceptive units in glabrous skin, J Physiol 286 (1979) 283-300. https://doi.org/10.1113/jphysiol.1979.sp012619
[24] N.T. Pickle, A.M. Grabowski, A.G. Auyang, A.K. Silverman, The functional roles of muscles during sloped walking, J Biomech 49(14) (2016) 3244-3251. https://doi.org/10.1016/j.jbiomech.2016.08.004
[25] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11
[26] J.H. Hollman, M.K. Watkins, A.C. Imhoff, C.E. Braun, K.A. Akervik, D.K. Ness, A comparison of variability in spatiotemporal gait parameters between treadmill and overground walking conditions, Gait Posture 43 (2016) 204-9. https://doi.org/10.1016/j.gaitpost.2015.09.024
[27] C.A. Fukuchi, R.K. Fukuchi, M. Duarte, Effects of walking speed on gait biomechanics in healthy participants: a systematic review and meta-analysis, Syst Rev 8(1) (2019) 153. https://doi.org/10.1186/s13643-019-1063-z
[28] L.H. Sloot, M.M. van der Krogt, J. Harlaar, Self-paced versus fixed speed treadmill walking, Gait Posture 39(1) (2014) 478-84. https://doi.org/10.1016/j.gaitpost.2013.08.022
[29] J. Tong, J. Zhang, E. Dong, C. Liu, S. Du, The Influence of Treadmill on Postural Control, IEEE Access 8 (2020) 193632-193643. https://doi.org/10.1109/ACCESS.2020.3019442

[30] A.T.V. Da Cruz Junior, B.H.B. Vasconcelos, T. Barroso, G.S. Souza, L.C.P. Monteiro, M.B. Xavier, et al., Plantar pressure distribution and altered postural control in multibacillary leprosy patients, BMC Infect Dis 24(1) (2024) 130. https://doi.org/10.1186/s12879-023-08749-0

[31] G. Arin-Bal, A. Livanelioglu, A. Leardini, C. Belvedere, Correlations between plantar pressure and postural balance in healthy subjects and their comparison according to gender and limb dominance: A cross-sectional descriptive study, Gait Posture 108 (2024) 124-131. https://doi.org/10.1016/j.gaitpost.2023.11.017

CHAPTER 7

EFFECTS OF 3D PRINTED SITE-SPECIFIC SOMATOSENSORY FOOT ORTHOSES WITH ADJUSTED KNOB HEIGHTS ON POSTURAL BALANCE AND CONTROL: A COMPUTERIZED DYNAMIC POSTUROGRAPHIC ASSESSMENTS

7.1 Introduction

Maintaining postural control requires the complex coordination of the body's sensory inputs, motor systems, and cognitive functions [1, 2]. Effective sensory inputs depend on the integration of visual cues, vestibular feedback, and tactile perceptions from the soles of the feet particularly during standing and walking [3, 4]. The brain relies on these sensory inputs, which interact simultaneously but to different extents depending on the nature of task or environment, to execute motor strategies and make necessary postural adjustments [2].

Glabrous foot skin on the soles of the feet is connected to four types of mechanoreceptors that convey somatosensory information to the cognitive system [5]. These mechanoreceptors are typically activated by pressure, touch, skin stretch, and vibration [6, 7]. Aging leads to a significant decline in mechanoreceptors, such as reductions of up to 90% of Meissner and Pacinian corpuscles in the feet [8]. This loss diminishes responses to mechanical stimuli, which contributes to impaired balance and stability. Orthotic interventions such as textured or somatosensory foot orthoses including shoe inserts or insoles have been recommended as artificial stimulation modality to enhance plantar tactile sensation and improve postural control.

Research shows that somatosensory foot orthoses can reduce body sway and enhance standing balance in older adults. However, traditional somatosensory foot orthoses often feature uniform protrusions across the entire plantar foot surface, which can increase frictional forces particularly in areas with higher plantar pressure and result in discomfort, calluses, and ulcer formation [9-11]. Most research have focused on the effectiveness of protrusions with uniform heights, shape, and distribution particularly into the flat structure somatosensory foot orthoses, there has been less emphasis on site-specific positioning as well as variation in protrusion heights based on the foot's tactile sensitivity [12-14]. A recent systematic review reported positive correlations between postural control and somatosensory foot orthoses with arch-support structures, and protrusions of site-specific positioning, taller heights, and rounded shapes (see Chapter 2). A recent study examined prefabricated somatosensory foot orthoses featuring arch-support and rounded protruding knobs, revealed evidence of enhanced postural control (see Chapter 3) [15]. Nonetheless, this study utilized protrusions distributed across the entire bottom surface. Since there are significant variations in tactile sensitivity across foot skin locations (see Chapter 4), existing approach with entire surface protrusions may not effectively stimulate mechanoreceptors for afferent firing [16].

A dose-response study, discussed in Chapter 5, investigated site-specific somatosensory foot orthoses with varying heights of protruding knobs. The findings suggest that strategically positioning knobs with increased heights can enhance mechanoreceptor stimulation and improve balance control. However, positioning knobs of uniform heights at different areas may lead to discomfort in certain areas. This indicates that site-specific somatosensory foot orthoses with adjusted knob heights can enhance somatosensory feedback while minimizing discomfort. This highlighted the importance of more tailored approaches that consider variations in tactile sensitivity and plantar pressure distribution across foot skin locations. Furthermore, although Chapter 6 explored the impact of such somatosensory foot orthoses on balance, stability, and gait while walking on different terrains, there remains a limited understanding of their effects on postural and motor control when responding to various perturbations and changes in somatosensory, visual and/or vestibular input conditions.

This study aims to examine the effects of site-specific somatosensory foot orthoses with adjusted knob heights on postural control and stability in older adults using computerized dynamic posturography (CDP) assessments. Unlike conventional foot orthoses, site-specific somatosensory foot orthoses feature strategically placed stimulating knobs with adjusted heights tailored to the tactile sensitivity and pressure patterns across glabrous foot skin locations. This targeted site-specific approach seeks to maximize sensory feedback through mechanoreceptors stimulation, thereby enhancing postural control and stability.

7.2 Methods

7.2.1 Participants

The study recruited healthy older adult participants, aged 65 years and above. They were screened for eligibility based on the following criteria: (1) ability to walk without external support (i.e., walking aids), (2) no history of neurological disorders, (3) no severe musculoskeletal or foot conditions that could interfere balance outcomes, and (4) no recent lower limb surgery, severe pain, and any condition that could affect foot tactile sensitivity, such as diabetic/peripheral neuropathy. Participants were assigned to either the target group, which received the novel site-specific somatosensory foot orthoses and placebo foot orthoses, or the control group, which received conventional flat foot orthoses with a simple randomization method.

7.2.2 Foot Orthoses

This investigation utilized the same foot orthoses as described in Chapter 6, which involved three distinct types: conventional flat foot orthoses, placebo foot orthoses without stimulating protrusions, and site-specific somatosensory foot orthoses equipped with strategically placed as well as adjusted height protruding knobs. For detailed fabrication methods, including the use of 3D printing devices, design software, and materials used, please refer to Chapter 6. The site-specific somatosensory foot orthoses and placebo foot orthoses were customized using 3D models of participants' feet. The somatosensory foot orthoses featured protruding knobs of varying sizes and heights, designed to target foot skin areas with lower plantar pressure and higher tactile sensitivity, as guided by previous research (see Chapter 5). Participants wore standard shoes and thin cotton socks during trials to minimize confounding effects.

7.2.3 Data collection and processing

The Bertec Balance Advantage System (Bertec Corporation, Columbus, OH, USA) was utilized to collect data on computerized dynamic posturography (CDP) [15, 17-19] (Figure 7-1). This system is built-in dynamic force plates that measure displacement in the participant's weight distribution on the foot in response to body movements. Additionally, it includes a visual display that shows anterior/posterior displacement to modify visual input using integrated software. Before data collection, participants received thorough demonstrations of each experimental component. This study employed a randomized parallel group design in which participants in the experimental group received two foot orthoses (SSFO and PFO [sham control]) conditions and participants in the control group received FFO [baseline control]. The sequence of foot orthosis conditions was randomized among participants to reduce potential confounding effects, such as learning effects. A rest period of 7 to 10 minutes was provided between testing conditions to minimize fatigue. For their safety and comfort, a harness was used to alleviate any fears of falling during the trials.

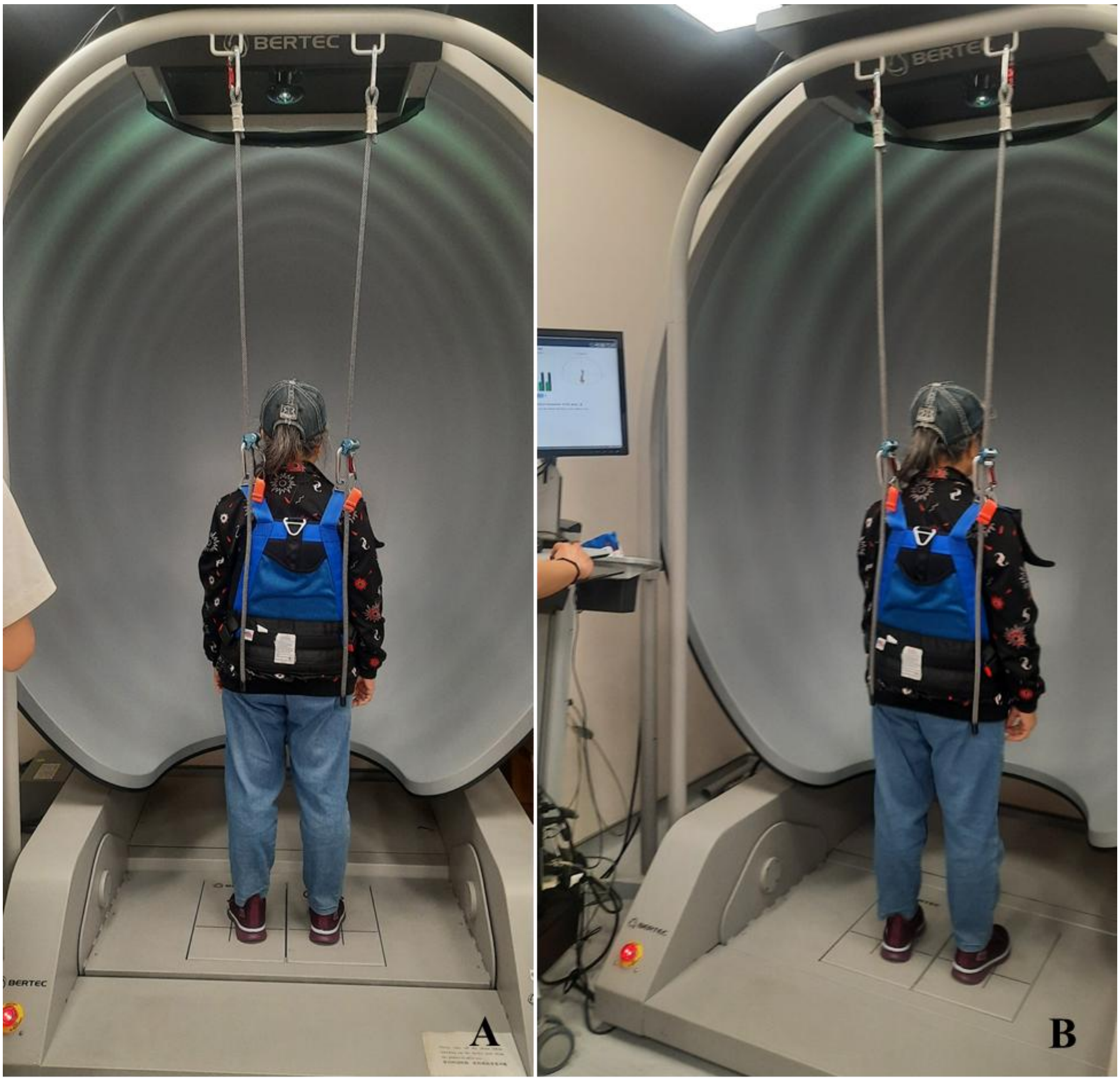


Figure 7-1. Experimental setup for computerized dynamic posturography: Participants stand upright on the force platform to assess postural stability.

Data collection and analysis involved three fundamental tests: the Sensory Organization Test (SOT), Motor Control Test (MCT), and Adaptation Test (ADT) [15]. The SOT comprised six experimental conditions, each with three trials lasting 20 seconds. The composite equilibrium score, a weighted average from the six conditions was measured. This score quantified center of gravity (CoG) sway or postural stability in the anteroposterior direction. The MCT included two conditions with three backward and three forward translations of the support surface. Each condition comprised three trials with random delays of 1.5–2.5 seconds between trials, lasting less than a second each. The MCT assessed latency score, amplitude scaling, and weight symmetry score

The ADT was conducted under two distinct conditions: ankle-centered rotations with the toes pointing upward and downward. Each condition comprised five trials, with the timing of rotations randomized to minimize participants' ability to anticipate the perturbations. Following each perturbation, the sway energy necessary for restoring balance was measured. The psychometric evaluation demonstrated that SOT and MCT scores exhibited excellent test-retest reliability for assessing balance in older adults, with ICC values of 0.90 and 0.85, respectively. For a detail description of the experimental procedures used in the CDP assessments—including SOT, MCT, and ADT—please see Chapter 3.

7.2.4 Statistical analysis

The normality in the collected data was tested using the Shapiro-Wilk test method. Independent samples t-tests (for normally distributed data) or Mann-Whitney U test (for not-normally distributed data) were performed to compare the effects of flat foot orthoses against both somatosensory foot orthoses and placebo foot orthoses. Bonferroni adjustments for multiple comparisons were applied as a post-hoc correction. Additionally, paired samples t-tests or Wilcoxon signed-rank test were used to compare somatosensory foot orthoses and placebo foot orthoses within the target group. Two-way ANOVA or Kruskal-Wallis were performed to explore the main and interaction effects of gender on foot orthoses. All statistical analyses were performed using IBM SPSS software (version 22, SPSS Inc., Chicago, IL). In all tests In every test conducted, statistical significance was determined using a p-value cutoff of 0.05.

7.3 Results

7.3.1 Participant characteristics

A total of 46 older adult participants were recruited and assigned to two groups: control and target (Table 7-1). The control group consisted of 23 participants, with 16 females and 7 males. Female participants had an average age of 71.63 ± 3.56 years, weight of 53.53 ± 7.63 kg, height of 154.25 ± 5.27 cm, and BMI of 22.57 ± 3.49. Male participants in the control group had an average age of 72.86 ± 3.85 years, weight of 62.46 ± 7.63 kg, height of 165.29 ± 6.55 cm, and BMI of 22.83 ± 2.05. The target group also comprised 23 participants, with 16 females and 7 males. Female participants in this group had an average age of 71.63 ± 2.60 years, weight of 55.03 ± 11.73 kg, height of 150.38 ± 8.02 cm, and BMI of 24.29 ± 4.71. Male participants in the target group had an average age of 72.29 ± 4.07 years, weight of 73.07 ± 8.40 kg, height of 168.50 ± 5.42 cm, and BMI of 25.91 ± 3.06. Notably, there were significantly higher composite equilibrium ($p=0.045$), latency ($p<0.001$), and amplitude scaling ($p<0.001$) observed in male than female participants (Table 7-2). However, no interaction of gender to foot orthoses effects were observed.

Table 7-1. Participant Demographics

Group	**Gender**	**Sample size**	**Age**	**Weight**	**Height**	**BMI**	**SWM**	**Shoe size (US)**
Control	Female	16	71.63±3.56	53.53±7.63	154.25±5.27	22.57±3.49	9.94±0.17	5.5-8.5
	Male	7	72.86±3.85	62.46±7.63	165.29±6.55	22.83±2.05	9.50±0.87	5.5-7.5
	Total	23	72.00±3.61	56.24±8.56	157.61±7.59	22.65±3.07	9.80±0.52	-
Target	Female	16	71.63±2.60	55.03±11.73	150.38±8.02	24.29±4.71	9.84±0.51	5.5-8.5
	Male	7	72.29±4.07	73.07±8.4	168.50±5.42	25.91±3.06	10.00±0.0	5.5-8.0
	Total	23	71.83±3.04	60.52±13.61	155.89±11.16	24.78±4.27	9.89±0.43	-

Table 7-2. Mean and standard deviation of parameters related to computerized dynamic posturography (CDP) under different foot orthosis conditions

Parameters	**Testing conditions**	**FFO**		**PFO**		**SSFO**		**PFO vs FFO**	**SSFO vs FFO**	**SSFO vs PFO**	Gender	FO*Gender
		Mean	SD	Mean	SD	Mean	SD					
Equilibrium, score	C-1	89.20	3.70	86.45	4.10	88.19	3.24	**0.010**	0.194	**0.028**	0.606	-
	C-2	88.14	4.74	86.58	4.84	86.99	5.11	0.262	0.317	0.820	0.698	-
	C-3	87.83	3.95	85.75	5.13	86.36	4.12	0.116	0.071	0.581	0.770	-
	C-4	59.84	10.82	59.54	9.24	61.46	9.40	0.919	0.590	0.285	0.052	0.943
	C-5	57.58	12.16	57.67	10.07	58.35	9.02	0.637	0.878	0.577	0.006	-
	C-6	53.18	12.32	55.70	9.75	55.49	9.63	0.965	0.956	0.892	0.098	-
	Composite	68.17	7.08	67.74	6.17	68.43	6.10	0.825	0.482	0.359	0.045	0.892
Latency, mm	LAT_BT_M	134.65	10.67	138.96	11.40	142.15	12.37	0.193	**0.033**	**0.014**	<0.001	0.262
	LAT_BT_L	136.76	8.55	141.78	9.91	140.41	8.04	0.073	0.143	0.417	0.001	0.534
	LAT_BT	137.30	8.22	140.37	9.95	141.28	9.19	0.261	0.129	0.254	<0.001	0.151
	LAT_FT_M	136.98	10.73	144.59	13.76	142.33	14.47	0.057	0.156	0.438	0.001	-
	LAT_FT_L	136.41	10.11	140.98	12.76	143.54	12.50	0.185	**0.035**	0.301	0.001	-
	LAT_FT	137.17	10.02	142.78	12.34	142.93	12.87	0.098	0.097	0.927	0.001	0.479
Weight symmetry, %	WS_BT_S	92.14	6.89	92.12	5.29	93.20	4.60	0.701	0.921	0.377	0.894	0.785
	WS_BT_M	89.65	8.10	91.79	5.36	93.72	5.48	0.296	**0.052**	0.165	0.315	-
	WS_BT_L	90.74	7.93	91.34	5.75	92.68	6.11	0.818	0.517	0.312	0.315	-
	WS_BT	90.54	7.30	91.75	5.14	93.20	5.12	0.801	0.170	0.248	0.373	-
	WS_FT_S	92.02	6.44	92.59	5.15	92.90	5.52	0.742	0.620	0.789	0.745	0.563
	WS_FT_M	91.26	7.07	91.76	5.65	92.68	5.48	0.956	0.583	0.477	0.234	0.444
	WS_FT_L	90.67	7.86	90.55	6.41	93.61	5.38	0.733	0.170	**0.033**	0.227	-
	WS_FT	91.30	6.27	91.63	5.33	93.06	5.06	0.974	0.410	0.083	0.212	-
Amplitude scaling	AS_BT_S	2.91	1.23	2.93	1.41	3.09	1.36	0.903	0.920	0.503	0.002	-
	AS_BT_M	4.22	1.55	4.70	1.48	4.65	1.58	0.290	0.352	0.850	<0.001	0.758
	AS_BT_L	4.61	1.61	4.93	1.51	4.93	1.69	0.482	0.507	1.000	<0.001	0.754
	AS_BT	3.91	1.37	4.19	1.37	4.23	1.46	0.499	0.458	0.844	<0.001	0.753
	AS_FT_S	3.50	1.51	3.50	1.31	3.67	1.07	1.000	0.654	0.517	<0.001	0.723
	AS_FT_M	4.43	1.33	4.87	1.44	4.59	1.40	0.219	0.698	0.226	<0.001	-
	AS_FT_L	4.96	1.76	5.50	1.46	5.35	1.65	0.261	0.442	0.460	<0.001	0.861
	AS_FT	4.30	1.45	4.62	1.26	4.54	1.25	0.322	0.338	0.432	<0.001	-
Sway energy, score	TU1	97.74	20.22	105.04	37.21	92.96	29.17	0.413	0.522	0.109	0.498	0.658
	TU2	98.96	33.74	90.87	37.61	83.70	27.67	0.447	0.101	0.354	0.155	0.228
	TU3	100.57	27.94	94.00	40.08	82.52	27.32	0.292	**0.018**	0.248	0.081	-

	TU4	94.74	25.81	94.09	33.84	84.61	31.47	0.684	0.159	0.267	0.114	-
	TU5	92.83	32.46	90.30	31.86	87.13	24.56	0.792	0.506	0.588	0.105	0.534
	Toes Up	96.97	21.98	94.86	29.44	86.18	19.41	0.785	0.085	0.063	0.093	0.460
	TD1	92.87	26.12	90.52	40.98	96.30	39.89	0.818	0.731	0.380	0.067	0.058
	TD2	94.83	30.11	97.09	37.74	87.30	27.53	1.000	0.379	**0.043**	0.874	-
	TD3	83.04	27.22	78.30	23.32	83.57	21.09	0.529	0.942	0.251	0.949	0.540
	TD4	83.22	30.78	76.61	30.39	82.65	31.89	0.379	0.709	0.420	0.889	-
	TD5	81.00	29.57	75.52	26.13	78.57	23.72	0.509	0.759	0.526	0.759	0.125
	Toes Down	86.99	25.22	83.61	25.85	85.68	24.57	0.656	0.859	0.466	0.580	0.209

"FO: foot orthoses; FFO: flat foot FO; PFO: placebo FO; SSFO: site-specific stimulating FO; COP: center of pressure, MLD: mediolateral displacement, APD: anteroposterior displacement, LV: level, UP: upward, DN; downward, EO: eyes open, EC: eyes closed, C-1: eyes open, C-2: eyes closed, C-3: eyes open with surrounding visual sway-referenced, C-4: eyes open with support surface sway-referenced, C-5: eyes closed with support surface sway-referenced, and C-6: eyes open with both surrounding visual and support surface sway-referenced. LAT_BT_M: latency during backward translation with medium speed; LAT_BT_L: latency during backward translation with large speed; LAT_BT: average latency during backward translation; LAT_FT_M: latency during forward translation with medium speed; LAT_FT_L: latency during forward translation with large speed; LAT_FT: average latency during forward translation; WS_BT_S: weight symmetry during backward translation with slow speed; WS_BT_M: weight symmetry during backward translation with medium speed; WS_BT_L: weight symmetry during backward translation with large speed; WS_BT: average weight symmetry during backward translation; WS_FT_S: weight symmetry during forward translation with slow speed; WS_FT_M: weight symmetry during forward translation with medium speed; WS_FT_L: weight symmetry during forward translation with large speed; WS_FT: average weight symmetry during forward translation; AS_BT_S: amplitude scaling during backward translation with slow speed; AS_BT_M: amplitude scaling during backward translation with medium speed; AS_BT_L: amplitude scaling during backward translation with large speed; AS_BT: average amplitude scaling during backward translation; AS_FT_S: amplitude scaling during forward translation with slow speed; AS_FT_M: amplitude scaling during forward translation with medium speed; AS_FT_L: amplitude scaling during forward translation with large speed; AS_FT: average amplitude scaling during forward translation; TU1: toes up trial 1; TU2: toes up trial 2; TU3: toes up trial 3; TU4: toes up trial 4; TU5: toes up trial 5; TD1: toes down trial 1; TD2: toes down trial 2; TD3: toes down trial 3; TD4: toes down trial 4; TD5: toes down trial 5"

7.3.2 Computerized Dynamic Posturography

In SOT, the equilibrium score was higher with the somatosensory foot orthoses compared to the placebo foot orthoses (MD=1.74; p=0.028), especially when participants stood with their eyes open without visual or platform sway referencing (Table 7-2, Figure 7-2). Additionally, the equilibrium score with the flat foot orthoses was higher compared to the placebo foot orthoses (MD=2.75; p=0.010). However, the differences in composite equilibrium scores across the foot orthoses conditions were non-significant.

Weight symmetry during backward translation at medium speed as well as forward translation at large speed increased with somatosensory foot orthoses compared to flat foot orthoses (MD=4.07; p=052) and placebo foot orthoses (MD=2.94; p=0.033), respectively. A trend towards increased weight symmetry was observed with somatosensory foot orthoses compared to both flat foot orthoses and placebo foot orthoses, particularly at medium and large speeds (Figure 7-3).

During backward translation at medium speed, the latency was higher with the somatosensory foot orthoses compared to both the conventional flat foot orthoses (MD=7.5; p=0.033) and the placebo foot orthoses (MD=3.19; p=0.014). Additionally, during forward translation at high speed, the latency was higher with the somatosensory foot orthoses compared to flat foot orthoses (MD=7.13; p=0.035) (Figure 7-4). However, the overall composite latency scores among the different foot orthoses conditions were non-significant. Additionally, there were no significance differences in amplitude scaling across both backward and forward translations at varying speeds (Figure 7-5).

The sway energy was decreased during the toes-up and toes down perturbations with somatosensory foot orthoses compared to flat foot orthoses (MD=-18.05; p=0.018) and placebo foot orthoses (MD=-9.79; p=0.043), respectively. Additionally, there were a trend towards decreased sway energy with somatosensory foot orthoses, particularly during toes up perturbations (Figure 7-6).

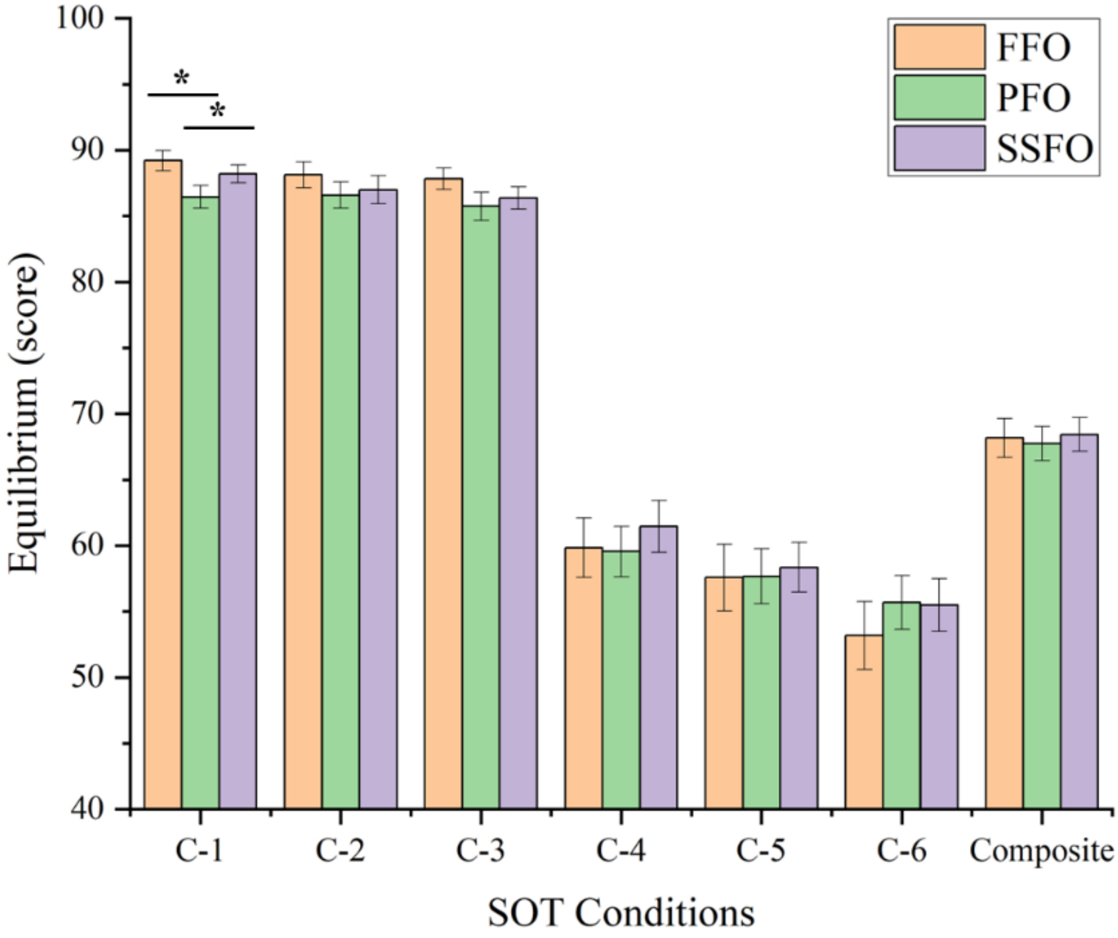


Figure 7-2. Equilibrium scores from the Sensory Organization Test (SOT) comparing flat foot orthoses (FFO), placebo foot orthoses (PFO), and somatosensory foot orthoses (SSFO) across six test conditions: C-1 (standing with eyes open), C-2 (standing with eyes closed), C-3 (eyes open while the visual surround moves in response to body sway), C-4 (eyes open while the support surface moves in response to body sway), C-5 (eyes closed with a sway-referenced support surface), and C-6 (eyes open with both the visual surround and support surface sway-referenced). An asterisk (*) indicates a statistically significant difference at $p < 0.05$.

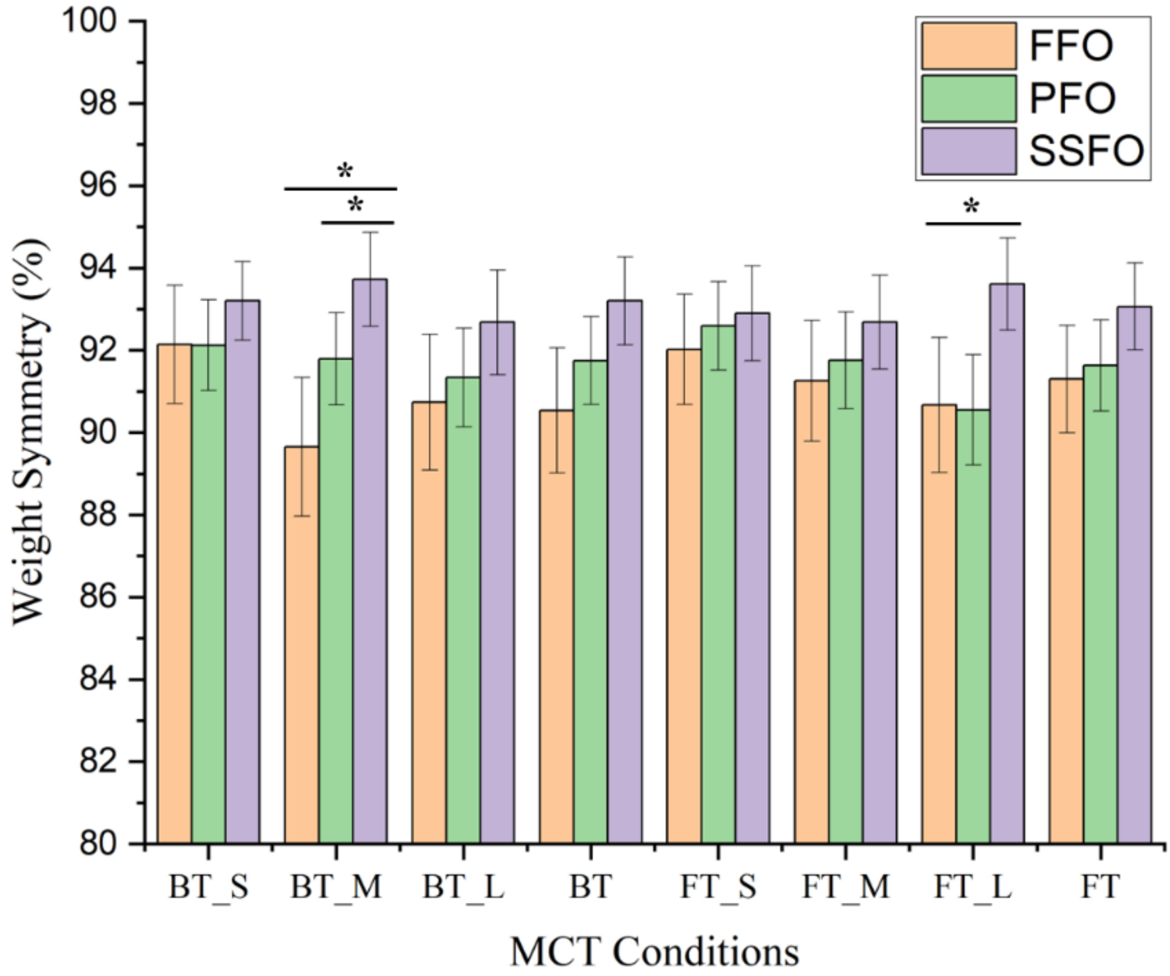


Figure 7-3. Weight symmetry outcomes from the Motor Control Test (MCT), comparing flat foot orthoses (FFO), placebo foot orthoses (PFO), and somatosensory foot orthoses (SSFO) under various translation conditions: WS_BT_S (weight symmetry during backward translation at slow speed), WS_BT_M (medium speed), WS_BT_L (large speed), and WS_BT (average weight symmetry during backward translation); WS_FT_S (weight symmetry during forward translation at slow speed), WS_FT_M (medium speed), WS_FT_L (large speed), and WS_FT (average weight symmetry during forward translation). An asterisk (*) indicates a statistically significant difference at $p < 0.05$.

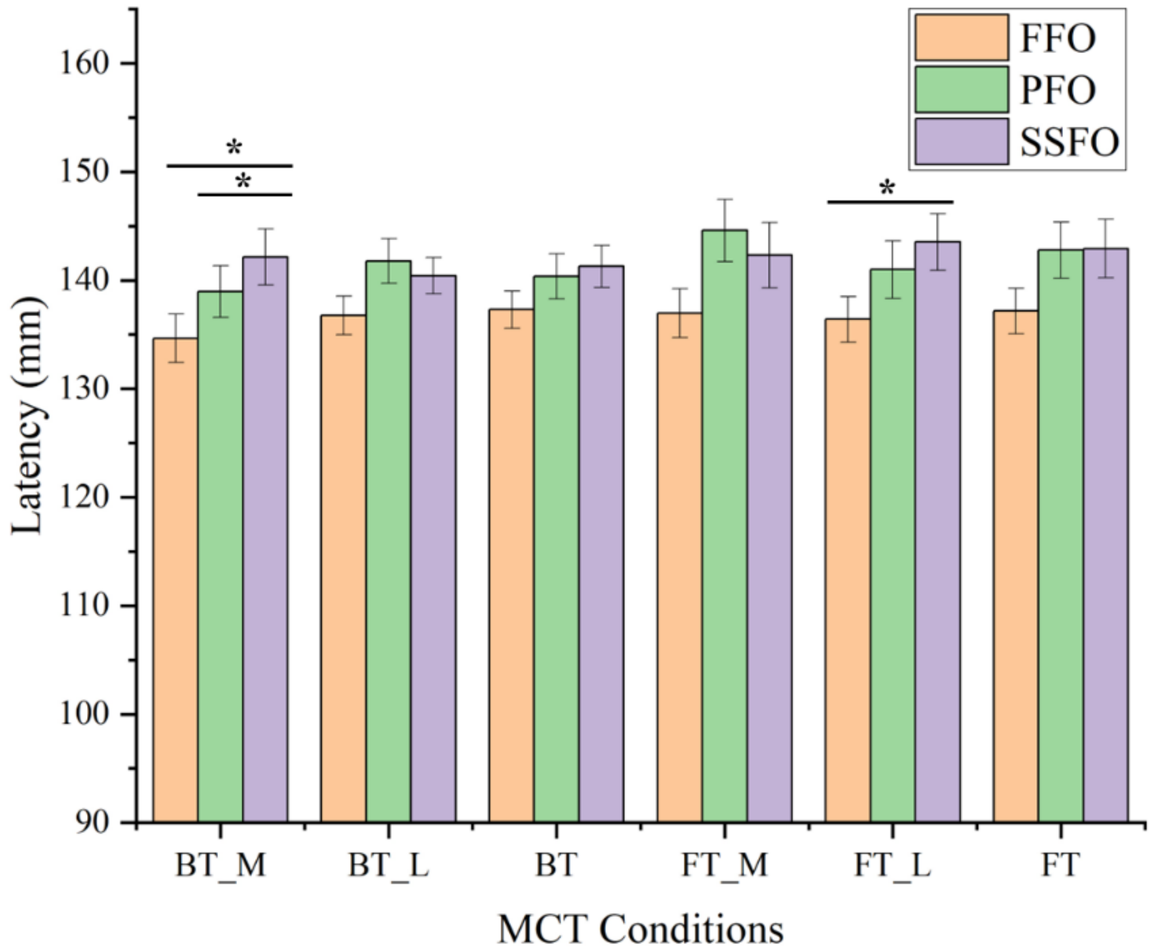


Figure 7-4. Latency measurements from the Motor Control Test (MCT), comparing flat foot orthoses (FFO), placebo foot orthoses (PFO), and somatosensory foot orthoses (SSFO) under different translation conditions: LAT_BT_M (latency during backward translation at medium speed), LAT_BT_L (backward translation at large speed), and LAT_BT (average latency during backward translation); LAT_FT_M (latency during forward translation at medium speed), LAT_FT_L (forward translation at large speed), and LAT_FT (average latency during forward translation). An asterisk (*) indicates a statistically significant difference at $p < 0.05$.

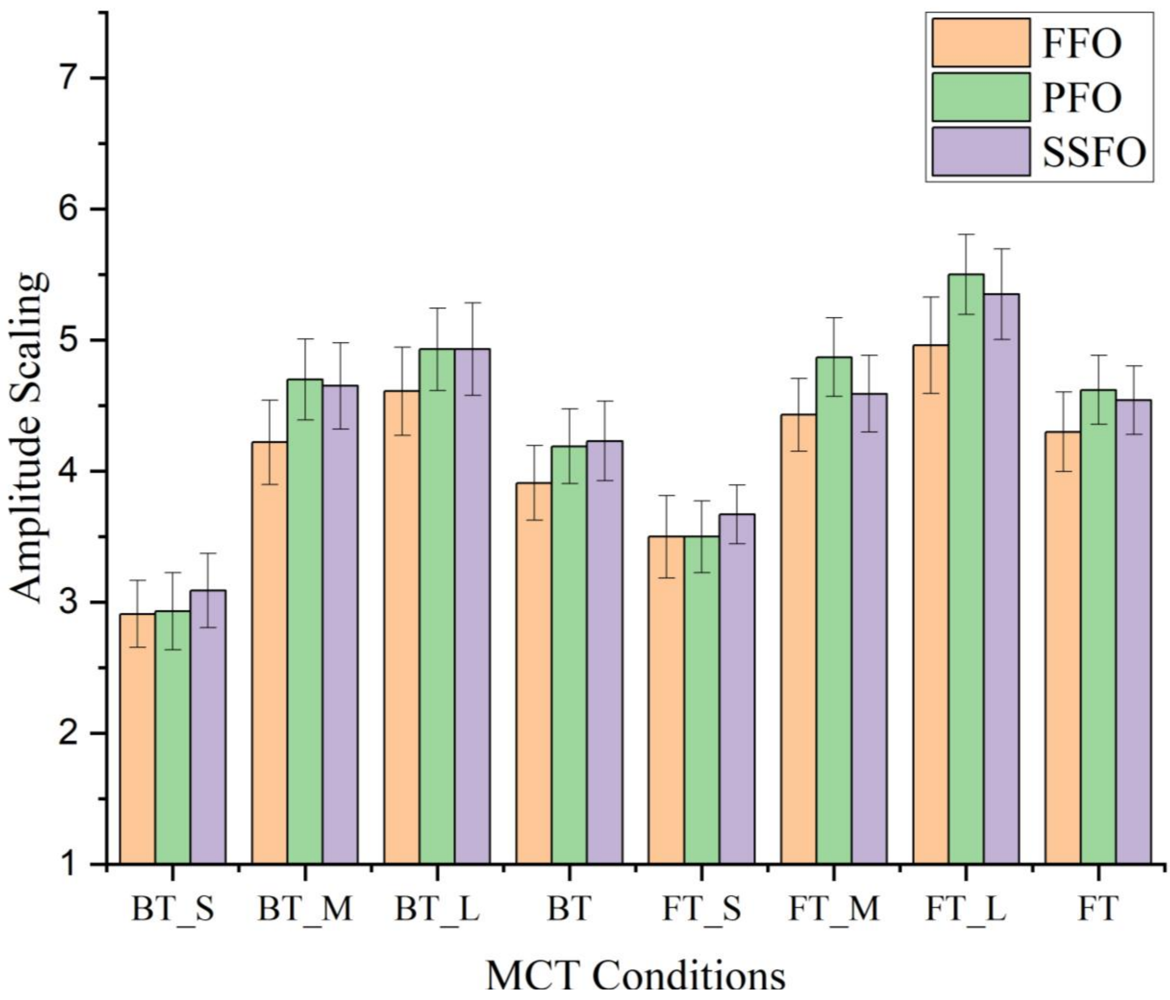


Figure 7-5. Amplitude scaling results from the Motor Control Test (MCT), comparing flat foot orthoses (FFO), placebo foot orthoses (PFO), and somatosensory foot orthoses (SSFO) across various translation conditions: AS_BT_S (amplitude scaling during backward translation at slow speed), AS_BT_M (medium speed), AS_BT_L (large speed), and AS_BT (average amplitude scaling during backward translation); AS_FT_S (amplitude scaling during forward translation at slow speed), AS_FT_M (medium speed), AS_FT_L (large speed), and AS_FT (average amplitude scaling during forward translation). An asterisk (*) indicates a statistically significant difference at $p < 0.05$.

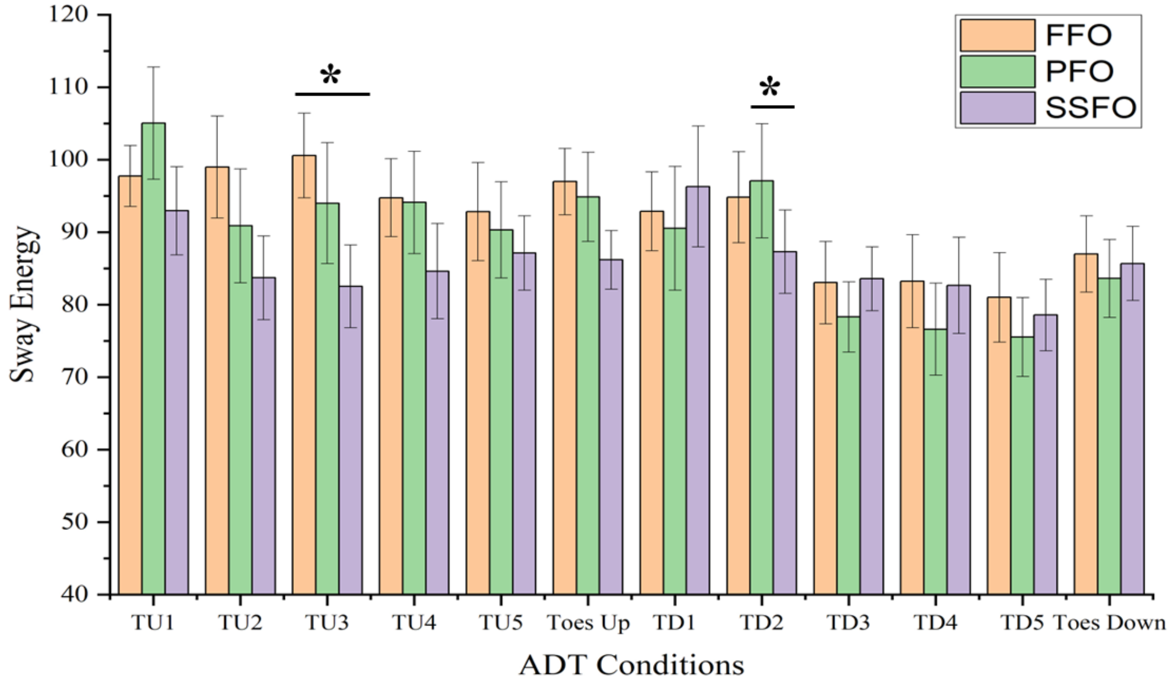


Figure 7-6. Sway energy measurements from the Adaptation Test (ADT), comparing flat foot orthoses (FFO), placebo foot orthoses (PFO), and somatosensory foot orthoses (SSFO) across multiple toes up and toes down conditions: TU1–TU5 (toes-up trials 1 to 5) and TD1–TD5 (toes-down trials 1 to 5). An asterisk (*) indicates a statistically significant difference at $p < 0.05$.

7.4 Discussion

The findings of this study underscore the potential benefits of novel site-specific somatosensory foot orthoses in enhancing postural balance and stability among older adults. The results from the CDP assessments indicate that the site-specific somatosensory foot orthoses, with adjusted knob heights, significantly enhances equilibrium, weight symmetry, and sway energy compared to the placebo foot orthoses, which lacks stimulating knobs. Previous studies that utilized prefabricated somatosensory foot orthoses featuring stimulating protrusions across the entire surface as well as site-specific somatosensory foot orthoses with taller height knobs reported supporting evidence to these results (see Chapter 3 and 5) [15]. The improvement can be attributed to the design of site-specific somatosensory foot orthoses, which incorporates strategically placed stimulating knobs tailored to the tactile sensitivity and pressure distribution of specific foot regions (see Chapter 4 and 5).

As the function of mechanoreceptors declines with age, indentation force with stimulating knobs may offer necessary touch, pressure or skin stretch to produce effective afferent feedback [8, 20]. In the case of placebo foot orthoses, the extended contact surfaces alone between the foot orthoses and the foot may not provide necessary force for effective mechanoreceptor stimulation. In contrast, the strategically placed stimulating knobs in the somatosensory foot orthoses are likely to offer necessary indentation forces via skin stretch or pressure, especially in regions with higher tactile sensitivity, which play a crucial role in afferent firing through mechanoreceptors stimulation, particularly in older adults [21]. By enhancing sensory feedback through these receptors, the site-specific somatosensory foot orthoses may improve the central nervous system's ability to integrate sensory information, thereby enhancing balance [22]. The observed improvements in weight symmetry and sway energy with somatosensory foot orthoses compared to flat foot orthoses in control group further provide robust evidence and support the effectiveness of this approach.

Prior studies have demonstrated that artificially enhanced cutaneous sensory input can lead to improved weight symmetry [23]. The somatosensory foot orthosis's ability to improve weight distribution may be attributed to the muscular coordination and symmetrical function between two leg sides. The strategically positioned protruding knobs might help activate Meissner's corpuscles and Merkel's discs, which are sensitive to light touch and pressure, as well as Ruffini endings and Pacinian corpuscles, which respond to skin stretch and deep pressure [24-26]. This can provide critical feedback about foot position and movement, enabling more precise motor control and symmetrical weight distribution. This enhanced proprioceptive feedback possibly facilitates better coordination and enhance postural stability.

The observed increase in equilibrium indicates enhanced balance, demonstrated more effective motor strategies and postural responses to perturbations by reduced anteroposterior CoG sway [27]. An equilibrium scores close to 100 indicates optimal stability, primarily achieved through the ankle strategy, while a score near 0 indicates a loss of balance that typically requires reliance on the hip strategy [27]. The novel somatosensory foot orthoses appear to further improve equilibrium and weight symmetry by enhancing the body's ability to process and coordinate signals from the somatosensory, visual, and vestibular systems. This enhanced sensory coordination, supported by tactile stimulation, may accelerate information transmission to the cognitive system and enable the musculoskeletal system to employ the ankle strategy more efficiently, ultimately contributing to better balance control [5].

The enhanced equilibrium observed in the eyes-open condition suggests that the integration of multiple sensory modalities may be more effective than relying solely on proprioceptive inputs. These findings align with the study described in Chapter 5. However, several previous studies have documented reductions in postural sway under eyes-closed conditions [28, 29]. It is worth mentioning that these studies utilized somatosensory foot orthoses featuring flat structure and small, uniformly protruding knobs. Such discrepancies in findings may be attributed to differences in orthosis design elements and placement of protruding knobs, as well as the interaction between the foot and the foot orthosis interface. Variations in these factors can affect mechanoreceptor stimulation and reflex mechanisms, thereby contributing to the differences in outcomes observed across studies [30, 31]. Another possible explanation is the interplay between visual and tactile inputs. Research has shown that tactile responses are quicker when visual input is present [32, 33]. Visual cues may offer an additional spatial reference for the body. This may enhance integration of tactile input with proprioceptive feedback and make tactile stimulation more effective in modulating balance. Further research is needed to explore these interactions and underlying mechanisms.

The increased latency observed with the somatosensory foot orthoses suggests a trade-off between stability and reaction time. Previous research reported supporting evidence on improved weight symmetry while increased latency with the somatosensory stimulation [23]. This trade-off might be beneficial in preventing falls, as stability through symmetrical weight distribution is often prioritized over speed in older adults [34, 35]. The increased latency could also be a result of the central nervous system taking additional time to process the enhanced sensory input provided by the somatosensory foot orthoses. Thus, the cognitive demands associated with deliberate muscular coordination and controlled movements for improved symmetrical weight distribution can slow response time [36]. Although the somatosensory foot orthoses might slow reaction time, possibly due to increased cognitive processing or adaptation to the novel orthoses, it concurrently enhances stability. This is further demonstrated by improved weight symmetry and decreased sway energy.

The reduction in sway energy of reaction forces with the somatosensory foot orthoses during perturbations underscore its stabilizing effect. The decreased sway energy suggests that the somatosensory foot orthoses help in minimizing unnecessary shifts in sway, possibly through enhanced sensory feedback, symmetrical weight distribution, and improved motor control. This result aligns with the role of mechanoreceptors in providing sensory feedback and influence motor and neuromuscular functions for maintaining postural control [37-39]. By maximizing somatosensory input, the site-specific somatosensory foot orthoses may facilitate more efficient postural adjustments, improve equilibrium and weight symmetry and reduce the energy required to maintain balance.

This study has several limitations that should be acknowledged. The strategic positioning of stimulating protrusions was concentrated solely on regions with higher tactile sensitivity. Exploring varying combination of distribution patterns could provide deeper insights into the potential for mechanoreceptor stimulation. Additionally, the design of the site-specific somatosensory foot orthoses was restricted to specific shapes, heights, and distributions of protrusions. Future research could benefit from experimenting with a combination of varying heights, shapes, densities, and materials to uncover a more comprehensive understanding of the stimulation mechanisms and potential benefits of somatosensory foot orthoses. Moreover, this study focused exclusively on healthy older adults. It would be advantageous to employ somatosensory foot orthoses on diverse populations, including individuals with specific balance deficits, to fully grasp its potential applications. Additionally, the study did not consider long-term adaptation to the somatosensory foot orthoses prior to the trials, which could have influenced the results. This study assessed the immediate effects of somatosensory foot orthoses. Future studies should consider the impact of prolonged use as well as allow adequate time for adaptation to these orthoses to better understand their long-term benefits.

7.5 Conclusion

This study was aimed to examine the effects of site-specific somatosensory foot orthoses with adjusted knob heights on postural control in older adults using computerized dynamic posturography assessments. The results indicate that somatosensory foot orthoses significantly improved equilibrium scores and weight symmetry, while also reducing sway energy, although it increased latency during certain conditions. These results suggest that strategic positioning of stimulating protrusions with adjusted heights can enhance mechanoreceptor stimulation and sensory feedback, offering a potential approach to improve balance in older adults. Future research should explore the prolonged effects of somatosensory foot orthoses, investigate underlying neural mechanisms in response to varying design modifications, and assess its impact on diverse populations to fully understand its potential applications.

References

[1] A. Shumway-Cook, M.H. Woollacott, Motor control: translating research into clinical practice, Lippincott Williams & Wilkins2007.

[2] B.L. Day, S.R. Lord, Balance, gait, and falls, Elsevier2018.

[3] R. Roll, A. Kavounoudias, J.P. Roll, Cutaneous afferents from human plantar sole contribute to body posture awareness, Neuroreport 13(15) (2002) 1957-61. https://doi.org/10.1097/00001756-200210280-00025

[4] M. Alfuth, D. and Rosenbaum, Effects of changes in plantar sensory feedback on human gait characteristics: a systematic review, Footwear Science 4(1) (2012) 1-22. https://doi.org/10.1080/19424280.2011.653990.

[5] V.E. Abraira, D.D. Ginty, The sensory neurons of touch, Neuron 79(4) (2013) 618-39. https://doi.org/10.1016/j.neuron.2013.07.051

[6] M. Patel, P.A. Fransson, R. Johansson, M. Magnusson, Foam posturography: standing on foam is not equivalent to standing with decreased rapidly adapting mechanoreceptive sensation, Exp Brain Res 208(4) (2011) 519-27. https://doi.org/10.1007/s00221-010-2498-6

[7] N.D.J. Strzalkowski, R.A. Ali, L.R. Bent, The firing characteristics of foot sole cutaneous mechanoreceptor afferents in response to vibration stimuli, J Neurophysiol 118(4) (2017) 1931-1942. https://doi.org/10.1152/jn.00647.2016

[8] D.R. Kenshalo, Sr., Somesthetic sensitivity in young and elderly humans, J Gerontol 41(6) (1986) 732-42. https://doi.org/10.1093/geronj/41.6.732

[9] A. Gefen, Why is the heel particularly vulnerable to pressure ulcers?, Br J Nurs 26(Sup20) (2017) S62-s74. https://doi.org/10.12968/bjon.2017.26.Sup20.S62

[10] H.B. Menz, G.V. Zammit, S.E. Munteanu, Plantar pressures are higher under callused regions of the foot in older people, Clin Exp Dermatol 32(4) (2007) 375-80. https://doi.org/10.1111/j.1365-2230.2007.02421.x

[11] V.V. Broderick, L.J. Cowan, Pressure injury related to friction and shearing forces in older adults, Journal of Dermatology and Skin Science 3(2) (2021). https://doi.org/10.29245/2767-5092/2021/2.1136.

[12] A. Nor Azhar, S.M. Bergin, S.E. Munteanu, H.B. Menz, Footwear, Orthoses, and Insoles and Their Effects on Balance in Older Adults: A Scoping Review, Gerontology 70(8) (2024) 801-811. https://doi.org/10.1159/000539591

[13] C.Z. Ma, W.K. Lam, B.C. Chang, W.C. Lee, Can Insoles Be Used to Improve Static and Dynamic Balance of Community-Dwelling Older Adults? A Systematic Review on Recent Advances and Future Perspectives, J Aging Phys Act 28(6) (2020) 971-986. https://doi.org/10.1123/japa.2019-0293

[14] J.H. Park, H.S. Jeon, J.H. Kim, H.B. Yoon, O.B. Lim, M. Jeon, Immediate effect of insoles on balance in older adults, Foot (Edinb) 47 (2021) 101768. https://doi.org/10.1016/j.foot.2020.101768

[15] A. Jor, C.H. Lai, M.J. Khan, Y. He, W.K. Lam, S.J. Winser, et al., Effects of somatosensory-stimulating foot orthoses on postural balance in older adults: A computerized dynamic posturography analysis, Gait Posture 119 (2025) 189-196. https://doi.org/10.1016/j.gaitpost.2025.03.016

[16] E.M. Hennig, T. Sterzing, Sensitivity mapping of the human foot: thresholds at 30 skin locations, Foot Ankle Int 30(10) (2009) 986-91. https://doi.org/10.3113/fai.2009.0986

[17] N.D. Eriksen, D.D. Hougaard, Age- and gender-specific normative data on computerized dynamic posturography in a cohort of Danish adults, Eur Arch Otorhinolaryngol 280(5) (2023) 2191-2200. https://doi.org/10.1007/s00405-022-07706-y

[18] P.R. Trueblood, M. Rivera, C. Lopez, C. Bentley, N. Wubenhorst, Age-based normative data for a computerized dynamic posturography system that uses a virtual visual surround

environment, Acta Otolaryngol 138(7) (2018) 597-602.
https://doi.org/10.1080/00016489.2018.1429653.

[19] A.A. Alharbi, E.G. Johnson, A.A. Albalwi, N.S. Daher, T.K. Cordett, O.I. Ambode, et al., Effect of visual input on postural stability in young adults with chronic motion sensitivity: A controlled cross-sectional study, J Vestib Res 27(4) (2017) 225-231.
https://doi.org/10.3233/ves-170534.

[20] W.D. Willis, 6.06 - Physiological Characteristics of Second-Order Somatosensory Circuits in Spinal Cord and Brainstem, in: R.H. Masland, T.D. Albright, T.D. Albright, R.H. Masland, P. Dallos, D. Oertel, et al. (Eds.), The Senses: A Comprehensive Reference, Academic Press, New York, 2008, pp. 87-116.

[21] S. Gravano, Y.P. Ivanenko, G. Maccioni, V. Macellari, R.E. Poppele, F. Lacquaniti, A novel approach to mechanical foot stimulation during human locomotion under body weight support, Human Movement Science 30(2) (2011) 352-367.
https://doi.org/10.1016/j.humov.2010.01.002

[22] B.L. Riemann, S.M. Lephart, The sensorimotor system, part I: the physiologic basis of functional joint stability, J Athl Train 37(1) (2002) 71-9.

[23] A.S. Aruin, N. Kanekar, Effect of a textured insole on balance and gait symmetry, Exp Brain Res 231(2) (2013) 201-8. https://doi.org/10.1007/s00221-013-3685-z

[24] D. Purves, G.J. Augustine, D. Fitzpatrick, W.C. Hall, A. LaMantia, R.D. Mooney, et al., Neuroscience, 6th ed., Sinauer Associates Inc2017.

[25] F. Iheanacho, A.R. Vellipuram, Physiology, mechanoreceptors, StatPearls, StatPearls Publishing, Copyright © 2024, StatPearls Publishing LLC., Treasure Island (FL), 2024.

[26] J. Turecek, D.D. Ginty, Coding of self and environment by Pacinian neurons in freely moving animals, bioRxiv (2023). https://doi.org/10.1101/2023.09.11.557225

[27] N. Vanicek, S.A. King, R. Gohil, I.C. Chetter, P.A. Coughlin, Computerized dynamic posturography for postural control assessment in patients with intermittent claudication, J Vis Exp (82) (2013) e51077. https://doi.org/10.3791/51077.

[28] A.L. Hatton, J. Dixon, K. Rome, J.L. Newton, D.J. Martin, Altering gait by way of stimulation of the plantar surface of the foot: the immediate effect of wearing textured insoles in older fallers, J Foot Ankle Res 5 (2012) 11. https://doi.org/10.1186/1757-1146-5-11

[29] F. Qiu, M.H. Cole, K.W. Davids, E.M. Hennig, P.A. Silburn, H. Netscher, et al., Enhanced somatosensory information decreases postural sway in older people, Gait Posture 35(4) (2012) 630-5. https://doi.org/10.1016/j.gaitpost.2011.12.013

[30] R.J. Peterka, Sensorimotor integration in human postural control, J Neurophysiol 88(3) (2002) 1097-118. https://doi.org/10.1152/jn.2002.88.3.1097.

[31] A.L. Hatton, J. Dixon, K. Rome, D. Martin, Standing on textured surfaces: effects on standing balance in healthy older adults, Age Ageing 40(3) (2011) 363-8. https://doi.org/10.1093/ageing/afr026.

[32] L. Tamè, E. Azañón, M.R. Longo, A Conceptual Model of Tactile Processing across Body Features of Size, Shape, Side, and Spatial Location, Front Psychol 10 (2019) 291. https://doi.org/10.3389/fpsyg.2019.00291.

[33] S. Reschechtko, J.A. Pruszynski, Voluntary modification of rapid tactile-motor responses during reaching differs from its visuomotor counterpart, J Neurophysiol 124(1) (2020) 284-294. https://doi.org/10.1152/jn.00232.2020.

[34] H. Reimann, R. Ramadan, T. Fettrow, J.F. Hafer, H. Geyer, J.J. Jeka, Interactions Between Different Age-Related Factors Affecting Balance Control in Walking, Front Sports Act Living 2 (2020) 94. https://doi.org/10.3389/fspor.2020.00094

[35] G. Yogev-Seligmann, Y. Rotem-Galili, A. Mirelman, R. Dickstein, N. Giladi, J.M. Hausdorff, How does explicit prioritization alter walking during dual-task performance?

Effects of age and sex on gait speed and variability, Phys Ther 90(2) (2010) 177-86. https://doi.org/10.2522/ptj.20090043

[36] M. Rubega, E. Formaggio, R. Di Marco, M. Bertuccelli, S. Tortora, E. Menegatti, et al., Cortical correlates in upright dynamic and static balance in the elderly, Sci Rep 11(1) (2021) 14132. https://doi.org/10.1038/s41598-021-93556-3

[37] M. Patel, M. Magnusson, E. Kristinsdottir, P.A. Fransson, The contribution of mechanoreceptive sensation on stability and adaptation in the young and elderly, Eur J Appl Physiol 105(2) (2009) 167-73. https://doi.org/10.1007/s00421-008-0886-4

[38] B.L. Riemann, S.M. Lephart, The Sensorimotor System, Part II: The Role of Proprioception in Motor Control and Functional Joint Stability, J Athl Train 37(1) (2002) 80-4.

[39] A. Ferlinc, E. Fabiani, T. Velnar, L. Gradisnik, The Importance and Role of Proprioception in the Elderly: a Short Review, Mater Sociomed 31(3) (2019) 219-221. https://doi.org/10.5455/msm.2019.31.219-221

CHAPTER 8
CONCLUSIONS AND FUTURE RESEARCH DIRECTIONS

8.1 Conclusions

This research was designed to address critical gaps in our understanding of how somatosensory foot orthoses can be optimized to improve postural balance and stability in older adults, particularly through the modification of protrusion design features. Prior to this study, the field was characterized by scattered and inconsistent findings regarding the efficacy of somatosensory foot orthoses and limited insight into the mechanisms by which specific design elements such as the structure, shape, height, hardness, and distribution of stimulating protrusions, affect postural control. The overarching purpose of this research was to systematically review existing evidence, experimentally evaluate the effects of various somatosensory foot orthoses designs, and elucidate the underlying sensory mechanisms, with the ultimate goal of facilitating the development of more effective orthotic interventions for mobility enhancement in the aging population. The research questions guiding this work focused on the overall effects of somatosensory foot orthoses on static and dynamic balance, the mapping of tactile sensitivity across the foot, the influence of design features, the dose-response relationship of protrusion height across the potential foot sites, and the comparative effectiveness of novel site-specific somatosensory foot orthoses.

The first objective sought to synthesize and critically appraise the existing literature on the impact of somatosensory foot orthoses on postural balance and stability in older adults, with a particular emphasis on the role of protrusion design features. The systematic review and meta-regression analysis revealed that somatosensory foot orthoses use was generally associated with reduced center of pressure (CoP) displacements during standing, especially in studies that evaluated immediate effects and utilized foot orthoses with specific design features such as arch-support structures and site-specific protrusions. Notably, the presence of arch-support, rounded knobs, and targeted protrusions correlated positively with improvements in postural sway. While somatosensory foot orthoses significantly improved Timed Up and Go scores, indicating enhanced functional mobility, the effects on broader gait and mobility measures were less consistent. These findings underscore the importance of design specificity in maximizing the benefits of somatosensory foot orthoses and highlight the need for orthotic interventions tailored to individual foot morphology as well as tactile sensitivity characteristics.

Guided by the synthesized evidence, the second objective experimentally assessed whether prefabricated somatosensory foot orthoses featured with protruding knobs distributed across the entire surface and integrated arch-support could enhance postural balance in the elderly. The results demonstrated that such orthoses led to significant reductions in CoP displacements at certain phases of stance during walking across downward terrain. Improvements were also observed in composite equilibrium scores and weight symmetry, as measured by computerized dynamic posturography, particularly in response to both static and dynamic perturbations. The redistribution of plantar forces and pressures, especially at the inner forefoot and toes, further supported the hypothesis that stimulating knobs and arch-support can effectively engage plantar mechanoreceptors to improve balance. However, the magnitude of improvement was variable across outcome measures, and significant effects were observed in only a subset of variables. These findings contribute to the growing body of literature supporting the role of tactile stimulation in enhancing postural control, while also emphasizing the need for further optimization of design parameters and validation through larger, randomized controlled trials.

The third objective addressed a fundamental gap in the field by mapping tactile sensitivity thresholds across 30 distinct glabrous skin locations on the foot in older adults. The study found substantial regional variation in tactile sensitivity, with the heel, lateral midfoot, and metatarsal heads exhibiting the highest sensitivity thresholds, and the medial and intermedius midfoot and bases of the metatarsals at the medial and lateral extension showing lower thresholds.

Interestingly, males exhibited higher tactile sensitivity thresholds at several locations compared to females, but no significant differences were observed based on age or BMI within the older adult population. These findings provide a critical foundation for the site-specific targeting of orthotic interventions, suggesting that regions with lower tactile thresholds may be more responsive to somatosensory stimulation. By identifying clusters of skin regions with similar sensitivity profiles, this research offers a critical framework for the design of somatosensory foot orthoses that can optimize sensory input and potentially improve postural balance in the elderly. Future studies should further investigate the relationship among tactile sensitivity, skin properties, and orthotic efficacy in larger and more diverse populations.

The fourth objective explored the dose-response effects of site-specific somatosensory foot orthoses with varying protruding knob heights on postural balance and stability. The findings indicated that taller protrusions were most effective in reducing CoP displacements, particularly during standing with eyes open, suggesting enhanced postural control. However, these same protrusions increased CoP maximum velocity during walking on slopes, highlighting a potential drawback between stability and dynamic adaptability. While equilibrium scores improved with taller protrusions, subjective satisfaction did not differ significantly across conditions, indicating that increased sensory input may come at the cost of comfort or perceived usability. This critical interplay between knob height, site-specific stimulation, and user comfort underscores the necessity of individualized orthotic design with adjusted knob heights at the potential foot skin locations. The results support the hypothesis that optimal protrusion height and location can maximize sensory feedback while minimizing discomfort, but also point to the need for further research to refine these parameters and assess long-term outcomes.

The final objective evaluated the effectiveness of a novel site-specific somatosensory foot orthoses with adjusted knob heights through both a randomized crossover study and a randomized controlled trial. The results demonstrated that the novel somatosensory foot orthoses significantly reduced anteroposterior CoP displacements during standing and mediolateral stability at heel strike during walking on upward terrain. Postural equilibrium as well as weight symmetry in response to perturbations were also improved compared to both placebo and conventional flat foot orthoses. The somatosensory foot orthoses also led to significant plantar pressure redistribution with reductions in maximum plantar forces at key foot regions during walking on varied terrains. Subjective feedback indicated higher effectiveness to balance control and safety with the novel somatosensory foot orthoses, while an increasing trend of comfort was also observed. However, the somatosensory foot orthoses increased latency during certain dynamic posturography tasks, suggesting a potential trade-off between enhanced stability and reaction time. These findings provide robust evidence that strategically positioned protrusions with adjusted heights can effectively stimulate plantar mechanoreceptors and improve balance in older adults. The implications are significant for the design and clinical application of orthotic devices, offering a promising avenue for mobility enhancement and fall prevention in the aging population. Nevertheless, the study also highlights the need for further research to explore the long-term effects, underlying neural mechanisms, and broader applicability of somatosensory foot orthoses across diverse populations and real-world settings.

In summary, this research has made substantial contributions to the field by systematically addressing key gaps, elucidating the mechanisms by which somatosensory foot orthoses design features influence postural balance, and providing evidence-based support for the development of personalized, site-specific orthotic interventions. The findings demonstrate that somatosensory foot orthoses with strategic protrusion design can potentially enhance postural control and stability in older adults. By integrating objective biomechanical measures with subjective user feedback, this work offers a comprehensive framework for future research and clinical practice. Ultimately, this research highlights the potential of somatosensory foot orthoses as a non-invasive, user-centered strategy for improving balance in the elderly, with significant implications for public health and quality of life in aging societies.

8.2 Limitations and Future Recommendations

This study presents several limitations that should be addressed in future research to enhance the understanding and application of site-specific somatosensory stimulation foot orthoses in improving balance and stability among older adults.

This study concentrated on specific foot skin locations identified by higher tactile sensitivity and lower plantar pressure. However, alternative arrangements of site-specific stimulation may enhance outcomes. Future research should investigate different arrangements of protrusion positioning to identify the optimal design for site-specific stimulation foot orthoses.

The development of the novel foot orthoses was based solely on variations in tactile sensitivity across different foot skin locations. It is important to consider that variations in tactile sensitivity at specific location among older adults could impact the results. Future studies should explore the effects of somatosensory stimulation across different levels of tactile sensitivity within participant groups.

This study utilized stimulation protrusions that were limited to one specific shape and level of hardness. Investigating strategic placement with varying hardness, shapes, and densities of protrusions could provide deeper insights into mechanoreceptor stimulation and balance improvement. Additionally, participants used the same shoes for both conventional and novel foot orthoses. The novel orthoses, with their contoured bottom and site-specific stimulation, may require improvement in shoe fitting.

The effects on balance and stability were assessed only in the laboratory setup with a fixed walking speed, while postural control mechanisms could be different across surface walkway or real-life situations. Future research should consider investigating effects on dynamic stability during overground walking conditions.

While this study primarily focused on balance metrics, somatosensory stimulation is also linked to the motor system and may affect the musculoskeletal system. Future research should examine the electromyographic (EMG) activity of lower extremity muscles to understand changes in muscle activity related to cognitive processing and motor activity with mechanoreceptor stimulation. Furthermore, assessing cognitive load through electroencephalography (EEG) could provide robust insights into the impact of foot orthoses stimulation on somatosensory feedback.

The present study has explored somatosensory stimulation foot orthoses effects on healthy older adults, excluding individuals with neuromuscular and neurological disorders such as Parkinson's disease, stroke, spinal cord injury, traumatic brain injury, diabetic neuropathy, or peripheral neuropathy. Future research should include older adults with varying health statuses, activity levels, and neurological or peripheral neuropathic conditions, particularly those at higher risk of falls. This would enhance the generalizability of site-specific somatosensory stimulation applications. Additionally, individuals with neuromuscular impairments may exhibit different tactile sensitivities, necessitating tailored somatosensory stimulation dosages and placements. Furthermore, the absence of a younger adult comparison group restricts our ability to determine whether age-related factors influence the efficacy of this novel foot orthoses. Including both younger and older adults in future studies would allow for direct comparisons and a deeper understanding of age-specific responses to the intervention, thereby enhancing the relevance and robustness of the findings.

This study has focused only on the immediate effects of somatosensory stimulation foot orthoses. Future research should examine the long-term effects and necessary adaptation periods to provide sustainable solutions for balance and stability issues. It may also be beneficial to consider adequate adaptation with placebo foot orthoses before employing somatosensory stimulation to achieve more robust outcomes.

Comparative analyses with other balance improvement modalities or interventions, as well as cost-effectiveness analyses of the orthoses compared to other available interventions, should be conducted in future studies.

Finally, the sample size was smaller. To enhance the generalizability and robustness of the findings, future research should involve longer-term investigations with larger sample sizes and employ randomized controlled trial strategies.

APPENDICES

APPENDIX A: Human Subjects Ethics Approval

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

To	Kobayashi Toshiki (Department of Biomedical Engineering)
From	Pang Marco Yiu Chung, Chair, PolyU Institutional Review Board
Email	marco.pang@ Date 22-Jan-2024

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 01-Sep-2022 to 31-Aug-2025:

Project Title:	A Novel Site-specific Somatosensory Stimulating Foot Orthosis to Improve Balance and Stability for Older Adults
Department:	Department of Biomedical Engineering
Principal Investigator:	Kobayashi Toshiki
Project Start Date:	01-Sep-2022
Project type:	Human subjects (clinical)
Review type:	Expedited Review
Reference Number:	HSEARS20231115003

You will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In case the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the PolyU Institutional Review Board in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

Pang Marco Yiu Chung

Chair

PolyU Institutional Review Board

Page 1 of 1

APPENDIX B: INFORMATION SHEET

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

INFORMATION SHEET

A Novel Site-specific Somatosensory Stimulating Foot Orthosis to Improve Balance and Stability for Older Adults

You are invited to participate in the above project conducted by Mr. Abu JOR (a postgraduate research student of the Department of Biomedical Engineering at The Hong Kong Polytechnic University (PolyU)), under the supervision of Dr. Toshiki KOBAYASHI.

Thank you for your interest in this project. This document introduces the details of this project and important things to be considered before participation. Please spend 5 minutes reading all the information.

Background and Purpose of the Project

Aging is one of the most critical risk factors of foot deformities and a major contributor to impaired balance, falls, and associated injuries. Impaired balance and subsequent falls have a serious impact on independence and quality of life and have become a major public health problem globally. Foot orthoses (FO) can be an effective intervention to promote gait performance in older adults. FO with tactile stimuli over the plantar soles can also improve postural response and balance in older adults with fall risk. However, the optimal design of applying tactile stimulation to mechanoreceptors via foot orthoses is still largely unknown. Therefore, this study aims to:

1. To design a novel site-specific somatosensory stimulating foot orthosis that improves balance and stability for older adults, in particular:
    - ➢ To identify the specific foot sites for tactile stimulation by exploring the tactile sensitivity over a glabrous area of the foot.
    - ➢ To design the shape and pattern of the knobs that produce an appropriate level of somatosensory stimulation.
    - ➢ To fabricate the foot orthosis using 3D printing.
2. To evaluate the effects of the novel foot orthosis on balance and stability.

Why are you invited?

The selection criteria are individuals who: (1) are able to walk without any external support for at least one hour and are free from pes-cavus, pes-planus, or foot pain, and (2) aged between 65

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk

and 80 years. Individuals with overweight (BMI > 40), major foot defects, peripheral neuropathy, and severe neuromuscular, and vestibular disorders will be excluded from the study.

How will you be involved?

This study consists of the following parts: (1) demographic data, (2) 36-item Short Form Health Activity Monitoring, (3) 3D scanning of the foot, (3) investigation of spatiotemporal and kinetic gait parameters using the Zebris Treadmill system, (4) investigation of lower extremity kinematics using VICON 3D motion analysis system, (5) Investigation of balance and stability using Bartec Balance Advantage System, (6) functional balance outcomes, and (7) survey questionnaire on subjective feedback

SN	Experimental parts	Day	Time
1	Demographic data	1	10 min
2	36-Item Short Form Health Activity Monitoring (SF-36)	1	20 min
3	3D scanning of the foot	1	30 min
4	Investigation of spatiotemporal and kinetic gait parameters using the Zebris Treadmill system	2	60 min
5	Investigation of lower extremity kinematics using VICON 3D motion analysis system	2	60 min
6	Survey questionnaire on subjective feedback	2	30 min
7	Investigation of balance and stability using the Bartec Balance Advantage System	3	60 min
8	Functional balance outcomes	3	90 min

On the first day, you will have to provide your demographic data and complete one questionnaire at PolyU. The questionnaire SF-36 evaluates the overall health status. After the collection of your personal data, a 3D scanning of your feet will be conducted. Completing tasks on day one will take you about 60 minutes or 1 hour.

On the second day, an investigation of kinetics, kinematics, and spatiotemporal parameters will be conducted inside the BME gait laboratory, PolyU. There you will be asked to wear skintight trousers before the experiment. You will be asked to wear the shoes provided by us. After that, we will place 16 reflective markers on the positions of your ankle, knee, and hip. At the beginning of the walking on the treadmill, we will provide a safety belt. After a 5-minute practice trial, we will start recording data for kinetics, kinematics, and spatiotemporal parameters. During the experiment, you may need to take off and put on your shoes three to four times. The total experimental process may take around 90 minutes including rest periods. On this day, you will also be requested to respond to a questionnaire related to satisfaction. In total, the complete tasks on day two will take you about 150 minutes or 2.5 hours.

On the third day, we will shift the experiment to another lab on the down floor. With similar costumes and safety belts, we will conduct a few more tests related to balance and stability. The maximum time duration for this experiment will be around 90 minutes including the rest periods. On this day, a few investigations on functional outcome measures will also be carried out inside the BME gait laboratory, PolyU. Here, you will be asked to do a few simple functional activities. The whole task on day three will take you about 150 minutes or 2.5 hours. Finally, the study ends when you finish all the tasks mentioned above.

Discomforts & inconveniences are expected.

The test should not result in any undue discomfort. If you feel unwell, please let the investigator know as soon as possible.

Possible benefits during your involvement

You will receive the STL file of your own feet, one report on your plantar pressure distribution, one report on GRFs, one report on your spatiotemporal gait parameters, one report on lower extremity kinematics, one report on your current balance and stability level, and one report on your current functional outcomes when you finish the entire study, allowing you to understand and review your existing balance and stability. Moreover, the data collected from your involvement will be valuable for the study investigating balance and stability and its connection with proprioceptive input. This would also contribute to future research related to preventing fall risk among elderly people.

Possible risks during your involvement

There might be some potential risks such as falling during the balance, and stability analysis inside the gait laboratory including investigation of kinetics, kinematics, spatiotemporal measures, and functional balance outcomes. Both the force plate integrated treadmill and Bertec balance advantage system are equipped with a safety harness device to prevent falls during data collection. To ensure safety, fitness, and comfort will be ensured by the investigator. During the tests inside the gait laboratory, the investigator may stay next to you for immediate assistance.

Confidentiality, anonymity & privacy

The information you provide will be used for research purposes only. Any research data from which you can be identified will be regarded as personal data and will be kept confidential and anonymous. Data collected after the test will be transmitted to a secure private memory immediately. The information will be kept for 5 years after the completion of the study. The Hong Kong Polytechnic University will take reasonable precautions to prevent the loss, misappropriation, unauthorized access, or destruction of the information you provide. We will minimize our use of personal data in the study and no personal data will be revealed in publications. The researcher and his team, supervisor, and collaborator will have access to personal data and research data for research purposes. Responsible members of The Hong Kong Polytechnic University may be given access to monitoring and/or audit of the research as well.

In case adverse events happen during the trial, how will you be handled?

The health and safety of the participant will always be the top priority. Adverse events during the trial will be handled in the following ways:

- The first step will be to immediately stop the trial if any of you experiences discomfort, pain, or any other adverse event.
- If the adverse event is severe, such as a fall or injury, immediate medical assistance will be provided. This could involve calling for an ambulance or providing first aid.
- After the event, the trial protocol will be reviewed to determine if changes need to be made to prevent similar incidents in the future. This could involve adjusting the equipment such as the safety harness and changing the instructions for you.
- We will try to ensure all members involved in the trial are adequately familiar with handling adverse events which may include training in first aid, emergency procedures, and how to operate the equipment safely.
- The Principal Investigator/Chief Investigator will report any SAE related to the study to the PolyU IRB within 48 hours of becoming aware of the event

Can I refuse to participate in/ withdraw from the study?

You have every right to refuse to participate in this research or withdraw from the study at any time without penalty of any kind.

Contact method.

If you have any questions, please do not hesitate to contact us. You may contact Abu JOR (tel. no.: 9812 / email: abu93.jor@), Dr. Toshiki KOBAYASHI (tel. no.: 2766 7672 / email: toshiki.kobayashi@), under the following situations:

a. If you have any other questions in relation to this study.
b. If, under very rare conditions, you become injured due to your participation in this study; or
c. If you want to get access to/or change your data.

In the event you have any complaints about the conduct of this research study, you may contact the Secretary, PolyU Institutional Review Board in writing (institutional.review.board@polyu.edu.hk) and state the responsible person, and the department of this study as well as the Reference Number.

Thanks again for your interest in this study.

Dr. Toshiki KOBAYASHI
Principal Investigator

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk

APPENDIX C: CONSENT FORM

THE HONG KONG
POLYTECHNIC UNIVERSITY
香港理工大學

CONSENT TO PARTICIPATE IN RESEARCH

A Novel Site-specific Somatosensory Stimulating Foot Orthosis to Improve Balance and Stability for Older Adults

I _______________________ hereby consent to participate in the captioned research conducted by Mr. Abu JOR (a research postgraduate student of the Department of Biomedical Engineering at The Hong Kong Polytechnic University (PolyU)), under the supervision of Dr. Toshiki KOBAYASHI (An associate professor of the Department of Biomedical Engineering at PolyU.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e., my details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefits and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant ___________________________________

Signature of participant ___________________________________

Name of guardian (if applicable) ___________________________________

Signature of guardian (if applicable) ___________________________________

Name of researcher ___________________________________

Signature of researcher ___________________________________

Date ___________________________________

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk

参與研究同意書

一種新型用於改善老年人的平衡和穩定性、針對特定部位的感覺刺激足部矯形器之研究

我__________________在此同意參與上述由 Abu JOR 先生（現就讀香港理工大學生物醫學工程學系之研究生）所主理、並在小林俊樹博士（香港理工大學生物醫學工程學系副教授）監督下開展的研究。

本人知悉此研究所得的資料可能被用作日後的研究及發表，但本人的私隱權利將得以保留，即本人的個人資料不會被公開。

研究人員已向本人清楚解釋列在所附資料卡上的研究程序，本人明瞭當中涉及的利益及風險；本人自願參與研究項目。

本人知悉本人有權就程序的任何部分提出疑問，並有權隨時退出而不受任何懲處。

參與者姓名 ____________________________________
參與者簽署 ____________________________________
家長或監護人(如適用)姓名________________________
家長或監護人(如適用)簽署________________________
研究人員姓名____________________________________
研究人員簽署____________________________________
日期____

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

Participant Recruitment

Inclusion criteria:

Items	**Yes**	**No**
Healthy older adults aged ≥ 65 years old		
Date of birth between 1944 to 1959 (Date of Birth:____________)		
Living in Hong Kong (convenience sampling)		
Occupation, community level, and social status (All kinds)		
Walk at least 150 minutes a week (for example, 30 minutes a day, 5 days a week) without external support		

Exclusion criteria:

Items	**Yes**	**No**
Participants with overweight (BMI > 40)		
Pes-cavus, pes-planus		
Not able to wear regular shoes		
Neuromuscular or central nervous system disorders (such as stroke, dementia, Parkinson, etc.), and vestibular disorders		
Major foot defects, i.e., severe foot pain, peripheral neuropathy/ulcers, previous history of foot surgery, and amputation of the lower limbs		
Inability to 10g Semmes-Weinstein monofilament (SWM) test (Lack of feeling in at least 4 of the 10 tested sites on the foot)		

Data will be obtained via self-reporting of the participants.

Demographic information

Age	Gender	Race	Body Weight	Body Height	BMI	Navicular Height		SWM
						NWB	WB	

BMI: body mass index; NWB: non-weight bearing; WB: weight bearing; SWM: Semmes-Weinstein monofilament.

Questionnaire for Vestibular disorder

Check the appropriate box if you have had any of the following:

Items	**Right Ear** 左耳	**Left Ear** 右耳	**Both Ear** 雙耳
Hearing loss 聽力問題			
Difference in pitch of sounds 音調差異			
Distortion of hearing 聽覺扭曲			
Noise in ears 耳內有雜音			
Fullness or pressure in your ear 耳朵漲痛或有壓力			
Pain in your ear 耳內疼痛			
Drainage from your ear 有液體從耳朵流出			

Mark '√' for 'Yes' and 'X' for 'No'

Semmes-Weinstein monofilament Test

10g Semmes-Weinstein monofilament Test: 10 sites on the foot

SN	**Items**	**Right**	**Left**
01	Plantar surface of the first digit		
02	Plantar surface of the third digit		
03	Plantar surface of the fifth digit		
04	Plantar surface of the first metatarsal head		
05	Plantar surface of the third metatarsal head		
06	Plantar surface of the fifth metatarsal head		
07	Plantar medial side of the midfoot		
08	Plantar lateral side of the midfoot		
09	Plantar area of the heel		
10	Dorsal surface of the foot between the base of the first and second toes		

Mark '√' for 'Yes' and 'X' for 'No'

Figure 1: 10 testing sites on the foot

Non-preferable days in the week for lab visit

星期一 Monday	星期二 Tuesday	星期三 Wednesday	星期四 Thursday	星期五 Friday	星期六 Saturday	星期日 Sunday

Non-preferable time slots in the days for lab visit

上午九點-中午十二點 9:00 AM – 12:00 PM	中午十二點-下午三點 12:00 PM – 3:00 PM	下午三點-下午六點 3:00 PM – 6:00 PM	下午六點-晚上九點 6:00 PM – 9:00 PM

請在可以出席理工大學的實驗日和時間上打勾☑，或在不能出席的日子和時間上打叉 X ((Put 'X' for non-preferable days/sessions))

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

3D Scanning of participant's foot

Participant ID ____

Name of Researcher ____

Signature of Researcher ____

Date ______________________________________

3D Scan of foot

Participant ID	Description	Right foot	Left foot
	AJ's Project	RF-Patient ID	LF-Patient ID

Participant ID: AJP_SN+Initial.Letter EXP/CON_SC/VC/ZB/BT

Anthropometric data

Foot length		Ball length MH1		Foot width		Ankle width (mm)		Knee width (mm)		Leg length (mm)	
Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right
Body mass (kg)											
Height (mm)											
Shoe Size											

APPENDIX D: SEARCH STRATEGY

Supplemental Table S1: Search strategies (From Inception to December 2024)

Keywords Category 1 [Population related]
(“older people” OR "aging population" OR older adults[MeSH] OR elderly[MeSH])
Keywords Category 2 [Intervention related]
("textured foot orthoses" OR "textured foot orthosis" OR "textured shoe inserts" OR “textured surface” OR somatosensory OR "mechanoreceptor stimulation" OR “tactile stimulation” OR “mechanical stimulation” OR “stimulating insole” OR “insole stimulation” OR “sole stimulation” OR “spike insole” OR “massage insole” OR “balance-enhancing insole” OR protrusion OR tactile stimulation[MeSH] OR textured insoles[MeSH])
Keywords Category 3 [Outcome related]
("static balance" OR "dynamic balance" OR "postural stability" OR "balance improvement" OR proprioception OR “tactile sensitivity” OR “tactile sensation” OR “center of pressure” OR “center of mass” OR “center of gravity” OR postural sway[MeSH] OR postural balance[MeSH] OR postural stability[MeSH])

SN	Database	Search syntax	N
1	PubMed	((((("older people") OR ("aging population")) OR (older adults[MeSH])) OR (elderly[MeSH])) AND (((((((((((((("textured foot orthoses") OR ("textured foot orthosis")) OR ("textured shoe inserts")) OR ("textured surface")) OR ("somatosensory")) OR ("mechanoreceptor stimulation")) OR ("mechanical stimulation")) OR ("stimulating insole")) OR ("insole stimulation")) OR ("sole stimulation")) OR ("spike insole")) OR ("massage insole")) OR ("balance-enhancing insole")) OR (protrusion)) OR (tactile stimulation[MeSH])) OR (textured insoles[MeSH]))) AND (((((((((((((("postural control") OR ("static balance")) OR ("dynamic balance")) OR ("postural stability")) OR ("balance improvement")) OR (proprioception)) OR ("tactile sensitivity")) OR ("tactile sensation")) OR ("center of pressure")) OR ("center of mass")) OR ("center of gravity")) OR (postural sway[MeSH])) OR (postural balance[MeSH])) OR (postural stability[MeSH])))	566
2	Scopus	TITLE-ABS-KEY ("older people") OR TITLE-ABS-KEY ("aging population") OR TITLE-ABS-KEY (“older adults”) OR TITLE-ABS-KEY (elderly) AND TITLE-ABS-KEY ("textured foot orthoses") OR TITLE-ABS-KEY ("textured foot orthosis") OR TITLE-ABS-KEY ("textured shoe inserts") OR TITLE-ABS-KEY ("textured surface") OR TITLE-ABS-KEY (somatosensory) OR TITLE-ABS-KEY ("mechanoreceptor stimulation") OR TITLE-ABS-KEY ("tactile stimulation") OR TITLE-ABS-KEY ("mechanical stimulation") OR TITLE-ABS-KEY ("stimulating insole") OR TITLE-ABS-KEY ("insole stimulation") OR TITLE-ABS-KEY ("sole stimulation") OR TITLE-ABS-KEY ("spike insole") OR TITLE-ABS-KEY ("massage insole") OR TITLE-ABS-KEY ("balance-enhancing insole") OR TITLE-ABS-KEY (protrusion) OR TITLE-ABS-KEY ("tactile stimulation") OR TITLE-ABS-KEY ("textured insoles") AND TITLE-ABS-KEY ("static balance") OR TITLE-ABS-KEY ("dynamic balance") OR TITLE-ABS-KEY ("postural stability") OR TITLE-ABS-KEY ("balance improvement") OR TITLE-ABS-KEY (proprioception) OR TITLE-ABS-KEY ("tactile sensitivity") OR TITLE-ABS-KEY ("tactile sensation") OR TITLE-ABS-KEY ("center of pressure") OR TITLE-ABS-KEY ("center of mass") OR TITLE-ABS-KEY ("center of gravity") OR TITLE-ABS-KEY ("postural sway") OR TITLE-ABS-KEY ("postural balance") OR TITLE-ABS-KEY ("postural stability")	361
3	Web of Science	(((ALL=(“older people”)) OR ALL=("aging population")) OR ALL=(older adults)) OR ALL=(elderly) AND (((((((((((((((ALL=("textured foot orthoses")) OR ALL=("textured foot orthosis")) OR ALL=("textured shoe inserts")) OR ALL=(“textured surface”)) OR ALL=(somatosensory)) OR ALL=("mechanoreceptor stimulation")) OR ALL=(“tactile stimulation”)) OR ALL=(“mechanical stimulation”)) OR ALL=(“stimulating insole”)) OR ALL=(“insole stimulation”)) OR ALL=(“sole stimulation”)) OR ALL=(“spike insole”)) OR ALL=(“massage insole”)) OR ALL=(“balance-enhancing insole”)) OR ALL=(protrusion)) OR ALL=("tactile stimulation")) OR ALL=("textured insoles") AND (((((((((((ALL=("static balance")) OR ALL=("dynamic balance")) OR ALL=("postural stability")) OR ALL=("balance improvement")) OR ALL=(proprioception)) OR ALL=(“tactile sensitivity”)) OR ALL=(“tactile sensation”)) OR ALL=(“center of pressure”)) OR ALL=(“center of mass”)) OR ALL=(“center of gravity”)) OR ALL=("postural sway")) OR ALL=("postural balance")) OR ALL=("postural stability")	280
4	Cochrane Library	(“older people” OR "aging population" OR "older adults" OR elderly) in All Text AND ("textured foot orthoses" OR "textured foot orthosis" OR "textured shoe inserts" OR “textured surface” OR somatosensory OR "mechanoreceptor stimulation" OR “tactile stimulation” OR “mechanical stimulation” OR “stimulating insole” OR “insole stimulation” OR “sole stimulation” OR “spike insole” OR “massage insole” OR “balance-enhancing insole” OR protrusion OR "tactile stimulation" OR "textured insoles") in All Text AND ("static balance" OR "dynamic balance" OR "postural stability" OR "balance improvement" OR proprioception OR “tactile sensitivity” OR “tactile sensation” OR “center of pressure” OR “center of mass” OR “center of gravity” OR "postural sway" OR "postural balance" OR "postural stability") in All Text - (Word variations have been searched)	67
5	CINAHL via EBSCOhost	AB ((“older people” OR "aging population" OR "older adults" OR elderly)) AND TX (("textured foot orthoses" OR "textured foot orthosis" OR "textured shoe inserts" OR “textured surface” OR somatosensory OR "mechanoreceptor stimulation" OR “tactile stimulation” OR “mechanical stimulation” OR “stimulating insole” OR “insole stimulation” OR “sole stimulation” OR “spike insole” OR “massage insole” OR “balance-enhancing insole” OR protrusion OR "tactile stimulation" OR "textured insoles")) AND AB (("static balance" OR "dynamic balance" OR "postural stability" OR "balance improvement" OR proprioception OR “tactile sensitivity” OR “tactile sensation” OR “center of pressure” OR “center of mass” OR “center of gravity” OR "postural sway" OR "postural balance" OR "postural stability"))	109

APPENDIX E: LIST OF EXCLUDED STUDIES FROM SYSTEMATIC REVIEW

Supplemental Table S2: List of excluded studies

Author (Year)	Title	Reason for exclusion
Abdullah et al., 20	Somatosensory stimulation of the foot versus Tai-Chi to improve dynamic balance in the elderly	Intervention other than stimulating or textured FO
Alaee et al., 2023	Immediate effect of textured insoles on the balance in patients with diabetic neuropathy	Population other than healthy older adults
Alshammari et al., 2014	Tactile Intervention as a Novel Technique in Improving Body Stability in Healthy Elderly and Elderly with Diabetes	Intervention other than stimulating or textured FO
Antonio et al., 2014	Quantifying stair gait stability in young and older adults, with modifications to insole hardness	Intervention other than stimulating or textured FO
Barela et al., 2018	Light touch compensates peripheral somatosensory degradation in postural control of older adults	Intervention other than stimulating or textured FO
Baron et al., 2019	Experiences of people with Multiple Sclerosis using textured insoles: an interpretive phenomenological exploration	Population other than healthy older adults
Bernard-Demanze et al., 2009	Can tactile plantar stimulation improve postural control of persons with superficial plantar sensory deficit?	Intervention other than stimulating or textured FO
Borgia et al., 2014	Finding Our Footing: The Potential Use Of Textured Insoles To Enhance Gait Mechanics In Older Adults.	Abstract only
Capecci et al., 2014	Postural Rehabilitation and Kinesio Taping for Axial Postural Disorders in Parkinson's Disease	Population other than healthy older adults
Clark et al., 2022	Enhancing Locomotor Learning with Transcutaneous Spinal Electrical Stimulation and Somatosensory Augmentation: A Pilot Randomized Controlled Trial in Older Adults	No primary outcome measures
Hasan et al., 2016	Changes in organisation of instep kicking as a function of wearing compression and textured materials	Population other than healthy older adults
Hatton et al., 2008	The effect of textured surfaces on postural stability and lower limb muscle activity	Population other than healthy older adults
Hatton et al., 2019	Textured shoe insoles to improve balance performance in adults with diabetic peripheral neuropathy: study protocol for a randomised controlled trial	Population other than healthy older adults
Hatton et al., 2022	Effects of wearing textured versus smooth shoe insoles for 12 weeks on gait, foot sensation and patient-reported outcomes, in people with multiple sclerosis: a randomised controlled trial	Population other than healthy older adults
Hatton et al., 2022	Immediate effects of wearing textured versus smooth insoles on standing balance and spatiotemporal gait patterns when walking over even and uneven surfaces in people with multiple sclerosis	Population other than healthy older adults
Hatton et al., 2024	The effects of wearing textured versus smooth shoe insoles for 4-weeks in people with diabetic peripheral neuropathy: a randomised controlled trial	Population other than healthy older adults
Kenny et al., 2019	The effects of textured insoles on quiet standing balance in four stance types with and without vision	Population other than healthy older adults
Lirani-Silva et al., 2017	Continuous use of textured insole improve plantar sensation and stride length of people with Parkinson's disease: A pilot study	Population other than healthy older adults
Maki et al., 2011	Reducing fall risk by improving balance control: Development, evaluation and knowledge-translation of new approaches	No primary outcome measures
Marchant et al., 2023	The effect of compression and combined compression-tactile stimulation on lower limb somatosensory acuity	Population other than healthy older adults
Menz et al., 2006	A tactile stimulus applied to the leg improves postural stability in young, old and neuropathic subjects	Intervention other than stimulating or textured FO
Menz et al., 2022	Effects of balance-enhancing footwear on postural sway when standing and walking in older women	Registered title
Paton et al., 2016	Getting the right balance: insole design alters the static balance of people with diabetes and neuropathy	Population other than healthy older adults
Robb et al., 2020	Textured Foot Orthotics on Dynamic Stability and Turning Performance in Parkinson's Disease	Population other than healthy older adults
Robb et al., 2024	The suppression of lower leg electromyography when walking in textured foot orthoses	Population other than healthy older adults
Sadeghi-Demneh et al., 2019	The effects of textured insoles on the balance of olde people with callous formation under the foot: A controlled study	Registered title
Salari-Moghadam et al., 2015	The Effects of Textured Insole on Ankle ProprioceptΘon and Performance Balance in Subjects with the Risk of Falling	Not written in English
Son et al., 2010	Do Ankle Orthoses Improve Ankle Proprioceptive Thresholds or Unipedal Balance in Older Persons with Peripheral Neuropathy?	Population other than healthy older adults
Valizadeorang et al., 2020	Effect of Textured Foot Orthoses on the Ground Reaction Force Components in the Older Adults During Walking	Not written in English
Wang et al., 2016	Effect of plantar cutaneous inputs on center of pressure during quiet stance in older adults	Intervention other than stimulating or textured FO
Wheat et al., 2014	Effects of textured socks on balance control during single-leg standing in healthy adults	Population other than healthy older adults
Wilson et al., 2008	Effect of textured foot orthotics on static and dynamic postural stability in middle-aged females	Population other than healthy older adults
Woo et al., 2014	Effects of Textured Compression Socks on Postural Control in Physically Active Elderly Individuals	No primary outcome measures
Registered title 2022	Effects of balance-enhancing footwear on postural sway when standing and walking in older women	Registered title