



# Comparison of two different designs of forefoot off-loader shoes and their influence on gait and spinal posture

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## ABSTRACT

**Background:** The purpose of forefoot off-loader shoes (FOS) is to unload the operated region of the foot in order to allow early mobilization and rehabilitation. However, little is known about the actual biomechanical effects of different designs of FOS on gait, pelvis and spine.

**Research question:** Aim of this study was to analyse and compare the effects of two different designs of forefoot unloader shoes.

**Methods:** Ortho-Wedge (FOS A) and Relief-Dual® (FOS B) were evaluated in this study during standing and while walking. Changes of the pelvic position and spinal posture were measured with a surface topography system and an instrumented treadmill. Gait phases were detected automatically by a built-in pressure plate.

**Results:** Both FOS resulted in a significant increase of pelvic obliquity, pelvic torsion, lateral deviation and surface rotation ( $p < 0.001$ ) while standing. Between both shoe models, pelvic obliquity and lateral deviation ( $p < 0.05$ ) were significantly different. During walking, both FOS had a significant effect on spine and pelvis ( $p < 0.05$ ), however only minor differences were found between the designs. All gait parameters were affected more, wearing FOS A than B. Step length were significantly longer by wearing FOS ( $p < 0.005$ ). However stance phase raised and swing phase is reduced on the leg wearing FOS A ( $p < 0.001$ ).

**Significance:** The study showed that FOS lead to significant changes in pelvic position and spinal posture during standing and while walking. A compensating shoe on the contralateral side is therefore recommend. Gait parameters however were affected more by the traditional FOS A half-shoe. The sole- design and shape of FOS B leads to a more physiological roll-over of the foot.

## 1. Introduction

In orthopaedics, forefoot off-loader shoes (FOS) are commonly used to protect and unload the forefoot, e.g. after hallux valgus, hallux rigidus or claw toe surgeries, since they allow early mobilization and rehabilitation by unloading the operated region [1,2]. In addition, FOS can also be used to prevent and successfully treat plantar ulcers in diabetic feet [3,4].

In general, FOS distribute pressure from the forefoot- to the rearfoot-region by introducing a rolling/rocking mechanism in the midfoot-region. Currently, there are multiple models of FOS available with various designs and rolling/rocking mechanisms. Most common is the so called “half-shoe design” with a high-profile outsole in the middle-/rearfoot region and a low-profile outsole in the forefoot-region [5,6]. The efficiency of the plantar pressure reduction in the forefoot area of the “half-shoe design” was previously shown in multiple pedobarographic studies [3,5].

Because of the elevated sole of these offloading shoes, they can cause leg length discrepancies (LLD) [7], which may result in asymmetrical joint movements and problems in the kinematic chain, possibly leading to acute and chronic clinical symptoms and disorders. Multiple studies have shown the association between LLD and low back pain, sacroiliac joint disorders, pelvic obliquity and knee and hip pain [8–10]. Another design characteristic is the negative heel wedge of most FOS. Thereby, body weight and plantar pressure is shifted to the rearfoot-region [3], potentially leading to an asymmetric, unstable gait and discomfort [1,3]. To compensate for the functional LLD and its negative effects on gait and posture it is therefore recommended to wear a compensating orthopaedic shoe (twin shoe) on the contralateral foot [7,11].

Because of the potentially negative effects of standard FOS, such as gait asymmetry and functional LLD as well as the need of wearing a twin shoe on the contralateral foot, novel FOS designs have been developed [5]. A new concept is used in the Relief Dual® FOS (DARCO

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**Table 1**

Epidemiological characteristics of the study group, separated by gender (male left column, female right column).

	males	females
<i>n</i>	24	31
Age (years)	26.2 ± 3.84	24.82 ± 2.98
Weight (kg)	79.83 ± 8.63	60.48 ± 6.56
Height (cm)	182.96 ± 5.99	167.94 ± 6.41

Europe GmbH, Raisting, Germany). This shoe has a low-profile outsole and does not contain a forefoot plateau area. The weight distribution during walking is obtained by a multi-layered composite of soles.

Multiple studies have addressed the offloading characteristics and ability of reducing pressure on the forefoot by analysing the plantar pressure distribution during walking [6,7,12,13]. Further studies compared different FOS regarding their comfort and balance [1,3,6]. However, little is known about the actual effects of different designs of FOS on gait, pelvic position and spinal posture in stance and during walking. Therefore, the purpose of this study was to compare and study the effects of two different designs of FOS -a traditional half-shoe and a novel model- on gait, pelvis and spine.

## 2. Methods

### 2.1. Participants

55 healthy subjects (m = 24, f = 31) without any history of spine, pelvic or lower limb pathology volunteered in this study (Table 1). The study protocol was approved by the local ethics committee (Study number: EK091/17).

### 2.2. Tested FOS

Two different designs of FOS (DARCO Europe GmbH, Raisting, Germany) were evaluated:

- The “OrthoWedge” shoe is a traditional FOS with a half-shoe design (FOS A). It has a high-profile outsole in the mid- and rearfoot area and a low-profile sole in the forefoot area. Thereby, the bodyweight is transferred to the mid- and rearfoot, reducing the pressure on the forefoot region (Fig. 1).
- The second shoe is the “Relief Dual®” FOS (FOS B). Its sole is completely low profile and contains no forefoot plateau area. The weight distribution is obtained by a multi-layered composite of soles and a rigid shank throughout the entire insole.

### 2.3. Measurement Protocol

For all measurements the volunteers were standing still or walking on a treadmill with 3 km/h. We chose the same walking speed for all volunteers, in order to standardized the treadmill measurements. For every subject a total of 10 measurements were performed (5 static and 5 dynamic):



**Fig. 1.** A traditional “Ortho-Wedge” shoe with half shoe design, negative heel and high-profile outsole (left picture) was compared with the “Relief Dual®” forefoot offloading shoe that contains a multi layered sole system and no forefoot plateau area (right picture).

### 2.3.1. A) static baseline measurements

First, subjects were measured without any FOS standing in a relaxed posture with extended knees. These measurements were considered as baseline measurements (Control).

### 2.3.2. B) Static measurements with two different FOS

For the static measurements all subjects wore the respective FOS on one foot, while being barefoot on the other. To adapt to the FOS, subjects stood for 60 s prior to the actual measurements. The order of shoes (FOS A or FOS B) was randomized, so that the same number of subjects were first measured wearing FOS A than those first wearing FOS B.

Performed measurements were:

- FOS A on left foot
- FOS A on right foot
- FOS B on left foot
- FOS B on right foot

### 2.3.3. C) Dynamic baseline measurements

After the static measurements, the dynamic baseline measurements were performed while the subjects were walking on a treadmill with 3 km/h without wearing any shoes.

### 2.3.4. D) dynamic measurements with FOS

Then, we performed measurements under dynamic conditions of subjects wearing the respective two FOS (FOS A & FOS B). Prior to the actual measurements, all subjects adapted to the FOS by walking for 60 s on the treadmill with 3 km/h. We also randomized the order of the FOS shoes following the above-mentioned protocol.

Performed measurements were:

- FOS A on left foot
- FOS A on right foot
- FOS B on left foot
- FOS B on right foot

## 2.4. Gait and spine analysis

For analysing gait and spinal parameters, a surface topography system in combination with an instrumented treadmill (Formetric 4D motion, Diers International GmbH, Germany) was used. This system has shown its high validity and reliability in multiple previous studies [9,14–16]. A projector generates a light-line image on the back, which is captured by a digital camera. The computer unit then calculates a three-dimensional model of the human back shape and spine by analysing the areas of the back surface [17]. These areas are linked to specific anatomical landmarks of the human spine and pelvis [18]. Consecutively, the shape of the spinal column is animated in three-dimensions based on a model created by Turner-Smith [19,20]. It is also possible to use the two lumbar dimples to measure pelvic obliquity based on their close relation to the underlying posterior superior iliac spines [18,21]. In a series of studies, rasterstereography has proven to have high reliability and validity, when compared to X-rays [16,22–24]. For the purpose of this study it is necessary to define certain terms regarding the parameters that were measured [9,15,16]:

Pelvic obliquity is the amount of tilt in millimetres from the horizontal line between the two lumbar dimples DL (left dimple) to DR (right dimple). A positive value indicates that the right dimple is higher than the left. Pelvic torsion (in degrees) is the rotation of the lumbar dimples (DL and DR). A positive pelvic torsion indicates a further anterior localization of the right hipbone. Surface rotation is defined as the vertebral rotation measured perpendicular to the back surface over the spinous processes as a central line from the spinous process of the 7th cervical vertebra (VP) to the midpoint between the two lumbar dimples measured in degrees. Lateral deviation is defined as the

deviation of the spinal midline from the line between the spinous process of the VP to the midpoint between DL and DR (DM) in the frontal plane [25]. For both parameters the root-mean square over the whole back is calculated, giving a parameter for overall surface rotation and lateral deviation of the spine. Gait parameters were evaluated by a pressure plate, which is built into the treadmill. By measuring the initial and terminal contact of each foot, the step length, swing and stance phase were calculated. The initial contact is the point in the gait cycle, when the foot initially makes contact with the ground. Mid stance is defined from the time the opposite limb leaves the floor until the body weight is aligned over the forefoot. Finally, terminal contact is the point, when the foot leaves the ground.

### 2.5. Data analysis

Statistical analysis was prepared using the IBM SPSS Statistics Software (IBM, Version 24, Chicago, IL, USA). Data were checked for Gaussian distribution by Chi-square test of normality. Differences between the groups (wearing no shoes, FOS A or B) were analysed by repeated measurement (RM) ANOVA testing. Bonferroni-adjusted post-hoc analysis was used to compare between the two groups. The level of significance was set at  $p < 0.05$ . Effect sizes of the differences were calculated using Eta squared ( $\eta^2$ ).

## 3. Results

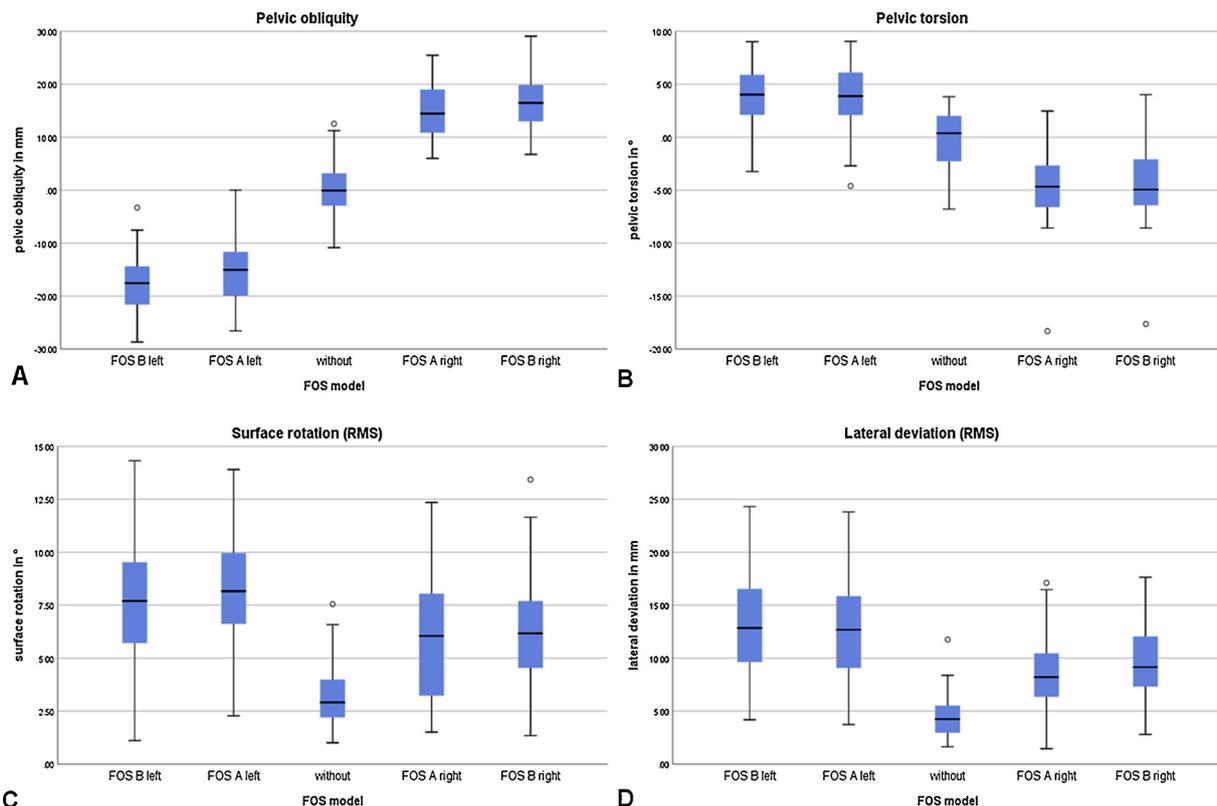
### 3.1. Static measurements

Both FOS led to an increase in pelvic obliquity on the side the shoe was worn (Fig.2 A). ANOVA testing revealed significant differences

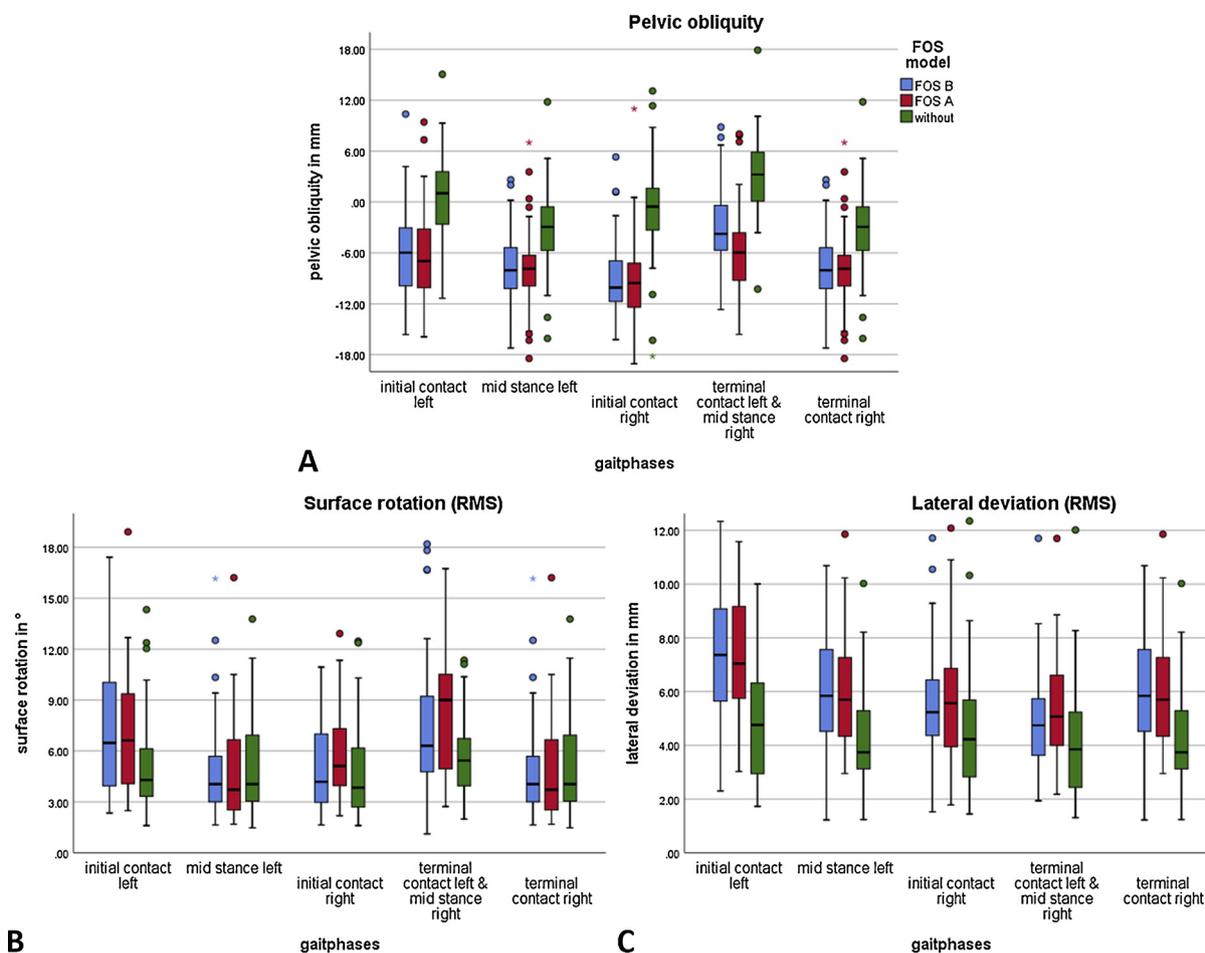
between groups in global testing ( $p < 0.001$ ) and high effect sizes ( $\eta^2 = 0.885$  and  $0.92$ ) were found. Bonferroni-adjusted post-hoc analysis revealed a significant difference ( $p < 0.001$ ) between the control group -wearing no shoes and both FOS models (independent of the side where the shoe was worn) ( $p < 0.001$ ). Comparing both shoes, the amount of pelvic obliquity was significantly higher wearing the FOS B (left:  $p < 0.001$ , right:  $p = 0.018$ ) than wearing FOS A. We also found significant differences for pelvic torsion ( $p < 0.001$ ;  $\eta^2 = 0.52$  and  $0.559$ ). Wearing FOS A or B significantly increased pelvic torsion on the side, where the shoe was worn compared to standing without shoes ( $p < 0.001$ ). Wearing the FOS on the right foot, the left hip bone moved further anterior and vice versa (Fig.2 B). Comparing both shoes, no significant differences were found between the two models for pelvic torsion using post-hoc testing (left:  $p = 1$  right:  $p = 1$ ). Standing with a FOS also resulted in significant changes of the spinal posture ( $p < 0.001$ ). An effect size of  $\eta^2 = 0.73$  (left) and  $\eta^2 = 0.514$  (right) for lateral deviation and  $\eta^2 = 0.709$  (left) and  $\eta^2 = 0.39$  (right) was found. We found a significant increase in lateral deviation and surface rotation of the spine by both FOS compared to the control without FOS using Bonferroni-adjusted post-hoc analysis ( $p < 0.001$ ) (Fig. 2 C, D). However, between FOS models no significant differences were found for lateral deviation of the spine (right:  $p = 0.079$ , left:  $p = 1$ ). Also, regarding surface rotation, we did not find a significant difference between the two FOS models (left:  $p = 0.263$ , right:  $p = 1$ ).

### 3.2. Dynamic measurements of pelvic and spine parameters

The observations made for pelvic obliquity under static conditions were also registered under dynamic conditions. Global testing revealed significant differences and strong effect-sizes between groups



**Fig. 2.** Static analysis of the effects wearing forefoot offloading shoes compared to the control group. Spinal and pelvic parameters were affected significantly. Wearing the FOS causes an increase of pelvic obliquity ipsilaterally ( $p < 0.001$ ). A significant difference between FOS A and B was shown (left:  $p < 0.001$ , right:  $p = 0.018$ ) (A). Wearing the FOS causes a further anterior positioning of the contralateral hip bone ( $p < 0.001$ ) (B). Surface rotation increased significantly by wearing the FOS ( $p < 0.001$ ). This effect was shown for both shoe models. However, a significant difference between both models was not shown (left:  $p = 0.263$ , right  $p = 1$ ) (C). A significant lateral deviation was caused by both shoe models compared with the control group wearing no shoes ( $p < 0.001$ ). No significant differences were shown between both FOS models (right:  $p = 0.079$ , left:  $p = 1$ ) (D). Level of significance was set at  $p < 0.05$ .



**Fig. 3.** Boxplot graphics show results under dynamic conditions for wearing the FOS (A = red box, B = blue box) compared to the control group (green box). **A:** Pelvic obliquity increased by wearing either one FOS. In the terminal contact phase of the shoe wearing leg (here left) the traditional FOS A leads to a significantly ( $p < 0.001$ ) greater pelvic obliquity compared to FOS B (A). Surface rotation (calculated in root mean square) of the spine increased in the initial contact and terminal contact on the ipsilateral side by wearing the FOS ( $p < 0.001$ ) (B). Mean lateral deviation was calculated as the RMS while walking (C). Lateral deviation of the spine was significantly higher in all gait phases ( $p < 0.001$ ), wearing FOS A and B on the left foot (A = red box, B = blue box) compared to barefoot (green boxes) walking. The measurements showed no significant differences between FOS A and B ( $p = .452-1$ ).

( $p < 0.001$ ;  $\eta^2 = 0.426-0.606$ ) in all gait phases. The post-hoc testing showed, that pelvic obliquity increased significantly ( $p < 0.001$ ) by both shoes in all gait phases compared to the control group (Fig. 3A). However, the traditional FOS A leads to a significantly ( $p < 0.001$ ) greater pelvic obliquity compared to FOS B in the terminal contact phase of the shoe wearing leg. For surface rotation significant differences were found in the initial and terminal contact phase using global ANOVA testing ( $p < 0.001$ ). Effect size showed low effects in ipsilateral midstance and terminal contact contralateral (both  $\eta^2 = 0.014$ ) to high effects in initial and terminal contact on the ipsilateral side ( $\eta^2 = 0.231$ ). Bonferroni-adjusted post-hoc analysis showed, that by wearing FOS A or B the surface rotation increased significantly in the initial and terminal contact phase ( $p < 0.001$ ) on the shoe-wearing side (Fig. 3B). However, no differences between the two shoe designs were found (initial contact:  $p = 1$ ; terminal contact  $p = 0.275$ ). For other gait phases testing showed no significant differences ( $p > 0.05$ ). Lateral deviation of the spine increased under dynamic conditions by wearing FOS A or B (Fig. 3C). Global testing showed significant differences between groups in all gait phases ( $p < 0.01$ ,  $\eta^2 = 0.123-0.435$ ). Comparing both models to the control group, the results showed a significant higher lateral deviation in all gait phases, wearing either FOS on the left foot ( $p < 0.05$ ). Between both FOS models however, no significant differences were found ( $p = 0.452-1$ ).

### 3.3. Measurements of gait parameters

ANOVA testing revealed significant differences for step length ( $p < 0.001$ ) and a higher effect-size on the contralateral leg (left:  $\eta^2 = 0.745$ ; right:  $\eta^2 = 0.466$ ) than on the ipsilateral leg (left:  $\eta^2 = 0.221$ ; right:  $\eta^2 = 0.373$ ). Post-hoc testing showed that step length was significantly affected by wearing either FOS compared to the subjects not wearing any footwear (Fig. 4). The step length was longer on the leg where FOS A or B was worn and shorter on the contralateral leg than in the control group ( $p < 0.05$ ). Comparing both FOS models, FOS A leads to a significant shorter step length on the contralateral leg than FOS B ( $p < 0.001$  in each case). The ratio between swing and stance phases were only influenced by FOS A. ANOVA testing showed that stance and swing phase of the ipsilateral -shoe wearing leg- were significantly affected ( $p < 0.001$ ;  $\eta^2 = 0.434-0.565$ ), whereas on the contralateral leg no significant differences appeared ( $p = 0.541-0.915$ ;  $0.002-0.012$ ). These results were supported by Eta-square analysis that showed high effect on ipsilateral  $\eta^2 = 0.434-0.565$ ) and no effect  $0.002-0.012$  on contralateral leg. Wearing the traditional FOS A, led to a significant extension of the swing phase from nearly 35% to 40% ( $p < 0.001$ ). The stance phase on the other hand was significantly shortened from nearly 65% to 60% ( $p < 0.001$ ). Gait phases were not influenced by wearing FOS B compared to the test group ( $p = 1$ ) (Fig. 5).

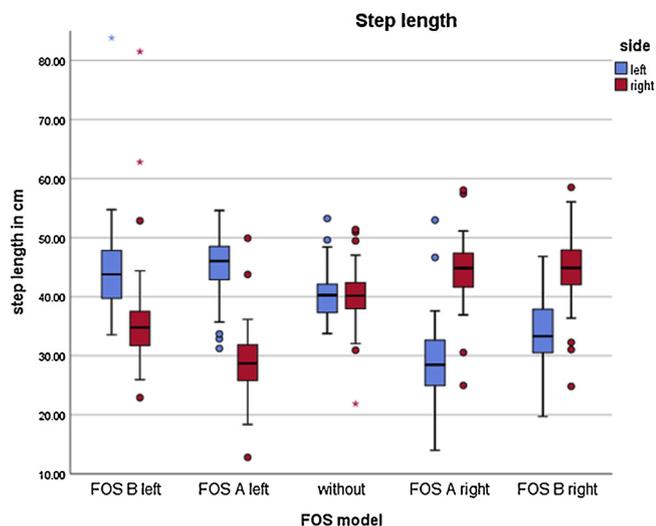


Fig. 4. Step length was significantly affected by wearing the FOS compared to the subjects not wearing any footwear. The step length was longer on the leg where the FOS was worn and shorter on the contralateral leg than in the test group ( $p < 0.001$ ). Comparing both FOS models, FOS A leads to a significant shorter stride length on the contralateral leg than FOS B ( $p < 0.05$ ).

#### 4. Discussion

The purpose of FOS is to preserve the weight transfer from forefoot to the ground and redistribute the bodyweight to the mid- and rearfoot. The design that traditionally is used to take the pressure of the forefoot goes with a higher outsole of the shoe, consequently creating a leg length inequality. Furthermore, the ascending shape of the insole and the rigid outsole may lead to an unphysiologically and uncomfortable fit under dynamic and static conditions. This does not only cause a lack of comfort while walking, but it can also increase the risk of falling especially in elderly patients [26,27]. In order to preserve pain in the contralateral extremity and asymmetrical gait, manufacturers recommend to wear a twin-shoe on the contralateral foot for compensation. However, clinical experience not only shows a lack of compliance wearing the half shoe [26] but also wearing the recommended twin-shoe. As a consequence, and to address the potential negative aspects of traditional FOS, new models have been developed and are recently being promoted [1,7]. In our study, we therefore not only evaluated the

effects of a traditional half shoe design FOS (FOS A) on posture and gait, but also tested and compared this shoe design to a full outsole FOS (FOS B) with a novel sole system.

This present study shows that both FOS cause significant changes in the pelvic position and spinal posture. Under static conditions pelvic obliquity and torsion as well as lateral deviation and surface rotation of the spine increased significantly wearing a FOS compared to the test group. The findings of the present study are supported by earlier work of Betsch et al. that showed similar results for the effects of simulated LLIs on the musculoskeletal apparatus [9,25]. Wünnemann et al. confirmed a significant lateral pelvic tilt caused by the Ortho Wedge shoe [7]. Referring to the present study, our results indicate that both shoe designs create a clinically relevant LLI. Previous studies showed, that the asymmetrical gait patterns caused by FOS can be at least improved by wearing a compensating twin shoe on the contralateral side as recommended by most manufacturers [7]. As an alternative to the traditional FOS (FOS A) a full contact shoe with multi-layered sole composite has been introduced to the market (FOS B). However, our results still revealed significant changes in pelvic position and spinal posture caused by both shoe types.

The measured height of the sole shows that FOS B creates a similar amount of LLI than FOS A. Under static conditions only pelvic obliquity was differently influenced by wearing FOS A or B. The amount of pelvic obliquity was higher wearing FOS B compared to FOS A. This, however changed under dynamic conditions. Further results showed that both shoe designs, the traditional Ortho Wedge shoe and the Relief Dual<sup>®</sup>, also had a significant influence on spinal posture and pelvic position while walking on a treadmill. These findings are in line with previous studies, showing the influence of simulated LLI on spine and pelvis under dynamic conditions [14].

Differences between the two shoe designs were only significant for pelvic obliquity and surface rotation in the terminal contact phase of the ipsilateral (shoe wearing) side. In contrast to the findings under static conditions, the FOS B led to a lesser pelvic obliquity in the terminal contact phase than FOS A while walking. The differences between both shoes may be caused by the half shoe design and negative heel, that is mostly involved in terminal contact.

The major differences between both shoe designs were revealed evaluating gait patterns. The results show that the Relief Dual<sup>®</sup> forefoot shoe (FOS B) leads to a more symmetrical gait pattern than the traditional Ortho-wedge shoe (FOSA), which may be caused by the sole design. The low-profile outsole and missing plateau area of the Relief

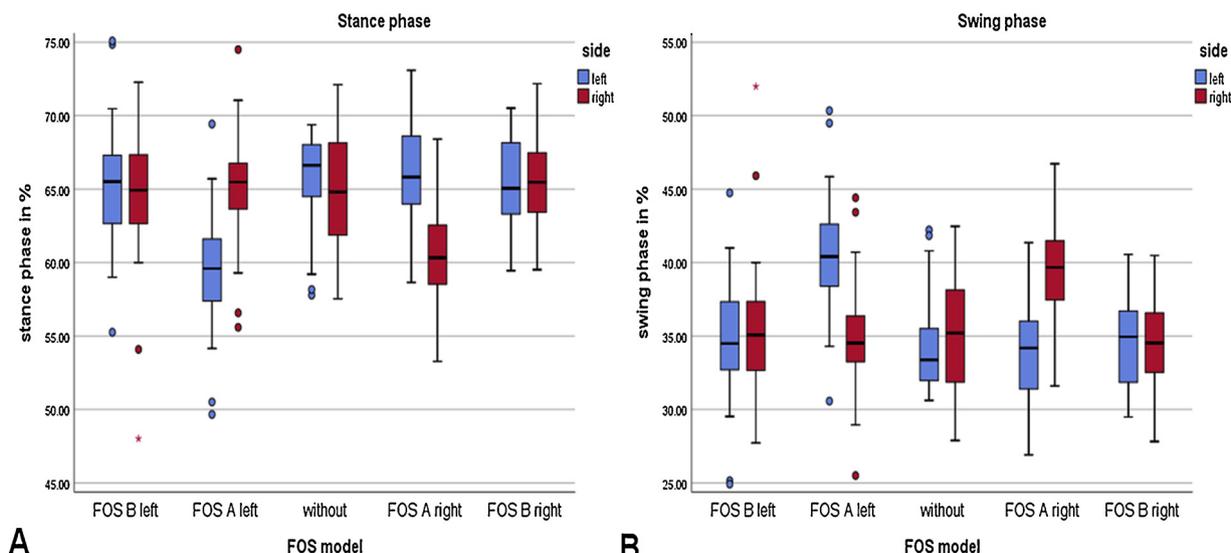


Fig. 5. Boxplot graphic shows gait phase changes wearing the FOS. The phases only significantly are influenced by wearing FOS A. The swing phase of the leg wearing FOS A is lengthened and the stance phase shortened ( $p < 0.001$ ).

Dual® allows a more physiological roll over of the foot. Wearing the Ortho-wedge shoe only allows a contact of rear- and midfoot due to the plateau area. This may cause an unphysiological gait with a shorter stance and a longer swing phase on the ipsilateral leg. The shorter time on the ground and a shorter step length of the FOS A wearing leg, can lead to a limping in the patient's gait. However, the compensation for a limp can depend on the physical status and the comorbidities of a patient. Armstrong et al. showed that the activity level of patients with diabetic ulcers wearing a FOS is reduced to 10% of their previous activity level [28]. Furthermore, Bus et al. [29] showed that gait symmetry and stability are compromised in patients with diabetic neuropathies that wear FOS. A study by Albright et al. also demonstrated that even in healthy subjects a negative heel FOS can increase the risk of falling and can cause gait instability [30].

Still, there is no evident proof for the increased risk of falling and any remaining clinical pathology caused by the temporary use of FOS. While the benefits in offloading the forefoot area in prevention, treatment and recovery, is shown in multiple studies, the reasons for wearing a FOS outweigh the discussed limitations [1–4]. FOS can be used to successfully treat ulcers in patients with diabetic neuropathies [3,4,31]. They are also a valuable tool in the postoperative care of patients following surgery, since they allow early mobilization and weight-bearing [1,2]. It was shown, that improved comfort and more physiological gait patterns in forefoot offloading shoes may increase therapeutic adherence and healing [31].

Based on the results of our study, we recommend to match the design of the prescribed FOS to patients gait stability. The Ortho-wedge shoe with negative heel and rigid high profile in rear- and midfoot and the shown effects on the rolling characteristics and patients' gait should be avoided in patients with pre-existing gait instabilities. The benefits of the Relief Dual® can therefore be used to enhance patient's compliance and allow more physiological characteristics in order to preserve falling. However, for a long-time use, both shoe models benefit from a contralateral twin shoe, since both models may negatively affect pelvic position and spinal posture.

There are also limitations of our study. First, we chose to measure healthy volunteers instead of actual patients following forefoot surgery. However, we believe that it is necessary first to investigate the effects of such shoes in a controlled population before evaluating real patients. Secondly, none of the volunteers were wearing shoes on the contralateral side. Being barefoot on one foot led to greater LLD and greater effects of the FOS on gait, pelvic position and spinal posture. However, by not having the subjects wear an individual shoe for compensation, we were able to control and measure just the effects of both FOS instead of having to worry about the shoe and its design on the contralateral side. Thirdly, we did not measure plantar pressure while walking with the respective FOS. However, focus of this study was to investigate the effects of FOS on gait, pelvic position and spinal posture and not to show reduction of plantar pressure, which was already demonstrated in previous studies [3,5,13,32].

## 5. Conclusions

As expected, our results showed that both here evaluated FOS lead to significant changes in pelvic position and spinal posture during standing and while walking. FOS create an LLD, which may be responsible for the effects on the musculoskeletal apparatus. Because of that companies and physicians recommend to wear a special support shoe on the contralateral side to compensate for the LLDs. However, most patients refuse to wear the support shoes, and can therefore be negatively affected by FOS. Our results showed that gait parameters are more affected by the traditional FOS half-shoe than by the "Relief Dual" shoe and that this shoe may lead to a more physiological roll-over of the foot.

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No funding was received for this study.

## Conflict of interest

The authors have none to declare.

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