Full length article

Effects of flexible and rigid rocker profiles on in-shoe pressure

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A B S T R A C T

Rocker profiles are commonly used in the prevention of diabetic foot ulcers. Rockers are mostly stiffened to restrict toe plantarflexion to ensure proper offloading. It is also described that toe dorsiflexion should be restricted. However, the difference in effect on plantar pressure between rigid rockers that restrict this motion and flexible rockers that do not is unknown. In-shoe plantar pressure data were collected for a control shoe and the same shoe with rigid and flexible rockers with the apex positioned at 50% and 60%. For 29 healthy female adults peak plantar pressure (PP), maximum mean pressure (MMP) and force-time integral (FTI) were determined for seven regions of the foot. Generalized estimate equation was used to analyse the effect of the different shoes on the outcome measures for these regions. Compared to the control shoe a significant increase of PP and FTI was found at the first toe for both rigid rockers and the flexible rocker with the apex positioned at 60%, while MMP was significantly increased in rockers with an apex position of 60% ($p < 0.001$). PP at the first toe was significantly lower in flexible rockers when compared to rigid rockers ($p < 0.001$). For both central and lateral forefoot PP and MMP were significantly more reduced in rigid rockers ($p < 0.001$), while for the medial forefoot no differences were found. The use of rigid rockers results in larger reductions of forefoot plantar pressures, but in worse increase of plantar pressures at the first toe compared to rockers that allow toe dorsiflexion.

1. Introduction

Up to 25% of all patients with Diabetes Mellitus (DM) will develop foot ulcers [1,2], which may eventually lead to amputation of the affected foot [1,3]. Most ulcers develop at the forefoot and first toe mainly due to changes in foot structures leading to elevated pressures at these sites [4–6]. Especially patients who have developed peripheral neuropathy as a result of DM are at high risk, because of reduced protective sensation [2,5].

Rocker profiles can be used to prevent development of diabetic foot ulcers by reducing pressure at the forefoot, where the metatarsal heads (MTH) are located, and the plantar tip of the first toe [7,8]. When designing a rocker profile, there are several features that can be altered to achieve the preferred offloading. The apex position, indicating the start of the rocker on the longitudinal axis of the shoe, is one of these variables. Previous studies have shown that offloading of the forefoot was achieved by an apex position placed between 50 and 60% of the longitudinal axis, measured from the heel [9–12]. Another variable that

can be altered is the apex angle, which indicates the angle between the apex and the longitudinal axis of the shoe. The apex angle is at 90° when placed perpendicular to the longitudinal and can be increased or decreased when the most lateral point of the apex is rotated in distal or proximal direction respectively [13].

Rocker profiles are mostly stiffened to limit sagittal plane motion of the Metatarsal phalangeal joints [10,13]. Flexibility that allows plantar flexion of the toes is never desired as it will compromise the rollover shape of the rocker profile, which can cause an increase in plantar pressure at the apex region. In literature it is sometimes stated that also dorsiflexion of the toes should be restricted to ensure that the ground reaction force is distributed over a larger area [10]. However, to the best of our knowledge, there have not been any studies that evaluated the difference in effect on plantar pressure between completely rigid rockers and flexible rocker profiles that only allow dorsiflexion of the toes. Therefore, the aim of the current study was to evaluate this difference in effect.

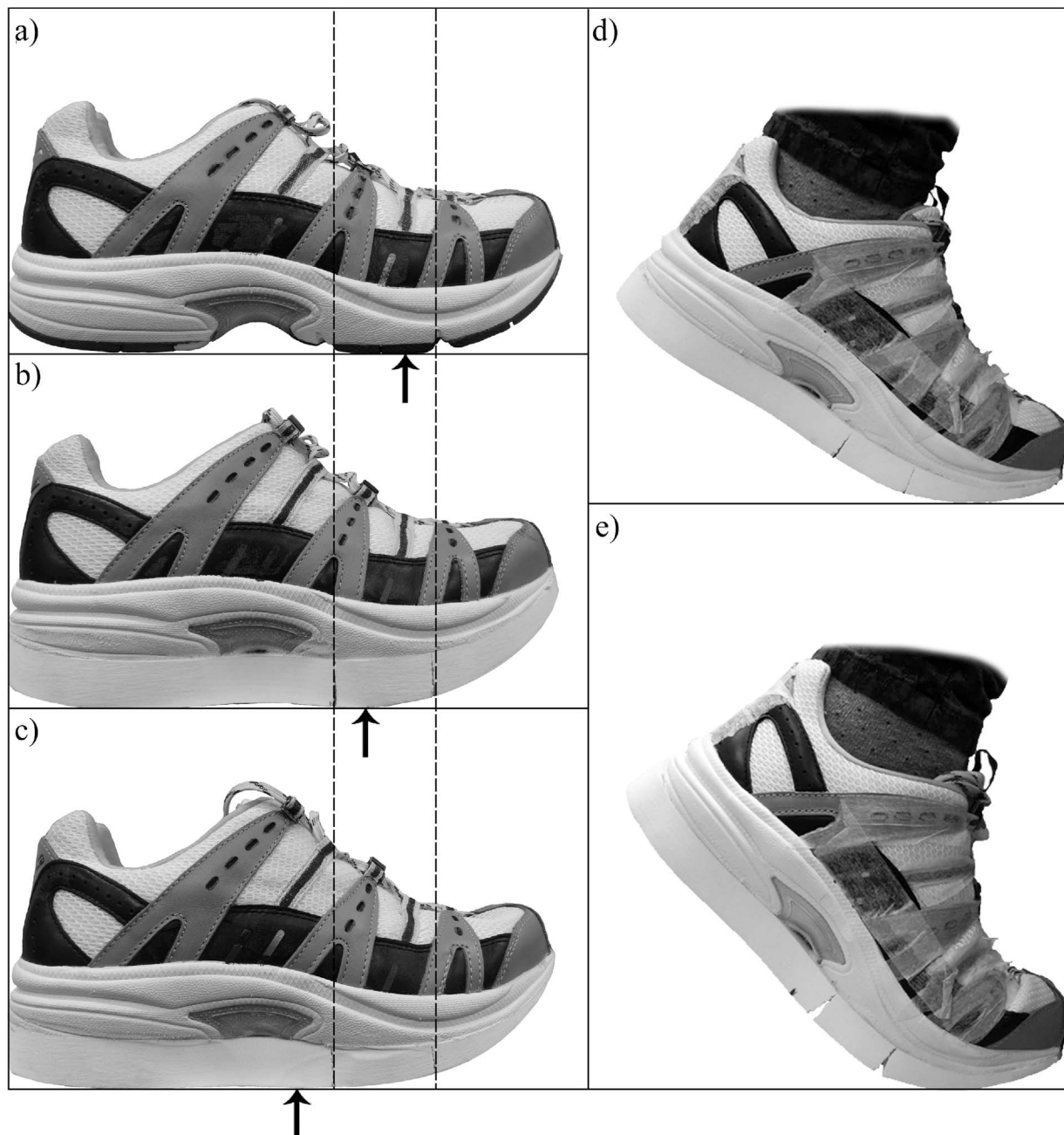We hypothesize that the use of completely rigid rocker profiles will

Fig. 1. Shoe modifications. On the left the apex positions for the control (a), modified shoe with apex position at 60% (b) and modified shoe with apex position at 50% (c) are indicated with a black arrow. The dashed lines indicate the position of the notches in the original sole and the cuts in the modified shoes. On the right the difference between the rigid (d) and flexible (e) configurations is shown (both loaded).

result in larger pressure reductions at the forefoot and first toe compared to rocker profiles that allow dorsiflexion of the toes. The hypothesis will be tested in rocker profiles with the apex positioned at 50% and 60% as these positions have shown to result in the best pressure reduction for the forefoot when walking on rigid rockers [10,11], while the apex angle remains similar to the control shoe. For the apex position we expect larger plantar pressure reduction at the forefoot compared to the control shoe when the apex positioned at 60% when compared to 50% [10,11].

2. Methods

2.1. Participants

Thirty healthy female adults participated in this study. Inclusion criteria were female sex, age 18 years and older, and shoe sizes EU38/39/40. This subgroup was selected to minimize the amount of shoes to be modified. Exclusion criteria were the use of custom inlays and self-reported pathologies or injuries that influence gait. All participants provided written informed consent before starting the experiments. The local Medical Ethics Committee approved conduct of this study (METc 2016.087).

2.2. Shoe conditions

Double depth shoes (Refresh-X, Dr Comfort, Mequon, WI, USA) sizes EU 38 M, 39 M and 40 M were used in this study. This type of shoes is commonly used in people with DM. For each size two pairs were modified, and one unmodified pair was used as control (Fig. 1a-c). The original soles of the modified pairs were sanded off and 20 mm of

Ethylene-vinyl acetate (EVA, 63 durometers, shore A) was used as replacement. The apex of the modified pairs was positioned at 50% and 60% of the total shoe length. For both modified pairs the apex angle (85°) and the radius (190 mm) were kept similar to the control shoe. Two cuts completely through the added EVA were made parallel to the apex at 55% and 70%, only allowing flexibility of the shoes for toe dorsiflexion (Fig. 1d-e). The position of these cuts corresponded to the notches that facilitate flexibility in the original sole design, and ensured that toe dorsiflexion is allowed for each participant as MTH1 is located between the cuts [10]. The force needed to dorsiflex the modified pairs was similar to the unmodified pair.

The modified shoes allowed for a total of four experimental configurations; 1) flexible with apex position at 50% (Flex50), 2) rigid with apex position at 50% (Rigid50), 3) flexible with apex position at 60% (Flex60), and 4) rigid with apex position at 60% (Rigid60). For rigid configurations the shoes were stiffened with removable carbon inserts. For flexible configurations and control shoes a cardboard insert of the same thickness was used. Flat EVA inlays (25 durometers, shore A, thickness: 6 mm) that came with the shoes were placed on top of the inserts for comfort. The mean(± SD) weight for each pair of shoes was 667(± 33), 686(± 20), 749(± 19), 728(± 37), and 790(± 41) grams for Control, Flex50, Rigid 50, Flex60, and Rigid60 respectively.

2.3. In-shoe pressure measurements

Pedar-X® insoles (Novel; Munich, Germany) were used to measure In-shoe plantar pressure. The insoles were calibrated by the manufacturer. The sampling frequency was set to 100 Hz and data were collected from both feet.

2.4. Experimental procedures

All measurements were performed at the Motion Lab of the Department of Rehabilitation Medicine, University Medical Center Groningen. Height and bodyweight were recorded and each participant was asked what foot she uses to kick a ball to determine the dominant foot. All participants were given the same type of socks (Ankle socks, Dr Comfort, Mequon, WI, USA). The control shoe was the first condition to determine the preferred walking speed. The following experimental conditions were first randomized on apex position (50% or 60%) after which flexible and rigid configurations were randomly assigned for each apex position. For each condition the Pedar-X® insoles were placed on top of the EVA inlays and zeroed as recommended by the manufacturer. For each condition three trials of walking up and down the aisle of the Motion lab were recorded. Preferred walking speed was determined using the SpeedClock application (Sten Kaiser, v9.1). Following trials in which the walking speed differed more than 10% from the preferred walking speed were deleted and repeated. Each participant scored shoe comfort after the last trial of each condition by placing a vertical line on a 100 mm Visual Analog Scale (VAS). The outmost left (0 mm) was labelled very uncomfortable and the outmost right (100 mm) was labelled very comfortable.

2.5. Data analysis

Only data from the dominant leg were analysed. For each trial the middle two steps for both walking up and down the aisle were selected using Pedar-X® Step analysis (Novel; Munich, Germany), resulting in twelve steps per condition for each participant [14]. Using Matlab (R2013a) data were further analysed. The sensors of the Pedar-X® insole were divided into seven masks (Fig. 2) representing: 1) first toe, 2) other toes, 3) medial forefoot, 4) central forefoot, 5) lateral forefoot, 6) midfoot and 7) heel [15]. Masks 1, 3, and 4 represent areas of the foot that are at largest risk for ulcerations [16]. Chapman et al. (2013) showed that changing apex positions and apex angles influences the pressure distribution across these masks [11]. Peak pressures (PP),
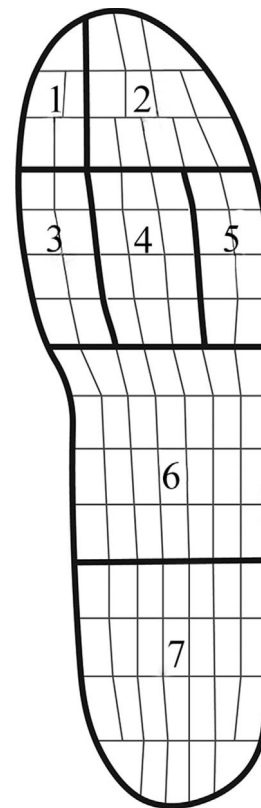

Fig. 2. Division of the 99 sensors of one Pedar® insole into seven masks. The numbers represent the following masks, 1: first toe, 2: other toes, 3: medial forefoot, 4: central forefoot. 5: lateral forefoot, 6: midfoot, and 7: heel.

maximal mean pressures (MMP) and force time integral (FTI) were calculated for each mask. PP was determined by selecting the peak pressures within each mask for every step. To determine MMP first the mean pressure for each mask was calculated for all timeframes within a single step, after which the timeframe with the maximum mean pressure was selected for every step. Finally, to determine FTI first forces were calculated for each sensor by multiplying all recorded pressures within a step with its own sensor area. Then FTI was determined as the sum of forces for each step divided by the frequency within each mask. VAS-scores were determined by measuring the distance from the left side of the scale up to the line drawn by the participant.

2.6. Statistical analysis

Means and standard deviations were determined to describe study population characteristics. PP, MMP and FTI were analysed separately using generalized estimate equation (GEE) with shoe condition, mask and step as within subject variables estimating the response of the shoe conditions. Natural log transformation was used for FTI as there was a positive skew the distribution. Friedman's test was used to analyse VAS for all shoe conditions. Post hoc Wilcoxon signed rank testing was used for pairwise comparison. All statistical analyses were performed using SPSS statistics (23.0.0.0). For both overall tests the level of significance was set at $p < 0.05$. For pairwise comparison using GEE and Wilcoxon signed rank testing Bonferroni correction was applied, resulting in a level of significance set at $p < 0.001$ and $p < 0.005$ respectively.

3. Results

Data for one participant were removed from the study, as it was not possible to select the needed steps with Pedar-X® Step analysis. For four of the remaining 29 participants one of the selected steps was removed

Table 1

Absolute values for in-shoe outcome parameters and p-values for corresponding pairwise comparisons. Flex 50: Flexible rocker with apex positioned at 50%. Flex 60: Flexible rocker with apex positioned at 60%. Rigid 50: Rigid rocker with apex positioned at 50%. Rigid 60: Rigid rocker with apex positioned at 60%. CI: Confidence interval. P_1: p-value found for comparison between control and Flex 50. P_2: p-value found for comparison between control and Rigid 50. P_3: p-value found for comparison between control and Flex 60. P_4: p-value found for comparison between control and Rigid 60. P_5: p-value found for comparison between Flex 50 and Rigid 50. P_6: p-value found for comparison between Flex 60 and Rigid 60. P_7: p-value found for comparison between Rigid 50 and Rigid 60. P_8: p-value found for comparison between Flex 50 and Flex 60. PP: Peak Plantar Pressure. MMP: Maximum Mean Pressure. FTI: Force-time integral. FF: Forefoot.

	Control mean [95% CI]	Flex 50 mean [95% CI]	Rigid 50 mean [95% CI]	Flex 60 mean [95% CI]	Rigid 60 mean [95% CI]	P_1	P_2	P_3	P_4	P_5	P_6	P_7	P_8
PP (kPa)													
First toe	215.0 [187.5; 242.5]	231.7 [201.9; 261.6]	258.2 [225.0; 291.3]	231.6 [204.6; 258.6]	256.9 [222.8; 291.1]	0.028	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.981	0.875
Other toes	133.0 [118.8; 147.3]	126.8 [113.3; 140.2]	126.7 [111.5; 142.0]	123.2 [110.9; 135.6]	118.7 [107.4; 130.0]	0.234	0.369	0.019	0.001	0.994	0.160	0.360	0.108
Medial FF	158.7 [144.2; 173.2]	151.5 [138.3; 164.8]	151.6 [137.3; 166.0]	149.0 [137.5; 160.6]	158.2 [143.8; 172.6]	0.009	0.055	< 0.001	0.881	0.972	0.008	0.226	0.014
Central FF	170.3 [160.2; 180.4]	154.5 [145.5; 163.4]	139.6 [130.5; 148.8]	159.3 [150.2; 168.4]	150.6 [141.0; 160.3]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.049	< 0.001
Lateral FF	137.8 [127.0; 148.6]	119.2 [110.3; 128.2]	107.6 [98.9; 116.2]	126.2 [115.3; 137.0]	114.7 [106.1; 123.2]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.018	0.014	0.001
Midfoot	82.6 [73.4; 91.8]	86.1 [76.5; 95.7]	88.2 [77.6; 98.8]	79.9 [70.9; 88.9]	85.4 [75.8; 95.0]	0.150	0.038	0.173	0.288	0.278	< 0.001	0.049	0.287
Heel	215.0 [201.4; 228.7]	236.9 [224.6; 249.2]	247.0 [232.8; 261.2]	241.3 [229.0; 253.7]	252.0 [235.5; 268.5]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.089	0.155
MMP (kPa)													
First toe	138.6 [123.0; 154.2]	146.0 [129.4; 162.7]	148.5 [130.9; 166.2]	151.0 [134.6; 167.4]	154.6 [137.4; 171.8]	0.073	0.063	< 0.001	0.000	0.476	0.141	0.108	0.206
Other toes	70.3 [63.6; 77.0]	68.5 [62.1; 75.0]	61.5 [55.1; 67.9]	67.6 [60.7; 74.6]	60.0 [54.3; 65.7]	0.437	< 0.001	0.137	< 0.001	< 0.001	< 0.001	0.596	0.349
Medial FF	98.4 [87.6; 109.2]	98.0 [88.2; 107.8]	96.9 [86.4; 107.3]	101.0 [91.0; 111.0]	104.5 [93.9; 115.0]	0.884	0.587	0.333	0.011	0.536	0.089	0.135	< 0.001
Central FF	108.4 [100.6; 116.2]	100.4 [95.0; 105.8]	90.1 [83.5; 96.8]	107.5 [100.9; 114.1]	101.9 [95.1; 108.8]	< 0.001	< 0.001	0.585	0.002	< 0.001	< 0.001	< 0.001	< 0.001
Lateral FF	90.9 [82.7; 99.0]	78.1 [71.0; 85.2]	72.3 [65.6; 79.1]	83.7 [75.9; 91.4]	76.7 [70.0; 83.3]	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Midfoot	25.0 [21.2; 28.8]	31.6 [26.9; 36.4]	29.1 [24.5; 33.8]	24.1 [20.7; 27.5]	25.1 [21.6; 28.7]	< 0.001	< 0.001	0.356	0.848	< 0.001	0.198	< 0.001	< 0.001
Heel	130.1 [121.2; 139.0]	141.0 [134.0; 147.9]	141.3 [133.6; 148.9]	140.8 [132.6; 148.8]	139.8 [130.8; 148.8]	< 0.001	< 0.001	< 0.001	< 0.001	0.783	0.356	0.902	0.382
FTI (N s)													
First toe	18.4 [15.8; 21.5]	20.6 [17.9; 23.6]	22.0 [19.0; 25.4]	21.8 [18.7; 25.5]	23.2 [20.0; 26.9]	0.006	< 0.001	< 0.001	< 0.001	0.014	0.012	0.058	0.159
Other toes	23.3 [20.2; 27.0]	22.8 [20.3; 25.6]	20.9 [18.5; 23.8]	23.7 [20.6; 27.2]	21.7 [19.2; 24.5]	0.633	0.015	0.724	0.058	0.007	< 0.001	0.363	0.331
Medial FF	27.3 [23.5; 31.7]	27.3 [23.8; 31.4]	28.8 [25.0; 33.1]	29.4 [25.4; 33.9]	30.7 [27.2; 34.7]	0.975	0.166	0.019	< 0.001	0.036	0.128	0.016	0.045
Central FF	51.2 [47.1; 55.5]	45.3 [42.6; 48.2]	42.8 [39.5; 46.3]	51.9 [48.3; 55.8]	49.6 [45.9; 53.5]	< 0.001	< 0.001	0.489	0.173	0.002	0.009	< 0.001	< 0.001
Lateral FF	31.6 [28.2; 35.4]	27.2 [24.7; 29.9]	26.3 [23.8; 29.2]	30.2 [27.3; 33.5]	28.4 [25.9; 31.1]	< 0.001	< 0.001	0.133	< 0.001	0.204	0.013	< 0.001	0.012
Midfoot	26.0 [20.2; 33.4]	33.8 [26.0; 44.0]	31.1 [23.8; 40.7]	26.3 [20.8; 33.2]	29.2 [23.4; 36.3]	< 0.001	< 0.001	0.860	0.002	0.006	0.053	0.002	0.195
Heel	110.5 [100.4; 121.7]	137.7 [130.8; 144.8]	137.6 [129.4; 146.3]	132.2 [125.2; 139.7]	130.2 [122.6; 138.3]	< 0.001	< 0.001	< 0.001	< 0.001	0.976	0.226	< 0.001	0.002
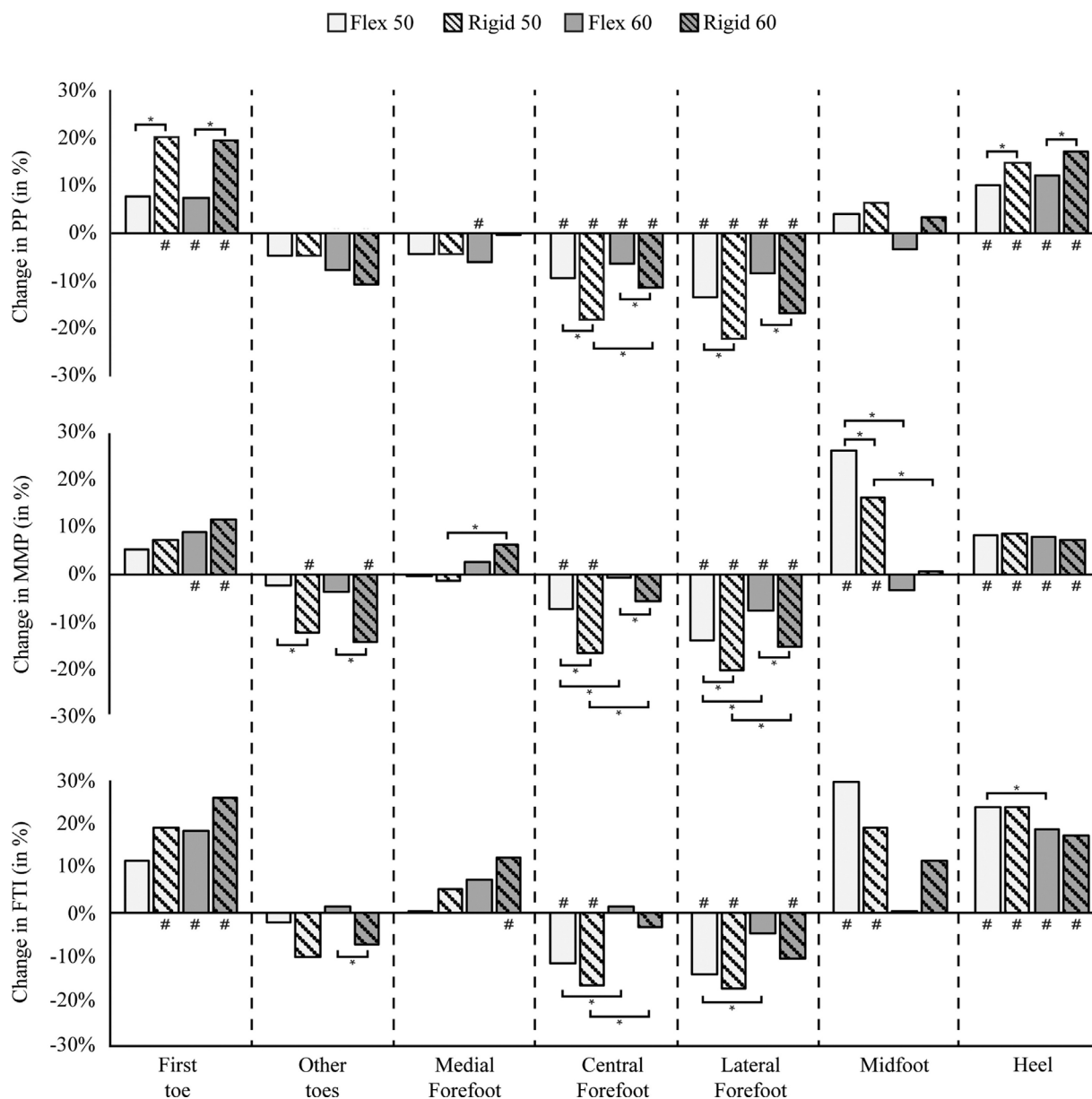
Fig. 3. Proportional differences (relative to the control shoe) in peak pressure (PP), maximal mean pressure (MMP) and force time integral (FTI) per mask for all four experimental conditions. Means of the experimental conditions were divided by the mean of the control shoe. Positive percentages indicate an increase in pressure compared to the control, while negative percentages indicate a decrease. Flex 50: Flexible rocker with apex positioned at 50%. Rigid 50: Rigid rocker with apex positioned at 50%. Flex 60: Flexible rocker with apex positioned at 60%. Rigid 60: Rigid rocker with apex positioned at 60%. #: Significant difference between the experimental conditions compared to control (p < 0.001). *: Significant difference between experimental conditions (p < 0.001).

because of missing data at the beginning or end of these steps. The analysed participants had a mean(± SD) age of 22(± 2) years, body-weight of 65.5(± 8.4) kg, and body height of 1.73(± 0.06) m. The average walking speed was 1.43(± 0.19) m/s.

Means and 95% confidence intervals for PP, MMP and FTI can be found in Table 1. The overall GEE, showed a significant difference between shoe conditions in PP (p = 0.032), MMP (p < 0.001) and FTI (p < 0.001). Differences in PP, MMP and FTI are visualized in Fig. 3.

Below only relevant statistically significant changes between rigid and flexible rockers (compared to the control) are described. Absolute values can be found in Table 1 and relative changes are represented in Fig. 3. Compared to the control PP was significantly increased in all rockers, except Flex50. The increase in PP was significantly larger (p < 0.001) in rigid rockers compared to flexible rockers.

For the medial forefoot only Rigid 60 resulted in a significant

decrease in PP compared to the control (p < 0.001). No significant differences in PP were found between rocker configurations for this mask. In both the central and lateral forefoot a significant decrease in PP was found for all rockers when compared to the control (p < 0.001). This was also found for MMP in the lateral forefoot, while in the central forefoot only rockers with the apex positioned at 50% resulted in a significant decrease in MMP (p < 0.001). In both masks, rigid rockers resulted in significantly lower PP (p < 0.001) and MMP (p < 0.001) compared to flexible rockers.

PP was significantly increased at the heel in all rockers compared to the control (p < 0.001). The increase was significantly larger (p < 0.001) in rigid rockers compared to flexible rockers.

The results for VAS are shown in Fig. 4. All experimental conditions scored significantly lower on comfort than the control shoe (p < 0.001). No differences were found between experimental conditions.
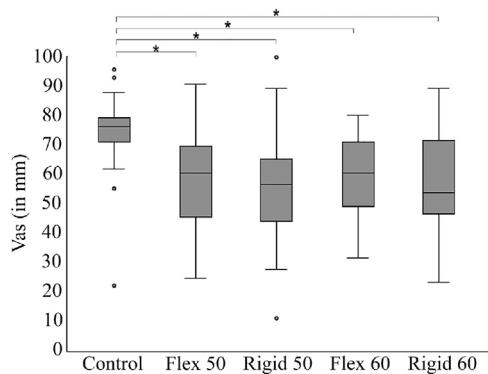
Fig. 4. Difference in comfort between conditions. Flex 50: flexible configuration, apex positioned at 50%, Rigid 50: rigid configuration, apex positioned at 50%, Flex 60: flexible configuration, apex positioned at 60% and Rigid 60: rigid configuration, apex positioned at 60%. *: significant difference (p < 0.005).

4. Discussion

To the best of our knowledge this is the first study that evaluated the difference in plantar pressure between rigid and flexible rocker profile shoes that only allow dorsiflexion. Compared to the control shoe rigid rockers showed larger plantar pressure reductions for the central and lateral forefoot than flexible rockers. For the medial forefoot however, no differences were found and for the first toe rocker shoes showed an increase in plantar pressure which was larger in rigid than in flexible rockers.

Compared to flexible rockers a significantly larger increase in PP was found for rigid rockers for in the first toe mask, where PP in rigid rockers were up to 26,5 kPa larger. While not significant, similar trends in effects were found in MMP and FTI. A similar increase in PP for rigid rockers with the apex positioned at 50% was found by van Schie et al. (2000) [10]. For the other toes there seemed to be a reduction in pressure compared to the control shoe. These findings were less pronounced than those of the first toe and were mainly supported by significant reduction in MMP for rigid rockers.

For both central and lateral forefoot masks, representing MTH2-5, a reduction in pressure was found which was more pronounced in rigid rockers as hypothesized, with differences in PP between 8.7 and 14.9 kPa. In contrast to previous studies [10,11], rigid rockers with an apex position at 50% resulted in a larger reduction than rockers with an apex position at 60%. There was hardly any change in pressure found compared to the control shoe for MTH1, which is represented by the medial forefoot mask. This is likely due to the apex angle (85°) which might be more suitable for offloading of MTH2-5 than for MTH1 [11].

For the midfoot there seemed to be an increase in pressures compared to the control shoe. Especially in MMP for rockers with the apex positioned at 50% there seemed to be a large proportional increase. However, the largest absolute increase in MMP was only 6.6 kPa, and the largest increase in PP was 5.6 kPa. Similar to some other studies [10,11] an increase in PP was found for the heel, which in this study are most likely due to the replacement of the soft original sole with harder EVA, resulting in less absorption of the forces at heel strike. This is supported by the significant larger increase in PP found for rigid rockers where the forces interact with a carbon plate that is more rigid than the EVA replacement.

The outcomes for VAS for comfort showed that all rockers were significantly less comfortable than conventional shoes. Between rockers no significant differences were found, indicating that in terms of comfort it likely does not matter for novel users if they wear rigid or flexible rockers. However, these findings may not be applicable for long term use, as the participants walked on each condition for a short time.

The results found in the current study cannot directly be generalized to all patients with DM as only healthy volunteers participated.

However, Chapman et al. (2013) showed that, despite differences in plantar pressure between healthy adults and low risk patients with DM, there are hardly any differences in the effect of the rocker variables between these groups [11]. Therefore, we consider the findings in this study to be very valuable for management of plantar pressure in patients with DM. Especially the findings for the first toe, that showed lower PP for flexible rockers compared to rigid rockers, give new insight in offloading of plantar pressures with rocker profiles as it concerns one of the high risk areas for ulcerations. These findings could be explained by the results found for the other toes, where a significantly larger reduction of MMP was found for rigid rockers compared to flexible rockers, while there were no differences in PP. This indicates that for rigid rockers there is less pressure in this mask suggesting that when toe dorsiflexion is allowed, plantar pressure is distributed across all toes while for rigid rockers it is mainly distributed across the first toe. We believe that the ground reaction force's point of application around push-off is forced towards the tip of the toe in rigid rockers as a result of the rocker features (apex position and apex angle), where in flexible rockers, because flexing of the shoe reduces the effects of these features, the point of application is shifted more towards the other toes.

For the first toe a flexible rocker may be the better choice, however, rigid rockers resulted in larger pressure reductions for the forefoot, which is also considered a high risk area. Depending on the areas at risk for each individual, determined by in-shoe pressure measurements, it can be decided what type of rocker suits best. Also, a hybrid between rigid and flexible rockers that allow toe dorsiflexion may result in better prevention of diabetic foot ulcers than completely rigid rockers.

There are some limitations to the current study. There was no real accommodation period before each condition, which might be needed with rocker shoes. Although the accommodation period was short, the data showed no systematic changes in pressures over the twelve measured steps within subjects, indicating no additional accommodation. Also, it would have been preferable to have used individually chosen apex angles, based on the foot progression angle of each individual. However, this would mean we had to make individual rockers for each subject. Another limitation is that the modified shoes were not equipped with a rubber sole to prevent slipping. Some of the participants' feet slid during push-off when they started walking, or when they slowed down at the end of the aisle. As only midgait steps were selected we expect that this will not have affected the outcomes. Finally, for four participants eleven steps were suitable for analysis where twelve are recommended when using Pedar-X® [14].

5. Conclusion

The current findings support the use of rigid rockers that restrict toe dorsiflexion for the reduction of plantar pressures at MTH2-5 but not for MTH1. For the first toe, restriction of toe dorsiflexion results in higher plantar pressures compared to rockers that do allow this motion. Further work is needed to evaluate if flexibility that allows dorsiflexion of the first toe also results in lower pressures for other apex angles and to evaluate the effects of a hybrid between rigid and flexible rockers that allow toe dorsiflexion.

Conflict of interest

The authors have no conflict of interest in this study.

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