Influence of medial wedge insoles while walking on different geometry and surface hardness

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***Abstract*—In order to understand medial wedge insoles while walking on different surface hardness and geometry, we investigated the plantar pressure and rearfoot movement. Twenty eight subjects with normal feet were recruited. Five trials were collected with and without insole conditions, both on a hard and soft surface and on level and stair walking. Six plantar pressure parameters (PP, CA, CT, MF, PTI and FTI) and five rearfoot parameters (TO, TD, Max, Min and Vel) were calculated. The soft surface did not change the effectiveness of the wedge insoles, but the surface geometry produced significant changes. Only the Max and Min recorded changes both in hardness and geometry.**

I. Introduction

Walking is among the most fundamental locomotory capabilities of the human body [25], and along with stair climbing, it is one of the most frequent activities performed on a daily basis [1], [25], [17]. Stair climbing compared to level walking is considered to offer a biomechanical and physiological challenge, demanding a larger range of motion from the lower extremities [1]. Also Liikavainio et al [9] states that there is a greater loading on the musculoskeletal system when descending on stairs compared to level walking. In order to protect the foot from damage caused by foot-surface interactions, people chose to wear shoes. The distribution of the plantar pressure varies depending on the area of the foot where a force is acting. Thus, the distribution can be even or uneven, depending on the stepping surface: geometry, hardness and materials [25].

Over 25% of the working people maintain painful and tiring postures for half of their time spent at work. Maintaining this type of postures can cause lower back and lower extremities pain and thus affect the social life, overall productivity and well-being of the workers. It has been shown that standing on a soft surface increases the comfort feeling and reduces the postural activity [10], [3]. However, when performing dynamic movements, Moritz and Farley [13] determined that there is a 50% increase in muscle activation when hopping on a soft surface compared to a hard floor. Furthermore, in regards to running, Kerdok et al. [6] identified an increase of almost 1/3 in leg stiffness when performing on a soft surface.

A walking surface consisting of soft materials has been shown to alter the normal gait pattern of healthy people [24]. Also, the normal biomechanical function could be inhibited when an outside factor such as, in-shoe orthotic intervention, is applied to the body [19]. Furthermore, a correlation between stair walking and higher demands in regards to joint range of motion, reaction forces and moments was found by Rao & Carter [17] when contrasted to level walking. The information provided by evaluating the plantar pressure while walking on stairs can be used when assessing the potential of foot pain development, damage to tissue or other symptoms [17]. Collecting precise, measurable data, in regards to plantar pressure is important as it provides information on deciding a diagnostic, offering feedback to the patients and customizing plantar orthotic interventions [21]. Information regarding the plantar pressure distribution can provide relevant information which can facilitate the optimization of the production of insoles [21].

The aim of the study was to investigate medial wedged insoles on two different surface hardness and geometry by looking at plantar pressure and rearfoot movement.

The purpose was to quantify the effects of the mentioned situations by measuring the plantar pressure and the rearfoot motion, thus the following hypotheses were tested :

- H1: A statistical significant difference will be observed between the surface geometries in regards to plantar pressure and rearfoot pronation angle.
- H2: No statistical difference will be observed between the hard and the soft surface in regards to the two measurements.
- H3: There will be statistical difference between wearing and not wearing medial wedge insoles.

II. Method

A. Subjects

A number of 28 healthy participants with no lower leg pain one week prior to testing [11] or history of trauma in the last six months were included in the study [17]. Twenty four men and four women with an average age of 25±1.8 years, height 180.07±7.56 cm, weight 76.64±9.69 kg and body mass index (BMI) of 24±2 gave their consent to participate in the study. The included participants needed to have their shoe size within the range of 40-45 of the full-length medial wedge insole (Rehband, Technogel® — Pes Velour). To determine if the subjects are qualified as having healthy feet, a Foot Posture Index, the six item version, (FPI-6) was carried out. The subjects within an index value of 0 to 5, the normal range, were accepted [11], [12]. All the assessments were made by the same researcher, a physical therapist [17].

B. Design

In this study the subjects had to perform walking activities on a course, while wearing off-the-shelf medial wedge insoles. To increase the effects caused by the insoles, the researchers doubled the height, by placing two pairs of insoles one on top of the other, thus producing a full length 10º medial wedge insole [12]. The 10º angle of the medial wedge insole has been identified by Mølgaard & Kersting [12] as the maximum height for insole wedges for osteoarthritis.

In order to evaluate the effectiveness of the insoles, plantar pressure and rearfoot pronation angle data were collected. Insoles have been determined as an effective solution in combating foot deformities and trauma [8], ergo, the quantification of plantar pressure and rearfoot movement were chosen to evaluate the derivative of wearing an insole.

C. Protocol

1) Service course : A course of 10m walkway [12] and 11 stairs (25cm high and 25cm deep) with a mix of hard and soft surface was prepared prior to testing. The hard surface (HS) was made out of concrete, covered by hone and wood. The soft surface (SS) was constructed by applying a foam of 3cm on top of the hard surface.

2) Walking situations: Participants were asked to walk at a self-selected walking speed within a range of ±5% [17], [11], monitored with the help of a stop watch. The stair walking was performed in a step-over-step manner. On the last stair, the subjects were asked to maintain their upright position, turn around and then descend in the same manner [17]. The trial ended when the subjects performed walking on a 10m walkway, ascend, turn, descend on stairs and walk 10m back to the starting point. Due to the mixed hardness of the course, the starting point was moved from one side to the other, thus ensuring an equal amount of steps and trials on each surface and walking condition.

Two interventions were tested on the course :

- without the 10º medial wedge insoles (WOI)
- with the 10º medial wedge insoles (WI)

The medial wedge insoles are made out of Technolgel®, a shock absorbing material, used to counteract pronation or supination by providing support medially or laterally to the foot [18]. A running shoe (Nike® Air Pegasus) was used as reference for both testing conditions.

Before the data collection was performed, the subjects were asked to familiarize themselves with the testing insoles for 10 minutes in order to ensure the proper fit of the wedge insoles and comfort of the subjects. Five trials were collected for each condition. To ensure standardization, the subjects were asked to start each trial with the same foot. A successful trial was considered when the subject performed the full course without any double steps of the same foot. The order of the testing condition and starting point were randomized using random.org.

Figure 1: Service course, where HS is the hard surface and SS is the soft surface

D. Measuring techniques

1) Plantar pressure measurement : The plantar pressure was measured using Pedar-X in-shoe system (Novel GmbH, Munich, Germany) in order to investigate if the effect of the medial wedge insoles was maintained over all environments: flat walking (Wk1), stairs ascending (Wk2), descending (Wk3) and surface conditions: HS and SS.

The pedar insoles are flexible pressure-sensing insoles comprised of 99 sensors with a width of 2 mm [2]. Using a trublu calibration device, each of the insoles were calibrated prior to testing. The accuracy of the novel system was confirmed by testing the system one week before data collection. A frequency of 100 Hz was used to measure the vertical plantar

(a) Medial wedge insole (Rehband, Technogel® — Pes Velour)

(b) Reference shoe (Nike® Air Pegasus)

Figure 2: Testing conditions and shoes

pressure. The data were transmitted via Bluetooth to the computer and stored on an SD card.

A 2-minute accommodation period, for wearing the system, was allocated to the subjects (see Figure 3b). Before any measurements were collected, the system is initialized to 0, by asking the subject to concomitantly unload the insoles [14].

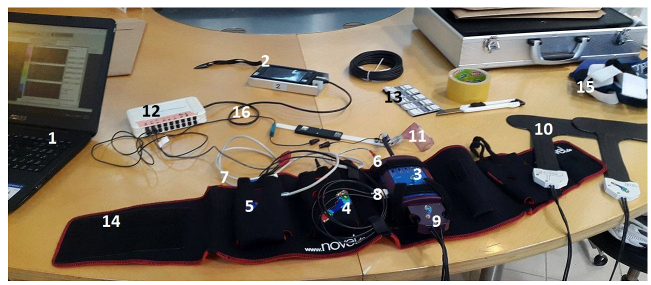
2) Rearfoot angle measurement: The inclination angle of the rearfoot was measured using a custom made heel electrogoniometer (See Figure 3a) in order to assess the impact of the wedge insoles over changes in environment and surface.

The electrical goniometer was mounted on the left heel of each subject. The goniometer was comprised of a guiding sleeve gliding on a plastic lever. The sleeve was secured on the bisectional line of the posterior aspect of the shank. The lever was coupled using a two-joint mechanism with a rectangular tail of thermoplastic. This lower segment was custom shaped to fit each of the subjects heel. It was mounted on the bisectional line of the calcaneus in a manner that followed the lever's alignment. On the two-joint mechanism, a potentiometer (MPC05 R5K, Megatron, Putzbrunn) was attached, such that it followed both the line of the subtalar joint and the bisectional line of the calcaneus. The device was properly secured with tape to prevent any movements during the recording of the data [7]. A calibration was done prior to testing by recording the values of 0° and ±45°. A frequency of 200 Hz was used to record the rearfoot angle. The data were transmitted to a minicomputer and saved as an ASCII file.

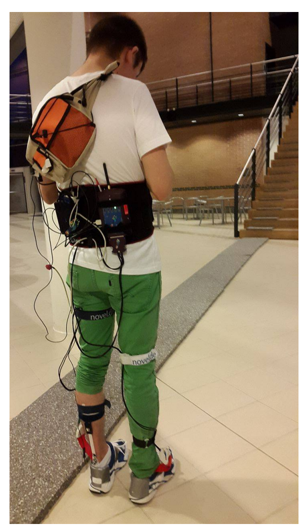
The Pedar-X and the goniometer were synchronized using the sync setup from Pedar-X recorder software. A reference measurement was made by collecting a static trial barefoot (BF), WOI and WI. The shod static trials were made by recording a static double limb support period of two seconds prior to every trial.

E. Data analysis

Even though, one step is considered distinct from another, when analyzing a healthy subject, there is no significant difference from the right step to the left one [16]. Hitherto,



(a) Equipment: 1. computer, 2. minicomputer, 3.pedar-x box, 4. pedar-x battery, 5. pedar-x sync box, 6. pedar-x battery cable, 7. pedar-x sync cable to the connector box, 8. pedar-x optical cable, 9. pedar-x double insole cable, 10. pedar-x insoles, 11. custom made goniometer, 12. connector box, 13. SD cards, 14. pedar-x belt, 15. velcro straps, 16. goniometer cables



(b) Equipment mounted on the subject

Figure 3: Experimental setup

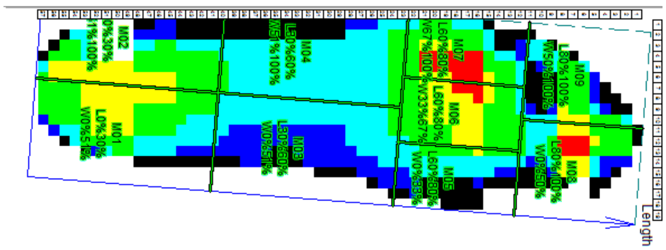


Figure 4: Percentile mask where: medial rearfoot (M01), lateral rearfoot (M02), medial midfoot (M03), lateral midfoot (M04), first metatarsal head (M05), second and third metatarsal head (M06), forth and fifth metatarsal head (M07), first and second toe (M08), third, forth and fifth toe (M09)

the right foot data collected were discarded and only the left was used.

It was observed during data processing that some sensors displayed faulty readings, thus requiring correction. Using Pedar Emedlink version 22.3.3 (Novel GmbH, Munich, Germany) the left steps were separated from the right ones and saved as individual files. The step files were divided into twelve categories:

- WOI on HS (WOIh) during flat walking (Wk_1)
- WOI on HS during stair ascending (Wk_2)
- WOI on HS during stair descending (Wk_3)
- WI on HS (WIh) during Wk_1
- WI on HS during Wk_2
- WI on HS during Wk_3
- WOI on SS (WOIs) during Wk_1
- WOI on SS during Wk_2
- WOI on SS during Wk_3
- WI on SS (WIs) during Wk_1
- WI on SS during Wk_2
- WI on SS during Wk_3

A total number of 8.400 steps, 25 for each category, were loaded into Novel Database Pro m version 22.3.41 (Novel GmbH, Munich, Germany). The foot was divided into ten regions taking into account the anatomic markers and the shape of the medial wedge insole. The pressure distribution picture was divided into ten masks in accordance with the anatomic regions. The masks were created using Novel multimask softwear: medial rearfoot (M01), lateral rearfoot (M02), medial midfoot (M03), lateral midfoot (M04), first metatarsal head (M05), second and third metatarsal head (M06), forth and fifth metatarsal head (M07), first and second toe (M08), third, forth and fifth toe (M09) and the total foot (M10). Descriptive statistics were rendered for six parameters: peak pressure (PP), maximum force (MF), contact area (CA), contact time (CT), pressure-time integral (PTI), force-time integral (FTI).

The data from the goniometer were synchronized with the force profiles from the Pedar-X and processed in Matlab R2015b version 8.6.0.267246 (© 1994-2016 The MathWorks, Inc., US), where the data were filtered using a second order Butterworth filter and divided into steps. For each step the take-off (TO), touch-down (TD), maximum angle (Max), minimum angle (Min), velocity (Vel) and static measurement were computed. Afterwards the data were exported into Excel where the twelve categories were constructed and descriptive statistics were rendered.

After the data were calibrated, the following definitions were established:

- negative angle values will describe a supinated foot
- positive values will characterize a pronated foot.

F. Statistics

The statistical analysis was realized with the help of R version 3.2.3 (© 2015, The R Foundation for Statistical Computing). For all data, a Q-Q plot was created and a Shapiro-Wilk test was applied in order to check for normal distribution. Not all data were normally distributed. For the normally ditributed data, a one-way Anova was applied to determine if there is any difference with the parameter data, if so a post-hoc multiple comparison Tukey HSD (honest significant difference) test was performed in order to analyze the effect of the insole, surface hardness, surface geometry, insole*hardness, insole*hardness*geometry. The analysis was divided into two sub-analyses, one pertaining the interaction between the insole and surface hardness (referred as conditions) and one pertaining the walking surface geometry. The statistical significance value was set at $p < 0.05$.

III. Results

This section was divided into three individual subsections for a better understanding of the results. The first subsection will contain the results for flat walking, ascending stairs and descending stairs (Wk1, Wk2 and Wk3). The second subsection will provide the results for the surface hardness (HS and SS). The last subsection will present the results for the insole conditions (WIh, WIs, WOIh and WOIs). The results will be presented as ratios.

The PP, CA and PTI were discarded from this study, due to the fact that PP is more commonly used in clinical studies [2]. The results for these three parameters were moved in the Workpapers Appendix.

A. Surface geometry

1) Contact time: Tabel I presents the results of parameter CT.

Statistical difference was seen medio-laterally between the midfoot masks, M03-M04 with a 9% increase in CT for Wk1, 6% decrease for Wk2 and 11% increase for Wk3. The Wk2 was found to be statistically significant from the other two walking geometries.

A significant increase of 5.6% in CT was observed between the medial (M05) and lateral forefoot masks (M07) when Wk1. The surface geometry Wk3 and Wk1 was found to be statistically different from Wk2.

However, in the toe masks M08-M09 the CT recorded a significant decrease of approximately 13% while Wk1. Furthermore, Wk1, Wk2 and Wk3 were found to be statistically different from each other.

A statistical significant difference in CT was seen between the rearfoot and the midfoot medial masks (M01-M03) with a 32.6% in Wk2. Also Wk2 was found statistically different from Wk1. Between the rearfoot and the midfoot lateral masks (M02-M04) a statistical increase of 11% was seen for Wk1, 21% for Wk2 and 16% for Wk3, however, only a statistical difference was found between Wk1-Wk2.

Also a statistical significance was found laterally between the midfoot and forefoot CT. A ratio of 66% was identified between M03-M05 for Wk3. Statistical difference was seen between M03-M06 for Wk1 with 9% and Wk3 with 17%. A significant increase of 12 % in CT was present while walking on Wk2 between M04-M06 and M04-M07. For the midfoot and forefoot walking on Wk2 was found to be statistically different than walking on Wk1 or Wk3.

Furthermore, statistical decrease was present in CT between the forefoot and the toe regions with 7% between M06-M08 for Wk2, 16% between M06-M09 and 18% between M07-M09 for Wk1. For the forefoot and toe regions the walking geometries were found to be statistically different from each other, except for M07 where no significance was found between Wk1 and Wk3.

Overall, when looking at the total CT (M10) statistical difference was found between all surface geometries.

2) Maximum force: The results for MF parameter are illustrated in Tabel II.

A significant increase in MF was seen medially from laterally in the midfoot masks (M03-M04) in Wk1 with 72% and in Wk3 with 75%. The walking surface geometries were found statistically different from each other in the midfoot masks.

A lower significant increased effect (14%) was seen in the forefoot masks M05 and M06 in Wk1. In the forefoot, Wk2 was statistically different from Wk1 and Wk3.

Further, a significant decrease of 78 % was also present in the toe masks M08-M09 while on Wk1. However, significant difference was seen between the walking surface geometries.

Significant difference was detected between the rearfoot and the midfoot medially (M01-M03) with 88 % for Wk2 and laterally (M02-M04) with 87% for Wk1, 30% for Wk2 and 28% for Wk3. All surface geometries recorded statistical significance from each other.

Between the midfoot and forefoot statistical difference was registered medially for M03-M05 (with 52% in Wk3) and M03-M06 (with 133% on Wk1 and with 91% on Wk3) and laterally (M04-M06 and M04-M07 with 82% in Wk2). All walking geometries were significant in the midfoot region, but in the forefoot no statistical significance was found between Wk1-Wk3, exception being the M06 mask were Wk2-Wk3 had no significance.

Moreover, between the toes and the forefoot a significant increases was recorded in MF at M06-M08 when Wk2 with around 114% and M06-M09 and M07-M09 with approximately 70% while Wk1. Significant changes were recorded in the toe regions between the walking geometries.

The total MF (M10) recorded significant changes in surface geometry between Wk1-Wk2, Wk1-Wk3, Wk2-Wk3.

3) Force-time integral: In Table III the results of the FTI parameter are presented.

Variables		*M01*	*M02*	*M03*	*M04*	*M05*	*M06*	*M07*	*M08*	*M09*	*M10*
WIh	*Wk1*	633.72±51.46	605.91±66.09	647.48±46.73	660.50±50.82	636.36±51.38	667.64±42.45	686.39±45.47	643.55±54.85	559.16±72.29	747.41±41.82
	Wk2	465.15±150.10	600.65±99.23	717.68±84.14	708.00±89.25	760.80±74.44	767.31±73.53	764.90±74.31	705.24±90.38	743.92±80.03	768.38±73.44
	Wk3	599.72±69.52	550.57±78.47	615.15±64.61	652.74±64.88	680.88±53.91	703.58±55.76	701.51±57.47	693.25±58.15	674.98±65.47	705.63±56.23
WIs	*Wk1*	654.35±45.90	628.74±57.99	687.44±40.09	683.30±44.78	685.52±42.11	702.80±38.15	713.08±42.66	692.77±52.55	581.16±69.49	764.17±38.89
	Wk2	520.27±137.34	646.28±91.97	748.54±89.30	756.19±85.67	792.17±74.45	798.05±74.23	797.23±73.97	741.51±89.58	791.46±74.37	798.48±74.17
	Wk3	645.42±62.87	603.00±70.77	650.88±59.63	658.20±59.28	699.36±55.11	701.17±54.83	698.34±55.45	692.90±59.99	666.86±69.37	706.83±54.90
WOIh	*Wk1*	587.87±54.40	571.80±62.61	550.51±58.16	660.23±46.41	625.82±42.23	651.82±36.08	666.83±36.69	628.47±52.07	576.24±53.19	726.94±36.95
	Wk2	531.69±139.97	477.98±142.10	707.39±91.38	618.85±112.85	758.73±68.48	763.29±68.57	760.56±69.18	712.62±77.57	746.61±69.23	754.95±67.26
	Wk3	527.04±84.84	493.73±92.04	501.47±83.38	627.52±58.64	676.78±49.19	678.94±53.03	676.76±56.32	672.91±51.73	662.70±57.67	680.72±49.99
WOIs	*Wk1*	600.79±50.22	606.04±59.84	591.07±52.57	698.27±45.01	664.79±40.82	684.89±38.75	697.91±37.53	660.78±42.77	589.30±62.05	752.50±38.27
	Wk2	586.27±136.54	519.13±142.06	743.78±94.32	682.76±100.70	784.87±81.97	786.58±81.84	784.10±80.07	748.88±86.37	772.03±83.38	775.57±81.30
	Wk3	588.29±75.53	569.03±78.80	572.09±74.97	662.60±59.36	697.19±60.00	700.85±57.03	699.92±57.19	690.93±60.31	677.40±67.65	701.99±58.00

Table I: Contact time (ms) Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

Variables		M01	M02	M03	M04	M05	M06	M07	M08	M09	M10
WIh	*Wk1*	310.49±30.92	206.98±27.06	48.83±10.45	63.34±15.14	119.64±20.99	205.08±14.08	163.87±24.06	165.78±30.28	71.08±16.34	792.74±37.99
	Wk2	42.09±22.64	120.01±42.68	95.20±24.43	84.12±23.22	111.48±19.23	181.26±15.81	152.15±26.96	39.76±9.47	96.87±22.70	744.93±38.21
	Wk3	192.15±54.14	122.15±33.94	82.53±20.08	93.71±21.41	120.16±20.11	189.77±20.92	159.17±22.87	81.04±25.14	42.06±16.13	894.53±66.20
WIs	*Wk1*	321.72±34.37	199.59±28.88	54.54±10.94	57.50±11.85	117.99±18.67	176.23±14.08	132.97±20.22	177.47±28.82	72.72±19.86	795.18±32.69
	Wk2	35.32±19.36	125.67±37.84	89.15±18.76	96.15±20.69	88.71±14.56	149.34±15.10	147.74±22.61	37.70±7.89	109.60±20.48	743.32±38.63
	Wk3	251.54±53.08	142.79±31.08	107.98±19.41	93.95±17.70	106.25±20.07	148.38±22.30	119.62±20.83	72.97±26.14	33.52±15.31	939.58±70.41
WOIh	*Wk1*	283.36±21.33	230.22±18.56	25.70±6.25	120.27±28.14	128.09±24.78	197.45±14.20	149.13±26.12	178.22±29.31	79.80±11.32	778.70±31.04
	Wk2	51.29±27.59	76.79±41.33	149.30±40.49	53.25±18.52	104.93±21.35	197.04±20.75	191.98±33.36	44.40±9.67	111.72±26.35	779.02±33.78
	Wk3	173.70±45.16	122.05±35.99	47.65±22.38	169.90±31.56	138.97±25.67	194.44±25.73	149.31±22.30	93.59±37.14	50.63±16.45	962.52±63.67
WOIs	*Wk1*	292.89±25.65	232.15±23.23	24.80±5.03	111.73±23.95	133.29±20.60	173.44±13.79	132.66±22.66	174.19±22.77	80.25±11.65	792.46±32.91
	Wk2	50.63±25.29	67.33±35.09	134.87±28.59	54.48±16.81	93.44±15.82	163.80±19.07	196.86±28.02	67.29±13.61	106.97±21.75	738.11±40.78
	Wk3	203.27±46.25	149.55±36.73	54.94±15.66	167.56±26.56	116.91±22.20	152.54±23.28	126.91±21.18	78.92±31.03	43.14±14.33	942.20±63.47

Table II: Maximum force (N) Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

A significant difference in FTI was seen between the medial and the lateral side of the rearfoor, midfoot and toe masks. A decrease of 40% on Wk1 and 54.8% on WK3 was present between M01-M02 and an increase of 76% for Wk2. The midfoot masks (M03-M04) recorded an increase of 81% on Wk1 respectively 72% on Wk3, but a 57% decrease on Wk2. Between M08-M09 a decrease of 79% was present for Wk1, 98% for Wk2 and 67% for Wk3.

Between the rearfoot and the midfoot a statistical difference was seen both medially and laterally. On the medial side the FTI decreased with over 100% when walking on Wk1 and Wk3, but the exact opposite was observed in Wk2. When Wk1, the lateral masks (M02-M04) recorded a decrease of 66%.

A significant increase of 80% was found medially when comparing the midfoot with the forefoot while on Wk1 and Wk3. Laterally, a statistical increase of around 50% was seen for Wk1 and Wk3, and around 90% for Wk2.

The toe regions registered a range ratio of 40% - 116% of significant increase at the forefoot in all walking conditions.

Overall there was no statistical significance between the walking surface geometries. However, when dividing the foot into anatomic regions results show statistical significant values in all of them. In the rearfoot Wk1 was significantly different from Wk2 and Wk3, in the midfoot the significance was seen between Wk2-WK3, in the forefoot between Wk1-Wk2 and in the toes Wk2 was statistical different in regards to Wk1 and Wk3.

4) Rearfoot angle : No statistical significant differences in surface geometry was found for the TD and TO angle, but the Min, Max and Vel reported statistical significance between Wk1-Wk2 and Wk1-Wk3.

B. Surface hardness

1) Contact time: Statistical significant difference was recorded between the hard surface (HS) and the soft surface (SS) in both insole conditions (WI and WOI), where the soft surface produced an increased CT of around 2% for the WI (HS: 747.41±41.82 and SS: 764.17±38.89) and 3.4 % for WOI (HS: 726.94±36.95 and SS: 752.50±38.27) while walking on a flat surface.

Also, ascending stairs produced a significant increase in CT between the two surface hardness and the two insole conditions, 3.4% for WI (HS: 768.38±73.44 and SS: 798.48±74.17) and 2.7% for WOI (HS: 754.95±67.26 and SS: 775.57±81.30).

Furthermore, when descending on stairs, a statistical increase of 3.1% was seen, but only in the WOI condition (HS: 680.72±49.99 and SS:701.99±58.00).

Overall, no statistical significance was found between the two surface hardness condition in the CT parameter.

2) Maximum force: A significant increase in MF between the hardness conditions while level walking was found for both WI and WOI with approximately 0.3% for WI (HS: 792.74±37.99 and SS: 795.18±32.69) and 1.8% for WOI (HS: 778.70±31.04 and SS: 792.46±32.91).

The MF recorded a significant decrease, while ascending stairs between the hard and the soft surface. With insole, a 0.2% difference was found (HS: 744.93±38.21 and SS:

Variables		M01	M02	M03	M04	M05	M06	M07	M08	M09	M10
WIh	Wk1	100.64±17.19	58.56±11.76	16.33±4.14	22.48±7.06	40.13±8.64	68.70±7.40	57.85±10.50	39.38±8.78	15.99±4.46	420.06±26.30
	Wk2	13.45±9.04	48.06±22.72	43.08±13.21	35.99±11.57	52.95±11.05	85.94±12.45	73.65±15.67	14.33±4.60	58.21±11.43	403.01±41.76
	Wk3	59.09±22.08	31.70±13.09	26.60±7.75	27.33±8.35	50.78±10.39	82.73±12.10	68.44±13.87	32.28±9.90	15.96±6.63	394.99±37.31
WIs	Wk1	109.07±16.82	60.64±12.86	19.72±4.43	20.71±5.58	42.20±7.50	63.37±6.51	50.38±8.43	48.26±9.30	18.06±5.73	432.41±23.84
	Wk2	12.63±8.99	55.91±23.04	40.29±10.07	41.42±10.73	45.12±8.39	76.37±9.46	75.50±12.08	15.87±4.32	49.73±11.55	413.01±40.20
	Wk3	86.91±26.30	39.76±13.66	38.17±7.66	29.59±7.31	47.04±10.10	66.37±11.57	52.82±11.49	30.47±10.48	12.37±6.06	404.07±40.68
WOIh	Wk1	85.24±13.15	67.34±11.46	6.84±1.71	47.00±13.59	41.26±10.09	67.69±6.97	54.69±10.42	42.36±10.10	19.87±3.84	432.30±24.32
	Wk2	18.16±12.36	26.98±19.24	65.28±22.45	19.06±6.98	49.71±11.64	94.11±14.50	87.81±18.37	16.31±4.70	40.07±13.09	417.73±39.19
	Wk3	45.14±17.66	28.36±12.89	9.98±6.91	51.94±15.05	57.08±12.53	83.87±12.90	63.03±11.90	35.45±13.28	19.19±6.58	394.38±37.64
WOIs	Wk1	89.94±12.61	68.70±10.83	7.96±1.62	44.43±11.24	44.93±8.75	61.32±5.92	51.39±9.52	44.85±8.41	21.59±4.03	435.30±25.32
	Wk2	20.29±13.53	26.73±19.29	63.61±18.53	20.88±7.61	49.36±10.08	84.96±12.53	86.11±15.55	18.74±5.29	46.10±12.37	417.00±45.93
	Wk3	62.66±22.05	42.15±16.35	14.18±5.12	61.85±15.04	50.36±11.30	67.87±12.69	56.84±12.20	30.32±12.89	16.85±6.89	402.62±43.33

Table III: Force-time integral (N*s) Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

743.32±38.63) and for without insole a 5.4% difference (HS: 779.02±33.78 and SS: 738.11±40.78).

The hard surface (962.52±63.67) recorded an significant decrease of 2.9% in MF from the soft surface (SS: 942.20±63.47) when the subjects did not have the wedge insole applied. This significance was found while descending stairs.

3) Force-time integral: No statistical significant difference in FTI was recorded between the two surface hardness conditions in all three surface geometries and insole conditions.

4) Rearfoot movement: Statistical significance was found in the static measurement of the rearfoot angle (see Table V) between the hard and the soft surface in a barefoot and with insole condition.

No statistical significant difference was identified in all rearfoot movement parameters between a hard surface and a soft one.

C. Insole conditions

1) Contact time: When walking on a hard surface between WI and WOI a decrease of 2.8% in CT was seen in level walking (WI: 747.41±41.82 and WOI: 726.94±36.95), 1.8% when ascending stairs (WI: 768.38±73.44 and WOI: 754.95±67.26) and 3.6% when walking downstairs (WIh: 705.63±56.23 and WOIh: 680.72±49.99). Statistical significance was found only on flat and downstairs walking. Walking on a soft flat surface however produced only a significant increase of 1.5% between WI and WOI.

Significant difference between the two insole conditions was only seen in the lateral rearfoot (M02) and medial midfoot (M03) in regards to CT.

2) Maximum force : Walking on a hard flat surface produced a decrease of 1.7% in MF between WI (792.74±37.99) and WOI (778.70±31.04) and when descending hard surface stairs an increase of 7.3% was seen (WI: 894.53±66.20 WOI: 962.52±63.67). The differences were found to be statistical significant. The MF however, recorded an even lower significant difference of 0.3 % between the two insole condition, when the hardness was changed. This significance was only valid for level walking, no statistical difference was seen for the rest of the surface geometries.

Statistical significant changes in MF were found only in the lateral midfoot between WI and WOI.

3) Force-time integral: No statistical significant difference in FTI was found between WI and WOI in all surface hardness and geometry conditions.

4) Rearfoot movement: A statistical significant difference was identified between WOI and WI when walking on a hard surface.

Statistical significance between WI and WOI was found for TO, TD, Min and Max on both surface hardness, but none for the surface geometry.

IV. Discussion

The hypotheses are confirmed only to an extent by the results.

The first hypotheses is partially confirmed, as statistical differences were identified in more than half of the parameters.

Conditions		TO(°)	TD(°)	Min(°)	Max(°)	Vel (rad/s)
WIh	*Wk1*	*-0.59±1.96*	*-0.86±2.11*	*-1.91±1.98*	*0.72±2.07*	*0.04±0.01*
	Wk2	*-1.44±2.43*	*-1.28±2.33*	*-3.56±1.88*	*1.62±2.46*	*0.06±0.01*
	Wk3	*-1.53±2.28*	*-1.61±2.30*	*-3.79±1.90*	*1.42±2.29*	*0.06±0.18*
WIs	*Wk1*	*-0.70±2.31*	*-0.97±2.51*	*-2.43±2.37*	*0.78±2.38*	*0.02±0.01*
	Wk2	*-1.30±2.92*	*-1.27±3.06*	*-4.17±2.53*	*1.84±2.71*	*0.03±0.01*
	Wk3	*-1.29±2.84*	*-1.07±2.95*	*-3.88±2.49*	*1.69±2.55*	*0.03±0.21*
WOIh	*Wk1*	*0.72±2.34*	*0.88±2.65*	*-0.62±1.93*	*2.31±2.90*	*0.02±0.01*
	Wk2	*1.27±3.58*	*1.32±3.61*	*-1.66±2.62*	*4.79±3.67*	*0.04±0.02*
	Wk3	*1.18±3.36*	*1.44±3.41*	*-1.50±2.47*	*4.45±3.23*	*0.03±0.21*
WOIs	*Wk1*	*0.72±2.54*	*0.50±2.69*	*-1.02±1.90*	*2.28±2.95*	*0.02±0.01*
	Wk2	*1.34±3.77*	*1.23±3.83*	*-1.92±3.05*	*4.78±3.42*	*0.04±0.01*
	Wk3	*1.20±3.76*	*1.05±3.58*	*-1.97±2.93*	*4.44±3.35*	*0.03±0.12*

Table IV: Rearfoot motion (Mean±SD), where negative values are regarded as a supination motion and positive values as a prontation motion

Condition	*HS*	*SS*
BF(°)	*-0.91 ± 0.43*	*-0.83 ± 0.28*
WOI(°)	*-0.81 ± 0.00*	*-0.79 ± 0.00*
WI(°)	*-0.36 ± 0.00*	*-0.48 ± 0.00*

Table V: Rearfoot angle - static measurement

In regards to plantar pressure, the contact time and maximum force had all surface geometries statistically different. The rearfoot maximum, minimum angle and angular velocity had statistical significance, but not for all surfaces. However the hypothesis was denied in regards to force-time integral, touch-down and take-off angles.

The second hypotheses was confirmed as no statistical significant differences were found for the plantar pressure and rearfoot movement parameters.

The third hypotheses was denied in regards to plantar pressure, as only one foot region showed statistical significance for contact time and maximum force. However, H3 is partially confirmed in regards to rearfoot movement as only angular velocity showed insignificant changes.

In spite of the fact that studies reported a decrease in maximum force between the medial and lateral side of the forefoot [4], [23], the results in the current study show a significant increase. The maximum force registered an increase while walking on a flat surface.

Even though the soft surface should affect the proprioception which will influence the gait and produce increase vertical forces [24], the results from this study show significant changes in two foot areas, the lateral midfoot and the central forefoot. Both of them having lower values for the soft surface.

The foot's expected structural response to the application of an insole is the increase in values in the midfoot, reduction of rearfoot pronation and redistribution in pressure [4]. It was seen in the present study that the only statistical significant decrease was in the rearfoot pronation angle.

The contact time recorded the longest contact in the lateral midfoot and medial and lateral forefoot, findings also recorded by Putti et al [16]. The only difference was that, in this study, the increase in contact time of the medial midfoot, in Putti et al [16] was seen in the first metatarsal. Putti et al [16] researched the repeatability of the Pedar-x system, thus the difference between the two studies could be justified by the effect of a medial wedge insole.

An increased force-time integral was registered in the rearfoot compared with the midfoot and the toes. These findings are partially confirmed by Putti et al [16], which registered three times bigger values in the heel than the rest of the foot.

The ankle joint transitions from supination to pronation, and back to supination, in a closed kinematic chain. The improper application of an wedge insole on a patient will increase the opposite desired motion and further add to the deviation from the normal gait [5]. Based on this statement, the authors of the present study changed the normal gait of the subjects by applying the medial wedge insoles towards an increased supinated foot. This fact was confirmed by the rearfoot movement results. The hardness of the walking surface had no impact on the changes.

The results from the present study show statistical significant differences in rearfoot angle between wearing and not wearing a medial wedge insole. These findings were refuted by Rodrigues et al. [20] which found no significant modifications between the two. Furthermore, the study confirmed that the application of a medial wedge insole improves pain relief and functionality to the lateral compartment of the knee [20].

The results regarding the ankle joint velocity showed no statistical significant change between the surface hardness and insole conditions. These facts are contradicted by Tessutti et al [22], which reported an increase in peak ankle velocity on surfaces with higher stiffness.

The rearfoot movement around the left ankle in the sagital plane, amplitude and velocity, displayed no statistical significance between the hard and the soft walking surfaces. These results are also confirmed by the findings presented in Madeleine et al. [10] .

According to Owings et al. [15] the maximum material height of an insole under the metatarsals is dictated by the depth of the shoe, and if the footwear limits are exceed there can be complications. Taking that statement into account a question can be asked regarding the results bias, as the authors of this study did not followed the manufacturers instructions and used double the height of the medial wedge insole. The answer is given by Rodrigues et al [20]which states that the use of a medial wedge insole between 8-10 mm offers the optimal relationship between comfort and efficiency.

V. Conclusion

The present study appraised the load distribution and the amplitude of heel movement affected by changes in surface hardness and geometry. Twenty eight healthy young subjects were tested while wearing medial wedge insoles.

The application of the wedge insoles lead to changes in plantar pressure and amplitude of the rearfoot movement. Subsequently it was attributed to the significant differences between the surface conditions. The fact that the wedge insoles showed no significant changes when the hardness of the surface varied, attests the effectiveness of the medial wedge insoles. The study design allows the appraisal of multiple surface conditions to be tested in regards to medial wedge insoles.

The methodology and data obtained from this study can be used for modifications and improvements to the insole design in order to maximize the desired effect of an corrective insole. The results showed that a 10º degree medial wedge insole maintains the effects through a multitude of variables, without causing additional injuries to the foot and ankle.

Further investigations should be conducted in order to understand the full biomechanical effect of wearing a wedge insole. The study design can be used to assess other shapes of insoles or surfaces and quantify the full effect of this corrective method.

VI. Limitations

The current study design aimed towards the study of the interaction between healthy subjects and medially applied wedge insoles, which may not apply to a more direct clinical approach like patients suffering from foot deformities. No kinematic analysis past the ankle joint was taken into consideration.

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Workpapers for
"Influence of medial wedge insoles while walking on different geometry and surface hardness"

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Supervisor : Uwe Kersting

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Contents

Chapter 1

Foot anatomy and biomechanics

1.1 Ankle structure

The ankle segment is formed by the distal end of the tibiofibular, tibiotalar, and fibulotalar articulations (see Figure 1.1). The lower termination of the tibiofibular joint is classified as a syndesmosis. The crural interosseous, anterior and posterior tibiofibular ligaments are aiding the joint congruency. At the ankle level the majority of movements are done by a hinge joint - the tibiotalar articulation, where the convex side of the superior talus joints with the concave side of the tibial distal termination. These three joints are enclosed in a capsule. The subtalar joint capsule displays a great thickness on the medial side while the posterior side width is extremely low. To the lateral side, the articulation is reinforced by the anterior and posterior talofibular ligaments and the calcaneofibular ligament. At the medial side, the joint stability is provided by the deltoid ligament [3].

1.1.1 Ankle joint movement

The motion is essentially made in the sagittal plane - flexion (dorsiflection) and extention (plantar flection). The ankle behaves like a hinge joint when performing the stance phase of the gait. However at some point within the motion amplitude few degrees of internal or external rotation will occur. A dorsiflection of 25 degrees will determine an external rotation of 2.5 degrees. Furthermore an ankle extention is correlated with a very small internal rotation - less than 1 degree. When loaded at 10 degrees of flexion, the ankle articulation is joined by 1.6 degrees of eversion, together with 2.1 degrees of tibial internal rotation. Smaller rotation angles occur when extending, 1.6 degrees of foot inversion accompanied with 1.3 degrees of tibial external rotation. When manipulated passively, the joint's cartilaginous surfaces together with the ligaments conduct the joint kinematics. The joint surfaces glide respective to each other without having considerable tissue deformation [3].

An important factor in facilitating both plantar flection and dorsiflection is the medial and lateral malleoli. While the ankle is crossed by tendons anteriorly and posteriorly, the presence of the malleoli channels the tension developed by these tendons and their corresponding muscles, facilitating the flexion and extention. The main dorsiflexors are tibialis anterior, extensor digitorum longus, peroneus longus. Assisting the dorsiflection is hallucis extensor longus. Spreading across two joints, the gastrocnemius twins and the soleus muscle are the main actors that execute the

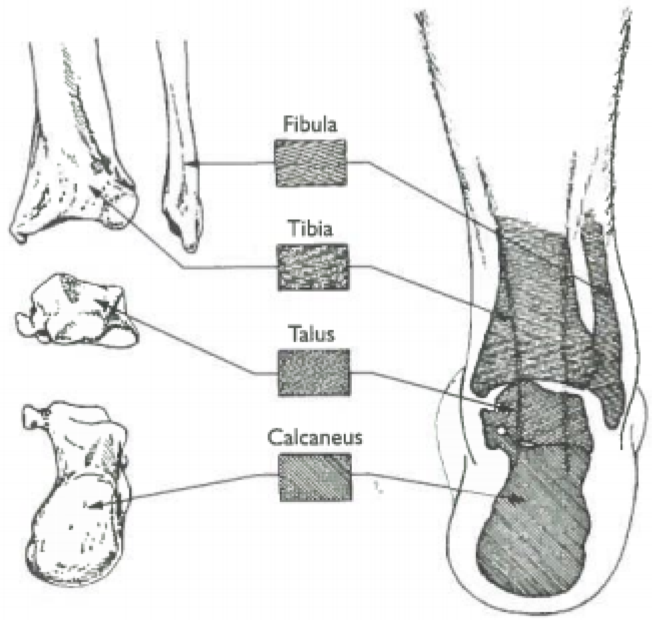


Figure 1.1: Ankle structure, posterior view [3]

plantar flexion of the foot. Important contribution is brought by the action of the tibialis posterior, peroneus longus, peroneus brevis, plantaris, flexor hallucis longus and flexor digitorum longus [3].

1.2 Foot structure

Similar with the hand, the foot is formed of multiple bone structures. Totaling a number of 26 bones with a generous amount of articulations. Consisting of: subtalar and midtarsal articulations and few tarsometatarsal, intermetatarsal, metatarsophalangeal and interphalangeal articulations. The bones and the joints work together in a close relationship that facilitate the support of the upright body and aiding for adaptation in regards to the terrain and amortize shocks[3].

1. Subtalar joint is an uniaxial joint present under the talus. The joint congruency is made by the presence of the superior calcaneus with it's sustentaculum tali jointing with the anterior and posterior sides of the talus [3].

2. Tarsometatarsal and Intermetatarsal joints

   These joints have the role of operating as a semirigid body, however they have slight flexibility that allow the foot to adapt to uneven surfaces when bearing weight. The tarsometatarsal and intermetatarsal joints are formed in such way that only allows gliding motions. This restriction in movement is also provided by the ligaments [3].

3. Metatarsophalangeal and Interphalangeal Joints

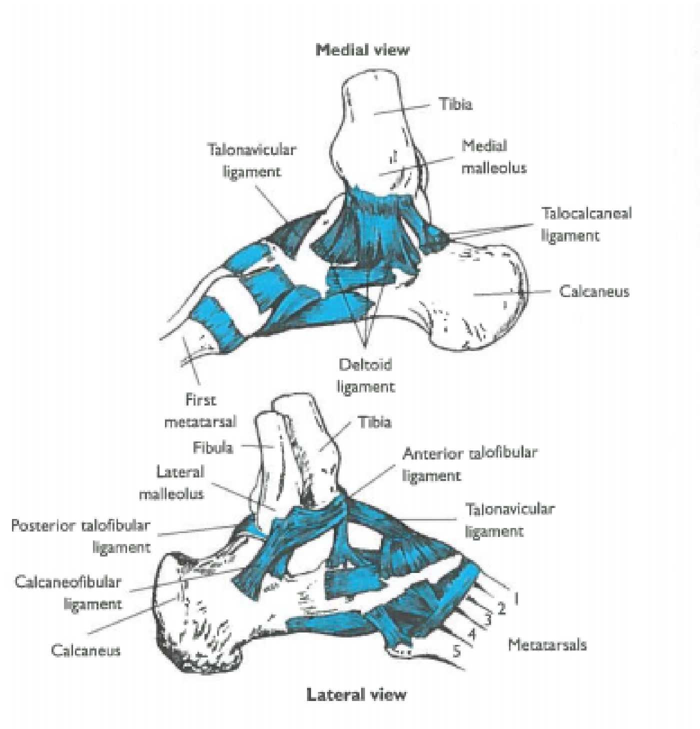


Figure 1.2: Ligaments of the foot [3]

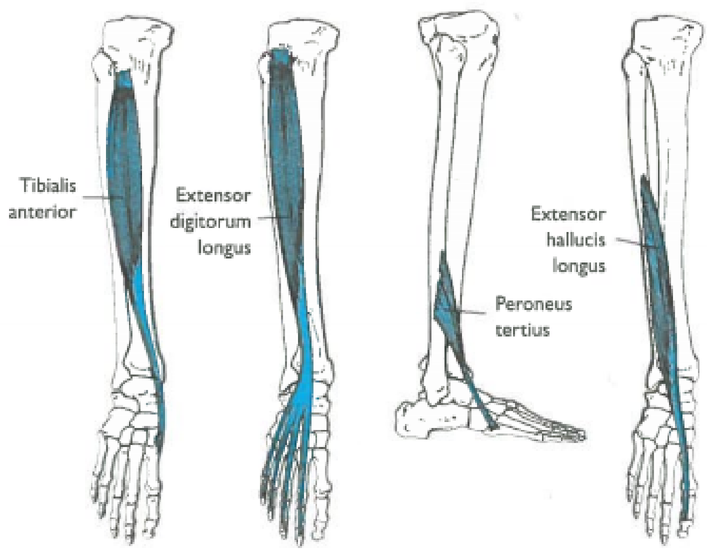


Figure 1.3: Dorsiflexion muscles [3]

The metatarsophalangeal and interphalangeal joints present similarities with the upper limb's distal segment, however the hand correspondent is a hinge joint while the former being a condyloid joint. This region displays a wide array of ligaments that add reinforcement. The great toe, also called the hallux, has a great implication in shifting the weight to the other foot when walking and adapts to weight bearing by pressing towards the ground in accordance with the load [3].

4. Plantar arches

   The foot displays three arches, formed by the bone geometry of the tarsal and metatarsal. In the longitudinal axis, spreading from the heel bone to the metatarsals and then to the tarsals are the medial and lateral arches. The transverse arch spreads from the head of the 1st metatarsal bone to the 5th. The plantar fascia together with several arches form the supporting structure of the plantar arches, the medial longitudinal arch is aided by the spring ligament, while the long plantar ligament brings support to the lateral counterpart with the short plantar ligament acting as a synergist. A complex structure of connective tissue consisting of strong fibrous bands form the plantar fascia, spreading from the calcaneus to the distal end of the metatarsal bones, providing stability to the longitudinal arch. Muscle tension also brings support to the foot arches, especially the activity of the tibialis posterior. When crossing the joints, these muscles provide stability. This complex structure of cartilaginous tissue of tendons and ligaments form a springy base that have a determining role in storing and spending energy in an efficient manner. Supplementary energy is saved by the gastrocnemius and soleus muscles as they elaborate eccentric tension. This intelligent system of utilizing energy contributes with metabolic consumption especially at the push-off phase of walking and/or running [3].

Chapter 2

Pressure

The ankle and foot complex provide support and flexibility necessary for weight bearing and flexibility amid gait and functional activity [11]. The field that studies the relation between the foot and the support surface is named plantar pressure [1]. Investigations of plantar pressure for the foot can lead to indication on how to assist in the determination and management of impairments caused by musculoskeletal, integumentary and neurological disorders. The data recorded are considered an important element in providing relevant information and assessments for physical therapist to help patients [11].

The magnitude of pressure is determined by dividing the force measured with the area of sensors defined by the foot contact area. From a mathematical point of view, the pressure (p) is constructed from force (F) per unit area (a). $P = F/a$. The System International (SI) describes the unit for pressure as being pascal (Pa) and 1Pa is defined by the force of 1N which is distributed over an area of $1m^2$ [11].

Foot biomechanics are described by a thorough examination of both kinematics and kinetics and namely [2]:

- external forces and moments acting on the body
- internal forces and moments produced by the musculoskeletal system
- movements and the time necessary to perform the movements in regards to linear and angular displacement, velocity and acceleration of the body as a whole or specific segments.

The load acting under the foot has been of interest since 1800 and since then there have been increasing attempts to measure and investigate it. Plantar pressure assessments is insufficient when investigating biomechanics, but has potentialities in research, clinics and podiatry[2]. The fields that make use of the plantar pressure analysis are various and still developing [1] :

- design of footwear
- investigation of sport performances
- prevention of injuries
- balance training and control

- diagnostic
- human identification
- biometric measurements
- monitoring of posture allocations
- rehabilitation

It is clear that more and more innovative applications have been achieved, and that the technology is more than able of an accurate and efficient measurement of the plantar pressure [1]. The appropriateness and generalization of it is still in question, due to lack of standardization[2].

On the market and in research facilities there are a large variety of plantar pressure systems that differ in sensor configurations depending on the requirements. Mainly there are three types of configurations: pressure platforms, imaging based technology and in-shoe pressure systems [1]. In general all the systems have the same major components [11]:

- the measuring device
- a computer for the recorded data
- a monitor displaying the data

Depending on the software capabilities installed with the hardware, some packages allows a more thorough analysis of the plantar pressure , by dividing the surface into regions or masks[11].

According to Razak et al.[1] plantar pressure is generally measured using two main types of systems:

- Platform system (see Figure 2.1) constructed under the form of a flat and rigid pressure sensors grouped in a matrix and usually integrated into the floor, thus allowing a more natural gait. This type of systems have both static and dynamic uses, but mostly bounded to laboratory set-ups. Due to the floor placement the systems are easily used, but need some degree of familiarization for the patient to hit the center of the platform for an accurate recording and still maintain a normal and natural gait [1].

Figure 2.1: Novel pressure platform [6]

- In-shoe systems (see Figure 5.1) consist out of flexible sensors which are placed in shoes to measure the relation between foot and shoe. The system is portable, thus allowing a wide variety of studies in different terrain condition and other orthotics interventions [1].

According to a review from 2011 [2], most of the commercial plantar pressure measurement devices and other prototypes were based only on pressure measurements. The technology used was based on optical devices, pneumatic discrete sensors, textile sensors, resistive and capacitive sensors. Giacomozzi [2]offers a brief description of the sensor technologies [2]:

1. Optical devices record pressure with the help of fixed platforms, but this type of technology is not used for in-shoe devices. One example for the system is the Sheffield optical pedobarograph, which is made out of a piece of plastic on top of illuminated glass. When the foot presses on the plastic, the image is recorded by a camera found at the bottom of the device. The image is digitized and the pressure is measured by the changes in voltage in the output of the camera [2].

2. Pneumatic discrete sensors is a hydrocell-based technology generally used in in-shoe systems. The sensors are described as being a polyurethane pack containing some incompressible fluid. A microsensor was isolated by a foil of dielectric and placed just beneath the pack. As specifications this type of systems can have up to 24 sensors per insole, a range to measure pressure between 0-625 kPa, a resolution of 2.5 kPa, a total height of the insole of 3 mm and a sample rate of 100 Hz [2].

3. Textile sensors is a fabric based pressure sensor, but still at the stage of prototype. The pressure sensor is achieved by mixing conductive sensing material with yarn and covered by a layer of silicon rubber. The recommended usage of the prototype is that of assessments in sport and fitness. As for the technical features for the sensor Giacomozzi [2] describes a sample rate of 100Hz and a pressure range up to 1000 kPa [2].

4. Resistive sensors can be used in discrete sensors, platforms and in-shoe pressure systems. The sensors function using electric current flow and the intensity of it is controlled by the pressure applied on the surface of the sensor. The electrical conductivity increases in a linear pattern with the contact area. If the conductive material suffers elastic deformities then the changes are caused by modifications in the volume of the conductivity and not the contact area [2].

5. Capacitive sensors are used in various commercial systems and the functioning principle consists of: variations of capacitance are caused by variations of pressure caused by the surface of the sensors. Both Novel pressure systems, platform and in-shoe, use capacitive sensors and thus taking advantage of the elasticity of the elastic dielectric material. A high pressure will produce a high capacitance, but a small thickness of the material [2].

Chapter 3

Goniometer

The goniometer is an instrument usually found in clinical setups, where the sole purpose is that of measuring the movement of a certain joint. The instrument is available in numerous shapes and versions. The principal behind the goniometer is to measure the angle between two arms connected by a protractor look-alike, where one of the arms is fixed and the other is mobile[14].

Electrogoniometers are defined as devices that can measure joint movements using electronic signals. They are the less expensive version of an motion capture system that can provide real-time data. The disadvantage of the device is that it obstructs to a certain degree, the free movement of the body due to the cables that need to be connected to the device recording the data [13]. The angle of the measured joint can be recorded in multiple planes, but no more than two plane axis [14].

One of the most frequently used electrogoniometer is the potentiometer based one . Comparable with a resistor, the potentiometer, measures the amount of voltage proportional to the joint movement. The potentiometer replaces the protractor, thus connecting the two arms of the electrogoniometer [13]. These types of goniometers are described in the literature as being protuberant and limited by their requirement to be positioned in the center of the joint. Therefor, depending on the joint of interest, measuring only in one axis [14].

The electrogoniometer has a problem when applied to joints that aren't true hinges, because the translational movements of the joint causes errors to the system. This can be solved by using the system illustrated in Figure 3.2b which contains a new technology developed by Hannah, Cousins and Foort. This system can measure the ankle, knee and hip in all three axes in the same time for both legs, all in real time. Another problem with the electrogoniometer is that, due to the fact that it only measures angle joint movements and not the overall movement of the segment, the data collected is unusable for inverse dynamics analysis [13].

A custom-made goniometer (see Figure 3.2) was used in this study, like the one used in Kersting et al [4]. The goniometer was made out of a gliding sleeve mounted on a plastic lever, fixed on middle of the shank. The lever was attached using a two-joint mechanism to a rectangular piece of thermoplastic, which was custom shaped to each individuals heel. The thermoplastic was secured to the subjects heel in such a manner that the two-joint mechanism was on the bisectional line of the calcaneus. A potentiometer (MPC05 R5K, Megatron, Putzbrunn) was attached onto the two-joint mechanism and was in line with the subtalar joint axis [4].

The calibration of electrogoniometers is really easy to perform. A manual goniometer can be

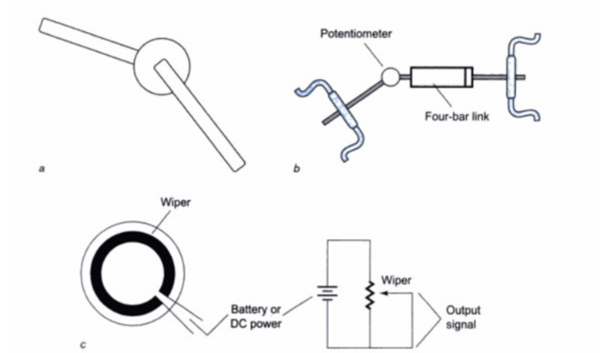


Figure 3.1: a. Manual goniometer b. Electrogoniometer c.Schematic description of potentiometric electrometer[13]

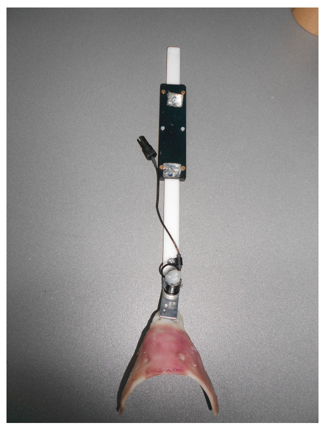


Figure 3.2: Custom-made goniometer

fixed on the electrical one and by moving the manual goniometer while collecting gata, the researcher can transform the voltage into angles. If this cannot be achieved, a similar situation can be applied if the angle performed by the goniometer is known at that specific time then the voltage can be extracted from the data [13].

A similar calibration was performed for this study, where a manual goniometer was attached to the electrogoniometer and a 0º, +45º and -45º measurement was recorded in that order, for 10 seconds each. The voltage for each measurement was extracted and converted into degrees. The formula used is the following :

- if the voltage values were on the negative scale: $Degree = Voltage * (-45)/a$, where a is the value of the volatage at -45º which was a fixed value prerecorded of -2.907873851
- if the voltage values were on the positive scale: $Degree = Voltage * 45/a$, where a is the value of the volatage at +45º which was a fixed value prerecorded of 2.543287965

Chapter 4

The Foot Posture Index - the six item version (FPI6)

Classified as a clinical tool, the Foot Posture Index, intended to help guide the classification of foot postures into three main categories: normal, supinated and pronated foot. The index uses a number of six criterion's and a scale from -2 to +2 to rate the foot, make it a innovative method [12].

The intention of Redmond's FPI was to create a simple method by evaluating different characteristics of the foot posture and quantifying them into one single result. The result will provide an indicator of the global posture of the foot. The index is conducted under weight-bearing conditions, by observing the patient in a relaxed and static position while sustaining a double limb support. This position was found to estimate the closest position of the foot during gait cycles [12].

The FPI was constructed by using assessments and pertinent measurements from over 140 papers. The search was narrowed by inputting the fallowing criteria [12]:

- Easily performed measurements
- Time-efficient conducted measurements
- Measurements done using low-costing technologies
- Easy interpretation of the results
- The results should have the form of a scale

The role of this criterion was to ensure an equally assessment of the foot posture in all three planes, thus providing postural information on the rearfoot, midfoot and forefoot. The user scores the posture based on their observations and grades the foot. A neutral foot posture is scored as zero, a pronated posture is scored with positive values and a supinated posture with negative values. The scoring is done for each of the criterion in the method and the results are combined, thus providing the overall evaluation of the foot posture. An overall result in the high positive scale denotes a pronated posture, while the results around 0 indicate a neutral one and the ones on the negative scale reveal a supinated posture [12].

The measurements are performed in relaxed double limb support and each foot is assessed individually. The patient is asked to maintain the stance position while looking straight ahead and keeping their arms relaxed on the side. The assessments take around two minutes to conduct, if the patient keeps still and doesn't try to turn around and observe the technician [12].

Originally, eight measurements were integrated into the index, but after a series of validation studies the index was reduced to six items [12]:

1. Talar head palpation were the head is palpated both laterally and medially of the anterior view of the ankle joint [12].

2. Supra and infra lateral malleolar curvature are observed and assessed if they are equal or not to each other. If the infra curve is more curved than the supra one then the foot posture is qualified as an pronated foot. The differences in curves are usually caused by the foot abduction and heel eversion. The opposite condition is valid for the supinated foot type [12].

3. Calcaneal frontal plane position is assessed by quantifying the bisectional axis of the calcaneus [12].

4. Bulging in the region of the talonavicular joint is visually assessed as to determine if the area under the talonavicular joint is flat. This will qualify the foot as a neutral one. The pronated foot is observed by a bulging in the area and a supinated foot is defined by a indentation [12].

5. Height and congruence of the medial longitudinal arch is the assessment of the height and shape for the longitudinal arch. If the curve is observed as being uniform and resembling a segment of a circle then the foot arch is qualified as normal. If the curve is more prominent in the posterior part of the arch, the foot is qualified as supinated. The opposite is valid for the pronated foot when the curve has a flat aspect [12].

6. Abduction/adduction of the forefoot on the rearfoot is measured by assessing the posterior aspect of the heel in-line with the medial longitudinal line of the foot. A neutral foot is considered to be the situation in which the forefoot is equally visible on the medial and lateral sides. If the amount of forefoot is more proeminent on the lateral side then the foot is qualified as pronated. The opposite is valid for the supinated foot [12].

Adding up all the scores from the six criteria, the index will provide a final score between -12 and +12, thus providing the overall assessment of the foot posture [12] .

Chapter 5

Pedar-X system

5.1 Description

The Pedar-X Recorder in-shoe system (Novel GmbH, Munich, Germany) is an electronic device that can measure the plantar pressure while the user is performing movement. Each of the insole is divided into 99 regions, each corresponding with a different capacitive sensor. The system is used in a variety of fields, such as: medical, ergonomic and for analyzing biomechanics [7, 10].

The system is formed by the following components [7, 10] (see Figure 5.1) :

1. Insoles
2. Double insole cable
3. Pedar box
4. Fiber optic cable
5. Belt
6. Battery
7. Battery cable
8. Battery charger
9. Sync box
10. Bluetooth dongle
11. Velcro straps
12. SD cards

The system has multiple modalities of collecting the data: online, online + SD and offline. For this study the online+SD method was used as it was considered the most appropriate at the given situation, as the subjects needed free range of movement. Therefore, collecting data online (via Bluetooth) will allow the researchers to observe the data in real time, but the Bluetooth connection

Figure 5.1: Pedar-X system: 1: insoles 2: Double insole cable 3: pedar-x box 4: battery 5: battery cable 6: velcro straps 7: SD card

in this study was weak which impaired a proper data collection. Simultaneously the full data is stored onto the SD card, thus ensuring that the collection of data is done properly in case the subject exceeds the area limit covered by the Bluetooth transmission[10, 7].

5.2 Preparing the equipment

The pedar-x computer box was placed onto the designated place on a pedar-x belt, which was also firmly secured with velcro straps. The battery was placed into the pocket next to it and a battery cable will be connected to the two. A synchronizing box was also mounted on the same belt closely to the pedar-x box, thus allowing the fiber optic cables to be connected between the two [10]. The pedar-x recorder was connected to the goniometer's amplifier connector box using a cable. The goniometer's connector box and minicomputer where also secured in a backpack and placed on the back of the subject (see Figure 5.2).

The corresponding insoles have been chosen in regards to the shoe size of the tested person and placed inside the standard shoes. The size of the insole placed is vital for the bias of the data, a smaller insole size will under evaluate the forces and pressures and a bigger one will be damaged. The subjects were instructed how to take the shoes on, so it wouldn't cause damage to the insoles or bias in the collected data. With the person in an upright position, the belt was firmly attached to the lower back and the insoles were connected to the pedar-x box by the double insole cable. Finally, velcro straps will be placed on the subjects lower limbs to secure the cables [10].

Figure 5.2: Subject wearing the systems

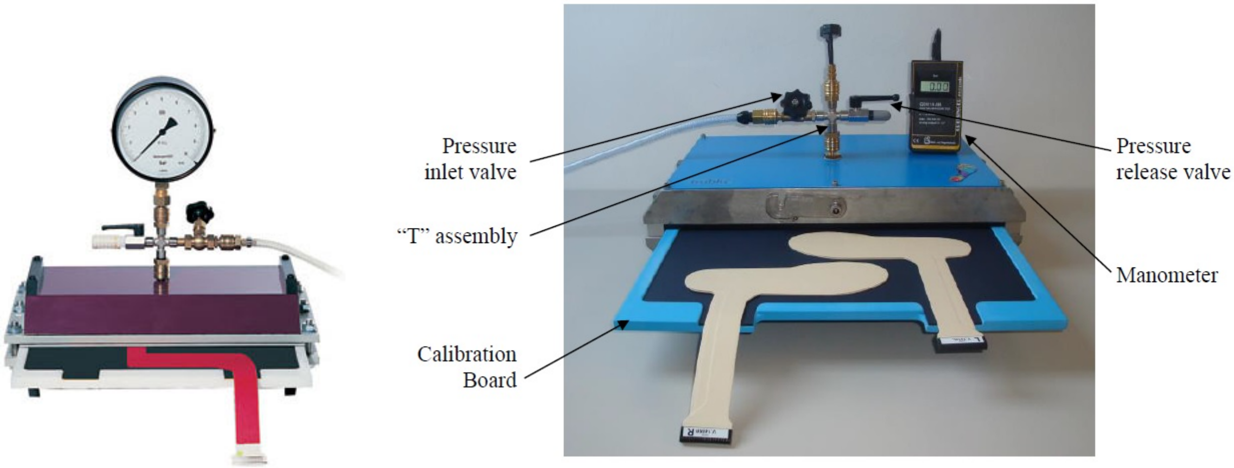


Figure 5.3: Calibration device [5]

5.3 Calibration

The software is available with default calibration settings together with configuration files, and are ready to use when the software is installed on the PC. The system, also contains a separate CD with the files needed for calibration and configuration. The configuration file holds the calibration file, data on the configuration of its respective measurement, settings in regards to synchronization and sensor display [10]. A new calibration was made prior to the testing for all the insoles using the trublu calibration system provided by Novel.

The trublu calibration unit (see Figure 5.3) is a specifically made device for Pedar, used for calibrating the insoles, by applying a known pressure via compressed air, homogeneously spread onto the insoles. After the trublu pressure system was accordingly set-up, the software will instruct the user upon the steps needed for calibrating the insoles. The software can provide the user with feedback in regards with the character of the calibration by generating a calibration line. Each pair of insoles was calibrated, and the calibration files were saved on the computer and all of the SD cards were formatted, after which the specified calibration file were mounted on the corresponding SD card, one for each pair of insoles [10].

5.4 Data collection

The Pedar-X software will connect using the Bluetooth connection to the system and test the connectivity to it. The corresponding insole configuration will be selected to match the SD card from the pedar-x box and the insoles. After all the settings are confirmed the system asks that the insoles be unloaded first left and then right. This process is described as being the zeroing process [10].

Usually the zeroing process is done with the subject in a sitting position and with the shoe laced untied [10]. For this study however, the subject was standing and the shoe laces where tied, thus

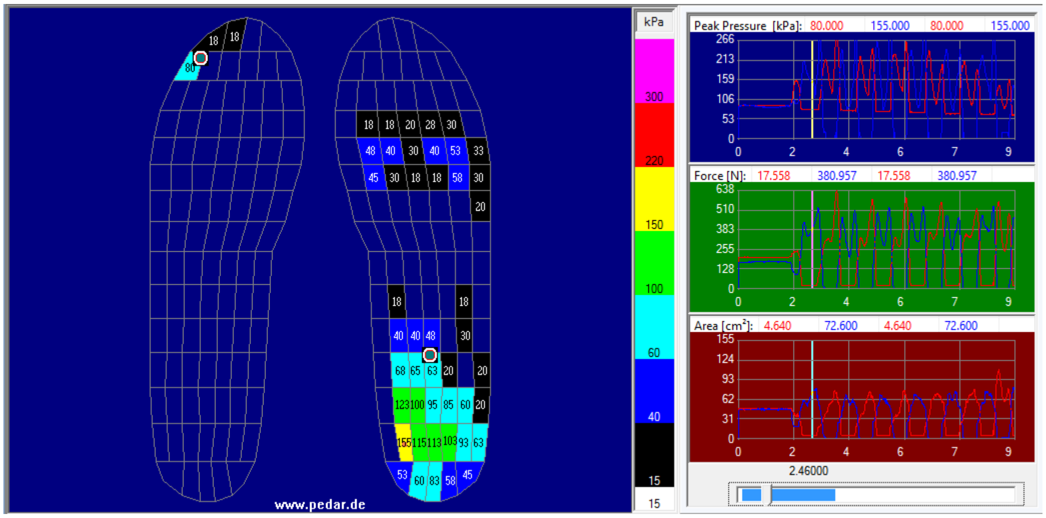


Figure 5.4: Sensor error

excluding the inshoe pressure produced by the tying of the laces. This process is needed every time the system is disconnected or the insoles are unplugged.

Each recording will be started using the start icon and stopped using the stop one. The data is automatically saved on the computer and SD card [10].

5.5 Detection and correction errors

After the data was collected, the files were reopened and checked for faulty data. Some of the trials presented sensors where one or more of them recorded data while in the swing phase as well. The instable signal of the data can produce a chain reaction through all the data processing and the results may be bias. A faulty signal can be visually observed by the user when looking at the pressure-time curve. If the curve doesn't reach a zero value when in the swing phase, then one or more of the sensors records extra values (see Figure 5.4) [10].

The read/define masks offers the user the option of creating and applying a mask where an automatic algorithm is implemented and the data is set to zero or interpolated using the neighboring data (see Figure 5.5). Using the later method can create some problems due to the fact that afterwards the user will not be able to discern between the real data and the interpolated one. In Figure 5.5 the sensors marked with red are the ones that gave erroneous data and were switched off. When the changes are applied to the files a new window where the system asks which of the two corrections the user would like to use [10]. For the purpose of this study and the fact that the sensor errors where not that big, a correction by using neighboring data was applied.

After the corrected data is stored. the user can take a look at the pressure-time curve and check if the correction was successful or if any other sensors still had errors (see Figure 5.6) [10] .

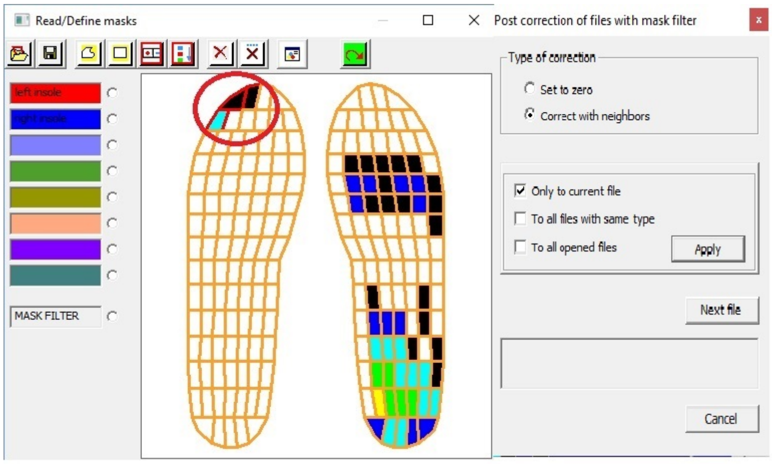


Figure 5.5: Corrective mask

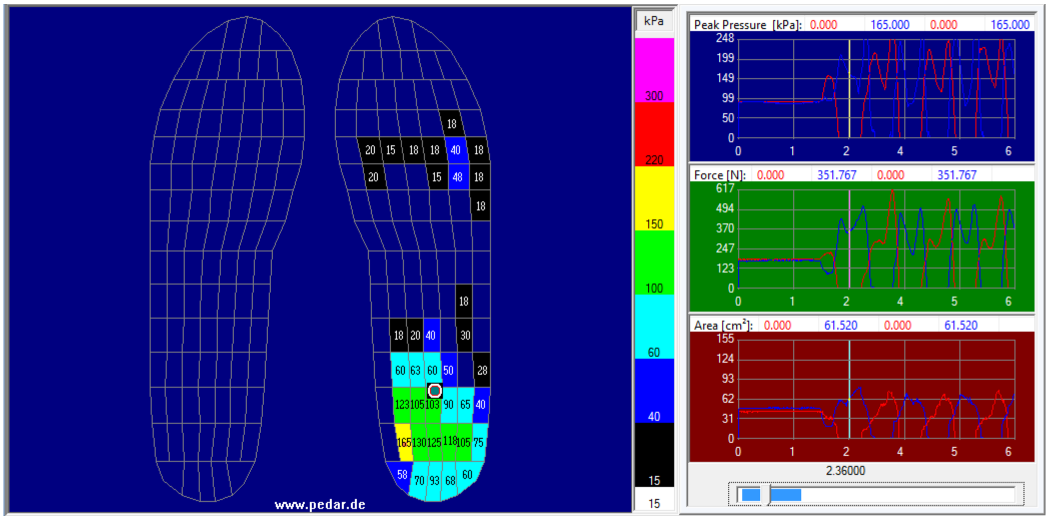


Figure 5.6: Corrected sensors and pressure

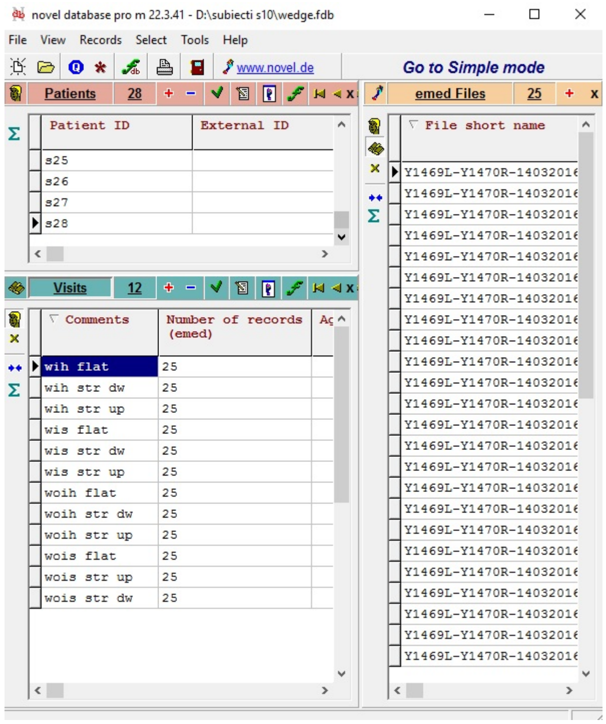


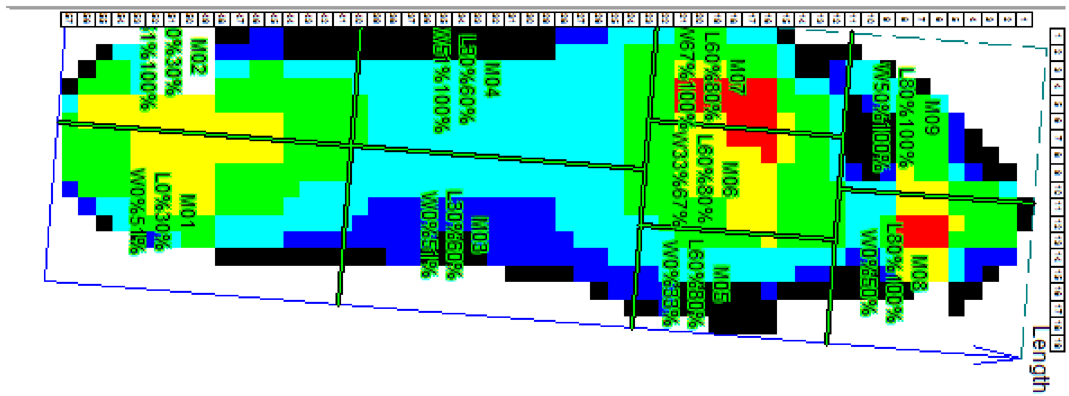
Figure 5.7: Database pro m

5.6 Novel Database data analysis

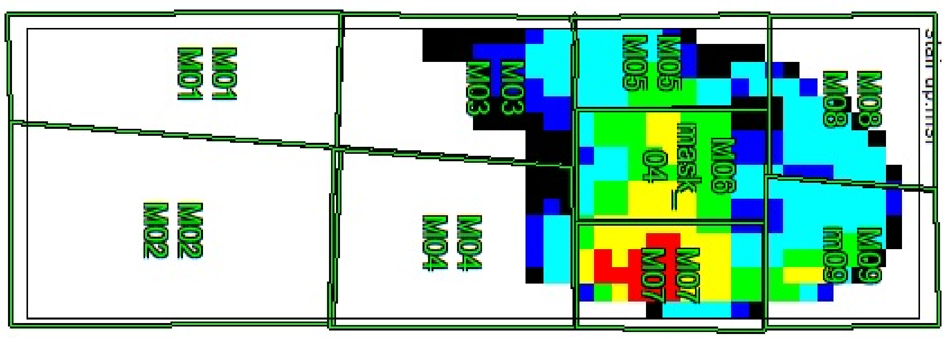
The Novel Database Pro M (22.3.41 novel gmbh Munich) offers the tool with which users can classify and analyze clinical data. The database is designed for use in both clinical and research areas and the clinical parameters computed have a wide use in assessments. The database can be optimized to the user's needs [8]. The software allows the user to analyze the data using only three physical parameters: pressure, position and time [9].

For the purpose of this study a number of 28 patients were added and for each one twelve visits and 25 emed step files for each visit were added. The visits contained a combination of all the relevant combination of conditions (without insole, with insole), surface hardness (hard and soft) and surface geometry (flat, ascending stairs and descending stairs) (see Figure 5.7).

Each step was analyzed over regional areas, named masks. Using this tool for each mask a number of relevant parameters are calculated and exported into the database and as ASCII. The mask used in this study was a percent mask (see Figure 5.8a), which applies the saved percentage of the pressure picture collected for each step. The algorithm behind the mask allows for it to be applied over a large number of sizes without customizing it for each one, while keeping the regional area the same [9]. This is only applicable for a full print of the step. In case of ascending stairs, a person applies only pressure on the forefoot, thus providing an incomplete print of the sole. In this condition, a relative mask (see Figure 5.8b)was constructed matching the percent one, thus ensuring that the same area per region were analyzed.



(a) Percent mask where M08: hallux and second toe, M09: third to fifth toe, M05: first metatarsal, M06: second and third metatarsals, M07: forth and fifth metatarsal, M08: medial midfoot, M09: lateral midfoot, M01: medial rearfoot, M02: lateral rearfoot.



(b) Relative mask where M08: hallux and second toe, M09: third to fifth toe, M05: first metatarsal, M06: second and third metatarsals, M07: forth and fifth metatarsal, M08: medial midfoot, M09: lateral midfoot, M01: medial rearfoot, M02: lateral rearfoot.

Figure 5.8: Masks

Each of the masks contained ten areas of interest for this study: hallux and second toe, third to fifth toe, first metatarsal, second and third metatarsals, forth and fifth metatarsal, medial midfoot, lateral midfoot, medial rearfoot, lateral rearfoot and the total foot.

The masks were applied and a groupmask evaluation was performed. A group was constructed over one visit at a time. This tool is used in order to perform evaluations and statistical analyses over dynamic pressure parameters. This is done over the different regions of the masks and for each group assigned. After the analyses is done a report containing the results for six parameters is saved as an ASCII file where the peak pressure, contact area, contact time, maximum force, pressure-time integral and force-time integral are computed over all the areas of the mask [9].

5.7 Mathematical algorithm used by Novel

For calculating the different parameters analyzed via Pedar-X, Novel Database software uses the following formulas:

- Maximum force (Fmax)[9]

$$F_{max} = Max\{\sum P_{(k,i)} * A_{(k)}\}$$

where :
F_{max} is the total maximum force,
$P_{(k,i)}$ is the pressure from the k-th sensor in the i-th time frame
$A_{(k)}$ is the area of the k-th sensor

- Peak pressure (PP) [9]

$$PP = \sum maxP_{(k,i)}$$

where:
PP is the total peak pressure
$P_{max_{(k,i)}}$is the maximum pressure in the k-th sensor in the i-th time frame

- Contact area (Ca) [9]

$$Ca = \sum A_{(k,i)}$$

where:
Ca is the total contact area
$A_{(k,i)}$is the area under the k-th sensor in the i-th time frame

- Contact time (Ct) [9]

$$Ct = \frac{1}{N} \sum (T_{end_j} - T_{beg_j} + \text{delta t})$$

where:
Ct is the total contact area
N is the total number of steps associated to the trial
T_{end_j} is the time correlated to the end of contact of the j-th step
T_{beg_j} is the time correlated to the beginning of contact of the j-th step
delta t is the duration of the time frames

- Force time integral (FTI) [9]

$$FTI = \sum(\sum(P_{(k,i)} * A_{(k)})) * \text{delta t})$$

where:
FTI is the force over a time integral
Pressure time integral (PTI) [9]

$$PTI = \sum(max\{P_{(k,i)}\} * \text{ delta t})$$

However, when the formulas are applied over steps the algorithm for each of the parameters changes, thus the following formulas are applied [9]:

1. Peak pressure: $PP = \frac{1}{N} \sum max(P_{(k,i,j)})$
2. Maximum force: $MF = \frac{1}{N} \sum F_{max_{(j)}}$
3. Contact area: $CA = \frac{1}{N} \sum A_{(j)}$
4. Contact time: $CT = \frac{1}{N} \sum (T_{end_j} - T_{beg_j} + \text{delta t})$
5. Pressure time integral: $PTI = \frac{1}{N} \sum PTI_{(j)}$
6. Force time integral $FTI = \frac{1}{N} \sum FTI_{(j)}$

where [9]:
N is the total number of steps associated to the trial
j is the current step over which the algorithm is applied

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Appendix A

Peak pressure results

The PP was found to be statistically significant with a $p < 0.05$ in all ten regions for all variables, exception being the M09 conditions, where a p-value of 0.12 was present, though the surface condition presented statistical differences for all (Wk1-Wk2,Wk1-Wk3,Wk2-Wk3).

In M01 the PP was found to be statistically different for WIs-WOIh and WIs-WOIs and all walking situations (Wk1- Wk2, Wk1-Wk3, Wk2- Wk3).

For M02, no statistical difference was found for WIh-WIs and WOIh-WOIs. Due to the fact that this region was one data set found to be normally distributed a more thorough analysis was possible, thus no statistical difference was also found for :

- WOIh-WOIs and WIs-WIh during Wk2
- WOIh-WIh, WOIs-WIh, WOIh-WIs, WOIs-WIs during Wk3-Wk2
- WOIs-WOIh, WIh-WOIh, WIh-WOIs, WIs-WIh during Wk3
- WOIs-WIs during Wk1-Wk3
- All condition comparison (WOIh-WOIs, WIh-WOIs, WIs-WOIs, WIh-WOIh, WIs-WOIh, WIs-WIh) during Wk1

In the M03 region statistical difference was found only for WIh-WOIs and Wk1-Wk2, Wk2-Wk3. The M04 region had similar results, but also found statistical significance for the WIh-WIs.

The PP in M05 and M06 had no statistical differences for WIh-WOIh and WIs-WOIs and furthermore there was no statistical difference in the M06 between Wk2-Wk3.

For M07 and M08, the PP recorded statistical differences between WIh-WIs, WIh-WOIs, WIs-WOIh, WOIh-WOIs and Wk1-Wk3. The only other difference between the two was that M07 recorded statistical difference for Wk1-Wk2 and M08 recorded statistical difference for Wk2-Wk3.

No statistical difference was seen between the medial side and the lateral side of the foot for all the walking surface geometries. The only statistical significance was in the toe region between M08 and M09 trough all insole conditions and geometries. Also a statistical difference was seen when on Wk3 between M05-M07. A significant decrease in PP was present between the rearfoot and the midfoot on the medial side, specifically between M01 and M03 and on the lateral side (M02-M04) the only significance was seen while walking on Wk1. An opposite effect was observed between the midfoot and the forefoot, where a significant increase of PP was present. Between the toes and the forefoot no statistical significance were seen between M06-M08 while walking on Wk1, M06-M08 and M07-M09 while walking on Wk2.

Variables		M01	M02	M03	M04	M05	M06	M07	M08	M09	M10
WIh	Wk1	233.39 ± 18.56	204.11 ± 17.96	93.67 ± 11.49	99.59 ± 18.93	173.24 ± 24.39	203.21 ± 16.06	187.99 ± 22.43	222.56 ± 42.29	120.88 ± 22.66	273.69 ± 26.82
	Wk2	54.95 ± 22.81	95.13 ± 26.48	116.04 ± 20.56	108.97 ± 19.37	152.3 ± 22.79	182.98 ± 16.54	176.77 ± 26.54	92.34 ± 19.09	159.40 ± 34.39	215.32 ± 25.58
	Wk3	157.13 ± 30.64	128.95 ± 26.85	101.96 ± 18.52	114.79 ± 19.87	181.11 ± 27.78	186.94 ± 21.87	172.33 ± 24.91	115.30 ± 33.29	83.39 ± 23.28	213.24 ± 24.89
WIs	Wk1	245.42 ± 19.78	204.84 ± 19.24	90.83 ± 9.49	83.39 ± 13.10	164.72 ± 23.05	174.62 ± 15.42	150.15 ± 19.67	224.29 ± 36.45	123.09 ± 27.90	269.20 ± 23.99
	Wk2	49.73 ± 18.20	98.20 ± 23.37	96.17 ± 15.46	108.17 ± 17.65	121.51 ± 17.76	152.82 ± 14.77	164.79 ± 24.51	89.27 ± 15.82	176.30 ± 34.31	201.11 ± 29.29
	Wk3	189.56 ± 31.98	151.51 ± 27.07	104.71 ± 14.59	97.98 ± 15.87	136.19 ± 26.65	141.51 ± 21.24	128.77 ± 23.76	105.14 ± 32.59	67.96 ± 24.08	214.20 ± 30.62
WOIh	Wk1	196.19 ± 12.94	183.96 ± 12.59	82.24 ± 7.61	104.35 ± 17.81	193.67 ± 30.89	213.96 ± 16.86	180.07 ± 23.52	234.20 ± 39.56	158.43 ± 16.05	269.34 ± 33.57
	Wk2	57.02 ± 21.25	55.03 ± 21.58	115.08 ± 26.18	85.95 ± 15.51	144.27 ± 27.52	185.39 ± 19.27	195.59 ± 33.06	104.97 ± 19.75	179.35 ± 42.71	231.44 ± 35.67
	Wk3	115.23 ± 26.08	101.03 ± 23.60	79.22 ± 19.79	116.76 ± 20.12	187.21 ± 35.10	192.19 ± 26.14	166.83 ± 24.46	135.72 ± 46.89	101.78 ± 30.82	221.88 ± 34.48
WOIs	Wk1	191.38 ± 15.98	181.10 ± 16.25	86.95 ± 7.28	93.68 ± 13.32	184.14 ± 25.99	169.17 ± 14.55	145.37 ± 19.23	203.51 ± 32.33	118.32 ± 15.89	233.95 ± 29.23
	Wk2	56.01 ± 19.16	53.86 ± 19.54	101.51 ± 17.12	79.82 ± 13.30	123.92 ± 20.34	150.27 ± 17.05	173.75 ± 28.46	88.71 ± 17.96	164.10 ± 33.57	221.21 ± 30.59
	Wk3	131.51 ± 28.74	117.67 ± 26.79	79.90 ± 13.11	105.97 ± 17.34	149.45 ± 30.04	146.87 ± 21.61	135.52 ± 22.20	111.98 ± 35.62	81.88 ± 23.11	192.30 ± 31.82

Table A.1: Peak pressure (kPa) Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

Appendix B

Contact area results

Results showed that in regards to CA, seven out of ten regions (M01, M02, M05, M06, M07, M08, M10) were found to have no statistical difference for the insole conditions, but did have statistical differences in regards to the walking surface geometry. In M03 the conditions WIs and WOIh, for M04, WIh-WOIh and WIh-WOIs, and for M09, WIh-WOIh, WIh-WOIs, WIs-WOIs were found to be statistically different from each other. Four regions M01, M03, M05 and M09 had all walking geometry conditions statistically different. Regions M04, M07 and M10 had Wk1-Wk2 and Wk2-Wk3 statistically different, but for M09 Wk1-Wk3 and Wk2-Wk3 showed a significant difference. The rest of the regions had only one walking surface geometry condition statistically significant, for M02 (Wk1-Wk3) and M06 (Wk1-Wk2).

No statistical significance was seen when looking at medial side compared to the lateral one of the foot between the forefoot regions M06-M07 walking on different surface geometries. Also in the M05 and M06 when walking on Wk3. Only between the rearfoot regions M01 and M02 no significance were found in Wk1 and Wk3.

A significant decrease in CA was seen between the rearfoot and the midfoot on the medial side in the masks M01 and M03 in all walking surface geometries. Also a significant decrease was present on the medial part of the foot between M02 and M04, but only when walking onWk2.

The CA was significantly increased on the medial side (M03-M06) and decreased on the lateral one (M04-M06 and M04-M07) when the load was transferred from the midfoot to the forefoot while walking on Wk1. However, a significant decrease was seen when ascending stairs (Wk2) between the midfoot and the forefoot in M03-M05 and M03-M06. Still no significance was maintained in the lateral side while walking on Wk3.

Between the forefoot and the toes no significant differences were seen between M06-M08 when walking on Wk1 and Wk3. Also no statistical difference was seen between the M05-M08 in Wk3.

Variables		*M01*	*M02*	*M03*	*M04*	*M05*	*M06*	*M07*	*M08*	*M09*	*M10*
	Wk1	24.15 ± 1.02	21.31 ± 1.26	13.53 ± 2.09	19.19 ± 2.44	13.29 ± 0.78	16.51 ± 0.38	15.08 ± 0.39	17.38 ± 0.87	12.47 ± 1.16	152.91 ± 3.97
WIh	*Wk2*	10.39±3.75	20.76±3.38	18.91±3.21	17.28±3.04	12.22±0.43	15.79±0.33	16.29±0.69	8.01±0.69	12.78±0.68	132.71±10.21
	Wk3	25.34±2.81	18.55±2.45	17.41±2.41	20.35±2.61	13.64±0.75	22.03±1.13	15.01±0.59	14.86±1.44	10.19±1.76	146.97±7.03
	Wk1	24.82±1.14	21.43±1.46	16.15±2.13	20.05±2.49	13.76±0.53	22.40±0.48	20.29±1.00	22.79±1.58	17.62±1.99	158.35±3.45
WIs	*Wk2*	9.96±3.72	22.58±2.74	19.06±2.74	19.63±1.94	12.18±0.32	15.55±0.40	16.69±0.63	7.57±0.68	13.41±0.52	136.83±8.65
	Wk3	23.00±1.82	19.05±1.76	20.87±1.77	23.12±2.21	14.07±0.72	16.08±0.59	14.88±0.57	14.72±1.87	9.47±1.95	149.63±5.91
	Wk1	24.52±0.70	22.99±0.72	8.53±1.79	27.94±1.91	12.57±0.56	16.20±0.46	15.40±0.30	18.20±0.47	13.18±0.80	159.44±3.64
WOIh	*Wk2*	13.80±4.63	18.15±5.55	22.91±2.42	12.30±3.93	12.44±0.37	16.50±0.23	17.61±0.46	8.17±0.63	13.77±0.61	135.93±13.69
	Wk3	22.58±2.25	20.39±2.34	12.66±3.45	28.53±2.06	13.54±0.78	15.93±0.84	14.82±0.79	15.82±1.78	11.69±1.50	155.93±7.25
	Wk1	24.85±0.50	23.32±0.74	8.32±1.69	28.13±2.22	12.94±0.70	16.14±0.45	15.40±0.27	18.05±0.34	13.40±0.65	160.69±3.92
WOIs	*Wk2*	14.35±4.48	18.53±5.29	23.79±1.85	14.17±3.63	12.54±0.34	16.59±0.23	17.86±0.43	8.43±0.57	13.81±0.62	140.26±12.45
	Wk3	23.29±1.30	21.59±1.64	15.27±2.80	29.44±1.34	13.71±0.75	15.92±0.66	14.77±0.56	15.21±1.98	11.40±1.62	160.57±5.29

Table B.1: Contact area (cm^2) Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

Appendix C

Pressure-time integral results

No significance was found in regards to PTI for regions M04, M05, M08 and M09 between the insole conditions, but statistical differences were seen between all walking surface geometry in M01, M06, M08 and M10.

No statistical significance was found in M02, M03, M06 and M07 between WIh-WIs and WOIh-WOIs, but in the M01 foot region a p-value < 0.0003 was found between WIh-WOIh, WIs-WOIh and WIs-WOIs and in M10 the p-value was 0.007 for WIh-WOIs.

In regards to the surface geometry a p-value < 0.0004 was seen between Wk1-Wk2 and Wk2-Wk3 in M02 and M05, but only for Wk1-Wk2 in M04. No significance was found between Wk1-Wk3 for foot regions M03, M07 and M09.

A statistical significant increase in PTI was noted between the medial and the lateral side of the toe regions between M08-M09 in Wk1 and Wk3, but an increase was present while walking on Wk2. Also statistical significance was seen between the medial and the lateral masks of the rearfoot (M01-M02) and midfoot (M03-04) while walking on Wk3. Additionally, a rise in PTI was observed also within the forefoot masks M05 and M07 while ascending stairs (Wk2).

No significance was discerned between the rearfoot and the midfoot for the lateral masks M02-M04 for Wk3. However, a significant increase was distinguished between the midfoot and forefoot masks for all walking surface geometries. Moreover, within the forefoot and the toes, no statistical difference was distinguished medially (M05-M08 and M06-M08) for Wk1 and laterally (M06-M09 and M07-M09) for Wk2.

Variables		M01	M02	M03	M04	M05	M06	M07	M08	M09	M10
WIh	Wk1	82.68±11.52	66.90±10.41	36.85±5.51	40.81±9.01	59.80±10.57	69.38±7.34	68.86±10.52	59.90±12.35	32.89±7.08	132.37±10.74
	Wk2	21.23±10.92	42.14±15.20	58.17±12.50	59.35±11.39	78.71±14.31	90.47±12.76	87.09±16.38	40.53±10.59	65.63±19.35	106.31±15.93
	Wk3	57.39±15.08	41.93±12.46	40.13±8.58	46.02±10.42	74.31±13.59	82.73±12.02	76.67±14.47	50.48±13.27	36.37±10.39	103.75±13.91
WIs	Wk1	88.96±11.09	69.50±10.49	39.30±4.89	37.33±6.52	64.17±9.87	64.33±6.50	58.65±8.38	69.96±12.54	35.88±9.10	132.35±10.37
	Wk2	21.37±10.73	47.73±14.29	52.66±9.53	58.82±9.67	66.19±10.65	82.26±9.61	88.62±14.21	41.97±9.63	85.90±18.61	108.13±16.25
	Wk3	69.76±16.90	50.41±13.58	41.99±7.48	41.71±8.20	65.60±13.12	66.97±10.98	59.78±12.72	50.98±14.03	31.42±10.93	99.19±16.07
WOIh	Wk1	62.23±8.46	57.10±8.16	27.24±4.10	44.24±9.01	62.23±12.07	69.86±7.02	64.89±9.80	60.85±12.66	43.11±6.36	120.28±10.40
	Wk2	23.91±11.55	21.99±11.62	58.27±15.49	40.96±8.93	73.77±15.91	90.71±13.28	91.84±17.65	42.56±10.25	71.78±20.37	111.92±17.84
	Wk3	34.82±11.17	29.07±9.88	24.49±8.78	44.39±10.62	78.08±15.12	83.50±12.26	73.09±12.70	55.48±16.06	42.31±11.50	98.71±14.68
WOIs	Wk1	63.69±8.15	58.49±7.76	28.66±3.84	42.16±7.42	62.25±10.21	61.10±5.71	57.88±8.62	63.20±11.58	37.67±5.71	114.25±10.30
	Wk2	25.49±11.47	24.16±11.45	55.32±12.12	41.54±8.56	69.63±12.91	79.99±11.26	88.07±15.69	42.62±10.04	76.25±18.74	103.91±16.61
	Wk3	46.60±14.24	38.50±12.14	29.75±7.06	42.45±9.62	66.43±14.18	65.73±11.87	60.35±12.79	47.47±15.05	35.21±9.75	89.34±15.02

Table C.1: Pressure-time integral (kPA*s)Mean±SD, where the variables represent: ten masks, four conditions and three walking surfaces

Appendix D

Matlab script

```
function [data_g, data_p, nSteps, To, Td, frames, minimum, maximum, xls] = process_data(force_filename, goniometer_filename, patient_static_hard, patient_static_soft)
limit=60; % force treshold

% import data
data_p = importdata(force_filename,'\t',9);
data_p = data_p.data;
data_g = importdata(goniometer_filename,'\t',7);
data_g = data_g.data;

% filter data
cutoff = 20/0.5 / 200;
[b,a] = butter(2,cutoff);

dyn = filtfilt(b,a,data_g(:,3));
force_left=data_p(:,2);
goniometer_data=dyn;

% resample 100Hz to 200Hz
resampled_force_left=resample(force_left, 200, 100);

firstZero=0; % switch for excluding static measurements at the start of each trial
firstStep=0; % switch for detecting if the first step as happened
go = 0; % switch that determinines if measurements are part of a step or not
noise_data = []; % list of measurements excluded before first step occured
noise_force_data = []; % list of force measurements exclude before first step occured
average_force_noise=0; % initialization of average variable
average_noise = 0; % initialization of average variable
noise_std = 0; % initialization of standar deviation variable
previous_value = 999999; % variable that holds previous value. Init to a large number
Td = []; % touch down angles of each step
To = []; % take off angles of each step
maximum = []; % maximum angle for each step
minimum = []; % minimum angle for each step
Mean = []; % mean angle for each step
Std = []; % standard deviation for each step
```

```
frames = []; % measurements divided in steps
nSteps = 1; % number of steps counter
velocity = []; % angular velocity for each step

% couters
jj=1;
jjj=1;

xls=[];

for i=1:length(resampled_force_left)
    if(firstZero == 0)
        if(i <= 200 ) % First second
            % add data to static ( first second )
            noise_data(jj)=goniometer_data(i);
            noise_force_data(jj)=force_left(i);
            jj = jj + 1;
        else
            % calculate average/std of static
            average_noise=mean(noise_data);
            noise_std=std(noise_data);
            average_force_noise=mean(noise_force_data);
            firstZero=1;
        end
    else
        if(resampled_force_left(i) >= limit)
           if(firstStep == 0)
              % detection of take off for first step
              if(resampled_force_left(i) <= average_force_noise)
                  % set take off angle
                  To(nSteps,1) = calculate_angle(goniometer_data(i), average_noise);
                  jjj = 1;
                  go = 1;
                  firstStep = 1;
              end
              % detection of take off for all steps except first one
           elseif(previous_value < limit)
              To(nSteps,1) = calculate_angle(goniometer_data(i), average_noise);
              jjj = 1;
              go = 1;
            end

          % valid step
          if(go == 1)
              % calculate angle for each measurement in step
              frames(jjj,nSteps) = calculate_angle(goniometer_data(i), average_noise
                  );
              jjj = jjj + 1;
          end

       elseif(resampled_force_left(i) < limit)
           go = 0;
           % detection of touch down
           if(previous_value >= limit)
               % calculate angle for touch down
               Td(nSteps,1) = calculate_angle(goniometer_data(i), average_noise);
               nSteps = nSteps + 1;
           end
```

```
        end
    end
    % update previous value
    previous_value=resampled_force_left(i);
end

% Process data and remove tail containing end of test ( incomplete step )
if(length(To) > length(Td))
    frames(:,length(To))=[];
    frames(~frames)= NaN;
    To(length(To)) =[];
end

% calculate statistics - min,max,mean,std,angular velocity
for ij=1:length(To)
    minimum(ij,1) = nanmin(frames(:, ij));
    maximum(ij,1) = nanmax(frames(:, ij));
    Mean(ij,1) = nanmean(frames(:, ij));
    Std(ij, 1) = nanstd(frames(:, ij));
    temp=frames;
    temp(isnan(temp))=0;
    velocity(ij,1)= mean(abs(diff(temp(:,ij))));


    xls(ij,:) = [To(ij,1), Td(ij,1), minimum(ij,1), maximum(ij,1), Mean(ij,1), Std(
        ij,1), velocity(ij,1), average_noise, noise_std];

end

% ploting figures
figure;
title(force_filename)

subplot(2,1,1)
plot(resampled_force_left(:,1));
title('Force')

subplot(2,1,2)
plot(dyn);
title('Angle')

workspace;


end

function angle = calculate_angle(goniometer_data, average_noise)

% calibration values
voltage = [-2.907873851;    -0.120217888;   2.543287965];
angles  = [-45;              0;             45];

% caluclate angles based on calibration values
if(goniometer_data == voltage(2))
    angle = angles(2);
elseif(goniometer_data > voltage(2))
    angle = (goniometer_data - average_noise) * angles(3) / voltage(3);
else
```

```
    angle = (goniometer_data - average_noise) * angles(1) / voltage(1);
end

end
```

Listing D.1: Matlab program

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Appendix E

R console script

```
# trm= insole conditions (WIh, WIs, WOIh, WOIs)
# var= surface geometry (f-flat, u-upstairs and d-downstairs)
# pmt= parameter (TO, TD, PP, CA etc)
# measurement= values

# Read Data,
data=read.table('alldata.txt' , header = TRUE )
data1=subset(data, data$pmt=="to")

# Calculate residuals
r1=residuals(lm(data1$measurement~data1$trm*data1$var))

# Q-Q plot
qqnorm(r1)
qqline(r1)

# Test for normal distribution
shapiro.test(r1)

# Normal distrbuted data calculate ANOVA and check confidence level
fit1=lm(data1$measurement~data1$trm*data1$var)
summary(fit1)
anova(fit1)
confint(fit1)

# Calculate post-hoc Tukey test
b1=aov(data1$measurement~data1$trm*data1$var)
TukeyHSD(x=b1, 'data1$trm:data1$var' ,
TukeyHSD(x=b1, 'data1$trm' , ordered = TRUE )
TukeyHSD(x=b1, 'data1$var' , ordered = TRUE )

# Not normal distributed data -calculate Kruskal test
kruskal.test(data1$measurement~data1$trm)
kruskal.test(data1$measurement~data1$var)
kruskalmc(data1$measurement~data1$trm)
kruskalmc(data3$measurement~data1$var)
```

Listing E.1: R script