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Medicovi H20 insoles test

variability of centre of pressure in healthy people during dynamic standing and gait

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MEDICOVI H2O INSOLES TEST

VARIABILITY OF CENTRE OF PRESSURE IN HEALTHY PEOPLE DURING DYNAMIC STANDING AND GAIT

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Background

Variability is a central characteristic of all human movement because of its role in motor learning and control (Latash and Anson 2006). A few studies have suggested a possible beneficial effect of e.g. varying load and movement pattern for the prevention of musculoskeletal disorders (Kilbom and Persson 1987; Madeleine et al. 2008a; Madeleine et al. 2008b; Madeleine 2010). To understand the nature and complexity of the motor variability, a collection of different types of variability measures need to be considered (Newell and Corcos 1993; Stergiou 2004). Thus, a combination of linear parameters along with nonlinear estimators such as approximate entropy or/and correlation dimension has been suggested (Stergiou 2004).

Linear descriptors such as standard deviation and coefficient of variation are commonly used to characterize the amount or size of variability in movements (Stergiou 2004). However, these approaches do not provide information about the true structure of motor variability (Buzzi et al. 2003; Slifkin and Newell 1999). Nonlinear techniques derived from chaos theory have contributed the understanding the variations over time of biological signals through e.g. aging and disease (Lipsitz 2002a; Vaillancourt and Newell 2002; Van Emmerik and Van Wegen 2002). In this context, approximate and sample entropy as well as correlation dimension can be computed to characterize the structural variability, i.e., complexity and dimensionality of the kinematics signals (Buzzi et al. 2003; Georgoulis et al. 2006; Madeleine and Madsen 2009). Thus, the idea of combining linear and nonlinear techniques is sound and may expand our knowledge on the amount and structure of variability, and thereby provide valuable information about motor strategies.

We hypothesized a positive effect of the H20 insoles on the variability of the centre of pressure (CoP) displacement during one-leg standing and walking. The expected effects were both an increase in the size and structure of variability (Van Emmerik and Van Wegen 2002).

Methods and Materials

Participants

Twenty-one healthy volunteers voluntarily participated in the study (11 of them female). Their mean age ± SD was 32.1±8.1 year; body mass: 71±12.9 kg; height: 1.7±0.08 m; BMI 24.3±3.6 kg/m^2. Informed consent was obtained from each participant. The study was approved by the local Ethical Committee (N 20100084) and conducted in accordance with the Declaration of Helsinki. FPI were used to classify the participants; and participants with the neutral foot (FPI equals 0-5) who were able to stand on a single limb for 30 s were included. Exclusion criteria were: people who have an abnormal foot, and suffering physical or mental disability which can potentially affect their balance. Participants were assigned to one of the different trials of 1) Walk with / without insoles, at least 12 steps; 2) static balance with / without insoles - standing balance for 30 seconds on each leg. PEDAR system (sampling rate 100Hz) was used to measure the pressure distribution. MEDICOVI H20, DUMMY insoles, and no insole were used as the independent variable. Degree of variability and structure of variability (standard variation, coefficient of variation, sample entropy) were analysed to answer the change at diversity in both amplitude and complexity.

FPI measurement

The subjects stayed in their relaxed stance position with double limb support, their arms relaxed at their side, looking straight ahead, and needed to stand still for about 2 min. Because the FPI has good intra-observer reliability but only moderate inter-observer reliability, all measurements were made by the same examiner. The six criteria used in the FPI were evaluated – talar head palpation, supra and infra malleolar curvature, calcaneal frontal plane position, prominence in the region of the talonavicular joint, congruence of the medial longitudinal arch, and abduction/adduction of the forefoot on the rear foot, scoring each criterion on a scale of −2, −1, 0, +1, or +2. The FPI cut points

to define the type of foot was; (a) highly supinated −5 to −10, (b) supinated −1 to −4, (c) neutral 0–5, (d) pronated 6–9 and (e) highly pronated +9.

Data analysis

The average force and displacement of the centre of pressure (CoP) in X (medial-lateral) and Y (anterior-posterior) directions for left and right foot were analysed. The force and CoP time series were low-pass filtered (6 Hz Butterworth order 2).

The mean, standard deviation (SD), coefficient of variation (CV), approximate entropy (ApEn), and sample entropy (SaEn) were computed for both the static (balance tests) and dynamic conditions.

Mean values represent global averages over the recording period.

Linear analysis of the force signals was performed to quantify the amount of variability. Standard deviation (SD) and coefficient of variation (CV) were calculated. SD reflects the amount of the variability, and CV is the relative variability. CV was derived from the absolute value of the mean and SD of the signal.

Nonlinear analysis of the force signals was performed to assess the structure of variability. Time dependent structure of force variability reveals deterministic and stochastic organization of the neurophysiological system. The degree of complexity of a signal is typically associated with the number of system elements and their functional interactions (Van Emmerik and Van Wegen 2002). ApEn and SaEn were computed for this purpose. ApEn and SaEn express the complexity of the recorded signal (Kuusela et al. 2002; Pincus 1991; Richman and Moorman 2000). SaEn is the negative logarithm of the relationship between the probabilities that two sequences coincide for m+1 and for m points, where larger value indicates more complex structure or lower predictability. The embedding dimension, *m*, and the tolerance distance, *r*, were set to m=2 and r=0.2×SD of the

force channel. ApEn and SaEn are unitless, non-negative numbers where lower entropy values represent less complex time series and higher values more complex time series.

For the static conditions: Mean, SD, CV, ApEn, and SaEn were calculated over 8 s epoch to ensure reliable estimation of ApEn (discarding the 1st and last 2 seconds of recordings). Average values were computed for further statistical analysis.

Similarly for the dynamic conditions: Mean, SD, CV, ApEn, and SaEn were calculated over 8 s epoch (discarding the 1st and last 4 seconds of recordings). Average values were computed for further statistical analysis.

Approximate entropy (ApEn)

$ApEn$ quantifies the complexity or structure of variability of a time series $x(i)$ (Pincus 1991; Pincus and Goldberger 1994). $ApEn$ is derived from the correlation function $C(r)$ (Grassberger and Procaccia 1983). First, the time series $x(i)$ with $i = 1 \dots N$ is divided into $N - m + 1$ vectors $u(i)$ of the state space:

$$u(i) = [x(i), x(i + \tau), x(i + 2\tau), \dots, x(i + (m - 1)\tau)]$$

where m is the embedding dimension and τ the time lag (set to 1). Then, the distance d is calculated as the maximal distance d between each vector in the state space:

$$d[u(i), u(j)] = \max(|u(i + k) - u(j + k)|), with\ 1 \leq j \leq N - m + 1\ and\ 0 \leq k \leq m - 1$$

C_i^m is the number of vectors $u(j)$ within the distance r from the template vector $u(i)$ computed as:

$$C_i^m(r) = (N - m + 1)^{-1} \sum_{i=1}^{N-m+1} H(r - |d(u(i), u(j))|)$$

with $H(\ )$ being the Heaviside step function where H is 1 if $\left(r - \left|d\left(u(i), u(j)\right)\right|\right) \geq 0$ and 0 otherwise. Then, $\Phi^m(r)$ representing the average of natural logarithm of C_i^m is computed as:

$$\Phi^m(r) = (N - m + 1)^{-1} \sum_{i=1}^{N-m+1} \ln C_i^m(r)$$

Finally, the $ApEn$ entropy is expressed as the difference between the logarithmic probability that vectors which are close for *m* points are also close if lengthened to *m+1* points.

$$ApEn(m, r, N) = \Phi^m(r) - \Phi^{m+1}(r)$$

$ApEn$ depends on the embedding dimension m, the criterion for similarity r and the number of data points N. In general, m is set to 1 or 2 to insure good statistical validity, r is set to 10 or 20 % of the standard deviation of the time series while N should exceed 800 points (Kuusela et al. 2002; Pincus 1991; Stergiou 2004; Vaillancourt and Newell 2000).

Sample entropy (SaEn)

$SaEn$ quantifies also the complexity of a time series but its computation differs from $ApEn$ as self-matches are now excluded, the first $N - m$ vectors are considered and the conditional probability are not estimated in a template manner (Richman and Moorman 2000). In practice, it means that when the distance d between $u(i)$ and $u(j)$ are computed, i is never equal to j.

$$d[u(i), u(j)] = \max(|u(i + k) - u(j + k)|), with\ 1 \leq j \leq N - m \text{ and } i \neq j$$

Now, $\Phi'^m(r)$ representing the average of natural logarithm of the probability of matches $C_i'^m$ is computed as:

$$\Phi'^m(r) = (N - m)^{-1} \sum_{i=1}^{N-m} C_i'^m(r)$$

Finally, $SaEn$ representing the negative logarithm of the relationship between the probability that two sequences coincide for m+1 and m points can be computed as:

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$$SaEn(m, r, N) = -\ln\left(\frac{\Phi'^{m+1}(r)}{\Phi'^{m}(r)}\right)$$

$SaEn$ also depends on the embedding dimension m, the criterion for similarity r and the number of data points N. m is in general also set to 1 or 2 to enable a more consistent estimation (Lake et al. 2002). SaEn decreases monotonically as r increases and does not depend in theory on N (Kuusela et al. 2002; Richman and Moorman 2000).

Statistics

The normalization of the data distribution has been tested by Q-Q plot. The distribution was not normal therefore the k-independent sample test (kruskal Wallis) was used for statistical analysis of the data. P values < 0.05 were considered as statistically significant.

Results

During 30 seconds one foot standing on right leg

The mean values of force (N) during 30 seconds one foot standing on right leg were similar over the three conditions.
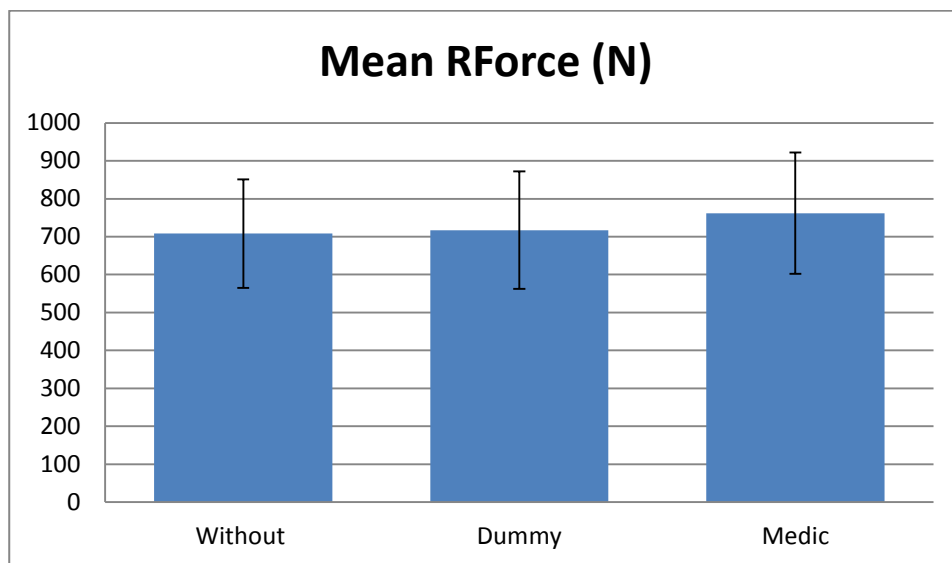
Mean RForce (N)

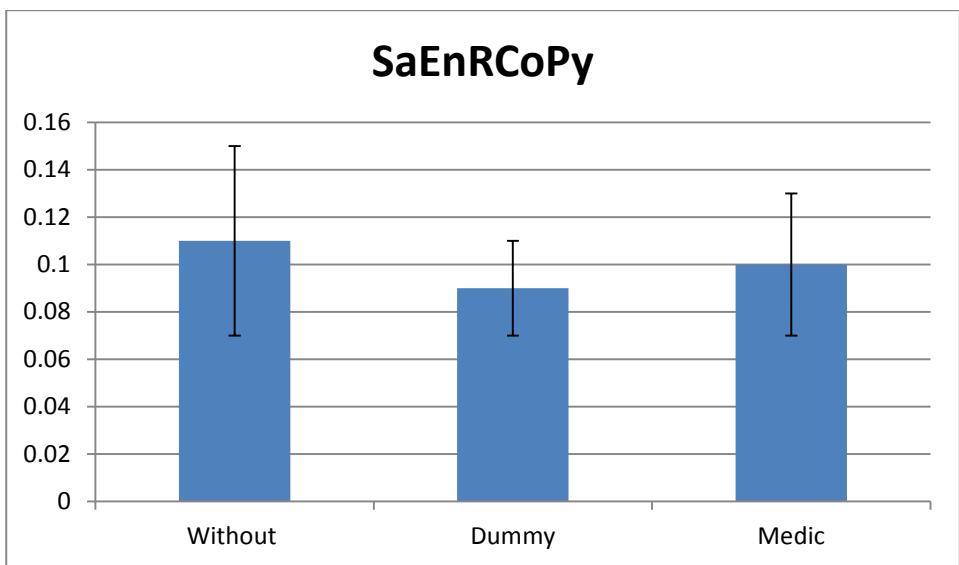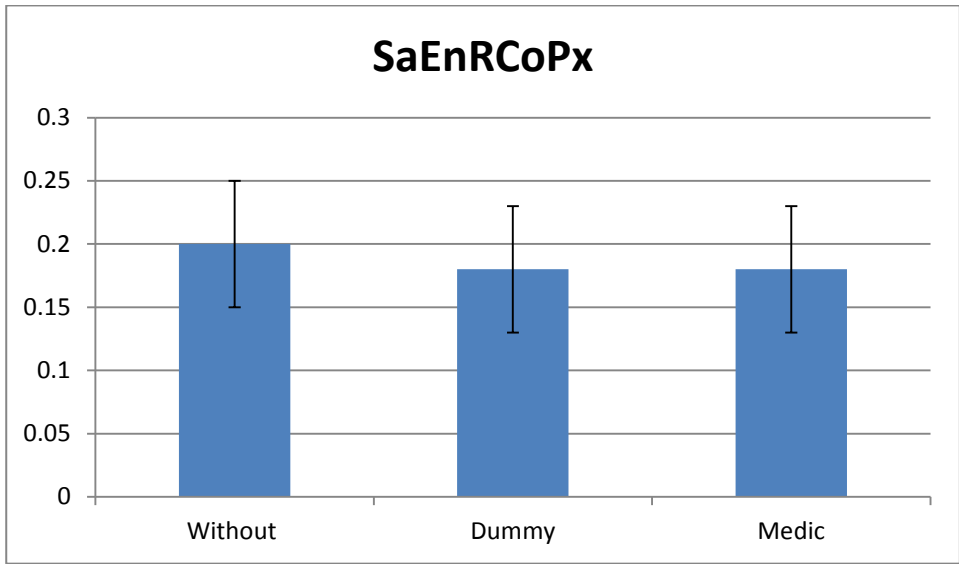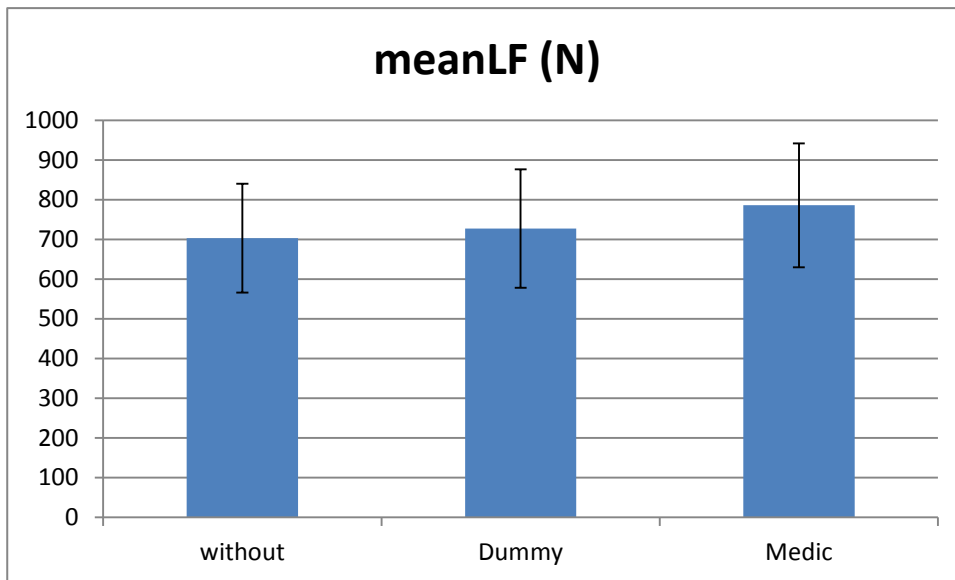The mean values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on right leg were similar over the three conditions.
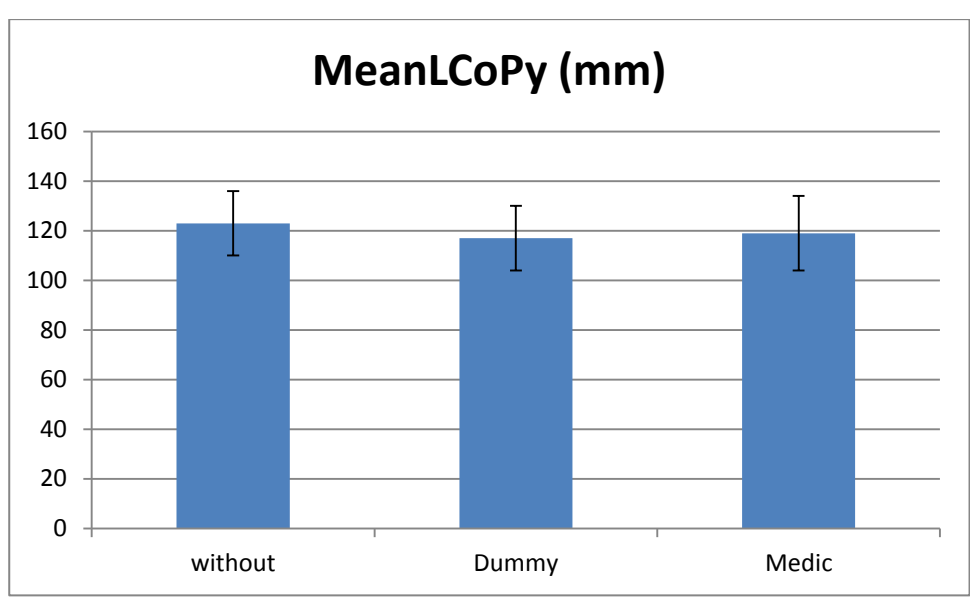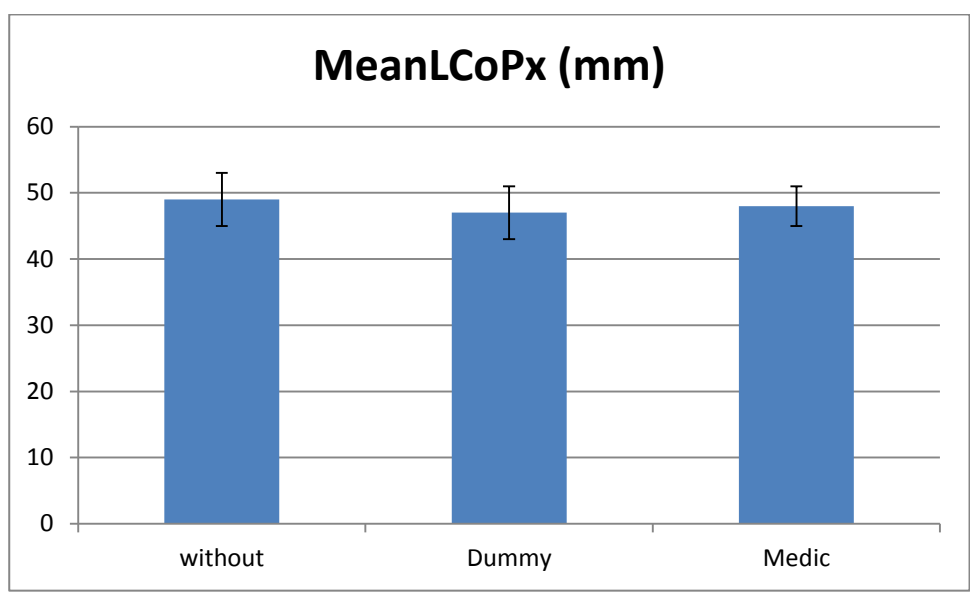

MeanRCoPx (mm)

MeanRCoPy (mm)

The standard deviation values of the force during 30 seconds one foot standing on right leg were similar over the three conditions.

SDRF (N)
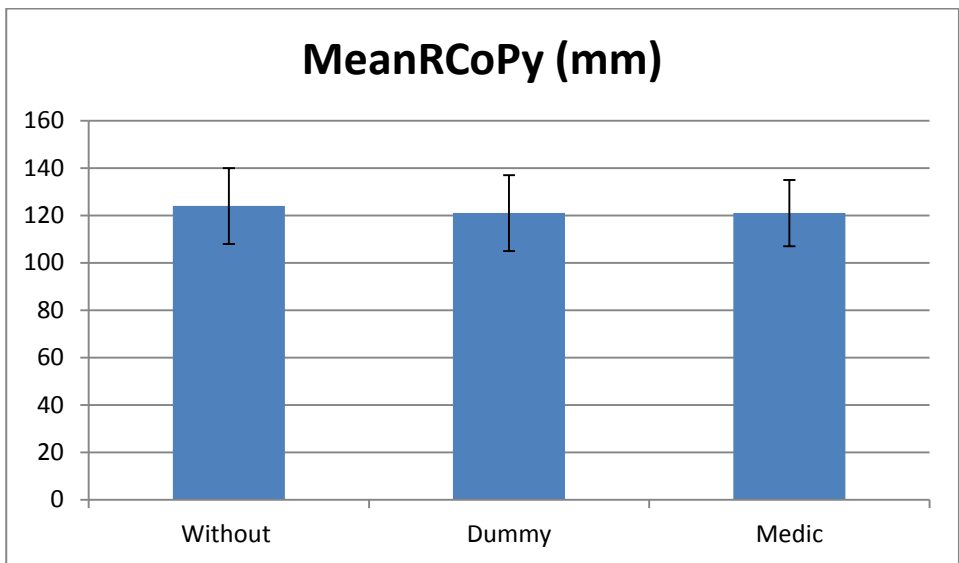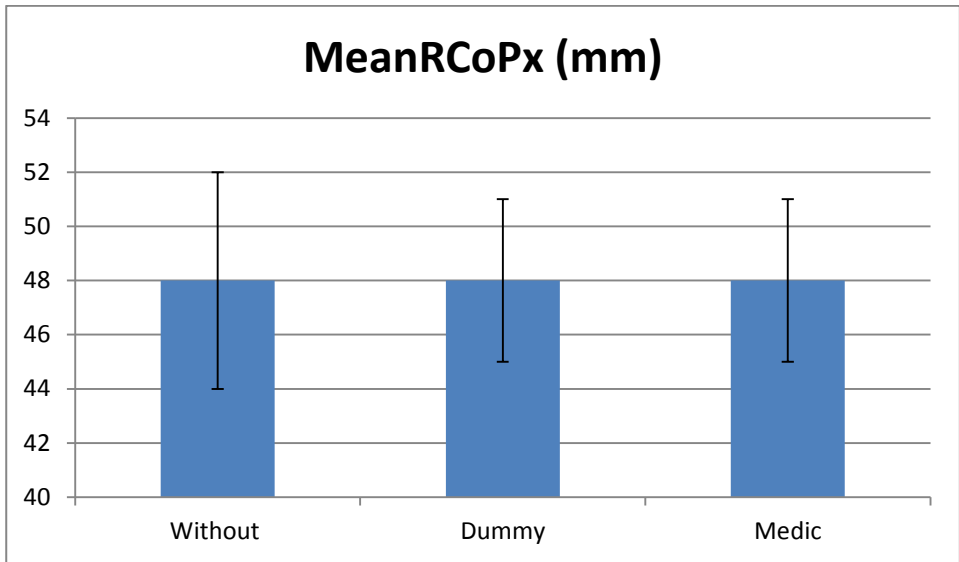
The standard deviation values of the centre of pressure in the X direction (medial-lateral) during 30 seconds one foot standing on right leg were statistically different over the three conditions. The standard deviation was lowest for the H20 insoles.
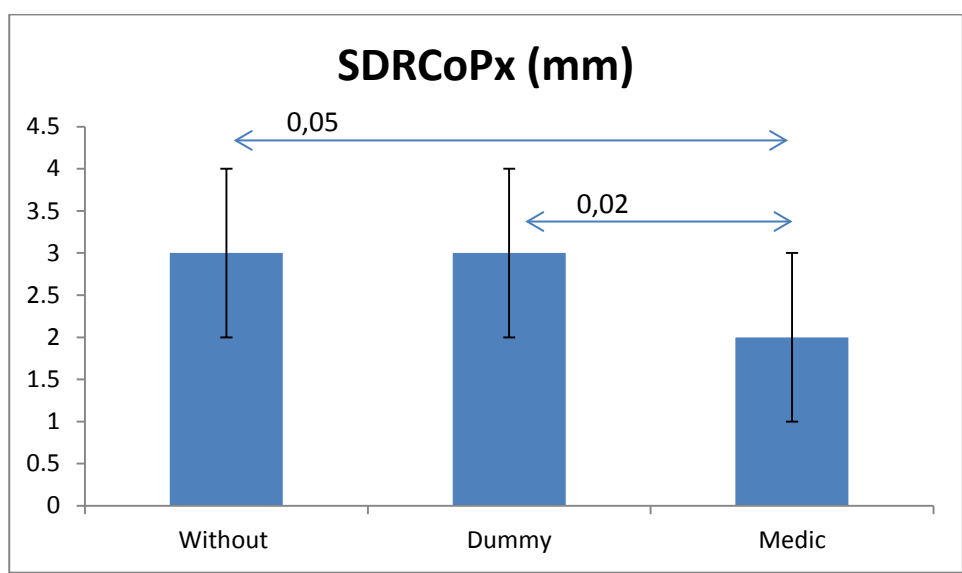
SDRCoPx (mm)

No differences in Y direction (anterior-posterior).

SDRCoPy (mm)

The coefficient variation values of the force during 30 seconds one foot standing on right leg were similar.

The coefficient of variation values of the centre of pressure in the X direction (medial-lateral) during 30 seconds one foot standing on right leg were statistically different. The coefficient of variation was lowest for H20 insoles.
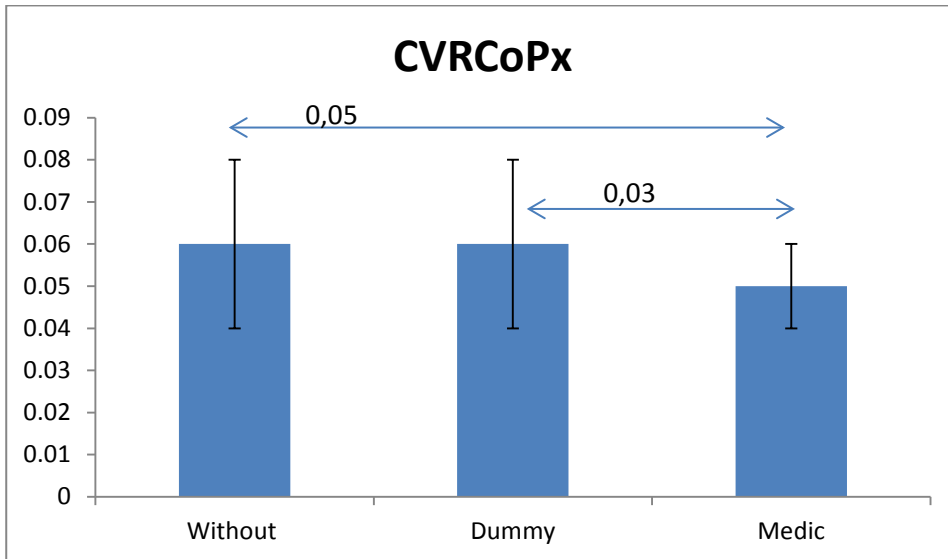
No differences in Y direction (anterior-posterior).

The approximate entropy values of the force during 30 seconds one foot standing on right leg were similar over the three conditions.

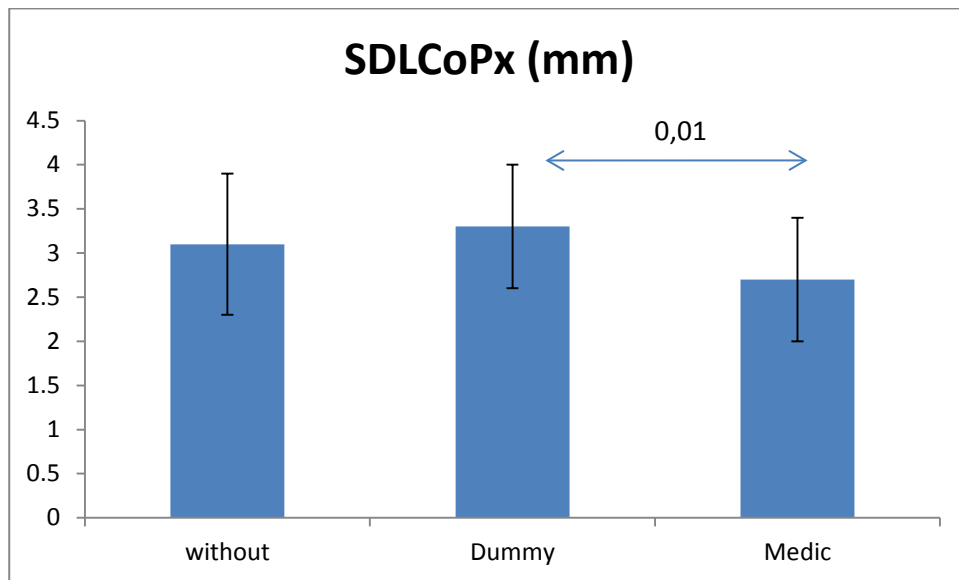The approximate entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on right leg were similar over the three conditions.
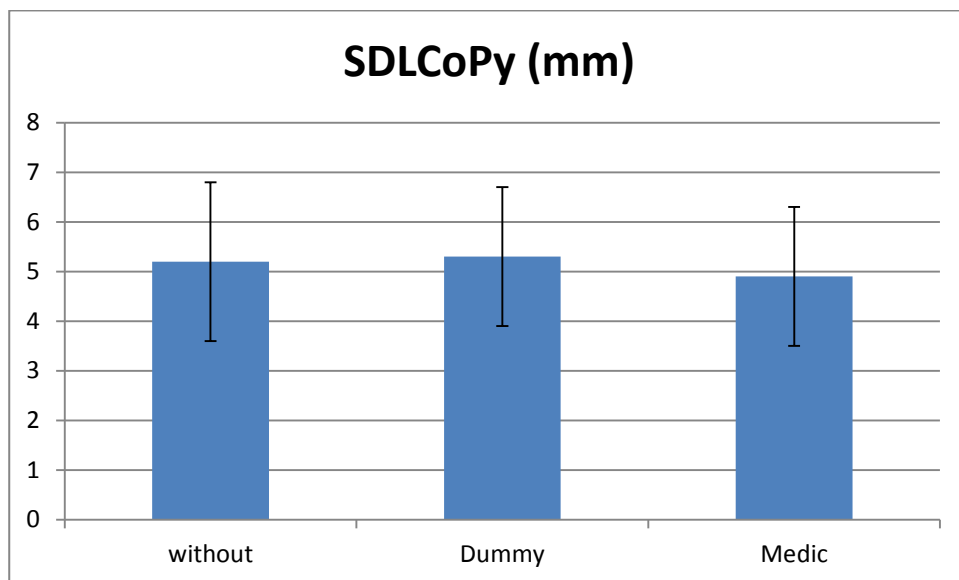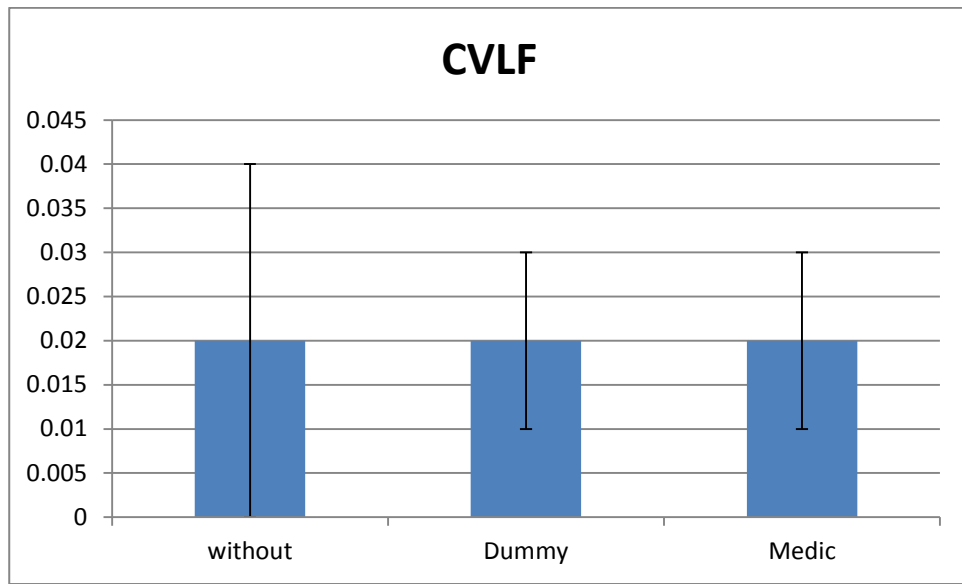
ApEnRCoPx

ApEnRCoPy

The sample entropy values of the force during 30 seconds one foot standing on right leg were similar over the three conditions.

SaEnRF

The sample entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on right leg were similar over the three conditions.

SaEnRCoPx

SaEnRCoPy
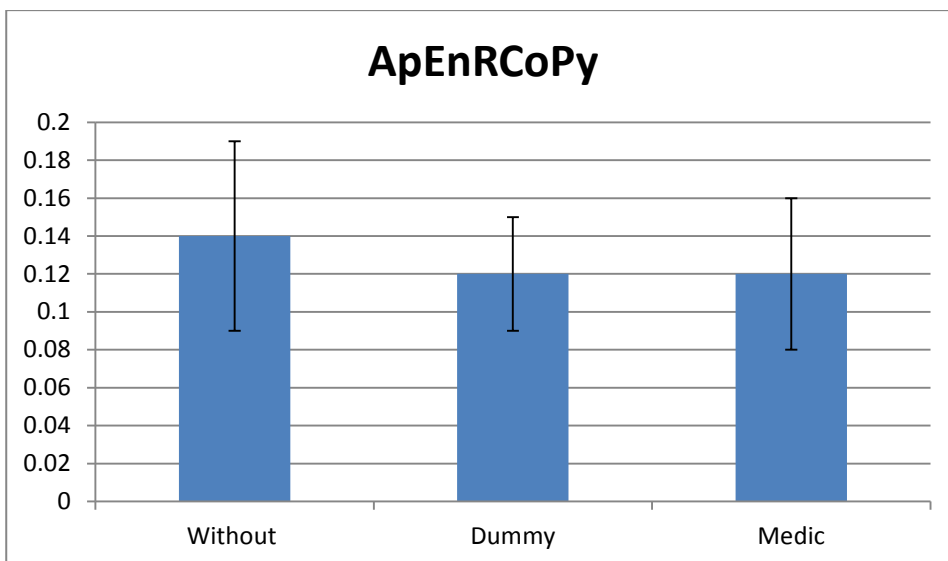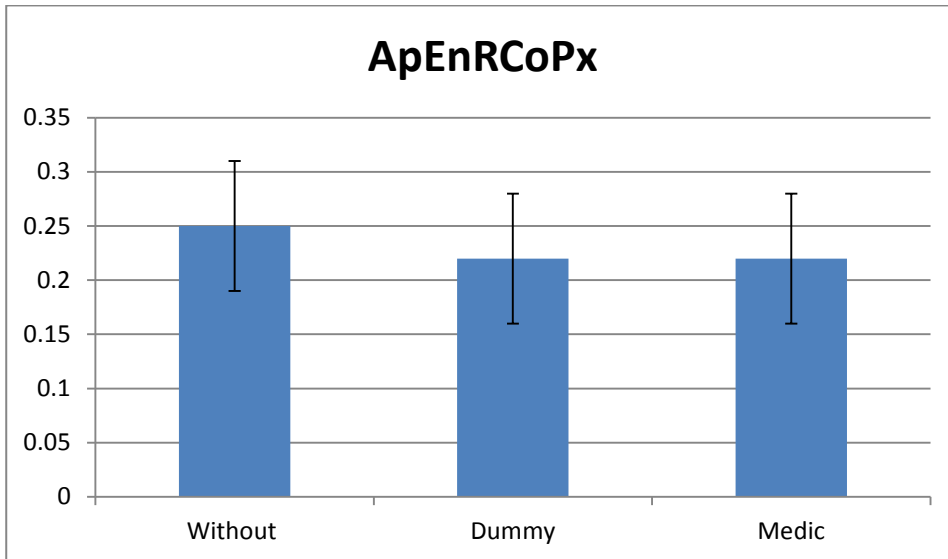
During 30 second one foot standing on left leg

The mean force (N) values during 30 seconds one foot standing on left leg were similar over the three conditions.

meanLF (N)

The mean values of the centre of pressure values in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on left leg were similar over the three conditions.

The standard deviation values of the force during 30 seconds one foot standing on left leg were similar in the three conditions.
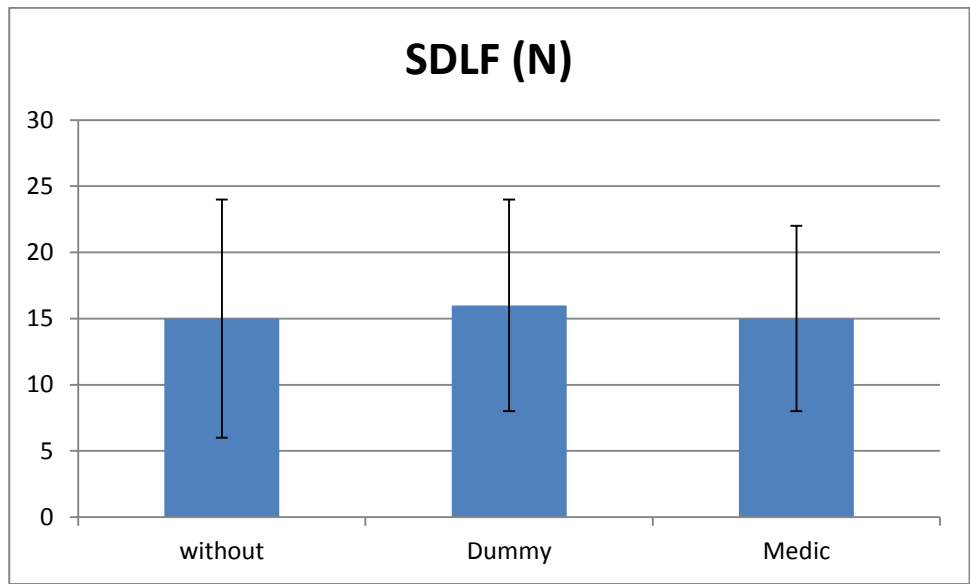
SDLF (N)
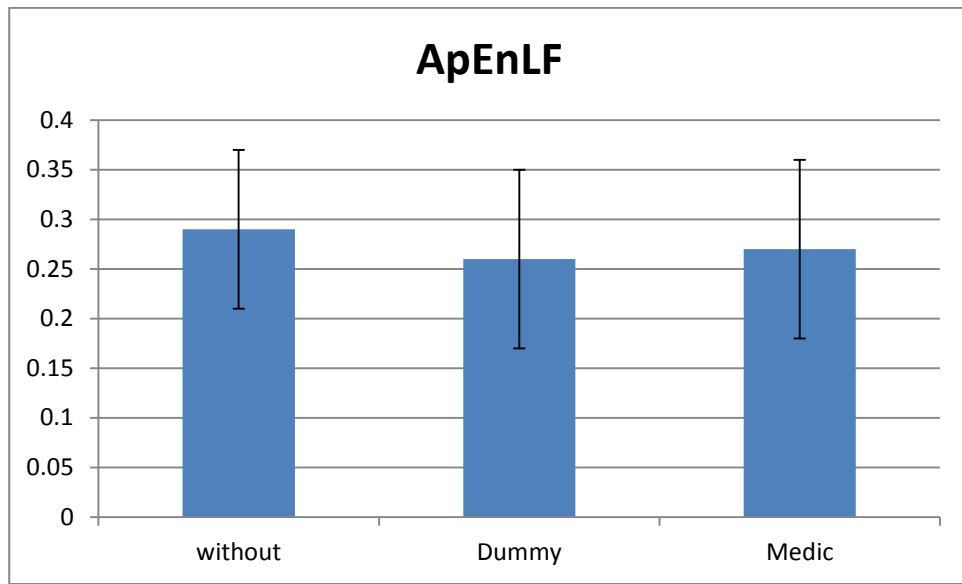
The standard deviation values of the centre of pressure in the X direction (medial-lateral) during 30 second one foot standing on left leg were statistically different. The standard deviation was lower for H20 insoles compared with dummy insoles.
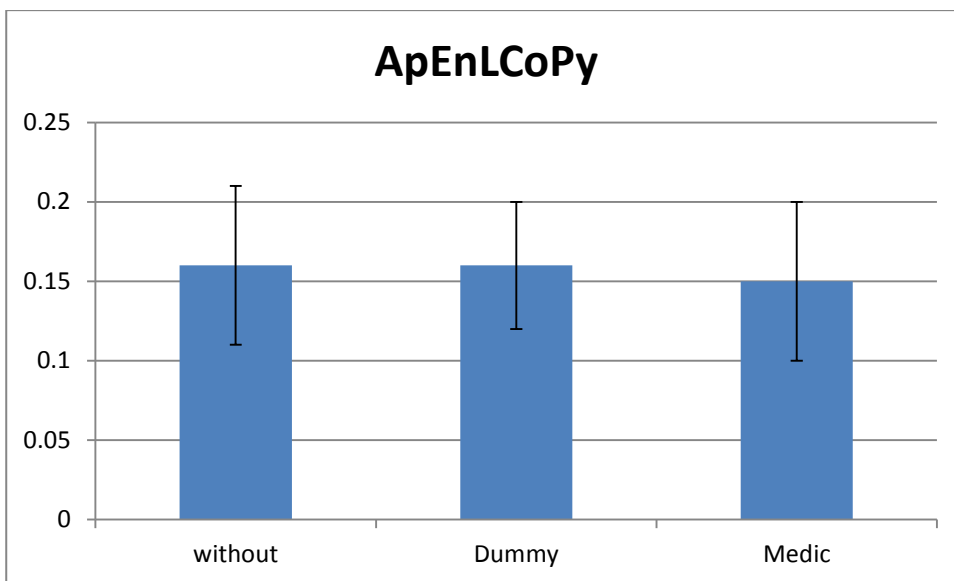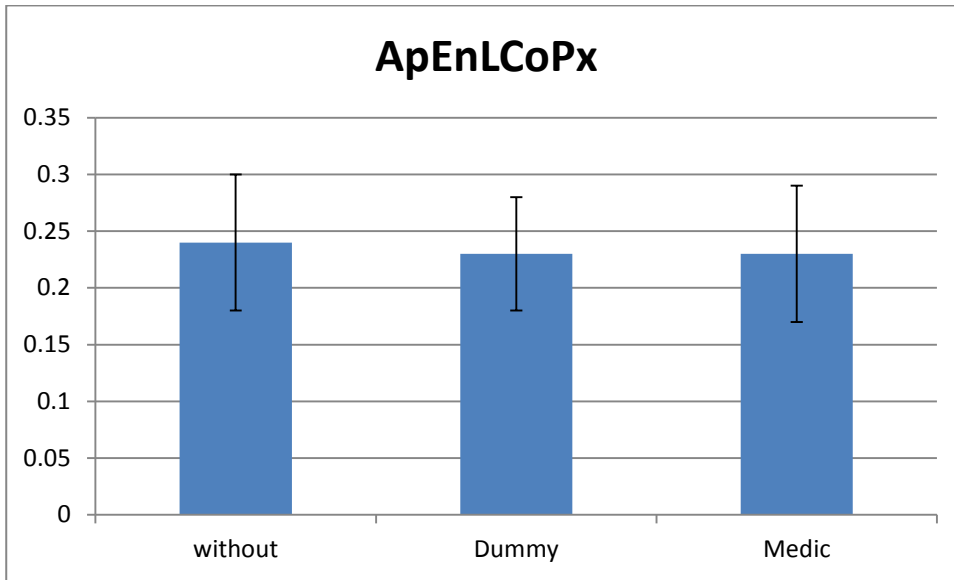
SDLCoPx (mm)

0,01

No difference in the Y direction (anterior-posterior).

SDLCoPy (mm)

The coefficient variation values of the force during 30 seconds one foot standing on left leg were similar over the three conditions.

The coefficient variation values of the centre of pressure in the X direction (medial-lateral) during 30 seconds one foot standing on left leg were statistically different. The coefficient of variation was lower for H20 insoles compared with dummy insoles.

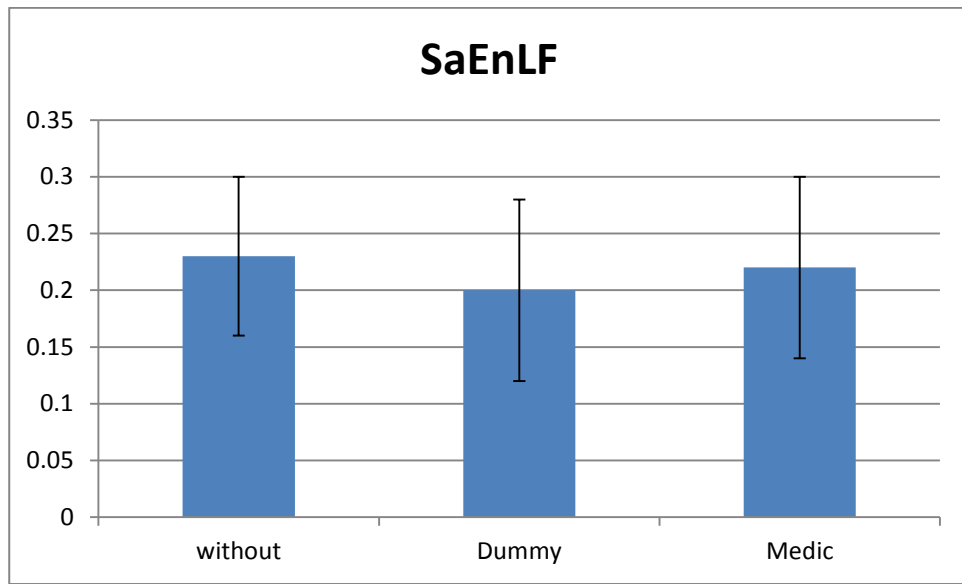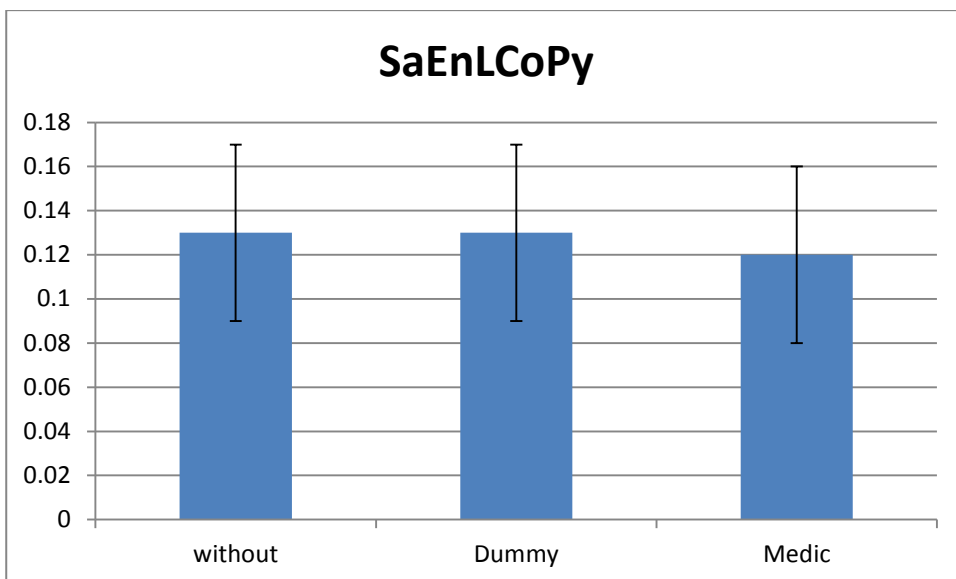

CVLCoPx

No difference in Y direction (anterior-posterior).

CVLCoPy

The approximate entropy values of the force during 30 seconds one foot standing on left leg were similar over the three conditions.
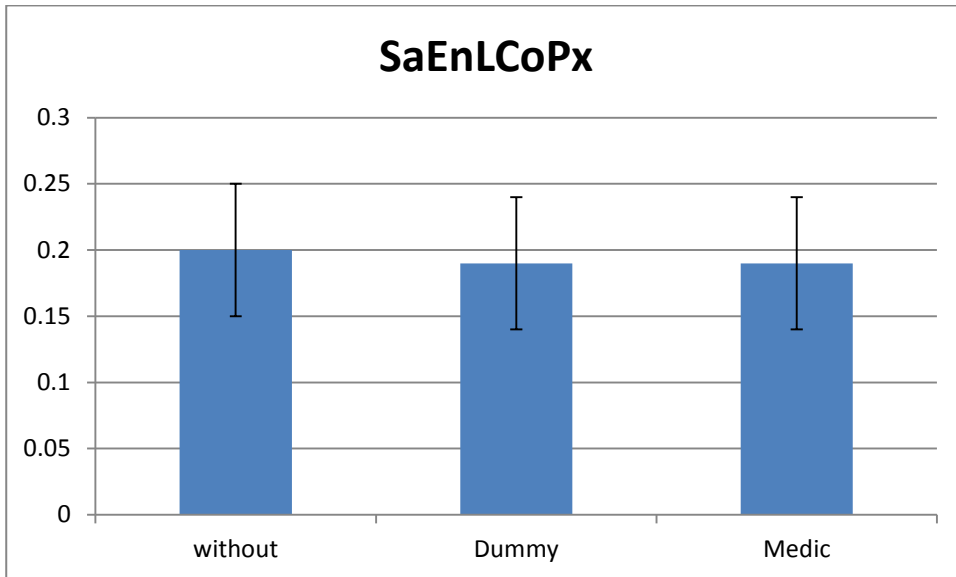
ApEnLF

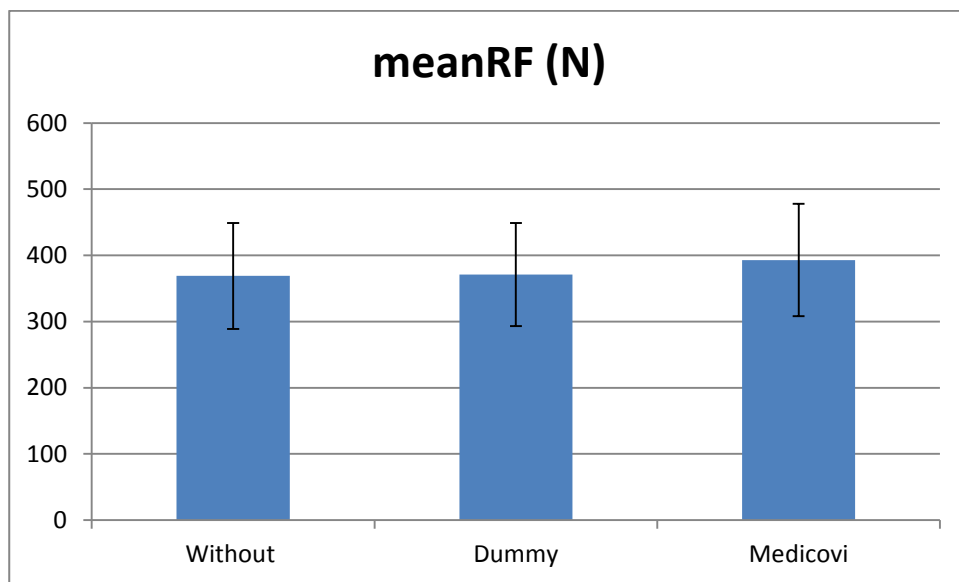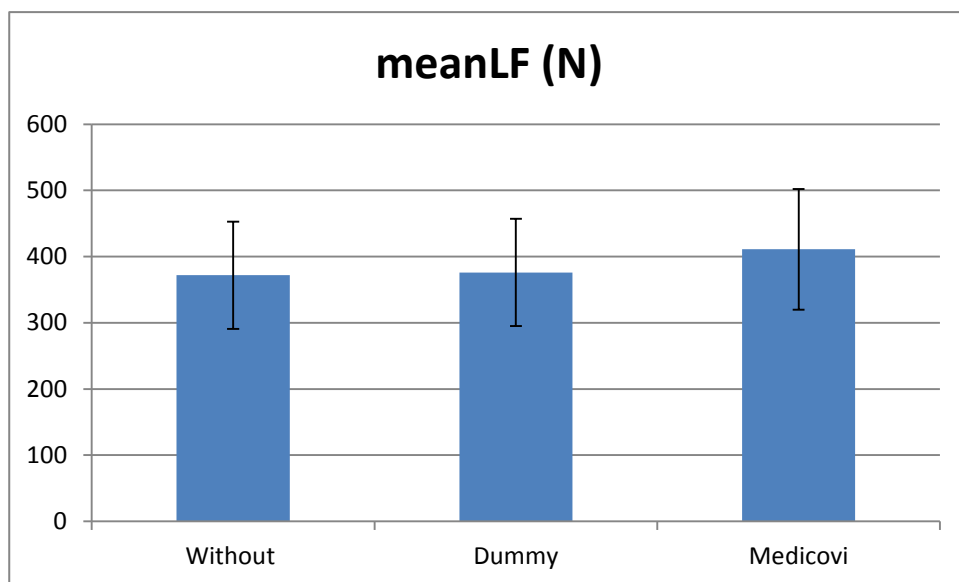The approximate entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on left leg were similar over the three conditions.

ApEnLCoPx

ApEnLCoPy

The sample entropy values of the force during 30 seconds one foot standing on left leg were similar over the three conditions.

SaEnLF

The sample entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 seconds one foot standing on left leg were similar over the three conditions.
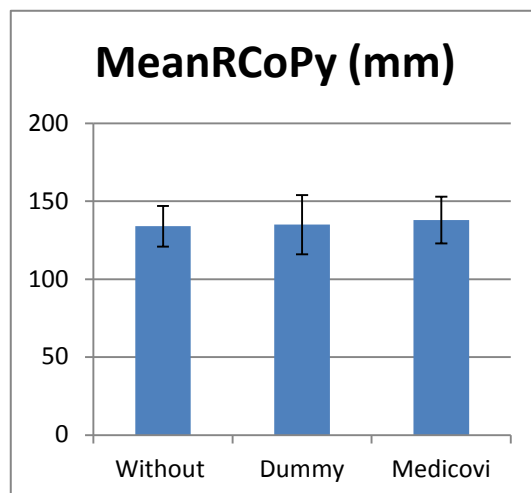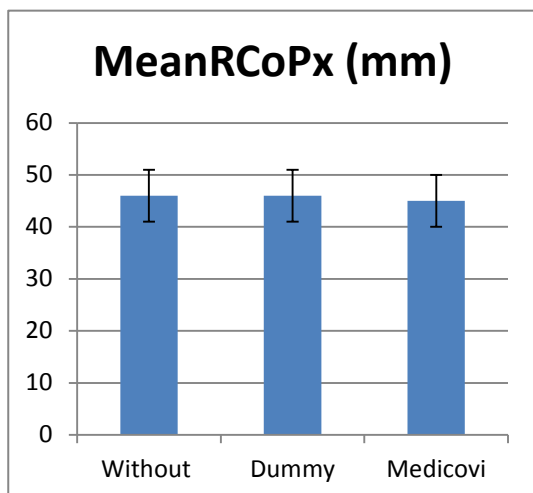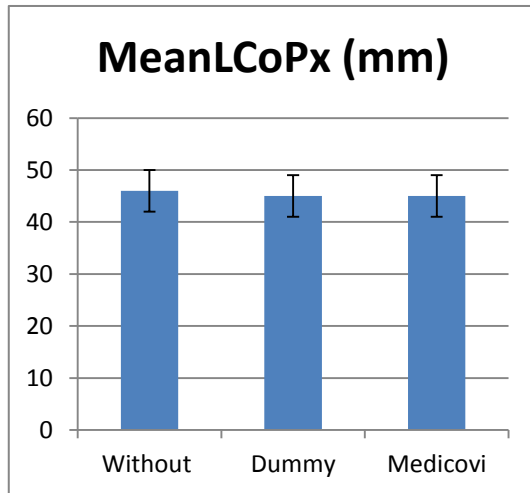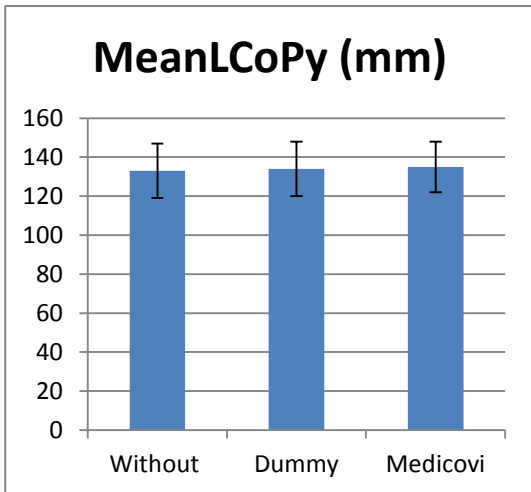

SaEnLCoPx

**SaEnLCoPy**

Parameters during Walking

The right & left foot mean force (N) values during 30 steps walking were similar over the three conditions.
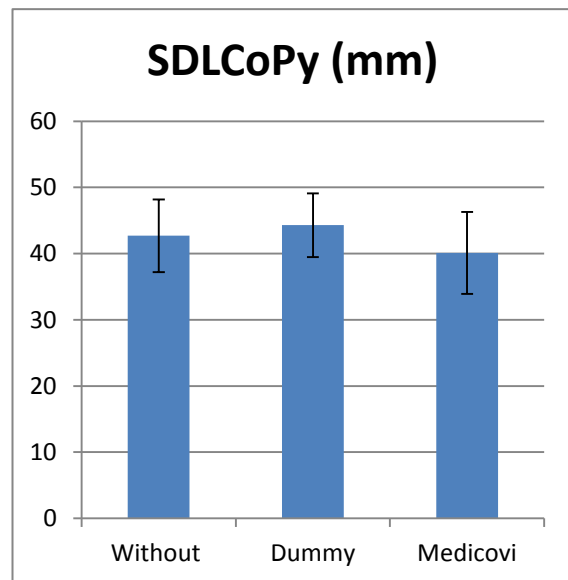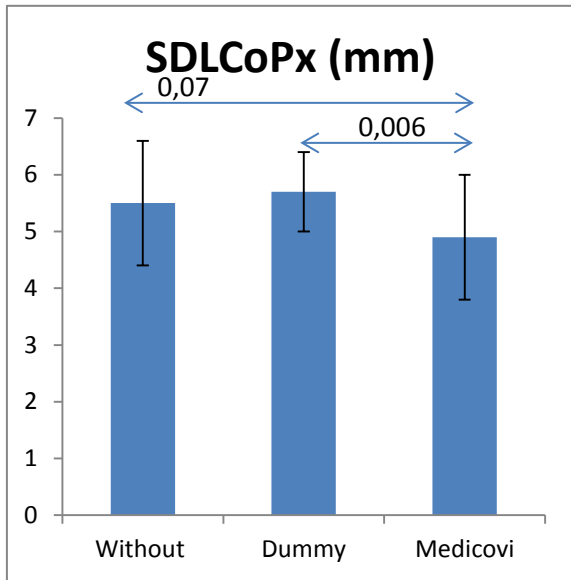
meanLF (N)

meanRF (N)

The mean values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) for right & left foot during walking were similar over the three conditions.
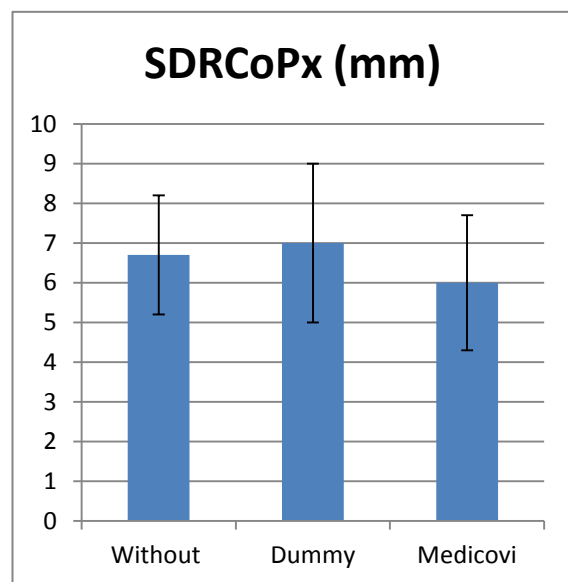
The standard deviation values of the force during 30 steps walking for right & left foot were similar over the three conditions.

SDLF (N)

SDRF (N)
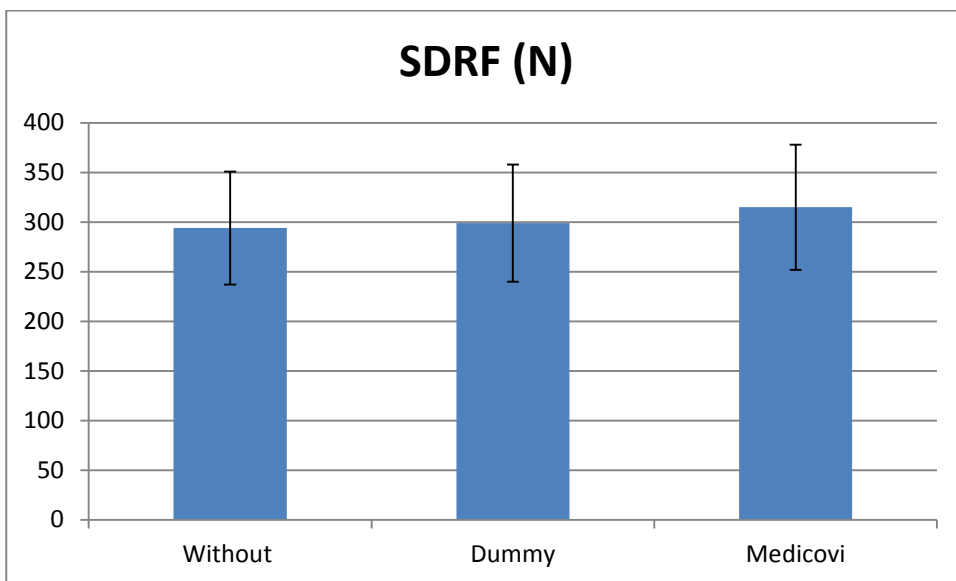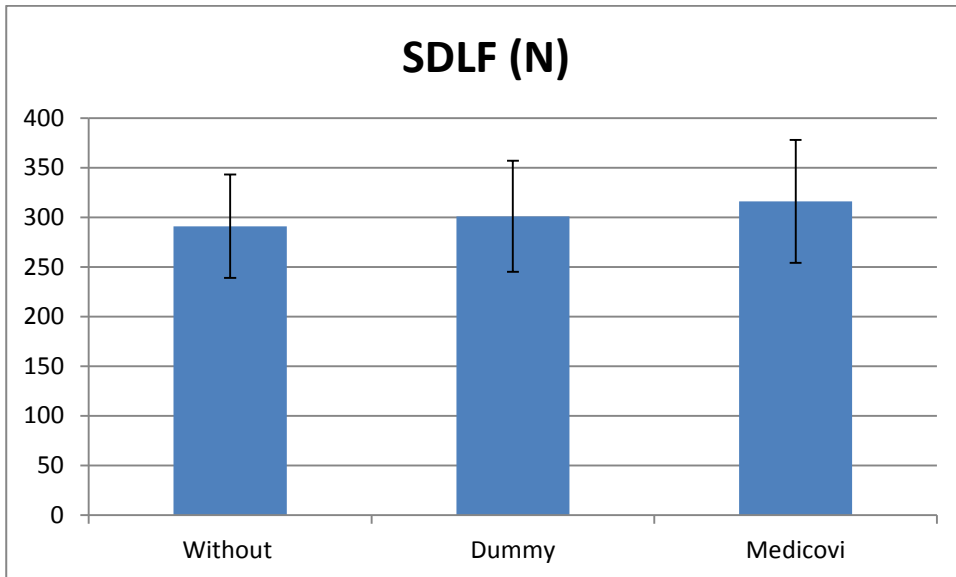
The standard deviation values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 steps walking for right & left foot.

The standard deviation for the left leg in the X direction (medial-lateral) was lowest for H20 insoles compared with the two other conditions.
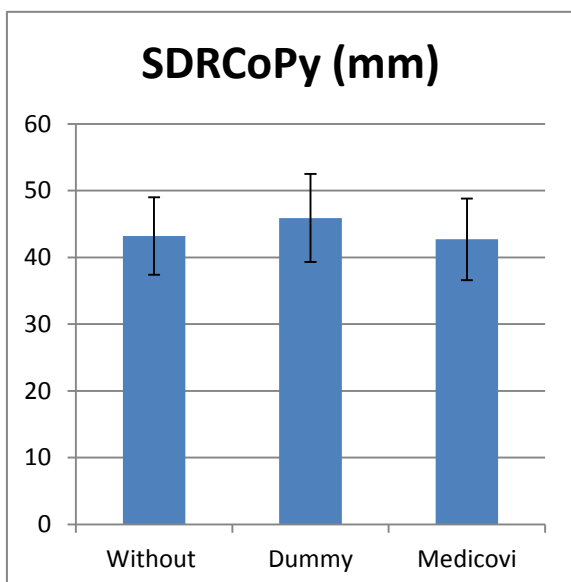
31

The coefficient variation values of the force during 30 steps walking for right & left leg were similar over the three conditions.

CVLF

CVRF

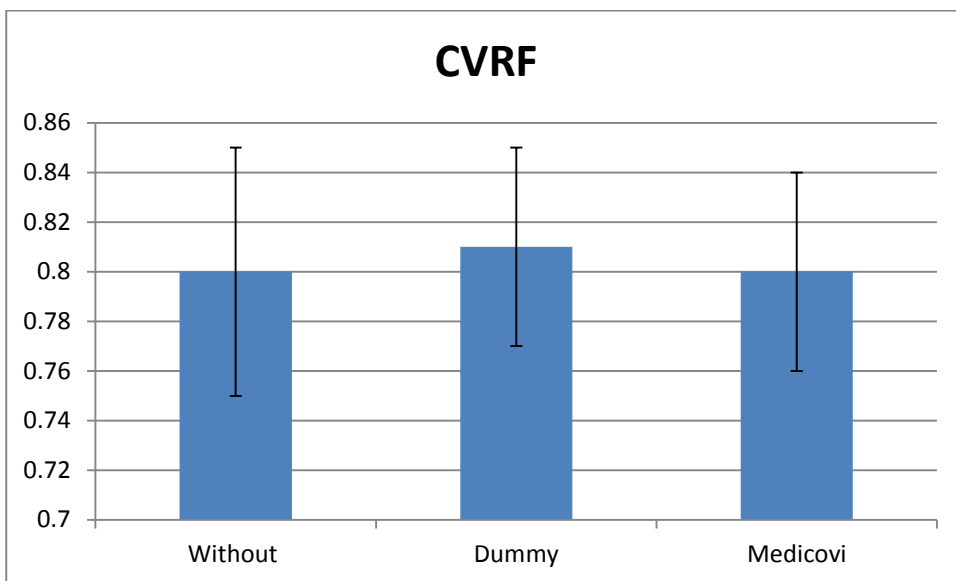The coefficient variation values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 steps walking for right & left leg were similar over the three conditions.

The approximate entropy values of the force during 30 steps walking for right & left foot were similar over the three conditions.

ApEnLF

ApEnRF

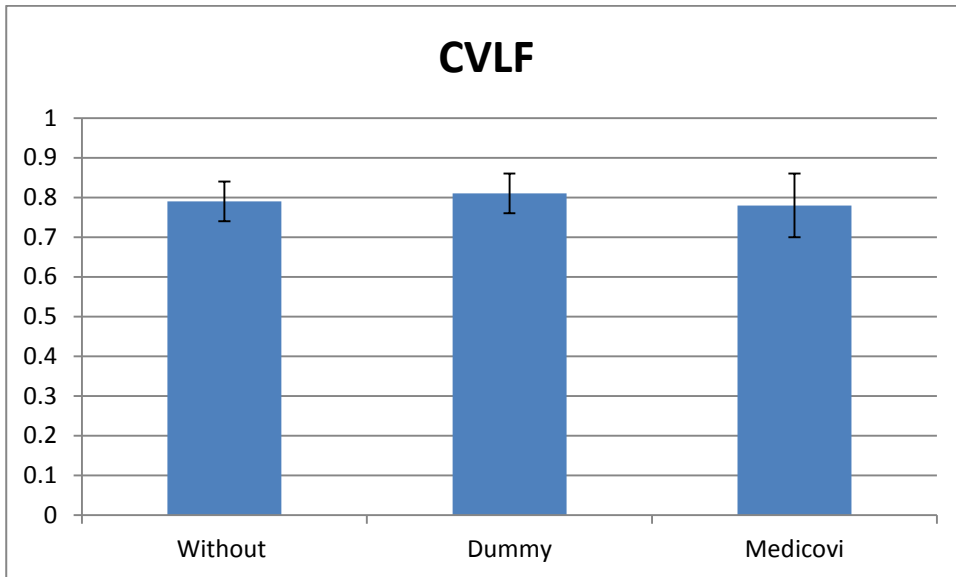The approximate entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 steps walking for right & left foot.
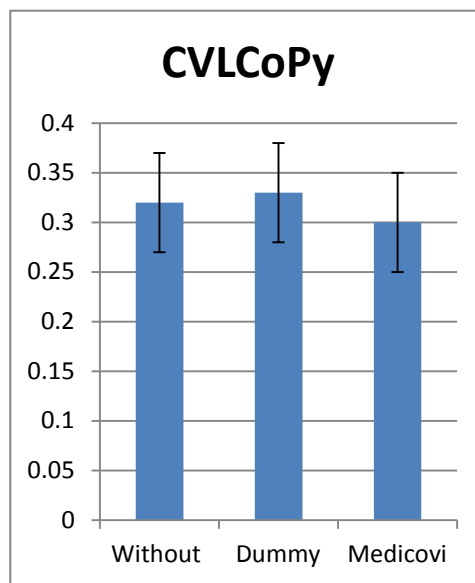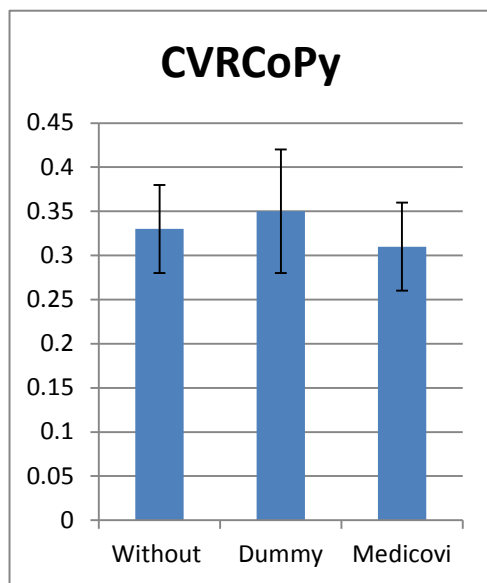

The approximate entropy of the left leg in the Y direction (anterior-posterior) was lowest for the H20 insoles compared with the two other conditions.

The sample entropy values of the force during 30 steps walking for right & left foot were similar over the three conditions.

SaEnLF

SaEnRF

The sample entropy values of the centre of pressure in the X & Y direction (medial-lateral and anterior-posterior) during 30 steps walking for right & left foot.
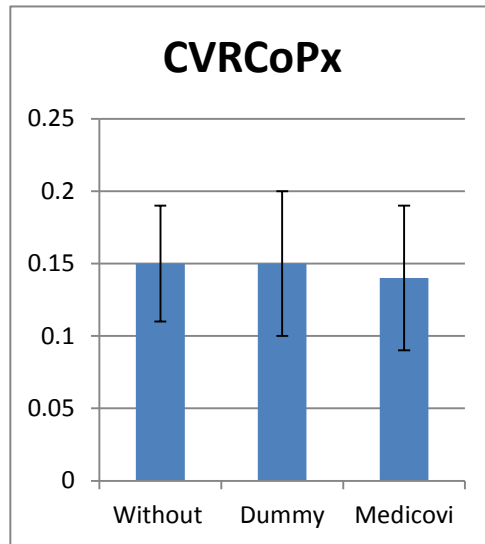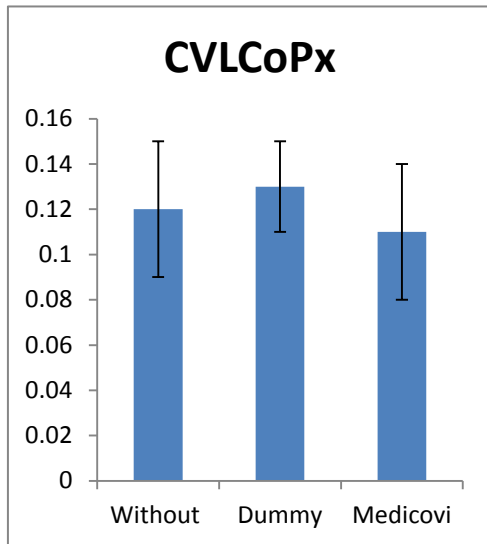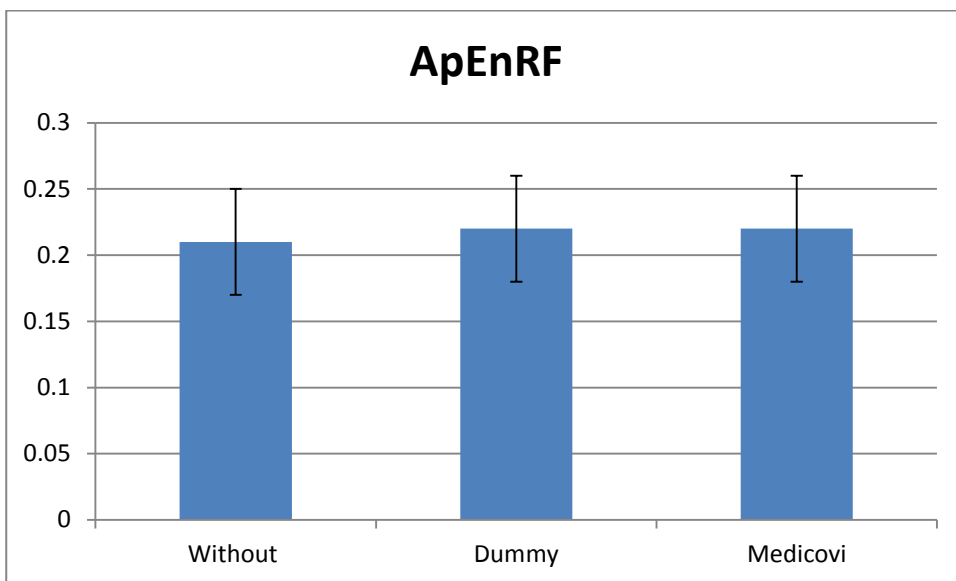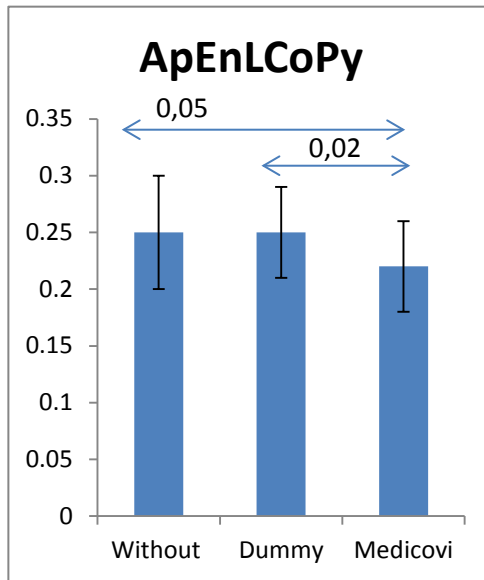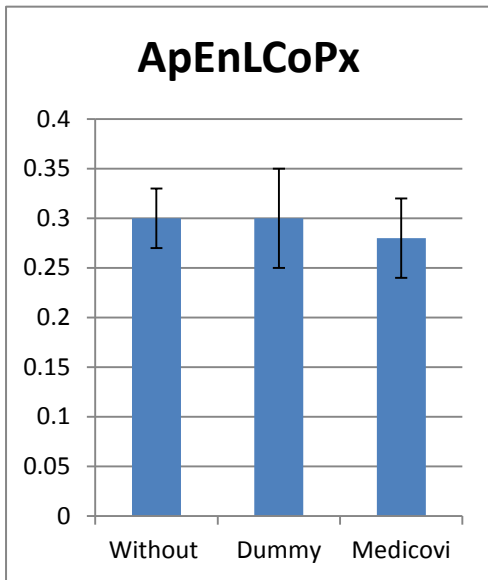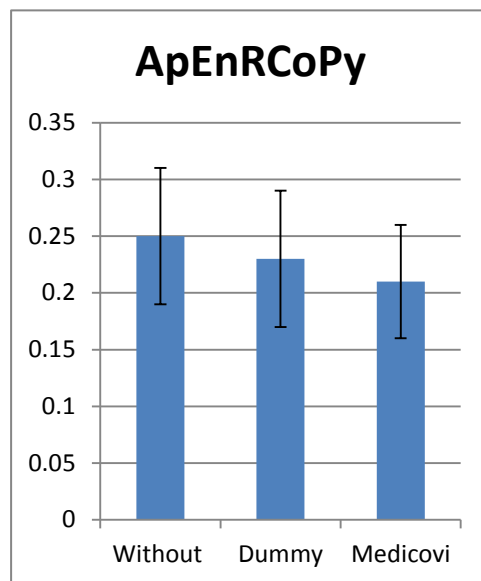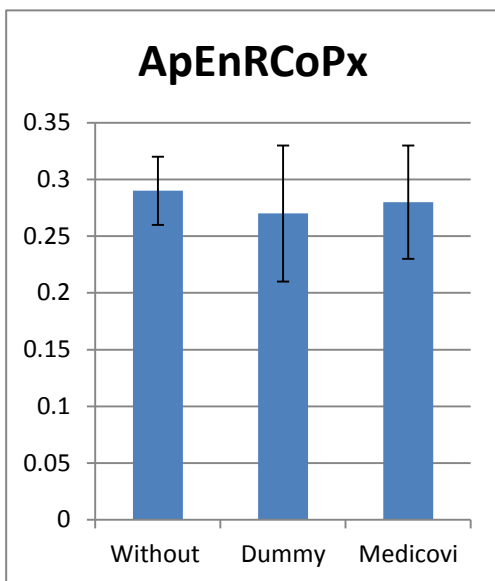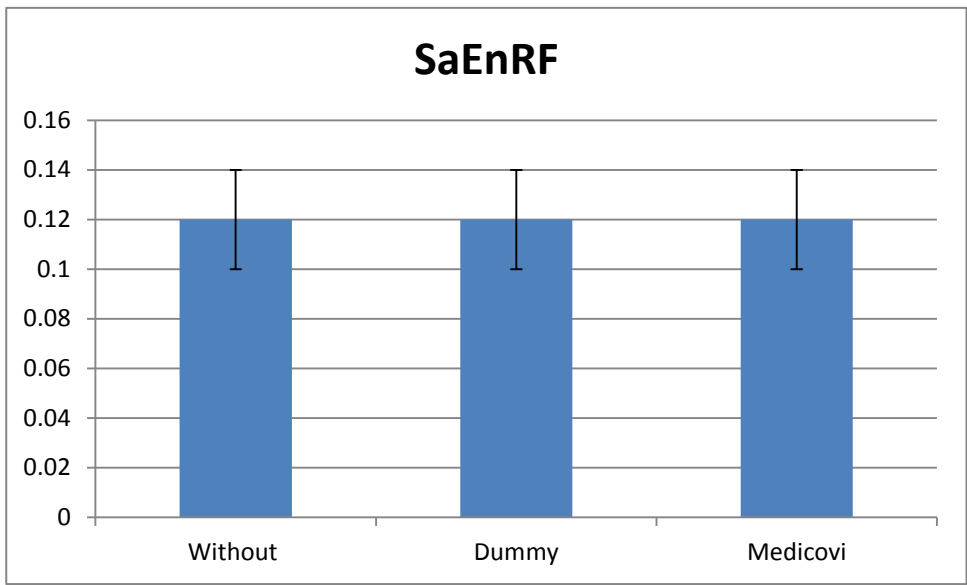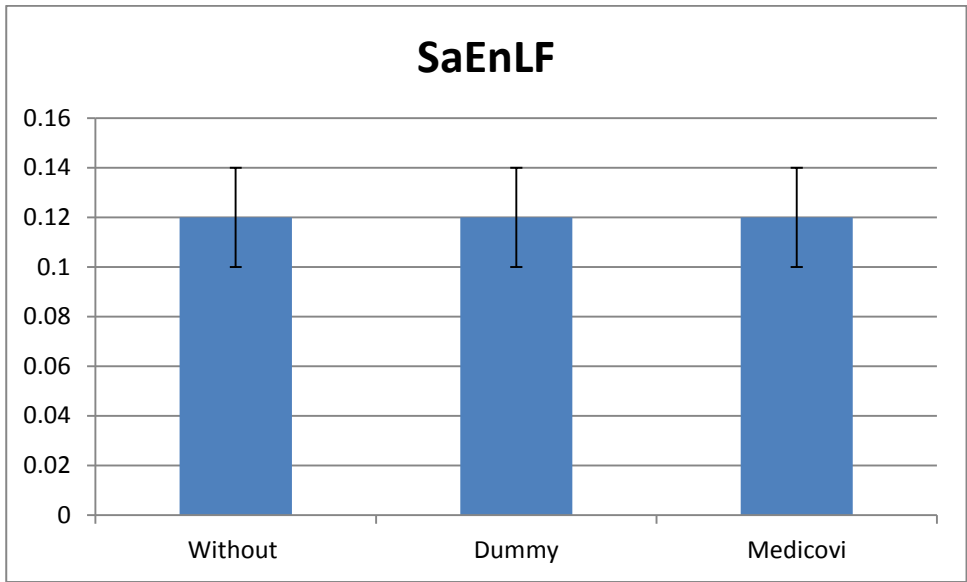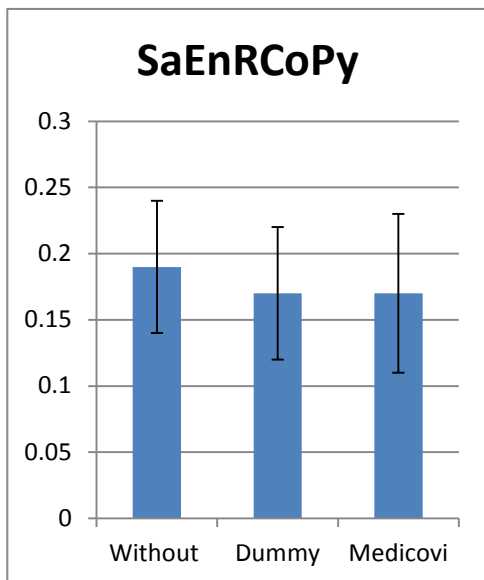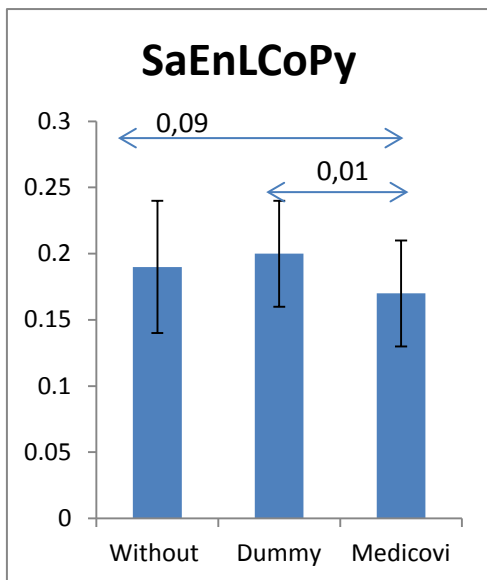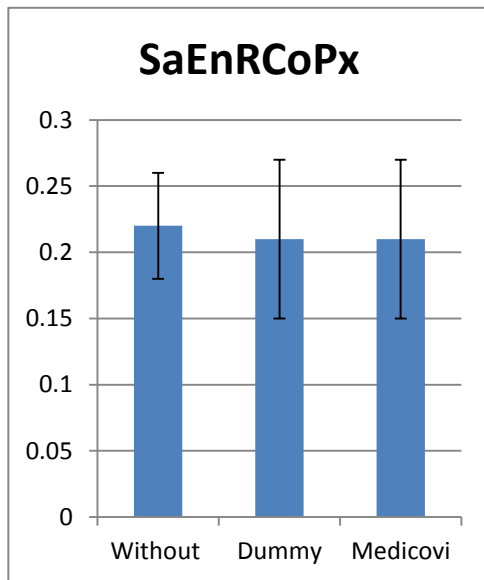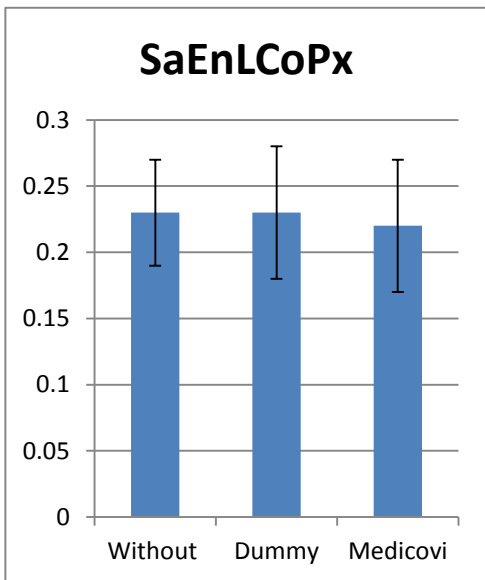

The sample entropy of the left leg in the Y direction (anterior-posterior) was lower for the H20 insoles compared with dummy insoles.

Conclusions

We investigated the immediate effects of the Medicovi H20 insoles with respect to no insoles and dummy insoles during dynamic standing (one-leg standing) and walking. The basic hypothesis of this work was that the H20 insoles should increase the variability of postural control and gait.

The mean force and centre of pressure time series were extracted from each foot pressure distribution recording. Estimators of size (SD and CV) as well as structure of variability were computed and compared.

The size of variability of the centre of pressure displacement decreased during one-leg standing with the H20 insoles (both SD and CV during standing on right and on left leg in the medial-lateral direction). This was contrary to what was expected but can be interpreted in a positive manner as it most likely reflect a more stable balance (decreased fluctuations) during a challenging task like one-leg standing (Madeleine et al. 2011).

Similarly the size of variability of the centre of pressure displacement decreased during walking with the H20 insoles (SD of the left leg in the medial-lateral direction). In parallel, the structure of variability of the centre of pressure displacement was found less complex with the H20 insoles (ApEn and SaEn of the left leg in the anterior-posterior direction). This was also against our initial hypothesis. As such, a decrease in complexity is suggested to be related with e.g. ageing or disease (Lipsitz 2002b; Vaillancourt and Newell 2002; Van Emmerik and Van Wegen 2002). However, this association has been challenged by recent studies reporting e.g. higher entropy values in pathological conditions (Rathleff et al. 2011; Rathleff et al. 2013). However Vaillancourt and Newell (2002) hypothesized that during dynamic rhythmic tasks such as human locomotion, an injury would cause an increase in movement complexity. Consequently, the present decrease in complexity could be favourable. Studies investigating the long-term effects of the H20 insoles as well as their effects in patients population are needed to confirm these findings.

Acknowledgements

Abbreviations

AP: anterior-posterior (Y direction)

ApEn: Approximate entropy

CoP: Center of pressure

CV: Coefficient of variation

L: Left

ML: medial-lateral (X direction)

R: Right

SaEn: Sample entropy

SD: standard deviation

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