Contents

1 Introduction

One of the aims of a prosthetic foot is to match an anatomical human foot as good as possible (Perry, 2010). Up to today, there has not been any prosthetic feet available that can match an intact foot in functionality. Little focus has been on research on the prosthetic foots performance in frontal plane motions while sagittal plane motions has been investigated. To choose the most appropriate foot can be a complex clinical decision, many factors are important to keep in mind like current and future level of activity of the patient, type of foot and cost. An oversight can influence product success and patients' potential in achieving his goals (Carroll, Rheinstein, & Pollard, 2013).

2 Background

The human gait is an artform of controlled falling. One requirement of normal gait is the ability to adapt it to a wide-ranging set of environments (Shumway-Cook & Woollacott, 2007b). Walking is an energy demanding task due to the movement off the body in three planes; sagittal, frontal and transversal. (Figure 1). The most noticeable movement during gait is in the sagittal plane. Because humans depend on bipedal motion there will always be some form of frontal plane movement and height change of centre of gravity (COG) as well (Perry & Burnfield, 2010). The COG does not stay within the support base of the feet, and thus the body is in a continuous state of imbalance. The only way to prevent falling is to place the swinging foot ahead of and lateral to the centre of gravity as it moves forward, thus ensuring control of the centre of mass (COM) relative to a moving Base of support (BoS) (Shumway-Cook & Woollacott, 2007a).

Most researches focus on motion in just one of these planes, sagittal. Even during straight line walking there is always some frontal plane motion as well sagittal (Evandro M. Ficanha, 2015). Therefore, there is a lack of understanding of what happens in the frontal plane during gait. As we walk there is a weight shift between feet. A foot needs to be able to function in other motions than straight line walking, e.g. turning, adapting to uneven terrain, ascending or descending slopes (Evandro Maicon Ficanha, Ribeiro, Dallali, & Rastgaar, 2016).

The anatomical ankle foot complex (AFC) needs to act as a dampener, support and rigid lever at different stages of the gait cycle. The foot consists of 28 bones and 25 joints. To ease for understanding of the different segments the AFC is commonly divided up in three segments, hindfoot, midfoot and forefoot (Mueller, 2005), see Figure 2. There are three motional pairs in the ankle foot complex which roughly follow the cardinal planes of motion. These are dorsiflexion/plantarflexion, inversion/eversion, abduction/adduction. Dorsiflexion/plantarflexion is the motion in sagittal plane, abduction/adduction is in transversal plane. Inversion/eversion follows the frontal plane. Eversion is when the plantar surface is brought away from the midline, inversion is the opposite. The terms pronation/supination is a term used to describe coupled movements of the terms above, e.g. pronation includes dorsiflexion, eversion and abduction were as supination is the opposite (Mueller, 2005). To be able to execute these

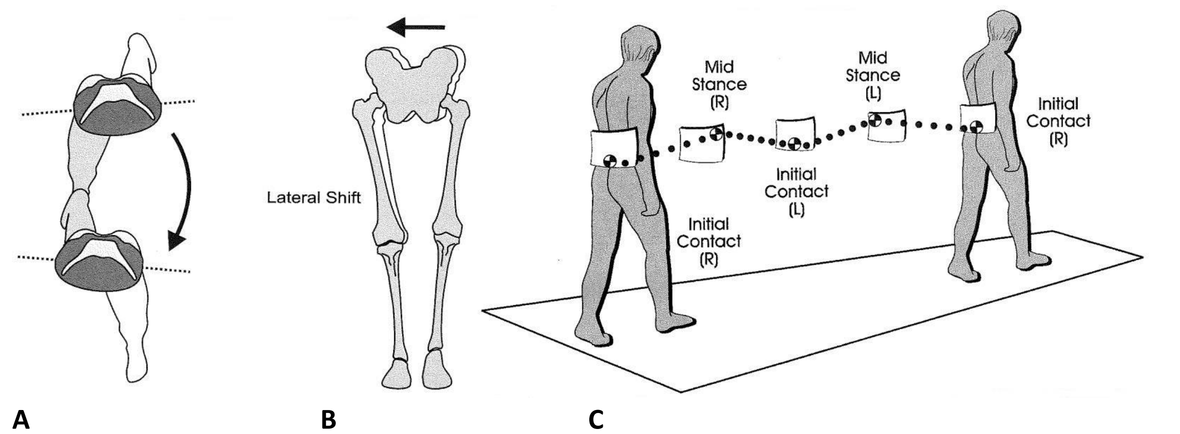


Figure 1; Movements during gait

A: Movement in transverse plane, B: Movement in frontal plane, C: movement in sagittal plane and translation of CoG during a gait cycle

Perry, J., & Burnfield, J. (2010). Gait analysis : Normal and pathological function (2.nd ed.). Thorofare, N.J.: SLACK.

demanding motional tasks in different situations there needs to be a certain control. These motions are coupled with muscles, bones, joints, ligaments and sensory organs and need to harmonise together like a symphony.

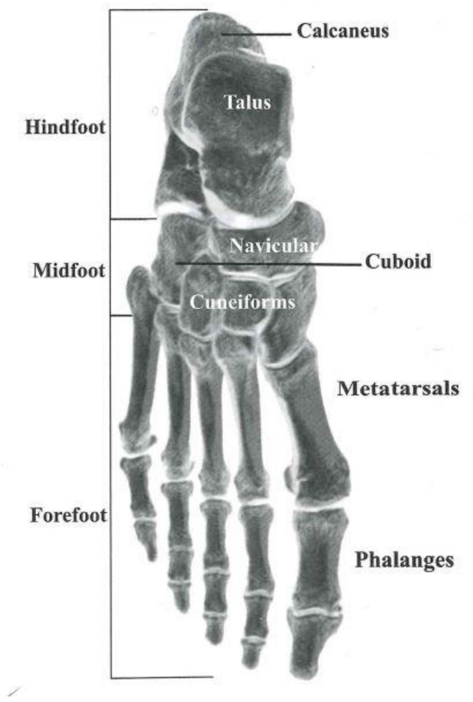


Figure 2; Division of the foot

Levangie, Norkin, & Norkin, Cynthia C. (2011). Joint structure and function : A comprehensive analysis (4.th ed.). Philadelpha: F.A. Davis.

Nonvascular amputees have higher energy levels allowing them to be more active, that allows them a wider range of activities and puts more pressure on their prosthetic foot to have wider range of function (Supan, Lebiedowska, Dodson, Verhulst, & Dufour, 2010)**.** Active amputees also have higher energy expenditure partly due to difficulty maintaining balance (Kim & Collins, 2017). That might be due to prosthetic feet and ankles having limited mobility and the user lacking distal muscle and sensory feedback. Because the prosthesis is an external helping aid it often lacks the possibility to adapt (Gates, Dingwell, Scott, Sinitski, & Wilken, 2012). Therefore, it is important to build further understanding of what happens in all planes of motion.

Because of these functional demands it is important to understand what happens in the simplest form of motion, straight line walking. By finding out if there is a measurable difference between different prosthetic feet it should be possible for the patient to have a wider choice of products suiting their needs. There is little evidence is available on how a prosthetic foot reacts to task that requires frontal plane motions like turning or side-stepping (Shell, Segal, Klute, & Neptune, 2017) or even straight-line walking. Currently, other researches are discussing that by adding another degree of freedom in powered prosthesis, inversion/eversion, greater balance can be achieved during walking (Kim & Collins, 2017). It has also been suggested that individuals use specific strategies during turning motions (Shell et al., 2017). The Talux® foot should in theory mimic motion of an anatomical foot in the sagittal plane because of its design. It is designed to allow motions in both sagittal- (dorsal- and plantarflexion) and frontal plane (in- and eversion) it even can handle small changes in heel height (Supan et al., 2010**)**.

When comparing prosthetic feet, a three-dimensional (3D) gait analysis system is often used. In a 3D gait analysis, a segmental model is used to determine inverse dynamics (Olney, 2005). The AFC is commonly set up as a single segment just like the shank or the thigh, that system has been useful in researches of the hip and knee (Okita, Meyers, Challis, & Sharkey, 2009). In fact, there are some marker models available that divide the ankle foot complex in more detail (Olney, 2005). The golden standard for multi segmental foot models (MFM) is to use intra-cortical bone markers, but there is also possible to use reflective markers (Seo et al., 2014). A research by Dixon et al. (2012) compared the Oxford foot model (OFM) to the Plugin gait model (PIG) from Vicon. Their results showed that a PIG model overestimates the power generation compared to the OFM. It is therefore important to use a MFM when considering intervention and/or solution for a foot related problem (Dixon, Böhm, & Döderlein, 2012). In their systematic review Deschamps et al. (2011) identified fifteen different MFMs and concluded that there was a need for a stronger evidence base so these models could be used clinically (Deschamps et al., 2011). The MFMs look at kinematics and kinetics, but if the interest lies in on focusing on just moments created and affecting the foot during a gait cycle there needs to be a simpler solution.

In this study a relatively new insole measuring system was used, founded in 2015 (vebitoSCIENCE, vebitosolution GmbH, Steinfurt, Germany) (Stief & Peikenkamp, 2015). The

Vebitosolution® Science (VSc) measuring system was developed by the Biomechanics research laboratory, Münster University of applied sciences, Germany (Dawin, Dirksen, Buss, & Peikenkamp, 2016). The VSc insole has five separate sensors that give multidimensional motion and stress analysis. It's made from a flexible, specially shaped material to allow the sensors to measure independently. The previous studies using the products from Vebitosolution® have not been many, and only one pilot study using prosthesis. This pilot study showed that prosthetic feet have a higher max moment than the intact side. There is indication of both subject specific and prosthetic foot specific gait characteristic (Wiesmann, Dawin, Altenhöfer, Stief, & Peikenkamp, 2017).

3 Aims

The aim of the study to investigate if the VSc system is capable of measuring torsional moments in frontal plane during straight line walk in two different types of prosthetic feet. The following research questions were asked:

> H0: There is no statistical significant difference between individually measured frontal plane moment in measuring sensor (one, two, three, four or five) in two different types of prosthetic feet, when the user walks in a straight line.
>
> H1: There is a statistical significant difference between individually measured frontal plane moments in measuring sensor (one, two, three, four or five) in two different types of prosthetic feet, when the user walks in a straight line.

4 Method

4.1 Participants

Participation inclusion criteria was being a unilateral transtibial (TT) amputee, with at least two years as active prosthetic users. They had to be of working age, between 18 and 67, and be active walkers. Exclusion criteria was having diabetes and/or any neurological disease, inability to walk 100+ meters at once. CPO's were asked to contact their patients that met the research criteria and ask if they were interested in participating. If they showed interest, an informational flier was sent to them via mail or e-mail with further information about the study and the researchers contact information. Participants were of similar height, weight, and wore the same type of shoe. Table 1 displays demographic data of the participants. Informed consent form and information flier can be seen in appendix one.

Table 1; demographic information of participants

	Gender	Age	Height (m)	Weight (kg)	Prosthesis side	Years amputated
P1	M	40	1.77	104	Right	7
P2	M	64	1.83	115	Left	2

4.2 Equipment

4.2.1 Vebito® Insole

The study used an insole measuring system (vebitoSCIENCE, Vebitosolution® GmbH, Steinfurt, Germany), see figure 3. The system consists of three units, the insole, digital Wi-Fi transmitter and software for analysis (Wiesmann et al., 2017).

Data acquisition and wireless data transmission to a computer are ensured by four-channel analogue-to-digital converter with Wi-Fi transmission (16 bit, 200 Hz, ME-Meßsysteme GmbH, Henningsdorf, Germany). Data acquisition and analysis are processed by special developed software (MERECS Engineering GmbH, Steinfurt, Germany). Strain gauges signals are converted into bending and torsional moments based on calibration data provided in the software. The measuring insoles are placed in the shoes and cables are affixed to the participants leg. In this research a size three of the VSc insole was used, that's equivalent to approximately size 40/41 in euro sizes.

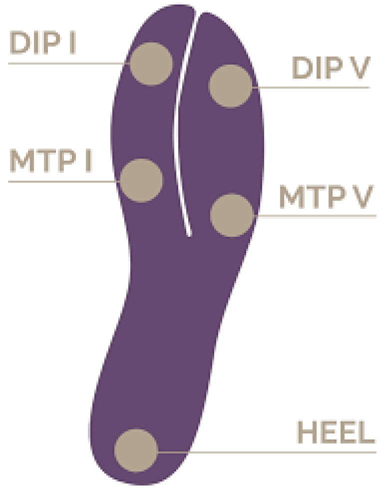


Figure 3; Sensor placement on the VSc insole

Vebitosolution (2018). Retreived 21. May from https://www.vebitosolution.com/was-wir-machen-33/vebitoscience.html

Strain gauges are mounted on a thin stainless-steel plate and can be found on both sides of the steel plate. They are programmed so the insole can measure simultaneously bending and torsional moments (Dawin et al., 2016). The special forked shape of the insole is to detect independent bending and torsional moments on the medial and lateral side (Stief & Peikenkamp, 2015), even to prevent cross-talk between the gauges (Wiesmann et al., 2017). The gauges are mounted on five different locations, proximal to metatarsophalangeal joints one and five (MTP I, MTP V), proximal to distal interphalangeal joints one and five (DIP I, DIP V) and distal to processus calcaneus (heel) (Wiesmann et al., 2017); (Dawin et al., 2016).

4.2.2 Prosthetic feet

Both prosthetic feet were of size 26 and category six.

4.2.2.1 Talux®

Talux® (Figure 4) has been designed to provide natural walking motion in various terrains. The Talux® has a Dual J-spring system to help with forward motion of the tibia. It even has a Carbon-X® active heel that stores energy during loading response and releases it with the forward progression. The Talux also is compliant to multi-axial surfaces and its full-length toe is designed to provide more support which results in improved walking dynamics.

Figure 4; Talux®

Össur (2018). Retrieved 21. May from https://www.ossur.com/prosthetic-solutions/products/dynamic-solutions/talux

4.2.2.2 Pro-flex®

Pro-Flex® (Figure 5) uses levers connected through pivots to create a mechanically-powered push off. The two joints are connected to carbon blades. These two joints in combination with the main joint provide energy storing and push off. Because of its mobility it provides up to 11% reduction in load on the contralateral limb.

Figure 5; Pro-flex®

Össur (2018). Retrieved 21. May from https://www.ossur.com/prosthetic-solutions/products/dynamic-solutions/pro-flex

4.2.3 Shoes

Participants wore a pair of Viking Apex II GTX (Figure 6). The shoes are made for trail running and are light weight, 297 grams. It is fitted with an EVA midsole for shock absorption and the rubber outsole has specially made for gripping in demanding situations. The shoes were matched for their intact anatomical foot, size 43 in euro sizes.

Figure 6; Viking shoe

Viking footwear (2018). Retrieved 21. May from https://www.vikingfootwear.com/products/apex-ii-gtx-m

4.3 Data collection

Participants were met and greeted by the researcher. Firstly, the participants were informed about the research and the devices used in it. This information was given both verbally and on a flier. After accepting to participate an informed consent was signed.

Participants were seated and their prosthesis was removed. The prosthetic feet were randomly selected under the prosthesis. After mounting and bench alignment of the first foot a dynamic alignment was done. When the participant and prosthetist were pleased with the alignment measurements could start. Shoes were removed and the VSc fitted in the shoes, figure 7 shows the setup on a patient. Participants were allowed to walk a few steps to see if any adjustments needed to be done before start of measurements. Before measurements could start the insole was reset. Participants were seated in a high chair so their feet were not touching the ground. When everything was ready participants then walked in a straight line approximately 20 meters, on a tartan walking strip, so that approximately ten strides could be measured. Then the same procedure was done for the second foot. Two measurements were performed for each foot.

4.4 Data analysis and statistics

Results from the Vebitosolution® software is shown as a mean of the measurements in Newton millimetres (Nmm) as a percentage of gait cycle. Statistical analysis was done with Wilcoxon signed ranks test analysis in SPSS.

Figure 7; Vebito setup on a patient

4.5 Ethical considerations

The research was approved by the Icelandic bioethical committee (ref.nr. VSNb210803002/03.01) and all participants signed an inormed consent.

5 Results

5.1 Participants

There was a total of six amputees suitable for this research, according to CPOs that were asked if they had clients that fitted the criteria. Of the total of six only two were willing to participate. Before measurements started the prothesis was bench aligned and dynamically aligned before measurements started for each foot. One participant (P2) had a wound on his distal end of the tibia, adjustments in alignment of the socket and application of socks were made so P2 could walk without pain. Because just one VSc insole size used for measurements that narrowed the availability of participants. But this also resulted in both participants using the same category of foot. Both participants used the same size shoe for their intact foot.

5.2 Description of results

The results are presented for each participant. Two measurements were taken for each foot and the results are presented as the average of these two measurements. The moments calculated represent external forces, positive moment is eversion and negative moment is inversion. Number representation of the sensors are as shown in table two.

Table 2: Sensor number representation

Number	*Sensor placement*
1	Heel
2	MTP1
3	DIP1
4	MTP5
5	DIP5

In tables two and three the maximal moment, in eversion and inversion, median of the moments and range for each sensor for the Pro-Flex® is shown for both participants. The range represents the alteration of load on the sensors. In the table 3 results for sensor two showed no inversion moment. Results for the Talux® can be seen in appendix two.

Table 3; Average moments for P1 at each sensor

P1	*RT1 PRFLX*	*RT2 PRFLX*	*RT3 PRFLX*	*RT4 PRFLX*	*RT5 PRFLX*
Max ER (Nmm)	4.37	53.37	32.42	10.40	2.00
Max IR (Nmm)	-6.31	-*	-10.10	-72.77	-83.81
Median (Nmm)	-0.34	20.47	0.89	-13.59	-2.57
Range (Nmm)	10.68	47.62	42.52	83.17	85.81

R: right, T: Torsion, Number: sensor placement, PRFLX: Pro-Flex®, Ev: eversion, In: inversion

** no inversion moment*

Table 4; average moments for P2 at each sensor

P2	*LT1 PRFLX*	*LT2 PRFLX*	*LT3 PRFLX*	*LT4 PRFLX*	*LT5 PRFLX*
Max ER (Nmm)	15.81	45.69	9.95	9.74	2.54
Max IR (Nmm)	-1.16	-5.79	-23.29	-18.66	-33.49
Median (Nmm)	4.43	4.89	-0.68	-3.57	-1.34
Range (Nmm)	16.98	51.49	33.24	28.40	36.03

L: Left, T: Torsion, Number: sensor placement, PRFLX: Pro-Flex®, Ev: eversion, In: inversion

In tables four and five results from a Wilcoxon signed ranks test can be seen. All null hypotheses (p < 0,05), except for one (p > 0,05), are rejected. That is for P2 in sensor three.

Table 5; Wilcoxon signed ranks test for P1

	RT1 TLX - RT1 PRFLX	RT2 TLX - RT2 PRFLX	RT3 TLX - RT3 PRFLX	RT4 TLX - RT4 PRFLX	RT5 TLX - RT5 PRFLX
Z	-8,725[b]	-6,614[b]	-2,962[c]	-8,725[c]	-2,431[b]
Asymp. Sig. (2-tailed)	,000	,000	,003	,000	,015

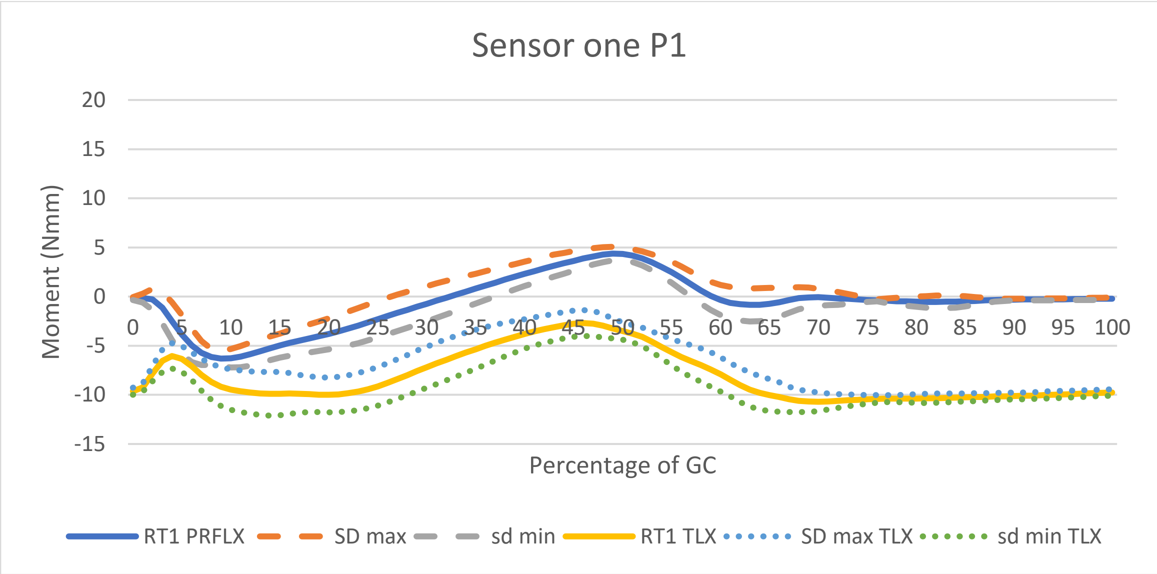
R: right, T: Torsion, Number: sensor placement, TLX: Talux®, PRFLX: Pro-Flex®, Ev: eversion, In: inversion

Table 6; Wilcoxon signed ranks test for P2

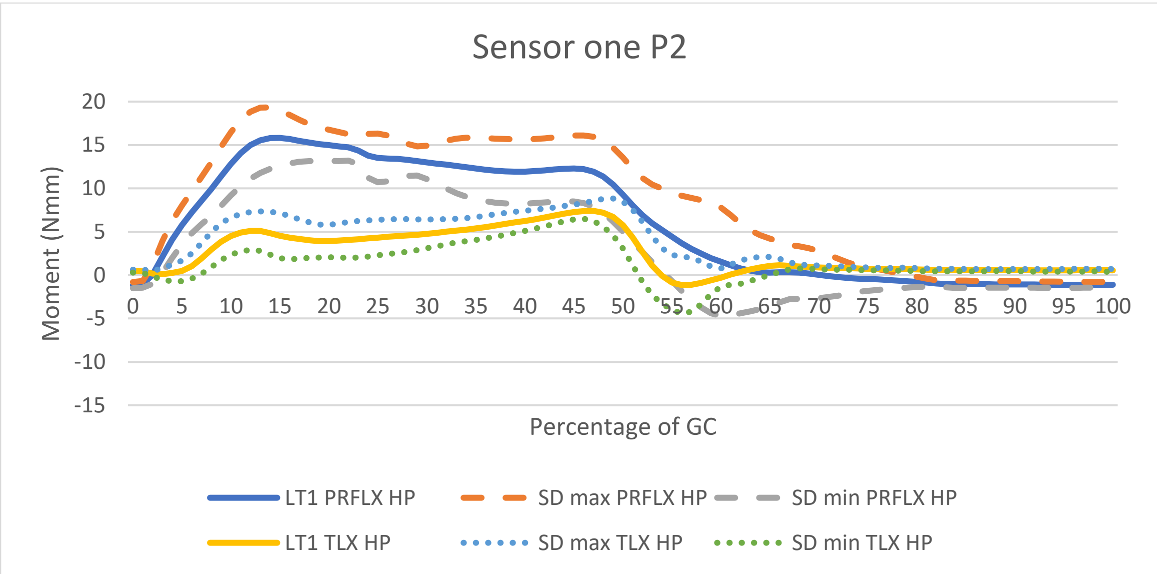
	LT1 TLX - LT1 PRFLX	LT2 TLX - LT2 PRFLX	LT3 TLX - LT 3 PRFLX	LT4 TLX - LT4 PRFLX	LT5 TLX - LT5 PRFLX
Z	-5,574[b]	-4,558[c]	-1,851[b]	-8,725[c]	-3,386[c]
Asymp. Sig. (2-tailed)	,000	,000	,064**	,000	,001

R: right, T: Torsion, Number: sensor placement, TLX: Talux®, PRFLX: Pro-Flex®, Ev: eversion, In: inversion
**(P > 0,05)

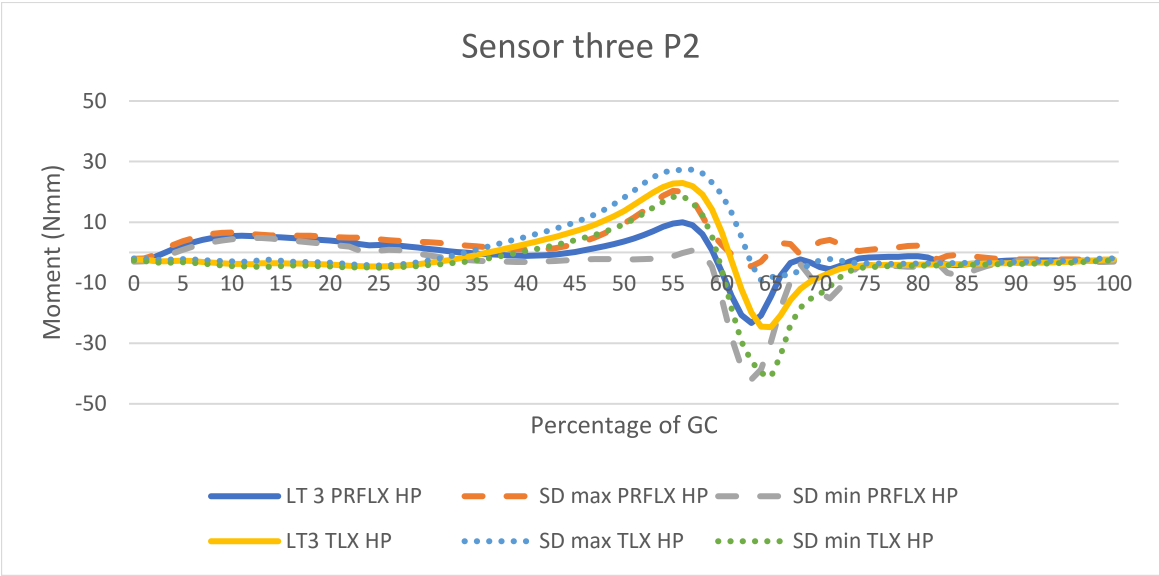
In graphs one and two the average moment for sensor one for both participants is shown and how the moment alters through the gait cycle. Graph three shows P2s moments for sensor three, where there was no statistical significant difference (P > 0.05). In appendix three graphs can be seen that show alterations of the moments for the other sensors. In the graphs the scales for each sensor is pair is the same, e.g. the same scale for sensor one in both graphs, graphs are also presented with standard deviation (SD) for each calculated mean.



Graph 1: Alteration of moments during a Gait cycle (GC), sensor one P1



Graph 2; Alteration of moment during a Gait cycle (GC), sensor one P2



Graph 3; alteration of moments during a Gait cycle (GC), sensor three P2

6 Discussion

The aim of this research was to find out if the VSc insole could measure difference in torsional moments in frontal plane in two different types of prosthetic feet in straight line walking. For each sensor a null hypothesis and a research hypothesis were designed

> H0: There is no statistical significant difference between individually measured frontal plane moment in measuring sensor (one, two, three, four or five) in two different types of prosthetic feet, when the user walks in a straight line.
>
> H1: There is a statistical significant difference between individually measured frontal plane moments in measuring sensor (one, two, three, four or five) in two different types of prosthetic feet, when the user walks in a straight line.

The major result from this research was that all null hypotheses except for one was rejected. That is, there was a statistical significant difference in all measuring sensors except for one. These results give the indication that the VSc is capable of detecting difference in different designs of prosthetic feet. When looking at data presented in graphs the results give an indication of a product specific pattern, specially sensors three and five. But, the tables give an indication that a personal moment pattern emerges when comparing results from the same prosthetic foot on different participant. These results are similar to those found in a prior study of the VSc insole by Wiesmen et al. (2017) when researching the bending moments of prosthetic feet (Wiesmann et al., 2017). That is a prosthetic user develops both a product specific- and personal gait pattern. This difference could also be result from different alignment preference of the participants, but closer look on that variable is needed. Looking at the moment range in the tables, they are more similar for the Talux®. That might be due to the Talux® has a multi-axial option and the Pro-flex® is more rigid. When looking at a prior study of VSc insole, where two types of shoes are compared in a population of healthy individuals, the standard deviation (SD) varies more in the torsional moments than the bending moments (Dawin et al., 2016**)**. This variation in the torsional moment might be due to the foot needs to react to different loads when dampening the sagittal and frontal motions happening during gait (Mueller, 2005; Shumway-Cook & Woollacott, 2007a).

The decision was made not to combine the measured results of the participants. One reason was due to that P2 had a wound on the distal end of the tibia, which might have affect his gait pattern. Also, due to the described differences by Wiesman et al. (2017). The problem for P2 was that his distal end of the tibia was hitting the bottom and anterior wall of the socket. The adjustments made were aligning the socket in flexion in regard to the foot, putting an eight-millimetre offset adapter and by applying thicker socks over the socket. These adjustments resulted in the patient being able to walk comfortably and without pain from his wounds. But these alignment changes might have affected his normal gait pattern, without being able to say it for certain. The participants were of similar height and weight which resulted in them using the same category of foot. Therefore, the research gives a certain idea of the effects on these particular feet, size and category. Because the VSc system is inserted into the shoe, a difference in stiffness of the soles could affect outcomes from studies using the VSc insole. In this research the participants used the same type of shoe so effects from the insole should be the same. The shoe size used was fitted for the intact anatomical foot, size 43, that might have given the insole a chance to slide in the shoe. At one sensor point at each foot for P1 it showed that he did not create any inversional moment. The reason for that is unknown, it might be due setup error, alignment fault or measurement error.

6.1 Comparison with a 3D analysis system

The gold standard in gait analysis is a 3D gait analysis system when observing the kinetic and kinematic effect of a prosthesis (Wiesmann et al., 2017)). One difference between these two systems is that the force sensors are in the floor in the 3D systems but inside the shoe in the VSc insole. If a comparison would be done for these two systems the sole of the shoe needs to be kept in mind because it might skew the resulted difference. Also, normal 3D gait analysis marker models usually look at the foot as a single segment (Okita et al., 2009). Therefore, a MFM should be used as it divides the foot into more segments and gives clearer picture of what is happening in the foot (Dixon et al., 2012). But for the MFMs to be used in a clinical environment more research is needed (Deschamps et al., 2011). It is also interesting to keep in mind if a difference in these two systems are somewhat affected by the fact that a comparison is being made between one big sensor in the 3D system to the five smaller ones in the VSc insole. The VSc system has an automatic heel detection. That results with initiation of every heels strike a new step is recorded. The results from the software gives its results as an average of the steps taken during a measurement. Because of the automatic heel detection, the measured average moment is presented as a percentage of a full gait cycle. This representation is similar to data representations from a 3D gait analysis system. The difference is that in the 3D system participants need to make contact to the force plate in several attempts. By having the heel detection in every step, we can gather more information from the same number of strides. The VSc system is compact enough to fit in a small case giving the ability for measurements to be done in different environments requiring only a few steps and a fully charged laptop with the software. This gives the ability for doing measurements in everyday situations outside a research facility were the participant could feel a bit overwhelmed. It should be said that the cables would need to be better arranged so the participant feels fully relaxed while walking. Because the cables go up medially of the lower extremity the participants might have felt as if they needed to walk with a wider base of support (BoS) to prevent the cables from hitting each other. That might affect the results of the current research. As a wider BoS demands greater movement in the frontal plane. Otherwise the system is simple and quick to fit for data sampling.

6.2 Limitations

This research was conducted in a short period of time, due to few uncontrollable events. The organization of the timeline could have been better executed so that when problems arose there would have been a plan of action. Due to these delays alterations of the research method had to be done. That resulted instead of executing a very ambitious and complicated research, using two different movement patterns and two analysis systems, in this more simple and compacted research. Even though the research is more compacted, time for data analysis and interpretations was limited which could have affected the outcome. This research method heroes therefore the VSc and its possibility in differentiating between these two feet.

The research was conducted in Iceland and the VSc insole came only in one size. That resulted in a limited population size and not everyone was willing to participate. To be able to give a firmer answer on the effect and difference of the two types of feet a more populated research needs to be done. This research used two different participants, with different stump size, shape and alignment preference so it is hard to justify comparing the two individuals and measurements together. Therefore, it is important to conduct a larger scale study with more measurements for each foot and more participants. By doing a study on a larger scale gives a better idea of how effective the VSc system is in detecting differences between products.

6.3 Future researches

Because the VSc insole measures what is happening between the foot and the shoe, many ideas come to mind for future researches. One important research is a comparison of this system to a 3D gait analysis system, then preferably to a MFM method, as discussed here above. It would also be interesting in future researches for patient populations with pathologies of the feet. In their systematic review Niels et al. (2016) concluded that alignment adjustments have little effect on spatio-temporal and kinematic gait data. But the adjustments had a significant in kinematic parameters (Niels, Maarten, Arjan, & Peter van Der, 2016). One kinetic variable is moment and thusly the VSc system might benefit when aligning a prosthesis, but further research is needed in that area. If this is a feasible solution then a prosthetist potentially has a new device for documentation. That is if a problem occurs this information can be referred to if alterations are needed (Knapp, 2013).

This study gives the impression that the VSc insole system is capable of detecting differences in moments in frontal between two different types of prosthetic feet. Therefore, it could be used in product development or even in the clinical environment when discussing what product would suit users best.

7 Conclusion

The major results from this research is that there is an indication that the VSc insole system is capable of measuring difference in frontal plane moments in two different types of prosthetic feet. There is an indication that both a product specific and user specific pattern emerges when walking in a straight line. This research is limited by its sample size and amount of measurements performed. Further researches are needed to improve documentation and increase knowledge were the VSc insole system is applicable. In the future it might be an instrument that prosthetists can use as a helping aid while aligning a prosthesis or choosing between products.

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Appendix one

Informed consent (upplýst samþykki) and information to participants (next page)

Upplýst samþykki

Can an insole measure torsion in two different types of prosthetic feet?
(getur innlegg metið vindu í tveim mismunadi týpum af gervifótum)

Samþykkis yfirlýsing vegna þátttöku í rannsókn á mati á vindu í gerfifótum

Ég undirrituð/-aður hefur fengið svör við þeim spurningum sem vaknað hafa og samþykkir með undirskrift sinni að taka þátt í rannsókninni. Undirrituð/-aður hefur lesið kynningarbréf með upplýsingum um tilhögun rannsóknarinnar og hefur í sinni vörslu eintak af bréfinu.

Reykjavík / 2018 Reykjavík /
2018

___________________________ ___________________________

Undirskrift rannsakanda Undirskrift
þátttakanda

JÖNKÖPING UNIVERSITY
School of Health and Welfare

ÖSSUR®

Can an insole measure torsion in two different types of prosthetic feet?

(getur innlegg metið vindu í tveim mismunadi týpum af gervifótum)

Ágæti þátttakandi.

Rannsókn þessi er liður í lokaverkefni í stoðtækjafræði við Háskólan í Jönköping. Rannsóknin er unnin í samstarfi við Össur og fara allar mælingar fram í húsnæði þeirra í Reykjavík. Hægt er að nálgast upplýsingar um rannsóknina hjá ábyrgðarmanni hennar, Antoni Jóhannessyni, ajohannesson@ossur.com eða rannsakanda hennar Bjarka Hjálmarssyni, hjbj1513@student.ju.se, 866-4401. Tilgangur rannsóknarinnar er að styrkja fræðilegan og vísindalegan bakgrunn við þróun og prófun gervifóta.

Markmið rannsóknarinnar er að athuga hvort innlegg frá Vebitosolution geti metið vindu í gervifæti samanborið við þekktan staðal, sem er þrívíddargöngugreiningar kerfi með kraftplötu. Prófunin felst í að ganga eftir 30 metra línu í tveimur mismundi tilfellum með tvo mismunandi fætur. Fyrst er gengið í beina línu svo er gengið í sömu línu nema við enda kraftplötunnar verður fyrirstaða í gangveginum þannig að einstaklingurinn þarft að víkja undan henni, með því að spyrna til hliðar og halda svo áfram göngunni. Möguleg áhætta við þátttöku er þessi spyrna til hliðar til að víkja undan fyrirstöðu (sem er ekki ósvipa því sem getur skeð í daglegu lífi). Til að minnka áhættuna þá verður þátttakandinn látin fara fyrst í gegnum gangveginn með stuðning og á hálfum hraða. Ef þátttakandinn sýnir óöryggi við þessar æfingar eða hætta á að missa jafnvægið þá verður honum/henni ekki boðið áframhaldandi þátttöku í þessum prófunum.

Rannsóknin er þér að kostnaðarlausu en þátttakendur fá heldur ekki greitt fyrir þátttöku.

Sem þátttakandi átt þú rétt á að hætta þátttöku í rannsókninni hvenær sem er án útskýringa og eftirmála og mun öllum gögnum um þig sem tengjast rannsókninni vera eytt. Þú getur neitað að svara spurningum og einnig getur þú farið fram á að gögnum sem aflað hefur verið um þig verði eytt og þau ekki notuð. Farið verður með allar upplýsingar um þátttakendur sem trúnaðarmál og nafnleyndar verður gætt við birtingu. Öll gögn rannsóknarinnar verða varðveitt á tölvutæku formi og vernduð með lykilorði. Rannsóknin hefur verið samþykkt af Jönköping University og Vísindasiðanefnd og verður öllum persónueinkennum eytt að rannsókn lokinni. Niðurstöður rannsóknarinnar verða birtar í lokaritgerð Bjarka Hjálmarssonar í stoðtækjafræði.

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Anton Jóhannesson

Ábyrgðarmaður rannsóknarinnar

Appendix two

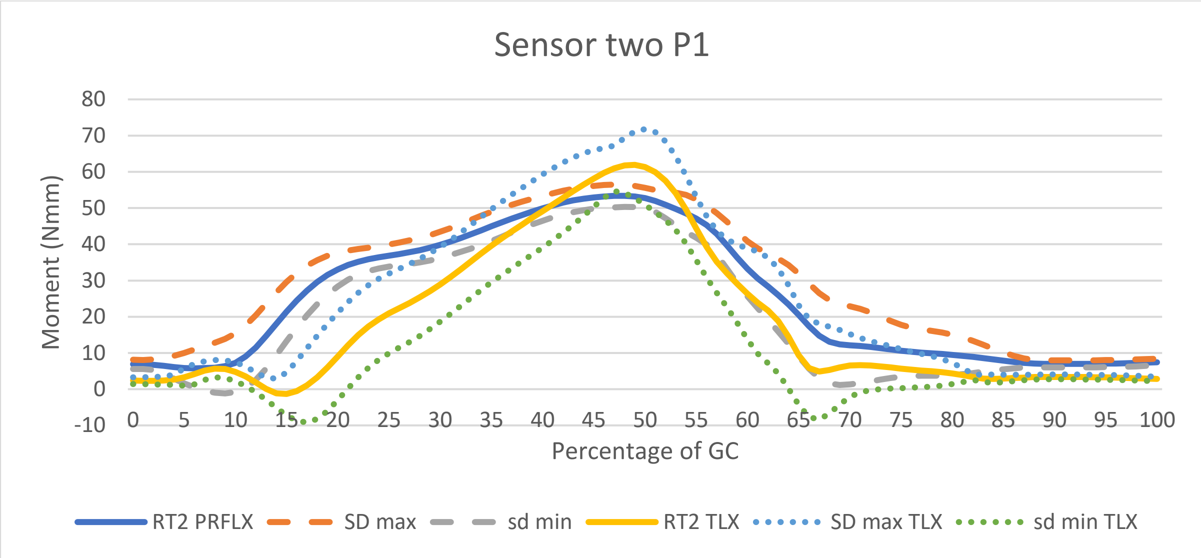
Tables for max inversion – and eversion moments for Talux

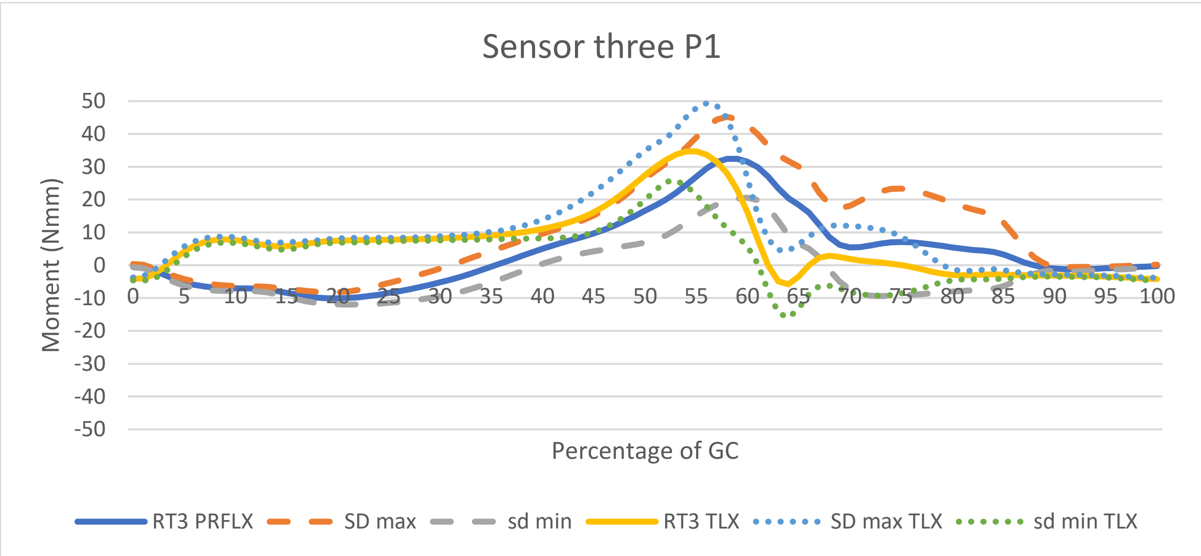
P1	*RT1 TLX*	*RT2 TLX*	*RT3 TLX*	*RT4 TLX*	*RT5 TLX*
Max ER (Nmm)	-2.70	61.93	34.70	21.14	4.12
Max IR (Nmm)	-10.70	-1.32	-5.80	-	-77.12
Median (Nmm)	-9.63	6.05	6.61	7.87	-5.26
Range (Nmm)	8.01	63.24	40.50	18.24	81.24

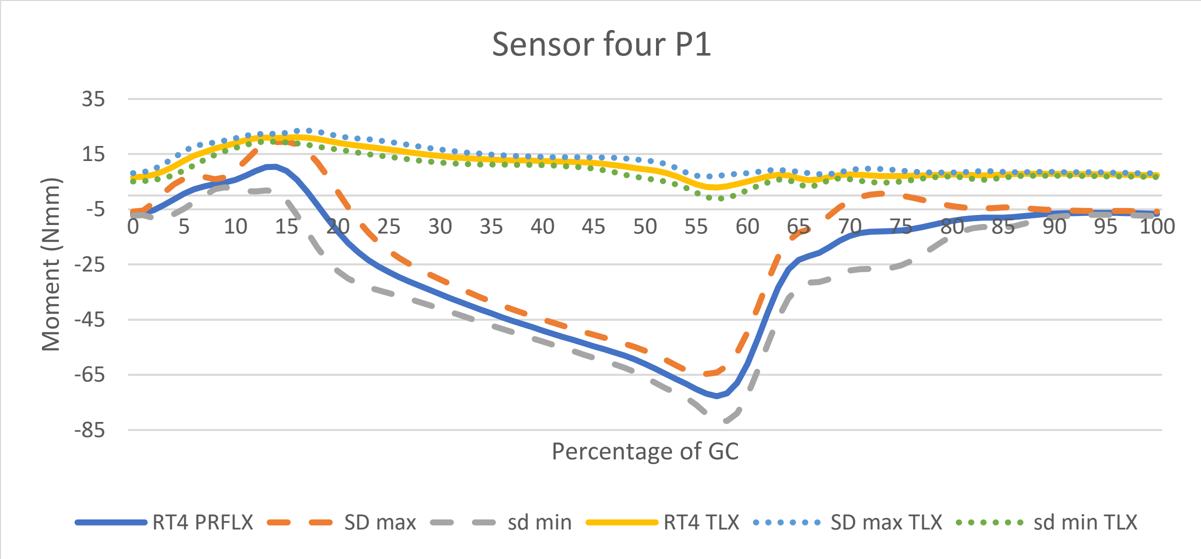
P2	*LT1 TLX*	*LT2 TLX*	*LT3 TLX*	*LT4 TLX*	*LT5 TLX*
Max ER (Nmm)	7.41	72.66	22.92	22.10	3.18
Max IR (Nmm)	-1.14	-1.56	-24.66	-3.12	-19.32
Median (Nmm)	1.04	3.17	-3.47	2.25	-0.73
Range (Nmm)	8.54	74.22	47.59	25.23	22.51

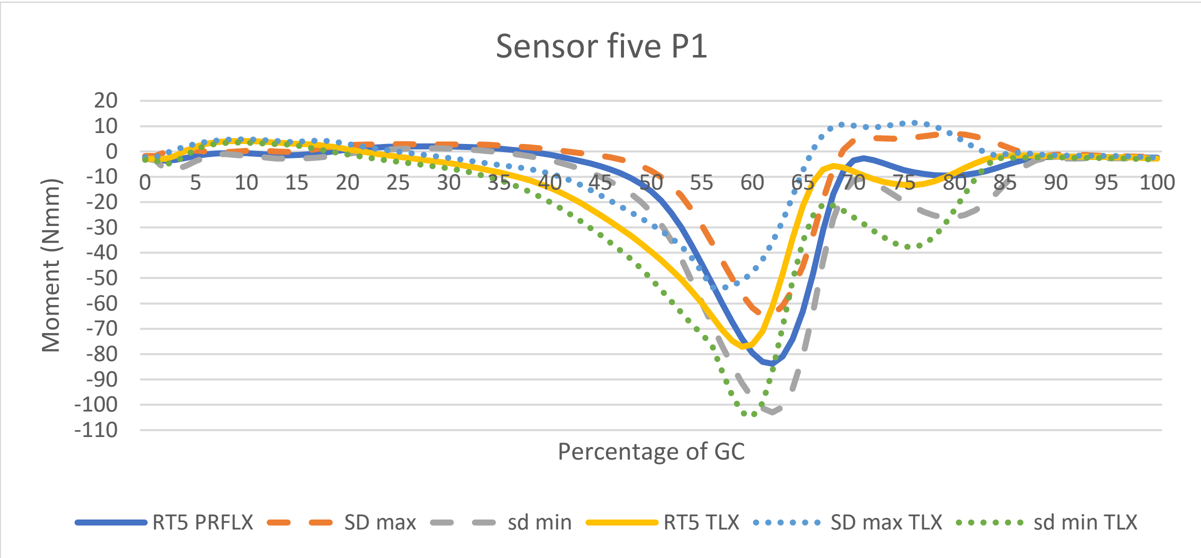
Appendix three

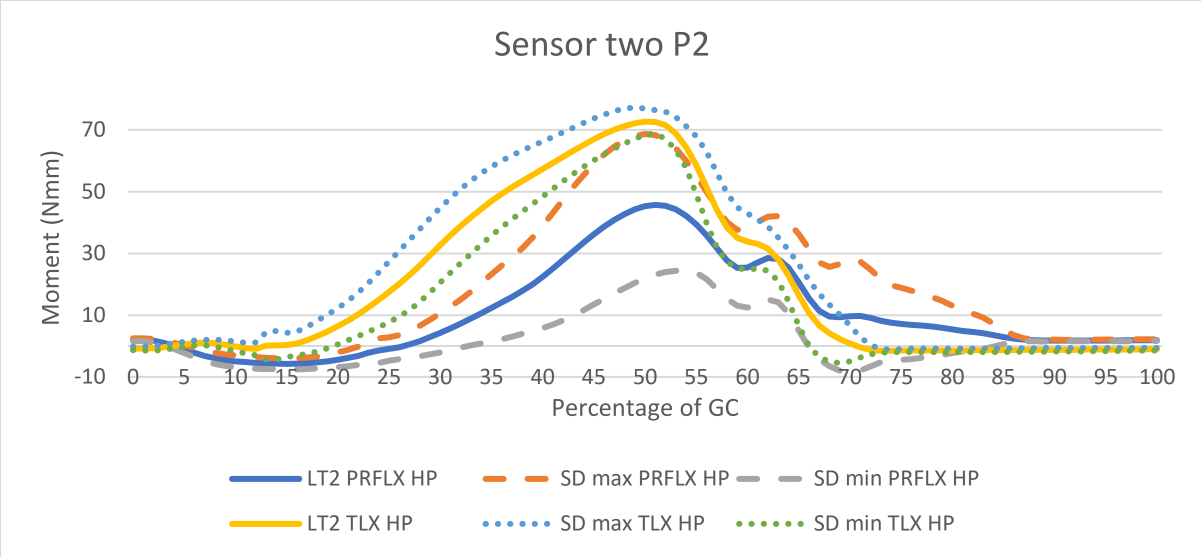
Graphs for individual sensors not included in paper

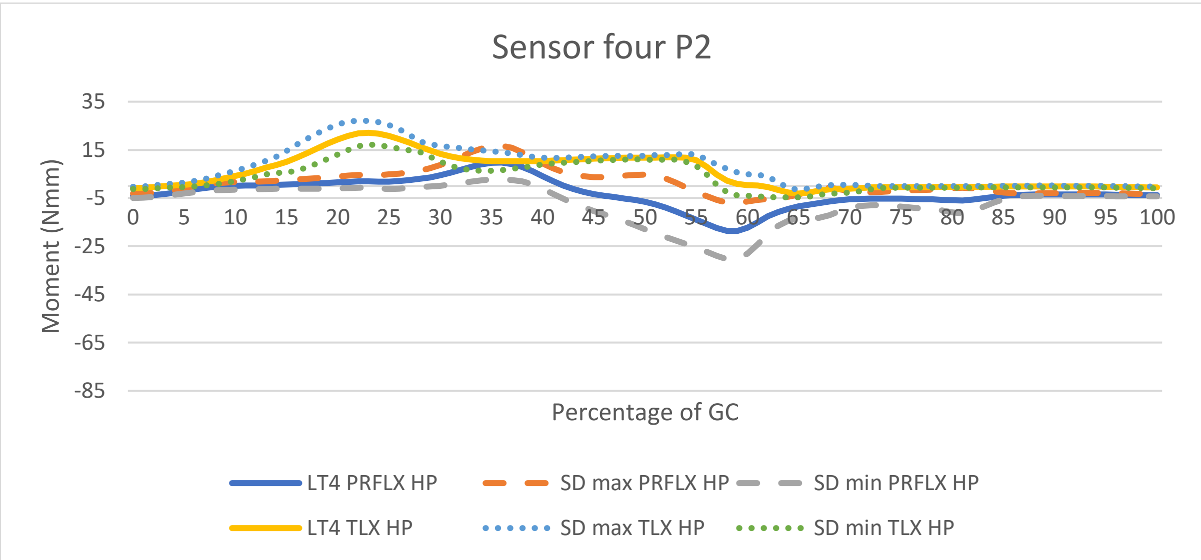


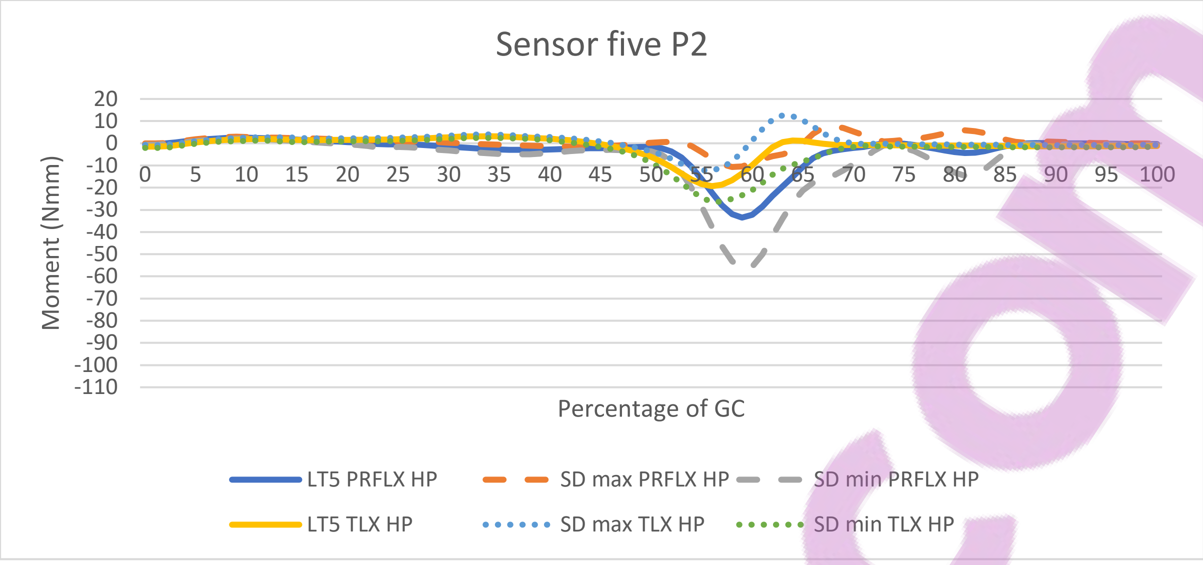



Sensor four P1
35
15
-5
-25
-45
-65
-85
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Moment (Nmm)
Percentage of GC
RT4 PRFLX
SD max
sd min
RT4 TLX
SD max TLX
sd min TLX


Sensor five P1
20
10
0
-10
-20
-30
-40
-50
-60
-70
-80
-90
-100
-110
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Moment (Nmm)
Percentage of GC
RT5 PRFLX
SD max
sd min
RT5 TLX
SD max TLX
sd min TLX


Sensor two P2
Moment (Nmm)
70
50
30
10
-10
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Percentage of GC
LT2 PRFLX HP
SD max PRFLX HP
SD min PRFLX HP
LT2 TLX HP
SD max TLX HP
SD min TLX HP


Sensor four P2
Moment (Nmm)
35
15
-5
-25
-45
-65
-85
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Percentage of GC
LT4 PRFLX HP
SD max PRFLX HP
SD min PRFLX HP
LT4 TLX HP
SD max TLX HP
SD min TLX HP


Sensor five P2
Moment (Nmm)
20
10
0
-10
-20
-30
-40
-50
-60
-70
-80
-90
-100
-110
0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100
Percentage of GC
LT5 PRFLX HP
SD max PRFLX HP
SD min PRFLX HP
LT5 TLX HP
SD max TLX HP
SD min TLX HP