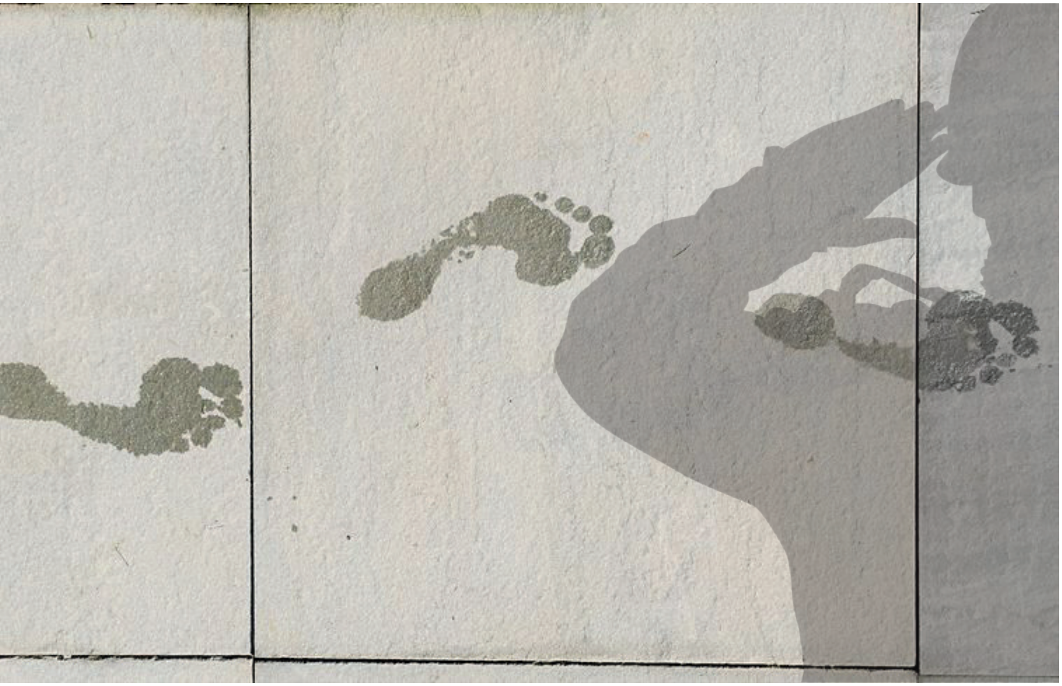
SKILLED FOR LIFE

Towards prevention of overuse lower limb injury with a smart wearable for military use



Master graduation thesis

by Laura Ahsmann

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Towards prevention of overuse lower limb injury with a smart wearable for military use

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TU Delft

Integrated Product Design
Delft University of Technology
13 March 2020

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PREFACE

I came into contact with the subject of this thesis at the European Conference of Sports Science in Prague in 2019. I saw many passionate researchers present their evidence of systematic injury-risk assessment. My background in Industrial Design Engineering and my tendency towards problem-solving made me think of design implementations of this scientific evidence. And in my view, the upcoming potential and applicability of Artificial Intelligence almost make connecting the dots almost straightforward.

Increasing the performance of the human body by means of design has always been something that I have I envisioned as a designer. I am glad to say that this thesis has brought me a small step nearer to achieving that. I couldn't have done so without the support and motivation of my supervisory team. Toon, thank you for providing me with excellent advice, feedback and ideas to explore. Henk, thank you for pushing me to get the most out of the project and for expressing your confidence in me. I also would like to thank Christian Linschoten and staff of the military department of TGTF for their support and advice in the study, Nikki Bouwman and Mitchel Knipscheer for their huge contribution in coding and Thijs Ahsmann for video editing. Lastly, I would like to thank my friends and family for their support throughout this project. This ride would have been much bumpier without your love and advice.

I would like to conclude this preface with a quote from physicist Bram van Ginneken: "Since software is momentarily better at diagnosing cancer than the radiologist, it would almost be unethical not to provide its service to the patient."

- L. Ahsmann,
Delft, March 2020

SUMMARY

This thesis explains the research into and implementation of overuse lower-limb injury prediction among military recruits, using wearable plantar-pressure sensing and biomechanical gait algorithms. The research has been done with the purpose of designing a usable, affordable and accurate injury-prevention tool, increasing both military wellbeing and operability.

For years, researchers have gathered evidence of correlations between specific gait biomechanics of individuals and their influence on injury incidence. Using various types of laboratory equipment, such as pressure plates, walkways and treadmills, researchers found a strong correlation between parameters like cadence, vertical loading, (time to peak) heel rotation and local peak pressure values and different types of common overuse injuries in the lower limbs. However, laboratory tests often neglect the influence of footwear, distraction and fatigue. In addition, they are expensive and time-consuming tasks.

One specific user group that suffers from a high incidence of overuse injuries is the military. About 3000 recruits follow basic military training each year, of which about 13% end up with one of three most common injuries: MTSS, iliotibial band syndrome and tibial stress fractures. Of those injured recruits, about 8% gets discharged from the military. This high rate is caused by the intensity of training, often accompanying high carried loads and pressure to perform. Specifically, the cumulation of repeated smaller impacts during marches is bound to cause overuse injury.

The ability of commercially-used pressure-sensitive insoles to measure abnormality in injury-predictive gait parameters was tested in a series of studies. First, measurements from the insoles were compared to a commonly used gait-analysis tool: a GAITRite walkway (n=20). This study found no statistical agreement in sample-to-sample predictability. To validate whether those results could be caused by methodical differences, a second study was performed comparing the insole measurements of injured soldiers to those of control subjects (n=10). This test did result in significant between-group differences for all measured parameters. Furthermore, significant differences in parameters were found between walking on military boots and running shoes.

A strategic study revealed that the product could find a competitive advantage in service and software innovation, with a focus on (a) accuracy while maintaining usability for specific user groups and (b) multi-diagnostic ability and spread market targeting (both b2b and b2c). Specific user demands were found and defined as a reduction in insecurity at various levels (e.g. where a soldier wants to be reassured about their personal fitness, a commander wants to ensure operation-readiness).

A design proposal was created (Figure 1), based on research insights. The concept insole not only meets military-specific embodiment, hardware needs and improved sensor placement, but a service-design proposal enables both direct users and important stakeholders to use the data for injury prevention, rehabilitation, adaptation of footwear, operational management, training customization and general overuse-injury research.

Besides meeting the needs within a military context, the product could be adjusted to meet the needs of other (occupational) overuse-injury sensitive users, such as police, hospital staff and factory workers. Clinical applications include automation of insole orthosis customization and prevention of ulceration among diabetic patients.

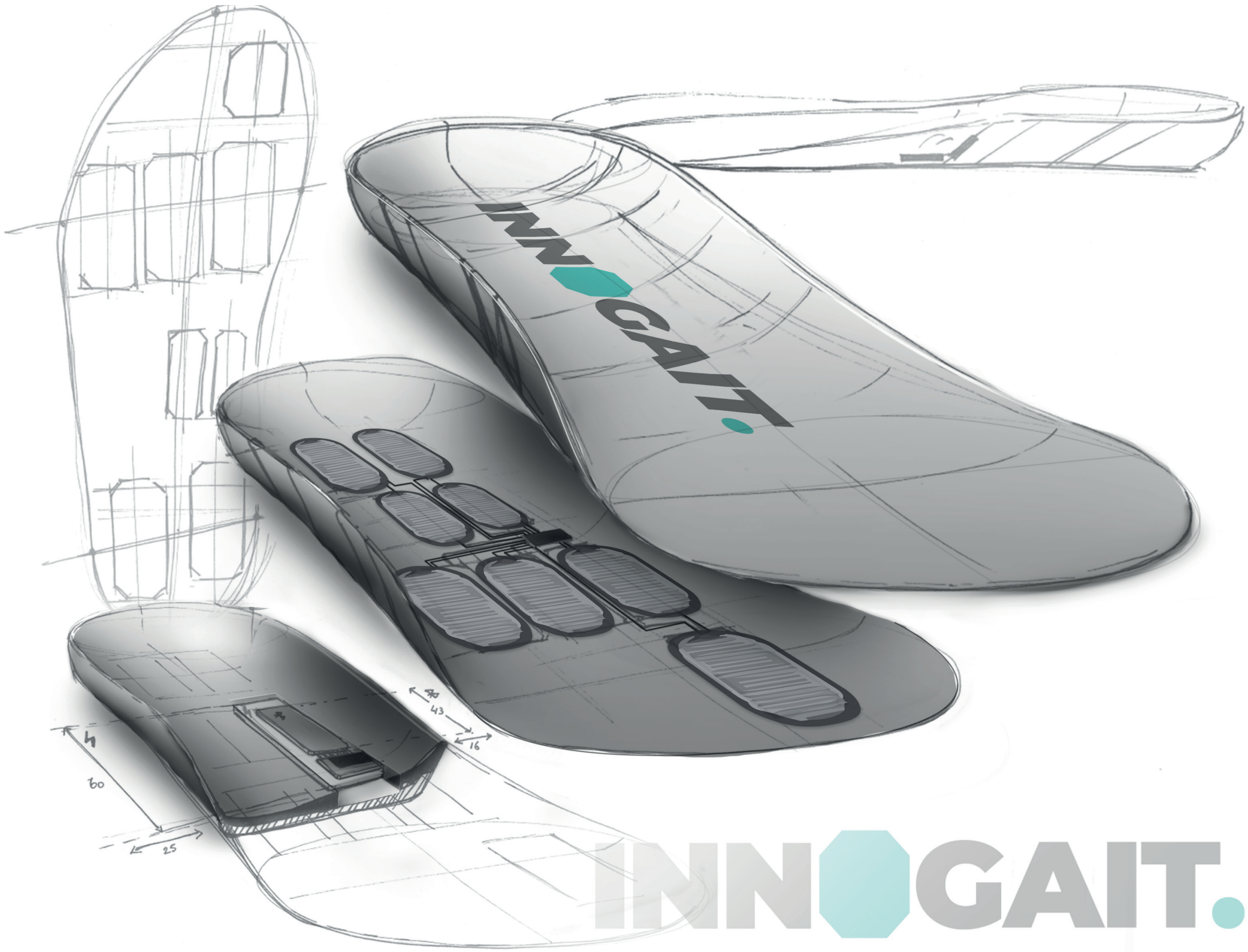


Figure 1. Insole design proposal

INDEX

INTRODUCTION

Military training is often very long and intensive. On top of that, they include heavy and repetitive load, continuously causing micro-traumas on sensitive muscle and tendon fiber areas (Hauret, 2010; Springer 2016). Lack of control and intervention causes overuse injury among military recruits with 25% to 82% incidence (Franklyn-Miller et al, 2014). The lower extremities cover the largest share of injury cases with 39% of the total, as recorded in the Department of Defense (DoD) (Hauret, 2010). In an ideal world, we would use the tools and (artificial) intelligence to predict those injuries before they happen. But why are we not making this ideal a reality?

Investigating intrinsic risk factors from foot function has been proven to be able to predict potential injury cases (Franklyn-Miller et al, 2014; Friedl, 2018; Daoud, 2012; Cowan, 1996; Milner et al, 2006; Sharma, 2007; Verrelst et al, 2018; Strauss et al, 2011). By measuring these risk factors, a researcher could potentially identify the problem causing the high incidence of overuse injury, which can be used to create suitable solutions.

Preventing injury would be beneficial not only for the individual recruit, but also for the entire military unit in terms of efficiency, the duty healthcare would be less occupied and it will eventually cut costs. On top of that, after enduring an injury, the chance of sustaining another injury increases (Andersen et al, 2016; Meeuwisse, 1994), which makes it even more effective to prevent the first one from happening. If risk for injury is detected early on, intervention methods could be used like orthopaedic insoles (Schrijver, personal communication, September, 2019) or practical gait retraining (Sharma, 2014; Zimmerman et al, 2018), reducing the risk for injury with around 60%.

Until now, the majority of kinetic and kinematic studies have been performed in a laboratory setting. A lab setting brings advantages such as enough space for a large setup, wires and computers, full attention from the participant, and privacy. But relocating is a long and expensive operation, according to D. van Tiggelen (personal communication, September 24, 2019). A lab setup also brings several disadvantages to research outcomes. A single force plate evokes ''platform targeting'' (Mann, 2016), allows for only one footfall per trial and requires barefoot running, which does not compare to shod running (Rothchild, 2015). A single data collection moment doesn't account for unexpected - involuntary - changes in kinematics (Verrelst, 2018) or effects of fatigue (Grech et al, 2016). In addition, many suggest that the factor of repetitions of smaller loading rates will result in higher risk of injury (Hauret et al, 2010; Keyserling 2000). A laboratory analysis will not account for the factor of repetition when assessing injury risk. Lastly, the contextual variables such as different terrain types are not included in laboratory studies (Lacirignola, 2017).

To use biomechanical measurements for large-scale injury prevention, data from every individual military trainee is desired. With a laboratory test setting, these test periods will be long, complex and expensive operations and - like mentioned in the previous section - not even very accurate.

ASSIGNMENT & PROJECT SCOPE

The aim of this thesis was to find a way for the military to perform large-scale injury prevention assessments, using an accurate, usable and affordable tool that can also measure outdoor situations. Using this tool, military recruits will be assured of increased personal wellbeing and the military in general will profit from increased operations and training efficiency and manning. The specific research question of this project is:

''How can we reduce the incidence of lower limb overuse injury among military recruits using an affordable, accurate and user-fitting wearable RT-PMS?

This thesis report outlines a context study and several innovation studies, separately concluding on its 'impact on design' and finally a design proposal. Unlike what was stated in the original project brief (Appendix 1), this thesis did not focus on the design and development of a new insole device, but alternatively review and redesign existing technology and conceptualize a service and software innovation. The decision to redefine the scope of the study was based on the market study which revealed a shift in relevance towards software innovation. Figure 2 illustrates the research and design process that this project went through, starting from the definition of the original project brief. After a short focus on Insole design (doing a literature study), it became clear that the market already offers several pressure-sensitive insoles. An analysis of new market-entry, technological capabilities and user value provided a list of shortcomings to be used in the design of a product-service system, consisting of software design, embodiment redesign and service-system design. An elaborate user- and use-analysis was necessary to discover actual demands to focus the design on. These analyses lead to the definition of a value statement: 'I want to reduce insecurity in military operations'.

The Military Department of Training Physiology and Training Healthcare (TGTF) was consulted for input on user demands and product application specifics.

The structure of this thesis is designed to take the reader through a journey of the project. The context study (Chapter 1) covers a literature review on the biomechanical and market side of the project scope (Section 1.1) and a user study (Section 1.2). The context study presents the answer to the following sub-research questions:

(i) "Why is there not yet a suitable solution to reduce lower limb overuse injury in the military?" (Section 1.1)
(ii) "How should injury-risk be measured and assessed?" (Section 1.1)
(iii) "How should a wearable PP analysis tool be designed to effectively meet and account for the needs, structure and advantages of military context?" (Section 1.2)

Chapter 2 subsequently presents a series of studies using different drives for innovation relevant to the main research question. They are designed to answer the following sub-research questions:

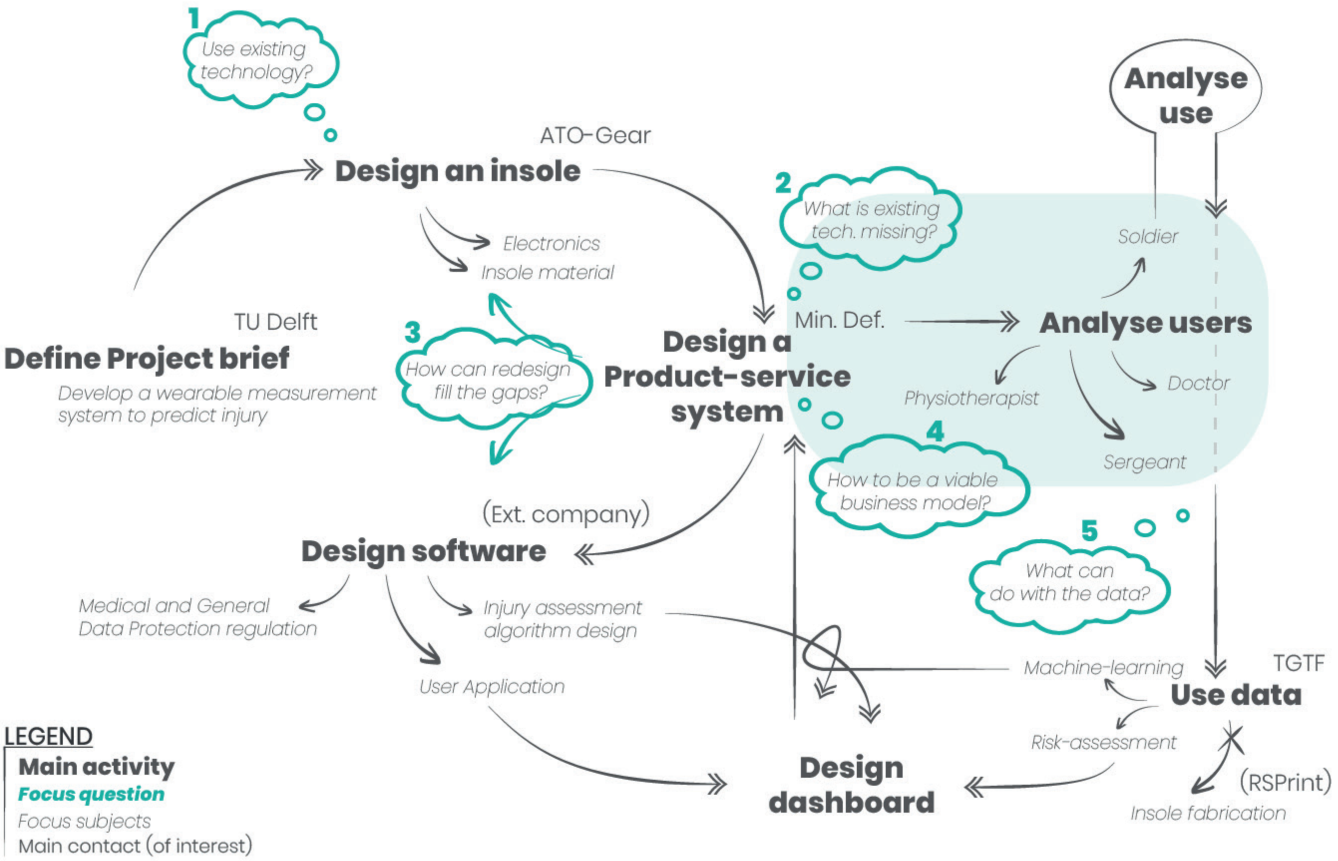


Figure 2. Project process

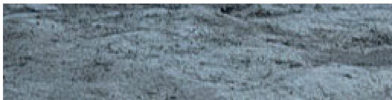
(iv) (technology-driven) "Is an FRS array - inside wearable measurement insoles - able to measure relevant gait parameters accurately enough to detect abnormality?" (Section 2.1)
(v) (value-driven) "Which (emotional) values are desired by the different stakeholders and how can a new tool (or service system) account for them?" (Section 2.2)

Key takeaways from these studies are translated into design requirements and recommendations, which are presented in a Design proposal in Chapter 3. Chapter 4 will discuss the studies and the project as a whole and provide recommendations for future work. Finally, Chapter 5 presents a project evaluation.

CHAPTER 1

CONTEXT STUDY

To understand the context of the problem and level of research done on the subject, a literature and user study were done. The insights as presented in this chapter are obtained from scientific papers and expert interviews.



MEASURING GAIT BIOMECHANICS

This section summarizes a literature review on the topic of overuse injury and more specifically on the relevant biomechanical parameters that can be measured from under the foot. The goal of this literature review is to get an answer to the sub-research question: Why is there not yet a suitable solution to reduce lower limb overuse injury in the military?
The answer to this research question will be approached from a medical, contextual, technical and market point of view, resulting in a set of key takeaways on design. The full literature review can be found in Appendix 3.

1.1.1 Injury sensitivity of the lower limbs

Of all injury-related musculoskeletal cases, the lower limbs are one of the most common locations of injury (39% in US DoD) (Hauret, 2010). The cause of this high rate has been studied widely in the past decade, often concluding in the effect of intrinsic and extrinsic factors. The feet are the first to contact the ground and therefore a key factor in absorption of reaction force (Williams et al, 2016). The body relies on damping or shock absorption of normal muscle activity when walking, running or jumping. With constraint overload, muscle fatigue, or extreme motion (such as hyperpronation), stress reactions will accumulate on muscle and bone tissue, resulting in several types of injury.

1.1.2 Everyone walks the same, but also differently

Generally speaking, how we all walk and run is based on the same sequence of biomechanical movements. Under the surface, however, everyone grows into a customized pattern, mostly based on anatomic build (L. Fuit, Personal communication, January 7th, 2020). Determining personal abnormality in gait is a key factor in defining injury-risk factors. But to find out when gait is abnormal, we first need to know what is normal. Why do some people endure an injury while others, with the same physical load, do not?

1.1.2.1 The universal gait cycle

The human gait cycle consists of a stance phase and a swing phase (Figure 3) (Torricelli et al, 2016). The stance phase is divided into starting with the heel strike (first

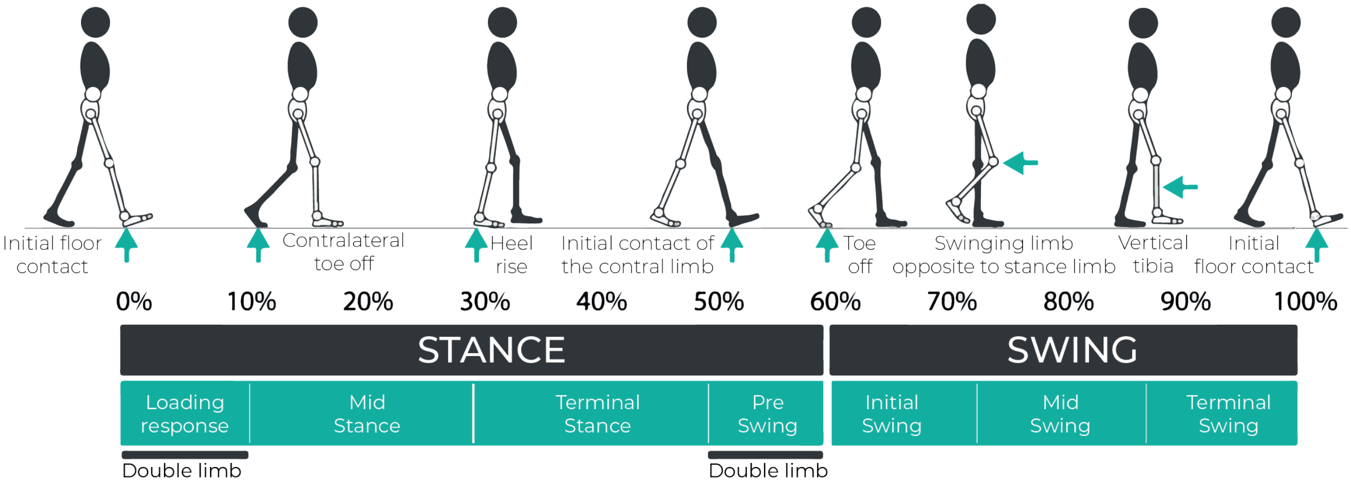


Figure 3. The gait cycle

moment of double support) and ending with toe-off (last moment of double support). The stance phase covers around 60% of the cycle of which 20% with double limb contact and 40% single leg support per leg. When walking speed increases towards running, the single leg support lengthens until the full gait consists of single leg support.

Along with increased walking speed, step frequency (cadence) increases. However, the way people adjust the cadence with increased speed is a personal characteristic and considered a key factor in injury risk assessment.

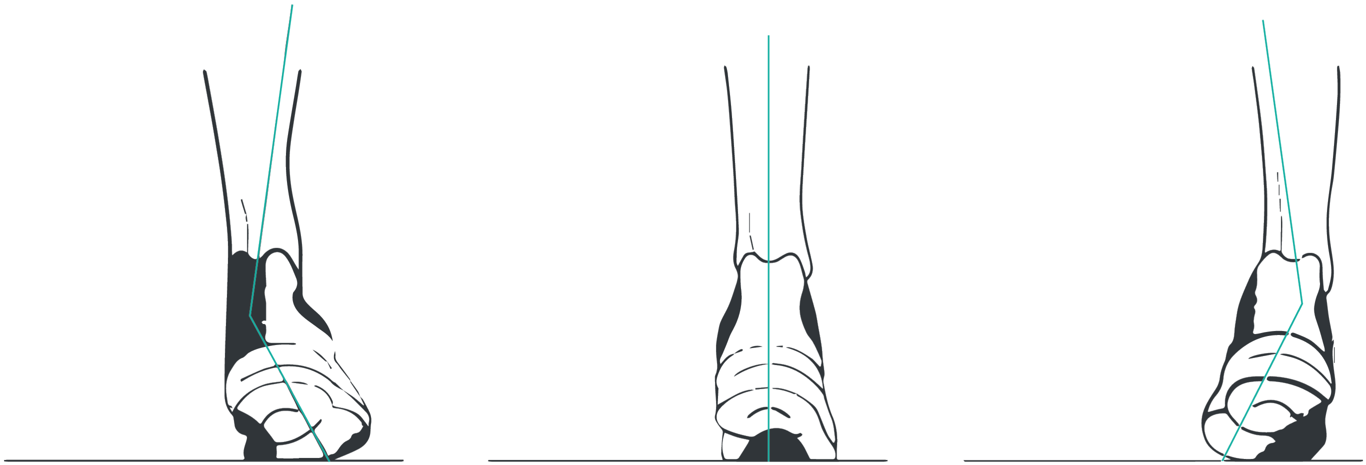


Figure 4. Ankle pronation (left), neutral (middle) and supination (right) locomotion

Additional to kinematics in gait phases, ankle kinematics also consists of eversion and inversion motions. More specifically: pronation, as a combination of dorsiflexion and eversion and supination, which is the opposite (Figure 4) (Nagano, 2018). The rate and timing of pronation during stance has impact on the impact loading and guides accommodation of weight on the ground surface (De la Cruz, 2014). Floor contact with a supinated ankle, for example, results in hyperpronation and accompanying internal tibial rotation (Negano, 2018).

1.1.2.2 Individual difference as a risk indicator

Overuse Lower Limb Injury (OLLI) is a collective term used to describe injuries caused by overtraining, overexertion, repetitive movement, forceful actions, extreme joint positions and prolonged static positioning (Hauret et al, 2010). Repetitive movements and overtraining, regardless of gait characteristics, cause micro-trauma in muscle fibres, eventually resulting in severe damage (Hauret, 2010). However, movements that deviate from the normal, like overexertion, forceful actions and extreme joint positions are subject to individual behaviour could provide extra indication of potential injury risk.

Besides biomechanical gait factors, other intrinsic factors such as age, flexibility, previous injury and somatotype (Figure 5) have been associated to contribute to injury risk (Meeuwisse, 1994).

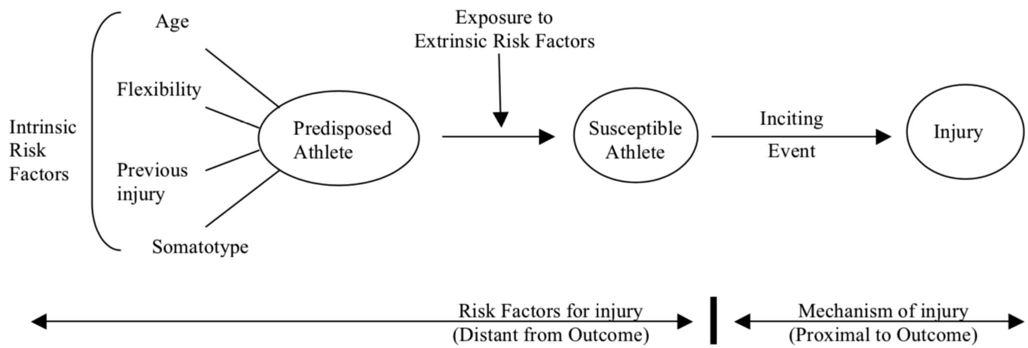


Figure 5. Multifactor model by Meeuwisse et al (1994)

1.1.2.3 Extrinsic risk factors

Additional to intrinsic risk factors, people in the military specifically are exposed to extreme extrinsic circumstances. Training intensity, mileage, terrain type, load carrying and the wearing of military boots are examples of extrinsic factors that play a role in the attribution of injury. Blacker et al (2008) and Knapik et al (2001) proved that fatigue can change mobility patterns resulting in increased load and injury risk. Sharma (2011) additionally found a strong correlation in smoking habit and overuse injury.

1.1.3 Injury types

OLLI's are generally located in the knee, heel, foot, ankle and upper and lower leg, but sometimes also the hip and lower back are considered for lower limb injury. Figure 6 shows a statistical overview of injury incidence in the military. In the Dutch Defence specifically, most common and impactful OLLI are Medial Tibial Stress Syndrome (MTSS, also known as Shin Splints), Iliotibial band syndrome (ITB) and Tibial Stress Fracture (TSF), together covering about 13% incidence among all recruits (van Rompay, 2011; D. van Tiggelen). Focusing on those injuries specific would have a significant impact. Table 1 in Appendix 3 shows an elaborate overview of the most occurring OLLI's and their morbidity impact.

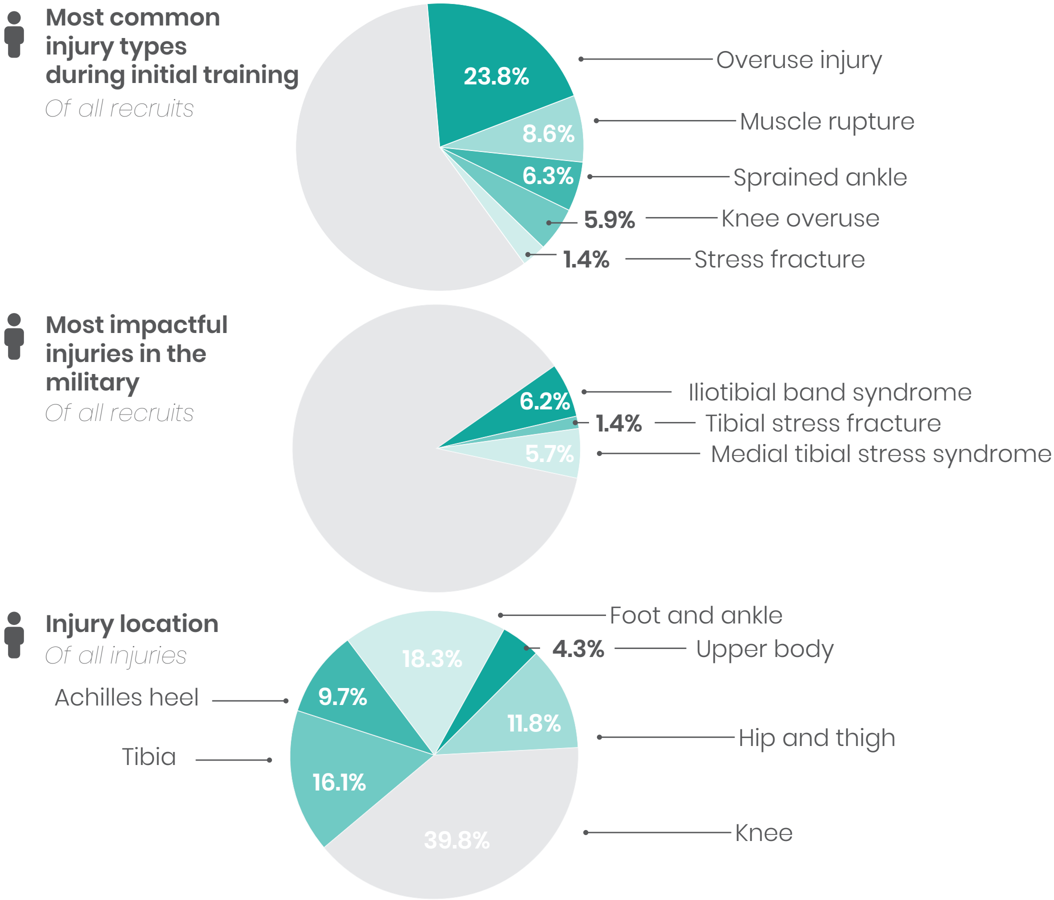


Figure 6. Injury in the military (based on van Rompay et al, 2011)

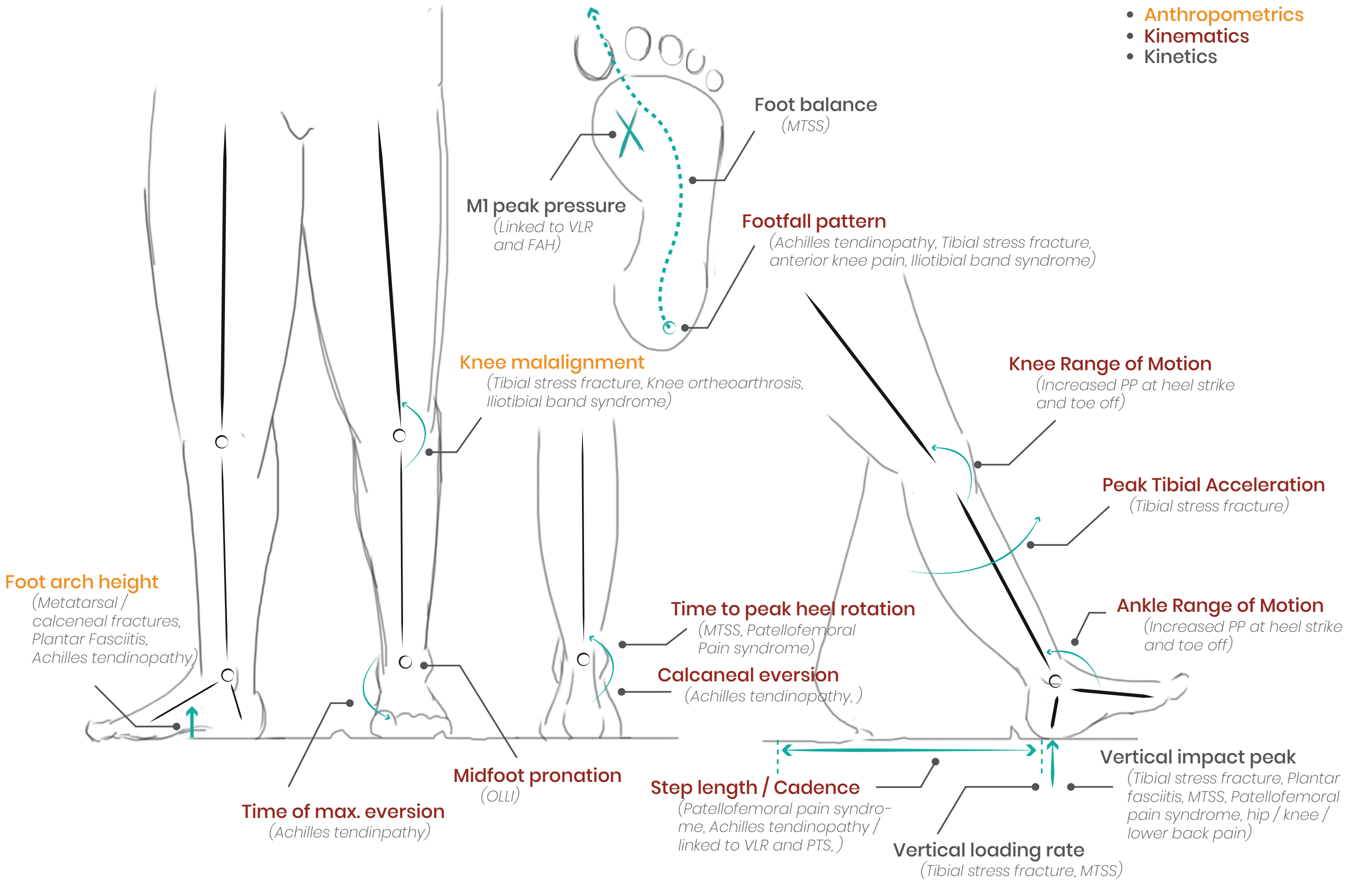


Figure 7. Risk factor overview

1.1.4 How to measure gait parameters

1.1.4.1 Risk Factor recognition

Intrinsic risk factors can be discovered in the field of anthropometrics (body build), kinematics (human motion) and kinetics (acting of external forces on a body in motion) parameters. Figure 7 shows a visual overview of biomechanical parameters and related injury types. A more elaborate table of risk factor studies and their authors can be found in Appendix 3, Chapter 6. The illustrated risk factors are selected based on their relevance in military context (Section 1.1.3).

Anthropometrics

Before considering walking parameters, static anthropometric data already provides insight into potential risk factors. Malalignment of the knees (varus or valgus) creates a greater bending moment on the medial tibial segment during gait and increases the risk for OLLI (Milner, 2006; Sharma, 2007; Strauss et al, 2011). Secondly, people with a high foot arch are less able to absorb shock, causing high peak forces in medial forefoot and lateral rearfoot and hereby increase the risk of fractures (Carson et al, 2012) and stress on connected ligaments (Schrijver, personal communication, October 3, 2019).

Kinematics, timing and consistency

Kinematics describes human motion - or lack of it - throughout the gait cycle. Footfall pattern (FFP) is the way a person lands at initial floor contact and subsequently determines the plantarflexion of the foot. A less-common forefoot strike (Figure 8) often shows an absence of an impact peak and a decreased loading rate. FFP has often been associated with heel and knee injury (Hamill, 2017).

Peak Tibial Acceleration (PTA), defined as the absolute acceleration of the tibia during swing phase, also has been found to increase risk of OLLI and has been associated with increased Vertical Loading Rate (Milner et al, 2006). Within the foot itself, increased Midfoot Pronation (MP) and Calcaneal Eversion (CE) have also been connected to OLLI (Milner et al, 2006; Schrijver, personal communication, October 3, 2019; Bennet et al, 2001; Nagano, 2018; Pohl, 2008; Ogbonmwan et al, 2018).

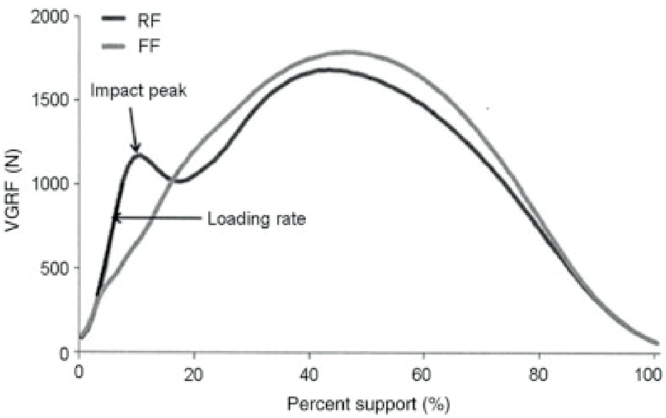


Figure 8. Vertical ground reaction forces of rearfoot (RF) and forefoot (FF) strike

While the absolute values of the above-mentioned variables can serve as an injury indicator, the timing and consistency of the parameter's execution tell something about its risk too. People with larger Stride Length with similar walking speed (low Cadence) compared to someone with smaller stride length commonly shows higher loading rate and PTA (Schrijver, personal communication, October 3, 2019; Arazpour, 2016; Ogbonmwan et al, 2018). On a smaller scale, timing within stance also affects load distribution. For example, a Delayed Maximal Eversion of the foot (caused by a lateral footfall) is found in participants that developed OLLI's (Willems, 2005-2007; Ogbonmwan et al, 2018). Studies by Sharma et al (2011) and Arazpour (2016) found a connection between Time to reach Peak Heel Rotation (TPHR = HL-HR) and lower limb injury. Furthermore, variability and fluctuations of gait parameters show evidence to predict overuse injury (Hamill, 2012).

Kinetics

Kinetics describe the force and pressure parameters acting on the human body while moving. During gait, the body balances itself applying weight distribution over one or two legs. This balance creates a continuous change in Centre of Pressure (CoP) under the foot (Booth et al, 2019). Sharma et al (2014) proposed an algorithm of the medial-lateral pressure differential to calculate Foot Balance (FB). FB data from the first 10% of the stance provides a factor for injury risk.

Vertical Impact Peak (VIP) is the highest peak value of vertical Ground Reaction Force during heel strike, as visible in Figure 8 (Daoud et al, 2012), which magnitude is a proven indicator for different OLLI (Milner et al, 2006; Daoud et al, 2012). The Vertical Loading Rate (VLR) is the difference in vGRF over a period of time. Milner et al (2006) found a significantly increased VLR at the heel among injured subjects. Others found significant lower VLR among pre-injured subjects at the M5 and HL , but a higher peak pressure under M1 at forefoot flat and heel-off (Willems, 2007).

1.1.4.2 Smart sensing technology

Assessment of biomechanical loading depends on which parameters (risk factors) are required for injury prediction and is typically done using three different methods: force/pressure sensing, contact area sensing or movement sensing. Most risk factors that are elaborated in Section 1.1.4.1 can be measured with Plantar Pressure (PP) analysis (Mann, 2016; Booth et al, 2018; Daoud et al, 2012). PP analysis is proven to be reliable in test–retest (Franklyn-Miller et al., 2014). Figure 9 shows a graph of peak PP depending on walking speed in different areas under the foot (Guldemond, 2007). Visible is that the peak pressure under the central forefoot reaches the highest values. According to Guldemond, 1000 KPa could be seen as a threshold towards medical implications. The toes mainly play an important role in reducing local PP peaks by increasing load-bearing area. This study gives an indication of the extent of detail to be obtained from PP analysis. An elaborate review of this and other sensor types can be found in Section 6.2 in Appendix 3.

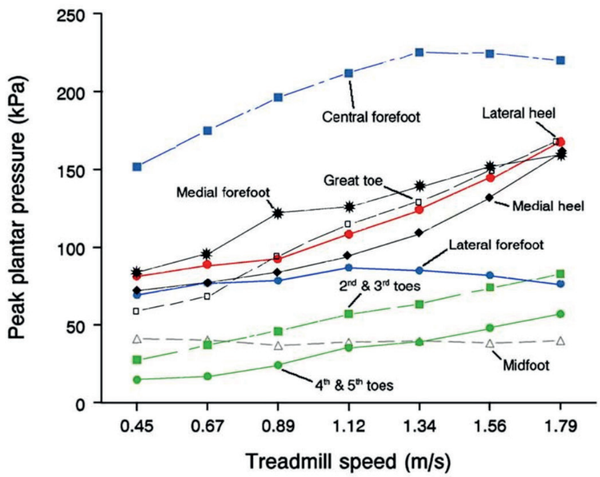


Figure 9. Peak plantar pressure distribution under the foot (Guldemond, 2007)

Pressure and force can be measured in different ways. Pressure, as opposed to force, takes accounts for contact area, which is useful when you are interested (like in this study) in plantar pressure distribution. Pressure plates and Walkways provide detailed and high spatiotemporal resolution data which makes the outcome very accurate. But as mentioned in the introduction, the use of a pressure plate or walkway is limited to laboratory use and the high spatial resolution of sensors - even though it provides high accuracy (Booth et al, 2018) - is not always necessary. Using appropriate algorithms, it is possible to calculate pressure values under the entire foot, without the need to cover the entire insole with sensors (Tan et al, 2015; J. van den Berg, personal communication, October 10, 2019). Additionally, highly correlated locations (Figure 10) could be merged according to a Regions-of-Interest method (Benocci et al, 2009; Lawrence & Schmidt, 1997).

A secondary important factor in PP measurement is temporal resolution. For measuring gait activities, a sampling frequency of minimum 200 Hz is necessary not to miss true peak values (Razak et al, 2012). Looking at a design point-of-view, the power consumption, flexibility, resistance to humid and force and dynamic range of sensors should be considered (Guldemond, 2007). This subject is elaborated in Appendix 3, Section 6.2.

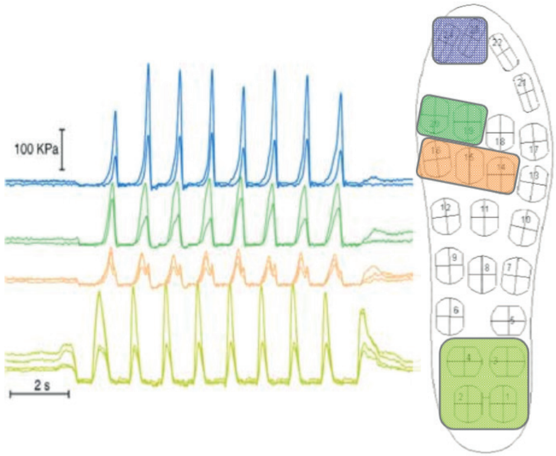


Figure 10. Groups of highly inter-correlated sensors of plantar pressure measurement (Benocci et al, 2009)

1.1.4.3 Use of commercial products (market study)

The current market for insole measurement devices is still relatively young and mainly focuses on research purposes (e.g. Pedar-r, Figure 11a). The embodiment of those insole measurement systems is often robust and requires external electronic pouches to be worn around the lower leg, which makes them inappropriate for commercial purposes or long-term use. An online market study reveals only a few insole PP measurement devices for consumer use. RUNVI, for example, is a Kickstarter project that intends to use 30 pressure sensors and two accelerometers for real-time run feedback. The electronics are integrated in the insole heel, giving the insole a predefined shape (Figure 11b). FeetMe is designed for rehabilitation of patients with a mobility disorder in hospitals. Similar to RUNVI, it uses pressure sensors and inertial sensors (Feetme, n.d.). Both these products have not been officially released on the market (Figure 11c).

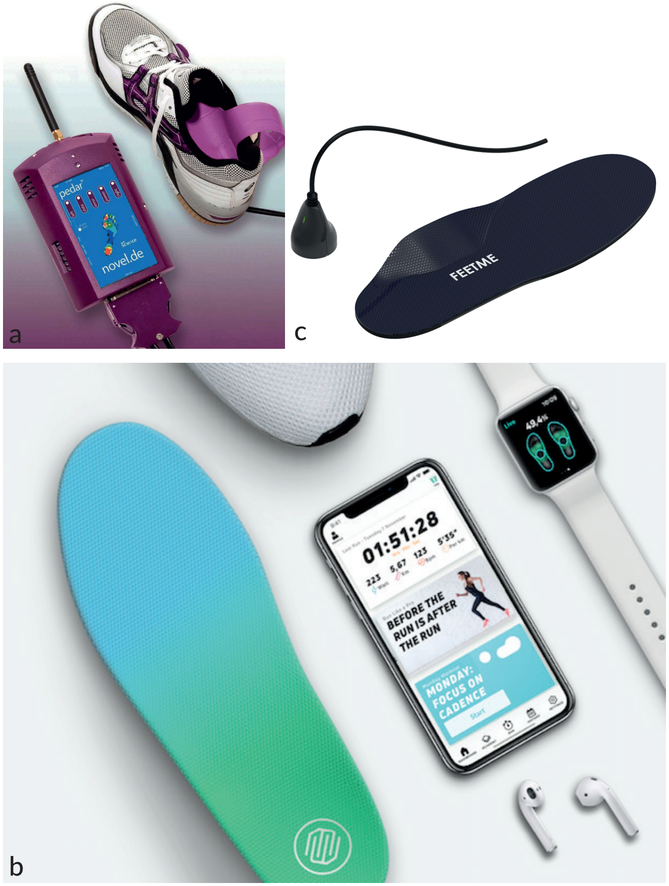


Figure 11. (a) Pedar-r insoles ("pedar-r:" , n.d.), (b) RUNVI insoles (von Waldthousen, 2018) and (c) FeetMe insoles ("Feetme insole", n.d.)

To analyse the market in a broader sense (physical activity monitoring), the products are categorized according to four types of specifications - derived from this section - and distributed on a two-axis visual overview (Figure 12):

1. Design purpose (elaborate vs usable)
2. User specification (user-centred vs design for all)
3. Business model (clinical vs commercial)
4. Measurement capability (injury specific vs multi-diagnostic)

Four generic product clusters can be distinguished from those overviews: research attributes, generic tools, products for the large professional market and niche-consumer products (Figure 12).

On the other hand, there were no products found on the market that target both a user-centred design and a purpose for elaborate measurement. Secondly, no products were found that offer a multi-diagnostic product for both the business and consumer market. Focusing on these strategic orientations, will create both user desirability and competitive advantage.

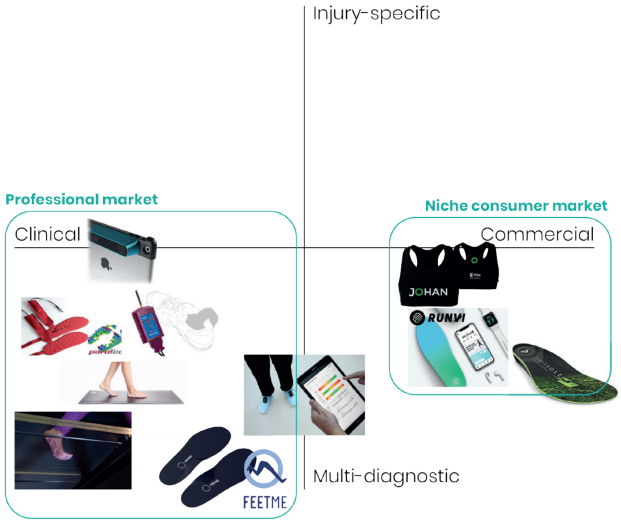


Figure 12. Market segmentation and clusters

IMPACT ON DESIGN (CONCLUSION)

To answer the research question of this section, there is not yet a suitable tool for this market and use purpose because existing commercial products do not focus on clinical assessment and existing clinical or research tools, on the other hand, are not suitable for (heavy) use by individual users. A competitive advantage will be created if a tool would combine accuracy in measurement with a user-centred design and offering multi-diagnostic performance for both business (or research) and consumer use. Additional insights are listed below.

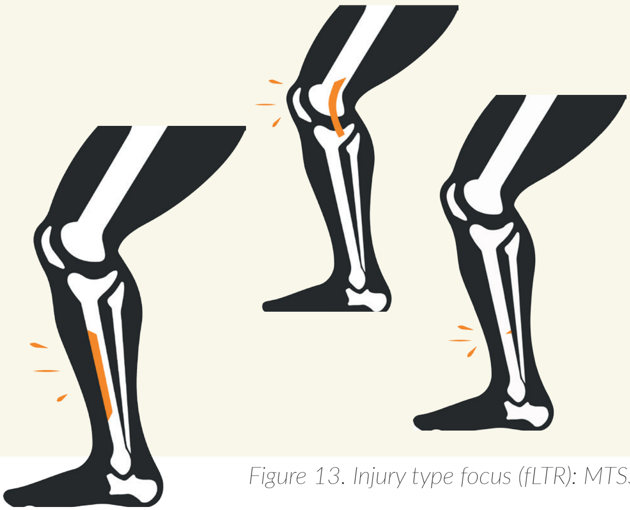


Figure 13. Injury type focus (fLTR): MTSS, ITB and TSF

1. To create personal risk assessment for specific injuries, both between-subject differences and similarities should be accounted for

Parameter deviation from the normal value is the way to measure biomechanical risk factors. Additionally, some parameters (such as TPHR) are linked to timing within stance. Therefore, the system should be able to calculate gait cycle parameters including heel strike, foot-flat and toe off (together forming the stance phase). Variability and fluctuations of gait parameters should also be monitored as they have been proven to have an effect on overuse injury.

2. Focus on MTSS, ITB and TSF

Targeting the three most common injuries in the military - Medial Tibial Stress Syndrome (MTSS), Tibial Stress Fracture (TSF) and Iliotibial Band Syndrome (ITB) - would have a significant positive impact on total drop-out rate, considering they cover at least 13 percent incidence of all recruits (van Rompay, 2011) and have high impact on morbidity (Figure 13).

3. Use pressure sensors to create both accuracy and usability

Values of VLR, VIP, TPHR, FB and local M1 peak pressure are (theoretically) able to assess risk of the three most common and impactful injuries. All of those parameters can be measured using plantar pressure

Table 1. Risk parameter selection and injury assessment criteria

Risk value	Parameter																
	Cad	**FAI**	**PTS**	**M1**	**TPHR**	**VLR**	**VIP**	**FB**	**KP**	**CE**		**iCOP**		**Rep. factor**			**Final Risk score**
	(s/m)	**(%)**	**(g)**	**(kPa)**	**(% of sta**	**(BW / s-1**	**(BW)**	**(kPa)**	**(deg)**	**(deg)**	**(kPa)**	**(mm)**					
Healthy (0)	>170	21-28	<5	<60	<25.5	<80	<1.7	<14	<3.9	<9.7	<178	<21		<10.000		*Healthy*	<25
Moderate risk (1)	<170	<21 / >28	>5	>60	>25.5	>80	>1.7	>14	>3.9	>9.7	>178	>21		>10.000		*Moderate risk*	>25
High risk (50)	<160	<15 / >34	>10	>100	>28.5	>90	>1.8	>18	*(>4,5)*	>11	>222	>25		>20.000		*High risk*	>50
Very high risk (100)	<150	*(<10 / >40)*	>15	(>130)	*(>31.5)*	>95	>1.85	>22	*(>5)*	>13	>250	>28		>30.000		*Very high risk*	>75
Formula (*100)	*20-(C-150)/20*	*IF<21: 11-(FAI-10)/11 IF>28: (FAI-28)/12*	*(PTS-5)/10*	*(MP-60)/70*	*(TPHR-25.5)/6*	*(VLR-80)/15*	*(VIP-1.7)/0.15*	*(FB-14)/8*	*(KP-3.9)/1.1*	*(CE-9.7)/3.3*	*(CE-178)/72*	*(iCoP-21)/7*		*1+(R-10000) /50000*			
Risk score MTSS	+	+	+	+	+	+	+	+				+	>	x	>	Risk score MTSS	
Risk score TSF	+		+			+	+	+	+	+		+	>	x	>	Risk score TSF	
Risk score ITBS	+		+	+					+			+	>	x	>	Risk score ITBS	

analysis. Selecting parameters based on sensor types will minimize hardware complexity and production cost, making it suitable as a consumer product. Force Resistive Sensors are appropriate for implementation for military insoles as they are thin, flexible, and resistant to humid and high forces.

4. Creation of an injury assessment wireframe

Studies by Sharma et al (2013 - 2015) have shown that by using combined risk factor models, the predictive power of assessment will increase. Using mean and standard deviation values from previous injury-prediction studies, an assessment form is created showing threshold values for healthy, moderate, high and very high-risk assessment (Table 1). Adding a factor of repetition will likely increase accuracy based on cumulative micro-trauma. It should be noted that the threshold values presented in Table 1 could be sensitive to context and calibration method. Normalizing parameters to Body Weight (BW) or overall peak or mean pressure will create a more consistent dataset.

5. Discovering unknowns with machine-learning

The accuracy of assessment will be increased by updating threshold values using machine-learning. Personal data input and external risk factors - such as footwear, terrain type and training intensity - will additionally help to improve the accuracy of injury prediction algorithm. The influence of repetition specifically is not yet discovered in previous studies and can be studied using this tool.

ABOUT THE MILITARY

In the military, laboratory-based trials are currently the only used method for performing clinical gait analysis (Lopez et al, 2011). But like mentioned in the introduction, this method brings many disadvantages, especially for a user group whose performance is highly affected by factors of outdoor training. This section aims to answer the sub-research question: How should a wearable PP analysis tool be designed to effectively meet and account for the needs, structure and advantages of military context?

1.2.1 The downwards hierarchal stream of between-user interaction

Each group of armed forces within the ministry of Defence consists of multiple military units in a hierarchy of ranks. A unit of soldiers in normal training circumstances mainly report to their commander, assisting corporals and sports instructors, providing them with military training. When soldiers get injured, they will enter a different interaction circuit involving therapists.

The overview in Figure 14 shows an (hierarchic) interaction overview of the main stakeholders, based on information provided by interviewed military personnel (Appendix 11). Interaction types can be influenced by external factors such as financial dependence and job security, which could presumably increase pressure and biased decision making.

What stands out is that interaction with a soldier mostly go one-way, presumably making it difficult for a soldier to reach out to the middle layer. Another interesting observation is the lack of personal communication between middle-layer stakeholders. According to soldier S. Dokter (Personal communication October 31st, 2019), personal interest and attention from a superior help the motivation for rehabilitation. While that attention is present during the rehabilitation, it rapidly disappears after returning to the force. Besides personal attention, it would be beneficial to track personal fitness after recovery to prevent relapse or a different injury. This subject will be further discussed in Section 1.2.4.3.

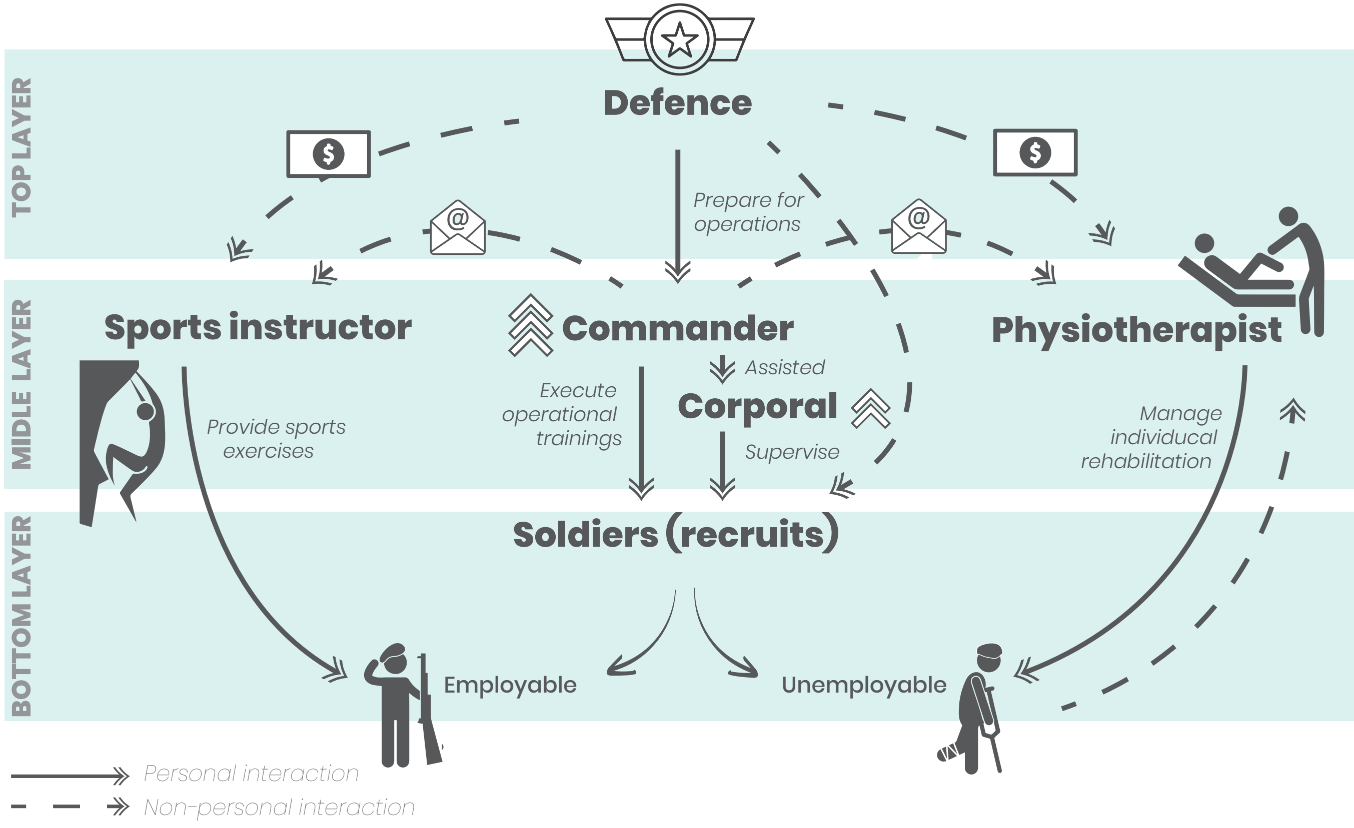


Figure 14. Stakeholder Interaction Framework

1.2.2 The unique impact of military training and equipment

To prepare for combat, military recruits all over the world undergo a series of training programmes. Initial training - including 'Algemene Militaire Opleiding' (AMO) - is considered one of the most important courses with around 2924 participants from the Dutch Armed Forces each year (Projectgroep Nulmeting opleidingen Defensie, 2008). Military training has proven itself as high injury risk with overall-injury occurrence of 25 to 82 percent (Franklyn-Miller et al, 2014). Marching and walking are key components in military training, but they show highest impact on musculoskeletal injury (Springer, 2010; Jordaan, 1994). Even though acute trauma might not occur during the march itself, every step creates cumulative micro-trauma on the muscles and ligaments in the lower limbs (Hauret et al, 2010).

As mentioned in Section 1.1.2.3, the extrinsic factors that come with military context are often not beneficial for personal wellbeing. Military boots, for example, are built to be strong and durable (see Figure 15). High sole stiffness is a requirement for the user context, but it has a negative effect on joint load (House et al, 2002). Wrong sizing or tight lacing also have shown to induce pain complaints (Zimmerman et al, 2014). Other factors that have been found to induce increased rates of injury are running/ training intensity and mileage (Havenetidis et al, 2011), walking on uneven or inclined terrain (Knapik et al, 1997), carried load (Attwells et al, 2006) and pressure to perform (Withrow, 2016).

Despite a lower intensity, most injuries occur in the first three weeks of initial training (Almeida et al, 1999; Sharma, 2015). This is explained by a lack of initial strength and adjustment time. The complexity of physical adjustment during AMO, make it an interesting test period for injury assessment. Additionally, the structure of initial training stays relatively constant over the years, allowing for a comparative repeated measure of large subject groups.

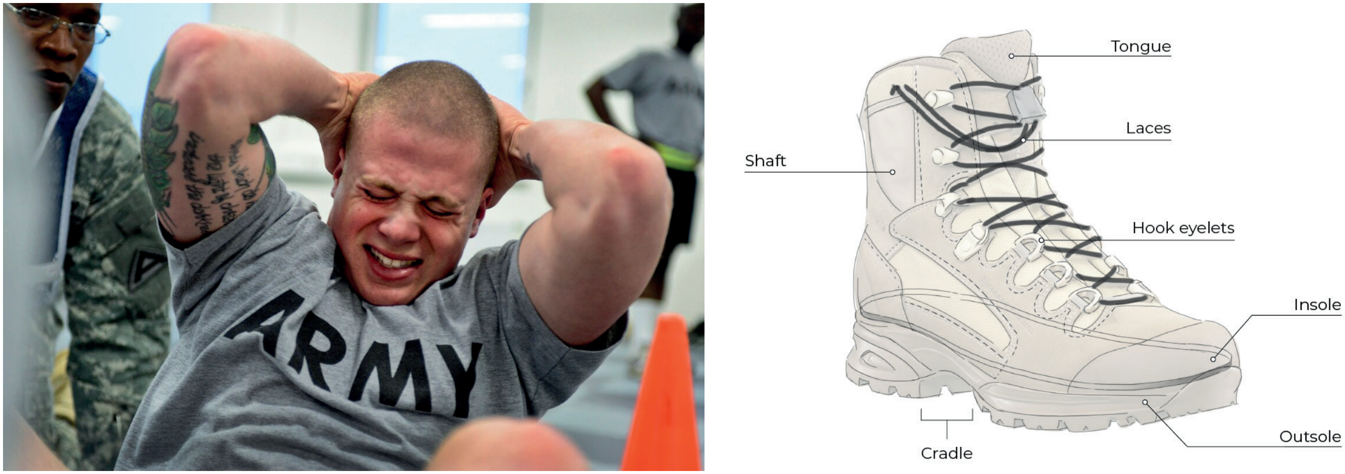


Figure 15. Standard military boot (HAIX, n.d.) and pressure during training (Withrow, 2016)

1.2.3 Discharge and impact

8.4 percent of recruits in the Dutch Defence goes through a rehabilitation programme after basic military training, resulting in a discharge of about 38 percent (Rompay, 2011). Discharge does not only have impact on the individual, but is also bad for morbidity, training time, resources and manning of the entire army (see Table 1, Appendix 3). Figure 16 shows a flowchart of the estimated financial impact of gait intervention. Sharma et al (2014) and found an increase of 7.1 percent injury-free after gait retraining intervention and an 11 percent increase with orthoses intervention was additionally found by Franklyn-miller et al (2011). Annual AMO costs for the Dutch Defence are estimated around at €190 million (Projectgroep Nulmeting opleidingen Defensie, 2008). Considering increased prevention of 18.1 percent injuries, €273 - €450 p.p. could be annually saved by preventing discharge, not even accounting for savings in rehabilitation costs. This money could easily be used to pay back the investment in the insoles, as long as their retail price (taking into account the product lifespan) and is lower than the saved costs.

1.2.4 Resources and Intervention

The benefit of injury prevention among recruits has been proven in the previous Section. But the current intervention methods used by the Dutch Defence do not allow for prevention, but for rehabilitation of injury.

1.2.4.1 Gait Retraining

The Dutch military department of training health & training physiology (TGTF) offers consultation and minor rehabilitation programmes. Gait Retraining is a combination of exercises to improve neuromuscular control, which has been shown to reduce biomechanical risk factors that lead to OLLI with about 75 percent within 26 weeks (Figure 17) (Sharma, 2014; Zimmerman et al, 2018).

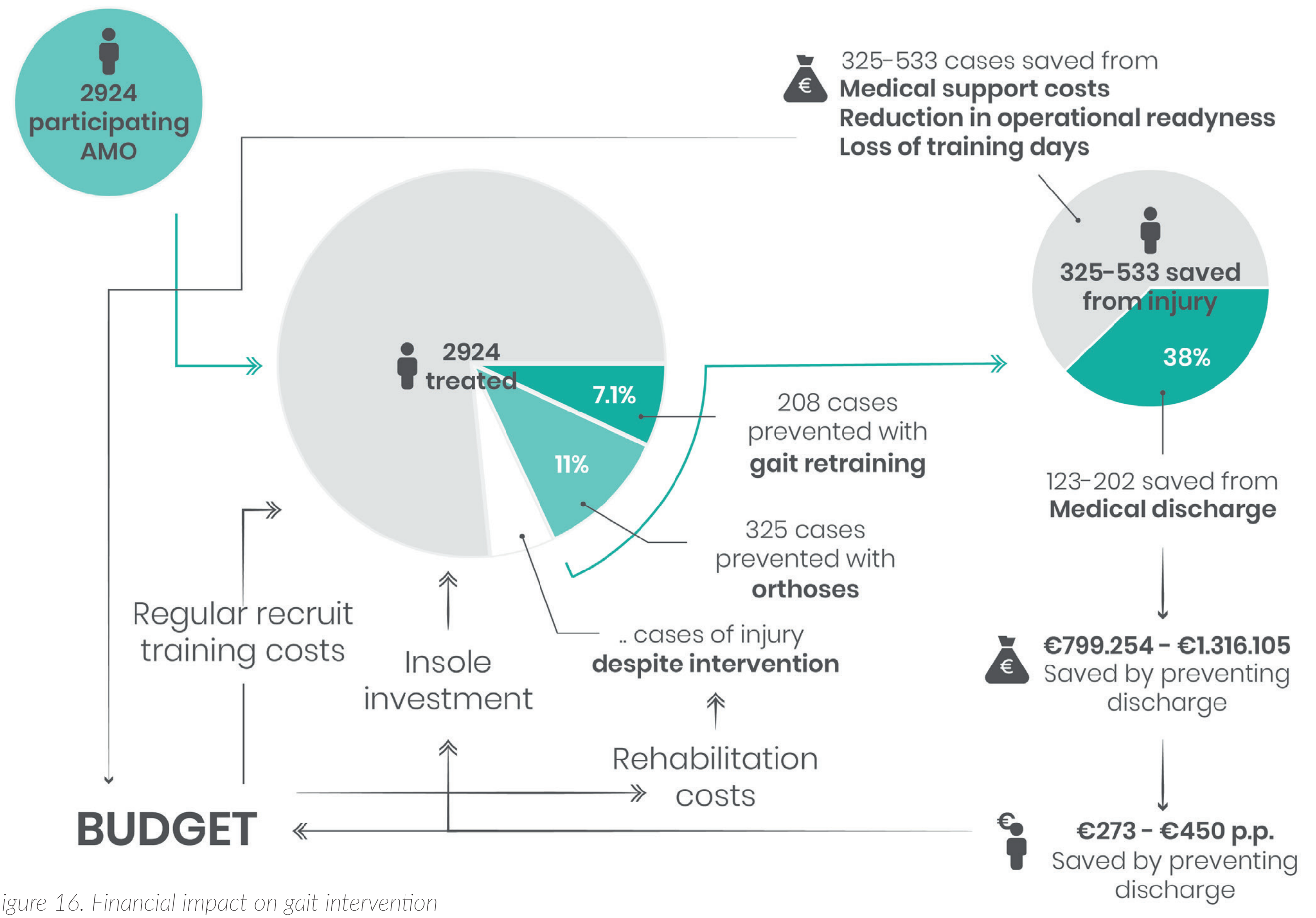


Figure 16. Financial impact on gait intervention

Diagnostics and medical exams at TGTF are done with static measurements (e.g. pronation while standing) and dynamic tests using video recordings on a treadmill (see Figure 19). Therapists base their judgement on three major factors: posture, footfall landing and cadence (Zimmerman, et al, 2018). Pressure data is not frequently used by the medical staff, because of its lack of informative presentation. According to Kap. C. Linschoten, physician examiner at TGTF (personal communication, December 4, 2019), numerical data should include segmented loading rate values, next to overall peak values.

Despite its potential, gait retraining is not yet used as a method of injury prevention as there is no method to detect recruits with increased risk. Additionally, according to van Valderen (personal communication, December 4, 2019), they have not been able to test the effects of gait retraining in outdoor situations.

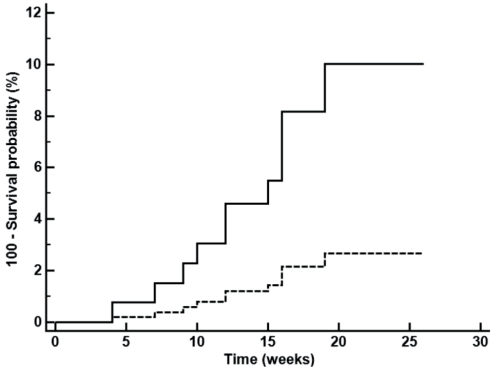


Figure 17. Survival probability plot for Medial Tibial Stress Syndrome. (Solid line, control; dashed line, intervention) (Sharma, 2014)

Figure 18. Rehabilitation lab TGTF

1.2.4.2 Insole orthoses

During the recruitment and selection phase, every applicant is tested for the medical necessity of insole orthoses (T. ter Hark, Personal communication, October 18th, 2019). Insole orthoses influence the load distribution and damping of the user's biomechanical behaviour during walking (Nagano, 2018). A contoured insole generally shows decreased peak pressure and tibial acceleration (Bonanno et al, 2019). Customized insole orthoses, however, effectively increase contact area, adjust resilience, provide arch support and optimize ankle and knee alignment, based on individual needs (Figure 19).

Figure 19. Customized orthosis (Breezemaxweb, 2019)

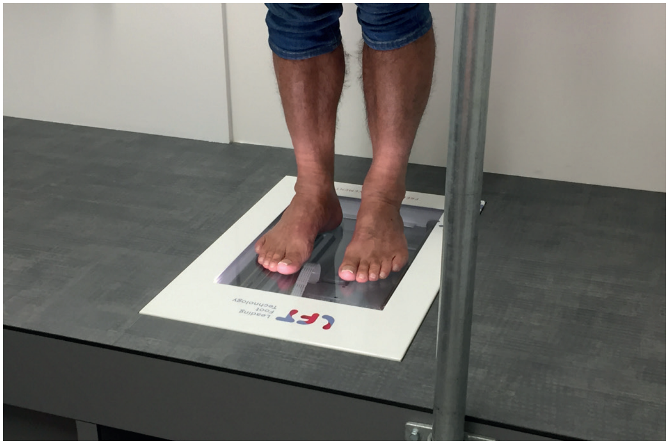


Figure 20. Static scan of foot sole shape

Plantar pressure measurements can be used to calculate insole correction factors (Franklyn-Miller et al, 2014). This creates an opportunity for automated insole fabrication. In contrary to static scans and measurements - currently used for orthosis design (Figure 20) - In-shoe PP measurements provide insight in real-life gait behaviour of patients and be insightful for a podiatrist to design better orthoses. After all, dynamic pressure distribution is different than static distribution (Ong & Wong, 2005). In addition, in-shoe measurement also accounts for the effect of an orthosis in combination with the shoe.

1.2.4.3 Coaching and feedback (DTCS)

Defence Training & Coaching System is a platform for military employees to stimulate and support exercising in a healthy and efficient way, which is designed for the Dutch Defence and will be launched later this year (Kap. M. de Jong, Personal communication and PowerPoint slides, January 15th, 2020). The system (illustrated in Figure 21) uses three sources of data input: electronically-connected gym equipment, wearable RT-PMS systems and a sports watch. Data is acquired on a digital dashboard and application by the individual soldier and group data is visible for commanders. Its purpose is for individual soldiers to be guided and stimulated in training individually and for commanders to be provided with practical information about individual and group fitness- and employability. This information can be used to design and adjust training schedules and test a group for operation-readiness.

The system can be used by external products with Bluetooth connectivity, which makes it highly suitable for a new insole measurement device to be incorporated. To be a suitable tool, a balance should be found between (i) limited data collection for easy, safe and efficient use and data interpretation and (ii) offer the input width and depth necessary to explore the unknown. Using methods described in Section 1.1.4.2, data can be converted without losing relevant accuracy. Additionally, personal data should be handled securely according to General Data Protection Regulation (GDPR or in Dutch: AVG) and medical data regulations specifically. Requirement ii can be met by saving raw data files of measurements for elaborate data analysis by scientists or, in the near future, machine-learning. The latter is already something that is included in the vision of DTCS developers.

With an eye on the future, the Dutch Defence strives to use technological developments for the realisation of new means and methods (Bos, 2019) and is therefore willing to invest in cooperation with knowledge institutes and companies. Interoperability using IT platforms is also part of the Defence future vision.

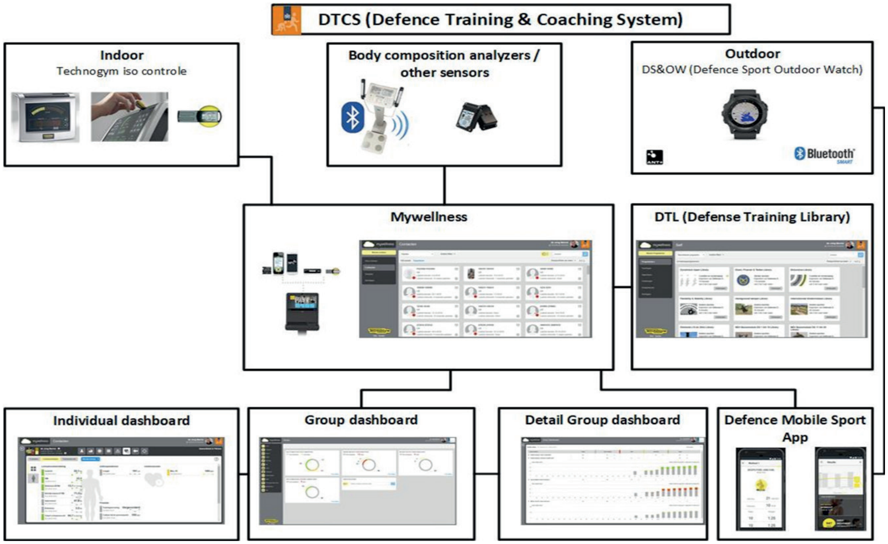


Figure 21. Defence Training & Coaching System (de Jong, 2020).

IMPACT ON DESIGN (CONCLUSION)

The section's research question 'How should a wearable PP analysis tool be designed to effectively meet and account for the needs, structure and advantages of military context?' was approached by looking at specific interactions, statistics in injury incidence and morbidity and financial impact. Current solutions and developments by the Dutch defense were also elaborated.

1. Data sharing services should comply with and improve the current military interaction structure

The military interaction structure is highly influenced by official ranking hierarchy. At the bottom of the pyramid, soldiers are obliged to be obedient to their superiors. This makes it (emotionally and technically) difficult for an injured soldier to reach out for help. Interaction between important stakeholders in the rehabilitation circuit could be improved as well. Focus on personal attention and communication efficiency attacks both these problems.

2. Initial injury-risk assessment during AMO

Initial military training is often very intensive and its high amounts of marching make it a sensitive period for OLLI. It would be beneficial to start this training with an initial injury-risk assessment, defining the recommended path throughout the rest of initial training. Initial training also offers the perfect test setup for longitudinal repeated-measure studies.

3. Injury assessment should account for military-specific influential factors and existing solution areas

Military boots have a significant influence on injury risk. Offering contoured design insoles should already reduce peak pressures under the foot. Measuring relevant parameters will define additional support requirements for customized orthopaedic insoles. Gait retraining, despite its demand, does not include outdoor measurements or patient monitoring. Additionally, physicians are not able to measure influence of military boots, carried load, terrain type and pressure to perform. Ideally, the measurement tool should be able to record all influential factors to use in data analysis.

4. Financial benefit of injury prevention

Decrease of discharge rate caused by OLLI and reduction of rehabilitation time will retain i.a. morbidity, training time, resources and manning of the entire army (van

Rompay, 2011; Sharma, 2015). Research has shown that about 18 percent additional injuries could be prevented with gait retraining and orthoses interventions (Sharma, 2014; Franklyn-miller et a, 2011). An investment in intervention tools such as measurement insoles of maximum €273,- p.p. will ensure a return within one year. An investment below €546,- will pay itself back in maximum two years, considering the insoles last for at least two years.

5. Design for integration in rehabilitation programmes and Defence Training & Coaching System

A suggested wearable measuring tool, should be a usable tool for the end-user in terms of embodiment and performance. The measurement insoles should fit inside standard military boots, without limiting its watertight design. Additionally, the product should be usable inside DTCS, meaning it should be wirelessly communicating via Bluetooth, allow for measurement by the direct user (not a medic), present limited data to that direct user and more detailed data to physicians and finally allow for gathering of big-data to be used for research purposes.

CHAPTER 2

PRODUCT INNOVATION STUDY

The literature review and User study (Chapter 1) provided contextual key insights and requirements for product improvement (see Appendix 6). To explore the direction of design solutions, two product-innovation studies are performed. A Technology-driven Innovation study (Section 2.1) starts with scientific research to validate the practical capability of wearable insole hardware to measure relevant parameters to make injury risk assessments. After that, the innovation process is studied from a value-driven viewpoint, answering the question: what do the users really need and how can a product or service meet those needs? (Section 2.2)

TECHNOLOGY DRIVEN INNOVATION

As mentioned in the Literature study, bringing biomechanical measurements to outdoor situations will provide researchers and therapists with new valuable insights. However, a decreased spatial resolution of sensors in the insoles (compared to laboratory equipment) limits data output, decreasing its accuracy (Booth et al, 2019). When selecting parameters that only require data that can be measured with the available sensors, the problem could be overcome.

From the literature study (Section 1.1), a set of six parameters with predictive capability were selected based on their theoretical capability to be measured with wearable pressure-sensitive insoles, using FRS technology: Cadence, Vertical Loading Rate, Vertical Impact Peak, Time to Peak Heel Rotation, Foot Balance and M1 Peak Pressure. A secondary set of parameters, will be measured to calculate other parameters and interpret results, making a total of fifteen variables (Figure 23).

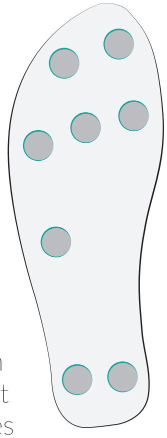
Hypothesis

This study validates the assumption that wearable pressure-sensitive commercial insoles, in combination with parameter algorithms, are able to accurately measure the six parameters. More specifically, the study hypothesizes that parameters calculated from data from the insoles will show statistical differences between distinguished subject groups of injury and footwear.

Method

The analysis consists of thee studies. In study 1, parameters measured with a set of commercial pressure-sensitive insoles (Arion™) are compared to parameters measured by a pressure-sensitive walkway (GAITRite™), commonly used in scientific research (McDonough et al, 2001).

The Arion insoles are commercially used to measure biomechanics for runners (About ATO-Gear, n.d.). They are integrated with eight Force Resistive



a

b

Figure 22. Arion insole (b) and sensor location (a)

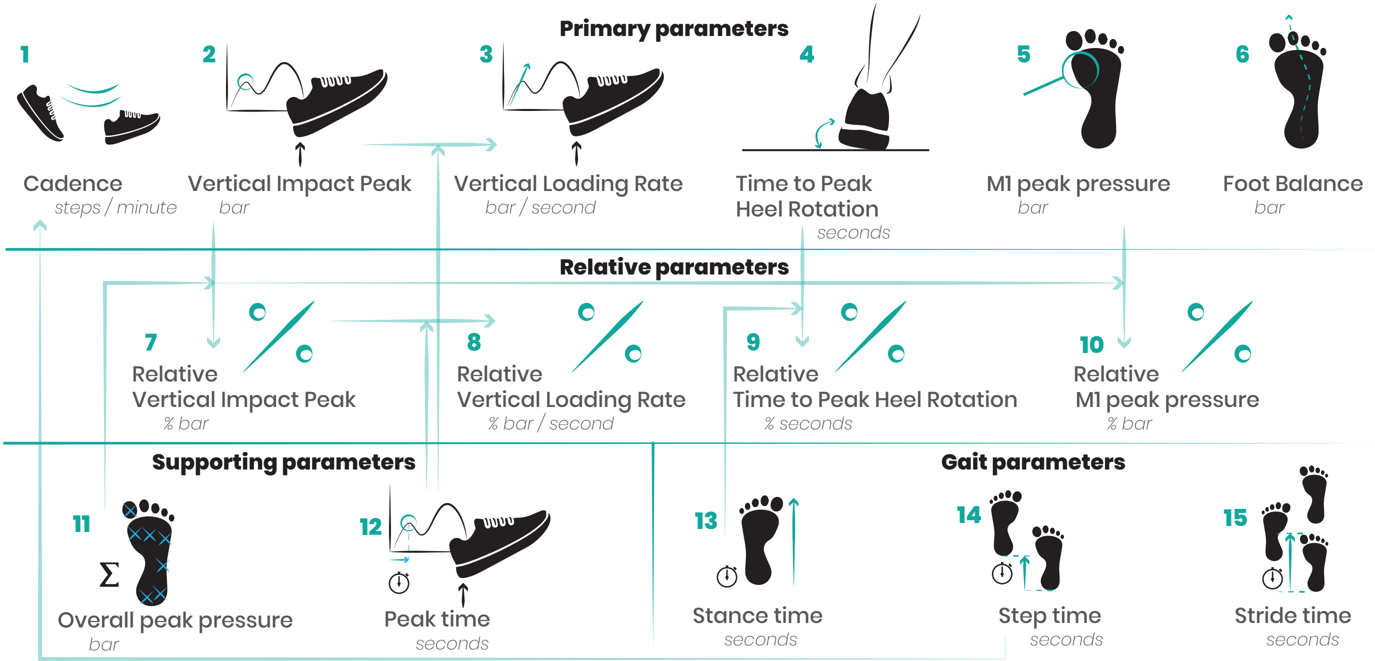


Figure 23. Stakeholder Interaction Framework

Sensors (Figure 22a) and can be inserted underneath the inner-insole of the shoe (b). Raw data from the insoles is translated to the fifteen parameters presented in Figure 23, using custom-designed algorithms (confidential).

In study 2, the insoles are used to compare parameters values between two different groups: injured military recruits and a healthy control group. Study 3 compares parameter values between two types of footwear: military boots versus regular running shoes (control group).

2.1.1 Study 1. Insoles vs Walkway

Study aim

The study aims to determine the statistical level of agreement in parameter values using two different measurement methods (measurement-insoles and a pressure-walkway system). Since the GAITRite walkway is commonly used and validated by gait research (McDonough et al, 2001), it could be assumed that statistical agreement with the GAITRite measurement indicates a good ability of the insoles to measure those specific parameters. Lack of agreement, on the other hand, does not necessarily indicate lack of measurement ability, as it could be caused by systematic variances.

Method

Twenty participants performed five repetitions of a seven-meter walk (normal pace) over the Walkway. The trials were designed so that both devices measure the exact identical footfall. To accomplish this, the subjects wore the insoles, taped under their feet, while walking over the GAITRite walkway (Figure 24). Both devices measuring pressure under the foot at the same time. For each subject, four steps from two trials were used in statistical analysis (n = 144).

Results

A Shapiro-Wilk test revealed a similar, but not always normally distributed spread of data between the two measurement methods. A test of variance additionally showed inconsistency in between-group variability. An ANOVA test showed significant differences of means for almost all parameters, except for TPHR. A Pearson Correlation revealed two-tailed item correlations for Cadence, Vertical Loading Rate and Foot Balance. With respective R2 values of 0.209, 0.031, 0.064, these correlations show that only a small percentage of the cases can be explained by the model. Finally, the Intraclass Correlation Coefficient of those three parameters (.411, .010 and -.135 respectively) indicates good agreement for Cadence (according to Fleiss, 1986) but poor agreement for VLR and FB.

Figure 24. The GAITRiteTM 7-meter Walkway in test setting including control monitors for video recording and control of the two measurement systems (a) and the insoles taped under the feet, stabilized with outer-sock (b).

Conclusion and Discussion

From this research, it can be concluded that parameters calculated with the Arion insoles and parameters calculated with a GAITRite Walkway do not show a clear statistical agreement, except for the variable Cadence (Figure 25b). A possible explanation is that the unit to which the parameters are calculated show too much between-subject difference in variance and group variance (Figure 25a). In addition, the GAITRite Walkway is limited in temporal detailing as it only provides pressure values per footfall and CoP values with a low sampling rate (60Hz). Another limitation is the normalization method used by GAITRite, which presents values as relative to peak pressure, making it inconsistent to the absolute pressure values measured by the insoles. Lastly, lack of significant agreement could be explained by low between-subject variability caused by walking at slow pace (instead of running) and all of them being injury-free. Based on the results, it cannot be concluded that the insoles are capable of measuring the parameters, but the test limitations additionally indicate that another test is needed to validate the actual insole measurements.

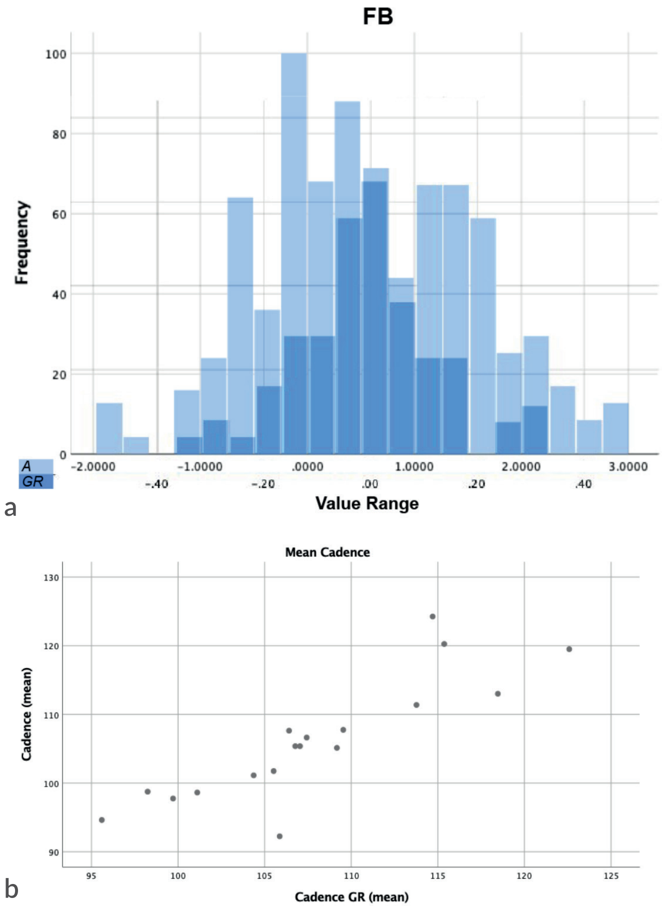


Figure 25. Normal distribution of Foot Balance (a) and mean scatter plot of cadence (b)

2.1.2 Study 2. Healthy vs Injured subjects

Study aim

Study 1 wasn't able to conclude on the capability of wearable insoles to measure the selected parameters, because of lack of between-group variation and comparability of measurement systems. This second study therefore aims to determine whether the insoles are able to accurately distinguish different subject groups based on parameter value.

Method

Six healthy and five injured (OLLI) male (age 20-34) subjects wore a set of insoles inside their own running shoes while walking on a treadmill at a constant speed (6 km/h), measuring gait parameters for a period of one minute (Figure 26). Sixty steps per subject were analysed, the first two steps of the recording were excluded. The same formulas for parameter calculation as in study 1 were used. Effect sizes for all significant results were calculated with Partial Eta Squared (ηp^2) and were interpreted as small (0.00 to <0.06), medium (0.06 to <0.14), and large (>0.14) according to Cohen (1988). Dat analysed in SPSS Statistics.

Figure 26. Treadmill tests with injured (a) and control (b) subjects

Results

Shapiro Wilk showed that none of the parameters is normally distributed, except for M1_Rel in the Healthy-boots group. No influence of weight, shoe size or insole mismatch (difference between shoe size and insole size) was found on the parameter values. For all parameters except M1, statistical difference was found between left and right side. The individual comparisons are done using only left-feet measurements.

Scatter plots (Figure 28) clearly show lower values in the healthy-shoes group than the injured group for overall peak pressure (µ = 10.3 vs 12.9), VIP_Rel (µ = 13.1 vs 24.1) and VLR_Rel (µ = 78 vs 161) values and even negative FB values (µ = -.56 vs .77). The healthy-shoes group also shows higher TPHR, but high variance makes it difficult to compare. There is no clear visible difference between absolute M1 PP value between both groups. A One-way ANOVA reveals a significant difference between the healthy and injured group for Cadence (P = .044, ηp^2 = .014), Overall peak pressure (P = .000, ηp^2 = .413), VIP (P = .000, ηp^2 = .724), VIP_Rel (P = .000, ηp^2 = .520), VLR (P = .000, ηp^2 = .521), VLR_Rel (P = .000, ηp^2 = .385), TPHR (P = .000, ηp^2 = .497), TPHR_Rel (P = .000, ηp^2 = .494), M1 (P = .000, ηp^2 = .122), FB (P = .000, ηp^2 = .716) Peak time (P = .000, ηp^2 = .031) and Stance time (P = .000, ηp^2 = .279), but not for for M1_Rel (P = .611).

Since the left and right feet show a significant difference in value, the difference between left and right side of the parameters was plotted by injury location (side and place). The charts show variation in mean difference according to injury side, for example in M1 relative peak pressure (Figure 27). Other charts and tables can be found in Appendix 5.

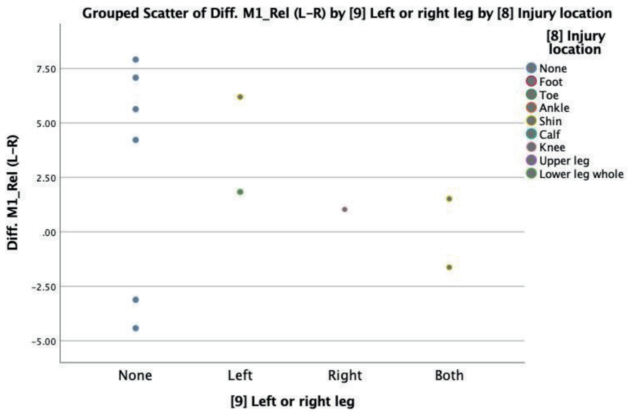


Figure 27. Scatter plots of Overall peak pressure, Vertical Impact Peak, Vertical Loading Rate and Foot Balance; values by subject ID

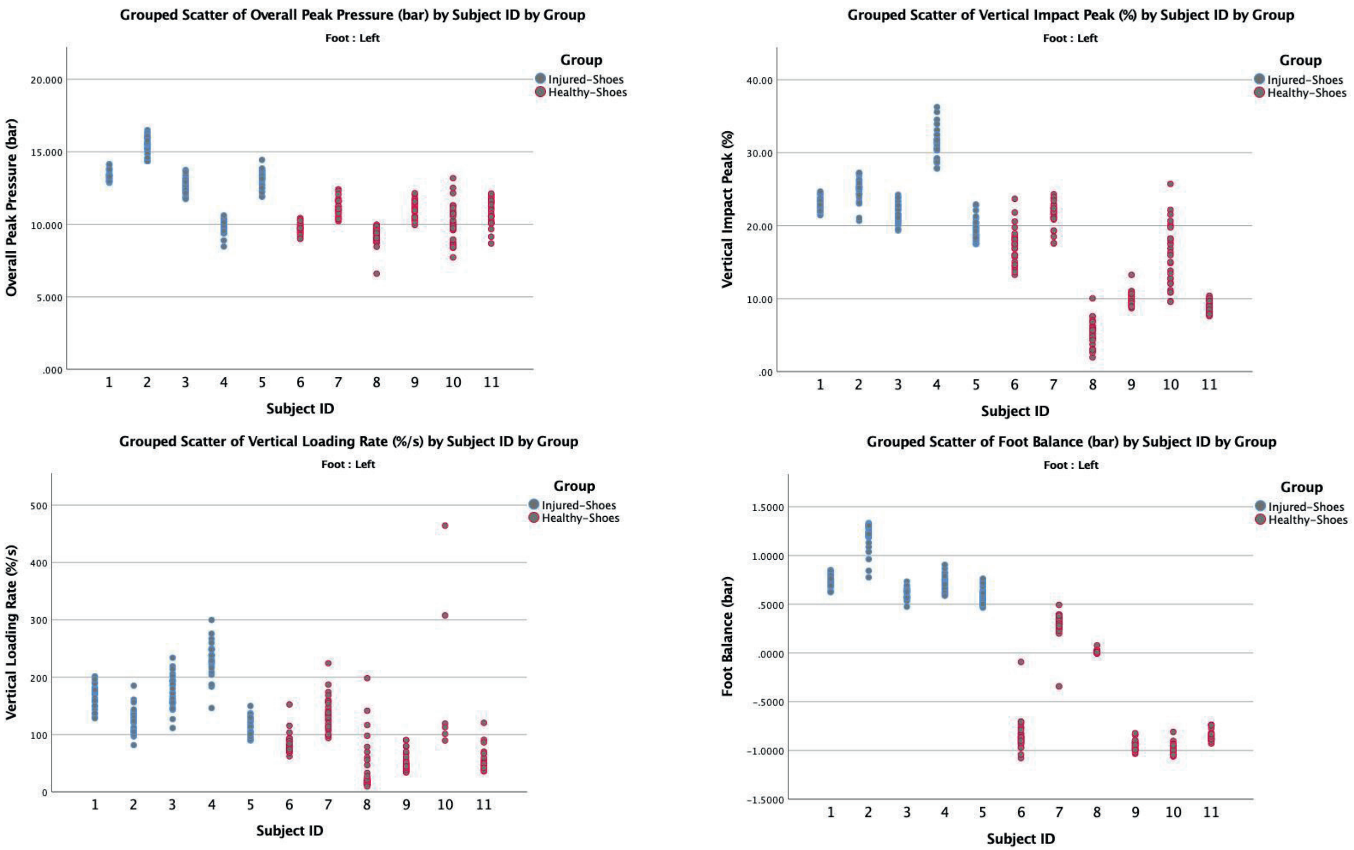


Figure 28. Scatter plots of Overall peak pressure, Vertical Impact Peak, Vertical Loading Rate and Foot Balance; values by subject ID

Conclusion and Discussion

The statistical analysis shows between-group variance based on the selected walking parameters. Little influence of personal characteristics was found, which could be coincidental and might change with a higher sample size. That same limitation also goes the other way around: the low sample size (n = 11) could influence the rate of between-group variation. Lack of normal distribution might affect accuracy of the results.

That considered, the statistical analysis shows a convincing number of parameters with significantly different results between the Injured and control group. Effect sizes show that a relatively large part of the results can be accounted for by the model (e.g. 72,4% by VIP), according to Cohen (1988). The results even show a difference between the injury location and parameter difference between left and right side of the same person. However, there are not enough participants within each group (left or right-side injury) to make an accurate statement about its proven effect. All with all, the results of this study make it very interesting and relevant to further research the capabilities of measuring parameters with wearable insoles using FRS technology. All charts and tables of this study can be found in Appendix 5.

2.1.3 Study 3. Boots vs Running shoes

Study aim

Study 2 already showed a significant difference between an injured and healthy group. This study explores the difference between parameter values of subjects walking in running shoes versus military boots, which are known to cause a difference in gait (see Section 1.2.2).

Method

Five healthy male subjects (who also participated in study 2) performed two trials of sixty seconds walking on a treadmill at a speed of 6 km/h. In the first trial they wore their own running shoes, in the second trial they wore a pair of army boots size 43 (Figure 29). Similar measures from study 2 were taken. The difference in parameter values between the two groups was analysed in SPSS Statistics.

Figure 29. Measuring gait with military boots

Results

The scatter plots (Appendix 5) show large differences between individual parameter values when wearing shoes or boots. However, the values are often not consistently higher or lower for either group (e.g. Figure 30).

A One-way ANOVA reveals a significant difference between the shoes and boots group for Cadence ($P = .000$, $\eta p^2 = .503$), VIP ($P = .007$, $\eta p^2 = .023$), VLR ($P = .044$, $\eta p^2 = .013$), TPHR ($P = .000$, $\eta p^2 = .107$), FB ($P = .000$, $\eta p^2 = .152$) and Stance time ($P = .008$, $\eta p^2 = .022$), but not for Overall peak pressure, VIP_Rel, VLR_Rel, M1, M1_Rel, Peak time and TPHR_Rel.

Conclusion and Discussion

Six of the thirteen tested parameters show capability of differentiating subjects between wearing running shoes or military boots. Effect sizes for those parameters, however, are a lot lower than tests comparing subject health (Study 2). This result can be explained by the subjects of study 3 being the same people in both groups, which makes the values lie closer to each other. The results do show a rather large individual difference between wearing shoes or boots (Figure 30), but some subjects show higher values for one type of shoes where the other subject shows the opposite.

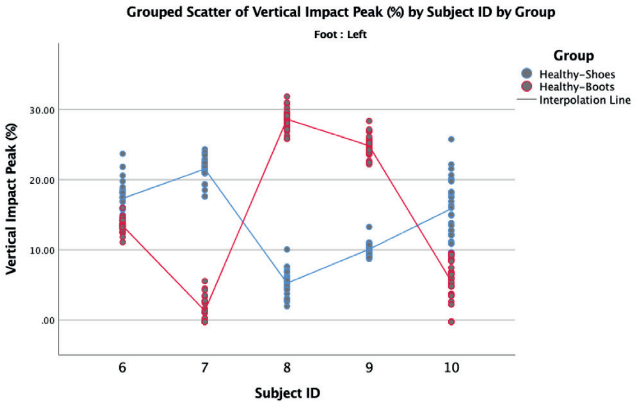


Figure 30. Scatter plot of Relative Vertical Impact Peak by Subject ID by Group

This means that there are significant effects of military boots on biomechanical gait parameters, but they do not clearly imply a positive or negative influence. The trials with military boots also showed higher incidence of technical errors in the data output. Presumably, this is caused by misplacement of the insole or wrong sizing of the insole. The latter, however, should then also have been visible in the running shoes trials, which was not the case. For a full documentation of charts and tables used in this study, see Appendix 5.

IMPACT ON DESIGN (CONCLUSION)

This study aimed to test the measurement capability of biomechanical gait parameters (Figure 23) by pressure sensitive insoles, primarily by (i) comparing values with those obtained by a commonly used pressure walkway, secondarily by (ii) investigating the difference in insole-measurements between subjects with Lower Limb Overuse Injury and a control group and lastly by (iii) measuring the effect of military boots versus regular running shoes on a set of biomechanical gait parameters.

Study 1 did not prove a statistical agreement between parameters measured with the insoles and the GAITRite walkway system. It was hypothesized that this could have been caused by technical differences between the two measurement devices. Therefore, studies 2 and 3 were performed to compare results between subject groups rather than methods. Study 2 showed convincing statistical evidence that all primary parameters and several supporting parameters (Figure 23) can be used to distinguish individual gait characteristics. Study 3 showed that five of the primary parameters and one secondary parameter can be used to measure the effects of military boots on gait characteristics. However, the effect sizes within study 3 were lower than those within study 2, concluding those group differences to be less substantiated by the system than in study 2.

Following these results, it can be concluded that the hypothesis - stating that parameters calculated from data from the insoles will show statistical differences between distinguished subject groups of injury and footwear - can be accepted.

In terms of insole (hardware) design, the results show that parameters including time reference are less consistent than those without time reference. A built-in automatic calibration between the two insoles could help overcome this problem. Especially the parameter TPHR too often measures a value of zero. This could either mean that either the subject does not perform initial Calcaneal Eversion (CE), or the system cannot measure it. Since the CE movement is rather subtle, it is likely that adapting the hardware to improve sensitivity would be potentially valuable in improving the chances of detecting this parameter. The parameter Foot balance does show consistent values for each subject, but the values need more interpretation and detailing to give usable information. The tests also showed a few cases of technical error caused by wrong insole placement or sizing, mostly when the insoles were worn inside military boots.

VALUE DRIVEN INNOVATION

Section 2.1 concluded that - from a product-centred viewpoint - a new customized design of pressure-sensitive insoles is necessary to serve the cause of injury prevention. A (re)design needs clear guidelines to accomplish product improvement and should eventually be tested on a set of product requirements and wishes. To find a clear direction for the redesign of the measurement insoles, the targeted domain is analysed from a different perspective in this section, namely from the user itself. The central question in this study is 'What does the user really need?'.

Based on results of Chapter 1, the targeted domain for innovation is defined as 'Wearable gait monitor device for military recruits to prevent injuries'. This definition describes the product type, intended user and purpose. How we can accomplish this domain is by analyzing the context of all three factors and set-up guidelines to meet relevant demands.

2.2.1 Context factors

Context factors are factual or observed developments, states, principles or trends that are relevant to the domain. They are categorized into nine themes and subsequently clustered to create relevant conclusive observations, illustrated in Figure 31.

When looking at the context as a whole, the one thing that strikes out most is the level of insecurity on different layers within military operations. For example, a soldier worries about its own fitness and reputation, a commander worries about the feasibility of his operations and a sports instructor worries about keeping everyone fit (on his watch). These different worries lead to different demands from the system. A general value-statement that describes the project goal is illustrated in Figure 32.

An artificial 'doctor' could increase morbidity efficiency

/ Military recruits don't ask for help
/ Feeling 'in charge' of body builds confidence
/ Feeling taken care for mental wellbeing
/ Sergeant bias: wants to finish the training
/ Recognition removes insecurity
/ Digital work preferred over analog

Machine-learning could lead to planning and logistics operations

/ Military is controlled environment
/ Repeated programmes
/ Planning missions with virtual personas
/ Mass-data gathering improves machine-learning
/ Digital work preferred over analog

Improved interaction between military stakeholders

/ Strong pyramid hierarchy
/ Difficult to reach out to superiors
/ Lack of personal attention
/ Bad communication between staff members
/ Digital work preferred over analog

Army boots are not built for long marches

/ Stiff soles which increase shock
/ Lacing affects bloodflow and injury risk
/ High repetition is harmful

Equipment is outdated

/ Stiff soles which increase shock
/ Improvement of insole orthoses with digital data
/ Digital work preferred over analog
/ High loads, humidity and heat

A simplified goal with elaborated methods increase results

/ Military context is a controlled
/ Many parameters are correlated
/ Repeated programmes
/ Lab research not convenient for domain

The system will pay itself back

/ Dutch healthcare is good (use it)
/ Recruits don't ask for help
/ 10-26% of military recruits get medically discharged
/ Rehabilitation takes long
/ One-year return with investment of €273,- per recruit

Practice makes perfect

/ Mass-data gathering improves machine-learning
/ High repetition is harmful
/ Cheaper and smaller technology available

Figure 31. Context factors of the domain 'wearable gait monitor device for military recruits to prevent injuries'

Figure 32. Value statement

2.2.2 Interaction framework

Section 1.2.1 introduced a general structure and interaction overview of the target group. It was observed that several types of interaction could be improved to increase efficiency and take away insecurity. On a concrete level, personal attention from a superior to a recovering soldier is desired, as well as efficient and frequent communication between a superior (commander) and the medical or training staff (physiotherapists and sports instructors). Lastly, there should be a line of communication for a soldier to reach out to superiors or supporting staff in case of (medical) insecurity.

Figure 33. User Interaction type of a soldier/recruit (a) and of a commander (b)

It is important that every stakeholder interaction is designed according to their specific needs. A soldier, for example, would desire a type of interaction based on respect, but also on comfort and support (Figure 33a). For a commander, interaction should be efficient and clear in order to plan operations and trainings (Figure 33b). A physiotherapist also requires clear and informative interaction, but for them it should be more detailed and personal. A sports instructor would want interaction to be simple, clear and mobile. Mood boards of Figure 33 are used for service design in Section 3.2, to offer personalized value for each stakeholder.

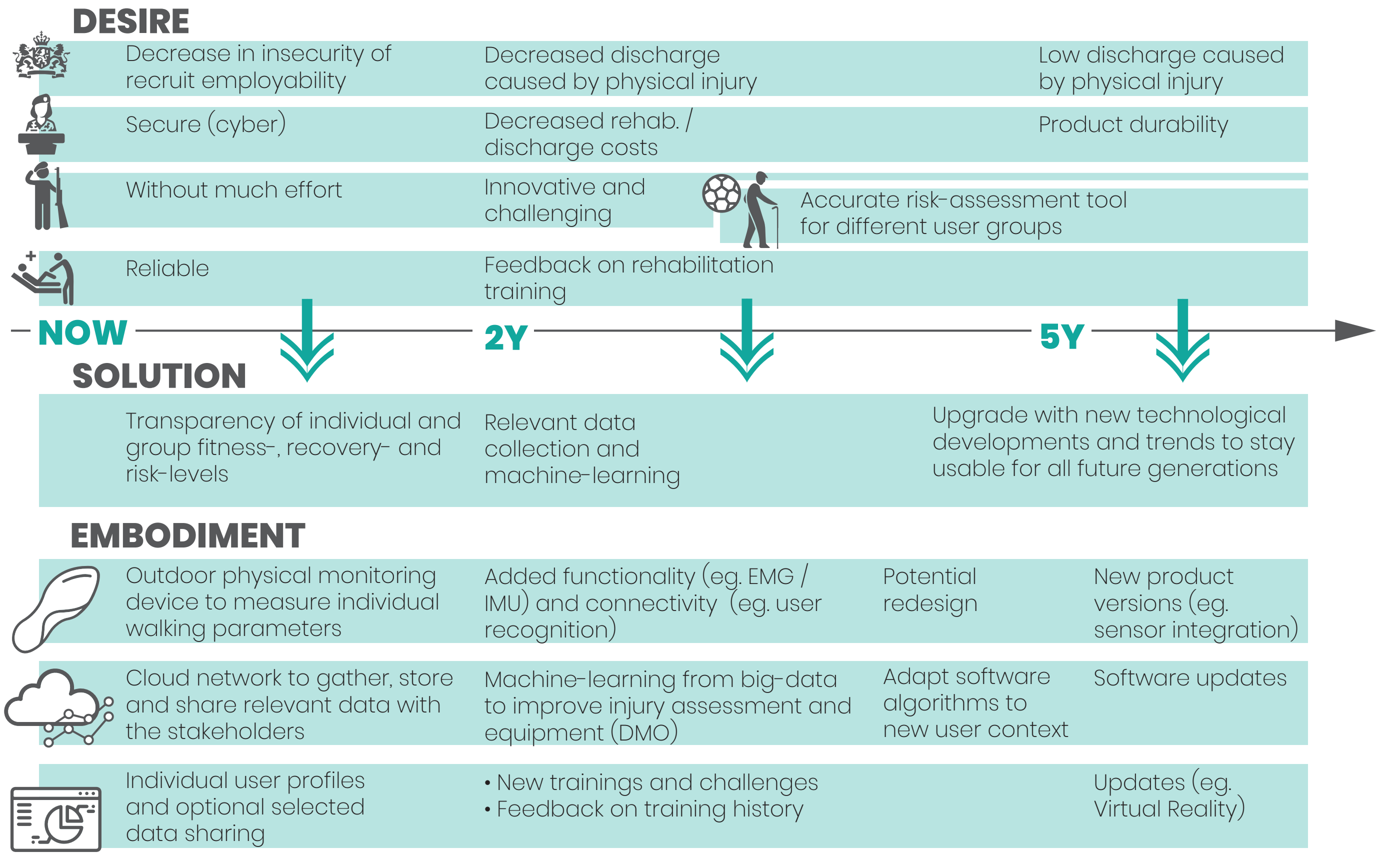


Figure 34. Future desirability and adaptations timeline

2.2.3 Future vision

Until here, this chapter focused on present Defence's context and values of the present. Innovation doesn't happen in one day and to account for long-term desirability, future changes should be considered. By answering the question 'What is desired now and what is desired in the (near) future?', the focus of product innovation will be subject to change in society and its specific (or new) user group. Figure 34 shows a timeline of changing desire (specified to user groups), with subsequently changing product solutions and embodiment. Visible is the overall change of focus from 'removing insecurity of recruit employability' to more practical goals of 'decreased discharge'. The solution and embodiment changes with the desired outcome and is personalized for each user group. For example, 'Individual user profiles' should focus on group-specific desires such as: gain insight in personal fitness (soldier), gain confidence about capabilities (soldier), get insight in patient data and compliance (doctors and therapists), get insight in a unit's readiness-for-operations (commander), get insight in training/exercise efficiency (sports instructor). To remain future value, the product should adapt to changes in society and market. The product could, for example, integrate electronics inside apparel, entail hands-free interactions or offer Virtual Reality applications.

IMPACT ON DESIGN (CONCLUSION)

The ViP analysis has brought new insights into values of the users and product requirements in future context. Besides functional performance, the product should focus on the emotional aspects of injury such as insecurity. All stakeholders have certain ''worries'' that the product should aim to solve. The particular worries of the stakeholders were translated into design goals and added to the List of Wishes (Appendix 6).
Combined context factors show a strategic path that focuses mainly on using computers as a ''brain'' to improve quality over larger quantity to help both the individual recruit as the entire army operation. Interaction mood boards were created to get a visualisation of interaction types of the different stakeholders with the same product. This does not only entail the interaction medium, but also the emotions and use factors. Lastly, a future roadmap was created to account for viability within a five years.

These insights were used within the product design track (presented in next chapter), which increased the viability of the result and herewith its chance of success on the market. Section 3.3 will elaborate on a proposed business strategy to bring the concept from its current state to a fully-grown self-sufficient company.

CHAPTER 3

PRODUCT DESIGN PROPOSAL

The technology-driven innovation study in Section 2.1 provided initial evidence of the capability of an FRS array to measure relevant parameters to use in injury-risk assessment, but also showed room for improvement of the insoles. In addition, Section 2.2 concluded that the answer to the research question - as defined in Chapter 'Assignment and project scope' - is not solely materialistic. The context study found that innovation should mainly focus on the smart integration of injury assessment software, using existing evidence of gait parameter algorithms. Next to that, innovation should take place in the form of a service system targeting specific user groups (in this case: military). All this combined should provide a competitive business model. This chapter will present design solutions, to conclude on study results if the entire report.

EMBODIMENT DESIGN

3.1.1 Boot fit

The electronic components of a pressure measurement insoles (e.g. battery, Bluetooth master and sim card) need to be integrated in the product. The options for integration of an external hub on a military boot was explored (Appendix 8), but all options significantly cause obtrusion to the military boot and its water tightness. Figure 35 shows an insole redesign where all electronics are integrated in the insole, underneath the medial arch. This integration will create a slight initial contoured shape of the product. Section 1.2.4.2 explained that contoured insoles cause instantaneous pressure relief, regardless of individual differences. It is therefore also advised to provide similar contoured insoles to all recruits to be throughout the training. The assessment of the measurement insoles will provide additional steps of action if necessary. The impact of the pre-shaped design should be validated before approval. Additionally, the studies in Section 2.1 showed a few cases of technical error caused by misplacement, folding or wrong-sized insoles. A thicker, contoured insole design will prevent folding or misplacement inside the shoe. The concept has been given the name ‘InnoGait’.

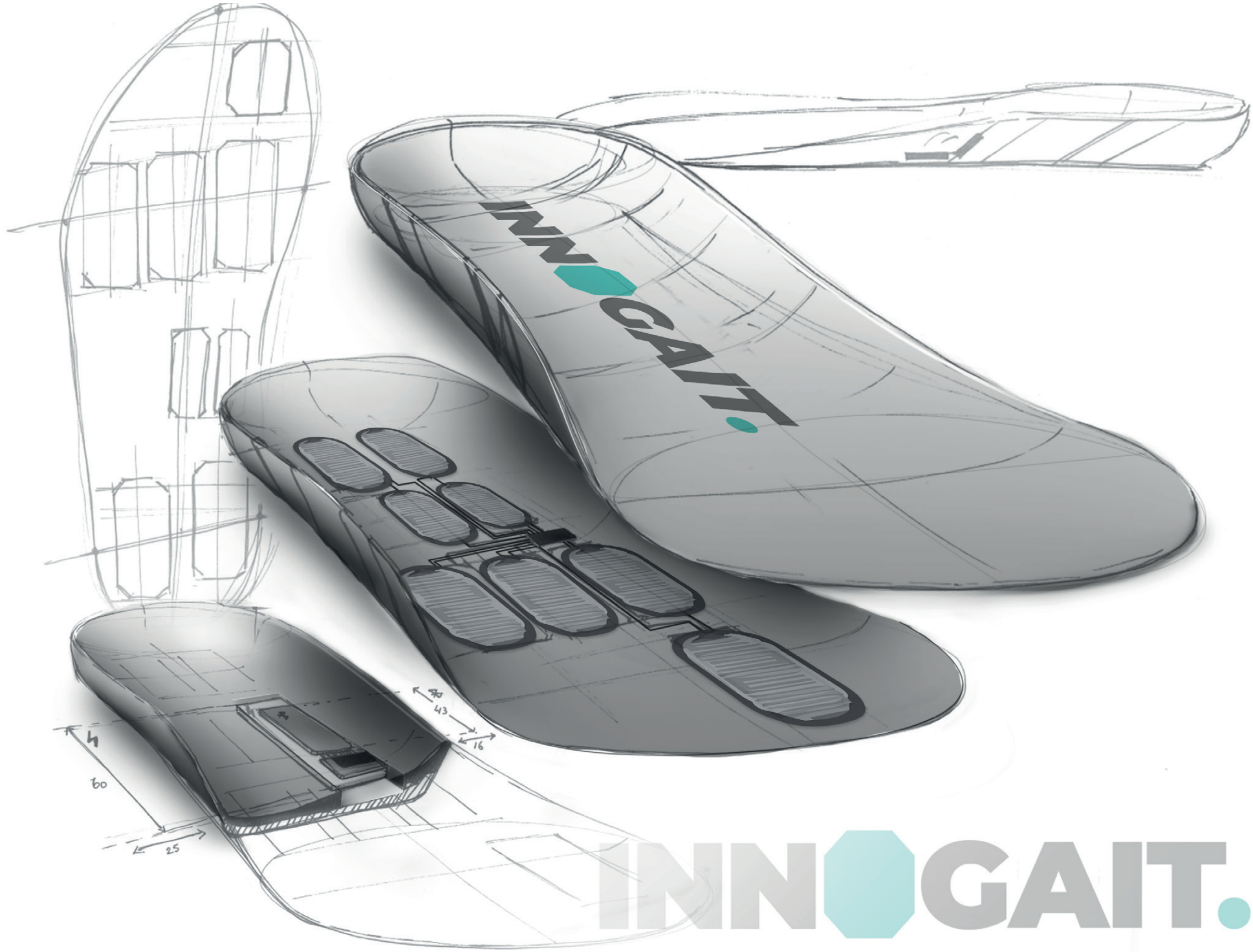


Figure 35. Exploded view of insole design

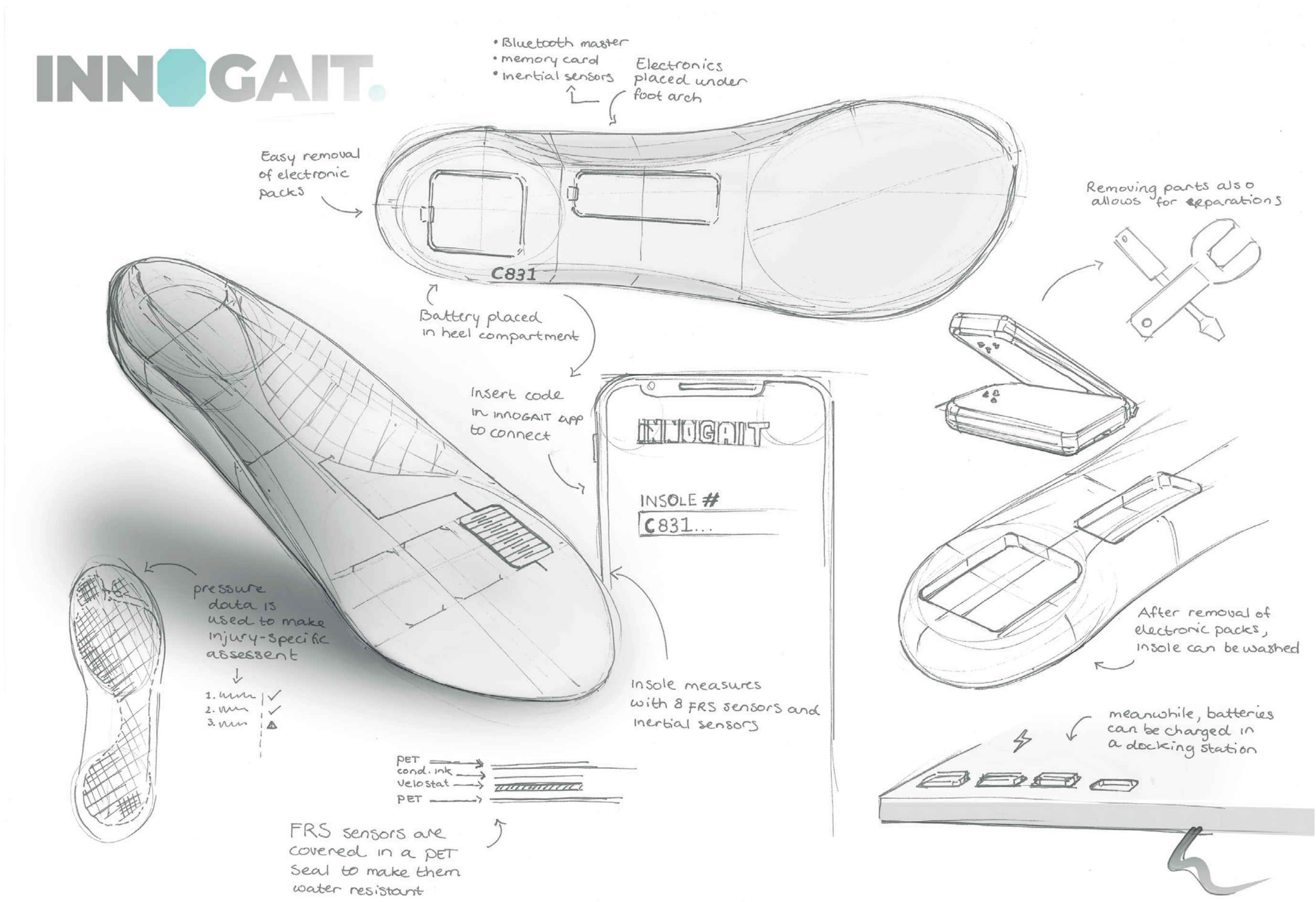


Figure 36. Design detailing

3.1.2 Design detailing

Besides fit, the insole design has been processed through a number of challenges, mostly derived from the List of Requirements (which summarizes the design-related takeaways from all studies within this thesis). Most important design challenges were defined as:

1. How could we measure as many parameters as possible with a minimum number of sensors?
2. How could we integrate sensors in the insole for minimum obtrusion and damage-sensitivity?
3. How could we charge and read-out data in bulk?
4. How could we design for repairability?

Appendix 8 provides an overview of brainstorm sketches and Appendix 9 shows a morphological map that lists and connects the found design solutions. One combination of solutions was selected and developed into a complete concept drawing, presented in Figure 36.

Hardware design is mainly based on demand for resistance and intrusiveness. A pre-shaped design allows for integration of electronics inside the insole itself, removing the need for an external hub. The electronics are divided into removable components, making them easy to charge or repair and making the insole suitable for washing.

3.1.3 Sizing

The literature study concluded a high potential for injury prediction based on biomechanical parameters. However, since every individual's foot is different in size and anthropometry, it is difficult to determine where the measurements should take place for every individual to measure the same parameter. An anthropometric study is performed with the hypothesis: 'An anthropometric framework consisting of longitudinal foot length and transverse forefoot and heel axes can be standardized for each shoe size.' (Appendix 10).

The analysis compared standard foot characteristics such as shoe size, maximum foot length and width to other anthropometric values relevant for insole sizing and sensor placement (see Figure 37). This was done with a CAD WALK pressure values dataset (Booth et al, 2018), processed in Paraview.

The statistical analysis revealed that shoe size can be used to predict Heel-Hallux length and forefoot width. Additionally, forefoot width and heel width are highly correlated, which makes it possible to normalize certain insole dimensions to shoe size. Considering these conclusions, the sizing chart in Table 2 is created.

Table 2. Proposed size chart

	Insole dimensions (min)									
Shoe size	*EF (mm)*	*CB (mm)*	*AD (% of EF)*	*EH (% of EF)*	*FF cross height (mm)*	*EG (% of EF)*	*H cross height (mm)*	*Alpha (deg)*	*Beta (deg)*	**Size cluster**
37	230	90								XXS
38	250	100								
39										XS
40	270									
41										S
42	280	110	19	71	42	12	12	63	72	
43										
44	290									M
45										
46	300									L
47		120								
48	310									XL

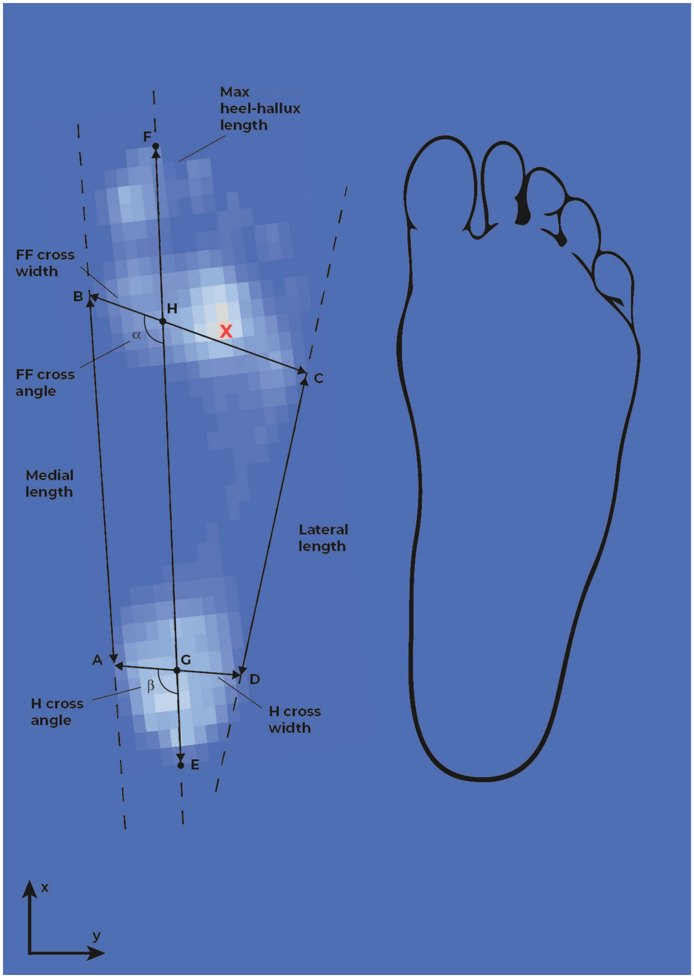


Figure 37. Anthropometric framework

3.1.4 Sensor placement

If the design requires that all participant's anthropometric cross lines should be covered by sensors, then sensors in the forefoot should cover a range of at least 42 mm in hight. The heel cross range, on the other hand, can be as small as 12 mm. Heel and forefoot crossline can have the same angle for all sizes (63 and 72 degrees respectively).

Using the same method as described above, locations of peak pressure were located to determine perpendicular distance between the normalized framework (Figure 37) and centre of pressure. From that analysis, it could be concluded that peak pressure locations are located either way higher or way lower than anthropometric cross lines. If the forefoot sensors were placed higher or lower than the lines, depending on the size, a sensor of only 40 mm high will be able to cover 82% of the peak pressure locations in the forefoot

Increasing the sensor range to 50 mm in height (either by increasing size or adding a sensor) for both locations, it will cover 96% (forefoot) and 94% (heel) of the peak pressure locations. For sizes L and XL, these sensor sizes would not suffice since they will not cover the forefoot cross line anymore. A larger or extra sensor would solve the problem. Sensors in the width of the foot do not need to differentiate between sizes. Figure 38 shows a proposed sensor distribution, based on the sizing chart and conclusions.

Besides the need for peak pressure locations, it is also important to consider the direction of pressure displacement over time, in order to calculate parameters such as heel rotation (see Section 1.1.4.1). Currently the midfoot section of the insoles only includes one sensor. This limits the detailing of information regarding midfoot pressure displacement. A second sensor in the midfoot Section would therefore be very valuable. For the full anthropometric study, see Appendix 10.

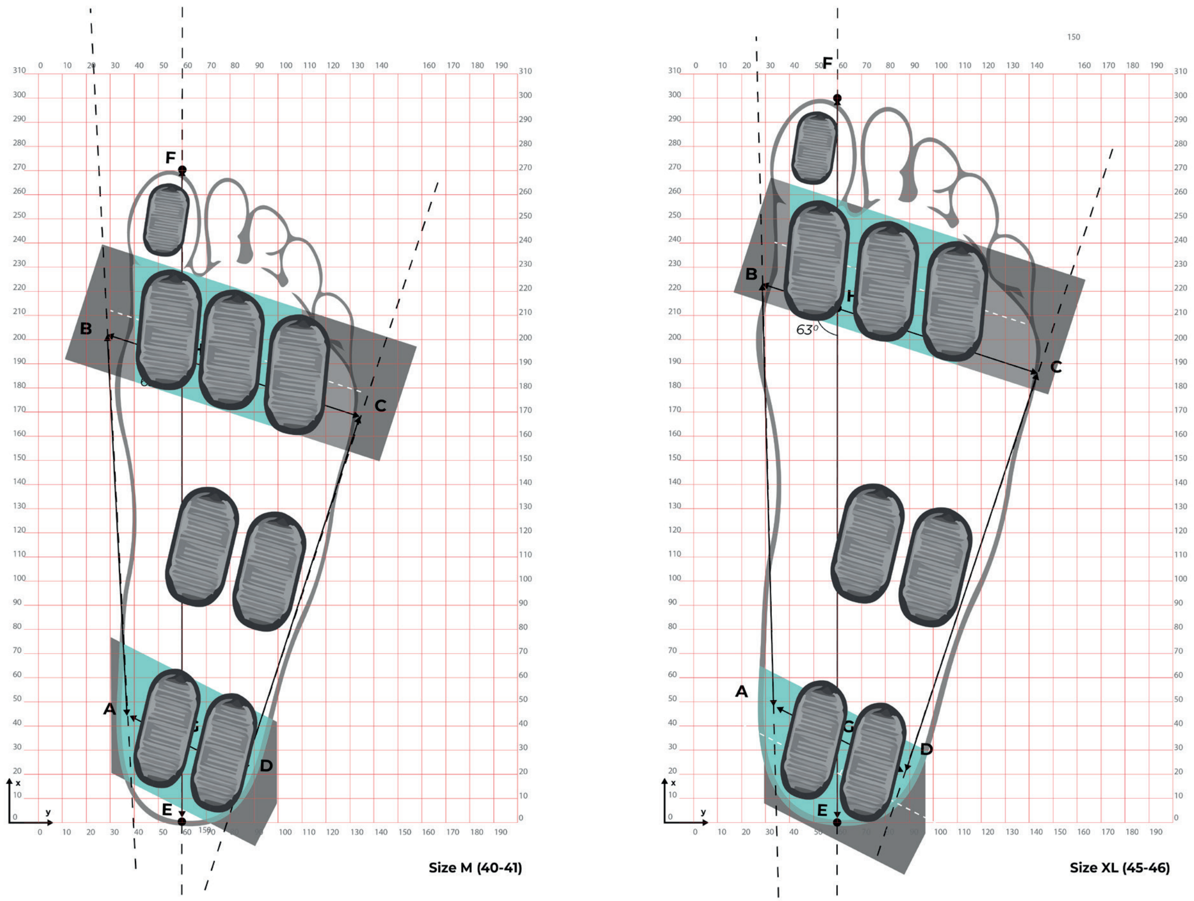


Figure 38. Proposed sensor placement for sizes M and XL

SERVICE DESIGN

Gathering large amounts of subject trials in a constant environment year after year, will provide controlled repeated measurements usable for comparative statistical research. Initial basic military training (AMO) provides this controlled environment, large subject group and high injury rate after a short period of time, making it a good test period. Additionally, - after sufficient software adaptation based on earlier trials - measurements at the start of AMO could be used for immediate intervention of risk subjects, decreasing the number of injuries of new recruits significantly.

3.2.1 Direct use (storyboard)

Figure 39 illustrates a storyboard of how the product would be used in a typical marching day of AMO. Typically, recruits are ought to pack their bags the night before a march. The next morning, recruits are woken up by a commander, after which he will hand out the InnoGait insoles. Each pair is marked by a unique tag number, to be registered in the personal InnoGait app by each recruit. The insoles are now linked to the user, making it possible for either connected live-feedback use or offline data registering to be read-out afterwards. The insoles are inserted in the recruit's boots and he'll make himself ready for the march. When all recruits are gathered in front of the base, static calibration is performed, measuring i.e. total weight and static weight distribution. During the march itself, every step is measured on biomechanical risk factors and repetitions. After returning to the base, the recruit can retrieve results of the measurement directly on his smartphone. The insoles are collected, charged and cleaned for a new round of use.

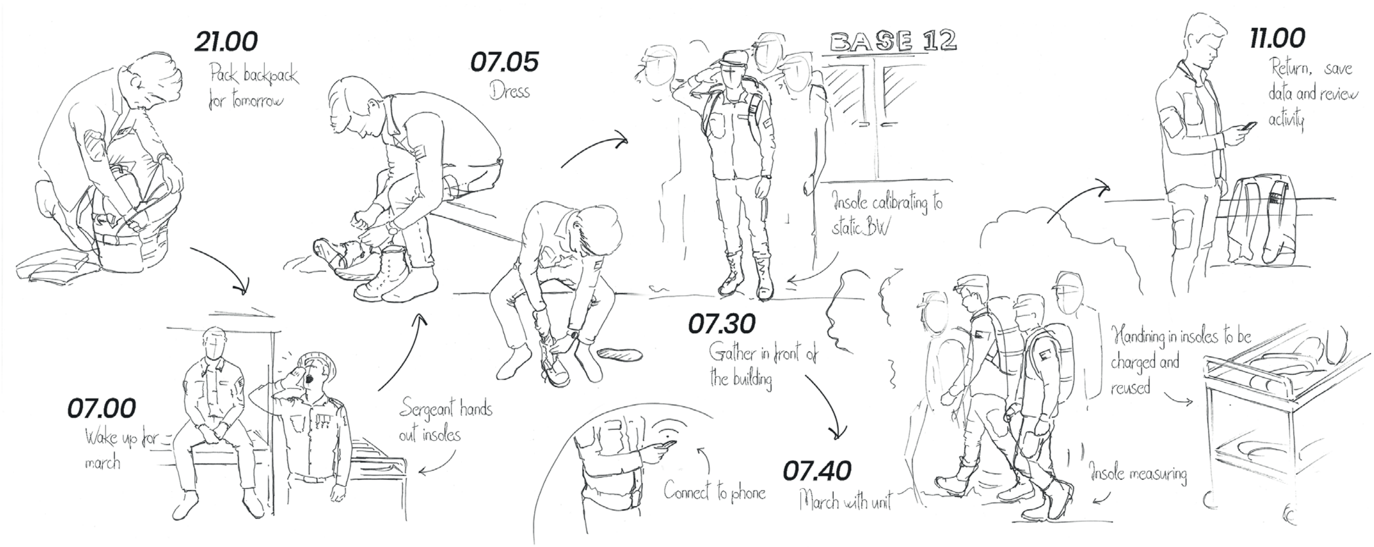


Figure 39. User cycle storyboard of a single measurement session

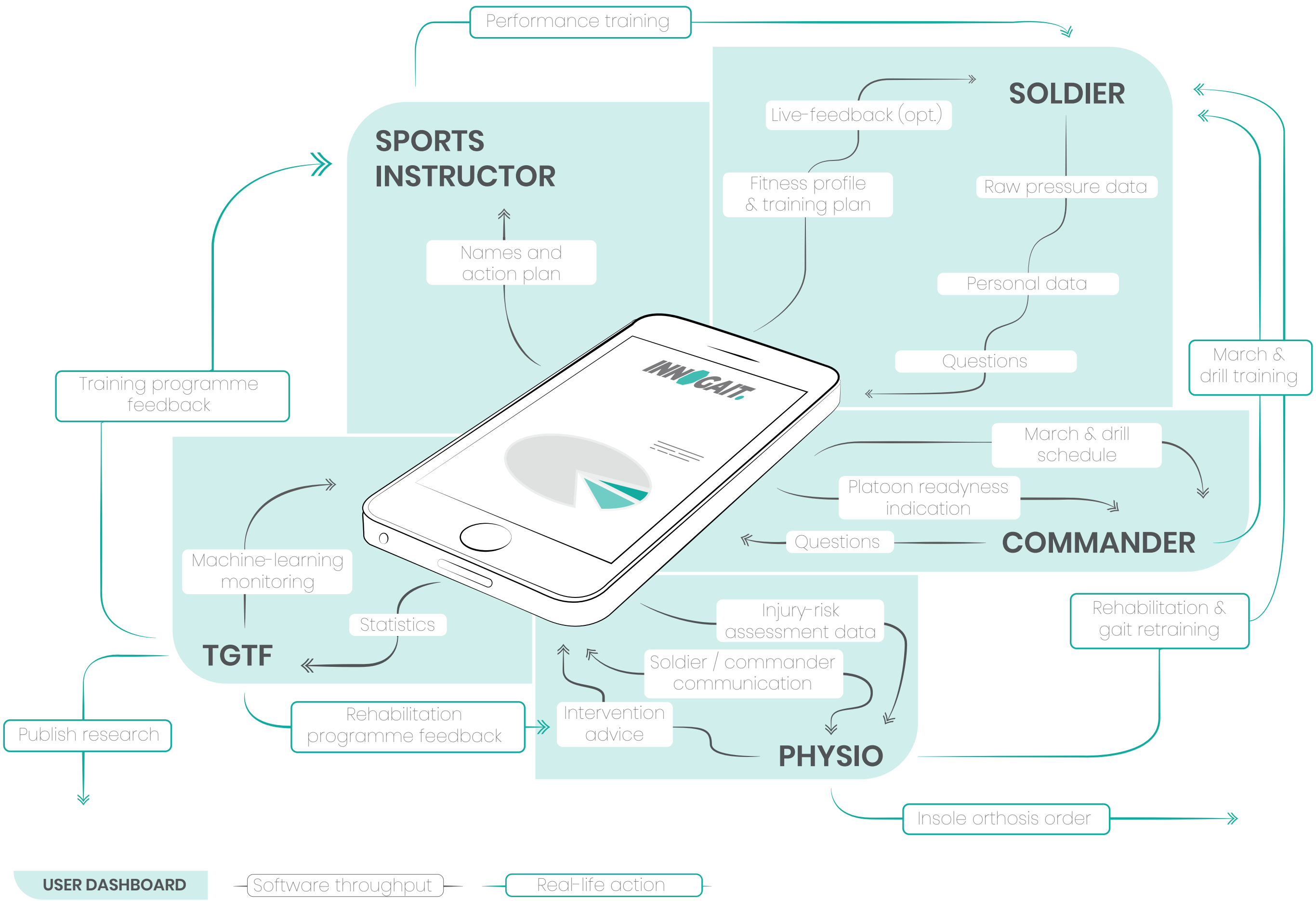


Figure 40. Data flowchart of user application

3.1.2 Data and software application

After completion of a measurement session during a group march (Figure 39), data from the insoles is collected by a user's smartphone and saved into a secure cloud, initially only showing a fitness profile. Additionally, the recruit is asked to share results with any of the relevant military stakeholders, to be used as a training assessment, injury monitoring and research. By providing an optional data-sharing functionality, with a 'private' setting by default, the General Data Protection Regulation (GDPR or in Dutch: AVG) is met. This functionality is already integrated in DTCS, in which the insoles will be designed to be used (Section 1.2.4.3). By letting the user record its own measurements, the medical regulations are also met.

Figure 40 presents a flowchart of data throughput possibilities after sharing the data by the recruit (soldier). These communication types are designed based on the interaction analysis of Section 2.2.2. Additional to the injury-risk assessment, the system includes communication possibilities, scheduling/planning possibilities and a live-feedback option for the soldier.

BUSINESS STRATEGY

According to Section 1.1.4.3, competitive advantage inside the current market is present because the product combines elaborate measurement with user-centred design and injury-specific analysis for both clinical and consumer user interaction (Figure 12).

Figure 41 presents a graphic timeline marking major milestones for a five-year business strategy. Within five years, the project could potentially go through a Start-up phase and finally become a Scale-up. It would be difficult for this project to become a steady-state company, as it is reliant on a very specific consumer: Defence. This makes it difficult to build a steady revenue stream. However, with a future vision on international sales and new-market entry, the project could still be profitable.

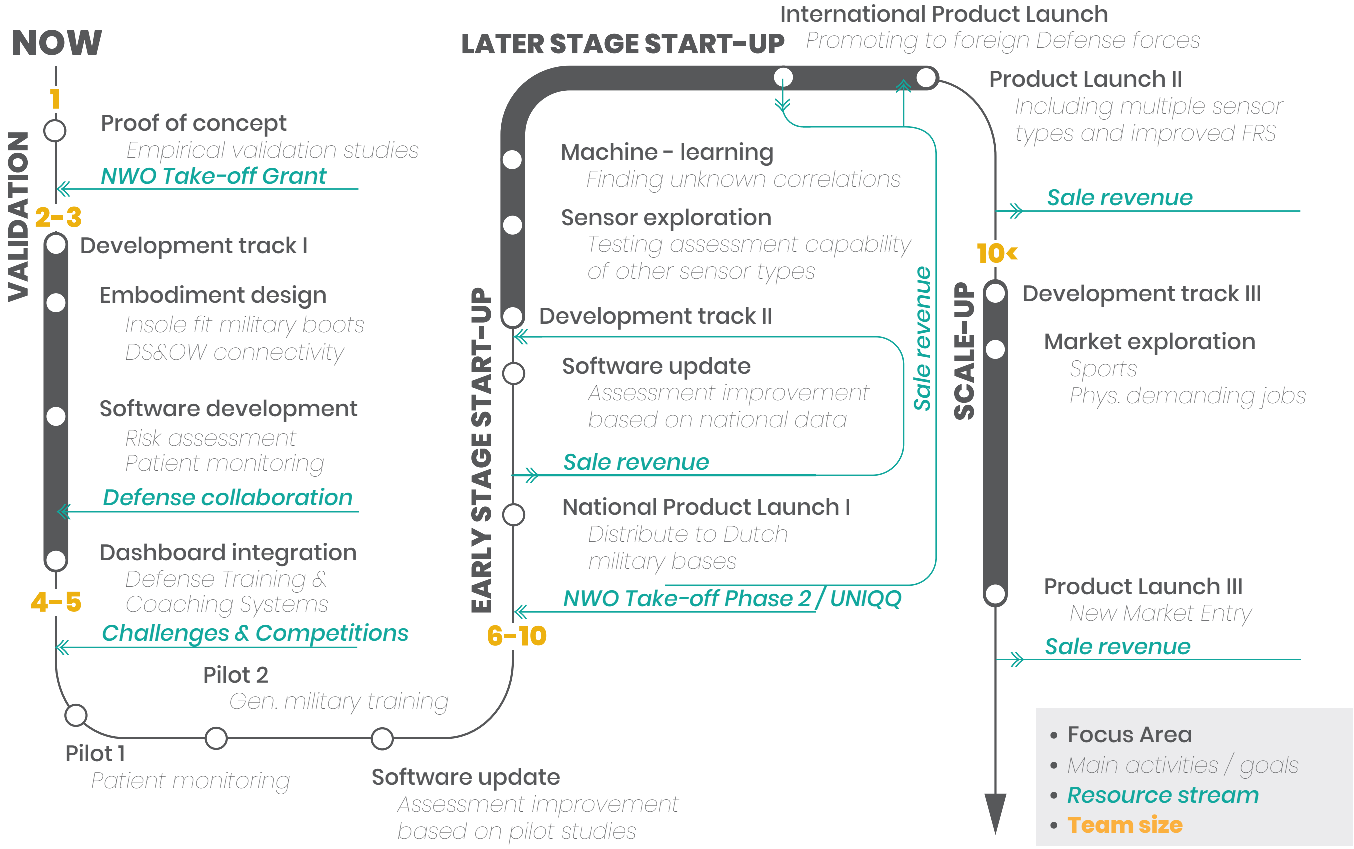
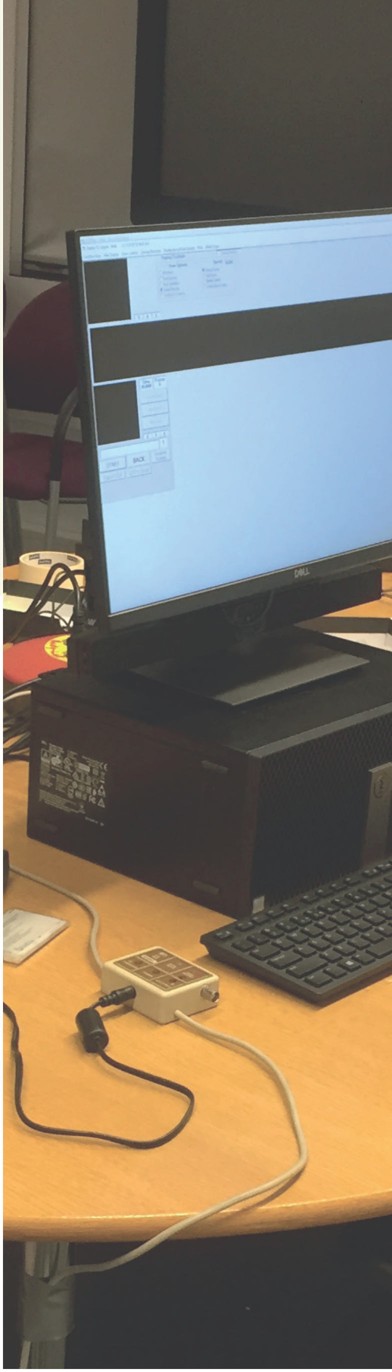


Figure 41. Business plan timeline

CHAPTER 4

EVALUATION

This report has provided initial systematic evidence of the capability of pressure-sensitive insoles to perform accurate, affordable and user-fitting injury-risk assessment and provided design proposals to execute this potential. While the results of Section 2.1 seem very promising and give motivation to research the subject further, the study also ran into some limitations.



DISCUSSION & RECOMMENDATIONS

Previous work

Contributing to previous work by i.a. Franklyn-Miller et al, 2014; Friedl, 2018; Daoud, 2012; Cowan, 1996; Milner et al, 2006; Sharma, 2007; Verrelst et al, 2018; Strauss et al, 2011, this report has provided systematic evidence of the predictive capacity of plantar pressure analysis on overuse injury. Additionally, this report shows novel scientific evidence of the use of wearable pressure-sensitive insoles to perform this assessment. A complementary design proposition additionally provides recommendations for product development, focussed on the military as a specific group with demand for innovation.

While the results of Section 2.1 seem very promising and give motivation to research the subject further, the study also has some limitations.

Study limitations

This study has merely focused on the act of walking, as marching is one of the major military activities. However, many overuse lower limb injuries become more evident when studying running, which is why most papers studied running-related injuries. Future validation of the algorithms should therefore investigate the influence of walking/ running speed on the parameters.

Study approach should be critically noted in cited work. Similar to the study done in Section 2.1, gait parameters were measured post-injury. Using this method, it is not clear if the parameter deviation was the cause for his/her injury or if it was a result of the injury. This could be tested by doing a longitudinal study measuring a large group before and after initial training, gathering injuries occurred between the measurement period.

While personal data (e.g. gender, age and shoe size) was included in statistical analysis, many other factors could influence the outcome that were not accounted for or not applicable in the first studies. Factors such as inadequate warm-up, loading (e.g. rucksack) poor (or worn-out) footwear, tightness of shoe lacing, accumulation of heat and humidity in the shoe, training intensity and terrain type can highly influence the incidence of injuries (Lacirignola, 2017; Preventing Injuries in Military Training, n.d.). Specific effects of these factors were not examined within the scope of this graduation project but should be picked up further along the road.

Lastly, studies in Section 2.1.2 and 2.1.3 showed inconsistent temporal variables. Presumably, they were caused by lack of proper calibration or low sampling frequency. Parameters depending on time should be reassessed when temporal variables are consistent.

Ethics

Besides those limitations, the project could also bring up some ethical questions. Some argue, for example, that it might be dangerous to use AI in clinical practice (Korteweg, 2020). The replacement of a human supervisor would presumably create a 'black box', in which control is lost. This argument is invalidated by Bram van Ginneken, AI can be told what to pay attention to and fragment stages of clinical research to be assessed by humans. Besides faster and more accurate diagnostics, AI is tireless, consistent and affordable, which makes it also suitable for countries with fewer physicians.

Recommendations for future research

After initial validation in this study, the next step would be to adopt design recommendations in a prototype and perform follow-up studies.

Firstly, the new prototype should be used in a large-scale longitudinal study, measuring all participants at the start of basic military training. A follow-up study after completion of the training (approx. 1 month) will provide injury complaints among all subjects. Initial measurements of those subjects should be compared to the control group.

Next-up, the system should be further developed. Main targets are the measurement and analysis of personal variability and fluctuation, bodyweight and carried - backpack - load, contact area and interpolation and step length, using inertial sensors. After that, the system could explore calculating more parameters and potentially more sensor types (Section 1.1.4.2). An example is the use of multiple IMU's on the lower limbs, enabling the system to track full lower-limb (joint) kinematics (Figure 42).

When the system has gathered a high amount of data, while keeping controlled test settings, the data should be analysed for factors of influence such as unexpected voluntary changes (Verrelst, 2018), fatigue (Grech et al, 2016), repetitions (Hauret et al, 2010; Keyserling 2000) and terrain types (Lacirignola, 2017). Additionally, the chances are high that we are currently unaware of many existing biomechanical risk factors. Those can be found and adapted in the system and later on be used for other markets.

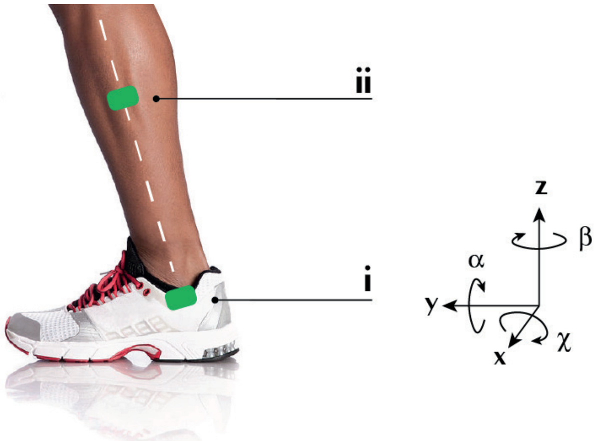


Figure 42. IMU sensor placement for joint kinematics

Recommendations for future markets

After exploring the potential inside the military market, the system could be adopted in new market segments. When overuse injuries occur during employment, they are commonly referred to as “repetitive strain injuries” or “work related musculoskeletal disorder”. Police officers, firefighters and paramedics, but also factory workers, nurses, surgions and other health-care employees are examples of occupations that - besides the military - demand high physical load from a prolonged static posture or walking either with or without carrying gear (Hauret et al, 2010).

Exploring further than occupational setting, (repetitive) overuse injury also occurs among recreational hikers and pilgrims. The annual hiking activity Nijmeegse Vierdaagse, for instance, causes many participants to endure physical injury (Janssen, 2014).

Plantar pressure analysis is not only valuable for injury prevention purposes. The method has frequently been adopted for diabetic patients, who endure foot ulceration and loss of sensitivity. The measurement insoles could be used to customize insole orthosis customization (Bennetts, 2012). Other medical applications of wearable plantar pressure insoles are the patient monitoring of knee or hip-replacement surgery, amputees or other rehabilitations.

Not only new target-users should be explored, but also new target applications of data outcomes. For example, The pressure data could be used for automated fabrication of insole orthoses, making the system faster, more accurate and more affordable. Insole orthoses could potentially be designed, fabricated and distributed without the need for a single doctor’s appointment. It should be noted that for a good insole orthosis, more information is required than just pressure distribution (see Section 1.2.4.2). Following the Pareto-principle, about 80% of the problem could presumably be solved with just pressure data, demanding just 20% of the effort.

Figure 43. Nijmeegse vierdaagse ("Intocht van de wandelaars", 2018)

Figure 44. Prolonged static posture during surgery (Siwicki, 2019)

REFLECTION

As mentioned in the Assignment and project scope, the project took a big turn shortly after kick-off. I intended to design and develop the embodiment and hardware of an innovative measurement tool, but it turned out that similar products were already on the market or getting there (Kickstarter). This was the first real challenge for me to be creative and to rephrase the project brief to structure a valuable project again. Looking back on that moment, I believe I did not only succeed in that challenge, but by doing so, I also made the project more interesting. It helped me to take a critical look at the value of that existing piece of technology and include a part of strategic innovation. The redefined project brief helped me to follow a clear direction from the start, protecting the project from ending-up too unspecific and general.

My approach has always been to experiment as much as possible and to follow the most promising paths that come across. In general, this approach helps me preventing “writer’s block” and making decisions as it will always give me something to do. But it does have its downfall. I might lose track of the purpose of my current activity. It makes me focus too much on getting valuable results from a single task, while it might not actually add that much value to the overall picture anymore. I should probably take more notice of the Pareto principle, stating that about 20 percent of our effort provides 80 percent of the result. Beyond that, only small pieces of improvement will be achieved. An example of this approach becoming a downfall, is when I was doing statistical analysis on the comparative study with the GAITRite walkway. While gathering data took about a week, analyzing it took almost three weeks. I was searching for a way to find to normalize output of the measurement methods to be compared, ending up with limited valuable results. Taking a step back and asking myself: ‘Is there another way to validate the research question?’, made me realise I could do another study, without all too much effort. This second research was eventually much more valuable than the first one.

In some cases, my experimental approach led to dead-end activities. For example, I studied the possibilities to measure step length, using inertial data from gyroscope and accelerometers. After significant effort, I decided to quit the study because it took too long and did not add enough value to the project. Another example is the exploration with Arduino and other prototyping material. After discussing with several electronics experts and my supervisors, it seemed more beneficial to use and experiment with existing insoles, than to build my own.

This decision did bring some limitations, of which mainly the dependency to the company associated company to provide me with enough tools and information to use the product as a research tool (which asked some of my time) and the confidentiality of company-owned intellectual property, making it difficult to use and publish specific parts of the study. In the end, however, the effort and limitations did not add up to the benefits and saved time of using the insoles, providing me with valuable study results. The negotiations were additionally rather educational

The main aspect that I am proud of in this project, is the number of interviews and consultations performed to validate different pieces of the research and design proposal. In total, I spoke to twelve valuable stakeholders and experts either in person or on the phone. Contact was often maintained via email or phone for follow-up questions. The input gathered from those people helped a lot in answering own-formulated questions, but also brought up unexpected insights and feedback. The acknowledgement of project value by many experts and potential users additionally gave me the motivation to explore full potential of the project. In the end, I am proud of the thesis lying before you. I hope you enjoyed reading it.

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