

UNIVERSITY OF TWENTE.

Faculty of Engineering Technology

INTERNSHIP REPORT

The effect of passivesupporting versus activesupporting ankle braces on physiological movement

> Marios Chrysanthou Student ID:s1724142 01 March 2017 – 31 August 2017

Title: Internship report Subtitle: The effect of passive-supporting versus active-supporting ankle braces on physiological movement

Period: 01 March 2017 – 31 August 2017 Name: Marios Chrysanthou Student ID: s1724142 Master track: Mechanical Engineering

Supervisor Charité Universitätsmedizin Berlin:

Dr.-Ing. Alison Agres Charité Universitätsmedizin Berlin Julius Wolff Institute for Biomechanics and Musculoskeletal Regeneration Augustenburger Pl. 1, 13353 Berlin, Germany P: 030 450559048

<u>Supervisor University of Twente:</u> Dr. Ir. D. Van de Belt University of Twente Faculty of Engineering Technology Horst - Ring (building no. 21), room W103, De Horst 2, 7522LW Enschede, The Netherlands P: +31534892457

PREFACE

As part of the master's curriculum of mechanical engineering, an internship must be carried out outside the university giving the opportunity to apply their knowledge in a company or at a research institute. This report documents the work done during the summer internship at Julius Wolff Institute (JWI), Charité - Universitätsmedizin Berlin, Germany under the supervision of Dr. -Ing. Alison Agres.

The institute stands in the tradition of Julius Wolff, the founder of the orthopedic clinic in the Charité, and his theory that shows the correlation between mechanics and medicine, and explains that the form and structure of bone constantly adapts to mechanical loading. This is highly relevant for the musculoskeletal research happening today, mainly investigating the influence of mechanical stimulation on biological reactions.

For me, this was not only part of my personal research interests but also a great opportunity to study abroad, to apply my theoretical knowledge in a practical environment and to increase my competences. Therefore, I started my internship research by looking at the ongoing research projects at J. W. Institute and to see whether any of them interested me. As soon as I came across Dr. Agres 's project, I contacted her and following a brief communication, we came up with a plan that met both her and my needs. I was really glad she offered me an Internship position.

It turned out to be a truly valuable experience. I had the chance to work with great professionals in various fields and be a part of an amazing research group. In addition, having direct contact with the patients was something new to me and it really helped me add a more personal note to my work. Finally, I had the opportunity to collaborate with our industrial partners from "Betterguards" which gave me a new insight of what it is like to work outside the university environment.

In conclusion, I learned a lot during my internship and I was able to apply what I had already learnt during my studies at UT.

SUMMARY

This report describes the work conducted during a six-month internship at Julius Wolff Institut (JWI), Charité - Universitätsmedizin Berlin. This internship is part of the master's curriculum of Mechanical Engineering of the University of Twente.

The prime focus of the study was to analyze the effect of restricted ankle movement in two planes (sagittal & frontal) compared to single-plane restriction (sagittal) by using passive and active supporting ankle braces, respectively. Patients with a history of sprained ankles were assessed first for their baseline physiological movement during walking and active tasks, such as a single-limb drop landing. Furthermore, patients were tested on an apparatus that will induce a sudden inversion on the ankle joint, to see how well the ankle can resist movement in the frontal plane. The entire test is repeated with either a passive or active-supporting ankle brace. Motion capture with VICON was used to assess the kinematics not only at the ankle but also at the knee.

I oversaw each measurement. I prepared the laboratory by calibrating the VICON Nexus cameras and preparing the markers and our equipment, shorty explaining the procedure to our new patients and finally I was in charge of recording the movement data on VICON Nexus software. At the end of each measurement, I collected and stored our data and later post process them on VICON Nexus and exported the markers trajectories. Finally using MATLAB and a self-written code, I calculated the ankle angle.

		i
1. Chronic ank	de instability	6
Introduction		6
Causes		6
Nonsurgical T	reatment	7
2. Betterguard	ds	
Introduction		
Product		
3. VICON Next	us	9
Introduction		9
Motion cap	ture	9
VICON Next	us Company	9
How Vicon	Works	10
Markers		10
Strobe		
Camera		11
Force plate	s	12
UKP - Umkr	nickplattform	
Patients		
Requireme	nts:	
4. Methodolo	gy	14
Preparation b	efore the measurement	14
Calibration	and preparation of the cameras	14
Patient pre	paration	16
Marker plac	cement	
Measurement	starts	
Session 1: n	novement	
Session 2: L	ЈКР	19
Repeat with	n orthoses	21
Day 2		21
VICON Proces	sing	22
MATLAB Proce	essing	25
Comparison o	f two days results	27
SPM		29
5. Results and	Discussion	

Contents

6.	References	31
7.	Appendices	32
/	Appendix A – Employer & Supervisor description	32
	Appendix B: VICON screenshots – Patient with markers	33
/	Appendix C – MATLAB data	37
		•••

1. Chronic ankle instability

Introduction

Chronic ankle instability is a condition characterized by a recurring giving way of the outer (lateral) side of the ankle. This condition often develops after repeated ankle sprains. Usually, the giving way occurs while walking or doing other activities, but it can also happen when you are just standing. Many athletes, as well as others, suffer from chronic ankle instability.^{1,2,3}

People with chronic ankle instability often complain about:

- A repeated turning of the ankle, especially on uneven surfaces or when participating in sports
- Persistent (chronic) discomfort and swelling
- Pain or tenderness
- The ankle feeling wobbly or unstable

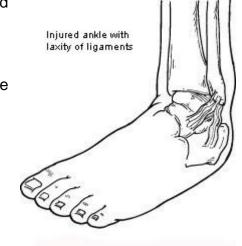


Figure 1: injured ankle with laxity of ligaments

Causes

Chronic ankle instability usually develops following an ankle sprain that has not adequately healed or was not rehabilitated completely. When you sprain your ankle, the connective tissues (ligaments) are stretched or torn. The ability to balance is often affected. Proper rehabilitation is needed to strengthen the muscles around the ankle and retrain the tissues within the ankle that affect balance. Failure to do so may result in repeated ankle sprains.^{1,2,3}

Repeated ankle sprains often cause—and perpetuate—chronic ankle instability. Each subsequent sprain leads to further weakening (or stretching) of the ligaments, resulting in greater instability and the likelihood of developing additional problems in the ankle.

Nonsurgical Treatment

Treatment for chronic ankle instability is based on the results of the examination and tests, as well as on the patient's level of activity.

Nonsurgical treatment may include:

- **Physical therapy.** Physical therapy involves various treatments and exercises to strengthen the ankle, improve balance and range of motion and retrain your muscles. As you progress through rehabilitation, you may also receive training that relates specifically to your activities or sport.
- **Bracing.** Some patients wear an ankle brace to gain support for the ankle and keep the ankle from turning. Bracing also helps prevent additional ankle sprains.
- **Medications.** Nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, may be prescribed to reduce pain and inflammation.^{1,2,3}

2. Betterguards

Introduction

Betterguards is a supplier and service provider within the orthotics industry. Currently they are developing various adaptive modules, which are being integrated into numerous products for all kind of areas, from medical to sports, to protection at work. A newly developed type of active brace is being developed from Betterguards and will be used in comparison with a passive brace to evaluate the restriction possibilities of it.⁴



Figure 2: Betterguards module

Product

The product being tested is developed to behave just like a car seat belt. It utilizes the chemical properties of shear-thickening fluids to allow movements below a certain

force level but restrict the ones that are high enough to cause an injury.

A patent module that contains the shearthickening fluid (figure 4) is insert on a mold that surrounds the ankle and ties in an insole of the shoe.



Figure 3: Betterguards module

In order for a product to prove to the investors that it does perform as claimed, research and testing must be carried out by a third-party independent institute or research center.

An independent institute is not biased by the results, as their purpose is not to launch the product but to test it. This ensures that any flaws in the product missed by the developers can be identified.

3. VICON Nexus

Julius Wolff Institute has a Gait lab equipped with cutting-edge equipment and machinery and is able to perform various gait analysis tests. It is equipped with 10 VICON Nexus cameras set periferantly a large volume area. In the center of cameras' focus, two force plate platforms are hidden underneath side by side.⁵

Introduction

Motion capture

Motion capture is the recording of movement by an array of video cameras in order to reproduce it in a digital environment. This three-dimensional reproduction has many uses:

- · Medical assessment of movement disorders
- Understanding of athletic techniques
- Generating lifelike character animation for movies, video games, broadcast and webcast.
- Incorporating motion into virtual environments for engineering design

The Vicon system includes hardware (cameras etc.) and software applications for the complete control and analysis of motion capture.

VICON Nexus Company

Vicon is the leading developer of motion capture products and services for the Life Science, Entertainment and Engineering industries.

They developed the first commercial motion capture system in the early 1980s and launched the world's most intelligent camera platform in 2015.

They have won an Academy-Award, an Emmy and several Queen's Awards for Export & Innovation.

How Vicon Works

A typical motion capture space comprises an area – the capture volume – surrounded by several high-resolution cameras. Each camera has a ring of LED strobe lights fixed around the lens. The subject, whose motion is to be captured, has a number of reflective markers attached to their body, in well-defined positions. As the subject moves through the capture volume, light from the strobe is reflected into the camera lens and strikes a light sensitive plate creating a video signal.

The Vicon Data station controls the cameras and strobes and collects these signals, along with any other recorded data (sound or analogue signals from force plates for gait analysis). It then passes them to a computer on which the Vicon software suite is installed. Workstation is the central application of the Vicon software suite used to collect and process the raw video data. It takes the two-dimensional data from each camera, combining it with calibration data to reconstruct the equivalent digital motion in three dimensions.

This can be viewed in Workstation as a virtual three-dimensional motion. After this reconstruction the data may be passed to other Vicon applications for analysis and manipulation or to third party applications such as those used for digital animation or virtual environments.

Markers

Passive optical system use markers coated with a retroreflective material to reflect light that is generated near the cameras lens. The camera's threshold can be adjusted so only the bright reflective markers will be sampled, ignoring skin and fabric.

The centroid of the marker is estimated as a position within the two-dimensional image that is captured. The grayscale value of each pixel can be used to provide sub-pixel accuracy by finding the centroid of the Gaussian.

Vendors have constraint software to reduce the problem of marker swapping since all passive markers appear identical. Unlike active marker systems and magnetic systems, passive systems do not require the user to wear wires or electronic equipment. Instead, hundreds of rubber balls are attached with reflective tape. The markers are usually attached directly to the skin (as in biomechanics), or they are velcroed to a performer wearing a full body spandex/lycra suit designed specifically for motion capture.

Strobe

The strobe is a circular set of light emitting diodes that fits around the lens of an individual camera. The markers reflect light from the strobe back into the camera.

Camera

The camera and strobe unit is the part of the Vicon system that collects light from the reflective markers on your subjects. The strobe emits light in time with the camera, illuminating the retro-reflective markers attached to the subject. The markers reflect light straight back to the camera where they pass through a filter that allows only light of the same wavelength through to be focused on the camera's sensitive plate. The camera and strobe are separate units. In the VICON cameras used in Julius Wolff Institute gait lab the strobe ring fits around the lens, being held in place by a magnetic strip. The strobe connects electrically via a short flying lead. Two types of strobe are available, visible and infrared. In the case of the infrared strobe, some caution must be executed because staring in the infrared light for an amount of time can hurt the eyes. If two calibrated cameras see a marker, a three-dimensional fix can be created. Typically, a system will consist of around 2 to 48 cameras. Extra cameras are required for full coverage around the capture subject and multiple subjects.



Figure 4: Nexus camera with strobe

Force plates

A force plate is designed to measure the forces and moments applied to its top surface as subject stands, steps, or jumps on it. Force plates are regularly used in research and clinical studies looking at balance, gait, and sports performance. Piezoelectric measurement technology ensures that forces and moments are registered accurately and that even the smallest shifts in the forces can be recorded.

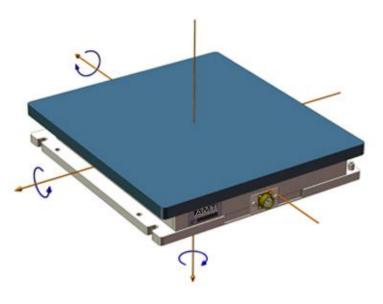


Figure 5: Ground force plate

UKP - Umknickplattform

A motorized supination test platform with an external force plate has been built by BTG. It can safely and reliably invert the ankle suddenly. The right-side platform, using a motor, can fall with the desired velocity.

Two different speeds will be used, 400°/s and 150°/s. Ten trials per section (five each speed and with a random order). 80% of the body weight must be on the dropping platform and the time of the drop varies so that the patient does not expect the drop. Patient wearing all markers on the UKP can be found in Appendix B.

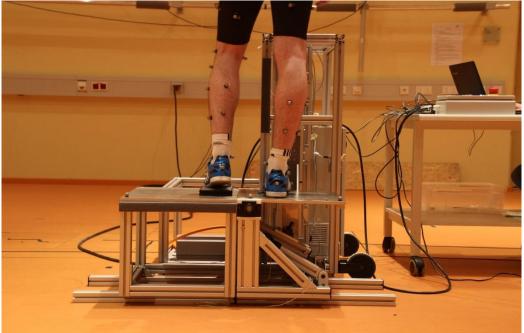


Figure 6: Patient standing on the UKP



Figure 7: UKP with platform dropped

Patients

The newly developed orthoses target young and sport active group patients. It is a product designed to let you freely do sports without interfering in any movement but when in case that a sprain may happen to restrain the ankle and so prevent it. The following criteria's for the patients to test was set. The project did pass through an ethics committee first.

 30 healthy, athletic volunteers (m/w, 25-40 years of age) with ankle instability/problems

Requirements:

- Age: 25-40
- (Repeated) ankle sprain on one side within the last year
- No history of any other injuries in the lower extremities
- Fitness: regular participation in sports/exercise with at least 3 hours per week

4. Methodology

Preparation before the measurement

Calibration and preparation of the cameras

Approximately thirty minutes before the patient arrives, the lab gets prepared. VICON Nexus system, the force plate platforms and the PC are powered on. When the cameras warm up a calibration of the room needs to be done.



Figure 8: gait lab

Before the calibration, a masking of the cameras is done to remove any reflections created by the room that may intervene with the real markers. In order to perform the calibration, a special wand provided by VICON is used. The wand has five markers in know distance from each other. The markers attached are at known positions and are used to calibrate the cameras and obtain their positions and the lens distortion of each camera is measured. Each camera is set to record 9000 registrations of the wand; this number is peaked for more accuracy since we work with high frequency. With the calibration, we describe the volume of the data to the cameras ensuring an accurate 3D volume capture.

Finally, the wand is placed in a flat known position in the middle of the focusing point of the cameras and the volume origin is set.

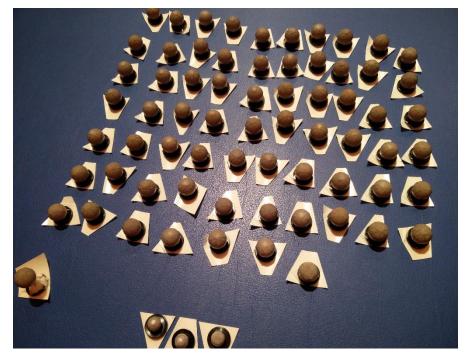


Figure 9: Calibration wand

After the calibration, a database in the VICON program is created with the patient code. (e.g. BTG_03).

Tools				(B) 2
		<mark>- 1</mark>	5 💿 🐵]
Wand:	5 Marker Wan	d & L-Fran	ne	~
L-Frame:	5 Marker Wan	d & L-Fran	ne	~
Video Calib	ration Setup	,		
	[Activa	te	
Mask Cam	eras			
		Star		Cancel
Aim Came	ras			
	[Star	1	Cancel
	[- D COIL-		Caricer
Calibrate C	ameras			
				Show Advanced
Calibration	Type:		Full Calibration	<u>~</u> ,
Cameras To	Calibrate:		All Cameras	
Refinement	frames:		1000	
DV Calibrati	on frames:		500	
Auto Stop:			6	-
		Star	:]	Cancel
Set Volume	e Origin			
		Star	t]	Cancel
Static Vide	o Calibration			
		Star	:]	Cancel
Manage Ca	mera Calibra	ation		
		Rese	t	Load
C	libration Fee	dhaak		
camera Ca	inpration ree			
		0	%	

Figure 10: Calibration window



Using double-sided adhesive tape, the markers are also prepared

Figure 11: Prepared markers

Patient preparation

When the patient first arrives at the gait lab is introduced at the environment to get familiar. Everyone in the room introduce himself to the patient and explains his part in the study and a general explanation of the purpose and the goal of the study is given. Next, there is a walk around the lab, so the patient can see the ten cameras and the UKP and explain them how they work and give them a brief explanation of the movements that they will perform. The patient is asked then to wear short pants and give his shoes so that a special insole required for the orthoses to grip on can be fitted, the shoe is then returned and asked to be worn.

Circumferences of thigh (proximal/middle/distal), shank (proximal/middle/distal), leg length (from Anterior Pelvis marker (L-/RASIS) to lateral malleolus marker (L-/RLMA)) and foot length (instep) for both legs are measured. Moreover, body weight and height are also measured and recorder.

In order to have a more in-depth knowledge of the injury and the activity level of each patient a questionnaire is handed were various questions are asked, for example the level of exercise before and after the injury, the frequency of pain and if they had received any treatment in the past etc.

Marker placement

The markers are stick in predefined anatomical points of the body.

The standard marker set consists of 59 markers as shown in the figure 12.

In order to have better visibility and more references on the foot, it was decided to add four more markers on each foot (two markers lateral and medial of the hind foot, a marker on the fifth toe and a marker on the big toe) as shown on figure 13. Julius Wolff Institute markerset of lower extremity and trunk

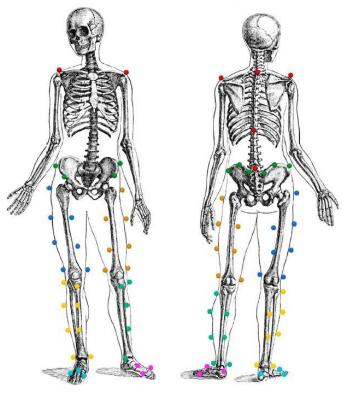


Figure 12: JWI marker set

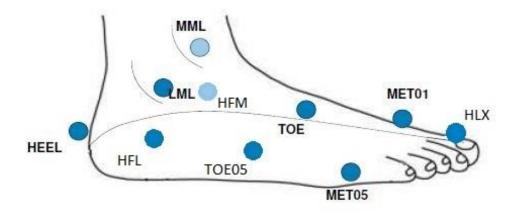


Figure 13: JWI foot marker set

Placing the markers correctly can be tricky and hard at the beginning. You must feel the bones of each patient and be able to understand what is what. A physiotherapist was helping us at the start until we get familiar with each anatomical point. Some markers are more important than others are, for example, the six shank markers placed between the knee and the malleolus do not have a specific point and are placed there more as reference. On the other hand, L5 marker, which is the one in the middle of the spine, must be placed exactly on the fifth vertebra and to do that the patient must bend forwards and starting from the last one down at the pelvis, count five up and place the marker.

Since body mass, muscles and general bone structure is different for each individual and since the markers are placed on the skin and not on the bone itself, an error in placing them is inevitable but we tried to minimize it.

Although sticking the markers with double-sided tape does help the placing of the markers to be done fast and rather precisely, it is not ideal. The tape does not stick well on hair and if the patient sweats the markers tent to fall and needs to be stick again, forcing the measurement to stop, mostly in the middle of a session and start again.

After the markers are placed, the measurement can start. Different trials are performed.

Measurement starts

Session 1: movement

Calibration activity

First, static trials and calibration movements are recorded. 200Hz will be used as a frame rate since there is no very fast movements that require higher frequency. Calibration movements include a star arc, knee flexion extension, foot flexion extension, foot circle and foot inversion eversion. This movements are performed for both legs. This movement's help in later identifying the anatomical joints of the body. The program uses these trials in order to label the trials afterwards correctly. The reason for the inversion and eversion movements are performed is to obtain the physiological range of motion as a baseline of comparison. The maximum inversion and eversion of the leg will be calculated in MATLAB and compare it with the maximum value from the inversion on the UKP. Furthermore, a one-leg stand for thirty seconds, once with open eyes and once with closed eyes is recorded and saved for a future usage.

Movement activities

Next, walking and jogging trials take place. The patients walk (and afterwards jogs) between two lines in the length of the laboratory and the movement is captured. Two force plates are hidden in the ground in the middle of the lab, side by side, and the patient must have at least five clean heel strikes on both foot on at least one of the platforms. This can take a while to complete and require a lot of back and forth movement because the patient is unaware of the platforms so that there is no timing between steps to hit them. The patient does not know about the platforms because we want to record a natural ground reaction.

Then, a small platform (height of a single step) is placed behind one of the force plates. The patient stands on the step with the non – injured foot raised and shift the body weight slightly in front until having the sensation of falling, and then proceeds to fall and land with the injured leg on the force plate and maintaining balance for 10 seconds. This trial is performed three times.

Lastly, regarding the movement trials, three double jumps are performed. The patient stands with one foot on each force plate and then squads and jumps as high as possible and then lands at the same position as launched. This is also performed three times.

The reason why single leg jump and double jump movements are performed is for a bachelor thesis, which will assess if wearing/using an orthosis helps the patient land more correctly/efficiently and so reduce the ground reaction forces.

Walking, jogging and one leg stand will be assessed later to conclude more about the performance of the product but not on the scope of this internship.

Session 2: UKP

When the above movements are complete, the frequency is changed from 200Hz to 400Hz due to the fast drop of the platform and the need for more data capturing for that purpose. The UKP is pulled in the middle of the lab and plugged in. We faced some troubles regarding the UKP, mostly about the position. The UKP was placed exactly in the center of focus of the cameras for maximum visibility. Since it is a bulky machine, with a big block containing the motor, many of the cameras could not see the markers on the foot that were directly behind the block. Furthermore, the patient was placed high above the ground when standing on the UKP.

To compensate about this low visibility, various rotations of the machine were used so that we can find the best position. An extension cable was used for the high current power source needed.

It is also connected to a PC that is operated by a person from BTG (UKP operator). A sheet containing a random order for the two different speeds is printed beforehand and is used from both BTG person that adjust the speeds and from the person operating the VICON system so that each trial is named correctly. Ten random trials are performed. Two different speeds are used (400°/s & 150°/s), five trials each. An external force plate, were the non-injured leg stands, is built in the UKP and is connected as an external port in the VICON system. The reason of this is that we want 80% of the bodyweight to be on the injured leg and on the dropping platform. The 20% of the bodyweight is calculated from the weight recorded in the start of the measurement.

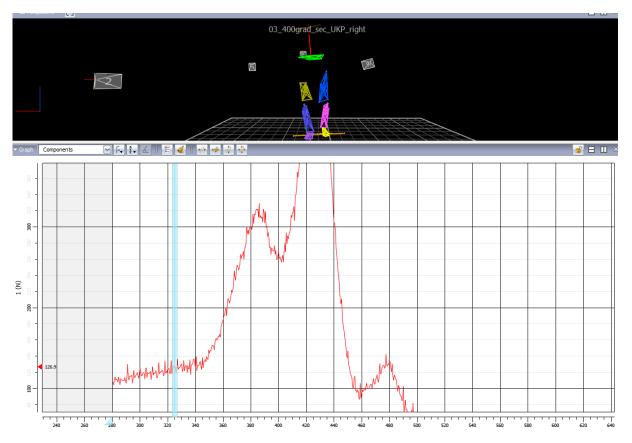


Figure 14: Force plate data just before the UKP drop. 20% of the bodyweight was calculated as 135N. The dropping happened at 126N

The patient then stands on the platform with the injured leg on the dropping plate and the other on the built-in force plate. The patient is asked if ready and when 20% of the body weight is on the force plate the person operating VICON starts the recording and gives a subtle signal to the UKP operator to drop the platform. The UKP operator, after receiving the signal, uses a random period of 1s ~ 3s before dropping the UKP. The subtle signal and the random period is used so that the patient does not expect the drop and therefore is not instinctively preparing himself to compensate the platform (by immediately shifting the weight from the injured leg to the non-injured or trying to stiffen the injured joint). The platform then drops with one of the two speeds and is repeated ten times.

The way this measurement is conducted does have some errors. Firstly, the external force plate was producing a lot of noise so accurately reading the force value was tricky. Second, since the force must be read from one PC and then signal the other one so that both start, time was lost and the way may had shifted off the 20% body weight. Moreover, if the patient was able to hear the mouse click or catch the signal, unintentionally there was a weight shift before the drop.

These trials were performed with the patient not wearing any type of orthoses.

Repeat with orthoses

The trials are now performed again, but this time wearing one of the two orthoses (placebo or BTG orthoses). The pick is random and only the person from BTG knows which one is used.

The inversion, eversion trial is left out this time so that nobody will be able to see which orthoses is being worn since these movements can 'show' which orthoses is. When all movement and UKP trials are done the patient then leaves.

Day 2

The patient returns in a time space of about ~3 days and repeat the whole movements described above but this time using the orthoses not used on Day 01. All the data collected from the specific patient are transferred to the main server for further processing.

VICON Processing

Using VICON Nexus, a core processing is executed and the reconstructed markers can be seen. For the core processing to run, a minimum of three cameras are required to start a marker construction and two to keep track of that marker, meaning that a marker must be seen by at least three cameras and stay in the visual range of two at least cameras

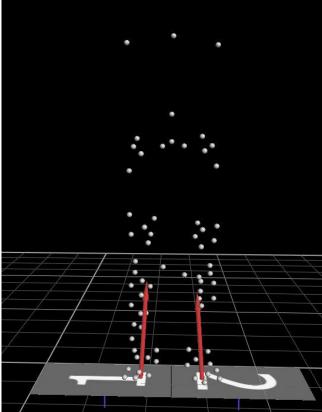


Figure 15: VICON markers unlabeled

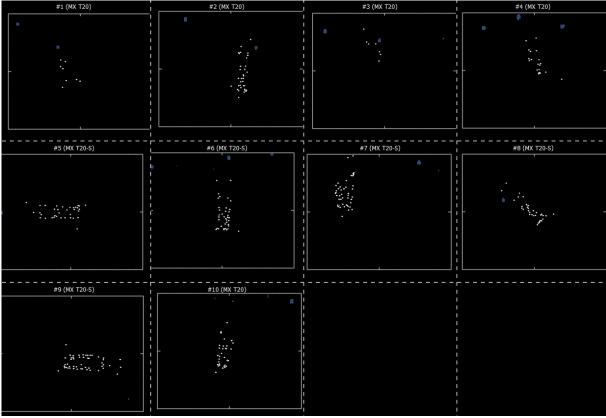


Figure 16: 10 camera cluster

A template containing the segments, joints and names of markers has to be created in the beginning. The purpose of the template is so that markers can be identified and for the trials to follow to be able to be auto labeled by the VICON software.

Using the markers generated by the core processing the template can be defined. Two markers are needed at least to create a segment but then the segment is defined as a line, three markers can create a plane and is recommended. Once all segments are defined, a relevant joint correlation with the neighbor segment is given. The joint can be defined as all types of joint, e.g. hinge joint, free joint. Lastly, each marker identified must be renamed to the corresponding marker name. Now that the template is created and loaded, manually each marker must be identified and labeled to create the skeleton. The next step is to calibrate the static and a functional trial because VICON Nexus has the ability to automatically label trials. Although if the visibility is not that good this feature fails most of the time. More figures of some VICON Nexus skeleton can be find In the Appendix B. When all trials have been labeled, the trajectories and header of all labeled markers are exported to an ASCII file (.csv file). This gives the ability to import them in MATLAB for further processing.

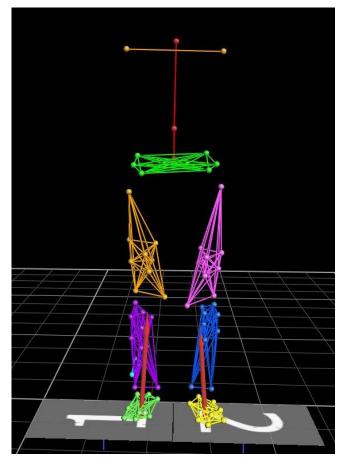


Figure 17: labeled VICON skeleton

MATLAB Processing

In order to calculate the ankle angle, a MATLAB code has been written. To obtain this angle, Helical Axis method was used because Helical method permits a description of body orientation without referring to arbitrary chosen axis of rotation. This means that the segment is free to move without restriction on which rotation comes first (Euler angles). This is practically preferable because the ankle is a complex joint and Helical angle can better decompose the small angle movements.

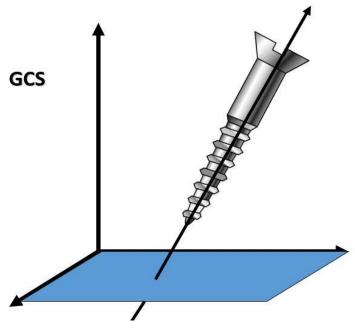


Figure 18: Helical/Screw principle

First, the static file is loaded and a loop to load one by one the UKP files is created. All markers trajectories are extracted from the csv files.

The two segments are then created (Shank and Foot). Different markers set was used for the calculations so that more accuracy is achieved.

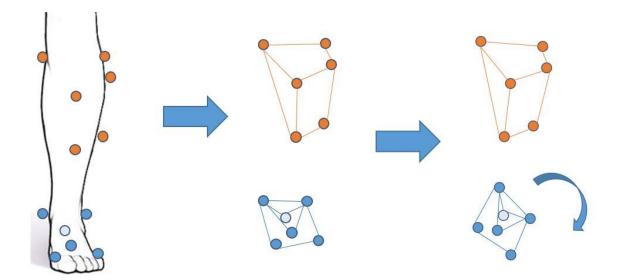


Figure 19: Two segments construction

A set of six, five, four and three markers for each segment was used and compared to find out which set offers the most accuracy. It was found that the set of six, five and four markers had the less error respectively but it was more prone on a marker disappearing during the capturing and so some sections of the produced angle to be completely off.

So, a set of three markers was decided to be used combined with a low pass filter to compensate for some marker shaking.

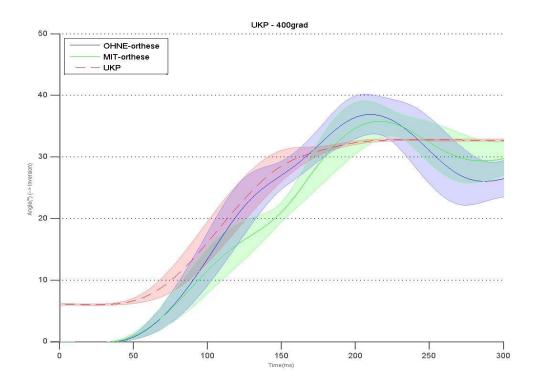
When the calculation of the angle is done, the first derivative is used to get the velocity of the ankle.

The angle is then normalized to zero so that a comparison will be possible. A time frame of 300ms is used because all the movement takes place in that specific time. Because we are using 400Hz, 300ms corresponds to 121 captured frames.

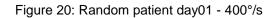
The obtained angles and velocities are stored in a corresponding MATLAB table (.mat) for further use. As the MATLAB code reads the patients file day by day the angles are stored: MIT_orthese_400, OHNE_orthese_400, MIT_orthese_150, OHNE orthese 150.

The data are then exported to an Excel file with an excel tab for each stored above mat file. The mean value and the standard deviation of the five trials is calculated and exported to Excel. A screenshot example can be found in appendix C.

Using MATLAB, graphs can be plot. A function called ShaddedErrorBar is used. This function uses the multiple trials to calculate a mean value and the standard deviation, and creates a 2-d line plot with a shaded error bar using patch.



Comparison of two days results



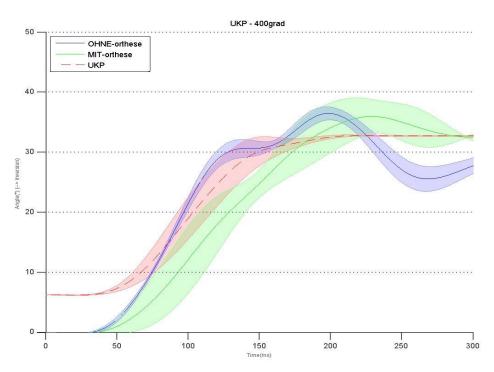


Figure 21: Random patient day02 - 400°/s

Comparing the both figures above, one can see that the blue line that is without orthoses is for both days almost identical and follow the same curve pattern. The only difference that is noticeable is that both lines does not start at the same time (~50ms) causing a small shifting at both lines but the pattern is the same. That is a result expected.

Seeing the green lines, which is with orthoses, some observations can be made.

- Both figures start at the same time (50ms)
- In figure 19 that is day01 we can see that the patient responds much better than day02 (figure 20). For example, at time 150ms, in day01 the angle was at ~20° were in day02 was at ~27°.
- Both graph lines reach a maximum of about 35° but day02 reaches it 50ms after.
- Because of the above, day02 requires more time to settle at a straight line at 30°.

The reason for these differences cannot be given by observing the graphs of only one patient. As this is a double blinded study, we do not know which one is the placebo module (A or B) and which one is the BTG module, and so a complete patient evaluation must be done.

However, by just comparing these graphs one may say that day01, in the above example, is the BTG module because it successfully restricts the ankle movement and lowers the angle significantly in comparison with wearing no orthoses. If this is the case, then it might be successful at restricting the ankle as stated and the hypothesis might be true.

Yet, one can claim that day02 is the BTG module as it still restricts the ankle movement in a significant degree and maybe day01 is the placebo module that acted stiff and thus the significant difference.

Whichever is the case, on the above patient it can be seen that the BTG module worked and that the placebo had an effect. More graphs can be found in Appendix C. Although in some plots it is easy to see the changes induced by the BTG module or the placebo effect, this is not always the case. Moreover, even when a graph shows such a difference this does not mean that there is a statistical significant difference. In order to have a correct comparison and statistical correctly results, a newly way of statistical processing will be used in this assessment, called SPM.

SPM

Statistical Parametric Mapping (SPM) refers to the construction and assessment of spatially extended statistical processes used to test hypotheses about functional imaging data. These ideas have been instantiated in software called SPM. It was developed in Neuroimaging in the mid-1990s, primarily for the analysis of 3D fMRI and PET images, and has recently appeared in Biomechanics for a variety of applications with dataset types ranging from kinematic and force trajectories to plantar pressure distributions and cortical bone thickness fields.⁶

Parametric statistics is a branch of statistics which assumes that sample data comes from a population that follows a probability distribution based on a fixed set of parameters.

Since a parametric model relies on a fixed parameter set, it assumes more about a given population than non-parametric methods do. When the assumptions are correct, parametric methods will produce more accurate and precise estimates than non-parametric methods, i.e. have more statistical power. However, as more is assumed by parametric methods, when the assumptions are not correct they have a greater chance of failing and for this reason are not robust statistical methods.⁷

In this assignment, spm1d going to be used, which is a package for one-dimensional Statistical Parametric Mapping (SPM). Spm1d is an open source program in Python and in MATLAB and uses Random Field Theory expectations regarding smooth, one-dimensional (random) Gaussian fields to make statistical inferences regarding a set of 1D measurements.⁸

5. Results and Discussion

It is still too early to say if the hypotheses that the BTG adapter protects better that the elastic placebo adapter is true or that it protects similarly.

First, the number of patients recruited until this time is low and has a reduced chance of detecting a true effect and so, the likelihood that a statistically significant result reflects a true effect is minimum.

Plotting the graphs, one can see significant angle differences when using the BTG orthoses versus the placebo orthoses or without any. This is not the case for all the patients and it depends from person to person.

Depending on the severity of the injury, the angle curve changes significantly. When wearing the placebo adapter, people with minimum injury on the ankle ligament tend to react better when the UKP is dropping unlike the more heavily injured ones. This is the case for the younger patients that they can react better and for the patients with not so fresh injury and are more used to the injured ligament.

However, even if the graphs show a difference between the two modules that does not mean that there is a statistical difference. This is where SPM is used and its advantage, over SPSS for example, were the two curves are compared point by point but also considering the slope before and after that point and so seeing for a significant difference.

6. References

- 1. https://www.foothealthfacts.org/conditions/chronic-ankle-instability
- 2. http://www.aofas.org/PRC/conditions/Documents/Chronic-ankleinstability.pdf
- 3. http://www.aofas.org/footcaremd/conditions/ailments-of-theankle/Pages/Ankle-Sprain-.aspx
- 4. http://betterguards.de/en/
- 5. https://www.vicon.com/products/software/nexus
- 6. Pataky T, Vanrenterghem J, Robinson M, *Statistical Parametric Mapping: theory, software and future directions,* 2016
- 7. https://en.wikipedia.org/wiki/Parametric_statistics
- 8. http://www.spm1d.org/

7. Appendices Appendix A – Employer & Supervisor description

Employer description

The Julius Wolff Institute is within the university structure of the Charité – Universitätsmedizin Berlin and is a merger of the research laboratory of the Center of Musculoskeletal Surgery of the Charité (CMSC) and the Clinical Biomechanics Laboratory of the Charité. The institute is headed by Prof. Dr. Georg Duda and his deputy, Prof. Dr. Georg Bergmann and it brings together national and international scientists from different areas of musculoskeletal research. In order to translate their findings into practice, they tightly collaborate with the Center for Musculoskeletal Surgery (CMSC), further clinical departments of the Charité Hospital, and with national and international partners from industry as well as science. The main goal of the Institute is to be able to develop new therapies and products for accelerating healing processes, through a better understanding of biological processes during healing.

Supervisor description

Dr.-Ing. Alison Agres - Principal Investigator

Dr. Agres is currently Postdoctoral Researcher with expertise in Bioengineering. She is also a Principal Investigator in quite a few ongoing projects at J.W Institute, including the one I participated. She has been a great mentor during my stay in Berlin, and has helped me to evolve in the field of musculoskeletal research.



Appendix B: VICON screenshots – Patient with markers

Figure 22: Patient standing on UKP when platform dropped

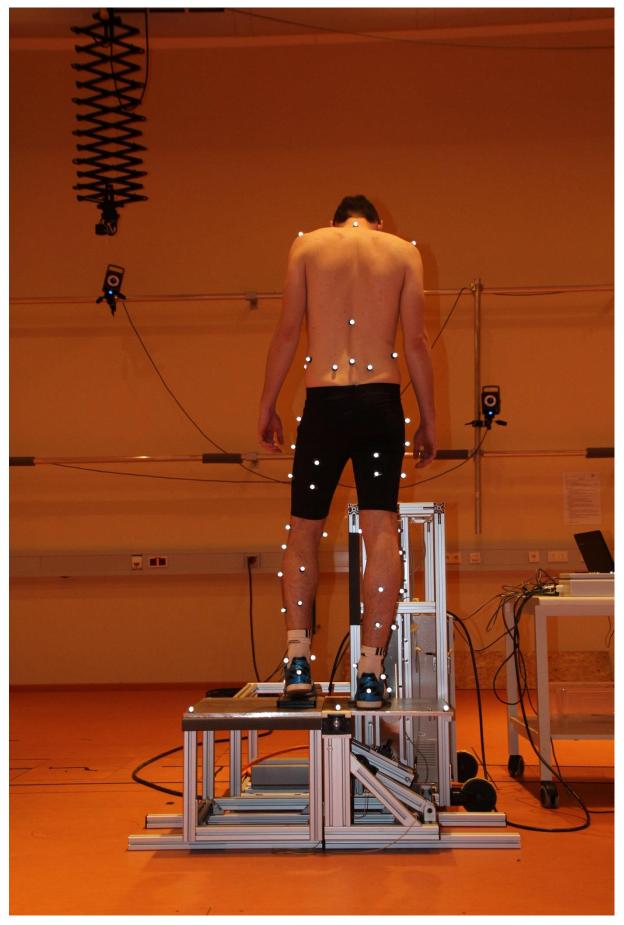


Figure 23: Patient standing on UKP before platform dropped

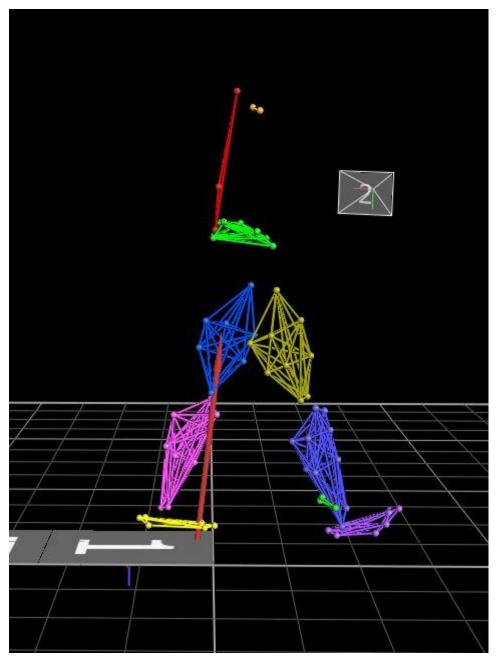


Figure 24: Walking trial screenshot - VICON Nexus

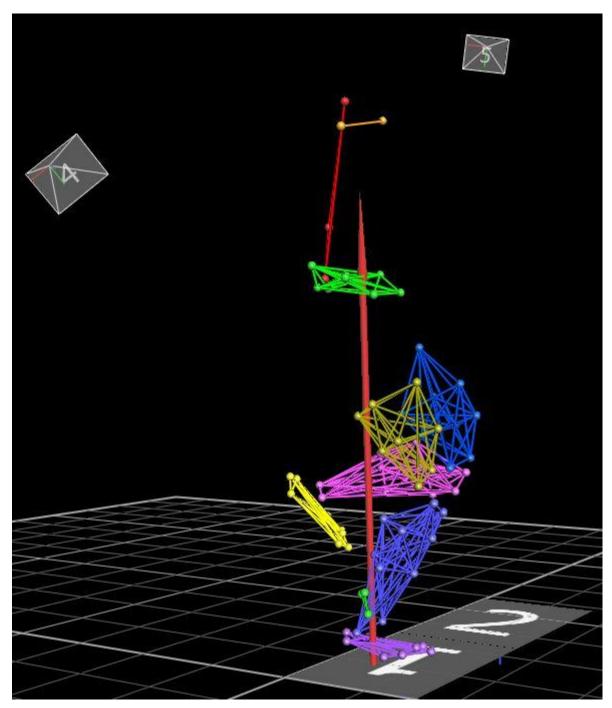


Figure 25: One leg jump trial screenshot – VICON Nexus

Appendix C – MATLAB data

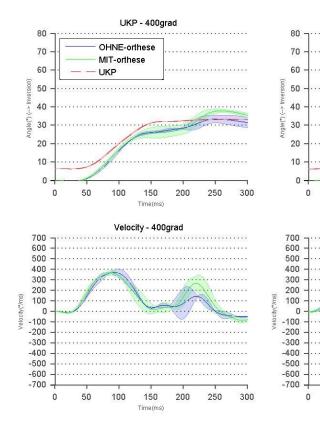
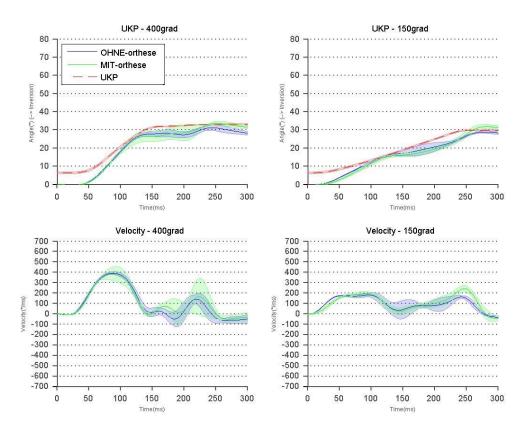


Figure 26: BTG_05 patient - Day01 graphs



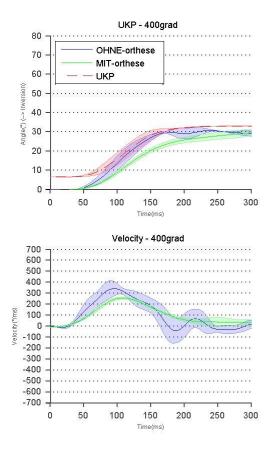
UKP - 150grad

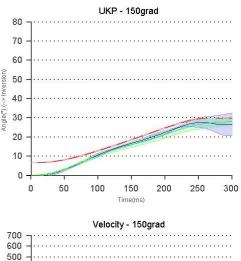
Time(ms)

Time(ms)

Velocity - 150grad

Figure 27: BTG_05 patient - Day02 graphs





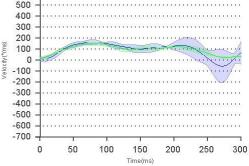


Figure 28: BTG_03 patient - Day01 graphs

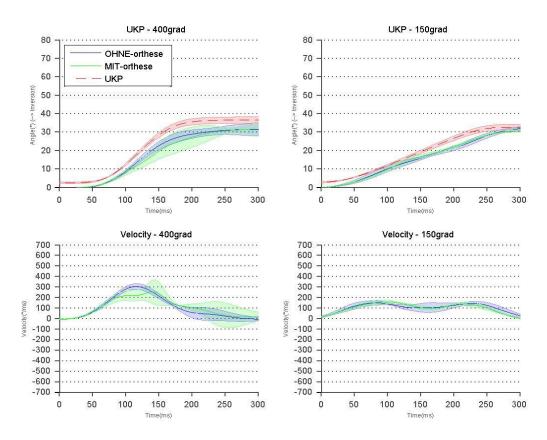


Figure 26: BTG_03 patient - Day02 graphs

Uddal <th< th=""><th>MeanValue StandardDev</th><th></th><th>17</th><th></th><th>marke</th><th>markersUsed</th><th></th><th></th></th<>	MeanValue StandardDev		17		marke	markersUsed		
6.15902252	0 0	0 7,40394	uata('/s) 7,40394788 -19,6325944 -19,1254132 -9,10832976 -22,6595343	-9,10832976 -22,6595343	Shank	LCAFI	LLMA	LMMA
DITUDICE OF	0,03156096 0,03076065	2,5 7,871	7,87143425 -23,3626763 -23,0000901 -12,159018 -26,7122233	-12,159018 -26,7122233	Foot	LHFM	LTOE05	LHEEL
5 -0,03818846 0,10748818 0,10531376 0,05316837 0,12342939 6,17455266 0,07	0,07024225 0,0661341	5 7,56/	7,56402118 -27,4076388 -27,2499843 -15,5421833 -31,1004397	-15,5421833 -31,1004397	UKP	UKP_Static	c UKP_Medial UKP_Lateral	UKP_Lateral
0,09202383 0,20118049 6,19341413 0,11	0,11711036 0,10569719	7,5 6,231	6,23184963 -31,7635442 -31,8707622 -19,2639825 -35,8152557	-19,2639825 -35,8152557				
0,14018378 0,29071863 6,21618053 0,17	0,17335121 0,14874697	10 3,637	3,63799983 -36,4209718 -36,8509367 -23,3254974 -40,8412964	-23,3254974 -40,8412964				
0,19849753 0,39282187 6,24347952 0,24	0,24025156 0,19431048	12,5 -0,419	-0,41982982 -41,364589 -42,1714923	-41,364589 -42,1714923 -27,7219878 -46,1564437				
0,2678025 0,50821298 6,275984 0,31	0,31916873 0,24117864	15 -6,087	-6,08717547 -46,572911 -47,8057649 -32,4422884 -51,7317994	-32,4422884 -51,7317994				
0,34890822 0,63754248 6,31440232 0,4	0,4114887 0,28796503	17,5 -13,4	17,5 -13,4327549 -52,0182899 -53,7196043 -37,4684113 -57,5319447	-37,4684113 -57,5319447				
0,44257925 0,78137234 6,3594674 0,5	0,5185742 0,33318765	20 -22,4	20 -22,4334331 -57,667167 -59,8718382 -42,7754048	-42,7754048 -63,51551				
0,54951776 0,94016112 6,41192431 0,64	0,64170588 0,3753683	22,5 -32,91	22,5 -32,9669381 -63,4806047 -66,2150388 -48,3315105 -69,6360506	-48,3315105 -69,6360506				
0,67034653 1,11425124 6,4725152 0,78	0,78202095 0,41314147	25 -44,81	-44,8141551 -69,4150975 -72,6965776	-54,098641 -75,8432004				
0,80559314 1,30385925 6,5419603 0,94	0,94045479 0,44536221	27,5 -57,67	-57,6713051 -75,4236387 -79,2599352	-60,033179 -82,0840514				
0,95567608 1,50906937 6,62093417 1,11	1,11769084 0,47120228	30 -71,1705054		-81,457 -85,8462151 -66,0870734 -88,3046917				
1,12089377 1,7298311 6,71003729 1,31	1,31412358 0,49022488	32,5 -84,5	32,5 -84,905716 -87,4651597 -92,3957955 -72,209183 -94,4518174	-72,209183 -94,4518174				
1,30141673 1,96596065 6,80976508 1,52	1,52983742 0,50243108	35 -98,46	-98,4605156 -93,3987992 -98,8500403 -78,3467991	-78,3467991 -100,47433				
1,49728372 2,21714647 6,92047784 1,76	1,76460266 0,50827381	37,5 -111,4	37,5 -111,434693 -99,2107777 -105,152981 -84,4472595	-84,4472595 -106,32483				
1,70840187 2,48295855 7,04237656 2,01	2,01788793 0,50863682	40 -123,4	-123,467861 -104,857491 -111,252876 -90,4595617 -111,960929	-90,4595617 -111,960929				
1,93455078 2,76286087 7,17548932 2,28	2,28888729 0,50477593	42,5 -134,2	-134,259356 -110,300026 -117,103563 -96,3358796 -117,346304	-96,3358796 -117,346304				
2,17539047 3,05622663 7,31967146 2,57	2,57655986 0,49821925	45 -143,5	-143,583993 -115,505046 -122,665521 -102,032899 -122,451458	-102,032899 -122,451458				
3,23276107 2,43047272 3,36235527 7,47462028 2,87	2,87967931 0,4906243	47,5 -151,	47,5 -151,302809 -120,445337 -127,906589 -107,512897 -127,254147	-107,512897 -127,254147				
2,65925447 3,3929234 3,55252754 2,69925496 3,68049064 7,63990259 3,1	3,1968902 0,48359832	50 -157,	50 -157,367718 -125,100017 -132,802303 -112,744516 -131,73946	-112,744516 -131,73946				
2,98111625 4,00983929 7,81499076 3,52	3,52676721 0,47850345	52,5 -161,4	52,5 -161,819556 -129,454395 -137,335844 -117,703202 -135,899584	-117,703202 -135,899584				
3,27537426 4,34958825 7,99930233 3,8	3,8678735 0,47628765	55 -	-164,78 -133,499527 -141,497642	-122,37129 -139,733262				
3,58130248 4,69892141 8,19223736 4,21	4,21881436 0,47739019	57,5 -166,4	57,5 -166,438601 -137,231519 -145,284652 -126,737767 -143,245006	-126,737767 -143,245006				
3,8981469 5,05703392 8,39320931 4,57	4,57828313 0,48175384	60 -167,0	-167,036315 -140,650671 -148,699423 -130,797738 -146,444125	-130,797738 -146,444125				
4,22514124 5,42314424 8,60166641 4,94	4,94509727 0,48893649	62,5 -166,1	62,5 -166,846972 -143,760534 -151,749006 -134,551652 -149,343633	-134,551652 -149,343633				
5,69594972 4,56152038 5,79650332 8,81710291 5,31	5,31822317 0,49827684	65 -166,	65 -166,158165 -146,566973 -154,443821 -138,00436 -151,959105	-138,00436 -151,959105				
4,90653128 6,17640108 9,03906138 5,69	5,69678938 0,50905709	67,5 -165,2	67,5 -165,252664 -149,077318 -156,79656 -141,164074 -154,307565	-141,164074 -154,307565				
5,25944146 6,56216999 9,26712856 6,08	6,08008847 0,52062203	70 -164,3	-164,390529 -151,299656 -158,821211 -144,041312 -156,406448	-144,041312 -156,406448				
5,61954474 6,95318611 9,50092783 6,46	6,46756805 0,53244144	72,5 -163,7	-163,791599 -153,242311 -160,532258 -146,647911 -158,272703	-146,647911 -158,272703				
5,98616452 7,34886787 9,74011123 6,85	6,85881144 0,54412427	75 -163,6	-163,618874 -154,913526 -161,944106 -148,996151 -159,922075	-148,996151 -159,922075				
6,3586549 7,74867306 9,98435299 7,25	7,25350881 0,5554027	77,5 -163,	77,5 -163,965194 -156,321345 -163,070739 -151,098052 -161,368583	-151,098052 -161,368583				
7,58791994 7,69571788 8,08497146 6,73640003 8,15209451 10,2333457 7,65	7,65142076 0,56610466	80 -164	-164,84673 -157,473678 -163,92562 -152,964875 -162,624215	-152,964875 -162,624215				
7,11881221 8,55865505 10,4867988 8,05	8,05233832 0,57612853	82,5 -166	-166,20595 -158,378513 -164,521795 -154,606813 -163,698838	-154,606813 -163,698838				
7 50522997/ 8 96790215 10 7AAA297 8 A5	R ASKAAADS D SSADASA S	85 -167 1	25 .167 Q74187 .159 DA717 .164 877151 .156 D37882 .154 60091	19C003 A31 156 037891				

Figure 29: Screenshot of the data exported to Excel