Design, construction and validation of a knee brace angle measuring device for online monitoring

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Synopsis:

The purpose of this study was to develop a product that could measure the knee angle during rehabilitation exercises. A product was created with a PolyPower stretch sensor placed on a silicone block that was attached to a CTi OTS knee brace. The stretch sensor provides a capacitance value that is proportional to the amount of stretch.

The product was tested in both static and dynamic movements. Three dynamic tests were performed, the first test consisted of five repeated squats, the second of five repeated lunges and the third test was a two times five minutes run on a treadmill, first with shorts on and second with pants on. The pants were worn to see if the device got affected by temperature and friction.

A high correlation between the capacitance and knee angle was found in the calibration. The results showed that the developed product has the potential to be used in knee angle measurements low dynamic movements. However, some unforeseen technical problem occurred which require further refinement. As soon as these refinements are in place the results produced by the product have to be compared to accurate reference methods.

Preface

This master thesis project has been completed by group 14gr1045 in relation to the master program Sports Technology at Aalborg University. The project has been developed from the 1st of February to the 2nd of June 2014. The project consists of an article and a worksheet part, which is an additional background for completing the article. This thesis has been made in cooperation with Danfoss PolyPower A/S, which has sponsored the needed stretch sensors.

We want to take the opportunity to thank a group of people that have been helpful with the development of the product and preparation of the project. First, we want to thank Danfoss PolyPower A/S and Alan Poole, for sponsoring the stretch sensors and supervision on the use of the sensors and Össur for sponsoring the knee braces. Next, we want to thank Kristian Rauhe Harreby for supervision on the use of silicone. We want to thank Bo Kristensen for helping with the construction of the product and testing and Gísli Lárusson for helping with the construction of the product. Last but not least, we want to thank Uwe Kersting and Mark de Zee for being our supervisors during the projects preparation.

A really big thank to all of you.

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Karina Kogut Toft Thomsen and Stefanía Júlíusdóttir
Aalborg University

2nd of June 2014

Abstract

The purpose of this study was to develop a product that could measure the knee angle during rehabilitation exercises. A product was created with a PolyPower stretch sensor placed on a silicone block that was attached to a CTi OTS knee brace. The stretch sensor provides a capacitance value that is proportional to the amount of stretch.

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A high correlation between the capacitance and knee angle was found in the calibration. The results showed that the developed product has the potential to be used in knee angle measurements low dynamic movements. However, some unforeseen technical problem occurred which require further refinement. As soon as these refinements are in place the results produced by the product have to be compared to accurate reference methods.

Keywords: DEAP stretch sensor, silicone, rehabilitation, dynamic movements.

Introduction

In Europe, playing sports or participating in some kind of physical activity is a common way to spend spare time. For example 30-40% of the population (age group 4-50 years) in the Netherlands and 56% of people over 16 years old in Denmark participate in some physical activity in their spare time (Pilgaard 2008, Dekker et al. 2000).

There are numerous benefits from being physically active; the overall physical fitness increases, the risk of diseases like obesity and diabetes decreases, and there are positive psychological and social effects (Dekker et al. 2000, Schneider et al. 2006).

Despite of these benefits there is also one big disadvantage; the injury risk. Injuries caused by sport participation rate second after home and leisure accidents in the cause of injuries (Schneider et al. 2006, Dekker et al. 2000, Damm, Laursen 2012). One of the most common sports injuries are knee injuries and they can account for up to 15-50% of the total amount of injuries. The risk varies between different sports but the risk is greatest in sports that include cutting movements and landing (Houck 2003, deLöes, Thomée & Dahlstedt 2000). In Denmark knee injuries account for 18% of soccer injuries, 13% of handball injuries, 16% of badminton injuries, 10% of gymnastics injuries and 6% of basketball injuries (Damm, Laursen 2012). The Anterior cruciate ligament (ACL) is especially vulnerable to injuries and every year it is expected that 22% of all knee injuries in females at the American collegiate level are ACL injuries (Bowerman et al. 2006). The recovery time after an ACL injury is often quite long. A study by Engstrom et al. (1991) showed that athletes need approximately 74 days of recovering before they start to train again after an ACL injury. The same study also showed that after ACL reconstruction athletes spend around 239 days in rehabilitation (Engström, Johansson & Törnkvist 1991).

The goal of rehabilitation is to get the patient to reach his former physical abilities. That is achieved by enhancing the recovery of the injured body part and to increase the range of motion and muscle strength. The rehabilitation is usually controlled by a physiotherapist and takes place at a private clinic or at a hospital (Porter 2008). Physiotherapists use different methods in the rehabilitation process; manual therapy such as massage, electrophysical devices such as ultrasound, thermotherapy such as heat or ice packs, and graded exercises. These methods can be used independently or together (Fransen 2004). In addition to these methods numbers of devices such as knee braces have been developed to minimize the detrimental effects of injuries (Baltaci et al. 2011).

During rehabilitation after a knee injury the exercises are assigned to a patient from the physiotherapist, which will result in increased muscle strength, improved motor control and joint stability (Hodges et al. 2007, Porter 2008). The exercises are first performed with supervision from the physiotherapist and later on in the rehabilitation process these exercises are performed at home without any supervision, which increases the risk of performing the exercises incorrectly. Incorrectly performed exercises can result in a longer rehabilitation period and can even cause damage instead of positive progression (Porter 2008). If the patient would have access to some kind of a feedback system which could give feedback right away while doing the exercises at home it could minimize the risk of performing the exercises incorrectly and thereby shorten the rehabilitation time. This feedback system should allow the patient to monitor the knee angle during the rehabilitation exercises (Hodges et al. 2007). Today a number of methods, like goniometer, video analysis, motion capture system and inertial measurement unit (IMU) sensors, can be used to measure the knee angle during physical activity. However, these different methods have some flaws, restrictions and disadvantages. The goniometer can be very hard to align with the joint and the alignment can vary over time during the movement. The video analysis requires some process of the video before the patient gets the feedback, like referencing to a background coordinate system or marking of the segments, so the calculations can be made. These manual inputs can be difficult to make and they can be inaccurate. The system is also expensive and it takes time to set it up. The IMU sensors consist of an accelerometer and a gyroscope. These sensors are strapped around body segments, and to calculate the joint angle, sensors are needed on the segments that are connected in a joint. For example for the knee angle, sensors need to be placed on the thigh and the lower leg. When the accelerometer and gyroscope are placed together in one sensor, the weight of the sensor is high compared to sensors which only consist of one of these components. The increased mass of a sensor could result in different movement of the sensor than the actual body segment movement due to inertia, and can thereby result in inaccurate measurements (Winter 2009).

When combining the advantages from the existing methods an optimal method to measure the knee angle could be developed. This optimal method should be accurate, like the motion capture system, easy in use both the set-up and the feedback system, like IMU sensors, cheap, like the goniometer, usable in all environments and situations, like IMU sensors, light weighted, durable, robust and comfortable.

Recently a new sensor technology from Danfoss Polypower A/S has become available. This is the Dielectric Electro Active Polymers (DEAP) sensor technology. The DEAP sensors are light weighted, small and easy to combine with different materials and equipment. The sensors only have one output signal which makes this technology a good option to be used in a feedback system. In this paper a new method for measuring knee angle during rehabilitation is proposed by using a combination of DEAP sensors and knee braces. By incorporating the sensor into the brace it is easier to place the product accurately at the same place on the knee every time compared to placing the sensor directly on the skin.

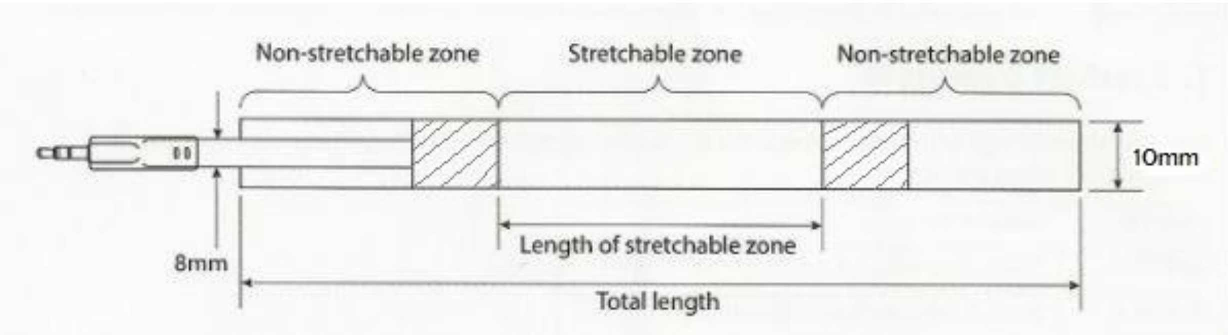

Figure 1. The stretch sensor used in this study consists of five different parts. The length of the stretchable zone is 50 mm and the total length of the sensor is 200 mm. The two shaded zones represent the non-attachment zones (adapted fromPolyPower 2012c).

Sensor structure and measurement principle

The DEAP sensor consists of five different parts: a stretchable zone, two non-stretchable zones, a cable and a jack plug (figure 1). To collect the signal from the sensor, the sensor comes with a wireless controller, a computer program and a mobile app (PolyPower 2012c).

The stretchable zone measures the capacitance change and it is extremely flexible due to the combination and properties of the materials (PolyPower 2012a). The two non-stretchable zones consist of two parts; the non-attachment zone and the attachments zone (figure 1). The non-attachment zone, shaded on figure 1, lies between the stretchable zone and the attachment zone. Like the name indicates, nothing should be attached to this zone to avoid potential damage. The attachment zone is positioned at each end of the sensor and consists of a non-woven textile. As the name indicates this zone is used to attach the sensor to different surfaces by sewing, taping, stamping or gluing. The cable is attached to one of the non-attachable zone and the jack plug at the other end. The cable is made of a flexible textile, is 230mm long and transfers the signal from the stretchable zone to the wireless controller (PolyPower 2012c).

The stretchable zone has a complex structure that consists of two layers of dielectric silicon material, with a corrugated surface, surrounded by a thin layer of elastomeric film with silver electrodes. In the middle of the sensor and on the outer sides of the electrodes there are layers of silicon conductor. The silicon conductor holds the sensor together and protects the electrodes from physical contact that could influence the electrical circuit (PolyPower 2012a).
The dielectric silicon material works as a capacitor, which changes its capacitance when the polymer gets deformed. This deformation, a decrease in thickness and an increase in area of the material, occurs when a mechanical force is applied and results in a higher capacitance. The correlation between the capacitance and the deformation of the material can be seen in equation 1.

$$\boldsymbol{C = \varepsilon_r \varepsilon_0 \frac{A}{d}} \qquad (1)$$

In equation 1, C is the capacitance in Farads, ε_r is the relative static permittivity of the material, ε_0 is the electric constant, A is the area in square meters and d is the thickness of the material in meters (PolyPower 2012a). The capacitance measured by the sensor should be in proportion to the amount of stretch of the sensor (PolyPower 2012b).

Due to the corrugated surface of the dielectric material and the stiffness of the elastomer film, the sensor can only elongates in the length direction (PolyPower 2012a). The stretchable zone of the sensor can handle up to 80% stretch (PolyPower 2012b).

Proposed design

The product was developed based on pros and cons of existing products. The goal was to design a product that measures the knee angle in all environments and situations. This product should be easy to put on and use, cheap, small, light weighted, strong and comfortable.

Based on the aims for the product, a design where a DEAP sensor was placed on top of a silicone block which was attached to a CTi OTS knee brace was developed. By placing the sensor on the knee brace the sensor gets bent and stretched when the knee is flexed, following the deformation of the mechanism. This stretch of the sensor causes the capacitance to increase. This design was considered to give a more reliable results compared to other designs and fulfil the predetermined aims. The final prototype can be seen on figure 2.

Figure 2. The final prototype.

Calibration

To get the correlation between the capacitance and the knee angle, a calibration was performed. The calibration was carried out by placing the subject's knee in six different static positions while the capacitance was recorded at 100 Hz with the PolyPower Wireless Sensor Controller program. The six different positions were at 20°, 40°, 60°, 80°, 100° and 120° knee flexion, measured with a goniometer.

The results from the calibration (table 1) show a higher correlation (R^2-value of 0.9913) between the capacitance and the knee flexion angle with a second order polynomial (figure 4) compared to the linear regression (R^2-value of 0.98) (figure 3). Due to a higher correlation, the second order polynomial regression was chosen for knee angle calculations in this study by the use of the following formula:

$$y = 12327x^2 - 10585x + 2243.9$$

Where y is the angle in degrees and x is the capacitance in nF.

Testing

Dynamic tests

Knowing the correlation between the capacity and knee angle the sensors ability to work during dynamic movements was tested in three different movements. In the first dynamic movement test, the capacitance was recorded while the subject performed five squats, going down to 90° of flexion and in the second test the subject performed five lunges. In the third test the subject ran two times 5 minutes on a treadmill with a velocity of 7.5 km/h, first wearing shorts and then wearing pants, while the capacitance was recorded. The pants were worn to see if the product would be affected by a higher temperature or friction, caused by the pants.

Creep test

After the dynamic test, a creep test was performed where the capacitance was measured both with no flexion and with maximum flexion of the product. Next the product was fixed in a position with maximum flexion for three days and then the measurements were performed again.

Results

Dynamic test

The results from the squat test (figure 5) show a consistent maximum knee flexion angle ranging from 71-73 degrees.
The maximum knee flexion angles in the lunge test are also consistent with values ranging from 77-84 degrees. Each lunge consists of three peaks, a small one- big one and a small one again (figure 6).

The running test, in shorts, results show a running pattern with a double knee bending per step both in the beginning and at the end of the run. However, the maximum peak values are decreased by approximately 70% from the beginning to the end of the run (figure 7 and 8). The results from the running test where the subject wore pants also show the running pattern both in the beginning and the end (figure 9 and 10). At the end of the run the pattern gets a little more inconsistent compared to the beginning (figure 10). The maximum knee angle decreases around 65% from the beginning to the end.

Creep test

The creep test results show a 130° difference, between the neutral position and the maximum bending, the first day. After three days the difference had decreased to 92° (table 2).

Table 1. The results from the calibration.

Capacitance [nF]	0.491	0.507	0.513	0.523	0.530	0.540
Angle [degrees]	20	40	60	80	100	120

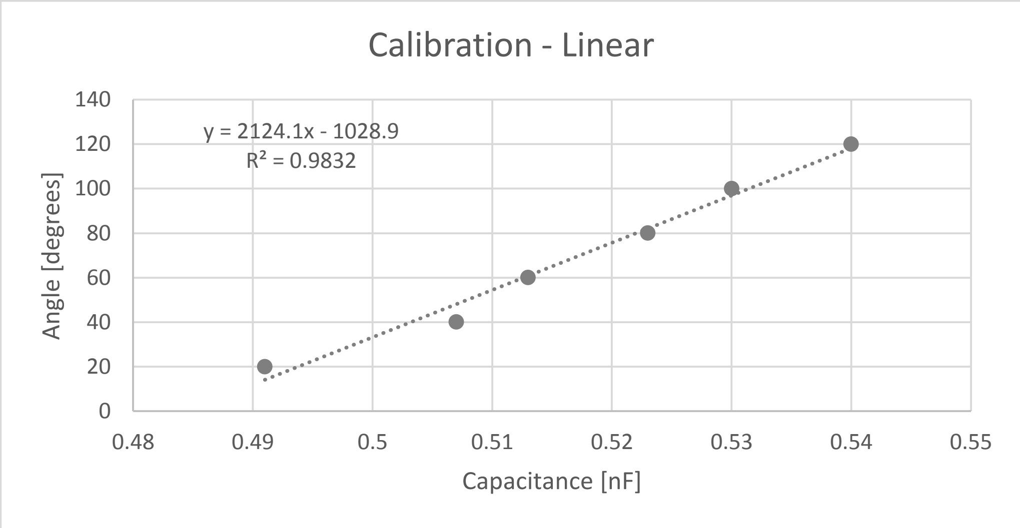

Figure 3. The correlation between the capacitance and the knee angle described with a linear regression.

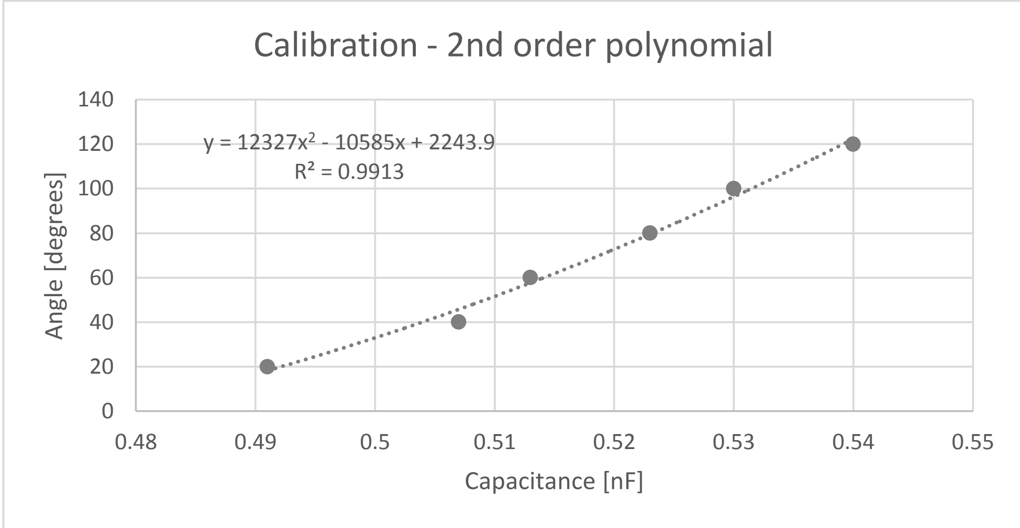

Figure 4. The correlation between the capacitance and knee angle described with a second order polynomial.

Figure 5. The results from the squat test shown graphically.

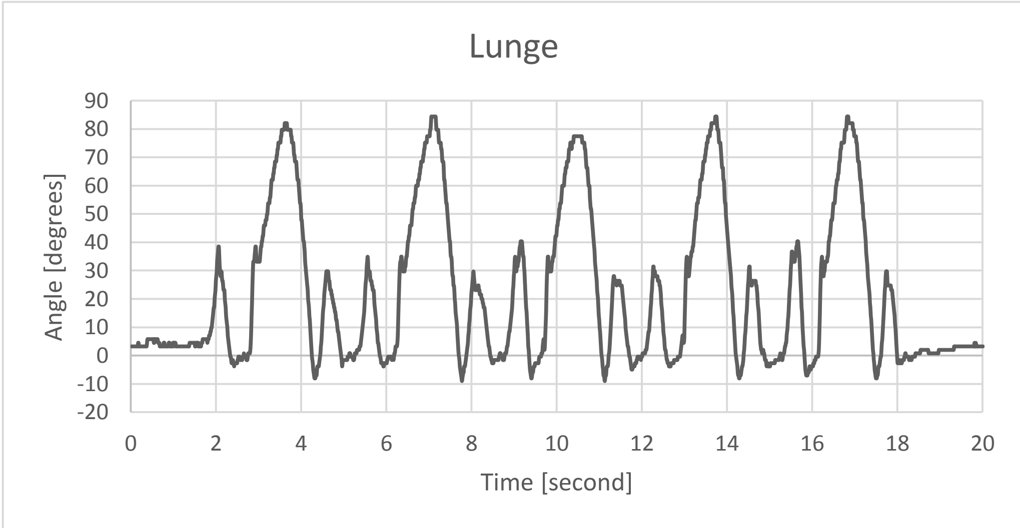

Figure 6. The results from the lunge test shown graphically.

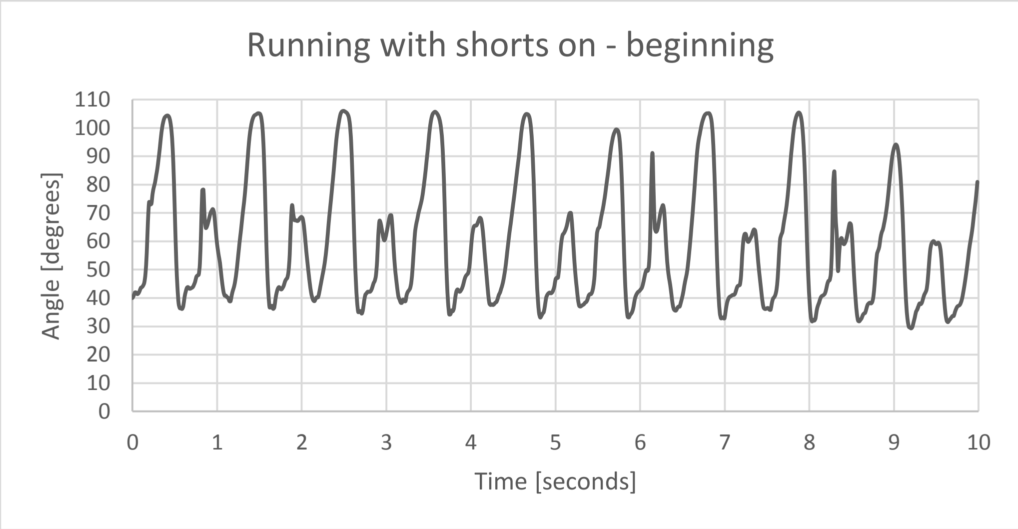

Figure 7. The results from the beginning of the running test with shorts on shown graphically.

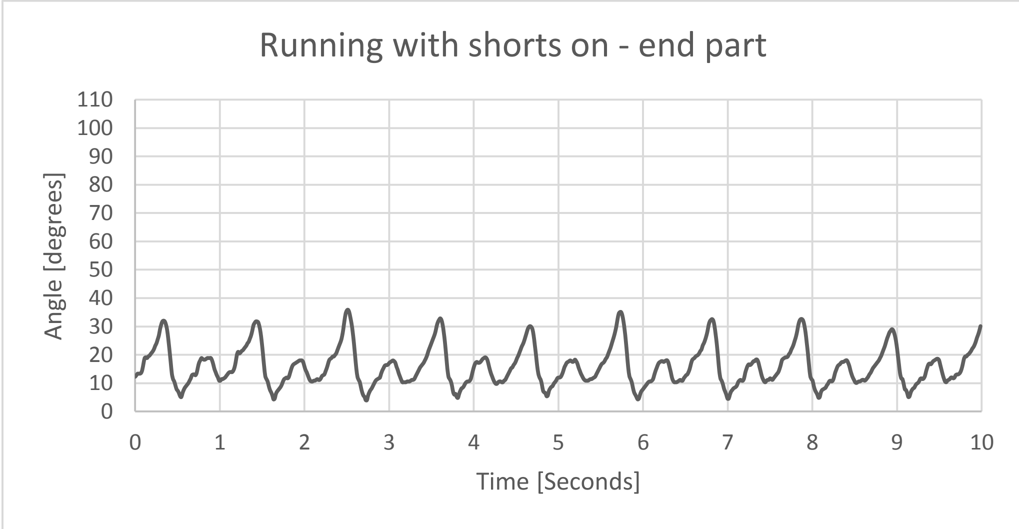

Figure 8. The results from the end of the running with shorts on shown graphically.

Figure 9. The results from the beginning of the running test with pants on shown graphically.

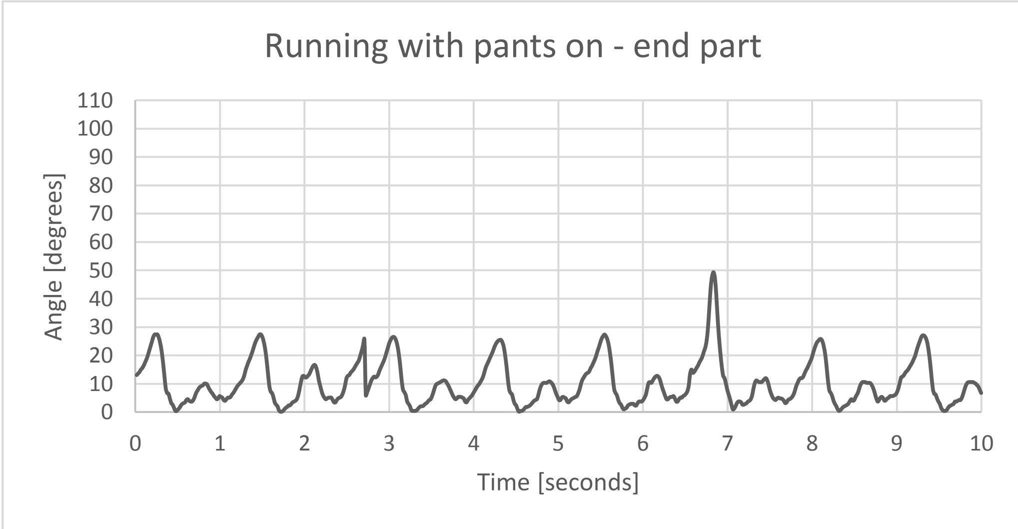

Figure 10. The results from the end part of the running test with pants on shown graphically.

Table 2. The results from the creep test.

	First day	After 3 days
0 degrees [degrees]	5	23
Maximum flexion [degrees]	135	115
Difference [degrees]	130	92

Discussion

In this study a product has been developed to measure the knee angle, to provide patients with ACL injuries feedback during rehabilitation exercises.

The results from the calibration show a good correlation between the capacitance and the knee angle, which means that the capacitance gets higher with an increased knee flexion angle. This correlation is described with a second order polynomial with an R^2-value 0.9913. It seems like the bending of the sensor is causing a non-linearity in the correlation, between the capacitance and the stretch of the sensor, since this relationship is better described with a second order polynomial than with a linear regression.

The creep test showed a 29% decrease in the range between the first and the second measurement, performed three days apart. These results indicate that the sensor got affected by being placed in an extreme flexion for three days. During the creep test a slipping of the sensor was observed. The displacement of the sensor most likely affected the results in the second set of measurements in the creep test. To avoid this slipping the attachment of the sensor to the silicone needs to be improved. Based on these results it should be recommended that the product is not left in an extreme position.

The results from the dynamic tests showed that the product can register consistent angles in low dynamic movements as squats and lunges. When looking at the results from the squat test it can be seen that the maximum knee flexion angles measured with the product and the goniometer are not equal. With the goniometer the angle was 90° while the product only measured a 70° flexion. However, the maximum angles recorded in the lunge test are approximately 80° which is possible in a lunge. By comparing these results it can be speculated that the goniometer measurement in the squat test was not accurate enough.
In the squat test the recorded movement only displayed the actual movement of the knee while in the lunge test, some additional peaks were displayed. By analysing the timing of the additional peaks it can be speculated that they are caused by impact at landing. By looking at the pattern in the beginning of the running, with shorts on, some additional peaks are also displayed. The timing of the additional peaks also fit to where initial ground contact occurs. At the end of the run, with the shorts on, these additional peaks are not displayed. These additional peaks in the beginning of the first run, with shorts on, were not displayed as clearly in the beginning of the second run, with pants on. Thereby it can be speculated that the pants minimize the influence on the signal from the product at ground impact.
By comparing the maximum knee angles from the beginning to the end a decrease around 70° was seen in the running with shorts on and a decrease around 45° in the running with pants on. A part of this decrease could be explained by a creep of the sensor. However the creep test only showed a 29% decrease over three days while the maximum values in the running decrease 70% and 65% over 5 minutes. Thereby, other factors such as low durability of the sensor and a changed running style, caused by fatigue of the subject, could have caused a decrease of the maximum knee angle. According to PolyPower the sensors are durable but they do not state any concrete values that define the durability.

To fully understand why there is a difference in the measured angle in the squat test, why the additional peaks occur in the lunge and the running tests and why the maximum angle decreases over time in the running tests, more accurate tests like motion capture and high speed video are needed.

Are the aims for the product fulfilled?

In the beginning of the design process the aim was to develop a product that measures knee angles by using a combination of DEAP sensor and a knee brace. The product was supposed to be usable in all environments and situations, easy to put on and use, comfortable, small and light weighted, strong and cheap.

The final product can be used both inside and outside and is not restricted to a lab or a room with a controlled light. As the results showed the product measures the knee angle in low dynamic movements. The product is easy to put on, comfortable and can easily be placed correctly due to the design of the knee brace. The final product weighs around 850g (brace 700g, silicone block with sensor 100g, the wireless controller 50g) and does not restrict the patients mobility more than what the brace is designed to do. The strength of the product has not been tested yet due to various reasons but that is needed before the product makes it out to the market. Compared to other existing products on the market, like motion capture and IMU sensors, this one is cheaper.

A few specific groups could benefit from a product like this, for example patients in rehabilitation and physiotherapists. Patients in rehabilitation would have the possibility of performing their rehabilitation exercises at home, without being observed of the physiotherapist. A feedback system could help them perform the exercises correctly instead of perform them incorrectly and thereby not slow down the rehabilitation process. By performing the rehabilitation at home, patients save money and time and are able to do the exercises at any time. This feedback system, that tells the patient when he goes too far down in a squat, might help the patient to get a better motion control of the body again.

By having this device, which makes patients able to perform their rehabilitation exercises correctly at home, physiotherapists could be treating more patients at each time and be confident that the exercises are performed correctly at home. However, even though this product has the potential of telling patients if they go too far down in for example a squat or not far enough it does not guarantee that the exercise will be performed correctly. The technique in the exercise could still be wrong even if the program cannot detect any error in the knee angle. For example the product cannot know if the knees are aligned with the toes, which is a common guideline for executing such exercises. So, deviations from anatomical alignments outside the measuring direction of the system cannot be quantified.

Perspective and future development

During this development some problems came up in connection with the PolyPower Wireless Sensor Controller program. The connection between the product and the computer program got lost often, even if the product was placed just beside the computer. This disadvantage has to be resolved in order to use the product in an efficient way.
To make the program and the app more user friendly it should be able to display the change in angle in degrees instead of the capacitance.

Further development of the program could include that the program would be able to release a warning sound to let the patient know if he goes further down than he should. It would also improve the product and make it useable in more situations if the app was able to record data. If this was possible the product could possibly be used in various sports where live feedback is not possible.

It is not only in rehabilitation where it is important to be able to observe the knee angle. In many different sports such as handball, volleyball, running, basketball and skiing the position of the knee is important in relation to landing and performance. Researchers could also be interested in these kind of a product where measurements could be done out on a field in real situations instead of inside of a lab.

The use of the product in different sports could well be possible in the future based on the results from the dynamic tests. Before this is possible the sensor needs some improvements, especially the durability, and further testing to validate the product.

Conclusion

The aim of this study was to develop a product that could measure the knee angle by combining a DEAP sensor and a knee brace during rehabilitation exercises. The results showed that the developed product has the potential to be used in knee angle measurements in low dynamic movements. However, some unforeseen technical problem occurred which require further refinement. As soon as these refinements are in place the results produced by the product have to be compared to accurate reference methods.

Acknowledgements

This study was made in cooperation with Danfoss PolyPower A/S and the knee braces used were provided by Össur.

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Worksheets

These worksheets are meant as additional reading for the background used to complete the article. The worksheets should not be considered as an independent report.

Contents

The Knee 1

1.1 The structure of the knee

The knee is the largest mobility joint in the human body. The function of the knee joint is to transfer weight from femur to tibia, which causes the knee joint to be exposed for the greatest mechanical impact compared to other joints. During static load, the forces on the knee joint can be 300-400 kg (Bojsen-Møller 2005, Martini, Nath 2009).

The knee joint consists of three bones, femur, patella and tibia, with three separate articulations: between the medial femur condyle and the medial tibia condyle, the lateral femur condyle and the lateral tibia condyle, and one between the patella and femur on the patella surface. The two first mentioned articulations contain a medial and lateral meniscus (figure 1.2), which act as cushion and can conform to shape of the articulating surface when the femur changes position. The joint is stabilized by manly seven ligaments: patellar ligament (figure 1.1), two popliteal ligaments, anterior cruciate ligament, posterior cruciate ligament, tibia collateral ligament and fibular collateral ligament (see figure 1.2 for location) (Martini, Nath 2009).

The knee is a complex hinge joint, which permits flexion, extension and some rotation when flexed. To perform these movements the knee uses nine muscles: biceps femoris, semimembranosus, semitendinosus, Sartorius, popliteus, rectus femoris, vastus intermedius, vastus lateralis and medialis. These muscles are sitting in two muscle groups called the quadriceps femoris and the hamstrings. Together with the ligaments these muscles help stabilizing the knee joint (Martini, Nath 2009).

Injuries in the knee joint are the most common injuries, because of the knee joints complexity. The anterior cruciate ligament (ACL) has a great risk of getting injured in sports. Every year 5-10 per 10,000 inhabitants get a ACL injury, and three out of four of those are sport related (LaPrade, Plerce et al. 2012).

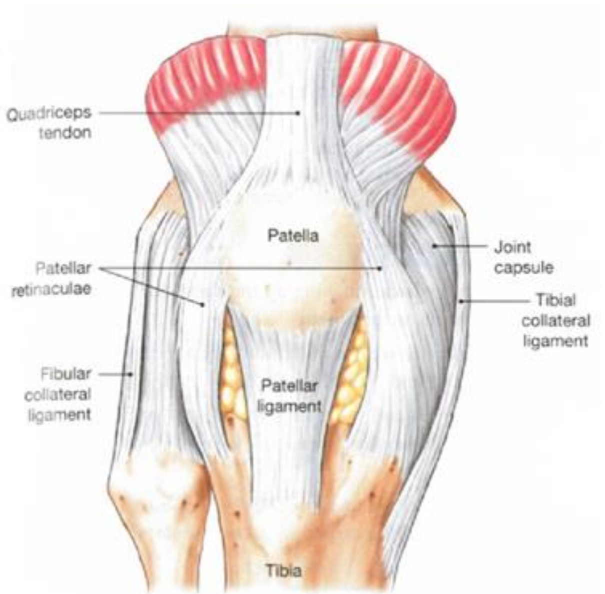

Figure 1.1. Superficial layer of the knee joint from an anterior view (Martini, Nath 2009).

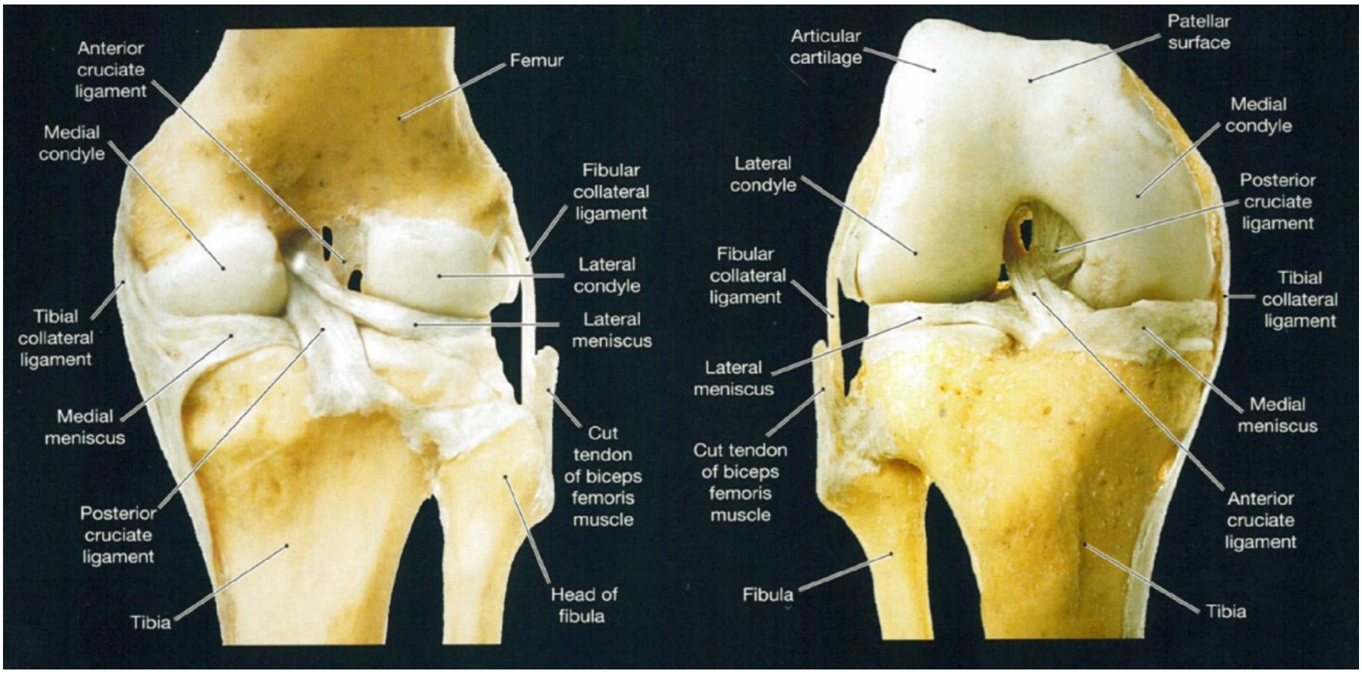

Figure 1.2. The knee joint seen from a posterior view (left) and anterior view (right) (Martini, Nath 2009).

1.2 Anterior cruciate ligament

The anterior cruciate ligament (ACL) is placed in the middle of the knee joint and is attached to the lateral intercondylar area of tibia and the medial condyle of femur. The ACL function is to maintain the alignment of the femoral and tibial condyles and limit the anterior and posterior movements of femur together with the posterior cruciate ligament (Martini, Nath 2009).

A cutting or twisting movement of the knee often causes an ACL injury (Pagliarulo 2012). When the ACL gets injured it most commonly tears completely, this can result in a reconstruction surgery. There can go from two to eight weeks before a reconstruction surgery can be performed, because of the swelling of the knee. While waiting on the surgery a brace can be used to prevent twisting movements and dislocation of the knee, which can cause an additional injury. The recovery and rehabilitation time after an ACL injury is commonly 6-9 months before the patient can return to sports that involve abrupt stops and impulsive turns (LaPrade, Plerce et al. 2012).

Extra fact:

The ACL has a strength of approx. 120 kg (Bojsen-Møller 2005).

1.3 Rehabilitation after ACL injury

The aim of rehabilitation is to get the patients back on their former physical level, as it was before the injury. Normally, a physiotherapist controls the rehabilitation, by examining the patient's situation and level of function, by compiling a rehabilitation program with different exercises and treatments based on the examination. The physiotherapist continues to change the program up until the patient has obtained former physical level (Pagliarulo 2012).

The physiotherapist will examine the patient both subjective, by asking about limitations in the daily life and pain level, and objective by getting the patient to perform different exercises and measure the range of motion in the exercises, e.g. with a goniometer. A normal range of motion of the knee can vary between individuals; the physiotherapist should therefore compare the injured knee with the healthy knee to define the patient's normality. For a typical knee, the range of motion is 0-10 degrees of extension and approximately 135-140 degrees of flexion (Pagliarulo 2012, LaPrade, Plerce et al. 2012)

During knee injuries the neuromuscular control, stability and range of motion changes. Therefore, the core of most of the programs that physiotherapist compile for the patients is physical exercises, to restore the neuromuscular function and rebuilding strength and range of motion. However, to restore normal level of these functions takes time, and it is therefore important that the patients complete daily home training exercises. The physiotherapist introduces the exercises at a training session, and afterwards the patient has to perform these exercises at home without any supervision. Under the rehabilitation process, the physiotherapist has to make changes in the rehabilitation program to fit the progression of the patient. The guide to follow the progression of the rehabilitation is pain, swelling and function of the knee. If the program causes pain or swelling, and thereby reducing the function, the program and the patient's way of performing these exercises has to be checked and modified, so the knee has a better chance of recovering. The rehabilitation program for the patient will be changed up until the patient has obtained former physical level (Pagliarulo 2012, LaPrade, Plerce et al. 2012).

Knee braces 2

Knee braces are used to treat all sorts of knee weaknesses (Ingimundarson 2014).The three different types of braces that are used are; rehabilitation braces, functional knee braces and prophylactic knee braces (Rishiraj, Taunton et al. 2009). The knee braces can be designed to impart forces on limbs that surround the knee joint or to reduce the load on the knee during sport, daily life or just after or before surgery (Ingimundarson 2014). The rehabilitation braces are designed to be used, as the name refers to, in rehabilitation. The functions of rehabilitation braces are to give the knee support, protection and stability. The functional braces are designed to control the range of motion (ROM) of the knee; either by fixating the knee or by having locks to secure that the motion of the knee does not exceed a certain amount of moving. The prophylactic braces, should prevent new injuries by stabilizing the previously injured part of the knee (American 2014).

The knee braces can be designed in different ways, depending on which function is needed. There are braces with; beams with hinges on both the medial and lateral side of the knee, a beam with hinge on only one side, a beam with hinge on only one side and with unloading straps, and with no beams. All these braces can be designed with or without patella support and the fixating can be in different ways, for example with foam and straps or with plates and straps.

The use of a knee brace should allow normal joint function and provide support to the knee. It should not reduce the subject's ability to participate in any daily activity or sports or impair the performance of the knee joint. That could however happen because the joint mechanics could possibly alter when an external device, like a knee brace, is applied to the knee. The brace weight, hinge friction, completeness of fit, migration and strap tightness are all factors that could possibly affect the performance of the knee (Houston, Goemans 1982, Greene, Hamson et al. 2000).

The CTi OTS brace used in this study consists of a top strap, upper subshell, femoral strut, upper cruciate strap, lower cruciate strap, bottom strap, lower subshell, anterior tibial strap, hinge assembly, condyle pad and a D-ring (figure 2.1) (Össur 2013).

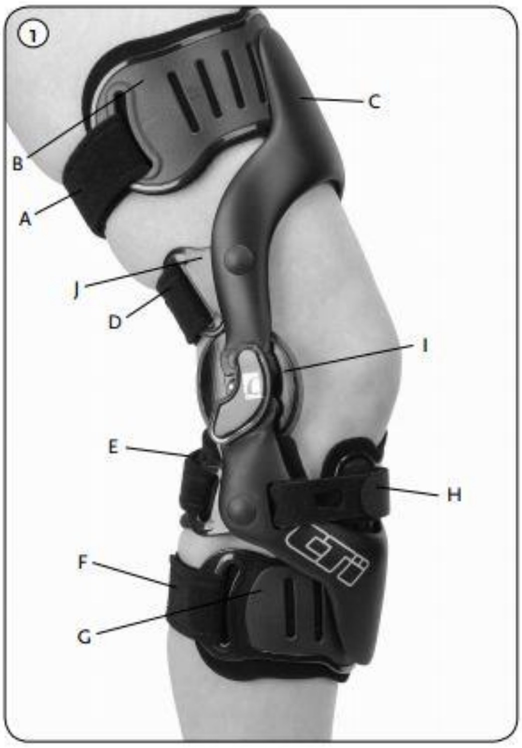

Figure 2.1. The Cti OTS brace. A is the top strap, B is upper subshell, C is femoral strut, D is upper cruciate strap, E is lower cruciate strap, F is bottom strap, G is the lower subshell, H is anterior tibial strap, I is condyle pad and J is the D-ring (Össur 2013).

The brace has a central axis, a frontal plane and a medial-lateral plane. The frontal plane is parallel to and intersects the central axis and the medial-lateral plane divides the brace into a medial and a lateral side. The hinge in the brace supports the knee joint, limits and controls the joint movement so the knee does not get reinjured due to hyperextension or flexion. The hinge also has to be able to simulate the complex movement of the knee. In flexion and extension of the knee, which are the two primary movements of the knee, the joint is not pivoting about a fixed axis like it does in a typical hinge joint such as in the elbow. In knee flexion, the axis of rotation shifts backwards and in extension the axis shifts forward. When the knee reaches a full extension the tibia is rotated inward and then the joint is in a locked position with the ligament taut. When this full extended locked position is reached the knee is more stable. When the knee is flexed again the tibia moves down and rotates a little bit externally. This small rotation of the tibia unlocks the joint and the tibia starts to rotate and roll about the joint until full flexion is reached. It is crucial that the hinge can simulate these movements (Ingimundarson, Romo et al. 2013).

PolyPower stretch sensor 3

The sensor used in this study is based on the Dielectric Electro Active Polymers (DEAP) technology. The principle in the DEAP technology is that the capacitance will change with a change in area and thickness of the material. This change in geometry occurs when the sensor gets stretched (PolyPower 2012).

The sensor consists of five different parts: a stretchable zone, two non-stretchable zones, a cable and a jack plug (figure 3.1). To collect the signal from the sensor, the sensor comes with a wireless controller, a computer program and a mobile app (PolyPower 2012).

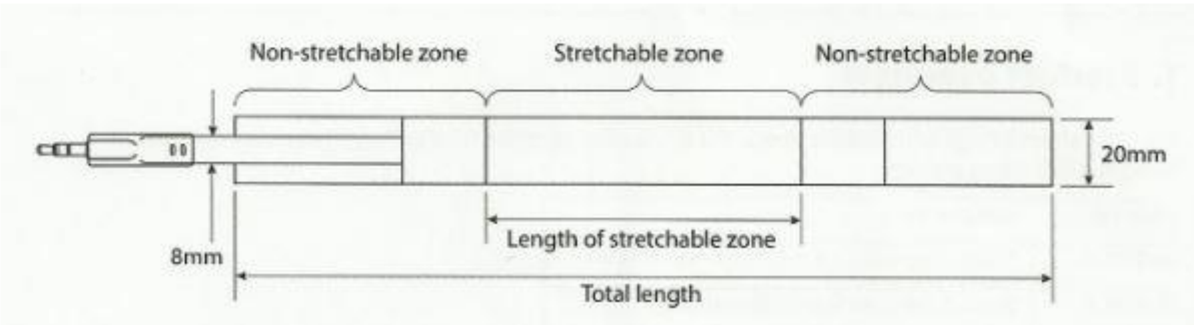

Figure 3.1. The different parts of the stretch sensor (PolyPower 2012).

The standard width of the sensor is 20mm but can be modified. The stretchable zone lies between the two non-stretchable zones and measures the capacitance change. The stretchable zone can be made in three standard lengths (50mm, 100mm and 200mm) and the combination and properties of materials makes it extremely flexible. The two non-stretchable zones consist of two parts; the non-attachment zone and the attachments zone (figure 3.2). The non-attachment zone lies between the stretchable zone and the attachment zone. Like the name indicates, nothing should be attached to this zone to avoid potential damage. The attachment zone is positioned at each end of the sensor and consists of a non-woven textile. As the name indicates this zone is used to attach the sensor to different surfaces by sewing, taping, stamping or gluing. The cable is attached to one of the non-attachable zone and the jack plug at the other end. The cable is made of a flexible textile, is 230mm long and transfers the signal from the stretchable zone to the wireless controller (PolyPower 2012).

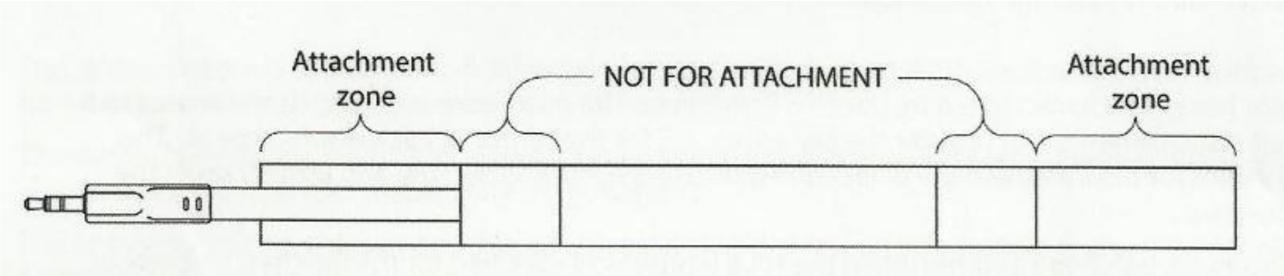

Figure 3.2. Shows how the non-stretchable zones are divided (PolyPower 2012).

When taking a closer look at the sensor, it can be seen that it has a complex structure (figure 3.3). The sensor consists of two layers of dielectric silicon material (the white boxes) with a thin layer of elastomeric film with metallic electrodes, silver in this study, on both sides (the red parts). In the middle of the sensor and on the outer sides of the electrodes there are layers of silicon conductor (the blue parts). The silicon conductor holds the sensor together and protects the electrodes from physical contact that could influence the electrical circuit (PolyPower 2012).

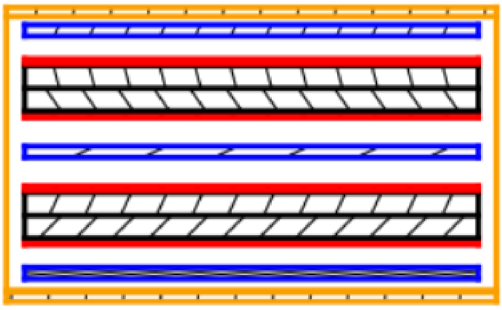

Figure 3.3. The structure of the stretchable part of the sensor. Blue indicates the silicone conductor, red indicates the elastomeric film with metallic electrodes and the white boxes indicate the dielectric silicon material (PolyPower 2013).

The dielectric silicon material works as a capacitor, which changes its capacitance when the polymer gets deformed. This deformation, a decrease in thickness and an increase in area of the material, occurs when a mechanical force is applied and results in a higher capacitance. The correlation between the capacitance and the deformation of the material can be seen in equation 3.1.

$$C = \varepsilon_r \varepsilon_0 \frac{A}{d} \qquad (3.1)$$

In equation 3.1, C is the capacitance in Farads, ε_r is the relative static permittivity of the material, ε_0 is the electric constant, A is the area in square meters and d is the thickness of the material in meters. The dielectric material has a corrugated surface and in combination with the stiffness of the elastomer film, the sensor can only elongates in the length direction. The sensor is able to stretch up to 80% of the stretchable zone length before it gets torn (PolyPower 2012).

The applied voltage is delivered through the electrodes. The electrodes close to the side of the sensor are negative charged, while the positive charged electrodes are placed in the middle of the sensor (figure 3.4) (PolyPower 2012).

Figure 3.4. Shows how the charge of the electrodes lies around the dielectric material.

3.1 Testing of the sensors linearity

The output signal from the sensor should be in proportion to the amount of stretch, according to PolyPower (PolyPower 2012). This has been verified by performing a simple stretch test. The sensor was put in a neutral position and stretched 1cm, 2cm, 3cm, 4cm, 5cm and 6 cm and the capacitance recorded at each length. The results showed a linear regression with a R^2-value of 0.9976 (figure 3.5).

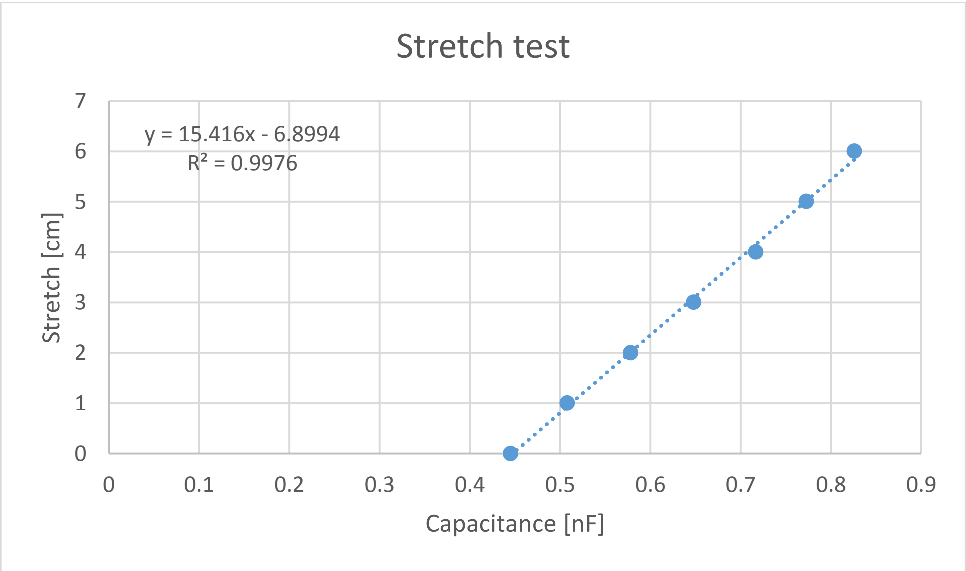

Figure 3.5. The correlation between the stretch and capacitance with a linear regression.

To find out if a twisting of the sensor has an influence on the above mentioned linearity between the capacitance and the stretch of the sensor, additional tests were performed. First the sensor was twisted 90° and the capacitance recorded with the sensor placed in neutral position and stretched 1cm, 2cm, 3cm and 4 cm. This was repeated with a 180° twist of the sensor. From the results it can be seen that the twisting of the sensor did not affect the linearity (figure 3.6 and 3.7).

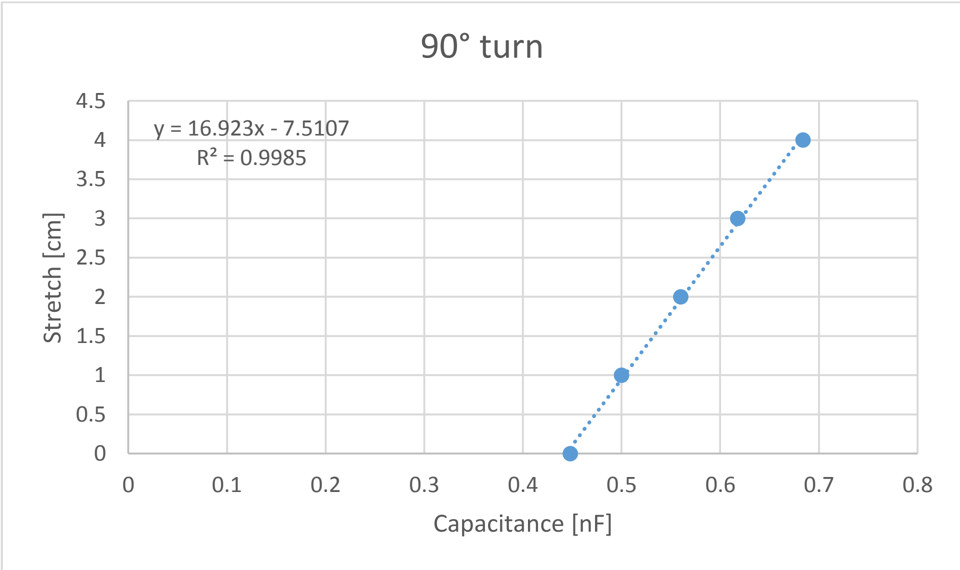

Figure 3.6. The correlation between stretch and capacitance when the sensor is twisted 90° with a linear regression.

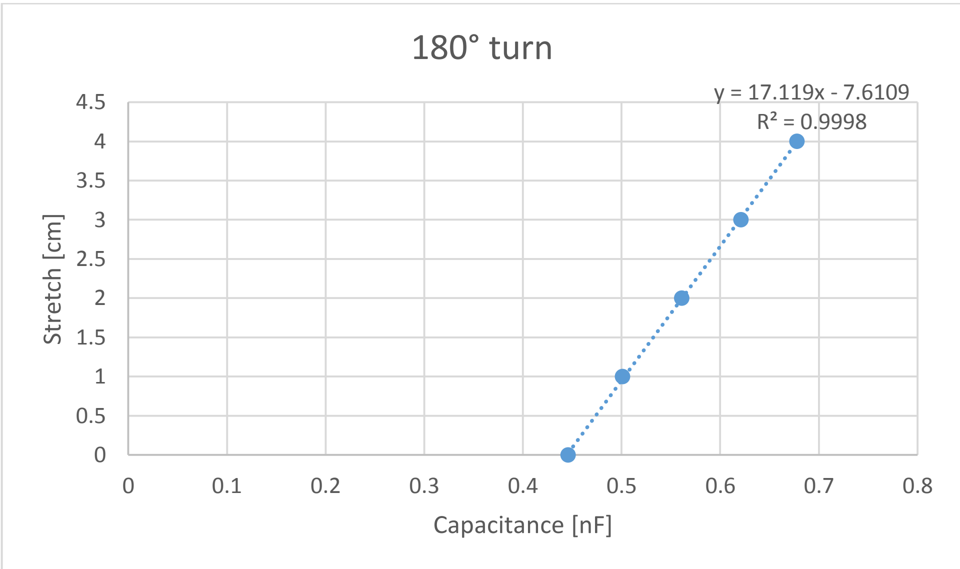

Figure 3.7. The correlation between stretch and capacitance when the sensor is twisted 180° with a linear regression.

Silicone 4

Silicone can be used in many different situations due to its chemical inertness, resistance to water and oxidation, and stability at both high and low temperatures. Silicone is used in various fields, from lubricating greases to electrical wire insulation and to biomedical implants such as breast implants (Encyclopædia Britannica Online).

The molecules in a silicone, or polysiloxane, consist of alternating silicon and oxygen atoms. These molecules differ from most industrial polymers because they do not contain carbon, which is the characteristic element of an organic compound, in their backbone structure. Due to this lack of carbon the silicone is categorizes as an inorganic polymer. Even though silicone is an inorganic polymer there usually are two organic groups attached to the silicon atom. These organic groups are most often vinyl (CH_2), methyl (CH_3) or phenyl (C_6H_5). The chemical formula for silicon is $(R_2SiO)_x$ where R stands for one of the organic group. Dimethylsilicone is the most common silicone compound and its chemical formula can be seen here below (figure 4.1) (Encyclopædia Britannica Online).

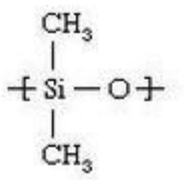

Figure 4.1. The chemical structure of dimethylsilicone (Encyclopædia Britannica Online).

Around the Si-O bond there are silicone molecules that rotate freely, so even with the organic groups (vinyl (CH_2), methyl (CH_3) or phenyl (C_6H_5)) attached to the silicone atoms, the molecule is highly flexible. The Si-O bond is also highly heat resistant and it is not easily attacked by oxygen or ozone. These factors make silicone remarkably stable. Silicone has the lowest glass-transition temperature which is the temperature below which the molecules are locked in a rigid, glassy state and it also has the highest permeability to gases of any polymer. However, the Si-O bond is susceptible to hydrolysis and attacks by acids and bases. This causes silicone plastics and rubbers to be relatively weak and easily swollen by hydrocarbon oils.

Silicone is manufactured in different ways. It can either be as a fluid, resin or elastomers depending on the molecular weight of the polymers and how the polymer chains are interlinked. Non-vulcanized, low-molecular weight silicone fluids are extremely stable to decomposition by water, heat or oxidizing agents. They are also good electrical insulators, make excellent lubricants and hydraulic fluids and emulsions for imparting water repellency to paper, textiles and some other materials. Silicone resin is used to laminate glass cloth, electrically insulate varnishes and it is also used in protective coatings. Silicone rubber is most often strengthened by fillers such as silica. Other fillers can also be mixed in to add bulk and color. Silicone rubbers are mostly used in heat resistant seals, electrical insulators, surgical implants, O-rings, gaskets and flexible molds (Encyclopædia Britannica Online).

Goniometer 5

A goniometer is a device that measures angles between two segments in degrees. The goniometer is a protractor that consists of two slender arms connected in the centre and it is made of metal or plastic (figure 5.1). At least one arm on the goniometer has to be movable in order to place it parallel to the body segments. There are at least five types of angle measuring devises available on the market today, the Protractor goniometer, the Inclinometer, the Hydrometer, the Pendulum goniometer and the Electrogoniometer. The Protractor goniometer is the most common in wrist, elbow, ankle, knee and hip angular measurements (de Araújo, Claudio G. S. 2004).

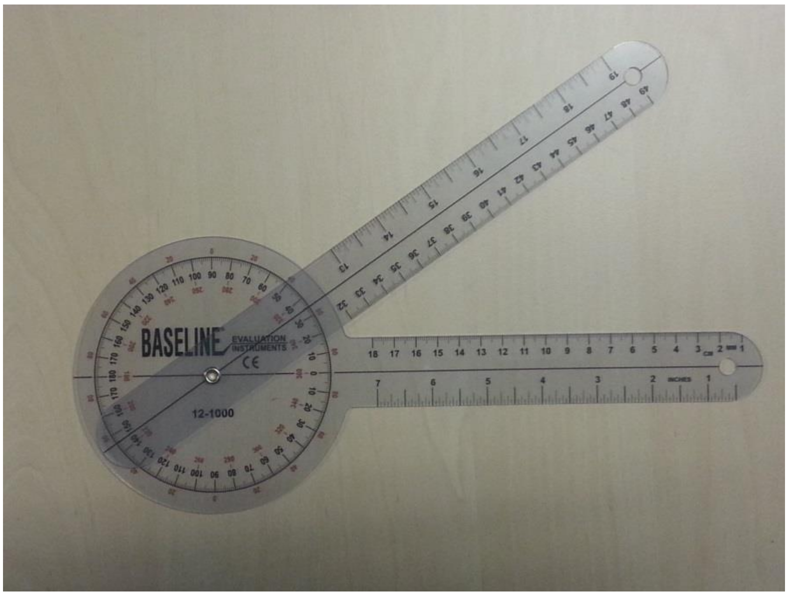

Figure 5.1. A 30 cm Baseline 360° goniometer used in the experiment.

The goniometer is most commonly used in flexibility tests which measure the flexibility, or the Range of motion, of a certain joint. These tests can be performed in an active or in a passive way. The active measurements are performed without any external help or support but the passive measurements are performed with either some help from the evaluator or by the use of some device. The active way is more often used than the passive way because to do a well performed passive measurement some trained evaluators are needed. The passive measurements almost always give a larger range of motion than the active measurements. In some joints or some specific situations a goniometric measurements are difficult or even impossible to carry out (de Araújo, Claudio G. S. 2004).

Methods 6

The goal of this project was to design a knee flexion angle-measuring device used in rehabilitation exercises, on patients recovering from ACL injuries, to give patients feedback immediately. In order to choose the best design the process was divided into three parts. First, the aims for the design were created. Next, a brainstorm was performed to generate design ideas and at last the best solution was selected.

6.1 Aims for the design

In order to guide the development of the product in the right direction, a set of aims for the product were created by looking at the pros and cons of the existing methods. The list of aims is shown below with a brief description.

- *Validity*

  The product should measure the knee flexion angle.

- *Useable in all environments*

  The device should be usable in all environments, so the patient can use it at home and outside and not be restricted to a lab or a room with controlled light.

- *Useable in all situations*

  The patient should be able to use the device in all rehabilitation exercises, both exercises were the patient is standing up and lying down.

- *Easy to put on*

  The product should be easy for the patient to put on without having a special education or skill. It should also be easy to place the product correctly so the measurements are reliable.

- *Easy to use*

  The patient should only need a short instruction on how to use the product in order to be able to handle it on his/her own.

- *Comfortable*

The product should be comfortable for the patient. If the product is not comfortable, the patient will probably not use it.

- *Small and Light weighted*

  The product needs to be small and light weighted so the mobility of the patient does not decrease.

- *Cheap*

  The product should be affordable so it is able to compete with existing products.

- *Strong*

  The product should not break easily and should be able to handle if the patient falls on it.

6.2 Brainstorm and selection

Different ideas came up during the brainstorming session. These ideas can be seen on the mind map below (figure 6.1).

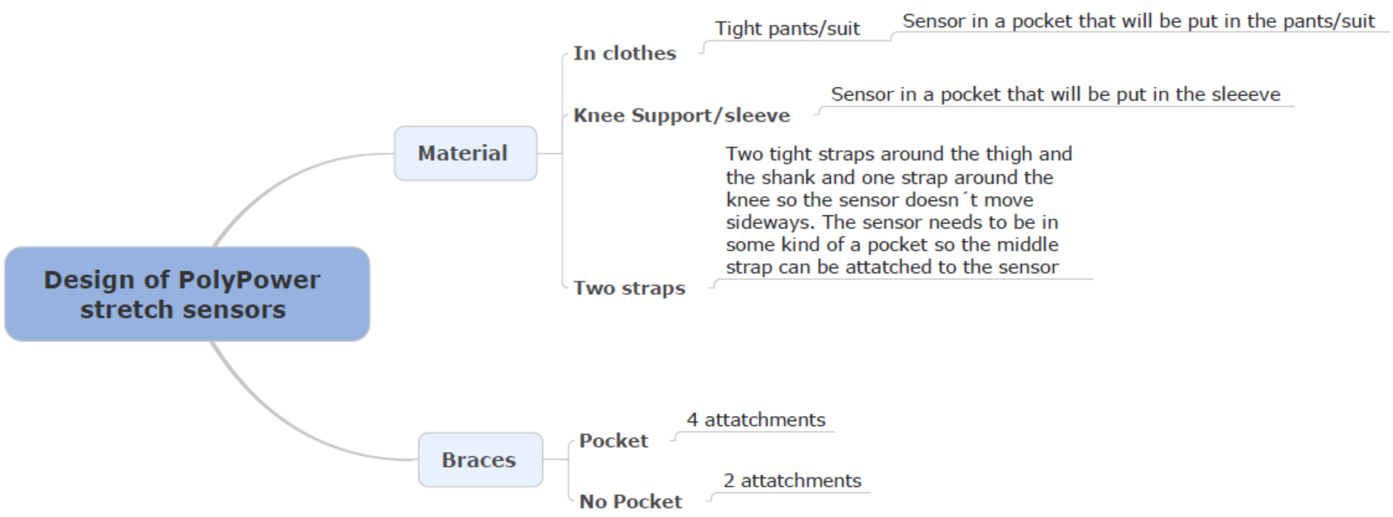

Figure 6.1. The ideas that came up during the brainstorming session.

Based on the aims for the product, the brace design got selected for further brainstorming. This design was chosen because it was considered to be easier to place the product correctly and in the same way each time, compared to when the sensor would be incorporated into some material or placed directly on the skin.

The further brainstorming of the brace design included 1) a design where the sensor was placed on the middle of the brace over the knee either in a pocket or not in a pocket and 2) a design where the sensor was placed on the side of the brace. Design idea number one was evaluated not to have a linear correlation between the knee flexion and the stretching of the sensor, because the knee shell would touch the sensor during flexion and the sensor would maybe move to the sides of the knee. Design idea number 2 was developed further. The main problem with the design idea was that the sensor is a thin long flexible sensor, which has no stiffness and therefore difficult to attach on the side of the brace. Therefore, a brainstorming session on how to attach the sensor on to the brace started. The final idea for attaching the sensor was to place the sensor on a block of silicon (figure 6.2). Silicone was chosen based on its elastic properties (see chapter 4).

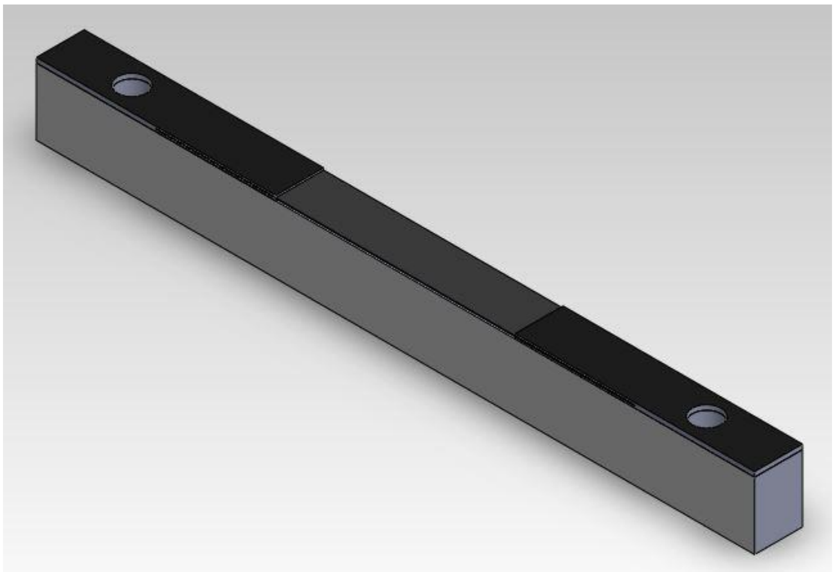

Figure 6.2. A computer drawing of the final idea where the sensor is attached to a silicon block.

The silicon block with the sensor on top would then be screwed to the braces side. A prototype of this idea was made and can be seen on figure 6.3 and 6.4.

Figure 6.3. The prototype of the silicone block with the sensor on top.

Figure 6.4. Shows how the silicone block with the sensor should be placed on the brace.

6.3 Construction

In order to construct the final design, the process was divided into three steps. The first step was to figure out how to work with silicone. The second step was to mould the silicone block and the third step was to place the silicone block on the brace.

To perform the first step, figuring out how to work with silicone, we contacted Mr. Kristian Rauhe Harreby, lecturer at Aalborg University, because Mr. Harreby is currently working with silicone. After the meeting with Mr. Harreby it was decided to form the silicone by using a casting mould and place the sensor inside the silicone block, because it is very hard to glue anything onto silicone. The sensor was placed below the centerline of the silicone block (figure 6.5) in order for the sensor to stretch and thereby elongate when the silicone block gets bent (Gere 2006).

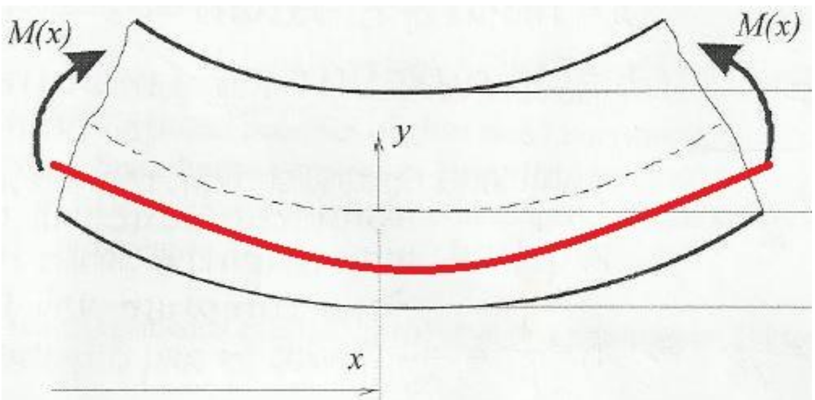

Figure 6.5. Shows how the sensor (the red line) was placed in the lower part, below the centerline, of the silicone block in order for the sensor to get stretched when the silicone block gets bent (Gere 2006).

The casting mould was made out of wood, and can easily be disassembled by screws (figure 6.6). The silicone that was used was a transparent Sikasil®-C. To secure a better attachment for the silicone, two iron plates were placed in each end so the screws, used to attach the silicone block to the brace, got a better grip in the silicone block (figure 6.7).

Figure 6.6.The casting mould filled with silicone and a sensor.

Figure 6.7. The iron plates were placed in the end of the silicon block.

When the silicone block had dried for a couple of days in the casting mould, it was screwed onto the brace.

To make sure the sensors controller box was close to the sensor a bag was made and placed on the femoral strut of the brace with Velcro (figure 6.8).

Figure 6.8. The pocket placed on the femoral strut of the brace.

6.4 Calibration

To test the product the software program PolyPower Wireless Sensor Controller and a goniometer were used. By placing the test subject´s knee at a certain angle, measured by the goniometer, and recording the capacitance, at 100 Hz, at different angles, a correlation between the capacitance and the knee flexion angle could be made. The capacitance was measured at six different angles; 20°, 40°, 60°, 80°, 100° and 120°.

However, there was a low correlation between the capacitance and the knee flexion angle. This low correlation might have been caused by the sensor being surrounded by silicone, the sensor being placed uneven in the silicone or the sensor placed too close to the centerline. Therefore, a new sensor was placed on the outside of the silicone block by using rubber bands (figure 6.9) and the capacitance was measured again at the same angles as before. This was done in order to figure out if there would be a better correlation between the knee angle and the capacitance when the sensor was placed on top of the silicone block. The sensor was placed on top of the silicone block to get a larger distance from the centerline.

Figure 6.9. The final prototype where the sensor is placed on top of the silicone block.

6.5 Testing

6.5.1 Dynamic tests

After the calibration, three dynamic tests were performed to observe the sensors behaviour in dynamic movements. In the first dynamic movement test, the capacitance was recorded while the subject performed five squats, going down to approximately 90° of flexion. In the second dynamic test the capacitance was recorded while the subject performed five lunges and in the last dynamic test the capacitance was measured during a 5 minute run on a treadmill with a velocity of 7.5 km/h. All three tests were performed with the subject wearing shorts and in addition a running test was performed where the subject wore pants over the product (figure 6.10). The pants were worn to see if the capacitance would be affected by a higher temperature or friction, caused by the pants. These three different dynamic movements were selected because they are likely to be used in rehabilitation and are performed with different intensity, where the squat is the least intense exercise and the run the most intense exercise.

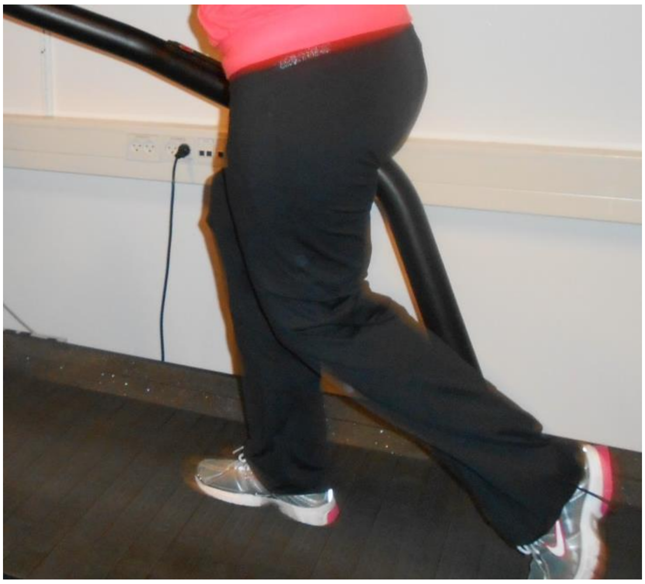

Figure 6.10. Shows how the pants were worn over the product during the running test.

6.5.2 Creep test

After the dynamic test, a creep test was made to see how the product is affected over time when left in an extreme position.in the creep test the capacitance was measured both with no flexion (figure 6.11) and with maximum flexion (figure 6.12) of the product.

Figure 6.11. The no flexion position in the creep test.

Figure 6.12. The maximum flexion position in the creep test.

Next the brace was fixed in a position with maximum flexion (figure 6.13) for three days and then the measurements were performed again. This was done in order to find out if the capacitance of the sensor would be affected after being stretched for some time.

Figure 6.13. Shows how the sensor is stretched when the brace was fixed in position of maximum flexion.

Results 7

This section includes all the results which will be shown in tables and figures. The results will be presented chronologically.

7.1 Calibration

The results from the calibration where the sensor is placed inside the silicone block can be seen in table 7.1 and figure 7.2.

Table 7.1. The results from the calibration, where the sensor is placed inside the silicone block.

Capacitance [nF]	0.210	0.153	0.207	0.118	0.267	0.271
Angle [degrees]	20	40	60	80	100	120

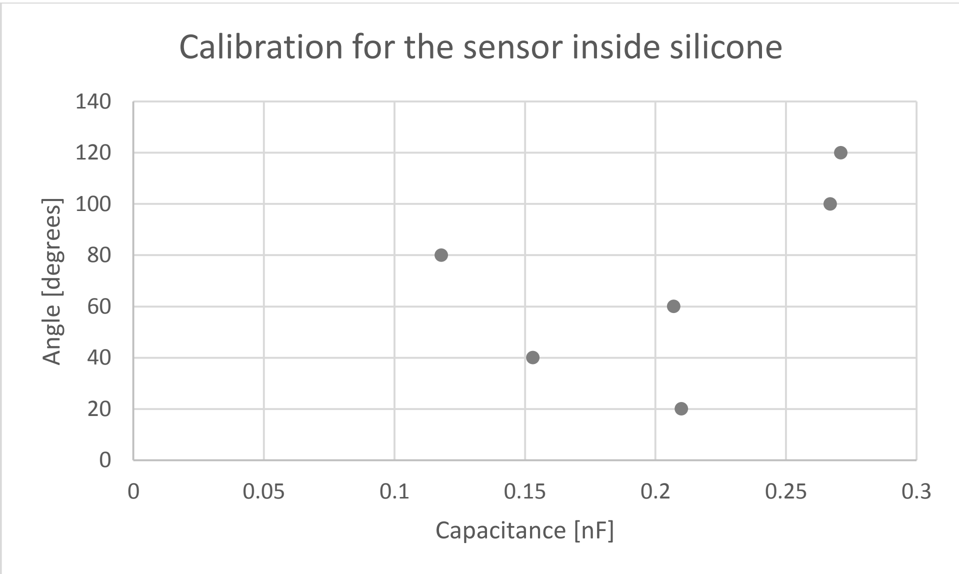

Figure 7.2. The correlation between the capacitance and knee angle, where the sensor is placed inside the silicone block.

As the result show there is low correlation between the capacitance and the knee flexion angle. This is also confirmed by the R^2-value for a linear correlation, which is only 0.24.

Therefore, a sensor was placed on top of the silicone block, and the result from the calibration can be seen in table 7.3 and figure 7.4 and 7.5.

Table 7.3.The results for the correlation between the capacitance and knee angle where the sensor is placed on top of the silicone block.

Capacitance [nF]	0.491	0.507	0.513	0.523	0.530	0.540
Angle [degrees]	20	40	60	80	100	120

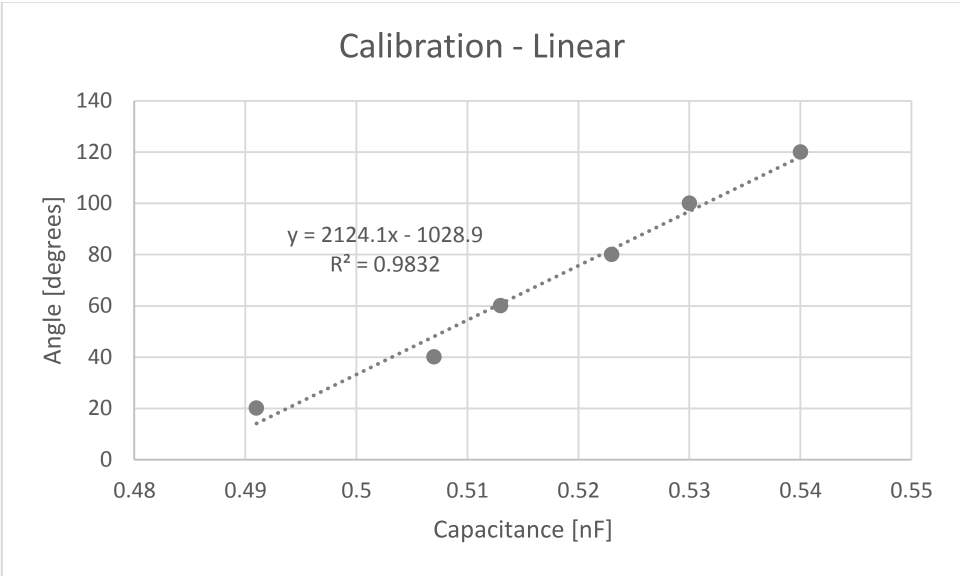

Figure 7.4.The correlation between the capacitance and knee angle, where the sensor is placed on top of the silicone block, with a linear regression.

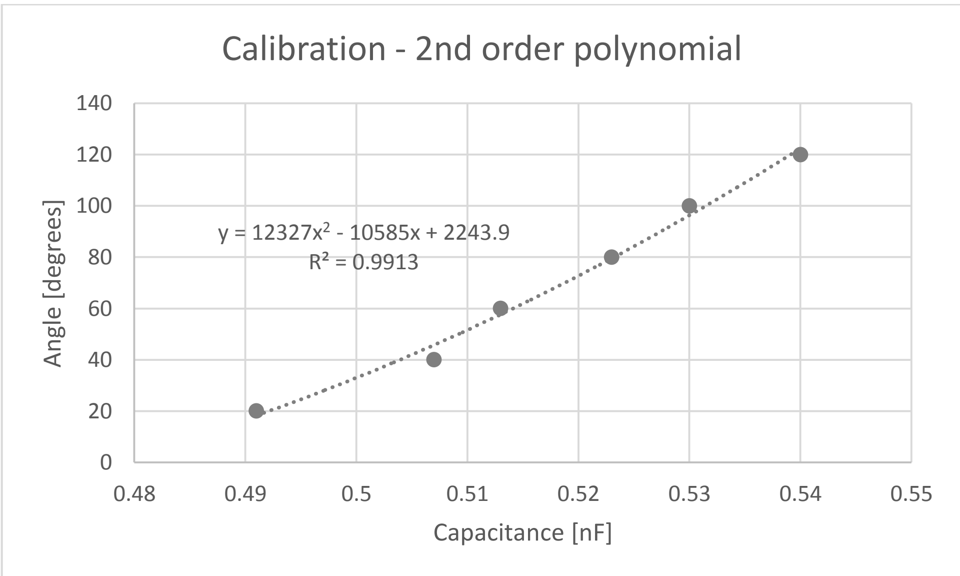

Figure 7.5. The correlation between the capacitance and knee angle, where the sensor is placed on top of the silicone block, with a second order polynomial regression.

When looking at the result from where the sensor is placed on top of the silicone, it can be seen that there is a higher correlation between the capacitance and the knee flexion angle compared to when the sensor was placed inside the silicone block. A linear regression gives an R^2-value of 0.9832 while a second order polynomial regression gives a R^2-value of 0.9913. The second order polynomial was chosen for further calculation, due to a higher correlation, by the use of the following formula:

$$y = 12327x^2 - 10585x + 2243.9$$

Where y is the angle in degrees and x is the capacitance in nF.

7.2 Dynamic tests

From table 7.6 and figure 7.7 it can be seen that the maximum knee flexion angles, and thereby the capacitance, are consistent with maximum values between 71-73 degrees, during all five squats. This indicates that the sensor is consistent in low intense dynamic movements.

Table 7.6. The maximum capacitance and flexion angle for each squat during the squat test.

Squat	1	2	3	4	5
Maximum capacitance [nF]	0.519	0.519	0.519	0.520	0.519
Maximum flexion [degrees]	71	71	71	73	71

Figure 7.7. .The results from the squat test shown graphically.

The results from the lunge test can be seen in figure 7.9. During the five lunges the maximum knee flexion angles have the same pattern where three peaks, small-big-small, represent one lunge. The maximum angle values range from 77 degrees to 84 degrees (table 7.8).

Table 7.8.The maximum capacitance and flexion angles for each lunge during the lunge test.

Lunge	1	2	3	4	5
Maximum capacitance [nF]	0.524	0.525	0.522	0.525	0.525
Maximum flexion [degrees]	82	84	77	84	84

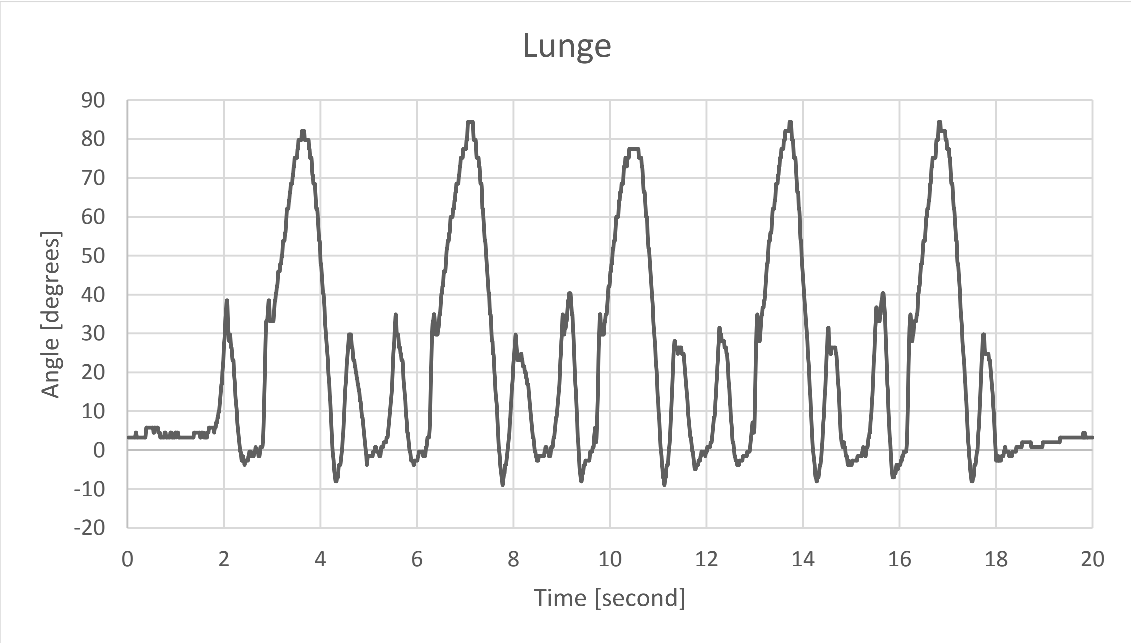

Figure 7.9. The results from the lunge test shown graphically.

The results from the running tests, when wearing shorts and pants, can be seen on figure 7.10, 7.11, 7.12 and 7.13. Figure 7.10 and 7.12 shows a 10 second interval from the beginning of the run and figure 7.11 and 7.13 shows a 10 second interval from the end of the 5 minute run.

Figure 7.10. The results from the beginning of the running test with shorts on shown graphically.

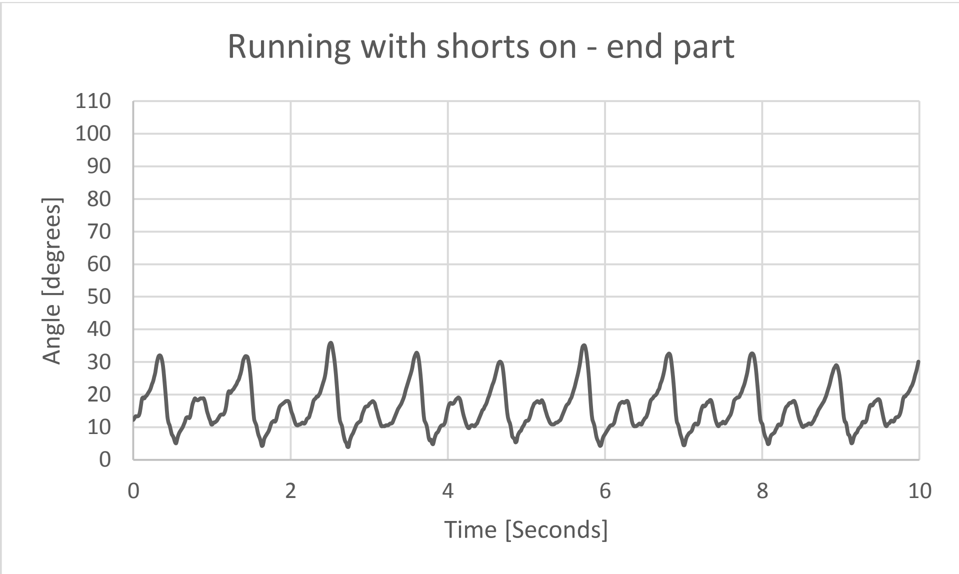

Figure 7.11. The results from the end part of the running test with shorts on shown graphically.

From figure 7.10 and 7.11 it can be seen that the product has recorded a running pattern, with a double knee bending per step. At the end of the run the angle decreases by approximately 70%, ranging from approximately from 102 to 30 degrees (figure 7.10 and 7.11).

Figure 7.12. The results from the beginning of the running test with pants on shown graphically.

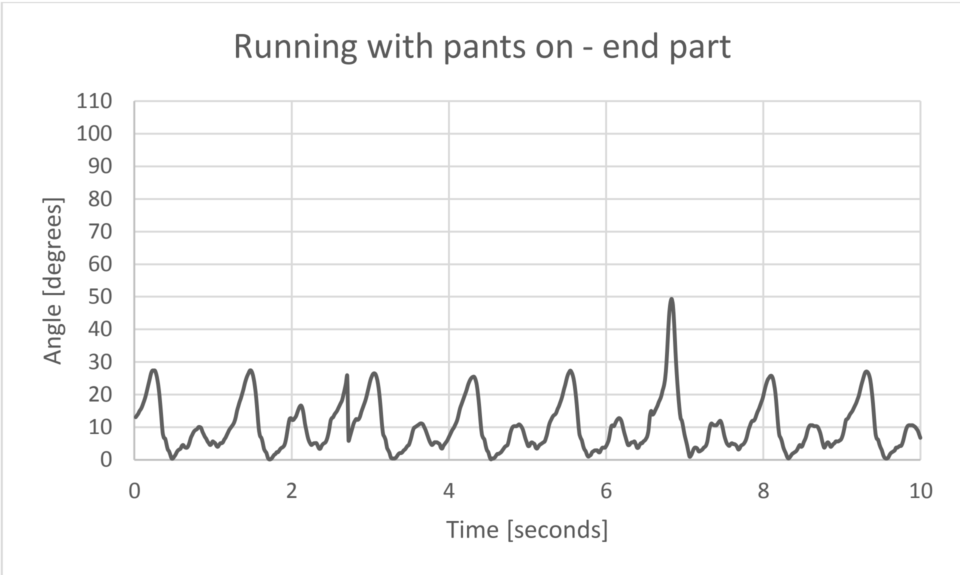

Figure 7.13.The results from the end part of the running test with pants on shown graphically.

Figure 7.12 and 7.13, where the subject wore pants, show the same tendency as when the subject wore shorts (figure 7.10 and 7.11) which is that the angle decreases from the beginning to the end of the run. The maximum knee angle decreases by 65%, ranging from approximately 71 to 25 degrees.

7.3 Creep test

The results from the creep test are shown in table 7.14.

Table 7.14. The results from the creep test.

	First day	After 3 days
0 degrees [degrees]	5	23
Maximum flexion [degrees]	135	115
Difference [degrees]	130	92

Table 7.14 shows that the difference in angle, when the product is not bended and when the product is bended to its maximum position, is 130° at day one. When the product had been fixed in the maximum bending position for three days the angle difference decreases by 29%.

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