HÁSKÓLINN Í REYKJAVÍK
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Development of Clinical Assessment strategies for patients undergoing Total Hip Arthroplasty (THA)

Benedikt Magnússon

Thesis of 60 ECTS credits
Master of Science in Biomedical Engineering

December 2013

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at Reykjavík University in partial fulfillment
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Abstract

Total hip arthroplasty (THA) is a common surgery that people suffering from hip pain and reduced mobility, generally caused by osteoartrhosis, undergo. In the surgery the head and neck of the femur bone are replaced with a prosthesis whose ball-like head fits into a cup that is inserted into the acetabulum. There are basically two implant technologies being used in the operation, either bone cement is used to fix the prosthesis into the femur or a press-fitting technique is used to insert the prosthesis into the femur. Both techniques have their advantages and disadvantages. However there are no established guidelines for quantitative assessment to use when selecting between them. More so there are no follow up assessment guidelines either, but as the rate of surgeries increases the need for post-operative recovery assessment tools becomes more urgent.

In this study, involving 39 THA patients undergoing their first THA, parameters to be used in quantitative assessment of THA patients both pre-operative for implant selection and post-operative for patient recovery assessment were studied. These parameters include bone- and muscle quality assessment using medical imaging processing techniques in Mimics, where the bone mineral density and muscle density are evaluated. Also included are measurements of spatial and temporal gait parameters along with pressure distribution and muscle activity measurements done with GAITRite® pressure sensing carpet and KinePro EMG recording device.

Parameters involving image processing in Mimics did prove useful as a pre-operative and recovery assessment tools. Most of the spatial and temporal gait parameters measured proved useful as recovery assessment tools and possibly pre-operative also. Parameters like pressure distribution and muscle activity measurements do need improvement should they be included in pre-operative or recovery assessment for THA patients.

Keywords:

Total hip arthroplasty, quantitative assessment parameters, bone mineral density, muscle density, gait analysis.

Útdráttur

Heildarmjaðmaliðarskipti er algeng skurðaðgerð vegna sársauka í mjöðm og minnkaðrar hreyfigetu, oftast vegna liðhrörnunar. Í aðgerðinni eru höfði mjaðmarliðarins skipt út með gervilið sem er kúla á stilk sem passar í bolla sem komið hefur verið fyrir í augnkarlinum. Það eru aðallega tvær aðferðir notaðar til þess að festa gerviliðinn ofan í lærlegginn; annars vegar er hann festur með bein-sementi og hinsvegar er honum þrýst með hamarshöggum, en báðar aðferðir hafa sína kosti og galla. Það eru ekki til nein magnbundin viðmið til að notast við þegar verið er að velja á milli þeirra. Þar að auki eru ekki til nein magnbundin viðmið til að notast við í eftirfylgni sjúklinganna.

Í þessari rannsókn, þar sem 39 sjúklingar sem voru að ganga í gegnum sín fyrstu mjaðmaliðarskipti tóku þátt í, voru mælistærðir til notkunar við frummat á sjúklingum fyrir val á gervilið og til að meta bata sjúklinga eftir aðgerð rannsakaðar. Þessar mælistærðir eru beinþéttni og vöðvaþéttni sem mældar voru í Mimics út frá tölvusneiðmyndum. Einnig voru tíma- og rúm mælistærðir göngugreiningar kannaðar ásamt þrýstingsdreifingu og vöðvavirkni með GAITRite® þrýstinema-mottu og KinePro vöðvarafrits mælibúnaði.

Mælistærðir sem voru rannsakaðar með myndgreiningarferlum reyndust vera góðar, bæði fyrir frummat sjúklinga við val á gervilið og við mat á bata sjúklinga. Flestar tíma- og rúm-mælistærðir göngugreiningarinnar reyndust nothæfar við mat á bata sjúklinga og hugsanlega gætu þær líka verið nothæfar í frummati sjúklinga. Mælistærðir fyrir þrýstingsdreifingu og vöðvavirkni þurfa endurbætur/viðbætur skuli þær vera notaðar við frummat eða við mat á bata sjúklinga.

Lykilorð:
Heildarmjaðmaliðarskipti, magnbundnar mælistærðir, beinþéttni, vöðvaþéttni, göngugreining.

Ritgerðin heitir á íslensku
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1. Introduction

1.1. Background

Total hip arthroplasty (THA) is one of the most common surgery done on the human musculoskeletal system today. In 2009 in Denmark and Norway there were around 230 surgeries per 100.000[1] and from 2010-2012, there were 276 THA surgeries annually in Landspitali [2]. There are mainly two types of surgeries, with or without bone cement for implant fixation. In Iceland, the uncemented surgeries have been 100 annually on average for the last three years while the cemented surgeries have been approximately 173 annually on average. The cost of a primary uncemented surgery has decreased in the last years from being 1.093.000 ÍKR in 2010 to 970.000 ÍKR in 2012. The cost of a primary cemented surgery has also decreased in the last years, but not as much, from being 1.086.000 ÍKR in 2010 to 1.022.000 ÍKR in 2012. The average cost of an uncemented revision surgery, a surgery that replaces an old/damaged prosthesis, during 2010-2013 is 1.470.000 ÍKR and the average cost of a cemented revision surgery from the same period is 1.509.000 ÍKR [2].

When surgeons choose implant for THA, they base their selection on the patients age and gender, because it is proven that elderly people, and especially elderly females, have worse bone quality than younger people [3]. The reason for the bone quality being so important in the decision making is because of the two different implant technologies. The cemented implant is fitted into the femur and fixed to the bone with bone cement, while the uncemented implant is press-fitted into the femur with hammer blows and thus dependent on the bone strength. It is therefore more likely that a femur receiving uncemented implant will suffer from intra-operative fractures than a femur receiving a cemented implant [4].

The effects of the THA procedure on the femur bone depend on the implant type, cemented- vs. uncemented. The reason for initiating the use of uncemented prosthesis is because in the 1980's, loss of bone stock and implant loosening, became a questionable complication of the cemented procedure and the uncemented implants were supposed to be the answer to the problem [5]. In the cemented procedure, there is a local weakening of the bone due to stress shielding which the fixation method causes. This leads to decrease of bone mineral density of the proximal femur and increased fracture risk [6]. When using the uncemented press-fitting procedure, the bone layers next to the implant are pre-loaded and therefore stimulate to bone growth. This should reduce the probabilities of loosening of the stem, which is a very common reason for revision surgeries [7] and bone loss [8].

Revision surgeries are considered one of the most challenging things in orthopedic surgery and they will be present as long as THA surgeries are performed. The problems surgeons have to deal with in revision surgeries include bone loss, bone deformation and stem fracture. Revision surgeries have to be done for both types of implants, and they can both cause problems, but since the cemented stem has been fixed to the femur with bone cement it can pose a greater threat to the surrounding bone than the uncemented one [9]. When removing a cemented stem, all bone cement on top of the prosthesis has to be removed and the surface between the stem and the bone has to be cleaned. An uncemented stem can be removed very easily if the component is loose, but if there has been some bone ingrowth into the component there could be some difficulties getting it out [10].

According to the Swedish Total Hip Replacement Registry from 2011, there were 347.129 primary THR surgeries and 34.981 revision surgeries, thus the revision surgeries account for 9,2% of all THR surgeries in Sweden during 1979-2011. For cemented implants the revision rate is 8,5% but for the uncemented implants 14,1%. The number of cemented surgeries has been rather steady since 2000, counting approx. 12000 surgeries per year, and approx 1000 of those being revision surgeries. The number of uncemented surgeries has been rapidly growing, from being 500 in the year 2000 of which almost 200 were revision surgeries to 2700 in the year 2011 while the number of revision surgeries is similar as before, approx 200 per year [7]. In a summary from the New Zealand joint registry from 1999-2006 Hooper et al. reports that 0,49% of cemented stems have to revised compared to 0,84% of the uncemented stems [11]. The Swedish Total Hip Replacement Registry also indicates that the cemented stems have lower revision rate up to six years after surgery but after that the uncemented stems have lower revision rates.

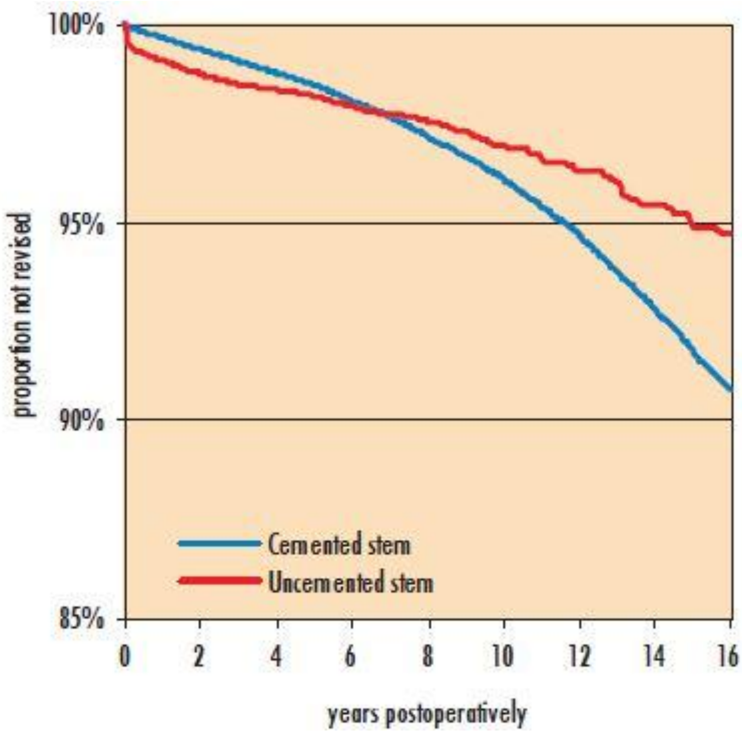


Figure 1. Shows the revision trend between cemented and uncemented stems years after surgery in Sweden [7].

It is clear that the uncemented implants have some advantages over the cemented ones: the primary surgery and revision surgeries are cheaper, they have less negative long term impact on the surrounding bone, the revision surgeries are generally not as complicated as the cemented ones and they have a greater long term revision rate. The advantages the cemented stems have are less fracture risk in operation and better short term revision rate. The cemented implants are used in greater numbers than the uncemented ones but the trend seems to be shifting.

1.2. Motivation

The population is growing older and therefore the THA surgery will be even more common and the demand for optimization will become greater. However there are currently no clear guidelines for the surgeons when deciding between surgical methods in total hip arthroplasty, neither are there any post operative assessment guidelines to monitor the patient recovery. Both implant methods have their pros and cons, but there are no tools currently in use to make the optimal selection for every patient. Monitoring the patients before- and after surgery can help to establish those tools, but also give valuable information about the patient's recovery progress.

1.3. Goals of the project

This project is a part of a larger project which aim is to create clinical guidelines for THA implant selection. The goals of this project are:

1. To develop quantitative pre-operative assessment tools helping the surgeon in his implant selection.
2. To develop quantitative assessment tools that can be used to assess the patients' recovery after THA.

The methods to be used in this project are pre- and postoperative:

3. Gait analysis, exploring spatial- and temporal gait parameters, pressure distribution symmetry between legs and activity periods of muscles during gait.
4. Bone- and muscle quality assessment using medical images.

The study was done on a group of THA patients, to see if these methods could be used to give valuable information on what implant type would suit the patients best and/or if they could be used to monitor patients recovery after THA.

1.4. Structure of the thesis

Chapter two covers the theoretical framework regarding THA, the surgery and things causing patients to undergo it, the different implant technologies and implant materials and the use of gait analysis and medical image analysis in THA patient assessment. Chapter three covers the methods used in the study, both the gait analysis techniques- and segmentation processes used. Chapter four lists the results from the measurements of the patients included in the study. Chapter five discusses the parameters measured, how they compare and their value. Final chapter gives conclusion of this study and discusses future steps for the study.

2. Theoretical framework

2.1. Introduction

This section includes the basic information about the THA surgery, the biology of the hip joint, the symptoms and medical conditions related to the THA. Then there is a chapter on the clinical treatment related to the THA, materials and different implant types are explored. Finally there is a chapter on post operative clinical assessment which goes into gait analysis and bone mineral density and their use in THA patient assessment.

2.2. Total Hip Arthroplasty (THA) definition

Total hip arthroplasty is a surgery that is performed on people that suffer from pain and/or reduced ability to move and attend to daily activities, when other help has failed. In the surgical procedure the head and the neck of the femur bone is removed. The canal inside the femur bone is reamed for the prosthesis to be fitted in there. The prosthesis is a metal stem with a sloping neck and a spherical head on top. The head fits into the acetabulum which has been prepared with the insertion of a plastic cup. The goal of the surgery is to relief the patient from pain and to make him better able to perform activities of daily living [12].

Figure 2. Shows a typical case of THA after sugery [13].

2.3. Biology of the hip joint

Bones have two very important roles, as they provide mechanical support for the body and protect the body, the bones are constantly modifying themselves as the body grows and they do their job the whole time. The other major role of the bones is storing minerals that are needed to keep the body in a homeostatic form. Bone tissue is generally divided in two major categories, compact and cancellous bone. The compact bone forms the smooth outer layers of the bones and is a very dense material. It makes up for the shaft on long bones such as the femur, creating a medullary canal. Cancellous bone is only present inside a cortical bone cover. The cancellous bone has a spongy appearance and a vast surface area [14].

Bone tissue is made of a combination of organic, inorganic parts and water. The inorganic part mainly consists of calcium phosphate and collagen, while the organic part is mostly made of collagen. Bones are both brittle and flexible material. How fragile they are depends on the combination and the amount of minerals, such as apatite and hydroxiapatite. The presence of collagen provides their ability to be flexible and support tense loads[14,15,16].

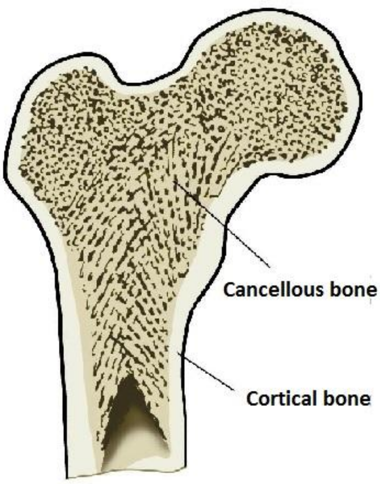


Figure 3. Shows the different types of bone tissue and their layout in the femur [15].

The longest and strongest bone in the human body is the femur, the length is required so normal gait can be accomplished and the strength is essential so muscular and weight bearing forces can be transmitted. Most of the femur is a cylindrical shaft, but on the top it has a neck that connects to the femoral head. The femoral head makes up for one part of the hip joint. The other part of the hip joint is the acetabulum where the femur head fits into and is able to rotate itself there to a certain level [17]. The movement of the femur head inside the acetabulum is supported by cartilage, ligaments and muscles. If there is damage to the bone, cartilage, ligaments or muscles at the hip joint, the gait will become pathological.

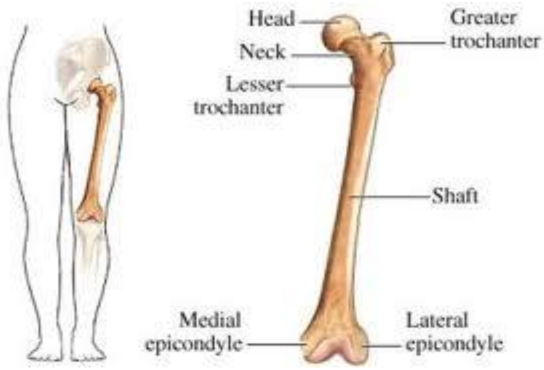


Figure 4. The layout of the femur and its main landmarks [18].

2.4. Symptoms and medical conditions

There are various reasons for patients need to undergo a THA. In a study from 2001 where 101 patients stated the problems they had in their daily lives leading to the surgery, the most common complaints were: walking (68%), pain (58%), limping (36%), night pain and walking stairs (both 35%) [19].

The underlying problems for all those daily complaints are medical conditions, the most common being severe osteoarthrosis. The Swedish Hip Register reports that osteoarthrosis is responsible for 79% of all primary THA surgeries done in Sweden during 1992-2011 and also for 74% of all revision surgeries during 1979-2011. Other reasons for surgery in their report of 170.129 THA (1992-2011) are: fractures in 11%, inflammatory arthritis in 3,5% and other reasons account in 6,5% [7].

Osteoarthrosis (OA) is an age related type of joint derangement, generally found in people older than 50 years. Osteoarthrosis is not an inflammatory disease but a mechanical breakdown of the cartilage and is the most common joint disease [20]. Other joints such as the knee, hand and foot can also suffer, but it is estimated that 2-3% of adults have to deal with pain caused by OA at a regular basis [21]. Its frequency is correlated with age, and is relatively equal between genders. Joint pain and stiffness are the most common symptoms. Because pain is activity related, it is felt more in the later part of the day whereas stiffness is felt in the morning. OA affects the entire joint, but the part that suffers the most is the articular cartilage that hinders the femoral head from rubbing against the acetabulum. When OA is present, the cartilage wears down or breaks into pieces. At first the pain is caused by the imflammation at the joint, but as the disease progresses the pain can be traced to the wearing of the cartilage [20, 22]. Definitions of other pathological conditions at the hip joint include: Rheumatoid arthritis (AR), where the cartilage is damaged because of chronic inflammation. Arthrosis, where cartilage is damaged in a trauma, called secondary arthrosis. Avascular necrosis, where blood supply to the femoral head is limited, causing the bone to collapse, following a trauma or some childhood hip diseases as Perthes [12, 23]

2.5. THA – Clinical treatment, materials and techniques

2.5.1. Before surgery

There are some different ways to treat patients while waiting for surgery. First there is physical management. After the problems with the hip begin the patients often limit their movement and exercise in daily living because of the pain they experience. This can lead to gaining weight that can possibly add to the hip problems and therefore patients are often advised to lose weight. General exercises are also positive for patients suffering from osteoarthrosis as pointed out by Lin et al. [24]. Patients can also use assisting devices, such as a cane or crutches for the opposite hand of the disease.

Patients can use analgesics for some period of time and research shows that sensible usage does not cause any damage like excessive usage of the drug [25]. Nonsteroidal anti inflammatory drugs (NSAID) are a medicine group that patients can use for pain relief after a doctor’s prescription. Their use is however not suggested for longer periods or for elderly people. An alternative to the NSAIDs is opioid analgesics. Steroid injections are also a possibility, but their usage has not been studied very widely [26].

2.5.2. The surgery

In the surgery the femoral head and neck are replaced with a prosthesis made of biocompatible materials. The different implants involve different implantation technologies which do affect the patient in different ways.

2.5.3. Materials

All implants are made from biocompatible materials, they are able to withstand corrosion and degradation and they have mechanical properties that mimic the function of a natural hip joint

[12]. The materials used to make the three components of the implants are different; the stem is made of titanium- or cobalt/chromium alloys, the ball is made of ceramics or cobalt/chromium alloys and the cup for the acetabulum is made of metal, polyethylene or a mixture of both materials and finally the bone cement is made of Poly(methyl methacrylate) (PMMA) or similar materials [9, 27].

If the new hip joint has metals rubbing against metals there can be some by-products of the wear that causes inflammatory response in the joint. To prevent this, a high molecular weight polyethylene is used to make a cup inside the acetabulum that the head of the stem fits into. It was first used by Sir John Charnley in 1962, who had previously failed to create a cup from other polymers. Now, an ultra high molecular weight polymer is used to produce the cup. The cups are cross-linked with thermal- or radiation treatment improving the cup's resistance to wear and oxidation [28].

Ceramics such as Aluminum Oxide and Zirconium Oxide are being used in THA as an acetabular socket and the ball fitting on top of the femoral component. Ceramics are biotolerant, strong and wear resistant. The production of Aluminum Oxide ceramic balls improved from 1970's until the 1990's from having low strength and wear resistance to being a complete prosthesis. The Zirconium Oxide balls have improved mechanical toughness over the Aluminum Oxide ones and it was also suggested that their mechanical properties would have advantages over the Aluminum Oxide ones when used along with a polyethyline as an acetabular component [29].

There are few metal alloys that are common in the field of THA implants. They can be used to create the stem, the ball fitting on the stem and also the acetabular component. There are three alloys that are mostly used in this field; stainless steel, cobalt based alloys and titanium based alloys. Stainless steel alloys have mostly been used in making bone screws, plates and such. Recently they have seen increase in usage in THA surgeries in Europe. Newer steel alloys have shown to be able to withstand more loading and be able to withstand the body’s environment better that previous alloys. Cobalt based alloys have high strength and good corrosion- and deformation resistance and are therefore ideal to use for THA prosthesis. The titanium alloys are the most studied implant materials around. They are highly biocompatible, have high strength and good fatigue resistance. The titanium alloys have lower elastic modulus than cobalt based alloys, making them better at transferring stress from implant to bone and minimize bone resorption [30].

2.5.3.1. Implant technology

There are two main methodologies in the total hip arthroplasy surgeries, that is, implants with bone cement and implants without bone cement. The femoral component of a THA replaces the femoral head, the femoral neck and elements in the femur between the greater and lesser trocanters. The idea behind the uncemented procedure is to achieve and maintain local tissue stresses within a certain range. The cemented procedure uses bone cement to reduce stresses by distributing loads [31].

In Iceland there are three types of hip prosthesis used, two for cemented- and one for uncemented operations. The one cemented (Figure 5. B) and the uncemented (Figure 5 A) are from the Zimmer company. They are similar in structure but each has some unique pieces. The other cemented stem (Figure 5 C) is from Smith&Nephew which has a very unique appearance compared to those from Zimmer [32, 33, 34].

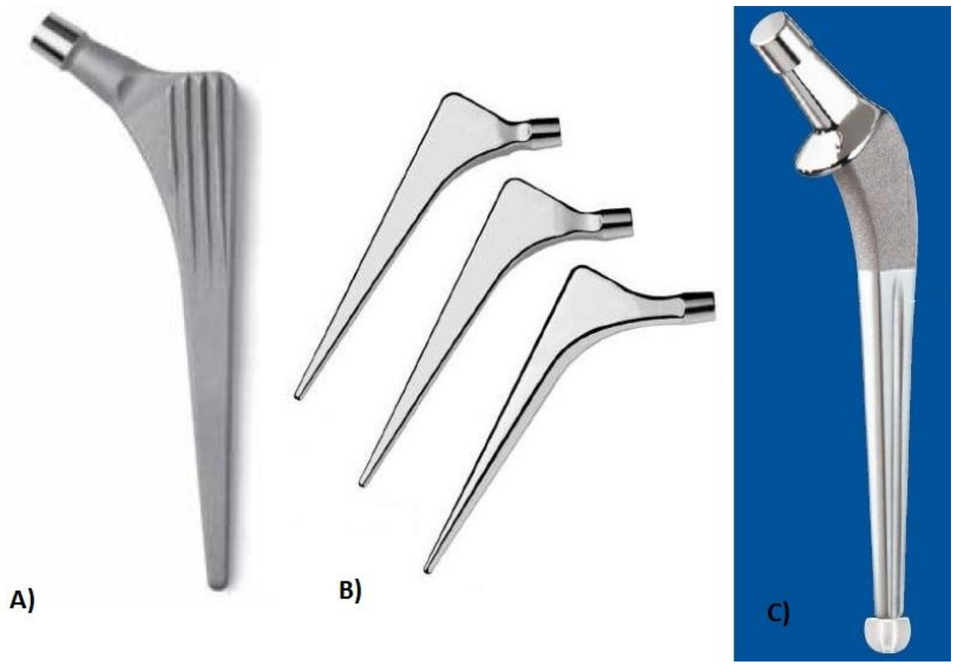


Figure 5. A) CLS tapered stem from Zimmer. B) CPT 12/14 Hip System stems from Zimmer. C) Spectron EF stem. [32, 33, 34].

The uncemented procedure

Uncemented surgeries are usually done on younger and more active patients. The method of using no bone cement was developed because the bone cement was known as promoting bone lysis and stem loosening. The stem is fixed into the femur bone with press-fitting method or

by biologic ingrowth, or a mixture of both. The stems are different from the stems used in cemented surgery because they can be porous or have raised edges whereas the cemented ones usually have polished or a flat surface [12].
The three best developed types of uncemented implants are: cylindrical, tapered and distal fixation types. There is one advantage the tapered one has, because he causes less thigh pain than the others [9]. The only uncemented type used in Iceland is a press-fitting CLS tapered stem from Zimmer. The CLS stem has proven to have low revision rate as Schreiner et al. reported only 1,8% of 335 stems had to be revised in a 7-11 year follow up and Grappiolo et al. reported that only 5% of 300 stems had to be revised after 10 years [35, 36].
In an uncemented surgery, the first step is to remove the femur head and part of the neck. Then a canal is made through the cancellous bone with an awl so the layout of the hole is correct. After that is completed the cancellous bone is compressed and the cortex bone is rapsed by inserting a rasp 3-4 sizes to small compared to the size of the stem to be used into the femur. That is done until the canal is a perfect fit for the preferred stem size. When the stem is inserted it is pressed into the femur with light hammer blows. This is done with much care because a blow too hard can fracture the cortex bone [32].

The cemented procedure

The cemented surgery is usually done on elderly patients as they are less active than younger patients. The groundwork for this type of surgery was made in the 1950's, but in the late 1960's sir John Charnley made it a feasible option for people with hip pain or reduced mobility in the hip. The method uses bone cement to fix the prosthesis into the femur bone [12]. The Spectron EF prosthesis that is one of two cemented stems used is Iceland has shown good survival rate, as early as in 1993 it had reported 98% survival rate at five year follow up [37].
The surgery starts off by cutting off the femoral head and neck just like for the uncemented one. Then a canal is made through the cancellous bone with an awl and the cavity is reamed with a rasp just like in the uncemented surgery. The seat for the cemented implant is made slightly longer than the implant and has a 1,5mm space along the stem for the bone cement. Then a small cap, called cement restrictor, is inserted into the distal end of the canal so the bone cement can be stopped from leaking into the distal end of the femur. The bone cement is put into the canal with a cement gun and the cement is then pressed into the canal until it becomes doughy. Finally the stem is inserted slowly into the canal and fitted to its predetermined position [33, 34].

2.5.4. Post operative rehabilitation

Most THA patients leave the hospital within three days of surgery. They are encouraged to start walking at the day of surgery. Patients use assistance devices and painkillers in the beginning, but it varies between individuals. Six weeks after surgery, the patients are generally free of activity restrictions, and they should resume to low impact activities, including, swimming and bike riding. The patients are advised not to engage in more impact activities such as jogging and contact sports [38]. The general rehabilitation does not include any physical therapy but patients can choose to use physical therapy if they feel their progress is not satisfying.

2.6. Clinical assessment of THA patients

2.6.1. Gait analysis definition

Walking is the human natural method of travelling some distances. If there are no pathological problems, the gait is supposed to appear coordinated, efficient and effortless [39]. If there are any problems, generated by disease or trauma, then the persons speed, coordination and other important gait characteristics can become limited, and the gait of the person becomes "pathological".

Gait analysis is used for the action of analyzing persons gait with various gait analysis technologies. According to the summary of Sutherland [40], gait analysis sciences were first developed in the 17th century. The groundwork made in the following centuries was solid, but major progresses in gait sciences were made in the 1950's, and have been in further development to this day. Gait analyses are used for various applications and with all kinds of different equipments and setups, but are not used to evaluate THA patients neither pre- or post operatively.

The posture and walking pattern of a person with no pathological problems can be described as a normal gait. The gait cycle is defined as the movements one makes during one stride. The cycle begins when one foot makes contact with the heel and ends when the heel makes contact again after that one stride has been performed.

The gait cycle is divided into seven phases [31, 39] which are divided by seven events. In one gait cycle all the events are defined from the point of view of either the left leg or the right leg.

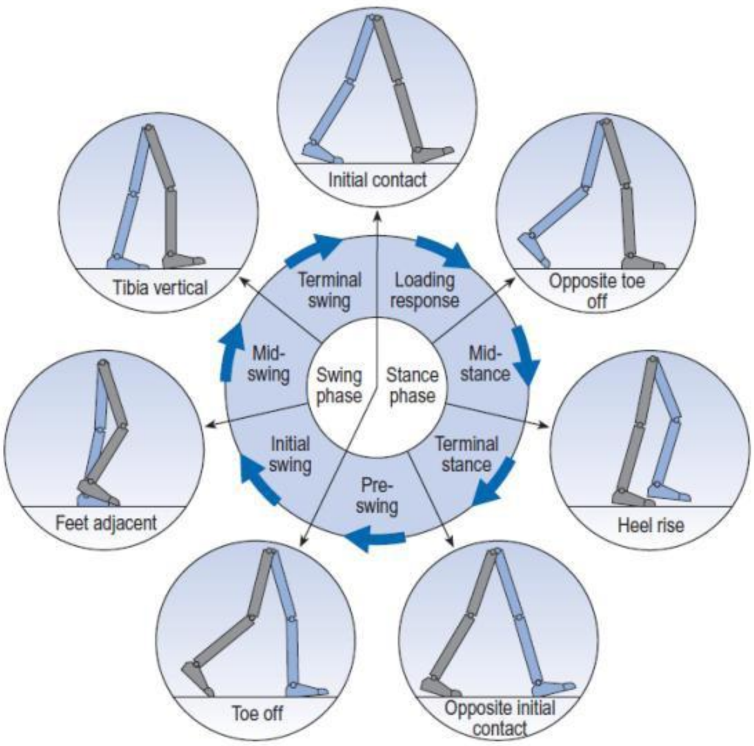


Figure 6. The seven phases of gait as defined by Whittle's gait analysis[31].

The phases of gait are:

1. Loading response: The phase begins when initial contact is made; the weight is loaded on the foot, the phase ends when the opposite toe is lifted from the ground.

2. Mid stance: The phase begins when the opposite toe has lifted from the ground; the loaded foot bears all the weight, the phase ends when the opposite foot has advanced to be in front of the other.

3. Terminal stance: The phase begins with a heel rise, the weight is transferred to the opposite foot, and the phase ends with the opposite foot making contact to the ground with the heel.

4. Pre-swing: The phase begins with the opposite foot making contact to the ground, the body loads the weight onto the opposite leg, the phase ends when the toes lift off.

5. Initial swing: The phase begins when the toe is off the ground, the foot advances and the phase ends when the feet are adjacent.

6. Mid swing: The phase begins when the feet are adjacent and ends when the tibia is vertical to the ground.

7. Terminal swing: The phase begins when the tibia is vertical and ends when the foot makes initial contact, and closes the gait cycle.

The phases are divided into two categories; stance phases and swing phases, phases 1-4 are stance phases and phases 5-7 are swing phases. To get a better visualization over the events and phases from the point of view of both legs look at Figure 7.

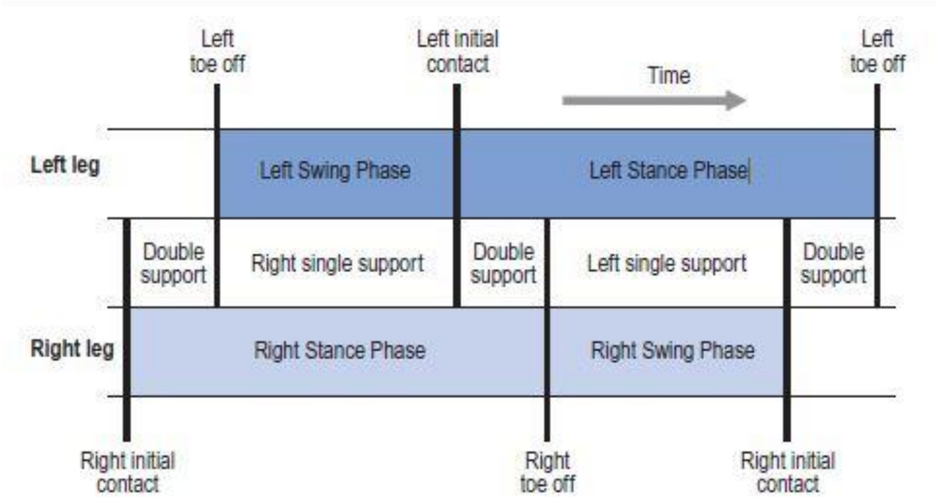


Figure 7.Shows how the gait cycle phases divide through the gait cycle [31].

Whittle's gait analysis from 2012[31] describes the four things the locomotor system must be able to do to perform a walk:

1. „Each leg in turn must be able to support the body weight without collapsing.

2. Balance must be maintained, either statically or dynamically, during single leg stance.

3. The swinging leg must be able to advance to a position where it can take over the supporting role.

4. Sufficient power must be provided to make the necessary limb movements and to advance the trunk."

When these four things are performed without any complications the gait of a person is deemed normal. When the tasks are performed with obvious abnormal movements and/or extra effort the gait is said to be pathological. When gait parameters do not follow normal pattern and do not fall within normal limits, the gait is possibly pathological. Pathological reasons hinder people from being able to walk without problems. Among the categories the pathological problems fall into are deformity, muscle weakness and pain. Other categories are sensory loss and impaired motor control, but THR patients are primary affected by the former three [39].

Deformity affecting THR patients could be abnormal joint contours, which affect the range of motion when walking. Muscle weakness affecting these patients could be due to atrophy following abnormal posture used for a long time and the weakness of muscles that are cut during the surgery. Pain affecting THR patients would be due to osteoarthrosis pre surgery and surgery related pain after the surgery.

THA patients can adopt known pathological gait patterns such as the Trendelenburg gait where patients suffer from abductor muscle weakness and move their weight over the affected side at the end of swing phase to prevent falling to the unaffected side [41].

The functions of many muscles contribute to the mechanism of gait. Their timing and contribution is described by Perry et al., both for stance phase and swing phase. Fourteen muscles contribute to controlling the knee during gait; these muscles contribute to stability and mobility, as they act both in flexion and extension of the knee during gait. Eleven muscles contribute to the motion of the hip, they act in extension, flexion, adduction and abduction [39].

2.6.2. Use of gait analysis in THA

Gait measurements are not a current assessment tool for evaluating THA patients, but surgeons can evaluate the patient by just looking at them and possibly categorize them into known gait-abnormality categories [41]. There have been numerous publications involving gait analysis measurements on THA patients, they mostly compare results before- and after surgery and THA patients with control groups.

Gait of THA patients is usually abnormal before the surgery and postoperative studies show that gait does not return to normal following a THA surgery according to Whittle’s gait analysis[31]. It also says that gait speed, cadence, step length and stride length can significally decrease following a THA, and some spatiotemporal parameters may never return to normal. Decreased gait speed has been correlated with the fact that THA patients are unable to fully extend the hip during late stance.

It has been suggested that long term follow up on THA patients should be done with restoring normal- and symmetrical gait pattern as its objective. The rehabilitation should focus on the hip's extensor and abductor strength and make hip extension flexibility better [31].

In a study on four THR patients from 1995, Loizeau reports that these patients have slower speed, shorter stride length and higher percentage of gait cycle in stance phase than normal patients [42].

R.M. Kiss & Á. Illyés reports that THA patients have lower cadence 12 months post surgery than before surgery. Step length of operated leg is measured shorter than of the non-operated leg pre-op, but improves during the follow up till 12 months post op. The results also indicate that double support period increases and swing period for both legs increases after surgery [43].

Tanaka research involving 43 women with osteoarthritis showed increase in stride length, cadence and velocity one year after surgery and higher percentage of gait cycle used in single support phase for both the operated and healthy leg one year after surgery [44].

V. Lugade et al shows increase in step length and single limb support for both legs four months after surgery, when 21 patients were investigated; they did not get as good results as the control group. It is also reported that symmetry index for these parameters increases after four months [45].

In a meta-analysis of THA recovery literature by Vissers et al. in 2010 are nine publications that include gait analysis. All nine report on increased walking speed, three after 1-3 months post surgery, three after 6-8 months post surgery and three 12 months post surgery. Five publication included stride length in their gait analysis, all report on longer stride length, three 1-3 months after surgery, and one each for 6-8 and 12 months post surgery. Three publications mention increase in cadence, two 1-3 months post surgery and one 6-8 months post surgery [46].

Miki et al. reports on increase in cadence, velocity, stride length and step length in a study on 17 patients undergoing unilateral hip replacement. Both operated and healthy legs were inspected and both showed better results in all categories three months after surgery and even better results twelve months after surgery for all parameters except step length which were though better that pre surgery [47].

In a study where THR patients suffering from hip dysplasia and osteonecrosis at the femoral head are compared between pre op and 12 months post op, both types of patients increase in cadence, speed, stride length. All patients showed increase in single support period and decrease in double support period. The only difference in the temporal gait parameters between the groups was that step time increased for the hip dysplasia patients but decreased for the patients suffering from osteonecrosis of the femoral head. The control group however showed better results for the cadence, speed, stride length and step time, but also lower percentage of gait cycle being used for double support and higher percentage of gait cycle being used for single support [48].

Nantel et. al reports that six months after surgery there is no significant difference between 10 THR patients and 10 control group subjects for parameters including walking speed, stride length, single support and double support [49].

In a research of uncemented patients, gait parameters of 11 patients were measured. Results showed increase in gait speed, cadence, stride length and step length. Results from phase parameters showed decreased % of GC of operated leg in stance phase and increased % of GC in single support for the operated leg [50].

In a research of 20 cemented patients measured preoperatively and 12 months post op cadence decreased. Step length increased for the operated leg and decreased for the healthy leg. Walking base for both legs decreased for both legs, double support phase % of GC increased but swing phase for both legs as a % of GC decreased [51].

Muscle volume at the thigh was measured in 20 THA patients by Adolphsson et. al. and results showed that the operated side had gained 19% of mass after 6 months. The control side had greater muscle volume, both pre op and after six months, than the operated side, and showed no significant changes [52]. Gargiulo et al. comes to the similar conclusion when measuring muscle density in 36 THA patients where 81% of the female population and 91% of the female population showed greater muscle density at the control leg then for the operated leg [53]. Studies have also shown that quadriceps strength, function, size and density decreases five months after THA [54], and even longer [55, 56].

2.6.3. Bone Mineral Density (BMD) definition

Bone mineral density (BMD) is a quantitative scale that indicates how much minerals there are per square/cubic centimeter of bone. Higher values are generally considered related to less fracture risk and better bone quality. Bone mineral density evaluation is a tool that can be used to assess the patients bone quality pre operatively and could play a part in doctors decision making in implant selection. There is some evidence that BMD of the femur could be correlated with strength of the femur [57]. Bone mineral density can be used as an indicator for fracture risk at the hip Melton et al. [58] and Burger et al. [59] reports that including BMD as a value in fracture risk evaluation increases the accuracy of the prediction. CT imaging can be used to evaluate fracture risk. Johannesdottir et. al. comes to the conclusion that the CT scanner can be a valuable tool and even give additional information to DXA scanning for this purpose. [60]

Patients with better bone quality are better suited to have an uncemented implant, while patients with low bone quality are better suited for an cemented implant. The fact that the mineralization of bones is correlated with age and gender has made the preoperative planning process easier since, higher age correlates with lower density and women generally have lower bone mineral density [61, 62, 63]. But these assumptions should not be generalized for every patient. The BMD quality can also be influenced by other factors like race, genetics and lifestyle [3]. When BMD is measured the femur is often divided into seven zones called Gruen zones [64].

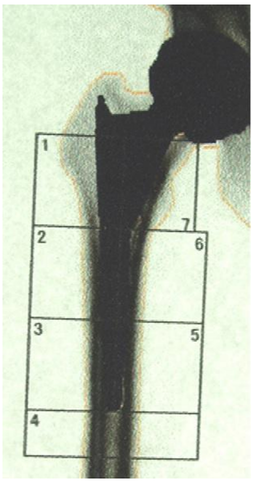


Figure 8. Shows how the femur is divided into Gruen zones, as the bone quality differs with location [64].

2.6.4. Use of BMD measurements in THA

Older patients seem to have better bone quality than younger patients in some cases but nevertheless receiving cemented implant, because no preoperative BMD evaluation is made [65]. Niinimäki et al measured the BMD for 25 THA patients in the operated femur and the control side. The results showed that the BMD was 13% higher for the control side nine years after operation[66]. Kröger et al. suggests that BMD follow up measurements should be compared to the pre op BMD of the same leg and not involving the non-operated leg [67]. In a study of 45 patients receiving uncemented implant, BMD (average over the 7 Gruen zones) was 1,504 g/cm^2 for the healthy side and 1,436 g/cm^2 for the operated side pre operatively. In a follow up on the healthy hips after six months the BMD had increased to 1,526g/cm^2 [68]. In another study of 100 patients receiving uncemented implant, results showed that BMD (average over the 7 Gruen zones) was 1,23g/cm^2. In a follow up of one year, two years and four years the average BMD was 1,18g/cm^2, 1,21g/cm^2 and 1,24g/cm^2 respectively [69]. In a research including 24 uncemented patients average BMD went from being 1,68g/cm^2 pre op down to 1,57g/cm^2 three years post op. This research also adds that BMD of the males was generally higher than BMD of females and the BMD of the control side did not change over the research period [70].

3. Methods

3.1. Introduction

The subject of this chapter is the methods used in the study. First there is general info about the setup of the study, including the gait analysis equipment and how it was used. Also in that chapter is info about the setup of the image acquisition and the transformation from Hounsfield Units (HU) to BMD values. Secondly, there is a chapter on artifact reduction and bone- and muscle segmentation. Finally the last chapter is on spatial and temporal gait parameters, maximum pressure distribution and electromyography (EMG) data processing.

3.2. Setup of the study

The patient group that took part in the study included 39 voluntary patients, 23 females and 16 males. The criteria for being included were that patients could not have had a previous THA or total knee arthroplasty (TKA). Eighteen of 39 patients received cemented implant and 21 uncemented implant, 12 patients were operated on the left side and 27 on the right. The youngest patient was 21 years old and the oldest 77. The implant selection for the patients was in the hands of their operating surgeon who based their selection on patient’s age, gender and general physical conditions.

Table 1: Shows age distribution between implant technologies.

	Both types	Uncemented	Cemented
Males	16 (54.69±13.31)*	11 (49.27±11.31)	5 (66.60±9.32)
Females	23 (64.04±7.52)	10 (59.20±6.48)	13 (67.76±5.81)
Total	39 (60.21±11.15)	21 (54.00±10.53)	18 (67.44±6.68)

*) Number of patients (average age (years)±standard deviation (years))

The setup of the study was as following:

Figure 9. Setup of the study.

3.2.1. Gait analysis

For each gait analysis there was at least one physical therapist and one technician present. There had to been at least two persons to operate the workstations. The technicians took care of the workstations and the setup of the equipment. The physical therapist took care of the patients and the setup of the equipment.

When patients showed up at Grensás rehabilitation center for the gait analysis, they were asked to wear shorts and have bare feet. The physical therapist applied three wireless electrodes on the patient's leg. When ready, the patient walked three times along the GAITRite® pressure sensing carpet in the same direction. At this point the physical therapist removed the electrodes and put them on the other leg and the patient walked along the pressure sensing carpet three times in the other direction. While walking on the pressure sensing carpet the patient's synchronized EMG muscle activity and video were recorded with the KinePro device.

3.2.1.1. GAITRite® Pressure sensing carpet

GAITRite® pressure sensing carpet, from CIR systems inc. (www.gaitrite.com) is a moveable gait analysis device with a computer interface that has existed since 1995. There have been numerous publications that have utilized the GAITRite® carpet with good results [71, 72, 73]. The carpet used in the clinical trial is 427 centimeters long and 61 centimeters wide. The pressure sensors are inside the carpet and they are placed on a grid with 127mm between them. There are 48 lines of sensors across the carpet and 336 sensors in each line along the carpet, making a total of 16.128 sensors. The system scans the sensors continuously to detect objects. The sensors have seven switch levels, the switch level depend on how much pressure is put on the sensors and they change levels when the amount of pressure on them changes. As the sensors are scanned and objects are detected, the footfalls of the patients on the carpet are displayed on the computer connected to the carpet. The program calculates instantly numerous gait parameters for the walk [74].

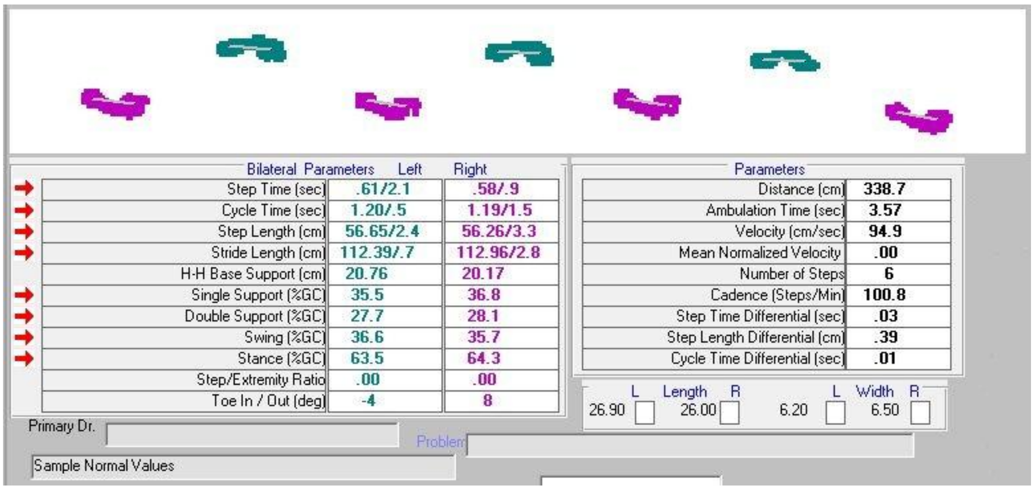


Figure 10. Shows the display of a walk in the GAITRite® program.

When the technician was ready he signaled the patient to start walking and simultaneously activated the data collection. The patient started walking, on self selected and comfortable speed. He was instructed to start walking three meters from the beginning of the carpet and not to slow down until he was three meters off the carpet. If the walk was successful the technician approved the walk, if not, the walk was suspended. This process was repeated until there were six acceptable walks that had been saved and stored.

Figure 11. Shows a patient walking along the GAITRite® carpet

3.2.1.2. KinePro EMG measurements

The electromyography (EMG) measurements were done simultaneously as the patient walked along the GAITRite® carpet. The device used was a wireless EMG measurement device called KinePro from Kine ehf. (www.kine.is). The device consists of wireless surface electrodes and their housing/charging device, video camera and a computer program. The housing device and the video camera are connected to the computer, so both video of the patient and his EMG measurements are visible in synchronization in the KinePro program.

The physical therapist prepared the skin of the patient with alcohol and applied three electrodes onto the muscles according to SENIAM guidelines [75]. The three muscles measured were rectus femoris, vastus lateralis and vastus medialis. They all have a role in the gait cycle, vastus lateralis and vastus medialis in the stance phase and rectus femoris in the break between stance- and swing phases, and they are all accessible for electrode placement. The quality of the EMG signal generated in the muscles however depends on things like distance of electrodes from muscle activity, quality of contact between skin and electrodes, thickness of skin and amount of body fat. When the patient was ready to go, he was signaled to start walking, at the same time the recording in KinePro was started and kept going for seven seconds. If the recording of all three EMG tracks and the video recording were good, the file was saved under the patient's name. After three successful walks in the same direction the physical therapist moved the electrodes to the same muscles of the other leg, and the patient finished three successful walks in the opposite direction.

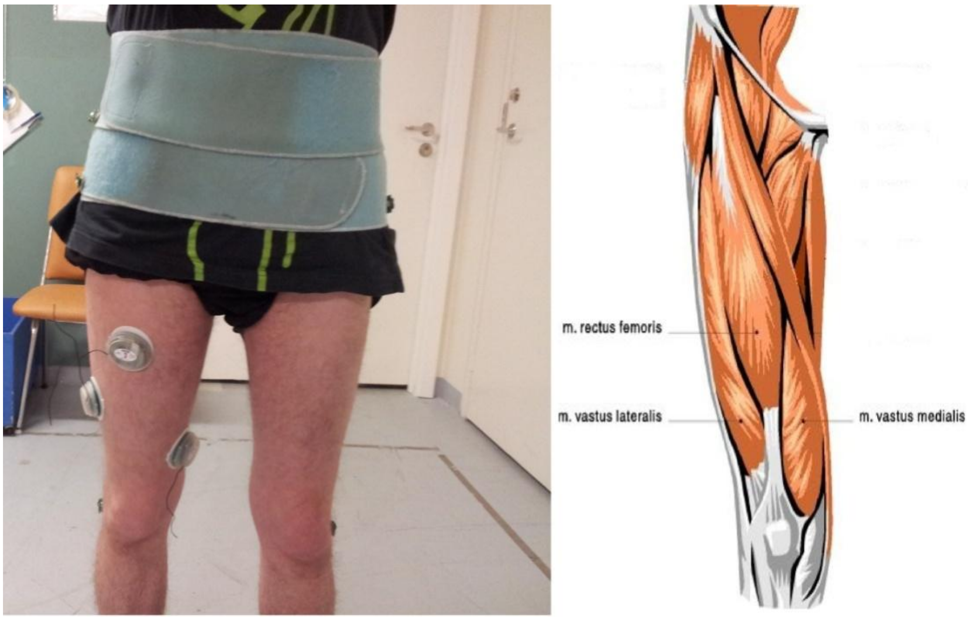


Figure 12.A, B. A shows the placement of the electrodes on a patient B. Reference drawing of the muscles[75].

3.2.2 Image acquisition

The patients were all scanned with a 64-slice spiral CT Philips Brilliance scanner at Landspitali Hospital Fossvogi. All patients were scanned with the same protocol, slice thickness was set to be 1mm, slice increment was set to 0.5mm and the tube voltage was set to 120KVp. The scanning area started at the iliac crest of pelvis and ended at the middle of the femur.

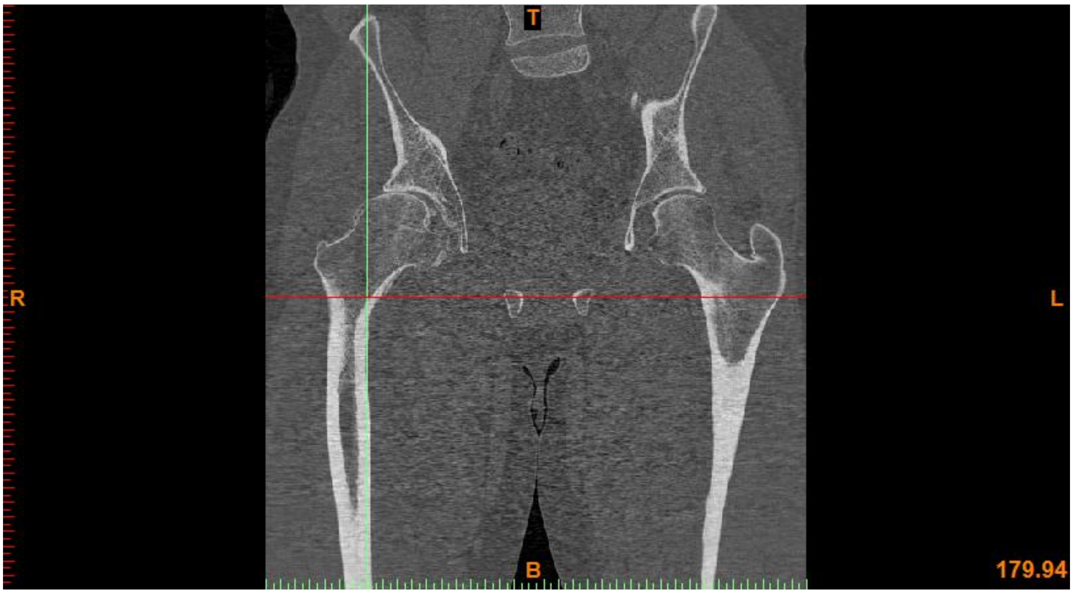


Figure 13. A coronal view of the scanned area in Mimics.

When the images from the CT scan are loaded into the Mimics software from Materialise (www.materialise.com) and a 3D workspace created, the radio density of each voxel (3D pixel) is measured in Hounsfield Units (HU). The definition of HU is following:

$HU = 1000 * (\mu_x - \mu_{water}) / \mu_{water}$,

where μ_{water} is the linear coefficient of water and μ_x is the linear coefficient of the voxel.

To establish accurate relationship between bone mineral density (BMD) and Hounsfield Units (HU) of the images from the CT scan, the scanner was pre-calibrated with Quasar phantom from Modus Medical Devices Inc. (www.modusmed.com) before each acquisition period (pre-op+post-op and one year post-op). The Qasar phantom contains five different elements with known physical density. The measured HU values of the phantom's five elements are plotted up versus their physical density. The elements in the phantom have a liner relationship above 0 HU and below 0 HU. When those linear relationships are united the equation of the linear regression for the BMD-HU transformation is available. The equation is

BMD [g/cm^3]= $-8 * 10^{-8} * HU^2 + 0.0006 * HU + 0.9456$.

The correlation coefficient for this calibration is R^2=0.99. When curves from different calibration periods are compared it shows that the changes in HU which values are less than 0 is less than 1.5% but the change in HU which values are greater than 0 is up to 4.13% (Figure 14.A).

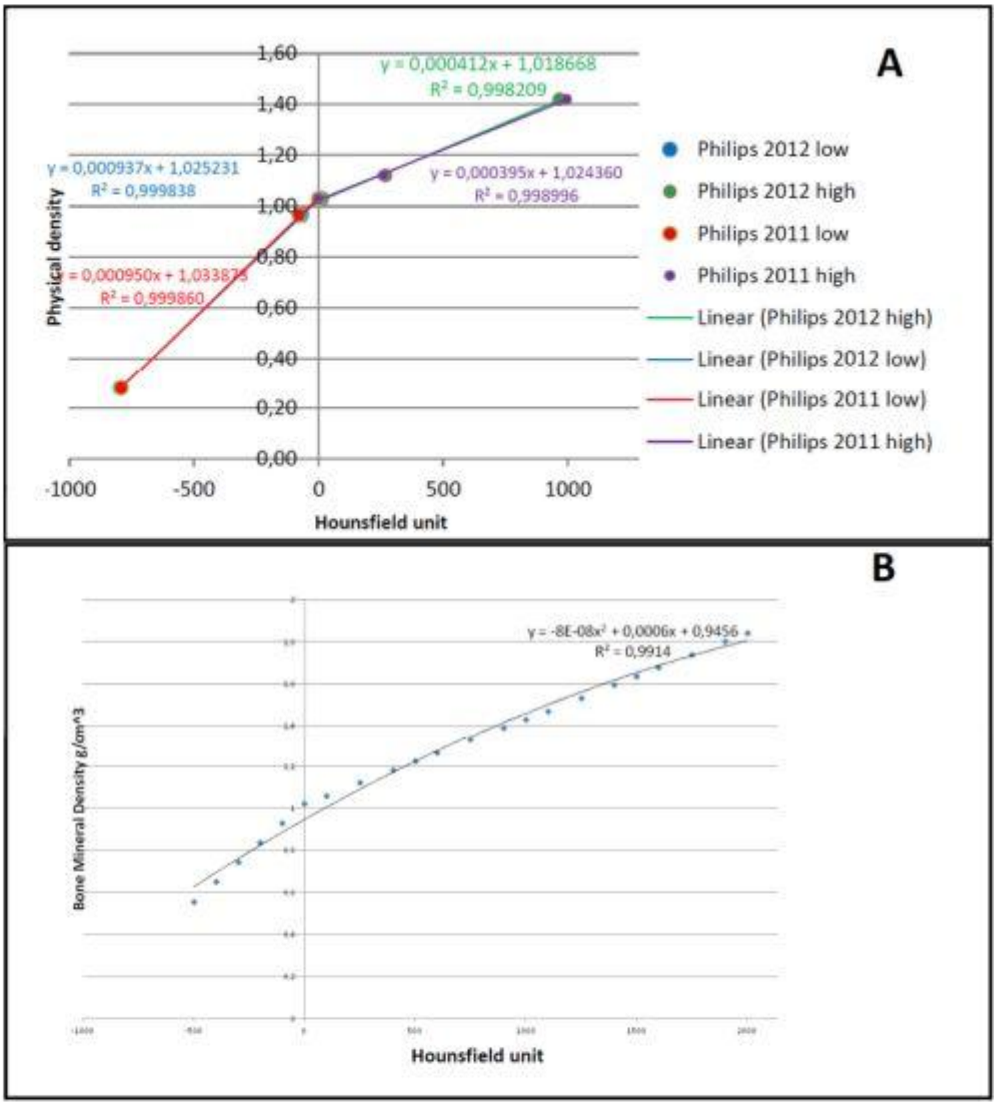


Figure 14 A,B: A shows the linear relationships of the elements in the Qasar phantom at two different calibration periods, both above and below zero HU. B shows the united linear relationships resulting in the equation used to transform HU to BMD [52].

3.3. Bone and muscle analysis

3.3.1. Artifact reduction

After the prosthesis has been implanted the images from the CT scans become corrupted in some areas because of metal artifacts. Streaks that originate from the implant cause damage to pixels of normal body tissues. The pixels that are damaged by the artifacts can contain valuable information about the surrounding body tissues. Those tissues can include bone and muscle tissues that this study focuses on. Therefore it is valuable to be able to clean the datasets from all artifacts, making the measurements more reliable and comparable with other datasets of the same patient with no implant.

To clean the images the Metal Deletion Technology (MDT) software from reVISION radiology (www.revisionrads.com) was used. The software preserves the original metal pixels from the CT scan images, and then reconstructs the image using only non-metal pixels and finally re-adds the metal pixels to the image.

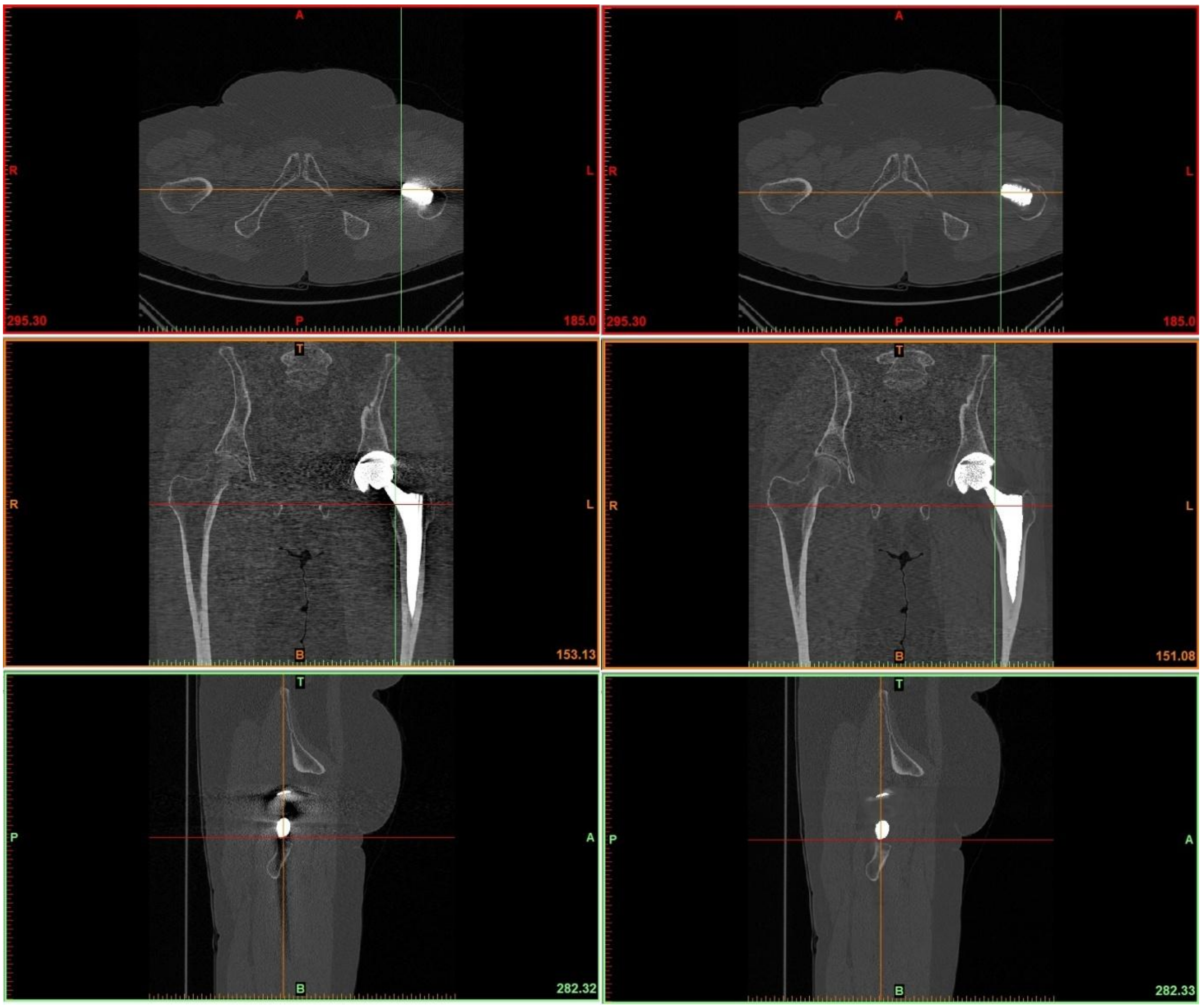


Figure 15. Shows the same dataset before (left) and after (right) the artifact reduction process in three planes; axial (top), coronal (middle) and sagittal (bottom).

3.3.2. Bone segmentation

There are five areas of interest that are isolated with the bone segmentation process. There is a large area on the proximal femur that would be most affected by the hammering in the uncemented surgery. There are four smaller areas, two on the proximal femur and two on the distal end of the implant, that are also of interest for BMD evaluation. The four smaller areas were chosen because they were likely affected by the surgery and the effect of artifacts on them was supposed to minimal, as they were chosen before the artifact reducing process was available. The changes in BMD for all the five areas are of interest but also the different results from the artifact reduced data and the original data.

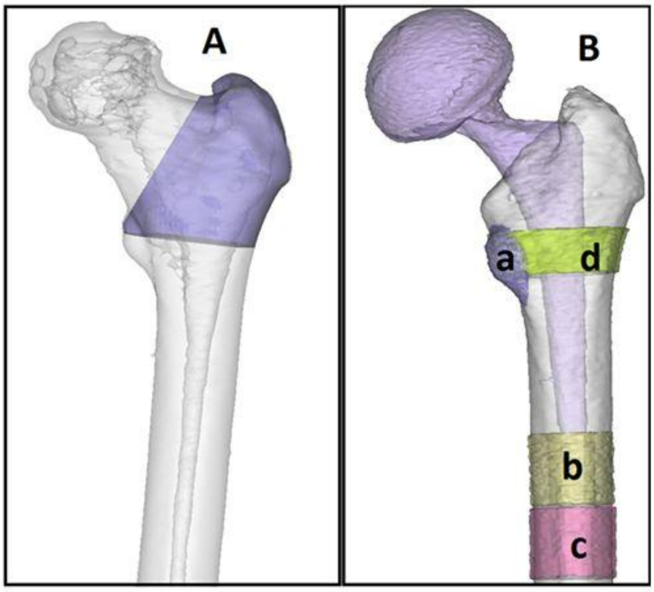


Figure 16 A,B: A shows the large area on the proximal femur that is affected by the hammering in the uncemented surgery. B shows the four smaller areas also investigated.

To work with the images acquired from the CT scan they are imported into the Mimics software. Each patient included in the bone segmentation part had to have three datasets available; pre op, one year post op (original) and one year post op (artifact reduced). The first phase of the segmentation is done in a one year post op artifact reduced dataset. The first step is to activate the "3D LiveWire" tool and use it to distinguish the contours of the femur in sagittal and coronal planes with approx. five slice intervals, when this is completed for both planes the segmentation process is activated which creates a 2D mask from the pixels that are inside the contours of the two planes. The same process is performed for the both legs.

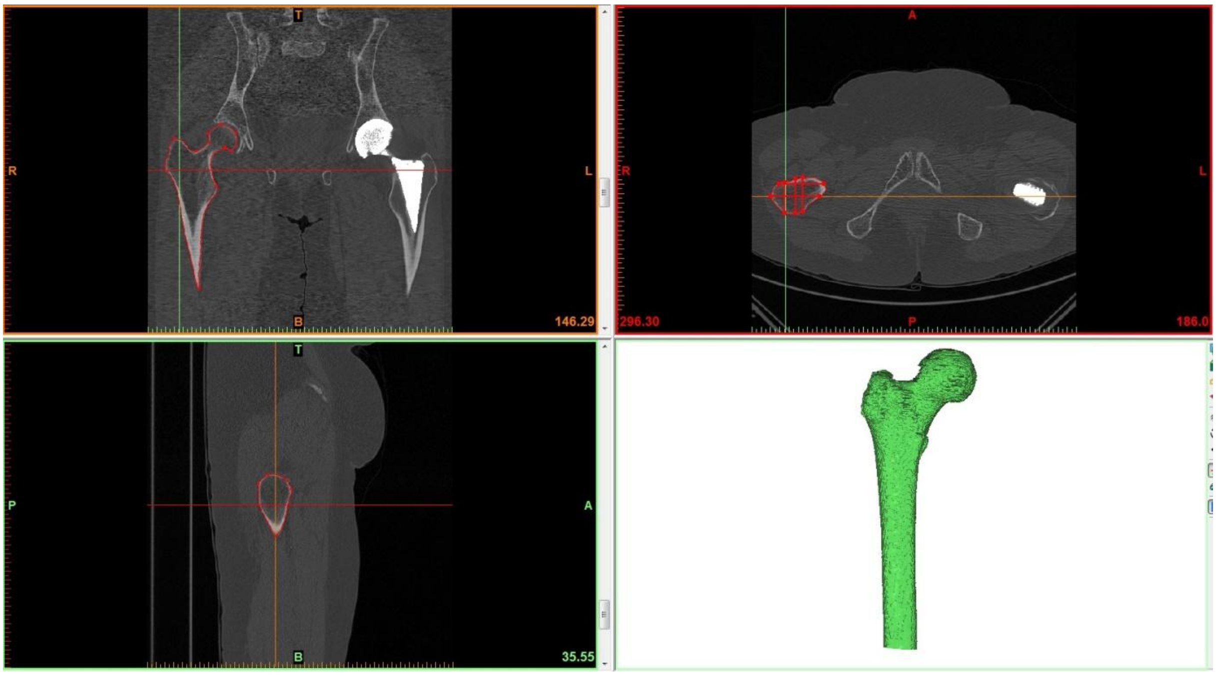


Figure 17. Shows the contours created in coronal- (top left) and sagittal (bottom left) planes. Top right shows the automated contours in the axial plane and finally the 3D structure of the bone is shown (bottom right).

Next step involves using the “Morphological” tool where the “Erode” option is selected for four pixels. This action creates a new mask from the first one without a four pixel thick outer layer; this new mask is then subtracted from the original femur mask, creating the third mask which is like a four pixel thick shell of the outer layers of the femur. Then the “Create 3D” function is used to create 3D objects of the femur shell and the original femur.

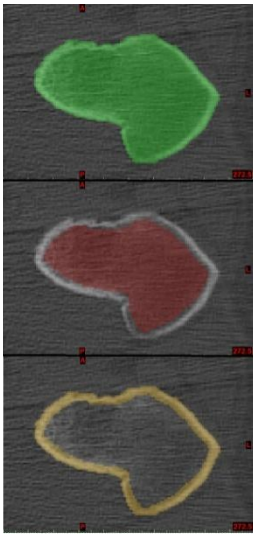


Figure 18. Shows the creation of the shell mask of the femur. On top there is the segmented femur, in the middle that mask has been eroded by four pixels, on the bottom the second mask has been subtracted from the first one, leaving a shell like mask of the femur, representing the compact part of the bone.

Next the “Cut with polyplane” function is used to cut out areas a and c from the shell mask and areas b, d (Figure 16,B) along with a large area at the proximal femur (Figure 16, A) from the full femur mask. The large are of the operated leg has to be manipulated some more because of the prosthesis inside the mask. To remove the metal pixels and some adjacent pixels that can possibly be affected by the metal pixels, a new mask of the prosthesis is created and dilated with five pixels. Finally this new mask is subtracted from the proximal femur mask of the operated leg.

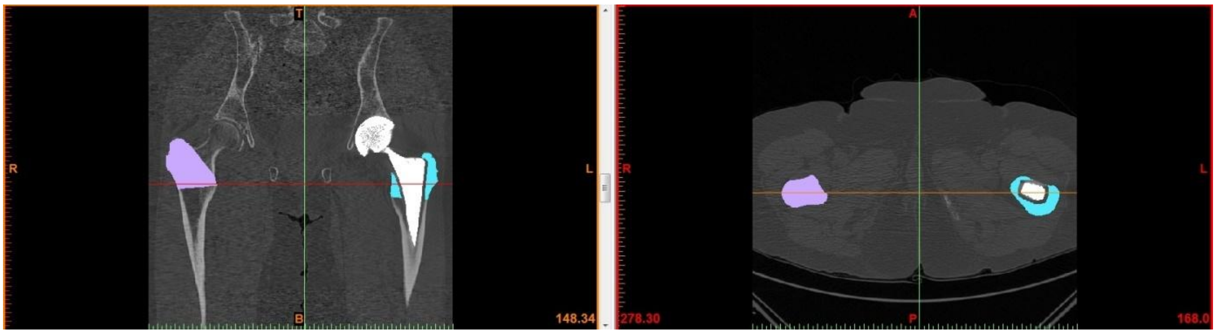


Figure 19. Shows on the the difference in the masks between the two legs, operated (light blue) and healthy (light purple), in two planes; coronal (left) and axial (right).

When all those masks are ready the average HU values for areas a, b, c, d (Figure 16,B) and the proximal area(Figure 16, A) are written down. The last action taken on this dataset is to create Stereo Lithography (STL) files from the ten cut out masks and the original femur mask from both feet, this is done so approximately the same pixel areas are measured in all three datasets. In the STL files the masks are saved as they are, both layout and coordinates. The second phase begins with opening the original dataset from one year post. Then the ten cut-out STL files are loaded into the dataset and since the dataset is the same as the first one, only with artifacts, the STL files do not have to be repositioned. Next step is to create masks from all the STL files and writing down the average HU for all ten masks. Third phase of the bone segmentation begins with opening the pre-op Mimics dataset and importing all the STL files. When the STL files have been imported they are not in the right position for direct creation of masks from the STL files and therefore they have to be repositioned. To have a successful reposition all the masks of the same leg are repositioned at the same time. When both of the legs have been repositioned successfully, masks are created from all the cut-out areas from both legs and their average HU value is written down.

Figure 20. Shows a pre-op dataset after the STL files have been loaded into it, before repositioning of the STL files (left) and after repositioning of the STL files (right).

3.3.3. Muscle segmentation

In the muscle segmentation part there are three things of interest; comparing the difference in muscle density (MD) of the three muscles between pre-op and one year post-op, comparing the different increase in MD between legs and investigating the effect of the artifact reduction process on the results.

The segmentation of the three muscles included in the study is done in Mimics. In the first phase of the muscle segmentation, the one year post op artifact reduced dataset is used. The first step is to create an empty mask. The second step is to find the slice that is closest to the pelvis and the muscle can be detected. Then “the multiple slice edit” tool is activated and the muscle visible in the slice is painted. Then the same muscle is painted in every 10th-40th slice (depending on the difference of the muscle layout) going downwards until the distal end of the muscle is reached.

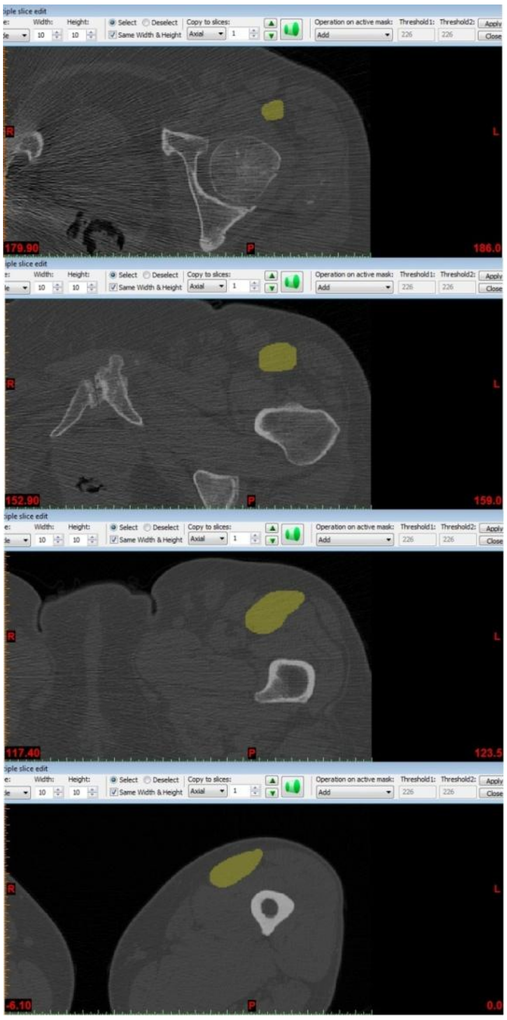


Figure 21. Shows the segmentation process of a rectus femoris muscle, from the proximal end (top) to the distal end (bottom).

Finally the “Interpolate” command is used and the program interpolates the mask between the painted slices. This is done for the three muscles of both legs, and their average HU value is written down. The final step of this phase is to export STL files from all six muscle masks. In phase two the one year post op original dataset is opened and the STL files loaded into it to create masks from all the STL files and writing down the average HU value. Phase three involves the same process as phase one, except the STL file exporting, on the pre operative dataset.

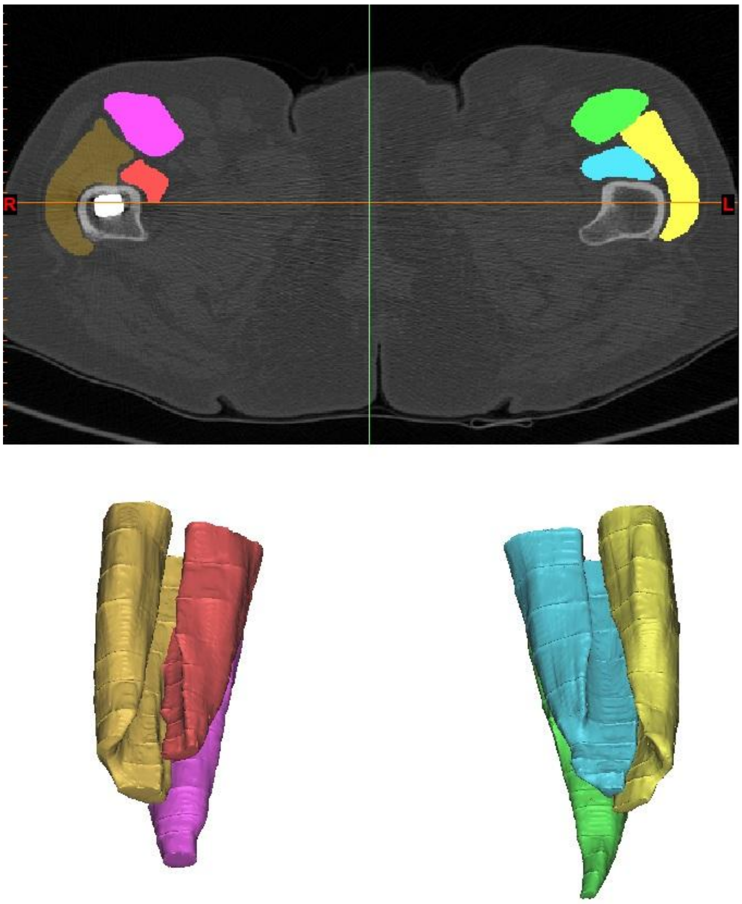


Figure 22. Shows the 2D masks of the six segmented muscles (top) and their 3D masks (bottom).

3.4. Data analysis

3.4.1. Spatial and temporal gait parameters

GAITRite® offers the option to create a test from the six walk files. In the test all the parameters are displayed as an average over the six walks as they were one continuous walk. The reason for measuring spatial and temporal parameters is to find out if pre operative assessment can influence the choice of implant and to post operatively evaluate the patient's recovery. The spatial and temporal gait parameters measured with GAITRite® and used in this study are:

Step time: the time from the heel strike of one foot to the heel strike of the other foot, measured in seconds.

Cycle time: the time from the heel strike of one foot to the next heel strike of the same foot, measured in seconds.

Step length: the distance along the carpet between sequential heel strikes of both feet, measured in centimeters.

Stride length: the distance of two consecutive steps along the carpet in success, from one heel strike to the next heel strike of the same foot, measured in centimeters.

Base support: side to side distance between the progression lines of the two feet, measured in centimeters.

Single support: period of the gait cycle (GC) completed with the support of only one leg, measured for both legs in percentages ((Single support left or right (s) / Cycle time (s)) * 100 = Single support as % of GC)

Double support: period of the gait cycle completed with the support of both legs, measured in percentages, ((Double support (s) / Cycle time (s)) * 100 = Double support as % of GC).

Swing: period of the gait cycle completed with one leg off the ground, measured for both legs in percentages, ((Swing left or right(s) / Cycle time (s)) * 100 = Swing as % of GC).

Stance: period of the gait cycle completed with one or both legs on the ground, measured in percentages, ((Stance(s) / Cycle time (s)) * 100 = Stance as % of GC)

Toe in/out: the angle between the progression line of the foot and a reference line of the sole of the foot, measured in degrees, positive if the toes point out, negative if the toes point in.

Velocity: distance between the first heel strike of the first footfall and the heel strike of the last footfall divided by the time that passes between those two footfalls, measured in centimeters/seconds.

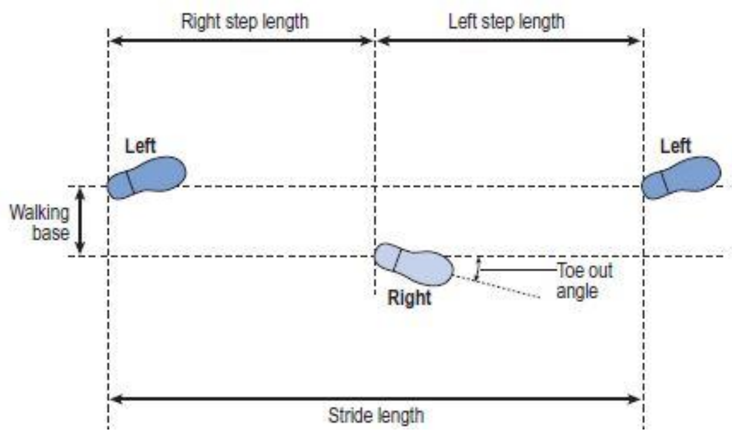


Figure 23. Shows the definition of some gait parameters, including walking base (base support), step length, stride length and toe in/out [30].

Symmetry index calculations between the operated leg and the healthy are performed for parameters that apply for one leg only, that is step time and step length.

The symmetry is calculated using Robinson symmetry index:

Symmetry Index (SI) = $|(X_R - X_L)| / (0.5 * (X_R + X_L)) * 100\%$,

where X_R and X_L are values measured for the right- and left leg respectively.

All gait parameters are further processed in Excel.

3.4.3. Pressure distribution

Comparison of pressure distribution between legs is a parameter that can help in evaluating the patient’s recovery. In the GAITRite® program there is an option to replay single walks to investigate pressure distribution. For each footfall the program creates a trapezoid that contains all the sensors activated by the footfall, this trapezoid is divided into twelve sections, six on the medial side and six on the lateral side of the foot. Inside each section there are a number of sensors activated and the program stores the maximum switching level inside each section. Each section is then given a value: maximum switching level of trapezoid / sum of maximum switching levels of all trapezoids. After a whole walk has been replayed an average over all footsteps is taken.

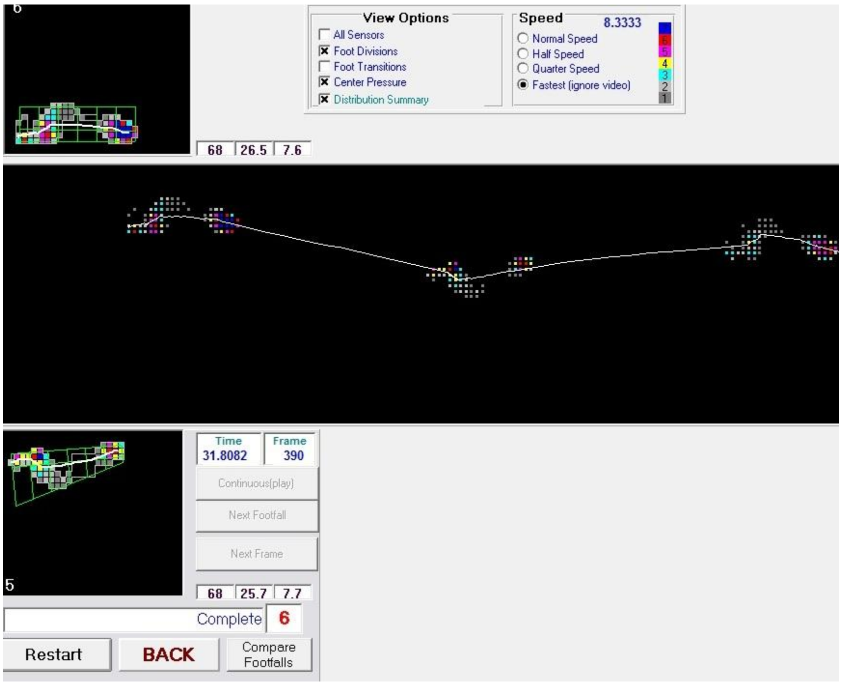


Figure 24. Shows a replayed walk in GAITRite® including one stride. The division of both feet can be seen in the smaller boxes on top and bottom. The values of the switching levels are color coded in the program, and the code can be seen on top of the figure as dark grey represents lowest switching level and blue represents the maximum switching level.

The values of the twelve trapezoids for both feet are entered into excel. This is repeated for all six walks of the patient, and an average of the six walks for each section is calculated. Finally the sum of the four sections of the forefoot is calculated, the sum of the four mid-foot section is calculated and the sum of the four section of the hind-foot is calculated. Symmetry calculations between legs are done for the pressure distribution. The Robinson symmetry index is calculated for each section of the foot. Then each section gets weight, forefoot and hind-foot get 45% each of the total symmetry and mid-foot gets 10% of the total symmetry.

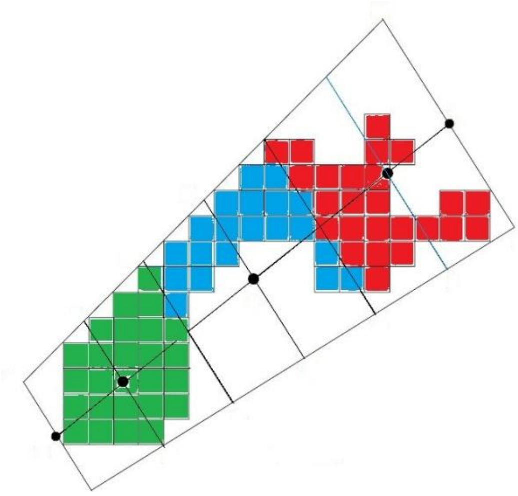


Figure 25. Shows the foot division by the GAITRite® program into twelve trapezoids. The three sections of the foot measured in this study are color coded: forefoot is red, mid-foot is blue and hind-foot is green.

3.4.4. Electromyography (EMG)

EMG measurements are made to evaluate the muscle function of patients pre operatively and one year after operation as it might help in recovery assessment. For the EMG measurements the activity period of each muscle was studied. First an onset/offset filter is applied to the raw EMG data with an on/off threshold set at 25% of the maximum value. With the synchronized video and EMG output, an initial contact is observed and marked as the beginning of the gait cycle and next observed initial contact is marked as the end of the gait cycle. The time period of the muscle´s onset inside the gait cycle is then divided by the time period of the gait cycle to find the activation time of each muscle as a percentage of the gait cycle. This is repeated for every gait cycle the test contains, more so there are three tests for each leg and the average activation periods are calculated. Those measurements are done on the files produced by the KinePro measurement device pre-op and one year post-op datasets.

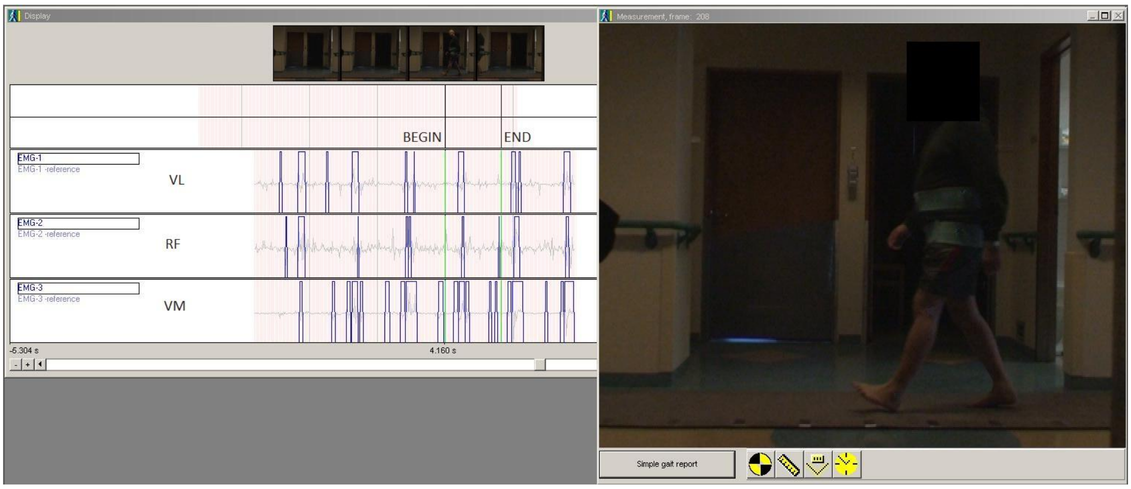


Figure 26. Shows a screenshot from the KinePro device. The video has been placed at a point where initial contact is taking place. On the three EMG channels that have and on/off filter on them the beginning and end of the gait cycle have been marked.

4. Results

4.1. Introduction

In this chapter the results from all experiments are displayed, both primary findings and secondary findings. Primary findings include: changes in BMD of the five areas of interest between pre-op and one year post-op. Change in MD of rectus femoris, vastus lateralis and vastus medialis between pre-op and one year post-op. Changes in every spatial and temporal gait parameter listed in the methodology chapter, from pre op, six weeks post op and one year post op. Changes in pressure distribution and symmetry between legs from pre op to one year post op. And finally the changes in activation periods of rectus femoris, vastus lateralis and vastus medialis during the gait cycle are explored. Secondary findings include: comparing values of BMD and MD before and after artifact reduction process has been performed.

4.2. Bone Mineral Density (BMD)

The BMD calculations were done on patients that had three complete datasets at the time of processing, pre op dataset and two datasets from one year post, artifact reduced and original. Those patients included: 16 uncemented patients (8 males and 8 females) and 12 cemented patients (3 males and 9 females).

Figures 27-31 display how the BMD data from the five different areas of interest is distributed, both pre-op and one year post-op and the increase in percentages. The graphs show how the data distribute with respect to gender, implant technique and the age of the patients. Table 2 shows the average BMD values pre-op and one year post-op for uncemented patients, also included in the table are average differences in BMD values (one year post-op – pre-op) and average BMD increase in percents. Table 3 shows the average BMD values pre-op and one year post-op for cemented patients, also included in the table are average differences in BMD values (one year post-op – pre-op) and average BMD increase in percents.

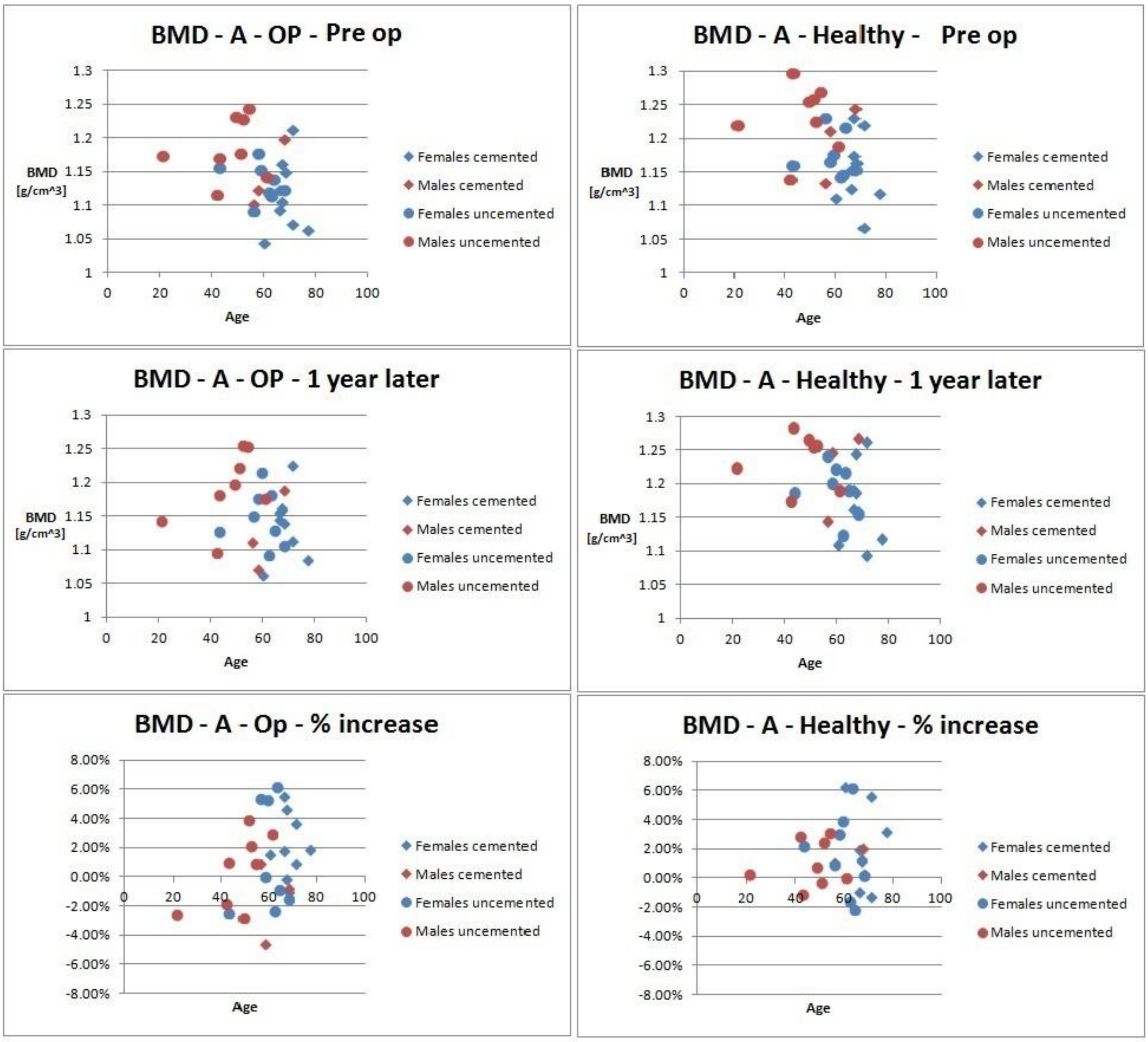


Figure 27. Shows BMD[g/cm^3] data from area A. On top are data from pre op, in the middle are date from one year post op and on the bottom is the increase, in percentages, in BMD from pre op to one year post op. Data from the operated leg are on the left and data from the healthy leg are on the right.

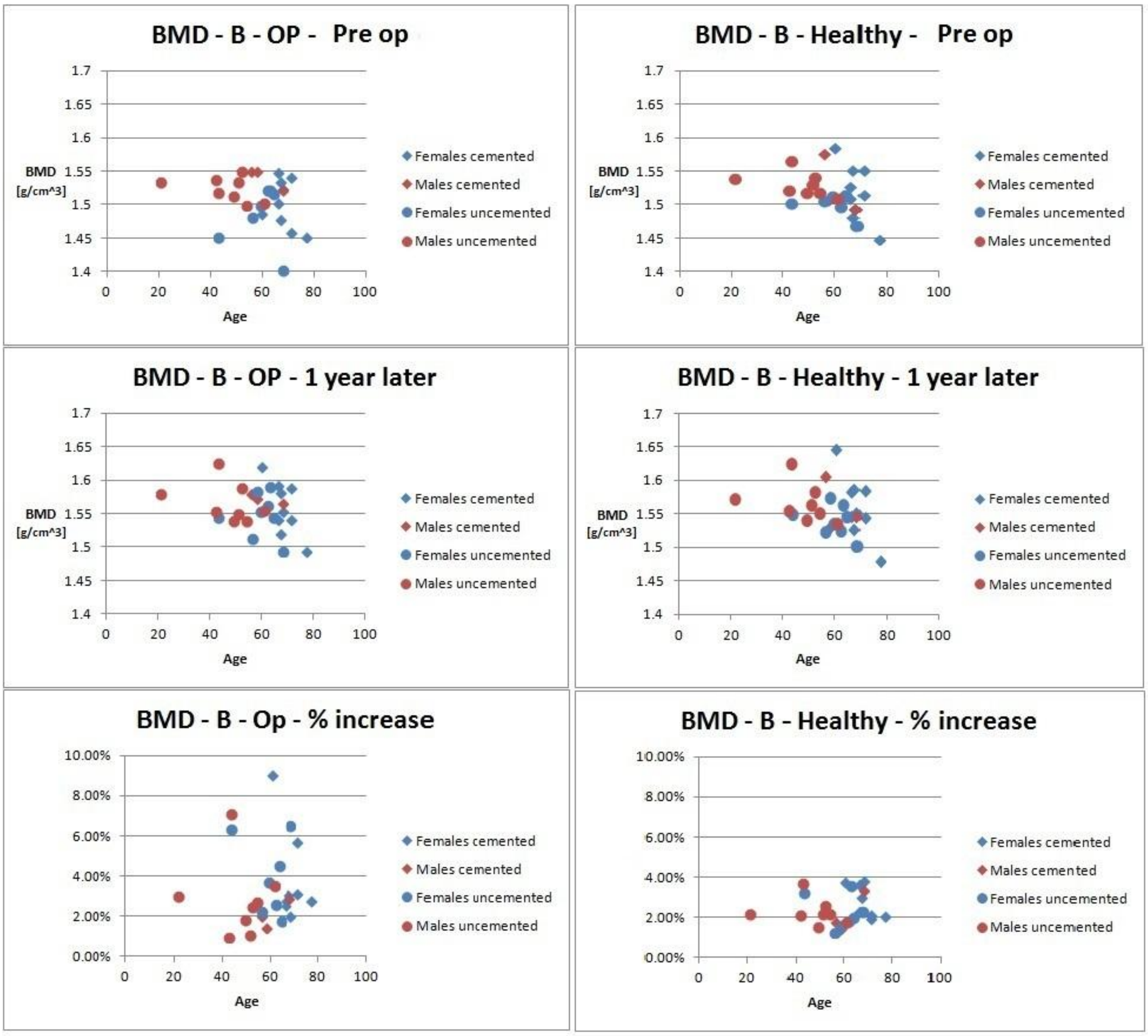


Figure 28. Shows BMD[g/cm^3] data from area B. On top are data from pre op, in the middle are date from one year post op and on the bottom is the increase, in percentages, in BMD from pre op to one year post op. Data from the operated leg are on the left and data from the healthy leg are on the right.

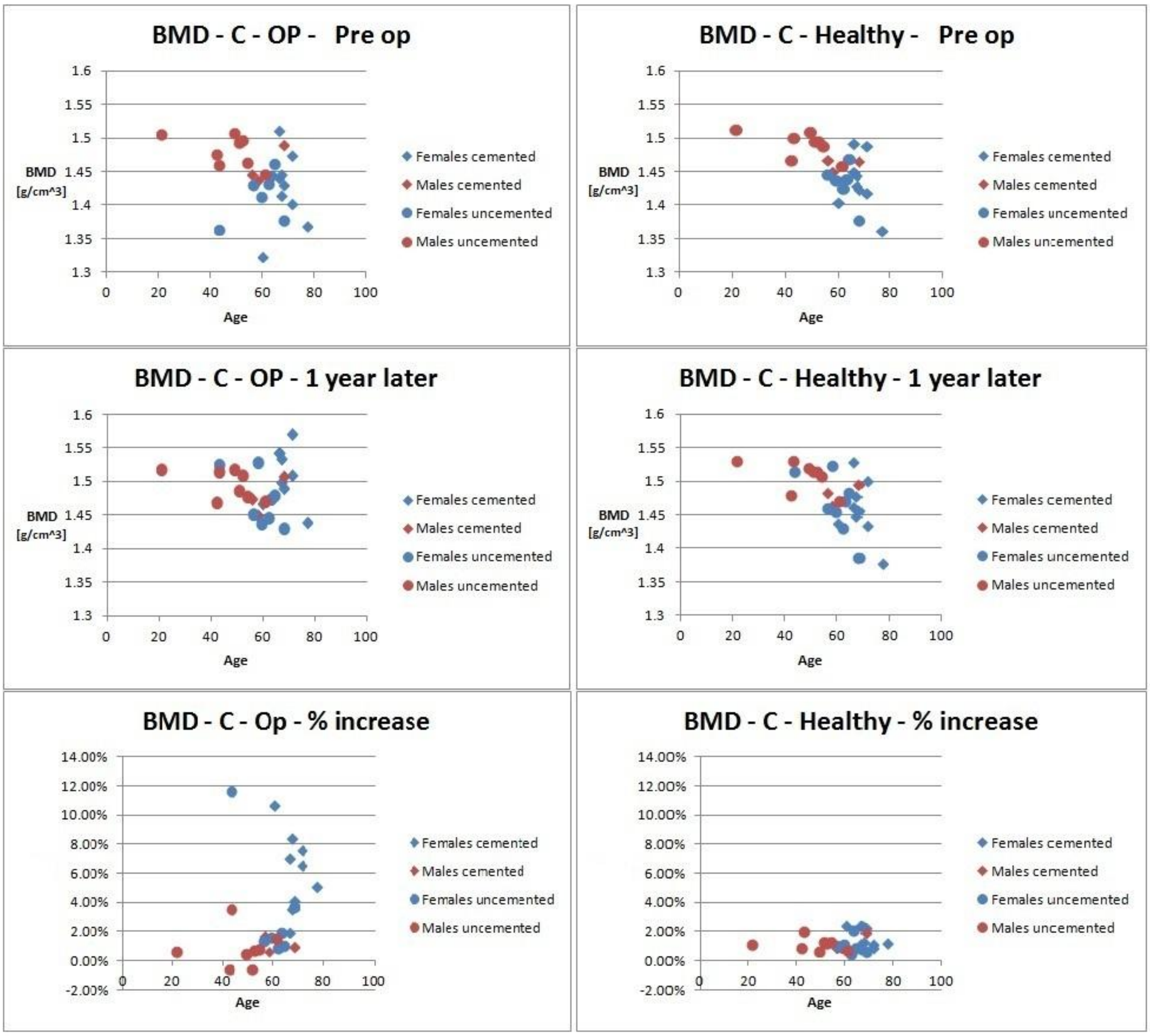


Figure 29. Shows BMD[g/cm^3] data from area C. On top are data from pre op, in the middle are date from one year post op and on the bottom is the increase, in percentages, in BMD from pre op to one year post op. Data from the operated leg are on the left and data from the healthy leg are on the right.

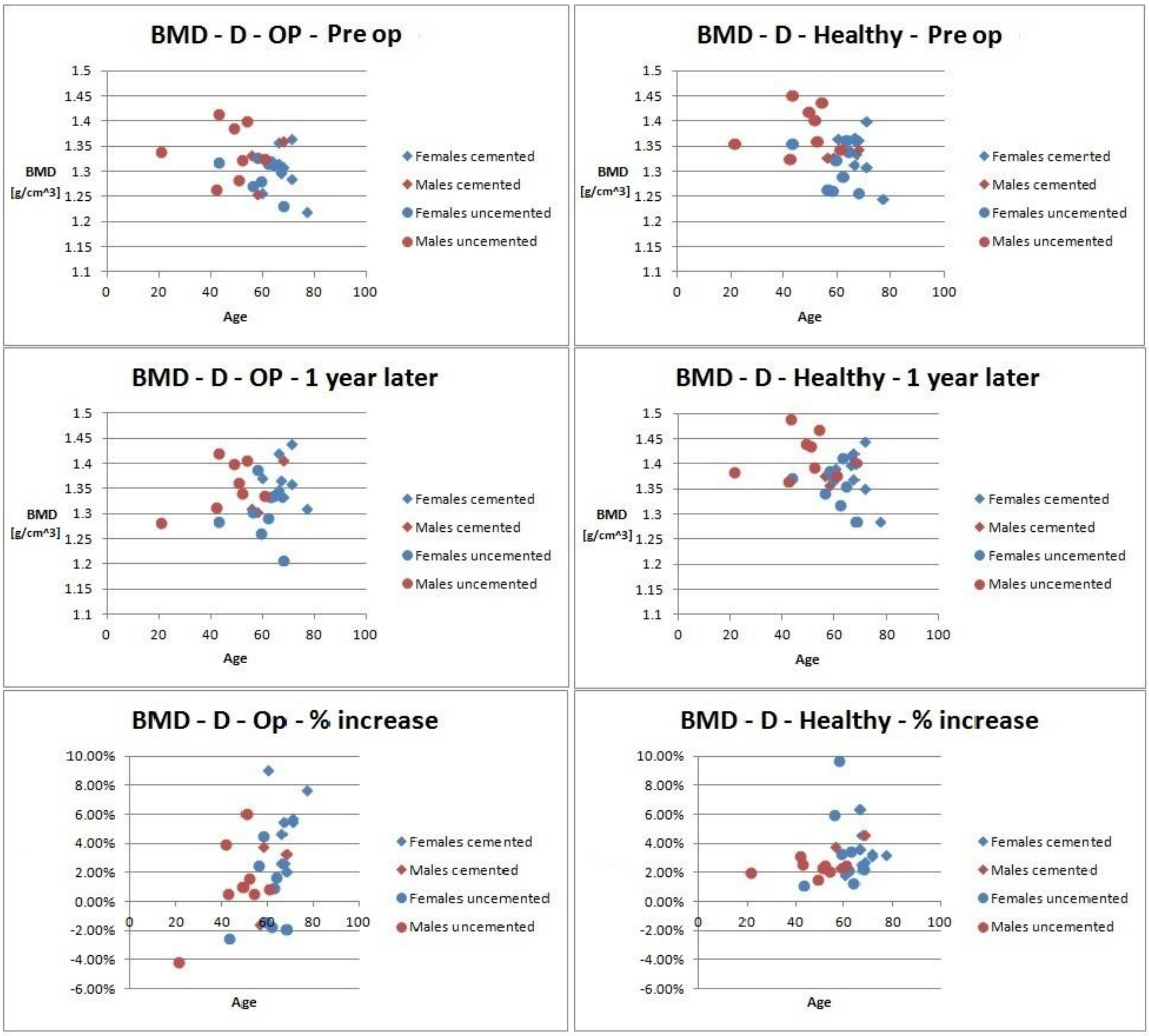


Figure 30. Shows BMD[g/cm^3] data from area D. On top are data from pre op, in the middle are date from one year post op and on the bottom is the increase, in percentages, in BMD from pre op to one year post op. Data from the operated leg are on the left and data from the healthy leg are on the right.

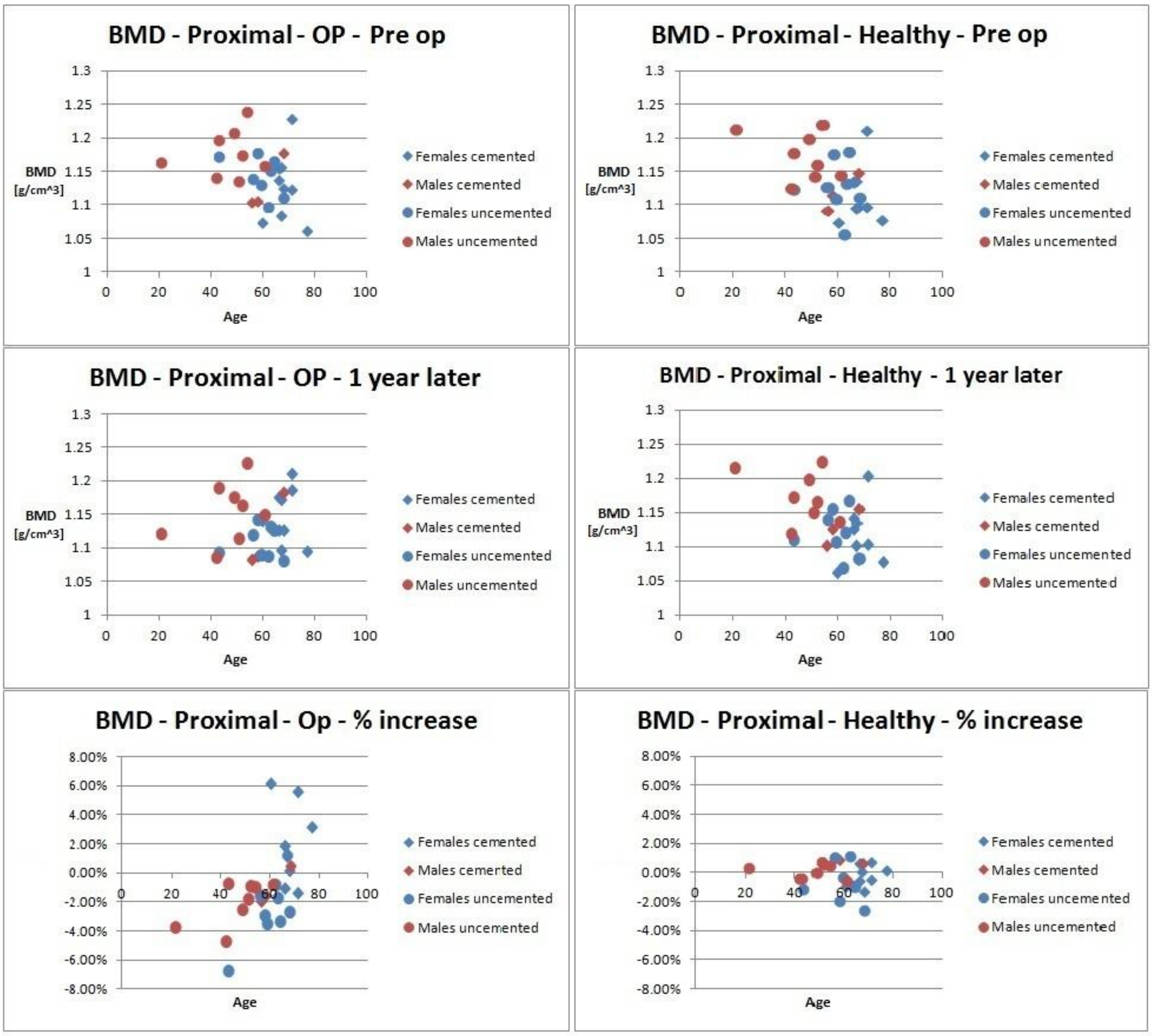


Figure 31. Shows BMD[g/cm^3] data from proximal area. On top are data from pre op, in the middle are date from one year post op and on the bottom is the increase, in percentages, in BMD from pre op to one year post op. Data from the operated leg are on the left and data from the healthy leg are on the right.

Table 2. Average BMD of uncemented patients.

Average ± Standard Deviation BMD [g/cm^3] (Uncemented)										
Pre	**A op**	**B op**	**C op**	**D op**	**Prox op**	**A h**	**B h**	**C h**	**D h**	**Prox h**
- Males	1,186 ± 0,045	1,524 ± 0,018	1,482 ± 0,023	1,343 ± 0,054	1,177 ± 0,035	1,232 ± 0,05	1,53 ± 0,018	1,491 ± 0,019	1,388 ± 0,047	1,172 ± 0,035
- Females	1,135 ± 0,027	1,486 ± 0,045	1,419 ± 0,035	1,298 ± 0,034	1,143 ± 0,029	1,173 ± 0,032	1,502 ± 0,016	1,432 ± 0,031	1,307 ± 0,044	1,127 ± 0,039
Total	1,16 ± 0,045	1,506 ± 0,038	1,453 ± 0,043	1,32 ± 0,049	1,16 ± 0,036	1,203 ± 0,051	1,517 ± 0,022	1,466 ± 0,039	1,347 ± 0,061	1,15 ± 0,043
Post										
- Males	1,191 ± 0,054	1,567 ± 0,03	1,496 ± 0,022	1,36 ± 0,049	1,154 ± 0,045	1,244 ± 0,046	1,566 ± 0,029	1,509 ± 0,022	1,42 ± 0,046	1,173 ± 0,037
- Females	1,148 ± 0,041	1,549 ± 0,033	1,472 ± 0,038	1,302 ± 0,054	1,11 ± 0,023	1,191 ± 0,038	1,541 ± 0,024	1,466 ± 0,045	1,355 ± 0,04	1,119 ± 0,034
Total	1,169 ± 0,052	1,558 ± 0,032	1,484 ± 0,032	1,331 ± 0,058	1,132 ± 0,041	1,218 ± 0,049	1,553 ± 0,028	1,487 ± 0,041	1,387 ± 0,054	1,146 ± 0,045
Average difference (post - pre)	**A op**	**B op**	**C op**	**D op**	**Prox op**	**A h**	**B h**	**C h**	**D h**	**Prox h**
- Males	0,005 ± 0,03	0,043 ± 0,03	0,013 ± 0,019	0,017 ± 0,039	-0,023 ± 0,017	0,012 ± 0,019	0,035 ± 0,011	0,018 ± 0,007	0,032 ± 0,006	0,001 ± 0,006
- Females	0,013 ± 0,041	0,058 ± 0,028	0,045 ± 0,061	0,004 ± 0,038	-0,033 ± 0,024	0,018 ± 0,023	0,034 ± 0,011	0,016 ± 0,005	0,048 ± 0,04	-0,008 ± 0,017
Total	0,009 ± 0,036	0,05 ± 0,028	0,028 ± 0,04	0,011 ± 0,035	-0,028 ± 0,019	0,015 ± 0,026	0,035 ± 0,011	0,017 ± 0,007	0,04 ± 0,026	-0,004 ± 0,012
Average difference (%)										
- Males	0,44 %	2,84 %	0,90 %	1,35 %	-1,97%	0,97 %	2,31 %	1,19 %	2,33 %	0,10%
- Females	1,20 %	3,95 %	3,22 %	0,28 %	-2,88%	1,57 %	2,27 %	1,10 %	3,71 %	-0,72%
Total	0,82 %	3,36 %	1,99 %	0,82 %	-2,42%	1,27 %	2,29 %	1,15 %	3,02 %	-0,31%

Table 3. Average BMD of cemented patients

Average ± Standard Deviation BMD [g/cm^3] (Cemented)										
Pre	**A op**	**B op**	**C op**	**D op**	**Prox op**	**A h**	**B h**	**C h**	**D h**	**Prox h**
- Males	1,141 ± 0,051	1,54 ± 0,017	1,459 ± 0,029	1,317 ± 0,055	1,13 ± 0,041	1,196 ± 0,057	1,527 ± 0,045	1,463 ± 0,01	1,334 ± 0,01	1,118 ± 0,028
- Females	1,115 ± 0,053	1,502 ± 0,036	1,424 ± 0,056	1,302 ± 0,046	1,127 ± 0,051	1,151 ± 0,052	1,519 ± 0,041	1,434 ± 0,041	1,34 ± 0,045	1,117 ± 0,042
Total	1,122 ± 0,052	1,512 ± 0,036	1,432 ± 0,052	1,306 ± 0,046	1,128 ± 0,047	1,162 ± 0,055	1,521 ± 0,04	1,441 ± 0,037	1,338 ± 0,039	1,117 ± 0,038
Post										
- Males	1,124 ± 0,059	1,573 ± 0,008	1,476 ± 0,029	1,342 ± 0,058	1,12 ± 0,056	1,22 ± 0,066	1,56 ± 0,04	1,481 ± 0,016	1,382 ± 0,024	1,128 ± 0,026
- Females	1,138 ± 0,047	1,559 ± 0,04	1,51 ± 0,042	1,367 ± 0,042	1,148 ± 0,041	1,17 ± 0,058	1,562 ± 0,047	1,458 ± 0,043	1,386 ± 0,047	1,116 ± 0,043
Total	1,134 ± 0,048	1,562 ± 0,035	1,502 ± 0,041	1,361 ± 0,045	1,141 ± 0,044	1,182 ± 0,061	1,561 ± 0,043	1,464 ± 0,039	1,385 ± 0,041	1,119 ± 0,038
Average difference (post - pre)	**A op**	**B op**	**C op**	**D op**	**Prox op**	**A h**	**B h**	**C h**	**D h**	**Prox h**
- Males	-0,017 ± 0,031	0,032 ± 0,011	0,017 ± 0,008	0,025 ± 0,039	-0,011 ± 0,015	0,024 ± 0,012	0,033 ± 0,015	0,019 ± 0,009	0,048 ± 0,016	0,01 ± 0,002
- Females	0,023 ± 0,024	0,057 ± 0,033	0,087 ± 0,036	0,066 ± 0,029	0,021 ± 0,029	0,019 ± 0,018	0,043 ± 0,012	0,024 ± 0,01	0,047 ± 0,018	-0,001 ± 0,008
Total	0,013 ± 0,03	0,051 ± 0,03	0,069 ± 0,044	0,055 ± 0,035	0,013 ± 0,029	0,02 ± 0,017	0,04 ± 0,013	0,023 ± 0,01	0,047 ± 0,016	0,001 ± 0,009
Average difference (%)										
- Males	-1,50%	2,11 %	1,17 %	1,91 %	-0,96%	1,99 %	2,19 %	1,28 %	3,58 %	0,89%
- Females	2,09%	3,79 %	6,16 %	5,07 %	1,93%	1,65 %	2,80 %	1,67 %	3,49 %	-0,13%
Total	1,19%	3,37 %	4,91 %	4,28 %	1,21%	1,73 %	2,65 %	1,57 %	3,52 %	0,13%

4.3. Muscle Density (MD)

Patients included in the muscle density calculation had to have three complete datasets at the time of processing, pre-op, and two datasets from one year post-op, original and artifact reduced. Those patients included: 16 uncemented patients (8 males and 8 females) and 16 cemented patients (4 males, 12 females).

Figures 32 and 33 compare the muscle density values, pre-op vs. one year post-op. All three muscles for both legs are included. Figure 34 shows the distribution of MD values of the operated leg, both pre-op and one year post-op. The data is presented with respect to gender, implant technique and the age of the patients. Figure 35 shows the increase in MD from pre-op to one year post-op. The data is displayed in percents for all three muscles of both operated and healthy legs. Tables 4 and 5 shows the average MD, average differences (one year post-op – pre-op) and average increase in percents.

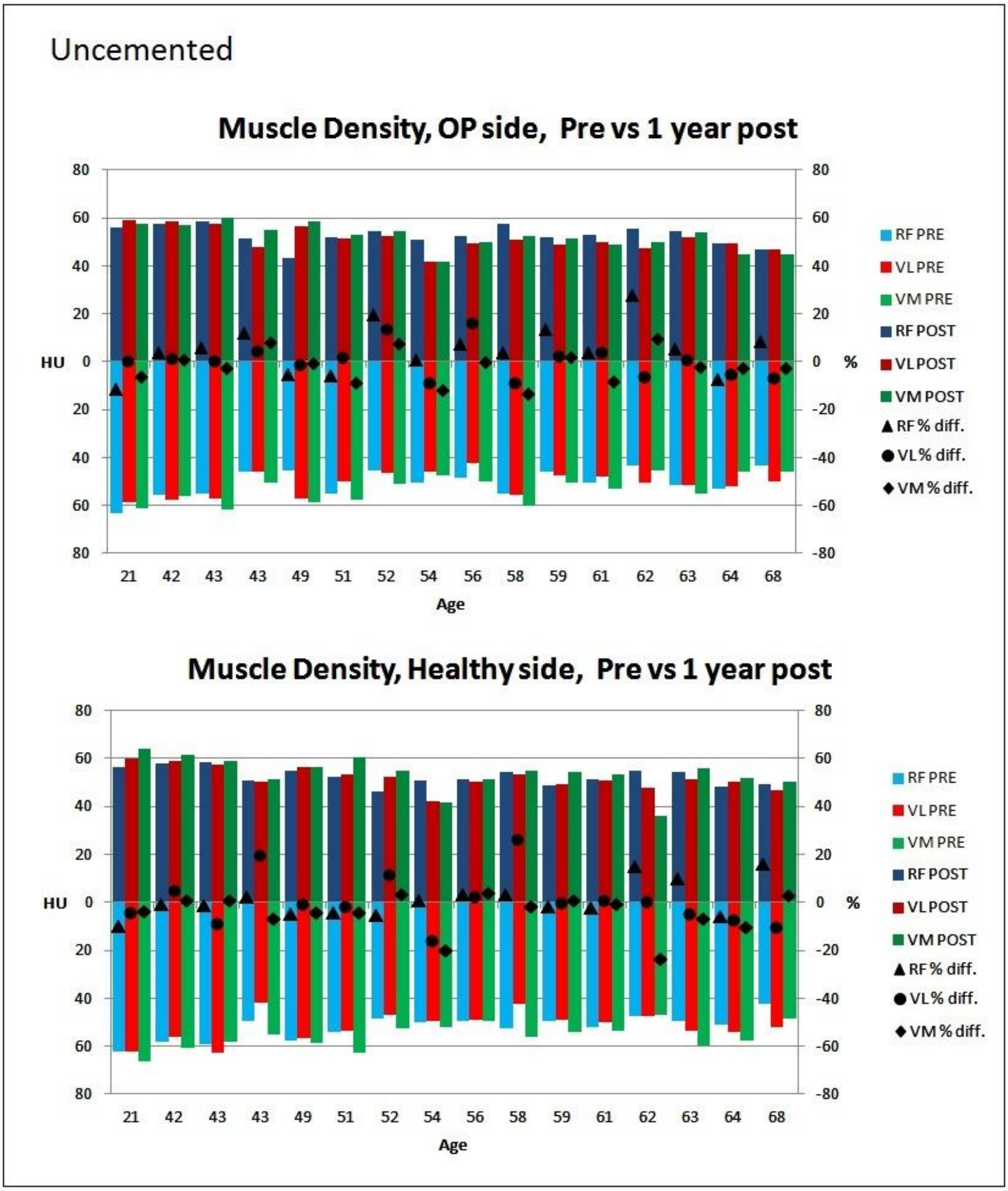


Figure 32. Muscle density (HU) of all muscles, pre op and one year post op, for uncemented patients. RF = rectus femoris, VL = vastus lateralis, VM = vastus medialis. Also shown is the difference in muscle density between pre-op and one year post-op.

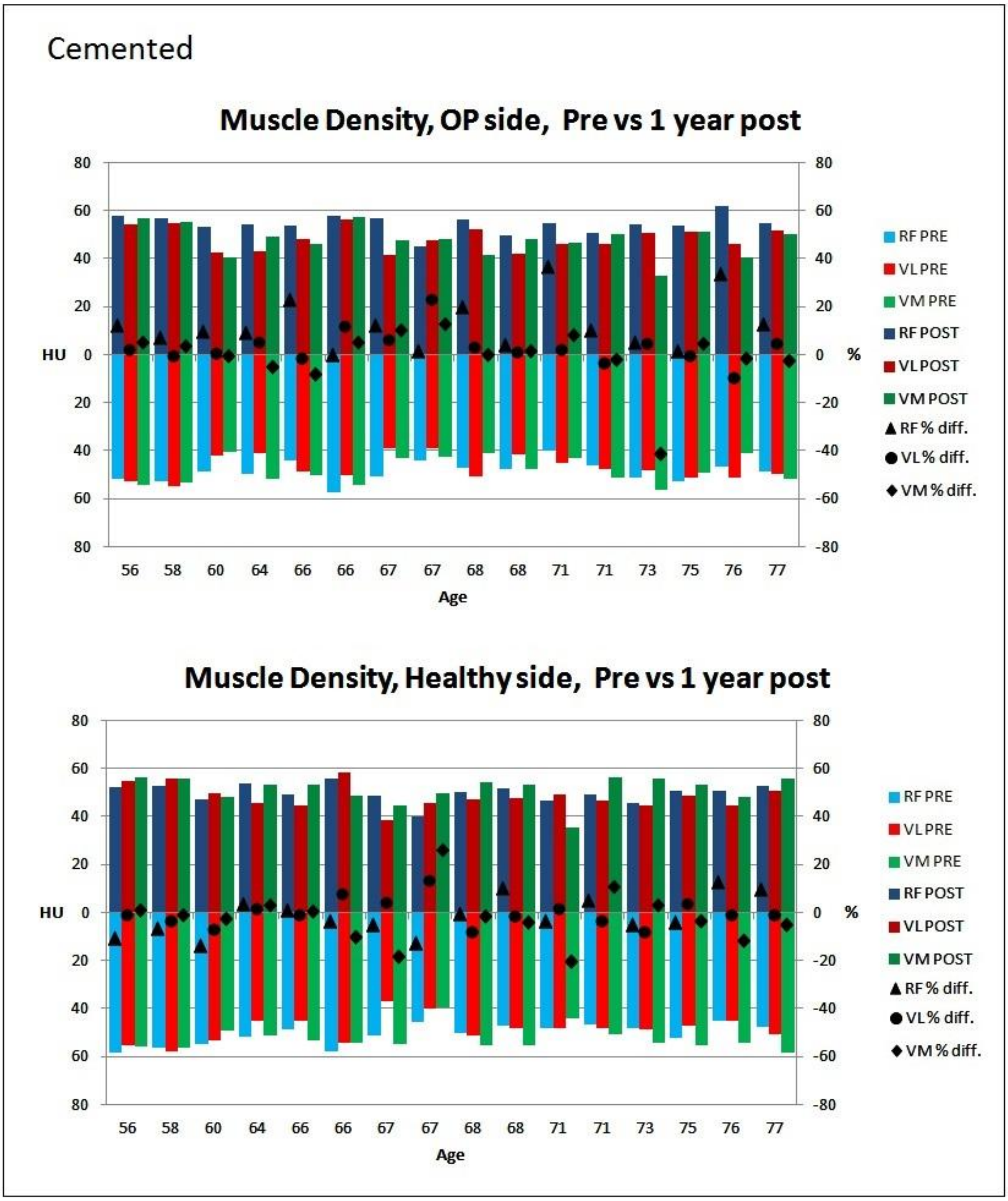


Figure 33. Muscle density (HU) of all muscles, pre op and one year post op, for cemented patients. RF = rectus femoris, VL = vastus lateralis, VM = vastus medialis. Also shown is the difference in muscle density between pre-op and one year post-op.

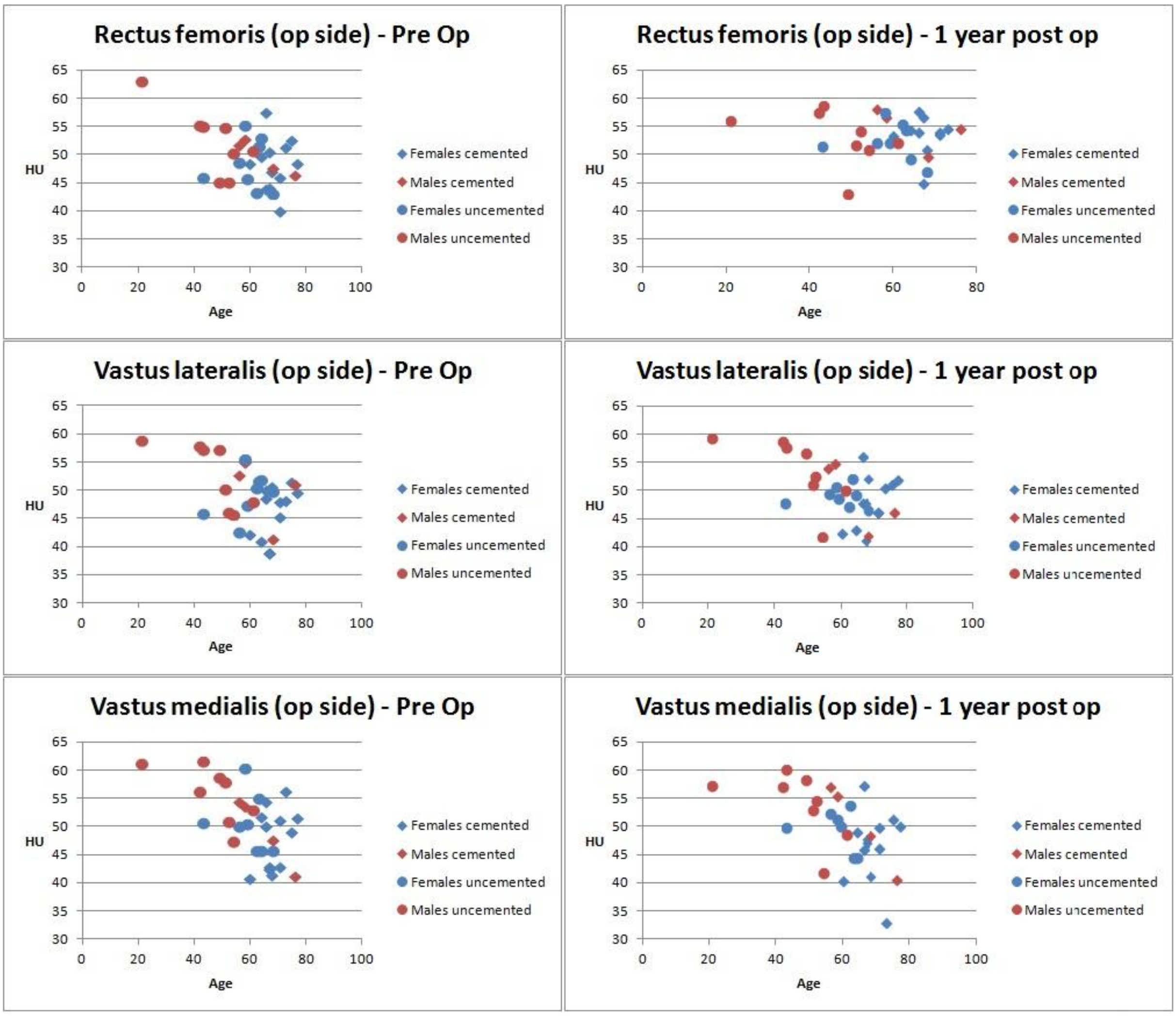


Figure 34. Muscle density (HU) of each of the three muscles of the operated leg. Rectus femoris on top, vastus lateralis in the middle and vastus medialis on the bottom. Pre-op values are shown on the graphs to the left and one year post-op values are shown on the graphs to the right.

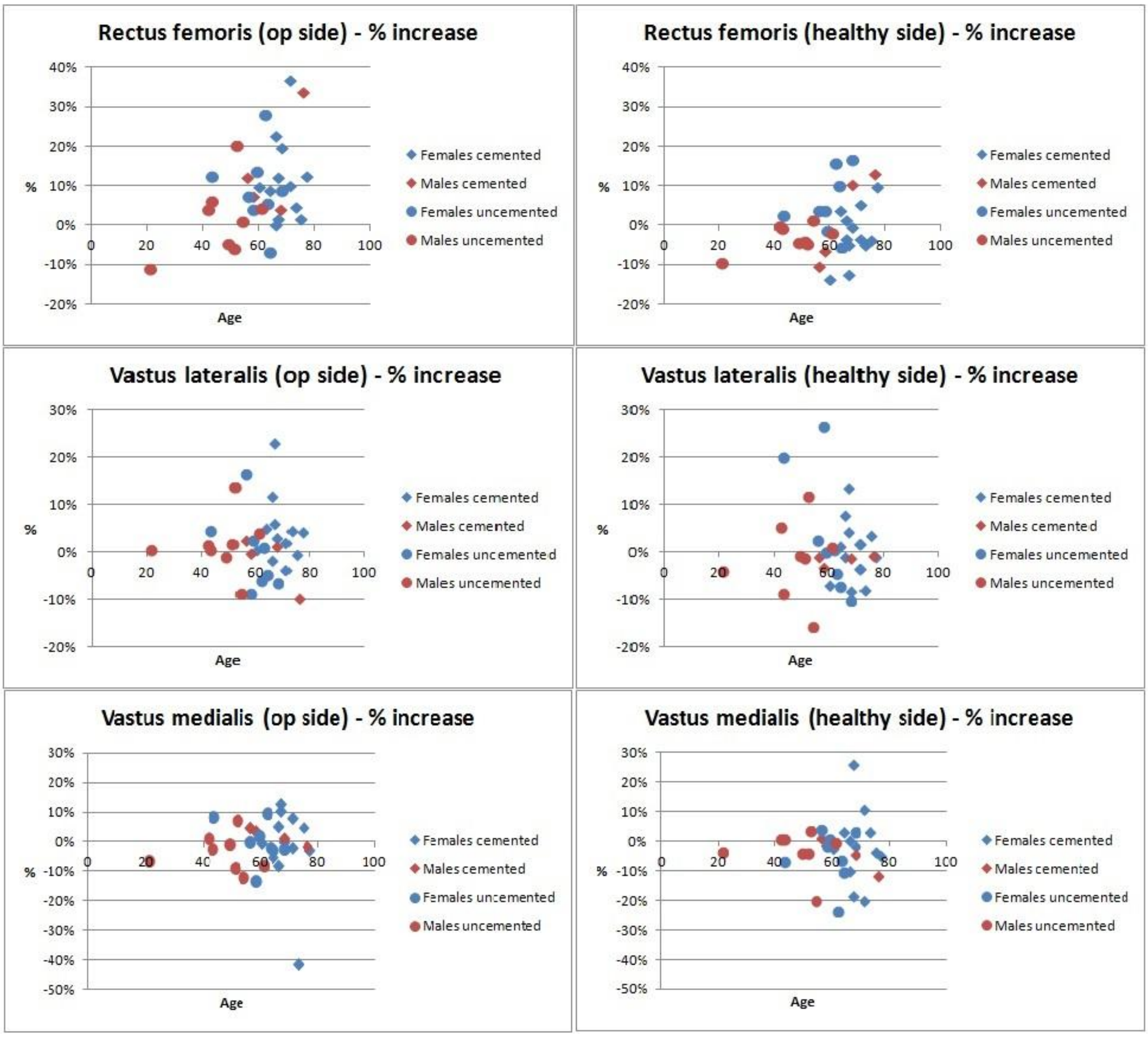


Figure 35. Shows the increase in muscle density (HU) from pre-op to one year post-op for each of the three muscles. Rectus femoris on top, vastus lateralis in the middle and vastus medialis on bottom. Graphs to the left represent the operated side and graphs to the left represent the healthy side.

Table 4. Muscle density, uncemented patients.

Average ± Standard Deviation Muscle density (HU) - Uncemented						
Average pre	**RF O**	**VL O**	**VM O**	**RF H**	**VL H**	**VM H**
- Males	52,47 ± 5,92	52,65 ± 5,66	55,8 ± 5,05	55,29 ± 4,82	54,83 ± 5,8	58,19 ± 5,07
- Females	48,29 ± 4,52	49,37 ± 4,02	50,38 ± 5,14	48,94 ± 3,04	48,68 ± 4,73	53,43 ± 4,64
Total	50,38 ± 14,03	51,01 ± 6,31	53,09 ± 10,96	52,11 ± 14,12	51,75 ± 7,32	55,81 ± 12,31
Average post						
- Males	53,09 ± 4,89	53,48 ± 5,87	53,83 ± 6,03	53,48 ± 4,27	53,82 ± 5,78	56,36 ± 6,85
- Females	52,39 ± 3,33	48,98 ± 1,81	50,14 ± 3,85	51,51 ± 2,75	49,91 ± 2,07	50,78 ± 6,36
Total	52,74 ± 6,38	51,23 ± 8,97	51,99 ± 9,03	52,5 ± 4,94	51,87 ± 9,22	53,57 ± 9,54
Average difference	**RF O**	**VL O**	**VM O**	**RF H**	**VL H**	**VM H**
- Males	0,61 ± 4,85	0,83 ± 2,84	-1,96 ± 3,25	-1,8 ± 2,05	-1,01 ± 4,28	-1,84 ± 3,83
- Females	4,1 ± 4,41	-0,38 ± 3,84	-0,24 ± 3,85	2,57 ± 3,61	1,23 ± 5,77	-2,65 ± 4,38
Total	2,36 ± 7,65	0,22 ± 2,66	-1,1 ± 1,94	0,38 ± 9,18	0,11 ± 1,9	-2,24 ± 2,77
% difference						
- Males	1,7%	1,7%	-3,6%	-3,2%	-1,6%	-3,3%
- Females	9,1%	-0,3%	-0,1%	5,6%	3,6%	-5,0%
Total	5,4%	0,7%	-1,8%	1,2%	1,0%	-4,1%

Table 5. Muscle density, cemented patients

Average ± Standard Deviation Muscle density (HU) - Cemented						
Average pre	**RF O**	**VL O**	**VM O**	**RF H**	**VL H**	**VM H**
- Males	49,61 ± 3,04	50,1 ± 5,94	49,12 ± 6,1	51,66 ± 6,71	51,63 ± 5,89	55,46 ± 0,83
- Females	48,34 ± 4,59	46,08 ± 4,64	47,85 ± 5,47	50,25 ± 3,58	47,39 ± 5,08	51,67 ± 5,34
Total	48,66 ± 4,2	47,08 ± 5,1	48,17 ± 5,45	50,6 ± 4,34	48,45 ± 5,43	52,62 ± 4,89
Average post						
- Males	56,51 ± 5,21	49,22 ± 6,2	50,26 ± 7,53	51,87 ± 0,91	50,72 ± 5,37	53,4 ± 3,78
- Females	53,71 ± 3,3	48,06 ± 4,44	46,7 ± 6,16	49 ± 4,16	47,36 ± 4,66	50,62 ± 6,05
Total	54,41 ± 3,87	48,35 ± 4,74	47,59 ± 6,46	49,72 ± 3,8	48,2 ± 4,89	51,32 ± 5,59
Average difference	**RF O**	**VL O**	**VM O**	**RF H**	**VL H**	**VM H**
- Males	6,9 ± 6,08	-0,87 ± 2,85	1,14 ± 1,46	0,22 ± 5,98	-0,91 ± 0,71	-2,06 ± 3,01
- Females	5,36 ± 4,31	1,98 ± 2,93	-1,16 ± 7,49	-1,25 ± 3,36	-0,03 ± 3,06	-1,05 ± 5,64
Total	5,75 ± 4,63	1,27 ± 3,09	-0,58 ± 6,53	-0,88 ± 3,98	-0,25 ± 2,67	-1,3 ± 5,04
% difference						
- Males	14,2%	-1,7%	2,1%	1,6%	-1,7%	-3,8%
- Females	11,8%	4,6%	-1,5%	-2,4%	0,3%	-1,5%
Total	12,4%	3,0%	-0,6%	-1,4%	-0,2%	-2,1%

4.4. Spatial and temporal gait parameters

Calculations on spatial- and temporal gait parameters included patients that had all three studies from the GAITRite® pressure carpet available at the time of processing, pre-op, six weeks post-op and one year post-op. Those patients included: 17 uncemented patients (8 males, 9 females) and 16 cemented patients (5 males, 11 females).

4.4.1. Temporal parameters

- Gait cycle

Figures 36 and 37 show the gait cycle division of uncemented (Figure 36) and cemented (Figure 37) patients at three different time points. The graphs can be interpreted from the point of view of both legs as the stance phase of the healthy leg also represents the swing phase of the operated leg and vice versa. Table 6 shows the average division of gait phases at the three different time periods, divided by implant type, gender and as a total.

Table 6. Shows division of the gait phases for uncemented and cemented patients.

Average ± Standard Deviation Gait cycle division (%)									
	Males			**Females**			**Total**		
Uncemented	Pre Op	6 Weeks post op	1 Year post op	Pre Op	6 Weeks post op	1 Year post op	Pre Op	6 Weeks post op	1 Year post op
-Double Support	21,16 ± 2,6	21,85 ± 2,43	18,21 ± 2,02	25,33 ± 7,52	23,31 ± 7,17	18,91 ± 2,57	23,37 ± 5,99	22,62 ± 5,37	18,58 ± 2,29
-Single Support H / Swing O	40,76 ± 1,87	40,16 ± 2,26	41,15 ± 1,69	39,19 ± 3,43	36,15 ± 8,98	40,49 ± 1,25	39,93 ± 2,84	38,04 ± 6,84	40,8 ± 1,46
-Swing H / Single support O	38,08 ± 1,7	37,99 ± 1,01	40,64 ± 1,39	35,48 ± 4,21	40,55 ± 8,65	40,6 ± 1,46	36,7 ± 3,45	39,34 ± 6,29	40,62 ± 1,38
Cemented									
-Double Support	22,7 ± 3,08	19,52 ± 5,66	19,22 ± 2,06	23,04 ± 4,17	22,2 ± 3,54	18,04 ± 2,4	22,93 ± 3,76	21,36 ± 4,31	18,41 ± 2,3
-Single Support H / Swing O	40,28 ± 1,04	39,5 ± 1	40,84 ± 1,17	40,69 ± 2,11	39,34 ± 1,41	40,76 ± 1,16	40,56 ± 1,81	39,39 ± 1,26	40,79 ± 1,12
-Swing H / Single support O	37,02 ± 3,11	40,98 ± 5,67	39,94 ± 0,93	36,27 ± 3,81	38,46 ± 2,65	41,2 ± 1,83	36,51 ± 3,52	39,25 ± 3,84	40,81 ± 1,68

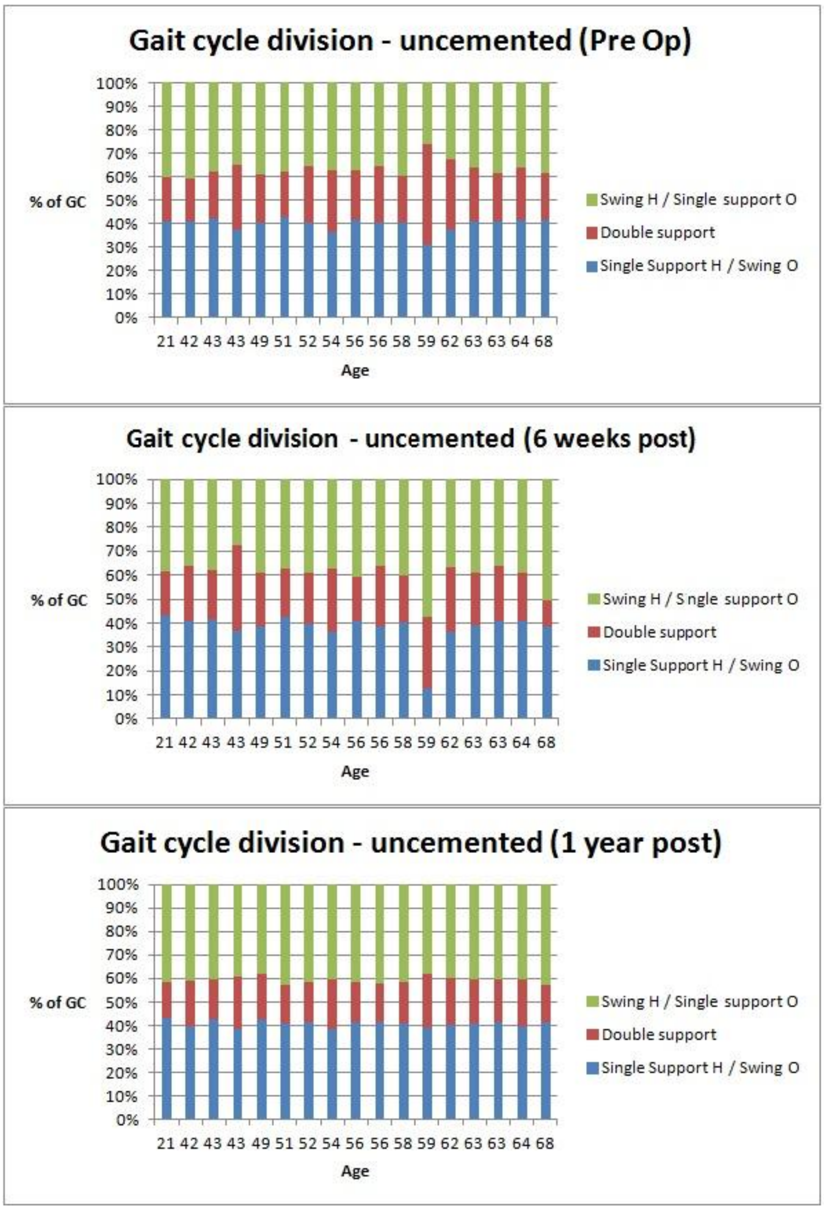


Figure 36. The gait cycle division of uncemented patients.

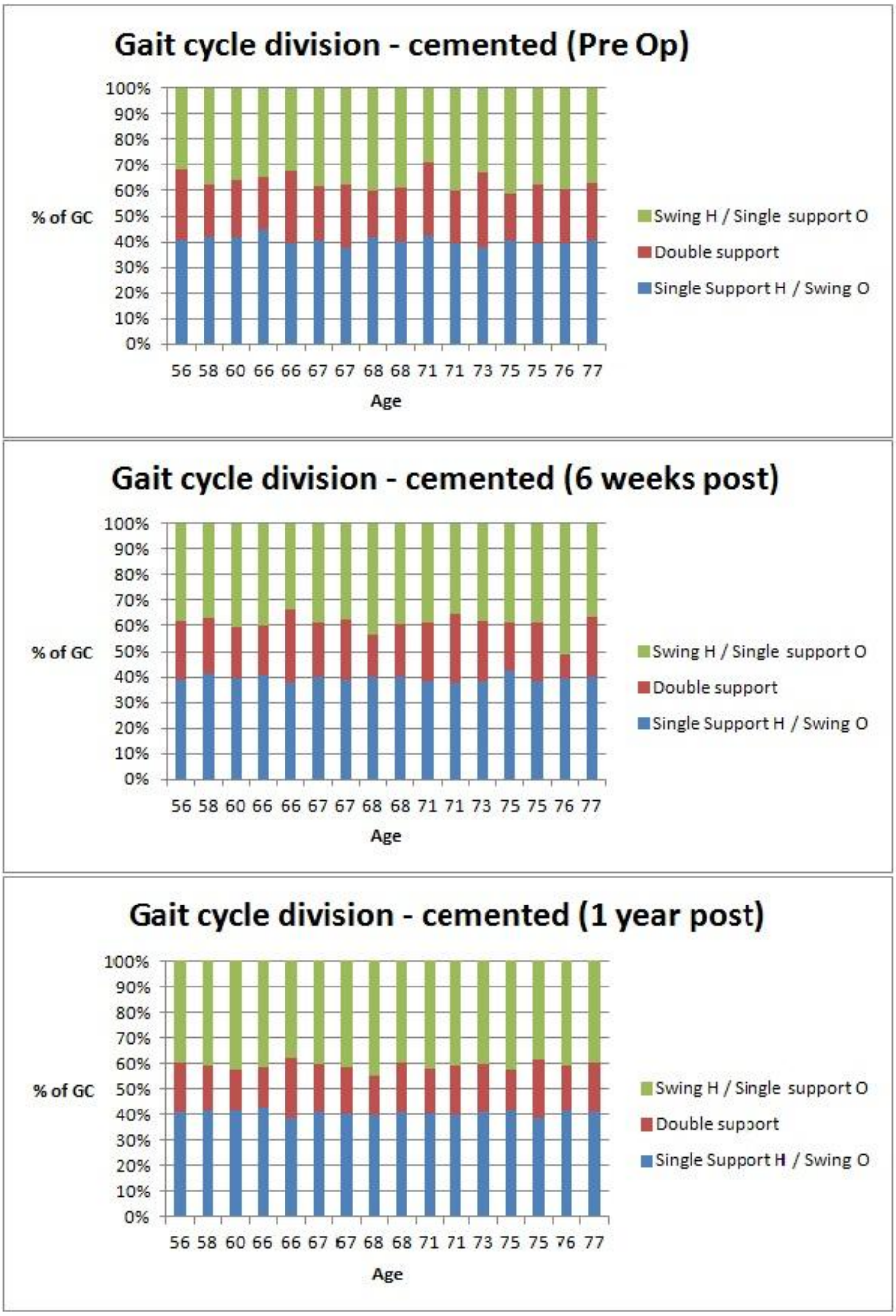


Figure 37. The gait cycle division of uncemented patients.

- Velocity

Figure 38 compares velocity values at three different time periods, and shows the increase in velocity from pre op to one year post op. Table 7 shows the average velocity values for all patients, divided by implant type, gender and as total.

Table 7. Average velocity values.

Average ± Standard Deviation Velocity (cm/s)	**Uncemented**			**Cemented**		
	Males	**Females**	**Total**	**Males**	**Females**	**Total**
Average (pre)	117,3 ± 20,7	94,8 ± 20,8	105,4 ± 23,2	93 ± 23,3	96,3 ± 24	95,3 ± 23,1
Average (6 weeks)	113,7 ± 11	96,3 ± 21,7	104,5 ± 19,2	96,6 ± 12,7	104,2 ± 19,8	101,8 ± 17,8
Average (1 year)	133,8 ± 10,3	118,9 ± 18,5	125,9 ± 16,6	110,4 ± 9,5	117,5 ± 19,7	115,3 ± 17,2
Average Difference (1year - Pre)	16,5 ± 17,3	24 ± 16	20,5 ± 16,6	17,4 ± 18,2	21,2 ± 26,1	20 ± 23,4
Average Difference in % (1year - Pre)	16,48%	32,55%	23,39%	24,83%	28,20%	27,14%

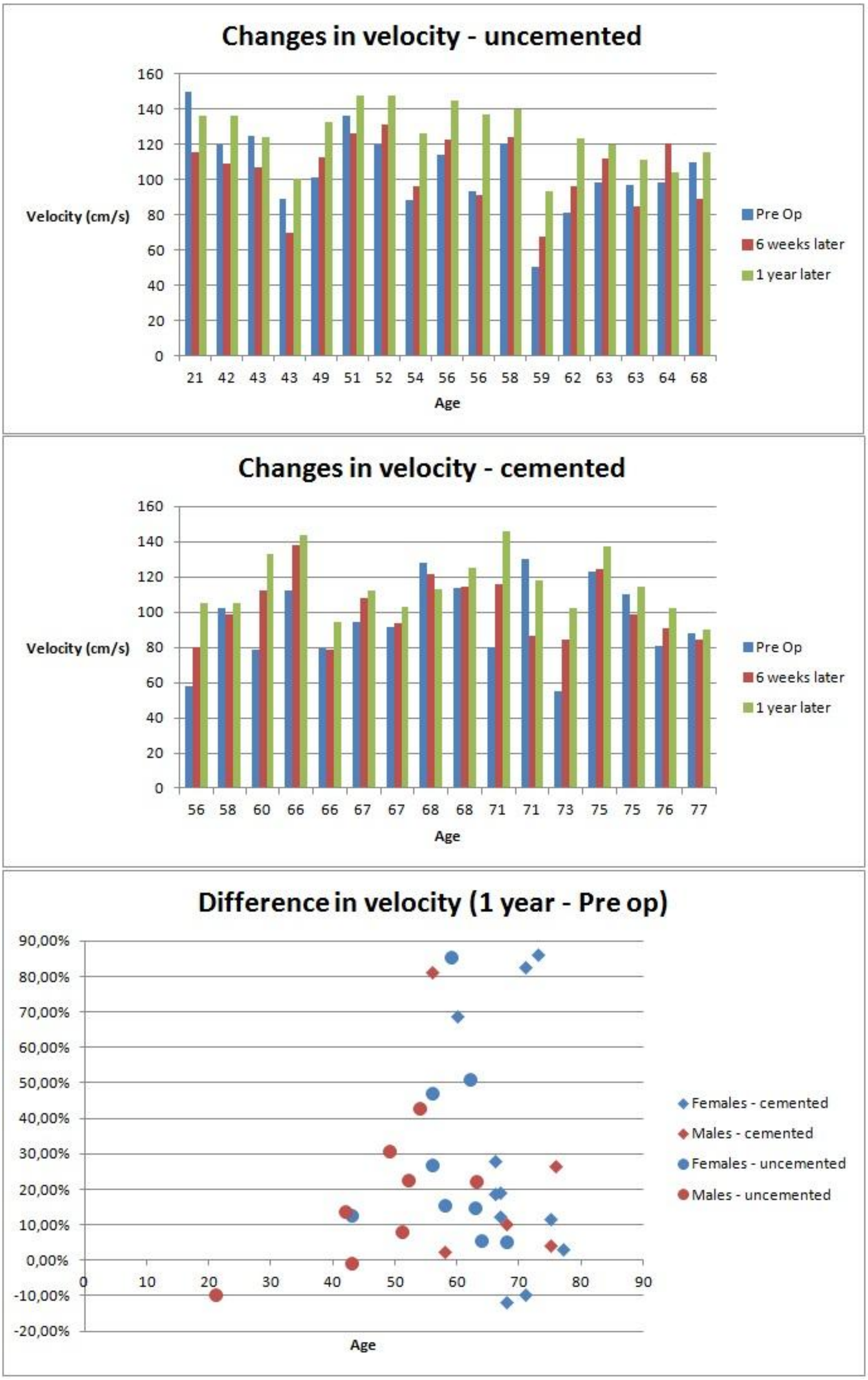


Figure 38. Velocity comparison at three time points (top, middle), and the increase in velocity from pre op to one year post op (bottom).

- Cycle time

Figure 39 compares cycle time values at three different time periods, and shows the increase in cycle time from pre op to one year post op. Table 8 shows the average cycle time values for all patients, divided by implant type, gender and as total.

Table 8. Average cycle time

Average ± Standard Deviation Cycle time (s)	**Uncemented**			**Cemented**		
	Males	**Females**	**Total**	**Males**	**Females**	**Total**
Average (pre)	1,12 ± 0,11	1,14 ± 0,16	1,13 ± 0,14	1,18 ± 0,09	1,12 ± 0,13	1,14 ± 0,12
Average (6 weeks)	1,11 ± 0,07	1,12 ± 0,13	1,11 ± 0,1	1,17 ± 0,08	1,1 ± 0,09	1,12 ± 0,09
Average (1 year)	1,05 ± 0,06	1,04 ± 0,09	1,04 ± 0,07	1,08 ± 0,05	1,05 ± 0,08	1,06 ± 0,07
Average Difference (1year - Pre)	-0,07 ± 0,08	-0,1 ± 0,1	-0,09 ± 0,09	-0,1 ± 0,08	-0,07 ± 0,12	-0,08 ± 0,11
Average Difference in % (1year - Pre)	-5,58%	-8,46%	-7,10%	-8,18%	-5,27%	-6,18%

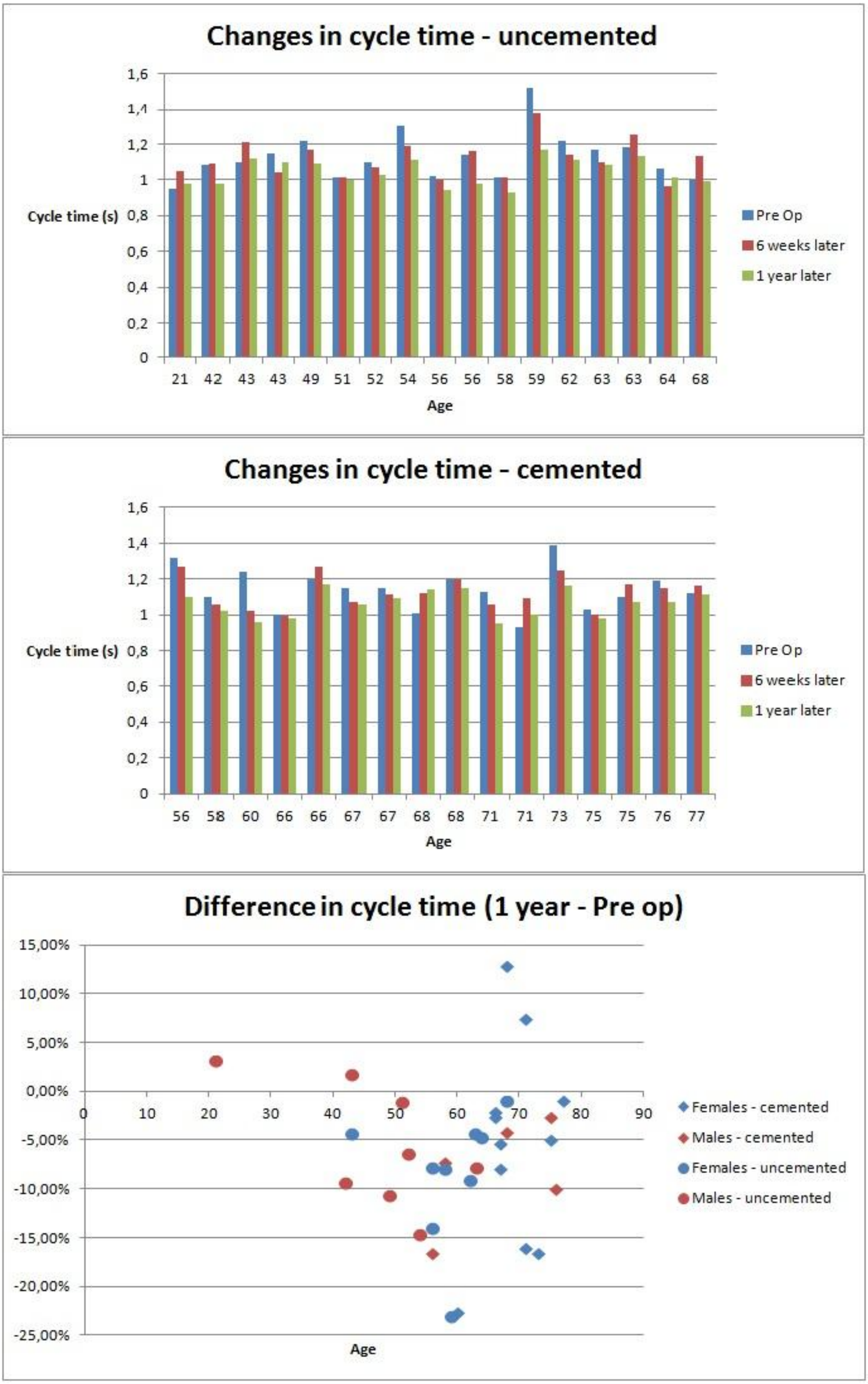


Figure 39. Compares cycle time at three different time points and displays the cycle time increase.

- Step time

Figure 40 compares the step time of both legs at three different time points and displays the increase in step time from pre op to one year post-op. Table 9 shows the average step time values of both legs. Figure 41 compares the step time of healthy leg vs. operated leg at pre-op and one year post-op for both cemented and uncemented patients. Table 10 shows the average difference in step time between operated and healthy legs at three different time periods and also the average symmetry index for the same time periods.

Table 9. Average step time values for both legs

Average ± Standard Deviation Step time (s)	Operated leg						Healthy leg					
	Uncemented			Cemented			Uncemented			Cemented		
	Males	Females	Total	Males	Females	Total	Males	Females	Total	Males	Females	Total
Average (pre)	0,57 ± 0,05	0,57 ± 0,07	0,57 ± 0,06	0,6 ± 0,06	0,58 ± 0,07	0,59 ± 0,06	0,55 ± 0,06	0,57 ± 0,09	0,56 ± 0,08	0,58 ± 0,04	0,54 ± 0,07	0,56 ± 0,06
Average (6 weeks)	0,55 ± 0,03	0,56 ± 0,07	0,56 ± 0,05	0,58 ± 0,03	0,55 ± 0,05	0,56 ± 0,04	0,56 ± 0,04	0,56 ± 0,07	0,56 ± 0,06	0,59 ± 0,05	0,55 ± 0,05	0,57 ± 0,05
Average (1 year)	0,51 ± 0,03	0,52 ± 0,05	0,52 ± 0,04	0,54 ± 0,03	0,52 ± 0,04	0,53 ± 0,04	0,54 ± 0,03	0,52 ± 0,05	0,53 ± 0,04	0,54 ± 0,02	0,53 ± 0,04	0,54 ± 0,04
Average Difference (1year - Pre)	-0,05 ± 0,04	-0,05 ± 0,04	-0,05 ± 0,03	-0,06 ± 0,06	-0,06 ± 0,07	-0,06 ± 0,07	0,02 ± 0,04	0,05 ± 0,07	0,03 ± 0,06	0,04 ± 0,03	0,01 ± 0,06	0,02 ± 0,05
Average Difference in % (1year - Pre)	-8,94 %	-9,62 %	-8,85 %	-9,80 %	-9,19 %	-9,38 %	-2,08 %	-9,06 %	-5,24 %	-6,34 %	-0,86 %	-2,57 %

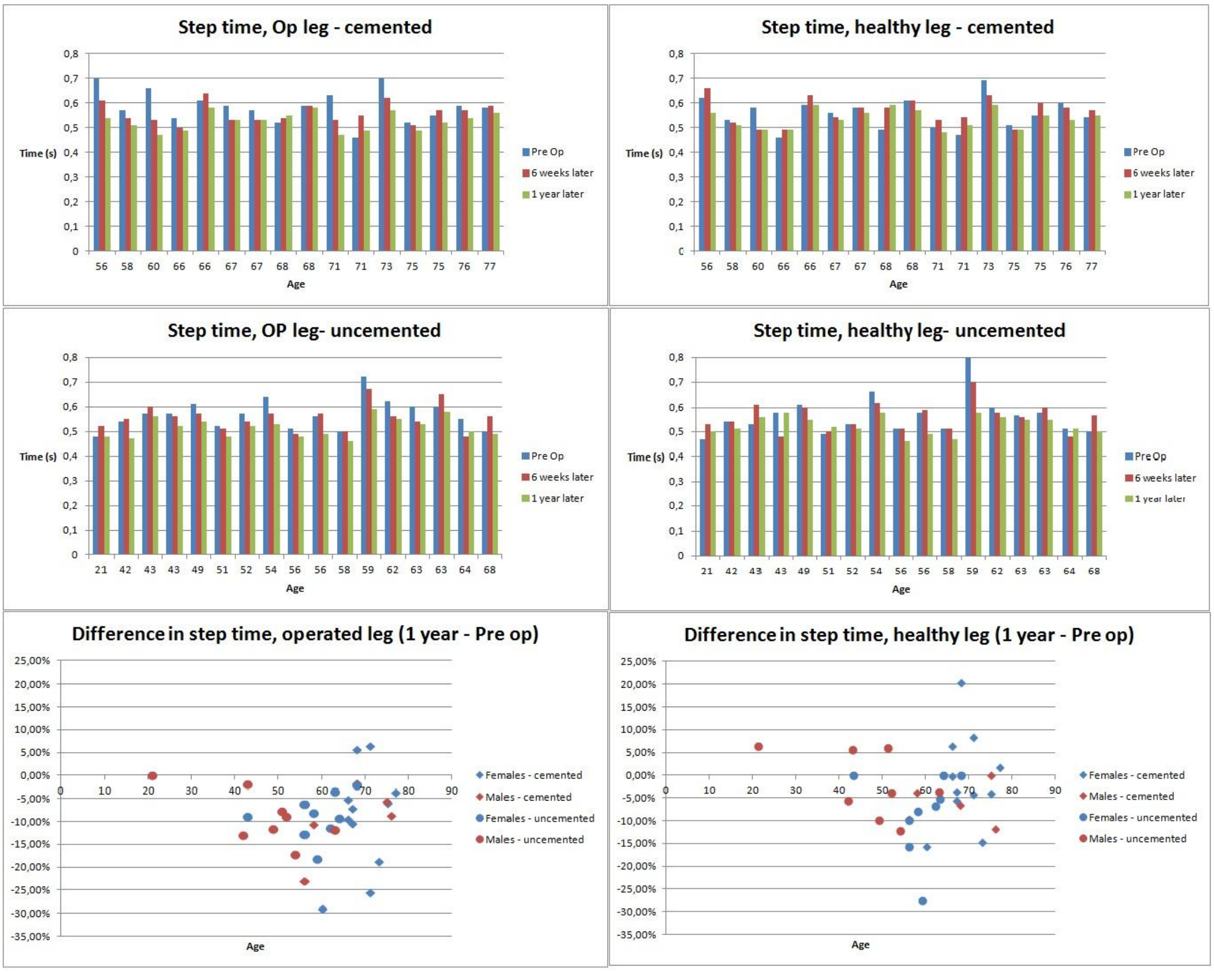
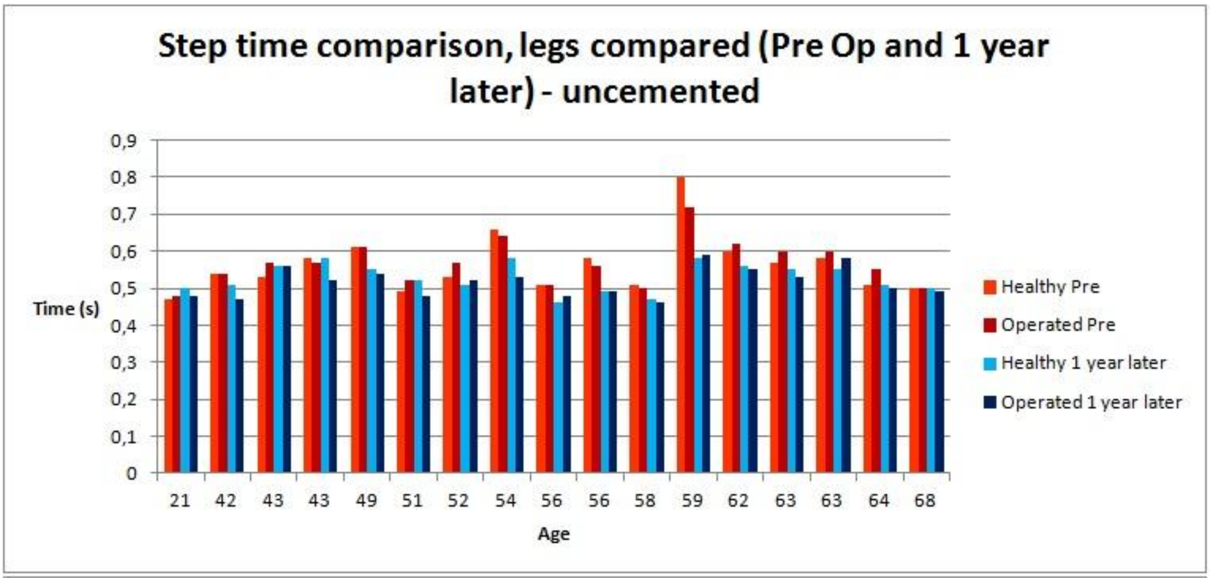


Figure 40. Compares step time of both legs at three time points and displays increase in step time for both legs.

Table 10. Average difference between healthy and operated leg and symmetry indices.

Average ± Standard Deviation Step time (s)	Uncemented			Cemented		
	Males	Females	Total	Males	Females	Total
Average Difference between legs, Op - healthy (Pre)	0,01 ± 0,02	0 ± 0,03	0 ± 0,03	0,06 ± 0,05	0,01 ± 0,03	0,03 ± 0,04
Average Difference between legs, Op - healthy (6 weeks)	0,01 ± 0,04	-0,02 ± 0,01	0 ± 0,03	0,01 ± 0,02	-0,01 ± 0,02	0 ± 0,02
Average Difference between legs, Op - healthy (1 year)	-0,02 ± 0,04	-0,01 ± 0,01	-0,01 ± 0,02	0 ± 0,01	-0,01 ± 0,02	-0,01 ± 0,02
Symmetry (Pre)	1,0%	0,9%	0,9%	1,2%	1,8%	1,6%
Symmetry (6 weeks)	0,8%	1,2%	1,0%	1,1%	0,9%	1,0%
Symmetry (1 year)	1,1%	0,8%	1,0%	0,6%	0,7%	0,7%



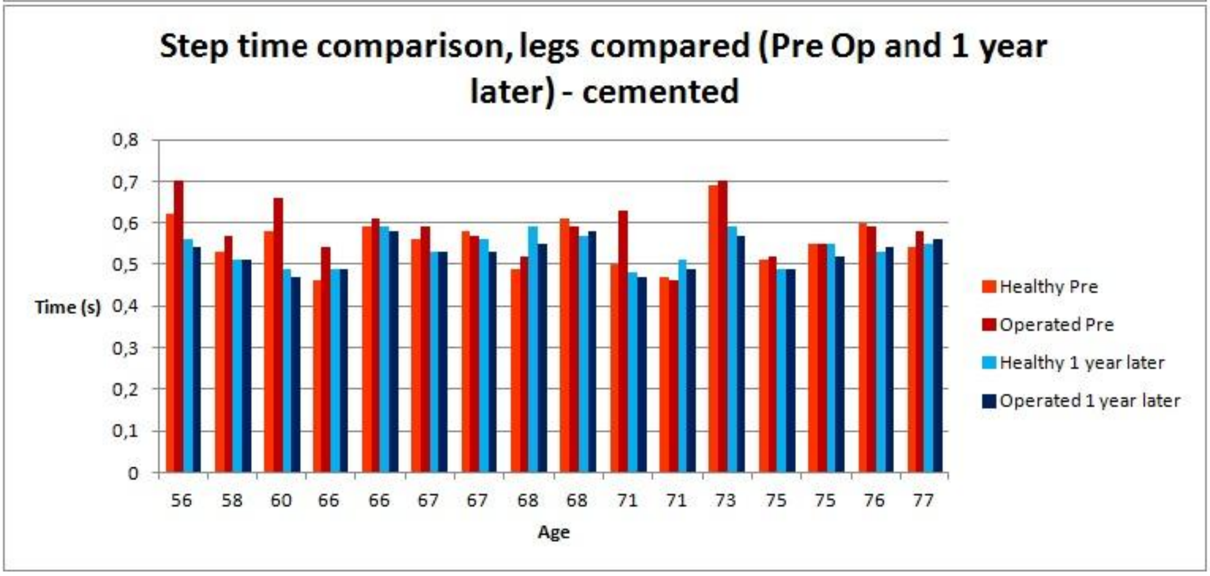


Figure 41. Compares step time of foot pares at two time periods.

4.4.2. Spatial parameters

- Stride length

Figure 42 compares stride length at three different time periods and shows the increase from pre-op to one year post-op. Table 11 shows the average stride length.

Table 11. Average and difference in stride length.

Average ± Standard Deviation Stride length (cm)	Uncemented			Cemented		
	Males	Females	Total	Males	Females	Total
Average (pre)	128,8 ± 10,6	105,9 ± 12,8	116,7 ± 16,4	108,3 ± 22,8	105,6 ± 16,2	106,4 ± 17,8
Average (6 weeks)	125,7 ± 8,2	105,7 ± 15,8	115,1 ± 16,1	112,4 ± 14,7	113,5 ± 14,6	113,1 ± 14,2
Average (1 year)	140,1 ± 7,9	122,5 ± 12,4	130,8 ± 13,7	119,7 ± 14,8	122,6 ± 12,8	121,7 ± 13
Average Difference (1year - Pre)	11,3 ± 11,7	16,6 ± 13,1	14,1 ± 12,4	11,4 ± 16,8	17 ± 17,9	15,3 ± 17,2
Average Difference in % (1year - Pre)	9,31%	16,78%	13,26%	13,48%	18,36%	16,84%

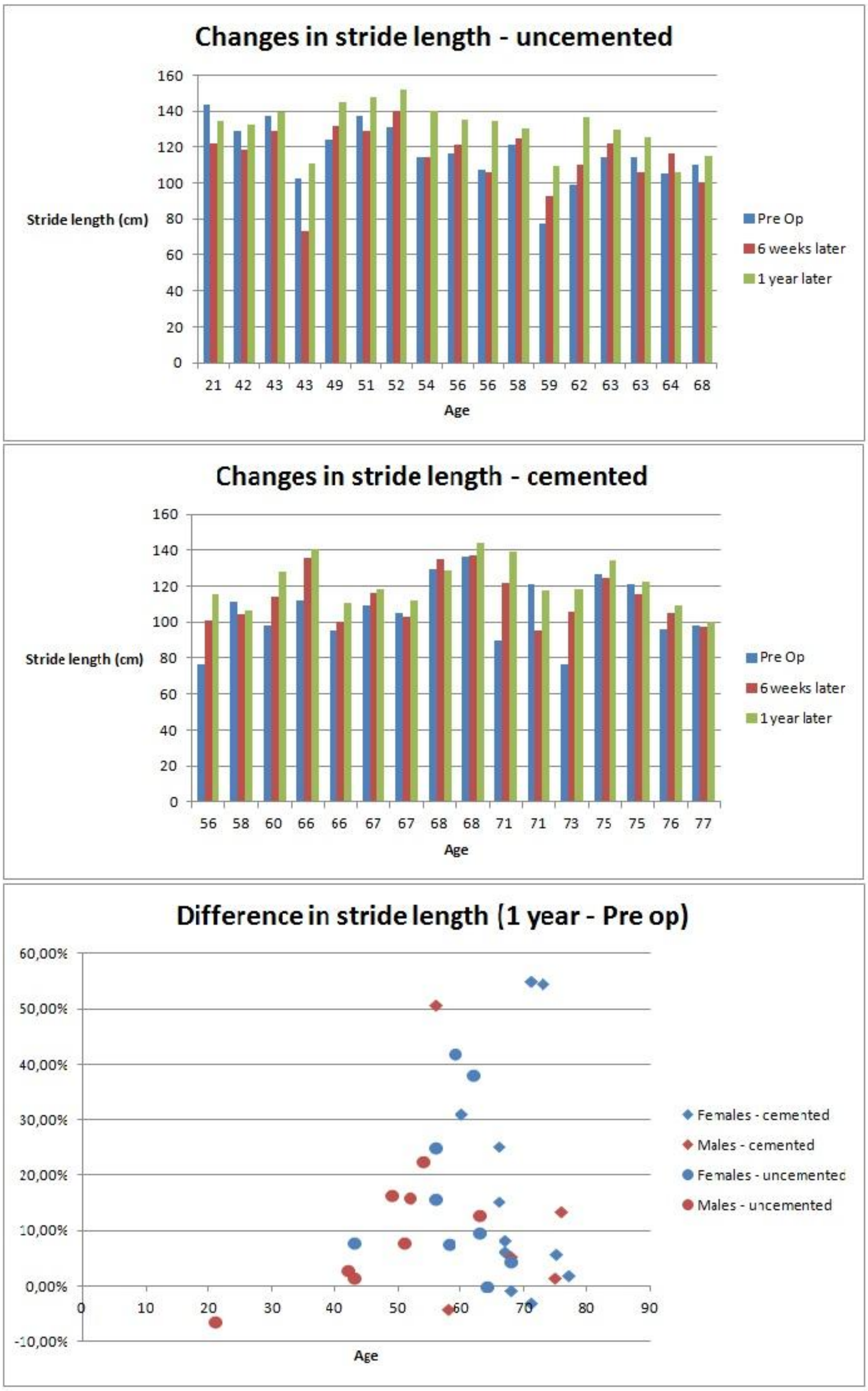


Figure 42. Compares stride length at three different time points and shows the difference in stride length from pre op to post op.

- Step length

Figure 43 compares step length at three different time periods and shows the increase in step length from pre op to one year post op. Table 12 shows the average step length values for both legs and both cemented and uncemented patients are included. Figure 44 compares the step length of operated leg vs. healthy leg. This comparison is made on pre op- and one year post data. Table 13 shows the average difference of step length between operated and healthy legs. Also displayed is the symmetry index between the legs for the three time periods.

Table 12. Average step length.

Average ± Standard deviation Step Length (s)	**Operated leg**						**Healthy leg**					
	Uncemented			**Cemented**			**Uncemented**			**Cemented**		
	Males	Females	Total	Males	Females	Total	Males	Females	Total	Males	Females	Total
Average (pre)	65,7 ± 5,8	54,1 ± 5,3	59,6 ± 8	53,9 ± 11,7	53,7 ± 9	53,8 ± 9,5	63,1 ± 4,9	51,8 ± 8,1	57,2 ± 8,8	54,4 ± 11,4	51,8 ± 7,6	52,6 ± 8,6
Average (6 weeks)	64,9 ± 4,8	53,7 ± 7	59 ± 8,2	55,4 ± 7,5	58,3 ± 6,9	57,4 ± 7	60,8 ± 5	52 ± 9,4	56,2 ± 8,7	57 ± 8,1	55,2 ± 8	55,8 ± 7,8
Average (1 year)	71,1 ± 4,4	61,3 ± 4,9	65,9 ± 6,8	58,7 ± 7,9	61,5 ± 5,9	60,6 ± 6,4	69,1 ± 4,9	61,2 ± 7,9	64,9 ± 7,6	61 ± 7,3	61,1 ± 7,1	61,1 ± 6,9
Average Difference (1year - Pre)	5,4 ± 5	7,2 ± 6,1	6,4 ±5,5	4,7 ± 6,9	7,8 ±8,9	6,8 ±8,2	-5,9 ± 7,3	-9,4 ± 8,1	-7,7 ± 7,7	-6,7 ± 10	-9,2 ± 9,5	-8,4 ± 9,4
Average Difference in % (1year - Pre)	8,65 %	15,92 %	11,58 %	11,21 %	16,90 %	15,12 %	10,00 %	21,61 %	15,40 %	15,83 %	20,10 %	18,77 %

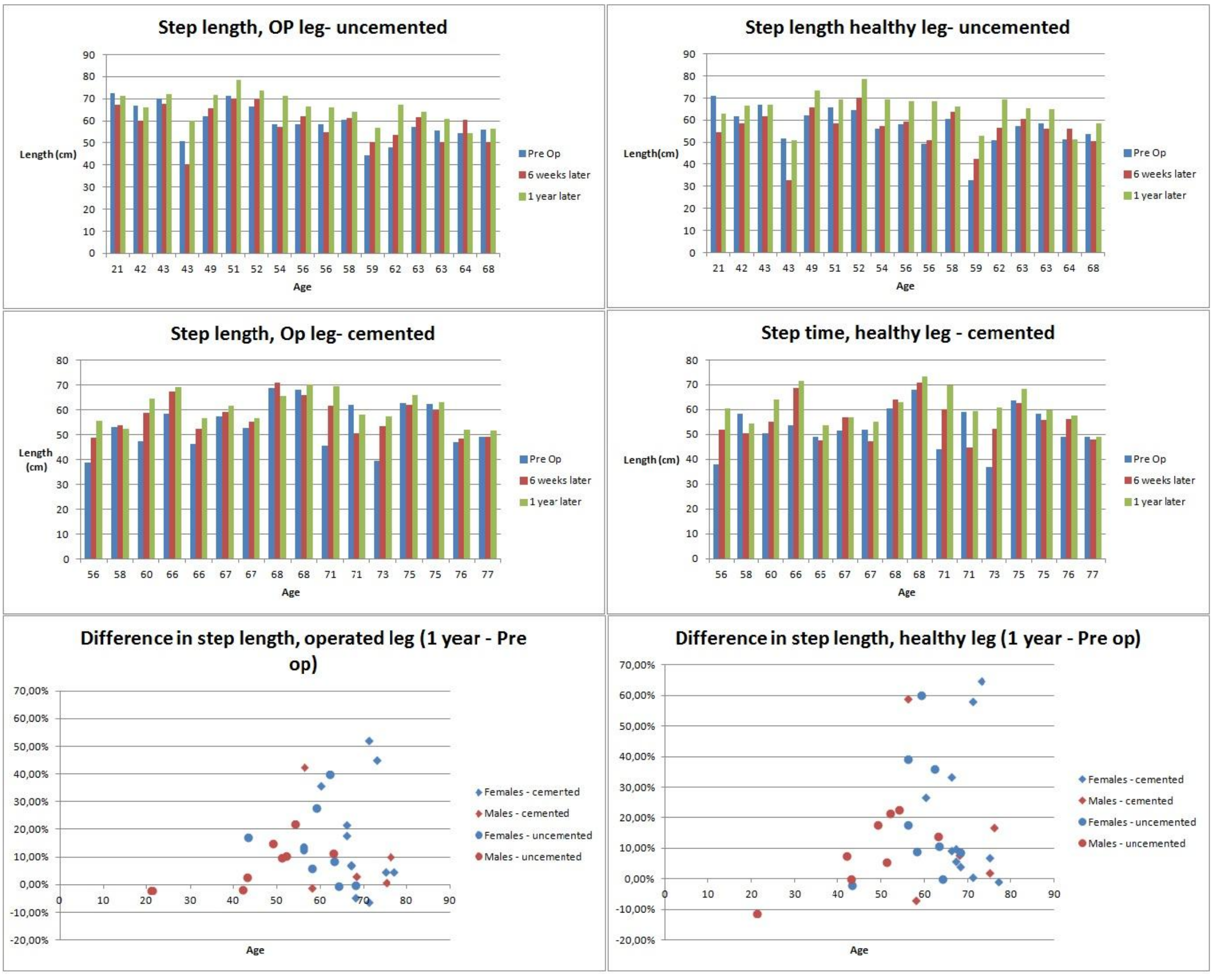
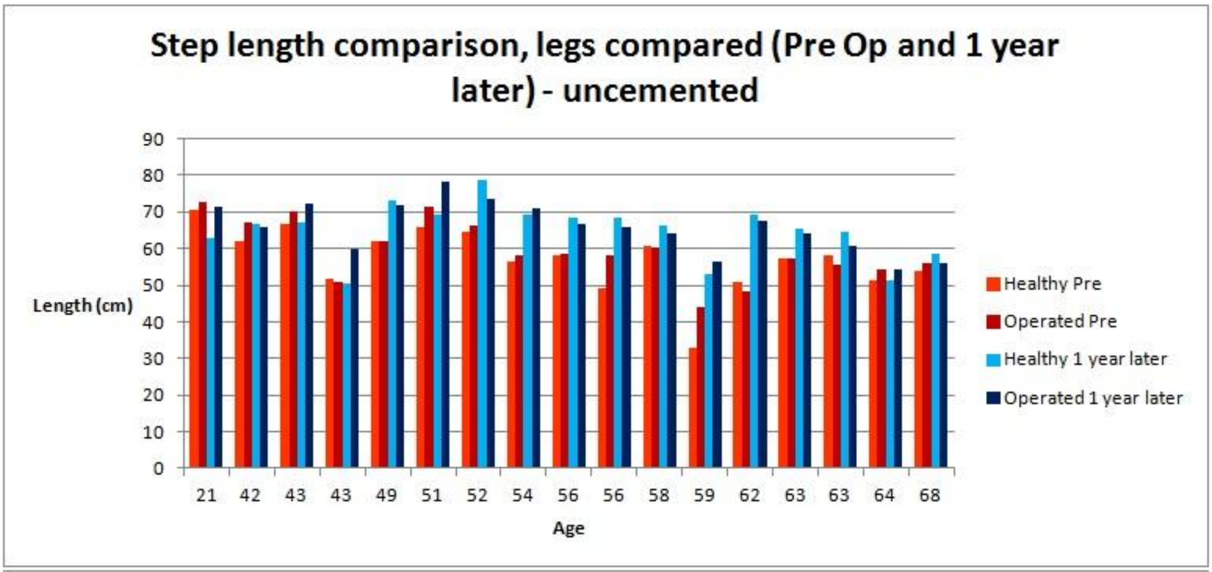


Figure 43. Comparison of stride length of both legs at three different time periods and the increase from pre-op to one year post-op.

Table 13. Average difference between healthy and operated legs and symmetry indices.

Average ± Standard deviation Step Length (s)	Uncemented			Cemented		
	Males	Females	Total	Males	Females	Total
Average Difference bewteen legs, Op - healthy (Pre)	1,9 ± 2,8	2,6 ± 4,7	2,3 ± 3,8	-1,8 ± 2,7	2,6 ± 3,3	1,2 ± 3,7
Average Difference between legs, Op - healthy (6 weeks)	2,9 ± 5,4	1,3 ± 3,5	2,1 ± 4,4	0,5 ± 4,8	2,6 ± 4,1	1,9 ± 4,3
Average Difference between legs, Op - healthy (1 year)	1,7 ± 5,6	-0,5 ± 2,3	0,5 ± 4,2	-0,9 ± 3,1	0,2 ± 3	-0,1 ± 3
Symmetry (Pre)	1,0%	1,9%	1,5%	1,2%	1,4%	1,3%
Symmetry (6 weeks)	1,7%	2,1%	1,9%	2,1%	1,6%	1,7%
Symmetry (1 year)	1,5%	1,5%	1,5%	1,6%	0,9%	1,1%



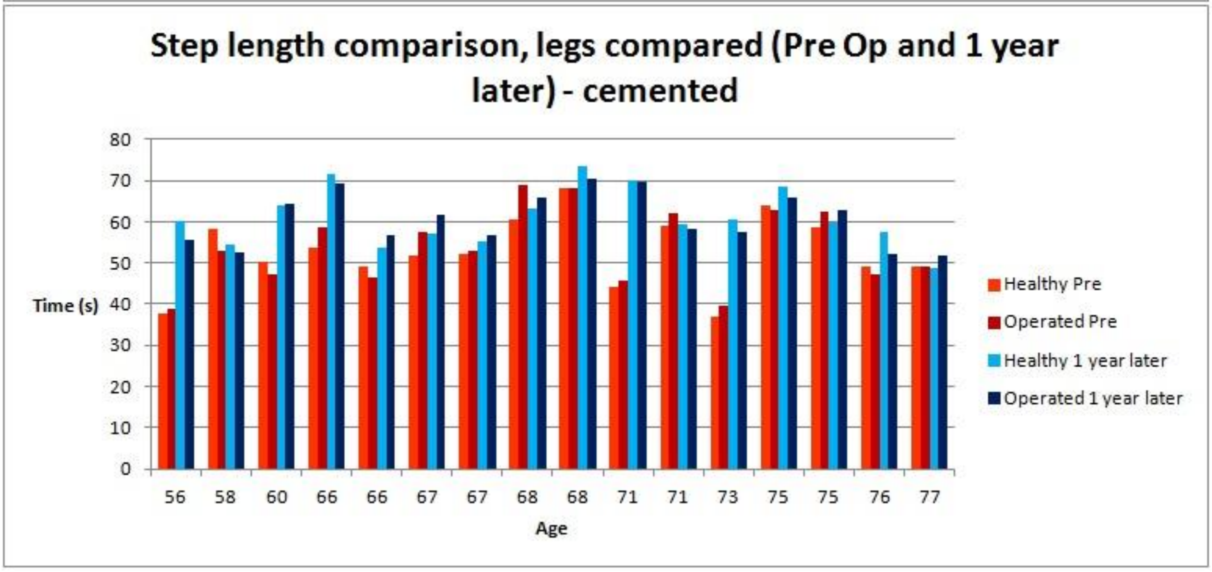


Figure 44. Shows comparison of step length between healthy and operated legs, pre-op and one year post-op.

- Base support

Figure 45 shows compares base support at three different time periods and displays the difference between pre-op and one year post-op. Table 14 shows the average base support and average differences.

Table 14. Average base support and average differences.

Average ± Standard deviation Base support (cm)	**Uncemented**			**Cemented**		
	Males	**Females**	**Total**	**Males**	**Females**	**Total**
Average (pre)	10,5 ± 3,2	15,4 ± 5,6	13,1 ± 5,1	10,1 ± 1,2	10,7 ± 3,2	10,5 ± 2,7
Average (6 weeks)	13,8 ± 3,3	16,2 ± 8,5	15,1 ± 6,5	10,7 ± 0,6	11,6 ± 3,7	11,3 ± 3,1
Average (1 year)	10,7 ± 2	10,4 ± 3,9	10,6 ± 3,1	11,4 ± 2,2	10,4 ± 2,7	10,7 ± 2,5
Average Difference (1year - Pre)	0,2 ± 2,1	-5 ± 5	-2,6 ± 4,6	1,2 ± 2,8	-0,3 ± 2	0,2 ± 2,3
Average Difference in % (1year - Pre)	5,41%	-28,34%	-12,46%	14,09%	-0,40%	4,13%

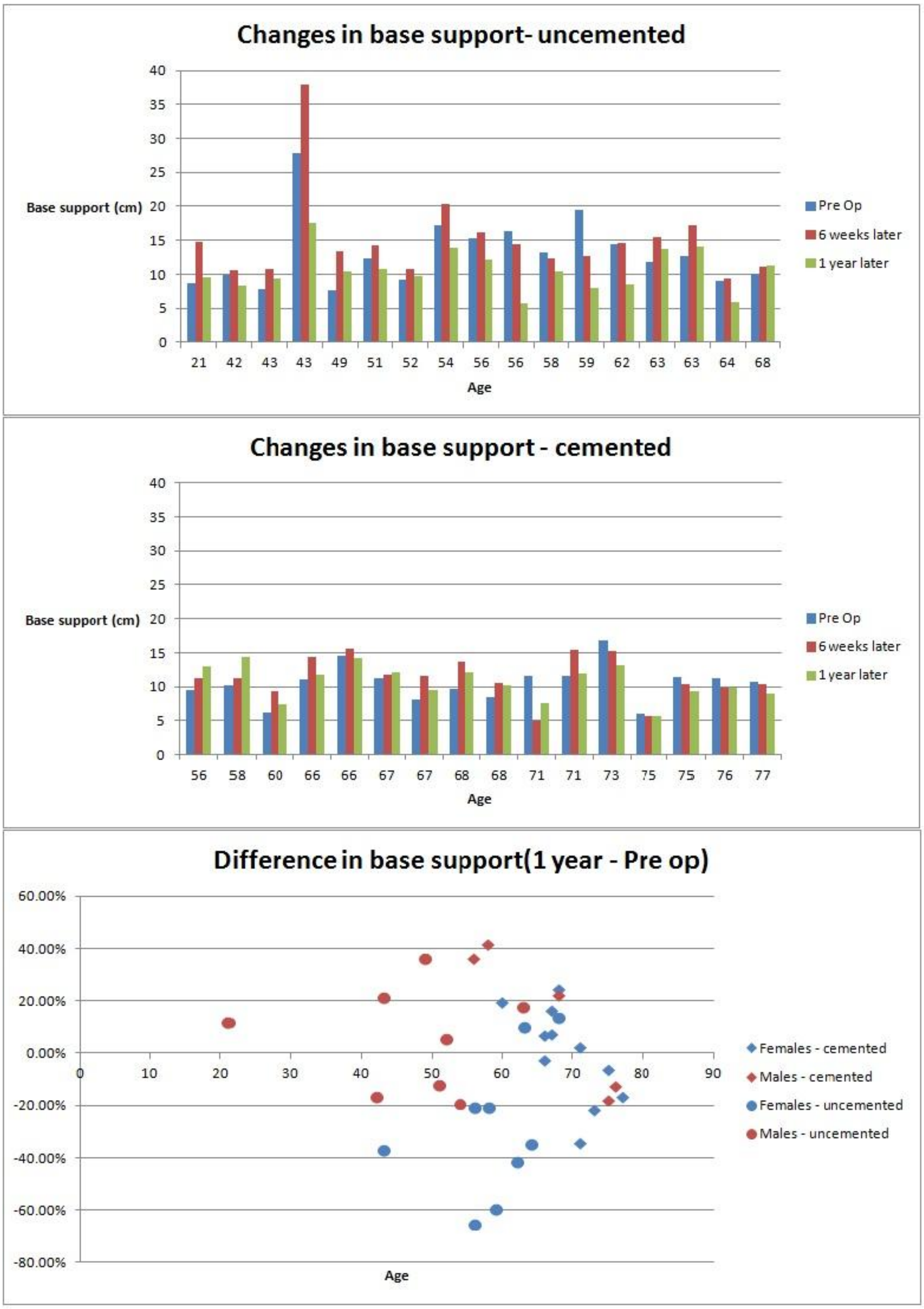


Figure 45. Comparison of base support at three different time periods, and the difference between pre-op and one year post-op.

- Toe in/out

Figure 46 compares the toe in/out parameter at three different time periods, also displayed is the difference between pre-op and one year post-op. Table 15 shows averages and average differences for the toe in/out parameter.

Table 15. Average toe in/out and average differences.

Average ± Standard deviation Toe in/out (deg)	Operated leg						Healthy leg					
	Uncemented			Cemented			Uncemented			Cemented		
	Males	Females	Total	Males	Females	Total	Males	Females	Total	Males	Females	Total
Average (pre)	5,5 ± 5,4	6,2 ± 6,4	5,9 ± 5,8	10,8 ± 8,3	6 ± 4,7	7,5 ± 6,2	5,1 ± 5,1	2,4 ± 7,1	3,7 ± 6,2	13,8 ± 5,9	3,1 ± 4	6,4 ±6,8
Average (6 weeks)	1,9 ± 6,4	1,9 ± 6,4	1,9 ± 6,2	6,4 ± 13,6	2,7 ± 3,3	3,9 ± 7,7	3,3 ± 5,1	2,7 ± 5,6	2,9 ± 5,2	12,4 ± 5	2 ± 5,1	5,3 ± 7
Average (1 year)	2,3 ± 6,3	3,2 ± 6,8	2,8 ± 6,4	9 ± 10,4	3,1 ± 3,5	4,9 ± 6,7	3,8 ± 5,3	3,8 ± 5,8	3,8 ± 5,4	13,8 ± 5,6	2 ± 5	5,7 ± 7,5
Average Difference (1year - Pre)	-3,3 ± 4	-3 ± 2,6	-3,1 ± 3,3	-1,8 ± 2,2	-2,9 ± 3,9	-2,6 ± 3,4	1,4 ± 1,3	-1,3 ± 6,6	-0,1 ± 4,9	0 ± 2,9	1,1 ± 1,6	0,8 ± 2,1

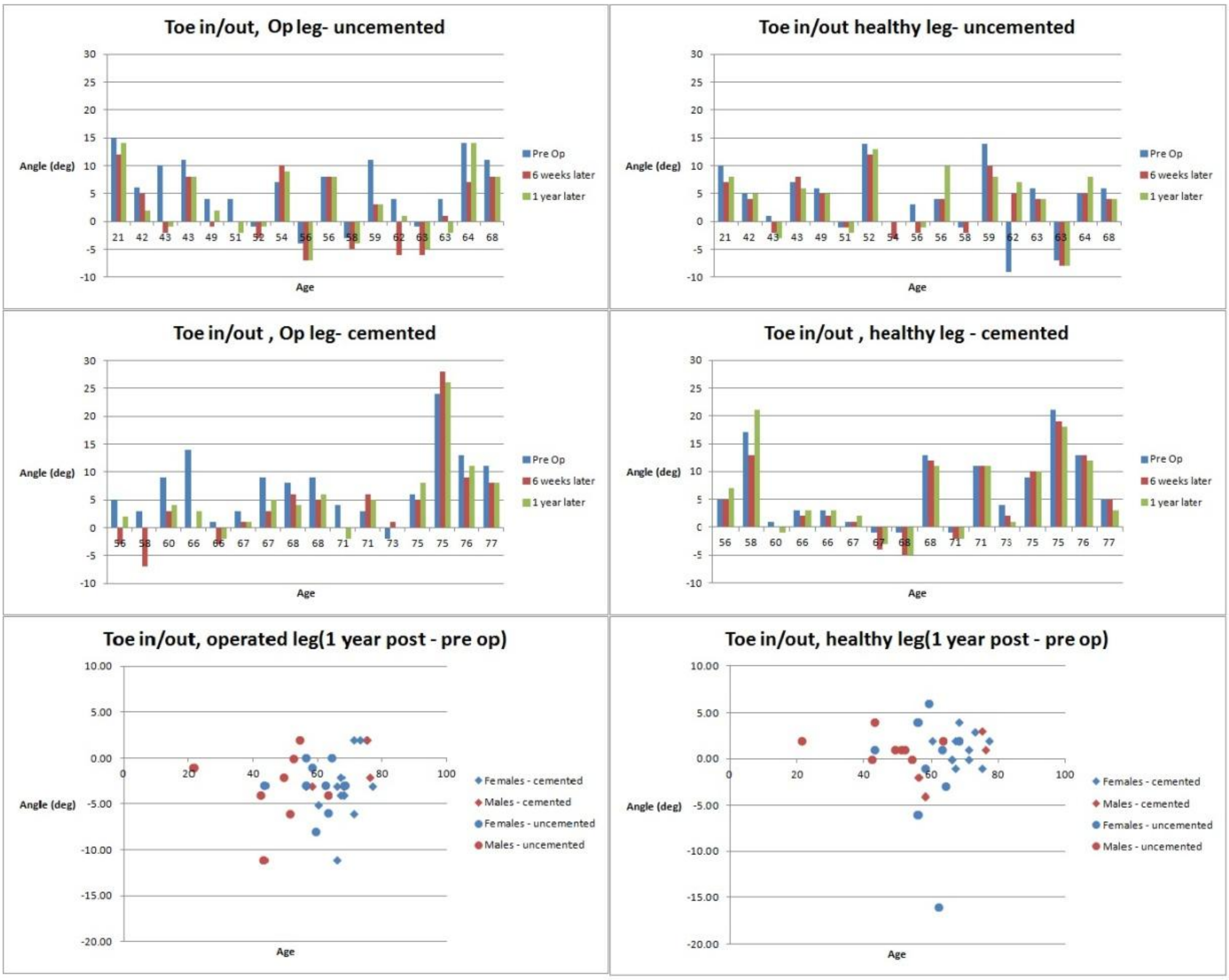


Figure 46. Compares the values of the toe in/out parameter at three different time periods and shows the increase from pre-op to one year post-op.

4.5. Pressure distribution

To be included in the pressure distribution calculations there had to be available datasets from the GAITRite® pressure carpet from pre-op and one year post-op. Included were 16 uncemented patients (7 males, 9 females) and 16 cemented patients (5 males, 11 females).
Figure 47 (uncemented) and figure 48 (cemented) compare the amount of pressure on the three defined areas of the foot: forefoot (red), mid-foot (blue) and hind-foot (green); operated legs are displayed in darker colors and healthy legs are displayed with lighter colors. Figure 49 displays the change in symmetry between pre op and one year post op. Note that positive values stand for decreased symmetry index and negative values stand for increased symmetry index. Tables 16 (uncemented) and 17 (cemented) show the average values of each pressure area of both feet. Also included in the tables are the symmetry indices.

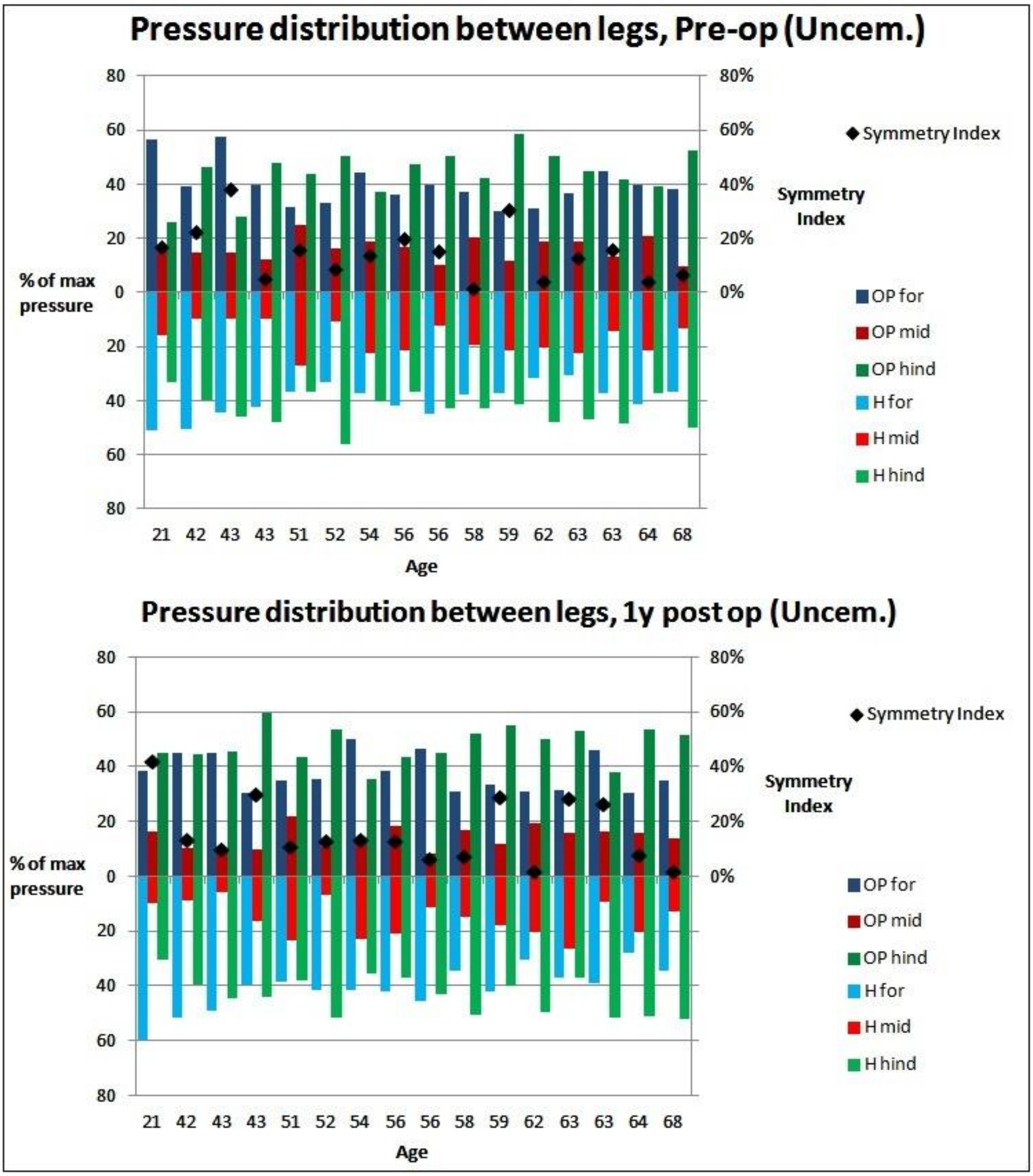


Figure 47. Comparison of the pressure distribution between the operated and healthy leg and the symmetry index between the feet, uncemented patients.

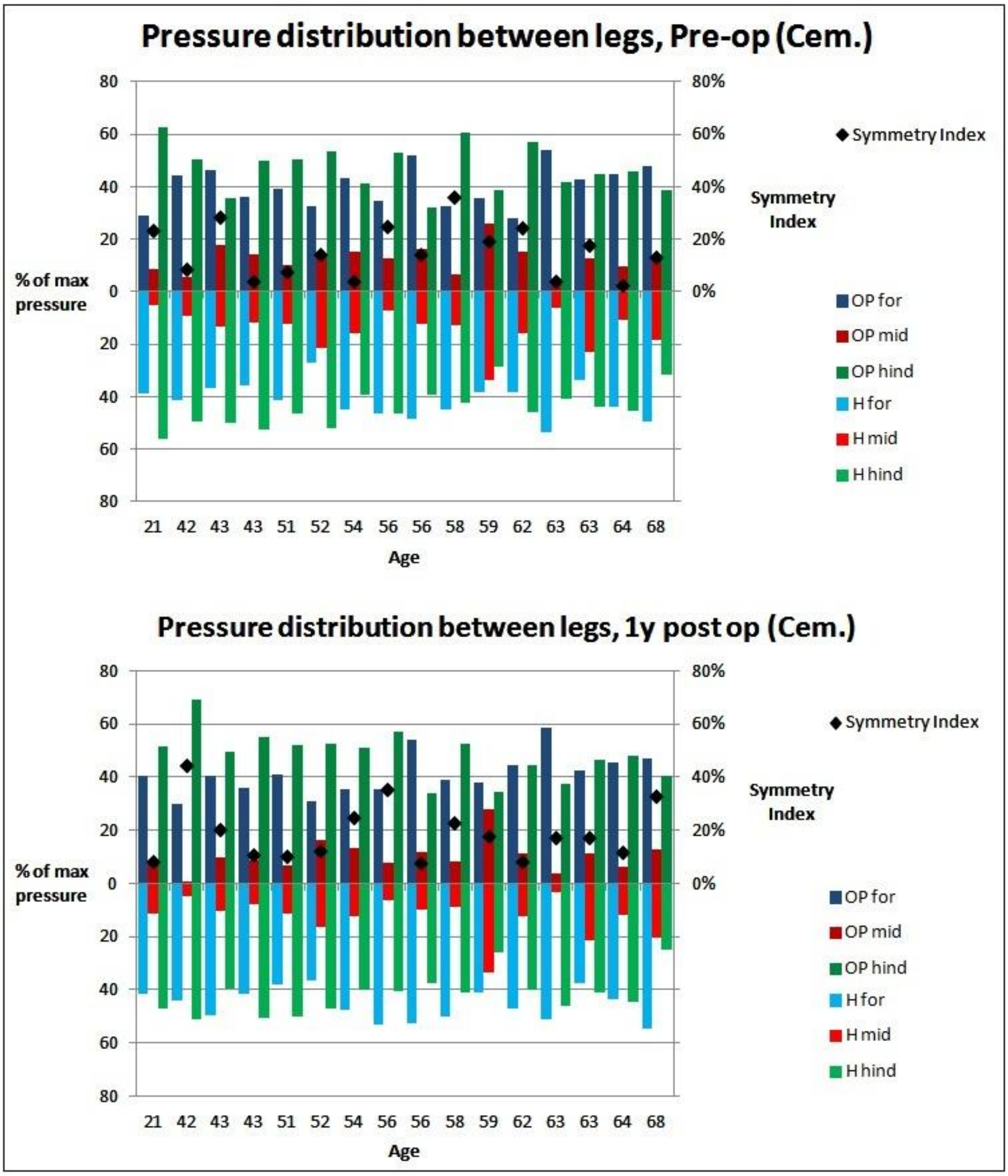


Figure 48. Comparison of the pressure distribution between the operated and healthy leg and the symmetry index between the feet, cemented patients.

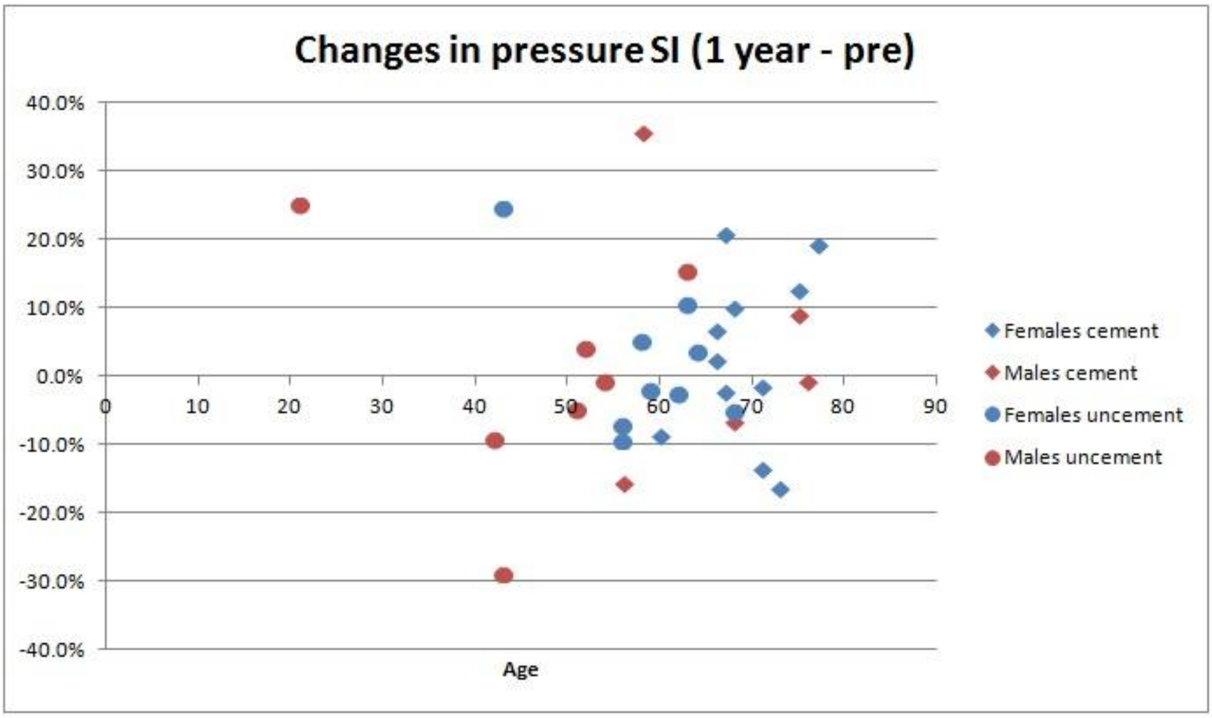


Figure 49. Increase in symmetry index from pre op to one year post op.

Table 16. Shows the pressure distribution and symmetry index between the feet of uncemented patients

Average ± Standard deviation, Pressure distribution(%) - Uncemented								
Pre	**O for**	**O mid**	**O hind**	**H for**	**H mid**	**H hind**	**SI**	
Males	42,66 ± 10,63	17,97 ± 3,49	39,37 ± 9,53	40,47 ± 8,29	16,84 ± 7,17	42,69 ± 7,64	18,36%	
Females	37,39 ± 4,6	14,8 ± 4,38	47,81 ± 5,94	39 ± 3,96	17,01 ± 4,57	43,99 ± 4,89	11,53%	
Total	39,69 ± 7,99	16,19 ± 4,21	44,12 ± 8,59	39,64 ± 6,03	16,94 ± 5,63	43,42 ± 6,05	14,52%	
Post								**SI Increase**
Males	40,03 ± 6,82	14,1 ± 4,37	45,87 ± 6,16	45,56 ± 8,22	14,81 ± 8,82	39,63 ± 6,81	18,61%	0,25%
Femals	35,78 ± 6,5	14,48 ± 3,78	49,74 ± 6,59	37,33 ± 5,82	16,07 ± 4,23	46,6 ± 5,73	13,53%	2,00%
Total	37,64 ± 6,78	14,31 ± 3,91	48,05 ± 6,51	40,93 ± 7,93	15,52 ± 6,41	43,55 ± 6,99	15,75%	1,23%

Table 17. Shows the pressure distribution and symmetry index between the feet of cemented patients.

Average ± Standard deviation, Pressure distribution(%) - Cemented								
Pre	**O for**	**O mid**	**O hind**	**H for**	**H mid**	**H hind**	**SI**	
Males	42,56 ± 8,37	10,42 ± 4,06	47,02 ± 10,9	41,2 ± 5,52	12,04 ± 6,65	46,76 ± 6,32	13,46%	
Females	39,42 ± 7,65	13,58 ± 5,42	47,01 ± 8,13	40,84 ± 7,41	15,92 ± 7,5	43,24 ± 7,4	16,56%	
Total	40,18 ± 7,97	12,65 ± 5,32	47,17 ± 8,93	41,41 ± 6,67	14,27 ± 7,21	44,32 ± 7,33	15,51%	
Post								**SI Increase**
Males	42,58 ± 8,76	7,62 ± 4,46	49,8 ± 12,69	43,88 ± 5,43	11,88 ± 5,95	44,24 ± 5,24	17,93%	4,47%
Females	40,75 ± 7,14	11,49 ± 6,19	47,76 ± 7,21	45,67 ± 6,4	13,7 ± 8,21	40,63 ± 8,14	19,12%	2,56%
Total	41,23 ± 7,65	10,3 ± 6,08	48,48 ± 9,05	45,61 ± 5,88	12,65 ± 7,4	41,74 ± 7,68	18,87%	3,35%

4.6. Muscle activation periods, EMG

To be included in the muscle activity calculations patients had to have datasets available from pre-op and one year post-op measurements with the KinePro device. Seven uncemented patients were included (2 males, 5 females) and 8 cemented patients (3 males, 5 females).

Figures 50, 51 and 52 display the activation periods of vastus lateralis, rectus femoris and vastus medialis respectively, as a percentage of a whole gait cycle. Both healthy and operated sides are included and patients are sorted by age, gender and implant type. Table 18 shows the average values of each muscles activation period, for both legs, pre-op and one year post-op and divided by implant type.

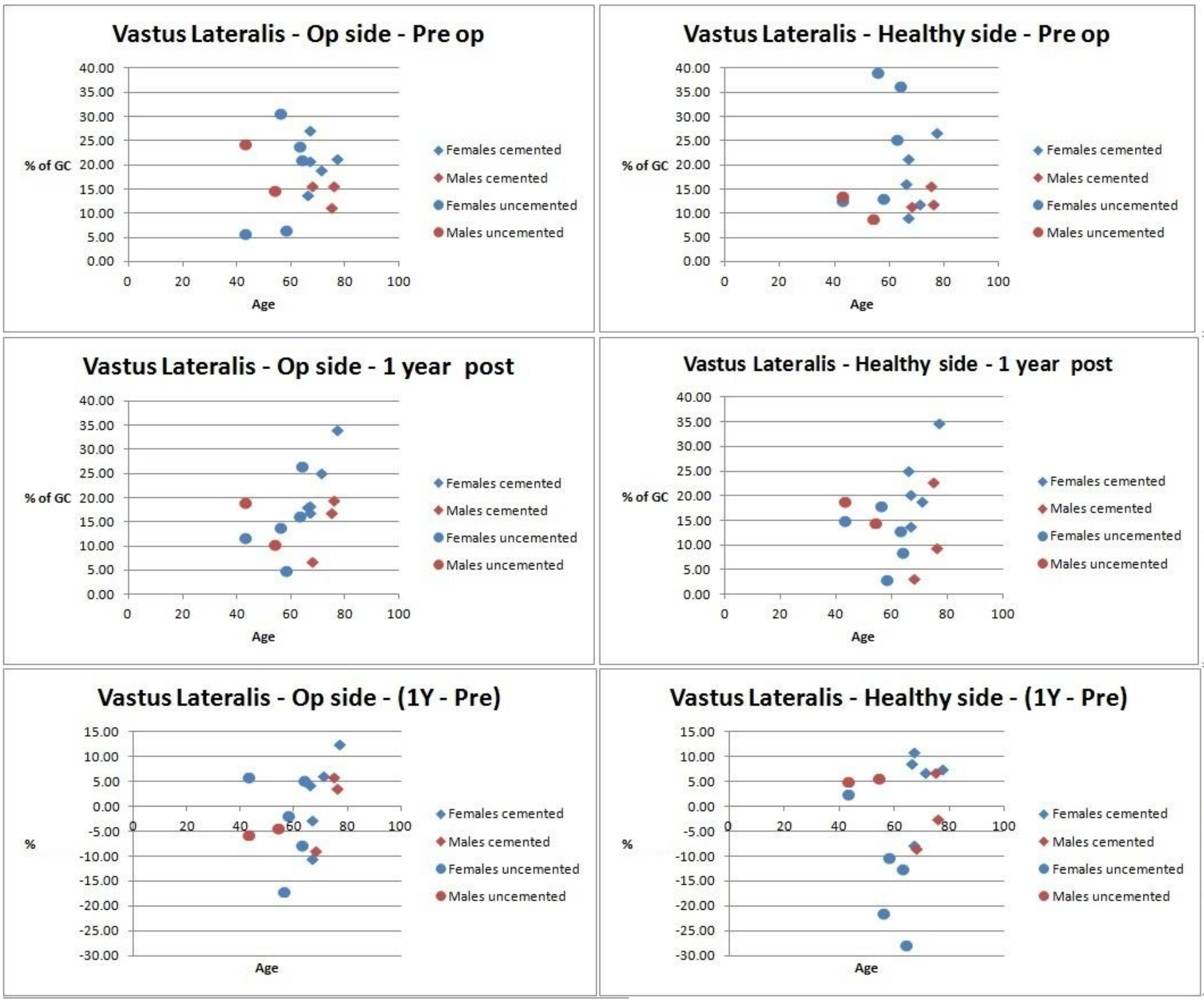


Figure 50. Activation period of vastus lateralis as a percent of the gait cycle and the increase from pre op to one year post op.

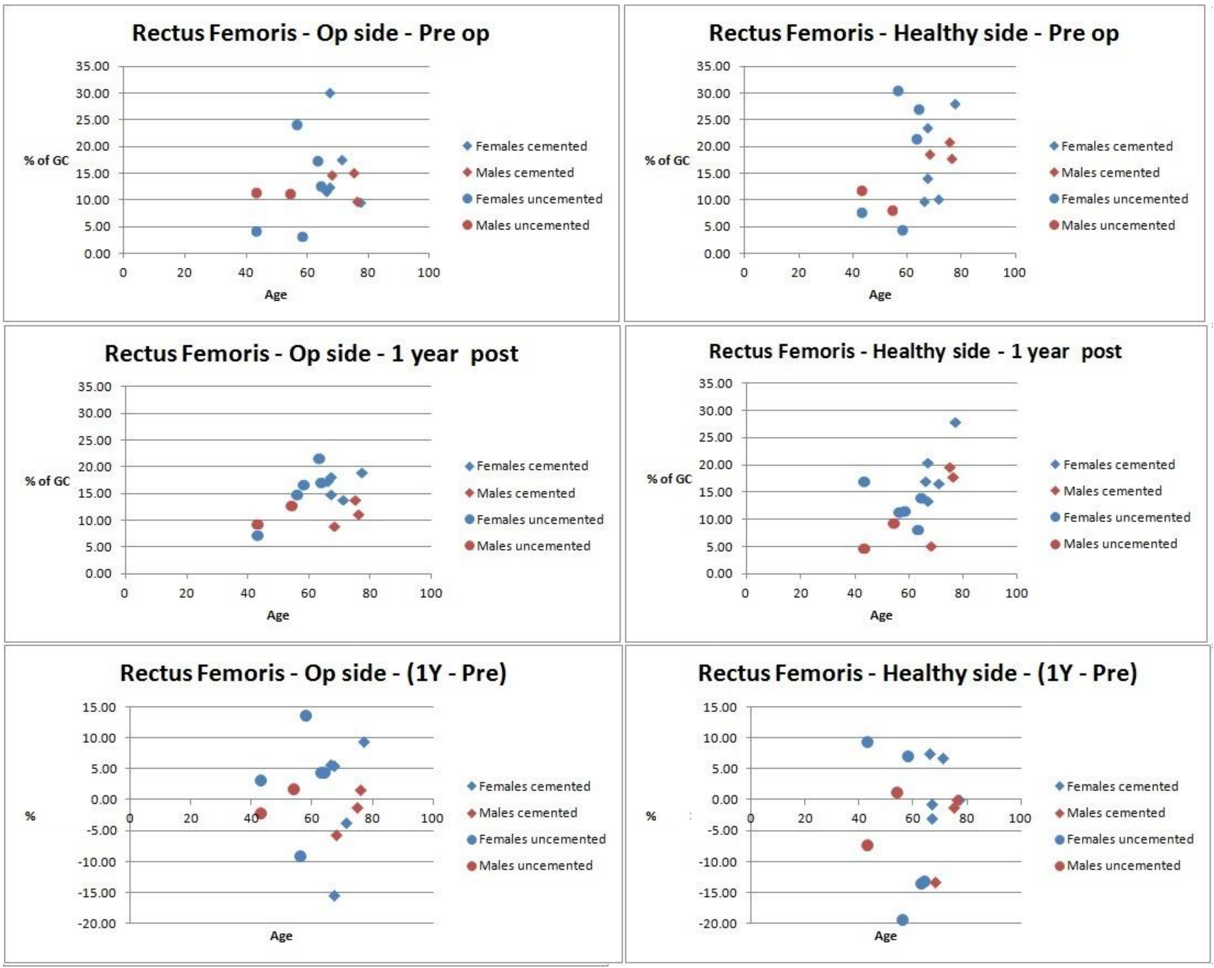


Figure 51. Activation period of rectus femoris as a percent of the gait cycle and the increase from pre op to one year post op.

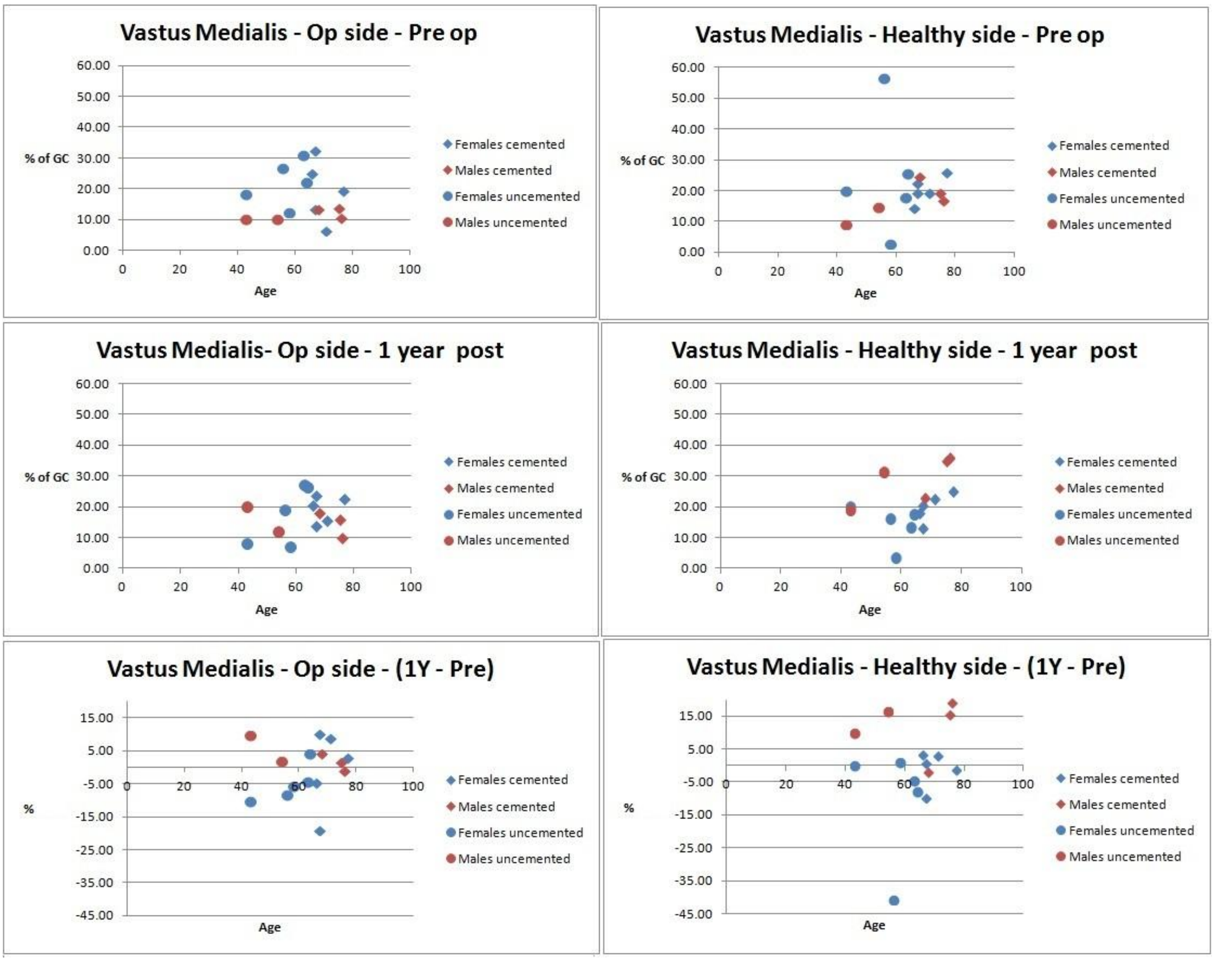


Figure 52. Activation period of vastus medialis as a percent of the gait cycle and the increase from pre-op to one year post-op.

Table 18. Displays the average activation periods of the three muscles, vastus lateralis (VL), rectus femoris (RF) and vastus medialis (VM), both for the operated side (O) and the healthy side (H).

Average ± Standard Deviation Muscle activation in gait cycle (%)						
	VL H	**RF H**	**VM H**	**VL O**	**RF O**	**VM O**
Cemented - pre	15,71 ± 5,92	17,92 ± 6,43	20,44 ± 3,92	18,09 ± 5,1	15,27 ± 6,7	16,92 ± 8,45
Cemented - post	18,59 ± 9,72	17,42 ± 6,48	24,17 ± 7,97	19,37 ± 7,72	14,81 ± 3,43	17,49 ± 4,64
Cemented - difference (post - pre)	2,88 ± 7,78	-0,5 ± 6,4	3,73 ± 9,36	1,27 ± 7,91	-0,46 ± 7,88	0,56 ± 9,2
Uncemented - pre	21,36 ± 12,41	16,08 ± 10,41	21,07 ± 17,39	18,29 ± 9,48	12,14 ± 7,29	18,7 ± 8,32
Uncemented - post	12,96 ± 5,54	11,06 ± 4,02	17,44 ± 8,32	14,67 ± 6,85	14,46 ± 4,95	17,09 ± 8,18
Uncemented - difference (post - pre)	-8,4 ± 13,37	-5,03 ± 11,1	-3,63 ± 18,31	-3,61 ± 7,88	2,32 ± 6,93	-1,61 ± 7,21

4.7. Secondary findings: use of artifact reduction software

All datasets that were used in the BMD calculations and MD calculations are included here to see how the artifact reduction process influences the values of the areas of interest.

Table 19 displays the different average BMD values before and after artifact reduction. Results are given for all areas of interest of both legs. The average difference between reduced- and original datasets is also given in (g/cm^3) and in percents. Table 20 displays the different average HU values before and after artifact reduction. Results are given for all muscles of both legs. The average difference between reduced- and original datasets is also given in (HU) and in percents. Values are categorized by implant type but also displayed as a total.

Table 19. Average BMD values of all datasets before- and after artifact reduction treatment. All areas of interest are displayed. Also average differences are displayed.

Average ± Standard Deviation Bone mineral density (g/cm^3)										
Uncemented	**O A**	**O B**	**O C**	**O D**	**O PROX**	**H A**	**H B**	**H C**	**H D**	**H PROX**
Original (average)	1,169 ± 0,052	1,558 ±0,032	1,484 ± 0,032	1,331 ±0,058	1,132 ±0,041	1,218 ±0,049	1,553 ±0,028	1,487 ±0,041	1,387 ±0,054	1,121 ±0,043
Reduced (average)	1,206 ± 0,036	1,557 ±0,031	1,484 ± 0,032	1,345 ±0,046	1,121 ±0,043	1,215 ± 0,05	1,553 ±0,029	1,488 ± 0,04	1,384 ±0,052	1,141 ±0,046
Difference (Red. - Orig.)	-0,037 ± 0,033	0,001 ±0,005	-0,001 ± 0,001	-0,014 ± 0,017	0,011 ±0,024	0,003 ±0,003	0 ±0,008	-0,001 ± 0,002	0,004 ±0,004	-0,02 ± 0,041
% difference (Red./Orig.)	-3,07%	0,05%	-0,04%	-1,06%	1,03%	0,26%	0,01%	-0,04%	0,28%	-1,66%
Cemented										
Original (average)	1,134 ±0,048	1,562 ±0,035	1,502 ± 0,041	1,361 ± 0,045	1,141 ±0,044	1,182 ±0,061	1,561 ±0,043	1,464 ± 0,039	1,385 ±0,041	1,054 ±0,062
Reduced (average)	1,217 ± 0,042	1,563 ± 0,035	1,508 ±0,037	1,352 ± 0,048	1,054 ±0,062	1,174 ± 0,06	1,561 ± 0,04	1,471 ±0,044	1,38 ± 0,04	1,113 ±0,039
Difference (Red. - Orig.)	-0,083 ± 0,038	0 ± 0,004	-0,006 ± 0,019	0,009 ± 0,032	0,087 ± 0,036	0,008 ± 0,006	0,001 ± 0,015	-0,006 ± 0,019	0,005 ± 0,013	-0,059 ± 0,053
% difference (Red./Orig.)	-6,79%	-0,01%	-0,41%	0,67%	8,46%	0,69%	0,04%	-0,42%	0,36%	-5,30%
Total										
Original (average)	1,154 ± 0,052	1,56 ± 0,033	1,491 ± 0,037	1,344 ± 0,054	1,136 ± 0,042	1,203 ± 0,056	1,557 ± 0,035	1,477 ± 0,041	1,386 ± 0,048	1,092 ± 0,061
Reduced (average)	1,211 ± 0,038	1,56 ± 0,032	1,494 ± 0,036	1,348 ± 0,046	1,092 ± 0,061	1,197 ± 0,057	1,556 ± 0,033	1,481 ± 0,042	1,382 ± 0,046	1,129 ± 0,045
Difference (Red. - Orig.)	-0,057 ± 0,041	0 ± 0,004	-0,003 ± 0,013	-0,004 ± 0,026	0,044 ± 0,048	0,005 ± 0,005	0 ± 0,011	-0,003 ± 0,013	0,004 ± 0,009	-0,037 ± 0,05
% difference (Red./Orig.)	-4,67%	0,02%	-0,20%	-0,32%	4,21%	0,44%	0,02%	-0,20%	0,31%	-3,22%

Table 20. Average MD values of all datasets before- and after artifact reduction treatment. Also displayed is the average difference between original- and reduced datasets.

Average ± Standard Deviation Muscle density (HU)						
Uncemented	**RF O**	**VL O**	**VM O**	**RF H**	**VL H**	**VM H**
Original (average)	59,5 ± 4,71	51,43 ± 5,19	58,12 ± 7,01	51,1 ± 4,04	51,49 ± 4,17	54,12 ± 6,95
Reduced (average)	52,74 ± 4,06	51,23 ± 4,79	51,99 ± 5,25	52,5 ± 3,62	51,87 ± 4,65	53,57 ± 7,01
Avg. Diff.(Red. - Orig.)	-6,76 ± 4,17	-0,2 ± 2,02	-6,14 ± 5,98	1,4 ± 0,85	0,37 ± 1,93	-0,55 ± 3,19
% difference (Red./Orig.)	-11,1%	-0,2%	-10,0%	2,8%	0,7%	-0,8%
Cemented						
Original (average)	74,16 ± 16,65	49,06 ± 9,03	46,57 ± 25,87	45,2 ± 6,85	44,92 ± 6,52	49,27 ± 7,69
Reduced (average)	54,41 ± 3,87	48,35 ± 4,74	47,59 ± 6,46	49,72 ± 3,8	48,2 ± 4,89	51,32 ± 5,59
Avg. Diff.(Red. - Orig.)	-19,75 ± 15,22	-0,71 ± 6,69	1,02 ± 20,31	4,52 ± 5,97	3,28 ± 6,28	2,04 ± 6,6
% difference (Red./Orig.)	-24,0%	0,6%	103,4%	12,6%	9,3%	6,5%
Total						
Original (average)	66,83 ± 14,15	50,24 ± 7,35	52,35 ± 19,55	48,15 ± 6,29	48,21 ± 6,33	51,7 ± 7,62
Reduced (average)	53,57 ± 3,99	49,79 ± 4,91	49,79 ± 6,21	51,11 ± 3,91	50,03 ± 5,05	52,44 ± 6,34
Avg. Diff.(Red. - Orig.)	-13,26 ± 12,81	-0,45 ± 4,87	-2,56 ± 15,17	2,96 ± 4,48	1,83 ± 4,8	0,75 ± 5,27
% difference (Red./Orig.)	-17,6%	0,2%	46,7%	7,7%	5,0%	2,8%

5. Discussion

5.1. Introduction

This chapter will cover every parameter measured in the study. The parameters will be evaluated based on how they measured compared to theory, how much information regarding implant selection and recovery assessment can be extracted from them, and eventually how feasible it is using them for future assessment of THA patients.

5.2. BMD

When figures of all the measured BMD areas are explored it is quite clear that they all follow the trend of decreasing with age more or less with few exceptions, which is in accordance to the literature [3]. This applies for both the operated and the healthy legs. The measured outcomes however differ between areas when the increase from pre-op to one year post-op is studied.

Areas B (Figure 28) and C (Figure 29) are positioned around- and under the distal part of the prosthesis, the increase in BMD for both areas of the healthy leg is quite minima as the values are always between zero and four percent. The increase in BMD of the operated leg is similar for the most part. Almost all uncemented patients and around half of the cemented ones show increase of less than four percent for area C and for area B there are a few patients from both categories that show more increase than four percent. The baseline created by measuring the healthy leg (who's BMD should show very little change between periods, but the change measured could possibly be explained by the differences show between calibration periods of the CT scanner) shows that most of the values of the operated leg are not showing remarkable change for those two areas.

The high values of cemented patients that show up for both areas are probably influenced by the fact the cement restrictor is either very close to their area or inside the measured area. Comparing BMD between patient groups for those two areas is not significant since the values of the cemented patients are influenced by the high BMD values of the cement restrictor. Comparing BMD for those areas from pre-op to one year post-op does not serve the purpose of this study since the measurements show very little difference between pre-op and post-op and could that be influenced by the small area they cover.

When the increase in BMD for area A on the proximal femur is compared between healthy and operated legs it is clear that they have very similar distributions, approximately between minus four percents and six percents. Since there are not supposed to be any changes in BMD for the healthy leg it is safe to assume that there are no changes for the operated leg either and therefore measurements on that area are not useful for the purpose of this study.

For area D most of the changes on the operated leg fall inside the zero to six percent increase boundary set by the healthy leg. There are though few values that show more increase and decrease. The values of high increase are all from cemented patients and it can be assumed that the high density of the bone cement is influencing the values. The values that decrease the most are mostly uncemented patients and is that the same as Brodner et al. finds out in his study, that is; BMD of uncemented patients is lower one year-post op than pre-op [69].

The large proximal area tells a similar story as area D. Most of the values of the operated leg are inside the boundaries set by the healthy leg that should show very minimal changes. The other extreme values behave in a same way they did for area D; a few cemented patients are measured very high because of the influences the high density of the bone cement has on the measurement, and few uncemented patients show more decrease than most. The decrease in BMD of the uncemented patients could be correlated to the fact that they did not show as much improvement in gait parameters as the cemented ones and could therefore not be putting as much stimuli on the leg.

The pre-op BMD measurements seem to be a real indicator of the status of the bones, as they follow the trend of decreasing with age. There are few patients whose values differ from the trend and indicate that they could have received different type of implant than they did. This parameter could therefore give valuable pre operative input into the selection of implant technique for THA patients.

The use of post-operative BMD measurements to evaluate the change in BMD after surgery looks like it could be used for recovery assessment, with some changes though. The information extracted from areas A, B and C is very limited. The information from area D and the large area on the proximal femur seem to give the right image of the BMD changes of the femur. Area D has less volume and the baseline set by the healthy leg is not as good as for the large area. The large area seems to be the best option for those measurements. There needs to be some modification to the measurement since it does not represent the real BMD of some cemented patients. There should be a method developed to get rid of the effects the bone cement can have on the measurement.

5.3. Muscle Density

The pre-operative muscle density measurements seem to follow the same trend as the BMD values to decrease with age which is only logical. There is no difference in the trends of any muscle between pre-op and on year post-op according to Figure 34 except for the rectus femoris of the operated leg. And when Figures 32 and 33 are explored the same trend can be seen. According to tables 3 and 4 there is very little increase, or decrease, for every muscle measured except the rectus femoris who is increasing in MD. The minimal changes at vastus lateralis and vastus medialis are according to literature [55, 56] that states that the general condition of the quadriceps decreases after THA. Rectus femoris is also a part of the quadriceps that act in the extension of the knee, but he also has a function in the flexion of the hip when swing phase is being initiated. The improved gait parameters discussed later in this chapter could be correlated to the increased density of the rectus femoris.

The pre operative MD measurements do follow the same trend as BMD, with muscle quality decreasing with age, which gives the same indication as mentioned in the BMD section, that patients with low MD should get cemented implant since greater muscle density can be related to better general shape and conditions, but other factors such as weight and height should be considered before the parameter is used in pre-operative planning. Increase in muscle density doesn’t seem to follow any trends but is rather random. Individual assessment is possible, but maybe there needs to be another acquisition session to get a clearer image of the recovery trends in MD. Also the higher increase in rectus femoris has not been explained, according to literature it should decrease as its fellow quadriceps. The way measurements are done could be affecting the values since there is not the exact same volume of muscle measured in both datasets.

5.4. Temporal and spatial gait parameters

5.4.1. Gait cycle divisions

From figures 38 and 39 it can be seen that the divisions of phases inside the gait cycle do vary pre op, both for cemented and uncemented patients. Six weeks post op the variation is even more obvious, which is probably related to little time passing since the patient underwent the surgery. At one year post-op the trend for all the patients is to have a relatively normal gait cycle division, as the swing phase of each foot should account for 40% of the gait cycle each and the double support period should account for 20% of the gait cycle [77].This applies for both cemented and uncemented patients. Table 5 strengthens this case since the standard deviations decrease for all phases from pre-op to one year post-op. Both males and females have very similar divisions although females seem to be worse off before the surgery but nonetheless recover to having very similar gait divisions as males. Most of the changes are related to transferring percents from to single support period of the operated leg from the double support phase. That can be related to less pain in the operated leg and therefore less reluctance to put as much weight on it as on the healthy leg.

This parameter gives good overall view of the patient recovery after surgery and can very well stand alone, however it could not stand alone as a pre-operative evaluation parameter for implant selection.

5.4.2. Velocity, cycle time and step time

These parameters are all directly related, higher velocity represents lower cycle time, and the cycle time is simply the sum of the step time of both feet. Almost every patient shows better results for those parameters one year post-op compared to pre-op. Females show better recovery in percentages than males. Both cemented and uncemented patients have almost identical increase in speed from pre op to one year post op, but in percentages the cemented patients show relatively better recovery. Same applies for the cycle time parameter. The step time of the operated leg decreases from pre-op to one year post-op, but for the healthy leg the step time varies. When comparing the step time between operated and healthy leg the average difference increases for cemented patients while the standard deviation decreases. For the cemented patients both average difference and standard deviation decrease. The symmetry index between the step time of the legs increases (negative development) for both patients groups but the change is more for cemented patients, however the index is so low it does not say much about the patients pathology.

These parameters do a good job evaluating the patient recovery. The fact that females recover better for every parameter related to the operated leg could indicate that more females are capable of receiving uncemented implant instead cemented. Good results in pre operative measurements of these parameters could give indication about using uncemented implant and vice versa, but for that the overall physique of the patient would need to be taken into account (leg length, weight, height).

5.4.3. Stride length and step length

These parameters are directly related to each other since the step length of both feet added accounts for the stride length. They are also related to the temporal parameters in last chapter, so the results are similar. The general result is that patients increase their stride length, and most patients also increase in step length of both feet. As before the females show better recovery than males and it can be interpreted the same way as before; more females are able to receive uncemented implant if their ability to recover is as great as these measurements tell. These parameters give good information about patient recovery and could be used for assessment purposes. And like the temporal parameters could be used in advance to give indications on implant selection, but not as standalone measurements. For future measurements it should be considered to reduce the amount of parameters measured (velocity, cycle time, step time, stride length, step length) since they all give similar indications on the recovery of the patients, while they could all be measured if there are special patient cases that need to be looked into.

5.4.4. Base support

For the base support measurements it is considered positive to decrease the base support, since decreased base support indicates better balance and more speed while walking. Again the females show the most improvement between pre-op and one year post-op.

The value of measuring the base support can give information about patient recovery, but it should not be considered priority to include it in measurements but rather look into in on special patient cases.

5.4.5. Toes in/out

The trend for this parameter seems to be random when looking at age, gender or implant type. From Figure 46 it seems to be that all patients trend to point the toes of their operated leg more inwards one year post op than pre op

It should be taken into account that the standard deviations in the table are very high and the parameter should not be generalized for any group of patients but rather looked into for individuals. The parameter should not be a priority when assessing the recovery of patients but rather used for special patient cases.

5.4.6. Summary

Most of the patients showed better results one year post-op than before the surgery and that is what other studies have showed [44, 46, 50]. The value of using this type of gait analysis to assess the recovery of THA patients is high. The parameters can give excellent indication about how the different parts of the gait recover. However the parameters are more or less related to one another in some way, so using only few of them for initial assessment should be enough, while if the patient was not recovering according to plan other parameters should be explored further.

The measurements give indication about cemented patients recovering faster than the uncemented ones. That is probably related to the fact that the load on the femur is less for the cemented patients and therefore more immediate recovery possible. The measurements could give some indication in pre-operative implant selection if the pre-op parameters were correlated to BMD and MD values and other physical factors such as leg length, height and weight.

5.5. Pressure distribution

When looking at figures 47 and 48 there is no obvious way of interpreting the results from the pressure distribution measurements, patients seem to have very random tendencies to adjust their pressure points after the THA. Figure 49 shows how the symmetry of pressure distribution changes from pre-op to one year post-op and there seem to be as many patients who increase their symmetry as who decrease their symmetry, which can for instance be related to the change in leg length before and after THA. From tables 16 and 17 it can be seen that cemented patients transfer pressure more to their forefeet after the surgery than the uncemented patients. That is probably related to the cemented patients showing greater improvement in most of the gait parameters, as higher velocity requires less ground contact by the hind-foot.

This parameter requires some processing and does not give immediate results. It should therefore be used to assess patients that do not recover in a satisfactory way.

5.6. Muscle activation periods

According to the literature the activation period of rectus femoris should be around 8% of the gait cycle and the activation period of vastus medialis and vastus lateralis should be around 25% of the gait cycle [39]. The values measured are not in accordance to that. The closest to

25% the vastus lateralis was 21% for uncemented patients pre op. The closest the rectus femors came to its normal 8% was 11% for uncemented patients post op. The closest the vastus medialis came to its normal 25% was for cemented post op where it measured 24%. Other averages are further away from the comparison values. Cemented patients increased or kept the activation periods almost the same for every muscle of both legs from pre op to post op but the uncemented patients only improved for the rectus femoris of the operated leg, every other muscle showed less activation period post op compared to pre op. This could be related to the cemented patients showing more improvement for the gait parameters, however the standard deviation is very high and the patients who were included in the measurement were few so the results do probably not reflect the real situation.

The overall value of using this parameter is limited since its measured values do not relate to normal muscle function; however that could be a matter of filter selection or electrode placement, so it could possibly be improved if those things were adjusted.

5.7. The use of artifact reduction software to clean artifact polluted datasets

From Table 19 it can be seen that the artifact reduction process does not have much effect on the smaller BMD areas (A,B,C and D), except for area A of the operated leg where the average difference between original and artifact reduced datasets is 4,67%. The effect the process has on the larger areas at the proximal femur are more obvious since the difference in BMD values between original and reduced datasets is 4,21% for the operated side and 3,22% for the healthy side. This is likely related to the fact that the large proximal area surrounds the prosthesis on the operated side but on the healthy side the difference can be caused by the longitudinal effects of the artifacts the prosthesis causes on such a large area. From Table 20 that shows the difference the process has on muscle segmentation data it is clear the effects of the software are greater. Influences on the values of vastus lateralis of the operated side and the vastus medialis of the healthy side are minimal. The effect on vastus lateralis and rectus femoris of the healthy leg is medium, 7,7% and 5% difference respectively, on the HU values compared between original and artifact reduced datasets. The most effects are on the rectus femoris and vastus medialis of the operated side, 17,6% and 46,7% difference respectively. The large number for vastus medialis is caused by one or two badly corrupted datasets while the difference of the rectus femoris is obvious throughout the table, with average difference of 13 HU per dataset while none of the other muscles exceeds three HU in difference. The large effects on rectus femoris on the operated side can be linked to the top of the rectus femoris being close to the proximal end of the implant where most of the artifacts are generated.

The software is very useful for the muscle segmentation if the rectus femoris muscle is to be segmented as the software completely changes the average for many datasets, other muscles can also benefit from the reduction process but that is more of a random nature. For the BMD calculations, the real effect of the software is on the measurements on the large areas of the proximal femurs. If BMD measurements are to be done on that area the reduction process is recommended for more stable results.

6. Conclusions

For implant decision making assistance the most useful parameters turned out to be the BMD measurements on the proximal area of the operated femur pre-operative because that is the biggest area measured and would therefore give the best overall picture on the quality of the bone. The pre-operative muscle density assessment does give some insight into the condition of the patient. Gait analysis in combination with these two parameters and other physical aspects of the patients could give a great input into the implant selection

For recovery assessment of THA patients, the BMD values at the proximal femur gives the most accurate information (of all the measured BMD areas) about how the bone responds after the surgery, measurements later in the recovery process should also be included to get more solid results for every patient. Gait analysis parameters were successful as measurements of patient recovery. These two parameters are solid recovery assessment tools for quantitative recovery assessment, and with more research the muscle density evaluation could also be included.

6.1. Future work

There needs to be some improvement in the BMD measurements of patients whose measurements are heavily affected by bone cement. With further exploration on the data that should be possible. A process to find correlation between parameters measured in the study has already started, that could help in explaining some trends not found in this study. That process can also help in optimizing the assessment since parameters that are represented by other parameters do not have to be measured. New parameters could also be considered as the artifact reduction process makes muscle volume assessment more feasible for example. Another group of patients has already been recruited and the work on their data will hopefully help to establish some of the methods explored in this study and solidify the trends discovered. Hopefully the groundwork of this study will lead to clinical guidelines for implant selection- and recovery assessment of THA patients being established.

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