Evaluation of Skin Strain during Knee Movement Using 3D Motion Analysis

University of Strathclyde

Bioengineering Unit

MSc Thesis

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Declaration of Authenticity and Author's Rights

This thesis is the result of the author's original research. It has been composed by the author and has not been previously submitted for examination which has led to the award of a degree.

Signed:

Date:

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ABSTRACT

As the average age and weight of the population in the UK increases, so does the number of people who require a Total Knee Replacement (TKR). In the post-operation stage, the TKR patients have a dressing applied to the wound, the adhesive section of which can cause blistering and aggravation of the skin by applying shear forces, which in turn increase skin strain. Due to the increasing demand for TKR it seems reasonable to predict that the amount of dressing blisters will increase. Because of this, it has been decided to conduct research into this field and develop a method to find the skin strain at areas of the knee at which a dressing would be affixed.

A 12 camera Vicon system was used to capture the skin displacement over the knee of 10 subjects (mean age 66.8). The skin movement was measured as the subject's flexed their knee from 0-105^0 in 15^0 increments.

The results showed that skin strain around the knee is highly variable in both direction and magnitude, with a maximum mean strain of 50% found longitudinally on the thigh.

Overall, the investigation showed that with a skin strain of up to 50%, knee dressings should have a degree of elasticity high enough to accommodate this strain, otherwise blistering associated with TKR will continue to be a problem area and more patients will suffer as a consequence.

CONTENTS

1. INTRODUCTION

1.1 Background

In the UK last year (2010), the National Joint Registry which collects statistics on all joint replacements performed in England and Wales, registered that 60,000 knee replacements were performed in England and Wales in NHS hospitals alone, with a further 25,000 plus being carried out in private hospitals. The majority of these patients were over 65 years of age and over half were female [1]. The main reason for these patients requiring a knee replacement is due to osteoarthritis [56]. With an increasing age and weight of the population, it seems reasonable to predict that in the future, cases for knee replacement surgery will steadily increase along with the need for driving down costs and increasing efficiency of the overall TKR process.

There are many post-operative problems associated with the wound created from Total Knee Replacement (TKR) and in particular due to the dressing. The dressing problems include maceration, folliculitis and allergic reactions, but a major problem is that of skin blistering due to the adhesive part of the dressing. This adhesive section of the dressing encourages shear forces to act on the skin during knee flexion, causing skin layer separation and blistering [24].

The skin strain around the knee area has been found to be between 30% and 70% with most of the strain occurring about 9 cm below the patella [42, 54]. This was however carried out on a young subject and at one angle of flexion (90^0) while squatting which will have placed a load on the skin not present during unloaded flexion. The properties of skin change with increasing age which results in an older person experiencing a far greater strain for the same applied stress [47].

The studies mentioned above are two of only three published studies found which investigate the skin strain in the knee/leg region. There is a large gap in the literature in this subject area which must be bridged if the knowledge of knee skin strain and associated blistering is to be advanced.

1.2 Objectives

The objectives of this MSc project are to: successfully derive and implement a method of measuring the amount of skin displacement around the knee for a variety of knee flexion angles; analyse and interpret the gathered data to calculate and quantify the strain due to the skins displacement; present and discuss the results so that a suitable conclusion can be formed on the method that was used and on the implications of the findings.

2. LITERATURE REVIEW

2.1 The Knee

The knee joint is the largest joint in the body, consisting of 4 bones and an extensive network of ligaments and muscles. The four main bones that comprise the knee are: The femur (thigh bone); the tibia (shin bone); fibula (outer shin bone); patella (kneecap). The distal end of the femur, posterior side of the patella and proximal end of tibia are covered in articular cartilage. This is an extremely hard and smooth substance and is specifically situated in these areas to decrease the frictional forces acting as the bones contact one another during movement. At the distal end of the femur is an indentation known as the intercondylar groove where the patella inserts. The proximal end of the fibula is attached to the proximal outer surface of the tibia and travels down to the ankle joint. Figures 2.1 and 2.2 below show the anatomy of the knee.

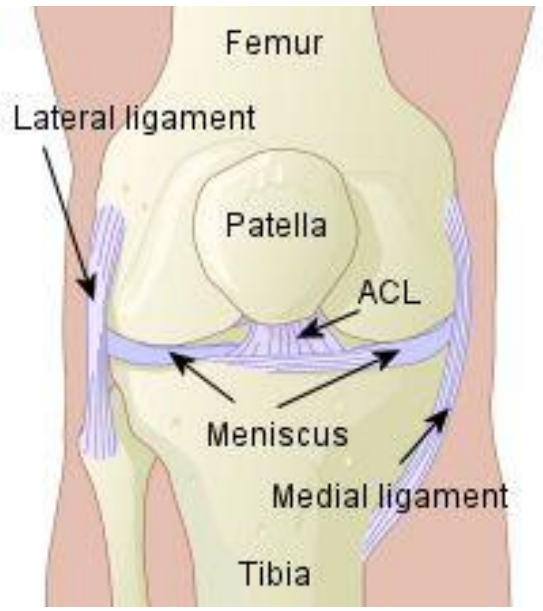

Figure 2.1 – Knee Joint Anatomy [2]

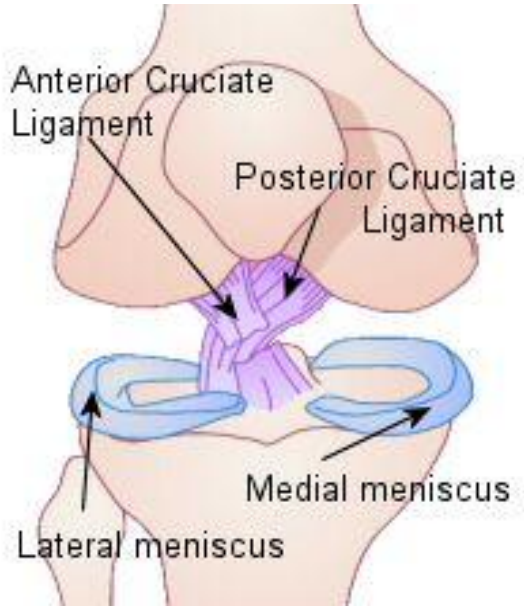

Figure 2.2 – ACL and Meniscus [2]

The entire knee is surrounded by a joint capsule and membrane (synovium) which is a thick ligament like tissue strengthened by the surrounding knee ligaments. The synovial membrane inside the capsule provides nourishment to all the structures within the knee. These structures include the infrapatellar fat pad and bursa which are effective cushions against exterior forces to the knee.

As can be seen from figures 2.1 and 2.2, four ligaments control the stability of the knee in various positions: The Medial Collateral Ligament (MCL) resists valgus forces acting on the knee; the later collateral ligament (LCL) resists varus forces; the anterior and posterior cruciate ligaments (ACL and PCL respectively) both wrap around each other forming a cross and resist torsional force acting on the knee.

The two major muscle groups interacting with the knee are the quadriceps and hamstrings and both play vital roles in moving and stabilizing the knee joint. The four individual muscles of the quadriceps join together to from the quadriceps tendon. This tendon connects the muscle to the patella which is then connected to the tibia via the patella tendon. Contraction of the quadriceps pulls the patella proximally and extends the knee. The hamstrings flex the knee joint and provide medial and lateral support.

The knee has Miniscal cartilage known as Minisci which is crescent-shaped and lies on the medial and lateral edges of the proximal tibial surface (Figure 2.2). They are essential components that absorb shock on the knee and help in correctly distributing the weight between tibia and femur. As well as the Minisci, the meeting ends of the femur and tibia are coated with cartilage which allows the bones to traverse each other almost friction free.

2.2 Osteoarthritis

Osteoarthritis or degenerative joint disease is a disease that affects body joints and is the most common type of arthritis affecting 8.5 million people in the UK alone [3]. The disease is more common in women, mostly affects people aged over 40 and is a major cause of disability and reduction in quality of life [3].

When a joint develops osteoarthritis, the surface of the joint becomes damaged which increases the frictional effects acting at the joint. The cartilage covering each end of the bone gradually roughens and thins. This happens over the main surface of the knee joint or in the cartilage beneath the patella. The bone beneath this thinned cartilage reacts by growing thicker and creating outgrowths (osteophytes). The synovium and capsule around the joint becomes inflamed and all the tissues within the joint thicken in response to repair the damage [4]. Figure 2.3 shows a healthy knee (left) and osteoarthritic knee (right).

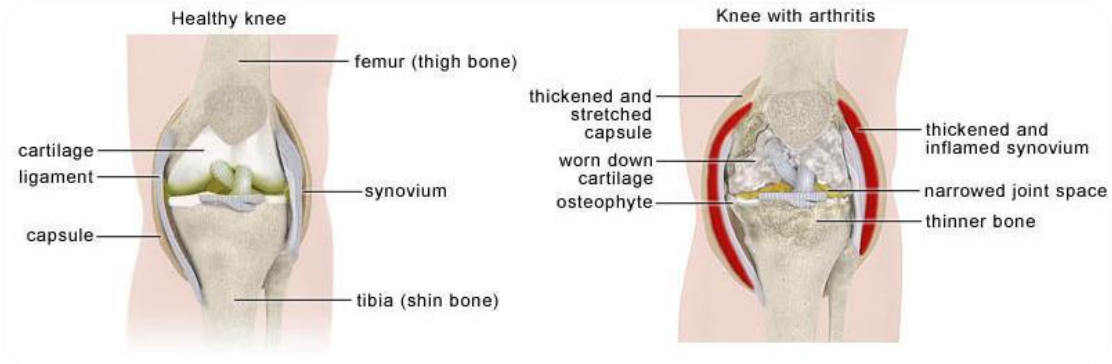

Figure 2.3 – Healthy and Osteoarthritic Knee Comparison [3]

Osteoarthritis is an incurable disease and can lead to severe pain, especially in the hip and knees. Apart from being over 40 and female, there is a greater risk of acquiring the disease if the person is overweight or obese, their ascendants have had the disease and/or the person has had a previous joint injury or operation. These risk factors, coupled with the increasing average weight and age of the population, mean that more people are being given a total knee replacement as treatment for osteoarthritis [3].

2.3 Total Knee Replacement (TKR)

TKR or knee arthroplasty is a surgical procedure carried out to resurface knee joints severely affected by arthritis. Although many types of arthritis can affect the knee such as rheumatoid or traumatic arthritis, osteoarthritis is the most common disease which leads to TKR [6]. The primary design goal for a TKR, as for any total joint replacement, is to restore joint function and reduce pain for the lifetime of the patient [5, 7]. TKR is only carried out as a last resort if the patient's symptoms can no longer be controlled with non-operative treatments.

Knee replacement is a major operation and has all the risks and complications which go with such types of invasive surgery. The need for a knee replacement may arise due to one of the following difficulties:

- The patient has severe knee pain which interferes with the quality of his/her life.
- The knee pain interferes with sleep.
- Physiotherapy and/or medication has been ineffective or worse, has caused side effects.
- The patient has had increased difficulty with everyday tasks.
- The pain and mobility loss is leading the patient to depression.
- The patient is unable to go to work or interact socially due to knee problems.

Other than the above difficulties, the TKR procedure has major risks such as: bleeding; blood clots in the legs and infection. The replacement joint may become loose, dislodges or may not work in the way it was intended [5]. If this is the case, further revision surgery will be required to replace the implant and is not as successful as the initial procedure. Nerves and blood vessels may be injured in the operation as it is quite a vigorous procedure and this may result in weakness numbness or both [5].

When a TKR is performed, the bone and cartilage on the end of the femur and top of the tibia are removed to make way for the implant and remove the damaged bone. This is performed using specialised instruments to create surfaces that accommodate the implant seamlessly and effectively, so that the implant can function as the new knee joint. An implant can consist of metal, plastic or ceramic parts depending on factors such as: cost; bone condition; patient condition; patient/surgeon preference etc. If the damage to the cartilage underneath the patella is severe then the patella surface may also be replaced.

In the 1960's and 70's, knee implants were only expected to last between 10 and 20 years but due to advances in material technology, surgical techniques and implant design, implants can last far beyond 20 years [9]. The longevity of an implant is influenced by patient lifestyle and weight and surgeon skill amongst other factors. The primary goal of a TKR implant is to last for the lifetime of the patient.

2.3.1 Methods of TKR

The main purpose of any method used in TKR is to resurface the parts of the knee joint that have been damaged by the disease. The surgical methods to do this have varied since the introduction of condylar (the modern standard of TKR) knee replacements in 1970s [7]. Approaches to surgery vary and include but are not limited to midvastus, subvastus, lateral and medial parapatellar arthrotomy. The most common is the medial parapatellar arthrotomy [8] which involves making an incision of between 20 – 30 cm down the front of the leg from lower thigh to upper shin as shown in figures 2.4 and 2.5.

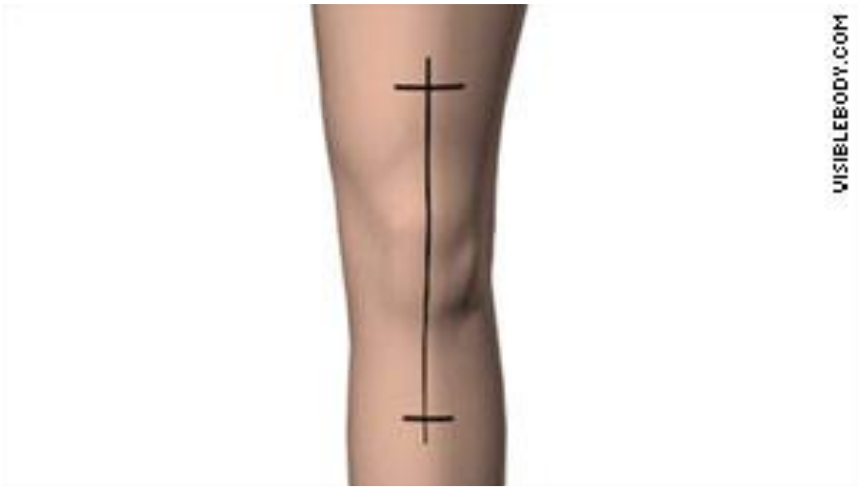

Figure 2.4 – Total Knee Replacement Incision [9]

The results of knee replacement using this type of incision have been excellent however the recuperation from knee replacement has been tedious and painful with the rehabilitation of leg movement post-operation being a daunting task for patients [8]. This has led to other methods being developed such as minimally invasive techniques using a mini-midvastus incision which would allow TKR to be practiced while minimizing surrounding soft tissue damage [7]. Surgery of this nature allows a smaller incision to be made which does not extensively disrupt the quadriceps muscles and suprapattela pouch. It still allows adequate exposure to allow the implant to be positioned and for ligament balancing and overall results in less pain and faster recuperation after surgery and possibly less blood loss [7].

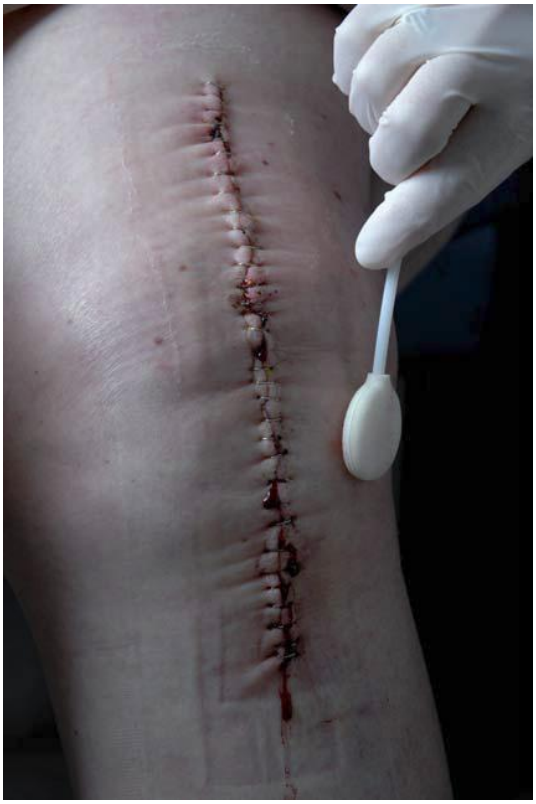

Figure 2.5 – TKA Stapled Wound [29]

2.3.2 Types of Implant

"The primary motion of the knee joint is flexion and extension in the sagittal plane" [10], so in order to restore function, prosthetic implants must be designed to provide this primary function and must be able to transmit normal functional loads. The motions and forces cannot be considered independently of one another. If the motion of the joint is altered in any way, such as by loss of function in any of the four knee ligaments (chapter 2.1), this will modify the forces transmitted and distributed by the joint and various structures of the knee respectively [7].

The kneecap movement against the new femoral component is an important design issue. Knee implants are designed with a groove for the kneecap to follow as the knee flexes and extends. This groove is important as its design has an impact on how mobile the knee is and a small impact on how comfortable the implant is for the patient [11].

The mechanism as a whole performs optimally when the components are sized according to the patient's frame [11]. To cater for this, implant manufacturers offer a range of sizes which the surgeon will choose from in order for the implant to best fit the patient's needs. An ill fitting implant can lead to soft tissue irritation and instability [11]

Implant components consist of a:

- Femoral Component – Made of metal (titanium or cobalt/chromium alloy) and curves up around the end of the femur. Has a central groove which allows the patella to move up and down smoothly as the knee flexes and extends.
- Tibial component – A flat metal (Titanium or cobalt/chromium alloy) platform with a polyurethane insert which has a double dish configuration for the femoral condyles and also either a notch to accommodate the cruciate ligaments (cruciate sparing), or a cam structure to replace them (Cruciate sacrificing) [11].
- Patella Component – A button or dome shaped piece of ultra-high molecular weight polyethylene which replicates the knee caps surface [11].

The types of implant vary and can be: fixed bearing; mobile bearing; PCL retaining or substituting, with implant parts being customizable to fit particular patients [11].

- Fixed Bearing – The most common TKR implant in use today (figure 2.6). The components for the femur and patella are as described above but the polyethylene cushion of the tibial component is fixed to the metal platform base [11].
- Mobile Bearings – The difference between a fixed-bearing implant and a mobile-bearing or medial-pivot implant is in the bearing surface. The polyethylene insert in a medial-pivot implant can rotate slightly around a conical post which imitates that of a natural knee joint. Medial-pivot implants are not without their drawbacks though. Compared with fixed-bearing, they are less forgiving of imbalance in soft tissue and may cost more.

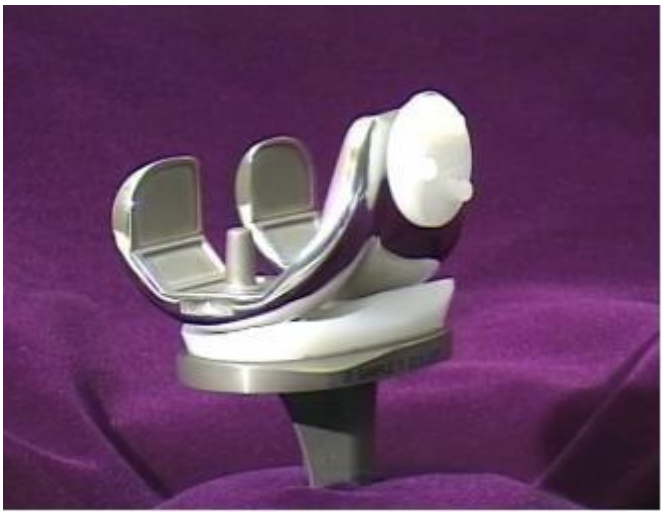

Figure 2.6 – Fixed Bearing Implant by DJO Surgical [11]

2.3.3 Post-operation

After the TKR, the patient will usually stay in the hospital for three to seven days after the surgery has been completed. A hospital will not usually discharge a patient who has had TKR surgery unless they can walk with the aid of crutches. The knee rehabilitation therapy begins as soon as possible after surgery completion and can go on for several months after the patient's discharge. The knee rehabilitation stage is paramount if a good recovery is to take place [12] and all rehab requires mobilisation of the joint while dressings are applied.

The rehabilitation process below is only an example of what a patient would go through post-op to rehabilitate their leg musculature and ROM. Times may vary for various reasons and is possible for the patient to be up and walking on the day of the operation [57].

1-2 weeks prior to the operation, the patient's home will be assessed and a post-operative exercise programme designed specifically for that patient. Day one after the operation, the patient will be taken through bedside exercises, e.g. ankle pumps and quadriceps sets. Also, the patient's weight bearing status will be reviewed and they will be trained to transfer between the bed and a chair [46].

At day two the patient will be given: Range of Motion (ROM) and terminal knee extension exercises; strengthening exercises of a more advanced form to that of day one; assisted gait training and functional transfer training (sit to stand from a toilet seat) [46].

Post operative days 3-5 or on discharge to a rehab unit, the patient will be given increased intensity ROM and strengthening exercises. They will also progress to walking on level surfaces and stairs [46].

On day 5 to 4 weeks, the patient will be given more advanced strengthening exercises such as seated leg extensions and standing hip abduction/adduction. Patients will stretch the quadriceps and hamstrings and increase their ambulation distance and increase their ability to perform everyday tasks [46].

TKR needs the patient to fully participate in this process of rehabilitation. The surgery is only the beginning of the work that needs to be done. Exercising the main muscle groups around the knee is very important both before and especially after surgery as the operating procedure will likely involve making an incision through the muscle.

Exercise routines are administered by physiotherapists in the hospital post-op and last for around 10 minutes, 6-8 times per day [13].

Exercises can range from inner range quad exercises (which involve lifting the leg in a fully extended position) to seated knee bends (which involve holding the knee in a flexed position for three seconds, extending and repeating) [13]. The level of mobility of the knee varies from patient to patient however it is expected that a patient should be able to flex their knee to 90^0 after their surgery and eventually be able to reach 110^0 of flexion in the fully healed knee [12]. It may be the extensive movement of the knee during rehabilitation that causes problems in blistering on the skin at the adhesive section of the dressing.

2.4 TKR Dressings

After TKR surgery, the wound is covered with a dressing in order to absorb excess fluids and protect the wound from bacteria. The wound dressing is changed after the drainage tube (which is sometimes installed during surgery to drain fluid build-up) is removed and is regularly changed for two weeks after the operation. A nurse will initially change the dressing but once the patient leaves the hospital it is up to the patient to change the dressing as guided by the doctor. A compression stocking is often but not always used after the surgery and attached to a device that circulates air into the stocking to massage the legs in order to reduce the likely hood of the formation of blood clots. These stockings are usually worn for two to three days post-operation [14].

Wound dressings can be divided into two types, passive and interactive dressings. Passive dressings consist of an absorbent tape-fixated wound pad and have traditionally been used for hip replacement wounds [36]. Interactive dressings interact with the wound surface and have the ability to maintain an appropriate moisture level on and around the wound [36]. One example of an interactive dressing is Hydrofibre™ by Aquacel discussed below.

Dressings currently used in orthopaedic practice include: adhesive; occlusive/vapour permeable; gauze and tape; hydro fibre [15].

Adhesive dressings

This dressing type has a high likelihood of causing blistering and this is thought to occur due to it being usually applied under tension [15]. A trial [16] investigated the effect of applying the dressing "tension-free" as advised by manufacturers. The investigation was a two-phase trial, the first of which involved pre-stretching the dressing before application and the second of which involved applying the dressing un-stretched. The findings suggested that there was no difference in skin blistering rates whether the dressing was pre-stretched or not. Another study [17] compared dressings held with either a perforated cloth tape or a non-stretchable silk tape.

The study found, by applying the dressings to avoid skin tension, that risk of skin blistering was 41% with the non-stretchable silk tape and 10% with the perforated cloth tape. This suggests that dressing material is very important if blistering is to be reduced.

Occlusive Dressings

This dressing type produces a moist and fairly hypoxic environment under the dressing [15]. Accelerated angiogenesis occurs due to the hypoxia and increases the speed at which the wound heals [18]. Occlusive dressings can contain small amounts of exudate without it leaking from the sides of the dressing. Studies [18, 19] have shown that, although there was no material to absorb this exudate, no problems occurred due to the softening of the skin. It actually resulted in less inflammation of the wound and no increase in infection rates. Patients exhibited less pain during dressing changes, the dressings were more comfortable and the fact that they are water-impermeable, allowed the patients to wash.

Hydrofibre Dressings

Hydrofibre dressings use a process known as vertical wicking to absorb fluid directly into the dressing body which increases the volume of fluid which can be absorbed. Any excess exudate is removed in the process and lateral wicking, a process that causes maceration of the wound edges, is prevented but the moist wound environment is still maintained. Hydrofibre dressings must be covered by another dressing made from either polyurethane film or hydrocolloid plate [20].

Hydrofibre dressings have a longer wear time than the more traditional adhesive dressings which also means that the number of dressing changes are reduced [21, 22]. However, Hydrofibre dressings are more expensive than their adhesive counterparts but this may be counterbalanced by the dressing change frequency.

2.4.1 Dressing Problems

Dressings associated with orthopaedic surgery give rise to a number of problems discussed below. All information was taken from the American Journal of Nursing [23].

Skin Stripping: This is a superficial injury which is caused by the removal of the tape adhesive and/or repeated applications of the tape to the same site. It involves the epidermis being stripped away.

Chemical Injury: This is caused by prolonged skin contact with irritating chemicals. This can occur when a chemical is trapped between the skin and the adhesive.

Tension Blisters: These can develop at the ends of the taped surface when the tape is pulled too tightly over the skin. Tape is often applied under tension to achieve compression of the wound after surgical procedures.

Maceration: Also known as “skin pruning”, maceration is caused when the skin is excessively hydrated by prolonged direct contact with moisture. This can lead to breaks in the skin due to a reduction in the elastic and strength properties of the skin.

Non-tension Mechanical Injury: This can be caused as the tape is applied/removed incorrectly or by using a tape adhesive that is too strong for the type or location of skin to be covered.

Folliculitis: The condition can lead to development of pustules and inflammation and is caused by irritation and inflammation of the hair follicles. Can arise if the skin was shaved by a razor for the operation or if chemicals, adhesive or bacteria become trapped in the hair shafts.

Allergic reactions: The least common of all taping problems and are caused by skin sensitization to a particular adhesive component. Longer exposure to the allergen gives rise to a more severe reaction.

The main problems with surgical wounds following hip and knee surgery are blistering and infection [15], with tape blisters being the main focus of this section.

"A blister is a fluid-filled swelling occurring within or just under the skin. A blister usually forms due to damage to the outer layer of the skin. Blisters can be caused by injuries such as heat, friction, the use of certain dressings, fracture and some medical conditions" [26].

A tape blister is an abrasion of the skin which occurs under the taped portion of surgical dressings and can lead to patient morbidity post-operation [24]. Figure 2.7 below shows an example of tape blistering. Notice that the blisters have formed on the skin at the site of tape adhesion. These blisters are caused by the separation of the epidermis from the dermis at the dermal-epidermal junction [25]. Studies suggest that the creation of shear forces at the dermal-epidermal junction, as well as a decreased blood supply to the dermis, is a major factor in the development of post-operative blistering [24, 26]. These points are better understood in section 2.5 where the skin is discussed in greater detail.

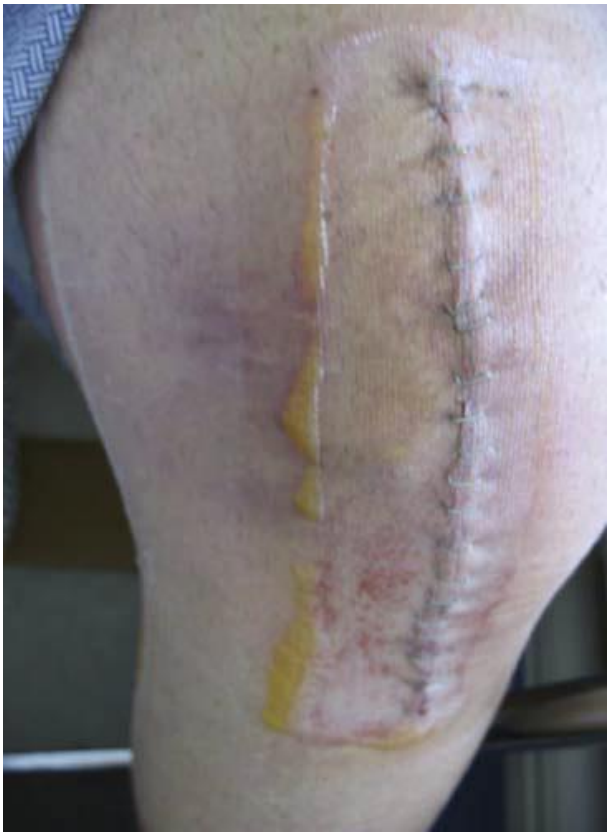

Figure 2.7 – Tape blistering [27]

A major cause of skin blister formation is tape which is resistant to stretching, largely due to the forces applied to the skin at and by the ends of the tape [24]. One study in particular recorded the occurrence of blisters using Mepore™ (Mölnlycke) on 11 patients recovering from hip replacement surgery [31]. Only one patient did not exhibit signs of erythema or blistering and it was suggested that this was because the tape used to secure the dressing was inelastic and caused friction when the patient moved. The same dressing was then applied to 12 different patients on the ward but using a different, more elastic tape. No complications occurred using this tape.

Another study by Gupta et al [16] compared the occurrence of blistering following the use of three different dressing types (Mepore™, Microdon™ and a spirit-soaked gauze attached with Mefix™). The dressings were attached to 100 patients who had undergone total hip or knee replacement. The study's results showed that the blistering rates were higher with Microdon™ and Mepore™ and no blistering occurred with Mefix™.

The researchers claimed that the reason this was the case was because the fibres of Mefix™ stretched in the same direction as the skin on the joint and the spirit acted as an antiseptic. These claims require further research to back them up. The study is however of interest and it provides a good basis for this thesis.

In order to reduce the risk of blistering, great care must be taken when selecting an appropriate post-operative dressing. Many studies have shown that tape related blistering injuries range from 2% to 24% in patients, which suggests that a specific choice of dressing and tape combination can greatly reduce the chances of blistering [16-19, 21, 22, 29].

Although skin blistering due to the dressing tape is a commonly reported problem, especially in orthopaedic surgery [26], it has rarely been reported in the literature [24]. This blistering can cause increased pain, delayed healing and increased patient morbidity as the skins integrity has been broken [16]. Orthopaedic nurses need to check the wound regularly for blistering and take care when handling the limb to avoid the blisters bursting and aggravating the skin further. If the blisters burst then this will allow bacterial entry to the wound and the consequences of infection following knee arthroplasty are very serious with Infections leading to increased length of hospital stay [28]. At the very least, blisters are unsightly and very sore for the patient who is recovering from the operation.

The blistering rate and amount of wound exudate can be reduced if a dressing is used that contains a clear film with a high moisture vapour rate (MVTR) and an absorbent pad. Dressings with these properties also improve patient satisfaction and can be worn in the bath/shower as they are waterproof [16, 32, 28].

Among other studies, Hahn et al. [33] examined the need for an alternative to traditional taping methods which has shown to be a fundamental reason for increased oedema and soft tissue damage that occurs post-op. The study carried out was a retrospective, descriptive, comparative study and involved 457 hip surgery patients who had a combined total of 499 operations over 10 years. The first 70 operations involved applying a roll Spica dressing (similar to a cotton stockinette) and securing it with tape (applied to the dressing only, not the skin).

The next 340 operations saw a single-piece compressive Spica wrap being used, which has a four-way cotton lycra™ stretch to conform to the patient's contours. This wrap also negates the need for tape.

The study also involved a control group who had undergone 89 operations of similar types to that of the wrap group and who had their dressings taped to their skin. From the study, four patients (1%) in the wrap group developed blisters compared with 13 (15%) in the control group. This study gives another example of how an elasticised dressing can help to reduce blistering.

The studies referred to previously have shown that tape dressings have quite a high likely hood of causing blisters to form under the adhesive portion of the dressing. With this in mind, it would seem obvious for it to be common practice to apply an alternative type of dressing in the theatre and post-operation, but this however is not the case. Cutiplast™ by Smith and Nephew (an absorbent perforated dressing with an adhesive border) is the dressing normally used for orthopaedic procedures in the NHS [15]. Traditional dressings such as Cutiplast™ and Mepore™ (also used for orthopaedic surgery) have given rise to complications such as blistering and infection but are still used because they are initially cost effective and successful [34]. The wounds generally heal without problems, infection is kept to a minimum and if tissue is handled gently then the wound can heal quickly with minimal scarring.

However, blistering is still a recurring problem at the adhesive portion of the dressings but, as it rarely increases the length of the patients stay in hospital, this has been largely ignored [34].

One study [15] compared Cutiplast™ with Aquacel™ covered with Tegaderm™ to give a water proof seal (Aquacel™ is a hydrofibre dressing by ConvaTec and Tegaderm™ is a vapour permeable dressing by 3M). 183 out of 200 patients who underwent elective and non-elective hip and knee surgery, were administered randomly with one of the two dressings. The patients were studied to monitor the condition of the wound and any skin complications that occurred, including blistering.

Table 2.1 gives an indication of the relationship between the wound dressing and the outcome. It suggests that if Cutiplast™ is used then it is 5.8 times more likely to result in wound complications. In terms of blistering, the study found that 22.5% of the patients with Cutiplast™ dressings had blistering whereas only 2.4% of the Aquacel™/Tegaderm™ group had blister occurrences.

Table 2.1 – Wound Dressing and Outcome [15]

	Cutiplast	Aquacel/Tegaderm	Totals
Dressing Failed	53	15	68
Wound Healed	45	70	115
Totals	98	85	183

Another study [35] performed at a unit in the Royal National Orthopaedic Hospital, compared the same Aquacel hydrofibre dressing (but without Tegaderm) discussed above with a central pad dressing by Mepore. The hydrofibre dressing is a hydrocolloid wound dressing which converts to a soft gel when in contact with wound exudate and can be folded into several layers on application. The Mepore dressing consists of an absorbent pad affixed centrally on a non-woven polyester coated fabric, coated with a layer of acrylic adhesive. 30 patients were allocated to the hydrofibre group with another 31 patients allocated to the central pad Mepore group.

The results of the study found the following:

- 43% of the patients in the hydrofibre group required a dressing change before 5 post-operative days whereas 77% of patients in the central pad group required a new dressing.
- 13% of the patients in the hydrofibre group developed blisters around the wound compared with 26% in the central pad group.
- The average hospital stay was increased by one day if the patient developed blistering.

A further study by Cosker et al [32] compared the effect of three post-operative dressings on wound healing. The prospective study involved 300 patients undergoing hip and knee surgery either as trauma or elective cases. The dressings used in the test were: Primapore and Tegaderm (used with an absorbent central pad) as discussed previously and also another dressing by Smith and Nephew called Opsite Post-Op. The latter dressing is a film dressing with low adherence, is waterproof and transparent and has the capacity to rapidly absorb serous exudates. It also has a high moisture vapour transmission rate (MVTR) which means that it can transfer moisture vapour at high rate whilst still maintaining a complete barrier against water and bacteria.

When the dressing required changing, the number of days since the operation was recorded along with the reason for change. Also recorded was information such as skin problems present including blistering and persistent exudate. All dressings were applied and removed according to manufacturer guidelines.

The study found that blistering occurred on the 5th or 6th day post-operation, with no significant difference in the amount of dressing changes between dressings for the 10 day average hospital stay. The study also found that persistent discharge required dressings to be changed more frequently, thus increasing costs and leading to a higher likely hood of wound infection due to frequent exposure. The results of the post-operative blister rate and additional problems are shown below.

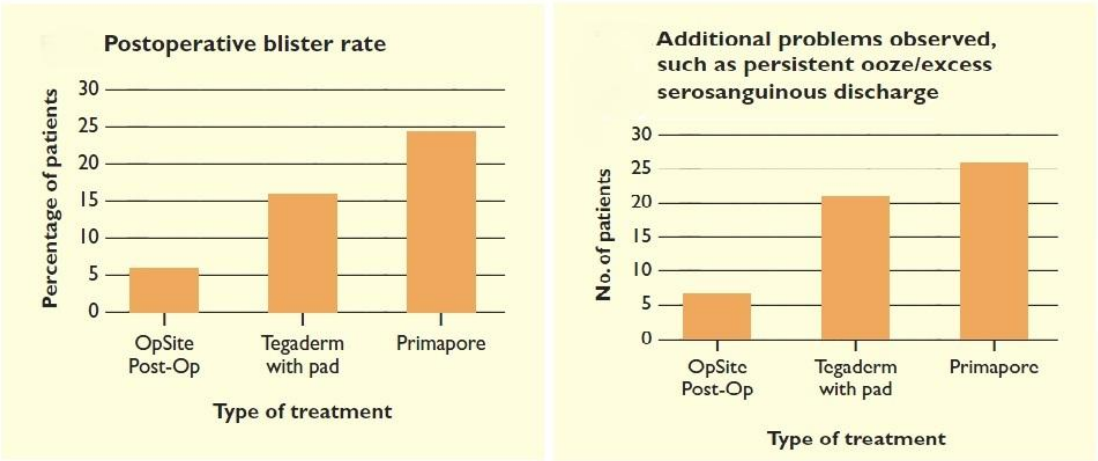

Figure 2.8 – Results of Three Dressing Study [32]

As can be seen from the results, the Opsite Post-Op dressing outperformed the two other dressings considerably in both areas. The Opsite dressing may have performed better due to its high MVTR (see above) which works out to be nearly 5 times that of Tegaderm and nearly 2.5 times more than Primapore. This allows the Post-Op dressing to have an effective vapour transmission which prevents the accumulation of fluid at the skins surface which in turn reduces the potential for maceration. Also, fluid handling capacity is increased due to the increase in transpiration as fluid is absorbed into the dressing.

Cosker and his associates also stated that another reason for the low blister rates in the Opsite dressing could be due to the fact that it is more elastic than the other two dressings.

"The lack of elasticity coupled with the post-operative wound oedema, has shown to be a contributing factor in wound blistering. This is the result of greater shear forces being applied at the epidermis/dermis interface." [32]

2.4.2 Ideal Dressing Specification

This section will discuss the properties a dressing should have in order to be ideal and fit for purpose. Dressings which have one or more of these properties missing may cause problems in the patient rehabilitation process and increase costs. The following criteria for a surgical wound dressing was modelled on information taken from Volume 15 of the nursing standard and the article by L Watret and R White [37]. These criteria cannot be fulfilled by any current individual dressing but can be achieved if combinations of dressings are used.

Conformability: If a dressing is not conformable, patient comfort and mobility will be hindered severely whether the wound is open or closed. Patient mobility is essential for orthopaedic rehabilitation as during the operation, surrounding musculature is damaged and recuperation of this lost muscle is gained post-operation.

Cohesive: Some fibrous dressings have a tendency to fall apart when soaked with exudate. This lack of cohesive strength makes it difficult and time consuming to apply to and remove the dressings from the wound. A dressing such as Hydrofibre, with a high cohesive strength when wet and dry would prevent this problem.

Non-adherent and non-toxic: Dressing adherence to the wound is a problem as it causes the patient pain and discomfort. Dressing adherence can be prevented if a good dressing selection is made and if the correct nursing and surgical approaches have been carried out. Toxicity is no longer an issue due to the regulations in dressing production and that dressings have to be non-toxic in order to gain a CE mark.

Moist environment: The theory that a moist wound environment promotes wound healing is well known and was first discovered by Hippocrates [15]. Moist wound dressings are on the most part, easier to remove from the wound and also cause fewer problems on removal than traditional dressings.

Easy to use: It is essential that a dressing application runs smoothly and that the whole process is easy to carry out. A dressing that is easy to use promotes good wound management as they rarely adhere to the wound, do not disintegrate (which would mean removal of the particles) and is less time consuming to apply and remove which lowers costs. A dressing that is easier to use is also desirable as it allows the patient to apply and remove the dressing themselves at their homes. This negates the need for carers to visit homes solely for this purpose.

Permit Bathing: Occlusive secondary dressings such as adhesive foams, films or hydrocolloids protect the wound from contamination and also allow the patient to wash. This is useful as it may allow a patient to wash themselves when they previously had to have a carer do so.

Absorbent: During early healing periods, surgical wounds produce a lot of exudate which needs to be absorbed by the dressings in order to prevent maceration. Primary dressings usually do not absorb enough exudate to be relied upon so have to be used with secondary dressings. More recently developed dressings however absorb and retain exudates while still maintaining a moist wound environment and preventing maceration.

Avoid cross-infection: Most dressings nowadays have properties which help form a barrier against viruses and bacteria. Some dressings reduce the dispersal of contaminating organisms into the air when they are removed, whereas other dressings absorb bacteria into their physical structure, reducing the chances of transferring infections.

Availability: The availability of certain dressings has increased in hospitals and on the drug tariff. This means desirable dressings are more readily available and is due partly to increasing clinical evidence recommending the dressings. The availability of a dressing should be considered in the wound management process of individual patients.

Cost-effectiveness: Due to the current climate and the financial constraints on the health services, the cost-effectiveness of dressing is very important. Data has been collated from many studies which have focussed on costs and economics. This data was derived from measurements taken from healing rates, wear times and time taken form nurses to change dressings [38]. It was seen in many of the studies [15, 16-19, 24, 26, 26, 33-35] previously looked at in chapter 2.2.1 that dressing choice has a major impact on post-operative costs. The right choice of dressing can reduce: bed occupancy times; nursing/carer requirements; patient discomfort; dressing change frequency.

2.5 Skin

The skin, also known as the cutaneous membrane is the largest organ in the human body and accounts for around 16% of the body's total weight. It is continually bombarded by micro-organisms, irradiated by sunlight and exposed to chemicals as well as being constantly worn away when it comes into contact with a surface. The skin is the body's first line of defence against any possible external intruders. This sub-chapter is written with the aid of Fundamentals of Anatomy and Physiology by Martini & Nath [39] and will cover the basics of the skin and the relationship between orthopaedic dressings and the occurrence of blistering associated with them.

The skin consists of three layers - the epidermis (the superficial epithelium which forms the skins surface), dermis (the area underlying the epidermis which is made up of connective tissue) and hypodermis (the layer beneath the dermis) - The combined function of these three layers is to:

- Protect the underlying tissues
- Excrete salts, water and organic waste
- Maintain body temperature
- Produce melanin to protect the underlying tissues from ultraviolet radiation
- Produce keratin to help protect against abrasion. Also provides water proofing.
- Synthesise vitamin D_3 which helps maintain the calcium metabolism
- Store lipids in the dermis and the hypodermis
- Detect touch, pressure, pain and temperature stimuli

Figure 2.9 gives a graphical representation of the 3 layers given above.

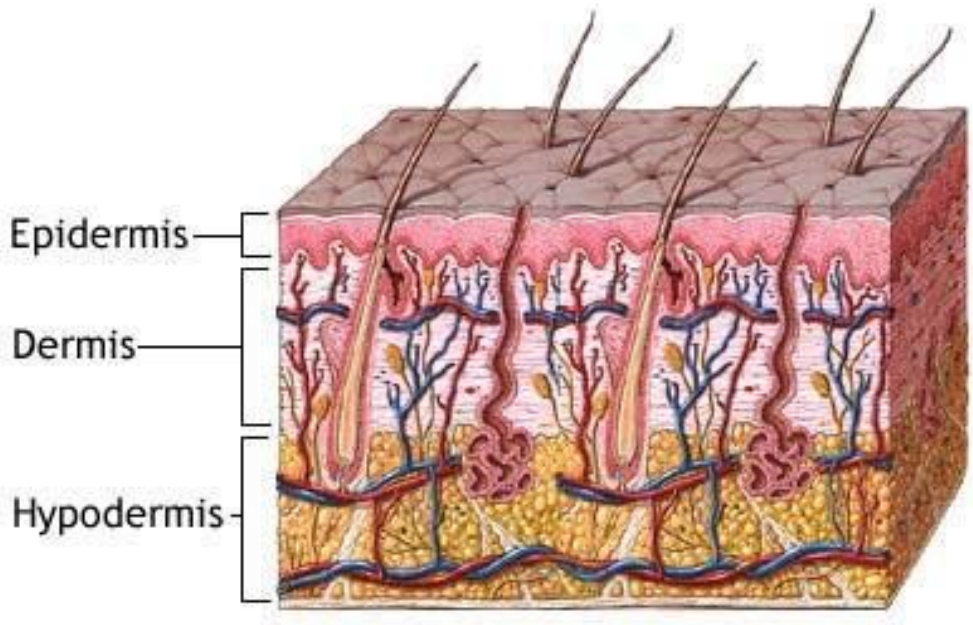

Figure 2.9 – Image Depicting the Skins Layers [40]

The epidermis consists of a stratified squamous epithelium which forms a barrier against micro-organisms. This epithelium is avascular so has no, and needs no blood supply as it is supplied with nutrients and oxygen that is diffused from capillaries within the dermis. This means that the cells closest to the dermal-epidermal junction have more metabolic demands than the external epidermal cells have little or no demands for nutrients as they are either inert or dead. The epidermis can either be thick or thin depending on how many epithelial cells are present and is usually determined by where it is on the body, e.g. the epidermis on the palms of the hands is thick and the epidermis around the knee/leg is thin. The thick epidermal layer has an extra strata/layer to provide more cushioning and protection.

The epidermis is attached to the Dermis by peg like structures (Figure 2.9). These peg like structures are formed by the stratum germinativum, the innermost epidermal layer. These pegs, called epidermal ridges, attach to the underlying dermal papillae (constructed from the dermis's areolar tissue) and the two are interlocked which increases the strength of the bond between the epidermis and dermis.

Both the interconnecting surfaces of the epidermis and the dermis, like any epithelium, produce a thin complex structure which binds the epidermis to the dermis. This film like structure is known as the basal lamina and coats the surface of the epidermal ridges and dermal papillae. It is when this structure is damaged and connections are broken between the lamina and ridges that blisters begin to form between the epidermal and dermal surface.

The dermis is the tissue layer that supports the more external epidermal layer. The dermis has two major components; the superficial papillary layer and the deeper reticular layer.

The papillary layer consists of the areolar tissue, capillaries, lymphatics and sensory neurones that supply the skins surface. The name papillary comes from the dermal papillae which project between the epidermal ridges.

The reticular layer which is deeper than the papillary layer, consists of a meshwork of dense irregular connective tissue contain both collagen and elastic fibres. The collagen fibres extend from the reticular layer, superficially into the more external papillary layer but are more interwoven when extending into the deeper hypodermis.

The reticular layer also contains networks of blood vessels, lymphatic vessels, nerve fibres and extracellular protein fibres. Due to the abundance of sensory receptors in the skin, in particular the dermis, infection and inflammation such as blistering can be very painful. If blisters burst, then infection can persist and can cause dermatitis which is an inflammation of the skin. This can be painful, itchy and can spread throughout the damaged papillary region.

The dermis, as mentioned above, contains both collagen and elastic fibres. Collagen fibres are easily bent and twisted but are very strong and resist stretching. Elastic fibres permit stretching but then recoil to their original length. The elastic fibres allow the dermis to tolerate stretching to a certain degree, limited only by the collagen fibres which limit the tissues flexibility preventing damage.

One can imagine what would happen if the epidermis was limited in its movement by an external source, say an adhesive portion of a dressing, and the underlying dermis (which was still allowed to move freely). The dermis, as it is physically attached to the underlying tissue and skeletal structure by interwoven fibres, would move with the underlying tissue and the epidermis, as it is connected to the dermis by a weaker bond (the basal lamina), would stay in the same place attached to the adhesive portion of the dressing. As was discussed above in this sub-chapter and in some of the studies researched in chapter 2.2.1, if this basal lamina becomes damaged, blisters will start to form.

2.5.1 Biomechanics of the Skin

Biomechanics is mechanics applied to biology and seeks to understand the mechanics of living systems [41]. For a material like skin, biomechanics helps us to understand its normal function and make assumptions on what will change in the material when alterations occur. The word "mechanics" can be applied to many topics, one of which is stress and strain distribution in materials and for this investigation in particular, we will focus on strain.

Like all biological tissues, skin has very complicated mechanical properties such as: it has a non-linear stress-strain relationship; its properties depend on anatomical location; its stiffness varies with direction; its stress level is a function of both strain and time [42].

In 1861, the fact that skins stiffness varies with direction (anisotropy) was characterised by an Austrian anatomist, Karl Langer, when he identified the directions of maximum in vivo skin tension that are now known as Langer lines [42]. These lines, along with other mechanical properties of skin, are formed from the complex cellular and macromolecular make-up of skin. As discussed above, the dermis is mainly an extracellular matrix made up of mostly collagen and elastin fibres, of which 75% of the skins weight is made up of the collagen fibres, with collagen type 1 being the most prominent [43]. When the skin is in a relaxed state and tension is low, the collagen and elastic fibres are in a wavy state [43].

Figure 2.10 below gives an indication as to the architecture of the dermis and annotates the important materials which determine the skins stress and strain. As well as the elastin and collagen, these include the fibroblasts which lie along the surface of the collagen and also the proteoglycan gel which surrounds the cells and fibres of the dermis. It also shows the direction of the Langer lines in relation to the fibres.

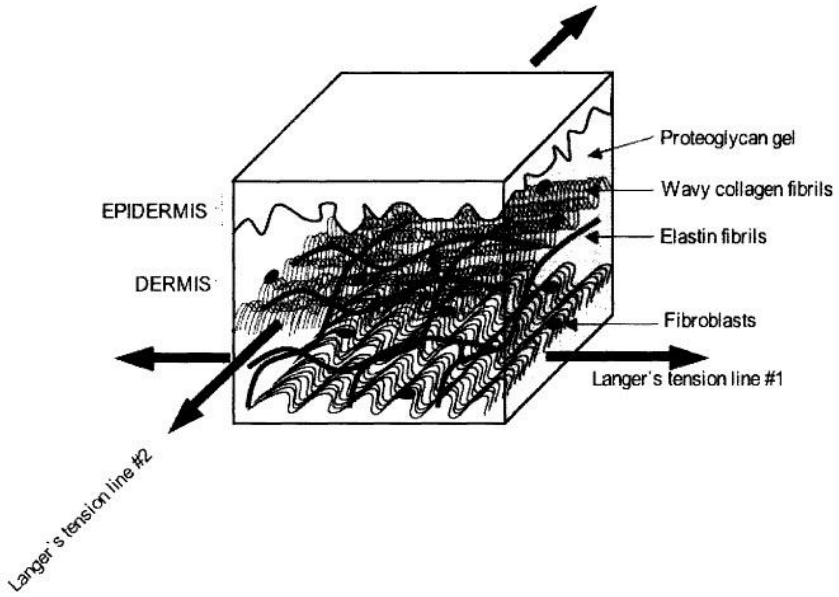

Figure 2.10 – Skin architecture [42]

Forces can either act externally on the skin or internally. Internal stresses in the dermis are transferred to the epidermis via basal keratinocytes (the bottom of the epidermis) and these stresses can either occur from passive tension in the collagen fibrils of the dermis, or can be caused by active cellular tension generated by the fibroblasts attached to the collagen fibrils [42]. External forces on the skin also cause tension between the basal keratinocytes in the epidermis. This causes the dermal – epidermal junction to stretch which results in stretching of elastic collagen fibrils and of the interface between the collagen and fibroblasts.

2.5.2 Strain

Strain relates the stresses acting on a solid, to the deformation which occurs due to the acting stresses [41]. If a length is stretched from an original length to a new length as shown in figure 2.11, this change can be described by a dimensionless ratio.

Figure 2.11 – Beam at Initial and Stretched Length

Strain is a dimensionless ratio and is calculated by using the following strain ratio equation:

$$\varepsilon = \frac{L - L_0}{L_0}$$

Equation 2.1 – Uni-axial Strain

Where: ε = Strain

L = New Length

L_0 = Initial Length

The ratio $\frac{L}{L_0}$ is called the "stretch ratio" and is denoted by the symbol λ.

The skins response to external forces can be described using a stress-strain curve which is initially concave up before becoming linear and then finally, concave down.

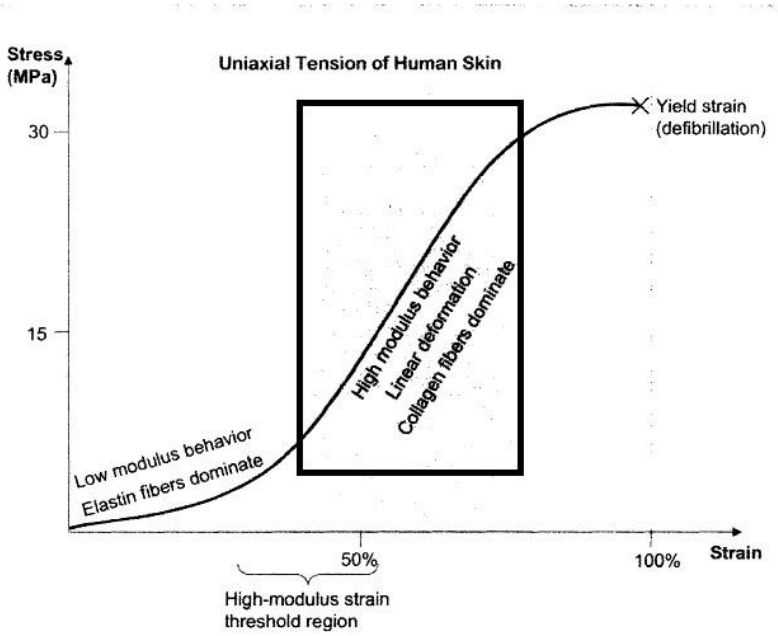

Figure 2.12 – Stress-Strain Curve for Human Skin [42]

Figure 2.12 above shows the approximate stress-strain curve for human skin. The initial low modulus behaviour is due to the deformation of the elastin fibres which bear the brunt of the tensile load while the collagen fibres stay relaxed and wavy. As the strain begins to increase, the collagen fibres resist the deformation and then begin to bear more load than the elastin fibres. This occurs in the linear high modulus region shown in the boxed area of figure 2.12 [42].

Figure 2.13 shows the stress-strain curve for human skin again, however it compares the curve of both young and aged skin. This figure is of some significance for this investigation as subjects over the age of 60 will be used due to people of this age being more likely to undergo TKA. The figure gives an indication as to what the affect may be on the results if a younger clientele was used for the investigation. It tells us that older skin may be initially slacker and thus allowed to be subjected to a lower stress to experience the same strain outcome as younger skin.

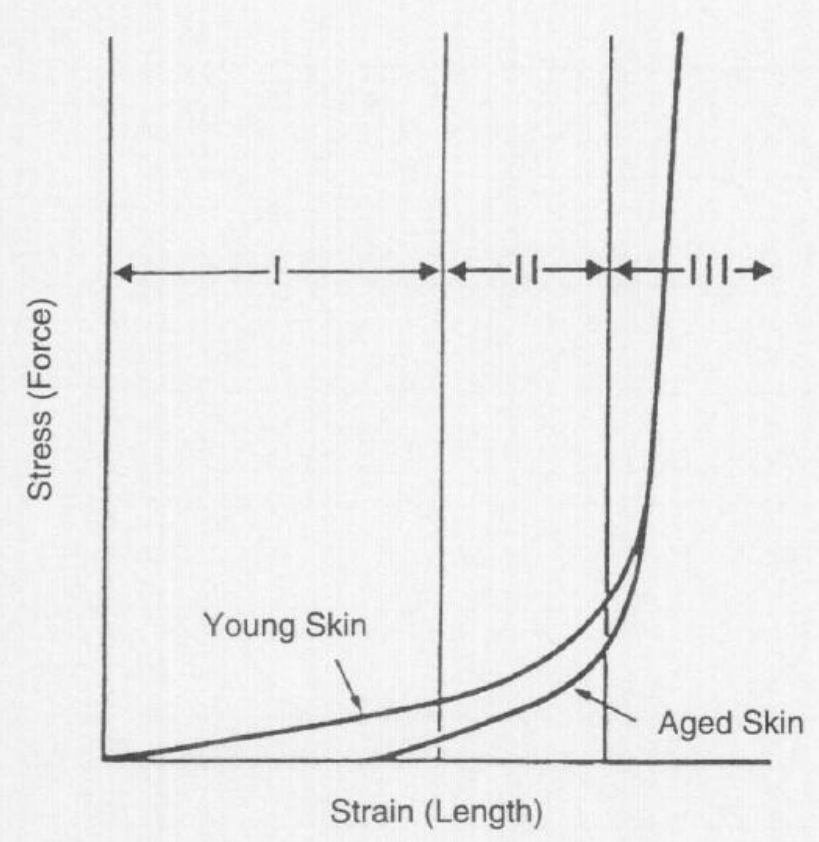

Figure 2.13 – Young Skin vs. Aged Skin [47].

Section 1 – Increasing strain with minimal stress elevation due to elastin fibre stretch.

Section 2 – Increase in stress required to produce further strain due to straightening of collagen fibres.

Section 3 – collagen has aligned and no more "slack" is available. Further strain increase is a result of collagen fibre stretch.

2.5.3 Previous Studies to Analyse Skin Strain

Few studies have been carried out to directly analyse the strain magnitude of the skin around the human knee. Four studies [48-51] have employed a tensile test or optical analysis to ex-vivo animal skin in order to find the Young's modulus, where as other studies [52, 53] have used indentation tests or optical analysis in-vivo, to discover the Young's modulus and skin strain respectively. These latter two techniques were used to look at the skin of the forearm and fingertips so as with the other 4 studies reviewed, don't directly relate to the scope of this thesis.

There are 3 studies [42, 54, 55] however which specifically analyse the skin strain around the knee region in vivo. The study by Bethke, K. [42], involved scanning the leg in 3 dimensions to measure the strain occurring longitudinally and circumferentially as well as the angular strain distortion. She found that the leg was under a low of 30% of longitudinal strain 6cm above the patella and at a high of 70% longitudinal strain 9cm below the patella. The study by Newman D.J. [54] involved placing 156 markers on the skin around the knee area and scanning these markers with a laser scanner and creating a 3D reconstruction. The results were similar to the study by Bethke, K. with longitudinal strain values ranging from 30% - 70% in the same regions of the leg. Both studies however had the subject squat from 0 to 90^0 which subjected the leg and skin to loads which will have influenced the amount of skin strain measured.

The study by Dillon, J.M. et al [55], is of direct relevance to this thesis as it involved analysing the strain on the knee during different angles of flexion as well as quantifying the strain properties of 4 different dressing types for comparison with the skin. This study found that at 90^0 of flexion for 85 patients, the strain had increased by an average of 21.8%. The strain was found by measuring the wound length which may be a limiting factor of the study (and also limits the extent at which this study can be compared to it) as the properties of skin on and around the wound will be different to that of healthy skin as the skin has scarred and been subjected to heavy trauma.

2.6 Research Summary

The studies discussed in this chapter conclude that dressing choice is of the utmost importance if post-operative complications are to be minimised. This dressing choice is also the responsibility of the surgeon as he/she will apply the initial dressing in the operating theatre post-operation. Although the dressings of choice currently used in orthopaedic practices seem to be cost effective and successful, the studies analysed in this investigation have shown that complications readily arise post-operation, with blistering being one such complication. These complications lead to further costs/problems such as increased hospital stays, patient discomfort, increased dressing change frequency and thus, increased costs.

Although some studies have focussed on measuring the skin strain around the knee area, very little has been done to measure the skin strain in the specific region at which TKR is to take place. However, the previous studies in this area may prove useful as they may be used as a guide with a view to validating the results of this investigation.

It is clear that further studies have to be carried out in this area so that professional recommendations can be made to the appropriate bodies. These recommendations may include using information from this thesis to show what areas of dressings need to stretch and to what extent. Because of this, this investigation quantifying the amount of strain occurring on the skin around the knee may be a contributing factor in resolving the issue of post-operative blistering in orthopaedic surgery.

3. Methodology

The investigation method was designed using the process seen in figure 3.1 below.

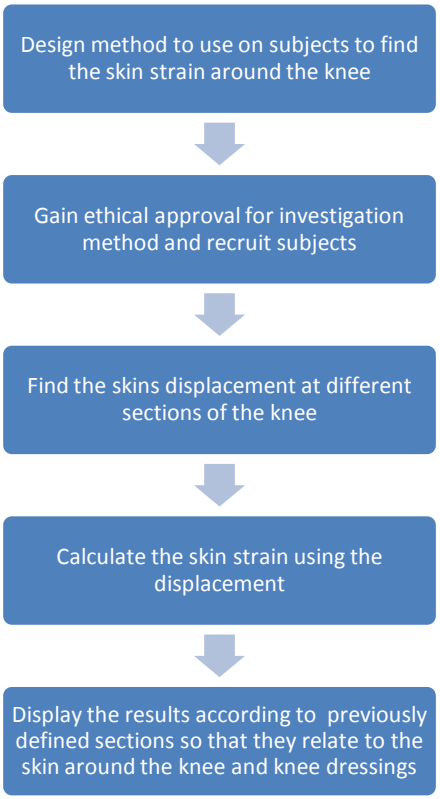

Figure 3.1 – Process Needed to Find and Display Skin Strain

This chapter will discuss the means by which the above process was carried out and how it was implemented in the investigation.

3.1 Equipment

3.1.1 VICON

The Biomechanics Laboratory in the Wolfson building has 12 Vicon T-series 16 megapixel cameras (6 on each side of the lab) all of which are directed towards the centre of the lab giving a working volume of approximately 5m x 10m x 3m. Figure 3.2 shows a T-series camera. The Vicon system captures data by firing infrared beams from each camera towards the centre of each reflective marker that has been placed on the subject. Figure 3.3 shows an example of such markers. This beam is then reflected from the marker back into the camera and from this, the location of each marker in 3-dimensional space can be calculated. This location is analysed by the software, reconstructed and output onto a dual screen user interface in the physical form at which it was captured.

Figure 3.2 – Vicon T-Series camera

Figure 3.3 – Five 3mm Vicon Reflective Markers with a 1 pence piece for size reference

Figure 3.4 below shows the user interface of Vicon Nexus and also shows the camera positions in relation to each other and working volume in the centre of the lab.

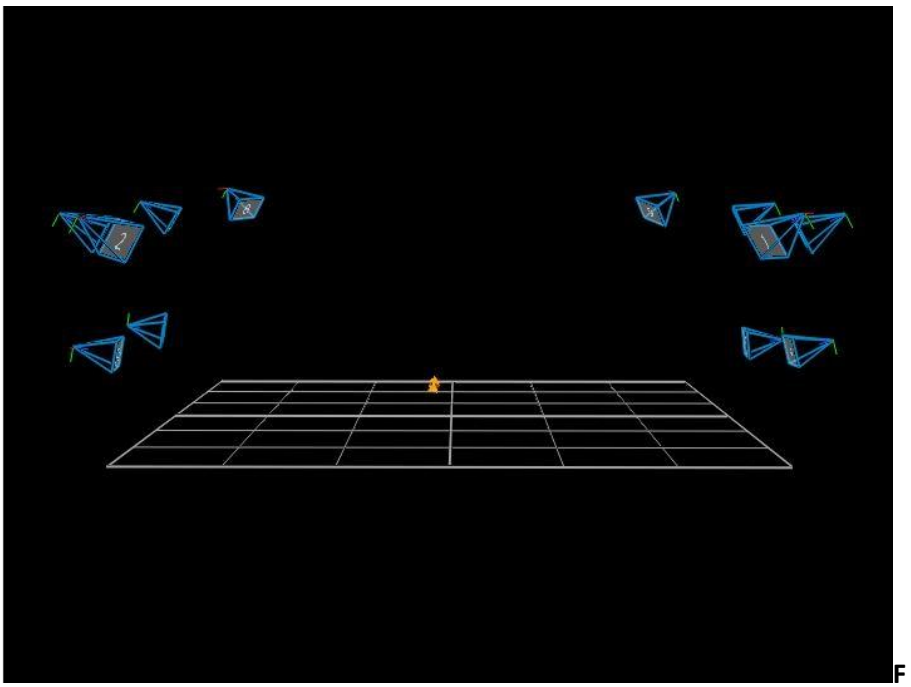

Figure 3.4 – Vicon Nexus User Interface Camera Positions

3.1.2 Pilot Testing

Before testing could begin, the method to be used had to be tested and perfected to ensure the process was appropriate and would run smoothly. This section covers the issues encountered in designing the final method.

1. A method had to be derived to allow the subject to flex their knee from 0^0 to 105^0 whilst keeping as still and as comfortable as possible at each flexion angle increment. The subject's leg also had to be in full view of as many cameras as possible to gain accurate data. Initially it was thought to have the subject seated on a chair in the centre of the capture area and have a series of blocks placed under their foot to support their leg at each flexion angle. This proved unworkable however because the cameras behind the subject could not see the markers due to the subject's upright torso. It was decided to have the subject lie on an adjustable backed hospital type bed in the centre of the capture area. This was helpful as it allowed the subject to lie on the bed so that all cameras could view the markers. It also allowed the subject to use their foot to support their leg at different angles of knee flexion rather than have to hover their foot and use their leg musculature, or place their foot on support blocks. The bed was also very comfortable which was of particular benefit for the 1^{st} couple of subjects as the method of capture used initially took a long time (around 25 minutes). This time reduced to around 8 minutes once the method was perfected.
2. The smallest markers initially available in the department were 10mm in diameter as this is the size required for gait analysis. The system was tested with these markers to see how close they could be placed together without the system mistaking them for either "ghost", "joined" or "duplicate" markers. It was found that the markers could be placed with 18-20mm between the markers centres before the system deleted them. This displacement wasn't feasible for this investigation as the skin is not flat and the displacement is measured as absolute displacement between markers. This means that the markers must be as close together as possible to ensure that as straight a line as possible is present between each marker centre.

As a result the 3mm markers (figure 3.3) had to be ordered directly from Vicon especially for this investigation. The diameter of these markers allows the markers centres to be much closer to each other, solving the skin curvature problem.

3. The 3mm markers hadn't previously been used with the new Vicon T-series cameras currently being used in the gait lab, by any of the staff at Strathclyde University. The system was also set up to monitor gait from a distance and wasn't set up for close-up skin analysis. Thus, it was possible that the cameras would monitor the smaller 3mm markers with less accuracy than with the 10mm markers. However, this was not considered to be a problem with this Vicon T-series system as it is "the most advanced digital optical motion capture system available" [44]. It also meant that the Vicon nexus software had to be calibrated to be used with the smaller markers. All of the calibration techniques were self taught due to the lack of previous experience in this area; this will be discussed further in the limitations section of this thesis.

3.1.3 Template

The hemispherical markers used were made by Vicon (Figure 3.3) and consisted of a rubber backing with a special reflective coating on the curved surface. A total of 43 of these markers were attached to each subject and to ensure they were attached in the same pattern for each subject, a template was created. This template was manufactured from a flexible high density polyethylene and had 43 drilled holes which place the markers in such a way as to measure the skins displacement around the knee in the most effective manner. The template, shown in Figure 3.5 has 16 markers (20mm apart) situated at the four corners of a fictional dressing, 20 markers down the front of the leg from lower thigh to upper shank and 7 markers laterally across the knee joint centre (all 10mm apart). The markers were placed 10mm apart or more due to limitations discussed in the limitations section of this thesis.

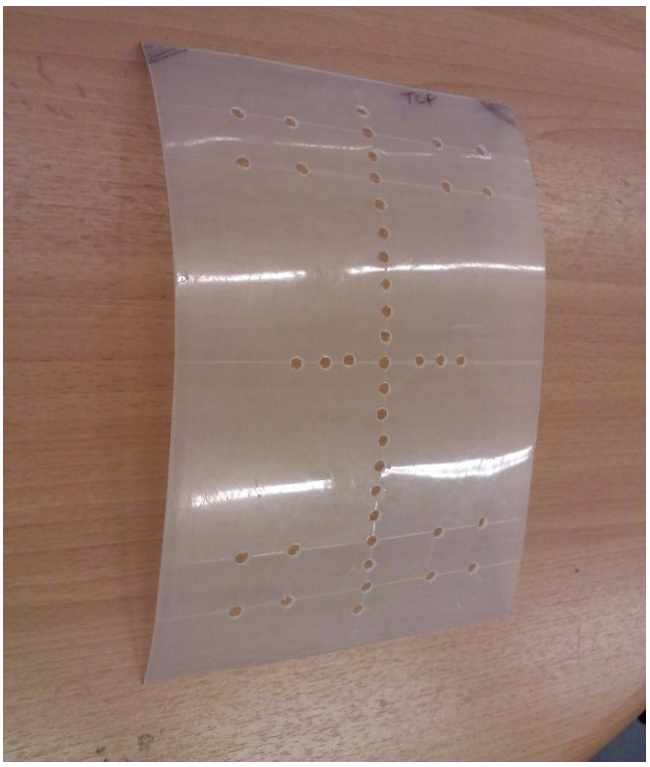

Figure 3.5 – Marker Template

Figure B1 in Appendix B shows a drawing of the marker template showing the different sections listed below, which will be referred to in the results and discussion sections.

1. Midline section – markers 17 – 37.
    1.1. Shank section – markers 17 – 23.
    1.2. Knee section – 24 – 30.
    1.3. Thigh section – 31 -37.
2. Bi-axial squares – markers 1 – 16.
    2.1. Lateral bi-axial square on shank – markers 1 – 4.
    2.2. Medial bi-axial square on shank – markers 5 – 8.
    2.3. Lateral bi-axial square on thigh – makers 9 – 12.
    2.4. Medial bi-axial square on thigh – markers 13 – 16.
3. Horizontal knee centre component – markers 38 – 43.
    3.1. Medial knee joint centre component – markers 38 – 40.
    3.2. Lateral knee joint centre component – markers 41 – 43.

3.1.4 Electronic Goniometer

The device used in this investigation to measure the angle of knee flexion was the Biometrics Ltd Twin axis SG series goniometer. This allows for simultaneous measurement of angles in up to two planes of movement [45]. The goniometer has two separate output connectors, one to measure flexion/extension (the output used here) and the other to measure radial/ulnar deviation. An image of the goniometer used for this investigation is shown below (Figure 3.5) and shows the goniomter along with the data logger which is used to output the angle from the channel that is being used. The goniometer has two green blocks, one to be attached to the thigh above the knee (the upper block in Figure 3.6) and one to be attached to the shank below the knee. The angle of the wire in between these two blocks is measured and output on the data logger which can be read by -2^0 in Figure 3.7. As only channel 1 is being used, the other channel data can be ignored. As with the Vicon system, the goniometer is easy to use but still needs a certain amount of familiarisation to be used effectively.

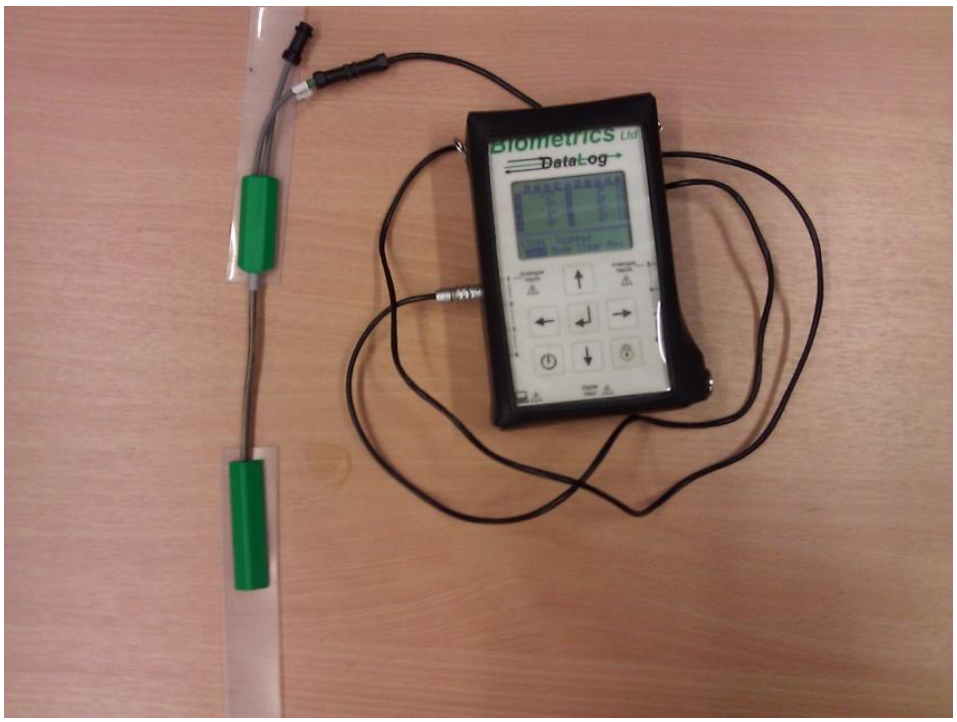

Figure 3.6 – Electronic Goniometer and Data

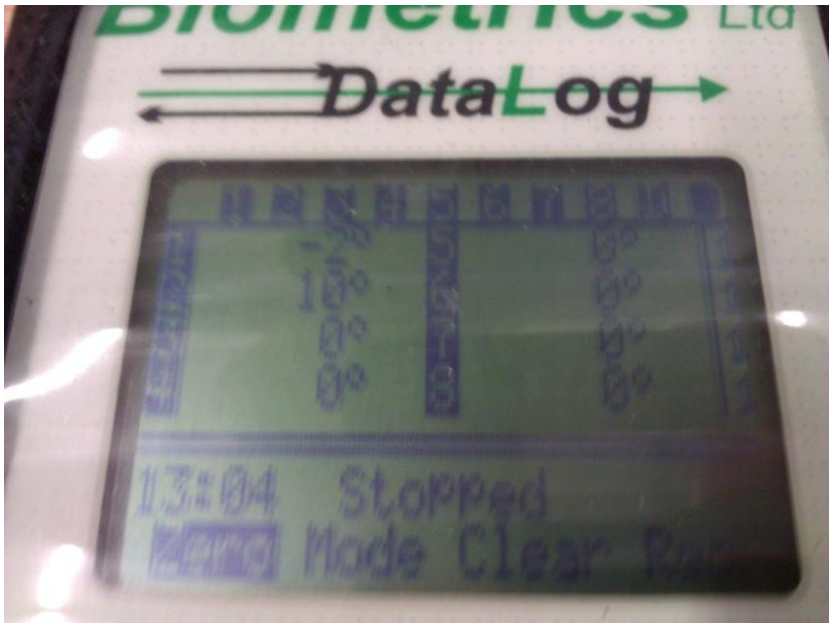

Figure 3.7 – Data Logger Output Screen

3.2 Procedure

3.2.1 Ethics and Subject Recruitment

The Bioengineering departmental ethics committee was approached for this investigation as it was not deemed necessary to approach the university or NHS ethics comities due to the type of procedure (non-invasive) and people involved. Strathclyde universities ethical application forms were filled in (Appendix C), in collaboration with the universities "Code of Practice on Investigations Involving Human Beings". Ethical approval was gained on the 1st of July 2011. Subjects were recruited as follows.

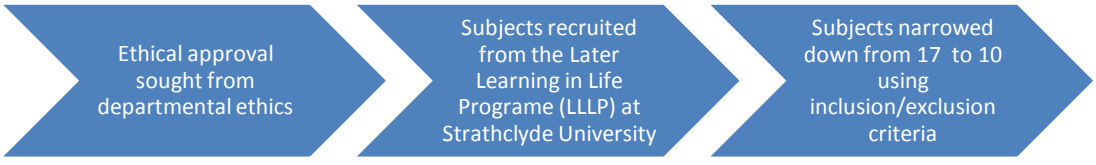

Figure 3.8 – Recruitment Process

17 Students showed interest and requested to be involved. However, only 10 subjects were required due to the time constraints and these subjects were recruited with the following criteria:

Inclusion Criteria

- Over 60
- Good leg musculature
- Available during mid-late July 2011

Exclusion Criteria

- Any previous surgery on the right leg. (The right leg was chosen to be the investigated leg so as to be consistent throughout the investigation with each subject).

All students, now subjects, were contacted the day prior to testing to ensure they were still available and were reminded to bring shorts to change into so that there leg could be accessed easily for marker and goniometer placement.

3.2.2 Subject Preparation

Once the subject had changed into a pair of shorts, they were asked to be seated next to the investigator for marker placement. Markers were affixed with 3 x 3mm sticky pads which had been previously attached to each marker prior to subject arrival. The first marker was attached as close to the centre of the subject's knee as possible using the femoral and tibial condyles as a guide. Once the first marker was in position, the subject extended their leg to 0^0 and rested it on a chair in front of them. The template was then held in place with the first marker slotting through the centre hole of the template. All markers were then attached to the skin by slotting them through the holes of the template. The template was then removed and as shown in Figure 3.9, the subject's leg was then ready to enter the capture area.

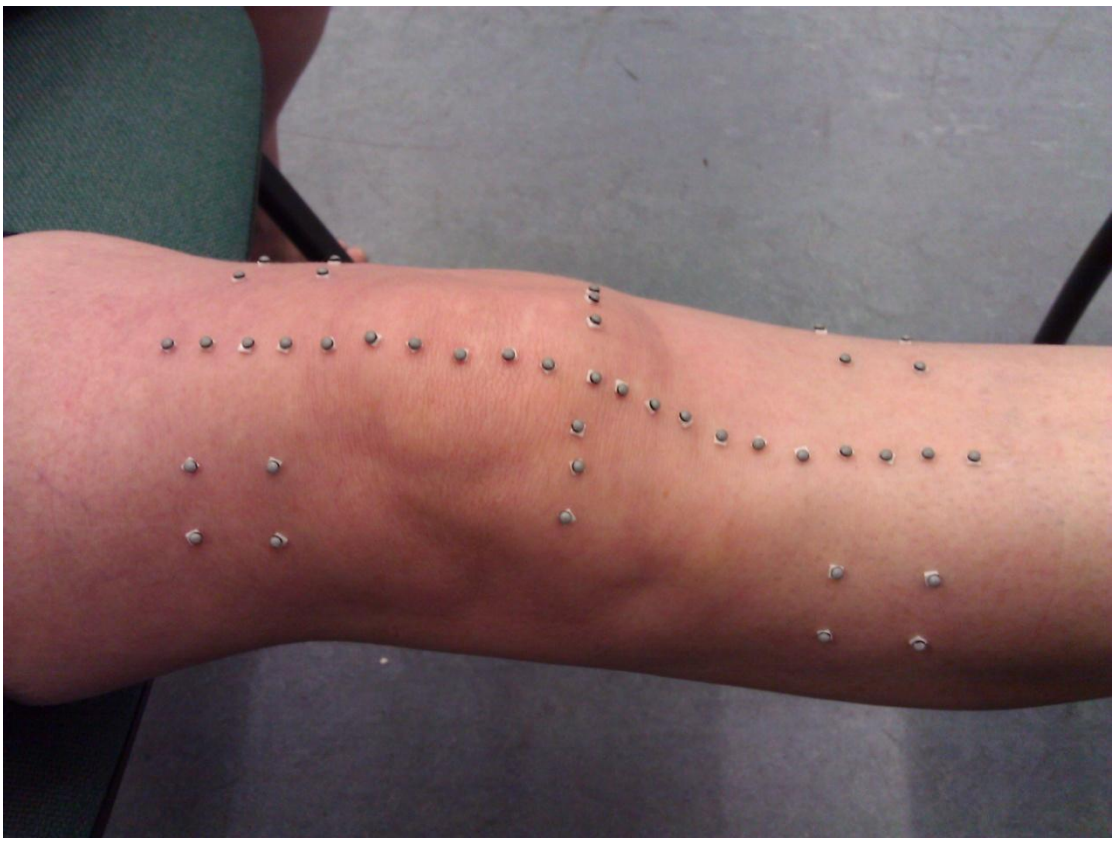

Figure 3.9 – Subject's Leg with all Markers in Place

With all markers securely in place, the subject lay on a firm bed in the centre of the capture area so that all 43 markers were in view of at least 3 cameras per marker. This would ensure that the positional data of each marker was accurate enough to be used for analysis. The bed was adjusted so that the subject was in more of a seated position with straight legs resting on the bottom half of the bed and a pillow placed behind their head. This was done for comfort reasons and so that the subject could comfortably hold the goniometers data logger in front of them to read off the angle of knee flexion. The goniometer was then calibrated to 0^0 with the subject's leg comfortably flat and straight. This can be seen in figure 3.10 below.

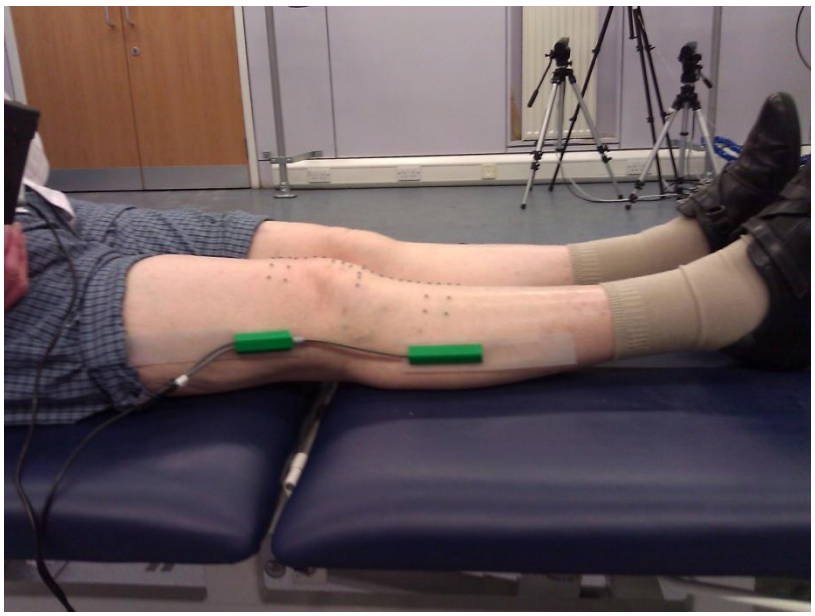

Figure 3.10 – Subject with Markers and Goniometer in Place for Calibration at 0^0

The subject was then given clear instructions, that when capture was taking place, to flex their leg in 15 degree increments from zero to 105^0 and hold their leg at each angle of flexion until told to increase the angle again/relax their leg. Figures 3.11 below shows the subject holding the data logger and reading off the angle of current knee flexion of around 45^0 which can also been seen in the sagittal plane in figure 3.12.

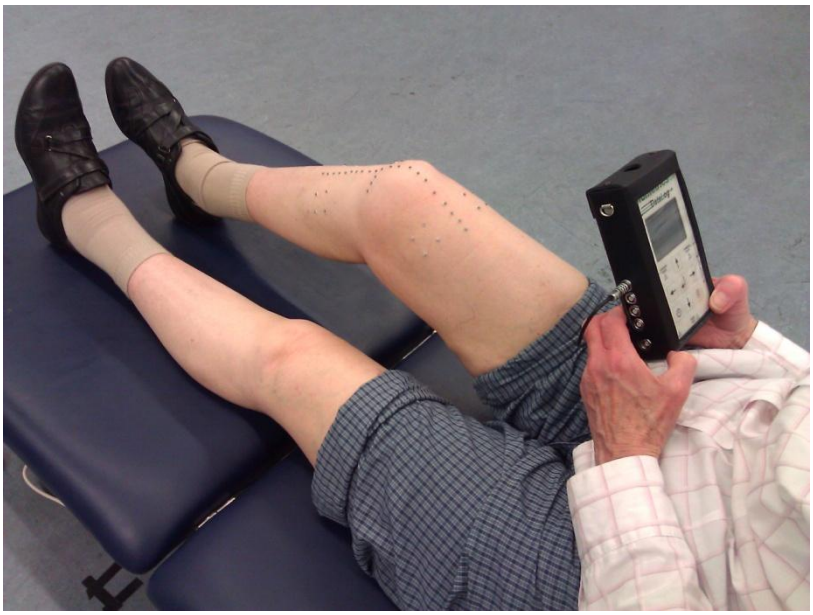

Figure 3.11 – Subject Reading Flexion Angle From Data Logger

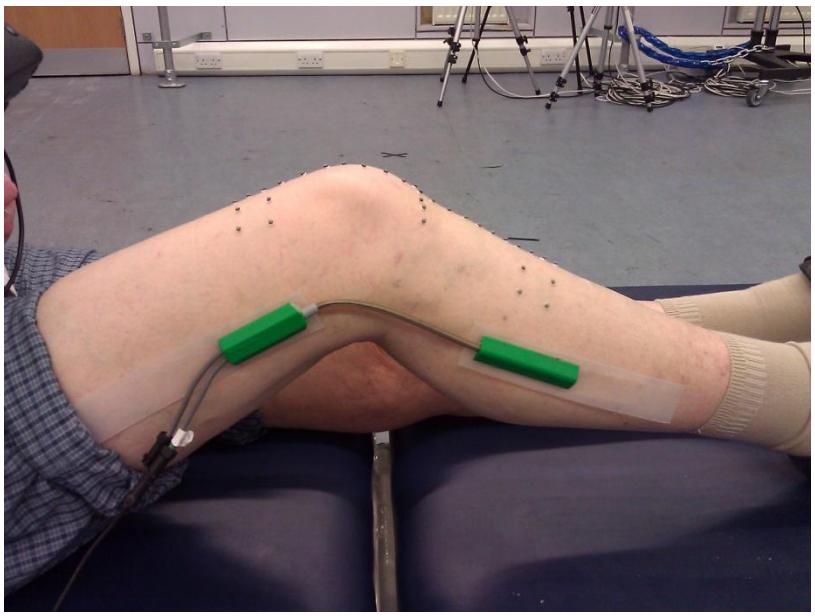

Figure 3.12 – Subject's Knee at Around 45^0 of Flexion

3.2.3 Data Capture

Once the subject was prepared, data capture using the Vicon cameras could begin. The software was calibrated prior to each subject arrival to ensure any other Vicon users had not changed the settings needed for this investigation.

The first angle to be captured was 0^0 so the subject was told to relax their leg and lay it flat on the bed to the calibrated zero degree angle of the goniometer. Once the angle was met, the subject called out the angle which assured the investigator that it was OK to capture data. The Vicon system was set to capture at 30 Hz as this is the lowest frame rate available in the software and seemed to be the most accurate for recognising the particular size of the markers in use. Around 4 seconds of footage was captured at this flexion angle so around 120 frames of data were captured. In theory, as the subject was to hold their leg in a static position at the flexion angle, all 120 frames of data should output the same Cartesian co-ordinates for each marker. This however was not the case as will be discussed later.

Figure 3.13 shows one frame of data captured by the Vicon cameras at 0^0 and reconstructed and output on the user interface.

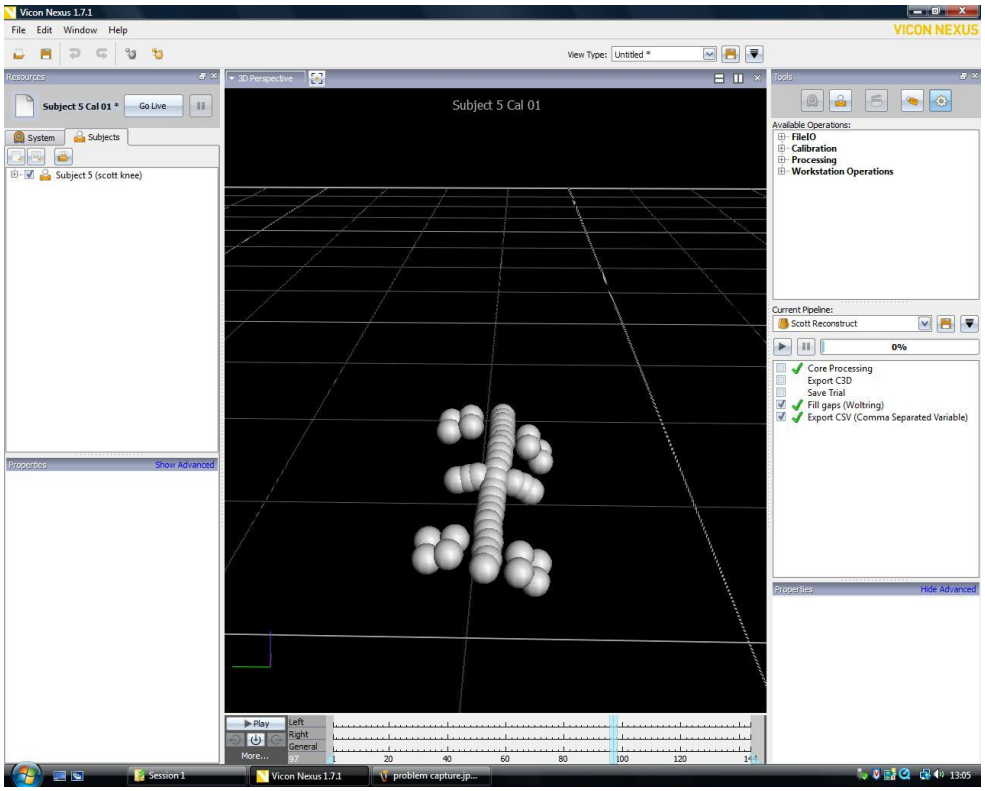

Figure 3.13 – Vicon Nexus User Interface Output at 0^0

The subject then increased the angle of knee flexion to 15^0 and then in 15 degree increments up to 105^0 with the aid of the goniometer for reference. For each angle of flexion, the procedure described above remained consistent.

3.2.4 Post-processing

After the data had been captured by the Vicon system of each markers position in space, this data needed to be post-processed in the Vicon Nexus software to be suitable for output to the data analysis software. This post-processing involved manipulating the captured data so that all the markers were visible, present and correct. If they were not, then the data output had missing data, or if the markers had been labelled incorrectly the data would be output in the wrong order.

Figure 3.14 gives an example of an issue that was had with the system during post-processing.

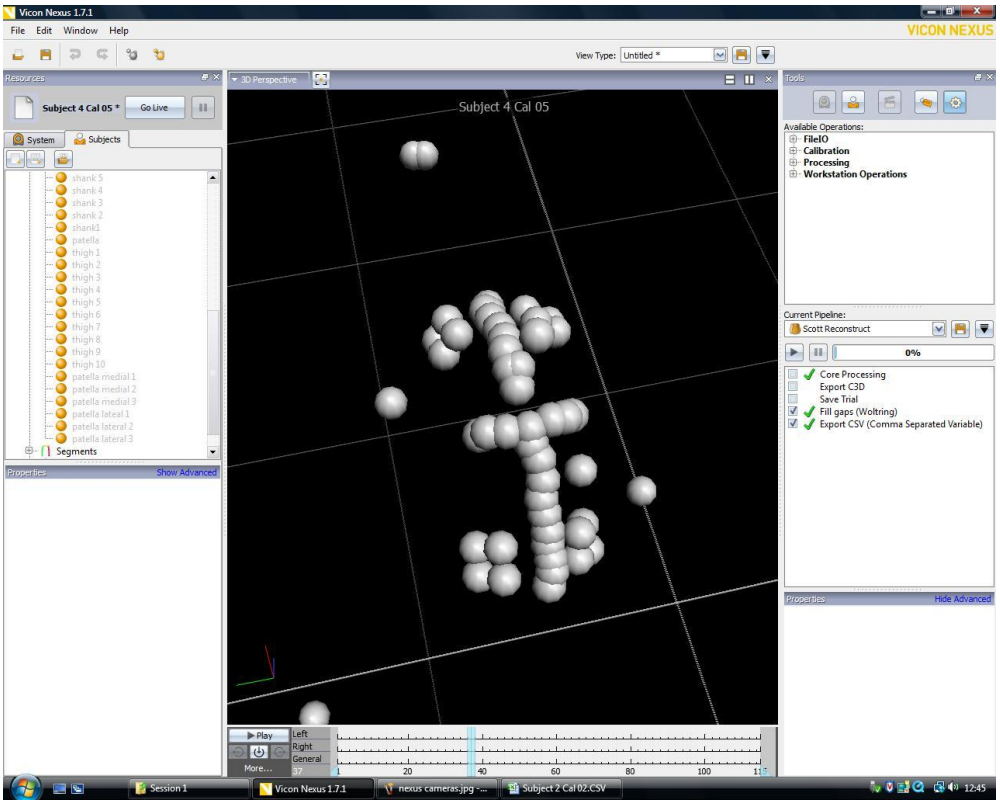

Figure 3.14 – Marker Addition and Deletion Problem

The problem shown above involved: the systems cameras being unable to see the markers; the software creating extra markers if it thought others were missing; the cameras picking up other reflections which interfered with the markers reflections.

The way that this problem was prevented was to use the Vicon Nexus cropping option. This involved cropping the capture so that all markers were visible in the first and last frames. This cropping option was used after the markers were labelled with the template key in figure B1. The markers were labelled so that when the data was output to the data analysis software, it would be made clear what data was associated with each marker.

A labelling template was constructed in the Vicon Nexus software prior to subject arrival and applied to the markers in the post-processing stage. This applied template can be seen below in figure 3.15 and can be compared with the unlabelled markers in figure 3.13.

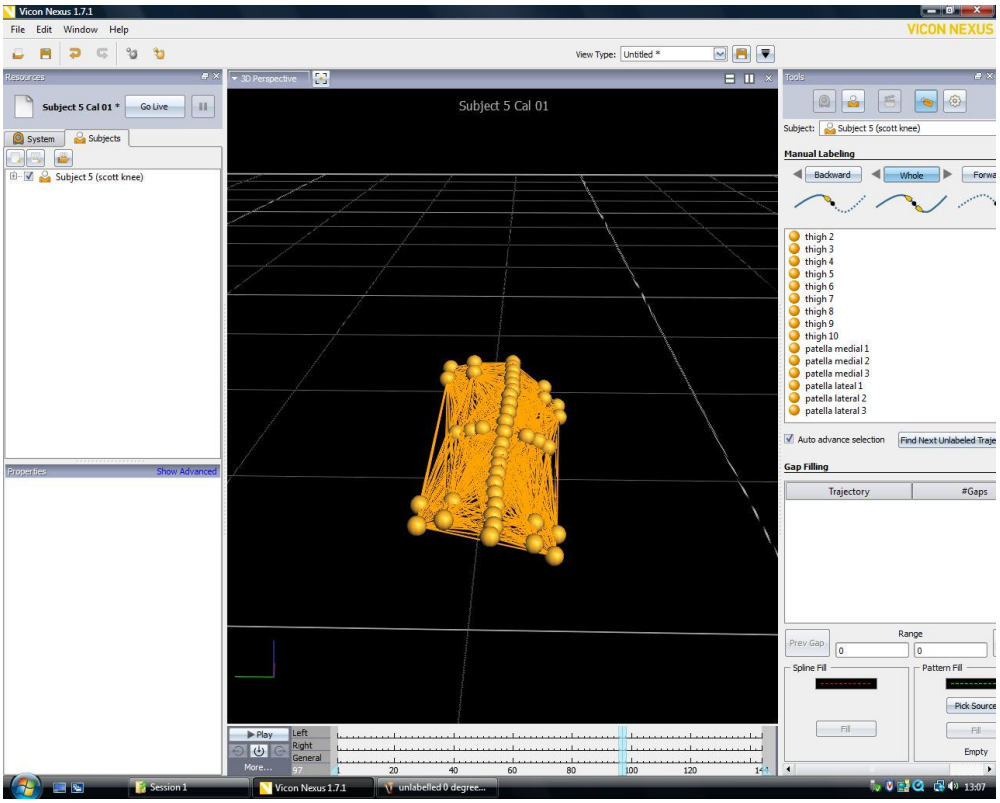

Figure 3.15 – Vicon Nexus with Labelled Markers

Figure 3.16 below shows a frame of labelled markers at a flexion angle of 75^0. Notice that some of the markers are missing below and laterally of the knee centre. This is where the cropping option would be used as described above. This would give the result of the first and last frame having a complete set of labelled markers (figure 3.15) and allow the data to be output in an ordered fashion.

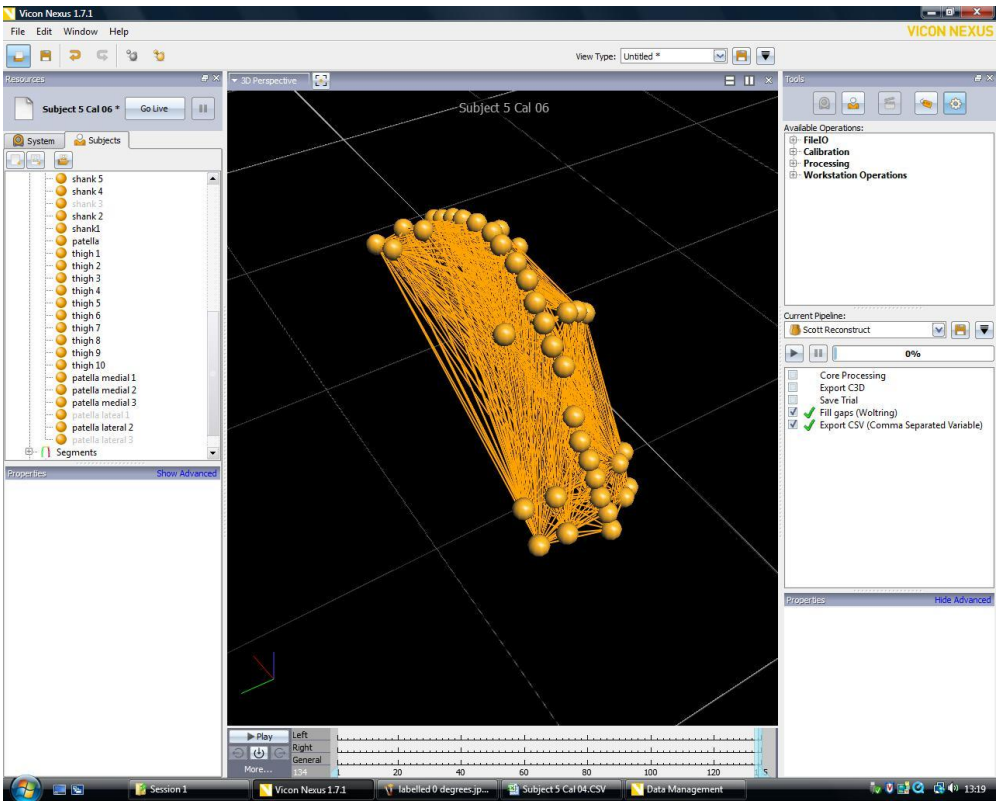

Figure 3.16 – Labelled Markers with 3 Missing Markers

3.2.5 Data Analysis

The data to be output from the Vicon Nexus software was of a Cartesian co-ordinate format for each marker for each flexion angle that data was recorded for. This only gave the point in space of each marker but this was all that was required as it was the absolute displacement between adjacent markers that was used to determine the strain. As the subjects knee flexes, in theory the skin should stretch and the markers attached should displace and the distance between each marker should increase.

As mentioned above, around 120 frames were captured at each flexion angle. This was done because the subject's leg was unlikely to remain perfectly still and also because the Vicon cameras may not have registered certain markers straight away. As only one co-ordinate per marker was needed rather than 120 per marker, an average of the captured frames was taken.

This proved to be adequate as the data output for all of the frames of co-ordinates for each marker seemed to be consistently within around 0.5 of a millimetre giving a 5% error from the original 10mm displacement.

The Cartesian data of the markers was output to Microsoft Excel (Microsoft Corp, Redmond, USA) from which the averaging of the frames was carried out which then allowed for the absolute displacement in 3-dimensional space between adjacent markers to be calculated.

The absolute displacement of the markers was also calculated in Microsoft excel using the Pythagoras equation for 3D shapes (equation 3.1).

$$Displacement = \sqrt{X^2 + Y^2 + Z^2}$$

Equation 3.1 – Pythagoras Equation for 3D Shapes

After the displacement was calculated, the absolute strain for each marker pair at each flexion angle was calculated using equation 2.1 (section 2.5.2).

4. RESULTS

The results section of this thesis will present the findings of the investigation with constant reference to the marker template groups in figure B1 and section 3.1.3.

4.1 Subject Demographics

Overall 10 subjects were successfully recruited. However, severe problems were encountered when post-processing subject 4's data due to an insufficient Vicon Nexus calibration, so data for subject 4 was discarded. Also, there was a problem at 105^0 of flexion with subject 3 which meant that the top of the thigh (markers 35-37) were not visible to the cameras and so were not registered by the software.

Subject demographics are shown it Table 4.1.

Table 4.1 – Subject Demographics

SUBJECT	GENDER	AGE (years)	WEIGHT (kg)	HEIGHT (cm)	BMI
1	Female	63	58	152.5	24.9
2	Female	73	83	165	30.5
3	Female	64	56	157	22.7
5	Female	63	86	158	34.4
6	Male	64	101	177.5	32.1
7	Male	63	111	183	33.1
8	Female	65	72	165	26.4
9	Male	69	79	168	28
10	Female	77	60	161.5	23
Mean		66.8	78.4	165.3	28.3

Notes of interest:

Subject 6 - Used evening primrose oil on whole leg once a day.

Used wintergreen cream on both knees once a day.

Took two collagen tablets per day.

Subject 7 - Hairy legs so marker adhesion/movement may have been an issue.

4.2 Skin Strain Measurements

Table 4.2 gives the mean strain and standard deviations for all of the subjects combined for the Mid-line sections only. Figure 4.1 gives a graphical representation of the means for the same sections using the SD to create error bars. Figures 4.2 – 4.5 giving graphical data for the actual values of each subject for the mid-line sections.

Table 4.2 – Mean Strain and Standard Deviations for Knee Mid-line Sections

Knee Angle (^{0})	Strain (%)							
	Full Mid-line section		Thigh		Knee		Shank	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00
15	7.8	2.09	11.4	2.70	8.6	4.52	2.4	2.13
30	14.6	2.65	23.3	5.11	15.2	6.39	3.8	3.07
45	20.0	3.65	31.0	7.37	21.5	7.25	5.8	3.55
60	25.3	4.24	37.9	9.10	28.0	6.94	8.8	4.39
75	29.5	4.57	42.6	10.68	32.7	7.10	11.8	5.02
90	33.0	5.21	45.6	11.12	36.4	7.68	15.6	6.51
105	35.3	5.60	48.0	12.54	38.5	7.56	18.0	6.17

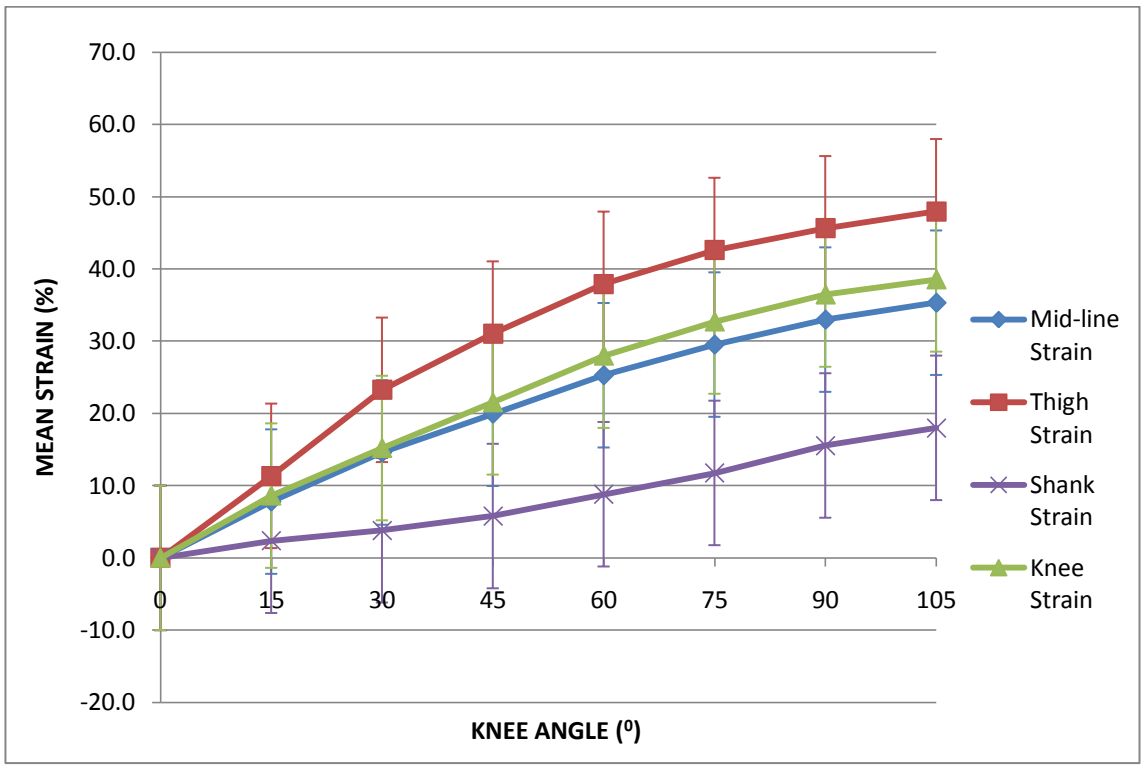

Figure 4.1 – Mean Strain for Each Section of the Mid-line

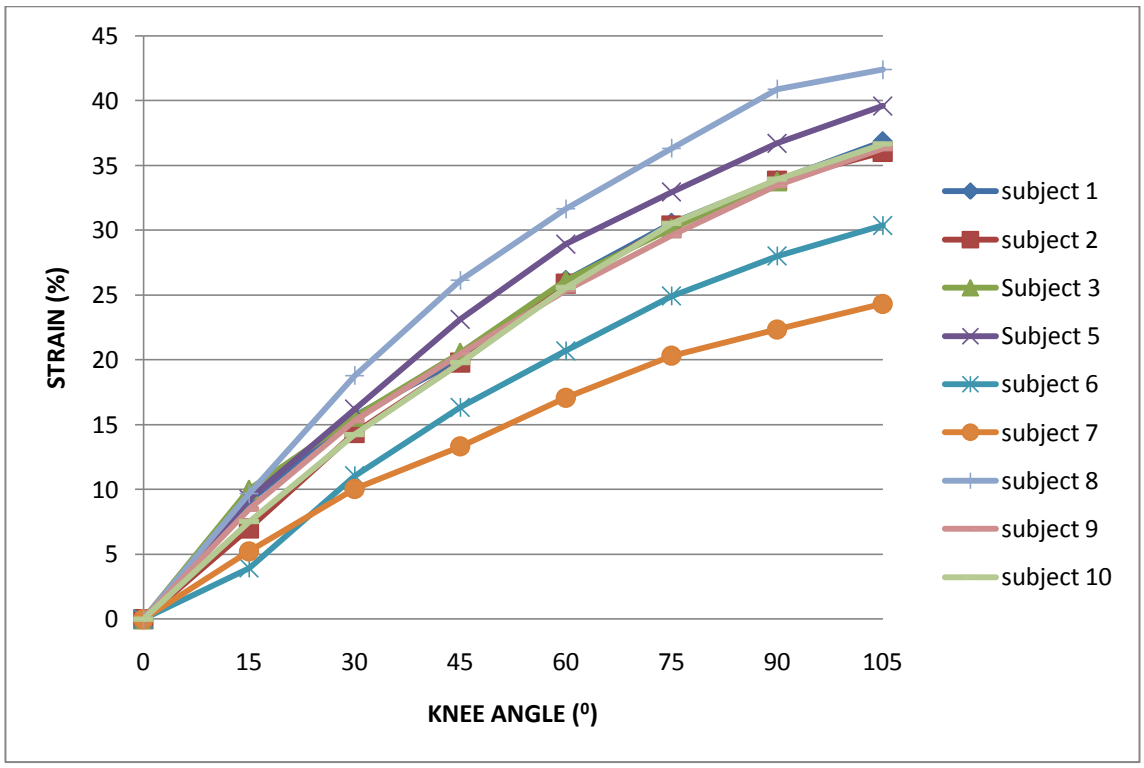

Figure 4.2 – Subject Comparison of the Strain for Whole Mid-line Section

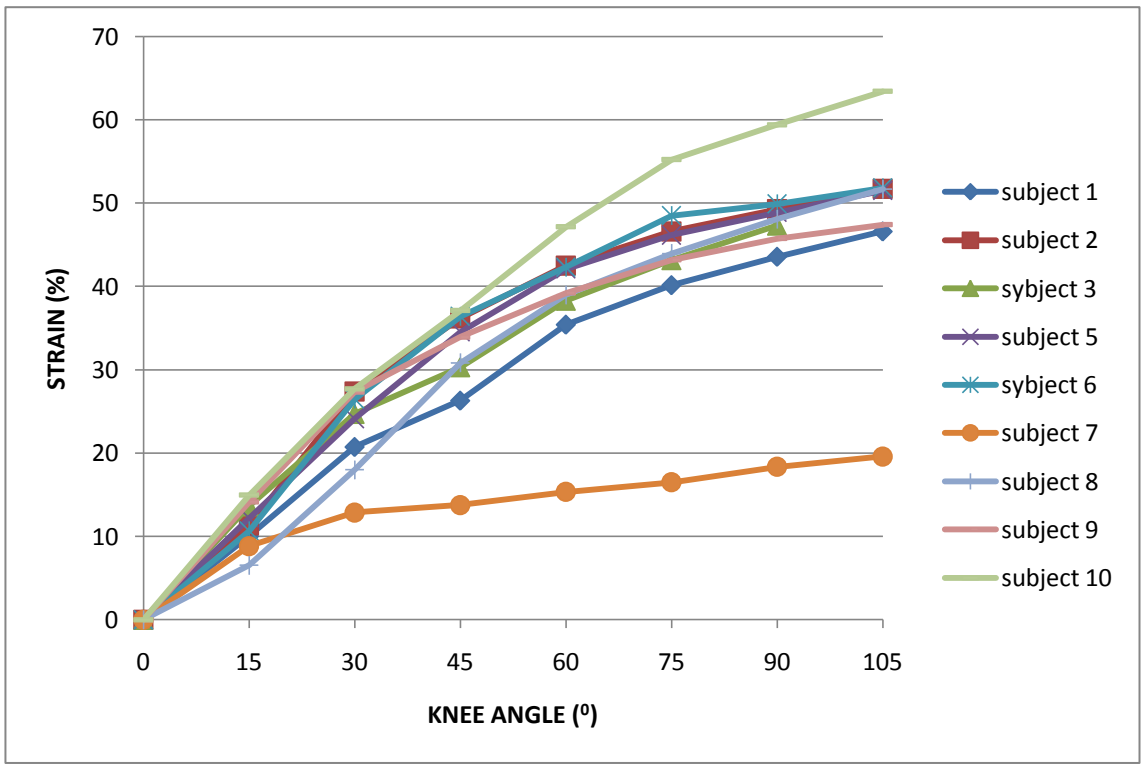

Figure 4.3 – Subject Comparison of the Strain for the Thigh Section

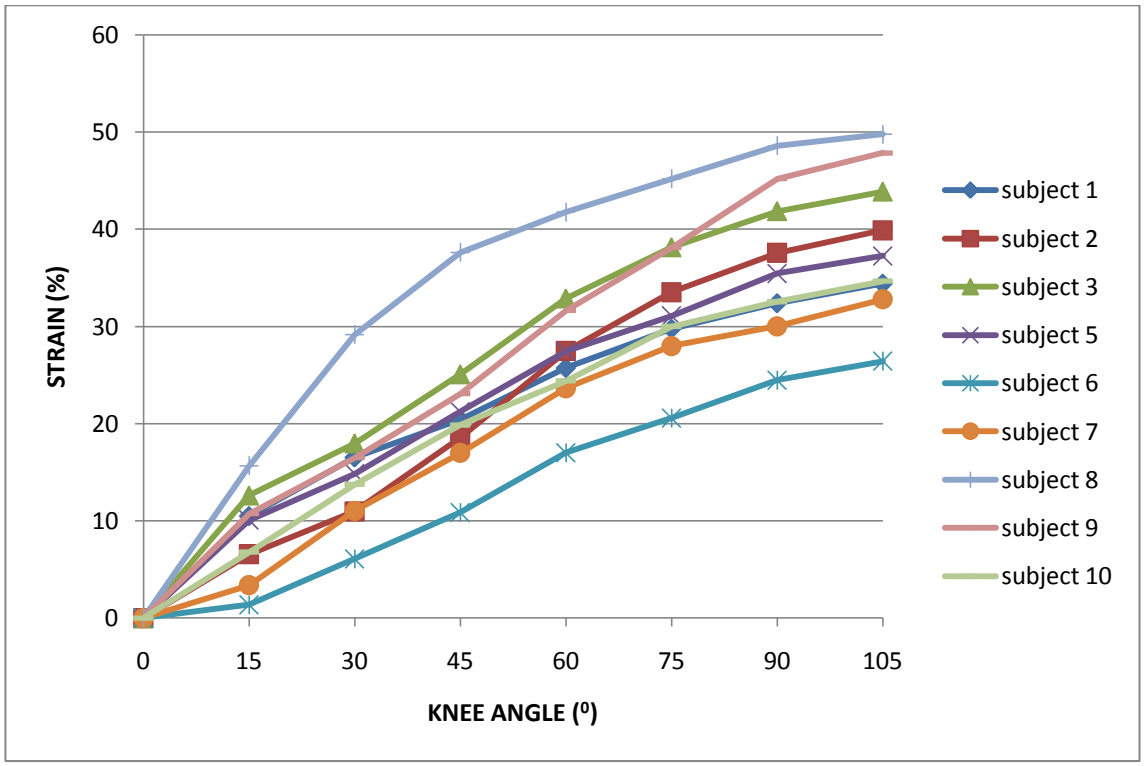

Figure 4.4 – Subject Comparison of the Strain for the Knee Section

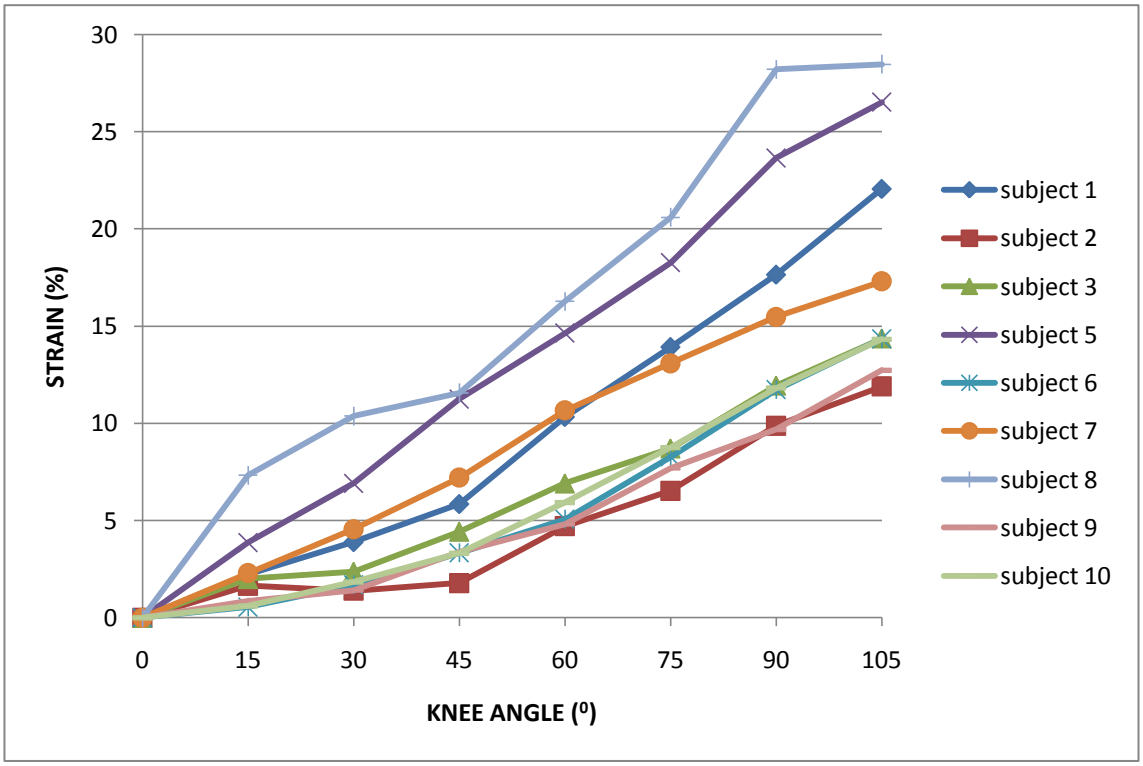

Figure 4.5 – Subject Comparison of the Strain for the Shank Section

Figure 4.6 shows what contribution each mid-line sub-section makes to the total overall strain of the whole section.

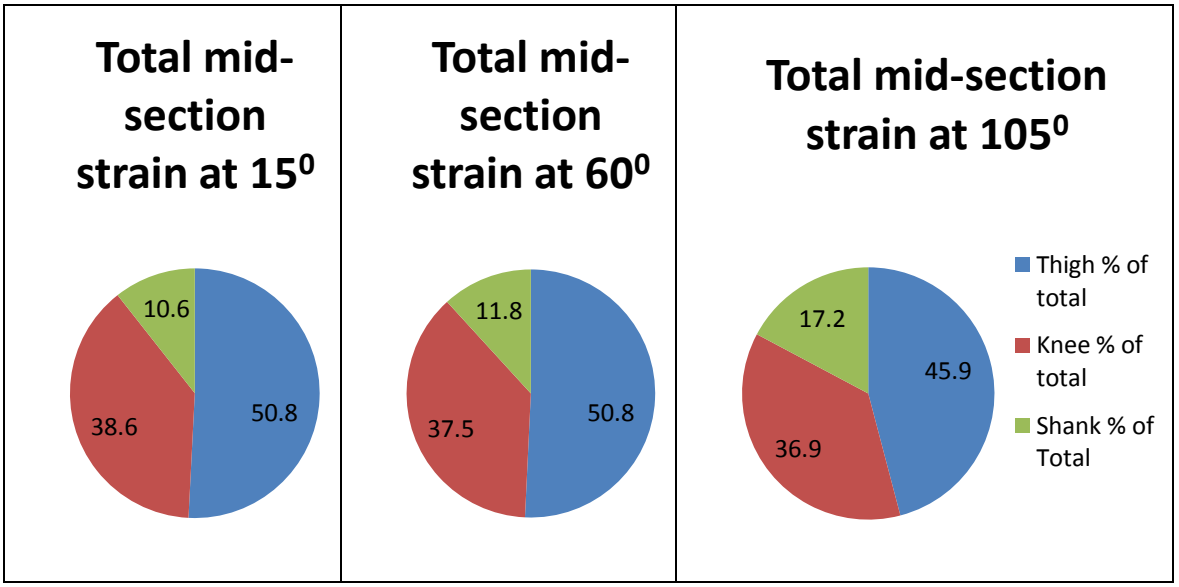

Figure 4.6 - Contribution of Each Mid-line Sub-section to the Total Mid-line Strain

Table 4.3 below gives the means and standard deviations for all of the vertical components of all bi-axial square sections (see section 3.1.2 and figure B1). Figure 4.7 gives a graphical representation of the means with SD error bars.

Table 4.3 – Mean Strain and Standard Deviations for Vertical Components of Bi-axial Square Sections

Knee Angle (^{0})	Strain (%)							
	Thigh lateral vertical		Thigh medial vertical		Shank lateral vertical		Shank medial vertical	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00
15	6.5	3.31	9.4	4.17	0.9	1.55	2.0	2.29
30	15.7	4.78	18.3	9.20	1.2	1.98	2.8	3.38
45	22.6	6.21	24.9	13.28	1.7	2.58	4.4	5.10
60	28.8	7.97	29.9	15.16	3.1	2.99	5.7	6.67
75	33.2	8.48	35.1	16.80	4.1	2.95	7.8	7.80
90	36.6	8.97	36.6	18.42	5.8	3.65	10.8	9.54
105	38.8	9.44	38.5	18.52	6.7	4.22	13.1	10.24

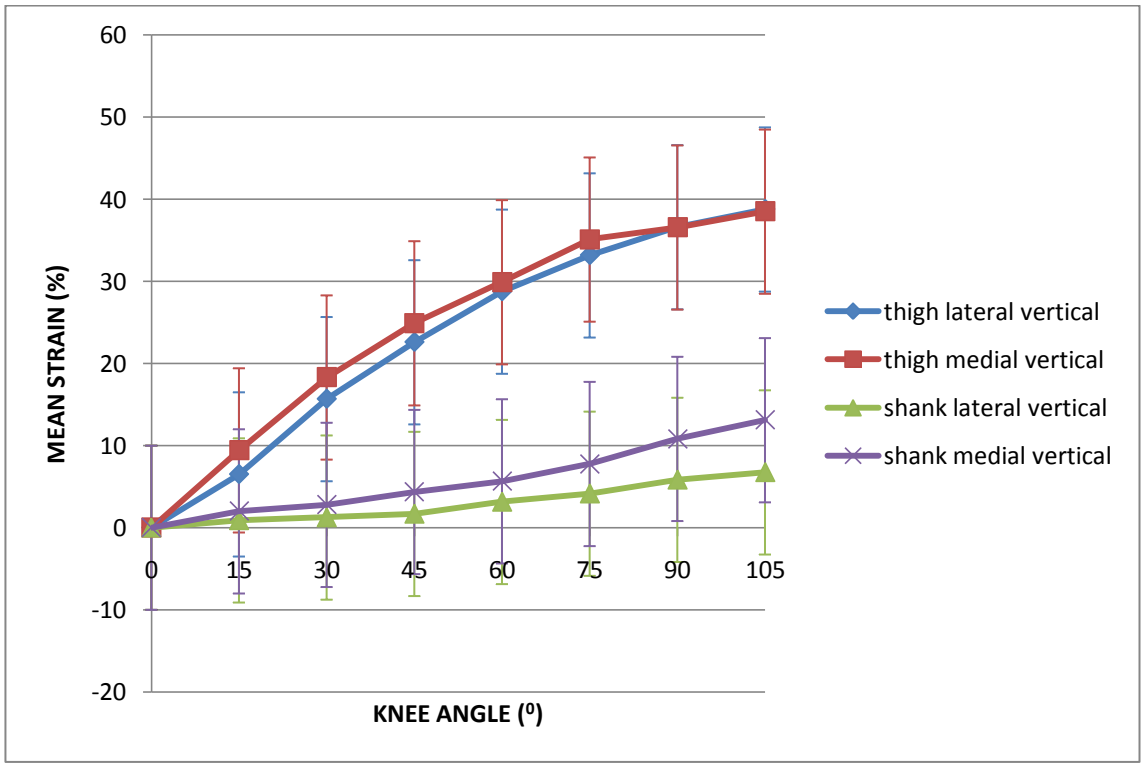

Figure 4.7 – Mean Strain for Vertical Components of Bi-axial Squares

Figures 4.8 and 4.9 show the vertical components of strain for the bi-axial sections at the medial thigh and shank for all subjects, with the rest of the vertical bi-axial results shown in Appendix D. The figures also show that there is a consistent rise in strain with increasing flexion angle for each subject.

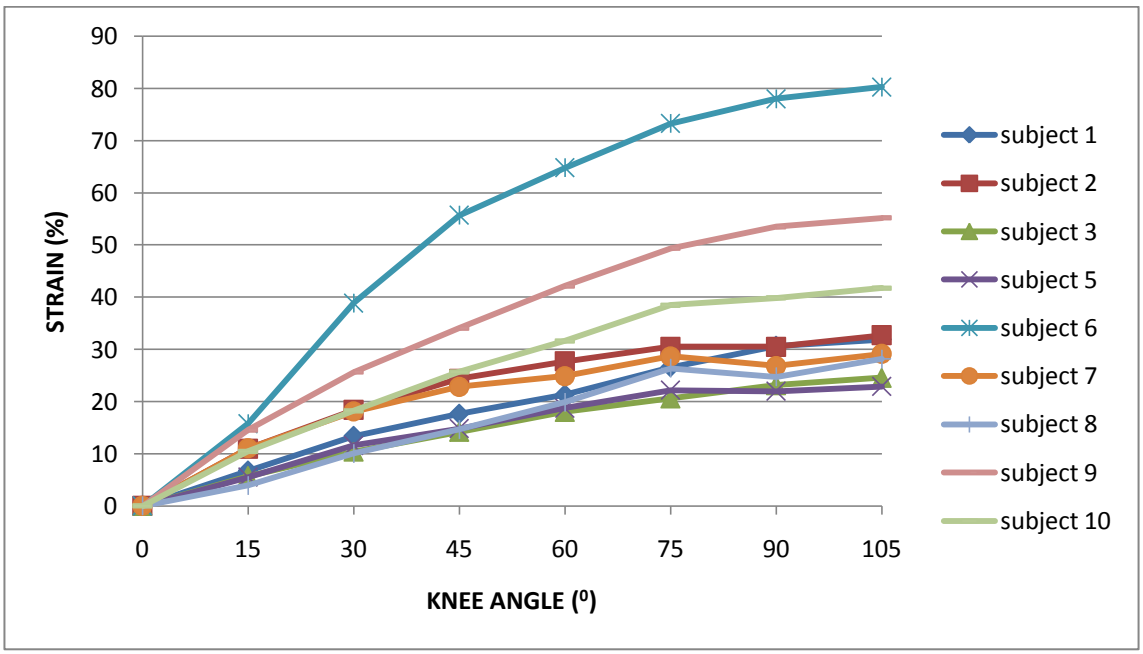

Figure 4.8 - Subject Comparison for Medial Thigh Bi-axial Square Vertical Component

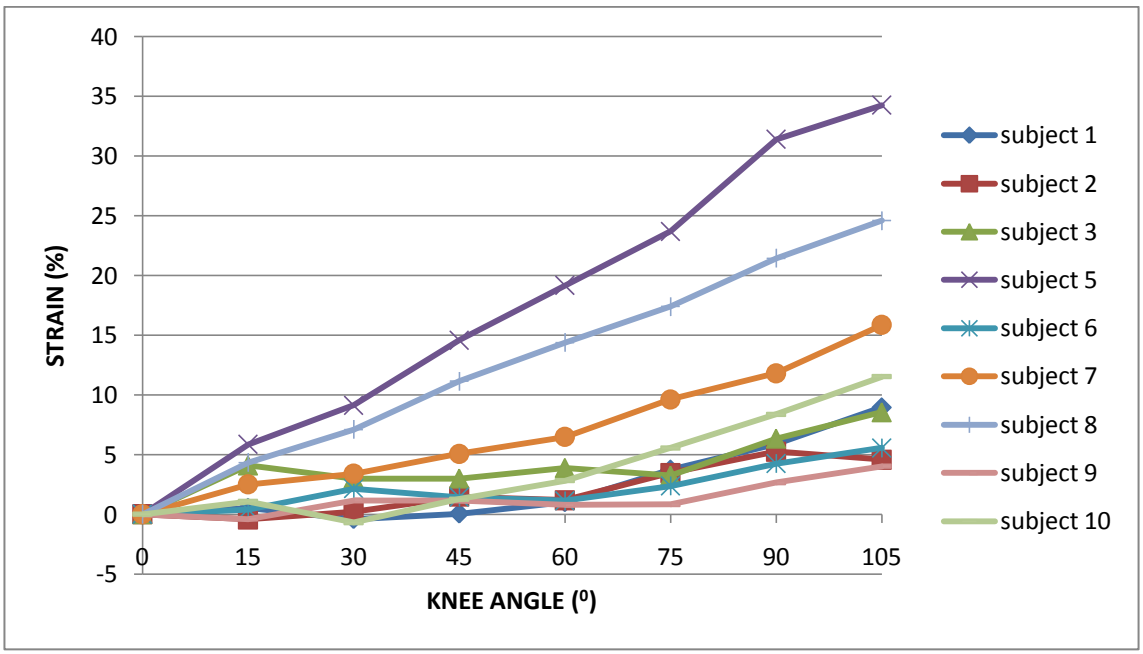

Figure 4.9 - Subject Comparison for Medial Shank Bi-axial Square Vertical Component

Table 4.4 gives the means and standard deviations for all of the horizontal components only for all bi-axial square sections. Figure 4.10 gives a graphical representation of the means with SD error bars.

Table 4.4 – Mean Strain and Standard Deviations for Horizontal Components of Bi-axial Square Sections

Knee Angle (^{0})	Strain (%)							
	Thigh lateral horizontal		Thigh medial horizontal		Shank lateral horizontal		Shank medial horizontal	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
0	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00
15	0.9	2.31	0.4	3.18	-0.9	2.03	0.9	1.96
30	1.5	3.14	3.5	4.03	-0.6	1.90	0.5	2.49
45	2.1	3.18	5.7	4.00	-0.1	2.26	-0.4	3.12
60	2.0	4.29	7.5	4.99	-0.8	2.72	-0.7	4.58
75	2.3	3.76	8.6	5.84	-1.6	2.87	-3.0	6.20
90	2.3	4.52	9.7	5.80	-3.3	4.57	-3.8	7.19
105	1.3	5.38	9.9	5.73	-3.4	3.65	-5.6	8.13

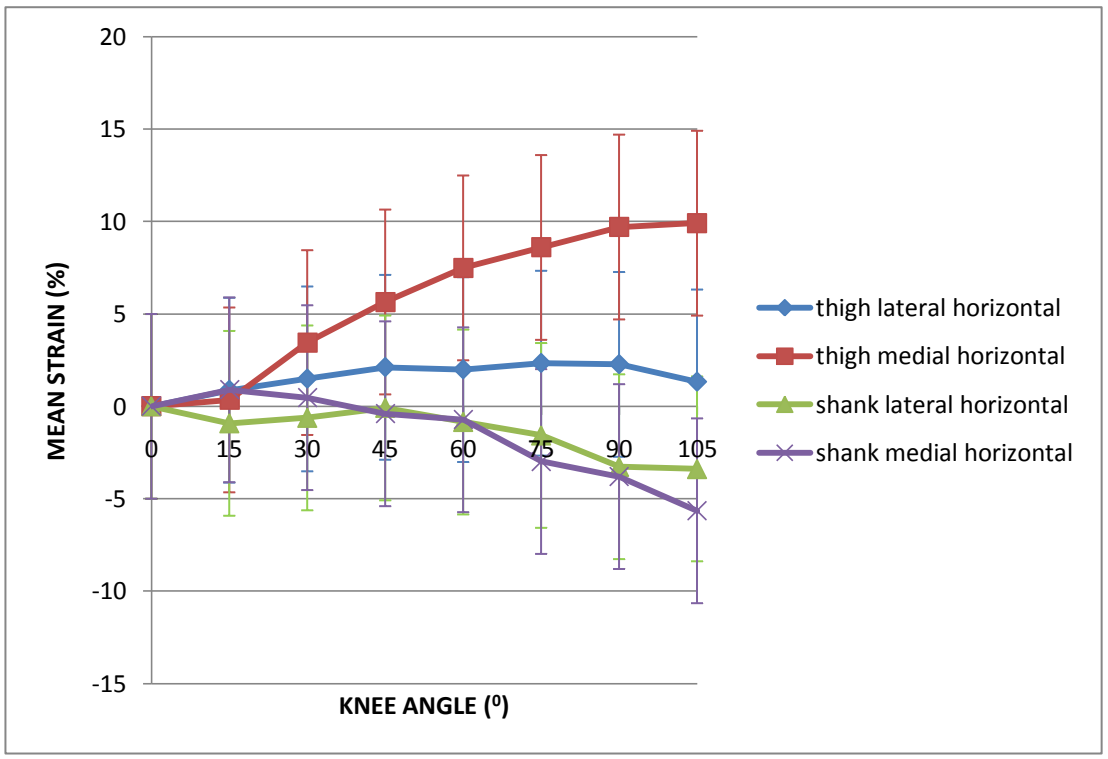

Figure 4.10 – Mean Strain for Horizontal Components of Bi-axial Squares

Figure 4.11 gives an example of the inconsistency of the results that was collected from all subjects, of the horizontal components of the bi-axial squares. The other horizontal components can be seen in Appendix D

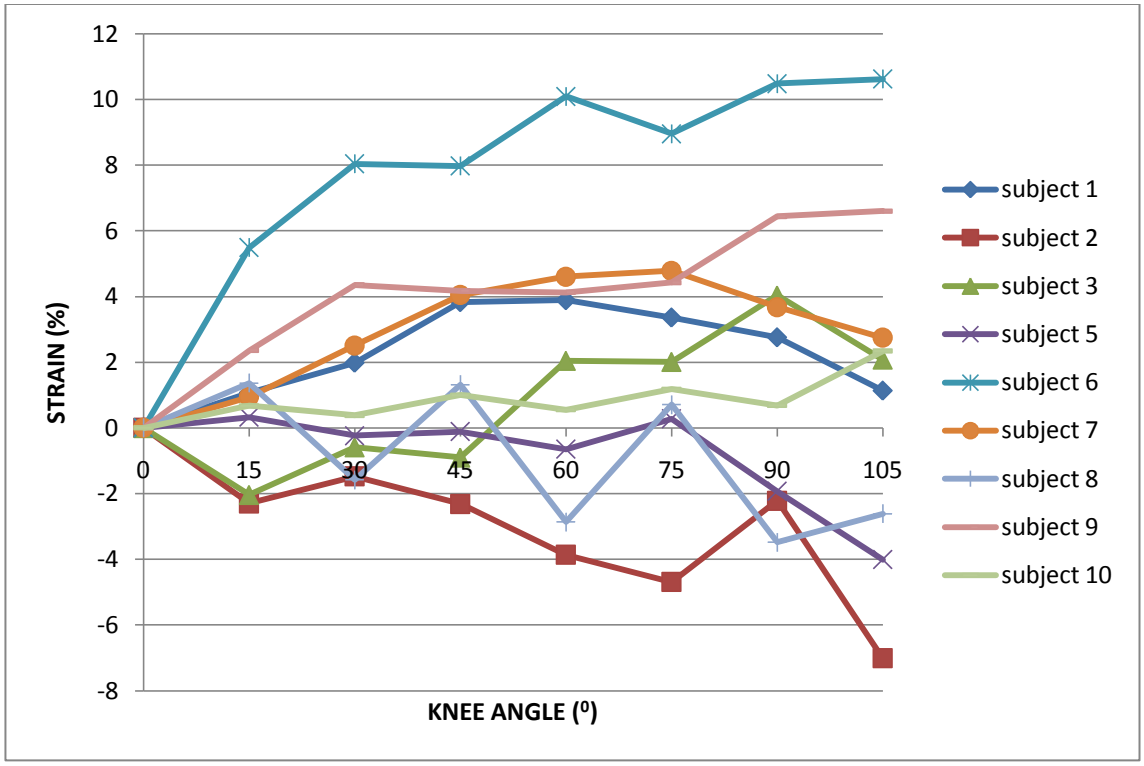

Figure 4.11 – Lateral Thigh Bi-axial Square Horizontal Component

Table 4.5 gives the means and standard deviations for the horizontal sections across the knee joint centre. Figure 4.12 gives a graphical representation of the means with SD error bars.

Table 4.5 – Mean Strain and Standard Deviations for Horizontal Knee Joint Centre Sections

Knee Angle (⁰)	Strain (%)			
	Lateral knee centre		Medial Knee Centre	
	Mean	SD	Mean	SD
0	0.0	0.00	0.0	0.00
15	-2.1	3.13	-2.3	4.70
30	-0.7	4.56	-2.8	2.89
45	-1.0	6.02	-4.0	2.30
60	-1.5	5.23	-3.3	3.31
75	-0.9	4.55	-4.8	3.69
90	-2.9	4.03	-1.9	4.71
105	-1.6	3.70	0.1	4.42

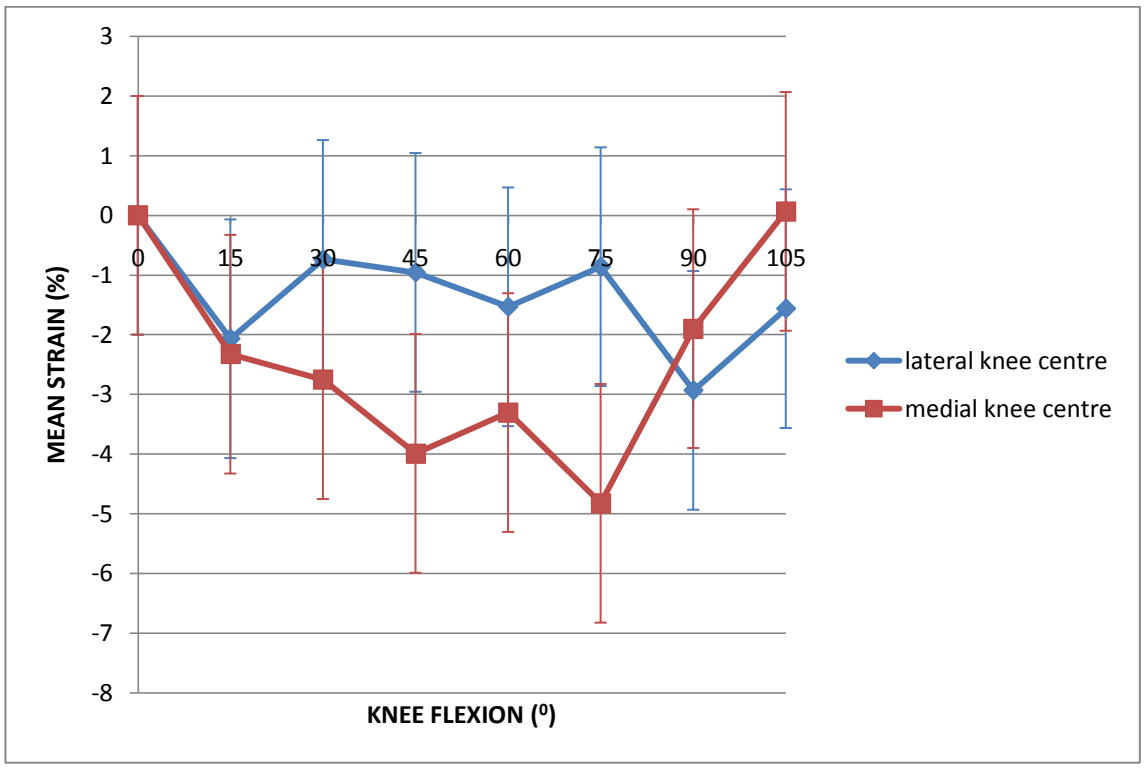

Figure 4.12 – Mean Strain for Horizontal Knee Joint Centre Sections

5. DISCUSSION

5.1 Vertical Components

It might be expected that the strain will increase over these sections as the knee is flexing and stretching the skin over the longitudinal anterior surface of the leg.

5.1.1 Mid-line Section Components

This sub-section will discuss the results for the mid-line section and all participating sub-sections.

Figure 4.2 shows how much total strain is present down the centre of the leg from 9cm above the knee joint centre all the way down to 9cm below the knee centre. The data is very consistent in the fact that every subject follows the same curve shape/trend of strain rising as knee angle increases. There were problems with subject 3's data at 105^0 as mentioned previously, hence the lack of data marker at 105^0. It can be predicted from the rest of subject 3's strain/knee angle curve, that at 105^0, their strain would be at around 36%.

Figure 4.2 can be compared with the literature of Dillon, J.M. et al [55] as it is associated with the same section of leg. Dillon's study recorded an average of 21.8% strain for the wound at 90^0 of flexion and the average strain for the same region in this investigation is around 35%. The increase of around 13% in this investigation may be due to the measurements being taken on healthy skin rather than scar tissue.

Two reviewed studies [42, 54] found the longitudinal strain on the shin to be around 70%, which compared with the maximum mean strain of around 18% in this investigation, is much greater. This may be due to the fact that the subject used in those studies was monitored while squatting which would have applied a far greater stress to the skin and may have resulted in increased strain over the shanks skin.

Another factor which may have affected the shank strain measured in this investigation, is the fact that the subject's foot was unsupported which is discussed further in section 5.1.2 and 5.3.

Figures 4.3 – 4.5 show the total strain for each separate section of the mid-line section for each subject. From figure 4.3 it can be seen that subject 7 has a significantly reduced strain when compared to the other subjects. The raw data, calculations and data management have been checked thoroughly with no anomalies being found in that data or management.

One explanation for this may be because subject 7 had hairy legs (section 4.1) which may have caused the markers to be improperly affixed to the skins surface as with the other subjects who's legs were relatively hair free (even the other men).

The key points to be taken when analysing the results is that on average:

- The thigh of each subject experiences more strain than the knee, which then experiences more strain than the skin on the shank (figures 4.1 - 4.6).
- The skin on the shank experiences less of an initial stretch during lower flexion angles, which may be due to the "slack" being taken up by the thigh (figure 4.1).
- At low-mid flexion angles, the skin on the knee is subject to around 4/5 of the strain of the thigh. The shank is subject to around 2/5 the strain of the thigh and around 1/2 that of the knee (Figure 4.1).

5.1.2 Bi-axial Section Components

Figures 4.8 and 4.9 show that there is significantly more strain in the skin on the front sides of thigh than on the front sides of the shank which is to be expected because as the knee flexes, it pulls the skin over the knee away from the thigh rather than over the knee away from the ankle. Figure 4.9 may have been substantially different if the subjects' ankle was kept at a constant flexion angle which will be discussed in section 5.3. In particular, this limitation may have been the effecter in the results of subjects 5 and 8, which may explain why they have more shank strain as their foot may have been plantar flexed, stretching the skin.

Subject 6 has nearly 80% strain over the thigh which is at least 25% more than the other subjects. This may be due to an anomaly with the data but this is unlikely as the data follows the same trends/curve shape as the other subjects.

It is possible that, as this subject went through a daily regime to combat skin tension loss and wrinkles, (see notes in subject demographics section) and it was noticed that his skin looked overly tight and young for his age, this regime may be responsible.

We would expect from the literature reviewed in section 2.5.2 that as people get older, their skin would show less strain for the same angle of knee flexion, assuming that increased knee flexion increases the stress acting on the skin. At higher knee angles however, this may be negated as the stress/strain relationship seems to be the same at higher stresses (figure 2.13).

If we associate the results for the mid-section with the subject demographics, we can see that the older subjects (2, 9 and 10) seem to conform with the average strain for the overall mid-line section, thigh section and knee section but are below the average for the shank section. The exception is that subject 10 shows above average strain for the thigh section. The results for the shank section seem to relate to that of the reviewed literature and the subjects may have weakened collagen fibres present in the skin around their shank. This is however a weak assumption because only a very small group of subjects within a small age range was recruited meaning that many intrinsic factors may influence the results such as age, diet, weight, activity level etc. It is also unlikely that the subjects would have a significant deficiency in collagen in their shank skin compared with their thigh skin.

5.2 Horizontal Components

As can be seen from the results for the horizontal components at each section, there is very little consistency in the skin strain measurements between each subject which can be seen in both the graphical data (figures 4.11 and D2 – D5) and the standard deviations.

So to clarify, these problem components are:

- All horizontal strain components of the bi-axial square sections.
- Both the lateral and medial horizontal components at the knee centre.

This inconsistency may be due to a number of things including:

- The markers were moving longitudinally as well as laterally (on two planes) rather than just longitudinally as with the vertical components of the mid-line previously discussed. The analysis used did not account for this dual plane movement.
- The marker displacement taken was a straight line approximation absolute value, so did not take into account the curvature of the skin which, at the bi-axial square and horizontal knee centre strip locations, is likely to be extreme.
- As the bi-axial squares and horizontal knee centre strip are effectively on the side of the leg, they become invisible to cameras on the opposite side of the leg to them. This reduction in camera visibility may have caused errors to occur in virtual marker placement.

There is a slight exception with the horizontal medial component at the thigh (Figure D1) in that all of the subjects seem to follow a similar trend, however the SD is still very high.

Although the results are inconsistent for the horizontal components, we can still conclude over certain aspects of the results.

- The horizontal components show a maximum of 10% strain which is a lot less than the maximum strain of nearly 40% for the bi-axial vertical components or nearly 50% for the maximum strain for the main wound section. This is expected it is the movement of knee flexion that is being investigated.
- There is over all, a horizontal compression in the shank bi-axial sections as opposed to a horizontal stretch in the thigh bi-axial sections. This may be because, as the knee flexes, the skin on the back of the leg compresses and also, as the posterior of the lower thigh and upper shin meet at around 90^0, it forces the skin to compress around the sides of the leg further promoting compression on the front of the leg.

This can be seen in figure 4.3 at between 75^0 and 105^0 there is a sharper drop in strain.

The results over all show that the skin stretches due to increasing knee angle. They also show the skin strain at different regions of the leg and the relative magnitude and direction of this strain. As well as showing that further research should be carried out in this field e.g. To find what affect the horizontal strain has on the vertical strain, the results also illustrate how the skin strain due to knee flexion may be a major contributing factor to blistering in orthopaedic rehab. The results also show which areas of the skin around the knee may be aggravated most by an inelastic dressing.

5.3 Limitations

As this investigation was carried out using methods which had not been previously employed, there were some limitations involved.

- The physical camera set-up used for marker capture was designed for gait analysis so there was a large working volume for the cameras. The use of very small markers within this large volume may have lowered the accuracy of the cameras. This could be improved by relocating the cameras to give a smaller working volume that contained only the subject's leg. This limitation could not be overcome as the cameras were affixed permanently to immovable scaffolding bars around the lab, as they were used by other people when not used for this investigation.
- To calibrate the systems cameras involved waving a T-shaped wand with markers affixed, in front of the cameras. The markers affixed to the wand were of 12.5mm diameter and not the 3mm markers used for the investigation. This may have lowered the accuracy of the calibration and thus, the data capture. The time scale of this project precluded the manufacture/purchase and set up of an appropriate calibration device.
- The investigator was not fully trained on the software for camera calibration and data capture as no member of staff or other student in the department was familiar with this sort of static data capture of markers this size.

- This may or may not have been a limitation as the investigator was self taught, however there may have been unknown options open to the investigator which may have assisted the investigation.
- The subject's foot on the investigated leg was not fixed in place so there was control over their ankle flexion. It was however noticed that most of the subjects, if not all, kept their foot at a 90^0 angle to their shank as it was more comfortable. As this angle was not controlled however, the strain on the front of the shank in particular may have been affected and to what extent is unknown. Unfortunately this fact went unnoticed during method design and pilot testing and was only realised during subject testing, by which time it was too late to change the protocol.
- As the absolute displacement was taken between marker pairs, skin curvature may have been an issue because the actual skin surface strain could not be calculated but just the strain between marker centres.
- As this was an MSc thesis investigation, time was an issue and virtually every aspect of the investigation had to be carried out to very demanding deadlines. This limited the amount of pilot testing and ability to identify and rectify/remove some of the listed limitation. Ideally more testing would have been carried out before subject testing.

A number of the limitations may have been prevented if the investigator was more experienced in the use of the equipment, however issues such as these are to be expected when carrying out pioneering research and the methodology used in this investigation may prove useful if an investigation of this nature is ever undertaken again.

6. CONCLUSION

6.1 Conclusion

From the reviewed literature, it is clear that the issues surrounding TKR, the dressings used post-operation and the skin problems associated with these dressings are an issue in both the NHS and private practices in the UK. It is also noticed from the reviewed literature that dressing associated blistering evolves from shear forces acting between the adhesive portion of the dressing and the skin during rehabilitation routines.

The blistering issue needs to be addressed and further research is required to increase the knowledge in this field and combat the problem. This investigation may lay the foundations for future investigation as the results found give an indication of the magnitude of strain occurring over the knee and specifically that dressings should be designed to comply with up to a 50% strain in certain areas.

The method was based on another method used to measure the strain of a TKR wound [55], but this study used different equipment and covered a greater area of skin. While this limits the extent to which direct comparisons can be drawn, the results collected are somewhat consistent with the literature of previous investigations which have been carried out in this field. The results also show that using infra-red 3D motion capture is a feasible method of finding skin displacements and strain.

APPENDIX A

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APPENDIX B

Marker Template

1. Lateral distal shank 2
2. lateral proximal shank 2
3. Lateral proximal shank 1
4. Lateral distal shank 1
5. Medial distal shank1
6. Medial distal shank 2
7. Medial proximal shank 2
8. Medial proximal shank 1
9. Lateral distal thigh 1
10. Lateral distal thigh 2
11. Lateral proximal thigh 2
12. Lateral proximal thigh 1
13. Medial distal thigh 1
14. Medial distal thigh 2
15. Medial proximal thigh 2
16. Medial proximal thigh 1
17. Shank 10
18. Shank 9
19. Shank 8
20. Shank 7
21. Shank 6
22. Shank 5
23. Shank 4
24. Shank 3
25. Shank2
26. Shank1
27. Knee joint centre
28. Thigh 1
29. Thigh 2
30. Thigh 3
31. Thigh 4
32. Thigh 5
33. Thigh 6
34. Thigh 7
35. Thigh 8
36. Thigh 9
37. Thigh 10
38. Patella medial 1
39. Patella medial 2
40. Patella medial 3
41. Patela lateral 1
42. Patella lateral 2
43. Patella lateral 3

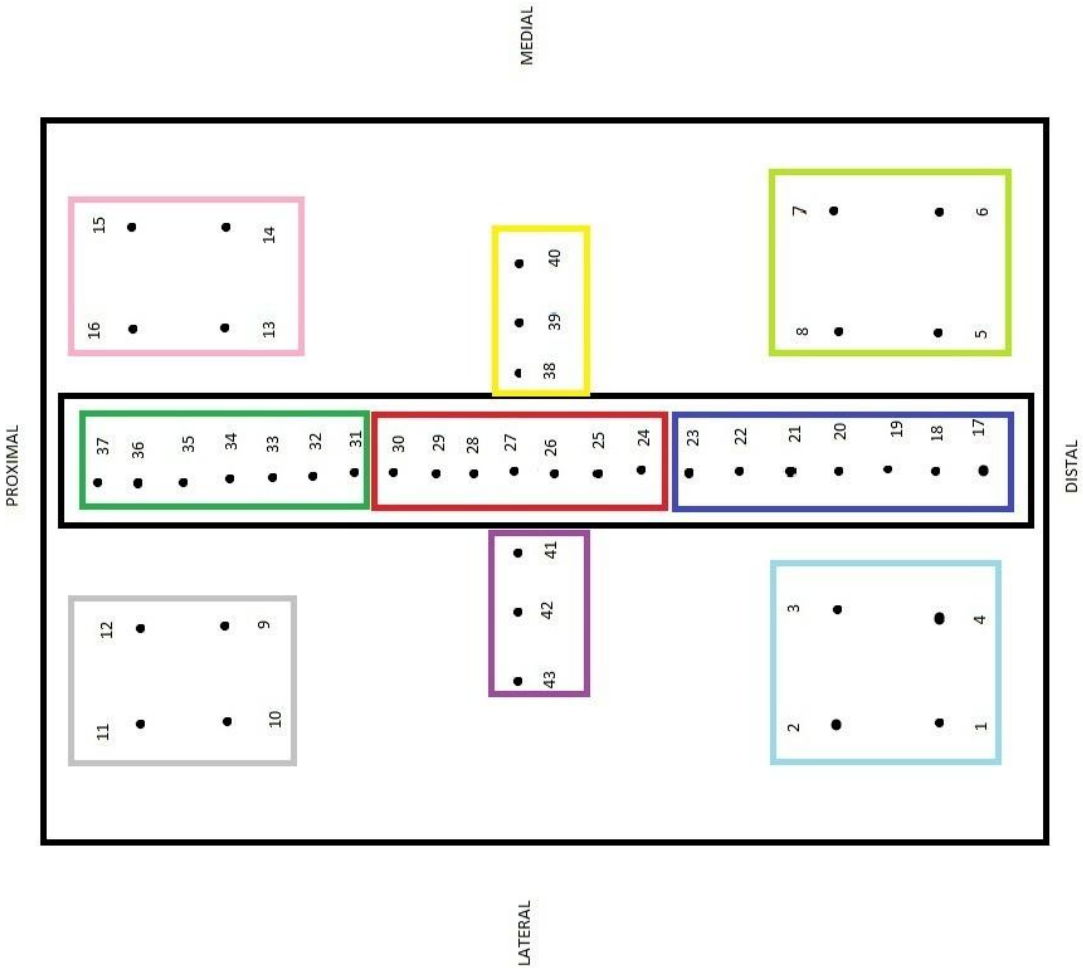

Figure B1 – Marker Template and Key

APPENDIX C

Ethics Forms

University and Departmental Ethics Committees Application Form

APPLICATION FORM FOR UNIVERSITY ETHICS COMMITTEE AND DEPARTMENTAL ETHICS COMMITTEES

Purpose

This form applies to all investigations (other than generic applications) on human participants undertaken by staff or students of the University that fall within the scope of the University's Code of Practice on Investigations involving Human Beings. Such investigations may fall within the remit of the University Ethics Committee (see Code of Practice Section B1) or the Departmental Ethics Committees (see Code of Practice Section B2). However, this form should NOT be used for generic applications (there is a separate form for this) or any investigation involving clinical trials or the National Health Service (including staff, patients, facilities, data, tissue, blood or organ samples from the NHS). Applications for investigations involving the NHS must be made under the governance arrangements for National Health Service Research Ethics Committees (see Code of Practice Section B9) and where ethical approval is required from the NHS the form to be used is that issued by IRAS.

Language

The form should be completed in language that is understandable by a lay person. Please explain any abbreviations or acronyms used in the application. Guidance on completing this application form is attached in order to assist applicants and further information is available in the Code of Practice.

Attachments

Information sheets for volunteers and consent forms to be used in the investigation must be submitted with the application form for consideration by the Committee. Templates for the information sheets and consent forms can be found on the Ethics web page. The application will be judged entirely on the information provided in this form and any accompanying documentation – full grant proposals to funding bodies should NOT be attached. Applications which are not signed and/or do not include the required additional information (e.g. information sheet and consent form) will not be considered by the Ethics Committee and will be referred back to the Chief Investigator.

Completion

The form is designed for completion in Word, and should in any case be typed rather than handwritten. The grey-shaded text boxes on the form will expand to allow you to enter as much information as you require. Please do not alter any of the text outside the shades areas. If you have any difficulty filling out the form in Word, please contact ethics@strath.ac.uk.

1

University and Departmental Ethics Committees Application Form

Please click on the for guidance on how to complete each section of the form.

PLEASE COMPLETE THE FORM IN BOLD TYPE FACE

Checklist of enclosed Documents

Document	Enclosed	N/A
Participant information sheet(s)	☒	☐
Consent form(s)	☒	☐
Sample questionnaire(s)	☐	☒
Sample interview format(s)	☐	☒
Sample advertisement(s)	☐	☒
Any other documents (please specify below)	☐	☒
	☐	☒
	☐	☒
	☐	☒

1. Chief Investigator (Ordinance 16 member of staff only)

Name: Philip Riches
Status: Course Leader — Professor ☐ Reader ☐ Senior Lecturer ☐ Lecturer ☒
Department: Bioengineering
Contact Details: Telephone: 0141 548 5703
E-mail: philip.riches@strath.ac.uk

2. Other Strathclyde Investigator(s)

Name(s): Scott Chalmers
Status (e.g. lecturer, post-/undergraduate): Post-Graduate
Department(s): Bioengineering
If student(s), name of supervisor: Angela Deakin
Contact Details: Telephone: 07872449829
E-mail: scott.chalmers.100@strath.ac.uk
Details for all investigators involved in the study:

3. Non-Strathclyde collaborating investigator(s)

Name(s): Angela Deakin
Status: Honorary research fellow
Department/Institution: Bioengineering Unit
If student(s), name of supervisor:
Contact Details: Telephone: 0141 951 5946
E-mail: Angela.Deakin@strath.ac.uk
Please provide details for all investigators involved in the study:

2

4. Overseas Supervisor(s)

Name(s):

Status:

Department/Institution:

Contact Details: Telephone:

E-mail:

I can confirm that the local supervisor has obtained a copy of the Code of Practice: Yes ☐ No ☐

Please provide details for all supervisors involved in the study

5. Title of the Investigation:

Evaluation of skin strain during knee movement using 3D motion analysis

6. Where will the investigation be conducted:

Biomechanics Lab 3
Department of bioengineering
Wolfson Building
106 Rottenrow
University of Strathclyde
Glasgow

7. Duration of the Investigation (years/months):

(Expected) start date: **01 / 07 / 2011**

(Expected) completion date: **29 / 07 / 2011**

8. Sponsor (please refer to Section C and Annex 3 of the Code of Practice):

NA

9. Funding Body (if applicable)

NA

Status of proposal – if seeking funding (please click appropriate box):

In preparation ☐ **Submitted** ☐ **Accepted** ☐

Date of Submission of proposal: / /

Date of start of funding: / /

10. Objectives of investigation (including the academic rationale and justification for the investigation)

The objective of this study is to monitor skin displacement around the knee of each participant using 3D (three dimensional) motion analysis. The findings will then be used to calculate the 3D strain of the skin in this region. During patient rehabilitation of TKA (total knee arthroplasty), the dressings used post-operation can cause blistering to occur around the wound. This blistering could be prevented if dressings were designed in such a way as to accommodate the movement of the skin. This investigation is important as it will allow this skin displacement to be quantified and the strain calculated, in order to determine how the design of dressings could be improved to combat the occurrence of blisters in TKA rehabilitation.

11. Nature of the participants:

Are any of the categories mentioned in Section B1(b) (participant considerations) applicable in this investigation? Yes ☐ No ☒

If 'yes' please detail:

Number: **10** Age (range): **Ideally Over 60 or Over 18.**

Please also include information on: recruitment methods (see section B4 of the Code of Practice); inclusion/exclusion criteria; and any further screening procedure to be used

Recruitment: E-mail to secretary/organiser of Learning in Later Life Programme (LLLP) with description of study and to ask if it would be possible for them to stock information sheets in the foyer of the LLLP. Information booklets will be available for the students to take away. The students will have up to 2 weeks to get in touch with the researcher. Patients will be given information on when to attend the lab when they show a definite interest in participating in the investigation. If this fails to meet recruitment targets, an e-mail will be sent round the Bioengineering department and a notice posted in the Wolfson building asking for recruits.

Exclusion Criteria
- Volunteers unable to bend their knee to 105°
- Volunteers with skin problems/delicate skin (such as may be found with diabetics)

Inclusion Criteria
- All recruited subjects must be healthy and able.
- Volunteers must have good motor control.

Investigations governed by the Code of Practice that involve any of the types of projects listed in B1(b) must be submitted to the University Ethics Committee for prior approval.

12. What consents will be sought and how?

The information sheets and consent forms to be used should be attached to this form.

Information sheets will be stocked in the foyer of the LLLP. The students will then have the chance to read over the information and show their interest. The participants will receive a consent form on arrival at the lab and prior to any testing and will have final chance to opt out of the study before testing is immediately begun.

13. Methodology:

Are any of the categories mentioned in the Code of Practice Section B1(a) (project considerations) applicable in this investigation? Yes ☐ No ☒

If 'yes' please detail:

Design: what kind of design/research method(s) is/are to be used in the investigation?

The design methods to be used involve using a VICON motion capture system to monitor markers attached to the skin of the participant's leg. The angle of flexion will be measured with an electronic goniometer.

Techniques: what specific techniques will be employed and what exactly is required of participants?

An electronic goniometer will be affixed to the participant's leg to measure the angle from 0° through 105° in 15° increments. Participants will have reflective markers attached to their skin. Markers will be positioned in a vertical single line in the frontal plane from distal thigh to proximal shin. Two horizontal lines of markers will be placed on the participant's skin in the frontal plane 7.5cm above and below the knee with 2 more markers placed either side of the central marker attached at the knee. The markers will be monitored at each set increment of 15°. The participant will be assisted in holding the leg in position by placing supports of different heights under the foot of the investigated leg. Participants will have photographs taken of them throughout the study and some may have a video taken of the process for referral purposes. The participant has the option to opt out of any media capture. The need

for media capture of the subject arises due to the need to illustrate the stages carried out in the study and for referencing purposes.

Investigations governed by the Code of Practice that involve any of the types of projects listed in B1(a) must be submitted to the University Ethics Committee for prior approval.

Has this methodology been subject to independent scrutiny? Yes ☐ No ☒

Please provide the name and contact details of the independent reviewer

Where an independent reviewer is not used, then the UEC/ DEC reserves the right to scrutinise the methodology.

14. Data collection, storage and security:

Explain how data are handled, specifying whether it will be fully anonymised, pseudo-anonymised, or just confidential, and whether it will be securely destroyed after use.

Data will be fully anonymised in a numbered format for the participants (participant X).

Explain how and where it will be stored, who has access to it, and how long it will be stored.

Anonymised data will initially be collected and stored on the VICON workstation before being stored on the University H: drive which is password protected. Access will be available to the above named investigators stored on password protected computers. Media will be stored on a secure external HDD and will only be available to above named investigators. Anonymised data and pictures may be kept indefinitely for future analysis.

Will anyone other than the named investigators have access to the data? If 'yes' please explain.

15. Potential risks or hazards:

If the participant has poor leg and hip musculature, they may find it hard to maintain leg position at the desired angle. The variable supports are in position under the foot to help the participant maintain position. If the participant is seated for an extended period, they may feel pain in the gluteus region. This may be combated with the use of a cushion. The participant may feel discomfort on the application and removal of the reflective markers and goniometer as they are applied with sticky pads. To ensure no damage is done by the sticky pads, those with a poor quality of skin will be excluded from the study.

16. Ethical issues:

The procedure is entirely non-invasive. However, the investigation relies on the participant giving up their time to take part in a study which may not have any direct benefit to them. Participants may be unsure as to whether their data is being kept entirely confidential throughout the investigation and after completion of the study. Participants may have an issue with having to bare their skin on the lower thigh and upper shin area. The only assurance that can be given to the participant on this matter is that no one other than the investigator and the participant will be allowed into the lab during testing. The subject may be uncomfortable with having pictures or video taken of them and will be asked in advance whether this will be appropriate. Considering the ethical issues with media capture, the subject of course has every right to refuse to have photos/video taken of them.

17. Any payment to be made:

NA

18. What debriefing, if any, will be given to participants?

NA

19. How will the outcomes of the study be disseminated? Will you seek to publish the results?

It is intended to publish the outcomes of the study at appropriate conferences and if of an appropriate standard, in a peer reviewed journal.

-The outcomes of the investigation will be published in the MSc thesis of Scott Chalmers

20. Nominated person (and contact details) to whom participants' concerns/ questions should be directed before, during or after the investigation.

Scott Chalmers

Scott.chalmers.100@strath.ac.uk

07872449829

21. Previous experience of the investigator(s) with the procedures involved.

Dr. Riches is competent in the use of the VICON system

Scott Chalmers will be given appropriate training in both the use of the VICON system and the electrogoniometer.

22. Chief Investigator and Head of Department Declaration

I have read the University's Code of Practice on Investigations involving Human Beings and have completed this application accordingly.

Signature of Chief Investigator

Please also type name here: Philip Riches

I confirm I have read and approved this application.

Signature of Head of Department

Please also type name here: PROF Terry Gourlay
Acting HoD

Date: 1 / 07 / 2011

N.B. Unsigned applications will not be accepted

23. Only for University sponsored projects under the remit of the DEC, with no external funding and no NHS involvement.

Head of Department statement on Sponsorship

This application requires the University to sponsor the investigation. This is done by the Head of Department for all DEC applications with exception of those that are externally funded and those which are connected to the NHS (those exceptions should be submitted to R&KES). I am aware of the implications of University sponsorship of the investigation and have assessed this investigation with respect to sponsorship and management risk. As this particular investigation is within the remit of the DEC and has no external funding and no NHS involvement, I agree on behalf of the University that the University is the appropriate sponsor of the investigation and there are no management risks posed by the investigation.

If not applicable, click here ☒

Signature of Head of Department

Please also type name here

Date: / /

For applications to the University Ethics Committee the completed form should be sent to ethics@strath.ac.uk with the relevant electronic signatures.

Participant Information Sheet

Name of department:

University of Strathclyde Glasgow
Bioengineering

Title of the study: Evaluation of skin strain during knee movement using 3D motion analysis.

Introduction

My name is Scott Chalmers and I am a postgraduate student undertaking the MSc in Bioengineering at the University of Strathclyde. Thank you for taking the time to read this information sheet and for showing interest in my project.

If you have any questions regarding this investigation, please don't hesitate to contact me via e-mail or phone of which contact details can be found at the end of this document.

What is the purpose of this investigation?

The objective of this study is to understand how the skin stretches around the knee when the knee is being bent. This is important because during rehabilitation following a knee joint replacement, the dressings used can cause blistering to occur around the wound. This blistering could be prevented if dressings were designed in such a way as to accommodate the stretch of the skin.

The purpose of this investigation is therefore to measure the stretch of the skin around the knee in order to inform the design of wound dressings to lessen the occurrence of blisters following knee replacement surgery.

Do you have to take part?

No. Participation is entirely voluntary, and even if you volunteer, you may withdraw at any time. Furthermore, participation or withdrawal will not affect, in any way, your standing with the University.

What will you do in the project?

If you volunteer, you will be invited to attend the Bioengineering Unit at the following address:

Bioengineering Unit
University of Strathclyde
Wolfson Building
106 Rottenrow
Glasgow
G4 0NW

Please could you bring a pair of shorts with you in which to change in to.

On arrival you'll be escorted to the biomechanics laboratory, and you'll be asked to change into your shorts in a private changing area. Once ready, a number of items will be attached to the skin around your knee using adhesive tape. These will be little (3mm) reflective balls that will measure the skin's movement, and a flexible device (called an electronic goniometer) that measures the bending of the knee.

You'll be surrounded by cameras that will be recording the position of the reflective balls. These cameras only pick up the ball location, and no other visual information is collected – i.e. you or your legs will not be seen. On the computer, all the researchers see are little white balls moving around on a black background. In addition to the motion analysis cameras, we may also like to take some normal photographs. These will help in the publishing of the project. Rest assured, all photos will have no distinguishing features (e.g. birth marks, tattoos) and will not include the face. You do not have to consent to being photographed, and you can still volunteer without the photographs being taken.

You'll be asked to sit in a chair with one leg fully extended and resting on a support, the other resting normally on the ground. The support will be positioned so you can comfortably bend your knee throughout the required range (0° – 105°) in seven steps of 15°. At each of these seven steps, you will be asked to hold your leg still in order to collect the data. This method of supporting the leg aims to prevent any discomfort while the investigation is carried out.

The reflective balls and the goniometer will be attached using sticky tape which may cause some discomfort on removal. It is also possible (although highly unlikely) that you may have a minor allergic reaction to the adhesive tape.

It is expected that the whole procedure should not take longer than 30 minutes.

Why have you been invited to take part?

You have been asked to volunteer for this investigation because you are an able bodied adult of an age where some of your peers undergo knee replacement surgery.

What are the potential risks to you in taking part?

This experiment is very simple, and we believe the only potential risk associated with you and this investigation is that your skin may be aggravated slightly by the use of the sticky tape.

What happens to the information in the project?

Your electronic data will be entirely anonymous and kept indefinitely on a password protected computer in the University. Furthermore, the University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

The data will be published in my MSc thesis, a copy of which will reside in the University library. Parts of this thesis may appear at appropriate conferences and be published in peer review journals. No information will be put in the public domain which will allow for your identity to be determined in any way.

What happens next?

If, after reading the above information, you are happy and willing to be involved with this investigation, **please let me, the researcher know by the 10th of July** and I'll be in contact to discuss an appropriate day and time for you to attend the laboratory. However, if you do not wish to be involved in the investigation, I thank you for your attention.

Researcher Contact Details:

Scott Chalmers
Bioengineering MSc student
E-mail: scott.chalmers.100@strath.ac.uk

Telephone: 07872449829

Chief Investigator Details:

Dr Philip Riches
Lecturer
Bioengineering Unit
E-mail: philip.riches@strath.ac.uk
Telephone: 0141 548 5703

Thank you for reading this information – please ask any questions if you are unsure about what is written here.

This investigation was granted ethical approval by the University of Strathclyde ethics committee. If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Secretary to the University Ethics Committee
Research & Knowledge Exchange Services
University of Strathclyde
Graham Hills Building
50 George Street
Glasgow
G1 1QE
Telephone: 0141 548 3707
Email: ethics@strath.ac.uk

Consent Form

University of Strathclyde Glasgow

Name of department: Bioengineering

Title of study: Evaluation of skin strain during knee movement using 3D motion analysis.

- I confirm that I have read and understood the information sheet for the above project and the researcher has answered any queries to my satisfaction.
- I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.
- I understand that I can withdraw my data from the study at any time.
- I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.
- I consent to being a participant in the project
- I consent to being video recorded and have pictures taken of me as part of the project
  Yes/ No

I (PRINT NAME)	Hereby agree to take part in the above project
Signature of Participant:	Date

APPENDIX D

Horizontal Strain Components

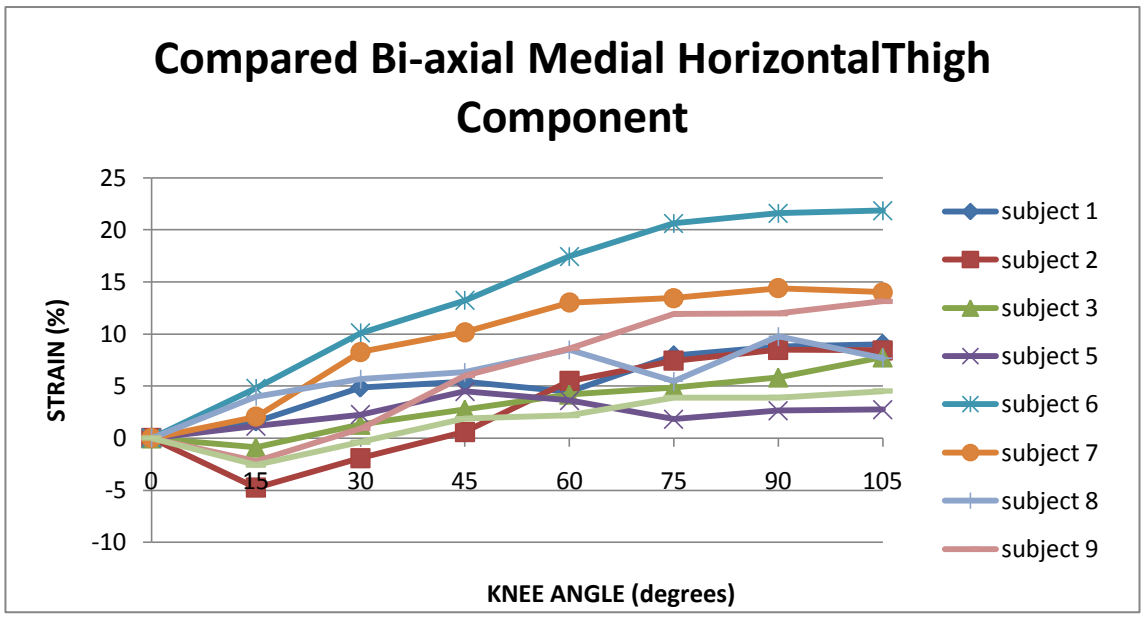

Figure D1 – Medial Thigh Bi-axial Square Horizontal Component

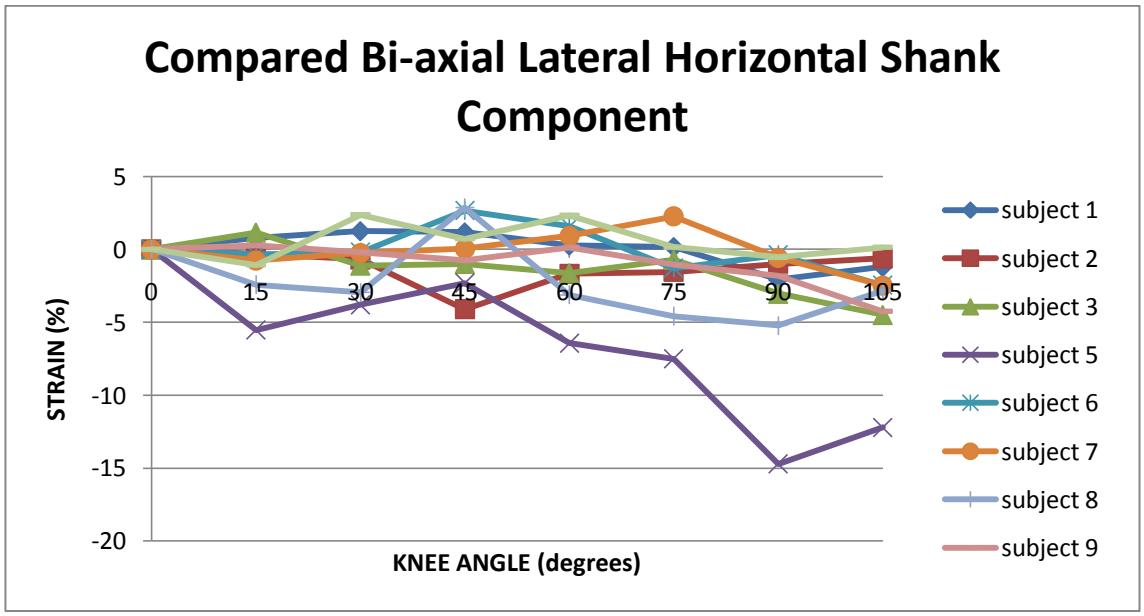

Figure D2 – Lateral Shank Bi-axial Square Horizontal Component

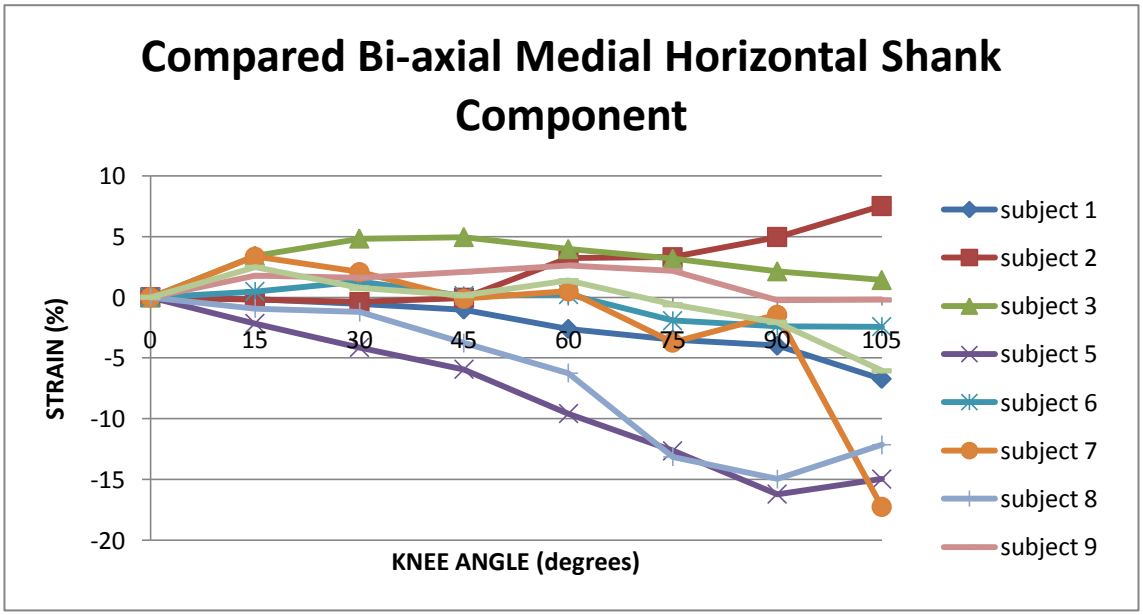

Figure D3 – Medial Shank Bi-axial Square Horizontal Component

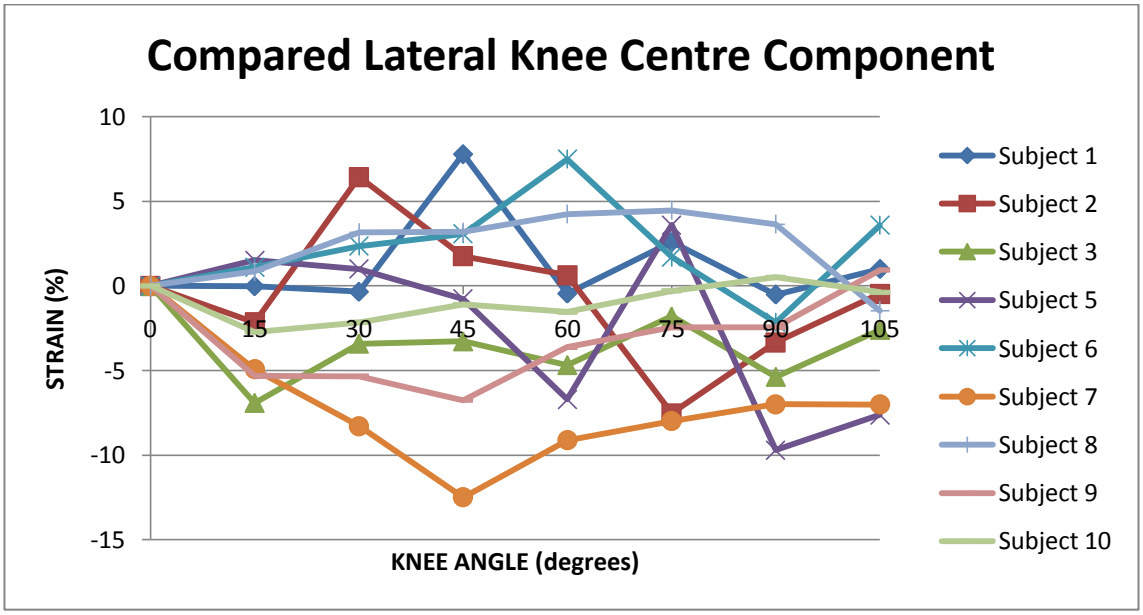

Figure D4 – Lateral Knee Centre Component

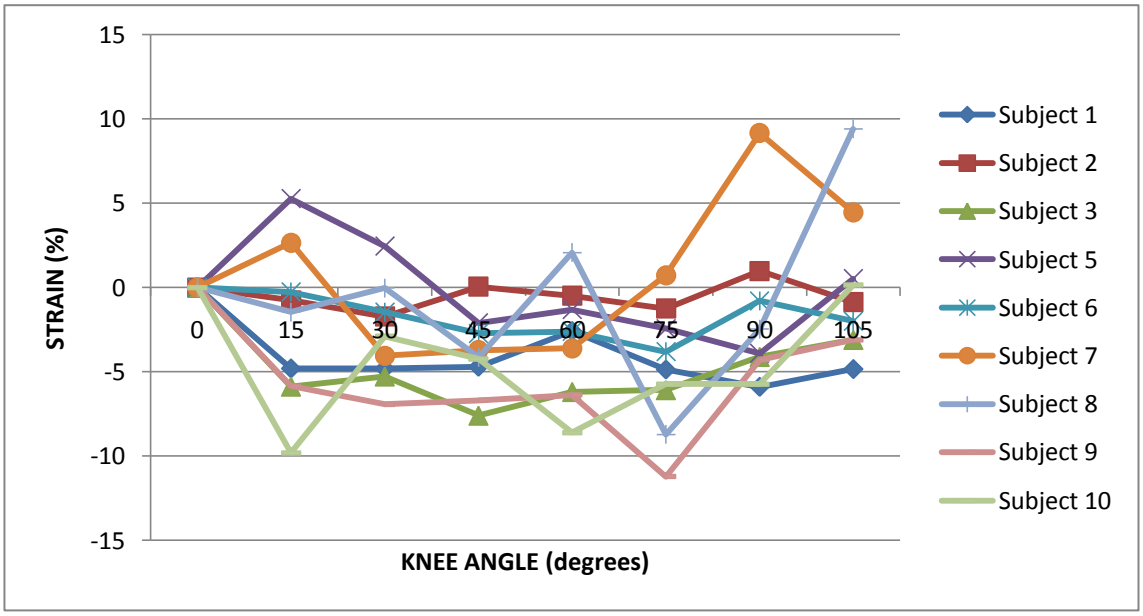

Figure D5 – Medial Knee Centre Component

VERTICAL STRAIN COMPONENTS

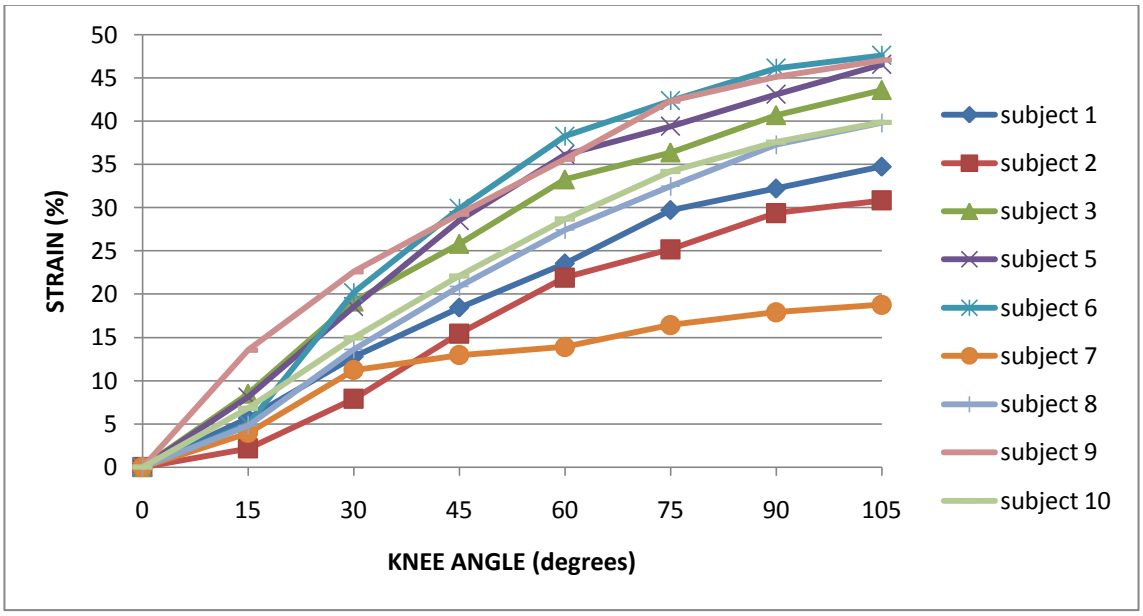

Figure D6 - Lateral Thigh Bi-axial Square Vertical Component

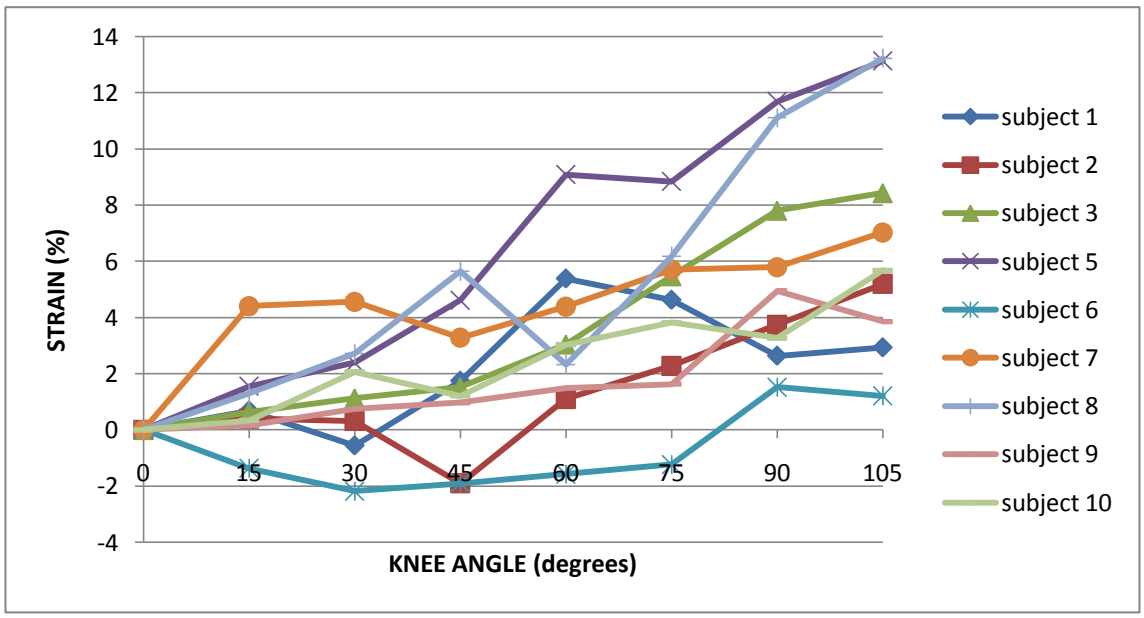

Figure D7 - Lateral Shank Bi-axial Square Vertical Component

APPEDNIX E

INDIVIDUAL SUBJECT RESULTS – MID-LINE TOTALS

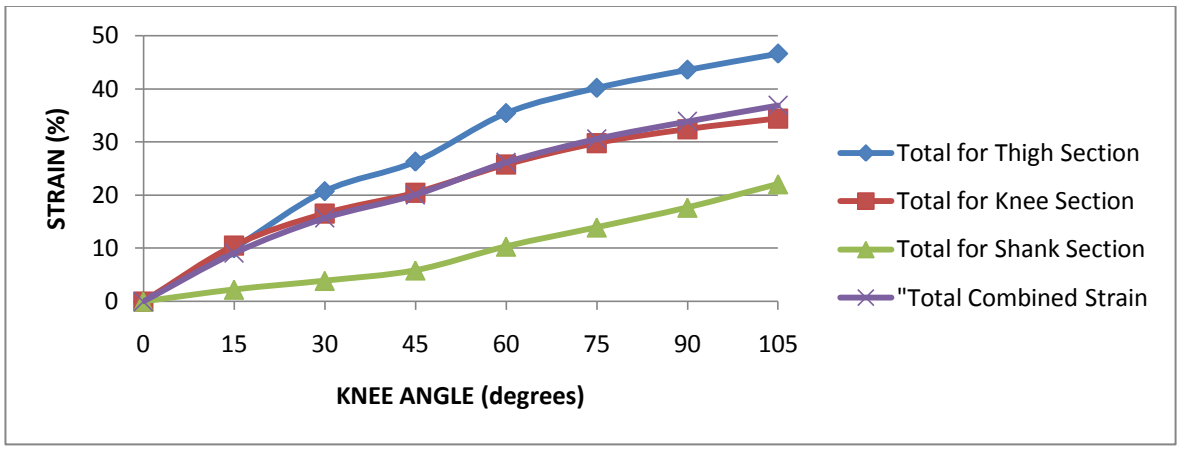

Figure E1 – Subject 1 mid-line Section Strain

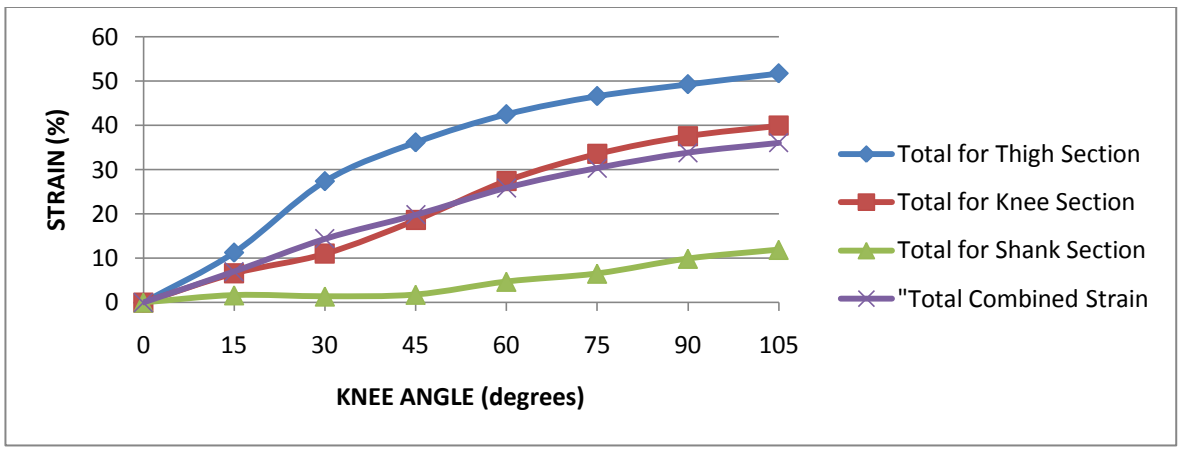

Figure E2 – Subject 2 Mid-line Section Strain

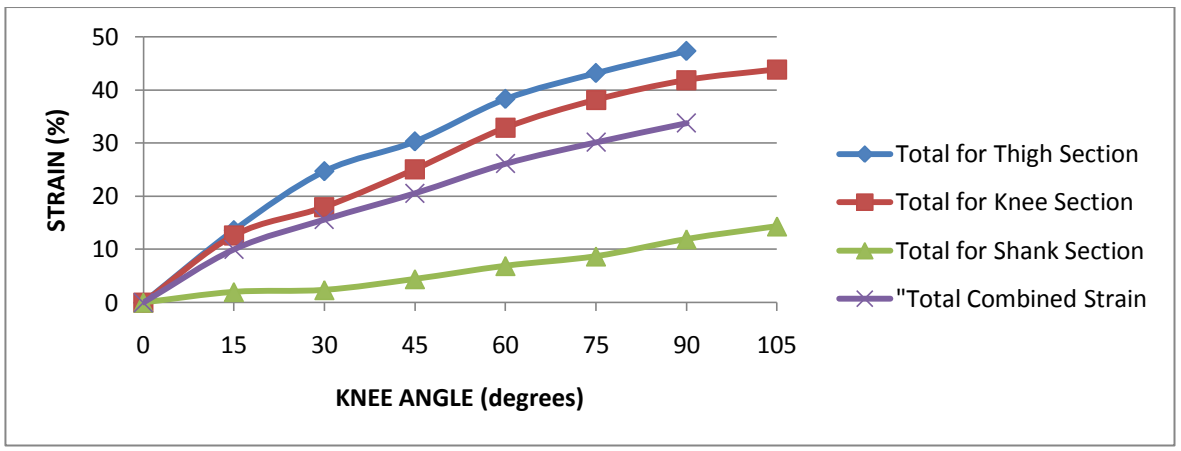

Figure E3 – Subject 3 Mid-line Section Strain

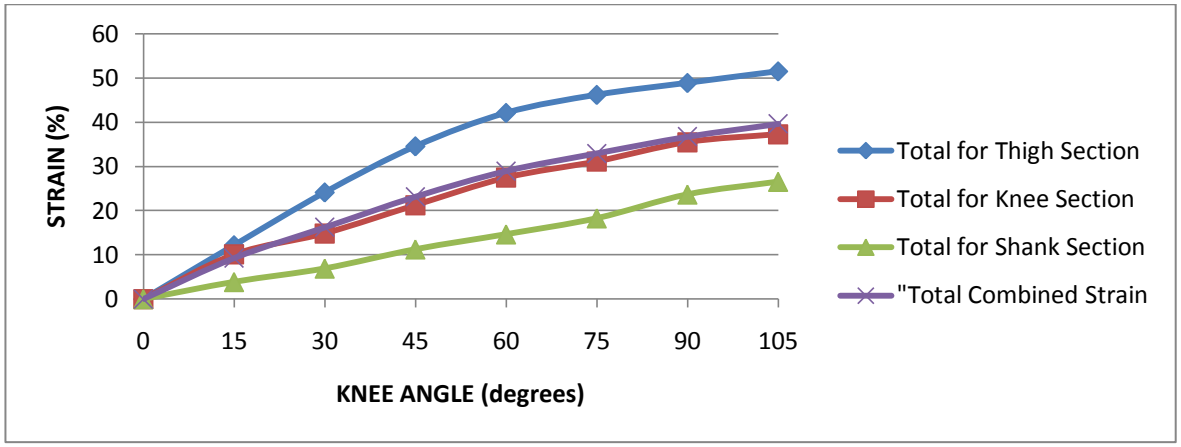

Figure E4 – Subject 5 Mid-line Section Strain

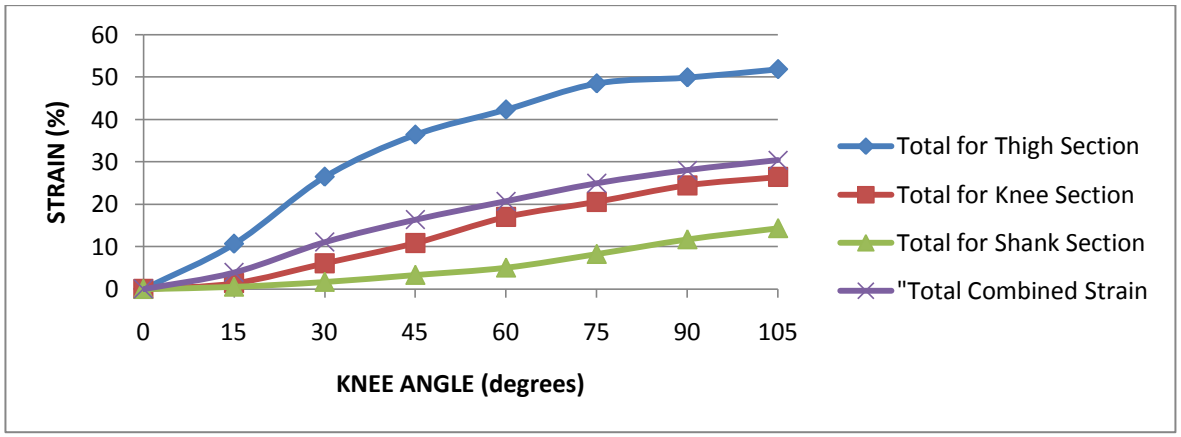

Figure E5 – Subject 6 Mid-line Section Strain

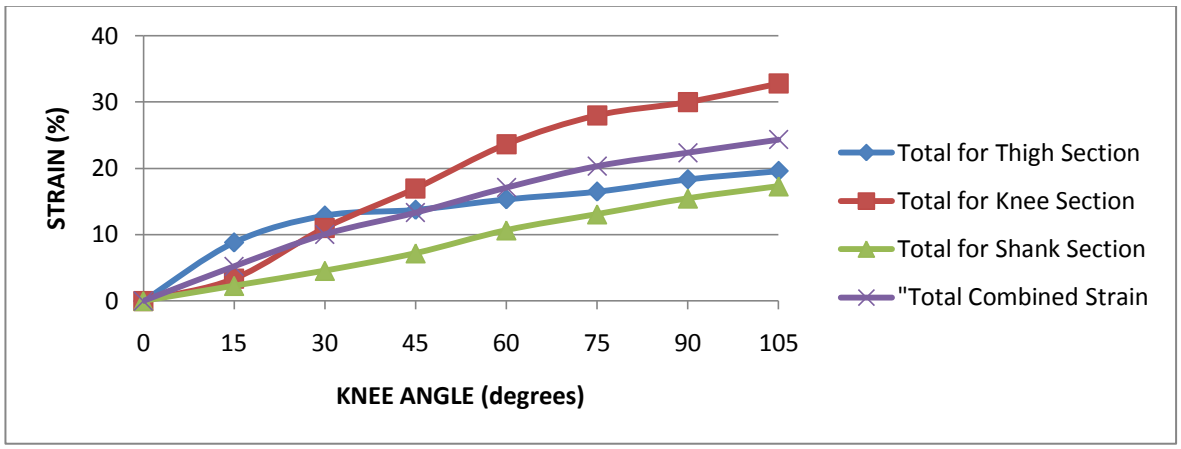

Figure E6 – Subject 7 Mid-line Section Strain

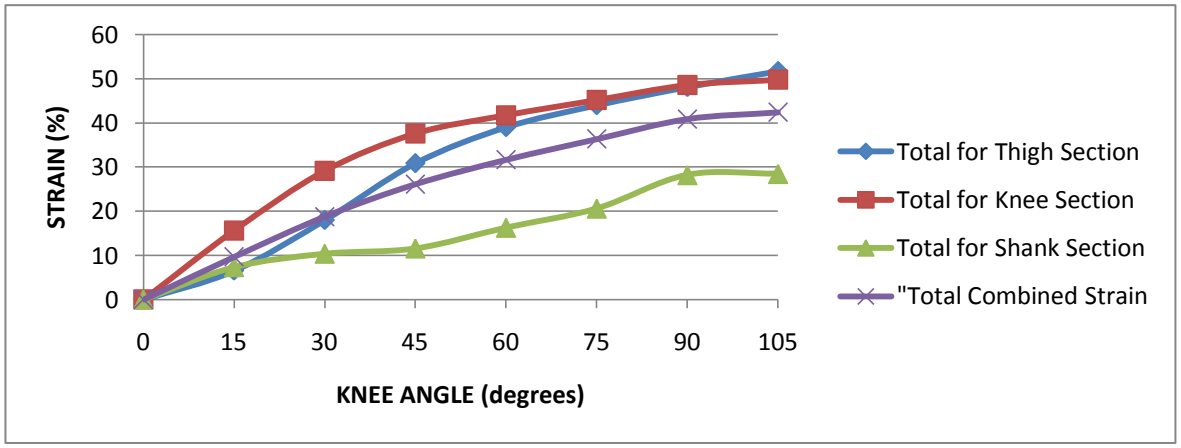

Figure E7 – Subject 8 Mid-line Section Strain

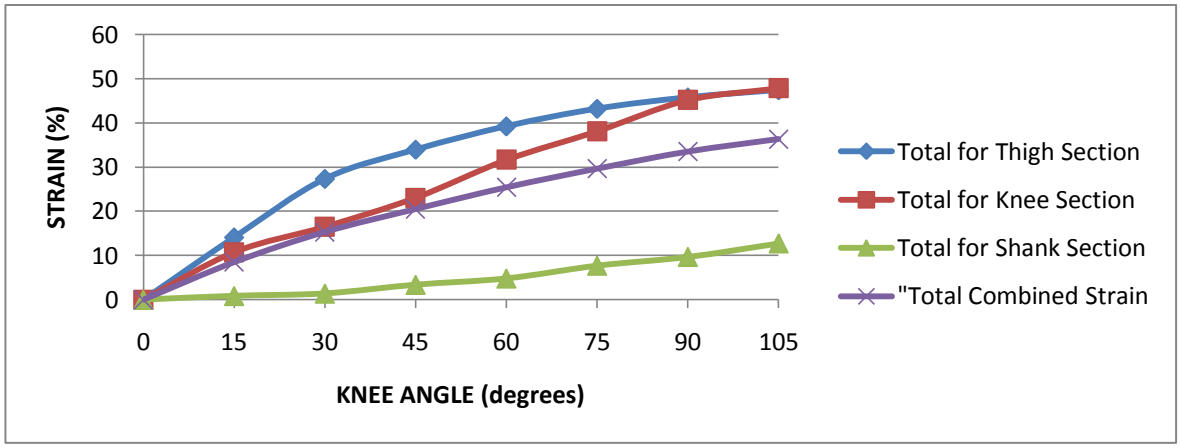

Figure E8 – Subject 9 Mid-line Section Strain

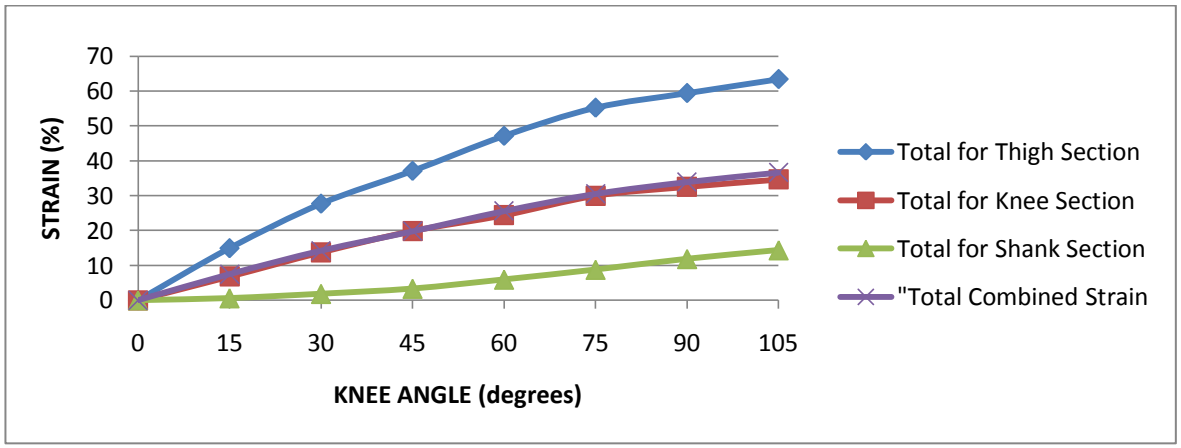

Figure E9 – Subject 10 Mid-line Section Strain

INDIVIDUAL SUBJECT RESULTS – MID-LINE MARKER PAIRS

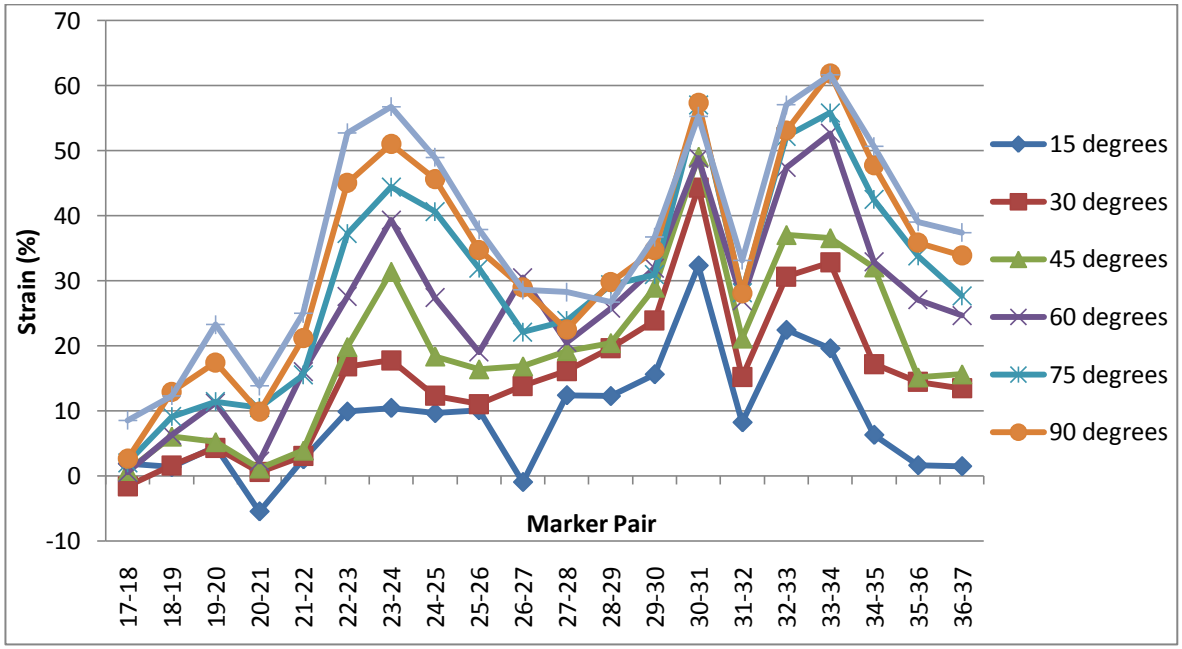

Figure E10 – Subject 1 Individual Marker Pair Strain on the Mid-line Section

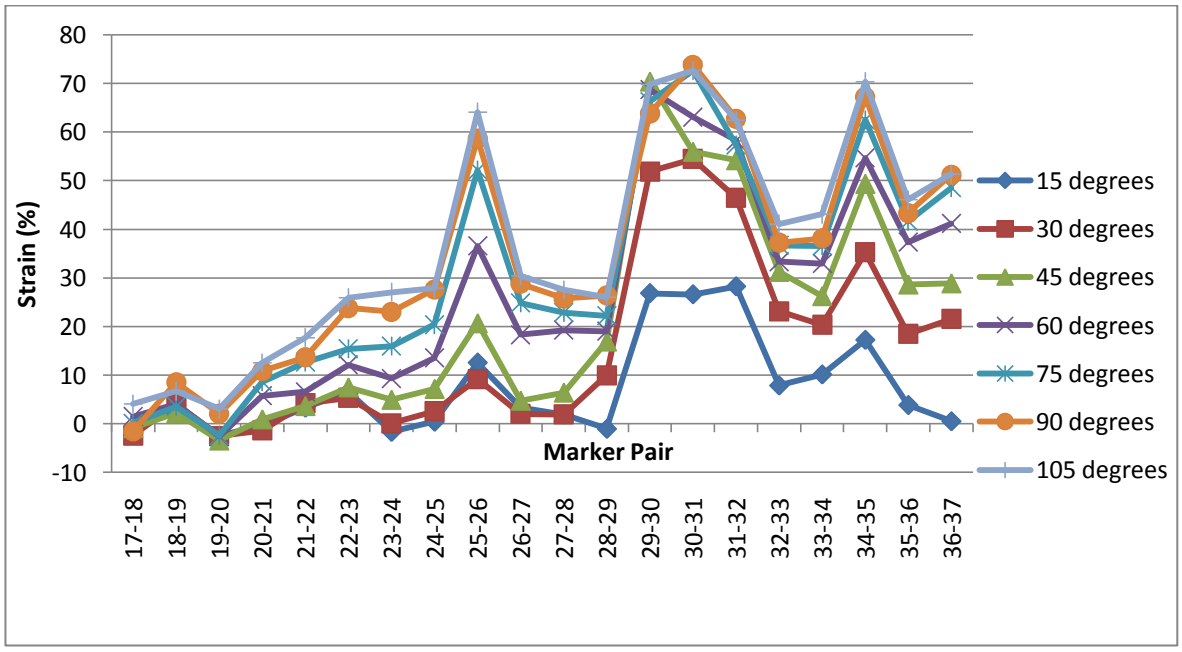

Figure E11 – Subject 2 Individual Marker Pair Strain on the Mid-line Section

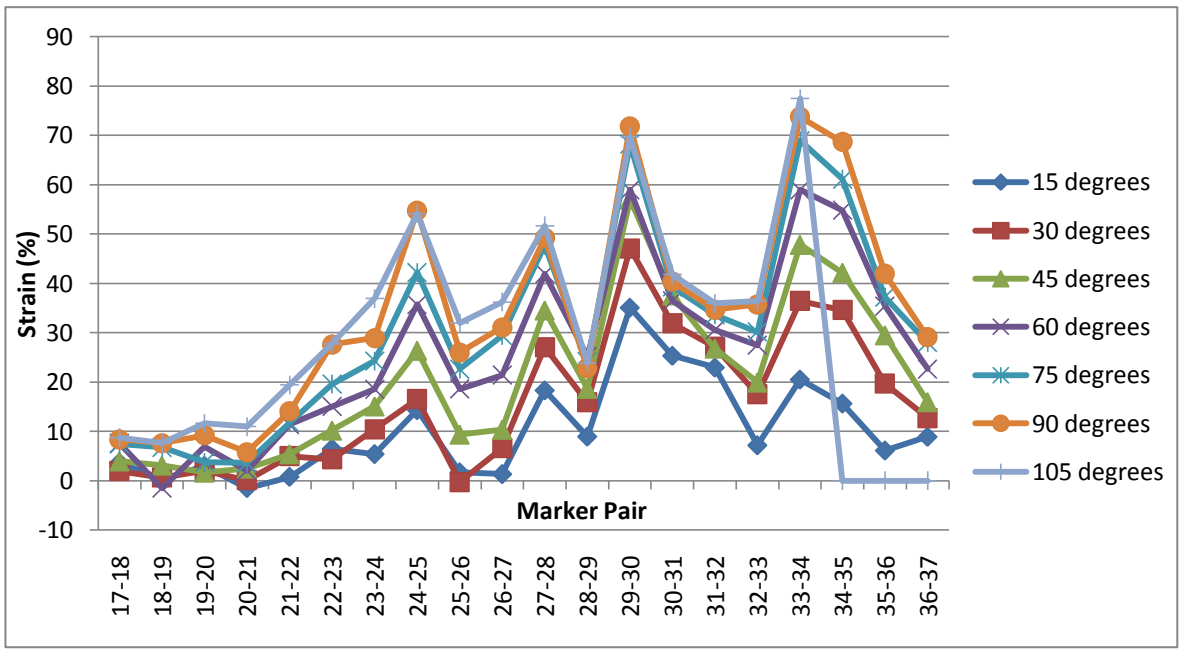

Figure E12 – Subject 3 Individual Marker Pair Strain on the Mid-line Section

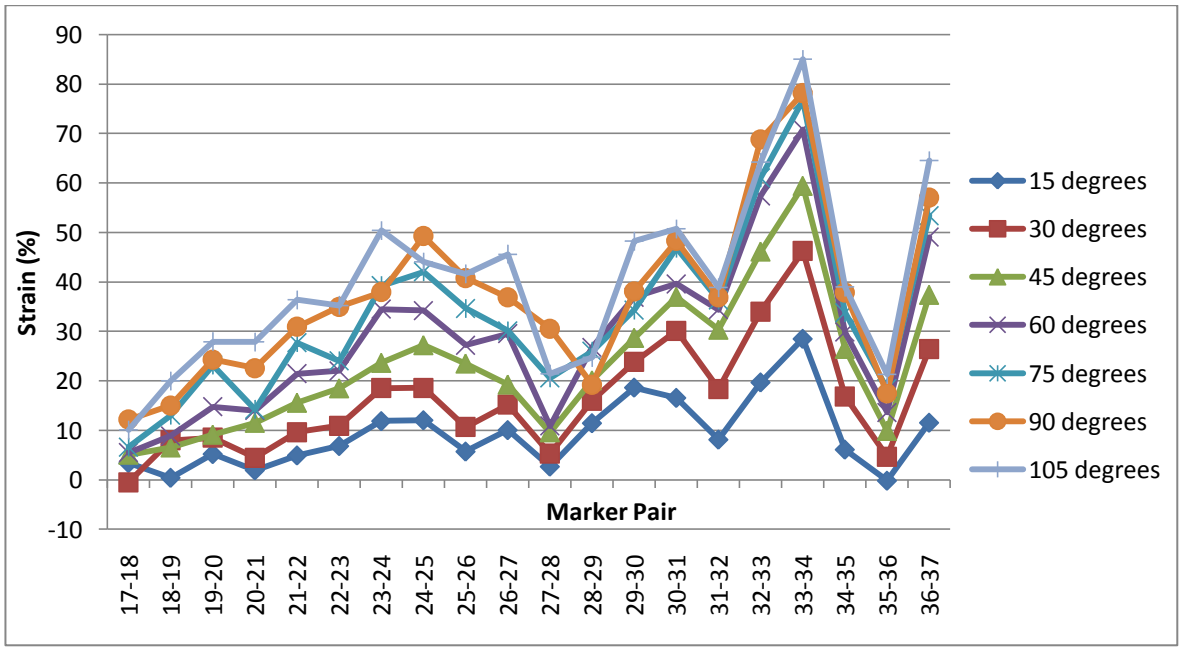

Figure E13 – Subject 5 Individual Marker Pair Strain on the Mid-line Section

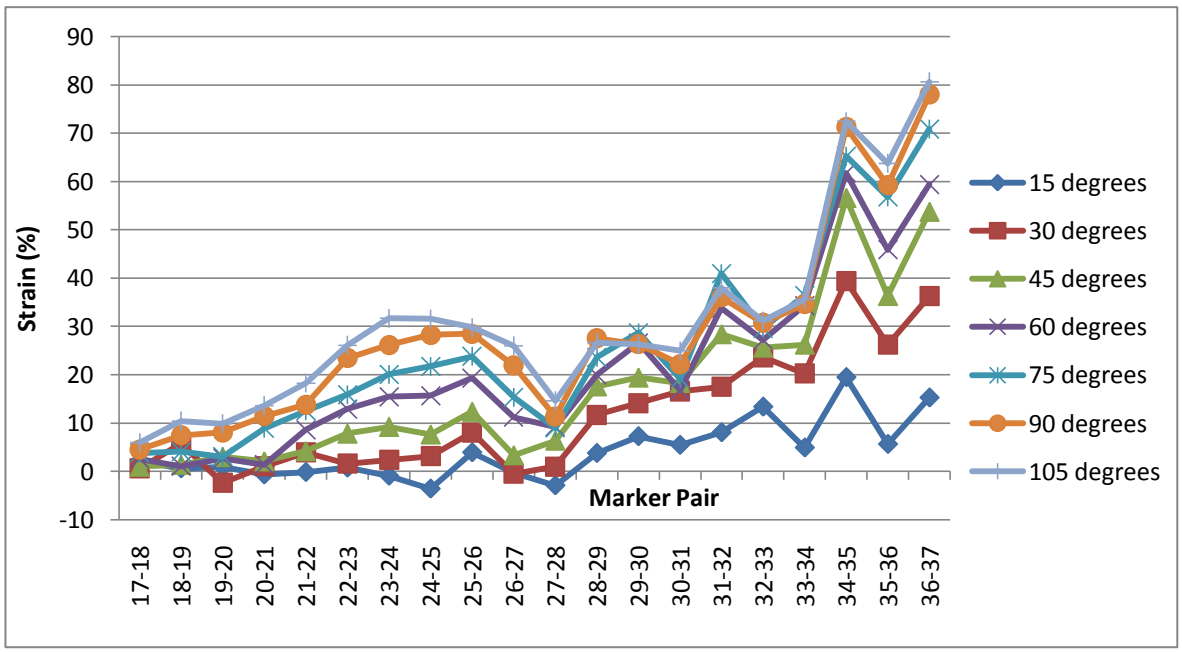

Figure E14 – Subject 6 Individual Marker Pair Strain on the Mid-line Section

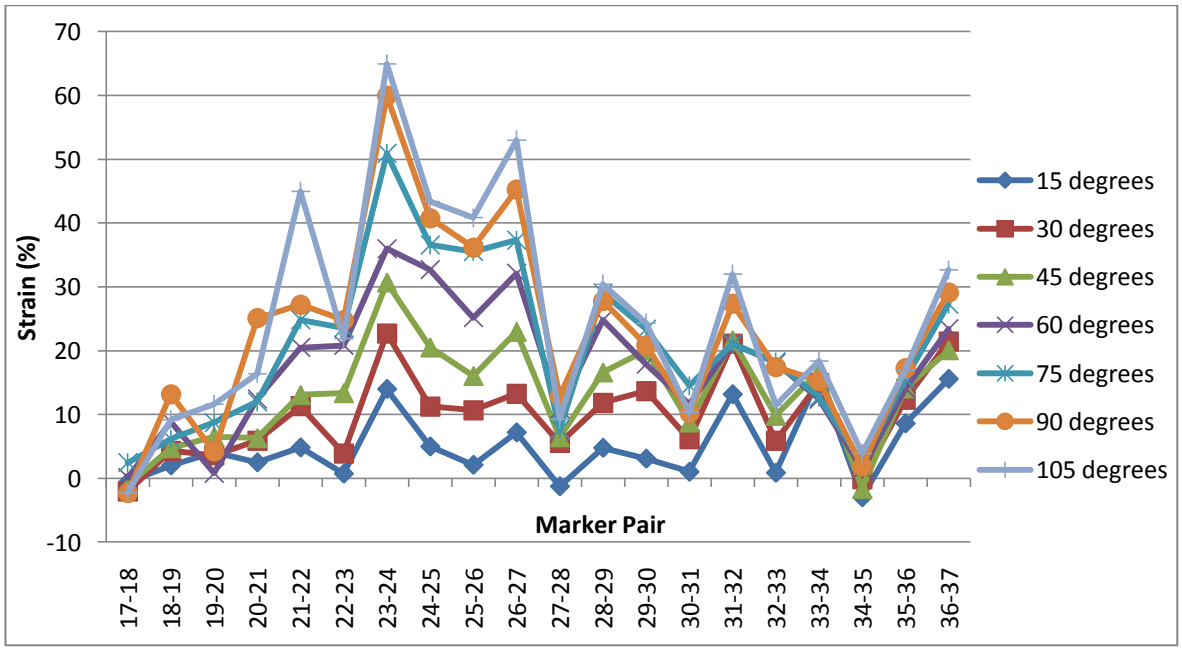

Figure E15 – Subject 7 Individual Marker Pair Strain on the Mid-line Section

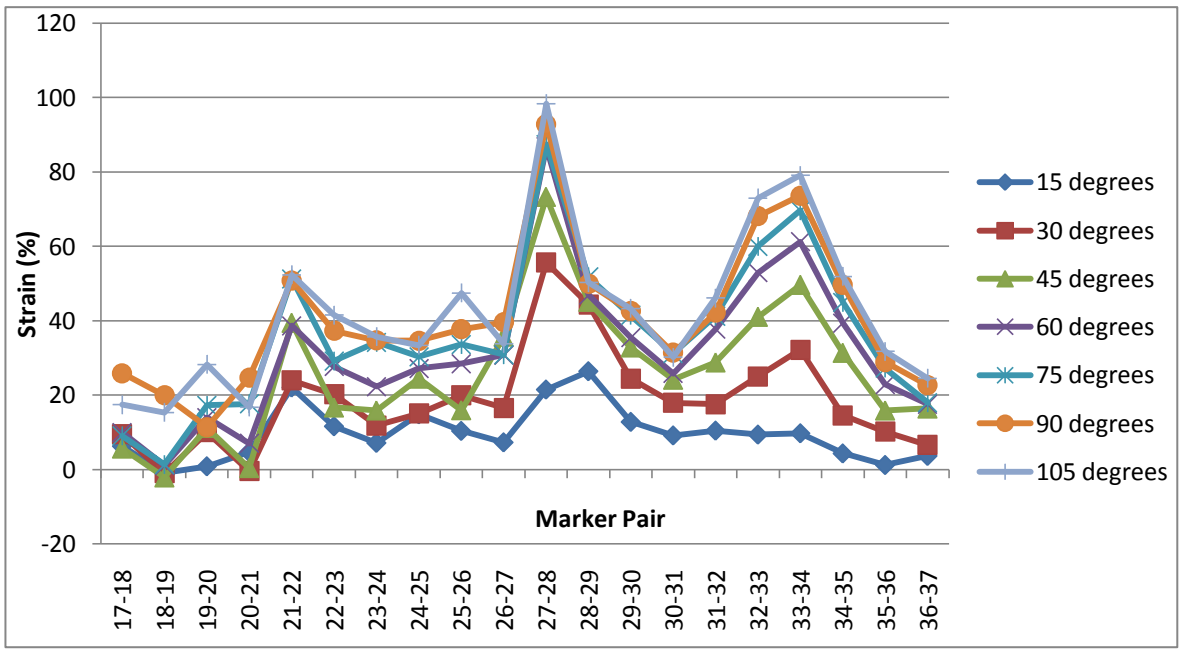

Figure E16 – Subject 8 Individual Marker Pair Strain on the Mid-line Section

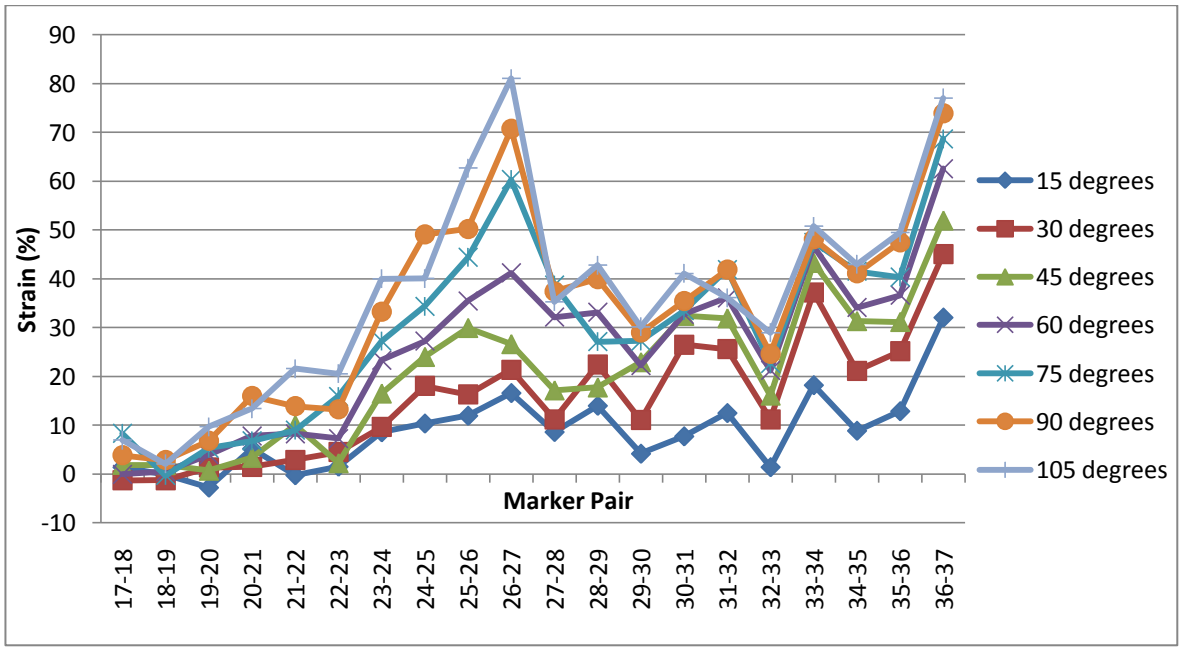

Figure E17 – Subject 9 Individual Marker Pair Strain on the Mid-line Section

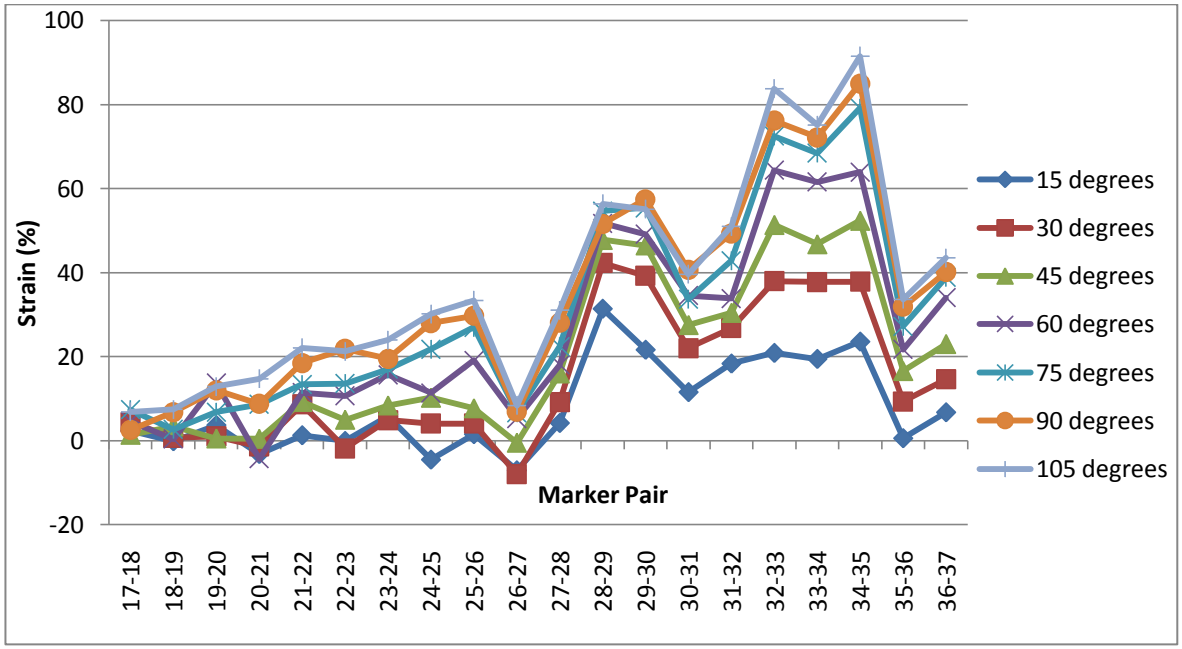

Figure E18 – Subject 10 Individual Marker Pair Strain on the Mid-line Section