Time to Safe Driving after Total Hip and Knee Replacement Surgery

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Abstract

Introduction: Osteoarthritis is the most common form of arthritis in the western world. With its increasing prevalence, total joint replacement is in high demand. After total hip replacement (THR) and total knee replacement (TKR) a period of driving cessation is necessary. For many patients, a period of driving cessation creates financial stress and threatens independence. The current recommendation for driving cessation following THR or TKR surgery is 6 weeks, however the literature surrounding this is varied.

Aims: To measure the average time it takes for a patient following either a THR or TKR to return to operating a motor vehicle safely; based on recovery of their pre-operative baseline transfer time to within 10%.

Methods: The transfer time from accelerator to a brake force of 100N (transfer time) was measured on a custom built rig. Patients were tested pre-operatively, and 1, 2, 4, and 6 weeks post-operatively. The time in weeks was measured to return to within 10% of their pre-operative transfer time. A quantitative questionnaire was used at each test to establish patient perception to the impediments to safe and confident driving.

Results: The median time to return to baseline in THR was 2.0 weeks (95% CI 1.3-2.7) and in TKR 5.5 weeks (Log rank score 0.034). 14.3% of THR and 62.5% of TKR patients failed to reach baseline in the test period. The median time to return to baseline for all operation groups was 3.3 weeks in males (2.6 – 4.0) and 2.0 weeks in females (1.4 – 2.6) (Log rank 0.67). 18.2% of males and 45.5% of females failed to return to baseline in the test period. Males recorded faster transfer times at baseline than females (414ms and 573 respectively). Joint pain decreased markedly over the test period when scored by visual analogue score. TKR felt more joint pain at 1 week postoperative than THR (VAS 5.26 and 2.0 respectively). Perceived driving confidence had improved to baseline by 2 weeks postoperative. When asked, patients reported joint stiffness as the most troublesome symptoms in the postoperative period.

Discussion: THR recovered to their baseline transfer time significantly quicker than TKR. This may be due to TKR experiencing more pain in the immediate post-operative period. Females recovered to baseline quicker than males, however this observation was not statistically significant. There was significant loss to follow up in this study, which particularly affected the TKR group. There were a significant number of TKR patients who did not reach baseline in the study period. Without data past 6 weeks follow up it is difficult to make recommendations for the TKR group. We suggest that THR are safe to return driving 3-4 weeks after their operation date. Due to the time limitations of the BMedSci (Hons) programme the study size was smaller than desired. Following
completion of this thesis data collection will continue to strengthen the findings of this study.
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LIST OF ABBREVIATIONS

ANOVA: Analysis of Variance

BPF: Brake Pedal Force

BRT: Brake Reaction Time

DHB: District Health Board

DVT: Deep Venous Thrombosis

GP: General Practitioner

IOT: Initiation of Transfer

MAF: Minimum Allowable Force

OA: Osteoarthritis

PE: Pulmonary Embolism

PJI: Prosthetic Joint Infection

THR: Total Hip Replacement

TKR: Total Knee Replacement
LIST OF DEFINITIONS

80% TRIMMED MEAN

Also known as truncated mean. When calculating an 80% trimmed mean the smallest and the largest numbers are eliminated, and the remaining numbers averaged. This reduces the skewing effect of outliers on the average.

ANOVA (ANALYSIS OF VARIANCE)

ANOVA is used to detect if the difference between two population means is greater than that expected by chance. With two populations it is equal to a two sample T-test. It is often used for comparison of 3 or more samples. (1)

LOG RANK TEST

The log rank test is used to test the null hypothesis that there is no difference between the populations in the probability of an event at any time point (2)

VISUAL ANALOGUE SCALE (VAS)

VAS is used for measuring parameters that cannot be measured directly. A horizontal line between two points is used and the test subject is asked to place him/herself on this line to indicate severity. (3)
CHAPTER 1: INTRODUCTION

Total hip replacements and total knee replacements are some of the most commonly performed operations worldwide. They are mainly done to treat osteoarthritis and are successful in reducing pain and disability in a high proportion of patients.

Following surgery, patient recovery of muscle strength, joint range of movement, and coordination is a gradual process. This is aided by early mobilization, adequate analgesia, physiotherapy and the use of walking aids.

A common issue related to surgery is the stand down period from driving a car in the post-operative period. Patients often ask; “How long until I can drive again?” In New Zealand, the ability to drive has become a fundamental element of what it means to be independent. It offers the ability to get to employment, complete activities of daily living, and maintain social contact. Many elderly patients either live alone, or have no reliable secondary driver. After surgery, they have no way of using their own transportation and must rely on costly taxi and bus services.

The current recommendation given to patients is that they should refrain from driving for 6 weeks. Following this, a functional evaluation by the surgeon is carried out at a follow-up clinic. The onus, however, is on the patient’s common sense and judgment on their physical abilities.

Published literature on the subject is varied. Over the last 25 years, a handful of studies have been performed which have attempted to quantify a reasonable
stand down time from driving following a lower limb joint replacement. A wide variety of recommendations have been suggested varying from 2 weeks to 8 months.

1.1 PRIMARY AIM

The primary aim of this study was to measure the average time it takes for a patient following either a THR or TKR to return to operating a motor vehicle safely based on recovery of their pre-operative baseline transfer time to within 10%. Furthermore, to provide recommendations for patients undergoing THR or TKR as to when they may able to return to driving after their operation.

1.2 SECONDARY AIMS

Secondarily, this study looked for differences in recovery time and pre-operative baseline performance between hip and knee replacements and between patient genders.

Using a questionnaire this study looked to establish patient perception of impediments to safe and confident driving.
CHAPTER 2: LITERATURE REVIEW


2.1 OSTEOARTHRITIS

2.1.1 DISEASE BURDEN

Osteoarthritis (OA) is the most common form of arthritis and very common in the western world (4). According to the WHO, "Worldwide estimates are that 9.6% of men and 18.0% of women aged over 60 years have symptomatic osteoarthritis" (5).

A Canadian report published in 2010 looked at the prevalence of Osteoarthritis within Canada and compared this with published rates around the world. In this report they acknowledge an increase in the prevalence from 1994 to 2002 (13.4% to 17.6%) within Canada. They go on to compare this with the prevalence of arthritis in the US. This was based on ‘self-reported doctor diagnosis’ of arthritis, and came back with a higher rate of 21.6%. They claimed this difference was best accounted for by ‘higher prevalence of inactivity and
obesity in US women’. They looked for the prevalence internationally with prevalence in the UK of 13.0% and 15-24% in Australasia. In all countries they observed a rate higher in females than in males, and a prevalence that increases with age. Lastly, looking at third world countries proved to show a prevalence as ranging from 2.3-11%, considerably lower than first world countries. An issue in comparing studies is differences in diagnostic definitions. The makes comparing prevalence rates less meaningful. However the differences between male and female patients is consistent through all research. (6)

The New Zealand Health Survey (NZHS) reported an ‘arthritis prevalence of 16.3% for females, 13.0% for males, and 14.8% for all adults aged 15 years and older’. This definition of arthritis included many forms other than OA. The prevalence for just OA was 6.5% for males, 10.1% in females, and 8.4% overall. (7)

Although the increase in OA worldwide can be attributed to the parallel increase in obesity, there is some evidence to suggest this is not the whole picture. The Framingham Osteoarthritis study found that over the years an increase in the prevalence of knee OA was observed in the population. They claim only 10-25% of the change can be explained by obesity alone. The reason for this increase is at this stage unknown (8).
2.1.2 Increasing Demand for Joint Replacements

The New Zealand joint registry published a report of collected data from January 1999 to December 2013. The most common replacement surgery was THR with 7,710 THRs done in 2013. This has almost doubled from 1999 where 4,114 THRs were completed. Age group analysis over this period showed that 52% of THRs occurred in women (47% men). The average age for female patients was 68.35 opposed to the slightly younger group of men at 65.23.

TKR was the second most common joint replacement surgery. In 2013 6,694 TKR operations occurred. This has increased almost 3 fold from 1999 where 2,429 TKR operations were performed. Similarly with TKR there is a gender disparity. 52% of TKR operations are performed on women and 48% on men. The average age of patients undergoing TKR surgery is 68. This is similar in both age groups.

The TKR had the highest survival rate of 94.49% and the lowest revision rate of 0.5 per 100 component years. The THR had a survival rate of 88.54% and a revision rate of 0.71 per 100 component years. (9).
2.2 **Total Joint Arthroplasty**

Osteoarthritis (OA) is a common arthritic condition affecting synovial joints. Pain associated with OA is typically exacerbated by activity and relieved by rest. With progression to severe disease this can lead to pain at rest or at night. Stiffness in the affected joint is another common presenting symptom frequently felt in the morning and improving within the first half an hour.

The goal of management of OA is to treat pain, reduce disability and maximize quality of life. Initially non-surgical treatment modalities are used in the form of physical and pharmacological therapies followed by joint arthroplasty surgery once the person has reached the end stage of joint destruction.

Postoperative recovery from total joint arthroplasty involves early mobilization and muscle re-strengthening, done with physiotherapist programmes. Patient cooperation is paramount when undertaking a rehabilitative programme. Patient motivation plays a big role in determining the time frame of recovery. A physiotherapy programme will generally include gait training, muscle strengthening, range of motion exercises, and training in completing activities of daily living.
2.3 **TOTAL HIP REPLACEMENT**

2.3.1 **THE HIP JOINT**

The Hip joint is the second most common joint involved in OA (10). Of ball and socket design, it involves the head of the femur articulating with the acetabulum of the pelvis. The hip joint allows for the movements of: flexion, extension, abduction, adduction, and rotation.

The capsular ligament (hip joint capsule) is a strong fibrous structure that surrounds the neck of the femur and attaches to the margin of the acetabulum. It is made up of circular and longitudinal fibers and secures the femoral head in the acetabulum. This capsule is strongest anteriorly and superiorly, and weakest posteriorly. The capsule is surrounded by a group of large strong muscles, which give the hip joint its strength and stability.

Posteriorly there are two major groups of muscles that act on the hip joint. The gluteal muscles are a strong group of muscles that make up the buttocks and insert into the greater trochanter of the femur. They include the gluteus maximus, gluteus medius, and gluteus minimus. These are shown in figure 1 below. The gluteus maximus facilitates hip extension and gluteus medius and minimus hip abduction. The adductor group originates from the pubis and insert into the medial and posterior surface of the femur and facilitate hip adduction. This group includes the adductor brevis, longus, and magnus, pectineus, and
Anteriorly the iliopsoas group originates from the vertebra and ilium and insert into the lesser trochanter of the femur. These muscles are responsible for flexion of the hip joint. Shown in figure 2 below.

The external rotator group arises below the acetabulum and insert into the greater trochanter. They include the obturator externus and internus, the piriformis, inferior and superior gemellus, and quadratus femoris. Shown in figure 2 below.
2.3.2 BIOMECHANICS OF ARTIFICIAL HIP JOINTS

There are several important biomechanical aspects to artificial hip joints to be considered. The range of motion of the prosthetic hip will affect the patients' ability to carry out activities of daily living. The range of movement is affected by the prosthesis design and component orientation. Ensuring a suitable center of rotation for the prosthetic joint will prolong the life of the joint and improve function. Adequate fixation of the femoral stem and the acetabular cup will reduce movement of the prosthesis components over time. As the prosthetic hip joint requires a large range of movement for function, it has a risk of dislocation.
The hip capsule is weaker posteriorly, and hence dislocation of the femoral head occurs predominantly in this direction.

FIGURE 3: PROSTHETIC HIP JOINT (12, 13)
2.3.3 Surgical Approach

The hip is a deep joint surrounded by large muscles, which makes access during surgery difficult. To gain access to the hip joint may require division of muscles, which can lead to weakness during the recovery phase. There are three difference surgical approaches to the hip joint.

The anterior approach (Smith-Peterson approach) involves gaining access to the hip joint capsule by creating a space between tensor fascia lata and sartorius without requiring muscle division. This is done with the patient is in the supine position.

The direct lateral approach (Hardinge approach) divides the anterior portion of the hip abductors to gain access to the anterior hip capsule. This can be done with the patient in either the lateral or supine position.

The posterior approach (Kocher Langenbeck approach) involves dividing the gluteus maximus muscle and short external rotators, to access the posterior hip capsule. The hip abductors are not divided in this approach.

2.3.4 Post-operative Hip Dislocation

Post-operative dislocation of the hip prosthesis is a serious complication and patients need to be informed about it. It can cause pain for the patient and put them at risk of damaging the prosthesis and surrounding muscles, causing a fall,
or injury to the individual. It occurs at an incidence of 2-3% and occurs most frequently in female elderly patients (14). Post-operative hip dislocations can occur in two ways: anterior or posterior.

Posterior dislocation is the most common direction of dislocation. This is when the prosthetic head of the femur slips out of the socket and moves posteriorly. This is most commonly seen following a posterior approach. A posterior hip dislocation normally occurs when the hip is put in a combination of flexion, adduction, and internal rotation.

This is a position encountered commonly when driving. A patient sitting in a car seat using the accelerator or the brake pedal can put the hip joint in this ‘at risk’ position. The height of the car seat is a contributing factor in the risk of posterior hip dislocation when driving. A low car seat will flex the hip beyond 90 degrees, which will put the hip joint replacement at risk of post-operative hip dislocation. Patients are generally advised that whilst seated they should avoid having their knees above the hips. This is a simple way of making sure flexion never exceeds 90 degrees.

Occurring less commonly is anterior dislocation. This is when the prosthetic head slips out of the joint capsule and moves anteriorly to the acetabulum. This is observed following a lateral or anterior approach. This is done when the hip is put into a combination of extension, adduction, and external rotation.

Most hip dislocations can be treated with simple closed reduction of the femoral head back into the socket under sedation or general anaesthetic. Generally, after relocation, 60-70% of first time dislocations won’t re-dislocate (14). Recurrent
dislocations will require revision surgery.

2.4 Total Knee Replacement

2.4.1 The Knee Joint

The knee joint is a modified hinge joint involving the articulation between the femoral condyles, the tibial plateau, and the patella. This creates a medial, lateral, and patellofemoral compartment. This allows the knee to move in flexion, extension, and with some rotation. The articulation between the femoral condyles and the tibial plateau is relatively shallow. The articular surface of the tibia is deepened by 2 menisci: medial and lateral. These fibrocartilagenous pads greatly increase the congruity of the articulation and hence the stability of the knee joint. Further increasing the stability are the intracapsular (anterior and posterior cruciate) and extracapsular (medial and lateral collateral) ligaments. Similar to the hip joint, the knee is another common site for development of OA. It is a load bearing joint which predisposes it to wear and tear over its lifetime. Figure 4 below shows the anatomy of a normal knee joint.
2.4.2 Total Knee Replacement

Total Knee Replacement surgery is the surgical insertion of a prosthetic knee joint. This involves removal of diseased cartilage and resurfacing the femoral condyles and the tibial plateau. The TKR is one of the most common orthopaedic operations performed and almost exclusively for treatment of advanced OA. (9)

Biomechanically there are two important factors to maintain for the prosthetic joint to have good functionality; namely stability and range of motion. Stability of the knee joint comes from the prosthesis design and the surrounding lateral collateral and medial collateral ligaments. Functionally, the range of
motion in the sagittal plane is important to be able to complete activities of daily living. Biomechanical studies of the knee joint have looked to activities of daily living in terms of required knee flexion. In order to get out of a standard chair 93 degrees of flexion is required and for a lower chair 105 degrees (16).

Figure 5 below shows the femoral and tibial components and how they articulate together

**FIGURE 5: COMPONENTS OF A PROSTHETIC KNEE JOINT (17).**
2.4.3 Surgical Technique

The knee is approached anteriorly with the patient lying supine with a flexed knee. Often a tourniquet is used. Most commonly the knee joint is accessed through a medial parapatellar approach. This involves making an incision in the quadriceps tendon along the medial patella and down to the medial tibial tubercle. Osteoarthritic knees often have some associated deformity. This is either a varus or valgus deformity. Knees with valgus or varus deformity often require capsular release to provide soft tissue balancing.

Preservation of the lateral collateral and medial collateral ligaments is important in the TKR surgery, as they provide support and stability for the knee. The anterior cruciate ligament can be sacrificed as the implants provide intrinsic stability in the sagittal plane whereas the posterior cruciate ligament is normally preserved.

2.4.4 Postoperative Stiffness

Following total knee joint replacement, prosthetic joint stiffness can be a troubling problem. This reportedly occurs at a rate between 8-12% in postoperative patients (18). Stiffness is an inadequate range of motion that reduces a patient’s ability to carry out activities of daily living. In prosthetic knee joints this manifests as a restriction of flexion. Generally a level of flexion of >90
degrees is aimed for post TKR.

There are many possible reasons for development of postoperative joint stiffness. These are grouped into pre-operative, intraoperative, and postoperative.

The amount of preoperative range of movement can determine the flexion achieved postoperatively. A total knee replacement done due to stiffness can lead to less flexion postoperatively.

Many intraoperative factors at time of prosthesis implantation can lead to a reduced amount of flexion postoperatively. A misaligned or poorly sized prosthesis will have reduced range of movement. If restriction is significant, revision surgery may be required. Inadequate tibial or femoral resection will not allow the prosthetic joint space to move and thus reduce range of movement. Failure to adequately resect posterior bony osteophytes will also impede flexion.

Post operatively pain, infection, and poor patient motivation may impair regaining a good range of movement in the operated knee (19).

The majority of postoperative joint stiffness is thought to be multifactorial in nature, contributed to by pre-, intra-, and postoperative factors.

In some patients suffering from a stiff prosthetic knee joint, manipulation under general anaesthesia may be indicated. This is done with the hip at 90 degrees flexion, and with adequate muscle relaxants, the knee is flexed to break adhesions to the joint. This is generally done by exerting force close to the knee, as to reduce the lever arm, and reduce the risk of complications. These are
reported as fracture, wound dehiscence, patellar ligament avulsions, and haemarthrosis (20)
2.5 Driving After Total Joint Arthroplasty

2.5.1 The Ability to Drive

The complex task of driving a car requires an array of different motor, visual, sensory, and cognitive tasks. All of these aspects are challenged on a daily basis when on the road. After major surgery, many of these may be compromised for a variable amount of time. In the short term, after any anaesthetic, patients are advised not to drive due to the effects anaesthetic drugs have on cognition. In the long term, after orthopaedic surgery, a major aspect to recovery is regaining muscle strength and coordination post-operatively which compromises patients’ ability to operate the motor vehicle. Recovery of sufficient muscle and joint function to drive a car can take variable amounts of time, depending on the patient. Motivation, presence of complications, post-operative stiffness, and pain all influence muscle strength recovery and regaining range of movement in the joint. This is true of any orthopaedic operation. Specific challenges exist for patients having had THR or TKR surgery.

2.5.2 Entering and Exiting the Vehicle

In New Zealand, cars drive on the left-hand side of the road. Hence the cars are right-hand drive. This means that the driver of a vehicle enters the car on the
right side requiring the driver to pivot on the right leg and maneuver the body into the seat. The hip will need to abduct and flex to perform this. The knee will need to flex enough to allow the driver to successfully sit on the seat. The lower the driver seat the more exacerbated these movements will need to be. Following this flexion and adduction at the hip lifts the right leg into the car.

This combination of movements can be very painful and difficult for patients immediately after THR or TKR surgery. In the direct lateral approach the hip abductors are often weak making the pivoting on the right hip challenging. In TKR surgery patients suffer from quadriceps weakness and joint stiffness. This makes supporting their weight in flexion whilst lowering themselves into the seat extremely difficult.

In order to exit the vehicle, the driver must swing the right leg out using hip flexion and abduction, to plant it on the ground. From there he or she must raise out of the seat using both the quadriceps and hip extensors.

TKR have quadriceps weakness making knee extension difficult. Following a posterior approach disruption to gluteus maximus makes rising out of a low seat hard without an aid.

This is undoubtedly one of the major reasons why patients undergoing Total Joint Arthroplasty are unsafe to drive early in the postoperative period. Patients attempting to perform this maneuver too early in the post operative period are at risk of injury. Should the patient fall, this could compromise their recovery as
a result of muscle injury, fracture or dislocation.

2.5.3 OPERATING THE PEDALS

Once seated in the car, another challenging aspect of driving is operating the pedals. It is worth noting that the configuration of the accelerator and brake pedals is standard worldwide. The right foot uses the accelerator and brake in both left hand and right hand drive cars. The ability to use both pedals will be affected in right-sided operations, but the pertinent pedal is the brake. In order to apply the brake this requires the patient to pivot their foot, adduct the hip, and press down forcefully on the brake with a flexed knee. The forceful push on the brake requires plantar flexion at the ankle, and stabilization of the knee in flexion.

Applying the brake forcefully may be difficult for patients following a TKR, as the quadriceps is weak and cannot stabilize the knee effectively. In contrast THR patients should be able to perform this maneuver successfully. However THR patients may find sitting with a flexed hip joint uncomfortable.

The ability to operate the brake pedal of a car following hip and knee replacements was the main aim of this study. The ability to enter and exit the car was not addressed in this research.
2.5.4 NEW ZEALAND STATISTICS

New Zealand is a developed nation that is highly car dependent. In a document produced by Statistics NZ in 2002 they claim that New Zealand is one of the most highly urbanized countries in the world, with 85.7 percent of its population living in urban areas (21). This document also showed that New Zealand has rapidly transitioned from a predominately rural population to an urbanized one.

FIGURE 6: URBANISATION IN NEW ZEALAND OVER 100 YEARS (21)

The public-transport systems however fell behind this rapid urbanization. Only major centres have railway as a form of public transportation, whereas most centres must rely on bus networks. Statistics New Zealand’s report on commuting pathways in NZ stated “Outside the major cities, census data showed that majority of commuters depended on motor vehicles as their main means of travel to work, largely because of the lack of availability of public transport” (22)
A document produced by the NZ Ministry of Transport has shown that the peak rate of car ownership was 698 light vehicles per thousand population in December 2007(23). That is, 70% of people in New Zealand own a car. Since 2007 that number has decreased slightly to 682 per 1000. This was due to the developing economic depression and a falling NZ dollar. This increase in ownership saw a concomitant rise in kilometers traveled per capita. This peaked in 2005 with 9000km traveled per capita annually (23). Following this, rising fuel prices caused this figure to drop.

In 2011 Australia and America had an average car age of just over 10 years. In comparison NZ had an average car age of over 12 years old(24).

From this document we can make some generalizations about the average New Zealand driver:

1. 7 out of 10 New Zealanders own their own car

2. New Zealand’s light vehicle fleet is on average 2 years older than Australia and the USA

3. The average New Zealander travels 9000km per year, around 5.5 times the length of the country

This illustrates the importance of the motor vehicle in a country like New Zealand. Furthermore if many New Zealanders are spending significant time traveling in cars, it is important to improve road safety by analyzing the risk factors involved.
Since the 70s the roads have become much safer for drivers in New Zealand. The highest ever death rate was 27.9 per 100,000 population in 1973. Since then the rate has steadily decreased to 6.4 per 100,000 populations in 2011. We stack up somewhere in the middle on the international scale. The US and Canada have worse rates but many European countries have safer roads.

There are many risk factors that influence road traffic injuries. Understanding these risk factors helps organisations and governments address these issues and plan public health interventions to help improve crash statistics. According to the World Health Organisation risk factors can be broken down into 4 categories affecting: exposure to risk, crash involvement, crash severity, post-crash injury outcomes.

The first category, factors influencing exposure to risk, is relevant to this research as it describes characteristics of at risk drivers. This category involves socio-economic depression, age, sex, length of trip, mode of travel, and mixing fast road users with vulnerable ones (25).

An interesting risk factor is the age of the driver. Looking at the age profile of the fatal crashes in NZ, there are 2 major groups causing over 40% of the deaths: The 15-19 year olds and the over 65s (26).

The 15-19 age category is associated with substance abuse and risk taking behavior causing crashes, especially in young males. However, the 65+ age group
is mostly put at increased risk by chronic medical conditions.

According to the New Zealand Transport Authority, the over 75s account for 5.7% of the population, and 4.6% of licensed drivers. Showing that although licensing in the elderly decreases with age, the over 75 group still accounts for a significant proportion of licensed drivers in New Zealand. They go on to state that most common crashes in the elderly are side impact crashes; for example pulling out of an intersection incorrectly and colliding with an oncoming car. This is usually through a failure in vision, particularly peripheral vision. These crashes are particularly dangerous in elderly drivers driving older models of cars as they are usually without side airbags. Pedal confusion is another common mechanism of crash in the elderly. Confusing the accelerator for brake can lead to crashes at intersections when intending to decelerate. Fatigue is also an important factor that impacts on many elderly drivers. This can be in many forms, both mental and physical fatigue. On longer car trips, fatigue has an increasing effect. In patients who are recovering from surgery, or have chronic medical conditions, physical fatigue can be a major problem that can cause crashes. In the over 65 group, crashes most commonly occur in the day time, whereas all other age groups have the highest crash rate at night. (27)

The young adult age groups tend to have the highest crash rate on the roads. However the over 75s have a much higher crash rate per mile travelled. This crash rate increases dramatically from the age of 80 up. According to the Centre for Disease Control (CDC), elderly crash statistics are mostly attributable to medical conditions, as opposed to becoming more prone to car accidents through
poor driving (28)

2.5.6 THE AGEING POPULATION

It is well documented that the age structure of the western world has changed in recent history. Developments in medicine have allowed the life expectancy to greatly extend in the last 100 years. With discovery of various drugs and treatments for previously fatal diseases, this has allowed the elderly population to live much longer than previously thought possible. Along with this infant mortality rate has plummeted, contributing to the changing age structure. In the last 22 years life expectancy has continued to increase. For example in New Zealand the life expectancy was 76 in 1990, increasing to 82 in 2012. (29)

Post WWII New Zealand experienced a large period of growth. Between 1949 and 1961 New Zealand had its highest ever-recorded birth numbers, 65,000 births in 1961. Since then, fertility rates in New Zealand have fallen significantly. Projections for 2061 predict that fertility rates may be between 1.7 and 2.1 births per woman. This would translate to the 65+ age group making up 24-28% of the population. The dependency ratio compares the over 65s with the 15-65s (working age citizens). There is currently about 1 over 65 for every 5 working age citizens. This would increase to 2 in every 5 in 2061. This does not necessarily translate to double the burden, as over 65s may contribute to society in ways outside paid employment. (30)
Internationally, the changing population age structure is worse in Australia, and Europe. This is likely due to New Zealand having had very high fertility post WWII compared with these countries. Countries like Hong-Kong and China are likely to develop very aged populations in the next 30 years and surpass New Zealand. (31)

This means new challenges for the health professionals treating and managing this part of the population. Chronic degenerative diseases as for example OA are going to become more prevalent as the population structure continues to change.

With the doubling of the over 65 age group of the population and chronic diseases growing in prevalence, evaluation of older drivers will become an increasing issue. Patients will be living longer, and functioning at a higher level
into their later years. This will make the role of the General Practitioner vital in determining the 'Medical fitness to drive'.

2.5.7 Evaluation of Driving in the Elderly

Taking away a patient's ability to drive is not a decision that should be taken lightly. Driving is an integral part of what it means to be truly independent. Patients who are rendered unable to drive are affected in multiple ways. It makes all activities of daily living more difficult and will affect physical recovery following a hip or knee replacement as access to physiotherapy and follow up clinic appointments might be impossible in some circumstances. Not only does the inability to drive affect the patient’s physical recovery, it also affects their mental health too. For elderly patients living alone, being unable to drive increases feelings of isolation. A study published by Curl, Stowe (32) showed that in the short term, cessation from driving predominantly effects what they call 'productive engagement' which involves paid employment and volunteering. Therefore when a doctor is being asked to assess an elderly patient on their ability to drive safely, a careful examination is vital.

The current system for license renewal in New Zealand involves renewal at age 75, 80 and every 2 years following this. This process begins with the driver getting a medical certificate from their GP. The GP will discuss health issues with the patient and test their eyesight. The medical assessment will consider a variety of conditions including: neurological, cardiovascular, diabetic, loco-
motor, visual, hearing, mental disorders, and medications, amongst others. This is detailed in ‘Medical Aspects of Fitness to Drive’ produced by New Zealand Transport Association (NZTA) (33). Following this assessment the GP will have 5 recommendations:

1. Medically fit to drive
2. Medically fit to drive with conditions
3. Medically fit to drive following passing road safety test
4. Medically fit to drive following confirmation from specialist
5. Not medically fit to drive

Should the patient be unfit to drive, their license will expire on their next birthday. (34)

Under the Land Transport act 1999, General Practitioners are required by law to do two things, in relation to fitness to drive:

1. To consider medical aspects of fitness to drive, when conducting a medical examination on whether an individual is fit to drive
2. To advise the chief medical advisor if an individual poses a risk to society by continuing to drive when told not to

In Section 18 of this act, the GP is not subject to civil or professional liability by disclosing confidential information about a patient posing risk to society by
continuing to drive (33).

The GP’s assessment of the patient is often what decides whether the patient can drive or not. Patients know this, and can often exert a large amount of pressure and influence over the GP’s decision. Many GP’s find this an extremely uncomfortable position to be in. They realize how important driving is to patients, and find the consultation unpleasant.

Often patients with medical conditions are advised to cease driving for a period of time whilst they are unwell or recovering. In interest to this research, is the temporary cessation of driving following surgery. The protocol and legislation around this issue are not as well defined as in license renewal of the elderly. At what point a patient is allowed to return to drive following surgery is primarily based around recommendations by the specialist in charge at time of follow up. This is usually based around subjective assessment of motor strength and general assessment of function. For example, a document produced by “The Women’s Health Service at Wellington Hospital” advises patients post laparotomy as follows: ‘You may start driving again when it is comfortable for you to do an emergency stop’. A fairly subjective way of determining safety to drive (35).

In Dunedin Hospital’s Department of Orthopaedic Surgery, patients receiving hip or knee replacement surgery attend an educational meeting before their surgery. Here, amongst other things, they are told that they should abstain for driving for 6 weeks. This is based on a relatively small body of literature, which presents conflicting recommendations. Much of the literature is 10-20 years old, when
operative techniques and rehabilitative protocols were different. This literature will be summarized in section 2.6.6 of this review.
2.6 REVIEW OF THE LITERATURE

2.6.1 INTRODUCTION

Over the past 20 years some research has been carried out into how long patients take to recover driving ability after THR or TKR surgery. The study design has been variable and there has been no consistent primary variable measured, the testing intervals were not consistent, and most studies had no control groups. This can make generalization between studies difficult.

2.6.2 MEASURED VARIABLES

In 1988 MacDonald and Owen (36) conducted the first known study of this nature. They used a variable they termed the ‘reaction time’. This was the time from the onset of the stimulus till the patient reached 100 Newtons (N) on the brake pedal. Further studies sub-classified this reaction time into two parts: the neurological recognition of the stimulus and the mechanical transfer time. What was termed ‘reaction time’ is now called ‘Total break reaction time’ (TBRT); the constituents of this are the ‘reaction time’ and ‘transfer time’. This is shown in Figure 8 below.

Most studies after MacDonald et al used the total break reaction time. However the inclusion of 100N brake pedal force as an end point in the definition varies. Studies choosing to omit the 100N end point will measure to the onset of
pressure on the brake pedal. Total brake reaction times achieved by patients are very different depending on which method was used. The omission of the 100N end point also limits the interpretation of the data. These studies are not able to conclusively say that patients have sufficient strength to perform an emergency stop.

**FIGURE 8: TOTAL BRAKE REACTION TIME**

2.6.3 **TOTAL HIP REPLACEMENT**

To our knowledge 3 studies have tested these parameters on patients before and after receiving a total hip replacement (THR). In 1988 MacDonald et al found that following a THR most patients were safe to drive by 8 weeks (36). Later in 2003 Ganz et al suggested that patients may be ready earlier at 4-6 weeks following surgery (37). In 2014 Jordan et al. published a study showing that most
patients who had a right THR have reached baseline by 6 weeks. These studies are summarized in Table 1 at the end of this chapter.

2.6.4 Total Knee Replacement

There have been five studies in the area of total knee replacement surgery. In 1994 Spalding et al found that after a TKR patient’s TBRT had not returned to preoperative levels until 8 weeks post surgery (38). Later in 2003 Pierson et al published research showing that 8 weeks may be too conservative and that patients were fit to drive after 6 weeks (39). Liebensteiner et al followed this finding that patients need not be restricted driving beyond 2 weeks, however this study had issues with statistical significance (40). Marques et al researched the left sided TKR exclusively, to look at recovery of the non-pedal operating leg. They concluded that left sided replacements were fit to drive by 30 days postoperative (41) Most recently Dalury et al found that all patients had sufficient BRT to resume driving 4 weeks following TKR (42). These studies are summarized in Table 2 at the end of this chapter.

2.6.5 Limitations

As described in the measured variables section above, a major issue when looking at the previous research was the different definitions of the total brake reaction time. This makes combining the results of the literature difficult and
making a general guideline impossible.

Many of these studies had issues with small number of participants, and large drop out rates. This meant the some studies had limited statistical significance.

The study design also differs when looking at these studies. There is no consistent testing interval, and some studies don’t include controls as a comparison.

2.6.6 Summary of Previous Literature

There is a diversity of results from previous research in the area of return to driving following hip or knee replacement surgery. Research on the hip has shown patients can return as early as 4-6 weeks but with some patients not recovering fully until 32 weeks after surgery. In the knee there has been a wide range of results from as early as 2-4 weeks to 8 weeks and beyond. These studies have a range of limitation including low sample numbers, high dropout rates, and differing design limiting generalizability between studies.
<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Testing Interval</th>
<th>Measured Variable</th>
<th>Conclusion</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>MacDonald (1988) (36)</td>
<td>25 Participants: 12 RTHR (8 men, 4 women), 9 LTHR (7 men, 2 women) 15 Controls</td>
<td>RTHR: Pre-op, 8w, 32wk  LTHR: Pre-op, 8w  Controls: one-off</td>
<td>Stimulation till 100N</td>
<td>Most RTHR fit to drive by 8w. Minority by 32w. LTHR had no difference from control</td>
<td>Low sample size  Lack of diagnosis control</td>
</tr>
<tr>
<td>Ganz (2003) (37)</td>
<td>90 Participants: 52 RTHR (24 men, 26 women), 38 LTHR (32 men, 8 women)</td>
<td>Pre-op, 1w, 4-6w, 26w, 52w</td>
<td>Reaction time (no force component)</td>
<td>Most RTHR are suitable by 4-6w and continue to improve at 6 years. LTHR does not largely affect right foot braking</td>
<td>No objective measure of hip strength  4-6 week testing interval too vague</td>
</tr>
<tr>
<td>Jordan (2014) (43)</td>
<td>40 Participants: 20 LTHR (15 men, 5 women), 20 RTHR (10 men, 10 women)</td>
<td>Pre-op, 8d, 6w, 12w, 52w</td>
<td>Total brake reaction time (force measured separately, not included in this measurement)</td>
<td>Most RTHR reached their pre-op baseline by 6 weeks. LTHR showed no limitation at 8d</td>
<td>Objective measure of strength not included in primary measured variable.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Testing Interval</td>
<td>Measured Variable</td>
<td>Conclusion</td>
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<tr>
<td>Spalding [1994][38]</td>
<td>29 Participants: 19 drivers (12R, 6L), 11 non-drivers (8R, 3L) 20 Controls</td>
<td>Pre-op, 4w, 6w, 8w, 10w</td>
<td>Visual Stimulus till 100N</td>
<td>RTKR were not back to baseline until the 8th week. LTKR had no effect</td>
<td>Low sample numbers and hence wide confidence intervals</td>
</tr>
<tr>
<td>Pierson [2003][39]</td>
<td>31 Participants: 13 bilateral, 18 unilateral, 17 men 14, women</td>
<td>Pre-op, 3w, 6w, 9w</td>
<td>Stimulus till complete compression of brake pedal</td>
<td>Patients were able to return to regular driving by 6w. Some as early as 3w</td>
<td>Measured variable not comparable to other literature, and does not include measure of muscle strength.</td>
</tr>
<tr>
<td>Marques [2008][41]</td>
<td>24 LTKR: 13 men, 11 women</td>
<td>Pre-op, 10d, 30d</td>
<td>Time till onset of brake pedal (no pedal force included)</td>
<td>Return by 30d</td>
<td>Measured variable no included measure of muscle strength. Only tested 1 side. No control group included.</td>
</tr>
<tr>
<td>Liebensteiner [2010][40]</td>
<td>31 Participants: 18 LTKR, 13 RTKR</td>
<td>Pre-op, 2w, 8w</td>
<td>Stimulus till onset of brake pedal (no pedal force included)</td>
<td>No significant increase in BRT after surgery. Patients should drive by 2w</td>
<td>Measured variable no included measure of muscle strength. No statistical significance, high dropout rate</td>
</tr>
<tr>
<td>Delary [2010][42]</td>
<td>29 RTHR: 18 female, 11 male</td>
<td>Pre-op, 4w, 6w, 8w</td>
<td>Stimulus till onset of brake pedal (no pedal force included)</td>
<td>Patients should return to driving at 4w</td>
<td>No measure of muscle strength.</td>
</tr>
</tbody>
</table>
CHAPTER 3: METHODOLOGY

3.1 GENERAL METHODS

3.1.1 ETHICAL APPROVAL

Firstly a research protocol was written which was peer reviewed through the Department of Surgical Sciences at Dunedin Hospital. Ethical approval was then sought through the University of Otago Human Ethics Committee (UOHEC) and locality consent through the Southern DHB as well as Maori consultation. Full ethical approval was obtained (project ID: 00985)

This documentation is attached for reference in the appendices.

3.1.2 INCLUSION AND EXCLUSION CRITERIA

A list of all patients booked for hip and knee replacement surgery was obtained through the Orthopaedic Department Booking Clerk. Eligible patients were identified and recruited at the preadmission clinic one week prior to surgery.

The Inclusion criteria for participants were as follows:
1. Diagnosed with hip or knee osteoarthritis
2. Between the ages of 30 and 85
3. Booked for right sided or bilateral hip or knee replacement surgery at Dunedin Hospital
4. Reside in Dunedin
5. Able to participate and willing to provide written informed consent

The Inclusion criteria for controls were as follows:

1. Reside in Dunedin
2. Between the ages of 30 and 85
3. Have no recorded diagnosis of hip or knee osteoarthritis
4. Able to participate and willing to provide written informed consent

The exclusion criteria for participants were as follows:

1. Left sided joint replacement
2. Outside the ages of 30 and 85
3. Undergoing a revision of either hip or knee prosthesis
4. Undergoing a partial joint replacement (hemiarthroplasty)
5. Pathology in the joint other than osteoarthritis
6. Reside outside of Dunedin
7. Not holding a valid New Zealand driver’s license
8. Significant comorbidities affecting reaction times

   a. Peripheral neuropathy, or other neurological diseases effecting reaction time (e.g. Parkinson’s disease)

   b. Glaucoma, or other causes for poor vision
9. Impaired vision
10. Not fluent in English
11. Unable to provide written informed consent
The exclusion criteria for controls were as follows:

1. Any pathology in the knee or hip joint
2. Outside the ages of 30 and 85
3. Reside outside of Dunedin
4. Not holding a valid New Zealand driver’s license
5. Significant comorbidities affecting reaction times (see above)
6. Impaired vision
7. Not fluent in English
8. Unable to provide written informed consent

3.1.3 Recruitment of Eligible Patients

Patients who fulfilled the required criteria were then sent a letter of invitation to participate in the study along with the information sheet. This was posted together with their information for the pre-admission clinic as part of their pre-admission clinic information package.

Patients were recruited during their pre-admission appointment. This appointment usually occurs 1 week before the date of surgery and carried out in the Orthopaedic Department Outpatient Clinic. Full informed consent was obtained at that time.

For a minority of patients recruitment during their pre-admission clinic was not possible. In that case they were recruited over the phone, and another appointment was made for informed consent and testing before their operation.
3.1.4 Informed Consent

Informed consent was undertaken by the principle researcher. During the meeting care was taken to ensure that the patient understood the aim of the research and what was expected of them if they decided to take part. In particular, issues around their ability to return to the hospital following the surgery were explored. Many patients either lived on their own or lived with a non-driving partner limiting their ability to get to the hospital for post-operative testing. These patients were offered taxis to assist them. Patients who had available transport post-operatively where offered petrol vouchers to offset their transport costs.

After obtaining informed consent patients were entered into the study. The information sheet and informed consent are attached in Appendix 2.

3.2 Study Design

3.2.1 Primary Variables

The primary variable was the transfer time, which measures the time from initiation of movement to achieving a brake pedal force of 100N. The
neurological reaction time is from onset of the stimulus to initiation of movement. Changes in the neurological reaction time were not addressed in this study.

Secondarily a questionnaire completed by participants at each test aimed to measure pain score, most disabling symptom, and perceived driving ability. The questionnaire is attached in Appendix 3.

3.2.2 Testing Intervals

Participants were tested a total of 5 times during the study. A pre-operative measurement was followed by measurements at 1, 2, 4, and 6 weeks post-operatively. Each time they completed a questionnaire.

Controls were measured twice during the study: a baseline measurement upon recruitment and a final measurement 6 weeks later. Controls did not fill out a questionnaire.

3.2.3 Adding to Past Literature

This study was designed to improve on past limitations and add new information in areas not previously researched.

Importantly the definition of TBRT that utilizes measuring the brake pedal force
was used. As the only cut off force used in the past has been 100N, this cut off was used. This was termed the ‘minimum allowable force’ (MAF).

The study intervals used were aimed at investigating the early post-operative period in more detail than had been done previously. By investigating patients at 1 and 2 weeks post-operatively we intended to measure performance of fast recovery in motivated patients.

A questionnaire was designed to collect data around driving confidence, and symptoms of pain/stiffness/weakness at various time points. This is an important part of the patient experience after a joint replacement, and may provide answers to the disparity in results.

Finally, this study is comparing THR and TKR surgery. Previous literature has studied a single operation and compared left and right sided operations. This study looked at the right-sided TKR and THR, as only the right leg operates the accelerator and brake in the motor vehicle, regardless of the side of the driver's seat.
3.3 Testing Protocol

3.3.1 Baseline Measurement

The accuracy of the baseline measurement is particularly important, as it is the measurement that every subsequent test is compared to. We elected to measure the time to return to baseline as opposed to time to a specific benchmark brake reaction time. This is a more meaningful result because given the patient is ‘safe to drive’ at the time of the baseline recording we can assume that returning to that baseline measurement will equate with return to safety. The baseline must reach a set of standards for the patient to be considered safe preoperatively. These criteria are detailed below:

3.3.2 Baseline Criteria

1. The trimmed mean of their 10 efforts must be below 700ms

2. A minimum of 8 out of 10 of these efforts must reach 100N.

A patient who did not provide a baseline measurement fulfilling these criteria was excluded from the remainder of the study. This was because their baseline did not equate with what is considered a reasonable result for the average safe driver. Their baseline data however was recorded and used for analysis of
people driving with advanced osteoarthritis.

3.3.3 Post-operative Testing

The first post-operative test was completed as close as possible to 1-week post surgery. This largely depended on the date of discharge from hospital. If a patient was discharged between 4 and 7 days following surgery then the 1-week measurement was taken on the day of discharge. If they were discharged before day 4 they were not tested as an in-patient and were required to return at the 7-day mark. From there they were further tested at 2 weeks, 4 weeks, and 6 weeks. The 6-week measurement was generally taken on the day of follow-up with their surgeon (which is usually at the 6-week mark).

3.3.4 Return to Driving Criteria

In order for the patient to be regarded ‘safe to return to driving’ they had to fulfill the following criteria:

1. They must reach a trimmed mean within 10% of their baseline
2. A minimum of 8/10 of their efforts must reach 100N brake pedal force

A patient that reaches their baseline before the final 6-week test monitored to record ongoing above-baseline performance.
A patient’s data was modeled on a line graph to calculate how many weeks they took to reach baseline.

### 3.4 Software

#### 3.4.1 Introduction

All data was recorded using the ‘SENSIT test and measurement’ software. This software is primarily designed for use in car testing workshops, and not for use in the context of clinical research. Thus it is not particularly user friendly, and all results must be calculated manually.

I spent some time developing my method for analysis of data using this software. This section details the step-by-step method to extract the data required for this study.

#### 3.4.2 Data Extraction Methodology

Testing occurs using the ‘Live Graphing’ feature of the software. To begin with the settings must be configured correctly. Following this, brake efforts can be recorded. The settings used are depicted below.
The software will produce a tracing, which includes both the accelerator and brake pedal. The Y-axis displays force (N) applied to either accelerator or brake pedal. The X-axis displays ‘Sample Numbers’. With the sampling rate set to the maximum of 100 samples per second, each sample represents 10ms.

The point at which the transfer from the accelerator to the brake pedal was initiated is referred to as the Initiation of transfer (IOT). Getting an accurate
sample number for the IOT is the most important step to obtaining an accurate measurement of the transfer time. To do this the point in the blue tracing (the accelerator pedal) where the pedal force sharply drops off has to be located. This can be obvious as in the case below, or as is discussed later, require more interpretation.

**FIGURE 10: INITIATION OF TRANSFER (IOT)**
Note that the sample number is NOT in sync with the cell number. For example, in this case the sample number we were looking for (278) corresponded to cell number 280.

From the searched sample number scroll down the spreadsheet until the point is found where the force on the brake pedal reaches the closest to 100N. Often 100N lies between two sample numbers. In this case the sample number that is closest to 100N, termed the Minimum allowable Force (MAF) is chosen. The
The sample number of the MAF is then calculated from the IOT.

As follows:

296-278=18

As a sample is taken every 10ms, 18 samples would be equivalent to 180ms or 0.18s
3.4.3 **Calculating Time to Baseline**

Once the patient has completed all testing, their time to baseline is calculated. Plotting their 4 post-operative measurements on a graph with the mean transfer time on the y-axis and number of weeks on the x-axis. Calculate at what point they cross their baseline+10% x-value. This is modeled with a straight line to estimate the true point at which they achieved baseline. This is shown in an example below:

**FIGURE 13: PROGRESSION OF TRANSFER TIME**

![Progression of Transfer Time](image)
3.5 The Testing Rig

3.5.1 Car Design

In motor vehicle design there are a set of standard measurements used to describe interior and exterior features. This ensures that cars can be accurately classified and safety standards can be maintained. This is described in a document released by The Society of Automotive Engineers International (SAE International) in 2001.

The measurement of interest in the design of our rig is called the H30. This vertical measurement is taken from the H-Point or Hip Point: the position of a dummy's hip when placed on a seat in its rearmost and lowermost position. It is taken vertically down to the Heel Point: the point where the heel touches the floor of the vehicle whilst on the accelerator. It is a way of categorizing the driver seat height in vehicles. (43)

FIGURE 14: H-30
The SAE international divides vehicles into two classes based on ‘driver seating arrangement dimensions’. This takes into account seat height, seat adjustability, steering wheel size, and Torso angulation. Of importance to this study is classification based on H-30 (seat height). Class A has an H-30 between 127mm and 405mm, and Class B between 405mm and 530mm.

According to the New Zealand Transport Authority, in 2013 the most commonly owned new car in New Zealand was the Toyota Corolla with 5995 registrations. The Suzuki Swift was runner-up with half the registrations, 2971 (44). These cars both fall into the category of Class-A vehicles. For our rig to represent commonly driven cars in New Zealand we designed our rig as to fall into the middle of the Class-A category with an H30 of 288mm.

3.5.2 The Frame and Seat

There were specific requirements regarding the physical dimensions, mechanics and portability of the rig, which had to be moved between various testing locations. Most of the testing was carried out in the Orthopaedic Outpatient Department at Dunedin Hospital. Previous studies had used large heavy rigs, the largest including the entire front half of an original car. We used a lightweight aluminum frame and kept the rig’s design as simple as was feasible.

The original rig was custom built as a driving simulator for gaming consoles. We made some specific modifications to it in order for it to meet our requirements.

The original seat was a bucket seat, which was difficult to get in and out of. It also
made it difficult for overweight or obese patients to use. The other issue with the seat design was the height. The frame needed to be redesigned as to raise the seat up. A replacement seat was purchased from a local car wrecker along with the slider rails the seat mounted to. This new seat was mounted at a fixed height of 470mm from the floor (including mounted wheels), and with an H30 of 288mm. The rails allowed the seat to be adjusted forward and back. Distance from the edge of the seat to the pedals was 35cm at the shortest and 55cm at the longest.

**FIGURE 15: DIMENSIONS OF SEAT**

3.5.3 THE PEDALS

The pedals used came with the original gaming rig (driving force GT range by
Logitech). There was an accelerator and a brake pedal. The pedals were cut and mounted to a base-plate. The resting angulation of the accelerator and the brake pedals are shown in the figure below. The resting angulation of the brake pedal was slightly steeper than that of the accelerator. This became troublesome in the early post-operative period, as there was a tendency for weaker patients to catch their foot as they attempted the pedal transfer. I did not however find this to be a significant issue overall.

**FIGURE 16: RESTING ANGULATION OF PEDALS**

3.5.4 THE SENSORS

There were two pedal force sensors used in this rig: one on the accelerator and one on the brake pedal. These were purchased from FUTEK Ltd (model number LAU200 item number FSH00219). These had a maximum load of 25lb and
maximum sampling rate of 100 samples/second. Please see the specification sheet in the appendices for more technical information. An aluminum mounting plate was screwed onto the curved pedal so that the flat bracket of the load cells could be mounted without damaging it. A USB conversion kit was used to convert the output from the sensors into USB format to be read by the testing laptop (USB 210 External USB Output kit).

### 3.6 The Questionnaire

Another aspect of the study was the quantitative questionnaire completed by patients at each test. The questionnaire was developed for this study. It was designed to contribute information on the subjective aspects of recovery. To our knowledge, none of the previous studies have used a questionnaire.

This had 4 questions:

The first question asked the patient to score their confidence in their ability to stop in an emergency situation, based on how they were feeling on the day (score from 1 to 10).

The second question asked the patient to choose which single factor affected their ability to brake most.

The options were a.) Pain, b.) Stiffness or c.) Weakness

The third question was a visual analogue scale asking patients to score the pain
experienced during testing (score from 1 to 10).

Lastly the fourth question was related to the level of confidence in their day-to-day driving, based on how they felt on the day (score from 1 to 10).

An example given was 'How confident would you feel driving to the supermarket today?'

Care was taken during completion of the survey to not phrase questions in a leading way and to let patients put their own number on the question.
CHAPTER 4: RESULTS

4.1 THE RETURN TO BASELINE ARM

4.1.1 RECRUITMENT AND GROUP CHARACTERISTICS

In the given time period 53 eligible patients were identified. 23 patients declined to participate and 30 were entered into the study.

Of the 30 participants eligible, 26 subjects completed satisfactory baseline measurements to be entered into the return to baseline arm of the study. Of the 26 entered into this arm of the study, 4 subjects were loss to follow up before the first recovery test. This left 22 subjects in the survival analysis. 2 due to severe pain, 1 due to persistent low blood pressure, and one loss of contact. This is shown in the figure below.

There were 19 patients entered in the Total Hip Replacement group; of these 10 were male and 9 female. 11 were recruited in the Total Knee Placement group; of these 4 were male and 7 female. The average age between the THR and TKR group was not significantly different with THR: 67.4 years and TKR: 67.0 years. The average age of all participants was 67.3. This group data is shown in tables 3 and 4 below.
FIGURE 17: RETURN TO BASELINE ARM RECRUITMENT

53 eligible patients

23 decline to participate

30 patients recruited into study

4 lost to follow up between recruitment and first test

26 patients completed satisfactory baseline measurements (<700ms)

4 patients record baseline measurement >700ms and are excluded from remainder of follow up

22 begin return to baseline follow up
TABLE 3 GROUP CHARACTERISTICS OPERATION

<table>
<thead>
<tr>
<th>Operation</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hip Replacement</td>
<td>67.5</td>
<td>19</td>
<td>10.6</td>
</tr>
<tr>
<td>Total Knee Replacement</td>
<td>67.0</td>
<td>11</td>
<td>9.4</td>
</tr>
<tr>
<td>Total</td>
<td>67.3</td>
<td>30</td>
<td>10.0</td>
</tr>
</tbody>
</table>

TABLE 4 GROUP CHARACTERISTICS GENDER

<table>
<thead>
<tr>
<th>Sex</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>68.9</td>
<td>14</td>
<td>10.9</td>
</tr>
<tr>
<td>Female</td>
<td>65.9</td>
<td>16</td>
<td>9.2</td>
</tr>
<tr>
<td>Total</td>
<td>67.3</td>
<td>30</td>
<td>10.0</td>
</tr>
</tbody>
</table>
4.1.2 Survival Analysis by Operation

In this survival analysis the event was a patient who returned to within 10% of their baseline recording. Table 5 below shows the number of events that occurred and the number of patient loss to follow up. Of the 22 patients, 15 returned to within 10% of their baseline measurement in the given time period. 7 patients were loss to follow up before returning to within 10% of baseline. 5 of the 7 total losses to follow up were in the knee group. The overall rate of censorship in all groups was 31.8%. The proportion of patients censored was 14.3% in THR and 62.5% in TKR.

<table>
<thead>
<tr>
<th>Operation</th>
<th>Total N</th>
<th>N returned to baseline within testing period</th>
<th>N failed to return to baseline within testing period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
<td>Percent</td>
</tr>
<tr>
<td>Total Hip Replacement</td>
<td>14</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Total Knee Replacement</td>
<td>8</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Overall</td>
<td>22</td>
<td>15</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 5: Return to Baseline Survival Analysis Summary Table
The Kaplan Meier curve below shows the difference in patient recovery between Total Hip Replacement (dashed) and Total Knee replacement surgery (solid). The two survival curves begin to diverge at one week and do not converge again in the observed time frame. The TKR group observed a significantly slower return to baseline than the THR group. All censorship happened at either 1 week or 6 week. One-week censorships were due to non-attempt of testing due to pain and/or muscle weakness. 6-week censorships were patients who did not reach within 10% of their baseline in the observed time frame.

FIGURE 18: TIME TO RETURN TO BASELINE BY OPERATION

The Log Rank test is a statistical measure designed to compare two survival
curves, in which the data is right skewed and censored. This test shows that the difference shown between these curves is statistically significant (0.034). The Breslow and Tarone-Ware methods are alternative measured for comparison of survival curves and were also significant (0.05, and 0.039 respectively). This is shown in Table 6 below:

<table>
<thead>
<tr>
<th></th>
<th>Chi-Square</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Rank (Mantel-Cox)</td>
<td>4.5</td>
<td>1</td>
<td>.034</td>
</tr>
<tr>
<td>Breslow (Generalized Wilcoxon)</td>
<td>3.8</td>
<td>1</td>
<td>.05</td>
</tr>
<tr>
<td>Tarone-Ware</td>
<td>4.2</td>
<td>1</td>
<td>.039</td>
</tr>
</tbody>
</table>

TABLE 6: LOG RANK TEST COMPARING SURVIVAL CURVES FOR THR AND TKR AND RECOVERY TIME TO BASELINE
Below table 7 shows the median time for a patient to return to their pre-operative baseline recording. For the total hip replacement the median time is 2.0 weeks (95% CI 1.338-2.66). For the total knee replacement the median time till baseline reached was 5.5 weeks. For all the participants the median time until baseline was reached is 2.8 weeks (95% CI 1.289-4.351).

**TABLE 7: MEDIAN TIME TO RETURN TO BASELINE**

<table>
<thead>
<tr>
<th></th>
<th>Number returned to baseline</th>
<th>Median</th>
<th>Std Error</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Hip Replacement</td>
<td>12</td>
<td>2.0</td>
<td>.338</td>
<td>1.3</td>
<td>2.7</td>
</tr>
<tr>
<td>Total Knee Replacement</td>
<td>3*</td>
<td>5.5</td>
<td>.</td>
<td>.</td>
<td>.</td>
</tr>
<tr>
<td>Overall</td>
<td>15</td>
<td>2.8</td>
<td>.781</td>
<td>1.3</td>
<td>4.4</td>
</tr>
</tbody>
</table>

*Shows the high number who did not return to baseline in the TKR group*
Table 8 below shows the percentile mean estimates for THR and TKR recovery to baseline. For THR 25% of patients had returned to within 10% of their baseline at 1.435 weeks (SE .435). 75% of THR patients had returned to within 10% of their baseline by 3.28 weeks (SE 1.567).

For Patients receiving TKR 25% of patients had returned to within 10% of baseline by 2.82 weeks (SE 1.22).

TABLE 8: 25% AND 75% PERCENTILE ESTIMATES OF MEDIAN FOR THR AND TKR

<table>
<thead>
<tr>
<th>Operation</th>
<th>75%</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Estimate</td>
</tr>
<tr>
<td>Total Hip Replacement</td>
<td>12</td>
<td>3.3</td>
</tr>
<tr>
<td>Total Knee Replacement</td>
<td>3</td>
<td>2.8</td>
</tr>
<tr>
<td>Overall</td>
<td>15</td>
<td>5.5</td>
</tr>
</tbody>
</table>
4.1.3 Survival Analysis by Gender

These 22 patients were then grouped by Gender. There were 11 Males and 11 Females entered into the survival analysis. Of the 7 censorships, 5 occurred in the Female group and 2 in the Male group. The proportion of loss to follow up was 45.5% in the female group and 18.2% in the male group.

<table>
<thead>
<tr>
<th>Sex</th>
<th>N</th>
<th>N returned to baseline</th>
<th>Failed to return to baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>11</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Overall</td>
<td>22</td>
<td>15</td>
<td>7</td>
</tr>
</tbody>
</table>
The Survival curve below shows all patients (TKR and THR) grouped by gender: the male group in dashed line and the female group in solid line. The two curves begin to diverge at the two-week mark. Then maintain their divergence until the 6-week mark where they converge again.

**FIGURE 19: TIME TO RETURN TO BASELINE BY GENDER**

Table 10 below shows the median time to baseline in Male and Female Participants in both operation groups. The Male group had a 3.3 weeks (95% CI 2.58-3.97) median time to baseline whereas the Female group returned with a
median time of 2.0 weeks (95% CI 1.4-4.35).

**TABLE 10: MEDIAN TIME TO BASELINE BY GENDER**

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>Std. Error</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>3.3</td>
<td>0.354</td>
<td>2.6</td>
<td>4.0</td>
</tr>
<tr>
<td>Female</td>
<td>2.0</td>
<td>0.303</td>
<td>1.4</td>
<td>2.6</td>
</tr>
<tr>
<td>Overall</td>
<td>2.8</td>
<td>0.781</td>
<td>1.3</td>
<td>4.4</td>
</tr>
</tbody>
</table>

Table 11 below shows the estimates of the median for different percentiles. This shows that 75% of Male patients had returned to baseline by 5.3 weeks (SE 0.21). 25% of Male patients had returned to baseline by 1.8 weeks (SE 1.16). 25% of Female patients had returned to baseline by 1.76 weeks (SE 0.51).

**TABLE 11: PERCENTILE ESTIMATES OF MEDIAN**

<table>
<thead>
<tr>
<th></th>
<th>75%</th>
<th>25%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate</td>
<td>Std. Error</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5.3</td>
<td>.207</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>5.5</td>
<td>.</td>
</tr>
</tbody>
</table>
The Statistical measures of Log Rank, Breslow and Tarone-Ware showed that the observed difference between genders were statistically insignificant (.72, .85, and .97 respectively).

<table>
<thead>
<tr>
<th></th>
<th>Chi-Square</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Rank (Mantel-Cox)</td>
<td>.134</td>
<td>1</td>
<td>.715</td>
</tr>
<tr>
<td>Breslow Generalized</td>
<td>.038</td>
<td>1</td>
<td>.845</td>
</tr>
<tr>
<td>Wilcoxon)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tarone-Ware</td>
<td>.001</td>
<td>1</td>
<td>.977</td>
</tr>
</tbody>
</table>

4.2 Baseline Comparison Arm

4.2.1 Recruitment and Group Characteristics

There were 53 eligible patients, and 15 eligible controls identified for the baseline comparison arm. 30 patients and 7 controls agreed to participate. This is shown in the figure below.
4.2.2 One way ANOVA of Gender

The baseline measurements of all 37 patients were compared. All groups were combined to look for a gender wide effect between all participants in the study. The two means were compared using the statistic method of one-way ANOVA. Firstly they were compared in regards to their gender.

There were 16 male participants and 21 female participants entered into the study who recorded baseline measurements. The characteristics of the gender groups are shown below.
TABLE 13 GENDER GROUP CHARACTERISTICS

<table>
<thead>
<tr>
<th>Sex</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>67.7</td>
<td>16</td>
<td>10.7</td>
</tr>
<tr>
<td>Female</td>
<td>63.8</td>
<td>21</td>
<td>10.8</td>
</tr>
<tr>
<td>Total</td>
<td>65.5</td>
<td>37</td>
<td>10.8</td>
</tr>
</tbody>
</table>

The average transfer time for males was 414 ms (95% CI 324-504) and higher for females at 573 ms (95% CI 450-695). The average transfer time across all participants was 504 ms (95% CI 423-585). This is shown in table 15 below.

When comparing two means using a one-way ANOVA, there are two assumptions: that the two groups have equality of variance, and that they are normally distributed. Levene statistic tests for an inequality of variance between the groups. This Levene Statistic below shows that there was no significant inequality between the male and female group (sig: 0.193). This is shown in table 16. Therefore it is appropriate to use a one-way ANOVA for comparison of the two groups.

The results of the 1-way ANOVA are described table 17 below. This shows that the observed difference between the two sexes is statistically significant (0.046)
### TABLE 14: MEAN BASELINE BY GENDER

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean Transfer Time</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>95% Confidence Interval for Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower Bound</td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>4.14</td>
<td>1.69</td>
<td>42.1</td>
<td>3234</td>
</tr>
<tr>
<td>Female</td>
<td>21</td>
<td>5.73</td>
<td>2.50</td>
<td>58.7</td>
<td>450</td>
</tr>
<tr>
<td>Total</td>
<td>37</td>
<td>6.04</td>
<td>2.42</td>
<td>39.8</td>
<td>423</td>
</tr>
</tbody>
</table>

### TABLE 15: LEVENE'S STATISTIC

<table>
<thead>
<tr>
<th>Levene Statistic</th>
<th>df1</th>
<th>df2</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.762</td>
<td>1</td>
<td>35</td>
<td>.193</td>
</tr>
</tbody>
</table>

### TABLE 16: ONE-WAY ANOVA OF GENDER

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>228890.328</td>
<td>1</td>
<td>228890.328</td>
<td>4.265</td>
<td>.046</td>
</tr>
<tr>
<td>Within Groups</td>
<td>1878176.74</td>
<td>35</td>
<td>53662.193</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2107067.06</td>
<td>36</td>
<td>53662.193</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FIGURE 21: MALE AND FEMALE BASELINE TRANSFER TIMES

The figure above shows the difference in baseline transfer time between male and female participants. This shows that male’s performed significantly quicker times than females with an average of 414ms (females 573ms).
4.2.3 One-Way ANOVA of Condition

The participants from the THR and TKR groups were combined into a group termed ‘Advanced Arthritis’. These were compared with normal controls using the same 1-way ANOVA technique described previously.

The characteristics for the condition group is shown below

**TABLE 17 CONDITION GROUP CHARACTERISTICS**

<table>
<thead>
<tr>
<th>Operation</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Arthritis</td>
<td>67.3</td>
<td>30</td>
<td>10.0</td>
</tr>
<tr>
<td>Control</td>
<td>57.8</td>
<td>7</td>
<td>11.6</td>
</tr>
<tr>
<td>Total</td>
<td>65.5</td>
<td>37</td>
<td>10.8</td>
</tr>
</tbody>
</table>

Below, Table 18 shows the average baseline transfer times achieved by each group. The control subjects had faster baseline recordings than patients with advanced arthritis. The controls recorded an average of 442ms (95% CI 267-616). The Advanced Arthritis group averaged 518ms (95% CI 424-613).

Levine Statistic for equality of variance showed that there was no statistically significant inequality between the variances of the two groups (sig: 0.639). Shown in Table 19 below.

Using the one-way ANOVA analysis this shows the differences between baseline transfer times the advanced arthritis group and the control group were not statistically significant (0.455). Shown in Table 20 below
### TABLE 18: MEAN BASELINE FOR CONDITION GROUPS

<table>
<thead>
<tr>
<th>Condition</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Arthritis</td>
<td>30</td>
<td>519</td>
<td>253</td>
<td>46.2</td>
<td>424</td>
<td>613</td>
<td>185</td>
</tr>
<tr>
<td>Control</td>
<td>7</td>
<td>442</td>
<td>188</td>
<td>71.2</td>
<td>267</td>
<td>616</td>
<td>258</td>
</tr>
<tr>
<td>Total</td>
<td>37</td>
<td>504</td>
<td>242</td>
<td>39.8</td>
<td>423</td>
<td>585</td>
<td>185</td>
</tr>
</tbody>
</table>

### TABLE 19: LEVINE'S STATISTIC

<table>
<thead>
<tr>
<th>Levene Statistic</th>
<th>df1</th>
<th>df2</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>.224</td>
<td>1</td>
<td>35</td>
<td>.639</td>
</tr>
</tbody>
</table>

### TABLE 20: ONE-WAY ANOVA OF CONDITION

<table>
<thead>
<tr>
<th></th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>33763</td>
<td>1</td>
<td>33763</td>
<td>.570</td>
<td>.455</td>
</tr>
<tr>
<td>Within Groups</td>
<td>2073303</td>
<td>35</td>
<td>59237</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2107067</td>
<td>36</td>
<td>33763</td>
<td>.570</td>
<td>.455</td>
</tr>
</tbody>
</table>
The bar graph above shows the observed difference between the Advanced Arthritis group at baseline with the normal control group. Patients suffering from advanced osteoarthritis performed slower baseline transfer times than normal controls. However the wide error bars on the control group intersect with that of the OA group.
4.3 QUESTIONNAIRE

4.3.1 VISUAL ANALOGUE SCORE OF JOINT PAIN

The VAS of pain pre-operatively at baseline had an average score of 4.55 (95% CI 2.527-6.523). This decreased at 1-week post operatively to 3.21 (95% CI 0.86-5.56). At 2 weeks post operatively the score decreased further to 1.93 (95% CI 0.59-3.27). At 4 weeks and 6 weeks the score plateaued at 1.2 and 1.07 (95% CI 0.79-1.61 and 0.81-1.33 respectively). It is worth noting in this scale a score of 1 is equal to no pain. It is not possible to score below 1. This is shown in the figure below.

FIGURE 23: VISUAL ANALOGUE SCORE OF PAIN

![Graph showing VAS of Joint Pain over time](image-url)
When stratifying by Operation, The patients with knee OA had an average VAS for pain higher than that of their hip OA counterparts pre-operatively; Hip patients had a mean VAS pain of 4.42 pre-operatively and Knee patients had a higher score of 5.22. 1 week post-operatively THR patients VAS pain decreased to 2.0 whereas VAS pain for TKR patients increased slightly to 5.28. By the 2-week post-operative test both THR and TKR VAS pain scores were low at 2.0 and 1.6 respectively. These scores remained low throughout the remainder of testing; The THR scored low VAS pain at 4 and 6 weeks with 1.1 and 1.08 respectively; The TKR scored 1.5 and 1.1 at the 4 and 6-week test. This is shown in the figure below.

FIGURE 24: PAIN PROGRESSION BY OPERATION
4.3.2 Driving Confidence

Perceived confidence in ability to perform an emergency stop was compared with a score of overall feeling of driving confidence. At the preoperative test, the average score for overall confidence was slightly higher than confidence in emergency brake with 9.48 and 9.32 respectively. Both of these scores dropped significantly by 1 week post-operative to 6.21 and 6.21. At the two week test the two scores diverged slightly with overall driving confidence improving slightly faster (8.93) than emergency stop confidence (8.31). Following this all participants in the test felt they were fully confident to perform both an emergency stop and driving with overall confidence. This is shown in the figure below.

FIGURE 25: DRIVING CONFIDENCE

![Figure 25: Driving Confidence](image-url)
4.3.3 Most Troublesome Symptom

Pre-operatively the most common symptom reported was pain. This was followed by stiffness. At the 1-week post-operative mark, the most common symptom reported was stiffness closely followed by weakness. This was largely unchanged at the 2-week mark. By 4 weeks reporting of weakness was largely reduced, however the reports of stiffness in the operated joint increased. At the final follow up point, 6 weeks, joint stiffness was the clear majority of reported symptoms. Over the testing period reporting of pain dropped off substantially.

To summarize the trends in each symptom:

a. Weakness increased post-operatively then dropped off
b. Joint stiffness was a consistently troublesome symptom at all time points, increasing at 4 and 6 weeks.
c. Pain was the clear majority in post-operative patients, this reduced rapidly following the operation

This is shown in the figure below.
FIGURE 26: PROPORTIONS OF TROUBLESOME SYMPTOMS

Most Troublesome Symptom

Frequency

- Pain
- Stiffness
- Weakness

pre-op 1week 2week 4week 6week
CHAPTER 5: DISCUSSION

5.1 MAJOR FINDINGS OF THIS STUDY

When comparing total hip and knee replacement surgery in terms of returning to a safe baseline transfer time, hip replacements recovered significantly quicker than knee replacements.

Patients with knee OA experienced more pain at baseline than those with hip OA. Similarly in the early post-operative period, total knee replacement patients experienced significantly more pain than total hip replacement patients.

Males had significantly quicker transfer times at baseline than females. However this difference did not confer quicker recovery times in males. Females recovered slightly faster than males, however this was not statistically significant.

Patients with advanced arthritis prior to total joint replacement surgery had slower baseline times than controls with no arthritis. Again this did not reach statistical significance.

The results of the questionnaire showed that pre-operative pain was the most troublesome symptom for patients but quickly dropped off post-operatively. Post-operative muscle weakness was a factor early on but became less of an issue by the end of follow up. Post-operative joint stiffness remained an issue for patients throughout the follow-up period. Patients were very confident in their
driving ability pre-operatively, but this dropped in the first week following surgery. This however recovered quicker than their physical ability.

## 5.2 Interpretation of Results

The results from the survival analysis showed that 50% of THR patients recovered to within 10% of their baseline transfer time by 2 weeks following surgery. By an average of 3.28 weeks the majority (75%) of THR patients had returned to their baseline. The quartile of fast recovering patients (25%) returned to baseline much earlier by an average of 1.43 weeks.

These findings would suggest that our current recommendations for return to driving following hip replacement surgery are on the conservative side. Our findings are also significantly faster than previous research has suggested. MacDonald and Owen (36) concluded that the majority of patients were safe to drive by 8 weeks but a small number were not ready until 32 weeks. They were the only investigators who used the same measurement of 100N brake pedal force used in this study. However MacDonald and Owen determined that patients were safe to resume driving when they had achieved reaction time below 700ms. This figure was taken from the British Highway Code, and not based on patient recovery. In our study we compared patients to their own pre-operative baseline performance rather than to an arbitrary number. We believe this gives a more accurate picture of safe driving recovery time following hip or
knee replacement surgery. If the patient is legally ‘safe to drive’ before surgery, then returning to the same level of driving ability post-operatively would be a more relevant measurement.

For knee replacement surgery the median time to reach baseline was 5.49 weeks. This result is comparable to previous work done on TKR’s. The only study to include 100N in their measured variable was Spalding et al (38) who concluded that 8 weeks recovery time was required. Other researchers did not include brake pedal force but concluded similar time scales: Pierson (39) 6 weeks, Liebensteiner (40) 4 weeks, and Dalury (42) 4 weeks. In our study the quickest recovering quartile (25%) of patients achieved the baseline by 2.82 weeks.

The knee group had issues with a lower number of participants and a higher drop out rate. 11 TKR patients were recruited compared to 19 in the hip group. This dropped to 8 TKR and 14 THR patients who completed the study. Over half (62.5%) of TKR replacements were censored from the Kaplan Meier curve. They either dropped out of the study or did not achieve their baseline in the observed time period. Three out of eight TKR patients achieved a return to baseline in the time period.

This reflects the difficult recovery faced by patients following TKR, especially in the first postoperative week. Figure 24 illustrates the difference between THR and TKR based on VAS pain scores. Patients with knee OA experienced on average more pain than those with hip OA. After surgery TKR replacement patients experienced a much greater level of pain in the first week of recovery in
comparison to their hip counterparts. By 2 weeks of recovery the difference in scores had converged and remained similar in the observed time period. This shows that using the brake pedal causes significantly more pain for TKR patients than THR in the early post-operative period. This in turn explains why the drop out rate in the first week was much higher in the TKR than THR group.

The survival curve shows clearly how the two groups diverged in their return to baseline. The THR group begins to diverge by the first testing point and does not converge again. Although the TKR data lacks in numbers, the observed difference in performance is statistically significant; the log rank test performed had a score of 0.034 validating the difference seen. This difference in performance is a new finding and this study is the first to compare the 2 operations. As the testing methodology and measured variables differ in previous studies, it makes comparing data between studies challenging. In this study we tested the two operations on the same testing rig with the same tester and the same measured variable.

There are many possible reasons as to why TKR patients perform poorer in the braking maneuver. If we consider the mechanics of operating the brake pedal itself, there are essentially two elements required to do this successfully: the person has to lift and transfer the braking leg, and to push down forcefully on the brake.

This movement will be controlled by a number of different muscles. In a study looking at muscle activation during emergency braking, 2 muscle groups were activated strongly: the anterior thigh (55% activation) and the posterior leg
(43% activation) (45). Theoretically one must engage the hip flexor muscles to lift the leg and transfer it between the accelerator and brake pedals. These muscles have the potential to be affected in THR surgery. Most hip replacements are inserted either through a lateral or a posterior approach; this spares the hip flexor muscles. An interesting point to note is how patients adapted to the transfer movement. Instead of lifting their leg during the transfer, many pivoted using the rotational movement of the foot on a flexed knee joint. This movement spares movement of the hip joint and the rotation occurs at the ankle. This technique allowed them to perform faster transfers.

To push forcefully on the brake pedal the patient has to extend the knee and plantar flex the ankle. There is no question that the quadriceps muscle is greatly weakened following knee replacement surgery (46) and to some extent the calf muscles too. This is crucial to the patient’s ability to perform the braking procedure. This weakness affected TKR patients test performance greatly. TKR patients did not have any major issues with transfer speed but they took longer to achieve the 100N minimum required braking force. During braking quadriceps and hamstring contraction is required to stabilize the knee joint in flexion. As post surgery quadriceps strength is less affected following THR surgery THR patients achieved the 100N MAF much earlier than their knee replacement counterparts.

We believe this is the critical reason as to why these two groups of patients performed differently when post-operative brake reaction time was measured.

Another reason as to why knees took longer to recover was post-operative pain.
Figure 24 depicts the difference in post-operative pain for TKR and THR patients. This affected both the dropout rate and early poor performance in the TKR group. Post-operative pain largely settled by the second week so this difference was mainly seen in the first week. This had a much larger effect on dropout rates than performance as very few patients recovered their baseline in the first week, regardless of group.

Male and female participants were compared in the survival analysis. There were equal numbers of both genders. Results of the Kaplan Meier analysis showed that women returned to baseline about a week earlier than men. Men had a median survival time of 3.28 weeks compared to women at just 2 weeks. Percentile data showed that an early group of males returned to their baseline by just 1.8 weeks (25%) and similarly in females by 1.76 weeks. The majority of men had returned by 5.29 weeks (75%). There was a higher rate of censorship in the female group as opposed to the male group. Just under half of women (45.5%) either dropped out or did not return to baseline in the time period. Comparatively this occurred in only 1 out of 5 male participants (18.2%). This difference in censorship makes it more difficult to evaluate the effect of gender on survival.

When looking at figure 19, there is a visible divergence in the gender survival curves. The curves diverge at 1 week, however they re-converge by 5 weeks. At 6 weeks the male curve has achieved a higher level than the female curve. The pattern of the survival curves is consistent with a high censorship rate in the female group. Log rank test of these survival curves showed the observed
difference was insignificant (0.715).

This data could suggest that women had a higher early post-operative pain threshold and more severe muscle weakness in the first 1-2 weeks. However the high censorship makes analysis of this data difficult.

When comparing the baseline pre-operative performance of all participants we noted that males performed faster transfer times compared to women. It is well known that males outperform females in reaction time to both auditory and visual stimuli (47). As strength is an inherent part of the measured variable, different levels of strength contribute to slower times recorded by female participants. A study by Miller et al found that when testing lower body strength women had about 2/3 the strength of men (48). It was therefore expected that men would record faster times than women at the outset. We further wanted to look at whether this resulted in faster recovery times. If anything the results of survival analysis showed the opposite. This may be because we measured return to baseline as opposed to time required to achieve a set time in milliseconds. If patient A records a fast baseline recording of 300ms and patient B records the slowest allowed baseline of 700ms, it will be easier to patient B to return to the baseline compared with patient A. This creates an interesting effect on the data. Say both these patients took 4 weeks to return to their respective baselines. Patient A must perform the manoeuvre almost twice as fast as patient B, which will require better mobility and faster recovery time. In the eyes of our study these patients will look exactly the same, both required 4 weeks until they
reached their pre-operative baseline. Therefore patients who record extremely fast baseline times will potentially require a shorter time until they were safe to drive than the data suggests. As male participants recorded faster baselines on average this may explain why female participants seemed to recover at a quicker rate early on then males.

When comparing the baseline scores of patients with OA and normal controls, we found that patients with OA recorded slower reaction times on average. This is likely due to joint pain, stiffness and weakness affecting the ability of OA patients from performing the transfer as fast as the control group who had normal joints. However there were low numbers of controls recruited into the study, resulting in wide error bars that intersected with the OA patients. This could be better clarified with the collection of more control data. When controlling for gender the effect of hip OA, knee OA, and controls on transfer time we found that knee OA patients performed the worst and controls the best.

The questionnaire was designed to provide some additional information about the patient experience of THR and TKR surgery and driving in the post-operative period. The VAS pain score showed just how successful these operations are at alleviating the pain of OA. By one week postoperatively the VAS pain scores reported by patients had almost halved. By 2 weeks the score had further dropped to 2/10 and thereafter reached the lowest level. When looking at how the THR and TKR operations differed in VAS pain scores, the difference was mainly in the first week: THR patients experienced an immediate reduction in pain, whereas TKR had the same level or greater pain in that first week. From the second week on both groups recorded low or no pain. This shows
why TKR patients struggled in that first week. For this reason some dropped out and may highlight a reason as to why TKR patients took over twice as long to reach baseline.

Asking patients to score their perceived level of driving and braking confidence was designed to assess whether patients’ subjective feeling of recovery progress matched with the objective data. From Figure 25 patients’ perceived confidence follows closely the decrease in pain levels and improvement of their transfer times post-operatively. There was a sharp drop in confidence early in the recovery and by 4 weeks every patient believed they could drive. In most cases post surgery driving confidence superseded driving confidence before surgery.

Finally the questionnaire addressed the patients’ most troublesome symptom. Pre-operatively pain was the main problem whereas after surgery both stiffness and weakness proved most bothersome. In the late recovery stages muscle weakness improved and stiffness remained an issue for many patients.

5.3 DISCUSSION POINTS ON THE TESTING RIG

Designing and building the testing rig was a difficult task. Every testing rig in previous studies was different both in design of the mechanical structures and in the use of hard and software used for measuring the brake reaction time.

Selection of the car seat was an important step in the design process. Many patients find the most difficult part of driving after a hip or knee replacement is getting in and out of the vehicle, far more so than the actual operation of the
pedals. This is partly based on joint stiffness and lack of muscle strength.

THR patients are told post-operatively to ‘never sit with your knee’s higher than your hips’. This is based on the hip safety guidelines, designed to help prevent post-operative hip dislocation. This generally stops patients sitting in low or deep seats. The seat height in our rig was at a fixed H-30 of 288mm. This is to mimic the category of seat heights found in the majority of New Zealand light fleet vehicles. For safety THR patients were offered firm cushions to keep their hips at a safe level of flexion. All patients reported that they felt comfortable in the seat. As maneuvering in and out of the seat was perceived as an issue, the seat was designed without any sides so that patients could easily sit down and swing their legs up onto the rig. This meant the seat bottom was flat and had no side arms. One disadvantage of this design was the lack of support handles to help patients get on and off the rig.

We would suggest for future researchers to design the rig as to make the transfer from wheelchair to car seat as easy as possible. This step was a large barrier for many participants. We would recommend to allow more backward adjustment of the seat as most patients preferred a longer distance from the pedals. There were some patients who were too tall to fit into the rig.
5.4 Discussion Points on Study Design

To allow for variability in participants performance, they were allowed a 10% margin to achieve their pre-operative baseline. This percentage was used as it does not increase the stopping distance to put the patient at risk. If you assume a 400ms thinking time and a 400ms transfer time at 100km/h, then adding 10% to the transfer time will change the stopping distance from 85m to 86m. For the slowest possible safe driver in the study under the same circumstances (700ms transfer time), this changes the stopping distance from 83m to 85m. We deemed this was a safe variation in performance.

However due to this margin being a percentage, it is not equal in actual time for different baseline speeds. A patient with a 400ms baseline has a 40ms margin, whereas a 700ms patient has 70ms. This arguably makes returning to baseline more difficult for faster patients and easier for slower patients. In future studies this could be remedied by setting a constant time interval as a margin for baseline rather than a percentage.

In this study participants were asked to react to a visual stimulus of a red traffic light. As in previous studies the time intervals between the stimuli were changed in a random fashion to decrease the chance for anticipation of the stimulus. However in this study the neurological aspect (‘thinking time’) was not measured, only the mechanical aspect of the brake reaction time. This theoretically makes anticipation of the visual stimulus irrelevant, as the transfer time should be a reflection of physical capability rather than being influenced by
anticipation.

In the pre-test instructions participants were told to press down lightly on the accelerator as though they were driving at a constant speed. Other studies (37, 38) standardized the level accelerator pressure by asking patients to completely depress the pedal or press with a minimum force.

5.5 **Anticipation of stimulus**

The plateau phase of the accelerator pedal often has a large amount of variation before the initiation of transfer. This is due to the patient anticipating the stimulus causing the accelerator pedal force to vary as they hold their right leg in waiting. This background variation can make interpretation of the accelerator tracing quite difficult. A large amount of variation in the accelerator pedal force can look very similar to the sharp drop of the initiation of transfer you are looking for. There are often situations where the patient may have been in the process of a variation and the IOT happened whilst the accelerator force was decreasing. In essence you have a downward slope superimposed over the sharp slope caused by the IOT. In most situations relying on the visual of the live graph gives the best indication of the true IOT. However in the situation depicted in the figure below, there is the superimposed gradient problem.
Through trial and error I calculated that most true IOT's happen at a gradient equal to or greater than 0.5N per sample. Therefore in the situation above, it is easiest to analyse the accelerator pedal from the Excel sheet rather than the graph.

In the accelerator tab of the Excel spread sheet, the point in time that corresponds with the superimposed gradients is located first. Then the gradient at each point in the area in question is worked out. The point where the gradient steepens beyond 0.5/sample is where the IOT is likely to lie. This process is shown in the figure below.
FIGURE 28: FINDING THE GRADIENT

Bracket 1: gradient 0.2N/sample, consistent with background variation

Bracket 2: gradient 0.4N/sample, consistent with anticipation

Bracket 3: gradient exceeding 0.5N/sample
5.6 LIMITATIONS OF THE STUDY

An issue with many studies in this area is the dropout of patients postoperatively. In this study the majority of dropouts were at the 1-week post surgery test. This study is the first to measure brake reaction times in this early period. We found interesting data in that it showed the significant recovery of patient strength and mobility in that first week. Some patients declined to attempt the testing as they felt they were physically unable. However if the patient was able to complete the transfer from wheelchair to the testing rig, they were capable of completing the testing. The majority of dropouts in this period were patients who refused to attempt the test, due to pain or lack of confidence. There were two who couldn't do the week 1 test due to complications in the form of DVT and hypotension.

One patient dropped out of the study as they were under the impression that if they tested safe they then had the green light to return driving. Care was taken, when consenting participants in the research, to ensure they understood that this was a research project and that they would not be allowed to drive earlier then at present. This patient dropped out of the study once they returned home.

All the patients who dropped out of the study did so before or at the week one test. This reflects the difficulty in performing the test in the early postoperative period. This study is the first to our knowledge to attempt to measure the transfer time performance in this early post-operative period. As
expected patients' recorded transfer times were vastly slower than at baseline. The transfer times then improved dramatically by the 2-week test. There was only 1 patient who recorded a faster than baseline time at the 1 week test.

However many patients who couldn’t do the week 1 test, returned for all further testing intervals. The Kaplan Meier survival curve allows use of all data points prior to loss to follow up.

When we calculated the time to return to baseline, we modeled patient’s progression of brake reaction times linearly. This allowed us to estimate a more accurate time of return to baseline. No other study has modeled the return to baseline in this way, and operates in terms of changes in absolute brake reaction times, rather than time to return to baseline.

The time when patients were often censored in the survival data was at 6 weeks. These are patients who failed to return to within 10% of their baseline brake reaction time in the testing period. 45.5% of female patients failed to reach baseline in the 6-week study period. This was often related to failure to reach 100N brake pressure. This may reflect slower recovery of muscle strength in women post TKR and THR surgery. We focused our measurement in the early recovery phase, as this best answered our research question. By doing this we limited our generalizability to the sub-group of patients who take longer to recover. Other studies (36, 37, 49) which measured patients out to 1-year post surgery found that there were some patients who take significantly longer than average to recover. This is an important sub-group of patients to consider when making recommendations for driving cessation after surgery. This highlights the
need to consider each patient individually when making decisions about the right time to return driving following THR or TKR.

When recording brake reaction times it became obvious that patients recorded poor reaction times in the first and second attempts. Even though patients were allowed 3 practice brakes to get used to the movement, they still recorded much slower times on the first 2-3 attempts. The brake reaction times improved and then remained stable over the last few attempts. This is an effect known as Motor Skill Learning. This is often measured by a technique called Serial Reaction Time Task (SRTT). This is a repeated test where a participant reacts to a stimulus, waits for a fixed interval and then repeats the same movement/sequence again. This technique has received some criticism and it is suggested that a more accurate way of determining if Motor Skill Learning is a factor is to conduct a SRTT and compare it to single tests carried out randomly with large intervals in between. This should eliminate motivation and fatigue as factors in the repeated measures testing. (50)

The testing protocol was developed from previous studies and utilizes both random intervals and pre-test practicing to try and reduce the Motor Skill learning effect. However I believe I observed some level of motor skill Learning in our testing. We would suggest testing the transfer time movement for evidence of Motor Skill Learning by comparing it with SRTT and random measures.

Many eligible patients declined to enter the study. These patients often felt they
had a big enough task ahead of them (going through surgery and recovery) and that the extra commitment of the study was beyond what they were capable of. Patients who did participate in the study may have been more motivated and capable in general. As highly motivated patients are more likely to recover quickly, this is a potential source of bias in our study. This selection bias may limit the generalizability of this research.

One of the inclusion criteria for our study was that the patient had to have a current NZ driver’s license. The intention was to only test people who were current drivers. All patients who satisfied this criteria should therefore have the potential to return to driving post-operatively. However even though all patients had the same potential, this did not mean that they had the same motivation to do so. Younger patients who were employed were possibly more motivated to return driving as this allowed them to go back to work. On the other hand elderly patients who lived alone had no other form of transport also had a high motivation to return to driving as this was their only way of completing activities of daily living like buying groceries. For patients with supportive spouses or family members, being unable to drive was not a major impediment.

Post-operative medication regimes were not addressed in this study. Patients recovering from hip or knee replacements require analgesia during recovery. For many this involved inclusion of opiate pain medications. Opiates can cause drowsiness and a lowered level of mental alertness. Interestingly a study comparing continuous morphine therapy with no therapy in cancer patients
experiencing pain found no significant difference in any functions related to
driving (including prolonged reaction time) (51). As pain is a limiting factor for
patients with OA when driving, we feel if anything, opiates would improve
reaction times as they treat pain.

As mentioned in section 6.6 above, anticipation of the stimulus made
determination of the true IOT difficult. Analyzing the change in gradient allowed
a consistent way of calculating IOT in these cases. The inaccuracy of the IOT in
some patients who anticipate the stimulus is a source of potential error in this
study.

In order to achieve a statistical power of 80% we estimated a required sample
size of 50 participants. However with the time constraints of the BMedSci (Hons)
programme we did not achieve this. Following the completion of this thesis, data
collection will continue to strengthen the findings in this study.
5.7 RECOMMENDATIONS

As a result of our research we recommend that patients undergoing THR surgery can return to safe driving 3-4 weeks after their operation date. There are a proportion of patients who would be capable of returning driving earlier but this would require a formal assessment of their brake transfer time. At the other end of the spectrum some patients are slower to recover driving skills following surgery. These patients need to be identified and advised appropriately on when to return driving.

In the knee group more data is needed before any change in advice can be given.

5.8 FURTHER RESEARCH

Further research needs to be done in the comparison of these two common operations. More data will strengthen our recommendations and will add weight to our results.

Clarification of how post-operative analgesia regimes affect patient’s driving performance following hip and knee replacements will further refine our recommendations.

Further research on the transfer time or brake reaction time movement to look into the effect of motor pattern learning is required to see if this affects the
validity of the results in this study.

A simple clinical test should be developed to test transfer time at follow up in clinic. This would create an individualized way of assessing a patient’s ability to drive. Ideally the ability to drive would be based on an objective test used by clinicians.
CHAPTER 6: CONCLUSION

Our research aimed at determining the time required to return to safe after THR or TKR surgery. We have shown that THR patients significantly outperformed TKR patients in this regard. Our recommendations are that patients refrain from driving for 3-4 weeks following a hip replacement and 6 weeks following a knee replacement. When looking at gender, the baseline recording of male participants was quicker than females. However looking at this over time, this did not result into a quicker recovery. At baseline patients who suffered arthritis performed poorer than normal controls. When asking patients about pain experienced during testing, this scored high before surgery, and quickly dropped during post-operative recovery. When asking patients what symptom troubled them the most, weakness and stiffness were both common in the early postoperative period. At the 6-week test stiffness remained a common problem.

In reality patient ability to drive cannot be distilled down to a simple test or a single figure. The ability to drive requires a multitude of physiological, mechanical, and psychological skills. A doctor can give the best evidence based advice possible but it is a driver's responsibility to know their limits and not to put other road users at risk by resuming driving before they can operate a motor vehicle safely.
APPENDICES

APPENDIX 1: FUTEK PEDAL FORCE SENSOR SPECIFICATION SHEET

FUTEK MODEL LAU200
Drawing Number: F11047-C

INCH [mm] R.O. = Rated Output

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<th>2</th>
<th>3</th>
</tr>
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<td>Description</td>
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<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Color</td>
<td>Black</td>
<td>Green</td>
<td>White</td>
</tr>
</tbody>
</table>

ACCELERATOR AND PEDAL FORCE SENSOR

+ OUTPUT
(Compression)

SHOWN WITH MOUNTING PLATE

TYPICAL APPLICATION

MODEL LAU200 INCLUDES
ONE OF EACH
TOTAL WEIGHT 2 lb [0.9 Kg]

ITEM# MCR00180 - Mounting Plate
100 KOHM Shunt Cal.
Carrying Case and
ITEM# FSMH01730 - (mating connector and 15 ft cable)

DO NOT LOAD SURFACE

specifications:
Rated Output: 2 mV/V
Safe Overload: 100% of R.O.
Zero Balance: ±1% of R.O.
Excitation (VDC or VAC): 20 MAX
Bridge Resistance: 750 ± 10
Off-Center Loading: ±3.4% or better (0.625 [15.8] from center)
Nonlinearity: ±0.2% of R.O.
Hysteresis: ±0.2% of R.O.
Non-repeatability: ±0.2% of R.O.
Temp. Shift Zero: ±0.01% of R.O. / °C (±0.01% of R.O. / °F)
Temp. Shift Span: ±0.01% of Load / °C (±0.01% of Load / °F)
Compensated Temp: 60 to 100°F [15 to 23°C]
Operating Temp: -40 to 200°F [-40 to 93°C]
Weight: 0.4177 kg
Material: 17-4PH S.S.
Material (Mounting Plate): Aluminum Red Anodized after S/N: 396658
Cable: 429 AWG 4 Conductor, Teflon Shielded, Yellow Cable
12 in [0.3 m] Long with 4 Pin LEMO Receptacle (PN: 09.304.1L00)
Accessories and Related Instruments Available
Calibration Test Excitation: 10 VDC
Calibration (STD)

MOUNTING PLATE (Aluminum, Red Anodized)

ITEM# MCR00180

10 THOMAS
IRVINE, CA 92618 USA
1-800-23-FUTEK (38835)

INTERNET:
http://www.futek.com

CAGE Code: # 1X8M6

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APPENDIX 2: INFORMATION SHEET AND CONSENT FORM

Participant Information Sheet

| Study title: | Time to safe driving after Hip and Knee replacement |
| Principal investigator: | Name: Prof. Jean-Claude Theis |
| | Department: Orthopaedics |
| | Position: Professor of Orthopaedic Surgery |
| Contact phone number: | 0272233879 |

Introduction

Thank you for your interest in this project. Please read this information sheet carefully and, if you wish, talk with relatives or friends, before deciding whether or not to participate.

If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you.

This research will be carried out by research student Peter Meffan, under the experienced supervision of Professor Jean-Claude Theis.

What is the aim of this research project?

A question many patients ask in relation to hip or knee joint replacement surgery is: 'When can I drive again?'. Often they will be told 6 weeks. There has been very little research into this and we want to find out when it is safe to drive following a hip or knee replacement.

Organising other drivers, taxis and shuttles is a hassle and very expensive. We are researching whether patients are safe to drive prior to the 6 week mark. We hope that earlier return to driving will be of benefit to patients and accelerate their restoration of independence.
Who is funding this project?
This project is funded by the Dunedin School of Medicine, Otago University in conjunction with the Dunedin Department of Orthopaedic Surgery.

Who are we seeking to participate in the project?
We are looking for participants who are scheduled to undergo either a total hip or knee joint replacement. Eligible participants must satisfy the following criteria:

1. You must be suffering from osteo arthritis.
2. You must be scheduled for a total replacement, involving both parts of the joint, as opposed to a partial replacement.
3. You must have a current New Zealand drivers licence.
4. You must not have other medical conditions which affect your ability to operate a car
5. You must have adequate vision
6. You must be able to speak and understand English well
7. You must reside in Dunedin

If you participate, what will you be asked to do?
We will be testing your reaction time on a testing station that resembles a standard manual car. You will be seated on a car seat and asked to push down on an accelerator pedal. You will then watch for a light to turn red. When the light turns red you will remove your foot from the accelerator and apply the brake forcefully. You will need to do this as quickly as is possible. This is to simulate an emergency stop that may happen when driving in real life. After the reaction time has been recorded you will be asked to place your foot back on the accelerator and wait for the next red light. You will have 3 practice trials to get used to the task, followed by 10 recordings. After the test we will ask you to fill out a form in which you will score the pain/discomfort you experienced during the testing. We will also undertake some measurements of the mobility you have in the operated joint. This will allow us to look into how pain and mobility affect braking ability.

You will be tested once before your surgery, and 4 times afterwards at 1 week, 2 weeks, 4 weeks, and 6 weeks from your surgery.

Please note that you can withdraw from the study at any point. Should you withdraw or decide against participation in this study, the standard of care delivered to you by the Doctors, Nurses, and Physiotherapists will in NO way be affected.

Participation is completely voluntary.

A $20 petrol voucher will be offered to you to help compensate for travel costs to testing.

Is there any risk of discomfort or harm from participation?
The act of forcefully braking may cause you some discomfort on the operated side. This study does not require any change to your pain relief medication. Please take what you are prescribed by your surgeon. If you are experiencing any unexpected pain you can let us know and we will give you additional pain relief.

Artificial hips carry with them a small risk of dislocation (slipping out of place) in the early postoperative phase. The testing equipment will be designed to minimise this risk and keep in mind the risk of your hip slipping out of place is low when proper precautions are taken.

The usual recommendation is that you do not drive for 6 weeks following your operation. There is a risk that during testing we discover you are still unsafe to drive at the 6 week mark. We are obligated to pass this information on to your regular GP and surgeon in charge of your care. Your GP and surgeon will then have a discussion with you about when to return driving.

What specimens, data or information will be collected, and how will they be used?

Data obtained will be stored in a computer in the department of orthopaedic surgery. Only information about how to contact you during the study will be kept. After the study is completed all identifying or personal information will be deleted.

What about anonymity and confidentiality?

Your involvement in this study is confidential. Upon publishing the data collected in this study no identifying or personal information will be used in any form. You may have access to your results if you wish.

Any questions?

If you have any questions now or in the future, please feel free to contact either:

<table>
<thead>
<tr>
<th>Name</th>
<th>Contact phone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prof. Jean-Claude Thes</strong></td>
<td>0272233879</td>
</tr>
<tr>
<td>Position: Professor, Orthopaedic Surgery</td>
<td>Department: Orthopaedics</td>
</tr>
<tr>
<td>Name: Peter Meffan</td>
<td>0272861626</td>
</tr>
<tr>
<td>Position: BMedSci(Hons) Student</td>
<td>Department: Orthopaedics</td>
</tr>
</tbody>
</table>

This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may
contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.
Time to Safe Driving Following Hip and Knee Replacement

Principal Investigator: Prof Jean-Claude Theis (jean-claude.theis@otago.ac.nz)

CONSENT FORM FOR PARTICIPANTS
Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant:..........................................................

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project at any time without disadvantage.
6. I know that as a participant my medical records will be available to researchers to find information about the operation and rehabilitation. I will be asked to fill out a form that scores pain/discomfort during the testing. I will have my mobility measured in the affected joint.
7. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.
8. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent
the data from the project, and that these will be placed in secure storage and kept for at least ten years.

9. I understand that the results of the project may be published and be available in the University of Otago Library

10. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.

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APPENDIX 3: QUESTIONNAIRE

DRIVING QUESTIONNAIRE

Name:
Operation:
Weeks since operation: (pre, 1, 2, 4, 6)

Please answer all the questions based on how you feel today

1. How confident are you in your ability to perform an emergency stop? (1-10)

1---------------------------------------------------------------10
(not at all confident) (extremely confident)

Answer:

2. What would you say is the main factor affecting your ability to emergency brake? (a, b, c)

   a. Pain
   b. Stiffness
   c. Weakness

3. On a scale from 1-10 how pain did you experience when performing an emergency stop today?

   1-----------------------------------------------------------------10
   (no pain) (worst pain imaginable)

   Answer:

4. Overall how comfortable would you feel if you were to return to driving today? (1-10)

   1-----------------------------------------------------------------10
   (not at all comfortable) (extremely comfortable)

   Answer:
APPENDIX 4: LETTER OF ETHICAL APPROVAL

Professor J-C Theis
Orthopaedic Surgery
Dept. of Surgical Sciences
Dunedin School of Medicine

4 March 2014

Dear Professor Theis,

I am again writing to you concerning your proposal entitled “Time to safe driving following hip and knee replacements”, Ethics Committee reference number H14/017.

Thank you for your e-mail of 3rd March 2014 addressing the issues raised by the Committee.

The Committee appreciates the clarification that i) data collection will be completed by 30th September 2014 giving Peter Meffan adequate time to write up the project and ii) the control group will receive an Information Sheet and undergo the same consenting process.

The Committee thanks you for making the amendments to the Information Sheet and for noting that should a participant at the 6 week mark be deemed unsafe to drive that this information will be passed on to the surgeon involved in the patients care and the patient’s GP.

On the basis of this response, I am pleased to confirm that the proposal now has full ethical approval to proceed.

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel 479 5216
Email: gary.witte@otago.ac.nz

C.C. Orthopaedic Surgery
REFERENCES


10. Gandhi R, Perruccio AV, Mahomed NN. Surgical management of hip osteoarthritis. CMAJ : Canadian Medical Association journal = journal de


43. Society of Automotive Engineers. Surface Vehicle Recommended Practice.


2013.


